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#### Megahed AM, et al.

**Original Article** 

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#### Preoperative Vaginal Preparation with Chlorhexidine Gluconate to Reduce Post-Cesarean Delivery Infectious Morbidity

#### Alaa Eldin Mahmoud Megahed\*<sup>[1]</sup>; Khaled Basal<sup>[2]</sup>; Abdullah Almilaibary<sup>[3]</sup>

<sup>1</sup> Department of Obstetrics and Gynecology, Damietta Faculty of Medicine, Al-Azhar University, Egypt

<sup>2</sup> Department of Obstetrics and Gynecology, Damietta General Hospital, Ministry of Health, Egypt.

<sup>3</sup> Department of Family and Community Medicine, Faculty of Medicine, Albaha University, Kingdom of Saudi Arabia

#### Background: Cesarean delivery is the commonest surgical procedure practiced by Obstetricians and its incidence continues to rise. It is associated with significant morbidity, and infection is Article information one of the most common postoperative complications. Different interventions are described to decrease the rate of infection. The use of vaginal antiseptics and antimicrobial was prescribed. However, the results are inconsistent. **Received:** 5-01-2022 The aim of the work: The current work aimed to determine the value of pre-surgical vaginal cleaning by a 5% chlorhexidine gluconate solution could reduce the risk of maternal infections after cesarean delivery. Accepted: 15-02-2022 Patients and Methods: This study included 400 women attending obstetrics and gynecology departments to deliver by elective cesarean section. The study had been completed between the DOI: 10.21608/ijma.2022.220085 beginning of January 2019 to the end of December 2021. All women were randomized to one of two equal groups. The first included 200 women where no wash was done [Control group]. The second included another 200 cases where wash with chlorhexidine gluconate was done \*Corresponding author [Study group]. At the time of hospital discharge and again at one month post delivery. The rate Email: dr.alaamegahed@gmail.com of endometritis and different wound complications were documented and compared between groups. Citation: Megahed AM, Basal K, Almilaibary Results: The control and study groups were comparable regarding female age, parity, gestational A. Preoperative Vaginal Preparation with age at delivery, primary cesarean section, operative time. However, postoperative hospital stay Chlorhexidine Gluconate to Reduce Postduration was significantly longer in control than the study group [43.26±10.62 vs. 39.69±9.21] Cesarean Delivery Infectious Morbidity. hours, respectively]. Hemoglobin concentrations revealed non-significant difference between IJMA 2022; 4 [2]: 2118-2123. DOI: the study and the control groups before and after cesarean delivery. However, it was 10.21608/ijma.2022.220085 significantly reduced in both groups after surgery than values before surgery. Endometritis was reported among 12.5% of the control group, compared to 7.0% of the study group, with no significant difference between the study and the control groups. However, the overall wound Authors contribution: All authors contributed equally in this work. complications were significantly increased among control than study group and composite complications were also significantly increased in control than the study group [12.0% vs 4.0% However, dr. Abdullah Almilaibary did not respectively]. Lower preoperative hemoglobin was the only significant associated factor for share in the clinical part, although he contributed to study conceptualization, development of endometritis. protocol preparation, statistical analysis, Conclusion: Peroperative vaginal preparation with 5.0% chlorhexidine gluconate solution is drafting and final revision of the associated with a reduction in post-cesarean infectious complications [mainly endometritis] manuscript. wound infection and other wound-related complications. It is recommended to be a routine practice before cesarean delivery.

Keywords: Cesarean Delivery; Antiseptic Solutions; Chlorhexidine; Endometritis; Comorbidities.

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#### ABSTRACT

#### **INTRODUCTION**

Cesarean section [CS] describes the operative delivery of the fetus. Its incidence witnesses an increase all over the world in recent years. It is as high as 25.0% of all deliveries in some countries <sup>[1]</sup>. This rise in CS incidence had been associated with increased incidence of CS-related comorbidities <sup>[2,3]</sup>.

It could be short-term complications [e.g., infection, hemorrhage and thromboembolism] or long-term complications [e.g., dysuria, dysmenorrhea, abnormal uterine bleeding and infertility] <sup>[2,4,5]</sup>.

The surgical site infection is the commonest post-CS complication [3-15%] and is the main cause of postpartum readmissions <sup>[6,7]</sup>.

Endometritis represents about 6-27% of the post-CS complication <sup>[8,9]</sup>. Post cesarean endometritis is more frequency after cesarean than vaginal delivery [up to 10 times more frequent]. It could be associated with serious comorbidities like bacteremia, peritonitis, intra-abdominal abscess, and sepsis <sup>[10,11]</sup>.

The causative organisms usually arise from ascending inoculation of the upper genital tract by cervico-vaginal flora <sup>[12]</sup>.

Besides reduction of postoperative infection achieved by prophylactic antibiotics, vaginal preparation with antiseptic solutions [e.g., povidone iodine, chlorhexidine] was associated with a reduction in the number of vaginal pool-recovered bacteria. This effect is rapid, occurring within 10 minutes, making it potentially useful directly before performing a cesarean delivery <sup>[13,14]</sup>.

Searching literature revealed that, different antiseptic solutions in different concentrations were used for vaginal preparation before cesarean delivery. However, and according to researchers best of knowledge, no one used chlorhexidine 5% solutions for preoperative vaginal preparation. The higher concentration was 4%. Here, we used high concentration than reported in previous literature, aiming to attain a bactericidal effect. We believe that, this concentration will be associated with better outcome.

#### THE AIM OF THE WORK

The aim of this work is to determine whether pre-CS vaginal cleaning with a 5% chlorhexidine gluconate solution can decrease the risk of postoperative cesarean section maternal infectious morbidities [e.g., endometritis] and other wound complications.

#### PATIENTS AND METHODS

This study included 400 patients attending the labor word in Damietta general hospital and Al-Azhar University Hospital [New Damietta] to deliver by elective cesarean section according to obstetric base. The study had been completed between the beginning of January 2019 to the end of December 2021.

Patients who were more liable to infection as premature rupture of membranes, prolonged labor, obstructed labor, diabetics and pre-eclampsia were excluded. Additionally, patients with past history of allergy to iodine containing solutions were excluded.

#### **Ethical considerations:**

The study protocol was submitted and approved by the local research ethics committee of Damietta Faculty of Medicine, Al Azhar University [IRB00012367-18-12-004]. All women were informed about the study and informed consent was signed by the pregnant mother and her husband. Females were randomized to one of two groups. The first group included 200 women where no wash was done [Control group]. The second group included another 200 cases where wash with chlorhexidine gluconate was done [Study group].

#### The method of randomization:

The assigned group was written on an index card as either "no wash" for the control group or "vaginal wash" for the study group. The cards were sequentially numbered and placed into opaque security envelopes and sealed. Upon consent, the next numbered envelope was opened and the patient's assignment to either the povidone iodine vaginal washing group or no vaginal washing group. The nurse informed about allocation arm and, upon arrival to operating room and after adequate anesthesia, the intervention group received a povidone iodine vaginal cleaning, in addition to the standard abdominal preparation.

Vaginal cleaning performed by the physician after spinal anesthesia was applied. Then, the abdominal scrub was completed. The vaginal scrub was consisted of 3 sponge sticks soaked in 5% chlorhexidine gluconate. The vaginal scrub included the vaginal apex to the introitus with great attention to the anterior, posterior, and lateral walls of vaginal fornicies.

The control group received the standard abdominal scrub. The SC then was performed. All women received the standard antibiotic prophylaxis during the procedure. The cesarean technique and skin closure procedures were done according to Rosenbloom *et al.* <sup>[15]</sup>.

At the time of hospital discharge and again at one month post delivery, data were collected by a trained assistant blinded to the allocation group.

#### **Outcome definitions**

Fever was defined as the temperature of  $\geq 38^{\circ}$ C, excluding the first day after cesarean delivery and any other causes of fever as mastitis, urinary tract infection and tonsillitis.

Endometritis was confirmed by the presence of lower abdominal pain and tenderness, plus one or more of rebound tenderness, tenderness with the motion of the cervix, adnexal tenderness, fever as defined previously, leukocytosis  $> 10,000/\text{mm}^3$ , elevated erythrocyte sedimentation rate [ESR] and endocervical swab showed gram -ve diplococci or +ve monoclonal antibody for Chlamydia in the cervical discharge <sup>[16]</sup>.

Wound complications were defined as wound infection managed by antibiotics, wound separation, seroma, hematoma, or requirement for debridement.

A composite complication outcome was defined as the presence of any one of endometritis, fever; sepsis; readmission to manage a condition related to CS, wound infection, or any other wound complications [e.g., seroma, separation]. Follow-up was done by history taking, physical examination and urine analysis.

#### Statistical analysis of data:

The collected data were anonymized and fed to personal computer. Then analysed by statistical package for social sciences version 16 [SPSS Inc., Chicago, USA]. Results were presented in short textual format, followed by the tabular. The mean, standard deviation [SD], minimum and maximum values were the statistical measures of parametric data. The independent sample student [t] test was used for comparison between two groups. On the other side, frequency and percentages were the statistical measures used to represent qualitative data. Chi square [X<sup>2</sup>] test or its equivalent was used to investigate the association between groups. For the interpretation of results, p value  $\leq 0.05$  was considered significant.

#### RESULTS

Both control and study group showed non-significant difference regarding maternal age, parity, gestational age at delivery, primary cesarean section, operative details and operative time. However, postoperative hospital stay duration was significantly longer in control than the study group [43.26 $\pm$ 10.62 vs. 39.69 $\pm$ 9.21 hours, respectively] [Table 1]. At the preoperative time and directly after CS, hemoglobin concentration revealed non -significant difference between study and control groups. However, in both groups, there was significant reduction of postoperative hemoglobin when compared to corresponding preoperative values [Table 2].

Regarding, temperature, there was a statistically significant increase in the temperature of the control group in comparison to the study group immediately postoperative, and at 6, 12, 18, 24, 30 and 36 hours postoperatively. This difference is insignificant at admission and at one month postoperatively [Table 3].

Endometritis was reported among 12.5% of the control group, compared to 7.0% of the study group, with no significant difference between the study and control groups. However, the overall wound complications were indecently increased among control than study group and composite complications were also significantly increased in control than the study group [12.0% vs 4.0% respectively] [table 4].

Searching for factors associated with endometritis, only lower preoperative hemoglobin was associated with endometritis [Table 5].

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	, operative details, operative time a		-	•	44	-
Variable		Control	Study	Total	test	р
		group	group			
Age [years]	Mean±SD	26.49±4.00	26.92±3.56	26.70±3.79	1.15	0.25[NS]
	MinMax	20-35	20-37	20-37		
Parity	Mean±SD	$1.44\pm0.52$	$1.40\pm0.54$	1.42±0.53	0.94	0.34
	MinMax	1-3	1-3	1-3		
Gestational age	Mean±SD	38.30±1.10	38.45±1.01	38.38±1.06	1.32	0.19
at delivery [weeks]	MinMax	28-40	37-41	28-41		
Primary CS	Previous one	160[80.0%]	154[77.0%]	314[78.5%]	0.53	0.46
	Previous two	40[20.0%]	46[23.0%]	86[21.5%]		
Operative details	Vaginal hand needed for delivery	6[3.0%]	5[2.5%]	11[2.8%]	0.09	0.76
-	Open cervix during delivery	122[61.0%]	126[63.0%]	248[62.0%]	0.17	0.68
	Abdominal drain	34[17.0%]	26[13.0%]	60[15.0%]	1.25	0.26
Operative time [min]	Mean±SD	39.78±3.46	40.38±3.82	40.08±3.65	1.65	0.10
	MinMax	32-50	34-49	32-50		
Hospital stay duration	Mean±SD	43.26±10.62	39.69±9.21	41.47±10.09	3.59	<0.001*
[hours]	MinMax	24-72	24-72	24-72		

 Table [1]: Comparison between study and control groups as regard age, parity, gestational age, primary CS, operative details, operative time and duration of hospital stay.

N.B: no cases had diabetes, hypertension or PROM. In all patients, the transverse incision was used and all had urinary catheterization.

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Table [2]: Comparison between study and control groups as regard pre-and post-operative hemoglobin [g/dl]								
Variable		Control group	Study group	Total	test	р		
Preoperative	Mean±SD	10.77±0.44	10.81±0.44	10.79±0.44	0.90	0.36		
Hemoglobin [g/dl]	MinMax	10-11.7	10-11.90	10-11.90				
Postoperative	Mean±SD	10.42±0.47	10.47±0.47	10.44±0.47	0.95	0.34		
hemoglobin [g/dl]	MinMax	9.50-11.4	9.5-11.60	9.5-11.60				
Paired	"t"	19.89	18.42	0.27.08				
comparison	р	< 0.001*	< 0.001*	< 0.001*				

Table [3]: Comparison between study and control groups as regard temperature
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Temperature	Control group	Study group	t	р
At admission	37.13±0.20	37.12±0.19	0.467	0.641
Immediately PO	37.37±0.28	37.27±0.25	3.78	< 0.01*
Six hours PO	37.40±0.39	37.19±0.23	6.67	< 0.01*
Twelve hours PO	37.42±0.36	37.25±0.41	4.32	< 0.01*
Eighteen hours PO	37.42±0.36	37.18±0.31	7.14	< 0.01*
Twenty-four H PO	37.51±0.29	37.23±0.26	3.23	< 0.01*
Thirty H PO	37.35±0.25	37.28±0.23	2.88	0.004*
Thirty-six H PO	37.30±0.18	37.23±0.16	3.73	< 0.01*
After one months	37.11±0.19	37.10±0.18	0.43	0.665

PO: postoperative

### Table [4]: Comparison between study and control groups as regard postoperative infection and complications

complications									
		Control group		Study group		Total		Test	P value
		n	%	n	%	n	%		
Endometritis	Yes	25	12.5%	14	7.0%	39	9.8%	3.43	0.09
	No	175	87.5%	186	93.0%	361	90.3%		
Wound	None	127	63.5%	167	83.5%	294	73.5%	20.63	< 0.001*
complications	Incisional infection	22	11.0%	11	5.5%	33	8.3%		
	Wound separation	23	11.5%	10	5.0%	33	8.3%		
	seroma	14	7.0%	6	3.0%	20	5.0%		
	Hematoma	14	7.0%	6	3.0%	20	5.0%		
Composite complications	Yes	24	12.0%	8	4.0%	32	8.0%	8.69	0.003*
	No	176	88.0%	192	96.0%	368	92.0%		

Table [5]: Comparison between women with endometritis complications in study and control groups as
regard studied variables

		Endometritis in Control group		Endometriti	. р	
		Mean	S. D	Mean	S. D	
Age		27.2000	3.22749	28.9286	4.04711	0.152
Parity		1.6400	.48990	1.5714	.51355	0.683
Gestational age		37.9200	2.19697	38.7143	1.20439	0.220
<b>Preoperative Hb</b>		10.7360	0.43193	11.1214	.20821	0.003*
Postoperative Hb		10.4320	.45709	10.6714	.45137	0.124
Operative time		41.5200	2.95973	41.0714	4.21470	0.699
Duration of hospital admission		40.6400	8.73632	44.0000	14.46481	0.370
Primary CS	Previous One	16	64.0%	6	42.9%	0.20
	Previous two	9	36.0%	8	57.1%	
Vaginal hand needed for delivery		2	8.0%	0	.0%	0.27
Opening cervix during CS		18	72.0%	7	50.0%	0.16
Abdominal drain		2	8.0%	0	0.0%	0.27

#### DISCUSSION

Previous studies investigating vaginal preparation with vaginal antiseptic and different maneuvers and addressed its effects on the incidence of postoperative infectious morbidity reported varying results, even with the same disinfectant. For example, Reid *et al.* <sup>[17]</sup> and Guzman *et al.* <sup>[18]</sup> used povidone iodine and reported different results.

Another study used chlorhexidine showed no reduction in endometritis or overall infectious complications <sup>[19]</sup>. However, a study using vaginal metronidazole reported an endometritis reduction but was limited by a small sample size <sup>[20]</sup>. Thus, the current work was established to determine the value of vaginal cleaning with a 5% chlorhexidine gluconate solution before CS and its effects on postoperative maternal infectious complications [e.g., endometritis and surgical site infection].

Results revealed significant reduction of hemoglobin concentration than corresponding preoperative values.

This could be attributed to blood loss during surgery. However, the values were non-significant between study and control groups. Similar results were reported by Eason *et al.* <sup>[21]</sup> who reported that, there was statistically insignificant difference between studied groups as regard pre and postoperative hemoglobin or degree of blood loss during surgery in both groups.

Endometritis was reported among 9.8% of all studied women, that was increased in control than study group [12.5% vs 7.0%]. However, the difference was not statistically significant. It was associated only with lower preoperative hemoglobin. Reid *et al.* <sup>[17]</sup> reported total incidence of 7.2%.

Ogah *et al.* <sup>[22]</sup> in a recent prospective study used chlorhexidine 1.0% for vaginal cleansing prior to CS [in the form of three standard gauzes soaked in 30 mL 1.0% chlorhexidine gluconate solution] and showed that, the overall postoperative endometritis incidence was significantly reduced in interventional than the non-interventional group [6.6% vs. 27.6% respectively].

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These results partially in line with the current study regarding higher endometritis incidence in the noninterventional group. However, they reported a significant difference that could not be achieved in the current study. This could be attributed to the different concentrations used of chlorhexidine. The higher chlorhexidine concentration used in the current one led to a reduction of reported endometritis in the interventional group [12.5%] which is lower than interventional group of Ogah et al. [22]. In addition, they included emergency CS, which not included in the current one. Furthermore, Ogah et al. [22] themselves explained the higher rate of endometritis in their study as an expected result, since the majority of their patients were already in labor before delivery. This fact was observed among the women in the control arm, where the endometritis incidence [26.7%] and composite post-CS infectious morbidities [36.8%] were very high as compared with the interventional arm.

Memon *et al.*<sup>[23]</sup> and Caissutti *et al.*<sup>[24]</sup> also reported on the beneficial role of vaginal cleaning by antiseptic solution prior to CS with a consequent decrease in postpartum infectious complications. The endometritis reduced risk after vaginal preparation with antiseptic solution was also reported in prior studies. For example, Aref *et al.*<sup>[25]</sup>, Ahmed *et al.*<sup>[26]</sup>, and Lakhi *et al.*<sup>[27]</sup> supported this beneficial role as observed in the current work, although it did not reach statistical significance.

The wound infection besides other complications were significantly reduced in study than control group. These results are different from Aref *et al.* <sup>[25]</sup> and Ahmed *et al.* <sup>[26]</sup>. However, Lekhi *et al.* <sup>[27]</sup> in a randomized controlled study of more than 1000 women reported significant decrease in the incidence of wound infection, when they used a solution of 4% chlorhexidine for pre-CS vaginal preparation even when compared to 10.0% povidone-iodine cleansing. This attributed to the higher microbial toxicity of chlorhexidine <sup>[22]</sup>.

Ogah *et al.* <sup>[22]</sup> reported significantly shorter duration of postoperative hospital stay in interventional than the non-interventional group; the results similar to that obtained in the present work regardless the duration itself. The longer duration of hospital stay in their study attributed to the policy of their institution, and type of abdominal incision. They reported early discharge with transverse incision, as in the current one.

The advantages of reducing endometritis and surgical site infection after CS includes increased patient satisfaction and reduced other comorbidities associated with infection [e.g., chronic pelvic pain, fallopian tube blockage, secondary infertility and prematurity]<sup>[28]</sup>.

The overall incidence of wound infection seen in the current study [8.3%] lies within the rates reported in previous studies. For example, Zejnullahu *et al.* <sup>[29]</sup> reported an incidence of 9.85%, Njoku *et al.* <sup>[30]</sup> reported an incidence of 8.5%. However, it was lower than, but lower than the finding of and Isanga *et al.* <sup>[31]</sup> who reported a rate of 15.5%.

Furthermore, Haas *et al.* <sup>[32]</sup> in a systematic review concluded that, vaginal preparation by antiseptic solutions [e.g., povidone-iodine or chlorhexidine] compared to placebo [e.g., saline or no cleansing before CS] probably reduces the risk of post-CS endometritis, with moderate grade of evidence power. However, as a simple and inexpensive intervention, obstetricians may consider the routine use of preoperative vaginal cleansing by povidone-iodine or chlorhexidine before CS.

In another network metanalysis, Roeckner *et al.* <sup>[33]</sup> concluded that, presurgical vaginal irrigation by povidone-iodine had been associated with a risk reduction of postoperative fever, infection [endometritis and/or surgical wound infections].

In short, results of the current study revealed that, peroperative vaginal preparation with 5.0% chlorhexidine gluconate solution is associated with a reduction in post-cesarean endometritis and wound infection. Thus, it is recommended to be a routine practice in our facilities.

### Financial and Non-financial Relationships and Activities of Interest

None to be disclosed

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