

The role of saline irrigation of subcutaneous tissue in preventing surgical site complications during cesarean section: A prospective randomized controlled trial

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Ethics Committee Approval

The study was approved by Istanbul Medipol University Clinical Research Ethics Committee. Written approval was obtained from Private Nisa Hospital before the data collection phase (Reference number: 10840098-772.02-E.61616, Date: 17/11/2020). All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest

No conflict of interest was declared by the authors.

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Abstract

Background/Aim: Following cesarean section, wound complications develop in 3 to 30% of the patients. The purpose of this study is to evaluate the effect of subcutaneous saline irrigation during caesarean section on postoperative surgical site complications.

Methods: This prospective randomized controlled study was conducted between November 17, 2020 and December 16, 2020 at Medipol University, Private Nisa Hospital. A total of 230 women undergoing elective cesarean delivery were divided into 2 groups. The subcutaneous tissue was irrigated with saline solution in group 1 (n=115), and not irrigated in the control group (n=115). On the 7th postoperative day, the surgical site was evaluated for hematoma, seroma, wound dehiscence, and superficial surgical site infection.

Results: The incidences of seroma (7% vs. 15.7%, $P=0.013$), hematoma (6.1% vs. 15.7%, $P=0.024$) and superficial surgical site infection (4.3% vs. 11.3%, $P=0.035$) were significantly lower in the saline irrigation group, while the groups were similar in terms of wound dehiscence ($P=0.176$).

Conclusion: Saline irrigation of the subcutaneous tissue during cesarean section decreased the rates of seroma, hematoma, and superficial surgical site infections significantly.

Keywords: Cesarean section, Subcutaneous tissue irrigation, Surgical site infection, Wound dehiscence, Seroma, Hematoma

Introduction

The incidence of cesarean section, one of the most common surgical procedures [1], has increased significantly in the last two decades, especially in developed countries [2]. After surgical procedures, wound complications develop in 3 to 30% of the patients [3]. There are 2 types of surgical site complications: Infectious and non-infectious (seroma, hematoma, wound dehiscence) [4, 5]. The incidence of surgical site infections (SSIs) ranges between 3% and 15% [6]. Today, thanks to modern antibiotic prophylaxis, infection rates after cesarean section have decreased but have not been eliminated completely [7]. Therefore, besides prophylactic antibiotics, other options have been considered in reducing infections after cesarean section.

In two separate meta-analyses in the literature, it was found that the irrigation of subcutaneous tissue with povidone iodine solution, topical antibiotic and saline solution just before the closure of the skin lowers the risk of surgical site infections [8, 9]. There are also studies emphasizing that irrigation of the subcutaneous tissue with saline solution decreases non-infectious wound complications such as seroma and hematoma [10].

This study aimed to investigate the effect of irrigation of the subcutaneous tissue with saline solution during caesarean section on post-cesarean infectious and non-infectious surgical site complications.

Materials and methods

This prospective randomized controlled study was conducted between November 17, 2020 and December 16, 2020 at Medipol University, Private Nisa Hospital. Ethics committee approval, institutional review approval and informed consents of the patients were obtained before the collection of data (Reference number: 10840098-772.02-E.61616, date: 17/11/2020). During conduction of this study, 1964 Helsinki Declaration, and ethical guidelines regarding studies on human participants were conformed with.

Five hundred pregnant women presented to the obstetrics outpatient clinics of Medipol University, Private Nisa Hospital between November 17, 2020-December 16, 2020. Two hundred and eighty underwent cesarean delivery, of which 128 were primiparae and 152, multiparae. G*Power (version 3.1) was used to calculate the sample size of the study. A literature review demonstrated that irrigation of subcutaneous tissue had an effect on postpartum surgical site complications [10]. Considering the literature review and relevant scientific literature, the minimum sample size was calculated as 220 ($n = 110$ for each group) with a type 1 error of 0.05 and a power of 0.95 ($\alpha = 0.05$, $1-\beta = 0.95$). However, bearing in mind the possible losses during the study, we decided to include 115 participants in each group.

The patients with even protocol numbers were included in the saline irrigation group, while those with odd protocol numbers constituted the control group. Randomization was generated using a computer-based random number generator with a 1:1 allocation (<https://stattrek.com/statistics/random-number-generator.aspx>). The experiment and control groups were enrolled into a list by the researchers. To avoid bias and to

standardize the surgical procedure, all patients were operated by the same surgical team.

The subcutaneous tissue was irrigated with 200 ml of saline solution (0.9% NaCl) in patients in the experimental group (Group 1, $n=115$), and not irrigated in those in the control group ($n=115$) before the skin was closed.

Patients between 20-40 years of age with a gestational age of 37-42 weeks who were to undergo cesarean section for the first or second time were included in the study. Those with an active infection, premature rupture of membranes, surgical drains, previous abdominal surgery, subcutaneous tissue thickness of >3 cm, allergic reaction, anemia, thrombocytopenia, preoperative leukocytosis, and patients using steroids/antibiotics or undergoing emergency caesarean section (acute hemorrhage, fetal distress), along with those with a body temperature above 38°C were excluded from the study.

Data collection procedure

All patients underwent the same standard pre-surgical preparations. Routine abdominal scrubs were used to clean the patients in all the groups. The following surgical method was followed in all patients: A Pfannenstiel skin incision was performed. Two grams of cefazolin sodium was administered to the patients intravenously for prophylaxis as soon as the umbilical cord was clamped. After uterine and peritoneal closure, the fascia was closed continuously with a 1/0 vicryl suture. Before closure, the subcutaneous tissue was irrigated with 200 ml of saline solution (0.9% NaCl) in the study group and not irrigated in the control group. Subcutaneous bleeding was stopped with electro-cauterization, and the skin was closed with a 3/0 Vicryl Rapid suture. All participants underwent routine postoperative care. Surgical dressing was changed 24 hours after the surgery and then at the 48th hour the patients were discharged from the hospital.

Patients' demographic characteristics, preoperative hemoglobin and hematocrit levels, duration of the operation, C reactive protein and procalcitonin values at the 24th postoperative hour and evaluations of the surgical site in terms of hematoma, seroma, wound dehiscence and superficial surgical site infection were performed through inspections and abdominal ultrasonography on the 7th postoperative day.

Seroma was diagnosed in the presence of serous fluid drainage without any signs of infection. Hemorrhagic drainage without any signs of infection indicated hematoma. Wound dehiscence was defined as the separation of the skin without infection. Purulent discharge or erythema, fever, induration, and tenderness in the surgical site, which required separation of the incision, indicated an infection.

Serum PCT levels were measured with the LUMI test (Berlin, Germany) and recorded as ng/ml. Serum CRP concentrations were assayed using a Cobas 6000 analyzer (Switzerland) and recorded as mg/dL.

The primary outcome of the study was the detection of surgical site complication rates.

Statistical analysis

Kolmogorov Smirnov test was used to find out whether the variables were distributed normally. Continuous variables were compared using independent samples t-test or Mann-Whitney U test. The categorical data were compared using Chi-

squared or Fisher's exact tests. *P*-values of less than 0.05 were considered statistically significant. The data were analyzed with IBM SPSS V23.

Results

This study included 230 pregnant women who underwent elective cesarean section. The comparison of the groups in terms of demographic characteristics demonstrated no differences in terms of age, BMI, and gestational age (*P*>0.05 for all).

The groups were similar with regards to preoperative hemoglobin and hematocrit levels, postoperative hemoglobin and hematocrit levels and duration of the operation (*P*>0.05). However, postoperative 24th hour CRP (*P*<0.001) and Procalcitonin (*P*<0.001) values were different. The mean CRP and procalcitonin values of the saline and control groups were 25 mg/dL vs 35 mg/dL and 0 ng/ml vs 0.1 ng/ml, respectively (Table 1).

Table 1: Comparison of the groups in terms of their demographic characteristics and laboratory values

	Saline solution group (n=115) Mean (SD)	Control group (n=115) Mean (SD)	<i>P</i> -value*
Age (Year)	30 (5.59)	29 (5.15)	0.334
BMI(kg/m2)	30.72(8.77)	30.66(8.69)	0.657
Gestational age (weeks)	38.1 (1.23)	38.3 (1.75)	0.304
Preoperative Hb (g/dL)	12.61 (1.18)	12.52 (1.24)	0.637
Preoperative HCT%	35.21 (2.11)	36.33 (1.71)	0.377
Postoperative Hb (g/dL)	11.61 (1.18)	11.81 (1.27)	0.053
Postoperative HCT%	33.26 (1.91)	33.57 (2.11)	0.486
Operation duration (min)	30.93 (11.11)	30.35 (14.07)	0.054
Postoperative 24 th hour CRP mg/dl	25.01 (5.2)	35.23 (5.7)	0.001
Postoperative 24 th hour PCT (ng/ml)	0.01 (0.11)	0.10 (0.05)	0.001
Postoperative fever 1 st week °C	36.20 (2.30)	36.89 (2.7)	0.001

* Mann-Whitney U Hb: hemoglobin, HCT: hematocrit, CRP: C Reactive Protein, PCT: procalcitonin, VAS: Visual analog score

The incidences of seroma (7% vs. 15.7%, *P*=0.013), hematoma (6.1% vs. 15.7%, *P*=0.024) and superficial surgical site infection (4.3% vs. 11.3%, *P*=0.035) were significantly lower in the saline irrigation group, while the groups were similar in terms of wound dehiscence (*P*=0.176) (Table 2).

According to logistic regression analysis, the incidences of seroma, hematoma, and SSI were lower in the saline group compared to the control group (seroma: OR=0.51, 95%:0.22-1.16, RR:0.55, *P*=0.037; hematoma: OR=0.34, 95%:0.14-0.87, RR:0.38, *P*=0.020; SSI: OR=0.43, 95%:0.15-1.17, RR:0.46, *P*=0.048) (Table 3).

Table 2: Comparison of the groups in terms of the surgical site complications

	Saline solution (n=115) n %	Control (n=115) n %	<i>P</i> -value*
Seroma	8 (7)	18 (15.7)	0.013
Hematoma	7 (6.1)	18 (15.7)	0.024
Wound Separation	9 (7.8)	6 (5.2)	0.176
Superficial surgical site infection	5 (4.3)	13 (11.3)	0.035

χ²: chi-square test statistics * Frequency (percentage)

Table 3: Comparison of the saline with the control group

	OR	Seroma 95%CI	RR	Hematoma 95%CI	RR	Surgical site infection 95% CI RR
Saline solution	0.40	0.16-0.96	0.44	0.14-0.87	0.38	0.12-1.03 0.38
			0.34		0.35	

OR: Odds ratio; CI: confidence interval; RR: relative risk

Discussion

In this study, there were significant differences between the study and control groups in terms of seroma, hematoma, and superficial surgical site infection development, while the groups were similar in terms of wound separation.

Consecutive stages of wound healing are hemostasis, inflammation, epithelialization, fibroplasia and maturation, and the entire process takes about 2 to 4 weeks. Hematoma is the collection of blood in the tissue, which occurs when blood leaks out of blood vessels into the surrounding tissue after an injury. Seroma is the accumulation of inflammatory exudate in the tissue due to surgical trauma [11]. The incidence of non-infectious surgical site complications such as seroma and hematoma after cesarean section ranges between 3% and 30%, which may result in wound dehiscence and surgical site infection [3, 12].

One of the most effective methods of preventing wound complications after surgery is the irrigation of the subcutaneous tissue. Irrigation removes debris and blood clots in the surgical site and reduces the possibility of seroma and hematoma development. In the literature, there are different opinions related to this issue. In their meta-analysis, Müller et al. [8] reported that irrigation of surgical sites with a topical antibiotic, povidone-iodine solution or saline solution reduced the risk of SSIs. However, in another meta-analysis, while the irrigation of surgical site with povidone iodine solution had a low impact on SSI, antibiotic irrigation had no effect [13]. In this study, there was a statistically significant difference between the group that underwent subcutaneous irrigation during cesarean section and the control group in terms of superficial surgical site infection development. We think that this difference stems from the fact that the samples included heterogeneous patient populations with different surgical site infections.

Different solutions are used for the irrigation of the subcutaneous tissue. However, the most preferred one is the saline solution since it is an isotonic solution. Saline solution does not adversely affect healing of the wound site, and it is used to remove blood clots and necrotic tissues from the wound. The net effect of irrigation with saline in reducing wound infection is unknown. The review of the literature demonstrated that while in some studies, irrigation of the subcutaneous tissue with saline solution decreased surgical site infections [14], in some others, there was no significant difference [9, 15, 16]. In their study, Aslan Çetin et al. [10] irrigated surgical sites of the women who underwent cesarean section with saline solution, reducing the risk of hematoma and seroma by 51% and 69% respectively. However, they did not find a significant difference in terms of surgical site infection and wound separation. Similarly, in our study, the incidence of seroma, hematoma and surgical site infection was lower in the saline group compared to the control group (seroma: OR=0.51, 95%:0.22-1.16, RR:0.55, hematoma: OR=0.34, 95%:0.14-0.87, RR:0.38, SSI: OR=0.43, 95%:0.15-1.17, RR:0.46).

Strengths and limitations of the study

A review of the literature demonstrated that there are a limited number of studies investigating both non-infectious and infectious surgical site complications in patients whose subcutaneous tissues were irrigated with Saline solution during

caesarean section. We believe that our study can contribute to the literature on this subject.

The limitation of our study is the nongeneralizability of our results, since we included pregnant women who were not in active labor and who were to undergo cesarean section for the first or second time. We recommend that future studies include larger samples of diverse groups to overcome this limitation.

Conclusion

In the present study, saline irrigation of the subcutaneous tissue of pregnant women during cesarean section decreased the rates of seroma, hematoma, and superficial surgical site infections significantly. However, there were no differences between the groups in terms of wound dehiscence. Prospective studies with larger patient groups are required to investigate this easily applicable and cost-effective method without any major side effects.

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