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REVIEW

Is a drain necessary after anterior resection of the rectum? A systematic review and meta-analysis

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Abstract

Objective The anastomotic leak rate in colorectal surgery is highest in patients receiving anterior rectal resections. The placement of prophylactic pelvic drains remains a routine option for preventing postoperative leaks, despite increasing evidence suggesting no clinical benefit. The present study seeks to identify a consensus on the use of prophylactic drains in anterior rectal resections.

Methods A systematic search was conducted of MEDLINE, Scopus, EMBASE, and Cochrane Library databases to identify clinical trials comparing the use of drainage to non-drainage in cases of colorectal anastomosis.

Results Three randomized clinical trials (RCTs) and two controlled clinical trials (CCTs) were identified that met the inclusion criteria, with a total of 1702 patients with rectal cancer who underwent anterior resection: 1206 with a pelvic drain and 496 without a pelvic drain. Meta-analysis showed that the use of a drain did not significantly improve the outcomes of anastomotic leaks; the overall reoperation rate during the 30-day postoperative period and the postoperative mortality were statistically lower in the drained group (OR 2.82, 95% CI 1.33 to 5.97; $I^2 = 0\%$).

Conclusions The use of prophylactic pelvic drainage after anterior rectal resections does not provide significant benefits with respect to anastomotic leaks and overall complication rates. However, an approximately threefold reduction of the postoperative mortality of the drained patients was observed. Given the limitations of the present study, these findings warrant the use of a drain after anterior rectal resection. Nevertheless, due to the low quality of the available data, further multicenter trials with uniform inclusion criteria are needed to evaluate drain usage in the anterior rectal resection.

Keywords Drain · Rectal cancer · Anterior rectal resection

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Introduction

Currently, the anterior rectal resection with colorectal or coloanal anastomosis is the gold standard treatment for rectal cancer [1]. An anastomotic leak (AL) is the most serious complication of this procedure, with a reported incidence of up to 24%, reaching 50% when clinically silent radiographic leaks are considered [2, 3]. Despite recent medical and technological advances, the rate of AL has remained unchanged for the last four decades [4]. Transanal endoscopic microsurgery represents a significant advance in the treatment of rectal cancer, as it is minimally invasive and requires no anastomosis. However, it is indicated only for highly selected cases [5–7].

Anastomotic leaks result in delayed wound healing, prolonged hospital stay, impaired long-term anorectal function, and reduced quality of life [4, 8–11]. In addition, it is associated with an increased rate of overall and cancer-specific mortality, accounting for one-third of deaths following colorectal surgery, and increased rates of local recurrence in patients who underwent rectal cancer surgery [4, 12–14]. Despite a large number of studies in the literature that have investigated risk factors, the fundamental causes of AL remain unclear [4]. Many surgeons routinely insert a prophylactic drain to minimize the postoperative complications that can follow colorectal surgery. However, the role of these drains in detecting and preventing anastomotic leaks remains a subject of debate with little consensus regarding their efficacy [1]. The arguments in favor of prophylactic drains are the removal of contaminated fluids, prevention of abscess formation within the extraperitoneal space, and reduced severity of symptoms when AL occurs [15]. In addition, it is believed that a drain can serve as an early warning system of AL [16].

However, these arguments are weakened by the conflicting evidence suggesting no clinical benefit of the prophylactic drains. Recent randomized controlled trials and meta-analytic studies have demonstrated comparable rates of overall complications and, more specifically, comparable incidences of an anastomotic leak between drained and non-drained surgical patients [17–20]. Other studies take this notion a step further, suggesting that the drainage devices themselves may present an additional risk for complications. Sagar et al. [21] and Yeh et al. [22] separately showed a higher incidence of anastomotic leaks in patients with drains compared with the no-drain groups. No contaminated material was evacuated through the drains in both studies, which underscores their poor sensitivity in detecting complications.

Given these conflicting results, several systematic reviews have been performed in an attempt to provide a definitive consensus on the efficacy of using prophylactic drains in colorectal surgery. However, these analyses lack a specific focus on anterior rectal resections. The present study aimed at evaluating randomized controlled trials to determine the necessity of placing a prophylactic drain after anterior resection of the rectum.

Methods

This systematic review was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement and flow diagram (Fig. 1). Details for the used protocol were derived from the Cochrane Handbook [23].

Search strategy

An exhaustive systematic search was conducted to identify all randomized and controlled clinical trials evaluating rectal cancer patients, receiving anterior rectal resection. The search was performed through the electronic databases MEDLINE, Scopus, EMBASE, and Cochrane Library. The search strategy included all studies published prior to the search date of 30 January 2018 and focused on identifying relevant articles using the following keywords: "drain," "colorectal," "surgery," and associated free terms. No language or publication date restrictions were imposed to limit the results. The search was for studies performed on human subjects, disregarding all animal studies.

Inclusion criteria

Studies were considered eligible for inclusion in this analysis provided they met the following criteria: (1) the study evaluated patients with rectal cancer undergoing curative rectal anterior resection with open or laparoscopic techniques; (2) use of a pelvic anastomotic drainage; (3) absence of pelvic anastomotic drainage used as a comparator; (4) the study was conducted as a randomized clinical trial (RCT) or controlled clinical trial (CCT).

Exclusion criteria

Studies were excluded from the analysis based on the following criteria: (1) patients with colon cancer were enrolled; (2) patients underwent emergency surgery; (3) patients underwent palliative surgery; (4) patients underwent other synchronous interventions for metastatic or locally advanced cancer.

Study selection and data extraction

The inclusion criteria were used to screen the title, abstracts, and full text of studies, produced in the search results. Two reviewers screened all citations on the titles and abstracts, produced by the search strategy, and retrieved all potentially relevant reports. Two additional independent readers then screened the full text of the studies to identify those items that met the inclusion criteria. Any disagreements were solved by consensus. Details of study design, surgery, characteristics of patients, and outcomes were independently extracted by the two reviewers, using a data extraction form, based on a pilot

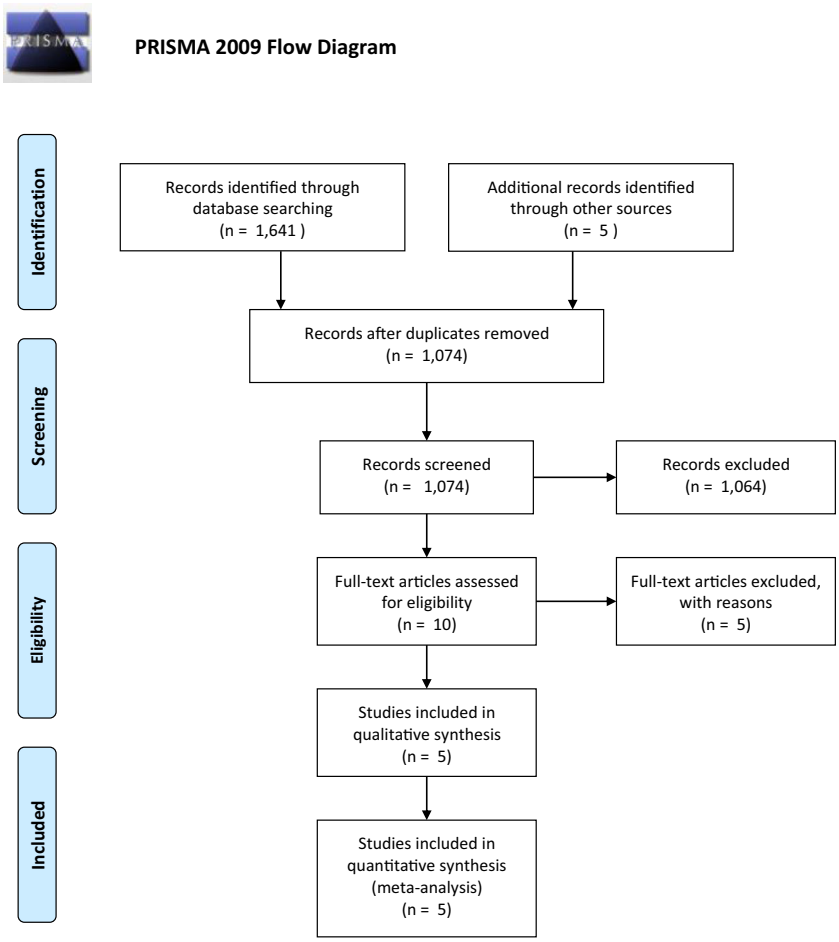

Fig. 1 PRISMA 2009 flow diagram

study. Differences in data extraction were solved by consensus, with referrals to the original article. The quality of the studies was evaluated using the risk of bias approach proposed by the Cochrane Collaboration [23].

Study outcomes

The primary outcomes of this study were 30-day postoperative mortality and surgical reinterventions rates. Secondary outcomes were the rates of overall complications, surgical complications (anastomotic leak, bleeding), medical complications, and percutaneous drainage until the 30th postoperative day. Both clinically manifested and clinically subtle but radiologically proven anastomotic leakages were included.

Quality assessment

The assessment of methodological quality of RCTs was performed by two authors who independently read the included studies and assessed their methodological quality (risk of bias) using the instructions and the items given in the Cochrane Handbook for Systematic Reviews of Interventions [23]. The quality of CCTs was evaluated using the revised and modified grading system of the Scottish Intercollegiate Guidelines Network (SIGN): <8, poor quality; 8–14, fair quality; ≥ 15, good quality [24].

Data analysis

Meta-analysis was performed using the Review Manager version 5.3 software package (Copenhagen: Nordic Cochrane Centre, Cochrane Collaboration, 2011). For outcomes with more than one trial, results for continuous variables were synthesized using a random effect inverse variance model with mean differences as the effect size. For dichotomous variables, an M-H random effect model was used with ORs as the effect size. Heterogeneity was assessed through an analysis of τ^2, χ^2, and I^2 statistics. When ranges were reported instead of standard deviations, standard deviations were estimated using the method suggested by Hozo et al. [25].

Results

The initial search produced 1646 potentially relevant articles. Duplicated items were removed to reveal 1074 articles

suitable for subsequent assessment. The titles and abstracts of these articles were screened to determine relevance and eligibility for inclusion. One thousand sixty-four articles were excluded, leaving ten studies for full-text evaluation. After the evaluation of the full texts, five studies were excluded and five studies [15, 21, 26–28] met the inclusion criteria and were considered eligible for the analysis (Table 1). A total of 1702 patients with rectal cancer were analyzed, all of whom underwent anterior resection: 1206 with a pelvic drain (71%) and 496 without a pelvic drain (29%).

Characteristics of the included studies

The characteristics of the included studies are summarized in Table 1. The five studies selected for inclusion were all published between 1995 and 2016. Patient enrollments occurred between May 1991 and July 2014, with exception of one study [17] which reported no data on their patient enrollment. Three studies were conducted as RCTs [21, 27, 28] and two were CCTs [15, 26]. Geographically, four of the trials [15, 21, 26, 28] were conducted in Europe, comprising the majority of study participants. The remaining study, which [27] was conducted in Asia, comprised 59 participants. Three studies were single-center trials and two were multicenter trials with research sites in the UK [21] and France [28].

Regarding the clinical characteristics, four studies reported data only for patients who underwent elective surgery (Table 2). One study [21] reported data on patients who underwent both elective and emergency surgeries. Pathological assessment of rectal cancer was performed in all studies. Only one study [21] reported patients with additional pathologies such as ulcerative colitis, Crohn's disease, ischemic colitis, constipation, endometriosis, and familial adenomatous polyposis.

Four studies [15, 21, 24, 28] reported the type of access to rectal resection (804 patients): 340 patients received open access (42.3%) and 464 had laparoscopic access (57.7%). One study reported data for both open and laparoscopic rectal anterior resections [28]. One study omitted data identifying the type of access [15].

Given that several surgical factors can influence the incidence of complications and anastomotic leaks, including the type of procedure, preoperative rectal washout, neoadjuvant chemoradiotherapy, localization of the tumor, and surgical skill level [4, 29], we evaluated the studies for reports of these factors. Only two studies [21, 27] reported data regarding the skill level of the surgeons performing the resection procedure. In both cases, the anterior rectal resection was performed by consultant surgeons.

Data regarding the inclusion of patients who underwent neoadjuvant therapy were reported in four studies [21, 26–28]. Two studies [21, 27] excluded these patients and another two [21, 25] included them.

Table 1 Summary of included studies

Trial	Multicenter/ monocenter	Type of study	Study locations	Language of publication	Time of enrollment in the study	Number of patients enrolled	Diagnosis of rectal pathology			
							Rectal cancer	Ulcerative colitis	Crohn's disease	Others*
Sagar [21]	Multicenter	RCT	United Kingdom	English	May 1991–November 1993	100	Yes	Yes	Yes	Yes
Brown [27]	Monocenter	RCT	Singapore	English	January–August 2000	59	Yes	No	No	No
Denost [28]	Multicenter	RCT	France	English	January 2011–July 2014	494	Yes	No	No	No
Peeters [15]	Monocenter	CCT	The Netherlands	English	January 1996–December 1999	924	Yes	No	No	No
Sica [26]	Monocenter	CCT	Italy	English	NR	150	Yes	No	No	No

*Ischemic colitis, constipation, endometriosis, and familial adenomatous polyposis

Table 2 Characteristics of included studies

Trial	Open and/or laparoscopic procedures	Skill of surgeons	Patients who underwent neoadjuvant therapy	Standard preoperative preparation of bowel	Prophylactic antibiotics	Elective surgery	Urgency surgery	Surgical treatment		
								Anterior resection	Reversal Hartman procedure	Others*
Sagar [21]	100/0	Consultant	None	Yes	Yes	Yes	Yes^	Yes	Yes	Yes
Brown [27]	60/0	Consultant	None	Yes	Yes	Yes	No	Yes	No	No
Denost [28]	30/464	NR	Yes**	Yes	NR	Yes	No	Yes	No	No
Peeters [15]	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Sica [26]	150/0	NR	Yes	Yes	Yes	Yes	No	Yes	No	No

^14 pts

*Restorative proctocolectomy, total colectomy, and ileorectal anastomosis

**Patients with T3, T4, or N+ mid- or low rectal cancer received neoadjuvant treatment using 50 Gy in 25 fractions during 5 weeks with concomitant chemotherapy (5-fluorouracil) followed by surgery 6 weeks later

Patients underwent anterior resection of the rectum in all studies (Table 3). The study by Sagar et al. [21] also included a small number of surgical cases undergoing reversal of the Hartman procedure after the resection. Additionally, all authors reported on the technique of colon-rectal anastomosis used, being either handsewn anastomosis or single stapler technique. Handsewn anastomoses are more time-consuming and rely heavily on surgical skill. In comparison, the single stapler technique relies on the efficiency of the anastomosis device. Two studies [27, 28] reported the location of the colon-rectal anastomosis, which was in the extraperitoneal portion of the pelvis.

In two studies, a diverting stoma was performed in all coloanal anastomosis [27, 28]. Only Denost et al. performed an ileostomy in selected colorectal anastomosis [28]. Sagar et al. did not perform a diverting stoma [21], whereas Sica et al. did not report any data [26] (Table 4).

In two studies [21, 26], the control of anastomosis was performed with a water-soluble contrast enema (gastrografin enema) during the first postoperative week. In contrast, Brown et al. [27] performed the control 1 month after the operation.

It has been suggested that drains may prevent and facilitate the early detection of the anastomotic leak or may serve as a therapeutic tool. We evaluated all studies for differences in drainage features (Table 5). Three studies [21, 27, 28] used closed suction drainage, which evacuates contaminated fluids using light negative pressure. One study used both closed suction drainage and gravity drainage [26]. All drains were positioned either close to the anastomosis [21, 28] or in the presacral space [27, 28].

In two studies [27, 28], the criterion for drain removal was a volume of serosanguinous exudate less than 100 ml. Among the five studies, the duration of drainage was heterogeneous. Brown et al. removed the majority of drains before the third postoperative day [27]. Denost et al. reported removal between 3 and 5 days after surgery [28]. Sagar et al. [21] and Sica et al. [26] were the only studies that reported drainage duration of at least seven postoperative days.

Table 3 Type of colorectal anastomosis used in the included studies

Trial	Colonic pouch, *n* (%)		Anastomotic height from anal verge (cm)		Height of anastomosis				Defunctioning stoma, *n* (%)	
					> 6 cm from anal verge		≤ 6 cm from anal verge			
	Drain	Not drain	Drain	Not drain	Drain	Not drain	Drain	Not drain	Drain	Not drain
Sagar [21]	NR	NR	NR	NR					NR	NR
Brown [27]	18 (58%)	13 (46%)	4 (1–9)	5 (2–8)					25 (68%)	16 (57%)
Denost [28]	NR	NR			17 (7.3%)	19 (8.3%)	215 (92.7%)	211 (91.7%)	180 (76.3%)	171 (73.4%)
Sica [26]			5–24	3–21						

Table 4 Characteristics of the rectal anterior resections used in the included studies

Trial	Pelvic location of colorectal anastomosis	Type of anastomosis	Covering stoma	Water-soluble contrast enema (gastrograffin enema) for control of anastomosis	Systematically postoperative evaluation of C-reactive protein
Sagar [21]	NR	Hand anastomosis or single stapler technique	No	Fifth to seventh postoperative days	No
Brown [27]	Extraperitoneal	Single stapler or double stapler technique	Covering ileostomy in all coloanal anastomosis and in selected colorectal anastomosis	1 month after the operation	No
Denost [28]	Extraperitoneal	Hand anastomosis or single stapler technique	Covering stoma in anastomosis below 6 cm from the anal verge	No	At days 3 and 6
Sica [26]	NR	Hand anastomosis or stapler technique	NR	At seven postoperative days	No

Risk of bias

The risk of bias among the included studies was evaluated as described above. Two RCTs [21, 27] were considered of poor quality, whereas one [28] had fair quality (SDC 1a–b). Both CCTs had "fair quality" with a mean score of 10/20 points (SDC 2).

Postoperative mortality

All studies reported data on 30-day postoperative mortality rates inclusive of 1702 participants. The rate of postoperative mortality was statistically lower in the drained group (15/1206, 1.24%) than in the non-drained group (16/496, 3.22%) (OR 2.82, 95% CI 1.33 to 5.97; $I^2 = 0\%$) (Fig. 2). However, the subgroup analysis of the three RCTs (participants = 628) revealed no statistical significance (OR 1.62, 95% CI 0.49 to 5.35; $I^2 = 0\%$).

Incidence of anastomotic leak

All five studies reported data on the incidence of AL inclusive of 1702 participants. The analysis with random effect model analysis failed to show that the incidence of clinical anastomotic leaks was significantly lower in the drained versus the non-drained patients (OR 1.35, 95% CI 0.64 to 2.84; participants = 1702; studies = 5; $I^2 = 67\%$) (Fig. 3). It was not possible to perform a subgroup analysis only of patients with diverting stoma or of those who underwent preoperative radiotherapy. In fact, only two studies reported patients with diverting stoma, and the inclusion criteria were heterogeneous [27, 28] (Table 1) and the rate of preoperative radiotherapy varies

Table 5 Characteristics of prophylactic drains used in the included studies

Trial	Type of drainage	Location of drainage	Criteria for drain remotion	Duration of drainage (days)
Sagar [21]	Closed suction (Redivac)	Closed to anastomosis	"Seven days. The original design of the trial permits drain to be left in situ longer if the volume of drainage after seven days was considered to be clinically significant; hover this not prove to be necessary"	"Seven days"
Brown [27]	Closed suction (Jackson-Pratt)	Presacral space	"At surgical discretion; essentially after the second post-operative day if volume of sero-sanguinous exudate was less than 100 ml"	"The majority of drains were removed before the third post-operative day"
Denost [28]	Closed suction	Forward sacrum, behind anastomosis	"The criteria of drain ablation are the absence of haemorrhagic liquid and/or undaily debit < 100 ml. Nursing care will be daily with change of bottle for collect pelvic serosity, accounting of quantity of collected liquid and realization of a dried bandage through contact with penetration of the drain"	"Between 3 and 5 days"
Sica [26]	Closed suction or gravity drainage	NR	NR	"Seven days"

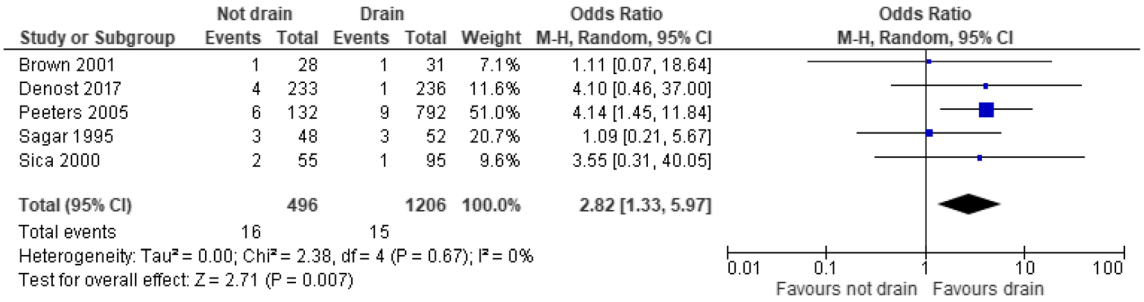

Fig. 2 Postoperative mortality rate during the 30-day postsurgical period

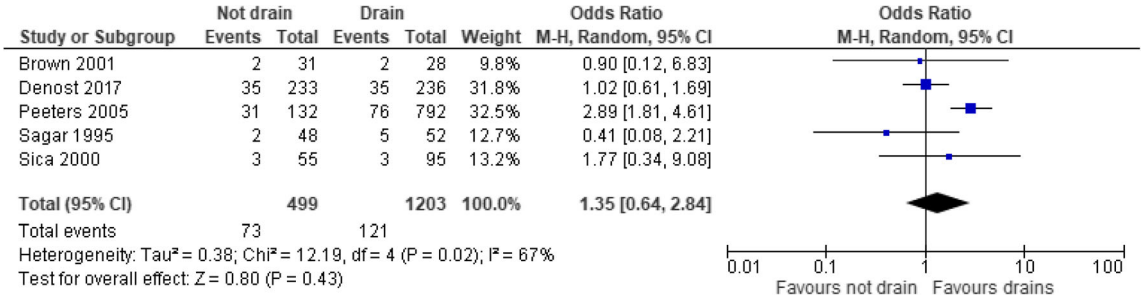

Fig. 3 Clinical anastomotic leak during the 30-day postoperative period

[26, 28] (Table 1). The Greccar trial reported the results of a univariate analysis, but they were not significant for the two outcomes (protective stoma $p = 0.170$, neoadjuvant treatment $p = 0.496$) [28].

Due to the high level of heterogeneity ($I^2 = 67\%$), a sensitivity analysis was conducted after excluding trials with a high risk of bias. We excluded the study by Sagar et al., which reported potentially confounding data, such as patients with rectal Crohn's disease and reversal Hartmann procedure [21] (Table 1). The sensitivity analysis was performed using a random effect model; however, the results were not significant (OR 1.62, 95% CI 0.76 to 3.42; $I^2 = 68\%$).

Reoperation rate

Three studies reported data on reoperation rates inclusive of 786 participants. The reoperation rate was lower in the drained group 24.08% (98/407) than in the non-drained group 35.70% (82/319), but this result was not statistically significant (OR 2.12, 95% CI 0.74 to 6.08; $I^2 = 0\%$) (Fig. 4). This data was reported in only one of the RCT studies [25], where the reoperation rate was lower in the drained group (16.6%) than in the non-drained group (21.0%), albeit not significant ($p = 0.22$).

Bowel obstruction

Two studies reported data on bowel obstruction inclusive of 528 participants. Bowel obstruction was the only adverse outcome reported. There were no significant differences in the rate of bowel obstruction between the non-drained group (33/261, 8.05%) and the drained group (50/267, 12.05%) (OR 0.62, 95% CI 0.39 to 1.01; $I^2 = 0\%$) (Fig. 5).

Discussion

This meta-analysis aimed at determining the value of placing a prophylactic drain following anterior resection of the rectum. Bowel resections are associated with several complications, including wound infection, abscess formation, and ALs [1]. The latter is more frequent in low anterior resections [8] with

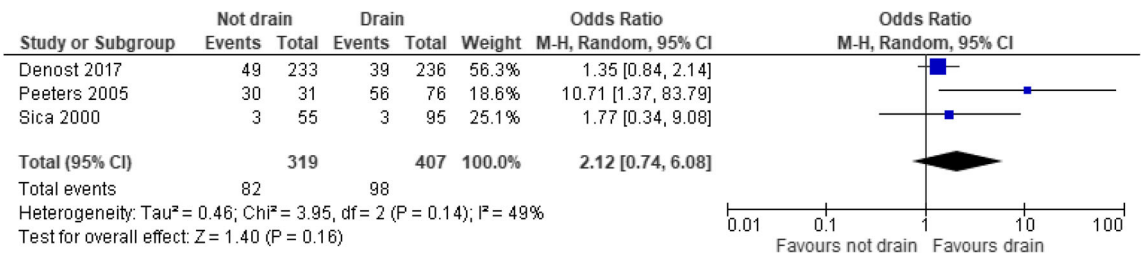

Fig. 4 Overall reoperation rate during the 30-day postoperative period

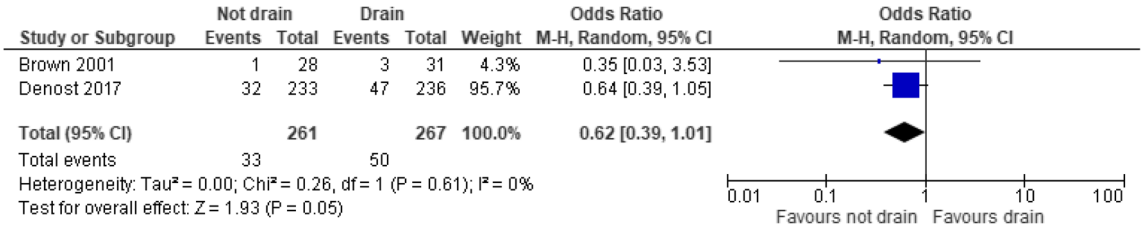

Fig. 5 Incidences of bowel obstruction during the 30-day postoperative period

5.4 to 6.5-fold increased risk for a leak in anastomoses up to 5 cm from the anal verge [4, 19]. AL is associated with delayed wound healing, increased rate of reinterventions and postoperative mortality, and significantly impaired long-term colorectal function.

The placement of a prophylactic pelvic drain may mitigate these effects by early detection of the leak and evacuation of the contaminated fluid. Many surgeons believe that this would provide an opportunity for early postoperative intervention before the worsening of the general condition [1, 16]. Others focus on the preventative role of the drains allowing for evacuation of the contaminated fluid out of the abdominal cavity, thereby preventing accumulation, anastomotic dehiscence, and infection [15, 19]. However, although evidence suggests these potential benefits of a pelvic drain, to date, as substantiated in this study, there is no statistically significant difference in AL between the cases with or without drains. The present meta-analysis included four studies from Europe and one from Asia [27], comprising 1203 cases of pelvic drain placement and 499 cases without a pelvic drain. As of today, our data provides the most robust evaluation of the clinical efficacy of pelvic drains in anterior rectal resection in contrast to other meta-analyses which included both colon and rectal cancer resections [1, 17, 19, 24]. The present study found a lower 30-day postoperative mortality rate in patients with pelvic drains. This may be explained by the fact that the intervention (such as reoperation) to treat the leak might have been performed earlier in patients with drain, and this might have affected the outcomes, avoiding a lethal clinical course. Still, additional data are required to confirm this hypothesis.

Our results differ from those observed by Menahem et al. [30], who analyzed three RCTs that reported on rectal anterior resections for cancer ($n = 660$; patients with extraperitoneal anastomosis after anterior rectal resection: 330 drained and 330 non-drained). In this systematic review and meta-analysis, the prophylactic use of pelvic drainage after extraperitoneal colorectal anastomosis had no impact on the incidence of anastomotic leakage or postoperative death. The results of this study must be interpreted in light of the timing of drainage removal, which was different among the included trials. Surprisingly, it has been reported that an anastomotic leak can be diagnosed between 3 and 45 days postoperative (42% after discharge and up to 15% after 30 postoperative days) [4, 31]. For this reason, the trials in which drains were planned to be removed early (e.g., before the seventh postoperative day) may have underestimated the differences in the outcomes between the groups. Another concern is the high rate of clinically silent ALs detected only on CT [4].

Our systematic review with meta-analysis has several strengths. First, it is important because it reports the best rate for outcomes (clinical anastomotic leak, overall reoperation rate, and postoperative mortality rates during the 30-day postoperative period) with the conventional use of pelvic drainage after rectal resection in patients with pelvic drainage as compared with without pelvic drainage. In this systematic review, we reported only one adverse outcome in drained patients: bowel obstructions that occur within the 30-day postoperative period, which is in unison with other reviews on the topic. The homogenous inclusion of only anterior rectal resections in contrast to the other systematic reviews and meta-analyses is another merit in contrast to the previous studies on this topic [1, 13, 15, 17, 24].

This meta-analysis may be limited by potential selection bias when identifying studies for consideration. The lack of stratification according to the neoadjuvant chemoradiotherapy (nCRT) and localization of the tumor is an additional source of bias given their significant influence on the rate of AL, although the causative role of nCRT is questionable [4]. The "low quality" of the included studies observed in this analysis is similar to the other meta-analyses on this topic, but the fundamental errors are harder to be identified and addressed.

Conclusion

The systematic use of prophylactic pelvic drainage after anterior rectal resections does not provide significant benefit with respect to the rate of anastomotic leaks and overall complication rates. However, approximately threefold reduction of the postoperative mortality of the drained patients was observed. Given the limitations of the present study, the finding still warrants the use of a drain after anterior rectal resection.

Further, multicenter trials with uniform inclusion criteria are therefore needed to provide more convincing arguments for the use of drainage after anterior rectal resection.

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Authorship All authors made a contribution in the concept and design of the study in addition to the collection, analysis, writing, and editing of data. All authors approved the manuscript.

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