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Povidone-Iodine versus Chlorhexidine-Alcohol Skin Preparation for Prevention of Surgical Site Infection after Caesarean Delivery in a Tertiary Medical Centre, South West, Nigeria

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ABSTRACT

Background: Surgical site infection is a major contributor to the increasing morbidity and mortality with caesarean section as compared to vaginal delivery. The incidence of surgical site infection following caesarean section is higher in developing countries. Prevention of surgical site infection with good skin antiseptic preparation before surgery is therefore a crucial part of care.
Objective: To compare the effectiveness of chlorhexidine alcohol and povidone iodine in preventing surgical site infection following emergency caesarean section.
Methods: The study is interventional, non-blinded, randomized study conducted at Federal Medical Centre, Owo, Nigeria. One hundred and eight (108) eligible women, who had emergency caesarean section were recruited into the study, fifty-four (54) in each arm. One group received chlorhexidine alcohol as the skin antiseptic before operation while the other arm received povidone iodine. Both groups were followed for 30 days and assessed for surgical site infection. Data obtained were analyzed using SPSS 21.
Results: The mean age of women in the study was 29 years (SD 6.5) and majority of the participants were artisans constituting 58.7%. No statistical difference in the rate of skin reaction to the two skin antiseptics (P = 0.591). Even though the incidence of SSI in the povidone group was less than in the chlorhexidine group (9.4% vs. 17.6%), this finding was not statistically significant (P = 0.477). The surgical site infection rate in this study was 13.5%.
Conclusion: There was no statistical difference in the effect of chlorhexidine alcohol and povidone iodine antiseptic skin preparation on the rate of surgical site infections following emergency caesarean section in 3Federal Medical Centre, Owo, Nigeria.

Keywords: Surgical site infection, Caesarean section, Skin reaction, Antiseptic skin preparation

INTRODUCTION

Caesarean section or delivery is a major obstetric surgery performed on women.[1] The caesarean section rate is rising worldwide. The rate of caesarean section is over 20% in

many countries, even reaching 70% in Brazil.[2] The risk of maternal morbidity and mortality is higher in caesarean section than in vaginal delivery, with wound site infection a major component of morbidity. The occurrence of these morbidities poses some challenges to the patient, the family and the health care system particularly with regards to prolonged hospital stay, hospital costs, patient satisfaction and social implications for the family as a whole. Surgical site infections are the third most frequently reported hospital acquired infection.[3] Women who deliver by caesarean section are exposed to the possibility of infection from their own, external or environmental sources of infection. Preventing infection by properly preparing the skin before incision is therefore a crucial part of the essential care given to women prior to caesarean birth.

Antiseptic techniques and the use of chemical antiseptics is a recent development in the history of surgery and medical treatment. Before the discovery of germs and Louis Pasteur's proof that they could cause diseases, Ignaz Semmelweis introduced washing of hands and instruments with soap and chlorine in 1847 to reduce maternal mortality due to puerperal sepsis.[4] Following Pasteur's publications, Joseph Lister introduced the use of carbolic acid spray, now known as phenol, on instruments, surgical incisions and dressings in 1865 to reduce the incidence of gangrene.[5] Many solutions - including alcohol and iodine, have been used since then to prepare operative sites to minimize incidence of surgical site infections. However, there is no certainty about the optimum antiseptic skin preparation for preventing surgical site infection. Estimates of rate of surgical site infections vary; it has been found to be 5-10% in some European studies[6] but has been found to be higher in developing countries.[7] Values of about 16% was recorded in Ibadan, Nigeria[8] while 24% was recorded in Tanzania.[9] Interventions with prophylactic antibiotics has reduced surgical site infections considerably but the rate of infection remains high.[10] These infections increase the cost of hospital care and put pressure on the limited available resources. The rate of infection is increased in the presence of other risk factors such as gross contamination of the operation site, prolonged and premature rupture of membrane, obstructed labour, chorioamnionitis, massive obesity and altered immune status.[11] Even in this modern era, surgical site infections remain a major public health problem in both developed and developing countries.[12] This study aims to determine the comparative effectiveness of povidone-iodine and chlorhexidine-alcohol pre-operative skin preparation for prevention of surgical site infections after caesarean delivery.

MATERIALS AND METHODS

Study design: It was an interventional, non - blinded, randomized single centre study at Fedearal Medical Centre Owo, Ondo State, Nigeria. All sequential obstetric patients who require emergency caesarean section were recruited with the following exclusion criteria. Patients with obvious features of infection, prolonged rupture of membranes, prolonged obstructed labour, known allergy/hypersensitivity to chlorhexidine or povidone iodine and Immunocompromised patients e.g. patients with HIV, diabetes mellitus. The hospital provides tertiary services to the people in the state and its environs. It serves as a major referral hospital for government owned and privately owned hospitals in Ondo State and the surrounding states.

Sample Size: Accepting a study power of 80%, confidence interval of 95%, study control ratio of 1:1, the sample size was determined using the statistical formula for comparing two proportions as follows:

$n = (Z\alpha + Z\beta)\ 2 \times P\ (1-P)$
$(Po-P1)\ 2$

N = minimum sample size per group

$Z\alpha$ = Standard normal deviation corresponding to the probability alpha, the probability of making a type 1 error, at 0.05 = 1.96.

Zβ = Standard normal deviation corresponding to the probability beta, the probability of making a type 2 error, at 0.20 (using a power of 80%) = 0.84
P = Arithmetic average of the two proportions (Po & P1)
Po = Estimated prevalence in the target population which is 16%.
P1 = Estimated prevalence in the control subjects which is 4%
P = 0.16 + 0.04 = 0.1
Therefore, n = (1.96+0.84)2 x 0.1(1-0.1)
(0.16-0.04) 2
17n = 7.84 x 0.1 x 0.9 = 49
0.0144
Ninety-eight (98) subjects were required to make the result statistically significant.
Assuming a percentage attrition of 10%, and also to ensure significance with loss to follow up, one hundred and eight (108) patients were recruited for this study, 54 on each arm.
Randomization: This was achieved by using sequentially labelled, sealed brown envelopes according to a secret randomization code generated by an independent statistician using a computer-generated random sequence. The sealed and secure envelopes were randomly placed in the labour ward theatre and were drawn serially by the surgeons before the procedure. Systematic bias was reduced by using the same standard procedure of skin preparation, skin culture and assessment of outcomes.

Procedure:

Patients had caesarean delivery using Pfannenstiel incision for the skin, vicryl 2 /o for the subcutaneous layer while the skin was closed with either vicryl 2 /o or nylon 2 /o for one previous caesarean section that failed vaginal birth after caesarean section (VBAC). The operations were done under spinal anesthesia unless otherwise indicated. The duration of surgery was noted. The demographic, obstetric and neonatal data were obtained from the case records of the patients. The surgical area was shaved on the surgical table just before commencing antiseptic skin preparation.
Envelopes were picked as described earlier to group patients into either of the two groups. For patients in the chlorhexidine –alcohol group, skin preparation was done with 18Valon® (containing chlorhexidine gluconate 0.3%w/v and cetrimide 3.0%w/v manufactured by Royal Priesthood Laboratories Limited) soaked in gauge. The quantity of Valon® was diluted with distilled water in 1:1 ratio. Scrubbing started from above the pubic bone to the suprapubic area, upwards to the subcoastal region and then from the hip to just above the knee, from the lateral to the medial sides, and the vulval area. This was repeated twice, making a total of three scrubbings. The area was then dried with a piece of sterile gauge in a similar pattern. Moko® (containing isopropyl alcohol 95%v/v manufactured by New Health way Co. Ltd) was then applied on the area in the same pattern and allowed to dry before appropriate draping of the surgical area was done. For patients who fell into the povidone iodine group, Wosan® (containing10% povidone iodine manufactured by Jawa pharmaceuticals) was used to scrub the operation area in a fashion similar to the chlorhexidine application, as explained above. Application was also done three times, with the third application used to paint the operation area, followed by appropriate draping. Prophylactic antibiotics in the form of intravenous
Amoxicillin / Clavulanic acid 600 mg stat and Metronidazole 500 mg were administered before anaesthesia was given. The placenta was delivered by controlled cord traction and removed manually only if retained for more than 5 minutes. The uterus was repaired in two layers. A standard sterile gauze dressing, with adhesive plaster was then applied to the wound after closure of the skin. The patient was counselled to keep the wound dressing dry.
Postoperatively, the patients wound and area of skin surrounding the wound were inspected on the third and seventh days. The dressings were changed on the third postoperative day or earlier if soaked. Swabs were taken for microscopy, culture and

sensitivity (MCS) from wounds determined to be infected and dressing instituted as appropriate.

After discharge, the women were instructed about the symptoms and signs of wound infection with written instruction sheets and a notebook for documentation. Subjects were discharged on post-operative day 4 unless otherwise indicated, seen for wound inspections on days 7 and 14 and then contacted every week up to 30 days after surgery, to assess symptoms of surgical site infections. Subjects who reported symptoms were evaluated at the emergency unit for surgical site infection. A modification of the Southampton wound infection scoring system was used to grade infections when present. Grade 0 is normal healing without any sign of infection; Grade 1 wound infection is normal healing with mild bruising or erythema; Grade II is presence of erythema plus other signs of inflammation; Grade III is discharge of haemoserous fluids from the surgical wound while Grade IV is discharge of pus from the wound and Grade V is discharge of pus and wound dehiscence.

Ethical clearance was obtained from the Federal Medical Centre Owo ethics and research committee. Verbal and written consent were obtained from the participants as well. Patient's refusal to participate in the study were respected with no attempt to induce or coerce to gain consent. Confidentiality of information was assured throughout the study.

RESULTS

A total of one hundred and eight (108) patients who had emergency lower segment caesarean section and fulfilled the inclusion criteria participated in the study. One (1) had midline incision, and three (3) patients were lost to follow up, leaving a total of one hundred and four (104) patients for analysis. Fifty-one (51) were in the chlorhexidine alcohol group while fifty-three (53) were in the povidone-iodine group. The first table (Table 1) showed the demographic data of participants.

The marital status, BMI, parity and the tribes were similar for the two groups with no statistic difference across all variables. The Indications for and duration of Surgery among the respondents was presented in Table 2. It was observed that cephalopelvic disproportion (CPD) was the most common indication for EMLCS accounting about half in both groups. This was closely followed by fetal distress and antepartum hemorrhage. Other indications were footling breech; cord prolapse and retained second twin with similar distribution in both groups of respondents. Most of the surgeries lasted one hour or less. No statistical difference in the duration of surgery between the two groups. (P=0.104).

It was observed that 94.1% of respondents had no skin reaction to chlorhexidine - alcohol and 96.2% respondents who had no skin reaction to povidone iodine.

The results of development of Surgical Site Infections and Causative Organism between Chlorhexidine-Alcohol and Povidone Iodine groups showed that the incidence of surgical site infection (SSI) from chlorhexidine-alcohol group was 9 (17.6%) while povidone iodine group was

5 (9.4%). However, the surgical site infection (SSI) incidence in the study was 13.5%.

The incidence of surgical site infection (SSI) was lower in the povidone iodine group but it was not statistically significant. All the respondents who had deep tissue breakdown were in the chlorhexidine group. However, there was no statistically significant difference between the chlorhexidine alcohol and povidone iodine groups. (P= 0.477). Staphylococcus Aureus was the commonest microorganism cultured among patients that developed Surgical Site Infection accounting for 9 (64.3%) of the 14 cases infected, E.Coli cultured in four cases with Proteus Mirabilis cultured in only one patient. There was no significant difference between arms of cleaning agents.

Table 1 Demographic distribution of Participants

variable	Chlorhexidine	Povidone	X^2	P-value
	(n=51) Freq (%)	(n=53) Freq (%)		
Age group (years)				
<20	23 (3.9)	2 (3.8)	3.536	0.618
20-24	15 (29.4)	12 (22.6)		
25-29	12 (23.5)	13 (24.5)		
30-34	14 (27.5)	16 (30.2)		
35-39	8 (15.7)	7 (13.2)		
>39	0(0.0)	3 (5.7)		
Occupation				
Artisan	30 (58.8)	31 (58.5)	2.252	0.522
Professional	15 (29.4)	18 (34.0)		
House wife	4 (7.8)	1 (1.9)		
student	2 (3.9)	3 (5.7)		
Social Class				
I	12 (23.5)	14 (26.4)	1.297	0.862
II	8 (15.7)	12 (22.6)		
III	22 (43.1)	20 (37.7)		
IV	8 (15.7)	6 (11.3)		
V	1 (2.0)	1 (1.9)		
Marital Status				
Married	49(96.1)	51(96.2)	0.002	0.969
Single	2(3.9)	2(3.8)		
Body Mass Index (BMI)				
Overweight	30(58.9)	23(43.4)	2.156	0.284
Obese	12(23.5)	18(34.0)		
Normal	9(17.6)	12(22.6)		
Parity				
Pra 1-4	38(74.5)	35(66.0)	0.892	0.345
Nullipara	13(25.5)	18(34.0)		
Tribe				
Yoruba	35 (8.6)	37 (69.8)	3.218	0.359
Igbo	8 (15.7)	12 (22.6)		
Others	6 (11.8)	4 (7.5)		
Hausa/Fulani	2 (3.9)	0 (0.0)		

Table 2 The Body Mass Index (BMI) and Social Class versus SSI

Variable	Respondents	(n=104)	X^2	Value
	No SSI (%)	SSI (%)		
BMI				
Normal	19 (90.5)	2 (9.5)	2.168	0.338
Overweight	48 (90.6)	5 (9.4)		
Obese	24 (80.0)	6 (20.0)		
Social Class				
I	25 (96.2)	1 (3.8)	5.173	0.270
II	18 (90.0)	2 (10.0)		
III	35 (83.3)	7 (16.7)		
IV	12 (85.7)	2 (14.3)		
V	1 (50.0)	1 (50.0)		

Table 3 Indications for and Duration of Surgery

variable	Chlorhexidine	Povidone	X^2	P-value
	(n=51)	(n=53)		
	Freq (%)	Freq (%)		
Indication for surgery				
CPD	21 (41.2)	27 (50.9)	2.645	0.450

Fetal distress	20 (39.2)	15 (28.3)		
APH	4 (7.8)	7 (13.2)		
others	6 (11.8)	4 (7.5)		
Duration of surgery				
Less than one hour	34 (66.7)	27 (50.9)	2.650	0.104
More than one hour	17 (33.3)	26 (49.1)		

CPD: Cephalopelvic Disproportion APH: Antepartum Haemorrhage

Table 4 Development of Surgical Site Infections and Causative Organisms between Chlorhexidine and Povidone Iodine Groups

variable	Chlorhexidine (n=51) Freq (%)	Povidone (n=53) Freq (%)	X^2	P-value
Type of Surgical Site Infection				
Normal healing without any sign of infection	42 (82.4)	48 (90.6)	3.506	0.477
Normal healing with mild bruising or erythema	4 (7.8)	3 (5.7)		
Erythema plus other inflammation	2 (3.9)	2 (3.8)		
Deep with tissue breakdown	2 (3.9)	0 (0.0)		
Clear or haemoserous discharge	1 (2.0)	0 (0.0)		
Organisms cultured				
No culture	42 (82.4)	48 (90.6)	2.474	0.480
S. aureus	5 (9.8)	4 (7.5)		
E. coli	3 (5.9)	1 (1.9)		
Proteus mirabilis	1 (2.0)	0 (0.0)		

DISCUSSION

The aim of this randomized controlled trial was to compare the effectiveness of chlorhexidine-alcohol against povidone iodine in preventing surgical site infection following emergency caesarean section. The maternal baseline characteristics of both groups were similar. Majority of the patients in both groups were artisans because the hospital is located in a rural area and most of the patients were also referred from nearby rural areas. This probably accounts for most of the patients belonging to social class III. Even though the effect of social class on surgical site infection was not found to be significant in this study, association has been demonstrated between low social status and postpartum morbidities, including infection.[13]

A large percentage of the patients were overweight, but surgical site infection was highest in the obese group, about 20%. Effect of Body Mass Index on wound infection was not found to be statistically significant in this study, but other researchers have documented significant association between Body Mass Index and higher incidence of surgical site infection.[14.15] Cephalopelvic disproportion (CPD) accounted for the highest indication for emergency caesarean section in this study, ahead of fetal distress. This could be because most of failure to progress in labour are termed CPD. CPD was also found to be the leading reason for caesarean section by Swende in Makurdi, Benue State, Nigeria in 2008[16] and Bukar et al in Gombe,[17] also in Nigeria in 2009. CPD was found to be responsible for 39.3% and 20.8% of the caesarean sections in both studies respectively.

The incidence of surgical site infection in this study was 13.5%. This is slightly lower than the findings of 16.4% reported by Morhassen Bello et al[8] in Ibadan but similar to the incidence documented by Ezechi et al in Lagos.[14] The rate of 13.5% in this study is lower than the 24% reported in a Tanzanian hospital[9] but higher than the incidence reported in Ethiopia by Demisew et al in 2011.[18] As expected from most developed

countries, the incidence reported in England[19]63 is much lower than the incidence in this study.

Povidone iodine has a lower incidence of infection than chlorhexidine-alcohol in this study, (9.4% vs 17.6% P-value = 0.477), though this finding was not statistically significant. A Cochrane systematic review of skin preparation for preventing infection following caesarean section by Hadiati et al, found no statistically significant difference in the occurrence of surgical site infection following skin preparation with chlorhexidine alcohol and povidone iodine.[1] This is contrary to findings by Darouchie et al who found chlorhexidine alcohol to be more effective than povidone iodine (9.5% vs 16.1%).[20] However, Swerson et al, documented that povidone iodine was more effective than chlorhexidine – alcohol when used as presurgical skin antiseptic (4.8% in the povidone iodine group vs 8.2% in the chlorhexidine group. P=0.001).[21]

The surgical site infection found in this study were mostly superficial, as reported in other trials.[8,22,23] However, there was a case of organ/space surgical site infection that required exploratory laparotomy about two weeks after the caesarean section.[24] The commonest organism in this study was Staphylococcus Aureus, which also constituted 37% of causative microorganism declared by Methodius Tuuli et al[22] in 2016. This was not unexpected, as the endogenous microorganism implicated in surgical site infection are mostly from the patients' skin and immediate environment.[25]

CONCLUSION

Although there was no statistical difference in the effect of chlorhexidine alcohol and povidone iodine antiseptic skin preparation on the rate of surgical site infections following emergency caesarean section in this study, the outcome of this study showed that povidone iodine, when properly used, has some benefits in preventing surgical site infection but with not enough evidence to recommend it over the traditional chlorhexidine alcohol. This study can serve as basis for further study in this area.

Declaration by Authors

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