

Preoperative bathing with chloroxylenol versus non-medicated soap in preventing surgical site infection following inguinal herniorrhaphy

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Abstract

Background/Aim: Surgical site infections (SSIs) remain prevalent in low- and middle-income countries, exceeding 2% even in clean procedures like elective inguinal herniorrhaphy. While preoperative bathing prevents SSIs, meta-analyses show no advantage of chlorhexidine over non-medicated soap. No studies have compared chloroxylenol soap with non-medicated soap.

Methods: We conducted a prospective randomized study of adults undergoing elective open inguinal herniorrhaphy using the Bassini technique under subarachnoid block. Patients bathed 1 h preoperatively with either chloroxylenol soap (Dettol®) or non-medicated soap (Lux®). We monitored wounds for 30 days using CDC infection criteria and analyzed data using IBM SPSS V 22.0.

Results: The study included 76 patients (93.42% male) with a mean age of 51.72 (18.70) years. The mean operative time was 49.58 (20.06) min. Right-sided hernias comprised 65.79% of cases, with 81.58% being indirect. SSI incidence was 2.63% (one patient per group), showing no significant difference between chloroxylenol and non-medicated soap ($P=1.000$).

Conclusion: Chloroxylenol soap offers no advantage over non-medicated soap in preventing SSIs after elective inguinal herniorrhaphy.

Keywords: preoperative bathing, chloroxylenol, non-medicated soap, surgical site infection

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Ethics Committee Approval

The study was approved by the Health Research Ethics Committee of the University of Benin Teaching Hospital, Nigeria with protocol number: ADME/E 22/A/VOL. VII/148292 on March 24, 2020.

All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest

No conflict of interest was declared by the authors.

Financial Disclosure

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Introduction

The development of antisepsis by Joseph Lister, followed by the propagation of asepsis by Ernst von Bergman, along with Alexander Fleming's discovery of penicillin in 1929, ushered in the antibiotic era. These advancements significantly reduced the rates of post-operative sepsis resulting from surgical site infections (SSIs) [1, 2].

The rate of SSI is significantly higher in Africa (14.8%) and Nigeria (14.5%) compared to developed nations, such as the United States (1.98%), China (4.5%), and Europe (10%) [3]. In Nigeria, the SSI rate following elective inguinal herniorrhaphy can reach up to 7.79% [4], exceeding the accepted upper limit of 2% for clean surgical procedures [5].

To reduce global SSI rates, the World Health Organization (WHO) recommended preoperative bathing [6]. However, following a meta-analysis of available studies, the WHO found no significant difference between using antiseptic soap versus non-medicated soap for preoperative bathing in the prevention of SSIs.

The researchers identified a gap in the existing literature, noting that chlorhexidine was the only antiseptic agent tested against non-medicated soap. Consequently, they recommended further studies on this topic using antiseptic agents other than chlorhexidine.

This study aimed to compare the efficacy of chloroxylenol-containing soap with non-medicated soap in preventing SSI. It also emphasizes the overall impact of preoperative bathing as a preventive measure against SSI.

Materials and methods

This study was conducted at the Department of Surgery, University of Benin Teaching Hospital, a tertiary health institution in southern Nigeria. The facility serves an estimated population of 3,218,332 and has 870 bed spaces.

This prospective, randomized comparative study involved 76 consenting adult patients, aged 18 years and older, who had unilateral inguinal hernias and underwent elective Bassini inguinal herniorrhaphy. Before surgery, patients received a preoperative bath with either chloroxylenol-containing soap or non-medicated soap. The primary endpoint was the presence or absence of a SSIs 30 days post-surgery.

The exclusion criteria included the following: recurrent inguinal hernias, bilateral inguinal hernias, immunosuppressed patients, the presence of infection near the operation site or at remote sites, patients on systemic antibiotics, and patients with known hypersensitivity to Dettol® and/or Lux® soap.

The study was conducted over 1 year, from April 2020 to March 2021. Patients were consecutively randomized in equal numbers using a simple balloting method.

One group took a preoperative bath with non-medicated soap on the morning of surgery, while the other group used medicated soap containing chloroxylenol (Dettol®, manufactured by Reckitt Benckiser Nigeria Limited). The non-medicated soap used in this study was Lux® (produced by New Home Products Industries Limited for Unilever Nigeria Plc.).

The product information is as follows: Dettol® is packaged as a 65g bar soap. Each bar contains the following

ingredients: Soap Base, talc, glycerin, sodium C14-C16 olefin sulfonate, water, fragrance, color, silicon emulsion, and chloroxylenol at 0.3% w/w. It also has a total fatty matter of not less than 64% w/w upon packaging. The batch number is ADO-053W. The date of manufacture is 20th April 2019, and the expiry date is April 2023.

The Lux® bar soap is packaged as a 65g bar and comprises several ingredients. These include Soap Base, Aqua, Glycerin, Parfum, *Rosa gallica* flower extract, *Jasminum officinale* flower extract, *Prunus amygdalus* oil, *Cymbopogon martini* oil, PEG-40 hydrogenated castor oil, *Mentha arvensis* leaf extract, Titanium dioxide, Citric acid, Alpha-isomethyl ionone, Methylpropional, and Potassium sorbate. The soap has a total fatty matter content of 67% w/w upon packaging. The batch number for this product is 154N2. It was manufactured on June 3, 2019, and has an expiry date of June 3, 2023.

Both groups received clean theatre apparel before being transferred to the theatre. After the bath, no cosmetics were applied. Additionally, none of the patients received prophylactic antibiotics.

All patients underwent evaluation, with age, gender, and hernia site recorded. Preoperative investigations included a full blood count, urinalysis, random blood sugar, and serum electrolytes, urea, and creatinine. Patients over 40 years old also received a chest x-ray and an electrocardiogram.

Each patient was admitted the day before surgery for a routine preoperative anesthetic review, during which informed consent was obtained. Patients were assigned to groups based on the serial numbers in a table of random numbers. The research assistant distributed the appropriate soap to each patient. The type of soap allocated to each patient was concealed from the researcher until after all data had been collected.

On the morning of surgery, trained assistants provided patients with instructions on the bathing procedure. Patients then took a shower within 1 h before surgery using the allocated soap and polyester sponge. This process included 15 min of bathing, with the affected groin cleansed for 5 min before a full body shower. A male or female research assistant, matched to the patient's sex, timed and supervised the bath. Separate shower rooms were available for patients. If shaving was necessary, the research assistant performed it with a shaving stick before the bath. There were no visible injuries reported after shaving. The researcher supplied both the soap and polyester sponges.

Surgeries were performed under subarachnoid block, and no preoperative antibiotics were administered. Skin preparation adhered to the protocol of applying Savlon twice, allowing it to dry, and then applying povidone-iodine. This was followed by isolation using the four-drape technique.

A transverse groin skin crease incision was made 2.5 cm above the medial two-thirds of the inguinal ligament. The incision was developed through the subcutaneous fat, and the external oblique aponeurosis was incised obliquely to the superficial ring to access the inguinal canal. Hemostasis was achieved with monopolar diathermy. In males, the spermatic cord was elevated, and the hernia sac was dissected off it. In females, the sac was dissected off the round ligament. High ligation of the hernia sac was performed using Vicryl 1 suture, and the sac was excised. The posterior wall repair for all patients employed the modified

Bassini technique. This technique involved approximating the conjoint tendon to the inguinal ligament using interrupted polypropylene 1 sutures. The first suture was placed through the inguinal ligament near its attachment to the symphysis pubis, then through the conjoint tendon on the opposite side, and tied without tension. These interrupted polypropylene sutures were continued from the medial end of the inguinal canal laterally, ensuring the spermatic cord was not included in the sutures and the internal ring was not made too tight. The spermatic cord was returned to the inguinal canal, and the external oblique aponeurosis was repaired over it with continuous Vicryl 1 suture. The subcutaneous layer was closed with interrupted Vicryl 2-0 sutures, and the skin was closed with Vicryl 2-0 sutures in a continuous subcuticular fashion. The wound was then cleaned with Savlon, dried, cleaned with povidone-iodine, and dressed. No antibiotics were administered postoperatively. Patients were transferred to the ward for recovery from anesthesia and observation for early complications. They were discharged the day after surgery and were seen on the 4th, 7th, 14th, and 30th day post-operation for wound inspection. These inspections were conducted by senior registrars in general surgery, who were blinded to the soap used by the patient and not involved in the surgical procedure. They assessed for signs of SSI such as fever, increasing pain and swelling at the operation site, erythema, tenderness, wound edema, serous or purulent discharge, or wound dehiscence.

Patients were instructed to contact the researcher between the scheduled visits if they experienced any wound complications, including pain, erythema, swelling, or serous or purulent discharge.

When an infection was suspected, the researcher collected wound swabs and promptly delivered them to the laboratory for microscopy, culture, and sensitivity tests. Wound care was prescribed as necessary. Identified organisms were documented.

SSIs was defined according to the CDC criteria [7]. Superficial incisional SSI is characterized by at least one of the following: purulent drainage from the superficial incision (involving only skin and subcutaneous tissue); organisms identified from an aseptically obtained specimen from the wound; or an incision deliberately opened by the surgeon for drainage, accompanied by any of the following symptoms: localized pain or tenderness, swelling, erythema, or heat.

Deep incisional SSI is characterized by at least one of the following criteria: purulent discharge from the deep incision, involving fascia and muscles; spontaneous dehiscence of the deep incision, or when it is deliberately opened or aspirated by the surgeon to drain pus; identification of organisms from the deep space, accompanied by the patient experiencing any of the following symptoms: fever (temperature greater than 38°C), localized pain, or tenderness.

Organ space SSI is indicated by at least one of the following criteria: organisms identified in the organ space; an abscess involving the organ space detected by histopathologic exam or imaging.

Statistical analysis

Data collected during the pre- and post-operative assessments were documented using a predesigned form. We analyzed the data with the IBM Corporation Statistical Package

for the Social Sciences (SPSS) Statistics for Windows, Version 22.0, Armonk, New York, United States of America. We compared infection rates in both groups using the chi-square test, with the significance level (p) set at 0.05. Results were presented in the form of tables, graphs, and charts.

Approval for this study was obtained from the Ethics Committee of the University of Benin Teaching Hospital in March 2020, under Protocol Number: ADM/E22/A/VOL, VII/148292.

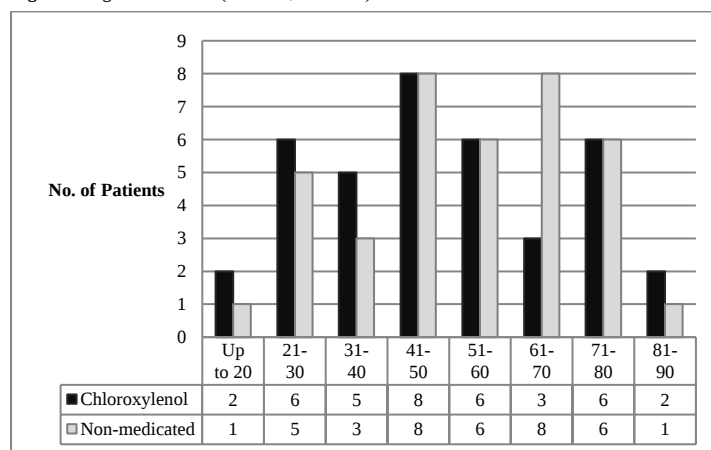
Patients were counseled on the nature of the study, and written informed consent was obtained prior to recruitment. Participation was voluntary, confidential, and incurred no additional financial cost to the participants.

Results

Seventy-six patients with uncomplicated inguinal hernias were recruited for this study. They were randomized into two groups of 38 patients each: one group received a preoperative bath with chloroxylenol-containing soap (Dettol®), while the other used non-medicated soap (Lux®). All patients completed the mandatory 30-day follow-up in the clinic.

Patient characteristics, including mean age distribution (Figure 1) and gender distribution (Table 1), did not have statistically significant effects on either group that might have influenced the outcome differently ($P>0.05$).

Figure 1: Age distribution. ($T=0.340$, $P=0.735$).



Most (65.79%) of the hernias occurred on the right side. However, the distribution between the groups was not statistically significant ($P=0.629$) (Table 2). Indirect inguinal hernias constituted 81.58 percent of the study population (Figure 2). In comparison, 92.11 percent of participants bathed with non-medicated soap, whereas 71.05 percent used chloroxylenol-containing soap. This disparity was statistically significant ($P=0.0179$) (Figure 3).

Table 1: Gender distribution.

	Total n=76	Chloroxylenol n=38	Non- medicated n=38	Stat test	P-value
Gender					
Male	71 (93.42%)	35 (92.11%)	36 (94.74%)	$\chi^2=0.214$	0.644
Female	5 (6.58%)	3 (7.89%)	2 (5.26%)		

Table 2: Hernia location.

	Total n=76	Chloroxylenol n=38	Non- medicated n=38	Stat test	P-value
Side					
Right	50 (65.79%)	26 (68.42%)	24 (63.16%)	$\chi^2=0.234$	0.629
Left	26 (34.21%)	12 (31.58%)	14 (36.84%)		

For indirect and direct inguinal herniorrhaphy, the difference in the mean duration of surgery was not statistically significant ($P=0.615$) (Table 3). Additionally, when comparing

both study arms, the mean duration of surgery was longer in the chloroxylenol group; however, this difference was also not statistically significant ($P>0.05$) (Table 4).

Two patients developed SSI, one in each group, resulting in identical infection rates of 2.63%. The SSIs were observed on the seventh day after surgery, evidenced by a seropurulent discharge. Wound cultures identified the presence of *Staphylococcus epidermidis*. There was no statistically Significant Difference In The SSI Rates Between The Two Groups ($P=1.000$; Table 5).

Figure 2: Type of hernia.

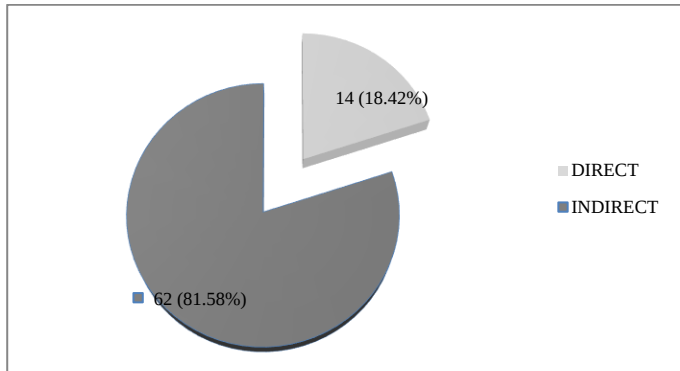


Figure 3: Type of hernia per group ($\chi^2=5.603$).

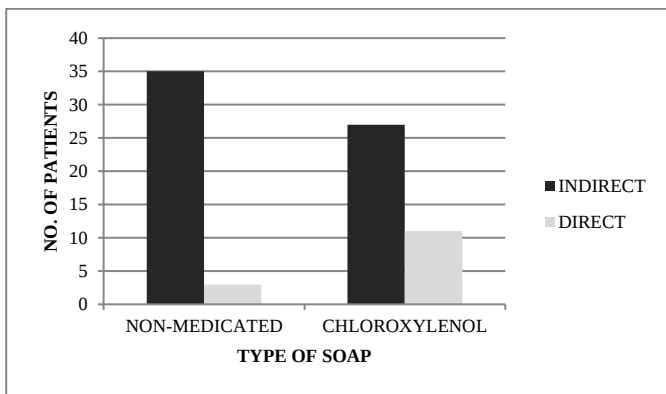


Table 3: Duration of surgery in minutes (direct vs indirect hernias) ($P=0.615$)

	Total n=76	Direct n=14	Indirect n=62	Stat test	P-value
Range	30-110	30-110	30-106	$t=0.505$	0.615
Mean (SD)	49.58 (20.06)	51.86 (25.96)	48.90 (18.20)		

Table 4: Duration of surgery in minutes (chloroxylenol vs non-medicated).

	Total n=76	Chloroxylenol n=38	Non-medicated n=38	Stat test	P-value
Range	30-110	30-105	30-110	$t=0.590$	0.557
Mean (SD)	49.58 (20.06)	50.79 (19.57)	48.11 (19.98)		

Table 5: Surgical site infection (chloroxylenol vs non-medicated).

	Total	Chloroxylenol	Non-medicated	Stat test	P-value
No. of hernias	76	38	38	$\chi^2=0$	1.000
No of infections	2	1	1		
SSI rate	2.63%	2.63%	2.63%		

Discussion

This study recruited 76 patients over 1 year, and all participants completed the 30-day follow-up. There were two infections, resulting in an overall SSIs rate of 2.63%. The infection rates were identical in both the chloroxylenol and non-medicated soap groups.

Both groups were similar in age, gender distribution, hernia characteristics, and the duration of surgery. However, there was a statistically significant difference between the groups concerning the distribution of direct and indirect hernias. Aside from the anatomical differences between direct and indirect

hernias, the preparation and surgical procedures were the same for both types, and there was no significant difference in the duration of surgery.

In this study, the age distribution of inguinal hernias peaked in the fifth decade of life. This finding aligns with Malviya et al. [8], who reported a peak age range in the 5th to 6th decades, and Awe et al. [9], who found peaks in the 4th to 5th decades. Ashindointiang et al. [10] observed a peak age in the 7th decade among an all-male population; notably, one-third of their patients were over 60 years old, which corresponds with this study, where 26 of the 76 subjects were above 60. These results differ from Burchart et al.'s [11] study in Denmark, which found a peak incidence in the 8th decade. The variation might be attributed to Denmark's higher life expectancy compared to developing countries like Nigeria [12,13] and an older population experiencing progressive muscle atrophy and an increased risk of hernia formation [11].

The majority of patients in this study were male, which aligns with the findings of Malviya et al. [8], where 94.6% of the subjects were also male. This pattern is likely due to the anatomical passage of the spermatic cord from the abdomen through the inguinal canal to the scrotum during intrauterine development. This process results in a wider deep ring and inguinal canal in males, making them more susceptible to inguinal hernias [14]. Additionally, males are often more involved in strenuous exercises and heavy lifting, activities that increase intra-abdominal pressure and contribute to the development of hernias [15].

This study identified a predominance of right inguinal hernias. Balamaddaiah et al. [15] reported similar findings. The occurrence could be attributed to the slower descent of the right testicle into the scrotum and the persistence of the processus vaginalis on the right side in males [8]. Additionally, a history of open appendectomy may contribute, as the procedure can potentially injure the iliohypogastric nerve, leading to weakness in the posterior wall of the inguinal canal [16].

The indirect type was more common than direct hernias. This is attributable to the existence of the deep ring (and persistent processus vaginalis) which is a preexisting defect through which inguinal hernias can occur [14].

Two SSIs were recorded during this study, resulting in an SSI rate of 2.63%. This rate slightly exceeds the maximum expected rate after clean surgery, which is 2% [5], yet it is lower than rates reported by Ugwu-Olisa et al. [17] at 3.9%, Ramyil et al. [4] at 7.79%, and Kumar et al. [18] at 10%. The lower incidence observed in this study may be attributed to the exclusion of patients at high risk of infection, who would have required prophylactic antibiotics, potentially affecting the uniformity of the sample.

Both groups experienced one infection each, resulting in an infection rate of 2.63%. Therefore, chloroxylenol-containing soap demonstrated no superiority over non-medicated soap in preventing SSIs following open inguinal herniorrhaphy.

Both infections were identified during a clinic visit on the 7th post-operative day, a timeframe typical for the emergence of SSIs symptoms [19].

Both patients exhibited seropurulent discharge from the operation site, leading to a classification of superficial incisional

SSIs. Wound swabs were taken and cultured, and both cases yielded *Staphylococcus epidermidis*. The isolates were multidrug-resistant, showing sensitivity only to Azithromycin and Gentamicin. This finding contrasts with Ehiaghe et al. [20], who identified *Pseudomonas aeruginosa* as the predominant bacterial isolate in 181 swabs from infected surgical wounds at the University of Benin Teaching Hospital. In that study, *S. epidermidis* was not isolated from any specimens.

S. epidermidis is a coagulase-negative, Gram-positive organism. It, together with *S. haemolyticus* and *S. saprophyticus*, represents the most common species among coagulase-negative staphylococci and forms part of the normal flora, particularly around the head, nares, and axilla [21]. This organism exhibits higher methicillin resistance (75–90%) compared to *S. aureus* (40–60%). Consequently, it has emerged as a significant cause of hospital-associated infections, especially in the context of medical devices [22].

Both patients experienced drainage of effluent through existing defects in their wounds, which were managed with wound dressings applied every other day. The wounds were cleaned with saline and dressed with sterile gauze in an outpatient setting. By their next clinic visit, 14 days post-operation, the infections had resolved. These patients with SSI incurred additional costs due to the need for dressing packs, normal saline, and transportation to and from the hospital every other day during the wound dressing period.

In this study, preoperative bathing with chloroxylenol-containing soap showed no difference in the incidence of SSIs compared to non-medicated soap; both groups experienced an SSI rate of 2.63%. This incidence is lower than those reported in other studies, which range from 3.9% to 10% [4,17,18]. However, these other studies did not specify whether preoperative bathing was mandatory for all patients.

Limitations

The inability to directly observe the baths, due to privacy and decency concerns, may have impacted full compliance with the bathing modalities. Additionally, the small patient sample size may limit the generalizability of our findings. To increase the acceptability of these research results, conducting a larger, multi-center study could help reduce bias.

Conclusion

The rate of SSIs was similar in both groups. However, the non-medicated soap is both more cost-effective and equally effective as chloroxylenol-containing soap in preventing SSIs after inguinal herniorrhaphy. Therefore, its routine use should be considered, particularly in low- to medium-income countries.

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