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Comparison of Single versus Double Drains after Modified Radical Mastectomy: a Randomized Clinical Trial

Gurkan Guneri[1], Melih Akinci[1], Kerim Bora Yilmaz[1], Zafer Ergul[1], Emine Ozturk[2], Duray Seker[1] and Hakan Kulacoglu[1]*

[1]Department of Surgery, Ankara Diskapi Teaching and Research Hospital, Turkey

[2]Department of Radiology, Ankara Diskapi Teaching and Research Hospital, Turkey

Abstract

Mastectomy is still a common procedure and the drain usage after this procedure is controversial mainly due to diverse recommendations. We aimed to investigate the effects of single versus double drains on patient's comfort, seroma formation and duration of hospital stay after Modified Radical Mastectomy (MRM). Eligible patients undergoing MRM were assigned randomly into single versus double drains groups. A negative pressure drain was inserted below the lower flap directing to the axilla in the single drain group or two similar drains were inserted into the axilla and below the lower flap in the double drains group. One day after removal of the drains, seroma under the flaps and in the axilla were examined by ultrasonography. Age, body mass index smoking history, coexisting diseases, length of hospital stay, duration of the drains, total drain output and the need and frequency of aspirations due to seroma formation were recorded. Patient comfort was measured with a comfort scale between 1-10 measuring incisional pain, pain caused by the drains, discomfort or sleep disturbances caused by the drains. Groups with thirty patients each were well matched for age, body mass index, smoking habits and coexisting diseases. Patient discomfort, length of hospital stay, duration of drains and need of aspiration for seroma were similar in two groups ($p \geq 0.05$). Seroma formation was higher in single drain group than in double drain group ($p<0.05$). Double drains after mastectomies have been shown to decrease seroma formation without increasing patients' discomfort and duration of hospital stay.

Keywords: Breast Cancer; Drains; Modified Radical Mastectomy; Patient Comfort; Seroma

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Correspondence:
Melih Akinci, Department of Surgery, Ankara Diskapi Teaching and Research Hospital, 3346. Cadde, 3340. Sokak, Yeşil Barış Sitesi Sitesi, 35/141, Alacaatlı Çankaya/Ankara 06810, Turkey,
E-mail: melihakinci@yahoo.com

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Introduction

The indication of routine double drains usage after modified radical mastectomies is controversial mainly due to diverse recommendations. The main purpose of drain after mastectomies is prevention of seroma. Seroma is one of the most common complications after mastectomies [1]. Seroma formation results in delays in wound healing, incisional dehiscence, infections and long hospital stay [2]. Although there are studies proving that drains do not prevent seroma formation [3,4], the use of drains for that purpose is still common [5]. On the other hand there is a debate whether decreasing the number of drains decreases patients' discomfort and duration of hospital stay without increasing seroma formation after mastectomies.

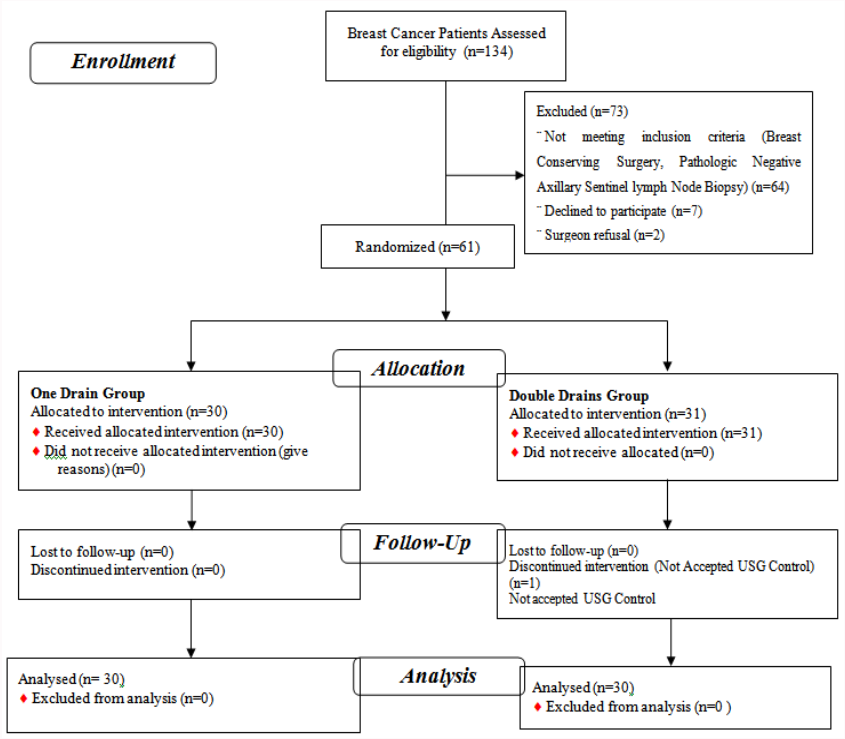
In this prospective randomized trial, we aimed to investigate the possible benefits of decreasing the number of drains after mastectomies.

Patients and Methods

This prospective randomized controlled trial was conducted at a Training and Research Hospital of an University. The ethics committees of hospital approved the study and all patients gave informed consent. The trial was registered on ClinicalTrials.gov (identifier: NCT02202252). A sample size of 60 patients (30 per group) was chosen to give 80% power at 0.05 two-tailed level of significance, assuming that a 40% incidence of seroma in one group would fall to 10% in the other group. The incidence of seroma formation varies widely between 15% and 81% in the literature [1].

Selection of the patients

Sixty one patients undergoing MRM were prospectively randomized into single versus double drains groups. Patients with diagnosis of breast carcinoma who did not prefer or were not appropriate for breast conservative surgery were enrolled into the trial. Exclusion criteria's for the



Flowchart 1: Total patient enrollment and excluded patients.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	3
Participants	4a	Eligibility criteria for participants	3
	4b	Settings and locations where the data were collected	3
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	3, 4
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	4
	6b	Any changes to trial outcomes after the trial commenced, with reasons	No change
Sample size	7a	How sample size was determined	3
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	3
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	3
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	3
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	3
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	3
	11b	If relevant, description of the similarity of interventions	-

Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	4
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	4
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	12
	13b	For each group, losses and exclusions after randomisation, together with reasons	12
Recruitment	14a	Dates defining the periods of recruitment and follow-up	4, 5
	14b	Why the trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	9 (Table 1)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	5
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	10,11 (Table 2 & 3)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	10,11 (Table 2 & 3)
Harms	19	All-important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	5
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	6
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	6, 7
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	6, 7
Other information			
Registration	23	Registration number and name of trial registry	**NCT02202252**
Protocol	24	Where the full trial protocol can be accessed, if available **The trial was registered on ClinicalTrials.gov (identifier: NCT02202252)**	3
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	none

patients were as follows: age fewer than 18 or over 80, male breast cancer, pathologic negative axillary sentinel lymph node biopsy, distant metastatic disease, coagulation disorder and patients who did not accept the registry and randomization. Total patient enrollment and excluded patients is detailed in (Flowchart 1).

Randomization

Eligible patients were assigned randomly to either single or double drain group. Patients were randomized by using sealed envelopes which included equal number of patients to be randomized either to the single drain arm or to the double drain arm.

Surgery

The mastectomies were performed either by supervised surgical residents or staff surgeons, all of whom were blinded to the study group during surgery. Modified radical mastectomy with axillary dissection was routinely performed. In condition of axillary sentinel lymph node biopsy was indicated, as mentioned above negative pathologic ones were excluded from the study. After mastectomy with axillary dissection and homeostasis control, group selection envelope was selected randomly by the operating room staff. A negative pressure drain will be inserted below the lower flap directing to the axilla in the single drain group or two similar drains will be inserted into the axilla and below the lower flap in the double drains group.

Follow-up and interventions

Patient demographics, body mass index, smoking history and coexisting diseases were recorded. All the patients were informed on the day of operation and their wounds were inspected daily till discharge. Seroma was defined as fluid accumulation below the flaps and was be examined daily by same surgical resident or same staff surgeon. Drains were removed if the daily output was less than 30 ml. One day after removal of the drains seroma under the flaps and in the axilla were examined by ultrasonography. In case of seroma, aspiration was performed in sterile conditions and if drainage fluid was purulent, sampled for microbial culture. Duration of the hospital stay, duration of the drains in place, total drain output in the first three days after the operation and the need and frequency of aspirations due to seroma formation were recorded. The duration of the longer staying drain in the double drain group was recorded for the duration of the drain in place parameter. Patient comfort was measured with a comfort scale between 1-10 measuring pain caused by the drains, incision pain, discomfort or sleep disturbances caused by the drains. Surgical wound area was also inspected after discharge up to 4 weeks if needed. In addition to seroma and wound infection, all postoperative local and systemic complications were also recorded throughout the follow-up period.

Primary and secondary outcomes

Patient comfort and seroma formation were the primary outcomes. Length of hospital stay, surgery wound complications, aspiration for seroma and total drainage output were secondary outcomes to be compared between the two groups.

Statistical analysis

The results were analyzed statistically using SPSS 10.0 for Windows program (SPSS, Chicago, Illinois). Comparisons of categorical variables between the two groups were performed by using the chi-square test with Yates' correction. Kolmogorov Smirnov test was used to test for the normal distribution of the numeric variables. Student t test and Mann Whitney U tests were used to compare the parametric and nonparametric variables between the two groups. *P* values less than 0.05 were considered as significant. Data is presented

Table 1: Comparison of single versus double drain groups regarding age, body mass index, smoking habits, coexisting disease, tumor diameter and the total number of dissected lymph nodes.

	Single Drain, n=30	Double Drain, n=30	p value
Age	54.1 ± 11.6	53.9 ± 11.5	0.929
Body Mass Index (kg/m²)	26.2 ± 4.8	26.9 ± 5	0.609
Smoking History	9 (30%)	10 (33%)	0.5
Coexisting Disease	13 (43%)	9 (30%)	0.211
Tumor Diameter (mm)	27 (12-95)	26 (5-90)	0.558
Total Dissected Lymph Nodes	21.2 ± 5.7	19.5 ± 7.8	0.347

Table 2: Comparison of single versus double drain groups regarding the total amount of the drainage output in postoperative three days, the incidence seroma formation, the length of hospital stay, and the duration of drains and the need for aspiration of seroma.

	Single Drain, n=30	Double Drain, n=30	p value
Total Three Day Drainage (ml)	407 ± 159	480 ± 195	0.118
Clinical Seroma	13 (%43)	8 (%27)	0.139
Seroma Diagnosed By USG	18 (%60)	10 (%33)	0.035
Length of Hospital Stay (day)	3 (2-7)	3 (2-17)	0.819
Duration of Drain/Drains (day)	9.9 ± 7	9.2 ± 7	0.669
Aspiration of Seroma	3 (0-16)	2 (0-12)	0.588

Data is given as mean ± standard deviation or median (minimum-maximum), n (%)

Table 3: Comparison of single versus double drain groups regarding patient comfort.

	Single Drain, n=30	Double Drain, n=30	p value
Pain Around the Drain	3.3 ± 1.7	3.7 ± 1.9	0.422
Discomfort Due to the Drain	3.1 ± 1.8	3.5 ± 2.1	0.49
Sleep Disturbance Due to the Drain	2 (1-6)	2 (1-7)	0.311
Pain / Discomfort Due to the Stewart Incision	5 (1-9)	4 (1-8)	0.179

Data is given as mean ± standard deviation or median (minimum-maximum), score system range between 0-10

as number of patients (%), mean ± standard deviation or median (minimum-maximum) where appropriate.

Results

Sixty (30 single drain group, 30 double drains group) patients with non-metastatic breast carcinoma who had a MRM procedure were analyzed in this study between July 2014 and February 2015. There was no mortality in the follow-up period. Groups were well matched for age, body mass index, smoking habit, coexisting diseases, tumor diameter, and total dissected lymph nodes ($p \pm 0.05$) (Table 1). The total drainage output during the postoperative three days, the rate of clinical seroma formation, the length of hospital stay, the duration of the drains and the need for aspiration of seroma were similar in the two groups ($p \geq 0.05$) (Table 2). Seroma formation which was diagnosed by ultrasonography was higher in single drain group than double drain group ($p<0.05$) (Table 2). Patient discomfort and pain due to the drains and incision were similar in both groups ($p \geq 0.05$) (Table 3).

There was an only one surgical wound infection diagnosed with microbial culture which was in the double drain group. There were also two ischemic flaps with little necrosis areas in the double drain group. The infection responded well to drainage with appropriate antibiotic therapy and no patient required debridement because of any flap associated complication.

Discussion

Axillary dissection with mastectomy is still a common procedure for a group of breast carcinoma patients. The indication of routine drain usage after modified radical mastectomies is controversial mainly due to diverse recommendations. The main aim of drain usage is the prevention of seroma formation which can be causative factor for wound complications such as wound healing, incisional dehiscence, and infections [2]. While drains effectively decrease seroma and seroma related aspiration procedures, they may increase the length of hospital stay [6]. On the other hand some authors have declared that drains did not prevent seroma formation [3,4]. However drains are generally used after MRM but their benefits are still questionable [7]. Finally Cochrane Database Systemic Review concluded that the benefit of the drains in decreasing seroma reduction should be balanced against an increased length of hospital stay in the drained population [8].

The output of drainage after axillary dissection may be reduced by decreasing the suction power of the drain. A prospective randomized clinical study compared the volume and the duration of drainage between full and half vacuum suction after modified radical mastectomy. They concluded that half drainage system is better with reduced seroma and shorter hospital stay when compared with full suction drainage [9]. In Memorial Sloan-Kettering Cancer Center, multiple (four) drains were prospectively compared with single drain in axilla after lymphadenectomy and they found similar duration of drainage and the authors recommended a single drain to the axilla after lymphadenectomy [10]. Decreasing the power of suction or the number of drains result may have possible benefits after mastectomies.

The single axillary drain after modified radical mastectomy has been recommended previously with the suggestion that there would

be no increase in postoperative complications such as seroma [5,11]. However contrarily current study established that double drains decreased the seroma formation when compared to a single drain. Our data suggest a trend toward an increased incidence of clinical seroma which was not statistically significant. However seroma diagnosed with ultrasonography was statistically higher in the single drain group than the double drain group. Ultrasonography examination for seroma formation which can diagnose seroma more accurately is a major difference of this study compared to the other studies.

Some authors showed that the patients with single drain after modified radical mastectomy had shorter hospital stays which were associated with less cost [5,11]. Whereas, our study has shown that numbers of drains have no effect on duration of the hospital stay. It may partly be related to the practice of discharging the patients with the drains in the current study. The early discharge after mastectomy before drain removal is currently an acceptable practice [12,13]. Early removal of post mastectomy drains is not recommended [14].

There is a hypothesis that the drains may cause pain, discomfort, postoperative wound infection. The pulling out of the drains is another psychologic distress for the patients. As mentioned before axillary node dissection can be managed with or without a drain. It was advocated that more office visits but less pain and discomfort can be expected if a drain is not used [5,11,15]. The current study investigated pain and discomfort both due to drain and incision. However patient discomfort and pain due to the drain and incision was found similar in single and double drain groups.

The shortcomings of our study are relatively small number of patients in each group and the lack of data about nutritional status that may influence the formation of seroma [16].

Conclusion

Compared to the single drain, double drains have been shown to decrease ultrasonography-confirmed seroma formation without increasing patients' discomfort and duration of hospital stay after mastectomies.

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