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TABLE OF CONTENTS

HEADER	1
ABSTRACT	1
PLAIN LANGUAGE SUMMARY	2
SUMMARY OF FINDINGS	3
BACKGROUND	5
OBJECTIVES	6
METHODS	6
RESULTS	8
Figure 1.	9
Figure 2.	10
Figure 3.	11
Figure 4.	13
DISCUSSION	14
AUTHORS' CONCLUSIONS	15
ACKNOWLEDGEMENTS	15
REFERENCES	16
CHARACTERISTICS OF STUDIES	19
DATA AND ANALYSES	28
Analysis 1.1. Comparison 1 Drain use versus no drain use, Outcome 1 Intra-peritoneal abscess.	28
Analysis 1.2. Comparison 1 Drain use versus no drain use, Outcome 2 Wound infection.	28
Analysis 1.3. Comparison 1 Drain use versus no drain use, Outcome 3 Morbidity.	29
Analysis 1.4. Comparison 1 Drain use versus no drain use, Outcome 4 Mortality.	29
Analysis 1.5. Comparison 1 Drain use versus no drain use, Outcome 5 Hospital stay.	29
Analysis 2.1. Comparison 2 Drain use versus no drain use (sensitivity analyses by excluding quasi-randomised trials), Outcome 1 Intra-peritoneal abscess.	30
APPENDICES	30
WHAT'S NEW	36
HISTORY	36
CONTRIBUTIONS OF AUTHORS	36
DECLARATIONS OF INTEREST	36
DIFFERENCES BETWEEN PROTOCOL AND REVIEW	37
INDEX TERMS	37

[Intervention Review]

Abdominal drainage to prevent intra-peritoneal abscess after open appendectomy for complicated appendicitis

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ABSTRACT

Background

Appendectomy, the surgical removal of the appendix, is performed primarily for acute appendicitis. Patients who undergo appendectomy for complicated appendicitis, defined as gangrenous or perforated appendicitis, are more likely to suffer from postoperative complications. The routine use of abdominal drainage to reduce postoperative complications after appendectomy for complicated appendicitis is controversial.

This is an update of the review first published in 2015.

Objectives

To assess the safety and efficacy of abdominal drainage to prevent intra-peritoneal abscess after open appendectomy for complicated appendicitis.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (the Cochrane Library, 2017, Issue 6), Ovid MEDLINE (1946 to 30 June 2017), Ovid Embase (1974 to 30 June 2017), Science Citation Index Expanded (1900 to 30 June 2017), World Health Organization International Clinical Trials Registry Platform (30 June 2017), ClinicalTrials.gov (30 June 2017) and Chinese Biomedical Literature Database (CBM) (1978 to 30 June 2017).

Selection criteria

We included all randomised controlled trials (RCTs) that compared abdominal drainage and no drainage in people undergoing emergency open appendectomy for complicated appendicitis.

Data collection and analysis

Two review authors identified the trials for inclusion, collected the data, and assessed the risk of bias independently. We performed the meta-analyses using Review Manager 5. We calculated the risk ratio (RR) for dichotomous outcomes (or a Peto odds ratio for very rare outcomes), and the mean difference (MD) for continuous outcomes with 95% confidence intervals (CI). We used GRADE to rate the quality of evidence.

Main results

We included six RCTs (521 participants), comparing abdominal drainage and no drainage in patients undergoing emergency open appendectomy for complicated appendicitis. The studies were conducted in North America, Asia and Africa. The majority of the participants had perforated appendicitis with local or general peritonitis. All participants received antibiotic regimens after open appendectomy. None of the trials was at low risk of bias.

There was insufficient evidence to determine the effects of abdominal drainage and no drainage on intra-peritoneal abscess at 14 days (RR 1.23, 95% CI 0.47 to 3.21; 5 RCTs; 453 participants; very low-quality evidence) or for wound infection at 14 days (RR 2.01, 95% CI 0.88 to 4.56; 5 RCTs; 478 participants; very low-quality evidence). The increased risk of 30-day overall complication rate (morbidity) in the drainage group was rated as very low-quality evidence (RR 6.67, 95% CI 2.13 to 20.87; 1 RCT; 90 participants). There were seven deaths in the drainage group (N = 183) compared to one in the no drainage group (N = 180), equating to an increase in the risk of 30-day mortality from 0.6% to 2.7% (Peto odds ratio (OR) 4.88, 95% CI 1.18 to 20.09; 4 RCTs; 363 participants; moderate-quality evidence). There is 'very low-quality' evidence that drainage increases hospital stay compared to the no drainage group by 2.17 days (95% CI 1.76 to 2.58; 3 RCTs; 298 participants).

Other outlined outcomes, hospital costs, pain, and quality of life, were not reported in any of the included studies.

Authors' conclusions

The quality of the current evidence is very low. The effect of abdominal drainage on the prevention of intra-peritoneal abscess or wound infection after open appendectomy is uncertain for patients with complicated appendicitis. The increased rates for overall complication rate and hospital stay for the drainage group compared to no drainage group is also subject to great uncertainty. Thus, there is no evidence for any clinical improvement by using abdominal drainage in patients undergoing open appendectomy for complicated appendicitis. The increased risk of mortality with drainage comes from eight deaths observed in just under 400 people recruited to the studies. Larger studies are needed to determine the effects of drainage on morbidity and mortality outcomes more reliably.

PLAIN LANGUAGE SUMMARY

Drain use after an open appendectomy for complicated appendicitis

We asked

Is drainage able to reduce the incidence of intra-peritoneal abscess (a localised collection of pus in the abdomen or pelvis) after an open appendectomy (removal of the appendix through a large incision in the lower abdomen, known as laparotomy) for complicated appendicitis?

Background

Appendicitis refers to inflammation of the appendix. Appendectomy, the surgical removal of the appendix, is performed primarily in individuals who have acute appendicitis. Individuals undergoing an appendectomy for complicated appendicitis, which is defined as gangrenous (soft-tissue death) or perforated (burst) appendicitis, are more likely to suffer from postoperative complications. The routine placement of a surgical drain to prevent intra-peritoneal abscess after an appendectomy for complicated appendicitis is controversial and has been questioned.

Study characteristics

We searched for all relevant studies up to 30 June 2017.

We identified six clinical studies involving a total of 521 participants. All six studies compared drain use versus no drain use in individuals having an emergency open appendectomy for complicated appendicitis. Studies were conducted in the USA, India, Kenya, Pakistan, and Turkey. The age of the individuals in the trials ranged from 0 years to 82 years.

Key results

The analyses were unable to show a difference in the number of individuals with intra-peritoneal abscess or wound infection when comparing drain use with no drain use. The death rate was higher in the drainage group than in the no drainage group. The hospital stay was longer (about two days - an 43.5% increase on an 'average' stay) in the drain group than in the no drain group. None of the studies reported the costs, pain, and quality of life. Overall, there is no evidence for any clinical improvement by using abdominal drainage in individuals undergoing open appendectomy for complicated appendicitis.

Quality of the evidence

All of the included studies had shortcomings in terms of methodological quality or reporting of outcomes. Overall, the quality of the current evidence is judged to be very low.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Drainage compared to no drainage for complicated appendicitis

Abdominal drainage to prevent intra-peritoneal abscess after open appendectomy for complicated appendicitis

Patient or population: people undergoing emergency open appendectomy for complicated appendicitis

Setting: hospital

Intervention: drainage

Comparison: no drainage

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with no drain use	Risk with drain use				
Intra-peritoneal abscess Follow-up: 14 days	107 per 1000	131 per 1000 (50 to 342)	RR 1.23 (0.47 to 3.21)	453 (5 studies)	⊕⊕⊕⊕ Very low ^{a,b,c}	
Wound infection Follow-up: 30 days	254 per 1000	511 per 1000 (224 to 1000)	RR 2.01 (0.88 to 4.56)	478 (5 studies)	⊕⊕⊕⊕ Very low ^{a,b,c}	
Morbidity Follow-up: 30 days	67 per 1000	445 per 1000 (142 to 1000)	RR 6.67 (2.13 to 20.87)	90 (1 study)	⊕⊕⊕⊕ Very low ^{a,c}	
Mortality Follow-up: 30 days month	6 per 1000	27 per 1000 (7 to 101)	Peto OR 4.88 (1.18 to 20.09)	363 (4 studies)	⊕⊕⊕⊕ Moderate ^c	
Hospital stay (days)	The mean hospital stay in the control groups was 4.60 days	The mean hospital stay in the intervention groups was 2.17 days higher (1.76 days to 2.58 days higher)	MD 2.17 days higher (1.76 higher to 2.58 higher)	298 (3 studies)	⊕⊕⊕⊕ Very low ^{a,d}	
Hospital cost	Not reported					
Pain	Not reported					
Quality of life	Not reported

*The basis for the **assumed risk** is the mean comparison group proportion in the studies. **The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **Peto OR:** Peto odds ratio; **RR:** risk ratio

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

^a Downgraded two levels for very serious risk of bias.

^b Downgraded one level for severe inconsistency (substantial heterogeneity as indicated by the I^2 statistic).

^c Downgraded one level for serious imprecision. For abscess, morbidity and infection, the confidence interval includes appreciable benefit and harm, and the sample size is small. For mortality, there are few events (8 deaths in total)

^d Downgraded one level for serious imprecision (small sample size).

BACKGROUND

Description of the condition

Appendicitis refers to inflammation of the appendix. Appendectomy, the surgical removal of the appendix, is performed primarily as an emergency procedure to treat acute appendicitis (Andersen 2005).

Acute appendicitis is the most common cause of acute abdominal pain (Andersen 2005; Rehman 2011; Sauerland 2010; Wilms 2011). The overall incidence of acute appendicitis varies between 76 and 227 cases per 100,000 population per year in different countries (Addiss 1990; Andersson 1994; Andreu-Ballester 2009; Buckius 2012; Ferris 2017; Körner 1997; Lee 2010; Pieper 1982; Williams 1998). The overall lifetime risk for acute appendicitis is approximately 7% to 8% in the USA, but as high as 16% in South Korea (Addiss 1990; Lee 2010). It affects all age groups, with the highest incidence in individuals 10 to 20 years of age (Addiss 1990; Wilms 2011).

The cause of acute appendicitis is an issue of considerable debate (Andersen 2005; Rehman 2011; Sauerland 2010; Wilms 2011). Acute appendicitis may be associated with obstruction of the appendix lumen (the inside space of the appendix), which could result in increased intraluminal pressure with transmural tissue necrosis (Andersen 2005; Rehman 2011; Sauerland 2010; Wilms 2011). Tissue necrosis is followed by bacterial invasion, which leads to inflammation of the appendix (Andersen 2005; Rehman 2011; Sauerland 2010; Wilms 2011).

Acute appendicitis can be divided into two subgroups: simple appendicitis (e.g. early appendicitis, uncomplicated appendicitis) and complicated appendicitis (e.g. gangrenous appendicitis, perforated appendix without phlegmon or abscess, perforated appendicitis with phlegmon or abscess) (Andersen 2005; Cheng 2017; Simillis 2010). The proportion of complicated appendicitis varies between 15% and 35% in different case series (Andersson 1994; Boomer 2010; Cheng 2017; Cueto 2006; Körner 1997; Livingston 2007; Oliak 2000).

Description of the intervention

Patients with complicated appendicitis usually require appendectomy to relieve symptoms and avoid complications (Andersson 1994; Santacroce 2017). Appendectomy is one of the most common emergency surgical procedures worldwide (Andersen 2005; Rehman 2011; Santacroce 2017; Sauerland 2010; Wilms 2011). There are two types of appendectomy: open appendectomy (removal of the appendix by laparotomy) and laparoscopic appendectomy (removal of the appendix by key-hole surgery) (Cheng 2012b; Cheng 2015; Yu 2017; Santacroce 2017; Sauerland 2010). Approximately 300,000 appendectomies are performed each year in the USA alone (Hall 2010).

The prognosis of complicated appendicitis is good (Santacroce 2017). The overall mortality rate of complicated appendicitis following appendectomy is less than 1% (Markides 2010; Santacroce 2017). The most common complication after an appendectomy for complicated appendicitis is surgical site infection (e.g. wound infection, intra-peritoneal abscess) (Andersen 2005; Cueto 2006). Patients with complicated appendicitis are more likely to suffer from surgical site infections than those with simple appendicitis (Markides 2010). Recent published reviews have

reported an approximately 10% incidence of surgical site infection (Markides 2010; Santacroce 2017). Patients with surgical site infections usually present with a mild fever, abdominal pain, and bowel dysfunction (e.g. diarrhoea, constipation) (Santacroce 2017). Surgical site infections are associated with increased hospital stays and costs (Horan 1992; Mangram 1999).

Various methods for the prevention of surgical site infections have been suggested, including antibiotic regimens, delayed wound closure, and the use of laparoscopic appendectomy (Andersen 2005; Duttaroy 2009; Markides 2010; Sauerland 2010). One of the most common and convenient interventions might be the application of surgical drains after appendectomy for patients with complicated appendicitis (Petrowsky 2004).

Surgical drains are used to remove blood, pus, and other body fluids from wounds (Durai 2009). There are two primary types of surgical drains: open and closed. An open drain is not air tight (Durai 2009; Gurusamy 2007a; Samraj 2007; Wang 2015). A closed drain consists of a tube that drains into a bag or bottle, the contents of which is air tight (Durai 2009; Gurusamy 2007a; Samraj 2007; Wang 2015).

How the intervention might work

The primary reasons for placing an abdominal drain after an appendectomy are as follows: (i) drainage of established intra-peritoneal collection; (ii) prevention of further fluid accumulation; (iii) identification and drainage of faecal fistula (Allemann 2011; Gurusamy 2007a; Jani 2011).

The use of abdominal drainage can avoid the accumulation of intra-peritoneal dirty collections, thereby reducing bacterial contamination of the surgical site (Greenall 1978; Jani 2011; Stone 1978; Tander 2003). Theoretically, abdominal drainage has the potential to reduce the rate of surgical site infection (Greenall 1978; Jani 2011; Stone 1978; Tander 2003).

However, abdominal drainage may fail to prevent intra-peritoneal abscess because a drain may become blocked and thus ineffective within a few hours after appendectomy (Greenall 1978; Haller 1973; Jani 2011; Magarey 1971). Additionally, the drain itself may act as a foreign body, which interferes with wound healing and increases the risk of surgical site infection (Jani 2011; Stone 1978; Magarey 1971). The use of a drain may also increase the length of the patient's hospital stay (Allemann 2011; Jani 2011; Stone 1978; Tander 2003).

Why it is important to do this review

The use of abdominal drainage after open appendectomy for complicated appendicitis is controversial (Narci 2007; Petrowsky 2004; Piper 2011). It may potentially decrease the risk of surgical site infection following open appendectomy, but it is also possible that it may have no therapeutic benefit and may be associated with negative outcomes (Jani 2011; Mustafa 2016; Petrowsky 2004).

The first version of this review was published in 2015 (Cheng 2015). Further randomised controlled trials (RCTs) evaluating the role of abdominal drainage after open appendectomy for complicated appendicitis have been published since the review, and these studies have now been assessed for inclusion and presented in this update.

OBJECTIVES

To assess the safety and efficacy of abdominal drainage to prevent intra-peritoneal abscess after open appendectomy for complicated appendicitis.

METHODS

Criteria for considering studies for this review

Types of studies

We included all randomised controlled trials (RCTs) (irrespective of sample size, language, or publication status) that compared drain use and no drain use in patients undergoing open appendectomy for complicated appendicitis. Quasi-randomised controlled trials (in which the allocation was performed on the basis of a pseudo-random sequence, e.g. odd/even hospital number or date of birth, alternation) were also included (Chapter 16 in *Cochrane Handbook for Systematic Reviews of Interventions*, Higgins 2011a).

Types of participants

We included all persons (irrespective of age, sex, or race) who underwent emergency open appendectomy for complicated appendicitis (irrespective of gangrenous appendicitis, perforated appendix without phlegmon or abscess, or perforated appendicitis with phlegmon or abscess), and receiving antibiotic regimens after open appendectomy.

Types of interventions

Use of drain (irrespective of type or material) versus no drain.

Types of outcome measures

Primary outcomes

- Intra-peritoneal abscess (e.g. intra-abdominal abscess, pelvic abscess) (14 days).

Secondary outcomes

- Wound infection (14 days).
- Morbidity (overall complication rate; graded by the Clavien-Dindo complications classification system) (30 days).
- Mortality (30 days).
- Hospital stay (days).
- Hospital costs.
- Pain (30 days, any validated score).
- Quality of life (30 days, any validated score).

Morbidity was defined by review authors and graded according to the Clavien-Dindo classification of surgical complications (Clavien 2009). Surgical site infection has been defined and classified as superficial incisional, deep incisional, and organ/space surgical site infection by the Centers for Disease Control and Prevention (CDC) (Anderson 2014; Horan 1992; Mangram 1999). We included intra-peritoneal abscess (organ/space surgical site infection) as the primary outcome. Wound infection (either superficial or deep incisional surgical site infection) as defined by the study authors.

Search methods for identification of studies

We designed the search strategy with the help of Sys Johnsen (Cochrane Information Specialist of the Cochrane Colorectal

Cancer Group). Searches were conducted 30 June 2017 irrespective of language, year, or publication status.

Electronic searches

We searched the following electronic databases with no language or date of publication restrictions:

- Cochrane Central Register of Controlled Trials (CENTRAL) (the Cochrane Library) (2017, Issue 6) (Appendix 1);
- MEDLINE (Ovid) (1946 to 30 June 2017) (Appendix 2);
- Embase (Ovid) (1974 to 30 June 2017) (Appendix 3);
- Science Citation Index Expanded (Web of Science) (1900 to 30 June 2017) (Appendix 4);
- World Health Organization International Trials Registry Platform search portal (apps.who.int/trialsearch/) (30 June 2017);
- ClinicalTrials.gov (www.clinicaltrials.gov/) (30 June 2017);
- Chinese Biomedical Literature Database (CBM) (1978 to 30 June 2017).

Searching other resources

Furthermore, we also searched the following databases 30 June 2017:

- Current Controlled Trials (www.controlled-trials.com/);
- Chinese Clinical Trial Register (www.chictr.org/);
- EU Clinical Trials Register (www.clinicaltrialsregister.eu/).

We also searched the reference lists of identified studies and meeting abstracts via the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) (www.sages.org/) and Conference Proceedings Citation Index to explore further relevant clinical trials. We planned to communicate with the authors of RCTs that were included for further information in the review.

Data collection and analysis

We conducted this systematic review according to the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b), and the *Cochrane Colorectal Cancer Group Module* (Andersen 2016).

Selection of studies

After completing the searches, we merged the search results using the software package Endnote X7 (reference management software) and removed duplicate records. Two review authors (CY, CN) independently scanned the title and abstract of every record identified by the search for inclusion. We retrieved the full text for further assessment if the inclusion criteria were unclear from the abstract. We included eligible studies irrespective of whether they reported the measured outcome data. We detected duplicate publications by identifying common authors, centres, details of the interventions, numbers of participants, and baseline data (Chapter 7, the *Cochrane Handbook for Systematic Reviews of Interventions*, Higgins 2011c). We excluded papers that did not meet the inclusion criteria and listed the reasons for their exclusion. A third review author (DY) resolved any discrepancy between the two review authors by discussion.

Data extraction and management

We used a standard data collection form for study characteristics and outcome data, which had been piloted on at least one study

in the review. Two review authors (LZ, ZL) extracted the following study characteristics from included studies:

- methods: study design, total duration study and run in, number of study centres and location, study setting, withdrawals, date of study;
- participants: number of participants, mean age, age range, gender, severity of condition, diagnostic criteria, inclusion criteria, exclusion criteria;
- interventions: intervention, comparison;
- outcomes: primary and secondary outcomes specified and collected, time points reported;
- notes: funding for trial, notable conflicts of interest of trial authors.

Two review authors (LZ, ZL) independently extracted outcome data from included studies. We resolved disagreements by consensus or by involving a third review author (DY). One review author (LZ) copied across the data from the data collection form into Review Manager 5 (version 5.3, [RevMan 2014](#)). We double-checked that the data were entered correctly by comparing the study reports with how the data were presented in the systematic review.

A second review author (ZL) cross-checked study characteristics for accuracy against the trial reports.

Assessment of risk of bias in included studies

Two review authors (CY, CN) independently assessed the risk of bias in the included trials, using the Cochrane 'Risk of bias' tool (Chapter 8, the *Cochrane Handbook for Systematic Reviews of Interventions*, [Higgins 2011d](#)). We assessed risk of bias for the following domains:

- random sequence generation;
- allocation concealment;
- blinding of participants and personnel;
- blinding of outcome assessment;
- incomplete outcome data;
- selective reporting bias;
- other sources of bias (baseline imbalances).

We judged each domain as low risk, high risk, or unclear risk of bias according to the criteria used in the Cochrane 'Risk of bias' tool (see [Appendix 5](#)) (Chapter 8.5.d, [Higgins 2011d](#)). We considered a trial to be at low risk of bias if we assessed the trial as at low risk of bias across all domains. Otherwise, we considered trials at unclear risk of bias or at high risk of bias regarding one or more domains as at high risk of bias. We resolved any difference in opinion by discussion. In case of disagreements, consensus was reached by discussion with a third review author (DY).

We presented the results of the risk of bias in two figures (a 'Risk of bias' graph and a 'Risk of bias' summary) generated by Review Manager 5 ([RevMan 2014](#)).

Measures of treatment effect

We performed the meta-analyses using the software package Review Manager 5.3 ([RevMan 2014](#)). For dichotomous outcomes, we calculated the risk ratio (RR) with 95% confidence interval ([Deeks 2011](#)). In the case of rare events (e.g. mortality), we calculated the Peto odds ratio (Peto OR) ([Deeks 2011](#)). For continuous outcomes,

we calculated the mean difference (MD) with 95% confidence interval ([Deeks 2011](#)).

Unit of analysis issues

The unit of analysis was the individual patient. We did not encounter any cluster-randomised trials.

Dealing with missing data

We contacted the original investigators to request further information in case of missing data. However, there was no reply. Thus, we used only the available data in the analyses.

Assessment of heterogeneity

We described heterogeneity in the data using the Chi² test ([Deeks 2011](#)). We considered a P value less than 0.05 to be statistically significant heterogeneity ([Deeks 2011](#)). We also used the I² statistic to measure the quantity of heterogeneity. In case of statistical heterogeneity or clinical heterogeneity (or both), we performed the meta-analysis but interpreted the result cautiously and planned to investigate potential sources of the heterogeneity.

Assessment of reporting biases

We planned to perform and examine a funnel plot to explore possible publication biases. However, as the number of trials included was less than 10, we did not produce any funnel plots as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions*, Chapter 10 ([Sterne 2011](#)).

Data synthesis

We performed the meta-analyses using the Review Manager 5 software provided by Cochrane (version 5.3, [RevMan 2014](#)). For all analyses, we employed the random-effects model for conservative estimation, except for the Peto OR which only has a fixed-effect method. We considered a P value less than 0.05 to be statistically significant.

Subgroup analysis and investigation of heterogeneity

We did not perform any planned subgroup analysis because too few trials were included in this review.

Sensitivity analysis

We performed a sensitivity analysis for the primary outcome Intra-peritoneal abscess by excluding quasi-randomised controlled trials to determine whether the conclusions were robust to the decisions made during the review process.

Trial sequential analysis

We performed trial sequential analysis (TSA) for the primary outcome if possible. TSA aims to reduce the risk of random error in the setting of repetitive testing of accumulating data, thereby improving the reliability of conclusions ([Brok 2008](#); [Wetterslev 2008](#); [Wetterslev 2009](#)). The required information size was calculated on the basis of a risk ratio reduction (RRR) of 20% ([Brok 2008](#); [Wetterslev 2008](#); [Wetterslev 2009](#)). The results of the trials were presented as a cumulative Z-curve. The trial sequential monitoring boundaries were constructed and the diversity-adjusted required information size calculated with a type 1 error of 5% and a type 2 error of 20% ([Brok 2008](#); [Wetterslev 2008](#); [Wetterslev 2009](#)). The results were presented as a graph

with the cumulative meta-analysis results entered. The TSA shows firm evidence of intervention effects (or no intervention effects) if the cumulative Z-curve crosses the monitoring boundaries; it also shows that additional trials may be needed if the boundaries are not crossed ([Brok 2008](#); [Wetterslev 2008](#); [Wetterslev 2009](#)). TSA was performed using Trial Sequential Analysis software ([TSA 2011](#)).

'Summary of findings' tables

We evaluated the quality of evidence using the GRADE ([Schünemann 2009](#)) approach for each outcome, including any subgroup analysis or sensitivity analysis.

We presented the quality of evidence in 'Summary of finding' table for the following comparison:

- drainage versus no drainage.

We justified judgements about the quality of the evidence (high, moderate, low, or very low), documented, and incorporated into the reporting of results for each outcome. The quality of evidence could be downgraded by one level (serious concern) or two levels (very serious concerns) applying to each of the following five reasons listed: risk of bias; inconsistency (unexplained heterogeneity, inconsistency of results); indirectness (indirect population, intervention, control, outcomes); imprecision (wide CIs, single trials); and publication bias.

RESULTS

Description of studies

See: [Characteristics of included studies](#) and [Characteristics of excluded studies](#) tables.

Results of the search

Date of search 30 June 2017.

In this updated review, we identified 746 records through the electronic searches of the Cochrane Library (46 records), MEDLINE (Ovid) (65 records), Embase (Ovid) (102 records), Science Citation Index Expanded (Web of Science) (231 records), and Chinese Biomedical Literature Database (CBM) (302 records). We identified two records through scanning reference lists of the identified randomised controlled trials ([Haller 1973](#); [Johnson 1993](#)). Of the 748 records, 677 records had already been assessed for the first version of this updated review (648 records prior to 2014 and 29 duplicates). Of the remaining 71 records, we excluded 68 clearly irrelevant records after reading titles and abstracts. The remaining three records were retrieved in full for further assessment ([Mustafa 2016](#); [Beek 2015](#); [Song 2015](#)). Two of these, [Beek 2015](#) and [Song 2015](#), were excluded being non-randomised studies. The study by [Mustafa 2016](#) was included in this updated review.

We identified six trials (with a total of 521 participants) comparing drainage with no drainage for persons undergoing appendectomy for complicated appendicitis ([Dandapat 1992](#); [Haller 1973](#); [Jani 2011](#); [Mustafa 2016](#); [Stone 1978](#); [Tander 2003](#)). Two hundred and sixty-two persons were randomised to the drainage group and 259 persons to the no drainage group. With so few participants, all of the analyses were underpowered. The study flow diagram is shown in [Figure 1](#).

Figure 1. Study flow diagram.

Figure 1. (Continued)

6 studies included
in quantitative
synthesis in this
update

Included studies

In the first published version of this review from 2015 (Cheng 2015), we included five trials, published between 1973 and 2003 (Dandapat 1992; Haller 1973; Jani 2011; Stone 1978; Tander 2003). In this update, we identified one recent trial (Mustafa 2016), to a total of six included trials (including 521 participants). All the six trials were completed trials and all of these provided data for the analyses. Details of the trials are shown in the table "Characteristics of included studies". Four trials were randomised controlled trials (Dandapat 1992; Jani 2011; Mustafa 2016; Tander 2003), and two trials were quasi-randomised controlled trials (Haller 1973; Stone 1978). All six trials compared drain use with no drain use for patients undergoing open appendectomy. Studies were conducted in the USA (Haller 1973; Stone 1978), India (Dandapat 1992), Kenya (Jani 2011), Pakistan (Mustafa 2016), and Turkey (Tander 2003). The age of the individuals in the trials varied between 0 years and 82 years. The mean proportion of females varied between 19% and 44%. There was no difference in the characteristics of patients in the intervention group or control in any of the trials. Overall, 32 (6.1%) participants had gangrenous appendicitis, 11 (2.1%) participants had appendiceal abscess, and 478 (91.8%) participants had perforated appendicitis in the trials.

All of the participants received antibiotic regimens after open appendectomy. The outcomes measured were intra-peritoneal abscess, wound infection, morbidity, mortality, and hospital stay.

Excluded studies

One randomised controlled trial was excluded because it focused on extraperitoneal wound drainage (Everson 1977). Another randomised controlled trial was excluded because it compared peritoneal lavage with abdominal drainage (Toki 1995). Two randomised controlled trials were excluded because the antibiotic regimens were used in a non-random manner (several participants received antibiotic regimens after appendectomy, whereas other participants did not) (Greenall 1978; Magarey 1971). None of the other excluded studies were randomised controlled trials (Allemann 2011; Al-Shahwany 2012; Beek 2015; Ezer 2010; Johnson 1993; Narci 2007; Piper 2011; Song 2015).

Risk of bias in included studies

The risk of bias of the included studies is shown in Figure 2 and Figure 3. None of the included trials were judged to be of low risk of bias.

Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Figure 3. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.

	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
Dandapat 1992	?	?	?	?	+	+	+
Haller 1973	-	?	?	?	+	+	+
Jani 2011	?	?	?	?	+	+	+
Mustafa 2016	?	?	?	?	+	-	+
Stone 1978	-	?	?	?	+	+	+
Tander 2003	?	?	?	?	+	+	+

Allocation

Random sequence generation was at unclear risk of bias in four trials (Dandapat 1992; Jani 2011; Mustafa 2016; Tander 2003) and high risk of bias in two trials where participants were randomised using pseudo-random sequences (odd/even hospital number) (Haller 1973; Stone 1978). Allocation concealment was at an unclear risk of bias in all six trials (Dandapat 1992; Haller 1973; Jani 2011; Mustafa 2016; Stone 1978; Tander 2003).

Blinding

Blinding of participants and personnel was at an unclear risk of bias in all six trials (Dandapat 1992; Haller 1973; Jani 2011; Mustafa 2016; Stone 1978; Tander 2003). Blinding of outcome assessment was also of unclear risk of bias in all six trials (Dandapat 1992; Haller 1973; Jani 2011; Mustafa 2016; Stone 1978; Tander 2003).

Incomplete outcome data

There was a low risk of bias for incomplete outcome data in all six trials ([Dandapat 1992](#); [Haller 1973](#); [Jani 2011](#); [Mustafa 2016](#); [Stone 1978](#); [Tander 2003](#)).

Selective reporting

The trial protocols were not available for any of the included trials. Five trials reported the primary outcomes of this review ([Dandapat 1992](#); [Haller 1973](#); [Jani 2011](#); [Stone 1978](#); [Tander 2003](#)). There may have been some selective outcome reporting in the secondary outcomes (secondary outcomes of this review were not reported), but the review authors considered these five trials to be free of selective reporting for the primary outcomes. One trial was at high risk of selective reporting bias as the primary outcome of the review was not reported ([Mustafa 2016](#)).

Other potential sources of bias

No baseline imbalances were observed, therefore this was at a low risk of bias in all six trials ([Dandapat 1992](#); [Haller 1973](#); [Jani 2011](#); [Mustafa 2016](#); [Stone 1978](#); [Tander 2003](#)).

Effects of interventions

See: [Summary of findings for the main comparison](#) Drainage compared to no drainage for complicated appendicitis

Primary outcome

Intra-peritoneal abscess

We identified five trials (453 participants) reporting intra-peritoneal abscess. The rate of intra-peritoneal abscess was 15.8% in the drainage group and 10.7% in the no drainage group. There was no evidence of a difference in the rate of intra-peritoneal abscess (including intra-abdominal abscess and pelvic abscess) between the groups (risk ratio (RR) 1.23, 95% confidence interval (CI) 0.47 to 3.21; $P = 0.67$; [Analysis 1.1](#)). We downgraded the quality of the evidence to very low due to risk of bias, serious imprecision, and serious inconsistency.

The Trials Sequential Analysis graph showed that the cumulative Z-curve did not cross the trial sequential boundaries ([Figure 4](#)). The analysis showed a diversity-adjusted required information size of 2570 participants (the number of participants needed to reach firm evidence of an intervention effect of 20% RRR). The number of participants included corresponded to only a small fraction (20.3%) of the diversity-adjusted required information size. Accordingly, we lack evidence to support or refute an intervention effect as data were too few.

Figure 4. Trial sequential analysis of drain use versus no drain use for intra-peritoneal abscess. Analysis was performed with an event rate of 10.7% (Pc) in the control group, a risk ratio reduction of 20%, alpha 5%, beta 20%, and observed diversity 63%. The cumulative Z-curve did not cross the trial sequential boundaries (inward sloping etched lines). The results showed that the observed diversity-adjusted required information size was 2,570 participants, corresponding to 20.3% of the total sample size in the included trials. Accordingly, the meta-analysis did not support or refute an intervention effect as data were too few.

Secondary outcomes

Wound infection

We identified 5 trials (478 participants) reporting wound infection. The rate of wound infection was 37.0% in the drainage group and 25.4% in the no drainage group. There was no evidence of a difference in the wound infection rate between the groups (RR 2.01, 95% CI 0.88 to 4.56; $P = 0.10$; [Analysis 1.2](#)). We downgraded the quality of the evidence to very low due to risk of bias, serious imprecision, and serious inconsistency.

Morbidity

We identified one trial (90 participants) reporting overall complication rate (morbidity). The overall complication rate defined according to the Clavien-Dindo classification was 44.4% in the drainage group and 6.7% in the no drainage group. The overall morbidity was higher in the drainage group than in the no drainage group (RR 6.67, 95% CI 2.13 to 20.87; $P = 0.001$; [Analysis 1.3](#)). We downgraded the quality of the evidence to very low due to risk of bias and serious imprecision.

Mortality

We identified four trials (363 participants) reporting mortality. The death rate was 3.8% in the drainage group and 0.6% in the no drainage group. Mortality was higher in the drainage group than in the no drainage group (Peto odds ratio (OR) 4.88, 95% CI 1.18 to 20.09; $P = 0.03$; [Analysis 1.4](#)). We downgraded the quality of the evidence to moderate due to serious imprecision.

Hospital stay

We identified three trials (298 participants) reporting hospital stay. The mean length of hospital stay was 6.6 days in the drainage group and 4.6 days in the no drainage group. The hospital stay was longer in the drainage group than in the no drainage group (mean difference (MD) 2.17 days (43.5% increase of an 'average' hospital stay); 95% CI 1.76 to 2.58; $P < 0.001$; [Analysis 1.5](#)). We downgraded the quality of the evidence to very low due to risk of bias and serious imprecision.

Hospital costs

None of the trials reported this outcome.

Pain

None of the trials reported this outcome.

Quality of life

None of the trials reported this outcome.

Reporting biases

We did not create funnel plots to assess reporting biases because the number of trials included was fewer than 10 ([Sterne 2011](#)).

Sensitivity analysis

We observed no change in the intra-peritoneal abscess outcome by excluding two quasi-randomised controlled trials ([Haller 1973](#); [Stone 1978](#)) ([Analysis 2.1](#)).

DISCUSSION

Summary of main results

Six studies with 521 people contributed data to the primary outcome of this review, and showed no evidence of difference in the incidence of intra-peritoneal abscess between the drainage group and the no drainage group. Very low-quality trials furthermore showed that abdominal drainage increased rate of wound infection, overall morbidity, mortality, and length of hospital stay.

The primary reason for the placement of a drain after appendectomy is to prevent intra-peritoneal abscess (e.g. intra-abdominal abscess, pelvic abscess). We found that the routine use of abdominal drainage after complicated appendectomy did not reduce the incidence of intra-peritoneal abscess. The possible reasons for the failure to decrease the incidence of intra-peritoneal abscess are as follows. First, surgical drains may become blocked by blood or fibrin clots ([Schein 2008](#); [Yates 1905](#)). Additionally, surgical drains cannot drain the entire abdominal cavity. Abdominal collections or abscesses can occur despite abdominal drainage ([Schein 2008](#); [Yates 1905](#)). Moreover, this review included six trials with only 262 participants undergoing abdominal drainage. This review may not have the statistical power to detect the any clinically meaningful difference between abdominal drainage and no drainage for the prevention of intra-peritoneal abscess even if such a difference was present. In addition, where differences were detected, confidence in these results is low, as the small numbers means they could be spurious results, and the impact of a bias can be exacerbated in underpowered analyses. Thus, it is not clear whether routine abdominal drainage has any effect on the prevention of intra-peritoneal abscess in patients undergoing open appendectomy for complicated appendicitis.

Overall completeness and applicability of evidence

All of the trials included patients undergoing emergency open appendectomy for complicated appendicitis (e.g. gangrenous appendicitis and perforated appendicitis). The majority (91.8%) of the patients had perforated appendicitis with local or general peritonitis. Thus, the results of this review are applicable to patients undergoing emergency open appendectomy for perforated appendicitis.

Quality of the evidence

None of the trials were at a low risk of bias. The trials included under each comparison were too few to assess inconsistency and publication bias. Direct comparisons of different types of drain were not available, only comparisons for each type of drain with no drain. In theory, these trials could allow indirect comparisons of the effect of different types of drain, however, small sample sizes and methodological flaws of the trials preclude such indirect comparison. The confidence intervals for the majority of outcomes were wide, indicating that the estimates of effect obtained are imprecise. Overall, we considered the quality of the evidence to be very low ([Summary of findings for the main comparison](#)).

Potential biases in the review process

There were several potential biases of note in the review process. First, there were only six trials with 521 patients included in the review; thus, there was a lack of data on this topic to date. Second, we did not create funnel plots to assess potential publication bias due to the small number of included trials. Third, we did not perform any planned subgroup analyses to assess heterogeneity because of the small number of trials included for each outcome. Additionally, patient selection processes and blinding were unclear for most of the studies. We contacted the original investigators to request further information. However, we did not receive any replies. Moreover, an important source of bias in the included studies was the use of antibiotic regimens ([Andersen 2005](#)). For example, the type and length of antibiotic therapy were important confounding factors for various outcomes (e.g. intra-peritoneal abscess, wound infection) ([Andersen 2005](#)). However, the type and length of antibiotic therapy varied a great deal in different trials. It was difficult to perform subgroup analyses to assess the heterogeneity. A final point is that the imputation of the standard deviation for hospital stay from the range might also introduce bias into this review.

Agreements and disagreements with other studies or reviews

There is increasing evidence in Cochrane Reviews that routine abdominal drainage after various abdominal operations is not essential ([Cheng 2016](#); [de Jesus 2004](#); [Gurusamy 2007a](#); [Gurusamy 2013](#); [Gurusamy 2007b](#); [Wang 2015](#)). The routine use of surgical drains has been questioned in other areas, including thyroid, gynaecological, and orthopaedic surgeries ([Charoenkwan 2017](#); [Gates 2013](#); [Parker 2007](#); [Samraj 2007](#)).

The systematic review by Petrowsky and colleagues ([Petrowsky 2004](#)) included five trials comparing drain use with no drain use in patients undergoing appendectomy for complicated appendicitis ([Dandapat 1992](#); [Greenall 1978](#); [Haller 1973](#); [Magarey 1971](#); [Stone 1978](#)). Two of these five trials, in which antibiotic regimens were used in a non-random manner (some participants received antibiotic regimens after appendectomy, whereas other participants did not), were not included in this review ([Greenall 1978](#); [Magarey 1971](#)). Petrowsky and colleagues concluded that abdominal drainage did not reduce postoperative complications and appeared harmful with respect to the development of faecal fistula ([Petrowsky 2004](#)). Thus, these authors recommended that abdominal drainage should be avoided at any stage of appendicitis ([Petrowsky 2004](#)). This review has not reached definitive conclusions, in part because the number of participants

included is low for detecting a benefit on intra-peritoneal abscess. A sample size of 2570 would be required to detect an absolute reduction in the intra-peritoneal abscess rate of 2% (from 10% to 8%) at 80% power and an alpha-error set at 0.05.

AUTHORS' CONCLUSIONS

Implications for practice

The effect of abdominal drainage for prevention of intra-peritoneal abscess after open appendectomy is uncertain for patients with complicated appendicitis due to the very low quality of evidence. The effect on wound infection after open appendectomy is also uncertain for patients with complicated appendicitis. The increased rates for overall complication rate and hospital stay for the drainage group compared to no drainage group is also subject to great uncertainty. The excess mortality in the drainage group was observed from eight deaths in total across the studies. There is no evidence for any clinical improvement by using abdominal drainage in patients undergoing open appendectomy for complicated appendicitis.

Implications for research

High-quality trials are urgently required. Investigators should employ adequate methods of randomisation, allocation concealment and blinding of outcome assessors to reduce the risk of bias. Studies with larger sample sizes will help to ensure that there is adequate power to detect effects on morbidity outcomes, and to provide further information on mortality. Future trials should specify a set of criteria for antibiotics use and define all of the patient-important outcomes (e.g. pain, quality of life) more accurately and report them in accordance with validated criteria.

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CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Dandapat 1992

Methods	Randomised controlled trial
Participants	Country: India

Abdominal drainage to prevent intra-peritoneal abscess after open appendectomy for complicated appendicitis (Review)

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Dandapat 1992 (Continued)

Number randomised: 86
 Post-randomisation dropout: 0 (0%)
 Children: 16 (19%)

 Adults: 70 (81%)
 Females: 16 (19%)

 Normal appendix: 0 (0%)
 Simple appendicitis: 0 (0%)
 Gangrenous appendicitis: 0 (0%)
 Perforated appendicitis: 86 (100%)
 Appendiceal phlegmon or abscess: 0 (0%)
 Inclusion criteria:

- Emergency appendectomy
- Appendectomy for perforated appendicitis
- Appendectomy for gangrenous appendicitis, associated with turbid infected fluid

 Exclusion criteria:

- Patients with an appendiceal abscess

Interventions	Participants with complicated appendicitis (n = 86) were randomly assigned to 2 groups Group 1: drainage (n = 40) Group 2: no drainage (n = 46)
Outcomes	The outcomes reported were wound infection, intra-peritoneal abscess, duration of postoperative fever, postoperative complications, mortality, and hospital stay
Notes	The drainage tube (corrugated rubber drain) was placed down into the right iliac fossa

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: no information provided
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no information provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: there were no post-randomisation dropouts

Dandapat 1992 (Continued)

Selective reporting (re-reporting bias)	Low risk	Comment: all of the primary outcomes were reported. There was some selective outcome reporting in the secondary outcomes, but the review authors considered this trial to be free of selective reporting for the primary outcomes
Other bias	Low risk	Comment: the study appears to be free of other sources of bias

Haller 1973

Methods	Quasi-randomised controlled trial
Participants	Country:USA Number randomised: 43 Post-randomisation dropout: 0 (0%) Children (0 - 14 years): 43 (100%) Adults: 0 (0%) Females: 10 (23%) Normal appendix: 0 (0%) Simple appendicitis: 0 (0%) Gangrenous appendicitis: 0 (0%) Perforated appendicitis: 43 (100%) Appendiceal phlegmon or abscess: 0 (0%) Inclusion criteria: <ul style="list-style-type: none"> Emergency appendectomy Appendectomy for perforated appendicitis with generalised peritonitis Exclusion criteria: <ul style="list-style-type: none"> Age was more than 14 years old
Interventions	Participants with complicated appendicitis (n = 43) were randomly assigned to 2 groups Group 1: drainage (n = 24) Group 2: no drainage (n = 19)
Outcomes	The outcomes reported were intra-peritoneal abscess, postoperative complications, mortality, and hospital stay
Notes	The drainage tube (Penrose drain) was placed through the wound down into the right iliac fossa and pelvis

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "Transperitoneal drainage was used in children with even hospital numbers and no drainage or wound drainage alone was used in children with odd hospital numbers" Comment: the allocation was performed on the basis of a pseudo-random sequence (odd/even hospital number)

Haller 1973 (Continued)

Allocation concealment (selection bias)	Unclear risk	Comment: no information provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no information provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: there were no post-randomisation dropouts
Selective reporting (reporting bias)	Low risk	Comment: all of the primary outcomes were reported. There was some selective outcome reporting in the secondary outcomes, but the review authors considered this trial to be free of selective reporting for the primary outcomes
Other bias	Low risk	Comment: the study appears to be free of other sources of bias

Jani 2011

Methods	Randomised controlled trial
Participants	<p>Country: Kenya Number randomised: 90 Post-randomisation dropout: 0 (0%) Age (13 to 26): 44 (49%)</p> <p>Age (27 to 54): 46 (51%) Females: 40 (44%)</p> <p>Normal appendix: 0 Simple appendicitis: 0 Gangrenous appendicitis: 0 (0%) Perforated appendicitis: 79 (87.8%) Appendiceal phlegmon or abscess: 11 (12.2%) Inclusion criteria:</p> <ul style="list-style-type: none"> • Emergency appendectomy • Appendectomy for perforated appendicitis • Patients without generalised peritonitis <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • Age < 13 years • Patients with simple appendicitis • Patients with generalised peritonitis • Patients undergoing laparoscopic appendectomy
Interventions	Participants with complicated appendicitis (n = 90) were randomly assigned to 2 groups Group 1: drainage (n = 45)

Abdominal drainage to prevent intra-peritoneal abscess after open appendectomy for complicated appendicitis (Review)

Jani 2011 (Continued)

Group 2: no drainage (n = 45)

Outcomes	The outcomes reported were wound infection, intra-peritoneal abscess, morbidity, postoperative complications, hospital stay, and duration of antibiotic use
Notes	The drainage tube (PVC suction catheter) was placed through a separate incision down into the right iliac fossa

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: no information provided
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no information provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: there were no post-randomisation dropouts
Selective reporting (reporting bias)	Low risk	Comment: all of the primary outcomes were reported. There was some selective outcome reporting in the secondary outcomes, but the review authors considered this trial to be free of selective reporting for the primary outcomes
Other bias	Low risk	Comment: the study appears to be free of other sources of bias

Mustafa 2016

Methods	Randomised controlled trial
Participants	Country: Pakistan Number randomised: 68 Post-randomisation dropout: 0 (0%) Age (18 to 25): 31 (46%) Age (26 to 33): 26 (38%) Age (34 to 39): 11 (16%) Females: 32 (47%) Normal appendix: 0 Simple appendicitis: 0 Gangrenous appendicitis: 0 (0%) Perforated appendicitis: 68 (100%)

Mustafa 2016 (Continued)

Appendiceal phlegmon or abscess: 0 (0%)

Inclusion criteria:

- Emergency appendectomy
- Appendectomy for perforated appendicitis

Exclusion criteria:

- Age < 18 years
- Patients with generalised peritonitis
- Immunocompromised patients

Interventions	Participants with complicated appendicitis (n = 68) were randomly assigned to 2 groups Group 1: drainage (n = 34) Group 2: no drainage (n = 34)
Outcomes	The outcomes reported were wound infection and hospital stay
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "These patients were randomly allocated into 2 treatment groups using lottery method" Comment: no information provided about the method of random sequence generation
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no information provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: there were no post-randomisation dropouts
Selective reporting (reporting bias)	High risk	Comment: the primary outcome was not reported
Other bias	Low risk	Comment: the study appears to be free of other sources of bias

Stone 1978

Methods	Quasi-randomised controlled trial
Participants	Country: USA Number randomised: 283

Abdominal drainage to prevent intra-peritoneal abscess after open appendectomy for complicated appendicitis (Review)

Stone 1978 (Continued)

Post-randomisation dropout: 0 (0%)
Children: not mentioned

Adults: not mentioned
Females: 124 (44%)

Normal appendix: 0 (0%)
Simple appendicitis: 66 (23%)
Suppurative appendicitis: 123 (44%)
Gangrenous appendicitis: 32 (11%)
Perforated appendicitis: 62 (22%)

Appendiceal phlegmon or abscess: 0 (0%)
Inclusion criteria:

- Emergency appendectomy
- Appendectomy for acute appendicitis

Exclusion criteria:

- Patients without acute appendicitis

Interventions	Participants with complicated appendicitis (n = 94) were randomly assigned to 2 groups Group 1: drainage (n = 49) Group 2: no drainage (n = 45)
Outcomes	The outcomes reported were wound infection, intra-peritoneal abscess, postoperative complications, and mortality
Notes	The drainage tube (Penrose drain) was placed through a separate incision down into the right iliac fossa

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "A Penrose drain was inserted through a separate stab wound if the final digit of the patient's hospital number was an odd figure. An even final digit dictated exclusion of any form of peritoneal drainage". Comment: the allocation was performed on the basis of a pseudo-random sequence (odd/even hospital number)
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no information provided
Incomplete outcome data (attrition bias)	Low risk	Comment: there were no post-randomisation dropouts

Stone 1978 (Continued)

All outcomes

Selective reporting (reporting bias)	Low risk	Comment: all of the primary outcomes were reported. There was some selective outcome reporting in the secondary outcomes, but the review authors considered this trial to be free of selective reporting for the primary outcomes
Other bias	Low risk	Comment: the study appears to be free of other sources of bias

Tander 2003

Methods	Randomised controlled trial
Participants	Country: Turkey Number randomised: 140 Post-randomisation dropout: 0 (0%) Children (0 - 11 years): 140 (100%) Adults: 0 (0%) Females: 38 (27%) Normal appendix: 0 (0%) Simple appendicitis: 0 (0%) Gangrenous appendicitis: 0 (0%) Perforated appendicitis: 140 (100%) Appendiceal phlegmon or abscess: 0 (0%) Inclusion criteria: <ul style="list-style-type: none"> Emergency appendectomy Appendectomy for perforated appendicitis Exclusion criteria: <ul style="list-style-type: none"> Continuous pus drainage from the peritoneum despite sufficient wash out Presence of any intra-abdominal pathology Abscess formation or any other collection, which requires drainage Multiple cavities into the peritoneum Presence of excessive adhesions and fibrins between bowel loops
Interventions	Participants with complicated appendicitis (n = 140) were randomly assigned to 2 groups Group 1: drainage (n = 70) Group 2: no drainage (n = 70)
Outcomes	The outcomes reported were wound infection, intra-peritoneal abscess, postoperative complications, mortality, hospital stay, and duration before oral intake
Notes	2 drainage tubes (Penrose drains) were placed through the wound down into the right iliac fossa and pelvis, respectively

Risk of bias

Bias	Authors' judgement	Support for judgement
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Tander 2003 (Continued)

Random sequence generation (selection bias)	Unclear risk	Comment: no information provided
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no information provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: there were no post-randomisation dropouts
Selective reporting (reporting bias)	Low risk	Comment: all of the primary outcomes were reported. There was some selective outcome reporting in the secondary outcomes, but the review authors considered this trial to be free of selective reporting for the primary outcomes
Other bias	Low risk	Comment: the study appears to be free of other sources of bias

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Al-Shahwany 2012	A non-randomised study
Allemann 2011	A non-randomised study
Beek 2015	A non-randomised study
Everson 1977	Randomised controlled trial about extraperitoneal wound drainage (wound drainage versus no wound drainage)
Ezer 2010	A non-randomised study
Greenall 1978	Randomised controlled trial in which antibiotic regimens were used in a non-random manner
Johnson 1993	A non-randomised study
Magarey 1971	Randomised controlled trial in which antibiotic regimens were used in a non-random manner
Narci 2007	A non-randomised study
Piper 2011	A non-randomised study
Song 2015	A non-randomised study
Toki 1995	Randomised controlled trial about peritoneal lavage versus abdominal drainage

DATA AND ANALYSES

Comparison 1. Drain use versus no drain use

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Intra-peritoneal abscess	5	453	Risk Ratio (M-H, Random, 95% CI)	1.23 [0.47, 3.21]
2 Wound infection	5	478	Risk Ratio (M-H, Random, 95% CI)	2.01 [0.88, 4.56]
3 Morbidity	1	90	Risk Ratio (M-H, Random, 95% CI)	6.67 [2.13, 20.87]
4 Mortality	4	363	Peto Odds Ratio (Peto, Fixed, 95% CI)	4.88 [1.18, 20.09]
5 Hospital stay	3	298	Mean Difference (IV, Random, 95% CI)	2.17 [1.76, 2.58]

Analysis 1.1. Comparison 1 Drain use versus no drain use, Outcome 1 Intra-peritoneal abscess.

Analysis 1.2. Comparison 1 Drain use versus no drain use, Outcome 2 Wound infection.

Analysis 1.3. Comparison 1 Drain use versus no drain use, Outcome 3 Morbidity.

Analysis 1.4. Comparison 1 Drain use versus no drain use, Outcome 4 Mortality.

Analysis 1.5. Comparison 1 Drain use versus no drain use, Outcome 5 Hospital stay.

Comparison 2. Drain use versus no drain use (sensitivity analyses by excluding quasi-randomised trials)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Intra-peritoneal abscess	3	316	Risk Ratio (M-H, Random, 95% CI)	0.76 [0.28, 2.02]

Analysis 2.1. Comparison 2 Drain use versus no drain use (sensitivity analyses by excluding quasi-randomised trials), Outcome 1 Intra-peritoneal abscess.

APPENDICES

Appendix 1. Search strategy for CENTRAL (2017, Issue 6)

- #1 MeSH descriptor: [Appendectomy] explode all trees
- #2 MeSH descriptor: [Appendicitis] explode all trees
- #3 appendectom* or appendic*:ti,ab,kw
- #4 (#1 or #2 or #3)
- #5 MeSH descriptor: [Drainage] explode all trees
- #6 MeSH descriptor: [Suction] explode all trees
- #7 MeSH descriptor: [Negative-Pressure Wound Therapy] explode all trees
- #8 ((negative pressure or negative-pressure) near/3 (dressing* or therap*)):ti,ab,kw
- #9 ((vacuum-assisted or vacuum assisted) near/3 closure*):ti,ab,kw
- #10 (drain* or suction*):ti,ab,kw
- #11 (#5 or #6 or #7 or #8 or #9 or #10)
- #12 (#4 and #11)

Appendix 2. Search strategy for MEDLINE (Ovid) (1946 to 30 June 2017)

1. exp Appendectomy/
2. exp Appendicitis/

3. (appendectom* or appendic*).mp.
4. 1 or 2 or 3
5. exp Drainage/
6. exp Negative-Pressure Wound Therapy/
7. exp Suction/
8. ((negative pressure or negative-pressure) adj3 (dressing* or therap*)).mp.
9. ((vacuum-assisted or vacuum assisted) adj closure*).mp.
10. (drain* or suction*).mp.
11. 5 or 6 or 7 or 8 or 9 or 10
12. 4 and 11
13. randomized controlled trial.pt.
14. controlled clinical trial.pt.
15. randomized.ab.
16. placebo.ab.
17. clinical trials as topic.sh.
18. randomly.ab.
19. trial.ti.
20. 13 or 14 or 15 or 16 or 17 or 18 or 19
21. exp animals/ not humans.sh.
22. 20 not 21
23. 12 and 22

Appendix 3. Search strategy for Embase (Ovid) (1974 to 30 June 2017)

1. exp appendectomy/
2. exp acute appendicitis/
3. exp appendicitis/
4. (appendectom* or appendic*).mp.
5. 1 or 2 or 3 or 4
6. exp drain/
7. exp abscess drainage/
8. exp abdominal drainage/
9. exp wound drainage/
10. exp surgical drainage/
11. exp vacuum assisted closure/
12. exp suction/

13. ((negative pressure or negative-pressure) adj3 (dressing* or therap*)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
14. ((vacuum-assisted or vacuum assisted) adj closure*).mp.
15. (drain* or suction*).mp.
16. 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15
17. 5 and 16
18. CROSSOVER PROCEDURE.sh.
19. DOUBLE-BLIND PROCEDURE.sh.
20. SINGLE-BLIND PROCEDURE.sh.
21. (crossover* or cross over*).ti,ab.
22. placebo*.ti,ab.
23. (doubl* adj blind*).ti,ab.
24. allocat*.ti,ab.
25. trial.ti.
26. RANDOMIZED CONTROLLED TRIAL.sh.
27. random*.ti,ab.
28. 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27
29. (exp animal/ or exp invertebrate/ or animal.hw. or nonhuman/) not (exp human/ or human cell/ or (human or humans or man or men or wom?n).ti.)
30. 28 not 29
31. 17 and 30

Appendix 4. Search strategy for Science Citation Index Expanded (1900 to 30 June 2017)

#1 Topic=(appendectom* OR appendic*)

#2 Topic=(drain* OR suction* OR negative pressure wound therap* OR negative-pressure wound therap* OR vacuum-assisted closure OR vacuum assisted closure*)

#3 Topic=(random* OR control* OR RCT* OR placebo OR trial* OR group*)

#4 (#1 AND #2 AND #3)

Appendix 5. Criteria for judging risk of bias in the 'Risk of bias' assessment tool

Random sequence generation

Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence.

Criteria for a judgement of
'Low risk' of bias.

The investigators described a random component in the sequence generation process such as:

- referring to a random number table;
- using a computer random number generator;
- coin tossing;
- shuffling cards or envelopes;
- throwing dice;

(Continued)

- drawing of lots;
- minimisation.*

*Minimisation may be implemented without a random element, and this is considered to be equivalent to being random.

Criteria for the judgement of 'High risk' of bias.

The investigators described a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, e.g.:

- sequence generated by odd or even date of birth;
- sequence generated by some rule based on date (or day) of admission;
- sequence generated by some rule based on hospital or clinic record number.

Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorisation of participants, e.g.:

- allocation by judgement of the clinician;
- allocation by preference of the participant;
- allocation based on the results of a laboratory test or a series of tests;
- allocation by availability of the intervention.

Criteria for the judgement of 'Unclear risk' of bias.

Insufficient information about the sequence generation process to permit judgement of 'Low risk' or 'High risk.'

Allocation concealment

Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.

Criteria for a judgement of 'Low risk' of bias.

Participants and investigators enrolling participants could not have foreseen assignment because one of the following, or an equivalent method, was used to conceal allocation:

- central allocation (including telephone, web-based and pharmacy-controlled randomisation);
- sequentially numbered drug containers of identical appearance;
- sequentially numbered, opaque, sealed envelopes.

Criteria for the judgement of 'High risk' of bias.

Participants or investigators enrolling participants could possibly have foreseen assignments and thus introduced selection bias, such as allocation based on:

- using an open random allocation schedule (e.g. a list of random numbers);
- assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or nonopaque or not sequentially numbered);
- alternation or rotation;
- date of birth;
- case record number;
- any other explicitly unconcealed procedure.

Criteria for the judgement of 'Unclear risk' of bias.

Insufficient information to permit judgement of 'Low risk' or 'High risk.' This is usually the case if the method of concealment was not described or not described in sufficient detail to allow a definite judgement; e.g. if the use of assignment envelopes was described, but it remained unclear whether envelopes were sequentially numbered, opaque and sealed.

Blinding of participants and personnel

Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.

Criteria for a judgement of 'Low risk' of bias.

Any one of the following:

(Continued)

- no blinding or incomplete blinding, but the review authors judged that the outcome was not likely to be influenced by lack of blinding;
- blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.

Criteria for the judgement of
'High risk' of bias.

Any one of the following:

- no blinding or incomplete blinding, and the outcome was likely to be influenced by lack of blinding;
- blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome was likely to be influenced by lack of blinding.

Criteria for the judgement of
'Unclear risk' of bias.

Any one of the following:

- insufficient information to permit judgement of 'Low risk' or 'High risk';
- study did not address this outcome.

Blinding of outcome assessment

Detection bias due to knowledge of the allocated interventions by outcome assessors.

Criteria for a judgement of
'Low risk' of bias.

Any one of the following:

- no blinding of outcome assessment, but the review authors judged that the outcome measurement was not likely to be influenced by lack of blinding;
- blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.

Criteria for the judgement of
'High risk' of bias.

Any one of the following:

- no blinding of outcome assessment, and the outcome measurement was likely to be influenced by lack of blinding;
- blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement was likely to be influenced by lack of blinding.

Criteria for the judgement of
'Unclear risk' of bias.

Any one of the following:

- insufficient information to permit judgement of 'Low risk' or 'High risk';
- study did not address this outcome.

Incomplete outcome data

Attrition bias due to amount, nature, or handling of incomplete outcome data.

Criteria for a judgement of
'Low risk' of bias.

Any one of the following:

- no missing outcome data;
- reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias);
- missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups;
- for dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate;
- for continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size;
- missing data were imputed using appropriate methods.

Criteria for the judgement of
'High risk' of bias.

Any one of the following:

(Continued)

- reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups;
- for dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate;
- for continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size;
- 'as-treated' analysis done with substantial departure of the intervention received from that assigned at randomisation;
- potentially inappropriate application of simple imputation.

Criteria for the judgement of
'Unclear risk' of bias.

Any one of the following:

- insufficient reporting of attrition/exclusions to permit judgement of 'Low risk' or 'High risk' (e.g. number randomised not stated, no reasons for missing data provided);
- study did not address this outcome.

Selective reporting

Reporting bias due to selective outcome reporting.

Criteria for a judgement of
'Low risk' of bias.

Any of the following:

- study protocol was available and all of the study's prespecified (primary and secondary) outcomes that were of interest in the review were reported in the prespecified way;
- study protocol was not available but it was clear that the published reports included all expected outcomes, including those that were prespecified (convincing text of this nature may be uncommon).

Criteria for the judgement of
'High risk' of bias.

Any one of the following:

- not all of the study's prespecified primary outcomes were reported;
- ≥ 1 primary outcomes were reported using measurements, analysis methods, or subsets of data (e.g. subscales) that were not prespecified;
- ≥ 1 reported primary outcomes were not prespecified (unless clear justification for their reporting was provided, such as an unexpected adverse effect);
- ≥ 1 outcomes of interest in the review were reported incompletely so that they could not be entered in a meta-analysis;
- study report did not include results for a key outcome that would be expected to have been reported for such a study.

Criteria for the judgement of
'Unclear risk' of bias.

Insufficient information to permit judgement of 'Low risk' or 'High risk.' It is likely that the majority of studies will fall into this category.

Other bias

Bias due to problems not covered elsewhere in the table.

Criteria for a judgement of
'Low risk' of bias.

Study appeared to be free of other sources of bias.

Criteria for the judgement of
'High risk' of bias.

There was ≥ 1 important risk of bias; e.g. the study:

- had a potential source of bias related to the specific study design used; or
- was claimed to have been fraudulent; or
- had some other problem.

Criteria for the judgement of
'Unclear risk' of bias.

There may be a risk of bias, but there was either:

(Continued)

- insufficient information to assess whether an important risk of bias existed; or
- insufficient rationale or evidence that an identified problem would introduce bias.

WHAT'S NEW

Date	Event	Description
31 August 2017	New citation required but conclusions have not changed	Searches updated 30 June, 2017. One new RCT identified and included in analyses.
31 August 2017	New search has been performed	Searches updated 30 June, 2017, and review updated accordingly with one new randomised controlled trial included. Author byline changed. This updated review furthermore included trial sequential analysis (TSA) for the primary outcome, aiming to reduce the risk of random error in the setting of repetitive testing of accumulating data, thereby improving the reliability of conclusions.

HISTORY

Protocol first published: Issue 10, 2012

Review first published: Issue 2, 2015

Date	Event	Description
11 December 2014	Amended	The authors changed the title in the review stage.

CONTRIBUTIONS OF AUTHORS

Li Z: drafted the final review, extracted data from the trials, entered data into RevMan, and carried out the analysis.

Zhao L: extracted data from the trials and entered data into RevMan.

Cheng Y: drafted the protocol, selected which trials to include, and assessed the risk of bias of the trials.

Cheng N: selected which trials to include and assessed the risk of bias of the trials.

Deng Y: revised the final review and secured funding for the review.

Li Z, Zhao L, and Cheng Y: contributed equally to developing the review.

DECLARATIONS OF INTEREST

Li Z: None known

Zhao L: None known

Cheng Y: None known

Cheng N: None known

Deng Y: None known

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We changed the title to reflect the primary outcome and open appendectomy because none of the trials included patients undergoing laparoscopic appendectomy. We included two quasi-RCTs and performed a sensitivity analysis by excluding the two trials according to the suggestions of the editors and reviewers. None of the included RCTs compared open drain with closed drain (tubes), or early drain removal with late drain removal. Thus, we did not consider these two types of interventions. We added that all patients received similar antibiotic regimens after open appendectomy in the intervention; studies that included participants who did not receive prophylactic antibiotics were excluded, because the use of antibiotic regimens after open appendectomy was found to have a positive effect on clinically relevant outcomes by another Cochrane Review ([Andersen 2005](#)). The trials did not report infection at 14 days, therefore the data for 30 days were reported as these data were still considered to be clinically relevant.

We also performed trial sequential analysis (TSA) for the primary outcome intra-peritoneal abscess. TSA aims to reduce the risk of random error in the setting of repetitive testing of accumulating data, thereby improving the reliability of conclusions.

INDEX TERMS

Medical Subject Headings (MeSH)

Abdominal Abscess [*prevention & control]; Appendectomy [*adverse effects]; Appendicitis [complications] [*surgery]; Drainage [*methods]; Emergencies; Length of Stay; Peritoneal Diseases [*prevention & control]; Postoperative Complications [*prevention & control]; Randomized Controlled Trials as Topic

MeSH check words

Humans