

APPENDICES

GUIDELINE FOR PREVENTION OF CATHETER-ASSOCIATED URINARY TRACT INFECTIONS

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APPENDIX 1A: SEARCH STRATEGY FOR GUIDELINES

Database	Platform
National Guideline Clearinghouse	http://www.guideline.gov/
MEDLINE	http://www.ovid.com/
Cochrane Library HTA	http://www3.interscience.wiley.com/
NIH Consensus Development Program	http://consensus.nih.gov/
US Preventive Services Task Force	http://www.ahrq.gov/clinic/uspstfix.htm

1. NATIONAL GUIDELINE CLEARINGHOUSE

Keyword	Search Results
"urinary tract infection"	79
"urinary catheterization"	10

2. MEDLINE

#	Search History	Results
1	exp Urinary Tract Infections/	32372
2	exp Urinary Catheterization/	10749
3	1 or 2	40511
4	limit 3 to (guideline or practice guideline)	56

3. COCHRANE LIBRARY

#	Search History	Results
#1	MeSH descriptor Urinary Tract Infections explode all trees	1776
#2	MeSH descriptor Urinary Catheterization explode all trees	431
#3	(#1 OR #2)	14

4. NIH CONSENSUS DEVELOPMENT PROGRAM

No relevant guidelines were found

5. US PREVENTIVE SERVICES TASK FORCE

No relevant guidelines were found

3 relevant guidelines were identified^{1,35,36}

APPENDIX 1B: SEARCH STRATEGY FOR SYSTEMATIC REVIEWS/PRIMARY LITERATURE

1. MEDLINE

#	Search History	Results
<i>PHASE 1: SEARCH TERMS FOR CATHETERIZATION</i>		
1	exp Urinary Catheterization/	10644
2	((urinary or urethral) adj10 catheter\$).mp.	13343
3	(intermittent\$ adj10 catheter\$).mp.	2172
4	(condom adj10 catheter\$).mp.	151
5	(suprapubic\$ adj10 catheter\$).mp.	698
6	exp Catheters, Indwelling/	12177
7	(indwelling adj10 catheter).mp.	2949
8	(urin\$ or urethra\$ or bladder).mp. [mp = title, original title, abstract, name of substance word, subject heading word]	393621
9	6 or 7	14224
10	8 and 9	2791
11	1 or 2 or 3 or 4 or 5 or 10	15311
<i>PHASE 2: SEARCH TERMS FOR INFECTION AND OBSTRUCTION</i>		
12	exp Urinary Tract Infections/ not exp Schistosomiasis/	30322
13	exp Cross Infection/ not exp Pneumonia, Ventilator-Associated/	32716
14	(urinary adj tract adj infection\$).mp.	32950
15	UTI.mp.	2941
16	catheter associated urinary tract infection\$.mp.	170
17	((cross adj10 infection\$) or (nosocomial adj10 infection\$)).mp.	38890
18	exp disease transmission, vertical/ or exp disease vectors/	28529

19	exp Disease Transmission/	34951
20	19 not 18	6422
21	nosocomial urinary tract infection\$.mp.	196
22	Bacteremia/	11127
23	funguria.mp.	50
24	Biofilms/	5608
25	encrustation.mp.	331
26	exopolysaccharide.mp.	1270
27	(obstruct\$ or block\$).mp.	606421
28	exp Urethral Obstruction/	7225
29	12 or 13 or 14 or 15 or 16 or 17 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28	701714

PHASE 3: SEARCH TERMS FOR DIAGNOSTICS AND INTERVENTIONS

30	Antibiotic Prophylaxis/	4920
31	exp bronchoalveolar lavage/ or exp gastric lavage/ or exp peritoneal lavage/ or exp vaginal douching/	4517
32	exp Irrigation/	17246
33	32 not 31	12729
34	Lubrication/	1164
35	exp antiparasitic agents/ or exp antiviral agents/	346651
36	exp Anti-Infective Agents/	959273
37	36 not 35	612622
38	Chlorhexidine/ or Povidone-Iodine/	5743
39	Hydrogen-Ion Concentration/	198534
40	(bacteriologic\$ adj10 monitoring).mp.	156
41	(bladder adj10 irrigat\$).mp.	537
42	(bladder adj10 washout).mp.	91
43	(bladder adj10 instillation).mp.	811
44	((open or closed) adj10 drainage).mp.	1820
45	(meatus or meatal).mp.	3763
46	urinary dipstick\$.mp.	56
47	exp kidney function tests/ or exp urinary catheterization/	58228

48	exp Diagnostic Techniques, Urological/	83022
49	48 not 47	24794
50	exp Education, Nursing/	57406
51	exp Hygiene/ not exp Oral Hygiene/	11771
52	exp Infection Control/ not exp Infection Control, Dental/	37395
53	exp Inservice Training/	17316
54	exp Nursing Care/	97685
55	(quality adj improvement).mp.	6840
56	exp Medical Informatics/	139920
57	Patient Education/	48433
58	exp Gels/ or gel.mp. or gels.mp.	319351
59	((antibiotic or antiseptic or silver) adj10 (coat\$ or impregnated)).mp. [mp = title, original title, abstract, name of substance word, subject heading word]	1406
60	exp Total Quality Management/	9150
61	exp Quality Assurance, Health Care/	166322
62	30 or 33 or 34 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61	1633474
PHASE 4: COMBINING THE PHASES		
63	11 and 29 (Phase 1 AND Phase 2)	6381
64	11 and 62 (Phase 1 AND Phase 3)	3214
65	63 or 64 (Phase 1 AND Phase 2) OR (Phase 1 AND Phase 3)	7645
PHASE 5: FILTERING FOR PUBLICATION TYPES		
66	(addresses or bibliography or biography or clinical conference or comment or congresses or consensus development conference or consensus development conference nih or dictionary or directory or duplicate publication or editorial or festschrift or historical article or interview or lectures or legal cases or news or newspaper article or patient education handout).pt.	846798
67	65 not 66	7523
PHASE 6: LIMITING TO HUMANS AND ENGLISH LANGUAGE		
68	limit 67 to (humans and english language)	5332

2. EMBASE

#	Search History	Results
PHASE 1: SEARCH TERMS FOR CATHETERIZATION		
1	exp Bladder Catheterization/	1837
2	exp SUPRAPUBLIC CATHETER/	147
3	exp CONDOM CATHETER/	9
4	exp BALLOON CATHETER/	6278
5	exp Urine Catheter/	1614
6	exp Intermittent Catheterization/	1013
7	exp Indwelling Catheter/	2167
8	(urin\$ or urethra\$ or bladder).mp. [mp = title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]	310690
9	7 and 8	913
10	1 or 2 or 3 or 4 or 5 or 6 or 9	10938
PHASE 2: SEARCH TERMS FOR INFECTION AND OBSTRUCTION		
11	exp Urinary Tract Infection/	28449
12	exp Cross Infection/	882
13	nosocomial infection.mp. or exp Hospital Infection/	20126
14	(urinary adj tract adj infection\$).mp. [mp = title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]	29735
15	uti.mp.	2992
16	Bacteremia/	12751
17	Bacteriuria/	2296
18	exp asymptomatic bacteriuria/ or exp leukocyturia/	639
19	exp Catheter Infection/	4426
20	disease transmission/ or bacterial transmission/ or fungus transmission/	23017
21	funguria.mp.	43
22	exp Biofilm/	7195

23	encrustation.mp.	270
24	exp EXOPOLYSACCHARIDE/	503
25	(obstruct\$ or block\$).mp. [mp = title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]	611065
26	urethral obstruction.mp. or exp Urethra Stenosis/	1032
27	or/11-26	701440

PHASE 3: SEARCH TERMS FOR DIAGNOSTICS AND INTERVENTIONS

28	exp Antibiotic Prophylaxis/	10045
29	exp BLADDER IRRIGATION/	736
30	exp LUBRICATION/	885
31	Urinary Tract Antiinfective Agent/	98
32	exp CHLORHEXIDINE/	4717
33	exp Povidone Iodine/	4559
34	exp Ph/	98612
35	(bacteriologic\$ adj monitoring).mp. [mp = title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]	72
36	exp CLOSED DRAINAGE/	5
37	open drainage.mp.	254
38	(meatus or meatal).mp. [mp = title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]	3008
39	urinary dipstick.mp.	39
40	exp diagnostic test/ or exp laboratory test/	275882
41	exp Nursing Education/	2047
42	exp PERSONAL HYGIENE/ or exp HOSPITAL HYGIENE/	5405
43	infection control/	22250
44	inservice training.mp. or exp Education/	245192
45	exp Nursing Care/ or exp Patient Care/	189701
46	quality improvement.mp. or exp Total Quality Management/	5105
47	exp Medical Informatics/	3313
48	exp Patient Education/	23613
49	gels.mp. or exp Gel/	31972
50	((antibiotic or antiseptic or silver) adj10 (coat\$ or impregnated)).mp. [mp = title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]	1225

51	or/28-50	845675
PHASE 4: COMBINING THE PHASES		
52	10 and 27 (Phase 1 AND Phase 2)	3509
53	10 and 51 (Phase 1 AND Phase 3)	1396
54	52 or 53 (Phase 1 AND Phase 2) OR (Phase 1 AND Phase 3)	4266
PHASE 5: FILTERING FOR PUBLICATION TYPES		
55	(book or conference paper or editorial or note or proceeding).pt.	967981
56	54 not 55	3900
PHASE 6: LIMITING TO HUMANS AND ENGLISH LANGUAGE		
57	limit 56 to (human and english language)	3089

3. CINAHL

#	Search History	Results
PHASE 1: SEARCH TERMS FOR CATHETERIZATION		
1	exp Urinary Catheterization/	1171
2	((urinary or urethral) adj10 catheter\$).mp.	1982
3	exp Catheters, Urinary/	715
4	exp Urinary Catheterization, Intermittent/ or (intermittent\$ adj10 catheter\$).mp.	434
5	exp condom catheters/ or (condom adj10 catheter\$).mp.	78
6	(suprapubic\$ adj10 catheter\$).mp.	79
7	(indwelling adj10 catheter).mp.	270
8	(urin\$ or urethra\$ or bladder).mp. [mp = title, subject heading word, abstract, instrumentation]	16101
9	7 and 8	180
10	1 or 2 or 3 or 4 or 5 or 6 or 9	2148
PHASE 2: SEARCH TERMS FOR INFECTION AND OBSTRUCTION		
11	exp Urinary Tract Infections/	2215
12	exp Cross Infection/	9178

13	(urinary adj tract adj infection\$).mp.	2549
14	UTI.mp.	414
15	catheter associated urinary tract infection\$.mp.	74
16	((cross adj10 infection\$) or (nosocomial adj10 infection\$)).mp.	9443
17	exp disease transmission, vertical/ or exp disease vectors/	1718
18	exp Disease Transmission/	2888
19	18 not 17	1170
20	nosocomial urinary tract infection\$.mp.	44
21	Bacteremia/	1081
22	funguria.mp.	1
23	Biofilms/	271
24	encrustation.mp.	38
25	exopolysaccharide.mp.	4
26	(obstruct\$ or block\$).mp.	19609
27	11 or 12 or 13 or 14 or 15 or 16 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26	33789

PHASE 3: SEARCH TERMS FOR DIAGNOSTICS AND INTERVENTIONS

28	Antibiotic Prophylaxis/	1433
29	lubrication.mp.	83
30	exp antitubercular agents/ or exp antiviral agents/ or exp leprostatic agents/ or exp antiparasitic agents/	9776
31	exp Antiinfective Agents/	23827
32	31 not 30	15091
33	Chlorhexidine/ or Povidone-Iodine/	719
34	Hydrogen-Ion Concentration/	1152
35	(bacteriologic\$ adj10 monitoring).mp.	9
36	(bladder adj10 irrigat\$).mp.	38
37	(bladder adj10 washout).mp.	8
38	(bladder adj10 instillation).mp.	22
39	exp DRAINAGE/ or exp CLOSED DRAINAGE/	1961
40	((open or closed) adj10 drainage).mp.	159
41	(meatus or meatal).mp.	75

42	urinary dipstick\$.mp.	2
43	exp Diagnosis, Urologic/	4186
44	exp kidney function tests/ or exp urinary catheterization/	2087
45	43 not 44	2297
46	exp Education, Nursing/	32413
47	exp Urologic Nursing/	535
48	exp Hygiene/	766
49	exp Infection Control/	20325
50	exp Nursing Care/	139877
51	(quality adj improvement).mp.	10239
52	exp Medical Informatics/ or exp nursing informatics	1811
53	Patient Education/	23144
54	exp Gels/ or gel.mp. or gels.mp.	1956
55	((antibiotic or antiseptic or silver) adj10 (coat\$ or impregnated)).mp. [mp = title, subject heading word, abstract, instrumentation]	119
56	exp Catheter Care, Urinary/	179
57	exp Urinary Bladder Irrigation/ or exp catheter irrigation, urinary/	26
58	exp Staff Development/	11367
59	exp Quality Improvement/	11174
60	28 or 29 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59	239992

PHASE 4: COMBINING THE PHASES

61	10 and 27 (Phase 1 AND Phase 2)	828
62	10 and 60 (Phase 1 AND Phase 3)	956
63	61 or 62 (Phase 1 AND Phase 2) OR (Phase 1 AND Phase 3)	1328

PHASE 5: FILTERING FOR PUBLICATION TYPES

64	(abstract or accreditation or anecdote or audiovisual or bibliography or biography or book or book chapter or cartoon or classification term or "code of ethics" or commentary or computer program or consumer patient teaching materials or diagnostic images or directories or editorial or equations & formulas or exam questions or forms or games or glossary or historical material or interview or journal description or legal cases or listservs or obituary or pamphlet or pamphlet chapter or pictorial or poetry or proceedings or questions & answers or research term definition or response or software or "tables or charts" or tracings or website).pt.	510619
65	63 not 64	867

PHASE 6: LIMITING TO ENGLISH LANGUAGE

66	limit 65 to english	839
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4. COCHRANE

#	Search History	Results
#1	MeSH descriptor Urinary Catheterization explode all trees	431
#2	MeSH descriptor Urinary Tract Infections explode all trees	1776
#3	#1 AND #2	219
Search results contained 4 Cochrane Reviews, 5 other reviews, 185 clinical trials, 3 Technology Assessments and 22 economic evaluations		

APPENDIX 2: EVIDENCE, GRADE AND STUDY QUALITY ASSESSMENT TABLES

(Notes: All abbreviations are listed on page 6 of main report; the numbers in the quality column correspond with those of the quality scales for the respective study design in Appendix 4; shaded results represent statistically significant results)

Question 1: Who should receive urinary catheterization?

1A. When is urinary catheterization necessary?

TABLE 1A: IS URINARY CATHETERIZATION NECESSARY FOR:

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
1A.1. Operative Catheterization					
Phipps, 2006 ³⁷	Systematic review 1,2,3,4,5,6,7,8	To establish the optimal way to manage urinary catheters following urogenital surgery in adults.	Randomized and quasi-randomized trials 39 RCTs	<p>Note: All results are RR (95% CI) unless otherwise noted.</p> <p>1. Using a urinary catheter vs not using a urinary catheter</p> <p>Retention of urine (1 study): 0.12 (0.03-0.47) UTI (4 studies): 1.35 (0.75-2.45) Recatheterization (3 studies): 0.32 (0.14-0.70) Post-op urethral stricture (1 study): 1.14 (0.90-1.44) Post-op hematuria (1 study): 0.73 (0.40-1.33)</p> <p>2. Urethral catheterization vs suprapubic catheterization</p> <p>UTI: Heterogeneous results, not combined. Of four trials, two suggested a moderate increase, one a large increase and one a large decrease. Recatheterization (2 studies): 3.66 (1.41-9.49) Post-op hematuria (1 study): 5.00 (0.21-116.31) Length of hospital stay in days (1 study) [WMD (95% CI)]: 1.10 (0.30-1.90) Catheter lockage or bypassing [OR (95% CI)] (2 studies): 0.20 (0.02-1.72)</p> <p>3. One type of catheter vs another</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>UTI: Urethral Foley catheter with extra drainage hole vs unmodified Foley catheter (1 study): 0.40 (0.15-1.04)</p> <p>Positive urine culture: Silver-coated Bardex catheters vs latex catheters (1 study): 0.53 (0.20-1.45)</p> <p>4. One type of catheter management vs another</p> <p>Retention of urine: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.99 (0.06-15.54)</p> <p>Dysuria: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.99 (0.06-15.54)</p> <p>Symptomatic UTI: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.61 (0.33-1.14)</p> <p>Bacteriuria/unspecified UTI: Cefotaxime 1 hour prior to catheter removal vs none (1 study): 0.08 (0.00-1.30)</p> <p>Neomycin/Sulfamethiazole vs placebo (1 study): 0.18 (0.06-0.55)</p> <p>Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 1.06 (0.70-1.51)</p> <p>Recatheterization:</p> <p>Neomycin/Sulfamethiazole vs placebo (1 study): 0.50 (0.24-1.04)</p> <p>5. Larger diameter catheter vs Smaller diameter catheter</p> <p>No trials found</p> <p>6. Bladder irrigation</p> <p>No trials found</p> <p>7. Shorter duration vs longer duration catheter</p> <p>Retention of urine: 1 day vs 3 days (1 study): 0.80 (0.38-1.69)</p> <p>1-2 days vs until urine clear (1 study): 1.02 (0.07-15.87)</p> <p>1 day vs 2 days (1 study): 4.64 (0.23-94.28)</p> <p>3 days vs 28 days (1 study): 3.00 (0.13-69.52)</p> <p>Post-op urethral stricture: <1 week vs 2 weeks (2 studies): 1.23 (0.82-1.84)</p> <p>3 days vs 28 days (1 study): 1.00 (0.73-1.36)</p> <p>UTI: Heterogeneous results, not combined. Shorter duration had lower risk of UTIs but the results were significant in only 1 trial</p> <p>1 day vs 3 days (3 studies): 0.50 (0.29-0.87)</p> <p>Recatheterization: 1 day vs 2 days (1 study): 1.03 (0.23-4.71)</p> <p>1 day vs 3 days (2 studies): 1.04 (0.36-3.01)</p> <p>1 day vs 5 days (1 study): 4.55 (1.68-12.37)</p> <p>4-6 days vs 14 days (1 study): 1.86 (0.14-25.38)</p> <p>1-2 days vs until urine clear (2 studies): 0.72 (0.24-2.20)</p> <p>Post-op hematuria: 1-2 days vs until urine clear (1 study): 2.04 (0.19-</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>21.81) 1 day vs 2 days (2 studies): 1.16 (0.34-3.90) Urinary leakage or incontinence: 1-2 days vs until urine clear (2 studies): 0.43 (0.07-2.88)</p> <p><u>8. Clamp and release vs free catheter drainage:</u> UTI (1 study): 4.00 (1.55-10.29) Delay in return to normal bladder function (1 study) - 2.50 (1.16-5.39)</p> <p><u>9. Catheter removal at one time of day vs another time of day</u> UTI: 12 am vs 6 am hours (1 study): 1.31 (0.65-2.66) Recatheterization: 12 am vs 6 am (4 studies): 0.61 (0.34-1.12) 6-7 am vs 10-11 pm (1 study): 1.36 (0.32-5.77) Time to first void in hours [WMD (95% CI)]: 12 am vs 6 am (1 study): 0.60 (-0.96 to 2.16) Volume of first void in ml [WMD (95% CI)]: 12 am vs 6 am (1 study): 53.00 (4.27-101.73)</p> <p><u>10. Trial of void protocol vs none</u> No trials found</p> <p><u>11. Prefilling bladder prior to catheter removal vs removal without prefilling</u> Recatheterization [OR (95% CI)] (1 study): 4.52 (0.79-25.97) Discharge on day of catheter removal (1 study): 1.36 (0.47-3.91)</p>	
Tang, 2005 ³⁸	RCT 1,2,3,4,5,6,7,8	To compare the outcomes of patients undergoing routine urethral catheterization and non-catheterization before gynecological laparoscopy with respect to bladder injury, postoperative urinary symptoms, and UTI.	Women undergoing elective or emergency laparoscopy 279	<p>Bacteriuria: Catheterization vs no catheterization: 13/131 vs 5/131; P = 0.09</p> <p>Symptomatic UTI: Catheterization vs no catheterization: 5/131 vs 3/131; statistical differences were not reported</p> <p>Bladder injury: There were no events in either group</p> <p>Recatheterization: Catheterization vs no catheterization: 3/131 vs 4/131; P = 1.00</p> <p>Catheterization was significantly associated with operative time > 90 min (P < 0.01)</p>	<p>F/U 1 week post-op</p> <p>UTI defined as bacterial count > 10⁵ cfu/ml in the urine culture on a mid-stream urine sample.</p> <p>Recatheterization: postoperatively, if the patient failed to pass urine after 6 hours, the bladder would be catheterized.</p> <p>80% power at an alpha of 0.05 to show a significant reduction in UTI in the non-catheterized patients from 12.5% to 2.5%.</p>
Iorio, 2000 ³⁹	RCT 1	To compare preoperative insertion of an indwelling catheter for 24 hours with	Patients undergoing unilateral total knee arthroplasty	Unspecified UTI: Short-term indwelling catheter vs catheter inserted as needed: 5/306 vs 6/346; P > 0.05	<p>F/U unclear</p> <p>UTI not defined</p>

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		postoperative insertion of a catheter on an as-needed basis only if symptoms of urinary retention developed.	652	Length of hospital stay (days): Short-term indwelling catheter vs catheter inserted as needed: 4.56 vs 4.29; P > 0.05 Hospital costs: Short-term indwelling catheter vs catheter inserted as needed: \$9071 vs \$8581; P < 0.01	Power not reported
Liu, 1999 ⁴⁰	RCT 1,7,8	To evaluate the necessity of urethral catheterization. Patients were randomized to either receive or not receive preoperative urinary bladder catheterization. For those patients randomized to receive a catheter (Foley), the catheter was inserted after induction of anesthesia and removed at the termination of the surgery.	Patients undergoing elective laparoscopic cholecystectomy 261	Unspecified UTI: Catheter vs no catheter: 3/127 vs 0/134; no significant differences Urinary retention: Catheter vs no catheter: 1/127 vs 1/134; no significant differences Postoperative bleeding: Catheter vs no catheter: 1/127 vs 2/134; statistical differences were not reported Wound infection: Catheter vs no catheter: 3/127 vs 1/134; statistical differences were not reported Visceral injury: Catheter vs no catheter: 0/127 vs 0/134; statistical differences were not reported Retained common bile duct stones: Catheter vs no catheter: 0/127 vs 2/134; statistical differences were not reported Cystic duct stump leak: Catheter vs no catheter: 0/127 vs 1/134; statistical differences were not reported	F/U 1 week post-op UTI not defined Power not reported
Normelli, 1993 ⁴¹	RCT 1	To study the effect of the use of an intraoperative indwelling urethral catheter when compared with no intraoperative catheter. All patients were if necessary intermittently catheterized in the postoperative period.	Patients admitted for spinal surgery 32	Bacteriuria: Catheter vs no catheter: 7/16 vs 2/16; P ≥ 0.05 Largest urine volume at one catheterization (mean in ml): Catheter vs no catheter: 528 vs 713; P ≥ 0.05 Days until voiding (mean): 3.1 vs 3.1; statistical differences were not reported Recatheterization: 14/16 vs 14/16; statistical differences were not reported	F/U one week postoperatively Positive culture was defined as ≥ 10 ⁵ cfu/ml. Not known how sample was obtained. The outcome of recatheterization denotes postoperative intermittent catheterization Power not reported
Carpiniello, 1988 ⁴²	RCT 1	To evaluate the effect of early bladder decompression either perioperatively or after joint replacement (via straight catheterization in the recovery room) on the incidence of urinary tract infections and	Elderly female patients undergoing total joint replacement. 77	Bacteriuria: SC vs NC: 5/31 vs 2/23 FC vs NC: 1/23 vs 2/23 Recatheterization SC vs NC: 20/31 vs 13/23 FC vs NC: 1/23 vs 13/23	F/U for duration of postoperative period: specifics unclear. Positive culture was defined as ≥ 10 ⁵ cfu/ml on a mid-stream urine sample The outcome of recatheterization for

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		subsequent catheterizations. Patients were randomized into 3 groups: straight catheterization performed in the recovery room (SC); Foley catheter inserted immediately preoperatively and removed 24 hours postoperatively (FC); and no catheterization performed in the recovery room (NC).		There were no events of deep sepsis in any of the three groups. [No significant differences between SC and NC groups. No statistical comparisons were made between SC and FC groups]	the SC and NC groups denotes the number of patients catheterized after recovery room. For the FC group, it is number of people recatheterized after Foley removal Power not reported
Akhtar, 1985 ⁴³	RCT 1,6,7,8,9	To determine if bladder catheterization was necessary in patients undergoing laparoscopy. No further details on catheterization were provided.	Patients undergoing laparoscopy 83	Bacteriuria: <i>Intention to treat</i> - Catheterization vs no catheterization: 9/42 vs 5/41; P = 0.03 <i>Per protocol</i> - Catheterization vs no catheterization: 9/42 vs 4/34; P = 0.049 Symptomatic UTI: <i>Intention to treat</i> - Catheterization vs no catheterization: 5/42 vs 1/41 <i>Per protocol</i> - Catheterization vs no catheterization: 5/42 vs 1/34; [Statistical differences were not reported for this outcome]	F/U 6 days after laparoscopy Infection was considered present if there were $> 10^5$ organisms/ml on a midstream urine specimen. The composite outcome of symptoms and infection was also measured Power not reported
Chaudhuri, 1983 ⁴⁴	RCT 1	To compare short-term indwelling catheterization (inserted immediately prior to operation and removed after a mean period of 22 hours) with no catheterization	Women undergoing cesarean section 173	Bacteriuria: Catheter vs no catheter: 30/141 vs 3/32; a chi-squared statistic of 2.39 was reported, no significant differences	F/U postoperatively UTI (significant bacteriuria) was deemed to have been present when the viable count was $> 10^5$ organisms/ml of a clean catch urine specimen Power not reported
Kumar, 2006 ⁴⁷	Retrospective controlled study 1,3	To investigate the rate of urinary retention after knee arthroplasty and to identify risk factors for urinary retention	Patients undergoing total knee arthroplasty 142	Unspecified UTI: No postoperative UTI occurred in any patient. Postoperative urinary retention: Preoperative catheterization vs no catheterization: 2/19 vs 28/123; statistical differences were not reported for this outcome Deep-joint sepsis: Preoperative catheterization vs no catheterization: 1/19 vs 2/123; statistical differences were not reported for this outcome Factors predicting those at significant risk of retention following knee arthroplasty - a past medical history of urinary retention (P = 0.05) and postoperative morphine requirement (P = 0.04)	Mean F/U ~2 years UTI not defined Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
Miskry, 2001 ⁴⁸	Prospective study with historical controls 1,3	To examine the feasibility of non-catheterization in patients undergoing laparoscopy. Patients in the intervention group were catheterized if bladder filling interfered with surgery, or postoperatively if they failed to pass urine within 6 hours. All historical controls were routinely catheterized.	Patients scheduled to undergo gynecological operative laparoscopy 80	Bacteriuria: No catheterization vs catheterization: 1/40 vs 5/40; P = 0.20 Recatheterization: 5 patients (12.5%) in the no catheterization group had to be catheterized intra and postoperatively (data only for test group) Bladder injury: There were no cases of intra-operative bladder trauma in either of the groups Catheterization was significantly associated with operative time > 100 min (P < 0.01)	F/U unclear Infection was considered to be present if there were $\geq 10^5$ micro-organisms/ml of urine on mid-stream or catheter specimen of urine Power was not reported, but it was suggested that the study was not powered to detect differences in infection.
Barnes, 1998 ⁴⁹	Retrospective Controlled Study 1,3,4	To evaluate the utility of urethral catheterization in patients undergoing hysterectomy or cesarean section.	Patients undergoing hysterectomy or cesarean section 329	Bacteriuria: Catheter pre or postoperatively vs never catheterized- 21/251 vs 0/70; P < 0.05	F/U perioperatively A colony count $> 10^6$ per ml and pyuria were the criteria to diagnose an infection in patients with urinary symptoms or unexplained fever. Power not reported

1A.2. Urinary incontinence

McMurdo, 1992 ⁴⁵	RCT (also included data on non-randomized patients) 1,2,7	To compare the costs and effects of management of intractable urinary incontinence by urinary catheterization or incontinence pads.	Elderly female patients with intractable urinary incontinence 78 randomized and 27 non-randomized patients	Urine infection: The median of the proportion of urine cultures positive: 0.7 vs 1.0 Equipment costs: Catheter vs pads: £19.20-24.65 vs £8.79-11.35 per patient per week. (The difference was mainly because of the cost of catheter care) Nursing time: Catheter vs pads: 15.4 vs 29 hours per patient per week Antibacterial treatment: Catheter vs pads: 73% vs 40% [Statistical differences were not reported]	F/U 26 weeks UTI not clearly defined Power not reported
Ouslander, 1987 ⁵⁰	Prospective controlled study 1,3,4,6	To examine the frequency of UTI and bacteriuria among patients managed with and without external catheters (EC).	Male nursing home patients with incontinence due to various neurological disorders (data on 30 continent patients were	Symptomatic UTI: EC continuously vs no catheter - 12/30 vs 1/13; P < 0.05 EC at night only vs no catheter: 3/19 vs 1/13; statistical differences not clearly reported EC continuously vs EC at night only: 12/30 vs 3/19; P> 0.05	Mean F/U 5.4 months Significant bacteriuria defined as a growth of $> 10^5$ colonies on clean catch urine specimens.

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
			not included) 62	Bacteriuria: EC continuously vs no catheter: 26/30 vs 6/13; P < 0.05 EC at night only vs no catheter: 10/19 vs 6/13; P > 0.05 EC continuously vs EC at night only: 26/30 vs 10/19; P < 0.05 Bacteriuria and pyuria: EC continuously vs no catheter - 12/30 vs 3/13; P > 0.05 EC at night only vs no catheter: 7/19 vs 3/13; P > 0.05 EC continuously vs EC at night only: 12/30 vs 7/19; P > 0.05 Risk factors for symptomatic UTI: <u>Univariate analysis:</u> All results are P values. Age: NS Length of time in the facility: NS Diabetic: NS Katz ADL score: NS Mental status score: NS % Ideal body weight: NS Skinfold thickness: NS Serum creatinine (mg/dl): NS Albumin: < 0.01 Hb (g/dl): NS Stool incontinence: NS Past genitourinary diagnoses: NS Catheter manipulation: NS Suppressive antibiotic therapy: NS Urinary acidifier: NS	Symptomatic UTI was defined as an episode in which: 1) the patient had one or more symptoms or signs of a UTI 2) other sources of fever had been excluded 3) the patient was treated with an antimicrobial for a urinary source of infection and 4) a urine culture grew 10^5 cfu of at least one pathogen. With 30 patients in each group, the power to detect differences of 30% in the proportion of patients developing infections was 75%
Rannikko, 1986 ⁵¹	Prospective controlled study 1,3	To compare bed-pads and long-term indwelling catheters in the treatment of urinary incontinence.	Elderly women with incontinence and dementia 22	Bacteriuria: At the end of 6 months, all patients in both groups had significant bacteriuria, Proteus species being the most common pathogen. Development of multiple resistance observed in both groups. Cost: Indwelling catheter significantly more economical (P < 0.01)	F/U 6 months Significant bacteriuria was defined as $\geq 10^5$ cfu/ml. Not known how sample was obtained. Power not reported
Nordqvist, 1984 ⁵²	Prospective controlled study 1,3	To study the clinical and economic consequences of catheter-free geriatric care. Patients in the test group, i.e., catheter-free group, underwent a continence training program in the 6 months preceding the study. Patients in the control group had indwelling catheters.	Patients in a geriatric hospital. Not specified.	Antibiotic prescription: Test 90% less than in control wards. Cost: Cost of laundry, hygiene and storage articles in test 46% of that in the control wards. Mortality: Test vs Control: 65% vs 72% No statistical differences were reported.	F/U 4 years UTI not measured Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
1A.3. Bladder Outlet Obstruction					
Egilmez, 2006 ⁵³	Prospective controlled study 1,3,4,6,7	To compare intraurethral metal stent with indwelling urinary catheter on the incidence of CAUTI.	Patients with bladder outlet obstruction 110	Bacteriuria: Indwelling catheter vs intraurethral stent: 27/34 vs 42/76; RR (95% CI) = 1.4 (1.2-2.0) RR (95% CI) after adjustment for infected urine at the time of insertion: 1.5 (1.2-2.1) RR (95% CI) after adjustment for clean urine at the time of insertion: 2.5 (1.4-3.8) RR (95% CI) after adjustment for prior UTI: 1.8 (1.0-3.0) RR (95% CI) estimates after adjustment for either diabetes or age were the same: 1.4 (0.8-2.2). Symptomatic UTI: Indwelling catheter vs intraurethral stent: 13/34 vs 4/76; statistical differences were not reported	F/U 1 month UTI was defined as $\geq 10^5$ cfu/ml on a mid-stream urine sample. Symptomatic UTI was measured but not defined. Power not reported
1A.4. Spinal Cord Injury/Neurogenic Bladder					
Adults					
De Ruz, 2000 ⁵⁴	Prospective controlled study 1,3,4,6,7	To identify risk factors for UTI.	Adult spinal cord injury patients with injury \leq 60 days before enrollment, neurogenic bladder dysfunction and injury below C4 128	Symptomatic UTI: All results OR (95% CI) <u>1. Univariate analysis</u> Age older than 40 yrs: 1.38 (1.01-1.88) Hyperreflexic bladder: 1.38 (1.03-1.86) Cervical injury: 1.39 (1.04-1.85) Functional independence measure score < 74: 1.49 (1.08-2.06) Indwelling catheterization greater than 30 days: 1.53 (1.12-2.10) Vesicoureteral reflux: 1.77 (1.12-2.81) Invasive procedure: 4.26 (3.15-5.76) Indwelling catheter: 7.77 (5.80-10.40) Clean intermittent catheterization: 0.42 (0.31-0.58) Condom catheter: 0.24 (0.15-0.40) Suprapubic catheterization: 0.04 (0.04-0.19) Normal voiding: 0.04 (0.01-0.17) Patient sex, time of evolution, type of injury, co-morbidity, etiology, lithiasis, surgery, previous antimicrobial treatment and immunosuppression were not associated. <u>2. Multivariate analysis: Model 1 (defined all risk factors in patients who presented with at least UTI episode during hospitalization)</u> Cervical injury: 2.99 (1.12-7.97) Invasive procedure: 2.62 (1.02-6.69) Indwelling catheterization greater than 30 days: 4.04 (1.24-13.06)	F/U 38 months UTI was defined as a colony count of $\geq 10^5$ cfu/ml without a fever of 38 C and two symptoms, including bladder overdistension, lower abdominal pain, increased urinary incontinence, increased spasticity, autonomic hyperreflexia, and/or increased sweating and malaise Bacteriuria was defined as a colony count of $\geq 10^5$ cfu/ml and no fever or other symptoms Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p><u>3. Multivariate analysis: Model 2 (defined risk factors in patients who presented with repeat UTIs during hospitalization)</u></p> <p>Functional independence measure score < 74: 9.96 (2.33-42.11) Vesicoureteral reflux: 22.86 (2.31-225.87)</p> <p>Bacteriuria: All results OR (95% CI) Indwelling catheter: 2.70 (2.32-3.20) Clean intermittent catheterization: 1.16 (1.01-1.35) Condom catheter: 0.46 (0.38-0.56) Suprapubic catheterization: 0.06 (0.04-0.10) Normal voiding: 0.05 (0.03-0.10)</p>	
Larsen, 1997 ⁵⁶	Retrospective controlled study 1,3	To compare long-term urologic complications in male patients with spinal cord injury managed with and without indwelling urinary catheters.	Spinal cord injured patients who receive continuous long-term medical care 204	<p>Patients with ≥ 1 Symptomatic UTI: Indwelling catheter vs no indwelling catheter: 48/56 vs 46/86; P < 0.01</p> <p>Urosepsis: Indwelling catheter vs no indwelling catheter: 12/56 vs 7/86; P = 0.02</p> <p>Recurrent pyelonephritis: Indwelling catheter vs no indwelling catheter: 7/56 vs 2/86; P = 0.02</p> <p>Epididymitis: Indwelling catheter vs no indwelling catheter: 12/56 vs 8/86; P = 0.04</p> <p>Deaths: Indwelling catheter vs no indwelling catheter: 5/56 vs 3/86; statistical differences were not reported</p> <p>Gross hematuria: Indwelling catheter vs no indwelling catheter: 23/56 vs 6/86; P < 0.01</p> <p>Bladder stones: Indwelling catheter vs no indwelling catheter: 34/56 vs 10/86; P < 0.01</p> <p>Renal stones: Indwelling catheter vs no indwelling catheter: 18/56 vs 6/86; P < 0.01</p> <p>Urethral fistula: Indwelling catheter vs no indwelling catheter: 5/56 vs 10/86; P = 0.01</p> <p>Urethral erosion: Indwelling catheter vs no indwelling catheter: 12/56 vs 6/86; P < 0.01</p> <p>Urethral stricture: Indwelling catheter vs no indwelling catheter: 13/56</p>	F/U 7 years UTI not defined, but labeled as symptomatic UTI Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>vs 4/86; P < 0.01</p> <p>Urethral abscess: Indwelling catheter vs no indwelling catheter: 5/56 vs 0/86; P = 0.01</p>	
Donovan, 1978 ⁵⁵	Prospective controlled study 1,3	To describe the effect of timing of initiation of intermittent catheterization on the incidence of UTI.	Patients with spinal cord injury undergoing intermittent catheterization 60	<p>Bacteriuria: Catheterization initiated within 1 month vs after 1 month: P = NS Pearson correlation coefficient: 0.31</p> <p>No. of catheterizations/day: Catheterization initiated within 1 month vs after 1 month: P = NS Pearson correlation coefficient: 0.31</p> <p>Host resistance: Host resistance (as measured by bacteriuria/catheterization) appeared to decrease until around the 5th and 6th weeks and subsequently remained unchanged over the ensuing 9 weeks.</p>	<p>F/U unclear</p> <p>Bacteriuria defined by the appearance of an organism in any amount on 2 successive days.</p> <p>A decrease in host resistance meant increase in bacteriuria/catheterization.</p> <p>Power not reported</p>

Children

Geraniotis, 1988 ⁴⁶	RCT 1	To examine the hypothesis that the prophylactic use of clean intermittent catheterization in infants and children with meningomyelocele would prevent urinary tract deterioration.	Infants and children with meningomyelocele and bladder sphincter incoordination 21	<p>Urinary tract deterioration: Clean intermittent catheterization vs self-voiding: 1/10 vs 6/11; P = 0.045</p>	<p>F/U 6-36 months</p> <p>UTI not defined and not reported clearly in the self-voiding group</p> <p>Power not reported</p>
Kochakarn, 2004 ⁵⁷	Retrospective controlled study 1,3	To compare the results of long term clean intermittent catheterization treatment for neurogenic bladder in children when it was performed early (< 1 year of age) and late (> 3 years of age).	Children with meningomyelocele 67	<p>Unspecified UTI (recurrent upper UTI): Early treatment vs late treatment: 9/36 vs 14/31; P = 0.08</p> <p>Hydronephrosis: Early treatment vs late treatment: 10/36 vs 18/31; P = 0.01</p> <p>Augmentation cytoplasty: Early treatment vs late treatment: 5/36 vs 10/31; P = 0.07</p> <p>Increased BUN or serum creatinine: Early treatment vs late treatment: 12/36 vs 19/31; P = 0.02</p>	<p>F/U 11 years</p> <p>UTI not defined</p> <p>Power not reported</p>
Ehrlich, 1982 ⁵⁸	Prospective controlled study 1,3,4	To compare clean intermittent catheterization with urinary diversion for patients with neurogenic bladder.	Children with meningomyelocele 33	<p>Symptomatic UTI: Clean intermittent catheterization vs ileal loop diversion: 5/24 vs 1/9; not significant</p> <p>Bacteriuria: Clean intermittent catheterization vs ileal loop diversion: 85/231 vs 34/55; P < 0.01 (Ns are number of cultures)</p>	<p>F/U 1 year</p> <p>A positive urine culture was defined as ≥ 10⁴ colonies/ml. A symptomatic UTI was defined as the onset of pyuria in</p>

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
					association with one or more of: fever, malaise, abdominal pain, and/or a transient change in serum creatinine level or creatinine clearance Power not reported

GRADE Table 1A

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE			Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response		
Catheter vs no catheter for operative patients	Symptomatic UTI*	2 RCT ^{38,43}	2 RCTs did not report statistical differences ^{38,43} .	High	0	0	-1	-1	0	0	0	0	Low
	Bacteriuria/ unspecified UTI*	1 SR ³⁷ 7 RCT ³⁸⁻⁴⁴ 3 OBS ⁴⁷⁻⁴⁹	1 SR showed no significant differences ³⁷ . 1 RCT ⁴³ and 1 OBS ⁴⁹ showed a significantly decreased risk with no catheterization. The other RCTs ^{38-42,44} and the 2 OBS ^{47,48} showed no significant differences, although there was some suggestion of increased risk with catheterization in higher quality studies.	High	-1	0	0	0	0	0	0	0	Moderate
	Urinary retention*	1 SR ³⁷ 1 RCT ⁴⁰ 1 OBS ⁴⁷	The SR showed a significantly decreased risk of urinary retention with catheterization ³⁷ . In the RCT, no significant differences were found ⁴⁰ and in the OBS ⁴⁷ , statistical differences were not reported.	High	-1	-1	0	0	0	0	0	0	Low
	Recatheterization*	1 SR ³⁷ 3 RCT ^{38,41,42} 1 OBS ⁴⁸	The SR showed a significantly decreased risk of recatheterization with the use of a urinary catheter ³⁷ . 3 RCTs showed no significant differences ^{38,41,42} . In the OBS, comparative data were not provided.	High	0	-1	0	-1	0	0	0	0	Low

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
	Length of Stay/Hospitalization	1 RCT ³⁹	No significant differences were found.	High	-1	0	0	-1	0	0	0	0	Low	
Catheter vs no catheter for incontinent patients	Bladder injury*	1 RCT ³⁸ 1 OBS ⁴⁸	There were no events in either group in both studies.	High	0	0	0	-1	-1	0	0	0	Low	Low
	Symptomatic UTI*	1 OBS ⁵⁰	Having no catheter had a significantly reduced risk compared with wearing the catheter continuously.	Low	0	0	0	0	0	0	0	0	Low	
	Bacteriuria/unspecified UTI*	1 RCT ⁴⁵ 2 OBS ^{50,51}	In 1 OBS, having no catheter had a significantly reduced risk compared with wearing the catheter continuously. No significant differences were found between having a catheter at night only and having no catheter ⁵⁰ . In the other OBS, all patients in both groups had bacteriuria ⁵¹ . Statistical differences were not reported in the RCT ⁴⁵ .	High	-1	-1	0	0	0	0	0	0	Low	
	Mortality	1 OBS ⁵²	Statistical differences were not reported.	Low	0	0	0	-1	0	0	0	0	Very Low	
Catheter vs stent for bladder outlet obstruction	Nursing time	1 RCT ⁴⁵	Statistical differences were not reported.	High	-1	0	0	-1	0	0	0	0	Low	Very Low
	Symptomatic UTI*	1 OBS ⁵³	Statistical differences were not reported; although there was a suggestion that stent was better than catheter.	Low	0	0	0	-1	0	0	0	0	Very Low	
Catheter vs no catheter for spinal cord injury patients	Bacteriuria*	1 OBS ⁵³	There was an increased risk of bacteriuria with the use of indwelling catheter.	Low	0	0	0	0	0	0	0	0	Low	Very Low
	Symptomatic UTI*	2 OBS ^{54,56}	Significantly reduced with no catheterization in both studies.	Low	0	0	0	0	0	0	0	0	Low	
	Bacteriuria*	1 OBS ⁵⁴	Significantly reduced with no catheterization.	Low	0	0	0	-1	0	0	0	0	Very Low	
	Urinary complications*	1 OBS ⁵⁶	Significantly reduced with no catheterization.	Low	0	0	0	-1	0	0	0	0	Very Low	
Catheter vs no catheter for children	Mortality	1 OBS ⁵⁶	Statistical differences were not reported.	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
	Symptomatic UTI*	1 OBS ⁵⁸	No significant differences were found.	Low	0	0	0	-1	0	0	0	0	Very Low	
	Bacteriuria/ unspecified UTI*	2 OBS ^{57,58}	Ileal loop diversion had a significantly greater risk when compared	Low	0	0	-1	0	0	0	0	0	Very Low	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
with neurogenic bladder			with clean intermittent catheterization in 1 OBS ⁵⁸ . There were no significant differences in early vs late clean intermittent catheterization in the other OBS ⁵⁷ .										Low	
	Urinary tract deterioration/Hydronephrosis*	1 RCT ⁴⁶ 1 OBS ⁵⁷	Clean intermittent catheterization significantly reduced urinary tract deterioration in the RCT ⁴⁶ and when used early as in the OBS ⁵⁷ .	High	-1	0	-1	0	0	0	0	0		

* These modifiers can impact the GRADE by 1 or 2 points

Study Quality Assessment Table 1A

Study	Systematic Review								Randomized Controlled Trial								Observational Controlled Study				Economic analysis									
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented	6. Sensitivity analyses performed
1A.1. Operative Catheterization																														
Phipps, 2006 ³⁷	x	x	x	x	x	x	x	x																						
Tang, 2005 ³⁸																														
Iorio, 2000 ³⁹																														
Liu, 1999 ⁴⁰																														
Normelli, 1993 ⁴¹																														
Carpiniello, 1988 ⁴²																														
Akhtar, 1985 ⁴³																														
Chaudhuri, 1983 ⁴⁴																														
Kumar, 2006 ⁴⁷																														
Miskry, 2001 ⁴⁸																														
Barnes, 1998 ⁴⁹																														
1A.2. Urinary incontinence									x	x					x															
McMurdo,																														

Study	Systematic Review				Randomized Controlled Trial				Observational Controlled Study				Economic analysis																
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented
1992 ⁴⁵ Ouslander, 1987 ⁵⁰																													
Rannikko, 1986 ⁵¹																													
Nordqvist, 1984 ⁵²																													
1A.3. Bladder Outlet Obstruction																													
Egilmez, 2006 ⁵³																													
1A.4. Spinal Cord Injury/Neurogenic Bladder																													
De Ruz, 2000 ⁵⁴																													
Larsen, 1997 ⁵⁶																													
Donovan, 1978 ⁵⁵																													
Geraniotis, 1988 ⁴⁶																													

Study	Systematic Review				Randomized Controlled Trial				Observational Controlled Study				Economic analysis																
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented
Kochakarn, 2004 ⁵⁷									x	x			x	x		x	x												
Ehrlich, 1982 ⁵⁸																													

1B. What are the risk factors for CAUTI?

TABLE 1B: RISK FACTORS FOR CAUTI

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results*	Comments
1B.1. Spinal cord injury/Neurogenic Bladder					
Seki, 2004 ⁷⁰ 1,3,4,6,7	Retrospective controlled study 1,3,4,6,7	To identify risk factors for febrile UTI.	Children with myelodysplasia who were treated by clean intermittent catheterization 76	Febrile UTI: <i>Univariate analysis:</i> All results P value Age: 0.03 Sex: 0.29 Hydronephrosis: 0.50 Vesicoureteral reflux: 0.03 Bladder trabeculation: 0.03 Maximum urethral closing pressure: 1.00 Bladder compliance < 10-< 0.01 Detrusor overactivity: < 0.01 Detrusor sphincter dyssynergia: 0.14 <i>Multivariate Analysis:</i> All results OR (95% CI) or P values Age: 1.02 (1.00: 1.03); P = 0.01 Sex: 0.84 Hydronephrosis: 1.00 Vesicoureteral reflux: 4.50 (1.04-19.40) Bladder trabeculation: 0.89 Maximum urethral closing pressure: 0.07 Bladder compliance < 10: 10.80 (2.17-54.00) Detrusor overactivity: 6.31 (1.14-34.90) Detrusor sphincter dyssynergia: 0.86	F/U 3 years Febrile UTI consisted of a positive urine culture associated with pyuria in a patient with a temperature of ≥ 38.5 C, symptoms or signs of UTI, and no other apparent infection. A urine culture was considered to be positive when ≥ 10 ⁴ organisms of a single or predominant species of urine were found in urine culture specimens. Power not reported
De Ruz, 2000 ⁵⁴	Prospective controlled study 1,3,4,6,7	To identify risk factors for UTI.	Adult spinal cord injury patients with injury ≤ 60 days before enrollment, neurogenic bladder dysfunction and injury below C4 128	Symptomatic UTI: All results OR (95% CI) <i>1. Univariate analysis</i> Age older than 40 yrs: 1.38 (1.01-1.88) Hyperreflexic bladder: 1.38 (1.03-1.86) Cervical injury: 1.39 (1.04-1.85) Functional independence measure score < 74: 1.49 (1.08-2.06) Indwelling catheterization greater than 30 days: 1.53 (1.12-2.10) Vesicoureteral reflux: 1.77 (1.12-2.81) Invasive procedure: 4.26 (3.15-5.76) Indwelling catheter: 7.77 (5.80-10.40) Clean intermittent catheterization: 0.42 (0.31-0.58) Condom catheter: 0.24 (0.15-0.40) Suprapubic catheterization: 0.04 (0.04-0.19) Normal voiding: 0.04 (0.01-0.17)	F/U 38 months UTI was defined as a colony count of ≥ 10 ⁵ cfu/ml without a fever of 38 C and two symptoms, including bladder overdistension, lower abdominal pain, increased urinary incontinence, increased spasticity, autonomic hyperreflexia, and/or increased sweating and malaise Bacteriuria was defined as a colony count of ≥ 10 ⁵ cfu/ml and no fever or other symptoms

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results*	Comments
				<p>Patient sex, time of evolution, type of injury, co-morbidity, etiology, lithiasis, surgery, previous antimicrobial treatment, and immunosuppression were not associated.</p> <p>2. Multivariate analysis: Model 1 (defined all risk factors in patients who presented with at least UTI episode during hospitalization)</p> <p>Cervical injury: 2.99 (1.12-7.97) Invasive procedure: 2.62 (1.02-6.69) Indwelling catheterization greater than 30 days: 4.04 (1.24-13.06)</p> <p>3. Multivariate analysis: Model 2 (defined risk factors in patients who presented with repeat UTIs during hospitalization)</p> <p>Functional independence measure score < 74: 9.96 (2.33-42.11) Vesicoureteral reflux: 22.86 (2.31-225.87)</p> <p>Bacteriuria: All results OR (95% CI)</p> <p>Indwelling catheter: 2.70 (2.32-3.20) Clean intermittent catheterization: 1.16 (1.01-1.35) Condom catheter: 0.46 (0.38-0.56) Suprapubic catheterization: 0.06 (0.04-0.10) Normal voiding: 0.05 (0.03-0.10)</p>	Power not reported
Keheller, 1996 ⁷¹	Retrospective controlled study 1,3,4,6	To identify risk factors for the development of symptomatic bacteriuria.	Children undergoing clean intermittent catheterization 159	<p>Symptomatic bacteriuria: <u>Univariate analysis:</u> All results P value</p> <p>Frequency of catheterization: 0.28 Reuse of the catheter: 0.12 Cleansing and storage of the catheter: 0.72 Cleansing of the urethral meatus: 0.07 Bowel management: 0.06 Prophylactic antibiotics: 0.96</p> <p>(Only univariate analysis was reported)</p>	F/U 1 year Symptomatic bacteriuria was defined as a colony count of $> 10^5$ colonies/ml of one organism and the presence of one or more of the following symptoms: increased urinary incontinence between catheterizations, abdominal or flank pain, temperature elevation of at least 99 F, chills or malaise Power not reported
Waites, 1993 ⁷²	Prospective controlled study 1,2,3,6	To estimate frequency of and evaluate risk factors for UTI.	Spinal cord injury patients receiving condom or intermittent catheterization 71	<p>Bacteriuria: <u>Univariate analysis:</u> All results are incidence rate ratio:</p> <p>IRR (95% CI) Female vs male: 1.2 (0.9-1.6) Black vs white: 1.6 (1.3-1.9) Quadriplegic vs paraplegic: 1.1 (0.9-1.3) Frankel grade (a) Sensory preserved vs motor non-functional: 1.5 (1.0-2.3) (b) Complete vs motor non-functional: 1.3 (1.0-1.7) Satisfactory vs excellent hygiene: 1.6 (1.3-2.0)</p>	F/U 1 year UTI was defined as a culture or dip slide containing $\geq 10^5$ cfu/ml on clean-catch or catheterized specimen. Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results*	Comments
				Condom vs intermittent catheter: 1.1 (0.9-1.4) Condom change frequency less than daily vs daily: 2.2 (1.6-3.1) Age > 50 vs ≤ 50: 1.1 (0.7-1.6) Years since injury ≤ 5 vs > 5: 1.2 (0.9-1.5) Annual income < \$10,000 vs ≥ \$10,000: 1.1 (0.8-1.5) Education 0-11 years vs 12+ - 1.1 (0.9-1.4) Antimicrobial prophylaxis was stated to be NS (Only univariate analysis was reported)	
Anderson, 1980 ⁷³	Prospective study with historical controls 1,3	To compare the infection rates of patients on non-sterile intermittent catheterization and antibiotic prophylaxis (oral nitrofurantoin/bladder instillation of neomycin and polymyxin) with a historical control group of patients on sterile intermittent catheterization and the same prophylaxis.	Male patients with acute (<30 days) spinal cord injury 50	Bacteriuria (per 1000 catheterizations): Non-sterile vs sterile: 8.3 vs 2.8; P < 0.05 Frequency of catheter change: 4 hours vs 8 hours: 6.1 vs 13.9 (P < 0.05)	F/U 28 weeks Infection was defined as a bacterial count of more than 10 ⁴ cfu/L Power not reported

1B.2. Intensive Care Unit

van der Kooi, 2007 ⁷⁴	Prospective controlled study 1,3,4,6,7	To examine the incidence of and risk factors for device-associated infections and mortality.	Patients without an initial infection staying in the ICU for at least 48 hours 2644	<p>Symptomatic UTI: <i>Univariate analysis:</i> All results OR (95% CI) Duration of catheterization 5-9 days vs 1-4 days: 1.6 (1.0-2.4); P < 0.05 Duration of catheterization ≥ 10 days vs 1-4 days: 3.3 (2.2-4.9) Duration was not included in the multivariate model</p> <p><i>Multivariate analysis:</i> All results RR (95% CI) Female sex – 1.4 (1.0-1.8) P > 0.05 Impaired immunity: 2.5 (1.5-4.0) Acute admission vs planned admission: 1.8 (1.0-3.3); P > 0.05 Systemic antibiotics at admission: 0.5 (0.3-1.0); P < 0.05</p> <p>Mortality: <i>Univariate analysis:</i> CAUTI vs not: 30.9% vs 20.2%; P = 0.06. It was not significantly associated with mortality in a multivariate model, though estimates were not provided.</p> <p><i>Multivariate analysis:</i> All results OR (95% CI) for mortality associated with having a urinary catheter Age 40-70 years vs ≤ 39 years: 1.6 (1.0-2.5); P < 0.05</p>	F/U until discharge, death, or day of withholding treatment CAUTI according to CDC definition Power not reported
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results*	Comments
				Age \geq 70 years vs \leq 39 years: 2.8 (1.8-4.4) APACHE II \geq 20 vs 0-19: 1.9 (1.5-2.4) Internal medicine vs surgery/traumatology: 1.9 (1.4-2.7) Cardiology/cardiosurgery vs Surgery/traumatology: 2.6 (1.8-3.8) Neurology/neurosurgery vs Surgery/traumatology: 1.8 (1.2-2.7) Acute admission vs planned admission: 1.4 (1.0-1.8); P < 0.05 Systemic antibiotics at admission– 1.5 (1.1-2.3) Ventilation– 4.8 (3.3-7.0) Central venous catheter: 1.8 (1.3-2.5)	
Bochicchio, 2003 ⁷⁵	Prospective controlled study 1,3,4,6,7	To identify risk factors for UTI .	Critically ill trauma patients admitted to the ICU. Presence of catheter not stated as an explicit inclusion criterion 1172	Symptomatic UTI: <u>Multivariate analysis:</u> All results P values Old age: P < 0.01 (specifics not provided) Female sex : P < 0.01 Mortality: Unclear if analysis was multivariate CAUTI vs not: 39% vs 15%; P < 0.01 Increased catheter days: <u>Univariate analysis:</u> All results P value Obesity: < 0.01 COPD: 0.02 Alcohol abuse, coronary disease, smoking, hypertension, diabetes, stroke, and drug abuse were NS	Study duration 2 years CAUTI according to CDC definition Power not reported
Leone, 2003 ⁷⁶	Prospective controlled study 1,3,6,7	To determine risk factors for CAUTI.	ICU patients requiring bladder drainage for longer than 48 hours 1987	Bacteriuria: <u>Univariate analysis:</u> All results P value Female sex : < 0.01 Age: 0.94 Admission diagnosis: 0.65 Antibiotics: 0.46 SAPS II Score: 0.05 Drainage System (simple vs complex): 0.19 Duration of catheterization in days: < 0.01 Length of ICU stay in days: < 0.01 <u>Multivariate analysis:</u> All results OR (95% CI) Female sex : 3.48 (1.72-7.06) Length of ICU stay in days: 1.09 (1.04-1.15) Duration of catheterization in days: 1.07 (1.01-1.13) SAPS II Score: 1.02 (1.00-1.04); P < 0.05 Antibiotic use: 0.40 (0.19-0.85)	F/U until 24 hours after catheter removal Bacteriuria was defined according to CDC definition of asymptomatic bacteriuria Power not reported
Tissot, 2001 ⁷⁷	Prospective controlled study 1,3,6,7	To identify risk factors for catheter-associated bacteriuria.	Catheterized medical ICU patients 137	Bacteriuria: <u>Univariate analysis:</u> All results OR (95% CI) Female sex :3.0 (1.4-6.5) Duration of catheterization > 11 days: 5.7 (2.4-13.3) Prior antibiotic exposure: 0.19 (0.08-0.40) Age > 60 years: 1.9 (0.9-4.0)	F/U until discharge or death Bacteriuria was defined as a quantitative culture containing \geq 10 ⁵ organisms/ml of the same

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results*	Comments
				<p>Immunosuppression: 0.45 (0.1-1.5) SAPS II at admission > 42 points: 1.01 (0.99-1.03) Diabetes mellitus: 1.3 (0.5-3.6) Neurologic disorders: 1.4 (0.3-9.2)</p> <p><u>Multivariate analysis:</u> All results OR (95% CI) Female sex :5.1 (1.9-13.5) Duration of catheterization > 11 days: OR (95% CI) = 19.4 (5.5-68.7) Prior antibiotic exposure: 0.06 (0.02-0.21)</p>	organism and no more than two species. Power not reported

1B.3. Transurethral Resection of Prostate (TURP)

Darouiche, 1999 ⁵⁹	RCT 1,2,5,6,7,8	To examine the efficacy of bladder catheters impregnated with minocycline and rifampin in reducing catheter-associated bacteriuria when compared with regular catheters.	Patients ≥ 35 years with prostate cancer who required the insertion of a bladder catheter while undergoing radical prostatectomy 141	<p>Survival analysis showed that it took significantly longer for patients who received the antimicrobial-impregnated catheter to develop bacteriuria than those who received the control catheter ($P < 0.01$ on log-rank test)</p> <p>Bacteriuria on day 7: Antibiotic-coated catheter vs control catheter: 15.2% vs 39.7%; $P < 0.05$</p> <p>Bacteriuria on day 14: Antibiotic-coated catheter vs control catheter: 58.5% vs 83.5%; $P < 0.05$</p> <p>Symptomatic UTI: Antibiotic-coated catheter vs control catheter: 1/56 vs 6/68; $P = 0.13$</p> <p>Risk factors for bacteriuria: <u>Multivariate analysis:</u> All results OR (95% CI) Use of uncoated catheter: 2.79 (1.19-6.56) Lack of local application of antimicrobial agents: 4.54 (1.30-15.90) Violation of catheter care: 8.72 (1.50-50.90) Presence of an immunosuppressive condition: 13.69 (2.23-84.00) (Only multivariate analysis was reported)</p>	F/U 14 days after surgery Urine samples were collected from the sampling port and bacteriuria was defined as $\geq 10^4$ cfu/ml Symptomatic UTI was measured, but not defined Power not reported The data on risk factors was considered to be observational for the purposes of this section
Stricker, 1988 ⁶⁰	RCT 1,7,8	To assess the efficacy of antibiotic prophylaxis (1 g ampicillin and 80 mg gentamicin preoperatively).	Patients with sterile urine undergoing TURP. Postoperative catheters were inserted 100	<p>Undefined UTI: Antibiotic vs control: 7/39 vs 8/54; $P = NS$</p> <p>Fever: Antibiotic vs control: 4/39 vs 1/54; $P = NS$</p> <p>Rigor: Antibiotic vs control: 1/39 vs 5/54; $P = NS$</p> <p>Orchitis: Antibiotic vs control: 0/39 vs 1/54; $P = NS$</p>	F/U 6 weeks Urine was defined as infected when there were $> 10^5$ organisms/ml of a pure or mixed growth or repeated pure cultures with more than 10^4 organisms/ml. However, it was not known if the

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results*	Comments
				<p>Positive blood culture: Antibiotic vs control: 0/39 vs 0/54; P = NS</p> <p>Total infective complications: Antibiotic vs control: 7/39 vs 9/54; P = NS</p> <p>Number of patients receiving therapeutic antibiotics: Antibiotic vs control: 6/39 vs 9/54; P = NS</p> <p>Catheterization > 4 days: Antibiotic vs control: 5/39 vs 4/54; P = NS</p> <p>Risk factors for undefined UTI: Break in the drainage system: P < 0.01</p>	UTI outcome used referred to bacteriuria or symptomatic UTI Power not reported
Colau, 2001 ⁷⁸ 1,3,6,7	Prospective controlled study	To investigate risk factors for bacteriuria.	Patients requiring TURP 128	<p>Bacteriuria: <u>Univariate analysis:</u> Significant factors were operating time, disconnection of the closed urine drainage system and postoperative catheterization ≥ 3 days. Age, ASA score, surgeon, weight, resection rate and blood loss were not significant (The quantitative results are not presented here as the baseline groups were not clearly specified for most comparisons)</p> <p><u>Multivariate analysis:</u> All results OR (95% CI) Operating time > 52 min: 9.0 (2.1-39.0) Disconnection of the closed urine drainage system: 26.3 (6.1-113.5) Duration of catheterization > 3 days: 4.1 (0.8-21.8)</p>	F/U 1 month postoperatively Patients with ≥ 10 ⁵ cfu/ml (with ≤ 2 bacterial strains) with 1 or a maximum of 2 bacterial strains on a mid-stream urine specimen were considered to present with bacteriuria Power not reported

1B.4. Nursing Homes

Ouslander, 1987 ⁷⁹	Prospective controlled study 1,3,4,6	To identify risk factors associated with symptomatic UTI.	Male nursing home patients with catheters 54	<p>Symptomatic UTI: <u>Univariate analysis:</u> All results P values.</p> <p>Age 65+: NS Diabetes: NS Stool incontinence: NS Hb level in gm/dl < 13: NS Hb level in gm/dl < 11: NS Albumin level in gm/dl < 3.5: < 0.05 Albumin level in gm/dl < 3.2: NS H/O urinary retention: NS Catheter blockage: NS Urinary acidifier: NS Prophylactic antibiotic: NS Antibiotic therapy for a non-urinary source: NS Suprapubic vs Indwelling: NS (Only univariate analyses were reported)</p>	F/U until discharge, death or catheter removal Symptomatic UTI was defined as an episode in which 1) the patient had one or more symptoms or signs of a UTI; 2) other sources of fever had been excluded; 3) the patient was treated with an antimicrobial for a urinary source of infection; and 4) a urine culture grew 10 ⁵ cfu of at least one pathogen. Power not reported
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results*	Comments
Ouslander, 1987 ⁵⁰	Prospective controlled study 1,3,4,6	To examine the frequency of UTI and bacteriuria among patients managed with and without external catheters (EC).	Male nursing home patients with incontinence due to various neurological disorders (data on 30 continent patients were not included) 62	Symptomatic UTI: EC continuously vs no catheter: 12/30 vs 1/13; P < 0.05 EC at night only vs no catheter: 3/19 vs 1/13; statistical differences not clearly reported EC continuously vs EC at night only: 12/30 vs 3/19; P > 0.05 Bacteriuria: EC continuously vs no catheter: 26/30 vs 6/13; P < 0.05 EC at night only vs no catheter: 10/19 vs 6/13; P > 0.05 EC continuously vs EC at night only: 26/30 vs 10/19; P < 0.05 Bacteriuria and pyuria: EC continuously vs no catheter: 12/30 vs 3/13; P > 0.05 EC at night only vs no catheter: 7/19 vs 3/13; P > 0.05 EC continuously vs EC at night only: 12/30 vs 7/19; P > 0.05 Symptomatic UTI: <u>Univariate analysis:</u> All results P values: Age: NS Length of time in the facility: NS Diabetic: NS Katz ADL score: NS Mental status score: NS % ideal body weight: NS Skinfold thickness: NS Serum creatinine (mg/dl): NS Albumin: < 0.01 Hb (g/dl): NS Stool incontinence: NS Past genitourinary diagnoses: NS Catheter manipulation: NS Suppressive antibiotic therapy: NS Urinary acidifier: NS	Mean F/U 5.4 months Significant bacteriuria defined as a growth of > 10 ⁵ colonies on clean-catch urine specimens. Symptomatic UTI was defined as an episode in which 1) the patient had one or more symptoms or signs of a UTI; 2) other sources of fever had been excluded; 3) the patient was treated with an antimicrobial for a urinary source of infection; and 4) a urine culture grew 10 ⁵ cfu of at least one pathogen. With 30 patients in each group, the power to detect differences of 30% in the proportion of patients developing infections was 75%

1B.5. Hospital or unspecified

Rogers, 2004 ⁶¹	RCT 1,2,3,4,5,6	To evaluate the efficacy of antibiotic prophylaxis with nitrofurantoin 100 mg.	Patients undergoing surgical correction of stress urinary incontinence and/or pelvic organ prolapse with suprapubic catheter placement. 435	Symptomatic UTI: <u>At suprapubic catheter removal:</u> Nitrofurantoin vs placebo: 7.2% vs 19.8%; P < 0.01 <u>During the 6-8 week postoperative period:</u> Nitrofurantoin vs placebo: 18.9% vs 32.6%; P < 0.01 <u>At the 6-8 week post-op visit:</u> Nitrofurantoin vs placebo: 1.8% vs 5.4%; P = 0.10	F/U 6-8 weeks post-op Symptomatic UTI defined as symptoms with > 10 ⁵ cfu/ml in urine. A total of 438 women were required to demonstrate a 50% decrease in bacteriuria rate with
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results*	Comments
				<p>Bacteriuria: <u>At suprapubic catheter removal:</u> Nitrofurantoin vs placebo: 31.7% vs 50.5%; P < 0.01</p> <p><u>During the 6-8 week postoperative period:</u> Nitrofurantoin vs placebo: 46.0% vs 61.0%; P < 0.01</p> <p><u>At the 6-8 week post-op visit:</u> Nitrofurantoin vs placebo: 16.8% vs 23.9%; P = 0.11</p> <p>Intraoperative complications: Nitrofurantoin vs placebo: 13.0% vs 13.0%; P = 1.00</p> <p>Postoperative complications: Nitrofurantoin vs placebo: 1.0% vs 13.0%; P = 0.22</p> <p>Mortality: Nitrofurantoin vs placebo: 0.0% vs 1.0%; P = 0.50</p> <p>Readmission: Nitrofurantoin vs placebo: 6.3% vs 4.7%; P = 0.33</p> <p>Length of surgery (minutes): Nitrofurantoin vs placebo: 218 vs 201; P = 0.01</p> <p>Length of stay: Nitrofurantoin vs placebo: P > 0.05 (group-wise data not provided)</p> <p>Duration of catheterization (days): Nitrofurantoin vs placebo: 11.0 vs 10.5; P = 0.64</p> <p>Risk factors Univariate analysis (All results P values)</p> <p><u>Symptomatic UTI:</u> No other postoperative infections: 0.04 Duration of catheterization: < 0.01</p> <p><u>Bacteriuria:</u> Preoperative mobility of the urethrovesical junction: ≤ 0.02 Blood loss- ≤ 0.02 Duration of catheterization: ≤ 0.02</p> <p><u>Undefined UTI:</u> Cystocele stage/grade: P = NS</p>	80% power and an alpha of 0.05

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results*	Comments
				High postvoid residual (> 100 cc): P = NS BMI: P = NS Postoperative complications: P = NS Intercourse: P = NS Patient adherence: P = NS Last post-void residual before SPC removal: P = NS	
Baan, 2003 ⁶²	RCT 1,2,4,7,8,9	To compare the effects of suprapubic catheterization vs transurethral catheterization.	Adult patients without UTI undergoing a major abdominal procedure requiring a standard bladder catheterization. 146	<p>Symptomatic UTI: <u>Intention to treat:</u> Suprapubic vs transurethral: 9/75 vs 8/71; RR (95% CI) = 1.06 (0.43-2.61) <u>Per protocol:</u> Suprapubic vs transurethral: 8/65 vs 8/68; P > 0.05</p> <p>Recatheterization: Suprapubic vs transurethral: 9/75 vs 4/71; statistical differences not reported</p> <p>Median duration of catheterization (days): Suprapubic vs transurethral: 6.5 vs 4.9; P > 0.05</p> <p>Patient satisfaction outcomes: All results %, P values for suprapubic vs transurethral <u>During catheterization:</u> Pain in the abdomen: 12 vs 8; > 0.05 Burning pain: 6 vs 7; > 0.05 Leakage of urine: 6 vs 10; > 0.05 False urge: 31 vs 45; > 0.05 Blood loss: 4 vs 2; > 0.05 <u>After catheterization:</u> Unpleasant removal: 27 vs 46; > 0.05 No spontaneous voiding: 4 vs 12; > 0.05 Burning pain during voiding: 10 vs 15; > 0.05 Incontinence: 4 vs 9; > 0.05 Abdominal cramps: 8 vs 5; > 0.05 Overall score (on 5-point Likert scale): Suprapubic vs transurethral: 8.4 vs 8.5 Risk factors for Symptomatic UTI: <u>Univariate analysis:</u> All results RR (95% CI) Female sex : 4.16 (1.40-12.20) Recatheterization: 7.16 (3.30-15.60) Duration of catheterization > 7 days: 3.40 (1.43-8.04) Relaparotomy: P = 0.07</p>	F/U 6 weeks after surgery UTI was defined as at least one or more of the clinical symptoms (fever, increased micturition frequency, burning pain during voidance and a pain in the lower abdomen), a positive sediment (> 10 leukocytes), and a positive urine culture (> 10 ⁵ bacterial colonies and <3 bacterial species) 62 patients in each group were needed to decrease UTI from 30% to 8% with a power of 90% and an alpha of 5%

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results*	Comments
Carapeti, 1996 ⁶³	RCT 1	To compare sterile vs non sterile urethral catheterization.	General surgical patients to be catheterized pre-operatively after induction of anesthesia 156	Unspecified UTI: Non-sterile vs sterile: 9/82 vs 7/74; P > 0.10 Female vs male: 10/84 vs 6/72; P > 0.10 Cost (£): Non-sterile vs sterile: 3.06 vs 7.49; statistical differences were not reported	F/U 3rd postoperative day UTI was defined as bacteriuria > 10 ⁵ with or without clinical symptoms Power not reported
Huth, 1992 ⁶⁴	RCT 1,2,3,6,7	To evaluate the efficacy of a junction seal applied after catheter insertion for preventing bacteriuria and reducing mortality. The seal was obtained by wrapping the drainage tube junction with adhesive tape.	Patients undergoing transurethral catheterization at a community hospital 1740	Death at hospital discharge: Tape seal vs no tape seal: 60/903 vs 67/837; P = 0.32 Bacteriuria: Tape seal vs no tape seal: 124/903 vs 125/837; OR (95% CI) = 0.91 (0.69-1.20) Survival curve analysis of patients stratified by sex and antibiotic use revealed no significant differences in the rate of bacteriuria between treatment groups. Duration of catheterization (days): Tape seal vs no tape seal: 4.0 vs 4.1; P = NS Risk factors for bacteriuria: <u>Multivariate analysis:</u> All results OR (95% CI) Lack of antibiotic use: 3.69 (2.84-4.80) Female sex: 2.73 (2.07-3.61) Age, hospital service, catheter care violations, and treatment randomization were not significant	F/U until catheter removal or patient discharge Bacteriuria was defined as a urine specimen containing ≥ 1000 cfu/ml of bacteria or yeast It was estimated that a final study population of 686 patients in each group would be needed to detect a 33% reduction in the infection rate at an alpha of 0.05 with 80% power
Huth, 1992 ⁶⁵	RCT 1,2,7	To determine the efficacy of a 1% silver sulfadiazine cream applied twice daily to the urethral meatus in preventing transurethral catheter-associated bacteriuria.	Adult patients who underwent closed urinary catheter drainage at a community hospital 696	Bacteriuria: Silver sulfadiazine vs no silver sulfadiazine: 38/332 vs 48/364; OR (95% CI) = 0.85 (0.53-1.37) Survival curve analysis of patients stratified by sex and antibiotic use revealed no significant differences. Onset of bacteriuria (days): Silver sulfadiazine vs no silver sulfadiazine: 3.8 vs 4.3; P = 0.44 Mean duration of catheterization (days): Silver sulfadiazine vs no silver sulfadiazine: 3.7 vs 3.9; P = 0.48 Death: Silver sulfadiazine vs no silver sulfadiazine: 13/332 vs 22/364; P = 0.27	F/U until catheter removal or patient discharge Bacteriuria was defined as a urine specimen containing ≥ 1000 cfu/ml of bacteria or yeast It was estimated that a final study population of 199 patients in each group would be needed to detect a 50% reduction in the infection rate at an alpha of 0.05 with 80% power

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results*	Comments
				<p>Risk factors for bacteriuria:</p> <p><u>Univariate analysis:</u> All results P values</p> <p>Duration of catheterization: P < 0.01</p> <p><u>Multivariate analysis:</u> All results OR (95% CI)</p> <p>Lack of antibiotic use: 4.61 (1.92-5.08)</p> <p>Female sex: 3.02 (1.31-3.50)</p> <p>Positive meatal culture: 3.89 (0.93-16.25)</p> <p>Randomization to the treatment group, age, lack of use of a urinemeter, catheter care violations, and hospital service were not associated with the development of bacteriuria, though no measures of association were provided.</p>	
Schneeberger, 1992 ⁶⁶	RCT 1,7	To evaluate the effect of povidone-iodine bladder irrigation prior to catheter removal on subsequent bacteriuria.	Urologic patients with an indwelling catheter 352	<p>Bacteriuria:</p> <p>Overall: Povidone-iodine irrigation vs control—47/264 vs 52/233; RR (95% CI) [for control vs povidone-iodine]: 1.25 (0.88-1.78)</p> <p>At 1-3 days: Povidone-iodine irrigation vs control: 18/128 vs 24/111; RR (95% CI) [for control vs povidone-iodine]: 1.54 (0.88-2.68)</p> <p>At 4-14 days: Povidone-iodine irrigation vs control: 29/136 vs 28/122; RR (95% CI) [for control vs povidone-iodine]: 1.08 (0.68-1.70)</p> <p><u>Stratified by duration of catheterization</u> All results Povidone-iodine irrigation vs control</p> <p>1-3 days: 5/74 vs 9/65; P < 0.05</p> <p>4-6 days: 6/29 vs 6/22; P = NS</p> <p>≥7 days: 7/25 vs 9/24; P = NS</p> <p>Mean duration of catheterization (days):</p> <p>Povidone-iodine irrigation vs control: 4.81 vs 4.97; P = NS</p> <p>Risk factors for bacteriuria: <u>Univariate analysis</u></p> <p>Duration of catheterization: P < 0.01</p>	<p>F/U until 14 days after catheter removal</p> <p>Positive urine culture was defined as > 10⁵ cfu/ml composed of one or two species of bacteria</p> <p>Power not reported</p> <p>Ns and events in the results column represent the number of urine cultures and not the number of patients</p>
Classen, 1991 ⁶⁸	RCT 1,2,7	To compare a polyantibiotic cream (containing polymyxin B, neomycin and gramicidin) with routine meatal care (cleansing of the meatal surface during daily bathing).	Adult patients undergoing closed urinary catheter drainage 747	<p>Bacteriuria: Polyantibiotic cream vs routine meatal care: 26/383 vs 37/364; P = 0.17</p> <p>Results were robust to definitions of bacteriuria</p> <p>There were no significant differences between the two groups, both overall and when stratified by sex.</p> <p>Risk factors for bacteriuria:</p> <p><u>Multivariate analysis:</u> All results OR (95% CI)</p> <p>Female sex: 3.48 (1.81-6.74)</p> <p>Positive meatal culture: 2.79 (1.48-5.25)</p>	<p>F/U until catheter removal</p> <p>Four definitions of bacteriuria were used: 10³ colonies/ml of any microbial species, 10⁵ colonies/ml of any microbial species, 10⁵ colonies/ml of gram-negative bacilli and/or enterococci, and 10³ colonies/ml of gram-negative bacilli and/or enterococci; the latter was used for the comparison.</p>

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				Antibiotic use: 0.52 (0.31-0.87) The other variables introduced in the regression model were not listed.	It was calculated that with an estimated incidence of bacteriuria of 14%, to show a 50% reduction in bacteriuria in the treated group, the study would require 325 patients in each group to have 90% power at a significance level of 5%.
Burke, 1983 ⁶⁷	RCT 1,2	To evaluate the efficacy of twice-daily meatal care with a poly-antibiotic ointment in delaying the onset of bacteriuria. Patients in the meatal care group received twice daily-treatment of the urethral meatus-catheter junction with neomycin-polymyxin B-bacitracin ointment.	Adult patients who underwent closed urinary catheter drainage. 428	Bacteriuria: Meatal care vs no meatal care: 14/214 vs 16/214; P > 0.05 Though not significant, the greatest difference between the two groups was seen in female patients ≥ 50 years old who were not receiving antibiotics during the study period. Results were robust to definitions of bacteriuria Risk factors for bacteriuria: <u>Multivariate analysis:</u> Female patients, a positive meatal culture, a non-surgical underlying illness, and absence of antibiotic use were not associated with bacteriuria (P > 0.05 for all)	F/U for duration of catheterization Bacteriuria was defined as ≥ 10 ³ colonies/ml Power not reported
Warren, 1978 ⁶⁹	RCT 1	To investigate the efficacy of antibiotic irrigation in preventing CAUTI. Patients were randomly assigned to receive either a closed drainage, triple-lumen, neomycin-polymyxin irrigated system or a closed drainage, double-lumen, non-irrigated catheter-system.	Adult medical, surgical, and gynecologic patients who required urinary catheterization. 187	Bacteriuria: Irrigated vs not irrigated: 18/98 vs 14/89; P = NS There were no differences between the two groups when stratified by sex, age, service, severity of disease, indication for catheterization and BUN with one exception: <u>in patients with low urine output (<1000ml/day)</u> Irrigated vs not irrigated: 4.4 vs 9.5; statistical differences were not reported. However, this may have been due to greater disconnections in the group not receiving irrigation. Mean duration of catheterization (days): Irrigated vs not irrigated: 3.3 vs 3.5; P = NS Risk factors for bacteriuria: Disconnection of catheter junction, old age, duration of catheterization, fatal diagnosis, elevated BUN, residence in ICU were stated as risk factors for bacteriuria, but statistical differences were not reported. Mortality: UTI vs no UTI: 34% vs 15%; statistical differences were not reported	F/U unclear UTI was defined as ≥ 10 ⁵ colonies/ml Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results*	Comments
Hazelett, 2006 ⁸⁰	Retrospective controlled study 1,3	To determine the frequency and appropriateness of indwelling catheter use and its association with UTI.	Patients admitted to an acute care hospital from an ED with an indwelling urinary catheter 379	Administration of indwelling catheter: Age ≥ 65 vs < 65: 30% vs 12%; P < 0.01 UTI by discharge: Indwelling catheter vs no indwelling catheter: 28% vs 10%; P < 0.01 Inappropriate placement of urinary catheters: UTI vs no UTI: 11/24 vs 93/200; statistical differences were not reported	Study duration 3 months The presence of a UTI on admission was defined as 1) an admission urine culture with ≥ 10 ⁵ organisms/ml or 2) the diagnosis and treatment of UTI by the ED physician Catheter appropriateness was determined using published criteria. Indwelling urinary catheters were considered appropriate for surgery, accurate measurement of intake and output, urinary retention, urinary incontinence posing a risk to the patient, urinary obstruction, altered blood pressure or blood volume status requiring accurate urine measurement, urine measurement in an uncooperative patient, bladder irrigation for a urinary tract hemorrhage, and palliative care for the terminally ill.
Saint, 2006 ⁸¹	Retrospective controlled study 1,3,4,6,7	To determine risk factors for nosocomial urinary tract-related bacteremia. A patient from whom a urine culture and a blood culture grew the same organism ≥ 48 hours after admission was considered a case. Control patients were those with significant bacteriuria ($\geq 10^5$ cfu/ml) detected ≥ 48 hours after admission who did not have a positive blood culture.	Hospitalized patients with condom or indwelling catheters 237	Bacteremia: Condom vs indwelling: 0/6 vs 83/203; P = 0.08 Risk factors for nosocomial urinary tract related bacteremia: <u>Multivariate analysis</u> All results OR [95% CI] Immunosuppressant therapy within 14 days: 8.13 (1.02-64.83) History of malignancy: 1.94 (1.06-3.55) Male sex : 1.88 (1.62-2.18) Smoking within the past 5 years: 1.26 (1.01-1.57) Number of hospital days before detecting bacteriuria: 1.03 (1.01-1.04) Antibiotic use within 3 days of detecting bacteriuria: 0.76 (0.68-0.85) Patients with diabetes < 70 years: 6.19 (1.30-29.40) Patients with diabetes ≥ 70 years: 0.11 (0.02-0.83) Patients < 70 years using corticosteroids within 7 days: 14.24 (4.76-42.63) Patients ≥ 70 years using corticosteroids within 7 days: 0.08 (0.02-0.34)	F/U unclear Bacteriuria defined as ≥ 10 ⁵ cfu/ml Nosocomial urinary tract-related bacteremia defined as when a urine culture and a blood culture grew the same organism ≥ 48 hours after admission Power not reported

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				Data were also collected on race, age, site of medical care, HIV infection, prostatic hypertrophy, urolithiasis, and serum creatinine level, but they were not included in the final multivariate model.	
Srinivasan, 2006 ⁸²	Prospective pre-post study 1,3,4,6,7	To evaluate the efficacy of silicone-based urinary catheters coated with silver alloy on both the internal and external surfaces when compared with non-silver silicone catheters.	Adult inpatients who had indwelling Foley catheters for > 48 hours 3036	<p>All results IRR (95% CI) per 1000 catheter days; silver-coated vs control catheter unless otherwise noted</p> <p>Unspecified UTI: Overall: 116/1165 vs 218/1871; RR (95% CI) = 0.88 (0.70-1.11) ICU: 0.80 (0.48-1.33) Non ICU: 0.90 (0.70-1.16) Preconnected systems: 0.80 (0.57-1.12) Component systems: 1.08 (0.77-1.49)</p> <p>Catheter-associated BSI: 9/1165 vs 7/1871; 2.13 (0.96-4.76)</p> <p>Risk factors for Unspecified UTI: Results HR (95% CI) <u>Univariate analysis</u> Female sex : 2.34 (1.86-2.96) Silver-coated catheter: 0.92 (0.73-1.15) Hospital service: NS (HR not reported) <u>Multivariate analysis</u> Female sex : 2.26 (1.78-2.89) Silver-coated catheter: NS (HR not reported) Hospital service: NS (HR not reported)</p>	F/U until 7 days after catheter removal Nosocomial urinary tract infections were identified by criteria set forth by the CDC Sample size of 1497 patients per catheter type to detect a 20% reduction in the incidence of UTI with 80% power and an alpha of 5%
Cardosi, 2003 ⁸³	Retrospective controlled study 1,3,4	To evaluate the role of prophylactic antibiotics.	Catheterized women undergoing radical hysterectomy 102	<p>Symptomatic UTI: Antibiotics vs no antibiotics: 1/9 vs 11/93; P = 0.95</p> <p>Risk factors for symptomatic UTI: <u>Univariate analysis:</u> All results P values Age: > 0.05 Comorbid medical conditions: > 0.05 Cancer: > 0.05 Extent of surgical resection: > 0.05 Operative urinary tract injury: > 0.05 Catheter type: > 0.05 Postoperative infectious complication: > 0.05 Duration of catheterization: > 0.05 Length of hospitalization: > 0.05 Operating surgeon: > 0.05</p>	F/U during postoperative period Women were diagnosed with a CAUTI if they reported suprapubic pain or bladder discomfort, irritability, or spasm and had culture documented bacteruria with 10^3 cfu of a single pathogen in the absence of systemic signs of infection. Power not reported
Johansson, 2002 ⁸⁴	Prospective controlled study 1,3	The aims of the study were (1) to describe the occurrence of UTI among patients with hip fracture before and after surgery; (2) to	Patients admitted to the hospital with traumatic hip fracture.	<p>Risk factors for bacteriuria: <u>Univariate analysis:</u> All results P values Female sex (vs male sex) : 92.7% vs 7.3%; statistical differences not reported Age: > 0.05</p>	F/U one week after last catheterization. Bacteriuria was defined as $\geq 10^5$

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results*	Comments
		compare intermittent catheters vs indwelling catheters; and (3) to compare the length of hospital stay among people with and without infection.	144	Diabetes: > 0.05 Bacteriuria: Intermittent vs indwelling (among patients who were free of UTI at admission): 20/63 vs 11/26; statistical differences were not reported Length of stay: Significantly longer hospital stay among patients with UTI ($P \leq 0.05$)	bacteria/ml Power not reported
Tambyah, 2002 ⁹	Prospective controlled study 1,3	To determine the additional direct costs of hospitalization attributable to CAUTI.	Hospitalized patients scheduled to receive an indwelling urethral catheter who were expected to be catheterized for more than 24 hours 1497	Bacteriuria: Female vs male: RR (95% CI) = 1.7 (1.6-2.0) (The main question was that of cost. Sex was the only risk factor reported)	F/u until discharge CAUTI defined as $> 10^3$ cfu/ml of bacteriuria or funguria Power not reported
Hustinx, 1991 ⁸⁵	Prospective controlled study 1,3,6,7	To investigate the impact of concurrent administration of antibiotics on the incidence of CAUTI.	Hospitalized patients with bladder catheters 342	Bacteriuria: Antibiotic usage ending > 48 hours prior to catheter removal vs no antibiotic usage: 11/19 vs 23/34; $P > 0.2$ Antibiotic usage ending ≤ 48 hours prior to catheter removal vs no antibiotic usage: 9/36 vs 23/34; $P < 0.01$ Antibiotic usage ending ≤ 48 hours prior to catheter removal vs antibiotic usage ending > 48 hours prior to catheter removal: 9/36 vs 11/19; $P < 0.05$ Risk factors for bacteriuria: <u>Multivariate analysis:</u> All results P values Antibiotic usage ending ≤ 48 hours prior to catheter removal: < 0.01 Duration of catheterization: < 0.01 Age: NS Sex: NS Immunocompromised: NS Anatomical abnormalities of the urinary tract: NS	F/U 2 months Significant bacteriuria defined as $\geq 10^3$ cfu/ml Power not reported
Johnson, 1990 ⁸⁶	Prospective controlled study 1,3,6,7	To evaluate the efficacy of a silver-oxide coated catheter in the prevention of UTI during acute bladder catheterization in a general hospital population and to characterize the clinical and microbiologic correlates of CAUTI in this setting.	Patients ≥ 17 years who had received a study catheter that was expected to remain indwelling for at least 24 hours 482	Bacteriuria: <u>Univariate analysis:</u> All results RR (P value) Male sex : 0.5 ($P < 0.01$) Antimicrobials during final 48 hours: 0.3 ($P < 0.01$) Catheter care violations: 2.7 ($P < 0.01$) Serum creatinine ≥ 2 mg/dl: 2.1 ($P = 0.04$) Not at strict bed rest: 0 ($P = 0.06$) Duration of catheterization > 7 days: 2.1 ($P = 0.01$) No association with UTI was seen for infection at another site, presence of an underlying genitourinary abnormality, advanced age, or the patient before catheter removal	F/U unclear A patient was considered to have a UTI when two consecutively collected catheter urine specimens grew the same microorganism in concentrations of $\geq 10^2$ cfu/ml or if the last available urine specimen of

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results*	Comments
				<p>admitting service. ORs were not provided for these risk factors</p> <p>Multivariate analysis: All results OR (P value) Antimicrobials during final 48 hours: 0.3 ($P < 0.01$) Female sex : 2.0 ($P = 0.02$) Renal dysfunction: 2.6 ($P = 0.02$) Catheter care violations: NS (OR not provided)</p> <p>Bacteriuria: Silver-coated catheter vs control: 19/207 vs 28/275; $P = 0.95$ After stratification by sex and antimicrobial use, a protective effect of the silver-coated catheter was seen among women not receiving antimicrobials ($P = 0.04$). There were no significant differences in the other three groups (men receiving antimicrobials, men not receiving antimicrobials, women receiving antimicrobials)</p> <p>Median duration of catheterization (days): Silver-coated catheter vs control: 3 vs 4; $P = 0.03$</p>	<p>had $\geq 10^5$ cfu/ml</p> <p>A sample size of 105 patients per group was needed to detect a 67% reduction in the incidence of UTI with the silver catheter at 5% significance level and 80% power.</p>
Lima, 1990 ⁸⁷ 1,3,4,6,7	Retrospective controlled study	To test the hypothesis that diarrhea and resultant local environmental microbial contamination might result in a higher risk for nosocomial infections.	Hospitalized patients 84	<p>UTI rate: With nosocomial diarrhea vs without nosocomial diarrhea: 9/33 vs 1/45; RR (95% CI) = 12.27 (1.64-92.20)</p> <p>UTI rate (per 1000 patient days): With nosocomial diarrhea vs without nosocomial diarrhea: 24.9 vs 2.4; IRR (95% CI) = 10.3 (1.7-63.1)</p> <p>CAUTI rate: With nosocomial diarrhea vs without nosocomial diarrhea: 8/16 vs 1/19; RR (95% CI) = 9.5 (1.5-58.5)</p>	<p>F/U until onset of the first nosocomial infection</p> <p>Nosocomial diarrhea was defined as the passage of three or more stools per day with onset > 72 hour after hospitalization</p> <p>Power not reported</p>
Jacono, 1988 ⁸⁸ 1,3,6,7	Retrospective controlled study	To examine the characteristics of patients who developed a nosocomial UTI.	Catheterized patients admitted to one of two units, one of which cared for patients with acute conditions and one providing long term care 71	<p>Bacteriuria: Females had a greater risk than males. Statistical differences were not reported.</p> <p>The effect of a meatal anti-bacterial agent was assessed in a pre-post fashion and it was found to result in a non-significant decrease in infection rate in males, but a paradoxical increase in females</p>	<p>F/U unclear</p> <p>Nosocomial UTI was defined as sterile urine culture upon admission and (1) Bacterial growth measuring $< 10^5$ organisms/ml but with a WBC count $> 5/\text{hpf}$ or (2) Bacterial count $> 10^5$ organisms/ml</p> <p>Power not reported</p>
Lanara, 1988 ⁸⁹	Prospective controlled study	To study the prevalence of UTI in catheterized inpatients in relation to the type of drainage system.	Patients who had a Foley catheter inserted in the	<p>Bacteriuria: Closed system vs open system: 68/270 vs 79/203; $P < 0.01$</p> <p>Closed system with chlorhexidine added vs open system: 6/40 vs</p>	<p>F/U unclear</p> <p>UTI defined as $\geq 10^5$ bacteria/ml</p>

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results*	Comments
	1,3		hospital that remained within the bladder for a minimum of 10 days 532	79/203; P < 0.01 Closed system vs closed system with chlorhexidine added: 68/270 vs 6/40; P > 0.1 Risk factors for bacteriuria: <u>Univariate analysis:</u> All results P values Women: < 0.01 Age ≥ 60 < 0.01 Medical (vs urological patients) < 0.05 Surgical (vs urological patients) > 0.05	48 hours after catheterization in the hospital Power not reported
Mulhall, 1988 ⁹¹	Prospective controlled study 1,3,6,7	To identify risk factors for bacteriuria during indwelling urethral catheterization.	Newly catheterized patients > 16 years old in whom the catheter remained in situ for longer than 24 hours 220	Incidence of bacteriuria: Recorded in 97 (44%) of 220 patients. In 42 of these 97 patients, bacteriuria was present by 48 hours of catheterization and in 55 patients, bacteriuria occurred after this time. A multivariate analysis of the relationship between bacteriuria and the following factors was made: sex, age, diagnosis, medical specialty of care, reason for catheterization, person performing the catheterization (no details provided), place of catheterization (no details provided), use of antimicrobial therapy, the number of days the catheter was in situ, disconnection of the drainage system, fecal incontinence, presence of another catheterized patient in adjacent bed or same ward, or health district Bacteriuria by 48 hours after catheterization: <u>Multivariate analysis:</u> All results P value Patients catheterized because of urinary incontinence were significantly more likely to have bacteriuria than other patients (< 0.01) Patients receiving antimicrobial therapy prior to catheterization were significantly less likely to have bacteriuria than other patients (< 0.01) Patients cared for in surgical, genito-urinary, and gynecological specialties were significantly less likely to have bacteriuria than patients in medical, orthopedic, or neurological specialties (< 0.01) Other factors were not significantly related (> 0.05) (Only multivariate analysis was reported) Bacteriuria more than 48 hours after catheterization: <u>Multivariate analysis:</u> All results P value The risk of developing bacteriuria between days 3 and 21: Significantly increased for each day the catheter was in situ (< 0.01) Significantly decreased with the use of antimicrobial therapy (< 0.01) Other factors were not significantly related (> 0.05) (Only multivariate analysis was reported)	F/U 21 days Bacteriuria was defined as > 10 ⁴ organisms/ml on two consecutive days. Urine cultured was aspirated from the catheter tubing. Power not reported

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Holliman, 1987 ⁹⁰	Prospective pre-post study 1,3	To test the effect of peroxide disinfection of drainage on CAUTI.	Orthopedic patients 57	<p>Bacteriuria: Peroxide vs control: 11/30 vs 17/27; P < 0.05</p> <p>Number of catheter bags with bacteriuria: Peroxide vs control: 5/30 vs 15/27; P < 0.01</p> <p>Average number of days without infection: Peroxide vs control: 8.5 vs 6.0; P < 0.02</p> <p>Mean duration of catheterization (days): Peroxide vs control: 12 vs 12; P = NS</p> <p>Risk factors for bacteriuria: <u>Univariate analysis:</u> All results P value Age: NS Female sex : <0.02 Duration of catheterization: NS</p>	F/U unclear Significant bacteriuria was defined as $\geq 10^4$ cfu/ml Power not reported
Saramma, 1987 ⁹⁶	Retrospective controlled study 1,3,6,7	To assess the effect of the following infection control practices on the rate of UTI: (1) Giving catheter care twice daily using freshly prepared Savlon and applying neomycin ointment at the meatal catheter junction; (2) Maintaining a closed urinary drainage system; (3) Changing collection bottle alone everyday, using another sterile bottle. Risk factors for bacteriuria were also identified.	Patients aged ≥ 12 years who underwent cardiopulmonary bypass 200	<p>Bacteriuria: Intervention vs control: 19/103 vs 30/97; P < 0.05</p> <p>Risk factors for bacteriuria: <u>Univariate analysis:</u> All results P value Female vs male: P = NS Catheter duration ≥ 72 hours vs < 72 hrs: P < 0.01</p> <p>Bacteriuria stratified by risk factor: Intervention vs control (males): P = NS Intervention vs control (females): P < 0.05 Intervention vs control (catheter duration < 72 hrs): P = NS Intervention vs control (catheter duration ≥ 72 hrs): P < 0.01</p>	F/U unclear Bacteriuria defined as ≥ 1000 colonies/ml of any pathogenic organisms Power not reported
Burke, 1986 ⁹⁵	Retrospective controlled study (secondary analysis of previously conducted RCTs) 1,3	To estimate the frequency of errors in catheter care over time and the relation of these errors to the rates of bacteriuria.	Adults from the medical, surgical, surgical subspecialty, and obstetrics and gynecology services who underwent closed urinary catheter drainage 1927 patients in 4 RCTs	<p>Errors in maintaining of closed sterile drainage: Opened connector: 11.5% Improperly suspended bag: 20.5% Any error: 29.0% No error: 71.0%</p> <p>Bacteriuria (%): <u>All comparisons type of error vs no error; P value</u> <u>Males receiving antibiotics</u> Opened connector vs no error: 5.8 vs 3.7; NS Improperly suspended bag vs no error: 5.2 vs 3.7; NS Any error vs no error: 6.0 vs 3.7; NS</p>	F/U until detection of $\geq 10^5$ organisms/ml Bacteriuria defined as $\geq 10^3$ organisms/ml for the purposes of this analysis Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results*	Comments
				<p><i>Males not receiving antibiotics</i></p> <p>Opened connector vs no error: 15.9 vs 13.2; NS</p> <p>Improperly suspended bag vs no error: 18.4 vs 13.2; NS</p> <p>Any error vs no error: 16.9 vs 13.2; NS</p> <p><i>Females receiving antibiotics</i></p> <p>Opened connector vs no error: 16.4 vs 16.2; NS</p> <p>Improperly suspended bag vs no error: 25.9 vs 16.2; P < 0.05</p> <p>Any error vs no error: 24.4 vs 16.2; P = 0.05</p> <p><i>Females not receiving antibiotics</i></p> <p>Opened connector vs no error: 16.7 vs 33.0; NS</p> <p>Improperly suspended bag vs no error: 29.6 vs 33.0; NS</p> <p>Any error vs no error: 28.3 vs 33.0; NS</p>	
Platt, 1986 ⁹⁴ 1,3,6,7	Prospective controlled study	To identify risk factors for nosocomial UTI.	Adult medical and surgical inpatients undergoing bladder catheterization 1458	<p>Bacteriuria: <i>Univariate analysis:</i> All results P values</p> <p>Increased duration of catheterization: < 0.01 (OR not clearly reported)</p> <p>Lack of urinometer drainage: < 0.01</p> <p>Colonization of drainage bag: < 0.01</p> <p>Diabetes: < 0.01</p> <p>Absence of systemic antibiotics during catheter courses shorter than 6 days: < 0.01</p> <p>Female sex : < 0.01</p> <p>Drainage during surgery or measurement of output: < 0.01</p> <p>Creatinine level > 2 vs < 1: < 0.01</p> <p>Lack of use of pre-sealed junction catheters- 0.20</p> <p>Prior indwelling catheterization: < 0.01</p> <p>Hospital service: < 0.01</p> <p>Person inserting catheter RN vs MD: < 0.01</p> <p>Disconnection of collection junction: < 0.01</p> <p>Age: < 0.01</p> <p>Drainage-bag change: < 0.01</p> <p>Prior UTI during current hospitalization: < 0.01</p> <p>No systemic antibiotic in week before catheterization: < 0.01</p> <p>Bag-outlet-tube error: < 0.01</p> <p>Agent used for catheter insertion and meatal care: 0.01</p> <p>Catheter change: 0.02</p> <p>Non-white vs white: 0.05</p> <p>Fatal vs non-fatal illness: 0.13</p> <p><i>Multivariate analysis:</i> All results OR (95% CI)</p>	<p>F/U until discharge</p> <p>UTI defined as recovery of $\geq 10^5$ cfu/ml of bacteria or yeasts.</p> <p>Power not reported</p>

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results*	Comments
				<p>Increased duration of catheterization: P < 0.01 (OR not clearly reported)</p> <p>Lack of urinometer drainage: 2.0 (1.2-3.8)</p> <p>Colonization of drainage bag: 3.8 (2.1-7.4)</p> <p>Diabetes: 2.3 (1.5-3.6)</p> <p>Absence of systemic antibiotics during catheter courses shorter than 6 days: P < 0.01</p> <p>Female sex : 2.5 (1.6-4.0)</p> <p>Drainage during surgery or measurement of output: 2.0 (1.2-3.6)</p> <p>Creatinine level > 2 vs < 1: 2.1 (1.0-4.3)</p> <p>Lack of pre-sealed junction catheters: P = 0.03 (OR not reported)</p> <p>Prior indwelling catheterization: 2.3 (1.2-4.6)</p> <p>Hospital service: P = 0.49 (OR not clearly reported)</p> <p>Person inserting catheter RN vs MD: 1.0 (0.3-3.7)</p> <p>Disconnection of collection junction: 1.14 (0.7-1.8)</p> <p>Old age (vs a younger age): 1.3 (0.4-4.0)</p> <p>Drainage-bag change: 1.0 (0.6-1.7)</p> <p>Prior UTI during current hospitalization: 1.5 (0.9-2.5)</p> <p>No systemic antibiotic in week before catheterization: 1.1 (0.5-2.2)</p> <p>Bag-outlet-tube error: 0.8 (0.4-1.8)</p> <p>Agent used for catheter insertion and meatal care (benzalkonium chloride vs povidone-iodine): 1.43 (0.5-4.1)</p> <p>Catheter change: 0.8 (0.4-1.5)</p> <p>Non-white vs white: 1.6 (0.7-4.0)</p> <p>Fatal vs non-fatal illness: 1.0 (0.6-1.7)</p>	
Shapiro, 1984 ⁹³	Prospective controlled study 1,3,6,7	To identify risk factors for catheter-associated bacteriuria	Patients catheterized for > 24 hours 112	<p>Bacteriuria: <i>Univariate analysis:</i> All results OR (95% CI)</p> <p>Orthopedics ward vs cardiac surgery ward: 60 (7.5-74.4)</p> <p>Neurology ward vs cardiac surgery ward: 14.0 (2.6-75.7)</p> <p>Urology ward vs cardiac surgery ward: 4.3 (0.8-22.8)</p> <p>Neurosurgery ward vs cardiac surgery ward: 4.4 (1.0-19.6)</p> <p>Intensive care unit: 1.6 (0.6-4.6)</p> <p>Age > 74 years: 2.8 (1.1-7.6)</p> <p>Female sex : 1.7 (0.7-4.0)</p> <p>Arabs vs Jews: 2.9 (1.0-8.5)</p> <p>BUN < 25 mg/dl: 2.8 (0.9-8.2)</p> <p>Indication for catheterization: incontinence/existent outflow obstruction vs output measurement or prevention of obstruction: 6.6 (2.7-15.9)</p> <p>Catheter inserted outside operating theater: 4.3 (1.9-9.8)</p> <p>Duration of hospitalization > 7 days: 1.4 (0.5-3.5)</p> <p>Lack of administration of antimicrobial drugs: 1.8 (0.8-4.1)</p> <p>Unsatisfactory catheter care: 3.9 (1.5-9.8)</p> <p>Prolonged duration (> 7 days) of catheterization: 47.2 (16.6-134.2)</p>	<p>F/U until discharge or death</p> <p>Bacteriuria was defined as a single culture of 10^2 cfu/ml of aspirated urine if systemic antibiotics had been administered within one day after obtaining the culture; otherwise, two consecutive cultures of 10^5 cfu/ml were required. Bacteriuria was regarded as catheter-acquired if the first positive urine culture had been preceded by a sterile culture</p> <p>Power not reported</p>

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results*	Comments
				<p>Extrapelvic vs pelvic operation: P > 0.10 (OR not provided) Steroids: P = NS (OR not provided) Bedridden vs mobile: P = NS (OR not provided)</p> <p><u>Multivariate analysis:</u> All results OR (95% CI) adjusted for all variables entering the regression equation Orthopedics ward vs cardiac surgery ward: 51.1 (7.6-341.0) Urology ward vs cardiac surgery ward: 4.1 (1.1-15.7) Insertion of a catheter after the sixth day of hospitalization: 8.6 (3.5-21.1) Prolonged duration (> 7 days) of catheterization: 6.8 (2.8-16.8) Arabs vs Jews: 6.5 (2.4-17.1) Location of catheter insertion outside operation theatre: 5.3 (1.7-16.7) Lack of administration of systemic antibiotics: 3.9 (1.9-8.3) Unsatisfactory catheter care: 3.1 (1.7-5.6)</p>	
Pien, 1983 ⁹²	Prospective controlled study 1,3,6	To evaluate risk factors for nosocomial UTI.	Hospitalized patients with indwelling closed drainage catheterization 90	<p>Bacteriuria: <u>Univariate analysis:</u> All results P values Female Sex: 0.7 Age > 50: P value was reported as 3.0 Severity of illness: 0.15 Surgical illness: < 0.02</p> <p>(Only univariate analysis was reported)</p>	F/U until catheter removal, discharge or death A colony count of ≥ 100 colonies per ml was considered to be significant bacteriuria Power not reported
Hartstein, 1981 ⁹⁸	Prospective controlled study 1,3	To identify risk factors for UTI.	Patients with indwelling urinary catheterization 108	<p>Bacteriuria: <u>Univariate analysis:</u> All results P values Exposure to antibiotics: < 0.05 Duration of catheterization: < 0.05 Age: > 0.05 Sex: > 0.05 Maintenance of closed system: > 0.05 Underlying host disease status: > 0.05 Catheter type (Teflon-coated latex vs silicon): > 0.05 Reason for catheterization (different types of surgery): > 0.05</p> <p>(Only univariate analysis was reported)</p>	F/U until discharge or death A UTI was defined as ≥ 10 ⁴ cfu/ml in the catheter or midstream specimen of urine Power not reported
Garibaldi, 1980 ⁹⁹	Prospective controlled study 1,3,6,7	To examine whether meatal colonization is a major risk factor for catheter-associated bacteriuria.	Patients needing an indwelling urinary catheter 1213	<p>Bacteriuria: Positive meatal culture vs negative meatal culture: 110/612 vs 28/601; < 0.01</p> <p>Bacteriuria was significantly higher in patients with positive meatal cultures than in patients with negative meatal cultures in all subgroups divided on basis of sex, age (≥50 vs < 50), receipt of antibiotics, and service (medical or surgical)</p>	F/U unclear A meatal culture was considered positive if gram negative bacilli or enterococci were isolated from the meatal swab Bacteriuria was defined as ≥ 10 ⁵

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results*	Comments
				Positive meatal culture: <i>Univariate analysis:</i> All results P values Females: < 0.01 Age > 50 years: NS No systemic antibiotics: < 0.01 Medical treatment (vs Surgical): < 0.01	colonies of gram-negative rods or enterococci per ml of urine collected by aseptic puncture of a sampling port in the drainage tube Power not reported
Hirsh, 1979 ¹⁰¹	Prospective controlled study 1,3	To determine whether the use of a condom catheter collecting system was associated with UTI. Patients were classified into two groups in one of which they were either cooperative or because of paralysis were unable to manipulate the collecting system. Patients were identified as being uncooperative if they manipulated, pulled off, or repeatedly caused kinking of the collecting system.	Male inpatients on the medical or surgical services of a Veterans Administration hospital Not specified	UTI: Cooperative vs uncooperative: 0/79 vs 8/15; statistical differences were not reported	F/U unclear Bacteriuria defined as $\geq 10^3$ colonies per ml Power not reported
Islam, 1977 ⁹⁷	Prospective controlled study 1,3	To compare two urinary drainage systems: System 1 (the catheter drained via a connecting tube into a sterile disposable plastic bag with a flutter valve to prevent retrograde flow) and System 2 (connected by a sterile tube to a drainable plastic bag with an outlet tap at the bottom through which chlorhexidine solution was introduced).	Hospitalized patients requiring continuous catheter drainage 200	Bacteriuria: System 1 vs System 2: 23/69 vs 24/79; P> 0.05 Risk factors for bacteriuria: <i>Univariate analysis:</i> All results P values Type of operative procedure: > 0.05 Antimicrobial agents: > 0.05 Duration of catheterization: <0.05 It was noted that infection occurred more frequently in patients whose catheter needed to be changed or whose bladder was washed with sterile saline. But statistical differences were not reported.	F/U 4 months Significant bacteriuria defined as $> 10^5$ /ml Power not reported
Garibaldi, 1974 ¹⁰⁰	Prospective controlled study 1,3,6	To identify risk factors for bacteriuria during indwelling urethral catheterization.	Inpatients who received indwelling urethral catheters and urinary drainage systems 405	Bacteriuria: <i>Univariate analysis:</i> All results P values Female vs male: < 0.01 Age > 50 yrs vs < 50 yrs: NS Rapidly fatal vs non-fatal illness: < 0.01 Non-surgical vs surgical illness: NS ICU: NS Violations in catheter care: NS Licensed nurse (vs RN or MD): < 0.01 Administration of systemic antibiotics: < 0.01 (Only univariate analysis was reported)	Study period 2 months Colony counts of $\geq 10^2$ organisms/ml indicated bacterial colonization of bladder urine. Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results*	Comments
1B.6. Home care					
Wilde, 2003 ¹⁰³	Retrospective controlled study 1,3,4,6	To investigate whether factors related to urine flow were associated with the risk of developing a UTI.	Patients in a home care agency with indwelling urinary catheterization for at least 3 months 24	Symptomatic UTI: <u>Univariate analysis:</u> All results P values. Catheter blockage: 0.02 Urine output < 1200 ml: 0.04 Bloody urine: NS Pulling catheter: NS Sluggish urine: NS Leaking: NS Position blocked urine flow: NS (Only univariate analysis was reported)	Study period 2 months UTI was diagnosed based on (1) new pain in the back over the kidney region or pain/tenderness over the bladder region (2) change in character of urine (3) lab tests showing new urine infection or blood in urine with a previous negative test (4) a medical diagnosis of UTI as written in the record Power not reported
White, 1995 ¹⁰²	Retrospective controlled study 1,3,4,6,7	To determine the characters of those who acquire UTI and the influence of the interval between catheter changes on the incidence of UTI.	Home care patients with catheters 106	Symptomatic UTI: <u>Multivariate analysis:</u> All results RH (95% CI) [RH = relative hazard] Catheter change interval ≤ 4 wk (compared to less frequently): 11.94 (5.46-26.22) Number of nurses changing catheter: 1.38 (1.22-1.65) Age: 0.99 (0.98-1.01) Ambulatory care group: 1.01 (0.99-1.03) Female sex :0.72 (0.34-1.53) (Only multivariate analysis was reported)	F/U until death or the end of home care or hospitalization UTI according to CDC definition Power not reported

* The direction of effect for all risk factors mentioned is to increase the risk of the outcomes examined

GRADE Table 1B

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE			Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response		

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE				GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
Old age	Symptomatic UTI*	6 OBS ^{50,54,75,79,83,102}	Independent risk factor in 1 large OBS ⁷⁵ , possible risk factor in 1 OBS ⁵⁴ . Not found to be a risk factor in 4 OBS ^{50,79,83,102} .	Low	0	0	0	0	0	0	0	0	Low	Low
	Bacteriuria*	17 OBS ^{64,65,72,76-78,84-86,89-94,98,100}	Possible risk factor in 3 OBS ^{89,93,94} . Not found to be a risk factor in 14 OBS ^{64,65,72,76-78,84-86,90-92,98,100} .	Low	0	0	0	0	0	0	0	0	Low	
Female sex	Symptomatic UTI*	5 OBS ^{54,62,74,75,102}	Independent risk factor in 1 OBS ⁷⁵ , possible risk factor in 1 OBS ⁶² . Not found to be a risk factor in 3 OBS ^{54,74,102} .	Low	0	0	0	0	0	0	0	0	Low	Low
	Bacteriuria/unspecified UTI*	21 OBS ^{9,63-65,67,68,72,76,77,82,85,86,89-94,96,98,100}	Independent risk factor in 8 OBS ^{64,65,68,76,77,82,86,94} , possible risk factor in 4 OBS ^{9,89,90,100} . Not found to be a risk factor in 9 OBS ^{63,67,72,85,91-93,96,98} .	Low	0	0	0	0	0	+1	0	0	Moderate	
Prolonged duration of catheterization	Symptomatic UTI*	5 OBS ^{54,61,62,74,83}	Independent risk factor in 1 OBS ⁵⁴ , possible risk factor in 3 OBS ^{61,62,74} . Not found to be a risk factor in 1 OBS ⁸³ .	Low	0	0	0	0	0	0	0	0	Low	Low
	Bacteriuria*	15 OBS ^{61,65,66,76-78,85,86,90,91,93,94,96-98}	Independent risk factor in 6 OBS ^{76,77,85,91,93,94} , possible risk factor in 7 OBS ^{61,66,78,86,96-98} .	Low	0	0	0	0	0	+1	+1	0	High	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE				GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
			Not found to be a risk factor in 2 OBS 65,90.											
Lack of administration of antibiotics	Symptomatic UTI*	4 OBS 50,54,74,79	Independent risk factor in 1 OBS 74. Not found to be a risk factor in 3 OBS 50,54,79.	Low	0	0	0	0	0	0	0	0	Low	Low
	Bacteriuria*	15 OBS 64,65,67,68,72,76,77,85,86,91,93,94,97,98,100	Independent risk factor in 10 OBS 64,65,68,76,77,85,86,91,93,94, possible risk factor in 2 OBS 98,100. Not found to be a risk factor in 3 OBS 67,72,97.	Low	0	0	0	0	0	+1	0	0	Moderate	
Impaired immunity	Symptomatic UTI*	2 OBS 54,74	Independent risk factor in 1 large OBS 74. Not found to be a risk factor in 1 OBS 54.	Low	0	0	0	0	0	0	0	0	Low	Very Low
	Bacteriuria*	3 OBS 59,77,85	Independent risk factor in 1 OBS 59. Not found to be a risk factor in 2 OBS 77,85.	Low	0	-1	0	0	0	0	0	0	Very Low	
Disconnection of the drainage system	Bacteriuria/unspecified UTI*	5 OBS 60,78,91,94,98	Independent risk factor in 1 OBS 78, possible risk factor in 2 OBS 60,94. Not found to be a risk factor in 2 OBS 91,98.	Low	0	0	0	0	0	0	0	0	Low	Low
Diabetes	Symptomatic UTI*	2 OBS 50,79	Not found to be a risk factor in 2 OBS 50,79.	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE				GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
	Bacteriuria*	3 OBS ^{77,84,94}	Independent risk factor in 1 large OBS ⁹⁴ . Not found to be a risk factor in 2 OBS ^{77,84} .	Low	0	0	0	0	0	0	0	0	Low	
Renal dysfunction	Symptomatic UTI*	2 OBS ^{50,79}	Not found to be a risk factor in 2 OBS ^{50,79} .	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
	Bacteriuria*	3 OBS ^{86,93,94}	Independent risk factor in 2 OBS ^{86,94} . Not found to be a risk factor in 1 OBS ⁹³ .	Low	0	0	0	0	0	0	0	0	Low	
Surgical illness	Bacteriuria*	4 OBS ^{67,89,92,100}	Possible risk factor in 1 OBS ⁹² . Not found to be a risk factor in 3 OBS ^{67,89,100} .	Low	0	0	0	0	0	0	0	0	Low	Low
Severity of illness	Bacteriuria*	5 OBS ^{76,77,92,94,100}	Independent risk factor in 1 OBS ⁷⁶ , possible risk factor in 1 OBS ¹⁰⁰ . Not found to be a risk factor in 3 OBS ^{77,92,94} .	Low	0	0	0	0	0	0	0	0	Low	Low
Orthopedic population	Bacteriuria*	2 OBS ^{91,93}	Independent risk factor in 2 OBS ^{91,93} .	Low	0	0	0	0	0	0	0	0	Low	Low
Neurology population	Bacteriuria*	3 OBS ^{77,91,93}	Independent risk factor in 1 OBS ⁹¹ , possible risk factor in 1 OBS ⁹³ . Not found to be a risk factor in 1 OBS ⁷⁷ .	Low	0	0	0	0	0	0	0	0	Low	Low
Hospital service	Bacteriuria/unspecified UTI*	3 OBS ^{64,65,82}	Not found to be a risk factor in 3 OBS ^{64,65,82} .	Low	0	0	0	0	0	0	0	0	Low	Low
Intensive care	Bacteriuria*	2 OBS ^{93,100}	Not found to be a risk	Low	0	0	0	0	0	0	0	0	Low	Low

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE				GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
unit			factor in 2 OBS 93,100.											
Catheter insertion outside of operating room	Bacteriuria*	2 OBS 91,93	Independent risk factor in 1 OBS 93. Not found to be a risk factor in 1 OBS 91.	Low	0	0	0	0	0	0	0	0	Low	Low
Person performing catheterization – Nurse vs MD or LPN vs (RN or MD)	Bacteriuria*	3 OBS 91,94,100	Possible risk factor in 2 OBS 94,100. Not found to be a risk factor in 1 OBS 91.	Low	0	0	0	0	0	0	0	0	Low	Low
Incontinence as a reason for catheterization	Bacteriuria*	2 OBS 91,93	Independent risk factor in 1 OBS 91, possible risk factor in 1 OBS 93.	Low	0	0	0	0	0	0	0	0	Low	Low
Catheter blockage	Symptomatic UTI*	2 OBS 79,103	Possible risk factor in 1 OBS 103. Not found to be a risk factor in 1 OBS 79.	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
Low albumin level	Symptomatic UTI*	2 OBS 50,79	Possible risk factor in 2 OBS 50,79.	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
Low hemoglobin level	Symptomatic UTI*	2 OBS 50,79	Not found to be a risk factor in 2 OBS 50,79.	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
Stool incontinence	Symptomatic UTI*	2 OBS 50,79	Not found to be a risk factor in 2 OBS 50,79.	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
Urinary acidifier	Symptomatic UTI*	2 OBS 50,79	Not found to be a risk factor in 2 OBS 50,79.	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
Race (non-white)	Bacteriuria*	2 OBS 72,94	Possible risk factor in 2 OBS 72,94.	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE				GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
vs white)														
Blood loss	Bacteriuria*	2 OBS ^{61,78}	Possible risk factor in 1 OBS ⁶¹ . Not found to be a risk factor in 1 OBS ⁷⁸ .	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
Non-sterile catheterization	Bacteriuria/unspecified UTI*	2 OBS ^{63,73}	Possible risk factor in 1 OBS ⁷³ . Not found to be a risk factor in 1 OBS ⁶³ .	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
Positive meatal culture	Bacteriuria*	4 OBS ^{65,67,68,99}	Independent risk factor in 1 OBS ⁶⁸ . Possible risk factor in 2 OBS ^{65,99} . Not found to be a risk factor in 1 OBS ⁶⁷ .	Low	0	0	0	0	0	0	+1	0	Moderate	Moderate
Lack of urinemeter drainage	Bacteriuria*	2 OBS ^{65,94}	Independent risk factor in 1 OBS ⁹⁴ . Not found to be a risk factor in 1 OBS ⁶⁵ .	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low

*These modifiers can impact the GRADE by 1 or 2 points.

Notes:

- All risk factors that were evaluated in two or more studies for a particular outcome were listed in the GRADE table.
- Definitions: “Independent risk factor” implies a variable was significant in a multivariate analysis; “possible risk factor” implies (1) it was significant in a univariate analysis and a multivariate analysis was not performed OR (2) it was significant in a univariate analysis and there were <10 events per variable examined in the multivariate analysis; “not a risk factor” implies that (1) it was not significant in a univariate/multivariate analysis when only one analysis was reported OR (2) it was significant in a univariate analysis and there were > 10 events per variable examined in the multivariate analysis
- RCTs included in the GRADE table were considered as observational for the purposes of grading study quality.

Study Quality Assessment Table 1B

Study	Systematic Review				Randomized Controlled Trial				Observational Controlled Study				Economic analysis																		
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented	6. Sensitivity analyses performed	
1B.1. Spinal cord injury/Neurogenic Bladder																x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Seki, 2004 ⁷⁰																x	x	x	x	x	x	x	x	x	x	x	x	x	x		
De Ruz, 2000 ⁵⁴																x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Keheller, 1996 ⁷¹																x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Waites, 1993 ⁷²																x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Anderson, 1980 ⁷³																x	x	x	x	x	x	x	x	x	x	x	x	x	x		
1B.2. Intensive Care Unit																x	x	x	x	x	x	x	x	x	x	x	x	x	x		
van der Kooi, 2007 ⁷⁴																x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Bochicchio, 2003 ⁷⁵																x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Leone, 2003 ⁷⁶																x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Tissot, 2001 ⁷⁷																x	x	x	x	x	x	x	x	x	x	x	x	x	x		
1B.3. TURP									x	x		x	x	x	x																
Darouiche, 1999 ⁵⁹								x	x		x	x	x	x	x																
Stricker, 1988 ⁶⁰								x			x		x	x	x																
Colau, 2001 ⁷⁸																x	x	x	x	x	x	x	x	x	x	x	x	x	x		
1B.4. Nursing Homes																															

Study	Systematic Review				Randomized Controlled Trial				Observational Controlled Study				Economic analysis																
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented
Ouslander, 1987 ⁷⁹																													
Ouslander, 1987 ⁵⁰																													

1B.5. Hospital or unspecified

Rogers, 2004 ⁶¹									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Baan, 2003 ⁶²									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Carapeti, 1996 ⁶³									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Huth, 1992 ⁶⁴									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Huth, 1992 ⁶⁵									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Classen, 1991 ⁶⁸									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Schneeberger, 1992 ⁶⁶									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Burke, 1983 ⁶⁷									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Warren, 1978 ⁶⁹									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Hazelett, 2006 ⁸⁰									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Saint, 2006 ⁸¹									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Srinivasan, 2006 ⁸²									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Cardosi, 2003 ⁸³									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Johansson, 2002 ⁸⁴									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Tambyah, 2002 ⁹									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Study	Systematic Review				Randomized Controlled Trial				Observational Controlled Study				Economic analysis																
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented
Hustinx, 1991 ⁸⁵																													
Johnson, 1990 ⁸⁶																													
Lima, 1990 ⁸⁷																													
Jacono, 1988 ⁸⁸																													
Lanara, 1988 ⁸⁹																													
Mulhall, 1988 ⁹¹																													
Holliman, 1987 ⁹⁰																													
Saramma, 1987 ⁹⁶																													
Burke, 1986 ⁹⁵																													
Platt, 1986 ⁹⁴																													
Shapiro, 1984 ⁹³																													
Pien, 1983 ⁹²																													
Hartstein, 1981 ⁹⁸																													
Garibaldi, 1980 ⁹⁹																													
Hirsh, 1979 ¹⁰¹																													
Islam, 1977 ⁹⁷																													
Garibaldi, 1974 ¹⁰⁰																													
1B.6. Home care																													
Wilde, 2003 ¹⁰³																													

Study	Systematic Review				Randomized Controlled Trial				Observational Controlled Study			Economic analysis																	
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented
White, 1995 ¹⁰²																													

1C. What populations are at highest risk of mortality from urinary catheters?

TABLE 1C: RISK FACTORS FOR MORTALITY AMONG CATHETERIZED PATIENTS

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
van der Kooi, 2007 ⁷⁴	Prospective controlled study 1,3,4,6,7	To examine the incidence of and risk factors for device-associated infections and mortality.	Patients without an initial infection staying in the ICU for at least 48 hours 2644	<p>Symptomatic UTI: <u>Univariate analysis:</u> All results OR (95% CI) Duration of catheterization 5-9 days vs 1-4 days: 1.6 (1.0-2.4); P < 0.05 Duration of catheterization ≥ 10 days vs 1-4 days: 3.3 (2.2-4.9) Duration was not included in the multivariate model</p> <p>Multivariate analysis: All results RR (95% CI) Female sex: 1.4 (1.0-1.8) P > 0.05 Impaired immunity: 2.5 (1.5-4.0) Acute admission vs planned admission: 1.8 (1.0-3.3); P > 0.05 Systemic antibiotics at admission: 0.5 (0.3-1.0); P < 0.05</p> <p>Mortality: <u>Univariate analysis:</u> CAUTI vs not: 30.9% vs 20.2%; P = 0.06. It was not significantly associated with mortality in a multivariate model, though estimates were not provided.</p> <p>Multivariate analysis: All results OR (95% CI) for mortality associated with having a urinary catheter Age 40-70 years vs ≤ 39 years: 1.6 (1.0-2.5); P < 0.05 Age ≥ 70 years vs ≤ 39 years: 2.8 (1.8-4.4) APACHE II ≥ 20 vs 0-19: 1.9 (1.5-2.4) Internal medicine vs surgery/traumatology: 1.9 (1.4-2.7) Cardiology/cardiosurgery vs surgery/traumatology: 2.6 (1.8-3.8) Neurology/neurosurgery vs surgery/traumatology: 1.8 (1.2-2.7) Acute admission vs planned admission: 1.4 (1.0-1.8); P < 0.05 Systemic antibiotics at admission: 1.5 (1.1-2.3) Ventilation: 4.8 (3.3-7.0) Central venous catheter: 1.8 (1.3-2.5)</p>	F/U until discharge, death, or day of withholding treatment CAUTI according to CDC definition Power not reported
Platt, 1982 ⁷	Prospective controlled study 1,3,6,7	To identify risk factors for mortality among catheterized patients.	Hospitalized patients catheterized ≥24 hours 1458	<p>Mortality: <u>Univariate analysis:</u> All results are OR (P value) Fatal vs non-fatal illness: 6.0 (< 0.01) Medicine vs general surgery: 6.9 (< 0.01) Infection: 5.6 (< 0.01) Duration of catheterization (days): ≥ 6 vs 1: 7.5 (< 0.01) Lack of urine-meter drainage: 3.5 (< 0.01) Creatinine at insertion > 2 mg/dl vs < 1 mg/dl: 5.3 (< 0.01) Prior indwelling catheterization: 4.0 (< 0.01) Drainage-bag change: 3.0 (< 0.01)</p>	F/U until discharge or death UTI defined as recovery of ≥ 10 ⁵ cfu/ml Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Person inserting catheter other than MD or RN vs MD: 3.8 (< 0.01) Collection-junction break: 2.5 (< 0.01) Lack of systemic antibiotics in week before catheterization: 2.7 (< 0.01) Prior UTI during current hospitalization: 2.5 (< 0.01) Colonization of drainage bag: 3.5 (< 0.01) Catheter change: 2.4 (0.01) Bag-outlet-tube error: 3.0 (0.01) Age (yr) > 70 vs < 30: 8.0 (0.02) Lack of systemic antibiotics during catheterization: 2.0 (0.02) Lack of preconnected presealed junction: 1.6 (0.04) Female sex: 1.5 (0.08) Povidone-iodine vs soap: 1.5 (0.25) Non-white vs white: 1.2 (0.65)</p> <p><i>Multivariate analysis:</i> All results are OR (95% CI) Infection: 2.8 (1.5-5.1) Age (yr) > 70 vs < 30: 7.0 (0.9-57.5) (P = 0.01 for the overall risk factor) Fatal vs non-fatal illness: 5.2 (3.1-8.7) Medicine vs general surgery: 3.4 (1.9-6.0) Duration of catheterization (days): ≥ 6 vs 1: 4.1 (1.9-9.1) Creatinine at insertion > 2 mg/dl vs < 1 mg/dl: 2.9 (1.3-6.4) Person inserting catheter other than MD or RN vs MD: 2.2 (1.0-4.8)</p>	

GRADE Table 1C

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
Old age	Mortality*	2 OBS ^{7,74}	Independent risk factor in 2 OBS ^{7,74} .	Low	0	0	0	0	0	0	0	0	Low	Low
Severity of illness	Mortality*	2 OBS ^{7,74}	Independent risk factor in 2 OBS ^{7,74} .	Low	0	0	0	0	0	0	0	0	Low	Low
Internal medicine (vs surgery)	Mortality*	2 OBS ^{7,74}	Independent risk factor in 2 OBS ^{7,74} .	Low	0	0	0	0	0	0	0	0	Low	Low
Administration of antibiotics	Mortality*	2 OBS ^{7,74}	Administration of antibiotics was an independent risk factor in 1 OBS ⁷⁴ and lack of administration of antibiotics was a possible risk factor in 1 OBS ⁷ .	Low	0	-1	0	0	0	0	0	0	Very Low	Very Low
CAUTI	Mortality*	2 OBS ^{7,74}	Independent risk factor in 1 OBS ⁷ . Not found to be a risk factor in 1 OBS ⁷⁴ .	Low	0	0	0	0	0	0	0	0	Low	Low

*These modifiers can impact the GRADE by 1 or 2 points.

Notes:

- All risk factors that were evaluated in two or more studies for a particular outcome were listed in the GRADE table.
- Definitions: “Independent risk factor” implies a variable was significant in a multivariate analysis; “possible risk factor” implies (1) it was significant in a univariate analysis and a multivariate analysis was not performed OR (2) it was significant in a univariate analysis and there were <10 events per variable examined in the multivariate analysis; “not a risk factor” implies that (1) it was not significant in a univariate/multivariate analysis when only one analysis was reported OR (2) it was significant in a univariate analysis and there were > 10 events per variable examined in the multivariate analysis.

Study Quality Assessment Table 1C

Study	Systematic Review								Randomized Controlled Trial								Observational Controlled Study								Economic analysis							
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented	6. Sensitivity analyses performed		
van der Kooi, 2007 ⁷⁴																		x	x													
Platt, 1982 ⁷																		x	x	x	x	x	x	x								

Question 2: For those who may require urinary catheters, what are the best practices?

2A. What are the risks and benefits associated with different approaches to catheterization?

TABLE 2A: RISKS AND BENEFITS ASSOCIATED WITH DIFFERENT APPROACHES TO CATHETERIZATION

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
2A.1. External vs Indwelling					
Short-term					
Saint, 2006 ¹⁰⁹	RCT 1,2,4,6,7,8,9	To compare condom and indwelling urinary catheters in terms of infection risk and patient satisfaction.	Hospitalized men ≥ 40 years at a VA medical center who required a urinary collection device and were not bacteriuric 75	<p>Bacteriuria: Indwelling vs condom catheter: 17/41 vs 13/34; statistical differences were not reported</p> <p><i>Incidence (per 1000 patient days):</i> Indwelling vs condom catheter: 111 vs 61; P = 0.11</p> <p><i>Median days to outcome:</i> Indwelling vs condom catheter: 7 vs 13; P = 0.15</p> <p>Mortality: Indwelling vs condom catheter: 4/41 vs 2/34; statistical differences were not reported</p> <p>Bacteriuria, symptomatic UTI or death: Indwelling vs condom catheter: 20/41 vs 15/34; statistical differences were not reported</p> <p><i>Incidence (per 1000 patient days):</i> Indwelling vs condom catheter: 131 vs 70; P = 0.07</p> <p><i>Median days to outcome:</i> Indwelling vs condom catheter: 7 vs 11; P = 0.09</p> <p>Univariate analysis: All results HR (95% CI) indwelling vs condom catheter All patients: 1.82 (0.90-3.67) Patients without dementia: 3.47 (0.94-12.74) Patients with dementia: 0.86 (0.23-3.27)</p>	F/U 30 days Bacteriuria was defined as ≥ 10^3 cfu/ml of a single or predominant species of bacteria. Symptomatic UTI was defined as bacteriuria accompanied by onset of one or more of the following symptoms or signs: fever > 38 C, dysuria or other irritative voiding symptoms, or suprapubic, flank or pelvic pain thought to be related to the urinary tract. Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Multivariate analysis: All results HR (95% CI) indwelling vs condom catheter (Adjusted for age, MMSE score, history of UTI and history of catheterization) All patients: 2.11 (1.03-4.31) Patients without dementia: 4.84 (1.46-16.02) [N = 44 for patients without dementia] Patients with dementia: 1.20 (0.33-4.35) [N = 41 for patients with dementia]</p> <p>Patient satisfaction outcomes: All results P value for the outcome's association with condom catheter Increased comfort: 0.02 Decreased pain: 0.02 Convenience: 0.74 Restriction of daily activity: 0.16 Embarrassment: 0.23</p>	
Saint, 2006 ⁸¹	Retrospective controlled study 1,3,4,6,7	To determine risk factors for nosocomial urinary tract related bacteremia. A patient from whom a urine culture and a blood culture grew the same organism \geq 48 hours after admission was considered a case. Control patients were those with significant bacteriuria ($\geq 10^5$ cfu/ml) detected \geq 48 hours after admission who did not have a positive blood culture.	Hospitalized patients with condom or indwelling catheters 237	<p>Bacteremia: Condom vs indwelling: 0/6 vs 83/203; P = 0.08</p> <p>Risk factors for nosocomial urinary tract related bacteremia: Multivariate analysis All results OR [95% CI]</p> <p>Immunosuppressant therapy within 14 days: 8.13 (1.02-64.83) History of malignancy: 1.94 (1.06-3.55) Male sex : 1.88 (1.62-2.18) Smoking within the past 5 years: 1.26 (1.01-1.57) Number of hospital days before detecting bacteriuria: 1.03 (1.01-1.04) Antibiotic use within 3 days of detecting bacteriuria: 0.76 (0.68-0.85) Patients with diabetes < 70 years: 6.19 (1.30-29.40) Patients with diabetes \geq 70 years: 0.11 (0.02-0.83) Patients < 70 years using corticosteroids within 7 days: 14.24 (4.76-42.63) Patients \geq 70 years using corticosteroids within 7 days: 0.08 (0.02-0.34) Data were also collected on race, age, site of medical care, HIV infection, prostatic hypertrophy, urolithiasis, and serum creatinine level, but they were not included in the final multivariate model.</p>	F/U unclear Bacteriuria defined as $\geq 10^5$ cfu/ml Nosocomial urinary tract-related bacteremia defined as when a urine culture and a blood culture grew the same organism \geq 48 hours after admission Power not reported

Long-term

Saint, 1999 ¹²³	Prospective controlled study	To determine the beliefs of older male patients and nursing staff about the	Men hospitalized on medical, rehabilitation	Results of patient interviews: <u>Multivariate analysis</u> All results OR [95% CI] for condom vs indwelling unless otherwise noted	F/U N/A
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
	(based on a survey) 1,3,6,7	relative merits and problems of condom and indwelling catheters.	and nursing home units using either an indwelling or a condom catheter and all members of the nursing staff on these units 104 patients and 99 nurses	<p>Comfort: 4.2 (1.1-15.6) Pain: 0.17 (0.05-0.64) Restriction: 0.23 (0.07-0.75) Convenience: P = 0.40 (OR not reported) Embarrassment: P = 0.50 (OR not reported)</p> <p>Results of nurse interviews: Most of the nursing staff respondents believed that condom catheters were less painful, less embarrassing, less restrictive for patients and were easier to apply, but they also believed that they fell off and leaked more often. Statistical differences were not reported for these comparisons.</p> <p><u>Univariate analysis</u> Results</p> <p>Nursing time: 5-10 minutes more per shift managing the condom catheter (P < 0.01)</p> <p><u>Multivariate analysis</u> All results OR [95% CI]</p> <p>Nursing convenience</p> <p>No. of patients cared for in the past year (P = 0.04) [Interpretation: The more positive the experience with condom catheters, the more likely nurses would prefer them.]</p> <p>Patient comfort</p> <p>As the number of minutes spent managing the indwelling catheter increased, the more likely the respondent was to prefer the condom catheter (P = 0.04).</p> <p>As the number of minutes spent managing the condom catheter increased, the more likely the respondent was to prefer the indwelling catheter (P = 0.07)</p> <p>For both nursing convenience and patient comfort, the respondent's type of licensure, nursing experience, sex, and hospital unit were not significant predictors</p>	UTI not measured Power not reported

2A.2. Intermittent vs indwelling

Short-term

Niel-Weise, 2006 ¹⁰⁴	Systematic review 1,2,3,4,5,6,7,8	To determine the advantages and disadvantages of alternative approaches to catheterization for short term bladder drainage in adults.	All randomized and quasi-randomized trials comparing catheter route of insertion for adults catheterized for up to 14 days 17 trials	<p><u>1. Urethral catheterization vs suprapubic catheterization</u> (all results RR [95% CI] unless otherwise noted)</p> <p>Bacteriuria (symptomatic and asymptomatic) (14 studies): 2.60 (2.12-3.18)</p> <p>Bacteriuria (symptomatic and asymptomatic) in males (2 studies): 1.71 (0.87-3.36)</p> <p>Bacteriuria (symptomatic and asymptomatic) in females (2 studies): 4.23 (1.87-9.54)</p>	
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Bacteriuria (symptomatic and asymptomatic) after colposuspension (1 study): 7.41 (1.02-54.10)</p> <p>Bacteriuria (symptomatic and asymptomatic) after vaginal repair (1 study): 1.60 (0.82-3.14)</p> <p>Bacteriuria (symptomatic and asymptomatic) without antibiotic prophylaxis (1 study): 6.28 (2.49-15.79)</p> <p>Bacteriuria (symptomatic and asymptomatic) with antibiotic prophylaxis (1 study): 6.88 (0.35-133.64)</p> <p>Bacteriuria (symptomatic and asymptomatic) after gynecological surgery (7 studies): 2.46 (1.95-3.10)</p> <p>Bacteriuria (symptomatic and asymptomatic) after abdominal surgery (3 studies): 1.90 (1.14-3.17)</p> <p>Bacteriuria (symptomatic) (1 study): 1.16 (0.54-2.48)</p> <p>Recatheterization (8 studies): 4.72 (2.94-7.56)</p> <p>Number of patients catheterized > 5 days (1 study): 0.62 (0.49-0.80)</p> <p>Mean duration of catheterization (1 study): WMD (95% CI) = -1.60 (-2.80 to -0.40) Unit of measurement was not specified. 8 other studies reported duration of catheterization, but data were not sufficient to calculate statistical differences.</p> <p>Number of patients with pain (2 studies): 9.30 (2.96-29.21)</p> <p>Number of catheter days with pain (1 study): 6.95 (3.03-15.92)</p> <p>Discomfort (4 studies): 2.98 (2.31-3.85)</p> <p>Catheter obstruction (2 studies): 0.18 (0.02-1.49)</p> <p>Gross hematuria (2 studies): 0.97 (0.25-3.74)</p> <p>Microscopic hematuria (2 studies): 0.93 (0.72-1.20)</p> <p>Pyuria (2 studies): 2.09 (1.63-2.68)</p> <p>Number of patients with febrile morbidity (1 study): WMD (95% CI) = 13.50 (10.94-16.06)</p> <p>Number of patients needing antibiotic therapy (1 study): 2.78 (1.47-5.28)</p> <p>Number of patients requiring drugs for relief of dysuria (1 study): 1.68 (1.23-2.28)</p> <p>Mean hospital stay (1 study): WMD (95% CI) = 1.10 (0.30 to 1.90)</p> <p>Number of patients with extended hospital stay (1 study): 1.79 (1.01-3.16)</p> <p>Number of patients leaving hospital with catheter (1 study): 3.33 (1.28-8.67)</p> <p>2. Urethral catheterization vs intermittent catheterization (all results RR [95% CI] unless otherwise noted)</p> <p>Number of patients with no return of bladder function 48 hours after surgery (1 study): 0.55 (0.30-1.02)</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Bacteriuria (symptomatic and asymptomatic) (2 studies): 2.90 (1.44-5.84)</p> <p>Urinary symptoms immediately after surgery (1 study): 1.54 (0.65-3.63)</p> <p>Postoperative pyrexia (1 study): 1.11 (0.63-1.95)</p>	
Tang, 2006 ¹¹¹	RCT 1,2,7	To compare the use of intermittent vs indwelling urinary catheterization. Subjects in the indwelling catheter group were treated with indwelling urinary catheterization, and a trial without a catheter was performed at least once weekly in this group. The indwelling urinary catheter was reinserted if post-voiding residual volume (PVRU) \geq 300 ml. If the trial without catheter was successful, PVRU would be monitored by bladder scan at least daily until day 14. Subjects in the intermittent catheter group had their PVRU monitored by bladder scan three times a day. Intermittent catheterization would be performed either when PVRU \geq 500 ml but remained asymptomatic or when PVRU \geq 300 ml with symptoms of retention.	Female patients \geq 65 years with urinary retention (PVRU \geq 300 ml) admitted to a female geriatric rehabilitation ward 81	<p>Symptomatic UTI: Intermittent vs indwelling: 1/22 vs 0/34; P = 0.40</p> <p>Bacteriuria: Intermittent vs indwelling: 14/22 vs 21/34; P = 0.89</p> <p>Subjects being catheter-free and having a PVRU < 150 ml: Intermittent vs indwelling: 16/27 vs 27/39; P = 0.40</p> <p>Mean PVRU on day 14 (ml): Intermittent vs indwelling: 77.6 vs 54.4; P = 0.14</p> <p>Mean time to become catheter-free (days): Intermittent vs indwelling: 8.6 vs 9.2; P = 0.61</p> <p>Median number of catheterizations: Intermittent vs indwelling: 1 vs 3; P = 0.03</p>	F/U 14 days Bacteriuria was defined as a growth of \geq 10 ⁵ bacteria per ml Symptomatic UTI was defined as either having fever in the absence of other sites of infection with or without symptoms of dysuria or suprapubic discomfort. Sample size of 80 needed to detect an increase in the proportion of weaning patients off catheter from 42% in the indwelling group to 75% in the intermittent group with 80% power and an alpha of 0.05.
Turi, 2006 ¹¹²	RCT 1	To compare the incidence of complications in patients practicing clean intermittent catheterization vs indwelling catheter.	Patients selected from outpatient department during evaluation for symptoms of bladder outlet obstruction or postoperative cases of stricture urethra or referred patients 80	<p>Pyelonephritis: Clean intermittent vs indwelling: 2/40 vs 10/40; P < 0.05</p> <p>Epididymo-orchitis: Clean intermittent vs indwelling: 1/40 vs 3/40; P > 0.05</p> <p>Urosepsis: Clean intermittent vs indwelling: 0/40 vs 2/40; P > 0.05</p>	F/U 6 months A colony count of $>$ 100 colonies per ml was considered to be significant bacteriuria Power not reported
Tangtrakul, 1994 ¹¹³	RCT 1	To compare the incidence of UTI using intermittent vs indwelling catheterization. Patients in the intermittent catheterization group were catheterized with a straight catheter just before the operation and were	Women who underwent cesarean section and had no history of UTI 98	<p>Bacteriuria: Intermittent vs indwelling: 16/51 vs 9/47; P > 0.05</p> <p>Urinary retention requiring recatheterization: Intermittent vs indwelling: 20/51 vs 0/47; statistical differences were not reported</p>	F/U unclear UTI was defined as \geq 10 ⁵ organisms/ml Urinary retention was

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		treated postoperatively with intermittent catheterization for urinary retention (defined as unable to void in the presence of clinically apparent bladder distension, or at least every 6 hours while awake). Any patient requiring catheterization more than twice would have a Foley catheter inserted for 24 hours. Patients in the other group had an indwelling Foley catheter placed just before the operation and removed on the following day.			defined as inability to void in the presence of clinically apparent bladder distension, or at least every 6 hours while awake Power not reported
Skelly, 1992 ¹¹⁴	RCT 1,2,6,7,8	To compare the use of indwelling catheters and intermittent catheterization in the management of urinary retention after surgical repair of hip fractures. Indwelling catheters were left in place for 48 hours. If the patient could not void, in-out catheterization was done at 8-hour intervals during the 24 hours. If voiding was still not possible, an indwelling catheter was inserted for another 48 hours. If residual urine was > 150 ml, retention was considered to be unresolved and an indwelling catheter was inserted for another 48 hours. At the end of 5 days, all patients who were not yet voiding underwent intermittent catheterization and were followed up until voiding resumed. Intermittent catheterization was done at 6-8 hour intervals in the intermittent group. Catheterization was stopped when the residual amount of urine after voiding was < 150 ml on two consecutive occasions.	Patients ≥ 60 years admitted with hip fracture and a residual urine volume of > 150 ml after initial monitoring. 67	Bacteriuria on post-op day 5: Intermittent vs indwelling: 12/32 vs 11/35; P > 0.05 Return of voiding on post-op day 5: Intermittent vs indwelling: 21/32 vs 13/35; P < 0.01 Mean number of days for return of voiding: Intermittent vs indwelling: 5.1 vs 9.4; P < 0.01 Mortality after post-op day 5: Intermittent vs indwelling: 2/32 vs 5/35; statistical differences were not reported	F/U until resumption of voiding. A colony count ≥ 10 ⁵ per ml was used to diagnose an infection Power not reported
Michelson, 1988 ¹¹⁰	RCT 1,6,7,8	To examine the efficacy and risks of two methods of urinary bladder management after total joint replacement surgery. In the indwelling group, indwelling catheters were	Patients undergoing total hip and knee replacement 96 patients undergoing	Urinary retention: Intermittent vs indwelling: 52% vs 27%; P < 0.01 Postoperative bacteriuria: Intermittent vs indwelling (among patients with negative preoperative urinary cultures): 7/47 vs 4/36; P > 0.05	F/U 7 days Urinary infection defined as ≥ 10 ⁴ cfu/ml

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		placed during the operation and removed the next morning. Thereafter, urinary retention was treated with intermittent straight catheterization. If retention continued beyond 36-48 hours after the removal of catheter, another indwelling catheter was placed which remained in place for 48 hours. In the intermittent group, urinary retention was treated by sterile intermittent catheterization as needed.	100 hip or knee replacements	<p>no catheter vs any catheter: 17% vs 5.6%; P > 0.05 Long term indwelling vs any other catheterization: 35% vs 6%; P < 0.05</p> <p>Bladder overdistension (> 700 ml): Intermittent vs indwelling: 25/56 vs 3/44; P < 0.01</p> <p>Risk factors for urinary retention: <i>Univariate analysis</i> (all results P values): Age > 60 yrs: < 0.05 (< 0.01 in the indwelling group, but > 0.05 in the intermittent group) Sex: > 0.05 (except men < 60 years undergoing intermittent catheterization < 0.05) It was not possible to prospectively identify patients who would require postoperative catheterization On the basis of a previous history of urinary symptoms, post-surgical retention or genitourinary surgery., 4 or more risk factors were present in only 20% of patients with retention and 19% of patients without retention.</p>	<p>Urinary retention was defined as inability to void in the presence of clinically apparent bladder distension, or at least every 6 hours while awake</p> <p>Power not reported</p>
Johansson, 2002 ⁸⁴	Prospective controlled study 1,3	The aims of the study were (1) to describe the occurrence of UTI among patients with hip fracture before and after surgery; (2) to compare intermittent catheters vs indwelling catheters; and (3) to compare the length of hospital stay among people with and without infection.	Patients admitted to the hospital with traumatic hip fracture. 144	<p>Risk factors for bacteriuria: <i>Univariate analysis:</i> Female sex (vs male sex): 92.7% vs 7.3%; statistical differences not reported Age: P > 0.05 Diabetes: P > 0.05</p> <p>Bacteriuria: Intermittent vs indwelling (among patients who were free of UTI at admission): 20/63 vs 11/26; statistical differences were not reported</p> <p>Length of stay: Significantly longer hospital stay among patients with UTI (P ≤ 0.05)</p>	<p>F/U one week after last catheterization.</p> <p>Bacteriuria was defined as ≥ 10⁵ bacteria/ml</p> <p>Power not reported</p>
Oishi, 1995 ¹²⁵	Retrospective controlled study 1,3,4	To compare an as-needed straight catheterization protocol (patients underwent straight catheterization if they did not void within 8 hours of their surgery and then 6 hours pre re nata for an inability to void; if bladder volume > 500 ml, an indwelling catheter was placed for 48 hours) with indwelling catheterization protocol (indwelling catheter placed during surgery and removed on the morning of the third post-op day).	Patients undergoing primary total hip arthroplasty 95	<p>UTI: Straight catheterization protocol vs indwelling catheterization protocol: 0/49 vs 1/46; P > 0.10</p> <p>Bacteriuria: Straight catheterization protocol vs indwelling catheterization protocol: 0/49 vs 1/46; P > 0.10</p> <p>Bladder distension: Straight catheterization protocol vs indwelling catheterization protocol: 20/49 vs 3/46; P < 0.01</p> <p>Urinary retention: Straight catheterization protocol vs indwelling catheterization protocol: 41/49 vs 3/46; P < 0.01</p>	<p>F/U until catheter removal</p> <p>UTI was defined as a catheterized urine specimen with bacteriuria in conjunction with abnormal leukocyte count (> 2/hpf)</p> <p>Bacteriuria was defined as a catheterized urine specimen with > 10⁵ colonies of bacteria with a urine leukocyte count ≤ 2/hpf</p>

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
					Bladder distension was defined as urine volume > 500 ml obtained at catheterization Urinary retention was defined as an inability to void following catheterization Power not reported
Ritter, 1989 ¹²⁴	Prospective controlled study 1,3	To compare different urinary tract catheterization protocols for urinary retention: (1) in-out urethral catheterization as needed; (2) in-out catheterization on the index episode and by anchorage of the closed system catheterization device if a second retention episode occurred and; (3) intraoperative sterile anchoring of a closed drainage system.	Joint arthroplasty patients 601	Bacteriuria: Group 1 vs Group 2: 1/165 vs 2/295; P = 0.20 Group 1 vs Group 3: 1/165 vs 0/140; P = 0.31 Group 2 vs Group 3: 2/295 vs 0/140; P = 0.54	F/U until discharge UTI was defined as $> 10^5$ cfu/ml. Power not reported
Furuhata, 1988 ¹²⁶	Prospective pre-post study 1,3	To evaluate the utility of intermittent catheterization in patients with urinary retention or residual urine	Patients undergoing surgery for prostatic hypertrophy 259	Postoperative bacteriuria: Intermittent catheterization vs spontaneous voiding: 38/76 vs 47/119 Indwelling catheterization vs spontaneous voiding: 26/31 vs 47/119 Intermittent catheterization vs indwelling catheterization: 38/76 vs 26/31 (No significant differences)	F/U 1-2 weeks after surgery Bacteriuria was defined as a bacteria count in culture of $\geq 10^5$ cells/ml or evidence of many cells after simple staining of urine sediment. Power not reported

Long-term

Shekelle, 1999 ¹⁰⁵	Systematic review 1,2,3,4,5,6,7,8	To identify risk factors for UTI	Controlled trials in adults and adolescents with neurogenic bladder dysfunction addressing the issue of risk factors for recurrent UTI	Sex: Two studies reported a higher risk for UTI in females, while 4 other studies did not. The authors concluded that the effect of being a female on the risk of UTI in people with neurogenic bladder remains unanswered. Level of function: Four studies did not find an increased rate of UTI among patients with tetraplegia compared with patients with	Qualitative SR. Studies were determined to be too clinically heterogeneous to support statistical pooling or risk prediction modeling.
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
			22 studies	<p>paraplegia. Three other studies reported significant increases in infection in persons with complete lesions while 3 studies did not. The authors felt that given the conflicting nature of the results, no conclusions could be drawn about the effect of completeness of lesion on the risk of UTI.</p> <p>Bladder physiology: As the residual volume increased to 300 ml, the rate of UTI over time increased between 4- and 5-fold. Another study reported that a > 20% post-void residual was associated with complications. It was likely that increased bladder residual volume was a risk factor for UTI in persons with neurogenic bladder.</p> <p>Method of drainage: Results were consistent in 7 of 8 studies that persons using intermittent catheterization had fewer infections than those with indwelling catheters and (when studied) persons voiding without catheters had the lowest rate of UTI in all groups</p> <p>Two RCTs did not find significant differences in UTI between sterile and clean methods for intermittent catheterization. Another non-randomized controlled trial found that a sheathed catheter (which amounted to a sterile method) resulted in fewer episodes of bacteriuria when compared with a standard catheter. The authors concluded that the evidence neither supported nor refuted the need to use sterile, as opposed to clean, intermittent catheterization.</p> <p>The authors concluded that the optimum frequency for change of condom catheters was unknown.</p> <p>Time since injury: The study measuring UTI in the most rigorous fashion among 3 studies addressing this issue found that a longer time since injury was significantly associated with a higher occurrence of UTI.</p> <p>Laboratory findings: A prospective cohort study reported that symptomatic UTIs occurred more frequently following relapsing asymptomatic bacteriuria (regrowth of same bacterium) compared to recurrent asymptomatic bacteriuria (regrowth of different bacterium); P <0.03</p> <p>There were no studies or the data were scarce assessing the effect of socioeconomic and insurance status; psychosocial, behavioral, and hygiene factors; and domicile on the risk of UTI</p>	
Vickrey, 1999 ¹⁰⁶	Systematic review 1,2,3,4,7,8	To answer the following key questions: (1) What combinations of signs,	Studies of adults and adolescents with neurogenic bladder due	<p>Indwelling vs intermittent catheterization</p> <p>Indwelling catheterization was associated with more frequent infections than that involving intermittent catheterization, which in turn was</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		<p>symptoms and laboratory findings are associated with infection risks to persons with paralysis due to neurogenic bladder?</p> <p>(2) What are the risk factors for recurrent UTIs?</p> <p>(3) What are the risks and benefits of long-term use of antibiotic prophylaxis?</p>	<p>to non-acute spinal cord dysfunction and relevant to a key question.</p> <p>306 studies</p>	<p>associated with more frequent infections than methods not involving a catheter.</p> <p>Antibiotic prophylaxis</p> <p>Antibiotic prophylaxis significantly reduced bacteriuria among acute spinal cord injury patients ($P < 0.05$) and there was a trend for reduction in bacteriuria among non-acute spinal cord patients ($P = 0.06$). However, antibiotic prophylaxis was not associated with a reduced number of symptomatic infections in the populations studied. Antibiotic prophylaxis resulted in a two-fold increase in the occurrence of antibiotic-resistant bacteria.</p>	

2A.3. Suprapubic vs indwelling urethral

Short-term

McPhail, 2006 ¹⁰⁸	Systematic review 1,2,3,4,5,7,8	To compare suprapubic and transurethral catheterization.	RCTs in general/abdominal surgery 6 RCTs	<p>All results RR (95% CI)</p> <p>Bacteriuria (5 studies): Transurethral catheterization vs suprapubic catheterization: 2.02 (1.34-3.04)</p> <p>Recatheterization (6 studies): Transurethral catheterization vs suprapubic catheterization: 1.97 (0.68-5.74)</p> <p>Pain or discomfort (4 studies): Transurethral catheterization vs suprapubic catheterization: 2.94 (1.41-6.14)</p>	
Niel-Weise, 2006 ¹⁰⁴	Systematic review 1,2,3,4,5,6,7,8	To determine the advantages and disadvantages of alternative approaches to catheterization for short term bladder drainage in adults.	All randomized and quasi-randomized trials comparing catheter route of insertion for adults catheterized for up to 14 days 17 trials	<p><i>1. Urethral catheterization vs suprapubic catheterization</i> (all results RR [95% CI] unless otherwise noted)</p> <p>Bacteriuria (symptomatic and asymptomatic) (14 studies): 2.60 (2.12-3.18)</p> <p>Bacteriuria (symptomatic and asymptomatic) in males (2 studies): 1.71 (0.87-3.36)</p> <p>Bacteriuria (symptomatic and asymptomatic) in females (2 studies): 4.23 (1.87-9.54)</p> <p>Bacteriuria (symptomatic and asymptomatic) after colposuspension (1 study): 7.41 (1.02-54.10)</p> <p>Bacteriuria (symptomatic and asymptomatic) after vaginal repair (1 study): 1.60 (0.82-3.14)</p> <p>Bacteriuria (symptomatic and asymptomatic) without antibiotic prophylaxis (1 study): 6.28 (2.49-15.79)</p> <p>Bacteriuria (symptomatic and asymptomatic) with antibiotic</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>prophylaxis (1 study): 6.88 (0.35-133.64)</p> <p>Bacteriuria (symptomatic and asymptomatic) after gynecological surgery (7 studies): 2.46 (1.95-3.10)</p> <p>Bacteriuria (symptomatic and asymptomatic) after abdominal surgery (3 studies): 1.90 (1.14-3.17)</p> <p>Bacteriuria (symptomatic) (1 study): 1.16 (0.54-2.48)</p> <p>Recatheterization (8 studies): 4.72 (2.94-7.56)</p> <p>Number of patients catheterized > 5 days (1 study): 0.62 (0.49-0.80)</p> <p>Mean duration of catheterization (1 study): WMD (95% CI) = -1.60 (-2.80 to -0.40) Unit of measurement was not specified. Eight other studies reported duration of catheterization, but data were not sufficient to calculate statistical differences.</p> <p>Number of patients with pain (2 studies): 9.30 (2.96-29.21)</p> <p>Number of catheter-days with pain (1 study): 6.95 (3.03-15.92)</p> <p>Discomfort (4 studies): 2.98 (2.31-3.85)</p> <p>Catheter obstruction (2 studies): 0.18 (0.02-1.49)</p> <p>Gross hematuria (2 studies): 0.97 (0.25-3.74)</p> <p>Microscopic hematuria (2 studies): 0.93 (0.72-1.20)</p> <p>Pyuria (2 studies): 2.09 (1.63-2.68)</p> <p>Number of patients with febrile morbidity (1 study): WMD (95% CI) = 13.50 (10.94-16.06)</p> <p>Number of patients needing antibiotic therapy (1 study): 2.78 (1.47-5.28)</p> <p>Number of patients requiring drugs for relief of dysuria (1 study): 1.68 (1.23-2.28)</p> <p>Mean hospital stay (1 study): WMD (95% CI) = 1.10 (0.30 to 1.90)</p> <p>Number of patients with extended hospital stay (1 study): 1.79 (1.01-3.16)</p> <p>Number of patients leaving hospital with catheter (1 study): 3.33 (1.28-8.67)</p> <p><i>2. Urethral catheterization vs intermittent catheterization</i> (all results RR [95% CI] unless otherwise noted)</p> <p>Number of patients with no return of bladder function 48 hours after surgery (1 study): 0.55 (0.30-1.02)</p> <p>Bacteriuria (symptomatic and asymptomatic) (2 studies): 2.90 (1.44-5.84)</p> <p>Urinary symptoms immediately after surgery (1 study): 1.54 (0.65-3.63)</p> <p>Postoperative pyrexia (1 study): 1.11 (0.63-1.95)</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
Phipps, 2006 ³⁷	Systematic review 1,2,3,4,5,6,7,8	To establish the optimal way to manage urinary catheters following urogenital surgery in adults.	Randomized and quasi-randomized trials 39 RCTs	<p><i>Note: All results are RR (95% CI) unless otherwise noted</i></p> <p>1. Using a urinary catheter vs not using a urinary catheter</p> <p>Retention of urine (1 study): 0.12 (0.03-0.47) UTI (4 studies): 1.35 (0.75-2.45) Recatheterization (3 studies): 0.32 (0.14-0.70) Post-op urethral stricture (1 study): 1.14 (0.90-1.44) Post-op hematuria (1 study): 0.73 (0.40-1.33)</p> <p>2. Urethral catheterization vs suprapubic catheterization</p> <p>UTI: Heterogeneous results, not combined. Of four trials, two suggested a moderate increase, one a large increase, and one a large decrease. Recatheterization (2 studies): 3.66 (1.41-9.49) Post-op hematuria (1 study): 5.00 (0.21-116.31) Length of hospital stay in days (1 study) [WMD (95% CI)]: 1.10 (0.30-1.90) Catheter lockage or bypassing [OR (95% CI)] (2 studies): 0.20 (0.02-1.72)</p> <p>3. One type of catheter vs another type of catheter</p> <p>UTI: Urethral Foley catheter with extra drainage hole vs unmodified Foley catheter (1 study): 0.40 (0.15-1.04) Positive urine culture: Silver-coated Bardex catheters vs latex catheters (1 study): 0.53 (0.20-1.45)</p> <p>4. One type of catheter management vs another</p> <p>Retention of urine: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.99 (0.06-15.54) Dysuria: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.99 (0.06-15.54) Symptomatic UTI: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.61 (0.33-1.14) Bacteriuria/unspecified UTI: Cefotaxime 1 hour prior to catheter removal vs none (1 study): 0.08 (0.00-1.30) Neomycin/Sulfamethiazole vs placebo (1 study): 0.18 (0.06-0.55) Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 1.06 (0.70-1.51) Recatheterization: Neomycin/Sulfamethiazole vs placebo (1 study): 0.50 (0.24-1.04)</p> <p>5. Larger diameter catheter vs smaller diameter catheter</p> <p>No trials found</p> <p>6. Bladder irrigation</p>	.

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>No trials found</p> <p>7. Shorter duration vs longer duration catheterization</p> <p>Retention of urine: 1 day vs 3 days (1 study): 0.80 (0.38-1.69) 1-2 days vs until urine clear (1 study): 1.02 (0.07-15.87) 1 day vs 2 days (1 study): 4.64 (0.23-94.28) 3 days vs 28 days (1 study): 3.00 (0.13-69.52)</p> <p>Post-op urethral stricture: < 1 week vs 2 weeks (2 studies): 1.23 (0.82-1.84) 3 days vs 28 days (1 study): 1.00 (0.73-1.36)</p> <p>UTI: Heterogeneous results, not combined. Shorter duration had lower risk of UTIs but the results were significant in only 1 trial 1 day vs 3 days (3 studies): 0.50 (0.29-0.87)</p> <p>Recatheterization: 1 day vs 2 days (1 study): 1.03 (0.23-4.71) 1 day vs 3 days (2 studies): 1.04 (0.36-3.01) 1 day vs 5 days (1 study): 4.55 (1.68-12.37) 4-6 days vs 14 days (1 study): 1.86 (0.14-25.38) 1-2 days vs until urine clear (2 studies): 0.72 (0.24-2.20)</p> <p>Post-op hematuria: 1-2 days vs until urine clear (1 study): 2.04 (0.19-21.81) 1 day vs 2 days (2 studies): 1.16 (0.34-3.90)</p> <p>Urinary leakage or incontinence: 1-2 days vs until urine clear (2 studies): 0.43 (0.07-2.88)</p> <p>8. Clamp and release vs free catheter drainage:</p> <p>UTI (1 study): 4.00 (1.55-10.29)</p> <p>Delay in return to normal bladder function (1 study): 2.50 (1.16-5.39)</p> <p>9. Catheter removal at one time of day vs another time of day</p> <p>UTI: 12 am vs 6 am (1 study): 1.31 (0.65-2.66)</p> <p>Recatheterization: 12 am vs 6 am (4 studies): 0.61 (0.34-1.12) 6-7 am vs 10-11 pm (1 study): 1.36 (0.32-5.77)</p> <p>Time to first void in hours [WMD (95% CI)]: 12 am vs 6 am (1 study): 0.60 (-0.96 to 2.16)</p> <p>Volume of first void in ml [WMD (95% CI)]: 12 am vs 6 am (1 study): 53.00 (4.27-101.73)</p> <p>10. Trial of void protocol vs none</p> <p>No trials found</p> <p>11. Prefilling bladder prior to catheter removal vs removal without prefilling</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				Recatheterization [OR (95% CI)] (1 study): 4.52 (0.79-25.97) Discharge on day of catheter removal (1 study): 1.36 (0.47-3.91)	
Branagan, 2002 ¹⁰⁷	Systematic review 1,2,3	To compare the use of suprapubic and urethral catheters.	Patients undergoing elective colorectal surgery 5 RCTs	UTI: 3 studies reported a significant increase in the urethral catheterization group Urinary retention: No difference between the two groups in 3 studies Duration of catheterization: Was increased in the suprapubic group in 2 studies and there were no differences in two other studies Pain/ discomfort: 2 studies reported an increase in the urethral catheterization group Patient preference: Suprapubic catheter was shown to be preferred by patients in 3 studies	
Baan, 2003 ⁶²	RCT 1,2,4,7,8,9	To compare the effects of suprapubic catheterization vs transurethral catheterization.	Adult patients without UTI undergoing a major abdominal procedure requiring a standard bladder catheterization. 146	Symptomatic UTI: <i>Intention to treat:</i> Suprapubic vs transurethral: 9/75 vs 8/71; RR (95% CI) = 1.06 (0.43-2.61) <i>Per-protocol:</i> Suprapubic vs transurethral: 8/65 vs 8/68; P > 0.05 Recatheterization: Suprapubic vs transurethral: 9/75 vs 4/71; statistical differences not reported Median duration of catheterization (days): Suprapubic vs transurethral: 6.5 vs 4.9; P > 0.05 Patient satisfaction outcomes: All results %, P values for suprapubic vs transurethral <i>During catheterization:</i> Pain in the abdomen: 12 vs 8; > 0.05 Burning pain: 6 vs 7; > 0.05 Leakage of urine: 6 vs 10; > 0.05 False urge: 31 vs 45; > 0.05 Blood loss: 4 vs 2; > 0.05 <i>After catheterization:</i> Unpleasant removal: 27 vs 46; > 0.05 No spontaneous voiding: 4 vs 12; > 0.05 Burning pain during voiding: 10 vs 15; > 0.05 Incontinence: 4 vs 9; > 0.05 Abdominal cramps: 8 vs 5; > 0.05 Overall score (on 5-point Likert scale): Suprapubic vs transurethral: 8.4	F/U 6 weeks after surgery UTI was defined as at least one or more of the clinical symptoms (fever, increased micturition frequency, burning pain during voidance, and a pain in the lower abdomen), a positive sediment (> 10 leukocytes), and a positive urine culture (> 10 ⁵ bacterial colonies and < 3 bacterial species) 62 patients in each group to decrease UTI from 30 to 8% with a power of 90% and an alpha of 5%

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				vs 8.5 Risk factors for Symptomatic UTI: <u>Univariate analysis</u> : All results RR (95% CI) Female sex: 4.16 (1.40-12.20) Recatheterization: 7.16 (3.30-15.60) Duration of catheterization > 7 days: 3.40 (1.43-8.04) Relaparotomy: P = 0.07	
Dunn, 2005 ¹²⁸	Retrospective controlled study 1,3	To evaluate the outcomes of patients with suprapubic vs transurethral catheterization.	Patients undergoing Burch cystourethropexy 217	Ns in the two respective groups were not reported Bacteriuria: Suprapubic vs transurethral: 2 vs 3; P = 1.00 Post-op fever: Suprapubic vs transurethral: 0 vs 1; P = 1.00 Hospital stay (days): Suprapubic vs transurethral: 3.0 vs 3.5; P = 1.00 Visits for pain (days): Suprapubic vs transurethral: 2.5 vs 3.5; P < 0.01 Duration of catheterization (days): Suprapubic vs transurethral: 9.61 vs 7.82; P < 0.01	F/U unclear UTI was diagnosed by the presence of white blood cells, red blood cells, leukocytes, and positive culture. Power not reported
Alli, 2003 ¹²⁷	Prospective controlled study 1,3	To compare urethral catheterization with combined urethral and suprapubic drainage after repair of intraperitoneal bladder injuries.	Patients with intraperitoneal bladder injuries 42	Ns in the two respective groups were not reported Mortality: Urethral vs combined: 3 vs 4; P = 0.68 Morbidity: Urethral vs combined: 1 vs 9; P < 0.01 Undefined UTI: Urethral vs combined: 1 vs 4; statistical differences were not reported Failure to micturate: Urethral vs combined: 0 vs 4; P = 0.04 Hospital stay (days): Urethral vs combined: 9.1 vs 15.5; P = 0.03	F/U unclear. Study period was 24 months. UTI not defined Power not reported
Horgan, 1992 ¹³⁰	Prospective controlled study 1,3	To compare suprapubic and urethral routes of catheterization.	Patients with acute urinary retention due to prostatomegaly who required catheterization 86	Bacteriuria: Suprapubic vs urethral: 10/56 vs 12/30; P < 0.05 Stricture: Suprapubic vs urethral: 0/56 vs 5/30; P < 0.01 Epididymo-orchitis: Suprapubic vs urethral: 0/56 vs 2/30; statistical differences were not reported Septicemia: Suprapubic vs urethral: 0/56 vs 1/30; RR (95% CI) statistical differences were not reported Dislodgement: Suprapubic vs urethral: 12/56 vs 1/30; statistical differences were not reported	F/U 48 hours post-op UTI defined as $\geq 10^5$ cfu/ml Power not reported
Dinneen, 1990 ¹²⁹	Prospective pre-post study 1,3	To compare suprapubic and urethral catheters.	Patients undergoing aortic surgery 131	Bacteriuria: Suprapubic vs urethral: 7/86 vs 16/45; P < 0.05 Stricture: Suprapubic vs urethral: 0/100 vs 11/52; P < 0.01	F/U unclear Bacteriuria defined as >

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
					100,000 bacteria per ml Power not reported Ns and events for bacteriuria are number of urine cultures and not number of patients
Verbrugh, 1988 ¹³³	Prospective pre-post study Sequential trial starting with no prophylactic therapy, then prophylactic therapy and then no prophylactic therapy. For purposes of the analysis, control groups were combined. 1,3,6,7	To determine the efficacy of norfloxacin in reducing the rate of catheter-associated bacteriuria and pyuria following reconstructive gynecologic surgery. Prophylaxis patients were given 200 mg oral norfloxacin qd from the second post-op day until catheter removal. Upon catheter removal, the first group of control patients was given nitrofurantoin 50 mg qid for 7 to 10 days. The second group received a course of norfloxacin (400 mg bid).	Patients undergoing reconstructive gynecologic surgery with bladder catheters 105	Bacteriuria at catheter removal: Prophylaxis vs no prophylaxis: 8/54 vs 32/51; P < 0.01 Pyuria score of ≥ 5-9 leukocytes/ HPF at catheter removal: Prophylaxis vs no prophylaxis: 3/54 vs 22/51; P < 0.01 The type of bladder drainage (suprapubic vs urethral) had no significant effect on the rates of bacteriuria and pyuria in either control or norfloxacin treated patients (data not shown) Median postoperative hospital LOS in days: Prophylaxis vs no prophylaxis: 11 vs 11; P = NS Drug-related side effects: Prophylaxis vs no prophylaxis: 0/54 vs 0/51; P = NS Dysuria: Prophylaxis vs no prophylaxis: 1/54 vs 3/51; P > 0.1	F/U 6 weeks after discharge Significant bacteriuria was defined as > 10 ³ cfu/ml. Power not reported
van Nagell, 1972 ¹³²	Prospective controlled study 1,3	To compare suprapubic vs urethral drainage.	Patients undergoing radical hysterectomy 102	Bacteriuria: Suprapubic vs urethral: 19/84 vs 8/18; statistical differences were not reported Fistula: Suprapubic vs urethral: 6/84 vs 2/18; statistical differences were not reported Intraoperative complications: Suprapubic vs urethral: 13/84 vs 1/18; statistical differences were not reported	F/U until catheter removal Urinary infection defined as > 10 ⁵ colonies/ml Power not reported
Hofmeister, 1970 ¹³¹	Prospective controlled study 1,3	To compare suprapubic vs Foley drainage.	Gynecological patients 448	Postoperative bacteriuria: Suprapubic vs Foley for 3-5 days: 9/96 vs 21/195; statistical differences were not reported Suprapubic vs Foley for 1 day: 9/96 vs 4/146; statistical differences were not reported Postoperative morbidity: Suprapubic vs Foley: 32.7% vs 21%;	F/U 2-3 months Significant bacteriuria defined as > 10,000 bacteria per ml Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>statistical differences were not reported</p> <p>Satisfactory voiding within 6-8 days: Suprapubic vs Foley: 31.8% vs 16.8%; statistical differences were not reported</p> <p>Postoperative LOS (> 14 days): Suprapubic vs Foley: 42/107 vs 19/195; statistical differences were not reported</p>	

Long-term

No studies were identified

2A.4. Suprapubic vs intermittent

Short-term

Jannelli, 2007 ¹¹⁵	RCT 1,2,6,7,8,9	To compare the risk of significant bacteriuria between clean intermittent self-catheterization (starting post-op day 1) and suprapubic catheterization.	Women without pre-op bacteriuria scheduled for surgery for stress urinary incontinence or anterior vaginal wall prolapse. 244	<p>Bacteriuria: Clean intermittent vs suprapubic: 31% vs 23%; P = 0.23</p> <p>Patient satisfaction: All results are mean scores on visual analog scale for clean intermittent vs suprapubic Overall pain: 3.4 vs 3.4; P = 0.85 Pain from the catheter: 1.4 vs 1.9; P = 0.13 Ease of catheter use: 2.5 vs 1.4; P < 0.01 Frustration: 2.7 vs 1.6; P = 0.01 Limitation on social activities: 1.3 vs 1.2; P = 0.83 Interest in using the method again: 7.1 vs 8.4; P < 0.01</p> <p>Mean duration of catheterization (days): Clean intermittent vs suprapubic: 5.3 vs 5.2; P = 0.97</p>	<p>F/U post-op day 7</p> <p>Significant bacteriuria defined as > 10⁵ cfu/ml</p> <p>A sample size of 113 patients per group was needed in order to detect a decrease in significant bacteriuria from 25% to 10% with 80% power and an alpha of 0.05</p>
Roberts, 2006 ¹¹⁶	RCT 1,6,7,8,9	To assess the potential benefits of intermittent self-catheterization (starting post-op day 5 until residual urine volume < 100 ml) over suprapubic catheterization in postoperative bladder care (until residual urine volume < 100 ml).	Women with early stage cervical cancer following radical hysterectomy 40	<p>Bacteriuria: All results intermittent vs suprapubic Day 3: 8/19 vs 1/17; P = 0.05 Day 5: 12/19 vs 3/17; P < 0.01 Day 7: 7/19 vs 6/17; P = 0.4 Day 14: 4/19 vs 9/17; P = 0.16 Day 21: 2/19 vs 2/17; P = 0.21</p> <p>Median length and requirement for bladder care (days): Intermittent vs suprapubic: 17 vs 20; P = 0.83</p> <p>Urinary symptom questionnaire: There were significant differences</p>	<p>F/U 21 days</p> <p>UTI defined as positive urine culture</p> <p>Power not reported</p>

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>in the frequency of nocturia ($P < 0.01$) and bladder emptying ($P = 0.05$), but the direction of effect was not reported.</p> <p>Patient acceptability questionnaire: Intermittent catheterization was significantly more acceptable ($P < 0.01$), allowed greater freedom to lead a normal life ($P = 0.00$), and caused fewer disturbances at night ($P < 0.01$) and less anxiety/embarrassment ($P < 0.01$)</p> <p>Quality of life questionnaire: There were significant differences between nausea/vomiting and insomnia, but the direction of effect was not reported.</p>	

Long-term

Noll, 1988 ¹³⁴	Retrospective pre-post study 1,3	To compare intermittent catheterization and suprapubic catheterization.	Patients with traumatic spinal cord injury 86	<p>Undefined UTI within the first 35 days post-injury: Intermittent vs suprapubic: 71.9% vs 50% ; $P < 0.05$</p> <p>Time to first infection: $P > 0.05$</p>	F/U unclear UTI not defined Power not reported
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2A.5. Clean intermittent vs sterile intermittent

Short-term

Carapeti, 1996 ⁶³	RCT 1	To compare sterile vs nonsterile urethral catheterization.	General surgical patients to be catheterized pre-operatively after induction of anesthesia 156	<p>All UTI: Non-sterile vs sterile: 9/82 vs 7/74; $P > 0.10$ Female vs male: 10/84 vs 6/72; $P > 0.10$</p> <p>Cost (£): Non-sterile vs sterile: 3.06 vs 7.49; statistical differences were not reported</p>	F/U 3 rd postoperative day UTI was defined as bacteriuria $> 10^5$ with or without clinical symptoms Power not reported
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Long-term

Shekelle, 1999 ¹⁰⁵	Systematic review 1,2,3,4,5,6,7,8	To identify risk factors for UTI.	Controlled trials in adults and adolescents with neurogenic bladder dysfunction addressing the issue of risk factors for recurrent UTI 22	<p>Sex: Two studies reported a higher risk for UTI in females, while 4 other studies did not. The authors concluded that the effect of being a female on the risk of UTI in people with neurogenic bladder remains unanswered.</p> <p>Level of function: Four studies did not find an increased rate of UTI among patients with tetraplegia compared with patients with paraplegia. Three other studies reported significant increases in</p>	Qualitative SR. Studies were determined to be too clinically heterogeneous to support statistical pooling or risk prediction modeling.
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>infection in persons with complete lesions while 3 studies did not. The authors felt that given the conflicting nature of the results, no conclusions could be drawn about the effect of completeness of lesion on the risk of UTI.</p> <p>Bladder physiology: As the residual volume increased to 300 ml, the rate of UTI over time increased between 4 and 5 fold. Another study reported that a > 20% post-void residual was associated with complications. It was likely that increased bladder residual volume was a risk factor for UTI in persons with neurogenic bladder.</p> <p>Method of drainage: Results were consistent in 7 of 8 studies that persons using intermittent catheterization had fewer infections than those with indwelling catheters and (when studied) persons voiding without catheters had the lowest rate of UTI in all groups.</p> <p>Two RCTs did not find significant differences in UTI between sterile and clean methods for intermittent catheterization. Another non-randomized controlled trial found that a sheathed catheter (which amounted to a sterile method) resulted in fewer episodes of bacteriuria when compared with a standard catheter. The authors concluded that the evidence neither supported nor refuted the need to utilize sterile, as opposed to clean, intermittent catheterization</p> <p>The authors concluded that the optimum frequency for change of condom catheters was unknown.</p> <p>Time since injury: The study measuring UTI in the most rigorous fashion among 3 studies addressing this issue found that a longer time since injury was significantly associated with a higher occurrence of UTI.</p> <p>Laboratory findings: A prospective cohort study reported that symptomatic UTIs occurred more frequently following relapsing asymptomatic bacteriuria (regrowth of same bacterium) than recurrent asymptomatic bacteriuria (regrowth of different bacterium); P <0.03</p> <p>There were no studies or the data were scarce assessing the effect of socioeconomic and insurance status; psychosocial, behavioral, and hygiene factors; and domicile on the risk of UTI</p>	
Moore, 2006 ¹¹⁸	RCT 1,2,6,7,8	To compare the onset of symptomatic UTI in patients randomized to clean vs sterile intermittent catheterization technique.	Adults with recent quadriplegia due to spinal cord injury who required on-going	<p>Symptomatic UTI: Clean vs sterile: 6/16 vs 9/20; P > 0.05</p> <p>Time to onset of symptomatic UTI (weeks): Clean vs sterile: 3.0 vs 3.6 (P = 0.49) ; HR (95% CI): 1.25 (0.44-3.59)</p>	F/U during hospitalization or until patients began self-catheterization, were placed on antibiotics, developed a

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
			intermittent catheterization 36	Bacteriuria: Clean vs sterile: 7/16 vs 9/20; statistical differences were not reported Cost (£): Clean vs sterile: 3.4 vs 7.5; statistical differences were not reported	symptomatic UTI, were discharged from hospital, or requested withdrawal. Symptomatic UTI was defined as $\geq 10^5$ cfu/ml, pyuria (> 10 WBC/hpf) with any of the following symptoms: chills, fever (≥ 38 C), general malaise, increased spasticity and/or autonomic dysreflexia, and the presence of usual pathogens Asymptomatic bacteriuria was defined as $\geq 10^5$ cfu/ml with one or more usual pathogens identified, absence of symptoms, and absence of pyuria Post-hoc power analysis suggested that the study sample size was capable of detecting a hazard ratio of 2.7 for symptomatic UTI at an alpha of 0.05 with 80% power.
Schlager, 2001 ¹²¹	Crossover RCT 1	To compare single-use sterile catheters and reused clean catheters.	Patients with myelomeningocele who had neurogenic bladder with reflux and were on intermittent catheterization 4 times per day 10	Bacteriuria: Clean vs sterile: 76% vs 73%; P = 0.54	F/U 8 months Bacteriuria was defined as a $\geq 10^4$ cfu/ml of urine obtained by bladder catheterization. Power not reported
Prieto- Fingerhut, 1997 ¹²⁰	RCT 1	To determine the effect of nonsterile and sterile intermittent catheterization on the incidence of UTI.	Patients with spinal cord injury 29	Symptomatic UTI: Nonsterile vs sterile: 9/15 vs 8/14; statistical differences were not reported UTI: Nonsterile vs sterile: 42.4% vs 28.6%; P > 0.05 (based on the results of culture; not sure what it represents)	F/U unclear UTI defined using the criteria published by the National Institute on

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Bacteriuria: Nonsterile vs sterile: 51.5% vs 39.3%; P > 0.05</p> <p>Pyuria: Nonsterile vs sterile: 54.5% vs 34.0%; P > 0.05</p> <p>Cost: All results nonsterile vs sterile Antibiotic therapy: \$640 vs \$275 Catheterization kits: \$1584 vs \$5880 Total cost: \$2224 vs \$6155 (Statistical differences were not reported for this outcome)</p>	Disability and Rehabilitation Research Bacteriuria defined as > 10,000 organisms/ml of urine. Pyuria defined as > 5 WBC/hpf Power not reported
Duffy, 1995 ¹¹⁷	RCT 1,7	To compare the safety and cost of clean vs sterile intermittent bladder catheterization.	Residents of long-term care facilities with urinary retention 82	<p>Symptomatic UTI: Clean vs sterile: 20/38 vs 22/42; P > 0.05</p> <p>Time to symptomatic UTI: Clean vs sterile (measured in terms of the days to first treatment episode): P = 0.71</p> <p>Number of treatment episodes: Clean vs sterile: 0.01/day vs 0.01/day; statistical differences not clearly reported</p> <p>Average cost per catheterization: Clean vs sterile: \$4.00 vs \$6.25; P < 0.01</p> <p>Antibiotic cost for the first treatment episode: Clean vs sterile: P > 0.05</p> <p>Mean nursing time (minutes): Clean vs sterile: 8 vs 9; P < 0.01</p> <p>Risk factors for symptomatic UTI: History of UTI (defined as ≥ 2 symptomatic episodes of UTI within the past 6 months): P < 0.05</p>	F/U 90 days UTI was defined as 1) the presence of > 10^5 colonies/ml of a single organism coupled with the presence of one or more signs or symptoms of UTI; 2) bacteriuria of a lesser colony count coupled with one or more symptoms or signs of UTI (3) The presence of one or more signs or symptoms of UTI coupled with > 10 WBCs/hpf on urinalysis Post-hoc power analysis showed 61% power to detect a 50% reduction in UTI at an alpha of 5%
Moore, 1993 ¹¹⁹	Crossover RCT 1,4,7,8	To compare clean intermittent self catheterization and sterile single use catheterization.	Children with spina bifida 30	<p>Bacteriuria: Clean vs sterile: 68/180 vs 68/180; P > 0.05</p> <p>Catheterization by self vs parent Females, clean catheters: 39% vs 40%; P > 0.05 Females, sterile catheters: 36% vs 42%; P > 0.05 Males, clean catheters: 43% vs 25%; P > 0.05 Males, sterile catheters: 33% vs 37%; P > 0.05</p>	F/U 12 months Positive culture defined as ≥ 10^3 cfu/ml Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
					Ns and events in the results column are the number of urine samples and not the number of patients
Joseph, 1991 ¹²²	RCT 1,6	To compare clean and sterile catheterization.	Nursing home patients 14	Symptomatic UTI: Clean vs sterile: 2/8 vs 3/6; statistical differences were not reported Major UTI: Clean vs sterile: 1/8 vs 1/6; statistical differences were not reported Deaths: Clean vs sterile: 0/8 vs 0/6; statistical differences were not reported Bacteremia: Clean vs sterile: 0/8 vs 0/6; statistical differences were not reported Cost per catheterization: Clean vs sterile: \$0.48 vs \$2.03; statistical differences were not reported	F/U ~ 12 weeks Bacteruria defined as a urine culture > 10^5 bacteria/ml Major UTI defined as temperature > 38 C, bacteruria, and transfer to acute care. Minor UTI were diagnosed on the basis of dysuria or frequency without elevation of temperature. Power not reported
Anderson, 1980 ⁷³	Prospective study with historical controls 1,3	To compare the infection rates of patients on non-sterile intermittent catheterization and antibiotic prophylaxis (oral nitrofurantoin/bladder instillation of neomycin and polymyxin) with a historical control group of patients on sterile intermittent catheterization and the same prophylaxis.	Male patients with acute (<30 days) spinal cord injury. 50	Bacteriuria (per 1000 catheterizations): Non-sterile vs sterile: 8.3 vs 2.8; P < 0.05 Frequency of catheter change: 4 hours vs 8 hours: 6.1 vs 13.9 (P < 0.05)	F/U 28 weeks A bacterial count of more than 10^4 cfu/L indicated infection. Power not reported

2A.6. Comparison among multiple methods

Short-term

No studies identified

Long-term

De Ruz, 2000 ⁵⁴	Prospective controlled study 1,3,4,6,7	To identify risk factors for UTI.	Adult spinal cord injury patients with injury \leq 60 days before enrollment, neurogenic bladder	Symptomatic UTI: All results OR (95% CI) <i>1. Univariate analysis</i> Age older than 40 yrs: 1.38 (1.01-1.88) Hyperreflexic bladder: 1.38 (1.03-1.86)	F/U 38 months UTI was defined as a colony count of $\geq 10^5$ cfu/ml without
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
			dysfunction and injury below C4 128	<p>Cervical injury: 1.39 (1.04-1.85) Functional independence measure score < 74: 1.49 (1.08-2.06) Indwelling catheterization greater than 30 days: 1.53 (1.12-2.10) Vesicoureteral reflux: 1.77 (1.12-2.81) Invasive procedure: 4.26 (3.15-5.76) Indwelling catheter: 7.77 (5.80-10.40) Clean intermittent catheterization: 0.42 (0.31-0.58) Condom catheter: 0.24 (0.15-0.40) Suprapubic catheterization: 0.04 (0.04-0.19) Normal voiding: 0.04 (0.01-0.17) Patient sex, time of evolution, type of injury, co-morbidity, etiology, lithiasis, surgery, previous antimicrobial treatment, and immunosuppression were not associated.</p> <p>2. Multivariate analysis: Model 1 (defined all risk factors in patients who presented with at least UTI episode during hospitalization) Cervical injury: 2.99 (1.12-7.97) Invasive procedure: 2.62 (1.02-6.69) Indwelling catheterization greater than 30 days: 4.04 (1.24-13.06)</p> <p>3. Multivariate analysis: Model 2 (defined risk factors in patients who presented with repeat UTIs during hospitalization) Functional independence measure score < 74: 9.96 (2.33-42.11) Vesicoureteral reflux: 22.86 (2.31-225.87)</p> <p>Bacteriuria: All results OR (95% CI) Indwelling catheter: 2.70 (2.32-3.20) Clean intermittent catheterization: 1.16 (1.01-1.35) Condom catheter: 0.46 (0.38-0.56) Suprapubic catheterization: 0.06 (0.04-0.10) Normal voiding: 0.05 (0.03-0.10)</p>	a fever of 38 C and two symptoms, including bladder overdistension, lower abdominal pain, increased urinary incontinence, increased spasticity, autonomic hyperreflexia, and/or increased sweating and malaise Bacteriuria was defined as a colony count of $\geq 10^5$ cfu/ml and no fever or other symptoms Power not reported
Weld, 2000 ¹³⁵	Retrospective controlled study 1,3,4	To compare the bladder management methods of chronic urethral catheterization, clean intermittent catheterization, spontaneous voiding and suprapubic catheterization in spinal cord injury patients.	Patients with post-traumatic spinal cord injury. 316	<p>Epididymitis: Urethral had a higher rate than suprapubic ($P < 0.01$), intermittent ($P < 0.01$), and spontaneous voiding ($P < 0.01$) groups. Spontaneous voiding had a higher rate than intermittent group ($P < 0.01$) No other significant differences</p> <p>Pyelonephritis: Urethral had a higher rate than intermittent group ($P < 0.01$) No other significant differences</p> <p>Upper tract calculi:</p>	Mean F/U 18 years UTI not defined Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Urethral had a higher rate than intermittent ($P < 0.01$) and spontaneous voiding ($P < 0.01$) groups No other significant differences</p> <p>Bladder calculi: Intermittent had a lower rate than suprapubic ($P < 0.01$) and spontaneous voiding ($P < 0.01$) groups No other significant differences</p> <p>Urethral stricture: Urethral had a higher rate than suprapubic ($P < 0.01$), intermittent ($P < 0.01$) and spontaneous voiding ($P < 0.01$) groups. No other significant differences</p> <p>Periurethral abscess: Urethral had a higher rate than intermittent group ($P < 0.01$) No other significant differences</p> <p>Vesicoureteral reflux: Intermittent had a lower rate than urethral ($P < 0.01$) and suprapubic ($P < 0.01$) groups Spontaneous had a lower rate than suprapubic group ($P < 0.01$) No other significant differences</p> <p>Abnormal upper tract: Intermittent had a lower rate than urethral ($P < 0.01$) and suprapubic ($P < 0.01$) groups No other significant differences</p>	
Lloyd, 1986 ¹³⁶	Prospective controlled study 1,3	To compare different methods of initial bladder management in spinal cord injured patients: (1) intermittent catheterization program within 36 hours of injury; (2) suprapubic trocar within 36 hours of injury; (3) urethral catheters in place for more than 36 hours before intermittent catheterization was begun; (4) indwelling urethral catheter drainage throughout the hospitalization and discharged from the hospital with indwelling catheters; and (5) intermittent catheterization in a community hospital.	Spinal cord injury patients 204	<p>Bacteriuria: All results presented in order of the groups given in study objective Infections between hospitalization and discharge from the hospital: 21/21; 21/21; 105/106; 23/23; 31/33 (no significant differences) Sterile at first annual follow-up visit: 5/17; 7/19; 36/99; 0/17; 11/29 (no significant differences) Infected > 1 time after discharge from hospital: 12/18; 14/20; 77/97; 17/17; 21/29 (no significant differences)</p> <p>Chills and fever (≥ 1 episode): All results in the order of the groups given in study objective From injury to hospital discharge: 4/21; 4/21; 9/104; 4/23; 2/33 (no significant differences) Discharge to 1 year after injury: 4/17; 8/18; 26/97; 8/16; 6/22 (no significant differences)</p>	F/U 1 year Urine cultures were considered positive if colony counts were 10^5 colonies/ml for clean catch specimens or 1000 colonies per ml for catheter specimens Power not reported.

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Urinary complications: All results in the order of the groups given in study objective</p> <p><u>At hospital discharge</u></p> <p>Orchitis-epididymitis: 0/21; 0/21; 2/106; 0/23; 2/33 Penile skin: 0/21; 1/21; 2/106; 0/23; 2/33 Bladder calculi: 1/21; 3/21; 13/106; 2/23; 4/33 Renal calculi: 0/21; 0/21; 1/106; 1/23; 1/33 Hyperreflexia: 1/21; 0/21; 5/106; 1/23; 1/33</p> <p><u>At 1 year after injury</u></p> <p>Orchitis-epididymitis: 1/21; 0/21; 2/106; 0/23; 1/33 Penile skin: 2/21; 2/21; 11/106; 0/23; 5/33 Bladder calculi: 1/21; 2/21; 9/106; 4/23; 6/33 Renal calculi: 1/21; 0/21; 1/106; 1/23; 1/33 Hyperreflexia: 0/21; 1/21; 5/106; 1/23; 1/33 (No significant differences)</p> <p>Severe pyelocaliectasis (% of renal units) All results in the order of the groups given in study objective</p> <p>At hospital discharge: 0; 0; 0; 0 (no significant differences) At 1 year after injury: 0; 0; 3.2; 0 (no significant differences)</p> <p>Urinary procedures: All results in the order of the groups given in study objective</p> <p><u>At hospital discharge</u></p> <p>Cystoscopy: 7/21; 11/21; 39/106; 3/23; 11/33 External sphincterotomy/bladder neck reconstruction: 1/21; 1/21; 1/106; 0/23; 0/33 Litholapaxy: 1/21; 0/21; 12/106; 2/23; 3/33 Cystolithotomy: 0/21; 0/21; 1/106; 0/23; 0/33 Cystotomy: 0/21; 0/21; 0/106; 0/23; 0/33</p> <p><u>At 1 year after injury</u></p> <p>Cystoscopy: 1/21; 3/21; 21/106; 6/23; 5/33 External sphincterotomy/bladder neck reconstruction: 0/21; 4/21; 3/106; 0/23; 0/33 Litholapaxy: 1/21; 1/21; 8/106; 4/23; 5/33 Cystolithotomy: 0/21; 0/21; 1/106; 0/23; 0/33 Cystotomy: 0/21; 0/21; 1/106; 0/23; 1/33 (No significant differences)</p>	

GRADE Table 2A

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
External vs indwelling catheterization	Bacteriuria, symptomatic UTI or death*	1 RCT ¹⁰⁹	Significantly increased risk with indwelling catheterization, particularly in men without dementia.	High	0	0	0	-1	0	0	0	0	Moderate	Low
	Bacteriuria*	1 RCT ¹⁰⁹	No significant differences were found.	High	0	0	0	-1	0	0	0	0	Moderate	
	Bacteremia	1 OBS ⁸¹	No significant differences were found.	Low	0	0	0	-1	0	0	0	0	Very Low	
	Mortality*	1 RCT ¹⁰⁹	Statistical differences were not reported.	High	-1	0	0	-1	0	0	0	0	Low	
	Patient satisfaction*	1 RCT ¹⁰⁹ 1 OBS ¹²³	Significantly increased comfort and decreased pain with condom catheterization in both studies. Also a significant decrease in restriction in the OBS ¹²³ .	High	0	0	0	0	0	0	0	0	High	
Intermittent vs indwelling catheterization	Symptomatic UTI*	2 RCT ^{111,112} 1 OBS ¹³⁵	Significantly decreased risk of pyelonephritis with intermittent catheterization 1 RCT ¹¹² and 1 OBS ¹³⁵ . No significant differences were found in the other RCT ¹¹¹ .	High	-2	0	0	0	0	0	0	0	Low	Low
	Bacteriuria/unspecified UTI*	3 SR ¹⁰⁴⁻¹⁰⁶ 4 RCT ^{110,111,113,114} 5 OBS ^{84,124-126,136}	Significantly decreased risk with intermittent catheterization in 1 SR ¹⁰⁴ . 2 SRs noted a decreased risk with intermittent catheterization, but statistical differences were not reported ^{105,106} . No significant differences were found in 4 RCTs ^{110,111,113,114} and 4 OBS ^{124-126,136} . Statistical differences were not reported in 1 OBS ⁸⁴ .	High	0	0	-1	0	0	0	0	0	Moderate	
	Bacteremia*	1 RCT ¹¹²	No significant differences were found.	High	-1	0	0	-1	0	0	0	0	Low	
	Urinary retention*	1 SR ¹⁰⁴ 4 RCT ^{110,111,113,114} 1 OBS ¹²⁵	Significantly increased risk with intermittent catheterization in 1 RCT ¹¹⁰ and 1 OBS ¹²⁵ , and decreased risk in 1 RCT ¹¹⁴ . Suggestions of increased risk were found in 1 SR ¹⁰⁴ and 2 RCTs ^{111,113} , although no significant differences were reported.	High	0	-1	0	0	0	0	0	0	Moderate	
	Calculi	2 OBS ^{135,136}	Significantly decreased risk of upper tract calculi with intermittent catheterization, but no significant differences in bladder calculi in 1 OBS ¹³⁵ . No significant differences in upper or lower tract calculi were found in the other OBS ¹³⁶ .	Low	-1	0	0	0	0	0	0	0	Very Low	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE			Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response		
	Stricture	1 OBS ¹³⁵	Significantly decreased risk with intermittent catheterization.	Low	-1	0	0	0	0	0	0	0	Very Low
	Vesicoureteral reflux	1 OBS ¹³⁵	Significantly decreased risk with intermittent catheterization.	Low	-1	0	0	0	0	0	0	0	Very Low
	Mortality	1 RCT ¹¹⁴	Statistical differences were not reported.	High	-1	0	0	-1	0	0	0	0	Low
Suprapubic vs indwelling urethral catheterization	Symptomatic UTI*	1 SR ¹⁰⁴ 1 RCT ⁶² 1 OBS ¹³⁵	No significant differences were found.	High	0	0	0	-1	0	0	0	0	Moderate
	Bacteriuria/unspecified UTI*	4 SR ^{37,104,107,108} 7 OBS ^{128-133,136}	Significantly increased risk with indwelling catheterization in 3 SR ^{104,107,108} and 2 OBS ^{129,130} . Discrepant results in 1 SR ³⁷ . No significant differences were found in 3 OBS ^{128,133,136} . Statistical differences were not reported in 2 OBS ^{131,132} .	High	0	-1	0	0	0	0	0	0	Moderate
	Bacteremia	1 OBS ¹³⁰	Statistical differences were not reported	Low	0	0	0	-1	0	0	0	0	Very Low
	Recatheterization*	3 SR ^{37,104,108} 1 RCT ⁶²	Significantly increased risk with indwelling catheterization in 2 SRs ^{37,104} . No significant differences were found in 1 SR ¹⁰⁸ . Statistical differences were not reported in the RCT ⁶² .	High	0	0	0	0	0	0	0	0	High
	Urinary retention	1 SR ¹⁰⁷ 1 OBS ¹³¹	No significant differences were found in the SR ¹⁰⁷ . Statistical differences were not reported in the OBS ¹³¹ .	High	-1	0	0	-1	0	0	0	0	Low
	Hospital length of stay	2 SR ^{37,104} 2 OBS ^{128,131}	Significantly increased risk with indwelling catheterization in 2 SRs ^{37,104} . No significant differences in 1 OBS ¹²⁸ . Statistical differences were not reported in 1 OBS ¹³¹ .	High	-1	0	0	-1	0	0	0	0	Low
	Duration of catheterization*	2 SR ^{104,107} 1 OBS ¹²⁸	Significantly increased risk with suprapubic catheterization in 1 SR ¹⁰⁴ and 1 OBS ¹²⁸ . Suggestion of increase in 1 SR ¹⁰⁷ .	High	0	0	0	-1	0	0	0	0	Moderate
	Pain/discomfort*	3 SR ^{104,107,108} 1 OBS ¹²⁸	Significantly increased risk with indwelling catheterization in all studies	High	0	0	0	0	0	0	0	0	High

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE			Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response		
Suprapubic catheterization vs intermittent catheterization	Patient satisfaction*	1 SR ¹⁰⁷ 1 RCT ⁶²	Suprapubic catheter was shown to be preferred in 1 SR ¹⁰⁷ . No significant differences in patient satisfaction outcomes were found in 1 RCT ⁶² .	High	0	-1	0	0	0	0	0	0	Moderate
	Stricture*	3 OBS ^{129,130,135}	Significantly increased risk with indwelling catheterization in all studies.	Low	0	0	0	0	0	+1	0	0	Moderate
	Dislodgement	1 OBS ¹³⁰	Statistical differences were not reported.	Low	0	0	0	-1	0	0	0	0	Very Low
	Calculi	2 OBS ^{135,136}	No significant differences were found.	Low	-1	0	0	0	0	0	0	0	Very Low
	Vesicoureteral reflux	1 OBS ¹³⁵	No significant differences were found.	Low	-1	0	0	0	0	0	0	0	Very Low
Suprapubic vs intermittent catheterization	Symptomatic UTI*	1 OBS ¹³⁵	No significant differences were found.	Low	0	0	0	-1	0	0	0	0	Very Low
	Bacteriuria/unspecified UTI*	2 RCT ^{115,116} 2 OBS ^{134,136}	Significantly increased risk with intermittent catheterization in 1 OBS ¹³⁴ and during early follow-up in 1 RCT ¹¹⁶ . No significant differences were found in 1 RCT ¹¹⁵ , 1 OBS ¹³⁶ and during late follow-up in 1 RCT ¹¹⁶ .	High	0	-1	-1	0	0	0	0	0	Low
	Duration of catheterization*	2 RCT ^{115,116}	No significant differences were found.	High	0	0	-1	0	0	0	0	0	Moderate
	Patient satisfaction*	2 RCT ^{115,116}	1 RCT ¹¹⁵ showed mixed results. The other RCT ¹¹⁶ showed significantly improved patient acceptability with intermittent catheterization.	High	0	-1	-2	0	0	0	0	0	Very Low
	Stricture*	1 OBS ¹³⁵	No significant differences were found.	Low	-1	0	0	0	0	0	0	0	Very Low
	Calculi*	2 OBS ^{135,136}	Significantly decreased risk of bladder calculi with intermittent catheterization, but no significant differences in upper tract calculi in 1 OBS ¹³⁵ . No significant differences in upper or lower tract calculi were found in the other OBS ¹³⁶ .	Low	-1	0	0	0	0	0	0	0	Very Low
	Abnormal upper tract*	1 OBS ¹³⁵	Significantly decreased risk with intermittent catheterization.	Low	-1	0	0	0	0	0	0	0	Very Low
	Vesicoureteral reflux*	1 OBS ¹³⁵	Significantly decreased risk with intermittent catheterization.	Low	-1	0	0	0	0	0	0	0	Very Low

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE			Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response		
Clean vs sterile intermittent catheterization	Symptomatic UTI*	4 RCT 117,118,120,122	No significant differences were found in 2 RCTs ^{117,118} . Statistical differences were not reported in 2 RCTs ^{120,122} .	High	-1	0	0	0	0	0	0	Moderate	Moderate
	Bacteriuria/unspecified UTI*	1 SR ¹⁰⁵ 6 RCT ^{63,118-122} 1 OBS ⁷³	Significantly decreased risk with the sterile method in the OBS ⁷³ . No significant differences were found in 1 SR ¹⁰⁵ and 4 RCTs ^{63,119-121} . Statistical differences were not reported in 2 RCTs ^{118,122} .	High	-1	0	0	0	0	0	0	Moderate	
	Time to infection	2 RCT ^{117,118}	No significant differences were found.	High	-1	0	0	0	0	0	0	Moderate	
	Nursing time	1 RCT ¹¹⁷	Significantly decreased with the clean method.	High	-1	0	0	-1	0	0	0	Low	
	Mortality	1 RCT ¹²²	Statistical differences were not reported.	High	-1	0	0	-1	0	0	0	Low	

* These modifiers can impact the GRADE by 1 or 2 points

Study Quality Assessment Table 2A

Study	Systematic Review				Randomized Controlled Trial				Observational Controlled Study				Economic analysis																		
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented	6. Sensitivity analyses performed	
2A.1. External vs indwelling									x	x		x		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Saint, 2006 ¹⁰⁹									x	x		x		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Saint, 2006 ⁸¹																															
Saint, 1999 ¹²³																															
2A.2. Intermittent vs indwelling									x																						
Niel-Weise, 2006 ¹⁰⁴	x	x	x	x	x	x	x	x																							
Tang, 2006 ¹¹¹									x	x																					
Turi, 2006 ¹¹²									x	x																					
Tangtrakul, 1994 ¹¹³									x	x																					
Skelly, 1992 ¹¹⁴									x	x	x																				
Michelson, 1988 ¹¹⁰									x	x	x																				
Johansson, 2002 ⁸⁴																															
Oishi, 1995 ¹²⁵																															
Ritter, 1989 ¹²⁴																															

Study	Systematic Review				Randomized Controlled Trial				Observational Controlled Study		Economic analysis																		
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented
Furuhata, 1988 ¹²⁶	x	x	x	x	x	x	x	x																					
Shekelle, 1999 ¹⁰⁵	x	x	x	x	x	x	x	x																					
Vickrey, 1999 ¹⁰⁶	x	x	x	x	x	x	x	x																					
2A.3. Suprapubic vs indwelling urethral																													
McPhail, 2006 ¹⁰⁸	x	x	x	x	x	x	x	x																					
Niel-Weise, 2006 ¹⁰⁴	x	x	x	x	x	x	x	x																					
Phipps, 2006 ³⁷	x	x	x	x	x	x	x	x																					
Branagan, 2002 ¹⁰⁷	x	x	x	x	x	x	x	x																					
Baan, 2003 ⁶²																													
Dunn, 2005 ¹²⁸																													
Alli, 2003 ¹²⁷																													
Horgan, 1992 ¹³⁰																													
Dinneen, 1990 ¹²⁹																													
Verbrugh, 1988 ¹³³																													
van Nagell, 1972 ¹³²																													
Hofmeister, 1970 ¹³¹																													

Study	Systematic Review				Randomized Controlled Trial				Observational Controlled Study				Economic analysis																		
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented	6. Sensitivity analyses performed	
2A.4. Suprapubic vs intermittent									x	x																					
Jannelli, 2007 ¹¹⁵																															
Roberts, 2006 ¹¹⁶									x																						
Noll, 1988 ¹³⁴									x	x																					
2A.5. Clean intermittent vs sterile intermittent									x																						
Carapeti, 1996 ⁶³									x																						
Shekelle, 1999 ¹⁰⁵	x	x	x	x	x	x	x	x																							
Moore, 2006 ¹¹⁸									x	x	x																				
Schlager, 2001 ¹²¹									x																						
Prieto-Fingerhut, 1997 ¹²⁰									x																						
Duffy, 1995 ¹¹⁷									x			x																			
Moore, 1993 ¹¹⁹									x			x																			
Joseph, 1991 ¹²²									x			x																			
Anderson, 1980 ⁷³									x			x																			
2A.6. Comparison among multiple methods																			x		x	x	x	x	x	x	x	x	x	x	
De Ruz, 2000 ⁵⁴																			x		x	x	x	x	x	x	x	x	x	x	
Weld, 2000 ¹³⁵																			x		x	x	x	x	x	x	x	x	x	x	

Study	Systematic Review				Randomized Controlled Trial				Observational Controlled Study		Economic analysis																		
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	x 1. All study groups derived from similar source/reference populations	x 2. Attrition not significantly different across all study groups	x 3. The measure of exposure is valid	x 4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented
Lloyd, 1986 ¹³⁶																													

2B. What are the risks and benefits associated with different catheters or collecting systems?

TABLE 2B: RISKS AND BENEFITS ASSOCIATED WITH DIFFERENT CATHETERS OR COLLECTING SYSTEMS

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
2B.1.a. Silver-coated Catheter					
Schumm, 2008 ¹³⁷	Systematic review 1,2,3,4,5,6,7,8	To determine the effect of type of indwelling urethral catheter on the risk of UTI in adults who undergo short-term urinary catheterization.	All randomized and quasi-randomized trials comparing types of indwelling urinary catheters for short term (≤ 14 days) catheterization in hospitalized adults 23 trials	<p>Note: All results are RR (95% CI) unless otherwise noted</p> <p>1. Antiseptic vs standard catheter</p> <p>Bacteriuria:</p> <p>Silver oxide catheters vs standard catheters (<1 week) (3 studies): 0.89 (0.68-1.15)</p> <p>Silver alloy catheters vs standard catheters (< 1 week) (7 studies): 0.66 (0.56-0.78)</p> <p>Silver alloy catheters vs standard catheters (> 1 week) (4 studies): 0.64 (0.51-0.80)</p> <p>Silver oxide catheters vs standard catheters in women (<1 week) (1 study): 0.63 (0.45-0.89)</p> <p>Silver oxide catheters vs standard catheters in men (<1 week) (1 study): 1.62 (0.91-2.88)</p> <p>Silver oxide catheters vs standard catheters in all participants receiving systemic antibiotics (<1 week) (1 study): 0.67 (0.45-0.99)</p> <p>Silver oxide catheters vs standard catheters in women receiving systemic antibiotics (<1 week) (1 study): 0.50 (0.31-0.79)</p> <p>Silver oxide catheters vs standard catheters in men receiving systemic antibiotics (<1 week) (1 study): 1.02 (0.49-2.13)</p> <p>For a crossover trial not included in meta-analysis (all results silver alloy vs control)</p> <p>Rate of bacteriuria per 1000 patient days: 0.79 (0.63-0.99)</p> <p>Rate of bacteriuria per 100 patients: 0.81 (0.65-1.01)</p> <p>Rate of bacteriuria per 100 catheters: 0.68 (0.54-0.86)</p> <p>Urethral secretions:</p> <p>Silver oxide catheters vs standard catheters (<1 week) (1 study): 0.72 (0.25-2.03)</p> <p>Pain:</p> <p>Silver oxide catheters vs standard catheters (<1 week) (1 study): 1.43 (0.48-4.27)</p> <p>2. Antibiotic-impregnated vs standard catheter</p> <p>Bacteriuria: All impregnated catheters (< 1 week) (4 studies): 0.47</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>(0.33-0.67) Minocycline and rifampicin-impregnated catheters (< 1 week) (1 study): 0.36 (0.18-0.73) Nitrofurazone-impregnated catheters (< 1 week) (4 study): 0.52 (0.34-0.78) All impregnated catheters (> 1 week) (2 studies): 0.85 (0.76-0.96) Minocycline and rifampicin-impregnated catheters (> 1 week) (1 study): 0.94 (0.86-1.03) Nitrofurazone-impregnated catheters (> 1 week) (1 study): 0.08 (0.00-1.33) Symptomatic UTI (1 study): 0.20 (0.03-1.63)</p> <p><u>3. One type of standard catheter vs another</u></p> <p>Bacteriuria: Silicone vs latex (1 study): 1.07 (0.23-5.01)</p> <p>Symptomatic UTI: Hydron-coated latex vs plain latex (1 study): 0.94 (0.66-1.34) Hydron-coated latex vs PVC balloon (1 study): 0.87 (0.63-1.19) PVC balloon vs plain latex (1 study): 1.09 (0.81-1.45) Hydrogel vs silicone (1 study): 0.82 (0.46-1.47)</p> <p>Burning in urethra: Silicon vs non-silicone (1 study): 0.28 (0.13-0.60)</p> <p>Urethritis: Silicon vs latex (1 study): 0.09 (0.01-0.68)</p> <p>Urethral reaction: All results WMD (95% CI) Hydrogel-coated latex vs siliconised latex (1 study): 0.00 (-3.51 to 3.51) Full silicone vs hydrogel-coated latex (1 study): -16.00 (-18.84 to -13.16) Full silicone vs siliconised latex (1 study): -16.00 (-18.96 to -13.04)</p>	
Crnich, 2007 ¹⁴¹	Meta-analysis NA	To test the hypothesis that the efficacy of silver-Hydrogel-coated (silver-alloy) catheters varies by control catheter type (latex or silicone).	Randomized or quasi-randomized trials of nitrofurazone-coated or silver alloy-coated antimicrobial urinary catheters short term (<30 days) bladder drainage. 7 trials	<p>Bacteriuria/unspecified UTI: Silver-alloy vs latex (4 studies): RR (95% CI) = 0.35 (0.23-0.55) Silver-alloy vs silicone (4 studies): RR (95% CI) = 0.82 (0.70-0.96)</p>	Reanalysis of data reviewed by Johnson et al. ¹⁰⁵
Phipps, 2006 ³⁷	Systematic review 1,2,3,4,5,6,7,8	To establish the optimal way to manage urinary catheters following urogenital surgery in adults.	Randomized and quasi-randomized trials 39 RCTs	<p>Note: All results are RR (95% CI) unless otherwise noted</p> <p><u>1. Using a urinary catheter vs not using a urinary catheter</u></p> <p>Retention of urine (1 study): 0.12 (0.03-0.47) UTI (4 studies): 1.35 (0.75-2.45)</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Recatheterization (3 studies): 0.32 (0.14-0.70) Post-op urethral stricture (1 study): 1.14 (0.90-1.44) Post-op hematuria (1 study): 0.73 (0.40-1.33)</p> <p>2. Urethral catheterization vs suprapubic catheterization UTI: Heterogeneous results, not combined. Of four trials, two suggested a moderate increase, one a large increase and one a large decrease. Recatheterization (2 studies): 3.66 (1.41-9.49) Post-op hematuria (1 study): 5.00 (0.21-116.31) Length of hospital stay in days (1 study) [WMD (95% CI)]: 1.10 (0.30-1.90) Catheter lockage or bypassing [OR (95% CI)] (2 studies): 0.20 (0.02-1.72)</p> <p>3. One type of catheter vs another type of catheter UTI: Urethral Foley catheter with extra drainage hole vs unmodified Foley catheter (1 study): 0.40 (0.15-1.04) Positive urine culture: Silver-coated Bardex catheters vs latex catheters (1 study): 0.53 (0.20-1.45)</p> <p>4. One type of catheter management vs another Retention of urine: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.99 (0.06-15.54) Dysuria: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.99 (0.06-15.54) Symptomatic UTI: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.61 (0.33-1.14) Bacteriuria/unspecified UTI: Cefotaxime 1 hour prior to catheter removal vs none (1 study): 0.08 (0.00-1.30) Neomycin/Sulfamethiazole vs placebo (1 study): 0.18 (0.06-0.55) Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 1.06 (0.70-1.51) Recatheterization: Neomycin/Sulfamethiazole vs placebo (1 study): 0.50 (0.24-1.04)</p> <p>5. Larger diameter catheter vs smaller diameter catheter No trials found</p> <p>6. Bladder irrigation No trials found</p> <p>7. Shorter duration vs longer duration catheter Retention of urine: 1 day vs 3 days (1 study): 0.80 (0.38-1.69) 1-2 days vs until urine clear (1 study): 1.02 (0.07-15.87)</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>1 day vs 2 days (1 study): 4.64 (0.23-94.28) 3 days vs 28 days (1 study): 3.00 (0.13-69.52) Post-op urethral stricture: < 1 week vs 2 weeks (2 studies): 1.23 (0.82-1.84) 3 days vs 28 days (1 study): 1.00 (0.73-1.36) UTI: Heterogeneous results, not combined. Shorter duration had lower risk of UTIs but the results were significant in only 1 trial 1 day vs 3 days (3 studies): 0.50 (0.29-0.87) Recatheterization: 1 day vs 2 days (1 study): 1.03 (0.23-4.71) 1 day vs 3 days (2 studies): 1.04 (0.36-3.01) 1 day vs 5 days (1 study): 4.55 (1.68-12.37) 4-6 days vs 14 days (1 study): 1.86 (0.14-25.38) 1-2 days vs until urine clear (2 studies): 0.72 (0.24-2.20) Post-op hematuria: 1-2 days vs until urine clear (1 study): 2.04 (0.19-21.81) 1 day vs 2 days (2 studies): 1.16 (0.34-3.90) Urinary leakage or incontinence: 1-2 days vs until urine clear (2 studies): 0.43 (0.07-2.88)</p> <p><i>8. Clamp and release vs free catheter drainage:</i> UTI (1 study): 4.00 (1.55-10.29) Delay in return to normal bladder function (1 study): 2.50 (1.16-5.39)</p> <p><i>9. Catheter removal at one time of day vs another time of day</i> UTI: 12 am vs 6 am (1 study): 1.31 (0.65-2.66) Recatheterization: 12 am vs 6 am (4 studies): 0.61 (0.34-1.12) 6-7 am vs 10-11 pm (1 study): 1.36 (0.32-5.77) Time to first void in hours [WMD (95% CI):] 12 am vs 6 am (1 study): 0.60 (-0.96 to 2.16) Volume of first void in ml [WMD (95% CI):] 12 am vs 6 am (1 study): 53.00 (4.27-101.73)</p> <p><i>10. Trial of void protocol vs none</i> No trials found</p> <p><i>11. Prefilling bladder prior to catheter removal vs removal without prefilling</i> Recatheterization [OR (95% CI)] (1 study): 4.52 (0.79-25.97) Discharge on day of catheter removal (1 study): 1.36 (0.47-3.91)</p>	
Johnson, 2006 ¹³⁸	Systematic review	To assess antimicrobial (nitrofurazone-coated or silver alloy-coated) urinary catheters for	Randomized or quasi- randomized trials of short term (<30 days) bladder drainage with	<p>Bacteriuria: Range of RRs (12 studies): 0.08 to 0.94 (95% CI included 1.0 for 7 studies)</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
	1,2,3,4,7,8	preventing CAUTI.	nitrofurazone-coated or silver alloy-coated antimicrobial urinary catheters 12 trials	Range of RRs for nitrofurazone coated catheters (3 studies): 0.08 to 0.68 (95% CI included 1.0 in all 3 studies) Range of RRs for pre-1995 silver-coated catheters (4 studies): 0.24 to 0.45 (95% CI was less than 1.0 for all studies) Range of RRs for post-1995 silver-coated catheters (5 studies): 0.53 to 0.94 (95% CI included 1.0 for 4 studies) (The difference between the median RRs for pre- and post-1995 studies was statistically significant; P < 0.01) The apparent protective effect of the test catheter was greater when the control catheter was latex rather than silicone. Studies involving urologic patients yielded larger effect sizes than those involving other types of patients, as did studies that excluded patients receiving antimicrobial agent therapy (quantitative summaries not available). Microbial resistance: Among studies that reported microbiological outcomes by study group, no evidence suggested that test catheter recipients experienced an increased incidence of specific microbial types that are typically resistant to the antimicrobial compound used.	
Niël-Weise, 2002 ¹³⁹	Systematic review 1,2,3,4,7,8	To compare the effectiveness of silver-coated vs uncoated catheters for the prevention of UTI in catheterized patients.	RCTs, clinical trials, and systematic reviews/meta-analyses which included patients undergoing bladder catheterization with either a silver-coated or an uncoated catheter 6 primary studies and 1 meta-analysis	Bacteriuria: Only 3 of the included studies demonstrated a significant effect favoring silver-coated catheters, and these were graded as poor quality by the authors. The study with the highest quality score did not demonstrate significant results. No meta-analyses were performed. The authors concluded that additional studies were required before silver-coated catheters could be recommended.	
Reiche, 2000 ¹⁴²	RCT 1,2,4,7,8	To test the effect on UTI of a newly designed urine-collecting system containing an antibacterial device which slowly releases silver ions onto the inner surface of the system.	Adults needing continuous indwelling bladder catheterization 170	Bacteriuria: Antibacterial system vs control system: 16/83 vs 21/87; HR (95% CI) = 0.68 (0.33-1.28) Log rank chi-squared = 1.55; P = 0.11 <u>Among patients receiving antibiotics:</u> Antibacterial system vs control system: 4/35 vs 7/33; P = 0.62	F/U 10 days The infection outcome was bacteriuria. Specific criteria unclear. Power not reported
Schaeffer, 1988 ¹⁴³	RCT 1,2	To assess the efficacy of silver oxide coating of the indwelling urinary catheter and catheter adapter and instillation of trichloroisocyanuric acid into the urinary drainage bag in the prevention of catheter-associated bacteriuria.	Adult inpatients on the spinal cord injury or neurosurgical services who required indwelling urethral catheterization. Patients required catheterization for > 24 hours during the study 74	Bacteriuria: <u>1. All patients</u> Silver oxide/ trichloroisocyanuric acid vs control: 11/41 vs 18/33; P = 0.02 <u>2. Patients receiving concurrent antimicrobial therapy</u> Silver oxide/ trichloroisocyanuric acid vs control: 3/23 vs 7/17; P < 0.01 <u>3. Patients not receiving concurrent antimicrobial therapy</u> Silver oxide/ trichloroisocyanuric acid vs control: 8/18 vs 11/16; RR	F/U until detection of bacteriuria, catheter removal, or discharge from the unit. Significant bacteriuria in bladder urine specimens was defined as $\geq 10^5$

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>(95% CI) = 0.65 (0.35-1.19)</p> <p>4. Systemic antimicrobial agents vs no systemic antimicrobial agents 10/40 vs 19/34; statistical differences were not reported</p> <p>Subgroup Analyses:</p> <p>The incidence of infection was greater in women than in men in the control group ($P = 0.05$). The incidence of infection among male and female test patients was similar (P value not reported). Interaction between group and sex was significant ($P = 0.03$)</p> <p>Patient age did not affect the incidence of bacteriuria. Patients ≥ 50 years acquired bacteriuria as often as their younger subgroups in both the test and control groups.</p> <p>There was no interaction between antimicrobial therapy and group assignment ($P = 0.86$)</p> <p>Time to bacteriuria:</p> <p>1. All patients (median duration in days) Silver oxide/trichloroisocyanuric acid vs control: 36 vs 8 ($P = 0.01$) Systemic antimicrobial agents vs no systemic antimicrobial agents: $P = 0.01$. However, the benefit of antimicrobials was seen during the first 4 days. Thereafter the rates were similar.</p> <p>Urethral meatal colonization as a source of bladder bacteriuria: Silver oxide/trichloroisocyanuric acid vs control: 5/11 vs 12/18; statistical differences were not reported.</p> <p>Microbial contamination of the drainage bag: Significantly reduced in the silver oxide/ trichloroisocyanuric acid, both before and after development of bladder bacteriuria ($P < 0.01$)</p> <p>Adverse events: No significant differences in metal irritation, urethral discharge, or other adverse events</p>	cfu/ml Power not reported
Seymour, 2006 ¹⁵⁹	Retrospective pre-post study 1,3	To evaluate the rate of UTI after introduction of a silver alloy-coated catheter as compared to a standard catheter.	Adult inpatients who underwent insertion of a Foley catheter 117	<p>Undefined UTI: Silver-coated catheter vs standard catheter: 3.2% vs 11.1%; statistical differences were not reported</p> <p>Bacteremia: Silver-coated catheter vs standard catheter: 0/63 vs 1/54; statistical differences were not reported</p> <p>Antibiotic usage: Silver-coated catheter vs standard catheter: 31/63 vs 30/54; statistical differences were not reported</p> <p>Device rate (CAUTI/1000 catheter days): Decreased by 69.9%; statistical differences were not reported</p>	F/U until 3 days after catheter removal, discharge from hospital or for a maximum of 28 days after catheterization UTI not defined Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Mean length of stay (days): Silver-coated catheter vs standard catheter: 17 vs 20; statistical differences were not reported</p> <p>Cost (£): £9140 saved by UTI reduction and £3583 saved by reduction of excess bed days; statistical differences were not reported</p>	
Srinivasan, 2006 ⁸²	Prospective pre-post study 1,3,4,6,7	To evaluate the efficacy of silicone-based urinary catheters coated with silver alloy both on internal and external surfaces. when compared with non-silver silicone catheters	Adult inpatients who had indwelling Foley catheters for > 48 hours 3036	<p><i>All results IRR (95% CI) per 1000 catheter days; silver-coated vs control catheter unless otherwise noted</i></p> <p>Unspecified UTI: Overall: 116/1165 vs 218/1871; RR (95% CI) = 0.88 (0.70-1.11) ICU: 0.80 (0.48-1.33) Non ICU: 0.90 (0.70-1.16) Preconnected systems: 0.80 (0.57-1.12) Component systems: 1.08 (0.77-1.49)</p> <p>Catheter-associated BSI: 9/1165 vs 7/1871; 2.13 (0.96-4.76)</p> <p>Risk factors for Unspecified UTI: Results HR (95% CI) <i>Univariate analysis</i> Female sex : 2.34 (1.86-2.96) Silver-coated catheter: 0.92 (0.73-1.15) Hospital service: NS (HR not reported) <i>Multivariate analysis</i> Female sex : 2.26 (1.78-2.89) Silver-coated catheter: NS (HR not reported) Hospital service: NS (HR not reported)</p>	F/U until 7 days after catheter removal NUTIs were identified by criteria set forth by the CDC Sample size of 1497 patients per catheter type needed to detect a 20% reduction in the incidence of UTI with 80% power and an alpha of 5%
Gentry, 2005 ¹⁶⁰	Retrospective pre-post study 1,3,4	To determine whether the use of a silver-alloy hydrogel-coated catheter reduced the incidence of CAUTI.	Adult patients who underwent insertion of an indwelling urinary catheter for continuous bladder drainage for > 24 hours 133	<p>Symptomatic UTI: Silver-coated catheter vs standard catheter: 5.1% vs 7.7%; statistical differences were not reported</p> <p>Device rate (per 1000 catheter days): Silver-coated catheter vs standard catheter: 5.1% vs 9.9%; statistical differences were not reported</p> <p>Duration of catheterization (days): Silver-coated catheter vs standard catheter: 9.9 vs 7.3; statistical differences were not reported</p> <p>Cost: It was estimated that two UTI were potentially avoided with the intervention resulting in a cost saving of £2654</p>	F/U 7-10 days after catheter removal or discharge, whichever was sooner UTI was defined based on National Nosocomial Infection Surveillance criteria Device rate was defined as the number of new CAUTIs divided by the number of urinary catheter days multiplied by 1000

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
					Power not reported
Madeo, 2004 ¹⁶¹	Prospective pre-post study 1,3	To evaluate the impact of using silver alloy urinary catheters in reducing UTI incidence.	Patients admitted into a general ICU, neurosurgical ICU, or high dependency unit requiring a urinary catheter 188	Bacteriuria/unspecified UTI: Silver vs control: 16/94 vs 17/94; P>0.05. No differences were observed by sex. Days to develop bacteriuria: Silver vs control: 24.00 vs 12.06; P = 0.06. No differences were observed by sex. Duration of catheterization: P> 0.05	F/U until 10 days after catheter removal Bacteriuria was defined as a positive urine culture with 10^5 cfu/ml with 2 or less species and present with classical signs/symptoms relating to a urine infection (adaptation of CDC definitions) Power not reported
Rupp, 2004 ¹⁶²	Prospective study with historical controls 3,4	To determine the efficacy of a silver-alloy, hydrogel-coated, urinary catheter in the prevention of CAUTI, to assess the cost-effectiveness of the coated catheter, and to test the emergence of silver-resistance in urinary microbial isolates.	10 patient care units in a tertiary medical center Not specified	Symptomatic UTI and asymptomatic bacteriuria (per 1000 catheter days): Silver-coated catheter vs standard catheter: 2.62 vs 6.13; P < 0.01 [Risk reduction (95% CI): 57% (27% - 75%)] Cost: Cost savings were \$13,469 to \$535,452 one year following the introduction of the coated catheter and \$5811 to \$484,070 two years following introduction Microbial resistance: No silver resistant microbes were discovered in the susceptibility tests.	F/U unclear UTI classified based on CDC definition Power not reported
Lai, 2002 ¹⁶³	Retrospective study with historical controls 3,4	To assess the efficacy of silver-Hydrogel-coated (alloy) urinary catheters in reducing nosocomial UTI. Surveillance for nosocomial UTI was performed during a 4-month period when the silver-coated catheter was being used and rates were compared to baseline rates before the introduction of the catheter.	Hospitalized patients at a university medical center. Not specified	Unspecified UTI (per 1000 patient days): Silver-coated catheter vs non-coated catheter: 2.7 vs 4.9; P = 0.10 Cost: The estimated cost savings using the silver-coated catheter ranged from \$12,564 to \$142,315	F/U unclear UTI defined according to CDC criteria Power not reported
Newton, 2002 ¹⁶⁶	Retrospective pre-post study	To compare the incidence of urinary tract infections with silver alloy-impregnated vs standard	Patients admitted with a diagnosis of acute burns who required a Foley catheter	Symptomatic UTI (per 1000 catheter days): Silver-coated catheter vs standard catheter: 4.4 vs 7.2; P = 0.03	F/U unclear UTI defined based on

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
	1,3,4	latex catheters.	1098		CDC criteria for SUTI only Power not reported Patients receiving silver-coated catheters also had new catheters placed on admission
Bologna, 1999 ¹⁶⁵	Prospective pre-post study 1,3,4,6,7	To compare the efficacy of a hydrogel/silver ion-coated (alloy) urinary catheter with standard latex catheters in reducing nosocomial UTI.	ICU patients at 5 different institutions Not specified	Device use ratio (the number of device days per number of patient days): Silver-coated catheter vs standard catheter: 0.78 vs 0.76; P = 0.31 Unspecified UTI (infections per 1000 catheter days): <u>Unadjusted:</u> Silver-coated catheter vs standard catheter: 4.5 vs 7.1; P = 0.01 <u>Adjusted:</u> Silver-coated catheter vs standard catheter: 4.9 vs 8.1; P = 0.13 (Adjusted to five different hospitals, three different types of ICU, time of year and severity of patient condition) Cost: The total cost savings were estimated at \$98,021.	Baseline period ranged from 3-12 months at the hospitals and the intervention period ranged from 7-19 months. Nosocomial UTIs were defined according to the CDC criteria Power not reported
Johnson, 1990 ⁸⁶	Prospective controlled study 1,3,6,7	To evaluate a silver-oxide coated catheter in the prevention of UTI during acute bladder catheterization in a general hospital population and to characterize the clinical and microbiologic correlates of CAUTI in this setting.	Patients ≥17 years who had received a study catheter that was expected to remain indwelling for at least 24 hours 482	Bacteriuria: Silver-coated catheter vs Control: 19/207 vs 28/275; P = 0.95 After stratification by sex and antimicrobial use, a protective effect of the silver catheter was seen among women not receiving antimicrobials (P = 0.04). There were no significant differences in the other three groups (men receiving antimicrobials, men not receiving antimicrobials, women receiving antimicrobials) Risk factors for bacteriuria: <u>Univariate analysis:</u> All results RR (P value) Male sex : 0.5 (P < 0.01) Antimicrobials during final 48 hours: 0.3 (P < 0.01) Catheter care violations: 2.7 (P < 0.01) Serum creatinine ≥ 2 mg/dl: 2.1 (P = 0.04) Not at strict bed rest: 0 (P = 0.06) Duration of catheterization > 7 days: 2.1 (P = 0.01) No association with UTI was seen for infection at another site, presence of an underlying genitourinary abnormality, advanced age or admitting service. ORs were not provided for the same	F/U unclear A patient was considered to have UTI when two consecutively collected catheter urine specimens grew the same microorganism in concentrations of ≥ 10 ² cfu/ml or if the last available urine specimen of the patient before catheter removal had ≥ 10 ⁵ cfu/ml A sample size of 105 patients per group was needed to detect a 67% reduction in the incidence of UTI with the silver

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Multivariate analysis: All results OR (P value) Antimicrobials during final 48 h: 0.3 (P < 0.01) Female sex : 2.0 (P = 0.02) Renal dysfunction: 2.6 (P = 0.02) Catheter care violations: NS (OR not provided)</p> <p>Median duration of catheterization (days): Silver-coated catheter vs control: 3 vs 4; P = 0.03</p>	catheter at 5% significance level and 80% power.
Akiyama, 1979 ¹⁶⁴	Prospective controlled study 3	To compare an open drainage system using the oligodynamic action of silver ions with the conventional open drainage system. The test system consisted of a Foley catheter coated in part with fine silver powder and a silver-plated connector fitted between the catheter and the drainage tube.	Postoperative patients and patients with urinary retention 122	<p>Bacteriuria: Test vs control: 0/102 vs 20/20; statistical differences were not reported</p> <p>Fever: Test vs control: 0/102 vs 5/20; statistical differences were not reported</p> <p>Urethral discharge: Test vs control: 0/102 vs 15/20; statistical differences were not reported</p> <p>Itching or burning sensation: Test vs control: 0/102 vs 4/20; statistical differences were not reported</p> <p>Reddening or edema of external meatus: Test vs control: 0/102 vs 2/20; statistical differences were not reported</p> <p>Duration of catheterization (range in days): Test vs control: 4-77 vs 3-4; statistical differences were not reported</p>	F/U 1-4 months Bacteriuria was defined as a catheter urine specimen with $\geq 10^5$ colonies per ml Power not reported
Plowman, 2001 ¹⁷⁹	Economic analysis 1,3,4,5,6	To develop an economic model to assess the economic burden of nosocomial UTIs and to examine the potential cost-effectiveness of silver-alloy coated catheters. The economic analysis was conducted from the perspective of the hospital sector. Cost and event rate estimates were obtained from public databases and/or published literature.	Adult non-day case patients admitted to the medical and surgical specialties of National Health Service hospitals throughout England. Not applicable	<p>Cost: A 14.6% reduction in the incidence of UTI in catheterized medical patients and a 11.4% reduction in catheterized surgical patients would cover the cost of using silver alloy-coated catheters.</p> <p>Sensitivity analysis: Examined the reductions needed under the assumptions of lower and higher incidence of nosocomial UTI. With a lower incidence, greater reduction in UTI was needed and with a higher incidence, lower reductions in UTI were needed to make silver-coated catheter cost-effective.</p>	
Saint, 2000 ¹⁸¹	Economic analysis 1,2,3,4,5,6	To assess the clinical and economic impact of using silver alloy urinary catheters in hospitalized patients when compared with standard non-coated catheters.	The hypothetical cohort in the decision-analytic model consisted of patients admitted to hospitals on general medical, surgical, urologic, and intensive care services requiring short-term (2-	<p>Cost: Use of silver alloy catheters resulted in estimated cost savings of \$4.09 per patient compared with standard catheter use (\$20.87 vs \$16.78).</p> <p>One-way sensitivity analysis: Probability of developing bacteriuria in the control group would have to be < 15% for silver-coated catheters to</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		The analysis was performed from the perspective of the health care payer and the time horizon was defined as the period of hospitalization. Costs were estimated from published literature, local hospital costs and oral communication. Event rates were estimated from the published literature.	10 days) indwelling urethral catheterization Not applicable	<p>not be cost saving.</p> <p>The probability of symptomatic UTI (without bacteremia) after developing bacteriuria would have to be < 5% for the silver-coated catheters to not provide cost savings.</p> <p>At a relative risk reduction associated with silver-coated catheters of 25% or greater, the clinical and economic superiority persisted.</p> <p>The cost of a silver-coated catheter would have to average \$9.40 more than a standard catheter for the silver-coated catheters to not provide cost savings.</p> <p>Multivariate sensitivity analysis using Monte Carlo simulation: This revealed a cost difference ranging from a savings of \$17.22 to an increase in overall cost of \$3.19 per catheterized patient. In the simulation, silver-coated catheters provided clinical benefits over standard catheters in all patients and cost savings in 84% of patients.</p>	

2B.1.b. Nitrofurazone-impregnated Catheter

Schumm, 2008 ¹³⁷	Systematic review 1,2,3,4,5,6,7,8	To determine the effect of type of indwelling urethral catheter on the risk of UTI in adults who undergo short-term urinary catheterization.	All randomized and quasi randomized trials comparing types of indwelling urinary catheters for short term (≤ 14 days) catheterization in hospitalized adults 23 trials	<p>Note: All results are RR (95% CI) unless otherwise noted</p> <p>1. Antiseptic vs standard catheter</p> <p>Bacteriuria:</p> <ul style="list-style-type: none"> Silver oxide catheters vs standard catheters (<1 week) (3 studies): 0.89 (0.68-1.15) Silver alloy catheters vs standard catheters (< 1 week) (7 studies): 0.66 (0.56-0.78) Silver alloy catheters vs standard catheters (> 1 week) (4 studies): 0.64 (0.51-0.80) Silver oxide catheters vs standard catheters in women (<1 week) (1 study): 0.63 (0.45-0.89) Silver oxide catheters vs standard catheters in men (<1 week) (1 study): 1.62 (0.91-2.88) Silver oxide catheters vs standard catheters in all participants receiving systemic antibiotics (<1 week) (1 study): 0.67 (0.45-0.99) Silver oxide catheters vs standard catheters in women receiving systemic antibiotics (<1 week) (1 study): 0.50 (0.31-0.79) Silver oxide catheters vs standard catheters in men receiving systemic antibiotics (<1 week) (1 study): 1.02 (0.49-2.13) <p><i>For a crossover trial not included in meta-analysis (All results silver alloy vs control)</i></p> <ul style="list-style-type: none"> Rate of bacteriuria per 1000 patient days: 0.79 (0.63-0.99) Rate of bacteriuria per 100 patients: 0.81 (0.65-1.01) Rate of bacteriuria per 100 catheters: 0.68 (0.54-0.86) 	
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Urethral secretions: Silver oxide catheters vs standard catheters (<1 week) (1 study): 0.72 (0.25-2.03)</p> <p>Pain: Silver oxide catheters vs standard catheters (<1 week) (1 study): 1.43 (0.48-4.27)</p> <p><i>2. Antibiotic and antiseptic-impregnated vs standard catheter</i></p> <p>Bacteriuria: All impregnated catheters (< 1 week) (4 studies): 0.47 (0.33-0.67) Minocycline and rifampicin-impregnated catheters (< 1 week) (1 study): 0.36 (0.18-0.73) Nitrofurazone-impregnated catheters (< 1 week) (4 study): 0.52 (0.34-0.78) All impregnated catheters (> 1 week) (2 studies): 0.85 (0.76-0.96) Minocycline and rifampicin-impregnated catheters (> 1 week) (1 study): 0.94 (0.86-1.03) Nitrofurazone-impregnated catheters (> 1 week) (1 study): 0.08 (0.00-1.33) Symptomatic UTI (1 study): 0.20 (0.03-1.63)</p> <p><i>3. One type of standard catheter vs another standard catheter</i></p> <p>Bacteriuria: Silicone vs latex (1 study): 1.07 (0.23-5.01)</p> <p>Symptomatic UTI: Hydron-coated latex vs plain latex (1 study): 0.94 (0.66-1.34) Hydron-coated latex vs PVC balloon (1 study): 0.87 (0.63-1.19) PVC balloon vs plain latex (1 study): 1.09 (0.81-1.45) Hydrogel vs silicone (1 study): 0.82 (0.46-1.47)</p> <p>Burning in urethra: Silicon vs non-silicone (1 study): 0.28 (0.13-0.60)</p> <p>Urethritis: Silicon vs latex (1 study): 0.09 (0.01-0.68)</p> <p>Urethral reaction: All results WMD (95% CI) Hydrogel-coated latex vs siliconised latex (1 study): 0.00 (-3.51 to 3.51) Full silicone vs hydrogel-coated latex (1 study): -16.00 (-18.84 to -13.16) Full silicone vs siliconised latex (1 study): -16.00 (-18.96 to -13.04)</p>	
Johnson, 2006 ¹³⁸	Systematic review	To assess antimicrobial (nitrofurazone-coated or silver alloy-coated) urinary catheters for	Randomized or quasi- randomized trials of nitrofurazone-coated or silver	<p>Bacteriuria: Range of RRs (12 studies): 0.08 to 0.94 (95% CI included 1.0 for 7 studies)</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
	1,2,3,4,7,8	preventing CAUTI.	alloy-coated antimicrobial urinary catheters for short-term (<30 days) bladder drainage 12 trials	Range of RRs for nitrofurazone-coated catheters (3 studies): 0.08 to 0.68 (95% CI included 1.0 in all 3 studies) Range of RRs for pre-1995 silver-coated catheters (4 studies): 0.24 to 0.45 (95% CI was less than 1.0 for all studies) Range of RRs for post-1995 silver-coated catheters (5 studies): 0.53 to 0.94 (95% CI included 1.0 for 4 studies) (The difference between the median RRs for pre and post 1995 studies was statistically significant; P < 0.01) The apparent protective effect of the test catheter was greater when the control catheter was latex rather than silicone. Studies involving urologic patients yielded larger effect sizes than those involving other types of patients, as did studies that excluded patients receiving antimicrobial agent therapy (quantitative summaries not available). Microbial resistance: Among studies that reported microbiological outcomes by study group, no evidence suggested that test catheter recipients experienced an increased incidence of specific microbial types that are typically resistant to the antimicrobial compound used.	

2.B.2. Miscellaneous antimicrobial catheters

Schumm, 2008 ¹³⁷	Systematic review 1,2,3,4,5,6,7,8	To determine the effect of type of indwelling urethral catheter on the risk of UTI in adults who undergo short-term urinary catheterization.	All randomized and quasi randomized trials comparing types of indwelling urinary catheters for short term (≤ 14 days) catheterization in hospitalized adults 23 trials	<p>Note: All results are RR (95% CI) unless otherwise noted</p> <p><u>1. Antiseptic vs standard catheter</u></p> <p>Bacteriuria:</p> <p>Silver oxide catheters vs standard catheters (<1 week) (3 studies): 0.89 (0.68-1.15) Silver alloy catheters vs standard catheters (< 1 week) (7 studies): 0.66 (0.56-0.78) Silver alloy catheters vs standard catheters (> 1 week) (4 studies): 0.64 (0.51-0.80) Silver oxide catheters vs standard catheters in women (<1 week) (1 study): 0.63 (0.45-0.89) Silver oxide catheters vs standard catheters in men (<1 week) (1 study): 1.62 (0.91-2.88) Silver oxide catheters vs standard catheters in all participants receiving systemic antibiotics (<1 week) (1 study): 0.67 (0.45-0.99) Silver oxide catheters vs standard catheters in women receiving systemic antibiotics (<1 week) (1 study): 0.50 (0.31-0.79) Silver oxide catheters vs standard catheters in men receiving systemic antibiotics (<1 week) (1 study): 1.02 (0.49-2.13) <i>For a crossover trial not included in meta-analysis (All results silver alloy vs control)</i></p>	
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Rate of bacteriuria per 1000 patient days: 0.79 (0.63-0.99) Rate of bacteriuria per 100 patients: 0.81 (0.65-1.01) Rate of bacteriuria per 100 catheters: 0.68 (0.54-0.86)</p> <p>Urethral secretions: Silver oxide catheters vs standard catheters (<1 week) (1 study): 0.72 (0.25-2.03)</p> <p>Pain: Silver oxide catheters vs standard catheters (<1 week) (1 study): 1.43 (0.48-4.27)</p> <p>2. Antibiotic and antiseptic-impregnated vs standard catheter</p> <p>Bacteriuria: All impregnated catheters (< 1 week) (4 studies): 0.47 (0.33-0.67) Minocycline and rifampicin-impregnated catheters (< 1 week) (1 study): 0.36 (0.18-0.73) Nitrofurazone-impregnated catheters (< 1 week) (4 study): 0.52 (0.34-0.78) All impregnated catheters (> 1 week) (2 studies): 0.85 (0.76-0.96) Minocycline and rifampicin-impregnated catheters (> 1 week) (1 study): 0.94 (0.86-1.03) Nitrofurazone-impregnated catheters (> 1 week) (1 study): 0.08 (0.00-1.33) Symptomatic UTI (1 study): 0.20 (0.03-1.63)</p> <p>3. One type of standard catheter vs another standard catheter</p> <p>Bacteriuria: Silicone vs latex (1 study): 1.07 (0.23-5.01)</p> <p>Symptomatic UTI: Hydron-coated latex vs plain latex (1 study): 0.94 (0.66-1.34) Hydron-coated latex vs PVC balloon (1 study): 0.87 (0.63-1.19) PVC balloon vs plain latex (1 study): 1.09 (0.81-1.45) Hydrogel vs silicone (1 study): 0.82 (0.46-1.47)</p> <p>Burning in urethra: Silicon vs non-silicone (1 study): 0.28 (0.13-0.60)</p> <p>Urethritis: Silicon vs latex (1 study): 0.09 (0.01-0.68)</p> <p>Urethral reaction: All results WMD (95% CI) Hydrogel-coated latex vs siliconised latex (1 study): 0.00 (-3.51 to 3.51) Full silicone vs hydrogel-coated latex (1 study): -16.00 (-18.84 to -13.16) Full silicone vs siliconised latex (1 study): -16.00 (-18.96 to -13.04)</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
Butler, 1968 ¹⁶⁷	Prospective controlled study 1,3	To evaluate the individual effects of (1) lubrication of the catheter with antibiotic (polymyxin)-containing material vs (2) use of catheters impregnated with antimicrobial materials: TMTS (tetramethyl-thiuram disulfide) or CTHA (cyclic thiohydroxamic acid).	Catheterized patients 758	Bacteriuria: <u>(1) Lubricated catheter vs control</u> Developed in 50% of patients after 8.6 days and 11.6 days with polymyxin and placebo lubricants respectively. No statistically significant differences were seen. <u>(2) Antibiotic-impregnated catheter vs control</u> No statistically significant differences were seen when impregnated and control catheters were compared.	F/U until catheter removal, discharge, or death Bacteriuria was defined as > 10 ⁵ colonies/ml Power not reported
Mooro, 1966 ¹⁶⁸	Prospective controlled study 1,3	To test the effect of furacin urethral inserts on the prevention of catheter fever.	Patients needing urethral manipulations 200	Fever: With insert vs without insert: 4/100 vs 18/100; statistical differences were not reported Ascending infection: With insert vs without insert: 0/100 vs 2/100; statistical differences were not reported	F/U not reported UTI not defined Power not reported

2B.3. Hydrophilic catheters

Schumm, 2008 ¹³⁷	Systematic review 1,2,3,4,5,6,7,8	To determine the effect of type of indwelling urethral catheter on the risk of UTI in adults who undergo short-term urinary catheterization.	All randomized and quasi-randomized trials comparing types of indwelling urinary catheters for short term (≤ 14 days) catheterization in hospitalized adults 23 trials	<p><i>Note: All results are RR (95% CI) unless otherwise noted</i></p> <p>1. Antiseptic vs standard catheter</p> <p>Bacteriuria:</p> <ul style="list-style-type: none"> Silver oxide catheters vs standard catheters (<1 week) (3 studies): 0.89 (0.68-1.15) Silver alloy catheters vs standard catheters (< 1 week) (7 studies): 0.66 (0.56-0.78) Silver alloy catheters vs standard catheters (> 1 week) (4 studies): 0.64 (0.51-0.80) Silver oxide catheters vs standard catheters in women (< 1 week) (1 study): 0.63 (0.45-0.89) Silver oxide catheters vs standard catheters in men (< 1 week) (1 study): 1.62 (0.91-2.88) Silver oxide catheters vs standard catheters in all participants receiving systemic antibiotics (< 1 week) (1 study): 0.67 (0.45-0.99) Silver oxide catheters vs standard catheters in women receiving systemic antibiotics (< 1 week) (1 study): 0.50 (0.31-0.79) Silver oxide catheters vs standard catheters in men receiving systemic antibiotics (< 1 week) (1 study): 1.02 (0.49-2.13) <p><i>For a crossover trial not included in meta-analysis (All results silver alloy vs control)</i></p> <ul style="list-style-type: none"> Rate of bacteriuria per 1000 patient days: 0.79 (0.63-0.99) Rate of bacteriuria per 100 patients: 0.81 (0.65-1.01) 	
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Rate of bacteriuria per 100 catheters: 0.68 (0.54-0.86)</p> <p>Urethral secretions: Silver oxide catheters vs standard catheters (<1 week) (1 study): 0.72 (0.25-2.03)</p> <p>Pain: Silver oxide catheters vs standard catheters (<1 week) (1 study): 1.43 (0.48-4.27)</p> <p>2. Antibiotic-impregnated vs standard catheter</p> <p>Bacteriuria: All impregnated catheters (< 1 week) (4 studies): 0.47 (0.33-0.67) Minocycline- and rifampicin-impregnated catheters (< 1 week) (1 study): 0.36 (0.18-0.73) Nitrofurazone-impregnated catheters (< 1 week) (4 study): 0.52 (0.34-0.78) All impregnated catheters (> 1 week) (2 studies): 0.85 (0.76-0.96) Minocycline and rifampicin-impregnated catheters (> 1 week) (1 study): 0.94 (0.86-1.03) Nitrofurazone-impregnated catheters (> 1 week) (1 study): 0.08 (0.00-1.33) Symptomatic UTI (1 study): 0.20 (0.03-1.63)</p> <p>3. One type of standard catheter vs another standard catheter</p> <p>Bacteriuria: Silicone vs latex (1 study): 1.07 (0.23-5.01)</p> <p>Symptomatic UTI: Hydron-coated latex vs plain latex (1 study): 0.94 (0.66-1.34) Hydron-coated latex vs PVC balloon (1 study): 0.87 (0.63-1.19) PVC balloon vs plain latex (1 study): 1.09 (0.81-1.45) Hydrogel vs silicone (1 study): 0.82 (0.46-1.47)</p> <p>Burning in urethra: Silicon vs non-silicone (1 study): 0.28 (0.13-0.60)</p> <p>Urethritis: Silicon vs latex (1 study): 0.09 (0.01-0.68)</p> <p>Urethral reaction: All results WMD (95% CI) Hydrogel-coated latex vs siliconised latex (1 study): 0.00 (-3.51 to 3.51) Full silicone vs Hydrogel-coated latex (1 study): -16.00 (-18.84 to -13.16) Full silicone vs siliconised latex (1 study): -16.00 (-18.96 to -13.04)</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
De Ridder, 2005 ¹⁴⁴	RCT 1,2,6,7	To compare the performance of hydrophilic-coated vs uncoated polyvinyl chloride (PVC) catheters. The hydrophilic coating consisted primarily of polyvinyl-pyrrolidone. In the uncoated group, catheters were lubricated manually using a water-soluble lubricant gel.	Male spinal cord injured patients who were ≥16 years, had been injured <6 months and presented with neurogenic bladder emptying disorders, needing intermittent catheterization at least 3 times a day. 123	Symptomatic UTI: Hydrophilic-coated vs uncoated: 39/61 vs 51/62; P = 0.02 Mean number of catheterizations per day: Hydrophilic-coated vs uncoated: 3.4 vs 3.6; P > 0.05 Bleeding: Hydrophilic-coated vs uncoated: 38/55 vs 32/59; P > 0.05 Bacteriuria: No significant differences except at the initial study visit where there was a higher incidence in the hydrophilic group (P = 0.03). The difference was eliminated at day 15. Hematuria: No significant differences except at the initial study visit where there was a higher incidence in the hydrophilic group (P = 0.02). The difference was eliminated at day 15. Leukocyturia: P > 0.05 Satisfaction for patients/care providers: <i>6 months</i> Hydrophilic-coated vs uncoated: 33.0% vs 15.4%; P > 0.05 <i>6 months</i> Hydrophilic-coated vs uncoated: 36.0% vs 21.9%; P > 0.05	F/U 12 months. UTI was defined as a clinical infection with symptoms of UTI and for which treatment was prescribed. The study was powered at 90% with an alpha of 0.05 to detect differences in symptomatic UTI and hematuria. Though the sample size was met, there was a very high rate of dropouts.
Stensballe, 2005 ¹⁴⁶	Crossover RCT 1,2,4,5,7	To compare the effects of three methods on withdrawal friction force and urethral micro-trauma: (1) a hydrophilic catheter with a ready-to-use coating; (2) a hydrophilic-coated catheter where water is added 30s prior to use; and (3) an uncoated silicon/PVC catheter with gel.	Adult volunteers with negative urine dipstick at the first visit and without experience of recurrent UTI 49	Mean withdrawal friction force (Newton): Ready-to-use hydrophilic vs hydrophilic with water added vs Uncoated: 0.14 vs 0.28 vs 0.20; P < 0.01 All pairwise comparisons were also statistically significant (P < 0.05) Hematuria: Ready-to-use hydrophilic vs hydrophilic with water added vs Uncoated: 58% vs 40% vs 67%; P < 0.01 Pairwise comparison between the latter two catheters was also statistically significant (P < 0.01) Bacteriuria: Not reported stratified by the type of catheter. Was found in 6 participants, 2 of whom were symptomatic Pain during insertion: Ready-to-use hydrophilic vs hydrophilic with water added vs Uncoated: 0% vs 0% vs 22%; P < 0.01	F/U unclear Significant bacteriuria defined as > 10 ⁵ cfu/ml A sample size of 35 would have 90% power to detect a mean difference of 0.07N in the withdrawal friction force at an alpha of 0.05

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>All pairwise comparisons were also statistically significant ($P < 0.05$)</p> <p>Pain during withdrawal: $P < 0.01$ on overall comparison of the three groups. Pairwise comparison significant only for ready-to-use vs uncoated ($P < 0.01$) [Group-wise data not provided]</p> <p>Dysuria: Ready-to-use hydrophilic vs hydrophilic with water added vs Uncoated: 30% vs 32% vs 55%; $P < 0.01$ No significant differences were seen in the pairwise comparisons.</p> <p>Catheter preference: All hydrophilic vs uncoated: 93% vs 2%; statistical differences were not reported</p>	
Cindolo, 2004 ¹⁴⁵	RCT 1,5,7	To compare a hydrophilic catheter to the standard PVC catheter with regard to bacteriological safety and overall comfort.	Patients with histologically proven primary bladder cancer eligible to receive intravesical immunochemoprophylaxis 100	<p>Symptomatic UTI: 2/50 vs 7/50; statistical differences were not reported</p> <p>Bacteriuria: Hydrophilic vs standard: 3.5% vs 7.4%; $P < 0.01$</p> <p>Mean VAS score for discomfort: Hydrophilic vs standard: 1.3% vs 2.1%; $P < 0.01$</p> <p>Hematuria: None</p> <p>Stricture: None</p>	F/U 2 days after instillation Symptomatic UTI not defined but referred as such Significant bacteriuria defined as $> 10^5$ cfu/ml Power not reported
Vapnek, 2003 ¹⁴⁷	RCT 1,6,7	To compare a hydrophilic-coated vs a standard PVC catheter.	Male patients who performed clean intermittent self-catheterization to manage neurogenic bladder 62	<p>Symptomatic UTI: Hydrophilic vs standard: $P > 0.3$. However, the rate of decline from baseline was significant in the hydrophilic group ($P = 0.01$), but not in the standard group</p> <p>Bacteriuria at 3 months: Hydrophilic vs standard: 21/27 vs 20/28; statistical differences were not reported</p> <p>Hematuria: Significantly decreased in hydrophilic group ($P = 0.03$)</p> <p>Pyuria: No significant differences</p> <p>Adverse events: Hydrophilic vs standard: 3/23 vs 3/26; statistical differences were not reported</p>	F/U 1 year UTI defined as $\geq 10^5$ cfu/ml and at least one clinical symptom such as fever, chills, malodorous urine, increased spasticity, or malaise Power not reported
Monson, 1974 ¹⁴⁸	RCT 1,3,7	To assess the efficacy of a hydrophilic, polymer-coated catheter in reducing bacteriuria.	Community hospital patients receiving urinary catheters with initially sterile urine specimen and	Bacteriuria: Hydrophilic vs control: $P > 0.05$	F/U until catheter removal, discharge or death

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
			who were followed for \geq 1 day. All patients received a closed drainage system. 287		Infection assessed by culturing the catheter specimen of urine Power not reported
Pachler, 1999 ¹⁶⁹	Prospective controlled crossover study 1,2,3	To compare a pre-lubricated hydrophilic PVC catheter or a non-hydrophilic PVC catheter self-lubricated by the patient using gel. Patients used one catheter for 3 weeks and transferred to the other for 3 weeks.	Patients with urinary retention caused by prostatic enlargement who performed clean intermittent self-catheterization. 43	Cystitis: One in each group. P > 0.05 Bacteriuria: None Hematuria: 2 in each group; P > 0.05 Epididymitis: None Urethritis: None	F/U 6 weeks. Significant bacteriuria was defined as $> 10^4$ cfu/ml Power not reported

2B.4. Other Catheter Types

Phipps, 2006 ³⁷	Systematic review 1,2,3,4,5,6,7,8	To establish the optimal way to manage urinary catheters following urogenital surgery in adults.	Randomized and quasi-randomized trials 39 RCTs	<p>Note: All results are RR (95% CI) unless otherwise noted</p> <p>1. Using a urinary catheter vs not using a urinary catheter</p> <p>Retention of urine (1 study): 0.12 (0.03-0.47) UTI (4 studies): 1.35 (0.75-2.45) Recatheterization (3 studies): 0.32 (0.14-0.70) Post-op urethral stricture (1 study): 1.14 (0.90-1.44) Post-op hematuria (1 study): 0.73 (0.40-1.33)</p> <p>2. Urethral catheterization vs suprapubic catheterization</p> <p>UTI: Heterogeneous results, not combined. Of four trials, two suggested a moderate increase, one a large increase and one a large decrease. Recatheterization (2 studies): 3.66 (1.41-9.49) Post-op hematuria (1 study): 5.00 (0.21-116.31) Length of hospital stay in days (1 study) [WMD (95% CI)]: 1.10 (0.30-1.90) Catheter lockage or bypassing [OR (95% CI)] (2 studies): 0.20 (0.02-1.72)</p> <p>3. One type of catheter vs another type of catheter</p> <p>UTI: Urethral Foley catheter with extra drainage hole vs unmodified Foley catheter (1 study): 0.40 (0.15-1.04)</p>	
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Positive urine culture: Silver-coated Bardex catheters vs latex catheters (1 study): 0.53 (0.20-1.45)</p> <p>4. One type of catheter management vs another</p> <p>Retention of urine: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.99 (0.06-15.54)</p> <p>Dysuria: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.99 (0.06-15.54)</p> <p>Symptomatic UTI: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.61 (0.33-1.14)</p> <p>Bacteriuria/unspecified UTI: Cefotaxime 1 hour prior to catheter removal vs none (1 study): 0.08 (0.00-1.30)</p> <p>Neomycin/Sulfamethiazole vs placebo (1 study): 0.18 (0.06-0.55)</p> <p>Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 1.06 (0.70-1.51)</p> <p>Recatheterization: Neomycin/Sulfamethiazole vs placebo (1 study): 0.50 (0.24-1.04)</p> <p>5. Larger diameter catheter vs Smaller diameter catheter</p> <p>No trials found</p> <p>6. Bladder irrigation</p> <p>No trials found</p> <p>7. Shorter duration vs longer duration catheter</p> <p>Retention of urine: 1 day vs 3 days (1 study): 0.80 (0.38-1.69) 1-2 days vs until urine clear (1 study): 1.02 (0.07-15.87) 1 day vs 2 days (1 study): 4.64 (0.23-94.28) 3 days vs 28 days (1 study): 3.00 (0.13-69.52)</p> <p>Post-op urethral stricture: <1 week vs 2 weeks (2 studies): 1.23 (0.82-1.84) 3 days vs 28 days (1 study): 1.00 (0.73-1.36)</p> <p>UTI: Heterogeneous results, not combined. Shorter duration had lower risk of UTIs but the results were significant in only 1 trial 1 day vs 3 days (3 studies): 0.50 (0.29-0.87)</p> <p>Recatheterization: 1 day vs 2 days (1 study): 1.03 (0.23-4.71) 1 day vs 3 days (2 studies): 1.04 (0.36-3.01) 1 day vs 5 days (1 study): 4.55 (1.68-12.37) 4-6 days vs 14 days (1 study): 1.86 (0.14-25.38) 1-2 days vs until urine clear (2 studies): 0.72 (0.24-2.20)</p> <p>Post-op hematuria: 1-2 days vs until urine clear (1 study): 2.04 (0.19-21.81) 1 day vs 2 days (2 studies): 1.16 (0.34-3.90)</p> <p>Urinary leakage or incontinence: 1-2 days vs until urine clear (2 studies): 0.43 (0.07-2.88)</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p><u>8. Clamp and release vs free catheter drainage:</u> UTI (1 study): 4.00 (1.55-10.29) Delay in return to normal bladder function (1 study): 2.50 (1.16-5.39)</p> <p><u>9. Catheter removal at one time of day vs another time of day</u> UTI: 12 am vs 6 am (1 study): 1.31 (0.65-2.66) Recatheterization: 12 am vs 6 am (4 studies): 0.61 (0.34-1.12) 6-7 am vs 10-11 pm (1 study): 1.36 (0.32-5.77) Time to first void in hours[WMD (95% CI)]: 12 am vs 6 am (1 study): 0.60 (-0.96 to 2.16) Volume of first void in ml [WMD (95% CI)]: 12 am vs 6 am (1 study): 53.00 (4.27-101.73)</p> <p><u>10. Trial of void protocol vs none</u> No trials found</p> <p><u>11. Prefilling bladder prior to catheter removal vs removal without prefilling</u> Recatheterization [OR (95% CI)] (1 study): 4.52 (0.79-25.97) Discharge on day of catheter removal (1 study): 1.36 (0.47-3.91)</p>	
Shafik, 1993 ¹⁴⁹	RCT 1	To assess the safety and efficacy of an electrified catheter vs a nonelectrified catheter in reducing UTI.	Patients scheduled for hemorrhoidectomy 24	<p>UTI: Electrified vs non-electrified: 0/12 vs 7/12; statistical differences were not reported</p> <p>Bacteremia: None in either group</p>	F/U 1 week UTI was defined as a pathogen count of > 10 ⁵ cfu/ml Power not reported
Chen, 2005 ¹⁷⁰	Prospective pre-post study 1,3	To compare the safety, effectiveness, and patient satisfaction of an intraurethral valve-pump catheter versus clean intermittent catheterization.	Women with hypocontractile or acontractile bladder or other concurrent conditions of the lower urinary tract without contraindication to having medical magnetic devices installed 273	<p>UTI: Test vs control: 30% vs 23%; statistical differences were not reported</p> <p>Bacteriuria: Test vs control: 56% vs 26%; statistical differences were not reported</p> <p>Discomfort: Test vs control: 31% vs 4%; statistical differences were not reported</p> <p>Incontinence: Test vs control: 61% vs 4%; statistical differences were not reported</p> <p>Hematuria: Test vs control: 8% vs 1%; statistical differences were not reported</p>	F/U unclear UTI not defined Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Frequency/urgency: Test vs control: 22% vs 6%; statistical differences were not reported</p> <p>Post-void residual (ml): Test vs control: 16.1 vs 20.3; P > 0.05</p> <p>Mean quality of life score: Test vs control: 25.9 vs 42.2; P < 0.01</p>	

2B.5. Drainage Systems

Phipps, 2006 ³⁷	Systematic review 1,2,3,4,5,6,7,8	To establish the optimal way to manage urinary catheters following urogenital surgery in adults.	Randomized and quasi-randomized trials 39 RCTs	<p><i>Note: All results are RR (95% CI) unless otherwise noted</i></p> <p>1. Using a urinary catheter vs not using a urinary catheter Retention of urine (1 study): 0.12 (0.03-0.47) UTI (4 studies): 1.35 (0.75-2.45) Recatheterization (3 studies): 0.32 (0.14-0.70) Post-op urethral stricture (1 study): 1.14 (0.90-1.44) Post-op hematuria (1 study): 0.73 (0.40-1.33)</p> <p>2. Urethral catheterization vs suprapubic catheterization UTI: Heterogeneous results, not combined. Of four trials, two suggested a moderate increase, one a large increase and one a large decrease. Recatheterization (2 studies): 3.66 (1.41-9.49) Post-op hematuria (1 study): 5.00 (0.21-116.31) Length of hospital stay in days (1 study) [WMD (95% CI)]: 1.10 (0.30-1.90) Catheter lockage or bypassing [OR (95% CI)] (2 studies): 0.20 (0.02-1.72)</p> <p>3. One type of catheter vs another type of catheter UTI: Urethral Foley catheter with extra drainage hole vs unmodified Foley catheter (1 study): 0.40 (0.15-1.04) Positive urine culture: Silver-coated Bardex catheters vs latex catheters (1 study): 0.53 (0.20-1.45)</p> <p>4. One type of catheter management vs another Retention of urine: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.99 (0.06-15.54) Dysuria: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.99 (0.06-15.54) UTI: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.61 (0.33-1.14) Cefotaxime 1 hour prior to catheter removal vs none (1 study): 0.08</p>	
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>(0.00-1.30) Neomycin/Sulfamethiazole vs placebo (1 study): 0.18 (0.06-0.55) Positive urine culture: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 1.06 (0.70-1.51) Recatheterization: Neomycin/Sulfamethiazole vs placebo (1 study): 0.50 (0.24-1.04)</p> <p><u>5. Larger diameter catheter vs Smaller diameter catheter</u> No trials found</p> <p><u>6. Bladder irrigation</u> No trials found</p> <p><u>7. Shorter-duration vs longer-duration catheter</u> Retention of urine: 1 day vs 3 days (1 study): 0.80 (0.38-1.69) 1-2 days vs until urine clear (1 study): 1.02 (0.07-15.87) 1 day vs 2 days (1 study): 4.64 (0.23-94.28) 3 days vs 28 days (1 study): 3.00 (0.13-69.52) Post-op urethral stricture: < 1 week vs 2 weeks (2 studies): 1.23 (0.82-1.84) 3 days vs 28 days (1 study): 1.00 (0.73-1.36) UTI: Heterogeneous results, not combined. Shorter duration had lower risk of UTIs but the results were not significant Recatheterization: 1 day vs 2 days (1 study): 1.03 (0.23-4.71) 1 day vs 3 days (2 studies): 1.04 (0.36-3.01) 1 day vs 5 days (1 study): 4.55 (1.68-12.37) 4-6 days vs 14 days (1 study): 1.86 (0.14-25.38) 1-2 days vs until urine clear (2 studies): 0.72 (0.24-2.20) Post-op hematuria: 1-2 days vs until urine clear (1 study): 2.04 (0.19-21.81) 1 day vs 2 days (2 studies): 1.16 (0.34-3.90) Urinary leakage or incontinence: 1-2 days vs until urine clear (2 studies): 0.43 (0.07-2.88)</p> <p><u>8. Clamp and release vs free catheter drainage:</u> UTI (1 study): 4.00 (1.55-10.29) Delay in return to normal bladder function (1 study): 2.50 (1.16-5.39)</p> <p><u>9. Catheter removal at one time of day vs another time of day</u> UTI: 12 am vs 6 am (1 study): 1.31 (0.65-2.66) Recatheterization: 12 am vs 6 am (4 studies): 0.61 (0.34-1.12) 6-7 am vs 10-11 pm (1 study): 1.36 (0.32-5.77)</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Time to first void in hours [WMD (95% CI)]: 12 am vs 6 am (1 study): 0.60 (-0.96 to 2.16)</p> <p>Volume of first void in ml [WMD (95% CI)]: 12 am vs 6 am (1 study): 53.00 (4.27-101.73)</p> <p>10. Trial of void protocol vs none No trials found</p> <p>11. Prefilling bladder prior to catheter removal vs removal without prefilling Recatheterization [OR (95% CI)] (1 study): 4.52 (0.79-25.97) Discharge on day of catheter removal (1 study): 1.36 (0.47-3.91)</p>	
van den Eijkel, 2006 ¹⁴⁰	Systematic review 1,2,3,4	To assess the evidence for the benefit of catheter valves for indwelling urinary catheters.	Randomized and quasi-randomized controlled trials comparing the use of catheter valves with catheter bag drainage system in subjects aged \geq 16 years. 4 trials	<p>Bacteriuria (2 studies): Catheter valve vs catheter bag: RD (95% CI) = -9% (-25 to +7%)</p> <p>Bladder spasms (1 study): No significant differences</p> <p>Pain (1 study): No significant differences</p> <p>Incontinence (1 study): No significant differences</p> <p>Patient preference (2 studies): Statistically significant preference for the catheter valve in both included studies ($P < 0.05$)</p>	
Leone, 2003 ¹⁵⁰	RCT 1,2,7,8,9	To compare the rate of acquisition of bacteriuria between a complex closed drainage system and a two-chamber drainage system. The two-chamber drainage system contained a Foley catheter connected to an output measure recipient and a urine collection bag. The complex drainage system consisted of a preconnected coated latex catheter, a tamper-discouraging seal at the catheter drainage tubing junction, a drip chamber, an anti-reflux valve, a drainage bag vent, and a povidone-iodine releasing cartridge at the drain port of the urine collection bag.	ICU patients who had an initial culture free of bacterial growth and an indwelling urethral catheter for $>$ 48 hours. 314	<p>Bacteriuria: Complex vs two-chamber: 14/162 vs 12/149; $P > 0.05$</p> <p>Onset of bacteriuria (days): Complex vs two chamber: 7.8 vs 12.4; $P < 0.05$ Probability of remaining uninfected until removal of the catheter showed no significant differences between the two groups on log rank test ($P = 0.22$)</p> <p>Length of ICU stay (days): Complex vs two chamber: 19 vs 29; $P < 0.05$</p> <p>Duration of catheterization (days): Complex vs two chamber: 15 vs 21.5; $P < 0.05$</p>	F/U for until a day after removal of the catheter. CDC's definition of asymptomatic bacteriuria was used 300 patients were needed to provide 80% power to detect a 10% difference in bacteriuria between the two groups.

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
Huth, 1992 ⁶⁴	RCT 1,2,3,6,7	To evaluate the efficacy of a junction seal applied after catheter insertion for preventing bacteriuria and reducing mortality. The seal was obtained by wrapping the drainage tube junction with adhesive tape.	Patients undergoing transurethral catheterization at a community hospital 1740	<p>Death at hospital discharge: Tape seal vs no tape seal: 60/903 vs 67/837; P = 0.32</p> <p>Bacteriuria: Tape seal vs no tape seal: 124/903 vs 125/837; OR (95% CI) = 0.91 (0.69-1.20) Survival curve analysis of patients stratified by sex and antibiotic use revealed no significant differences in the rate of bacteriuria between treatment groups.</p> <p>Duration of catheterization (days): Tape seal vs no tape seal: 4.0 vs 4.1; P = NS</p> <p>Risk factors for bacteriuria: <i>Multivariate analysis: All results OR (95% CI)</i> Lack of antibiotic use: 3.69 (2.84-4.80) Female sex: 2.73 (2.07-3.61) Age, hospital service, catheter care violations and treatment randomization were not significant</p>	F/U until catheter removal or patient discharge Bacteriuria was defined as a urine specimen containing ≥ 1000 cfu/ml of bacteria or yeast It was estimated that a final study population of 686 patients in each group would be needed to detect a 33% reduction in the infection rate at an alpha of 0.05 with 80% power
Classen, 1991 ¹⁵¹	RCT 1,5	To assess the prevention of bacteriuria in patients using a three-way system that included a hydrophilic polymer-coated and preconnected sealed catheter system, daily catheter care, and disinfection of the outflow tube of the drainage bag with povidone-iodine (i.e., methods to block bacterial entry at the urethral insertion site, at the catheter drainage tube junction, and at the outflow tube).	Hospitalized patients with catheters 606	<p>Bacteriuria: Treated vs control: 14/300 vs 15/306; P = NS</p> <p>Duration of catheterization (days): P = NS</p>	F/U until the duration of the first catheterization Bacteriuria was defined as a colony count of ≥ 1000 cfu/ml with gram negative bacilli, enterococci, or both A sample size of 560 patients would be required to have a 70% power to detect a 50% reduction in the incidence of bacteriuria, based on an expected 12% incidence of bacteriuria in the control population
Al-Juburi, 1989 ¹⁵²	RCT 1	To evaluate a new drainage system consisting of: 1) a cartridge that released povidone-iodine into the outlet tube of the urine collection bag;	Patients on most services of a university hospital who had an initial urine culture free of bacterial growth and an indwelling urethral catheter for	<p>Bacteriuria during first 5 days of catheterization: Test vs control: 1/52 vs 10/57; P < 0.01</p> <p>Bacteriuria during entire time catheterized: Test vs control: 3/52 vs 13/57; P < 0.01</p>	F/U for the duration of catheterization UTI was determined by the presence of

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		2) a hydrophilic surface-coated catheter; 3) an antireflux mechanism; and 4) a tamper-discouraging seal at the catheter-drainage tubing connection. This system was compared with a standard closed drainage system (<i>control group</i>) that had only an antireflux mechanism.	more than 48 hours. 109	Mean number of days catheterized without infection: Test vs control: 3.3 vs 4.0; P = NS Mean day of first appearance of microorganisms in bag urine: Test vs control: 5.3 vs 3.9; P = NS Mean day of first appearance of microorganisms in bladder urine: Test vs control: 5.7 vs 5.3; P = NS	microorganisms in the bladder urine. Power not reported
DeGroot-Kosolcharoen, 1988 ¹⁵³	RCT 1	To compare a pre-connected closed drainage system with a standard system that had the Foley catheter attached to the closed drainage bag after it had been inserted.	Male surgical and medical patients 202	Bacteriuria: Preconnected closed drainage vs standard closed drainage: 11/97 vs 14/105; P > 0.05 Symptomatic UTI: Preconnected closed drainage vs standard closed drainage: 3/97 vs 1/105; P > 0.05 Duration of catheterization (days): Preconnected closed drainage vs standard closed drainage: 6.4 vs 7.6; P > 0.05 Costs: Cost savings with pre-connected system: \$4 Reduction in bacteriuria needed to realize cost savings: 8%	F/U until 5 days after catheter removal Catheter associated bacteriuria was defined as the onset of bacteriuria (> 10 ³ cfu/ml) after insertion of catheter or within five days of catheter removal CAUTI was defined as the onset of bacteriuria accompanied with signs and symptoms (fever > 99 F orally, not accompanied by other events in the clinical course, and accompanied by chills, burning, or lower back discomfort, or isolation of the same organism in urine and blood) Power not reported
Klarskov, 1986 ¹⁵⁴	RCT 1,6	To test a urinary drainage system in which the catheter was preconnected and sealed with tape to the drainage tube which was connected to a vented drip chamber and non-return valve.	Female patients > 16 years referred for urological or gynecological surgery, which routinely included an indwelling urethral catheter for ≥ 3 days	Bacteriuria: Test system vs control system: 1/30 vs 9/30; P < 0.05 Urethral discharge: Test system vs control system: 8/30 vs 8/30; statistical differences were not reported Suprapubic pain/ urethral burning: Test system vs control system:	F/U not reported Bacteriuria defined as ≥ 10 ⁵ colonies/ml Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		This was compared with a regular system consisting of a Foley catheter with exchangeable collecting bags with non-return valves.	60	6/30 vs 4/30; statistical differences were not reported Incontinence: Test system vs control system: 3/30 vs 0/30; statistical differences were not reported	
Platt, 1983 ¹⁵⁶	RCT 1,2,5	To compare preconnected sealed junction catheters and unsealed junction catheters.	Catheterized inpatients 1476	Bacteriuria: <i>Subjects who received an antibiotic</i> Unsealed vs sealed: 48/643 vs 46/613; RR (95% CI) = 1.0 (0.7-1.5) <i>Subjects who received no antibiotic</i> Unsealed vs sealed: 29/108 vs 11/112; RR (95% CI) = 2.7 (1.5-5.0) Mortality: <i>Subjects who received an antibiotic</i> Unsealed vs sealed: 32/643 vs 26/613; RR (95% CI) = 1.2 (0.6-2.2) <i>Subjects who received no antibiotic</i> Unsealed vs sealed: 15/108 vs 4/112; RR (95% CI) = 3.4 (1.1-10.7) Catheter disconnections: Unsealed vs sealed: RR (95% CI) = 1.2 (1.0-1.5); P = 0.04 Median duration of catheterization (days): Unsealed vs sealed: 3 vs 3; P > 0.05 Colonization of drainage bag: Unsealed vs sealed: 35/759 vs 28/735; statistical differences were not reported	F/U unclear Infection was defined as the presence of $\geq 10^5$ cfu/ml of any organism in catheter urine It was calculated that a sample size of 1500 was needed to reduce bacteriuria from 15% for the unsealed catheters to 10% for sealed catheters
Keys, 1979 ¹⁵⁵	RCT 1,6	To compare a top-vented (air vent on the top of the catheter connector) vs a bag-vented (on the upper face of the drainage bag) closed-drainage system.	Adult patients requiring indwelling urinary catheterization 236	Bacteriuria: Top vented vs bag vented: 16/113 vs 13/123; P > 0.05 Antibiotic vs no antibiotic: 15/202 vs 10/34; statistical differences not reported Time of onset of bacteriuria: Top vented vs bag vented: P > 0.05	F/U unclear Bacteriuria defined as $\geq 10,000$ cfu/ml urine Power not reported
Monson, 1977 ¹⁵⁷	RCT 1,3,5	To compare a top-vented urinary drainage system with an otherwise identical non-vented drainage system.	Patients in a community hospital 506	Bacteriuria: Vented vs non-vented: 26% vs 66%; P < 0.05 Vented vs non-vented (males): 12/91 vs 12/99; P > 0.05 Vented vs non-vented (females): 17/160 vs 40/156; P < 0.05 Hemoglobinuria: Vented vs non-vented: 90% vs 90%; statistical differences not reported	F/U until discharge, death or catheter removal Power not reported Significant bacteriuria was defined as a catheter urine specimen with $\geq 10^5$ colonies per ml in 2

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
					consecutive specimens
Cleland, 1971 ¹⁵⁸	RCT 1	To test the effectiveness of perineal care and a specific type of drainage system in preventing bacteriuria. Effect of antimicrobial prophylaxis was also reported (observational data). Perineal care: (A) Twice daily perineal care: mechanical cleansing using a hexachlorophene soap solution; (B) same as A, but with sterile gloves; (C) dressings with bacitracin-neomycin ointment; (D) combination of B and C; and (E) No perineal care. Two drainage systems were compared in which one of them had an air barrier between bag and tubing and the air vent was protected against accidental wetting (designated as "Test drainage system" for the purposes of the review). Antimicrobial prophylaxis was classified as bacteriostatic, narrow/ broad-spectrum bactericidal.	Adult female patients in whom a catheter was in place for at least 60 hours 184	Bacteriuria: <u>Perineal care</u> : A vs B vs C vs D vs E: 20/35 vs 18/38 vs 15/26 vs 25/46 vs 20/39; P> 0.05 <u>Perineal care stratified by drainage system</u> Test drainage system: A vs B vs C vs D vs E: 10/17 vs 8/17 vs 9/12 vs 12/24 vs 10/17; P> 0.05 Control drainage system: A vs B vs C vs D vs E: 10/18 vs 10/21 vs 6/14 vs 13/22 vs 10/22; P> 0.05 <u>Test drainage system vs control drainage system</u> : 49/87 vs 49/97; P> 0.05 Antibiotic prophylaxis Bacteriostatic vs broad-spectrum bactericidal vs narrow spectrum bactericidal vs none: 10/21 vs 9/38 vs 7/11 vs 62/82; P < 0.01 <u>Broad-spectrum antibiotic prophylaxis stratified by risk</u> High risk: Broad-spectrum bactericidal vs no prophylaxis: 6/15 vs 29/33; P < 0.01 Low risk: Broad-spectrum bactericidal vs no prophylaxis: 3/23 vs 33/49; P < 0.01	F/U unclear Bacteriuria was defined as $\geq 10^5$ colonies/ml of one pathogenic species in the catheterized specimen. Power not reported
Wille, 1993 ¹⁷²	Prospective controlled study 1,3	To compare the incidence of nosocomial bacteriuria using two closed urinary drainage systems. A simple closed drainage system containing an antireflux valve was compared with a complex drainage system containing: 1) a preconnected, coated catheter; 2) a tamper-discouraging seal at the	Patients > 16 years in neurology, urology, and gynecology departments who needed continuous bladder drainage 181	Bacteriuria: Complex drainage system vs simple drainage system: 34% vs 36%; P > 0.05 Median duration of catheterization (days): Complex drainage system vs simple drainage system: 5 vs 5; P > 0.05 Time of onset of bacteriuria: Complex drainage system vs simple drainage system ; P > 0.05	F/U unclear A catheter-associated bacteriuria was defined as $\geq 10^5$ cfu/ml Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		catheter-drainage tubing junction; 3) a drip chamber; 4) an antireflux valve; 5) a hydrophobic drainage bag vent; and 6) a povidone-iodine releasing cartridge in line with the outlet tube of the urine collection bag.			
Danchaivijitr, 1988 ¹⁷¹	Prospective controlled study 1,3,4	To compare open vs closed urinary drainage systems.	Patients admitted to medical wards who had indwelling urethral catheters 53	All UTI: Open vs closed: 13/32 vs 6/21; P > 0.05 Symptomatic UTI: Open vs closed: 7/32 vs 3/21; P > 0.05 Bacteremia: Open vs closed: 3/32 vs 1/21; P > 0.05 Death due to UTI-related infections: Open vs closed: 5/32 vs 1/21; P > 0.05 Duration of catheterization (days): Open vs closed: 5.28 vs 4.57; P > 0.05 Cost: The cost of maintaining the open was about 3 times that of the closed drainage system	F/U until discharge or death UTI not defined Power not reported
Lanara, 1988 ⁸⁹	Prospective controlled study 1,3	To study the prevalence of UTI in catheterized inpatients in relation to the type of drainage system.	Patients who had a Foley catheter inserted in the hospital that remained within the bladder for a minimum of 10 days. 532	Bacteriuria: Closed system vs open system: 68/270 vs 79/203; P < 0.01 Closed system with chlorhexidine added vs open system: 6/40 vs 79/203; P < 0.01 Closed system vs closed system with chlorhexidine added: 68/270 vs 6/40; P > 0.1 Risk factors for bacteriuria: <u>Univariate analysis:</u> All results P values Women: < 0.01 Age ≥ 60 < 0.01 Medical (vs urological patients) < 0.05 Surgical (vs urological patients) > 0.05	F/U unclear UTI defined as ≥ 10 ⁵ bacteria/ml 48 hours after catheterization in the hospital Power not reported
Islam, 1977 ⁹⁷	Prospective controlled study 1,3	To compare two urinary drainage systems: System 1 (the catheter drained via a connecting tube into a sterile disposable plastic bag with a flutter valve to prevent retrograde flow) and System 2 (connected by a sterile tube to a drainable plastic bag with an outlet tap at the bottom through which	Hospitalized patients requiring continuous catheter drainage 200	Bacteriuria: System 1 vs system 2: 23/69 vs 24/79; P > 0.05 Risk factors for bacteriuria: <u>Univariate analysis:</u> All results P values Type of operative procedure: > 0.05 Antimicrobial agents: > 0.05 Duration of catheterization: < 0.05 It was noted that infection occurred more frequently in patients whose catheters needed to be changed or whose bladders were washed with	F/U 4 months Significant bacteriuria defined as > 10 ⁵ /ml Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		chlorhexidine solution was introduced).		sterile saline. But statistical differences were not reported.	
Hardyck, 1998 ¹⁷³	Retrospective controlled study 1,3,4,6,7	To compare a non-drainable bag (NDB) system (containing a bacteria inhibiting polymer that inhibits biofilm formation) with the usual Foley drainable bag (DB) system.	Elderly home care patients 82	Mean number of symptomatic UTI: <u>All patients</u> NDB vs DB: 1.11 vs 22.14; P < 0.01 <u>After adjusting for the duration of time each device was used</u> NDB vs DB: 2.80 vs 12.1; P < 0.01 Costs: The cost for the non-hospitalization UTIs was estimated at \$1,153,665 for DBs when compared with \$57,890 for NDBs. The corresponding hospital costs were \$274,170 and \$15,540 respectively. No formal cost analyses were performed.	F/U unclear UTI was defined as bacterial counts > 10 ⁵ /ml and isolation of pathogenic organisms accompanied by fever, chills, flank pain, and strong urine odor. Power not reported
Montagnino, 1988 ¹⁷⁴	Retrospective controlled study 1,3	To compare the incidence of UTI in children managed with a closed urinary drainage system and open double diapering system (1 diaper applied normally and then sandwiching the catheter between this and a second diaper).	Children managed by an intubated urinary diversion after undergoing repair of hypospadias and/or chordee for a complication of previous urethral surgery 100	Bacteriuria: Open double diapering system vs closed drainage system: 12/50 vs 12/50; P > 0.05	F/U until catheter removal Positive urine culture defined as a catheter urine specimen with ≥ 10 ⁴ colonies per ml Power not reported
Madeo, 2005 ¹⁷⁵	Prospective pre-post study 1,3,4,6,7	To determine whether the use of a pre-connect urinary catheter system reduced the incidence of nosocomial UTI.	Patients in medical wards 205	Symptomatic UTI (per 1000 catheter days): Pre-connect catheter vs conventional catheter: 22.4 vs 37.8; IRR (95% CI) = 0.59 (0.35-0.99) Median number of days to symptomatic UTI: Pre-connect catheter vs conventional catheter: 6 vs 10; P = 0.045	F/U during 2 six-month surveillance periods UTI based on CDC definitions Power not reported
Leone, 2001 ¹⁷⁶	Prospective pre-post study 1,3	To compare the rate of acquisition of bacteriuria between a complex closed drainage system and a two-chamber drainage system. The two chamber drainage system used a Foley catheter connected to an output measure recipient and a urine collection bag. The complex drainage system consisted of a preconnected coated latex catheter, a tamper-discouraging seal at the catheter	ICU patients who had an initial culture free of bacterial growth and an indwelling urethral catheter for > 48 hours. 224	Bacteriuria: Complex vs two-chamber: 15/111 vs 12/113; P > 0.05 Onset of bacteriuria (days after catheterization): Complex vs two-chamber: 13 vs 14; P > 0.05 Duration of catheterization (days): Complex vs two-chamber: 19 vs 19; P > 0.05 ICU length of stay (days): 22 vs 25; P > 0.05 Risk factors for bacteriuria: <u>Univariate analysis:</u> All results P values Duration of catheterization: <0.05	F/U for until a day after removal of the catheter. UTI defined as ≥ 10 ⁵ cfu/ml

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		drainage tubing junction, a drip chamber, an anti-reflux valve, a drainage bag vent, and a povidone-iodine releasing cartridge at the drain port of the urine collection bag.		ICU length of stay: <0.05 Women: < 0.05	
Blenkharn, 1985 ¹⁷⁷	Prospective pre-post study 1,3	To compare two different kinds of closed urinary drainage systems: a conventional system consisting of a urine meter and a chamber connected to a re-usable collecting bag and a test system (Urofix 500) consisting of a similar urine meter and a chamber with 4 interconnected compartments connected to a single-use disposable collecting bag. It further had a drip chamber with baffle plate to protect the catheter connection tube from retrograde transmission of organisms.	All patients > 16 years admitted to a general ICU 1088	Bacteriuria: Test system vs conventional system: 70/576 vs 137/512; P < 0.01 Duration of catheterization (days): Test system vs conventional system: 2.4 vs 2.7; P > 0.05	F/U unclear Counts of bacteria of a single species $> 10^5$ /ml or of two or more species, one of which was present in numbers $> 10^4$ /ml was considered significant Power not reported
Drach, 1971 ¹⁷⁸	Prospective controlled study 1,3	To evaluate the effect of antibiotic prophylaxis and a closed drainage system on catheter-induced infection.	Post-prostatectomy patients 113	Cystitis: <u>Systemic cephaloridine/local neomycin-polymyxin plus closed catheter system vs systemic cephaloridine plus open catheter system:</u> At catheter removal: 1/57 vs 14/32; P < 0.01 At discharge: 2/57 vs 8/32; P < 0.01 At 1 month: 3/57 vs 9/32; P < 0.01 <u>Systemic cephaloridine/local neomycin-polymyxin plus closed catheter system vs no prophylaxis plus open catheter system:</u> At catheter removal: 1/57 vs 9/24; statistical differences were not reported At discharge: 2/57 vs 13/24; statistical differences were not reported At 1 month: 3/57 vs 15/24; statistical differences were not reported <u>Systemic cephaloridine plus open catheter system vs no prophylaxis plus open catheter system:</u> At catheter removal: 14/32 vs 9/24; P > 0.05 At discharge: 8/32 vs 13/24; P > 0.05 At 1 month: 9/32 vs 15/24; P < 0.05	F/U 1 month Cystitis was the infection outcome but was not clearly defined Power not reported
Platt, 1989 ¹⁸⁰	Economic analysis 3,4,5,6	To assess the implications of four strategies for catheter care on the number of infections, the number of deaths and the cost of hospitalization: (1) antimicrobial	Not specifically defined; implicit for patients requiring catheterization Not applicable	Risks and costs per patient: <u>1. Antibiotic prophylaxis for all patients</u> Infection: 0.07 Death: 0.02 Cost: \$37	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		<p>prophylaxis for all catheterized patients; (2) use of catheters with sealed junctions for all patients; (3) use of catheters with sealed junctions only for patients who are not receiving antimicrobial prophylaxis for some other reason; and (4) no antibiotic prophylaxis and no junction seals.</p> <p>Costs and event rates were obtained from the published literature.</p>		<p><u>2. Sealed junction catheter for all patients</u> Infection: 0.08 Death: 0.02 Cost: \$42</p> <p><u>3. Sealed junction catheter if no antibiotic</u> Infection: 0.08 Death: 0.02 Cost: \$41</p> <p><u>4. No antibiotic prophylaxis and no junction seals</u> Infection: 0.11 Death: 0.02 Cost: \$55</p> <p>Sensitivity analysis: The overall cost of each life saved by routine use of sealed catheters compared with selective use of these catheters was \$4793. This cost was \$1798 in a high risk population whose risk of death without infection was 5% (and whose risk of death with infection was 12.84%). However, routine use of sealed junction catheters was less expensive than selective use of those catheters if their extra cost was less than \$3.13 Sensitivity analysis indicated that the overall cost of the antibiotic prophylaxis strategy exceeded that of routine use of sealed junction catheters for costs of antibiotic greater than \$35, as was the case for most parenteral antibiotic regimens. When there was no extra cost of sealed junction catheters, their use was less expensive than the oral prophylaxis strategy if the total cost of oral prophylaxis was greater than \$15 For costs of infection between \$25 and \$114, the strategy of selective use of sealed junction catheters was least expensive. For costs greater than \$114, oral prophylaxis was least expensive. For costs greater than \$641, routine use of sealed junction catheters was the next least expensive after oral prophylaxis</p>	

GRADE Table 2B

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
Silver-coated catheter vs control	Symptomatic UTI*	2 OBS 160,166	Significantly decreased risk with silver-alloy catheters in 1 OBS ¹⁶⁶ . Statistical differences were not reported in 1 OBS ¹⁶⁰ .	Low	0	0	0	0	0	0	0	0	Low	Low
	Bacteriuria/unspecified UTI*	3 SR ¹³⁷⁻¹³⁹ 7 OBS 82,159,161-163,165	Significantly decreased risk with silver alloy catheters in 1 SR ¹³⁷ and 1 OBS ¹⁶² . There was a possible decrease in risk in 1 OBS ¹⁶⁵ . 1 SR found a significantly decreased risk with silver oxide catheters in women ¹³⁷ . 2 SRs that did not pool data found a decreased risk with silver-coated catheters, particularly when compared with latex rather than silicone catheters ¹³⁸ , or in studies of poorer quality ¹³⁹ . We performed meta-analyses for silver-alloy catheters using the data from the most recent SR ¹³⁷ . We found that silver-alloy catheters significantly decreased the risk of bacteriuria when compared with latex catheters, but not when compared with silicone catheters both at <1 week and at > 1 week. The results were robust to inclusion or exclusion of non peer-reviewed studies. No significant differences were found in 3 OBS ^{82,161,163} . Statistical differences were not reported in 1 OBS ¹⁵⁹ .	High	0	0	-1	0	0	0	0	0	0	Moderate
	Time to bacteriuria	1 OBS ¹⁶¹	No significant differences were found, although there was a suggestion of decrease.	Low	0	0	0	-1	0	0	0	0	Very Low	
	Bacteremia	2 OBS ^{82,159}	No significant differences were found in 1 OBS ⁸² . Statistical differences were not reported in the other OBS ¹⁵⁹ .	Low	0	0	0	-1	0	0	0	0	Very Low	
	Duration of catheterization	4 OBS 86,160,161,164	Significantly decreased risk with silver-oxide catheters in 1 OBS ⁸⁶ . No significant differences were found in 1 OBS ¹⁶¹ and statistical differences were not reported in 2 OBS ^{160,164} .	Low	-1	0	0	0	0	0	0	0	Very Low	
	Antimicrobial resistance*	1 SR ¹³⁸ 1 OBS ¹⁶²	No antimicrobial resistance was found with the use of silver coated catheters.	High	-1	0	0	-1	0	0	0	0	Low	
	Urethral discharge*	1 SR ¹³⁷ 1 OBS ¹⁶⁴	No significant differences were found in the SR ¹³⁷ . Statistical differences were not reported in the OBS ¹⁶⁴ .	High	-1	0	0	-1	0	0	0	0	Low	
	Pain/itching/burning*	1 SR ¹³⁷ 1 OBS ¹⁶⁴	No significant differences were found in the SR ¹³⁷ . Statistical differences were not reported in the OBS ¹⁶⁴ .	High	0	0	-1	-1	0	0	0	0	Low	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
Nitrofurazone-impregnated catheters vs control	Symptomatic UTI*	1 SR ¹³⁷	No significant differences were found.	High	-1	0	0	-1	0	0	0	0	Low	Low
	Bacteriuria/unspecified UTI*	2 SR ^{137,138}	Significantly decreased risk in 1 SR ¹³⁷ . No significant differences were found in the other SR ¹³⁸ .	High	0	0	-2	0	0	0	0	0	Low	
	Antimicrobial resistance*	1 SR ¹³⁸	No antimicrobial resistance was found.	High	0	0	-2	0	0	0	0	0	Low	
Hydrophilic coated catheter vs control	Symptomatic UTI*	3 RCT ^{144,145,147} 1 OBS ¹⁶⁹	Significantly decreased risk in 1 RCT of long term intermittent catheterization ¹⁴⁴ . No significant differences were found in 1 RCT ¹⁴⁷ and 1 OBS ¹⁶⁹ . Statistical differences were not reported in 1 RCT ¹⁴⁵ .	High	-1	-1	0	0	0	0	0	0	Low	Very Low
	Bacteriuria/unspecified UTI*	1 SR ¹³⁷ 4 RCT ^{144,145,147,148} 1 OBS ¹⁶⁹	Significantly decreased risk in 1 RCT ¹⁴⁵ . No significant differences were found in 1 SR ¹³⁷ , 3 RCTs ^{144,147,148} and 1 OBS ¹⁶⁹ .	High	-1	-1	-1	0	0	0	0	0	Very Low	
	Hematuria*	4 RCT ¹⁴⁴⁻¹⁴⁷ 1 OBS ¹⁶⁹	Significantly decreased risk in 2 RCTs ^{146,147} . No significant differences were found in 2 RCTs ^{144,145} and 1 OBS ¹⁶⁹ .	High	-1	-1	0	0	0	0	0	0	Low	
	Urethritis	1 OBS ¹⁶⁹	No significant differences were found.	Low	0	0	0	-1	0	0	0	0	Very Low	
	Patient satisfaction*	2 RCT ^{144,146}	No significant differences were found in 1 RCT ¹⁴⁴ . Statistical differences were not reported in 1 RCT ¹⁴⁶ . However, there was a suggestion of increased satisfaction in both.	High	0	0	0	-1	0	0	0	0	Moderate	
	Pain/discomfort*	2 RCT ^{145,146}	Significantly decreased risk in both RCTs.	High	0	0	0	-1	0	0	0	0	Moderate	
	Dysuria	1 RCT ¹⁴⁶	No significant differences were found.	High	0	0	-1	-1	0	0	0	0	Low	
	Stricture	1 RCT ¹⁴⁵	No significant differences were found.	High	0	0	-1	-1	0	0	0	0	Low	
Closed vs open	Symptomatic UTI*	1 OBS ¹⁷¹	No significant differences were found in 1 OBS ¹⁷¹	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
drainage system	Bacteriuria*	1 OBS ⁸⁹	Significantly decreased risk.	Low	-1	0	0	0	0	0	0	0	Very Low	
	Bacteremia*	1 OBS ¹⁷¹	No significant differences were found.	Low	0	0	0	-1	0	0	0	0	Very Low	
	Mortality*	1 OBS ¹⁷¹	No significant differences were found.	Low	0	0	0	-1	0	0	0	0	Very Low	
	Duration of catheterization	1 OBS ¹⁷¹	No significant differences were found.	Low	0	0	0	-1	0	0	0	0	Very Low	
Complex vs simple drainage system	Bacteriuria*	4 RCT ^{150-152,154} 3 OBS ^{172,176,177}	Significantly decreased risk in 2 RCTs ^{152,154} and 1 OBS ¹⁷⁷ , all of which were published prior to 1990. No significant differences were found in 2 RCTs ^{150,151} and 2 OBS ^{172,176} .	High	0	-1	-1	0	0	0	0	0	Low	
	Time to bacteriuria	2 RCT ^{150,152} 2 OBS ^{172,176}	Significantly decreased risk in 1 RCT ¹⁵⁰ . No significant differences were found in 1 RCT ¹⁵² and 2 OBS ^{172,176} .	High	0	-1	-1	0	0	0	0	0	Low	
	Length of ICU stay	1 RCT ¹⁵⁰ 1 OBS ¹⁷⁶	Significantly decreased risk in 1 RCT ¹⁵⁰ . No significant differences were found in 1 OBS ¹⁷⁶ .	High	0	-1	-1	0	0	0	0	0	Low	
	Duration of catheterization	2 RCT ^{150,151} 3 OBS ^{172,176,177}	Significantly decreased risk in 1 RCT ¹⁵⁰ . No significant differences were found in 1 RCT ¹⁵¹ and 3 OBS ^{172,176,177} .	High	0	-1	-1	0	0	0	0	0	Low	
	Urethral discharge	1 RCT ¹⁵⁴	No significant differences were found.	High	-1	0	0	-1	0	0	0	0	Low	
	Incontinence	1 RCT ¹⁵⁴	No significant differences were found.	High	-1	0	0	-1	0	0	0	0	Low	
	Pre-connected/Sealed junction catheter vs control	Symptomatic UTI*	1 RCT ¹⁵³ 1 OBS ¹⁷⁵	Significantly decreased risk in 1 OBS ¹⁷⁵ . No significant differences were found in 1 RCT ¹⁵³ .	High	-1	-1	0	0	0	0	0	Low	Low
		Bacteriuria*	3 RCT	Significantly decreased in patients not receiving antibiotics in 1 RCT ¹⁵⁶ .	High	-1	0	0	0	0	0	0	Moderate	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders	
		64,153,156	No significant differences were found in 2 RCTs ^{64,153} .										Moderate
	Mortality	2 RCT ^{64,156}	Significantly decreased in patients not receiving antibiotics in 1 RCT ¹⁵⁶ . No significant differences were found in 1 RCT ⁶⁴ .	High	-1	0	0	0	0	0	0	0	
	Time to symptomatic UTI	1 OBS ¹⁷⁵	Significantly decreased.	Low	0	0	0	0	0	0	0	0	
	Duration of catheterization	3 RCT 64,153,156	No significant differences were found.	High	-1	0	0	0	0	0	0	0	
Catheter valve vs catheter bag	Bacteriuria/unspecified UTI*	1 SR ¹⁴⁰	No significant differences were found.	High	0	0	0	-1	0	0	0	0	Moderate
	Pain/bladder spasms*	1 SR ¹⁴⁰	No significant differences were found.	High	0	0	0	-1	0	0	0	0	Moderate
	Incontinence	1 SR ¹⁴⁰	No significant differences were found.	High	0	0	0	-1	0	0	0	0	Moderate
	Patient satisfaction*	1 SR ¹⁴⁰	Significantly increased for catheter valve.	High	0	0	0	-1	0	0	0	0	Moderate

* These modifiers can impact the GRADE by 1 or 2 points

Study Quality Assessment Table 2B

Study	Systematic Review								Randomized Controlled Trial								Observational Controlled Study				Economic analysis								
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented
2B.1.a Silver-coated catheter																													
Schumm, 2008 ¹³⁷	x	x	x	x	x	x	x	x																					
Phipps, 2006 ³⁷	x	x	x	x	x	x	x	x																					
Johnson, 2006 ¹³⁸	x	x	x	x	x	x	x	x																					
Niel-Weise, 2002 ¹³⁹	x	x	x	x	x	x	x	x																					
Reiche, 2000 ¹⁴²										x																			
Schaeffer, 1988 ¹⁴³									x																				
Seymour, 2006 ¹⁵⁹																													
Srinivasan, 2006 ⁸²																			x	x									
Gentry, 2005 ¹⁶⁰																		x	x	x									
Madeo, 2004 ¹⁶¹																		x	x	x									
Rupp, 2004 ¹⁶²																		x	x	x									
Lai, 2002 ¹⁶³																		x	x	x									

Study	Systematic Review								Randomized Controlled Trial								Observational Controlled Study				Economic analysis									
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented	6. Sensitivity analyses performed
Newton, 2002 ¹⁶⁶	x	x	x	x	x	x	x	x										x	x	x	x	x	x	x	x	x	x	x	x	x
Bologna, 1999 ¹⁶⁵																														
Johnson, 1990 ⁸⁶																														
Akiyama, 1979 ¹⁶⁴																														
Plowman, 2001 ¹⁷⁹																														
Saint, 2000 ¹⁸¹																														
2B.1.b. Nitrofurazone-impregnated catheter																														
Schumm, 2008 ¹³⁷	x	x	x	x	x	x	x	x																						
Johnson, 2006 ¹³⁸	x	x	x	x	x	x	x	x																						
2.B.2. Miscellaneous antimicrobial catheters																														
Schumm, 2008 ¹³⁷	x	x	x	x	x	x	x	x											x											
Butler, 1968 ¹⁶⁷																			x	x										
Mooro, 1966 ¹⁶⁸																			x	x										
2B.3. Hydrophilic catheters																														
Schumm, 2008 ¹³⁷	x	x	x	x	x	x	x	x																						

Study	Systematic Review								Randomized Controlled Trial								Observational Controlled Study				Economic analysis								
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented
De Ridder, 2005 ¹⁴⁴	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Stensballe, 2005 ¹⁴⁶																													
Cindolo, 2004 ¹⁴⁵																													
Vapnek, 2003 ¹⁴⁷																													
Monson, 1974 ¹⁴⁸																													
Pachler, 1999 ¹⁶⁹									x										x	x	x								

2B.4. Other Catheter Types

Phipps, 2006 ³⁷	x	x	x	x	x	x	x	x	x																			
Shafik, 1993 ¹⁴⁹																												
Chen, 2005 ¹⁷⁰																			x	x	x							

2B.5. Drainage Systems

Phipps, 2006 ³⁷	x	x	x	x	x	x	x	x	x																			
van den Eijkel, 2006 ¹⁴⁰	x	x	x	x	x	x	x	x	x																			
Leone, 2003 ¹⁵⁰																												
Huth, 1992 ⁶⁴																												
Classen, 1991 ¹⁵¹																												

Study	Systematic Review								Randomized Controlled Trial								Observational Controlled Study				Economic analysis								
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented
Al-Juburi, 1989 ¹⁵²	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
DeGroot-Kosolcharoen, 1988 ¹⁵³																													
Klarskov, 1986 ¹⁵⁴	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Platt, 1983 ¹⁵⁶																													
Keys, 1979 ¹⁵⁵	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Monson, 1977 ¹⁵⁷	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Cleland, 1971 ¹⁵⁸																													
Wille, 1993 ¹⁷²																													
Danchavijitr, 1988 ¹⁷¹																													
Lanara, 1988 ⁸⁹																													
Islam, 1977 ⁹⁷																													
Hardyck, 1998 ¹⁷³																													
Montagnino, 1988 ¹⁷⁴																													
Madeo, 2005 ¹⁷⁵																													
Leone, 2001 ¹⁷⁶																													

Study	Systematic Review								Randomized Controlled Trial								Observational Controlled Study								Economic analysis							
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented	6. Sensitivity analyses performed		
Blenkharn, 1985 ¹⁷⁷																		x	x													
Drach, 1971 ¹⁷⁸																		x	x													
Platt, 1989 ¹⁸⁰																		x	x													

2C. What are the risks and benefits associated with different catheter management techniques?

TABLE 2C: CATHETER MANAGEMENT TECHNIQUES

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
2C.1. Antibiotic Prophylaxis					
Short-term					
Niel-Wiese, 2006 ¹⁸²	Systematic review 1,2,3,4,5,6,7,8	To determine the effect of antibiotic policies for prevention of urinary tract infections, complications, quality of life, and cost effectiveness.	All randomized and quasi-randomized trials comparing antibiotic policies for short-term (up to and including 14 days) catheterization in adults 6 RCTs	<p><i>All results RR (95% CI) unless otherwise noted</i></p> <p><i>(1) Antibiotic prophylaxis vs giving antibiotics when clinically indicated:</i></p> <p>Symptomatic UTI: Prophylaxis vs control (1 study): 0.20 (0.06-0.66)</p> <p><i>(2) Antibiotic prophylaxis vs giving antibiotics when microbiologically indicated:</i></p> <p>Unspecified UTI in surgical patients: Prophylaxis vs control (2 studies): Results were not pooled: 0.12 (0.01-0.90); 0.21 (0.13-0.33)</p> <p>Unspecified UTI in urological-surgery patients: Prophylaxis vs control (1 study): 0.15 (0.02-1.13)</p> <p>Unspecified UTI in non-surgical patients: Receiving prophylactic antibiotics the day of catheter insertion vs not (2 studies): 0.22 (0.13-0.39)</p> <p>Receiving prophylactic antibiotics during bladder drainage vs not (1 study): 0.93 (0.51-1.69)</p> <p>Receiving prophylactic antibiotics the day of catheter insertion vs the day of bladder drainage (1 study): 0.29 (0.09-0.91)</p> <p>Pyuria: Prophylaxis vs control (1 study): 0.25 (0.14-0.47)</p> <p>Adverse drug reactions: No data</p> <p>Antibiotic resistance: No data</p>	<p>Clinically indicated: e.g., pain, fever</p> <p>Microbiologically indicated: e.g., growth of bacteria from a specimen of urine in the absence of clinical symptoms, density of bacteria taken as positive as defined by the trials</p>
Phipps, 2006 ³⁷	Systematic review	To determine the optimal way to manage urinary catheters	Randomized and quasi-randomized trials	<i>Note: All results are RR (95% CI) unless otherwise noted</i>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
	1,2,3,4,5,6,7,8	following urogenital surgery in adults.	39 RCTs	<p>1. Using a urinary catheter vs not using a urinary catheter</p> <p>Retention of urine (1 study): 0.12 (0.03-0.47) UTI (4 studies): 1.35 (0.75-2.45) Recatheterization (3 studies): 0.32 (0.14-0.70) Post-op urethral stricture (1 study): 1.14 (0.90-1.44) Post-op hematuria (1 study): 0.73 (0.40-1.33)</p> <p>2. Urethral catheterization vs suprapubic catheterization</p> <p>UTI: Heterogeneous results, not combined. Of four trials, two suggested a moderate increase, one a large increase and one a large decrease. Recatheterization (2 studies): 3.66 (1.41-9.49) Post-op hematuria (1 study): 5.00 (0.21-116.31) Length of hospital stay in days (1 study) [WMD (95% CI)]: 1.10 (0.30-1.90) Catheter lockage or bypassing [OR (95% CI)] (2 studies): 0.20 (0.02-1.72)</p> <p>3. One type of catheter vs another type of catheter</p> <p>UTI: Urethral Foley catheter with extra drainage hole vs unmodified Foley catheter (1 study): 0.40 (0.15-1.04) Positive urine culture: Silver-coated Bardex catheters vs latex catheters (1 study): 0.53 (0.20-1.45)</p> <p>4. One type of catheter management vs another</p> <p>Retention of urine: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.99 (0.06-15.54) Dysuria: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.99 (0.06-15.54) Symptomatic UTI: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.61 (0.33-1.14) Bacteriuria/unspecified UTI: Cefotaxime 1 hour prior to catheter removal vs none (1 study): 0.08 (0.00-1.30) Neomycin/Sulfamethiazole vs placebo (1 study): 0.18 (0.06-0.55) Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 1.06 (0.70-1.51) Recatheterization: Neomycin/Sulfamethiazole vs placebo (1 study): 0.50 (0.24-1.04)</p> <p>5. Larger diameter catheter vs Smaller diameter catheter</p> <p>No trials found</p> <p>6. Bladder irrigation</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>No trials found</p> <p>7. Shorter-duration vs longer-duration catheter</p> <p>Retention of urine: 1 day vs 3 days (1 study): 0.80 (0.38-1.69) 1-2 days vs until urine clear (1 study): 1.02 (0.07-15.87) 1 day vs 2 days (1 study): 4.64 (0.23-94.28) 3 days vs 28 days (1 study): 3.00 (0.13-69.52)</p> <p>Post-op urethral stricture: < 1 week vs 2 weeks (2 studies): 1.23 (0.82-1.84) 3 days vs 28 days (1 study): 1.00 (0.73-1.36)</p> <p>UTI: Heterogeneous results, not combined. Shorter duration had lower risk of UTIs but the results were significant in only 1 trial 1 day vs 3 days (3 studies): 0.50 (0.29-0.87)</p> <p>Recatheterization: 1 day vs 2 days (1 study): 1.03 (0.23-4.71) 1 day vs 3 days (2 studies): 1.04 (0.36-3.01) 1 day vs 5 days (1 study): 4.55 (1.68-12.37) 4-6 days vs 14 days (1 study): 1.86 (0.14-25.38) 1-2 days vs until urine clear (2 studies): 0.72 (0.24-2.20)</p> <p>Post-op hematuria: 1-2 days vs until urine clear (1 study): 2.04 (0.19-21.81) 1 day vs 2 days (2 studies): 1.16 (0.34-3.90)</p> <p>Urinary leakage or incontinence: 1-2 days vs until urine clear (2 studies): 0.43 (0.07-2.88)</p> <p>8. Clamp and release vs free catheter drainage:</p> <p>UTI (1 study): 4.00 (1.55-10.29)</p> <p>Delay in return to normal bladder function (1 study): 2.50 (1.16-5.39)</p> <p>9. Catheter removal at one time of day vs another time of day</p> <p>UTI: 12 am vs 6 am (1 study): 1.31 (0.65-2.66)</p> <p>Recatheterization: 12 am vs 6 am (4 studies): 0.61 (0.34-1.12) 6-7 am vs 10-11 pm (1 study): 1.36 (0.32-5.77)</p> <p>Time to first void in hours [WMD (95% CI)]: 12 am vs 6 am (1 study): 0.60 (-0.96 to 2.16)</p> <p>Volume of first void in ml [WMD (95% CI)]: 12 am vs 6 am (1 study): 53.00 (4.27-101.73)</p> <p>10. Trial of void protocol vs none</p> <p>No trials found</p> <p>11. Prefilling bladder prior to catheter removal vs removal without prefilling</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Recatheterization [OR (95% CI)] (1 study): 4.52 (0.79-25.97)</p> <p>Discharge on day of catheter removal (1 study): 1.36 (0.47-3.91)</p>	
Esposito, 2006 ¹⁸⁵	RCT 1,2,7,9	To evaluate the efficacy of levofloxacin 250 mg oral daily, placebo one tablet oral daily, and ciprofloxacin 500 mg oral twice daily in preventing bacteriuria in postsurgical catheterized patients.	Patients undergoing a planned surgical intervention requiring catheterization with an estimated duration of between 3 and 14 days 82	<p>Symptomatic UTI: <u>At end of prophylaxis:</u> Levofloxacin vs placebo: 0/25 vs 0/25; P = NS Ciprofloxacin vs placebo: 0/21 vs 0/25; P = NS</p> <p><u>At final follow-up:</u> Levofloxacin vs placebo: 0/18 vs 1/20; P = NS Ciprofloxacin vs placebo: 0/19 vs 1/20; P = NS</p> <p>Bacteriuria: <u>At end of prophylaxis:</u> Levofloxacin vs placebo: 2/25 vs 4/25; P = NS Ciprofloxacin vs placebo: 0/21 vs 4/25; P = NS</p> <p><u>At final follow-up:</u> Levofloxacin vs placebo: 0/18 vs 1/20; P = NS Ciprofloxacin vs placebo: 0/19 vs 1/20; P = NS</p> <p>Pyuria: <u>At end of prophylaxis:</u> Levofloxacin vs placebo: 0/25 vs 3/25; P = NS Ciprofloxacin vs placebo: 0/21 vs 3/25; P = NS</p> <p><u>At final follow-up:</u> Levofloxacin vs placebo: 1/18 vs 2/20; P = NS Ciprofloxacin vs placebo: 0/19 vs 2/20; P = NS</p> <p>Nosocomial infections: <u>At final follow-up:</u> Levofloxacin vs placebo: 0/18 vs 1/20; P = NS Ciprofloxacin vs placebo: 0/19 vs 1/20; P = NS</p> <p>Drug-related adverse events: Levofloxacin vs placebo: 0/28 vs 0/27; P = NS Ciprofloxacin vs placebo: 0/27 vs 0/27; P = NS</p> <p>Urinary retention: Levofloxacin vs placebo: 1/28 vs 0/27; P = NS Ciprofloxacin vs placebo: 0/27 vs 0/27; P = NS</p>	F/U 4-6 weeks after end of treatment The study was said to be double-blind for the levofloxacin group but single blind for the ciprofloxacin group Though two different definitions of bacteriuria were used in the study, $> 10^5$ cfu/ml was used as the definition for purposes of the review Pyuria was defined as ≥ 10 leukocytes/ mm ³ or ≥ 3 leukocytes/microscopic field Symptomatic UTI defined based on CDC criteria 40 patients for each treatment group were needed to detect a difference of at least 35% between levofloxacin and placebo with a power of 80%.

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Duration of hospitalization (days):</p> <p><u>Pre-surgery:</u> Levofloxacin vs placebo: 3.9 vs 5.9; statistical differences not reported Ciprofloxacin vs placebo: 3.3 vs 5.9; statistical differences not reported</p> <p><u>Post-surgery:</u> Levofloxacin vs placebo: 6.0 vs 7.6; statistical differences not reported Ciprofloxacin vs placebo: 7.4 vs 7.6; statistical differences not reported</p> <p>Duration of catheterization (days): Levofloxacin vs ciprofloxacin vs placebo: 4.9 vs 4.7 vs 5.1; P>0.05</p>	
Rogers, 2004 ⁶¹	RCT 1,2,3,4,5,6	To evaluate the efficacy of antibiotic prophylaxis with nitrofurantoin 100 mg.	<p>Patients undergoing surgical correction of stress urinary incontinence and/or pelvic organ prolapse with suprapubic catheter placement</p> <p>435</p>	<p>Symptomatic UTI:</p> <p><u>At suprapubic catheter removal:</u> Nitrofurantoin vs placebo: 7.2% vs 19.8%; P < 0.01</p> <p><u>During the 6-8 week postoperative period:</u> Nitrofurantoin vs placebo: 18.9% vs 32.6%; P < 0.01</p> <p><u>At the 6-8 week post-op visit:</u> Nitrofurantoin vs placebo: 1.8% vs 5.4%; P = 0.10</p> <p>Bacteriuria:</p> <p><u>At suprapubic catheter removal:</u> Nitrofurantoin vs placebo: 31.7% vs 50.5%; P < 0.01</p> <p><u>During the 6-8 week postoperative period:</u> Nitrofurantoin vs placebo: 46.0% vs 61.0%; P < 0.01</p> <p><u>At the 6-8 week post-op visit:</u> Nitrofurantoin vs placebo: 16.8% vs 23.9%; P = 0.11</p> <p>Intraoperative complications: Nitrofurantoin vs placebo: 13.0% vs 13.0%; P = 1.00</p> <p>Postoperative complications: Nitrofurantoin vs placebo: 1.0% vs 13.0%; P = 0.22</p> <p>Mortality:</p>	<p>F/U 6-8 weeks post-op</p> <p>Symptomatic UTI defined as symptoms with > 10⁵ cfu/ml in urine.</p> <p>A total of 438 women were required to demonstrate a 50% decrease in bacteriuria rate with 80% power and an alpha of 0.05</p>

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Nitrofurantoin vs placebo: 0.0% vs 1.0%; P = 0.50</p> <p>Readmission: Nitrofurantoin vs placebo: 6.3% vs 4.7%; P = 0.33</p> <p>Length of surgery (minutes): Nitrofurantoin vs placebo: 218 vs 201; P = 0.01</p> <p>Length of stay: Nitrofurantoin vs placebo: P > 0.05 (group-wise data not provided)</p> <p>Duration of catheterization (days): Nitrofurantoin vs placebo: 11.0 vs 10.5; P = 0.64</p> <p>Risk factors <u>Univariate analysis</u> (All results P values)</p> <p><i>Symptomatic UTI:</i> No other postoperative infections: 0.04 Duration of catheterization: < 0.01</p> <p><i>Bacteriuria:</i> Preoperative mobility of the urethrovesical junction: ≤ 0.02 Blood loss: ≤ .02 Duration of catheterization: ≤ 0.02</p> <p><i>Undefined UTI:</i> Cystocele stage/grade: P = NS High postvoid residual (> 100 cc): P = NS BMI: P = NS Postoperative complications: P = NS Intercourse: P = NS Patient adherence: P = NS Last post-void residual before SPC removal: P = NS</p>	
Wazait, 2004 ¹⁸⁶	RCT 1,2,3,4,5,6	To assess if a 48-hour course of ciprofloxacin (500 mg every 12 hours) starting 2 hours before catheter removal decreased the incidence of subsequent UTI.	Patients who had a urethral catheter in-situ for 2-7 days. 48	<p>Symptomatic UTI: Ciprofloxacin vs placebo: 2/25 vs 1/23; P = NS</p> <p>Bacteriuria: Ciprofloxacin vs placebo: 4/25 vs 3/23; P = NS</p> <p>Mean duration of catheterization (days): 4.0 vs 4.5; P = NS</p>	<p>F/U 14 days after catheter removal</p> <p>A catheter specimen of urine was defined as positive if 10^2 cfu/ml were present. A midstream urine sample was defined as positive if $\geq 10^5$ cfu/ml urine were present in asymptomatic patients or if $\geq 10^4$ cfu/ml urine were present in symptomatic patients.</p>

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
					Power not reported
Lukkarinen, 1997 ¹⁸⁷	RCT 1,7	To determine whether ciprofloxacin and ceftazidime were equally effective in preventing infective complications in patients undergoing TURP. Dosage regimens were 500 mg of ciprofloxacin orally twice daily or 1 g of ceftazidime IV twice daily. Antibiotic medication was started on the evening preceding the operation and continued until the day following the removal of the catheter, for total 3 days. The catheter was removed on the second postoperative day.	Patients admitted for TURP with urinary retention and an indwelling catheter. 118	Bacteriuria <u>At catheter removal:</u> Ciprofloxacin vs Ceftazidime: 2/35 vs 1/42; P = NS <u>At 1 month:</u> Ciprofloxacin vs Ceftazidime: 5/35 vs 7/42; P = NS Length of stay (days): Ciprofloxacin vs Ceftazidime: 6.5 vs 6.6; statistical differences were not reported Septicemia: Ciprofloxacin vs Ceftazidime: 0/35 vs 0/42; P = NS Death: Ciprofloxacin vs Ceftazidime: 0/35 vs 0/42; P = NS Tamponade: Ciprofloxacin vs Ceftazidime: 4/35 vs 3/42; statistical differences were not reported Changed catheter: Ciprofloxacin vs Ceftazidime: 2/35 vs 0/42; statistical differences were not reported Fever: Ciprofloxacin vs Ceftazidime: 1/35 vs 1/42; statistical differences were not reported Mean duration of operation (minutes): Ciprofloxacin vs Ceftazidime: 56 vs 52; P = NS	F/U 1 month Bacteriuria was defined as $\geq 10^5$ cfu/ml Power not reported
Lukkarinen, 1996 ¹⁸⁸	RCT 1,2	To compare the efficacy of 250 mg of ciprofloxacin twice daily and 500 mg/160 mg of sulfadiazine-trimethoprim twice daily in the prevention of UTI. Antibiotic medication was started on the evening preceding the operation and continued up to the day following the removal of the catheter.	Patients admitted for elective TURP with indwelling catheter 398	Bacteriuria <u>At catheter removal:</u> Ciprofloxacin vs sulfadiazine-trimethoprim: 7/220 vs 15/178; P < 0.05 <u>At 1 month:</u> Ciprofloxacin vs sulfadiazine-trimethoprim: 8/220 vs 13/178; P = NS Length of stay (days): Ciprofloxacin vs sulfadiazine-trimethoprim: 6.5 vs 6.6; statistical differences were not reported Tamponade: Ciprofloxacin vs sulfadiazine-trimethoprim: 26/220 vs 23/178; statistical differences were not reported Changed catheter: Ciprofloxacin vs sulfadiazine-trimethoprim: 8/220 vs 3/178; statistical differences were not reported	F/U 1 month Urinary culture was positive if the concentration of bacteriuria was $> 10^5$ /ml of midstream urine Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Fever: Ciprofloxacin vs sulfadiazine-trimethoprim: 10/220 vs 3/178; statistical differences were not reported</p> <p>Mean duration of operation (min): Ciprofloxacin vs sulfadiazine-trimethoprim: P = NS</p>	
Vollaard, 1989 ¹⁸⁹	RCT 1,2,3,5,7	To evaluate the utility of antibiotic prophylaxis using a suspension of 200 mg norfloxacin and 500 mg amphotericin B as a 10 ml suspension in preventing bacteriuria.	Female patients with hip fractures needing medium term transurethral catheterization 58	<p>Time to bacteriuria: 50% of patients in the placebo group were bacteriuric by day 7, compared with day 17 in the norfloxacin group (P < 0.01)</p> <p>Bacteriuria: Test vs placebo: 11/17 vs 12/17; statistical differences were not reported</p> <p>Gram negative bacteriuria: Test vs placebo: 0/17 vs 6/17; statistical differences were not reported</p> <p>Median duration of catheterization (days): Test vs placebo: 14 vs 23; P = 0.07</p>	F/U ~ 2-3 weeks A colony count $\geq 10^3$ cfu per ml was used to diagnose bacteriuria Power not reported
Stricker, 1988 ⁶⁰	RCT 1,7,8	To assess the efficacy of antibiotic prophylaxis (1 g ampicillin and 80 mg gentamicin preoperatively).	Patients with sterile urine undergoing TURP; postoperative catheters were inserted 100	<p>Undefined UTI: Antibiotic vs control: 7/39 vs 8/54; P = NS</p> <p>Fever: Antibiotic vs control: 4/39 vs 1/54; P = NS</p> <p>Rigor: Antibiotic vs control: 1/39 vs 5/54; P = NS</p> <p>Orchitis: Antibiotic vs control: 0/39 vs 1/54; P = NS</p> <p>Positive blood culture: Antibiotic vs control: 0/39 vs 0/54; P = NS</p> <p>Total infective complications: Antibiotic vs control: 7/39 vs 9/54; P = NS</p> <p>Number of patients receiving therapeutic antibiotics: Antibiotic vs control: 6/39 vs 9/54; P = NS</p> <p>Catheterization > 4 days: Antibiotic vs control: 5/39 vs 4/54; P = NS</p> <p>Risk factors for undefined UTI: Break in the drainage system: P < 0.01</p>	F/U 6 weeks Urine was deemed infected when there were $> 10^5$ organisms/ml of a pure or mixed growth or repeated pure cultures with more than 10^4 organisms/ml. However, it was not known if the UTI outcome used referred to bacteriuria or symptomatic UTI Power not reported
Grabe, 1984 ¹⁹⁰	RCT 1	To evaluate the effects of giving a short course of potent antibiotic (Cefotaxime) exclusively postoperatively,	Patients undergoing TURP for prostatic obstruction. Patients with hypersensitivity to penicillin	Bacteriuria at 4 months (patients without preoperative bacteriuria): Cefotaxime vs control: 3/20 vs 6/17; P > 0.1	F/U 4 months A colony count $> 10^5$ per ml was considered significant.

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		<p>starting at the time of catheter removal.</p> <p>One g of Cefotaxime was given IM every 12 hours to a total of 3 g with the first dose given on the day of removal of the indwelling catheter.</p>	<p>or cephalosporins and patients who had received antibiotics during the week before admission were excluded. Closed bladder drainage was maintained.</p> <p>96</p>		<p>10^4 to 10^5 per ml were classified as non-significant</p> <p>Postoperative septicemia was defined as positive blood culture with high fever and systemic symptoms.</p> <p>Power not reported</p>
Little, 1974 ¹⁹¹	RCT 1	To assess the efficacy of various antibiotics for prevention of CAUTI.	<p>Men admitted for relief of prostatic obstruction. All patients received a closed urinary drainage system.</p> <p>747</p>	<p>Bacteriuria: Antibiotics vs control: 132/597 vs 101/150; statistical differences were not reported</p> <p>Lymecycline 200 mg four times daily: 19/50</p> <p>Doxycycline 100 mg daily: 15/50</p> <p>Sulfamethoxazole 1g twice daily: 20/50</p> <p>Nitrofurantoin 100 mg nightly: 49/125</p> <p>Ampicillin 500 mg four times daily: 4/50</p> <p>TMP-SMX 960 mg twice daily: 11/150</p> <p>Pivampicillin 350 mg four times daily: 6/28</p> <p>Amoxicillin 250 mg three times daily: 6/48</p> <p>Amoxicillin : 2/46</p>	<p>F/U unclear</p> <p>Infection defined using culture of a catheter specimen of urine</p> <p>Power not reported</p>
Cleland, 1971 ¹⁵⁸	RCT 1	<p>To test the effectiveness of perineal care and a specific type of drainage system in preventing bacteriuria. Effect of antimicrobial prophylaxis was also reported (observational data).</p> <p>Perineal care: A) Twice-daily perineal care: mechanical cleansing using a hexachlorophene soap solution; B) same as A, but with sterile gloves; C) dressings with bacitracin-neomycin ointment; D) combination of B and C; and E) no perineal care.</p> <p>Two drainage systems were compared in which one of them had an air barrier between bag and tubing and the air vent was protected against accidental</p>	<p>Adult female patients in whom a catheter was in place for at least 60 hours</p> <p>184</p>	<p>Bacteriuria: <u>Perineal care:</u> A vs B vs C vs D vs E: 20/35 vs 18/38 vs 15/26 vs 25/46 vs 20/39; $P > 0.05$</p> <p><u>Perineal care stratified by drainage system</u></p> <p>Test drainage system: A vs B vs C vs D vs E: 10/17 vs 8/17 vs 9/12 vs 12/24 vs 10/17; $P > 0.05$</p> <p>Control drainage system: A vs B vs C vs D vs E: 10/18 vs 10/21 vs 6/14 vs 13/22 vs 10/22; $P > 0.05$</p> <p><u>Test drainage system vs control drainage system:</u> 49/87 vs 49/97; $P > 0.05$</p> <p><u>Antibiotic prophylaxis</u></p> <p>Bacteriostatic vs broad-spectrum bactericidal vs narrow spectrum bactericidal vs none: 10/21 vs 9/38 vs 7/11 vs 62/82; $P < 0.01$</p> <p><u>Broad-spectrum antibiotic prophylaxis stratified by risk</u></p> <p>High risk: Broad-spectrum bactericidal vs no prophylaxis: 6/15 vs 29/33; $P < 0.01$</p> <p>Low risk: Broad-spectrum bactericidal vs no prophylaxis: 3/23 vs 33/49; $P < 0.01$</p>	<p>F/U unclear</p> <p>Bacteriuria was defined as $\geq 10^5$ colonies/ml of one pathogenic species in the catheterized specimen.</p> <p>Power not reported</p>

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		wetting (designated as "Test drainage system" for the purposes of the review). Antimicrobial prophylaxis was classified as bacteriostatic, narrow-/broad-spectrum bactericidal.			
Cardosi, 2003 ⁸³	Retrospective controlled study 1,3,4	To evaluate the role of prophylactic antibiotics.	Women undergoing radical hysterectomy who were catheterized 102	Symptomatic UTI: Antibiotics vs no antibiotics: 1/9 vs 11/93; P = 0.95 Risk factors for symptomatic UTI: <u>Univariate analysis:</u> All results P values Age: > 0.05 Comorbid medical conditions: > 0.05 Cancer: > 0.05 Extent of surgical resection: > 0.05 Operative urinary tract injury: > 0.05 Catheter type: > 0.05 Postoperative infectious complication: > 0.05 Duration of catheterization: > 0.05 Length of hospitalization: > 0.05 Operating surgeon: > 0.05	F/U during postoperative period Women were diagnosed with a CAUTI if they reported suprapubic pain or bladder discomfort, irritability, or spasm and had culture-documented bacteriuria with 10^3 cfu of a single pathogen in the absence of systemic signs of infection. Power not reported
Hustinx, 1991 ⁸⁵	Prospective controlled study 1,3,6,7	To investigate the impact of concurrent administration of antibiotics on the incidence of CAUTI.	Hospitalized patients with bladder catheters 342	Bacteriuria: Antibiotic usage ending > 48 hours prior to catheter removal vs no antibiotic usage: 11/19 vs 23/34; P > 0.2 Antibiotic usage ending ≤ 48 hours prior to catheter removal vs no antibiotic usage: 9/36 vs 23/34; P < 0.01 Antibiotic usage ending ≤ 48 hours prior to catheter removal vs antibiotic usage ending > 48 hours prior to catheter removal: 9/36 vs 11/19; P < 0.05 Risk factors for bacteriuria: <u>Multivariate analysis:</u> All results P values Antibiotic usage ending ≤ 48 hours prior to catheter removal: < 0.01 Duration of catheterization: < 0.01 Age: NS Sex: NS Immunocompromise: NS Anatomical abnormalities of the urinary tract: NS	F/U 2 months Significant bacteriuria defined as $\geq 10^3$ cfu/ml Power not reported
Verbrugh, 1988 ¹³³	Prospective pre-post study	To determine the efficacy of norfloxacin in reducing the rate of catheter-associated	Patients undergoing reconstructive gynecologic surgery with bladder	Bacteriuria at catheter removal: Prophylaxis vs no prophylaxis: 8/54 vs 32/51; P < 0.01	F/U 6 weeks after discharge Significant bacteriuria was

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
	Sequential trial starting with no prophylactic therapy, then prophylactic therapy and then no prophylactic therapy. For purposes of the analysis, control groups were combined. 1,3,6,7	bacteriuria and pyuria following reconstructive gynecologic surgery. Prophylaxis patients were given 200 mg oral norfloxacin qd from the second post-op day until catheter removal. Upon catheter removal, the first group of control patients was given nitrofurantoin 50 mg qid for 7-10 days. The second group received a course of norfloxacin (400 mg bid).	catheters 105	Pyuria score of \geq 5-9 leukocytes/ HPF at catheter removal: Prophylaxis vs no prophylaxis: 3/54 vs 22/51; P < 0.01 The type of bladder drainage (suprapubic vs urethral) had no significant effects on the rates of bacteriuria and pyuria in either control or norfloxacin treated patients (data not shown) Median postoperative Hospital LOS in days: Prophylaxis vs no prophylaxis: 11 vs 11; P = NS Drug-related side effects: Prophylaxis vs no prophylaxis: 0/54 vs 0/51; P = NS Dysuria: Prophylaxis vs no prophylaxis: 1/54 vs 3/51; P > 0.1	defined as $> 10^3$ cfu/ml. Power not reported
Shohet, 1983 ²³²	Prospective controlled study 1,3	To study the efficacy of prophylactic sulfamethoxazole in preventing UTI in children with hypospadias.	Children with catheters undergoing surgery for correction of hypospadias 78	Bacteriuria: Antimicrobial prophylaxis vs control: 3/41 vs 10/37; P < 0.05 Reflux: Antimicrobial prophylaxis vs control: 9/41 vs 2/37; statistical differences were not reported Urinary complaints: Antimicrobial prophylaxis vs control: 0/41 vs 0/37; statistical differences were not reported Fever: Antimicrobial prophylaxis vs control: 0/41 vs 4/37; statistical differences were not reported	F/U 10 days UTI defined as $\geq 10^4$ cfu/ml Power not reported
Seal, 1982 ²³³	Prospective controlled and pre-post study 1, 3	To evaluate the efficacy of aseptic techniques combined with antiseptic use in reducing infection rate and cross-infection in patients undergoing urinary catheterization. The components of the intervention were: 1) cleaning the perianal area with chlorhexidine/cetrimide ('savlodil') before catheterization; 2) using an antiseptic catheter lubricant (lignocaine/chlorhexidine); 3) ensuring that the drainage bag	All patients admitted to the general medical and surgical wards of two district general hospitals in the United Kingdom 1264	Bacteriuria: Surgical ward (new techniques) vs medical ward (existing techniques) after implementation: 61/339 vs 232/925; P < 0.01 Surgical ward vs medical ward before implementation: 385/856 vs 295/925; statistical differences were not reported Antibiotic prophylaxis vs no prophylaxis: 14/141 vs 14/198; P < 0.05 Cross infection: Surgical ward (new techniques) vs medical ward (existing techniques) after implementation: 0/339 vs 6/925; statistical differences were not reported Bag contamination: There was no bacterial growth from 22 bag specimens showing that chlorhexidine was effective in preventing bacterial growth in bags.	F/U 6 months Bacteriuria was defined as $> 10^4$ /ml of the same organism on midstream urine specimen Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		<p>did not touch the floor and that its drip chamber remained vertical 4) securing the catheters to the thigh in female patients; 5) disinfecting the catheter bag using chlorhexidine solution; 6) cleaning the catheter-meatal junction with savlodil after which chlorhexidine cream was applied; and 7) maintaining catheters strictly as a closed drainage system.</p> <p>The new techniques were implemented on the patients in the surgical wards and were compared with the standard techniques used on patients in the medical wards.</p>			
Cafferkey, 1980 ²³⁴	Prospective controlled study 1,3	To assess the efficacy of prophylactic antibiotics (ampicillin) in preventing postoperative urinary infection.	<p>Patients undergoing transurethral prostatectomy or transurethral resection of bladder tumors with indwelling catheters.</p> <p>145</p>	<p>Bacteriuria:</p> <p><u>All patients</u></p> <p>Antibiotic vs no antibiotic: 10/67 vs 50/78; P < 0.01</p> <p><u>Patients undergoing postoperative drainage only</u></p> <p>Antibiotic vs no antibiotic: 5/41 vs 26/49; statistical differences were not reported</p> <p><u>Patients undergoing both pre-operative and postoperative drainage</u></p> <p>Antibiotic vs no antibiotic: 5/21 vs 24/29; statistical differences were not reported</p>	<p>F/U unclear</p> <p>Infection was diagnosed when 10^5 organisms/ml were grown from any specimen</p> <p>Power not reported</p>
Drach, 1971 ¹⁷⁸	Prospective controlled study 1,3	To evaluate the effect of antibiotic prophylaxis and a closed drainage system on catheter induced infection.	<p>Post-prostatectomy patients</p> <p>113</p>	<p>Cystitis:</p> <p><u>Systemic cephaloridine/local neomycin-polymyxin plus closed catheter system vs systemic cephaloridine plus open catheter system:</u></p> <p>At catheter removal: 1/57 vs 14/32; P < 0.01</p> <p>At discharge: 2/57 vs 8/32; P < 0.01</p> <p>At 1 month: 3/57 vs 9/32; P < 0.01</p> <p><u>Systemic cephaloridine/local neomycin-polymyxin plus closed catheter system vs no prophylaxis plus open catheter system:</u></p> <p>At catheter removal: 1/57 vs 9/24; statistical differences were not reported</p> <p>At discharge: 2/57 vs 13/24; statistical differences were not reported</p>	<p>F/U 1 month</p> <p>Cystitis was the infection outcome but was not clearly defined</p> <p>Power not reported</p>

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>At 1 month: 3/57 vs 15/24; statistical differences were not reported</p> <p><u>Systemic cephaloridine plus open catheter system vs No prophylaxis plus open catheter system:</u></p> <p>At catheter removal: 14/32 vs 9/24; P > 0.05</p> <p>At discharge: 8/32 vs 13/24; P > 0.05</p> <p>At 1 month: 9/32 vs 15/24; P < 0.05</p>	
Platt, 1989 ¹⁸⁰	Economic analysis 3,4,5,6	<p>To assess the implications of four strategies for catheter care on the number of infections, the number of deaths and the cost of hospitalization: 1) antimicrobial prophylaxis for all catheterized patients; 2) use of catheters with sealed junctions for all patients; 3) use of catheters with sealed junctions only for patients who are not receiving antimicrobial prophylaxis for some other reason; and 4) no antibiotic prophylaxis and no junction seals.</p> <p>Costs and event rates were obtained from the published literature.</p>	<p>Not specifically defined; implicit for patients requiring catheterization</p> <p>Not applicable</p>	<p>Risks and costs per patient:</p> <p><u>1. Antibiotic prophylaxis for all patients</u></p> <p>Infection: 0.07</p> <p>Death: 0.02</p> <p>Cost: \$37</p> <p><u>2. Sealed junction catheter for all patients</u></p> <p>Infection: 0.08</p> <p>Death: 0.02</p> <p>Cost: \$42</p> <p><u>3. Sealed junction catheter if no antibiotic</u></p> <p>Infection: 0.08</p> <p>Death: 0.02</p> <p>Cost: \$41</p> <p><u>4. No antibiotic prophylaxis and no junction seals</u></p> <p>Infection: 0.11</p> <p>Death: 0.02</p> <p>Cost: \$55</p> <p>Sensitivity analysis: The overall cost of each life saved by routine use of sealed catheters compared with selective use of these catheters was \$4793. This cost was \$1798 in a high risk population whose risk of death without infection was 5% (and whose risk of death with infection was 12.84%). However, routine use of sealed junction catheters was less expensive than selective use of those catheters if their extra cost was less than \$3.13</p> <p>Threshold analysis indicated that the overall cost of the antibiotic prophylaxis strategy exceeded that of routine use of sealed junction catheters for costs of antibiotic greater than \$35, as was the case for most parenteral antibiotic regimens. When there was no extra cost of sealed junction catheters, their use was less expensive than the oral prophylaxis strategy if the total cost of oral prophylaxis was greater than \$15</p> <p>For costs of infection between \$25 and \$114, the strategy of selective use of sealed junction catheters was least expensive. For</p>	UTI not defined

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				costs greater than \$114, oral prophylaxis was least expensive. For costs greater than \$641, routine use of sealed junction catheters was the next least expensive after oral prophylaxis	

Long-term

Niel-Wiese, 2006 ¹⁸³	Systematic review 1,2,3,4,5,6,7,8	To compare catheter policies in terms of prevention of urinary tract infections and complications.	All randomized and quasi-randomized trials comparing catheter policies for long-term (> 14 day) catheterization in adults. 7 trials	<p><i>All results IDR (95% CI) unless otherwise noted</i></p> <p><u>(1) Indwelling urethral catheterization vs suprapubic catheterization</u> No eligible trials were identified</p> <p><u>(2) Indwelling urethral catheterization vs intermittent catheterization</u> No eligible trials were identified</p> <p><u>(3) Suprapubic catheterization vs intermittent catheterization</u> No eligible trials were identified</p> <p><u>(4) Antibiotic prophylaxis vs antibiotics when clinically indicated:</u> Symptomatic UTI (per catheterization week): <u>Intermittent catheterization</u> Prophylaxis vs control (1 study): 8/15 vs 11/15; 0.50 (0.17-1.44) Prophylaxis vs control (1 study): 8/15 vs 11/15; statistical differences were not reported Prophylaxis vs control (1 study): 4 UTI in 430 catheterization weeks vs 2 UTI in 389 catheterization weeks; statistical differences were not reported <u>Indwelling urethral</u> Prophylaxis vs control (1 study): 1 UTI in 276 catheterization weeks vs 12 UTI in 259 catheterization weeks; statistical differences were not reported Encrustation: Prophylaxis vs control (1 study): 4 events in 276 catheterization weeks vs 19 events in 259 catheterization weeks; statistical differences were not reported Catheter obstruction: Prophylaxis vs control (1 study): 2 events in 276 catheterization weeks vs 8 events in 259 catheterization weeks; statistical differences were not reported Adverse events: Prophylaxis vs control (1 study): 596 events in 276 catheterization weeks vs 744 events in 259 catheterization weeks; statistical</p>	<p>Clinically indicated: e.g., pain, fever</p> <p>Microbiologically indicated: e.g., growth of bacteria from a specimen of urine in the absence of clinical symptoms, density of bacteria taken as positive as defined by the trials</p>
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>differences were not reported</p> <p>Improvement in general condition: Prophylaxis vs control (1 study): 12/23 vs 1/23; statistical differences were not reported</p> <p>Microbial resistance pattern: Prophylaxis vs control (1 study): 20 resistant strains/22 isolated strains vs 8 resistant strains/41 isolated strains; statistical differences were not reported</p> <p>(5)Antibiotic prophylaxis vs giving antibiotics when microbiologically indicated</p> <p>Unspecified UTI: Prophylaxis vs control (2 studies): 0.61 (0.44-0.87) Prophylaxis vs control (1 study): 9 events in 90 weeks vs 25 events in 85 weeks; statistical differences were not reported At least one episode of symptomatic/asymptomatic bacteriuria: Prophylaxis vs control (1 study): RR (95% CI) = 0.86 (0.72-1.02)</p> <p>Bacteriuria (per catheterization week): Prophylaxis vs control (1 study): IDD (95% CI) = -0.05 (-0.08 to -0.02)</p> <p>Symptomatic bacteriuria (per catheterization week): Prophylaxis vs control (1 study): 0.56 (0.27-1.15) Other results: At least one episode of symptomatic bacteriuria: Prophylaxis vs control (1 study): RR (95% CI) = 0.19 (0.07-0.53)</p> <p>Adverse events (per catheterization week): Prophylaxis vs control (1 study): 0.74 (0.53-1.02) Other results: At least one episode of adverse events: Prophylaxis vs control (1 study): RR (95% CI) = 0.86 (0.64-1.14)</p> <p>At least one episode of antibiotics for UTI: Prophylaxis vs control (1 study): RR (95% CI) = 0.78 (0.62-0.97)</p> <p>At least one episode of bacteriuria due to TMX-SMX resistant organisms: Prophylaxis vs control (1 study): RR (95% CI) = 0.95 (0.77-1.17)</p>	
Vickrey, 1999 ¹⁰⁶	Systematic review 1,2,3,4,7,8	To answer the following key questions: 1) what combinations of signs, symptoms and laboratory findings are associated with infection risks to persons with paralysis due to neurogenic	Studies relevant to a key question of adults and adolescents with neurogenic bladder due to non-acute spinal cord dysfunction	<p>Indwelling vs intermittent catheterization Indwelling catheterization was associated with more frequent infections than that involving intermittent catheterization, which in turn was associated with more frequent infections than methods not involving a catheter.</p> <p>Antibiotic prophylaxis</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		bladder?; 2) what are the risk factors for recurrent UTIs?; and 3) what are the risks and benefits of long-term use of antibiotic prophylaxis?	306 studies	Antibiotic prophylaxis significantly reduced bacteriuria among acute spinal cord injury patients ($P < 0.05$) and there was a trend for reduction in bacteriuria among non-acute spinal cord patients ($P = 0.06$). However, antibiotic prophylaxis was not associated with a reduced number of symptomatic infections in the populations studied. Antibiotic prophylaxis resulted in a two-fold increase in the occurrence of antibiotic resistant bacteria. Methenamine and nitrofurantoin significantly reduced the risk of bacteriuria among acute spinal cord injury patients. There was no effect on symptomatic infections or on bacteriuria among non-acute spinal cord injury patients.	
Clarke, 2005 ¹⁹²	RCT 1,2,7	To evaluate the impact on UTI of using prophylactic antibiotics.	Children undergoing clean intermittent catheterization (most had myelomeningocele) 85	Symptomatic UTI: Antibiotics vs no antibiotics: 20/31 vs 3/22; $P < 0.01$	F/U until development of UTI. UTI was defined as $> 10^5$ cfu/ml in the presence of clinical symptoms of fever, nausea, vomiting, or abdominal pain. Infecting organisms showed resistance to prophylactic antibiotics at time of urine collection. Power not reported
Waites, 2004 ¹⁹³	RCT 1,2,5,7	To examine effects of cranberry extract on bacteriuria and pyuria.	People with spinal cord injury residing in the community who were ≥ 1 year postinjury with neurogenic bladder managed by intermittent catheterization or external collection device and a baseline urine culture demonstrating at least 10^5 cfu/ml of bacteria 48	Symptomatic UTI: Cranberry extract vs control: 10/26 vs 8/22; statistical differences were not reported Bacteriuria: Cranberry extract vs control: $P > 0.05$ Intermittent catheter vs external catheter: $P > 0.05$ Pyuria: Cranberry extract vs control: $P > 0.05$	F/U 6 moths. Symptomatic UTI was diagnosed based on signs or symptoms such as fever, chills, and changes in urine characteristics Bacteriuria was defined as a urine colony count of $\geq 10^4$ cfu/ml and pyuria was defined as ≥ 10 urinary leukocytes/ml of urine Power not reported
Firestein, 2001 ¹⁹⁴	RCT 1	To study the effect of meropenem on UTI during routine replacement of long-term catheters	Residents at a geriatric care unit with long-term urinary catheters	Bacteriuria: Meropenem vs control: 30/32 vs 28/28; statistical differences were not reported	F/U 28 days after catheter replacement

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		urinary catheter.	70	Positive blood culture: Meropenem vs control: 0/32 vs 1/28; statistical differences were not reported Urosepsis: Meropenem vs control: 3/34 vs 1/36; statistical differences were not reported Mortality: Meropenem vs control: 2/34 vs 1/36; statistical differences were not reported	Bacteriuria represents positive urine culture Power not reported
Schlager, 1999 ¹⁹⁵	Crossover RCT 1,3,5,7,8	To determine the effect of 2 ounces of cranberry juice on rates on bacteriuria and symptomatic UTI.	Children living at home with neurogenic bladder and receiving clean intermittent catheterization 15	Symptomatic UTI: Cranberry vs placebo: 2/15 vs 3/15; statistical differences were not reported Bacteriuria: Cranberry vs placebo: 120/160 vs 114/151; statistical differences were not reported	F/U 6 months Bacteriuria was defined as $\geq 10^4$ cfu/ml of urine obtained by bladder catheterization. Ns represent urine cultures UTI was defined as bacteriuria with fever, abdominal pain, change in continence pattern, or change in color or odor of urine. Power not reported
Schaeffer, 1988 ¹⁴³	RCT 1,2	To assess the efficacy of silver oxide coating of the indwelling urinary catheter and catheter adapter and instillation of trichloroisocyanuric acid into the urinary drainage bag in the prevention of catheter-associated bacteriuria.	Adult inpatients on spinal cord injury or neurosurgical services who required indwelling urethral catheterization; patients required catheterization for > 24 hours during the study 74	Bacteriuria: <u>1. All patients</u> Silver oxide/ trichloroisocyanuric acid vs control: 11/41 vs 18/33; P = 0.02 <u>2. Patients receiving concurrent antimicrobial therapy</u> Silver oxide/ trichloroisocyanuric acid vs control: 3/23 vs 7/17; P < 0.01 <u>3. Patients not receiving concurrent antimicrobial therapy</u> Silver oxide/ trichloroisocyanuric acid vs control: 8/18 vs 11/16; RR (95% CI) = 0.65 (0.35-1.19) <u>4. Systemic antimicrobial agents vs no systemic antimicrobial agents</u> 10/40 vs 19/34; statistical differences were not reported <u>Subgroup analyses:</u> The incidence of infection was greater in women than in men in the control group (P = 0.05). The incidence of infection among male and female test patients was similar (P value not reported). Interaction between group and sex was significant (P = 0.03) Patient age did not affect the incidence of bacteriuria. Patients ≥ 50 years acquired bacteriuria as often as their younger subgroups in both the test and control groups.	F/U until detection of bacteriuria, catheter removal, or discharge from the unit. Significant bacteriuria in bladder urine specimens was defined as $\geq 10^5$ cfu/ml Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>There was no interaction between antimicrobial therapy and group assignment ($P = 0.86$)</p> <p>Time to bacteriuria: <u>1. All patients (median duration in days)</u> Silver oxide/trichloroisocyanuric acid vs control: 36 vs 8 ($P = 0.01$) Systemic antimicrobial agents vs no systemic antimicrobial agents: $P = 0.01$. However, the benefit of antimicrobials was seen during the first 4 days. Thereafter the rates were similar.</p> <p>Urethral meatal colonization as a source of bladder bacteriuria: Silver oxide/ trichloroisocyanuric acid vs control: 5/11 vs 12/18; statistical differences were not reported.</p> <p>Microbial contamination of the drainage bag: Significantly reduced in the silver oxide/ trichloroisocyanuric acid, both before and after development of bladder bacteriuria ($P < 0.01$)</p> <p>Adverse events: No significant differences in metal irritation, urethral discharge or other adverse events</p>	
Salomon, 2006 ²³⁵	Prospective controlled study 1,3,4	<p>To determine the safety and efficacy of a weekly oral cyclic antibiotic (WOCA) regimen that consisted of alternate administration of an antibiotic once per week to prevent UTI. During the first week, the patient was given a single antibiotic; during the second week, the patient was given another antibiotic.</p> <p>Antibiotics were chosen that were efficient for UTI, well-tolerated and had low selection pressure: amoxicillin, cefixime, fosfomycin, nitrofurantoin and TMP/SMX.</p>	<p>Adult patients with spinal cord injury and neurogenic bladder undergoing clean intermittent self-catheterization</p> <p>38</p>	<p>Symptomatic UTI (per patient-year): <u>Symptomatic UTI:</u> Under WOCA vs before WOCA: 1.8 vs 9.4; $P < 0.01$</p> <p><u>Febrile UTI:</u> Under WOCA vs before WOCA: 0.31 vs 0.74; $P = 0.04$</p> <p>Bacteriuria: Under WOCA vs before WOCA: 31.8% vs 98.4% ($P < 0.01$)</p> <p>Hospitalization (per patient-year): Under WOCA vs before WOCA: 0.09 vs 0.23; $P < 0.01$</p> <p>Total hospital days (per patient-year): Under WOCA vs before WOCA: 1.18 vs 3.97; $P < 0.01$</p> <p>Total duration of antibiotic (days): Under WOCA vs before WOCA: 68 vs 111; $P = 0.04$</p> <p>Broad-spectrum antibiotic: Under WOCA vs before WOCA: 12.1% vs 77.7%; $P < 0.01$</p>	<p>F/U 2 years</p> <p>UTI defined as orchitis or prostatitis or pyelonephritis with or without fever</p> <p>Bacteriuria represents positive urine culture</p> <p>Power not reported</p>

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				MDR colonized patients: Under WOCA vs before WOCA: 2/38 vs 6/38; P = NS	

2C.2. Urinary Antiseptics

Short-term

Shiotz, 2002 ¹⁹⁶	RCT 1,2,3,4,5,6,7,8,9	To assess the value of prophylactic treatment with methenamine hippurate.	Women admitted for routine gynecologic laparotomy or vaginal plastic surgery with use of a catheter. A Foley catheter was inserted immediately before surgery and removed the next morning. Sterile intermittent catheterization was carried out on patients unable to void after catheter removal or if a bladder volume > 500 ml was suspected. 145	Symptomatic UTI: Methenamine vs placebo: 2/73 vs 10/72; OR (95% CI) = 0.17 (0.02-0.87) Bacteriuria: Methenamine vs placebo: 22/73 vs 36/72; OR (95% CI) = 0.43 (0.21-0.90) Delayed voiding: Methenamine vs placebo: 8/73 vs 9/72; P ≥ 0.05 Adverse event: Methenamine vs placebo: 6/73 vs 5/72; statistical differences were not reported Urinary pH: Methenamine vs placebo: P ≥ 0.05	F/U 1 month Cultures were defined as positive when a midstream urine specimen yielded $\geq 10^5$ cfu/ml or a catheter specimen yielded $\geq 10^4$ cfu/ml. UTI was defined as a positive culture associated with pyuria and one or more of dysuria, pain, fever (> 38.5 C on two occasions), or sepsis. Asymptomatic bacteriuria was defined as a positive culture in the absence of symptoms of infection. 69 subjects would be needed in each arm to reduce bacteriuria from 40% to 15% with 80% power and an alpha of 0.05
Tyreman, 1986 ¹⁹⁷	RCT 1	To evaluate the efficacy of methenamine hippurate (1g the night before surgery, 1g twice on the day of surgery and 1g three times daily on the 5 days following surgery) in preventing bacteriuria.	Women operated on for uterovaginal prolapse and nursed with an indwelling catheter for 3 days in the postoperative period 109	Symptomatic UTI: Methenamine vs control: 1/45 vs 14/49; P < 0.01 Bacteriuria: Methenamine vs control: 4/45 vs 8/49; P > 0.05	F/U 7 days post-op Bacteriuria defined as $> 10^5$ organisms/ml Power not reported

Long-term

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
Vickrey, 1999 ¹⁰⁶	Systematic review 1,2,3,4,7,8	To answer the following key questions: 1) what combinations of signs, symptoms and laboratory findings are associated with infection risks to persons with paralysis due to neurogenic bladder?; 2) what are the risk factors for recurrent UTIs?; and 3) what are the risks and benefits of long-term use of antibiotic prophylaxis?	Studies relevant to a key question of adults and adolescents with neurogenic bladder due to non-acute spinal cord dysfunction 306 studies	Indwelling vs intermittent catheterization Indwelling catheterization was associated with more frequent infections than that involving intermittent catheterization, which in turn was associated with more frequent infections than methods not involving a catheter. Antibiotic prophylaxis Antibiotic prophylaxis significantly reduced bacteriuria among acute spinal cord injury patients ($P < 0.05$) and there was a trend for reduction in bacteriuria among non-acute spinal cord patients ($P = 0.06$). However, antibiotic prophylaxis was not associated with a reduced number of symptomatic infections in the populations studied. Antibiotic prophylaxis resulted in a two-fold increase in the occurrence of antibiotic resistant bacteria. Methenamine and nitrofurantoin significantly reduced the risk of bacteriuria among acute spinal cord injury patients. There was no effect on symptomatic infections or on bacteriuria among non-acute spinal cord injury patients.	
Kostiala, 1982 ²³⁷	Prospective controlled study 1,3	To determine whether prophylactic medication would induce any change in the course of the appearance of bacteriuria and antibody-coated bacteriuria (ACB). Patients were divided into three groups: nitrofurantoin (NF) 50 mg thrice daily, methenamine hippurate (MH) 1 g twice daily, and a control group.	Elderly patients requiring an indwelling catheter for incontinence or retention due to cerebrovascular disorders 123	Bacteriuria: Within 2 weeks of catheter use, all controls had significant bacteriuria; in the MH group 77% and in the NF group 58% had bacteriuria. Virtually all patients had bacteriuria within 6 weeks. Statistical differences were not reported Antibody-coated bacteriuria: The level of 50% positivity was reached earliest in the control group and last in the NF group. By 5 weeks approximately 70% of patients in all groups had ACB. Time to antibody-coated bacteriuria: The mean time until ACB test positivity after the appearance of bacteriuria was 1.7 weeks in the controls and 2.2 weeks in the MH group. In the NF group it was significantly ($P < 0.02$) longer (4.6 weeks)	F/U until the catheter could be removed, death or discharge from the hospital occurred, or the prophylactic medication scheme was changed. Significant bacteriuria was defined as $\geq 10^4$ /ml Power not reported
Nyren, 1981 ²³⁸	Prospective controlled study 1,3,4	To investigate the effects of two prophylactic drugs, methenamine hippurate (MH) and nitrofurantoin (NF).	Elderly patients requiring an indwelling catheter for incontinence or retention due to cerebrovascular disorders 123	Mortality: MH vs control: 13/40 vs 22/41; $P < 0.05$ NF vs control: 12/42 vs 22/41; $P < 0.05$ MH vs NF: 13/40 vs 12/42; statistical differences were not reported Symptomatic UTI: MH vs control: 7/40 vs 16/41; statistical differences were not reported	F/U until the catheter could be removed, until death or discharge from the hospital, or until the prophylactic medication scheme was changed. Significant bacteriuria was

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				<p>NF vs control: 9/42 vs 16/41; statistical differences were not reported MH vs NF: 7/40 vs 9/42; statistical differences were not reported</p> <p>Bacteriuria: During the first weeks, a larger number of patients developed bacteriuria in the control group. Within 6 weeks, all patients were infected irrespective of treatment used. Statistical differences were not reported</p> <p>Sepsis: MH vs control: 1/40 vs 2/41; statistical differences were not reported NF vs control: 1/42 vs 2/41; statistical differences were not reported MH vs NF: 1/40 vs 1/42; statistical differences were not reported</p> <p>Decrease in antibiotic requirement: MH vs control: $P < 0.05$ NF vs control: $0.05 < P < 0.10$</p> <p>Mean duration of catheterization (days): MH vs NF vs control: 20 vs 18 vs 39; statistical differences were not reported</p> <p>Drug related adverse event: MH vs NF vs control: 0/40 vs 2/42 vs 0/41; statistical differences were not reported</p> <p>Time to antibody-coated bacteriuria: NF significantly delayed the appearance ($P < 0.05$)</p>	defined as $\geq 10^4$ /ml Power not reported
Wibell, 1980 ²³⁶	Prospective controlled study 1,3,4	To assess the efficacy of methenamine hippurate in reducing infection. In the first group, patients received methenamine for 6 weeks and were then observed for 6 weeks without treatment. In the second group, patients were not treated for the first 6 weeks, but received methenamine for the following 6 weeks.	Chronically ill elderly patients with indwelling catheters 52	<p>Symptomatic UTI: Methenamine vs control: 0/52 vs 5/52; statistical differences were not reported</p> <p>Bacteriuria (mean total bacterial counts): Methenamine vs control: $P = 0.07$</p> <p>Catheter change due to encrustation: Methenamine vs control: $P > 0.05$</p>	F/U 12 weeks UTI not defined Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
Norrman, 1976 ²³⁹	Prospective pre-post study 1,3,4	To evaluate the effect of methenamine hippurate on clinical infection and catheter blockage.	Elderly female inpatients with chronic diseases 29	Symptomatic UTI: Methenamine vs control: 4/22 vs 17/22; statistical differences were not reported Bacteriuria: Persisted in all subjects during control and treatment periods. Statistical differences were not reported Catheter change/day (mainly due to encrustation): Methenamine vs control: 0.03 vs 0.04; P < 0.01 Hematuria: Methenamine vs control: 0/22 vs 1/22; statistical differences were not reported	F/U 8 months UTI not defined Power not reported

2C.3. Bladder Irrigation

Intermittent

Pearman, 1991 ¹⁹⁹	RCT 1,7	To compare the effect of Trisdine instillation into the bladder at the end of each catheterization with a special introducer to improve asepsis. The solution was instilled into the bladder and left there.	Patients with acute spinal cord trauma and bladder involvement requiring intermittent catheterization for more than 5 days 43	Bacteriuria (incidence/catheterization): Males: Trisdine vs introducer: 0.58% vs 1.16%; P = 0.02 Females: Trisdine vs introducer: 0.48% vs 2.93%; P < 0.01	F/U unclear A diagnosis of significant bacteriuria was made when a catheter specimen of urine showed either (1) ≥ 1000 cfu/ml with the same species of microorganisms in 3 consecutive specimens when the catheter was passed 6 or 8 hourly or in two consecutive specimens when the catheter was passed 12 hourly or (2) ≥ 10,000 cfu/ml in one specimen when the catheter was passed daily Power not reported
Pearman, 1988 ¹⁹⁸	RCT 1	To compare the efficacy of Trisdine and kanamycin-colistin bladder instillations in reducing bacteriuria during intermittent catheterization. The solution was instilled into the bladder and left	Patients with acute spinal cord injury undergoing intermittent catheterization 18	Bacteriuria (incidence/catheterization): Kanamycin-colistin vs Trisdine: 0.53% vs 0.56%; P = NS This data represents male patients. A comparison could not be made for females as there were only 3 female patients. Hematuria: No events	F/U during catheterization A diagnosis of significant bacteriuria was made when a catheter specimen of urine showed colony count ≥

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		there.		Chemical cystitis: No events	1000/ml with the same species of micro-organism in 3 consecutive specimens when catheters were passed 6 or 8 hourly, or in 2 consecutive specimens when catheters were passed 12 hourly or colony count \geq 10,000/ml when catheters were passed daily Power not reported
Pearman, 1979 ²⁴⁰	Prospective controlled study 1,3	To determine whether or not kanamycin-colistin bladder instillations were of value in reducing UTI.	Patients with acute spinal cord trauma undergoing intermittent catheterization 47	Bacteriuria (incidence/catheterization): Males: Kanamycin-colistin vs control: 0.75% vs 1.43%; P < 0.05 Females: Kanamycin-colistin vs control: 1.07% vs 2.48%; P < 0.05	F/U during catheterization Significant bacteriuria was diagnosed if a catheter specimen of urine showed: (1) colony count $>$ 1000 per ml with same species of micro-organism in 3 consecutive specimens if catheters passed every 6 or 8 hours or in 2 consecutive specimens if catheterized every 12 hours (2) colony count $>$ 10,000 per ml in one specimen if catheter passed daily Power not reported

Indwelling

Adesanya, 1993 ²⁰⁰	RCT 1,6	To compare chlorhexidine irrigation with saline irrigation of the bladder.	Patients with benign prostatic hypertrophy and indwelling catheters undergoing transvesical prostatectomy 32	Undefined UTI: Chlorhexidine vs control: 12/15 vs 16/17; P = 0.25 Wound infection: Chlorhexidine vs control: 10/15 vs 15/17; P = 0.15 Postoperative septicemia: Chlorhexidine vs control: 0/15 vs 3/17; P = 0.14 Intraoperative septicemia: Chlorhexidine vs control: 0/15 vs 6/17; P = 0.01	F/U during perioperative period Cultures yielding $>$ 10 ⁵ cfu/ml were considered positive Power not reported
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Postoperative hospital length of stay (days): Chlorhexidine vs control: 16 vs 20; P = 0.05</p> <p>Duration of catheterization (days): Chlorhexidine vs control: 11 vs 15; P = 0.03</p> <p>Duration of surgery (min): Chlorhexidine vs control: 90 vs 93; P = 0.26</p> <p>Vesical calculi: Chlorhexidine vs control: 2/15 vs 1/17; statistical differences were not reported</p>	
Schneeberger, 1992 ⁶⁶	RCT 1,7	To evaluate the effect of povidone-iodine bladder irrigation prior to catheter removal on subsequent bacteriuria.	Urologic patients with an indwelling catheter 352	<p>Bacteriuria: Overall: Povidone-iodine irrigation vs control: 47/264 vs 52/233; RR (95% CI) [for control vs povidone-iodine]: 1.25 (0.88-1.78) At 1-3 days: Povidone-iodine irrigation vs control: 18/128 vs 24/111; RR (95% CI) [for control vs povidone-iodine]: 1.54 (0.88-2.68) At 4-14 days: Povidone-iodine irrigation vs control: 29/136 vs 28/122; RR (95% CI) [for control vs povidone-iodine]: 1.08 (0.68-1.70)</p> <p>Stratified by duration of catheterization: All results Povidone-iodine irrigation vs control 1-3 days: 5/74 vs 9/65; P < 0.05 4-6 days: 6/29 vs 6/22; P = NS ≥7 days: 7/25 vs 9/24; P = NS</p> <p>Mean duration of catheterization (days): Povidone-iodine irrigation vs control: 4.81 vs 4.97; P = NS</p> <p>Risk factors for bacteriuria: Univariate analysis Duration of catheterization: P < 0.01</p>	F/U until 14 days after catheter removal Positive urine culture was defined as > 10 ⁵ cfu/ml composed of one or two species of bacteria Power not reported Ns and events in the results column are the number of urine cultures and not the number of patients
Ball, 1987 ²⁰¹	RCT 1,4,6	To determine the effect of postoperative chlorhexidine bladder irrigation.	Men with prostatectomy or other transurethral procedures on the lower urinary tract 119	<p>Bacteriuria: Chlorhexidine irrigation vs saline: 5/40 vs 18/49; P<0.02</p> <p>Mean duration of catheterization (days): Chlorhexidine irrigation vs saline: 2.5 vs 2.7; P = NS</p>	F/U 6-23 weeks post-discharge A colony count > 10 ⁴ per ml in catheter specimens or 10 ⁵ per ml in midstream urine were used to diagnose infection. Power not reported

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van den Broek, 1985 ²⁰²	RCT 1,7	To evaluate the effectiveness of post-catheterization irrigation of the bladder with povidone-iodine in preventing UTI.	All patients admitted to an orthopedics department who were catheterized. 78	Bacteriuria: Povidone-iodine vs control: 1/28 vs 8/29; P = 0.03 Bacteriuria with pyuria: Povidone-iodine vs control: 1/28 vs 3/29; statistical differences were not reported.	F/U unclear Bacteriuria was defined as $\geq 10^5$ bacteria of one species per ml Power not reported
Savage, 1982 ²⁰³	RCT 1	To determine the value of continuous irrigation of the bladder with an antimicrobial agent which was not systemically absorbed. The three groups were: 1) closed catheter drainage; 2) continuous bladder irrigation with neosporin; and 3) continuous bladder irrigation with saline.	Women undergoing their first intracavitary radium insertion for treatment of gynecologic cancer 90	Bacteriuria: Closed drainage vs saline irrigation: 3/30 vs 9/30; P > 0.05 Antibiotic irrigation vs saline irrigation: 3/30 vs 9/30; P > 0.05 Closed drainage vs antibiotic irrigation: 3/30 vs 3/30; P > 0.05	F/U 3 days after radium insertion Bacteriuria was defined as $\geq 10^5$ cfu/ml Power not reported
Kirk, 1979 ²⁰⁴	RCT 1,2	To evaluate the value of chlorhexidine bladder irrigation in the prevention of CAUTI	Male patients requiring catheterization after emergency urological admission 125	Bacteriuria $> 10^2 /ml$: Chlorhexidine vs control: 24/62 vs 37/63; statistical differences were not reported $> 10^5 /ml$: Chlorhexidine vs control: 17/62 vs 24/63; statistical differences were not reported Sterile urine: Chlorhexidine vs control: 52% vs 26%; P < 0.01 Antibiotic usage: Chlorhexidine vs control: 3/62 vs 4/63; statistical differences were not reported Mean duration of catheterization (days): Chlorhexidine vs control: 9.3 vs 9.6; P = NS	F/U until catheter removal or discharge Detectable bacteriuria defined as a growth $> 10^2 /ml$ in catheter specimen of urine Power not reported
Warren, 1978 ⁶⁹	RCT 1	To investigate the efficacy of antibiotic irrigation in preventing CAUTI. Patients were randomly assigned to receive either a closed drainage, triple-lumen, neomycin-polymyxin irrigated	Adult patients on the medical, surgical, and gynecologic services who required urinary catheterization 187	Bacteriuria: Irrigated vs not irrigated: 18/98 vs 14/89; P = NS There were no differences between the two groups when stratified by sex, age, service, severity of disease, indication for catheterization, and BUN with one exception: <i>in patients with low urine output (<1000ml/day)</i> Irrigated vs not irrigated: 4.4 vs 9.5; statistical differences were not reported. However, this may have been due to greater disconnections in the group not receiving irrigation.	F/U unclear UTI was defined as $\geq 10^5$ colonies/ml Power not reported

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		system or a closed drainage, double-lumen, non-irrigated catheter-system.		<p>Mean duration of catheterization (days): Irrigated vs not irrigated: 3.3 vs 3.5; P = NS</p> <p>Risk factors for bacteriuria: Disconnection of catheter junction, old age, duration of catheterization, fatal diagnosis, elevated BUN, residence in ICU were stated as risk factors for bacteriuria, but statistical differences were not reported.</p> <p>Mortality: UTI vs no UTI: 34% vs 15%; statistical differences were not reported</p>	
Chamberlain, 1975 ²⁰⁵	RCT 1	To investigate the effect on infection rate of rhythmically irrigating and completely emptying the bladder on a tidal flow principle. There were 3 groups: 1) irrigation with antibiotic 2) irrigation with saline irrigant 3) gravity drainage.	Patients who had an indwelling catheter inserted after vaginal surgery 111	<p>Bacteriuria Day 5: Antibiotic irrigation vs gravity drainage: 10/34 vs 21/43; statistical differences were not reported. Saline irrigation vs gravity drainage: 22/34 vs 21/43; statistical differences were not reported.</p> <p>Day 10: Antibiotic irrigation vs gravity drainage: 24/34 vs 13/43; statistical differences were not reported. Saline irrigation vs gravity drainage: 12/34 vs 13/43; statistical differences were not reported.</p> <p>Recatheterization: Antibiotic irrigation vs gravity drainage: 13/34 vs 16/43; statistical differences were not reported Saline irrigation vs gravity drainage: 10/34 vs 16/43; statistical differences were not reported</p> <p>Administration of antibiotics: Antibiotic irrigation vs gravity drainage: 23/34 vs 32/43; statistical differences were not reported Saline irrigation vs gravity drainage: 31/34 vs 32/43; statistical differences were not reported</p>	F/U 10 days post-op UTI was defined as $\geq 10^5$ colonies/ml Power not reported
Clark, 1973 ²⁰⁶	RCT 1,3,4,6	To assess the value of bladder instillation of neomycin solution in the prevention of post-catheterization bacteriuria.	Patients with indwelling catheters undergoing major gynecological surgery 251	<p>Bacteriuria: <i>1. Catheter not left indwelling</i> (patients had the catheter removed immediately after the instillation of the solution) Neomycin vs saline: 3/19 vs 17/27; P < 0.01</p> <p><i>2. Catheter left indwelling for 1 day</i> Neomycin vs saline: 7/75 vs 21/68; P < 0.01</p>	F/U unclear A bacterial count of $> 100,000$ organisms/ml was considered significant bacteriuria Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<i>3. Catheter left indwelling for 31 day</i> Neomycin vs saline: 3/31 vs 20/31; P < 0.01	
Cox, 1966 ²⁴¹	Prospective controlled study 1,3,4	To compare antibiotic (neomycin-polymyxin) vs saline irrigation of indwelling urinary catheters.	Adult patients undergoing major vascular surgery, primarily on the abdominal aorta or renal arteries 200	Symptomatic UTI: Antibiotic vs saline: 30/139 vs 25/61; statistical differences were not reported Bacteriuria: Antibiotic vs saline: 16/139 vs 17/61; statistical differences were not reported Bacteriuria (symptomatic and asymptomatic): Antibiotic vs saline: 46/139 vs 42/61; P < 0.01	F/U unclear Cultures of catheter or clean-catch specimens containing > 10 ⁵ organisms/ml were considered positive Power not reported
Thornton, 1966 ²⁴²	Prospective controlled study 1,3	To compare the effect of short-term (<10 days) vs long-term bladder irrigation using a solution of neomycin sulfate and polymyxin B sulfate.	Ward, medical, surgical, and gynecological patients requiring indwelling urinary catheters 22	 Bacteriuria: Short-term bladder rinse vs long-term bladder rinse: 3/14 vs 6/9; statistical differences were not reported	F/U at least for the duration of catheter drainage Significant bacteriuria was defined as ≥ 10 ⁵ colonies/ml of urine per species of bacteria Power not reported

2C.4. Antiseptic instillation in drainage bag

Washington, 2001 ²⁰⁷	RCT 1	To investigate whether a one-time instillation and drainage of 3% hydrogen peroxide or sterile distilled white vinegar into urinary drainage bags decreased bacteriuria.	Patients with long-term indwelling urethral catheters 20	Bacteriuria: Differences in mean values of categories of colony counts. All results hydrogen peroxide vs distilled vinegar vs control 0 hours: 6.2 vs 6.7 vs 6.6; P = 0.91 24 hours: 5.6 vs 6.5 vs 7.3; P = 0.64 48 hours: 5.3 vs 3.0 vs 7.2; P < 0.01 72 hours: 3.8 vs 4.6 vs 5.2; P = 0.22	F/U 3 days Categories of colony count: Score 3: > 100,000 Score 2: 10,000-100,000 Score 1: < 10,000 Power not reported
Sweet, 1985 ²⁰⁸	RCT 1,2,7	To determine the efficacy of intermittent drainage bag instillation of hydrogen-peroxide in patients requiring indwelling catheters.	Patients admitted to special care units of a community teaching hospital who had an indwelling Foley catheters for ≥ 5 days 238	 Symptomatic UTI: Peroxide vs control: 5/67 vs 8/67; statistical differences were not reported Bacteriuria: Peroxide vs control: 17/67 vs 19/67; statistical differences were not reported Bag source bacteriuria: Peroxide vs control: 4/67 vs 4/67; statistical differences were not reported Bag contamination: Peroxide vs control: 12/67 vs 23/67; P ≤ 0.05	F/U until infection A colony count > 10 ⁵ per ml was considered significant. Symptomatic UTI was defined as fever > 101 F developing within 24 hours of positive culture Bag contamination was

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
					defined as occurring when colony counts were $\geq 10^5$ per ml Bag source bacteriuria not explicitly defined Post hoc power for bacteriuria was 96%.
Thompson, 1984 ²⁰⁹	RCT 1,4,6	To assess the effect of periodic instillations of hydrogen peroxide into urinary drainage systems on prevention of catheter-associated bacteriuria.	Adults on all medical, surgical, and subspecialty services who required indwelling urethral catheterization 668	Bacteriuria: Peroxide vs control: 39/353 vs 29/315; P = NS Bag source bacteriuria: Peroxide vs control: 3/353 vs 2/315; P = NS Bag contamination: Peroxide vs control: 27/353 vs 51/315; P < 0.01 Mean duration of catheterization (days): Peroxide vs control: 4.0 vs 4.2; statistical differences were not reported	F/U until the development of bacteriuria or discontinuation of catheterization. Bacteriuria was defined as $\geq 10^5$ cfu/ml and drainage bag contamination was defined as $\geq 10^3$ cfu/ml Bag source bacteriuria not explicitly defined Power not reported
Gillespie, 1983 ²¹⁰	RCT 1,2,6	To determine whether the addition of disinfectant (10 ml of 5% chlorhexidine digluconate) to urine drainage bags prevented infection in catheterized patients.	Men undergoing prostatectomy or other operations on the lower urinary tract 58	Bacteriuria: Chlorhexidine vs control: 15/29 vs 13/29; P = NS	F/U until discharge Urinary infection was diagnosed when the number of viable bacteria exceeded 10^4 /ml Power not reported
Maizels, 1980 ²¹¹	RCT 1	To determine if the incidence of catheter-associated bacteriuria could be reduced significantly either by draining urine into sterile bags or by periodically adding hydrogen peroxide to the drainage system. Patients were randomized into 3 groups: 1) <i>hydrogen peroxide group</i> : conventional closed drainage with an attached secondary bag for instillation of	Patients with acute spinal cord injury who required continuous indwelling urethral catheter drainage and who received no antimicrobial therapy. 31	Bacteriuria: Peroxide vs saline vs control: 6/9 vs 9/10 vs 11/12; P < 0.05 for peroxide vs control Median time to bacteriuria (days): Peroxide vs saline vs control: 7 vs 5 vs 4.5; statistical differences were not reported Bag contamination: <u><i>Patients without bladder bacteriuria</i></u> Peroxide vs saline: 0/44 vs 9/46; P < 0.01 Peroxide vs control: 0/44 vs 11/34; P < 0.01 <u><i>Patients with bladder bacteriuria</i></u> Peroxide vs saline: 2/38 vs 27/27; P < 0.01	F/U until detection of significant bacteriuria on at least 2 consecutive days, catheter removal, administration of antibiotics, or discharge of the patient. Bladder bacteriuria of $\geq 10^4$ organisms per ml was considered significant. Bag bacteriuria was defined as $\geq 10^4$ organisms per ml in

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		30 ml 3% hydrogen peroxide into the primary bag and collection of urine; 2) <i>saline group</i> : conventional closed drainage with an attached sterile secondary bag for instillation of 30 ml sodium chloride into the primary bag and collection of urine; and 3) <i>control group</i> : conventional closed drainage.		Peroxide vs control: 2/38 vs 24/24; P < 0.01	patients without bladder bacteriuria and ≥ 10 bacteria/ml in patients with bladder bacteriuria Power not reported
Wongsatanapong, 1988 ²⁴³	Prospective controlled study 1,3	To study the efficiency of 5% chlorhexidine instillation into the urinary drainage bags to reduce UTI.	Patients in the ICU 58	Undefined UTI: Chlorhexidine vs no chlorhexidine: 8/39 vs 9/19; P < 0.05	F/U unclear UTI not defined Power not reported
Holliman, 1987 ⁹⁰	Prospective pre- post study 1,3	To test the effect of peroxide disinfection of drainage on CAUTI.	Orthopedic patients 57	Bacteriuria: Peroxide vs control: 11/30 vs 17/27; P < 0.05 Number of catheter bags with bacteriuria: Peroxide vs control: 5/30 vs 15/27; P < 0.01 Average number of days without infection: Peroxide vs control: 8.5 vs 6.0; P < 0.02 Mean duration of catheterization (days): Peroxide vs control: 12 vs 12; P = NS Risk factors for bacteriuria: <u>Univariate analysis</u> : All results P value Age: NS Female sex: < 0.02 Duration of catheterization: NS	F/U unclear Significant bacteriuria was defined as $\geq 10^4$ cfu/ml Power not reported
Sujka, 1987 ²⁴⁴	Prospective study with historical controls 3	To study the effect of Betadine instillation in the drainage bag on UTI.	Patients undergoing abdominoperineal resection for rectal carcinoma. 56	Bacteriuria: Betadine vs control (males) 33% vs 61%; statistical differences were not reported Betadine vs control (females): 100% vs 86%; statistical differences were not reported Duration of catheterization (days): Betadine vs control (males): 11 vs 10; statistical differences were not reported Betadine vs control (females): 11 vs 11; statistical differences were not reported	F/U unclear UTI defined as $> 10^5$ colonies per ml Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				not reported	
Samuels, 1983 ²⁴⁵ 1,3	Prospective controlled study	To study the effect of hydrogen-peroxide instillation in catheter drainage bags.	Patients with an indwelling urinary catheter for at least 72 hours who had not received an antimicrobial therapy for 48 hours prior to entering the study 20	Undefined UTI: Peroxide vs control: 8/10 vs 6/10; statistical differences were not reported Mean duration of catheterization (days): Peroxide vs control: 5.7 vs 8.4; statistical differences were not reported Time to infection (days): Peroxide vs control: 2.4 vs 6.5; statistical differences were not reported	F/U 15 days UTI not defined Power not reported

2C.5. Periurethral care

Phipps, 2006 ³⁷ 1,2,3,4,5,6,7,8	Systematic review	To establish the optimal way to manage urinary catheters following urogenital surgery in adults.	Randomized and quasi-randomized trials 39 RCTs	<p><i>Note: All results are RR (95% CI) unless otherwise noted</i></p> <p>1. Using a urinary catheter vs not using a urinary catheter</p> <p>Retention of urine (1 study): 0.12 (0.03-0.47) UTI (4 studies): 1.35 (0.75-2.45) Recatheterization (3 studies): 0.32 (0.14-0.70) Post-op urethral stricture (1 study): 1.14 (0.90-1.44) Post-op hematuria (1 study): 0.73 (0.40-1.33)</p> <p>2. Urethral catheterization vs suprapubic catheterization</p> <p>UTI: Heterogeneous results, not combined. Of four trials, two suggested a moderate increase, one a large increase and one a large decrease. Recatheterization (2 studies): 3.66 (1.41-9.49) Post-op hematuria (1 study): 5.00 (0.21-116.31) Length of hospital stay in days (1 study) [WMD (95% CI)]: 1.10 (0.30-1.90) Catheter lockage or bypassing [OR (95% CI)] (2 studies): 0.20 (0.02-1.72)</p> <p>3. One type of catheter vs another</p> <p>UTI: Urethral Foley catheter with extra drainage hole vs unmodified Foley catheter (1 study): 0.40 (0.15-1.04) Positive urine culture: Silver-coated Bardex catheters vs latex catheters (1 study): 0.53 (0.20-1.45)</p> <p>4. One type of catheter management vs another</p> <p>Retention of urine: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.99 (0.06-15.54) Dysuria: Vaginal cleansing before catheter insertion vs vaginal</p>	
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>cleansing after catheter insertion (1 study): 0.99 (0.06-15.54)</p> <p>Symptomatic UTI: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.61 (0.33-1.14)</p> <p>Bacteriuria/unspecified UTI: Cefotaxime 1 hour prior to catheter removal vs none (1 study): 0.08 (0.00-1.30)</p> <p>Neomycin/Sulfamethiazole vs placebo (1 study): 0.18 (0.06-0.55)</p> <p>Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 1.06 (0.70-1.51)</p> <p>Recatheterization: Neomycin/Sulfamethiazole vs placebo (1 study): 0.50 (0.24-1.04)</p> <p><i>5. Larger diameter catheter vs Smaller diameter catheter</i> No trials found</p> <p><i>6. Bladder irrigation</i> No trials found</p> <p><i>7. Shorter-duration vs longer-duration catheter</i> Retention of urine: 1 day vs 3 days (1 study): 0.80 (0.38-1.69) 1-2 days vs until urine clear (1 study): 1.02 (0.07-15.87) 1 day vs 2 days (1 study): 4.64 (0.23-94.28) 3 days vs 28 days (1 study): 3.00 (0.13-69.52) Post-op urethral stricture: < 1 week vs 2 weeks (2 studies): 1.23 (0.82-1.84) 3 days vs 28 days (1 study): 1.00 (0.73-1.36) UTI: Heterogeneous results, not combined. Shorter duration had lower risk of UTIs but the results were significant in only 1 trial 1 day vs 3 days (3 studies): 0.50 (0.29-0.87) Recatheterization: 1 day vs 2 days (1 study): 1.03 (0.23-4.71) 1 day vs 3 days (2 studies): 1.04 (0.36-3.01) 1 day vs 5 days (1 study): 4.55 (1.68-12.37) 4-6 days vs 14 days (1 study): 1.86 (0.14-25.38) 1-2 days vs until urine clear (2 studies): 0.72 (0.24-2.20) Post-op hematuria: 1-2 days vs until urine clear (1 study): 2.04 (0.19-21.81) 1 day vs 2 days (2 studies): 1.16 (0.34-3.90) Urinary leakage or incontinence: 1-2 days vs until urine clear (2 studies): 0.43 (0.07-2.88)</p> <p><i>8. Clamp and release vs free catheter drainage:</i> UTI (1 study): 4.00 (1.55-10.29) Delay in return to normal bladder function (1 study): 2.50 (1.16-5.39)</p>	

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				<p>9. Catheter removal at one time of day vs another time of day UTI: 12 am vs 6 am (1 study): 1.31 (0.65-2.66) Recatheterization: 12 am vs 6 am (4 studies): 0.61 (0.34-1.12) 6-7 am vs 10-11 pm (1 study): 1.36 (0.32-5.77) Time to first void in hours[WMD (95% CI)]: 12 am vs 6 am (1 study): 0.60 (-0.96 to 2.16) Volume of first void in ml [WMD (95% CI)]: 12 am vs 6 am (1 study): 53.00 (4.27-101.73)</p> <p>10. Trial of void protocol vs none No trials found</p> <p>11. Prefilling bladder prior to catheter removal vs removal without prefilling Recatheterization [OR (95% CI)] (1 study): 4.52 (0.79-25.97) Discharge on day of catheter removal (1 study): 1.36 (0.47-3.91)</p>	
Webster, 2001 ²¹²	RCT 1,2,4,6,7,8	To assess the efficacy of 0.1% chlorhexidine gluconate for periurethral cleaning prior to urinary catheterization.	Pregnant women admitted for delivery in whom an indwelling catheter was to be a required part of routine management 506	<p>Bacteriuria: Chlorhexidine vs water: 9.2% vs 8.2%; OR (95% CI) = 1.13 (0.58-2.21)</p> <p>Duration of catheterization: P = 0.09</p>	F/U 24 hours Bacteriuria defined as > 10 ⁶ cfu/ml 220 women in each group would be needed to provide a 90% power to show a 20% increase in the proportion of women diagnosed with a UTI
Bardwell, 1999 ²¹³	RCT 1,7	To compare the meatal hygiene of patients with indwelling catheters using either soap and water or povidone-iodine.	Men on the urology unit who had an indwelling catheter in situ for 36-48 hours 90	<p>Positive meatal swab: Of 18 men with positive swabs, 9 were treated with povidone-iodine and 9 were cleansed with soap and water.</p>	F/U unclear UTI not defined Power not reported
Huth, 1992 ⁶⁵	RCT 1,2,7	To determine the efficacy of a 1% silver sulfadiazine cream applied twice daily to the urethral meatus in preventing transurethral catheter-associated bacteriuria.	Adult patients who underwent closed urinary catheter drainage at a community hospital 696	<p>Bacteriuria: Silver sulfadiazine vs no silver sulfadiazine: 38/332 vs 48/364; OR (95% CI) = 0.85 (0.53-1.37) Survival curve analysis of patients stratified by sex and antibiotic use revealed no significant differences.</p> <p>Onset of bacteriuria (days): Silver sulfadiazine vs no silver sulfadiazine: 3.8 vs 4.3; P = 0.44</p> <p>Mean duration of catheterization (days): Silver sulfadiazine vs no silver sulfadiazine: 3.7 vs 3.9; P = 0.48</p>	F/U until catheter removal or patient discharge Bacteriuria was defined as a urine specimen containing ≥ 1000 cfu/ml of bacteria or yeast It was estimated that a final study population of 199

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Death: Silver sulfadiazine vs no silver sulfadiazine: 13/332 vs 22/364; P = 0.27</p> <p>Risk factors for bacteriuria:</p> <p><u>Univariate analysis:</u> All results P values</p> <p>Duration of catheterization: P < 0.01</p> <p><u>Multivariate analysis:</u> All results OR (95% CI)</p> <p>Lack of antibiotic use: 4.61 (1.92-5.08)</p> <p>Female sex: 3.02 (1.31-3.50)</p> <p>Positive meatal culture: 3.89 (0.93-16.25)</p> <p>Randomization to the treatment group, age, lack of use of a urinometer, catheter care violations, and hospital service were not associated with the development of bacteriuria, though no measures of association were provided.</p>	patients in each group would be needed to detect a 50% reduction in the infection rate at an alpha of 0.05 with 80% power
Classen, 1991 ⁶⁸	RCT 1,2,7	To compare a polyantibiotic cream (containing polymyxin B, neomycin and gramicidin) with routine meatal care (cleansing of the meatal surface during daily bathing).	Adult patients undergoing closed urinary catheter drainage 747	<p>Bacteriuria: Polyantibiotic cream vs routine meatal care: 26/383 vs 37/364; P = 0.17</p> <p>Results were robust to definitions of bacteriuria.</p> <p>There were no significant differences between the two groups, both overall and when stratified by sex.</p> <p>Risk factors for bacteriuria:</p> <p><u>Multivariate analysis:</u> All results OR (95% CI)</p> <p>Female sex: 3.48 (1.81-6.74)</p> <p>Positive meatal culture: 2.79 (1.48-5.25)</p> <p>Antibiotic use: 0.52 (0.31-0.87)</p> <p>The other variables introduced in the regression model were not listed.</p>	<p>F/U until catheter removal</p> <p>Four definitions of bacteriuria were used: 10^3 colonies/ml of any microbial species, 10^5 colonies/ml of any microbial species, 10^5 colonies/ml of gram-negative bacilli and/or enterococci, and 10^3 colonies/ml of gram-negative bacilli and/or enterococci. The latter was used for the comparison.</p> <p>It was calculated that with an estimated incidence of bacteriuria of 14%, to show a 50% reduction in bacteriuria in the treated group, the study would require 325 patients in each group to have 90% power at a significance level of 5%.</p>
Sanderson, 1990 ²¹⁴	Crossover RCT 1	To evaluate the effects of chlorhexidine antisepsis, soap, and antibiotics on bacteriuria, perineal colonization and	Patients undergoing rehabilitation after spinal injury. Bladder drainage was by sterile intermittent	<p>Bacteriuria:</p> <p><i>1. Patients not receiving antibiotics:</i></p> <p>Males: Chlorhexidine antisepsis vs washing in soap: 143/237 vs 240/324; P < 0.01</p>	<p>F/U 8 weeks</p> <p>Bacteriuria defined as $\geq 10^5$ cfu/ml</p>

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		environmental contamination	catheterization with penile condom drainage between catheterizations in most patients 827 urine cultures	Females: Chlorhexidine antisepsis vs washing in soap: 29/37 vs 69/78; P > 0.05 <u>2. Patients receiving antibiotics:</u> Males: Chlorhexidine antisepsis vs washing in soap: 33/146 vs 39/120; P > 0.05 Females: Chlorhexidine antisepsis vs washing in soap: 4/6 vs 22/34; P > 0.05 Perineal colonization: Chlorhexidine antisepsis vs washing in soap: P > 0.05 Antibiotics vs no antibiotics: P < 0.01 Contamination of bedsheets and environmental sites: Chlorhexidine antisepsis vs washing in soap: P > 0.05 Antibiotics vs no antibiotics: P > 0.05	Power not reported All Ns and events are urine cultures
Burke, 1983 ⁶⁷	RCT 1,2	To evaluate the efficacy of twice-daily meatal care with a poly-antibiotic ointment in delaying the onset of bacteriuria. Patients in the meatal care group received twice daily treatment of the urethral meatus-catheter junction with neomycin-polymyxin B-bacitracin ointment.	Adult patients who underwent closed urinary catheter drainage. 428	Bacteriuria: Meatal care vs no meatal care: 14/214 vs 16/214; P > 0.05 Though not significant, the greatest difference between the two groups was seen in female patients ≥ 50 years old who were not receiving antibiotics during the study period. Results were robust to definitions of bacteriuria Risk factors for bacteriuria: <u>Multivariate analysis:</u> Female patients, a positive meatal culture, a non-surgical underlying illness, and absence of antibiotic use were associated with higher rates of bacteriuria in each of the treatment subgroups (P > 0.05 for all)	F/U for duration of catheterization Bacteriuria was defined as ≥ 10 ³ colonies/ml Power not reported
Burke, 1981 ²¹⁵	RCT 1	To evaluate the efficacy of daily cleansing of the urethral meatus-catheter junction in preventing bacteriuria during closed urinary drainage using two different regimens (in two different RCTs): 1) twice-daily applications of povidone-iodine solution and ointment; and 2) once-daily cleansing with a non-antiseptic solution of green soap and water.	Adult patients who underwent closed urinary catheter drainage 394, 452	Bacteriuria: Povidone-iodine vs no cleaning: 32/200 vs 24/194; P > 0.05 Green soap/water vs no cleaning: 28/229 vs 18/223; P > 0.05 <u>Subgroup analyses:</u> Significantly higher rates of bacteriuria were found in patients who did not receive antibiotics, but who did receive any form of meatal care (P = 0.03) In female patients with positive meatal cultures, significantly higher rates of bacteriuria were noted in the meatal care groups (P < 0.05) In older women with positive meatal cultures, significantly higher rates of bacteriuria were noted in the meatal care groups (P <	F/U unclear Bacteriuria was defined as ≥ 10 ³ colonies/ml Ns represent the sample sizes of the two RCTs (394 – povidone-iodine; 452 – green water) Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				0.05)	
Cleland, 1971 ¹⁵⁸	RCT 1	<p>To test the effectiveness of perineal care and a specific type of drainage system in preventing bacteriuria. Effect of antimicrobial prophylaxis was also reported (observational data).</p> <p>Perineal care: A) twice-daily perineal care: mechanical cleansing using a hexachlorophene soap solution; B) same as A, but with sterile gloves; C) dressings with bacitracin-neomycin ointment; D) a combination of B and C; and E) no perineal care.</p> <p>Two drainage systems were compared in which one had an air barrier between bag and tubing and the air vent was protected against accidental wetting (designated as the "test drainage system" for the purposes of the review).</p> <p>Antimicrobial prophylaxis was classified as bacteriostatic, narrow/ broad-spectrum bactericidal.</p>	<p>Adult female patients in whom a catheter was in place for at least 60 hours</p> <p>184</p>	<p>Bacteriuria: <i>Perineal care:</i> A vs B vs C vs D vs E: 20/35 vs 18/38 vs 15/26 vs 25/46 vs 20/39; P > 0.05</p> <p><i>Perineal care stratified by drainage system</i></p> <p>Test drainage system: A vs B vs C vs D vs E: 10/17 vs 8/17 vs 9/12 vs 12/24 vs 10/17; P > 0.05</p> <p>Control drainage system: A vs B vs C vs D vs E: 10/18 vs 10/21 vs 6/14 vs 13/22 vs 10/22; P > 0.05</p> <p><i>Test drainage system vs control drainage system:</i> 49/87 vs 49/97; P > 0.05</p> <p>Antibiotic prophylaxis</p> <p>Bacteriostatic vs broad-spectrum bactericidal vs narrow-spectrum bactericidal vs none: 10/21 vs 9/38 vs 7/11 vs 62/82; P < 0.01</p> <p><i>Broad-spectrum antibiotic prophylaxis stratified by risk</i></p> <p>High risk: Broad-spectrum bactericidal vs no prophylaxis: 6/15 vs 29/33; P < 0.01</p> <p>Low risk: Broad-spectrum bactericidal vs no prophylaxis: 3/23 vs 33/49; P < 0.01</p>	<p>F/U unclear</p> <p>Bacteriuria was defined as $\geq 10^5$ colonies/ml of one pathogenic species in the catheterized specimen.</p> <p>Power not reported</p>
Ross, 1966 ²¹⁶	RCT 1	<p>To compare two different catheterization regimes in the prophylaxis of UTI.</p> <p>Test group: The pre-operatively shaved genitalia were sprayed with polybacctrin: a combination of polymyxin, zinc bacitracin and neomycin. After this, the patient</p>	<p>Catheterized gynecological patients</p> <p>292</p>	<p>Undefined UTI: Test vs control: 42/132 vs 76/160; statistical differences were not reported</p>	<p>F/U unclear</p> <p>Infection defined on the basis of pus cells and bacterial counts, but no clear levels specified.</p> <p>Power not reported</p>

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		was swabbed with Savlon . The end of a disposable catheter was treated with neomycin and polymyxin and the catheter inserted. With the catheter in situ, the bladder was treated with Savlon. When the catheter was removed, the bacitracin spray was again applied. Control group: The patient's vulva, prior to catheterization, was swabbed with benzalkonium chloride . A rubber catheter was then inserted aseptically. After the bladder was emptied, chlorhexidine was poured into the bladder using a sterile glass funnel.			
Koskeroglu, 2004 ²⁴⁶	Prospective controlled study 1,3	To investigate the efficacy of antiseptic meatal care in preventing CAUTI in patients with indwelling urinary catheter in an ICU. There were four groups which received an antiseptic (once and twice daily chlorhexidine and povidone-iodine) and a control group.	Patients who received a urethral catheter and mechanical ventilation in the ICU 130	Bacteriuria: All antiseptics vs control: 13/100 vs 3/30; statistical differences were not reported	F/U 10 days UTI defined as $\geq 10^5$ cfu/ml Power not reported
Matsumoto, 1997 ²⁴⁷	Prospective controlled study 1,3	To determine whether urethral meatal care treatment was useful for short-term catheterization when using a closed drainage system. Group A received a once-daily application of povidone-iodine; group B received a twice-daily application of povidone iodine; and group C received a once-daily application of povidone iodine cream.	Patients who received an indwelling urethral catheter after various urological procedures 72	Bacteriuria on postoperative day 14: <i>Females:</i> Group A: 57% Group B: 29% Group C: 62% Statistical differences were not reported <i>Males:</i> Group A: 36% Group B: 0% Group C: 100% by post-op day 3 Statistical differences were not reported	F/U unclear UTI was defined as bacteriuria $\geq 10^4$ cfu/ml Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
Jacono, 1988 ⁸⁸	Retrospective controlled study 1,3,6,7	To examine the characteristics of patients who developed a nosocomial UTI.	Patients admitted to either a unit for patients with acute conditions or one that provided long-term care 71	Bacteriuria: Females had a greater risk than males. Statistical differences were not reported. The effect of a meatal anti-bacterial agent was assessed in a pre-post fashion and it was found to result in a non-significant decrease in infection rate in males, but a paradoxical increase in females	F/U unclear Nosocomial UTI was defined as sterile urine culture upon admission and 1) bacterial growth measuring $< 10^5$ organisms/ml but with a WBC count $> 5/\text{hpf}$ or 2) bacterial count $> 10^5$ organisms/ml Power not reported

2C.6. Frequency of catheter or bag change

Keerasuntonpong, 2003 ²¹⁷	RCT 1	To compare the incidence of UTI in hospitalized patients with indwelling catheters who receive a drainage bag change every 3 days vs those who receive no bag change. In the latter group, the bags were changed only when the urethral catheters were changed or the urinary drainage bags were torn or damaged.	Patients aged > 12 years who were admitted to a medical ward and were catheterized for at least 3 days 153	Symptomatic UTI (episodes per 1000 catheter days): 3 day change vs no change: 11/79 vs 8/74; P = 0.70 Bacteriuria: 3 day change vs no change: 29/79 vs 27/74; P = 0.90 Mean duration of catheterization (days): 3 day change vs no change: 10.1 vs 9.5; P = 0.10	F/U until the catheters were removed, the patient died or the patient was diagnosed as having a UTI. The diagnostic criteria for CAUTI were those defined by the CDC. Power not reported
Dille, 1993 ²¹⁸	RCT 1	To determine the safety of 4-week re-use of vinyl urinary leg and bed bags when decontaminated daily with dilute bleach (sodium hypochlorite) rinse.	Patients admitted to a rehabilitation unit with diagnoses of spinal cord injury, stroke, head injury, or other neuromuscular conditions 54	Symptomatic UTI: 4 weeks vs 1 week: P = NS Bacteriuria 4 weeks vs 1 week: P = NS Leakage of bags: None of the bags leaked Cost: The 4-week group saved \$238.68 per patient compared to the 1-week group	F/U 4 weeks UTI not defined 80% power to detect a difference (0.4) at a power of 0.80 and an alpha of 0.05
Priefer, 1982 ²¹⁹	RCT 1	To determine whether or not clinical UTI is influenced by frequency of catheter change. In group A, catheters were changed only for obstruction	Nursing home patients 17	Symptomatic UTI: Group A vs Group B: 6/7 vs 3/10; P = NS	F/U 6 months A clinical UTI was defined as one in which there was a rectal temperature of greater

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		and/or infection. In group B, catheters were changed on a regular monthly schedule as well as for obstruction and/or infection.			than 101 F or a clinical picture compatible with a UTI in the absence of fever (i.e., lethargy, anorexia, nausea, vomiting, personality change, and/or leukocytosis). These symptoms may or may not have been accompanied by chills or flank pain and in addition, no other sources of infection could be found. Power not reported
Stelling, 1996 ²⁴⁸	Prospective controlled study 1,3	To compare daily changing of condom catheters to changing them every other day.	Outpatients with spinal cord injury 113	<u>All results %; P value</u> Undefined UTI: Every other day vs daily: 24.2 vs 31.3; NS Bladder stone: Every other day vs daily: 6.1 vs 1.3; NS Renal stone: Every other day vs daily: 0 vs 1.3; NS Redness: Every other day vs daily: 21.2 vs 30.0; NS Grade 1 pressure ulcer: Every other day vs daily: 21.2 vs 28.8; NS Excoriation: Every other day vs daily: 3.0 vs 10.0; NS Swelling: Every other day vs daily: 9.1 vs 7.5; NS	F/U 5 years UTI not clearly defined Power not reported
White, 1995 ¹⁰²	Retrospective controlled study 1,3,4,6,7	To determine the characteristics of those who acquire UTI and the effect of the interval between catheter changes on the incidence of UTI.	Home care patients with catheters 106	Symptomatic UTI: <i>Multivariate analysis:</i> All results RH (95% CI) [RH = relative hazard] Catheter change interval ≤ 4 wk (compared to less frequently): 11.94 (5.46-26.22) Number of nurses changing catheter: 1.38 (1.22-1.65) Age: 0.99 (0.98-1.01) Ambulatory care group: 1.01 (0.99-1.03) Female sex: 0.72 (0.34-1.53) (Only multivariate analysis was reported)	F/U until the end of home care, hospitalization, or death UTI according to CDC definition Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
Reid, 1982 ²⁴⁹	Prospective controlled study 1,3,5	To compare daily and weekly bag-changing regimens.	Elderly catheterized patients 12	<p>Pus at meatus: Daily vs weekly: P = NS</p> <p>Leakage/blockage requiring bag change: Daily vs weekly: P = NS</p> <p>Pyrexial episodes: Daily vs weekly: P = NS</p> <p>Courses of antibiotics: Daily vs weekly: P = NS</p> <p>Pyelonephritis: No episodes</p> <p>Subgroup analysis: Latex and silastic catheters were also compared as subgroups within the categories. Statistical differences were not reported with the exception of pyrexia which was significantly higher with latex catheters (P < 0.01)</p>	F/U unclear Though UTI was defined, it was not reported as a separate outcome Power not reported

2C.7. Catheter lubricants

Fera, 2002 ²²⁰	RCT 1	To compare the lubrication of urethral catheters with 0.1% gentamicin cream vs 2% lidocaine jelly.	Patients undergoing intermittent bladder catheterization and having normal renal function and a normal urinary tract on ultrasonography 20	<p>Symptomatic UTI: Gentamycin vs Lidocaine: 1/10 vs 2/10; P = NS</p> <p>Bacteriuria:</p> <p><u>Sample 1:</u> Gentamicin vs Lidocaine: 8/10 vs 4/10; P = NS</p> <p><u>Sample 2:</u> Gentamicin vs Lidocaine: 7/10 vs 4/10; P = NS</p> <p><u>Sample 3:</u> Gentamicin vs Lidocaine: 6/10 vs 4/10; P = NS</p> <p><u>Sample 4:</u> Gentamicin vs Lidocaine: 8/10 vs 5/10; P = NS</p> <p><u>Sample 5:</u> Gentamicin vs Lidocaine: 8/10 vs 6/10; P = NS</p> <p>Leukocyturia: Gentamicin vs Lidocaine: P = NS</p>	F/U 4 months. Bacteriuria was defined as bacteriuria $\geq 10^5$ cfu/ml Power not reported
Giannantoni, 2001 ²²¹	Crossover RCT 1,3,5,6	To compare the safety and patient acceptance of a prelubricated nonhydrophilic	Patients with spinal cord injury on intermittent catheterization	Symptomatic UTI: Prelubricated vs conventional: 4 vs 12; P = 0.03	F/U 7 weeks Symptomatic UTI was defined

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		catheter and a sterile single-use PVC silicon-coated catheter which was lubricated with gel by the patient.	18	Bacteriuria: Prelubricated vs conventional: 8 vs 18; P = 0.02 Patient satisfaction score: Prelubricated vs conventional: 4.72 vs 2.33; P = 0.02 Urethral bleeding: Prelubricated vs conventional: 0 vs 2; statistical differences were not reported	as cloudy and odorous urine, onset of urinary incontinence, increased spasticity, autonomic dysreflexia, increased sweating, and malaise or a sense of unease associated with pyuria and significant bacteriuria. Asymptomatic bacteriuria was defined as uropathogenic colonization of the urinary tract without symptoms of infection. Power not reported
Cohen, 1985 ²²²	RCT 1,4,7,8	To compare the value of a povidone-iodine lubricating gel as a catheter lubricant when compared with a control jelly (K-Y lubricating jelly).	Normal adult volunteers 30	Mean colony count (/5 ml aspirated urine post-catheterization) Povidone iodine jelly vs control jelly: 3.6 vs 69.6; P < 0.03 Stinging/burning: Povidone iodine jelly vs control jelly: 14/15 vs 10/15; statistical differences were not reported	F/U until shortly after catheterization Urine aspirated suprapublically from the bladder was cultured to test for contamination Power not reported
Kunin, 1971 ²²³	RCT 1	To compare 1) a test lubricant consisting of methylcellulose, propylene glycol, disodium edetate, benzalkonium chloride, polymyxin B, ethylene dioxide and distilled water; 2) a placebo lubricant with Polymyxin B and benzalkonium chloride; and 3) No lubricant.	Adult patients who required catheter care 314	Bacteriuria: on day 6: <i>1. Males</i> Polymyxin B lubricant: 21.7% Placebo lubricant: 25.0% No lubricant: 22.2% P > 0.05 <i>2. Females</i> Polymyxin B lubricant: 25.0% Placebo lubricant: 27.3% No lubricant: 58.3% Among the females, the polymyxin lubricant was found to be significantly better than no lubricant on days 5 to 8 while the placebo was significantly better only on days 6 and 7	F/U unclear: at least 10 days. Bacteriuria defined as $\geq 10^5$ colonies/ml Power not reported
Kambal, 2004 ²⁵⁰	Prospective pre-post study 1,3,4	To measure the impact of an antiseptic anesthetic urethral lubricant (Instillagel) on UTI rate, with or without the use of a pre-sealed catheter and bag system,	Patients undergoing gynecological surgery 149	Symptomatic UTI: <i>Area 1:</i> Instillagel and unconnected catheter vs no lubricant: 12.8% vs 21.4%; statistical differences were not reported Instillagel and pre-connect catheter vs no lubricant: 15.1% vs	F/U 3 months UTI diagnosed by the following criteria: 1) patient has a urethral catheter in situ

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		compared with no lubricant.		<p>21.4%; statistical differences were not reported</p> <p><u>Area 2:</u> Instillagel and unconnected catheter vs no lubricant: 5.5% vs 17.6%; statistical differences were not reported Instillagel and pre-connect catheter vs no lubricant: 7.1% vs 17.6%; statistical differences were not reported</p> <p>Bacteriuria:</p> <p><u>Area 1:</u> Instillagel and unconnected catheter vs no lubricant: 1/39 vs 0/28; statistical differences were not reported Instillagel and pre-connect catheter vs no lubricant: 1/33 vs 0/28; statistical differences were not reported</p> <p><u>Area 2:</u> Instillagel and unconnected catheter vs no lubricant: 0/18 vs 0/17 statistical differences were not reported Instillagel and pre-connect catheter vs no lubricant: 0/14 vs 0/17; statistical differences were not reported</p>	<p>and $\geq 10^4$ micro-organisms/ml from a catheter specimen of urine and one or more of the following with no other recognized cause: loin pain, loin or suprapubic tenderness, fever (≥ 38 C skin temperature), or pyuria ($\geq 10^4$ WBC/ml); 2) physician diagnoses UTI and institutes appropriate antimicrobial therapy and the patient has two or more of the following with no other recognized cause: loin pain, loin or suprapubic tenderness, or pyuria ($\geq 10^4$ WBC/ml)</p> <p>Asymptomatic UTI was a positive urine culture with no symptoms</p> <p>Power not reported</p>
Schiotz, 1996 ²⁵¹	Prospective controlled study 1,3,4	To evaluate the effect of an antiseptic lubricating gel used at catheter insertion on the rates of postoperative UTI.	Women not taking antibiotics admitted for elective gynecological surgery 519	<p>Symptomatic UTI: Gel vs no gel: 23/132 vs 71/387; P = 0.95 Results were robust to surgical categories (laparotomy, vaginal or retropubic surgery), catheterization for 1 or 3 days, positive and negative preoperative cultures, and age.</p>	<p>F/U postoperatively</p> <p>Cultures were defined as positive when a mid-stream urine specimen yielded $> 10^5$ cfu/ml of any organism or a catheter specimen yielded $> 10^4$ cfu/ml.</p> <p>UTI defined as a positive culture associated with dysuria, pain, fever, or sepsis.</p> <p>Power not reported</p>
Harrison, 1980 ²⁵²	Prospective controlled study 1,3	To compare microbicidal povidone-iodine gel with placebo gel as a catheter lubricant.	Male patients who required urethral catheterization 50	<p>Bacterial count on urethral swab: The reduction in bacterial counts achieved by povidone-iodine gel was significantly greater than that achieved with placebo gel (P < 0.02)</p> <p>Stinging or burning:</p>	<p>F/U not reported</p> <p>UTI not defined</p> <p>Power not reported</p>

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				P = NS	
Chavigny, 1975 ²⁵³	Prospective controlled study 1,3	To assess the value of polymyxin B as a urethral lubricant to reduce the post-instrumental incidence of bacteriuria.	Catheterized patients on the obstetrical/gynecological service 100	Bacteriuria: Polymyxin B vs no lubricant: 4/50 vs 12/50; P < 0.05 Duration of catheterization (days): Polymyxin B vs no lubricant: 1.92 vs 2.00; statistical differences were not reported	F/U unclear Positive urine culture defined as $\geq 10^5$ colonies/ml in catheterized specimens Power not reported
Butler, 1968 ¹⁶⁷	Prospective controlled study 1,3	To evaluate the individual effects of 1) lubrication of the catheter with antibiotic (polymyxin) containing material; 2) use of catheters impregnated with antimicrobial materials: tetramethyl-thiuram disulfide (TMTS) or cyclic thiohydroxamic acid (CTHA); and 3) a control.	Catheterized patients 758	Bacteriuria: <i>(1) Lubricated catheter vs placebo lubricant</i> Developed in 50% of patients after 8.6 days and 11.6 days with polymyxin and placebo lubricants respectively. No statistically significant differences were seen. <i>(2) Antibiotic-impregnated catheter vs control catheters</i> No statistically significant differences were seen when impregnated and control catheters were compared.	F/U until catheter removal, discharge or death Bacteriuria defined as $> 10^5$ colonies/ml Power not reported
Nooyen, 1966 ²⁵⁴	Prospective controlled study 1,3,4	To test the effect of instillation of polymyxin B benzalkonium chloride jelly into the urethra in preventing CAUTI.	Catheterized obstetric patients 500	Symptomatic UTI: Polymyxin vs no lubricant: 6/370 vs 12/130; statistical differences were not reported	F/U unclear Patients complaining of dysuria, frequency, urgency or fever that could not be explained by other reasons were considered as having UTI Power not reported

2C.8. Securing devices

Darouiche, 2006 ²²⁴	RCT 1,2,4,7,8	To assess the anti-infective benefit of using StatLock, a securing device that prevents the to-and-fro movement of the catheter, compared to traditional methods (tapes, straps) or no method.	Adult patients who were diagnosed with neurogenic bladder and required a long-term indwelling transurethral or suprapubic bladder catheter 127	Symptomatic UTI: StatLock vs Control: 8/60 vs 14/58; RR (95% CI) = 0.55 (0.25-1.22) Catheter dislodgement: StatLock vs Control: 1/60 vs 3/58; P = NS Meatal erosion: StatLock vs Control: 2/60 vs 3/58; P = NS Mean duration of catheterization (days): StatLock vs Control: 50 vs 49; P = NS	F/U 8 weeks Symptomatic UTI was diagnosed by the presence of significant bacteriuria ($\geq 10^4$ cfu/ml) and pyuria (> 10 WBC/hpf) plus 1 or more of the following clinical signs and symptoms for which no other etiology could be identified: fever (oral
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
					temperature > 100 F), suprapubic or flank discomfort, bladder spasm, increased spasticity, and worsening dysreflexia 65 patients would be needed to randomized to each study group to have 80% power at an alpha of 0.05 to reduce the rate of symptomatic UTI from 50% in the control group to 25% in the StatLock device group. The study may have been underpowered because observed rates of symptomatic UTI were almost twice lower than that expected

2C.9. Bacterial interference

Darouiche, 2005 ²²⁵	RCT 1,3,4,5,7,9	To examine the efficacy of bacterial interference (colonization with <i>Escherichia coli</i> 83972) in preventing UTI.	Adult patients with SCI for a duration of \geq 1 year who had a neurogenic bladder that required indwelling or intermittent catheter drainage and experienced frequent symptomatic episodes of UTI (\geq 2 episodes during the preceding year) 27	Symptomatic UTI: <u>Number of patients</u> Bacterial interference vs control: 13/21 vs 6/6; P = 0.07 <u>Mean number of episodes</u> Bacterial interference vs control: 1.6 vs 3.5; P = 0.04 <u>Survival analysis</u> Bacterial interference vs control: P < 0.01 for the protective effect of bacterial interference	F/U 1 year UTI defined as significant bacteriuria (bacteriuria ($\geq 10^5$ cfu/ml) and pyuria (> 10 WBC/hpf) plus 1 or more of the following clinical signs and symptoms for which no other etiology could be identified: fever (oral temperature > 100 F), suprapubic or flank discomfort, bladder spasm, increased spasticity, and worsening dysreflexia
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2C.10. Catheter cleansing

Moore, 1990 ²²⁶ 1,4	Crossover RCT	To compare cetrimide and liquid detergent for cleaning urethral catheters used for clean	Children with neurogenic bladder who were on clean intermittent catheterization	Sterile catheter tips: Cetrimide vs soap and water: 26/60 vs 37/60; P < 0.05	F/U unclear Bacteriuria defined as $\geq 10^3$
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		intermittent catheterization.	for 2 months or more 32	Mean colony count per catheter: Cetrimide vs soap and water; P = NS	cfu/ml but not compared between the two groups Symptomatic bacteriuria was defined as $\geq 10^3$ cfu/ml plus any of the following symptoms: fever, malaise, flank pain, suprapubic pain, dysuria, hematuria, urgency, and/or incontinence but was not compared between the two groups Power not reported
Sims, 1993 ²⁵⁵	Retrospective controlled study 1,3,4,6,7	To compare two catheter care procedures for clean intermittent catheterization: a wet procedure in which the catheter was washed with soap and water and stored in a dilute povidone-iodine solution between uses, and a dry procedure in which the catheter was washed with soap and water and then stored and left to air dry.	Spinal cord-injured patients undergoing clean intermittent catheterization 48	Symptomatic UTI: Wet procedure vs dry procedure: 13 vs 28 episodes; P = 0.02 Adjusting for catheterization intervals and antibiotic use between the two groups did not result in significant differences between the two groups in symptomatic bacteriuria. However, after controlling for bladder volumes, significant bacteriuria occurred significantly more frequently in the dry group (P = 0.05) Catheterization intervals (hours): Wet procedure vs dry procedure: 4.8 vs 5.9; P < 0.01 Bladder volumes: P = 0.40. No other relevant comparison provided Antibiotic use: Wet procedure vs dry procedure: 5/23 vs 6/25; statistical differences were not reported	F/U unclear Symptomatic bacteriuria was defined as the presence of $\geq 10^5$ colonies/ml and at least one of the following: temperature > 99 F, malaise, increased muscle spasticity, episodes of autonomic dysreflexia, more frequent or new urinary leakage between catheterizations, or changes in color, clarity, or odor of urine Power not reported

2C.11. Catheter removal strategies

Griffiths, 2007 ¹⁸⁴	Systematic review 1,2,3,4,5,6,7,8	To determine the best strategies for the removal of catheters from patients with a short-term indwelling urinary catheter. Four comparisons were made: 1) removal of catheter at one time of day vs another; 2) shorter vs longer duration of catheter use; 3) flexible vs fixed duration of	All randomized and quasi-randomized trials that compared the effects of alternative strategies for removal of short term (≤ 14 days) indwelling urethral catheters on patient outcomes were considered for inclusion in the review	<p>(1) Removal of IUC at one time of day vs another</p> <p>Volume of first void (2 studies): Midnight vs morning [WMD (95% CI)] : 30.72 (-4.38 to 65.81)</p> <p>Volume of first void following urological surgery and procedures (3 studies): Midnight vs morning [fixed difference (95% CI)]: 95.82 (62.02 to 129.62)</p> <p>Volume of first void following TURP (1 study): Midnight vs morning [fixed difference (95% CI)]: 27.00 (22.73 to 31.27)</p> <p>Time to first void (2 studies) Midnight vs morning [WMD (95% CI)]: 0.99 (0.24 to 1.73)</p>	
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		catheter use; and 4) clamping vs free drainage before catheter removal.	People of all ages having a short-term (\leq 14 days) indwelling urethral catheter in any setting (hospital, community, nursing home) were included in the review 26 trials	<p>Time to first void following urological surgery and procedures (3 studies): Midnight vs morning [Fixed difference (95% CI)]: 46.85 (29.53 to 64.18)</p> <p>Time to first void following TURP (1 study): Midnight vs morning [Fixed difference (95% CI)]: 15.00 (-66.82 to 96.82)</p> <p>No. of patients not discharged on the day of catheter removal (6 studies): Midnight vs morning [RR (95% CI)]: 0.71 (0.64-0.79)</p> <p>Recatheterization (8 studies): Midnight vs morning [RR (95% CI)]: 0.80 (0.58-1.08)</p> <p>Removal of catheter to discharge decision (2 studies): Midnight vs morning [WMD (95% CI)]: 0.08 (-5.96 to 6.12)</p> <p>Post discharge urinary retention (1 study): Midnight vs morning [RR (95% CI)]: 0.98 (0.38-2.48)</p> <p>Post discharge difficulty in passing urine (1 study): Midnight vs morning [RR (95% CI)]: 1.10 (0.45-2.71)</p> <p>Post discharge pain while passing urine (1 study): Midnight vs morning [RR (95% CI)]: 2.20 (0.70-6.86)</p> <p>Post discharge loin pain (1 study): Midnight vs morning [RR (95% CI)]: 3.91 (0.45-34.24)</p> <p>Post discharge fever (1 study): Midnight vs morning [RR (95% CI)]: 1.71 (0.52-5.62)</p> <p>Post discharge incontinence (1 study): Midnight vs morning [RR (95% CI)]: 0.62 (0.25-1.53)</p> <p><i>(2) Shorter vs longer duration of catheter use</i></p> <p>Short term urinary retention: Heterogeneous populations not pooled. Nonsignificant in 8 studies, significantly increased in 1 study with shorter duration.</p> <p>Recatheterization: Heterogeneous populations not pooled. Nonsignificant in 6 studies, significantly increased in 1 study with shorter duration.</p> <p>Chronic urinary retention: Heterogeneous populations not pooled. Non significant in 3 studies.</p> <p>Undefined UTI: Heterogeneous populations not pooled. Nonsignificant in 6 studies, significantly decreased in 1 study with shorter duration.</p> <p>Urethral pain and discharge: Nonsignificant in one study</p> <p>Secondary hemorrhage: Heterogeneous populations not pooled. Nonsignificant in 2 studies,</p> <p>Deep venous thrombosis: Nonsignificant in one study</p> <p>Epididymitis:</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>Non significant in one study</p> <p>Strictures: Non significant in one study</p> <p>Epididymitis: Non significant in 2 studies</p> <p>Urinary complications: Non significant in one study</p> <p>Post-op fever: Non significant in one study</p> <p>Length of stay: Significantly decreased with shorter duration in 3 studies. Non significant in 3 studies</p> <p>Patient satisfaction: Non significant in one study</p> <p><i>(3) Flexible vs fixed duration of catheter use</i> No eligible trials compared flexible with fixed duration of catheterization,</p> <p><i>(4) Clamping vs free drainage before catheter removal</i> Undefined UTI: Non significant in one study</p> <p>Urinary retention: Non significant in one study</p> <p>Recatheterization: Non significant in one study</p> <p>Time to first void: Significantly decreased in 2 studies</p> <p>Voiding dysfunction: Non significant in one study</p> <p>No trials assessed prophylactic alpha sympathetic blocker drugs prior to catheter removal</p>	
Phipps, 2006 ³⁷	Systematic review 1,2,3,4,5,6,7,8	To establish the optimal way to manage urinary catheters following urogenital surgery in adults.	Randomized and quasi-randomized trials 39 RCTs	<p><i>Note: All results are RR (95% CI) unless otherwise noted</i></p> <p><i>1. Using a urinary catheter vs not using a urinary catheter</i> Retention of urine (1 study): 0.12 (0.03-0.47) UTI (4 studies): 1.35 (0.75-2.45) Recatheterization (3 studies): 0.32 (0.14-0.70) Post-op urethral stricture (1 study): 1.14 (0.90-1.44) Post-op hematuria (1 study): 0.73 (0.40-1.33)</p> <p><i>2. Urethral catheterization vs suprapubic catheterization</i></p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>UTI: Heterogeneous results, not combined. Of four trials, two suggested a moderate increase, one a large increase and one a large decrease.</p> <p>Recatheterization (2 studies): 3.66 (1.41-9.49)</p> <p>Post-op hematuria (1 study): 5.00 (0.21-116.31)</p> <p>Length of hospital stay in days (1 study) [WMD (95% CI)]: 1.10 (0.30-1.90)</p> <p>Catheter lockage or bypassing [OR (95% CI)] (2 studies): 0.20 (0.02-1.72)</p> <p><i>3. One type of catheter vs another type of catheter</i></p> <p>UTI: Urethral Foley catheter with extra drainage hole vs unmodified Foley catheter (1 study): 0.40 (0.15-1.04)</p> <p>Positive urine culture: Silver-coated Bardex catheters vs latex catheters (1 study): 0.53 (0.20-1.45)</p> <p><i>4. One type of catheter management vs another</i></p> <p>Retention of urine: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.99 (0.06-15.54)</p> <p>Dysuria: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.99 (0.06-15.54)</p> <p>Symptomatic UTI: Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 0.61 (0.33-1.14)</p> <p>Bacteriuria/unspecified UTI: Cefotaxime 1 hour prior to catheter removal vs none (1 study): 0.08 (0.00-1.30)</p> <p>Neomycin/Sulfamethiazole vs placebo (1 study): 0.18 (0.06-0.55)</p> <p>Vaginal cleansing before catheter insertion vs vaginal cleansing after catheter insertion (1 study): 1.06 (0.70-1.51)</p> <p>Recatheterization: Neomycin/Sulfamethiazole vs placebo (1 study): 0.50 (0.24-1.04)</p> <p><i>5. Larger diameter catheter vs Smaller diameter catheter</i></p> <p>No trials found</p> <p><i>6. Bladder irrigation</i></p> <p>No trials found</p> <p><i>7. Shorter duration vs longer duration catheter</i></p> <p>Retention of urine: 1 day vs 3 days (1 study): 0.80 (0.38-1.69)</p> <p>1-2 days vs until urine clear (1 study): 1.02 (0.07-15.87)</p> <p>1 day vs 2 days (1 study): 4.64 (0.23-94.28)</p> <p>3 days vs 28 days (1 study): 3.00 (0.13-69.52)</p> <p>Post-op urethral stricture: < 1 week vs 2 weeks (2 studies): 1.23</p>	

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>(0.82-1.84) 3 days vs 28 days (1 study): 1.00 (0.73-1.36) UTI: Heterogeneous results, not combined. Shorter-duration catheter had lower risk of UTIs but the results were significant in only 1 trial 1 day vs 3 days (3 studies): 0.50 (0.29-0.87) Recatheterization: 1 day vs 2 days (1 study): 1.03 (0.23-4.71) 1 day vs 3 days (2 studies): 1.04 (0.36-3.01) 1 day vs 5 days (1 study): 4.55 (1.68-12.37) 4-6 days vs 14 days (1 study): 1.86 (0.14-25.38) 1-2 days vs until urine clear (2 studies): 0.72 (0.24-2.20) Post-op hematuria: 1-2 days vs until urine clear (1 study): 2.04 (0.19-21.81) 1 day vs 2 days (2 studies): 1.16 (0.34-3.90) Urinary leakage or incontinence: 1-2 days vs until urine clear (2 studies): 0.43 (0.07-2.88)</p> <p><i>8. Clamp and release vs free catheter drainage:</i> UTI (1 study): 4.00 (1.55-10.29) Delay in return to normal bladder function (1 study): 2.50 (1.16-5.39)</p> <p><i>9. Catheter removal at one time of day vs another time of day</i> UTI: 12 am vs 6 am (1 study): 1.31 (0.65-2.66) Recatheterization: 12 am vs 6 am (4 studies): 0.61 (0.34-1.12) 6-7 am vs 10-11 pm (1 study): 1.36 (0.32-5.77) Time to first void in hours [WMD (95% CI)]: 12 am vs 6 am (1 study): 0.60 (-0.96 to 2.16) Volume of first void in ml [WMD (95% CI)]: 12 am vs 6 am (1 study): 53.00 (4.27-101.73)</p> <p><i>10. Trial of void protocol vs none</i> No trials found</p> <p><i>11. Prefilling bladder prior to catheter removal vs removal without prefilling</i> Recatheterization [OR (95% CI)] (1 study): 4.52 (0.79-25.97) Discharge on day of catheter removal (1 study): 1.36 (0.47-3.91)</p>	
Alessandri, 2006 ²²⁷	RCT 1,2,6,7,8	To assess whether the immediate removal of an indwelling catheter after hysterectomy affected the rate of abnormal uterine bleeding,	Women who underwent hysterectomy for various benign diseases (fibroids, abnormal uterine bleeding,	<p>Symptomatic UTI: Immediate removal vs removal at 6 hrs: 1/32 vs 4/30; P = NS Immediate removal vs removal at 12 hrs: 1/32 vs 5/32; P = NS</p>	F/U unclear The diagnosis of symptomatic UTI was based on the

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		recatheterization, symptomatic UTI, time of ambulation, and hospital stay when compared with removal at 6 hours and 12 hours after the operation.	and persistent cervical dysplasia) 96	Recatheterization: Immediate removal vs removal at 6 hrs: 6/32 vs 0/30; P < 0.01 Immediate removal vs removal at 12 hrs: 6/32 vs 0/32; P < 0.01 Mean first ambulation time (hr) Immediate removal vs removal at 6 hrs: 4.3 vs 6.5 ; P < 0.05 Immediate removal vs removal at 12 hrs: 4.3 vs 9.4 ; P < 0.05 Hospital stay (hours) Immediate removal vs removal at 6 hours: 36.2 vs 50.4 ; P < 0.05 Immediate removal vs removal at 12 hours: 36.2 vs 55.2; P < 0.05	following criteria: significant bacteruria ($\geq 10^5$ cfu/ml of an identified single uropathogen) accompanied by at least one of the following symptoms: dysuria, increased frequency of urination, urinary urgency, suprapubic pain, burning on micturition and onset or aggravation of urinary incontinence. Time to ambulation was defined as the interval between the completion of surgery and the time when the patient could stand up and walk supported by a nurse. Length of hospital stay was defined as the time interval between the completion of surgery and hospital discharge Power not reported
Schiotz, 1995 ²²⁸	RCT 1,6	To see whether reducing transurethral Foley catheterization from 3 days to 1 day would lead to fewer UTIs without retention becoming a problem.	Women undergoing elective vaginal plastic repair surgery 165	Symptomatic UTI: 1 day vs 3 days: 12/82 vs 17/83; P = 0.43 Retention: 1 day vs 3 days: 18/82 vs 12/83; P = 0.26 Recatheterization: 1 day vs 3 days: 7/82 vs 3/83; P = 0.31	F/U 1 month Cultures were defined as positive when a mid-stream urine specimen yielded $> 10^5$ cfu/ml of any organism or a catheter specimen yielded $> 10^4$ cfu/ml. UTI was defined as a positive culture associated with dysuria, pain, fever, or sepsis. Intermittent catheterization was performed if the patient was distressed or if a bladder volume > 500 ml was suspected. Urinary retention was defined as the need for intermittent catheterization at

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
					least once Power not reported
Wald, 2005 ²⁵⁶	Retrospective controlled study 1,3,4,6,7	To explore the relationship between extended indwelling urinary catheterization and outcomes for patients sustaining hip fractures discharged to skilled nursing facilities.	Medicare admissions to skilled nursing facilities of patients discharged from a hospital with a primary diagnosis of hip fracture 111330	Rehospitalization for UTI: Adjusted OR for catheter vs no catheter: 1.58; P < 0.01 Rehospitalization for sepsis: Adjusted OR for catheter vs no catheter: 1.22; P < 0.01 Discharge to community: Adjusted OR for catheter vs no catheter: 0.93; P < 0.01 Mortality: Adjusted OR for catheter vs no catheter: 1.31; P < 0.01	F/U 30 days UTI not defined Power not reported

2C.12. Assessing urine volumes

	Systematic review 1,2,3,4,5,6,7,8	To identify risk factors for UTI.	Controlled trials in adults and adolescents with neurogenic bladder dysfunction addressing the issue of risk factors for recurrent UTI 22 studies	Sex: Two studies reported a higher risk for UTI in females, while 4 other studies did not. The authors concluded that the effect of being a female on the risk of UTI in people with neurogenic bladder remained unclear. Level of function: Four studies did not find an increased rate of UTI among patients with tetraplegia compared with patients with paraplegia. Three other studies reported significant increases in infection in persons with complete lesions while 3 studies did not. The authors felt that given the conflicting nature of the results, no conclusions could be drawn about the effect of completeness of lesion on the risk of UTI. Bladder physiology: As the residual volume increased to 300 ml, the rate of UTI over time increased between 4-fold and 5-fold. Another study reported that a > 20% post void residual was associated with complications. It was likely that increased bladder residual volume was a risk factor for UTI in persons with neurogenic bladder. Method of drainage: Results were consistent in 7 of 8 studies that persons using intermittent catheterization had fewer infections than those with indwelling catheters and (when studied) persons voiding without catheters had the lowest rate of UTI in all groups. Two RCTs did not report significant differences in UTI between sterile and clean methods for intermittent catheterization. Another non-randomized controlled trial found that a sheathed catheter	Qualitative SR. Studies were determined to be too clinically heterogeneous to support statistical pooling or risk prediction modeling.
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				<p>(which amounted to a sterile method) resulted in fewer episodes of bacteriuria when compared with a standard catheter. The authors concluded that the evidence neither supported nor refuted the need to utilize sterile, as opposed to clean, intermittent catheterization</p> <p>The authors concluded that the optimum frequency for change of condom catheters was unknown.</p> <p>Time since injury: The study measuring UTI in the most rigorous fashion among 3 studies addressing this issue found that a longer time since injury was significantly associated with a higher occurrence of UTI.</p> <p>Laboratory findings: A prospective cohort study reported that symptomatic UTIs occurred more frequently following relapsing (regrowth of same bacterium) asymptomatic bacteriuria than recurrent (regrowth of different bacterium) asymptomatic bacteriuria; $P < 0.03$</p> <p>There were no studies or the data were scarce assessing the effect of socioeconomic and insurance status; psychosocial, behavioral, and hygiene factors and domicile on the risk of UTI</p>	
Polliack, 2005 ²²⁹	RCT 1	<p>To compare the impact of volume-dependent intermittent catheterization (VDIC) and time-dependent intermittent catheterization (TDIC) on financial burden and clinical outcomes in patients with spinal cord lesions.</p> <p>VDIC was performed when the volume in the bladder exceeded 300 ml on portable ultrasound. TDIC was performed every 6 hours.</p>	<p>Patients with neuropathic bladder who required intermittent catheterization; all had spinal cord lesions</p> <p>24</p>	<p>Number of catheterizations/ patient/day: VDIC vs TDIC: 2.02 vs 3.62; $P < 0.01$</p> <p>Number of urine volume measurements/ patient/day: VDIC vs TDIC: 2.53 vs 3.62; $P < 0.01$</p> <p>Time required to perform catheterizations and urine volume measurements (minutes): VDIC vs TDIC: 21.16 vs 41.17; $P < 0.01$</p> <p>Total cost (New Israeli Shekel) VDIC vs TDIC: 32.25 vs 59.99; $P < 0.01$</p> <p>Spinal cord independence measure scale (represents bladder management functioning) VDIC vs TDIC: 6.32 vs 4.82; $P = 0.13$</p> <p>Undefined UTI: VDIC vs TDIC: 0/13 vs 3/11; statistical differences were not reported</p>	<p>Mean F/U 19-20 days</p> <p>UTI not defined</p> <p>Power not reported</p>

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
Anton, 1998 ²³⁰	RCT 1,2,7	To evaluate the clinical utility of a new portable ultrasound device in the management of intermittent catheter programs.	Adult patients with neuropathic bladder who had a bladder capacity of \geq 200ml and underwent intermittent catheterization 57	Undefined UTI: Portable ultrasound vs control: 2/18 vs 3/20; statistical differences were not reported Mean catheters per day: Portable ultrasound vs control: 2.99 vs 4.12; P = 0.03 Mean episodes of overdistension per subject: Portable ultrasound vs control: 12.45 vs 14.76; P = 0.61 Patient satisfaction: Subjects generally expressed satisfaction with the portable ultrasound: 16 of 18 patients were at least somewhat satisfied with the device	F/U one month UTI defined as fever documented by the physician and thought to represent UTI Bladder overdistension defined as a catheter volume of $>$ 550ml Power not reported

2C.13. Mixed methods

Moyad, 1968 ²³¹	RCT 1	To compare the following methods of bladder irrigation with no irrigation: 1) Manual irrigation of the Foley catheter and bladder with 150 ml normal saline. 2) Manual irrigation of the Foley catheter and bladder with 150 ml normal saline and 1 g oral Gantrisin qid. 3) Irrigation of the Foley catheter and bladder with 150 ml normal saline and 1 g oral mandelamine qid. 4) Irrigation of the Foley catheter and bladder with 150 ml Furacin solution tid. 5) Control.	Medical, urologic, and surgical patients 92	Bacteriuria: Group 1 vs 2 vs 3 vs 4 vs 5: 58% vs 35% vs 25% vs 10% vs 60%; statistical differences were not reported	F/U 96 hours Bacilluria defined as the presence of $\geq 10^5$ bacterial colonies/ml of one pathogenic species in a valid urine specimen Power not reported
Saramma, 1987 ⁹⁶	Retrospective controlled study 1,3,6,7	To assess the effect of the following infection control practices on the rate of UTI: 1) Giving catheter care twice daily using freshly prepared Savlon and applying neomycin ointment at the meatal catheter junction.	Patients aged \geq 12 years who underwent cardiopulmonary bypass 200	Bacteriuria: Intervention vs control: 19/103 vs 30/97; P < 0.05 Risk factors for bacteriuria: Female vs male: P = NS Catheter duration \geq 72 hours vs < 72 hrs: P < 0.01 Bacteriuria stratified by risk factor: Intervention vs control (males): P = NS	F/U unclear Bacteriuria defined as ≥ 1000 colonies/ml of any pathogenic organisms Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		<p>2) Maintaining a closed urinary drainage system.</p> <p>3) Changing only the collection bottle every day, using another sterile bottle.</p> <p>Risk factors for bacteriuria were also identified.</p>		<p>Intervention vs control (females): P < 0.05</p> <p>Intervention vs control (catheter duration < 72 hrs): P = NS</p> <p>Intervention vs control (catheter duration ≥ 72 hrs): P < 0.01</p>	
Wyatt, 1987 ²⁵⁷	Prospective pre-post study 3,4	<p>To evaluate the effect of a policy for indwelling catheter care on the infection rate. The main features of the policy were:</p> <p>1. Insertion of catheter:-</p> <ul style="list-style-type: none"> a. Antiseptic hand wash and disposable gloves. b. Use of the smallest sized catheter. c. Disinfection of the external genitalia with chlorhexidine and cetrimide prior to catheterization. d. Use of a lignocaine/chlorhexidine gel before passing the catheter. e. Chlorhexidine irrigation of bladder after inserting the catheter. <p>2. Catheter care:</p> <ul style="list-style-type: none"> a. Chlorhexidine added to the drainage bag. b. An aseptic procedure for draining the bag. c. Maintaining a closed system d. Mental toilet with chlorhexidine cream. e. Drainage tube anchored to thigh. <p>3. Collection of samples:</p> <ul style="list-style-type: none"> a. Collection of urine samples 	All hospital patients with an indwelling urinary catheter 268	<p>Bacteriuria: Pre-intervention vs post-intervention: 69% vs 32%; statistical differences were not reported</p>	<p>N denotes the number of catheters investigated.</p> <p>F/U 11 months</p> <p>A colony count > 10⁴ per ml was considered significant.</p> <p>Power not reported</p>

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		using a sterile needle and syringe.			
Hoy, 1985 ²⁵⁸	Prospective pre-post study 1,3,6	To test the effect of a protocol consisting of single-dose perioperative antibiotics and earlier catheter removal (2-3 days after protocol compared with 7 days before protocol) on the incidence of postoperative UTI.	Renal transplant patients 268	Bacteriuria: After protocol vs before protocol: 26/100 vs 93/168; P < 0.01 The incidence of UTI was significantly decreased in males (P < 0.01) but not in females. It was significantly decreased in nondiabetics overall (P < 0.01) and nondiabetic males (P < 0.01). There were no significant differences in diabetics (either males or females).	F/U up to 7 days UTI was defined as > 10^5 ml of the same organism on midstream urine specimen. Power not reported
Seal, 1982 ²³³	Prospective controlled and pre-post study 1, 3	To evaluate the efficacy of aseptic techniques combined with antiseptic use in reducing infection rate and cross infection in patients undergoing urinary catheterization. The components of the intervention were: a. Cleaning the perianal area with chlorhexidine/cetrimide ('savlodil') before catheterization. b. Using an antiseptic catheter lubricant: lignocaine/chlorhexidine c. Ensuring that the drainage bag did not touch the floor and that its drip chamber remained vertical. d. Securing the catheters to the thigh in female patients. e. Disinfecting the catheter bag using chlorhexidine solution. f. Cleaning the catheter-meatal junction with savlodil after which chlorhexidine cream was applied. g. Catheters were maintained strictly as a closed drainage.	All patients admitted to the general medical and surgical wards of two district general hospitals in the United Kingdom 1264	Bacteriuria: Surgical ward (new techniques) vs medical ward (existing techniques) after implementation: 61/339 vs 232/925; P < 0.01 Surgical ward vs medical ward before implementation: 385/856 vs 295/925; statistical differences were not reported Antibiotic prophylaxis vs no prophylaxis: 14/141 vs 14/198; P < 0.05 Cross infection: Surgical ward (new techniques) vs medical ward (existing techniques) after implementation: 0/339 vs 6/925; statistical differences were not reported Bag contamination: There was no bacterial growth from 22 bag specimens, showing that chlorhexidine was effective in preventing bacterial growth in bags.	F/U 6 months Bacteriuria was defined as > 10^4 /ml of the same organism on midstream urine specimen Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		The new techniques were implemented on the patients in the surgical wards who were compared with the patients in the medical wards where old techniques were still used.			

GRADE Table 2C

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE		GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response		
Antibiotic prophylaxis for short-term bladder drainage	Symptomatic UTI*	1 SR ¹⁸² 3 RCT ^{61,185,186} 1 OBS ⁸³	Significantly decreased risk in 1 SR ¹⁸² . In 1 RCT of suprapubic catheters, risk was significantly decreased at catheter removal and during follow-up, but not at the end of follow-up ⁶¹ . No significant differences were found in 2 RCTs ^{185,186} and 1 OBS ⁸³ .	High	0	0	-1	0	0	0	0	Moderate	Low
	Bacteriuria/unspecified UTI*	2 SR ^{37,182} 7 RCT ^{60,61,185,186,189-191} 7 OBS ^{85,133,158,178,232-234}	Significantly decreased risk in 5 OBS ^{133,158,232-234} . In 1 SR, risk was significantly decreased in surgical and non-surgical population, but not in urologic surgery, although there was a suggestion of decrease ¹⁸² . In 1 SR, risk was significantly decreased using neomycin/sulfamethiazole, but no significant differences were found with Cefotaxime ³⁷ . In 1 RCT, risk was significantly decreased at catheter removal and during follow-up, but not at the end of follow-up ⁶¹ . In 1 OBS, risk was significantly decreased at end of follow-up but not during follow-up ¹⁷⁸ . In 1 OBS, risk was significantly decreased only when antibiotic was used within 48 hours of catheter	High	0	-1	0	0	0	0	0	Moderate	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
Antibiotic prophylaxis for long-term bladder drainage			removal ⁸⁵ . No significant differences were found in 4 RCTs ^{60,185,186,190} and statistical differences were not reported in 2 RCTs ^{189,191} .											Low
	Time to bacteriuria	1 RCT ¹⁸⁹	Significantly decreased risk	High	0	0	0	-1	0	0	0	0	Moderate	
	Pyuria	1 SR ¹⁸² 1 RCT ¹⁸⁵ 1 OBS ¹³³	Significantly decreased risk in 1 SR ¹⁸² and 1 OBS ¹³³ . No significant differences were found in 1 RCT ¹⁸⁵ .	High	-1	-1	0	0	0	0	0	0	Low	
	Duration of catheterization	5 RCT ^{60,61,185,186,189}	No significant differences were found in all RCTs, although suggestion of decrease in 1 RCT of medium term catheterization published prior to 1990 ¹⁸⁹ .	High	0	0	-1	0	0	0	0	0	Moderate	
	Mortality	1 RCT ⁶¹	No significant differences were found.	High	0	0	-1	-1	0	0	0	0	Low	
	Septicemia	1 RCT ⁶⁰	No significant differences were found.	High	-1	0	0	-1	0	0	0	0	Low	
	Therapeutic antibiotic usage	1 RCT ⁶⁰	No significant differences were found.	High	-1	0	0	-1	0	0	0	0	Low	
	Adverse events*	1 RCT ¹⁸⁵ 1 OBS ¹³³	No significant differences were found in 1 RCT ¹⁸⁵ and 1 OBS ¹³³ .	High	0	0	-1	-1	0	0	0	0	Low	
	Symptomatic UTI*	2 SR ^{106,183} 1 RCT ¹⁹² 1 OBS ²³⁵	Significantly increased risk in 1 RCT ¹⁹² and decreased risk in 1 OBS ²³⁵ (clean intermittent catheterization in both). Heterogeneous results were found in 1 SR ¹⁸³ . No significant results were found in 1 SR ¹⁰⁶ .	High	0	-1	0	0	0	0	0	0	Moderate	
Urinary tract infection prevention	Bacteriuria*	2 SR ^{106,183} 2 RCT ^{143,194} 1 OBS ²³⁵	Significantly decreased risk in 1 SR ¹⁸³ and 1 OBS ²³⁵ . In 1 SR, there was a significantly decreased risk in acute and a suggestion of decrease in non-acute spinal cord injury patients ¹⁰⁶ . Statistical differences were not reported in 2 RCT ^{143,194} .	High	0	-1	0	0	0	0	0	0	Moderate	Low
	Time to bacteriuria*	1 RCT ¹⁴³	Significantly decreased, especially during the first 4 weeks.	High	0	0	-1	-1	0	0	0	0	Low	
	Encrustation/catheter obstruction*	1 SR ¹⁸³	Statistical differences were not reported.	High	-1	0	-1	0	0	0	0	0	Low	
	Urinary tract infection prevention	1 RCT ¹⁴³	Significantly decreased risk in 1 RCT ¹⁴³ .	High	0	0	-1	-1	0	0	0	0	Low	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
Urinary antiseptics for short-term bladder drainage	Adverse events*	1 SR ¹⁸³	No significant differences were found or statistical differences were not reported.	High	-1	0	0	-1	0	0	0	0	Low	Low
	Microbial resistance*	2 SR ^{106,183} 1 OBS ²³⁵	1 SR reported a two-fold increase in resistance, though it was not mentioned whether it was statistically significant ¹⁰⁶ . No significant differences were found or statistical differences were not reported in 1 SR ¹⁸³ . No significant differences were found in 1 OBS ²³⁵ .	High	-1	0	0	-1	0	0	0	0	Low	
	Therapeutic antibiotic usage	1 SR ¹⁸³ 2 OBS ^{235,238}	Significantly decreased risk in 1 SR ¹⁸³ and 1 OBS ²³⁵ . No significant differences were found with nitrofurantoin in 1 OBS ²³⁸	High	-1	0	0	-1	0	0	0	0	Low	
	Septicemia	1 RCT ¹⁹⁴	Statistical differences were not reported.	High	-2	0	0	0	0	0	0	0	Low	
	Mortality	1 RCT ¹⁹⁴	Statistical differences were not reported.	High	-2	0	0	0	0	0	0	0	Low	
Urinary antiseptics for long-term bladder drainage	Symptomatic UTI*	2 RCT ^{196,197}	Significantly decreased risk in both RCTs	High	0	0	-1	0	0	0	0	0	Moderate	Very Low
	Bacteriuria*	2 RCT ^{196,197}	Significantly decreased risk in 1 RCT ¹⁹⁶ , but no significant differences were found in 1 RCT ¹⁹⁷ .	High	0	0	-1	0	0	0	0	0	Moderate	
	Urinary retention	1 RCT ¹⁹⁶	No significant differences were found.	High	0	0	-1	-1	0	0	0	0	Low	
	Adverse events*	2 RCT ^{196,197}	Statistical differences were not reported.	High	0	0	-1	-1	0	0	0	0	Low	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
	Therapeutic antibiotic usage	1 OBS ²³⁸	Significantly decreased risk.	Low	0	0	0	-1	0	0	0	0	Very Low	
	Duration of catheterization	1 OBS ²³⁸	Statistical differences were not reported although there was a suggestion of decrease.	Low	0	0	0	-1	0	0	0	0	Very Low	
	Encrustation*	2 OBS ^{236,239}	Significantly decreased risk in 1 OBS ²³⁹ . No significant differences were found in 1 OBS ²³⁶ .	Low	0	0	0	-1	0	0	0	0	Very Low	
	Adverse events*	1 OBS ²³⁸	Statistical differences were not reported.	Low	0	0	0	-1	0	0	0	0	Very Low	
Bladder irrigation	Symptomatic UTI*	1 OBS ²⁴¹	Statistical differences were not reported.	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
	Bacteriuria*	10 RCT ^{66,69,199-206} 3 OBS ²⁴⁰⁻²⁴²	Significantly decreased risk examining intermittent catheterization in 1 RCT ¹⁹⁹ and 1 OBS ²⁴⁰ . The remaining studies examined indwelling catheterization. There was a significantly decreased risk in 3 RCTs, two of which were with antiseptic irrigation ^{201,202} and one was with antibiotic irrigation ²⁰⁶ . Significant decrease in one of three bacteriuria measures in 1 RCT ²⁰⁴ . No significant differences were found in 4 RCTs ^{66,69,200,203} , except a significantly decreased risk in patients undergoing catheterization for 1-3 days in 1 RCT ⁶⁶ . Statistical differences were not reported in 1 RCT ²⁰⁵ and 2 OBS ^{241,242} , although there were suggestions of decrease.	High	-1	-1	0	0	0	0	0	0	Low	
	Postoperative septicemia	1 RCT ²⁰⁰	No significant differences.	High	-1	0	0	-1	0	0	0	0	Low	
	Intraoperative septicemia	1 RCT ²⁰⁰	Significantly decreased risk.	High	-1	0	0	-1	0	0	0	0	Low	
	Length of stay	1 RCT ²⁰⁰	Significantly decreased risk.	High	-1	0	0	-1	0	0	0	0	Low	
	Calculi	1 RCT ²⁰⁰	Statistical differences were not reported.	High	-1	0	0	-1	0	0	0	0	Low	
	Antibiotic usage	2 RCT ^{204,205}	Statistical differences were not reported.	High	-1	0	0	-1	0	0	0	0	Low	
	Duration of catheterization	5 RCT ^{66,69,200,201,204}	Significantly decreased risk in 1 RCT of patients with benign prostatic hypertrophy undergoing transvesical prostatectomy ²⁰⁰ . No significant differences were seen in 4 RCTs ^{66,69,201,204} .	High	-1	0	-1	0	0	0	0	0	Low	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
Antiseptic instillation in drainage bag	Symptomatic UTI*	1 RCT ²⁰⁸	Statistical differences were not reported.	High	-1	0	0	-1	0	0	0	0	Low	Low
	Bacteriuria*	5 RCT ²⁰⁷⁻²¹¹ 4 OBS ^{90,243-245}	Significantly decreased risk in 1 RCT ²¹¹ and 1 OBS ⁹⁰ . Significantly decreased risk with vinegar at 48 hours but not at 24 or 72 hours in 1 RCT ²⁰⁷ . No significant differences were found in 1 RCT ²⁰⁹ and statistical differences were not reported in 2 RCTs ^{208,210} and 3 OBS ²⁴³⁻²⁴⁵ .	High	-1	-1	0	0	0	0	0	0	Low	
	Time to bacteriuria	1 RCT ²¹¹ 2 OBS ^{90,245}	Significantly decreased risk in 1 OBS ⁹⁰ . Statistical differences were not reported in 1 RCT ²¹¹ and 1 OBS ²⁴⁵ , but there were suggestions of decrease.	High	-2	0	0	0	0	0	0	0	Low	
	Bag contamination	3 RCT ^{208,209,211} 1 OBS ⁹⁰	Significantly decreased risk in all studies.	High	-1	0	0	0	0	0	0	0	Moderate	
	Bag source bacteriuria	2 RCT ^{208,209}	No significant differences were found in 1 RCT ²⁰⁹ and statistical differences were not reported in 1 RCT ²⁰⁸ .	High	-1	0	0	0	0	0	0	0	Moderate	
	Duration of catheterization	1 RCT ²⁰⁹ 3 OBS ^{90,244,245}	No significant differences were found in 1 OBS ⁹⁰ and statistical differences were not reported in 1 RCT ²⁰⁹ and 2 OBS ^{244,245} .	High	-1	0	0	0	0	0	0	0	Moderate	
Periurethral care	Bacteriuria*	8 RCT ^{65,67,68,158,212,214-216} 3 OBS ^{88,246,247}	No significant differences were found in 5 RCTs ^{65,67,68,158,212} and 1 OBS ⁸⁸ . In 1 RCT, no significant differences were seen, except a decreased risk in men not receiving antibiotics ²¹⁴ . In 1 RCT, no significant differences were seen except a higher risk in patients not receiving antibiotics and in females and older women with positive meatal cultures ²¹⁵ . Statistical differences were not reported in 1 RCT ²¹⁶ and 2 OBS ^{246,247} .	High	0	-1	0	0	0	0	0	0	Moderate	Moderate
	Time to bacteriuria	1 RCT ⁶⁵	No significant differences were found.	High	-1	0	0	-1	0	0	0	0	Low	
	Duration of catheterization	2 RCT ^{65,212}	No significant differences were found.	High	0	0	0	-1	0	0	0	0	Moderate	
	Positive meatal swab	1 RCT ²¹³	No significant differences were found.	High	-2	0	0	-1	0	0	0	0	Very Low	
	Mortality	1 RCT ⁶⁵	No significant differences were found.	High	-1	0	0	-1	0	0	0	0	Low	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
	Perineal colonization	1 RCT ²¹⁴	No significant differences were found.	High	-2	0	0	-1	0	0	0	0	Very Low	
Routine catheter/bag change	Symptomatic UTI*	3 RCT ²¹⁷⁻²¹⁹ 2 OBS ^{102,249}	No significant differences were found in 3 RCTs ²¹⁷⁻²¹⁹ and 1 OBS ²⁴⁹ . Significantly increased risk with more frequent catheter change in 1 OBS ¹⁰² .	High	-1	0	-1	0	0	0	0	0	Low	Low
	Bacteriuria*	2 RCT ^{217,218} 1 OBS ²⁴⁸	No significant differences were found.	High	-1	0	-1	0	0	0	0	0	Low	
	Duration of catheterization	1 RCT ²¹⁷	No significant differences were found.	High	-1	0	0	-1	0	0	0	0	Low	
	Leakage of catheter/bag	1 RCT ²¹⁸ 1 OBS ²⁴⁹	No significant differences were found.	High	-1	0	-1	0	0	0	0	0	Low	
	Calculi	1 OBS ²⁴⁸	No significant differences were found.	Low	0	0	0	-1	0	0	0	0	Very Low	
	Ulcer/excoriation/redness (with condom catheters)	1 OBS ²⁴⁸	No significant differences were found.	Low	0	0	0	-1	0	0	0	0	Very Low	
	Antibiotic usage	1 OBS ²⁴⁹	No significant differences were found.	Low	0	0	0	-1	0	0	0	0	Very Low	
Lubricants	Symptomatic UTI*	2 RCT ^{220,221} 3 OBS ^{250,251,254}	Significantly decreased risk in 1 RCT comparing prelubricated nonhydrophilic catheter with conventional catheter lubricated by patient ²²¹ . No significant differences were found in 1 RCT which compared two gel types ²²⁰ and 1 OBS which compared gel with no gel ²⁵¹ . Statistical differences were not reported in 2 OBS which compared lubricant to no lubricant ^{250,254} , although there was a suggestion of decrease.	High	-1	-1	-1	0	0	0	0	0	Very Low	Very Low
	Bacteriuria*	4 RCT ²²⁰⁻²²³ 3 OBS ^{167,250,253}	Significantly decreased risk in 1 RCT comparing prelubricated nonhydrophilic catheter with conventional catheter lubricated by patient ²²¹ , 1 RCT which compared lubricants ²²² and 1 OBS which compared lubricant with no lubricant ²⁵³ . Significantly decreased risk when lubricants used in females but not males in 1 RCT ²²³ . No significant differences were found in 1 RCT ²²⁰ and 1 OBS ¹⁶⁷ comparing different lubricants. Statistical differences were not	High	-1	-1	-1	0	0	0	0	0	Very Low	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
Catheter associated urinary tract infection			reported in 1 OBS ²⁵⁰ .										Low	
	Patient satisfaction*	1 RCT ²²¹	Significantly increased.	High	0	0	-1	-1	0	0	0	0		
	Urethral bleeding	1 RCT ²²¹	Statistical differences were not reported.	High	0	0	-1	-1	0	0	0	0		
	Stinging/ burning	1 RCT ²²² 1 OBS ²⁵²	No significant differences were found in 1 OBS ²⁵² . Statistical differences were not reported in 1 RCT ²²² . Both studies compared iodine gel to placebo gel.	High	0	0	-1	-1	0	0	0	0		
	Duration of catheterization	1 OBS ²⁵³	Statistical differences were not reported.	Low	0	0	0	-1	0	0	0	0		
Securing devices	Symptomatic UTI*	1 RCT ²²⁴	No significant differences were found.	High	0	0	-1	-1	0	0	0	0	Low	
	Dislodgement	1 RCT ²²⁴	No significant differences were found.	High	0	0	-1	-1	0	0	0	0		
	Meatal erosion*	1 RCT ²²⁴	No significant differences were found.	High	0	0	-1	-1	0	0	0	0		
	Duration of catheterization	1 RCT ²²⁴	No significant differences were found.	High	0	0	-1	-1	0	0	0	0		
Bacterial interference	Symptomatic UTI*	1 RCT ²²⁵	Significantly decreased risk.	High	0	0	0	-1	0	0	0	0	Moderate	Moderate
Clamping vs free drainage	Bacteriuria*	2 SR ^{37,184}	No significant differences were found in 1 SR ¹⁸⁴ . Significantly increased risk in 1 SR ³⁷ .	High	-1	0	-1	0	0	0	0	0	Low	
	Time to first void	2 SR ^{37,184}	Significantly decreased in 1 SR ¹⁸⁴ . Significantly increased in 1 SR ³⁷ .	High	-1	0	-1	0	0	0	0	0		
	Urinary retention*	1 SR ¹⁸⁴	No significant differences were found.	High	-1	0	-1	0	0	0	0	0		
	Recatheterization*	1 SR ¹⁸⁴	No significant differences were found.	High	-1	0	-1	0	0	0	0	0		
Shorter vs longer duration of catheterization for postoperative drainage	Symptomatic UTI*	2 RCT ^{227,228}	No significant differences were found.	High	0	0	-1	0	0	0	0	0	Moderate	Moderate
	Bacteriuria/unspecified UTI*	2 SR ^{37,184}	There was a suggestion of decrease with shorter duration in 2 SR ^{37,184} . Significantly decreased risk in 1 study comparing 1 vs 5 days ^{37,184} and in a meta-analysis of studies comparing 1 vs 3 days ³⁷ .	High	0	0	-1	0	0	0	0	0	Moderate	
	Hematuria	2 SR ^{37,184}	No significant differences were found.	High	0	0	-1	0	0	0	0	0	Moderate	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
Stricture Urinary retention* Recatheterization* Urethral pain/discharge Length of stay* Time to ambulation* Patient satisfaction	Stricture	2 SR ^{37,184}	No significant differences were found.	High	0	0	-1	0	0	0	0	0	Moderate	
	Urinary retention*	2 SR ^{37,184} 1 RCT ²²⁸	No significant differences were found.	High	0	0	-1	0	0	0	0	0	Moderate	
	Recatheterization*	2 SR ^{37,184} 2 RCT ^{227,228}	Significantly increased risk in 1 RCT ²²⁷ . No significant differences were found in 2 SRs ^{37,184} and 1 RCT ²²⁸ .	High	0	0	-1	0	0	0	0	0	Moderate	
	Urethral pain/discharge	1 SR ¹⁸⁴	No significant differences were found.	High	0	0	-1	-1	0	0	0	0	Low	
	Length of stay*	1 SR ¹⁸⁴ 1 RCT ²²⁷	Significantly decreased in 1 RCT ²²⁷ . Heterogeneous results were found in 1 SR ¹⁸⁴ .	High	0	0	-1	0	0	0	0	0	Moderate	
	Time to ambulation*	1 RCT ²²⁷	Significantly decreased.	High	0	0	-1	0	0	0	0	0	Moderate	
	Patient satisfaction	1 SR ¹⁸⁴	No significant differences were found.	High	0	0	-1	-1	0	0	0	0	Low	
Portable ultrasound to assess bladder volume	Unspecified UTI*	2 RCT ^{229,230}	Statistical differences were not reported.	High	-1	0	0	-1	0	0	0	0	Low	Low
	Number of catheterizations per day*	2 RCT ^{229,230}	Significantly decreased risk in both RCTs.	High	-1	0	0	0	0	0	0	0	Moderate	
	Patient satisfaction	1 RCT ²³⁰	Patients were generally satisfied with the portable ultrasound, although statistical differences were not reported.	High	-1	0	0	-1	0	0	0	0	Low	
Wet vs dry procedure for catheter cleansing	Symptomatic UTI*	1 OBS ²⁵⁵	Significantly decreased risk with wet procedure.	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
	Catheterization interval	1 OBS ²⁵⁵	Significantly decreased with wet procedure.	Low	0	0	0	-1	0	0	0	0	Very Low	
	Antibiotic usage	1 OBS ²⁵⁵	No significant differences were found.	Low	0	0	0	-1	0	0	0	0	Very Low	

Study Quality Assessment Table 2C

Study	Systematic Review				Randomized Controlled Trial				Observational Controlled Study				Economic analysis																
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented
Niel-Wiese, 2006 ¹⁸²	x	x	x	x	x	x	x	x																					
Phipps, 2006 ³⁷	x	x	x	x	x	x	x	x																					
Esposito, 2006 ¹⁸⁵																													
Rogers, 2004 ⁶¹																													
Wazait, 2004 ¹⁸⁶																													
Lukkarinen, 1997 ¹⁸⁷																													
Lukkarinen, 1996 ¹⁸⁸																													
Vollaard, 1989 ¹⁸⁹																													
Stricker, 1988 ⁶⁰																													
Grabe, 1984 ¹⁹⁰																													
Little, 1974 ¹⁹¹																													
Cleland, 1971 ¹⁵⁸																													
Cardosi, 2003 ⁸³																													
Hustinx, 1991 ⁸⁵																													
Verbrugh, 1988 ¹³³																													
Shohet, 1983 ²³²																													
Seal, 1982 ²³³																													
Cafferkey, 1980 ²³⁴																													

Study	Systematic Review				Randomized Controlled Trial				Observational Controlled Study				Economic analysis																
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented
Drach, 1971 ¹⁷⁸																													
Platt, 1989 ¹⁸⁰																													
Niel-Wiese, 2006 ¹⁸³	x	x	x	x	x	x	x	x											x										
Vickrey, 1999 ¹⁰⁶	x	x	x	x	x	x	x	x											x										
Clarke, 2005 ¹⁹²																													
Waites, 2004 ¹⁹³																													
Firestein, 2001 ¹⁹⁴																													
Schlager, 1999 ¹⁹⁵																													
Schaeffer, 1988 ¹⁴³																													
Salomon, 2006 ²³⁵																													
2C.2. Urinary Antiseptics																													
Shiotz, 2002 ¹⁹⁶									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Tyreman, 1986 ¹⁹⁷									x	x																			
Vickrey, 1999 ¹⁰⁶	x	x	x	x		x	x												x										
Kostiala, 1982 ²³⁷																			x	x	x	x	x	x	x	x	x		
Nyren, 1981 ²³⁸																			x	x	x	x	x	x	x	x	x		
Wibell, 1980 ²³⁶																			x	x	x	x	x	x	x	x	x		
Norrman, 1976 ²³⁹																			x	x	x	x	x	x	x	x	x		
2C.3. Bladder Irrigation																													

Study	Systematic Review				Randomized Controlled Trial				Observational Controlled Study				Economic analysis																
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented
Pearman, 1991 ¹⁹⁹	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Pearman, 1988 ¹⁹⁸	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Pearman, 1979 ²⁴⁰	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Adesanya, 1993 ²⁰⁰	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Schneeberger, 1992 ⁶⁶	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Ball, 1987 ²⁰¹	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
van den Broek, 1985 ²⁰²	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Savage, 1982 ²⁰³	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Kirk, 1979 ²⁰⁴	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Warren, 1978 ⁶⁹	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Chamberlain, 1975 ²⁰⁵	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Clark, 1973 ²⁰⁶	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Cox, 1966 ²⁴¹	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Thornton, 1966 ²⁴²	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
2C.4. Antiseptic instillation in drainage bag																													
Washington, 2001	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	

Study	Systematic Review								Randomized Controlled Trial								Observational Controlled Study				Economic analysis										
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented	6. Sensitivity analyses performed	
207																															
Sweet, 1985 ²⁰⁸	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Thompson, 1984 ²⁰⁹																															
Gillespie, 1983 ²¹⁰																															
Maizels, 1980 ²¹¹																															
Wongsatanapong, 1988 ²⁴³																															
Holliman, 1987 ⁹⁰																															
Samuels, 1983 ²⁴⁵																															
Sujka, 1987 ²⁴⁴																															
2C.5. Periurethral care																															
Phipps, 2006 ³⁷	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
Webster, 2001 ²¹²																															
Bardwell, 1999 ²¹³																															
Huth, 1992 ⁶⁵																															
Classen, 1991 ⁶⁸																															
Sanderson, 1990 ²¹⁴																															
Burke, 1983 ⁶⁷																															
Burke, 1981 ²¹⁵																															

Study	Systematic Review				Randomized Controlled Trial				Observational Controlled Study				Economic analysis																
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented
Cleland, 1971 ¹⁵⁸	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Ross, 1966 ²¹⁶																													
Koskeroglu, 2004 ²⁴⁶																													
Matsumoto, 1997 ²⁴⁷																													
Jacono, 1988 ⁸⁸																													

2C.6. Frequency of catheter or bag change

Keerasuntonpong, 2003 ²¹⁷	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Dille, 1993 ²¹⁸																													
Priefer, 1982 ²¹⁹																													
Stelling, 1996 ²⁴⁸																													
White, 1995 ¹⁰²																													
Reid, 1982 ²⁴⁹																													

2C.7. Catheter lubricants

Fera, 2002 ²²⁰	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Giannantoni, 2001 ²²¹																													
Cohen, 1985 ²²²																													
Kunin, 1971 ²²³																													

Study	Systematic Review				Randomized Controlled Trial				Observational Controlled Study				Economic analysis																
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented
Kambal, 2004 ²⁵⁰																													
Schiottz, 1996 ²⁵¹																													
Harrison, 1980 ²⁵²																													
Chavigny, 1975 ²⁵³																													
Butler, 1968 ¹⁶⁷																													
Nooyen, 1966 ²⁵⁴																													
2C.8. Securing devices																													
Darouiche, 2006 ²²⁴									x	x	x	x	x	x															
2C.9. Bacterial interference																													
Darouiche, 2005 ²²⁵									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
2C.10. Catheter cleansing																													
Moore, 1990 ²²⁶									x		x																		
Sims, 1993 ²⁵⁵									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
2C.11. Catheter removal strategies																													
Griffiths, 2007 ¹⁸⁴	x	x	x	x	x	x	x	x																					
Phipps, 2006 ³⁷	x	x	x	x	x	x	x	x																					
Alessandri, 2006 ²²⁷									x	x																			
Schiottz, 1995 ²²⁸									x																				

Study	Systematic Review				Randomized Controlled Trial				Observational Controlled Study				Economic analysis																
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented
Wald, 2005 ²⁵⁶	x	x	x	x	x	x	x	x																					

2C.12. Assessing urine volumes

Shekelle, 1999 ¹⁰⁵	x	x	x	x	x	x	x	x	x																					
Polliack, 2005 ²²⁹																														
Anton, 1998 ²³⁰									x	x						x														

2C.13. Mixed methods

Moyad, 1968 ²³¹									x																					
Saramma, 1987 ⁹⁶										x	x																			
Wyatt, 1987 ²⁵⁷											x	x					x	x												
Hoy, 1985 ²⁵⁸											x	x				x	x	x												
Seal, 1982 ²³³												x	x					x	x	x										

2D. What are the risks and benefits associated with different systems interventions?

TABLE 2D: SYSTEMS INTERVENTIONS

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
2D.1. Multifaceted Infection Control/Quality Improvement Programs					
Jain, 2006 ²⁶⁰	Prospective pre-post study 1,3	To assess the efficacy of 4 changes that were implemented 1) physician-led multidisciplinary rounds; 2) daily "flow" meeting to assess bed availability; 3) "bundles" (sets of evidence-based practices); and 4) culture changes with a focus on the team decision making processes. The UTI bundle consisted of: a. Regularly assess continued need of catheter b. Use sterile technique at insertion c. Perform perineal care daily and after bowel movements d. Keep drainage bag lower than patient's bladder at all times including during transport e. Secure all catheters f. Use silver-coated catheter in selected cases	ICU patients Not specified	Unspecified UTI: Decreased from 3.8 to 2.4 per 1000 catheter days; P = 0.17	Study duration 3 years UTI defined using CDC criteria Power not reported
Reilly, 2006 ²⁶¹	Retrospective pre-post study 1,3	To evaluate the effect of a checklist and a decision-making algorithm for the appropriate use of Foley catheters Criteria indicating appropriate Foley catheter use: <ul style="list-style-type: none">• 24-hour urine collection• Epidural catheter• Neurological head injury• Skin breakdown in sacral area• Spine X-rays not cleared• Acute neurogenic bladder• Clinical need for a Foley, such as when patient is chemically paralyzed and sedated	ICU patients 207	Unspecified UTI: Decreased by 33% one year post-intervention. Statistical differences were not reported Duration of catheterization (days): Decreased from 4.72 preintervention to 2.98 post-intervention. Statistical differences were not clearly reported	F/U 1 year post-intervention UTI defined according to CDC criteria Power not clearly reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		<ul style="list-style-type: none"> • Crush injury • Pelvic fracture • Hemodynamic instability needing accurate input and output monitoring • Hourly input and output monitoring • Inability to void • Strict input and output monitoring required and patient incontinent • Gastric bypass surgery • Renal surgery 			
Stephan, 2006 ³	3	<p>To test the hypothesis that the implementation of a multifaceted prevention strategy could decrease the incidence of UTI after surgery.</p> <p>After a baseline surveillance period, the intervention was implemented in orthopedic surgery patients; abdominal surgery patients served as controls.</p> <p>The intervention combined specifically tailored, locally developed guidelines, educational sessions, and posters with a visual display of the guidelines focusing on perioperative urinary catheter management</p> <p>In the operating room, urinary catheterization was restricted to patients with 1) interventions with a foreseen duration of surgery > 5 hours; 2) total hip replacement or related surgery, if the patient met 1 of the following conditions: age > 75 years, an ASA class ≥3, obesity, or urinary incontinence; and 3) total knee replacement, if the patient met 1 of the following conditions: age > 80 years, obesity, or urinary incontinence.</p> <p>In the postanesthesia care unit (PACU), the decision to insert a urinary catheter followed these criteria: 1) the decision required the clinical judgment of a physician; (2) there was no routine</p>	<p>Patients scheduled to undergo surgery in the orthopedic and abdominal surgery departments (and thus likely to be exposed to urinary catheterization)</p> <p>529</p>	<p>Unspecified UTI (episodes per 100 patients): <u>Intervention group (orthopedic surgery patients)</u> : Changed from 29 episodes per 100 patients to 10 episodes per 100 patients post-intervention. The incidence density ratio was 0.41 (0.20-0.79).</p> <p><u>Control group (abdominal surgery patients)</u>: Changed from 6 episodes per 100 patients to 3 episodes per 100 patients. The incidence density ratio was 0.62 (0.14-2.50).</p> <p><i>All results P value for pre- vs post-intervention in the intervention group (orthopedic surgery patients) unless otherwise noted</i></p> <p>Bladder catheterization in the PACU or surgical ward: 3.9% vs 6.6%; P = 0.17 In the control group, the incidence of urinary catheterization in the surgical ward remained unchanged at 2%.</p> <p>Bladder ultrasound examination in the PACU: 12.8% vs 10.4%; P = 0.46 Less frequent during the post-intervention phase in the control group; 0.06 (number of patients); P = < 0.01 (number of episodes)</p> <p>Duration of catheterization: <u>Days</u>: 5.0 vs 3.9; P = 0.02 <u>≤ 3 days</u>: 51.5% vs 67%; 0.04</p> <p>Antibiotics for UTI: P < 0.01 (significantly decreased post-intervention)</p> <p>Noninfectious complications: 0.46</p>	<p>F/U ~3 years</p> <p>A quantitative urine culture was performed if laboratory analysis suggested infection (e.g., suggested the presence of bacteriuria, pyuria, leukocyturia, or significant hematuria or positive test results for nitrite)</p> <p>A sample size of 310 patients would ensure 90% power for the detection of a 30% reduction in the incidence of UTI.</p>

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		<p>requirement for urination before discharge; 3) there was no routine determination of bladder volume by ultrasound and no decision for catheterization based on bladder volume measurement; and 4) a urinary catheter inserted because of long duration surgery must be removed before discharge from the unit.</p> <p>In the surgical wards, the urinary catheter was removed 1) on postoperative day 2 after total hip replacement or related surgery or 2) on postoperative day 1 after total knee replacement.</p>			
Verdier, 2006 ²⁶²	Prospective pre-post study 1,3,4,6,7	<p>To evaluate the impact of an infection control program based on isolation in an ICU by comparing two 6-month periods before and after the intervention.</p> <p>The program consisted of increasing staff awareness of standard hygiene measures, requiring use of non-sterile single-use gloves and gowns after each patient contact, allowing only senior physicians to prescribe antibiotics, and requiring hand disinfection with an alcohol-based rub after each patient contact. Patients in the ICU were cohorted into 4 different areas.</p>	<p>Patients hospitalized in the ICU for > 48 hours</p> <p>336</p>	<p>Bacteriuria (per 1000 catheter days): After intervention vs before intervention: 15.9 vs 12.2; P = NS</p> <p>Bacteriuria with multi-drug resistant pathogens (per 1000 catheter days): After intervention vs before intervention: 0.76 vs 3.7; P = NS</p>	<p>F/U for the two 6 month periods</p> <p>UTI was defined as $> 10^5$ organisms per ml of urine culture</p> <p>Power not reported</p>
Topal,2005 ²⁶³	Prospective pre-post study 1,3,4	<p>To assess whether an intervention consisting of computerized feedback to physicians (see below) along with a nurse-driven protocol and handheld bladder scanners would decrease the incidence of nosocomial CAUTI</p> <p>Computerized feedback: If a urinary catheter was inserted in the ED, the documentation was added as part of the electronic ED to floor nursing report, which in turn was sent as an alert via the computerized physician order entry system to the physician as part of the</p>	<p>Patients admitted to general medical units</p> <p>303</p>	<p>Symptomatic UTI (per 1000 catheter days): Two years post-intervention vs one year post-intervention vs baseline: 11 vs 19 vs 36; P < 0.01</p> <p>Device use (% of days that catheter was in): Two years post-intervention vs one year post-intervention vs baseline: 3 vs 10 vs 16; P < 0.01</p> <p>Inappropriateness of catheter use (%): One year post-intervention vs baseline: 14.8 vs 24; statistical differences were not reported</p>	<p>Patients were followed for 53 days in the spring of each year from 2002 to 2004</p> <p>UTI was diagnosed based on CDC criteria</p> <p>Catheter use was considered appropriate if the patient met one or more of the following criteria: acute urinary retention or obstruction, urinary output monitoring if the patient was unable to collect urine,</p>

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		admission orders. This alert would then prompt the physician to 1) discontinue the device; 2) maintain the catheter for a time limit of 48 hours; or 3) maintain the device chronically.			postoperative requirements in specific urologic or gynecologic procedures or on contiguous structures of the genitourinary tract, urinary incontinence with open sacral or perineal wounds, and end-of-life care. Power not reported
Misset, 2004 ²⁶⁴	Prospective controlled study 1,3,6,7	To study the effect of a continuous quality improvement program on nosocomial infection rates. Guidelines for preventing UTI included catheter insertion and handling by trained nurses, skin disinfection with 10% povidone-iodine solution, insertion using aseptic technique and sterile equipment, drainage with a closed sterile system, aseptic technique for urine sampling, maintenance of unobstructed urine flow, and monitoring of UTI rates. Universal measures for preventing person-to-person transmission included hand-washing before and after each patient contact, wearing of gloves for handling secretions or contaminated objects, and a gown when soiling was anticipated and/or when the patient had MDR bacteria, and geographical isolation of all patients.	A medical-surgical ICU of a tertiary care center 962	Unspecified UTI: Latter 2.5 years vs first 2.5 years (following intervention): 66/529 vs 89/433; Unadjusted HR (95% CI) = 0.63 (0.46-0.87), Adjusted HR for SAPS II score (95% CI) = 0.65 (0.47-0.91) Time to unspecified UTI: Increased; P < 0.01	Study duration 5 years Thresholds above which cultures were considered positive were 10^5 cfu/ml urine for UTI, but UTI were not clearly defined Power not reported
Rosenthal, 2004 ²⁶⁵	Prospective pre-post study 1,3,4	To evaluate the effect of education and performance feedback regarding compliance with catheter care and hand hygiene on rates of CAUTI in ICUs. Major emphasis was on compliance with handwashing with antiseptic soap before catheter insertion and positioning catheter to prevent compression by a leg, avoiding obstruction to urinary flow. Education was implemented during the intervention period regarding hand	All adult ICU patients who had a urinary catheter in place for at least 24 hours 1301	Symptomatic UTI (per 1000 catheter days): Intervention vs pre-intervention: 12.39 vs 21.30; RR (95% CI) = 0.58 (0.39-0.86) Compliance with urinary catheter care (%): Intervention vs pre-intervention: 96.0 vs 83.0; RR (95% CI) = 1.15 (1.03-1.28) Compliance with handwashing (%): Intervention vs pre-intervention: 65.2 vs 23.1; RR (95% CI) = 2.82 (2.49-3.20)	Study period 2 years CDC definitions for symptomatic UTI Power not reported

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		hygiene in the healthcare settings and urinary catheter care. Performance feedback regarding compliance with infection control practices was provided to the ICU staff.			
Berg, 1995 ²⁶⁶	Prospective pre-post study 1,3,4	To test the effectiveness of general and targeted interventions to control nosocomial infections. For UTI, the intervention consisted of using closed drainage systems. Relevant general intervention involved a series of educational sessions to improve nurses' and physicians' aseptic technique (eg hand washing, use of gloves).	Patients treated in an ICU for > 24 hours 253	Symptomatic UTI: Post-intervention vs pre-intervention: 8/130 vs 9/123; P > 0.05	F/U 6 months A nosocomial UTI was defined as a urine culture with $\geq 10^5$ colonies/ml of urine (with no more than two species of organisms) along with fever or pyuria and/or clinical findings of dysuria, frequency, or urgency The power of the study was calculated to be 0.95 on the basis of 120 patients in each period, a nosocomial infection rate of 40% before interventions, an expected nosocomial infection rate of 20% after intervention, and a significance level of 0.05
Cools, 1988 ²⁶⁷	Prospective pre-post study 1,3	To study the effect of an infection control program in a skilled nursing facility. The program consisted of recording the antimicrobial drugs prescribed and the site of infection, culture of urine, restriction of long-term indwelling urinary catheterization, and restricted use of antimicrobial drugs.	Patients in a skilled nursing facility in the Netherlands An average of 530 patients per year	Number of treatments for bacteriuria: Decreased by 74%. Number of courses for recurrent infection decreased from 18% to 6%. Number of patients who did not require antimicrobial therapy increased from 51% to 70%. Statistical differences were not reported. Number of patients with indwelling catheters: 6 years after intervention vs in the first year of intervention: 52/527 vs 109/515 ; statistical differences were not reported.	F/U 6 years Bacteriuria was defined as $> 10^5$ organisms per ml of a single species in voided urine or 1-2 species in catheter-drained urine Power not reported

2D.2. Reminders

Saint, 2005 ²⁶⁸	Prospective controlled and pre-post study 1,3,4,6,7	To study the efficacy of a physician reminder in reducing the incidence of indwelling urethral catheterization in hospitalized patients. Two wards were used for the intervention and the other two wards were used as control. Also, the	Patients on medical/surgical units at a tertiary care referral medical center 5678	Duration of catheterization: <i>Intention-to-treat analysis:</i> Relative increase in control group: 15.1% Relative decrease in intervention group: 7.6% (P < 0.01 overall). <i>Per-protocol analysis (excluding noncomplying physicians):</i> Relative increase in control group: 15.1%	UTIs could not be evaluated in the study.
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		<p>period of the study was divided into two eight-month phases: pre- and post-intervention.</p> <p>A urethral catheter reminder was attached to the physician notes of the charts of all patients in the intervention group who had been catheterized for 48 hours. Charts of patients in the control group did not receive the reminder. To improve physician response, the following additions were made: plastic tape flags asking physicians to "Sign Here" were attached to the relevant page of the chart; following periods of staff turnover, the medical director of infection control sent e-mails alerting new staff to complete the reminders; systematic use of alphanumeric paging was introduced to alert staff who did not complete reminders that they needed to do so. The overall response ratio was 58.6%</p>		<p>Relative decrease in intervention group: 25.7% ($P < 0.01$ overall).</p> <p>Recatheterization: There was no significant difference between the two groups in urethral recatheterization ($P = 0.41$)</p> <p>Costs: <i>Intention-to-treat analysis:</i> The intervention would result in net savings of about \$249 per year. <i>Per-protocol analysis:</i> The intervention would result in net savings of more than \$50,832 per year.</p>	
Huang, 2004 ²⁶⁹	Prospective pre-post study 1,3	<p>To evaluate the efficacy of nurse-generated non-computerized daily reminders (not known if computerized/oral/paper reminders) to physicians to remove unnecessary catheters 5 days after insertion.</p> <p>The study consisted of a 12-month observation phase followed by a 12-month intervention phase.</p>	All patients admitted to the adult ICU 6297	<p>Bacteriuria (per 1000 catheter days): Intervention phase vs observation phase: 8.3 vs 11.5; $P = 0.01$</p> <p>Duration of urinary catheterization (days): Intervention phase vs observation phase: 4.6 vs 7.0; $P < 0.01$</p> <p>Cost of antibiotics used to treat CAUTI (excess monthly cost in dollars): Intervention phase vs observation phase: 1220 vs 4021; $P < 0.01$</p>	<p>Study period was 24 months.</p> <p>CAUTI was defined as significant bacteriuria ($\geq 10^5$ cfu/ml) that occurred while a patient had an indwelling urinary catheter.</p> <p>Power not reported</p>
Cornia, 2003 ²⁷⁰	Prospective controlled study 1,3,4	<p>To assess the utility of a computer-based order for inserting an indwelling urinary catheter with physician reminders (after 72 hours) that the catheter was in place. On the study ward, physicians had the option of computerized order entry (CPOE) vs written order vs no order, whereas the control ward had no CPOE option.</p>	Patients admitted to the medicine and cardiology services of a VA medical center who had a newly inserted urinary catheter 70	<p>Symptomatic UTI: Study ward vs control ward: 5/36 vs 3/34; $P = 0.71$</p> <p>Documentation of catheterization: Study ward vs control ward: 33/36 vs 10/34; $P < 0.01$</p> <p>Duration of catheterization (days): Study ward vs control ward: 5 vs 8; $P = 0.03$</p>	<p>Study period was 4 months.</p> <p>CAUTI was defined by growth from a urine specimen aseptically aspirated from the catheter of ≥ 100 cfu of a predominant pathogen or ≥ 10 WBC per high power field on urinalysis in a patient with a clinical diagnosis of UTI.</p>

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
					Power not reported

2D.3. Bacteriologic Monitoring

Garibaldi, 1982 ²⁵	Prospective pre-post study 1,3	To evaluate the efficacy of a daily bacteriologic monitoring program for preventing UTI.	Patients with indwelling urethral catheters 1044	<p>Bacteriuria: The monitoring program reduced the rate of bacteriuria from 17.9% to 12.5% ($P < 0.05$) In patients with symptomatic vs asymptomatic UTI: 72% vs 71%; $P > 0.05$</p> <p>Preventable UTI: However, during the intervention period, only 24 symptomatic episodes among 1,140 catheterizations (2%) were considered potentially preventable (defined as occurring ≥ 24 hours after the first positive urine culture)</p> <p>Association between bacteriuria and antibiotic prophylaxis: Use of antibiotics in patients with bacteriuria vs no bacteriuria: 31% vs 54%; $P < 0.05$</p>	<p>Study duration 15 months</p> <p>Bacteriuria was defined as $\geq 10^3$ pathogens/ml from catheter urine specimens</p> <p>Symptomatic infections were diagnosed when bacteriuria was accompanied by fever ≥ 100 F for 12 or more hours in the absence of other sites of infection or when the patient complained of symptoms referable to the urinary tract</p> <p>Power not reported</p>
Jacobson, 1981 ²⁷¹	Retrospective pre-post study 1,3	To identify the effect of regular bacteriologic monitoring of urine from catheterized patients on recognition and treatment of hospital acquired UTI.	Hospitalized catheterized patients 300	<p>Total number of episodes of bacteriuria identified: Before monitoring vs during monitoring: 7/100 vs 28/200; statistical differences were not reported</p> <p>Median duration of catheterization (days): Before monitoring vs during monitoring: 3 vs 3; $P = NS$</p> <p>Empiric treatment of suspected UTI with negative cultures: Significantly decreased during the monitoring period; $P = 0.03$</p> <p>Percent of episodes of bacteriuria treated: 100% (7/7) infections identified by deliberate culturing (prior to the monitoring program) but only 29% (8/28) of those identified by the monitoring program were treated; $P < 0.01$</p>	<p>Overall F/U unclear</p> <p>Bacteriuria was defined as ≥ 1000 cfu/ml in a catheter urine specimen and $\geq 10^5$ cfu/ml in a clean voided specimen.</p> <p>Power not reported</p>

2D.4. Hand hygiene

Pickard, 1996 ²⁵⁹	RCT 1	To compare two sterile techniques for urethral catheterization: 1) a shorter technique consisting of a hand wash of 30	Spinal cord injury patients	<p>Need for antibiotics: Shorter vs longer: 4/21 vs 10/25; $P > 0.05$</p> <p>Leukocyte growth: There was no significant difference in leukocyte</p>	F/U unclear. Study period 4 months.
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
		seconds and double gloving; or 2) a longer technique consisting of a 3 minute wash from fingertips to elbows and the wearing of a sterile gown and one pair of gloves.	46	growth. Numbers unclear.	A UTI was qualified by either of two categories: 1) specimens showing growth and leukocytes of $50 \times 10^6/\text{liter}$ or 2) patients requiring antibiotics Power not reported
Fendler, 2002 ²⁷²	Prospective controlled study 1,3	To determine the effect of the use of alcohol gel hand sanitizer by caregivers on infection types and rates in an extended care facility.	All hospitalized patients in an extended care facility specializing in rehabilitation and subacute care (reported results were specific to patients with Foley catheters) Not specified	Unspecified UTI (per 1000 patient days): Hand sanitizer units vs control units: 0.63 vs 0.77; statistical differences were not reported	F/U 34 months Nosocomial infections defined using CDC criteria/McGeer definitions Power not reported

2D.5. Patient placement

Fryklund, 1997 ²⁷³	Prospective controlled study 1,3	To compare the transmission rate of urinary bacterial strains between indwelling urinary catheter patients nursed in the same vs separate rooms.	Patients with bacteriuria and an indwelling urinary catheter 40	Transmission rate of urinary strains: Significantly higher within rooms (5/9 possible transmissions) than between rooms (9/53 possible transmissions); P = 0.02	F/U 4 weeks Typing were performed on isolates which were possible candidates between patients. Power not reported
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2D.6. Catheter teams

Wyndaele, 1990 ²⁷⁴	Prospective study with historical controls 3	To compare intermittent self-catheterization with intermittent catheterization performed by a catheter team.	Paraplegic patients 73	Unspecified UTI: Self-catheterization vs catheter team: 6/25 vs 13/48; P = NS Catheter-free: Self-catheterization vs catheter team: 18/25 vs 38/48; P = NS Urethral trauma: Self-catheterization vs catheter team: 0/25 vs 2/48; P = NS Patient satisfaction: 84% found self-catheterization not difficult and 90% thought that it was not time consuming. 94% thought that it was easy during weekends. 39% were afraid of traumatizing themselves	F/U until discharge UTI not defined, but based on urine culture Catheter-free implies patients being free of bladder drainage at discharge Power not reported
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
				with the catheter and 90% thought that their family had a positive reaction.	

2D.7. Feedback

Goetz, 1999 ²⁷⁵	Prospective pre-post study 1,3	To ascertain the efficacy of providing nursing staff with regular reports of unit-specific rates of catheter-related UTI in reducing overall UTI rates. At the end of the pre-intervention phase, a video review of catheter care was given to all nursing staff. Thereafter, nursing staff members were provided with a quarterly report with catheter-related UTI rates depicted graphically by unit.	Patients with indwelling urinary catheters Not specified	Unspecified UTI: Pre- vs post-intervention period: 32/1000 catheter-patient-days vs 17.4/1000 catheter-patient-days; P = 0.00 Cost: The estimated cost savings were \$403,000	F/U 2 years Nosocomial UTIs were identified using the CDC definition Power not reported
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2D.8. Nurse-directed catheter removal

Dumigan, 1998 ²⁷⁶	Prospective pre-post study 1,3	To evaluate an intervention aimed at reducing CAUTI. Medical indications were developed for urinary catheter placement and criteria that allowed the registered nurse to remove a catheter without a physician's order when no longer medically necessary. A computer prompt was created to assure a urinalysis accompanied all urine cultures.	Medical, surgical, and coronary ICU patients at a community teaching hospital Not specified	Unspecified UTI (per 1000 catheter days): SICU: Before program vs after program: 10.3 vs 8.6 (P = 0.32) MICU: Before program vs after program: 15.8 vs 11.2 (P = 0.10) CICU: Before program vs after program: 15.1 vs 8.3 (P = 0.03)	F/U 5 years UTI according to CDC definition Power not reported
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GRADE Table 2D

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
Multifaceted infection control/quality improvement programs	Symptomatic UTI*	3 OBS 263,265,266	Significantly decreased risk with performance feedback and education on hand hygiene and maintaining unobstructed urine flow in 1 large OBS ²⁶⁵ . Significantly decreased risk with computerized feedback, nurse driven protocol and handheld bladder scanners in 1 large OBS ²⁶³ . No significant differences were found with closed drainage systems and handwashing education in 1 smaller OBS ²⁶⁶ .	Low	0	0	0	0	0	0	0	0	Low	Low
	Bacteriuria/unspecified UTI*	5 OBS 3,260-262,264	Significantly decreased risk in 2 large OBS examining perioperative catheter management ³ and a multifaceted quality improvement program ²⁶⁴ . No significant differences were found in 2 OBS examining multifaceted quality improvement programs ^{260,262} . Statistical differences were not reported in 1 OBS evaluating a checklist and an algorithm for Foley catheter use ²⁶¹ , although there was a suggestion of a decrease.	Low	0	0	0	0	0	0	0	0	Low	
	Duration of catheterization*	2 OBS ^{3,261}	Significantly decreased with a program focusing on perioperative catheter management in 1 OBS ³ . Statistical differences were not reported in 1 OBS evaluating a checklist and an algorithm for Foley catheter use ²⁶¹ , although there was a suggestion of a decrease.	Low	0	0	0	0	0	0	0	0	Low	
	Number of patients with indwelling catheters	1 OBS ²⁶⁷	Statistical differences were not reported, although there was a suggestion of a decrease.	Low	0	0	0	-1	0	0	0	0	Very Low	
	Antibiotic usage	2 OBS ^{3,267}	Significantly decreased with a program focusing on perioperative catheter management in 1 OBS ³ . Statistical differences were not reported, although there was a suggestion of a decrease in 1 OBS ²⁶⁷ .	Low	0	0	0	0	0	0	0	0	Low	
	Appropriateness of catheter use	1 OBS ²⁶³	Statistical differences were not reported	Low	0	0	0	-1	0	0	0	0	Very Low	
	Time to unspecified UTI	1 OBS ²⁶⁴	Significantly increased with a multifaceted quality improvement program	Low	0	0	0	0	0	0	0	0	Low	
Reminders	Symptomatic UTI*	1 OBS ²⁷⁰	No significant differences were found in 1 small OBS ²⁷⁰ .	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
	Bacteriuria*	1 OBS ²⁶⁹	Significantly decreased risk.	Low	0	0	0	0	0	0	0	0	Low	
	Recatheterization*	1 OBS ²⁶⁸	No significant differences were found.	Low	0	0	0	-1	0	0	0	0	Very Low	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE				Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
	Duration of catheterization*	3 OBS ²⁶⁸⁻²⁷⁰	Significantly decreased in 3 OBS ²⁶⁸⁻²⁷⁰ .	Low	0	0	0	0	0	0	0	0	Low	
Bacteriologic monitoring	Bacteriuria*	2 OBS ^{25,271}	Significantly decreased risk in 1 larger OBS ²⁵ . Statistical differences were not reported in 1 smaller OBS ²⁷¹ .	Low	0	0	-1	0	0	0	0	0	Very Low	Very Low
	Empiric UTI treatment	1 OBS ²⁷¹	Significantly decreased risk.	Low	0	0	0	-1	0	0	0	0	Very Low	
	Treatment of bacteriuria	1 OBS ²⁷¹	A significantly lower percentage of the infections identified by monitoring were treated compared with no monitoring.	Low	0	0	0	-1	0	0	0	0	Very Low	
Hand hygiene with alcohol gel	Unspecified UTI*	1 OBS ²⁷²	Statistical differences were not reported.	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
Less vs. more intense handwashing	Unspecified UTI*	1 RCT ²⁵⁹	No significant differences were found.	High	-1	0	-1	-1	0	0	0	0	Very Low	Very Low
Patient placement (patients in same rooms vs. separate rooms)	Transmission of urinary strains*	1 OBS ²⁷³	Significantly higher risk when patients occupy the same room.	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
Catheter team vs. self-catheterization	Unspecified UTI*	1 OBS ²⁷⁴	No significant differences were found.	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
	Being catheter free	1 OBS ²⁷⁴	No significant differences were found.	Low	0	0	0	-1	0	0	0	0	Very Low	
	Urethral trauma	1 OBS ²⁷⁴	No significant differences were found.	Low	0	0	0	-1	0	0	0	0	Very Low	
Feedback to nursing staff	Unspecified UTI*	1 OBS ²⁷⁵	Significantly decreased risk.	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
Nurse-directed catheter removal	Unspecified UTI*	1 OBS ²⁷⁶	Significantly decreased risk in CICU, but not in SICU and MICU.	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low

* These modifiers can impact the GRADE by 1 or 2 points

Study Quality Assessment Table 2D

Study	Systematic Review	Randomized Controlled Trial	Observational Controlled Study	Economic analysis
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Study	Systematic Review				Randomized Controlled Trial				Observational Controlled Study				Economic analysis																	
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented	6. Sensitivity analyses performed
Fendler, 2002 ²⁷²																		x	x											
2D.5. Patient placement																														
Fryklund, 1997 ²⁷³																		x	x											
2D.6. Catheter teams																			x	x										
Wyndaele, 1990 ²⁷⁴																			x	x										
2D.7. Feedback																		x	x											
Goetz, 1999 ²⁷⁵																		x	x											
2D.8. Nurse-directed catheter removal																		x	x											
Dumigan, 1998 ²⁷⁶																		x	x											

Question 3: What are the best practices for preventing CAUTI associated with obstructed urinary catheters?

TABLE 3: PREVENTING UTI ASSOCIATED WITH OBSTRUCTED URINARY CATHETERS

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
3.1. Methods to Prevent or Reduce Encrustations or Blockage					
Mayes, 2003 ²⁷⁷	Systematic review 1,2,3	To study the role of citric acid bladder instillations (Suby G and Solution R) in preventing blockage of long term urinary catheters	Primary evidence addressing the study question 1 RCT	<p>Catheter blockage: Suby G vs Solution R vs saline: 48% vs 26% vs 41%; statistical differences were not reported</p> <p>Duration of catheterization (days): Suby G vs Solution R vs saline: 14.3 vs 14.2 vs 16.3; P = NS</p> <p>Catheter removal: Suby G vs Solution R vs saline: 29 vs 27 vs 44; statistical differences were not reported</p> <p>Crystals in fluid: Significantly more crystals were observed in fluid from saline instillations than in either of citric acid solutions (P < 0.01)</p>	
Muncie, 1989 ²⁷⁸	Crossover RCT 1,7	To assess the effect of once-daily catheter irrigation with normal saline on catheter obstructions and febrile episodes	Female adult patients who had indwelling urethral catheters for ≥ 30 consecutive days 50	<p>Nonprescribed removal (episodes): Irrigation vs non-irrigation: 87 vs 63; P = NS</p> <p>Obstruction (episodes): Irrigation vs non-irrigation: 39 vs 32; P = NS</p> <p>Leakage (episodes): Irrigation vs non-irrigation: 11 vs 21; P = NS</p> <p>Febrile episodes (per 100 days): Irrigation vs non-irrigation: 1.7 vs 1.1; P = NS</p> <p>Febrile episodes of possible urinary origin (per 100 days): Irrigation vs non-irrigation: 1.2 vs 0.9; P = NS</p> <p>Deaths: Irrigation vs non-irrigation: 3 vs 4; statistical differences were not reported</p>	F/U 24 weeks UTI not measured Catheter obstruction was defined as the absence of urine flow from the catheter that irrigation could not restore. Catheter leakage was defined as the patient's bed being wet with urine with the catheter still connected to the collection tube. Nonprescribed removals were defined as a patient or attendant accidentally or a patient purposefully removing the catheter Power not reported
Burns, 1984 ²⁸⁰	Prospective pre-post study 1,3	To study the efficacy of oral acetohydroxamic acid in reducing urinary catheter encrustations.	Patients with bladder dysfunction who had indwelling or suprapubic urinary catheters. All the patients had	Encrustation: Acetohydroxamic acid significantly decreased the quantity of encrusted material by 61-91% (average 81%); P < 0.05	F/U unclear UTI not defined Catheter blockage not defined

Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
			UTIs that persisted throughout the study. 5		Power not reported
Ruwaldt, 1983 ²⁸¹	Prospective crossover study 1,3	To determine whether or not catheter irrigation with a sterile nonbacteriostatic solution should be part of routine care. Irrigation consisted of the instillation of 30-40 cc of Suby solution G into the bladder with a syringe after which the solution was allowed to drain from the bladder	Long term nursing home residents. All patients had infected or colonized urine at the beginning of the study. 10	Catheter blockage episodes: Irrigation vs non-irrigation: 12/520 catheter days vs 36/515 catheter days; P < 0.01	F/U unclear UTI not defined Catheter blockage not defined Power not reported

3.2. Catheter materials preventing blockage

Kunin, 1987 ²⁷⁹	Crossover RCT 1	To determine the effect of catheter materials on formation of encrustations in long term indwelling urinary catheters	Patients > 65 years who were managed with long term indwelling urinary catheters in a nursing home 22	<p>Encrustation/blockage:</p> <p><i>All patients:</i> All results P values</p> <p>Silicone vs silicone-coated: > 0.05</p> <p>Silicone vs Teflon-coated: <0.05</p> <p>Silicone vs latex: < 0.01</p> <p>Silicone-coated vs Teflon-coated: > 0.05</p> <p>Silicone-coated vs latex: > 0.05</p> <p>Teflon-coated vs latex: > 0.05</p> <p><i>Stratified by blockers and non-blockers</i></p> <p>Among “non-blockers”, the range of encrustations was within plus or minus one grade of 1+. None of the catheter types appeared to be consistently more or less encrusted than another.</p> <p>Among the “blockers”, the extent of encrustations was 2+ or greater in 92% of the observations. Silicone catheters were found to form minimal encrustations, followed by silicone-coated, latex and Teflon-coated catheters.</p>	<p>F/U unclear. Study duration maximum of 2 months.</p> <p>Each segment of catheter was graded as 4+ (completely blocked), 3+ (almost blocked, but with a narrow patent channel), 2+ (grossly visible encrustations with slight narrowing of the channel), 1+ (roughened surface), and 0 (smooth surface). The extent of encrustations on the catheters was considered to be minimal when 2+ or less and extensive/heavy when 3+ or greater. Blockage was defined as totally clogged or flow time of ≥ 22 sec.</p> <p>On completion of the study, the population was divided into “nonblockers” and “blockers”. A “nonblocker” was defined as an individual whose catheters never became clogged and the extent of encrustations on any catheter never exceeded 2+. A “blocker” was defined as an individual in whom one or more catheters became clogged or were graded as 3+ or 4+</p>
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Author, Yr (Reference)	Study Design Quality	Study Objective	Population and Setting N	Results	Comments
					Power not reported

GRADE Table 3

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE			Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base	
					Study Quality*	Consistency*	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response		
Preventing/reducing encrustations or blockage	Blockage/encrustation*	1 SR ²⁷⁷ 1 RCT ²⁷⁸ 2 OBS ^{280,281}	Significantly decreased risk in 1 OBS with Suby G ²⁸¹ and in 1 OBS with oral acetohydroxamic acid ²⁸⁰ . No significant differences were found in 1 RCT with normal saline catheter irrigation ²⁷⁸ and statistical differences were not reported in 1 SR ²⁷⁷ .	High	-2	0	0	0	0	0	0	Low	Low
	Catheter removal	1 SR ²⁷⁷ 1 RCT ²⁷⁸	No significant differences were found in 1 RCT ²⁷⁸ and statistical differences were not reported in 1 SR ²⁷⁷ .	High	-2	0	0	0	0	0	0	Low	
	Duration of catheterization	1 SR ²⁷⁷	No significant differences were found.	High	-2	0	0	-1	0	0	0	Very Low	
	Mortality	1 RCT ²⁷⁸	Statistical differences were not reported.	High	-2	0	0	-1	0	0	0	Very Low	
Catheter materials	Blockage/Encrustation*	1 RCT ²⁷⁹	Significantly decreased risk with silicone catheters when compared with Teflon-coated or latex catheters. No significant differences were found between silicone and silicone-coated catheters. No significant differences were found in comparisons between Teflon-coated, silicone-coated and latex catheters. Silicone catheters were particularly effective in patients classified as 'blockers'.	High	-1	0	0	-1	0	0	0	Low	Low

* These modifiers can impact the GRADE by 1 or 2 points

Study Quality Assessment Table 3

Study	Systematic Review				Randomized Controlled Trial				Observational Controlled Study				Economic analysis																
	1. Search terms described	2. Databases searched described	3. Inclusion/exclusion criteria defined	4. Reasons for exclusions described	5. Screening by two independent reviewers	6. Data extracted by two independent reviewers	7. Individual study quality assessed	8. Heterogeneity assessed	1. Randomized	2. Randomization appropriately performed	3. Double-blind	4. Outcome assessor blinded	5. Study participant blinded	6. Investigator blinded	7. Attrition described	8. Attrition smaller than 10-15% of assigned patients	9. Attrition appropriately analyzed	1. All study groups derived from similar source/reference populations	2. Attrition not significantly different across all study groups	3. The measure of exposure is valid	4. The measure of outcome is valid	5. Investigators blinded to endpoint decision	6. Potential confounders identified	7. Statistical adjustment for potential confounders performed	1. Perspective defined	2. Time horizon defined	3. Decision tree(s) or rule(s) made explicit	4. Sources of cost estimates presented	5. Sources of event rate estimates presented
3.1. Methods to prevent/reduce encrustations or blockage																													
Mayes, 2003 ²⁷⁷	x	x	x																										
Muncie, 1989 ²⁷⁸									x																				
Ruwaldt, 1983 ²⁸¹																			x										
Burns, 1984 ²⁸⁰										x									x	x									
3.2. Catheter materials preventing blockage								x											x	x									
Kunin, 1987 ²⁷⁹																													

APPENDIX 3: SILVER ALLOY META-ANALYSES

SUMMARY

Comparison	RR (95% CI) for each analysis			
	Analysis 1	Analysis 2	Analysis 3	Analysis 4
NUMBER WITH ASYMPTOMATIC BACTERIURIA (<1 WEEK)				
Latex Control	0.33 (0.23-0.48)	0.33 (0.23-0.48)*	0.41 (0.26-0.64)*	0.30 (0.20-0.46)
Silicone Control	0.85 (0.34-2.14)	0.75 (0.57-0.99)*	0.85 (0.34-2.14)	0.85 (0.34-2.14)
Pre-1995	0.33 (0.21-0.51)	0.33 (0.21-0.51)	0.33 (0.21-0.51)	0.29 (0.17-0.49)
Post-1995	0.50 (0.20-1.27)*	0.61 (0.36-1.03)*	0.61 (0.36-1.03)*	0.50 (0.20-1.27)*
Overall	0.37 (0.26-0.52)	0.45 (0.30-0.67)*	0.45 (0.30-0.67)*	0.36 (0.24-0.52)
NUMBER WITH ASYMPTOMATIC BACTERIURIA (> 1 WEEK)				
Latex Control	0.60 (0.47-0.76)	0.60 (0.47-0.76)	0.60 (0.47-0.76)	0.60 (0.43-0.84)
Silicone Control	0.88 (0.50-1.55)	0.88 (0.50-1.55)	0.88 (0.50-1.55)	0.88 (0.50-1.55)
Pre-1995	0.59 (0.42-0.85)	0.59 (0.42-0.85)	0.59 (0.42-0.85)	No studies
Post-1995	0.67 (0.50-0.90)	0.67 (0.50-0.90)	0.67 (0.50-0.90)	0.67 (0.50-0.90)
Overall	0.64 (0.51-0.80)	0.64 (0.51-0.80)	0.64 (0.51-0.80)	0.67 (0.50-0.90)

* Only random effects results are shown. All other results shown are fixed effects.

Analysis 1 (all studies in Schumm* without studies of silicone coated latex)

Analysis 2 (all studies in Schumm* including abstracts and including Maki under "Silicone catheters")

Analysis 3 (all studies in Schumm* including abstracts and including Maki under "Latex catheters")

Analysis 4 (all studies in Schumm* excluding abstracts)

Note: Karchmer was not used as it was a crossover trial and data prior to crossover were not available

ANALYSIS 1 (all studies in Cochrane Review without studies of silicone coated latex)

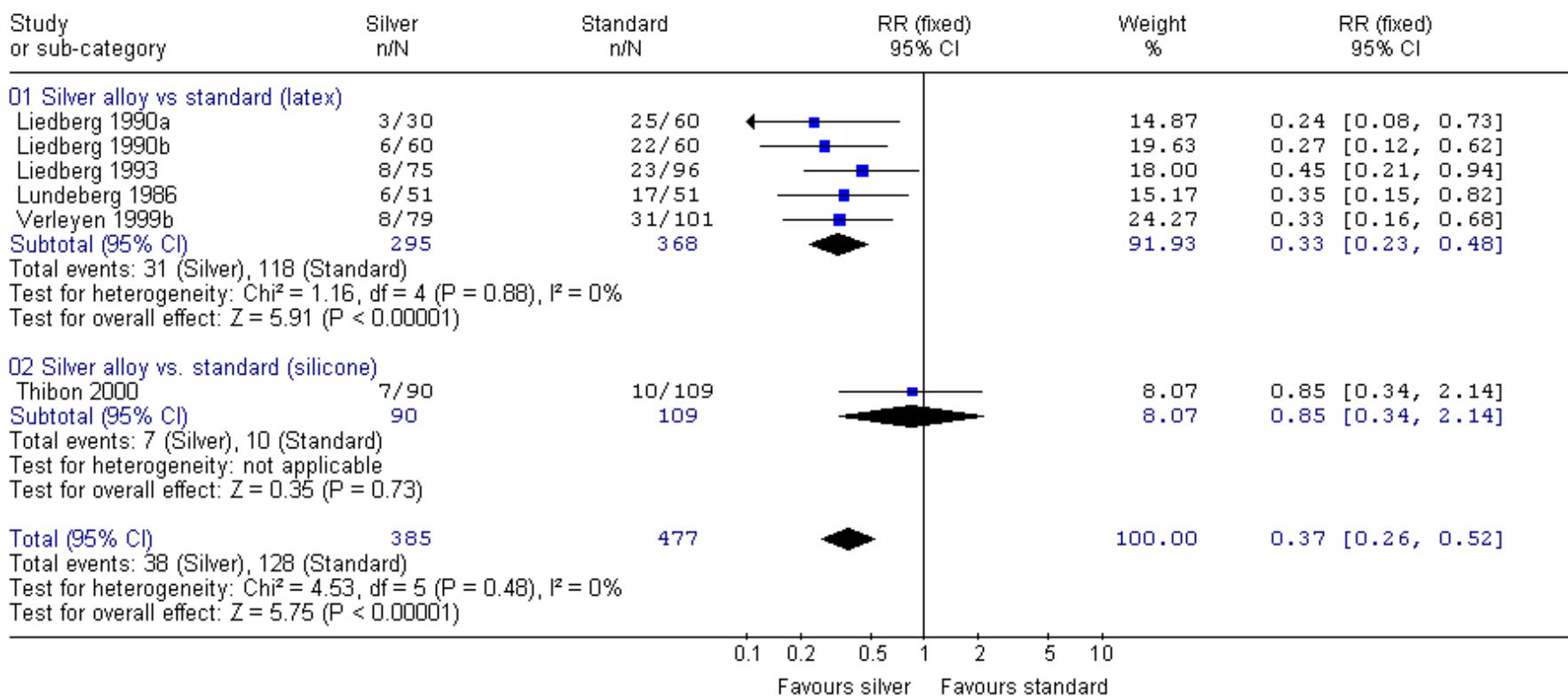
A. STRATIFIED BY TYPE OF CONTROL CATHETER

1. Number with asymptomatic bacteriuria (<1 week)

Review: Guideline for Prevention of Catheter-associated Urinary Tract Infections

Comparison: 01 Silver alloy vs standard (stratified by type of control catheter)

Outcome: 01 Number with asymptomatic bacteriuria (<1 week)

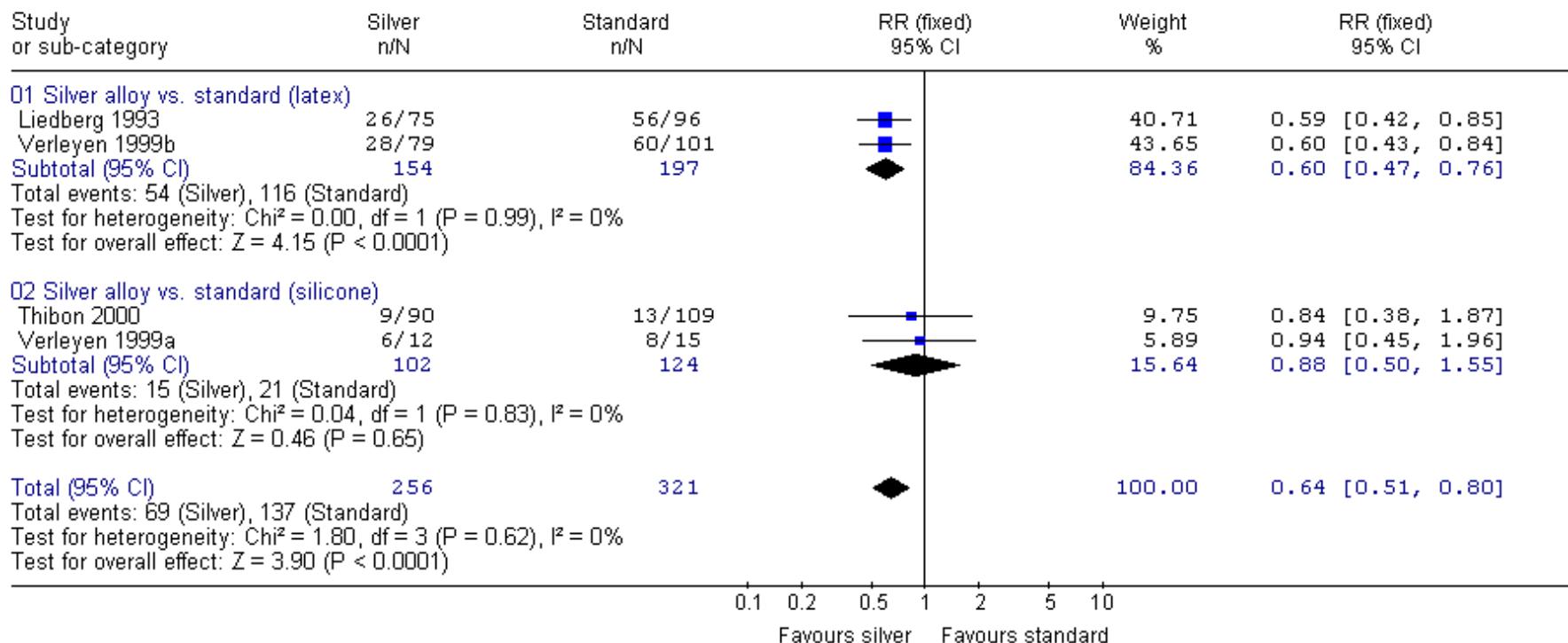


2. Number with asymptomatic bacteriuria (> 1 week)

Review: Guideline for Prevention of Catheter-associated Urinary Tract Infections

Comparison: 01 Silver alloy vs standard (stratified by type of control catheter)

Outcome: 02 Number with asymptomatic bacteriuria (>1 week)



B. STRATIFIED BY YEAR OF PUBLICATION

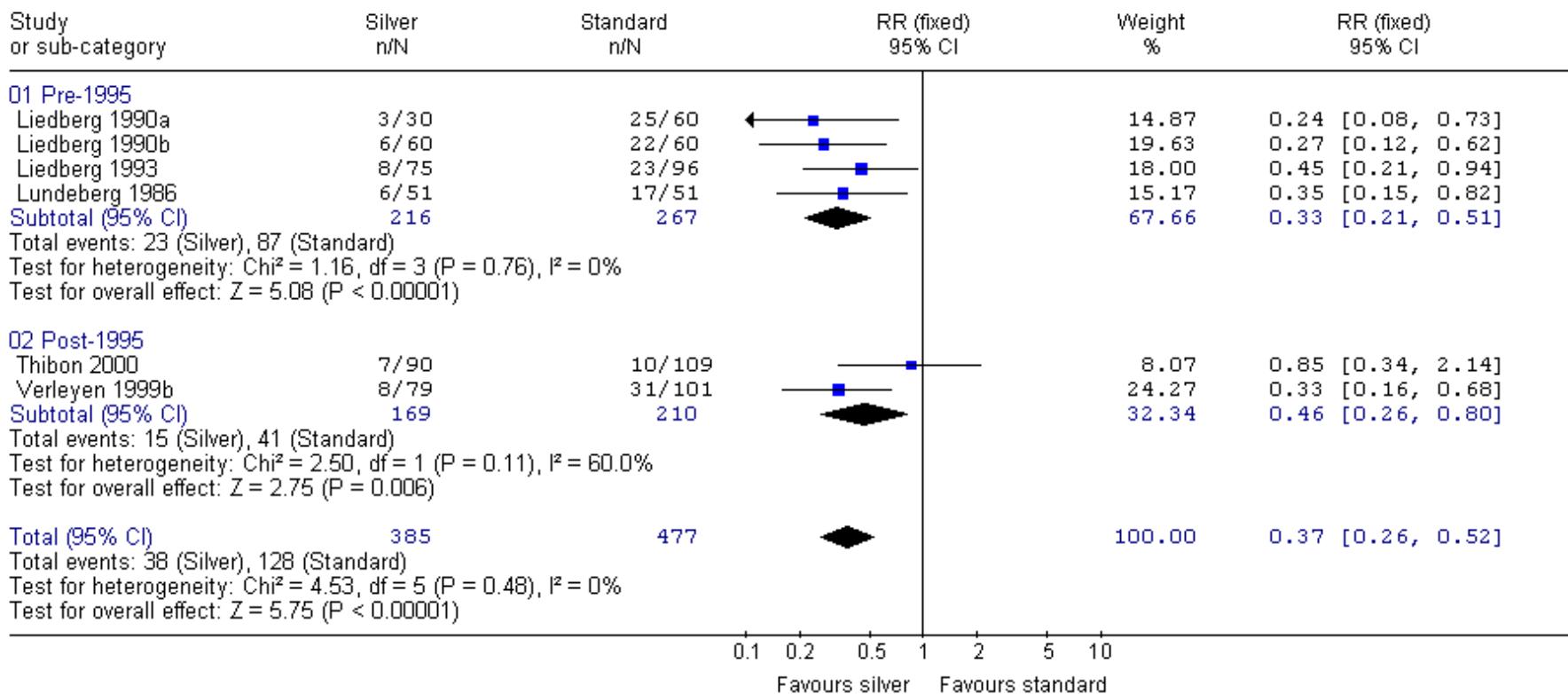
1. Number with asymptomatic bacteriuria (<1 week)

a. Fixed Effects

Review: Guideline for Prevention of Catheter-associated Urinary Tract Infections

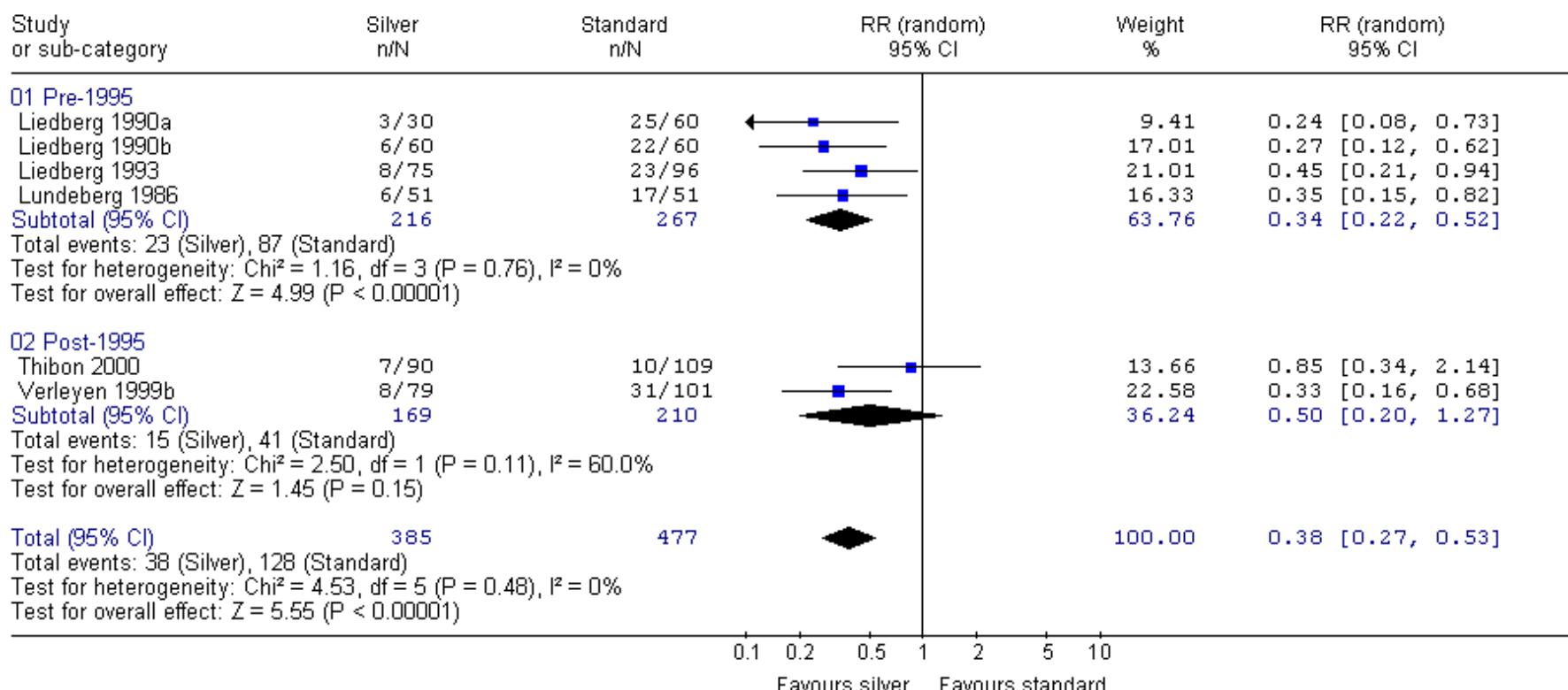
Comparison: 02 Silver alloy vs. standard (stratified by year of publication)

Outcome: 01 Number with asymptomatic bacteriuria (<1 week)



b. Random Effects

Review: Guideline for Prevention of Catheter-associated Urinary Tract Infections
 Comparison: 02 Silver alloy vs. standard (stratified by year of publication)
 Outcome: 01 Number with asymptomatic bacteriuria (<1 week)

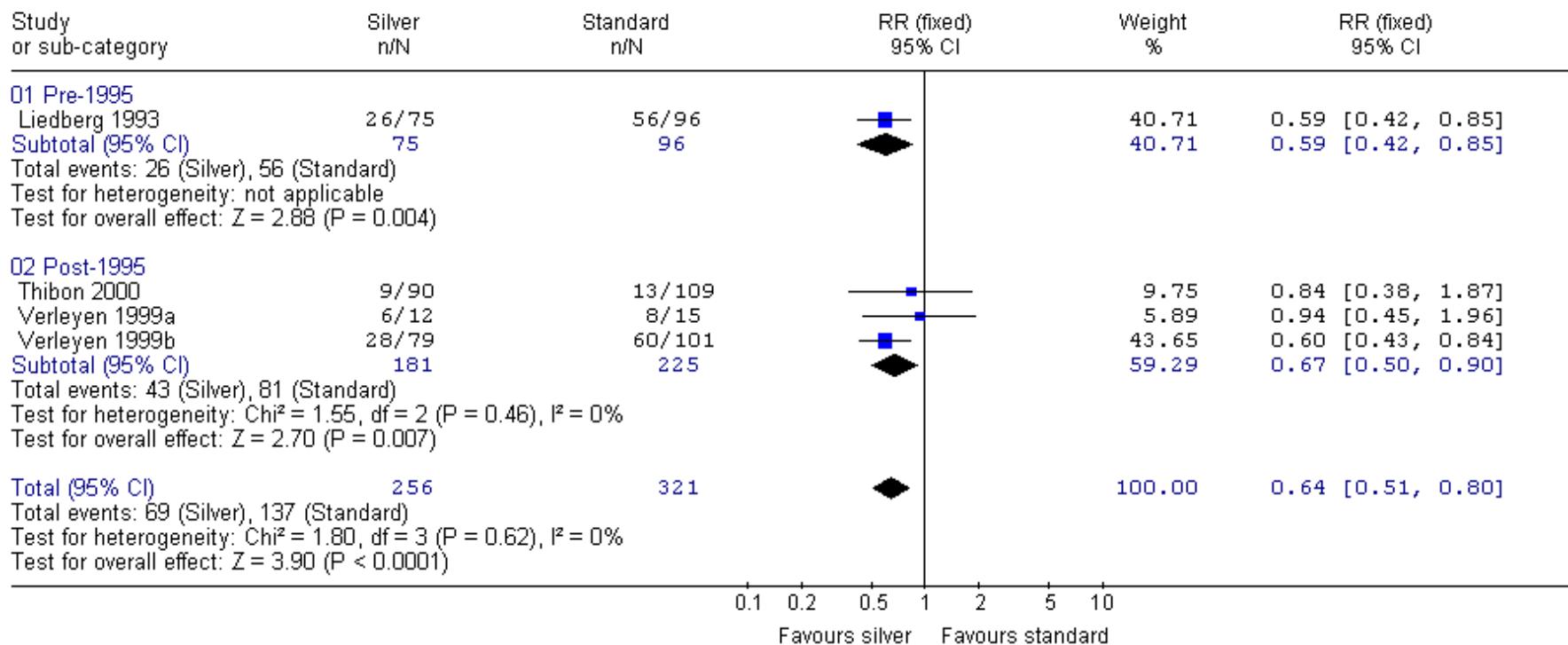


2. Number with asymptomatic bacteriuria (> 1 week)

Review: Guideline for Prevention of Catheter-associated Urinary Tract Infections

Comparison: 02 Silver alloy vs. standard (stratified by year of publication)

Outcome: 02 Number with asymptomatic bacteriuria (>1 week)



ANALYSIS 2 (all studies in Cochrane Review including abstracts, Maki et al. under “Silicone catheters”)

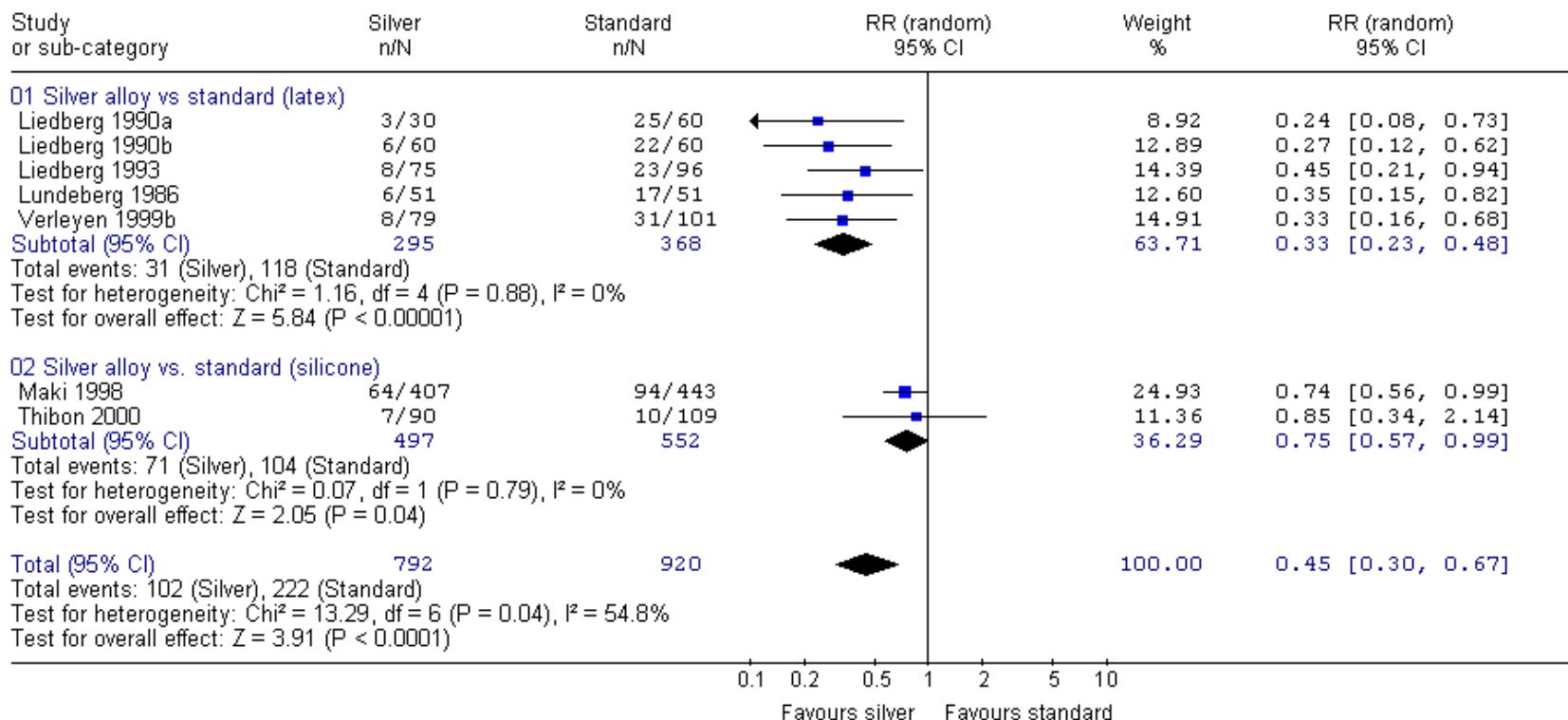
A. STRATIFIED BY TYPE OF CONTROL CATHETER

1. Number with asymptomatic bacteriuria (<1 week)

Review: Guideline for Prevention of Catheter-associated Urinary Tract Infections

Comparison: 01 Silver alloy vs standard (stratified by type of control catheter)

Outcome: 01 Number with asymptomatic bacteriuria (<1 week)

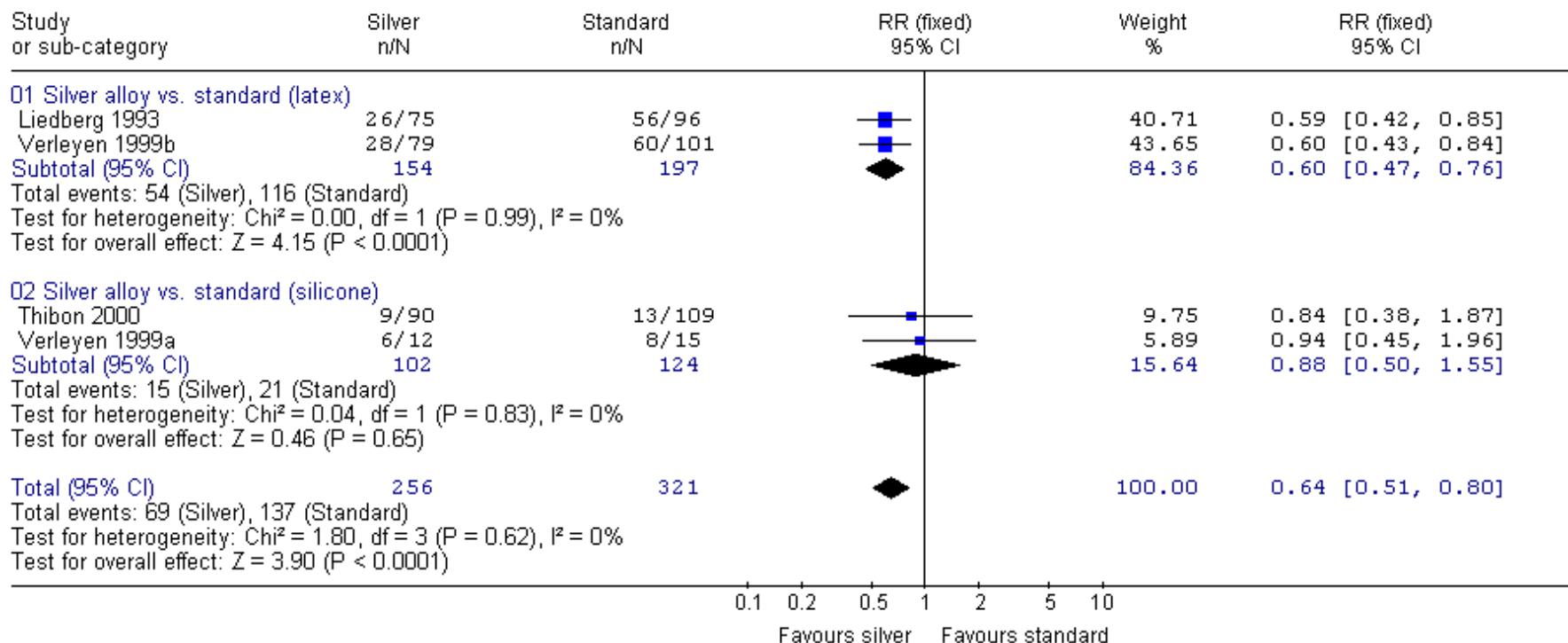


2. Number with asymptomatic bacteriuria (> 1 week)

Review: Guideline for Prevention of Catheter-associated Urinary Tract Infections

Comparison: 01 Silver alloy vs standard (stratified by type of control catheter)

Outcome: 02 Number with asymptomatic bacteriuria (>1 week)



B. STRATIFIED BY YEAR OF PUBLICATION

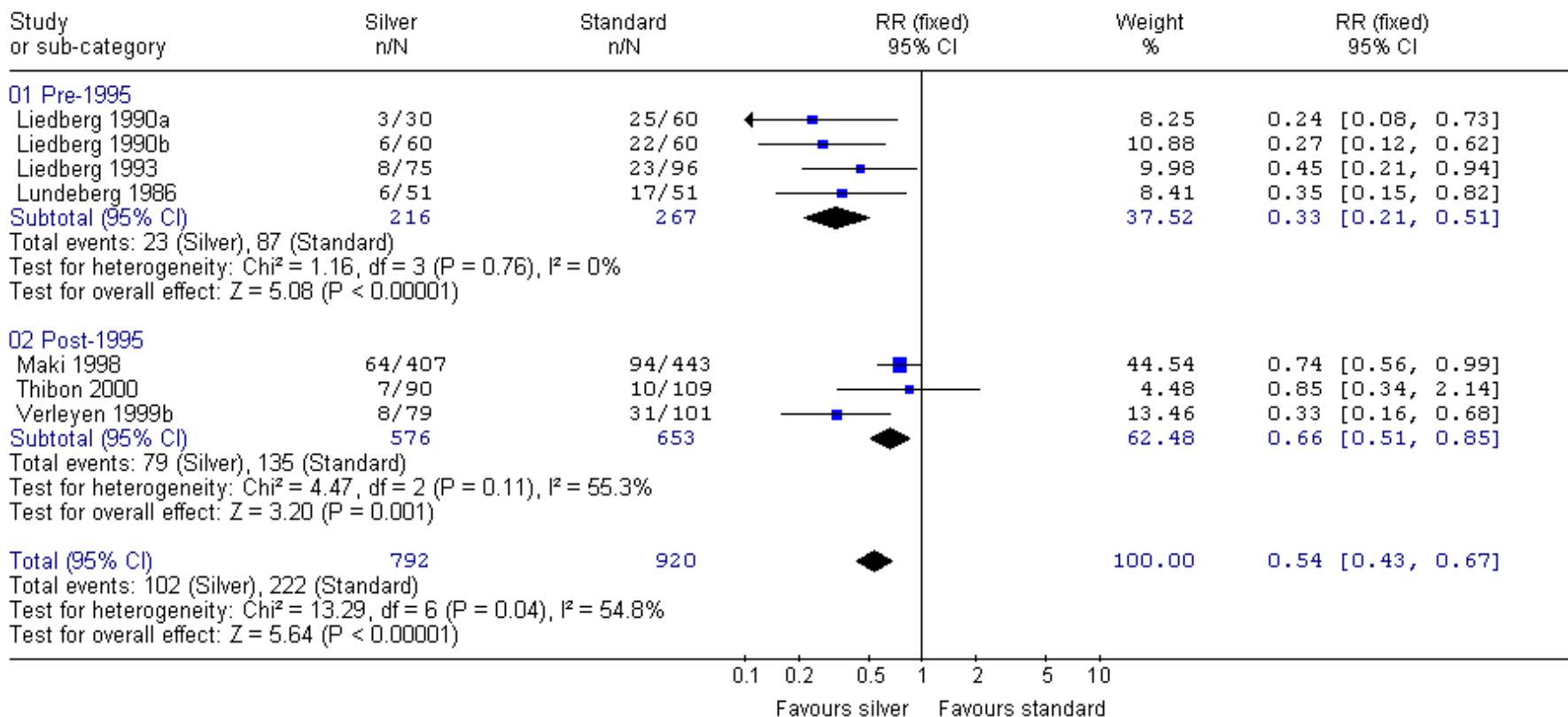
1. Number with asymptomatic bacteriuria (<1 week)

a. Fixed Effects

Review: Guideline for Prevention of Catheter-associated Urinary Tract Infections

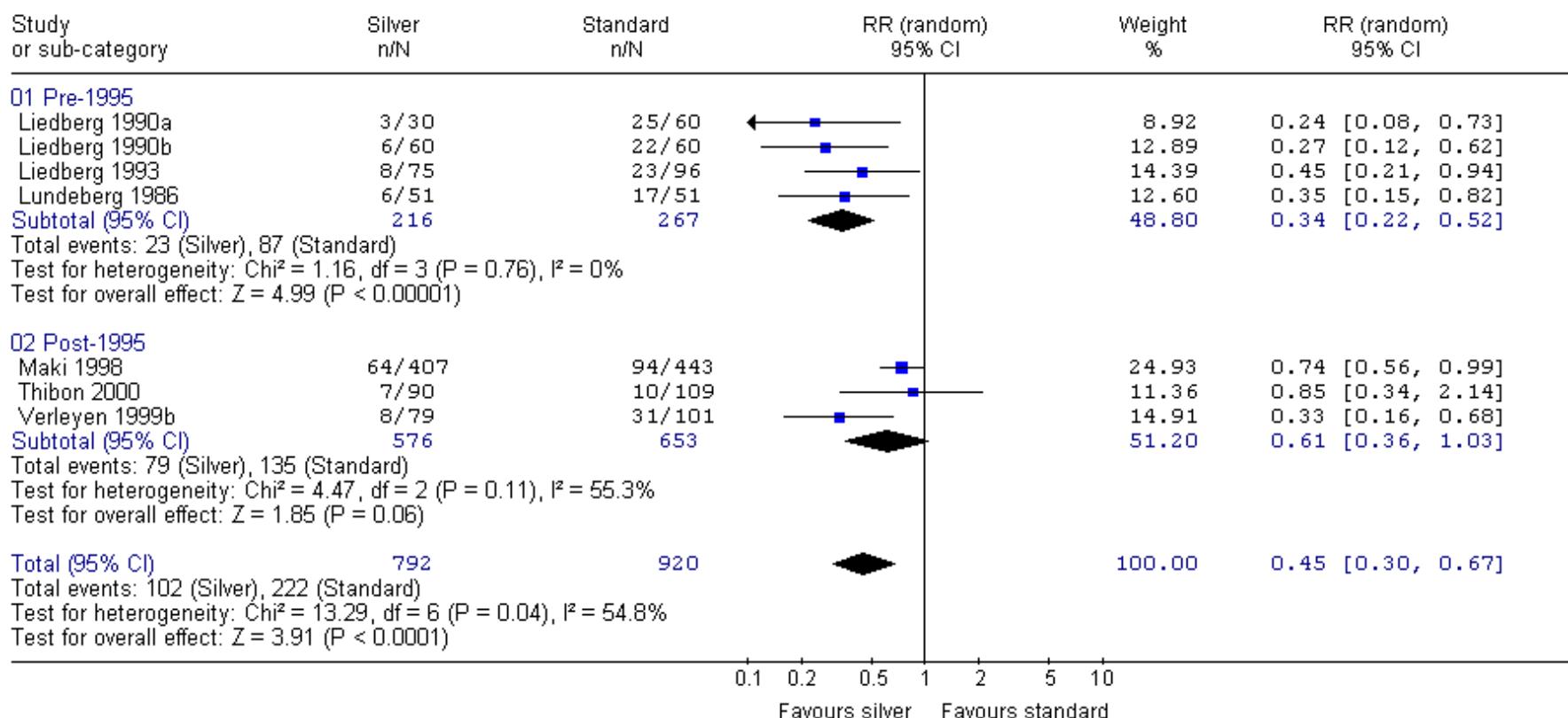
Comparison: 02 Silver alloy vs. standard (stratified by year of publication)

Outcome: 01 Number with asymptomatic bacteriuria (<1 week)



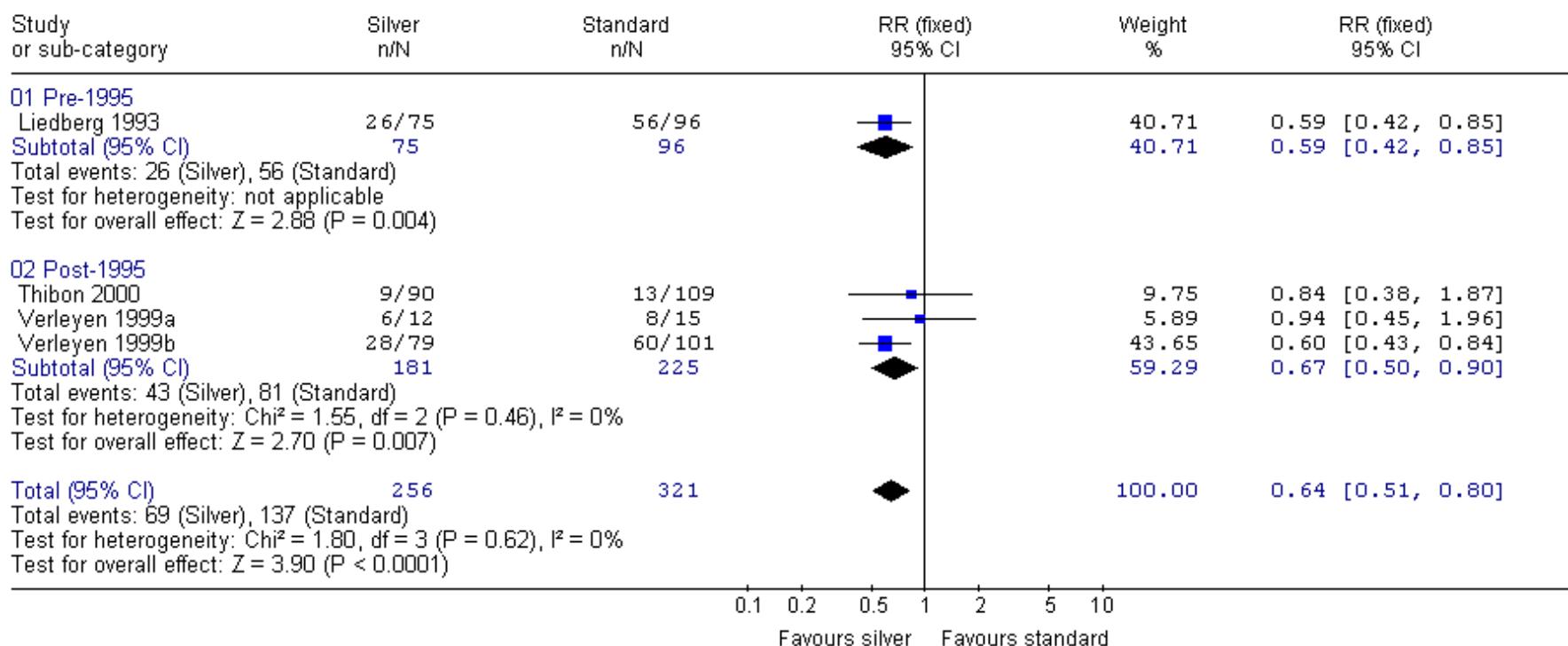
b. Random Effects

Review: Guideline for Prevention of Catheter-associated Urinary Tract Infections
 Comparison: 02 Silver alloy vs. standard (stratified by year of publication)
 Outcome: 01 Number with asymptomatic bacteriuria (<1 week)



2. Number with asymptomatic bacteriuria (> 1 week)

Review: Guideline for Prevention of Catheter-associated Urinary Tract Infections
 Comparison: 02 Silver alloy vs. standard (stratified by year of publication)
 Outcome: 02 Number with asymptomatic bacteriuria (>1 week)



ANALYSIS 3 (all studies in Cochrane Review including abstracts, Maki et al. under “Latex catheters”)

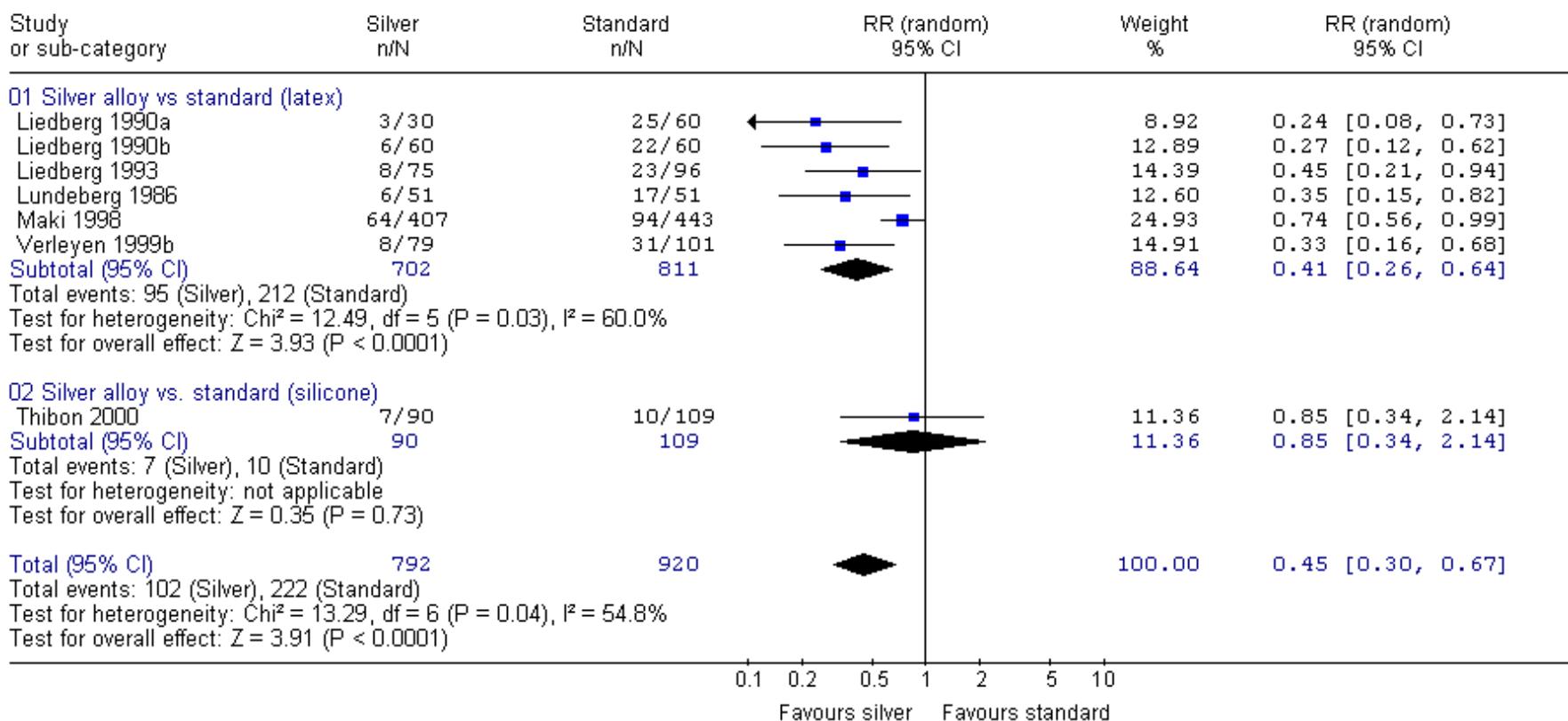
A. STRATIFIED BY TYPE OF CONTROL CATHETER

1. Number with asymptomatic bacteriuria (<1 week)

Review: Guideline for Prevention of Catheter-associated Urinary Tract Infections

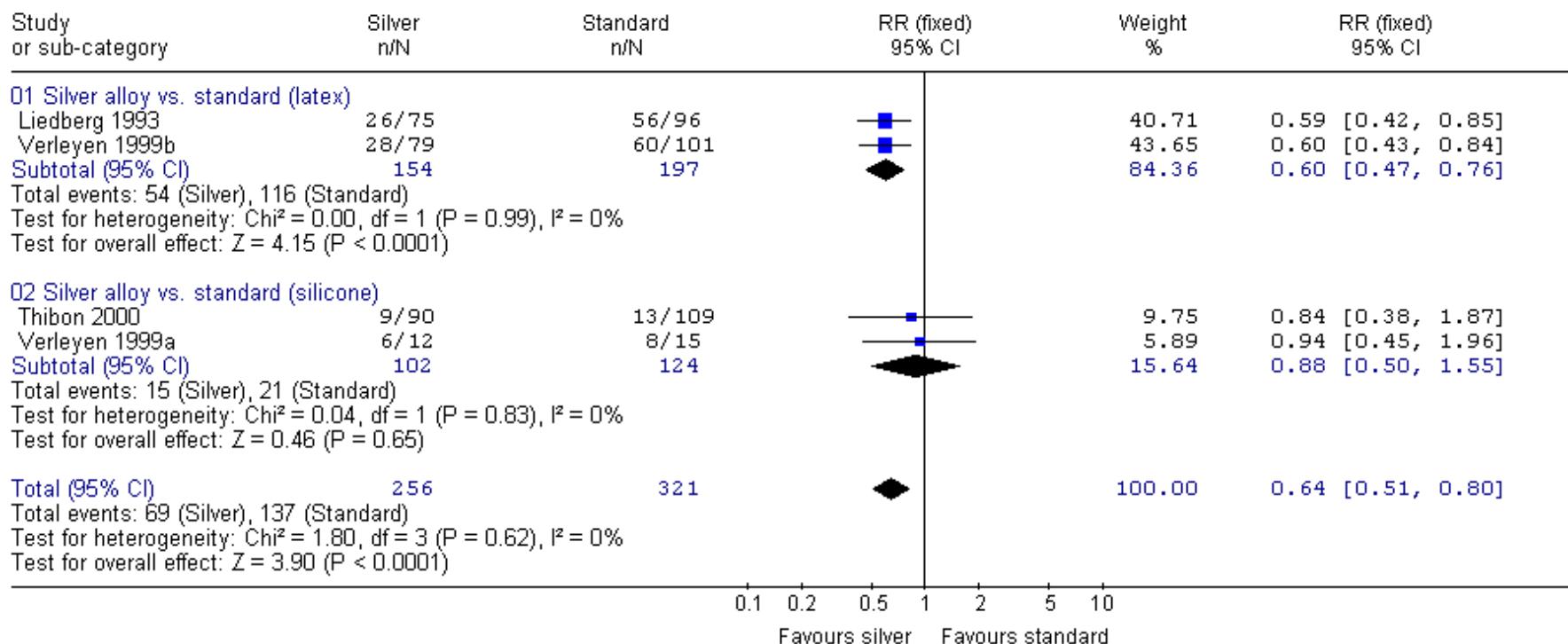
Comparison: 01 Silver alloy vs standard (stratified by type of control catheter)

Outcome: 01 Number with asymptomatic bacteriuria (<1 week)



2. Number with asymptomatic bacteriuria (> 1 week)

Review: Guideline for Prevention of Catheter-associated Urinary Tract Infections
 Comparison: 01 Silver alloy vs standard (stratified by type of control catheter)
 Outcome: 02 Number with asymptomatic bacteriuria (>1 week)



B. STRATIFIED BY YEAR OF PUBLICATION

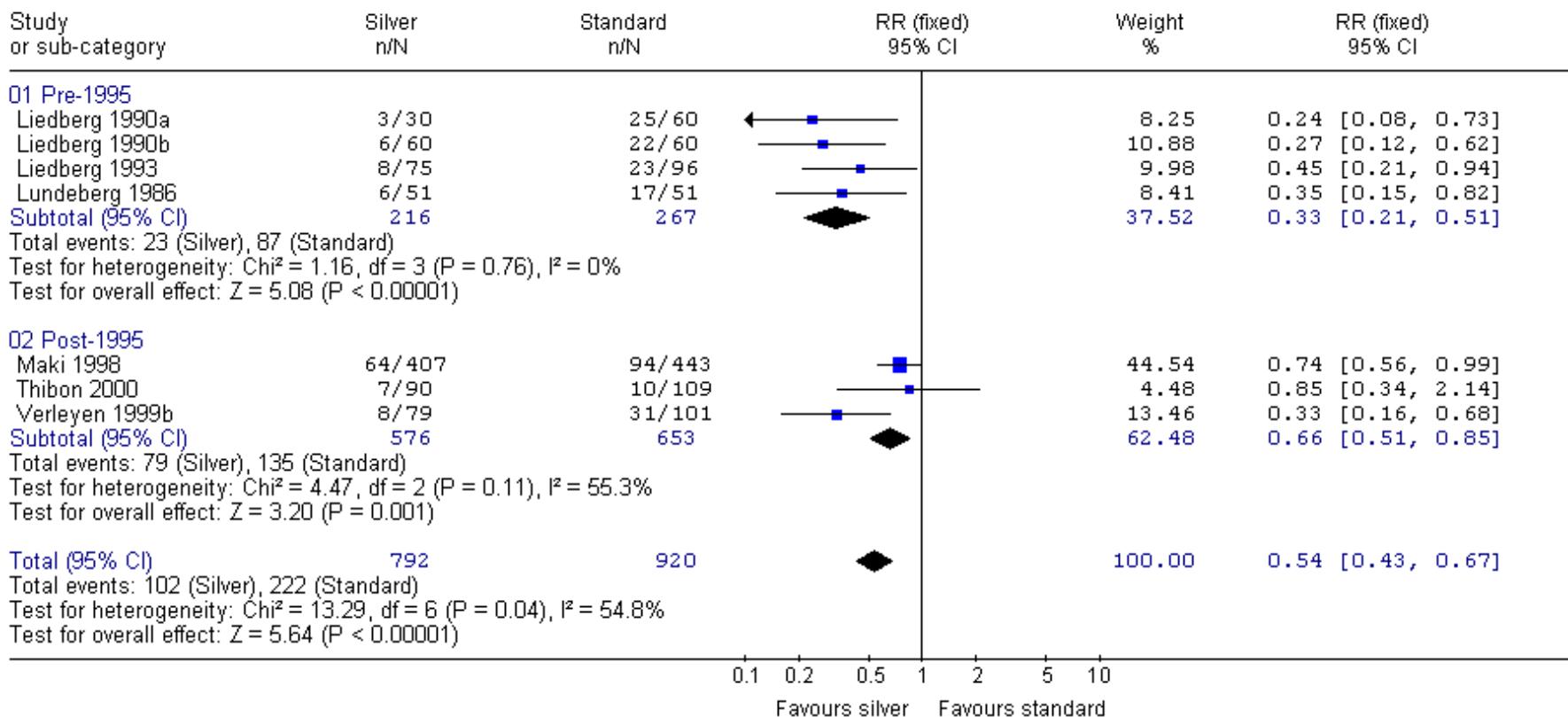
1. Number with asymptomatic bacteriuria (<1 week)

a. Fixed Effects

Review: Guideline for Prevention of Catheter-associated Urinary Tract Infections

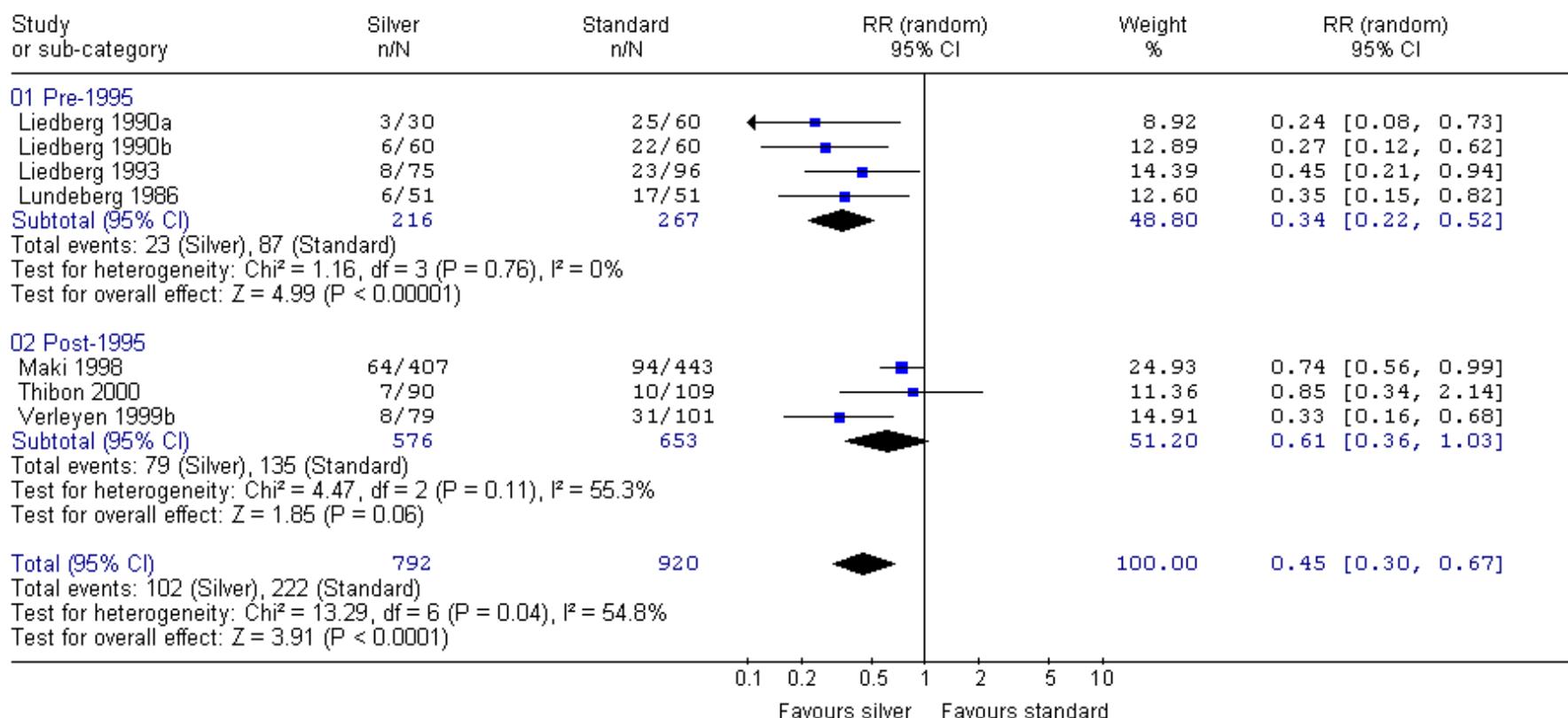
Comparison: 02 Silver alloy vs. standard (stratified by year of publication)

Outcome: 01 Number with asymptomatic bacteriuria (<1 week)



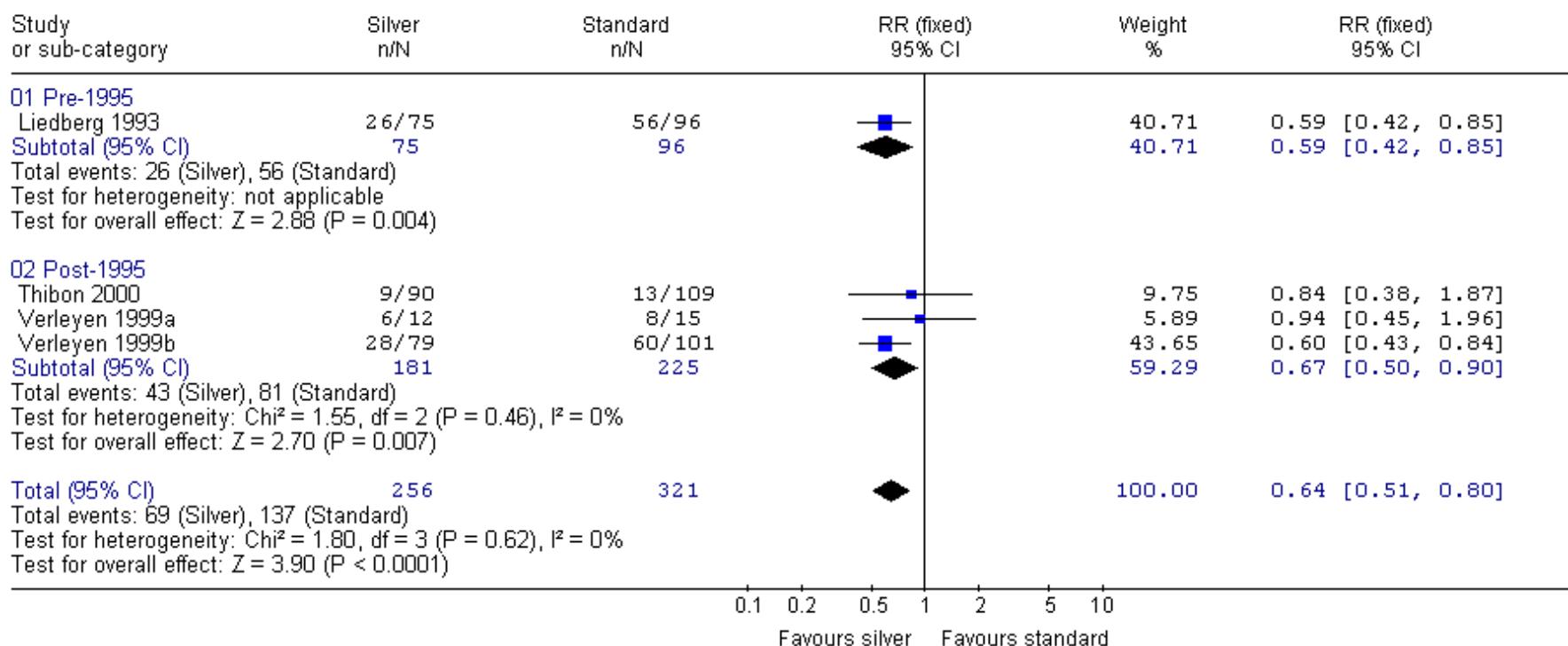
b. Random Effects

Review: Guideline for Prevention of Catheter-associated Urinary Tract Infections
 Comparison: 02 Silver alloy vs. standard (stratified by year of publication)
 Outcome: 01 Number with asymptomatic bacteriuria (<1 week)



2. Number with asymptomatic bacteriuria (> 1 week)

Review: Guideline for Prevention of Catheter-associated Urinary Tract Infections
 Comparison: 02 Silver alloy vs. standard (stratified by year of publication)
 Outcome: 02 Number with asymptomatic bacteriuria (>1 week)



ANALYSIS 4 (all studies in Cochrane Review excluding abstracts)

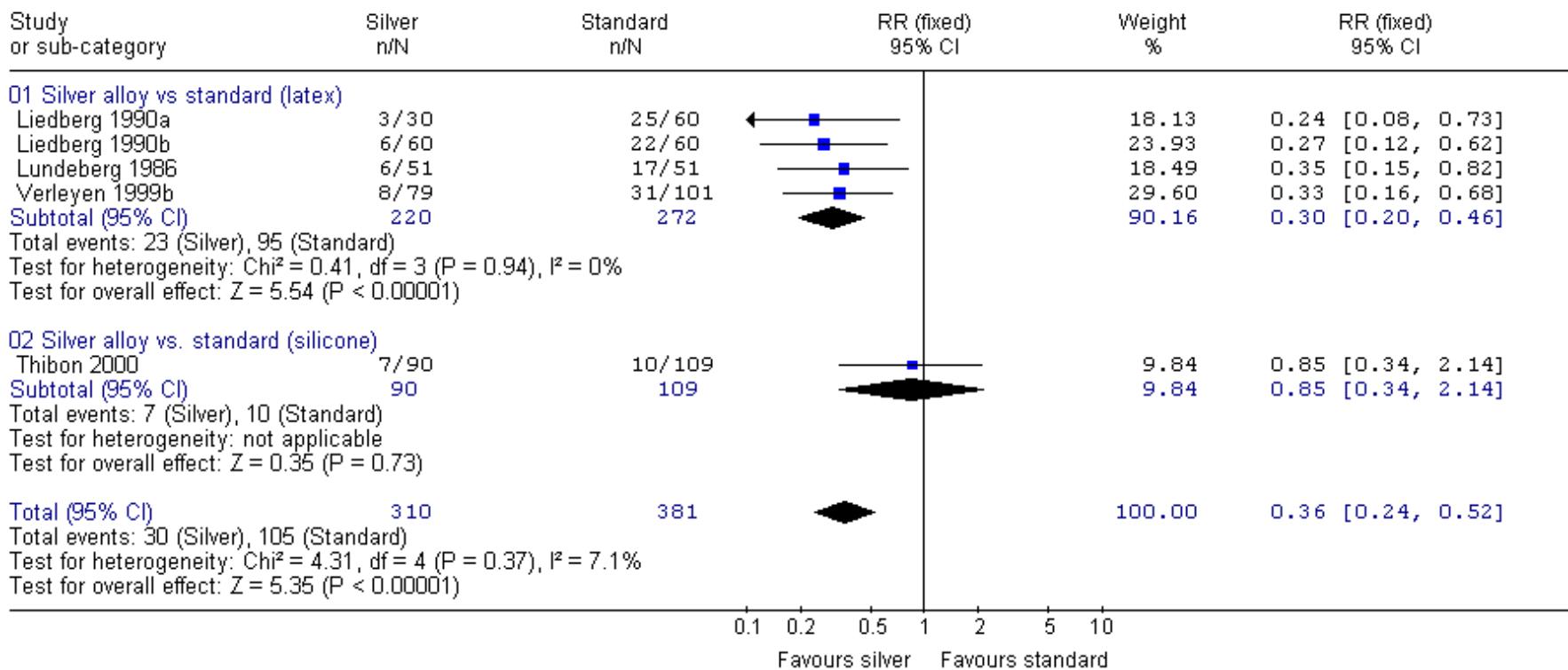
A. STRATIFIED BY TYPE OF CONTROL CATHETER

1. Number with asymptomatic bacteriuria (<1 week)

Review: Guideline for Prevention of Catheter-associated Urinary Tract Infections

Comparison: 01 Silver alloy vs standard (stratified by type of control catheter)

Outcome: 01 Number with asymptomatic bacteriuria (<1 week)

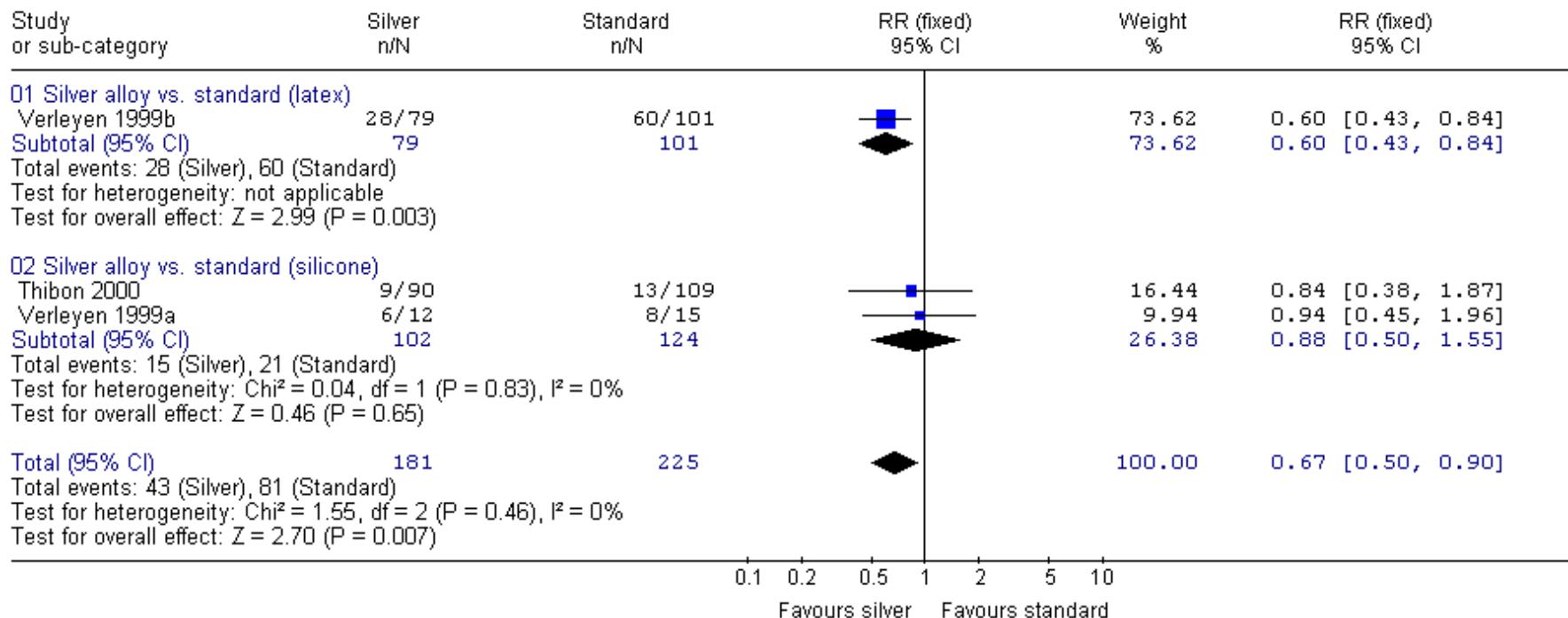


2. Number with asymptomatic bacteriuria (> 1 week)

Review: Guideline for Prevention of Catheter-associated Urinary Tract Infections

Comparison: 01 Silver alloy vs standard (stratified by type of control catheter)

Outcome: 02 Number with asymptomatic bacteriuria (>1 week)



B. STRATIFIED BY YEAR OF PUBLICATION

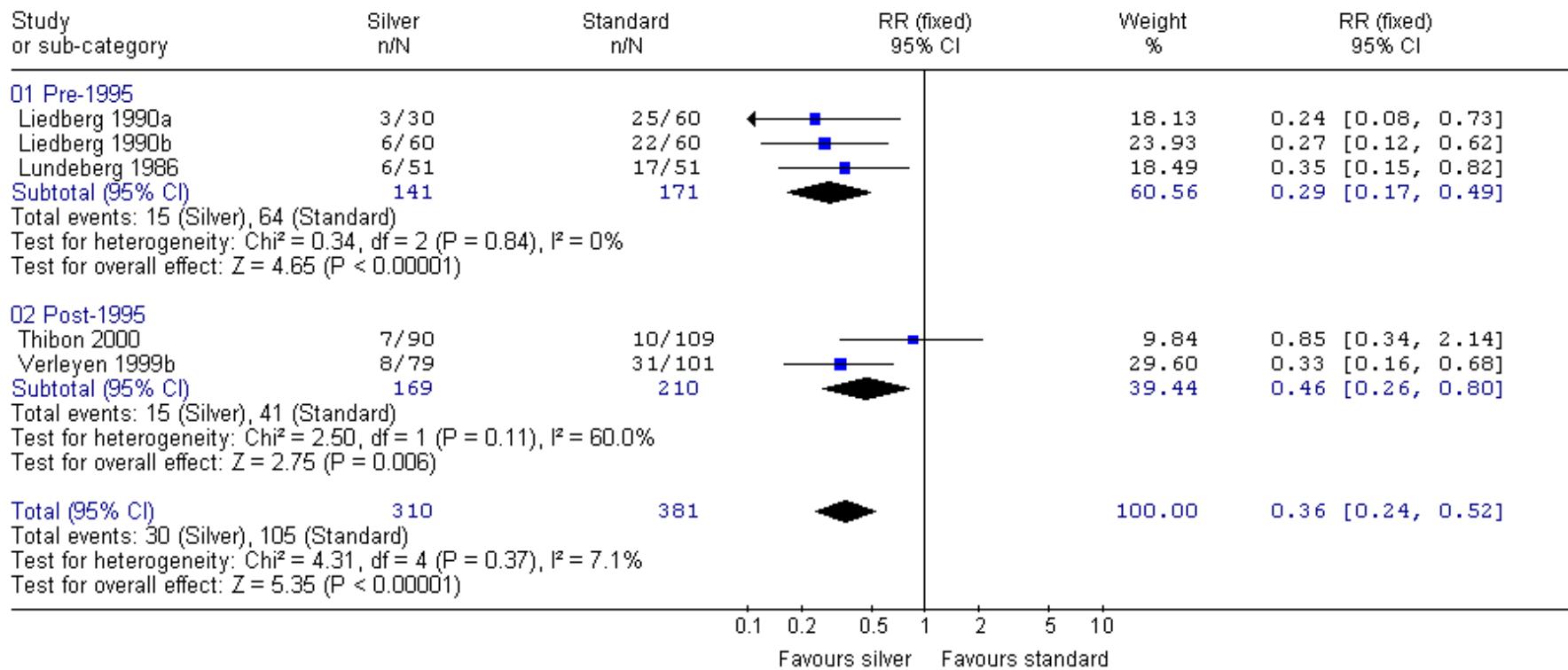
1. Number with asymptomatic bacteriuria (<1 week)

a. Fixed Effects

Review: Guideline for Prevention of Catheter-associated Urinary Tract Infections

Comparison: 02 Silver alloy vs. standard (stratified by year of publication)

Outcome: 01 Number with asymptomatic bacteriuria (<1 week)

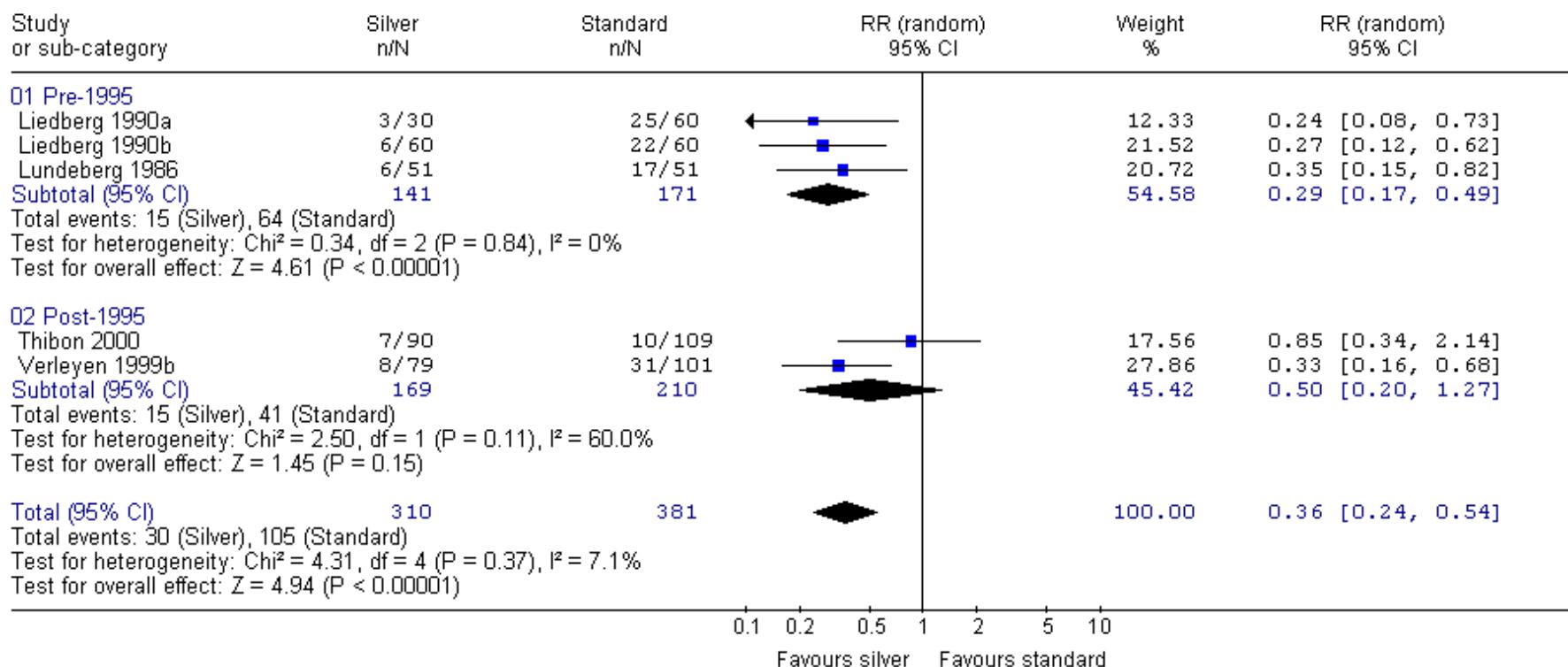


b. Random Effects

Review: Guideline for Prevention of Catheter-associated Urinary Tract Infections

Comparison: 02 Silver alloy vs. standard (stratified by year of publication)

Outcome: 01 Number with asymptomatic bacteriuria (<1 week)

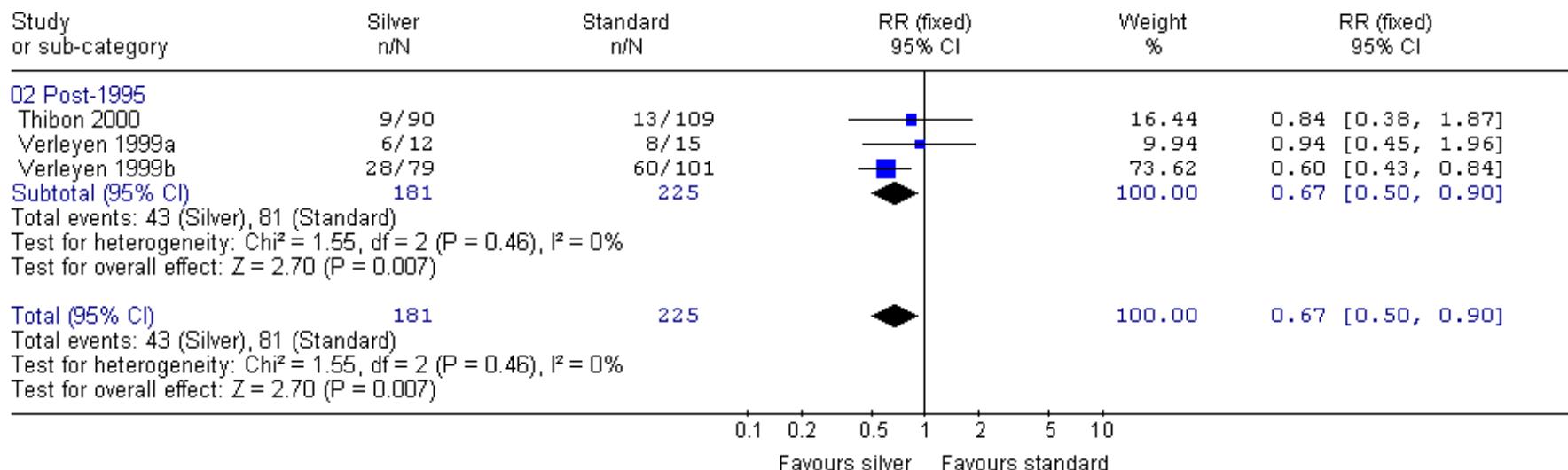


2. Number with asymptomatic bacteriuria (> 1 week)

Review: Guideline for Prevention of Catheter-associated Urinary Tract Infections

Comparison: 02 Silver alloy vs. standard (stratified by year of publication)

Outcome: 02 Number with asymptomatic bacteriuria (>1 week)



APPENDIX 4: QUALITY CHECKLISTS

I. Systematic reviews

1. Search terms described.
2. Searched databases described.
3. Inclusion/exclusion criteria described.
4. Numbers of included/excluded studies along with reasons for exclusions described.
5. Studies screened by two independent reviewers for inclusion.
6. Data extracted by two independent reviewers.
7. Individual study quality assessed.
8. Heterogeneity between study results assessed qualitatively and/or quantitatively.

II. Randomized Controlled Trials

1. Described as randomized.
2. Randomization appropriately performed.
3. Described as double-blind.
4. Outcome assessor blinded.
5. Study participant blinded.
6. Investigator blinded.
7. Attrition described.
8. Attrition less than 10-15% of assigned patients.
9. Attrition appropriately analyzed (i.e., intention-to-treat analysis for superiority studies)

III. Cohort Studies/Case Control Studies

1. All study groups derived from similar source/reference populations.
2. Attrition not significantly different across all study groups.

3. The measure of exposure is valid.
4. The measure of outcome is valid.
5. Investigators blinded to endpoint assessment.
6. Potential confounders identified.
7. Statistical adjustment for potential confounders performed.

IV. Diagnostic Studies

1. Valid selection of study sample (i.e., consecutive or randomly selected subjects).
2. Valid reference standard.
3. Diagnostic test and reference standard performed independently on each subject.
4. Diagnostic test and reference standard evaluated independently on each subject (blinding).

V. Economic Evaluations

1. Perspective defined (e.g., societal, payer, provider).
2. Time horizon defined.
3. Decision tree(s) or rule(s) explicit.
4. Sources of cost estimates identified.
5. Sources of event rate estimates identified.
6. Sensitivity analyses performed.

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