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Chlorhexidine-alcohol compared with Povidone-iodine for surgical site antisepsis in elective caesarean section: A multi-centre randomized controlled trial

Authors
Okoli EN, Anate A, Alu FE, Otubu Joseph AM, Kwari SD, Bello O, Chibundu O
Department of Obstetrics and Gynaecology, Kubwa General Hospital, Federal Capital Territory Administration, Abuja , Nigeria.

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I. Introduction

Surgical site infection (SSI) is an infection of a surgical incision, space, or organ within 30 days of surgery.[1] It is a healthcare-associated infection in which wound infection occurs after an invasive procedure.[2]The incidence of surgical site infection ranges from 3-15% worldwide.[3-5] SSI is the most common healthcare-associated infection in the developing world with sub-Saharan Africa having an incidence of about 14.8%.[1,2,6] Nigeria has an average incidence of 14.5% and Obafemi Awolowo University Teaching Hospital Ile-Ife reported an incidence of 13.6% following elective caesarean section.[6,7] It is the third most reported hospital-acquired infection and the most common cause of postoperative complications following caesarean section.[3,8] SSI after a caesarean section has been strongly associated with severe maternal morbidity, prolonged hospital stay, re-admission, re-operation, increased cost of medical care and late return to work.[8-12]

Caesarean section is a major obstetric surgical procedure and the incidence is on the increase worldwide.[3,5,7-12] Skin is the major source of pathogens causing surgical site infection.[2,3,5,11] During caesarean section the integrity of the skin is breached by the surgical incision thus allowing for migration of the organism living in harmony into the wound thereby causing infection.[10]

According to the Centre for Disease Control and Prevention, SSIs are classified as incisional surgical site infection (superficial and/or deep) and Organ/space surgical site infections. Superficial SSI is evidenced by the presence of pain or tenderness, indurations, erythema, local warmth of the wound site, purulent discharges and organisms isolated from the fluid/tissue of the superficial incision. It is limited to the skin and subcutaneous tissue. Deep SSI involves the skin, subcutaneous layer, the fascia and the muscle. It is characterized by the presence of purulent discharges/drainages without organ/space involvement, fascial dehiscence or a deep abscess is identified by direct examination or during reoperation, or by radiologic examination. The organ/space SSI is when internal organs or spaces are involved, such as in pelvic abscesses and endometritis.[8] Superficial SSIs are commoner than deep SSIs and incisional types are commoner than organ/space wound infections with superficial incisional SSIs accounting for more than half of all categories of SSI.[12,13]

Pre-operative skin antisepsis using antiseptic agents is performed to reduce the risk of SSIs by removing soil and transient organisms from the skin where a surgical incision will be made and is a vital step in preventing SSI. Antiseptics are thought to be toxic to bacteria and therefore aid their mechanical removal.[1,5,11,13] Alcohol, combined with either Chlorhexidine (CHG) or an iodophor (Povidone –iodine), is synergistic in enhancing skin preparation and prevention of SSI.[14]The current NICE guideline regarding skin preparation across surgeries is: "Prepare the skin at the surgical site immediately before the incision using antiseptic aqueous or alcohol-based preparation: Povidone-Iodine or Chlorhexidine is most suitable.[11] The effectiveness of skin preparation is thought to be dependent on the antiseptic agent used and the method of its application.[5,15] Appropriate use of an effective skin antiseptic agent during caesarean section is one of the evidence-based strategies in the prevention of SSI following caesarean section.[3,5,13,16-18] The Chlorhexidine gluconate in alcohol solution and Povidone-iodine in aqueous solution are the most commonly used skin antisepsis for the prevention of surgical site infection during caesarean section.[6,16]

Chlorhexidine Gluconate (CHG) is thought to be effective against a wide range of Gram–positive and Gram-negative bacteria, yeast, and some viruses.[5,6] It is both bacteriostatic and bactericidal and acts by membrane disruption of bacteria microorganisms.[6] Alcohol denatures the cell wall protein of bacteria. It is effective against Gram-positive and Gram –negative, Tubercle bacilli, many fungi and viruses.[5,12] Alcohol when used in combination with CHG enhances antiseptic effectiveness against SSIs.[15] Povidone-iodine (PI) acts by

penetrating cell wall, oxidizes and substitutes microbial contents with free iodine. PI solutions are effective against a wide range of Gram-positive and Gram –negative bacteria, the tubercle bacillus, fungi and viruses.[2,5]

The Association of peri-operative Registered Nurses (AOPRN) guidelines stipulate that for an antiseptic agent to be effective in reducing SSIs after surgery, it should be applied in concentric circles starting from the incision site to the periphery. The area prepared should be sufficient to include any potential incision site divorced from the main incision site, such as a possible area for the insertion of a drain. A dedicated instrument (sponge holding forceps and sterile gauze) should be used and discarded once the periphery is reached, and time allowed for the solution to dry especially when alcoholic solutions are used as these are flammable.[1,5]

A review of available literature showed conflicting reports as to which of these two skin antiseptic agents was most effective for the prevention of SSI. Some studies reported that chlorhexidine –alcohol was superior to povidone-iodine,[7,10,11,19-22] while some reported no difference.[8,17,23]

A critical look at these studies revealed that some did not exclude co-morbidity factors, while some involved both obstetric and non-obstetric surgeries and some did not adhere strictly to evidenced-based perioperative interventions and methods of skin preparation. A study that will exclude obvious co-morbidities that predispose patient to SSI as well as adhere strictly to pre-operation patient's preparation is most desirable to determine effectiveness of these two antiseptic agents following elective caesarean section. There has not been any study in either Asokoro or Maitama District Hospitals to guide the use and choice of skin antisepsis, neither are there such studies in any hospital in the Federal Capital Territory (FCT) Abuja, Nigeria to our knowledge. Chlorhexidine Alcohol and PI are readily available and are the most commonly used antiseptic agents in Asokoro and Maitama District Hospitals during surgical procedures. Therefore, there is the need to determine which of these two antiseptic agents is most effective in the prevention of SSIs in both hospitals. The findings from this study may add to the body of existing knowledge and inform the recommendations on the use of skin antiseptic agents in these two hospitals and other healthcare institutions for the reduction in the incidence of SSI. It may also impact positively on obstetric practice in the West African Sub-region.

We hypothesized that there is no statistically significant difference in terms of prevention of SSI following the use of chlorhexidine –alcohol and the use of povidone-iodine in elective caesarean section and set out to compare their efficacy in preventing SSI by comparing the incidences of SSI in the two groups of patients used for the study.

II. Subjects And Methods

This multi-centre randomised controlled trial was conducted from September 2020 to March 2021 in the Obstetrics and Gynaecology Department of Asokoro District Hospital and Maitama District Hospital Abuja, Federal Capital Territory, Nigeria.

The study population comprised booked pregnant women aged between eighteen (18) and forty-five (45) years with term pregnancy, who had elective caesarean section and gave informed consent. Women with pre-labour rupture of membranes, body mass index >35kg/m^2, pre-operation Packed cell volume (PCV) less than 30%, previous midline abdominal surgical incision, more than 4 previous caesarean sections, diabetes mellitus, retroviral disease, any obvious skin infection, current use of immunosuppressive therapy including steroids, cigarette smoking or alcohol consumption, allergy to either Chlorhexidine-alcohol or Povidone-iodine or withheld consent were excluded from the study.

Ethical approval was obtained from the Federal Capital Territory Health Research Ethics Committee (FHREC) with approval number FHREC/2020/01/46/29-05-20.

A total of 200 participants were recruited for the study by the researchers and four trained research assistants (two in each hospital) were also involved in the study.

Patients, at the beginning of the study, were selected by consecutive sampling method in which all eligible patients who were admitted for elective caesarean section and consented to participation in the study were selected until the two hundred patients required were recruited. Information about patients was collected by the administration of a questionnaire that contained the patient's biodata, obstetric characteristics, physical examination, and relevant laboratory investigation results.

The subjects that met the inclusion criteria were randomized in the ratio of 1:1 into either the skin antiseptic preparation group A (CH-A group): 0.3% Chlorhexidine Gluconate in 70% isopropyl alcohol or skin antiseptic preparation group B (PI group):10% Povidone-iodine (PI) aqueous solution using computer-generated random sequence. To avoid selection bias, each treatment group was printed on a paper, cut to size and concealed in identically sealed, sequentially numbered opaque envelopes kept in each of the theatres.

The study participants were all admitted a day before surgery, fasted overnight, had a normal bath the morning before surgery and there was no perioperative surgical site hair removal. The sequentially numbered, sealed opaque envelopes were serially drawn by each of the participant as soon as she entered the theatre for surgery. The serial number on each of the envelopes was carefully noted by the research assistants and written

boldly on the participant's treatment folder for identification. This number was matched with the corresponding treatment group extracted from the computer at the end of the study by the principal researcher for data analysis. Each drawn envelope was handed over to the scrub nurse who then opened the sealed envelope revealing the antiseptic group with which the surgeon cleaned the operation site before the surgical incision. Ceftriaxone 1 gram was received by each participant within one hour prior to the skin incision.The surgeon was either a consultant or a senior registrar to be certain that the requisite surgical skill was maintained during the surgery.

For participants in group A, the surgeon cleaned the operation site, first with three applications of sterile gauze soaked with chlorhexidine gluconate B.P. 0.3% w/v ("PURIT" manufactured by SARO Lifecare Limited) which was diluted with distilled water in a 1:1 ratio, followed by one application of Isopropyl 70% alcohol v/v (manufactured by LEYJAY Nigerian Limited).

For group B, the skin was similarly cleaned with three applications of aqueous solution of 10% Povidone-iodine containing Polyvinyl pyrrolidine iodine/iodophor (manufactured by the (JAWA international limited). The antiseptics were applied in a concentric manner using sterile gauze and sponge-holding forceps starting from the incision site to the periphery. The antiseptics were allowed to dry before sterile draping was done.

For all the participants, the Pfannenstiel incision was made and a routine lower-segment caesarean section was done. The skin was closed using the subcuticular suturing technique with Vicryl 2/0 suture. The area of the surgical incision was cleaned with the corresponding antiseptic group, allowed to dry, and sterile dry dressing was applied. Each participant received the same post-operative antibiotics 12 hourly for 24 hours followed by oral antibiotics for 5 days.

All the participants were examined for evidence of fever on the second post-operative day, while the wound dressing was opened on the third operative day by one of the principal researchers and one research assistant in each of the hospitals and assessed for evidence of surgical site infection according to the CDC definition of SSI: redness or heat, swelling or indurations, purulent discharge, or wound breakdown. The wound site was assessed daily thereafter until the patient was discharged and thereafter weekly up to 30 days post-operation. Skin reaction around the surgical incision and on the areas of antiseptic solution application was also assessed. The fever was defined as a temperature of 38.0 degree Celsius or above after 24 hours of surgery measured on two occasions at least four hours apart. Where there was purulent discharge, the wound swab was taken for microscopy, culture and sensitivity. The infected wound was treated by either wound dressing alone or wound dressing and antibiotics as appropriate. Before discharge from the hospital, participants were educated on the signs and symptoms of surgical site infection as well as wound care. They were educated on the need to avoid the application of any form of home remedy. They were instructed to return to the hospital weekly for wound assessment or earlier should they notice any signs and symptoms of surgical site infection. Those who missed their weekly appointment were contacted through the telephone numbers they supplied during admission. At every visit, inquiry was made for symptoms of SSI and the surgical site was assessed for evidence of SSI and recorded on the clinical Proforma.

The data collected was analysed using the statistical package for social sciences, SPSS version 22 (SPSS Inc. Chicago, IL).

The continuous variables were represented as means ± standard deviation (SD) and the categorical variables were represented as frequency/percentage. The continuous variables were compared between the two arms of the trial by student's t-test while the categorical variables were compared between the two arms of the trial by Chi-square test.

The P-value < 0.05 was considered significant for inferential statistics purpose.

The sample size was determined by the formula for comparing two independent proportions thus.[24]

$$n = \frac{Z^2_{1-\alpha/2}[\, p_1(1-p_1) + p_2(1-p_2)\,]}{ME^2} = \frac{Z^2_{1-\alpha/2}\,[\, p_1(1-p_1) + p_2(1-p_2)}{ME^2}$$

$$ME^2 = \varepsilon^2 (p_1+p_2)$$

where,

n = the minimum sample size for each group.

$Z_{1-\alpha/2}$ = is the percentage point of standard normal deviation set at 95% confidence interval =1.96

P_1 = proportion of anticipated success rate for group A (chlorhexidine –alcohol) was calculated from a previous study done at OAUTH Ile-Ife 12% prevalence rate of SSI (88% effective).[7]

P_2 = proportion of anticipated success rate from group B (Povidone iodine), SSI prevalence of 15%

ME = margin of error= $\varepsilon(p_1+p_2)$ = 10%

ε = precision or relative error.

Therefore, $n = 1.96^2[0.88(1-0.88) + 0.85(1-0.85)]/0.1 \times 0.1 = 1.96 \times 1.96[0.1056 + 0.1276]/0.01$.

$n = 3.8416 \times 0.2332/0.01 = 0.8959/0.01 = 89.58$. This was approximated to 90.

To make allowance for loss to follow-up, a 10% attrition rate was added, and the number was rounded up to 100 for each group making a total of 200 participants.

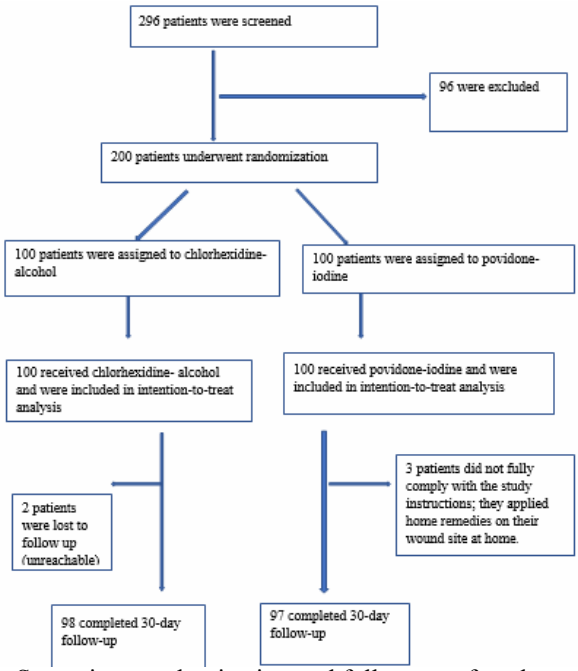

Figure 1: Screening, randomization and follow-up of study participants

III. Results

A total of two hundred women (100 in each of the chlorhexidine-alcohol group and Povidone- iodine group) were recruited into the study. Two patients in the chlorhexidine group were lost to follow-up. Three patients from the povidone-iodine group did not complete the study due to the application of home remedies even without evidence of SSI. However, all 200 study participants were included in the intention-to-treat analysis. See Figure 1.

Table 1 shows the socio-demographic and obstetric distribution of the participants. The majority of the participants were in the 27-36 years age group (74.5%), while 92 (46%) were civil servants, 127 (63.5%) had tertiary level of education, and 114 (60%) were multiparous.

Table 1: Socio-demographic and obstetric distribution of participants

Variables	Frequency(N=200)	Percent
Age Group		
18-26	45	22.5
27-36	149	74.5
37-45	6	3.0
Tribe		
Hausa	37	18.5
Ibo	77	38.5
Yoruba	38	19.0
Others	48	24.0
Religion		
Islam	45	22.5
Christianity	155	77.5
Educational Level		
Primary	2	1.0
Secondary	71	35.5
Tertiary	127	63.5
Occupation		
Civil Servant	92	46.0
Trader	74	37.0
Unemployed	34	17.0
Marital Status		
Married	200	100.0
Parity		
0	21	10.5
1	58	29.0
2	92	46.0
3	27	13.5

4	2	1.0

Table 2 shows the comparison of maternal characteristics among the antiseptic groups. They were similar with respect to age, body mass index, occupation, educational status, gestational age, and previous caesarean section with no statistically significant difference.

There was also no statistically significant difference among the groups with respect to pre-operative PCV, indication for surgery, duration of surgery, blood loss, post-operative PCV and the cadre of the surgeon.

Table 2: Comparison of maternal characteristics among the antiseptic groups

Variables	Chlorhexidine- alcohol Mean±SD	Povidone iodine Mean±SD	T	P-value
Age (years)	32.7±3.3	32.4±3.8	0.716	0.475
Gestational age	38.2±0.6	38.3±0.7	0.428	0.669
BMI	30.2±0.7	30.3±0.6	0.317	0.751
Admission PCV	37.1±1.9	37.3±1.6	0.915	0.361
Post op PCV	33.9±1.5	33.7±1.6	0.823	0.411
Surgery duration	58.6±8.2	59.0±4.9	0.468	0.641
Blood loss	638.5±206.8	630.0±89.3	0.377	0.707
	n=100 n(%)	n=100 n(%)	χ^2	P-value
Parity			1.593	0.810
0	8(8.0)	13(13.0)		
1	30(30.0)	28(28.0)		
2	46(46.0)	46(46.0)		
3	15(15.0)	12(12.0)		
4	1(1.0)	1(1.0)		
Status of surgeon			0.397	0.529
Consultant	30(30.0)	26(26.0)		
Senior registrar	70(70.0)	74(74.0)		
Surgery indication			9.485	0.394
1PCS+MR	5(5.0)	11(11.0)		
IPCS+PIH	7(7.0)	7(7.0)		
2PCS	43(43.0)	31(31.0)		
3PCS	5(5.0)	4(4.0)		
1PCS+BMI	20(20.0)	22(22.0)		
1PCS+TL	13(13.0)	21(21.0)		
1PCS+Post Date	3(3.0)	1(1.0)		
Twin Gestation	1(1.0)	0(0.0)		
1PCS+Multiple Gestation	0(0.0)	1(1.0)		
1PCS+BREECH	3(3.0)	2(2.0)		

SD-standard deviation, T-test statistic, χ^2- chi-square statistic

Key: PCS: previous caesarean section, BMI: body mass index, PIH: pregnancy-induced hypertension, MR: maternal request, TL: transverse lie

Figure 2shows the distribution of indications for the caesarean section. The commonest indication was 2 previous caesarean section which accounted for about 74 (37%) of all overall surgery, one previous caesarean section and twin gestation were the least common indications 1(0.5%).

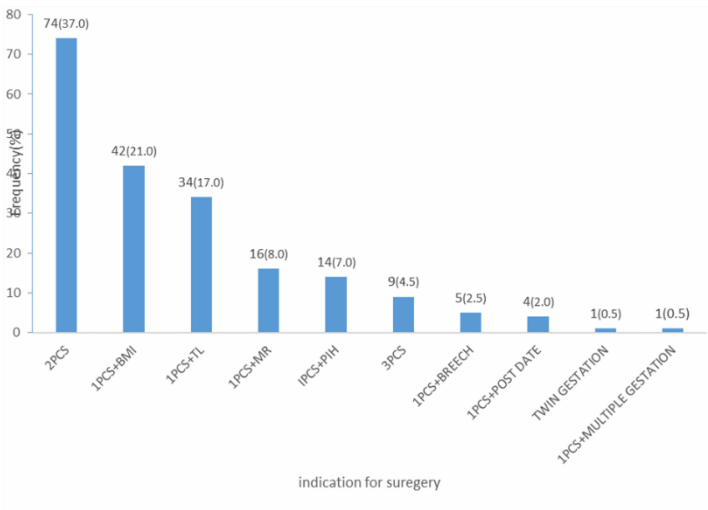

Figure 2: Distribution of indication for the caesarean section. PCS: previous caesarean section, BMI: body mass index, PIH: pregnancy-induced hypertension, MR: maternal request, TL: transverse lie.

The overall surgical site infection in the total population was 10%. The incidence of surgical site infection following the use of chlorhexidine-alcohol was 4.5% (9/100) while the incidence following the use of Povidone-iodine was 5.5% (11/100) but the difference was not statistically significant as shown in table 3.

Table 3: Distribution of surgical site infection among the antiseptic groups.

Surgical site infection	Chlorhexidine- alcohol n=100 n (%)	Povidone- iodine n=100 n (%)	Total	RR(CI)	P-value
Present	9(9.0)	11(11.0)	20(10.0)	0.9(0.5-1.5)	0.637
Absent	91(91.0)	89(89.0)	180(90.0)	1.1(0.7-1.7)	0.637

RR-Relative risk CI- confidence interval

Table 4: This shows the type of surgical site infection among the two antiseptic groups. The superficial surgical site infection was the commonest SSI type 16(8%) while the deep was 4(2%). However, the difference between the incidences of superficial SSI in the chlorhexidine-alcohol compared with povidone-iodine was not statistically significant, (7% vs 9%, P-value 0.602, RR 0.9, CI, 0.5-1.5).

Table 4: Comparison of the type of surgical site infection among the antiseptic groups

Outcome	Chlorhexidine- alcohol n=100 n (%)	Povidone- iodine n=100 n (%)	Total N=200 n (%)	RR(CI)	P-value
Primary					
Surgical site infection	9(9.0)	11(11.0)	20(10.0)	0.9(0.5-1.5)	0.637
Secondary					
Superficial Incisional	7(7.0)	9(9.0)	16(8.0)	0.9(0.5-1.5)	0.602
Deep Incisional	2(2.0)	2(2.0)	4(2.0)	0.5(0.1-2.7)	0.621[f]

RR-Relative risk CI- confidence interval [f]-Fisher's exact test

IV. Discussion

This study shows that there is no significant difference in the incidence of SSI when either Chlorhexidine-alcohol or Povidone-iodine is used for skin antisepsis for elective caesarean section. The sociodemographic and clinical characteristics of the study participants were similar in both groups.

The overall surgical site infection in this study was 10%, which falls within the 3-15% reported worldwide [3-5] but less than 14.5% reported in Nigeria.[6] This may be because this study was conducted among pregnant women who had elective caesarean section, while 14.5% in Nigeria is for all types of surgeries including caesarean section.[6] The overall infection rate in this study is also lower than the 13.6% reported by Aworinde O et al in Ile-Ife whose study was similar and comparable.[7] Although both studies were conducted among women undergoing elective caesarean section, the study participants in Ile-Ife had surgical site hair shaving prior to surgery and prophylactic antibiotic was given after umbilical cord clamping, whereas in this study, the participants received prophylactic antibiotics about one hour prior to the surgical incision which may have allowed for adequate antibiotic tissue penetration during the surgery and none of the participants in our study had surgical site hair shaving prior to skin incision. Data from available literature shows that perioperative shaving causes micro-abrasion, thus breaching the protection offered by the skin which may facilitate microorganism invasion and may lead to surgical site infection. The World Health Organization's global guidelines for the prevention of surgical site infection states that antibiotic should be administered within one hour prior to surgical skin incision and where it is absolutely necessary, shaving should be done in the theatre by the surgeon and preferably with clippers.[1] Strict adherence to these recommendations may explain the lower rate of SSI in our study.

The overall incidence of SSI in this study was also lower than those reported by Nisreen AA et al, Kesani VP et al, and Darouiche RO et al, whose overall infection rates were 12.0%, 21.23% and 25.6% respectively.[10,14,19]The higher infection rate in their studies may be due to the inclusion of patients that had both elective and emergency caesarean sections, as well as those that underwent surgeries for different surgical conditions from other departments with or without overt risks for sepsis, compared to our study where all the participants were pregnant women that underwent elective caesarean section and had no overt risk for infection.

In this study, there was less surgical site infection with the use of chlorhexidine-alcohol than Povidone-iodine, although the difference was not statistically significant. This finding is similar to findings in the studies by Aworinde O et al., Hadiati DR et al. and Bibi S et al.[7,8,21] but in contrast with the findings by Nisreen AA et

al., Kesani VP et al. and Darouiche RO et al, where use of Chlorhexidine-alcohol was shown to be statistically more protective than povidone-iodine.[10,14,19]The difference between the chlorhexidine-alcohol and povidone-iodine groups (4.3% vs 7.7%, P=0.014) reported in the study by Nisreen AA et al. may be due to the lower concentration of Povidone-iodine used in their study.[10] They used 2% chlorhexidine gluconate and 70% isopropyl alcohol and 0.75% povidone-iodine, whereas in our study 0.3% chlorhexidine gluconate, 70% isopropyl alcohol and 10% povidone-iodine were used. The 10% povidone-iodine is said to liberate 1% iodine molecule and a higher concentration of iodine molecule may offer a greater antiseptic advantage over a lower concentration as seen in their study. Similarly, the reported reduction in the rate of surgical site infection with chlorhexidine-alcohol compared with povidone (6.95vs14.28%, P=0.005) recorded by Kesani VP et al was probably due to the use of a higher concentration of 2% chlorhexidine solution compared to our study where a lower concentration of 0.3% chlorhexidine was used.[14] This may have contributed to the significant difference in the two antiseptic agents in their study.

In this study, there was more superficial incisional surgical site infection type than the deep type (16.0% vs. 4.0%),and there was no organ/space type. This is in keeping with the fact that the superficial incision SSI is the commonest type of SSI and incisional types are commoner than organ/space.[12] In this study, there is no statistically significant difference in the incidence of superficial SSI when Chlorhexidine-alcohol was used and when Povidone-iodine was used (7%vs 9%, p=0.602). The study by Kesani VP et al showed that the rate of superficial incisional infection was higher than deep incisional (15.59% vs. 6.12%) and that chlorhexidine-alcohol was significantly more protective than Povidone-iodine against both superficial incisional infection (5.49% vs 10.10%, P=0.043) and deep incisional (1.46% vs 4.18%, 0.05).[14] The difference may be due to the large sample size of 560 (five hundred and sixty) in their study compared with the 200 used in this study.

Our study showed that no skin reaction was observed in both the chlorhexidine-alcohol and Povidone iodine. This finding is in contrast to the finding in the study by Aworinde O et al that reported a 4.8% skin reaction rate, though the report did not state in which antiseptic group the reaction occurred.[7] However, in the study by Nisreen AA et al. there was skin reaction in both the chlorhexidine-alcohol and povidone-iodine (2.3% vs 1.9%), P=0.67), although the difference was not statistically significant.[10] The difference may have been due to the fact that the antiseptic agents used in our study were allowed to dry completely before applying the sterile wound dressing as well as the smaller sample size studied.

V. Conclusion

From the findings in our study, it is still unclear which of the two antiseptic agents (Chlorhexidine-alcohol and Povidone-iodine) should be recommended over the other for the prevention of surgical site infection. Chlorhexidine–alcohol and povidone-iodine are both effective for the prevention of surgical site infection when properly used as skin antisepsis during elective caesarean section and are therefore recommended.

The strength of the study includes the use of an operational manual/ standard operational procedure for the study process and comprehensive training of the research assistants which ensured standardization of the study process thus eliminating systemic error and making the study easy to replicate. Patients with overt risk for infections were excluded from the study, and this to a certain extent controlled for possible confounding variables. The use of the computer-generated random sequence controlled for allocation and observers' bias to an extent.

The findings from the two hundred participants may not be sufficient to generalize for surgical site infection in all other obstetric patients including emergency caesarean sections**.**

Further multi-centre studies involving many other hospitals in the FCT Abuja is recommended.It is expected that the findings from such studies would be more representative and have wider clinical applications. Chlorhexidine-alcohol and povidone-iodine have different colours which were easily distinguishable making it difficult to have total blinding which would have completely eliminated observer bias.

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