



Prophylactic drainage after laparoscopic cholecystectomy for acute cholecystitis: a systematic review and meta-analysis

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Received: 6 December 2018 / Accepted: 25 March 2019 / Published online: 3 April 2019
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Abstract

In the literature, there is a large evidence against the use of drains in laparoscopic cholecystectomy (LC) in elective surgery. However, evidence is lacking in the setting of acute cholecystitis (AC). The present meta-analysis was performed to assess the role of drains to reduce complications and improve recovery in LC for AC. An electronic search of the MEDLINE, Science Citation Index Expanded, SpringerLink, Scopus, and Cochrane Library database from January 1990 to July 2018 was performed to identify randomized clinical trials (RCTs) that compare prophylactic drainage with no drainage in LC for AC. Odds ratio (OR) with confidence interval (CI) for qualitative variables and mean difference (MD) with CI for continuous variables were calculated. Three RCTs were included in the meta-analysis, involving 382 patients randomized to drain (188) versus no drain (194). Morbidity was similar in both the study groups (OR 1.23; 95% CI 0.55–2.76; $p=0.61$) as well as wound infection rate (OR 1.98; 95% CI 0.53–7.40; $p=0.31$) and abdominal abscess rate (OR 0.62; 95% CI 0.08–4.71; $p=0.31$). Abdominal pain 24 h after surgery was less severe in the no drain group (MD 0.80; 95% CI 0.46–1.14; $p<0.000$). A significant difference in favor of the no drain group was found in the postoperative hospital stay (MD 1.05; 95% CI 0.87–1.22; $p<0.000$). No significant difference was present with respect to postoperative fluid collection in the subhepatic area and operative time. The present study shows that prophylactic drain placement is useless to reduce complications in LC performed to treat AC. Postoperative recovery is improved if drain is not present.

Keywords Acute cholecystitis · Laparoscopic cholecystectomy · Drainage

Introduction

Acute cholecystitis (AC) is one of the most common biliary diseases and laparoscopic cholecystectomy (LC) is the gold standard treatment [1]. In a survey over the surgical management of AC, the most part of the surgeons reported to use a prophylactic abdominal drainage after LC [2]. It is widely accepted that prophylactic drainage in abdominal surgery is useful to remove intra-abdominal collections and to detect early postoperative complications, such as bleeding and leakage. In particular, in the setting of a contaminated

abdomen, the insertion of a drain is claimed to avoid abscess formation [3]. However, other surgeons do not recommend the use of drain, because it is related to an increased incidence of wound and chest infections [4]. There are reports, such as the one by Shein [5], questioning the utility of prophylactic drain in contaminated and infected abdomen and a recent meta-analysis did not support the utility of prophylactic drain in the surgery for complicated appendicitis [6]. In the literature, there is a large evidence against the use of drains in LC in elective surgery [7–12]. However, evidence is lacking both for open and LC with respect to AC and a claim was made for high-quality randomized-controlled trials (RCTs) according to the CONSORT statement (www.consortstatement.org) to improve evidence [7, 8, 13].

The aim of the present study was to perform a systematic review and meta-analysis, including RCTs which assessed the utility of prophylactic drainage to reduce complications and improve recovery after emergent LC.

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Materials and methods

The systematic review and meta-analysis was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses Statement (PRISMA) recommendations [14]. The study methods were documented in a protocol registered and accessible at <http://www.crd.york.ac.uk/prospero/> (registration CRD42018103235).

Types of studies, participants, and interventions

RCTs (irrespective of language, blinding, or publication status) compare prophylactic subhepatic drainage (irrespective of the type of drain used) with no drainage in LC for AC. We excluded non-RCTs (case series, case–control study, and cohort study), and reviews.

According to population, interventions, comparators, outcome measures, and setting (PICOS) criteria, patients were included if they were 18 years or older, had AC (as diagnosed using ultrasonographic and clinical criteria) for which laparoscopic cholecystectomy was indicated. Exclusion criteria were evidence of cholangitis, pancreatitis, or malignancy of the gallbladder.

Types of outcome measures

Primary outcomes were mortality at maximal follow-up, morbidity (within 4 weeks after surgery), and presence and quantity (mL) of subhepatic fluid collection 24 h after surgery, measured with ultrasound examination.

Secondary outcomes were operative time (minutes), abdominal pain 24 h after surgery (measured using a visual analog scale), and postoperative hospital stay (days).

Subgroup analyses

No subgroup analyses were performed.

Search strategy and data collection

An electronic search of the MEDLINE, Science Citation Index Expanded, SpringerLink, Scopus, and Cochrane Library database from January 1990 to July 2018 was performed. The studies in Medline were identified using the following search terms: (((“cholecystectomy, laparoscopic”[MeSH Terms] OR (“cholecystectomy”[All Fields] AND “laparoscopic”[All Fields]) OR “laparoscopic cholecystectomy”[All Fields] OR (“laparoscopic”[All Fields] AND “cholecystectomy”[All Fields])) AND (“drainage”[MeSH Terms] OR “drainage”[All Fields] OR “drain”[All Fields])) AND (“random allocation”[MeSH

Terms] OR (“random”[All Fields] AND “allocation”[All Fields]) OR “random allocation”[All Fields] OR “randomized”[All Fields])) AND (“cholecystitis”[MeSH Terms] OR “cholecystitis”[All Fields]). In the other databases a Boolean search was performed as follows: (laparoscopic cholecystectomy) AND (cholecystitis) AND (drain*) AND (random*). References of the identified trials were analyzed to collect further relevant trials.

Data extraction

All data were extracted independently by three reviewers (ADF, MS, and OT) using a paper data extraction pro forma. The accuracy of the extracted data was further confirmed by a fourth author (ADC).

The information collected from each study was author, study design, number and gender of participants, presence and type of drain, inclusion criteria, exclusion criteria, and outcomes.

Assessment of risk of bias in included studies

Two raters (MP and ES) independently assessed the methodological quality of the included studies according to the Cochrane Collaboration guidelines [15].

Statistical analysis

We performed the meta-analysis using the software package Review Manager Version 5.3 software (Cochrane Collaboration). For dichotomous variables, we calculated the odds ratio (OR) with 95% confidence interval (CI). For continuous variables, we calculated the mean difference (MD) with the 95% CI. Medians with either range or interquartile range were converted to means with standard deviation (SD) using the technique described by Wang et al. [16]. We used the Mantel–Haenszel method to calculate the weighted summary OR. Heterogeneity was assessed by the I^2 measure of inconsistency, statistically significant if I^2 was > 50%; whenever I^2 was < 50%, the fixed-effects model results were used; otherwise, the random-effects model results were preferred. A p value of less than 0.05 was considered statistically significant. Forest plots were used for graphical display of the results.

Results

Study selection

The database search retrieved 169 citations. After exclusion of duplicate results, 8 RCTs remained for title and abstract review. We excluded the study of Prevot et al.

[17], because it was a post hoc analysis of an RCT focused on the value of postoperative antibiotic therapy in patients with AC. Two studies [18, 19] were excluded, because they were not RCTs. One study did not report data on patients with ACC separately and another one did not report this information [20, 21]. We selected 3 RCTs for full-text examination and final inclusion in the meta-analysis. All trials compared the use of prophylactic subhepatic drainage with no drainage in LC for AC [22–24]. Figure 1 shows the PRISMA flowchart for study inclusion and exclusion.

Characteristics of the included studies

Table 1 summarizes the characteristics of the three selected studies. Three hundred and eighty-two patients were included in the meta-analysis: 188 patients in the drain group and 194 in the no drain group. The average age of participants in the RCTs ranged between 55 years and 67 years. All the trials used closed suction drains, positioned in the subhepatic space.

Risk of bias

The trial of Lucarelli et al. [23] had no risk of bias. The absence of a sham drainage in the other two selected studies was likely to affect the blinding of the participants and personnel and induce bias on the results [22, 24]. The summary of the risk of bias is shown in Fig. 2.

Primary outcomes

No mortality was reported. Complications were present in 14 (7.4%) patients in drain group and 12 (6.2%) patients in the no drain group. Pooled analysis showed no statistically significant OR (OR 1.23; 95% CI 0.55–2.76; $p=0.61$; Fig. 3).

Two studies provided information about wound infection and abdominal abscess occurrence [23, 24]. Wound infection was present in 6 out of 173 patients (3.5%) in drain group and 4 out of 179 patients (2.2%) in the no drain group. Pooled analysis did not show statistically significant OR (OR 1.58; 95% CI 0.44–5.73; $p=0.48$; Fig. 4). An abdominal abscess was documented in 1 out of 173 patients (0.6%) in drain group and in 2 out of 179 patients (1.1%) in the no drain group. Pooled analysis did not show statistically

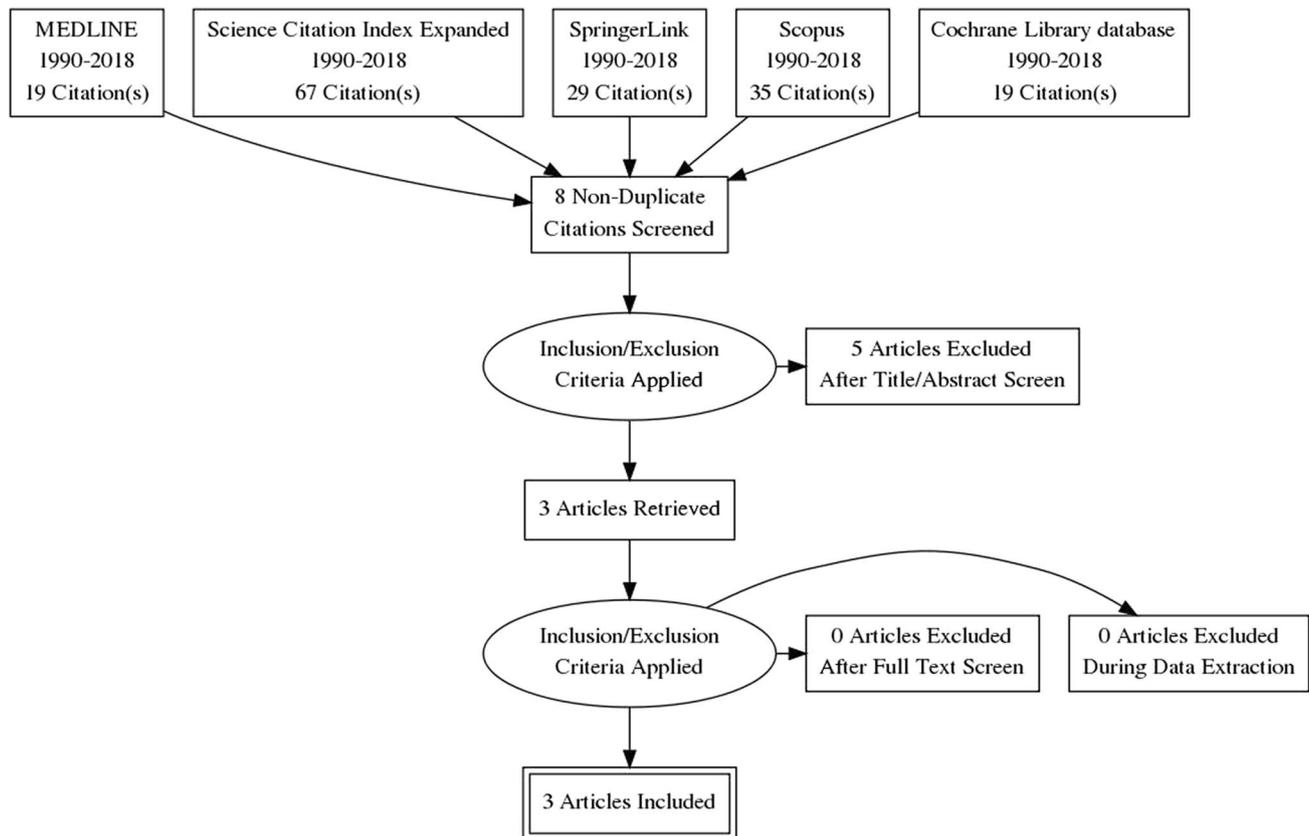


Fig. 1 Article identification and selection algorithm

Table 1 Summary of characteristics of the included studies

Study	Study design	No. of patients	Intervention	Inclusion criteria	Exclusion criteria	Main outcomes
Kim [22]	RCT (multicentre)	193 (92 F)	Suction drain (<i>n</i> = 94) No drain (<i>n</i> = 99)	Laparoscopic cholecystectomy for acute cholecystitis	Non acutely inflamed gallbladder (e.g., chronic cholecystitis or GB polyp), patients who had gallbladder perforation, concomitant organ dysfunctions, reduced port surgery or concurrent operation in other organs, patients in an immunodeficient state due to organ transplantation history or HIV infection, previous upper abdominal operation history, hollow viscus organ injury, common bile duct (CBD) exploration, or conversion to laparotomy during operation, surgery for malignancy of the gallbladder, patients who were of concern because of delayed bile leakage due to incomplete cystic duct ligation during the operation or who had high risk of bleeding due to liver cirrhosis or hematology disease	Primary endpoint: postoperative morbidity Secondary endpoints: postoperative pain, length of postoperative hospital stay, and re-intervention or readmission
Lucarelli [23]	RCT (multicentre)	30 (20 F)	Suction drain (<i>n</i> = 15) No drain (<i>n</i> = 15)	Laparoscopic cholecystectomy for acute calculous cholecystitis	Symptoms present for > 1 week, gangrenous or emphysematous cholecystitis, previous upper abdominal surgery, presence of significant medical diseases, coexisting common bile duct stones with ductal dilatation, acute cholangitis, acute pancreatitis	Primary endpoint: presence of subhepatic fluid collection at ultrasonographic examination of the abdomen 24 h after surgery. Secondary endpoints: postoperative abdominal and shoulder tip pain, use of analgesics, and morbidity
Park [24]	RCT (single center)	159 (62 F)	Suction drain (<i>n</i> = 79) No drain (<i>n</i> = 80)	Laparoscopic cholecystectomy for acute cholecystitis	Evidence of cholangitis or pancreatitis, the presence of any contraindication for the laparoscopic approach, if a common bile duct exploration or any other additional procedure was required, if the final pathologic report was gallbladder cancer; if The American Society of Anesthesiologists physical status was IV/V, presence of septic shock	Primary endpoint: collection of postoperative intra-abdominal fluid, including abscess Secondary endpoints: the presence of postoperative complications and cumulative length of the hospital stay

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Kim 2015	+	+	?	+	+	+	?
Lucarelli 2015	+	+	+	+	+	+	+
Park 2014	+	+	?	+	+	+	?

Fig. 2 Risk of bias summary of the included studies

significant OR (OR 0.62; 95% CI 0.08–4.71; $p=0.31$; Fig. 5).

Two studies assessed the presence of a subhepatic fluid collection with ultrasonographic examination: one on the first postoperative day [22] and the other one on the seventh postoperative day [24]. Both studies did not detect any significant difference between the two study groups.

Secondary outcomes

Two studies provided information about operative time and abdominal pain 24 h after surgery [22, 23]. All the included trials reported the postoperative hospital stay [22–24]. Postoperative pain was significantly reduced when drain was not inserted (MD 0.80; 95% CI 0.46–1.14; $p<0.000$; Fig. 6). Operative time was similar in both the study groups (Fig. 7). A significant difference in favor of the no drain group was found in the postoperative hospital stay (MD 1.05; 95% CI 0.87–1.22; $p<0.000$; Fig. 8).

Discussion

The main reason to use prophylactic drainage in LC is to reduce surgery-related complications, because drain can evacuate subhepatic fluid collection. Local complications occurred in 4.8% of LC for AC in a large survey [2]. In particular, bile leak is frequent, with a 2–3% reported rate

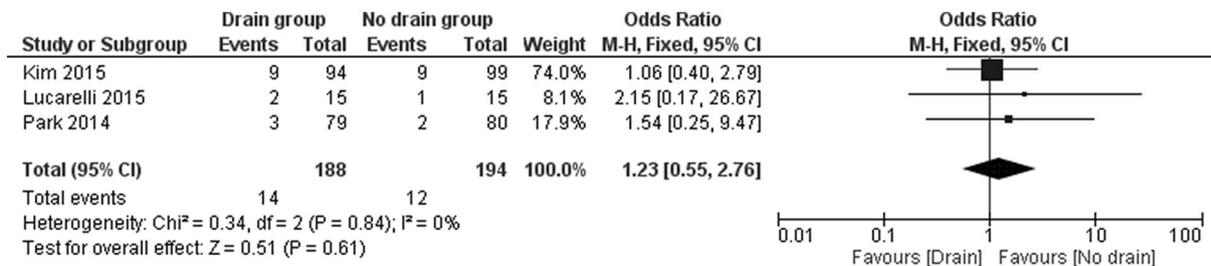


Fig. 3 Forest plot demonstrating postoperative morbidity in drain group compared to no drain group

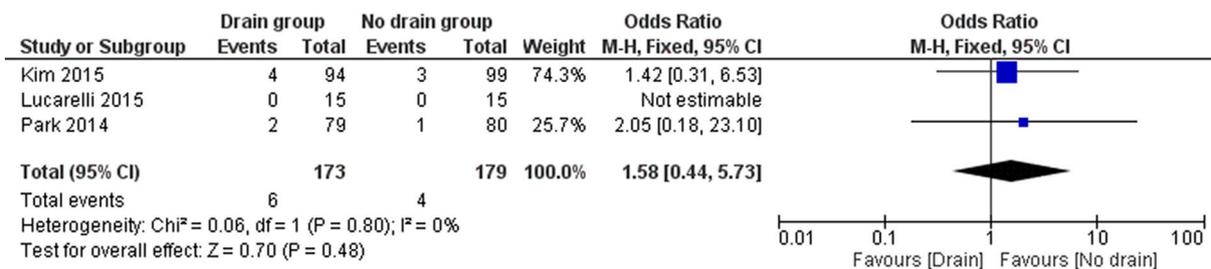


Fig. 4 Forest plot demonstrating wound infection rate in drain group compared to no drain group

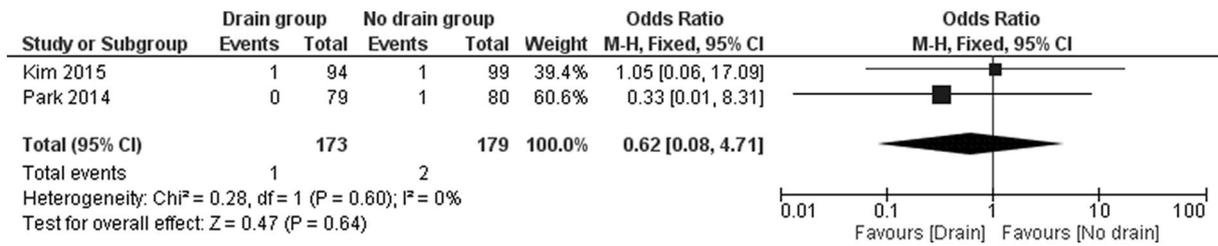


Fig. 5 Forest plot demonstrating abdominal abscess occurrence in drain group compared to no drain group

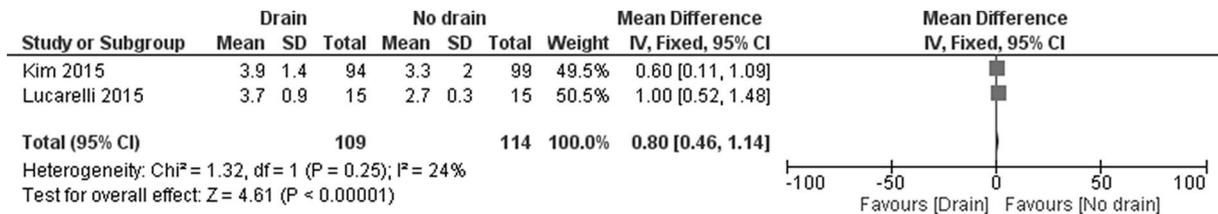


Fig. 6 Forest plot demonstrating the severity of abdominal pain 24 h after surgery in drain group compared to no drain group

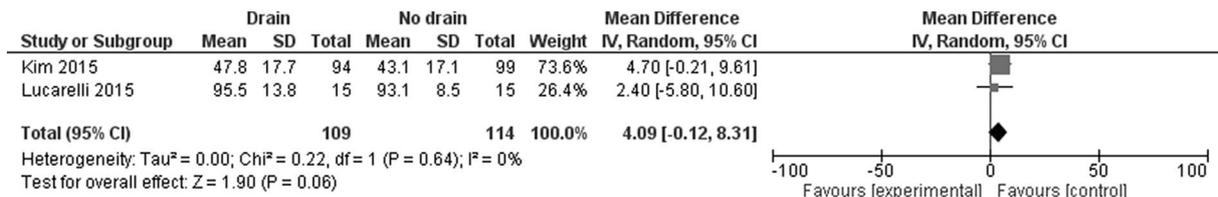


Fig. 7 Forest plot demonstrating the operative time (min) in drain group compared to no drain group

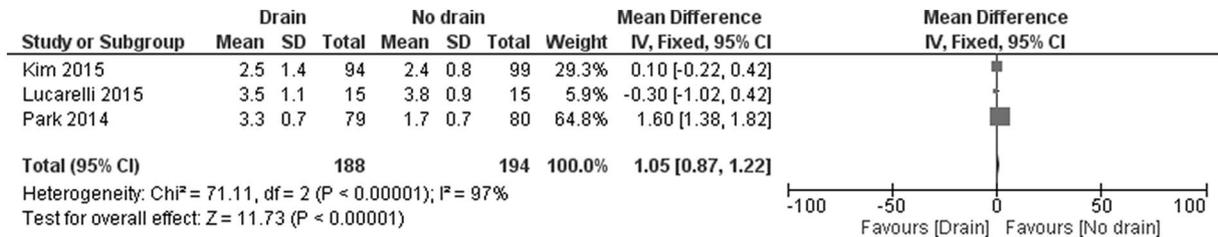


Fig. 8 Forest plot demonstrating the postoperative hospital stay (days) in drain group compared to no drain group

[2, 25, 26]. It is thought that drain is efficient in draining fluid collections such as bile and blood, so that it is reasonable to place a drain if a surgeon worries about a potential bile leak or excessive oozing. However, the most part of collections after cholecystectomy are asymptomatic and are absorbed by the peritoneum. Cholescintigraphy, performed 1 day after LC for AC, documented the presence of bile leak without symptoms [27]. Moreover, in the era of open cholecystectomy, placement of a drain was showed to be ineffective to prevent bile peritonitis [28, 29]. Wound and intra-abdominal infections are quite common after

surgery for AC. Wound infection occurred with a rate of 2.3% in a large survey [2] with a significant increase in severe AC [30]. There is conflicting evidence in the literature about the improved risk of wound infection if drains are placed in LC [31, 32]. The present meta-analysis clearly shows that drain has no role in reducing morbidity and preventing local complications such as surgical site infection also in the setting of AC. A possible explanation is the fact that drain is inefficient in draining postoperative fluid collection in the subhepatic area. This datum was confirmed by multiple meta-analyses in the setting of

elective LC [8–10]. The present meta-analysis confirms that drains do not reduce intra-abdominal fluid collections also in the setting of AC.

In the literature, the effect of subhepatic drain on postoperative pain is controversial. Significant reduction of postoperative pain in patient without drain insertion with respect to those with subhepatic drains was reported in the trial of Picchio et al. [32]. On the contrary, the study of Hawasli et al. [33] failed to find any difference. However, results of meta-analyses comparing studies, in which pain was assessed by means of a VAS score 24 h after surgery, showed a significant reduction of pain if drain was not placed in elective LC [8–10]. The present meta-analysis showed that the insertion of a drain is associated with an increased severity of abdominal pain 24 h after surgery, also if LC is performed for AC.

It is reasonable that operative time may be prolonged when a drain is inserted, but the time spent for this procedure is usually short with a value around 5 min [13]. Our data confirm that insertion of a drain requires a short time, which is not clinically relevant.

Postoperative hospital stay is not a reliable parameter to assess recovery, because there are many factors not strictly related to the surgical outcome, which can bias the results. In particular, factors influencing the postoperative discharge such as patient's motivation, external uncontrolled advice, and insurance coverage for disability may vary in different studies from different countries and health care systems. This consideration may partly explain why lower rates of morbidity and reduced abdominal pain in patients without drain insertion do not impact on postoperative hospital stay, as reported in previous meta-analyses [7–10]. However, the present meta-analysis showed a significant reduction in postoperative hospital stay, if drain is not inserted, although the results are highly affected by the trial of Park et al. [24].

The strengths of our study are that it is the first meta-analysis assessing the role of prophylactic drain in LC for AC with exclusive inclusion of RCTs with satisfactory methodological quality. The site and type of drain were similar. The main limitation is the little number of trials included and the presence of a single high-quality pilot RCT [23], which claims for future trials adhering to CONSORT guidelines [34]. Moreover, no subgroup analysis was performed according to the severity grading proposed by the Tokyo guidelines [35].

In conclusion, the present meta-analysis shows that prophylactic drain placement after LC for AC is related to more postoperative pain and a prolonged hospital stay. Although further high-quality RCTs are necessary to improve evidence, it is reasonable to avoid drain placement in LC for AC.

Acknowledgements The authors thank Dr. Federico Ottaviani for copy-editing the manuscript.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest. The authors declare that no foundations are involved in the study.

Research involving human participants and/or animals All procedures performed in studies involving human participants were in accordance with ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent For this type of study, formal consent is not required.

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