

Antiseptic Skin Preparation for Preventing Surgical Site Infection at Caesarean Section

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Abstract

Purpose: To compare the effect of chlorhexidine-alcohol and povidone iodine on surgical site infection (SSI) after caesarean section. **Methodology:** A randomized control trial of 374 patients (188 in the chlorhexidine-alcohol group and 186 in the povidone iodine group) who had elective caesarean section with no overt risk for SSI was done. Patients were followed up until thirty days after delivery to assess for symptoms and signs of SSI. **Results:** Fifty-one (13.6%) of the study population developed SSI. Although the incidence of SSI was lower in the chlorhexidine-alcohol group than the povidone iodine group (12.2% vs. 15.1%; $p = 0.26$); the difference was not statistically significant. The incidence of adverse skin reaction in Chlorhexidine-alcohol vs. povidone iodine was also not statistically significant (4.0% vs. 5.4%; $p = 0.40$). **Conclusion:** The study demonstrates that there was no statistically significant difference in antiseptic property and side effect profile of chlorhexidine-alcohol and povidone-iodine when used as skin antiseptics in caesarean section.

Keywords

Antisepsis, Infection, Chlorhexidine, Povidone Iodine, Caesarean Section

1. Introduction

Surgical site infection (SSI) occurs in 5% - 10% of caesarean deliveries [1]. It causes significant morbidity and

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mortality in these patients resulting in increased duration of hospitalization and cost of healthcare [2]. Considering the fact that caesarean section is the most common major obstetric surgery carried out on women worldwide, everything should be done to reduce the attendant morbidity and mortality [3].

The skin being a major source of pathogens that cause SSI, thus requires, proper preoperative skin preparation in order to decrease the likelihood of SSI [4]. Unfortunately, there is little evidence to guide the choice of antiseptic for skin preparation at surgery [5]. A Cochrane review on preoperative skin antiseptics for preventing surgical wound infections after clean surgery concludes that there is uncertainty about which antiseptic skin preparation is the most effective for preventing postoperative SSI [6]. A Cochrane review on skin preparation for preventing infection following caesarean section further suggests that there is a need for high-quality, properly designed randomized controlled trials with larger sample sizes especially comparing chlorhexidine-alcohol and povidone iodine [3]. The present study therefore aimed at comparing the effect of two different antiseptic skin preparations: chlorhexidine-alcohol and povidone iodine on surgical site infection rates post caesarean section in a Nigerian teaching hospital.

2. Methods

This randomized control trial was carried out in the Department of Obstetrics and Gynaecology of the Obafemi Awolowo University Teaching Hospitals Complex (OAUTHC), Ile-Ife, Osun State, Nigeria between August 2012 and July 2013. The study was approved by the Ethics committee of the hospital and all participants provided informed consent. Sample size was determined based on the formula for estimating sample size for the comparison of two independent population as described by Armitage *et al.* [7]. 15% prevalence rate of SSI in povidone iodine group and a 70% reduction (5% prevalence) in chlorhexidine-alcohol group was used [1]. In order to make allowance for attrition, 35% of the estimated sample size was added making 384 patients.

A total of 384 patients (192 in each of chlorhexidine-alcohol and povidone iodine group) who had elective caesarean section at OAUTHC, Ile-Ife were randomized into either group after informed consent was obtained. Patients with known allergy to chlorhexidine or povidone-iodine; immunocompromised patients and those with previous midline scar were excluded from the study. Patients with overt risk for infection like obstructed labour, prolong prelabour rupture of membranes, maternal febrile conditions were excluded.

Randomization was achieved using sequentially numbered sealed packets from a computer generated random sequence. The sealed envelopes were placed in the labour ward theatre and were drawn from serially by the surgeons just before the procedure. Blinding both patients and physicians to the antiseptic used for skin preparation (double-blinding) would have been ideal, however, it was not feasible in this trial. Systematic bias was minimised by using the same standard procedures of skin preparation, skin culture and assessment of outcomes.

Prior to surgery, all patients had a bath with a non-antiseptic soap to include the area of surgery. Shaving of the lower abdomen was done on the surgical table just before commencing antiseptic skin preparation. Subjects had pfannenstiel incision, which was closed with vicryl 2/0 subcuticular sutures. The subcutaneous layer was closed with vicryl 2/0. The surgery was done under spinal anaesthesia unless otherwise indicated. Demographic, obstetric, neonatal data and variables known to be related to SSI were recorded.

For patients who fell into the chlorhexidine-alcohol group, skin preparation with gauze soaked in Valon[®] (containing Chlorhexidine gluconate 0.3% w/v and Cetrimide 3.0% w/v manufactured by Royal priesthood laboratory ltd) which was diluted with distilled water in a 1:1 ratio was done. A centrifugal scrubbing motion was used starting from the area of the intended incision and covered the abdomen from the subcoastal margin to the midaxillary line down to the middle of the thigh. This was repeated twice. The area was then dried with a piece of dry gauze in the same centrifugal manner. Moko[®] (containing Isopropyl alcohol 95% v/v manufactured by New-Health way Co. Limited) was then applied on the area in the same centrifugal manner and allowed to dry before draping off the area.

For patients who fell into the povidone iodine group, Wosan[®] (containing 10% povidone iodine manufactured by Jawa international limited) was used. The povidone iodine was painted on the aforementioned area and then left to dry completely before draping the area and commencing the surgery.

The same prophylactic antibiotic-intravenous cefuroxime 750 mg stat was administered after clamping of the cord. The placenta was removed with gentle traction and exterior massage of the uterus, and removed manually only if it was retained for more than 5 minutes. The uterus was then exteriorized before repair. On completion of the surgery, a standard sterile gauze dressing kept in place with plaster to ensure non-exposure of the gauze and

underlying wound was applied. The patients were then counseled to keep the wound dressings dry.

Postoperatively, the patients' wound and area of the skin on which the antiseptics was applied were inspected on the third and seventh day. The dressing was changed on the third post operative day or earlier if soaked. Wounds that were determined to be infected had wound swabs taken for microscopy, culture and sensitivity and daily dressings instituted as appropriate. A modification of the Southampton's wound infection scoring system [8] was employed for grading infections when present.

After discharge, the women were instructed about the signs and symptoms of wound infection and they were given written information leaflets about SSI. Subjects were contacted weekly up to 30 days from delivery, to assess symptoms of surgical site infections. Patients who reported symptoms were evaluated at the obstetric emergency unit for surgical site infection.

Study data was processed using SPSS version 17 (IBM, Armonk, NY, USA). Frequency tables were made and results were tested for significance using the student t-test for continuous variables and chi square or Fisher exact test for categorical variables with level of significance (α) set at 0.05.

3. Results

Three hundred and eighty-four patients who had elective caesarean section were recruited into the study. Ten were excluded from the analysis due to the fact that they were lost to follow up or ended up having a midline scar. One hundred and eighty-eight were in the chlorhexidine-alcohol group and one hundred and eighty-six in the povidone iodine group.

Table 1 shows the sociodemographic characteristics and perioperative characteristics of patients in both groups. There was no statistically significant difference between both groups in terms of their characteristics.

Table 2 shows development of skin reaction by type of antiseptic used. Eighteen (4.8%) of the patients recruited developed skin reactions following administration of the skin antiseptic.

Table 3 shows that fifty-one (13.6%) of the total study population developed surgical site infection. There was however no statistically significant difference between the chlorhexidine-alcohol group and the povidone iodine group (23, 12.2%) vs. 28, 15.1%); $p = 0.26$.

4. Discussion

The incidence of 13.6% for SSI in this study was comparable to the incidence of 10% finding by Fasubaa *et al.* [9], but lower than the 23.4% got by Makinde [10] from the same centre. The SSI rate of 13.6% in this study is similar to the findings of other workers in Nigeria [11] [12]. It should be noted that although the rate of 13.6% is within 0% to 20.5% reported by Moir-Bussy and colleagues in a hospital survey in London, it is much higher than figures reported from most developed countries [13].

The findings from this study show that there is no statistically significant difference in the incidence of SSI (12.2% vs. 15.1%; $p = 0.26$) in both groups. Although there was a 19% reduction in incidence of SSI in the chlorhexidine-alcohol group, this was lower than the findings of Darouchie *et al.* [4] where a 41% reduction (9.5% vs. 16.1%, $p = 0.004$) was found in the chlorhexidine-alcohol group and with the work of Levin *et al.* [1] where a 69% reduction in SSI (14.6% vs. 4.5%, $p = 0.011$) was found in the chlorhexidine-alcohol group. In the two cited studies the difference was statistically significant. The lower benefit gotten in the present study compared to the two cited studies might be due to the fact that the studies were done in general surgical and gynaecological patients respectively. Berry *et al.* also compared povidone iodine with chlorhexidine-alcohol in 371 patients undergoing clean surgery. Significantly more patients (28/176; 15.9%) in the povidone iodine group developed an infection compared with the patients cleansed with chlorhexidine (8/195; 4.1%) [14]. Unfortunately, there is no known literature regarding surgical site infection rates using chlorhexidine-alcohol and povidone iodine in elective caesarean section with which the findings of this study could be compared.

The finding of beneficial effect of chlorhexidine-alcohol over povidone iodine, however, contrasts with the findings of Swenson *et al.* [15] in general surgical patients, where they found that iodine containing antiseptics were more protective against the development of SSI than chlorhexidine-alcohol containing antiseptics.

A Cochrane review of skin preparation for preventing infection following caesarean section [3] found no significant difference in the incidence of SSI between skin antiseptics used in the six trials included in the review. Of the five trials included none compared chlorhexidine alcohol with povidone iodine. The reviewers concluded that "little evidence was available from the included randomised controlled trials to evaluate different agent

Table 1. Characteristics of patients.

Characteristic	Total patient population N = 374	Chlorhexidine-alcohol group N = 188	Povidone iodine group N = 186	P value
Mean age (years)	32.01 ± 6.13	32.13 ± 6.03	31.89 ± 6.25	1.00
Parity	1.61 ± 0.42	1.60 ± 0.59	1.70 ± 0.64	0.84
Social class				
I	156 (41.7%)	75 (39.9%)	81 (43.5%)	0.25
II	133 (35.6%)	66 (35.1%)	67 (36.0%)	
III	69 (18.4%)	41 (21.8%)	28 (15.1%)	
IV	15 (4.0%)	5 (2.7%)	10 (5.4%)	
V	1 (0.3%)	1 (0.5%)	0	
Tribe				
Yoruba	277 (74.1%)	139 (73.9%)	138 (74.2%)	1.00
Ibo	59 (15.8%)	30 (16.0%)	29 (15.6%)	
Hausa	20 (5.3%)	10 (5.3%)	10 (5.4%)	
Others	18 (4.8%)	9 (4.8%)	9 (4.8%)	
Occupation				
Professional	140 (37.4%)	70 (37.2%)	70 (37.6%)	0.93
Artisan	60 (16.0%)	28 (14.9%)	32 (17.3%)	
Housewife	96 (25.7%)	50 (26.6%)	46 (24.7%)	
Student	78 (20.9%)	40 (21.3%)	38 (20.4%)	
Educational status				
Tertiary	204 (54.5%)	104 (55.3%)	100 (53.8%)	0.98
Secondary	112 (29.9%)	55 (29.3%)	57 (30.6%)	
Primary	35 (9.4%)	18 (9.6%)	17 (9.1%)	
No formal education	23 (6.1%)	11 (5.8%)	12 (6.5%)	
Body mass index				
Normal	23.75 ± 3.33 280 (74.9%)	23.70 ± 3.26 141 (75.0%)	23.81 ± 3.43 139 (74.7%)	0.98
Over weight	61 (16.3%)	31 (16.5%)	30 (16.1%)	
Obese	33 (8.8%)	16 (8.5%)	17 (9.2%)	
Indications for surgery				
1 caesarean section + another complication	115 (30.7%)	61 (32.4%)	54 (29.0%)	0.13
Major placenta praevia	54 (14.4%)	32 (17.0%)	22 (11.8%)	
2 previous C/S or more	53 (14.3%)	27 (14.4%)	26 (14.0%)	
Abnormal lie at term	43 (11.5%)	24 (12.8%)	19 (10.2%)	
Previous uterine surgery	24 (6.4%)	12 (6.4%)	12 (6.5%)	
Breech presentation	45 (12.0%)	20 (10.6%)	25 (13.4%)	
Others	40 (10.7%)	12 (6.4%)	28 (15.1%)	
Duration of surgery				
Less than 1 hour	371 (99.2%)	187 (99.5%)	184 (98.9%)	0.56
More than 1 hour	3 (0.8%)	1 (0.5%)	2 (1.1%)	
Anaesthesia used				
Spinal	371 (99.2%)	186 (98.9%)	185 (99.5%)	0.57
General	3 (0.8%)	2 (1.1%)	1 (0.5%)	

Table 2. Development of skin reaction by type.

Type of skin reaction	Chlorhexidine-alcohol group N = 188	Povidone iodine group N = 186	Total N = 374	P value
Any skin reaction	8 (4.4%)	10 (5.4%)	18 (4.8%)	0.40
Pruritus	4 (2.2%)	6 (3.2%)	10 (2.7%)	
Erythema	4 (2.2%)	4 (2.2%)	8 (2.1%)	

Table 3. Development of surgical site infection by type and microorganism.

Type of surgical site infection	Chlorhexidine-alcohol group N = 188	Povidone iodine group N = 186	Total N = 374	P value
Any type of surgical site infection	23 (12.2%)	28 (15.1%)	51 (13.6%)	0.26
I Normal healing with mild bruising or erythema	3 (1.6%)	4 (2.2%)	7 (1.9%)	
II Erythema plus other signs of inflammation	7 (3.7%)	10 (5.3%)	17 (4.5%)	
III Clear or haemoserous discharge	7 (3.7%)	6 (3.2%)	13 (3.5%)	
IV Pus	5 (2.7%)	7 (3.8%)	12 (3.2%)	
V Deep or severe wound infection with/without tissue breakdown	1 (0.5%)	1 (0.5%)	2 (0.5%)	
Microorganism cultured				
<i>Staphylococcus aureus</i>	10 (5.3%)	11 (5.9%)	21 (5.6%)	
<i>Escherichia coli</i>	6 (3.2%)	8 (4.3%)	14 (24.1%)	
<i>Pseudomonas aeruginosa</i>	3 (1.6%)	3 (1.6%)	6 (3.7%)	
<i>Proteus mirabilis</i>	4 (2.1%)	6 (3.2%)	10 (2.7%)	

forms, concentrations and methods of skin preparation for preventing infection following caesarean section” [3].

Most of the cases of SSI were of the superficial type which was similar to findings of other investigators [13] [16]. In this study, the commonest causative organism isolated for SSI was *Staphylococcus aureus* followed by *Escherichia coli*. This is similar to the findings of other investigators in Ile-Ife [16] [17]. Shittu *et al.* [17] found that *Staphylococcus* species made up about 41% of the isolates from infected wounds while Adisa *et al.* [16] found that *Staphylococcus aureus* made up 62.5% of the isolates found in their study. This is in keeping with the fact that most SSI occurs from commensal organisms such as *Staphylococci* species which are consistently present on a patient’s skin, compared with transient organisms that are more easily removed [18].

Incidence of skin reaction was found to be higher in the povidone iodine group than the chlorhexidine-alcohol group. The reaction consisted mainly of pruritus and erythema but none was life threatening. These reactions were attributed to the antiseptic because they involved the entire area the antiseptic was used on and not just the incision site.

The true incidence of chlorhexidine allergy is unknown [19]. However, it is believed that it is more prevalent than quoted and cases may have been overlooked due to the nature of the reaction and lack of suspicion of chlorhexidine as a culprit [20]. Incidence varies from 0.47% - 5% [19] [20]. The incidence of 5% gotten by Apisarnthanarak *et al.* [20] is similar to the findings of 4.4% in this study. Povidone iodine is also known to be associated with adverse reactions ranging from minor skin irritation to anaphylaxis [21], although like chlorhexidine, pruritus is the most commonly reported allergic reaction. Most reports of povidone iodine allergy in the literature are case reports making comparison of the incidence gotten in this study with previous works almost impossible.

The result of this study shows that although chlorhexidine-alcohol skin antiseptic has some benefit over povidone iodine in terms of lower incidence of SSI and skin reaction, the evidence is not sufficient enough to recommend it over povidone iodine. The study goes further to serve as a reference for future work involving skin antiseptics and caesarean section.

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