The Role of Surgical Drainage on Complications after Sentinel Lymph Node Biopsy for Melanoma

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Background: The real benefit of using drains for reducing the risk of complications in sentinel lymph node biopsy (SLNB) has not been investigated yet. We aimed to evaluate the role of drain after SLNB and to determine if a correlation exists between drains and early complications.

Methods: This is a retrospective study of patients who underwent SLNB for melanoma from 2016 to 2021. Patients were dichotomized into two groups according to the use of drain. The between-group comparison (drainage group versus no drainage group) was performed by using Mann-Whitney U test and chi-square test. A regression analysis was conducted to identify predictors of complications.

Results: Of 218 individuals analyzed, 18 (8.4%) had postoperative complications. The most common complications were seroma (5.1%) and wound dehiscence (1.4%). The between-group analysis showed no significant differences in complication rate, whereas the operative time was significantly higher in the drainage group (P = 0.007), as well as the hospital stay (P = 0.0001) and the duration of postoperative antibiotic therapy (P = 0.02). The regression analysis found body mass index and multiple basins of SLNB (axilla with groin) to be significant predictors of having a complication (P = 0.03 and P = 0.05, respectively). The operative time was found to be a predictor of seroma (P = 0.04).

Conclusions: Drainage use in SLNB prolonged hospital stays and duration of postoperative antibiotic therapy, thus resulting in higher costs. The preemptive use of drainage is suggested in selected settings of patients. (Plast Reconstr Surg Glob Open 2022;10:e4642; doi: 10.1097/GOX.0000000000004642; Published online 3 November 2022.)

The incidence of cutaneous melanoma across the developed world is increasing, and it represents 5.6% of all new cancer cases and the fifth most common cancer in the United States.1 Sentinel lymph node biopsy (SLNB) is a minimally invasive procedure that allows for nodal evaluation, and it is considered the gold standard of staging for melanoma. SLNB is usually recommended for patients with intermediate-thickness and thick melanomas (T2 or higher, Breslow ≥1 mm), and it may be considered for thin melanomas that are either 0.8–1.0 mm Breslow or less than 0.8 mm with ulceration (T1b).2

Although SLNB is considered a relatively simple, well-established, and safe procedure, several postoperative complications have been described in the literature, with highly variable complication rates ranging from 1.8% to 29.9%. Among these, seromas, surgical site infections, and hematomas are considered to be among the most common complications.3

Seroma formation after SLNB is a nuisance both for patient and surgeon, as it may require numerous return visits to outpatient clinics, multiple aspirations, ultrasound-assisted drain placement, or additional surgery. Surgical wound drainage may be considered to prevent excessive fluid collection in the anatomical “dead” spaces created by surgical dissection with consequent hematoma or seroma formation during the healing process. However, although the use of drainage after lymph node dissection is widely accepted, the real benefit of using surgical suction drains in preventing early complications in SLNB has not been fully investigated yet. Many surgeons still have several concerns about their use. They feel that it is unnecessary either because they believe it could increase the risk of infection or discomfort to a very demanding group of patients.

The main aim of our study was to describe the role of surgical wound drains after SLNB in patients with cutaneous melanoma and to determine if a correlation exists between the use of drains and complications, such as seroma, hematoma, and infections. Our secondary aim was to identify preoperative and perioperative predictors for early postoperative complications after SLNB.

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MATERIALS AND METHODS

Study Design
The research was designed as a retrospective cohort study. The study followed the STROBE guidelines, and it was conducted according to Good Clinical Practice requirements and the 1975 Declaration of Helsinki principles.

Participants
An institutional review board (Comitato Etico Regione Marche, 2021/472) approved a retrospective chart review of patients who underwent SLNB for cutaneous melanoma in our hospital from January 1, 2016 to June 30, 2021.

Inclusion criteria: patients with cutaneous melanoma considered for SLNB in the period between 2016 and 2021 were enrolled, regardless of age, sex, ethnicity, and mental or physical condition. Exclusion criteria: patients who underwent only wide local excision of the primary excision of melanoma without SLNB, patients who underwent SLNB without identification of the sentinel lymph node, and patients whose clinical records were not available.

Patients were classified into two groups according to the use of surgical drains after SLNB: “drainage group” if closed-suction drains were used at the end of the surgery, and “no drainage group” if drains were not used.

Study Variables
Independent Variables
We collected the following demographics and clinical data from the electronic medical records of our hospital: age, sex, kind of comorbidity, comorbidity burden, diagnosis of diabetes, smoking status, and body mass index (BMI). We evaluated the comorbidity burden through Cumulative Illness Rating Scale Severity Index (CIRS-SI) and Comorbidity Index (CIRS-CI), which measure the chronic illness burden while considering the severity of chronic diseases. We also recorded data about the primary tumor location, Breslow thickness, kind of anesthesia, site of SLNB, the use of surgical drain, and postoperative antibiotic therapy.

Dependent Variables
We collected data regarding early postoperative complications (within 30 days postoperative), length of hospital stay, time to drain removal, the total amount of fluid drained, and pain intensity assessment by using the numerical rating scale (NRS).

Seromas and hematomas were considered clinically significant and recorded if they required invasive procedures, such as needle aspiration or additional surgery. Infection was diagnosed if clinical signs and symptoms, such as redness, swelling, or tenderness at the site of SLNB, were observed.

Sentinel Lymph Node Biopsy Procedure and Postoperative Management
The technique used for SLNB was the standard method of preoperative technetium-99–based lymphoscintigraphy followed by the intraoperative location of node(s) using a hand-held gamma probe. The lymphoscintigraphy was usually performed the day before the operation. The choice to use the surgical drain was usually based on intraoperative evaluation of bleeding and the amount of surgical dissection of the tissues performed for SLNB according to usual clinical practice. Compressive dressings were applied during the early postoperative period in all patients.

Statistical Analysis
The distribution of clinical and demographic variables was studied using descriptive statistics. All variables that resulted normally distributed were described in terms of mean and standard deviation (SD). The others were treated as nonparametric variables and described using median and interquartile range. We used the Mann-Whitney U test for between-group comparison (drainage group versus no drainage group) of continuous variables. Category variables were described as percentages and compared using the chi-square test. Logistic regression analysis was used to estimate the relationships among the nominal dependent variables (presence and type of complications, and presence of pain) and independent factors (age, sex, BMI, smoking, diabetes, comorbidities, CIRS, Breslow thickness, site of primary melanoma, draining nodal basins, site of SLNB, hospital stay, anesthesia, and postoperative antibiotic therapy). The significance level was set at a P value less than or equal to 0.05. Statistical analysis was performed using StatView, Version 5.0.

RESULTS
Two hundred eighteen patients were included in the study: 121 subjects in the drainage group and 97 in the no drainage group. The descriptive analysis of the sample is summarized in Tables 1 and 2, which show patients’ clinical characteristics and surgical outcomes.

The mean patient age was 61.5 ± 15.62 years, and 117 (53.7%) of 218 patients were men without differences between the two groups. The mean BMI was 26.81 ± 4.60, and it was significantly higher in the drainage group (P = 0.007). There were no significant differences in the number of smokers or diabetics in the two groups, or in the kind of comorbidity and the comorbidity burden. No significant differences were observed in terms of Breslow thickness, the number of draining nodal

Takeaways

Question: We aimed to evaluate the use of drains after sentinel lymph node biopsy and to determine if a correlation exists between drains and early complications.

Findings: The study showed that drainage use in sentinel lymph node biopsy prolonged hospital stays and duration of postoperative antibiotic therapy, thus resulting in higher costs. No significant differences in complication rates were observed.

Meaning: Preemptive drain placement at primary operation should be considered in selected cases.
basins, and the number of lymph nodes removed. In contrast, the site of primary melanoma ($P = 0.02$) and the site of SLNB ($P = 0.008$) resulted significantly different. The operative time was significantly higher in the drainage group (84.7 ± 25.10 minutes versus 75.75 ± 25.37 minutes; $P = 0.007$), as well as the hospital stay (4.00 ± 1.35 days versus 2.80 ± 0.83 days; $P = 0.0001$) and the duration of postoperative antibiotic therapy (1.56 ± 2.49 days versus 0.74 ± 1.72 days; $P = 0.02$). Additionally, no significant differences were detected in the type of anesthesia and postoperative pain intensity.

Among the 218 individuals who underwent SLNB, 18 patients (8.4%) had one postoperative complication within 30 days of surgery. The most common

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**Table 1. Demographics and Clinical Data (Continuous Variables) of the Study Population**

| Total (Mean ± SD) | Drainage Group, n = 121 (Mean ± SD) | No Drainage Group, n = 97 (Mean ± SD) | Between-group Analysis ($P$)* |
|-------------------|-------------------------------------|--------------------------------------|-------------------------------|
| Age (y)           | 61.50 ± 15.62                       | 62.20 ± 14.86                       | 60.63 ± 16.55                | 0.60                          |
| BMI (kg/m²)       | 26.81 ± 4.60                        | 27.56 ± 4.87                        | 25.88 ± 4.09                 | 0.007                         |
| CIRS-CI           | 0.66 ± 0.86                         | 0.67 ± 0.88                         | 0.65 ± 0.84                  | 0.87                          |
| CIRS-SI           | 0.14 ± 0.15                         | 0.14 ± 0.16                         | 0.13 ± 0.15                  | 0.72                          |
| Breslow thickness (mm) | 1.94 ± 1.84                      | 2.00 ± 1.75                         | 1.88 ± 1.96                  | 0.12                          |
| Draining nodal basins (no.) | 1 (0)†                            | 1 (0)†                              | 1 (0)†                       |                               |
| No. of LN removed | 2.24 ± 1.55                         | 2.26 ± 1.45                         | 2.25 ± 1.66                  | 0.39                          |
| Hospital stay (d) | 3.46 ± 1.29                         | 4.00 ± 1.35                         | 2.80 ± 0.83                  | 0.0001                        |
| Operative time (min) | 80.72 ± 25.53                     | 84.7 ± 25.10                        | 73.75 ± 25.37                | 0.007                         |
| Total fluid collected (ml) | —                                 | 50.90 ± 69.30                     | —                            |                               |
| Time to drain removal (d) | —                                 | 4.13 ± 2.16                        | —                            |                               |
| Postoperative pain intensity (NRS scale) | 0.08 ± 0.29              | 0.10 ± 0.33                         | 0.06 ± 0.23                  | 0.01                          |
| Duration of postoperative antibiotic therapy (d) | 1.19 ± 2.20                  | 1.56 ± 2.49                         | 0.74 ± 1.72                  | 0.02                          |

* Mann-Whitney U test ($P \leq 0.05$).
† Median (IRQ).

**Table 2. Demographics and Clinical Data (Category Variables) of the Study Population**

| Total, N (%) | Drainage Group, n = 121 | No Drainage Group, n = 97 | Between-group Analysis ($P$)* |
|--------------|-------------------------|----------------------------|-------------------------------|
| Sex          |                         |                            |                               |
| • Male       | 117 (53.7)              | 67 (55.4)                  | 50 (51.5)                     | 0.57                          |
| • Female     | 101 (46.3)              | 54 (44.6)                  | 47 (48.5)                     |                               |
| Smoking      |                         |                            |                               |
| • Yes        | 41 (19.3)               | 23 (19.7)                  | 18 (19)                       | 0.89                          |
| • No         | 171 (80.7)              | 94 (80.3)                  | 77 (81)                       |                               |
| Diabetes     |                         |                            |                               |
| • Yes        | 20 (9.4)                | 13 (11.1)                  | 7 (7.4)                       | 0.35                          |
| • No         | 192 (90.6)              | 104 (88.9)                 | 88 (92.6)                     |                               |
| Comorbidities|                         |                            |                               |
| • Yes        | 138 (65.1)              | 75 (64.1)                  | 63 (66.3)                     | 0.73                          |
| • No         | 74 (34.9)               | 42 (35.9)                  | 32 (33.7)                     |                               |
| Site of primary melanoma |            |                            |                               |
| • Head/neck  | 21 (9.6)                | 6 (5)                      | 15 (15.5)                     | 0.02                          |
| • Trunk      | 93 (42.7)               | 37 (37.1)                  | 36 (37.1)                     |                               |
| • Upper extremity | 47 (21.6)           | 30 (24.8)                  | 17 (17.5)                     |                               |
| • Lower extremity | 57 (26.1)           | 28 (23.1)                  | 29 (29.9)                     |                               |
| Draining nodal basins |            |                            |                               |
| • Single-nodal basin | 197 (90.4)         | 112 (92.6)                 | 85 (87.6)                     | 0.21                          |
| • Multiple-nodal basin | 21 (9.6)            | 9 (7.4)                    | 12 (12.4)                     |                               |
| Site of SLN biopsy |             |                            |                               |
| • Head/neck  | 22 (10.1)               | 6 (5)                      | 16 (16.5)                     | 0.008                         |
| • Axilla     | 120 (55)                | 77 (63.7)                  | 43 (44.3)                     |                               |
| • Groin      | 69 (31.7)               | 35 (28.8)                  | 34 (35.1)                     |                               |
| • Other (axilla and groin) | 7 (3.2)            | 3 (2.5)                    | 4 (4.1)                       |                               |
| Antibiotic therapy |              |                            |                               |
| • Yes        | 77 (36.7)               | 48 (41.7)                  | 29 (30.5)                     | 0.09                          |
| • No         | 133 (63.3)              | 67 (58.3)                  | 66 (69.5)                     |                               |
| Anesthesia   |                         |                            |                               |
| • Local      | 81 (37.1)               | 46 (38)                    | 35 (36.1)                     | 0.88                          |
| • Regional block | 18 (8.4)            | 9 (7.6)                    | 9 (9.5)                       |                               |
| • Spinal     | 30 (13.8)               | 16 (13.2)                  | 14 (14.4)                     |                               |
| • General    | 98 (44.9)               | 53 (43.8)                  | 45 (46.4)                     |                               |
| Postoperative pain |             |                            |                               |
| • Yes        | 55 (26.2)               | 33 (28.7)                  | 22 (23.2)                     | 0.36                          |
| • No         | 155 (73.8)              | 82 (71.3)                  | 73 (76.8)                     | 0.66                          |
| Complications|                         |                            |                               |
| • No         | 197 (91.6)              | 109 (92.4)                 | 88 (90.7)                     | 0.12                          |
| • Yes        | 18 (8.4)                | 9 (7.6)                    | 9 (9.5)                       |                               |
| Seroma       | 11 (5.1)                | 3 (2.5)                    | 8 (8.5)                       |                               |
| Hematoma     | 2 (0.9)                 | 1 (0.9)                    | 1 (1)                         |                               |
| Wound dehiscence | 3 (1.4)            | 3 (2.5)                    | 0 (0)                         |                               |
| Infection    | 1 (0.5)                 | 1 (0.9)                    | 0 (0)                         |                               |
| Lymphangitis | 1 (0.5)                 | 1 (0.9)                    | 0 (0)                         |                               |

* Chi-square test ($P \leq 0.05$).
complication was seroma (5.1%), followed by wound dehiscence (1.4%) (Table 2). Among the 11 patients developing symptomatic seromas, all but one were managed conservatively with needle aspiration in outpatient, while one patient needed surgical revision. In the group without drains, there were nine postoperative complications (eight seromas and one hematoma) for an overall complication rate of 9.3%. The same number of postoperative complications was observed in the drainage group (three seromas, three wound dehiscence due to fat necrosis, one hematoma, one infection, and one case of lymphangitis) with an overall complication rate of 7.6%. Nevertheless, the difference between the two groups was not statistically significant ($P = 0.66$). Regarding the type of complication, a higher rate of seromas was detected in the group without drains (8.3% versus 2.5%), but this difference was not significant ($P = 0.12$).

The logistic regression analysis found BMI and multiple basins of SLNB (axilla with groin) to be significant predictors of having a postoperative complication ($P = 0.03$ and $P = 0.05$, respectively). An association between the male gender and the incidence of complications was observed, even if we did not find it a predictor of complications ($P = 0.09$). The operative time was found to be a predictor of seroma ($P = 0.04$), contrarily to age, smoking status, comorbidities, diabetes mellitus, and tumor characteristics. Moreover, the logistic regression analysis showed that the presence of postoperative pain was not associated with the use of surgical drains, whereas BMI and the site of primary melanoma (upper extremity) were significantly associated with pain ($P = 0.01$ and $P = 0.006$, respectively).

Finally, to clarify the association between BMI and complications, we used Spearman rank correlation between BMI and operative time that resulted significant as for $P = 0.05$ ($Z = 1.9$).

**DISCUSSION**

The current study investigated the role of suction wound drainage in SLNB in patients with cutaneous melanoma and its influence on the incidence of early postoperative complications, such as seroma, hematoma, or infection. Furthermore, we aimed to identify preoperative and perioperative predictors for early postoperative complications after SLNB, to individualize those settings of patients who could most benefit from the use of drainage.

In recent years, increasing numbers of studies have questioned the necessity of wound drainage as a possible tool to prevent seromas in several plastic surgery procedures with controversial conclusions. Although the use of drains is widely accepted in the lymph node dissection, there are almost no data available on the use of closed-suction drains following SLNB for melanoma.

Seroma rates after SNLB are highly variable in the literature, also depending on the type of tumor. A retrospective review of 667 women undergoing breast-conserving surgery and SLNB for breast cancer showed an axillary seroma rate of 19%. A systematic review by Moody et al showed that seroma represents the most common complication after SLNB for cutaneous melanoma. The crude seroma rate ranged from 0% to 38%, with an estimated overall incidence of 5.1%. Similar results were described by Wrightson et al, who reported a seroma rate of 2.3% in 2130 patients, while Roaten et al reported a rate of seroma of 1.2% in 339 patients. More recently, Lindqvist et al described a seroma rate of 6.4% in 886 patients with cutaneous melanoma. Our results are mainly consistent with the literature with an overall seroma rate of 5.1% in 218 patients. Although we observed a higher rate of seromas in the group without drainage (no drainage group, 8.3% versus drainage group, 2.5%), the difference was not statistically significant. Therefore, drains did not reduce seroma risk after SLNB in our cohort.

Many surgeons still have several concerns about the use of drains due to the presumed higher risk of wound-specific complications such as infection. Regarding the overall postoperative complications, no significant differences were observed between the two groups with similar complication rates (no drainage group, 9.3% versus drainage group, 7.6%) and only one case of infection. Our findings are consistent with the study of Ling et al, which concluded that using a closed system drain tube did not increase the risk of complications. Conversely, Roaten et al observed a significantly higher complication rate in patients undergoing SLNB with drain placement than the patients who were not drained (13.2% versus 2.2%; $P < 0.001$), thus discouraging the routine use of closed-suction drains for SLNB in patients with melanoma. Nevertheless, of the 15 reported complications, these authors observed only three cases of wound infection. Based on these observations, we can conclude that if, on the one hand, the use of drainage does not reduce the risk of postoperative seroma, on the other hand, suction drains are not burdened by a higher rate of infections.

It has also been hypothesized that drainage can be a source of pain and significant discomfort to a very demanding patient group and cause sleep disturbances and prolong hospital stay. However, there are no available data regarding the effect of drains on patients’ comfort levels and well-being following lymphatic surgery for cutaneous melanoma. In our study, we tried to assess the patient’s discomfort by measuring postoperative pain. Our results showed no difference either in the presence of postoperative pain between the drain and the no-drain groups ($P = 0.36$) or in pain intensity measured using numerical rating scale [(NRS), $P = 0.41$]. Nevertheless, there was a highly significant difference in the duration of hospital stay between the two groups (drain group, 4.00 ± 1.35 days versus no-drain group, 2.80 ± 0.83 days; $P < 0.0001$). Moreover, a significant difference in the duration of postoperative antibiotic therapy between the groups was observed (drain group, 1.56 ± 2.49 days versus no-drain group, 0.74 ± 1.72 days; $P = 0.02$). Therefore, although the use of drainage did not affect postoperative pain in our cohort, it significantly prolonged hospital stay and the duration of antibiotic therapy in our study. It is known that early hospital discharge certainly has positive implications not only in terms of economic effect on resources but also on the psychological well-being of patients.
the patient. Nevertheless, in our study, we did not use any focused questionnaire to specifically assess patients’ comfort levels and well-being, as we used only a rating scale for self-report of pain intensity, which may be conditioned by several factors. It may be useful to collect data on quality of life related to drain use so that both surgeons and patients can make a reasonable choice based on quantifying potential benefits.

Considering the possible discomfort caused to the patient, we should assess whether drains are necessary for every individual case or should only be placed in specific high-risk groups. In this scenario, identifying predictors for early postoperative complications after SLNB could be helpful to consider the routine use of drains in SLNB in selected populations. Gunn et al. analyzed 667 women undergoing breast-conserving surgery and SLNB for breast cancer and concluded that preemptive drain placement at the initial operation was not necessary, except for diabetic or smoking patients who were found to be at higher risk of seroma formation.

Previous studies identified several predictors for complications, such as the inguinal location of the nodal basin, BMI, diabetes, male gender, smoking, ulceration of primary melanoma, and the number of lymph nodes excised. Diabetes and male sex were notably associated with hospital readmission for surgical complications in inguinal SLNB procedures, while smoking was a predictor of hospital readmission for overall SLNB procedures.

Our results are quite consistent with the literature. BMI was found to be a risk factor for developing a complication (P = 0.03) in our cohort, as well as the groin nodal basin, but only in the case of multiple-nodal basin drainage with axilla (P = 0.05). However, the subgroup analysis performed in the drainage group revealed that drains had not a site-specific impact on the surgical outcomes (P = 0.29 and chi-square = 3.8). An increased incidence of complications was observed in male patients, even though this difference was not statistically different (P = 0.09). Previous findings on smoking and diabetes as risk factors could not be replicated in this study.

Interestingly, the duration of the surgical procedure was significantly associated with an increased risk of postoperative seroma (P = 0.04) in our cohort. This finding could probably be explained by a more difficult and extensive dissection performed to identify the sentinel lymph node in some patients. Therefore, prolonged dissection could cause excessive fluid collection in the anatomical “dead” spaces. The higher operative times recorded in the drainage group are probably due to the higher number of axilla nodal basins observed in this group. Usually, the axilla basin is a more challenging site for SLNB due to anatomical features of this area. Differences in the anatomy of the groin compared with the axilla could also account for the lower rate of seroma observed in the drainage group. In fact, in the drainage group, there was a proportionally lower number of inguinal nodal basins compared with the no drainage group (28.8% versus 35.1%). The inguinal lymph node basin was found to be a predictor for seroma formation by Persa et al. These authors claimed that the groin drains larger amounts of lymphatic fluid compared with the axilla, making seroma more likely. Furthermore, the more shallow structure of the groin could also contribute to an increased seroma formation compared with the axilla by making this complication more visible. Therefore, although the operative times recorded in the drainage group are higher compared with the no drainage group, the proportionally lower number of inguinal nodal basins in the drainage group may explain the lower rate of seromas observed in this group of patients.

Identification of SLNB in obese patients with higher BMI and larger amounts of subcutaneous fat could be more challenging and time-consuming. Our study confirmed this by the Spearman rank correlation between BMI and operative time that resulted significant (P = 0.05). We observed a significantly higher BMI in the drainage group at the between-group analysis (P = 0.007). This was confirmed by the logistic regression analysis, which showed that the presence of drainage was associated with a higher BMI (P = 0.0099; R squared = 0.025; Coef = 0.086, chi-square = 6.651). Therefore, the use of drainage in selected patients with higher BMI should be considered, in our opinion.

Our study has many strengths and limitations. We included patients treated at a single institution by the same provider postoperatively. We have tried to standardize surgical procedures and patients’ instructions, even if minor variations in surgical technique for the SLNB may have occurred during the study period, as well as slight differences in treatment protocols.

The main limitations of our study are the relatively small number of patients and the retrospective methodology. As the choice to place drain or not was decided intraoperatively according to extensive and prolonged dissection or intraoperative bleeding, this could represent a further limitation of our research. Moreover, there are some significant differences between the two groups, such as the site of SLNB, which could affect complication rates.

We are aware that the aforementioned points limit the validity and impact of the study. However, these limitations mainly depend on the retrospective nature of the study. Therefore, randomized trials are needed to prove the role of drainage in preventing complications after SLNB for cutaneous melanoma.

CONCLUSIONS

Although seroma incidence is low after SLNB for cutaneous melanoma compared with lymph node dissection, it remains a common postsurgical complication. The use of suction drainage in SLNB prolonged hospital stays and the duration of postoperative antibiotic therapy in our cohort study, thus resulting in higher costs, and did not demonstrate any benefit in a recent postoperative time. However, there was no association between drainage use and an increased risk of infections or increased patient discomfort in our study. Therefore, we suggest evaluating the use of drainage in selected patients such as obese patients with high BMI. In our study, these patients were at greater risk of
complications and reported a longer duration of the intervention, which predisposes them to a higher risk of seromas.

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