Vaginal Preparation with Antiseptic Solution before Cesarean Section for Reducing Post partum Morbidity

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Abstract: The aim of this study was to investigate the effect of vaginal preparation with antiseptic solution (cetrimide) before cesarean section for reducing post partum morbidity. Design: A quasi-experimental design was utilized in this study. Setting: This study was conducted at the operative room of Obstetrics and Gynecologic Department in Mansoura University Hospital from May 2014 until August 2014. The study Subjects included 200 pregnant women undergoing elective cesarean delivery, who were selected by purposive sampling technique, then divided into control and intervention group 100 per each group. The intervention group: receive vaginal cleaning before cesarean section by antiseptic Cetrimide and standard abdominal scrub. Control group: receive standard abdominal scrub only. Tool was used of data collection included: general data and anthropometric measures, data related to C.S type and time and data related to follow up as fever, wound infection and endometritis. Study results: Shows there was statistically significant difference regards fever and endometritis among both groups, while there was no statistically significant difference was found regards wound infection. Conclusion: Using antiseptic Cetrimide (Setavlon) for cleaning the vagina before cesarean section decreased the occurrence of postpartum morbidity as fever and endometritis.

Key words: Antiseptic Cetrimide, Cesarean Section, Post partum Morbidity, Vaginal Preparation.

1. Introduction

Cesarean delivery is a surgical delivery of the baby. It is the highest surgical procedure performed by obstetricians (Belfort et al.,2010). Cesarean section deliveries represent a large percentage of all births worldwide (Boyle and Reddy,2013) for example, in the US, cesarean delivery represents 30% of all births and operation represents the most common method of major surgery for women (MaDorman et al., 2008). In Egypt, the caesarean section rate is 22%, with higher rates observed in private hospitals (Khawaja et al., 2004)

For women undergoing Caesarean range 5-20 times more susceptible to infection than are women with normal vaginal delivery. Infectious complications after cesarean delivery is a major cause of maternal morbidity and perhaps prolong the stay in the hospital. These include fever, sore wounds and inflammation of the lining of the uterus after childbirth (Mohamed, 2014).

The rate of post cesarean section infection varies from 7-20% depending on operating time, maternal body mass index, duration of labor, number of vaginal examinations during labor, the amount of blood loss, emergency or elective caesarean delivery and surgeon experience (Mona,2013).

Post cesarean wound infection and endometritis still a serious morbidities, in spite of use of strategies to prevent these complications with respect to patient complain, patient cost, use of antibiotics and prolonged hospital stay. The risk of post cesarean infectious morbidity is reported to range from 5-85%.The most recognized risk factors for developing post cesarean endometritis involve pathways that introduce high quantities of bacteria into the uterine cavity (Ameer, 2009).

Preoperative vaginal cleansing by povidone-iodine before hysterectomy reduces the incidence of postoperative infectious morbidity (Haas, 2012). Also (Ameer, 2009) showed that preoperative vaginal cleansing with povidone -iodine decreases the incidence of post-caesarean endometritis. But there is little information in the literature on the use of preoperative vaginal preparation with antisepic Cetrimide (Setavlon) as a prophylactic against infectious morbidity subsequent Caesarean section. So the aim of this study was to investigate the effect of using antiseptic Cetrimide for cleaning the vagina before cesarean section to reduces the risk of postpartum morbidity, including fever, endometritis and wound infection.

Operational definitions
Postpartum endometritis: defined as presence of fever, purulent lochia and fundal tenderness, needed antibiotic therapy

Postoperative wound infection: defined as erythema, purulent drainage from the site of operation and tenderness with or without fever, requiring antibiotic therapy.
Postoperative fever defined: as body temperature more than 38 degrees

Significant of the study:
Puertial infection rate remains the most common causes of morbidity and mortality in developing countries. With an estimated 5-20-fold increase in the incidence, CS is the most important factor in the possibility of puertial infection (Olsen et al., 2008). Postpartum infectious morbidity after cesarean delivery effect women return to normal function and potentially its junction with the infant. It can also cause worthy medical problems and sequelae. Find an easy and inexpensive method to decrease this risk could have major, effect on public health in both developed and developing countries

Aim of the study: The aim of this study was to investigate the effect of vaginal preparation with antiseptic solution (cetrimde) before cesarean section for reducing post partum morbidity.

Research hypothesis: The women who are undergoing vaginal preparation with antiseptic solution (cetrimde) before cesarean section will have less post partum morbidity.

II. Materials and Method

Research design: Quasi- experimental design was utilized in this study

Research Setting: This study was conducted at the operative room of Obstetrics and Gynecologic Department in Mansoura University Hospital from the period of May 2014 until August 2014.

Subjects of the study:
A total of 200 pregnant women undergoing elective cesarean delivery were recruited in the study. The subjects were divided into two groups:

Group (A): intervention group: consisted of 100 pregnant women who receiving vaginal cleaning before cesarean section by antiseptic Cetrimide solution and standard abdominal scrub.

Group (B): Control group: consisted of 100 pregnant women who receiving standard abdominal scrub only.

Inclusion criteria:-
1- Full term pregnant women. 2- Elective cesarean delivery  3- Age ranged between 20 -35 years.

Exclusion criteria:-
- Women who are at risk for developing postpartum infection as premature rupture of membranes, diabetes mellitus, anemia.
- History of post cesarean section infection, obstructed labor, or preeclampsia
- Women whose given history of being allergic to antiseptic Cetrimide solutions.

Sample size:
A total of 200 pregnant women undergone elective cesarean delivery were recruited in the stud. Sample size was calculated by using spss sample power 3. The pilot study revealed that the incidence of endometrits were 10% and 25% both intervention and control groups respectively. With alpha error of 5% and study power of 80% the sample size 100 in each group.

Sampling Technique:
Purpose sample was recruited for the study. Women were undergoing elective cesarean section at the study setting were included in the study until the sample size was completed. By random assignment, the intervention and control group were assigned. From the prepared list of caesarian section the odd numbers were recruited as the intervention group and the even numbers are recruited as control group.

Written Approval
A letter containing the title and aim was directed to the director of Mansoura University Hospital then the approval for data collection was obtained. The aim of the study was explained to each woman before applying the study to gain their confidence and trust. Witten consent was obtained from each woman to participate in the study, after ensuring that data collected will be treated confidentially. All ethical considerations were clarified to each woman before explaining the nature of the study.

Tool for data collection
The tool of data collection consists of three part:
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Part I: Includes general data and anthropometric measures as age, para, gravid and weight.
Part II: Includes data related to C.S type and time and hospital stay.
Part III: Includes data related to follow up after one week as (fever, wound infection and endometritis).

Development of Study Tools Validity

Tool used in the study were developed by the researchers after reviewing of the current local and international related literatures using books, articles and scientific magazines. This helped them to be acquainted with the problem, and guided them in the process of tools' designing. Tool was reviewed by jury of 3 expertise's in the field of the study to test its contents and face validly.

A Pilot study

A pilot study was conducted on 20(10%) woman from the aforementioned setting to measure the feasibility of the study setting , content validity of the tools and time required for the completion of each tool. Results obtained were useful in appraisal and modification of the tools; these subjects were later excluded from the study sample.

Field work
- Collection of data covered a period of 4 months from beginning of May 2014 until end of August 2014. The researcher attained predetermine setting 3 days per week.
- The intervention and control group were assigned; where the odd numbers were recruited as intervention group and the even numbers are recruited as control group.
- Women were assessed and their medical records were reviewed according to inclusion and exclusion criteria, paternal demographic details were recorded along with the indication of caesarean section, the suitable cases were asked to give written consent for participation in study.
- At operating room, intervention group received vaginal cleaning by50cc of diluted antiseptic Cetrimide (Setavlon) (0.5 cc Setavlon and 49.5 cc of tape water ) used as a single syringe one push in the vagina. antiseptic Cetrimide contains 0.3% Chlorhexidine gluconate and 0.3%Stremed after anesthesia is given to the woman and before scrubbing of the abdomen by the nursing staff. The control group received the standard abdominal scrub only, then after that at the end of operation estimated the time that operation take.
- Then the cesarean delivery was performed. All women were receiving the standard antibiotic prophylaxis during and after the operation.
- All women received the routine post operative care without other intervention before discharge from hospital, the women estimated for the time of stay in hospital before discharge.
- After 1 week the women return to outpatient clinic for assess postpartum morbidity as fever, endometritis and wound infection.

Statistical Analysis

Statistical Package for Social Sciences (SPSS) version 17.0 was used for quantitative data analysis. Quality control was done at the stages of coding and data entry. Data were presented using descriptive statistics in the form of frequencies and percentages for qualitative variables, and means and standard deviations for quantitative variables. Qualitative variables were compared using T test and Correlation (r) test. Cronbach’s α (alpha) is used for test score reliability measure of sample Statistical significance was considered at p-value <0.05, highly significant difference obtained at P < 0.01 and non significant difference obtained at P > 0.05.

III. Results

Table (1): General Data and anthropometric Measure between Intervention and Control Groups:

<table>
<thead>
<tr>
<th>Variable</th>
<th>Interventions Group (100)</th>
<th>Control group (100)</th>
<th>Significant test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age Mean± SD.</td>
<td>27.850±4.987</td>
<td>27.870±4.967</td>
<td>t=0.03, p=0.98 ,NS</td>
</tr>
<tr>
<td>Gravid Mean± SD.</td>
<td>1.610±0.723</td>
<td>1.600±0.681</td>
<td>t=0.1, p=0.92 ,NS</td>
</tr>
<tr>
<td>Para Mean± SD.</td>
<td>1.2700±5.09</td>
<td>1.230±0.422</td>
<td>t=0.6, p=0.55 ,NS</td>
</tr>
<tr>
<td>Weight Mean± SD.</td>
<td>77.430±9.975</td>
<td>82.260±10.894</td>
<td>t=3.3 , p=0.001</td>
</tr>
</tbody>
</table>
Table (1) presents data related to general and anthropometric measure between intervention and control groups, there was no statistically significant difference between both groups regarding to maternal age, gravid and Para p value > 0.05. While there was highly statistically significant difference between both groups regarding to maternal weight p = 0.001.

### Table (2): Comparison between Both Groups as Regards Types and Causes of Cesarean Section:

<table>
<thead>
<tr>
<th>Items</th>
<th>Intervention (100)</th>
<th>Control (100)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NO</td>
<td>%</td>
<td>NO</td>
</tr>
<tr>
<td>C.S Type</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Primary                 | 36     | 36%   | 49     | 49%   | x= 3.45  
| Secondary               | 64     | 64%   | 51     | 51%   |

| Causes of CS            |        |       |        |       |        |
|-------------------------|        |       |        |       |        |
| Previous cs             | 38     | 38%   | 44     | 44%   | x=2.6, p=0.76 NS |
| Malpresentation or position | 30 | 30%  | 23     | 23%   |
| Maternal distress       | 7      | 7%    | 11     | 11%   |
| Fetal distress          | 11     | 11%   | 11     | 11%   |
| Premature rupture of membranes | 5 | 5%   | 4      | 4%    |
| Suspected Macrosomic    | 9      | 9%    | 7      | 7%    |

Regarding to types and causes of cesarean section: Table (2) shows (36%) of intervention group had primary C.s compare to (49%) of control group and (64%) of intervention group had secondary C.s compare to 51% of control group there no statistically significant difference was found. Also this table shows that the most common cause of c.s is previous c.s (38% ) of intervention group compare to(44% ) of control group and(30%) of intervention group had malpresentation and position compare to (23%) of control group. There no statistically significant difference was found between both groups.

### Table (3): Comparison between both Groups as Regards Cesarean Section Time

<table>
<thead>
<tr>
<th>variable</th>
<th>Interventions Group (100)</th>
<th>Control Group (100)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cs Time Mean ± SD.</td>
<td>41.580±14.714</td>
<td>40.160±12.515</td>
<td>t=0.74, p=0.46 NS</td>
</tr>
</tbody>
</table>

Table (3) shows no statistically significant difference between both groups regarding to cesarean section time.

**Fig (1): Comparison between both groups as regards hospital stay**

**Hospital Stay among studied groups**

- 9% stay 1 day in intervention group
- 91% stay 1 day in control group
- 10% stay 2 day in intervention group
- 90% stay 2 day in control group

**Fig 1** shows that duration of hospital stay ranged from one to two days. About 91% of mother in intervention group stay one day compare to 90% in control group. There was no statistically significant difference between both groups regarding hospital stay.
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Table 4: Comparison between both Groups as Regards Post operative Fever , Wound Infection and Endometritis after one week

<table>
<thead>
<tr>
<th>Items</th>
<th>Intervention (100)</th>
<th>Control (100)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NO</td>
<td>%</td>
<td>NO</td>
</tr>
<tr>
<td>Fever</td>
<td>10</td>
<td>10%</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wound infection</td>
<td>5</td>
<td>5%</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endometritis</td>
<td>6</td>
<td>6%</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

Table (4) shows that there was statistically significant difference regards fever and endometritis among both groups. While there was no statistically significant difference found regards wound infection among both groups.

IV. Discussion

Cesarean section operation are frequently complicated by postpartum morbidities as wound infection, and endometritis. These morbidities causes pain and discomfort, longer hospital stay, delay in a return to normal function (French and Smaill,2000).

The causal organisms of endometritis frequently occur from ascending of the upper genital tract by cervicovaginal flora. These bacteria have been responsible for failure of antibiotic prophylaxis during cesarean deliveries. Moreover, some prophylactic antibiotic regimens are not effective, and the vagina may become colonized with resistant organisms following surgical prophylaxis (Graham et al., 2003).

There are different methods, to decrease the risk of infection. These include preoperative antiseptic vaginal douching on the morning of surgery. The intervention of vaginal cleansing is a safe and very quickly perfect procedure that can easily be done before abdominal scrub (Hass et al., 2010).

At the present time, there is no clear recommendation for or against vaginal cleansing before cesarean delivery. So, The aim of this study was to investigate the effect of vaginal preparation with antiseptic solution (cetrimide) before cesarean section for reducing post partum morbidity.

The results of the study showed that using antiseptic Cetridime for cleaning of the vagina before cesarean section operation decreased the occurrence of postpartum morbidity as fever and endometritis. This findings supported the study hypotheses that the women who are undergoing vaginal preparation with antiseptic solution (cetrimide) before cesarean section will have less post partum morbidity.

The results of the present study showed that general data of the study subjects as age, gravid, and para were not show any significant difference between control and intervention group. This insignificant difference between the general and obstetric characteristics data of both groups are reported by many studies Hayat et al (2014, Haas et al (2010), and Raeid et al (2001).

Regarding to Postoperative fever study findings revealed that there was statistical significant difference between intervention and control group. These findings were in agreement with Hayat et al (2014) who study the effect of vaginal cleaning before cesarean delivery to reduce post cesarean section & postpartum infection and founded that there was statistically significant increase in temperature of control group in comparison to study group. Also study results in the same line with Ried et al (2001) who study effect of vaginal preparation on postcesarean infectious morbidity and reported that 7.2% of subjects under study had oral temperature elevated to 37.7 of or greater after the day of surgery.

While study results were in disagreement with Ameer (2009) who evaluate the risk of postcesarean endometritis with preoperative vaginal preparation and reported that there was no measurable effect of a vaginal scrub on the development of postoperative fever.

As regard to endometritis study results showed that there was statistical significant difference between both groups. The current results in agreement with Hayat et al (2014) who reported that endometritis was found in 10% of control group Vs 5% of study group. Study results in the same line with Reid et al (2001) who reported that 7.2% had endometritis, Also Rouse et al (2007) study effect of Chlorhexidine vaginal irrigation for the prevention of peripartal infection and reported that the incidence of postpartum infection morbidities such as endometrities appears to be decreases with vaginal preoperative cleansing with povidone iodeine.

On the other hand, the study of the group of Pitt et al (2009) intra vaginal povidone iodine done before cesarean delivery showed a significant reduction in post-cesarean endometritis, Also the group of Starr et al (2005) a small trial using providone iodine and reported a reduction rate of post cesarean endometritis.

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In addition to study results in agreement with Ameer (2009) who reported that Post- Cesarean endometritis occurred in (14%) of control patients and in (7%) patients who received a preoperative vaginal scrub (P < 0.5). Also Pitt et al (2009) reported that the use of preoperative intravaginal metronidazol gel decrease the incidence of post- cesarean endometritis, presumably by reducing the local exposure of anaerobic bacteria during a caesarean delivery, while study findings were in disagreement with Reid et al (2009) who reported that vaginal preparation do not affect the incidence of postoperative endometritis

In relation to wound infection study findings revealed that the rate of wound infection was lower in the intervention group however the difference is not statistically significant. These study results were in agreement with Reid et al (2009) who reported that vaginal preparation do not affect incidence of postoperative wound infection, Ameer (2009 ) also reported that preparation vaginal with iodine before Cs do not reduce incidence of postoperative wound infection. While our study results in contrast with Hayat et al (2014) who reported that there was statistical significant increase of wound complications in control group compare to study group

Interpretation of the study findings suggests that a preoperative vaginal scrub with antisepetic Cetrimide solution decreases the risk of post-cesarean fever and endometritis. This intervention, however, does not seem to reduce the risk of postoperative wound infection. Differences in reported postoperative morbidity rates could be attributed to the technique and materials used for the vaginal preparation itself or the amount of antisepetic used for the preparation might affect infectious outcomes.

V. Conclusion

Study concluded that using antisepetic Cetrimide for cleaning of the vagina before cesarean section operation decreased the occurrence of postpartum morbidity as fever and endometritis.

VI. Recommendations

- Physicians and Nurses should be used antisepetic Cetrimide for vaginal cleaning as regular practice before cesarean deliveries.
- Apply vaginal preparation with anti septic solution before C.S operation for high risk group for infection as premature rupture of membranes, diabetes, anemia.

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