

# Pre-operative Vs. Post-operative Vaginal Cleansing with Povidone-iodine and Post-caesarean Infectious Morbidity: A Randomized Controlled Study

## Abstract

**Background:** Post-caesarean maternal infectious morbidity is still a big challenge despite prophylactic antibiotics use and other modalities adopted to prevent it. Pre-operative or post-operative vaginal cleansing with povidone-iodine may have effect on post-caesarean maternal infectious morbidity. **Aim:** The aim of this study was to compare the effectiveness of pre-operative vs. post-operative vaginal cleansing with povidone-iodine in reducing post-caesarean maternal infectious morbidities in a teaching hospital, South East Nigeria. **Materials and Methods:** This was a randomized controlled trial involving 244 pregnant women who underwent elective or emergency lower segment caesarean section at Alex Ekwueme Federal University Teaching Hospital, Abakaliki, Nigeria. Recruited patients were randomized into two groups: Group 1 had pre-operative vaginal cleansing with 5% povidone-iodine, whereas group 2 had post-operative vaginal cleansing with 5% povidone-iodine. Post-operatively, patients were monitored for clinical symptoms and signs of endometritis, wound infection, and pyrexia daily till discharge and at 2 weeks post-partum visit. Both groups received same post-operative care. **Data Analysis:** Data were analysed using Statistical Package for Social Sciences (IBM SPSS) software (version 20, Chicago, IL, USA). Continuous variables were presented as mean and standard deviation (mean  $\pm$  2SD), whereas categorical variables were presented as numbers, frequencies, and percentages. The *t*-test was used for comparison between groups for quantitative variables, whereas the  $\chi^2$  test was used to compare categorical variables. Relative risk and 95% confidence interval were calculated for outcome measures. *P*-value < 0.05 was considered significant. **Results:** The overall infectious morbidity rate was 14.3% (34/239) in all the study participants. The rate was 1.7% (4/239) among women in the pre-operative vaginal cleansing group and 12.6% (30/239) among women in the post-operative vaginal cleansing group. This was statistically significant [(*P* < 0.05); relative risk (RR) 0.13, 95% confidence interval (CI) 0.05–0.36]. Endometritis occurred in 13/239 (5.4%) women with 0.8% in the pre-operative group and 4.6% in the post-operative vaginal cleansing group. This was also statistically significant (*P* = 0.009; RR 0.18, 95% CI 0.04–0.78). Wound infection occurred in 11/239 (4.6%) women with 0.8% in the pre-operative group and 3.8% in the post-operative vaginal cleansing group (*P* = 0.032; RR 0.22, 95% CI 0.05–0.98). Pyrexia occurred in 10/239 (4.2%) women with 0 (0%) in the pre-operative group and 4.2% in the post-operative vaginal cleansing group. This was also statistically significant (*P* = 0.0007; RR 0.01, 95% CI 0.007–0.16). These were commoners among women with ruptured foetal membranes (*P* = 0.001; RR 0.22, CI 0.08–0.61) and those who had emergency caesarean delivery (*P* = 0.0001; RR 0.14, CI 0.05–0.37). **Conclusion:** Pre-operative vaginal cleansing with povidone-iodine is more effective in the reduction of composite post-caesarean maternal infectious morbidity compared with immediate post-operative vaginal cleansing with povidone-iodine, especially in women with ruptured foetal membranes and those who had emergency caesarean section.

**Keywords:** Endometritis, infection, povidone-iodine, pyrexia

## Introduction

Caesarean section is the commonest major surgical procedure performed by obstetricians worldwide.<sup>[1]</sup> The rate of caesarean section has witnessed astronomical increase worldwide and the incidence varies from country to country

and within a country, a rate of 34% had been reported in the USA,<sup>[2]</sup> whereas a rate of 30.7% had been reported in Abakaliki Southeast Nigeria.<sup>[3]</sup>

Maternal infectious morbidities are common complications of caesarean section and are the third leading cause of death among pregnant women in Nigeria<sup>[4]</sup> and accounts

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for 15% of maternal deaths worldwide.<sup>[5]</sup> These complications include endometritis, uterine subinvolution, foul smelling lochia, maternal fever, wound infection with or without dehiscence, and pelvic abscess. The pathophysiology is usually polymicrobial with a significant proportion occurring as a result of ascending contamination from the cervicovaginal flora. Organisms commonly implicated include *Staphylococcus* species, *Enterococcus faecalis*, *Escherichia coli*, *Proteus mirabilis*, *Pseudomonas* species, and *Citrobacter* spp.<sup>[3]</sup> These organisms occasionally found in the vagina at term may ascend to the endometrium and operation site during and immediately after caesarean delivery. The incidence of post-partum maternal infectious morbidity is about 5–20 times higher in caesarean delivery compared with vaginal delivery.<sup>[6,7]</sup> The incidence varies from place to place but it is lower in Western countries with documented incidence of 0.1–0.6 per 1000 deliveries<sup>[8]</sup> when compared with low-income countries, in which 7.0% and 12.5% were recorded in Abakaliki and Nnewi, Southeast Nigeria, respectively.<sup>[3,6,9]</sup>

Post-operative maternal infectious morbidity causes prolonged hospital stay, impairs mother and child bonding and establishment of lactation, creates worry and anxiety on the patient and relatives, and constitutes source of outbreak of nosocomial infections among health staff. It increases the overall burden and cost of surgery both on the individual and community levels and may have long-term complications such as chronic pelvic pain, increase risk of ectopic pregnancy, secondary infertility, and widespread aversion to caesarean section.<sup>[6,10,11]</sup>

Different pre-operative modalities have been employed in an attempt to reduce the incidence of post-caesarean maternal bacterial infections. These modalities include antibiotic prophylaxis, pre-operative vaginal cleansing with povidone-iodine, pre-operative shower with antiseptics, clipping rather than shaving pubic hairs, avoiding unnecessary vaginal examinations in labor, avoiding unnecessary instrumentation in labor, skin preparations with an antiseptic agent, avoiding manual removal of the placenta and foetal membranes, avoiding closure of the skin with staples, maintaining strict glycaemic control in women with diabetes, and early removal of bladder catheters post-operatively.<sup>[6,12-16]</sup> Though antibiotic prophylaxis is the most popular among these modalities especially in low-resource settings, its practice is still being challenged by resistance, efficacy, non-availability, and cost.<sup>[17]</sup>

Povidone-iodine is an iodinated polyvinyl polymer with broad-spectrum antimicrobial activity. It is used in surgery as a topical agent either on skin or mucous membranes for the treatment and prevention of infection in wounds, taking the advantage of antiseptic properties of iodine. Iodine has been recognized as an effective broad-spectrum bactericide, and is also effective against yeasts, molds, fungi, viruses, and protozoans. Povidone-iodine is included in the essential drug list of the Federal Republic of Nigeria<sup>[18]</sup> and is certified safe by the Nigerian National Agency for Food

and Drug Administration and Control (NAFDAC) for topical use. Though povidone-iodine is the most commonly used antiseptics for surgical vaginal preparation in the USA and currently the only recommended antiseptics to be used in the vagina, its practice is not yet popular in Nigeria.<sup>[19,20]</sup>

Although a lot of information about the role of pre-operative vaginal preparations with povidone-iodine in reducing maternal infectious morbidity after caesarean delivery is available in the literature, these were conducted in well-resourced health settings of the industrialized world.<sup>[12,21,22]</sup> In furtherance, it is not known whether change in timing of the vaginal cleansing, that is, immediately after caesarean delivery while patient is in theatre under anaesthesia, will have any effect on post-caesarean maternal infectious morbidity. The recent Cochrane Review of 7 studies involving 2,635 women reported that vaginal cleansing with povidone-iodine immediately before caesarean delivery was associated with a reduced risk of post-caesarean endometritis,<sup>[23]</sup> but some of the data analysed had conflicting results. Likewise, the World Health Organization (WHO) recently conditionally recommended pre-operative povidone-iodine vaginal cleansing of all women undergoing caesarean section to reduce the risk of peripartum maternal infectious morbidity,<sup>[24]</sup> but this practice is not yet popular in Nigeria perhaps due to a dearth of local studies on its practice. This study compared pre-operative with post-operative vaginal cleansing using povidone-iodine and determined associated post-operative maternal morbidity. This study will help to determine the most appropriate timing of this intervention in prevention of post-caesarean infectious morbidity and make appropriate recommendations.

### Study site

This study was carried out at the Alex-Ekwueme Federal University Teaching Hospital, Abakaliki, Nigeria (AE-FUTHA) between October 2018 and May 2019. It is one of the two tertiary health facilities in Ebonyi State. It receives referrals from all parts of the state and neighbouring states of Abia, Benue, Enugu, and Cross River. The hospital has a very busy obstetric unit. The antenatal clinics hold Mondays through Fridays led by consultants. Based on departmental policy, caesarean deliveries are carried out only by the consultants and senior registrars in the department. There were about 12,000 antenatal women in 2017 and about 725 caesarean deliveries per year with an average of 60 caesarean deliveries per month. According to the most recent published work by Agboeze *et al.*,<sup>[3]</sup> the caesarean section rate in FETHA was 30.7%.

### Study population

This study was carried out among consented pregnant women after the age of viability who had given consent to undergo either elective or emergency caesarean delivery in the Department of Obstetrics and Gynaecology of AE-FUTHA, Ebonyi State, Nigeria within the study period.

## Study design

This was an equivalence randomized controlled trial of the effectiveness of pre-operative vs. immediate post-operative vaginal cleansing with povidone-iodine on post-caesarean maternal infectious morbidity at AE-FUTHA.

## Inclusion criteria

All consented parturient admitted in AE-FUTHA for either elective or emergency caesarean section after the age of foetal viability ( $\geq 28$  weeks gestational age) were included.

## Exclusion criteria

Patients with refusal of consent, known allergy to topical povidone-iodine or on treatment with iodine or radiotherapy, placenta praevia, cord prolapse, face presentation with ruptured membranes, ruptured uterus, and thyroid disorders were excluded.

## Sample size determination

The minimum sample size was determined using the formula for calculating the sample size of a clinically equivalence randomized controlled trial for dichotomous variables by Zhong<sup>[25]</sup>:

$$N = 2 \times \left( \frac{z_{1-\alpha} + z_{1-\beta}}{\delta_0} \right)^2 \times p \times (1-p)$$

$N$  = sample size for each group,

$Z$  = standard normal deviate for a one- or two-sided  $x$ ,

$\delta_0$  = a clinically accepted margin,

$S^2$  = pooled standard deviation of both comparison groups.

Substituting for,

$Z_{1-\alpha} = 1.96$  (where  $\alpha = 0.05$ )

...

2

$Z_{1-\beta} = 0.845$  (where  $\beta = 0.20$ )

$\delta_0 = 10$

$P = 7$  (from a study by Haas *et al.*<sup>[24]</sup>)

$$N = \frac{2 \times (1.96 + 0.845)^2 \times 0.07(1-0.07)}{(0.10)}$$

$$N = \frac{2 \times (2.805)^2 \times 0.0651}{(0.10)}$$

$$N = 2 \times (28.05)^2 \times 0.0651$$

$$N = 2 \times 786.80 \times 0.0651$$

$$N = 102.44 \sim 102$$

Providing 10% attrition, 102/10  $\sim$  10

$N = 112$

112 women would be required per arm.

## Procedure for randomization

This study was by non-blinded simple randomization. The participants were approached and introduced to the study before recruitment. The recruitment was done in the antenatal ward for the elective cases, whereas emergency cases were recruited in the emergency unit of the department. Thereafter, informed consent was obtained. Each consented participant that met the criteria, after counselling, picked a card at random from an envelope containing a pool of 224 shuffled deck cards. Half of these cards (122) with even numbers P002, P004, ..., P224 belonged to group 1 (pre-operative vaginal cleansing group), whereas the remaining half of the cards (122) with odd numbers Q001, Q003, ..., Q243 belonged to group 2 (post-operative vaginal cleansing group). They were mixed such that each card in the envelope had the same probability to be picked every time. Each participant was allocated to the group based on what she picked. Group 1 received pre-operative vaginal cleansing with 5% povidone-iodine, whereas group 2 received post-operative vaginal cleansing with 5% povidone-iodine.

## Study procedure/intervention

All participants, irrespective of the group the individual belonged, received prophylactic antibiotics (single dose intravenous ceftriaxone 1 g and metronidazole 500 mg) 30 min before anaesthesia and the routine anterior abdominal wall scrub with chlorhexidine and methylated spirit. Vital signs including temperature and pulse rate were recorded. The patient was placed in supine position with 15° lateral tilt after administration of spinal anaesthesia, and an indwelling Foley urethral catheter was inserted under complete aseptic techniques. In group 1 (pre-operative vaginal cleansing group), within 1 min before anterior abdominal wall cleaning, two research assistants each supported the patient's legs in dorsal position. Sterile gloves worn and two pieces of 4 × 4 cm sterile gauze held with sponge holding forceps was soaked in 5% povidone-iodine in a sterile galipot. The gauze soaked in 5% povidone-iodine was used to cleanse the vagina within a duration of 30 s starting from the vaginal apex to the introitus with attention to the anterior, posterior, and lateral vaginal walls.

After vaginal cleansing, the sterile gloves were changed to perform the routine abdominal scrub with chlorhexidine and methylated spirit. In group 2 (immediate post-operative vaginal cleansing), following the delivery of the baby and closure of the uterine and abdominal wound and within

1 min of applying sterile dressing on the anterior abdominal wall with the patient still under anaesthesia, the blood clots in the vagina were evacuated. This was followed by vaginal cleansing for a period of 30 s with two pieces of 4 × 4 cm gauze in a sponge-holding forceps soaked in 5% povidone-iodine in a sterilized galipot starting from the vaginal apex to the introitus with attention to the anterior, posterior, and lateral vaginal walls. All the participants had spinal anaesthesia. The uterine repairs were done with vicryl sutures, anterior abdominal wall repaired with Vicryl 2 for rectus sheath, Vicryl 2/0 for subcutaneous tissues, and skin closure was with either subcuticular skin closure technique using Vicryl 2/0 or simple mattress suturing technique with Nylon 2/0. All participants received post-operative antibiotics: intravenous ceftriaxone 1 g daily for 48 h, intravenous metronidazole 500 mg 8 hourly for 48 h, and thereafter received oral cepodoxime 200 mg 12 hourly for 5 days and oral metronidazole 400 mg 8 hourly for 5 days. Participants who develop fever within the period of admission had blood film for malaria parasite to exclude malaria and urine microscopy and culture and sensitivity done to exclude urinary tract infections as causes of fever. All patients were reviewed daily from the period of surgery to discharge from hospital for the development of febrile morbidity, clinical diagnosis of endometritis, and wound infection or breakdown. The evaluation was done 12 hourly till discharge. Patients' clinical data, including vital signs chart for temperature and pulse rate, were reviewed during admission and before discharge from hospital and at 2 weeks post-natal visit.

#### Determination of outcomes

Participants were assessed clinically for the development of endometritis, fever, and surgical site infections throughout the period of admission and at 2 weeks post-natal visit. Prior to hospital discharge, participants received clear instructions on symptoms of infection and the need to return for 2 weeks post-natal visit. Participants were advised to return to hospital if they develop symptoms of infections such as hotness of the body, foul smelling vaginal discharge, persistent/increasing lower abdominal pain, wound discharge, swelling, redness, or dehiscence. Definitions of components of post-caesarean maternal infectious morbidity were based on Centre for Diseases Control and Infection Prevention (CDC) criteria.<sup>[26]</sup>

#### Post caesarean maternal infections

The occurrence of any of the outcomes described below (endometritis, fever and wound infections). For the purpose of this study, composite maternal infectious morbidity was regarded as the occurrence of any of the above (endometritis, fever, and wound infection) irrespective of its severity.

#### Post caesarean endometritis:

Temperature of 38°C or higher ≥24 h after surgery with foul smelling lochia, lower abdominal pain, and/or uterine tenderness.

#### Puerperal pyrexia

Temperature of 38°C or higher ≥24 h after surgery but within the first 10 days.

#### Post-operative wound infections

Erythema, purulent discharge, and wound breakdown.

#### Primary outcome

The primary outcome measure was post-caesarean endometritis.

#### Secondary outcome

The secondary outcome measures were post-caesarean wound infection, post-operative fever, duration of hospitalization due to infectious morbidity, and adverse reaction to povidone-iodine.

#### Data analysis

This analysis was as per protocol. Data collected included sociodemographic data such as age, social status (according to Olusanya *et al.*),<sup>[27]</sup> booking status, parity, and gestational age; medical history such as obesity, anaemia, diabetes, and hypertensive disorders; status of foetal membranes (intact membranes or ruptured membranes); type of surgery (elective or emergency caesarean delivery); duration of labour; and duration of hospital stay. These data were collated, tabulated, and analysed using Statistical Package for Social Sciences (IBM SPSS) software (version 20, Chicago, IL, USA). Continuous variables were presented as mean and standard deviation (mean ± 2SD), whereas categorical variables were presented as numbers, frequencies, and percentages. Student's *t*-test was used for comparison between groups for quantitative variables, whereas the  $\chi^2$  test was performed in comparing proportions between the two groups. Relative risk and 95% confidence interval (CI) were calculated for outcome measures. A difference with *P*-value <0.05 was considered statistically significant.

#### Ethical approval

Approval for this research was obtained from the Research and Ethics Committee of the AE-FUTHA.

#### Results

Figure 1 is the CONSORT diagram and shows that 239 consented women completed the study and were analyzed. Table 1 shows the sociodemographic and obstetrics characteristics, side effects, and duration of hospital stay among the study participants. The baseline maternal characteristics were similar in both pre-operative and post-operative vaginal cleansing groups. The mean age of the pre-operative vaginal cleansing group was 29.4 ± 5.4 and that of the post-operative vaginal cleansing group was 30.4 ± 5.0. Majority of the women were multiparous 130 (54.4%), booked 142 (59.4%), and with term pregnancy 198 (82.8%). Also, majority of the women were in the lower socio-economic class (classes 4 and 5). One hundred and

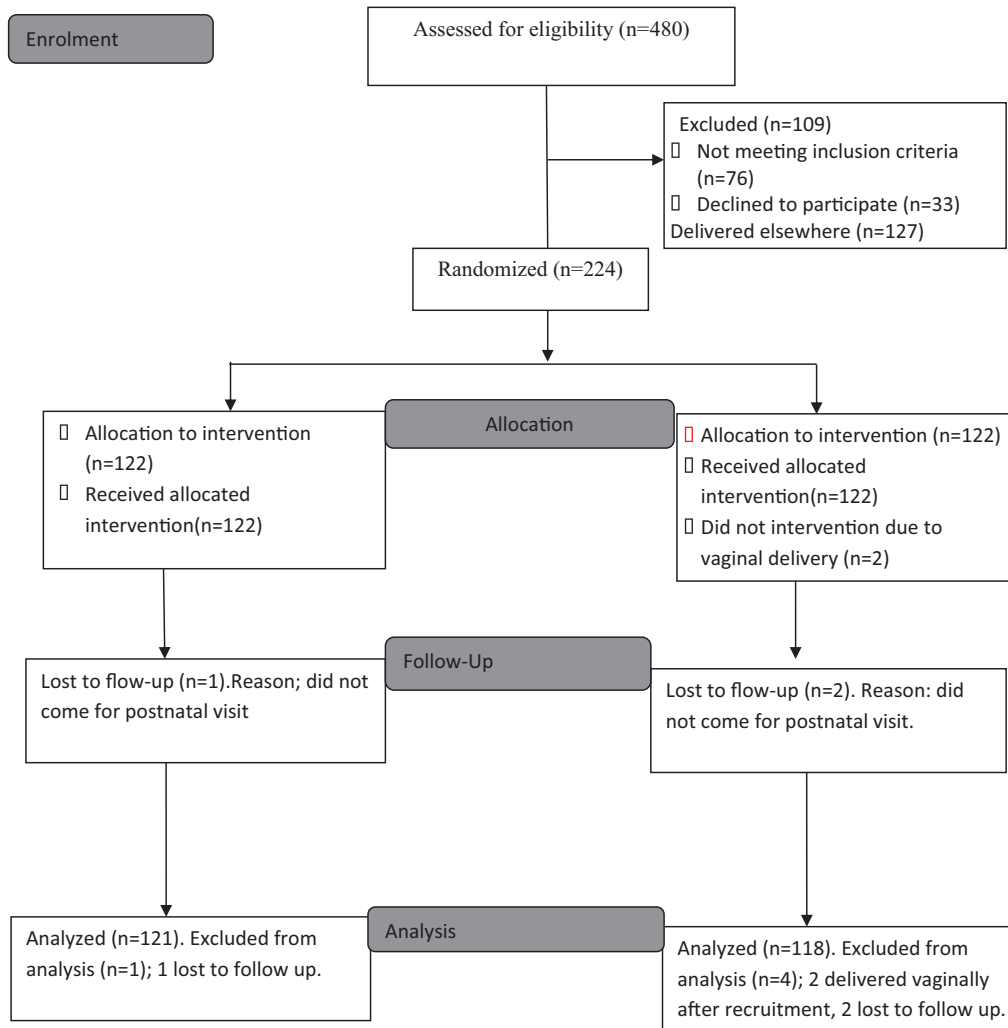


Figure 1: Consort flow diagram

eighteen (49.4%) had intact foetal membranes, whereas 121 (50.6%) of the women had rupture of foetal membranes prior to the caesarean section while 85 (35.6%) had duration of membrane rupture beyond 12 h. Thirty (12.5%) of the women had a diagnosis of obstructed labour prior to the surgery. Most of the surgeries were emergency caesarean section 162 (67.8%) and the majority [192 (80.3%)] of the women who had surgery were discharged within 7 days. There was no statistically significant difference between the two groups in terms of age, marital status, parity, gestational age, booking status, social class, number of vaginal examinations, membrane status, duration of membrane rupture, type of caesarean section, and duration of hospital stay. No participant reacted to povidone-iodine.

Table 2 shows the comparison of the medical disorders of pregnancy between the pre-operative and post-operative vaginal povidone iodine groups. There was no statistically significant difference between the two groups.

Table 3 shows the summary of the distribution of outcomes. There were 34/239 (14.3%) total cases of post-caesarean maternal infectious morbidity among the study population:

4/121 (1.7%) in the pre-operative povidone-iodine vaginal cleansing group and 30/118 (12.6%) in the immediate post-operative vaginal cleansing group [ $P = 0.00005$ , relative risk (RR) 0.13, 95% CI 0.05–0.36]. This was statistically significant. There were 13/239 (5.4%), 11/239 (4.6%), and 10/239 (4.2%) cases of post-caesarean endometritis, wound infection, and pyrexia, respectively. The infectious morbidities were more in the post-operative vaginal povidone iodine cleansing group than in the pre-operative vaginal cleansing group (4.6%, 3.8%, and 4.2% compared to 0.8%, 0.8%, and 0%) for endometritis, wound infection, and pyrexia, respectively.

The incidence of post-caesarean maternal infectious morbidities among the study participants stratified by whether the membrane was intact or ruptured is shown in Table 4. The subgroup analysis shows that among women with intact foetal membranes, there was no statistically significant difference in post-caesarean maternal infection (sum of endometritis, wound infection, and pyrexia) between the pre-operative and post-operative vaginal cleansing groups (0% vs. 1.7%,  $P$ -value=0.51). Similarly,

**Table 1: Sociodemographic and obstetric characteristics, side effect, and duration of hospital stay**

Variables	Pre-operative (121)	Post-operative (118)	P-value	RR (95% CI)
Mean age	29.4 ± 5.4	30.4 ± 5.0	0.23	
Marital status				
Single	5 (2.1)	10 (4.2)		
Married	116 (48.5)	108 (45.2)	0.26	0.64 (0.31–1.33)
Parity				
Primigravida	42 (17.6)	35 (4.6)		
Multipara	62 (25.9)	68 (28.5)	0.37	0.94 (0.76–1.00)
Grand multipara	17 (7.1)	15 (6.3)		
Gestational age (weeks)				
Pre-term	9 (3.8)	5 (2.1)		
Term	100 (41.8)	98 (41.0)	0.11	0.57 (0.44–1.35)
Post-term	12 (5.0)	15 (6.3)		
Booking status				
Booked	72 (30.1)	70 (29.3)		
Unbooked	49 (20.5)	48 (20.1)	0.97	1.0 (0.78–1.30)
Social class				
1	16 (6.7)	21 (8.8)		
2	21 (8.8)	30 (12.6)		
3	20 (8.4)	15 (6.3)	0.84	1.0 (0.99–1.75)
4	30 (12.6)	26 (10.9)		
5	30 (12.6)	26 (10.9)		
No. of vaginal examinations				
None	42 (17.6)	54 (22.6)		
1–5	27 (11.3)	15 (6.3)	0.07	1.71 (0.79–2.31)
>5	52 (21.8)	49 (20.4)		
Membrane status				
Intact	58 (24.3)	60 (25.1)		
Ruptured	63 (26.4)	58 (24.3)	0.35	0.94 (0.73–1.21)
Duration of membrane rupture				
≤12h	20 (8.4)	16 (6.7)		
>12 h	43 (18.0)	42 (17.6)	0.76	1.1 (0.77–1.57)
Obstructed labour				
Yes	18 (7.5)	12 (5.0)		
No	103 (43.1)	102 (44.4)	0.36	1.19 (0.87–1.65)
Type of caesarean section				
Elective	41 (17.2)	36 (15.1)		
Emergency	80 (33.5)	82 (34.3)	0.97	1.08 (0.83–1.40)
Duration of hospital stay				
≤7	97 (40.6)	95 (39.7)		
8–14	18 (7.5)	15 (6.3)	0.3	0.74 (0.15–1.0)
>14	6 (2.5)	8 (3.3)		

CI = confidence interval

there was no statistically significant difference between the two groups for the development of endometritis [(0% vs. 0%),  $P$ -value=1], wound infection [(0% vs. 1.7%),  $P$ -value=0.51], and pyrexia [(0% vs. 0%),  $P$ -value=1].

However, among women with ruptured foetal membranes, composite post-caesarean maternal infection (sum of endometritis, wound infection, and pyrexia) showed a statistically significant difference between pre-operative vaginal cleansing group and post-operative vaginal cleansing group [4 (6.4%) vs. 17 (29.3%), respectively, with  $P$ -value=0.001; RR 0.22, CI 0.08–0.61]. Post-caesarean endometritis occurred in 2 (3.2) and 8 (13.8%) women in

pre-operative and post-operative vaginal cleansing groups, respectively. This was however not statistically significant (3.2% vs. 13.8%) ( $P = 0.04$ ; RR 0.23, 95% CI 0.05–1.02). Similarly, post-operative pyrexia and wound infection did not show statistically significant difference between the two groups [0 (0%) vs. (4) 6.9%,  $P = 0.04$ , RR 0.40, 95% CI 0.08–2.08] and [(3.2% vs. 8.6%),  $P = 0.26$ , RR 0.37, 95% CI 0.07–1.82] respectively.

Table 5 shows the analysis of women who had elective caesarean delivery or emergency caesarean delivery and their infectious morbidity. Among women who had elective caesarean section, there was no post-caesarean maternal

**Table 2: Comparison of medical disorders of pregnancy among the two groups**

Variables	Pre-operative N=121	Post-operative N=118	P-value	RR (95% CI)
Obesity				
Yes	2 (1.7)	1 (0.8)	0.51	1.32 (0.59–2.9)
No	119 (98.3)	117 (99.2)		
Diabetes				
Yes	1 (0.8)	1 (0.8)	0.74	0.99 (0.25–3.9)
No	120 (99.2)	117 (99.2)		
Anaemia				
Yes	5 (4.1)	5 (4.2)	0.97	0.99 (0.52–1.9)
No	116 (95.9)	113 (95.8)		
Hypertension				
Yes	9 (7.4)	12 (10.2)	0.78	0.88 (0.53–1.5)
No	106 (89.8)	112 (92.6)		

**Table 3: Distribution of the outcomes among the study groups**

Outcome variables	Group 1 121 (50.6%)	Group 2 118 (49.6%)	Total 239 (100%)	P-value	RR (95% CI)
Total infectious morbidity	4 (1.7%)	30 (12.6%)	34 (14.3%)	0.00005	0.13 (0.05–0.36)
Endometritis	2 (0.8%)	11 (4.6%)	13 (5.4%)	0.009	0.18 (0.04–0.78)
Wound infection	2 (0.8%)	9 (3.8%)	11 (4.6%)	0.032	0.22 (0.05–0.98)
Pyrexia	0 (0%)	10 (4.2%)	10 (4.2%)	0.0007	0.01 (0.007–0.16)

**Table 4: Comparison of incidence of post-caesarean maternal infectious morbidity among women stratified by intact or ruptured membranes**

Variables	Pre-operative N=58	Post-operative N=60	P-value	RR/95% CI
Intact membranes				
Total infections	0 (0%)	1 (1.7%)	0.51	1.01
Endometritis	0 (0%)	0 (0%)	1	1
Wound infection	0 (0%)	1 (1.7%)	0.51	1.01
Pyrexia	0 (0%)	0 (0%)	1	1
Ruptured membranes				
Total infection	4 (6.4%)	17 (29.3%)	0.001	0.22 (0.08–0.61)
Endometritis	2 (3.2%)	8 (13.8%)	0.04	0.23 (0.05–1.03)
Wound infection	2 (3.2%)	5 (8.6%)	0.26	0.37 (0.07–1.82)
Pyrexia	0 (0%)	4 (6.9%)	0.04	0.40 (0.08–2.08)

CI = confidence interval

**Table 5: Comparison of the incidence of post-caesarean infectious morbidity among women stratified by elective or emergency caesarean section**

Variables	Pre-operative N=41	Post-operative N=36	P-value	Relative risk/95% CI
Elective				
Total infections	0 (0%)	0 (0%)	1	1
Endometritis	0 (0%)	0 (0%)	1	1
Wound infection	0 (0%)	0 (0%)	1	1
Pyrexia	0 (0%)	0 (0%)	1	1
Emergency				
Total infection	4 (5%)	30 (36.6%)	0.0001	0.14 (0.05–0.37)
Endometritis	2 (2.5%)	11 (13.4%)	0.02	0.19 (0.04–0.81)
Wound infection	2 (2.5%)	9 (11%)	0.03	0.23 (0.05–1.02)
Pyrexia	0 (0%)	10 (12.2%)	0.002	0.12 (0.06–0.52)

infectious morbidity recorded in either the pre-operative or post-operative vaginal cleansing group. However, among women who had emergency caesarean delivery, the total post-caesarean maternal infectious morbidity rate, respectively, in the two arms was 5% vs. 36.6% ( $P=0.0001$ , RR 0.14, 95% CI 0.05–0.37), and this was statistically significant. There was also statistically significant difference in the rate of post-caesarean endometritis and pyrexia between pre-operative and post-operative vaginal cleansing groups (2.5% vs. 13.4%;  $P=0.02$ ; RR 0.19, 95% CI 0.04–0.81) and (0% vs. 12.2%;  $P=0.002$ ; RR 0.12, 95% CI 0.06–0.52), respectively. However, the wound infection rate did not show statistically significant difference between the two groups (2.5% vs. 11%;  $P=0.03$ ; RR 0.23, 95% CI 0.51–1.02).

## Discussion

This study compared the effectiveness of pre-operative vs. post-operative vaginal cleansing with 5% povidone-iodine in the reduction of post-caesarean maternal infectious morbidity such as endometritis, wound infection, and post-operative pyrexia. The greater number of women in this study were of low socio-economic class (social classes 4 and 5), multiparous, booked, and at term. The majority of the caesarean sections 162 (67.8%) were done as emergency. The previous study by Onoh *et al.*<sup>[28]</sup> had noted that 75.2% of caesarean sections in the study centre were emergency. The reason for high rate of emergency caesarean section in this study may not be unconnected with the observed trend in which some women who had antenatal care in the centre and were selected for elective caesarean section would rather decline and labour at home and/or (traditional birth attendant) TBA's homes only to present in emergency. This is pathetic and attributable to worsening poverty and ignorance among the women. There was no significant difference between the sociodemographic and obstetric characteristics and risk factors among the study population.

This study showed a significant reduction in the incidence of composite maternal post-caesarean infections morbidity (endometritis, wound infections, and pyrexia) among women who had pre-operative vaginal cleansing with povidone-iodine compared with women who had immediate post-caesarean vaginal cleansing with povidone-iodine. There were a total of 34/239 (14.3%) cases of post-caesarean maternal infectious morbidity among the study population: 4/121 (1.7%) in the pre-operative povidone-iodine vaginal cleansing group and 30/118 (12.6%) in the immediate post-operative vaginal cleansing group. The overall infectious morbidity rate of 14.3% noted in this study was higher than 7% earlier reported by Agboeze *et al.*<sup>[3]</sup> in Abakaliki and slightly higher than 12.5% reported by Onyegbule *et al.*<sup>[9]</sup> in Nnewi and 10.8% reported by Ezechi *et al.*<sup>[11]</sup> in Lagos, Nigeria. This variation may be attributable to increasing caesarean section rates, especially emergency caesarean

sections with its attendant problems as well as the low socio-economic status of the participants.

There were 13/239 (5.4%), 11/239 (4.6%), and 10/239 (4.2%) cases of post-caesarean endometritis, wound infection, and pyrexia, respectively. The infectious morbidities were more in the post-operative vaginal povidone-iodine cleansing group than the pre-operative vaginal cleansing group (4.6%, 3.8%, and 4.2% compared with 0.8%, 0.8%, and 0%) for endometritis, wound infection, and pyrexia, respectively. It may be that during the delivery process, bacteria from the vagina might have been inadvertently inoculated into the operation site and so the harm must have been done before the post-operative vagina cleansing. It may also be that interaction of povidone-iodine with blood/lochia within the vagina immediately after the caesarean section reduces the potency of povidone-iodine. The benefit of pre-operative vaginal cleansing over post-operative vaginal cleansing was generally noted more among women with already ruptured foetal membranes. However, there was no statistically significant reduction in each of the individual post-caesarean maternal infectious morbidity rates: endometritis, wound infection, and pyrexia among the two arms. However, among women who had emergency caesarean section, there was a statistically significant reduction in the incidence of post-caesarean endometritis and pyrexia, but wound infection did not show a significant reduction between the two arms. Among women with intact membranes or those who had elective caesarean section, pre-operative vs. postoperative vaginal cleansing with povidone-iodine did not show any statistically significant difference for the development of post-caesarean maternal infectious morbidity between the two groups.

The findings in this study are similar to the findings of Starr *et al.*,<sup>[12]</sup> Yildirim *et al.*,<sup>[21]</sup> Haas *et al.*,<sup>[24]</sup> Ashgania *et al.*,<sup>[20]</sup> Mwangi,<sup>[29]</sup> Roeckner *et al.*,<sup>[30]</sup> and Memom *et al.*<sup>[31]</sup>: that pre-operative vaginal cleansing with povidone-iodine reduces post-caesarean maternal infectious morbidity among high risk women but disagrees with Reid *et al.*,<sup>[32]</sup> Tewfik *et al.*,<sup>[33]</sup> and Aref<sup>[34]</sup>; that vaginal cleansing with povidone-iodine reduces maternal infections in low-risk women. Endometritis was the primary outcome in this study as was in the above studies. However, these studies considered intervention only for pre-operative vaginal cleansing with povidone-iodine but the control group had no vaginal cleansing. Yildirim *et al.*<sup>[21]</sup> showed a lower incidence of endometritis in women cleansed with povidone-iodine compared to those who had no vaginal cleansing that was statistically significant (6.9% vs. 11.6%; RR 1.69; 95% CI 1.03–2.76]. The reduction in the incidence of endometritis was found to be significant among high-risk women, as was the case in our study. Similarly, as in our study, there was no statistically significant difference noted between the two groups among low-risk women at the time of caesarean delivery, and no differences noted when women with ruptured membranes were excluded from the analysis.



However, in their studies, there was no decrease in the overall risk of post-operative fever or wound infection and thus similar to findings by Starr *et al.*<sup>[12]</sup> and Haas *et al.*<sup>[22]</sup> These studies are done in well-resourced area of the developed world.

Haas *et al.*<sup>[22]</sup> reported that women with ruptured foetal membranes prior to caesarean section had a significant decrease in endometritis from 15.4% in the control group to 1.4% in the treatment group, and this finding is similar to the findings on endometritis in this study with a decrease from 13.4% in the post-operative vaginal cleansing group to 2.5% in the pre-operative vaginal cleansing group. This may be accounted for by the fact that in the pre-operative vaginal cleansing group, there is prior inhibition of growth and ascent of bacteria from the vagina into the endometrial cavity by the effect of povidone-iodine unlike those who had post-operative vaginal cleansing where the bacteria may have ascended to the upper genital tract during the delivery of the presenting part.

Similarly, Memon *et al.*<sup>[31]</sup> in Pakistan found that pre-operative vaginal cleansing with povidone-iodine showed a statistically significant reduction in the risk of post-operative infectious morbidities [ $P < 0.02$ , odds ratio 0.335 (95% CI 0.125–0.896)], particularly frequency of endometritis ( $P < 0.03$ ). This effect appeared to be more marked for women with ruptured membranes and those who had emergency caesarean section. This study is important because it was conducted in a developing country like Nigeria. However, some common risk factors among the women mentioned in our study, such as obstructed labour, were not stated in their study.

Mwangi<sup>[29]</sup> in Nairobi, Kenya compared the effect of pre-operative vaginal cleansing with povidone-iodine vs. none in women with low and high risk for post-caesarean maternal infections morbidity. His findings show an overall reduction in the incidence of composite measure of post-caesarean maternal infections among those who had pre-operative vaginal cleansing compared with those who had none [7.5% vs. 11.70%,  $P = 0.006$ , RR 0.43 (0.23–0.80)]. There was also a reduction in the incidence of surgical site infections. Endometritis and pyrexia, however, did not show any statistical significant reduction in either of the two arms. It is worthy of note that this study shares some common features with our study in methodology and findings, except that all the women irrespective of the arm they belong had post-operative vaginal toileting with povidone-iodine as a routine practice in the University of Nairobi Teaching Hospital, Kenya. Again, the concentration of povidone-iodine used in their study was not stated.

Our finding in this study disagrees with the report of Aref<sup>[34]</sup> in Saudi Arabia in the aspect of pre-operative vaginal cleansing. The study recruited 226 women for elective caesarean section and randomized them into

pre-operative vaginal cleansing with povidone-iodine vs. no vaginal cleansing and noted a statistically significant reduction in the pre-operative vaginal cleansing arm when compared with the non-vaginal cleansing arm [7.5% vs. 20.7%;  $P = 0.003$ , RR 0.3 (0.2–0.7)]. The study of Aref has some resemblance to the study in sample size and sample population. With same method of recruitment and reporting, it excluded women with ruptured membranes and those who had emergency caesarean section. This may mean higher rate of reduction of infectious morbidity if the study had included women with high risks for post-caesarean maternal infections. This study recruited women in poor resource settings of low and high risks for post-caesarean maternal infectious morbidities, such as those with medical conditions in pregnancy, ruptured foetal membranes, multiple vaginal examinations, prolonged labour, obstructed labour, and those billed for emergency caesarean section. The inclusion of women with both low and high risks for infectious morbidity was necessary so that vaginal preparation with povidone-iodine especially in a low-resourced setting becomes embedded within the standard practice of caesarean delivery and so can hardly be overlooked.

The study by Reid *et al.*<sup>[32]</sup> in North Carolina showed no difference between the two arms in terms of sociodemographic and obstetric characteristics and risk for maternal infection, just as was the case with my study. However, my study disagrees with their study in that they did not find any advantage in the reduction of incidence of endometritis, wound infection, and fever among high-risk women who had pre-operative vaginal cleansing with povidone-iodine compared with women who had no vaginal cleansing. They further reported that pre-operative vaginal povidone-iodine predisposed women already in labour to more risk of post-caesarean endometritis. High concentration (10%) povidone-iodine was used in their study and this concentration is capable of irritating the cervicovaginal area, predisposing to more infections morbidity. The 5% povidone-iodine used in this study is a more appropriate concentration, easily available, affordable, and did not cause any adverse reaction among the studied population. Lower concentration of 1% was used by Haas *et al.* and still had positive results on the women studied.

The surgical steps and speed for caesarean section may differ from one surgeon to another and may be difficult to have a uniform step in the delivery of the foetus and placenta, especially in difficult cases such as obstructed labour. Some of the clinical parameters assessed in the outcome measures may be subjective; example, in endometritis, “uterine tenderness” depends on how individual patients perceived pain. The final assessment for evidence of infection was done at the second week visit, but it was not impossible that some women may have developed some infectious morbidity beyond the 2 weeks’ visit.

In conclusion, pre-operative vaginal cleansing showed some advantage over post-operative vaginal cleansing, especially among women at high risk for post-caesarean infectious morbidity. Vaginal cleansing with povidone-iodine did not manifest any adverse effect among the studied population.

### Recommendation

The practice of pre-operative or post-operative vaginal cleansing with povidone-iodine should be adopted as a routine practice, especially in low resource environment to help reduce post-caesarean section infectious morbidity. There is need for further studies on this area such as use of vaginal cleansing in low-risk women without concurrent antibiotics.

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### Conflicts of interest

There are no conflicts of interest.

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