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Single vs. double drain in modified radical mastectomy: A randomized controlled trial

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ABSTRACT

Objective: It was aimed to test the hypothesis that the use of a double drain results in less seroma formation, duration of the hospital stay, surgical site infection (SSI), postoperative pain, hematoma, flap necrosis compared to a single drain in patients undergoing modified radical mastectomy.

Material and Methods: This parallel-group, single-institution randomized controlled trial was conducted at the department of surgery of our institute between April 2015 and July 2018. Women undergoing modified radical mastectomy were randomly allocated to either a single drain (n= 98) or double drain (n= 98).

Results: Both groups were comparable for baseline variables such as age, co-morbidity, BMI, and tumor characteristics. The variables of single drain yielded no better outcomes compared to double drain with estimated blood loss (101.67 ± 25.14 vs.101.67 ± 24.40, p> 0.001), drain volume (898.81 ± 116.42 vs 803.97 ± 103.22 mL, p> 0.001), duration of surgery in minutes (103.19 ± 15.96, 103.19 ± 15.93) and seroma formation (13.4% vs 6.1%, p= 0.082). However, single drain yielded less postoperative pain (mean 2.5 ± 0.70 vs 5.22 ± 5.10, p< 0.000). On multivariable Cox regression analysis, single drain was associated with a lower risk of significant postoperative pain [adjusted relative risk 0.14 (95% confidence interval (CI) 0.070-0.25)] and overall complications [adjusted relative risk 0.47, (95% CI 0.26-0.86)]. On multiple linear regression, the duration of drains in the single drain group was 0.01 days less than double drain (r2= 0.00, b= 0.388, p> 0.001).

Conclusion: The use of a single drain significantly reduces postoperative discomfort and pain while demonstrating similar morbidity to the patient with two drains. We thus recommend preferential use of a single drain in modified radical mastectomy (NCT02411617).

Keywords: Modified radical mastectomy, seroma, postoperative pain, single drain

INTRODUCTION

Despite increasing trends toward breast conservation surgery, modified radical mastectomy (MRM) remains the most commonly performed surgical procedure for breast cancer (1). The complications following MRM include seroma, wound infection, hematoma, postoperative pain, flap necrosis, and prolonged axillary drainage (2). Operative morbidity associated with MRM is between 30 and 50%, which is attributed to large raw surface after mastectomy (1). Seroma is one of the most common complications after MRM, which has been reported to occur in 85% of cases (reference). It mainly delays wound healing, causes wound dehiscence, infections, and results in a longer hospital stay (3,4).

The use of drains during MRM remains one of the most investigated and at the same time, controversial of all techniques aimed at reducing the rate of seroma formation (4-7). It is believed that closed suction drainage in MRM accelerates wound healing and decreases overall complications (7,8). However, confusion exists regarding optimal suction pressure, the number of drains, duration of drainage, and in fact whether the drain should be used at all following MRM (4,9,10). There are few good-quality studies comparing the use of single and multiple drains in breast cancer surgery (7,8). In a previous study assessing single drain versus double drain, no significant difference has been observed in seroma formation (30.4% vs. 36.4%), total drain volume (244.80 ± 95.31 vs. 283.80 ± 111.75 mL) and drain days (9.25 ± 2.16 vs. 9.89 ± 0.54) (4). However, many surgeons still do not prefer single drain because they think that it increases seroma formation. The reason for using seroma formation as a priority in the study is based on the reports

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of common occurrence after breast surgery and since the study aimed to show that seroma was less related to both single and double drain thus proving the previous studies' results. Hypothesis of the study is:

H_0 single drain ≠ single drain

H_A single drain = double drain

Our study was initiated to compare the use of a single drain with two drains following MRM in a controlled, randomized prospective setting. Previously conducted studies have not led surgeons to a consensus regarding the number of drains mainly because of study limitations, including single-arm study, nonrandomized design, and randomized study with inadequate sample size and presence of confounders (2,4,6,10). We thus planned this randomized controlled trial to determine whether a single drain has a role in reducing operative morbidity compared to two drains. This study aimed to evaluate the effect of the number of drains primarily on seroma formation rate followed by postoperative pain, flap necrosis, wound infection, hematoma, and hospital stay during the immediate postoperative period after MRM for breast cancer.

MATERIAL and METHODS

Study Design

We conducted this randomized controlled trial at the department of surgery of our institute from April 2015 to July 2018. Being a tertiary care hospital, breast diseases are managed in an integrated and evidence-based manner. Every breast cancer case is thoroughly discussed in weekly breast tumor board meetings comprising a breast surgeon, medical oncologist, radiation oncologist, histopathologists, radiologist, and a specialist nurse to formulate an individualized management strategy for each patient. Cancer staging is performed according to the American Joint Committee on Cancer staging system.

Subject Selection and Randomization

We included all women who underwent MRM for biopsy-proven carcinoma of the breast. Those who refused surgery and had immediate reconstruction were excluded from the study. Selected patients who consented to surgery were included, and a statistician placed them in a computer-generated randomization sequence. The sequence was communicated to the surgeon only once the patient was in the operating room.

Surgical Procedure

All procedures were performed by a single surgeon who had more than five years of experience in breast surgery. Skin incision was made with a conventional scalpel, and flaps were raised. Breast tissue was reflected off the pectoralis major muscle with electrocautery, and the medial and lateral borders of the pectoralis minor muscle were defined. The pectoralis minor was retracted, and a standard level II axillary clearance was performed in all patients. Venous branches and lymphatics in the axilla were clipped and ligated. Hemostasis was secured followed by the placement of either one drain in the axilla or two drains, with one in the axilla and the other placed under the flaps according to randomization. Staplers were used to approximate the wound edges. Postoperative treatment was uniform throughout the study in keeping with clinical pathways.

Enrollment Criteria

Establishing inclusion and exclusion criteria for study participants is a standard, required practice when designing high-quality research protocols. As we set the inclusion criteria, we also set the exclusion criteria. Common exclusion criteria include characteristics of eligible individuals that make them highly likely to be lost to follow-up, miss scheduled appointments to collect data, provide inaccurate data, have comorbidities that could bias the results of the study, or increase their risk for adverse events (most relevant in studies testing interventions).

Follow-Up

All patients were given intravenous paracetamol six-hourly to control pain in the immediate postoperative period. Most of our patients were discharged with drains on the first postoperative day. A follow-up visit was scheduled in the outpatient clinic with further instructions to report back immediately if the drain bottle filled up, lost vacuum, or peri drain leak was encountered. A card was given at the time of discharge to every patient to be able to record drain volume at home daily at a specific time after placing the bottle on a flat surface. In this study, out of 221 participants, 25 patients were lost to follow-up and were excluded from the study. The drains were removed on follow-up once the volume was less than 30 mL per 24 hours.

Outcome Variables

Outcome variables were seroma formation, duration of hospital stay, wound infection, postoperative pain, and flap necrosis. Seroma was defined as the presence of fluid collection beneath the skin flaps after the removal of the drains to cause patient discomfort within 30 days of surgery. Superficial skin infection (SSI) was assessed as per U.S. Centers for Disease Control and Prevention criteria. SSI was defined as an infection of the skin and subcutaneous tissue that occurred within 30 postoperative days along with at least one of the following criteria: (1) purulent drainage from the superficial incision, (2) organisms (other than *Staphylococcus epidermidis*) isolated from an aseptically obtained culture of fluid or tissue from the superficial incision, (3) at least one of the given signs or symptoms of infection (i.e. pain or tenderness, localized swelling, redness, heat or superficial incision deliberately opened by the surgeon with culture-

positive pus or tissue) and diagnosis of SSI by the surgeon or attending physician (4). Postoperative pain was evaluated 24 hours after surgery by a nurse using a visual analog score ranging from 0 to 10 (minimum to maximum pain), a visual analog scale score of C4 was labeled as significant pain.

Sample Size

World Health Organization software was used to calculate sample size for different outcome variables, the highest sample size was formulated for total drain days reported in a previous study. A sample size of 96 participants in each group was calculated for the mean of total drain days for single drain versus double drain with standard deviation of 1-2 days at 5% level of significance (one sided) and 80% power. An ideal set of 141 people were required for this analysis where 71 patients in each group would have been sufficient for the analysis. According to Andrede (2020), in quantitative studies, a sample that is larger than necessary will be better representative of the population and will hence provide more accurate results. It prevents type II error.

Our study sample included a total of 196 patients in which only two cases had missing data and eventually resulted in 96 participants in each group.

RESULTS

In each intervention group, 96 patients were recruited consecutively (Figure 1). Two patients were excluded from each group

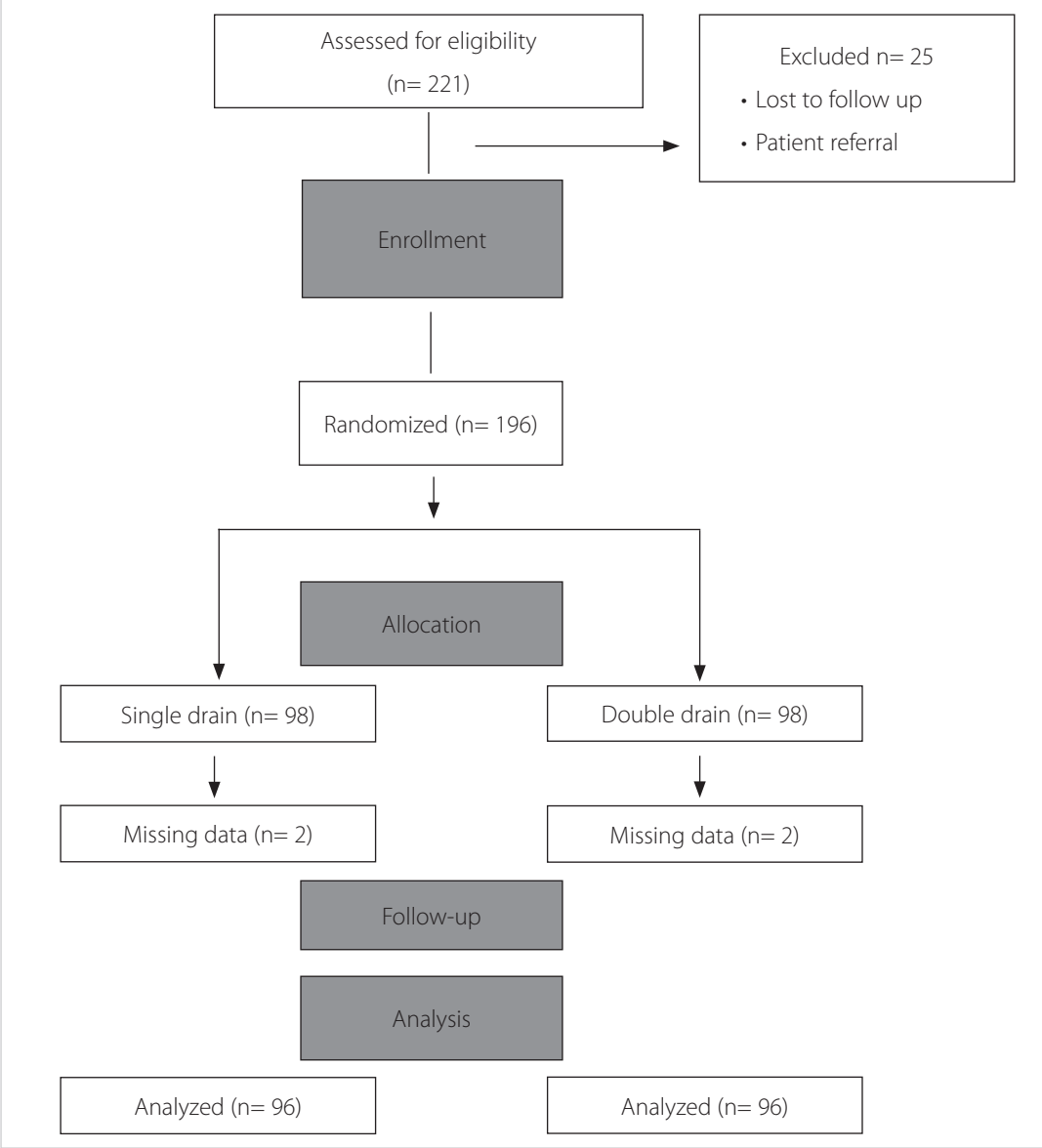

Figure 1. Consort flow diagram of the participants.

due to missing data. Both groups were comparable in terms of baseline variables with a mean age of 55.13 ± 9.0 and 55.37 ± 8.4 years, respectively (Table 1). Further analysis showed that double drain did not yield better outcomes (Table 2) compared to single drain, with estimated blood loss (101.67 ± 24.402 vs. 101.24 ± 25.15, p= 0.90), drain volume (803.97 ± 103.22 vs. 898.81 ± 116.42, p= 0.743), drain days (7.62 ± 2.44 vs. 7.14 ± 2.53, p= 0.145), seroma formation (6.1% vs. 13.4%, p= 0.08), operative time (103.19 ± 15.96 vs. 103.97 ± 15.93 min, p= 0.49), and SSI (3 vs. 4%, p= 0.570). Double drain was not better than

Table 1. Baseline variables between single vs. double drain groups

Variable	Single drain (n= 96)	Double drain (n= 96)	p
Age	55.13 ± 9.0	55.37 ± 8.4	0.848[a]
BMI	23.21 ± 3.5	23.21 ± 3.2	0.988[a]
Comorbidities			
DM	20 (20.4%)	16 (16.3%)	0.290[b]
HTN	13 (13.4%)	17 (17.3%)	0.276
Smoking	0	0	0.636[b]
Breast weight (grams)	818.80 ± 168.91	826.14 ± 162.24	0.757[a]
Clinical TNM stage			
I	4 (4.1%)	5 (5.1%)	
II	49 (50.0%)	59 (60.2%)	
III	45 (45.9%)	34 (34.7%)	0.277[b]
Clinical T stage			
I	4 (4.1%)	5 (5.1%)	
II	31 (31.6)	46 (46.9%)	
III	45 (45.9%)	46.9 (35.5%)	
IV	18 (18.4%)	13 (13.3%)	0.147[b]
Clinical N stage			
N1	33 (33.7%)	46 (46.9%)	
N2	52 (53.1%)	41 (41.8%)	
N3	13 (13.3%)	11 (11.2%)	0.165[b]
No. of nymph nodes			
Retrieved	15.43 ± 4.11	16.23 ± 4.01	0.172[a]
Neoadjuvant therapy	32 (33%)	37 (37.4%)	0.521[b]
Menopause	62 (63.9%)	63 (63.6%)	0.967[b]
Receptor status			
ER positive	58 (59.8%)	58 (58.6%)	0.863[b]
PR positive	58 (59.8%)	56 (56.6%)	0.570[b]
Her-2/neu positive	41 (42.3%)	32 (32.3%)	0.150[b]
Histology			
Ductal carcinoma	90 (92.8%)	95 (96%)	0.334[b]
Lobular	7 (7.2%)	4 (4%)	0.370[b]
Tumor grade			
I	28 (28.9%)	17 (17.2%)	
II	46 (47.2%)	46 (46.7%)	
III	23 (23.7%)	36 (36.4%)	0.063[b]

[a]t-test.
[b]X^2 test.
[c]Mann-Whitney U test.

Table 2. Comparison of outcome variables between single and double drain groups

Outcome	Single drain (n= 96)	Double drain (n= 96)	p
Seroma	13 (13.4%)	6 (6.1%)	0.082[b]
Number of puncture	0.103 ± 0.39	0.04 ± 0.244	0.182[a]
Total volume drained	898.81 ± 116.42	803.97 ± 103.22	0.743[a]
Duration of drain	7.62 ± 2.44	7.14 ± 2.53	0.145
Hospital stay	1.04 ± 0.198	1.05 ± 0.221	0.735[a]
Wound infection	3 (3.1%)	4 (4%)	0.570[b]
Hematoma	1 (1%)	1 (1%)	0.988[b]
Flap necrosis	0 (0%)	1 (1%)	0.321[b]
Pain	2.5 ± 0.70	5.22 ± 5.10	0.001[c]
Blood loss	101.24 ± 25.14	101.67 ± 24.40	0.904[a]

[a]t-test.
[b]X^2 test.
[c]Mann-Whitney U test.

Table 3. Univariate and multivariable regression analysis for significant postoperative pain

Covariate	Univariate CRR (95% CI)	Multivariate ARR (95% CI)
Intervention		
Single	**1**	**1**
Double	0.14 (0.08-0.25)	0.14 (0.07-0.25)
Age up to 50	1	1
C51	0.96 (0.63-1.46)	0.99 (0.65-1.51)
Weight of specimen		
Up to 850 g	1	1
C851 g	1.22 (0.82-1.84)	1.28 (0.84-1.89)
Neoadjuvant therapy		
No	1	1
Yes	0.83 (0.56-1.24)	0.74 (0.50-1.11)
BMI		
Normal	1	1
Overweight	1.40 (0.92-2.13)	1.41 (0.91-2.12)
Obese	1.02 (0.41-2.51)	0.88 (0.35-2.18)

CRR: Crude relative risk, CI: Confidence interval, ARR: Adjusted relative risk.

single drain for overall complications. Mean postoperative pain was significantly less in single drain as compared to double drain (2.5 ± 0.70 vs. 5.22 ± 5.10, p< 0.000).

DISCUSSION

In this randomized controlled trial, we assessed the use of double drain versus single drain in patients undergoing MRM and found that the outcomes of double drain had not significantly altered the results in its favor compared to single drain. Single drain significantly reduced postoperative discomfort (postoperative pain) without increasing drain volume, drain duration, and overall complications (seroma, flap necrosis, and SSI) to the patient.

The use of drains in MRM is one of the most investigated techniques aiming to reduce seroma formation (11,12). Seroma is the most common complication seen after mastectomy and axillary surgery with an incidence of 3-85%, which ultimately leads to wound problems such as impaired healing, dehiscence and infections (13). There are still controversies regarding the number of drains, duration of drainage, and whether these drains should be at all used in breast cancer surgery (7,9,11).

Table 4. Univariate and multivariable regression analysis for overall complications

Covariate	Univariate CRR (95 % CI)	Multivariate ARR (95 % CI)
Intervention		
Single	1	1
Double	0.46 (0.17-1.21)	0.46 (0.17-1.22)
Neoadjuvant therapy		
No	1	1
Yes	1.17 (0.44-3.09)	1.14 (0.43-3.02)
BMI		
Normal	1	1
Overweight	0.77 (0.25-2.34)	0.74 (0.24-2.26)
Obese	1.03 (0.13-7.47)	1.00 (0.13-7.60)

CRR: Crude relative risk, ARR: Adjusted relative risk, CI: Confidence Interval.

Previously conducted studies have not shown that double drains yield better outcomes than a single drain (4,14). Additionally, single drain placement in MRM surgery results in less postoperative pain (15,16). In order to increase internal validity, we controlled the confounders at the design phase by restricting the inclusion criteria to a single procedure, i.e. MRM. A few variables that may affect the outcomes are the weight of the mastectomy specimen, age, BMI, and preoperative chemotherapy. All of these variables were comparable between the groups at baseline, making possible a valid comparison of outcomes between both groups.

This study has several limitations. Because the decision of putting the number of drains was communicated at the time of surgery, it was not possible to blind the surgeons or assessors from the intervention. So as to reduce reviewer's bias, different people were involved at various phases of the study, including randomization, pain score evaluation, and assessment of wound-related outcomes. All surgeries were performed by a single operating surgeon to overcome operator-dependent bias. The sample size was calculated for drain volume and drain days, which was not powered enough to compare other individual outcomes, such as seroma, SSI, and hematoma. Therefore, we compared overall and individual complications between the two groups including the proportion of patients with any of the above-mentioned complications. Because of certain uncontrollable factors, such as evaporation, suction usage, and irrigation, EBL measurement always carries a non-differential misclassification bias. Ideally, measurement of pre- and postoperative hemoglobin and hematocrit should support estimation of blood loss during surgery.

Seroma and other wound-related complications cause undue patient anxiety, require multiple hospital visits, and delay any required adjuvant chemotherapy (17,18). Every attempt should be made to decrease the morbidity associated with MRM, which enticed researchers to identify the association of the number of the drain with seroma and other complications. Earlier studies have found that the use of multiple drains is an effective way of reducing the incidence of seroma and associated complications (19). However, it is associated with long hospital stay and significant postoperative pain (15). With equal morbidity reported for either of the modality, inclination to place the second drain has been dwindling. Terrell et al., in their study, have found that the rate of seroma formation is equal in both single and two-drain groups (20,21). Similarly, a comparison study authored by Kapoor et al. has not found any significant difference in seroma and other complications between one and two drain groups in MRM (22). Another research by Puttawibul et al. have opined that the single drain group did not differ significantly from two drains when it came to the incidence of seroma formation, aspirated fluid volumes, and other related complications. The study by Hashemi et al. has concluded that the single, most important determinant of seroma formation is the type of breast cancer surgery and the number of lymph nodes retrieved, both of which were controlled in our study thanks to proper selection criteria and randomization (4).

On the other hand, controversies exist whether decreasing the number of drains decreases patients' pain and hospital stay without an associated increase in the risk of seroma after mastectomies. Guneri et al., in their randomized controlled trial, have found that the use of two drains in MRM is associated with less seroma formation while having similar pain and hospital stay as a single drain (14). The sample size in the study was small and they also included patients with sentinel lymph node biopsy. Moreover, the surgeries were performed by more than one surgeon, including residents, and thereby incorporating a learning curve as a possible confounder in the trial, which in the end, limited the authors from drawing a definite conclusion.

Our trial proves the benefit of the single drain in pain control after overcoming the above-stated limitations. We also found significant reductions in pain between the two groups. Moreover, these findings can also be attributed to a larger sample size of our study compared to other studies.

The results of this randomized trial can be generalized especially in developing countries where this disease usually presents at an advanced stage and mastectomy is the preferred method of surgical treatment.

CONCLUSION

The use of single drain after MRM results in less pain although the morbidity is equal to that of double drain. We recommend the use of single drain in MRM.

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Ethics Committee Approval: This study was approved by Memon Medical Institute Hospital Ethics Committee (Decision no: ERC-07-2013 MMIH, Date: 17.05.2014).

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Author Contributions: Concept - SK, MK; Design - SK; Supervision - SK; Data Collection and/or Processing - SK, MK; Analysis and/or Interpretation - SK, AW; Literature Review - MK, AW; Writer- SK, MK, AW; Critical Review - SK, MK.

Conflict of Interest: The authors have no conflicts of interest to declare.

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ORİJİNAL ÇALIŞMA-ÖZET
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Modifiye radikal mastektomide tek ve çift dren karşılaştırması: Randomize kontrollü bir çalışma

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ÖZET

Giriş ve Amaç: Modifiye radikal mastektomi uygulanan hastalarda çift dren kullanımının tek drene göre daha az seroma oluşumu, hastanede kalış süresi, cerrahi alan enfeksiyonu (CAE), postoperatif ağrı, hematom, flep nekrozuyla sonuçlandığı hipotezinin test edilmesi amaçlandı.

Gereç ve Yöntem: Bu paralel gruplu, tek kurumlu, randomize kontrollü çalışma, Nisan 2015 ile Temmuz 2018 tarihleri arasında enstitümüzün cerrahi bölümünde gerçekleştirildi. Modifiye radikal mastektomi uygulanan kadınlar rastgele olarak tek dren (n= 98) veya çift dren (n= 98) olarak gruplara ayrıldı.

Bulgular: Her iki grup yaş, eşlik eden hastalık, VKİ ve tümör özellikleri gibi temel değişkenler açısından karşılaştırılabilirdi. Tahmini kan kaybı (101,67 ± 25,14'e karşı 101,67 ± 24,40, p> 0,001), dren hacmi (898,81 ± 116,42'ye karşı 803,97 ± 103,22 mL, p> 0,001), dakika olarak cerrahi süre ve seroma oluşumu (%13,4'e karşı %6,1, p= 0,082) gibi tek dren değişkenleri çift drene kıyasla daha iyi sonuç vermedi (103,19 ± 15,96, 103,19 ± 15,93). Ancak, tek dren daha az postoperatif ağrıyla sonuçlandı (ortalama 2,5 ± 0,70'e karşı 5,22 ± 5,10, p< 0,000). Çok değişkenli Cox regresyon analizinde, tek dren, postoperative ağrı açısından daha düşük risk [düzeltilmiş bağıl risk 0,14 (%95 güven aralığı (CI) 0,070-0,25)] ve daha düşük genel komplikasyonlar [düzeltilmiş bağıl risk 0,47 ile ilişkilendirildi (%95 CI 0,26-0,86)]. Çoklu lineer regresyonda tek drenli grupta dren süresi çift drenli gruptan 0,01 gün daha azdı (r2= 0,00, b= 0,388, p> 0,001).

Sonuç: Tek dren kullanımı ameliyat sonrası rahatsızlık ve ağrıyı önemli ölçüde azaltırken iki dren kullanan hastalarla benzer morbidite gösterir. Bu nedenle, modifiye radikal mastektomide (NCT02411617) tek drenin tercihli kullanımını öneriyoruz.

Anahtar Kelimeler: Modifiye radikal mastektomi, seroma, postoperatif ağrı, tek dren

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