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Original Article

Postoperative Vaginal Cleansing with Chlorhexidine Gluconate Versus Povidone-Iodine for Prevention of Post-Caesarean Endometritis: A Randomized Controlled Trial.

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Abstract

Background: Maternal infectious morbidity is a common complication of caesarean section. Despite prophylactic antibiotics, endometritis following caesarean section is still a big challenge. Preoperative vaginal cleansing with povidone may not be feasible in emergencies necessitating its use postoperatively, and comparing its efficacy with cheaper and readily available solutions. The aim is to compare the effectiveness of post-operative vaginal cleansing with povidone-iodine(PI) versus chlorhexidine gluconate (CHG) in reducing post-caesarean endometritis.
Methodology: This was a single-blinded randomized controlled trial. One hundred and twenty participants had post-operative vaginal cleansing with Povidone-iodine and one hundred and nineteen with Chlorhexidine gluconate, with attrition of 2 and 3 participants from the PI and CHG groups, respectively. Both groups received prophylactic antibiotics. They were reviewed for endometritis daily till discharge or up to 7 days. Data was analysed with SPSS.
Result: The study showed that post-caesarean vaginal cleansing with either agent did not detect any case of endometritis. Although the duration of ruptured membranes prior to surgery was statistically significant, with a mean of 19.26±44.4, 8.7±10.9 for PI and CHG, respectively, p-0.038; RR-0.627-21.561. Post-operative fever was recorded in the PI group (0.02%) but was not statistically significant. p=2.773; RR=1.667; 95%CI (0.624-3.957). No adverse effect was reported with either agent, Anaphlactic reaction=0, and local irritation was 1.67% with P=0.498
Conclusion: Post-operative vaginal cleansing with CHG was not superior to PI in preventing the occurrence of post-Caesarean endometritis. Although CHG had a better side effect profile when compared with PI, the findings were not statistically significant. CHG may be recommended for use following result from multicentre studies.

Keywords: Post Operative, Vaginal Cleansing, Povidone Iodine, Chlohexidine Gluconate

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Introduction

Caesarean section is one of the major surgeries performed by obstetricians.[1] The World Health Organization reported an increase of 10 to 15% increase beyond the required threshold for caesarean section.[2] Although caesarean section is a life-saving procedure, it could be associated with infection after the procedure.[1]

A systematic review for preoperative vaginal cleansing with povidone iodine and chlorhexidine solution showed a low incidence of endometritis.[3] They concluded that vaginal cleansing before cesarean section, particularly with povidone solutions, reduces the incidence of postoperative endometritis.[3]

Although studies have shown successful reduction in postpartum endometritis following preoperative vaginal cleansing with both povidone iodine and chlorhexidine solution,[4] preoperative vaginal cleansing may not be feasible in emergencies, especially in cases of vaginal bleeding where the blood can wash off the cleansing agent or may stall the procedure, necessitating the need for post-caesarean vaginal cleansing with antiseptic solutions.

Widely used antiseptic solutions for vaginal cleansing are Povidone iodine and chlorhexidine solution. They are cheap and easily accessible,[5] however, most studies have not shown the effectiveness of post-caesarean vaginal cleansing with these antiseptic solutions in the prevention of postpartum endometritis.

The objectives of this study are to compare post-caesarean vaginal cleansing with PI and CHG in the prevention of postpartum endometritis and to compare the side effect profile between both groups.

Materials and Methods

Study Design

This was a single-blinded superiority randomized controlled trial on the effectiveness of chlorhexidine gluconate and povidone iodine in reducing the rate of post-caesarean endometritis. The intervention model was by parallel assignment, whereby the participants were allocated to receive either chlorhexidine gluconate or povidone iodine solution but did not knowwhich group they were assigned to.

Study Location

The study was done at the Alex Ekwueme Federal University Teaching Hospital, Abakaliki (AE-FUTHA) and St. Patrick's Mile 4 Hospital, Abakaliki, Ebonyi State. Ebonyi state is one of the 5 southeastern states. It was created in 1996 and is inhabited predominantly by the Igbo ethnic group, with Abakaliki as its state capital. The state has a population of about 3 million people and occupies a land mass of 5932 square miles. Literacy level is low while poverty is prevalent among this population. Alex Ekwueme Federal University Teaching Hospital, Abakaliki (AE-FUTHA) was established in December 2011 following the merger between the Federal Medical Centre, Abakaliki, and the defunct Ebonyi State University Teaching Hospital, Abakaliki. It receives referrals from all parts of the state and neighboring states. The hospital runs a busy obstetric unit. Preliminary data showed that the hospital has an average of 1,953 deliveries, and the caesarean section rate was 36.82%. Of the 719 caesarean sections in 2018, 517 of them were emergency caesarean sections.
St. Patrick's Mile 4 Hospital, Abakaliki, was established in 1948. It is a missionary hospital managed by reverend sisters. It is one of the hospitals in which residents from the AE-FUTHA pass through for their labour ward posting and/or rural posting in Obstetrics and Gynecology. It had 3636 deliveries in 2018. The caesarean section rate was 19.0%, while 79.3% of the total caesarean sections were emergencies (i.e., 547 emergency caesarean sections out of 690 caesarean sections).

Study Population
Participants for this study were drawn from the population of women admitted for emergency caesarean sections at AEFUTHA and St. Patrick's Mile 4 Hospital, who met the inclusion criteria.

Inclusion Criteria
This included all pregnant women at ≥ 28 weeks gestational age undergoing emergency caesarean section, eligible women for emergency caesarean sections, and women who consented to participate in the study.

Exclusion Criteria
This included women for elective caesarean section, known allergy to povidone iodine or chlorhexidine gluconate, participants with Diabetes mellitus/ glucose intolerance, asymptomatic placenta praevia undergoing elective caesarean section, Patients who have chorioamnionitis, immunosuppressive conditions like AIDS, steroid use, and patients who have coexisting uterine fibroids.

Sample Size Determination
The minimum sample size (N) was determined using the formula for calculating a randomized controlled trial (i.e., clinical superiority trial) when the endpoint is categorical data.[6]

$$N = \frac{2 \times (Z_{1-\alpha} + Z_{1-\beta})^2 \, XPX(1-P)}{(d - \delta_0)}$$

$Z_{1-\alpha}$: Standard normal deviate at 5% type 1 error= 1.645, $Z_{1-\beta}$: standard normal deviate at 80% power = 0.845, d = difference between the two treatment effect =0.260[7], δ_0 :the clinically acceptable margin = 0.1, p= the expected incidence of post caesarean endometritis=0.357. [7] This gave a sample size of 111, but with an attrition rate of 10%, the total sample size became 122 for each group. That is the overall sample size of 244 for both groups.

Study Duration
The duration of the study was for 3 and a half months, from 1st June 2020 to 14th September 2020.

Randomization and Allocation Concealment
Using this software research randomizer, one hundred and twenty-two numbers were randomly generated from a pool of two hundred and forty-four numbers (1-244) and assigned to groups 1 and 2. Groups 1 and 2 received postoperative vaginal cleansing with 5% Povidone-iodine and 0.5% chlorhexidine gluconate, respectively, in addition to the routine prophylactic antibiotics and abdominal scrub. Allocation/concealment was done by a pharmacist using sequentially numbered opaque sealed envelopes. The numbers (1-244) were inscribed on the envelopes, and the inscription, "povidone or chlorhexidine", was on a piece of paper put into it and sealed. The agents administered based on the content of the sequentially numbered envelope that was kept in a locker accessible to all researchers. All eligible women received adequate information and education about the trial, but were not informed about the arm of the study to which they were assigned. An informed consent form was signed by those who met the eligibility criteria and consented to the study. Those enrolled were given a sequential study number, and the corresponding numbered opaque sealed envelope was then allocated to the patient.

Study Procedure
Women who met the inclusion criteria and consented to caesarean section in AEFUTHA and St Patrick's Mile 4 Hospital had the indication for the surgery confirmed. History and physical examination were

conducted on all patients. The patients were reviewed by the anesthetists. Those who met the inclusion criteria were counseled on the details of the study. Those who gave informed consent to participate in the study by signing the consent form were enrolled. All participants, irrespective of the group they belonged to, received prophylactic antibiotics (intravenous ceftriaxone 1 gram statim and intravenous metronidazole 500mg statim) at induction of anaesthesia. The routine anterior abdominal wall cleaning with chlorhexidine and methylated spirit was done after anaesthesia. All caesarean sections were lower segment caesarean sections and were performed by senior obstetricians. Placentas were delivered by cord traction and inspected for completeness. The endometrium was not cleaned. All uterine repairs were with Vicryl 2 sutures. Anterior abdominal wall repair was with Vicryl 2 for rectus sheath, Vicryl 2/0 for subcutaneous tissue, while 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 1g daily for 48 hours, intravenous metronidazole 500mg 8 hourly for 48 hours, and thereafter received oral cefpodoxime 200mg 12 hourly for 5 days and oral metronidazole 400mg 8 hourly for 5 days. When the surgery was completed and the wound dressing applied, the intervention was done. In the control group, vaginal cleansing was done with 3 pieces of gauze on a sponge holding forceps soaked in 30ml of 5% povidone-iodine for each patient. The soaked gauze was inserted into the vagina, rotated 360 ° for 30 seconds[8] from the upper to the lower vaginal wall. In the treatment group, vaginal cleansing was done with 3 pieces of gauze on a sponge holding forceps soaked in 30ml of 0.5% plain chlorhexidine gluconate for each patient. The soaked gauze was inserted into the vagina, rotated 360 ° for 30 seconds from the upper to the lower vaginal wall. This was done when clots had been evacuated from the vagina with dry gauze on a sponge holding forceps according to departmental protocol. This was done after clots had been evacuated from the vagina with dry gauze on a sponge holding forceps according to departmental protocol. Subsequently, information including demographic data, booking status, obstetric history (parity, gestational age), medical history, cervical dilatation, duration of rupture of membranes, duration of labour, duration of surgical time, and duration of hospital stay were noted and filled on the proforma. All participants were evaluated from day 1 post-surgery till discharge for fever, endometritis (clinically), and side effects of the agents used. Clinical features of endometritis include fever of 38 °C or more starting from Day 1 post caesarean section, abnormal uterine pain/ tenderness, uterine sub-involution, and foul-smelling vaginal discharge, were looked for. The presence of two or more of the features was considered suggestive of endometritis. Information about side effects, such as vaginal irritation and allergy, was obtained. Patients with features suggestive of endometritis or major side effects were reviewed by a consultant obstetrician (as a second opinion) and appropriate treatment administered. Participants who developed fever without other features of endometritis within the period of admission had a blood film for malaria parasite done to exclude malaria and urinalysis done to exclude urinary tract infections as causes of fever. Systemic examinations based on the participant's complaint to rule out other causes of fever were also done. Required information was entered into the data collection sheet, which was kept safe to be used for analysis.

Outcome Measures

Primary outcome

The primary outcome measure was post-caesarean endometritis

Secondary outcomes

The secondary outcome measures were the occurrence of; Post-operative fever, duration of hospital stay, and side effects of the two antiseptic agents.

Data Analysis

Data were collated, tabulated, and then statistically analyzed using the Statistical Package for Social Science (IBM SPSS) software (version 24, Chicago II, USA). Continuous variables were presented as mean and standard deviation (Mean ± 2SD), while categorical variables were presented as numbers, frequencies, and percentages.

Student t test was used for comparison between groups for continuous variables. Chi-square test was used for comparison between groups for categorical variables. Relative risk and 95% confidence interval were calculated for outcome measures. A difference with a P-value <0.05 was considered statistically significant.

Ethical Approval

The ethical approval for the study was obtained from the Health Research Ethics Committee of Alex Ekwueme Federal University Teaching Hospital, Abakaliki, Ebonyi State, Nigeria, with ethical approval number: AEFUTHA/REC/VOL2/2019/294, with clinical trial number: NCT06936475.

Quality Control

This was done by ensuring that all the antibiotics and antiseptics to be used for this study were procured from a reputable pharmaceutical company. The batch number, date of manufacture, and NAFDAC registration number were noted and had not expired. All the antiseptics had the same strength. All Povidone-iodine used was 5% Povidone-iodine (WOSSAN, by JAWA) and was properly stored. The chlorhexidine gluconate was 0.5% obtained by dilution of 5% solution solely prepared by a reputable pharmacist at AEFUTHA and properly stored. All the agents were NAFDAC certified.

Result

We assessed 301 patients for eligibility during the study period. Out of this, 244 participants were randomized, fifty (50) patients did not meet the inclusion criteria, and 7 declined consent. Out of the two hundred and forty four (244) randomized patients, 122 patients were allotted into each group; 2 participants were lost to follow-up in the Povidone-iodine arm, while three participants were lost to follow-up in the Chlorhexidine gluconate arm and were removed from the study. One hundred and twenty (120) participants were analyzed in the control group (povidone iodine), while 119 participants were analyzed in the study group, as summarized in the chart below. Analysis was done by per protocol method.

Consort Diagram

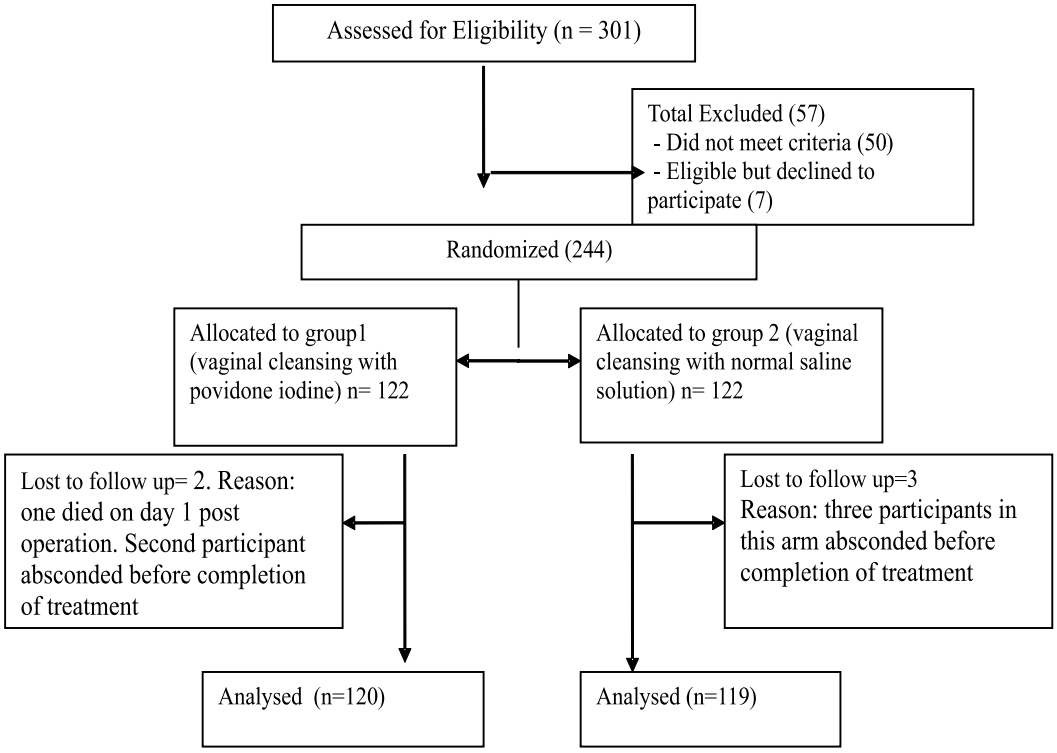

Table 1: Comparison of socio-demographic characteristics between the two groups.

Variables	Povidone iodine group n=120 (%)	Chlorhexidine Gluconate group n=119	χ2/Exact	P-value
Age(mean)	30.03±5.26	29.91±4.74		
15-19	2 (1.7)	0 (0)		
20-24	14 (11.7)	14(11.8)		
25-29	42 (35.0)	47(39.2)	3.664*	0.622
30-34	35 (29.2)	35 (29.4)		
35-39	26 (21.7)	20(16.8)		
40-44	1 (0.8)	3(2.5)		
Parity				
0	40 (33.3)	46(38.7)		
1-4	58 (48.3)	62(51.7)	4.214	0.122
≥5	22(18.3)	11(9.2)		
Marital status				
Single	3 (2.5)	3(2.52)	0.000*	1.000
Married	117 (97.5)	116(97.48)		
Educational level				
No formal	3(2.5)	4(3.36)	0.305*	0.984
Primary	11(9.2)	11(9.24)		
Secondary	64(53.3)	61(51.3)		
Tertiary	42(35)	43(36.1)		

*Fisher's Exact

Table 1 shows the socio-demographic characteristics of the participants. There were no statistically significant differences in the participants' age, parity, marital status, and educational qualification (p value = > 0.05).

Table 2. Comparison of baseline obstetric parameters/risk for infection between the two groups

Parameters	PI n=120	CHG group. N=119	T-test/$\chi 2$	p-value	(95% CI)
Gestational Age (weeks).					
Mean± SD	38.49± 2.55	38.62± 2.34	-0.419	0.675	-0.756-0.491
Parity.					
Mean ± SD	2.19 ± 2.20	1.78± 1.93	1.535	0.126	--0.116-0.937
Duration of membrane rupture (hours). Mean ± SD	N=69 19.26± 44.4	N=75 8.17±10.9	2.095	0.038	0.627-21.561
Duration of surgery (minutes). Mean ± SD	N=118 76.8 ± 19.06	N=117 77.7 ± 22.89	-0.317	0.752	-6.281-4.541
Booked Status					
Booked	102(85)	97(81.5)	0.301*	0.583	
Unbooked	18(15)	22(18.5)			
Membrane rupture at the time of presentation					
Yes	69(57.5)	75(63)	0.548*	0.459	
No	51(42.5)	44(37)			
Timing of antibiotics					
Preoperative	110(91.7)	111(93.3)	0.051*	0.821	
Intra operative	10(8.3)	7(5.9)	0.236*	0.627	
Postoperative	120	119	-	-	

* Fisher's exact test

Table 2 shows a comparison of baseline obstetric parameters/risks for infection during caesarean section between the two groups. There was no statistically significant difference between the study and control groups on the mean gestational age, mean parity, booking status, status of membrane at presentation, mean duration of membrane rupture before emergency caesarean section, the mean duration of caesarean section, timing of antibiotics use, and cadre of surgeon ($p > 0.05$).

Table 3. Comparison of indications for caesarean section between the two groups

Parameters	PI N=120 (%)	CHG N=119(%)	χ2/Exact	p-value
Cord Prolapse	4(3.3)	7(5.9)	0.399*	0.375
Obstructed labour	14(11.7)	9(7.6)	0.733	0.392
Failed VBAC	10(8.3)	10(8.4)	0.000	1.000
Eclampsia	5(4.2)	3(2.5)	0.121*	0.722
Suspected fetal distress	15(12.5)	20(16.8)	0.576	0.448
≥2Previous CS in labour	17(14.2)	10(8.4)	1.447	0.229
Symptomatic Placenta Previa	7(5.8)	6(5.0)	0.000	1.000
Severe preeclampsia	12(10)	18(15.1)	1.001	0.317
Retained 2nd twins	1(0.8)	1(0.8)	0.000*	1.000
PPROM	5(4.2)	2(1.7)	0.572*	0.446
Poor BPP	3(2.5)	4(3.4)	0.000	0.722
Transverse lie in labour	1(0.8)	3(2.5)	0.263*	0.370
Previous CS/multiple gestation in labour	2(1.7)	1(0.8)	0.000*	1.000
Failed IOL/SOL	5(4.2)	5(4.2)	0.000	1.000
Abruptio placenta	6(5)	9(7.6)	0.303	0.582
CPD	21(17.5)	22(18.5)	0.001	0.976
Breech in labour	12(10)	10(8.4)	0.041	0.839

*Fishers exact

Table 3 shows the indications for emergency caesarean section between the two groups. There was no statistically significant difference in the indications for emergency caesarean section between the two groups (p>0.05).

Table 4: Comparison of incidence of outcome measures between the two groups.

Parameters	PI N=120(%)	CHG N=119(%)	T test χ2/Exact	P-value	RR(95% CI)
Postpartum fever	2(0.02)	0(0)	2.773*	0.498	1.667(0.624-3.957)
Uterine subinvolution	6(5)	7(5.9)	0.091***	0.988	1.188(0.387-3.644)
Abnormally tender uterus	1(0.8)	0(0)	0.000*	1.000	0.500(0.440-0.568)
Foul-smelling discharge	0(0)	1(0.84)	1.013*	0.498	0.496(0.436-0.564)
Duration of hospital stay (days). Mean±SD	5.58 ± 5.40	4.87 ± 1.72	1.381**	0.168	-0.306-1.742

*Fishers exact, **T test, ***Chi square

Table 4 shows the comparison of participants for the incidence of the outcome measures. Post-operative vaginal cleansing as an adjunct with either 0.5% chlorhexidine gluconate solution or 5% povidone iodine showed that post-operative fever was recorded in two participants of the control group, but there was no statistically significant difference between groups. There was no statistically significant difference in the mean duration of hospital stay between groups.

Table 5. Comparison of side effects between the two groups.

Parameters	PI N=120(%)	CHG N=119(%)	χ2/Exact	P-value	RR(CI)
Anaphylactic reaction	0	0	-	-	
Local irritation	2(1.67)	0	2.773	0.498	0.498(0.438-0.566)

No significant side effect was noted in the participants following the application of either antiseptic.

Discussion

This study showed that the majority of the participants in both control and study groups were between the ages of 25 and 29 years, booked, multiparous, married, and had a secondary level of education. There was no statistically significant difference in the socio-demographic characteristics between the two groups. This is similar to the findings reported at the University Coventry Hospital, UK, and Kenyatta National Hospital, Nairobi, though these studies did not compare povidone iodine with any other antiseptic agent.[7, 9]

Fifty seven percent of the patients in the control arm had membrane rupture, while 63% of the chlorhexidine arm had membrane rupture (p =0.459). All the participants in both arms received postoperative antibiotics. Eight point three percent and 5.9% in the control and study arm, respectively, who missed preoperative antibiotics got intraoperative antibiotics (p=0.627). These differences were not statistically significant,

likewise other risk factors like indication for the emergency caesarean section and the duration of membrane rupture. Mwangi et al and Ugadu et al in their RCT study compared pre-operative vaginal cleansing with povidone iodine to post-operative vaginal cleansing with the same agent. He found no statistically significant difference in terms of risk factors in the postoperative arm with povidone iodine.[9,10]

None of the participants in either group had post-Caesarean endometritis, giving an incidence of 0% for both groups (p =1; RR =1). The complete prevention of endometritis noted in this study could be a result of the short duration of follow-up of participants up to hospital discharge, of about 7 days. This is in contrast to the findings by La Verde et al [3] and Lakhi et al [11] that found that Povidone iodine was more effective in the prevention of postpartum endometritis and that 4% chlorhexidine showed a higher significance in the reduction of wound infection.

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Only 2 participants in the control arm (Povidone iodine) had post-operative fever, which lasted for about 24 hours, as against none in the Chlorhexidine gluconate arm. However, there was no statistically significant difference between the two groups in the number of participants with post-operative fever [p = >0.05; RR= 1.667, 95%CI (0.624-3.957)]. This finding suggests a low rate of postoperative fever following post-Caesarean cleansing with povidone iodine or chlorhexidine gluconate. Birchenall and Mwangi also noted a reduction in postoperative fever. [7,9]

Local vaginal irritation was reported with povidone iodine in 1.67% of participants, p=0.498. This is in contrast with the findings by Birchenall and Mwangi, who noted no adverse effect with 5% povidone iodine, but in consonance with the findings of Lakhi et al.[11]

Mean duration of hospital stay in the PI and CHG was 5.58 ±5.40 days and 4.87±1.72 days, respectively (p=0.168, CI= -0.306-1.742). There was no significant difference in the duration of hospital stay between the PI group and the chlorhexidine group. Participants were discharged between the 4th and 5th postoperative days. Birchenall and Mwangi et al also noted a reduction in hospital stay.[7,9] The early hospital discharge resulting from post-caesarean vaginal cleansing with either 5% povidone iodine or 0.5% plain chlorhexidine gluconate could encourage acceptance of orthodox care in subsequent pregnancies.

Conclusion

No cases of endometritis were detected in either group within 7 days postpartum. Due to the low event rate and small sample size, the study lacks power to compare efficacy. Larger multicentre trials are needed.

Limitations

Post-caesarean endometritis involves genital tract infection up to the 42nd day postpartum. These patients were followed up until hospital discharge, so the diagnosis may be missed in some patients after discharge.

Acknowledgements

None.

Declaration of Patient's Consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their clinical information to be reported in the journal. The patient(s) understand that their names and initials will not be published and due efforts will be made to conceal their identity.

Declaration of Helsinki
The study was conducted in accordance with the ethical principles of the Helsinki Declaration.

Financial Support and Sponsorship
Nil.

Conflicts of Interest
There are no conflicts of interest.

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