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Original Article

Kathryn Kennedy, MD, Jennifer Gaertner-Otto*, DO and Eav Lim, DO, FACOOG

Reduction in deep organ-space infection in gynecologic oncology surgery with use of oral antibiotic bowel preparation: a retrospective cohort analysis

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Abstract

Context: Deep organ-space infection (OSI) following gynecologic surgery is a source of patient morbidity and mortality. There is currently conflicting evidence regarding the use of bowel preparation prior to gynecologic surgery to reduce the rates of infection. For the additional purpose of improving patient recovery at our own institution, a retrospective cohort study compared the rate of deep OSI in patients who received oral antibiotic bowel preparation per Nichols–Condon bowel preparation with metronidazole and neomycin.

Objectives: The primary aim of this study was to compare the rate of deep organ-space surgical site infection in gynecologic surgery before and after institution of an oral antibiotic bowel preparation, thus assessing whether the preparation is associated with decreased infection rate. The secondary objective was to identify other factors associated with deep organ-space site infection.

Methods: A retrospective cohort study was performed. Demographic and surgical data were collected via chart review of 1,017 intra-abdominal surgeries performed by gynecologic oncologists at a single institution from April 1, 2019 to December 1, 2021. Of these, 778 met the inclusion criteria; 444 did not receive preoperative oral antibiotic bowel preparation, and 334 did receive preoperative bowel preparation. Odds ratios (ORs) were calculated, and a logistic regression model was utilized for categorical variables. Multivariable regression analysis was performed.

Results: A total of 778 patients were included. Deep OSI rate in patients who did not receive oral antibiotic bowel preparation was 2.3 % compared to 0.3 % (OR 0.13, confidence interval [CI] 0.06–1.03, p=0.02) in patients who did. Receiving oral antibiotic bowel preparation predicted absence of deep OSI (OR 0.04, CI 0.00–0.87, p=0.04). Laparotomy (OR 20.1, CI 1.6–250.2, p=0.02) and Asian race (OR 60.8, CI 2.6–1,380.5, p=0.01) were related to increased rates of deep OSI.

Conclusions: Oral antibiotic bowel preparation predicts a reduced risk of deep OSI. This preparation is inexpensive and low-risk, and thus these clinically significant results support a promising regimen to improve surgical outcomes, and provide guidance for prospective larger studies.

Keywords: antibiotics; bowel preparation; deep organ-space infection; gynecologic surgery

Deep organ-space infection (OSI) is a major source of patient morbidity and mortality following gynecologic surgery. The National Healthcare Safety Network of the Centers for Disease Control and Prevention (NHSN/CDC) divides it into superficial incisional, deep incisional, or deep OSI, with deep OSI carrying the greatest clinical consequences. These include a high likelihood of readmission and intervention, reduced quality of life, and increased healthcare costs including from prolonged hospitalization, antibiotic course, or drain placements [1]. In addition, readmission for deep OSI within 30 days is reportable and can affect a hospital's Centers for Medicare & Medicaid Services (CMS) star rating, which can affect reimbursements. Due to these implications, this study focused on deep OSIs. Entry into the bowel is a known risk factor for deep OSI, and in gynecologic oncology, 20–50 % of patients undergoing cytoreductive surgery will require bowel resection [2–4]. Surgeons as early as the 19th century recommended mechanical bowel preparations to reduce risks of infection in bowel surgery; however, mechanical preparations decrease stool burden without affecting the high stool bacterial concentration [5–8]. Oral antibiotic bowel preparation was first proposed in 1971, and

***Corresponding author: Jennifer Gaertner-Otto**, DO, Division of Gynecologic Oncology, WellSpan York Hospital, 1001 S. George Street, York, PA 17402, USA, E-mail: jgaertner-otto@wellspan.org. https://orcid.org/0009-0004-0589-2164

Kathryn Kennedy, MD **and Eav Lim,** DO, FACOOG, Division of Gynecologic Oncology, WellSpan York Hospital, York, PA, USA

since then, the use of oral antibiotic bowel preparation has been shown to decrease deep OSI rates in colorectal surgery by nearly 60 % [9–11]. Avoiding mechanical bowel preparation also improves patient satisfaction, reduces preoperative dehydration and electrolyte imbalances, and decreases the risk of postoperative ileus [12, 13].

In gynecologic oncology surgery, existing evidence on bowel preparation is conflicting. A database analysis of 224,687 hysterectomy patients failed to show that any type of bowel preparation protects against all deep OSI. However, among these patients, only 3.2 % had bowel resection, and 2.9 % had oral antibiotic bowel preparation alone [14]. This does not reflect the overall gynecologic oncology population or provide guidance regarding oral antibiotic bowel preparation specifically. Single-institution experiences with oral antibiotic bowel preparations do suggest a benefit. At Memorial Sloan Kettering, the infection rate for any type of deep OSI for gynecologic oncology patients undergoing colon resection decreased from 37 to 12 % ($p \leq 0.001$) with the use of a perioperative bundle that included preoperative oral antibiotics with optional mechanical bowel preparation [15]. At Johns Hopkins, an initiative that included preoperative oral antibiotics in conjunction with mechanical bowel preparation before ovarian debulking surgery resulted in a reduction in all types of deep OSI from 33 to 7 % ($p<0.001$), specifically for patients undergoing bowel resection, and from 20 to 30 % in the group overall ($p<0.001$) [16]. Other institutions have had similar findings; however, these interventions were implemented simultaneously with Enhanced Recovery After Surgery (ERAS) protocols and similar bundles, so the impact of oral antibiotic bowel preparation alone has not been definitively shown [17].

Our institution implemented ERAS protocols in 2017 (Table 1), but the deep OSI rate remained higher than expected based on NHSN/CDC guidelines. This drastically affected our hospital's CMS rating along with a decrease in patient satisfaction with care, outcome, and reimbursement. Therefore, as a quality and patient improvement practice, the division of gynecologic oncology was tasked to evaluate and improve our perioperative care for the major gynecologic oncology surgeries. The gynecologic oncology division instituted antibiotic bowel preparation prior to intra-abdominal surgery on August 1, 2020, with the prescription of 1 g of neomycin and 500 mg of metronidazole taken at 2, 3, and 9 pm the day before surgery. The specific bowel regimen is based on the Nichols–Condon bowel preparation, a well-studied and established preparation in colorectal surgery [18]. Metronidazole has been shown to have improved tolerability, excellent anaerobic coverage, and proven clinical efficacy, and was therefore selected over the authors' original erythromycin base [9, 19, 20]. If a patient were to report a history of allergy to one or both medications, that drug or the complete preparation would have been omitted, although this issue did not arise in the time frame of the study. Following ERAS protocol, patients preoperatively received 2 g or 3 g cefotetan based on body mass index (BMI), and the surgical site was prepped with ChloraPrep (2 % chlorhexidine gluconate in 70 % isopropyl alcohol), and/or vaginal prep with povidone iodine solution unless patient allergies dictated otherwise. Patients were draped in normal sterile fashion, and no Ioban was utilized.

Table 1: The enhanced recovery after surgery (ERAS) protocol.

Day before surgery[a]
– Clear liquid diet until midnight day before surgery
– Twenty-ounce Gatorade to be consumed and completed 2 hours prior to scheduled surgery
PACU
– Tylenol 975 mg PO x1 dose
– Cefotetan 2 g IV (3 g for higher BMI patients)
– Body wipes
– Nasal wipes
– Heparin 5,000 subcutaneous
Intraoperative
– Volume monitoring for euvolemia
– Temperature monitoring for normothermia
– TAP block (physician preference)
Postoperative
– Sequential compression stockings
– Lovenox 40 mg subcutaneous injection 24 h post-surgery
– Early ambulation encouraged
– Clear liquid diet
– Discontinue IV fluids when tolerating oral fluid intake
– Discontinuation of Foley catheter
– Gum chewing encouraged
– Toradol 15 mg every 6 h for 5 days
– Tylenol and oral motrin
– Gabapentin 300 mg at bedtime (qHS)
– Magnesium oxide

[a]On the day before surgery, in addition to adhering to ERAS protocol, patients received Neomycin and Flagyl at 2, 3, and 9 pm. BMI, body mass index; ERAS, enhanced recovery after surgery; IV, intravenous; PACU, postanesthesia care unit; TAP, transverse abdominis plane.

The primary objective of this study was to compare the rate of deep OSI in patients who received oral antibiotic bowel preparation with the rate in those who did not. We hypothesized that the use of oral antibiotic bowel preparation would be associated with reduced rates of infection.

Methods

A retrospective cohort study was performed via chart review. The protocol was reviewed by the WellSpan Institutional Review Board (IRB) and met the criteria for exemption because it involved only information collection and

analysis involving the authors' use of identifiable health information (exemption category 45 CFR 46.104(d)). The study was approved for waiver of consent. It was registered with ClinicalTrials.gov under Identifier NCT05210556.

The electronic medical record was reviewed from April 1, 2019 to December 1, 2021. The review was completed in January 2022 via direct examination of the surgical schedule and operative reports by the research team. The patients who underwent scheduled intra-abdominal surgery with a gynecologic oncologist were identified. Patients aged 18 years and older were included, and patients who underwent unplanned urgent or emergent surgery were excluded. The patient's chart was reviewed for demographic data including age, race, and BMI. Patient comorbidities, type of surgery, and presence or absence of malignancy on final pathology were recorded by research team members as they were observed in the medical record. Race, as reported by the patient upon intake into the health system, was recorded as it was documented in the electronic medical record. It was pertinent to include race in this study given that racial disparities in the surgical and overall outcomes for gynecologic cancer patients have been reported [18, 21].

If patients received a prescription for the full regimen of neomycin and metronidazole, and there was no documentation regarding failure to administer or acquire the antibiotic, they were noted to have received oral antibiotic bowel preparation. Patients were asked and verbally acknowledged taking the oral antibiotic bowel preparation on the morning of the procedure. Patients with OSI were identified based on the NHSN/CDC definition of deep OSI: infection occurring within 30 days of the procedure, and infection involving any part of the body deeper than the fascia [1]. Evidence of infection could include the following: purulent drainage from a drain that is placed into the organ/space, organisms identified on culture or microbiological testing from aseptically obtained fluid or tissue in the organ-space, an abscess or other evidence of infection involving the organ/space on gross anatomical or histopathologic examination, or imaging consistent with infection [1]. Data entry was performed by the authors and verified by the principal investigator (E.L.).

Sample size determination was made based on the primary outcome of rate of deep OSI. The institutional predicted rate of infection at the time that the study was conducted was 2.5 % [22]. Based on existing literature, a decrease of up to 50–60 % could be anticipated, to a rate of 1–1.25 %. Thus, the study was designed to detect a decrease to 1.12 %. At a power of 80 % and alpha=0.05, 773 cases were needed. The time selected allowed for approximately equivalent numbers of patients before and after institution of the standard oral antibiotic bowel preparation. The duration of time pre- and post-institution of the bowel prep are approximately equivalent, and an adequate number of cases were assessed to satisfy the power as above. However, the number of cases did decrease slightly in the latter portion of the study during the COVID-19 pandemic.

The observed frequency of deep OSI for patients who did and did not receive oral antibiotic bowel preparation was computed. Patient characteristics were analyzed for both groups utilizing *t* tests and chi-square tests. The association between these factors with the presence of OSI was then tested utilizing *t* tests and chi-square tests. Logistic regression was performed to identify categorical variables that were predictors of deep OSI. Multivariable logistic regression was then performed to compare the effects of utilizing an oral antibiotic bowel preparation compared to the other risk factors for OSI identified. STATA SE 17.0 and SPSS 25 software were utilized.

Results

There were 1,017 surgical cases, including minimally invasive surgeries and laparotomies, performed by this institution's fellowship-trained gynecologic oncologists between April 1, 2019 and December 1, 2021. Among these, 778 cases met the criteria of scheduled intra-abdominal surgery and were included. A total of 444 patients did not receive a preoperative oral antibiotic bowel preparation, while 334 patients did receive preoperative antibiotic bowel preparation. There were no patients who underwent surgery after August 1, 2020 who were ineligible for the oral antibiotic bowel preparation due to a documented allergy (Figure 1). Demographic and surgical data were compared between the two groups (Table 2).

Among the demographic and surgical characteristics, only the length of surgery differed significantly, with the average surgical time for those not receiving a bowel preparation significantly longer at 157.3 (±85.7) minutes than those who did receive a bowel preparation at 133.9 (±70.7) minutes ($p<0.001$). The full list of patient characteristics and demographics for those who experience deep organ-space pelvic infection are outlined in Table 3.

For the primary outcome of deep OSI rate, only 1 patient (0.3 %) who received antibiotic bowel preparation developed an infection, compared with 10 patients (2.3 %) who did not receive antibiotic bowel preparation (OR 0.13, CI 0.06–1.03, $p=0.02$). Several additional factors were demonstrated to be associated with deep OSI (Table 4).

In the initial analysis, factors associated with a greater risk of OSI included Black or Asian race ($p=0.04$), longer surgical time ($p=0.003$), higher estimated blood loss ($p=0.027$), laparotomy rather than a minimally invasive approach ($p<0.001$), and entry into the gastrointestinal (GI) tract ($p<0.001$). Factors for

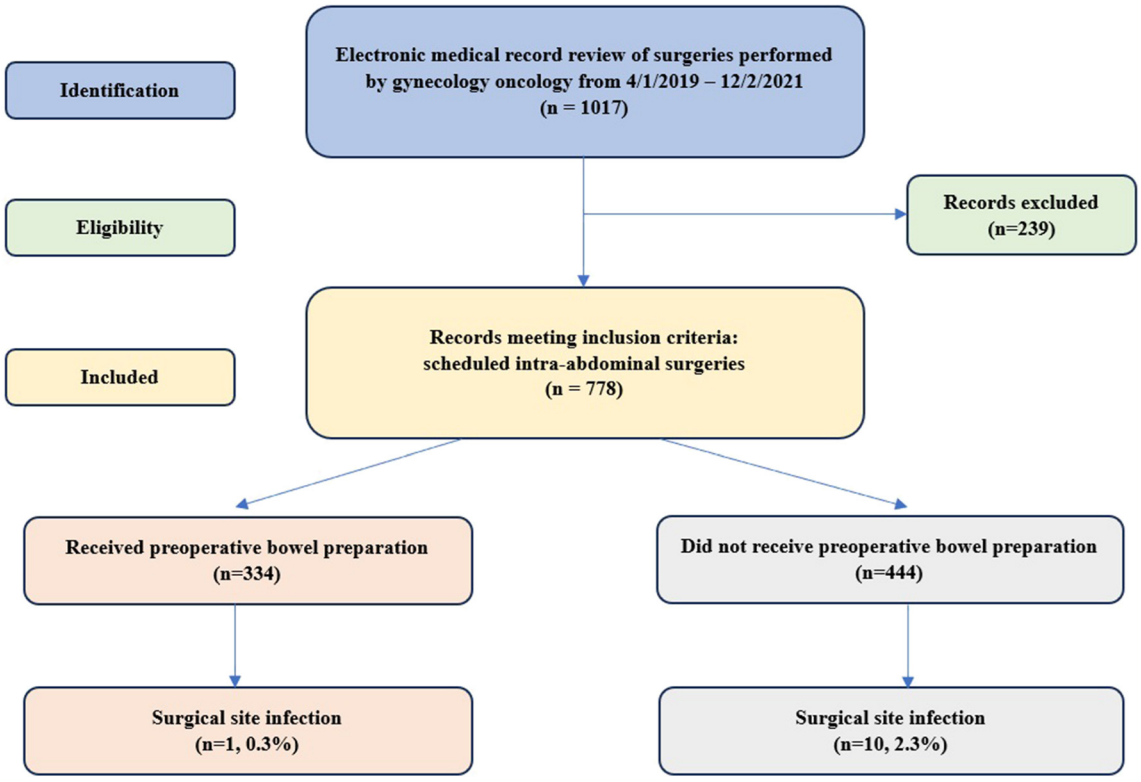

Figure 1: Flow diagram of patient identification, eligibility criteria review, and inclusion or exclusion from the study.

which no association was identified included age (p=0.18), BMI (p=0.55), ethnicity (p=0.46), smoking (p=0.86), diabetes (p=0.06), malignant pathology (p=0.07), and receipt of blood transfusion (p=0.4). Multivariable regression analysis was then performed to properly compare the effects of utilizing an oral antibiotic bowel preparation compared to the other risk factors for SSI identified (Table 3). This allowed for accurate determination of the effect size of the oral antibiotic bowel preparation. Receiving an oral antibiotic bowel preparation was suggestive of an absence of OSI with an OR 0.04 (CI 0.00–0.87, p=0.04). In contrast, surgery via laparotomy (OR 20.1, CI 1.6–250.2, p=0.02) and Asian race (OR 60.8, CI 2.6–1,380.5, p=0.01) were both indicative of increased occurrence of deep OSI. Length of surgery, estimated blood loss, and GI tract entry were not related to OSI on multivariable analysis.

Discussion

Summary of main results

This study demonstrates that the use of this oral antibiotic bowel preparation in gynecologic oncology surgeries is indicative of reduced deep OSI rate on multivariable regression analysis. Factors that increased the risk for deep OSI included Asian race and laparotomy approach. However, due to the low number of Asian patients included in this analysis, it would be prudent to view the statistical significance with caution, and specifics cannot be generalized without increasing the number of Asian patients included in future studies.

Results in the context of published literature

This was a unique opportunity to investigate the impact of oral antibiotic bowel preparation given that there were no further changes to institutional policies, surgeons, or ERAS bundles since implementation. The previously mentioned large database study and single institution reports were unable to pinpoint the effects of oral antibiotic bowel preparation on deep OSI specifically, as other interventions were bundled simultaneously. This single-institution study therefore provides more granular information on the use of oral antibiotic bowel preparation and confirms the potential of this regimen to reduce deep OSI.

It is worth noting that certain factors historically noted to be associated with OSI were not found to be significant: high BMI, smoking, diabetes on initial analysis, length of surgery, estimated blood loss, and GI tract entry on multivariable analysis. This result is quite interesting and could be due to

Table 2: Patient demographic, clinical, and surgical characteristics by group.

		Bowel preparation				
		No bowel prep (n=444)		Received bowel prep (n=334)		
		Mean age: 58.4 ± 14.7 years		Mean age: 57.9 ± 14.2 years		
		Mean BMI: 33.6 ± 9.5 kg/m^2		Mean BMI: 32.7 ± 9.1 kg/m^2		
		Count	%	Count	%	p-Value
Race	White	421	94.8 %	304	91.0 %	0.091
	Black	20	4.5 %	24	7.2 %	
	Asian	3	0.7 %	6	1.8 %	
Ethnicity	Non-Hispanic	421	94.8 %	322	96.4 %	0.290
	Hispanic	23	5.2 %	12	3.6 %	
Deep pelvic infection	No infection	434	97.7 %	333	99.7 %	0.022
	Infection	10	2.3 %	1	0.3 %	
Type of surgery	MIS	311	70.0 %	245	73.4 %	0.312
	Laparotomy	133	30.0 %	89	26.6 %	
Transfusion	No	421	94.8 %	323	96.7 %	0.203
	Yes	23	5.2 %	11	3.3 %	
GI tract entry	No	346	77.9 %	275	82.3 %	0.129
	Yes	98	22.1 %	59	17.7 %	
Current smoker	No	399	89.9 %	296	88.6 %	0.579
	Yes	45	10.1 %	38	11.4 %	
Diabetic	No	343	77.3 %	255	76.3 %	0.767
	Yes	101	22.7 %	79	23.7 %	
GYN malignancy on final pathology	Benign	234	52.7 %	188	56.3 %	0.321
	Malignant	210	47.3 %	146	43.7 %	

GYN, gynecology; MIS, minimally invasive surgery.

several explanations. For instance, our minimally invasive approach was 72.4 % for the entire cohort. It is known that minimally invasive surgery has improved outcomes in terms of postoperative recovery [23]. Further, there is a possibility that improvements in perioperative care including ERAS protocol, tight glycemic control, normothermia, adherence to sterile technique, and antibiotic use minimized these traditionally seen differences for this patient sample. However univariate analysis showed no significant association between diabetes, blood loss, and smoking on deep OSI, and although the study was not powered to determine an association, it can be assumed that a larger study with greater numbers of patients would reveal consistency with these previously established associations, which was not the goal of this research.

Strengths and weaknesses

The study was substantiated by including patients from both groups within the same institution, and all patients underwent the same ERAS protocol (Table 1). No major changes in surgical technique occurred over the duration of the study period. The same surgeons operated on patients both before and after August 1, 2020 when the oral antibiotic bowel preparations were standardized. The study was further strengthened by the accessibility of metronidazole and neomycin, which are low-risk and inexpensive antibiotics, allowing this regimen to be highly generalizable. The oral antibiotic bowel preparation utilized in this study held both statistically and clinically meaningful results that impacted both individual patients in terms of individual morbidity, and overall health system by decreasing the NHSN/CDC reportable rates of infection. Metronidazole and neomycin are inexpensive in comparison to hospitalization for a deep OSI: $12.21 for the medications vs. an average of $60,000 in this hospital system at the time of the study [24]. These antibiotics are also safe, with the literature only having case reports of hypersensitivity reactions to oral administration of either one [25–27]. Therefore, the authors [21] recommended adding this oral antibiotic regimen as part of the armamentarium

Table 3: Patient characteristics with deep organ-space pelvic infection.

Patient	1	2	3	4	5	6	7	8	9	10	11		
Received bowel prep?	No	No	No	No	No	No	No	No	No	No	Yes	Mean	Mean (no bowel prep)
Age, mean	79	66	64	58	66	84	59	47	48	65	67	64	64
BMI, kg/m^2	29.96	37.1	25.3	32.9	34.6	30.8	33.4	42.3	23.8	28.5	28.5	32	32
Race													
White	x	x	x	x	x	x	x		x	x		82 %	90 %
Black								x				9 %	10 %
Asian											x	9 %	0 %
Ethnicity													
Non-Hispanic	x	x	x	x	x	x	x	x	x	x	x	100 %	100 %
Hispanic												0 %	0 %
Smoking status													
Smoker									x			9 %	10 %
Nonsmoker	x	x	x	x	x	x	x	x		x	x	91 %	90 %
Diabetes status													
Diabetics												0 %	0 %
Nondiabetics	x	x	x	x	x	x	x	x	x	x	x	100 %	100 %
Cancer on final pathology													
Gynecologic malignancy	x	x	x	x		x	x			x	x	73 %	70 %
Benign					x			x	x			27 %	30 %
Type of surgery													
[a]Minimally invasive								x				9 %	10 %
Laparotomy	x	x	x	x	x	x	x		x	x	x	91 %	90 %
Length of surgery, minutes	67	198	70	202	112	421	450	294	245	165	190	219	222
Estimated blood loss, ml	40	350	150	150	130	500	1,200	500	250	650	200	375	392
Intraoperative blood transfusion	No	No	No	No	No	No	No	No	Yes	No	No	9 %	10 %
GI tract entry	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	73 %	70 %

[a]Minimally invasive includes robotic-assisted, laparoscopic, and transvaginal hysterectomy/surgery. BMI, body mass index; GI, gastrointestinal.

Table 4: Patient demographic, clinical, and surgical factors associated with organ-space infection.

Patient factors	No infection (n=767)	Organ-space infection (n=11)	p-Value
White	716 (93.4 %)	9 (81.8 %)	0.04
Black	43 (5.6 %)	1 (9.01 %)	
Asian	8 (1.0 %)	1 (9.01 %)	
Received oral antibiotic bowel prep	333 (43.4 %)	1 (9.1 %)	0.022
Did not receive oral antibiotic bowel prep	434 (56.6 %)	10 (90.9 %)	
Laparotomy	212 (27.6 %)	10 (90.9 %)	<0.001
MIS (laparoscopic, robotic)	555 (72.4 %)	1 (9.1 %)	
Length of surgery, mean, SD	146.2 (79.2) min	219.5 (127.2) min	0.003
Estimated blood loss, mean, SD	154.8 (325.6) mL	374.6 (332.8) mL	0.027
GI tract entry	618 (80.6 %)	3 (27.3 %)	<0.001
No GI tract entry	149 (19.4 %)	8 (72.7 %)	

GI, gastrointestinal; MIS, minimally invasive surgery; SD, standard devation.

to reduce deep OSIs. In the future, a multi-institution randomized controlled trial would be beneficial to remove the limitations of this study's retrospective and single-institution approach. A thorough cost analysis would also be indicated.

Potential confounders to the study are innate to that of a retrospective study. Certain information of interest was not previously documented. For instance, adverse effects of oral antibiotic bowel preparation were not consistently noted, and no scoring system for the severity of any adverse effects was instituted. There were several patient reports of mild nausea and mild diarrhea after oral antibiotic administration, but more detailed information was not gathered. Similarly, while verbal compliance with bowel

preparation was confirmed the morning of surgery, there is always the possibility that compliance was not perfect, and there was no verification via chemical or lab testing. If the patient experienced emesis after bowel preparation, they were documented as not receiving the antibiotic bowel prep. One additional confounder between the two arms is that of surgical time (Table 4); the group that did not receive antibiotic bowel preparation had a significantly longer mean surgical time (157.3 ± 85.7 min) than the group receiving antibiotic bowel preparation (133.9 ± 70.7 min, $p<0.001$). Although other characteristics between groups were well-balanced, this could have affected the rate of deep OSI for the group of patients who did not receive antibiotic bowel preparation.

Implications for practice and future research

Instituting an oral antibiotic bowel preparation before major gynecologic oncology surgery with neomycin and metronidazole demonstrated a statistically significant reduction in deep OSIs. The results suggest an inexpensive and feasible regimen that may definitively improve surgical outcomes in future, prospective, larger studies.

Conclusions

These results support utilizing an inexpensive, low-risk oral antibiotic bowel preparation regimen to improve surgical outcomes and to reduce the risk of deep OSI, and these results provide a basis for pursuing larger-scale prospective studies.

Research ethics: The protocol was reviewed by the WellSpan Institutional Review Board and met criteria for exemption as it involved only information collection and analysis involving the authors' use of identifiable health information (exemption category 45 CFR 46.104(d)). The study was approved for waiver of consent. It was registered with ClinicalTrials.gov under Identifier NCT05210556.

Informed consent: The study was approved for waiver of consent. It was registered with ClinicalTrials.gov under Identifier NCT05210556.

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Conflict of interest: None declared.

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Data availability: Data sharing was performed via deidentified demographic and surgical data is shared on Mendeley Data, V1, DOI: 10.17632/zm3sb7s3by.1. Data was published June 14, 2022, and will be available in perpetuity to the public online via search of the DOI above for review and research purposes.

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