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Research Article

PROPHYLACTIC DRAINAGE OF EXTRAPERITONEAL COLORECTAL ELECTIVE ANASTOMOSES. A SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMIZED CLINICAL TRIALS

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ABSTRACT

Objective: To evaluate the benefits of routine prophylactic drainage in extraperitoneal anastomoses in elective colorectal surgeries. Methods: Systematic review of the literature and meta-analysis of randomized clinical trials. The electronic databases PubMed, Embase and Lilacs were searched. Included studies evaluated the benefits of routine prophylactic drainage in elective extraperitoneal colorectal surgery compared to non-drainage. Results: 9310 studies were identified. After reading the titles and abstracts, 99 studies were found to be duplicate publications and another 9,202 were excluded for not meeting the inclusion criteria. Nine studies remained for full analysis, of which five were excluded for not complying with Cochrane Collaboration eligibility criteria for controlled clinical trials. Thus, four randomized controlled clinical trials involving a total of 1147 participants were selected for data extraction and subsequent meta-analysis. Clinical dehiscence at the site of the anastomosis was compared in four studies (1120 participants, DM = 0.01, 95% CI = -0.01 to 0.03, P = 0.85, I^2 = 0%);radiological dehiscence was compared in three studies (651 participants, DM = 0.75, 95% CI = 0.38 to 1.49, P = 0.63, I^2 = 0%); mortality was compared in three studies (651 participants, DM = 0.83, 95% CI = 0.39 to 1.77, P = 0.98, I^2 = 0%); extra-abdominal infections were compared in four studies (1120 participants, DM = 0.81, 95% CI = 0.60 to 1.09, P = 0.83, I^2 = 0%); the reoperation rate was compared in three studies (1061 participants, DM = 0.97, 95% CI = 0.70 to 1.35, P = 0.14, I^2 = 48%); operative wound infection was compared in three studies (651 participants, DM = 1.02, 95% CI = 0.54 to 1.93, P = 0.26, I^2 = 25%); and intestinal obstruction compared in three studies (1020 participants, DM = 1.43, 95% CI = 0.96 to 2.13, P = 0.58, I^2 = 0%). Conclusion: in the currently available literature there is no high-quality scientific evidence demonstrating benefits from prophylactic drainage of extraperitoneal colorectal anastomoses in elective surgery.

INTRODUCTION

Techniques of coloproctological surgery for reconstructing intestinal transit have evolved to more effectively preserve the sphincter mechanism.[1]Low colorectal anastomosis and coloanal anastomosis have presented particularly marked improvement since the advent of double stapling with mechanical suturing devices, given that, besides facilitating the surgery, the technique has increased the safety of surgeries performed in extraperitoneal space. However, despite such evolution, no decrease has been observed in important surgical complications, such as anastomotic dehiscence. Fistulas due to dehiscence of the anastomosis are significant complications that could result in reoperation, severe sepsis, anastomotic stenosis, permanent stomata, longer hospitalization, death and increased hospital costs. Routine drainage of extraperitoneal anastomoses in colorectal surgery has been employed by surgeons worldwide. However, prophylactic drainage has remained controversial since it was first introduced by Theodore Billroth in 1877. The controversy over prophylactically draining extraperitoneal anastomoses in elective colorectal surgery has led to the publication of an increasing number of studies on the subject.

In 1986, Hoffman *et al*. conducted the first prospective randomized study on prophylactic drainage in intra-abdominal colonic anastomoses, concluding that there was no benefit in the evolution of anastomotic dehiscence.[2,3,4]A retrospective study by Scott *et al*. including 156 elective rectal anterior resection patients with extraperitoneal anastomosis concluded that pelvic drainage did not affect the anastomosis dehiscence

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rate (P> 0.0010).[5,6] Jesus *et al*. (2004) conducted a systematic review of prophylactic drainage in intra-abdominal colorectal surgery. The review included six randomized trials with a total of 1140 participants and compared prophylactic drainage or not following an anastomosis in elective intraperitoneal colorectal surgery. Overall mortality rates of 3% and 4% were found for drained and non-drained patients, respectively (i.e. no statistically significant difference). In their final considerations, the authors suggested that anastomosis leakage is predominantly extraperitoneal.[7] using database research, a2004 retrospective study by Peters *et al*. Determined whether anastomotic fistulas were a risk factor in patients whose anastomoses were performed under the peritoneal reflex, finding that pelvic drainage made a significant difference due to lower reoperation rates.[8]

In 2005 Bretagnol *et al*. published a systematic review and meta-analysis of three randomized trials whose participants were undergoing colorectal surgery with extraperitoneal anastomosis either with or without pelvic cavity drainage, finding against prophylactic drainage in elective extraperitoneal anastomoses.[9]In 2007 Patel *et al*. published a study on the importance of anastomotic fistulas as a clinical indicator in patients undergoing colorectal surgery, given that the presence of a fistula greatly impacts patient care, including lengthier hospital stays and increased hospital costs. The authors found that the dehiscence rate for anastomoses in the intra-abdominal cavity was less than 1.5%, whereas it was up to four times greater for extraperitoneal anastomoses, thus significantly elevating morbidity and mortality rates.[10,11,12]In 2013 Rondelli *et al*. performed a systematic review and meta-analysis of randomized clinical trials and non-randomized studies whose participants were undergoing colorectal surgery with extraperitoneal anastomosis. The results of the meta-analysis, which investigated the role of prophylactic extraperitoneal pelvic drainage in colorectal anastomosis, were that pelvic drainage is useful for preventing fistula formation in colorectal anastomoses and reduces the reoperation rate, especially in patients with intraoperative complications.[13] Zhang *et al*. (2016) published a meta-analysis of randomized studies evaluating the drainage of intraperitoneal and extraperitoneal colorectal anastomosis, concluding that routine use of prophylactic drainage in colorectal anastomosis does not reduce postoperative complications.[14]

In light of this state of affairs, the objective of this review was to evaluate whether the prophylactic drainage of an extraperitoneal anastomosis in elective colorectal surgery confers any benefit.

METHODS

We conducted a systematic review of the literature with a meta-analysis of randomized clinical trials on the benefits of prophylactically draining extraperitoneal colorectal anastomoses in elective surgeries. The review was conducted according to methodological guidelines outlined in the *Cochrane Handbook for Systematic Reviews of Interventions*.[15]The study was approved by the Research Ethics Committee of UNIFESP, EPM.

Search strategy and eligibility criteria

An electronic search was performed in the Pubmed, Embase and Lilacs databases for studies published between 1972 and December 2016, irrespective of language or publication type. Two authors independently assessed the titles and abstracts, and publications meeting the eligibility criteria were separated for a complete reading and detailed analysis. The included studies evaluated the benefits of prophylactic drainage over non-drainage in elective extraperitoneal colorectal anastomosis.

Selection of studies for meta-analysis

Two reviewers independently assessed the data extracted from the selected studies through a standardized form. The risk of bias in each included study was assessed according to Cochrane Collaboration recommendations using a tool called the Bias Risk Table. The quality of the evidence was evaluated according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.[16] Homogeneous results from the studies were grouped and summarized in the form of forest plots, and the quantitative or meta-analysis was performed in Review Manager version 5.3.[17] For outcomes in which quantitative analysis could not be performed, the results of the individual studies were presented as a narrative (qualitative synthesis).

Outcomes evaluated

The primary endpoint was assessed in relation to clinical anastomotic dehiscence. Secondary outcomes were divided into radiological evaluation of the anastomosis, mortality, surgical wound infection, infection of extra-abdominal sites, intestinal obstruction and ostomy closure up to 6 months postoperatively.

Statistical analysis

For dichotomous outcome data, the relative risk (RR) was calculated using a 95% confidence interval (95% CI). For continuous outcome data, the difference of means (DM) with a 95% CI was calculated. If different outcome scales or scores were used in outcome data grouped for meta-analysis, the standardized mean difference (SMD) with a 95% CI was calculated. The presence of statistical heterogeneity between studies was determined using the chi-square test (chi2). The extent of heterogeneity was assessed using the I^2 statistic. As recommended by Higgins and Green (2011),[18] I^2 values greater than 50% were considered indicative of significant heterogeneity between studies in the same meta-analysis. Where there was no heterogeneity or heterogeneity less than or equal to 50%, the analyses were performed using fixed-effect models. In the presence of significant inter-study heterogeneity (I^2> 50%), the analyses were performed using random effects models, and the clinical and methodological differences between the studies were explored to investigate potential causes of heterogeneity.

RESULTS

A total of 9310 studies were identified in the electronic databases. After reading the titles and abstracts, 99 duplicate studies were excluded and another 9202 were excluded because they did not comply with Cochrane Collaboration guidelines. Nine studies remained for full reading by the reviewers (Figure 1). After full review, five of these were excluded for not

conforming to Cochrane Collaboration controlled clinical trial eligibility criteria (Table 1). Thus a total of four controlled clinical trials including a total of 1147 participants were selected for meta-analysis, (Table 2).

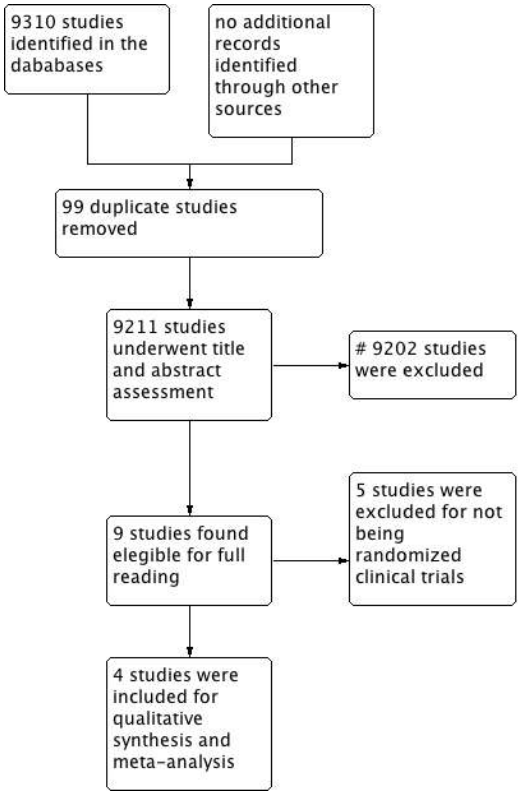

Figure 1 Flowchart ofstudy selection for systematic review

Table 1 Characteristics of the excluded studies.

Johnson *et al.* 1987 [23]	**Prospective quasi-randomized study, low scientific evidence and high risk of allocation bias**
Yeh *et al*. 2005 [24]	Prospective non-randomized study
Tsujinaka *et al*. 2008 [25]	Prospective non-randomized study
Akiyoshi *et al*. 2011 [26]	Prospective non-randomized study
Guinkova *et al*. 2013 [27]	Prospective non-randomized study

Table 2 Characteristics of the included studies.

Sagar *et al*. (1994)	Randomized clinicaltrial
Merad *et al*. (1999)	Randomized clinicaltrial
Brown *et al*. (2001)	Randomized clinicaltrial
Denost *et al*. (2016)	Open-label randomized clinical trial

Two studies (Brown, 2001; Denost, 2016)[19,20] evaluated only individuals with malignant rectal tumours,while the other two studies (Sagar 1994; Merad, 1999)[21,22] evaluated malignant tumours and other benign pathologies affecting the large intestine that called for surgical treatment and anastomosis. One study (Sagar, 1994) evaluated 8 patients in the control group and 6 patients in the intervention group who underwent emergency operations. One study (Merad, 1999) included participants with pathologies located throughout the large intestine, provided that resection was elective and anastomosis was performed in the pelvic space below the promontory at or below S3 in the rectum or anus. However, when evaluating the results, the authors divided anastomoses in the supraperitoneal space from rectal anastomoses in the infraperitoneal region, the latter being subdivided into rectal anastomosis and anal canal anastomosis.

All included studies had a low risk of bias for participant blinding. The risk of bias was uncertain with respect to the outcome assessors, since they were not described in the four studies (Figure 2).

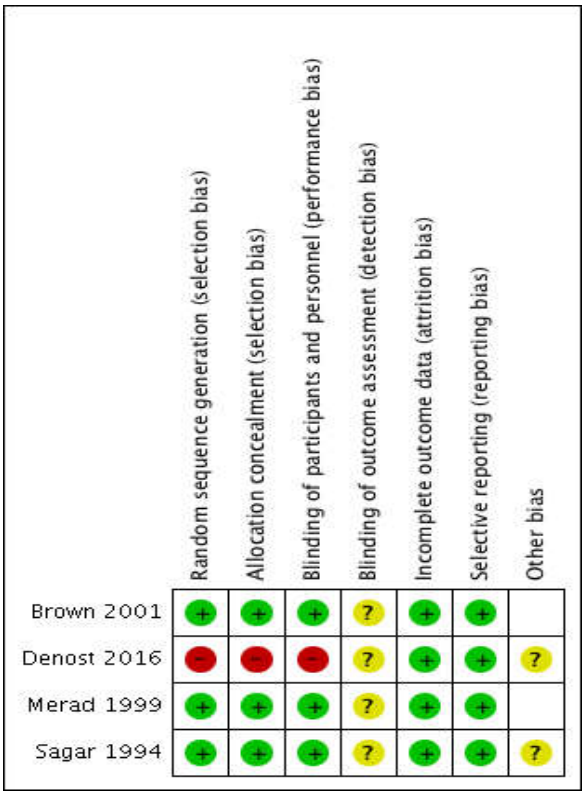

Figure 2 Risk of bias summary: the authors' decisions about each risk of bias item for each included study. Green indicates a low risk of bias, yellow indicates an uncertain risk of bias and red indicates a high risk of bias.

Intervention effects

Clinical anastomotic dehiscence was compared in the four studies through a meta-analysis of 1120 total participants, DM = 0.01; 95% CI = (-0.01 to 0.03); P-value = 0.85, and no clinically significant difference was found; Heterogeneity (I^2) = 0% (Figure 3).

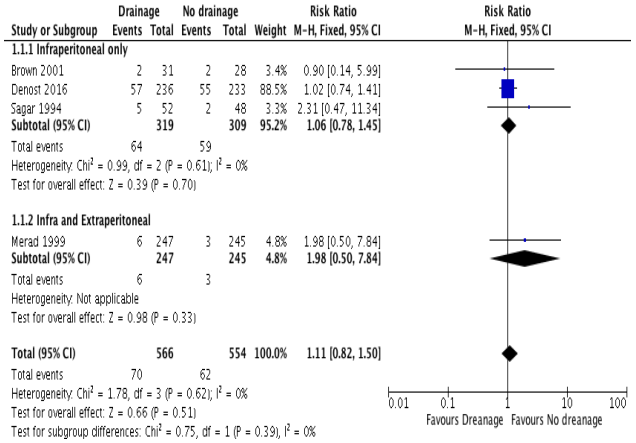

Figure 3 Forest plot comparingthe effects of anastomosis drainagevs. non-drainageonpostoperative clinical dehiscence.

Radiological anastomotic dehiscence was compared in 651participants from three studies, DM = 0.75; 95% CI = (0.38 to 1.49); P-value= 0.63; Heterogeneity (I^2) = 0%, andno clinically significant difference was found (Figure 4). Mortality was compared in 651 participants from three studies, DM = 0.83; 95% CI = (0.39 to 1.77); P-value = 0.98.

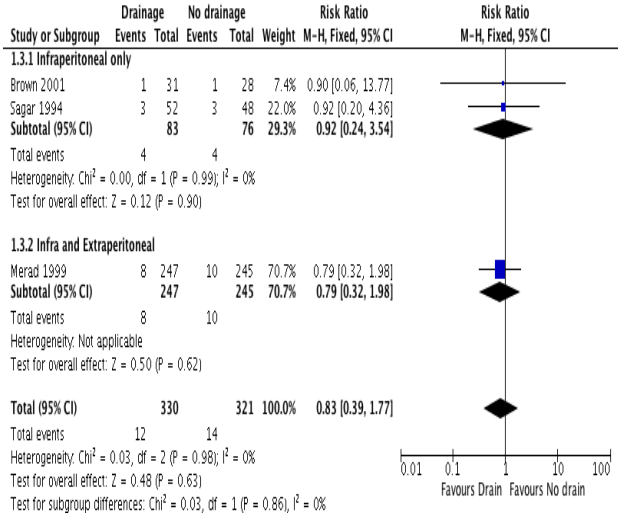

Figure 4 Forest plot comparingthe effects of anastomosis drainagevs. non-drainageon postoperative radiological dehiscence.

Heterogeneity (I^2) = 0%, andNo clinically significant difference was found (Figure 5).

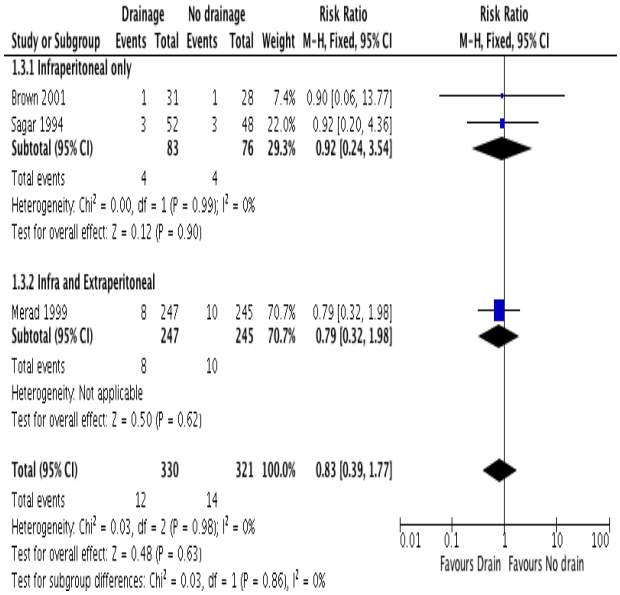

Figure 5 Forest plot comparingthe effects of anastomosis drainagevs. non-drainageonpostoperative mortality.

Infection in extra-abdominal sites was evaluated in 1120 participants from four studies, DM = 0.81; 95% CI = (0.60 to 1.09); P-value = 0.83; Heterogeneity (I^2) = 0%, and no clinically significant difference was found (Figure 6).

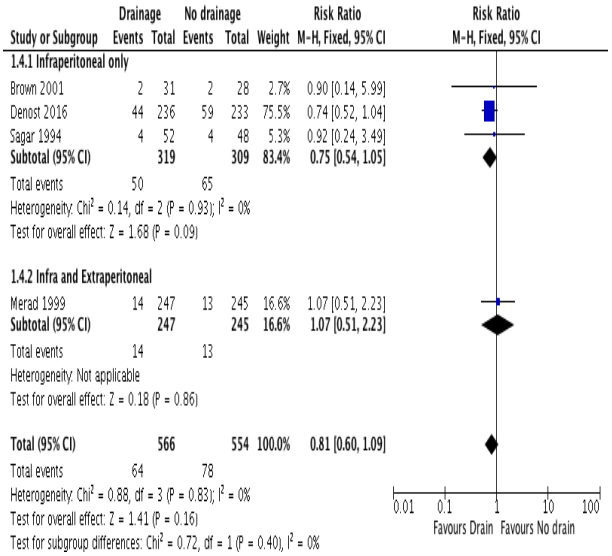

Figure 6 Forest plot comparingthe effects of anastomosis drainagevs. non-drainageon postoperative infection in extra-abdominal sites.

The reoperation rate was assessed in 1061 participants from three studies, DM = 0.97; 95% CI = (0.70 to 1.35); P-value = 0.14; Heterogeneity (I^2) = 48% (significant heterogeneity> 50%), and no clinically significant difference was found (Figure 7).

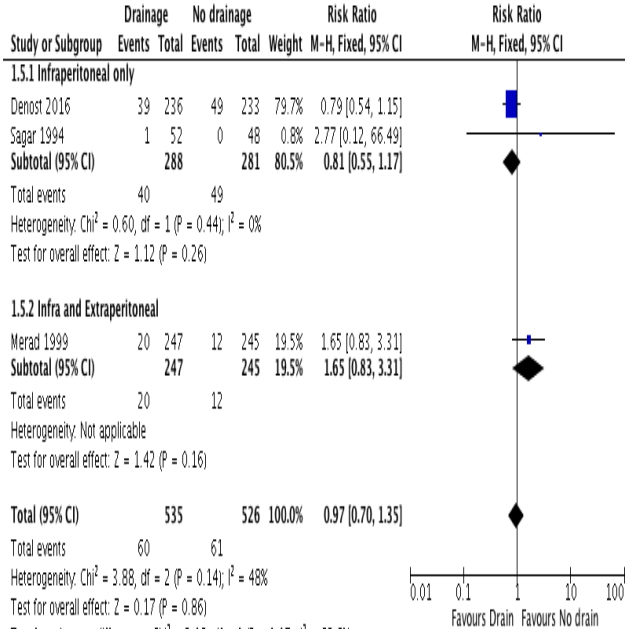

Figure 7 Forest plot comparingthe effects of anastomosis drainagevs. non-drainageon postoperative reoperation rate.

Surgical wound infection was evaluated in 651 participants from two studies, DM = 1.02; 95% CI = (0.54 to 1.93); P-value = 0.26; Heterogeneity (I^2) = 25%, and no clinically significant difference was found (Figure 8).

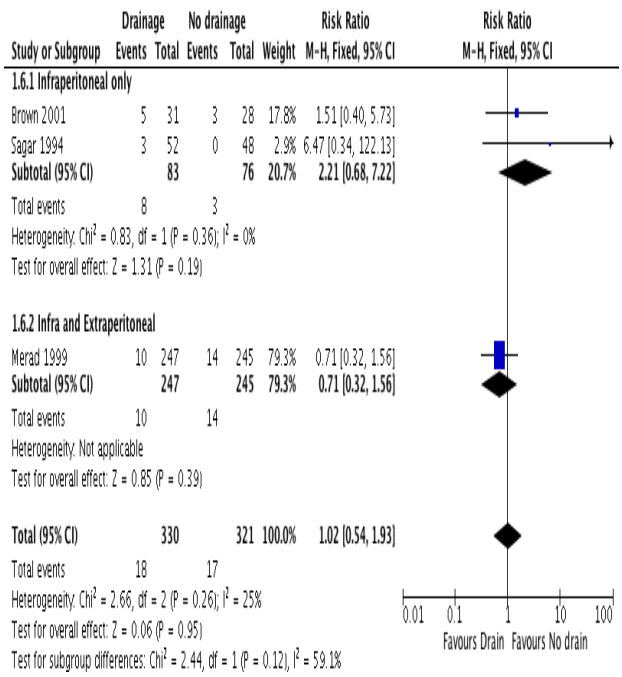

Figure 8 Forest plot comparing the effects of anastomosis drainagevs. non-drainage on postoperative surgical wound infection.

Intestinal obstruction was assessed in 1020 participants from three studies, DM = 1.43; 95% CI = (0.96 to 2.13); the P-value = 0.58; Heterogeneity (I^2) = 0% and no clinically significant difference was found (Figure 9). Only Denost *et al*. (469 total participants) described the ostomy closure rate over a six-month follow-up period.

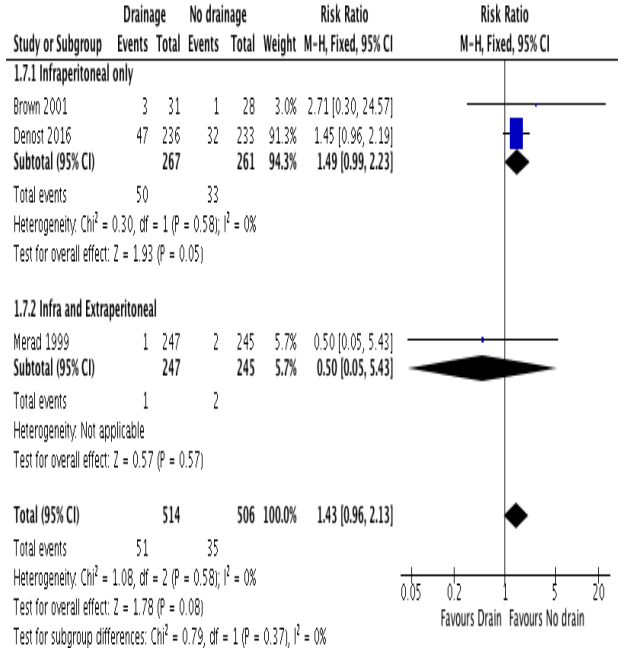

Figure 9 Forest plot comparing the effects of anastomosis drainagevs. non-drainage on postoperative intestinal obstruction.

Subgroups were created for each outcome in the forest plots (Figures 3-8) to evaluate the results of Merad *et al*.(492 total participants), since they discriminated between supra- and infraperitoneal anastomoses.

DISCUSSION

This review evaluated the potential benefits of prophylactically draining extraperitoneal colorectal anastomoses in elective procedures. Seven outcomes were evaluated during the participants' in-hospital period and outpatient follow-up until the sixth postoperative month. After an extensive systematic search of the literature, four randomized clinical trials were included with a total sample of 1147 participants. Meta-analysis of the primary endpoint was possible in the four included studies, as were the secondary endpoints in most of them. No significant heterogeneity was observed between the studies, except for the participants' clinical characteristics and certain procedures, such as the inclusion of patients with different preoperative colon preparations, the use of different types of drains, different types of colorectal disease, different stages of malignant diseases, the inclusion of a small sample of urgently treated patients, with or without intervention analysis. Although these features involve variables theoretically capable of influencing the incidence of complications, they are not effectively determinant. Thus, from a methodological, statistical and risk of bias point of view, the studies included in this investigation could be considered homogeneous.

Based on the results of the included studies, we can conclude that there was no statistically significant difference in the described outcomes (i.e., clinical dehiscence, radiological dehiscence, mortality, surgical wound infection, extra-abdominal infection, reoperation and intestinal obstruction) between the intervention group, which consisted of participants whose extraperitoneal colorectal anastomoses were drained, and non-drained controls.

Our investigation can be considered an update and methodological improvement of Bretagnol *et al*.(2005), a systematic review and meta-analysis of three randomized clinical trials comparing patients who underwent elective colorectal surgery with extraperitoneal anastomosis with or without prophylactic drainage. These authors emphatically concluded that draining extraperitoneal anastomoses does not protect against the occurrence of clinical dehiscence in the postoperative period, in contrast with the results of a retrospective observational study by Peeters *et al*. (2005), who concluded that placing one or more pelvic drains may limit the consequences of anastomosis failure. It is important to point out that Bretagnol *et al*.admittedtheir study was limited by a high risk of bias and a small sample size.

Rondelli *et al*. (2013), on the other hand, performed a systematic review and meta-analysis of three randomized clinical trials and five observational studies evaluating prophylactic drainage in elective extraperitoneal colorectal anastomoses. Their meta-analysis, when considering only the included randomized clinical trials, also showed no benefits from the drainage procedure; however, when the observational studies were considered, an association was found between the intervention (drainage) and a lower incidence of clinical anastomotic dehiscence. It is also important to point out that these authors did not perform arisk of bias assessment in their study.

A review and meta-analysis by Zang *et al*. (2016) included eleven randomized clinical trials evaluating the prophylactic drainage of anastomoses in routine intra- and extraperitoneal

colorectal surgery and concluded that drainage did not reduce postoperative complications. In our opinion, their inclusion of participants with intraperitoneal anastomoses involves an important sampling bias, since a number of studies have recognized that intraperitoneal anastomosis has a lower risk of complications than extraperitoneal anastomosis.

The included studies presented a degree of variability with respect to certain clinical and methodological aspects that might influence the results of a review, which could affect the applicability of the results for clinical practice.

This variability includes outpatient follow-up time, which in our study was performed within the first 30 days after discharge, with no significant difference observed in the effects of anastomotic drainage. It should be pointed out that the vast majority of anastomotic complications occur within this postoperative time period.

Regarding the nature of the included patients' conditions, it is noted that while some authors (Brown *et al*. and Denost *et al*.) included only participants with adenocarcinoma of the rectum, others (Sagar *et al*. and Merad *et al*.) included participants with benign and malignant diseases. Although this clinical heterogeneity is quite frequent in the literature, it is possible that the effect of randomization could minimize the occurrence of bias when comparing anastomosis groups with and without drainage.

Other variables that should be considered as inducing some bias are the experience level of the surgeons who performed the procedures and the surgical techniques employed. Thus, multicenter studies such as Denost *et al*., Sagar *et al*. and Merad *et al*., involved different skill levels as well as laparotomic and videolaparoscopic procedures in their analyses. The degree of influence that such variables have on outcomes could also be minimized by the random nature of patient inclusion in clinical trials, and analysis by subgroups could be a methodological solution for this effect.

The types of drains and the different techniques of peritoneal cavity drainage were not considered in the studies included in this systematic review and meta-analysis and, undoubtedly, could have influenced the results of the outcomes. The scope of this study, however, was to determine whether a drainage procedure could be recommended or not based on its intervention effects, leaving specific types and techniques of drainage as foci for future investigations.
The relevance of our research question and the magnitude of the controversy over whether to drain or not increases in light ofthe fact that coloanal anastomosis, which involves a very distalsuture application, is increasingly performed due to the considerable technological evolution in recent times. Nevertheless, in our sample few such anastomoses were observed.

It should be highlighted that this systematic review included only studies with a methodologically adequate randomization process and classified as low risk of bias. Moreover, the large sample size (n = 1147) should have sufficient statistical power to demonstrate the existence of any outcome differences between groups. The recommendations of the *Cochrane Handbook for Systematic Reviews of Interventions* were rigorously observed for all stages of the review, which, combined with a broad and sensitive search strategy, allowed the literature to be tracked and updated, potentially including the vast majority of existing clinical trials.

Given the results obtained in this review, our proposal for general clinical practice is that drains should not be placed prophylactically in elective extraperitoneal colorectal anastomoses. The use of drains in the pelvic cavity is not free of complications, which can include pain at the drain site, intestinal loop perforation or vascular injury due to the drain, and more bedridden patients, which promotes respiratory infection. However, the final decision to prophylactically drain an elective extraperitoneal colorectal anastomosis will depend on factors such as the surgeon's clinical experience and the patient's comorbidities and should always take into account evidence from sound systematic reviews, as well as the possible complications inherent in a drainage procedure.

We also believe that further randomized clinical trials of high methodological quality and greater homogeneity should be conducted in the future. Considering its multifactorial aspect, studies on colorectal anastomosis should allow for patients with the same coloproctological condition to be grouped together. Thus, we also suggest that future clinical trials evaluate a single disease and a single type of surgical procedure.

CONCLUSION

The results of this investigation show that there is currently no high-quality scientific evidence available in the literature demonstrating the benefits of prophylactically draining extraperitoneal colorectal anastomoses in elective surgery.

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