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A Comparitative Study to Assess the Effectiveness of Prophylactic Systemic Antibiotics in Inguinal Hernioplasty

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ABSTRACT

INTRODUCTION: Though there is no controversy in the use of prophylactic antibiotics in clean contaminated, contaminated and dirty wounds, there is still some controversy surrounding use of prophylactic antibiotics in clean wounds like Lichtenstein mesh hernioplasty. Inadvertent use of antibiotics in these cases leads to unnecessary increase in cost to the patient as well as development of antibiotic resistance, as development of resistance to antibiotics by microorganisms have become a growing concern. Hence we conduct a case control study at Hitech Medical College And Hospital, Bhubaneswar from august 2019 to july2021 to assess if systemic antibiotic prophylaxis prevents wound infection in Lichtenstein inguinal hernioplasty

AIMS & OBJECTIVES: To determine the effectiveness of prophylactic antibiotics to prevent post-operative wound infection in mesh inguinal hernioplasty.

MATERIAL & METHODS: The study period was two years including follow-up, comprising of 100 cases randomized into two groups. First group received no antibiotics and the second group received 3rd generation cephalosporin prior to the surgery.

OBSERVATION &RESULTS: The study revealed 2 cases of infection in the case group and 1 in the control group. The difference was statistically insignificant (p= 0.3436).

CONCLUSION: From our study it can be concluded that regular use of antibiotic prophylaxis is not necessary in low risk patients undergoing hernioplasty.

I. INTRODUCTION

Hernia repair is one of the most commonly performed general surgical procedures worldwide.[1]Mesh repair is, in many countries, rapidly becoming the most popular technique for repair of inguinal hernia,[2-3] of the mesh repair techniques, the Lichtenstein hernia repair is most frequently used. The Lichtenstein technique is a tension free repair of the weakened inguinal floor using a polypropylene mesh.[4] since many randomized trails and meta-analysis have shown that mesh repair reduces the risk of hernia recurrence, the prosthetic repair is worldwide accepted as the gold standard in inguinal hernia repair.[5]

SSI (surgical site infection) is the most frequent complication in inguinal herniorrhaphy.[6] though there is no controversy in the use of prophylactic antibiotics in clean contaminated, contaminated and dirty wounds, there is still some controversy surrounding use of prophylactic antibiotics in clean wounds like Lichtenstein mesh hernioplasty.

The incidence of infection after inguinal hernia repair has been reported to vary from 0%-9%.[7] when a foreign body like polypropylene mesh is used, a deep infection should be prevented. On the contrary inadvertent use of antibiotics in these cases leads to unnecessary increase in cost to the patient as well as development of antibiotic resistance, as development of resistance to antibiotics by microorganisms have become a growing concern.

Hence we conduct a case control study at Hitech Medical College and Hospital, Bhubaneswar from august 2019 to july2021 to assess if systemic antibiotic prophylaxis prevents wound infection in Lichtenstein inguinal hernioplasty.

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AIMS AND OBJECTIVES

To determine the effectiveness of prophylactic antibiotics to prevent post-operative wound infection in mesh inguinal hernioplasty.

II. MATERIALS AND METHODS

SOURCE OF DATA: All patients of inguinal hernia presenting to Department of General Surgery of Hitech Medical College and Hospital, Bhubaneswar requiring mesh inguinal hernioplasty.

DURATION OF STUDY: August 2019 to july 2021

SAMPLE SIZE: 100 cases.

STUDY DESIGN: Prospective study.

STUDY PLACE: Hitech Medical College and Hospital, Bhubaneswar

INCLUSION CRITERIA:

- inguinal hernia requiring hernioplasty
- age group 18-70 years
- males

EXCLUSION CRITERIA:

- age <18 or >70
- females
- irreducible hernia
- obstructed hernia
- strangulated hernia
- recurrent hernia
- femoral hernia
- need for antibiotics for a different reason(UTI, respiratory infection, BPH)
- Immunosuppressive disease (diabetes mellitus, malignancy, HIV)
- Immunosuppressive medication (glucocorticoid therapy).

III. METHOD OF COLLECTION OF DATA:

These patients presented with either swelling in the groin/pain in the groin area of varying duration. Patients with these symptoms were admitted to surgical ward with the diagnosis of direct or indirect uncomplicated inguinal hernia. A detailed relevant clinical history was taken and physical examination including general, systemic and local examination was done as the Proforma approved by the guide.

Investigations were carried out to assess the fitness of patients for surgery and to exclude other co-morbid conditions.

These include:

(1) Blood: Hb Percentage/Total and Differential White Cell Count/Bleeding Time and Clotting Time/Fasting /Random Blood sugar/Blood Urea and Serum Creatinine.
(2) Urine: Albumin/ Sugar/Microscopy
(3) Electrocardiogram
(4) X-ray of the chest was done to rule out any lung pathology.
(5) Ultrasound of the abdomen and pelvis was done to rule out benign enlargement of the prostate.
(6) Cardiac evaluation such as 2D ECHO, Pulmonary function test (PFT) evaluation of BPH in patients with associated Co-morbidities.

Once the patients were deemed fit from the respective specialists and met inclusion criteria, patients were divided into two groups of 50 each randomly. Surgical procedure will be explained and informed consent will be taken. 1st group will receive antibiotic (ceftriaxone + sulbactum) at the time of induction, antibiotic was chosen after considering the most common pathogen and its antimicrobial resistance from surgical site infections at Hitech hospital. 2nd group will receive no antibiotic. Parts preparation was done on the day of surgery using electronic trimmer. Patients were advised bathing on the morning of surgery using carbolic acid soap. All surgeries were posted as the first case of the day. Patients skin was painted with povidone iodine solution extending well beyond the margins of surgical site and waited for the solution to dry before incision. Draping was done using sterilized standard double thickness linen cloth. Spinal anaesthesia was preferred in all cases.

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IV. OPERATIVE TECHNIQUE:

A classical incision was used for hernia repair, i.e., above and parallel to the medial 3/5th of the inguinal ligament and then the fascia of the external oblique muscle was incised to open the inguinal canal. Using blunt dissection superior and inferior flaps of the external oblique aponeurosis elevated. Cord is mobilised.

For **Indirect hernia** repair, a high dissection of the neck of the hernial sac is performed.
For **direct hernia** repair, floor of the inguinal canal may be imbricated with stitches, if needed.

A 6 x 3 inch polypropylene mesh is tailored to fit the patient's inguinal floor and placed, after soaking it in diluted gentamycin solution (80 mg in 250 ml NS), the first stitch is taken over the connective tissue at pubic tubercle with polypropylene 2-0, the mesh is fixed with polypropylene 2-0 suture material, inferiorly to the inguinal ligament by intermittent stitches upto deep ring laterally. A slit is made at the lateral end of the mesh, after positioning the cord between the two tails of the mesh the upper edge of the mesh is sutured to the internal oblique aponeurosis or muscle using few interrupted sutures. The lower edges of the two tails are fixed to the inguinal ligament in the end.

After achieving haemostasis, 14 Fr drain is placed in select patients were extensive dissection, excessive oozing was noted. The external oblique aponeurosis was closed with continuous interlocking stitches using Polyglyconate 2-0.

After removing all the dead tissue from subcutaneous plane, sub cutaneous tissue was approximated using Polyglyconate 3-0 in obese patients. Skin was approximated using Nylon 3-0.

POST OPERATIVE: Total duration of surgery noted, all patients were managed in post-operative ward. Adequate analgesic was administered to all patients. Drain was removed at the earliest after assessing drain output.

FOLLOW UP: patients wound was inspected for infections in terms of increasing pain at operated site, erythema, tenderness, edema, abscess, pus on post op day 2, before discharge, at first follow up and 1 month after surgery.

Wounds that showed signs of infection were given a trial of broad spectrum antibiotics, surgical drainage of the wound done at the earliest indication and specific antibiotics started based on C/S report.

V. OBSERVATIONS AND RESULTS

The present study was carried out in the department of General Surgery, Hitech Medical College and Hospital, Bhubaneswar 100 patients who met inclusion criteria were selected in the study after obtaining written consent. Patients were divided into two groups. 50 patients in case group received no antibiotics, 50 patients in control group received ceftriaxone+ sulbactum antibiotic at the time of induction. Lichtenstein mesh hernioplasty was performed as per standard protocol in all patients observing strict aseptic precautions. The patients were followed up in post-operative period for symptoms and signs of surgical site infection on post op day2, at discharge, first follow up and 1 month after surgery.
The following observations were made during the course of the study:

1. AGE DISTRIBUTION:

AGE	CASE	CONTROL
18-30	22	7
31-40	13	12
41-50	7	13
51-60	6	9
61-70	2	9
TOTAL	50	50

Table 2: Age Distribution

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Fig 15: Graph showing age distribution in cases and controls Of the 50 cases in case group majority were in the age group of 18- 40 years comprising nearly35 patients. In the control group majority of the cases were in the age group of 30-60 comprising 34 patients.

2. LATERALITY:

SIDE	CASE	CONTROL
RIGHT	29	30
LEFT	21	20
TOTAL	50	50

Table 3: Laterality

Fig 16: Graph showing laterality in cases and controls

Most of the patients presented with right sided hernia in both the groups accounting for nearly 60 % in both case and control group.

3. TYPE:

TYPE	CASE	CONTROL
DIRECT	20	21
INDIRECT	29	29
COMBINED	1	0
TOTAL	50	50

Table 4: Type of Hernia

Fig 17: Graph showing type of hernia

29 patients had indirect inguinal hernia in both groups comprising almost 60 % of the cases, the remainder 40% of the cases were direct inguinal hernias expect 1 case in case group were both direct and indirect component was seen.

4. DURATION OF SURGERY

GROUP	DURATION IN MINUTES
CASE	59.1
CONTROL	59.3

Table 5: Duration of Surgery

Fig 18: graph comparing duration of surgery

There was no difference noted in the mean duration of surgery between the two groups with a mean duration of

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59.1 mins in case group and 59.3 mins in control group.

5. POST OPERATIVE WOUND INFECTION

	SSI	DSI	TOTAL	PERCENTAGE
CASES	**1**	**1**	**2**	**4%**
CONTROLS	**1**	**0**	**1**	**2%**

Table 6: Post-Operative Wound Infection

Fig 19: Graph Showing Post-Operative Wound Infection

Of the 100 patients who underwent hernioplasty 50 patients received antibiotics and 50 did not receive any antibiotics. 3 cases of post-operative wound infection was noted, 2 in the case group and 1 in the control group. The difference was not statistically significant (p = 0.3536).

All the infected cases had indirect sac and the mean duration of surgery was 90 mins among the infected cases in comparision with 58.25 mins among the non-infected cases.

In the case group 1 superficial surgical site infection (SSSI) and 1 deep space infection (DSI) was noted.

In the control group single case of SSI was noted.

Details of the patients with infection are summarized in the following table:

	Group	Time of diagnosis	Type of infection	Culture sensitivity	Treatment	Outcome
1	case	Pod 5	SSI	Not done	antibiotic	No recurrence
2	case	Pod 2	DSI	Staph aureus	Antibiotics and drainage	Sinus formation with gradual healing over 3 months
3	control	Pod 2	SSI	Not done	antibiotics	No recurrence

Table 7: patient details of the infected cases

The patients with SSSI showed sufficient improvement with antibiotics alone, there was no need for incision and drainage (I&D), on follow up there was no recurrence or extension of the infection to deep space.

Patient with DSI developed purulent pus discharge from the wound on post op day (POD) 2, immediate drainage of the wound was done and pus sent of culture sensitivity. Patient was initially started on cephalosporins and later clarithromycin was added based on culture report. Discharge gradually reduced over time and the wound healed over the period. There was no need for mesh removal.

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Fig 20: superficial surgical site infection

Fig 21: deep surgical site infection

VI. DISCUSSION

Inguinal hernia is the most common surgical abdominal entity in adults. Lichtenstein repair since its introduction in 1989 has become the gold standard for treatment of inguinal hernias mainly due to the reduction in recurrences noted. Owing to its high incidence in the population a significant number of people undergo hernioplasty every year. Among the several complications like inguinodynia, haematoma, seroma, ischemic orchitis, testicular atrophy etc. associated with the surgery, wound infection seems to be the most common of them.[8]

Incidence of wound infection post hernioplasty varies from 1- 14 % in several studies.it is clear that antibiotic prophylaxis is necessary for most clean contaminated surgical procedures to prevent infectious complications. For surgeries requiring prosthesis like joint arthroplasty, cataract surgery, cardiac or vascular implant the use of antibiotic prophylaxis is justified.[9] However in hernioplasty, low rates of

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infection and straight forward treatment in cases of infection may preclude need for prophylaxis. However, Infection in a hernia wound has been reported to be associated with a fourfold increase in the recurrence rate and therefore may cause serious sequelae.[10]

Several risk factors for surgical site infection have been identified which includes both intrinsic factors like diabetes, obesity, chronic smoking, steroid use, and extrinsic factors like scrubbing technique, pre op skin preparation, ventilation of the OT room, duration of surgery and use of mesh. since the intrinsic factors cannot be modified, the incidence of surgical site infection can be reduced by influencing the extrinsic factors. With mesh repair, wound infection rate is higher with absorbable mesh (10%) than the permanent mesh.[11]

The overall incidence of surgical site infection in our study was found to be at 3% with 4% incidence in case group and 2% incidence in control group in comparision to other studies Yerdel et al [12] noted an overall incidence of 4.64% with 0.7% incidence in antibiotic group and 8.6% incidence in placebo group. Amit et al [13] noted an overall incidence of 2% with 1% incidence in antibiotic group and 3% incidence in placebo group. Lovellen et al [14] noted an overall incidence of 12.72% with 10.34% in the antibiotic group and 15.38% in the placebo arm. Raja Najam-ul-Haq et al [15] noted an incidence of 3% in his study which included only cases where no antibiotic was given.

Several other complications noted with mesh insertion noted in other studies include seroma formation, [16] chronic pain. In a randomized double blind study conducted by Yerdel [17] one case of ischemic orchitis was found in the antibiotic group, which was the only infected case in that group. During follow-up, this patient developed testicular atrophy. However, its relation to infection could not be established.

STUDY	PLACEBO (%)	ANTIBIOTIC (%)	OVERALL (%)	P VALUE
Yerdel et al	8.6	0.7	4.64	0.00153
Sanabria et al	2.89	1.38	2.15	<0.05
Jian-Fang Li	4.2	1.7	2.72	0.04
Amit et al	3	1	2	0.33
Lovellen et al	15.38	10.34	15.38	> 0.05
Aufenacker et al	1.8	1.6	1.7	0.82
OUR STUDY	4	2	3	0.3536

Table 8: Comparision with Other Studies

Yerdel et al [18] concluded that there was a significant (10-fold) decrease in overall wound infections when single-dose, intravenous antibiotic was used during Lichtenstein hernia repair. Deep infections and wound infection-related readmissions were also reduced by the use of antibiotics. Sanabria et al [19] concluded Antibiotic prophylaxis use in patients submitted to mesh inguinal hernioplasty decreased the rate of surgical site infection by almost 50%.

Similarly Jian-Fang Li [20] following a meta-analysis proposed that antibiotic prophylaxis use in patients undergoing tension-free hernioplasty decreases the rate of incision infection by 55%. Celdran et al suspended for ethical reasons when differences reached values close to statistical significance and concluded antibiotics reduce incidence of wound infection following hernioplasty.

Though the above studies favour for antibiotics during hernioplasty several randomized prospective and meta-analysis differ in their observations and conclusions. Amit et al, [51] Lovellen et al,[21] Raja Najam-ul-Haq et al [22] concluded that there was no evidence of increased infection risk with mesh implant, and even there is no need to use prophylactic antibiotics provided complete aseptic measures are taken. The drawback with these randomized trials has been their small sample size. Aufenacker et al with adequate sample size of more than 500 cases in both case and control group found no difference between the antibiotic prophylaxis or placebo group, and concluded antibiotic prophylaxis is not indicated in low-risk patients. Aiken et al [23] could not come to any conclusion following their meta-analysis.

A major problem occurs when the mesh is infected. Several studies reported late-onset of mesh infection or chronic groin sepsis[24] eventually leading to complete mesh removal. In our study, 1 deep infection was found, Staphylococcus aureus was cultured, and there was no need for mesh removal.

VII. SUMMARY

This study was conducted at Hitech

Medical College and Hospital, Bhubaneswar over a period of 2 years including follow up between august 2019 to july 2021.

100 patients who met inclusion criteria during the period of study were divided into 2 groups. One group was administered antibiotics and the other did not.

All patients underwent Lichtenstein hernioplasty with polypropylene mesh under strict aseptic precautions.

Occurrence of Post-operative wound infection was noted in both groups regularly.

Statistical analysis was done accordingly and a p-value of < 0.05 was considered significant.

On analysis there was no statistical significant difference in the incidence of wound infection in both groups.

All infected cases had indirect sac with a prolonged duration of surgery.

VIII. CONCLUSION

Our study shows that there is no clear benefit in administering prophylactic systemic antibiotics prior to hernioplasty.

The incidence of surgical site infection in our study was found to be similar in comparision with the incidence found in other studies.

Thus, it can be concluded from our study that regular use of antibiotic prophylaxis is not necessary in low risk patients undergoing hernioplasty.

However in cases with prolonged duration of surgery, and cases where dissection is more as in congenital sacs antibiotics have to be given post operatively.

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