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Full versus half suction drainage after modified radical mastectomy for breast cancer: A longitudinal study

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Abstract--Background: Suction drains are routinely used after modified radical mastectomy and are an important factor contributing to increased hospital stay as the patients are often discharged only after their removal. Amongst various factors that influence the amount of postoperative drainage, the negative suction pressure applied to the drain has been reported to be of great significance. While a high negative suction pressure is expected to drain the collection and reduce the dead space promptly, it may also prevent the leaking lymphatics from closing and lead to increased drainage from the wound. Against this background a prospective randomized clinical study was conducted to compare the amount and duration of drainage between a half negative suction and full vacuum suction drainage in patients following modified radical mastectomy. The associated postoperative morbidity was also compared between the two groups. Methods: 40 FNAC (fine needle aspiration cytology) proven cases of locally advanced breast cancer were randomized. (Using randomly

ordered sealed envelopes, which were opened immediately before the closure of the wound) in to 20 patients with full vacuum suction (pressure = 700 g/m²) and 35 cases in to half vacuum suction drainage (pressure = 350 g/m²) groups. The two groups were comparable in respect of age, weight, and technique of operation and extent of axillary dissection. Surgery was performed by the same surgical team comprising of five surgeons (two senior and three resident surgeons) using a standardized technique with electrocautery. External compression dressing was provided over the axilla for first 48 hrs and following that patients were encouraged to do active and passive shoulder exercises. The outcomes measured were morbidity and the length of hospital stay. The total drain output was measured and recorded daily in both the groups, the drains were removed once the output was less than 30 ml in 24 hrs and the patients were discharged on the same day. The mean total drain output was measured in each group and compared. Descriptive studies were performed with SPSS version 10 and group characteristics were compared using student t-test. Results: Total drain volume was significantly more in cases of Full suction (327.50±62.77) as compared to Half suction (223.25±69.23); Total hospital duration was significantly more in cases of Full suction (12.65±3.37) as compared to Half suction (9.95±2.56); Wound infection was observed in only 1 patient in Half suction whereas 4 in Full suction. (p>0.05); seroma formation was observed in only 1 patient in Half suction whereas 7 in Full suction. (p<0.05). Some degree of flap and cuticular necrosis was seen in 1 in the Half Suction group and 3 in Full Suction group. Conclusions: Half negative suction drains provide an effective compromise between no suction and full or high suction drainage after modified radical mastectomy by reducing the hospital stay and the post operative morbidity including post operative seromas.

Keywords---seroma, modified mastectomy, breast surgery, morbidity, wound.

Introduction

Breast cancer is one of the most common malignancies in women and a leading cause of cancer death among women. It accounts for 33% of all female cancers and is responsible for 20% of the cancer related deaths in women. New therapy has evolved to include both surgical resection for local and medical therapy for systemic diseases.^{1,2} Surgery still has a central role to play but there has been a gradual shift towards more conservative techniques.³ Modified Radical Mastectomy (MRM) is a safe operation with low morbidity and mortality. Halstead, who first carried out mastectomy in the year 1882, surgeons have faced many problems such as breakdown of the wound, necrosis of skin flaps, hematoma, seroma and infection⁴ and should be aware of the morbidity unique to mastectomy and that of axillary node dissection. Seromas is the most frequent complication of mastectomy, developing in about 30% of patients.⁵⁻⁶ It is an abnormal collection

of serous fluid, Viewed by many surgeons as a necessary evil, it accounts for increased patient discomfort which led's to pain, delayed wound healing, skin flap necrosis and infection.⁷⁻⁸ Adding for increased financial burden is caused by late onset seroma formation, which requires multiple visits with manual or USG guided evacuation of accumulated fluid. With incidence rates varying from 15 to 90 % there is extensive study and literature on this topic. Consensus however is lacking with respect to pathophysiology as well as preventive measures. Emphasis will be placed on surgical aspects, as it is surgery that is at the root of seroma formation.⁹⁻¹⁰

Although yet not fully understood the pathophysiology of seroma formation has been linked to several factors.¹¹The dead space created by dissected tissue is occupied with serous fluid.¹²This fluid changes its composition in the postoperative days following surgery. Suction drainage in the management of mastectomy patients was used for the first time in 1947 and has been found in various studies superior to other methods of fluid evacuation to reduce the dead space.¹³ The mechanism seems to be the suction helps skin flaps to adhere to the chest wall and axilla sealing off the leaking lymphatics. It reduces the chances of post-operative seromas, hematoma and flap necrosis which are known complications of modified radical mastectomy.¹⁴ When no suction drains were used the incidence of seromas was found to be high in various studies. Prolonged drainage, may increase the hospital stay and increase the risk of infection by retrograde migration of bacteria.¹⁵ Premature withdrawal of postoperative drains irrespective of the amount of fluid drained may be accompanied by an increase in the axillary seromas formation. If kept for longer duration it has been observed that drain itself might increased drainage and the risk of infection with increased total hospital stay resulting in wastage of the hospital resources.¹⁶

The amount of postoperative drainage is influenced by various factors like the profile of the patient including the body mass index, extent of axillary lymph node dissection, number of lymph nodes dissected, use of electrocautery, co morbid conditions and also the negative pressure on the suction drain.¹⁷ The amount of postoperative fluid drained seems to be significantly influenced by the negative pressure on the suction drainage. While the negative suction drain seems logically expected to drain the fluid, a high negative suction drain may prevent the leaking lymphatics from sealing off leading to prolonged drainage causing increased hospital stay.¹⁸ It now believed to be a side effect of surgery than its complication. Associated morbidity in the form of prolonged drainage is not only problematic to the patient but also significantly impact treatment via delaying adjuvant therapy and increasing the risk of infection. A reoperation may be necessary for cases of chronic persistent seroma. Although there are many studies proving that drains does not prevent seroma formation, the use of drains for that purpose is still more common .¹⁹ 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.²⁰ In this prospective randomized trial, we aim at comparing the efficacy of half versus full suction drainage after modified radical mastectomy for breast carcinoma.

Material and Methods

Forty FNAC proven patients with age above 30 year with operable breast cancer over the period of 18 months of the study with fitness taken from Anaesthetists and Physicians were enrolled in this study. The sample size was calculated with the help of Open Epi Calculator with Confidence Interval as 99% and Power as 95% with Mean 20 (for Half Suction) and 20 (Full Suction) and Standard deviation 9.2 for (mrm) and 24.6 (for full suction) as per the study done by Anandravi B.N., Praveen P. Nair et al.⁴⁴ The sample size for all the intra-operative and post-operative parameters were calculated and highest sample size amongst them is being taken for the current study. All the patients were submitted to detailed history taking, complete physical examination, routine laboratory test, mammogram, ultrasound of both the breasts and metastatic work up to exclude its presence. FNAC or Trucut needle biopsy was done for all patients preoperatively.

Breast cancer patients were divided into full suction or half suction by the operating surgeon depending upon the indication and requirement. Following parameters were assessed. Total drainage volume ;Time taken to remove drain ;Wound infection ;Flap necrosis and Hospital stay 40 FNAC proven cases of operable cancer were randomized (using randomly ordered sealed envelopes, which were opened immediately before the closure of the wound) into full vacuum suction (pressure = approximately 700 g/m²) group – (A) and cases into half vacuum suction (pressure = approximately 350 g/m²) group – (B)¹³². The two groups were comparable in respect of age, weight and type of operation i.e. modified radical mastectomy (MRM). Following complete routine and metastatic work up Axillary dissection was done up to level- III in all the cases. Two silicone tube drains (12Fr) (one axillary and pectoral) were inserted in all the patients Both the drains were connected to a single 600 ml suction bottle (Romovac - Romson).

In-group A, drainage was performed using complete vacuum negative suction (700 g/m²) and in group B with half vacuum suction drainage (350 g/m²). The pressure was also measured by attaching a manometer to the exit opening of the drainage bottle. The two groups were comparable with respect to age, weight (body mass index), type of operation indicating the success of randomization. The drain was emptied every 24 hours to reset suction at the respective pressures and to measure the daily drain output. External compression dressing was provided over the axilla for first 48 hrs and following that the patients were encouraged to do active and passive shoulder exercises. The drains were removed once the output was less than 30 ml in 24 hrs and the patients were discharged on the same day. The mean total drain output was measured in each group and compared.

Routine investigations before and after interventions were performed including Complete blood count (CBC) ;BT/CT ;PT-INR ;Blood group ;Serum Urea ,Creatinine ,SGOT ;SGPT ;Sodium & Potassium ;RBSL ;Urine ;Albumin ;Sugar ;ECG ;Chest X ray PA view ;Mammography ;Ultrasound ;Biopsy ;Computerized Tomography (CT) scan ;FNAC ;Biochemical studies (Alkaline Phosphatase, Gamma Glutamyl Transaminase, Urinary Hydroxyproline etc.) and Search for distant metastases

(Chest X-ray, Bone X-ray, Bone scan, Liver scan etc). Patients were followed up for 1 months after surgery and symptoms, if any, were documented and investigated only if they persisted beyond 1 month of surgery.

Statistical Analysis

A descriptive statistical analysis was performed using statistical package for social sciences (SSPS) version 20 .Continuous variables were summarized by the number of observations, mean and standard deviation. Data collected from the study were analysed using Chi-square test, Student's t-test and Mann-Whitney U test. The level of statistical significance was set at P = 0.05. The data was analyzed with 5% significance level and 80 % power for study.

Results

The mean age of study population in full suction group 58.6 ±11.92 and in half suction group 51.65 ±10.97 (p0.06). There was statistically significant decrease in the mean drain removal day in the group with half suction drain compared to the group with full suction drain. (P=0.002774). Duration of hospital stay, the primary outcome measure was shorter(9.95±2.56) in half suction group as compared to full suction group(12.65±3.37) as shown in table 1. The difference was quite significant with P=0.006968. The half suction system drain less fluid in average total (223.25±69.23) compared with full suction drain total (327.5±62.77)as shown in table 1. The results were quit significant p=0.00001374. The groupwise patient characteristics were summarized in Table 1.

Table 1
Result of full versus half suction

PARAMETERS	FULL SUCTION	HALF SUCTION	P-VALUE	DF
MEAN AGE (YEARS)	58.6(SD11.92)	51.65(SD10.975)	-	-
SURGERY	MRM	MRM	-	-
DRAIN REMOVAL [^]	7.75(SD1.019546)	6.75(SD0.966546)	P(0.002774)	38
MEAN DRAIN VOLUME(ML) [^]	327.5(SD62.77571)	223.25(SD69.23026)	P(0.00001374)	38
MEAN HOSPITAL STAY (DAYS) [^]	12.65(SD3.375999)	9.95(SD2.564433)	P(0.006968)	38
WOUND INFECTION*	7	1	P(0.043)	-
SEROMA FORMATION*	4	1	P(0.278)	-
FLAP NECROSIS*	3	1	P(0.302) unpaired t test	-

* Fisher exact test with p-value (2-tail)

[^] Unpaired T test

DF- Degree of Freedom

Discussion

Seroma formation is the most frequently observed early complication after breast and axillary surgery. The use of closed suction drainage is a common practice that has been shown to reduce the incidence of seroma formation¹⁻⁶. These drains are generally removed once the lymph production falls to less than 35–50 ml/24 hours, a level generally reached between 3–17 days after surgery¹. The length of postoperative axillary drainage is a major cause of morbidity after axillary dissection as the patients are usually discharged once the drains are removed. The patients with suction drains in situ are normally managed in the hospital (although some authors advocate discharge with the drains in situ)¹³. Migration of bacteria along these drains has also been observed to increase the risk of infection if the drains stay in situ for a long time⁷. Early or premature removal however has been found to be associated with an unacceptably high incidence of seroma formation and its continuation until fluid discharge is acceptably low leads to a prolonged stay in the hospital, which has a bearing on the cost of surgical management of breast cancer^{1,11-13}.

Shortening the hospital stay has been shown to be an effective way of reducing the costs in the case of surgery for breast cancer and axillary drains are the main obstacles in achieving it.^{1,8-10} To reduce the hospital stay after MRM, early discharge with the drains in situ has been reported but discharging patients with drains in situ has an inherent difficulty faced by the patients in management of drains besides higher incidence of wound infection.^{13,14} The other disadvantages are discomfort for the patients, with difficulties undressing or using the toilet. It may be feasible with patients of higher cultural and social standing, but not all the patients have the required background. In a third world country where the patients are poor, uneducated coming from far and remote areas with limited medical facilities, there is an added difficulty in management of the drains away from the hospital. As most of our patients come from far flung rural areas with limited education, poor medical and communication facilities they were managed indoors until the drains were removed.

There are other solutions proposed for prevention or reduction of fluid accumulation and early discharge after axillary dissection e.g by Patrek et al^{15,16} where several parallel drains were used. Suture obliteration of axillary space under skin flaps with sutures to the chest wall, approximation of the pectoralis major and the latissimus dorsi muscle in the form of axillary padding has been suggested by some authors^{9,17}. The incidence of seroma formation had reduced but the length of drainage was not specified in these studies. Further more suture approximation of the muscles may limit movement of the arm leading to shoulder dysfunction. Harada et al¹⁴ used fibrin glue in rats to occlude transected lymph channels and obliterate the subcutaneous cavity. The association of seroma formation with large amounts of drainage before removal of the drain has already been established¹⁸⁻²⁰. In one study it was observed that when the amount of fluid drained before removal of the catheter was less than 250 ml in three days no seromas developed and they concluded that it is safe to remove drains if the total amount of fluid drained during the first postoperative days is low. Few studies reported that removal of drains after 48 hours did not result result in seroma

formation if the total amount of fluid drained before removal was less than 150 ml.²⁰⁻²²

Conclusions

Reducing the negative suction pressure applied to the drain (making it half suction) along with external compression dressings applied for first 48 hours can significantly reduce drainage from the axilla following modified radical mastectomy without increasing the incidence of seroma formation as was observed in this randomized prospective clinical study. The hospital stay was reduced considerably compared to a matched group with full suction drain ($p < 0.001$). Half suction drain following axillary dissection in patients with carcinoma breast may thus be recommended as an effective approach to reducing the hospital stay and the cost of treatment without adding to the morbidity.

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