

## A COMPARATIVE STUDY BETWEEN HALF VACUUM SUCTION AND FULL VACUUM SUCTION DRAINAGE IN PATIENTS UNDERGOING MODIFIED RADICAL MASTECTOMY

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Received : 28/12/2022  
Received in revised form : 07/02/2023  
Accepted : 20/02/2023

**Keywords:**

Duration of the drain, drain output, hospital stay, flap necrosis, seroma formation, wound infection, staging, half vacuum suction, full vacuum suction.

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DOI: 10.47009/jamp.2023.5.2.94

Source of Support: Nil,  
Conflict of Interest: None declared

*Int J Acad Med Pharm*  
2023; 5 (2); 449-452



### Abstract

**Background:** Suction drains are widely utilized following modified radical mastectomy and significantly contribute to an increased hospital stay because patients are frequently discharged after removal. Thus, the prospective randomized clinical trial compared post-operative wound drainage in patients with full and half vacuum suction drainage systems. **Materials and Methods:** The study was conducted in the general surgery department of Madurai medical college for over one year. 100 trucut biopsy-proven cases of locally advanced breast cancer are randomized into the full vacuum (n=50) and half vacuum (n=50) suction drainage system. Two groups were compared for age, BMI, staging, type of suction, drain output, duration of hospital stays, seroma, flap necrosis, wound infection, duration of the drain, and cost. **Result:** Mean age was 51.42 in both the study and control group (ages ranging from 20-80 years). The study group showed a significantly decreased rate of post-operative wound infection (10%) compared to the control group (32%). The study group showed a significantly decreased amount of drain, duration of the drain, duration of hospital stays, and cost of hospital stay compared to the control group. The amount of seroma formation and flap necrosis was more or less equal in the study and control groups. **Conclusion:** During a modified radical mastectomy, half-negative suction drains efficiently compromise between no suction and full or high suction drainage by minimizing hospital stay and post-operative morbidity, including post-operative seromas.

## INTRODUCTION

Breast cancer is a major public health problem for women throughout the world.<sup>[1,2]</sup> Suction drainage in the management of mastectomy patients was used for the first time in 1947 and found in various studies superior to other methods of fluid evacuation to minimize the dead space. The proposed mechanism is the suction helps skin flaps to adhere to the chest wall and axilla, sealing off all leaking lymphatics. This reduces the incidence of post-operative seroma, hematoma formation, and flap necrosis and recognizes complications of modified radical mastectomy. Seromas' incidence was unacceptably high in various studies when no post-operative suction drains were used.<sup>[3-5]</sup>

The amount of post-operative drainage is influenced by various factors like the patient's clinical profile, including body mass index, the extent of axillary lymph node dissection, number of lymph nodes dissected, use of electrocautery, co-morbid conditions, and also negative pressure on the suction

drain. Negative pressure on suction drainage significantly influences the amount of post-operative fluid drained. While the negative suction drain is logically expected to drain fluid, a high negative suction drain may prevent leaking lymphatics from sealing off, thus leading to prolonged drainage and an increased hospital stay.<sup>[4-7]</sup>

Thus, the present prospective randomized clinical trial compared post-operative wound drainage in patients with full suction drains and those with half vacuum drainage systems. The study also compared drain volume, average hospital stays, and post-operative morbidity between full-vacuum and half-vacuum suction groups.

## MATERIALS AND METHODS

The study was conducted in the general surgery department of Madurai medical college for over one year. 100 trucut biopsy-proven cases of locally advanced breast cancer are randomized (using randomly ordered sealed envelopes, which are

opened immediately before the closure of the wound) into full vacuum suction (pressure =700g/m2) group – (A) and 50 cases into half vacuum suction (pressure = 350g/m2) group – (B).

Inclusion criteria: Patients with a Body mass index of less than 30, patients who consented to inclusion in the study according to designated proforma, and patients with locally advanced breast cancer (stage 2b,3a,3b) were included.

Exclusion criteria: Patients with a body mass index of more than 30 did not consent to inclusion in the study, and patients with metastatic breast cancer were excluded.

The two groups were comparable regarding age, weight, and the type of operation, i.e., modified radical mastectomy (MRM). Following the complete routine and metastatic workup, all patients received three cycles of the Neoadjuvant chemotherapy (NACT) using the CAF regime (Cyclophosphamide, Adriamycin, 5-Fluorouracil) and underwent Patey's modified radical mastectomy after three weeks of last cycle. Surgery was performed by the same surgical team comprising four surgeons (two senior and two resident surgeons) using a standardized technique with electrocautery. Axillary dissection was done up to level- III in all the cases. The boundaries of axillary dissection were defined by the superior limit, the posterolateral border of Pectoralis major muscle and axillary vein; the medial limit, the clavipectoral fascia or Hallstead's ligament; the lateral limit, the anterior border of latissimus dorsi and the inferior limit the angular vein joining the thoracodorsal vein. The long thoracic and thoracodorsal nerves were identified, dissected, and preserved. All patients were inserted in two tube drains of size (14Fr) (one axillary and pectoral). All resected specimens were examined, and the lymph nodes were dissected, counted, and assessed histopathologically for metastases.

Both drains were connected to a single 800 ml suction bottle. In- group A (n = 50), drainage was performed using complete vacuum negative suction (700 g/m2), and in group B (n = 50) 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 concerning age, weight (body mass index), and 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 the first 48 hours, and following that, patients were encouraged to do active and passive shoulder exercises. The outcomes measured include morbidity and the length of hospital stay.

The total drain output was measured and recorded daily in both 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. Both groups recorded and compared the total drain output, mean hospital stay, and the associated morbidity in seroma formation, flap necrosis, and wound infection during the post-operative period.

Data were entered in Microsoft Excel and analyzed using Statistical Package for Social Sciences (SPSS) software's latest version. Data on a continuous scale were represented as mean and standard deviation. Categorical data were represented as numbers and percentages—association of categorical variable with outcome variable assessed by Chi-Square Test. Results were represented as Graphs and Tables.

## RESULTS

We have compared the distribution of cases and controls according to age groups, BMI, staging, type of suction, drain output, duration of hospital stays, seroma, flap necrosis, wound infection, duration of the drain, and cost of the stay. Table 1 indicates that most (58%) subjects in both groups were >45 years old. BMI classification showed that 52% of subjects in both groups had BMI between 20-25Kg/m2, whereas 48% of subjects in both groups had BMI between 26-30Kg/m2. Few subjects had seroma formation, flap necrosis, and wound infection [Table 1].

**Table 1: Distribution of Subjects according to age groups, BMI, staging, type of suction, drain output, duration of hospital stays, seroma, flap necrosis, wound infection, duration of the drain, and cost of stay**

Variables		Cases	Control
Age group	<35 years	11 (22%)	11 (22%)
	35 – 45 years	10 (20%)	10 (20%)
	>45 years	29 (58%)	29 (58%)
BMI Classification	20-25	26 (52.0%)	26 (52.0%)
	26-30	24 (48.0%)	24 (48.0%)
Staging	Stage 2B	16 (32%)	16 (32%)
	Stage 3A	17 (34%)	17 (34%)
	Stage 3B	17 (34%)	17 (34%)
Type of suction	Half vacuum (group B)	50 (100.0%)	0
	Full vacuum (group A)	0	50 (100.0%)
Duration of drain	<8 days	23 (46%)	5 (10%)
	9 – 12 days	26 (52%)	21 (42%)
	>12 days	1 (2%)	24 (48%)
Duration of hospital stay	<8 days	35 (70%)	7 (14%)

	9 – 12 days	13 (26%)	37 (74%)
	>12 days	2 (4%)	6 (12%)
Seroma	Yes	5 (10%)	5 (10%)
	No	45 (90%)	45 (90%)
Flap Necrosis	Yes	11 (22%)	11 (22%)
	No	39 (78%)	39 (78%)
Wound infection	Yes	5 (10%)	16 (32%)
	No	45 (90%)	34 (68%)
Drain Output	500 – 800ml	26 (52%)	5 (10%)
	801 – 1000ml	24 (48%)	21 (42%)
	>1000ml	0	24 (48%)
Cost of stay	< Rs. 500	5 (10%)	3 (6%)
	Rs. 500 – 1000	43 (86%)	37 (74%)
	>Rs. 1000	2 (4%)	10 (20%)

Additionally, we have compared the distribution of cases and controls according to age, BMI, staging, type of suction, drain output, duration of hospital stay, seroma, flap necrosis, wound infection, duration of the drain, and cost of stay according to half vacuum and full vacuum drainage system. Table 2 indicates that the mean age, BMI, staging of disease, seroma formation, and flap necrosis do not significantly vary between groups. In contrast, the drain duration, duration of hospital stays, wound infection, drain output, and cost of stay was significantly less in the study group than in the control group [Table 2].

**Table 2: Association of age, BMI, staging, type of suction, drain output, duration of hospital stay, seroma, flap necrosis, wound infection, duration of the drain, and cost of stay according to half vacuum and full vacuum drainage system**

Variables		Half Vacuum	Full Vacuum	p-value
Age		51.42 ± 15.77	51.42 ± 15.77	1.000
BMI	20 – 25	26 (52%)	26 (52%)	1.000
	26 - 30	24 (48%)	24 (48%)	
Staging	Stage 2B	16 (32%)	16 (32%)	1.000
	Stage 3A	17 (34%)	17 (34%)	
	Stage 3B	17 (34%)	17 (34%)	
Drain output	500 – 800ml	26 (52%)	5 (10%)	<0.0001
	801 – 1000ml	24 (48%)	21 (42%)	
	>1000ml		24 (48%)	
Duration of Drain	<8 days	23 (46%)	5 (10%)	<0.0001
	9 – 12 days	26 (52%)	21 (42%)	
	>12 days	1 (2%)	24 (48%)	
Duration of Hospital stay	5 – 10 days	35 (70%)	7 (14%)	<0.0001
	11 – 15 days	13 (26%)	37 (74%)	
	>15 days	2 (4%)	6 (12%)	
Cost of stay	<Rs. 500	5 (10%)	3 (6%)	0.024
	Rs.500 – 1000	43 (86%)	37 (74%)	
	>Rs. 1000	2 (4%)	10 (20%)	
Seroma	Yes	5 (10%)	5 (10%)	1.000
	No	45 (90%)	45 (90%)	
Flap Necrosis	Yes	11 (22%)	11 (22%)	1.000
	No	39 (78%)	39 (78%)	
Wound Infection	Yes	5 (10%)	16 (32%)	0.007
	No	45 (90%)	34 (68%)	

## 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 reduces the incidence of seroma formation. These drains were generally removed once the lymph production becomes less than 30ml/24 hours, a level generally reached between 3–15 days after surgery.<sup>[4,8]</sup>

The length of post-operative axillary drainage is a major cause of morbidity after axillary dissection, as these patients are usually discharged once the drains are removed. Early or premature removal is associated with an unacceptably high incidence of seroma formation. Its continuation till fluid discharge is low and leads to prolonged stay in the hospital, which increases the cost of surgical management of

breast cancer. Shortening the hospital stay effectively reduces costs in case of surgery for breast cancer, and the axillary drains are the main obstacles in achieving this.<sup>[9,10]</sup>

To reduce hospital stay after modified radical mastectomy, discharge with the drains in situ has been reported but discharging patients with drains in situ has an inherent difficulty faced by patients in the management of drains other than a higher incidence of wound infection. The incidence of seroma formation was reduced, but some studies did not specify the drainage length.<sup>[9,10]</sup> Harada et al. used the fibrin glue in rats to occlude the transected lymph channels and obliterate the subcutaneous cavity.<sup>11</sup> The association of the seroma formation with larger amounts of drainage before removal of the drain has already been established.<sup>[9-11]</sup> In one study, it was observed that no seromas developed when the

amount of fluid drained before the removal of the catheter was less than 250 ml in three days. They concluded that it is safe to remove drains if the total amount of fluid drained during the first post-operative days is low. Yii et al. reported that removal of drains after 48 hours does not result in seroma formation if the total amount of fluid drained before the removal was less than 150 ml.<sup>[12]</sup>

Patrek et al. examined factors influencing fluid drainage. Only two (many positive lymph nodes and the previous biopsy) predicted greater drainage.<sup>[13]</sup> Use of electrocautery has been reported to be associated with an increased incidence of seroma formation compared to the cold knife. It has been reported that the tissue ligation around the axillary vein rather than the mere transaction with a knife or diathermy can reduce the amount of post-operative discharge. This technique was followed in the presented study.<sup>[14]</sup>

More seromas are seen when more lymph nodes are dissected from the axilla. The higher lymph node yield may be an indirect measure of extensive dissection. The drainage also reflects the damage to lymph vessels, so the number of lymph nodes dissected affects the amount of drainage.<sup>[15]</sup> In our study, it was observed that the patient's higher lymph node yield had a higher volume and duration of drainage. However, it was not found to be significantly different in both groups because they were matched in all respects except the negative suction pressure of the drainage.

There are studies to suggest that the high negative suction may be beneficial in the sense that the amount of drainage would be more, thus allowing the early adherence of walls of the axilla to the chest wall and reduction in seroma formation.<sup>[12,16]</sup> However, in the present study, high suction caused prolonged drainage, which the hypothesis can explain that high negative suction may not allow leaking lymphatics to close. Therefore, no suction or high suction drainage might contribute to the same result: a higher incidence of seroma formation and longer hospital stay.

To strike a balance between not having suction and having a high full negative suction, half-negative suction drainage was used in the present study to achieve shorter hospital stay without an increase in the rate of post-operative seroma formation. The external compression dressings in the first 48 hours perhaps helped adhere to the flaps and reduce dead space without compromising shoulder mobility. This reduced the hospital stay effectively and did not increase post-operative morbidity compared to the full negative suction group.<sup>[10]</sup>

## CONCLUSION

As seen in this randomized prospective clinical study, reducing the negative suction pressure used to drain

(to half suction). Applying an external compression dressing for the first 48 hours can significantly reduce drainage from the axilla following modified radical mastectomy without increasing the incidence of seroma formation. In individuals with carcinoma breasts, a half-suction drain following axillary dissection may be a successful technique for minimizing hospital stay and treatment costs without increasing morbidity.

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