ORIGINAL ARTICLE

The role of prophylactic cefazolin in the prevention of infection after various types of abdominal wall hernia repair with mesh

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Summary *Objective:* There are controversies about the benefits of prophylactic antibiotics in the prevention of postoperative surgical site infection (SSI) in mesh herniorrhaphy for a long time. This study aimed to evaluate the effectiveness and efficacy of systemic prophylactic cefazolin in prevention of wound infection in various types of hernia repair with mesh materials.
Methods: This is a prospective randomized control study. We evaluated wound infection rates in 395 patients with various kinds of hernia who underwent elective mesh repair using polypropylene mesh from 2007 to 2011. A total of 237 (60.0%) patients received prophylactic cefazolin (study group) and the remaining 158 (40.0%) patients did not receive any prophylactic antibiotics (control group). Patients were followed for infection at the following periods after the operation by an independent surgeon: 10 days, 30 days, 12 months, and then annually for at least 2 years.
Results: Eight (2.03%) patients had infection in the site of surgery [2 (1.27%) in the control group and 6 (2.53%) in the study group]. The distribution of infection was not significantly different between the two groups ($p = 0.364$). The superficial infections were managed by drainage and irrigation. One patient from the study group developed deep SSI and was readmitted and subsequently received antibiotic therapy, drainage, and debridement.
Conclusion: Preoperative administration of single-dose cefazolin for prosthetic hernia repairs did not markedly decrease the risk of wound infection. Our results do not support the use of

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1. Introduction

Abdominal wall hernia is defined as an abnormal protrusion of an organ through actual anatomic weaknesses or defects. The most commonly involved sites are the inguinal and femoral region (75%), umbilical and epigastric region (10%), and midline and sites of prior incisions (15–20%). The actual incidence of incisional hernia is unknown but 3–20% of laparotomies performed annually may result in ventral hernia.[1]

Inguinal hernia's lifetime risk is 27% and 3% in men and women, respectively. In the field of general surgery, hernia repair is one of the most common and important operations performed because of the significant lifetime incidence of hernia and availability of a variety of successful treatment procedures.[1,2] After the introduction of prosthetic material for hernia repair, because of its role in reduction of recurrence rate between 50% and 75% and simple performance,[3–5] mesh repair has been worldwide accepted as the gold standard in the elective management of inguinal hernia types.[6] Various mesh herniorrhaphy techniques include tension-free reconstruction of the posterior inguinal canal with anterior approach (Lichtenstein), anterior preperitoneal repairs through standard groin incision (Read-Rives) or through lower midline incision (Stoppa), and Rives procedure in which the prosthesis is placed between the rectus abdominis muscle and the posterior sheath.[6] Although the hernia repair operations are considered clean procedures, surgical site infections (SSIs) are common complications, leading to increases in length of hospitalization and costs. The incidence of SSI after these surgeries varies from 1.7% to 14% that can be influenced by the location of incision, elective or emergent condition, length of operation, surgical techniques including poor closure, tissue trauma, wound contamination, hemostasis, tissue damage, diabetes, chronic steroid use, smoking, malnutrition, obesity, prior hernia incision infections, foreign material in surgical site, chronic skin infections, and other site infections.[5,7–10]

The infection can produce pain and lead to poor wound healing and increases in hospital stay and costs. The risk of infection can be decreased using a proper operative technique, decreasing operative time, using a preoperative antiseptic skin cleaner, and by appropriate shaving.[1,7–9] Although several studies were performed to evaluate the benefits of different kinds of antibiotics in prevention of postoperative SSI after inguinal mesh herniorrhaphy, their role remains controversial.[7,11–15]

To our knowledge, only a few studies evaluated the role of prophylactic antibiotics in preventing postoperative SSI after repair of other types of abdominal wall hernia with mesh.[16] Thus, this study aimed to evaluate the effectiveness and efficacy of systemic prophylactic cefazolin in the prevention of wound infection in various types of hernia repair with mesh materials.

2. Patients and methods

This is a prospective randomized control study, which was performed to evaluate the effectiveness and efficacy of systemic prophylactic cefazolin in the prevention of postoperative wound infection in various hernia repairs with mesh materials. Participants included 395 patients with various kinds of hernia (inguinal, femoral, bilateral, incisional, umbilical, and lumbar hernias) who were candidates for elective mesh repair in Imam Reza Hospital, Mashhad University of Medical Sciences, Mashhad, Iran from September 2007 to October 2011. We excluded the following: patients undergoing emergency operations; immunocompromised patients with underlying diseases such as renal failure, cirrhosis, diabetics, malignancy; corticosteroid and immunosuppressive drug users; patients with use of preoperative antibiotics for different reasons > 1 week prior to surgery; patients' allergy to antibiotics; and patients under the age of 18 years. All patients were recommended to take a bath the night prior to surgery.

Based on an alternate-day randomization system, after anesthesia administration prior to the incision, the study group received 50 mL sterile saline with 1 g intravenous cefazolin. The control group did not receive any antibiotics. Cefazolin was chosen because of its bactericidal activity against the pathogenic organisms in skin wound infections. The half-life time of cefazolin is 1.5–2.5 hours, and therefore, it will have effective therapeutic levels during the course of the procedure. In the operating room, after shaving the surgical site and completion of skin preparation with povidone–iodine solution, we used a plastic sterile drape over the surgical site. All patients received general anesthesia. The following operation procedures were performed: Lichtenstein [in 58 (14.7%) patients], Read-Rives [in 52 (13.2%) patients], Stoppa [in 143 (36.2%) patients], and Rives [in 142 (35.9%) patients].

The mesh material was a monofilament polypropylene mesh (Promesh Light, Pe'ters Surgical, France) whose size varied from 6 cm × 11 cm to 30 cm × 30 cm. Based on the size of the hernia, at least 10 cm overlap of the mesh with margins of abdominal wall defect was considered. The closed suction drains were used in all Stoppa and Rives procedures. In addition, the wound closure was performed with running subcuticular suture.

If there was no event in the postoperative period, patients were discharged from the hospital according to the surgeon's discretion. Drains were removed when the 24-hour drainage decreased below 40–50 cm^3/d.

All patients were followed for the 1st postoperative month. Thereafter, all patients were followed by telephone call and only 128 (32.3%) patients who reported complaints were visited. The patients were followed on Day 10, Day 30, and 12 months after the operation for signs of infection, recurrence, edema, and hematoma. The patients were visited and their data were collected by a surgeon who was not involved in surgery. Infection was described when the incision became erythematous and tender or had purulent discharge up to 1 year. In these situations the stitches were removed, the wound was irrigated with saline, and the depth of infection and mesh involvement was determined. In cases of deep infection (mesh infection), the wound was opened, and then it was irrigated. After mesh debridement, a delayed closure was planned. Postoperative complications such as seroma, hematoma, and urinary fistula were recorded throughout the follow-up period for at least 2 years after the surgery.

Descriptive statistics such as frequency and percentage were used for categorical data and the mean and standard deviation for numerical variables. Statistical inferences such as independent sample t (student), Chi-square, and Fisher exact tests were performed to check the significant difference or the association between the variables.

3. Results

In this study, 395 patients with different kinds of hernia selected to receive elective surgery were enrolled. Of them, 278 (70.4%) were male and 117 (29.6%) were female with the mean age of 52.43 ± 16.57 years (Table 1). Based on an alternate-day randomization system, patients were assigned to the study and control groups. Two hundred and thirty seven (60.0%) patients (study group) received prophylactic cefazolin, and the remaining 158 (40.0%) patients did not receive any prophylactic antibiotics (control group). The mean age of patients in the control group was 50.6 ± 17.83 years and 53.67 ± 15.59 years in the study group, which was not significantly different (p = 0.078). The frequency distribution of sex in the two groups is presented in Table 1. There was a significant difference between sex and use of prophylactic cefazolin (p < 0.001).

Two (0.5%) patients had abdominal wall endometriosis, 10 (2.5%) patients had epigastric hernia, 101 (25.6%) patients had incisional hernia, 31 (7.8%) patients had umbilical hernia, and 253 (64.1%) patients had inguinal hernia (Table 2). Seventy-one (18.0%) patients had recurrent hernia with a history of previous operation: 15 (21.1%) patients

Table 2 Distribution of type of hernia in each group (p < 0.001).

Prophylactic antibiotic	Epigastric	Incisional	Inguinal	Umbilical	Total
No	3 (1.9)	7 (4.5)	138 (87.9)	9 (5.7)	157
Yes	7 (2.9)	94 (39.5)	115 (48.3)	22 (9.2)	238
Total	10 (2.5)	101 (25.6)	253 (64.1)	31 (7.8)	395

Data are presented as n (%).

with incisional hernia, 46 (64.8%) with inguinal hernia, and 10 (14.1%) with umbilical hernia.

The most common incisions were midline [66 (44.0%)], inguinal [46 (30.7%)], and Pfannenstiel [13 (8.7%)]. Stoppa was the most common technique performed [143 (36.2%) patients]. Other procedures were Lichtenstein [58 (14.7%) patients], Rives [142 (35.9%) patients], and Read-Rives [52 (13.2%) patients; Table 1].

Drains were removed when the 24-hour drainage decreased < 40−50 cm³/d. However, unfortunately, duration of drains left *in situ* was not recorded.

The mean hospital stay was 3.1 ± 0.7 days. The reason for this seemingly high mean hospital stay is due to the insertion of drains in patients receiving Rives or Stoppa techniques (55.7%) who were discharged after removal of the drains.

As shown in Table 3, in the postoperative period, 26 (6.6%) patients had a complaint of pain, six (1.5%) patients had hematoma, and six (1.5%) patients had seroma formation. There was no significant difference between the two groups in the types of complications (p > 0.05). All seromas were confined to the area of the incision and diagnosed by aspiration of clear serous fluid, and were managed expectantly without sequelae. Only one (0.3% of total) patient in the study group developed urinary fistula after Stoppa, which was characterized by the exit of urine from the drain. The patient was managed conservatively with catheterization without the need for prosthesis removal. Eight (2.03%) patients had an infection in the site of surgery [2 (1.27%) in the control group and 6 (2.53%) in the study group], all detected during the follow-up period. The distribution of infection was not significantly different between the two groups (p = 0.364). The distribution of superficial infection was as follows: four patients who received Rives, one patient who received Read-Rives, and two patients who received Stoppa repairs. There was no significant difference

Table 1 Patients characteristics in each group.

Characteristics		Control (n = 158, 40.0%)	Study (n = 237, 60.0%)	p
Mean Age ± SD		53.67 ± 15.59	50.6 ± 17.83	0.078
Sex	Male	136 (86.1)	142 (59.9)	<0.001
	Female	22 (13.9)	95 (40.1)	
Type of operation	Lichtenstein	37 (23.4)	21 (8.9)	<0.001
	Rives	18 (11.4)	124 (52.3)	
	Read-Rives	33 (20.9)	19 (8.0)	
	Stoppa	70 (44.3)	73 (30.8)	

Data are presented as n (%) or mean ± SD.

Table 3 Postoperative complications in each group.

Type of complications		Control (n = 158, 40.0%)	Study (n = 237, 60.0%)	p
Pain	No	148 (93.7)	221 (93.2)	0.868
	Yes	10 (6.3)	16 (6.8)	
Hematoma	No	156 (98.7)	233 (98.3)	0.734
	Yes	2 (1.3)	4 (1.7)	
Seroma formation	No	154 (97.5)	235 (99.2)	0.184
	Yes	4 (2.5)	2 (0.8)	
Urinary fistula	No	158 (100.0)	236 (99.6)	0.312
	Yes	0 (0.0)	1 (0.4)	
Wound infection	No	156 (98.7)	230 (97.5)	0.364
	Yes	2 (1.3)	6 (2.5)	
DSSI		0 (0.0)	1 (16.7)	0.430
SSSI		2 (100.0)	5 (83.3)	

Data are presented as n (%).
DSSI = deep surgical site infection; SSSI = superficial surgical site infection.

between infection and types of hernia repairs (p = 0.599). One (0.25%) patient who received Rives repair in the study group developed deep SSI, which necessitated readmission and partial debridement of the mesh without complete excision. Cultures showed aerobic Gram-positive streptococci organisms. These patients underwent wound drainage and infected prosthesis were subjected to drainage, debridement, and antibiotic therapy without the need for complete mesh removal (Table 4). In the follow-up period, only two (0.5%) patients of the study group (who received the Stoppa procedure) had recurrence in the site of surgery, which was not significantly different (p = 0.519).

4. Discussion

The true incidence of incisional hernia is unknown but in general 3–20% of laparotomies annually may result in ventral hernia; the rate doubles if the operation is associated with an SSI and wound dehiscence.[1] Inguinal hernia surgery has evolved drastically since first performed in ancient Egypt (from simple tissue repairs with suture to tension-free repairs with prosthetic materials) in parallel with the development of our anatomical understanding and improvements in surgical techniques.[4] Hernia repair using mesh was introduced 50 years ago. With the development of advanced methods, mesh was used for a variety of primary and recurrent hernias of the abdominal wall. Some of the methods of repair used are Lichtenstein, Read-Rives, Stoppa, Rives, and laparoscopic mesh repair. In addition, different mesh materials have been introduced. After installation of the mesh, the fibroblasts penetrate the mesh and after some days it becomes completely infiltrated with connective tissue. Based on the material of the mesh, the time of this infiltration varies.[17]

Seroma formation and implementation of foreign bodies such as prosthesis are two important risk factors associated with the high risk of bacterial contamination and infection, which may ultimately lead to significant morbidity (mesh removal and possible recurrence) and also mortality.

The incidence rate of infection following an inguinal herniorrhaphy, with or without prosthesis material, is between 1.7% and 14%.[5,7,10]

Because many factors influence the risk of wound infection, it is not possible to eliminate the infection completely; but infections can be reduced by improving surgical conditions and using proper equipment.

Along with the application of prosthetic mesh, prophylactic antibiotics were also traditionally used to prevent postoperative SSI. However, because of the low risk of wound infection and high incidence of drug resistance and side effects of antibiotics, the role of antibiotics in this regard is still a matter of debate.[10]

Considering the high rate of abdominal wall hernia repair annually performed worldwide, prevention of infection is so important.

For a long time, several studies advocated the benefits of different kinds of antibiotics (such as cefazolin, ampicillin/sulbactam, and amoxicillin/clavulanic acid) in prevention of postoperative SSI after inguinal mesh herniorrhaphy.[7,11–16] To our knowledge, there are only a few studies that evaluated the role of prophylactic antibiotics in postoperative SSI after abdominal incisional hernia repair using mesh.[16] By contrast, some studies demonstrated that antibiotic prophylaxis in elective inguinal hernia repair with mesh cannot decrease the risk of wound infection.[5,18–21]

Table 4 Details of infected patients.

Patient No.	Group	Type of operation	Microorganism cultured	Type of infection	Management	Outcomes
1	Study	Rives	S. epidermidis	SSSI	Drainage	Recovered
2	Study	Rives	S. epidermidis	SSSI	Drainage	Recovered
3	Study	Rives	S. epidermidis	SSSI	Drainage	Recovered
4	Study	Rives	S. epidermidis	SSSI	Drainage	Recovered
5	Study	Rives	S. aureus and S. epidermidis	DSSI	Antibiotics, drainage, and debridement	Recovered
6	Study	Read-Rives	S. epidermidis	SSSI	Drainage	Recovered
7	Control	Stoppa	S. epidermidis	SSSI	Drainage	Recovered
8	Control	Stoppa	S. epidermidis	SSSI	Drainage	Recovered

DSSI = deep surgical site infection; S. aureus = Staphylococcus aureus; S. epidermidis = Staphylococcus epidermidis; SSSI = superficial surgical site infection.

Sanchez-Manuel and colleagues[5] performed a Cochrane meta-analysis of 13 randomized trials that evaluated the benefits of antibiotic prophylaxis in inguinal hernia repair; of these 13 trials, seven used a prosthetic material. A total of 6825 patients were included (4188 in the prophylaxis group and 2637 in the control group). The rate of infection in patients with hernioplasty was 1.4% and 2.9% in the prophylaxis and control groups, respectively. Based on these results, the authors recommended the use of antibiotics only in cases with high rates of wound infections, and not universally for all patients undergoing elective inguinal hernia repair.[5] Perez and colleagues[22] also performed a prospective, randomized, double-blind, placebo-controlled trial to compare single-dose 1 g intravenous cefazolin with placebo in 360 patients undergoing open inguinal hernia using polypropylene mesh. Their results also showed no benefit of antibiotic prophylaxis (1.7% vs. 3.3%, $p = 0.50$).

Another double-blind prospective randomized trial in 200 patients selected to receive elective inguinal hernia surgery with mesh repair demonstrated no significant difference between the cefazolin and placebo groups (7% in the study group and 5 % in the placebo group, $p = 0.38$). They concluded that antibiotic prophylaxis has no benefit in the incidence of SSI in elective repair of inguinal hernias with mesh.[18]

Similar results were documented by Jain et al,[19] Tzovaras et al,[20] and Aufenacker et al,[21] which did not support the use of prophylactic antibiotics in low-risk patients with inguinal mesh hernioplasty.

The nationwide Danish Hernia Database, which records > 10,000 inguinal and 400 femoral hernia repairs annually, suggests that routine prophylactic antibiotics are not indicated.[23]

Antibiotics used for prophylaxis should be safe, cost-effective, and effective against common pathogens based on procedure type. Therefore, in accordance with previous studies we used cefazolin because of its bactericidal activity against the pathogenic organisms in skin wound infection. The majority of the studies were on inguinal hernia repair, and there were only a few reports that studied the relationship between prophylactic antibiotics and extent of hernia site, prosthesis size, operation time, and extent of tissue dissection. Increase in the size of the hernia leads to an extended dissected area, and consequently larger size of mesh and increased operative time. All these factors predispose the wound to seroma formation, increased bacterial contamination, and decreased prosthesis adhesion to tissue due to a delay in fibroblast migration, and ultimately prosthesis infection.[17]

Some important risk factors mentioned earlier such as hernia site and prosthesis size were considered in the design of our study to evaluate the role of cefazolin as prophylaxis for postoperative wound infection. Unfortunately, other risk factors such as the mean operating time, obesity, and history of smoking were not considered in this study.

Seroma formation was noted in four (2.5%) patients in the control group and in two (0.8%) patients in the study group, and none of them progressed to SSI. Hematoma formation was noted in 0.01% of patients with no progression to wound infection.

The overall risk of infection was 2.03%, which was similar to other studies.[5,7,10] The rate of wound infection was 2.5% in the study group versus 1.3% in the control group with no significant difference between the two groups ($p = 0.364$).

Based on the Chi-square test, there was no significant difference regarding infection between patients who received Rives and Read-Rives repair ($p = 0.219$).

One patient in the study group developed deep SSI. Although there was no significant difference between the two groups, cefazolin does not seem to have any beneficial effects in prevention of wound infection.

In some studies, deep SSI eventually led to graft loss,[13,22] but in our study the infected prosthesis was subjected to debridement without the need for graft removal.

The European Hernia Society guideline for inguinal repair recommended antibiotic prophylaxis in the presence of wound infection risk factors such as recurrence, advanced age, immunosuppressive conditions and steroid use, emergency conditions, long operating duration, and use of drains; it is not recommended for low-risk patients ($< 5\%$) and in endoscopic hernia repair.[24]

In conclusion, with regard to an outbreak of bacterial resistance and less cost effectiveness of prophylactic antibiotics, our results suggest that preoperative administration of cefazolin does not decrease the risk of postoperative wound infection in low-risk patients, and thus, does not support the use of cefazolin prophylaxis for mesh hernia repair.

Finally, because of the low infection rate in this study, it was not possible to evaluate the impact of factors such as previous history of hernia repair, hernia site, the extent of dissection, mesh size, and length of operation on wound infection. Thus, future studies with a larger sample size are needed to evaluate these factors.

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