Original Article

Effectiveness of Cefotaxime in the prevention of surgical site infections in children undergoing elective inguinal surgery at the University Teaching Hospital, Lusaka, Zambia

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ABSTRACT

***Introduction and objectives**:* Inguinal operations are the most performed surgeries in children. There is a divergent view on use of pre-operative antibiotic prophylaxis to prevent Surgical site infections (SSI) after these surgeries. The aim of this study was to detect if the use of cefotaxime had a significant impact on prevention of SSI in children under 8 years undergoing elective inguinal surgery at the University Teaching Hospitals (UTHs), Lusaka.

Method: This was a cohort study. A total of 170 patients below 8 years of age undergoing elective inguinal herniotomy, orchidopexy or patent processus vaginalis (PPV) ligation at UTHs were enrolled. Group A with 85 patients received pre-operative cefotaxime while group B with 85 patients did not receive any antibiotics. A data collection sheet was used to record pre-operative demographic details. Intraoperative variables and post-operative outcomes. No patient received post-operative antibiotics. Follow up to look for SSI was done at 2 weeks and 30 days.

Results: Out of 170 patients, 11(6.47%) had SSI. Six of the 85 that received surgical antibiotic prophylaxis (SAP) had SSI while 5 of the 85 that did not receive SAP had SSI (P=0.551). Deep SSI were seen in 2 patients that did not receive SAP (p=0.155) and grew Staphylococcus aureus in their cultures. Only 1 adverse allergic reaction to preoperative antibiotics was noted.

***Conclusion**:* Despite a low risk of adverse reactions, there is no benefit of using pre-operative antibiotics to prevent SSI in children undergoing elective inguinal surgery.

INTRODUCTION

Herniotomy for inguinal hernias is the most commonly performed operation in paediatric surgery worldwide.[1] Hydrocoeles are also common and are corrected using the same procedure in children, though referred to as ligation of a patent processus vaginalis. Orchidopexy for undescended testes also involves ligation of patent processus vaginalis followed by an additional procedure to fix the testes in the scrotum.

Surgical site infections (SSIs) are defined as infections occurring up to 30 days after surgery (or up to one year after surgery in patients receiving implants) and affecting either the incision or deep tissue at the operation site.[2]

SSIs are potential complications of any type of surgical procedure. Although SSIs are among the most preventable healthcare-associated infections, they still represent a significant burden in terms of

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Keywords: *Surgical site infections, Surgical antibiotic prophylaxis, Inguinal surgery, PPV ligation, Herniotomy, Orchidopexy.*

patient morbidity, mortality, and additional costs to health systems and service payers worldwide.[3]

Center for Disease Control (CDC) guidelines state that 'administer preoperative antimicrobial agents only when indicated based on published clinical practice guidelines and timed such that a bactericidal concentration of the agents is established in the serum and tissues when the incision is made' (Category IB–strong recommendation; accepted practice.).[2]

Few Randomised Control Trials (RCT's) have been described comparing SSI with use of pre-operative antibiotics for herniotomy. Most of these studies have not been able to recommend or reject the use of pre-operative antibiotics for herniotomy. Children above 8 years of age require repair of a defect in their abdominal wall after a herniotomy and this procedure has proven benefit from pre-operative cephalosporin use.[4]

There is a scarcity of RCTs for SSI in the paediatric population.[5] Systematic reviews on the topic have no clear guidelines for SAP use in paediatric inguinal surgery and advice for larger studies.[6]A study in 2016 supports that a quality-improvement intervention should take into account local contexts, with development of hospital policies, education on SAP recommendations, and dissemination of data on adherence to recommendations.[7]Most developed country literature does not recommend SAP for herniotomy, orchidopexy and PPV ligation while literature from developing countries is divided on SAP use for these operation**s.**A landmark systematic review in 2012 of interventional studies for prevention of SSIs in sub-Saharan Africa concluded that there is extremely limited research from sub-Saharan Africa on interventions to curb the occurrence of SSI. Although some of the existing studies are weak, several high-quality studies have been published in recent years. Standard methodological approaches to this subject are needed.[8] The main limitation noted were nonstandard definition of SSI, weak randomization techniques, and lack of the use of sample size calculations.[6]

A retrospective review in USA found that SAP did not reduce the risk of postoperative SSI, readmissions, or hospital visits. Patients who received SAP had significantly increased odds of perioperative allergic reaction.[9] This demonstrated that the risks of SAP outweigh the benefits in children undergoing orchidopexy. Peri-operative reactions to the antibiotics were seen in 1.4 percent of patients included.[9]

Antibiotics have been shown to be responsible for 12 to 15 percent of perioperative anaphylaxis reactions in a French series.[10] Studies in the United States of America showed that antibiotics accounted for over 50 percent of all anaphylaxis reactions.[11,12,13] Hence their use should be restricted to when they have been shown to be effective and not for all operations.[3]

A study in Zambia in 2007 found no significant benefit of SAP in preventing SSI in adult patients undergoing clean abdominal surgeries when compared to post-operative antibiotic use.[14] Patients receiving SAP had infection rates of 7.3% while those that did not receive SAP had infection rates of 10.1%.[14] This study did not include any paediatric patient and was only comparing pre-op antibiotic use in the two groups. Both groups received same regimen of post-operative antibiotic prophylaxis.[14]

At the University Teaching Hospitals paediatric surgery unit no guidelines exist with regards to pre-operative antibiotic use and there is no documentation of complications from inguinal surgeries done.Anecdotal data shows that theater notes at the UTHs do not mention if SAP was given or not. The current surgeons in the department (consultants and registrars) have divided opinions on use of SAP for herniotomy. SSIs are seen in the outpatient review clinics in UTH but there is no documentation of infection rates, other complications, and the type of SSI based on department audits.

Cefotaxime, a third generation broad spectrum antibiotic is cheap, easily accessible and has been proven effective as SAP in various operations.[15] It is currently the antibiotic of choice for SAP for general paediatric surgical operations at the UTHs.

The aim of this study was to evaluate the benefit of pre-operative antibiotic prophylaxis with cefotaxime in the prevention of postoperative SSI in patients undergoing herniotomy, orchidopexy and PPV ligation.

METHODOLOGY

This was a Cohort study done in the Department of Paediatric Surgery, at the University Teaching Hospitals, Lusaka from June 2018 to June 2019. SSI was classified as per WHO guidelines into superficial, deep, and organ space infection. Patients under 8 years with inguinal hernia, hydrocoeles and cryptorchidism scheduled for elective surgery were included. A sample size of 166 patients was obtained using the open Epi sample size calculator for cohort studies.

Excluded patients were those with a recent non-reducible hernia, those known allergy to Cefotaxime and those with a recurrent hernia or those due for staged orchidopexy were excluded.

A systematic sampling was done. Every second patient due for the concerned operations was recruited till the sample size was achieved. Being an observational study, the selection criteria to determine which patient receive antibiotics was determined by the preference of the operating surgeon on their use of SAP for these operations.Patients were recruited by the principal investigator, after consent to operation was obtained and the patient was included on the operating list.

Standard operations of herniotomy, PPV ligation, and orchidopexy were done according to current practice in paediatric surgery at UTH. Patients had a regular morning bath with warm water. A single brand of Cefotaxime (Erixime) was used for all patients that received antibiotics during the study. Adverse reaction to pre-operative antibiotic were recorded in the data collection tool and patient's file. Pre-op cleaning with povidone iodine was done in theater. All wounds were dressed with sterile dressing post-operative.

Patients were told to remove the dressing on day 2 and to clean the wound with soap and water. A phone call to care givers on day 2 post operation was made to remind them hence ensure this is done on the specified day. No oral antibiotic was **given after the procedure.**

Reviews were done by surgeons to assess for SSI as defined in this study. The definition of SSI in this study was adopted from the 2017 CDC guidelines below for non-mesh/prosthesis abdominal wall/GIT operations.[2]

Superficial incisional SSI- Date of event for infection occurs within 30 days after surgical procedure AND involves only skin and subcutaneous tissue of the incision AND patient has at least one of the following:

a. Purulent drainage from the superficial incision.
b. Organisms identified from an aseptically-obtained specimen
c. Superficial incision that is deliberately opened by a surgeon or attending physician or other designee and culture or non-culture based testing is not performed. AND Patient has at least one of the following signs or symptoms: pain or tenderness; localized swelling; erythema; or heat.
d. Diagnosis of a superficial incisional SSI by the surgeon or attending physician or other designee.

Deep incisional SSI- Date of event for infection occurs within 30 days after the surgical procedure AND involves deep soft tissues of the incision AND patient has at least one of the following:

a. Purulent drainage from the deep incision.
b. A deep incision that spontaneously dehisces, or is deliberately opened or aspirated by a surgeon or

attending physician or other designee and organism is identified by a culture or non-culture based microbiologic testing method which is performed for purpose of clinical diagnosis or treatment or culture or non-culture based microbiological method is not performed patient has at least one of the following symptoms: fever (>38oC); localized pain or tenderness.

c. An abscess or other evidence of infection involving the deep incision that is detected on gross anatomical or histopathologic exam, or imaging test.

Organ/Space SSI -Date of event for infection occurs within 30 days after the surgical procedure AND infection involves any part of the body deeper than the fascial/muscle layers, that is opened or manipulated during the operative procedure AND patient has at least one of the following:

a. Purulent drainage from the drain that is placed into the organ/space
b. Organism identified from an aseptically-obtained fluid or tissue in the organ/space by a culture or non-culture based microbiologic testing method
c. An abscess or other evidence of infection involving the organ/space that is detected on gross anatomical or histopathologic exam, or imaging test evidence suggestive of infection.

When a SSI was identified, patients were treated as per current treatment practices of SSI in the department and swabs for microscopy, culture and sensitivity (M/C/S) obtained.

Statistical software STATA version 13 was used to analyse the Data. Rates of SSIs were calculated for those that received SAP and those that did not receive SAP. The rate of adverse reactions was also calculated for those that received SAP.

Bivariate analysis (using chi square test) of SAP with post-operative infection and occurrence of adverse effects was done. Univariate and multivariate logistic regression was done. Independent variables included age, weight, haemoglobin, WBC count, care giver education level, type of suture, type of incision, time of surgery and bilateral hernia. Dependent variables were SSI and adverse reactions to antibiotic.

RESULTS

A total of 170 participants were enrolled in the study between November 2018 and July 2019.

Table 1: Baseline Characteristics of study participants undergoing inguinal surgery

Characteristic		
	Category	Proportion n (%)
Gender	Male	154(90.6)
	Female	16(9.4)
Residence	Low Density	52(30.6)
	High Density	118 (69.4)
Caregiver education level	Primary	67(39.4)
	Secondary	53(31.2)
	Tertiary	50(29.4)
HIV status	Positive	3(1.8)
	Negative	167(98.2)
Z-Score (nutrition status)	-3	8(4.7)
	-1	13(7.7)
	0	120(70.6)
	1	16(9.4)
	3	13(7.6)

The majority of patients were males, with only 16 females with inguinal hernia. Most patients were residents of low-cost areas of Lusaka accounting for 69.4% of study participants. The Primary care giver had completed tertiary education in 29.4% of participants. Many participants were HIV negative. Only 1.8% were positive and on treatment. The majority of children were in the normal weight for age charts accounting for 87.7% of participants.

The patients in the study were between 5 and 96 months as shown in figure 4.1 below. The median age for males was 27 months (IQR 18-48 months) while the median age for females was 26 months (IQR 26-38 months).

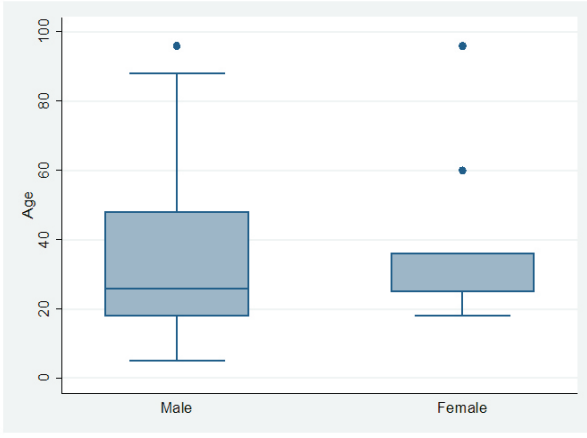

Figure 1: Age distribution between male and females in months

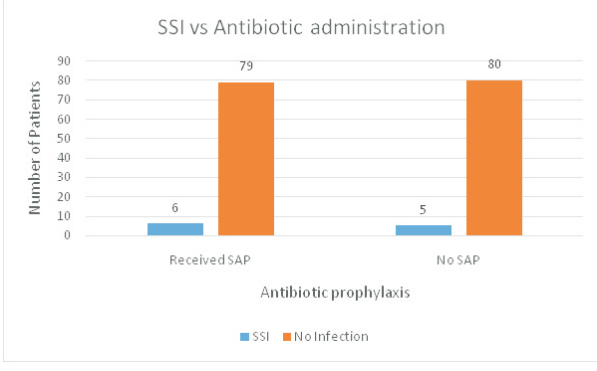

Figure 2: Association between SAP administration and presence of SSI

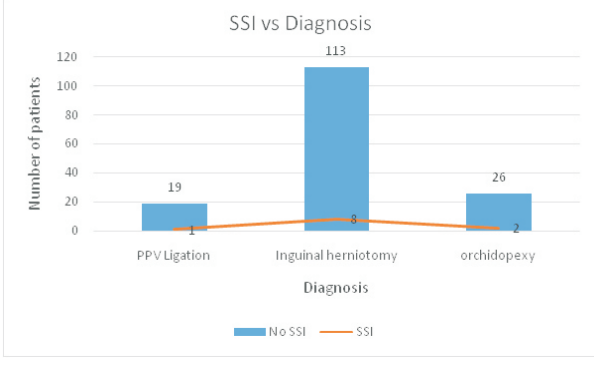

Figure 3: SSI among the various surgical procedures done.

The infection rate was the highest in the patients that had orchidopexies done with an overall infection rate of 7.1%. The infection rate for PPV ligation was 5.26% while it was 6.6% in patients with inguinal hernias as seen in figure 3.

Table 2: Association between types of SSI and SAP.

	No infection	Superficial SSI	Deep SSI	Organ space	Total
Group A: SAP	79	6	0	0	85
Group B: No SAP	80	3	2	0	85
	159	9	2	0	170
Pearson Chi Square 2.98		P Value Overall: 0.225			
		P Value Deep SSI: 0.155			

Of the 11 cases of SSI seen, 9 were superficial SSIs and 2 were deep infections. The patients that had deep infections did not receive SAP.

Table 3: Multiple logistic regression analysis of the association between SSI and pre-operative variables.

Variable	Univariate			Multivariate	
	OR	95% CI	P value	95% CI	P Value
Gender	1	-	-	-.08-0.18	0.439
Age	1.075	1.14-4.77	**0.020**	-0.08-0.18	0.439
Address	6.5	0.37-1.33	**0.012**	0.11-0.32	**0.000**
Education Status	2.04	0.85-4.87	0.109	0.01-0.12	0.11
Z score	0.72	0.41-1.24	0.239	-0.56-0.17	0.294
Hb	2.1	1.32-3.34	**0.035**	-0.01-0.68	0.157
WBC	1.05	0.97-1.14	0.254	-0.53-0.08	0.379
HIV Status	1	-	-	-0.53-0.07	0.144
Diagnosis	1.05	0.14-1.68	0.255	-0.11-0.04	0.342
Laterality	0.56	0.14-2.20	0.407	-0.16-0.33	0.192
Position of Testes	2.3	0.71-7.8	0.159	-0.42-0.22	0.081

No female patients post inguinal hernia repair developed an SSI. All the cases of SSI were in HIV negative patients. Age was a significant factor

associated with SSI on univariate analysis with p value of 0.02. Nine of the 11 patients that developed an SSI were between ages 6- and 7-months' age.

Increased infections in patients staying in a low-density area (13.4%) compared to high density area that had a surgical site infection rate of 4.2%. A Haemoglobin value of less than or equal to 10.4g/dl was associated with increased SSI.

Table 4: Multiple logistic regression analysis of the association between SSI and intra perioperative variables

Variable	Univariate			Multivariate	
	OR	95% CI	P value	95% CI	P Value
Antibiotic	1.43	0.43-4.7	0.551	-0.646-0.085	0.646
Time of day	2.25	0.27-18.1	0.447	-0.056-0.22	0.237
Time Interval	0.99	0.87-1.12	0.905	-0.011-0.007	0.623
Type of skin incision	0.14	0.003-5.7	0.298	-0.43-0.02	0.081
Aponeurosis incision	0.17	0.003-7.5	0.356	-0.23-0.16	0.731
Suture on sac	2.52	0.4-15.2	0.313	-0.04-0.12	0.308
Sac excision	1.15	0.11-12.3	0.906	-0.14-0.22	0.643
Duration of surgery	1.06	096-1.17	0.220	-0.004-0.007	0.613

There was only one case of an adverse reaction to SAP representing rate of 1.17% among the 85 patients that received SAP. This was an allergic reaction post administration of cefotaxime identified as a rash around the intravenous (IV) cannula and left hand just after the drug was given. This was treated with hydrocortisone and simple observation. The patient did not present with an SSI at review. There was no statistical significance at bivariate analysis (P= 0.699 95% CI) of occurrence of adverse reaction and reduction SSI prevention in the patients that received antibiotics.

DISCUSSION

The overall rate of SSI in the study was 6.47%. This was comparable to studies done by Ekpemo et al who had an overall infection rate of 6.35%.[16] Our infection rate was much lower than Ibrahim et al[17] that had an infection rate of 9.27% for inguinal surgeries in children. It was also much less than the review by Ameh et al[6] that showed children in Africa undergoing clean elective surgeries having infection rates up to 14.3%. It was lower when compared to Shirimpaka et al[14] that showed SSI of 8.7% at our institution in clean surgeries in adults.

Our infection rate was higher than most other studies in developing countries. Vaze et al from India, Kekre et al, Dhakne from India, Joda from Iraq and Osuigwe from Nigeria that had infection rates of 2.89%, 0.4%, 2%, 3.3% and 4.7% respectively.[5,18,19,20,21] Of note, most of these studies did not use the WHO or CDC definitions of SSI in their studies hence may have led to some variations in recoding of outcomes as highlighted.[5] Lee et al[22] reported no SSI in their study.The studies from developed countries showed much lower SSI rates. Rensing et al[9] found and SSI rate of 0.1% and Kwok et al[23] found an infection rate of 2%.

Most of the SSI in this study were superficial SSIs. Only 2 of the 170-patient developed deep SSI. Most other studies as most did not classify infections as superficial and deep.[5,16]

The SSI rate in the group that received pre-operative cefotaxime was 7.05% compared with 5.89% in the group that did not receive cefotaxime. There was no statistical significance in this difference hence no overall benefit was noted in prevention of SSI with use of pre-operative cefotaxime in inguinal surgery in children. This finding was in keeping with literature from developed countries as well as some in African studies with similar demographic characteristics of participants.[5,9,20,21,24,25] Our results were in contrast to Usang et al[26] in Nigeria who had noted a benefit in reduction of SSI when using pre-operative antibiotics for herniotomies. This could have been due to an overall lower rate of SSI of 4.8% and a smaller sample size of 88 patients in their study.

Nine patients in the study had superficial SSIs. These were treated without antibiotics with emphasis given to parents on wound care. They all healed with minimal scaring at 30-day review.

There were 2 cases of deep SSI occurring in the group that did not receive pre-operative antibiotics. These patients received a course oral Cloxacilllin upon making the diagnosis of the SSI. Swabs that were collected in these two patients found *Staphylococcus aureus* as the causative organism and were sensitive to penicillins, and cefotaxime. *Staphylococcus aureus* was also the causative organism in other similar studies.[14,26,27]

Our choice of antibiotic was Cefotaxime. A single brand(Erixime) was used in the study patients that received this antibiotic. It is broad spectrum antibiotic that is the current choice of antibiotic for SAP at UTH in patients undergoing clean general surgical operations. Cephalosporins have been used in other studies for the inguinal surgeries in other studies.[16] Some studies used Ampiclox and Gentamycin.[20,28]

The main controlled factor in the study-antibiotics-did not show any significance in reduction of SSI in the study population (P= 0.551). On univariate regression analysis, age was a significant factor (P=0.02) that was associated with the occurrence of SSI. Age less than or equal to 7 months was a higher risk for developing SSI in our study. This observation was not significant on multivariate analysis however. This finding was similar to Usang et al[28] that showed more SSI in pre-school children compared to school going children, though exact ages were not specified.

The residence of patients was significantly associated with SSI. Patients that resided in high density areas were less susceptible to SSI than those that stayed in low density areas. This showed that the social class of patients did not correlate to SSI. A possible explanation for this could be due to less antibodies in patients from low density areas as they have had very few exposures to infecting organisms in the past. This was in contrast to Ekpemo et al[16], however was in agreement with the study showing that SSI were unrelated to caregivers education level. In this study, SSI were not significantly associated with the education level of the primary care giver.

The pre-operative haemoglobin of less than 10.4g/dl was significantly associated with SSI on univariate analysis. The sensitivity and the specificity of having an SSI with an Hb of less than 10.4g/dl was 81% and 62% respectively.The difference in infection rates amongst the specific surgical procedures, i.e., herniotomy, orchidopexy and PPV ligation was not significant P=0.255. This lack of association was noted in other studies as well.[5,24] The interval between antibiotic administration and incision ranged from 1 to 33 minutes. The mean was 10.7 minutes (95% CI 9.1-12.4 minutes). The exact duration of antibiotic administration prior to incision was not significantly associated with SSI in this study P=0.905.

There was one case of adverse reaction to pre-operative cefotaxime representing an adverse reaction rate of 0.59% in the study population. The study was designed to look out for immediate adverse reactions that are of an allergic type only. The particular adverse reaction did not increase length of post-operative stay for the patient. The incidence in this study was much lower than the 1.4% found by Rensing et al.[9] This difference could be because of long term adverse reaction monitoring that was included in their study.

One of the limitations of this study was that only anaphylactic adverse reactions to cefotaxime were investigated. Long term adverse effects such as Clostridium difficile diarrhoea were not investigated.The lack of a formal randomization of patients in the study was a limiting factor as well.

CONCLUSION

The rate of SSIs in patients that received pre-operative antibiotic prophylaxis with cefotaxime

was 7.06 % while it was 5.9% in those that did not receive cefotaxime. There was a higher rate of deep SSI in the patients that did not receive SAP with cefotaxime. These associations were not statistically significant hence SSI rates were not reduced using SAP with cefotaxime and their routine use is unwarranted in our environment.

There was no significant anaphylactic reaction when using cefotaxime as an antibiotic for pre-operative prophylaxis. The factors that were significantly associated with an increased incidence of SSI were patients that lived-in low-density areas and patients with an age of less than 7 months.

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