

TIMING OF DRAIN REMOVAL AFTER MODIFIED RADICAL MASTECTOMY; A PROSPECTIVE RANDOMIZED STUDY

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ABSTRACT

BACKGROUND : Axillary lymph node dissection (ALND) is a standard procedure in the treatment of breast cancer. Current practice following ALND involves several days of drainage of the axilla to reduce the formation of seroma. The aim of this study is to compare 5 days to 8 days drainage after modified radical mastectomy (MRM). **STUDY DESIGN :** A prospective randomized trial was performed comparing 5 days drainage to 8 days drainage. The primary outcome measure was duration of hospital stay. Formation of seroma and wound related complications were secondary outcome measures. **RESULTS :** Thirty patients were randomized to the 5 days drainage group (A), 30 patients to 8 days drainage

group (B). Seroma aspiration was required in 46.7% (14 patients) after 5 days drainage, and in 33.3% (10 patients) after 8 days drainage ($P=0.07$). Infectious complications were seen in 4 patients after 8 days drainage versus 1 after 5 days drainage ($P=0.0001$). **CONCLUSION:** Five days drainage following ALND is feasible and facilitates early hospital discharge. Furthermore, 5 days drainage is not associated with excess wound related complications compared to long-term drainage.

Key words : - breast cancer, seroma, hospital stay.

INTRODUCTION

Suction drainage in the management of mastectomy patients was used for the first time in 1947 (1) and

has been found in various studies superior to other methods of fluid evacuation to minimize the dead space. The mechanism proposed is that the suction helps skin flaps to adhere to the chest wall and axilla sealing off all the leaking lymphatic (2,3). This reduces the incidence of post-operative seromas, hematoma formation and flap necrosis, which are, recognized complications of modified radical mastectomy (2,3). Prolonged drainage may increase the hospital stay and increase the risk of infection by allowing retrograde migration of bacteria (4). The amount of postoperative drainage is influenced by various factors like the clinical 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 (4-10).

However; there is a lack of data relating to how long suction drains should stay in situ after MRM. In our study we compared the efficacy of 5-days postoperative drainage with 8- day postoperative drainage after MRM in

order to suggest an optimal drain removal time.

PATIENTS AND METHODS

Sixty female Patients with primary cancer breast admitted to Mansoura Univeristy hospitals from April 2003 to October 2004 requiring mastectomy and axillary clearance as part of their treatment. Patients who had surgery to their axilla before or who were undergoing simultaneous breast reconstruction were excluded from the study. None of the studied patients were diabetic. Written, informed consent was obtained. Routine laboratory investigations and metastatic work up was done for all cases. The operations of modified Patey mastectomy and axillary clearance were performed. Diathermy dissection and electrocautery was used in all cases. All patients were randomly allocated to having drains removed on day 5 or day 8 post-operatively. Volumes of drainage were recorded on a daily basis until both drains were removed. The number of lymphoceles was recorded as detected on clinical examination at the outpatient clinic. Where present, all lymphoceles were aspirated to dryness and the

aspirate volume recorded.

All data were recorded on printed pro-formas and later transferred to a computer database. SPSS version 10.1 was used for statistical analysis. All data are presented as mean\SD. Comparison between groups was by independent chi square, Student's t-test. Statistical significance was assumed when a P value of less than 0.05 was obtained.

RESULTS

Sixty patients were randomized into two groups (the 5-day group and the 8-day group). They were comparable in terms of the age, body mass index and extent of disease (table 1, 2 & 3). The average age was 45.4 ± 8.1 years for 5 days group and 45.2 ± 0.4 years for the 8 days group ($P = 0.516$). Body mass index (BMI) ranged between 22 and 35 kg/m^2 : 28.1 ± 2.7 vs. 29.92 ± 4.0 kg/m^2 ($p = 0.27$). The average volume of drainage from both groups in the post-operative days was not statistically significant (54.2 ± 6.6 vs 48.3 ± 7.28). The stage of disease in

both groups was also insignificant ($P=0.273$). The number of lymph nodes removed ranged between 5 and 26 with a mean of 10.5 ± 0.6 .

Tables 2 shows TNM staging of both groups with no significant difference ($P=0.273$). And also table 3 shows no significant differences between the number of lymph nodes resected ($P=0.4$) and infiltrated ($P=0.2$) of both groups.

Table 4 shows the number of lymphoceles and infection complications in the two patient groups. There were 14 (46.7%) lymphoceles in the 5-day group and 10 (33.3%) in the 8-day group. There were a total of 47 aspirations in the 5-day group with a total cumulative lymphocele volume of 750 ml. A total of 26 aspirations were required in the 8-day group with a total cumulative lymphocele volume of 475 ml. Infectious complications were seen in 4 patients after long-term drainage versus one patient after 5 days drainage ($p = 0.001$). There were no cases of flap necrosis..

Table (1) Demographic Characteristics of the Studied Groups

	5 days Group (A) (n=30)		8 days Group (B) (n=30)		P
	Range	Mean \pm SD	Range	Mean \pm SD	
Age	32.0-63.0	45.4 \pm 8.1	33.0-64.0	45.2 \pm 8.4	0.516
Weight (Kg)	48.0-73.0	64.7 \pm 8.5	52.0-79	65.4 \pm 9.1	0.163
Height (cm)	145.0-171.0	155.6 \pm 6.74	147.0-174.0	156.8 \pm 7.4	0.164
Mean volume drained (ml)/day	48.0- 155.0	54.2 \pm 6.6	45.0-170.0	48.3 \pm 7.28	0.32

Student t test

Table (2) Tumor Staging in the Studied Groups

	5 days Group (n=30)		8 days Group (n=20)		P
	No	%	No	%	
I	3	10.0	2	6.7	0.273
II	14	46.7	16	53.3	
III	13	43.3	12	40	
VI	0	0	0	0	
Total	30	100.0	30	100.0	

Chi-square test.

Table (3) Number of resected and Infiltrated lymph node(ln) in the Studied Groups

	5 daysGroup (n=30)		8 days Group (n=30)		
	Range	Mean \pm SD	Range	Mean \pm SD	
No. of ln resected	7.0-22.0	12.6 \pm 4.27	8.0-21.0	14.4 \pm 4.1	0.14
No. of positive ln	0.0-11.0	4.80 \pm 4.50	0.0-13.0	6.5 \pm 4.56	0.2

Student t tes

Table (4): Postoperative complications in both groups:

	5 days Group (n=30)		8 days Group (n=20)		P
	No	%	No	%	
Seroma	14	46.7	10	33.3	0.08
Infection	1	3.3	4	13.3	0.001

Chi-square test.

DISCUSSION

Breast cancer is the most common malignancy in women. Modified radical mastectomy and axillary clearance are standard operations for the treatment of breast cancer. Drainage of the mastectomy site and the axilla is often required to allow accumulating blood and inflammatory fluids to escape. The optimal timing of drain removal remains uncertain.

Surgery of the axilla is associated with numerous complications, including infection, lymphedema of the ipsilateral upper extremity and collection of fluid in surgical site (seroma). Most common complication after breast cancer surgery is wound seroma. The exact etiology of seroma formation remains controversial. Several interventions have been reported with the aim of reducing seroma formation including the use of ultrasound scissors in performing lymphadenectomy (12), buttress suture (13), fibrin glue (14), fibrin sealant (15), bovine thrombin application (16), and altering surgical technique to close dead space (17). However, it has been suggested that although the use of these interventions might reduce the risk of seroma

formation, further studies are needed to verify the real impact on long-term morbidity of such techniques (12).

It has been suggested that the restriction of arm movements may also reduce the incidence of seroma formation (18). This observation however was challenged by others who showed that there is no significant disadvantage in early arm motion (19). Porter et al (20) reported that the use of electrocautery to create skin flaps in mastectomy reduces blood loss but increases the rate of seroma formation. In addition, an association of postoperative seroma formation with neoadjuvant chemotherapy was also noted (21).

Compression dressing to prevent seroma formation was a common method used by many surgeons. A study demonstrated that routine use of a pressure garment to reduce postoperative drainage after axillary lymph node dissection for breast cancer is not warranted (22). However, many authors reported that the use of pressure garment and prolonged limitation of arm activity not only reduces seroma formation but also may in-

crease the incidence of seroma formation after removal of drain (12) and even might cause shoulder dysfunction (16).

Several studies have been performed to investigate factors related to post-surgical seroma. These studies have observed that the early or premature removal of drains might led to unacceptable increased incidence of seroma formation (22-25), whereas others have shown that drains removal time had no influence on seroma formation (5,7,26,27).

Barwell et al. (7) studied the length of time that suction drains should remain after breast surgery with axillary dissection. Sixty-three patients who underwent either axillary clearance (n=37) or mastectomy (n=26) were studied. Suction drains were removed after a median of 4 days (range 1-7 days). Thirty-two patients (51%) developed seromas which required drainage. In our study, the 5-day group showed a similar incidence in seroma formation (64.7%), whereas the 8-day group had a lower incidence (33.3%). The authors concluded that keeping drains in longer did

not protect against seroma production.

Another randomized trial of suction drainage of the axilla in breast surgery patients showed that drainage reduces subsequent seroma formation (5). In this study 20 patients received no drainage, whereas another 20 patients received drainage until there was less than 25 ml of fluid drained in 24 h. There was a significant increase ($P < 0.04$) in post-operative seroma formation in the non-drain group (n = 9) compared to the drain group (n=2).

Yii et al. (26) had studied the effects of early drain removal and time of discharge from hospital in breast cancer surgery patients. This prospective trial was performed in order to assess whether suction drains could be removed and patients discharged within 48 h of major breast surgery. Fifty patients were discharged when drainage was considered acceptable (long-stay group). Another 50 patients had their drains removed and were discharged 48 h post-operatively (short-stay group). In this study the long-stay patients had their suction

drains in situ for a mean duration of 3.9 (range 1-12) days and a mean hospital stay of 4.5 (range 1-14) days. In the short-stay group five patients (10%) developed seromas compared to three patients (6%) in the long-stay group. This difference was not significant. In our study showed a higher incidence of seroma formation in patients in the 5-day group (seroma = 13) compared to the 8-day group (seroma = 10). The difference in seroma formation between our 5-day group and the 8-day group is not significant.

Parikh et al. (27) examined the effect of early drain removal following modified radical mastectomy. In this study 100 patients with operable breast cancer were randomized to post-operative drain removal on day 3 or day 6. There was no significant difference in the mean number of aspirations between the two groups (2.9 vs 2.2). The study concluded that early drain removal and discharge is safe and economically beneficial.

The findings from our study also indicated that the length of time drains are left did not influence the

seroma rate. Similar observation was reported by a another studies where the use of drains did not prevent seroma formation. On the other hand it was associated with a longer postoperative hospital stay and more pain after surgery for breast cancer (14,28).

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 axilla. Drains are the main obstacles in achieving it (8-9,23). 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 (11-12,29). It may be feasible with patients of higher cultural and social standard, but not all the patients have the required background. In a third world country where the patients are poor, uneducated coming from far 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 rural areas with limited education, poor medical and communication facilities they were managed in hospital until the drains were removed.

Our study has shown that removal

of drains on the 5th post-operative day is safe but is associated with an insignificant increase in number of lymphocoeles requiring aspiration in the outpatient clinic. The removal of drains on day 5 post-operatively allows for better utilization of community resources without adversely impacting on patients physical or psychological welfare, or outpatient facilities.

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