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Original Article

Effectiveness of Prophylaxis Antibiotic Used for Tension-free Hernioplasty: A Randomized Double-blinded Placebo-controlled Trial

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Abstract

Objective: **To evaluate the effectiveness of prophylaxis antibiotic used for tension-free hernioplasty on prevention of surgical wound infection.**

Materials and Methods: **After having permission from the Ethical Review Board of the hospital, this randomized double-blinded placebo-controlled trial was performed from September 2010 to June 2011. One hundred and six patients with inguinal hernias, American Society of Anesthesiologists (ASA) Class 1-2, who never had allergy to cephalosporin and aged over 18 years-old were included. Fifty and 56 patients were allocated to the intervention and control groups, respectively.**

Results: **At one-week follow-up, there was no difference of infection rate among the control and intervention groups. In other words, there was no sign of wound infection found in all of 106 patients. All patients did well without sign of wound infection at one-month follow-up.**

Conclusion: **There is no clear benefit of preoperative prophylactic antibiotic for prevention of post inguinal hernioplasty wound infection. For deep surgical site infection, a longer follow-up at one year is needed for completion of CDC criteria.**

Key words: **inguinal hernioplasty, mesh graft, prophylactic antibiotic, surgical wound infection**

INTRODUCTION

Inguinal hernioplasty is a common general surgical procedure. In the past, conventional hernia repair, without mesh graft, needed no prophylactic antibiotic. However, contemporary surgeons increasingly prefer tension-free hernioplasty due to its low recurrent rate and clean wound in nature. Different from conventional hernia repair by using mesh graft, which is a synthetic material, its risk of surgical wound infection might be increased[1,2].

Incidence of surgical wound infection after inguinal hernioplasty ranged from 0.4-1.3%[3]. In Thailand, this incidence especially in cases using mesh graft is still unknown and there has been no clinical practice guideline recommending prophylactic antibiotic for this procedure. Therefore, empirical antibiotic prophylaxis is routinely used in most institutes without any medical evidences. Till now, there have been controversies in this issue whether prophylactic antibiotics are useful for inguinal hernioplasty[4-7].

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At present, European hernia society guideline[8], which is an evidence-based guideline, recommends that there is no need for preoperative prophylactic antibiotic in low-risk patients. However, their data came from European studies which have different population from our South-East Asia, in races, public-health systems, climates, and environments, which can affect patients' surgical wound infections.

This study aimed to evaluate the effectiveness of prophylactic antibiotic used for tension-free hernioplasty on prevention of surgical wound infection after surgery.

Materials and Methods

After having permission from the Ethical Review Board of the hospital, this randomized double-blinded placebo-controlled trial was performed from September 2010 to June 2011. All patients with inguinal hernias, American Society of Anesthesiologists (ASA) class 1-2, never had an allergy to cephalosporin, and aged over 18 years-old were included after informed consents obtained.

Patients were divided into two groups according to a computer-generated random sequence developed by a hospital pharmacist. These allocations were accomplished without knowing by author or the nurse injecting drugs because either cefazolin (1 gram) or placebo looked the same by naked eyes. These drugs were given by intravenous injection 30 minutes before surgical incision. The reason for using cefazolin was its efficacy over Staphylococcus aureus and Staphylococcus epidermidis which commonly caused mesh graft related surgical wound infections[1,2,4], and it had enough half-life for inguinal hernioplasty. The placebo was normal saline solution.

Aside from cefazolin or placebo as mentioned above, all patients had the same Lichtenstein inguinal hernioplasty under local anesthesia using 40 ml of 1% xylocain and 20 ml of 0.5% bupivacain. Preoperative local preparations were done by cleansing with 2% chlorhexidine-70% alcohol solution and shaving in the operating theatre. Every patient had mesh graft, lightweight polypropylene mesh [Ultrapro-Ethicon] sized 8 × 15 cm, placed by a day-case surgery. Follow-ups were done at one week and one month after surgery to evaluate superficial surgical site infection according to CDC criteria and other surgical-related infections.

Results

From September 2010 to June 2011, there were 106 patients included. Placebo group consisted of 56 patients (aged 25-84 years old), 53 males and 3 females. Twelve patients in this group had more than one co-morbidity. One patient had recurrent and one had bilateral hernias. The cefazolin group consisted of 50 patients (aged 20-82 years old), all were male. Ten of this group had more than one co-morbidity. Two patients had recurrent and one had bilateral hernias (Table 1).

No patients needed to be observed in the recovery room. Every patient was able to return to their residences immediately after surgery. There was no acute urinary retention or wound hematoma found. No one needed re-admission from either surgical complications or post-operative pain. At one-week

Table 1 Demographic data of all patients

Characteristics	Control group (N = 56)	Intervention group (N = 50)
Age (mean and range in years)	57.3 (25-84)	52.5 (20-82)
Gender		
Male	53	50
Female	3	0
Types		
Direct	37	37
Indirect	19	14
Incarcerated	4	4
Recurrent	1	2
Laterality		
Unilateral	55	49
Bilateral	1	1
Comorbidity		
Hypertension	14	14
Cardiovascular diseases	8	6
Diabetes mellitus	5	4
Respiratory diseases	3	4
Dyslipidemia	6	3
Gouty arthritis	1	2
Chronic kidney diseases	2	2
Cerebrovascular diseases	0	2
Hyperthyroidism	1	0
Cirrhosis	1	0

follow-up, every patient had total stitches off and there was no difference of wound infection rate among the control and the intervention groups (0%, 95% CI 0-6.4% vs 0%, 95%CI 0-7.1%, respectively, p >0.999). In other words, there was no sign of wound infection found in all of 106 patients (0%, 95% CI 0-3.4%). All patients did well without any sign of wound infection at one-month follow-up.

Discussion

Lichtenstein inguinal hernioplasty is a surgical procedure using mesh graft placed into the surgical wound. If there is surgical wound infection, it will be very complex in treating it. Preoperative prophylactic antibiotic is an intervention that may decrease the risk of this infection, but there are some studies not supporting this intervention for every case of inguinal hernia[4,9,10]. The reason is this intervention cannot definitely decrease post operative infection rate while increasing expenses and unnecessary use of antibiotics that might also increase bacterial resistance rate in communities[6]. In addition, patients who receive this intervention are at certain risk of hypersensitivity/ allergic reaction.

In this study, the patients did not need prior admission to the hospital and after surgery, they could return to their residences almost always immediately. There was no difference of wound infection rate among the two groups, in other words, there was no wound infection found in this study. However, one-year follow-up is still needed according to CDC criteria of deep surgical site infection.

Previous study by Sanchez-Manuel et al [11] reported no definite benefit from prophylactic antibiotic used for decreasing wound infection rate after inguinal hernioplasty. Aufenacker et al[7] also found that preoperative prophylactic antibiotic did not decrease wound infection rate after inguinal hernioplasty. These results were in contrast with a study by Sanabria et al[9] reporting that preoperative prophylactic antibiotic could decrease wound infection rate after inguinal hernioplasty by 50%.

In a Spanish study of preoperative prophylactic antibiotic conducted in patients undergoing inguinal hernioplasty under local anesthesia, similar to this study, Celdrán et al[10] reported that cefazolin could decrease surgical wound infection. They found infection rate of 4/49 in control group. This was in contrast to the studies by Othman[12] and Shankar et al[13] which reported no difference in surgical wound infection rate found after inguinal hernioplasty among control and intervention groups. They also recommended that prophylactic antibiotic should not be routinely used in every case undergoing inguinal hernioplasty but might be used in some selected cases with high-risk of surgical wound infection.

At present, there is still no definite benefit from preoperative prophylactic antibiotic for prevention of post inguinal hernioplasty wound infection. This surgical procedure still has many measures for infection prevention such as proper surgical site skin preparation, aseptic technique, patient selection, surgical technique, type of mesh graft, and finally, duration of surgery[8].

From this study, the author could only explain about superficial surgical site infection, which is only a surrogate end point. For deep surgical site infection, which is a primary end point, one-year follow-up is still needed to be done, for completion of CDC criteria.

Conclusion

Preoperative prophylactic antibiotic does not prevent superficial surgical site infection after a tension-free inguinal hernioplasty. There is still no definite benefit from preoperative prophylactic antibiotic for prevention of post inguinal hernioplasty wound infection. Therefore, there is no need for prophylactic antibiotic in every case undergoing this procedure. Some patients who may need it may include some high-risk patients such as immuno-compromised or poor-controlled diabetes mellitus ones.

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