

Effect of oral antibiotic bowel preparation versus no preparation on surgical site infections in elective colorectal surgery: a randomized trial

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Purpose: Surgical site infections (SSIs) represent a significant cause of morbidity following colorectal surgery. While mechanical bowel preparation combined with oral antibiotics is known to reduce SSIs, the independent effect of oral antibiotics alone remains unclear. This study compared the efficacy of oral antibiotic bowel preparation (OABP) versus no bowel preparation (NBP) in reducing SSIs among patients undergoing elective colorectal surgery.

Methods: A prospective, randomized, double-blinded trial was performed at a tertiary care center in India. Eighty-six patients scheduled for elective colorectal surgery were randomized to receive either OABP (oral ciprofloxacin and metronidazole) or placebo, in addition to standard intravenous antibiotics. The primary outcome was the rate of SSIs. Secondary outcomes included anastomotic leak, length of hospital stay, overall morbidity, and readmission rates.

Results: Baseline characteristics were comparable between the groups. The incidence of SSI was significantly lower in the OABP group compared to the NBP group (14.0% vs. 41.9%, $P < 0.01$). The severity of infections and postoperative complications was also reduced in the OABP group ($P < 0.01$). Although rates of anastomotic leak, readmission, and reoperation were higher in the NBP group, these differences were not statistically significant. The mean duration of hospital stay was shorter for patients in the OABP group (8.09 days vs. 11.28 days, $P < 0.01$). No adverse effects related to oral antibiotics were observed.

Conclusion: OABP without mechanical cleansing significantly reduces SSIs, postoperative morbidity, and length of hospital stay in elective colorectal surgery. This approach is safe and effective, offering a strategy to improve surgical outcomes.

Keywords: Bowel preparation methods; Surgical wound infection; Preoperative care; Colorectal surgery

INTRODUCTION

Surgical site infections (SSIs) account for approximately 30% of all hospital-acquired infections and contribute to 5% of morbidity

among surgical patients. Reducing the incidence of SSIs not only decreases morbidity but can also reduce treatment costs by as much as 4-fold [1]. Colorectal operations are classified as clean-contaminated procedures, and the combination of a con-

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taminated surgical field with frequently poor nutritional status in patients increases the risk of wound infection. In open colorectal surgery, SSI incidence can range from 2% to 25% [2].

Various strategies have been employed to decrease SSIs in colorectal surgery, including mechanical bowel preparation (MBP) and antimicrobial prophylaxis. Despite these measures, SSI rates remain elevated. Recent prospective analyses suggest that combining oral antibiotics with intravenous prophylaxis may further lower SSI rates [3]. However, most available evidence is derived from studies where MBP was administered alongside oral antibiotics, and mechanical preparation can sometimes cause dehydration or electrolyte disturbances [4, 5].

Several randomized controlled trials have demonstrated the benefit of using oral antibiotic bowel preparation (OABP) together with MBP for reducing SSIs [6, 7]. However, no studies have evaluated the effect of oral antibiotic preparation alone, without concomitant mechanical preparation. This study aimed to compare SSI rates in patients undergoing elective colorectal surgery who received OABP versus those who received no bowel preparation (NBP).

METHODS

Ethics statement

This study was approved by the Institutional Review Board of Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER; No. IEC/2020/058). Written informed consent was obtained from all participants prior to enrollment, with full freedom granted to withdraw from the study at any time. All procedures were conducted in accordance with the Declaration of Helsinki, and the CONSORT (Consolidated Standards of Reporting Trials) guidelines were followed for reporting.

Study design and patient selection

This study was a prospective, randomized, double-blinded trial conducted in the Department of Surgical Sciences at JIPMER, a tertiary care facility in Southern India. We included all consecutive patients over the age of 18 who underwent elective colorectal surgery during the study period. Patients were excluded if they had already received MBP at the time of screening, had any allergies to the drugs used in the oral antibiotic regimen, or had undergone concomitant surgical procedures. Patients were also excluded if MBP had been administered prior to enrollment. No patients were withheld standard care as part of the study design. Additionally, we excluded patients with severe obesity (body mass index $> 35 \text{ kg/m}^2$), significant preoperative impairment in renal function (defined as a glomerular filtration rate $< 30 \text{ mL/min/1.73}$

m^2), and those who had already undergone an emergency diversion procedure planned for definitive surgery following neoadjuvant therapy.

Randomization and blinding

All eligible patients were randomly assigned in a 1:1 ratio to either the intervention (OABP) group or the control (NBP) group. Randomization was performed 1 day before surgery using computer-generated random numbers. Allocation concealment was ensured through the use of the sealed numbered opaque sealed envelope technique. The sealed envelopes were prepared by a person independent of the investigators, and neither the sequence of randomization nor the contents of the envelopes were disclosed to the investigators. Both patients and investigators were blinded to group allocation. The sealed envelopes containing either drugs or placebos were administered to patients by the duty nurse, and the sequence and contents remained concealed from investigators.

Study procedure

Patients in the OABP group received 2 doses of oral ciprofloxacin 500 mg, administered 12 hours apart, and 3 doses of oral metronidazole 400 mg, administered 8 hours apart, beginning 24 hours before surgery. The timing and administration were in accordance with instructions provided in a sealed envelope. In addition, all patients received 1 g of intravenous ceftriaxone 30 minutes prior to surgical incision. The choice of ciprofloxacin and metronidazole, while differing from regimens commonly used in Western practice, was based on local antimicrobial sensitivity patterns and drug availability. Similar protocols have been used in recent Asian studies, and ciprofloxacin provides effective gram-negative coverage relevant to the patient population studied.

Patients in the NBP group received placebo capsules (containing starch) instead of oral antibiotics, administered at the same intervals as the OABP group, along with the same intravenous ceftriaxone regimen 30 minutes prior to incision.

Outcomes

Data collection was performed using a standardized proforma. Preoperative data included age, sex, body mass index, comorbidities, American Society of Anesthesiologists (ASA) physical status, and preoperative albumin and hemoglobin levels. Intraoperative variables recorded were the type of surgery, creation of a stoma, and duration of the procedure.

The primary outcome was the incidence of SSIs in both the NBP and OABP groups. The diagnosis of SSIs was made according to the guidelines of the US Centers for Disease Control and Prevention (CDC) and confirmed by physical examination whenever fea-

sible [8]. Secondary outcomes included the rates of anastomotic leak, length of hospital stay, postoperative morbidity, and need for readmission or reoperation within 30 days postoperatively. Follow-up was conducted on postoperative day (POD) 10 and again by telephone contact on POD 30 to assess for any complications. On POD 30, patients were contacted by phone, and those reporting symptoms suggestive of infection were advised to return for in-person evaluation by a surgical resident or consultant.

Statistical analysis

No prior studies were available directly comparing OABP with NBP. The sample size was calculated based on a randomized controlled trial by Washington et al. [9], which included 2 equal groups with a dichotomous outcome. Using a significance level (α) of 5% and a power of 80%, and assuming an SSI rate of 35% in the control group and 8% in the intervention group, the required sample size was 39 participants per group. Accounting for an anticipated 20% dropout rate, the final adjusted sample size was 43 per group.

Categorical variables were reported as percentages and proportions, while continuous variables were expressed as mean or median depending on their distribution. The difference in categorical variables between NBP and OABP groups was assessed using the chi-square test and Fisher-Freeman-Halton exact test. The Kolmogorov-Smirnov test was used to assess normality of continuous

variables. The independent t-test was used for normally distributed variables, and the Mann-Whitney U-test for those not normally distributed. Differences in proportions were considered statistically significant when the P-value was ≤ 0.05 . All statistical analyses were performed using IBM SPSS ver. 19.0 (IBM Corp).

RESULTS

A total of 114 patients were scheduled for elective colonic resection. After the exclusion of 28 patients, 86 patients were randomly assigned to either the NBP group or the OABP group (Fig. 1). Table 1 presents the general demographic characteristics of the study population. The OABP group included 43 patients with a mean age of 53.98 ± 14.86 years, consisting of 25 men and 18 women. The NBP group also comprised 43 patients, with a mean age of 57.09 ± 14.10 years, including 30 men and 13 women. Other parameters, such as smoking history, preoperative hemoglobin and albumin levels, comorbidities, and ASA physical status, were comparable between the 2 groups.

Table 2 summarizes the colonic pathology and operative details. The pathological distribution was notably similar between the groups: benign cases were observed in 3 patients (7.0%), while malignant cases were observed in 40 patients (93.0%) in both cohorts. Right colon pathology was observed in 14 patients (32.6%) in the NBP group and 12 patients (27.9%) in the OABP group. The prev-

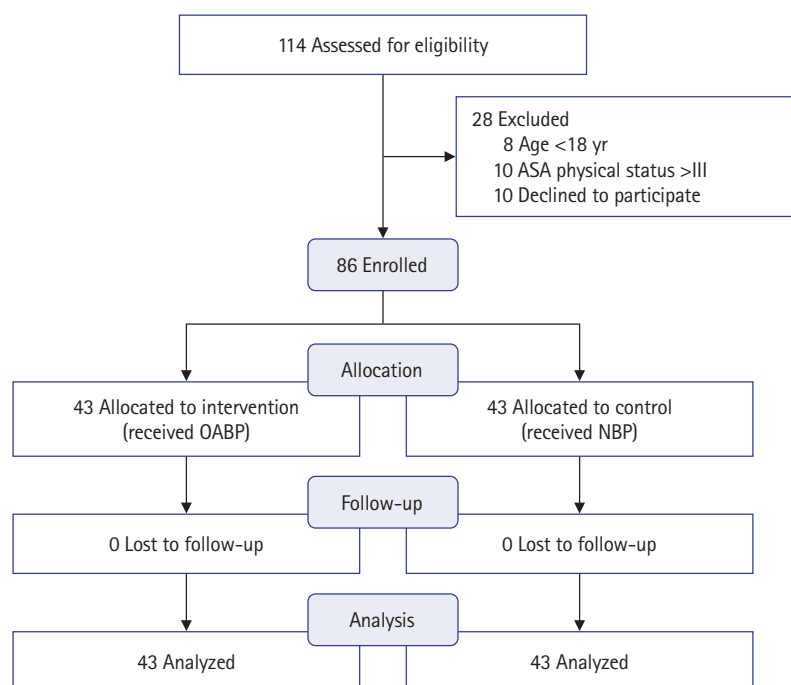


Fig. 1. CONSORT (Consolidated Standards of Reporting Trials) flowchart. ASA, American Society of Anesthesiologists; OABP, oral antibiotic bowel preparation; NBP, no bowel preparation.

Table 1. Baseline demographic characteristics (n = 86)

Characteristic	NBP group (n = 43)	OABP group (n = 43)	P-value
Age (yr)	57.09 ± 14.10	53.98 ± 14.86	0.81
Sex			0.26
Male	30 (69.8)	25 (58.1)	
Female	13 (30.2)	18 (41.9)	
Body mass index (kg/m ²)	22.09 ± 2.68	22.06 ± 3.04	0.91
Hemoglobin (mg/dL)	11.10 ± 2.65	10.10 ± 2.56	0.07
Albumin (g/dL)	3.82 ± 0.45	3.69 ± 0.47	0.17
Comorbidity			0.12
None	19 (44.2)	29 (67.4)	
HTN	6 (14.0)	6 (14.0)	
DM	7 (16.3)	2 (4.7)	
Both HTN and DM	5 (11.6)	5 (11.6)	
Coronary artery disease	2 (4.7)	0 (0)	
ASA physical status			0.09
I	26 (60.5)	32 (74.4)	
II	13 (30.2)	11 (25.6)	
III	4 (9.3)	0 (0)	
Smoking history	6 (14.0)	12 (27.9)	0.11

Values are presented as mean ± standard deviation or number (%).

NBP, no bowel preparation; OABP, oral antibiotic bowel preparation; HTN, hypertension; DM, diabetes mellitus; ASA, American Society of Anesthesiologists.

absence of left colonic pathology was 14.0% (6 patients) in the NBP group and 25.6% (11 patients) in the OABP group, while rectal pathology accounted for 23 patients (53.5%) and 20 patients (46.5%) in the NBP and OABP groups, respectively. The overall P-value for tumor location was 0.40, indicating no statistically significant difference. Regarding preoperative treatment, 13 patients (32.5%) in the NBP group and 11 patients (26.8%) in the OABP group received neoadjuvant chemoradiotherapy ($P = 0.57$). In terms of surgical approach, open surgery was performed in 33 patients (76.7%) in the NBP group and 32 patients (74.4%) in the OABP group, while laparoscopic procedures were undertaken in 10 (23.3%) and 11 (25.6%), respectively ($P = 0.82$). Intraoperative drain placement occurred in 32 patients (74.4%) in the NBP group and 36 patients (83.7%) in the OABP group ($P = 0.28$). Lastly, stomas were created in 24 patients (55.8%) in the NBP group and 23 patients (53.5%) in the OABP group ($P = 0.82$). Collectively, these findings demonstrate the comparable distribution of colonic pathology and surgical management between the groups.

Table 3 displays the postoperative outcomes. The incidence of SSIs was significantly higher in the NBP group, with 18 cases (41.9%), compared to 6 cases (14.0%) in the OABP group ($P < 0.01$). Analysis of infection depth revealed 13 superficial infections (30.2%), 4 deep infections (9.3%), and 1 organ space infection

Table 2. Colonic pathology and operative details (n = 86)

Parameter	NBP group (n = 43)	OABP group (n = 43)	P-value
Pathology			0.90
Benign	3 (7.0)	3 (7.0)	
Malignant	40 (93.0)	40 (93.0)	
Location			0.40
Right colon	14 (32.6)	12 (27.9)	
Left colon	6 (14.0)	11 (25.6)	
Rectum	23 (53.5)	20 (46.5)	
Preoperative NACTRT	13 (30.2)	11 (25.6)	0.57
Surgical approach			0.82
Open	33 (76.7)	32 (74.4)	
Laparoscopy	10 (23.3)	11 (25.6)	
Intraoperative drain placement	32 (74.4)	36 (83.7)	0.28
Stoma	24 (55.8)	23 (53.5)	0.82

Values are presented as number (%). Percentages may not total 100 due to rounding.

NBP, no bowel preparation; OABP, oral antibiotic bowel preparation; NACTRT, neoadjuvant chemoradiotherapy.

Table 3. Postoperative outcomes (n = 86)

Outcome	NBP group (n = 43)	OABP group (n = 43)	P-value
SSI	18 (41.9)	6 (14.0)	< 0.01
Depth of SSI			< 0.01
Superficial	13 (30.2)	5 (11.6)	
Deep	4 (9.3)	1 (2.3)	
Organ space	1 (2.3)	0 (0)	
Anastomotic leak	3 (7.0)	0 (0)	0.24
Readmission	7 (16.3)	1 (2.3)	0.24
Reoperation	3 (7.0)	0 (0)	0.24
Clavien-Dindo classification			< 0.01
Grade I	15 (34.9)	23 (53.5)	
Grade II	14 (32.6)	5 (11.6)	
Grade III	3 (7.0)	0 (0)	
Grade IV	2 (4.7)	0 (0)	
Length of hospital stay (day)	11.28 ± 2.15	8.09 ± 3.10	< 0.01

Values are presented as number (%) or mean ± standard deviation.

NBP, no bowel preparation; OABP, oral antibiotic bowel preparation; SSI, surgical site infection.

(2.4%) in the NBP group, whereas the OABP group had 5 superficial infections (11.6%) and 1 deep infection (2.3%). The difference in infection depth was also statistically significant ($P < 0.01$). Anastomotic leaks were infrequent, occurring in 3 patients (7.0%) in the NBP group and none in the OABP group ($P = 0.24$). Readmission rates were higher in the NBP group, with 7 patients (16.3%) requiring readmission compared to 1 patient (2.3%) in the OABP group; however, this difference was not statistically significant

($P=0.24$). In terms of reoperation, 3 patients (7.0%) in the NBP group required additional surgical procedures and none in the OABP group ($P=0.24$). Regarding the Clavien-Dindo classification, 15 patients (34.9%) in the NBP group had grade I complications and 14 (32.6%) had grade II complications. In contrast, the OABP group exhibited a significantly lower rate of complications, with 23 patients (53.5%) classified as grade I and 5 patients (11.6%) as grade II ($P<0.01$). The length of hospital stay was also significantly longer in the NBP group compared to the OABP group (11.28 days vs. 8.09 days, $P<0.01$).

DISCUSSION

SSIs remain a major concern in colorectal surgery. While advances in surgical techniques and bowel preparations have contributed to reducing SSI rates, this study specifically aimed to evaluate the effectiveness of oral antibiotics alone as a preoperative bowel preparation compared to no preparation. Most existing literature supports the use of combined mechanical preparation with oral antibiotics to reduce SSI, but studies examining oral antibiotics alone are limited, especially within India [10, 11]. Consequently, this is the first study in India to directly compare OABP and NBP groups. This study focused on patients who had not yet received MBP, and exclusion occurred before any bowel preparation was administered, thus avoiding ethical conflicts.

The mean age of patients in our study was 55 years, which is lower than the 67 years reported in similar studies [12, 13], likely due to our inclusion of both malignant and benign cases. The male to female ratio was 1.77, which is consistent with the higher incidence of colorectal diseases in men. Most patients were classified as ASA physical status I or II, indicating optimal preoperative fitness for surgery. The incidence of colorectal malignancies, particularly rectal cancer, is notably higher in the Asian population [14]. In our study, rectal disorders were the most common indication for surgery in both NBP and OABP groups. The high rate of rectal cancers in our cohort reflects the institutional profile as a tertiary referral center for advanced malignancies, particularly low rectal tumors. In a study conducted by Kobayashi et al. [12] in Japan, 50% of patients in both the NBP and OABP groups required surgery for rectal cancers. In contrast, a study from the West conducted by Morris et al. [13] found that only 26.4% of patients in the NBP group and 26.6% in the OABP group underwent rectal surgery. This highlights differences in the spectrum of colorectal malignancies observed across populations. The incidence of SSI is comparatively lower among patients undergoing laparoscopic surgery [15]. Nevertheless, only 23.3% of patients in the NBP group and 25.6% of patients in the OABP group underwent

laparoscopic procedures. The predominance of open surgery is attributable to evolving laparoscopic proficiency during the early phase of minimally invasive surgery implementation at our center. We acknowledge that our sample size estimation was based on an older study, which may not fully reflect current SSI rates. However, the observed reduction in SSIs from 41.9% to 14.0% in our study still demonstrates a statistically and clinically significant benefit of OABP.

Drain placement is associated with increased morbidity, leading to longer hospital stays and delayed early mobilization. In our study, the rate of drain placement was significantly higher than typically reported in the literature. Most of these patients had rectal cancer and underwent neoadjuvant chemoradiotherapy. This group is at higher risk of postoperative anastomotic leak or collections due to dissection in an irradiated rectum [16], which explains the increased incidence of drain placement and the relatively high rate of diversion stoma construction (54.6%) observed in our study.

The overall incidence of SSIs was 41.9% in the NBP group and 14.0% in the OABP group. The rate of SSI after colorectal surgery can vary significantly, ranging from 3% to 30% [17, 18]. In the Indian population, reported SSI rates range from 23% to 38%, whereas in Western populations, rates typically fall between 0.5% and 15% [19]. A study conducted in China by Anjum et al. [20] found that 27.3% of patients in the control group developed SSIs, compared to only 8.4% in the intervention group. In the study by Kobayashi et al. [12], 10.7% of the patients in the NBP group and 7% of the patients belonging to the OABP group developed SSIs. Similarly, Hata et al. [6] reported that 12.8% of patients in the NBP group and 3.4% in the OABP group developed SSI. In the study by Morris et al. [13], SSI incidence was 14.9% in the NBP group and 6.5% in the OABP group. These findings support our conclusion that OABP effectively reduces the incidence of deep-seated infections. Additionally, the rate of anastomotic leaks in our study was 3.4%. This is similar to the study by Anjum et al. [20] where 4.21% of patients in the NBP group and none in the intervention group developed anastomotic leak. Hata et al. [6] reported a leak rate of 2.1% in the NBP group and 1.7% in the OABP group, whereas Morris et al. [13] reported rates of 4.6% in the NBP group and 2.3% in the OABP group. The higher incidence of anastomotic leaks observed in our study can be attributed to the advanced stage of malignancy in patients who required neoadjuvant chemoradiotherapy, which increases the risk of postoperative leaks [21]. In the OABP group, the frequency of anastomotic leaks was lower than in the NBP group, further demonstrating the efficacy of oral antibiotic bowel preparation. Additionally, the NBP group experienced increased rates of readmis-

sion due to higher incidences of SSIs and anastomotic leaks. The development of SSI led to prolonged hospital stays for patients in the NBP group, as this necessitated extended antibiotic treatment and wound care.

The postoperative morbidity, as assessed by the Clavien-Dindo classification, was distributed as follows: in the NBP group, 34.9% of patients were classified as grade I, 32.6% as grade II, and 7.0% as grade III. In the OABP group, 53.5% were grade I, 11.6% grade II, and none grade III. This distribution is consistent with a retrospective study by Wang et al. [22], in which 74.4% of patients were classified as grade 0 (no postoperative complication) and 25.3% as grade II. In the present study, mild adverse reactions to oral antibiotics were observed in 2% of patients. Although Wren et al. [23] reported an increased incidence of *Clostridium difficile* infections with oral non-absorbable antibiotics, none of the patients in this study experienced diarrhea.

This investigation represents the first double-blind randomized controlled trial in India to compare the effects of OABP with NBP. The results demonstrate the efficacy of oral antibiotics in comparison to no preparation. The observed reduction in SSIs, readmission rates, and length of hospital stay can be attributed to the presence of a relatively sterile surgical field resulting from decreased bacterial load. These outcomes are in line with previous findings from Western settings [13]. Based on our findings, we recommend OABP 1 day prior to surgery to improve outcomes in patients undergoing elective colorectal surgery in routine clinical practice.

Limitations

However, this study is not without limitations. It was conducted in a single center with a predominance of open surgery (over 75%), which reflects the current practice pattern in our region. Therefore, extrapolation of these results to centers with predominantly laparoscopic colorectal practice should be made with caution.

Conclusions

OABP significantly reduces the rates of SSIs, readmission, reoperation, and length of hospital stay compared to NBP, while the rates of anastomotic leaks remain similar.

ARTICLE INFORMATION

Conflict of interest

No potential conflict of interest relevant to this article was reported.

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Author contributions

Conceptualization: RN, RK, PP; Data curation: KM, RT, BG; Formal analysis: KM, RT, BG; Methodology: RN, RK, PP; Resources: KM; Writing—original draft: KM, RT; Writing—review & editing: all authors. All authors read and approved the final manuscript.

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