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Comparative study of single dose preoperative antibiotic versus five days antibiotic course in preventing surgical site infection for pediatric inguinal herniotomy

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ABSTRACT

Aim: To compare single dose preoperative antibiotic versus five days antibiotic course in preventing surgical site infection for the pediatric inguinal herniotomy.

Materials and Methods: The present study was conducted on 100 patients of elective inguinal herniotomy from January 2019 to April 2020 and compared on the basis of single dose preoperative antibiotic versus five days antibiotic course. All the patients were evaluated on the 3rd, 7th and 28th post-operative period and instructions were given to the guardians about wound care and to attend for early follow up if any signs & symptoms of wound infection appear.

Results: 50% of the patients were treated with prophylactic single dose antibiotic, i.e. inj. Ceftriaxone (30 mg/kg/dose) at the time of induction only and rest 50% were treated with inj. Ceftriaxone(30mg/kg/dose) at the time of induction as well as postoperatively at night followed by four days of oral antibiotic with Syr/Tablet. Cephalixin (25mg/kg/day) three times daily for another 4 days.

Surgical Site Infection (SSI) in Group-B (4.0%) was higher than that of Group-A (2.0%) on day 3 but it was not significant (p=0.40). There was no significant difference in health status of the patients of the two groups when compared on post-operative day 7 and day 28 (p=0.99, p=0.99 respectively).

Conclusion: Implementation of single dose antibiotic prophylaxis regimes tailored to the prevalent organisms in the institution can result in enormous savings, as the study shows significant reduction in hospital stay with no significant increase in incidence of SSI.

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1. Introduction

Surgical antimicrobial prophylaxis refers to the use of antibiotics administered prior to an operation. Its function is to reduce the burden of contamination from endogenous and exogenous sources of infection. Despite major progress in the infection control, postoperative wound infection is still a major source of morbidity among the surgical patients.

Surgical site infections (SSI) are among the most common hospital acquired problems & is an important reason for morbidity & mortality in all patients.^{1,2}

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The incidence of SSI is 2-5% in the adult patients undergoing inpatient surgery.³ Risk factors related with SSI included co-morbidities, advanced age, risk indices and surgical complexity.⁴ In children the rate of SSI ranged from 2.5 to 5.4%. Dirty wounds, prolonged surgery or certain surgical disciplines (cardiovascular, neurosurgery, orthopedics) were connected with increased risk of developing an SSI.⁵

Prophylactic administration of antibiotics can reduce post-operative morbidity, shorten hospital stay & reduce the overall costs. But it increases the risk of side effects of drugs, allergic reactions, drug interactions &

thrombophlebitis. A study displays that peri-operative antibiotics significantly increase the risks of developing *Clostridium difficile* infection & provides yet more compelling indication that giving even a single dose of prophylactic antibiotics is not without hazard. Peri-operative drug reactions may arise in 1 in 5000 to 1 in 25,000 cases with a mortality of up to 6%.⁶

Cefuroxime⁷ has a broad range of coverage against gram positive and gram negative organisms. It is bactericidal and covers the spectrum of bacteria that causes SSI.

It is important to emphasize that surgical antibiotic prophylaxis is an adjunct to good surgical procedure. Numerous clinical studies have clearly revealed that suitably timed “single shot” prophylaxis is as effective as multiple-dose prophylaxis. There is proven efficiency & cost-effectiveness of pre-operative antibiotic prophylaxis in clean surgeries like herniotomy & inguinal orchidopexy.⁸

In spite of wide knowledge about the effectiveness of antibiotic usage, the administrative regimens are often inappropriately implemented.

We hypothesized that the timing of prophylaxis is essential for success, yet antibiotics are often administered at a wrong time or for too long. It has been suggested that elective inguinal herniotomy with single dose preoperative antibiotic is better than five days antibiotic course in preventing surgical site infection. This study, therefore, was aimed to comparatively study single dose preoperative antibiotic versus five days antibiotic course in preventing surgical site infection for the pediatric inguinal herniotomy. It is hoped that this knowledge will help in improving the overall outcome of patients & make inguinal hernia repair, which is such a common surgical technique in this young population, more safe and acceptable.

2. Material and Methods

The present study was conducted on the patients of elective inguinal herniotomy and compared on the basis of single dose preoperative antibiotic versus five days antibiotic course. It is a randomised prospective study conducted from 1st January 2019 to 15th April 2020 and included 100 patients.

2.1. Inclusion criteria

1. All children of age group 1 month to 12 years.
2. Uncomplicated inguinal hernia admitted for elective surgery.

2.2. Exclusion criteria

1. Recurrent and complicated (irreducible, obstructed or strangulated) hernias.
2. Allergic to cephalosporin.
3. Associated Comorbidities.
4. H/O use of antibiotics in past 7 days

5. Any break in aseptic technique

2.3. Statistical analysis

Statistical Analysis was performed with help of Epi Info (TM) 7.2.2.2 which is a trademark of the Centers for Disease Control and Prevention (CDC).

Children were distributed randomly in two groups having 50 children in each group.

Group A children received prophylactic single dose antibiotic, i.e. inj. Ceftriaxone (30 mg/kg/dose) at the time of induction. All children were discharged the next day with no antibiotics.

Group B children received inj. Ceftriaxone (30mg/kg/dose) at the time of induction as well as postoperatively at night. All children were discharged the next day with Syr/Tablet. Cephalexin (25mg/kg/day) three times daily for another 4 days.

In both groups same oral analgesics were given for post-operative pain relief.

All the patients were evaluated on the 3rd, 7th and 28th post-operative period and instructions were given to the guardians about wound care and to attend for early follow up if any signs & symptoms of wound infection appear.

Any patient of group A, who developed any sign of infection, was further treated with standard protocol of oral antibiotics for five days.

The Criteria adopted for diagnosing surgical site infection was the CDC criteria (Centre for Disease Control) which are redness, swelling around the wound, pus or serous discharge from the wound.

3. Results and Discussion

Postoperative wound infection has been the greatest obstacle to advancement of surgery down the centuries. Many factors are associated with the development of SSI. Appropriate administration of prophylactic antibiotics reduces the incidence of these infections.⁹ In developed countries, a single dose antibiotic has proven to be effective prophylaxis for many types of surgeries.¹⁰ Herniotomy and orchiopexy are clean surgeries performed on a large scale in the pediatric age group. The patients are usually aged about 1-8 years & in good health. The surgeries are done through a small incision & no contamination is faced during the course of surgery and tissue handling is also nominal.

We used a randomized prospective study form for our study so as to differentiate the use of the antibiotics i.e. single dose use & prolonged use in the two groups. Alike methodology was used by Ranjan A et al¹¹ to compare single-dose preoperative antibiotic prophylaxis versus routine long-term postoperative prophylaxis in elective general surgical cases, Rajarajan S et al⁹ to study prophylactic antibiotic versus empirical antibiotic in prevention of surgical site infection and Vasu S et

al¹² comparing the efficacy of single dose prophylactic ceftriaxone versus post-operative ciprofloxacin and metronidazole combination in reducing post-operative wound infection after clean surgeries. Also Vaze D et al¹⁰ studied the risk of surgical site infection in paediatric herniotomies without any prophylactic antibiotics using the same methodology.

In the present study the majority of children were of the age group ranging from 1 year to 4 years (38.0%) followed by age group 5-9 years (35.0%) with mean age of the children of group A as 5.12±3.55 years and group B as 5.46±3.43 years and the association was found to be statistically insignificant (p>0.05). Table 1

Table 1: Distribution according to age of the patients in the two groups

Age Group (in years)	Group-A (n=50)	Group-B (n=50)	Total
<1	4	4	8
Row %	50.0	50.0	100.0
Col %	8.0	8.0	8.0
1 - 4	19	19	38
Row %	50.0	50.0	100.0
Col %	38.0	38.0	38.0
5 - 9	18	17	35
Row %	51.4	48.6	100.0
Col %	36.0	34.0	35.0
9.1 - 12.1	9	10	19
Row %	47.4	52.6	100.0
Col %	18.0	20.0	19.0
Total	50	50	100
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
Mean±s.d.	5.12±3.55	5.46±3.43	
Median	5	5	
Range	0.25 - 12.00	0.33 - 12.10	

Row% - Provides the comparison between two groups (i.e. Group-A and Group-B).

Col% - Provides the comparison within a group (i.e. (i.e. Group-A or Group-B).

X²=0.08; p=0.99 NS- Not Significant

Chi-square (X²) test showed that there was no significant association between age and the patients of two groups (p=0.99).

Also t-test showed that there was no significant difference in mean age of the patients of two groups (t₉₈=0.48; p=0.62). Thus the patients of two groups were matched for their ages.

Our findings were in accordance with the study performed by Vaze D et al¹⁰ who reported the mean age as 31.62 and 35.93 months respectively for group A and B (p>0.05). Ekpemo SC et al¹ in their study depicted that the ages ranged from 1-14years with a median of 2 years (p>0.05).

In our study the majority of the studied patients were male in both the groups (42 in each i.e. 84.0%) while

the females were on 16.0% out the total 100 patients and the association was found to be statistically insignificant (p>0.05). Similar findings were presented by Vaze D et al¹⁰ who reported 99.01% males in group A and 95.35% males in group B (p>0.05).

It is known that pediatric hernia is common in males. The younger ages dominated in this study with 46 (46.0%) patients below the age of five years. This finding is similar to other studies where the patients were operated to correct congenital hernias as early as possible to prevent intestinal obstruction.

Table 2: Distribution of gender and the patients of two groups

Gender	Group-A (n=50)	Group-B (n=50)	Total
Male	42	42	84
Row %	50.0	50.0	100.0
Col %	84.0	84.0	84.0
Female	8	8	16
Row %	50.0	50.0	100.0
Col %	16.0	16.0	16.0
Total	50	50	100
Row %	50	50	100.0
Col %	100.0	100.0	100.0

X²=0.01; p=0.99 NS- Not Significant

Chi-square (X²) test showed that there was no significant association between gender and the patients of two groups (p=0.99).

Thus the patients of the two groups were matched for their gender.

Table 3: Diagnostic distribution of the patients of two groups

Diagnosis	Group-A (n=50)	Group-B (n=50)	Total
Bilateral Inguinal Hernia	2	3	5
Row%	40.0	60.0	100.0
Col %	4.0	6.0	5.0
Left Inguinal Hernia	15	13	28
Row%	53.6	46.4	100.0
Col %	30.0	26.0	28.0
Right Inguinal Hernia	33	34	67
Row%	49.3	50.7	100.0
Col %	66.0	68.0	67.0
Total	50	50	100
Row%	50.0	50.0	100.0
Col %	100.0	100.0	100.0

X² =0.35; p=0.83 NS- Not Significant

Chi-square (X²) test showed that there was no significant association between diagnosis and the patients of two groups (p=0.83).

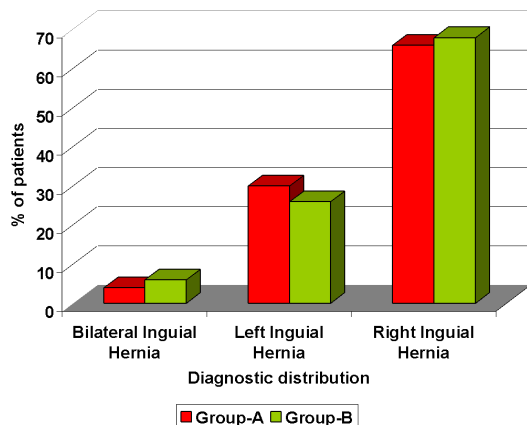
Thus the patients of the patients of two groups were comparable for their diagnosis.

Table 4: Distribution of health status of the patients of two groups at 3rd day and 7th day after surgery

Health Status	Group-A (n=50)	Group-B (n=50)	Total	Group-A (n=50)	Group-B (n=50)	Total
Without Infection	49	48	97	50	50	100
Row%	50.5	49.5	100.0	50.0	50.0	100.0
Col %	98.0	96.0	97.0	100.0	100.0	100.0
With Surgical Site Infection	1	2	3	0	0	0
Row %	33.3	66.7	100.0	0.0	0.0	0.0
Col %	2.0	4.0	3.0	0.0	0.0	0.0
Total	50	50	100	50	50	100
Row %	50.0	50.0	100.0	50.0	50.0	100.0
Col %	100.0	100.0	100.0	100.0	100.0	100.0

Table 5: Distribution of health status of the patients of two groups at 28th day after surgery

Health Status	Group-A (n=50)	Group-B (n=50)	Total
Without infection	50	50	100
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
With infection	0	0	0
Row %	0.0	0.0	0.0
Col %	0.0	0.0	0.0
Total	50	50	100
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0

**Fig. 1:** Bar graph showing the diagnostic distribution of the patients of two groups

3.1. Distribution of health status of the patients of two groups at 3rd day, 7th day and 28th day after surgery

Overall though at 3rd day after surgery the proportion of SSI in Group-B (4.0%) was higher than that of Group-A (2.0%), two types of drugs were more or less equally effective to control SSI after surgery. Also the association was found to be statistically insignificant ($p > 0.05$). In this study we can find an economical advantage in using pre-operative single dose prophylactic antibiotic than post-operative continuation of therapy. The patients in both

groups showed more or less the same complications. Short term administration of antibiotic minimizes the risk of antibiotic resistance in patients, so it is more effective than using antibiotics for a longer period of time.

At 3rd postoperative day—Proportion of Surgical Site Infection (SSI) in Group-B (4.0%) was higher than that of Group-A (2.0%) but it was not significant ($Z = 0.82$; $p = 0.40$). Table 4

Since two of the cell frequencies were zero Chi-square (X^2) test could not be applied. However, Fisher exact showed that there was no significant difference in health status of the patients of the two groups ($p = 0.99$).

According to many literatures, the rate of postoperative wound infection in clean surgery is between 1.5 – 4.0%. Joda AE¹³ shows 3.33% rate of surgical site infection in both groups, 2.66% when prophylactic antibiotics was used in the control group & 4% when prophylactic antibiotics not used in the case group.

In a study conducted by Basant RK et al,¹⁴ wound infection was developed among 3 patients in study group 2, 2 (4%) male and 1 (2%) females while among the 50 participants of control group 2 (4%) male and 2 (4%) females developed wound infection. In contrast to Ranjan A et al,³ post-operative wound infection was more common among females among both group 25% and 20% in study group and control group while 7.1% and 6.25% among male participants in study group and control group respectively.

Ekpemo SC et al¹ reported that the surgical site infection rate was 4.7% (3 out of 63) patients in group A that used

antibiotics and 7.9% (5 out of 63) patients in group B that did not use antibiotics. There was no statistically significant difference in the rate of SSI between the two groups.

Many studies have been conducted on the choice of antibiotic and timing of use of antibiotics. One of them was conducted by Jayalal JA et al¹⁵ has recommended the first dose to be given 30- 60 min prior to surgery, and long-acting antibiotics must be selected.

This may indicate that there are other factors implicated in the development of SSI. Studies have shown that factors such as inadequate hemostasis, hypothermia, dead space, rough tissue handling, improper use of suture materials and inadvertent entry into hollow viscus may play a more vital role in the development of surgical site infection after clean surgical procedures. The importance of this is that efforts are to be directed towards obviating these factors rather than concentrating on giving antibiotics. On the other hand^{16,17} some studies have shown that in settings where the operating environment might be contaminated or the hygienic state of the patient's home is uncertain, it may be prudent to give prophylactic antibiotics to minimize or prevent surgical site infection.

Since two of the cell frequencies were zero Chi-square (X^2) test could not be applied. However, Fisher exact showed that there was no significant difference in health status of the patients of the two groups ($p=0.99$). Table 5

Although at 3rd day after surgery the proportion of SSI in Group-B (4.0%) was higher than that of Group-A (2.0%), two types of drugs were more or less equally effective to control SSI after surgery.

4. Conclusion

Surgical site infection is the condition that may increase the morbidity and hospital stay of the patient. Injudicious use of antibiotics should be avoided as it may lead to increased cost burden, emergence of drug resistant microbes and risk of side effects of drugs on the patients.

In a resource deficit nation like ours, implementation of single dose antibiotic prophylaxis regimes tailored to the prevalent organisms in the institution can result in enormous savings, as the study shows significant reduction in hospital stay with no significant increase in incidence of SSI.

5. Conflict of Interest

The authors declare that there are no conflicts of interest in this paper.

6. Source of Funding

None.

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