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REVIEW

Prophylactic subcutaneous drainage reduces post-operative incisional infections in colorectal surgeries: a meta-analysis of randomized controlled trials

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Abstract

Background Due to lack of high-level evidences, prophylactic subcutaneous drainage has so far not been recommended in relevant guidelines as a countermeasure against incisional infections. This meta-analysis aims to clarify the efficacy of subcutaneous drainage in reducing incisional infections in colorectal surgeries.

Methods Cochrane Library, Embase, and PubMed were searched for randomized controlled trials comparing the incidence rate of incisional infections between patients receiving prophylactic subcutaneous drainage (interventions) and those not receiving (controls) after digestive surgeries. Results from included RCTs were pooled multiple times according to different surgical types. Heterogeneity, publication bias, and certainty of evidences were estimated.

Results Eight randomized controlled trials were included. Three RCTs each included patients receiving all sorts of digestive surgeries (gastrointestinal, hepatobiliary, and pancreatic); pooled incisional infection rates between the drainage group and the control group were not significantly different (RR = 0.76, 95%CI: 0.48–1.21, $p = 0.25$). Four RCTs included patients receiving colorectal surgeries; pooled incisional infection rate in the drainage group was significantly lower than that in the control group (RR = 0.34, 95%CI: 0.19–0.61, $p = 0.0004$). Four RCTs included patients receiving upper GI and/or HBP surgeries; pooled incisional infection rates in the drainage group and the non-drainage group were not significantly different (RR = 0.85, 95%CI: 0.54–1.34, $p = 0.49$).

Conclusions Prophylactic subcutaneous drainage significantly reduces post-operative incisional infections in colorectal surgeries but was not efficacious in digestive surgeries in general.

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Keywords Subcutaneous drainage · Incisional infection · Colorectal · Surgery · Meta-analysis

Introduction

Surgical site infection (SSI) is one of the most common complications after digestive (gastrointestinal, hepatobiliary, and pancreatic) surgeries. It refers to infections that influence the incision or deep tissues at the operation site within 30 days after a surgical procedure [1] and was first introduced in 1992 to replace an old term surgical wound infection [2]. SSI can significantly increase the risk of mortality and frequently lead to other post-operative complications, extending hospital stay and increasing medical costs, meanwhile imposing excessive load on healthcare systems [1]. To date, a number of measures have been proposed to reduce the incidence of SSI, some of which, like control of the peri-operative level of blood glucose, application of prophylactic antibiotics, glove change, and wound wash before closing abdomen, have been widely accepted by the general surgery community. In 2016, WHO updated its recommendations on measures to reduce SSIs, in which a novel technique called prophylactic negative pressure wound therapy (NPWT) was conditionally recommended (for high-risk wounds only) [3]. Yet, the cost of NPWT is unusually high (a unit of single-use NPWT system costs up to $500), whereas its efficacy in laparotomy is still controversial [4]. In recent years, the potential efficacy of subcutaneous drainage has drawn quite some attention with a significant advantage in reducing SSIs in colorectal surgeries [5, 6]. The subcutaneous drainage device is mostly disposable, economical, and conveniently applicable, yet so far has not been recommended in any relevant guidelines [3, 7–10] due to lack of high-level evidence.

In this meta-analysis, we pooled results from randomized controlled trials (RCT) reporting the efficacy of subcutaneous drainage in digestive surgeries, particularly in colorectal surgeries, in an effort to acquire meaningful evidence to facilitate future clinical decision-making.

Methods

Registration and search strategy

The protocol of this meta-analysis was developed by a series of group discussions (participated primarily by K.P., Peilin, S., and J.L.) and registered a priori on PROSPERO (CRD42020196501) [11].

Cochrane Library, Embase, and PubMed were searched for relevant studies with no limitation on publication time. Search results from 3 databases were exported and further handled with Mendeley Desktop software (3 digital files available as appendix material). Keywords in search strategy included: *SUBCUTANEOUS DRAINAGE*, *SUBCUTANEOUS DRAIN*, *ABDOMINAL*, *DIGESTIVE*, *WOUND INFECTION*, *SURGICAL SITE INFECTION*, *SSI*, *RANDOMIZED*, though specific combinations of words varied when searching on different databases (detailed search strategy available in Supplementary File). Database searching was conducted by one experienced researcher (Na. Z.). Each of subsequent screening processes (duplicate removing, title screening, abstract screening) was conducted by two researchers independently and simultaneously (X.Y. and Lei, J.), where disputes were settled a senior researcher (Lan, J.). Full-text review was conducted mostly by one senior researcher (K.P.), with the help of a series of group discussions (participated by K.P., Peilin, S., J.L., X.Y., Lei, J., and Lan, J.).

Endpoints

The sole endpoint was post-operative incisional infections, of which accurate definition was not pursued, as certain early publications may not have cohered to the latest CDC criteria for SSI [12] and an exact technical definition might therefore not be practical, nor necessary.

Eligibility criteria

Considering the fact that some researches focusing on digestive surgeries in general rather than specifically on colorectal surgeries might also have independent and extractable colorectal subgroup, we expanded our literature search range to include those focusing on digestive surgeries, rather than solely on colorectal surgeries. Therefore, randomized controlled trials focusing on the efficacy of subcutaneous drainage in reducing incisional infections after digestive surgeries (i.e., gastrointestinal, hepatobiliary, and pancreatic) were included. The intervention was subcutaneous drainage only, with the control group receiving identical treatment except for the absence of subcutaneous drainage. Researches were excluded if they focused on wrong types of drainage (e.g., cavity drainage), included patients receiving wrong types of surgeries (e.g., gynecological, obstetrical, orthopedic), or arranged inappropriate interventions and controls. Publications written in a language other than English or included less than 30 patients in either arm were also excluded.

Evaluation of RCT quality

The risk of bias of included studies was assessed with the Cochrane Collaboration's tool [13] (by K.P. and Peilin, S.

independently, where disagreements were settled by Lan, J.). Direct quotes or supporting points gathered from literature texts that facilitated the assessment were arranged into a table for convenient reviewing (Supplementary File). Registration information of included RCTs was sought and reviewed additionally for potentially useful information.

Data extraction

Items extracted for a table summarization of included RCTs were author, journal name and year of publication, sample size, definition of endpoint, surgical site, immune suppression status, wound classification, drainage type (with or without suction), irrigation through the drain (Y/N), time of removal, and conclusive recommendation of subcutaneous drainage.

Items extracted for pooling were number of incisional infection cases in the drainage group, total number of cases in the drainage group, number of incisional infection cases in the non-drainage group, and total number of cases in the non-drainage group.

Data were extracted by two researchers (Lei, J. and X.Y.) independently. The two versions of results were combined after a consistency check by a third researcher (K.P.).

Statistics

Statistical analyses in this systematic review consist of pooling of outcomes, test of heterogeneity, and assessment of publication bias.

Pooling was conducted a total of 3 times (in each time, different sets of RCTs were pooled) so as to acquire the pooled outcomes for, respectively, digestive surgeries in general (twice) and colorectal surgeries. Data to be pooled were dichotomous; therefore, the relative risk with corresponding 95% confidence interval was calculated with the Mantel-Haenszel (M-H) model [14], as the M-H model has better statistical properties when events are few. Heterogeneity was assessed with chi-square test and I^2 test [15], where $I^2 < 25\%$ [16] was considered insignificant and a fixed-effect model was used, and $I^2 \geq 25\%$ [16] or $p < 0.1$ [15] was considered significant and a random-effect model was adopted [17]. These analyses were performed on Revman software, version 5.4.

Due to the fact that less than 10 studies were included in this research, the funnel plot was not suitable for the assessment of publication bias [18]; instead, we performed Egger's test that was conducted separately on STATA software, version 15.0. Egger's test with $p < 0.1$ [19, 20] was considered significant publication bias.

Evaluation of pooled evidence

Results from each pooling were subjected to an evaluation of certainty according to the criteria of the GRADE system [21, 22] (conducted by K.P. and Peilin, S., where disputes were settled by Z.Z.).

Results

Study selection

According to the specified search strategy, a total of 14,867 items were identified across 3 databases. After removal of duplicates, the remaining 10,295 items were screened by title for a first round and then by abstract for a second round, where 10,280 items were further discarded for low relevance (e.g., drainage not subcutaneous, not on digestive surgeries, obviously not RCT, plainly not relevant, etc.). The remaining 15 items were subjected to full-text review, where 4 were excluded for being non-RCTs [23–26], 1 was excluded for being an RCT with less than 30 cases in either arm [27], 1 was excluded for being an RCT written in German (desired information items not extractable due to the language) [28], and 1 was excluded for being an RCT with inappropriate control [29] (Fig. 1).

Characteristics of included studies

A total of 8 randomized controlled trials [5, 6, 30–35] were included. Three RCTs [30–32] included patients receiving all sorts of digestive surgeries (upper GI, lower GI, and HBP), of which 1 RCT [30] has extractable colorectal subgroup information; 3 RCTs [5, 6, 33] included only patients receiving colorectal surgeries; 1 RCT [34] included patients receiving upper GI surgeries only; and 1 RCT [35] included patients receiving liver surgeries only. Detailed characteristics of respective studies were gathered and displayed in Table 1. Notably, we found no studies reporting specifically patients receiving small intestine surgery or with extractable small intestine subgroup information.

Risk of bias

The risk of bias of included RCTs was rated and summarized in Fig. 2. Additionally, a complete table with quotes and comments facilitating our rating was presented in the Supplementary File. Notably, the performance bias and detection bias were particularly high because surgical interventions are generally difficult to be blinded to as compared to drug interventions [38].

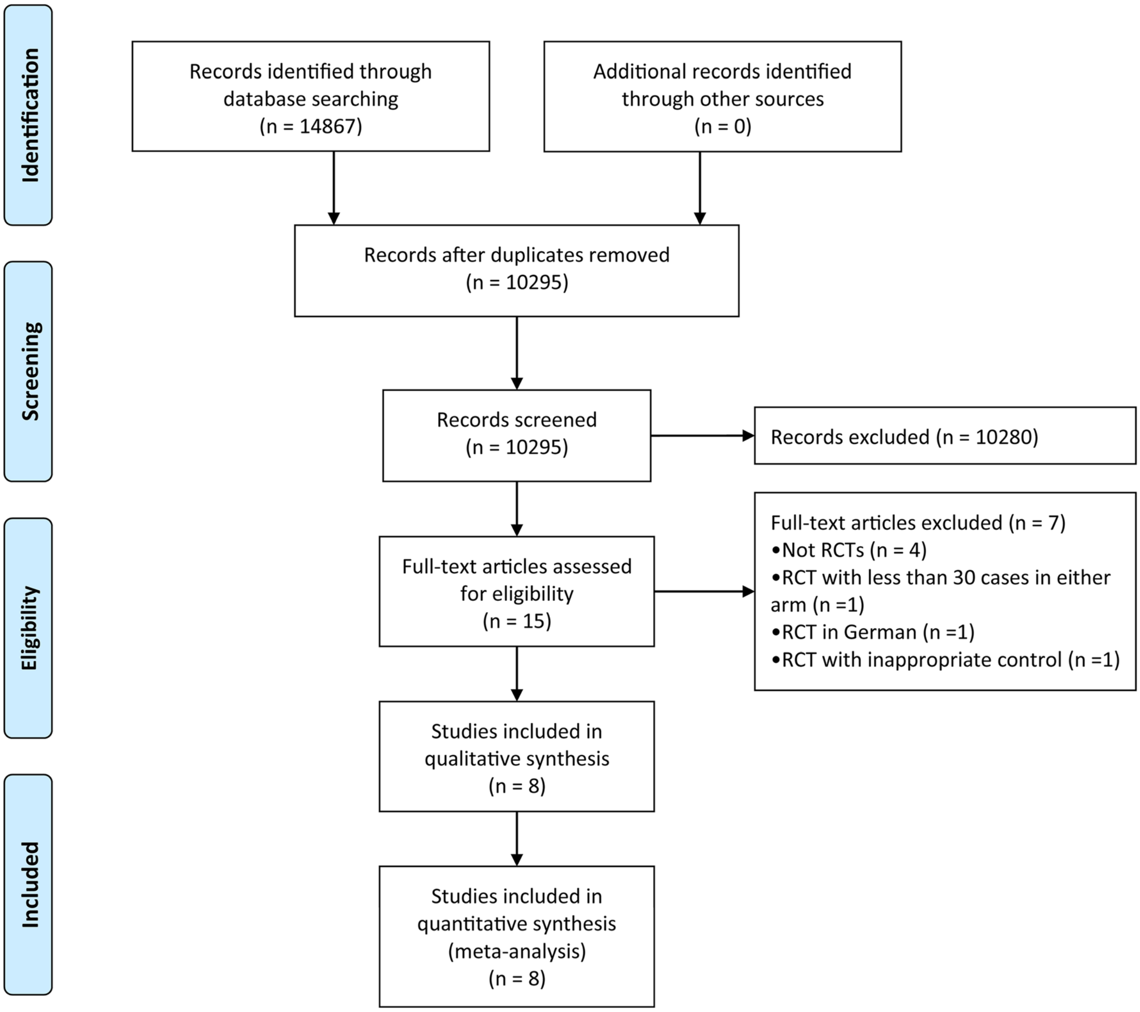


Fig. 1 Flowchart of the literature screening process

Efficacy of subcutaneous drainage in digestive surgeries in general

All 8 included RCTs [5, 6, 30–35] compared the incidence rate of SSI between the drainage group and the non-drainage group. Seven RCTs focused on drainage with suction and the other 1 focused on drainage without suction. Pooled results of all 8 RCTs indicated that the SSI rate in the drainage group was significantly lower than the non-drainage group (RR = 0.66, 95%CI: 0.48–0.89, $p = 0.007$) (Fig. 3a). A fixed-effect model was adopted for the analysis as heterogeneity in this pooling was not significant ($p = 0.45$, $I^2 = 0\%$). Egger's test indicated no significant publication bias ($p = 0.387$). Additionally, pooled results of the 7 RCTs [5, 30–35] focusing on drainage WITH SUCTION (subgroup analysis) indicated that the SSI rate in the drainage (with suction) group was significantly lower than the non-drainage group (RR = 0.70, 95%CI: 0.51–0.97, $p = 0.03$) (Fig. 3a) as well. A fixed-effect model was adopted for the analysis as heterogeneity in this pooling was not significant ($p = 0.55$, $I^2 = 0\%$). Egger's test indicated no significant publication bias ($p = 0.715$).

As 3 [30–32] out of the 8 RCTs each included patients receiving all sorts of digestive surgeries (upper GI, lower GI, and HBP), a separate pooling of these 3 RCTs (all focused on drainage with suction) was conducted. The result indicated that SSI rates between the drainage (with suction) group and the non-drainage group were not significantly different (RR = 0.76, 95%CI: 0.48–1.21, $p = 0.25$) (Fig. 3b). A fixed-effect model was adopted for the analysis as heterogeneity in this pooling was not significant ($p = 0.40$, $I^2 = 0\%$). Egger's test indicated no significant publication bias ($p = 0.427$).

Efficacy of subcutaneous drainage in colorectal surgeries

Four RCTs [5, 6, 30, 33] compared the incidence rate of SSI between the drainage group and the non-drainage group in colorectal surgeries, of which 3 [5, 30, 33] focused on drainage with suction and 1 [6] focused on drainage without suction. Pooled results of all 4 RCTs indicated that the SSI rate in the drainage group was significantly lower than the non-

Table 1 Characteristics of included RCTs

Items	Specification of 8 included RCTs							
Author	E. Kaya [30]	P.K. Baier [31]	D. Lubowski [32]	D. Shaffer [34]	H. Nakayama [35]	J.C. Lauscher [5]	J. Watanabe [33]	M. Numata [6]
Journal	Acta Chir Belg	Int J Colorectal Dis	Med J Australia	Ann Surg	J Hepato-Bil-Pan Sci	Langenbecks Arch Surg	Int J Colorectal Dis	Int J Colorectal Dis
Year	2010	2010	1987	1987	2014	2016	2016	2014
Surgical site	Digestive[†]	Digestive[†]	Digestive[†]	Upper GI	Liver	Colorectal	Colorectal	Colorectal
Wound classification	II, III	II, III, IV	I, II, III, IV	II	NS	NS	II	II, III
Endpoint[#]	Superficial/deep SSI[a]	Superficial/deep/cavity (organ) SSI[a]	"Wound infection"[b]	"Wound infection"[c]	Superficial/deep SSI[a]	SSI[d]	Superficial/deep SSI[a]	Superficial SSI[a]
Size (exp/ctrl)	210/192	100/100	192/157	102/92	131/129	50/53	112/117	124/122
Method of fascial closure	Continuous	NS	NS	Interrupted	Interrupted	NS	NS	NS
Material of fascial closure	Non-absorbable suture (polypropylene)	Absorbable suture (PDS®)	Non-absorbable suture (nylon)	Non-absorbable or absorbable suture	Absorbable suture	Absorbable suture (Vicryl®)	Absorbable suture (Vicryl®)	Absorbable suture (Vicryl®)
Laparoscopy involvement	NS	Yes (but not further specified)	No (indiscriminately for both groups)	No (indiscriminately for both groups)	No (indiscriminately for both groups)	No (indiscriminately for both groups)	37/112 vs 47/117	No (indiscriminately for both groups)
Peri-operative antibiotics	Yes (indiscriminately for both groups)	Yes (indiscriminately for both groups)	Yes (indiscriminately for both groups)	Yes (indiscriminately for both groups)	Yes (indiscriminately for both groups)	Yes (indiscriminately for both groups)	Yes (indiscriminately for both groups)	Yes (indiscriminately for both groups)
Immuno-suppression[§]	NS	15/100 vs 15/100	NS	NS	NS	2/50 vs 2/53	NS	NS
Drainage type	Suction	Suction	Suction	Suction	Suction	Suction	Suction	No suction
Specific name of the drainage device	Hemovac drain	Redon drain	Redi-Vac drain	NS	Jackson-Pratt drain	NS	Blake drain	Penrose drain
Irrigation through drain	No	No	No	No	No	No	No	No
Day of removal (post-operative)	3rd day	2nd day	1st day or later	Not certain	3rd day	2nd day or later	5th day	3rd day
Recommendation on drainage	Conditional[*]	No	No	No	No	No	Yes	Yes

NS not specified, *SSI* surgical site infection, *GI* gastrointestinal

[†] Study included patients undergoing all sorts of digestive surgeries (upper GI, lower GI, hepatobiliary, and pancreatic)

[#] Definition of endpoints varies across different studies

[a] In accordance with CDC criteria [36]

[b] By surgeons' visual inspections, criteria not specified

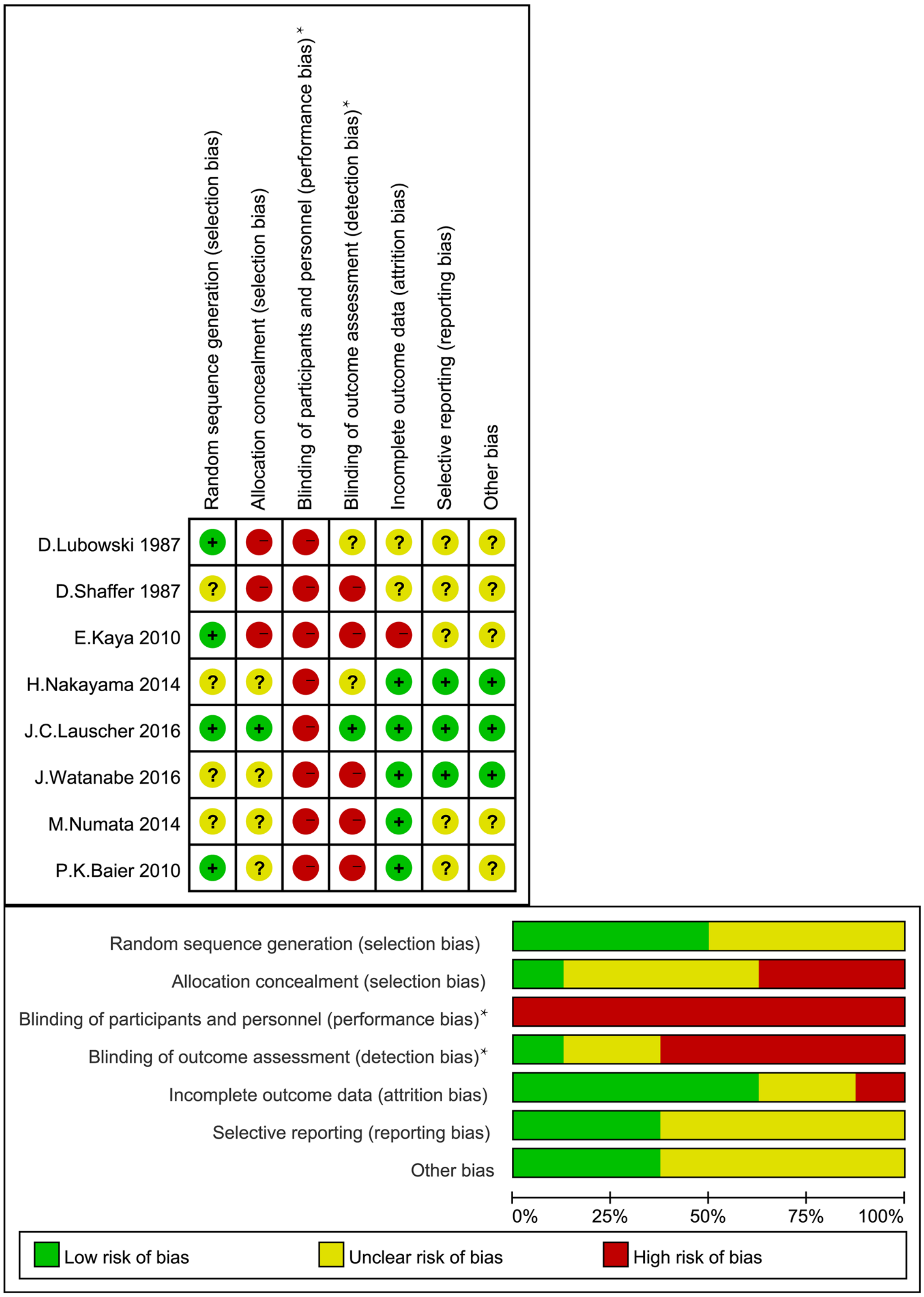
[c] Wounds were defined as infected "if pus was present at the incision site," whereas "serous drainage with negative bacterial cultures and without clinical evidence of infection were not considered wound infections"

[d] Defined as "purulent discharge from the wound or detection of bacteria in wound samples taken using aseptic technique; The severity of SSIs was graded using a modified CDC Classification System [37]." Notably, in the research of P.K. Baier et al., cavity (organ) SSI cases were separable and were thus excluded when extracting data for pooling, as cavity (organ) SSIs are technically no longer incisional infections, and in the research of J.C. Lauscher et al., "intraabdominal and organ SSI cases" were separable and were also excluded when extracting data for pooling

[§] Refers to immunosuppressive status caused by drugs (steroids, chemo, etc.), radiotherapy, etc.

[*] Recommended only for a subgroup of patients (i.e., colorectal malignancies with lower abdominal incisions)

Fig. 2 Risk of bias assessment



drainage group (RR = 0.34, 95%CI: 0.19–0.61, p = 0.0004) (Fig. 4). A fixed-effect model was adopted for the analysis as heterogeneity in this pooling was not significant (p = 0.69, I^2 = 0%). Egger's test indicated no significant publication bias (p = 0.412). Additionally, pooled results of the 3 RCTs focusing on drainage with suction (subgroup analysis) indicated that the SSI rate in the drainage (with suction) group was significantly lower than the non-drainage group as well (RR = 0.34, 95%CI: 0.17–0.70, p = 0.003) (Fig. 4). A fixed-effect model was adopted for the analysis as heterogeneity in this pooling was not significant (p = 0.49, I^2 = 0%). Egger's test was not viable due to the insufficiency of studies.

GRADE score of certainty and importance

For a convenient overview, the GRADE score of certainty and importance of the evidence that have had all pooled results (overall significance, heterogeneity, Egger's test) considered were summarized in the 3rd section of Supplementary File.

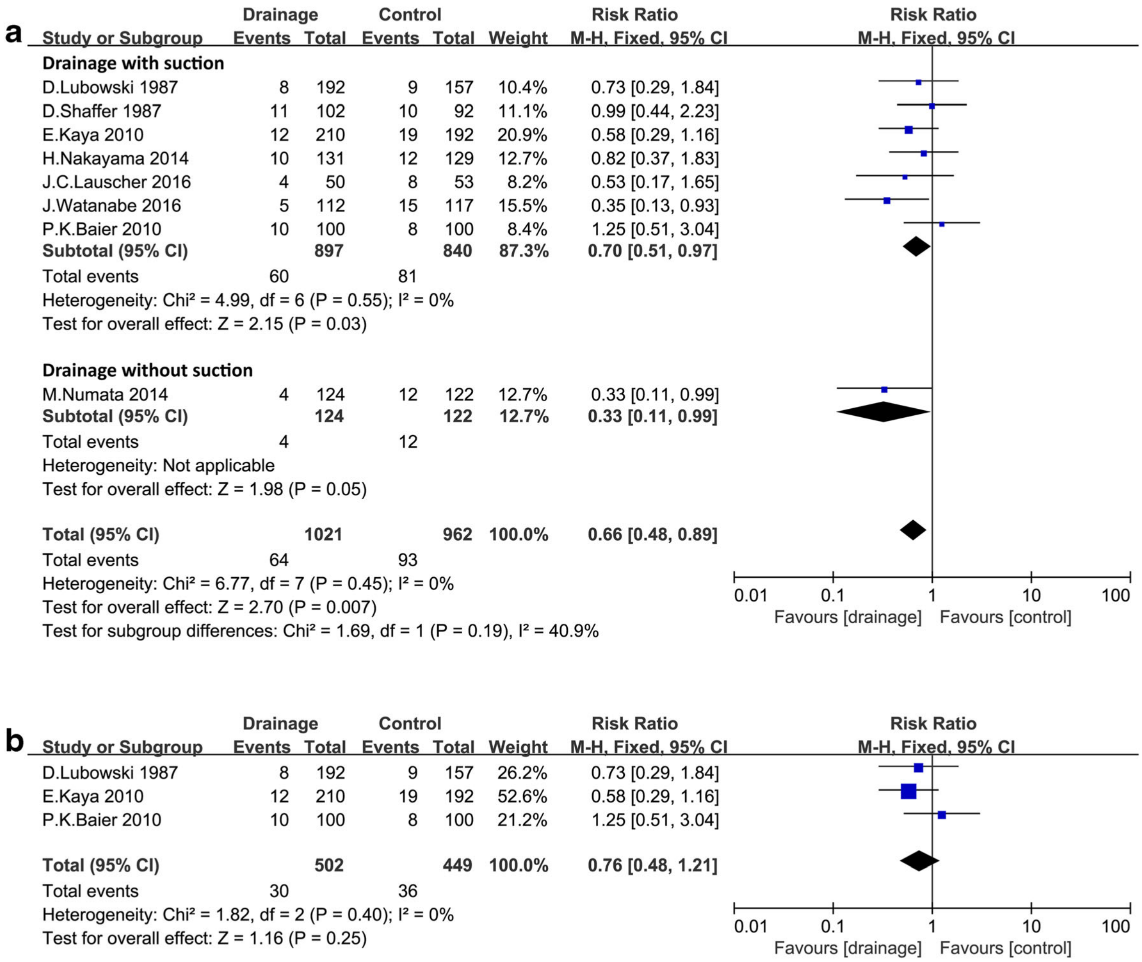


Fig. 3 Efficacy of subcutaneous drainage in digestive surgery in general. **a** Pooling of all included studies, with subgroup analysis (suction subgroup and no suction subgroup); **b** pooling of studies that included patients receiving all sorts of digestive surgeries rather than a specific type (upper GI, lower GI, HBP) of digestive surgeries

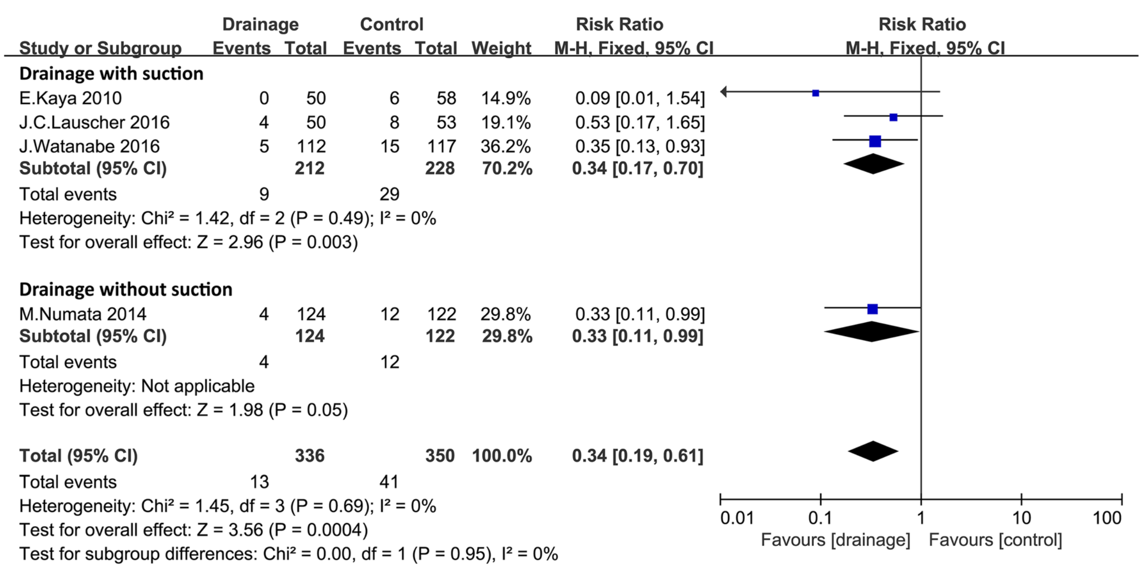


Fig. 4 Efficacy of subcutaneous drainage in colorectal surgeries. Pooling of studies that included patients receiving colorectal surgeries, with subgroup analysis (suction subgroup and no suction subgroup)

Discussion

The RCTs included in this meta-analysis can be conveniently tagged as all-digestive, upper GI, HBP, and colorectal, according to the surgical type of their included patients. Therefore, we pooled outcomes based on categorization and explored the efficacy of subcutaneous drainage in digestive surgeries in general and in colorectal surgeries, respectively. Indicated by the results displayed in Fig. 4, subcutaneous drainage can reduce incisional infections significantly in colorectal surgeries. Interestingly, as pooling was conducted two separate times to check out subcutaneous drainage's efficacy in digestive surgeries in general (one time all included studies were pooled, the other time only studies each including all sorts of digestive surgeries was pooled), conflicting results (Fig. 3a and b) were acquired. A subsequent thorough inspection on Fig. 3 suggested that results in Fig. 3a were obviously influenced and deviated to a heavy extent by the 3 colorectal studies, whereas results in Fig. 3b can more objectively reflect the true efficacy of subcutaneous drainage in digestive surgeries in general. Notably though, no RCTs, or even cohort studies, specifically focused on the efficacy of subcutaneous drainage in surgeries on small intestines to date, which is worthy of conducting an RCT to fill up the missing piece of the puzzle.

Subcutaneous drainage devices currently in the application can generally be categorized into active/suction drainage (Blake drain [33], Jackson-Pratt drain [35], Redon drain [31], etc.) and passive drainage (Penrose drain [6]), depending on the involvement of negative pressure. In this meta-analysis, all included RCTs focused on drainage with suction except for Numata's research [6]. Therefore, whenever a pooling involved Numata's RCT (i.e., in Figs. 3a and 4), subgroup analysis was conducted specifically for the suction drainage subgroup. As results on digestive surgeries in general in Fig. 3a were heavily deviated by the 3 colorectal RCTs and therefore cannot reflect the true efficacy of subcutaneous drainage in digestive surgeries in general, it will not be subjected to further discussion. In Fig. 4 though, subcutaneous drainage with suction is efficacious in colorectal surgeries (test for overall effect: $p = 0.003$; heterogeneity: $p = 0.49$, $I^2 = 0\%$), which was in line with the overall efficacy of subcutaneous drainage (with and without suction combined) in colorectal surgeries (test for overall effect: $p = 0.0004$; heterogeneity: $p = 0.69$, $I^2 = 0\%$), but the absence of Egger's test for publication bias reduced its strength of evidence.

In 2019, a meta-analysis including 8 RCTs concluded that "the presence of prophylactic subcutaneous suction drain does not impact significantly on the incidence of SSI in clean-contaminated abdominal surgery" [39]. However, it is apparently flawed research for it included an RCT that arranged inappropriate controls [29], where patients in the intervention groups received irrigation with saline (after fascia closure) and placement of subcutaneous drainage, and patients in the control group received no subcutaneous drainage, but received irrigation with ANTIBIOTICS after fascia closure and prior to skin closure, resulting in wound infection rates of 4.4% in the intervention/drainage group and 4.1% in the control/no-drainage group. Notably though, this particular RCT included 659 patients respectively in both intervention and control group and surely deviated to a heavy extent the overall outcome, as well as the original purpose of that meta-analysis. Also, it failed to include two RCTs focusing on colorectal surgeries and did not attempt to perform analysis regarding subtypes of digestive surgeries.

In conclusion, prophylactic subcutaneous drainage significantly reduced post-operative incisional infections in colorectal surgeries but was not efficacious in digestive surgeries in general.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00384-021-03908-8.

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Declarations

Conflict of interest The authors declare no conflict of interest.

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