

Preoperative mechanical bowel preparation in elective colorectal surgery. An update of systematic review of the literature and meta-analysis

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ABSTRACT: The belief that mechanical bowel preparation is related to the reduction of complications in elective colorectal surgery is based on observational studies and expert opinion. This question led the authors to a systematic literature review, with the completion of meta-analysis, followed by three updates. **Method:** The sources of information were EMBASE, LILACS, MEDLINE, IBECs, the Cochrane Controlled Trials Register and letters to the authors. The studies were included according to the randomization criteria. The studied variables were: anastomotic dehiscence, mortality and operatory wound infection. The analysis was divided into two comparisons: one group with mechanical preparation (Group A) compared with a group without preparation (Group B) (Comparison I) and a group submitted to rectal enema (Comparison II). **Results:** We analyzed 5,805 patients in 20 clinical trials. In comparison I, anastomotic leak occurred in 4.4% (101/2,275 patients) in Group A and 4.5% (103/2,258 patients) in Group B. In comparison II, anastomotic leak occurred in 4.4% (27/601 patients) in Group A and 3.4% (21/609 patients) in Group B. **Conclusion:** Despite the inclusion of more studies, evidences found in studies did not show any benefit obtained from the use of preoperative mechanical bowel preparation or rectal cleansing enemas in elective colorectal surgery.

Keywords: colorectal surgery; review; meta-analysis; postoperative complications; anastomotic leak.

RESUMO: A crença de que o preparo mecânico do cólon está relacionado à diminuição de complicações na cirurgia colorretal eletiva é baseada em estudos observacionais e opinião de especialistas. Seu questionamento motivou os autores na busca sistemática da literatura, com a realização de meta-análise, seguida de três atualizações. **Método:** Fontes de informação foram EMBASE, LILACS, MEDLINE, IBECs, Registros de Ensaios Clínicos Casualizados da Colaboração Cochrane e cartas para os autores. Os estudos foram incluídos de acordo com os critérios de casualização. Os desfechos clínicos estudados foram: deiscência anastomótica, mortalidade e infecção da ferida operatória. A análise dos grupos foi dividida em duas comparações: comparação I, grupo submetido a preparo mecânico do cólon (Grupo A) comparado ao grupo sem preparo (Grupo B); comparação II, Grupo A, submetido a preparo do cólon e Grupo B, realizado apenas enema retal. **Resultados:** Foram analisados 5.805 doentes em 20 ensaios clínicos. Na comparação I, deiscência anastomótica ocorreu em 4,4% (101/2.275 doentes) no Grupo A e 4,5% (103/2.258 doentes) no Grupo B. Na comparação II, deiscência anastomótica ocorreu em 4,4% (27/601 doentes) no Grupo A e 3,4% (21/609 doentes) no Grupo B. **Conclusão:** Apesar da inclusão de mais estudos, as evidências encontradas não demonstraram benefício no uso do preparo mecânico pré-operatório do cólon, assim como de enemas de limpeza do reto em cirurgia colorretal eletiva.

Palavras-chave: cirurgia colorretal; revisão; meta-análise; complicações pós-operatórias; fistula anastomótica.

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INTRODUCTION

The constant concern about the high incidence of infectious complications in elective colorectal surgery has been present in the traditional ritual of preoperative mechanical bowel preparation¹⁻³. The exhaustive cleansing of intestinal content, given its high potential for contamination, is considered the most important factor in the prevention of complications by most surgeons. Since Halsted, the presence of stool inside the bowel has been listed as the main cause of anastomotic dehiscences⁴. It is difficult to state with precision when the preoperative mechanical bowel preparation appeared in this history of colorectal surgery. Maunsell, in early 1890's, introduced the bowel and rectum cleansing⁵. Since then, several methods of mechanical colon cleansing have been used, via antegrade and/or retrograde routes, which indicates that, so far, no standard mechanical bowel preparation method has been established. Based on some studies⁶⁻⁸, where the authors clinically investigated the exclusively antibiotic prophylaxis administration in elective colorectal surgery, the importance of stool in the anastomotic area started to be questioned. Reports of emergency surgeries⁹⁻¹² also aroused suspicions regarding the need for mechanical bowel preparation in elective colorectal surgery. In 1966, Hughes said that mechanical preparation would please the surgeon, who likes to operate a clean bowel, and that such measure would not bring reduced surgical morbimortality. The same author, some years later, published a randomized clinical study¹³ on elective colorectal surgery and suggested that the preparation would not be required, as there was no significant difference between the group that received preoperative mechanical preparation and the group that did not receive it.

Randomized clinical trials¹⁴ are the best type of study to answer questionings and help in the adoption of a certain clinical practice. However, this type of study can involve several technical and/or financial difficulties and require a long follow-up period. A solution for such questionings is to find all clinical trials performed, evaluate them regarding their methodological quality and synthesize them. It can be performed in a systematic review of clinical trials, which is a reproducible method and presents defined evaluation criteria for the inclusion and exclusion of studies, according to

their quality, synthesizing the information in an understandable manner, to help in clinical decision-making process^{15,16}. Then, we decided to conduct a systematic review of the literature, with a meta-analysis, if possible. We attempted to review and synthesize the clinical evidences found about updates on the mechanical bowel preparation in elective colorectal surgery.

This review has its original publication and two other prior updates, in which more studies were included. The latest update provides the analysis of new studies and the inclusion of a second comparison: mechanical bowel preparation *versus* rectal enema, as some authors from included studies believe that rectal cleansing, in low colorectal surgeries, can promote easier handling at the moment of anastomosis¹⁷⁻²¹. A more comprehensive version of this update will be available at the Cochrane Library.

OBJECTIVE

Analyze the results of the comparison between the use, or nonuse, of the preoperative bowel mechanical preparation in elective colorectal surgery with anastomotic dehiscence as the primary clinical outcome.

The purpose of the update is to determine whether the mechanical preparation before the elective colorectal surgery is really essential for the patients.

MATERIAL AND METHODS

The study method was a systematic review and a meta-analysis of randomized clinical trials, conducted in the Postgraduate Program in Surgical Gastroenterology at the Universidade Federal de São Paulo/Escola Paulista de Medicina, at the Brazilian Cochrane Centre and the Colorectal Cancer Group of the Cochrane Collaboration in Copenhagen (Denmark).

Inclusion criteria

This study included randomized clinical trials that compared the mechanical bowel preparation to non-preparation, or the mechanical bowel preparation to rectal enema, in patients submitted to elective colorectal surgery. Participants: patients – adults or children – submitted to elective colorectal surgery. Interventions: no restriction was considered regarding the type of preparation used.

Identification of trials

No restriction was made regarding dates or idioms; these trials were obtained from the following computer databases: EMBASE, LILACS, MEDLINE, IBECs, CCTR (Cochrane Controlled Trials Register). The search strategy was that of the Cochrane Collaboration for randomized clinical trials²² (Table 1).

Selection of trials

The randomization process description was carefully observed, and the trial inclusion depended especially in this evaluation. Only articles classified as A (suitable) or B (undetermined) were included.

Selection of clinical outcomes

The following outcomes were relevant to the study:

- Anastomotic dehiscence: bowel content discharge through the anastomosis site, with clinical symptoms. It can be confirmed using clinical or radiological methods. Analyzed globally and stratified as low colorectal, with anastomosis below the splenic flexure, and colonic, with intraperitoneal anastomosis;
- Mortality: defined as the number of intra-hospital deaths due to complications from the intervention;
- Operatory wound infection: presence of contaminated secretion at the abdominal wound.

Data collection

The following computer program was used: Review Manager (RevMan), Version 5.1. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2011), in which the relevant data were introduced and organized.

Statistical analysis

The statistical analysis was performed with Metaview (RevMan 5.1.2), using the method of absolute risk difference, with confidence interval of 95% (model of random effect)²³ and $p \leq 0.05$. The statistical heterogeneity test was used when required.

Sensitivity analysis

The sensitivity analysis was performed in two manners: the first included the trials with suitable randomization and the second included trials in which all patients had been submitted to primary anastomoses. Data were calculated for the clinical outcomes of anastomotic dehiscence and operatory wound infection.

Table 1. Literature search strategy.

#1	Search strategy of the Cochrane Collaboration for RCT ²²
#2	tw INTESTIN* or tw BOWEL
#3	tw LARGE or tw GROSSO or tw GRUESO
#4	#2 and #3
#5	tw COLO* or tw CECO
#6	tw RECT* or tw RET*
#7	#4 or #5 or #6
#8	#3 and #7
#9	tw PREPARA*
#10	tw SURGERY or SURGICAL
#11	#8 and #9 and #10
#12	#1 and #11

ECC: Randomized Clinical Trials.

RESULTS

Description of trials

The first review publication included five trials²⁴⁻²⁸, with total 824 participants: 408 patients in the group with mechanical bowel preparation (Group A) and 416 patients in the group without mechanical bowel preparation (Group B). The evidences found were insufficient to show statistical significance between the groups and a result that favored the group submitted to mechanical bowel preparation did not occur. The doubt about rectal surgery with cleansing enema appeared among the authors of some trials included and among the reviewers.

The first update included four new trials^{17,21,29,30} and total 830 patients: 414 in Group A and 416 in Group B. Heterogeneous clinical outcomes were observed, but the authors suggested to skip the mechanical bowel preparation, as it would be associated with higher incidence anastomotic dehiscence in colorectal surgery.

With the second update, five other trials were included: four published trials³¹⁻³⁴ and one unpublished trial (Jung 2006) – a personal communication of Peer Wille-Jørgensen with author Bärbel Jung in December 2006 – totaling 3167 patients: Group A=1595 and Group B=1572. The result remained without statistic difference between the groups.

The third update included six new trials^{18-20,35-37}, with total 838 patients: Group A=493 and Group B=495.

Overall, 19 published trials and one unpublished trial (Jung, 2006) were included, totaling 5,805 participants. The analysis of both groups was made in two comparisons:

- Comparison 1: With mechanical bowel preparation (Group A=2305) versus without mechanical bowel preparation (Group B=2290)^{24,37} and Jung (2006, personal communication);
- Comparison 2: Mechanical bowel preparation (Group A=601) versus rectal enema (Group B=609)^{17,21}.

The studies conducted by Van't Sant³⁷ and Jung (2006, personal communication) allowed the evaluation of some clinical outcomes only, as data were obtained from larger trials^{31,32}; they analyzed the patients submitted to low colorectal surgery.

Seven trials were excluded since the first publication, due to several reasons: series of patients³⁸; no

control group^{39,40}; data verification in congress¹³; retrospective study⁴¹; case-control study⁴²; study evaluating antimicrobial substances⁷.

Four authors of the trials included in our review^{14,18,20,24} answered our correspondence and sent data that allowed to stratify anastomoses as colic and low colorectal.

Eight trials included in our review were multi-center studies^{17,21,27,29,31,32,35} and Jung (2006, personal communication).

Some studies included procedures without anastomosis^{24,26,28,30,36}; two excluded these participants from the clinical outcome of anastomotic dehiscence^{24,36}; four excluded patients not submitted to primary anastomosis^{19,20,25,27}. Some authors performed temporary decompression of anastomosis, with ileostomy or colostomy^{18,19,35} (Table 2).

Table 2. List of trials included in the systematic review and meta-analysis.

Trial	Sample size	Mechanical preparation	
		With (Group A)	Without (Group B)
Bretagnol et al., 2010 ³⁵	178	89	89
Brownson et al., 1992 ²⁴	179	86	93
Bucher et al., 2005 ¹⁷	153	78	75
Burke et al., 1994 ²⁵	169	82	87
Contant et al., 2007 ³¹	1354	670	684
Fa-Si-Oen et al., 2005 ²⁹	250	125	125
Fillmann et al. 1995 ²⁶	60	30	30
Jung 2006 (personal contact)	44	27	17
Jung et al., 2007 ³²	1343	686	657
Leiro et al., 2008 ³⁶	129	64	65
Miettinen et al., 2000 ²⁷	267	138	129
Moral et al., 2009 ¹⁸	139	69	70
Pena-Soria et al., 2007 ³³	97	48	49
Platell et al., 2006 ¹⁹	294	147	147
Ram et al., 2005 ³⁴	329	164	165
Santos et al., 1994 ²⁸	149	72	77
Scabini et al., 2010 ²⁰	244	120	124
Tabusso et al., 2002 ³⁰	47	24	23
Van't Sant et al., 2010 ³⁷	449	236	213
Zmora et al., 2003 ²¹	380	187	193
Total*	5,805	2,906	2,899

*not including the study conducted by Van't Sant et al., 2010³⁷, which is a subanalysis of Contant et al., 2007³¹.

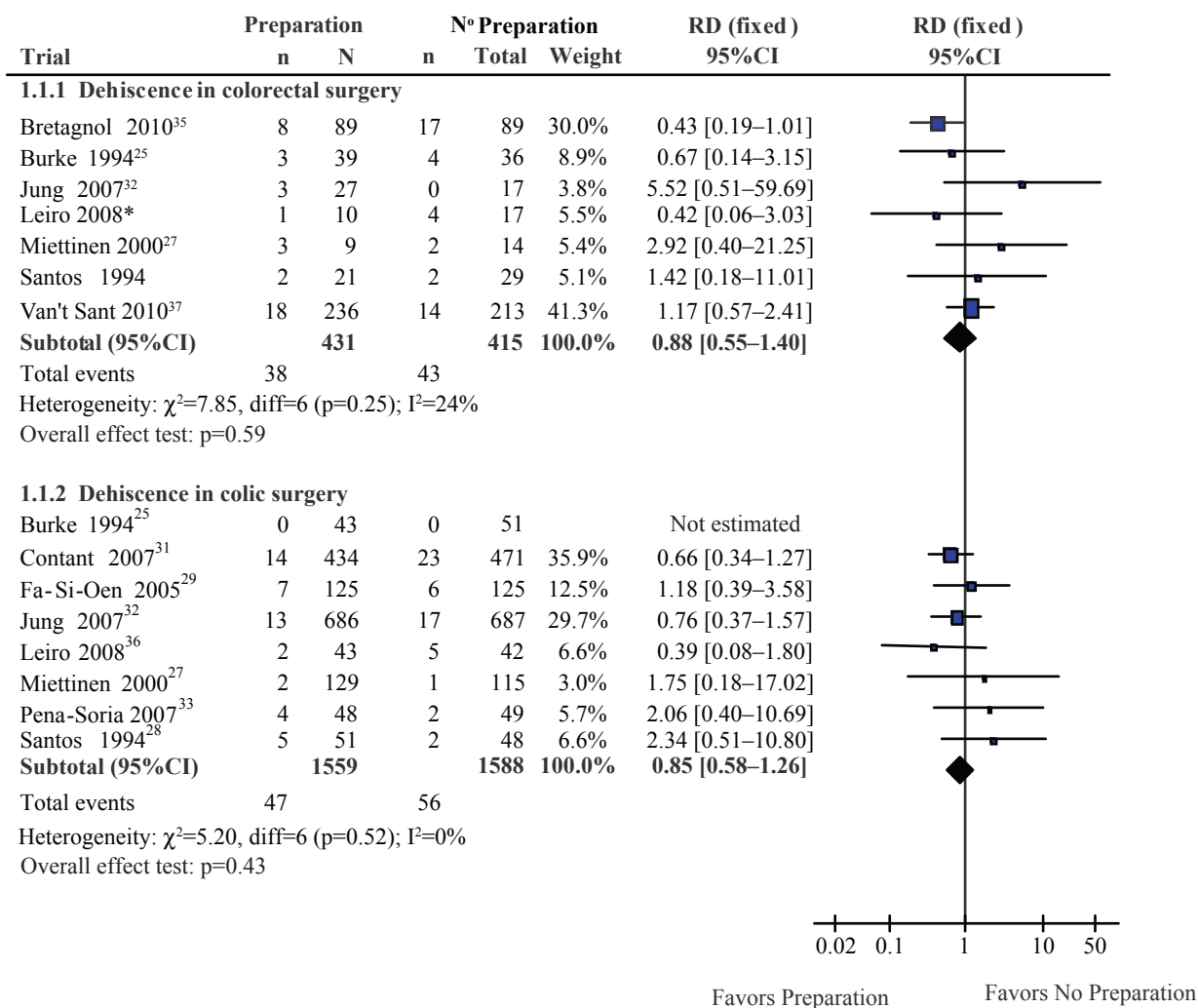
Clinical outcomes analyzed

I. Comparison 1: *With mechanical preparation versus without mechanical preparation*

(i) Stratified anastomotic dehiscence:

- Low colorectal: 88% in Group A (38 in 431 patients), compared to 10.3% in Group B (43 in 415 patients). Peto odds ratio (OR) 0.88, 95% confidence interval: 0.55–1.40: not significant. Without statistical heterogeneity in the trials included^{25,27,28,35-37} and Jung (2006, personal communication).

- Colic: 3.0% in Group A (47 in 1559 patients) compared to 3.5% (56 in 1558 patients) in Group B. Peto OR 0.85, 95% confidence interval: 0.58–1.26: not significant. Without statistical heterogeneity^{25,27,29,31-33,36}.
- Overall anastomotic dehiscence: 4.5% in Group A (104 in 2302 patients) and 4.5% (103 in 2275 patients). Peto OR 1.01, 95% confidence interval: 0.76–1.34: not significant. Heterogeneity test: χ^2 test=22.91, diff=13 (p=0.04); $I^2=43\%$ ²⁴⁻³⁶ and Jung (2006, personal communication) (Figures 1 and 2).



n: number of events; N: group; RD: risk difference; CI: confidence interval; fixed: fixed effect model.

*Personal communication with the authors.

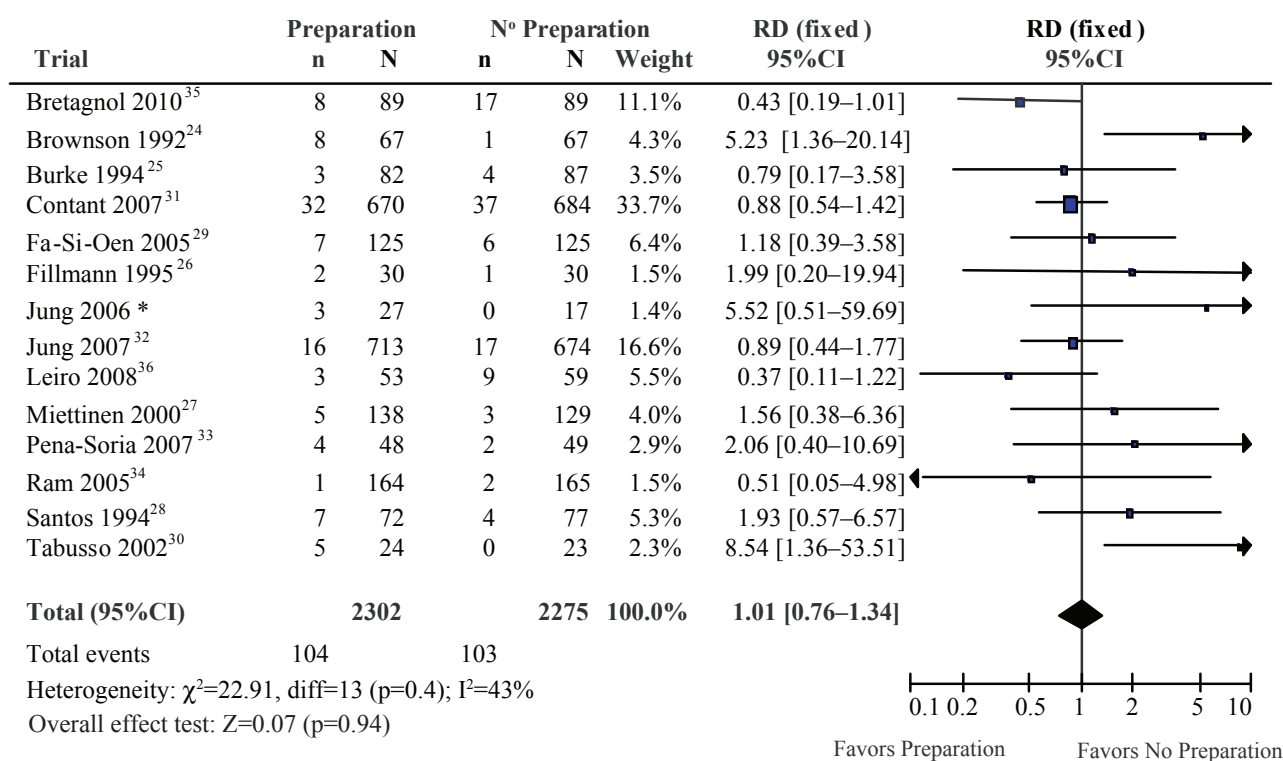
Figure 1. Representation of the results from Comparison 1: stratified anastomotic dehiscence.

- (ii) Mortality: 1.6% in Group A (35 in 2094 patients), compared to 1.8% in Group B (38 in 2072 patients). Peto OR 0.93, 95% confidence interval: 0.58–1.47: not significant. Without statistical heterogeneity^{25-28,31-36}.
- (iii) Operatory wound infection: 9.6% in Group A (223 in 2305 patients) and 8.5% in Group B (196 in 2290 patients). Peto OR 1.16, 95% confidence interval: 0.95–1.42: not significant. Without sta-

tistical heterogeneity in the trials included²⁴⁻³⁶ (Table 3 and Figures 1 and 2).

Sensitivity analysis

- (iv) Trials with suitable randomization: without statistical difference, with p values of 0.46 in Group A and 0.27 in Group B^{26-29,31-33,35,36}.
- (v) Trials in which the patients were submitted to primary anastomoses: without statistical differ-



n: number of events; N: group; RD: risk difference; CI: confidence interval; fixed: fixed effect model.

*Personal communication with the authors.

Figure 2. Chart of the results from Comparison 1: overall anastomotic dehiscence.

Table 3. Summary of the results of clinical outcomes analyzed: Comparison 1.

Clinical outcome Comparison 1		With Mechanical Preparation (Group A)	Without Mechanical Preparation (Group B)
Stratified anastomotic dehiscence	Colorectal	38/431 (8.8%)	43/415 (10.3%)
	Colic	47/1559 (3.0%)	56/1588 (3.5%)
Overall anastomotic dehiscence		104/2302 (4.5%)	103/2275 (4.5%)
Mortality		35/2094 (1.6%)	38/2072 (1.8%)
Operatory wound infection		223/2305 (9.6%)	196/2290 (8.5%)

x/x: number of events/total number of patients.

ence in the studies included and p values of 0.71 in Group A and 0.53 in Group B^{24,25,27,29,31-33,35}.

The funnel plots for clinical outcomes – overall anastomotic dehiscence and operatory wound infection – did not significant asymmetry and, consequently, no publication bias (Figure 3).

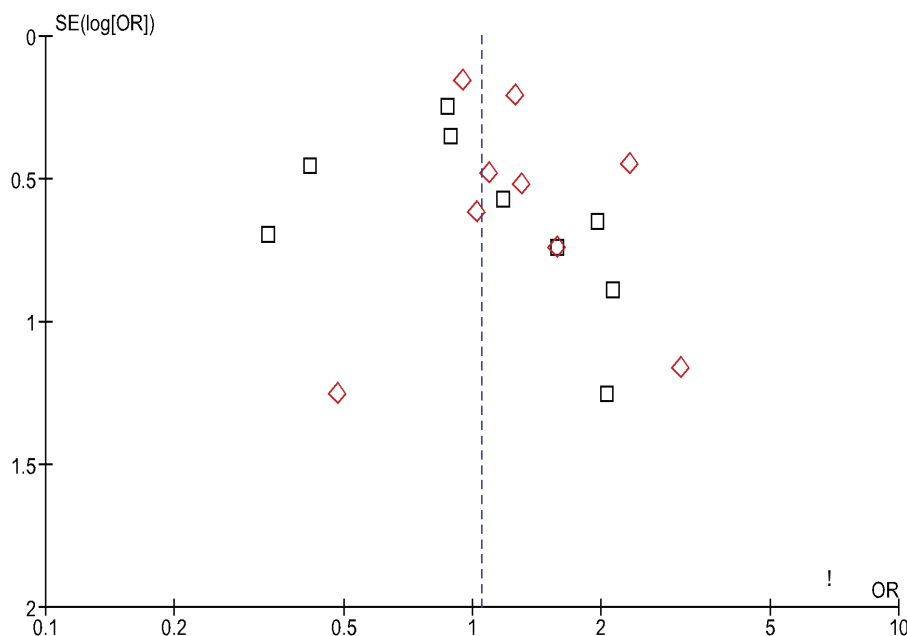
II. Comparison 2: Mechanical preparation versus rectal enema

(i) Stratified anastomotic dehiscence:

- Low colorectal: 7.4% in Group A (8 in 107 patients), compared to 7.9% in Group B (7 in 88 patients). Peto OR 0.93, 95% confi-

dence interval: 0.34–2.52: not significant. Without statistical heterogeneity^{18,20,21};

- Colic: 4.0% in Group A (11 in 269 patients) compared to 2.0% (6 in 299 patients) in Group B. Peto OR 2.15, 95% confidence interval: 0.79–5.84: not significant. Without statistical heterogeneity^{18,20,21}.
- Overall anastomotic dehiscence: 4.4% in Group A (27 in 601 patients) and 3.4% in Group B (21 in 609 patients). Peto OR 1.32, 95% confidence interval: 0.74–2.36: not significant. Heterogeneity test: χ^2 test=4.49, diff=4 (p=0.34); I²=11%¹⁷⁻²¹ (Figures 4 and 5).



EE: estimated effect; RD: risk difference; □: overall anastomotic dehiscence; ◇: operatory wound infection.

Figure 3. Funnel Plot of the meta-analysis. Sensitivity analysis presentation.

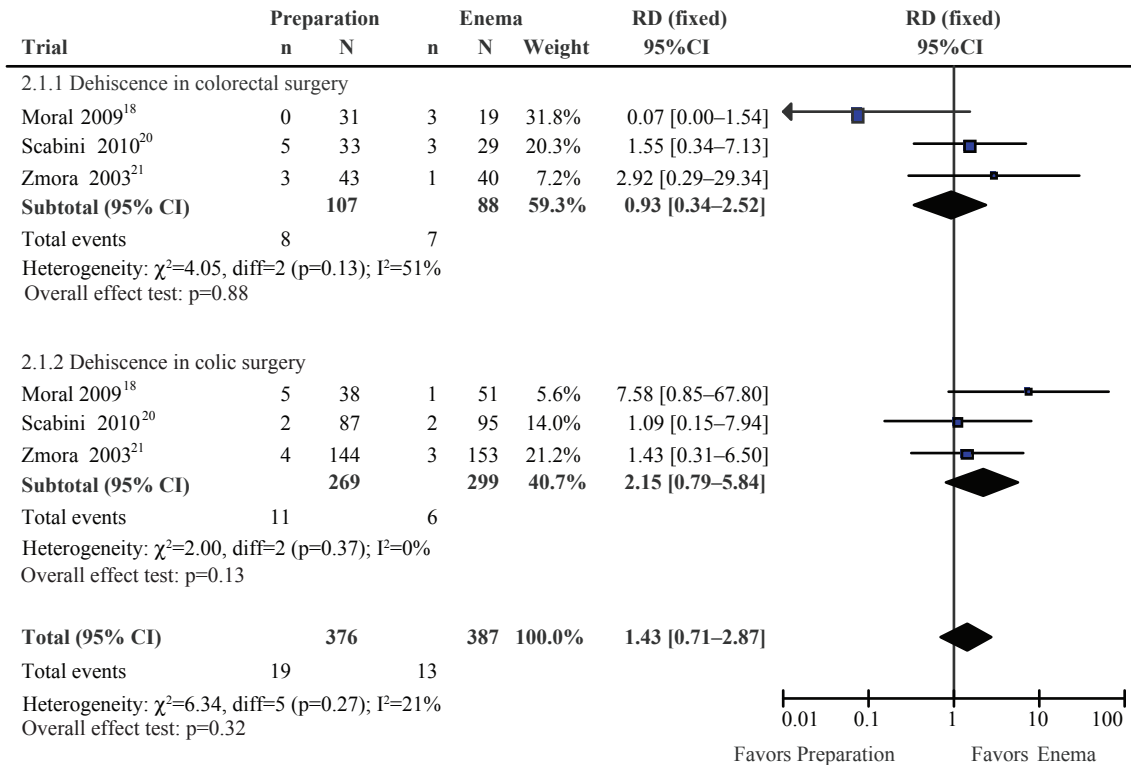
Table 4. Summary of the results of clinical outcomes analyzed: Comparison 2.

Clinical outcome Comparison 2		With Mechanical Preparation (Group A)	Rectal Enema (Group B)
Stratified anastomotic dehiscence	Colorectal	8/107 (7.4%)	7/88 (7.9%)
	Colic	11/269 (4.0%)	6/299 (2.0%)
Overall anastomotic dehiscence		27/601 (4.4%)	21/609 (3.4%)
Mortality		9/601 (1.4%)	6/609 (0.9%)
Operatory wound infection		60/601 (9.9%)	49/609 (8.0%)

x/x: number of events/total number of patients.

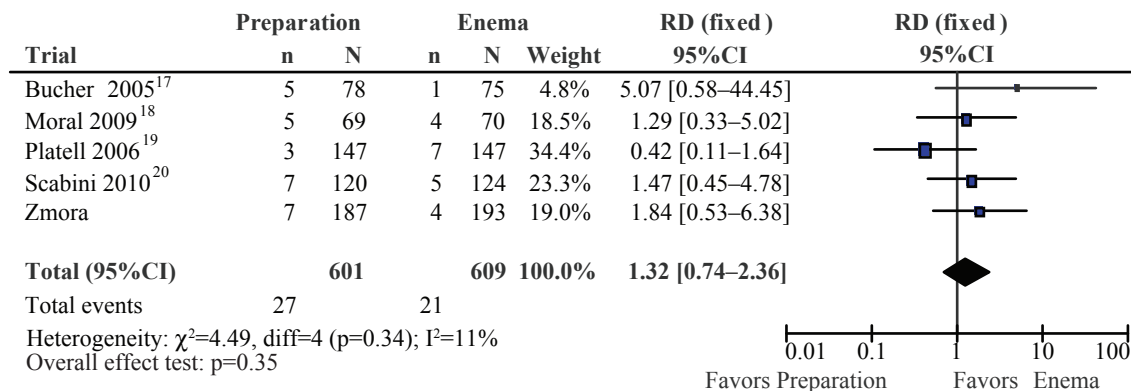
(ii) Mortality: 1.4% in Group A (9 in 601 patients), compared to 0.9% in Group B (6 in 609 patients). Peto OR 1.47, 95% confidence interval: 0.56–3.90: not significant. Without statistical heterogeneity¹⁷⁻²¹.

(iii) Operatory wound infection: 9.9% in Group A (60 in 601 patients) and 8.0% in Group B (49 in 609 patients). Peto OR 1.26, 95% confidence interval: 0.85–1.88: not significant. Without statistical heterogeneity¹⁷⁻²¹ (Table 4 and Figures 4 and 5).



n: number of events; N: group; RD: risk difference; CI: confidence interval; fixed: fixed effect model.

Figure 4. Representation of the results from Comparison 2: stratified anastomotic dehiscence.



n: number of events; N: group; RD: risk difference; CI: confidence interval; fixed: fixed effect model.

Figure 5. Chart of the results from Comparison 2: overall anastomotic dehiscence.

DISCUSSION

In the conference made by Hughes¹³ in 1972, none of the participants considered his suggestion to skip the mechanical bowel preparation in elective colorectal surgery. In 1987, when Irving & Scrimgeour⁴⁰ published their study, demonstrating in a randomized clinical trial that bowel preparation does not reduce the risks of anastomotic dehiscence, they were vehemently criticized by one of the magazine editors⁴¹. Our review, since its first publication⁴², has also received a great deal of criticism. Studies have been conducted and published along the time worldwide. And today, the reaction of the medical class, based on statistical results, has another connotation⁴³⁻⁴⁸. Studies have also changed and more careful randomization has been a constant concern of the authors, which improves the study quality⁴⁹.

Inadequate bowel preparation, with the presence of liquid content, increases the risks of infectious complications⁵⁰. Some authors have described inflammatory alterations related to the preparation, with increased infectious morbidity¹⁷.

The indication of antibiotic prophylaxis is unanimous among the authors of the included studies. Several schemes, with cephalosporins, aminoglycoside or metronidazole, were prescribed before the surgeries. In 1981, Baum et al.⁸ compared the incidence of operatory wound infection and mortality in two groups: one that received antibiotic prophylaxis and one that received placebo. The author suggested that studies without antimicrobial prophylaxis should not be conducted anymore, due to the high rate of complications.

The authors of trials included in this review used bowel preparation methods such as mannitol, polyethylene glycol, phospho soda, laxatives, glycerin solutions and diets; all of them already exhaustively tested by them, in terms of complications. We believe that there is no bias regarding this condition.

Some criticism may be received regarding, for instance, the inclusion of patients without restoration of colon continuity. We performed the sensitivity analysis, excluding these results, and no statistically significant difference was observed.

Another comment is about the surgeon's experience, which directly influences anastomosis-related complications; however, the authors of included trials describe that

the surgeries were performed by a senior surgeon, or a resident under direct supervision of the preceptor.

The methodology quality of the trial was the main condition for the trial inclusion in the analysis. Only prospective and randomized studies were selected. When these data were not in the publication, the authors were contacted for full completion of data sheet.

Multicenter studies are also subjected to bias; however, heterogeneity is dissipated when using suitable randomization and well defined inclusion and exclusion criteria.

The authors of this review believe that the inclusion of a greater number of participants will not provide a significant change in the results of clinical outcomes in elective colon surgery. An Italian study in progress may be included in our analysis as soon as it is concluded by the authors (www.clinicaltrials.gov NCT00940030).

Regarding rectal surgery exclusively, some doubts are still unsolved. New studies that analyze low anterior anastomosis (extraperitoneal position) should be included. Is the presence of stool in the rectal ampulla a condition that disturbs the surgeon at the moment of performing mechanical or manual anastomosis? Is the cleansing with rectal enema sufficient? We believe that these questions remain without an answer.

Laparoscopic surgery is another debate question. Only three trials included laparoscopic surgeries^{17,19,35} – in equal number in both groups. Some surgeons say that the solid content of bowel, combined with gravity, enables better visualization. Others believe that the movement of full and heavy bowel is more difficult. Are these truths or expert opinions? Studies that analyze groups especially and exclusively submitted to laparoscopic procedures should be included, perhaps in another review.

CONCLUSION

Implications for medical practice

Preoperative mechanical bowel preparation in elective colorectal surgery has no value in the prevention of infectious complications. This review suggests that the bowel preparation should not be performed only in cases of small tumors, which have not been submitted to colonoscopy, or when postoperative colonoscopy is required.

Implications for medical research

In terms of elective colorectal surgery, as well as laparoscopic surgery, further clinical, prospective and randomized studies should be conducted, with well defined inclusion criteria, with the discussion on whether to include, or not, patients previously submitted to radiotherapy.

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NOTE

The figures were taken from the systematic review that will be published by the Cochrane Library.

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