VAGINAL CLEANSING BEFORE EMERGENCY CESAREAN SECTION AND POST-OPERATIVE INFECTIOUS MORBIDITY; CLINICAL TRIAL IN A LOW RESOURCE SETTING

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ABSTRACT

Objective: To assess the effectiveness of preoperative vaginal cleansing by looking at the frequency of infectious morbidity after emergency cesarean section.

Methodology: A randomized trial of patients, aged 15-45 years, in labour for > 6 hours, was conducted from May 2019 to December 2019 at the Department of Obstetrics and Gynaecology, Women and children Teaching Hospital, Bannu. A total of 400 patients at term gestation were included and assigned to either the interventional; "Vaginal cleaning" or the control; "No vaginal cleaning" groups, based on whether they received vaginal cleansing only or vaginal cleansing as well as abdominal cleansing or not. The development of infectious morbidity was assessed by following all patients up to six weeks postoperatively.

Results: The age of the women was in the range of 24-38 years. In interventional versus control groups, the frequency of fever was 8 (6%) versus 17 (11%) (p=0.149), and wound infection was 15 (17.5%) versus 16 (8%) (p=0.851) respectively. There was a significant reduction in the frequency of postoperative endometritis, 4 in the interventional group and 18 in the control group (p=0.00). However, on further analysis, in patients with a history of premature rupture of membranes (PROM), there was a significantly lower incidence of endometritis, fever, and postoperative wound infection in the intervention groups (p=0.00).

Conclusions: Using preoperative antiseptic for vaginal cleaning decreases the incidence of postoperative endometritis, more significantly in women with a history of PROM in patients undergoing emergency cesarean section.

Keywords: Vaginal cleansing; Emergency cesarean section; Endometritis; Wound infection.

INTRODUCTION

Worldwide, the incidence of cesarean delivery is, accounting for one-third of deliveries in the USA.[1] However, it is associated with significant morbidities such as urinary tract infections, pyelonephritis, endometritis, postoperative wound infections, and pneumonia.[2] Postpartum endometritis occurs in 6-27% of patients, being more common post-cesarean section than vaginal delivery. It usually presents as fever, offensive vaginal discharge, pain lower abdomen and menorrhagia.[3,4] There are numerous risk factors associated with postpartum infectious morbidity after cesarean section, including prolonged labor, prolonged rupture of membranes (PROM), repeated vaginal examinations, maternal anemia, obesity, pre-existing pelvic and vaginal infection, and diabetes.[5] Various methods have been used to lower the incidence of postoperative infections.

These include hair clipping, antiseptic showering, avoiding manual delivery of the placenta, cervical dilatation during a cesarean, and changing surgical techniques.[6] The use of preoperative antibiotics and antiseptic solution for abdominal preparation have been employed as the standard practice to reduce the risk of infectious morbidities after surgery.[7] Literature reports heterogeneous results regarding preoperative vaginal cleaning in reducing the frequency of postoperative infections.[8,9] A study of 200 women, assessing the effect of vaginal cleaning preoperatively in a tertiary care hospital in Pakistan, has shown a significant reduction in the frequency of postoperative infections.[10] However, there is limited local data available on this problem. Due to the high prevalence of postoperative infectious morbidity in our hospital, we aimed to conduct a trial to see the effect of preoperative vaginal cleansing on postsurgical infections.

METHODOLOGY

We conducted a randomized trial (ACTRN12622000336785) at the Department of Obstet-

rics and Gynaecology, Women and children Teaching Hospital, Bannu from May 2019 to December 2019 using a non-probability consecutive sampling method. A sample size of 400 was calculated using WHO software, with a confidence interval of 95% and 5% margin of error, and 200 patients were included in each group. After obtaining informed consent, the women were randomly divided using computed blocks into the "Vaginal cleaning" and the "No vaginal cleaning" group. A total of 200 numbers were randomly generated from a pool of 400 numbers, and they were included in the "Vaginal cleaning" group while the other 200 patients were included in the No vaginal cleaning group. The inscription "Vaginal cleaning" group or No vaginal cleaning group was written on paper that was kept inside the envelopes and then sealed. All the eligible candidates were assigned sequential numbers and allocated the envelopes.

Two medical officers were assigned to include patients in the study. A third medical officer, who was not part of the study sample selection, was assigned to randomization of patients.

We included all patients at 37 to 41+6 weeks gestation, who had emergency cesarean section after more than six hours of labour. We excluded women with hemoglobin less than 7g/dl, fever ≥38°C, heavy vaginal bleeding, obstructed labor, and clinical chorioamnionitis. The outcomes of this study were to see for complications like wound infection, endometritis, and fever. Endometritis is diagnosed as having uterine tenderness and offensive vaginal discharge up to three weeks postoperatively. Postoperative fever is defined as any temperature of 38°C, 24 hours after cesarean delivery. Wound infection was taken as erythema, wound edges separation with associated pussy discharge, requiring treatment.

Vagina was cleaned with two gauzes using povidone-iodine 10% in the intervention group only. Each gauze was rotated 360-degrees in the vagina for half a minute. Povidone-iodine was also used for abdominal cleansing using 3 gauze sponges in both groups. A structured proforma was used for the data collection on variables like age, education, BMI, parity, full blood count preoperatively and postoperatively.

The two groups were followed up by a consultant blinded to the allocation of both groups, at one and six weeks postoperatively. SPSS-20 was used for data analysis. Quantitative data were expressed as the median and interquartile range (IQR), while frequency and percentages were used to present categorical data like fever, endometritis, and wound infection. To compare complications in both groups, the Chi-square test was used. A p-value of ≤ 0.05 was taken as statistically significant. The hospital's ethical review committee approval was taken prior to conducting the study (206 (A)/BMC/2017).

RESULTS

The median age was 35 years (25-38) in the "No vaginal cleaning group" and 32 years (24-38) in the Vaginal cleaning group respectively. The median BMI of both groups was 36 (29-37) and 36 (36-37) respectively. Age, education, hemoglobin, and pre and postoperative white blood cell count in both groups were not statistically different (Table 1). Overall, 120 (30%) patients presented with PROM. The frequency of postoperative fever was 8.5%, wound infection was 7.75%, and endometritis was 5.5% in the two groups. Endometritis occurred significantly more in the control group, (p< 0.00), especially in women with ruptured membranes. Unlikely, the frequency of postoperative fever and wound infections in the two groups did not differ significantly (p< 0.07 and p< 0.85 respectively) (Table 2). There was a significantly low frequency of fever, endometritis, and wound infection in women with a history of PROM in the intervention group (p=0.00) (Table 3). All wound infections were treated with antibiotics and local wound care while broad-spectrum antibiotics given intravenously were used for treating endometritis and all eventually recovered.

DISCUSSION

Our study showed that vaginal cleaning in addition to abdominal washing, before emergency cesarean delivery resulted in a significant difference in postoperative endometritis. There was a reduction in wound infection (p <0.85) and fever (p<0.07) but it was not significant. However, on sub-analysis, the incidence of both wound infection and fever became significant in patients with a history of PROM (p-value<0.00).

A vast literature is available to see the effect of preoperative vaginal washing with antiseptic solutions preoperatively.[11] Osborn et al. evaluated the role of vaginal and perineal scrubbing in decreasing bacteria and showed a 48% reduction in vaginal bacterial flora with a vaginal wash before surgery using povidone-iodine.[12] Ogah et al. and Pitt et al. also demonstrated a significantly low rate of wound infection using chlorhexidine vaginal washing and vaginal metronidazole respectively.[13,14]

Few studies in the literature have used povidone-iodine for vaginal washing before cesarean section showing varying results.[8,9] Similar to the findings of our study, a clinical trial of 434 patients conducted in the Department of Obstetrics and Gynecology of a tertiary care hospital Islamabad, Pakistan, reported a significant reduction in post-cesarean endometritis, using preoperative povidone-iodine for vaginal cleansing with povidone-iodine.[15] A Cochrane review of than 3,400 women and 11 trials on preoperative vaginal cleaning prior to cesarean section showed a reduction in the incidence of endometritis from 8.7% to 3.4% and wound

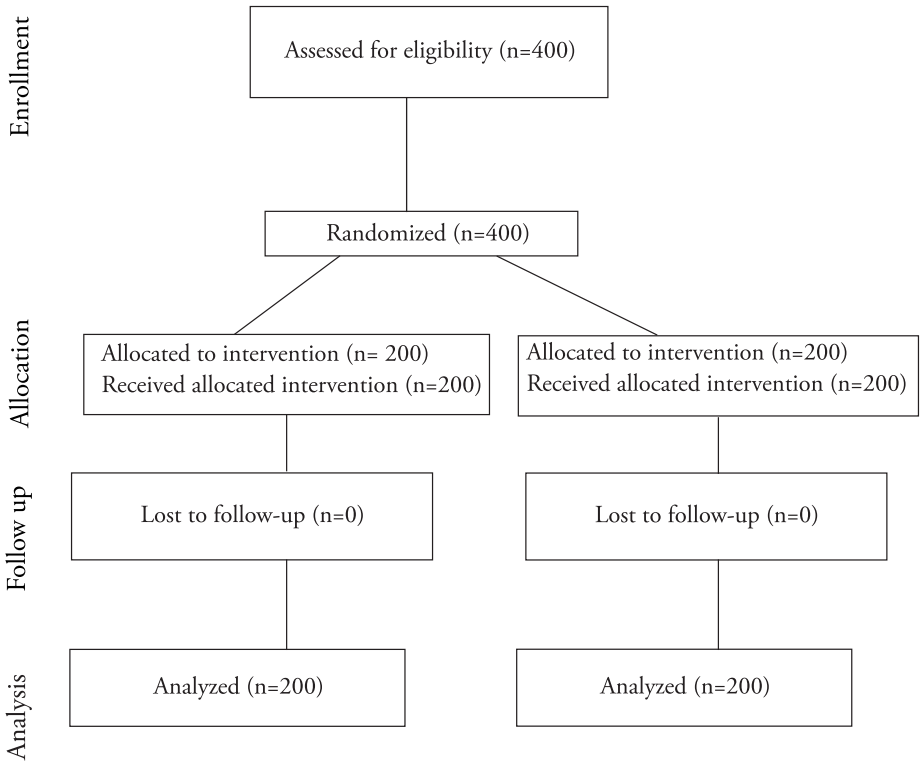

Figure 1: CONSORT Flow Diagram

Table 1: Characteristics of subjects in both groups

Variables		Vaginal cleaning group (n = 200)	No vaginal cleansing group (n = 200)	p-value
Age	15-24 Years	48 (24%)	50 (25%)	0.82
	25-34 Years	49 (24.5%)	53 (26.5%)	
	35-45 Years	103 (51.5%)	97 (48.5%)	
Education	Uneducated	103 (51.5%)	109 (54.5%)	0.73
	Primary	58 (29%)	53 (26.5%)	
	High school	26 (13%)	29 (14.5%)	
	University	13 (6.5%)	09 (4.5%)	
Gravidity	≤2	111 (55.5%)	103 (51.5%)	0.42
	>2	89 (44.5%)	97 (48.5%)	
Body Mass Index (kg/m2)	≤30	59 (29.5%)	41 (20.5%)	0.03
	>30	141 (70.5%)	159 (79.5%)	
Hemoglobin, before surgery	≤ 10	64 (32%)	59 (29.5%)	0.58
	>10	136 (68%)	141 (70.5%)	
Hemoglobin, after surgery	≤ 11	51 (25.5%)	44 (22%)	0.41
	>11	149 (74.5%)	156 (78%)	
White Blood Cells before surgery	≤10000/mm^3	139 (69.5%)	151 (75.5%)	0.17
	>10000/mm^3	61 (30.5%)	49 (24.5%)	
White Blood Cells after surgery	≤11000	46 (23%)	34 (17%)	0.13
	>11000	154 (77%)	166 (83%)	

infections by about 50%. This was more pronounced in those with preoperative PROM. Most studies employed povidone-iodine for vagina preperation. All the solutions used were safe with no reported adverse complications in the mother or baby.[16] According to Amstey et al, vaginal cleansing decreases not only gram-positive and gram-negative rods, but also anaerobes, and enterococci.[17]

Unlike our study, a randomized trial of term pregnant women who underwent elective cesarean section did not show any significant decrease in postoperative infections. The incidence of postoperative endometritis was 7.5% in the control group and 5.5% in the experimental group (RR= 0.86; 95% confidence interval, 0.61 –1.21; P=0.417). Similarly, the frequency of fever and wound infection also didn't vary significantly between the groups. However, this study enrolled elective cesarean delivery patients only and excluded patients with PROM.[18] Likewise, Reid et al. showed a non-significant effect of preoperative vaginal preparation on the risk of fever and wound infection.[9] The association between PROM and postoperative infectious morbidity is widely reported in the literature.[19]

The strengths of our study are its large sample size to find the primary outcome, its randomization of subjects to avoid bias, and the use of standardized antibiotic prophylaxis in both groups. We followed all the patients to ensure maximum follow-up and to keep track of the study outcomes. To limit bias, data analysis, and postoperative follow-up were done by consultants unaware of the randomization of patients.

This study has certain limitations like its single centered and all the procedures were not performed by the same surgeon. Futher, we followed patients only till six weeks with the possibility of missing patients who developed these complications later on. Future research is recommended to see the effect

Table 2: Overall postoperative infectious morbidities in both groups (n=400)

Variables	Vaginal cleaning group (n = 200)	No vaginal cleaning group (n = 200)	p-value
Fever	8 (6%)	17 (11%)	0.07
Wound infection	15 (7.5%)	16 (8%)	0.85
Postoperative Endometritis	4 (2%)	18 (9%)	0.00

Table 3: Postoperative infectious morbidities in both groups (n=120)

Variables	Vaginal cleansing group (n= 88)	No vaginal Cleansing (n= 32)	p-value
Fever	8 (9%)	17 (53%)	0.00
Wound Infection	15 (17.4%)	16 (50%)	0.00
Postoperative Endometritis	4 (4.5%)	18 (56.2%)	0.00

of vaginal cleansing on infectious morbidities over a longer duration.

CONCLUSION

There is a significant reduction in the frequency of endometritis after emergency cesarean sections with preoperative vaginal preparation using povidone-iodine. However, women with a longer duration of PROM revealed a significant decline in postoperative fever and surgical site infection also. Since it is not expensive, and safe, it should be employed in vaginal cleansing along with abdominal preparation preoperatively, especially in resource settings.

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Author's Contribution

SA conceived the idea and drafted the manuscript, while ES contributed to the data analysis. SSH played a crucial role in collecting the data and assisting in the write-up of the manuscript. Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of Interest

Authors declared no conflict of interest

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None

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.