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The Efficacy of Subcutaneous Swabbing of Cesarean Section Wounds with Povidone Iodine to Prevent Post-Operative Wound Infection: A Randomized Controlled Study

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Abstract

Background: Cesarean delivery is one of the most common surgical procedures performed by obstetricians. Infectious morbidity after cesarean delivery can have a tremendous impact on the postpartum woman's return to normal function and her ability to care for her baby. Despite the widespread use of prophylactic antibiotics, post-operative infectious morbidity still complicates cesarean deliveries [1]. Wound irrigation with povidone-iodine, an antiseptic solution, may be useful for reducing infection, but it is of uncertain efficacy and risk. Povidone-iodine irrigation is a simple and inexpensive solution with the potential to prevent surgical site infection [2].

Patients and Methods: This study was a randomized controlled prospective study in Assiut University Women's Health Hospital on women undergoing cesarean delivery in the period from November 2015 to September 2016. Study group (Group A) the subcutaneous tissue was swabbed with 10cc of undiluted 10% povidone iodine and was not mobbed. Group B; no swabbing.

Aim of Study: To assess the efficacy of subcutaneous swabbing of cesarean section wounds with povidone iodine to prevent post-operative wound infection.

Results: In our study, there was no statistically significant difference in personal and clinical history as regarding age, education, residence, urgency of cesarean section, presence of labor, gravidity, number of abortion but there was a statistical difference between the study groups in number of living children and number of previous cesarean section. There was no statistically significant difference in clinical examination as regarding BP, temperature, gestational age, presentation, presence of tender scar and rupture of membranes. There was a statistical difference between the study groups in pulse. There was a statistical difference between the study groups in investigations as regarding WBCs, estimated fetal weight and amniotic fluid index but there was a statistical difference in HB and platlets. There was no statistically significant difference in the operative data as regarding visceral and parietal peritoneal closure and duration of the procedure but there was a statistical difference in the level of the surgeon. There was no statistical difference between the study groups in presence of post-operative infection.

Conclusion: There was no benefit of subcutaneous tissue swabbing with povidone iodine in decreasing wound infection following cesarean section.

Key Words: *Cesarean section – Wound infection – Povidone iodine.*

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Introduction

CESAREAN delivery defines the birth via the abdominal route [3]. From 1970 to 2010, the cesarean delivery rate in the United States rose from 4.5 percent of all deliveries to 32.8 percent [4]. In Egypt the rate of cesarean delivery is 51.8% of all deliveries [5].

Cesarean delivery is one of the most common surgical procedures performed by obstetricians. Infectious morbidity after cesarean delivery can have a tremendous impact on the postpartum woman's return to normal function and her ability to care for her baby. Despite the widespread use of prophylactic antibiotics, post-operative infectious morbidity still complicates cesarean deliveries [1].

Wound infection is an infrequent but serious complication of surgery. Post-operative infection often requires repeat surgery and prolonged hospitalization, and it may compromise ultimate surgical outcomes [6].

If prophylactic antimicrobials are given, the incidence of abdominal wound infection following cesarean delivery ranges from 2 to 10 percent depending on risk factors [7,8].

Numerous good quality trials have proved that a single dose of an antimicrobial agent given at the time of cesarean delivery significantly decreases infection morbidity [9].

Wound irrigation with povidone-iodine, an antiseptic solution, may be useful for reducing infection, but it is of uncertain efficacy and risk. Povidone-iodine irrigation is a simple and inexpensive solution with the potential to prevent surgical site infection [2].

Multiple studies investigated the use of povidone-iodine irrigation in multiple types of surgery. The infection rate was 2.9% in the treatment group and 15. 1% in the control group (p<0.001). The treatment group did not experience any interference with wound healing or adverse reactions [2].

Povidone-iodine (Betadine) is an antiseptic solution consisting of polyvinylpyrrolidone with water, iodide and 1% available iodine; it has bactericidal ability against a large array of pathogens [10]. Although a vast amount of literature exists regarding its use as a topical antibacterical agent in surgery, its use as a prophylactic irrigation solution against surgical site infection has been examined to a lesser degree [2].

The aim of the study is to assess the efficacy of subcutaneous swabbing of cesarean section wounds with povidone iodine to prevent postoperative wound infection.

Patients and Methods

This study was conducted in Assiut University Women's Health Hospital including women undergoing cesarean delivery.

Study design:

Two armed randomized controlled clinical trial. The study has 2 groups. Group A in which the subcutaneous tissue will be swabbed with 10cc of undiluted 10% povidone iodine and will not be mobbed. Group B; no swabbing.

Inclusion criteria: All women who were admitted to labor ward either for elective or emergent; first time or repeat cesarean delivery.

Exclusion criteria: Women with prolonged rupture of membranes more than 12 hours, women with morbid obesity with BMI >35, women with diabetes, hypertension or anemia with haemoglbin <10, women on corticosteroid therapy, women with intraoperative heamorrhage or hematoma formation, women allergic to betadine, the cesarean section which duration exceed one hour or associated with other surgical procedure.

Patients enrollment:

Ladies coming to emergency room or outpatient clinic for cesarean section were interviewed for feasibility to be enrolled in this study. The aim of the study and the procedure were explained to every woman in both verbal and written manner. Written or verbal consent was obtained according to patient education.

Pre-operative assessment: All patients underwent full history taking and clinical examination to ensure the diagnosis, indication of CS and to ensure that they comply with the inclusion and exclusion criteria.

All participating women underwent the following:

History taking regarding age, menstrual history, and obstetric history (gravidity, parity, nature of previous deliveries), general examination including weight, height, pulse, blood pressure, temperature, cardiac and chest examination to exclude any significant maternal disease, abdominal examination to detect fetal movement, scar of previous operations, fundal level, fetal lie and position, sterile speculum examination to diagnose rupture of membranes, complete blood picture, urine analysis and random blood sugar were done to all the patients.

Operative technique: Spinal anesthesia was utilized in all patients. Pre-operative single dose prophylactic antibiotics (Cefazolin 1g) were given to the patients on induction of anesthesia. Insertion of urinary catheter under complete aseptic conditions. Skin antisepsis with usual antiseptic solution (povidone iodine), draping with sterile covers. Opening skin by Pfannstiel incision, opening the anterior abdominal wall in layers, opening the uterus by sharp incision, delivery of the fetus, Spontaneous delivery of the placenta, closure of uterus in two layers, insuring homeostasis, closure of anterior abdominal wall in layers; the same type of suturing material; vicryl No1 was used in rectus Sheath, the subcutaneous tissue was closed, the same type of suturing material; vicryl NO 2/0 was used in subcutaneous tissue and skin.

Group allocation: Before closure of the subcutaneous tissue the patients were randomized into two groups: Group A (study group); the subcutaneous tissue was swabbed with 10cc of undiluted

10% povidone iodine and was not mobbed and group B (control group); no swabbing was done.

Post-operative care and patient discharge: In the first hour after an uncomplicated cesarean section, the patient was monitored closely in the postpartum ward where urine output, pulse, blood pressure, respirations, and any evidence of bleeding can be closely observed. Once any nausea has abated, the patient was encouraged to take fluids orally and she can eat when she felt hungry. Early ambulation; getting the patient out of bed as soon as regional anesthesia had worn off was encouraged. The urinary catheter was removed 12 hours post-operatively unless this was be in the evening in which case it was removed in the following morning.

Wound care: The dressing was removed 24 hours after the caesarean section, specific monitoring for fever, the wound was assesed for signs of infection (such as increasing pain, redness, hotness, tenderness, oazing or discharge, separation or dehiscence), gentle cleaning and drying of the wound daily, the patients were discharged 24 hours post-operatively.

Patients follow-up: Patients were followed-up in the outpatient clinic while came to remove the stitches and a month later, patients who had their stitches removed outside the hospital were followed-up by telephone for symptoms of post-operative wound infection and were asked to come and meet the researcher if any suspension existed. Patients who had any signs of infection were seen daily until complete wound healing was obtained.

Outcome: The study outcome was to detect and record the incidence of surgical wound infection in both groups. It is a composite outcome with presence of any of the following was considered infection; induration , swelling of the wound edges, discharge of pus or wound dehiscence [11], purulent drainage with or without laboratory confirmation, from the superficial incision, pain or tenderness with redness, or heat, superficial incision being deliberately opened by surgeon [12]. The presence of infection means the presence of two or more of the following signs: (Fever, hotness, redness, tenderness, induration) or one or more of the following signs: (Swelling, ooze, discharge, dehiscence).

Sample size estimation: It was calculated that 299 patients are required in each arm to detect a 5% difference (from 2% to 7%) in wound infection rate between study and control groups respectively using PS program.

Statistical analysis:

Data was collected, coded then, analyzed by computer software SPSS (statistical program for social science Version 16) as follows; numerical variables were expressed as mean or median whenever appropriate, categorical variables were presented as number of cases and percentage, Chi-square test was used to compare categorical variables between groups (fisher's exact if numbers in any column below 5), between groups comparison of contineous variables was performed by unpaired test (student's test) if they show normal distribution or ManWhitney test if they show non parametric distribution. Pearson correlation test was used for detection of correlation between variables, difference in variables was expressed by p-value (>0.05 is non significant, <0.05 is significant, and <0.001 is highly significant.

Results

This study included women undergoing cesarean delivery in the Women Health Hospital, Assuit University in the period from November 2015 to September 2016. There were 695 women eligible for the study 350 women in group A and 345 in group B. There were 51 women lost in follow-up either in first or second visit from group A and 46 women lost from group B. The net result was 598 women included in our analysis (299 in each group). There was no statistically significant difference in personal and clinical history as regarding age, education, residence, urgency of cesarean section, presence of labor, gravidity, number of abortion but there was a statistical difference between the study groups in number of living children and number of previous cesarean section. There was no statistically significant difference in clinical examination as regarding BP, temperature, gestational age, presentation, presence of tender scar and rupture of membranes. There was a statistical difference between the study groups in pulse. There was a statistical difference between the study groups in investigations as regarding WBCs, estimated fetal weight and amniotic fluid index but there was a statistical difference in HB and platlets. There was no statistically significant difference in the operative data as regarding visceral and parietal peritoneal closure and duration of the procedure but there was a statistical difference in the level of the surgeon. There was no statistically significant difference between the study groups in presence of post-operative infection.

There was a statistical difference in the level of the surgeon (as the infection rate was higher in cesarean sections done by specialists) and in women with rupture of membranes.

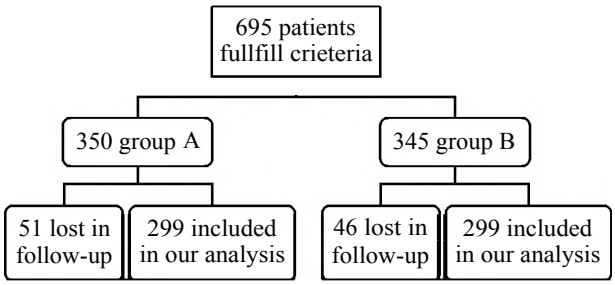

Fig. (1): Patient enrollment.

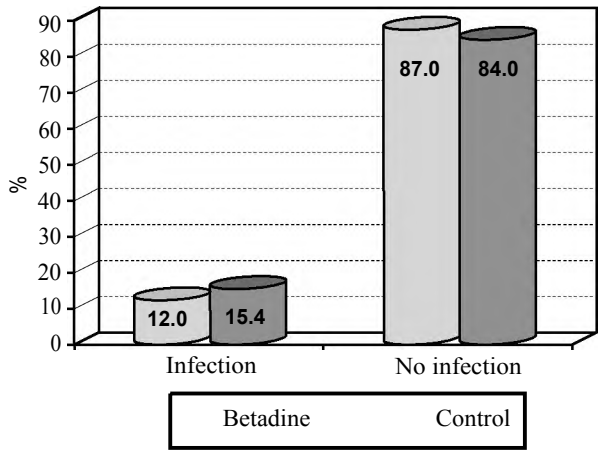

Fig. (2): The presence of either infection.

Table (1): Personal and clinical history.

	Betadine (n=299)		Control (n=299)		*p*-value
	No.	%	No.	%	
Age: (years):					0.926
Mean ± SD	26.4±5.1		26.4±4.6		
Range	15.0-40.0		16.0-40.0		
Education:					0.907
No	186	62.2	178	59.5	
Primary	11	3.7	12	4	
Preparatory	17	5.7	20	6.7	
Secondary	78	26	84	28	
College	7	2.3	5	1.7	
Residence:					0.301
Rural	204	68.2	191	63.9	
Urban	95	31.8	108	36.1	
Urgent or elective:					0.463
Elective	218	72.9	220	73.6	
Urgent	81	27	79	26.4	
Labour:					0.463
Not in labour	218	72.9	220	73.6	
In labour	81	27	79	26.4	
Gravidity	2.93±1.8		2.96±1.7		0.496
FTD	1.7±1.4		1.7±1.5		0.912
No. of abortion	0.24±0.72		0.25±0.6		0.323
No. of living children	1.66±1.46		1.69±1.5		0.016*
No. of cesarean section	1±1		0.96±0.97		0.047*

Table (2): Examinations.

	Betadine (n=299)	Control (n=299)	*p*-value
Pulse:			0.039*
Mean ± SD	86.20±4.4	85.5±4.6	
Range	72.0-97.0	70.0-95.0	
Systolic BP (mm Hg):			0.110
Mean ± SD	111.5±5.9	110.6±7.2	
Range	100.0-130.0	100.0-130.0	
Diastolic BP (mm Hg):			0.142
Mean ± SD	70.7±5.91	70.0±6.3	
Range	60.0-80.0	60.0-80.0	
Temperature (c):			0.501
Mean ± SD	36.99±0.07	36.99±0.04	
Range	36.0-37.2	36.6-37.0	
Gestational age (weeks):			0.496
Mean ± SD	39.1±1.1	39.0±2.4	
Range	38.0-40.0	37.0-40.0	
Presentation: No. (%):			0.321
Cephalic	288 (96.3%)	291 (97.3%)	
Breech	11 (3.7%)	8 (2.7%)	
Tender scar: No. (%):			0.584
Yes	32 (10.7%)	27 (9%)	
No	267 (89.3%)	272 (91.0%)	
Rupture of membranes: No. (%):			0.1
Yes	37 (12.4%)	49 (16.4%)	
No	262 (87.6%)	250 (83.6%)	

Table (3): Investigations.

	Betadine (n=299)	Control (n=299)	*p*-value
Hb (gm%):			
Mean ± SD	11.72±0.56	11.59±0.57	0.006*
Range	10.3-13.0	10.2-12.7	
WBCs:			
Mean ± SD	6.94±0.88	6.87±0.81	0.290
Range	4.2-11.7	5.3-9.5	
PLT:			
Mean ± SD	262±51.167	248±55.575	0.002*
Range	158.4-450.0	128.2-400.0	
EFW (kg):			
Mean ± SD	3.509±1.216	3.536±0.720	0.720
Range	2.3-4.4	2.5-4.5	
AFI: No. (%):			
Average	223 (74.6%)	203 (67.9%)	0.336
Decreased	76 (25.4%)	96 (32.1%)	

Table (4): Operative data.

	Betadine (n=299)		Control (n=299)		*p*-value
	No.	%	No.	%	
Level of surgeon:					
Resident	284	94.9	268	89.6	0.02*
Specialist	15	5.1	31	10.4	
Visceral perit closure:					
Yes	287	95.9	282	94.3	0.3 89
No	12	4.1	17	5.7	
Parietal perit. closure:					
Yes	290	97	284	95	0.348
No	9	3	15	5	
Duration: (min):					
Mean ± SD	33.59±5.57		33.57±5.46		0.969
Range	20.0-49.0		20.0-48.0		

Table (5): First visit.

	Betadine (n=299)		Control (n=299)		*p*-value
	No.	%	No.	%	
Temperature (c):					
Mean ± SD	37.03±0.18		37.04±0.19		0.588
Range	36.5-38.0		36.0-38.0		
Redness	16	5.4	21	7	0.249
Hotness	13	4.3	18	6	0.461
Tenderness	17	5.7	21	7	0.616
Induration	12	4	14	4.7	0.842
Swelling	9	3.0	14	4.7	0.396
Ooze of serous fluid	23	7.7	38	12.7	0.028*
Discharge of pus	8	2.7	8	2.7	1
Dehiscence	7	2.3	4	1.3	0.545
Infection	32	10.7	41	13.7	0.318
Fever (Temp >37.5)	8	2.7	9	3.0	1
Infection score:					
Mean ± SD	0.51±1.6		0.67±1.8		0.254
Median (range)	0.0 (0.0-11.0)		0.0 (0.0-10.0)		

- There was a statistically significant difference in the presence of ooze.

Table (6): Second visit.

	Betadine (n=299)		Control (n=299)		*p*-value
	No.	%	No.	%	
Temperature:					
Mean ± SD	36.9±0.03		37.00±0.01		0.194
Range	36.5-37.0		36.9-37.1		
Redness	0	0.0	3	1	0.249
Hotness	0	0.0	1	0.3	0.5
Tenderness	1	0.3	1	0.3	–
Induration	0	0.0	1	0.3	0.5
Swelling	0	0.0	1	0.3	0.5
Ooze	3	1	5	1.7	0.505
Discharge	3	1	3	1	
Dehiscence	3	1	1	0.3	0.374
Infection	2	0.7	5	1.7	0.287
Fever	0	0.0	0	0.0	–
Infection score:					
Mean ± SD	0.064±0.63		0.084±0.75		0.725
Median (range)	0.0 (0.00-7.0)		0.0 (0.00-11.00)		

There was no statistically significant difference.

Table (7): Presence of either first or second visit infection.

Presence of either infection	Betadine (n=269)		Control (n=269)		*p*-value
	No.	%	No.	%	
Infection	36	12.0	46	15.4	0.285
No infection	263	87.0	253	84.0	

There was no statistically significant difference.

Table (8): Multiple logistic regression analysis.

	p-value	OR	95% C.I.	
			Lower	Upper
Level of surgeon (resident)	0.014*	0.408	0.200	0.835
Rupture of membranes	0.015*	2.059	1.153	3.678
Group (Betadine)	0.426	1.214	0.753	1.957
Constant	0.001	0.282		

Discussion

The study found an overall rate of CS wound infection of 13.7%.

The overall incidence of post-operative infection in group A was 12% and 15.4% in group B but this difference was not statistically significant. The presence of rupture of membranes was associated with a significant increase in the risk of CS infection and surgery done by residents was associated with significantly less risk of infection.

Study strengths and limitations:

Random assignment and blinding of the patients to the assigned group is a point of strength. There was also a representative control group for evaluation. We used standard outcome measures by using the CDC definition of surgical site infection.

However, the investigator was not blinded to the assigned group as she had to do the majority of these surgeries. Due to financial restrictions, culture of wound could not be done.

In this study the overall rate of post cesarean infection was 13.7% which is consistent with a prospective cohort study for infection predictors where the overall rate of post cesarean infection was 12.4% **[13]** and another prospective study with an overall rate 13.9% **[14]**.

However, post-cesarean infection rate was reported to vary from 1.1 to 25% in different studies, but comparison is difficult because of different populations, definitions, classifications and observation time **[8,15-20]**.

Regarding level of surgeon, studies concluded that surgeons were responsible for their wound infection rates and the predisposition for succeeding wound infection was laid in the operating room [21].One study reported that registrars had significantly worse infection rates than consultant but also more infection rate than senior house officer [22].Another study found the overall infection rate for registrars and consultants operating on clinic patients, was double that for consultants operating on private patients **[23]**. This means that other

factors may have contributed to the difference in CS infection risk. As this was not the main scope of research, we did not collect data on these factors e.g. number of personnel in the OR and surgical competence [24].

Although ROM was not prolonged in this study (not more than 12 hours) it was found to statistically significantly increase SSI after CS. Multiple studies found that presence of rupture of membranes is significantly associated with incidence of post-cesarean infection [25-27]. Nielsen and Hökegård, 1982 found that duration of ruptured membranes prior to operation is significantly associated with incidence of infection (*p* less than 0.001) [13]. This means that rupture of membranes per se regardless of the duration can be a risk for CS infection. The presence of genital infection is a predisposing factor for rupture of membranes [28,29]. These organisms may ascend after rupture of membranes to the uterus causing endometritis or wound infection.

The fact that povidone iodine use peroperative reduces CS infection was previously reported in general surgery in multiple systematic reviews [2,30]. 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. It is to be mentioned that they included clean, partially contaminated and contaminated surgeries.

The lack of a statistically significant difference between the two study groups in our study was reported by others [31,32]. In the first study, betadine applied after closure of the fascia was not statistically significantly higher than no irrigation but they included all women eligible for cesarean section unless they were allergic to betadine [31]. In the second study, no difference between betadine and another antiseptic chlorhexidine in surgical site infection in elective cesarean section [32]. This means that the addition of povidone iodine before wound closure confers no added benefit in the reduction of surgical site infection following low infection risk cesarean section.

Conclusion:

There was no benefit of subcutaneous tissue swabbing with povidone iodine in decreasing wound infection following cesarean section.

Recommendations:

Recommendations for research: Auditing the implementation of interventions that reduce cesarean section rate, assessment of the operating room environment and compliance of different staff with infection control measures, assessment of surgical competence of the staff performing CS to evaluate the infection reducing measures, microbiological investigation of lower genital tract and intra amniotic spaces of women with recent rupture of membranes as the mere rupture of membranes was associated with increased risk of CS infection.

Recommendations for practice: The department must adopt interventions that reduce CS rate, training and refresher training of the operating room staff to infection control measures in operating room, regular assessment on the job of surgeons performance of essential procedures such as CS, patient with premature rupture of membranes should undergoe survillance for infection.

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فعالية مسح آنسجة تحت الجلد بمحلول بوفيدون اليود فى العملية القيصرية فى منع عدوى الجرح؛ دراسة عشوائية منضبطة

تقييم فعالية مسح تحت الجلد فى الجروح القيصرية بإستخدام بوفيدون اليود للوقاية من عدوى الجرح بعد العملية الجراحية.

كانت هذه الدراسة دراسة مستقبلية محكومة عشوائيا فى مستشفى صحة المرآة بجامعة آسيوط على النساء اللواتى يخضعن لعملية قيصرية فى الفترة من نوفمبر ٢٠١٥ إلى سبتمبر ٢٠١٦. تم مسح مجموعة الدراسة (المجموعة آ) الآنسجة تحت الجلد مع ١٠سم مكعب من ١٠٪ غير مخفف اليود بوفيدون ولم تتم إزالته. المجموعة باء، لم يتم إستخدامه.

نتائج البحث: فى دراستنا، لم يكن هناك فروق ذات دلالة إحصائية فى التاريخ الشخصى الفحص الإكلينيكى فيما يتعلق بالعمر والتعليم والإقامة والإلحاح فى العملية القيصرية ووجود آعراض ولادة وعدد مرات الحمل والإجهاض ولكن كان هناك فرق إحصائى بين مجموعات الدراسة فى عدد الآطفال وعدد القيصريات السابقة. لم يكن هناك فرق ذو دلالة إحصائية فى الفحص السريرى فيما يتعلق بضغط الدم، درجة الحرارة، آسابيع الحمل، وضع الجنين، وجود آلم بمكان القيصرية السابقة وتمزق الآغشية. كان هناك فرق إحصائى بين مجموعات الدراسة فى النبض. كان هناك فرق إحصائى بين مجموعات الدراسة فى التحاليل فيما يتعلق كرات الدم البيضاء، ووزن الجنين ومؤشر السائل الذى يحيط بالجنين ولكن كان هناك فرق إحصائى فى نسبة الهيموجلوبين والصفائح الدموية. لم يكن هناك فرق ذو دلالة إحصائية فى تفاصيل القيصرية فيما يتعلق بالإغلاق البريتونى ومدة العملية ولكن كان هناك فرق إحصائى فى مستوى الجراح. لم يكن هناك فرق إحصائى بين مجموعات الدراسة فى وجود عدوى ما بعد الجراحة.

الخلاصة: لم يكن هناك فائدة من مسح الآنسجة تحت الجلد بإستخدام بوفيدون اليود فى خفض عدوى الجرح بعد العملية القيصرية.