African Urology 2025;5:98-103
https://doi.org/10.36303/AUJ.0235

AFRICAN UROLOGY
ISSN 2710-2750 EISSN 2710-2750

ORIGINAL RESEARCH

Comparing the antibacterial effectiveness of chlorhexidine and methylated spirit with povidone-iodine and methylated spirit for skin preparation in paediatric groin surgeries

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Background: Surgical site preparation is a standard part of the preoperative preparations done to reduce contamination of the surgical wound by skin-borne bacteria. This research aimed to determine the antibacterial effectiveness of two skin preparation methods (0.3% chlorhexidine and 3% cetrimide scrub, followed by 70% methylated spirit paint, and 7.5% povidone-iodine in 70% methylated spirit scrub and paint) for groin surgery in paediatric surgical patients. The study compared the antibacterial effectiveness of both preoperative skin preparation methods in paediatric groin surgery in Ile-Ife, Nigeria.

Methods: This was a prospective, parallel group, randomised trial, without any control, of children aged between one day and 15 years, who required elective groin surgery. The patients were recruited from the paediatric surgery outpatient clinic of Obafemi Awolowo University Teaching Hospitals Complex (OAUTHC). The patients were manually randomised into two arms. The patients' groin skin at the site of the proposed surgery was swabbed with two moistened swab sticks at anaesthesia induction before skin preparation, three minutes after skin preparation, and at the end of the surgery. The samples collected were cultured. Data were analysed using the Statistical Package for the Social Sciences (SPSS) version 20. Data were expressed as the mean and standard deviation as required. A criterion of $p < 0.05$ was used to determine statistical significance.

Results: A total of 70 patients were recruited for the study. The patients' age range was two months to 15 years, with a mean of 4.66 years. There were 63 males (90%) and seven females (10%), resulting in a male-to-female ratio of 9:1. Both skin preparation methods significantly affected the bacterial colony count, as demonstrated by McNemar's chi-square test.

Conclusion: This study's findings indicate that both skin preparation methods have significant antibacterial effects, with no statistically significant difference in their antibacterial effectiveness.

Keywords: antibacterial effectiveness, chlorhexidine, povidone-iodine, paediatric groin surgeries

Introduction

Surgical site infections (SSI) occur in up to 15% of all patients undergoing surgery and are associated with significant morbidity and mortality, including increased length of hospitalisation, further surgical procedures, prolonged antibiotic use, a negative impact on quality of life, and increased in-hospital costs.[1-4] Antibiotic use to prevent or treat infections leads to the generation of increasingly antibiotic-resistant bacteria almost as quickly as the antibiotics are introduced.[5,6] Some authors found that SSI prevention may substantially decrease morbidity and mortality, improve patient outcomes, and reduce the economic burden of the healthcare system.[7]

Human skin is colonised with millions of bacteria and is the major source of infectious pathogens, including *Staphylococcus* spp.[3,8] The bacteria usually migrate from the deeper layers of the skin into the surgical wound. The hollow viscera, if breached, can also be a source of wound contamination. Breaches of aseptic technique are also contributory. *Staphylococcus* and *Corynebacterium* spp. are the most abundant organisms colonising the groin, consistent with culture data suggesting that these organisms prefer areas of high humidity.[9,10]

Disinfectant use for preoperative skin preparation is an important intervention aimed at reducing the risk of acquiring SSIs. Several studies have shown that it decreases the concentration of bacteria colonising the skin. However, the effectiveness varies with the formulation or concentration, and the effective contact period on the skin. The use of skin antisepsis is recommended by professional and public health organisations, such as the Centers for Disease Control and Prevention (CDC), World Health Organization (WHO), and the National Institute for Health and Care Excellence (NICE).[10-12]

The three main agents commonly used for surgical skin antisepsis are chlorhexidine gluconate (CHG), iodophor, and alcohol.[3,13] Alcohol is frequently combined with CHG or iodophor to optimise the activity of the surgical skin antisepsis. These agents are well tolerated, and adverse reactions (predominantly mild skin reactions) are rare, occurring in < 1% of patients.[14]

The CDC and the French Society for Hospital Hygiene guidelines recommend using an alcohol-based skin preparation for patients; however, they do not prescribe any antiseptic agent over another.[3] The WHO and the NICE guidelines recommend chlorhexidine-alcohol as the first-line antiseptic agent for surgical site preparation,

unless contraindicated.[12,15] However, this recommendation is controversial, as some authors write that it is unclear which antiseptic agent is better when comparing chlorhexidine with povidone-iodine, based on current evidence.[16]

Iodine, which oxidises sulfhydryl groups and affects microbial protein structure and function, was used in the operating room for decades but is no longer favoured due to its propensity for skin allergies.[17] Chlorhexidine functions by destroying the bacterial cell membrane. Both antiseptic agents decrease bacterial count, and thus the risk of SSI. The effectiveness of these agents in comparison to one another in preventing SSI is not well documented (or studied) in Nigerian children undergoing groin surgery. Most groin surgeries are clean surgeries, and a low incidence of SSI is expected.[18] The common groin surgeries that we performed include herniotomies, orchidopexies, and hydrocelectomies.

Preoperative skin antisepsis is performed to reduce the risk of developing postoperative wound infections by removing transient organisms from the skin. Antiseptics are thought to be both toxic to bacteria and aid their mechanical removal. The effectiveness of preoperative skin preparation is thought to depend on both the antiseptic used and the method of application; however, it remains unclear which antiseptic is most effective.[16,18]

This study compared the effectiveness of 0.3% chlorhexidine and 3% cetrimide scrub, followed by 70% methylated spirit paint, with 7.5% povidone-iodine in 70% methylated spirit scrub and paint in preventing bacterial skin contamination in elective groin surgery. Other aims were to compare the bacterial colony count immediately before surgery, immediately after skin preparation, and immediately after surgery. The rate of SSI after elective groin surgery was also compared between the two groups, although the study was not powered to detect any statistically significant differences between the two arms for SSI.

Materials and methods

All the eligible patients had a thorough preoperative history and physical examination at the outpatient clinic of the Paediatric Surgery Unit, Department of Surgery, Obafemi Awolowo University Teaching Hospitals Complex (OAUTHC), Ile-Ife, Osun State, Nigeria. Patients were counselled to use non-medicated soap for their baths during the week before surgery. Hand scrubbing was done with CHG skin cleanser according to the unit's protocol.

Patients were manually randomised and assigned in a 1:1 ratio to have the skin at the surgical site preoperatively scrubbed with three sponge sticks soaked in 0.3% chlorhexidine and 3% cetrimide, then dried with sterile 2 × 2 inch gauze, and 70% methylated spirit applied using a sponge stick, or preoperatively scrubbed and then painted with a solution of 7.5% povidone-iodine in 70% methylated spirit on sponge sticks.

The 7.5% povidone-iodine in 70% methylated spirit was prepared by mixing equal volumes of 7.5% povidone-iodine and 70% methylated spirit. A contact time of three minutes was observed for each method. Randomisation was performed with replacement using an envelope containing two different cards, one for each skin preparation method. The current practice of skin preparation is at the surgeon's discretion, but usually one of the two methods is adopted.

$$s = \sqrt{\frac{\Sigma(xi - \bar{x})^2}{n-1}}$$

The skin swab samples (two per stage, per patient) were collected immediately before skin preparation, three minutes after skin preparation, and immediately after surgery, before wound cleaning. The wounds were closed with polyglactin sutures using the subcuticular technique. The wounds were dressed with dry, sterile gauze and covered with adhesive plaster for protection. Caregivers were instructed to keep the dressings intact and dry until the first postoperative visit, when the wounds were inspected. Preoperative prophylactic antibiotics were not given to the patients. Antibiotics were only given if the patients developed SSI, and wound swabs were obtained before antibiotic treatment commenced.

The swabs were taken to the medical microbiology lab of Obafemi Awolowo University, Ile-Ife, immediately after each groin procedure. There, the swabs were streaked across chocolate agar, blood agar, and MacConkey agar, and cultured using aerobic techniques.

Patients were discharged when they were fit to go home. All procedures were day-cases. The patients were seen in the clinic on the 7th, 14th, 21st, and 28th day after surgery. Those with SSI, as determined by the CDC criteria, had their wounds swabbed and cultured.[19]

Study duration

The study started in March 2016 and ended in December 2016.

Subject selection

The parents/guardians were appropriately counselled, and informed consent was obtained.

Sample size

A retrospective analysis of the surgical records of the Paediatric Surgery Department at OAUTHC for the previous day-case surgeries in 2010, 2011, 2012, and 2013 revealed that 58, 91, 78, and 76 groin surgeries were done, respectively. The arithmetic mean of this series is 75.8. This analysis was not part of the study and was used to generate a sample size. It was performed to determine the number of surgeries typically done in the hospital, which helped gauge the reasonable number of patients that could be obtained during a 12-month study period. Following this, it was assumed that reasonable numbers could be obtained, and the study was then performed prospectively. A standard deviation of 13.6 was calculated using the formula:[20]

The minimum sample size was estimated using the formula:[21]

$n = Z^2S^2 = 28.4 = 28$ children

The sample size of this study consists of 56 children, with 28 in each arm of the study. However, to increase the power, 70 patients were recruited. The study was not powered to detect any difference in SSI.

Exclusion criteria

Patients were excluded from the study if they had an infective process in the groin, took antibiotics up to one week before surgery, had a history of allergy associated with any material used in the study, had comorbidities such as sickle cell disease and congenital heart defects (as they would not be day-cases), took chronic steroids, or had immune suppressive illnesses.

Consent

Informed consent was obtained from the parents or guardians to allow their children to participate in the study. This consent was written out and explained to them, and they were required to sign the consent form or place their fingerprint on it if they were unable to write. The consent was also translated into Yoruba, the native language, for easier understanding.

Data collection

Sociodemographic data, patient diagnosis, surgical procedure performed, laboratory results, and adverse reactions to the skin preparations were recorded.

Ethics

Ethical approval was obtained from the OAUTHC ethical committee before the study commenced.

Data analysis

The data collected were entered into the study pro forma. Data analysis was done using SPSS version 20 (SPSS Inc., Chicago, United States). Data were expressed as the mean and standard deviation. The data obtained were presented in tables and frequency charts as required. A criterion of $p < 0.05$ was used to determine the statistical significance of all the tests.

Results

During the study period, 70 patients were recruited for the study. Their ages ranged from two months to 15 years, with a mean of 4.66 years. There were 63 males (90%) and seven females (10%), resulting in a male-to-female ratio of 9:1 (Table I).

Hernias were the most common indication for groin surgery in 42 patients, representing 60% of the study population. The remainder of the study population comprised hydroceles (n = 16, 22.9%) and undescended testes (n = 12, 17.1%). Patients with hernia had groin exploration and high ligation of the hernia sac (herniotomy). Patients with hydrocele had groin exploration, ligation of the processus vaginalis (if it was patent), and hydrocelectomy. Patients with undescended testes had subdartos orchidopexy (Table II).

The primary end point was the antibacterial effect of the two skin preparation methods on the bacterial count of the groin skin. Both

Table I: Sociodemographic characteristics of the study participants

Variable	*n*	%
Age group		
1 month to 5 years	47	67.1
6–10 years	16	22.9
11–15 years	7	10.0
Sex		
Male	63	90.0
Female	7	10.0

Note: age is as of the last birthday.

Table II: Diagnosis

Diagnosis	Laterality	Frequency	%	Operation
Hernia	Right	23	32.9	High ligation of hernia sac (herniotomy)
	Left	17	24.3	
	Bilateral	2	2.9	
Hydrocele	Right	9	12.9	Ligation of patent processus vaginalis and hydrocelectomy
	Left	5	7.1	
	Bilateral	2	2.9	
Undescended testis	Right	4	5.7	Groin exploration with subdartos orchidopexy
	Left	7	10.0	
	Bilateral	1	1.4	
Total		70	100.1	100.1% is due to rounding

Table III: Antibacterial effect of both skin preparation agents

Test	Statistic	Value	*p*-value	Partial eta squared
McNemar's chi-square test	*p*		0.00	
Mixed ANOVA interaction effect	Wilks' lambda, *F* (2, 67)	0.90, 3.67	0.03	0.10
Mixed ANOVA main effect (time)	Wilks' lambda, *F* (2, 67)	0.24, 104.42	< 0.0005	0.76
Mixed ANOVA main effect (between subjects)	*F* (1, 68)	1.06	0.31	0.02

ANOVA – analysis of variance

Table IV: Bacterial contamination rate

Skin preparation technique	Pre-application (%)	Post-application (%)	At closure (%)
		Positive culture	
0.3% chlorhexidine + 3% cetrimide	32/36 (88.9)	0/36 (0.0)	10/36 (27.8)
7.5% povidone-iodine	31/34 (91.2)	2/34 (5.9)	17/34 (50.0)

skin preparation agents were found to be effective in reducing the bacterial count from the groin skin, but neither was found to be more effective than the other (Table III).

There was a significant effect of both skin preparation methods, as demonstrated by McNemar's chi-square test. The bacterial colony count was substantially reduced when the pre-application counts of both preparation methods were compared with their post-application counts ($p = 0.00$), and when pre-application counts were compared with those at closure ($p = 0.00$).

A mixed between-within subject analysis of variance (ANOVA) demonstrated that there was significant interaction between subject variable 0.3% chlorhexidine and 3% cetrimide scrub, followed by 70% methylated spirit paint, and 7.5% povidone-iodine in 70% methylated spirit scrub and paint and time (Wilks' $\Lambda = .90$, $F(2, 67) = 3.67$, $p = .03$, partial $\eta^2 = .10$). There was a substantial main effect for time (Wilks' lambda = 0.24, F [2, 67] = 104.42, partial $\eta^2 = 0.76$; $p < 0.0005$), with both groups showing a reduction in colony number statistics test scores across the three timepoints. This also indicates that both agents have antibacterial effectiveness.

The main effect of the between-subject factor (comparing 0.3% chlorhexidine and 3% cetrimide scrub, followed by 70% methylated spirit paint, with 7.5% povidone-iodine in 70% methylated spirit scrub and paint) was not statistically significant (F [1, 68] = 1.06, partial $\eta^2 = 0.02$; $p = 0.31$). This indicates that 0.3% chlorhexidine and 3% cetrimide scrub, followed by 70% methylated spirit paint, did not demonstrate higher antibacterial effectiveness than 7.5% povidone-iodine in 70% methylated spirit scrub and paint. In this case, post hoc tests were not necessary because there were only two skin preparation methods.

The 0.3% chlorhexidine and 3% cetrimide scrub, followed by 70% methylated spirit paint, completely cleared the operative area of bacteria in all patients at the beginning of the operation (Table IV). However, 10 patients (27.8%) became positive for the eliminated organisms at the end of the surgery. The growths at the end of the surgery were light growth (+), which occurred in patients with initial heavy bacterial contamination (+++).

The 7.5% povidone-iodine in 70% methylated spirit scrub and paint also completely cleared the operative area of bacteria in all patients at the beginning of the operation. However, 17 patients (50.0%) became positive for the eliminated organisms at the end of the surgery. The growths at the end of the surgery were light growth (+), which occurred in patients with initial heavy bacterial contamination (+++).

Surgical site infections

There was one case of superficial incisional SSI from each arm of the study. *Staphylococcus aureus* was isolated from both infections.

Adverse reactions

There was no incidence of skin reaction from either of the skin preparation methods.

Discussion

This study aimed to evaluate the antibacterial effectiveness of two skin preparation methods, which may help reduce the bacterial load of the groin skin and, ultimately, reduce the incidence of SSI. Both methods are commonly used in surgical site preparation in OAUTHC, Ile-Ife. The 0.3% chlorhexidine and 3% cetrimide scrub, followed by 70% methylated spirit paint, and 7.5% povidone-iodine in 70% methylated spirit scrub and paint, were both effective in reducing the bacterial colony count from the groin skin. This result is similar to that obtained by Hemani et al.,[22] who found that alcohol-containing solutions exhibit sustained and durable antimicrobial activity in the groin.

The bacterial colony counts were substantially reduced when comparing pre-application counts with post-application counts, and when comparing pre-application counts with counts after surgery. However, none were significantly more effective than the other, although the 0.3% chlorhexidine and 3% cetrimide scrub, followed by 70% methylated spirit paint, had lower bacterial colony counts at the end of the surgery than 7.5% povidone-iodine in 70% methylated spirit scrub and paint.

The bacterial growth at the end of the surgery was light colony-forming units (CFU) (+), unlike the growth before skin preparation, which was heavy CFUs (+++). Both skin preparation agents had no bacterial colony count immediately after the skin preparation. This may be because the agents are most effective soon after they are applied, lose potency gradually afterwards, or, more importantly, are recolonised by the patient's normal flora after some time.

Alcohol-based skin preparation agents are documented to have a long-lasting effect, even after the alcohol has evaporated. Hemani et al.[22] and Duffy et al.[23] demonstrated that both chlorhexidine and povidone have an excellent antibacterial effect on bacterial counts. Mimoz et al.[24] also noted that alcohol-based skin preparation agents were superior to aqueous, povidone-based agents. This differs from the findings of Swenson et al.,[25] who found iodophor-based compounds superior to chlorhexidine-based skin preparation agents. Conversely, Wade et al.[26] found that chlorhexidine in alcohol was superior to povidone-iodine.

There was one case of superficial incisional SSI from each arm of the study. *Staphylococcus aureus* was isolated from both infections. In one of the infections, the preoperative bacteria were *Staphylococcus epidermidis*, although not in excessive counts. It was not possible to trace the preoperative bacterial growth of the other infection. It is difficult to point out any risk factor as the cause of the SSI. Consequently, there was no difference in SSI incidence between the two groups. This is similar to the findings of Ostrander et al.[27] and Sistla et al.[28]

The skin swabs obtained post-surgery grew bacteria from both arms of the study in some of the patients. This finding may be due to the patients' immunity, which was able to eliminate the bacterial colonies that had reappeared at the end of the surgery, as the colonies were not heavy, and the patients were all healthy, apart from their surgical pathology. The pathogenicity of the resident skin flora in such patients is expected to be low, as documented by Kampf et al.[29] The influence of host resistance, bacterial dose, and bacterial virulence was also examined by Altemeier et al.[30] in their work. There was no incidence of skin reaction from either of the two skin preparation methods.

Study limitations

The study was limited by the inability to perform anaerobic culture on the swabs collected, since the medical microbiologist deemed them inappropriate specimens for anaerobic culture. Additionally, the study was limited by the inability to ensure that patients avoided medicated soap for a week prior to surgery.

Conclusion

This study's findings indicate that both the 0.3% chlorhexidine and 3% cetrimide scrub, followed by 70% methylated spirit paint, and 7.5% povidone-iodine in 70% methylated spirit scrub and paint have significant antibacterial effects. However, there is no significant difference between their antibacterial effectiveness. There was no significant difference in the SSI rate or incidence of adverse skin reactions between the two skin preparation methods.

Recommendation

According to the study's results, the author recommends that both methods described in this work may be used to prepare the groin skin before surgery, as they are both effective in reducing bacterial count.

Conflict of interest

The authors declare no conflict of interest.

Funding source

The research cost was supported by a grant from the former employer of the corresponding author, University of Calabar Teaching Hospital, Calabar.

Ethical approval

Ethical approval was obtained from the Ethics and Research Committee of the OAUTHC (reference numbers: IRB/IEC/0004553, NHREC/2702/2009a).

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