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"ROLE OF ANTIBIOTIC PROPHYLAXIS IN OPEN MESH REPAIR OF PRIMARY INGUINAL HERNIA – A RANDOMISED PROSPECTIVE STUDY"

General Surgery

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ABSTRACT

Background: Inguinal hernia is the most common form of groin hernia and open inguinal hernioplasty is considered as the gold standard treatment for the same. The mesh used in this procedure if infected is difficult to manage and in most cases needs to be removed which can lead to recurrence. **Aim:** The aim of this study was to determine the role of antibiotic prophylaxis in tension free open mesh repair of primary inguinal hernia. **Study Design**: It was a prospective, double blind, randomized, Placebo controlled study. **Material And Methods:** The study was conducted in the department of general surgery, Ispat General Hospital, Rourkela between August 2016 to February 2018. A total of 114 patients admitted for elective open mesh repair of primary inguinal hernia were included in this study. The patients were divided in to 2 groups, named as antibiotic group (receiving single dose of antibiotic during induction of anaesthesia) and control group (receiving similar amount of normal saline as placebo) randomly by using standard randomisation method. Postoperative surgical site infection (SSI) was noted during the hospital stay and after using a standard study Performa. **Results:** The incidence of SSI at the time of discharge, 7 days, 2 week and 4 week in the antibiotic group was 0, 1(1.8%), 2(3.5%) and 1(1.8%) respectively. In the placebo group the incidence for the same was 0, 1(1.8%), 2(3.5%) and 2(3.5%) respectively. The overall SSI incidence was 4(7.1%) and 5(8.8%) in the antibiotic group and placebo group respectively. All the SSI were found to be superficial. **Conclusion:** In our study even though the rate of SSI was high in both antibiotic and placebo group the difference was not statistically significant. This indicates that routine use of prophylactic antibiotics does not decrease the incidence of SSI in Lichtenstein tension free open mesh hernioplasty.

KEYWORDS

Open hernioplasty, Prophylactic antibiotic, Surgical site infection.

INTRODUCTION:

Hernias are one of the most common anatomical derangements in men and women. Out of all hernias 75 % occur in the groin, inguinal hernia being the most common form.[1] Surgical management is the treatment of choice for inguinal hernia. Lichtenstein's tension free mesh repair is considered as the "gold standard" now a days.[2-4]

Inguinal hernia repair is associated with postoperative complications like seroma formation, hematoma, neuralgia, urinary retention and surgical site infection (SSI). SSI is one of the common complication of hernia surgery, Postoperative wound infection occur in 0%-9% of inguinal hernia repairs.[6] The use of antibiotic prophylaxis to avoid surgical infection is recommended in 'clean-contaminated' procedures and 'clean procedures' where foreign material is used.[7] If mesh is used for inguinal hernia repair, there is a theoretical increase in risk of infection, so prophylactic antibiotics becomes a necessity.[8]

In developing country like India where government institutions have limited funds, irrational use of antibiotics in a common procedure like hernia mesh repair will influence the cost effectiveness and withholding it not only can reduce the overall monetary burden but also the side effects of the medication and possible development of bacterial resistance or super infections,.[9-11]

Although most double-blind randomised controlled trials (RCTs) do not confirm the reduction of SSI with use of antibiotic prophylaxis,[5,11-14] there are some studies in favour of using antibiotic prophylaxis.[21-24] Surveys conducted at hospitals in London and the South East of England shows that majority of surgeons are in favour of using antibiotic prophylaxis when performing hernia repair procedures with a mesh (84%). Their opinion is based on their own beliefs and experience.[25]

The European Hernia Society (EHS) does not recommend routine antibiotic prophylaxis for elective inguinal hernia repair procedures using a mesh in low-risk patients but recommends considering prophylaxis where there are patient-related risks (recurrence, old age, immunosuppression) or procedure- related risks (long duration of surgery, use of a drain post operatively).

The contradictory results from various reported clinical trials investigating the effectiveness of antibiotic prophylaxis and the lack of proper guidelines in India about its use were the reason behind our decision to evaluate the effectiveness of prophylactic antibiotic in tension free open mesh repair of primary inguinal hernia.

AIMS AND OBJECTIVES:

AIM:

To study the role of antibiotic prophylaxis in tension free open mesh repair of primary inguinal hernia.

OBJECTIVE:

To study postoperative surgical site infection after tension free open mesh repair of primary inguinal hernia.

MATERIALS AND METHODS:

The study was conducted in the department of general surgery, Ispat General Hospital, Rourkela between August 2016 to February 2018. It was a prospective, double blind, randomized, Placebo controlled study. All patients above 18 years admitted to Ispat General Hospital, Rourkela for elective open mesh repair of primary inguinal hernia were included in this study. Patients with irreducible, strangulated, femoral hernia or evidence of systemic disease (e.g. renal or liver impairment, diabetes), history of antibiotic allergy, Immuno-compromised patients or patients taking steroid medications, local skin infection or disease at the site of incision, using or had used antibiotics less than a week before surgery were excluded from the study.

Keeping the confidence interval 5% and confidence level of 95%, by applying sample size calculator software from http://www.raosoft.com/samplesize.html, the sample size for my study came as 114. The patients were divided in to 2 groups, named as antibiotic group (receiving single dose of antibiotic during induction of anaesthesia) and control group (receiving similar amount of normal saline as placebo) randomly by using standard randomisation method. Clearance required from research and ethical committee was obtained before starting the study. All patients planned for inguinal hernia repair were admitted one day before surgery. Informed consent was taken from all patients. After enrolling the patients, appropriate pre operative investigations were done. All surgeries were performed by the same surgeon who has performed more than 500 cases as per standard steps of Lichtenstein's tension free open mesh repair of inguinal hernia. No

postoperative antibiotics were used. Surgical site was examined after 48 hours of surgery and patients were discharged to revisit after one week for wound assessment and suture removal. The patients were asked for follow up after two week and four week of discharge by a surgeon who did not know whether the patient was belonging to control group or antibiotic group.

Wound infections were classified as per the CDC(Centre for Disease Control) criteria as superficial SSI and deep SSI. Southampton wound grading system was used to asses post-operative wound.[26]

Statistical Analysis:
Statistical analysis was done using SPSS 18.0 and R environment ver.3.2.2. P value: <0.05 was considered significant.

RESULTS:

Table 1: Overall infection distribution in two groups of patients

Infection (Overall)	Antibiotic Group (n=57)	Placebo Group (n=57)	Total (n=114)	p Value
No	53 (92.9%)	52 (91.2%)	105 (92.1%)	0.728
Yes	4 (7.1%)	5 (8.8%)	9 (7.9%)	

The incidence of SSI was analyzed in both the groups and there was no statistically significant difference in antibiotic and placebo group (p=0.728).

Table 2: Infection distribution in two groups of patients studied at discharge

Infection (At Discharge)	Antibiotic Group (n=57)	Placebo Group (n=57)	Total (n=114)	p Value
No	57 (100%)	57 (100%)	114 (100%)	1.000
Yes	0 (0%)	0 (0%)	0 (0%)	

No patient in both antibiotic as well as placebo group showed features of SSI at the time of discharge.

Table 3: Infection distribution in two groups of patients at suture removal

Infection (Suture removal)	Antibiotic Group (n=57)	Placebo Group (n=57)	Total (n=114)	p Value
No	56 (98.2%)	56 (98.2%)	112 (98.2%)	1.000
Yes	1 (1.8%)	1(1.8%)	2 (1.8%)	

One patient from each antibiotic and placebo group showed features of SSI at the time of suture removal on 7th post operative day.

Table 4: Infection distribution in two groups of patients at 2 week

Infection (At 2 week)	Antibiotic Group (n=57)	Placebo Group (n=57)	Total (n=114)	p Value
No	55 (96.5%)	55 (96.5%)	110 (96.5%)	1.000
Yes	2 (3.5%)	2 (3.5%)	4 (3.5%)	

When patients were reexamined during follow up after 2 weeks after surgery, 2 patients from each group showed features of SSI.

Table 5: Infection distribution in two groups of patients at 4 week

Infection (At 4 week)	Antibiotic Group (n=57)	Placebo Group (n=57)	Total (n=114)	p Value
No	56 (98.2%)	55 (96.5%)	111 (97.4%)	1.000
Yes	1 (1.8%)	2 (3.5%)	3 (2.6%)	

During follow up of the patients at 4 week after surgery, 3 patients had SSI out of which 1 patient was from antibiotic group while 2 patients were from placebo group. The diffrence between two groups is not statistically significant (p=1.000).

Table 6: Southampton grade distribution in two groups of patients studied

Southampton grade	Antibiotic group	Placebo group	Total
0	53 (93%)	52 (91.2%)	105 (92.1%)
1a	0 (0%)	0 (0%)	0 (0%)
1b	0 (0%)	0 (0%)	0 (0%)
1c	0 (0%)	0 (0%)	0 (0%)
2a	0 (0%)	0 (0%)	0 (0%)
2b	0 (0%)	1 (1.8%)	1 (0.9%)
2c	0 (0%)	1 (1.8%)	1 (0.9%)
2d	1 (1.8%)	0 (0%)	1 (0.9%)
3a	2 (3.5%)	1 (1.8%)	3 (2.6%)
3b	1 (1.8%)	2 (3.5%)	3 (2.6%)
3c	0 (0%)	0 (0%)	0 (0%)
3d	0 (0%)	0 (0%)	0 (0%)
4a	0 (0%)	0 (0%)	0 (0%)
4b	0 (0%)	0 (0%)	0 (0%)
5	0 (0%)	0 (0%)	0 (0%)
Total	57 (100%)	57 (100%)	114 (100%)

Table 7: Type of SSI

Type of SSI	Antibiotic group	Placebo group	Total
Nil	53 (93%)	52 (91.2%)	105 (92.1%)
Superficial	4 (7%)	5 (8.8%)	9 (7.9%)
Deep	0	0	0

p Value: 1.000

All SSI occurred in antibiotic as well as placebo group in this study were found to be superficial SSI, no deep SSI was found in either of the group.

DISCUSSION:

Wound infection is one of the most commonly occurring surgical complications. Infection of a wound may result from a number of factors both intrinsic and extrinsic to patient. Although many of intrinsic factors can not be modified, the external ones can certainly be influenced. In particular those are related to aseptic conditions, surgical technique and perioperative care. However even under the most scrupulous aseptic conditions and with a careful technique, post-operative wound infection still present a very serious problem.

The overall SSI incidence was found to be 7.9% in our study population. This incidence is slightly higher than the other studies and was near higher range of that reported in literature, which may be due to small sample size and type 1 error. However a few other studies done by authors from South India like Vinoth et al[18] and Shankar et al[15] shows an incidence of 8.33% and 8.7% respectively**.** There is no reliable data regarding the wound infection rates in the hospitals in the developing world. The present study may play a role in enlightening us the reality about SSI in developing countries. The incidence of surgical site infection following mesh repair of inguinal hernia has been ranging from 0% to 9%.[6] Such a wide range on SSI rates is due to the fact that studies differed in various aspects like difference in study design (retrospective, non-randomized versus prospective, randomized), surveillance methods (surgical team versus independent observer), definition of wound infection (no definition versus CDC definitions), duration of follow-up and type of operation (mesh repair versus non-mesh repair).[27]

Antibiotic Used:
In this study Broad spectrum antibiotic intravenous 1.2 g of amoxicillin and clavulanic acid combination in 20 ml of sterile saline was used and given by anaesthetist at the time of administration of anaesthesia for patients in antibiotic group. Boonchan et al in their meta-analysis of antibiotic prophylaxis for prevention of surgical-site infection after groin hernia surgery concluded that ß-Lactam/ß-lactamase inhibitors followed by first-generation cephalosporins ranked as the most effective SSI prophylaxis for adult patients undergoing groin hernia repair. [32] In a cross-sectional survey in London and the south-east of England on antibiotic prophylaxis in adult elective inguinal hernia repair, Aiken et al found a dose of 1.2 g of co-amoxiclav was the most popular antibiotic choice for both hospital guidelines and surgeon's usage.[25] Similar antibiotic was used as prophylaxis in the studies done by Ullah et al,[24] Goyal et al,[16] Othman et al,[11] Jain et al[5] and Tzovaras et al[14].

Wound Assessment:
Southampton wound assessment scale was used to assess post-operative wounds which enable to grade the wound according to specific criteria and therefore provide a more objective assessment of the wound. Similar assessment scale was used in studies done by Sethi et al[20] and Alagarsamy et al.[19]

Studies Favouring Use Of Prophylactic Antibiotic:
The incidence of SSI was 9% in control group and 0.7% in the antibiotic group in the study done by Yerdel et al which showed a significant difference in SSI between the antibiotic and control group.[21] A study done by Usang et al reported SSI rate of 4.8% and 0% in the control group and antibiotic group respectively and had similar

results.[23] Celdran et al reported significant difference in SSI rates of placebo group (8%) and antibiotic group (0%).[22]

Sanabria et al. (2007) in their meta-analysis on the prophylactic use of antibiotic in mesh hernia repair concluded that antibiotic prophylaxis decreased the rate of surgical site infection almost by 50%.[29] Jhang et al in their a meta-analysis of RCTs studying the use of antibiotic prophylaxis to prevent postoperative complications in patients undergoing tension-free hernioplasty concluded that antibiotic prophylaxis use in patients undergoing tension-free hernioplasty decreases the rate of incision infection by 55%.[30] In a literature search done by Yuan et al in databases of MEDLINE, EMBASE, and Cochrane Central Register of Controlled Trials, where concluded that antibiotics did reduce the rate of SSI after mesh inguinal hernia repair.[31]

Studies Against Use Of Prophylactic Antibiotics:

Aufenacker et al showed that the incidence of SSI was 1.8% in the control group and 1.6 % in the antibiotic group and concluded that prophylactic antibiotics did not prevent SSI in open mesh repair of inguinal hernias.[12] Perez et al in their study did not find any benefit with antibiotic prophylaxis.[13] A similar conclusion was drawn by Tzovaras et al[14], Jain et al[5], Shankar et al[15], Ergul et al[17], Othman et al[11] and Goyal et al[16].

In a Cochrane review conducted by Sanchez- Manuel and Seco-Gil 2006, including 8 RCTs based on the results of 2,907 patients concluded as: "In conclusion, the results of this metaanalysis show that antibiotic prophylaxis may be useful to prevent wound infection in open elective hernia repair. However, the data are sufficiently strong neither to recommend its universal administration nor to recommend against its use when high rates of wound infections are observed."[28]

Time of diagnosis of SSI:

No patient in our study developed SSI before discharge; all were diagnosed during follow up, most often during their first scheduled visit after suture removal in the second postoperative week. In the studies done by Perez et al,[13] Celdran et al,[22] Usang et al,[23] Ergul et al,[17] Sethi et al[20] all the infections were diagnosed after discharge. So our study is in concurrence with literature. Yerdel at al found 5 of 13 of infections during hospital stay with in-hospital rate of 30.7%. However the infection rate is very high in his study.[21]

Superficial Vs Deep:

Vast majority of SSI occurring after hernia repair are superficial SSI. All SSI occurred in our study were superficial while no SSI was deep. All the SSI reported in the studies done by Ergul et al,[17] Jain et al,[5] Celdran et al,[22] Tzovaras et al,[14] Vinoth et al,[18] Alagarsamy et al[19] were superficial infections. So our study is in concurrence with literature.

Mesh Removal:

The incidence of mesh infection reported in literature varies from 0.35% to 1%. None patient had mesh removal due to SSI in our study similar to the studies done by Alagarsamy et al,[19] Tzovaras et al,[14] Ergul et al[17] and Goyal et al[16]. Aufenacker et al reported an incidence 0.3% for deep SSI in their study within a follow up period of 3 months. No patients in their study required mesh removal similar to our study.[12] Perez et al reported deep SSI rate of 0.6% in both group. 1 patient was detected to have deep infection and subsequent mesh removal was required in both of them.[13] Yerdel et al reported 1 patient (0.7%) with deep SSI in antibiotic group and 3(2.2%) patients in placebo group. The difference was not statistically significant (p=0.367). Three patients of placebo group required mesh removal.[21] The incidence of deep SSI by Shankar et al was 0.6% with one patient in each group having deep SSI. One patient required mesh removal in their study.[15] Othman et al also noticed one patient in each group with deep SSI giving deep SSI rate of 2%. No patient required mesh removal.[11]

Risk Of Recurrence:

In case of SSI (especially deep SSI), the risk of recurrence should also be evaluated. However the results of Celdran et al suggested that occurrence of infection does not increase rate of recurrence.[22] Even when the removal of mesh has been necessary to resolve infection, the fibrotic reaction around posterior wall of the inguinal canal may prevent the recurrence. No recurrence was noticed in our study in infected patients however follow up time of our patients was very small.

CONCLUSION:

The present study is a comparative double blind study between antibiotic and placebo group for SSI prevention in open hernia surgery. The study was conducted with an intention to observe the effect of prophylactic antibiotic in prevention of SSI after Lichtenstein's tension free open mesh hernia repair. The patients were followed up in the postoperative period at intervals of one week, two week and four week. Patients were assessed for presence of SSI defined by CDC criteria.

In our study we found that SSI is not an uncommon complication following Lichtenstein's tension free open mesh hernioplasty. Rate of SSI was high both in the antibiotic and placebo group compared to the incidence of SSI reported worldwide though they were comparable to the SSI rates found in the studies done in India. In our study even though the rate of SSI was high in both antibiotic and placebo group the difference was not statistically significant. This indicates that routine use of prophylactic antibiotics does not decrease the incidence of SSI in Lichtenstein tension free open mesh hernioplasty.

There are few limitations to our study including a small sample size, lack of data about the patient-related factors that may affect the risk of development of wound infectionlike nutritional status, obesity, and smoking status of patients, relatively short duration of the study and the requirement for a longer follow up period.

Recommendations:

On the basis of our study, we make following recommendations: Antibiotic prophylaxis should not be used routinely in cases of Lichtenstein tension free open mesh hernioplasty, however to further validate the study findings, we recommend a multi-centric study with larger sample size. Further studies should be done considering associated risk factors for SSI development and classifying patients preoperatively in high risk and low risk. Studies comparing economic burden of use of antibiotic prophylaxis versus treatment of SSI after Lichtenstein tension free open mesh hernioplasty can be done to evaluate its cost-effectiveness. We also recommend establishing a specific in-hospital hernia-repair centre with improved infection-control procedures to reduce rate of SSI.

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