

A comparative study of the effect of prophylactic intravenous antibiotics and triclosan-coated sutures in the prevention of surgical site infection in pediatric groin surgeries

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Abstract

Background

Surgical site infections (SSIs) continue to occur following clean pediatric groin surgeries, despite being considered low-risk procedures. Various preventive measures have been explored to reduce this morbidity.

Objectives

This study aimed to compare the effectiveness of a single-dose prophylactic intravenous antibiotic regimen with triclosan-coated suture material in preventing SSI in pediatric groin surgeries.

Materials and Methods

A prospective comparative study was conducted on pediatric patients who underwent repair of inguinal hernias or hydroceles at the University of Nigeria Teaching Hospital (UNTH), Enugu. Participants were assigned to two groups: Group A received wound closure with triclosan-coated polyglactin-910 (Vicryl-Plus), and Group B received a single preoperative intravenous dose of ampicillin/cloxacillin 30 minutes before incision. All patients were followed up for 30 days. Data were analyzed using IBM SPSS version 21.0. Categorical variables were summarized using frequencies and percentages, while continuous variables were analyzed using means and standard deviations. Chi-square tests assessed associations between categorical variables, and T-tests compared means. Statistical significance was set at $p < 0.05$.

Results

A total of 96 groin surgeries were performed on 86 patients, including 10 bilateral hernia repairs. There were 63 males (73.3%) and 23 females (26.7%). Forty-one (47.7%) had unilateral inguinal hernias, 10 (11.8%) bilateral hernias, and 35 (40.7%) hydroceles. Only one SSI (1.0%) occurred, observed in the antibiotic group ($\chi^2=1.011$, $p = 0.315$). Seroma occurred in 2.1% (1/48) of the Vicryl-Plus group and 4.2% (2/48) of the antibiotic group ($\chi^2=0.344$, $p = 0.557$). The SSI was superficial and resolved with an alternate-day dressing.

Conclusion

Triclosan-coated sutures and single-dose antibiotics showed similarly low SSI rates in pediatric groin surgeries. The only SSI occurred in the antibiotic group. Triclosan-coated sutures may reduce antibiotic use without compromising outcomes.

Introduction

Surgical site infections constitute up to 20% of all healthcare-associated infections, and at least 5% of patients undergoing a surgical procedure develop a surgical site infection [1]. It is known that this incidence varies depending on the surgical procedure, the surveillance criteria used, and the quality of data collection [2]. Antibiotic prophylaxis is of significant benefit where the surgical site infection rate is greater than 5% [3, 4]

At the University of Nigeria Teaching Hospital, single-dose prophylactic antibiotics are used routinely for pediatric groin surgeries. The prevailing environment and risk of surgical site infections fuel this practice. Despite the prevalence of surgical site infection in our environment, there is a paucity of research on the prevention of surgical site infection in children, especially in the use of antimicrobial-coated sutures for surgical wound closure. This intervention has been reported to be effective in preventing surgical site infection. Hence, this study compares the effects of prophylactic intravenous antibiotics and antimicrobial-coated suture in the prevention of surgical site infection in pediatric groin surgeries.

Methods

The study aimed to determine the effect of antimicrobial-coated sutures on postoperative surgical site infections compared with prophylactic intravenous antibiotics. This was a prospective comparative randomized study carried out on pediatric patients who were operated for uncomplicated inguinal hernias and hydroceles at the pediatric surgery unit of the University of Nigeria Teaching Hospital, Ituku/Ozalla, Enugu, between 1st May 2016 and 31st August 2017. At UNTH Enugu all patients undergoing herniotomy received a single-dose prophylactic intravenous ampicillin/cloxacillin antibiotic combination. This study compares the effectiveness of a single-dose prophylactic intravenous ampicillin/cloxacillin combination and triclosan-coated Vicryl suture (Vicryl-plus) in preventing surgical site infection in day-case groin surgeries in children. Vicryl sutures used were of the Ethicon brand by Johnson and Johnson, while ampicillin/cloxacillin used was Labaclox from Laborate Pharmaceuticals, India. Ethical clearance was obtained from the Hospital Research and Ethics Committee of the University of Nigeria Teaching Hospital, Ituku/Ozalla. Written informed consent was obtained from the patients' parents or guardians.

Subject Selection

Participants were included in the study if they were patients aged 2 months to 15 years, were admitted for an elective groin surgical procedure, had uncomplicated inguinal hernias or hydroceles, and informed consent was obtained from parents or responsible caregivers. Exclusion criteria included patients aged less than 2 months, presence of generalized debilitating disease, sickle cell disease patients irrespective of their status, history of use of antibiotics within the past seven days, history of allergy to penicillin antibiotics, associated undescended testis, and those for whom the parents or caregivers were not willing to give consent.

Participants who met the study criteria were recruited consecutively. A research assistant conducted simple random sampling using a double-blind approach. Eighty-six (86) sealed envelopes were prepared, forty-three (43) containing folded papers labeled A and forty-three (43) containing folded papers labeled B. Group A represented participants who would be on Vicryl-plus, while Group B represented those who would be on intravenous antibiotics. The envelopes were mixed thoroughly in a bag before a participant was asked to pick one, and the process was repeated for every patient to maintain randomization. After it was picked, the envelope was not returned to the bag. Participants were grouped according to the envelope they picked up.

Sample Size Calculation

A pilot study at UNTH Enugu showed an average of 96 (SD 7.75, approximated to 8) for uncomplicated inguinal hernia and hydrocele surgeries per year. Armed with information, sample size (n) was calculated using the formula [5]

$$n = 2[(Z_{\alpha} + Z_{\beta})\delta/d]^2$$

where $Z_{\alpha} = 1.96$, $Z_{\beta} = 0.84$, $\delta = 8$, and $d = 5$. The estimated sample size was about 40 per group. The total sample size was set at 80, with 6 extra participants added for attrition, resulting in a final sample size of 86.

Pre-operative preparation

Patients who had a respiratory tract infection, diarrhea, or fever were treated before joining the study. Following the diagnosis, caregivers were counseled on the diagnosis and treatment plan explained to them. The patient's hemoglobin levels and genotypes (for those of age six months and above) were obtained. Those with hemoglobin levels of less than 9g/dl had their hemoglobin level optimized, while patients with SS genotypes were excluded. Patients for the study had their biodata, history, and clinical examination findings documented in their folders at first presentation to the pediatric outpatient clinic. The anesthesiologists reviewed the patients and confirmed their fitness for general anesthesia.

Informed consent was obtained for the study and for the surgery. Pre-admission information given to the caregiver included: the date and time of the surgery, preoperative fasting guidelines (6 hours for solid foods, 4 hours for breastmilk or formula, and 2 hours for clear fluids using 8 am as the reference time), and advice on personal hygiene. They were also notified of the possibility of admission for observation should it become necessary post-operatively; otherwise, patients would be discharged home following full recovery from anesthesia, and were free to report to the Children's Emergency Room if they developed any problems related to the surgery at home. This was communicated to the parents and caregivers in a written leaflet.

Surgical technique

The surgeries were done under general anesthesia (GA) with endotracheal intubation and multi-channel monitoring. Participants in Group B received a single dose of ampicillin/cloxacillin antibiotics (50mg/kg) 30 minutes before skin incision. The surgeon, assistant, and scrub nurse were scrubbed and gowned appropriately. Each patient was positioned supine, and the operation fields were cleaned with 0.5% chlorhexidine solution in water and subsequently dried with sterile gauze. The skin preparations were completed with 7.5% povidone iodine solution. A low transverse inguinal skin crease incision was made (about 3-4cm length) with the medial end above and lateral to the pubic tubercle. Hemostasis was achieved with electrocautery. The incision was deepened with diathermy (in cutting mode with needle point electrode) through the Camper's and Scarpa's fasciae until the external oblique aponeurosis was seen.

Further dissection inferiorly and laterally on the external oblique was done to expose the external inguinal ring, and the spermatic cord was identified and delivered into the wound. For older patients, the external oblique muscle aponeurosis was opened in the direction of its fibers up to the deep ring. The coverings of the cord were bluntly dissected on the antero-medial surface to expose the hernia/hydrocele sac (patent processus vaginalis). The vas deferens and spermatic vessels were identified and protected from injury. The sac was then divided between two artery forceps, and the proximal segment of the sac was dissected proximally up to the internal ring (until preperitoneal fat was seen). The empty sac was twisted and transfixed with either 3/0 Vicryl Plus or 3/0 standard Vicryl, depending on the study group. Transfixing and ligation of the hernia or hydrocele sac was done with Vicryl-plus for Group A, and standard Vicryl for Group B. The distal end of the sac was completely or partly excised, and the testis was returned to its hemiscrotum.

Wound closure

Patients in study Group A had their superficial fasciae approximated with Vicryl plus 3/0, and a continuous subcuticular closure of the skin was performed with Vicryl plus 3/0. In Group B, the superficial fasciae were approximated with standard Vicryl 3/0, and a continuous subcuticular closure of the skin was performed with standard Vicryl 3/0. Wounds in both groups were cleaned with an antiseptic solution and dried before application of dry gauze wound dressing.

Postoperative care

Post-operatively, every patient received 15mg/kg of oral paracetamol, either as syrup or tablets, eight-hourly for three days. Patients were discharged home the same day (Day case surgery) after full recovery from anesthesia with stable vital signs and general conditions, and scheduled for follow-up at the Pediatric Surgical Out-Patient clinic.

After full recovery from anesthesia, patients with stable vital signs and a satisfactory general condition were discharged home on the same day. Caregivers received instructions on the discharge process and

monitoring at home for any postoperative complications. Every patient was scheduled for follow-up visits at the Pediatric Surgical Outpatient Clinic. The surgical wounds were examined after 7, 14, and 30 days postoperatively. Patients were followed up for a period of 6 weeks, during which wound healing was assessed through regular clinical examinations and documentation of any signs of infection or wound breakdown. Contact phone numbers were obtained from Caregivers in case of any failed appointments. The wounds were assessed for the primary endpoints, incisional (superficial and deep) surgical site infections, in line with the Centre for Disease Control (CDC) criteria for defining surgical site infections, and for wound dehiscence. All patients were evaluated by another pediatric surgical Senior Registrar who was blinded to the study groups.

Data Collection

A proforma was used for data collection. Data collected included: age, sex, hospital number, weight, phone number, diagnosis, investigations, surgical procedure, treatment group, and postoperative wound complications.

Statistical Analysis

The data were entered into and analyzed with IBM SPSS (Statistical Package for Social Sciences), version 21.0 (IBM Corp, Armonk, NY, USA). Median values and standard deviation were obtained for age. Means were compared using the Student's t-test. In cases where the data were skewed, such as age, the Mann-Whitney U-test was employed. A chi-square test was conducted to assess the homogeneity of proportions and to examine the independence between categorical variables of interest. The level of statistical significance was set at a P-value of less than 0.05.

This study adhered to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline for cohort studies to ensure completeness, transparency, and methodological rigor in reporting.

Results

Eighty-six patients participated in this study, and none defaulted. Of the 86 patients, 63(73.3%) were males, and 23(26.7%) were females, giving a male-to-female (M:F) ratio of about 2.7:1. (Table 1)

Table 1: Sex distribution of patients in the two study groups

The majority of the participants in the Vicryl-plus group (68.8%) as well as the antibiotic group (83.3%) were males ($\chi^2=2.802$, $p=0.094$) The overall mean age was 4.2 ± 3.7 years (Range: 0.2-15years). The mean age in the Vicryl-plus group was 4.1 ± 3.8 (Range: 0.2-15years) and the mean age in the antibiotic group was 4.4 ± 3.6 years (Range: 0.3-15years), (Mann-Whitney U-test, $p=0.710$). The median age in both the Vicryl-plus and antibiotic groups was 3years (Table 2).

A total of 96 groin surgeries were performed in 86 patients; 10 had bilateral inguinal hernias. Of 96 groin surgeries performed, 48 were in the Vicryl-plus group and 48 in the antibiotic group. The age distribution of patients who underwent surgery in both treatment groups showed that the majority of procedures 32 (66.7%) were performed on patients aged five years and younger. In contrast, the smallest proportion in both groups was observed among patients aged eleven years and above, as shown in Table 3.

Statistical analysis indicated that this variation in age distribution between the groups was not significant, with a chi-square value of 0.183 and a p-value of 0.913.

Forty-one (47.7%) of the patients had unilateral inguinal hernias, 10 (11.6%) had bilateral inguinal hernias, and all 35 (40.7%) cases of hydroceles were unilateral. The 10 cases of bilateral inguinal hernias were seen in the age group aged 2months-5years. The majority of the unilateral inguinal hernias, 30 (34.9%), and hydroceles, 19 (22.1%), were right-sided, 11 (12.8%), and hydroceles, 16 (18.6%), were on the left (Figure 1) and (Table 4)

Out of the 96 surgeries performed, the highest proportion performed in the Vicryl-plus group, 24\48 (50.0%) and the antibiotic group, 16\48(33.3%), were for right-sided inguinal hernias. Fewer surgeries were performed on the left 5\48 (10.4%) in the Vicryl-plus group and 8\48 (16.7%) in the antibiotic group. This difference was not statistically significant. ($\chi^2=7.619$, $p=0.055$).

The overall mean hemoglobin value of participants was 11.6 ± 1.4 g/dl (Range: 9.2-16.1). For the Vicryl-plus group, it was 11.5 ± 1.3 g/dl, the antibiotic group was 11.8 ± 1.4 g/dl (Student $t=1.333$, $p=0.186$).

Wound outcome

Overall, two sets of complications were recorded and occurred in 4 (4.2%) participants. Of these, 1 (1%) was a superficial surgical site infection, and this was in the antibiotic group 1/48 (2.1%). No infection was observed in the Vicryl-plus group. Three postoperative seromas occurred, 2.1% (1/48) in the Vicryl-plus group; 4.2% (2/48) in the antibiotic group. The difference was not statistically significant ($\chi^2=0.344$, $p=0.557$). (Table 5) The superficial surgical site infection was detected on day 4 post-operation and resolved within 7 days on alternate-day saline dressings. Seromas were diagnosed at the first postoperative visit, and all cases resolved spontaneously.

Discussion

This study primarily compared the effect of prophylactic intravenous antibiotics and antimicrobial-coated suture in the prevention of surgical site infection in pediatric groin surgeries.

The predominance of participants aged 5 years and younger aligns with previous studies on pediatric inguinal hernia by Usang et al. [6] and Shah et al. [7] Another observation from the study was that inguinal hernia and hydroceles occurred more on the right side, which agrees with similar studies on inguinal hernia and hydroceles. [8, 9] This is due to the delayed descent of the right testicle during the

intra-uterine life. This study also demonstrated that there were more cases of inguinal hernias than hydroceles. This is likely due to the spontaneous regression of some hydroceles before the age of two years. [10]. There is a predominance of males with inguinal hernia and hydroceles than females, which is in keeping with the observations made by Parveen et al. [11] and Erdogan et al. [12] in their studies involving inguinal hernias and hydroceles. The male-to-female ratio of 2.7:1 in the present study is slightly lower than the 3.6:1 reported by Erdogan et al. [13] This difference in ratio may likely be due to the smaller sample size of this study when compared to the Erdogan et al. study, where 3776 children were studied.

The overall low incidence of surgical site infection of 1% noted in this study may be accounted for by the effectiveness of both antimicrobial agents used in reducing surgical site infection. A study by Ibrahim et al in Kano on open herniotomy in 428 children documented wound infection rate of up to 8.73% without use of any antimicrobial agent during the surgery [13] while a comparative study by Usang et al. in Ile-Ife Nigeria reported that use of prophylactic antibiotic significantly reduced the incidence of surgical site infection when compared with the study arm that did not receive any antimicrobial agent during herniotomy. [4] However, the studies by Ekpemo et al. [14] in Nigeria and Vaze et al. [15] in India observed a lower incidence of surgical site infections in those who received preoperative antibiotics compared to those who did not receive antibiotics during herniotomies, but the findings were not statistically significant.

Renko et al., working on clean pediatric surgeries in Finland, reported a surgical site infection rate of 3% in the study group when triclosan-coated suture was used in the surgical wounds, and 6% rate of wound infection when wounds were closed with standard suture without the use of antibiotics. [16] Similarly, in a single-arm study by Samra et al., 149 participants with clean surgical wounds closed with triclosan-impregnated suture recorded a surgical site infection rate of 0.7%, [17] which is comparable to the findings in this study in wounds closed with Vicryl plus suture. Likewise, another study in Egypt discovered that triclosan-coated sutures reduced the rate of surgical site infection from 15% to 7%, although the study was in adults with clean surgical wounds. [18] This buttresses the findings in the present study demonstrating the value of triclosan-coated suture in reducing surgical site infections. Ahmed et al., in their systematic review and meta-analysis on triclosan-coated suture, also reported the effectiveness of triclosan-coated sutures in reducing surgical site infections in clean surgical wounds, as was obtained in this study and in contaminated surgical wounds. [19] In pediatric cerebrospinal shunt surgery, Rozzelle et al. [20] demonstrated a 4.3% rate of surgical site infection when antimicrobial suture was used for wound closure and 21% rate of surgical site infection when this technique was not used. This observation agrees with in vitro and in vivo studies on triclosan-coated sutures, which showed that triclosan can inhibit bacterial colonization of sutures and eliminate bacteria associated with surgical site infections. [21, 22]

The study indicates that seroma can occur following open herniotomy irrespective of prophylactic intravenous antibiotic or triclosan-coated suture, with an overall incidence rate of 3.1%. This rate contrasts with findings by Askarpour et al., who reported a 0.4% rate of seroma [23] and Ibrahim et al.,

who documented a 1.32% rate of seroma during herniotomy in children. [24] The observance by Askarpour et al. could be due to the retrospective nature of their study, with attendant difficulties with data retrieval.

The main limitations of this study were the relatively small sample size and its single-institution nature.

Conclusion

The results of the study indicate that triclosan-coated suture and prophylactic intravenous antibiotics reduced the incidence of surgical site infections in pediatric inguinal incisions for hydroceles and hernias. The observed difference in favor of triclosan-coated suture was not statistically significant. The occurrence of wound seroma was not significantly different between the two groups. Surgical site infections that occurred resolved without significant morbidity following outpatient wound care.

Recommendations

Based on the findings of this study, triclosan-coated Vicryl sutures alone may serve as an effective alternative to prophylactic intravenous antibiotics in settings where surgical site infection rates remain elevated following pediatric groin surgeries. This approach may help to reduce antibiotic usage, thereby minimizing the risk of antibiotic-resistant bacteria and drug-induced side effects. Further research with larger sample sizes and multi-institutional designs is recommended to strengthen the evidence base.

Declarations

Author Contributions: EIN, EPN, UOE, and SOE, contributed to the conception, data collection, analysis of the work, and writing of the paper. CCA, ICO, ONA, and IOI were involved in the first critical review of the paper. All authors undertook the final revision of the paper.

Ethical approval: Ethical clearance was obtained from the University of Nigeria Teaching Hospital Research and Ethics Committee. Approval number: NHREC/05/01/2008B-FWA00002458-1RB00002323, Date: 21st October, 2015.

Informed consent: Written informed consent was obtained from the patients' parents or guardians before enrolment into the study.

Declaration of Helsinki: The study was conducted according to the ethical principles of the Helsinki Declaration of 1975, as revised in 2013.

Availability of research data: The data is available upon request through the corresponding author.

Clinical Trial Number: Not Applicable.

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Conflict of Interest Statement. The authors declare no conflict of interest.

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Tables

Tables 1 to 5 are available in the supplementary files section

Figures

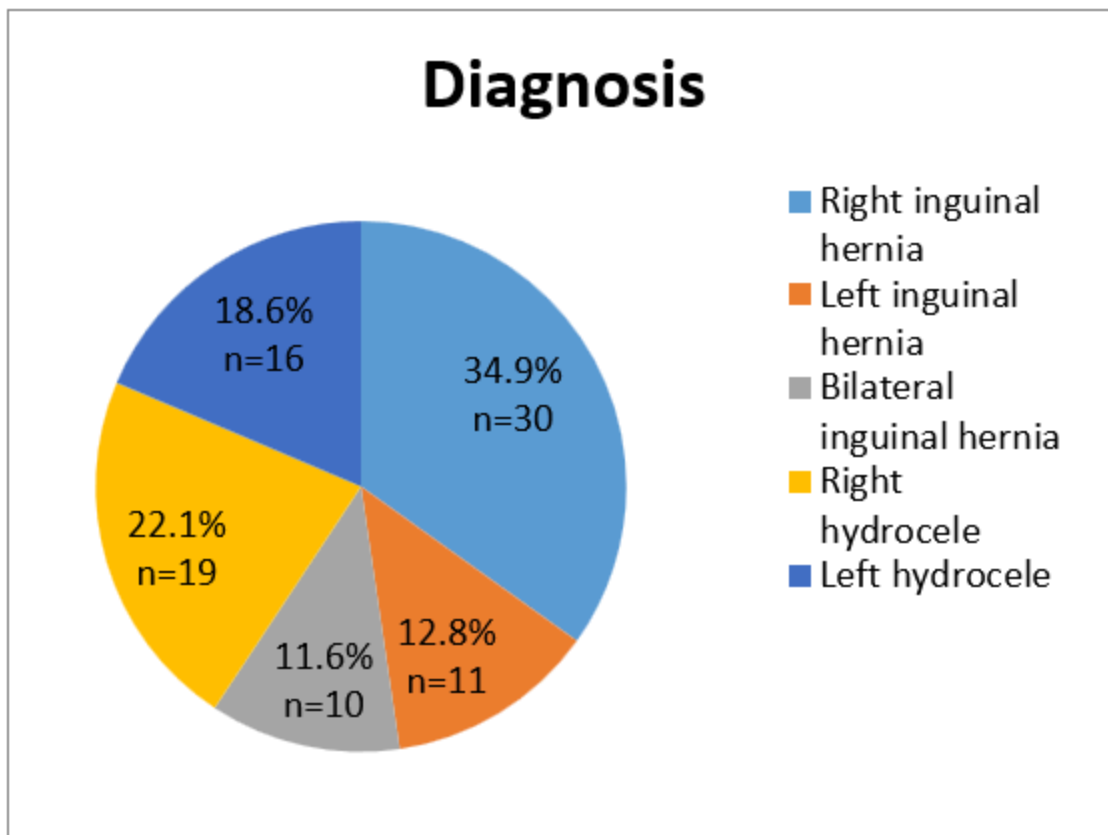


Figure 1

Pie chart showing the diagnosis of the patients

Supplementary Files

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