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A randomized controlled trial of closure or non-closure of subcutaneous fatty tissue after midline vertical incision

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All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

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Abstract

Background/Aim: There are limited studies that evaluate the closure of subcutaneous tissue, particularly among gynecologic oncology patients, a group with a high rate of obesity and more co-morbidities. This prospective randomized controlled study aimed to assess the effects of subcutaneous closure versus non-closure on wound complication rate in patients with subcutaneous tissue thicknesses of more than >4 cm.
Methods: All patients with a subcutaneous tissue depth≥4 cm measured with ultrasonography and undergoing gynecologic surgery via a midline vertical incision from February 2019 to March 2020 in the gynecologic oncology department at a teaching hospital were considered for inclusion. Patients were intraoperatively and sequentially randomized as 1:1 only when the measurement of subcutaneous tissue depth was verified to be 4 cm or more.
Results: A total of 82 patients who underwent randomization were assigned to undergo or not undergo subcutaneous closure with sutures (41 patients each). Subcutaneous wound depth (mean: 6.36 cm, range: 4-11 cm), vertical incision length (mean: 24.32 cm, 12-36 cm), body mass index (33.82 kg/m^2, 19.6-52 kg/m^2) were similarly distributed between the groups (P>0.05 for all). Wound complications were observed in 17 (20.7%) patients. Wound infection occurred in two patients in the closure group as compared to three patients in the control group (P=0.644). Seroma and wound dehiscence were seen more often in the control group, but neither of these findings reached statistical significance (P=0.077, P=0.284).
Conclusion: We found no significant differences in the rate of surgical wound complications with suture approximation of the subcutaneous tissue in patients with 4 cm or more subcutaneous thickness undergoing gynecologic surgery via a vertical midline incision.

Keywords: Subcutaneous closure, Obesity, Wound complication, Midline vertical incision

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Introduction

Obese patients have a high rate of surgical incision complications including wound dehiscence, infection, and subcutaneous seroma or hematoma after gynecologic surgery. In patients with BMI ≥30 kg/m^2 who underwent surgery through a midline vertical incision, wound complication rates as high as 46% have been reported [1, 2]. The increase in wound complications was attributed more specifically to the thickness of the subcutaneous tissue [3, 4].

A prospective study on 150 patients undergoing hysterectomy reported that the wound infection rate was proportional to the thickness of subcutaneous tissue. Wound infection rates in patients with a subcutaneous fat thickness of 3, 4, 5, ≥6cm were 15%, 17%, 21%, and 40% respectively [3].

Wound complications in obese patients are possibly associated with insufficient vascular supply of the subcutaneous tissue, hematoma formation, and serous fluid collection [5].

There have been multiple studies to determine the most appropriate technique for surgical abdominal wall incision closure, yet there is still a debate about this. Many of these studies are retrospective and limited by their lack of standardization of surgical methods, patient selection criteria, and definitions of wound complications [6, 7].

There are limited studies evaluating the closure of subcutaneous tissue, particularly in gynecologic oncology patients, a group with a high rate of obesity and other co-morbidities. Although the closure of subcutaneous tissue may prevent dead space, hence decrease serous fluid collection, additional suture materials have the potential of increasing the risk of wound infection.

This prospective randomized controlled study aimed to assess the effect of subcutaneous closure versus non-closure on wound complication rate in women with subcutaneous tissue depths of ≥4 cm.

Materials and methods

All women with subcutaneous tissue depths≥4 cm measured with ultrasonography and undergoing elective gynecologic surgery via a midline vertical incision from February 2019 to March 2020 in the gynecologic oncology department at a teaching hospital were considered for inclusion. The study protocol was approved by Bursa Uludag University Faculty of Medicine Clinical Research Ethics Board on 12.02.2019 with the decision number 2019-3/19.

We intraoperatively and sequentially randomized patients as 1:1 when the measurement of subcutaneous fat thickness was verified as 4 cm or more. Exclusion criteria were a history of abdominal midline incision, a preexisting or repaired umbilical hernia, planned intestinal surgery or enterotomy, or not consenting to participate in the study. Traditionally, in surgical practice, there is a tendency for subcutaneous suturing in patients with thick subcutaneous adipose tissue. Because this is a non-blind randomized trial, 1:1 sequential randomization was strictly followed to avoid selection bias.

The surgical procedure for incision and closure of the wound was standardized. No subcutaneous drains were placed. All patients received antibiotic prophylaxis with cefazolin (if allergic, clindamycin) before the operation. An additional dose was administered if the operation lasted longer than three hours or the patient lost more than 1500 ml of blood.

The skin was incised using a scalpel, and subcutaneous tissue was incised using cutting electrocautery. At the end of the surgery, two looped polydioxanone sutures (PDS) were used to close the fascia, starting at the proximal and distal ends of the incision, and being knotted in the middle. Following fascia closure, the length of the incision and subcutaneous tissue thickness were measured via a sterile metallic ruler from the deepest part of the incision, from the fascia to the skin surface, to determine patient eligibility. The incision was irrigated with warm saline solution. In the subcutaneous closure group, subcutaneous tissue was closed with continuous running sutures using absorbable vicryl 2/0. Vicryl® is a synthetic suture absorbed in up to 70 days [8]. Closed suction drains were not used. The skin was closed with staples, which were removed in the second week.

All patients were seen in the second, fourth, and eighth weeks postoperatively in the outpatient clinic to assess the state of the surgical wound. They were examined to find out whether they have the following wound complications:

-Seroma or hematoma: Serous fluid accumulation or presence of blood in the subcutaneous space without signs of infection.

-Wound disruption: Spontaneous or iatrogenic dehiscence of the wound edges by more than 1 cm.

-Wound infection: Wound erythema and swelling requiring additional antibiotics or surgical management.

Additional demographic characteristics and perioperative data associated with wound complications were also noted.

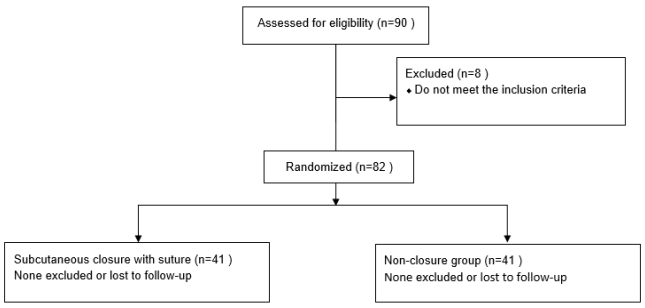
Statistical analysis

Descriptive statistics were analyzed. Fisher's exact test and Mann-Whitney's test were used to compare the percentages between groups. SPSS version 23.0 for Windows was used for statistical analysis. A *P*-value <0.05 was considered statistically significant.

Results

A total of 82 patients who underwent randomization to undergo subcutaneous closure with sutures or non-closure (n=41 in each group) were included in the analysis. No cases were lost during the 8-week follow-up after surgery (Figure 1).

Figure 1: Flow diagram of the study



The demographic and clinical characteristics of the closure and non-closure groups were similar (*P*>0.05 for all) (Table 1). The mean age of the patients at operation was 59.1 years (range: 37–80 years). Among all, 73.1% were operated on

with the diagnosis of malignancy. The most common surgical procedure in the cohort was hysterectomy with bilateral salpingo-oophorectomy and pelvic and/or paraaortic lymphadenectomy.

Subcutaneous wound depth (mean: 6.36 cm, range: 4-11 cm), vertical incision length (24.32 cm, range: 12-36 cm), body mass index (BMI) (33.82 kg/m^2, 19.6-52 kg/m^2) and other variables were similarly distributed between groups. Wound complications were observed in 17 (20.7%) patients (Table 2).

Table 1: Patients' characteristics

Parameters	Closure group (n=41) Mean (SD)	Non-closure group (n=41) Mean (SD)	*P*-value
Age (years)	60.3 (11.3)	57.9 (10.3)	0.316
Weight (kilogram)	85.5 (18.6)	81.4 (18.4)	0.267
Body mass index	34.7 (7.3)	32.9 (7.1)	0.235
Subcutaneous depth (cm)	6.5 (2.1)	6.2 (1.8)	0.480
Incision length (cm)	23.8 (5.9)	24.8 (4.8)	0.402
Duration of surgery (mins)	122 (46.6)	138 (56.7)	0.243

Table 2: Wound complications

	Closure group (n=41)	Non-closure group (n=41)	*P*-value
Cellulitis or infection	2	3	0.644
Wound dehiscence	3	4	0.692
Seroma or hematoma	2	7	0.077
Any complication	6	11	0.284

Wound infection occurred in two patients in the subcutaneous suture group as compared to three patients in the control group. One patient in each group was hospitalized and treated with vacuum-assisted closure (VAC). The other patients were treated only with antibiotics. Seroma and wound dehiscence were more frequent in the non-closure group, but neither of these findings reached statistical significance.

Discussion

The technique used for closing a vertical incision is crucial for wound complications. Suturing of the subcutaneous fatty tissue is recommended by several studies to close the dead space [9]. On the other hand, there is a possibility that the suture itself may act as foreign material and cause more wound infections than it prevents. Currently, there is no consensus on the method of subcutaneous closure. Therefore, our randomized study aimed to determine the role of subcutaneous closure in vertical midline incisions performed in patients with ≥4 cm subcutaneous thicknesses.

After a vertical midline incision, surgical site infection is reported in up to approximately 15% of patients [10]. This rate highly varies between different reports, which is probably very much related to different surgical procedures, cohorts, and definitions of infection. In the present trial, the surgical site infection rate was 6.1% in the whole study group. We observed no significant differences in the rate of surgical site infections between the closure and non-closure groups. In a Cochrane database, analyses evaluating subcutaneous tissue closure versus non-closure after abdominal surgical operations reported no significant differences in terms of surgical site infections between the two groups (RR 0.84; 95% CI 0.53 to 1.33; I2 = 0%) [7].

In our trial, we observed no significant differences in wound dehiscence rates between the subcutaneous closure and non-closure groups. A meta-analysis reviewed six trials on suture approximation after cesarean delivery and reported that subcutaneous closure in patients with more than 2 cm of subcutaneous thickness resulted in a 34% decrease in wound dehiscence [11]. On the other hand, Cardosi et al. [6] evaluated the subcutaneous tissue of vertical midline incisions with 3 cm or more of subcutaneous tissue and similar to our results, found that wound dehiscence rates did not significantly differ between the closure and non-closure groups (7.7% vs 11.7%, *P*=0.6). Lack of a standard definition for surgical wound dehiscence can make it difficult to compare results. Exposure to different physical tensile forces in transverse and vertical incisions may result in different results.

A prospective study of 60 patients with 2.5 cm or more subcutaneous tissue thickness evaluating the closure or non-closure of the subcutaneous space after gynecological surgery found no significant differences between the closed and unclosed groups. [12]. We found insignificantly fewer seromas in the closure group. The relatively small number of participants in the trial may explain this result.

Limitations

The major strength of our study is its prospective randomized controlled nature and evaluation of women with ≥4 cm subcutaneous fat thickness only. On the other hand, this study remains underpowered in terms of primary outcome due to the relatively small number of participants and a lower than anticipated rate of wound complications. However, determining the optimal means of reducing wound complications requires a multicenter randomized trial with much larger sample sizes.

Conclusion

We found no significant differences in the rate of surgical wound complications with suture approximation of the subcutaneous tissue in patients with 4 cm or more subcutaneous thickness undergoing gynecologic surgery via a vertical midline incision.

Subcutaneous closure has the potential to increase cost due to prolonged operation time and additional suture material. If subcutaneous closure has no remarkable benefit and costs more, it may not be routinely applied.

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