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Comparison of Negative Suction Subcutaneous Drain versus Simple Closure in Caesarean Section among High-Risk Patients to Prevent Postoperative Wound Complication

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ABSTRACT

Background and Aim: High-risk women, particularly those with obesity and diabetes, are prone to wound complications after Caesarean section. This randomized controlled trial aimed to compare negative suction subcutaneous drainage and simple closure in reducing seroma formation and surgical site infection in this population. **Materials and Methods:** This study was conducted at Shaikh Zayed Hospital, Lahore, Obstetrics and Gynecology Department over a period of 6 months from July 2024 to December 2024. Eighty women scheduled for elective Caesarean section with BMI ≥30 kg/m^2 and controlled diabetes were randomized to receive either negative suction drainage or simple closure. Preoperative care was standardized. Outcomes were assessed clinically and statistically analyzed with SPSS 26.0; $p<0.05$ was considered significant. **Results:** Baseline characteristics were comparable between groups. Seroma formation occurred in 5 (12.5%) women with negative suction drainage versus 13 (32.5%) with simple closure (p=0.032). Surgical site infection was observed in 3 (7.5%) patients in the drainage group and 11 (27.5%) in the simple closure group (p=0.019). Stratified analysis showed the most pronounced benefit of drainage among women aged 31–45 years (seroma: 2 (9.5%) vs. 11 (42.3%), p=0.012; SSI: 1 (4.8%) vs. 10 (38.5%), p=0.013) and in normoglycemic patients (seroma: 1 (7.1%) vs. 7 (41.2%), p=0.045; SSI: 0 (0%) vs. 5 (29.4%), p=0.048). No significant differences in wound complications were found when stratified by parity or in patients with pre-existing or gestational diabetes. **Conclusion:** Negative suction subcutaneous drainage significantly reduced the frequency of seroma formation and surgical site infection compared to simple closure, particularly in older and normoglycemic high-risk women undergoing elective Caesarean section.

INTRODUCTION

The incidence of caesarean section (CS) deliveries in South Asian countries, notably Pakistan, has surged from 3.2% in 1990 to 20% in 2018 [1]. With this rise, particularly in obese women, postoperative complications like surgical site infection, suture breakdown, and seroma have increased, affecting 3–15% of cases [2]. These issues extend hospital stays and exacerbate morbidity. Key risk factors include high BMI, obesity, diabetes mellitus, malnutrition, smoking, ASA class, prolonged operative time, contaminated surgeries, and antimicrobial-resistant pathogens, with obesity and diabetes as notable independent risks for CS and wound complications [3].

Modern wound complication prevention techniques in Caesarean sections include pre-operative skin preparation, antiseptic surgical methods, prophylactic antibiotics, and sterile post-operative dressings. However, wound complications remain prevalent [4]. Prophylactic negative suction drainage has gained attention as a potential method to reduce such complications. Negative pressure suction drains, particularly subcutaneous drains, remove blood or serous fluid from the subcutaneous space, potentially reducing post-operative pain and infection risk (Mehdorn *et al.*, 2021; Vazifdar *et al.*, 2021). In general surgery, vacuum-assisted devices for superficial wound infections with dehiscence have shown to accelerate healing [6]. Cochrane collaboration meta-analysis does not provide a definitive recommendation on negative suction drains for reducing surgical site infections (SSI) or postoperative seroma [7].

Several studies have examined the use of subcutaneous drainage in reducing wound complications after abdominal surgeries. One prospective study involving patients undergoing emergency midline laparotomy found

that the group managed with a closed suction drain experienced fewer wound complications, less postoperative pain, and a lower rate of seroma and surgical site infection compared to those without a drain [8]. In a separate intervention study, the use of a single-use negative pressure wound therapy (NPWT) system at cesarean delivery in women with risk factors for postoperative complications resulted in a lower rate of overall infectious morbidity, though rates of wound dehiscence remained similar between groups [9]. Another retrospective study focused on morbidly obese women undergoing cesarean section and noted that prophylactic incisional negative pressure therapy was associated with fewer surgical site infections, although the difference did not reach statistical significance [10]. The value of prophylactic subcutaneous drainage continues to be debated, as evidence remains mixed. Expert recommendations increasingly emphasize careful patient selection, targeting those at highest risk, to maximize potential benefit. Given these considerations, the present study seeks to evaluate the effectiveness of negative suction subcutaneous drainage for the prevention of wound complications specifically in high-risk women undergoing Caesarean section.

MATERIAL AND METHODS

This randomized controlled trial was carried out at the Department of Obstetrics and Gynecology, Shaikh Zayed Hospital, Lahore, from July 2024 to December 2024. The aim was to compare the frequency of wound complications, namely seroma formation and surgical site infection between high-risk women undergoing Caesarean section who received either negative suction subcutaneous drainage or simple closure of the wound. A total sample of 80 patients was determined using established statistical parameters (95% confidence interval, 80% power) and based on anticipated seroma rates of 42% without drainage and 14% with drainage, as described in previous studies [8].

Eligible participants were women over 18 years of age with a body mass index of 30 kg/m^2 or higher, hemoglobin level of ≥ 10 g/dL, and subcutaneous tissue thickness exceeding 2 cm, measured using a scalpel handle against a standard ruler. Only women scheduled for elective Caesarean section and having controlled diabetes (pre-existing or gestational, with a recent HbA1c ≤7%) were included. Exclusion criteria comprised current immunosuppressive therapy, preeclampsia, significant comorbidities such as chronic liver, heart, kidney, or pulmonary disease, ASA class IV or higher, accidental drain removal, intraoperative complications such as visceral injury or major hemorrhage, and the need for blood transfusion.

After obtaining informed consent, participants were enrolled and underwent preoperative assessment. Randomization was performed using computer-generated random numbers. Sequentially numbered, opaque, sealed envelopes were used to allocate participants into two groups in a 1:1 ratio: Group 1 underwent simple abdominal wall closure, and Group 2 received subcutaneous negative suction drainage. The allocation sequence was managed by an independent staff member who was not involved in the surgical or postoperative care, ensuring allocation concealment.

Each patient came to the hospital a day before their surgery to allow time for necessary preparation and infection control steps. These included giving cefazolin (2 grams) within an hour before the skin was cut, shaving the pubic area, and carefully cleaning the skin with a mix of chlorhexidine and alcohol. All operations used a low transverse (Pfannenstiel) incision. The surgeons made cuts through the fat and muscle layers using an electric surgical tool, then opened the lining of the abdomen by hand. Bleeding was controlled with electrical cautery. In women assigned to the simple closure group, the skin was stitched closed with interrupted Prolene sutures in a mattress pattern, then covered with a clean dressing. For those in the drainage group, a Redivac drain was placed under the skin through a small side opening and tied in place with silk. The drain stayed in for up to 48 hours or until daily fluid output dropped below 10 mL, at which point it was removed.

Outcomes were evaluated as per operational definitions. Seroma was defined as an accumulation of at least 50 mL of serous fluid confirmed by aspiration or ultrasound. Surgical site infection was diagnosed clinically within 10 days postoperatively based on local signs of inflammation or purulent discharge, and further categorized as superficial or deep incisional. All outcomes were assessed both during hospitalization and at the postoperative day 10 follow-up. Any wound complications were managed according to standard institutional protocols.

Data were documented on a structured proforma and analyzed using SPSS version 26.0. Categorical variables were summarized as frequencies and percentages, while continuous data were reported as means and standard deviations or medians and interquartile ranges, depending on normality assessed by the Shapiro-Wilk test. Comparative analyses were conducted using the chi-square or Fisher's exact test, as appropriate. Stratification was performed for parity, gestational age, and diabetic control. Statistical significance was defined as a p-value less than 0.05.

RESULTS

Eighty high-risk women were randomized to negative suction drainage or simple closure. Baseline characteristics were comparable. Seroma (12.5% vs. 32.5%, p=0.032) and surgical site infection (7.5% vs. 27.5%, p=0.019) were significantly lower with drainage, especially among women aged 31–45 years and those who were normoglycemic; no significant differences emerged by gravidity or diabetes type (Table 1).

In the analysis of primary outcomes, seroma formation was significantly less frequent in the negative suction drain group, occurring in 5 (12.5%) patients, compared to 13 (32.5%) in the simple closure group (p=0.032). Surgical site infection was observed in 3 (7.5%) patients in the drainage group, while 11 (27.5%) patients experienced this complication in the simple closure group (p=0.019).

Seroma formation was reported in 5 (12.5%) patients with negative suction drainage compared to 13 (32.5%) with simple closure (p=0.032). Surgical site infection was observed in 3 (7.5%) with drainage and 11 (27.5%) with

closure (p=0.019). The most pronounced benefit was among women aged 31–45 years, where seroma was 2 (9.5%) with drainage versus 11 (42.3%) with closure (p=0.012), and surgical site infection was 1 (4.8%) versus 10 (38.5%) (p=0.013). Among normoglycemic patients, seroma was 1 (7.1%) with drainage and 7 (41.2%) with closure (p=0.045); surgical site infection was 0 (0%) versus 5 (29.4%) (p=0.048). No significant differences were seen when stratified by parity or in those with diabetes or gestational diabetes (Table 3).

Table 1

Comparison of Baseline Characteristics and Laboratory Parameters

Variable	Negative Suction Drain (n=40)	Simple Closure (n=40)	P-value
Age (years	32.8 ± 6.3	34.6 ± 5.6	0.186
Age group 31-45 years	21 (52.5%)	26 (65.0%)	0.256
BMI (kg/m^2)	35.9 ± 2.5	34.9 ± 2.6	0.093
BMI Class 2	25 (62.5%)	21 (52.5%)	0.475
Gravidity ≥3	25 (62.5%)	28 (70.0%)	0.748
Diabetes status			0.732
Normoglycemic	14 (35.0%)	17 (42.5%)	
Pre-existing diabetes	15 (37.5%)	12 (30.0%)	
Gestational diabetes	11 (27.5%)	11 (27.5%)	
HBA1C (%	6.4 ± 0.6	6.3 ± 0.6	0.465
Hemoglobin (g/dL)	10.9 ± 0.8	10.9 ± 0.7	1.000

Table 2

Primary Postoperative Wound Complications in High-Risk Women Undergoing Elective Caesarean Section.

Outcome	Negative Suction Drain (n=40)	Simple Closure (n=40)	P-value
Seroma formation	5 (12.5%)	13 (32.5%)	0.032
Surgical site infection	3 (7.5%)	11 (27.5%)	0.019

Table 3

Stratified Analysis of Primary Outcomes by Parity, Age, and Diabetic Status

Stratification Variable	Outcome	Negative Suction Drain	Simple Closure	P-value
Parity				
Primigravida (n=9)	Seroma	1/6 (16.7%)	1/3 (33.3%)	1.000
	SSI	1/6 (16.7%)	1/3 (33.3%)	1.000
Gravida 2 (n=18)	Seroma	1/9 (11.1%)	4/9 (44.4%)	0.294
	SSI	1/9 (11.1%)	3/9 (33.3%)	0.576
Gravida 3 (n=41)	Seroma	3/19 (15.8%)	7/22 (31.8%)	0.292
	SSI	1/19 (5.3%)	4/22 (18.2%)	0.350
Multigravida ≥4 (n=12)	Seroma	0/6 (0%)	1/6 (16.7%)	1.000
	SSI	0/6 (0%)	3/6 (50.0%)	0.182
Age Group				
18-30 years (n=33)	Seroma	3/19 (15.8%)	2/14 (14.3%)	0.905
	SSI	2/19 (10.5%)	1/14 (7.1%)	1.000
31-45 years (n=47)	Seroma	2/21 (9.5%)	11/26 (42.3%)	0.012
	SSI	1/21 (4.8%)	10/26 (38.5%)	0.013
Diabetic Status				
Normoglycemic (n=31)	Seroma	1/14 (7.1%)	7/17 (41.2%)	0.045
	SSI	0/14 (0%)	5/17 (29.4%)	0.048
Pre-existing diabetes (n=27)	Seroma	2/15 (13.3%)	5/12 (41.7%)	0.185
	SSI	2/15 (13.3%)	4/12 (33.3%)	0.357
Gestational diabetes (n=22)	Seroma	2/11 (18.2%)	1/11 (9.1%)	1.000
	SSI	1/11 (9.1%)	2/11 (18.2%)	1.000

DISCUSSION

The rate of surgical site infection in the group with negative suction drains was 7.5%, which was much lower than the 27.5% seen in those who had simple closure. Likewise, seroma developed in 12.5% of women with drains, compared to 32.5% in the group without drains. These results indicate that adding subcutaneous drainage offers a real advantage for women at higher risk of wound problems.

Comparison with the largest randomized trial to date, conducted by Magann et al. (2002), is instructive. That study randomized 964 women with ≥2 cm subcutaneous fat into three arms and found no significant difference in wound disruption rates across no closure (9.7%), suture closure (10.4%), and closed drainage (10.3%) [11]. These rates are comparable to the Simple Closure group in the current study but notably higher than the NSSD group, possibly reflecting advancements in wound management or differences in population selection, as the present cohort was exclusively high-risk with meticulous perioperative protocols.

The potential advantage of drainage is supported by Vazifdar et al. (2021), who reported only 4% wound discharge in the negative pressure group versus 14% in the standard group after lower segment Cesarean section (LSCS), and a reduction in wound gape (0% vs. 4%). These results are congruent with the present study's lower complication rates in the NSSD group and highlight the utility of negative pressure drainage in minimizing seroma and wound dehiscence [12]. Similarly, Bindal et al. (2017) documented fewer seroma and superficial wound breakdowns in the drain group and a shorter average hospital stay (8.2 vs. 9.4 days) [13].

In women with class 2 obesity, there was a clear drop in surgical site infections when negative suction drains were used. Gillespie and colleagues reviewed data from ten different trials with over 5,000 participants, showing fewer surgical site infections when negative pressure wound therapy was used, with a modest but meaningful decrease in risk [14]. Looby and team also reported that for women with a BMI of 40 or higher, the chance of infection was nearly cut in half when special wound care methods were used [15]. On the other hand, Peterson and Wihbey did not see a meaningful difference in wound problems when comparing negative pressure dressings to standard care in women with higher BMI, though they did notice a trend suggesting possible benefit. Overall, these findings suggest that the advantages of drainage or negative pressure wound therapy might be most clear in certain high-risk groups or with particular surgical approaches [16] [17].

Diabetes status appeared to influence the efficacy of drainage in this study. Among normoglycemic patients, the NSSD group exhibited a significant reduction in both seroma (7.1% vs. 41.2%, p=0.045) and SSI (0% vs. 29.4%, p=0.048) compared to Simple Closure, but no such difference was observed in those with pre-existing or gestational diabetes. The lack of significant benefit in diabetic subgroups is consistent with the well-established impairment in wound healing mechanisms associated with hyperglycemia and microvascular disease. Kagita et al. (2019) demonstrated a dramatic reduction in SSIs (12.5% with drainage vs. 69.4% without), underscoring the clinical relevance of wound drainage, particularly in emergency abdominal surgery [18]. Rizwan et al. (2021) and Harish et al. (2021) both reported lower infection rates and shorter hospital stays in groups managed with subcutaneous drains (6.7% vs. 11.1% for infection; 9.7 vs.

10.8 days for hospital stay), closely mirroring the outcomes observed in the current analysis [19] [20]. Conversely, several large-scale randomized studies have failed to demonstrate a significant reduction in wound complications with negative pressure wound therapy (NPWT) or subcutaneous drains. Hussamy et al. (2019) observed a composite wound morbidity rate of 18% with no difference between NPWT (17%) and standard dressings (19%) [21]. Tuuli et al. (2020) similarly reported near-identical SSI rates between NPWT and standard dressing groups (3.6% vs. 3.4%, p=0.70), though an increased risk of skin blistering was noted with NPWT (7% vs. 0.6%, p<.001) [22]. These results, along with those from Ruhstaller et al. (2017), who found no significant difference in wound infection rates (3.3% vs. 6.9%, p=0.44), suggest that the benefit of NPWT or drainage is likely context- and population-dependent [23].

This study's main strength is its randomized design with clear inclusion criteria, allowing for a focused evaluation of negative suction drainage in high-risk Caesarean patients. The present study is strengthened by its controlled design, focus on elective high-risk Cesarean patients, and stratified analysis by age, BMI, and glycemic status. However, the exclusion of emergency cases and women with poorly controlled diabetes may limit generalizability. Future research should involve larger, multi-center trials and include a wider range of high-risk patients to better define the clinical benefits and potential risks of negative suction drainage in diverse obstetric populations.

CONCLUSION

Negative suction subcutaneous drainage, when compared to simple closure, led to a significant reduction in seroma formation and surgical site infection among high-risk women undergoing elective Caesarean section. No significant differences were observed across parity or in women with pre-existing or gestational diabetes. These findings support the use of negative suction drainage to minimize wound complications in selected high-risk obstetric cases. Further studies are needed to confirm these results in broader populations.

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