



THE EFFICACY OF THE VAGINAL WASH WITH POVIDONE IODINE SOLUTION BEFORE CAESAREAN SECTION TO PREVENT INFECTIOUS MORBIDITIES IN THE PATIENTS OF EASTERN INDIA

Obstetrics & Gynaecology

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ABSTRACT

Objectives: To evaluate the efficacy of the vaginal wash with povidone iodine solution before caesarean section (CS) to prevent infectious morbidities in the patients of eastern India. **Materials and Methods:** This investigation was a prospective observational study for the period of 16 months from January 2019 to June 2020. We enrolled 149 pregnant mothers in which 9 cases were excluded and finally 140 mothers considered. The total samples were equally distributed (n = 70 in each) for group A (povidone iodine solution used before CS) and group B (povidone iodine solution not used) in our setting. The demo-socio profiles and feto-maternal parameters were studied. **Results:** Post-operative endometritis between the groups was statistically significant (P=0.016). Comparison regarding age, religion, education, socio-economic status, BMI, gravida, parity and number of previous CS, indication of CS, period of gestation, pre- and post-operative Hb, fall in Hb, post-operative fever, birth weight, APGAR score (1 min. and 5 mins.), NICU admission required did not obtain significant changes. **Conclusion:** This study demonstrated that, for endometritis, vaginal preparation with a 5% povidone iodine solution before CS had a beneficial effect, especially for women who had intact membranes at the time of CS.

KEYWORDS

Endometritis, Eastern India, Post-caesarean Infectious Morbidity, Pre-operative Vaginal Wash, Povidone Iodine

INTRODUCTION

Since 1985, the international healthcare community has considered the ideal rate for CS to be between 10-15%. Since then, CS have become increasingly common in both developed and developing countries.^{1,2} As per the latest data (National Family Health Survey 2015-16 (NFHS-4), the CS rates at population level in India seem to be 17.2%.³

Infections, such as endometritis and surgical site infection (SSI), are one type of morbidity associated with CS. Since it has been documented that CS might have ten folds higher the risk of infection compared to vaginal delivery, which is a great concern.⁴

The use of prophylactic antibiotics for CS is supported by evidence to lower post-operative infections, the expense of hospitalization, and the length of stay by 60–70%.^{5,8} The rationale behind vaginal cleansing immediately before caesarean delivery is to reduce the bacterial count, as this is a major etiology of post-operative endometritis.⁹ The pathophysiology of endometritis is an ascending polymicrobial infection of cervical and vaginal normal flora to infect uterus.¹⁰ The bacterial species isolated in post-caesarean endometritis include gram-negative bacilli, aerobic and anaerobic gram-positive cocci, and anaerobic bacilli associated with bacterial vaginosis. Between 60% and 70% of infections are due to both aerobes and anaerobes.¹¹

The vaginal epithelium is cleaned with an antiseptic solution during vaginal preparation in order to lower the bacterial load and, in turn, lessen the risk of an ascending genital tract infection.¹² In women undergoing elective CS, Tewfik et al. analysed comparatively the effectiveness of chlorhexidine and povidone iodine in preventing postpartum endometritis and associated febrile morbidity.¹³ Hass et al. reported that povidone iodine was utilized before CS procedures, which reduced the risk of postpartum endometritis. Furthermore, the World Health Organization (WHO) already recommended the usage of povidone iodine for vaginal cleansing immediately prior to CS for reducing maternal infection morbidities.¹⁴ Some recent systematic reviews and meta-analyses revealed the efficacy of povidone iodine to prevent SSI and endometritis.^{15,16} But the study is lacking in the tertiary care hospital in the eastern part of India.

The objective of the present study was to evaluate the efficacy of the vaginal wash with povidone iodine solution before caesarean section to prevent infectious morbidities in the patients of eastern India.

MATERIALS AND METHODS

Study Design: A prospective, observational comparative study.

Study Area: This study was conducted in R. G. Kar Medical College

& Hospital among the indoor patients who required CS of the Department of Obstetrics and Gynaecology, Kolkata, India.

Duration of Study: This study was conducted for 16 months between January 2019 to June 2020.

Study Population: According to inclusion criteria of our study, antenatal mothers booked at antenatal clinic or admitted in labour room through emergency requiring elective Caesarean delivery in Obstetrics and Gynaecology department of R.G.KAR Medical College and Hospital.

Sample Size Calculation and Justification

A trial conducted by Guzman et al.¹⁷ indicated that postoperative endometritis was significantly less in the group receiving preoperative vaginal cleansing with povidone iodine compared to without cleansing group (2.5% vs 16.3%). Using these results as guidance data, sample size of 70 in each group was taken to show a significance level of 5% (z alpha= 1.96) and power of study was taken as 80% (z beta= 0.84). This study is non-randomized.

Patients calculated per group as per following formula:

$$n = [P1(1-P1) + P2(1-P2)] \times f(a, b) / (P2-P1)^2$$

$$= 149 \text{ samples.}$$

The group allocation was performed, and a flowchart is depicted in Fig 1.

*Women who did not give consent for the study (36 cases).

**Women who had received prior antibiotic therapy (2 cases), women who received blood transfusion for intraoperative blood loss (2 cases).

*** Women who had received prior antibiotic therapy (3 cases), women who received blood transfusion for intraoperative blood loss (2 cases).

As per the above-mentioned data, we considered group A and group B are as follows:

- Group A – Women with pre-operative vaginal cleansing with Povidone Iodine solution just before CS.
- Group B – Women with no such pre-operative vaginal cleansing before CS.

Therefore, each group had considered 70 patients.

Patients who were delivered by elective CS at term were included in the study as per inclusion & exclusion criteria. Informed written consent were taken from each study subject. Those who did not wish to give consent were excluded.

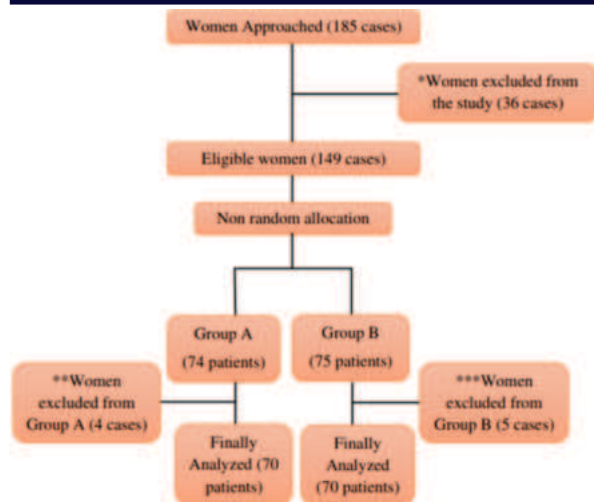


Fig 1: Group Allocation Representation

Inclusion Criteria

- Term singleton pregnancy undergoing elective CS.
- Haemoglobin >9 gm%.
- Immunocompetent.

Exclusion Criteria

- Diabetic women.
- Any form of compromised Immune status like HIV, HBsAg or Anti HCV positive, history of Leukemia or history of Chemotherapy or Radiation Therapy in last 6 months before conception, post-transplant patients or any patient with Autoimmune disorders taking Immuno-modulator drugs.
- Haemoglobin <9gm%.
- Patients who underwent CS elsewhere and transferred to R. G. Kar Medical College & Hospital.
- Any intra-operative complication like haemorrhage, blood transfusion.
- Emergency CS with complications like haemorrhage, blood transfusion.
- History of fever on receiving antibiotics in 7 days preceding CS.
- History of premature or prolonged rupture of membrane.

Study Variables

Patient's demo-socio profiles and feto-maternal parameters were obtained at the time of inclusion.

Variables

1. Age
2. Religion
3. Body Mass Index (BMI)
4. Educational status
5. Socio-economic status
6. Parity
7. Gravidity
8. Gestational age
9. Indication of CS
10. Birth weight of baby
11. Apgar score
12. NICU admission
13. Incidence of postoperative endometritis
14. Incidence of pre- and post-operative Hb
15. Incidence of postoperative fever.

Procedure

A detailed medical & obstetrical history, complete medical & obstetrical examination was done. Laboratory tests were done according to need. In our hospital, elective caesarean section is performed by senior residents and consultants of respective units. Commonly for women with no pre-operative vaginal cleansing only abdominal preparation with povidone iodine solution is done immediately before caesarean section. For women with pre-operative vaginal cleansing, before abdominal preparation, Vaginal preparation was done with two gauzes sponge impregnated with 5% povidone iodine. Each gauze sponge was rotated 360° in all parts of the vagina especially in the fornices and also in the vaginal walls. The preparation process lasted for 30 seconds, in both the groups, abdominal

preparation was done with 5% povidone iodine solution. All women received the standard antibiotic prophylaxis as our institutional protocol. All women received the routine postoperative care without other intervention before discharge from hospital. During hospital stay the women were assessed for post-partum morbidity as fever, endometritis and wound infection. Routinely, sutures were removed on 6th post-operative days and patients were discharged with advice of routine postoperative care on 7th postoperative day if no complications developed. Those who developed any wound complication were discharged after proper wound management.

The Following Outcomes were Noted

Postoperative endometritis, surgical site infection, wound seroma, wound dehiscence, postoperative fever, duration of hospital stays post-operatively, need for hospital readmission and need for secondary suturing.

Data Collection and Interpretation

Data were collected from detailed history taking, examination and case sheets of the subjects. They were entered and recorded into the study proforma. The data were then be studied, analysed and compared with suitable statistical methods and correlation between different findings were established.

After applying the exclusion criteria, eligible women were enrolled in the study. Then women were divided into two groups (A & B) alternatively, 115 women in each arm, once the patient had consented to take part in the study after the procedure, process, aims and prospective results has been properly explained to her in her own language. The women were selected. After counselling and informed consent, a detailed history was taken from every study woman.

Statistical Analysis

For statistical analysis, the relief of symptoms and efficacy had been evaluated by validated questionnaire on follow up visits at 3 and 6 months of the treatment. Data were entered into a Microsoft Excel spreadsheet and then analysed by SPSS (version 23.0; SPSS Inc., Chicago, IL, USA). The data categorical variables were expressed as frequency and percentage (%). The data of continuous variables were expressed as mean $\pm$ standard deviation ($M \pm SD$). Chi-square test was used for categorical data and Independent Students t-test was used for continuous data. Statistical significance in all evaluations were considered $P < 0.05$.

RESULTS

Table 1 describes the baseline parameters between group A and B. Comparison regarding age, religion, education, socio-economic status, BMI, gravida, parity and number of previous CS did not observe significant changes.

Table 1: Baseline Parameters Between Group A and B

Variables	Group A (n = 70)	Group B (n = 70)	P value
Age in years (n, %)			
16-20	17 (24.3%)	19 (27.1%)	P = 0.772
21-25	29 (41.4%)	31 (44.3%)	
26-30	23 (32.9%)	18 (25.7%)	
>30	1 (1.4%)	2 (2.9%)	
Religion (n, %)			
Hindu	11 (15.7%)	9 (12.9%)	P = 0.889
Islam	55 (78.6%)	57 (81.4%)	
Others	4 (5.7%)	4 (5.7%)	
Education (n, %)			
No formal education	3 (4.3%)	4 (5.7%)	P = 0.565
Primary	11 (15.7%)	6 (8.6%)	
Secondary	30 (42.9%)	38 (52.3%)	
Higher secondary	22 (31.4%)	18 (25.7%)	
Graduation	4 (5.7%)	4 (5.7%)	
Socio-economic status (n, %)			
Lower	5 (7.1%)	9 (12.9%)	P = 0.492
Lower middle	21 (30%)	16 (22.9%)	
Upper lower	29 (41.4%)	33 (47.1%)	
Upper middle	15 (21.4%)	12 (17.1%)	
Body mass index (Kg/m2, M ± SD)	20.70 ± 1.840	20.49 ± 1.770	P = 0.483
Gravida (n, %)			

Primigravida	24 (34.3%)	22 (31.4%)	P = 0.719
Multigravida	46 (65.7%)	48 (68.6%)	
Parity (n, %)			
Nullipara	26 (37.1%)	22 (31.4%)	P = 0.431
Primipara	11 (15.7%)	17 (24.3%)	
Multipara	33 (47.1%)	31 (44.3%)	
No. of Previous CS (n, %)			
0	48 (68.6%)	50 (71.4%)	P = 0.932
1	21 (30%)	19 (27.1%)	
2	1 (1.4%)	1 (1.4%)	

Table 2 describes the obstetrics parameters between group A and B. Comparison regarding indication CS and period of gestation did not obtain significant changes.

Table 3 describes the maternal and fetal outcomes between group A and B. Comparison regarding pre- and post-operative Hb, fall in Hb, post-operative fever, birth weight, APGAR score (1 min. and 5 mins.), NICU admission required did not obtain significant changes. But post-operative endometritis between the groups was statistically significant (P=0.016).

Table 2: Obstetrics Parameters Between Group A and B

Variables	Group A (n = 70)	Group B (n=70)	P value
Indication (n, %)			
Post Caesarean pregnancy at term	20 (28.6%)	17 (24.3%)	P = 0.973
Severe Pre-eclampsia	10 (14.3%)	8 (11.4%)	
Obstetric Cholestasis	8 (11.4%)	9 (12.9%)	
Breech Presentation	7 (10%)	10 (14.3%)	
Oligohydramnios	7 (10%)	9 (12.9%)	
Pathological CTG	7 (10%)	6 (8.6%)	
IUGR	5 (7.1%)	4 (5.7%)	
Abnormal Doppler Study	4 (5.7%)	6 (8.6%)	
Maternal Request	2 (2.9%)	1 (1.4%)	
Period of gestation (Weeks, M ± SD)	38.49 ± 1.073	38.59 ± 1.097	P = 0.586

Table 3: Maternal and Fetal Outcomes Between Group A and B

Variables	Group A (n = 70)	Group B (n = 70)	P value
Pre-operative Hb (gm/dl, M ± SD)	11.201 ± 1.035	11.287 ± 0.910	P = 0.604
Post-operative Hb (gm/dl, M ± SD)	10.096 ± 1.023	10.171 ± 0.886	P = 0.641
Fall in Hb (gm/dl, M ± SD)	1.058 ± 0.161	1.073 ± 0.144	P = 0.750
Post-operative endometritis (n, %)			
Yes	2 (2.9%)	10 (14.3%)	P = 0.016
No	68 (97.1%)	60 (85.7%)	
Post-operative fever (n, %)			
Yes	10 (14.3%)	15 (21.4%)	P = 0.270
No	60 (85.7%)	55 (78.6%)	
Birth weight (Kg, M ± SD)	2.703 ± 0.324	2.753 ± 0.295	P = 0.341
APGAR score of neonates at 1 min. (n, %)			
<7	13 (18.6%)	12 (17.1%)	P = 0.825
≥7	57 (81.4%)	58 (82.9%)	
APGAR score of neonates at 5 mins. (n, %)			
<7	8 (11.4%)	9 (12.9%)	P = 0.796
≥7	62 (88.6%)	61 (87.1%)	
NICU admission required (n, %)			
Yes	8 (11.4%)	9 (12.9%)	P = 0.796
No	62 (88.6%)	61 (87.1%)	

DISCUSSION

Endometritis is a postpartum infective complication that is more common after caesarean delivery compared to vaginal delivery. A fever of at least 100.4°F, fundal soreness, and purulent discharge from the uterus are all symptoms of postpartum endometritis, which is caused by a polymicrobial infection of the uterine decidua.^{18,19}

Over the years, as rates of caesarean section increased worldwide, obstetricians were prompted to search for some cost-effective prophylactic measure to reduce post-caesarean endometritis and its

impact on maternal and child health and healthcare systems. There has been a growing interest in evaluating the possible advantages of cleansing the vagina before surgery. In order to reduce the likelihood of postoperative endometritis, particularly in those who are in labour or have a ruptured membrane, vaginal preparation prior to a CS has been shown to be effective.²⁰

In the present study, post-operative endometritis was lower frequency in the cases of group A when compared to group B, which was observed statistically significant (P=0.016). Similar findings regarding the efficacy of Povidone Iodine solution were reported by many investigators.^{13,14,15,16}

As a result, the current research showed that vaginal preparation with povidone-iodine solution right before a caesarean delivery reduced the risk of postoperative endometritis in women with preterm membrane rupture. The evidence indicates that using povidone-iodine to clean the vagina reduces the chance of post-operative endometritis.^{12,20}

CONCLUSION

All measures must be taken to lower the risk of infection after a CS. One such attempt was the preoperative vaginal washing procedure using 5% povidone iodine. This prospective observational study demonstrated that, especially for endometritis, vaginal preparation with a 5% povidone iodine solution before CS had a beneficial effect, especially for women who had intact membranes at the time of CS.

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Conflict of Interest: Authors declare no conflict of interest.

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