Original Research Article

Routine Subcutaneous Drain versus No Drain in Cesarean Section for Diabetic Obese Women: A Randomized Controlled Trial

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A B S T R A C T

Objective of the study is to evaluate the role of routine placing of a subcutaneous drain in obese diabetic women at cesarean section. Obese diabetic term pregnant women, admitted for cesarean section included in this study. The included women randomly allocated to one of two groups: group I, including women who had a subcutaneous drain left before closure of the skin; and group II, including women who had no subcutaneous drain left. The primary outcome measures; rate of superficial surgical site infection (SSI), Secondary outcome measures; wound seroma, superficial wound breakdown, postoperative fever and postoperative pain. There was no significant difference between two studied groups regarding; superficial SSI, superficial wound breakdown and post-operative fever. There was significant difference between group I (Drain group) and group II (No Drain) regarding; wound seroma (8 cases 8 (9.6%) versus 23 cases (26.7%); respectively)), relative risk was 0.3 (95%CI; 0.17-0.75) and postoperative pain required analgesics (median 5 (range; 3-6) versus 16 (range; 12-18); respectively), relative risk was 3.3 (95%CI; 1.2-8.6). Routine subcutaneous drainage in cesarean section for obese diabetic women seems to be significantly associated with reduced rates of wound seroma and post-operative pain.

Introduction

Cesarean section (CS) is one of the most common operative procedures performed in modern obstetrics (Mackeen *et al.,* 2012).

Despite being that, common, surgical techniques and steps do widely vary (Tully *et al.,* 2002). These variations depend on many factors including surgeon's preferences, patient's characteristics and available facilities and circumstances (Berghella *et al.,* 2005).

The most common complications of CS are superficial surgical site complications including sepsis, seroma formation and breakdown (Hofmeyr *et al.,* 2008). Obesity and diabetes mellitus are currently prevailing diseases. CS procedures performed for obese and/or diabetic women are increasing nowadays (Wahabi *et al.,* 2014).

Such superficial surgical site complications commonly encountered in CS for obese and diabetic women (Leth *et al.,* 2011). One of the common, yet debatable, practices in CS is to use a subcutaneous drain in obese or diabetic women. The advantage of such a practice is to drain any blood or serous fluid that may accumulate in the subcutaneous space, which cause post-operative pain or provide a good medium for microbial growth and infection (Gates and Anderson, 2005 and Gates and Anderson, 2013). Some surgeons, however, have raised much argument about the value of subcutaneous drains (Enkin, 1995).

The aim of this study was to evaluate the role of routine placing of a subcutaneous drain in obese diabetic women at CS.

Patients and methods

This randomized controlled trial conducted at Ain Shams University during the period between December 2012 and November 2013. The study protocol was in agreement with the Helsinki Declaration for Ethical Medical Research (last updated in Seoul, South Korea, 2008). All participating women signed informed written consent after thorough explanation of the purpose and procedure of the study. The study included obese diabetic term pregnant women, admitted from the causality for delivery by CS. Obesity was defined when the woman's body mass index (BMI) (calculated as weight (in kilograms) divided by squared height (in squared meters)) was above 30 kg/m^2. All included women had controlled gestational or pre-existing diabetes mellitus, maintained on insulin therapy.

Controlled diabetes mellitus was defined when a recent (no earlier than 2 weeks) glycated hemoglobin (HbA1C) was equal to or less than 7% (Rafat and Ahmad, 2012).

The included women randomly allocated to one of two groups: group I, including women who had a subcutaneous drain left before closure of the skin; and group II, including women who had no subcutaneous drain left.

Randomization performed using a computer-generated randomization system. Concealed allocation applied. Allocation numbers encased in serially numbered opaque sealed envelopes that only opened after closure of the uterine incision.

CS procedures performed by by lecturer of the causality (lecturer of the causality; who had passed the residency program for 3 years and having an experience for 3 years as assistant lecturer, with MD degree), assisted by a registrar of the causality (Yehia *et al.,* 2014).

In studied women, the skin incised through a low transverse incision. Sharp dissection always followed. The lower uterine segment opened through a C-shaped incision. After delivery of the fetus, the placenta and membranes delivered by controlled cord traction. The uterine incision is closed in two continuous layers using number 1 delayed absorbable polyglatin (Vicryl®, Ethicon, United States) stitches. The visceral and parietal layers of peritoneum not closed. The fascial layer was closed using number 1 continuous delayed absorbable polyglatin (Vicryl®, Ethicon, United States) stitches. In women of both groups, the subcutaneous fat was closed by number 2/0 interrupted delayed absorbable polyglatin (Vicryl®, Ethicon, United States). The skin closed using subcuticular continuous non-absorbable polypropylene (Prolene®, Ethicon, United States) stitch. The drain left in women of group I was Nelaton's catheter (Size Ch/Fr 14, Apexmed International Keizersgracht, Amsterdam) that was manually fenestrated (4-5 fenestrae) using a

pair of scissors and was exited from the skin through a separate opening about 2 Cm lateral to one of the wound angles. The drain stitched to the skin, connected to a urinary bag and left in place for 48 hours. Women who had major intraoperative complications as; bowel or urinary tract injuries or massive blood loss or transfusion excluded from the study. In all included women, the subcutaneous layer thickness measured using the scalpel hand, which then measured against a standard ruler.

The primary outcome measures; rate of superficial surgical site infection, defined as presence of wound discharge that yielded a positive result on bacteriological culture. Secondary outcome measures; wound seroma, superficial wound breakdown (defined as skin and/or subcutaneous dehiscence with intact fascial layer), postoperative fever (defined as temperature $\geq 38^{\circ}$C, 24 hours postoperatively) and postoperative pain (judged after 24 hours, through visual analogue scale (VAS); with 0 meaning no pain, and 10 meaning the worst pain).

Sample size and statistical anlysis

The required sample size was calculated using G* Power software, version 3.17 for sample size calculation [*Heinrich Heine Universität; Düsseldorf; Germany], setting the α-error probability at 0.05, power [1-β error probability] at 0.95%, and effective sample size [w] at 0.3. The effective size [w] was calculated as follows: $w = \sqrt{\chi^2/N}$, where X2 is the chi-square test and N is the total sample size. The number of participants' $\geq$ 134 needed to produce a statistically acceptable figure.

Data were collected and statistically analyzed using SPSS (Statistical Package for Social Sciences); computer software version

18 (Chicago, IL, USA). Mean and SD (standard deviation) were used to represent numerical variables, while, number and percentage were used to represent categorical variables. Independent student's t-test, used for numeric parametric variables, and Chi-square (x^2) test for categorical variables analysis. The risk association presented in terms of risk ratios (RRs) and their 95% confidence intervals, as well as the absolute risk reduction (ARR) calculated. P value <0.05 was considered significant.

Results and Discussion

One hundred and seventy-four eligible women recruited in this trial. Figure 1 shows a flow diagram showing the study course, excluded cases and reasons for exclusion.

There was no significant difference between group I (Drain group) and group II (No Drain) regarding; mean age (28.3 ± 5.2 versus 27.9 ± 4.4 years; respectively), mean BMI (34.1 ± 1.9 versus 34.2 ± 1.7; respectively), mean gestational age (37.2 ± 2.8 versus 37.4 ± 2.6 weeks; respectively). In addition, there was no significant difference between group I and group II regarding; median parity (1 (Range; 1-2) versus 1 (Range; 1-2); respectively) and mean HbA1C (6.25 ± 0.32 versus 6.29 ± 0.33%; respectively) (Table 1).

There were no significant differences between two studied groups regarding; operative time and subcutaneous layer thickness. In addition, there was no significant difference between two studied groups regarding; superficial SSI, superficial wound breakdown and post-operative fever (Table 2).

There was significant difference between group I (Drain group) and group II (No Drain) regarding; wound seroma [8 cases 8

(9.6%) versus 23 cases (26.7%); respectively)], relative risk was 0.3 (95% CI; 0.17-0.75), and postoperative pain required analgesics [median 5 (range; 3–6) versus 16 (range; 12-18); respectively], relative risk was 3.3 (95%CI; 1.2-8.6) (Table 2).

The current trial showed significant difference between group I and group II regarding; wound seroma [8 cases 8 (9.6%) versus 23 cases (26.7%); respectively)], relative risk was 0.3 (95%CI; 0.17-0.75) and postoperative pain required analgesics [median 5 (range; 3–6) versus 16 (range; 12-18); respectively], relative risk was 3.3 (95%CI; 1.2-8.6). However, the benefit of subcutaneous drain regarding; post-operative fever, superficial SSI and wound breakdown was statistically insignificant.

An old Cochrane systematic review conducted by Enkin (1995), to evaluate role of routine wound drainage in cesarean section in which two trials included (Loong *et al.,* 1988; Saunders and Barclay, 1988). Enkin concluded that the use of such drainage may be of benefit if hemostasis is inadequate, but a benefit from a routine use has not been established (Enkin, 1995).

Seven trials (1993 women) were included in the review conducted by Gates et al (Gates and Anderson, 2005), to compare the effects of using a wound drain versus no drain at caesarean section wound, on maternal health and healthcare resource use. Meta-analysis found no difference in the risk of wound infection, other wound complications, febrile morbidity or endometritis in women who had wound drains compared with those who did not. There was some evidence that caesarean sections may be about five minutes shorter and that blood loss may be slightly lower when drains were not used (Gates and Anderson, 2005).

Another recent large Cochrane systematic review done by Gates and Anderson (2013) to compare the effects of using a wound drain versus no drain at caesarean section wound, and of different types of drain, on maternal health and healthcare resource use (Gates and Anderson, 2013). Meta-analysis found no difference in the risk of wound infection, other wound complications, febrile morbidity or pain in women who had wound drains compared with those who did not. There was some evidence from one trial that a subcutaneous drain may increase wound infection compared to a sub-sheath drain (RR 5.42; 95% CI 1.28 to 22.98). No differences in outcomes were found between subcutaneous drainage and subcutaneous suturing in the three trials that made this comparison (Gates and Anderson, 2013).

The definition of febrile morbidity was variable between studies. The definition that most suitable for the target of subcutaneous drainage was that used in the current trial: a temperature $\geq$ 38°C after 24 hours postoperatively. Exclusion of the first 24 hours excludes the reactionary fever that may occur due to the surgical trauma of cesarean section itself. Some authors defined febrile morbidity as that required antibiotic treatment (CAESAR study, 2010).

The later definition, however, should confuse between febrile morbidity and sepsis, and is, therefore, not appropriate in our opinion.

A total of 3033 women were studied by CAESAR study collaborative group to evaluate effect of alternative surgical techniques in women undergoing cesarean section including liberal versus restricted use of drains (CAESAR study, 2010).

Table.1 Demographic data of studied women

Variables	Group I (Drain Group) (Number 83)	Group II (No Drain) (Number 86)	P value (95% CI), Significance
Age (years) Mean ± SD	28.3 ± 5.2	27.9 ± 4.4	P = 0.06 (-1.0, 0.4, 1.8), Non-Significant*
BMI (kg/m2) Mean ± SD	34.1 ± 1.9	34.2 ± 1.7	P = 0.1 (-0.6, -0.1, 0.44), Non-Significant*
Parity Median (Range)	1 (1 − 2)	1 (1 − 2)	P = 1 (1,96), Non-Significant**
Repeat cesarean section Number (%)	45 (54.2%)	41 (47.7%)	P = 0.6 (1.96), Non-Significant**
Gestational Age (weeks) Mean ± SD	37.2 ± 2.8	37.4 ± 2.6	P = 0.2 (-1.01, -0.2, 0.61), Non-Significant*
HbA1C (%) Mean ± SD	6.25 ± 0.32	6.29 ± 0.33	P = 0.6 (-0.1, 0.04, 0.05), Non-Significant*

**Analysis using Chi-square ($X2$) test
*Analysis using independent student's t-test
BMI: Body mass index
HbA1C: Glycated hemoglobin

Table.2 Superficial SSI, wound seroma, wound breakdown, post-operative fever and pain in both studied groups

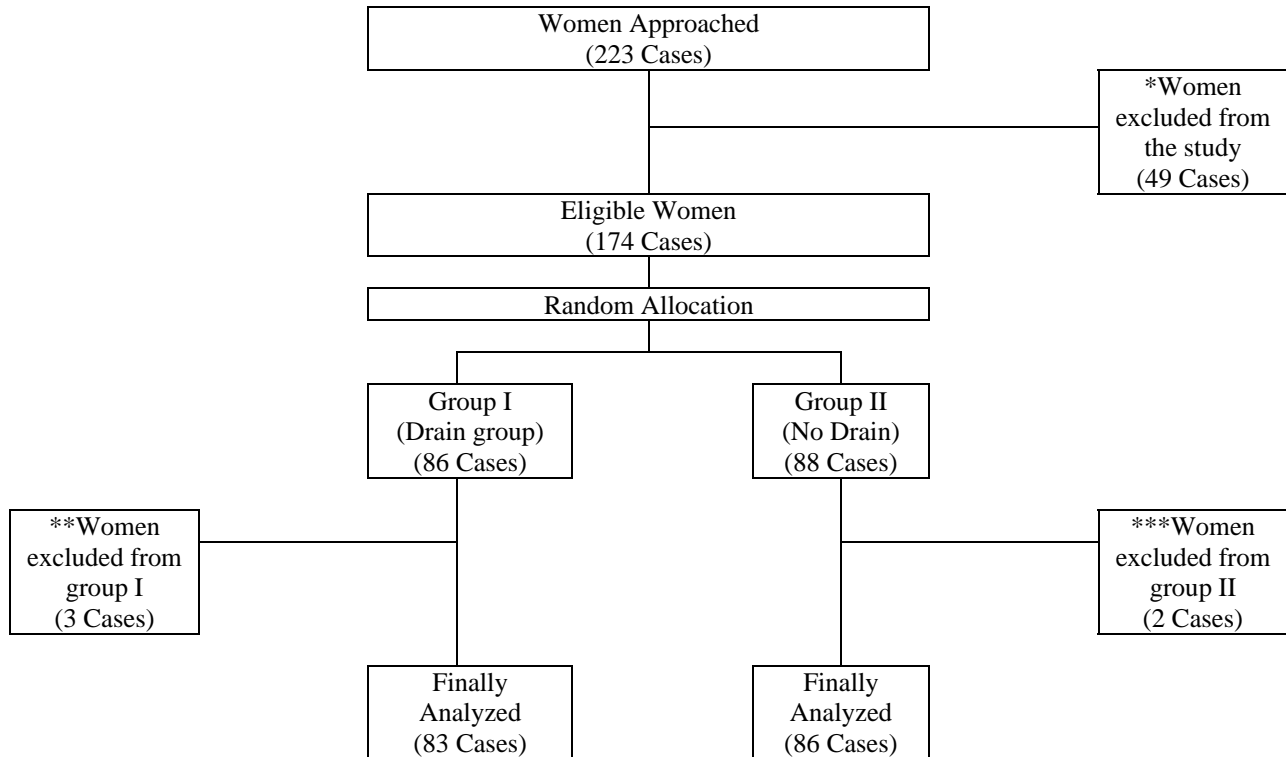| Variables	Group I (Drain Group) (Number 83)	Group II (No Drain) (Number 86)	P value	RR (95% CI)	ARR
Superficial SSI Number (%)	5 (6%)	6 (7%)	0.6* (NS)	0.86 (0.27 - 2.72)	0.95%
Wound seroma Number (%)	8 (9.6%)	23 (26.7%)	0.01* (S)	0.3 (0.17 - 0.75)	12.34%
Superficial breakdown Number (%)	4 (4.8%)	7 (8.1%)	0.4* (NS)	0.59 (0.18 - 1.95)	3.32%
Postoperative fever Number (%)	10 (12%)	15 (17.4%)	0.3* (NS)	0.69 (0.33 -1.45)	5.39%
Postoperative pain Median (Range)	5 (3 − 6)	16 (12 − 18)	0.01* (S)	3.3 (1.2 - 8.6)	11.23%

*Analysis using chi-squared (X^2) test
RR (95% CI): Relative Risk and its 95% Confidence interval
SSI: Surgical site infection
S: Significant difference
NS: Non-Significant difference

Figure.1 Flow diagram of the study course, excluded cases and reasons for exclusion

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┌─────────────────────────┐
│   Women Approached      │
│     (223 Cases)         │
└─────────────────────────┘           ┌──────────────┐
            │                         │  *Women      │
            │─────────────────────────│ excluded from│
            │                         │  the study   │
            │                         │  (49 Cases)  │
            │                         └──────────────┘
┌─────────────────────────┐
│    Eligible Women       │
│     (174 Cases)         │
└─────────────────────────┘
┌─────────────────────────┐
│    Random Allocation    │
└─────────────────────────┘
        │            │
┌──────────────┐  ┌──────────────┐
│   Group I    │  │   Group II   │
│ (Drain group)│  │  (No Drain)  │
│  (86 Cases)  │  │  (88 Cases)  │
└──────────────┘  └──────────────┘
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┌──────────────┐   ┌──────────────┐
│ **Women   │   │ ***Women   │
│ excluded from│   │ excluded from│
│   group I   │   │   group II   │
│ (3 Cases)   │   │ (2 Cases)   │
└──────────────┘   └──────────────┘

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┌──────────────┐  ┌──────────────┐
│   Finally    │  │   Finally    │
│  Analyzed    │  │  Analyzed    │
│  (83 Cases)  │  │  (86 Cases)  │
└──────────────┘  └──────────────┘
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*Women excluded from the study (49 cases); uncontrolled diabetes (22 cases), women who did not consent for the study (13 cases), women who had their cesarean section after prolonged trial of labor with frequent vaginal examination (6 cases) and women who had preoperative sepsis (chorioamnionitis or urinary tract infection) (8 cases).
**Women excluded from group I (3 cases); 1 case of bladder injury, 1 case of bowel injury and 1 case of blood transfusion for intraoperative blood loss.
*** Women excluded from group II (2 cases); 1 case of bladder injury and 1 case of blood transfusion for intraoperative blood loss.

In addition; significant reduction of post-operative pain after usage of subcutaneous drain in cesarean section was concluded by CAESAR and Kumar (CAESAR study, 2010; Kumar, 2004). Both Kumar and CAESAR studies used the VAS as a semi-objective tool for assessment of pain (CAESAR study, 2010 and Kumar, 2004).

In conclusion, routine subcutaneous drainage in cesarean section for obese diabetic women seems to be significantly associated with reduced rates of wound seroma and severe post-operative pain. However, the benefit regarding post-operative fever, superficial SSI and wound breakdown was statistically insignificant.

Acknowledgment

Conflict of interest: Authors declare that they have no conflict of interest in relation to this study.

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