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A Randomized Control Trial Comparing the Incidences of Surgical Site Infections in Elective Inguinal Herniotomy with and Without Prophylactic Antibiotics

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Abstract

Introduction: Inguinal herniotomy is one of the most frequently performed surgeries in paediatric patients. It is basically a clean surgery which is performed through a small incision. Many studies show that patients undergoing clean surgeries do not require any antimicrobial prophylaxis as the rate of surgical site infection (SSI) in clean surgeries is very low. Inspite of that, most of the surgeons continue to use perioperative prophylactic antibiotics in routine paediatric herniotomy due to unnecessary fear of wound infection. Meta-analysis of comparable studies do not support nor discard the use of prophylactic antibiotics for prevention of surgical site infections in clean surgeries. Moreover there is rarity of controlled clinical trials in paediatric patients. So this randomized controlled trial was undertaken to see whether prophylactic antibiotics are really needed in inguinal herniotomy in children.

Methods: A randomized control study was conducted from August 2017 to September 2019. All the cases of inguinal hernia requiring inguinal herniotomy below 12 years of age were included in the study. The patient's socio-demographic data, relevant clinical history, operative data, haematological reports and surgical site infection data were recorded in preformed structured proforma. Data collected were analyzed using SPSS-version-21 (IBM Corp., IL USA). Student t test (two tailed, independent) and Fisher's exact test were used for comparison of the two groups.. A p-value of <0.05 was taken as significant.

Results: 130 patients were recruited for the study, 65 in control group (I) and 65 in intervention group (II). Majority of the patients are in the age group 48 to 72 months (55%). Most of the patients in this study are of male gender (73.1%). Majority of the patients have haemoglobin between 12 to 16 g/dl in both the control and intervention group. Mean length of surgical incision is 2.71±0.23 overall, 2.74±0.22 in group I, 2.67±0.23 in group II. Mean duration of surgery is 17.87±4.18 minutes overall, 17.98±3.94 minutes in group I, 17.75±4.43 minutes in group II. Only one patient in group II developed Southampton wound grade 2 on post-operative day 2. All the other patients in both the groups had normal wound healing (Southampton grade 0).

Conclusion: There is no significant difference in the incidence of surgical site infections between the control (antibiotics) group and the intervention (no antibiotics) group. It can be concluded that the incidence of SSI in paediatric inguinal herniotomy is very low and prophylactic antibiotics are unnecessary and should not be recommended in routine cases in the absence of risk factors for infection.

Keywords: randomized control trial, herniotomy, Southampton wound grade.

Introduction

Inguinal hernia is one of the most common surgical conditions in paediatric patients.[1] In this condition, there is incomplete obliteration of processus vaginalis which is a peritoneal pouch which comes down through the deep ring and inguinal canal during descend of testis.[1,2,3,4] It normally gets obliterated after birth. Inguinal hernia in children is almost always indirect type of hernia due to patent processus vaginalis. It is more common in boys (1:50) and more common on the right side (2:1) with bilateral hernia comprising of 15%.[4,5]. Treatment is always surgical and always better to perform surgical repair i.e. inguinal herniotomy as soon as the diagnosis is made in order to avoid incarceration and strangulation**.**

Inguinal herniotomy is one of the most frequently performed surgeries in paediatric patients.[2,3,4] Paediatric herniotomy is basically a clean surgery which is performed through a small incision and does not involve any opening of or contamination from gastrointestinal tract.[6]

Many studies show that patients undergoing clean surgeries do not require any antimicrobial prophylaxis as the rate of surgical site infection in clean surgeries is very low.[7,8,9] Inspite of that, most of the surgeons continue to use perioperative prophylactic antibiotics in routine paediatric herniotomy without any proper indication due to unnecessary fear of wound infection. Again, the use of antibiotics to prevent SSI has become a subject of controversy as some studies are finding antibiotic prophylaxis useful for prevention of surgical site infection even in clean cases too.[10,11]

Despite advances in surgical science, surgical site infection still remains responsible for most of the postoperative morbidity and mortality. Many studies showed prophylactic antibiotics are unnecessary in clean surgeries. But these studies are mostly done in developed countries with high standard of living and good hospital conditions. Only few studies are done in developing countries like India. Some study emphasized the importance of prophylactic antibiotics in paediatric patient in clean herniotomy cases as these patients are prone for contamination from nappies and cannot maintain personal hygiene themselves.[11] Meta-analysis of comparable studies do not support nor discard the use of prophylactic antibiotics for prevention of surgical site infections in clean surgeries. Moreover, there is rarity of controlled clinical trials in paediatric patients. So, this randomized controlled trial was undertaken to see

whether prophylactic antibiotics are really needed in inguinal herniotomy in children which is one of the most commonly performed clean surgery in paediatric surgery department of our hospital.

Materials and Methods

A randomized controlled trial was conducted from August, 2017 to September 2019 in Manipur at the Department of Surgery, RIMS. The study population was all the patients of both sexes aged 12 years and below admitted for elective herniotomy in the Department of Surgery at Regional Institute of Medical Sciences, Imphal during the study period. Patients who have taken antibiotics within 7 days prior to surgery for some other medical conditions, immuno-compromised, with co-morbidities, allergy to cephalosporin group of antibiotics, any infective focus in the body or skin near the incision site and complicated inguinal hernia are excluded from the study. Consecutive sampling was done until the required sample size was reached. Inguinal herniotomy was performed by the same surgeon for all the cases.

Randomization

Done using computer generated random number table, patients were allotted either of the two groups- Group I (Control group) or Group II (intervention group). Group I underwent inguinal herniotomy with conventional single dose preoperative prophylactic antibiotics (third generation cephalosporin antibiotic, in the dose of 50mg/kg body weight, maximum dose = 1g) given intravenously at the time of induction of anaesthesia as prophylactic antibiotic. Intervention group underwent elective inguinal herniotomy without any prophylactic antibiotics both pre or post-operatively.

Sample size

Taking significance at 5% ($Z\alpha$=1.96), 90% power ($Z\beta$=1.28), proportion of intervention group with desired outcome (P_1) as 96.3% and proportion of control group with desired outcome (P_2) as 97.1% and test margin(d) as 10%, and using the non-inferiority trial formula,[6]

$$n = \frac{(Z\alpha+Z\beta)^2[P_1\,(100-P_1) + P_2\,(100-P_2)]}{(P_1-P_2-d)^2}$$

Sample size in each group is 65.

Thus, total sample size = 2×65 =130.

Study variables

Independent variables are age, sex, weight, socioeconomic condition, level of haemoglobin, duration of surgical procedure, grade of wound infection, length of hospital stay and dependent or outcome variable is surgical site infection.

Data collection

A pre designed, pre tested, semi structured proforma was used for data collection. Collected data were checked for completeness and consistency and necessary rectification was made.

Operational definition

Infection occurring at the surgical site at any depth within 30 days of the surgery was considered as SSI.

Southampton wound grading system was used for wound grading.

Major findings	Additional findings	Grade
Normal healing		0
Normal healing with mild bruising or erythema		1
	Some bruising	1a
	Considerable bruising	1b
	Mild erythema	1c
Erythema plus other signs of		2

inflammation		
	At 1 point	2a
	Around sutures	2b
	Along wound	2c
	Around wound	2d
Clear or haemoserous discharge		3
	At one point <=2 cm	3a
	Along wound; >2 cm	3b
	Large volume	3c
	Prolonged drainage (>3 days)	3d
Pus		4
	At 1 point only; ≤2 cm	4a
	Along wound; >2 cm	4b
Deep or severe wound infection	With or without tissue breakdown or hematoma requiring aspiration	5

Table 1 Showing Southampton wound grading system.

Statistical analysis

The data analysis was done using SPSS software version 21 (IBM corp., IL USA) and R environment ver.3.2.2 were used. Student t-test (two tailed, independent) was used to find the significance of study parameters on continuous scale (age, weight, haemoglobin, length of surgical incision, duration of surgery) between two groups (Inter-group analysis) on metric parameters. Leven's test for homogeneity of variance has been performed to assess the homogeneity of variance, Fisher Exact test has been used to find the significance of study parameters of surgical site infection between the two groups. P-value less than 0.05 is considered statistically significant.

Ethical issues: Approval was taken from the Research Ethics Board, RIMS, Imphal before the commencement of the study.

Results

In total 130 patients, 65 in control group (received prophylactic single dose 3rd generation cephalosporin intravenously) and 65 in intervention group (did not receive any antibiotic), were recruited for this randomised control study which was conducted for the span of two. Only one patient (in group II) developed SSI.

Majority of the patients are in the age group 48 to 72 months (55%). Mean age of the patients is 59.26± 31.48 months overall, 59.45± 26.95 months in group I and 59.08± 35.64 months in group II. Minimum age in this study is 12 months and maximum age is 144 months. Most of the patients in this study are of male gender (73.1%). In group I (with antibiotics), 70.8% are males and in group II (no antibiotics), 75.4% are male patients. Overall male-female ratio is 2.7:1. Majority of the patients belong to the weight group 10 to 20 kg (80%), 83.1% in group I (with antibiotic) and 76.9% in group II (no antibiotic). Overall mean weight is16.55±4.99 kg. Mean weight in group I is 16.39±4.21 kg and group II, it is 16.70±5.69 kg. Overall, right sided hernia constituted 59.2%, bilateral hernia constituted 31.5%, and left sided hernia constituted 9.2%. Majority of the patients have haemoglobin between 12 to 16 g/dl in both the control and intervention groups. None of the patients in this study has anaemia. Most of the patients (93.1%) have length of incision in between 2.5 to 3 cm. Mean length of surgical incision is 2.71±0.23 overall, 2.74±0.22 in group I, 2.67±0.23 in group II. Mean duration of surgery is 17.87±4.18 minutes overall, 17.98±3.94 minutes in group I, 17.75±4.43 minutes in group II.

All the patients stayed at hospital for 2 days after surgery except for 1 patient who stayed longer (5 days) due to surgical site infection. The difference between the two groups is not statistically significant. Only one patient in the intervention group where there is no use of prophylactic antibiotics got a score of Southampton wound grade 2 on post-operative day 2. All the other patients in both the groups had normal wound healing (Southampton grade 0).

Variables	Group I (With Antibiotics)	Group II (No Antibiotics)	Total	p-value
Age in months	59.45±26.95	59.08±35.64	59.26±31.48	0.947
Weight in kg	16.39±4.21	16.70±5.69	16.55±4.99	0.726
Haemoglobin of the patients in g/dl	12.48±0.65	12.44±0.58	12.46±0.62	0.766
Length of surgical incision	2.74±0.22	2.67±0.23	2.71±0.23	0.082
Duration of surgery in minutes	17.98±3.94	17.75±4.43	17.87±4.18	0.754

Table 2: Showing comparison of means of the age, weight, haemoglobin, length of surgical incision and duration of surgery between the two groups.

Presence of surgical site infection	Use of prophylactic antibiotics		Total
	Group I (With Antibiotics)	Group II (No Antibiotics)	
Yes	0(0%)	1(1.5%)	1(0.8%)
No	65(100%)	64(98.5%)	129(99.2%)
Total	65(100%)	65(100%)	130(100%)

Table 3: Showing SSI in Group I and Group II.

P=1.000, Not significant, Fisher Exact test.

It was found that only one patient in group II (no antibiotic) developed surgical site infection. No patient developed surgical site infection in the group I (with antibiotic) The overall incidence of SSI is 0.8% while it is 1.5 % in the no antibiotics group. P-value was found to be 1.000 not statistically significant.

Discussion

Inguinal herniotomy in children is a clean type of surgery with very low infection rate. It is the most common operation performed in paediatric age groups. Duration of surgery is very short in terms of minutes. It is performed through a very small incision and does not involve much tissue handling and manipulation. Inguinal herniotomy is basically a clean operation as it does not involve entry into GIT, respiratory and genito-urinary tracts which are potential source of bacterial contamination.[12] Also, paediatric patients are usually healthy without medical co-morbidities unlike adults. So theoretically, chance of infection is very less.

Surgical site infection is the third most common nosocomial infection overall and the most common nosocomial infection among surgical patients.[13,14] There are three main risk factors for developing postoperative surgical site infection: host related factors, surgical or environmental factors and microbiological risk factors.[16] Prophylactic antibiotics should not be regarded as a substitute for proper surgical techniques. Surgical site infection in a clean surgery is always attributed to exogenous bacteria that usually result from breaks in the aseptic technique by the operating team.[14] So proper surgical technique and maintenance of strict aseptic and antiseptic conditions can prevent a number of surgical site infections.

This study was done to compare the incidence of surgical site infections in paediatric patients undergoing elective inguinal herniotomy with prophylactic antibiotics and those without antibiotics. All the patients with risk factors for developing surgical site infection were excluded so that the result of the study is not biased.

Surgery was done by the same surgeon for all the cases who does not have any idea regarding antibiotic prophylaxis status of the patient. The wound was examined for any sign of infection on day 2, day 14 and day 30. Only one patient, out of the total 130 patient, developed wound infection with a wound grade 2 which was a minor surgical site infection. This study shows a very low infection rate of 0.8% overall, 0% in control group where prophylactic antibiotics were used and 1.5% in intervention group where prophylactic antibiotics were not used. This rate of infection is less as compared to other studies where the rate of postoperative wound infection is found to be between 1.5 – 4%.[6, 17, 18, 19, 20] again statistical analysis shows that there is no significant difference in the rate of infection between the two groups. So, this study concluded that prophylactic antibiotics are not useful in paediatric inguinal herniotomy for the prevention of SSI. The Cochrane meta-analysis showed that prophylactic antibiotic in clean surgeries cannot be absolutely recommended or neglected.[21]Another reviewers at the Cochrane Collaboration in 2012 stated that there is no clear benefit of prophylactic antibiotics in preventing surgical site infection in clean surgeries.[22] This is in agreement with the finding of this study.

Judicious use of prophylactic antibiotic can result in less postoperative morbidity and mortality, psychological effect to the patient and party, shorter hospitalization period & reduce the overall healthcare cost due to infection. On the other hand, overuse and misuse of antibiotics results in several drawbacks like drug side effects and reactions, interactions, thrombophlebitis, emergence of multi-drug resistant bacteria & the large economic burden on the government.[23,24,25]A study showed that perioperative antibiotic significantly increased the risk of *Clostridium difficile* infection. Even a single dose of prophylactic antibiotic is not free of risks. A literature by Harper et al in 2009 revealed that approximately 15% of anaesthesia-related anaphylactic reaction are due to antibiotics.[26] The consequence of anaphylaxis to intravenous antibiotics could be catastrophic with a mortality of up to 6%. These observations necessitate a risk-benefit assessment before establishing a protocol for giving the prophylactic antibiotic. According to a study done by N. Hatam, the overuse of antibiotics result in almost 10 USD extra cost per every patient & the hospitals under that study paid 6,840 USD extra-expense every year due to non-adherence to **American Society of Health-System Pharmacists** (ASHP) guidelines regarding the usage of antibiotic in surgery.[27] On the contrary, a substantial cost savings for the healthcare system can be achieved by strictly following these guidelines.[28] Sasse et al. reported that a potential saving of 6.1 million USD could be made if surgical antibiotic prophylaxis were given according to recommendations.[29]

Conclusion

This study shows no statistically significant difference in the incidence of surgical site infections between the control (antibiotics) group and the intervention (no antibiotics) group. It can be concluded that the incidence of SSI in paediatric inguinal herniotomy is very low and prophylactic antibiotics are unnecessary and should not be recommended in routine cases in the absence of risk factors for infection.

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