Inpatient vs. outpatient care for uncomplicated diverticulitis

David Wilkins

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42M presents with 2 weeks diarrhoea, sharp pain and tenderness in hypogastric region and mildly elevated WCC. No fever, other systemic symptoms or significant comorbidities. Sigmoid diverticulitis confirmed on CT.

Should we:

1. Send patient home on oral antibiotics?
2. Keep patient in hospital for two nights on IV antibiotics, then send them home on oral antibiotics?

Is there any benefit to keeping an uncomplicated diverticulitis patient in hospital for IV antibiotics vs. sending them home on oral antibiotics?

Population: Patients with uncomplicated diverticulitis

Intervention: Outpatient oral antibiotics

Comparator: Inpatient IV antibiotics

Outcome: Further medical or surgical intervention (complications or recurrence)

This is a **therapy** question. The best evidence for this question would be a **large-scale, high-quality RCT** or a **systematic review or metaanalysis including such RCTs**.

Medline, Embase, and Cochrane Database of Systematic Reviews

# ▲	Searches	Results
1	▶ Diverticulitis/ or Diverticulitis, Colonic/ or uncomplicated diverticulitis.mp.	18006
2	▶ antibiotic*.mp. or Anti-Bacterial Agents/	1259442
3	▶ (intravenous or IV).mp.	2161162
4	▶ 1 and 2 and 3	546
5	▶ (Randomized Controlled Trial or Review or Meta-Analysis).pt.	5073168
6	▶ 4 and 5	123

Outpatient Versus Hospitalization Management for Uncomplicated Diverticulitis

A Prospective, Multicenter Randomized Clinical Trial (DIVER Trial)

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Study design

Inclusion criteria

≥ 18 yo, uncomplicated diverticulitis, oral intake, pain and fever controlled

Exclusion criteria

> ‘complicated colonic diverticulitis (grade Ib: confined pericolic abscess; grade II: pelvic, intra-abdominal, or retroperitoneal abscess; grade III: generalized purulent peritonitis; and grade IV: fecal peritonitis); **absence of symptom relief (maintenance of tenderness, fever, or/and persistence or worsening of acute pain after analgesic and first doses of antibiotics)**; pregnancy or breastfeeding; intake of antibiotic for colonic diverticulitis in the month previous to actual diagnosis; colorectal cancer suspicion at computed tomographic findings; concomitant unstable comorbid conditions; immunosuppression (cortisone or immunosuppressive drug intake, transplantation, chronic renal failure with hemodialisis, acquired or congenital immunodeficiency, active malignant neoplasm); cognitive, social, or psychiatric impairment; intolerance to oral intake and persisting vomiting; and patients’ rejection of written consent.’

- Eligible patients randomised by computer into two groups ‘stratified by center’
- Both groups received first dose of IV antibiotics in the ED
- Antibiotic treatment in both groups discontinued after 10 days

Inpatient group

- IV Augmentin 1g per 125 mg TDS
- If allergy, IV ciprofloxacin 200 mg BD and metronidazole 500 mg TDS
- IV fluids
- Fluids and antibiotics ceased after oral feeding tolerated
- ?Discharged with oral antibiotics

Outpatient group

- Oral Augmentin 875 mg per 125 mg TDS
- If allergy, oral ciprofloxacin 500 mg BD and metronidazole 500 mg TDS
- Daily phone call from treating physician to monitor temperature, oral intake, bowel habit and pain

Treatment failure defined as:

> ‘persistence, increase, or recurrence of abdominal pain and/or fever, inflammatory bowel obstruction, need for radiological abscess drainage or immediate surgery due to complicated diverticulitis, need for hospital admission, and mortality during the first 60 days after discharge’

Results

To evaluate the primary end point, noninferiority limit of 10%, method based on confidence interval of the unilateral difference of 95% of the percentage of nonrelapse between the 2 groups was used. Intention-to-treat analyses were done.

Comparative analyses of the quantitative data were performed using nonparametric test (Mann-Whitney *U* test). The χ^2 test for proportions or Fisher exact test was used in the analysis as appropriate.

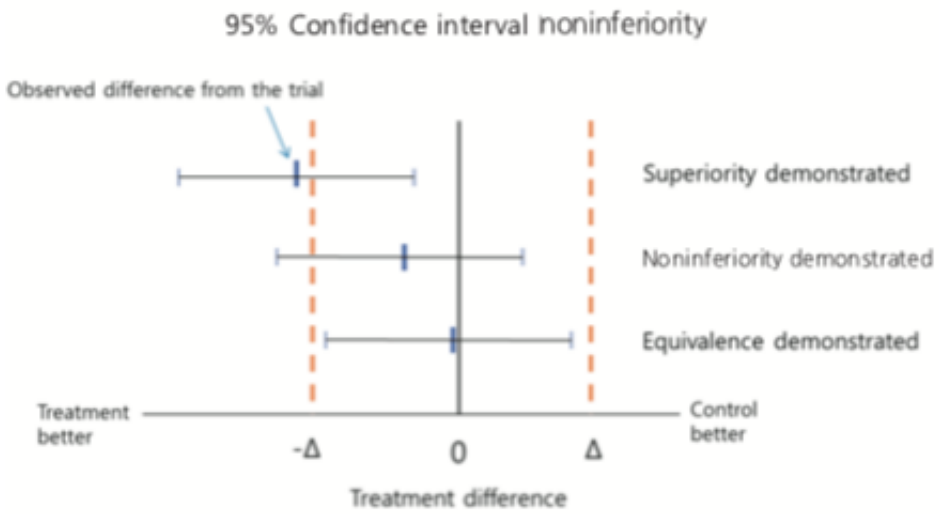

Fig. 1. Testing superiority, equivalence/noninferiority. Δ: margin for equivalence/noninferiority.

Hahn, S. Understanding noninferiority trials. Korean J Pediatr 55, 403–407 (2012).

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Seven patients (5.3%) of all the series were readmitted because of failure of medical treatment: 4 patients (6.1%) in group 1 and 3 patients (4.5%) in group 2. No differences were observed between the 2 groups ($P = 0.619$). No patients needed emergency surgery as a consequence of readmission and no mortality was observed.

Assessment of bias

Cochrane risk of bias tool

Criterion	Judgement
Random sequence generation	
Allocation concealment	
Blinding of participants and personnel	
Blinding of outcome assessment	
Incomplete outcome data	
Selective reporting	
Other sources of bias	

Randomization was performed by using a computer-generated random code and stratified by center. The random code was held centrally in a sealed envelope and distributed to each center by the monitor of the study. Surgeons on call in the different centers (in most

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Other sources of bias	

Exclusion criteria

77 of the 258 eligible patients met the exclusion criteria.

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Strengths and weaknesses

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- Large number of patients excluded for unclear reasons
- No blinding of outcome assessment

Conclusions

Evidence provided by this study

1. No good evidence is provided by this study.
2. The study does not support a change in clinical practice.

Relevence of study to patient

This study would have been relevent to my patient if:

1. The statistical analysis was appropriate.
2. The sample size was large enough to detect a clinically relevent difference.

Unanswered questions

1. What do the data from this study show if a non-inferiority test is correctly applied?
2. Are there any differences between the treatment groups beyond 60 days (e.g. in diverticulitis recurrence rates)?

Questions?