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The value of subcutaneous tissue closure and drain in obese women undergo elective caesarean section: a randomized controlled trial

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Abstract

Objective to compare the efficacy and safety of subcutaneous suture reapproximation alone versus suture plus subcutaneous drain or non-closure for the prevention of wound complications in obese women undergoing elective cesarean delivery (CD).

Methods This randomized controlled open label trial was conducted on 352 obese women candidates for elective CD. Participants were randomized into 4 groups: group I ($n=89$) were allocated for interrupted closure of subcutaneous tissue with insertion of subrectus drain, group II ($n=88$) were allocated for interrupted closure of subcutaneous tissue, group III ($n=88$) were allocated for insertion of subrectus drain, group IV ($n=87$) were allocated for non-closure of subcutaneous tissue without insertion of subrectus drain The primary outcome parameter was the development of wound complications including seroma, infection and dehiscence. Secondary outcome included postoperative pain assessed by VAS, postoperative fever, time of hospital stay and duration of surgery.

Results There were significant differences between the 4 groups regarding the mean duration of surgery (48.67 ± 2.84, 46.56 ± 4.80, 45.95 ± 4.29, and 41.59 ± 5.08 in combined, sutures only, drain only and none groups, respectively, $P<0.001$).

Assessment of outcome parameters revealed significant differences between the 4 groups regarding postoperative pain (2.93 ± 1.95, 3.62 ± 2.26, 3.83 ± 2.16, and 3.99 ± 2.032, $P=0.006$), postoperative fever (3/68 (3.5%),5/86 (5.8%),3/68 (3.5%),, and 12/86 (14%), $P=0.017$) wound infection (4/68 (4.7%),7/86 (8.1%),4/68 (4.7%),, and 13/86 (15.1%), $P=0.035$) and wound dehiscence (4/68 (4.7%),6/86 (7%),8/68 (9.3%),, and 16/86 (18.6%), $P=0.011$) and highly statistical significant differences regarding wound seroma (4/68 (4.7%),13/86 (15.1%),6/68 (7%),, and 21/86 (24.4%), $P<0.001$) and redressing(10/68 (11.6%),17/86 (19.8%),19/68 (22.1%), and 32/86 (37.2%), $P<0.001$) 08 in combined, sutures only, drain only and none groups, respectively.

Conclusion The additional use of a subcutaneous drain along with a standard subcutaneous suture reapproximation technique is effective for the prevention of wound complications named seroma, redressing, dehiscence and infection in obese women undergoing CD.

Trial Registration NCT04177381 Date of registration: 21/11/2019.

Keywords Caesarean section, Obese, Subcutaneous drains, Subcutaneous sutures, wound complications, Surgical site infection

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A Why was this study conducted?

To compare the efficacy and safety of subcutaneous suture reapproximation alone versus suture plus subcutaneous drain or non-closure for the prevention of wound complications in obese women undergoing elective cesarean delivery (CD).

B What are the key findings?

- Postoperative pain score and fever were significantly lower in obese women with combined use of subcutaneous drain and suturing compared to women in other 3 groups.
- All wound complications named seroma, infections, dehiscence and redressing were significantly higher in women who did not undergo neither drain nor suturing compared to women in the other 3 groups

C What does this study add to what is already known?

- This study confirmed the value of combined use of subcutaneous drain with subcutaneous tissue suturing in decreasing postoperative pain and fever in obese women undergoing elective CD.
- The combined use of subcutaneous drain with subcutaneous tissue suturing is associated with decreased incidence of wound seroma, dehiscence, redressing and infection in obese women undergoing elective CD.
- An individual area based cost effective assessment should be carried guided by the available resources to reach the decision of routine use of drain with suturing or its use in a certain degree of obesity.

Introduction

Cesarean delivery (CD) is the commonest surgical procedures conducted all over the world with over one million operations conducted in the United States only yearly [1].

Worldwide, CD rates exceed 21% of all births which is higher than the WHO recommended rates of 10–15%. CD rates increased in both well developed and underdeveloped countries, but the incidence vary largely among developing countries ranging from < 5% in sub-Saharan Africa to reach > 50% in Egypt [2].

Although CD can be a lifesaving procedure in some cases and is associated with lower risk of maternal pelvic floor and neonatal birth injuries, the maternal morbidity during CD is twice its equivalent during vaginal births [3].

These risks included higher rates of hemorrhage, infections, anesthetic, thromboembolic complications, and even death. Later risks in future pregnancies include uterine rupture and placenta accretta spectrum [4].

The rate of primary CD is higher in obese women undergoing trial of labor. It reaches 23–49% and positively correlates with maternal body mass index (23–46%, 30–47%, 45–49% for BMI ≥ 30, ≥ 40 and ≥ 50 kg/m^2 respectively). The most common indications for cesarean delivery are arrest of labor (61%) and non-reassuring fetal heart rate (28%) [5].

CD in obese women carries a higher risk of peri-operative surgical and anesthetic complications. These include infections, increased blood loss, and longer operative times and thromboembolic events [6].

Surgical Site Infection (SSI) is the infection in the incision site that occurs within 30 days of the operation [7].

Wound complications including dehiscence and infection, affect 10% of obese women after CD [8] and may reach 30% in morbidly obese women [9].

Techniques of management of subcutaneous tissue space during CD especially in obese women is considered a large area of debates. In a Cochrane review, closure of subcutaneous space in women with space thickness more than 2 cm is associated with lowered the risks of wound complications named seroma, separation, hematoma and infection [10].

In a systematic review the closure of subcutaneous space in women with space thickness more than 2 cm is associated with 34% decrease in the wound disruption risks [11] and that was confirmed in a more recent meta-analysis [12].

The placement of subcutaneous drain was suggested as an alternative to subcutaneous suturing. Earlier studies demonstrated that the placement of subcutaneous drain after CD was associated with increased rates of wound infections [13].

More recent studies demonstrated that subcutaneous drain placement is associated with a decreased risk of all wound complications [14, 15].

The placement of subcutaneous drain to prevent wound complication is controversial [16].

The aim of this study is to compare the efficacy and safety of subcutaneous suture reapproximation alone versus suture plus subcutaneous drain or non-closure for the prevention of wound complications in obese women undergoing elective cesarean delivery.

Material and methods

This randomized controlled open label trial was conducted on 352 obese women candidates for elective cesarean delivery at kasr Alainy maternity hospital between March 2021 and November 2022. The study was conducted according to CONSORT guidelines. The study's aim, details, risks and benefits were explained

to all participants and their right to withdraw from the study at any time. The study was conducted in accordance with the Declaration of Helsinki and registered on clinical trial registration number NCT04177381.

The inclusion criteria were obese women (BMI ≥30 kg/m2) carrying a single living non anomalous fetus candidate for elective lower segment cesarean delivery, age between 25 and 35 years and the gestational age between 37 and 41 weeks (calculated by sure dates of LMP and confirmed by a first trimester ultrasound). Their body mass index ranged between 30 and 40 kg/m2.

The exclusion criteria were medical disorders that can affect wound healing as uncontrolled diabetes, anemia, kidney or liver diseases, women with skin infections or previous history of wound infection, women with immunodeficiency disorders and those on steroid therapy. Women with hypoalbuminemia, obstetric complications as placenta previa or hypertensive disorders with pregnancy and those with intraoperative complications as intestinal injury were also excluded from the study. A written informed consent was signed by all women to participate in the study.

The planned sample size for this investigation was based on a clinically significant difference in the effect of subcutaneous tissue closure in obese women with BMI more than 30 on wound complications. We used epi info software to calculate the sample size while expected frequency =14.4 and margin of error =5% on power 80%, We found that 81 patients for each group (total =324) is needed. An expected drop rate between 5 and 10%, the number was increased to 352. [17].

All participants were subjected to complete assessment through history and examination to ensure adherence to the study inclusion and exclusion criteria. All women were assessed by obstetric ultrasound to confirm fetal viability, gestational age, placental site and other routine evaluation. Participants were randomized the night before surgery using a computer-generated random numbers into 4 groups: group I (n= 89) were allocated for interrupted closure of subcutaneous tissue with insertion of subrectus drain, group II (n= 88) were allocated for interrupted closure of subcutaneous tissue, group III (n= 88) were allocated for insertion of subrectus drain, group IV (n= 87) were allocated for non-closure of subcutaneous tissue without insertion of subrectus drain.

All women received prophylactic antibiotics (2 g of cefazolin) 30–60 min before the operation [18].

The operation started by induction of spinal anaesthesia after preload with 20 ml per kilogram body weight of 6% hydroxyl ethyl starch or ringer's lactate through 18G cannula followed by injection of 10 mg of 0.5% hyperbaric bupivicaine and 20 mg of fentanyl through 25G spinal needle inserted between lumbar vertebrae 3 and 4 [19].

All operations were conducted by obstetricians with close surgical experience using the same technique. The operation started by a transverse incision (Pfannenstiel incision) with sharp dissection through the subcutaneous tissue, Incision of the fascia at midline, separation of the fascial sheath from the underlying rectus muscles, dissection of the transversalis fascia and preperitoneal fat to reach the underlying peritoneum which was incised sharply, the reflection of peritoneum above the upper margin of the bladder and overlying the anterior lower uterine segment termed the bladder flap was grasped in the midline with forceps and incised transversely with scissors.Bladder flap creation effectively moves the bladder away from the planned hysterotomy site and prevents bladder laceration if an unintended inferior hysterotomy extension occurs during fetal delivery, delivery of the Fetus and placenta, the uterine incision then closed with two layers of continuous No.1 absorbable suture polyglactin 910 (Vicryl), rectus fascia was closed by a continuous, nonlocking technique with a delayed absorbable suture of vicryl No 1. Skin was closed with a running subcuticular stitch using 2–0 non-absorbable suture.

Women assigned to subcutaneous sutures underwent suture closure with interrupted 2–0 polyglactin 910 (Vicryl) with 1 cm intervals between sutures [20]. While women assigned to drain had a closed nonvacuum drain inserted in the tissue and exit from the skin through a separate opening and stitched to the skin [14]. The drain was left until the drainage rate was less than 30 ml/day or after 72 h [21].

Transfer to recovery room and fluid therapy (3 L in 24 h) was achieved. Pain was controlled using NSAID. The urinary catheter was removed after 2- 4 h with maternal mobilization. Oral fluids were allowed with mobilization. Postoperative thromboprophylaxis in the form of LMWH 0.6 mg/kg/day started 12 h after surgery [22].

Assessment of postoperative pain was done using the visual analogue scale (VAS) which is a psychometric response to questionnaires. It measures the subjective characteristics that cannot be measured directly. It is a 10 cm scale ranging from 0 no pain to 10 maximum pain [23].

Two follow up visits after 1 and 2 weeks of the operation to assess the wound.

The primary outcome parameter was the development of wound complications including seroma (defined as a collection of subcutaneous clear serous fluid at or near the wound), infection (defined as expression of purulent discharge from the wound associated with signs of inflammation as redness and hotness) and dehiscence

(defined as partial or complete separation of wound layers after closure) [19].

Secondary outcome included postoperative pain assessed by VAS, postoperative fever, time of hospital stay and duration of surgery.

Quantitative and qualitative data was presented as mean (SD) or number (percentage), respectively using statistical package for the social sciences (SPSS, v. 22, IBM, Armonk, New York, United States). Comparison between groups were analyzed using ANOVA followed by posthoc test for significant outcomes. A P value < 0.05 and < 0.001 were considered statistically significant and highly significant, respectively.

Results

We assessed 514 women for inclusion, 391 of them met the inclusion criteria. After exclusion of 39 women (refused to participate or sign the informed consent), 352 women were randomized to the 4 groups (89,88,88, and 87 respectively). We analysed 86 women in each group after we lost 3,2,2, and 1 woman in the 4 groups respectively.

Table 1 shows that the 4 study groups were statistically not different in age, gravidity, parity, body mass index, gestational age, the number of previous CD, indications for CD or in postoperative fluid therapy.

There were significant differences between the 4 groups regarding the duration of surgery being longer in both drain and sutures followed by sutures only then drain only and the shortest duration were found in women without subcutaneous suturing or drain (Table 1).

Assessment of outcome parameters revealed significant differences between the 4 groups regarding postoperative pain, postoperative fever, wound infection and wound dehiscence and highly significant differences regarding wound seroma and redressing (Table 2).

Post-hoc analysis for all significant differences were described in Table 3. Table 4 shows subgroup analysis in primipara and in primary caesarean delivery.

Discussion

The VAS pain score was worst in none group followed by drain only then suture only and least in both groups. This can be explained by the tissue exudates in the large subcutaneous tissue. This exudate irritates the nerve endings and increases the pain sensation. This exudate can be decreased by drain insertion and further reduction can be achieved through suturing and closing this dead space preventing collection.

Postoperative fever was higher in none group then suture group and similar in both combined and drain only. Similarly, to pain it can be explained by the tissue exudates in the large subcutaneous tissue. This exudate is rich in pyrogenic mediators with the resultant increase in body temperature. This exudate can be decreased by drain insertion and further reduction can be achieved through suturing and closing this dead space preventing collection.

The findings of our study confirmed that all wound complications named seroma, infections, dehiscence and redressing were significantly lower in women who underwent combined suturing and drain compared to women in the other 3 groups.

Table 1 Clinical and operative data of the studied groups

		Group 1 both sutures and drain ($n = 86$)	Group 2 sutures only ($n = 86$)	Group 3 drain only ($n = 86$)	Group 4 none ($n = 86$)	Total (= 344)	*P* value
Age (years)		30.31 ± 3.24	30.2 ± 3.21	30.27 ± 3.21	30.13 ± 3.23	30.23 ± 3.21	0.983
Parity		1.85 ± 0.77	1.78 ± 0.77	1.69 ± 0.77	1.8 ± 0.76	1.78 ± 0.77	0.566
BMI (kg/m^2)		32.15 ± 1.23	32.68 ± 1.50	32.57 ± 1.62	32.66 ± 1.46	32.51 ± 1.47	0.476
Gestational age (weeks)		38.73 ± 1.14	38.47 ± 0.98	38.20 ± 1.76	38.48 ± 4.06	38.47 ± 2.22	0.174
Previous CS		6 (7.0%)	1 (1.2%)	1 (1.2%)	2 (2.3%)	10 (2.9%)	0.095
Surgery duration (minutes)		48.67 ± 2.84	46.56 ± 4.80	45.95 ± 4.29	41.59 ± 5.08	45.69 ± 5.03	< 0.001*
Indications of CS	Malpresentation	14 (16.3%)	13 (15.1%)	24 (27.9%)	20 (23.3%)	71 (20.6%)	0.09
	IUGR	16 (18.6%)	18 (20.9%)	9 (10.5%)	7 (8.1%)	50 (14.5%)	
	CPD	7 (8.1%)	3 (3.5%)	3 (3.5%)	7 (8.1%)	20 (5.8%)	
	Maternal request	9 (10.5%)	15 (17.4%)	11 (12.8%)	13 (15.1%)	48 (13.9%)	
	Fetal distress	34 (39.5%)	36 (41.9%)	38 (44.2%)	37 (43%)	845 (24.6%)	
	Previous CS	6 (7%)	1 (1.2%)	1 (1.2%)	2 (2.3%)	10 (2.9%)	
Postoperative fluid therapy (liter)		3.29 ± 1.00	3.25 ± 1.09	3.47 ± 1.01	3.36 ± 98		0.50

Data are presented as mean ± SD or number (percentage)

BMI body mass index; CPD Cephalopelvic disproportion; CS Cesarean section

Table 2 Postoperative events in the studied groups

	Group 1 both sutures and drain (*n* = 86)	Group 2 sutures only (*n* = 86)	Group 3 drain only (*n* = 86)	Group 4 none (*n* = 86)	Total	*P* value
Postoperative pain (VAS)	2.93 ± 1.95	3.62 ± 2.26	3.83 ± 2.16	3.99 ± 2.032	3.59 ± 2.13	0.006
Postoperative fever	3 (3.5%)	5 (5.8%)	3 (3.5%)	12 (14.0%)	23 (6.7%)	0.017
Wound redressing	10 (11.6%)	17 (19.8%)	19 (22.1%)	32 (37.2%)	78(22.7%)	< 0.001
Wound seroma	4 (4.7%)	13 (15.1%)	6 (7.0%)	21 (24.4%)	44(12.8%)	< 0.001
Wound infection	4 (4.7%)	7 (8.1%)	4 (4.7%)	13 (15.1%)	28(8.1%)	0.035
Wound dehiscence	4 (4.7%)	6 (7.0%)	8 (9.3%)	16 (18.6%)	34(9.9%)	0.011
Secondary sutures	1 (1.2%)	2 (2.3%)	2 (2.3%)	3 (3.5%)	8 (2.3%)	0.83
Time of drain removal (d)	2.36 ± 0.68	–-	2.73 ± 0.64	–-		0.001
Duration of hospital stay (d)	2.46 ± 0.64	3.24 ± 0.98	3.86 ± 1.36	3.34 ± 1.1		< 0.001

Data are presented as mean ± SD or number (percentage)

D Days; VAS Visual Analogue scale

Table 3 Post Hoc analysis between the 4 study groups

	Group 1	Group 2	Group 3	Group 4
Duration of surgery				
Group 1		< 0.001	< 0.001	< 0.001
Group 2			0.004	< 0.001
Group 3				0.015
Pain	1	2	3	4
Group 1		0.143	0.028	0.006
Group 2			0.915	0.653
Group 3				0.975
Fever	1	2	3	4
Group 1		0.469	1.00	0.015
Group 2			0.469	0.074
Group 3				0.015
Redressing	1	2	3	4
Group 1		0.142	0.067	< 0.001
Group 2			0.708	0.011
Group 3				0.03
Seroma	1	2	3	4
Group 1		0.021	0.514	< 0.001
Group 2			0.088	0.125
Group 3				0.002
Infection	1	2	3	4
Group 1		0.044	< 0.001	0.133
Group 2			0.044	0.08
Group 3				0.132
Duration of hospital stay				
Group 1		< 0.001	< 0.001	< 0.001
Group 2			< 0.001	0.817
Group 3				< 0.001

Group 1 both sutures and drain

Group 2 sutures only

Group 3 drain only

Group 4 none

We also noted that all wound complications named seroma, infections, dehiscence and redressing were significantly higher in women who did not undergo neither drain nor suturing compared to women in the other 3 groups.

The occurrence of wound dehiscence and redressing was higher in the drain group compared to suture group while wound seroma and infection were higher in sutures group compared to drain group.

For our investigation, we evaluated the concurrent use of a drain with suture subcutaneous tissue reapproximation under the hypothesis that the concurrent use of postsurgical drainage of the subcutaneous space theoretically would provide further reduction in potential dead space and removal of residual fluid and blood from the wound that could serve as a medium for bacterial growth. We selected women with 2 cm or more of subcutaneous tissue thickness for randomization into our trial to evaluate efficacy in a population for postcesarean wound complications. The additional use of a subcutaneous drain along with a standard subcutaneous suture reapproximation technique was effective for the prevention of wound complications in obese women undergoing CD.

Allaire and colleagues [14] compared the use of subcutaneous suture closure with subcutaneous drain in 76 women undergoing CD. They found a higher incidence of overall complication rate as well as major complication (disruption or infection) in those left without drain and without subcutaneous tissue suturing compared to women subjected to either subcutaneous suture closure or subcutaneous drain.

Magann and colleagues [15] in their RCT conducted on 590 women with a subcutaneous depth of 2 or more cm to evaluate subcutaneous stitch closure, insertion of a subcutaneous drain and no closure. They found no

Table 4 Subgroup analysis of outcomes

		Group 1 both sutures and drain	Group 2 sutures only	Drain 3 Group only	Group 4 none	*P* value
Primipara	Postoperative fever	1/33	1/37	2/43	6/35	0.046
	Wound redressing	7/33	7/37	6/43	8/35	0.763
	Wound seroma	2/33	5/37	4/43	7/35	0.314
	Wound infection	1/33	4/37	3/43	2/35	0.625
	Wound dehiscence	2/33	3/37	5/43	10/35	0.024
	Duration of hospital stay (d)	2.46 ± 0.65	3.25 ± 0.97	3.86 ± 1.35	3.32 ± 1.1	< 0.001
Primary CD	Postoperative fever	3/80	5/85	3/85	10/84	0.09
	Wound redressing	10/80	17/85	19/85	31/84	0.002
	Wound seroma	4/80	13/85	6/85	21/84	< 0.001
	Wound infection	4/80	7/85	4/85	14/84	0.020
	Wound dehiscence	4/80	5/85	8/85	16/84	0.009
	Duration of hospital stay (d)	2.46 ± 0.65	3.24 ± 0.98	3.86 ± 1.36	3.34 ± 1.1	< 0.001

Data are presented as numbers or mean ± SD

significant difference in the incidence of either major wound disruptions or incidences of seroma, hematoma or infection in the 3 groups. However, in this trial only major disruptions were reported, and they have a high rate of dropout cases reaching 24%.

Chelmow and colleagues [11] confirmed the benefits of subcutaneous suture closure in their meta-analysis that included 5 RCTs. They found that subcutaneous suture closure in women with subcutaneous tissue thickness equal or more than 2 cm was associated with a significant reduction in the rate of wound disruption and seroma when compared with wounds with no suture closure. The potential benefits of subcutaneous drainage provide further reduction in potential dead space and removal of residual fluid and blood from the wound that could serve as a medium for bacterial growth.

In our study the duration of hospital stay was not different between the 4 study groups. This finding was similar to the findings of the CAESAR trial [24] that reported a duration of hospital stay of 4.8 ± 1.9 days in the drain group versus 4.7 ± 1.8 days in the no drain group ($P = 0.09$).

In our study the duration of surgery was significantly longer in women with combined sutures and drain, followed by sutures then drain then non group. This was expected as the time needed for suturing is slightly longer than the time needed for drain insertion. Although this difference was statistically significant, it does not present a clinically significant difference.

This study is the first well designed randomized trial with properly calculated sample size that compared 4 groups of for either sutures and/or drain in all possible combinations in the middle east.

The main limitations of the study were the short term follow up for only 2 weeks while other wound complications as keloid need a longer follow up. However, this was not possible due to the expected high rates of dropout cases in our community. Another limitation was the non-blinding of the participants to the interventions that could affect the subjective outcomes as postoperative pain. However, as the evolution of wound complications was done by objective assessment, that would not have a major impact.

We concluded that the additional use of a subcutaneous drain along with a standard subcutaneous suture reapproximation technique is effective for the prevention of wound complications named seroma, redressing, dehiscence and infection in obese women undergoing CD. Also, the combined use of drain and subcutaneous sutures is associated with less postoperative pain and fever.

Supplementary Information

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Supplementary Material 1.

Supplementary Material 2.

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Authors' contribution
Authors' contribution MAS: project development, Data collection, writing, revision and approval of manuscript HHM: Data collection; data analysis, writing, revision and approval of manuscript AMM project development, data analysis, writing, revision and approval of manuscript YAB project development, revision and approval of manuscript NS data analysis, writing, revision and approval of manuscript And all authors reviewed the manuscript.

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Data availability
The data is attached as a supplementary file.

Declarations

Ethics approval and consent to participate
The study was approved by Kasr Aliany ethical committee on 18/01/2020 with MS- 338–2019 number. The study was conducted in accordance with the Declaration of Helsinki.
All participants give their written consent to participate.

Consent for publication
All participants give their approval for publication.

Competing interests
The authors declare no competing interests.

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