Research Article

Are prophylactic antibiotics justified in pediatric patients with inguinal hernia repair?

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Abstract

Background: There are different studies highlighting the role of using prophylactic antibiotics in clean surgeries, but still there is conflicting evidence regarding whether prophylactic antibiotics are beneficial or not in preventing post-operative surgical site infection.

Aim: This study aims to evaluate the use of peri-operative prophylactic antibiotics in preventing or reducing surgical site infection in the elective open repair of pediatric inguinal hernia.

Patients and method: Over a ten-month period a total 150 pediatric patients underwent elective surgical repair for inguinal hernia were enrolled in this randomized prospective study, they were categorized into two equal Groups alternating at the time of operation. The patients in group A (Control) were followed a standard regimen of giving pre-operative parenteral antibiotic (in the ward or at the beginning of anesthesia) & then post-operative oral antibiotics for five days duration, while the patients in group B (Case) underwent the same surgery, but neither preoperative nor post-operative antibiotics were given. A written informed consent from the parents or child guardian was obtained after explanation. The rate of surgical site infection was compared between the two groups. A p value of less than 0.05 was considered to be significant statistically.

Results: The total infection rate in both (case and control groups) was 3.33%, the rate of postoperative wound infection in "case group" was 4 % compared to that in "control group" which was 2.67 %. This noticed variance was statistically insignificant (P value by Chi-Square Test = 0.9883, Two –tailed p value using paired samples- t test was = 0.6578). 80% of the infections were mild (grade 1 & 2) & 60% was noticed in the 3rd post-operative day.

Conclusion: This study pointed out that peri-operative prophylactic antibiotics are not justified routinely in pediatric inguinal herniotomy as there is no significant increased risk of postoperative wound infection in "group B" compared to "group A" (p value = 0.6578 using paired samples t- test), & this low risk of wound infection does not warrant the economic burden of their usage in such clean surgical operations.

Key words: Prophylactic antibiotic, clean surgery, herniotomy, wound infection.

INTRODUCTION

Surgical site infection is a common problem facing us in surgery; it usually results from several risk factors, although some of them are innate to the patient & cannot be altered, the extrinsic ones especially those regarding the theater environment & peri-operative wound care can be easily influenced to improve the result. The classical system (1) of classifying wound infection had been founded to give us a clinical assessment of the potential risk of bacterial contamination during the procedure. Clean Wounds: when there is no entry into a normally colonized viscus or lumen of the body, the expected infection rate in this category is less than 2%. Clean-Contaminated Wounds: when there is entry into a colonized viscus or cavity of the body, but under elective and controlled conditions, the infection rate is about 5%. Contaminated Wounds: when there is gross contamination at the surgical site in the absence of obvious infection, like laparotomy for penetrating injury with intestinal spillage or elective intestinal procedures with gross contamination of the surgical site, the infection rate is about 15%. Dirty Wounds: when there is already an active infection, like abdominal exploration for acute bacterial peritonitis and intra-abdominal abscess, the infection rate is about 40%.

The wound of an elective repair of an inguinal hernia is a type of clean surgery. There is minimal risk of wound infection & it usually originates from contaminated theatre environment, surgical personnel, or from endogenous source of infection in the patient himself & Staphylococcus aureus constitutes the most common pathogen encountered.(2) The rate of wound infection in this type of surgery should not exceed 4%, depending upon other clinical variables.(3) recently the NNIS (National Nosocomial Infections Surveillance) risk index have been adopted as a highly predictive index for development of surgical site infection (4), it ranges from 0 to 3 points depending on three different variables. One point is given for each of the following if present:

•American Society of Anesthesiology (ASA) physical status classification of > 2.

•Contaminated or dirty / infected wound classification.

•Length of operation > T-point (where T-point is the 75th percentile of duration of the specific operation in hours).

Initially antibiotics were praised highly as the agent with the magical effect to eliminate infection, but this effect has not been realized completely and the use of prophylactic antibiotics to prevent surgical site infection has become a matter of argument in clinical practice.

Several literatures concluded that most of the patients undergoing clean surgical operations does not need Prophylactic systemic antibiotics (5,6). In spite of that, they are still being used widely in clean operations by most of our surgeons because of the exaggerated fear of infection in their mind.

The misuse of antibiotic leads to possible drug adverse effect, super infection, increased cost of healthcare and emergence of highly resistant strains of bacteria in the community (7,8,9).

While in conditions of contaminated and dirty surgeries, the risk of catching a surgical site infection often outweigh the drawbacks of antibiotic usage. Thus, it is universally agreed that the prophylactic antibiotics are useful in such surgeries. But this should not be applied in case of clean surgeries; like elective repair of inguinal hernia especially without use of prosthetic mesh (as in pediatric patients) because of the very low risk of infection in such surgeries. It is so low that some preliminary studies recommended the non-usage of antibiotics in clean surgeries (5). Therefore, we assumed that prophylactic antibiotics are not justified in such surgeries. In contrast, an old study had confirmed efficacy and cost-effectiveness of using prophylactic antibiotics in clean surgeries like herniotomy (10). But the meta-analyses of comparable studies do not encourage or dismiss the use of peri-operative prophylactic antibiotics (11,12). Moreover, the issue is further complicated by the rarity of controlled clinical trials in the pediatric patients.

PATIENTS AND METHODS

This study was implemented at the surgical department of the Central child teaching hospital in Baghdad as a randomized prospective study. Patients with clean surgery of an inguinal herniotomy on elective basis were considered for this study. The results were assessed after a complete follow-up period of four weeks. The following groups of patients were not eligible for enrollment in the study:

1. Generalized debilitating disease, malnourished, immunocompromised patients.
2. Any infective focus in the body/on the skin near the incision site.
3. Patients who received a blood transfusion in the perioperative period.
4. Allergy to cephalosporin.
5. History of antibiotics usage within the past seven days.
6. Neonate with hyperbilirubinemia.
7. Any break in aseptic technique.
8. Patients whose parents refused to participate in the study.

150 patients Out of 173 were considered for the study, 18 patients were having one or more of the previously mentioned reasons so were excluded from the study, also there were five patients (three from the case group and two from the control group) were excluded from the study due to loss of follow up postoperatively. A written informed consent was gained from all patients' parents or their guardians.

A randomization of the sample was done by dividing the patients into two groups on the basis of numerical status; Patients with odd numbers were the group -A (control group) whereas those with even numbers were the group -B (case group). A standard regimen of prophylactic antibiotic was given to all patients in the Group A (Control Group) in a form of single dose of ceftriaxone (Novosef), (Zentiva a Sanofi company member) in a dose of 50 mg/kg intravenous slowly over 2- 5 minutes pre-operative in the ward or in the operating room with the induction of anesthesia followed by postoperative oral suspension of cephalexin (ACAFLEX) 250 mg (ACAI company) in a dose of 25mg / kg three times daily for five days (fig.1). The following parameters were recorded: the generic name of antibiotic, timing of first preoperative dose in relation to the first incision time, the first preoperative antibiotic dosage, and the duration of the surgical procedure, in addition to the duration of antibiotic prophylaxis postoperatively.

Antibiotics were given by assessing the prescriptions against SIGN guidelines (published by the Scottish Intercollegiate Guidelines Network) [13] which were considered the best, compared with others, regarding evidence-based and strength of recommendations. Patients in Group B (Case Group) underwent the same surgical procedure with a similar operation theatre discipline, but without pre-operative or post-operative antibiotics.

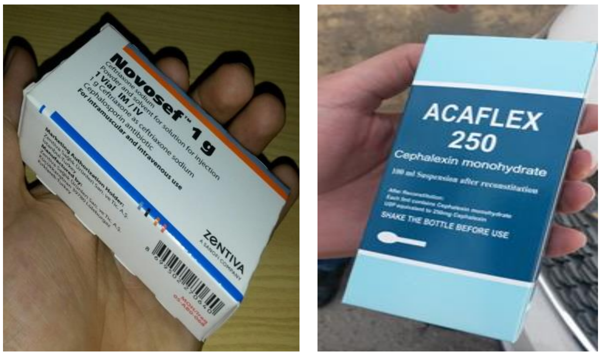

Fig.1: Antibiotics used

All the Patients were evaluated for development of post-operative fever, and the wounds were followed up for four weeks period for any discharge and signs of skin inflammation, the first change of dressing was done on third postoperative day and instructions were given to the family about wound care & to attend for examination if any sign & symptoms of infection appear. The second examination was done at time of stitch removal on the 7th postoperative day. After removal of stitches, patients with healthy wound were discharged and then followed-up on outpatient basis. The Criteria adopted for diagnosing wound infection in this study was the CDC criteria [14] (Centre for Disease Control) which are redness, swelling around the wound, pus or serious discharge from the wound. When there was a wound infection, the patient was treated appropriately, swab or pus was sent for culture and sensitivity, regular antiseptic dressings, using the appropriate antibiotics and where necessary incision and drainage were performed.

The statistical analysis was done using medcalc.org software program, the ordinal data were analyzed using paired sample t-test, while categorical data were analyzed using chi-square test. A P-value of less than 0.05 was accepted as statistically significant.

RESULT

We compare the patients in case and control groups regarding the vital parameters specifically age, gender, and weight, taking in consideration other factors that may influence the development of wound infection in order to reduce or preclude the confounding aspects that would affect the results of the study like level of hemoglobin, pre-operative bath, length of surgical incision and duration of the procedure. The two groups were seemed to be comparable regarding these variables [Table.1].

In group-A, the age range was one month – seven years with mean age 26.14 months. In group-B, the age range was one month – five years with mean age 27.81 months. The majority of patients were male in both the groups (92%). Male constitute 93.3% in group A, 90.6% in group B.

Table.1: comparative presentation of demographic parameters & rate of infection

Parameter	All	Control group A	Case group B
Age (mean in month)	26.97	26.14	27.81
Sex (male %)	138 (92%)	70 (93.3%)	68 (90.6%)
Weight (mean in kg)	14.82	13.78	15.86
Hemoglobin (mean in g %)	11.3	10.8	11.8
Pre-operative bath (%)	48 (32%)	23 (30.6%)	25 (33.3%)
Length of incision (mean in cm)	3.2	2.9	3.5
Operation time (mean in min.)	30.36	27.20	33.52
Infection (%)	5 (3.33 %)	2 (2.67 %)	3 (4 %)

In both groups, five patients (3.33%) were developed postoperative wound infection (Table. 1), two of them were seen in the control group A (accounting 2.67%) when perioperative antibiotics were used while the remaining three cases were seen in the Case group (accounting 4%) when prophylactic antibiotic not used at all.

The infection was noticed on the third postoperative day in three patients and on the seventh postoperative day in the remaining two patients (table.3). Grading of wound infection was done depending on Southampton wound scoring system [15], Grade 1 wound infection was seen in two patients, grade 2 in two patients & grade 3 in one patient (table.2). The low rate of surgical site infection seen in Group-A as compared to Group-B (2/75 Vs 3/75) was not statistically significantly by Chi-Square Test, (P value = 0.9883). Two –tailed p value using paired samples t test was (p = 0.6578).

Table.2: grading of Wound infection

Grade of infection	Group A (control)	Group B(case)
Grade 1	1	1
Grade 2	1	1
Grade 3	0	1
Grade 4	0	0
Grade 5	0	0

Table.3: timing of occurrence of wound infection

Timing of occurrence	Group A (control)	Group B(case)
3rd postoperative day	1	2
7th postoperative day	1	1

When univariate analysis applied to the study, we find that the variables of age, sex, weight, bathing before operation and use of antibiotic prophylaxis were separately associated with the incidence of surgical site infection, and a multivariate analysis demonstrated that the age with P value = 0.2383, (OR = 0.9476; 95% CI = 0.8653-1.0377) but the weight having a P value = 0.0256, (OR = 0.7888; 95% CI = 0.6310-0.9860) which were significantly correlated with surgical site infection. As the two variables (age & weight) are inter-dependent so they were subjected to an interactive model of testing; the ideal weight for age of a child was calculated using Leffler formulation [16].

M = 1/2.am + 4

M = the ideal weight of the child in kilogram.

am = the number of months the child is.

A value of "0" was recorded when the weight of the child was equal or more than the expected weight and a value of "1" was recorded when the weight of the child was less than ideal weight. When a univariate analysis was done using these new values the result was insignificant (P value = 0.7492).

OR = 0.7039; 95% CI = O.O763 – 6.4970.

DISCUSSION

Clean surgery means a procedure without break in the sterile technique and there is no entry into GIT, respiratory and genito-urinary tracts [1]. There are three main risk factors for developing postoperative wound infection :host related factors, surgical / environmental factors & microbial risk factors [17]. Prophylactic antibiotics cannot be regarded as a substitute for proper surgical practice including strict aseptic technique [18] . Surgical site Infection in a clean operation is always attributed to exogenous bacteria that usually result from breaks in the aseptic technique by the operating team [18] .

We aim in this study to evaluate the use of prophylactic antibiotics in inguinal herniotomies (clean surgery) which are commonly performed in the pediatric age group. We try to exclude all the patients with the risk factors for developing surgical site infection in order not to affect the result of our study.

According to many literatures, the rate of postoperative wound infection in clean surgery is between 1.5 – 4% [2,3,5,19].Our study shows 3.33 % rate of surgical site infection in both groups , 2.66% when prophylactic antibiotics was used in control group & 4% when prophylactic antibiotics not used in case group.

The surveillance of Cochrane meta-analysis dictated that prophylactic antibiotic in clean surgeries cannot be absolutely recommended or neglected [12] but the findings in our study goes with another reviewers at the Cochrane Collaboration in 2012, which stated that there is no clear beneficial indication of prophylactic antibiotic in preventing postoperative wound infections [20].

Even in adult with increased use of prosthetic mesh in inguinal hernia repair, although theoretically there would be an increased risk of surgical site infection, but routine prophylactic antibiotic is still controversial [21].In a recent Cochrane meta-analysis about the use of prophylactic antibiotic in inguinal hernia repair, seven of thirteen trials were using mesh repair & also concluded that "administration of antibiotic prophylaxis for elective inguinal hernia repair cannot be universally recommended" [12]. So, we can say that the identification of the risk factors for infection would be useful to recognize those patients who may benefit from prophylactic antibiotics.

The overuse of prophylactic antibiotic in surgery really is a big problem, a study done in 2010 shows that prophylactic antibiotic were used in 98% of surgeries, while only 68% of that surgeries need them according to the ASHP guidelines (American Society of Health-System Pharmacists) [22].Moreover, the non- compliance in the adherence to guidelines for surgical antibiotics prophylaxis is another problem, Marise et al.[23] in their review found a great variations regarding appropriate indication, administration at correct time, choice of correct antibiotic & adequate discontinuation of antibiotic. A survey done by Heineck et al. in Brazil in a single teaching hospital where the policy of that hospital stated that no antibiotic prophylaxis should be used for inguinal hernia repair, they found that antibiotics were given in 20/43 of these operations [24].

According to a questionnaire among a number of pediatric surgeons in three pediatric hospitals in Baghdad, there was a great variation in the adherence to the guidelines of using prophylactic antibiotic in surgery. Many pediatric patients do not receive antibiotic when it is indicated. On the other hand, the vast majority of pediatric patients received antibiotic without clear benefit. This variation is possibly attributed to inexperienced clinician, lack of health education among families, pressure from the local health authority to reduce the rate nosocomial infection and uncertain diagnosis of some diseases.

Although the proper use of prophylactic antibiotic in the indicated situations can result in less postoperative morbidity, shorter hospitalization & reduce the overall cost due to infection, but on the other hand overuse of antibiotics results in several drawbacks, like drug reactions, interactions, thrombophlebitis, upgrowth of resistant organisms & the large economic burden on the health authority [25,26,27] . even a single dose of prophylactic antibiotic is not free of risks. A literature by Harper et al.[28] in 2009 revealed that approximately 15% of anaesthesia-related anaphylactic reaction are due to antibiotics. This ratio had been increased in last years may be because of increased exposure to antibiotics in the community & 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 [29] in a neighboring country, 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 ASHP guidelines (American Society for Health-system Pharmacist) regarding the usage of antibiotic in surgery. On the contrary, a substantial cost savings for the healthcare system can be achieved by committing these guidelines [30], 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 [31]. We didn't find a study about the economic burden of prophylactic antibiotic in surgery in our country, but according to the records of one hospital in Baghdad (central child teaching hospital), about 580 operations of inguinal hernia repair were performed electively during the year 2015 and we can imagine the cost of unjustified antibiotic.

In the developed countries, most of the studies say that there is no need for prophylactic antibiotic in clean surgery, but this attitude may be difficult to be applied in developing countries where there are great differences in operation theatre environment, post-operative wound care, patient health education, nutrition, social hygiene, etc…

In this study, we noticed that most of the wound infections are detected within the first three days after surgery (table.3), this indicates that these infections are acquired during the operative procedure. Improving surgical technique from an antiseptic to strict aseptic has clearly minimized the bacterial threat. Handling the tissues gently and avoidance of any residual necrotic tissue or clot which may act as culture media for the contaminating pathogens have significantly limit the postoperative wound infection.

We analyzed the parameters used in our study that may affect the rate of surgical site infection and these were age, sex, weight, socioeconomic status of the family, whether the child had taken bath last night before surgery, duration of the surgical procedure, & length of surgical incision. Among these data, a multivariant analysis showed that age (OR = 0.9476; CI = 0.8653-1.0377) and weight (OR = 0.7888; CI =0.6310 -0.9860) of the child were associated significantly with the incidence of wound infection. But because the age & weight of the child are dependent variables so we subjected these two factors to an interactive model of testing & it was appeared that these factors didn't affect the outcome. About 45.3 % (68/150) of our patients had their weights less than ideal for their age, but the incidence of wound infection in this subgroup was not increased (2.8%).

CONCLUSION:

This study points out that the rate of postoperative wound infection in the elective repair of inguinal hernia is very low even in those children with lesser weight expected for their age and the difference in the rate of wound infection between the two groups (with antibiotic & without antibiotic) was statistically insignificant. The result of our preliminary study mandate the non-use of a prophylactic antibiotic in clean surgery hopefully a bigger size study will be implemented in the future.

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