Closure Versus Non Closure of Subcutaneous Tissue in Cesarean Section in Diabetic Women: A Randomized Controlled Trial

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ABSTRACT

Background: caesarean section is one of the most commonly performed abdominal operations on women in most countries of the world. Its rate has increased markedly in recent years and is about 20–25% of all child-births in most developed countries. **Aim of the work:** this study aimed to assess the surgical site infection rate and patient satisfaction following closure of the subcutaneous tissue compared to non-closure of subcutaneous tissue in the diabetic women undergoing cesarean section. **Patients and methods:** this randomized prospective controlled study was conducted in Ain Shams University, Maternity Hospital. Elective cesarean section was done during the period from June 2016 to May 2017 to a sample of 88 pregnant women with diabetes mellitus. **Results:** there was no significant difference between closure and non –closure of the subcutaneous tissue in cesarean section in the diabetic women regarding SSI and wound complications. However, there was a significant difference between closure and non- closure of the subcutaneous tissue as regard the time needed for cesarean section closure which was in favor of non - closure of the subcutaneous tissue. **Conclusion:** closure of the subcutaneous tissue was superior to non-closure as regard patient satisfaction and cosmetic outcome. **Recommendations:** subcutaneous tissue closure can be used in diabetic patients undergoing cesarean section as long as it was not associated with significant increase in SSI, it had better cosmosis and patients' satisfaction.

Keywords: closure, non-closure subcutaneous tissue, cesarean section, diabetic women.

INTRODUCTION

Cesarean section is one of the most common operative procedures performed in modern obstetrics [1]. Cesarean section rates showed wide variation among countries in the world, ranging from 0.4 to 40 percent and a continuous rise in the trend has been observed in the past 30 years [2]. Closure of the subcutaneous fat theoretically decreases tension on the above skin layer. Suture closure of the subcutaneous fat could therefore result in superior cosmetic outcome by decreasing tension on the skin layer. Evidence suggested that suture closure of the subcutaneous fat at the time of CS reduced the risk of wound disruption in women with a subcutaneous tissue larger than two centimeters [3].

Gestational diabetes mellitus (GDM) is a condition characterized by glucose intolerance during pregnancy and is associated with a variety of adverse birth outcomes, including excessive fetal weight gain and related increases in the rate of cesarean delivery and perinatal injury [4]. The most common complications of CS are superficial surgical site complications including sepsis, seroma formation and breakdown [5]. This study aimed to assess the surgical site infection rate and patient satisfaction following closure of the subcutaneous tissue compared to non- closure of subcutaneous tissue in diabetic women undergoing cesarean section.

PATIENTS AND METHODS

This was a randomized prospective controlled study conducted in Ain Shams University, Maternity Hospital during the period from June 2016 to May 2017.In this study elective cesarean section was done to a sample of 88 pregnant women with diabetes mellitus.

Sample size calculation

The required sample size had been calculated using the G*Power Software (Universität Düsseldorf, Germany), setting the type 1 error (α)at 0.05and the power (1- β)at 0.8. Data from a previous study showed that the incidence of surgical site infection associated with closure of subcutaneous tissue was 2% compared to 7% in association with non-closure of subcutaneous tissue [6]. So, it is estimated that a total sample size of 88 patients equally randomized into either study group (n=44 patients per group).

Inclusion criteria

1. Pregnant women in childbearing period (25-35 years).
2. Women planned for elective cesarean section.
3. Pregnant women with gestational diabetes or women with type 2 diabetes according to medical records according to ACOG classification [7]

Exclusion criteria

1. Hemoglobin less than 10g/dl.

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2. Intra operative events that may themselves predispose to postoperative infection (e.g. operative time more than 90 minutes).
3. Rupture of membranes more than 12 hours.
4. Receive corticosteroid medications.
5. Immunosuppressive disease or Auto immune disease.
6. Concurrent infection (e.g. signs of pyelonephritis, chest infection).

• All participants in the study had consent.

Procedure:-

All included women were subjected to the following:

1. History

Full history included: personal, present, past and obstetrics history.

2.Clinical examination including:

- **General examination**:

1. Assessment of vital data (blood pressure, heart rate, Respiratory rate and body temperature).
3. Cardiac and chest examination, to exclude any contraindication for anesthesia.
4. BMI **≤ 30kg/m2**.

- **Abdominal examination:**

Assessment of fundal level for fetal dating, fetal lie and fetal heart sound was done.

3. Investigations:

- **Laboratory**

Complete blood picture.
Random blood sugar.

- **Ultrasonography:**

Fetal biometry for fetal dating and fetal viability was done.

4. Informed consent was obtained from each subject following a detailed explanation of the objective of the study.
5. Fulfilling the items in the patient's file of Ain Shams University Maternity Hospital.
6. All cesarean section procedures were performed by surgeons who at least have 2 years' experience in practicing cesarean sections (senior resident).
7. All participants operated under general or spinal anesthesia. Prophylactic antibiotic was given according to the approved protocol of Ain Shams Maternity Hospital
8. Scrubbing and cleaning of the abdomen starting from the level of xiphisternum till the knee, using povidine iodine 7.5% antiseptic solution,then10% iodine was washed.
9. Any scar of previous cesarean section was removed.
10.In group A (closure group) the subcutaneous fat was closed with three to five interrupted sutures using absorbable polyglatin (Vicryl®, Ethicon, United States). **In group B** (non- closure group) the subcutaneous fat was not sutured.
11. In all participants skin was closed by subcuticular stitches using absorbable polyglactin 910 suture(Ethicone VICRYL RAPIDE™ 2-0)].
12. Dressing was removed after 24 hours postoperatively and the wound was inspected 48 hours, 7 days and one month after the cesarean section.

Randomization and allocation:

Women who were incorporated in the study were randomly allocated into two groups**:-**

1.Group A (closure group): included 44 pregnant women who
were undergoing elective cesarean section with closure of subcutaneous tissue.

2.Group B (non- closure group): included 44 pregnant women who were undergoing elective cesarean section without closure of subcutaneous tissue.

Randomization is performed using computer-generated randomization system.

Outcome measures:

Primary outcome measures were surgical site infection and wound dehiscence (Wound separation) or positive culture. Secondary outcome measures were wound seroma, postoperative pain and postoperative fever

The study was done after approval of ethical board of Ain Shams university and an informed written consent was taken from each participant in the study.

Data management and analysis:

The collected data were coded, tabulated and statistically analyzed using SPSS program (statistical package for social since) software version 18.0. Descriptive statistics were done for numerical parametric data as mean ±SD (standard deviation) and minimum &maximum of the range, while they were done for categorical data as number and percentage. Analyses were done for quantitative variables using independent t- test in case of two independent groups with parametric data. Analyses were done for qualitative data using Chi square test for independent variables. The level of significance was taken at p value <0.05 is significant.

RESULTS

88 participants were categorized into **group 1**(subcutaneous tissue closure) and **group 2** (subcutaneous tissue non closure).

All included women were diabetic blood sugar (140 mg /dl)

The mean preoperative blood sugar was 149.3.
The mean postoperative blood sugar was 159.6.

The included women were randomized into two groups:

1. Group 1: subcutaneous tissue closure (n=44) included women who had the subcutaneous tissue closed via simple interrupted sutures using vicryl sutures.

2.Group 2: subcutaneous tissue non closure (n=44): included women who had the subcutaneous tissue left unclosed.

Table 1: difference between both groups regarding descriptive data:

	Group I (Subcutaneous tissue closure group) (n=44)	**Group II (Subcutaneous tissue non closure group) (n=44)**	**P value**
Age(years)			
Range	18 – 34	18 - 35	0.320*
Mean ± SD	25.3 ± 4.5	25.8± 4.4	
Parity			
Range	0 – 3	0 - 3	0.946**
Median(IQR)	1(1)	1(1)	
Gestational age			
Range	36 – 38	36 - 38	0.236*
Mean ± SD	37.29 ± 0.66	37.27± 0.65	
C.S (N0.%)			
Primary	19(43.2%)	19(43.2)	0.281***
Repeat	25(56.8)	25(56.8)	

*Using independent sample t – test, **using mann-whitny test.

***Chi-square test

This table showed no statistically significant difference between the groups as regard age, parity, gestational age and number of cesarean section with p- value > 0.05(Non significant).

Table 2: difference between both groups regarding closure time:

Closure time (min)	**Group I cutaneous tissue closure group) (n=44)**	**Group II utaneous tissue non closure group) (n=44)**	**P - value**
	9 - 18	7 - 17	**0.005**
± SD	15.1± 1.8	12.5± 2.16	

Using independent sample t test

P –value< 0.05 significant p value> 0.05 non-significant.

This table showed significant difference between the two groups as regard closure time as p value is < 0.05.

The mean closure time (skin subcutaneous tissue) was higher in women of **group 1** when compared to that in women of group which affected the overall timing of the cesarean section. In **group 1** mean wa 15.1± 1.8, while in **group 2** mean was 12.5± 2.16, p-value 0.005.

Table 3: difference between both groups regarding postoperative pain ((VAS scale-10):

Post Operative pain	**Group I (subcutaneous tissue closure)**	**Group II (subcutaneous tissue non closure)**	**P - value**
After 2 days Mean ± SD	6.97 ± 0.87	5.70 ± 0.59	0.507*
After 7 days Mean ± SD	3.90 ± 0.8	3.92 ±0.7	0.914*
After 30 days Mean ± SD	0.71 ± 0.55	0.63 ±0.48	0.334*

*Using independent sample t test; p value >0.05 NS.

This table showed no statistically significant difference between groups as regards postoperative pain.

Table 4: difference between both groups regarding wound collection

Wound collection	Group I (subcutaneous tissue closure)	Group II (subcutaneous tissue non closure)	P - value	RR(95% CI)
After 2 days	0 (0%)	0 (0%)	NE	NE
After 7 days	4 (9.09%)	12 (27.27%)	**0.024**	.10 (0.56 to 17.06)
After 30 days	0 (0%)	0 (0%)	NE	NE

RR (95%CI) relative risk and its confidence interval
NE:not estimable due to nullity of one or both categories.
Chi-square test ;p value< 0.05 (Significant).
This table showed stastically significant difference between the two groups as regard wound collection 7 days.

Table 5: difference between both groups regarding scar appearance [according to visual analogue scale (Durani *et al*)] [10].

Scar appearance	Group I (subcutaneous tissue closure)	Group II (subcutaneous tissue non closure)	P - value
Good	**9 (20.45%)**	**9 (20.45%)**	**0.396**
Very good	**23 (52.27%)**	**20 (45.46%)**	
Excellent	**11 (25%)**	**9 (20.45%)**	
poor	**1 (2.28%)**	**6 (13.64%)**	

Chi-square test;p value> 0.05 **(Non Significant).**
This table showed no statistical significant difference between the two groups as regard scar appearance.

Table 6: difference between both groups regarding cosmetic patient view (Satisfaction)

Patient satisfaction	Group I (subcutaneous tissue closure)	Group II (subcutaneous tissue non closure)	P - value
satisfied	35 (79.5%)	30 (68.2%)	**0.024**
unsatisfied	9 (20.5%)	14 (31.8%)	
total	44 (100%)	44 (100%)	

Chi-square test; p value< 0.05 (Significant).
This table showed statistical significant difference between the two groups as regard patient satisfaction.

DISCUSSION

This study was a randomized controlled trial conducted in Ain Shams Maternity Hospital in the period from June 2016 to May 2017.It was included 88 women planned for elective cesarean section who have diabetes and they were randomized into groups:

Group I (Closure of subcutaneous tissue): included 44 women in final analysis who had subcutaneous tissue closed with simple interrupted sutures.

Group II (Non closure of subcutaneous tissue): included 44 women in final analysis who had subcutaneous tissue left unclosed.

This study showed that there was no statistically significant difference in demographic data between the two groups as parity, gestational age, operative details, BMI and type of CS.

As regard the age, in **group I** the mean age in was 25.29 ± 4.28 years with range 18 – 34, while in **group II** it was 23.72 ± 4.36) years with range18 - 35 (p- value was 0.320).

In both groups the median of parity was 1 with range 0 – 3 (p value was 0.946) The mean gestational age in **group I** was 37.29 ± 0.66 and range was 36 – 38,while in **group II** it was 37.27 ± 0.65 and range was36 – 38 with p-value 0.236.

According to type of cesarean section, in **group I** 19(43.2%) were primary and 25(56.8%) were repeated in comparison to 19 (43.2%) primary C.S. and 25(56.8%) repeated C.S. in

group II with p-value 0.281.The mean BMI in **group I** was 25.7 ± 1.6 and range was 24 - 29 and in **group II** the mean was 25.9 ± 1.3 and range was 24 – 27.9 with p-value 0.196.

As regard type of diabetes in **group I** it was 34 (77.27%) were gestational DM, 10 (22.73%) were type 2 DM, while in **group II** it was 32 (72.73%) were gestational DM, 12 (27.27%) they were type 2 DM with p-value 0.315.

There was no statistical difference between the two groups.as regard type of cesarean section and type of diabetes.

All included women were either primigravida, primi-cesarean section.All the cesarean sections were elective due to malpresentations and previous sections.

Husselin *et al.* [6] did not specify the indication for cesarean sections, but they included all pregnant women between 18 – 45 years old of caucasian race and literate in German language while their exclusion criteria included clinical signs of infection at time of c s, HELLP syndrome or preeclampsia, history of keloids and previous transverse keloid scar. As regard closure time of cesarean section, this study showed statistically significant difference between the two groups.The mean closure time (Skin S.C. tissue) was higher in **group I**/when compared to that in women of **group II** which affected the overall timing of the cesarean section.

In **group I,** the mean closure time was15.1± 1.8, while in **group II** the mean closure time was 12.5± 2.16 with p-value (0.005).

This is in line with results of **Gaertner *et al.*** [8] who stated that suture closure of the subcutaneous tissue increased the total time of C.S by 4 to 5 minutes when compared to closure of skin by either staples versus intracutaneous sutures, they recommend closure of skin by intercutaneous sutures regardless closure of C.S tissue or not.

Husselin *et al* [6] found that operative time was not different between the two groups (closure group median 25 min with range 12-18) versus non closure median 23 min and range 14-51.

Regarding post- operative pain, this study showed no statistically significant difference between the two groups as regard post- operative pain 2,7 and 30 days postoperatively.

This is in accordance with results of **Islam *et al.*** [9] who used the same VAS and had the same outcome as our study.

Regarding wound collection, this study showed statistically significant difference between the two groups as regard wound collection 7 days postoperatively.

In **group I** (subcutaneous tissue closure) after 7 days post-operative there was 4 positive cases stated for 9.09 %, while in **group II** (subcutaneous tissue non closure) there was 12positive cases stated for 27.27%,with RR: 3.10(0.56 to 17.06).

In this study, there were no cases of wound collection in either **groups 2** days postoperatively. There were no cases of wound collection in either the groups 30 days postoperatively.

This is in agreement with **Husslein *et al.*** [6] who stated that suture closure of subcutaneous fat resulted in significantly less wound hematomas. Hematoma predispose to wound morbidity, often represent major concern to the patients and therefor to be avoided. there were 11 cases of hematomas in non-closure group in comparison with only 2 cases in S.C tissue closure group with RR: 17 (0.04 to 0.73) and p-value 0.005.

Islam et al. [9] stated that closing subcutaneous tissue may reduce the risk of hematomas and seroma. Further researches are needed to investigate how these outcomes affect the recovery and well-being of the patient.

Chelmow *et al.* [3] stated that theoretically by suturing the fat tissue and closing the subcutaneous dead space the formation of hematomas and seroma could be prevented by preventing wound disruption.

Regarding wound inflammation, this study showed no statistically significant difference between the two groups.

In **group I** (subcutaneous tissue closure) after 7 days post-operative there were 8 positive cases stated for 18.18%,while in **group II** (subcutaneous tissue non closure) there was 10 positive cases stated for 22.73% with RR: 0.889 (0.231 to 3.418)

In this study, there were no cases of wound inflammation in either the groups 2 days postoperatively. There were no cases of wound collection in the groups 30 days postoperatively.

Regarding wound dehiscence, this study showed no statistically significant difference between the two groups after 2,7 and 30 days postoperatively.

In **group I** (subcutaneous tissue closure) after 7 days post-operative there was 4 positive cases stated for 9.09%, while in **group II** (subcutaneous tissue non closure) there was 6 positive cases stated for 13.63% with RR: 1.167 (0.655 to 2.079).

In **group I** (subcutaneous tissue closure) after 30 days post-operative there was 1 positive cases stated for 2.8%,while in **group II** (subcutaneous tissue non closure) there was 2 positive cases stated for 4.5%.

In this study, there were no cases of wound inflammation in the groups 2 days postoperatively.

There was not a single case of positive culture in the two groups.

This is in line with results of **Husslein *et al*.** [6] who stated that they found no difference regarding the rate of SSI or wound disruption between both groups.

Islam *et al.* [9] stated that there was no difference in the risk of wound infection alone or other short outcomes as found in group 1 S.C tissue non closure were 35 cases in comparison to 34 cases in group 2 S.C tissue closure regarding superficial wound infection.

Chelmow *et al* [3] in their meta-analysis study they found that in absence of subcutaneous tissue closure the baseline incidence of complications were hematoma 1.6%,seroma 8.5%,wound infection 7.1% and wound disruption 14.3% and there was a reduction in the incidence of hematomas, seroma and wound disruption.

In this study, by using stony brook scar evaluation scale, there was no stastical significant difference between the two groups as regard scar appearance with p-value 0.396.

Husslein *et al.* [6] showed that scar assessment at sex months after C.S revealed no significant difference between the two groups with respect to objective or subjective POSAS summary scores, VSS summary scores or patient self-rating on the presence of retraction of the scar below the level of the skin.

Islam *et al.* [9] found that cosmetic results in both groups were equally good in group 1 (1970) patients had good cosmetic results compared to (1975) patients in group 2 with p-vale=0.497.

As regard patient satisfaction in the present results, the rate of patient satisfaction was significantly higher in women of **group 1**(subcutaneous tissue closure) compared to women in **group 2** (subcutaneous tissue non closure). In **group I**, satisfied women were 35 patients (79.5%) and unsatisfied women were 9 patients (20.5%). In **group II**, satisfied women were 30 patients (68.2%) and unsatisfied women were 14 patients (31.8%) with p-value 0.024. This showed statistical significant difference between the two groups as regard patient satisfaction.

The results of **Husslein *et al.*** [6] in their randomized controlled trial suggested that suture closure of the subcutaneous fat compared to non-closure of subcutaneous fat at time of cesarean section did not affect the long term cosmetic outcome. However, closure of subcutaneous fat reduced wound hematoma and seroma, had a neutral effect on cosmoses and previously demonstrated to reduce wound disruption in women with subcutaneous fat larger than 2 cm. So this study supported a low threshold for suture closure of subcutaneous closure fat at time of cesarean section.

Islam *et al.* (2011) [9] stated that patient psychological satisfaction was higher in group 1 than group 2 despite non –closure of S.C fat in group 1 the skin was closed with subcuticular vicryl sutures in comparison with closing skin in group 2 with subcuticular polyprelene non-absorbable sutures, which was not the condition in this study as patients of both groups since their skin closed by subcuticular stitches using non-absorbable polypropylene 2- 0.

Chelmow *et al.* [3] did not discuss the patient satisfaction as separate item, but they concluded that closure of the subcutaneous tissue decreases the incidence of formation of hematomas and wound disruption which enhanced the overall appearance and cosmetic outcome of the wound after cesarean section.

CONCLUSION

This study demonstrated that there was no significant difference between closure and non – closure of the subcutaneous tissue in cesarean section in diabetic women regarding SSI and wound complications.

However, there was a significant difference between closure and non- closure of the subcutaneous tissue as regard the time needed for cesarean section closure which was in favor of non -closure of the subcutaneous tissue.

Closure of the subcutaneous tissue was superior to non-closure as regard patient satisfaction and cosmetic outcome.

So, subcutaneous tissue closure can be used in diabetic patients undergoing cesarean section as long as it was not associated with significant increase in SSI, had better cosmosis and patients' satisfaction.

List of abbreviations

HELLP:	Hemolysis elevated liver enzymes, low platelet count
AADE	American Association of Diabetes Educators
ACOG	American College of obstetrics and Gynecology
	Body mass index

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