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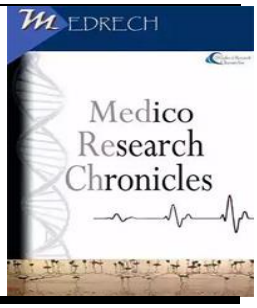

Role of prophylactic antibiotic of single dose versus multiple doses in uncomplicated groin Hernia Surgery

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ABSTRACT

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Background: Surgical site infection is the most common complication encountered in inguinal hernia (IH) surgery. Antibiotic prophylaxis for groin hernia surgery may limit wound infection. However, there is a debate to use in general. **Objectives:** The aim of this study is to compare the effect of prophylactic single dose versus multiple doses antibiotic in uncomplicated groin hernia patients were admitted in a tertiary care hospital. **Methods:** This randomized clinical trial was conducted for twenty-four months in the department of Surgery of Rangpur Medical College and Hospital. A total of 132 patients with uncomplicated groin hernia were included after considering the inclusion and exclusion criteria. Informed written consent was obtained from the participants. Ethical clearance was obtained before beginning of the study from the ERC. Detailed history was taken and clinical examination was done. Patients were randomly divided into two groups. Group A received antibiotic prophylaxis of single dose and Group B received multiple doses antibiotic. Patients were followed up at 3rd and 5th postoperative day and surgical site infection was evaluated by ASEPSIS scoring system. Statistical analyses of the results were be obtained by using window-based Microsoft Excel and Statistical Packages for Social Sciences (SPSS-24). **Results:** The mean age of the patients was 48.94±10.04 and 50.26±10.37 years in group A and B accordingly. Male predominance was observed in both groups A and B. Age and gender was statistically similar in both groups. Surgical site

infection was significantly high among patients who received multiple doses antibiotic (9.09% Vs 6.06%). Group A patients were discharged comparatively early than group B patients with statistical significance. Mean hospital stay was also longer in group B patients than group A patients (3.93±1.41 days Vs 3.34±1.41 days). **Conclusion:** Present study findings indicate that surgical site infections could be reduced by using a prophylactic single dose antibiotic prior to surgical treatment for uncomplicated inguinal hernia. But before finalizing the comment, further larger study is recommended.

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INTRODUCTION

'Hernia' is a protrusion of a viscus or part of a viscus through an abnormal opening in the walls of its containing cavity. About 75% of all hernia occurs in the groin where the inguinal and femoral hernia is the most familiar form. Inguinal hernias account for 75% of abdominal wall hernias, with a lifetime risk of 27% in men and 3% in women. [1] Two-thirds of the inguinal hernias are usually indirect. Surgical repair is the definitive treatment for an inguinal hernia. [2] Inguinal hernia repair is one of the most common general procedures performed worldwide, with more than 20 million operations performed annually, with rates ranging from 10 per 100,000 of the population in the United Kingdom to 28 per 100,000 in the United States. [3] The average global incidence of hernia repair is 3 per 1000 population yearly; Bangladesh has a population of 180 million where more than half a million hernia surgeries are performed every year. [4] Though Hernia repair is regarded as a clean surgery the most common complication of this procedure is superficial surgical site infections (SSSIs). The incidence of post-operative infection is considered to be around 1-2% that can present significant challenges in post-operative management. The higher rates of surgical site infections are associated not only with higher morbidity and mortality but also with increased medical costs. [5] Studies have shown that surgical wound infection prolongs hospitalization for approximately oneweek and adds 20–30% cost to the hospital bill. [6] Although SSI rates after urgent or emergency repair are higher than after elective repair, bundled care aimed at reducing SSIs is effective for hernia repair procedures. So antibiotic prophylaxis plays an essential role in decreasing the wound infection rate. However, some studies do not confirm that antibiotic prophylaxis statistically reduces the rate of SSI. Prophylactic antibiotics are given to the patients before the contamination or infection has occurred, and in surgical patients, these are given just before or during the surgery.

This activity aimed at reducing the intraoperative level of microorganisms to a quantitywhich can be successfully dealt with by the patient's immune system. [7] On the other hand inappropriate and indiscriminate use of prophylactic antibiotics may increase the cost and unnecessary drug use and growth of resistant organisms. Though there are no specific guidelines for antibiotic prophylaxis, and the surgeon is responsible for determining whether a patient needs antibiotics or not and either uses single or multiple doses. [8] Arvind Diwaker and Sumukha have shown that Single doses antibiotic prophylaxis is as effective as multiple doses of antibiotics and potentially cost-effective (Sumukha 2020; Diwaker et al. 2018). [7, 9] Due to the scarcity of data in our country, this comparative study was to assess the comparative superiority of prophylaxis versus multiple doses antibiotic in uncomplicated groin hernia patients admitted to Rangpur medical college hospital.

METHODOLOGY

This comperative study was carried out in the Department of surgery in Rangpur medical college hospital, Rangpur during January 2020 to December 2021. A total of 132 patients were participated in the study. Among them 66 patients in Group-A (Patients having prophylactic single dose antibiotic) and 66 patients in Group-B (Patients having multiple doses antibiotic). Patients with uncomplicated groin hernia those are admitted into surgery department of Rangpur Medical College and Hospital, Rangpur. After taking consent and matching eligibility criteria, data were collected from patients on variables of interest using the predesigned structured questionnaire by interview, observation. Statistical analyses of the results were be obtained by using window-based Microsoft Excel and Statistical Packages for Social Sciences (SPSS-24).

RESULTS

Table-1: Age distribution between group A & B (n=132)

Age group (years)	Group A (n=66)	Group B (n=66)	Total (n=132)	p-value
18-30	03 (4.55)	03(4.55)	06 (4.55)	1*
31-40	09 (13.66)	11 (16.67)	20 (15.15)	0.627*
41-50	22 (33.33)	25 (37.88)	47 (35.61)	0.585*
51-65	32 (48.48)	27 (40.91)	59 (44.70)	0.381*
Mean±SD	48.94±10.04	50.26±10.37	49.60±10.19	0.459#

p-value was determined by *Chi square ($\chi 2$) test

The mean age of group A was 48.94±10.04 & group B was 50.26±10.37. In group A 4.55% were in 18-30 years age group, 13.66% were in 31-40 years age group, 33.33% were in 41-50 years age group and 48.48% were 51-65 years age group. In group B 4.55% were 18-30 years age group, 16.67% were 31-40 years age group, 37.88% were 41-50 years age group and 40.91 were 51-65 years age group.

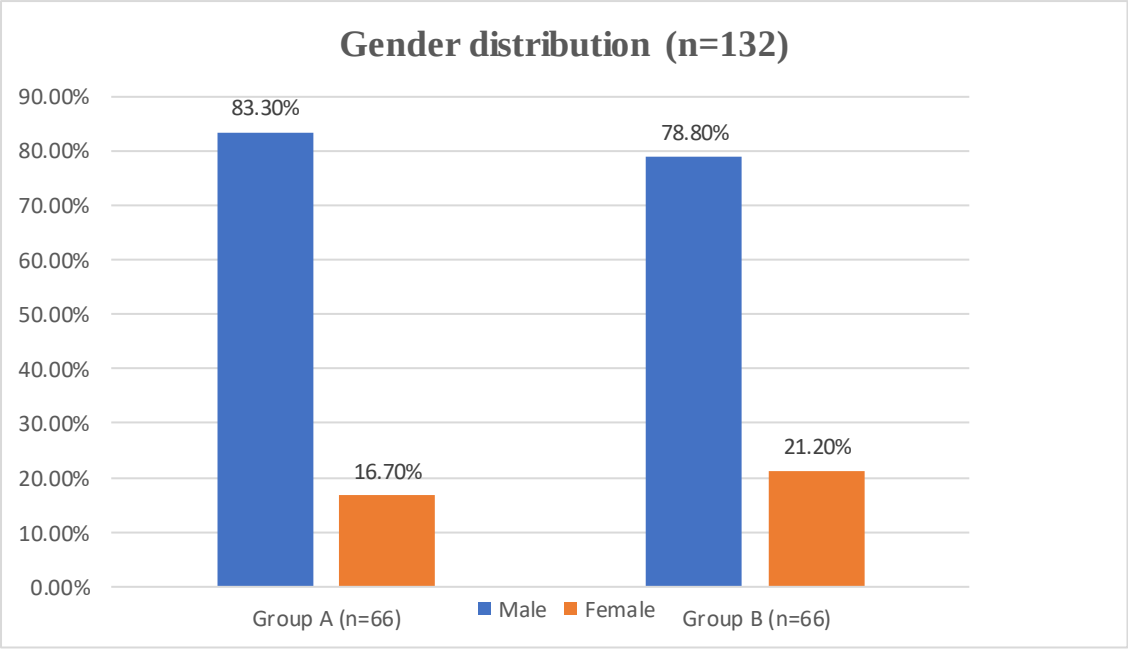

Figure 1: Gender distribution between group A & B (n=132)

Gender distribution of the patients was matched between two groups (P=0.329). In group A 83.3% were male and 16.7% were female, in group B 78.8% were male and 21.2% were female.

Table 2: General health status of the respondents (n=132)

General health status	Group A (n=66) n	Group B (n=66) n	Total (n=132) n	p-value
Appearance				
Ill looking	04 (6.06)	05 (7.58)	09 (6.82)	0.500*
Well	62 (93.94)	63 (95.45)	123 (93.18)	
Nutritional status				
Good	30 (45.45)	28 42.42)	58 (43.94)	0.868*
Average	34 (51.52)	35 (53.03)	69 (52.27)	
Below average	02 (3.03)	03 (4.55)	05 (3.79)	
Anemia				
Absent	54 (81.82)	50 (75.76)	104 (78.79)	0.857*
Mild	08 (12.12)	11 (16.67)	19 (14.39)	
Moderate	03 (4.55)	04 (6.06)	07 (10.61)	
Severe	01 (1.52)	01 (1.52)	02 (1.52)	
Jaundice				
Present	02 (3.03)	01 (1.52)	03 (2.27)	0.500*
Absent	64 (96.97)	65 (98.48)	129 (97.73	

p-value was determined by *Chi square ($\chi 2$) test

Majority of the patients 93.94% & 95.45% were well looking in group A & B respectively, 51.52% & 53.03% were average nutritional status, 81.82% & 75.76% were non-anemic and had no jaundice of 96.97% & 98.48% in group A & B respectively.

Table 3: Distribution of the respondents by clinical presentations (n=132)

Clinical presentations	Group A (n=66)	Group B (n=66)	Total (n=132)	p-value
Swelling in groin	66 (100)	66 (100)	132 (100)	
Heaviness in groin				
Present	41 (62.12)	38 (57.58)	79 (59.8)	0.361*
Absent	25 (37.89)	28 (42.42)	53 (40.2)	
Pain in groin				
Present	43 (65.15)	40 (60.61)	83 (62.9)	0.359*
Absent	23 (34.85)	26 (39.39)	49 (37.1)	
Burning sensation in groin				
Present	42 (63.64)	37 (56.06)	79 (59.8)	0.239*
Absent	24 (36.36)	29 (43.94)	53 (40.2)	
BOO				
Present	3 (4.54)	7 (10.60)	10 (7.57)	
Absent	63 (95.45)	59 (89.39)	122 (107.69)	

p-value was determined by *Chi square ($\chi 2$) test

All the patients had groin swelling (100%). In group A 62.12% & in group B 57.58% had groin heaviness, 65.15% & 60.61% had groin pain, burning sensation was present 63.64% & 56.06% and other presentations were 22.73% & 18.18% in group A & group B respectively.

Table 4: Distribution of duration of groin swelling between group A & B (n=132)

Clinical presentations	Group A (n=66)	Group B (n=66)	Total (n=132)	p-value
0-3	18 (27.27)	19 (28.79)	37 (28.03)	0.846*
4-6	10 (15.15)	09 (13.64)	19 (14.39)	0.804*
7-12	11 (16.67)	12 (18.18)	23 (17.42)	0.818*
>12	27 (40.91)	26 (39.39)	53 (40.15)	0.859*
Mean±SD (months)	**10.32±7.87**	**11.18±8.19**	**10.75±8.03**	**0.538#**

p-value was determined by *Chi square ($\chi 2$) test.

The mean duration of groin swelling in group A was 10.32±7.87 and in group B was 11.18±8.19. In group A, 27.27% patients had 0-3 months of groin swelling, 15.15% had 4-6 months, 16.67% had 7-12 months and 40.91% of the patients had more than 12 months of groin swelling. In group B, 28.79% patients had 0-3 months of groin swelling, 13.64% had 4-6 months, 18.18% had 7-12 months and 39.39% patients had more than 12 months of groin swelling.

Table 5: Distribution of risk factors between group A & B (n=132)

Risk factors	Group A (n=66)	Group B (n=66)	Total (n=132)	p-value
Family history				
Present	06 (9.09)	04 (6.06)	10 (7.58)	0.372*
Absent	60 (90.91)	62 (93.94)	122 (92.42)	
H/O smoking				
Present	15 (22.73)	16 (24.24)	31 (23.48)	0.500*
Absent	51 (77.27)	50 (75.76)	50 (75.76)	
H/O weight lifting				
Present	21 (31.82)	25 (37.89)	46 (34.85)	0.292*
Absent	45 (68.18)	41 (62.12)	86 (65.15)	
H/O chronic cough				
Present	07 (10.61)	06 (9.09)	13 (9.85)	0.500*
Absent	59 (89.39)	60 (90.91)	119 (90.15)	
H/O constipation				
Present	14 (21.21)	11 (16.67)	25 (18.94)	0.329*
Absent	52 (78.79)	55 (83.33)	107 (81.06)	
Other factors				
Present	14 (21.21)	12 (18.18)	26 (19.70)	0.414*
Absent	52 (78.79)	54 (81.82)	106 (80.30)	

p-value was determined by *Chi square ($\chi 2$) test.

Table 6: Distribution of the respondents by clinical examination in group A and B (n=132)

Types of Hernia	Group A (n=66)	Group B (n=66)	Total (n=132)	p-value
Side				
Right	32 (48.48)	28 (42.42)	60 (45.45)	0.679*
Left	29 (43.94)	34 (51.52)	63 (47.73)	
Both	05 (7.58)	04 (6.06)	09 (6.82)	
Types				
Direct	36 (54.55)	35 (53.03)	71 (53.79)	0.500*
Indirect	30 (45.45)	31 (46.97)	61 (46.21)	
Reducibility				
Reducible	55 (83.33)	54 (81.82)	109 (82.58)	0.500*
Irreducible	11 (16.67)	12 (18.18)	23 (17.42)	
Complete/Incomplete				
Complete	17 (25.76)	15 (22.73)	32 (24.24)	0.420*
Incomplete	49 (74.24)	51 (77.27)	100 (75.76)	

p-value was determined by *Chi square ($\chi 2$) test.

Majorities in group A were presented with right sided (48.48%) & in group B left sided (51.52%) groin hernia. In group A 54.55% & in group B 53.03% were direct, in group A 83.33% & in group B 81.82% had reducible and 74.24% & 77.27% had incomplete groin hernia.

Table 7: Time taken for the procedure between group A & B (n=132)

Procedure time (minutes)	Group A (n=66) n	Group B (n=66) n	Total (n=132) n	p-value
<30	17 (25.76)	15 (22.73)	32 (24.24)	0.684*
30-45	20 (30.30)	24 (36.36)	44 (33.33)	0.460*
45-60	22 (33.33)	21 (31.82)	43 (32.58)	0.852*
>60	07 (10.61)	06 (9.09)	13 (9.85)	0.770*

p-value was determined by *Chi square ($\chi 2$) test.

In group A, time taken for the procedure of patients 25.76% was less than 30 minutes, 30.30% were 30-40 minutes, 33.33% were 45-60 minutes and 10.61% patient's procedure time was more than 60 minutes. In group B, 22.73% patient's procedure time was less than 30 minutes, 36.36% patients were 30-40 minutes, 31.82% were 45-60 minutes and 9.09% patient's procedure time was more than 60 minutes.

Table 8: Duration of post-operative hospital stay between group A & B (n=132)

Day of discharge	Group A (n=66) n	Group B (n=66) n	Total (n=132) n	p-value
Operated day	02 (3.03)	02 (3.03)	04 (3.03)	1*
1st POD	09 (13.64)	08 (12.12)	17 (12.88)	0.794*
2nd POD	25 (37.88)	27 (40.91)	52 (39.39)	0.721*

3rd POD	24 (36.36)	24 (36.36)	48 (36.36)	1*
4th POD	06 (9.09)	05 (7.58)	11 (8.33)	0.752*
Mean±SD	2.35±0.94	2.33±0.90	2.34±0.91	0.925#

p-value was determined by *Chi square (χ2) test.

The mean post-operative day in group A was 2.35±0.94 & in group B was 2.33±0.90. Majority of the patients were discharged on 2nd POD (post-operative day) 37.88% & 40.91% in group A & group B respectively. 36.36% patients were discharged on 3rd POD from both group A & group B. 9.09% & 7.58% were discharged on 4th POD in group A & group B respectively and 3.03% patients were discharged on operated day in both group A & group B.

Table XI: Distribution of surgical site infection between group A & B (n=132)

Surgical site infection	Group A (n=66) n	Group B (n=66) n	Total (n=132) n	p-value
Present	04 (6.06)	06 (9.09)	10 (7.58)	0.372*
Absent	62 (93.94)	60 (90.91)	122 (92.42)	

p-value was determined by *Chi square (χ2) test.

In group A, 6.06% patient had surgical site infection & 93.94% had no surgical site infection. In group B, 9.09% patient had surgical site infection and 90.91% patient had no surgical site infection.

DISCUSSION

Hernia surgery is the most common procedure in the surgery department. [10, 11] Hernia can be defined as an abnormal protrusion of any viscus, or part of a viscus, through the wall of its containing cavity. [12] It occurs when an organ of the body pushes itself through an opening in the muscle or tissue that is supposed to hold it in place. [2] To reduce the risk of surgical site infection and further complications prophylactic single dose antibiotic has an important role, it is also recommended in many. [13]

According to this study, the mean age of group A was 48.94±10.04 & group B was 50.26±10.37. In group A 4.55% were in 18-30 years age group, 13.66% were in 31-40 years age group, 33.33% were in 41-50 years age group and 48.48% were 51-65 years age group. In group B 4.55% were 18-30 years age group, 16.67% were 31-40 years age group, 37.88% were 41-50 years age group and 40.91 were 51-65 years age group. Shankar et al documented the mean age group 44.44±15.59 & 45.56±16.43 in antibiotic & control group respectively. From another study, found mean age was 57.5±11.26 years. [4]

In this study, gender distribution of the patients was matched between two groups (P=0.329). In group A 83.3% were male and 16.7% were female, in group B 78.8% were male and 21.2% were female. From the study Cai et al, they found 93% males and 07% females, from Kabir et al, 94% male & 06% female. Ugwu-Olisa & Ogadi, they found 80.8% male & 19.2% female. [14]

In this study, all the patients had groin swelling (100%). In group A 62.12% & in group B 57.58% had groin heaviness, 65.15% & 60.61% had groin pain, burning sensation was present 63.64% & 56.06% and other presentations were 22.73% & 18.18% in group A & group B respectively. According to Kabir et al study, all of them (100%) complaints of groin swelling. Groin pain, sensation of heaviness in groin, burning sensation in groin, swelling in scrotum, features of obstruction

features of strangulation noted in 64%, 62, 57%, 29%, 7%, 4% respectively. [4]

In this study, the mean duration of groin swelling in group A was 10.32±7.87 and in group B was 11.18±8.19. In group A, 27.27% patients had 0-3 months of groin swelling, 15.15% had 4-6 months, 16.67% had 7-12 months and 40.91% of the patients had more than 12 months of groin swelling. In group B, 28.79% patients had 0-3 months of groin swelling, 13.64% had 4-6 months, 18.18% had 7-12 months and 39.39% patients had more than 12 months of groin swelling. According to the study Kabir et al, they found among 100 study patients in 41 patient's duration of symptoms were more than 12 months. Mean duration 8.03±8.15 months. [15]

In this study, majorities in group A were presented with right sided (48.48%) & in group B left sided (51.52%) groin hernia. In group A 54.55% & in group B 53.03% were direct, in group A 83.33% & in group B 81.82% had reducible and 74.24% & 77.27% had incomplete groin hernia. According to Kabir, found that right sided, left sided, bilateral hernias were found in 49%, 45% and 6% study patients respectively. Direct hernias, indirect pantaloons hernias seen were in 57%, 30%, 7% study patient respectly.81% hernia was reducible and 88% was incomplete. [4]

According to this study, in group A, time taken for the procedure of patients 25.76% was less than 30 minutes, 30.30% were 30-40 minutes, 33.33% were 45-60 minutes and 10.61% patient's procedure time was more than 60 minutes. In group B, 22.73% patient's procedure time was less than 30 minutes, 36.36% patients were 30-40 minutes, 31.82% were 45-60 minutes and 9.09% patient's procedure time was more than 60 minutes. According to Mazaki et al study, the mean duration of surgery of antibiotic & placebo group was 66.3±25.4 & 65.2±27.1 respectively. [16]

In group A, 6.06% of patients had surgical site infection & 93.94% had no surgical site infection. In group B, 21.2% of patients had surgical site infections and 86.4% of patients had no surgical site infection. Surgical site infection was statistically higher in patients of group B. From the study Ogwu-Olisa & Ogadi, the post-operative wound infection was found to be 3.9%. [14] From the study Muzaki et al, SSI developed in 2 of 100 patients (2%) in the anantibiotic prophylaxis group and 13 of 100 patients (13%) in the placebo group. [16] According to the study Kirchhoff et al, they found that AP does not have any beneficial effect in laparoscopic incisional hernia repair. [8] Yerdel et al. documented a significant decrease in overall wound infection rate 9% to 0.7% when single dose, intravenous amipicillin sulbactam was used during Lichtenstein hernia repair. [17]

Limitations of the study

The present study was conducted in a very short period due to time constraints and funding limitations. The small sample size was also a limitation of the present study.

CONCLUSION

In this study, both surgical site infections and hospital stay were more or less same. So, the single dose prophylactic antibiotic prior to surgical treatment for uncomplicated inguinal hernia Surgery is appropriate and convenient and multiple doses antibiotic use only economical loss.

RECOMMENDATION

This study can serve as a pilot to much larger research involving multiple centers that can provide a nationwide picture, validate regression models proposed in this study for future use and emphasize points to ensure better management and adherence.

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The wide range of disciplines involved in role of prophylactic antibiotic of single dose versus multiple doses in uncomplicated groin hernia surgery research means that editors need much assistance from referees in the

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