

Influence of Different Scrubbing Methods of Surgical Team on Surgical Site Infection in Cesarean Section

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ABSTRACT

Background: Cesarean section is the most performed major abdominal surgery. While cesarean delivery is usually an uncomplicated procedure, up to 20% of patients can experience a complication following cesarean delivery with infectious complications being the most common. Nosocomial infections represent one of the major sources of morbidity and mortality in hospitalized patients around the world.

Objective: The aim of the current work was to evaluate if the different scrubbing methods of surgical team before cesarean section by different materials change the rates of post-operative surgical site infection or not.

Patient and methods: This randomized controlled trial (RCT) study included a total of 278 pregnant women, attending at Departments of Obstetrics and Gynecology, Menouf General Hospital and Menoufia University Hospitals, during the period of September 2019 till August 2020.

Result: there was no statistically significant difference between the studied groups regarding their demographic and clinical data. There was no statistically significant difference between group A and group B regarding offensive odor at day 10 and 15 post-operatively. No offensive odor reported after day 25 or 30 postoperative ($p > 0.05$). Also, there was no statistically significant difference between group A and group B regarding approximation at day 10, 20, 25 and 30 post-operatively ($p > 0.05$). There was no statistically significant difference between group A and group B regarding hotness, redness, tenderness, swelling, discharge and offensive odor at day 10, 20, 25 and 30 post-operatively ($p > 0.05$).

Conclusion: It could be concluded that for the increasing rates of CS being performed without a clear medical indication; new practice protocols should be implemented to reduce the rate of cesarean deliveries as CS surgery has a 5–20 times higher risk of post-partum infection as compared to vaginal deliveries.

Keywords: Betadine, Cesarean Section, Sterillium, Surgical wound Infection

INTRODUCTION

Cesarean section is the most performed major abdominal surgery in the USA and almost one-third of births in the USA are cesarean deliveries. While cesarean delivery is usually an uncomplicated procedure, up to 20% of patients can experience a complication following cesarean delivery with infectious complications being the most common. Nosocomial infections represent one of the major sources of morbidity and mortality in hospitalized patients around the world. Out of those infections, the most common one is the surgical site infection⁽¹⁾.

According to the World Health Organization, in developing countries, the risk of infection related to health care practices is from 2 to 20 times higher than that in developed countries. The unnoticed transmission of bacteria to patients' wounds during surgery may cause surgical site infection. Surgical site infection is one of the most common causes of health-care related infections for patients who undergo surgery⁽²⁾.

The bacteria that cause surgical site infection come from different sources in the operating room, including hands and surgical equipment, All the team members use sterile gloves to prevent spreading bacteria to the patient and vice versa. However, gloves

may get punctured during surgery, thus it is important to have the hands germ-free. This can be achieved through surgical hand antisepsis right before wearing the gloves for the surgical procedure⁽³⁾.

The characteristics of an ideal antiseptic would be: immediate action, persistent (lasting several hours), cumulative activity (repeated exposure provides enhanced inhibition of the bacterial growth), broad spectrum of activity, and safe use by the operating room staff. The Association for Perioperative Practice recommends washing the hands before applying antisepsis. The purpose of hand washing is to remove dust and major gross contaminants. After that, the recommendation is to use plastic spatulas to clean the nails under running water. Finally, to perform either a traditional or water-free antisepsis⁽⁴⁾.

Therefore, surgical hand antisepsis is one of the major factors in reducing the transmission of bacteria. Several studies have tested new interventions that attempt to decrease these infectious complications including pre-operative bathing, appropriate use of pre-operative antibiotics, type of pre-operative scrub utilized, hair clipping, vaginal cleansing, maintaining intra-operative normothermia, closure of subcuticular skin and type of skin closure⁽⁵⁾.



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PATIENT AND METHODS

This randomized controlled trial (RCT) study included a total of 278 pregnant women, attending at Departments of Obstetrics and Gynecology, Menouf General Hospital and Menoufia University Hospitals, during the period of September 2019 till August 2020.

Ethical considerations:

All procedures were carried out in accordance with the ethical standards of the institutional committee and with the 1964 Declaration of Helsinki. **The study received the approval of ethical committee of faculty Medicine, Menoufia University.** The aim and steps of the study were explained to the participants and written informed consent were obtained from them.

Inclusion criteria: Pregnant females aged 20-40 years (childbearing period).

Exclusion criteria: Pregnant females with bleeding disorders or on anticoagulant therapy. Systemic chronic diseases as chronic liver diseases, chronic kidney disease, hypertensive patients. Obstetric emergencies, such as antepartum hemorrhage, preeclampsia, Eclampsia, Obese pregnant females with pre-pregnancy body mass index (BMI) >30 kg/m² and Diabetic patients.

Sample size: The sample sizing assumes that the expected percentage response in Group of hand rubbing is 44% and in Group of hand scrubbing is 28% to achieve 80% power to detect this difference with a significance level of 5% it is estimated that 137 subjects per group would be required. With a withdrawal/non-evaluable subject rate of 10% a total of 153 per group subjects will be recruited leading to a total required sample size of 306 subjects.

All participants included in this study were subjected to the following:

Patient Preparation: Patients were submitted to thorough history taking, clinical, examination and investigations.

All the patients underwent: History taking included detailed medical history from each patient with special emphasis on medical and surgical history. history of general disease e.g., diabetes mellitus.

Examination: General including blood pressure, pulse, temperature and respiratory rate, obstetrical examination.

Investigations: Obstetric ultrasound to detect any obstetric disorder, preparation for cesarean section with preoperative investigations in the form of complete blood count, prothrombin time, blood

glucose level, liver and kidney function.

Therapeutic modalities

The patient was scrubbed by Povidone Iodine 10% starting from the site of incision first then upward to xiphisternum and then from downward of the site of the incision to the knee, last symphysis pubis and labia, and then by a new gauze the site of incision was rescrubbed again then was left to dry, the patient was towed by a sterile towel to cover the patient except 5cm above and down the incision site. The skin was opened (Pfannenstiel incision) by scalpel, The anterior abdominal wall was opened by layers till reach the uterus, The uterus was opened by C shape in lower segment and the baby and the placenta were delivered, The uterus was closed by two layers, The peritoneal wall and all abdominal wall layers were closed by layers, The skin was closed with continuous subcutaneous synthetic absorbable suture, At the end of the procedure, a sterile dressing was applied to the closed skin incision, and vaginal toilet was done ⁽⁶⁾.

Postoperative evaluation: All the patients were subjected to the follow up during 30 days post-operative regarding to Hotness, Redness, Swelling, Tenderness, Bad odor Pus drainage and were compared between the two groups ⁽⁶⁾.

Primary outcomes: Hotness, redness, swelling, tenderness, bad odor, pus drainage and were compared between the two groups ⁽⁶⁾.

Secondary outcomes: Scar keloid, incisional hernia, uterine scar niche.

Statistical Methodology: the data were collected, tabulated and statistically analyzed using both IBM compatible personal computer with Statistical Package for the Social Sciences (SPSS) version 25. The description of data was in the form of mean (FOBI) SD for quantitatively data, and frequency and proportion for qualitative data. The mean is the sum of all observations by the number of observations. While the standard deviation is a measure the degree of scatter of individual varieties around their mean. Analytical statistics: included student-t test (t), Chi-Squared (χ^2), Fisher's exact test. Results were considered significant if $P \leq 0.05$ and highly significant if $P \leq 0.01$.

RESULTS

In the current study, there was no statistically significant difference between the studied groups regarding their demographic and clinical data ($p > 0.05$). The mean age of the studied patients in group A was 26.9 ± 4.6 years while it was 26.1 ± 3.7 years in group B. The mean BMI in group A was 27.51 ± 1.72 kg/m² Vs. 27.44 ± 1.71 kg/m² in group B. also, most of studied patients in the two groups had one previous C.S, and mean gestational age with 38.52 ± 1.12 weeks in group A Vs. 38.5 ± 1.13 weeks in group B, (**Table 1**).

Table (1): Comparison between the studied groups regarding demographic and clinical data (Sahu *et al.*, 2020).

Socio-demographic and clinical data	Group (A) n=138		Group (B) n=140		t test	P-value
	No	%	No	%		
Age (years):						
Mean ±SD	26.9±4.6		26.1±3.7		1.736	0.084 ^{NS}
Range	20-39		20-37			
BMI: kg/m²						
Mean ±SD	27.51±1.72		27.44±1.71		0.348	0.728 ^{NS}
Range	25-30		25-30			
Parity:						
PG	24	17.4	33	23.6	x ² =5.873	0.209 ^{NS}
G2P1	40	29	44	31.4		
G3P2	45	32.6	45	32.2		
G4P3	21	15.2	16	11.4		
G5P4	8	5.8	2	1.4		
Previous C.S:						
PG	26	18.8	36	25.7	x ² =3.513	0.476 ^{NS}
Previous one	48	34.8	48	34.3		
Previous two	43	31.2	43	30.7		
Previous three	19	13.8	12	8.6		
Previous four	2	1.4	1	0.7		
Gestational age (weeks):						
Mean ±SD	38.52±1.12		38.5±1.13		0.161	0.873 ^{NS}
No history of post-operative SSI	138	100	140	100	-	-

Max.: Maximum; **SD:** standard deviation; **t:** Student t test; **X²:** Chi square test; **NS:** non-significant. **Group (A):** povidone iodine 7.5%; **Group (B):** Sterillium; **SSI:** Surgical site infection **Min.:** Minimum;

There was no statistically significant difference between the studied groups regarding laboratory investigations (p>0.05). The mean HEMOGLOBIN level of the studied patients was 11.72±0.56 While, the mean platelet in group A was 262±51.167. Also, the mean WBCs count was 6.94±0.88. Also, they found there was a statistical difference between povidone iodine group and controls the study groups in investigations as regarding WBCs, HEMOGLOBIN and platelets, (Table 2).

Table (2): Comparison between the studied groups regarding laboratory data.

Laboratory investigations	Group (A) n=138	Group (B) n=140	t test	P-value
Hemoglobin: (g/dl)				
Mean ±SD	11.42±0.65	11.43±0.66	0.224	0.823 ^{NS}
Platelet: (x10³/μl)				
Mean ±SD	196.1±34.5	195.8±36.1	0.078	0.938 ^{NS}
WBCs: (x10³/μl)				
Mean ±SD	7.24±1.09	7.1±1.19	0.841	0.401 ^{NS}
RBCs: (x10⁶/μl)				
Mean ±SD	93.6±12.7	94.9±12.4	0.82	0.413 ^{NS}
INR:				
Mean ±SD	1.036±0.04	1.038±0.04	0.384	0.701 ^{NS}
Urea: (mg/dl)				
Mean ±SD	16.9±2.9	16.2±2.7	0.517	0.321 ^{NS}
Creatinine: (mg/dl)				
Mean ±SD	0.81±0.2	0.8±0.19	0.492	0.623 ^{NS}

SD: standard deviation; **t:** Student t test; **NS:** non-significant **Group (A):** povidone iodine 7.5%; **Group (B):** Sterillium; **SSI:** Surgical site infection; **Hemoglobin;** **WBCs:** white blood cells; **RBCs:** Red blood cells; **INR:** International normalized ratio

The number of patients who had surgical site infection was increased in day 10 and 15 than day 5 among group A and group B. Then, it was decreased in day 20 and continued in decreasing in day 25 and day 30 (p>0.05). That povidone iodine use preoperative reduces CS infection was previously reported in general surgery in multiple systematic reviews. Povidone-iodine irrigation to be significantly more effective at preventing surgical site infection than the comparison interventions of saline, water or no irrigation.

There was no statistically significant difference between group A and group B regarding offensive odor at day 10 and 15 post-operatively. No offensive odor reported after day 25 or 30 postoperative ($p > 0.05$). Also, there was no statistically significant difference between group A and group B regarding approximation at day 10, 20, 25 and 30 post-operatively ($p > 0.05$), (Table 3).

Table (3): Summary table describing post-operative progress of positive clinical signs in groups A & B.

Presence of post-operative clinical signs	5-day		10-day		15-day		20-day		25-day		30-day	
	No	%	No	%	No	%	No	%	No	%	No	%
Hotness:												
Group A	6	4.3	7	5.1	7	5.1	7	5.1	3	2.2	1	0.7
Group B	2	1.4	6	4.3	6	4.3	6	4.3	2	1.4	0	0
X²	FE=2.11		0.09		0.09		0.09		FE=0.21		FE=1.01	
P value	0.171		0.756		0.756		0.756		0.683		0.496	
Redness:												
Group A	7	5.1	7	5.1	7	5.1	7	5.1	4	2.9	3	2.2
Group B	6	4.3	6	4.3	6	4.3	6	4.3	6	4.3	2	1.4
X²	0.09		0.09		0.09		0.09		FE=0.38		FE=0.21	
P value	0.756		0.756		0.756		0.756		0.535		0.683	
Tenderness:												
Group A	5	3.6	7	5.1	7	5.1	6	4.3	2	1.4	1	0.7
Group B	5	3.6	6	4.3	6	4.3	5	3.6	2	1.4	0	0
X²	--		0.09		0.09		0.11		--		FE=1.01	
P value	--		0.756		0.756		0.740		--		0.496	
Swelling:												
Group A	3	2.2	6	4.3	6	4.3	4	2.9	1	1.7	1	0.7
Group B	2	1.4	5	3.6	5	3.6	2	1.4	1	1.7	0	0
X²	FE=0.21		0.11		0.11		FE=0.71		--		FE=1.01	
P value	0.683		0.769		0.769		0.445		--		0.496	
Discharge:												
Group A	3	2.2	3	2.2	3	2.2	3	2.2	2	1.4	2	1.4
Group B	4	2.9	5	3.6	3	2.1	1	0.7	1	0.7	1	0.7
X²	FE=0.13		1.83		2.07		2.45		2.41		FE=0.35	
P value	1.0		0.608		0.466		0.484		0.300		0.621	
Offensive odour:												
Group A			2	1.4	2	1.4	1	0.7				
Group B			0	0	1	0.7	1	0.7				
X²	--		FE=2.04		FE=0.35		--		--		--	
P value	--		0.246		0.621		--		--		--	
Less than 3 mm separation:												
Group A	3	2.2	3	2.2	2	1.4	2	1.4	1	0.7	1	0.7
Group B	3	2.1	4	2.9	2	1.4	0	0	0	0	0	0
X²	--		1.14		--		2.04		2.04		2.04	
P value	--		0.65		--		0.36		0.36		0.36	
Skin & subcutaneous fat separation:												
Group A			1	0.7	1	0.7	1	0.7	1	0.7	1	0.7
Group B			0	0	1	0.7	1	0.7	0	0	0	0
X²	--		1.14		--		2.04		2.04		2.04	
P value	--		0.65		--		0.36		0.36		0.36	

FE: Fischer's exact test

X²: Chi square test;

NS: non-significant

Group (A): povidone iodine 7.5%;

Group (B): Sterillium

DISCUSSION

Among several products, the procedure using the propanol-based hand rub Sterillium was found to be significantly more effective under in-vivo conditions than the reference disinfection. In healthy volunteers, surgical hand rubbing with this formulation using a 1.5 min application was recently demonstrated to be as effective as a 3 min application, according to the European standard EN 12791 (7). The study included 278 patients (divided in to two groups group A 138 Patients and group B 140 patients) who were subjected to cesarean section. It showed that, there was no statistically significant difference between the studied groups regarding their demographic and clinical data. The mean age of the studied patients in group A was 26.9 ± 4.6 years while it was 26.1 ± 3.7 years in group B. The mean BMI in group A was 27.51 ± 1.72 kg/m² Vs. 27.44 ± 1.71 kg/m² in group B. also, most of studied patients in the two groups had one previous C.S, and mean gestational age with 38.52 ± 1.12 weeks in group A Vs. 38.5 ± 1.13 weeks in group B. These results were consistent with the study conducted by **Mohammad et al.** (8) found no statistically significant difference in personal and clinical history between povidone iodine group and controls regarding age, education, residence and urgency of cesarean section but there was a statistical difference between the study groups in number of previous cesarean section.

There was no statistically significant difference in clinical examination as regarding BP, temperature and gestational age. Also, results were consistent with that reported by **Akl et al.** (9) who revealed that, the mean age of the studied patients using povidone iodine was 26.12 ± 2.88 years, the mean BMI was 28.98 ± 1.15 Kg/m² and the mean gestational age was 38.49 ± 0.70 weeks. As well, **Ketare** (10) found that, the mean age of the participants in the control group was 28.5 ± 4.8 years and in the povidone iodine group was 29.1 ± 4.7 years; this was similar study done by **Reid et al.** (11) in which the mean age of 27.1 ± 4.6 in the control group and 27.2 ± 5.0 in the treatment group was investigated. Moreover, **Memon et al.** (12) reported that, the mean parity of participants was 2.51 ± 2.27 in the control group and 2.40 ± 2.25 in the povidone iodine group, and the mean gestational age was 36.86 ± 2.46 in the control group and 36.65 ± 2.05 in the treatment group.

This study showed that, there was no statistically significant difference between the studied groups regarding laboratory investigations ($p > 0.05$). The mean hemoglobin level of the studied patients in group A was 11.42 ± 0.65 while it was 11.43 ± 0.66 in group B. While, the mean platelet in group A was 196.1 ± 34.5 Vs. 195.8 ± 36.1 kg/m² in group B. Also, the mean WBCs count was 7.24 ± 1.09 in group A Vs. 7.1 ± 1.19 in group B. Our findings were similar to **Mohammad et al.** (8) who revealed that, the mean hemoglobin level of the studied patients was 11.72 ± 0.56 While, the mean platelet in group A was 262 ± 51.167 . Also, the mean WBCs

count was 6.94 ± 0.88 . Also, they found there was a statistical difference between povidone iodine group and controls the study groups in investigations as regarding WBCs, hemoglobin and platelets. This agreed with the study conducted by **Kaur et al.** (6) the mean Preoperative hemoglobin level was 11.4 ± 1.46 , while the Postoperative level was 11.6 ± 1.38 .

This study showed that, the number of patients who had surgical site infection was increased in day 10 and 15 than day 5 among group A and group B. Then, it was decreased in day 20 and continued in decreasing in day 25 and day 30. Our findings are consistent with **Mohammad et al.** (8) who reported that, the fact that povidone iodine use preoperative reduces CS infection was previously reported in general surgery in multiple systematic reviews **Chundamala and Wright** (13). They found povidone-iodine irrigation to be significantly more effective at preventing surgical site infection than the comparison interventions of saline, water or no irrigation. Also, **Chundamala and Wright** (13) demonstrated that, Povidone-iodine irrigation is a simple and inexpensive solution with the potential to reduce surgical site infection. This agreed with **Haas et al.** (14) found povidone-iodine irrigation to be significantly more effective at preventing surgical site infection than the comparison interventions of saline, water or no irrigation. Our findings were in conflict with the studies investigated by **French and Smaill** (15) as they did not find povidone-iodine irrigation to be significantly more effective at preventing surgical site infection than the comparison interventions of saline, water or no irrigation. Also, with **Akl et al.** (9) demonstrated that, there was no benefit of subcutaneous tissue swabbing with povidone iodine in decreasing wound infection following cesarean section. One of the reasons for this varied presentation of wound infection after appendectomy is the inconsistent or non-standardized definitions of wound infection. In most of the local studies mentioned above the definition or criteria to label the wound as infected was not clearly mentioned **Mohammad et al.** (8).

This study showed that, there was no statistically significant difference between group A and group B regarding hotness and redness at day 5, 10, 15, 20, 25 and 30 post-operatively. Hotness and redness increased among the two groups at day 10 then it was decreased at day 25 and 30 postoperative. This was consistent with **Yildirim et al.** (16) a non-significant reduction in endometritis after caesarean delivery was noted with 10% povidone-iodine solution in a previous study. Postpartum care was the same for both groups and included vital signs taken every 4 h, discontinuation of the Foley catheter, and advancement of the diet on the first day following surgery. Signs of wound infection (erythema, swelling, discharge, or tenderness), vaginal discharge, uterine consistency and height, and peritonitis were assessed daily in all participants, found that preoperative vaginal cleansing with povidone-iodine

decreased the incidence of post-caesarean endometritis.

This agreed also, with a recent Cochrane review by **Haas *et al.*** ⁽¹⁴⁾ concluded that vaginal preparation with povidone–iodine solution immediately prior to caesarean delivery reduces the risk of post-operative endometritis, mainly in women undergoing caesarean delivery with ruptured membranes. Another study conducted by **Mohammad *et al.*** ⁽⁸⁾ revealed that, there was no statistically significant difference between betadine and control groups regarding redness and hotness at first and second visit. 5.4 % of patients had redness and 4.3% had hotness at first visit. While no patients had redness and hotness atsecond visit. At a study performed by **Mohammad *et al.*** ⁽⁸⁾ it was concluded that surgical hand antisepsis using alcohol preparations are effective and have benefits related to cost reduction, water saving, lower application time, lower skin damaging effects, and ecological gains.

Strength of the study:

- Our study included sufficient number of sample size (n=278).
- The present study was conducted in two large hospital (Menoufia University andMenouf general hospitals).
- In our study, there was a different variation in age of pregnant women preparedfor elective cesarean section.
- In our study, there was a different variation in numbers of previous CS inpregnant women prepared for elective cesarean section.
- In our study there was no selection for any socioeconomic standard.

Limitation of the study:

- Our study was not included obese pregnant women.
- Our study was neglect of subcutaneous fat tissues thickness.
- We were not determined the types of antibiotics used after CS.

CONCLUSION

It could be concluded that for the increasing rates of CS being performed without a clear medical indication; new practice protocols should be implemented to reduce the rate of cesarean deliveries as CS surgery has a 5–20 times higher risk of post-partum infection as compared to vaginal deliveries.

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