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ORIGINAL ARTICLE

Pre-Caesarean Section Vaginal Preparation with Chlorhexidine Solution in Preventing Puerperal Infectious Morbidities: A Randomized Controlled Trial

Préparation Vaginale Avant Césarienne Avec Une Solution de Chlorhexidine Dans la Prévention des Morbidités Infectieuses Puerpérales : Un Essai Control Randomisé

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ABSTRACT

BACKGROUND: Globally, peripartum or puerperal infections account for about one tenth of maternal mortality, most of which occur in low income countries. Therefore, vaginal preparation with an antiseptic prior to a caesarean delivery could be considered an additional measure to prevent subsequent infectious morbidities.

OBJECTIVES: To evaluate vaginal preparation with 0.3% chlorhexidine solution in the prevention of endometritis, surgical site infection and post-operative fever following emergency caesarean section.

METHODS: This prospective randomized controlled trial (RCT) was conducted among 240 participants planned for emergency caesarean sections (CS) at term in the University of Medical Sciences Teaching Hospital Complex, Ondo State, Nigeria. Participants were randomised into either group "A" (study) or "B" (control). The former had vaginal preparation with 0.3% chlorhexidine gluconate immediately after anaesthesia while the latter received normal saline. Participants were followed up post-operatively during which clinical features of puerperal infectious morbidities were observed for each during admission as well as 8th and 14th days after delivery.

RESULTS: The rate and risk of endometritis were significantly lower in the study group compared to the control; 5.0% versus 13.3%, respectively (χ^2=5.004; p=0.042, RR = 0.38; 95% CI = 0.15–0.94; p = 0.042; RRR = 0.62). Post-operative fever and surgical site infection, were also lower in the study group compared to the controls, but the difference was not statistically significant.

CONCLUSION: When compared to placebo, pre-caesarean section vaginal preparation with 0.3% chlorhexidine solution significantly reduced only the rate and risk of post-operative endometritis among infectious morbidities. **WAJM 2022; 39(4): 369–374.**

Keywords: Chlorhexidine, vaginal preparation, puerperal infectious morbidity, caesarean section, endometritis, post-operative fever, surgical site infection.

RÉSUMÉ

CONTEXTE: À l'échelle mondiale, infections péripartum ou puerpérales représentent environ un dixième de la mortalité maternelle, dont la plupart se produisent dans les pays à faible revenu. Par conséquent, la préparation vaginale avec un antiseptique avant un accouchement par césarienne pourrait être considéré comme un mesure supplémentaire pour prévenir les morbidités infectieuses subséquentes.

OBJECTIFS: Évaluer la préparation vaginale avec 0.3%solution de chlorhexidine dans la prévention de l'endométrite, site chirurgical infection et fièvre postopératoire après une césarienne d'urgence section.

MÉTHODES: Cet essai prospectif randomisé contrôlé (ECR)a été menée auprès de 240 participants prévus pour une urgence césariennes (CS) à terme à l'Université des sciences médicales Complexe hospitalier universitaire, État d'Ondo, Nigéria. Les participants étaient randomisé dans le groupe "A" (étude) ou "B" (témoin). Celui-là avait une préparation vaginale avec 0.3 % de gluconate de chlorhexidine immédiatement après l'anesthésie alors que ce dernier a reçu une solution saline normale. Les participants ont été suivis postopératoirement au cours desquels des caractéristiques de morbidité infectieuse puerpérale ont été observées pour chaquelors de l'admission ainsi que les 8ème et 14ème jours après la livraison.

RÉSULTATS: Le taux et le risque d'endométrite étaient significativement plus faibles dans le groupe d'étude par rapport au groupe témoin; 5.0 % contre 13.3 %, respectivement (χ2=5.004; p=0.042, RR = 0.38; 95% CI = 0.15–0.94; p = 0.042; RRR = 0.62). Fièvre postopératoire et infection du site chirurgical, étaient également plus faibles dans le groupe d'étude par rapport aux témoins, mais lela différence n'était pas statistiquement significative.

CONCLUSION: Par rapport au placebo, pré-césarienne préparation vaginale avec une solution de chlorhexidine à 0.3% significativement réduit uniquement le taux et le risque d'endométrite postopératoire chez morbidités infectieuses. **WAJM 2022; 39(4): 369–374.**

Mots-clés: Chlorhexidine, Préparation Vaginale, Infection Puerpéral emorbidité, Césarienne, Endométrite, Fièvre Postopératoire, Infection Du Site Chirurgical.

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Abbreviations: °C, Degree Celsius; **ARR**, Absolute risk reduction; **CI**, Confidence interval; **HIV/AIDS**, Human immuno-deficiency virus/ Acquired immune deficiency syndrome; **Kg/m²**, Kilograms per square-metre; **O & G**, Obstetrics and Gynaecology; **OSHREC**, Ondo State Health Research and Ethics Committee; **POF**, Post-operative fever; **RR**, Relative risk; **RRR**, Relative risk reduction; **SPSS**, Statistical Package for the Social Sciences; **SSI**, Surgical site infection; **UNIMEDTHC**, University of Medical Sciences Teaching Hospital Complex; **WHO**, World Health Organisation.

INTRODUCTION

Globally, peripartum or puerperal infections account for about one tenth of the causes of maternal mortality.[1,2] Annually, these childbirth-linked infections cause an estimated 75,000 maternal deaths, mostly in low-income countries.[3] Apart from deaths and acute morbidities associated with these infections, long-term disabilities such as chronic pelvic pain and secondary infertility from tubal blockage could also occur.[4] Peripartum infections also have a considerable impact on rates of newborn morbidity and mortality. An estimated one million newborn deaths are associated with such infections annually.[5] Aside increased cost of care, these infections and the resultant prolonged hospital stay can also interfere with mother-infant bonding.[6]

Endometritis, surgical site infection (SSI) and post-operative fever (POF) are common manifestations of sepsis following caesarean deliveries especially in high-risk conditions such as prolonged rupture of membranes. Caesarean sections are considered clean-contaminated procedures as the surgical wound could be in contact with vaginal flora.[7] There is, therefore, a likelihood of higher risk of maternal infections following emergency caesarean section compared to elective ones.

Prophylactic antibiotics and skin preparation have been standard practices in caesarean sections shown to be effective in prevention of post-operative endometritis and SSI.[8] Vaginal preparation with antiseptic solutions were then used immediately prior to caesarean section and found to also reduce the risk of postpartum endometritis.[9] It is now known that most pathogens causing such maternal infections following caesarean deliveries colonise from the vagina[10]. Similar applications have also been common practice in abdominal and vaginal hysterectomies with resultant reduced risk of post-operative sepsis.[11]

The World Health Organisation (WHO) acknowledges that though the evidence on vaginal preparation before caesarean section was largely derived from trials using povidone-iodine, benefit was demonstrated overall for other antiseptics, especially chlorhexidine solution.[12] There are several reasons to believe that vaginal preparation with chlorhexidine would be an appropriate alternative to povidone-iodine including its ready availability in some low resource settings and lack of vaginal staining when used. A study showed significant reduction in skin flora following application of chlorhexidine compared to povidone-iodine.[13] Another randomized controlled trial comparing povidone-iodine with chlorhexidine gluconate for vaginal application at elective caesarean sections suggested that chlorhexidine was superior.[14]

Lumbiganum, *et al,* in their systematic review analysis concluded that since chlorhexidine solution is safe, inexpensive and easy to use, they advocated for more well-designed randomized controlled trials using different methodologies.[15] There is also a need to reinforce the value of chlorhexidine in an environment like ours where there is a paucity of such comparative trials. Our study, therefore, aimed to evaluate the vaginal preparation with 0.3% chlorhexidine solution in prevention of endometritis, SSI and POF following emergency caesarean section.

SUBJECTS, MATERIALS AND METHODS

The study was conducted in the University of Medical Sciences Teaching Hospitals Complex, Ondo state (UNIMEDTHC). It is a 428-bedded state-run hospital and apex referral centre, attracting patients from surrounding states like Osun, Edo, etc. In the Department of Obstetrics and Gynaecology (O&G), an average of 250 deliveries are conducted per month, out of which about 65 are by emergency caesarean section.

The participants were consenting eligible pregnant women admitted and scheduled for emergency caesarean section for intra- or antepartum indications, at gestational ages greater than or equal to 37 weeks, from 15th of July, 2019 to 31st of May, 2020. The exclusions included women for elective caesarean delivery, in second stage of labour, on antibiotics at time of recruitment as well as with co-existing conditions like proven allergy to chlorhexidine, chorioamnionitis, umbilical cord prolapse, antepartum haemorrhage, fetal anomalies, diabetes mellitus and HIV/AIDS. A study proforma was administered to each participant to capture necessary information.

The minimum sample size for this study was obtained using the formula for comparative study for two population proportions.[16] Based on a previous related study, proportion of participants expected to develop endometritis in the group that had vaginal preparation with chlorhexidine as well as control were 2.9% and 13.2%, respectively.[17] With these estimates a sample size of 218 participants would give a power of 80% at confidence level of 95%. Considering the attrition rate, 250 women were recruited for our study.

The primary outcome was clinical endometritis and the secondary were surgical site infection (SSI) and post-operative fever (POF). Endometritis was defined as presence of fever (38^0C or above) in association with uterine tenderness and/or foul smelling lochia. Surgical site infection was diagnosed with presence of either peri-incisional scar induration and tenderness, wound dehiscence or sero-purulent discharge. The postoperative fever was defined as any temperature of 38^o C or more, measured on two or more occasions, six hours apart, after 24 hours of surgery.

To ensure equal chance of participation among participants and eliminate selection bias, randomization was 1:1 using random number generated table by computer-based programme (www.randomization.com). The allocation of participants into groups were concealed to reduce bias. Two hundred and fifty sequentially numbered, sealed opaque envelopes each enclosing a paper with a letter A or B, were used. Each participant picked one envelope from the set that was then only opened in theater at the time of application of agent. The letter in the envelope either A (study group) or B (control) determined where each participant belonged.

In the theatre, vaginal preparation with either 0.3% chlorhexidine gluconate solution (study group) or normal saline (control) was done. Participants were

placed in dorsal positions and under aseptic conditions, 50mls of chlorhexidine solution or normal saline was emptied into each gallipot. Square gauzes were mounted on sponge-holding forceps and soaked in either solution for gentle 30-second vaginal cleansing in a clockwise manner starting from upper to the lower region. The procedures were done by the lead or co-researchers after instituting anaesthesia and prior to urinary bladder catheterisation. The participants were, therefore, blinded to the agent used. After the applications, all other theatre standard operating procedures were adhered to, ensuring participants' safety. The trained research assistants collecting data for outcome measures were also blinded to the treatment group to further minimise detection bias. Neither the vaginal preparation agent nor group were written on the participants' notes.

The post-operative management and outcomes were recorded in individual study proforma. Monitoring of axillary temperature commenced 24 hours post-operation using digital thermometer. The incisional wound was inspected for SSI from the second post-operative day by identifying the presence of surrounding induration, dehiscence and/or sero-purulent discharge. The presence of lower abdominal pain, uterine tenderness and purulent discharge as well as foul smelling lochia were sought for in each participant. Their durations of hospital stay were documented along with telephone numbers and home addresses for easy follow-up.

The latter visits were on the post-operative days 8 and 14. Reminders were sent to participants via telephone calls and text messages two to three days prior to the scheduled visits and most complied. During these visits, clinical assessments were done through history taking and physical examinations, to identify features of endometritis and/or SSI once again.

The data obtained from this study were cleaned, coded, and analysed using Statistical Package for the Social Sciences (SPSS) for windows version 25. The frequency and proportion were generated for categorical data and these were compared using chi-square. Mean and standard deviation were generated for continuous variables and compared by t- test. P-value was set at 0.05 and any significant association was subjected to bivariate analysis. The data were presented using appropriate tables.

Ethical approval with protocol number OSHREC/19/02/2019/103 was obtained for our study from the Ondo State Health Research and Ethics Committee at the Ministry of Health, Akure. A written informed consent was obtained from the participants after explaining the details of the procedure emphasising that harm to them or their newborn was not envisaged during the course of the trial. They were also informed of their right to withdraw from the study at any time without the withholding of services due to them.

RESULTS

A total of 250 women (125 in each group) participated in this study out of which only 240 were analysed as 10 of them were lost to follow up (five in each group). The study flow chart is illustrated in Figure 1. There were no adverse reactions to vaginal preparation agents recorded in both groups. Most participants were married, primiparous, completed secondary school, between age ranges of 25 to 29 years old and about 38 weeks gestation. The differences in measured parameters of the participants in both groups are not statistically significant. The details of socio-demographic and obstetric characteristics of the study participants are shown in Table 1.

There was a statistically significant lower rate as well as decreased risk of endometritis in the study group compared to control. In addition, the rates and risks of POF and SSI were lower in the study group compared to the control, but these differences were not statistically significant. The details of infectious morbidity outcomes among the study participants are shown in Tables 2 and 3.

DISCUSSION

This study evaluated the vaginal preparation with 0.3% chlorhexidine solution in the prevention of puerperal infectious morbidities following emergency caesarean sections at the UNIMEDTHC, Ondo State in Nigeria. There were no significant differences in socio-demographic and obstetric characteristics. These could be explained by the randomization process which would have eliminated selection bias.

The absence of allergic reactions in the study group participants attested to the safety of chlorhexidine as a

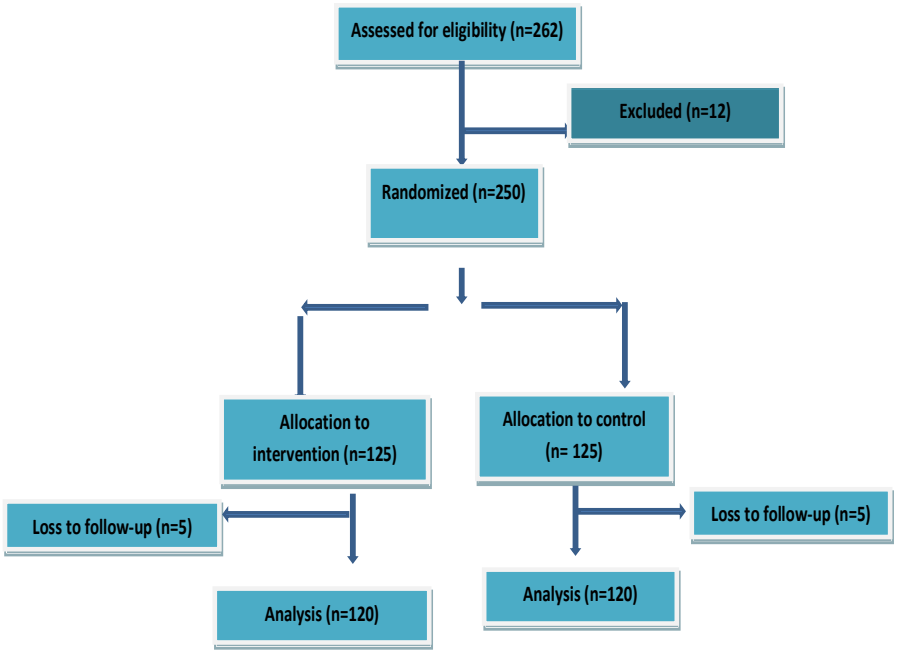

Fig. 1: Flow Chart Diagram showing Randomisation to Analysis

Table 1: Socio-demographic and Obstetric Characteristics

	Trial Group		
	Study N = 120 (%)	Control N = 120 (%)	Statistics
Age Ranges (years)			
15 – 19	0 (0.0)	2 (1.7)	$\chi^2 = 10.729$
20 – 24	25 (20.8)	30 (25.0)	df = 6
25 – 29	46 (38.3)	46 (38.3)	$p = 0.097$
30 – 34	24 (20.0)	32 (26.7)	
35 – 39	18 (15.0)	8 (6.7)	
40 – 44	5 (4.2)	2 (1.7)	
>/= 45	2 (1.7)	0 (0.0)	
Level of Education			
Primary	10 (8.3)	12 (10.0)	$\chi^2 = 2.614$
Secondary	61 (50.8)	71 (59.2)	df = 2
Tertiary	49 (40.8)	37 (30.8)	$p = 0.271$
Marital Status			
Single	11 (9.2)	4 (3.3)	$\chi^2 = 3.848$
Married	109 (90.8)	116 (96.7)	df = 1
			$p = 0.062$
Body Mass Index (kg/m^2)			
Underweight (<18.5)	0 (0.0)	1 (0.8)	$\chi^2 = 10.068$
Normal weight (18.5–24.9)	22 (18.3)	40 (33.3)	df = 5
Overweight (25.0–29.9)	56 (46.7)	39 (32.5)	$p = 0.073$
Class I obesity (30.0–34.9)	31 (25.8)	29 (24.2)	
Class II obesity (35.0–39.9)	5 (4.2)	7 (5.8)	
Morbid obesity (>40)	6 (5.0)	4 (3.3)	
Booking Status			
Booked	80 (66.7)	76 (63.3)	$\chi^2 = 0.293$
Unbooked	40 (33.3)	44 (36.7)	df = 1
			$p = 0.588$
Parity			
Primiparous	76 (63.3)	87 (72.5)	$\chi^2 = 2.314$
Multiparous	44 (36.7)	33 (27.5)	df = 1
			$p = 0.128$
Estimated Gestation (weeks)			
37	18 (15.0)	13 (10.8)	$\chi^2 = 9.818$
38	41 (34.2)	48 (40.0)	df = 6
39	5 (4.2)	13 (10.8)	$p = 0.133$
40	35 (29.2)	33 (27.5)	
41	18 (15.0)	8 (6.7)	
42	2 (1.7)	2 (1.7)	
43	1 (0.8)	3 (2.5)	
Previous Caesarean Section			
0	74 (61.7)	87 (72.5)	$\chi^2 = 3.212$
1	37 (30.8)	27 (22.5)	df = 2
2	9 (7.5)	6 (5.0)	$p = 0.201$

preparation agent. However, the 5% rate of endometritis among these same participants was higher than the earlier reported rate of 2.9% by Ahmed et al in their study in those who underwent elective caesarean section.[17] The difference in these rates could be due to the fact that our study was conducted in patients who had emergency surgeries which generally carry higher risks for infections when compared to elective ones.

In addition, the significantly lower risk of endometritis in the chlorhexidine group was comparable to the findings of subgroup analysis of the three trials that used same agent as the intervention compared with placebo or no treatment in a systematic review and meta-analysis by Caissutti, *et al.*[18] The latter study involved 16 randomized controlled trials with smaller sample sizes and different study populations. The risk reduction in the vaginal preparation with chlorhexidine on endometritis following emergency caesarean section could be due to its bactericidal and bacteriostatic actions which cover a wide range of aerobic and anaerobic bacteria, including those implicated in puerperal infections.[19] In our study, the rates of POF and SSI were lower in the chlorhexidine group compared to the control, but these differences were not statistically significant. These findings were consistent with previous studies by Guzman, *et al*[20] and Memon, *et al*[21] in which vaginal application of povidone-iodine was tested with resultant reduction in rates of infectious morbidities but not statistically significant for POF and SSI.

The major limitation of our study was that the researcher applying the agents in theatre could not be blinded due to the very nature of the intervention. However, the participants as well as the trained research assistants collecting data for the outcome measures were blinded to the intervention.

In conclusion, our study showed that vaginal preparation with 0.3% chlorhexidine before emergency caesarean section was safe as well as effective in significantly reducing the rate and risk of post-operative endometritis. It also reduced the rates and risks of POF and SSI, though these were statistically insignificant.

It is recommended that vaginal preparation with 0.3% chlorhexidine solution prior to emergency caesarean sections be adopted as a routine intervention to reduce puerperal infectious morbidities in health facilities. A further study comparing vaginal preparation using chlorhexidine with povidone-iodine in those undergoing emergency caesarean sections would be of benefit in determining which is superior in safety and effectiveness in a low resource setting like ours.

Table 2: Puerperal Infectious Morbidity Outcomes

	Trial Group		
	Study N = 120 (%)	Control N = 120 (%)	Statistics
Post-operative Fever			
Yes	7 (5.8)	11 (9.2)	$\chi^2 = 0.961$
No	113 (94.2)	109 (90.8)	df = 1
			$p = 0.463$
Endometritis			
Yes	6 (5.0)	16 (13.3)	$\chi^2 = 5.004$
No	114 (95.0)	104 (86.7)	df = 1
			$p = 0.042$
Surgical Site Infection			
Yes	9 (7.5)	12 (10.0)	$\chi^2 = 0.470$
No	111 (92.5)	108 (90.0)	df = 1
			$p = 0.649$

Table 3: Relative Risk of Puerperal Infectious Morbidity

	Trial Group				
	Study N = 120	Control N = 120	RR (95%CI)	RRR	ARR
Post-operative Fever	7 (5.8%)	11 (9.2%)	0.64 (0.26 – 1.60)	0.36	3.4%
Endometritis	6 (5.0%)	16 (13.3%)	0.38 (0.15 – 0.94)	0.62	8.3%
Surgical Site Infection	9 (7.5%)	12 (10.0%)	0.75 (0.33 – 1.71)	0.25	2.5%

RR (95%CI) is relative risk and its 95% confidence interval
RRR is relative risk reduction and ARR is absolute risk reduction.

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None.

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Not applicable.

Conflicting Interest

None.

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