The Egyptian Journal of Hospital Medicine (January 2025) Vol. 98, Page 1248- 1253

Vaginal Preparation with Povidone Iodine before Caesarean Delivery: A Randomized Control Trial

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ABSTRACT

Background: Infection is the commonest complication associated with Caesarean section (CS). There is a need to modify our practice to reduce infectious morbidity associated with Caesarean section.

Objectives: The study aimed at investigating the effect of vaginal preparation with antiseptic lotion on post-Caesarean infection rate, namely; maternal febrile morbidity, endometritis and wound infection.

Subjects and Methods: A randomized trial where patients were randomly assigned into two groups: Intervention group and a control group with 65 patients in each group. Patients were reviewed within the 3rd and 5th postoperative day to look for predefined variables for maternal febrile morbidity, endometritis and wound site infection.

Results: Vaginal preparation with povidone-iodine was found to decrease the risk of post-Caesarean febrile morbidity, endometritis and wound infection. There was a statistically significant reduction in endometritis observed in the intervention group (p= 0.041)

Conclusion: Vaginal preparation with antiseptic lotion significantly reduced post-operative Caesarean endometritis, and composite infectious morbidity hence beneficial. Since this intervention is expensive, it gives a lot of relief and benefits at virtually no cost.

Keywords: Caesarean section, Povidone-iodine, Vagina, Endometritis, Wound infection.

INTRODUCTION

Caesarean delivery is one of the most common surgical procedures performed by obstetricians. Infectious morbidity after Caesarean delivery can have a tremendous impact on the postpartum woman's return to normal function and her ability to care for her baby. Infection morbidity after CS is a major problem and is reported to be as high as 5–85%, commoner in low socioeconomic groups [1].

Despite the use of prophylactic broad-spectrum antibiotics, infectious complications still develop in up to 20% of women. With a global increase in CS rate, it is expedient to further investigate other ways of making this, a much safer procedure. Several risk factors have been recognised for post-Caesarean infectious morbidity, such as vaginal examinations in labour, prolonged duration of active labour, prolonged rupture of membrane and use of internal foetal monitoring [1,2]. All of these factors involve pathways that introduce large quantities of bacteria existing in the female lower genital tract into the uterine cavity. Ascending bacterial infection from the vagina is thought to be an aetiological factor in post-operative endometritis. They may become pathogenic in the uterine cavity because of haematomas and devitalized tissue within.

The causal organisms in endometritis and infectious morbidity often arise from ascending inoculation of the upper genital tract by cervicovaginal flora**.** These bacteria have been demonstrated to be responsible for failure of antibiotic prophylaxis during Caesarean deliveries. Additionally, some prophylactic antibiotic regimens are not consistently effective, and the vagina may become colonized with resistant organisms following surgical prophylaxis [1].

In the course of pregnancy and parturition, there is a constant change in the composites of the vaginal normal commensal. **Larsen** and **Galask** [1] noted that anaerobic species located in the vagina increase drastically by the third postpartum day. In many cases, the surgeon's hand, reaching below the infant's head or presenting part, is in direct contact with the vagina. Vaginal bacterial floras have been cultured from the delivering surgeon's glove in 79% (95% confidence interval [CI] 58%, 100%) of Caesareans that follow labour. In these cases, vaginal flora is delivered directly to the uterus, abdominal cavity, and the abdominal incision.

Previous studies evaluated whether vaginal preparatory cleansing can reduce the incidence of postoperative infectious morbidity. Currently, there is no clear recommendation for or against vaginal cleansing before Caesarean delivery. As a simple, generally inexpensive intervention, providers could consider implementing preoperative vaginal cleansing with an antiseptic solution such as povidone-iodine before performing Caesarean deliveries if found to significantly reduce post-caesarean delivery morbidity. Povidone-iodine has been found to be highly effective at eradicating bacterial biofilms, which is a vitally important consideration for wound care and infection control [3]. Vaginal preparation has been shown to decrease the quantitative load of vaginal microorganisms as well as to remove certain species of bacteria. Of the many antimicrobial agents available,

Received: 16/10/2024
Accepted: 17/12/2024

iodophore-based formulations such as povidone iodine have remained popular after decades of use for antisepsis and wound healing applications due to their favourable efficacy and tolerability [4]. Thus, the objective of this study is to determine whether cleansing the vagina with an antiseptic solution before Caesarean delivery decreases the risk of maternal infectious morbidities including endometritis and wound complications.

METHODOLOGY

Randomized controlled trial of patients undergoing Caesarean delivery that was conducted in Ladoke Akintola University of Technology Teaching Hospital, State Hospital Asubiaro, and Jaleyemi Catholic Hospital all in Osogbo. This study included both elective and emergency CS.

Inclusion criteria: Women with term gestation that require CS. were recruited while,

Exclusion criteria: Women with an allergy to povidone-iodine, chorioamnionitis on admission, fever on admission, abnormal vaginal discharge during pregnancy (foul smelling discharge with pruritus, which could stain underwear), emergency CS (due to foetal distress, vaginal bleeding of placenta praevia or abruption placenta), Sickle cell disease patients with pregnancy and diabetes mellitus in pregnancy.

Pre-operative preparation

In the theatre after adequate anaesthesia, all patients had urethral catheterization with Foley's catheter under sterile condition. Both groups received standard surgical preparation of abdomen in usual manner. In the intervention group, the vagina was scrubbed for 30-60 seconds using two 4 x 4 cm gauze soaked in 10% povidone-iodine solution in a sterilized bowl. This was scrubbed by rotating movements (360°) from the upper part of vagina to the outlet with attention to the anterior, posterior and lateral wall. After vaginal cleansing, the gloves were changed and an abdominal scrub performed. Lower segment CS was performed. The control group did not receive a vaginal scrub. All participants will benefit from the usual routine postoperative management without intervention.

Data collection and interpretation:

Other information, including demographic data (age, occupation & education), obstetric history (parity, gestational age), medical history (prior infection, anaemia & diabetes), number of vaginal examinations, duration of rupture of membranes, duration of surgical time, duration of labour and presence of meconium, were extracted from the patients' notes. Subjects received 1gm of ceftriazone i.v., intra-operatively then three doses, 12 hourly postoperatively. Temperature was checked routinely while uterine tenderness was checked on the third day just below the umbilicus. Lochia abnormality was sought for, and incision checked on 1st postoperative day and every day during hospitalization. At the time of hospital discharge, data was collected by a trained research assistant, blinded to the allocation group. The diagnosis was given at the time of clinical evaluation, between the 3rd and 5th day after the operation. The bias was minimal as all data was reviewed by trained physicians, without the knowledge of patient assignment to either arm of the study. Before reviewing of data, operational definitions for principal outcome were established. Patients who had post-operative wound infection, had wound care and dressing with antibiotics at the outpatient department. Endometritis was defined by a temperature evaluation of $\geq$ 38.0 ° C which persisted beyond the 1st postoperative day, in association with uterine tenderness and foul-smelling lochia, in the absence of physical or laboratory evidence of other infection. Wound infection was diagnosed as erythema or wound edge separation with purulent drainage. Febrile morbidity was defined as, any postoperative temperature $\geq$ 38 °C, excluding the 1st day after the operation. Other sources of infection that contributed to a high fever, such as a urinary tract infection, pneumonia, atelectasis, breast engorgement or drug sensitivity were not considered as post-Caesarean operation febrile morbidity. Composite wound infection consists of the three component outcomes all together, making up post-Caesarean infection morbidity, namely endometritis, wound site infection and maternal febrile morbidity.

Statistical analysis: Data was analysed using SPSS version 20. Data were described as mean and standard deviation or frequency (%) as appropriate. The χ^2 and t-test were used to compare the two groups. A p value of ≤ 0.05 was considered significant.

Ethical Consideration: Ethical clearance was obtained for this study from The Ethical Clearance Committee of the Ladoke Akintola University of Technology Teaching Hospital, Osogbo, with registration number LTH/EC/2015/02/0119. All participants were informed about the study and they had the right to withdraw for whatever reasons at any stage of the study without penalty. All eligible women gave informed consents obtained after receiving adequate information about the trial but were not informed about the arm of the study to which they will be assigned. Patients for elective CS gave consent a day prior to delivery in the antenatal ward, while emergency cases gave consent immediately at decision for CS is made. The Helsinki Declaration was followed all through the study.

RESULT

The total number of women who randomized was 130, with 65 each in the control and vaginal cleansing group. In the age distribution, only 3 (2.3%) of the women were below 20 years of age, while 64 (49.2%) were 30 years and above. About three-quarter of the women, 106 (81.5%) were between gravida1-3, while 24 (18.5%) were gravida 3 and above. Majority of the patients, 76 had between 1-3 (58.5%) deliveries. Primary CS was 49, while 81 of the 130 patients had a

previous CS. About half of the patients were civil servants 51 (39.2%) as Osun State was majorly a civil servant state. Educational level was generally high among the patients, 80 (61.5%) were with tertiary education, secondary were 45 (34.6%) and primary were 5 (3.8%). Emergency lower segment CS were 96 (73.8%) while elective lower segment CS was 34 (26.2%). Medical history of patients indicated hypertension in 19 (14.6%), other which included urinary tract infection and positive HBsAg in blood screening 4 (3.1%) and those without any medical illness were 107 (82.3%). Those who had no vaginal examination performed 39 (30%), between 1-5 vaginal examinations were 47 (36.2%) while greater than 5 vaginal examinations were 44 (33.8%). Membrane was ruptured in 63 (48.5%) and not ruptured in 67 (51.5%). The statistical representation of the study groups showed no significant differences. The study groups were similar in all considerations of socio-demographic/obstetric parameters (Table 1).

Table (1): Socio demography/obstetric data

Variables	Frequency	Percentage
Age Group		
< 20 yrs	3	2.3
20-24 yrs	21	16.2
25-29 yrs	42	32.3
30-34 yrs	37	28.5
35 yrs	27	20.8
Gravidity		
1-3	106	81.5
>3	24	18.5
Parity		
None	49	37.7
1-3	76	58.5
>3	5	3.8
Number of children alive		
None	53	40.8
1-3	74	56.9
>3	3	2.3
Occupation		
Unemployed	31	23.9
Self employed	48	36.9
Civil servant	51	39.2
Education level		
Primary	5	3.8
Secondary	45	34.6
Tertiary	80	61.5
Type of C/S		
Emergency Lower segment C/S	96	73.8
Elective Lower segment C/S	34	26.2
Medical history		
Hypertension	19	14.6
Others	4	3.1
None	107	82.3
Number of vaginal examinations		
None	39	30.0
1-5	47	36.2
>5	44	33.8
Membrane ruptured		
Yes	63	48.5
No	67	51.5
Liquor appearance		
Clear	106	81.5
Meconium stained	24	18.5
Uterine tenderness		
Yes	12	9.2
No	118	90.8

Fifteen (23.1%) of the control developed postoperative fever, while it was recorded in 9 (13.8%) of the case group. Although, there was a decrease observed in the intervention group, it was however not statistically significant (p=0.175). Surgical wound site infection showed wound infection in 12 (18.5%) of the control group and 10 (15.4%) of the case group. There was a notable decrease in the case group, however not statistically significant (p=0.640). Endometritis is seen in 6 (9.2%) of the control, and in 1 (1.5%) of the case group. There was a decrease noted in the case group, which was statistically significant (p=0.041). The only patient with endometritis in the case group was referred from a birth attendant with history of prolonged labour, over 16 hours duration with membrane rupture of over 20 hours. In the control group, 3 patients had cephalopelvic disproportion, and 2 had prolonged labour. The common factor in this group was the number of vaginal examinations. The minimum number of vaginal examinations was 6 each in 2 of the patients, 10 each in 2 patients, and 12 each in 2 patients, while only 1 had 1vaginal examination performed before surgery. All patients who had endometritis were in the active phase of labour before surgery (Table 2 & figure 1)).

Table (2): Comparative socio-demographic/obstetric parameters of study groups

Variable	Control (Mean ± SD)	Case (Mean ± SD)	T value	P value
Age (years)	29.83±5.34	29.35±5.69	0.493	0.623
Gravidity	2.51±1.43	2.25±1.13	1.158	0.249
Parity	1.29±1.37	1.06±1.07	1.071	0.286
Number of the children alive	1.12±1.23	0.89±0.94	1.202	0.231
Gestational age (weeks)	38.92±1.64	38.84±2.03	0.238	0.812
Packed cell volume (%)	33.79±2.54	33.94±2.67	0.323	0.747
Duration of labour (hours)	7.92±7.84	8.48±8.32	0.391	0.697
Duration of membrane rupture (hours)	6.01±8.33	4.85±6.79	0.877	0.382
Duration of labour before surgery (hours)	8.52±7.89	8.37±8.39	0.108	0.914
Duration of surgery (mins)	63.39±15.88	63.49±16.62	0.038	0.970

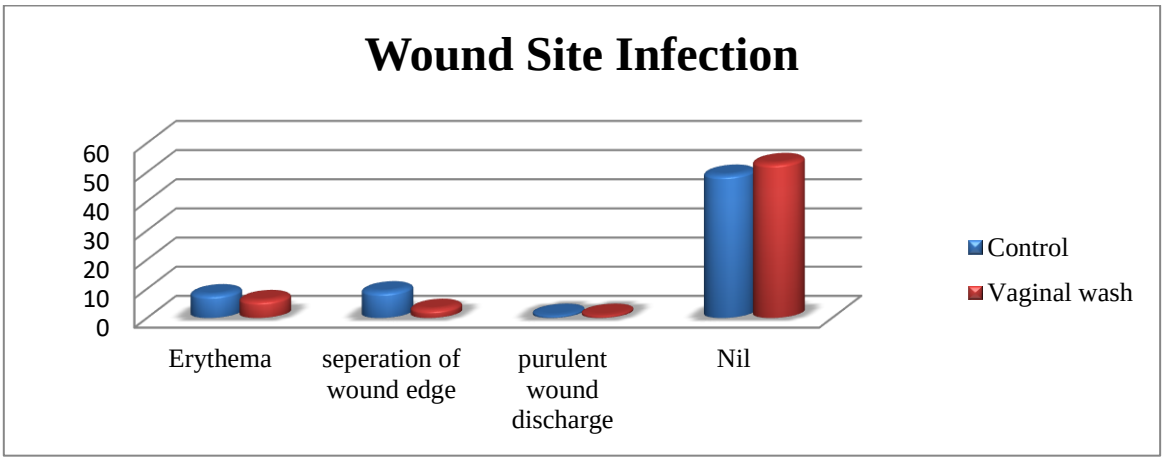

Figure (1): Wound site infection.

Composite infectious morbidity decreased in the case group 20 (30.7%) compared to the control 33 (50.5%). This decrease was statistically significant (p=0.037). Majority of the patients with composite infection, 47 (88.7%) had emergency lower segment CS and 30 (56.6%) had ruptured membranes before surgery. There was no adverse reaction to povidone-iodine in the vaginal wash group (Table 3).

Table (3): Morbidity outcome for the study groups

		Control N (%)	Cases N (%)	Df	χ^2value	P value
Composites	Present	33 (50.8)	20(30.8)	1	4.327	0.037
	Absent	32 (49.2)	45(69.2)			
Fever	Present	15 (23.1)	9(13.8)	1	1.840	0.175
	Absent	50 (76.9)	56(86.2)			
Wound site infection	Present	12 (18.5)	10(15.4)	1	0.219	0.640
	Absent	53 (81.5)	55 (84.6)			
Endometritis	Present	6 (9.2)	1 (1.5)	1	4.166	0.041
	Absent	59 (9.8)	64 (98.5)			

DISCUSSION

The findings from this study showed that vaginal cleansing with povidone-iodine before CS had a statistically significant reduction of post-Caesarean section endometritis and composite infectious morbidity, which is the combination of the three-component outcome in this study. This intervention is particularly of more benefit in patients who were already in labour and with ruptured membranes at the time of surgery. Similar studies with povidone-iodine carried out in the past had varying result outcomes.

Reid *et al.* [5] who did a similar study did not find a statistically significant reduction in postoperative infectious morbidity. However, he did not have a composite wound infectious morbidity outcome that included wound complications. Composite outcomes are often used in obstetric trials and have several advantages, which included statistical and resource efficiency [6]. There was also a selective bias when he removed 68 participants with chorioamnionitis who had been randomized from the pool, which was 13.5% of the original sample because it distorted the outcome result, giving a high rate of postoperative fever and infection.

Guzman *et al.* [7] had similar results, with non-statistically significant reduction in post-operative endometritis, fever and wound infection. He used povidone-iodine for vaginal wash in the case, then normal saline for vaginal wash in the control. This has the tendency to reduce vaginal flora in the control group and thereby reduce the baseline postoperative infectious morbidities. Infection in the uterine endometrium and decidua results in an inflammatory process known as endometritis. Approximately 94% of postpartum patients have positive endometritis cultures, but only a small subset actually develops the infection. This implies that it takes more than just colonization of the endometrial cavity by bacteria for pathogenesis. Ascending bacteria from the vagina colonize the innermost layer of the endometrium. **Amstrey *et al.*** [8] reported that a preoperative vaginal cleansing with povidone-iodine eliminated anaerobic gram-positive bacilli and significantly decreased gram-negative bacilli and aerobic and anaerobic gram-positive cocci. Similarly, **Monif *et al.*** [9] demonstrated that a povidone-iodine douche significantly reduced vaginal bacteria for 10 min following administration. This is in keeping with the stratified data of women with ruptured membrane and women with intact membrane in two trials carried out by **Guzman *et al.*** [7] and **Haas *et al.*** [6]**.** Both trials reported on the outcomes of endometritis and postoperative fever. There was a statistically significant reduction in the rate of endometritis for women receiving vaginal preparation with povidone-iodine solution preoperatively with ruptured membrane (1.4% in the vaginal cleansing group versus 15.4% in the control group; RR 0.13, 95% CI 0.02 to 0.66). There was no statistically significant difference for postoperative fever and wound site infection. **Asghania *et al.*** [10] also reported recently that vagina cleansing with povidone iodine may reduce post-operative endometritis. A recent Cochrane review concluded that vaginal preparation with povidone–iodine solution immediately prior to Caesarean delivery reduces the risk of post-operative endometritis, mainly in women undergoing Caesarean delivery with ruptured membranes.

In this study all the patients with endometritis were in active labour and with ruptured membrane. There was no significant reduction in post-operative fever and wound site infection following povidone iodine vaginal wash immediately prior to CS, which is similar to the results obtained in the studies carried out by **Haas *et al.*** [6], **Guzman *et al.*** [7], **Reid *et al.*** [5], **Asghania *et al.*** [10] and **Starr *et al.*** [11]. The reason for insignificant difference in the wound site infection could be due to the fact that reasons, other than bacterial could be traced to wound infection, such as haematoma, seroma, obesity, and even method of skin closure which could also lead to wound separation [12].

This study had several strengths, including the fact that both control and case group had similar demographic and pregnancy profiles making the postoperative result of infectious morbidity reliable. The composite infectious morbidity was statistically significant. Also, a strong factor; in that it helps us in making decisions as to the worth of the intervention and its implementation. This is associated with increased statistical efficiency, despite the limited sample size since this is a combination of three endpoint infectious morbidities.

There was no record of the neonatal outcome or weight of the babies delivered. This is due partly to the fact that previous trials recorded neither any adverse neonatal effect, nor reactions to povidone iodine. These parameters were thought to be directly unrelated to the objectives of this study, which are postoperative infectious morbidities.

CONCLUSION

This study showed that vaginal cleansing with povidone iodine before Caesarean delivery had benefit. This simple and inexpensive intervention will be of great benefit in our practice especially in Nigeria where lots of our women present in labour and with ruptured membrane, having been managed in traditional birth attendant home before presentation at the hospital. As more clinicians implement this intervention opens more opportunity for more studies and improvement in reduction of postoperative infectious morbidity to further make Caesarean delivery safer. There is obviously no doubt that more elaborate studies are required in this area to ensure that universal acceptance have concluded the benefit of this intervention in reducing post Caesarean infection morbidity.

Funding: None.

Conflict of Interest: Nil.

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