Original Research Article

Vaginal cleansing with povidone–iodine at cesarean section to reduce postpartum endometritis: A randomized controlled trial

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Abstract

Objective: To compare the incidence of post-caesarean endometritis in vaginal cleansing with povidone – iodine group versus control group.
Methods: The present study was a prospective randomized controlled trial in which study subjects received a vaginal cleansing with povidone – iodine solution immediately prior to caesarean delivery while controls received no vaginal preparation. The primary outcome measured in the present study was incidence of postpartum endometritis. Secondary outcomes included wound infection, febrile illness and duration of hospital stay.**Results:** There was no significant difference in post-caesarean endometritis in the group that received the povidone–iodine vaginal preparation (n = 75) compared with the control group (n = 75) [1.3 vs. 6.6%; RR = 0.2; 95% CI = 0.02–1.67]. There were also no statistically significant differences in the incidence of febrile illness and wound infection between the experimental and control groups. However, subgroup analysis showed significant decrease in the incidence of postpartum endometritis in the group that received the povidone–iodine vaginal preparation (n = 20) compared with the control group (n = 13) [5% vs. 38.4%; RR = 0.13; 95% CI = 0.01–0.99]. **Conclusion:** Vaginal cleansing with povidone–iodine solution immediately prior to a caesarean delivery does not reduce the risk of post-operative endometritis. However, beneficial effect of reduction in the incidence of endometritis was seen in women who had premature rupture of membranes.

Keywords: Caesarean section, randomized controlled trial

Introduction

Caesarean section is the commonly performed obstetric surgery. The caesarean section rates are increasing worldwide[1].However, there are increased chances of infection to the women who give birth by caesarean section. There are both endogenous as well as exogenous sources of infection. Common infection related complications seen with caesarean section are surgical site infections (SSIs) and endometritis. Due to these complications after caesarean section, there is increased duration of hospital stay and more financial burden on the patients. There have been several interventions to prevent post operative infections like modification of operative techniques, duration of cervical dilatation during delivery, and vaginal cleansing. Still, prolonged rupture of membranes is a significant risk factor for post caesarean endometritis[2,3].Vaginal preparation includes the cleansing of the vaginal epithelium with an antiseptic solution to reduce the bacterial load which thereby reduces the ascending genital tract infection. There are different types of antiseptics that are designed for topical application: iodine or iodophors, alcohol, chlorhexidine gluconate, hexachlorophene, parachlorometaxylenol, and triclosan.

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A literature review indicates both positive as well as no effects of povidone –iodine on the incidence of endometritis[4-7]. A Cochrane review in 2018 concluded that there was insufficient evidence available from the included RCTs to fully evaluate different agents and methods of skin preparation for preventing infection following caesarean section [8]. Therefore, it is not yet clear what sort of skin preparation would be most effective for preventing post-caesarean surgical site infection, or for reducing other fetal and maternal adverse outcomes. The main objective of the present study was to compare the incidence of post-caesarean endometritis in vaginal cleansing with povidone – iodine group versus control group.

Materials and methods

The present study was conducted from January to December2020 at the Tertiary care Hospital at Udaipur, Rajasthan. The institute ethics committee approval was obtained prior to study commencement. All pregnant women age more than 18 years, gestational age greater than 34 weeks and caesarean delivery (elective or emergency) were eligible for the study. Exclusion criteria for the study were placenta previa, a known suspected or proven chorioamnionitis and allergy to povidone–iodine. A written informed consent was taken from participants before enrolment. After enrolment, randomization was performed by members of the research team of the project. Participants were placed into either the povidone–iodine vaginal preparation group or the control group through a computer-generated randomization process. Sealed envelopes containing random numbers were opened upon study enrolment of the patient, and the participant was placed into a group according to the number. The patients enrolled in control group received abdominal skin

preparation with povidone–iodine solution prior to section. While, women in the experimental group received a similar abdominal preparation along with a 30-second vaginal cleaning with povidone–iodine solution before urinary catheter insertion.All participants received a single antibiotic dose just before the skin incision given at the time of the caesarean section. Both groups were provided same postpartum care. Signs of wound infection (erythema, swelling, discharge, or tenderness), vaginal discharge, uterine consistency and height, and peritonitis were assessed daily in all participants. Urinalysis and complete blood count was performed post operatively in all the study participants. The participants were discharged on postpartum day 3 if there were no signs of complication or infection. Prior to discharge, participants were instructed regarding signs of infection and scheduled follow-up. Participants returned to the Hospital at 2 and 4weeks post-delivery to assess signs of infection. The primary outcome measured in the present study was incidence of postpartum endometritis. Secondary outcomes included wound infection, febrile illness and duration of hospital stayBlinding could not be done because of the nature of the intervention. The study statistician was unaware of the patients' treatment assignments while performing the final analyses.The sample size of 75 per group including 10% attrition rate (total 150) was required to achieve 80% power to detect 15% absolute risk reduction in post-operative infections using a 2-sided z-test with 0.05 significance level. Data was entered in a Microsoft Excel 2010 spreadsheet and then validated. Intention to treat analysis was done. Normality of data was checked with Kolmogorov - Smirnov Z test. Data was summarized as mean with standard deviations (± SD) or median with interquartile ranges (IQR), or proportions. Continuous data was compared by Student's t-test (if normally distributed) or Mann-Whitney U test(if non-normally distributed). Binary outcome was analysed with use of the chi-square test (Fisher's exact test if cell frequencies were small). IBM PASW statistics (SPSS)-version 19.0 software (SPSS Inc. Chicago, Illinois) and Epi Info ™ 7 (7.0.9.7, CDC) were used for data analysis.

Results

The present study included 150 participants. The experimental group which received vaginal cleaning prior to surgery consisted of 75 women, and the control group consisted of 75 women. Study flow is presented in figure 1.Baseline characteristics were similar in both the groups. There were no significant differences between groups based on whether labour began prior to caesarean section or not. The groups were also similar regarding the number of per vaginal examinations, duration of labour after admission, duration of premature rupture of membranes, and amniotic fluid appearance. There were no complications noted with povidone–iodine vaginal wash.Participants had a mean age of 28 years, 21% of women were in labour at the time of randomization, 22% had rupture of membranes, 92% had a singleton pregnancy, and 80% of women had had a previous CS. Table 1 provides the details of participant baseline characteristics. Of 235 women screened, 150 (64%) were eligible. Of these, 75 women were enrolled in vaginal cleansing group and 75 women were enrolled in control group after randomization.There was no significant difference in post-caesarean endometritis in the group that received the povidone–iodine vaginal preparation (n = 75) compared with the control group (n = 75) [1.3 vs. 6.6%; RR = 0.2; 95% CI = 0.02–1.67]. There were also no statistically significant differences in the incidence of febrile illness and wound infection between the experimental and control groups (Table 2). However, subgroup analysis showed a significant decrease in the incidence of postpartum endometritis in the group that received the povidone–iodine vaginal preparation (n = 20) compared with the control group (n = 13) [5% vs. 38.4%; RR = 0.13; 95% CI = 0.01–0.99]. (Table 3)

Table 1: Baseline characteristics

Parameters	Vaginal cleansing (n=75)	No vaginal cleansing (n=75)
Age ±(SD)	27.8 ± 6.4	28 ± 6.6
Labour status (n,%) In labour Not in labour	 15 (20%) 60 (80%)	 17 (22.6%) 58 (77.4%)
Premature rupture of membranes (n,%)	16 (21.3%)	17 (23%)
Parity ± (SD)	1.4± 0.8	1.3± 0.9
Primary caesarean sections (n,%)	14 (18.6%)	16 (21.3%)
Previous abdominal surgery (n,%)	3 (4%)	2 (2.6%)
Period of gestation at delivery (n,%)	37.8 ± 3.2	38 ± 2.9
Gestational diabetes(n,%)	7 (9.3%)	9 (12%)
Pregnancy induced hypertension(n,%)	6 (8%)	5 (6.7%)

Table 2: Study outcomes

	vaginal cleansing	No vaginal cleansing	p value	Relative risk (95%CI)
Primary outcome				
Postpartum endometritis	1 (1.3%)	5 (6.6%)	0.13	0.2 (0.02 to 1.67)
Secondary outcomes				
Febrile illness	5 (6.6%)	7 (9.3%)	0.54	0.71 (0.23 to 2.15)
Wound infection	2 (2.6%)	4 (5.3%)	0.41	0.5(0.09 to 2.64)
Duration of hospital stay	3.2 ± 1.2	3.4 ± 1.3	0.12	

Table 3: Subgroup analysis (Study outcomes in patients with premature rupture of membranes)

	Vaginal Cleansing (n=20)	No vaginal cleansing (n=13)	p value	Relative risk (95%CI)
Primary outcome				
Postpartum endometritis	1 (5%)	5 (38.4%)	0.04	0.13 (0.01 to 0.99)
Secondary outcomes				
Febrile illness	3 (15%)	6 (46%)	0.07	0.32 (0.09 to 1.07)
Wound infection	2 (10%)	3 (23%)	0.3	0.43(0.08 to 2.25)
Duration of hospital stay	3.6 ± 1.6	3.8 ± 1.9	0.9	

Discussion

The present study demonstrated that vaginal preparation with povidone – iodine solution immediately prior to caesarean delivery reduced the risk of post-operative endometritis in women with premature rupture of membranes. These results suggest that povidone–iodine vaginal cleansing reduces the risk of post-operative endometritis. Postpartum endometritis is an inflammation of uterine endometrium due to infection. In a study by Vincenzo et al, approximately 94% of postpartum patients have positive endometritis cultures, but only a small subset actually develops the infection. Therefore, factors other than simple colonization affect pathogenesis. Bacteria typically ascend from the vagina and initially colonize the innermost layer of the endometrial cavity[9].Amstrey and colleagues reported that a preoperative vaginal cleansing with povidone–iodine eliminated anaerobic gram-positive bacilli and significantly decreased gram-negative bacilli and aerobic and anaerobic gram-positive cocci[4].Similarly, Monif and colleagues demonstrated that a povidone–iodine douche significantly reduced vaginal bacteria for 10 min following administration[10].A non-significant reduction in endometritis after caesarean delivery was noted with 10% povidone–iodine solution in a previous study[6].. Hass and colleagues[11] reported similar results; however, that study had several limitations. Starr and colleagues found that preoperative vaginal cleansing with povidone–iodine decreased the incidence of post-caesarean endometritis. However, this study had several bias related to selective reporting. Asghania et al[12]also recently reported that vaginal preparation with povidone– iodine may reduce the risk of post-caesarean endometritis. In the present study, the experimental and control groups were similar with respect to the factors that increase postpartum endometritis, including the number of participants with ruptured membranes, duration of membrane rupture, the incidence of diabetes, the incidence of patients who were in labor at the time of delivery and the number of per vaginal examinations done.The strength of the study is that it was a prospective randomized controlled trial, and baseline characteristics were similar in both the experimental and control groups who subsequently developed post-caesarean infection. While, the primary limitation was that it was a single centre study. Moreover, in our study, per vaginal examinations were not done prior to the section in patients who presented with intact membranes. Despite these limitations, the findings of the present study revealed that vaginal preparation with povidone–iodine solution immediately prior to caesarean delivery reduces the risk of post-operative endometritis. However, the benefits of vaginal cleansing with povidone–iodine were found only in women with ruptured membranes.

Conclusion

Vaginal cleansing with povidone–iodine solution immediately prior to a caesarean delivery does not reduce the risk of post-operative endometritis. However, beneficial effect of reduction in the incidence of endometritis was seen in women who had premature rupture of membranes .However , the practice of vaginal cleansing may be adopted in all cases of caesarean section pre-operatively at the time of catheterization.

Conflict of Interest: Nil
Source of support:Nil

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