

RESEARCH ARTICLE

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The effect of preoperative vaginal preparation with povidone-iodine on post-caesarean section infection

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Submitted: 13th May 2024

Accepted: 2nd September 2024

Published: 31st December 2024

[ID](#): Orcid ID

Abstract

Objective: To evaluate the effect of preoperative vaginal antiseptic cleansing with Povidone-iodine on the occurrence of post-caesarean section infectious morbidity.

Methodology: A single-blind randomized controlled study of 180 women who had preoperative vaginal preparation with povidone-iodine before emergency CS at the University of Ilorin teaching hospital during the study period, The primary outcome measures were fever, endometritis and wound infection. Analysis was done using Chi-square tests, t-tests and logistic regression.

Results: The study result shows that the prevalence of post-caesarean section infection morbidity was 26.5%. There was a statistically significant difference in educational level attained and social class ($p < 0.001$) between both groups. The incidence of post-caesarean infection was significantly lower among the subjects compared to the controls (16.3% vs.36.6%, $p < 0.003$). Using univariate and multivariate binary logistic regression, PVP-I use and chorioamnionitis remain significant independent predictors of infectious morbidity. PVP-I is associated with lesser odds (OR; 0.307) while those with chorioamnionitis are eight times more likely to have a postoperative infection ($p < 0.006$).

Conclusion: The incidence of post-caesarean fever and endometritis was significantly reduced in those scrubbed with both abdominal and vaginal Povidone-iodine compared to those who had standard abdominal scrub alone for emergency caesarean section. Vaginal cleaning with Povidone-iodine is safe.

Keywords: Preoperative, Vaginal preparation, Povidone-iodine, Post caesarean Infection

Plain English Summary

The research was carried out at the Department of Obstetrics and Gynaecology, University of Ilorin Teaching Hospital and it involves cleaning the vaginal with an antiseptic solution known as povidone-iodine at least 10mins before the start of emergency caesarean section. The reason for the cleansing of the vaginal before surgery is to note whether the risk of infection following emergency caesarean section will be reduced when compared with the group without vaginal cleansing. A total of 180 women were recruited for the study and they were divided into two equal group's namely the vaginal cleaning group and no vaginal cleaning group. Eighteen of these women were lost to follow-up. The outcomes that were looked for in both groups were the presence of fever, infection of the lining of the womb and infection of the abdominal wound following the surgery. It was discovered that the risk of infectious complications following emergency caesarean section was 26.5%. Also found was that cleaning the vaginal with povidone-iodine reduces the risk of fever, infection of the lining of the womb and infection of the abdominal wound when compared with those with no vaginal washing however the difference in

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the risk between the two groups was only significant in those with fever and infection of the lining of the womb. Hence there is a need to encourage the use of cleaning the vaginal with povidone-iodine before emergency caesarean section alongside other standard measures in order to reduce post-operation infectious complications.

Background

Caesarean (CS) section is a commonly performed surgical procedure in obstetrics practice and it is one of the oldest operations in surgery. It is increasingly used for delivery; on account of foetal and maternal indication in elective or emergency cases. In the past 35 years, the rate of caesarean section has steadily increased from 5% to approximately 30% (1). Despite the advances in surgical techniques and broad-spectrum antibiotic use, infectious morbidity remains one of the frequent complications of CS and a major cause of fever, wound infection and endometritis (2). The risk of post-caesarean infectious morbidity is reported to be as high as 5–85% (3). Generally, infections are 5 to 20% more common after CS compared to vaginal delivery (4), while endometritis was reported in 6-27% of CS (5). Endometritis is about 10 times more common after CS compared with vaginal delivery and can lead to bacteraemia, peritonitis, intra-abdominal abscess collection and sepsis (6). A report described the occurrence of other complications including post-caesarean pyrexia in 5 to 24% and wound complications (including seroma, haematoma, infection and breakdown of surgical incision) in 2-9% (7). Despite the use of prophylactic broad-spectrum antibiotics, infectious morbidity persists in 15% of women who had abdominal delivery (8). These can result in significant pain and discomfort, delay in a return to normal function, prolonged hospital stays, reduced maternal-child bonding and loss of man-hours of caregivers.

The development of post-caesarean endometritis occurs as a result of bacteria gaining access to the uterine cavity. This probably occurs from repeated vaginal examinations in labour, prolonged duration of active labour, prolonged membrane rupture, and absence of antimicrobial prophylaxis.⁹ Other reported risk factors include nulliparity, adolescence, immune-compromised states, such as diabetes mellitus or human immunodeficiency virus infection, use of internal monitors in labour and the presence of intrapartum bacterial vaginosis (9, 10).

Post-caesarean endometritis occurs via ascending polymicrobial inoculation of cervicovaginal organisms into the uterus, with haematogenous spread through exposed edges of the incised myometrium. The organisms implicated in post-caesarean endometritis and wound infection include gram-negative bacilli, aerobic and anaerobic gram-positive cocci, and

anaerobic bacilli associated with bacterial vaginosis (8, 11, 12). These organisms also develop resistance after preoperative surgical antibiotic prophylaxis (10, 12, 13). Currently, it is standard care to give antibiotics to women having a caesarean delivery, but the occurrence of post-caesarean infections remains a problem (10).

Previous studies have evaluated whether vaginal cleansing before the caesarean section with an antiseptic solution can reduce the incidence of postoperative infection (4, 14, 15, 16, 17). The use of Povidone-iodine, Chlorhexidine, and vaginal metronidazole has been reported with varying results (4, 14, 15, 16, 17).

Vaginal preparation has been shown to decrease the quantitative load of vaginal microorganisms as well as to remove certain species of bacteria (3). Finding a complementary effective method such as improved surgical technique in addition to prophylactic antibiotics that has better efficacy against a wide range of bacteria is of great importance (8). In the University of Ilorin Teaching Hospital (UIITH), vaginal preparation with Povidone-iodine before the caesarean section is not routinely practised and there has not been any study done to determine the effect of preoperative vaginal preparation with Povidone-iodine on post-caesarean-infection. This study aims to evaluate the effect of preoperative vaginal Povidone-iodine preparation on postoperative infectious morbidity.

Methodology

Study Location

The study was carried out at the Department of Obstetrics and Gynaecology of the University of Ilorin Teaching Hospital (UIITH), Ilorin, Kwara State, Nigeria. The Obstetrics and Gynaecology department is housed in a two-storey building. On the ground floor is the Obstetric Emergency Ward which also doubles as the Gynaecological Emergency Ward. The first floor houses a 25-bed postnatal surgical ward for those who had Caesarean delivery. The ultrasound and foetal assessment unit, obstetric theatre, labour ward and neonatal intensive care unit are also on the first floor. The second floor houses the antenatal and postnatal medical wards; each of which contains 30 beds.

The Obstetric unit is run by four firms; each firm consists of Consultants, Resident doctors and House officers. The obstetric patients are seen on Mondays to Fridays. The booking clinic is on Monday while antenatal and postnatal clinics are

run concurrently from Tuesdays to Fridays by the different firms. Each Obstetric patient is seen by all cadres of medical doctors which include a consultant, a senior registrar, two junior registrars and an intern. Also, at least one midwife is assigned to each patient. The annual delivery ranges between 2000 and 2500 with CS accounting for 27 – 35% of all deliveries. Most of the CS done are emergencies (65%) while 35% are electives.

Study Population

The study population consisted of pregnant women for emergency caesarean delivery previously in labour at the University of Ilorin Teaching Hospital.

Inclusion Criteria

Pregnant women in labour scheduled for emergency caesarean section also consent to participate in the study.

Exclusion Criteria

Refusal of patients to participate in the study, those with active herpes infection, antepartum haemorrhage, fetal distress and reported allergy to iodine-containing solution. Women previously on antibiotics therapy for more than 24 hours before surgery irrespective of indication and those on steroid therapy were excluded.

Study Design

In a single-blind randomized controlled study; the researcher was blinded by not being in the operating room while the vaginal wash was carried out by the research assistant. Study subjects had preoperative vaginal cleansing with Povidone-iodine 10 minutes before surgery while the control group had no vaginal wash. Both groups had routine standard abdominal scrub as practiced in this centre which involves a centrifugal scrubbing motion of the operation field three times with a 10% Povidone-iodine-soaked gauze held with a sponge holding forceps and prophylactic antibiotics administered thereafter. The research assistants were registrars and house officers. The researcher carried out patient recruitment, vital sign monitoring, blood sample collection, side effects assessment as well as entry data on an information sheet. The research assistants assisted in instances when the researcher was not available. The primary surgeons were senior registrars.

Procedure

One hundred and eighty patients recruited were reviewed by the anaesthetist before surgery. All recruited patients had their haematocrit and urinalysis done and documented before surgery. Blood sample for blood grouping and cross-

match for appropriate units of blood was performed as per departmental protocol. Shaving of pubic hair was done at decision-making for surgery. The patient's vital signs were taken before surgery and documented.

At the operating theatre, patients were placed in the supine position. Two intravenous (IV) accesses using 16G cannulae were secured and preloaded using a litre of crystalloid for those intended for regional anaesthesia. Following induction of anaesthesia, all subjects received antibiotics prophylaxis for the procedure, intravenous Augmentin/Ceftriaxone with or without metronidazole depending on the indication (chorioamnionitis). The patients were then placed in the dorsal position and an indwelling two-way urethral catheter was passed and retained using an aseptic technique. The interventional group had vaginal cleansing done along with the usual abdominal scrub by the research assistant without the researcher knowing. Vaginal cleansing was done with three pieces of sterile gauze soaked in 10% Povidone in a sterilized bowl by a research assistant previously trained and each gauze was folded and grasped with a sterile sponge stick. The scrubs are done from the vaginal vault to the introitus with attention to the anterior, posterior and lateral vaginal walls as well as the fornices. Each sponge was rotated 360° in the vagina such that the entire process lasted about 30 seconds and was repeated thrice. After vaginal cleansing, routine cleaning and draping of the patient was performed. The interval between vaginal scrub and incision was at least 10 minutes. The control group receives the standard abdominal scrub with Povidone-iodine but no vaginal preparation. A centrifugal scrubbing motion with Povidone-iodine was done for the abdominal scrub.

An incision was made on the anterior abdominal wall using the Pfannenstiel or the midline infra-umbilical incision to gain access into the abdominal cavity. Following access into the abdominal cavity, a lower segment transverse incision was made on the uterus thereafter was widened and the foetus was delivered. Oxytocin was administered after delivery of the baby, followed by double clamping of the cord and cutting between the cord clamps with scissors. The placenta was delivered by cord traction without intrauterine cleaning after placenta delivery. The uterine incision was closed with vicryl 2 in a double layer. The anterior abdominal wall was closed in layers. The skin closure procedures were with absorbable number 2/0 vicryl subcuticular sutures or 2/0 nylon interrupted sutures. On completion of the surgery, a standard sterile gauze dressing is kept in place with plaster to ensure non-exposure of the gauze and underlying wound. The cadre of

surgeons were senior registrars in all cases and all participants received the routine postoperative care. Patients were followed up and examined after caesarean section while in the wards.

Postoperative vital signs were monitored closely; quarterly for an initial two hours, then half hourly for another two hours and hourly until stable, thereafter twice daily. Appropriate intravenous antibiotics were administered for 48 hours. Lochia discharge, uterine consistency, height, and peritonitis were assessed daily in all participants. Discontinuation of the Foley catheter and commencement of the graded diet was on the first day following surgery except otherwise stated like obstructed labour. Patient wounds were inspected on the third day post-operatively for signs of wound infection (erythema, swelling, discharge or tenderness) and the dressing was changed. In case of infection, complete blood count, appropriate sample (wound and lochia) microscopy culture, sensitivity, and the daily dressing were individualised. However, the diagnosis was purely clinical in this research. The participants were discharged on postpartum day five if there were no signs of complication or infection. Before discharge, participants had verbal and written instructions regarding signs of infection and scheduled follow-up appointments. Participants were also contacted weekly by the researchers up to six weeks from delivery via mobile phone, to assess symptoms of infectious morbidity. Participants were counselled to return to the hospital at the second and sixth weeks post-delivery to assess complications and signs of infection in addition to other postnatal care. Duration of admission in the hospital before discharge was recorded.

Sample Size

The Sample size was determined by using this formula (18).

$$N = \frac{2(Z\alpha + Z\beta)^2 \times P(1 - P)}{(P1 - P2)^2}$$

N is the Minimum sample size per group, $Z\alpha$ is the probability of making a type 1 error at 5% while $Z\beta$ is the probability of making a type 2 error using a power of 90%. P1 and P2 are the prevalence for the case and control group obtained from a previous study (19).

The sample size calculated for each group was 39.1. To make provision for attrition 10% of the sample size; 4 was added. The total sample size was 43 in each arm of the study, which approximated the total size was 45 in each arm. To allow for more representation of the study population, each arm sample size was doubled

to 90 in each and therefore a total of 180 participants were enrolled for the study.

Sampling Technique

It was a single-blind randomized controlled trial. Patient selection was based on consecutive sampling in which all eligible and consenting parturients admitted for emergency CS were randomly assigned into two groups, A and B by blind randomization using computer-generated random numbers (Random numbers generator version 3.4.0) prepared by an independent statistician. The plan of intervention was sealed in closed envelopes, and numbered per the randomization tables. The number randomly picked by the patient was used to pick the appropriate numbered envelope and then instruction of either vaginal wash or no wash is carried out appropriately. The investigator did not know whether a patient received a vaginal wash or not (single-blinding) because the vaginal wash was done before the investigator enters the operating room. The randomization coding tables were concealed from the investigator till the end of the study. A tag with 'A' or 'B' written on it was attached to the patient's folder for ease of identification of the folders by the researcher when the participants came for follow-up. The study group A consisting of 90 subjects received preoperative vaginal preparation with Povidone-iodine 10 minutes before surgery along with routine Povidone abdominal scrub; the other ninety only received routine anterior abdominal wall Povidone-iodine scrub without vaginal cleansing. This served as control group B.

Outcome Measures

The primary outcome measures were fever, endometritis and wound infection while secondary outcomes included readmission, use of therapeutic antibiotics, secondary wound closure, side effects of vaginal preparation with povidone-iodine (PVP-I) (rash, hives, itching, difficulty in breathing, tightness in chest, swelling of the mouth, tongue, lip and face).

Data Analysis

The data was analysed using Statistical Products and Service Solution software version 24.0 Chicago Illinois, USA. The data was presented in frequency tables and pie charts. Chi-square analysis and odds ratios with 95% confidence intervals were used to compare proportions and Student's t-test the difference in mean between continuous data. Probability (p) values less than 0.05 will be accepted as statistically significant.

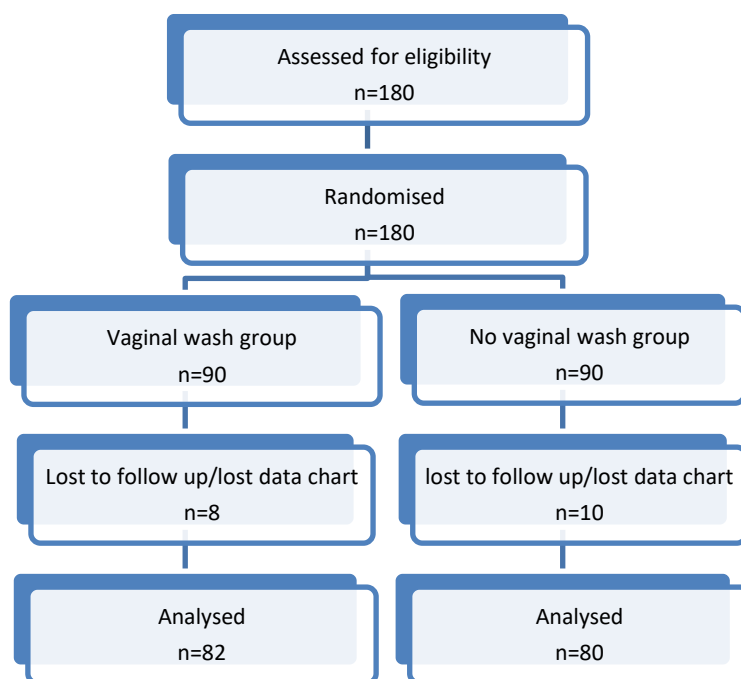


Figure 1: Study Consort flow diagram

Results

One hundred and eighty women for emergency caesarean section were enrolled during the study period. Of these, 18 were excluded: twelve were lost to follow-up and six due to lost data chart. The remaining 162 women with complete and available data were analysed and this consist of 82 women who received vaginal cleaning (experimental group) and the control group consisted of 80 women. The prevalence of post-caesarean section infection morbidity was 26.5%. There was no recognised side effect of Povidone-iodine in the study group.

Table 1 showed all consenting women were 17-42 years. The mean age of the case group was 30.80± 5.47 years while that of the control was 29.74± 5.36 years. There was no statistically significant difference in the age groups (p = 0.330). However, there was a statistically significant difference in educational level attained (P <0.001) and social class (p<0.001) between both groups. Most of the participants in the vaginal wash group had a parity of 2-4 with a mean parity of 1.61 ±1.33 while the mean parity for the no vaginal wash group was 1.29± 1.19 and mostly of parity 2-4 (p=0.108). This was not statistically significant. Other parameters with no statistical significance between both groups were gestation age and preterm delivery.

Socio-demographic characteristics

Table 1: Socio-demographic characteristics of study participants

Variable	Group		Total N (%)	χ ² /t	p-value
	Subject n = 80 (%)	Control n = 82 (%)			
Age (years)					
≤ 20	2 (2.5)	3 (3.7)	5 (3.1)	3.430 ^y	0.330
21 – 30	37 (46.3)	48 (58.5)	85 (52.5)		
31 – 40	41 (51.3)	29 (35.4)	70 (43.2)		
> 40	0 (0.0)	2 (2.4)	2 (1.2)		
Mean ± SD	30.80 ± 5.47	29.74 ± 5.36		1.241	0.217
Range	17 – 40	19 – 42			
Education					
Tertiary	33 (41.3)	74 (90.2)	107 (66.0)	49.369	<0.001*
Secondary	39 (48.8)	2 (2.4)	41 (25.3)		
Primary	8 (10.0)	6 (7.3)	14 (8.6)		
Upper	33 (41.3)	58 (70.7)	91 (56.2)	15.868	<0.001*
Middle	38 (47.5)	16 (19.5)	54 (33.3)		
Lower	9 (11.3)	8 (9.8)	17 (10.5)		
Parity					

0	20 (25.0)	27 (32.9)	47 (29.0)	1.247 ^Y	0.742
1	20 (25.0)	22 (26.8)	42 (25.9)		
2 – 4	37 (46.3)	32 (39.0)	69 (42.6)		
> 4	3 (3.8)	1 (1.2)	4 (2.5)		
Mean ± SD	1.61 ± 1.33	1.29 ± 1.19		1.615	0.108
Range	0 – 5	0 – 5			
Gestational age (weeks)					
< 37	15 (18.8)	15 (18.3)	30 (18.5)	1.145	0.564
37 – 39	56 (70.0)	53 (64.6)	109 (67.3)		
≥ 40	9 (11.3)	14 (17.1)	23 (14.2)		
Mean± SD	37.91± 1.82	38.17± 1.81	-0.916		0.361
Range	32-41	31-41			

χ²: Chi-square test, ^Y: Yates corrected, t: Independent samples T-test, *: p-value < 0.05 (statistically significant)

Comparison of Post caesarean infectious morbidity

Table 2 revealed the incidence of post-caesarean infection was significantly lower

among the vaginal wash group compared to the no-vaginal wash group (16.3% vs.36.6%, p-0.003).

Table 2: Comparison of incidence of Post CS infectious morbidity

Post-infectious morbidity	Subject n (%)	Control n (%)	Total N (%)	OR (95% CI)	χ ²	p-value
Yes	13 (16.3)	30 (36.6)	43 (26.5)	0.336 (0.160 – 0.708)	8.588	0.003*
No	67 (83.8)	52 (63.4)	119 (73.5)			
Total	80	82	162			

χ²: Chi square test; OR: Odds ratio; 95% CI: 95% Confidence Interval; *: p value <0.05

In Table 3, Postoperative fever was less common in the vaginal wash group compared to no vagina wash group (15% vs 31.7%; p-0.012), endometritis was less common in the vaginal wash group compared to the vaginal wash group

(3.8% vs 23.2%; p<0.001). The wound infection rate was 3.8% vs 9.8% (p-0.129) for the vaginal wash group and the no vaginal wash group respectively.

Table 3: Post caesarean infection morbidity

Variable	Group Subject n = 80 (%)	Control n = 82 (%)	Total N (%)	χ ²	p-value
Endometritis					
Yes	3 (3.8)	19 (23.2)	22 (13.6)	13.014	<0.001*
No	77 (96.3)	63 (76.8)	140 (86.4)		
Post-op fever					
Yes	12 (15.0)	26 (31.7)	38 (23.5)	6.295	0.012*
No	68 (85.0)	56 (68.3)	124 (76.5)		
Wound infection					
Yes	3 (3.8)	8 (9.8)	11 (6.8)	2.308	0.129
No	77 (96.3)	74 (90.2)	151 (93.2)		

χ²: Chi square test, *: p value < 0.05 (statistically significant)

Predictors of Post caesarean infectious Morbidity

Table 4 shows predictors of post-CS fever using univariate binary logistic regression. PVP-I, number of vaginal examinations and chorioamnionitis are the only variables that show significant association with Post CS febrile morbidity (p; 0.017, 0.017 and <0.001 respectively). Chorioamnionitis and an increased

number of vaginal examinations have significantly increased the odds ratio of fever while PVP-I has a smaller odds ratio of febrile morbidity (OR; 12.51 (3.187 – 49.163) and 1.274 (1.045 – 1.554) vs. 0.380 (0.176 – 0.821) respectively). BMI, diabetes mellitus and duration of surgery were not statistically significant with odds of 1.007, 1.649 and 1.018 respectively.

Table 4: Predictors of post-op fever (using Univariate binary logistic regression)

Variable	Univariate analysis			Multivariate analysis	
	B	p-value	OR (95% CI)	p-value	aOR(95% CI)
Povidone-iodine use	-0.967	0.014*	0.380 (0.176 – 0.821)	0.017*	0.364 (0.159 – 0.833)
Age	-0.024	0.492	0.977 (0.913 – 1.045)		NA
Education					NA
Tertiary ^{REF}					
Secondary	0.133	0.750	1.142 (0.503 – 2.594)		
Primary	-1.429	0.179	0.240 (0.030 – 1.921)		
Social class					NA
Upper ^{REF}					
Middle	-0.337	0.415	0.714 (0.318 – 1.605)		
Lower	-0.514	0.449	0.598 (0.158 – 2.265)		
BMI	0.007	0.853	1.007 (0.935 – 1.084)		NA
Ruptured membranes	0.907	0.243	2.477 (0.540 – 11.357)		NA
Chorioamnionitis	2.527	<0.001*	12.517(3.187 – 49.163)	<0.001*	13.438(3.276 – 55.119)
Diabetes mellitus	0.500	0.687	1.649 (0.145 – 18.698)		NA
Number of vaginal examinations	0.242	0.017*	1.274 (1.045 – 1.554)	0.626	1.857 (0.154 – 22.389)
Duration of surgery	0.018	0.062	1.018 (0.999 – 1.038)		NA

B: Coefficient of logistic regression, *: p-value <0.05 (statistically significant), OR (95% CI): Odds ratio at 95% confidence interval, aOR (95% CI): Adjusted Odds ratio at 95% confidence interval

Table 5 shows univariate binary logistic regression evaluating the predictors of endometritis. Povidone-iodine use was the only variable that showed a significant association with endometritis (p- 0.001*). Study participants with ruptured membrane, chorioamnionitis, low social class and diabetes mellitus had increased odds ratio as shown in the

table. However this was not found to be statistically significant (p- 0.912, 0.174, 0.906, 0.178 respectively). Age as well as the duration of surgery showed no statistical significance with an odds ratio of 1.043 and 1.004 respectively. A multivariate analysis was not done as all other variables did not show a significant association at the univariate level.

Table 5: Predictors of endometritis (using Univariate binary logistic regression)

Variable	Univariate analysis		
	B	p-value	OR (95% CI)
Povidone-iodine use	-2.231	0.001*	0.107 (0.029 - 0.401)
Age	0.042	0.406	1.043 (0.944 - 1.153)
Education			
Tertiary ^{REF}			
Secondary	-0.558	0.343	0.572 (0.180 – 1.816)
Primary	-0.898	0.402	0.407 (0.050 – 3.322)
Social class			
Upper ^{REF}			
Middle	-0.903	0.127	0.405 (0.127 – 1.292)
Lower	0.082	0.906	1.086 (0.277 – 4.249)
BMI	-0.025	0.666	0.975 (0.871 - 1.093)
Ruptured membranes (> 24hrs duration)	0.097	0.912	1.102 (0.198 - 6.134)
Chorioamnionitis	1.134	0.174	3.110 (0.606 - 15.960)
Diabetes mellitus	2.233	0.178	9.332 (0.363 - 239.940)
Number of vaginal examinations	-0.128	0.486	0.880 (0.615 - 1.260)
Duration of surgery	0.004	0.765	1.004 (0.976 - 1.033)

B: Coefficient of logistic regression, *: p-value <0.05 (statistically significant), OR (95% CI): Odds ratio at 95% confidence interval

Shown in Table 6 are the predictable variables for Post caesarean infectious morbidity using univariate and multivariate binary logistic regression. PVP-I use and chorioamnionitis remain significant independent predictors of

infectious morbidity. PVP-I is associated with lesser odds (OR; 0.307(0.160 – 0.708)) while those with chorioamnionitis are eight times more likely to have a postoperative infection (OR (95% CI): 10.235(2.623 - 39.935); p-0.006).

Table 6: Predictors of postoperative infectious morbidity (Univariate and multivariate binary logistic regression)

Variable	Univariate analysis			Multivariate analysis	
	B	p-value	OR (95% CI)	p-value	aOR (95% CI)
Povidone-iodine use	-1.090	0.004*	0.336 (0.160 – 0.708)	0.004*	0.307 (0.138 – 0.680)
Age	-0.043	0.197	0.958 (0.897 – 1.023)		NA
Education					
Tertiary ^{REF}					
Secondary	-0.014	0.973	0.986 (0.438 – 2.221)		NA
Primary	-0.310	0.652	0.734 (0.191 – 2.818)		NA
Social class					
Upper ^{REF}					
Middle	-0.336	0.402	0.714 (0.325 – 1.568)		NA
Lower	0.041	0.944	1.042 (0.334 – 3.251)		NA
BMI	-0.014	0.707	0.986 (0.919 – 1.059)		NA
Ruptured membranes	1.084	0.162	2.957 (0.647 – 13.506)		NA
Chorioamnionitis	2.326	0.001*	10.235(2.623 - 39.935)	0.006*	8.143 (1.849 – 35.866)
Diabetes mellitus	0.331	0.789	1.393 (0.123 – 15.761)		NA
Number of vaginal examinations	0.237	0.017*	1.267 (1.043 - 1.539)	0.265	1.135 (0.909 – 1.417)
Duration of surgery	0.016	0.090	1.016 (0.997 – 1.035)		NA

B: Coefficient of logistic regression, *: p-value <0.05 (statistically significant), OR (95% CI): Odds ratio at 95% confidence interval, aOR (95% CI): Adjusted Odds ratio at 95% confidence interval

Figure 2 shows indications for CS among study participants, the two commonest indications were cephalo-pelvic disproportion (36.3% vs. 30.5%) and breech presentation (19.5% vs. 18.8%).

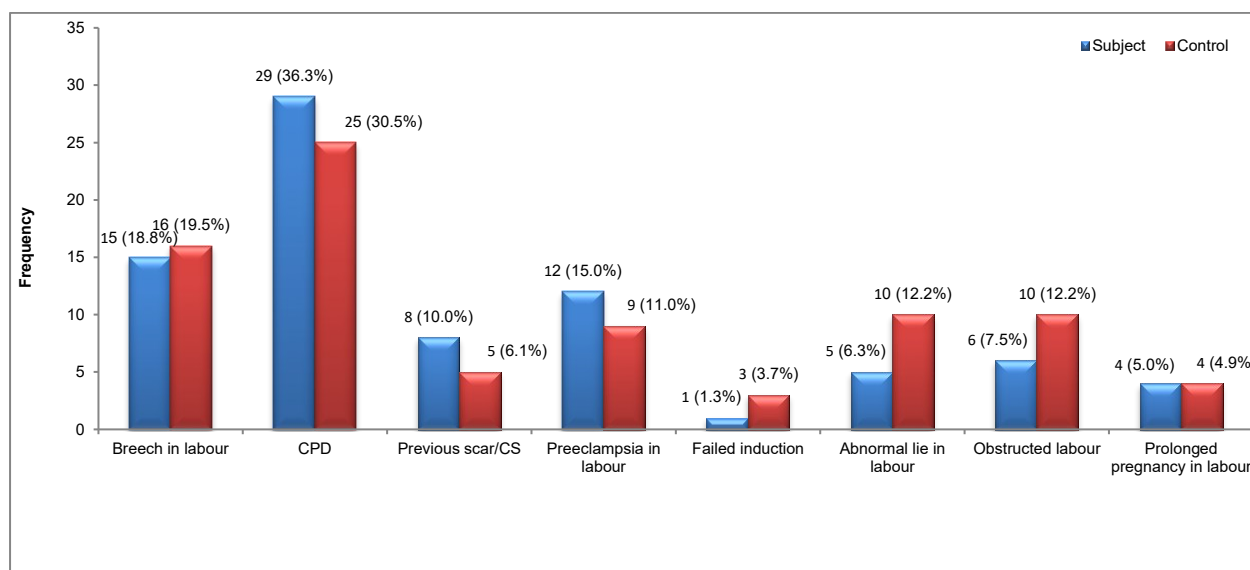


Figure 1: Indications for Caesarean Section

Discussion

Since more than a century earlier, the concepts of antiseptic and infection prevention have been evolving and have reduced the burden of infection morbidity. However, infection still ranks as the third most common cause of maternal mortality, especially in developing countries (20, 21).

The present study shows that the prevalence of post-caesarean section infection morbidity was 26.5%. There was a statistically significant difference in educational level attained and social

class (p<0.001) between both groups. The incidence of post-caesarean infection was significantly lower among the vaginal wash compared to the no-vaginal group (16.3% vs.36.6%, p=0.003). PVP-I use and chorioamnionitis remain significant independent predictors of infectious morbidity. PVP-I is associated with lesser odds (OR; 0.307) while those with chorioamnionitis are eight times more likely to have a postoperative infection (p=0.006). The incidence of post-caesarean fever and endometritis was significantly reduced in the

vaginal wash group compared to the no-vaginal wash group. None of the participants in both groups had a therapeutic course of antibiotics, or secondary wound closure nor were re-admitted due to post-surgery infectious morbidity. Vaginal cleansing with Povidone-iodine is safe.

Maternal age is a known risk factor for infection morbidity (22, 23). This is true in younger women, who had significantly fewer prenatal visits than older women and therefore less opportunity for diagnostic testing. However, in this index study, maternal age was not found to be a predictor of endometritis probably because of the low prevalence of the younger age group. Other studies reviewed found no significant difference in terms of age (16, 24, 25).

There is a significant difference in the educational status and social class between both groups however when these cofounders were analyzed using logistic regression, they were not significant. Olsen et al (22), determined that the risk of endometritis increased linearly with decreasing age however reason wasn't known despite the use of multivariate analysis attributing it to residual confounding that may exist because of undiagnosed STI or group B streptococcal vaginal colonization. It also found endometritis to be marginally associated with a proxy for low socioeconomic status, and lack of private health insurance (OR, 1.72 [CI, 0.99-3.00]). Magann et al (26) also found the highest infection rate in young indigent women. Ashgania et al (27), found no statistical significance between the vaginal wash and no wash groups concerning occupation and education, other reviewed studies did not consider the educational status and social class.

The incidence of post-caesarean infection morbidity was determined in the index study. The overall incidence was 26.5%, which was much more than the 9% reported by Haas et al (28). The lower incidence reported by Haas may be accounted for by the inability to reach the target sample size because of unexpectedly slow recruitment. It could also be due to more than half of the participants were not in labour at the time of CS because the risk of infection may be even greater in women undergoing CS after labour had begun, particularly for a more urgent indication. Having low composite prevalence in Haas study is quite biased considering that their study population was obese and at particular risk of infectious morbidity.

With preoperative vaginal cleaning with PVP-I, there is a significant reduction in the incidence of infectious morbidity, this was found to be comparable to Memmon et al. (24). Haas et al found the same outcome but was not significant, most likely due to subjects being low-risk groups.

Vaginal cleansing with Povidone iodine solution reduced the risk of post-caesarean fever from 31.7% to 15% in the present study, other studies reviewed did not find a significant reduction in febrile morbidity with PVP-I use (5, 24, 27,28). In this present study, other non-pelvic causes of fever such as malaria, mastitis, thrombophlebitis, drug fever etc. were not excluded. In other studies, reviewed, chorioamnionitis which is a risk factor for febrile morbidity was excluded.

Vaginal cleansing with Povidone iodine solution reduced the risk of endometritis from 23.2% in the control group to 3.8% in the intervention groups. This risk reduction was found to be statistically significant. This could be explained by Osborne and Wrights that a preoperative Povidone-iodine vaginal scrub decreased the total number of bacterial species in the vagina by at least 98% which would have ascended to cause endometritis (29). This was found to be consistent with other studies (14, 15, 24, 27, 30). However, Yavuz et al in Turkey (31), reported that there was no postpartum endometritis in either subjects or controls which may be related to their exclusion of early membrane rupture and chorioamnionitis in their study, which are risk factors for endometritis. Other studies did not find a reduction in the risk of endometritis with vaginal povidone (4, 25, 28). This finding may be a result of most subjects not being in labour, the exclusion of chorioamnionitis and elective surgeries accounted for their findings.

Wound infection was reported to be reduced with vaginal antisepsis but was not found to be statistically significant. This was in agreement with other studies (14, 15, 17, 19, 23). This may be related to the ability of PVP-I to decrease the load of microorganisms in the vagina that may ascend to the uterus and subsequently be inoculated into the surgical site thereby resulting in wound infection.

A logistic regression model that consisted of variables including age, education, social class, body mass index, duration of surgery, number of vaginal examinations, duration of membrane rupture, chorioamnionitis, and diabetes mellitus, shows that PVP-I use is protective of post-CS febrile morbidity (aOR;0.364,95%CI;0.159-0.833) and this may be attributed to its wide range of microbicidal activity. During the study, chorioamnionitis is significantly associated with post-operative febrile morbidity, as well as, an increasing number of vaginal examinations. Povidone-iodine had lesser odds (chance) of having endometritis (OR: 0.107; 95% CI: 0.029 – 0.401). This shows that PVP-I use was significantly protective against endometritis. This is in support of an earlier assertion made that PVP-I reduced the risk of endometritis. This is in congruence with a study by Ashgania et al (OR:

0.03, 95% CI: 0.008-0.7 [p<0.02]) (27). Overall, PVP-I use is associated with less chance of post-operative infectious morbidity (aOR:0.307, 95%CI:0.138-0.680), while those with chorioamnionitis are 8 times more likely to have post-operative infectious morbidity than those without chorioamnionitis.

The possible side effects of PVP-I include rash, hives, itching, facial swelling, tightness in the chest and difficulty in breathing. It is worthy of note that no subject had any of the mentioned side effects or adverse reactions. This is the same with a few studies reviewed that categorically stated no adverse reaction with the use of PVP-I for the vaginal cleansing group (24, 28).

Strengths and limitations of the study

The study has several strengths, including that it is a prospective randomised investigation; it is one of the few studies carried out to determine the effect of vaginal antiseptics on infectious morbidity following CS and the first at the study site. The study involved emergency rather than elective CS which involves a high-risk group, further demonstrating the actual/real-time findings in a clinical setting.

On the other hand, this study had some limitations. There was no particular attention made to keep the operative team and surgical procedure identical for all patients; in particular, the performance of the intervention by the same surgical team would have ensured the similarity of procedure for all patients, from abdominal access to peritoneal closure. A variation between surgical teams in surgery may explain any difference in postoperative results however this was not considered.

The diagnosis was clinical and not microbiological. Other preventive strategies: intravenous antibiotics, and abdominal preparation also decrease infection morbidity. Pre-operative diagnosis of ongoing infections was not excluded. The proportion of participants that had chorioamnionitis and ruptured membrane and their aggregations between both groups were not well elucidated.

Conclusion

This study demonstrates the benefit of preoperative vaginal preparation with Povidone-iodine before an emergency caesarean section. The incidence of post-caesarean fever and endometritis was significantly reduced in those scrubbed with both abdominal and vaginal Povidone-iodine compared to those who had standard abdominal scrub alone for emergency caesarean section.

Vaginal cleaning with Povidone-iodine is a safe, readily available, cheap and well-tolerated

adjunct to prophylactic antibiotics before caesarean section to reduce the bacterial exposure of endometrium and other maternal tissue.

While this study provides some information on this subject, large multicentre control trials are needed in this country to establish the use of Povidone iodine to reduce post-caesarean endometritis.

Vaginal antiseptics with Povidone-iodine should be considered for use preoperatively before emergency caesarean section, especially in high-risk groups like chorioamnionitis.

Declarations

Ethical approval and consent to participate

Approving Authority: Institutional approval was obtained from the Ethical Review Committee of the University of Ilorin Teaching Hospital before the commencement of the study. UITH ERC Protocol Number (ERC PIN/2017/01/0524) and Approval number (ERC PAN/2017/02/1540)

Voluntary Participation: Subjects' participation in this study was voluntary and they had the liberty to withdraw at any stage if they wished.

Confidentiality: All the data obtained from the study were made confidential and used solely for the study and any publication arising from it.

Beneficence: The study will contribute to general knowledge and society at large will benefit. The cost of all the investigations stated was borne by the researcher.

Non-maleficence: The procedure was generally safe with minimal discomfort to the patient. There is no additional risk due to participation.

Justice: All participants were treated with the same degree of respect and equity was ensured.

Dignity: Participants were treated with dignity. Unnecessary exposure of the participants was avoided and a female chaperon was present when necessary.

Consent for publication

All the authors gave consent for the publication of the work under the Creative Commons Attribution- Non-Commercial 4.0 license.

Availability of data and materials

The data and materials associated with this research will be made available by the corresponding author upon reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

The project was self-sponsored, in addition to the dissertation grant from the University of Ilorin

Teaching Hospital, Ilorin. There was no transfer of cost to the participants in the study.

Author contributions

AAE: Concept, Data collection and processing and drafting of manuscript
BTY: Literature review, Analysis and interpretation
DJK: Study design and materials
AMG: Literature review, and drafting of manuscript
SHA: Data collection
OAO: Supervision and critical review
FAA: Supervision and critical review

Acknowledgement

We need to acknowledge the contributions of all residents and interns in the department of Obstetrics and Gynaecology, UITH who helped in the recruitment processes and most especially the senior registrars who carried the surgical procedure. Also, to the management of UITH and Bowen University, Iwo who gave us the platform to carry out the research.

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