

**Critical Review Form
Therapy**

PGY-4

Isacson D, Thorisson A, Andreasson K, Nikberg M, Smedh K, Chabok A. Outpatient, non-antibiotic management in acute uncomplicated diverticulitis: a prospective study. Int J Colorectal Dis. 2015 Sep;30(9):1229-34.

Objectives: "to evaluate the safety and feasibility of outpatient management without the use of antibiotics in acute uncomplicated diverticulitis, with regard to complications, recurrences, and diverticulitis-related admissions, within a 3-month follow-up period." (p. 1229)

Methods: This prospective, observational study was conducted at two Swedish hospitals, from March 2012 until December 2013 at one hospital and from May 2012 until August 2012 at the other. Adult patients over 18 years of age with signs of acute uncomplicated left-sided diverticulitis on CT scan were eligible for inclusion. Exclusion criteria included the presence of complications of diverticulitis on CT (abscess, fistula, or free air); high fever, peritonitis, or septicemia; ongoing antibiotics therapy; or need for IV hydration or pain management.

All included patients were either discharged from the ED, or were discharged after CT scan but within 24 hours of presentation in those admitted for CT. All patients filled out a daily journal that assessed pain score, body temperature, oral intake, bowel habits, and the use of analgesics. Patients were also contacted via telephone on a daily basis by a nurse. Patients had blood work drawn after one week, and followed up with a physician at 3 months. All CT scans were later reevaluated and graded according to the [Ambrosetti classification system](#). Management failure was defined as hospital readmission within one month.

A total of 161 patients were enrolled in the study, of whom 6 were excluded (3 due to interrupted participation, 2 due to protocol violation, and 1 who had a CT performed > 24 hours after admission). This left 155 patients in the study of whom 65% were female. The mean age was 57.4 years.

Guide		Comments
I.	Are the results valid?	
A.	Did experimental and control groups begin the study with a similar prognosis (answer the questions posed below)?	
1.	Were patients randomized?	No. This was a prospective observational study with a single treatment arm.
2.	Was randomization concealed (blinded)? In other words, was it possible to subvert the randomization process to ensure that a patient would be “randomized” to a particular group?	N/A
3.	Were patients analyzed in the groups to which they were randomized?	Yes. There was only one treatment arm, and hence patients were only analyzed in one group. Patients given antibiotics were still analyzed in the study, and admission for IV antibiotics was considered a treatment failure.
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	N/A. There was only one group, hence no way to compare.
B.	Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?	
1.	Were patients aware of group allocation?	Yes. This was not a blinded study and there was only one treatment arm.
2.	Were clinicians aware of group allocation?	Yes. This was not a blinded study and there was only one treatment arm.
3.	Were outcome assessors aware of group allocation?	Yes. This was not a blinded study and there was only one treatment arm.
4.	Was follow-up complete?	No. There were five patients (3.2%) lost to follow-up. It is unknown if these patients had any complications or recurrence of disease. In one patient, the CT scan was not able to be reevaluated as planned.
II.	What are the results (answer the questions	

	posed below)?	
1.	How large was the treatment effect?	<ul style="list-style-type: none"> • The WBC and CRP normalized within 1 week in 84% of patients. • The mean pain score on day 3 was 1.8, and only 30% of patients required any analgesics. • Four patients (2.6%, 95% CI 1.0-6.5) returned and required readmission within 14 days of discharge. Two of these patients had a perforation and one had an abscess (treated with ultrasound drainage). The fourth patient had no signs of complication on CT scan. None of these patients required surgery and all were treated successfully with antibiotics. • There were five patients (3.3%) with a recurrence within 3 months. • CT reevaluation revealed complicated diverticulitis in 3 patients, including the abscess that was ultimately treated with ultrasound drainage. In the other two cases (one pericolic abscess and one with extraluminal gas), the patients were successfully treated without antibiotics.
2.	How precise was the estimate of the treatment effect?	See above.
III.	How can I apply the results to patient care (answer the questions posed below)?	
1.	Were the study patients similar to my patient?	No. This study was conducted in Sweden with a very homogeneous, predominantly white population of patients. Additionally, these patient would have easy access to early follow-up for reevaluation, while many patients in our system have no health insurance, no primary care physician, and no access to follow-up. The safety of outpatient management without antibiotics in such a population would be quite different.
2.	Were all clinically important outcomes considered?	No. The authors did not evaluate cost (which would likely be much lower), patient satisfaction, quality of life, or loss of work.
3.	Are the likely treatment benefits worth the potential harm and costs?	Uncertain. This was a relatively small, observational study with a single arm. The study does not compare the complication rates or other outcomes between groups treated with and without antibiotics, making it impossible to determine if antibiotics have any benefit in terms of reducing complications, time to recovery, or pain. While this study suggests that complication

		rates are low when select patients with uncomplicated diverticulitis are treated as outpatients without antibiotics, further randomized controlled trials will be needed to demonstrate that this is not significantly inferior to treatment with antibiotics.
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Limitations:

1. The authors only report **p-values** for some of the outcomes, and do not present any measures of efficacy or 95% **confidence intervals**.
2. This was an observational study without **blinding** and with only one treatment arm, making it impossible to compare a no antibiotics treatment regimen with conventional antibiotic therapy.
3. Nearly 2/3 of patients with CT-confirmed uncomplicated diverticulitis who were eligible for the study were NOT enrolled (**selection bias**).
4. It is likely that the racial make-up and prevalence of comorbidities is different in this Swedish population than we see in the US (**external validity**).

Bottom Line:

This prospective, observational study conducted at two hospitals in Sweden demonstrated low complication rates in patients with acute, uncomplicated diverticulitis discharged from the ED without antibiotics. Only 4 of 155 patients (2.6%) required readmission within 14 days of discharge, and none required surgical intervention. The primary limitation of the study is that it was a non-randomized study with only a single arm, precluding the ability to compare treatment with antibiotics to treatment without antibiotics. It is also concerning that only about 1/3 of eligible patients were actually enrolled in the study.