



Mechanical Bowel Preparation for Elective Colon and Rectal Surgery

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Refer to Algorithm in Fig. 4.1

- A. The use of mechanical bowel preparation (MBP) prior to an elective colorectal surgery was the standard of care for many years aiming to clear the bowel of fecal matter and to lower the risk of postoperative infectious complications. The initial evidence questioning the usefulness of mechanical bowel preparation has been derived from studies on the management of colorectal trauma. Multiple studies have shown that despite the fact that the colon is unprepared, the mechanism of injury is not as controlled as in elective surgery, and there is often a delay between the injury and the repair, primary repair of the colon is safe in the setting of trauma.
- B. Postoperative complications such as surgical site infection (SSI) and anastomotic leak are of major concern both in emergent and elective colorectal surgery. Despite the improvement in surgical techniques, and powerful antibiotics for the control of sepsis, the rate of these complica-

tions is still high, leading to morbidity and mortality, prolonged length of stay, and higher cost. SSIs occur in about 15% of colorectal cases. Additionally, the risk for anastomotic leak is reported as between 3% to 20% following colorectal surgery, leading to a significantly higher mortality rate in these patients.

- C. The use of MBP in elective colon and rectal surgery has been assessed in several single and multicenter randomized controlled trials, which showed that MBP did not decrease the risk for postoperative complications. These results led to decreasing use of MBP.
- D. It seems that there is a trend towards decreased use of bowel preparation (see Algorithm in Fig. 4.1). In 2003, a survey including more than 500 surgeons (American Society of Colon and Rectal Surgeons members) showed that 98% of the surgeons participating in the survey used MBP and 75% were using oral antibiotics. A few years later (2006), a multinational survey in Europe and the US showed that 86–97% of patients received bowel preparation. In a recent large multicenter national cohort, about 50% of the patients undergoing elective colectomy received bowel preparation.
- E. Recent data generated from several independent analysis of large databases show that MBP in combination with oral antibiotics is associated with reduced risk of postoperative SSI and anastomotic leak in patients undergoing elective colorectal surgery. This reduction has not been shown in randomized controlled trials.

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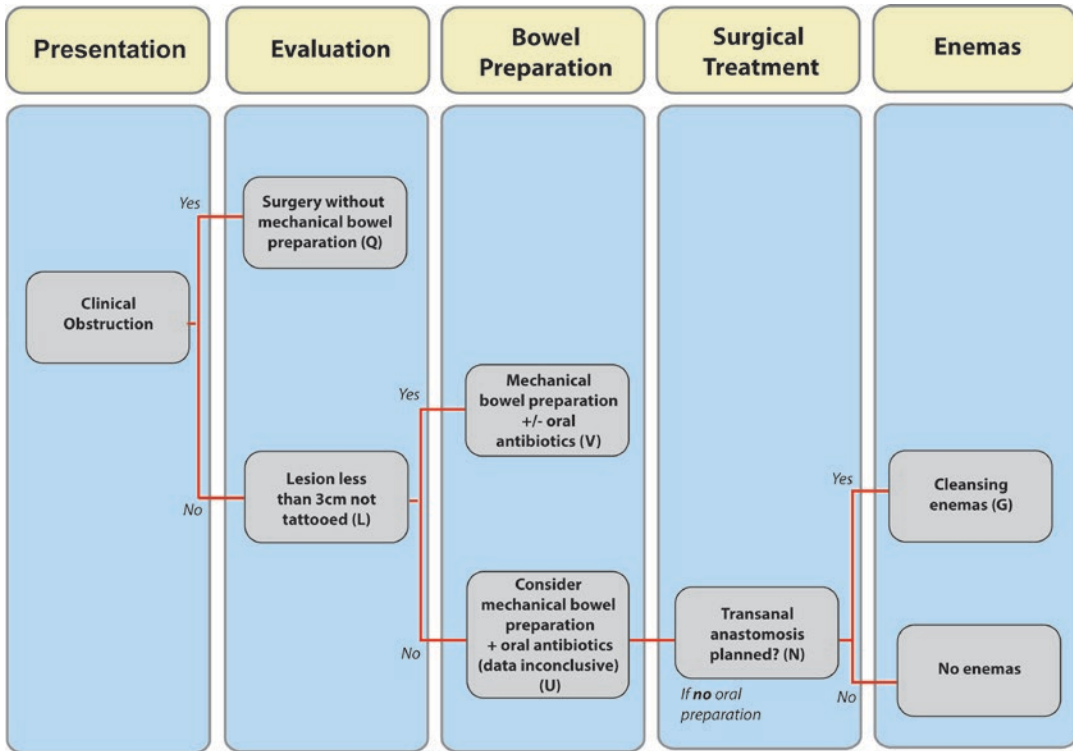


Fig. 4.1 Algorithm for mechanical bowel preparation for elective colon and rectal surgery

Single Center Studies

F. Brownson et al. were the first to publish on this topic in 1992, with their randomized trial of 179 patients to either preparation with polyethylene glycol or no mechanical preparation. This pioneer study was published as a meeting abstract, which was not followed by a full manuscript. Surprisingly, patients who had received preparation experienced a significantly increased rate of anastomotic leak and intra-abdominal infection, compared to patients without preparation. However, there was no significant difference in the rate of wound infection. This finding was followed by two studies, which were published in the 1990s by Burke et al. and Santos et al. both of which failed to show any significant difference in the intra-abdominal infection rate. However, wound infection, was more common in patients who had received mechanical preparation in the latter study.

G. Between 2000 and 2007, several larger well designed single center studies were performed. In 2003, the senior author published the largest non-multicenter study published, which included 380 patients undergoing elective colon and rectal surgery with primary anastomosis, of whom 193 were randomized to colon and rectal surgery without preoperative mechanical bowel preparation. Importantly, all patients from both groups received oral antibiotics prior to surgery. Patients undergoing rectal surgery were given one phosphate enema on the day of surgery, to avoid extrusion of stool when using a trans-anally inserted stapling device. Importantly, patients with tumors smaller than 2 cm in diameter were excluded from the study, as palpation of small tumors may be difficult in an unprepared bowel, and these patients may require intra-operative colonoscopy to identify these smaller lesions. Patients who required a diverting stoma proximal to the anastomosis were excluded from the

data analysis, thereby reducing the number of low rectal or coloanal anastomoses in this study. The two groups were well matched in parameters of demographic characteristics, indications for surgery and type of surgical procedure. There was no difference in the rate of surgical infectious complications between the two groups. Overall, infectious complication rate was 10.2% in the preparation group, and 8.8% in the non-preparation group. Wound infection, anastomotic leak, and intra-abdominal abscess occurred in 6.4%, 3.7%, and 1.1% in the bowel preparation group versus 5.7%, 2.1%, and 1%, in the no bowel preparation group.

- H. Ram et al. used the exact same protocol to randomize 329 patients, and found no significant difference in infectious and overall complication rate between patients who underwent preoperative mechanical bowel preparation and those who had not, and Miettinen et al. randomized 267 patients, in a similar fashion, and found slight and non-significant increase in anastomotic leak and wound infection rates in patients who had preoperative mechanical bowel preparation. Pena-Soria et al. also presented similar results from a randomized trial including 129 patients that underwent an elective colon or proximal rectal resection with a primary anastomosis by a single surgeon.
- I. Several studies suggested that when an ileocolonic anastomosis is planned, for instance, in a right, subtotal or total abdominal colectomy, surgery can be safely performed without mechanical bowel preparation. Advocates of this approach suggest that since the column of stool proximal to the anastomosis, which may mechanically disrupt the anastomosis, is avoided in these cases, mechanical cleansing may not be required. We have performed a subgroup analysis of our data, including only patients with left-sided anastomoses, in order to assess whether this type of anastomosis may be safely performed in the elective setting without mechanical bowel preparation. We included 249 patients with colo-colonic and colo-rectal anastomosis, and showed that the overall infectious com-

plication rate was 12.5% in the preparation group, and 13.2% in the non-preparation group. Wound infection, anastomotic leak, and intra-abdominal abscess were not significantly different among the groups, occurring in 6.6%, 4.2%, and 1.6% in the preparation group, versus 10%, 2.3%, and 0.7% in the non-preparation group. Bucher et al. prospectively randomized 153 patients undergoing colon and rectal surgery with left-sided anastomosis, and found a significantly increased complication rate in patients who received mechanical bowel preparation. The overall rate of abdominal infectious complications was 22% in the preparation group and 8% in the non-preparation group, and this difference was statistically significant. Anastomotic leak occurred in 6% of the preparation group and 1% in the non-preparation group (non-significant), and mean length of hospital stay was longer for patients who had mechanical bowel preparation (14.9 days versus 9.9 days).

- J. The only single center randomized study suggesting that mechanical bowel preparation given prior to colon and rectal surgery may actually lead to improved outcomes was published by Platell et al. in 2006. In this study, 335 patients were randomized to receive either oral mechanical bowel preparation using polyethylene glycol, or trans-anal preparation using phosphate enema. Patients undergoing any type of elective resection of colon or rectum with anastomosis were eligible for this study, with or without defunctioning stoma. Although there was no significant difference in overall anastomotic leak rate between the two groups, there was a significant difference in the severity of the leaks. Six out of seven patients, who developed anastomotic leak following preparation with enema only, required re-operation, as compared to none of the three patients who received oral mechanical preparation and leaked. Owing to this difference in re-operation rates, the study was prematurely terminated, before reaching its accrual goal. Three of the patients who required re-operation for anastomotic leak underwent

ultra-low anterior resection, a procedure which was not within the inclusion criteria of most other randomized trials.

- K. Single center studies have the advantage of relative homogeneity of the operative and perioperative techniques, which is an important factor influencing the surgical outcome. However, assuming an infectious complication rate of 10%, designing a prospective study which will be able to detect a difference of 5% in the infection rate, in a one tailed statistical test (which only examines if the treatment is better than the control, and not the possibility that treatment is actually worse), assuming an alpha level of 0.05, with a statistical power of 90%, approximately 770 patients are required to be randomized into each group, for a total of 1540 patients. It is virtually impossible for one institution to acquire such a large number of patients in a reasonable timeframe. Thus, single center studies have the advantage of homogeneity in techniques, but usually lack sufficient power leading to type II error.

Special Considerations

Localization of Small Lesions

- L. Mechanical bowel preparation may have several advantages unrelated to the risk of infection. It facilitates palpation of the entire colon during surgery, and enables the surgeon to perform intra-operative colonoscopy, if required. The intraoperative localization of small tumors may require careful palpation of the colon, which may be more difficult if the colon is loaded with fecal material. Large tumors would usually be easily distinguished from solid feces, but the identification of small tumors may be difficult. In our randomized controlled trial, we have excluded all patients with tumors smaller than 2 cm in diameter and reported no difficulties in tumor localization. Platell et al. did not exclude small tumors leading to difficulty in localization of the tumor in six patients. Thus, we strongly advise selective mechanical bowel preparation in patients with small tumors that have not been marked preoperatively with endoscopic tattoo, to allow for adequate palpation and possibly intraoperative endoscopy for tumor localization, if required.
- M. In addition, the unprepared bowel does not allow palpation of the rest of the bowel to exclude synchronous lesions. In the era of modern endoscopy and other imaging techniques, the vast majority of patients have high-quality colonic workup prior to surgery, and the necessity of intraoperative palpation is thus limited. In cases where adequate preoperative full endoscopic colonoscopy or high quality virtual colonoscopy is not possible, mechanical bowel preparation should be considered.

Low Rectal or Coloanal Anastomosis

- N. Most randomized controlled trials assessing the utility of mechanical bowel preparation did not include patients with low rectal or coloanal anastomosis. In our daily practice, most of the patients undergoing coloanal anastomosis concomitantly underwent temporary proximal diversion and were thereby excluded from our study. Interestingly, in the study by Platell and his colleagues, half of the patients who required re-operation for anastomotic leak underwent ultra-low rectal anastomosis with enema preparation only. Additionally, in a propensity score matching analysis by Kim et al., the authors compared the outcomes between patients receiving MBP vs. patients who did not receive bowel preparation. However, patients who underwent left-sided or rectal resection who did not receive MBP had received rectal enemas. In this study, there were significantly higher rates of severe post-operative complications in these patients compared to patients that received MBP (14% vs. 2%, $p = 0.03$). In a randomized trial, the French GRECCAR III study, it was

showed that MBP prior to rectal surgery decreases the rate of postoperative morbidity, including infectious complications. Nevertheless, the MBP was not tolerated well by the patients. Following that study, Pittet et al. conducted a matched study comparing MBP to rectal enema in patients with rectal cancer undergoing resection with primary anastomosis and protective ileostomy. The authors reported no difference between the groups in regard to the rate of anastomotic leak, pelvic abscess formation, or wound infection. Furthermore, a recent meta-analysis including 11 studies, 1258 patients, demonstrated no beneficial effect for MBP on all 30-day morbidity, anastomotic leak, and SSI in patients undergoing proctectomy.

- O. Since there is not enough data to support the safety of low rectal or coloanal anastomosis without mechanical bowel preparation and at least one study raises question on its safety, we feel that caution should be taken in omitting mechanical bowel preparation in these patients. Further studies specifically addressing the safety of low rectal or coloanal anastomosis without mechanical bowel preparation are required.

Laparoscopic Colon and Rectal Surgery

- P. Most of the randomized controlled trials dealing with mechanical bowel preparation for colon and rectal surgery, including the two large multicenter studies mentioned above, were limited to patients undergoing open surgery. The utility of mechanical bowel preparation in laparoscopic colon and rectal surgery may have special consideration, which may be less important with laparotomy. Mechanical bowel preparation facilitates intraoperative palpation of the colon, improving tumor localization when not evident on the serosal surface and allowing intraoperative colonoscopy in cases of uncertain localization. In laparoscopic surgery, tactile sensation is absent, and palpation of the colon is blunted. Thus, intraoperative assessment of the colon relies largely on the visual appearance of the colon during laparoscopy. Colonic pathology, however, is often confined to the mucosa, and cannot be correctly assessed by visualizing the serosal surface.
- Q. To assess the safety of laparoscopic colon and rectal surgery without mechanical bowel preparation, we have retrospectively reviewed our own experience. Our policy was to give mechanical preparation to all patients with tumors smaller than 3 cm in diameter prior to laparoscopic surgery. Patients who underwent left sided colectomy had one phosphate enema prior to surgery. One hundred and thirty-two patients had laparoscopic colon resection without preoperative oral mechanical bowel preparation, 122 of them for potentially curable colon cancer. Sixteen (8%) of these patients required intraoperative endoscopy for tumor localization, all for tumors in the left side of the colon, which were successfully performed with preoperative phosphate enema preparation only. In one patient alone, conversion to laparotomy was required owing to difficulty in localization. This series suggests that with adequate selection criteria, laparoscopic colon and rectal surgery may also be safely performed without mechanical bowel preparation. Conversely, if localization had served as the main indication for mechanical bowel preparation, 131 patients in this study would have undergone preoperative bowel preparation in order to avoid one conversion.
- R. Anastomotic techniques are generally performed in the same fashion whether by laparotomy or laparoscopy; therefore, the infectious complication rates should be similar as we found in our study. Chan et al. also showed similar results. Though, in a recent study by Morris et al., the authors reported that combined bowel preparation is associated with lower rates of SSI, anastomotic leak, and ileus in patients undergoing laparoscopic resection using the ACS-NSQIP data.

Technical Aspects and Spillage Control

- S. Many surgeons feel reluctant to operate on patients without preoperative mechanical bowel preparation because they subjectively feel that this omission of prep may be less convenient. Besides the obvious inconvenience to the patient, mechanical bowel preparation is also associated with the risk of fluid and electrolyte imbalance and patients undergoing mechanical preparation are often dehydrated.
- T. From an experiential perspective, after performing several hundreds of colon and rectal operations without mechanical bowel preparation, we can say that it is much easier to milk out solid stool away from the area of the anastomosis, and work in a cleaner field, rather than dealing with the liquid content frequently found in the colon following the use of preparation agents. Indeed, we have found that spillage of bowel content into the peritoneal cavity was significantly more common in patients who did have mechanical cleansing, and this was significantly correlated with increased risk of postoperative infectious complications.

Bowel Preparation with Oral Antibiotics Alone

- U. It is controversial whether oral antibiotics preparation alone has benefit regarding postoperative complications. Cannon et al. showed that patients receiving oral antibiotics with or without MBP had significantly lower SSI rates compared to no bowel preparation (9.0% versus 18.1%; $p < 0.0001$). The authors did not find a difference between patients receiving oral bowel preparation alone and those receiving combined bowel preparation (8.3% versus 9.2%; $p = 0.47$). Lewis et al. also showed lower rates of SSI in patients receiving oral antibiotics in addition to systemic antibiotics in comparison to systemic antibiotics only. However, Scarborough et al. reported no difference in
- outcomes between patients receiving no bowel preparation to patients receiving oral antibiotics only. Although their analysis showed these results, the number of patients receiving oral antibiotics alone was relatively small (91 patients) and thus can subject the results to type II error. A recent RCT evaluated whether IV perioperative antibiotics are inferior to combined preoperative oral and perioperative IV antibiotics in patients with colorectal cancer undergoing surgery. The study included 515 patients that were randomized to these two groups. The authors reported no difference in the rate of SSI, anastomotic leakage, intra-abdominal abscess, adverse events and postoperative complications.

Clostridium difficile Infection

- V. Several studies suggest that the risk of *Clostridium difficile* colitis following oral antibiotics alone or combined bowel preparation is not higher compared to patients who receive no bowel preparation or only MBP. A recent study by Kim et al., using the Michigan Surgical Quality Collaborative, found that the risk for *Clostridium difficile* infection was lower in patients receiving combined bowel preparation compared to no bowel preparation. Sadahiro et al. also showed in a prospective randomized trial that the risk of *Clostridium difficile* was not different between patients receiving combined bowel preparation and patients receiving no bowel preparation. However, Toneva et al. reported higher rates of *Clostridium difficile* colitis in patients receiving oral antibiotics. Additional studies are needed regarding the effect of oral antibiotics (with or without MBP) on the rate of *Clostridium difficile* infection.

Risk of Cancer Recurrence

- W. In 2014, Collin et al. assessed the long-term survival of cancer patients participating in the Swedish multicenter randomized controlled

trial, using the patients' charts. Four hundred eighty-eight patients with cancer received MBP compared to 391 that underwent surgery without mechanical bowel preparation. In 10 years follow up, 80 patients (17.9%) in the MBP group and 88 patients (22.5%) in the no-MBP group developed cancer recurrence ($p = 0.093$). Cancer-specific survival was better after bowel preparation compared to no bowel preparation (84.1% versus 78.0%; $p = 0.019$), but there was no difference in overall survival (58.8% versus 56.0% respectively; $p = 0.186$). It is important to mention that the original study was not designed to assess cancer related recurrence and survival, and the mechanism of this effect of mechanical bowel preparation on cancer related survival is unclear. Two centers that have participated in the Dutch multicenter trial have assessed cancer related survival and overall survival in 382 cancer patients participating in this study, with a median follow up of 7.6 years, and did not show such an effect of mechanical bowel preparation.

Meta-analyses of Randomized Controlled Studies

In order to overcome the low power of a single center studies, several meta-analysis of these single center studies were performed. The first review of the literature was published by Platell et al. in 1998, and included only small studies from the 1990s. Three additional meta-analyses were published in 2004 and 2005. In addition, a Cochrane systematic review regarding bowel preparation was performed in 2005 and was updated in 2009. This review included a total of 13 RCTs with 4777 participants, and included the two multicenter randomized trials mentioned below; 2390 allocated to MBP, and 2387 to no preparation, before elective colorectal surgery. In this analysis, there was no statistically significant difference in overall anastomotic leak rate between patients that received MBP compared to patients that did not receive bowel preparation (4.2% versus 3.4%; OR 1.26; 95% CI: 0.941–

1.69). Interestingly, there was no difference in anastomotic leak rate in patients that underwent low anterior resection with and without MBP (10% versus 6.6%; OR 1.73; 95% CI: 0.73–4.10). Additionally, there was no difference in the rates of wound infection between the two groups (9.6% versus 8.3%; OR 1.19, 95% CI: 0.98–1.45).

Slim et al. reviewed seven randomized controlled trials with 1464 patients. In this meta-analysis, mechanical bowel preparation was significantly associated with increased rate of anastomotic leak. Interestingly, the authors of this meta-analysis separately assessed the four studies that used polyethylene glycol for oral preparation, and those that used other oral agents. They found that whereas the use of polyethylene glycol was associated with increased risk of anastomotic leak, the pooled data of the studies that used different agents did not show significant difference in anastomotic leak rate.

In 2012, the enhanced recovery after surgery society (ERAS) stated that bowel preparation should not be routinely used in colonic surgery, since randomized controlled studies failed to show beneficial effects, and showed potential adverse effects such as dehydration, postoperative ileus, and patient discomfort.

Although meta-analysis of several randomized controlled studies has the power to compare a large group of patients, may have a major drawback due to the heterogeneity in methods and included populations in the different studies.

Multi-center Studies

Although several single center studies suggested that mechanical bowel preparation is not useful in preventing complications in colon and rectal surgery, these studies included an insufficient number of patients needed to draw meaningful conclusions. Thus, multicenter studies with a large number of patients were needed to demonstrate generalizability of these results. In 2005, Fa-Si-Oen et al. presented a multicenter, randomized trial comparing the outcomes in 250 patients undergoing open colon surgery with and without

bowel preparation. The authors found no difference in rates of wound infections (7.2% vs. 5.6%, $p = 0.61$) and anastomotic leaks (5.6% vs. 4.8%, $p = 7.78$) between patients receiving mechanical bowel preparation and patients without preoperative preparation of the bowel. However, this multicenter study also suffered from insufficient statistical power.

The first published large and well powered multicenter randomized controlled trial is a Swedish trial, which was published in June 2007. The study included 1505 patients undergoing elective open surgery for cancer, adenoma, or diverticular diseases with primary anastomosis in 20 Swedish and 1 German colorectal units, of which 1343 were eligible for data analysis. Six hundred eighty-six patients were randomly assigned to have preoperative mechanical bowel preparation and 657 patients were assigned to have no mechanical preparation. The agents used for mechanical preparation was not standardized, and was based on local protocol of each participating unit. Polyethylene glycol was used for preparation in 47% of the patients and sodium phosphate in 48.5%. Preparation with enema only was used in the remaining patients. All the patients received intravenous prophylactic antibiotics, but the selection of antibiotic agent was according to each participating unit protocol. Anastomotic leak was diagnosed in 2.3% of the patients who had the mechanical preparation, and in 2.6% of the patients without the preparation. There were no significant differences between the groups in the rates of cardiovascular, general infectious or surgical site infectious complications. The type of oral agents used for bowel preparation had no effect on the incidence of cardiovascular, infectious or surgical site complications. The authors of this study concluded that the collective evidence from this and other trials strongly suggest that mechanical bowel preparation is of no benefit in terms of anastomotic healing or infection rates, or for improving the overall postoperative course in patients undergoing colon resection; thus, this practice should be abandoned.

The second multicenter randomized controlled trial was from the Netherlands. In this trial, 1431 patients undergoing elective open colon and rectal surgery with primary anastomosis were randomized to mechanical preparation or no mechanical preparation. The incidence of anastomotic leak was similar in the two groups, 5.4% in patients who did not have mechanical bowel preparation and 4.8% in patients who did have mechanical preparation. There was no significant difference in other septic complications or mortality. Again, the authors of this study concluded that elective colon and rectal surgery can be safely carried out without mechanical bowel preparation, and therefore mechanical bowel preparation should be abandoned.

Kim et al. have recently reviewed the Michigan Surgical Quality Collaborative–Colectomy Best Practices Project between 2007 and 2011. This retrospective cohort study compared postoperative complications in patients receiving full bowel preparation (mechanical bowel preparation and oral antibiotics) versus matched patients who did not receive bowel preparation, and included a total of 1914 patients in the analysis. Patients receiving full preparation were less likely to have any SSI (5.0% versus 9.7%; $P = 0.0001$), organ space infection (1.6% versus 3.1%; $P = 0.024$), and superficial SSI (3.0% versus 6.0%; $P = 0.001$). Patients receiving full preparation were also less likely to develop postoperative *Clostridium difficile* colitis (0.5% versus 1.8%, $P = 0.01$). This study suggests that mechanical bowel preparation combined with oral antibiotics was useful in elective colorectal surgery.

Moghadamyeghaneh et al. used the American College of Surgeons National Quality Improvement Program (ACS-NSQIP) to evaluate the association between bowel preparation and postoperative outcomes in patients with colon cancer undergoing resection during 2012 to 2013. This retrospective study included 5021 patients and compared between patients who received combined bowel preparation to patients who received MBP only, oral antibiotics only, and patients who received no bowel preparation

at all. The authors reported no decrease in complication rate in patients receiving MBP only or oral antibiotics only compared to patients who received no bowel preparation at all. Interestingly, this finding was true for both left and right side colon resections. However, patients who received combined bowel preparation (MBP and oral antibiotics) had significantly lower rates of overall morbidity ($p < 0.01$), superficial SSI ($p < 0.01$), anastomotic leak ($p < 0.01$), and intra-abdominal infections ($p < 0.01$). Likewise, Scarborough et al. reported similar results, using the ACS-NSQIP data. They showed that the risk for SSI and anastomotic leak is significantly lower in patients undergoing colorectal surgery for diverticular disease, cancer, and non-malignant polyps who received combined bowel preparation. Also in 2015, Morris et al. reviewed the ACS-NSQIP data as well and compared the postoperative outcomes between patients receiving MBP only, combined bowel preparation, and no bowel preparation who underwent colon resection. They found similar results, with lower rates of SSI, shorter length of stay, and lower readmission rates in patients receiving combined bowel preparation compared to no bowel preparation or MBP only.

A recent multicenter randomized trial from Finland randomized 396 patients undergoing colorectal surgery with anastomosis for preoperative mechanical bowel preparation and oral antibiotics. Approximately half of the patients had right-sided colectomy. There was no significant difference in anastomotic leak rate, surgical site infection, and overall complication rate between the two groups. Although this study may be underpowered to detect small differences, it does put into question the benefit of the combined mechanical in oral antibiotic preparation which has been suggested by studies generated from large databases.

Thus, despite the limitations of databases, the most recent data show clear benefits to the routine use of a combination of oral and cathartic antibiotic bowel preparation.

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