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Research article

The effect of antibiotic prophylaxis on the incidence of surgical site infection after laparoscopic appendectomy for chronic appendicitis

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ABSTRACT

Background: The guidelinesthat specify whether antibiotic prophylaxis should be administered before laparoscopic clean-contaminated wound to prevent postoperative surgical site infection (SSI) need to be improved. Studies have shown that elective laparoscopic cholecystectomy with clean-contaminated wound does not require antibiotic prophylaxis. However, there are no studies on the effect of antibiotic prophylaxis on SSI after laparoscopic appendectomy for chronic appendicitis (LCA), which is a clean-contaminated wound.

Methods: We conducted a single-center, double-blind, randomized controlled clinical trial. A total of 106 effective patients were randomly divided into the antibiotic group and saline group. Cefuroxime or clindamycin was administered intravenously in the antibiotic group (n = 52). Saline (0.9%) was administered intravenously in the saline group (n = 54). Interventions were administered as a single dose 30 min before surgery.

Results: Among the 106 effective patients (median age, 37 years old [IQR, 25–45]; females, 77 [72.6%]), there were 6 cases (5.70%) of SSI: 3 cases (5.56%) in the saline group and 3 cases (5.70%) in the antibiotic group (OR = 1.00, [95% CI (0.20–5.4)], P = 0.96). There were no significant differences in the clinical outcomes of anal exhaust time, postoperative complications, and the symptom of primary abdominal pain between the two groups.

Conclusion: For patients with chronic appendicitis undergoing laparoscopic appendectomy, preoperative intravenous antibiotic prophylaxis did not reduce the risk of SSI within 30 days of the surgery compared to the saline group.

Trial registration: Registration number of China Clinical Trials Registration Center: ChiCTR2100048336.

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1. Introduction

In the field of surgery, antibiotic prophylaxis plays an important role in preventing surgical site infection (SSI). According to the Chinese guidelines for the Prevention of SSI [1], the Center for Disease Control (CDC) [2], the National Institute of Health and Clinical Optimization (NICE) [3], and the World Health Organization (WHO) [4], operative wounds in which the respiratory, alimentary, genital or urinary tracts are entered under controlled conditions and without unusual contamination are defined as clean-contaminated wounds. Specifically, operations involving the biliary tract, appendix, vagina and oropharynx are included in this category, provided there is no evidence of infection.

In recent years, the mode of surgery has changed, and laparoscopic surgery has gradually increased. Minimally invasive surgery, represented by laparoscopic surgery, has become the predominant way of elective abdominal surgery. Compared to open surgery, the benefits of laparoscopic surgery include reduced postoperative pain, shortened hospital stay, and a decrease in postoperative complications and SSI [5].

For laparoscopic surgery with a clean-contaminated wound, due to the innovation of surgical instruments, equipment, methods, and the possibility of contamination of the surgical site is much less than that associated with open surgery. However, the existing guidelines for perioperative antibiotic prophylaxis in China and abroad are not specific. Antibiotic prevention guidelines for laparoscopic surgery need to be improved [1–4]. Therefore, it is important to study the necessity of antibiotic prophylaxis before laparoscopic surgery. Laparoscopic appendectomy is used in the treatment of chronic appendicitis [6–12], and it has some advantages like small incision, better abdominal exploration, and removal of intra-abdominal infection. The incidence of SSI in laparoscopic appendectomy is lower than that associated with open surgery [13]. The purpose of this study was to evaluate the effect of single-dose antibiotic prophylaxis on the incidence of SSI in patients with chronic appendicitis undergoing laparoscopic appendectomy and to verify the necessity of single-dose antibiotic prophylaxis in laparoscopic appendectomy.

2. Patients and methods

The study was conducted upon the approval obtained from the Ethics Committee of Affiliated Hospital of Guizhou Medical University with Decision No. 217 taken in April 2020. Our study was conducted in accordance with the principles of the Helsinki Declaration.

2.1. Patients

Patients with chronic appendicitis scheduled for a laparoscopic appendectomy at the Department of Gastrointestinal surgery of the Guizhou Medical University were included in the study. Due to the particularity of chronic appendicitis, it cannot be fully diagnosed by clinical data before operation. If the patient meets the following three criteria, we consider the clinical diagnosis of chronic appendicitis. The patients were recruited after obtaining the informed consent. The diagnostic criteria of chronic appendicitis are as follows: 1. Three or more weeks of recurrent right lower abdominal pain with or without digestive tract symptoms [9]; 2. physical examination shows lower right abdominal tenderness; and 3. Barium meal examination of the appendix and computed X-ray tomography indicate chronic appendicitis [14]. Finally, the diagnosis of chronic appendicitis was confirmed based on the pathological diagnosis of the surgically excised appendix tissue. Based on the differences in the patient's physical condition and systemic immunity, the following exclusion criteria were used: (1) Patients <14 and >75 years old; (2) patients having a history of acute attack within 1 week before the surgery; (3) patients having immunodeficiency disease, hemorrhagic disease, bacterial infectious disease, and being treated with corticosteroids; (4) patients having infection in other parts of the body before the surgery or acute infection indicated by blood routine examination and body temperature before the surgery, and are treated with antibiotics; (5) Certain observations made during the surgery, such as suppuration of the appendix, rupture of the appendix, conversion to laparotomy, and surgical time more than 3 h; (6) patients with diseases of heart and lung, and pregnancy, ASA grade ≥ 3 before the surgery. The patients were recruited from October 2019 to July 2021. A total of 120 patients were included in the study. The final follow-up date was October 31, 2021.

2.2. Intervention, randomization, and blindness

Patients who signed informed consent were directed to the anesthesia preparation room 1 h before the surgery, and the nurses in the operating room randomly assigned the patients to the antibiotic (cefuroxime 1.5 g + 0.9% sodium chloride 100 ml, intravenous drip) and saline groups (0.9% sodium chloride 100 ml, intravenous drip) by random sequence. The random sequence was generated by an electronic random number generator (www.randomizer.org). Then, the patients in the antibiotic group were administered the cefuroxime skin test, and the patients in the saline group were administered the saline skin test. If the cefuroxime skin test was positive, 0.9 g clindamycin was administered intravenously. The appearance of the three drugs was the same, and the drug amounts (1.5 g cefuroxime and 0.9 g clindamycin) were in accordance with the guidelines for prophylactic use of antibiotics before surgery [1]. The antibiotic and saline interventions were performed by the operating room nurse 30 min before the surgery, and it was ensured that the patient and the surgeon were blinded to it.

2.3. Quality control

(1) The patient's anesthesia was combined intravenous, inhalation, general anesthesia, and a laparoscopic appendectomy was

performed by a senior physician; (2) the three-trocar method was used in laparoscopic appendectomy, and the three sites of trocar insertion were as follows: the 10-mm port used for the laparoscope was placed at the umbilicus, the 12-mm port used for main surgical operations in the suprapubic region, and the 5-mm port used for auxiliary operation in the right iliac fossa. The surgical procedure was unified; (3) the appendiceal specimens were removed using an extraction bag through the trocar; (4) perioperative management [15–17]: fasting for 6 h before the surgery, getting out of bed on the same day after the surgery, drinking a small amount of water 6–8 h after the surgery, and a small amount of liquid diet on the second day after the surgery; (5) patients were discharged on the second day of the surgery.

2.4. Outcome measures

The main outcome was SSI. The diagnostic criteria of SSI used were as follows: According to CDC, SSI refers to the infection related to the surgical site within 30 d of the surgery, which can be categorized into the surgical incision and organ/space infections. Surgical incision infection is further categorized into SSI of the skin and subcutaneous tissue (SSI of superficial incision) and SSI of the deep soft tissue (SSI of deep incision). CDC has described the three types of SSI in detail [18]. Patients were diagnosed with SSI if they meet one of the following three diagnostic criteria: 1. There are purulent secretions at the surgical site; 2. the results of bacterial culture of the secretions from the surgical site were positive; and 3. the attending physician diagnosed SSI. The third diagnostic criterion is subjective and we cited it very carefully during the study. We quoted the first or/and second criterion to diagnose SSI, except for one case of abdominal infection judged to be a space SSI by a senior attending physician and two chief physicians. It is worth noting that fat liquefaction, tissue necrosis, and suture rejection, which are easily misdiagnosed as surgical incision infection, do not belong to SSI according to the definition by CDC.

Secondary outcomes were the patient's clinical outcomes, including postoperative complications, time to recovery of gastrointestinal function, and resolution of primary abdominal pain symptoms. Postoperative complications are surgery-related complications other than SSI, such as abdominal hemorrhage, leaky gut, and appendix stumpitis. The recovery time of gastrointestinal function was the time of postoperative anal exhaust, and the patient recorded the time of first postoperative anal exhaust and informed us at the first follow-up. The main symptom of patients with chronic appendicitis is intermittent lower right quadrant pain. Abdominal pain is a subjective feeling of the patient and will be affected by the surgery. To eliminate the influence of the surgery, the patients were asked, 3 months after the surgery, whether the primary abdominal pain symptoms had disappeared.

2.5. Data collection and follow-up

The data collectors recorded the basic information and baseline data of the patients, and the data follow-up investigators performed the specified follow-up on the patients and assessed the outcomes during the follow-up. The data collectors and the follow-up investigators were independent of each other.

The following information was collected by the data collectors from the Hospital Information System: sex, age, height, weight, preoperative white blood cell count, preoperative neutrophil percentage, preoperative fever, type of surgery, diagnosis, history of diabetes, hypertension, smoking, and drinking, preoperative albumin level, hemoglobin level, intraoperative skin closure (intermittent suture, biological adhesion), name of the surgeon (main knife), surgery time and postoperative pathologic diagnosis. To ensure that the follow-up persons know nothing about the grouping of patients, the data collectors learned from the operating room nurse whether the patient used antibiotics prophylactically before surgery, and encoded this information and recorded it in EpiData software. EpiData was used to record the information and follow-up data of patients.

The patients were followed up over the telephone once a week for 30 days after discharge, and SSI, postoperative complications, and the time of anal exhaust were judged and recorded. About 90 days after the surgery, a telephonic follow-up was performed to record whether the symptoms of primary abdominal pain had disappeared. If the patient had signs of SSI (fever, redness, pain, swelling, wound dehiscence, purulent drainage, or body temperature >38 °C), a hospital visit for SSI diagnosis and appropriate treatment was necessary.

2.6. Statistics

Data were analyzed using statistical packages in R (The R Foundation; http://www.r-project.org; version 3.4.3) and Empower (R) (www.empowerstats.com, X&Y solutions, inc. Boston, Massachusetts). The Chi-square test or Fisher's exact test was used for the comparison of counting data (%) between groups. Measurement data that followed a normal distribution are expressed as $X \pm s$, and those that did not follow a normal distribution are expressed as M (IQR). Continuous *t*-test or rank-sum test were used for comparison between groups. A two-way inspection was used. A $P < 0.05$ indicated statistical significance. Single-factor regression analysis and generalized linear mixed model were used to analyze the sensitivity of the results, and the results are expressed as OR (95% CI).

3. Results

3.1. Patients

A total of 120 patients were admitted to the affiliated Hospital of Guizhou Medical University. Of these, 9 patients were excluded. Of the remaining patients, 56 patients were administered intravenous antibiotic prophylaxis and 55 patients received 0.9% saline.

After randomization, 5 patients were lost to follow-up, and data of 106 patients (52 in the antibiotic group and 54 in the saline group) were available for analysis (Fig. 1). The baseline characteristics of the patients are shown in Table 1.

3.2. Pathological diagnosis and SSI

A total of 94 patients were pathologically diagnosed as chronic appendicitis after the surgery. The correct rate of diagnosing chronic appendicitis by clinical symptoms, physical examination and imaging before the surgery was 88.68%. In 12 cases of non-chronic appendicitis, the vast majority were acute simple appendicitis, and only 1 case was appendiceal mucocele. Among 94 patients with chronic appendicitis diagnosed using pathology, 6 patients had SSI, while 12 patients with non-chronic appendicitis had no SSI. Fisher's exact test showed that there was no significant difference between them.

3.3. SSI and clinical outcome

All cases were cured successfully and there was no death. There were 6 cases of SSI in total. Of which, 3 cases of superficial SSI were cured by intensive dressing change and oral administration of antibiotics (cefuroxime). A case of deep SSI was cured by incision and drainage, local infrared irradiation, and oral antibiotics (cefuroxime). Another 2 cases of organ/space SSI were cured by abdominal drainage, systemic intravenous administration of antibiotics (cefuroxime combined with tinidazole), and support treatment.

The 2 cases of organ/space SSI occurred only in the saline group. Fisher's exact test was used to analyze the difference in the incidence of organ/space SSI between the antibiotic and control groups, and there was no significant difference. There were 3 cases of SSI in the saline group and 3 cases in the antibiotic group. According to the main outcome of the study, SSI, there was no significant difference between the saline and antibiotic groups. There were also no significant differences between the two groups in the other secondary outcome indicators, including complications, the time of anal exhaust, and primary abdominal pain symptoms (Table 2).

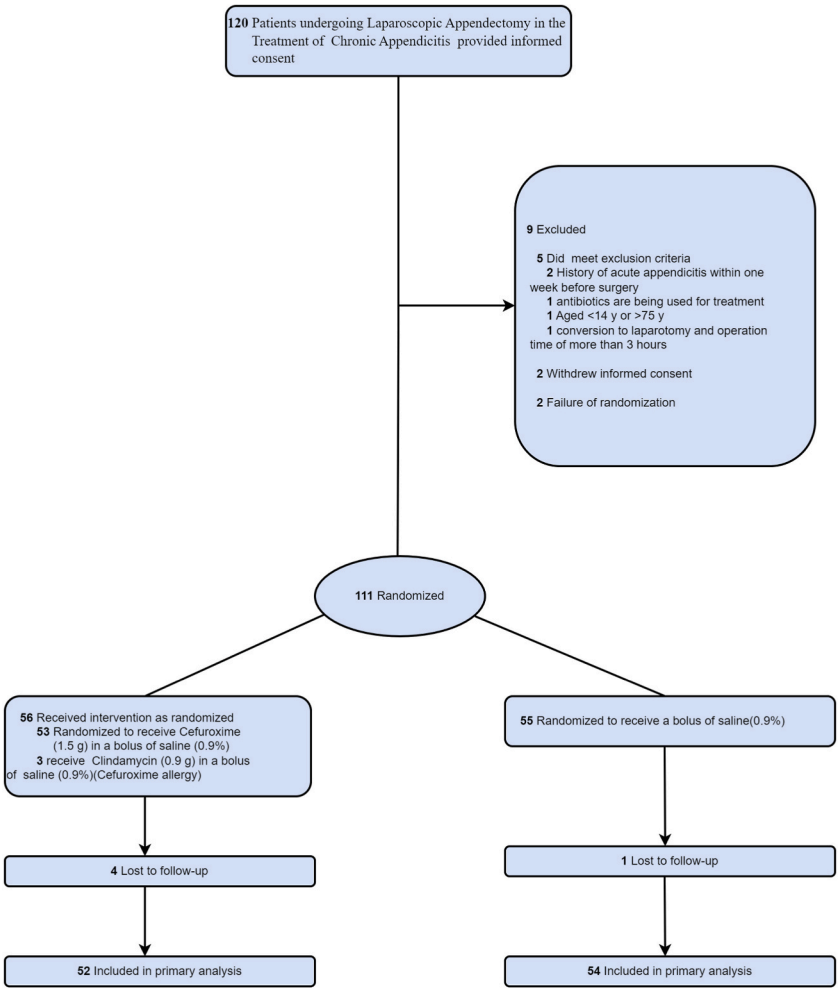

Fig. 1. The consort flow diagram.

Table 1
Baseline characteristics of the patients.

Characteristics	Saline Group	Antibiotic Group
Number of cases	54	52
Age, M (IQR), y	37.00 (25.00–44.75)	34.00 (23.75–50.50)
Sex, N (%)		
Women	38 (70.37%)	39 (75.00%)
Men	16 (29.63%)	13 (25.00%)
[a]BMI, M (IQR)	21.64 (19.61–23.70)	21.63 (18.95–23.69)
Albumin, $\bar{x} \pm s$, g/L	46.93 ± 2.94	46.76 ± 2.96
Hemoglobin, M (IQR), g/L	141.00 (133.25–151.00)	139.50 (133.75–151.75)
White Blood Cells, M (IQR), $\times 10^9$/L	6.11 (5.18–7.45)	5.74 (5.25–6.81)
Diabetics, N (%)		
NO	54 (100.00%)	50 (96.15%)
YES	0 (0.00%)	2 (3.85%)
Hypertension, N (%)		
NO	51 (94.44%)	51 (98.08%)
YES	3 (5.56%)	1 (1.92%)
Smoking, N (%)		
NO	48 (88.89%)	47 (90.38%)
YES	6 (11.11%)	5 (9.62%)
Drinking, N (%)		
NO	51 (94.44%)	49 (94.23%)
YES	3 (5.56%)	3 (5.77%)
Type of surgery, N (%)		
Laparoscopic appendectomy	12 (22.22%)	13 (25.00%)
Laparoscopic appendectomy + Intestinal adhesiolysis	42 (77.78%)	39 (75.00%)
Duration of surgery, M (IQR), min	60.00 (50.00–90.00)	60.00 (60.00–90.00)
Intraoperative blood loss, M (IQR), ml	10.00 (5.00–20.00)	7.50 (5.00–11.25)
Suturing way of surgery Incision, N (%)		
Interrupted suture	18 (52.94%)	16 (47.06%)
Bio-adhesive bonding	36 (50.00%)	36 (50.00%)
Pathologic Diagnosis, N (%)		
Chronic Appendicitis	50 (92.59%)	44 (84.62%)
Non-Chronic Appendicitis	4 (7.41%)	8 (15.38%)

The H value was calculated using the Kruskal–Wallis rank-sum test.
[a] , BMI (Body Mass Index) = weight (kg)/height $(m)^2$.

Table 2
Clinical outcome of the patients.

	Saline group (n = 54)	Antibiotic group (n = 52)	OR (95%CI)P
SSI, N (%)	3 (5.56%)	3 (5.77%)	0.05 (0.20 , 5.41) 0.96
Complication, N (%)	0 (0%)	0 (%)	−0.10 (0.37 , 2.48) 0.92
The time of anal exhaust, M (IQR), h	13 (9.5 ~ 18)	16 (8 ~ 23)	−0.50 (-4.21 , 2.50) 0.62
Primary abdominal pain symptoms, N (%)	4 (7.41%)	4 (7.69%)	0.06 (0.25 , 4.40) 0.96

4. Discussion

This is a single-center, double-blind, randomized controlled trial of patients with chronic appendicitis undergoing elective laparoscopic appendectomy. We did not find that preoperative intravenous antibiotic prophylaxis reduced the risk of SSI within 30 d of the surgery compared to the saline group.

The current study was a single-center, double-blind, randomized controlled trial of patients with chronic appendicitis undergoing elective laparoscopic appendectomy. We did not find that preoperative intravenous antibiotic prophylaxis reduced the risk of SSI within 30 days of the surgery compared to the saline group.

According to the current guidelines for prophylactic use of antibiotics in China and abroad, LCA is a clean-contaminated wound. However, since the surgical site involves the digestive tract and there are a large number of bacteria in the digestive tract, they may contaminate the surgical site during the surgery and lead to infection. This infection may be prevented with antibiotic prophylaxis. Surgical experience at our center suggests that the risk of SSI is low, due to the following reasons: 1. The pathological changes of chronic appendicitis were different degrees of fibrosis of the appendiceal wall and chronic inflammatory cell infiltration, and the ratio of white blood cells and neutrophils was normal before the surgery. There were no symptoms of bacterial infection, such as fever and chills. 2. Laparoscopic appendectomy led to lesser trauma and bleeding, and the surgical time was often less than 2 h. 3. After an appendectomy, the excised organ was put into an extraction bag without contact with other abdominal organs and cavities to avoid contamination of the abdominal organs or lacunae by residual bacteria in appendix. 4. Compared to open surgery, the surgical excision using trocar may avoid the possible contamination of the surgical incision by intestinal bacteria. In summary, our center believes that

although LCA is a clean-contaminated wound, it is not necessary to use antibiotics before the surgery to prevent SSI. The current randomized controlled trial was designed to verify the claim.

The incidence of SSI in LCA reported in this study is about 5.6%. There are no relevant studies on SSI of chronic appendicitis. The average incidence of SSI in abdominal clean -contaminated wounds is about 6.67% [19]. The SSI of chronic appendicitis is slightly lower than the average incidence of SSI of abdominal clean-contaminated wounds, mainly because the risk of infection at the surgical site of LCA is lower than that of general abdominal surgery for clean -contaminated wounds.

The risk of SSI was similar between elective laparoscopic cholecystectomy and LCA. A meta-analysis study pointed out that the incidence of SSI in the non-antibiotic group and the antibiotic group was 3.2% and 2.4%, respectively, in the 19 studies related to antibiotic prophylaxis and selective laparoscopic cholecystectomy [20]. In the current study, a high rate of SSI was observed: the incidence of SSI in the non-antibiotic group and antibiotic group of chronic appendicitis was 5.56% and 5.77%, respectively. However, the incidence of SSI in these 19 separate studies ranged from 0% to 10% [21–39].

Cefuroxime, used in this study, is a second-generation cephalosporin. Cefuroxime is a broad-spectrum antibiotic and sensitive to most gram-positive Bacteroides, gram-negative Bacteroides, and anaerobes. It is stable to lactamases and effective against enzyme-producing drug-resistant bacteria. Its antibacterial activity against gram-positive bacteria is similar to that of first-generation cephalosporins, and the antibacterial effect against gram-negative bacteria is better than that of first-generation cephalosporins [40]. It is widely used in clean-contaminated wounds involving the gastrointestinal tract, urinary tract, lungs, and so on. If the patient is allergic to cefuroxime, clindamycin is used to prevent infection according to the guidelines for the clinical application of antibiotics in China [1]. Therefore, the choice of antibiotics in the current study for prophylactic use was appropriate.

The guidelines of the American Society of Health-System Pharmacists suggest that the timing of prophylactic administration of antibiotics is mainly based on the time when the drug concentration peaks. The peak concentration of cefuroxime occurs 30 to 45 min after intramuscular injection. Antibiotics should, therefore, be administered within 30 to 45 min before the incision. The assigned intervention was performed during this period. Retrospective studies have shown that prophylactic administration of antibiotics before and during the surgery is sufficient in patients with uncomplicated appendicitis. Prolonging the time of postoperative use of antibiotics does not reduce the incidence of SSI and significantly increases the incidence of postoperative diarrhea and Clostridium infection [41, 42]. The American Association of Health-System Pharmacists recommends repeated antibiotic prophylaxis if the surgical time exceeds 2 half-lives of the antibiotic (half-life of cefuroxime is 70 min) [43]. In the current study, if the surgical time exceeded 140 min, the patient needed to be administered prophylactic antibiotics again. However, the surgical time was less than 140 min for all the patients. Therefore, the time and frequency of the use of antibiotics did not affect the results of the study.

According to the results of this study, there was no significant difference between the antibiotic group and the saline group in SSI and other clinical outcomes. This indicates that antibiotic prophylaxis cannot reduce the risk of SSI and improve the clinical outcome of patients with chronic appendicitis after laparoscopic appendectomy. Considering the consumption of medical resources [4] and the pain of patients, both caused by SSI, and the grim situation of bacterial resistance caused by overuse of antibiotics [44], this study is overall important for patient safety and antibiotic stewardship.

5. Limitations

This study has several limitations. Firstly, only a single antibiotic, cefuroxime (or clindamycin if the cefuroxime skin test was positive), was studied. The effect of other types of antibiotics on SSI for LCA is not yet known. Secondly, some studies have reported that the use of second-line prophylactic antibiotics may increase the chance of SSI if the skin test for first-line prophylactic antibiotics is positive, and the identification of false-positive allergies should be enhanced [45]. Further screening of patients with cefuroxime allergy was not performed due to the feasibility of the study. The impact of clindamycin on the results of this study is unclear. Thirdly, this study only investigated the role of preoperative application of prophylactic antibiotics. The role of intraoperative and post-operative prophylactic application of antibiotics for SSI is unclear. Fourthly, no sample size calculation was performed since the baseline data in doing that were too scarce in patients undergoing laparoscopic appendectomy for chronic appendicitis. Fifthly, the non-prophylactic use of antibiotics may have serious consequences on high-risk SSI patients, we excluded high-risk SSI patients. The effect of prophylactic use of antibiotics on high-risk SSI patients could not be determined. The purpose of this study was to determine the effect of prophylactic use of antibiotics on patients with low-risk chronic appendicitis. In future studies, the risk of SSI can be stratified to determine the preventive effect of antibiotics on all risk levels of SSI.

6. Conclusion

In this study, preoperative intravenous antibiotic prophylaxis did not reduce the risk of SSI within 30 days of the surgery compared to the saline group in patients with chronic appendicitis after a laparoscopic appendectomy. Therefore, preoperative prophylactic use of antibiotics may be unnecessary.

Author contribution statement

Li Dai: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Xiangren Jin: Conceived and designed the experiments; Wrote the paper.

Haitao Xie; Tong He: Performed the experiments; Contributed reagents, materials, analysis tools or data.

Honggang Cheng; Yinwu Zhu; Xin Gou: Analyzed and interpreted the data.
Liuxing wang; Fu Huang; Baichuang Liang; Qian Wang: Performed the experiments.
Haibin Wang: Conceived and designed the experiments; Performed the experiments; Wrote the paper.

Data availability statement

Data included in article/supplementary material/referenced in article.

Declaration of interest's statement

The authors declare no conflict of interest.

Found

This research received no external funding.

Institutional review board statement

The study was conducted in accordance with the Declaration of Helsinki, and approved by the Ethics Committee of Affiliated Hospital of Guizhou Medical University (Approval Number: 2020 Ethics Review No. 217;Date: April 9, 2020).

Informed consent statement

Informed consent was obtained from all subjects involved in the study.

Acknowledgments

NO.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2023.e15578.

Abbreviations

The following abbreviations are used in this manuscript

SSI	surgical site infection
LCA	laparoscopic appendectomy for chronic appendicitis
CDC	Centers for Disease Control
NICE	National Institute of Health and Clinical Optimization
BMI	Body Mass Index

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