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Efficacy of observational care versus antibiotic therapy for treatment of acute uncomplicated diverticulitis

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ABSTRACT
A clinical decision report using:

for a patient with acute uncomplicated diverticulitis.

Keywords: acute uncomplicated diverticulitis, infection, non-operative

Clinical-Social Context
Mrs. Mary Lee [pseudonym] (she/her) is a 57 y/o woman who presented to the emergency department with symptoms of left-lower quadrant pain, nausea, emesis, fever, and anorexia. Mrs. Lee has a past medical history of essential hypertension and anxiety and a past surgical history of two cesarian-sections, a right inguinal hernia repair, and an umbilical hernia repair. Mrs. Lee works remotely as a personal assistant and lives with her husband and mother, for whom she is the primary caregiver.

Upon physical exam, she had a tender left-lower quadrant, a fever of 38.4º C, and a white blood cell count of 16,000. CT of the abdomen showed fat stranding and thickening of the sigmoid colon, classified as a Class Ib on the Hinchey grading scale for diverticulitis. Mrs. Lee was diagnosed with acute uncomplicated diverticulitis and admitted to the surgical GPU floor for management due to the severity of her pain, emesis, and dehydration status. We started to resuscitate Mrs. Lee, administer IV antibiotics, ciprofloxacin 1000mg and metronidazole 1500mg IV daily, and encouraged rest and ambulation.

Despite adequate resuscitation, ambulation, and rest, Mrs. Lee’s physical exam still revealed an acutely tender left lower quadrant and her white count had only decreased to 12,000 after two days of our initial treatment plan.

When we went to go discuss Mrs. Lee’s progress with her, she seemed very stressed by the need for continued IV antibiotics. She explained that her mother had advanced Alzheimer’s and Mrs. Lee was her primary caregiver as her husband was also traveling for work. Mrs. Lee felt she had a responsibility to be the primary caregiver while also working a remote job to pay the bills. It was clear Mrs. Lee was experiencing significant distress and entrusted
Clinical Question
Is the use of antibiotics in treating acute uncomplicated diverticulitis necessary for treatment compared to conservative therapy alone, especially considering patients who have significant responsibilities that would be hindered by a lengthy hospital stay?

Research Article

Description of Related Literature
A PubMed search with the key terms acute uncomplicated diverticulitis AND antibiotics was conducted, yielding 208 results. The results were filtered to select for randomized controlled trials, which yielded nineteen results. Twelve of these results were excluded due to lack of relevance to our clinical question, leaving six randomized clinical control trials for review that specifically compared antibiotic versus conservative treatment for treatment of acute uncomplicated diverticulitis. The “similar articles” function was also used, yielding one related RCT.

Mora-López et al. published a RCT in 2021 examining the effect of antibiotic versus conservative treatment in the outpatient setting for diverticulitis would impact hospital admission rates. This trial’s focus on outpatient treatment and hospital admissions rates did not directly apply to our patient’s situation and clinical question, and it was excluded.

In 2017 Daniels et al. published a RCT comparing the efficacy of antibiotic therapy versus observation in CT-diagnosed acute diverticulitis. Their sample size was 538 and aimed to compare the 6-month follow-up rates for the two groups. This was a double-blind study that found no significant difference between groups for outcome, time to recovery, and readmission rates due to recurrence of diverticulitis. However, this study also had a short period of follow-up for recurrence rates of only 6 months and was excluded for that reason.

In 2021, Juang et al. published a double-blind RCT examining the effect of placebo versus antibiotic therapy in the management of acute diverticulitis. Their study included 180 patients, given a regimen of either IV cefuroxime (750mg every six hours), oral metronidazole (400 mg every eight hours), and Augmentin (625mg every eight hours), or the placebo treatment. They found there was no significant difference between the placebo group and antibiotic group with regards to hospital length of stay, 30-day readmission rates, or need for further surgical interventions. This study was not chosen due to small sample size.

Mora-Lopez et al. published a RCT to determine the effects of antibiotics therapy versus anti-inflammatory treatment on outcomes in patients with acute diverticulitis. Their control group received amoxicillin-clavulanate (875/125 mg every eight hours), acetaminophen (1g every eight hours), omeprazole (20 g every eight hours), and a low-fiber diet. The observational group received the same dosing of omeprazole and a low-fiber diet but only received acetaminophen (1 g every eight hours) and ibuprofen (600mg every eight hours). They found no significant difference in recurrence rates between the two groups. While this study was of
interest, the use of other medications like omeprazole and dietary changes affect the applicability for our patient, Mrs. Lee, and was excluded.

Chabok et al. published a RCT known as the AVOD trial that analyzed the impact of antibiotic treatment versus observation for 12-month outcomes for patients with CT-diagnosed diverticulitis. Patients were treated with either IV ceftriaxone and metronidazole or a carbapenem and piperacillin-tazobactam. Their study found that there was no significant difference in recurrence, complications, and re-hospitalization rates for completion. However, this follow-up time for evaluation of recurrence gives a limited picture for the longer-term impact of difference between treatment groups.

Unlü C et al. published the design of a RCT in 2010 that studied the effect of antibiotic therapy versus conservative treatment without antibiotics on patient outcomes in a population of 533 people that would become the DIABOLO study. It would later be followed up for long-term analysis by van Dijk et al., which reported the 24-month outcomes of this study.

van Dijk et al. as part of the DIABOLO trial examined the long-term complications and risks of antibiotic vs observational therapy for acute uncomplicated diverticulitis, including Hinchey type 1a and b acute diverticulitis that was CT-confirmed. They followed 528 patients over 24 months, assigning 262 patients to observational therapy and 266 patients to a regimen of amoxicillin-clavulanate. The rates of recurrent diverticulitis and sigmoid resection were the same between groups, with a higher but not significant number of patients in the observational group seeking elective sigmoid resection. This study was chosen because it has a large sample size and had the longest follow-up period for patient outcomes for recurrence and complications compared to other studies that were reviewed. This provides the benefit of being able to base clinical decision making on multiple-year trials compared to 6-month or shorter follow up.

The strength of recommendation is A using the SORT criteria, based on multiple randomized controlled trials with consistent findings.

Critical Appraisal

The DIABOLO trial enrolled patients from 22 different Dutch hospitals for a total of 528 patients in the study. The goals of this non-blinded randomized control trial were to identify the long-term outcomes of patients with acute uncomplicated diverticulitis. At the 24-month follow-up, there were 227 patients in the observation group and 241 in the antibiotic group with a follow-up rate of 86.6% for the observational group and 90.6% in the antibiotic group.

The primary endpoint studied in this trial was determining full-time recovery within follow-up period of 6 months, defined as eating a normal diet, pain under a 4 using the Visual Analogue Scale (VAS), no use of pain medication, and resuming regular activity levels. Secondary outcomes reported were patients who developed complicated diverticulitis which was identified as abscess, perforation, stricture, or fistula, requirements of surgical or non-surgical interventions, antibiotic side effects, and recurrence rates at 12 and 24 months.

The data showed similar number of individuals had a recurrence of acute diverticulitis with 15.4% in the observational group and 14.9% in the control group. Rates of complicated diverticulitis were similar with 4.8% for observational versus 3.3% control, with complications being defined as abscess, perforation, obstruction, or fistula, or diverticular bleed. Long-term surgical interventions between groups were also similar, with a higher but not statistically significant number of patients in the observational group (9.0%) versus the antibiotic group (5.0%) undergoing sigmoid resections (p = 0.085). Rates of emergent sigmoid resection were similar for the observational group (1.3%) and the antibiotic group (0.8%).

Treatment with antibiotics versus observation was not a risk factor for recurrent or complicated diverticulitis, with a calculated odds ratio of 1.18 (95% CI 0.69-2.02). Increased age (<50 years) was an independent risk factor for development of recurrent or complicated diverticulitis with a odds ratio of 1.86 (95% CI 1.05-3.32). A VAS score of greater than 8 was also discovered to be an independent risk factor for development of recurrent or complicated diverticulitis (OR 1.89; 95% CI 1.06-3.35). The development of diverticulitis under the age of 50 was an independent risk factor for increased risk of recurrent diverticulitis with an odds ratio of 1.80 (95% CI 1.05-3.11).

Limitations to interpretation of this data include the lack of provided patient demographics, which limits our understanding of the risk factors and biases in this data. These results weren’t stratified by age, which poses questions surrounding the co-morbidities and relative health of the groups which could impact the efficacy of treatment and relative risk of recurrence. While it was noted that age under 50 was an independent risk factor for development of recurrent diverticulitis, we don’t know how many individuals were included in this study were under the age of 50 or how their inclusion influenced the overall picture the data paints. This study was not double-blinded, which also decreases our confidence in the relative bias included in the conduction of this study and the subsequent data analysis.

Patients who were placed in the antibiotic group received hospital-level treatment for their diverticulitis versus the observational group, who were monitored from home. While the outcomes for these patients were relatively the same, the environments each of these patients were being treated for their diverticulitis varied significantly, creating unequal treatment of the groups. However, this may be a limitation of the study design since unnecessary hospital admissions and stays for patients in the observational group would be unnecessary and pose potential risks for the patients like hospital-acquired infections and decreased activity levels. There were no funding biases and no publication biases noted for this study.

As a well-designed non-blinded randomized control trial, this study is level 2 evidence based on the SORT criteria. These outcomes align with previous studies outcomes discussed above in our description of related literature, providing further evidence to a growing body of knowledge surrounding treatment of acute uncomplicated diverticulitis. While further investigation with greater sample sizes and longer follow-up is warranted, the existing evidence paints a clear picture of the necessity of changing in clinical decision making for patients with acute uncomplicated diverticulitis.

Clinical Application

We met with Mrs. Lee and her sister to discuss the management of her diverticulitis and what we could do to better support her as she managed her loved one’s care from her hospital bed. We discussed that there was a growing body of literature indicating that treatment did not have to include IV antibiotics. We discussed how these studies had not been conducted in the US, and that the variables that contribute to the development and recovery from diverticulitis varies from patient to patient. In van Diejk et al. there was a non-significant increase in re-hospitalization in the observational group versus the antibiotic group. However, these groups had similar outcomes over time, and the growing body of literature suggested that observation alone was enough to treat acute diverticulitis, which we communicated to Mrs. Lee.

Ultimately, Mrs. Lee opted to continue with antibiotic treatment for acute diverticulitis. She worried if she was to come back, she would truly have no one to take care of her mother, as her mother once also had diverticulitis and had been told “antibiotics were the best way to treat any infection.” We emphasized how she needed to take care of herself while she is taking care of someone else and offered her resources for other home health care for her mother for extra support once she was discharged.

New Knowledge Related to Clinical Decision Science

As physicians, we are good at taking care of others, often before we take care of ourselves. However, when we are faced with a patient who is grappling with the same struggles, it feels easier to counsel them to put themselves first when we understand the reality of how difficult that choice is. Mrs. Lee was challenged by attempting to coordinate her hospital stay with her own mother’s care and this is not an uncommon issue; family caregiving will be a challenge we will continue to face as the geriatric population in the US continues to expand. We must focus on our ability to care for patients like Mrs. Lee while keeping the sociocultural factors in mind that may make it hard for patients to be fully present for their care.

The treatment of patients with diverticulitis also challenges the values of the American healthcare system. Antibiotic prescription has often been used as a “treatment” for everything from viral colds to idiopathic conditions. Mrs. Lee’s statement about ultimately choosing antibiotics reflects these same thoughts and values that many people in the US, including physicians, share.

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The emerging data we have supporting conservative treatment of diverticulitis poses a question for the status quo: are we capable of doing nothing for our patients, if that is what the data tells us is best for them? It is often easier to do something for our patients than provide them with the emotional support and reassurance that supportive treatment is enough. Shifting our attitudes in American medicine from the need for instant cures and gratification, to an attitude of patience and support, is one that would benefit our patients greatly.

Lastly, for our elderly patients, we must think about the dangers of poly-pharmacy and antibiotic resistance. Reducing unnecessary antibiotic prescriptions will decrease both antibiotic-related side-effects along with increasing antibiotic resistance at the micro, meso, and macro level. We provided Mrs. Lee with her options for treatment of her diverticulitis and gave her the opportunity to participate in her healthcare. Giving patients what they need to make the best decisions that align with their values and needs is a priority as we move toward patient-centered care.

The clinical decisions related to in-patient care frequently involve disruption of caregiving responsibilities. Because there are frequent opportunities to see patients for routine health maintenance and because decisions during future hospitalizations are affected by caregiving responsibilities, an opportunity arises to add inquiries about such responsibilities to routine health maintenance visits. Simple descriptive data about the frequency of such ongoing responsibilities and their potential impact on hospital care would be both informative and help direct anticipatory guidance and care planning—a significant burden for society as pointed out by this Clinical Decision Report. Thus, “preventative services” become asking about this type of social setting.

Conflict Of Interest Statement
The authors declare no conflicts of interest.

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