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Original Research Article

Effect of vaginal cleansing with povidone iodine prior to emergency caesarean section on post-operative infectious morbidity in a Nigerian tertiary hospital

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ABSTRACT

Background: Post-caesarean infectious morbidities, including endometritis and wound infections, remain significant contributors to maternal morbidity, particularly in low-resource settings. This study evaluated the effectiveness of preoperative vaginal cleansing with 10% povidone iodine in reducing post-operative infections following emergency caesarean section.
Methods: We conducted a randomized controlled trial involving 266 pregnant women booked for emergency caesarean section randomly assigned to either intervention group with povidone iodine vaginal cleansing (n=133) or control group with no vaginal preparation (n=133). Routine prophylactic antibiotics were administered to all participants. The primary outcome was the incidence of post-caesarean endometritis and the secondary outcome was surgical site infection.
Results: Of the 266 participants enrolled, only 260 were analysed, 37 (14.2%) of whom developed infectious morbidity. Twenty-nine (22.1%) had infectious morbidity in the control group and 8 (6.2%) in the intervention group. Endometritis occurred in 18 (13.7%) of the control and 4 (3.1%) in the intervention group (p=0.01). Wound infection occurred in 11 (8.4%) of the control and 4 (3.1%) in the intervention group (p=0.07). Vaginal cleansing significantly reduced the risk of endometritis [Risk ratios (RR)=0.21, absolute risk reduction (ARR)=0.11; number needed to treat (NNT=9)] and wound infection (RR=0.38, ARR=0.05; NNT=20), with no reported adverse effects.
Conclusions: Preoperative vaginal cleansing with 10% povidone iodine significantly reduced the incidence of post-caesarean endometritis and wound infection. It is a simple, safe, and cost-effective intervention that can improve maternal outcomes, especially in women with prolonged labour or ruptured membranes.

Keywords: Caesarean section, Endometritis, Surgical-site infection, Povidone iodine, Vaginal cleansing, Infectious morbidity

INTRODUCTION

Caesarean section (CS) is a life-saving surgical procedure but carries a risk of infectious complications, particularly in emergency cases.[1] CS rate in Nigeria is about 35%, 21.5% in UK and 29.5% in USA.[2-5] Post-caesarean infections such as endometritis and surgical site infections (SSIs) contribute significantly to maternal morbidity and prolonged hospital stay. These infections are often caused by ascending polymicrobial flora from the vagina and cervix, especially when membranes are ruptured or labour is prolonged.[6,7]

Although antibiotic prophylaxis is standard practice, its effectiveness alone may not fully prevent infection as post-operative infectious morbidities still complicate caesarean deliveries.[8,9] Post-CS endometritis and its sequelae are often the result of the presence of bacteria in the vagina

and cervix that ascend higher in the genital tract to infect the uterus.[10,11]

Vaginal preparation with antiseptics such as povidone iodine has shown promise in reducing post-operative infections, but its routine use before CS is not yet established in many settings, including Nigeria.[12,13]

This study aimed to evaluate the effectiveness of vaginal cleansing with povidone iodine in reducing post-operative infectious morbidity in women undergoing emergency CS.

METHODS

Study design and setting

This was a prospective, open-label, randomized controlled trial conducted at the University of Abuja Teaching Hospital, Nigeria, from September 2017 to August 2018.

Participants

Women undergoing emergency CS were eligible. Exclusion criteria included elective CS, allergy to iodine, active vaginal bleeding, and known thyroid disorders.

Sample size

The sample size was calculated using the formula for comparing two proportions (two independent groups):

$n=[1/(1-f)\times 2\ (z\alpha+z\beta)^2\ p(1-p)/(p0-p1)^2]$[14]

Where, P^0=93% and P^1=99% using a power of 80%, 95% confidence level, and expected difference in infection rates of 6%[15] and attrition rate of 10%, a minimum of 266 participants was calculated, 133 on each arm.

Randomization

Participants were randomized using computer-generated numbers into either the intervention group (vaginal cleansing with 10% povidone iodine) or the control group (no cleansing). Allocation concealment was maintained using sealed opaque envelopes.

Intervention

In the intervention group, vaginal cleansing was performed with a sterile gauze soaked in 10% povidone iodine, swabbed circumferentially for 30 seconds prior to skin incision. Control group received no vaginal preparation.

Primary outcome

Clinical diagnosis of post-caesarean endometritis (fever ≥38°C after 24 hours, uterine tenderness, foul lochia).

Secondary outcome

Surgical site infection (erythema, induration, pus at incision site within 10 days post-operatively). All participants received routine prophylactic antibiotics.

Follow-up

Participants were assessed during hospital stay and clinic review within 10 days of surgery.

Data analysis

Data were analysed using SPSS version 20. Categorical variables were compared using chi-square or Fisher's exact test. RR, ARR, and NNT were calculated. A $p<0.05$ was considered statistically significant.

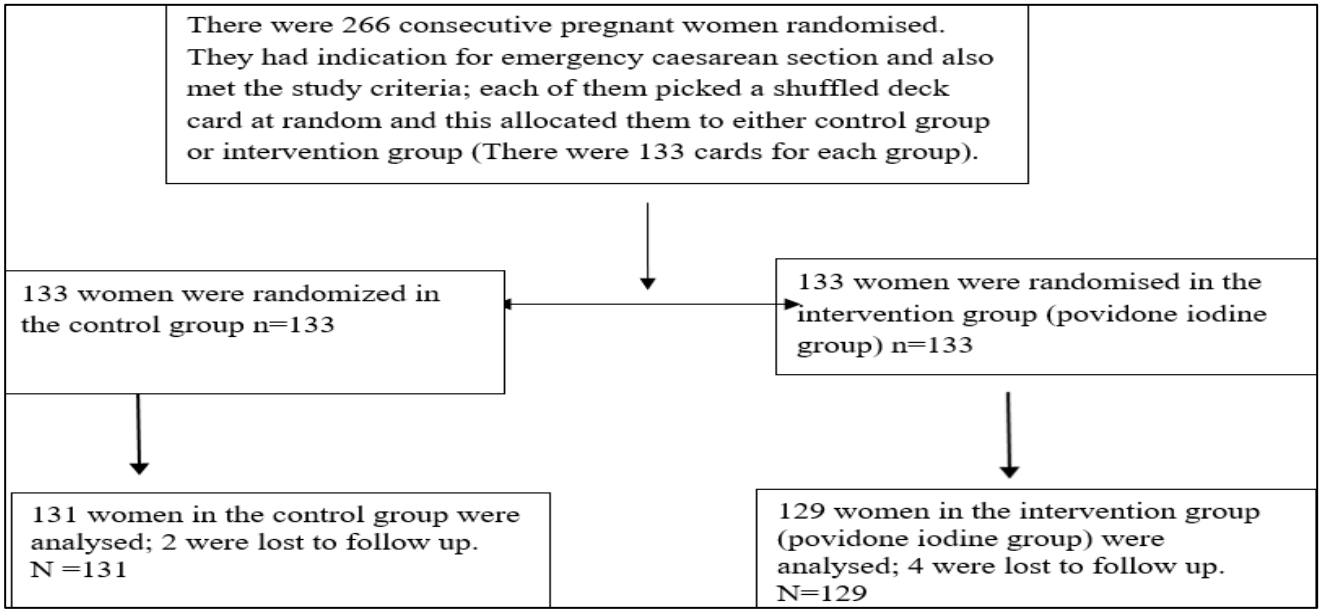

Figure 1: Flowchart.

RESULTS

Baseline characteristics

A total of 266 women were enrolled; 260 completed the study and were analysed (129 in intervention group, 131 in control group) of which 6 (2.3%) were lost to follow-up and were not analysed, 2 from the control arm and 4 from the intervention arm.

Table 1 shows the demographic characteristics of the participant. The mean ages of participants in the control and intervention groups were comparable (28.5±4.8 years vs. 29.1±4.7 years, p=0.310).

In terms of educational status, the two groups were similar, with most participants having attained tertiary education (59.5% in control vs. 59.7% in intervention, p=0.981).

Occupational distribution was also comparable across both groups, with professionals forming the largest category (35.9% in control vs. 34.1% in intervention).

Baseline characteristics (age, parity, indication for CS, rupture of membranes) were comparable between groups.

Table 2 shows outcome in terms of infectious morbidity.

Infectious morbidities were more frequent in the control group compared to the intervention group. Endometritis occurred in 18 participants (13.7%) in the control group versus 4 (3.1%) in the intervention group, while wound infection was seen in 11 (8.3%) of the control group compared to 4 (3.1%) of the intervention group.

Overall, 22.1% of participants in the control group developed infectious morbidities, compared to only 6.2% in the intervention group. A small proportion developed both endometritis and wound infection (2.2% versus 0.78%, respectively). Conversely, the majority of participants in the intervention group (93.8%) had no infectious morbidity, compared with the 80.2% in the control group.

Table 3 shows obstetric and surgical characteristics of participants. The obstetric and surgical characteristics of participants were generally comparable between the control and intervention groups as shown in the Table 3.

Table 4 shows the obstetric and surgical factors that may predispose to endometritis.

Endometritis was significantly more common in the control group compared to the intervention group. This risk was particularly higher among women with ruptured membranes and prolonged labour, both of which were statistically significant (p=0.040).

Table 5 shows the obstetrics and surgical characteristics of participant who developed wound infection.

A significant difference was observed regarding the status of the membranes. In the control group, most women who developed wound infection had ruptured membranes prior to CS (90.9%) whereas the majority in the intervention group had intact membranes (75.0%), a finding that was statistically significant (p=0.033).

The number of vaginal examinations and the duration of labour showed no consistent patterns, although prolonged labour (≥18 hours) was more common among those in the control group.

Overall, rupture of membranes prior to CS emerged as the most important obstetric factor associated with the higher incidence of wound infection in the control group compared with the intervention group.

Infectious morbidity

Endometritis: Occurred in 18 (13.7%) in the control group vs. 4 (3.1%) in the intervention group (p=0.01).

Wound infection: Occurred in 11 (8.4%) in the control group versus four (3.1%) in the intervention group (p=0.07).

Overall infectious morbidity: 29 (22.1%) in the control vs. 8 (6.2%) in the intervention group.

Risk reduction analysis

Endometritis: RR=0.21, ARR=0.11 and NNT=9

Wound infection: RR=0.38, ARR=0.05 and NNT=20

No adverse reactions to the povidone iodine were reported.

Table 1: Demographic characteristics of study participants.

Characteristics	Control, n=131	Intervention, n= 129	Chi-square	P values
Age (in years)				
Mean	28.5±4.8	29.1±4.7	1.0 (-1.8-0.5)	0.310*
18-23	17 (13.0)	14 (10.9)	0.3	0.597
24-29	63 (48.1)	43 (33.3)	5.9	0.015
30-35	44 (33.6)	63 (48.8)	6.2	0.012
>35	7 (5.3)	9 (7.0)	0.3	0.584

Continued.

Characteristics	Control, n=131	Intervention, n=129	Chi-square	P values
Education				
None	4 (3.1)	4 (3.1)	<0.001	0.630¶
Primary	15 (11.5)	14 (10.9)	0.02	0.878
Secondary	34 (26.0)	34 (26.4)	0.01	0.941
Tertiary	78 (59.5)	77 (59.7)	0.001	0.981
Occupations				
Professionals	47 (35.9)	44 (34.1)	0.1	0.768
Technicians and associate professionals	9 (6.9)	7 (5.4)	0.2	0.628
Clerical support workers	17 (13.0)	18 (14.0)	0.1	0.818
Service and sales workers	28 (21.4)	25 (19.4)	0.2	0.690
Skilled agricultural, forestry and fishery workers	2 (1.2)	1 (0.8)	0.3	0.506¶
Craft and related trades workers	12 (9.2)	17 (13.2)	1.1	0.303
Elementary occupations	16 (12.2)	17 (13.2)	0.1	0.815

*t-test statistic, ¶ Fisher's exact test.

Table 2: Outcome of participants.

Outcome	Control, n=131	Intervention, n=129
Endometritis	18 (13.7%)	4 (3.1%)
Wound infection	11 (8.3%)	4 (3.1%)
Total infectious morbidities	29 (22.1%)	8 (6.2%)
Developed both endometritis and wound infection	3 (2.2%)	1 (0.78%)
Had no infectious morbidity	105 (80.2%)	121 (93.8%)

Table 3: Obstetrics and surgical characteristics of study participants.

Characteristics	Control, n=131	Intervention, n=129	Chi-square	OR(CI)	P value
Boking status					
Booked	70 (53.4)	72 (55.8)	0.1	0.9 (0.6-1.5)	0.700
Unbooked	61 (46.6)	57 (44.2)	0.1	0.9 (0.6-1.5)	0.700
Parity					
Para 0	40 (30.5)	30 (23.3)	1.8	1.5 (0.8-2.5)	0.186
Para 1	31 (23.7)	31 (24.0)	0.01	0.9 (0.6-1.7)	0.945
Para 2	32 (24.4)	28 (21.7)	0.3	1.2 (0.7-2.1)	0.602
Para 3	11 (8.4)	23 (17.8)	5.1	0.4 (0.2-0.9)	0.624
Para 4	14 (10.7)	8 (6.2)	1.7	1.8 (0.7-4.5)	0.194
Para ≥5	3 (2.3)	9 (7.0)	3.2	0.3 (0.1-1.2)	0.072¶
Gestational age (in weeks)					
28 to <37	63 (48.1)	65 (50.4)	0.1	0.9 (0.6-1.5)	0.711
37 to <42	56 (42.7)	56 (43.4)	0.01	0.9 (0.6-1.6)	0.914
≥42	12 (9.2)	8 (6.2)	0.8	1.5 (0.6-3.9)	0.371
Duration (in hours)					
Duration of CS≤2	127 (96.9)	129 (100.0)	4.0	-	0.122¶
Duration of CS>2	4 (3.1)	0			
Membranes					
CS with intact membranes	86 (65.6)	90 (69.8)	0.5	0.8 (0.5-1.4)	0.478
CS with ruptured membranes	45 (34.4)	39 (30.2)	0.5	0.8 (0.5-1.4)	0.478
Number of VE					
CS with no prior VE	11 (8.4)	3 (2.3)	4.7	3.9 (1.0-14.1)	0.251¶
CS after 1 to 3 VE	57 (43.5)	67 (51.9)	1.9	0.7 (0.4-1.2)	0.174
CS after ≥4 VE	63 (48.1)	59 (45.7)	0.1	1.1 (0.7-1.8)	0.704

Continued.

Characteristics	Control, n=131	Intervention, n=129	Chi-square	OR(CI)	P value
Duration of labour (in hours)					
<6	39 (29.8)	38 (29.5)	0.003	1.0 (0.6-1.7)	0.956
6-<12	31 (23.7)	41 (31.8)	2.1	0.7 (0.4-1.2)	0.144
12-<18	26 (19.8)	18 (14.0)	1.6	1.5 (0.8-2.9)	0.205
18-<24	17 (13.0)	15 (11.6)	0.1	1.1 (0.5-2.4)	0.741
≥24	18 (13.7)	17 (13.2)	0.03	1.1 (0.5-2.1)	0.894

¶Fisher's exact test, VE: Vaginal Examination

Table 4: Obstetrics and surgical characteristics of participants who developed endometritis.

Characteristics	Control, n=18	Intervention, n=4	Chi-square	OR(CI)	P values
Boking status					
Booked	8 (44.4)	3 (75.0)	1.2	0.2 (0.02-3.1)	0.269¶
Unbooked	10 (55.6)	1 (25.0)	1.2	0.2 (0.02-3.1)	0.269¶
Parity					
Para 0	5 (27.8)	3 (75.0)	3.2	0.1 (0.01-1.5)	0.117¶
Para 1	3 (16.7)	1 (25.0)	0.1	0.6 (0.05-7.9)	0.696¶
Para 2	5 (27.8)	0	-	-	-
Para 3	4 (22.2)	0	-	-	-
Para 4	1 (5.6)	0	-	-	-
Gestational age (in weeks)					
28 to <37	11 (61.1)	3 (75.0)	0.3	0.5 (0.05-6.09)	0.601¶
37 to <42	6 (33.3)	1 (25.0)	0.1	1.5 (0.1-17.7)	0.746¶
≥42	1 (5.6)	0	-	-	-
Duration (in hours)					
Duration of CS≤2	15 (83.3)	4 (100.0)	0.8	-	0.380¶
Duration of CS>2	3 (16.7)	0			
Membranes					
CS with intact membranes	4 (22.2)	3 (75.0)	4.2	0.1 (0.01-1.2)	0.040¶
CS with ruptured membranes	14 (77.8)	1 (25.0)	4.2	0.1 (0.01-1.2)	0.040¶
No. of VE					
CS with no prior VE.	3 (16.7)	1 (25.0)	0.2	0.6 (0.05-7.9)	0.696¶
CS after 1 to 3 VE.	6 (33.3)	1 (25.0)	1.1	0.2 (0.10-4.5)	0.386¶
CS after ≥4 VE.	9 (50.0)	2 (50.0)	0.02	1 (0.1-8.7)	0.707¶
Duration of labour (in hours)					
<6	1 (5.6)	0		-	-
6-<12	2 (11.1)	0		-	-
12-<18	2 (11.1)	0		-	-
18-<24	3 (16.7)	2 (50.0)	2.1	0.2 (0.02-2.0)	0.746¶
≥24	10 (55.6)	2 (50.0)	4.2	1.3 (0.1-10.9)	0.041¶

¶ Fisher's exact test

Table 5: Obstetrics and surgical characteristics of participants who developed wound infection.

Characteristics	Control, n=11	Intervention, n=4	Chi-square	OR(CI)	P values
Boking status					
Booked	5 (45.5)	3 (75.0)	1.0	0.3 (0.02-3.6)	0.310¶
Unbooked	6 (54.5)	1 (25.0)	1.0	0.3 (0.02-3.6)	0.310¶
Parity					
Para 0	3 (27.3)	1 (25.0)	0.01	1.1 (0.1-15.5)	0.930¶
Para 1	2 (18.2)	0	-	-	-
Para 2	1 (9.1)	0	-	-	-
Para 3	5 (45.5)	2 (50.0)	0.02	0.8 (0.1-8.2)	0.876¶
Para 4	0	1 (25.0)	-	-	-

Continued.

Characteristics	Control, n=11	Intervention, n=4	Chi-square	OR(CI)	P values
Gestational age (in weeks)					
28 to<37	4 (36.4)	1 (25.0)	0.2	1.7 (0.1-22.5)	0.680¶
37 to<42	4 (36.4)	3 (75.0)	1.8	0.2 (0.01-2.5)	0.282¶
≥42	3 (27.3)	0	-	-	-
Duration of CS (in hours)					
Duration of CS≤2	10 (90.9)	4 (100.0)	0.4	-	0.533¶
Duration of CS>2	1 (9.1)	0	-	-	-
Membranes					
CS with intact membranes	1 (9.1)	3 (75.0)	6.5	0.3 (0.01-0.7)	0.033¶
CS with ruptured membranes	10 (90.9)	1 (25.0)	6.5	0.3 (0.01-0.7)	0.033¶
Number of VE					
CS with no prior VE	1 (9.1)	0	-	-	-
CS after 1 to 3 VE	2 (18.2)	1 (25.0)	0.1	0.7 (0.04-10.3)	0.770¶
CS after ≥4 VE	8 (72.7)	3 (75.0)	0.0	0.9 (0.1-12.3)	0.930¶
Duration of labour (in hours)					
<6	1 (9.1)	0	-	-	-
6-<12	1 (9.1)	1 (25.0)	0.6	0.3 (0.01-6.4)	0.476¶
12-<18	0	1 (25.0)	-	-	-
18-<24	5 (45.5)	1 (25.0)	0.5	2.5 (0.2-32.2)	0.604¶
≥24	4 (36.4)	1 (25.0)	0.2	1.7 (0. 1-22.5)	0.680¶

¶ Fisher's exact test.

DISCUSSION

Endometritis, which was a primary outcome in this study was present in 18 (13.7%) of 131 participants in the control group and 4 (3.1%) of 129 participants in the intervention group. The rate of post-CS endometritis in the control group (13.7%) was similar to findings from Ile Ife, Nigeria.[16] However, the researchers used povidone iodine-alcohol for skin preparation on women going for elective CS. It is also within the range of post-operative wound infections following CS (0 to 20.5%) reported in a hospital survey in England conducted by Moir-Bussy and colleagues.[17] The 3.1% rate of endometritis in the intervention group showed significant advantage over the 13.7% rate in the control group. Similar beneficial outcome (7.2% vs 3.6%) was recorded by Haas et al and (7% vs 1%), Memon et al as well as other studies.[8,18-20] The result from our study was similar to that of Reid et al which showed no difference in developing endometritis in both groups in terms of maternal age, parity, tribe, education, prior CS, type of anaesthesia, labour before current CS and gestational age at delivery.[21] Other studies also showed similar results.[8,19] A significantly higher rate of endometritis was found among participants with ruptured membranes prior to CS in the control group compared with the intervention group with a p=0.040 which is statistically significant. This is similar to finding by Haas et al.[8]

This probably due to inhibition of growth and ascent of bacteria from the vagina into the endometrial cavity by the effect of povidone iodine. Duration of labour of ≥24 hrs in the control group was significantly associated with development of endometritis (p=0.040). Similar result was reported by Memon et al.[15] We did not record any adverse reaction to povidone iodine similar to findings in other studies.[8,15,18,20-22] Our study reaffirms the safety of povidone iodine for vaginal cleansing.

Surgical wound infection which was a secondary outcome of this study was present in 11 (8.4%) in the control group and 4 (3.1%) in the intervention group. The rate of wound infection in the control group (8.4%) was within the range of post-operative wound infections following CS reported in a hospital survey conducted by Moir-Bussy and colleagues in England.[17] In Nigeria, studies in Kano and Lagos reported rates within this range.[23,24] Rupture of membranes before CS was significantly associated with surgical site infection in the control group with a p=0.033. Similar observation was reported in other studies.[8,15,18]

Overall, there was significant reduction in the rate of endometritis and wound infection in the treatment group than in the control group in this study similar to what was reported in other studies.[8,15,18] The risk of developing endometritis in the intervention group was 3.1% and in the control group, was 13.7%. Relative risk reduction of developing endometritis in intervention group was 8% and the number needed to treat (application of povidone iodine) to prevent one case of endometritis was 9. This means that for every population treated with povidone iodine, 11% will be prevented from developing endometritis. Conversely, rate of developing wound infection in the intervention group was 3.1% as against 8.4% in the control group with relative risk reduction of developing wound infection from 6.2% to 3.8%. Twenty persons needed to be treated in order to prevent one case of wound infection. These outcomes are significant and very important in low resource settings like ours with higher rate of post-CS endometritis and wound infection.[18,19,21,22] Puerperal sepsis is one of the major causes of maternal mortality in Nigeria (14.2%) with a

high mortality index of 79.3% as was recorded in a nationwide study in Nigeria on maternal mortality and near misses by Oladapo et al.[25] In addition, those who survived this infection may develop morbidities like local spread of infection to cause salpingitis, oophoritis, peritonitis, wound infection, pelvic abscess, septicaemia and spread to any organ or system.[8,25] These complications may result in prolonged hospital stay, more expenditures on investigations and antibiotic treatment, surgical re-exploration, inability to breast feed and take care of her new born and increase in economic burden.[25] Long term complications that may occur include uterine synechia, pelvic adhesions, tubal factor infertility and chronic pelvic pain.[8,25]

A meta-analysis of 16 clinical trials also showed that vaginal cleansing with povidone iodine immediately before caesarean delivery for women in labor and women with ruptured membranes reduces the risk of postoperative endometritis.[26] However, none of the studies in this meta-analysis was from the West African sub-region.

This study has shown that, post-operative endometritis and surgical site infection can be reduced by a simple, safe and cheap procedure of cleansing the vagina with 10% povidone iodine prior to emergency CS. This is important in low resource settings like ours.

CONCLUSION

This study demonstrated that vaginal cleansing with 10% povidone iodine prior to emergency CS significantly reduced the risk endometritis and SSIs. The intervention is simple, safe, and cost-effective, making it highly applicable in low-resource settings. The relatively low NNT further supports its public health value.

Recommendations

Vaginal cleansing with 10% povidone iodine is recommended prior to CS in patient with rupture of membranes and prolonged labour for prevention of post operative infectious morbidity.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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