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A Meta-Analysis of Randomized Controlled Trials on the Use of Suction Drains Following Rectal Surgery

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Keywords
Pelvic anastomosis · Extraperitoneal anastomosis · Colorectal surgery · Drain

Abstract
Background: Anastomotic leakage is one of the most feared complications of rectal resections. The role of drains in limiting this occurrence or facilitating its early recognition is still poorly defined. We aimed to study whether the presence of prophylactic pelvic drains affects the surgical outcomes of patients undergoing rectal surgery with extraperitoneal anastomosis. ***Methods:*** PubMed, EMBASE, and the Cochrane Library were systematically searched for randomized controlled trials comparing drained with undrained anastomoses following rectal surgery. We evaluated possible differences on the relative incidences of anastomotic leakage, pelvic collection or sepsis, bowel obstruction, reoperation rate, and overall mortality. A meta-analysis of relevant studies was performed with RevMan 5.3. ***Results:*** A total of 760 patients from 4 randomized controlled studies were considered eligible for data extraction. The use of drains did not show any advantage in terms of anastomotic leak (OR 0.99), pelvic complications (OR 0.87), reintervention (OR 0.84) and mortality. Contrariwise, the incidence of postoperative bowel obstruction was significantly higher in the drained group (OR 1.61). ***Conclusions:*** The routine utilization of pelvic drains does not confer any significant advantage in the prevention of postoperative complications after rectal surgery with extraperitoneal anastomosis. Moreover, a higher risk of postoperative bowel obstruction can be of concern.

Introduction

The diffusion of minimally invasive surgery – together with the introduction of total mesorectal excision and multimodal treatment, especially neoadjuvant chemoradiotherapy – has dramatically enhanced the outcomes of patients undergoing rectal surgery over the last decades [1–5]. Despite this, the incidence of postoperative morbidity and mortality, essentially connected with the occurrence of anastomotic failure, continues to be noticeable regardless of surgical approaches and techniques [5–7].

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Historically, the presence of a pelvic drainage has been considered having the potential to reduce the incidence of anastomotic fistula, or at least to limit its clinical relevance [8–10]. Indeed, the utilization of a prophylactic drain theoretically allows the egress of possible extraperitoneal fluid collections, thus limiting the risk of subsequent contamination [8–9]. Second, it is thought that in the case of anastomotic leakage, it might help in its early detection and thus facilitate its appropriate and prompt management [8–10]. Conversely, according to some authors, the employment of a prophylactic drain in the case of extraperitoneal anastomosis does not have clear advantages on surgical outcomes and possibly can do more damage than good [8, 11, 12].

Actually, while there is a relative consensus for drain placement in the presence of a recognized risk of bleeding or anastomotic failure [8, 10], the use of prophylactic drains on a routine basis is still debatable [10, 13–15]. This focus has been investigated by a number of studies (including some meta-analyses) over the last decades for different abdominal surgeries. Despite this, specific data on systematic drainage following rectal surgery with extraperitoneal anastomosis, such as low colorectal, coloanal, or ileoanal anastomosis are still scarce [8–10, 16].

Therefore, the purpose of this study is to systematically assess the available inherent literature to investigate whether prophylactic drainage provides any appreciable advantage on the surgical outcomes of patients undergoing rectal surgery featuring extraperitoneal anastomosis.

Methods

Preferred Reporting Items for Systematic reviews and Meta-Analyses standard guidelines [17] were followed in order to identify randomized controlled trials (RCT) reporting on surgical outcomes of drained versus undrained patients following rectal resection with primary anastomosis, including colorectal, rectorectal, coloanal and ileorectal, or ileoanal anastomosis. Before data collection, an itemized protocol to perform the analysis was produced. Data for meta-analysis were extrapolated from the eligible manuscripts following the pre-established pattern. Two authors (F.G. and G.G.) performed an independent literature search up to October 9, 2016. The PubMed/Medline, EMBASE, and Cochrane databases were searched with the following words: "colorectal surgery" OR "rectal surgery" OR "rectum" AND "extraperitoneal drain" OR "infraperitoneal drain" OR "pelvic drain" OR "pelvic drainage". English language was the only restriction adopted for the search strategy. Case reports and small series with <10 patients were also excluded.

The 2 authors independently screened titles and abstracts of the retrieved records. Differences in opinion were solved by discussion and the input of a third author (D.C.) was required, where needed. Full-text versions of the studies considered for inclusion were appraised and all references were hand-searched to find additional, eligible works.

Potentially eligible reviews were investigated and eventually included in the meta-analysis if the following criteria were met:

Patients undergoing rectal resection were included

Randomized trials were performed with a group of patients with prophylactic drain placement and a comparator group without drain.

Detailed data on surgical outcomes of patients with extraperitoneal anastomosis (including colorectal, rectorectal, coloanal, ileorectal, or ileoanal anastomosis) were available.

According to the preestablished protocol, from each eligible study, 2 independent reviewers (G.G. and D.C.) retrieved the following data: study design, number of patients, indication for surgery and type of procedure, anastomotic leakage, postoperative pelvic complication (intended as the presence of pelvic collection with or without clear signs of fecal contamination), postoperative bowel obstruction, postoperative length of hospital stay, and overall mortality. When the same authors published multiple studies with overlap among patients groups, the most recent or the one with the most informative relevant data was considered.

Eventual discrepancy between the 2 authors on the extracted data was resolved by consensus. The Cochrane Handbook for Systematic Reviews of interventions [18] served as a guideline to assess methodological quality of the included RCTs

Statistical Analysis

Values are presented in descriptive statistics. Statistical analysis was performed using the Statistical Package for the Social Sciences version 20.0 (SPSS Inc., Chicago, IL, US). Meta-analyses of RCTs were performed using Review Manager 5.3 (Cochrane Collaboration, Oxford, England). The drain effect was described by OR such that a given value <1 favors the presence of the drain. The weighted pooled ORs were calculated under the fixed effects model and reported with a 95% CI. Statistical heterogeneity was assessed by inspecting the forest plots and I^2 statistics.

The Z-test for overall effect and its 2-sided p value were also assessed. Discrete variables were analyzed using the X^2 or the Fisher exact test. Statistical significance was set at the 0.05 probability level.

Results

Studies Selection

The electronic search yielded 3,403 records. On the basis of titles and abstract, a total of 27 potentially relevant articles were identified. Six further studies were identified through hand searching of references. After the evaluation of full-texts, 4 studies [12, 13, 19, 20] eventually met all the inclusion criteria and were included in the meta-analysis. The flow diagram in Figure 1 describes the selection process. Studies and patients characteristics are summarized in Table 1.

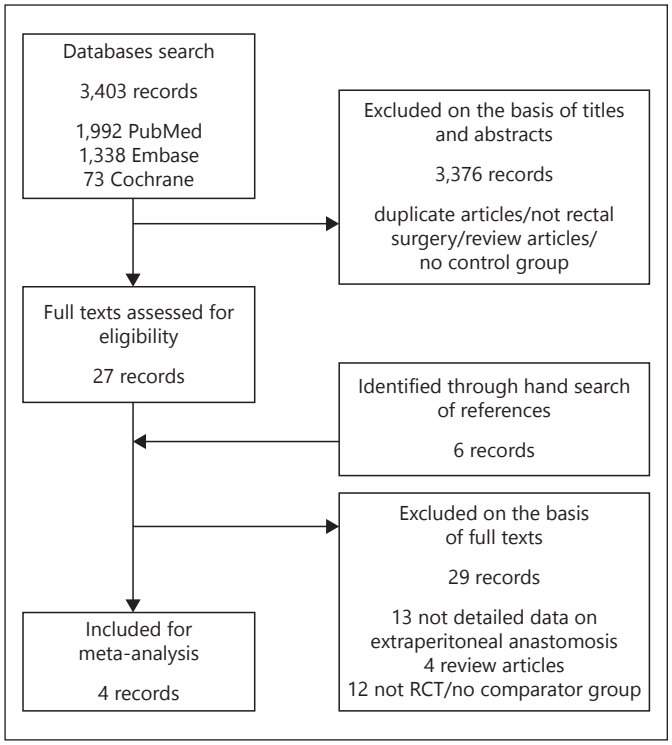

Fig. 1. Flow diagram describing the selection process.

Quality Assessment and Risk of Bias

All 4 RCTs reported appropriate random sequence generation and allocation concealment. Overall, all studies presented unclear risk of blinding bias as well as low risk of attrition and reporting bias. All RCTs were open label studies and the most apparent methodological limit was the lack of specific description of outcome assessment and detailed criteria for outcomes diagnosis. A summary of risk of bias summary is presented in Figure 2. In all measurements, the inspection of forest plots and the I^2 index revealed a low risk of heterogeneity (I^2 = 0–36%)

Characteristics of Patients and Procedures

A total of 760 patients were finally included in the analysis, 382 patients with drains and 378 patients without drains.

Three [12, 13, 20] of the included studies were from Europe and one from Asia [19]. Three studies included only patients with extraperitoneal anastomoses [12, 13, 19], whereas the other RCT [20] referred to any type of anastomosis following rectal surgery but provided specific data concerning the group of patients with extraperitoneal anastomosis (132 patients out of 494). In all RCTs, closed suction drains were used. In 3 [12, 19, 20] out of the 4 trials, drains were removed at the surgeon's discretion, while in the other trial [13], drains were maintained until postoperative day 7.

With regard to surgical procedures, 3 out of the 4 included studies [12, 13, 19] provided detailed data covering a total of 628 patients. In particular, 606 patients (96%) received colorectal or coloanal anastomosis following anterior rectal resection (599 patients) or Hartmann reversal (7 patients), while 29 patients (4%) had ileorectal or ileoanal anastomosis following total colectomy (9 patients) or restorative proctocolectomy (13 patients).

The same 3 studies [12, 13, 19] provided detailed data about surgical indications. Overall, 584 out of 628 patients (93%) received surgery for cancer, while 44 patients (7%) received surgery due to benign disease. Of note, 24 patients (4%) received surgery for inflammatory bowel disease [13].

Two out of the 4 RCTs reported anastomotic height. The median level of anastomosis was 4–5 centimeters as reported by Brown et al. [19], while it was at a mean of 3.5 (±1.9) centimeters as reported by Denost et al. [12].

Only one study provided specific data on the administration of neoadjuvant treatments; no statistically significant difference was present between drained and undrained patients on the relative percentage of patients who had preoperative therapy [12].

Outcomes Evaluation

With regard to anastomotic failure, all included studies had specific data described in detail. Overall, 106 patients (14%) had clinical or radiological anastomotic leak with no statistically significant difference between drained (53 out 382) and undrained (53 out 378) patients (Fig. 3a; OR 0.99, 95% CI 0.65–1.49, $p = 0.95$).

The trials by Brown et al. [19] and Sagar et al. [13] provided specific data divided between clinical and radiological anastomotic leakages. No statistical difference was noted in the incidence of clinical or radiological anastomotic failures on 159 patients (drain: 81, no drain 78, $p = 0.36$). Notably, clinical leaks were noted in 7 patients with drain and in 3 patients without drain, whereas radiologic failures were detected in 3 patients with drain and 6 patients without drain.

Circumstantial data on postoperative pelvic collection and/or sepsis were provided by 3 [12, 13, 20] of the included studies. In total, 76 out of 701 patients experienced some pelvic complications (11%). The 2 relative incidences were 10% (36 out of 351 patients) and 11% (40 out of

Table 1. General characteristics of the included studies

	Sagar et al. [13]	Merad et al. [20]	Brown et al. [19]	Denost et al. [12]
Year	1995	1999	2000	2016
Patients	100	132	59	469
Drained	52	63	31	236
Undrained	48	69	28	233
Male to female ratio	50/50	249/245*	36/23	316/153
Randomization	1:1 (after anastomosis)	1:1 (after anastomosis)	1:1 (before surgery)	1:1 (before surgery)
Age				
Drained	64 (19–89)	66 (30–92)*	66 (36–85)	64±11.5
Undrained	58 (17–82)	66 (24–98)*	64 (41–85)	65.5±11.4
Indications for surgery	Malignancy and benign disease (including inflammatory bowel disease)	Malignancy and benign disease (including inflammatory bowel disease)	Malignancy	Malignancy
Preparation	Yes	Yes	Yes	Yes
Technique	Open	Open	Open	Laparoscopy (93%)
Level of anastomosis (centimetres from anal verge)	n/a	n/a	n/a	3.5±1.9
Drained	n/a	n/a	4 (1–9)	3.4±1.9
Undrained	n/a	n/a	5 (2–8)	3.5±2.0
Type of anastomosis, *n* (%)				
Hand sewn	n/a	67 (51)	n/a	207 (46)
Stapled	n/a	65 (49)	n/a	262 (54)
Type of drain	Suction	Suction	Suction	Suction
Days with drain	7	<5	2–3	5.6±3.7
Stoma creation, *n* (%)	None	n/a	41 (69)	351 (75)
Neoadjuvant therapy	n/a	n/a	None	325 (69)

Data are presented as medians (with ranges) or means (with SDs) depending on availability from the included reports.
* Data are referred to the whole series.
n/a, data not available from the included reports.

350) for drained and undrained patients respectively (Fig. 3b; OR 0.87, 95% CI 0.54–1.40, $p = 0.57$).

From the data provided by 2 studies [12, 19] including a total of 528 patients, the relative rates of postoperative intestinal obstruction were investigated. Clinically relevant postoperative intestinal obstruction was experienced by 83 patients (16%) – 50 patients in the drain group and 33 in the no-drain group. This difference elicited statistical significance (Fig. 3c; OR 1.61, 95% CI 1.00–2.60, $p = 0.05$).

The overall reintervention rate was 15% (detailed data from 3 studies, 628 patients) [12, 13, 19], 14 and 16% being the relative rates for drained and undrained patients respectively. This difference had no statistical significance (Fig. 3d; OR 0.84, 95% CI 0.54–1.31, $p = 0.44$).

Detailed data on postoperative length of hospital stay were provided by 3 studies [12, 13, 19]. Overall, no statistical difference was elicited between the 2 groups for each study.

Overall mortality was 2% (13 deaths registered in 628 patients). Information regarding postoperative mortality was provided in detail by 2 studies [13, 19], including 159 patients. In total, 4 patients succumbed in each group, eliciting no statistically significant difference ($p = 0.90$).

Main outcomes of the included studies are given in Table 2.

Discussion

The clinical value of prophylactically placed drains in colorectal surgery has been studied more frequently in comparison with other gastrointestinal surgeries and a

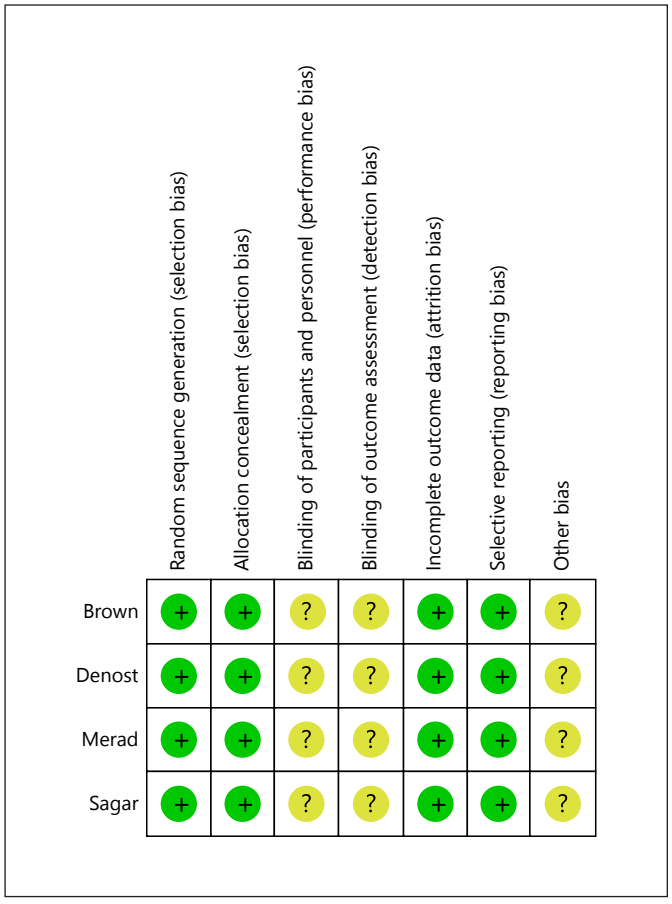

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Fig. 2. Risk of bias summary: review of authors' judgments about each risk of bias item for each included study. Green indicates low risk of bias. Yellow and red indicate unclear and high risks respectively.

general trend favoring a no-drainage policy has been observed [8, 9, 21–23]. In particular, over the last 2 decades, a number of reports have suggested that routine drainage following rectal surgery might be unnecessary and possibly connected with increased morbidity [8–10, 14, 16]. Conversely, other experiences continue to favor the placement of drains on a routine basis [9–11]. Our meta-analysis suggests that prophylactic drainage does not confer any advantage in enhancing the surgical outcomes of patients receiving rectal surgery with extraperitoneal anastomosis. Moreover, a trend toward an increased incidence of postoperative bowel obstruction can be of concern.

Several authors are convinced that pelvic drains are needed to allow the egress of postoperative fluid collections, especially in the case of low anastomosis [8, 21, 23–26]. This is essentially in connection with 2 factors: first, the pelvis consists of a confined, narrow, and antigravity space that is prone to fluid collections; second, the fluid absorptive potential of its non-peritonealised area can be considered lower than in other abdominal districts [8]. Despite this, other authors consider it unlikely that a pelvic drain, which usually rapidly becomes clogged by clots, debris, or adjacent structures, can favor the egress of substantial amounts of fluid [8, 14, 27].

The other major role attributed to pelvic drains is related to the early detection of complications such as anastomotic leak [8, 21, 23–26]. The average timing for the detection of an anastomotic leak is reported to range between postoperative day 7 and 16, and the relative range for radiological diagnosis is between postoperative days 4 and 14 [8, 28, 29]. Interestingly, according to the study by Denost et al. [12] the overall interval between surgery and the diagnosis of postoperative pelvic sepsis was 7.8 ± 5.4 – specifically 9.0 ± 6.8 for drained patients and 6.7 ± 3.3 for undrained patients. Moreover, the average delay to reintervention was shorter for patients without pelvic drains. Although this difference did not reach statistical significance, it suggests a trend toward delayed diagnosis of anastomotic leak when pelvic drains were present. Indeed, drains were removed at a mean of 5.6 ± 3.7 days following surgery and eventually demonstrated no role in affecting the timing of diagnosis for leakage or sepsis. This is consistent with our findings, which showed no statistical difference between drained and undrained patients on clinical or radiological leaks. We can easily deduce that if pelvic drains are expected to give reliable information about correct anastomotic healing, they should be maintained for a significant number of days postoperatively. This might eventually translate into prolonged postoperative hospitalization, increased medical costs, and possibly an increased risk of drain-related complications [8, 28].

It is interesting to note that in the present meta-analysis, the relative rate of postoperative bowel obstruction was higher when drains were present (OR 1.61). In the 2 studies that provided details upon this issue [12, 19], it was not clear if the higher incidence of obstruction in the drained group had direct correlation with the presence of drains. However, it is reasonable to consider that surgical drains may promote dense adhesions formation or even be directly responsible for postoperative intestinal obstruction [20, 30], especially if they are not removed early in the postoperative course [31]. Nonetheless, there was no global difference between the 2 groups in terms

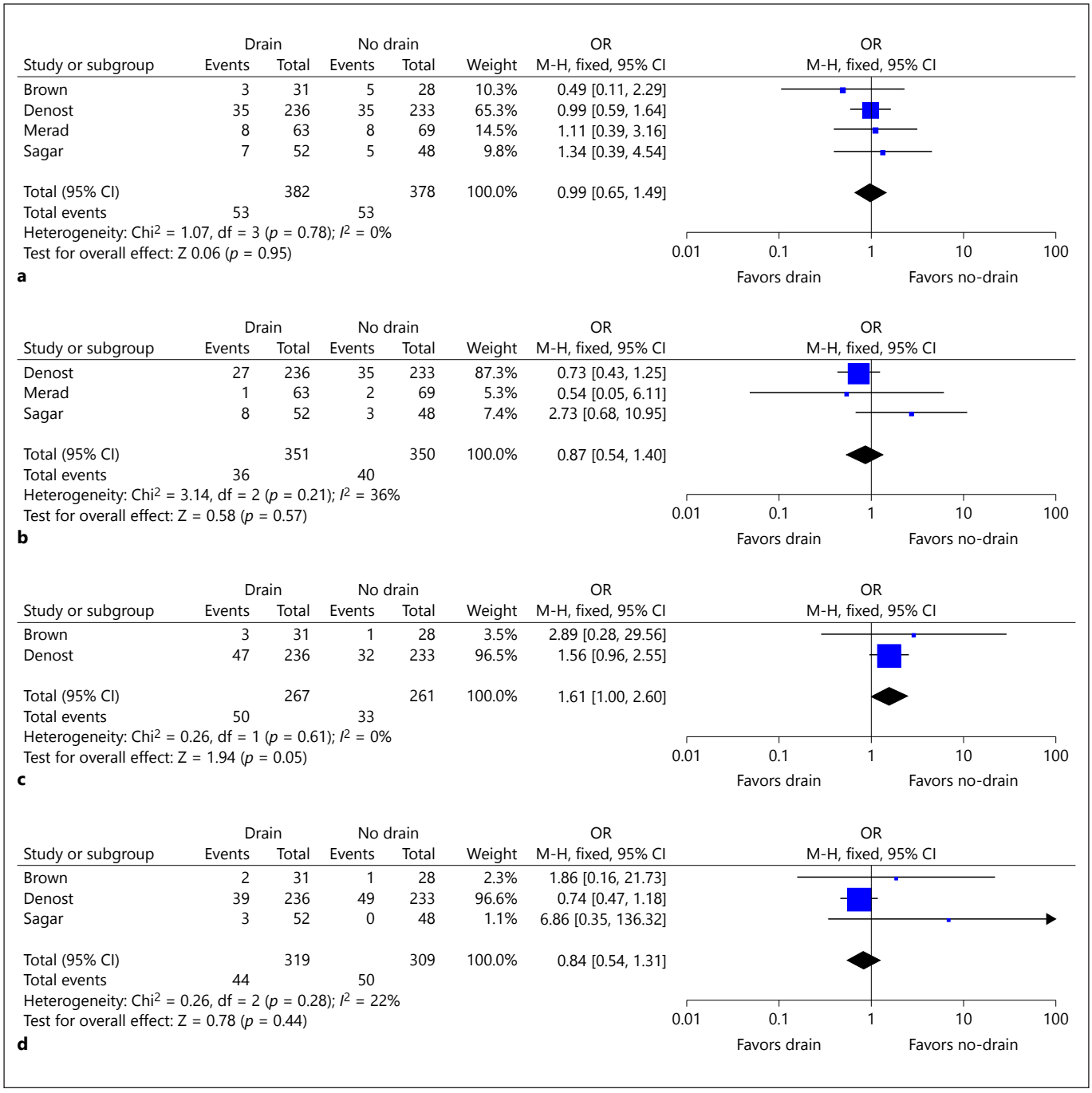

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Fig. 3. Forest plots showing the OR for anastomotic leakage (**a**) pelvic collection/sepsis (**b**) intestinal obstruction (**c**) and repeat surgery (**d**).

of the rate of reoperations, thus suggesting only a mild severity of complications directly related to the presence of drains.

All included RCTs used closed suction drainage systems. The efficiency with which fluid is removed from the pelvis by such type of drains has been frequently compared to that of non-suction systems [8, 9, 11, 32, 33]. It has been suggested that the utilization of closed suction drains may decrease the risk of postoperative bacterial contamination [8, 9, 11, 27]. Nevertheless,

Table 2. Surgical outcomes of the included studies

	Sagar et al. [13]	Merad et al. [20]	Brown et al. [19]	Denost et al. [12]	Total
Patients (DR/UN)	100 (52/48)	132 (63/69)	59 (31/28)	469 (236/233)	760 (382/378)
Leakages (CL/RA), *n* (%)	12 (7/5)	16	8 (4/4)	70	106 on 760 (14)
Drained (CL/RA)	7 (5/2)	8	3 (2/1)	35	53
Undrained (CL/RA)	5 (2/3)	8	5 (2/3)	35	53
Pelvic collection/sepsis, *n* (%)	11	3	n/a	62	76 on 701 (11)
Drained	8	1	n/a	27	36
Undrained	3	2	n/a	35	40
Reoperation, *n* (%)	3	–	3	88 (18.8)	94
Drained	3	–	2	39 (16.6)	45
Undrained	0	–	1	49 (21)	50
Postoperative obstruction, *n* (%)	–	–	4	79	83 on 528 (16)
Drained	–	–	3	47	50
Undrained	–	–	1	32	33
Postoperative hospital stay	–	–	–	12.2±9.0	–
Drained	13 (10–14)	–	7 (3–30)	12.2	–
Undrained	11 (9–13)	–	7.5 (3–28)	12.2	–
Mortality, *n* (%)	6	–	2	5	13 on 628 (2)
Drained	3	–	1	–	–
Undrained	3	–	1	–	–

Data are presented as medians (with ranges) or means (with SDs) depending on availability from the included reports.

DR, drained patients; UN, undrained patients; CL, clinical leaks; RA, radiological leaks; n/a, data not available from the included reports.

definitive conclusions cannot be drawn, essentially due to the lack of specific, high-evidence analyses. Currently, the available evidence from the literature shows that closed suction drains do not offer advantages over passive drainage in terms of surgical outcomes [11, 32, 33].

To the best of our knowledge, this is currently the most comprehensive meta-analysis reporting on the highest-quality evidence comparing drained to undrained rectal surgeries with extraperitoneal anastomosis. From the analysis of a total of 760 patients, no difference exists with regards to prevention and diagnosis of anastomotic leakage or pelvic collection. In light of such aspects, our data are consistent with what have been presented by a number of previous studies on this matter over the last years. Zhang et al. [8] have recently presented an elegant and timely meta-analysis investigating the role of prophylactic drains following colorectal surgery. Overall, 11 RCTs were included in the study for a total of 1,803 patients. The authors found that no significant difference was elicited between drained and undrained patients on the rate of anastomotic leak, mortality, and postoperative morbidity, including the need for reintervention. However, RCTs were included for meta-analysis, regardless of the type of drain and anastomotic height, which was anywhere along the colon and rectum. Nevertheless, intraperitoneal and extraperitoneal anastomoses were studied separately within specific subgroup analyses. As far as only extraperitoneal anastomoses were concerned, only a total of 291 patients from 3 studies were examined, and no statistically significant difference was noticed between drained and undrained patients. Less recently, Rondelli et al. [9] have investigated the role of prophylactic pelvic drains for extraperitoneal colorectal anastomosis. According to the results of the analysis of pooled data from RCTs and non-RCTs, the presence of drains reduced significantly the incidence of anastomotic failure. Nevertheless, these findings were not confirmed when considering RCTs only. Similarly, in our analysis, the rate of anastomotic dehiscence was not affected by the presence or absence of drains (OR 0.99), although a slight, and not a significant, advantage of drained over undrained patients was noticed in terms of postoperative pelvic collection or sepsis (OR 0.87) or in terms of the need for reintervention (OR 0.84).

The present study has several limitations. First, there was a large variability in terms of timing and criteria for

drain removal. Second, the surgeon's experience and habits (including methods of intraoperative anastomosis check) may have varied over time (the included studies span more than 20 years) and were not assessed in detail by each study. Similarly, some other variables such as the extent of surgery and inhomogeneous definitions employed to define sepsis and anastomotic leak are to be acknowledged. Finally, it was not possible to assess specific outcomes according to possible confounding factors such as the height of the anastomosis, presence of a protective stoma, or perioperative chemoradiotherapy, due to the lack of detailed data to perform specific subgroup analyses.

Conclusions

Our meta-analysis suggests that pelvic drainage is not useful and may even add to the postoperative morbidity of patients receiving rectal surgery with extraperitoneal anastomoses.

Disclosure Statement

All the aforementioned authors declare no competing commercial, personal, political, intellectual, or religious conflicts of interest in relation to the present work. No grant or other financial support has been received for conducting this study.

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