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Risk of surgical site infection in paediatric herniotomies without any prophylactic antibiotics: A preliminary experience

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ABSTRACT

Background: Different studies underline the use of pre-operative antibiotic prophylaxis in clean surgeries like herniotomy and inguinal orchiopexy. But, the meta-analyses do not recommend nor discard the use of prophylactic pre-operative antibiotics. The scarcity of controlled clinical trials in paediatric population further vitiates the matter. This study assessed the difference in the rate of early post-operative wound infection cases in children who received single dose of pre-operative antibiotics and children who did not receive antibiotics after inguinal herniotomy and orchiopexy. **Materials and Methods:** This randomised prospective study was conducted in Paediatric Surgery department of PGIMER Chandigarh. Out of 251 patients, 112 patients were randomised to the case group and 139 were ascribed to the control group. The patients in control group were given a standard regimen of single dose of intravenous antibiotic at the time of induction followed by 3-4 days of oral antibiotic. Case group patients underwent the surgical procedure in similar manner with no antibiotic either at the time of induction or post-operatively. **Results:** The incidence of surgical site infection in case group was 3.73 % and that in control group was 2.22%. The observed difference in the incidence of surgical site infection was statistically insignificant (*P* value = 0.7027). The overall infection rate in case and control group was 2.89%. **Conclusions:** Our preliminary experience suggests that there is no statistically significant difference in the proportion of early post-operative wound infection between the patients who received single dose of pre-operative antibiotics and the patients who received no antibiotics after inguinal herniotomy and orchiopexy. The risk of surgical site infection in paediatric heriotomies does not increase even if the child's weight is less than his/her expected weight for age.

Key words: Antibiotic prophylaxis, clean surgeries, herniotomy, orchiopexy, surgical site infections

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INTRODUCTION

Wound infection is one of the most common surgical complications. Infection of a wound may result from a number of factors, both intrinsic and extrinsic to the patient. Although many of the intrinsic factors cannot be modified, the external ones can certainly be influenced; particularly those related to aseptic conditions, the surgical technique and peri-operative care.

In case of clean contaminated and dirty surgeries, a risk of contracting a surgical site infection overwhelmingly exceeds the potential ill effects of an antibiotic usage. Thus, the benefits of antibiotic prophylaxis in such surgeries are universally accepted.

Same contention cannot be made in case of clean surgeries; especially in those without use of prosthetic material (e.g. paediatric herniotomies and orchidopexies). In such surgeries infection rate is very low. It is so low that it has been recommended by some preliminary studies that antibiotics need not be given in clean surgeries.[1] Thus, we presume that antibiotics may not be required for such surgeries.

In contrast, some studies have proven efficiency and cost-effectiveness of pre-operative antibiotic prophylaxis in clean surgeries like herniotomy and inguinal orchiopexy.[2] But the meta-analyses of similar studies do not recommend or discard the use of prophylactic pre-operative antibiotics.[3-5] The problem is further compounded by scarcity of controlled clinical trials in the paediatric population.

MATERIALS AND METHODS

This randomised prospective study was conducted at our department according to a protocol verified and accepted by the Ethics Committee of the Institute. Sampling technique was proposed to be non-probability convenience. Patients undergoing clean surgeries of

inguinal herniotomy and orchiopexy with a marginal risk for anaesthetic complications were considered for the study. It was also mandatory for them to be available for complete follow-up. Following classes of patients were excluded from the study:

1. Patients with any generalised debilitating disease.
2. Any infective focus in the body/on the skin.
3. Poor quality of the skin or ongoing infection at the incision site.
4. Allergy to routinely used antibiotic.
5. History of use of antibiotics within past 7 days.
6. Patients requiring admission due to some reason.

Out of 282 patients, 251 were considered for the study. The remaining 31 patients were excluded from the study for reasons cited in Table 1.

There were five and four patients from the case and control group, respectively, who did not comply with the full month (4 weeks) follow-up period of the study and hence were excluded for lack of follow-up [Figure 1].

A written informed consent was obtained from all the parents. After randomisation by an unbiased blinded observer, patients in Group A (Control Group) were administered a standard regimen of single dose of intravenous antibiotic at the time of induction followed by 3-4 days of oral antibiotics. Group B (Case Group) patients underwent the surgical procedure in similar manner with no pre-induction or post-operative antibiotics.

Patients were evaluated for post-operative fever (developing or persisting 48 hours after the surgery), discharge from the wound and overlying skin inflammation by a blinded independent observer. The wound was examined on 3rd, 7th, 28th post-operative day and 2 months. Centre for Disease Control (CDC) criteria were used to define the surgical site infection in all the patients. Culture and sensitivity report of the pus guided further management and the use of antibiotic in case of an infection. If wound infection was noted, the patient was discontinued from the study and appropriate management was instituted.

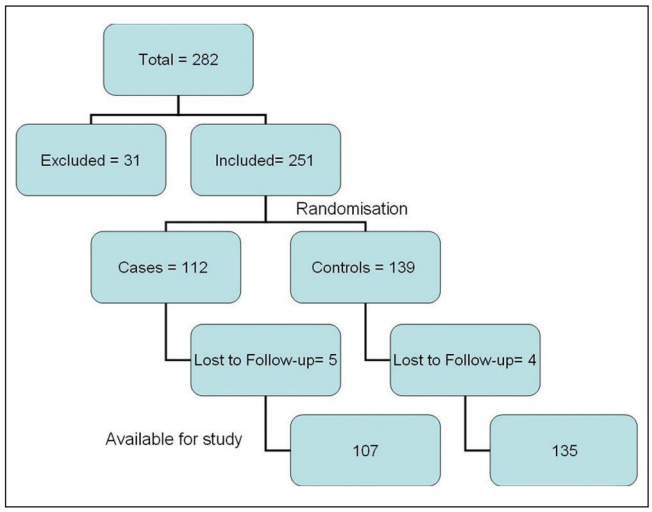


Figure 1: Inclusion and randomisation statistics

Unpaired *t*-test was used to analyse ordinal data while chi-square test was used to analyse categorical data. A *P*-value of less than 0.05 was accepted as statistically significant.

RESULTS

The patients in case and control groups were compared on the basis of the vital parameters, namely age, gender, and weight. Other factors that directly or indirectly affect the occurrence of surgical site infections were also considered to minimise and eliminate various confounding factors that would affect the results of the trial. The two groups were found comparable with respect to these variables [Table 2].

The incidence of surgical site infection in case group was 3.73% and that in control group was 2.22%. The observed difference in the incidence of surgical site infection was statistically insignificant (*P* value = 0.7027). The overall infection rate in case and control group was 2.89%.

Table 1: Table showing reasons for exclusion of certain cases

Reason for exclusion	Number of patients
Did not undergo day care surgery	14
Antibiotic prophylaxis administered for other indications	12
Infective endocarditis prophylaxis administered for congenital heart lesion	5

Table 2: Comparative representation of demographic data and intra/post operative parameters

	All	Cases	Controls	*P* value
Age (months)	34.02	31.62	35.93	> 0.05
Males (%)	97.11	99.01	95.35	> 0.05
Weight (kg)	12.04	11.30	12.63	> 0.05
Haemoglobin (g%)	10.3199	10.45	10.20	> 0.05
% of non-pre-operative bath (%)	23.55	25	22	> 0.05
Length of incisions (cm)	3.097	2.91	3.24	> 0.05
Operative time (min)	23.47	20.72	25.67	> 0.05
Infection (%)	2.89	3.73	2.22	> 0.05

Univariate analysis showed that age, gender, weight, socioeconomic class, pre-operative bath and use of antibiotic prophylaxis were independently associated with the incidence of surgical site infection.

Multivariate analysis showed that age (*P* value = 0.0356) (OR = 0.9127; CI = 0.8381-0.9939) and weight (*P* value = 0.0108) (OR = 1.4528 CI = 1.0900-1.9362) were significantly associated with surgical site infection. An interaction model was also tested using the above two variables as these variables are inter-dependent. The expected weight of a child was calculated using Leffler formula.[6] If the weight of the child was less than expected weight then a value of '1' was returned. If it was more or equal to the expected weight then a value of '0' was returned. When a univariate analysis was done using these values the result was insignificant (*P* value = 0.2007).

DISCUSSION

Herniotomy and orchiopexy are clean surgeries performed on a large scale in the paediatric age group. The patients are generally aged about 1-8 years and in good health except for the surgical problem, which is largely local. The surgeries are done through a small incision and no contamination is encountered during the course of surgery (no opening of bowel, etc.). Tissue handling is minimal. The time taken at expert hands is just over 10 minutes.

Prophylactic administration of antibiotics can decrease post-operative morbidity, shorten hospitalisation and reduce the overall costs attributable to infections. But use of antibiotics is not free from antecedent ill-effects. It increases the risk of drug side effects, allergic reactions, drug interactions and thrombophlebitis. A study shows that peri-operative antibiotics significantly increased the odds of developing Clostridium difficile infection and provides yet more compelling evidence that giving even a single dose of prophylactic antibiotics is not without risk. Peri-operative drug reactions may occur in 1 in 5000 to 1 in 25,000 cases with a mortality of up to 6%.[7,8] Antibiotic-associated anaphylaxis is one of the most serious adverse reactions and it accounts for 8.3-27.9% of all peri-operative drug reactions.[7,9] These observations warrant a risk-benefit analysis before a formal protocol for antibiotic prophylaxis is structured.

A majority of studies mention that there is no need of antibiotic prophylaxis in clean surgical cases. Many of these studies are carried out in developed countries and hence experience cannot be directly applied to scenario in developing countries where the operation theatre environment, post-operative wound care, patient literacy, nutrition, social hygiene, etc., differ to a great extent.

A significant variation is observed in usage of antibiotic prophylaxis for the most commonly performed operations in paediatric surgery. Many children do not receive antibiotics when prophylaxis is indicated while relatively greater proportion may have received antibiotics when there is no clear benefit. There are several potential explanations for the variation in antibiotic usage rates observed between hospitals. Diagnostic uncertainty, increasing pressure from hospitals and regulatory agencies to reduce nosocomial infection rates, inexperienced clinicians and patient preferences have all been found to influence decision making in this regard.[10] Overuse of antibiotics results not only in the emergence of resistant organisms but also causes great economic burden on the health system.[11-16]

In resource limited settings, the dilemma further worsens as there is constant fear of surgical site infection attributable to poor social hygiene, malnutrition, etc., on one side and a pressure to cut costs on the other. In such circumstances, the fear of infection supervenes and surgeons use antibiotics with no clear rationale. This fear seems unreasonable in clean cases as infection rates are low in these cases.[17-21]

The rate of infection observed in our study was 2.89% with the incidence of surgical site infection in case group of 3.73% and that in control group of 2.22%. The rate of surgical site infections in both the groups was comparable. This observation of ours is in line with the observations of Cochrane meta-analysis, which stated that antibiotic prophylaxis (especially in clean surgeries) cannot be firmly recommended or discarded. This lack of definite conclusion made these investigators to call for identification of risk factors for infection, which would be useful to identify those groups of patients that may benefit from antibiotic prophylaxis.[22]

We analysed our data with respect to multiple factors, which are known to increase the risk of a surgical site infection. Our data specifically focused on age of the child, sex, his/her weight, his/her parent's socio-economic class, whether the child had taken pre-operative bath, length of incision, time required for the surgery and use of prophylactic antibiotic.

Multivariate analysis (non-interaction model) showed that age (OR = 0.9127; CI = 0.8381-0.9939) and weight (OR = 1.4528; CI = 1.0900-1.9362) of the child were associated significantly with the incidence of surgical site infection.

Since weight of a child and his or her age are dependent variables we decided to test the interaction model of these two factors. It was inferred that these two factors did not significantly contribute to the outcome, in an interaction model. Nearly 36% of our patients had their weights less than expected for their age. But the incidence of infection was not seen to increase in this subgroup; it was about 1.16%.

Thus, age and weight of the child seem to be the only significant factors responsible for incidence of infection. When these factors were considered in an interaction model, the results were insignificant.

This study highlights that the rate of surgical site infections for clean surgeries is very low even in children with lesser weights expected for their age. With this observation we are hopeful that the results in our preliminary study (i.e., antibiotic prophylaxis is not warranted in clean surgeries) shall reflect in a study with a bigger sample size.

CONCLUSIONS

Our preliminary experience suggests that there is no statistically significant difference in the proportion of early post-operative wound infection cases between the patients who received single dose of pre-operative antibiotics and the patients who received no antibiotics after clean surgeries of inguinal herniotomy and orchiopexy. The risk of surgical site infection in paediatric herniotomies does not increase even if the weight of the child is less than his/her expected weight for age.

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