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## Original Article

# Vaginal cleansing prior to caesarian section: To do or not to do?: A randomized trial



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### ABSTRACT

**Purpose:** To evaluate the efficacy of preoperative vaginal cleansing using povidone-iodine solution 10% on rates of post cesarean section (CS) infectious morbidities (endometritis, febrile morbidity and wound infection).

**Methods:** This prospective randomized trial was conducted among 226 pregnant women scheduled for term elective CS. Patients were equally divided into two groups by simple randomization method. The study group had preoperative vaginal cleansing using povidone-iodine solution 10% for about 1 min, while the control group did not. All cases received the prophylactic antibiotics and the usual abdominal scrub. Adverse post CS infectious morbidities such as endometritis, febrile morbidity and wound infection were observed at the time of hospital discharge and weekly for 6 weeks postpartum.

**Results:** Both groups were matched regarding the baseline patients' characteristics. Overall, post-CS infectious morbidity was significantly reduced from 20.7% in the control group to 7.5% in the intervention group. Marked significant reduction was seen in the incidence of endometritis (11.8% in the control group versus 2.8% in the intervention group). However, maternal fever and wound infection showed no significant difference between both groups.

**Conclusion:** Vaginal cleansing with povidone-iodine solution 10% prior to elective CS appears to be effective in reducing rates of post-CS infectious morbidity mainly endometritis.

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## Introduction

Cesarean section (CS) is considered as an international surgical intervention as rates have been increasing all over the world. Post cesarean section (CS) infectious morbidity is a major health problem, which can lead to maternal health morbidities in addition to economic burden. Endometritis, febrile morbidity and wound infection are considered of the most frequent complications of post cesarean infections [1]. Endometritis is the commonest complication as it accounts up to 27%, followed by clinically significant fever, which was reported as 5–24%, while the incidence of wound infection is about 2–9% [2].

Of great concern, postpartum endometritis which is more frequent in caesarian deliveries when compared to vaginal ones, and can be complicated by peritonitis, pelvic abscess even up to septicemia [3,4]. Although maternal mortality from these complications is rare, with an incidence of 6 deaths per 10,000 caesarian deliveries, but it may increase the personal and economic burden with prolonged hospital stay and hospital readmissions [5,6].

Although the current approach to reduce the risk of post cesarean infection morbidity is by using preoperative prophylactic broad spectrum antibiotics [7,8], there is evidence from recent randomized clinical trials that antibiotic prophylaxis did not reduce postoperative infectious morbidity, even, for low risk and elective CS cases [8,9]. Currently, it is a standard care to give antibiotics to women receiving a cesarean delivery, but the rate of post cesarean infectious morbidity remains a problem [5].

In addition to antibiotic prophylaxis, preparation of surgical field with povidone-iodine to minimize the bacterial and fungal organisms' presence at the skin or vagina has been widely recommended. Hence, finding a new, safe, available, cheap and easy to use method that has better efficacy against a wide range of organisms is of great importance [8].

There is a well – established evidence in the literature that, preoperative vaginal sterilization with povidone – iodine before abdominal hysterectomy is effective in decreasing the incidence of postoperative infectious morbidity [10]. However current available data regarding effect of such measure on post-cesarean infectious morbidity is controversial as some studies have shown no significant effect [11] while other studies have reported significant reduction of post cesarean infections with use of povidone-iodine solution [1,2]. This has inspired us to investigate the efficacy of

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vaginal preparation with povidone-iodine solution 10% on post CS infectious morbidity rates and – if proved positive – to recommend its routine use.

## Materials and methods

The study was carried out in accordance to the ethical principles for medical research involving human subjects included in Helsinki declaration. This prospective randomized single blinded trial has been conducted among women subjected to term elective CS during the period from the start of September 2016 to the end of December 2017 at the Obstetrics and Gynecology department of King Abd AL-Aziz Hospital, Jeddah, KSA.

Women with term singleton pregnancy prepared for elective CS were included in the study. Cases of emergency CS, premature rupture of membranes and patients who had positive bacterial vaginosis and / or group B streptococcus culture within 2weeks before CS were excluded from the study. Also, patients with auto immune diseases or immune-compromised status (e.g. diabetes mellitus and long-term steroid therapy) were excluded from the study. All women fulfilling the study criteria were counseled to participate in our study and received an explanation of the study then informed written consent was obtained from all participants.

Randomization of eligible women (n=226) was performed by simple randomization method using 2 sealed envelopes half of which contained notes labeled as “study group” and the other half was labeled as “control group”. Eligible women were asked to choose one of these envelopes to determine the group to which she would be allocated either study or control group. Each group comprised 113 pregnant women, meeting the selection criteria. The required sample size was calculated using  $\alpha$ -error of (0.05), this means that a sample size of 226 calculated overall rates of postpartum infectious morbidity, relative risks (RR), and 95% confidence intervals (CI) for the effect of vaginal preparation. As designed and reported, the trial had at least 80% power to detect a 10% or greater absolute difference in rates of overall infectious morbidity (two-tailed,  $\alpha=0.05$ ) [12].

All patients received adequate spinal anesthesia and then patients were catheterized with Foley’s catheter under aseptic conditions. After catheterization, the study group received a povidone-iodine solution 10% vaginal cleansing. Vaginal cleansing was done with two sterile gauze pieces of povidone-iodine solution 10% and the scrub was done from the vaginal apex including all vaginal fornices in a clockwise manner to the vaginal introitus for about 1 min. Preparation of the vagina was done by the scrub nurse, while the surgeons performed the abdominal scrub as

usual. Control group did not receive vaginal cleansing with any solutions even with normal saline and had only routine abdominal scrub. All cases received the prophylactic antibiotic in the form of cefotaxime 1 g I.V immediately before skin incision. All participants received the routine postoperative care. Signs of wound infection (erythema, swelling, discharge, or tenderness), offensive vaginal discharge, uterine consistency, height were monitored daily in all participants till hospital discharge and weekly to the end of postpartum period. In addition to, symptoms of urinary tract infection were monitored, and complete urine analysis was performed. Meanwhile, during the period of follow-up 7 cases were lost in the intervention group, while 12 cases were also lost in the control group.

Endometritis was defined as postoperative fever of 38.4 C or more at least twice 24h after delivery associated with uterine tenderness and persistent offensive lochia. Postoperative febrile morbidity was defined as temperature of 38 C and greater after the first 24h of surgery in the absence of other clinical findings suggestive of infection (chest infection, UTI, breast engorgement and so on). Wound infection was based on a diagnosis of erythema or wound edge separation with purulent discharge involving the cesarean incision site that requires antibiotics therapy and wound care.

Data were statistically analyzed in terms of mean and standard deviation, frequencies (number of cases) and percentages when appropriate. Comparison between groups was done using Chi-Square test in the cross tabulation. P values less than 0.05 were considered statistically significant. All statistical calculations were done using computer program SPSS (Statistical Package for Social Science; SPSS Inc., Chicago, IL, USA) release 22 for Microsoft Windows.

## Results

Baseline maternal characteristics of the studied participants are presented in Table 1. No statistically significant difference was noted between both groups regarding the age, BMI, parity, Hb%, gestational age at delivery, operative time or postoperative hospital stay. The mean age was 28 years in intervention group, while it was 29 years in control group. The most common indication for CS was previous CS delivery (69% and 63% in the intervention and control groups, respectively).

The main outcome measures of the study are presented in Table 2. Regarding the incidence of post-CS infectious morbidity a statistically significant reduction from 20.7% in the control group to be 7.5% in the intervention group. Marked reduction was noticed

**Table 1**  
Baseline maternal characteristics in the whole studied participants.

		Intervention group (n = 113)		Control group (n = 113)		p-value
Maternal age (years)	Mean $\pm$ SD	28.7 $\pm$ 9.2		29.4 $\pm$ 7.8		0.7 (NS)
Maternal BMI (kg/m <sup>2</sup> )	Mean $\pm$ SD	29.6 $\pm$ 2.8		30.1 $\pm$ 3.3		0.2 (NS)
Parity	Nulliparous	16	14.1%	17	15.1%	0.8 (NS)
	Para 1–2	60	53.1%	62	54.8%	
	$\geq$ Para 3	37	32.8%	34	30.1%	
Gestational age at delivery (weeks)	Mean $\pm$ SD	38.1 $\pm$ 1.3		38.4 $\pm$ 1.8		0.2 (NS)
Operative time (minutes)	Mean $\pm$ SD	47.8 $\pm$ 10.6		52.3 $\pm$ 7.9		0.07 (NS)
Preoperative Hb (gm/dl)	Mean $\pm$ SD	10.9 $\pm$ 1.2		10.7 $\pm$ 1.7		0.6 (NS)
Postoperative hospital stay (days)	Mean $\pm$ SD	2.7 $\pm$ 1.3		3.2 $\pm$ 1.1		0.06 (NS)
Indications for CS	Previous CS	78	69.2%	72	63.7%	0.5 (NS)
	Mal presentation	4	3.5%	6	5.5%	0.8 (NS)
	Maternal request	21	18.5%	23	20.3%	0.9 (NS)
	CPD	7	6.2%	8	7.1%	0.9 (NS)
	Previous CR	3	2.6%	4	3.5%	0.9 (NS)

NS: not statistically significant (p-value > 0.05).

BMI: Body Mass Index, Hb: Hemoglobin, CPD: Cephalo- Pelvic Disproportion, CR: Classical Repair, CS: Caesarian Section.

**Table 2**

Post caesarean section infectious morbidities in both groups.

	Intervention group (n = 106)		Control group (n = 101)		p-value	RR (95% CI)
Overall post CS infectious morbidity	8	7.5%	21	20.7%	0.003*	0.3 (0.2–0.7)
Endometritis	3	2.8%	12	11.8%	0.008*	0.2 (0.06–0.7)
Fever	1	0.9%	3	2.9%	0.6 (NS)	0.5 (0.09–2.6)
Wound infection	4	3.7%	6	5.9%	0.5 (NS)	0.6 (0.2–1.8)

NS: not statistically significant (p-value &gt; 0.05).

RR: relative risk, CI: confidence interval.

\* Statistically significant difference.

also in the incidence of post-CS endometritis (11.8% in the control group versus 2.8% in the intervention group; p values < 0.05). However, the situation was different for fever and wound infection as there was no significant difference between both groups. Only one woman (0.9%) in the vaginal cleansing group and three (2.9%) in the control group had febrile morbidity. Only four patients (3.7%) in intervention group developed wound infection in comparison to six (5.9%) in the control group; they were treated with broad spectrum antibiotics and wound dressing.

## Discussion

The issue of using preoperative vaginal cleansing is not recent and it was previously used since the early seventies prior to abdominal hysterectomy and was proved to be associated with lower postoperative infectious morbidity, as well as, documented reduction in the bacteria count in vagina by at least 98% with povidone iodine solution [13].

Various studies have been done to evaluate whether vaginal cleansing before a cesarean delivery with an antiseptic solution can reduce the incidence of postoperative infection. Povidone iodine use has been reported in some studies for this purpose with contradictory results [1,2,11].

This has inspired us to perform our randomized single blinded study to assess the efficacy of vaginal preparation with povidone iodine solution on post cesarean infectious morbidity rates. This means that the clinical postoperative follow up care teams were blinded to the intervention and were not aware of preoperative vaginal sterilization procedure or to either arm of the study; we opted to this different type of methodology to minimize risk of bias in comparison to previous studies [1,13]. The present study has shown that preoperative vaginal cleansing with 10% Povidone iodine solution immediately prior to CS is effective in reducing overall post-CS infectious morbidity as incidence of overall post-CS infectious morbidity shown a statistically significant reduction; from 20.7% in the control group to be 7.5% in the intervention group. Noteworthy, our study showed significant reduction of endometritis rate in the intervention compared to the control group (2.8% versus 11.8%, respectively), while no significant difference was demonstrated between both groups in either febrile morbidity or wound infection. Of great concern, the overall post-CS infectious morbidity (20.7%) reflect all morbidity parameters (endometritis, febrile morbidity and wound infection) which is comparable with some studies [13,14].

Post CS infectious morbidity is a result of the presence of bacteria in the vagina that move higher in the genital tract to infect the uterus. These bacteria have been shown to be responsible for failure of antibiotic prophylaxis during cesarean deliveries. Additionally, some antibiotics do not consistently eradicate some bacteria and the vagina has been shown to become colonized with

antibiotic-resistant bacteria after pre-operative surgical antibiotic prophylaxis even for low risk and elective caesarean sections [5]. Bacteria typically ascend from the vagina and initially colonize the innermost layer of the incised endometrial cavity. Interestingly, povidone-iodine solution 10% produces a dramatic fall in the numbers of total aerobes and anaerobes organisms from the vaginal wall in the first 10 min following administration [13]. Also an earlier reports have proved the effectiveness of preoperative vaginal scrub with povidone-iodine in removing anaerobic gram-positive bacilli and dramatically decrease the quantities of gram-negative bacilli and aerobic and anaerobic gram-positive cocci while the presence of those pathogens in the vagina is a known predisposing factor for post-CS infectious morbidity especially endometritis by ascending from vagina into the uterus with hematogenous spread through exposed edge of incised myometrium [15].

In accordance to our results, Memon et al. in their study on 200 women undergoing CS, assessed the role of preoperative vaginal sterilization with povidone-iodine solution on overall post cesarean infectious morbidity and found that it was reduced from 16% to 6% and endometritis from 7% to 1%. However, fever and wound infection showed no significant difference between both groups in their study [15]. Our findings are in agreement also with an Egyptian study by Madny et al. [13] in their prospective study on 218 women undergoing CS, assessed the role of preoperative vaginal sterilization with povidone-iodine solution on post CS infectious morbidity which was reduced from 25% to 8.8% and endometritis from 14.3% to 2.9%. A recent Cochrane review concluded that vaginal preparation with povidone-iodine solution immediately prior to caesarean delivery reduces the risk of post-operative endometritis, mainly in women undergoing CS [5].

Reid et al. in their prospective study on 501 women undergoing CS either (emergency or elective), assessed the role of preoperative vaginal sterilization with povidone-iodine solution on post CS infectious morbidity and could not find any significant difference in postoperative endometritis, fever and wound infection in their cases [2]. Also, our findings are not in agreement with a recent trial by La Rosa et al., who investigated protocols for vaginal preparation with antiseptic solution in 523 women undergoing CS during labor [16]. The discrepancies to our results probably reflect the strict inclusion / exclusion criteria adopted by our study as we only included women with term elective CS, the single blind methodology, randomization method, sample size in addition to cultural and socioeconomic differences.

The present study had several strengths, including that it was a prospective randomized trial with microbiological assessment for all participants before CS to eliminate any study bias, in addition to similar demographic and pregnancy profiles were found among those in both the intervention and control groups who subsequently developed post CS infection morbidity. On the other hand,

the present study had limitation, the relative small sample size in our study population. Hence, we recommend a larger scale study addressing this limitation. Despite that limitation, the findings of the present study revealed that vaginal preparation with povidone iodine solution immediately prior to caesarean delivery reduces the risk of post-CS infectious morbidity. The beneficial effects, safety, simplicity and low cost of the intervention support its adoption as a method to reduce maternal morbidity.

### Declaration of interest

The author report no conflict of interest or financial support.

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