



Microbes and Infectious Diseases

Journal homepage: <https://mid.journals.ekb.eg/>

Original article

Effect of clindamycin vaginal pessary before cesarean section on postpartum infectious morbidity

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ARTICLE INFO

Article history:

Received 3 December 2021

Received in revised form 16 January 2022

Accepted 21 January 2022

Keywords:

Endometritis
Cesarean section
Postpartum infectious morbidity
Clindamycin

ABSTRACT

Background: Post-cesarean section (CS) infections, namely, endometritis, fever and wound infection are considered a major health problem which necessitates effective interventions. Antibiotic prophylaxis before CS cannot completely eliminate the risk of postpartum infections. Preoperative antiseptic vaginal cleansing is one of the commonest methods to reduce infectious morbidities after CS. **Aim of the work:** The aim of this work is to evaluate the effect of prophylactic administration of clindamycin vaginal suppository before elective CS on postpartum infectious morbidity. **Methods:** 196 patients were included in this intervention. They were divided equally into two groups (each 98 patients); intervention group (which received clindamycin 100 mg vaginal suppository at bedtime for 3 nights before CS) and control group (which received nothing). Both groups were followed till the end of puerperium for the development of postpartum infections namely, endometritis, fever, and wound infection. **Results:** There was statistically significant decrease in the frequency of endometritis, fever, and wound infection in the intervention group when compared to control group. Also, there was highly statistically significant decrease in the frequency of overall post-CS infectious morbidity in the intervention group when compared to control group. There was statistically significant difference between both groups as regard white blood cells count and C-reactive protein level 24 hours after cesarean section. **Conclusion:** Prophylactic administration of clindamycin vaginal suppository before elective CS reduces the risk of postpartum infections namely endometritis, fever, wound infection and overall post-CS infectious morbidity. Preoperative clindamycin vaginal suppository could be protective against post-CS infectious morbidities.

Introduction

Infectious morbidities following cesarean delivery are considered major health problems in different countries resulting in high economic burden on health services. Wound infection, endometritis and fever are considered the commonest post-cesarean section (CS) infections [1]. Incidence of endometritis, fever and wound infection is about 6-27%, 5-24%, 2-9% respectively [2]. When compared to vaginal delivery,

endometritis is 10 times more common following cesarean section and can be easily complicated by generalized or localized peritonitis and septicemia [3].

Post-CS infectious complications cannot be completely eliminated by the use of preoperative or intraoperative broad-spectrum antibiotics, and they still could occur in about 20% of cases [1]. Although preoperative prophylactic broad spectrum antibiotics administration is considered the

DOI: 10.21608/MID.2022.110068.1215

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standardized method to reduce the risk of postpartum infectious complications, there is still evidence from many studies that antibiotic prophylaxis did not completely eliminate the risk of post-cesarean section infection, even, for elective and low risk CS cases [4].

The most common source for post-CS infections is the bacteria which colonize the vagina and ascend through the lumen of the genital tract to infect the exposed edges of incised uterus or even spread hematogenously. Some antibiotics do not kill certain types of bacteria and the vagina may become colonized with antibiotic-resistant bacteria even with the use of preoperative prophylaxis [5].

The risk of post-CS infections can be more reduced by different methods. Preoperative antiseptic vaginal douching is one of the commonest methods which is considered safe and rapid and could be done just before abdominal scrub by antiseptics. Five randomized clinical trials were evaluated to detect the effect of povidone iodine vaginal douching on post-cesarean infections. They found a low-quality evidence that the risk of postpartum endometritis could be reduced if povidone iodine vaginal cleansing is used immediately before CS. In cases of elective CSs, vaginal douching decreases the risk of ascending infections. Infective conditions such as endometritis could be reduced using vaginal povidone iodine, chlorhexidine, and metronidazole [6]. Some results showed that vaginal povidone iodine could prevent postpartum endometritis, and this could not be provided by other antiseptic solutions [5].

Ascending infection by vaginal anaerobic bacteria is the main cause of endometritis [7]. Preoperative administration of antibiotic before cesarean delivery could reduce the incidence of infective morbidities by about 60–70% when compared with placebo or no treatment [3, 8].

Clindamycin is a lincosamide antibiotic. In vitro, Clindamycin can kill staphylococci (staph, aureus) streptococci (group A and B streptococci, microaerophilic streptococci and *Streptococcus pneumoniae*), pneumococci, most anaerobic bacteria (including over 90% of *Bacteroides fragilis*), *Chlamydia trachomatis* and certain protozoa. It has broader anaerobic coverage than most cephalosporins. Also, it has excellent activity against Gram-positive cocci, Gram-positive anaerobes, and Gram-negative anaerobes. [9-12].

The aim of our work is to evaluate the effect of prophylactic administration of clindamycin

vaginal suppository before elective CS on postpartum infectious morbidity.

Patients and Methods

Type of the study, duration and setting

This prospective randomized controlled interventional trial was performed during the period from October 2014 to October 2019 at Obstetrics and Gynecology Department of Zagazig University Hospitals, Zagazig Faculty of Medicine.

Inclusion and exclusion criteria

Our intervention included females with singleton pregnancy prepared for elective cesarean section at term (from 37 weeks to 40 weeks) and free of any medical disorders. Age ranged between 18-36 years. BMI of the included women ranged between 18-25 kg/m². Timing of delivery was determined depending on a reliable last menstrual period (LMP); if the LMP was not remembered by the patient, early ultrasound data were used. Indications for CS were previous CS, maternal request, non-cephalic presentations, and previous successful repair of complete perineal tear. Cases of urgent or emergent CSs, abnormal vaginal secretion (bad smelling yellowish secretion, whitish cheesy discharge with pruritus, bloody discharge; etc...), history of post CS infection, feverish patients, known hypersensitivity to clindamycin, patients with suspected or confirmed intra-amniotic infection, patients with term premature rupture of membranes or with placenta previa and immunocompromised patients (e.g. diabetes mellitus, hepatic patients and corticosteroid administration) were excluded from our intervention. Also, patients lost during follow up were excluded from the final analysis.

Consent and randomization

Informed written consents were obtained from all participants and their husbands. Women fulfilling the inclusion criteria (196 patients) were divided equally into two groups (each 98 patients); intervention group (which received the intervention) and control group (which received nothing) by simple randomization method with the aid of a computer. So each group consisted of 98 pregnant women prepared for elective CS for the previously mentioned indications.

Intervention

After review of the first day of the LMP and/or early ultrasound data and determination of the expected time of CS, patients of the intervention group were instructed to insert clindamycin 100 mg vaginal

suppository by using the included applicators at bedtime for 3 nights before CS. The control group did not receive any vaginal medications during the period of intervention. All patients (intervention and control group) were informed not to practice coitus, or use any vaginal products (such as douches, tampons or any type of pessary) during the period of intervention. Also, no vaginal examination was performed to all participants within 3 days of the CS.

Steps of cesarean section

Preoperative investigations included complete blood count (CBC), coagulation profile (PT, PTT, INR), blood grouping (ABO) and viral markers (HBsAg, HCV Ab and HIV) were performed to all participants. All patients performed CS at morning (between 8am and 11am) about 8 to 12 hours from the last vaginal suppository. One gram single intravenous dose of cefazolin was given to all patients within 60 minutes of skin incision [13]. All participants were given spinal anesthesia. Patients were catheterized with Foley's catheter no 16 F under complete aseptic conditions then abdominal scrub was performed as usual using povidone iodine. Pfannenstiel incision was performed as usual. Transverse incision was performed in the lower uterine segment followed by delivery of the baby and the placenta and membrane. The cervix was not dilated from inside the uterine cavity using finger insertion into the cervical canal to avoid contamination from the vagina. No intrauterine cleaning after placental delivery as long as the whole placenta and membrane were delivered. Any residual membranes in the uterine cavity were removed by simple stripping by fingers. Uterine incision was repaired in two layers inside the abdominal cavity using Vicryl sutures. Visceral and parietal peritoneum were not sutured. Abdominal muscles were not approximated. Rectus sheath was repaired in continuous manner using Vicryl sutures. Fat was approximated using Vicryl sutures only if more than 2 cm. Skin was approximated using proline subcuticular sutures, then the wound was covered by a sterile pad. No vaginal cleansing was done to any participants either before or after the CS.

Follow up after cesarean section

All patients received the routine postoperative care without further interventions. No further antibiotics were given either intraoperatively or postoperatively. After 24 hours of CS, a blood sample was obtained from all participants for performing CRP (C-reactive protein) and white blood cells count (WBC). All participants were

followed after CS for development of maternal infections such as endometritis, fever and wound infection at the time of hospital discharge and weekly till the end of puerperium.

Diagnosis of post-CS infectious morbidity

Endometritis was defined as postoperative fever of 38.4 °C or more at least twice 24 h after delivery associated with uterine tenderness and persistent offensive lochia. Postoperative febrile morbidity was defined as temperature of 38 °C or more after the first 24 h of surgery in the absence of other clinical findings suggestive of infection (chest infection, urinary tract infection, 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 [14].

Statistical analysis

Data analysis was done using the software SPSS (Statistical package for the social sciences) version 23. Quantitative data was represented using the means and standard deviations. Categorical variables were represented using their absolute frequencies. Kolmogorov-Smirnov (distribution type) and Levene (homogeneity of variables) tests were utilized to prove suppositions for use in parametric tests. For quantitative variables, independent samples t-test (t) was used to compare means of two groups. For categorical variables, Chi square (X²) and Fisher's exact tests were used to compare the studied groups and odds ratio (95%CI) was done to evaluate the protective effect of the exposure to the intervention. *p* value < 0.05 indicates significant results.

Results

During the period of follow-up, six cases were lost in the intervention group (92 cases were included in the final analysis), while 4 cases were lost in the control group (94 cases were included in the final analysis). There was no statistically significant difference between both groups as regard their clinical characteristics as shown in **table (1)**.

On doing univariate analysis for the difference between the studied groups regarding post-CS infectious morbidities, there was statistically significant decrease in the percent of endometritis, fever, wound infection and overall post-CS infectious morbidities among the intervention group when compared to the control group {(*p*-value 0.01, 0.02, 0.01&0.001 and odds ratio [95%CI] 0.1[0.013-0.84], 0.2[0.06-0.85],

0.1[0.013-0.83], 0.12[0.045-0.33]) respectively, interestingly these findings indicate that preoperative clindamycin vaginal suppository is protective against post-CS infectious morbidities as shown in **table (2)**.

White blood cells (WBC) and C-reactive protein (CRP) 24 hours after CS were statistically significantly lower among the intervention than the control group (*p*-value 0.005& 0.002) respectively as shown in **table (3)**.

Table 1. Characteristics of the studied groups.

Characteristics of the studied groups	Intervention group (n=92)	Control group (n=94)	<i>p</i> -value
Maternal age (years)	27.5± 5.5 (18-36)	27.7± 4.5 (18-36)	0.78#
Gestational age at the time of delivery (weeks)	39.1± 5.3 (37-40)	39.4± 5.8 (37-40)	0.71#
BMI (kg/ m ²)	23.2 ±4.7 (18-25)	23.3± 5.1 (18-25)	0.9#
Parity (n)	1.8±0.41 (1-3)	1.9±0.52 (1-4)	0.14#
Primary CS (n)	18(18.3%)	15(15.3%)	0.5^
Operative time (min)	53.6± 10.4 (41-65)	52.1± 10.9 (40-64)	0.3#
Estimated blood loss (ml)	701.5±121.4 (582.3-832.5)	731.4±109.1 (580.1-834.7)	0.077#
Cases received blood transfusion (n)	3(3.1%)	2(2.1%)	0.67^^
Perioperative organ injury (n)	1(1.1%)	3(3.2%)	0.62^^
Subcutaneous or intraperitoneal drain (n)	7(7.1%)	8(8.2%)	0.78^
Preoperative hemoglobin (g/ dl)	10.9± 2.8 (8-14)	10.7± 3.1 (7.5-14)	0.64#
Preoperative hematocrit (%)	32.6± 5.4 (26.6-39.7)	33.8± 5.7 (26.8-39.5)	0.14#
Postoperative hemoglobin (g/dl)	9.9± 1.9 (7-12.1)	9.8± 2.3 (7.4-12.2)	0.74#
Postoperative hematocrit (%)	31.6± 4.5 (25.6-37.2)	30.9± 4.3 (26.1-36.8)	0.27#
Postoperative hospital stay (days)	2.12± 0.4 (1-3)	2.18± 0.6 (1-3)	0.42#

Data were presents as mean± SD (range) or frequency (%).

#*p*-value for independent t-test.

^*p*-value for Chi Square test

^^*p*-value for Fisher Exact test (FET)

Table 2. Frequency of post-CS infectious morbidities among the studied groups.

Infectious morbidities	Intervention group (n= 92)	Control group (n= 94)	p-value	Odds ratio (95%CI)
Endometritis	1(1.1%)	9 (9.6%)	0.01 ^{^^*}	0.1(0.013-0.84)
Fever	3(3.3%)	12(12.8%)	0.02 ^{^^*}	0.2 (0.06-0.85)
Wound infection	1 (1.1%)	9(9.6%)	0.01 ^{^^*}	0.1 (0.013-0.83)
Overall post-CS infectious morbidity	5(5.4%)	30(31.9%)	0.001 ^{^^*}	0.12(0.045-0.33)

*Statistically significant different. (p-values < 0.05), ** Highly statistically significant different. (p-values < 0.001), ^P-value for Chi Square test, ^^P-value for Fisher Exact test (FET)& CI=Confidence interval.

Table 3: Post-CS WBCs and CRP among the studied groups.

24 hours post-cesarean section	Intervention group (n= 92)	Control group (n= 94)	p-value#
WBCs (x10 ³ /mm ³)	10.4±1.9 (7-13)	11.3±2.4 (8.5-15.2)	0.005*
CRP (mg/dl)	25.3±6.4 (17.1-34.5)	27.9±5.2 (20.4-41.5)	0.002*

Data were presents as mean±SD (range), WBCs= White Blood Cells, CRP= C-reactive protein, #P-value for independent t-test. *Statistically significant different. (p-values < 0.05).

Discussion

A systematic review was done by **Haas et al.** to determine if post-CS infectious morbidities are reduced by preoperative vaginal cleansing with an antiseptic solution or not. They found that vaginal cleansing with betadine or chlorhexidine just before CS most probably decreased the risk of post CS endometritis when compared to saline or not cleansing (post CS endometritis incidence was reduced from 8.7% in control groups to 3.8% in vaginal cleansing groups). Postoperative fever and wound infection may be slightly reduced by preoperative vaginal cleansing. As a simple and inexpensive procedure, doctors may consider performing preoperative vaginal preparation with betadine or chlorhexidine before CS [6].

To our best knowledge, this is the first intervention to evaluate the effect of prophylactic administration of clindamycin vaginal suppository before elective CS on postpartum infectious morbidity. So, we will compare the results of our intervention with other studies using antiseptic preparations for vaginal cleansing before CS.

A randomized controlled intervention was performed by **Ahmed et al.** to determine if Chlorhexidine vaginal wipes before elective CS decreases maternal infectious morbidity or not.

They found that post-CS infectious morbidity was significantly decreased from 24.4% in the control group to 8.8% in the intervention group; p value <0.05. The incidence of endometritis was markedly decreased from 13.2% in the control group to 2.9% in the intervention group; p value <0.05. On the other side, fever and wound infection were not significantly reduced [14]. In our intervention the overall, post-CS infectious morbidity was significantly decreased from 31.9% in the control group to 5.4% in the intervention group; (p value=0.001). Marked reduction was seen in the incidence of endometritis (9.6% in the control group versus 1.1% in the intervention group; p value<0.05). In contrast to **Ahmed et al.** our intervention showed that, fever was reduced from 12.8% in the control group to 3.3% in the intervention group; and wound infection was reduced from 9.6% in the control group to 1.1% in the intervention group.

An intervention was performed by **Asghania et al.** to determine if preoperative vaginal cleansing with povidone-iodine decreases the risk of post CS infectious morbidity or not. They found that postpartum endometritis was reduced from 2.5% in the control group to 1.4% in the intervention group. However, fever and wound infection were not significantly reduced. They concluded that vaginal

cleansing with betadine may help in reducing the risk of post CS endometritis [4].

Yildirim et al. performed a randomized controlled trial to evaluate if preoperative vaginal cleansing with betadine decreases the risk of post CS endometritis or not. They found that post CS endometritis was reduced in the intervention group when compared to the control group. There was no significant difference between the two groups as regard fever and wound infection [1].

Göymen et al. performed an intervention to evaluate the effect of vaginal cleansing with povidone iodine versus benzalkonium chloride before CS on postpartum infectious morbidities. Povidone iodine group showed statistically significant reduction in both postoperative pain and CRP levels 24 hours after CS, when compared to the control group [15]. In our intervention there was statistically significant difference (p value=0.005) between the intervention group (received vaginal clindamycin) and the control group (received nothing) as regard white blood cells (WBC) count 24 hours after CS and, also there was statistically significant difference (p value=0.002) between both groups as regard C-reactive protein (CRP) 24 hours after CS with lower WBC count and C-reactive protein level in the intervention group.

Mohamed et al. performed an intervention to evaluate the effect of vaginal cleansing with Cetrimide solution before CS in decreasing post CS infectious morbidity. They found that fever and endometritis was statistically significantly decreased in the intervention group. There was no statistically significant difference as regard wound infection between both groups [16].

Starr et al. found in their intervention that preoperative vaginal cleansing with povidone iodine decreases the incidence post CS endometritis from 14.5% in the control group to 7% in the intervention group [17]. **Pitt et al.** found that the use of preoperative vaginal metronidazole reduces the incidence of post CS endometritis, most probably by decreasing the local exposure of anaerobic bacteria during CS [18]. Reid et al., found that vaginal cleansing did not decrease the incidence of post CS endometritis [2].

We can explain our results as follow: bacteria are naturally present in the vagina and cervix and could move up to infect the raw placental bed during or immediately after the CS. Vaginal clindamycin acts locally by decreasing the bacterial load in the lower genital tract specially the

anaerobes which cause endometritis. The use of antibiotics before or during CS is used to reduce the risk of infections, but some women still suffer from these complications as some antibiotics do not consistently eradicate all bacteria and antibiotic-resistant bacteria may also be present [19]. Systemic absorption of clindamycin during the 3 days before CS from the blood vessels surrounding the lower genital tract could explain its role in reducing postoperative fever and wound infection.

The present intervention had several strengths, including that it was a large prospective randomized controlled trial, and similar demographic and pregnancy profiles were found among those in both the experimental and control groups who subsequently developed post-caesarean infection. Active and easy identification of the cases through the use of our reliable sources added strength to this intervention. No negative side-effects were reported in the intervention group as the drug was given locally in the vagina. Compared to other studies, post-operative fever and wound infection were significantly reduced.

The major limitation in our intervention is lack of prior research studies on the same topic. To our knowledge, this is the first intervention which used clindamycin for vaginal preparation before CS. We did not test the benefits of clindamycin vaginal preparation among women with ruptured membranes and women who were in labor at the time of the caesarean delivery. Actually, our findings cannot be generalized as we need further studies in this field using larger sample size to prove or disprove our results.

Conclusion

We can conclude that prophylactic administration of clindamycin vaginal suppository before elective cesarean section reduces the risk of postpartum infectious morbidity namely endometritis, fever, wound infection and overall post-CS infectious morbidity. Preoperative clindamycin vaginal suppository could be protective against post-CS infectious morbidities. We recommend inserting clindamycin suppository vaginally for 3 days before the elective CS. More studies on larger sample size are needed to prove our results.

Declaration of interest

No conflict of interest or financial support. All authors have approved the final article.

Informed Consent

All patients gave an informed written consent before starting the intervention and had the right to leave the intervention at any time.

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