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ROUTINE SUBCUTANEOUS DRAIN VERSUS NO DRAIN IN CAESAREAN SECTION FOR OBESE WOMEN- A PROSPECTIVE OBSERVATIONAL COMPARATIVE STUDY

Dr Sudip Mukhopadhyay[1], Dr Animesh Naskar[2], Dr Nitu Kumari[3], Dr Pallab Kumar Mistri[4], Dr Sujata Dalai[5]
[1]Assistant Professor, Dept. of Obstetrics And Gynaecology, Raiganj Government Medical College, Raiganj, West Bengal, India
[2]Associate Professor, Dept. of Obstetrics And Gynaecology, Sarat Chandra Chattopadhyay Government Medical College And Hospital, Uluberia, Howrah, West Bengal, India
[3]Senior Resident, Dept. of Obstetrics And Gynaecology, Raiganj Government Medical College, Raiganj, West Bengal, India
[4]Professor, Dept. of Obstetrics And Gynaecology, NRS Medical College, Kolkata, West Bengal. India
[5]Professor, Dept. of Anaesthesiology, Raiganj Government Medical College, Raiganj, West Bengal. India

Corresponding Author

Dr Animesh Naskar
Associate Professor, Dept. of Obstetrics And Gynaecology, Sarat Chandra Chattopadhyay Government Medical College And Hospital, Uluberia, Howrah, West Bengal, India

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Abstract

Background: The rate of Caesarean section is going up globally due to various reasons despite strong recommendations by the World Health Organisation to reduce the same. As with any surgery, caesarean sections are associated with many wound complications, and the prevalence of which is higher in obese mothers. Use of a subcutaneous drain to prevent wound complications is a common practice.
Aim: To compare clinical outcomes of subcutaneous drain versus no drain in caesarean section for obese women.
Methods: This hospital-based prospective observational comparative study was conducted from June 2018 to May 2019 among 180 obese pregnant women who underwent cesarean section in the department of Obstetrics and Gynaecology, R G Kar Medical College, Kolkata. The participants were divided into two groups, with 90 women in each group based on inclusion and exclusion criteria. A subcutaneous drain was inserted in women of Group-1 (n=90), and no subcutaneous drain was given in Group-II (n=90). Data collection and comparisons were done on clinical outcomes between the two study groups. Chi-square tests were used for categorical data, and Student's t-test was used for continuous data. Statistical significance in all evaluations was defined as $P<0.05$.
Result: The wound seroma and post-operative pain were significantly higher in women having no subcutaneous drain after cesarean section. Wound seroma was seen in 10% of the drain group and 21.1% of those without a drain (P=0.04). Post-operative pain was monitored as the Numerical Pain Rating Scale. Mild pain (1-3) in 22 cases in the drain group versus 11 cases in without drain group; moderate pain (4-6) in 66 cases in drain group versus 67 cases in without drain group; severe pain (7-10) in 2 cases in drain group versus12 cases in the without-drain group (P=0.004).
Conclusion: Post-caesarean subcutaneous drain placement in obese women has significantly reduced the post-caesarean wound complications like wound seroma and postoperative pain.

Keywords: Caesarean section, Subcutaneous drain, Seroma, Obesity.

INTRODUCTION

Cesarean sections (CS) are on the rise across the world.[1] It is one of the most frequently performed operative procedures in modern obstetrics.[2] There are many possible ways of performing a caesarean section operation, and operative techniques vary widely.[3] The techniques used may depend on many factors, including the surgeon`s preferences, the patient's characteristics and available facilities and circumstances.[4] The most common complications of caesarean section are superficial surgical site complications, including sepsis, seroma formation and breakdown.[5] Independent risk factors for an early wound infection are premature rupture of membranes, emergency cesarean delivery, twin delivery, diabetes, hypertension, and obesity.[6] Obesity is a lifestyle disorder and a growing and significant healthcare issue nowadays. The prevalence of obesity has increased markedly over the past two decades, with over one-third of

reproductive age women being classified as obese.[7] From a surgical standpoint, obesity is associated with a multitude of complications, including impairments of cutaneous wound healing, total wound failure, and fascial dehiscence.[8]
Moreover, Obese women are more likely to be delivered by Caesarean section than women of normal weight, and hence, they are at increased risk for operative morbidity, including wound complications.[9,10,11] Hence, there is an upcoming need for economical and effective practices to reduce these complications following CS in obese mothers.
One of the common but controversial practices in CS is to insert a subcutaneous drain for the wound in obese women. Types of drains that may be used at caesarean section include closed suction drains, in which the blood loss can be measured in a collection bottle. This can give an early indication of intra-abdominal bleeding and has the advantage of containing fluid loss. Corrugated drains and wide-bore tube drains are also sometimes used, but their disadvantage is that any fluid drained needs to be soaked up by dressings.[12]
Whereas the use of high-grade antimicrobial agents can come up with chances of systemic adverse effects and antibiotic resistance, drain placement in subcutaneous tissue in such obese patients can pose as an effective and safe technique to reduce post-operative infective complications. The advantage of such a practice is to drain any blood or serous fluid that may accumulate in the subcutaneous space, which causes post-operative pain or provide a good medium for microbial growth and infection.[12]
Surgical drains of varying types have been used, with the best intentions, in different operations for many years. Sub-rectus sheath drains, or drains between the sheath and the skin (subcutaneous), are sometimes used after caesarean section operations. Drains are used routinely by fewer than 10% of obstetricians in the UK, but in a survey, 52% used them when indicated at the time of operation.[3] The use of closed suction drainage in the subcutaneous space may reduce the incidence of postoperative wound complications in obese women who have at least 2 cm of subcutaneous fat and undergo cesarean delivery.[13] We found that placing a subcutaneous drain is a little more effective way of preventing wound complications of cesarean section abdominal incision in obese females whose subcutaneous layer thickness is 2.5 cms or more.[14] Thus, it is assumed that drains can reduce the burden of surgical site infection. Some surgeons, however, have raised many arguments about the value of subcutaneous drains.[15] Placement of a regular subcutaneous drain is also not suggested by some studies.[16] Despite this, it is evident that it is still widely used in clinical practice.[5]
Different studies have shown conflicting results on the use of subcutaneous drains following cesarean section in obese mothers, and adequate data are lacking in our setting regarding this. Therefore, comprehensive research is required to establish definitive conclusions. This study aims to evaluate the role of routine placement of a subcutaneous drain in obese women to reduce post-operative morbidity after caesarean section.

METHODOLOGY

The prospective, observational, comparative study was conducted in the Department of Obstetrics and Gynaecology, R. G. Kar Medical College & Hospital, Kolkata, from June 2018 to May 2019, after obtaining the Ethical clearance for the study protocol from the Institutional Ethics Committee (vide memo No. RKC/Ethics/22 dated 05.12.2017). After obtaining the written informed consent, a total of 180 obese pregnant women who underwent caesarean section were included in the study by non-randomised allocation. All the included women were divided into two groups: 90 women in each. Group I included women with a subcutaneous drain inserted, and Group II included women without a subcutaneous drain.

Inclusion criteria: Pregnant women with a BMI of more than 30kg/m^2, singleton term pregnancy with haemoglobin more than 9 gm%, were included in the study.

Exclusion criteria: Women with Diabetes, any intraoperative complications like haemorrhage, blood transfusion, or BMI<30kg/m2 were excluded from our study.

Sample Size Calculation:

The sample size was calculated based on a study conducted on the Indian population, which indicated that wound seroma formation was significantly less in the drain group (10%) in comparison to the group without a drain (26%).[17] Using these results as guidance data, a sample size of 90 in each group was taken for my study. The level of significance was taken as 5 % (z alpha=1.96), and the power of the study was taken as 80 % (z beta=0.84).

Method of Data Collection:

Women who met the inclusion criteria were given a full description of the study, and those who gave written informed consent were assigned to one of the two study groups. Women who were unable to read the consent form had the forms read to them in their native language. Those who did not wish to participate were excluded from this study.
The study technique included detailed history taking and clinical examination. Demographic details like age, parity, gravidity, ethnicity, BMI, etc. were recorded. Caesarean sections were performed by senior residents on emergency duty. The lower uterine segment was opened through a lower segment transverse incision. Standard operative technique was

followed. After delivery of the fetus, the placenta and membranes were delivered by controlled cord traction. Following closure of the uterine incision using No.1-0 delayed absorbable poly-galactin suture, the visceral and parietal layers of peritoneum, followed by the rectus sheath, were closed. In women of both groups, the subcutaneous fat was closed by number 2-0 interrupted sutures using Rapide Vicryl. A drain was placed in the subcutaneous tissue in women of group I and no drain in group II patients. A perforated tube drain was used and it was exited from the surgical wound through a separate opening about 2 cm lateral to one of the wound angles. The drain was stitched to the skin and connected to urinary bag and was left in place for 48 hours. Skin was closed using non- absorbable No.2-0 polyamide suture. The patients were monitored closely in the post-operative period during their hospital stay, and findings were recorded in the proforma. Follow-up visits after 10 days of the operation to assess the wound. The post-operative pain was judged after 24 hours through the numerical pain rating scale (NPRS). The rating 1-3 was considered as mild pain, 4- 6 as moderate pain and 7-10 as severe pain. The following outcomes were noted: superficial surgical site infection, wound seroma, superficial wound dehiscence, postoperative pain, postoperative fever, and duration of hospital stay postoperatively.

STATISTICAL ANALYSIS: Data was collected and statistically analysed using SPSS (Statistical Package for Social Science)19 (SPSS Inc., Chicago, IL, USA). Chi-square tests were used for categorical data, and Student's t-test was used for continuous data. Statistical significance in all evaluations was defined as $P<0.05$.

RESULTS:

Tables

Table 1: Comparison of demographic parameters between the study groups (n=180)

Parameters	Group I: With Drain (n=90)	Group II: No drain (n=90)	p-value
Age in years (mean ± SD)	21.2 ± 3.21	21.5 ± 3.27	NS
Gestational age in weeks (Mean ± SD)	38.4 ± 0.84	38.2 ± 0.83	0.23; 95% CI= -0.046 TO 0.446 (NS)
BMI 30 - < 35	67 (74.4%)	71 (78.9%)	0.61 (NS)
BMI ≥35	23 (25.6%)	19 (21.1%)	*0.61(NS)*

Table 2: Duration of surgery in both groups

Duration of Surgery (In minutes)	Drain (n=90)	No Drain (n=90)	p-value
MEAN	49	48	0.22(NS)
SD	±5.99	±4.92	

Table 3: Outcome parameters

Parameters	Group I: Drain (n=90)	Group II: No Drain (n=90)	p-value
Severe post-operative pain	2 (2.22%)	12 (13.33%)	**0.004 (S)**
Post-operative fever	9 (10%)	12 (13.3%)	0.49 (NS)
Superficial skin site infections	10 (11.1%)	14 (15.6%)	0.38(NS)
Wound seroma	9 (10%)	19 (21.1%)	**0.04(S)**
Wound dehiscence	6 (6.7%)	12 (13.3%)	0.13(NS)
Duration of hospital stay in days (mean)	8.2 ± 1.34	8.4 ± 1.44	0.34(NS)
Re-admission	1 (1.1%)	3 (3.3%)	0.312(NS)

RESULTS

We approached and assessed 225 women for inclusion. After exclusion of 45 women (refused to participate or sign the informed consent), 180 women were allocated by non-randomised allocation into two groups having equal number of

participants.
Subcutaneous drain was inserted in group I (n=90) patients, and no drain in group II(n=90) patients. Here, we attempted to compare the outcome of subcutaneous drain versus no drain in cesarean section for obese women.
In this study, both groups had comparable demographic characteristics.
Table 1 shows that the 2 study groups were statistically not different in age, body mass index, and gestational age. The majority of the subjects were in the age group of 18-22. 70% of those were in the drain group, and 73.3% of those were in the no-drain group. There was no significant difference in the age distribution of the two groups. P value being 0.10. There was no statistically significant difference between the drain group and the no-drain group regarding mean gestational age (38.4±0.84 versus 38.2±0.83 weeks, respectively). P value being 0.23. The majority of the population had a Body Mass Index (BMI) between 30 and < 35. Of this, 74.4% were in the drain group, while 78.9% in the no-drain group. However, there was no statistically significant difference, P value being 0.61.
Table 2 shows that the duration of surgery was 49 minutes in the drain group as compared to 48 minutes in the no-drain group; the P value was 0.22, which was statistically insignificant.
Table 3 shows that the number of patients suffering from post-operative fever was little higher in no drain group (13.3%) than drain group (10%). However, there was no statistically significant difference, P value being 0.49. Superficial SSI was slightly more in no drain group (15.6%) than the drain group (11.1%). Wound seroma was more in without drain group (21.1%) as compared to 10% in with drain group. P value being 0.04 that was statistically significant difference. Superficial wound dehiscence was more in group II (without drain) 13.33% as compared to 6.7% in group I (with drain). The incidence of post-operative pain was significantly higher (13.33% vs 2.22%) in Group II (no-drain).

DISCUSSION

In this study, the majority of the subjects were in the age group of 18-22 years, and the mean age of study participants was 21.98 ± 3.52 years. Of those, 70% were in group I (with a drain), and 73.3% of those were in group II (no drain). There was no significant difference in the age distribution between the two groups, P value being 0.10.
There was no significant difference between group I (drain) and group II (no drain) regarding mean gestational age (38.4±0.84 versus 38.2±0.83 weeks; respectively), P value being 0.23. It was also noted that the majority of the population had a BMI between 30 and <35. 74.4% were in drain group while 78.9% were in the no-drain group. However, there was no statistically significant difference. P value being 0.61. Present study shows that the duration of surgery was 49 minutes in the group I as compared to 48 minutes the group II; P value being 0.22 that was statistically insignificant. Our findings in this regard, were consistent with **Khalifa** et al.[18] who found there was no significant difference in mean age, BMI, gestational age, and surgical duration between the two studied groups. **CAESAR**[19] study in 2010 reported two trials, which found no difference in operative duration in both groups, where the duration of surgery was 3.4 minutes longer in the drain group. It would be expected that an operation including insertion of a drain would take a longer time, and it is not clear whether differences in the duration of operation of a few minutes have any impact on women's health.
There was significant difference in severe post-operative pain in both groups when compared on the NPRS scale. Group I (subcutaneous drain) patients experience much less pain than Group II (no-drain), and this difference was significant (2.22% vs 13.33%) with a p-value of 0.00064. This finding is concurrent with Najam et al.[14] which concluded that there is a significant reduction in post-operative pain after the use of subcutaneous drain, unlike CAESAR[19] study; 2010, which did not find any difference between the two groups.
Our study shows that the number of patients suffering from post-operative fever was slightly higher in the no-drain group (13.3%) than drain group (10%). However, there was no statistically significant difference, P value being 0.49. In this regard, **Khalifa** et al.[18] found 17.4% versus 12% (P=0.3), **Bindal J** et al.[17] found 16% versus 10%, and **Najam** et al.[14] found 20% versus 11.7%,S respectively (P=0.21), which was very similar to our study. They all found there was no statistically significant difference between the two groups**. But, Ramesh Babu** et al.[20] found a significant difference in post-operative fever between the two groups (P=0.002). They noted the Post-operative fever was seen in 70 cases out of 656 in no drain group as compared to 30 out of 525 in with drain group.
In the current study, superficial SSI was slightly higher in the no-drain group (15.6%) than the drain group (11.1%), P value being 0.38, which was statistically insignificant which is similar to **Khalifa et al.**[18] who found superficial SSI in 7% of the no-drain group and 6% of the drain group (P=0.6).

S. No.	Author	Incidence of wound seroma (%)	
		Drain (Group I)	No drain (Group II)
1.	Khalifa et al.[18]	9.6%	26.7%
2.	Allaire et al.[13]	0%	12%
3.	Ramsey et al.[22]	10%	11%

4.	Bindal J et al.[17]	10%	26%
5.	Najam et al.[14]	10%	40%
6.	Present study	10%	21.1%

Wound seroma was more in group II (without drain), 21.1%, as compared to 10% in group I (with drain). P value being 0.04, which was a statistically significant difference. In this regard, there was a significant difference also noted **by Khalifa** et al.**[18]** who showed 26.7% versus 9.6% (P=0.01), **Bindal J** et al.**[17]** 26% versus 10%, and **Najam** et al.**[14]** reported 40% versus 10% (P=0.03%). Superficial wound dehiscence was more in without without-drain group 13.33% as compared to 6.7% in the group I (with drain). There was no significant difference (P=0.13). **Khalifa** et al.**[18]** found 8.1% versus 4.8% (P=0.4), **Bindal** J et al.[17] found 8% versus 4%, which are consistent with our report.
The present study shows that the mean duration of hospital stay was 8.2±1.34 days in the drain group and 8.4±1.44 days in the no-drain group, P value being 0.33, which was statistically insignificant. In contrast, **Ramesh Babu** et al.**[20]** found a significant difference (P <0.01**) in this regard. Ochsenbein**-Imhof et al. (2001) **[21]** found that hospital stay was 0.9 days shorter in no no-drain group. Readmission to hospital was only for 1 case in the drain group and 3 cases in without drain group, P value being 0.31, which was statistically nonsignificant. Two studies, **Ramsey et al. (**2005)**[22]** and **CAESAR[19]** study 2010 reported that regarding readmission to hospital, there was no difference between the groups.s

Limitations:
The main limitations of the study were the short-term follow-up for only 10 days postoperatively. Another limitation was the non-blinding of the study groups to the interventions, which could bias the subjective outcomes as postoperative pain. Results were not compared differently for elective and emergency cesarean sections as we all know complications are more prone to emergency sections.

CONCLUSION:
We found that using a subcutaneous drain is a little more effective way of curbing wound complications of cesarean section in obese females, as postoperative pain and wound seroma formation are reduced with the help of a drain. But there was no difference seen in duration of surgery, post-operative fever, superficial SSI, superficial wound dehiscence, mean duration of hospital stay, or readmission to hospital. The number of women suffering from these conditions was almost similar.

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