

Surgical Management of Stones: American Urological Association/Endourological Society Guideline, PART II



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Purpose: This Guideline is intended to provide a clinical framework for the surgical management of patients with kidney and/or ureteral stones. The summary presented herein represents Part II of the two-part series dedicated to Surgical Management of Stones: American Urological Association/Endourological Society Guideline. Please refer to Part I for introductory information and a discussion of pre-operative imaging and special cases.

Materials and Methods: A systematic review of the literature (search dates 1/1/1985 to 5/31/2015) was conducted to identify peer-reviewed studies relevant to the surgical management of stones. The review yielded an evidence base of 1,911 articles after application of inclusion/exclusion criteria. These publications were used to create the Guideline statements. Evidence-based statements of Strong, Moderate, or Conditional Recommendation were developed based on benefits and risks/burdens to patients. Additional directives are provided as Clinical Principles and Expert Opinions when insufficient evidence existed.

Results: The Panel identified 12 adult Index Patients to represent the most common cases seen in clinical practice. Three additional Index Patients were also created to describe the more commonly encountered special cases, including pediatric and pregnant patients. With these patients in mind, Guideline statements were developed to aid the clinician in identifying optimal management.

Conclusions: Proper treatment selection, which is directed by patient- and stone-specific factors, remains the greatest predictor of successful treatment outcomes. This Guideline is intended for use in conjunction with the individual patient's treatment goals. In all cases, patient preferences and personal goals should be considered when choosing a management strategy.

Abbreviations and Acronyms

EHL = electrohydraulic lithotripsy
MET = medical expulsive therapy
PCNL = percutaneous nephrolithotomy
SWL = shock-wave lithotripsy
URS = ureteroscopy

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GUIDELINE STATEMENTS

Treatment of Adult Patients with Ureteral Stones. 7. Patients with uncomplicated ureteral stones ≤ 10 mm should be offered observation, and those with distal stones of similar size should be offered MET with α -blockers.

(Index Patient 3) (Strong Recommendation; Evidence Strength: Grade B)

Natural history studies have shown that the likelihood of spontaneous stone passage correlates with stone size and location.¹ Several pharmacologic agents for medical expulsive therapy, including α_1 receptor

antagonists and calcium-channel blockers, have recently been tested for their ability to change the natural history of ureteral calculi by increasing spontaneous passage rates. The Panel's meta-analysis showed superior stone free rates in patients with <10 mm distal ureteral stones treated with α -blockers (77.3%) compared to placebo or no treatment (54.4%) (OR 3.79, 95% CI 2.84-5.06) (fig. 1). This effect was largely accounted for by trials

in which tamsulosin 0.4 mg was administered daily in patients with <10 mm distal ureteral calculi.²

8. Clinicians should offer reimaging to patients prior to surgery if passage of the stone is suspected or if stone movement will change management. Reimaging should focus on the region of interest and limit radiation exposure to uninvolved regions. (Clinical principle)

Forest plot: Odds ratio of stone free rate for distal ureteral stones <10 mm in patients receiving any α -Blocker vs. Control

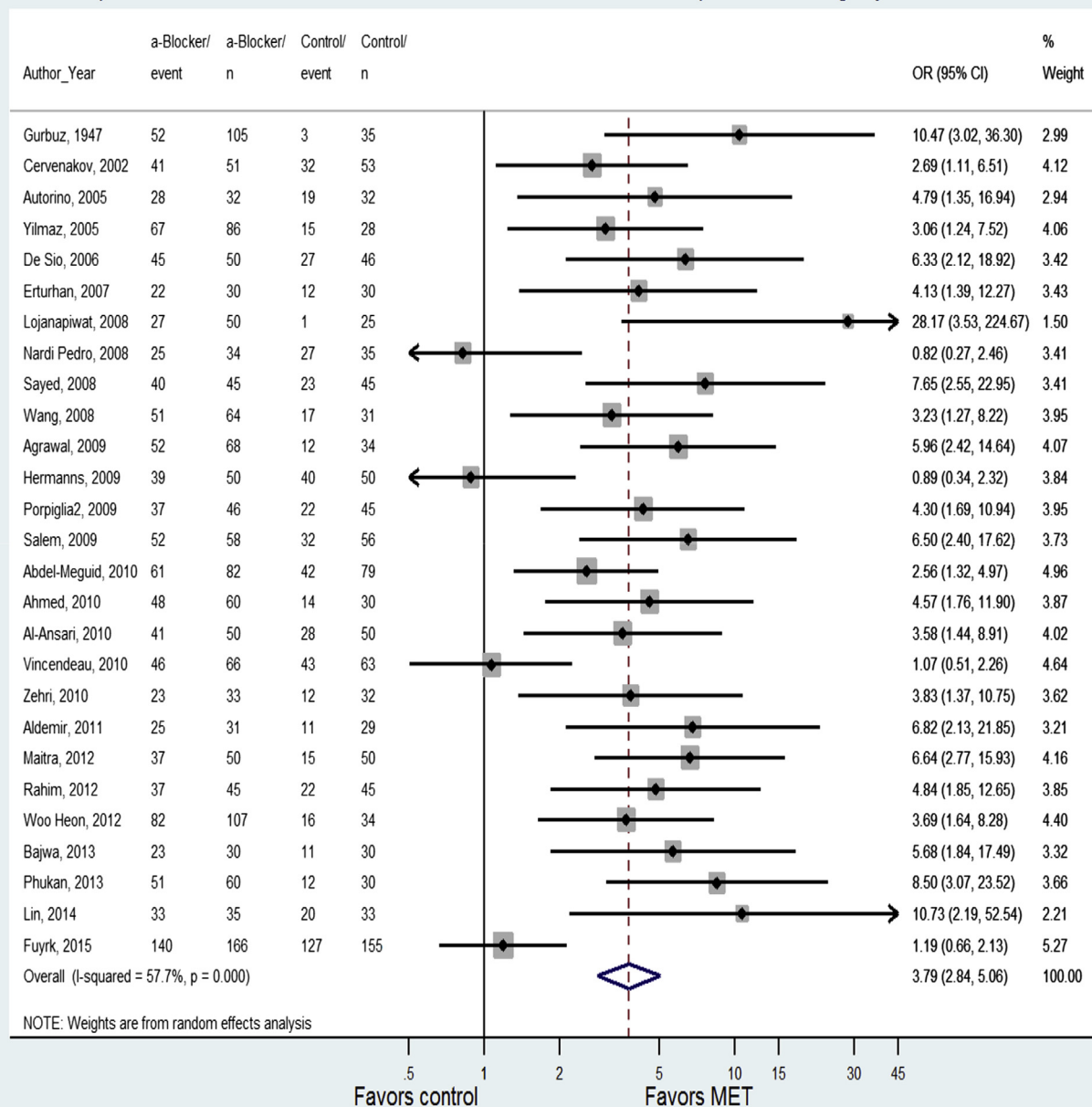


Figure 1.

A change in stone position may influence treatment approach, particularly if passage of the stone is suspected. If a patient is in the process of ureteral stone passage, clinicians should offer repeat imaging prior to stone intervention if symptoms have changed because a change in stone position may influence treatment approach (ureteroscopy versus shock-wave lithotripsy versus continued observation), particularly if passage of the stone is suspected. Repeat imaging can include KUB x-ray, renal/bladder ultrasound, or computed tomography. If feasible, a tailored approach should be utilized to limit radiation exposure.

9. In most patients, if observation with or without MET is not successful after four to six weeks and/or the patient/clinician decide to intervene sooner based on a shared decision making approach, the clinician should offer definitive stone treatment. (Index Patients 1-3) (Moderate Recommendation; Evidence Strength: Grade C)

While the maximum time duration for which a trial of MET is considered safe has not been clearly elucidated, experimental data on the effects of complete unilateral ureteral obstruction on renal function suggest the interval of conservative therapy should not exceed six weeks from initial clinical presentation in order to avoid irreversible kidney injury.³

10. Clinicians should inform patients that SWL is the procedure with the least morbidity and lowest complication rate, but URS has a greater stone-free rate in a single procedure. (Index Patients 1-6) (Strong Recommendation, Evidence Strength: Grade B)

The Panel's analysis of studies comparing URS and SWL for treatment of ureteral calculi showed superior stone-free rates for URS over SWL (90% for URS versus 72% for SWL, OR SWL/URS 0.29, 95% CI 0.21-0.40, $p < 0.001$) (fig. 2).²

11. In patients with a mid or distal ureteral stone who require intervention (who were not candidates for or who failed MET), clinicians should recommend URS as first-line therapy. For patients who decline URS, clinicians should offer SWL. (Index Patients 2, 3, 5, 6) (Strong Recommendation; Evidence Strength: Grade B)

URS is associated with significantly higher stone-free rates in a single procedure compared to SWL (see Statement 10). The disparity in stone-free outcome was particularly notable for patients with <10 mm mid and distal ureteral calculi (see table). Nonetheless, patients should be counseled that SWL is an acceptable alternative.

12. URS is recommended for patients with suspected cystine or uric acid ureteral stones

who fail MET or desire intervention. (Expert Opinion)

Stone targeting with fluoroscopy may be problematic for SWL as such stones as they are often faintly radio-opaque or radiolucent. URS with intracorporeal lithotripsy is an effective strategy for treating the majority of patients with ureteral stones, regardless of composition.⁴ In addition, cystine stones are often refractory to fragmentation with SWL.

13. Routine stenting should not be performed in patients undergoing SWL. (Index Patients 1-6) (Strong Recommendation; Evidence Strength: Grade B)

Previous Guidelines on the management of ureteral calculi recommended *against* routine stenting with SWL based on comparable stone-free rates with or without stent placement.^{5,6} A recent systematic review and meta-analysis comprising 8 RCTs and 876 patients compared stented versus *in situ* SWL for renal and ureteral stones and found no significant difference in stone-free rates between the 2 groups (RR 0.97, 95% CI 0.91-1.03, $p=0.27$).⁷

14. Following URS, clinicians may omit ureteral stenting in patients meeting all of the following criteria: those without suspected ureteric injury during URS, those without evidence of ureteral stricture or other anatomical impediments to stone fragment clearance, those with a normal contralateral kidney, those without renal functional impairment, and those in whom a secondary URS procedure is not planned. (Index Patients 1-6) (Strong Recommendation; Evidence Strength: Grade A)

Based on the best available evidence, a selective approach to stent placement seems the most prudent strategy for patients undergoing URS.⁸ Stent placement should be strongly considered in patients who sustain a ureteral injury during URS, have evidence of anatomical impediment to stone fragment clearance such as ureteral wall edema, have a large initial stone burden (>1.5 cm), have an anatomically or functionally solitary kidney or renal functional impairment, and for whom another ipsilateral URS is likely.

15. Placement of a ureteral stent prior to URS should not be performed routinely. (Index Patients 1-6) (Strong Recommendation; Evidence Strength: Grade B)

Despite an association in retrospective studies between pre-stenting and higher stone-free rates or shorter operative time,⁹⁻¹¹ in the absence of prospective data and high level evidence, the Panel recommends against systematic routine stent placement prior to URS when the sole purpose is to enhance stone-free rates or reduce operative times.

Forest plot: Odds ratio of stone free rate in adults_SWL vs. URS

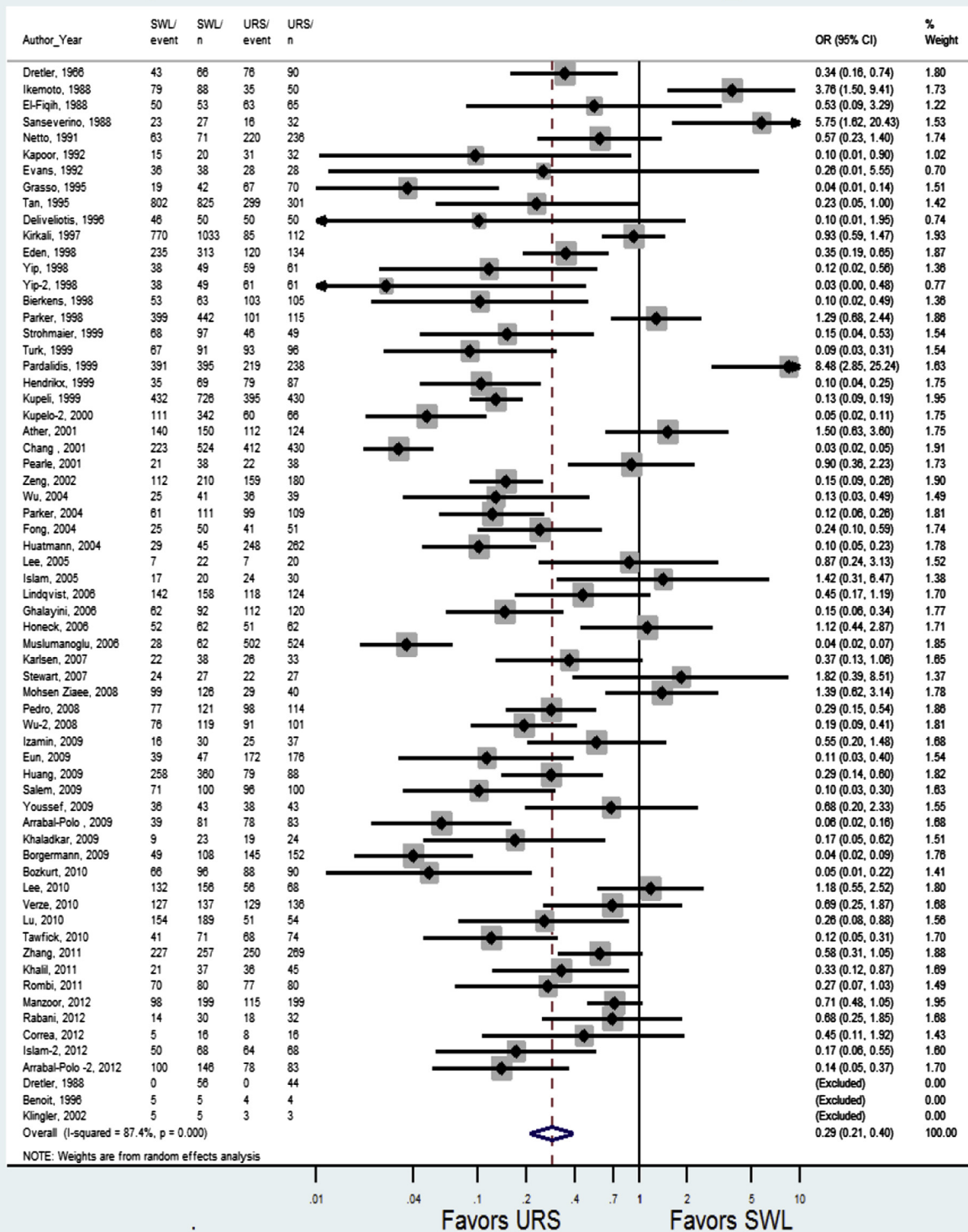


Figure 2.

Table. Stone-free rates for SWL and URS in the overall population after all sessions performed

Distal Ureter	Overall			Size < 10 mm			Size > 10 mm		
	No. Studies/Total Population	Median	CI (95%)	G/P	Median	CI (95%)	G/P	Median	CI (95%)
SWL									
All forms	81/16573	74.65%	(74-75)%	29/11420	73.96%	(73-75)%	22/3785	71.47%	(70-73)%
Bypass	-	-	-	-	-	-	-	-	-
In situ	7/826	76.3%	(73-79)%	16/259	86.5%	(82-90)%	11/994	73.84%	(71-77)%
Pushback	-	-	-	-	-	-	-	-	-
Other	8/486	71%	(57-82)%	3/35	90%	(75-98)%	1/1	84%	(15-100)%
URS									
All forms	119/15938	93.58%	(93-94)%	19/4008	94.21%	(93-95)%	14/1705	92.26%	(91-93)%
Flexible	4/159	96.8%	(92-99)%	-	-	-	-	-	-
Mixed flexible	9/431	93%	(89-96)%	1/38	97%	(88-100)%	1/10	79%	(50-96)%
Rigid	63/4254	89.9%	(89-90)%	13/181	90.6%	(85-94)%	8/533	94.7%	(92-96)%
Semi-rigid	30/5169	97.25%	(97-98)%	3/231	98.70%	(96-100)%	3/132	95.4%	(90-98)%
Total Ureter	Overall			Size < 10 mm			Size > 10 mm		
	No. Studies/Total Population	Median	CI (95%)	G/P	Median	CI (95%)	G/P	Median	CI (95%)
SWL									
All forms	36/36215	68.95%	(68-69)%	50/18879	63.96%	(63-65)%	38/7433	61.62%	(61-63)%
Bypass	1/67	92%	(84-97)%	1/23	87%	(59-91)%	-	-	-
In situ	6/904	52.21%	(49-55)%	27/598	86.79%	(84-89)%	19/1683	65.18%	(63-67)%
Pushback	-	-	-	1/59	83%	(72-91)%	-	-	-
Other	-	-	-	11/196	88%	(81-93)%	10/698	70%	(57-82)%
URS									
All forms	101/29875	89.42%	(89-90)%	38/11879	92.53%	(92-93)%	31/5619	83.25%	(82-84)%
Flexible	6/481	94.59%	(92-96)%	2/81	97.5%	(91-99)%	-	-	-
Mixed flexible	-	-	-	7/209	87%	(81-92)%	5/94	81%	(67-92)%
Rigid	26/6430	84.99%	(83-85)%	20/1715	87.35%	(86-89)%	16/1641	71.48%	(69-74)%
Semi-rigid	45/9984	91.86%	(91-92)%	6/2329	69.35%	(95-97)%	7/1064	90.79%	(89-92)%

16. Clinicians may offer α -blockers and anti-muscarinic therapy to reduce stent discomfort. (Index patients 1-6) (Moderate Recommendation; Evidence Strength: Grade B)

α -blockers have been shown in multiple meta-analyses and systematic reviews to have benefit in relieving stent related discomfort.¹²⁻¹⁵ Other medications that can be used to alleviate stent discomfort include anticholinergics/antimuscarinics, bladder analgesics for dysuria, non-steroidal anti-inflammatory agents, and narcotic analgesics.

17. In patients who fail or are unlikely to have successful results with SWL and/or URS, clinicians may offer PCNL, laparoscopic, open, or robotic assisted stone removal. (Index patients 1-6) (Moderate Recommendation; Evidence Strength: Grade C)

In some patients with large or complex ureteral stone burdens, percutaneous antegrade URS may allow for more expeditious stone clearance, as larger and more efficient instrumentation can be utilized.¹⁶ Benefits must be weighed against the increased invasiveness and risk of complications for percutaneous nephrolithotomy. Ureterolithotomy may also be considered as an alternative therapy in these rare clinical scenarios. Both laparoscopic and

robotic-assisted ureterolithotomy provide results equivalent to open surgery, but with reduced morbidity.¹⁷

18. Clinicians performing URS for proximal ureteral stones should have a flexible ureteroscope available. (Index Patients 1, 4) (Clinical Principle)

The limitations of semi-rigid URS in accessing stones in the middle and proximal ureter are overcome by flexible URS. Flexible URS has been shown in both prospective and retrospective studies to have high overall success rates with low morbidity/complications for <2 cm proximal ureteral stones.¹⁸

19. Clinicians should not utilize EHL as the first-line modality for intra-ureteral lithotripsy. (Index patients 1-6, 13, 15) (Expert Opinion)

The major disadvantage of electrohydraulic lithotripsy (EHL) is its propensity to damage the ureteral mucosa, resulting in ureteral perforation as shown in a prospective randomized trial of EHL versus pneumatic lithotripsy during URS (17.6% versus 2.6% incidence of ureteral perforation, respectively).¹⁹

20. In patients with obstructing stones and suspected infection, clinicians must urgently drain the collecting system with a stent or

nephrostomy tube and delay stone treatment. (Strong Recommendation; Evidence Strength: Grade C)

When infection is suspected in the face of ureteral obstruction, the collecting system must be drained, either by a nephrostomy tube or a ureteral stent, to allow drainage of infected urine and antibiotic penetration into the affected renal unit.²⁰

Treatment of Adult Patients with Renal Stones.

21. In symptomatic patients with a total non-lower pole renal stone burden ≤ 20 mm, clinicians may offer SWL or URS. (Index Patient 7) (Strong Recommendation; Evidence Strength: Grade B)

For cumulative stone burdens <20 mm, stone-free rates for both URS and SWL are acceptable and have less morbidity than PCNL. Of these treatment options, PCNL stone-free rates are the least affected by stone size, while stone-free rates of both SWL and URS decline with increasing stone burden.²¹ Compared to SWL, URS is associated with a lower likelihood of repeat procedure; therefore, the patient will become stone-free quicker than with SWL.²²

22. In symptomatic patients with a total renal stone burden >20 mm, clinicians should offer PCNL as first-line therapy. (Index Patient 8) (Strong Recommendation; Evidence Strength: Grade C)

PCNL offers a higher stone-free rate than SWL or URS and is less invasive than open surgery or laparoscopic/robotic assisted procedures. In a RCT comparing PCNL to URS for >2 cm renal pelvic stones, the stone-free rate was higher for PCNL compared to URS (94% versus 75%), although predominantly semi-rigid URS was used in this study.²³ Furthermore, the success rate of PCNL is less dependent on stone composition, density and location.

25. In patients with total renal stone burden >20 mm, clinicians should not offer SWL as first-line therapy. (Index Patient 8) (Moderate Recommendation; Evidence Strength: Grade C)

Studies have reported significantly reduced stone-free rates and increased need for multiple treatments with SWL compared to PCNL in this setting.²⁴ The success of SWL is dependent on a variety of factors, including obesity, skin-to-stone distance, collecting system anatomy, stone composition and stone density/attenuation.²⁵ As such, patients selected for SWL should generally have favorable parameters in order to maximize stone free rates.

27. Clinicians may perform nephrectomy when the involved kidney has negligible function in patients requiring treatment.

(Index Patients 1-14) (Conditional Recommendation; Evidence Strength: Grade C)

When considering nephrectomy for the poorly functioning kidney, overall renal function and the condition of the kidney on the contralateral side should be considered. The risk of the procedure must be weighed against the benefit to the patient and will depend on multiple clinical factors (e.g., age, medical co-morbidities, body habitus).²⁶

28. For patients with symptomatic (flank pain), non-obstructing, caliceal stones without another obvious etiology for pain, clinicians may offer stone treatment. (Index Patient 12) (Moderate Recommendation; Evidence Strength: Grade C)

Eradication of flank pain with stone removal has been described in this setting; therefore, the Panel feels that patients with pain and non-obstructing caliceal stones (without another obvious source of pain) may be offered surgical intervention for stone treatment.

29. For patients with asymptomatic, non-obstructing caliceal stones, clinicians may offer active surveillance. (Conditional Recommendation; Evidence Strength: Grade C)

Observation of such patients is appropriate as long as the patient is counseled about the risk of stone growth, passage, and pain. If observation is chosen, active surveillance with follow-up imaging studies to assess for stone growth or new stone formation is recommended.

30. Clinicians should offer SWL or URS to patients with symptomatic ≤ 10 mm lower pole renal stones. (Index Patient 9) (Strong Recommendation; Evidence Strength: Grade B)

A multi-centered, prospective randomized trial found no statistically significant difference in the stone-free rates between URS and SWL for ≤ 10 mm lower pole stones. Intraoperative complications were somewhat higher with URS, but not statistically significantly so, and patient-derived quality of life measures were somewhat better with SWL in this study.²⁷

31. Clinicians should not offer SWL as first-line therapy to patients with >10 mm lower pole stones. (Index Patient 10) (Strong Recommendation; Evidence Strength: Grade B)

Endoscopic approaches in this patient population offer substantial benefit over SWL with regard to stone-free rate with a moderate associated increase in risk.² For lower pole stones 10-20 mm in size, the median success rate for SWL was 58% compared to 81% for URS and 87% for PCNL. When the stone burden exceeded 20mm, the median success rate of SWL declined to 10%.

32. Clinicians should inform patients with lower pole stones >10 mm in size that PCNL has a higher stone-free rate but greater morbidity. (Index patient 10). (Strong Recommendation; Evidence Strength: Grade B)

Randomized trials demonstrated that PCNL is associated with superior single-treatment stone-free rates, but with greater morbidity than URS or SWL.^{27,28} URS and SWL are options for the management of these stones, but clinicians should inform patients that retreatment rates are higher, and stone-free rates are significantly lower, with a higher likelihood of clinical stone recurrence due to retained fragments.

33. In patients undergoing uncomplicated PCNL who are presumed stone-free, placement of a nephrostomy tube is optional. (Conditional Recommendation; Evidence Strength: Grade C)

Tubeless PCNL was introduced to limit the adverse effects associated with nephrostomy tube drainage. Renal drainage can be established with an indwelling or externalized stent, or the patient can be left without a stent. The tubeless approach should not be undertaken if there is active hemorrhage or it is likely that another percutaneous procedure will be needed to remove residual stones.

34. Flexible nephroscopy should be a routine part of standard PCNL. (Strong Recommendation; Evidence Strength: Grade B)

Stone fragmentation (intracorporeal lithotripsy) is commonly performed during PCNL for large stones, and the fragments generated may migrate into areas of the collecting system that cannot be safely accessed with a rigid nephroscope. If not removed, these fragments may result in future stone events.^{29–31} The utilization of flexible nephroscopy during PCNL has been demonstrated to improve stone-free rates.³²

35. Clinicians must use normal saline irrigation for PCNL and URS. (Strong Recommendation; Evidence Strength: Grade B)

Normal saline is the standard irrigation solution as it is isotonic and isoosmolar and does not lead to significant electrolyte abnormalities when absorbed.³³ The use of a non-isotonic solution increases the risk of hemolysis, hyponatremia, and heart failure if sufficient volume is absorbed.³⁴

39. In patients not considered candidates for PCNL, clinicians may offer staged URS. (Moderate Recommendation; Evidence Strength: Grade C)

While PCNL is the optimal treatment for most patients with complex, high-volume, and branched renal stones, some anatomic abnormalities and/or patient factors may constitute relative

contraindications to PCNL, including use of anti-coagulation or anti-platelet therapy that cannot be discontinued or the presence of contractures, flexion deformities, or other anatomic derangements that may preclude proper positioning for PCNL. In these clinical scenarios, URS is a viable option, although it may require staged or repeated procedures to treat large stone volumes and may not render patients completely stone-free.³⁵

40. Clinicians may prescribe α -blockers to facilitate passage of stone fragments following SWL. (Moderate Recommendation; Evidence Strength: Grade B)

The Panel's meta-analysis of 24 RCTs assessing the efficacy of adjunctive therapy to facilitate stone passage after SWL for renal or ureteral stones showed a nearly 2-fold higher stone-free rate with adjunctive therapy (OR 1.878, 95% CI, 1.508–2.339). Many of these studies had limitations (inadequate randomization and blinding), which downgraded the quality of evidence.²

43. SWL should not be used in the patient with anatomic or functional obstruction of the collecting system or ureter distal to the stone. (Strong Recommendation; Evidence Strength: Grade C)

The use of SWL in this patient population is associated with lower stone-free rates. Abnormalities, such as UPJ obstruction, urinary diversion with ureteral anastomotic narrowing, ureteral stricture, and caliceal diverticula, are associated with retained stone fragments after SWL resulting in low stone-free rates.^{36–39}

44. In patients with symptomatic caliceal diverticular stones, endoscopic therapy (URS, PCNL, laparoscopic, robotic) should be preferentially utilized. (Strong Recommendation; Evidence Strength: Grade C)

The Panel's meta-analysis demonstrated a low stone-free rate associated with SWL (13–21%) compared to that of URS, PCNL, laparoscopic and robotic surgery (18–90% with URS and 62.5–100% with PCNL).² The choice of optimal endoscopic approach should be based on stone location and size, relation to surrounding structures, and patient preference.

45. Staghorn stones should be removed if attendant comorbidities do not preclude treatment. (Clinical Principle)

The Panel endorses stone removal in patients who are able to tolerate the rigors of long and perhaps multiple procedures and their attendant risks.

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DISCLAIMER

This document was written by the Surgical Management of Stones Guideline Panel of the American Urological Association Education and Research, Inc., which was created in 2014. The Practice Guidelines Committee of the AUA selected the committee chair. Panel members were selected by the chair. Membership of the panel included specialists in urology with specific expertise on this disorder. The mission of the panel was to develop recommendations that are analysis-based or consensus-based, depending on panel processes and available data, for optimal clinical practices in the treatment of stones.

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While these guidelines do not necessarily establish the standard of care, AUA seeks to recommend and to encourage compliance by practitioners with current best practices related to the condition being treated. As medical knowledge expands and technology advances, the guidelines will change. Today these evidence-based guidelines statements represent not absolute mandates but provisional proposals for treatment under the specific conditions described in each document. For all these reasons, the guidelines do not pre-empt physician judgment in individual cases.

Treating physicians must take into account variations in resources, and patient tolerances, needs, and preferences. Conformance with any clinical guideline does not guarantee a successful outcome. The guideline text may include information or recommendations about certain drug uses ("off label") that are not approved by the FDA (Food and Drug Administration), or about medications or substances not subject to the FDA approval process. AUA urges strict compliance with all government regulations and protocols for prescription and use of these substances. The physician is encouraged to carefully follow all available prescribing information about indications, contraindications, precautions and warnings. These guidelines and best practice

statements are not intended to provide legal advice about use and misuse of these substances.

Although guidelines are intended to encourage best practices and potentially encompass available technologies with sufficient data as of close of the literature review, they are necessarily time-limited. Guidelines cannot include evaluation of all data on emerging technologies or management, including those that are FDA-approved, which may immediately come to represent accepted clinical practices.

For this reason, the AUA does not regard technologies or management which are too new to be addressed by this guideline as necessarily experimental or investigational.

CONFLICT OF INTEREST DISCLOSURES

All panel members completed COI disclosures. Those marked with (C) indicate that compensation was received. Disclosures listed include both topic- and non-topic-related relationships.

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