Original Article

Effect of One versus Two Drain Insertion on Postoperative Seroma Formation after Modified Radical Mastectomy

Farzaneh Ebrahimifard[1*]

[1] Department of Surgery, Shahid Beheshti University of Medical Sciences, Tehran, Iran

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Abstract

Background: Modified radical mastectomy (MRM) is still one of globally accepted surgical techniques for breast cancer and in some selected patient is the gold standard type of surgery. The most frequent complication of this procedure is seroma under skin flaps or in the axilla as reported as much as 30% in some studies. The use of closed suction drainage system to reduce the incidence of this complication has been routinely accepted by surgeons; however, length of catheter stay and the number of catheters inserted in the wound are still controversial. The present study compares the results of single versus double drain insertion in patients undergoing MRM for breast cancer.

Materials and Methods: The study was conducted on 100 women with breast cancer who were candidate for MRM surgery during 2007-2010 referred to Modarres hospital, Tehran, Iran as a randomized group matched controlled trial.

Results: There was no significant difference between the two groups in terms of age, BMI, and tumor weight (P=0.406) (Table 1). Similarly, the difference between the two groups was insignificant in tumor size (T) and number of lymph nodes involved (P=0.145). There was no significant difference between the two groups in timing of axillary drain removal (P=0.064). No significant differences were observed between the two groups in mean aspirated fluid (P=0.071) and mean aspirated sera (P=0.484) after removal of drains.

Conclusion: This study revealed one drain insertion in MRM surgery is as effective as two drain and probably less morbidity and cost.

Keywords: MRM, modified radical mastectomy, drain, seroma

***Corresponding Author:** Farzaneh Ebrahimifard, Department of Surgery, Shahid Beheshti University of Medical Sciences, Tehran, Iran. Email: drebrahimifard@gmail.com

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Introduction

Breast cancer is the most common type of cancer in women worldwide[1]. Incidence of breast cancer has increased in recent decade[2,3]. In proportion to the incidence of the disease in developed countries, its mortality has reduced due to improved diagnostic and treatment methods and thus, its early treatment[4].

In the modern era, breast cancer treatment is a multimodality approach including local and medical systemic therapy. Once breast cancer is diagnosed, the type of therapy offered to patient is determined based on the stage of the disease. In the absence of metastasis, surgery is the mainstay of loco-regional control of breast cancer. The selection of surgical procedures depends on patient's characteristics (including age, family history, menopausal status, and overall health), patient's preferences and other clinical

and pathological variables[5-7].

Although breast preserving surgery is currently the standard treatment for early stage breast cancer, mastectomy is still the choice in some patients. Generally, mastectomy is recommended for patients with large tumor, small breasts, special pathologic status and patients with any contraindications to radiation therapy[8-10]. In addition, detecting the pathologic status of the axillary lymph nodes is one of the most important prognostic factors in patients with breast cancer. Lymphatic mapping and dissection of sentinel lymph nodes is a growing technique for detecting lymph node involvement by tumor; however axillary lymph node dissection remains the standard of care for many patients with breast cancer especially those with locally advanced breast cancer or positive sentinel nodes[6,9,11,12].

Modified radical mastectomy (MRM) is one of globally accepted surgical techniques for breast cancer and in some selected patient is the gold standard type of surgery [5,6,8]. In this procedure, the skin flaps are fully developed first and the fascia of pectoral muscle and overlying breast tissue are elevated and completely removed. Thereafter, axillary lymph node dissection is performed in level I and II[1,2,13,14]. The most frequent complication of this procedure is seroma under skin flaps or in the axilla as reported as much as 30% in some studies[3,4]. Various methods are used to reduce seroma formation by reducing dead space including flap fixation, reducing shoulder movements after surgery, use of adhesive glue, and drainage. The use of closed suction drainage system to reduce the incidence of this complication has been routinely accepted by surgeons; however, length of catheter stay and the number of catheters inserted in the wound are still controversial. It appears that early removal of drain leads to increased accumulation of seroma, while leaving the catheter for longer periods increases the risk of infection and patient disability. Some surgeons prefer to insert more than one catheter, but some studies showed that it discomforts patients[1,15-17].

The present study compares the results of single versus double drain insertion in patients undergoing MRM for breast cancer.

Methods

This randomized clinical trial was conducted on any women with breast cancer who were candidate for MRM surgery during 2007-2010 referred to Modarres hospital, Tehran, Iran. For various reasons, breast preservation surgery could not be performed on these women with invasive breast cancers, and they had been referred for MRM surgery.

Exclusion criteria: All patients with distant metastases, synchronous or meta-chronous contra-lateral breast cancers, involvement of chest wall by tumor (T4), previous history of breast cancer, radiotherapy, chemotherapy, history of any previous breast or axillary surgery, impaired wound healing, and use of anti-coagulation drugs, were excluded. Furthermore, patients with locally advanced breast cancers who, according to the surgeon and oncologist required pre-operative neo-adjuvant chemotherapy were excluded. Also patients who could not follow the study for one month or were afflicted with wound infection, dehiscence or flap necrosis were excluded.

At the outset, the goal and method of the study and any potential complications were explained to patients, and after obtaining their consents, the patients were divided into two separate groups randomly. All patients underwent general anesthesia and MRM surgery was performed according to Madden method in all. After surgery, removed breast masses were weighed, and sent for pathologic evaluation and the results were recorded in TNM staging system.

Then, for the first group of patients, one drain was inserted in axillary area, and for the second group, two drains were inserted one in pectoral (under skin flap over pectoral muscle) and one in axillary areas. Normal dressing was applied. All operations were performed by the same surgeon.

After surgery, patients were followed up for one month. Patients were discharged with drains after 48 hours, depending on general health condition (fever, nausea, vomiting, wound complications, normal physical activity). Patients were trained how to empty the drains, and measure and record the volume of the fluid and were advised to return to hospital for removing drains when their discharge was below 30 cc per day or on the 10^{th} post-operative. Patients were also visited on the 2^{nd} and 10^{th} days. After removing

the last drain, all patients were visited weekly for one month, and if the surgeon detected any seroma formation, it was aspirated and the wound was dressed with compressive bandages.

In the setting of seroma formation, wounds were checked every other day to determine re-accumulation of seroma. Aspiration continued until no further seroma was observed. Timing of seroma formation and volume of aspirated fluid were recorded.

Data were analyzed with SPSS-20 software. Student t-test was used to compare two groups' weight, tumor weight, and number of lymph nodes involved, and Mann-Whitney test was used to compare their cancer types. Comparison of volume of aspirated liquid during follow-up was performed using Repeat Measure ANOVA. The significant level was considered 0.05.

Results

In total, 100 patients remained in the study after exclusion. There was no significant difference between the two groups in terms of age, BMI, and tumor weight (P=0.406) (Table 1). Similarly, the difference between the two groups was insignificant in tumor size (T) and number of lymph nodes involved (P=0.145). Only two cases of distant metastases were observed, one in each group.

In the two-drain group, mean time to remove pectoral drain was after 2.89±0.89 days. There was no significant difference between the two groups in timing of axillary drain removal (P=0.064). Seroma formed in 14 patients from the first group (30.4%), and 16 from the second group (36.4%) (P=0.551). No significant differences were observed between the two groups in mean aspirated fluid (P=0.071) and mean aspirated seroma (P=0.484) after removal of drains.

To assess the effect of two-drains on removal of axillary drain, accumulated fluid, seroma formation, and aspirated seroma, its pure effect and also its effect after adjustment with age, BMI, tumor weight, and TNM staging were calculated and no statistically difference between 2 groups was observed.

Discussion

This study indicated that there is no statistical difference in seroma formation, volume of accumulated fluid or timing of axillary drain removal according to insertion of one versus two drain insertion in MRM surgery.

Seroma formation is the most common early complication of breast cancer surgery with axillary dissection[18]. Although this complication is still unpreventable, but its possibility can be reduced[19]. Seroma formation risk factors include heavy weight, extensive surgery, and large drained volume in the

Table 1: Comparison of patients' details, tumor details, aspirated liquid, and seroma formation in the two groups.

	Group 1 (1 drain) Mean ± SD	Group 2 (2 drains) Mean ± SD	P value
Age (years)	53.59 ± 14.45	54.23 ± 12.17	0.815
Height (m)	1.63 ± 0.05	1.63 ± 0.06	0.818
Weight (kg)	68.82 ± 10.06	70.96 ± 9.96	0.293
BMI (kg/m^2)	25.92 ± 3.58	26.65 ± 3.64	0.319
Weight of excised tumor (g)	354.80 ± 207.10	402.40 ± 238.60	0.294
Axillary drain removal day	9.25 ± 2.16	9.89 ± 0.54	0.064
Volume of drain discharge	244.80 ± 95.31	283.80 ± 111.75	0.071
Aspirated seroma	26.78 ± 55.99	43.72 ± 121.32	0.484

first 3 days of surgery[20]. Different studies suggest different seroma reduction methods[18]. One method to reduce seroma formation is by inserting drain. There is controversy concerning treatment and prevention roles of drain, and also the number of drains[21].

Ebner et al., in a retrospective study has shown insignificant differences in incidence of complications between patients with and without drains after MRM surgery. However, this was not a controlled clinical trial, and data were collected from patients' files[21]. In a prospective study by Taylor et al., on the results of surgery before and after implementing 'no drains policy' in a hospital in UK, there was no significant difference in occurrence of symptomatic seroma, frequency of aspiration, wound infection or re-hospitalization in patients undergoing MRM surgery with or without drain insertion. The only difference was prolonged hospitalization of patients with drain. Thus, they suggested that "no drain" policy should be considered as a policy adopted after MRM[22]. Amdeweg et al., in a cohort study, compared duration of drain stay in two groups of patients. They showed that incidence of seroma increases with short-term axillary drain, and recommended long term axillary drainage for patients undergoing MRM surgery[23]. Results of the two review studies showed higher frequency of seroma formation in patients without drain, or short-term drainage[24,25].

Advantages and disadvantages of multi-drain insertion have been examined in some studies. In a retrospective study Saratzis et al., have evaluated women undergoing MRM in three groups of one, two, and three drains. Results showed insignificant differences in volume of seroma produced among the three groups. However, women with only one drain experienced less discomfort and hospital stay[26]. In a clinical trial, Puttawibul et al., compared one and two drains in patients undergoing MRM. Same as in the present study, their results revealed insignificant differences in seroma formation, volume of aspirated liquid, or complications after surgery[27]. In a clinical trial, insertion of one or two drains in axillary area in MRM patients was compared. Results showed insignificant differences in seroma formation and duration of drain stay[28]. In another clinical trial Terrell and Singer compared insertion of an axillary drain with axillary and pectoral drains after MRM. Results showed insignificant differences in complications between the two groups[29].

The study by Hashemi et al., showed that seroma occurred in 35% of patients. In multivariate logistic regression analysis, an association of postoperative seroma formation was noted with modified radical mastectomy (OR=2.83, 95% CI 1.01–7.90, P=0.04). No other factor was found to significantly affect the seroma formation after breast cancer surgery. They found no association between drain count and seroma formation, similar to our study[30].

In a study by Woodworth et al., seroma developed in 39 of the 252 operations (incidence of 15.5 percent). Seroma formation was significantly lower in those patients receiving MRM with immediate reconstruction than in those receiving MRM surgery alone (2.5% vs 19.6%; P=0.009) and tended to be lower than that for patients receiving breast preservation with axillary node dissection (14.06%; P=0.052). Neo-adjuvant chemotherapy was performed in 18 patients, of whom 6 developed seroma (P=0.030). They found no association between drain count and seroma formation, similar to our study[31].

Another study by Burak et al., demonstrated that significant risk factors for seroma formation included increased age, patient weight, initial 72-hour wound drainage, and LAD. No statistically significant differences were observed between single and double drain insertion, similar to our study.

Generally, there are not many clinical trials that have compared one and two drains so far, and according to cohort studies or some clinical studies, existing evidence tends to support one drain. The present RCT study showed no difference between people with one or two drains, and according to results, seroma formation occurred in 30% of women after MRM, with insignificant differences between the two groups, and insertion of two drains made no difference in incidence of seroma. Furthermore, there was an insignificant difference in timing of removal of axillary drain between the two groups. According to results, it can be argued that there is no need for the second drain after MRM, and the same results can be obtained by axillary drain alone. However, in the present study, there were no groups with no drain or with short-term drain (for instance, 3 days)[32-38].

It is recommended that a study be conducted with several groups to include no drain, short-term drain, one long-term drain, and two drains to design a proper treatment protocol that both satisfies patients and has fewer complications. In addition to symptoms and length of hospitalization, patients' satisfaction and mobility should also be investigated.

Conclusion

According to the obtained results, one-drain and two-drain insertion techniques are equally effective methods to reduce the seroma formation after modified radical mastectomy; however, fewer drain insertion leads to more patient satisfaction at all and it is recommended to evaluate patient compliance and comfort regarding the number of drains in future studies.

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References

1. Schwartz's principles of surgery. 2010;461-4.
2. Schwartz's principles of surgery. 2010;336.
3. Surgical Complications; Nadey S. Hakim Vassilios E. Papalois. 2007;169-70.
4. Surgical Complications. Nadey S. Hakim Vassilios E. Papalois. 2007;175-7.
5. Bland KI, Chang HR, et al. Modified radical mastectomy and total (simple) mastectomy, in Bland KI, Copeland EM III (eds): The Breast: Comprehensive Management of Benign and Malignant Diseases. Philadelphia: WB Saunders. 1998;881.
6. Simmons RM, Adamovich TL. Skin-sparing mastectomy. Surg Clin North Am. 2003;83:885.
7. Pogson CJ, Adwani A, Ebbs SR. Seroma following breast cancer surgery. Eur J SurgOncol. 2003;29(9):711–7.
8. Fisher B, Jeong JH, Anderson S, et al; 25 year follow up of a randomized trial comparing radical mastectomy, total mastectomy and total mastectomy followed by irradiation. N Engl J Med. 2002;347:567-575.
9. Guiliano AE, Hunt KK, Ballman KV, et al: Axillary dissection vs no axillary dissection in women with invasive breast cancer and sentinel node metastasis. JAMA. 2011;305;569-75.
10. Horttobagyi GN, Singletary SE, et al. Treatment of locally advanced and inflammatory breast cancer, in Harris JR, et al: Diseases of the Breast. Philadelphia; Lippincott Williams and Wilkins. 2000;645.
11. Giuliano AE, et al. Prospective observational study of sentinel lymphadenectomy without further axillary dissection in patients with sentinel node negative breast cancer. J Clin Oncol. 2000;18(13):2553–9.
12. Lucci A, et al. Surgical complications associated with sentinel lymph node dissection (SLND) plus axillary lymph node dissection compared with SLND alone in ACA oncology Group Trial, Z0011. J clinical oncology. 2007;25:3657.
13. Woodworth PA, McBoyle MF, Helmer SD, Beamer RL. Seroma formation after breast cancer surgery: incidence and predicting factors. Am Surg. 2000;66:444-50.
14. Burak WE, Goodman PS, Young DC, Farrar WB. Seroma formation following auxiliary dissection for breast cancer: risk factors and lack of influence of bovine thrombin. J Surg Oncol. 1997; 64:27-31.
15. Aitkin DR, Minton JP. Complications associated with mastectomy. Surg Clin North Am. 1983;63:1331-52.
16.Porter KA, O'Connor S, Rimm E, Lopez M. Electro cautery as a factor in seroma formation following mastectomy. Am J Surg. 1998;176:8-11.
17. O'Hea BJ, Ho MN, Petrek JA. External compression dressing versus standard dressing after axillary lymphadenectomy. Am J Surg. 1999;177:450-3.
18. Lotze M, et al. Early versus delayed shoulder motion following axillary dissection. Ann Surg. 1981;193:288-95.
19. Schultz I, Barrholm M, Grondal S. Delayed shoulder exercises in reducing seroma frequency after modified radical mastectomy: a prospective randomized study. Ann SurgOncol. 1997;4:293-7.
20. Porter KA, et al. Electrocautery as a factor in seroma formation following mastectomy. Am J Surg. 1998;176(1):8-11.
21. Keogh G, et al. Seroma formation related to electrocautery in breast surgery — A prospective, randomized trial. Breast. 1998;7:39-41.
22. Classe J, et al. Axillary padding as an alternative to closed suction drain for ambulatory axillary lymphadenectomy. Arch Surg. 2002;137:169–173.
23. O'Hea BJ, Ho MN, Petrek JA. External compression dressing versus standard dressing after axillary lymphadenectomy. Am J Surg. 1999;177(6):450-3.
24. Cameron AE, et al. Suction drainage of the axilla: a prospective randomized trial. Br J Surg. 1988;75(12):1211.
25. Rice DC, et al. Intraoperative topical tetracycline sclerotherapy following Mastectomy: a prospective, randomized trial. J Surg Oncol. 2000;73(4):224-7.
26. Somers R, Jablon L, Kaplan M. The use of closed suction drainage after lumpectomy and axillary dissection for breast cancer: a prospective randomized trial. Ann Surg. 1992;215:146-9.
27. Burak W, Goodman P, Young D. Seroma formation following axillary Dissection for breast cancer: risk factors and lack of influence of bovine thrombin. J Surg Oncol. 1997;64:27-31.
28. Langer S, Guenther JM, DiFronzo LA. Does fibrin sealant reduces drain output and allows earlier removal of drainage catheters in women undergoing operation for breast cancer? Am Surg. 2003;69(1):77-81.
29. Berger A, et al. Sealing of postoperative axillary leakage after axillary lymphadenectomy using fibrin glue coated collagen patch: a prospective randomized study. Breast Cancer Res Treat. 2001;67(1):9-14.

30. Moore M, et al. Fibrin sealant reduces the duration and amount of fluid drainage after axillary dissection: a randomized prospective clinical trial. J Am CollSurg. 2001;192(5):591-9.
31. Grobmyer SR, Graham D, Brennan MF, et al. High-pressure gradients generated by closed-suction surgical drainage systems. Surg Infect (Larchmt). 2002;3:245.
32. Barwell L. Campbell R. Watkins M, Teasdale C. How long should suction drains stay in after breast surgery with axillary dissection? Ann R Coll Surg Engl. 1997; 79(6):435-7.
33. Puttawibul P, et al. Mastectomy without drain at pectoral area: a randomized controlled trial. J Med Assoc Thai. 2003;86(4):325-31.
34. Pogson CJ, Adwani A, Ebbs SR. Seroma following breast cancer surgery.Eur J Surg Oncol. 2003;29(9):711–7.
35. Bonnema J, et al. The composition of serous fluid after axillary dissection.Eur J Surg. 1999;165:9-13.
36. Harris JR, Lippman ME, Morrow M, Osborne C. Diseases of the breast. Philadelphia: Lippincott, Williams and Wilkins. 2000.
37. Pogson CJ, Adwani A, Ebbs SR. Seroma following breast cancer surgery. Eur J Surg Oncol. 2003;29:711-7.
38. Budd DC, Cochran RC, Sturtz DL, Fouty WJ. Surgical morbidity after mastectomy operations. Am J Surg. 1978;135:218–20.