The Egyptian Journal of Hospital Medicine (July 2023) Vol. 92, Page 2634- 2639

Study of The Effect of Subcutaneous Negative Pressure Drain on Midline Surgical Wound in Major Gynecological Operation

Mohamed A. Wasfy, Fatma Ramadan Emohamed Omar*, Khalid Fathy Helal, Tarek Mohamed El-Behiedy
Department of Obstetrics and Gynecology, Faculty of Medicine, Zagazig University, Egypt
***Corresponding author:** Fatma Ramadan Emohamed Omar, **Mobile:** (+20)01102903860, **E-mail**: fatmahasen1980@gmail.com

ABSTRACT

Background: Subcutaneous wound drains have demonstrated a high degree of efficacy in a number of surgical procedures. However, wound drains' usefulness in gynecological surgery, such as caesarean section, remains debatable.
Objective: The aim of the current study was to assess the role of subcutaneous negative pressure drain in wound healing following major gynecological surgery.
Patients and methods: A randomized controlled clinical trial was carried out at Obstetrics and Gynecology Department, Zagazig University Hospital. This study included 60 cases, divided in 2 groups, 30 cases in each group; ***Group 1*** included subcutaneous negative pressure drain patients who have undergone subcutaneous tissue re-approximations and ***Group 2*** included cases who have subcutaneous tissue re-approximation only.
Results: Statistical significant differences were found of body mass index and age between studied groups. There is a significant difference between the two groups regarding low hematocrit and preoperative elevated serum blood glucose level. Regarding post-operative complications, there were significant higher frequencies of hematoma, dehiscence infection, and seroma in ***Group 1*** compared with ***Group 2***. Also there is significant difference between them as regard duration of postoperative hospital stay that was more in drain group.
Conclusion: In gynecologic surgery, a subcutaneous negative pressure drain is a useful tool for managing wounds.
Keywords: Subcutaneous negative pressure Drain, Gynecological operation, Post-operative complications.

INTRODUCTION

Wound problems occur in 5-35 percent of patients receiving surgery for gynecologic cancer [(1)]. Complications from wounds result in longer hospital admissions, lower quality of life, and higher healthcare expenses [(2)].

Increased rates of readmission and postoperative death as well as delays in chemotherapeutic treatment following abdominal surgery have been linked to wound problems in gynecological cancer [(3)].

Many methods have been explored to lessen the potential for wound complications. Postoperative wound problems can be prevented, in part, by shortening the duration of the operation, the use of prophylactic antibiotics during surgery, proper irrigation of the surgical site, establishment of adequate hemostasis, avoidance of dead space, and execution of precise operations [(4)].

These methods are predicated on the idea that less dead space in the subcutaneous tissue means less opportunity for germs to thrive. The serous fluid or blood that collects in this area has the potential to become infected, leading to further wound disruption [(5)].

Since wound complications are a major source of surgical morbidity, it is crucial that we learn how to minimize them following a midline surgical wound during a large gynecological operation. Subcutaneous drainage's efficacy has been mixed between research, which may be due to methodological, demographic, and statistical discrepancies between the studies [(6)].

About 20 years ago, subcutaneous wound drains were developed to remove exudate from wounds. These drains limit the buildup of transudate from surgical wounds, hence decreasing the risk for dead space in the subcutaneous tissue [(5)].

The use of subcutaneous wound drains has shown great promise in a number of surgical specialties. However, the use of wound drains in gynecological procedures, including as caesarean sections, is still debated. Most studies only contain a handful of patients, so we don't know much about the effectiveness of wound drains in gynecological malignancy operations on their own, some of whom also have gynecological benign disorders [(7)].

There would be a considerable decrease in postoperative wound problems if major gynecological operations used subcutaneous suture closure with a drain after the midline surgical incision [(6)].

The current clinical trial aimed for assessment of assessment of the role of subcutaneous negative pressure drain in wound healing following major gynecological surgery.

PATIENTS AND METHODS

A randomized controlled clinical trial was carried out at Obstetrics and Gynecology Department, Zagazig University Hospital. This study included 60 cases, divided in 2 groups, 30 cases in each group; ***Group 1*** included subcutaneous negative pressure drain patients who have undergone subcutaneous tissue re-approximations and ***Group 2*** included cases who have subcutaneous tissue re-approximation only.

Inclusion criteria:

All women undergo midline surgical wound for major gynecological surgeries, including: Midline incision, Elective surgery, Normal laboratory investigation, and Hemoglobin 10gm/dl.

Received: 20/01/2023
Accepted: 21/03/2023

Exclusion criteria:

Women who had any of the following conditions were not included: cases of immunosuppressive treatment like rheumatoid arthritis and Systemic lupus erythematosis, Pfannestiel incision, Associated morbidity, Emergency laparotomy, Associated mistakes like reactions to anesthetic, shock, and surgical trauma, patients who undergo secondary surgery owing to disease recurrence and Women had previous midline incision.

All cases were subjected to the following:

1. Complete history assessment.
2. General and local examinations to check abdominal scars.
3. Lab tests performed before surgery: To rule out comorbid conditions, a complete blood count, random blood sugar, PT, PTT, INR, SGOT, SGPT, Serum Creatinine, and Urine tests are performed.

Technique:

The preoperative, operative, and postoperative care of each patient was the same, with the exception of the placement of wound drains. Our institution follows a defined policy that requires one of five gynecologic oncology physicians to perform all surgical operations.

Within 60 minutes of the incision, 1 gm of a second-generation cephalosporin was given intravenously as preventive antibiotic treatment. For 5-7 days after surgery, Patients were allowed to receive prophylactic doses of antibiotics via intravenous administration, with doses of 1 gm of a second-generation cephalosporin, 500 mgm of metronidazole, and 400 mgm of aminoglycoside being the most common.

The bowels of all patients were cleansed with a polyethylene glycol solution measuring 4 liters before surgery. Low molecular weight heparin injections as well as sequential compression devices were employed for venous thromboembolic prophylaxis.

Surgery in the upper abdomen required a low midline incision beginning at the symphysis pubis, circling the umbilicus, and ending at the xiphoid process.

A scalpel and electrocautery were used to make incisions during the operation. Diathermy pen electrode was used in cutting method for cutting through the rectus sheath and subcutaneous tissue. Rupture of the parietal peritoneum causes a lot of pain. Large subcutaneous veins were ligated with sutures and coagulation diathermy was used to stop the bleeding in both sets of patients.

- In contrast, *Group 1*, Perforated silicone round tubes with an inner diameter of 1.6 mm and an outside diameter of 3.2 mm, known as Jackson-Pratt drains, were placed into the subcutaneous area and extended out through a separate stab surgical incision to collect any fluid that had collected there. A silicone bulb reservoir of 200 mL was attached to the drains, from which subcutaneous discharge was continually drawn using negative pressure (GMS vacuum 16 French).

- Due to the lack of subcutaneous tissue closure, stainless steel staples were used to close the skin. When daily drainage was reported to be less than 1 mL, the drains were left in situ.

- *Group 2*: No subcutaneous wound drains were set up for them. Close proximity of the skin was achieved using staples, and the subcutaneous tissue was sealed using an interrupted suture. The skin was bandaged using adhesive closure strips and gauze.

Outcome evaluation: Wound complications following cancer surgery were evaluated at all dressing changes, staple removals, and subsequent outpatient clinic visits that occurred within 8 weeks of surgery. The outcomes of all inpatient and outpatient wound complications were documented.

Ethical approval:

This study was ethically approved by the Institutional Review Board of the Faculty of Medicine, Zagazig University. Written informed consent was obtained from all participants. This study was executed according to the code of ethics of the World Medical Association (Declaration of Helsinki) for studies on humans.

Statistical Analysis

The collected data were introduced and statistically analyzed by utilizing the Statistical Package for Social Sciences (SPSS) version 20 for windows. Qualitative data were defined as numbers and percentages. Chi-Square test, Fisher's exact test and Chi-Square for Linear Trend were used for comparison between categorical variables as appropriate. Quantitative data were tested for normality by Kolmogorov-Smirnov test. Normal distribution of variables was described as mean and standard deviation (SD), and independent sample t-test was used for comparison between groups. P value ≤ 0.05 was considered to be statistically significant.

RESULTS

Significant differences were found of body mass index and age between studied groups.

Table (1): Demographic characteristics of both groups.

Variable	Range	Group1 (n=30) Suture with Subcutaneous negative pressure drain	Group2(n=30) Suture without drain	t-value	P- value	Sig.
		$\overline{X}$ ± SD	$\overline{X}$ ± SD			
Age (in years)	45 – 74	52.3±6.9	51.6±6.5	0.4	0.6	NS
BMI(in kg/m²)	20 -29	**26.09±2.19**	**25.54±2.36**	2.2	0.03	S

Regarding parity, majority of both group were >2 with non-statistical significant difference between groups.

Table (2): Obstetric characters distribution between groups.

Variable			Group 1 (n=30)	Group 2 (n=30)	t/ X^2	P-value
Gravidity	**Virgin**	**N**	**6**	**1**	**6.94**	**0.074**
		%	**19.8%**	**3.3%**		
	P 0	**N**	**6**	**6**		
		%	**19.8%**	**19.8%**		
	1-2	**N**	**4**	**5**		
		%	**13.2%**	**16.5%**		
	>2	**N**	**14**	**18**		
		%	**46.6%**	**60%**		
Total		**N**	**30**	**30**	---	
		%	**100.0%**	**100.0%**		

Regarding post-operative complications, there were significant higher frequencies of hematoma, dehiscence infection, and seroma in ***Group 1*** compared with ***Group 2***.

Table (3): Comparing subcutaneous drain and cases without subcutaneous drain for postoperative complications.

Complication	Group 1 (n=30)		Group 2 (n=30)		Significance test	
	N	%	N	%	Fisher's exact	P-value
Hematoma	1	3.3	2	6.6	38.684	<0.001**
Infections	13	43.3	10	33.3	29.628	<0.001**
Dehiscence	0	0	1	3.3	31.749	<0.001**
Seroma	1	3.3	3	10	19.148	<0.001**

*Chi square test.

Table 4 shows that infection didn't differ statistically between both groups.

Table (4): Infection incidence among both groups

Variable	Studied groups		Relative risk (95% CI)	P-value
	Group 1 (n=30)	Group 2 (n=30)		
Infection 3 days				
Incidence rate	4/30 13.2%	3/30 10%	2 (0.39 -10.3)	0.65
Infection occurred in 1 week				
Incidence rate	9/30 29.7%	9/30 29.7%	1.13 (0.48 –2.62)	**0.7**2
Infection occurred in 2 weeks				
Incidence rate	None	None	-	-

Table 5 shows that hematoma incidence differed statistically between both groups.

Table (5): Haematoma incidence among 2 studied groups.

Variable	Studied groups		Relative risk (95% CI)
	Group 1 (n=30)	**Group 2 (n=30)**	
Haematoma 3 days	2/30 6.6%	1/40 3.3%	2 (0.19 – 21.19)
Incidence rate			
Haematom in 1 week	**No**	No	---
Incidence rate			
Haematoma in 2 weeks	**No**	No	---

Table 6 shows that dehiscence incidence differed significantly between both groups.

Table (6): Dehiscence incidence among both groups.

Variables	**Studied groups**		**Relative risk (95% CI)**
	Group 1 (n=30)	**Group 2 (n=30)**	
Dehiscence three days			
Incidence rate	**No**	No	---
dehiscence in one week			
Incidence rate	**No**	1/30 6.6%	---
Dehiscence 2 weeks			
Incidence rate	**None**	None	---

Table 7 shows that seroma incidence differed significantly between both groups.

Table (7): Seroma incidence among both studied groups

Variable	**Studied groups**		**Relative risk (95% CI)**
	Group 1 (n=30)	**Group 2 (n=30)**	
Seroma three days			
Incidence rate	**No**	No	---
Seroma in one week			
Incidence rate	**No**	No	---
Seroma two week			
Incidence rate	**1/30 6.6%**	3/30 10%	0.03 (0.04 – 3.07)

Operative time did not differ significantly between studied groups, while there is significant difference between them as regard duration of postoperative hospital stay that was more in drain group (**Table 8**).

Table (8): Operative time as well as duration of hospital stay of the two groups.

Variable	**Group 1 (n=30)**	**Group 2 (n=30)**	**T test**	**P-value**
Operative time (hours) Mean ± SD	2.2 ± 0.27	1.84± 0.37	1.987	0.060
Hospital stay (days) Mean ± SD	10.8± 1.93	6.68± 0.940	**17.459**	**<0.001****

DISCUSSION

Complications from wound care are a headache for everyone involved, from patients and doctors to healthcare providers and payers. The detrimental effects of wound complications on patients' quality of life are undeniable, and they're also linked to longer hospital stays and a large monetary cost [(2)].

The goal of these methods is to lessen the amount of dead space in the subcutaneous tissue and hence cut down on bacterial growth. Serous fluid or blood can develop in this area and lead to infection and eventual wound disruption if left untreated [(5)].

About two decades ago, subcutaneous wound drains were created for the purpose of removing wound transudate. These drains limit the buildup of transudate from surgical wounds, hence decreasing the risk for dead space in the subcutaneous tissue. Subcutaneous wound drains have demonstrated a high degree of efficacy in a number of surgical procedures. There is ongoing debate about wound drains' usefulness in gynecological surgeries [(7)].

This study was a randomized controlled clinical trial carried out at Obstetrics and Gynecology department, Zagazig University Hospital.

The results of the current study were: Hematoma, infection, dehiscence, and seroma were higher in group 2 after surgery compared to group 1. While there is no statistically significant difference in operative time between the groups, there is a significant difference in the postoperative hospital stay duration, which was longer in the drain group.

In agree with our result, **Cruse and colleagues [(8)],** Following their prospective study of 23,659 surgical wounds showing a lower wound infection rate (1.8 percent vs. 2.4 percent) using a closed suction drain system than a Penrose wound drain, closed suction drain systems have been chosen over open systems. After that point, the term "subcutaneous wound drain" is universally used to denote a closed suction drain system.

Similarly, **Panici and colleagues [(9)]**, showed that the rate of wound complications dropped significantly from 6% to 2% when a subcutaneous wound drain was used ($p = 0.003$).

Opposite to our results **Gallup and colleagues [(10)]** analysed the effectiveness of a subcutaneous wound drain in morbidly obese women undergoing gynecologic procedures in a prospective randomised study. Neither the wound drain group nor the controls showed significantly different rates of wound complications (20% vs. 31%; P=0.09).

Hellums and colleagues [(5)] analytically, subcutaneous drainage would seem advantageous for women after gynaecological surgery, according to the results of a meta-analysis looking into the clinical uncertainties around its usage. Subcutaneous drains are intended to get rid of any remaining fluid and blood in a wound so that it doesn't become a breeding ground for bacteria. There is little evidence in the literature to support the theoretical benefits of subcutaneous drainage [(11)].

Higson and Kettlewell [(12)] compared 250 abdominal surgery incisions to either a Penrose drain or no drain at all. The incisions were classified into 3 groups; clean (100), potentially contaminated (100) and frankly contaminated (50 Wounds). Each group was further divided into two equal groups (drain or no drain). Patients in the third group received intraparietal ampicillin powder. Open parietal drains, they found, are harmful when used in clean wounds and of uncertain utility in potentially contaminated wounds, but are an acceptable alternative to topical antibiotic powder for the treatment of highly contaminated wounds.

In a non-randomized clinical trial, **Morrow and colleagues [(13)]** reported wound infections were much lower in women who had a subcutaneous suction drain installed (20 women) compared to women who did not have a drain (19 women).

While **Kozol and colleagues [(14)]** found no difference in wound infection, skin separation, or hematoma between patients who underwent closed suction drainage of the subcutaneous area and patients who underwent stay suture closure of this gap in a randomised trial including 98 patients.

Allaire and colleagues [(15)] assessed 76 women who were about to have caesarean sections participated in a prospective randomised experiment. Patients were randomly assigned to one of three groups: group 1, which underwent subcutaneous tissue suture closure; group 2, which underwent implantation of a subcutaneous closed suction drain; and group 3, which underwent neither subcutaneous tissue suture closure nor drainage. The researchers drew the conclusion that closed suction drainage of the subcutaneous area after surgery might help cut down on wound complications.

Al-Inany and colleagues [(16)] assessed 118 obese pregnant women having a caesarean section were randomly assigned to 1 of 2 groups. Two groups were compared: one with a subcutaneous drainage system and one without. Both groups were frequently administered prophylactic antibiotics. Patients who also got prophylactic antibiotics did not benefit much from having a subcutaneous drain placed.

Prophylactic subcutaneous drainage following caesarean delivery has been studied and found to have no positive effects, according to a meta-analysis published in the **Cochrane Library [(17)].** Wound infection, wound complications, febrile morbidity, endomitritis, blood loss, surgical time, and postpartum hospital stay were all accounted for in the Cochrane meta-analysis [(17)].

Ten trials involving 5,248 women were included in the meta-analysis on wound drainage published in the **Cochrane Library [(17)]**. Women who had wound drains did not have a lower incidence of infection, other wound complications, or pain than those who did not, according to a meta-analysis. One trial suggested that, in comparison to a sub-sheath drain, a subcutaneous drain may increase wound infection (RR 5.42, 95% CI

1.28 to 22.98). In 3 clinical trials that compared subcutaneous drainage to subcutaneous suturing, the results were similar [17].

To establish the clinical relevance of subcutaneous wound drainage in surgery, **Kosins and colleagues** [18] conducted the largest systematic review and meta-analysis to date, using data from 52 trials involving a total of 6930 procedures. The drain group had 3495 procedures, while the no-drain group saw 3435. There was only a statistically significant benefit to prophylactic subcutaneous drainage for: (1) hematoma prevention (2) seroma prevention. The surgeon's decision to use drains after surgery depends on a number of criteria, not just the nature of the procedure and the patient's body mass index [18].

Our research shows that there are several advantages to adopting a closed suction system with a subcutaneous negative pressure drain instead of subcutaneous sutures. First, there was a noticeable decline in the amount of bleeding and/or pus coming from the incision. Second, superior surgical outcomes in terms of wound healing were clearly associated with fewer surgical operations, including omitting the subcutaneous suture and having no leftover suture material in the subcutaneous tissue. Finally, there was no problem with managing suture tension, which can be tricky for beginner.

The strong points of this study were:

1) There was no discernible difference between the two groups in terms of risk factors or patient characteristics; 2) Consistently the same surgeon carried out all surgical procedures, including the insertion of a subcutaneous drain; 3) There is no difference in the perioperative treatment of the wound between the two surgeons. This includes things like skin and bowel preparation, antibiotic administration, wound dressing, and the removal of stitches.

Weak points of this study were: 1) Study period was short; 2) Small sample size.

CONCLUSION

Our results showed that the use of a subcutaneous wound drains improved wound outcomes following gynecologic procedures, including faster healing and less wound disruption. In gynecologic surgery, a subcutaneous negative pressure drain is a useful tool for managing wounds.

Sponsoring financially: Nil.
Competing interests: Nil.

REFERENCES

1. **Novetsky A, Zighelboim I, Guntupalli S *et al.* (2014):** A phase II trial of a surgical protocol to decrease the incidence of wound complications in obese gynecologic oncology patients. Gynecol Oncol., 134:233-7.
2. **Mahdi H, Gojayev A, Buechel M *et al.* (2014):** Surgical site infection in women undergoing surgery for gynecologic cancer. Int J Gynecol Cancer, 24:779-86.
3. **O'Donnell R, Angelopoulos G, Beirne J *et al.* (2019):** Impact of surgical site infection (SSI) following gynaecological cancer surgery in the UK: a trainee-led multicentre audit and service evaluation. BMJ Open, 9:e024853. doi: 10.1136/bmjopen-2018-024853.
4. **Nygaard I, Squatrito R (2015):** Abdominal incisions from Creation to closure. Obstet Gynecol Surv., 51:429-36.
5. **Hellums E, Lin M, Ramsey P (2007):** Prophylactic subcutaneous drainage for prevention of wound complications after cesarean delivery. AMJ Obstet Gynecol., 197(3):229-35.
6. **Ramsey P, White A, Guinn D *et al.* (2005):** subcutaneous tissue reapproximation, alone or in combination with drain, in obese women undergoing cesarean delivery. Obstet Gynecol., 105(5 Pt 1):967-73.
7. **Cardosi R, Drake J, Holmes S *et al.* (2006):** Subcutaneous management of vertical incisions with 3 or more centimeters of subcutaneous fat. Am J Obstet Gynecol., 195:607-14.
8. **Cruse P, Foord R (1973):** A five-year prospective study of 23,649 surgical wounds. Arch Surg., 107:206-10.
9. **Panici P, Zullo M, Casalino B *et al.* (2003):** Subcutaneous drainage versus no drainage after minilaparotomy in gynecologic benign conditions: a randomized study. Am J Obstet Gynecol., 188:71-5.
10. **Gallup D, Gallup D, Nolan T *et al.* (2013):** Use of a subcutaneous closed drainage system and antibiotics in obese gynecologic patients. Am J Obstet Gynecol., 175:358-61.
11. **Berghella V, Baxter J, Chauhan S (2015):** Evidence-based surgery for cesarean delivery. Am J Obstet Gynecol., 193:1607-17.
12. **Higson R, Kettlewell M (2010):** Parietal wound drainage in abdominal surgery. Br J Surg., 65:326-9.
13. **Morrow C, Hernarde W, Townsed D *et al.* (2012):** Pelvic celiotomy in the obese patient. Am J Obstet Gynecol., 127(4):335-9.
14. **Kozol R, Fromm D, Ackerman N *et al.* (2013):** Wound closure in obese patients. Surg Gynecol Obstet., 162(5):442-4.
15. **Allaire A, Fisch J, McMahon M (2016):** Subcutaneous drain vs. suture in obese women undergoing cesarean delivery. J Reprod Med., 45:327-31.
16. **Al-Inany H, Youssef G, El Maguid A *et al.* (2015):** Value of subcutaneous drainage system in obese females undergoing cesarean section using Pfannenstiel incision. Gynecol Obstet Invest., 53:75-8.
17. **Gates S, Anderson E (2013):** Wound drainage for caesarean section. Cochrane Database Syst Rev., 12:CD004549. doi: 10.1002/14651858.CD004549.
18. **Kosins M, Scholz T, Cetinkaya M *et al.* (2013):** Evidence-Based Value of Subcutaneous Surgical Wound Drainage: The Largest Systematic Review and Meta-Analysis. Plast Reconstr Surg., 132(2):443-50.