

Evaluation of Prophylactic Antibiotic Prescription in Post-Operative Infection in Patients Undergone Inguinal Herniorraphy Surgery with Prolene Mesh: A Randomized Double Blind Study

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Abstract: Inguinal hernia is one of the most common surgical problems in general population and herniorraphy is one of the most common surgical procedures done in general surgery. In recent years, many progresses have been achieved in this field as using prosthetic materials to reduce the recurrence. Although, it has some disadvantages such as adhesions and infections. The goal of this study is to evaluate the effect of prophylactic antibiotic in reduction of post operative infection in these patients. This is an interventional double blind randomized trial on 212 patients undergone Lichtenstein Inguinal Herniorraphy. A total of 100 cases received prophylactic antibiotic and 112 patients did not receive any antibiotic. They were all examined by another surgeon on 3, 7, 14, 30 and 60th day post operative and the results were put in an information sheet. We used SPSS software to analyze the data and Chi-square (χ^2) and exact fisher test were used to evaluate the results. Mean age of patients was 51.1 ± 4.6 . Range was 20-81 years; 91.5% were male, 8.5% were female. About 5.2% had Diabetes Mellitus (DM), 7.1% had HTN and 6.6% had previous IHD. About 95.5% had simple inguinal hernia, 2.4% had femoral hernia, 2.3% had incarcerated inguinal hernia, 53.3% right side, 42% left side and 4.7% were bilateral hernia. The incidence of infection in antibiotic group was 2% and in group without prophylactic AB was 2.7% which was not statically significant ($p = 0.4$). As there is no significant difference between two groups, prophylactic AB has no effect on post operative infection thus, according to high cost of routine antibiotic prescription and possible complications such as resistance and side effects and reactions of these drugs, it is justified to limit the antibiotic to therapeutic purposes and those who have risk factors for severe infections.

Key words: Resistance, SPSS software, prosthetic, materials, hernia, antibiotic, reduction, Iran

INTRODUCTION

Inguinal hernia is one of the most common diseases in general surgery and herniorraphy is one of the most common surgical procedures. Comments on treatment of inguinal hernia return to 1st century after Christ, although formal elaboration and explanation about repair method of inguinal hernia with surgery was not present until the 15th century. In recent years, great changes was revolved in its surgical method. Such these essential changes it could be mentioned as use of prosthesis (mesh) in reducing recurrence rate as Lichtenstein method now is the method of choice in the United States (Aufenacker *et al.*, 2004). According to Lichtenstein, reducing tension correlates with decrease chance of suture unroll and thereafter reduces recurrence rate. Despite many advantages, use of these materials may cause problems such as infection that necessitates contrivance adoptions to reduce complications. Such as these contrivances is prophylactic

or therapeutic use of antibiotics (Shankar *et al.*, 2010). According to classification of these wounds as ID 16, controversies about effect of antibiotics in such surgical procedures exists. Some believe that antibiotics significantly reduces the infection rate (Yerdel *et al.*, 2001; Gravante *et al.*, 2008; Shankar *et al.*, 2010). But some believe that it has no significant effect (Aufenacker *et al.*, 2004; Thakur *et al.*, 2010). Some suggest IV and some oral antibiotics (Kuzu *et al.*, 2005). High costs, drug resistance and complications of antibiotic therapy conflict these theories. On the other hand, infection causes serious complications and problems in these patients (recur sepsis, adhesion, etc.). This problem persuades many surgeons to inappropriate use of antibiotics. In this study, we decide to evaluate and assess benefit of antibiotics in prevention of infection of surgical suture.

Epidemiology: About 75% of abdominal wall hernias occur in groin. Prevalence of indirect hernia is 2 times of

direct hernia and femoral hernia constitute low percent. Hernia in groin region is more common on right side and male to female ratio for inguinal hernia is 7-1. Femoral hernia constitutes <10% of all hernias in groin region. Overall current risk for a man for inguinal hernia was 18% and its life time risk is 24%. Bilateral life time risk was 39%. (Age 25-34 = 31%, age 65-74 years = 45% and age >75 = 59%) (Brunicardi *et al.*, 2009).

MATERIALS AND METHODS

This interventional study was done among patients suffering from inguinal hernia referring to Rasool Akram and Sadr Hospitals, Tehran, Iran since date 21 March, 2007 till 3 March, 2007 and undergone herniorrhaphy surgery with mesh (Lichtenstein method). A total of 100 patients who received cefazolin 1 g in the operating room before surgery as prophylactic antibiotic (AB+) were compared with 112 patient who did not receive any antibiotic (AB-). Patients with underlying diseases and active infection during and after surgery and also emergency surgical cases (strangulation) were omitted from study (exclusion criteria). A total of 100 cases who received antibiotics were compared with 112 cases who did not receive any antibiotic for mentioned variables.

Maximum duration of admission is 3 days. At 3, 7, 14, 30 and 60th day post operation, clinical examinations was performed and any sign indicating infection was assessed with laboratory tests (CBC and blood culture); signs such as redness, pain, fever and pussy discharge indicate infection and patient is classified as infection (+) and absence of such signs classifies patients in infection (-) group then these patients were checked with antibiotic +/- table. Method of selecting patients to receive antibiotics is random (odd days -/even days +). Operated people were treated with antibiotics on even days. Examiner is not informed about receiving or not receiving antibiotics (blinding).

Inclusion criteria: Any patient suffering from inguinal hernia undergone lichtenstein herniorrhaphy.

Exclusion criteria: Age >82, immunosuppressive drugs, any recent infection (1 week) refusing to enter the study, recurrent hernia with excessive dissection, HIV+, strangulation and intestinal anastomosis.

Data collection method

Collection method; observation: Tabular information that is registered on days after operation according to method of performing study and based on clinical examinations and if necessary laboratory tests.

Method of assessing and analyzing information: After concordance of tables and numbering of patients (Double blind), the processor is not aware from receiving or not receiving antibiotics (blinding). Data was analyzed with SPSS software.

RESULTS

The power of the trial (p = 0.05, 80%, 2-sided) was based on the assumption that antibiotic prophylaxis reduces the wound infection rate from 4% (average in literature) to 1% (Aufenacker *et al.*, 2004). In this study, 212 patients were assessed. Mean age of patients was 51.1±11.6 years and their age range was between 20-81 years. Mean duration disease was 3.09±1.5 months and its range was between 6 months to 7 years.

Sex frequency of studied patients: About 194 patients (91.5%) of studied patients were male and 18 patients (8.5%) were female (Table 1).

Frequency of type of diagnosed hernia in studied patients: About 202 patients (95.3%) had inguinal hernia, 5 patients (2.4%) had femoral hernia, 5 patients (2.4%) had incarcerated hernia (Table 2).

Frequency of underlying disease in studied persons: About 11 patients (5.2%) among studied patients had history of diabetes mellitus, 15 patients (7.1%) had history of blood pressure and 14 patients (6.6%) had history of ischemic heart diseases (Table 3). About 202 patients (95.3%) of studied patients had unilateral hernia that 89 cases of them was left side and 113 of them was right side. About 10 patients (4.7%) of studied patients had bilateral hernia. In this study, patients were classified into two groups based on receiving antibiotics or not receiving. First group that received prophylactic antibiotic case group (100 patients) and 2nd group that did not received prophylactic antibiotic (112 patients).

Sex distribution of patients in studied group: In case group, 90% of patients were male and 10% were female

Table 1: Frequency of gender of the patients

Sex	Numbers	Percent
Male	194	91.5
Female	18	8.5
Total	212	100.0

Table 2: Frequency of different types of hernia diagnosed in patients

Types of hernia	Numbers	Percent
Incarcerated	5	2.4
Femoral	5	2.4
Simple inguinal	202	95.3
Total	212	100.0

Table 3: The frequency of different underlying diseases

Diseases	Numbers	Percent
Diabetes	11	5.2
HTN	15	7.1
IHD	14	6.6

Table 4: Evaluation of Hernia type found in the studied groups

AB prophylaxis	Incarcerated	Simple inguinal	Femoral	Total
Yes	5	92.0	3.0	100
Percent	5	92.0	3.0	100
No	0	110.0	2.0	100
Percent	0	98.2	11.8	100

Table 5: The history of DM, HTN and IHD found in the studied groups

Medical history	AB prescription		p-value
	Yes (%)	No (%)	
DM	5	5.4	0.90
HTN	8	6.3	0.62
IHD	9	4.5	0.81

and also men constitute majority of patients in control group (92.4%). Statistically, there was no significant difference in sex frequency between two groups and two groups were similar in sex distribution of patients.

Evaluation of types of hernia in studied group: In this study, it is obvious that statistically, there was no significant difference reported between two groups about type of hernia. In AB+ group 92% of patients had simple inguinal hernia and in AB- group 98.2% of patients had simple inguinal hernia.

About femoral hernia, its prevalence in AB+ group is 3% and in AB- group was 1.8% (Table 4). In AB+ group 5% had DM 8% had HTN and 9% had a history of IHD and in AB- group 5.4% had DM 6.3% had HTN 4.5% had IHD history (Table 5).

Evaluation of frequency of unilateral or bilateral types of hernia in studied population: In AB+ group, 57% of patients had right sided hernia and 40% of patients had left sided hernia whereas in AB- group 50% of patients had right sided hernia and 43.8% of patients had left sided hernia that there was no significant difference between two groups about frequency of unilateral or bilateral types of hernia.

Evaluation of post operative infection prevalence in two studied group: In this study, it is obvious that post operative infection is less in AB+ group. In AB+ group prevalence of post operative infection was 2% and in AB- groups it was 2.7%. But this difference was not statistically significant (Fisher's exact test) (p = 0.4). Also in this study, we assess age, sex, type of hernia in patients with infection and without infection that is as follows:

Table 6: Evaluation of mean age of patients with and without infection

Infection	Mean	SD	SEM
Yes	50.0000	6.00000	2.68328
No	51.1449	11.79881	0.82007

Evaluation of mean age of patients with infection and those without infection: In present study, mean age of patients with infection was 50±6 years and mean age of patients without post operative infection was 51.14±11 years (p = 0.8, Table 6).

Evaluation of underlying disease: None of 5 patients who suffered from post operative infection had significant risk factor such as DM. A study with different design and may be more cases is necessary to evaluate the role of these risk factors.

Evaluation of frequency of type of hernia in patients with infection and without infection: In patients with infection, 80% of patients had simple inguinal hernia 0% had femoral hernia and 20% had incarcerated hernia. In patients without infection, 95.7% of patients had simple inguinal hernia, 1.9% of patients had femoral hernia and 2.4% of them had incarcerated hernia. Statistically, there was no significant difference between type of hernia and post operative infection (p = 0.21).

DISCUSSION

In brief aim of present study was evaluation of prophylactic antibiotic effect on post operative infection in patients undergone inguinal hernioraphy surgery with prolene mesh. It is obvious in the study that prevalence of infection in groups received prophylactic antibiotic was 2% and in control group was 2.7% that there was no significant statistical difference between two groups. Similar studies performed about this issue also approve a foresaid results (Shankar *et al.*, 2010). In 2003, a Cochrane meta-analysis, 86 concluded that antibiotic prophylaxis for elective inguinal herniarepair cannot be firmly recommended or discarded and further studies are needed, particularly on the use of mesh (Terzi, 2006). For example in a study performed by Jain SK on 120 patients in year 2008, it is obvious that prophylactic antibiotic use had no effect on reducing post operative infection (Jain *et al.*, 2008) or in a study performed by Tzavoras G in year 2007 on 396 patients undergone inguinal hernioraphy surgery with mesh, there was no significant difference in prevalence of infection between group receiving antibiotic and control group (Tzavoras *et al.*, 2007). As it was shown, prophylactic antibiotic use reduces risk of post operative infection in hernioraphy surgery with mesh but this decrease is not statistically

significant. Its cause might be pathogenesis of post operative infection and also presence of a foreign body in patients. Possible mechanism mentioned for this problem is decrease blood supply at operated region due to presence of foreign body and also decreased function of neutrophils. Also in studies risk factors for wound infection after inguinal hernioraphy with mesh were mentioned:

- Use of meshes >10 cm
- Diabetes mellitus, overweight, immunosuppressive conditions
- Use of multi filamentous mesh versus of propylene type that we should reduce these risk factors as possible to reduce post operative infection after hernioraphy infection with mesh (Pessaux *et al.*, 2006)

In some studies, prophylactic antibiotic effect causes more reduction in post operative infection after hernioraphy surgery with mesh compare to the study for example in meta analysis study reported by Sanabria *et al.* (2007), it is obvious that prophylactic antibiotic use cause 50% reduction in post operative hernioraphy surgery with mesh that is higher compare to the study.

Prevalence of post operative infection in present study is 2% in those receiving prophylactic antibiotic and 2.7% in AB- group. Similar studies performed in this issue reported statistics similar to our statistics; for example in a meta analysis study performed by Sanabria *et al.* (2007) on 2507 patients undergone hernioraphy surgery with mesh, prevalence of infection was 1.38% in patients receiving prophylactic antibiotic and 2.8% in control group or in a meta analysis done by Sanchez-Manuel and Seco-Gil (2007), prevalence of infection in patients receiving antibiotic was 2.9% and in control group was 3.9%.

What observed in all studies performed in this issue is reduction of post operative infection prevalence with prophylactic antibiotics that this reduce in prevalence was significant in some studies and not significant in others but it is important to know that prophylactic antibiotic use causes reduction in prevalence of infection. And this reduce in prevalence of infection is correlates with reduce of complications in operated patients such as fistula formation, post operation adhesion and that with reduce of this complications further surgeries and recurrent admission and so many medical cost will be reduced for these patients.

Relation of post operative infection with age, sex and type of hernia. In this study, it is obvious that there is no significant difference between ages of patients with infection $p > 0.05$.

Although, mean age of patients with infection was a little higher than patients without infection that its cause may be reducing immunity system function with increasing age that susceptible patient to infection.

In this study due to low number of positive cases for infection, it has not high specificity and sensitivity and these instances should be further evaluated with more complete studies. For relation of patients sex with frequency of cases who had infection, although prevalence of infection was higher in male than female patients but statistically, this difference was not significant and may be due to less sex ratio prevalence. For assessing relation of infection with risk factors of diabetes mellitus, blood pressure and ischemic heart disease in present study, more patients with these risk factors seems to be necessary.

In studies performed in this issue, diabetes mellitus is mentioned as a risk factor predisposing the patient to infection and also it is mentioned in studies that prophylactic antibiotic has significant effect in reducing wound infection in patients with risk factors. But this study shows against that of others that it may be result due to low number of positive samples for wound infection that limits comparison and should be completed with further studies. For patients with wound infection, one case in a month after surgery and one case in 2 weeks after surgery developed complications and for control group 3 cases of infection were seen, one case after 3 weeks, one case after 1 month and a case in 1.5 months after surgery developed such complication that for management, these patients were admitted and received broad-spectrum antibiotics (clindamycin-gentamycin).

Site of infection was drained with clamp and wound was left open and daily dressing was continued until leukocytosis and fever sub-sided as described in literature (Hernandez-Granados *et al.*, 2000; Brunicardi *et al.*, 2009). Then oral cefixim was prescribed for patients for 7-10 days and mesh was not removed in any cases with infection and re-operation was not necessitated.

CONCLUSION

It was shown in this study that prophylactic antibiotic treatment reduces infection from 2.7-2%. This reduce in prevalence of infection accompanies with reduce in other complications such as adhesions and fistula formation. In different studies, the incidence rate was similar and there is no absolute consensus about routine administration of preop prophylactic antibiotic. So, prophylactic antibiotic treatment for patients who are

candidate for hernioraphy surgery with mesh does not significantly reduce the infection prevalence. A similar study is suggested with higher number of samples that it could evaluate risk factors predisposing to post operative infection. So according to high cost of routine antibiotic prescription and possible complications such as resistance and side effects and reactions of these drugs it is justified to limit the antibiotic to treatment purpose and those who have risk factors for severe infections.

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