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CLINICAL TRIAL

The effectiveness of i.v. cefuroxime prophylaxis of surgical site infection after elective inguinal hernia repair with mesh: A retrospective observational study

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Abstract
Purpose The efficacy of routine antibiotic prophylaxis for prevention of surgical site infection (SSI) after elective inguinal hernia repair with a mesh patch remains uncertain. The authors of a recent Cochrane meta-analysis based on 17 randomized trials were unable to draw a definitive conclusion on this subject. The purpose of this study was to determine the effectiveness of prophylactic antibiotics for prevention of SSI after elective inguinal hernia repair with mesh and the risk factors for SSI.
Methods All low-risk patients who underwent elective inguinal hernia repair with mesh at our institution between 2010 and 2015 were enrolled in this study, with the exception of patients with recurrent hernias or immunosuppressive diseases. All patients received a single intravenous (i.v.) injection of cefuroxime (1.5 g) within 2 h prior to surgery at the discretion of the surgeon. SSI was defined using criteria of the Centers for Disease Control and Prevention. The variables which could influence the rate of SSI were analyzed by multivariate analysis to determine the independent risk factors for SSI.
Results Among the 605 patients who underwent elective inguinal hernia repair with mesh during the study period, 553 were eligible for enrolment in the study. Of these, 331 received a single dose of cefuroxime preoperatively. The overall SSI rate was 5.4 %; 9.4 % of those patients who did not receive preoperative antibiotic prophylaxis developed SSI versus 2.8 % of those who did receive prophylaxis ($P=0.001$). All infections were superficial. Factors independently associated with SSI were advanced age, smoking and preoperative stay.
Conclusions The incidence of SSI among low-risk patients who did and did not receive preoperative antibiotic prophylaxis after elective inguinal hernia repair with mesh differed significantly, particularly among patients of advanced age, smokers and patients with a prolonged preoperative stay in the hospital.

Keywords Elective inguinal hernia repair with mesh · Surgical site infection · Preoperative antibiotic prophylaxis · CDC criteria

Introduction

Hernia repair is one of the most common procedures in general surgery, with an estimated 20 million operations performed annually worldwide [1], of which 5.1 million are performed in China [2]. Therefore, even minor improvements in treatment could have a large medical and economic impact.

The efficacy of antibiotic prophylaxis for hernia repair is controversial. The majority of hernia repair surgeries performed nowadays involve the use of a mesh based on Lichtenstein's tension-free mesh repair technique [3] due to the low recurrence rate of this approach [4]. Mesh repair is classified as a so-called clean surgical procedure [5], but the reported incidence of surgical site infection (SSI) following such procedures ranges from 0 to 9 % [6], which is clearly higher than the average SSI rate of other so-called clean surgeries (2 %) [7]. Randomized controlled trials (RCTs) to evaluate the role of the routine use of antibiotic prophylaxis have shown various

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results, with most of the studies unable to obtain results supporting their use [8]. However, two of three Cochrane meta-analyses conducted in 2012 [9–11] favored the efficacy of antibiotic prophylaxis [9, 10]. In addition, the standpoints of different clinical guidelines vary on this subject [12].

Antibiotic prophylaxis is widely used in inguinal hernia repair with mesh in China due to the fear of subsequent infection caused by the introduced prosthetic materials [13]. Clinical practice varies from the administration of a single dose of antibiotics intravenously prior to the operation to the use of topical antibiotics together, on occasion, with antibiotic doses postsurgery. Nevertheless, inappropriate and indiscriminate use of prophylactic antibiotics may increase the cost of the surgery, as well as the risk of toxic and allergic side-effects and the growth of resistant organisms [14].

To assess whether systemic antibiotic prophylaxis prevents SSI in elective inguinal hernia repair with mesh, we carried out the retrospective analysis reported here on data from patients who underwent this surgerical procedure in a single large academic health institution in China.

Patients and methods

Characteristics of patients

The study population included all patients who had undergone inguinal hernia repair with mesh at our hospital (a teaching general hospital with 1800 beds) between 2010 and 2015. Data were collected by reviewing the electronic medical record and existing paper charts of each patient. This study was approved by the Review Board of the First Affiliated Hospital of Shantou University Medical College.

Patients with immunosuppressive diseases (i.e. diabetes mellifluous, malignancy, human immunodeficiency virus) and those on glucocorticoid medication were excluded from the study, as were patients with missing documentation on the postoperative valuation.

Surgical technique and antibiotic prophylaxis

All surgical operations were performed by two surgeons: one senior doctor and one resident doctor. Ioprep was the antiseptic used for preoperative skin preparation in all patients. The groin of the patient was shaved the day before surgery. The surgical technique used for all patients was a standard tension-free mesh repair procedure with polypropylene mesh. Drains were not used in any patient.

Depending on the surgeon's preference, some patients received an intravenous injection of 100 ml sterile saline with cefuroxime 1.5 g within 2 h prior to surgery, and other patients did not receive any antibiotics during the study period, unless the developed postoperative complications.

Data collection and follow-up

Wounds were inspected daily during the patients' stay in the hospital. All patients were requested to return for a physical examination 30 days after the surgery which was the length of the follow-up period. All patients were informed of the symptoms and signs of SSI and were instructed to report to their doctors when any such symptoms and signs developed. SSI was diagnosed according to the guidelines of the Centers for Disease Control and Prevention (CDC), as follows: (1) superficial infection that occurs within 30 days after surgery and involves only skin or subcutaneous tissue; (2) deep infection that involves the fascial and muscle layers and which, if a prosthesis is in place, may occur up to 1 year following surgery [15, 16]. Patients' parameters were recorded, including demographic data, history of smoking (>10 years), preoperative hospital stay (yes/no), type of hernia, comorbid illnesses if any, type of anesthesia, length of preoperative stay, duration of surgery, incidence of SSI and complications.

Statistical analysis

The association between SSI following inguinal hernia repair with mesh and antibiotic prophylaxis, patient clinical factors, type of hernia, length of procedure and length of hospital stay was assessed using Pearson χ^2 test for categorical variables and Student's t test or analysis of variance for continuous variables. Individual variables found to have a significant association with SSI risk were then analyzed using multivariable logistic regression. Statistical significance was assigned at $p < 0.05$. All calculations were performed with SPSS version 17.0 (IBM Corp., Armonk, NY).

Results

A total of 605 patients who underwent inguinal hernia repair with mesh during the study period were identified. Of these, 52 met the exclusion criteria and were not enrolled in the study(48 had diabetes and four had missed their follow-up examination), leaving 553 patients eligible for analysis. According to the electronic medical records of the patients, 331 received a single dose of cefuroxime preoperatively, and 222 did not receive any antibiotics during the study period. There were no significant differences in patient characteristics between patients who received antibiotics prior to surgery and those who did not receive any antibiotics (Table 1).

An overall SSI rate of 5.4 % (32/589 hernia operations) was observed, with 9.4 % of patients who did not receive preoperative antibiotics developing SSI compared with 2.8 % of patients who were given antibiotics prior to surgery ($p = 0.001$). No deep infections were observed necessitating removal of the mesh (Table 2). All cases of superficial SSI

Table 1 Baseline characteristics of patients who received preoperative antibiotic prophylaxis versus patients who did not receive antibiotics

Characteristic	Patients who received preoperative antibiotic prophylaxis ($n = 331$)	Patients who did not receive any antibiotics ($n = 222$)	p value
Age (years)	59.14 ± 16.61	58.37 ± 16.14	0.587
Sex			
Male	323 (97.6)	214 (96.4)	0.414
Female	8 (2.4)	8 (3.6)	
BMI (kg/m^2)	22.90 ± 3.42	22.38 ± 3.05	0.068
Serum albumin (g/l)	41.54 ± 3.97	40.97 ± 4.11	0.102
Hypertension			
Present	63 (19.0)	32 (14.4)	0.158
Absent	268 (81)	190 (85.6)	
Type of hernia			
Unilateral	308 (93.1)	209 (94.1)	0.610
Bilateral	23 (6.9)	13 (5.9)	
Comorbidity			
Present	97 (29.3)	70 (31.5)	0.576
Absent	234 (70.7)	152 (68.5)	
Smoking for years			
Yes	27 (8.2)	10 (4.5)	0.092
No	304 (91.8)	212 (95.5)	
Preoperative stay (days)	2.33 ± 1.30	2.25 ± 1.21	0.475
Anesthesia			
GA	13 (3.9)	11 (5.0)	0.186
Combined IV + SA	159 (48.0)	125 (56.3)	
Combined IV + Epidural	85 (25.7)	39 (17.6)	
Combined SA + Epidural	14 (4.2)	10 (4.5)	
Epidural	60 (18.1)	37 (16.7)	
Duration of surgery (min)	71.36 ± 26.15	73.16 ± 24.48	0.417

Data are presented as the mean ± standard deviation (SD) or as the number with the percentage in parenthesis, as appropriate

BMI, Basal metabolic rate; GA, bronchial intubation anesthesia; SA spinal spinal anesthesia/block; IV intravenous anesthesia; Epidural, epidural block

Table 2 Postoperative complications of patients who received preoperative antibiotic prophylaxis versus those who did not receive antibiotics

Variable	Patients who received preoperative antibiotic prophylaxis ($n = 331$)	Patients who did not receive antibiotics ($n = 222$)	p value
Superficial wound infection[a]	10 (2.8)	22 (9.4)	0.001
Deep wound infection[a]	0	0	
Postoperative complications[b]	2 (0.6)	4 (1.8)	0.225
Pneumonia[b]	0	4 (1.8)	0.026
Cardiopulmonary failure and died finally[b]	1 (0.3)	0	1.000
Reoperation within 3 days because of ecchymoma[b]	1 (0.3)	0	1.000

Data are presented as the mean ± SD or as a numbers with the percentage in parenthesis, as appropriate

[a] The denominator was the number of hernias operated on. There were 23 bilateral hernia operations performed in patients receiving preoperative antibiotic prophylaxis and 13 in those without. Thus, 354 and 235 hernias were surgically treated in patients who received preoperative antibiotic prophylaxis and in those who did not receive any antibiotics, respectively

[b] The denominator was the number of patients operated on

met CDC criteria and were detected during the patient's hospital stay. Six patients developed postoperative complications other than SSI (Table 2; $p = 0.225$), including one who died of cardiopulmonary failure; the postoperative complications of the remaining five patients were resolved by conservative treatment.

Clinical and procedural characteristics of patients diagnosed with SSI were compared with those who were not (Table 3). Patients who developed SSI were more likely to be older (59.20 ± 16.27 vs. 52.88 ± 17.79 years; $p = 0.034$) and to have a history of smoking (18.8 vs. 6.0 %; $p = 0.005$). Other significant risk factors included a longer preoperative stay (2.81 ± 1.38 vs. 2.28 ± 1.24 days; $p = 0.022$) and duration of surgery (82.78 ± 6.02 vs. 72.33 ± 25.63 min; $p = 0.022$).

The multivariate analysis of age, history of smoking, preoperative stay and duration of surgery as risk factors for developing SSI (Table 4) revealed that the use of preoperative antibiotic prophylaxis was significantly associated with a decreased SSI risk [odds ratio (OR) 0.103, 95 % confidence interval (CI) 0.033–0.315]. Other significant factors included advancing age (OR 1.022, 95 % CI 1.001–1.043), history of smoking (OR 15.395, 95 % CI 3.895–60.854) and preoperative stay (OR 0.696, 95 % CI 0.522–0.878).

Discussion

Surgical site infection is a commonly occurring healthcare-associated infection that can increase morbidity, mortality and the economic burden of the healthcare system. Placement of prosthetic materials is a high-risk factor for SSI after inguinal hernia repair [13]. The benefit of antibiotic prophylaxis has been demonstrated in various procedures involving implantation of a prosthesis, such as in joint

Table 3 Clinical and procedural characteristics of patients based on the development of a surgical site infection

Variable	Development of a SSI ($n = 32$ hernia operations)	No SSI development ($n = 521$ hernia operations)	p value
Age (years)	59.20 ± 16.27	52.88 ± 17.79	0.034
Sex			
Male	32 (100)	505 (96.9)	0.615
Female	0	16 (3.1)	
BMI (kg/m^2)	23.23 ± 3.59	22.66 ± 3.26	0.346
Serum albumin (g/l)	41.58 ± 2.93	41.28 ± 4.10	0.686
Hypertension			
Present	5 (15.6)	90 (17.3)	0.810
Absent	27 (84.4)	431 (82.7)	
Type of hernia			
Unilateral	29 (90.6)	488 (93.7)	0.455
Bilateral	3 (9.4)	33 (6.3)	
Comorbidity			
Present	12 (37.5)	155 (29.8)	0.354
Absent	20 (62.5)	366 (70.2)	
Smoking for years			
Yes	6 (18.8)	31 (6.0)	0.005
No	26 (81.3)	490 (94.0)	
Preoperative stay (days)	2.81 ± 1.38	2.28 ± 1.24	0.022
Anesthesia			
GA	1 (3.1)	23 (4.4)	0.052
Combined IV + SA	24 (75.0)	258 (49.5)	
Combined IV + Epidural	3 (9.4)	121 (23.2)	
Combined SA + Epidural	2 (6.3)	22 (4.2)	
Epidural	2 (6.3)	97 (18.6)	
Duration of surgery (min)	82.78 ± 6.02	72.33 ± 25.63	0.022
Postoperative stay (days)	8.91 ± 3.34	6.17 ± 2.32	0.000
Total hospital stay (days)	11.38 ± 3.31	8.45 ± 2.62	0.000

Data are presented as the mean ± SD or as a numbers with the percentage in parenthesis, as appropriate

Table 4 Multivariable logistic regression analysis of association between surgical site infection after elective inguinal hernia repair with mesh and other risk factors

Covariate	*p* value	Odds ratio	95 % Confidence interval
Receipt of prophylactic preoperative antibiotics	0.000	0.103	0.033–0.315
Advanced age of patient	0.037	1.022	1.001–1.043
History of smoking	0.000	15.395	3.895–60.854
Preoperative stay	0.002	0.696	0.522–0.878

replacement and cardiac or vascular implantation [17, 18]. However, the benefit of antiobiotic prophylaxis remains uncertain in inguinal hernia repair procedures with mesh. The main finding of our study is that SSI following inguinal hernia repair with mesh was less common in patients receiving preoperative prophylactic antibiotics than in those who did not receive antibiotics.

The overall incidence of SSI following inguinal hernia repair with mesh was 5.4 % among the patients enrolled in this study, which is within the range of 0–9 % [6] or 1–8 % [19] reported in the literature. However, it is much higher than the average SSI rate for so-called clean surgeries in China (0.3 %) [20]. These data have resulted in there being a strong majority of surgeons in China and the UK who are in favor of using antibiotic prophylaxis in this procedure [12].

The SSIs observed in our study were all superficial SSI (SSIs), which is consistent with the results reported by Celdran et al. [21] and Tzovaras et al. [22]. In our study the SSI rate of in patients who did not receive antibiotics was high (9.4 %) in comparison to the average SSI rate in the placebo group (5.8 %) reported by Celdran et al. [21]. However, our 9.4 % SSI rate is in accordance with the 13 % rate reported in the placebo group by Mazaki et al. [23], in which all infections were also superficial. Based on our results, we conclude that there was no correlation between superficial SSI and deep infection in our patients because none of the patients with superficial SSI developed mesh infection. All infections (22 with localized redness and swelling; 10 with pus discharge) were resolved with the administration of antibiotics prior to hospital discharge, without any readmission. Superficial SSIs were managed in the same way as reported by Tzovaras et al. [22].

The reported incidence of deep SSIs varies from 0.35 to 1 % [24–26]. Deep SSIs frequently necessitate complete removal of the mesh. That no DSSIs were recorded among our patients is likely due to all surgeries being performed primarily by one senior doctor. The skill of the surgeon is a potential significant risk factor for SSI [27]. To the contrary, our follow-up period was too short for DSSI to develop due to the tendency of this type of infection to appear long after the surgery, even several years after implantation.

The mechanism for SSI after inguinal hernia repair with mesh is currently unclear. The potential mechanisms and the results of the culture studies are given in the Electronic Supplementary Material.

We observed that patients who received preoperative prophylactic antibiotics were significantly less likely to develop SSI than those who did not receive any antibiotics (2.8 vs. 9.4 %, respectively). This result is consistent with the values reported by Yerdel et al. [24] who showed a significant (10-fold) decrease in wound infections with intravenous adminstration of antibiotic prophylaxis in mesh repair. Celdran et al. [21] reported SSI incidences of 8 and 0 % in their control and antibiotic prophylaxis group, respectively, and reached similar conclusions as we did. A recently published RCT [23] also reported similar results, with SSI rates of was 13 and 2 % in the placebo and antibiotic prophylaxis groups, respectively ($p = 0.003$). The conclusion of the authors of a recent meta-analysis (2013) of 12 RCTs [8] was that antibiotic prophylaxis is efficacious for the prevention of SSI after open mesh hernia repair. The National Institute of Clinical Excellence (NICE) recomends antibiotic prophylaxis for clean surgeries with implanted material in England and

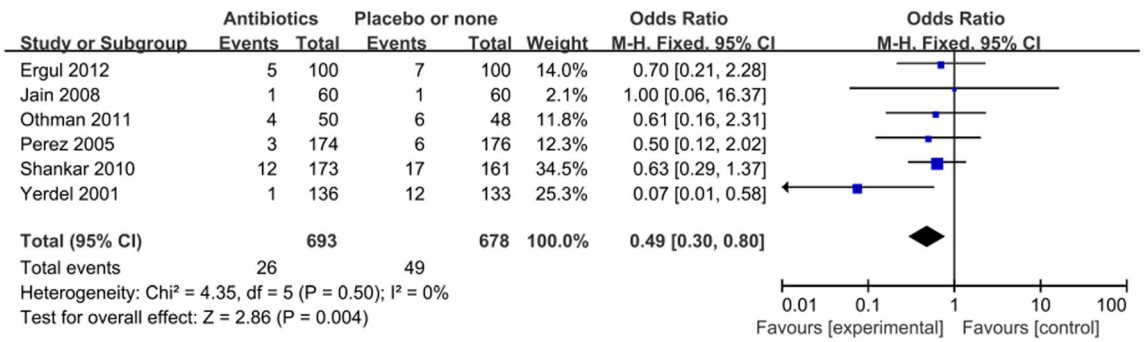

Fig. 1 Meta-analysis of the effectiveness of antibiotic prophylaxis on surgical site infection in patients who have had elective inguinal hernia repair with mesh in developing countries. *CI* Confidence interval

Wales [28]. In addition, the European Hernia Guidelines [29] state that prophylaxis should be considered for patients with risk factors for wound infection in elective open or laparoscopic groin hernia repair.

SSIs may result from many factors, both intrinsic and extrinsic to the patient. Although many intrinsic factors can not be ameliorated, the external ones can certainly be managed to varying degrees, with emphasis on those are related to aseptic conditions, surgical technique and perioperative care. Sanitary conditions among developing countries differ little. As shown in Fig. 1, a meta -analysis of six RCTs [24, 30–34] (a total of 693 patients in the antibiotic prophylaxis group and 678 in the placebo group) performed in four developing countries (Turkey, India, Egypt, Philippines) on the effect of antibiotic prophylaxis in SSI prevention after inguinal hernia with mesh revealed that patients receiving antibiotic prophylaxis had a significantly lower risk of developing SSI than patients receiving placebo (OR 0.49, 95 % CI 0.30–0.80; $p = 0.004$). Consequently, although the use of antibiotic prophylaxis has not been recommended by the authors of most of RCTs performed to date [22, 25, 30–36], the results of our study may reflect the current reality regarding the effectiveness of antibiotic prophylaxis in inguinal hernia with mesh in developing countries.

We found a correlation between advanced age, smoking and preoperative stay as risk factors for the development of SSI. Increasing age in adults has often been identified as a risk factor for SSI [37]. However, controversy exists as to whether age serves simply as a marker for underlying illness or whether immunologic senescence associated with increased age leads to an increased risk of infection [38]. Smokers who undergo general surgery have a higher incidence of wound infection than nonsmokers [39]. The proposed mechanism is a detrimental effect of smoking on tissue oxygen, which impairs the reparative process of wound healing and the neutrophil defense against surgical pathogens [40]. We also found that preoperative stay was an additional risk factor for SSI. It has been reported that the risk for SSI increases by 1.1-fold for each extra 3-day period of preoperative hospital stay [41]. Colonization of pathogen microorganisms during the prolonged preoperative hospital stay may be responsible for this increased SSI risk.

Our study has a number of limitations, including the drawback of being a retrospective single-centre design, a small sample size and a short follow-up period, all of which make it difficult to generalize our results. Consequently, there is an urgent need for a well-designed prospective randomized controlled study recruiting significantly larger numbers of patients to establish the actual benefit of antibiotic prophylaxis after inguinal hernia repair with mesh. In addition, because the impact on bacterial resistance is unknown, our findings should be balanced with the potential for adverse events and increasing microbial resistance with widespread use of antibiotics. The cost effectiveness of antibiotic prophylaxis should also be examined in a future study.

In conclusion, in our retrospective observational study, we recorded a remarkable improvement in the rate of SSI after inguinal hernia repair with mesh in low-risk patients who received antibiotic prophylaxis. Future prospective randomized trials are needed to compile evidence on the value of antibiotic prophylaxis after inguinal hernia repair with mesh. Impeccable surgical techniques and the microenvironment of the wound also play important roles in SSI prevention; sole reliance on antibiotic prophylaxis is not a reasonable approach to prevent SSI.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no competing interest.

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