

# Mechanical bowel preparation for elective colorectal surgery: a multicentre randomised trial

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## Summary

**Background** Mechanical bowel preparation is a common practice before elective colorectal surgery. We aimed to compare the rate of anastomotic leakage after elective colorectal resections and primary anastomoses between patients who did or did not have mechanical bowel preparation.

**Methods** We did a multicentre randomised non-inferiority study at 13 hospitals. We randomly assigned 1431 patients who were going to have elective colorectal surgery to either receive mechanical bowel preparation or not. Patients who did not have mechanical bowel preparation had a normal meal on the day before the operation. Those who did were given a fluid diet, and mechanical bowel preparation with either polyethylene glycol or sodium phosphate. The primary endpoint was anastomotic leakage, and the study was designed to test the hypothesis that patients who are given mechanical bowel preparation before colorectal surgery do not have a lower risk of anastomotic leakage than those who are not. The median follow-up was 24 days (IQR 17–34). We analysed patients who were treated as per protocol. This study is registered with ClinicalTrials.gov, number NCT00288496.

**Findings** 77 patients were excluded: 46 who did not have a bowel resection; 21 because of missing outcome data; and 10 who withdrew, cancelled, or were excluded for other reasons. The rate of anastomotic leakage did not differ between both groups: 32/670 (4·8%) patients who had mechanical bowel preparation and 37/684 (5·4%) in those who did not (difference 0·6%, 95% CI –1·7% to 2·9%,  $p=0\cdot69$ ). Patients who had mechanical bowel preparation had fewer abscesses after anastomotic leakage than those who did not (2/670 [0·3%] vs 17/684 [2·5%],  $p=0\cdot001$ ). Other septic complications, fascia dehiscence, and mortality did not differ between groups.

**Interpretation** We advise that mechanical bowel preparation before elective colorectal surgery can safely be abandoned.

## Introduction

Symptomatic anastomotic leakage is the most important surgical complication after colorectal surgery and can cause morbidity and mortality. Mechanical bowel preparation has been regarded as an efficient strategy to prevent anastomotic leakage and septic complications. Observational data and expert opinions<sup>1–4</sup> have traditionally held that mechanical bowel preparation before colorectal surgery reduces faecal mass and bacterial count in the lumen. However, in the past few decades, the practice has been questioned.<sup>5–10</sup> In two studies, anastomotic leakage was more likely to occur in patients who had received mechanical bowel preparation before surgery.<sup>7,8</sup> However, these trials were underpowered, because of insufficient participants. We aimed to compare the outcome of elective colorectal resections with and without mechanical bowel preparation in terms of anastomotic leakage and other complications.

## Methods

### Study participants

Between April, 1998, and February, 2004, we enrolled patients at 13 participating hospitals (including nine teaching hospitals) in the Netherlands. The main criterion for inclusion was an indication for elective colorectal surgery with primary anastomosis. Patients

were excluded if they had an acute laparotomy; had laparoscopic colorectal surgery; had a contraindication for the use of mechanical bowel preparation; had an a priori deviating ileal stoma; or were aged younger than 18 years. Surgeons in the participating hospitals enrolled patients in the study at the last visit before they were scheduled to have elective colorectal surgery. We obtained written informed consent from all patients.

### Procedures

Enrolled patients were randomly assigned to either receive mechanical bowel preparation or not. A computer-generated randomisation list, stratified by centre, was prepared by the trial statistician (WCJH) at a central coordination centre. At the hospital where the trial was coordinated, patients were allocated to each intervention by means of numbered sealed envelopes that corresponded to the randomisation list; other centres were advised by telephone of the intervention allocated to each patient. The study was reviewed and approved by the ethics committees at participating hospitals.

Mechanical bowel preparation consisted of 2–4 L of polyethylene glycol bowel lavage solution in combination with bisacodyl (at 11 hospitals) or sodium phosphate solution (at two hospitals). Patients who had mechanical bowel preparation had a fluid diet (of beverages, yoghurt,

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and soup) on the day before their operations. Patients who did not were allowed to have normal meals.

Before their operations, all patients were given intravenous antibiotic prophylaxis according to the guideline for prevention of surgical-site infection issued by the infectious diseases department of each hospital. All procedures were done by open laparotomy. Anastomoses were done according to the judgement of the surgeon.

The primary endpoint of the study was anastomotic leakage. Clinical suspicion based on persistent fever, abdominal pain, local or generalised peritonitis, or leucocytosis was followed by contrast radiography, CT scan, or laparotomy to substantiate the diagnosis. No effort was made to screen for asymptomatic leakage. Secondary endpoints were septic complications (wound infection, urinary infection, pneumonia, and intra-abdominal abscesses); fascia dehiscence; and death. Wound infection was regarded as mild if it manifested only with erythema or discharge of seroma, and severe if it was characterised by discharge of pus, wound necrosis, or wound dehiscence. We suspected urinary tract infections on the basis of clinical signs such as painful micturition, frequent micturition or urge, lower abdominal pain, or fever. The diagnosis of urinary infection was made for a urinary sample with a bacterial density of more than  $10^2$  per mL of urine for patients with symptoms and without a catheter, and of more than  $10^5$  per mL of urine for patients with a catheter. Clinical suspicion of pneumonia was based on cough, saliva, dyspnoea, or fever. We diagnosed pneumonia if radiography of the thorax showed infiltrative signs, and a saliva swab was positive for bacteria. The suspicion of an intra-abdominal abscess was based on clinical symptoms such as intermittent rise in temperature, persistent ileus, or abdominal pain. If an intra-abdominal abscess was suspected, we used CT or ultrasonography to investigate. This diagnosis could be also supported by perioperative findings. Fascia dehiscence was defined as receding of the abdominal fascia at the site or next to the fascia suture. The follow-up period was defined as the time from the operation until first outpatient visit, which usually took place 2 weeks after discharge from the hospital.

### Statistical analysis

The study was designed to test the hypothesis that patients given no mechanical bowel preparation before colorectal surgery do not have a higher risk of anastomotic leakage than those given mechanical bowel preparation. We specified that for non-inferiority to apply, the upper limit of the two-sided 95% CI for the difference in anastomotic leakage rates (no mechanical bowel preparation group minus bowel preparation group) had to be less than 3%. We calculated that we would need a sample of 1400 patients to show with 80% probability that the upper limit of the 95% CI did not exceed the margin of

3%, assuming that the rate of anastomotic leakage in both groups was 5%.

We used the  $\chi^2$  test or Fisher's exact test to compare complication rates between groups, and the Mann-Whitney test to compare continuous or graded outcomes. The same tests were used in a univariate exploratory analysis to assess the risk of anastomotic leakage associated with: age, presence of hypertension, American Society of Anesthesiologists (ASA) classification, concurrent use of corticosteroids, preoperative radiation therapy, diabetes, coronary or peripheral ischaemic disease, smoking, body-mass index, indication for operation, type of anastomosis, technique of anastomosis (stapled versus handsewn), type of surgeon (length of training), and perioperative blood loss. We used multiple logistic regression to test risk factors simultaneously for any association with anastomotic failure. We regarded  $p=0.05$  as the limit of significance in all analyses. This study is registered with ClinicalTrials.gov, number NCT00288496.

### Results

The figure shows the trial profile. Between April, 1998, and February, 2004, we enrolled 1431 patients. 77 patients were excluded from analysis of the primary endpoint: 46 (3.2%) because they did not have a bowel resection; 21 (1.5%) because we did not have outcome data; and 10 (0.7%) because they either withdrew consent, died, had an acute laparotomy, underwent surgery

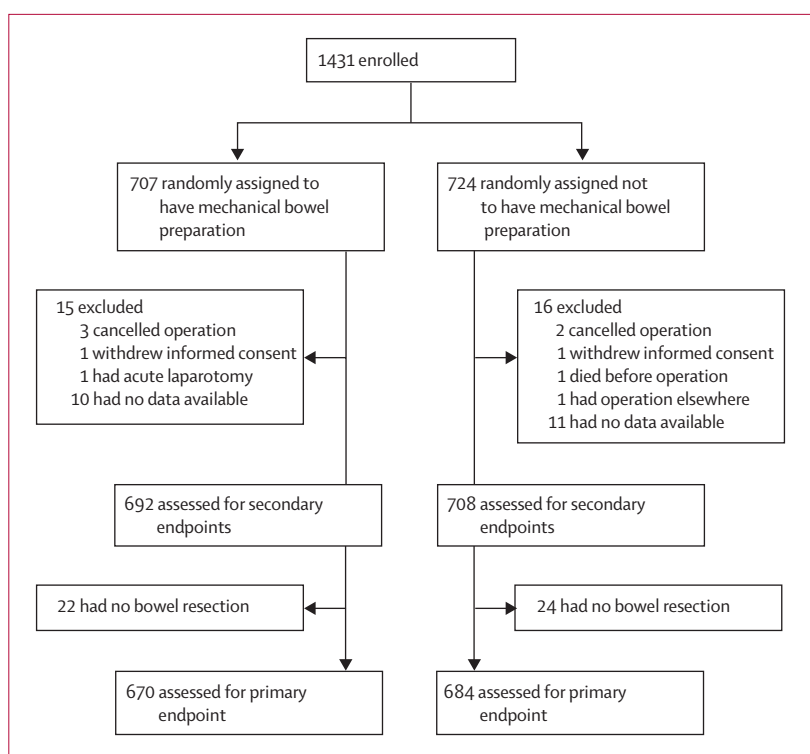


Figure: Trial profile

	Mechanical bowel preparation (n=670)	No mechanical bowel preparation (n=684)
Mechanical bowel preparation solution		
Polyethylene glycol	588 (88%)	602 (88%)
Sodium phosphate	82 (12%)	82 (12%)
Sex		
Female	333 (50%)	339 (50%)
Male	337 (50%)	345 (50%)
Mean age (years)	67 (13)	67(12)
ASA classification		
I	207 (31%)	212 (31%)
II	384 (57%)	386 (56%)
III	77 (12%)	83 (12%)
IV	2 (0.3%)	3 (0.4%)
Diabetes	66 (10%)	76 (11%)
Radiation	32 (5%)	22 (3%)
Corticosteroids	32 (5%)	27 (4%)
Coronary ischaemic disease	98 (15%)	109(16%)
Peripheral ischaemic disease	38 (6%)	36 (5%)
Smoking	165 (25%)	118 (17%)
Body-mass index		
≤25 kg/m <sup>2</sup>	329 (50%)	346 (52%)
>25 kg/m <sup>2</sup>	328 (50%)	319 (48%)
Indication for operation		
Colorectal cancer	487 (73%)	538 (79%)
Inflammatory bowel disease	122 (18%)	105 (15%)
Other*	61 (9%)	41 (6%)
Antibiotic prophylaxis		
Cefuroxim+metronidazole	320 (48%)	329 (48%)
Cefazolin+metronidazole	83 (12%)	80 (12%)
Cefamandole+metronidazole	70 (10%)	80 (12%)
Gentamycine+metronidazole	51 (8%)	56 (8%)
Amoxicillin-clavulanate	128 (19%)	130 (19%)
Others	19 (3%)	9 (1%)
Type of anastomosis		
Ileocolic	190 (28%)	209 (31%)
Colocolic	217 (31%)	237 (35%)
Colorectal	236 (34%)	213 (31%)
Other†	27 (4%)	25 (4%)
Technique of anastomosis I		
Stapled	207 (30%)	208 (30%)
Handsewn	444 (66%)	462 (68%)
Technique of anastomosis II		
End-to-end	291 (43%)	304 (46%)
Side-to-end	238 (37%)	239 (34%)
Side-to-side	93 (15%)	109 (17%)
End-to-side	19 (3%)	14 (2%)
Pouch	9 (1%)	5 (1%)

The number of patients for whom data were missing was less than 1% for all variables except body-mass index (n=34), technique of anastomosis I (n=75), and technique of anastomosis II (n=73). ASA=American Society of Anaesthesiologists. Data are number (%) or mean (SD). \*Other reasons were radiation induced stenosis, endometriosis, and correction of Hartmann's procedure. †Coloanal anastomosis or ileorectal anastomosis.

**Table 1: Baseline characteristics of patients who had bowel resection**

elsewhere, or cancelled their operation. Baseline characteristics are shown in table 1. By chance, more patients who smoked and had inflammatory bowel disease were assigned to have mechanical bowel preparation.

Table 2 sets out postoperative complications, and shows that the rate of anastomotic leakage was about 5%, whether patients had mechanical bowel preparation or not (difference 0.6%, 95% CI -1.7% to 2.9%, p=0.69). The treatment effect did not differ between the 13 participating centres (OR homogeneity, p=0.67). 30 of the 69 cases of anastomotic leakage were verified by radiographic examination. 57 of the 69 patients had major anastomotic leakages that needed relaparotomy. The rate was about 4% in each group, whether patients had mechanical bowel preparation or not (difference 0.6%, 95% CI -1.6% to 2.8%, p=0.64). 6 patients in each group had minor anastomotic leakages that were treated conservatively. The median follow-up time for the 1354 patients who had bowel resection was 24 days (IQR 17–34).

Table 2 shows that fewer intra-abdominal abscesses happened after anastomotic leakage in those who had mechanical bowel preparation than in those who did not (p=0.001, 95% CI 0.9–3.4% for the difference). Of the 17 patients who did not have mechanical bowel preparation, and who developed intra-abdominal abscesses after anastomotic leakage, only three needed a relaparotomy for drainage of the abscess.

Rates of other septic complications, fascia dehiscence, and mortality did not differ between the two groups (table 2). Faecal contamination, number of days until resumption of a normal diet, and duration of hospital stay were similar in both groups (table 2). Results were similar when we analysed the 1400 patients for whom we had some outcome data, except that the rate of intra-abdominal abscesses did not differ between the groups (data not shown).

Exploratory univariate analysis of putative risk factors for anastomotic leakage showed that type of anastomosis (ie, ileocolic, colocolic, and colorectal anastomosis); ASA classification; and blood-loss during operation were associated with anastomotic leakage. These three associations remained significant in multivariate analysis (table 3). The two factors that were not well balanced between study groups (smoking and indication for operation), were not related to the primary outcome. Furthermore, the requirement for a stoma during the operation did not affect the leakage rate (table 3).

## Discussion

Our study did not show any differences in anastomotic leakage between patients who were given preoperative mechanical bowel preparation before elective colorectal surgery and those who were not. Mortality and length of hospital stay were also similar in the two groups. However, patients who did not have mechanical bowel preparation had a slightly higher rate of intra-abdominal

	With mechanical bowel preparation† n=670	Without mechanical bowel preparation† n=684	Difference (95% CI)	p value
No postoperative complication	462 (69.0%)	452 (66.1%)	-2.9 (-7.9 to 2.1)	0.28
Anastomotic leakage	32 (4.8%)	37 (5.4%)	0.6 (-1.7 to 2.9)	0.69
Minor anastomotic leakage	6 (0.9%)	6 (0.9%)	0.0 (-1.0 to 1.0)	1.0
Major anastomotic leakage	26 (3.9%)	31 (4.5%)	0.6 (-1.6 to 2.8)	0.64
Wound infection	90 (13.4%)	96 (14.0%)	0.6 (-3.2 to 4.4)	0.82
Mild wound infection	49 (7.3%)	51 (7.4%)	0.1 (-2.7 to 2.9)	1.0
Severe wound infection	41 (6.1%)	45 (6.6%)	0.4 (-2.2 to 3.0)	0.83
Fascia dehiscence	19 (2.8%)	16 (2.3%)	-0.5 (-2.2 to 1.2)	0.69
Urinary tract infection	71 (10.6%)	70 (10.2%)	-0.4 (-3.6 to 2.9)	0.90
Pneumonia	39 (5.8%)	51 (7.5%)	1.6 (-1.0 to 4.3)	0.27
Intra-abdominal abscess	15 (2.2%)	32 (4.7%)	2.4 (0.5 to 4.4)	0.02
Abscess without anastomotic leakage	13 (1.9%)	15 (2.2%)	0.3 (-1.3 to 1.8)	0.85
Abscess with anastomotic leakage	2 (0.3%)	17 (2.5%)	2.2 (0.9 to 3.4)	0.001
Secondary intervention	58 (8.7%)	58 (8.5%)	-0.2 (-3.2 to 2.7)	0.99
Deaths	20 (3.0%)	26 (3.8%)	0.8 (-1.1 to 2.7)	0.50
Faecal contamination*	..	..	..	0.42
Clean contaminated	389 (58.1%)	380 (55.8%)	-2.3 (-7.6 to 2.9)	0.41
Contaminated	250 (37.4%)	276 (40.5%)	3.2 (-2.0 to 8.4)	0.26
Dirty	30 (4.5%)	25 (3.7%)	-0.8 (-2.9 to 1.3)	0.54
Operation time (min)	120 (90-150)	120 (90-144)	0.0 (-5.0 to 5.0)	0.48
Resumption of normal diet (days)	6 (4-8)	6 (4-8)	0.0 (-0.4 to 0.4)	0.91
Hospital stay (days)†	10 (8-14)	10 (8-13)	0.0 (-1.0 to 1.0)	0.40

Data are number (%) or median (IQR) unless otherwise specified. The number of patients for whom data were missing was less than 1% for all variables except for days until resumption of a normal diet (n=31) and hospital stay (n=29). \*Clean contaminated=colon resection with minimal spill; contaminated=colon resection with severe spill of bowel contents, no pus; and dirty=intraperitoneal pus or bowel perforation. †Excluding postoperative deaths.

**Table 2: Postoperative complications, surgery data, and hospital stay for the 1354 patients who had bowel resections**

abscesses after anastomotic leakage. We did not regard the very low rate of abscesses to be of major clinical importance; abscesses did not influence the number of reinterventions, length of hospital stay, or mortality.

Efficient mechanical bowel preparation is generally supposed to help to prevent infectious complications after colorectal surgery. Theoretically, this procedure diminishes faecal load in the bowel and prevents disruption of the anastomosis by reduction of faecal impaction at the site of the anastomosis. Therefore, the risks of faecal contamination or infection of the peritoneal cavity and the abdominal wound are thought to be decreased. However, mechanical bowel preparation liquefies solid faeces, which could increase the risk of intraoperative spillage of contaminant.<sup>3,11</sup> Although some investigators believe that mechanical bowel preparation can reduce the bacterial load in the bowel, the large number of microorganisms in the digestive tract makes this almost impossible.<sup>7,12</sup> Mechanical bowel preparation has been shown to have potentially negative side-effects in terms of bacterial translocation,<sup>13,14</sup> electrolyte disturbance,<sup>15-18</sup> and discomfort to patients.<sup>15,19-21</sup> Despite these drawbacks, mechanical bowel preparation is still commonly practised in colorectal surgery, without evidence from randomised trials that it decreases complication rates in patients.<sup>6-9,22</sup>

Of the three published meta-analyses, the first showed that in three trials, with 497 patients, those who had mechanical bowel preparation had a significantly greater rate of wound infection than those who did not.<sup>23</sup> The second meta-analysis showed that in nine trials, with 1592 patients, mechanical bowel preparation was associated with a higher rate of anastomotic leakage, although wound infection and other complications did not differ between groups.<sup>24</sup> The third meta-analysis showed that in seven trials, with 1454 patients, those who had mechanical bowel preparation were significantly more likely to have anastomotic leakage.<sup>25</sup> Only one recent study has reported an increased risk of anastomotic leakage in patients who had colorectal resections after mechanical bowel preparation with a single phosphate enema compared with oral polyethylene glycol.<sup>21</sup> Mortality was higher in the oral polyethylene glycol group, but neither septic complications nor length of hospital stay differed between groups. After submission, we learned of another randomised trial of mechanical bowel preparation for elective colonic resection, in which the results paralleled ours.<sup>26</sup>

Multivariate analysis showed that ASA classification, type of anastomosis, and blood loss during operation were independent risk factors for anastomotic leakage. A possible explanation for risk associated with loss of blood

	Leakage rate	Odds ratio (OR)	95% CI	Multivariate analysis p values	Univariate analysis p values
<b>Mechanical bowel preparation</b>					
No	37/684 (5.4%)	1.0*	..	..	..
Yes	32/670 (4.8%)	0.81	0.48–1.34	0.42	0.69
<b>ASA classification</b>					
I	15/419 (3.6%)	1.0*	..	..	..
II	35/770 (4.5%)	1.33	0.71–2.47	0.37	..
III/IV	19/165 (11.5%)	3.83	1.87–7.84	0.0002	0.001‡
<b>Type of anastomosis</b>					
Ileocolic	12/399 (3.0%)	1.0*	..	..	..
Colocolic	23/454 (5.1%)	1.56	0.74–3.29	0.24	0.007§
Colorectal	32/449 (7.1%)	2.14	1.05–4.35	0.04	..
Other	2/52 (3.8%)	0.93	0.18–4.91	0.93	..
<b>Operation indication</b>					
Carcinoma	48/1025 (4.7%)	1.0*	..	..	..
Inflammatory bowel disease	14/227 (6.2%)	1.22	0.64–2.34	0.55	0.46¶
Other	7/102 (6.9%)	1.60	0.66–3.86	0.30	..
<b>Smoking</b>					
No	51/1066 (4.8%)	1.0*	..	..	..
Yes	18/283 (6.4%)	1.32	0.73–2.36	0.36	0.36
<b>Blood loss</b>					
<median†	22/664 (3.3%)	1.0*	..	..	..
≥median†	47/677 (6.9%)	1.93	1.12–3.32	0.02	0.004
<b>Diverting stoma peroperatively</b>					
No	63/1257 (5.0%)	1.0*	..	..	..
Yes	6/97 (6.2%)	0.99	0.38–2.59	0.99	0.79

Data are number (%), unless otherwise specified. ASA=American Society of Anaesthesiologists. \*Reference category. †Median blood loss was 400 mL. ‡p value for trend. §p value for trend, excluding "other" types of anastomosis. ¶Overall p value.

**Table 3: Anastomotic leakage rates, according to various factors and results of multivariate analysis for the 1354 patients who had bowel resection**

is that decreased oxygen delivery at the anastomotic site due to anaemia might compromise anastomotic healing and therefore cause anastomotic leakage. Golub and colleagues<sup>27</sup> reported that a perioperative transfusion of more than two units of blood was independently associated with leakage, and suggested that the immunosuppressive effect of blood transfusions might have a role.

Our trial had several limitations. First, observers were not blinded to whether a patient had mechanical bowel preparation or not. However, since the number of surgical interventions for severe leakages did not differ between groups, the lack of double blinding probably did not cause bias. Second, we did not register all eligible patients who could potentially have been enrolled. However, because the characteristics of the patients in our study (table 1) corresponded closely to those of patients in the three published meta-analyses, we do not think that the external validity of our study was compromised by this omission.

Third, we used two different oral regimes for mechanical bowel preparation, since two hospitals had switched from

use of polyethylene glycol to sodium phosphate for mechanical bowel preparation, on the basis of a report that these substances were equally effective and safe.<sup>19</sup> Our analysis showed that neither the difference in the rate of anastomotic leakage nor the difference in overall complication rate varied according to which type of mechanical bowel preparation was used.

Fourth, we did not record the exact height of anastomosis below the pelvic verge. Anastomotic leakage has been studied in relation to patient characteristics (such as malnutrition, body-mass index, cardiovascular disease, steroid use, smoking, alcohol abuse, and preoperative pelvic irradiation) and to surgery (level of anastomosis, operating time, perioperative blood transfusion, ASA classification, and intraoperative contamination of the operative field). The factor most consistently shown to predict leakage is a low rectal anastomosis.<sup>27</sup> Two recent randomised studies advised that patients undergoing elective anterior resections that were low or very low, should have mechanical bowel preparation because of a high risk of anastomotic leakage in extraperitoneal anastomosis.<sup>28,29</sup> However this advice was not based on solid evidence, since one study excluded extraperitoneal anastomosis<sup>28</sup> and the other only included 79 patients with a (low) anterior resection.<sup>29</sup> Platell and colleagues<sup>21</sup> studied 294 patients, 60% of whom had a low anterior resection. All anastomoses under the pelvic verge were radiologically assessed for leakage, whereas intra-abdominal anastomoses were only assessed if clinically indicated.<sup>21</sup> Although radiological assessment of anastomotic leakage did not differ between patients who did and did not have mechanical bowel preparation, both clinically relevant anastomotic leakage and severe anastomotic leaks were more common in the enema group.<sup>21</sup> In our study, 449 patients underwent a colorectal anastomosis below the level of the peritoneal verge. In this subgroup, we noted no differences with regard to anastomotic leakage or septic complications, whether patients had mechanical bowel preparation or not (data not shown).

Last, although we only analysed 1354 patients, statistical power was not greatly reduced because the resulting confidence interval for the primary endpoint was sufficiently narrow to exclude a relevant difference. Therefore, the conclusion that elective colorectal surgery can be safely done without mechanical bowel preparation is justified. In view of possible disadvantages of this practice, patient discomfort, and the absence of clinical value, we advise that mechanical bowel preparation before elective colorectal surgery should be abandoned.

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