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ORIGINAL ARTICLE

Antibiotic Prophylaxis in Elective Laparoscopic Cholecystectomy: a Systematic Review and Network Meta-Analysis

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Abstract

Objective To determine the effectiveness and harms of using antibiotic prophylaxis (ABP) versus placebo/no intervention in patients undergoing elective laparoscopic cholecystectomy (eLCC) to prevent surgical site infection (SSI).

Methods We searched MEDLINE (OVID), EMBASE, LILACS, and the Cochrane Central Register of Controlled Trials (CENTRAL) from inception to October 2017. We included clinical trials which involved adults at low risk undergoing eLCC and compared ABP versus placebo/no intervention. The primary outcome was SSI and secondary outcomes were other infections and adverse effects. Cochrane Collaboration tool was used to assess the risk of bias. We performed the statistical analysis in R and reported information about risk difference (RD) with a 95% confidence interval (CI). Heterogeneity was evaluated using the I^2 test. We produced network diagrams to show the amount of evidence available for each outcome and the most frequent comparison.

Results We included 18 studies in qualitative and quantitative analysis. The antibiotics most commonly studied were cefazolin and cefuroxime. We found high risk of detection bias in one study and attrition bias in another. Unclear risks of selection, performance, and detection bias were frequent. For SSI, we found no heterogeneity $I^2 = 0\%$ and no inconsistency $p = 0.9780$. No significant differences were found when compared ABP versus placebo/no intervention. Cefazolin had a RD of − 0.00 (95% CI − 0.01 to 0.01). We found no differences in regular meta-analysis, with a RD of − 0.00 (95% CI − 0.01 to 0.01) as well as for intra-abdominal and distant infections. Adverse effects were only assessed in one study, without any case reported.

Conclusions This systematic review demonstrated no differences between ABP versus placebo/no intervention when using to prevent SSI and intra-abdominal and distant infections in patients at low risk undergoing eLCC.

Keywords Cholecystectomy · Laparoscopic · Antibiotic prophylaxis · Systematic review · Meta-analysis

Introduction

Cholelithiasis is one of most common abdominal conditions among adults,[1,2] and cholecystectomy is the preferred procedure for treating symptomatic cases.[3] Historically surgical site infection (SSI) has been recognized as the most frequent complication of cholecystectomy performance[4], which is congruent with the requirement of antibiotic prophylaxis (ABP), since it is a clean-contaminated wound.[5,6] In terms of minimally invasive surgery for cholelithiasis, many advances have been found, as an increase of quality of life of operated patients and a decrease in length of stay,[7] costs,[8] postoperative pain, and time to return to work.[9] Nevertheless, the ABP panorama and international recommendations remain the same and do not include a specific statement for laparoscopic cholecystectomy (LCC).

Currently, LCC is the recommended approach for cholecystectomy under normal conditions, when it is available;[10] it has a lesser SSI rates since it decreases manipulation and environment exposure,[11] which explains the growing trend in

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supporting the ABP avoiding the uncomplicated cases.[12,13] Over 20 years ago, some studies showed that despite the benefit of ABP in open cholecystectomy, probably, it could be unnecessary in elective LCC (eLCC).[14,15] These findings were supported by posterior systematic reviews and meta-analyses.[11,16–19]

An updated and recent systematic review and meta-analysis suggest a benefit on ABP administration; however, it did not include some studies, including in previous researches.[20] Controversy continues, and non-specific recommendations for ABP in eLCC have been made by international organizations.[21] Actually, the Centers for Disease Control and Prevention (CDC) recommendations remain unchanged, and if followed, a first-generation cephalosporin has to be administered before incision.[22] Therefore, we planned this new systematic review and meta-analysis to make a recommendation. Thus, the objective of present study was to determine the effectiveness and harms of using ABP versus placebo or no intervention in patients undergoing eLCC to prevent SSI and to determine the best antibiotic to choice.

Materials and Methods

We performed this review according to the recommendations of the Cochrane Collaboration and following the PRISMA Statement. The PROSPERO registration number is CRD42017076934.

Inclusion Criteria

We included clinical trials which involved adults undergoing eLCC, with preoperative diagnosis of cholelithiasis or other benign diseases of the gallbladder. The intervention was ABP and the comparator was no intervention or placebo. The primary outcome was surgical site infection (SSI) defined as CDC and Prevention's National Healthcare Safety Network classification for SSI,[23,24] or other definitions used by researchers. Secondary outcomes were other infections such as distant infection defined as any infection remote from the surgical site (i.e., the urinary or respiratory tract) or intra-abdominal infection defined as infections affecting intra-abdominal organs, peritonitis, or intra-abdominal abscesses; and adverse effects. For all outcomes, studies should be at least 1-week follow-up. There were no setting or language restrictions. The exclusion criteria were pregnant or breast-feeding women, antibiotic allergy, antibiotic therapy within 48 h to 7 days prior to surgery, clinically active infection at the moment of surgery, and evidence or suspicion of common bile duct stones. We also excluded studies with a 24-h prolonged ABP, since the latest recommendation of CDC is preventing to administer additional prophylactic antimicrobial agent doses after the surgical incision is closed in the operating room, even if drains are present.[25]

Information Sources

Literature search was conducted in accordance with the recommendations by Cochrane. We used medical subject headings (MeSH), Emtree language, DeCS, and text words related in a complete search strategy (Appendix 1). We searched MEDLINE (OVID), EMBASE, LILACS, and the Cochrane Central Register of Controlled Trials (CENTRAL) from inception to October 2017. To ensure literature saturation, we scanned references from relevant articles identified through the search, conferences, thesis databases, Open Grey, Google scholar, clinicaltrials.gov, among others. We contacted authors by e-mail in case of missing information.

Data Collection

We reviewed each reference by title and abstract. Then, we scanned full texts of relevant studies, apply prespecified inclusion and exclusion criteria, and extract the data. Disagreements were resolved by consensus, and where disagreement could not be solved, a third reviewer dissolved conflict.

Relevant data were collected in duplicate by using a standardized data extraction sheet that contained the following information: author names, year of publication, title, study design, geographic location, objectives, inclusion and exclusion criteria, number of patients included, losses to follow-up, timing, definition of outcomes (infection), outcomes and association measures, and funding source.

Risk of Bias

The assessment of the risk of bias for each study was made using the Cochrane Collaboration tool for assessing the risk of bias, which covers sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting, and other biases. We judged about the possible risk of bias from extracted information, rated as "high risk," "low risk," or "unclear risk." We computed graphic representation of potential bias using RevMan 5.3.

Data Analysis/Synthesis of Results

We performed the statistical analysis in R[26] with the command netmeta. For outcomes, we reported information about risk differences (RD) with 95% confidence intervals according to the type of variables, and we pooled the information with a fixed effect network meta-analysis according to the heterogeneity expected. The results were reported in forest plots of the estimated effects of the included studies with a 95%

confidence interval (95% CI). Heterogeneity was evaluated using the I^2 test. For the interpretation, it was determined that the values of 25, 50, and 75% in the I^2 test corresponded to low, medium, and high levels of heterogeneity, respectively.

Assumption of transitivity was plausible and evaluated according to the kind of comparisons and considering the similarity of the distribution of the potential effect modifiers across the different pairwise comparisons. Additionally, for every treatment, we estimated the probability of being at each possible rank to infer the relative ranking of the treatments.

Publication Bias

An evaluation was conducted to identify reporting or publication bias using Egger and Begg statistical tests.

Sensitivity Analysis

We performed sensitivity analysis extracting weighted studies and running the estimated effect to find differences.

Geometry of the Network

We produced network diagrams to show the amount of evidence available for each outcome and the most frequent comparison. The size of the nodes was proportional to the total number of patients allocated to the treatments across all trials, and the width of the lines was proportional to the total number of RCTs evaluating the comparisons.

Assessment of Inconsistency

We evaluated and stated consistency within indirect and direct comparisons. We assessed statistical inconsistency (i.e., the agreement between direct and indirect evidence) by a loop-specific approach, which evaluates inconsistency in every closed loop of evidence. We ultimately found a consistent loop.

Results

Study Selection

A total of 707 studies were found with the search strategies, and there were 91 duplicates that were removed. Five hundred seventy-six were excluded in title-abstract screening, and finally, 18 studies were included in the qualitative and quantitative analysis[14,27–43] (Fig. 1).

Characteristics of Included Studies

A total of 4087 patients with a mean of 227 patients per study (range 43–547) were included. Eleven studies used placebo as comparator[27,29,30,32,34,36–40, 42] and seven used no antibiotic.[14,28,31,33,35,41,43]

Infection definition was not available in three articles[31,37,42], but it was according to CDC definition in three studies.[29,34,35] Other studies defined infection by presence of purulent exudate[14] and pus drainage[28] or presence of inflammation or pus discharge.[33] In the rest, infection definition was determined by a series of signs and symptoms such as body temperature higher than 38 °C or culture findings positive for pathogens.[27,30,32,36,38–41,43]

The most frequently follow-up was 30 days, which was performed in nine studies.[27,29,30,32,36,38,40–42] Two studies have a follow-up of 7 days,[31,33] two studies more than 30 days,[28,34] one study had 15 days,[14] four studies of 4 weeks,[35,37,39,43] one completed a 6-week follow-up by phone[37] (Table 1).

Excluded Studies

We excluded five studies which considered to use antibiotic postoperatively[15,44–47]; additionally, one study was excluded because it was an abstract and there was no answer to email request.[48]

Summary of Network Geometry

A total of 2122 patients undergoing eLCC received ABP. The antibiotics most commonly studied were cefazolin, which was used in nine studies (1298 patients)[14,27–34] and cefuroxime, which was used in three studies (329 patients).[38,41,43] Ciprofloxacin was used in two studies (248 patients),[35,40] the same as that for cefotetan (161 patients)[27,36], while ceftazidime (100 patients), cefotaxime (44 patients), ceftriaxone (50 patients), and ampicillin-sulbactam (41 patients) were used for each study[35,37,39,42]. Placebo was used as the comparator arm in 11 studies and no antibiotic in seven studies, for a total of 1967 patients in the control group (we blended these two groups in one for the final analysis). The most frequently comparison was cefazolin versus control ($n = 9$). Mixed comparisons were performed in 2 studies, one of which compared cefazolin versus cefotetan,[27] and the other compared ciprofloxacin versus ampicillin-sulbactam,[35] summing up 188 participants of the control group that were part of crossover studies (Fig. 2).

Risk of Bias

We found high risk of detection bias in one study,[28] since they included unblinded patients assessed by phone calls. In Higgins 1999, there was high risk of attrition bias[27] because 38 of 450 patients were excluded from the statistical analysis for protocol violation. In general, the risk for attrition, reporting, and other biases were assessed as low; however, a great proportion of studies had unclear risk of selection

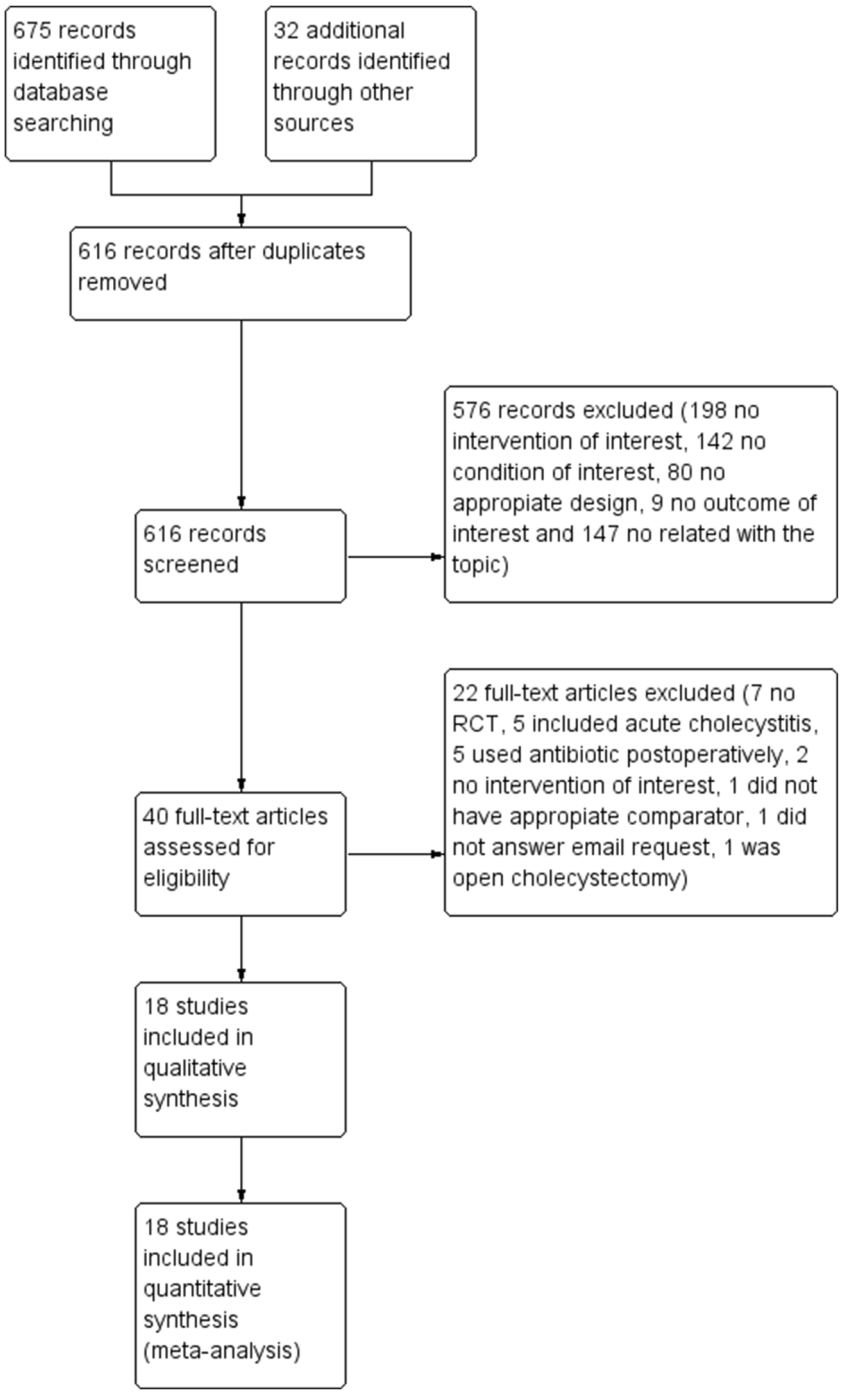

Fig. 1 Flowchart of selected studies

because there was not enough information about the random sequence generation process or the concealment method was not described or it was not described in sufficient detail to allow a definitive evaluation. Unclear risk of performance and detection bias was also frequently found because there were many studies in which it was not specified how both groups were blinded or it was not possible to identify if a blinding process was performed in participants, personnel, or outcome assessment group (Fig. 3).

Exploration for Inconsistency and Ranking

For SSI outcome, we found no heterogeneity $I^2 = 0\%$ ($p = 0.8636$) and no inconsistency $p = 0.9780$. The rank value (p score) was higher for ceftazidime (0.70), cefotetan (0.65), and ciprofloxacin (0.61). For abdominal infections, we did not find heterogeneity ($I^2 = 0\%$) nor inconsistency, and the rank value was higher for cefotaxime (p score = 0.75).

Table 1 Characteristics of included studies

Author (year)	Country	Antibiotic dose	Control	Infection definition	Follow-up	N Patients (intervention:control)
Csendes (1995)	Chile	Cefazolin 1 g IV	No antibiotic	Presence of purulent exudate	15 days	105 (50:55)
Higgins (1999)	USA	One group with cefazolin 1 g IV and other with cefotetan 1 g IV	Placebo	A superficial SSI was defined as erythema and/or purulent drainage at the surgical site above the fascia. A deep SSI is defined as purulent material deep to the fascia or near the gallbladder fossa.	30 days	412 [277 (140 in cefazolin and 137 in cefotetan):135]
Dobay (1999)	USA	Cefotetan 1 g IV	Placebo	A wound: with purulent drainage, with a microorganism cultured or not; with serous drainage, but only if a microorganism was cultured; that were deliberately opened, but only if purulent drainage occurred or a microorganism was cultured	30 days	53 (24:29)
Tocchi (2000)	Italy	Cefotaxime 2 g IV	Placebo	NA	4 weeks (6 weeks by phone)	84 (44:40)
Mahatharadol (2001)	Thailand	Cefazolin 1 g IV	No antibiotic	Presence of pus drainage	> 30 days	100 (50:50)
Kuthe (2006)	India	Cefuroxime 1.5 g IV	Placebo	Pus drainage and extra-abdominal infections (pyrexia of more than 38 °C, excluding the first postoperative day), positive bacteriological culture from possible infection sites such as wounds and the urinary or respiratory tract	30 days	93 (40:53)
Uludag (2009)	Turkey	Cefazolin 1 g IV	Placebo	CDC definition	30 days	144 (68:76)
Yildiz (2009)	Turkey	Cefazolin 1 g IV	Placebo	Body temperature higher than 38 °C, purulent discharge from the incisions, and any abdominal signs of infection	30 days	208 (105:103)
Sharma (2010)	India	Ceftriaxone 1 g IV	Placebo	Superficial: erythema or purulent discharge at the surgical site above the deep fascia. Deep: purulent material deep to the fascia or near the gallbladder fossa. Distant: any infection remote from the surgical site	4 weeks	100 (50:50)
Gaur (2010)	India	Ciprofloxacin 200 mg + metronidazole 500 mg IV	Placebo	Wound erythema, pus discharge, and serous discharge with positive culture were considered as superficial infection. Intra-abdominal collection or abscesses and infections of the respiratory or urinary tract were considered deep sepsis. Postoperative fever above 38.5 °C was evaluated to find any relation to the surgery	30 days	417 (208:209)
Al-Qahtani (2011)	Saudi Arabia	Cefuroxime 1.5 g IV	No antibiotic	Superficial wound infection (signs of inflammation with or without discharges/collection). Deep seated infection in the form of collection or abscesses in the abdominal cavity. Distant infections away from the surgical site, such as respiratory and urinary tract infections	30 days	221 (112:109)
Shah (2012)	Nepal	Cefazolin 1 g IV	No antibiotic	NA	7 days	310 (154:156)
Hassan (2012)	Egypt	Ceftazidime	Placebo	NA	30 days	200 (100:100)
Turk (2013)	Turkey	Cefazolin 1 g IV	Placebo	Infectious complications were defined as pyrexia with a body temperature higher than 38 °C twice a day (excluding the first postoperative day) and/or a culture positivity of pathogens from infectious sites such as the wound site, urinary or respiratory tract, or the abdominal cavity. If bacteria were found in the culture, sensitivity to antimicrobial drugs was determined	30 days	547 (278:269)
Naqvi (2013)	Pakistan	Cefuroxime 1.5 g IV	No antibiotic	Infectious complications were defined as pyrexia with a body temperature higher than 38 °C twice a day (excluding the first postoperative day) and culture findings positive for pathogens from	4 weeks	350 (177:173)

Table 1 (continued)

Author (year)	Country	Antibiotic dose	Control	Infection definition	Follow-up	N Patients (intervention:control)
				infectious sites such as trocar wounds and the abdominal cavity		
Mirani (2014)	Pakistan	Cefazolin 1 g IV	No antibiotic	Presence of inflammation, or pus discharge	7 days	310 (154:156)
Spaziani (2015)	Italy	One group with ampicillin-sulbactam 3 g IV and other with ciprofloxacin 400 mg IV	No antibiotic	CDC definition	4 weeks	134 [81 (41 Ampi-Sulb and 40 ciprofloxacin):53]
Ruangsin (2015)	Thailand	Cefazolin 1 g IV	Placebo	CDC definition	> 30 days	299 (150:149)

NA not available

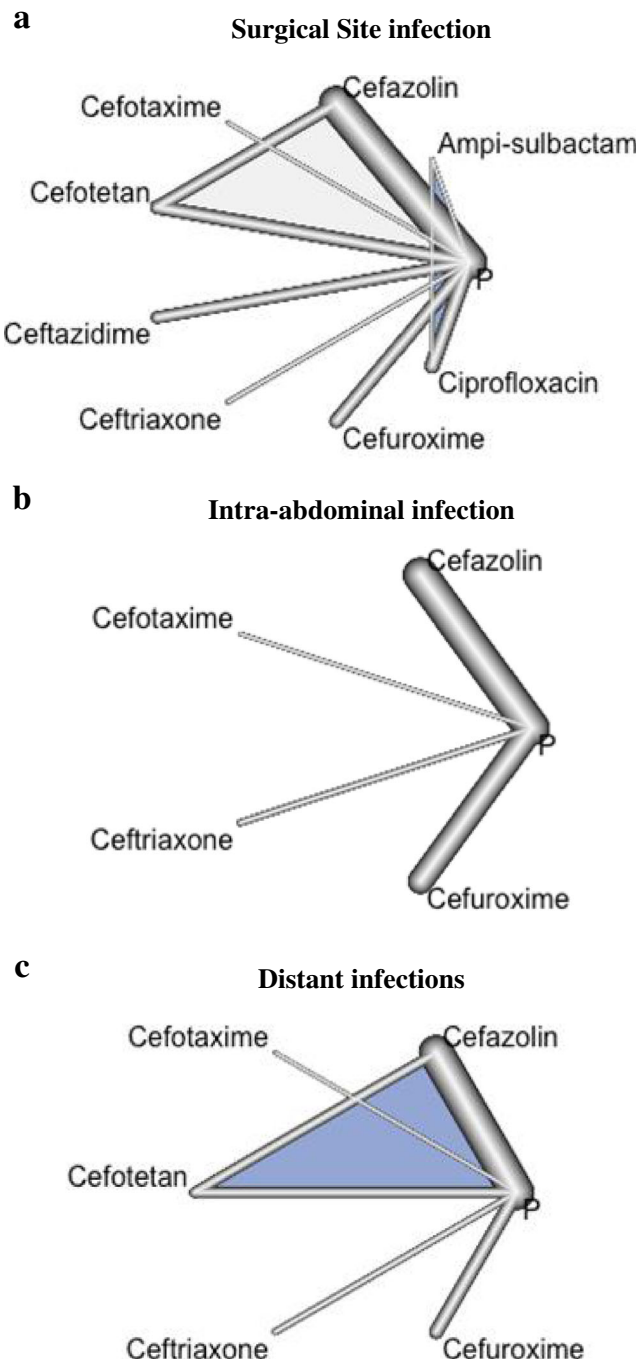

Fig. 2 Network for **a** surgical site infection, **b** intra-abdominal infection, and **c** distant infections

For distant infections, there was no heterogeneity ($I^2 = 0\%$) nor inconsistency (0.9770); however, the rank values were higher for placebo/no intervention (p score = 0.66).

Surgical Site Infection

No significant differences for mixed comparisons were found when ampicillin-sulbactam, cefazolin, cefotaxime, cefotetan, ceftazidime, ceftriaxone, cefuroxime, and ciprofloxacin were

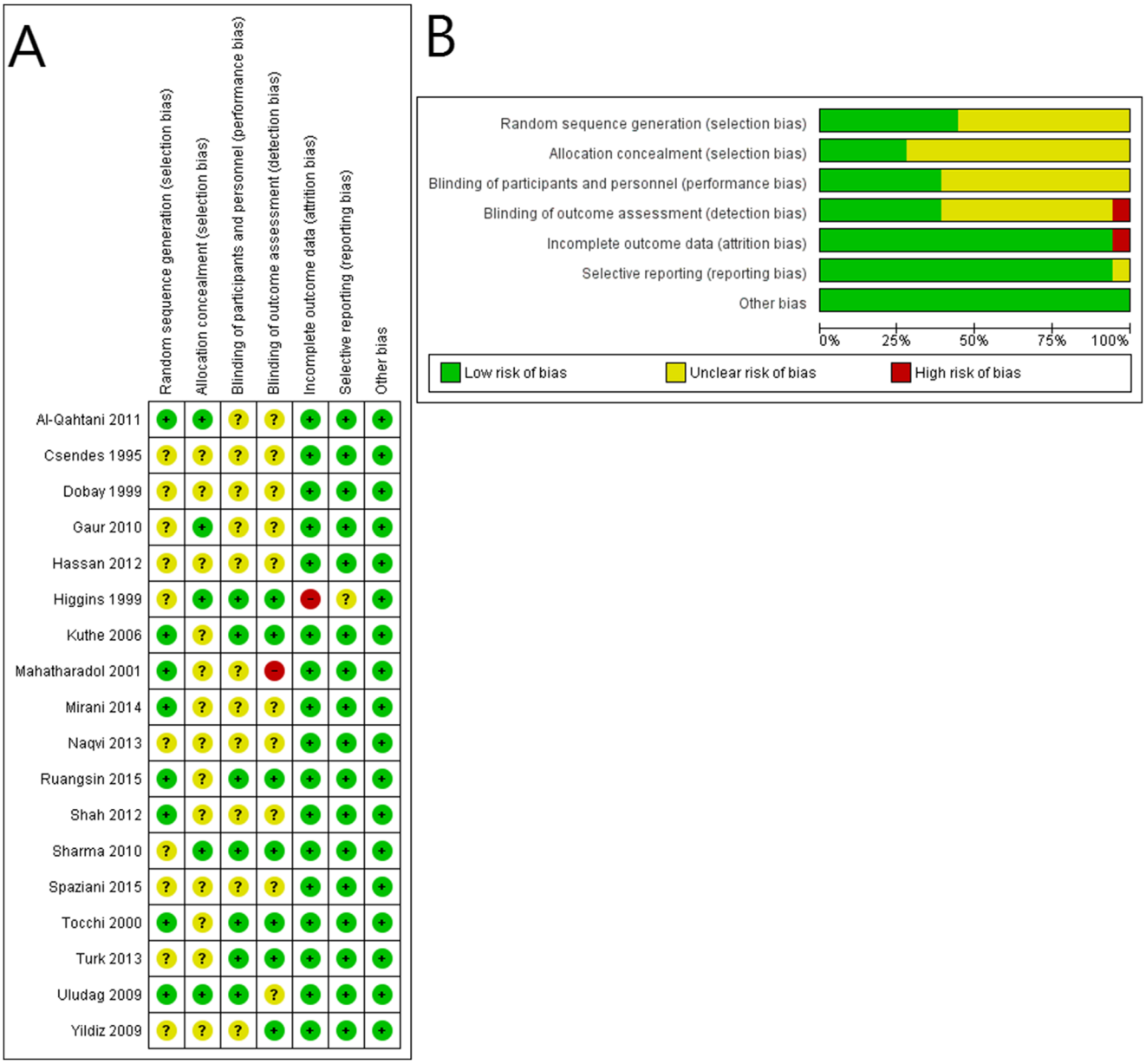

Fig. 3 Assessment of risk of bias **a** within studies and **b** across studies

each compared versus placebo for surgical site infection. For cefazolin, which was the most used antibiotic, there was a RD of − 0.00 (95% CI − 0.01 to 0.01) (Fig. 4a). Furthermore, a regular meta-analysis was performed for no-specific ABP versus placebo/no intervention; 2122 and 1967 patients were included in each branch, respectively; we found no differences, with a RD of − 0.00 (95% CI − 0.01 to 0.01).

Secondary Outcomes

Intra-abdominal and distant infections were evaluated. There were no significant differences for mixed comparisons when cefazolin, cefotaxime, ceftriaxone, and cefuroxime were each compared versus placebo for intra-abdominal infection (Fig. 4b), as well as when cefazolin, cefotaxime, cefotetan, ceftriaxone, and cefuroxime were each compared versus placebo for distant infection (Fig. 4c). Additionally, adverse effects were only assessed in one study,[36] without any case reported.

Discussion

Summary of the Main Results

Regarding the SSI outcome, we found no differences between antibiotic and no intervention (RD − 0.00, 95% CI − 0.01 to 0.01). Additionally, there were no differences when mixed comparisons were assessed. There were no statistical

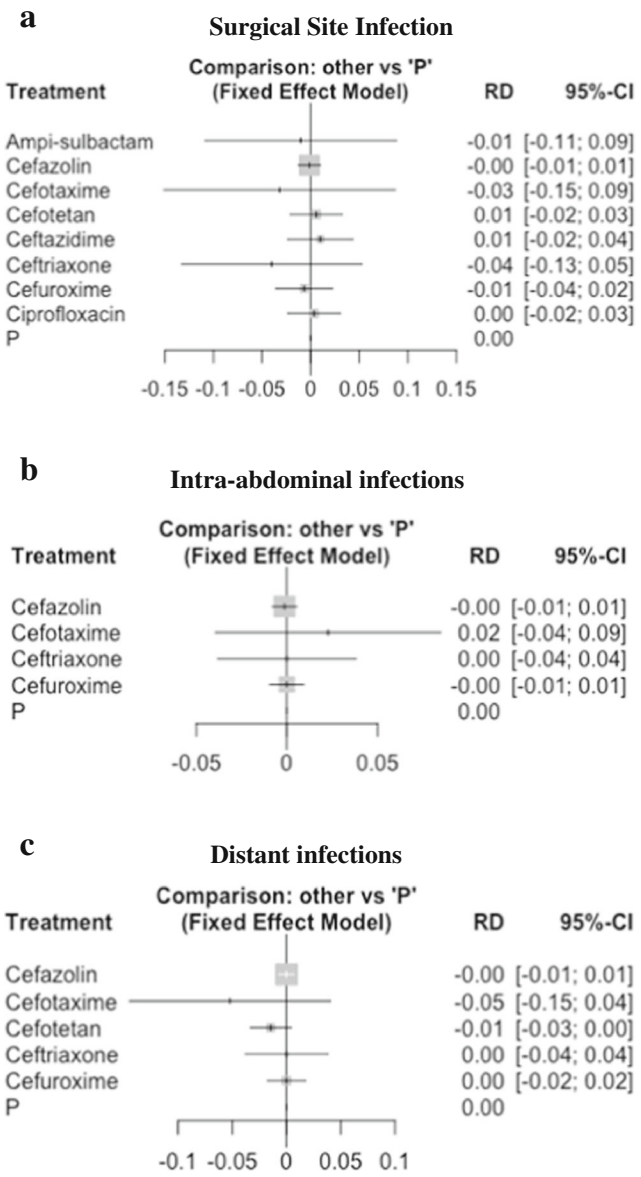

Fig. 4 Meta-analysis of antibiotic versus placebo. **a** Surgical site infection **b** Intra-abdominal infection. **c** Distant infections

differences for cefazolin, cefotaxime, ceftriaxone, and cefuroxime versus no intervention for intra-abdominal and distant outcomes.

Comparing Against Other Systematic Reviews and Literature

Previous systematic reviews using clinical trials only do not suggest the use of ABP in patients at low risk.[11,16–19,49] Sanabria et al.[11] could not find evidence to support or refute the use of ABP in these patients, but there were no statistical differences in the occurrence of surgical site infections and existing trials indicated that it may not be needed.

Pasquali et al.[50] showed that antibiotics administered before eLCC in low- to moderate-risk patients are not effective in preventing SSI. Furthermore, adverse effects in the studies included in their meta-analysis were poorly reported (only reported in tow patients of one study). Yan et al.[19] had similar results since they found there was no significant risk reduction in the ABP group with regard to overall, wound major, or distant infections. Nonetheless, they found that ABP reduced the time of hospital stay.

Al-Ghnaniem et al.[49] found that results did not support the use of ABP in patients at low risk in a systematic review. On the other side, Liang et al.[20] showed that ABP reduced the incidence of surgical site infections in patients undergoing eLCC. Nonetheless, this systematic review and meta-analysis presented several limitations since they excluded studies without following right inclusion criteria. Additionally, it included one study in which participants had a previous laparoscopic cholecystectomy, it excluded studies included in previous reviews without confident reasons, and some extracted data did not correspond when compared with original studies.

As mentioned above, we excluded five studies which considered to use antibiotic postoperatively[15,44–47] according to the latest recommendation of CDC to prevent the administration of additional prophylactic antimicrobial agent doses after the surgical incision is closed in the operating room. Of them, Matsui et al.[45] recommend the perioperative administration of prophylactic antibiotics to prevent postoperative infections; meanwhile, the other four studies found that ABP does not affect the incidence of postoperative infections or complications; additionally, Koc et al.[44] concluded that ABP is justified only in high-risk patients undergoing eLCC.

Strengths and Limitations

This is the first network meta-analysis performed on this topic, and we did not found significant differences in SSI and intra-abdominal and distant infections for mixed comparisons. Cefazolin was the most used antibiotic which agrees with CDC recommendations to administer as first-generation cephalosporin, but no significant differences were found. We also performed a conventional meta-analysis which showed no differences. Since there is no heterogeneity or inconsistency, it was possible to perform a frequentist network meta-analysis.

Additionally, it is important to mention that the number of participants in the studies was low and adverse effects were not reported in the included studies. There was a high proportion of studies with unclear risk of bias (not enough information to support evaluation); therefore, it was not possible to determine if bias affected outcomes.

Implications for Practice

Studies included showed that ABP does not reduce the incidence of SSI and the rate of postoperative infective complications in low-risk patients undergoing eLCC. The available clinical trials on this topic suggest the avoidance of ABP in these patients.

Changes in current recommendations on ABP in low-risk patients undergoing eLCC might be considered because of the lacking of evidence supporting its use and the increasing studies that refute its administration. Furthermore, as highlighted by some of the included studies, the inappropriate use of antibiotics adds to the cost and increases the emergence of multidrug resistance.[31,33,39,40] Higgins et al. (27) estimated that US$30,060 could have been saved per year in their institution if they had not used prophylactic antibiotics. Although adverse effects were poorly assessed, there are still important factors to be also considered to make new recommendations.

Conclusion

This systematic review demonstrated no differences between ABP versus placebo/no intervention when using to prevent SSI and intra-abdominal and distant infections in patients at low risk undergoing eLCC.

Author's Contribution Juan Camilo Gomez-Ospina: design, analysis, and interpretation of data for the work; drafting the work; revising it critically for important intellectual content; final approval of the version to be published; and agreement to be accountable for all aspects of the work.

James A. Zapata-Copete: design, analysis, and interpretation of data for the work; drafting the work; revising it critically for important intellectual content; final approval of the version to be published; and agreement to be accountable for all aspects of the work.

Monica Bejarano: design, analysis, and interpretation of data for the work; drafting the work; revising it critically for important intellectual content; final approval of the version to be published; and agreement to be accountable for all aspects of the work.

Herney Andrés García-Perdomo: design, analysis, and interpretation of data for the work; drafting the work; revising it critically for important intellectual content; final approval of the version to be published; and agreement to be accountable for all aspects of the work.

Compliance with Ethical Standards

Ethics Statement This systematic review and meta-analysis accomplish all the ethics requirements according to Helsinki declaration and all international statements.

Appendix

Search Strategies

Medline (Ovid):

Exp Cholecystectomy, Laparoscopic
(Laparoscopic adj2 cholecystectomy).mp
(Elective adj2 laparoscopic cholecystectomy).mp
Exp Cholecystectomy
Or/
Exp Anti-bacterial agents
Anti-bacterial agent$.mp
Antibacterial agent$.mp
(anti*bacterial adj2 agent*).mp
Exp Antibiotic Prophylaxis
(Antibiotic adj2 prophylaxis).mp
Antibiotic$.mp
Or/
randomized controlled trial.pt
controlled clinical trial.pt
clinical trial.pt
randomized.ab
placebo.ab
randomly.ab
trial.ab
(clinical adj2 trial).mp
(randomi*ed adj2 controlled adj2 trial).mp
exp double-blind method
or/

Embase:

'laparoscopic cholecystectomy'/exp
(laparoscopic next/2 cholecystectomy):ti,ab
(elective next/2 laparoscopic cholecystectomy):ti,ab
'cholecystectomy'/exp
or/
'antiinfective agent'/exp
Antiinfective agent*:ti,ab
Antibacterial:ti,ab
'antibiotic prophylaxis'/exp
Antibiotic prophylaxis:ti,ab
antibiotic*:ti,ab
Or/
'randomized controlled trial'/exp
(randomi*ed NEXT/2 controlled NEXT/2 trial):ti,ab
'clinical trial'/exp
(clinical NEXT/2 trial):ti,ab
'controlled clinical trial'/exp
'double blind procedure'/exp
or/

Central (Ovid)

Exp Cholecystectomy, Laparoscopic
(Laparoscopic adj2 cholecystectomy).mp
(Elective adj2 laparoscopic cholecystectomy).mp
Exp Cholecystectomy
Or/
Exp. Anti-bacterial agents
Anti-bacterial agent$.mp
Antibacterial agent$.mp
(anti*bacterial adj2 agent*).mp
Exp. Antibiotic Prophylaxis

(Antibiotic adj2 prophylaxis).mp
Antibiotic$.mp
Or/

LILACS

(mh:"colecistectomía" OR mh:"colecistectomía Laparoscópica" OR tw:"colecistectomía Laparoscópica" OR tw:"colecistectomía") AND (mh:"antibacterianos" OR mh:"profilaxis antibiótica" tw:"profilaxis antibiótica") AND (mh:"ensayo clínico" OR tw:"doble ciego" OR tw:"experimento clínico" OR mh:"estudios de cohortes" OR mh:"Estudios de casos y controles")

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