

A Study of the Effect of Preoperative Vaginal Antiseptic on Occurrence of Postoperative Infection in Cesarean Section

Original
Article

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ABSTRACT

Aim: Cesarean delivery is one of the most common surgical procedures in obstetric practice and its incidence is rising worldwide. In Egypt, the past decade has witnessed a sharp increase in the CS rate to reach about 52%. 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. 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%. This complication, up to 10 times more frequent after a cesarean delivery than after vaginal delivery.

Materials and Methods: This study was conducted on 54 females undergoing elective cesarean section, admitted to El-Shatby Maternity University Hospital. Patients were divided into two groups, each group contained 27 cases. The first group received Preoperative vaginal cleaning with 10% povidone iodine for 30 seconds. The second group did not receive preoperative vaginal cleaning.

Results: The Comparison between the two studied groups regarding incidence of febrile morbidity, post-operative endometritis and wound infection were statistically significant; $P = (0.009)$, (0.024) and (0.018) respectively. Applying povidone iodine reduced the rate from 37% in the control group to 7.4% in the treatment group, post-operative endometritis rate from 29.6% in the control group to 3.7% in the treatment group and post-operative wound infection rate from 33.3% in the control group to 7.4% in the treatment group.

Conclusion: This study has shown that vaginal cleaning with povidone iodine prior to cesarean section can prevent post-operative febrile morbidity.

Key Words: Cesarean delivery, febrile morbidity, post-operative endometritis, povidone iodine, preoperative vaginal cleaning, wound infection.

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INTRODUCTION

Cesarean delivery is one of the most common surgical procedures in obstetric practice and its incidence is rising worldwide. The cesarean section rate is 21.5% in UK and 29.5% in USA^[1,2]. In Egypt, the past decade has witnessed a sharp increase in the prevalence of CS with the most recent Egypt Demographic and Health Survey (EDHS) documenting a CS rate of 52%^[3].

Post cesarean section 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^[4]. 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%^[5].

These complications are up to 10 times more frequent after a cesarean delivery than after vaginal delivery, can lead to serious complications of bacterial infection in the blood (10% to 20%), peritonitis, intra-abdominal abscess and sepsis^[6,7]. Although maternal mortality from these complications is rare, with an incidence of 6 deaths per 10,000 caesarean deliveries, but it may increase the personal and economic burden with prolonged hospital stay and hospital readmissions^[8,9].

Post-cesarean endometritis and infectious morbidity are the result often of the presence of bacteria in the vagina and cervix that move higher in the genital tract to infect the uterus^[10]. These bacteria have been shown to

be responsible for failure of antibiotic prophylaxis during cesarean deliveries^[11,12]. Additionally, some antibiotics do not consistently eradicate some bacteria (such as *Enterococcus* species), and the vagina has been shown to become colonized with antibiotic resistant bacteria after preoperative surgical antibiotic prophylaxis^[13-14].

Currently, it is standard care to give preoperative antibiotics to women receiving a cesarean delivery,^[15] but the rate of post-cesarean infections remains a problem. As many pelvic organ infections after surgeries contain organisms from the vagina, cleansing the vagina with antiseptic solutions preoperative - such as before hysterectomies - has been performed for years, but not before cesarean deliveries!!^[16,17] After operative delivery, the uterus remains potentially exposed to the vagina through the cervix. Reducing the bacterial content before a cesarean delivery could reduce post cesarean infections of the uterus.

Different types of antiseptics have been tried to clean the vagina prior to uterine surgeries to prevent post-operative infections. These include povidone iodine, chlorhexidine and metronidazole. Results of one efficacy over another are conflicting, but their safety has been widely documented^[18].

Povidone iodine is a stable chemical complex of polyvinylpyrrolidone and contains 9.0% to 12.0% iodine. It is completely soluble in cold and mild-warm water which makes it suitable for vaginal cleansing. It kills microbes by iodination of lipids and oxidation of cytoplasmic and membrane compounds. Pathogens do not show resistance to this agent and it exhibits a broad range of microbicidal activity against bacteria, fungi, protozoa, and viruses^[19]. Thus povidone iodine has been chosen for this study for its efficacy and safety over other antiseptic agents^[20]. The aim of this work was to study the effect of preoperative vaginal antiseptic on occurrence of postoperative infection in cesarean section.

PATIENTS AND METHODS

This study was conducted for 6 months between February till July 2020. It was carried out on 54 patients that were admitted to El-Shatby Maternity University Hospital; the patients were allocated in two groups 27 patients for control group and 27 patients for the study group. Using two proportions power analysis in NCSS & PASS program, a minimum sample size to detect difference of the effect of preoperative vaginal antiseptic on occurrence of postoperative infection in cesarean section was found to be 27 females per group, that achieve 80% power at significance level 5 %. Inclusion criteria were pregnant women booked for elective cesarean section more than 37 weeks gestation and with active infections. We excluded emergency cesarean delivery, premature ruptured membranes, diabetes Mellitus, gestational Diabetes,

severe anemia (Hb <7 g/dL), immune-compromised Status, allergy to iodine solution, any febrile condition (Temperature \geq 38 c) and Abnormal vaginal discharge.

The study was a non-blinded prospective randomized controlled study; we used the envelope method for randomization. Each consecutive participant that met the criteria for the study picked a card at random from an envelope that contains 54 shuffled deck cards. Half of the cards with even numbers belonged to the povidone iodine group while the remaining half of the cards with odd numbers belonged to the control group. Informed consent was obtained from each woman involved in the study and was approved by the ethics committee of Alexandria Faculty of Medicine.

Detailed and careful personal, obstetric and medical history was taken from the woman, especially any vaginal infections, discharge and antibiotic usage. Routine general examination, abdominal examination was carried out and pelvic examination to detect any abnormal vaginal discharge and rupture of membranes. Preoperative laboratory investigations included blood hemoglobin level, random blood sugar level and urine analysis. Obstetric ultrasound was performed for monitoring gestational age and viability, in addition to exclude congenital anomalies.

All patients were in supine position after they 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 cleaning. Vaginal cleaning 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 30 seconds. 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 cleaning with any solutions even with normal saline and had only routine abdominal scrub.

All cases received the prophylactic antibiotic in the form of cefotaxime 2 g I.V immediately before skin incision. All participants received the routine postoperative care. For the first 24 hours post-operative, the patients were monitored for Signs of wound infection (erythema, swelling, discharge, or tenderness), offensive vaginal discharge, uterine consistency and height. Patients were discharged home after that period if there were no other complications. Removal of sutures was done after 10 days then they were monitored weekly to the end of the postpartum period.

Post-operative fever was diagnosed when temperature of the patient was 38C or more after the first 24 hours of surgery in the absence of other clinical findings suggestive of infection. Fever was treated by antipyretics^[21].

Post-operative endometritis was diagnosed by the presence of fever ($\geq 38^{\circ}\text{C}$) for ≥ 24 hours occurring after first post-operative day, uterine tenderness and purulent vaginal discharge. It was managed by analgesic, anti-inflammatory and proper antibiotics^[21]. Post-operative wound infection was diagnosed by the presence of erythema, tenderness, and purulent drainage from the incision site, with or without fever and was treated by aseptic wound dressing in addition to antibiotics^[21].

STATISTICAL ANALYSIS

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Qualitative data were described using number and percent. The Kolmogorov-Smirnov test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation, median and interquartile range (IQR). Significance of the obtained results was judged at the 5% level.

RESULTS

A total of 81 Patients were recruited into this study, from to El-Shatby Maternity University Hospital out patients' clinic. 21 dropped out, mainly because they did not come for follow up before or after stitch removal. Other two cases were excluded from the study due to severe postpartum hemorrhage and one for significant chest infection post-operative. So recruitment continued till 54 patients were randomized (by closed envelop system) with 27 cases in each study group.

As regards the age of the patients, parity, Gestational ages and Number of Cesarean sections, there were no statistically significant difference between the two studied groups. As shown in (Table 1).

Table 1: Comparison between the two studied groups according to age, parity, gestational ages and No. of CS

Age	Cases (n = 27)		Control (n = 27)		P
	No.	%	No.	%	
20 – 30	17	63.0	13	48.1	MCp= 0.691
31 – 40	9	33.3	13	48.1	
>40	1	3.7	1	3.7	
Min. – Max.	20.0 – 43.0		21.0 – 41.0		0.494
Mean ± SD.	29.85 ± 5.10		30.89 ± 5.93		
Median (IQR)	30.0(26.5 – 32.0)		31.0(26.0 – 36.0)		
Parity	Cases (n = 27)		Control (n = 27)		P
	No.	%	No.	%	
0	9	33.3	8	29.6	MCp= 0.591
1	6	22.2	10	37.0	
2	6	22.2	3	11.1	
>2	6	22.2	6	22.2	
Min. – Max.	0.0 – 4.0		0.0 – 4.0		0.727
Median (IQR)	1.0(0.0 – 2.0)		1.0(0.0 – 2.0)		
GA	Cases (n = 27)		Control (n = 27)		P
	No.	%	No.	%	
37 – 38	17	63.0	16	59.3	0.780
39 – 40	10	37.0	11	40.7	
Min. – Max.	37.0 – 40.0		37.0 – 39.0		0.841
Median (IQR)	38.0(38.0 – 39.0)		38.0(38.0 – 39.0)		
No. of CS	Cases (n = 27)		Control (n = 27)		P
	No.	%	No.	%	
0	9	33.3	8	29.6	MCp= 0.892
1	8	29.6	11	40.7	
2	6	22.2	4	14.8	
>2	4	14.8	4	14.8	
Min. – Max.	0.0 – 4.0		0.0 – 4.0		0.892
Median (IQR)	1.0(0.0 – 2.0)		1.0(0.0 – 2.0)		

MC: Monte Carlo p: p value for comparing between the studied groups

As regards Post-operative fever, in control group, post-operative fever was present in 10 patients (37%) and in study group, post-operative fever was present in 2 patients (7.4 %) with a statistically significant difference ($P=0.009^*$). Cases diagnosed to have Endometritis, in control group, were 8 patients (29.6 %) and in only one case (3.7 %) in

the study group, with a statistically significant difference ($P= 0.024$). in control group, wound infection was present in 9 patients (33.3 %) while in study group, 2 patients only suffered wound infection (7.4 %) with a statistically significant difference ($P= 0.018$). as shown in (Table 2).

Table 2: Comparison between the two studied groups according to postoperative complications

Postoperative complication	Presence / absence	Cases (n = 27)		Control (n = 27)		χ^2	p
		No.	%	No.	%		
Fever	No	25	92.6	17	63.0	6.857*	0.009*
	Yes	2	7.4	10	37.0		
Endometritis	No	26	96.3	19	70.4	6.533*	0.024*
	Yes	1	3.7	8	29.6		
Wound infection	No	25	92.6	18	66.7	5.594*	0.018*
	Yes	2	7.4	9	33.3		

χ^2 : Chi square test

p: p value for comparing between the studied groups

*: Statistically significant at $p \leq 0.05$

DISCUSSION

Since the early 1970s, using preoperative vaginal cleaning prior to abdominal hysterectomy was practiced and proved to be associated with lower postoperative infectious morbidity in addition to documented reduction in the vaginal bacterial count^[22]. This study was conducted on 54 females undergoing elective cesarean section, admitted to El-Shatby Maternity University Hospital. Patients were divided into two groups, each group contained 27 cases. The first group received Preoperative vaginal cleaning with 10% povidone iodine for 30 seconds. The second group did not receive preoperative vaginal cleaning. The main limitation of this study was the dropped cases which we overcome by increasing recruitment number and time.

This study has shown that vaginal cleaning with povidone iodine prior to cesarean section can prevent post-operative febrile morbidity (reducing the rate from 37 % in the control group to 7.4 % in the treatment group ($P= 0.009$), post-operative endometritis (reducing the rate from 29.6 % in the control group to 3.7% in the treatment group ($P= 0.024$) and post-operative wound infection (reducing the rate from 33.3 % in the control group to 7.4 % in the treatment group ($P= 0.018$). No side effects or adverse outcome were recorded from the use of povidone iodine. Other obstetrics and surgical factors in this study, such as age of the patient ($p=0.494$), parity ($p=0.727$), gestational age ($p=0.841$) and number of cesarean sections ($p=0.892$), did not show any significant difference in developing post-operative infection.

Post CS infectious morbidities were results of the presence of bacteria in the vagina that move higher in the genital tract to infect the uterus and/ or the surgical wound. These bacteria have been shown to be responsible for failure of antibiotic prophylaxis during cesarean deliveries^[23]. Povidone iodine is an antiseptic solution which causes 98% reduction in the total number of bacteria in vagina

with preoperative cleaning as reported by Osborne and Wright^[17]. It was a cheap, easy and practicable intervention. In our study, the cleaning solution was well tolerated by the patients with no increased allergic reactions or skin irritation.

In accordance to our result; Cochrane Systematic Review by Haas *et al* (2020)^[24] included 21 trials, reporting results for 7038 women evaluating the effects of vaginal cleaning (17 using povidone iodine, 3 chlorhexidine, 1 benzalkonium chloride) on post-cesarean infectious morbidity. Trials were performed in 10 different countries (Saudi Arabia, Pakistan, Iran, Thailand, Turkey, USA, Egypt, UK, Kenya and India). Vaginal preparation with antiseptic solution immediately before cesarean delivery probably reduced the incidence of postcesarean endometritis from 7.1% in control groups to 3.1% in vaginal cleaning groups. This reduction in endometritis was seen for both iodine-based solutions and chlorhexidine-based solutions. Risks of postoperative fever and postoperative wound infection were also probably reduced by vaginal antiseptic preparation. No adverse effects were reported with either the povidone-iodine or chlorhexidine vaginal cleaning^[24]. In a study conducted by Aref *et al* (2019)^[25]; This prospective randomized trial was conducted among 226 pregnant women scheduled for term elective CS. The study group had preoperative vaginal cleaning 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. The results showed that; 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.

our study showed that vaginal cleaning with povidone iodine prior to cesarean section can prevent post-operative febrile morbidity (reducing the rate from 37 % in the control group to 7.4 % in the treatment group ($P= 0.009$)). similar results were obtained by Kiani *et al* in 2018^[26] who revealed that vaginal cleaning with povidone iodine prior to CS resulted in a statistically significant reduction in post-operative endometritis, but did not reduce incidence of fever or wound infections. Fever was seen in 9 (4.1%) women in group A and 16 (7.4%) in group B ($p=0.149$), Endometritis was noted in 3 (1.4%) women in group A and 19 (8.8%) in group B ($p=0.000$). lastly, Wound Infection occurred in 3 (1.4%) women in group A and 8 (3.7%) in group B ($p=0.126$). The trial was conducted on 434 patients. Similar results were obtained from Yildirim *et al* in 2012(4), Memon *et al* (2011)^[23] and Asghania *et al* (2011)^[27].

Other researchers reported no differences in infectious morbidities with or without vaginal antiseptics prior to cs. A trial by La Rosa *et al* in 2018^[28] investigated protocols for vaginal preparation with antiseptic solution in women undergoing CS during labor. A total of 523 women delivered in institutions with vaginal antiseptics policies before cesarean delivery and 1,490 delivered in institutions without such policies were compared. There was no difference in superficial and deep surgical site infection rates between women with and without vaginal preparation (5.5% vs 4.1%; odds ratio [OR] 1.38, 95% CI 0.87-2.17), even after adjusting for possible confounders.

Haas *et al.* (2010)^[8] compared 155 vaginal cleansing subjects with 145 control subjects. Overall, 9.0% developed the composite outcome, with fewer women in the cleansing group (6.5%) relative to the control group (11.7%), although the difference was not statistically significant (relative risk, 0.55; 95% confidence interval, 0.26-1.11; $P = .11$). the same results was concluded by Reid *et al*^[5] these different conclusions may be resulted from longer surgery time, being in labor, having a dilated cervix or severe maternal anemia.

CONCLUSION

Vaginal preparation with povidone iodine solution immediately prior to cesarean delivery reduced the risk of post CS infectious morbidity. There was a statistically significant difference between the two studied groups regarding incidence of post- operative febrile morbidity, endometritis and wound infection. The beneficial effects, safety, simplicity and low cost of the intervention support its adoption as a method to reduce maternal morbidity.

CONFLICT OF INTERESTS

There are no conflicts of interest.

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