IMPACT OF LOW VERSUS HIGH VACUUM SUCTION DRAINAGE ON DURATION OF HOSPITAL STAY AFTER MODIFIED RADICAL MASTECTOMY

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ABSTRACT

Objective: To determine the efficacy of low pressure vs high vacuum suction drains after modified radical mastectomy in terms of earlier removal and its impact on duration of hospital stay.

Study Design: A randomized clinical trial.

Place and Duration of Study: The study was conducted at Military Hospital Rawalpindi and CMH Peshawar over a period of 12 months from March 2010 to March 2011.

Patients and Methods: Sixty trucut/biopsy proven, early invasive breast cancer patients undergoing modified radical mastectomy were randomized into groups A (n=30) and B (n=30) to receive high vacuum (400 mm Hg) suction drains or low vacuum suction drains (200 mm Hg) at completion of operation. Drains were recharged to the specified pressure daily and drain output was recorded. Drains were removed when the daily drainage reduced to 30 ml.

Results: 28 patients in group A & 27 patients in group B were finally included in the study. Mean hospital stay in low vacuum suction group was 4.96 ± 0.898 days which was 32.9% shorter than 7.39 ± 1.397 days for high pressure suction group ($p < 0.005$).

Conclusion: The use of low vacuum vs high vacuum drains after modified radical mastectomy reduces the hospital stay significantly.

Keywords: Breast cancer, Modified radical mastectomy, Seroma.

INTRODUCTION

Despite centuries of theoretical and scientific inquiry, breast cancer remains one of the most dreaded of human diseases. Breast cancer is the second commonest cancer in females and the commonest cause of cancer related female mortality throughout the world[1].

The surgical treatment of choice for these patients is either modified radical mastectomy (MRM) or breast preservation depending upon stage of the disease and various patient factors. Axillary lymph node dissection (ALND) is integral part of modified radical mastectomy and is the preferred treatment of clinically positive or sentinel node biopsy (SNB) positive axillary lymph nodes[1,2]. MRM is the more widely used treatment modality in Pakistan because of delayed presentation of patients, surgical practices in vogue and unreliable patient follow up.

Post-operative fluid collections under skin flaps or seromas are the commonest complication of breast cancer surgery, whether it be MRM, SNB or breast conservation therapy (BCT). The use of closed suction drainage postoperatively is a common practice that has been shown to reduce, but not prevent seromas[3]. 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.

In the absence of metastasis, status of axillary lymph nodes is the most important factor determining treatment modality and their sequencing and predicting loco-regional recurrence and survival[2]. Women with node-negative disease have less than a 30% risk of recurrence, compared with as much as a 75% risk for women with node-positive disease. Surgery (in from of MRM or BCT) is the cornerstone of treatment of early and locally advanced breast cancer, improving loco-regional control and survival[1-2].

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Even in present era of modern surgical practice wound complications including infection, flap necrosis, nerve damage, shoulder dysfunction and lymphedema of arm are not infrequent[4-6]. But seroma under mastectomy flaps and axilla in MRM is so common as to be considered by some surgeons to be a necessary evil of breast surgery rather than a complication[7]. Seroma formation is also the commonest side effect of SNB and ALND. The exact incidence varies wildly from study to study (range 4%–92%), based on the authors' classification criteria[8-10]. The incidence of seroma has been shown to correlate with patient's age, breast size, hypertension, presence of malignant nodes in the axilla, previous surgical biopsy and use of heparin. It is more frequent if the flaps are raised by electrocautery than by scalpel, as well as occurring more often in modified radical mastectomy than in breast-conserving surgery, in axillary lymph node dissection than in sentinel lymph node dissection, and in modified radical mastectomy without immediate reconstruction than with immediate reconstruction[5,10-13]. Besides the economic loss due to prolonged hospital stay and delay in rehabilitation, seroma formation also adds to psychological trauma. This is, in addition, often to the embarrassment of the operating surgeon, whose experience in surgery does not influence the incidence of seroma after mastectomy[14].

Of the measures employed to manage mastectomy wound fluid collections, closed suction wound drainage has been used most extensively since 1947[15]. The mechanism proposed is that the suction helps skin flaps to adhere to the chest wall and axilla, sealing off all the leaking lymphatics[16]. Several alternatives and adjuncts to the use of drains have been explored, including suturing the flaps to the chest wall, fibrin sealant, external compression dressings and intraoperative tetracycline and tranexamic acid and use of depot steroids with varying results and use of closed drainage systems still continues to be the most used modality[5,17-20]. Regular practice is to insert two tube drains, one under pectoral flaps and one in axilla, usually connected to single drain bottle. Comparison of single axillary drain to two or three drains found no significant difference in complication rate between the two, with increased discomfort with more drains[21-22]. Open mastectomy drains have been shown to be inferior to closed drains and the performance of siphon drains (drains without suction) have been found comparable to that of suction drains[23]. Use of drains is associated with a longer postoperative hospital stay, increased risk of infection, limited patient mobility and more pain after surgery for breast cancer[24]. These drains are generally removed once the lymph production falls to less than 35–50 ml/24 hours[25]. Early or premature removal however has been found to be associated with an unacceptably high incidence of seroma formation, but if kept for longer periods it has been observed that drain itself might contribute to increased drainage and the risk of infection, leads to a prolonged stay in the hospital, increasing the cost of surgical management of breast cancer[15,19,25,26]. In a third world country where the patients are poor and uneducated, coming from far and remote areas with limited and medical facilities, there is an added difficulty in management of the drains so they have to be hospitalised.

The purpose of this study was to determine whether lowering the suction pressure in drains could affect their removal time, keeping the endpoint drainage of 30 ml/24 hours.

MATERIAL AND METHODS

This randomised controlled trial was conducted in two surgical units of two tertiary care centres (female surgical unit Military hospital Rawalpindi and Surgical department Combined Military Hospital Peshawar) over a period of one year from March 2010 to March 2011. Sixty FNAC (fine needle aspiration cytology)/trucut biopsy proven female patients of early breast cancer, without metastatic disease, undergoing modified radical mastectomy were randomized (by using randomly ordered sealed envelopes, which were opened immediately before the closure of the wound) to receive either high vacuum suction drain (pressure=400 mmHg, group–A) or low vacuum suction drain (pressure=200 mmHg, group–B). All the patients were

females, normotensive and none had received neo-adjuvant chemo/radiotherapy. No immediate breast reconstruction was performed. Patients who were hypertensive, had received neo-adjuvant radio /chemotherapy, or had undergone prior sentinel lymph node biopsy were excluded from the study.

Following complete routine and metastatic work up all patients underwent Auchincloss' modified radical mastectomy. Surgery was performed by two surgical teams using a standardized technique. Pectoral skin flaps over breast were raised with diathermy while ALND was performed using sharp dissection. Axillary dissection was done up to level-II in all the cases. The boundaries of axillary dissection were defined by superior limit as the posterolateral border of the pectoralis major muscle and axillary vein, medial limit being clavipectoral fascia or Hallstead's ligament, lateral limit as the anterior border of latissimus dorsi and the inferior limit being the lower border of 6th rib. Two silicone tube drains (12Fr) (Redon perforated drain tube, Mediline Inc.) with multiple holes were inserted in all the patients, one in axilla and one under pectoral skin flaps. Each drain was connected to a separate 400 ml suction bottle (Redon-bottle 400cc, Mediline Inc). In-group A (n=30), drainage was performed using complete vacuum negative suction (400 mm Hg) and in-group B (n=30) with half vacuum suction drainage (200 mm Hg). Twenty eight patients in group-A and 27 patients in group-B were finally included in the study.

Preoperative, operative and postoperative management were identical in all patients except for the use of drains. The drain was emptied every 24 hours to measure the daily drain output and to reset suction at the respective pressures with suction machine (Dominant-50, Medela Inc, Baar/Switzerland). 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. Dressings were changed every 3-4 days, at which time complications were noted and appropriate treatment instituted.

The outcomes measured were drain volume (separately from axillary and pectoral drains) and the length of hospital stay (counted from day of operation as day 0). The total drain output was measured directly from calibrations on suction bottles and recorded daily in both the groups. The drains were removed once the output was less than 30 ml in 24 hours and the patients were discharged on the same day. The associated morbidity in the form of seroma formation, flap necrosis and wound infection during the postoperative period was also recorded.

Table-1: Group statistics.

	Group	N	Mean	Std. Deviation	Range	Std. Error Mean
Age	low pressure	27	52.00	8.385	36-72	1.614
	high pressure	28	51.04	9.074	34-72	1.690
Weight	low pressure	27	66.0000	8.27880	53-85	1.59326
	high pressure	28	67.1786	6.80443	53-76	1.28592
BMI	low pressure	27	26.3200150	3.24301031	20.58-32.89	.62411763
	high pressure	28	27.1598707	3.55710690	19.00-34.23	.67223002

Table-2 : Mean hospital stay.

	Group	N	Mean (days)	Std. Deviation	Std. Error Mean
Hospital stay	low pressure	27	4.96	.898	.173
	high pressure	28	7.39	1.397	.264

Statistical Methods

Statistical Package for the Social Sciences

(SPSS) version 15 was used for data analysis. Mean and standard deviation of patient age, weight, BMI and hospital stay for each group were calculated. Total and average volume drained were calculated and compared between the two groups. Descriptive studies were performed and group characteristics were compared using student t-test. The level of significance was set at a *p*-value of 0.05. The mean total drain output (axillary and pectoral separately and in total) was calculated in each group and compared. Drain output for initial three post-operative days was compared in both groups. The mean hospital stay in both the groups was calculated and compared.

RESULTS

A total of 60 patients were recruited into the study. Thirty patients had high pressure suction drainage (400 mmHg)-group A while 30 patients had low pressure suction drainage (200 mm Hg)-group B. Data of five patients in total was excluded from results due to following reasons. Out of 30 patients in high pressure group-A, one patient developed flap necrosis and one was lost to follow up due to social reasons. Out of 30 patients in group-B one patient had surgical site infection, requiring opening of wound and exclusion from study while two patients were lost to follow up due to social reasons.

Duration of hospital stay, the primary outcome measure was %32.9 shorter (p<0.005) in low pressure suction group (4.96 ± 0.898 days) as compared to high pressure suction group (7.39 ± 1.397 days) as shown in table-2. The difference was quite significant with p<0.001. The low pressure suction system drained less fluid in total (539.26 ± 132.21 ml), less fluid per day (mean 110.78 ± 13.91 ml) and less fluid in first three post-op days (415.93 ± 65.119) compared with the high pressure suction drain (1003.04 ± 309.699 ml, 135.9 ± 18.51 ml and 583.21 ± 110.86 ml respectively). The same are depicted in fig. The results were quite significant (p<0.5). On average %77 of total drain was collected in first three days in low pressure suction group while only %58 was collected in first three days in case of high suction group.

The two groups were comparable in respect of age, weight and body mass index (BMI) as shown in table-1.

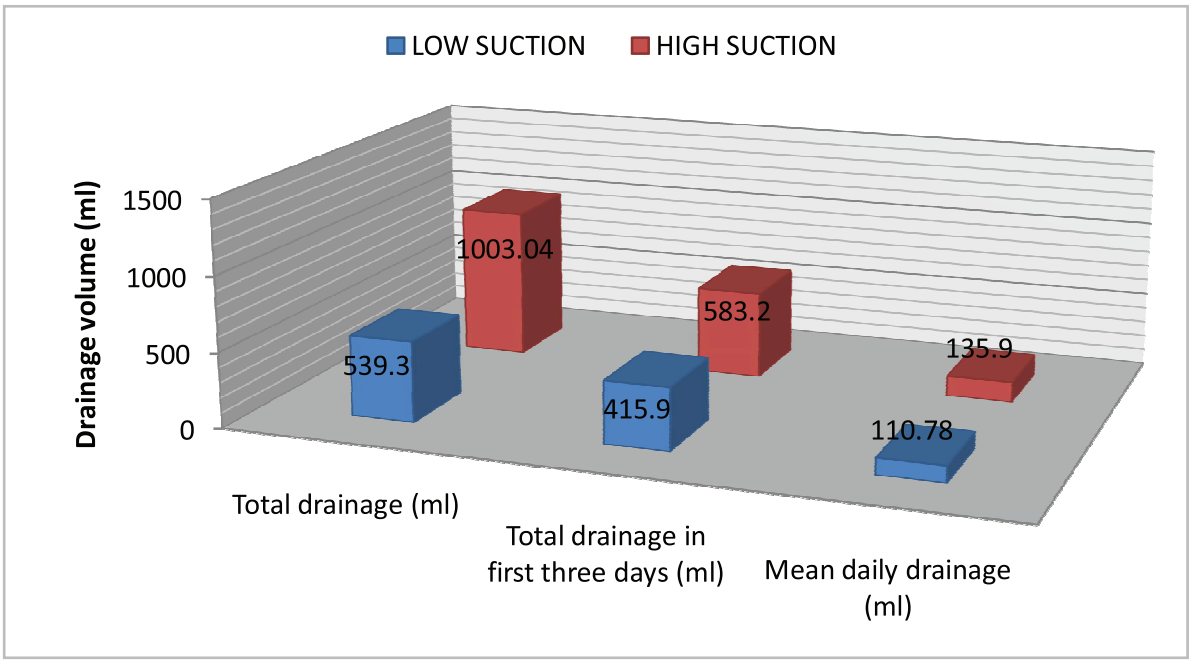

Figure: Drainage volumes in the two groups.

DISCUSSION

To improve upon the time honoured practice of closed drainage system in preventing seroma formation various studies have attempted to find the optimal time of drain removal, optimal pressure in active drains and the superior type of drains. Since evidence of five out of eight trials by 2005 showed that wound drainage reduced the rate of seroma formation, further studies have focused to facilitate early drain removal so that drain associated complications and discomfort be reduced[24-27]. We hypothesized that low pressure vacuum suction drains can be removed earlier than high pressure vacuum suction drains with same end point of 30 ml drain in 24 hrs. The rationale being that high suction pressures although removes fluid collections more effectively, the high suction may prevent closure of lymphatic channels, keeping them open and causing prolonged drainage.The same hypothesis has been tested in five randomized controlled trial (RCTs) to date. Study by Bonnema found no significant difference in hospital stay between low and high vacuum group (9.5 versus 10 days)[18]. Van Heurn reported a significant early removal of low pressure suction drains as compared to high pressure suction drains (p=0.02)[28]. Chintamani et al demonstrated significant early removal of low vacuum suction drains (350 g/m2) at 6 ± 1.414 days as compared to high vacuum suction (700 g/m2) at 10.8 ± 1.603 days[25]. Wedderburn et al. found no significant difference in hospital stay (p=0.7) between low and high pressure suction drainage following axillary clearance[17]. In contrast Britton observed that high vacuum Redivac units drained stayed in place for a day less than the low vacuum Portovac units and were emptied less often.

In our study low vacuum suction drains were removed significantly earlier at (4.96 ± 0.898 days) as compared to high pressure suction group (7.39 ± 1.397 days) (p<< 0.001). It may be due to the fact that we used two drains each connected separately to suction bottle and each removed on its own merit. In this way the drains were removed in fact when combined drainage was less than 60 ml (30 ml in each drain) but in other studies one bottle was connected to both drains and they were removed when combined drainage fell to 30 ml. Its impact on seroma formation needs further study. We found that in 6 out of 27 cases in low pressure group pectoral drain was removed a day earlier than the axillary drain, whereas it was removed a day earlier in 8 out of 28 cases and two days earlier in 1 out of 28 cases in high pressure suction group. In all previous studies both drains were removed simultaneously since they were attached to single drain bottle[29].

The amount of postoperative fluid drained has been proposed to be significantly influenced by the negative pressure on the suction drainage. It has been proposed that total drainage reflects the magnitude of lymphatic interruption after mastectomy and consequently, the likelihood of lymphatic insufficiency and lymphedema[29]. Seroma formation was associated with a larger total suction drain volume in study of Barwell[3]. No statistically significant differences were found between the drainage volume among low vacuum group and the high vacuum group by Bonnema and Wedderburn[17,18]. In contrast, the mean volume of seroma evacuated with a low vacuum system was 386 (±26) ml (n=38) compared with 537 (±43) ml with a high vacuum system (n=40) (p<0.005) in the study by van Heurn[28]. Chintamani et al reported similarly significantly reduced drain volumes in low vacuum suction groups (325 ml ± 39.6 ml versus (525 ± 66.28 ml) p<0.001[25]. Our results favour low vacuum suction drains as they drained significantly less fluid in total. High vacuum drains removed 1003.04 ± 309.699 ml whereas low vacuum suction drains drained 539.26 ± 132.21 ml (p<0.001). Two kinds of drain output trends were identified: continuously decreasing and undulating. While the negative suction drain is logically expected to drain the fluid, a high negative suction drain may prevent the leaking lymphatics from sealing off thus leading to prolonged drainage and hence increased hospital stay[25,26]. This may explain the higher total drainage in high vacuum group.

A positive association between drainage volume during the initial 3 postoperative days before drain removal were assessed in terms of

seroma formation.[12,26]. Studies have found increased incidence of seroma and edema of arm if drain in first three post-op days was more than 500 ml[14,]. Our study showed that low vacuum suction drained less fluid in total , less fluid per day and less fluid in initial three post –operative days as compared to high vacuum suction. This lead to earlier removal of low vacuum drains and earlier discharge from hospital.

CONCLUSION

We conclude that low vacuum suction drains were removed earlier than high vacuum suction drains and hence reduced the hospital stay significantly. The impact of earlier removal of low vacuum suction drains on incidence of seroma and lymphedema needs further evaluation.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

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