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A prospective randomized study on management of suction drains in patients undergoing modified radical mastectomy

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ABSTRACT

Background and Objectives: Seroma, a subcutaneous collection of serous fluid, is the most common morbidity after modified radical mastectomy. Closed suction drains are used for drainage of serous fluid after MRM to obliterate the space beneath skin flaps and thus to decrease seroma formation. Amongst various factors that influence the amount of postoperative drainage, the negative suction pressure applied to the axillary drain has been reported to be of significance. The aim of this study was to evaluate the correlation between duration of negative suction pressure and timing of drain removal on amount and duration of axillary drain fluid and seroma formation in patients undergoing Modified Radical Mastectomy.

Design: A prospective randomized study from September 2012 to December 2014. Setting: Department of General Surgery, Pt. B.D. Sharma PGIMS, Rohtak.

Material and methods: Seventy five patients of primary breast cancer who underwent modified radical mastectomy with axillary lymphadenectomy performed up to level III were randomized into three groups of 25 each. Surgery was performed by the same surgical team using a standardized technique with electrocautery in all the patients. In Group A-Pectoral drain was removed on 2nd post-operative day and negative suction was also removed from axillary drain on the same 2nd post-operative day while in Group B- Pectoral drain removed on 2nd post- operative day and negative suction was removed from axillary drain on 5th post-operative day. In Group C-Pectoral drain was removed on 5th post-operative day and negative suction was continued on axillary drain till its removal. In all the patients' axillary drain was removed once last 24 hour output falls below 30cc. Following discharge patients were assessed for seroma formation on OPD basis up to 1 month and seroma was managed with needle aspiration. Main outcome measure: Postoperative seroma formation, correlation of duration of negative suction pressure and timing of drain removal with period of seroma formed. Statistical methods used: Data was analysed using IBM SPSS STATISTICS version 20 using ANOVA, independent t-test, and correlation (Pearson's coefficient of correlation) test

Results: Incidence of seroma formation in our study was 40%. Axillary drainage of 1st two days correlated positively with subsequent seroma formation (p=0.044), however, total axillary drainage volume was not associated significantly with formation of seroma after removal of drains (p=0.137) Incidence of seroma formed (A= 48% vs. B=32% vs. C= 40%) as well as volume of seroma formed (A=143 cc v/s B= 173 cc v/s C=129 cc) was not related to duration of negative suction pressure and it was statistically not significant (p=0.672) amongst the groups. There is no added advantage of keeping pectoral drain for more than for 48 hrs, rather its presence increases the total drain output and subsequent in-patient stay (p

INTRODUCTION

Surgery has been the principal mode of treatment for management of the breast cancer and it has evolved from radical mastectomy to modified radical mastectomy and now to breast conservation surgery.[1] However, Modified Radical Mastectomy (MRM) is still the gold standard treatment for breast cancer and is the most common surgery performed in patients of breast cancer in India. Axillary lymph node dissection (ALND) performed up to level III during MRM is standard treatment for positive axilla.[2,3] Modified Radical Mastectomy is associated with several complications such as infection, hematoma, wound breakdown and flap necrosis. The complications like arm edema, decreased range of shoulder movements, paraesthesia of the medial arm and axilla, breast shoulder dysfunction and seroma formation are attributed to Axillary Lymph Node Dissection (ALND) performed during MRM.

Seroma formation is the most frequent postoperative complication seen after mastectomy with an incidence of 3% to 85% depending on the definition of seroma or assessment methods.[4]It is so common that it is now believed to be a side effect of surgery rather than a complication.In clinical practice, the term seroma is used for any collection created in dead space after any surgery. Different terminologies have been used regarding fluid collection in the dead space under flap and axilla after mastectomy. This fluid has been variously called as axillary drain fluid or seroma.In this study, the word axillary drain fluid is used for the serous fluid drained till the drains are in-situ while the word seroma is used for subcutaneous palpable collection of serous fluid which occurs under the skin flaps or in the axillary dead space once the drains are removed.

The origin of seroma remains unclear but several risk factors and predictors are age, breast size, co-morbid conditions, presence and number of malignant nodes in the axilla, extent of surgery and previous surgical biopsy; thus, leading to varying incidence of seroma in different studies.[5]It has been hypothesized that seroma form as an exudate from an acute inflammatory reaction following surgical trauma to increase serous fluid collection in response to increased fibrinolytic activity in serum and lymph.[6,7]

Seroma formation typically delays recovery and adds to morbidity such as increased length of hospital stay, delay in the initiation of adjuvant therapy, increased predisposition to wound infection, delayed wound healing and has also been linked to lymph edema of the arm and the over-stretching of the health budget**.** Although association with morbidity and financial problems are clear, the optimal ways to reduce the incidence of seroma formation are not well known. There have been various methods for preventing seroma collection, such as prolonged suction drainage, shoulder immobilisation, suturation of dead place, perioperative use of tranexamic acid, octreotide usage, dressing compression, tissue sealers, etc., but these methods for the prevention and treatment of seroma remain varied and inconclusive.[8,9]

Drains are important factor in affecting the hospital stay as the patients are often discharged only after their removal. It has not been proven that prolonged drainage prevents subsequent seroma formation. The use of closed suction drainage in patients who underwent mastectomy accelerates wound healing and is also associated with a lower incidence of wound infection, necrosis, and breakdown.[10,11]Closed suction drains have been widely practiced and usually two drains are placed: one under the flap in the pectoral region and one in the axilla to obliterate the space beneath skin flaps and thus to decrease seroma formation. The length of hospital stay after modified radical mastectomy mainly depends upon the drain management of the patient, although some surgeons advocate discharge with the drain in-situ. The appropriate duration of time needed to drain the axilla after modified radical mastectomy varies according to institution and surgical practices therefore still, there is no uniformity about number of drains to be placed after modified radical mastectomy and timing of drain removal. Drains are often left in place until the volume of drainage is minimal (<30 mL/ day).

Amongst various factors that influence the amount of postoperative drainage, the negative suction pressure applied to the drain has been reported to be of significance. While a high negative suction pressure is expected to drain the collection, and reduce the dead space promptly and prevent the seroma formation it may also prevent the leaking lymphatics from closing and ultimately leading to longer hospital stay. The present study has been conducted to correlate the timing of drain removal and effect ofduration of negative suction pressure on amount and duration of axillary drain fluid and seroma formation in patients undergoing Modified Radical Mastectomy.

MATERIAL AND METHODS

This prospective study was conducted in the department of surgery, Pt.B.D.Sharma PGIMS, Rohtak on patients of primary breast cancer who presented in the time period from September 2012 to December 2014. Seventy five patients of primary breast cancer having histologically proven invasive carcinoma of the breast in whom modified radical mastectomy (MRM) was planned were included in the study. Patients of primary breast cancer with metastatic spread, those who have received prior radiotherapy or who were planned for immediate breast reconstruction or breast conserving surgery were excluded.

The patients in whom breast cancer was suspected tissue diagnosis of carcinoma breast was established either by Fine Needle Aspiration Cytology (FNAC) or by Trucut biopsy. If patient had already underwent lumpectomy outside; the blocks and slides were reviewed in the institute to confirm the malignancy. Clinical TNM staging was done and metastatic work was performed depending upon clinical stage of the patient on outpatient basis. Patients of locally advanced breast cancer (LABC) were given neoadjuvant chemotherapy (CEF / Taxane based) before contemplating surgery.

Modified radical mastectomy was performed by the same surgical team using a standardized technique with electrocautery in all the patients. Axillary dissection was performed upto level III following Aushincloss method of axillary dissection, sparing both pectoralis major and pectoralis minor. Electrocautery was used to control all small blood vessels and lymphatics. Once adequate hemostasis was achieved, two silicone tube drains (Romson's 14 Fr) one in the pectoral region and one in the axilla were inserted intraoperatively in all the patients via two different stab wounds. The end of the axillary drain was placed in the top of the axilla and a flap drain was kept below the inferior flap. A single negative suction drain set (Romo Vac Set) was used and the two drains: axillary and pectoral were connected with a Y-connector to the negative suction drainage set. No attempts were made to close the dead space in the axilla or the breast wound by additional measures. Incisions were closed in a standard fashion using proximate skin stapler 35w and standard perioperative antibiotics were used in all the patients.

75 cases of modified radical mastectomy were randomised (using randomly ordered sealed envelopes, which were opened immediately before the closure of the wound)in three equal groups of 25 each, Group A and Group B served as study groups while Group C served as control. In group 'A' pectoral drain was removed on 2^{nd} post-operative day along with removal of negative suction on axillary drain on the same day. In group 'B' pectoral drain removed on 2^{nd} post-operative day but negative suction on axillary drain was removed on 5^{th} post-operative day. In the control group 'C' pectoral drain was removed on 5^{th} post-operative day and negative suction was continued on axillary drain till its removal. In all the patients, daily drain output was recorded and the axillary drain was removed once last 24 hour output fell below 30cc. Following axillary drain removal patients were discharged from ward and each patient had one scheduled OPD visits in the first postoperative week, and weekly thereafter or more frequently as needed. At each visit, the pectoral region and axilla was assessed for seroma formation and signs of infection.

The following information were recorded: age, sex, any comorbidity, BMI, clinical and pathologic stage, neoadjuvant chemotherapy, total amount of drainage post operatively, timing of removal of negative suction from drains, timing of drain removal, total duration of stay in hospital post operatively. For each patient we calculated total volume of seroma formed and number of aspirations done. Other complications, including hematoma, flap necrosis or wound infections were also recorded.

STATISTICAL ANALYSIS

Data was compiled and analysed using IBM SPSS STATISTICS version 20 using ANOVA, independent t-test, and correlation (Pearson's coefficient of correlation) test. For continuous variables the mean value and its range were evaluated. Categorical variables were described in terms of number and percentage of each subgroup. Pearson coefficient of correlation was used to evaluate linear correlations. Analysis of variance (ANOVA) is a collection of statistical models used to analyse the differences between group means and their associated procedures. ANOVA provides a statistical test of whether or not the means of several groups are equal, and therefore generalizes the t-test to more than two groups.

RESULTS

85 patients of carcinoma breast underwent MRM in our surgical unit during the time period from September 2012 to December 2014, out of which 10 patients were excluded from the study as per exclusion criteria. Remaining 75 patients were randomized into following three groups of 25 each depending upon the management of drains and duration of negative suction pressure used. Mean age of the patients in our study ranged from 24 years to 75 years. The mean age of patients in the present study was 50.92±11.21 years. Out of 75 patients, 3 patients (4%) were male and 72 female patients (96%). Overall 39(52%) patients were younger than 50 years. Mean BMI of the patients was 23.52$\pm$3.9. Majority of the

patients belonged to early stage disease as 44 patients out of 75 studied (58.67%) belonged to Stage I and Stage II. Approximately more than 30% of patients belong to stage III (locally advanced breast cancer). Out of 75 patients, 30 patients (40%) who belonged to locally advanced breast cancer received neoadjuvant chemotherapy (NACT). Out of 75 patients, 65.3% cases were positive for lymph nodes metastasis; average number of lymph nodes harvested in each case was 12.20±4.75 out of which 2.52±3.12were positive for metastasis. **Table I** shows the characteristics of patients in each group.

Table I: Characteristics of Patients In Each Group

Factors	Group A (N= 25)	Group B (N= 25)	Group C (N= 25)	Overall (N=75)
Mean Age (years)	51.80 (S.D=12.26)	50.44 (S.D=10.21)	50.52 (S.D=11.50)	50.92 (S.D=11.21)
BMI	22.52 (S.D=3.43)	23.88 (S.D=2.69)	24.16 (S.D=3.84)	23.52 (S.D=3.93)
Stage >Early Ca breast	12	15	17	44
>LABC	13	10	8	31
Upfront surgery	12	15	18	40
Post NACT	13	10	7	30
No. of nodes removed	11.68 (S.D=4.76)	11.56 (S.D=3.75)	13.56 (S.D=5.51)	12.20 (S.D=4.75)
No. of positive nodes	2.32 (S.D=3.19)	2.48 (S.D=2.88)	2.52 (S.D=3.12)	2.41 (S.D=3.03)
% positivity of nodes	64%	68%	64%	65.3%

The mean axillary drainage volume of 75 patients was 248.2±104.0 cc in first two post-operative days and 406.0±145.1cc on 5th post-operative day; while the mean total axillary drainage volume was 634.8±293.6cc. Axillary drains were removed on an average of 9.92±3.88 days and seroma formation after removal of the drain occurred in 30 patients (40%) in this study which was comparable to other studies in the available literature. The mean seroma volume was 148.8±107.02cc and mean number of aspiration required for seroma were 2.54±1.55. 30 patients (40%) had superficial to full thickness flap necrosis. Wound infection occurred in 11 patients (14.67%) and hematoma formation occurred in 2 patients (2.67%). See **Table II:**

Table II: Drainage Volumes, Hospital Stay and Complications in Each Group

Factors	Group A (N= 25)	Group B (N= 25)	Group C (N= 25)	Overall (N=75)
Mean Drainage vol. POD-2 (cc)	228.6 (S.D=110.7)	253.2 (S.D=105.7)	262.8 (S.D=106.6)	248.2 (S.D=104.0)
Mean Drainage vol. POD-5 (cc)	360.4 (S.D=145.3)	440.8 (S.D=163.7)	416.8 (S.D=126.2)	406.0 (S.D=145.1)
Mean Total drainage vol. (cc)	524.2 (S.D=258.0)	589.0 (S.D=243.4)	761.2 (S.D=329.7)	634.8 (S.D=293.6)
Mean duration of Hospital stay (days)	8.20 (S.D=1.89)	8.84 (S.D=2.01)	12.72 (S.D=5.14)	9.92 (S.D=3.88)
Seroma formed	12 (48%)	8 (32%)	10 (40%)	30 (40%)
Mean Volume of seroma (cc)	143.7 (S.D=104.2)	173.1 (S.D=130.0)	129.6 (S.D=86.9)	148.8 (S.D=107.02)
Mean no. of aspirations	2.36 (S.D=1.01)	2.67 (S.D=1.87)	2.60 (S.D=1.77)	2.54 (S.D=1.55)
Flap necrosis	8	11	11	30
Wound infection	3	5	3	11
Hematoma formation	0	1	1	2

DISCUSSION

Already at the beginning of the 20th century the first studies evaluating methods of reducing seroma formation after breast amputation surgery were conducted. In 1913 Halsted described a suturing technique of attaching a flap to the pectoral muscle fascia in order to reduce seroma formation. Drainage of the postoperative wound after modified radical mastectomy was first proposed by Murphy in 1947.[12] Despite a wide number of proposed options of seroma formation management, to date no optimal and fully efficient algorithm has been established. It appears that only comprehensive analysis of several factors influencing seroma formation may eventually allow the development of methods effective in reducing duration of seroma formation and hospitalization, improving patients' quality of life, decreasing the number of follow-up visits in the postoperative period and, as a result, reducing the overall costs of treatment. In the current study, it was found that age and body mass index are risk factors for prolonged axillary drainage volume. Seroma formation is not affected by age, BMI, stage of disease, neoadjuvant chemotherapy, presence of pectoral drain, duration of negative suction pressure and timing of drain removal, size of tumour, number of lymph nodes removed and positive status of lymph nodes. On correlating total axillary fluid drainage volume with age and BMI; (**fig 1 and fig 2)** it was observed that the total axillary fluid drainage volume increased constantly with increase in patients age and BMI, which was statistically significant (p=0.028 and p=0.031 respectively).

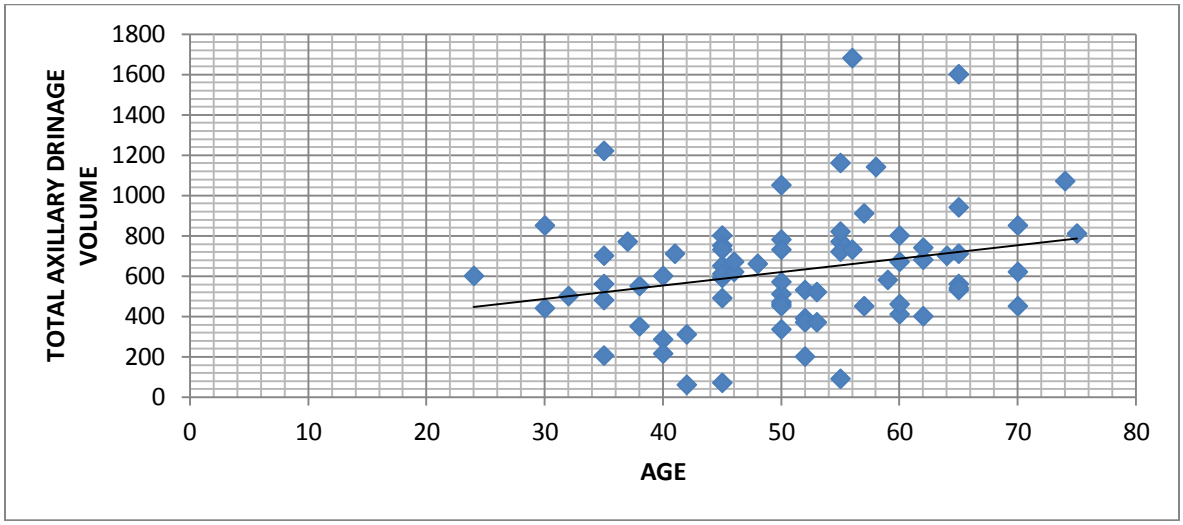

Figure 1: Correlation of Total Axillary Fluid Drainage Volume with Age (Pearson's Coefficient Of Correlation C=0.253 And P=0.028)

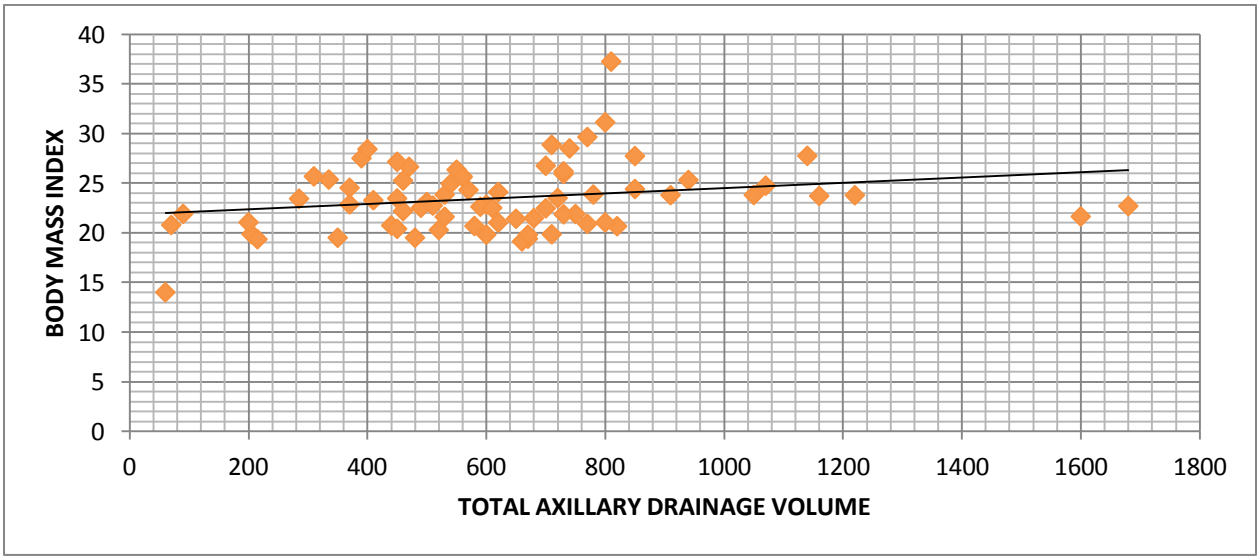

Figure 2: Correlation of Total Axillary Drainage Volume With BMI (Pearson's coefficient of correlation c=0.250 and p=0.031)

However, age and BMI were found to be weakly correlated with total volume of seroma formed and was statistically not significant (p=0.497 and p=0.380 respectively) **(fig 3 and fig 4)**. Thus, age and BMI are risk factors for high axillary fluid drainage volume but not for seroma formation showing aging and adiposity increases the probability of amount of axillary drainage volume. The available literature suggest that evidence is inconclusive for age and body mass index for seroma formation, nonetheless our results corroborated with the study of Douay et al and Banerjee D et al that obesity predisposes to increased auxillary drainage following nodal clearance.[13,14]

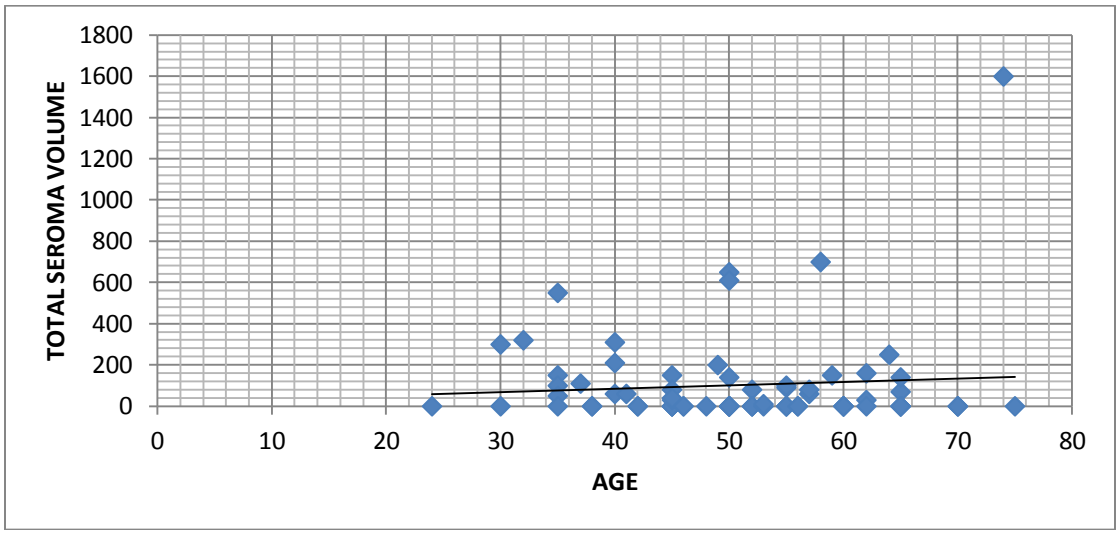

Figure 3: Correlation Of Total Seroma Volume With Age (Pearson's coefficient of correlation was c=0.080 and p=0.497)

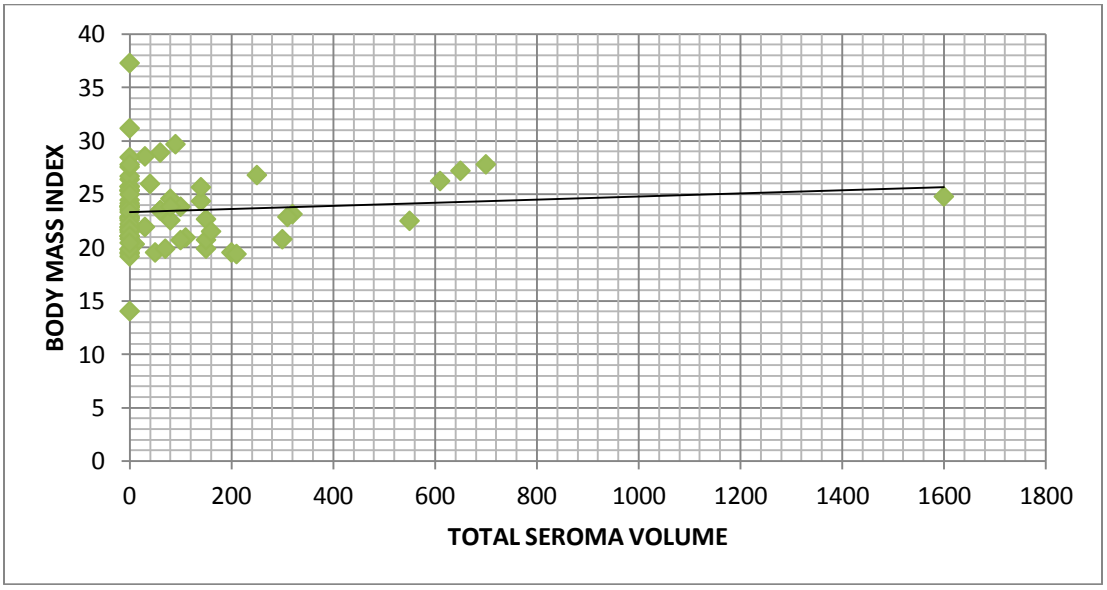

Figure 4: Correlation of Total Seroma Volume with BMI (Pearson's coefficient of correlation c=0.103 and p=0.380)

On correlating mean total axillary fluid drainage volume and mean total volume of seroma with stage of disease the difference amongst the patients presenting in various stages of breast cancer was statistically not significant (p=0.087 and p=0.081 respectively).Thus, stage was not associated with mean total axillary drainage volume or with volume of seroma formed. **(Figure 5).**

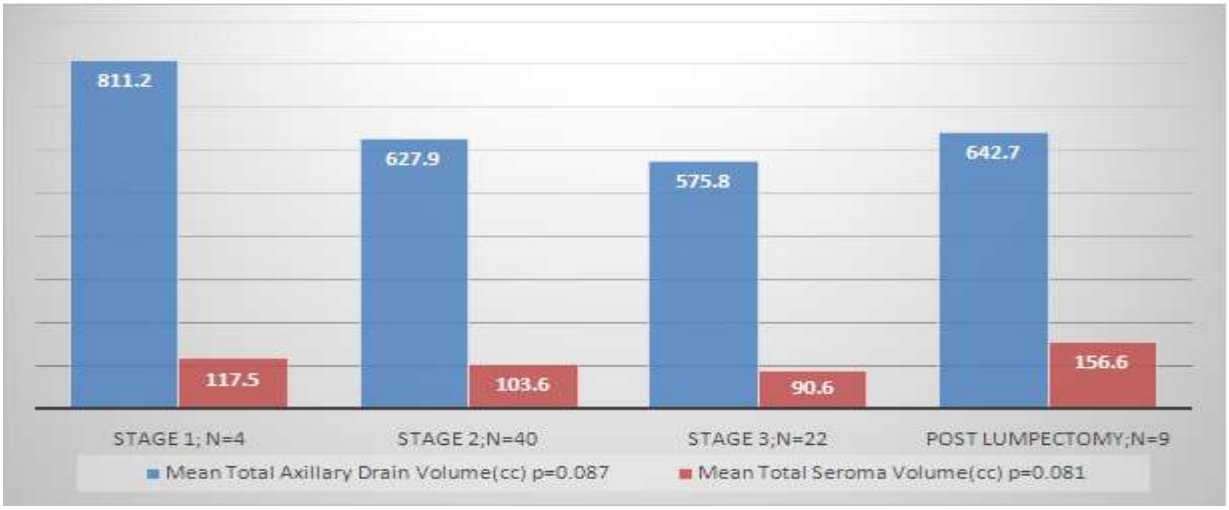

Figure 5: Correlation of Mean Total Axillary Fluid Drainage Volume and Mean Total Seroma Volume with Stage of Disease

Out of 75 patients, 30 patients (40%) who belonged to locally advanced breast cancer received neoadjuvant chemotherapy (NACT) (CEF or Taxane based) to downstage the disease. Mean Total Axillary Drainage Volume who received NACT was 668.8cc v/s 558.6cc in those who underwent upfront surgery; and the difference was statistically not significant (p=0.11). Similarly, Mean Total Seroma Volume in patients who received neoadjuvant chemotherapy was 99.3cc v/s 135.4cc in whom upfront surgery was done; the difference was again statistically not significant (p=0.31). Thus, neoadjuvant chemotherapy did not influenced total axillary drain volume and volume of seroma formed and same results were shown in an RCT by Forouhi et al [15] **(Figure 6)**

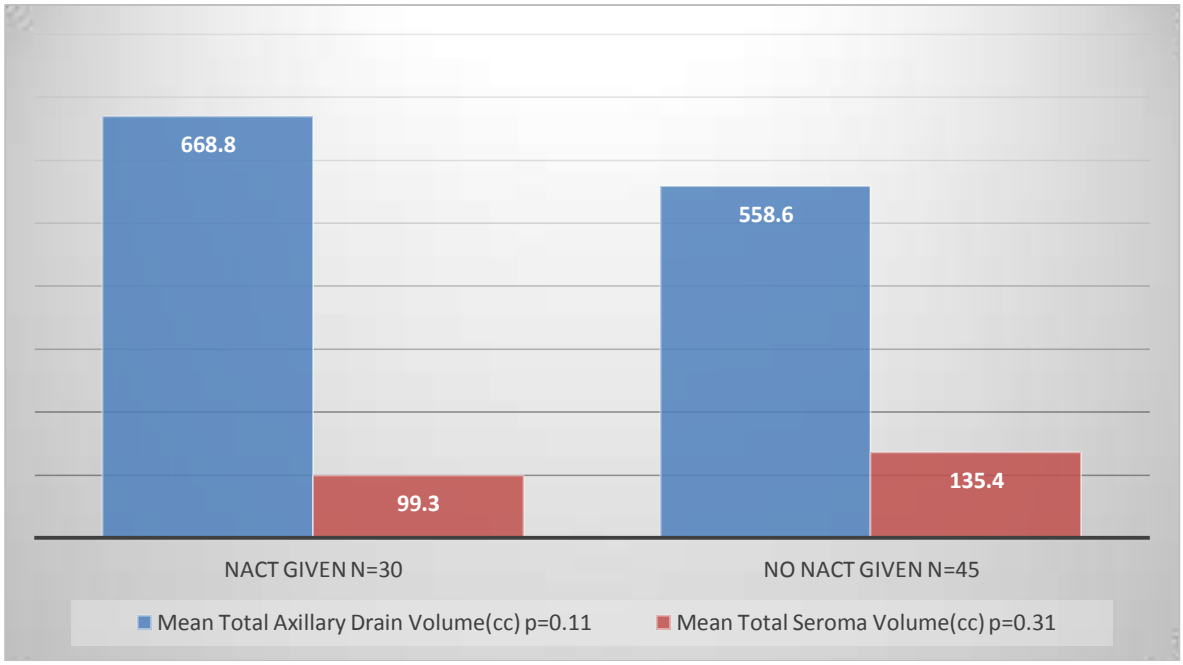

Figure 6: Correlation of Total Axillary Fluid Drainage Volume and Total Seroma Volume with Neo-Adjuvant Chemotherapy

When axillary drainage volume of first two post-operative days was correlated with total seroma formation the association was statistically significant (p=0.044) **(Figure 7).**However, when total axillary drainage volume (till the last day of drain removal) was correlated with seroma formation the correlation was weak c=0.173 and not significant p=0.137. Thus, axillary drainage volume of first two days predicted seroma volume. In previous studies, it has been shown that 48 hours

after surgery, as much as 74% of the total volume of seroma has been drained. It has also been observed that drains may be safely removed after axillary dissection, if the total drainage during the first 3 days is less than 250 mL.[16,17]

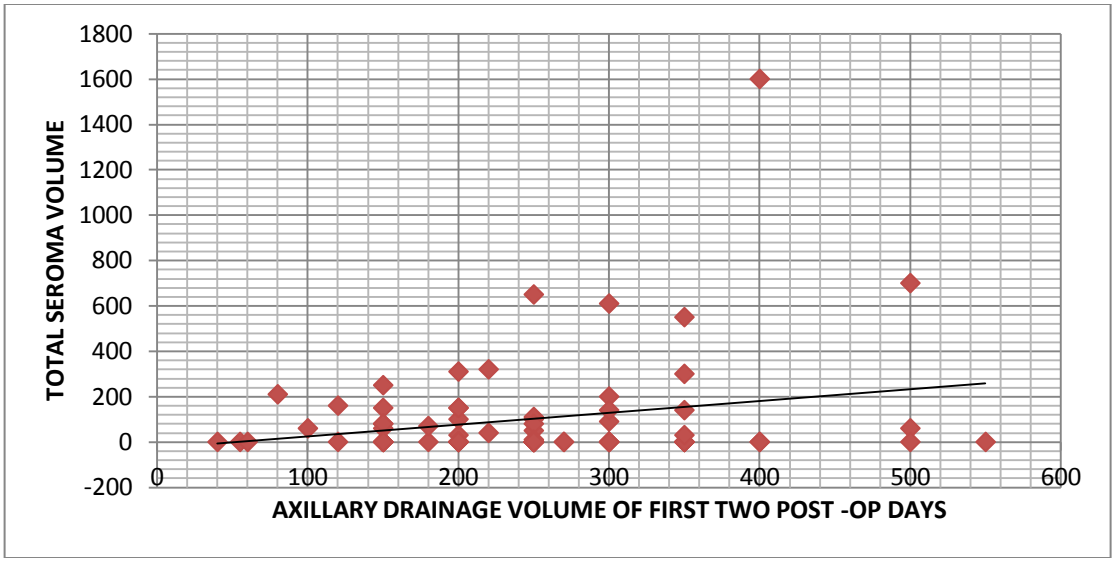

Figure 7: Correlation of Axillary Drainage Volume of First Two Post Operative Days with Total Seroma Volume

In the present study the patients were discharged after drain removal. Overall, the mean duration of hospital stay was 9.92±3.88days (range 5-35 days). In group A, mean duration of hospital stay was 8.20±1.89 days (range 5-13). In group B, mean duration of hospital stay was 8.84±2.01 days (range 7-16). In control Group C, mean duration of hospital stay was 12.72±5.14 days (range 8-15). Amongst groups, the p value was statistically significant between study and control groups ($p<0.01$ between A and C) and ($p=0.01$ between B and C), but was not significant ($p=0.113$) between Group A and Group B.

The total axillary drainage volume was found to be positively correlated ($c=0.671$) with the timing of axillary drain removal (duration of stay) which was statistically highly significant ($p<0.01$) reflecting patients having higher axillary drainage volume had drains-in-situ for a longer period of time. But when timing of axillary drain removal was correlated with total volume of seroma formed ($c=0.059$) it was found to be statistically not significant ($p= 0.615$) which meant that the timing of drain removal was not associated with subsequent seroma formation.

Several RCTs comparing timing of drain removal have provided complicated results. For example, in an RCT comparing removal of the drain on the fifth POD with removal on the eighth POD, the incidence of seroma formation was significantly high in the former.However, in that study, the drain was also removed when drainage volume fell to 30 ml or less per day for 2 consecutive days, and the actual day of drain removal between two groups was not provided.[18]In the study by Inwang et al. drains were usually removed at the 10th to 14th POD.[19]On the other hand, evidence was inconclusive when seroma formation was compared between drain removal on the first or third POD, and when drainage volume fell to a minimal level.In two RCTs, by Kopelman D et al and Dalberg K et al, showed early removal of drains increased seroma formation.[17,20]Whereas two other prospective studies, conducted by Yii et al and Talbot ML et al, did not find a significant association.[21,22]In addition, in a study by Parikh et al, there was no significant difference in the incidence of seroma formation between removal on the third POD and on the sixth POD.[23]

Overall, out of 75 cases of MRM, seroma formation occurred in 30 patients. Thus, incidence of seroma was 40% in our study.In Group A, seroma occurred in 12 patients (48%), while in group B seroma formation occurred in 8 patients (32%). In control group seroma formation was seen in 10 patients (40%). **(Figure 8)**The difference amongst the groups in terms of incidence of seroma formed ($p=0.693$) as well as in the volume of seroma formed ($p=0.672$) was statistically not significant. Thus, there was no association between incidence and volume of seroma formed with the duration of negative suction pressure. The result was consistent with other studies done by Britton BJ et al, van Heurn et al and Bonenna J et al who compared seroma formation with the duration of negative suction pressure, with the number of drains, or by the choice of closed suction drainage or passive drainage.[24,25,26]

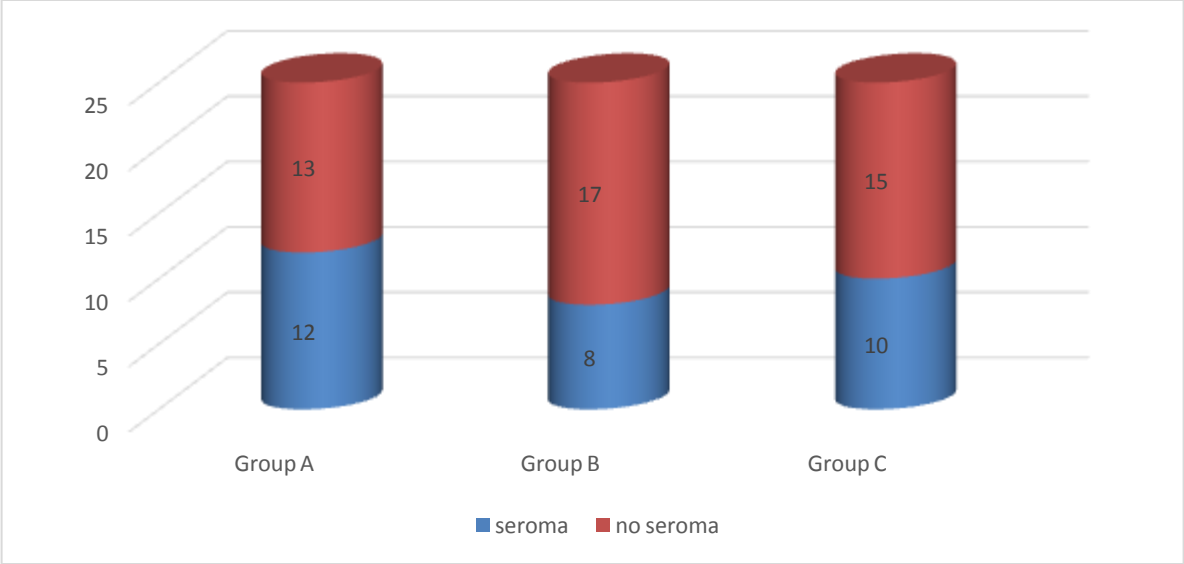

Figure 8: Incidence of Seroma Formation amongst the Groups

We studied whether prolonging the duration of pectoral drain conferred any added advantage over single axillary drain: the patients were divided in two groups. In group I (study group A and B), pectoral drain was removed earlier after 48hrs on POD2 and in group II (control group C) it was kept for 5 days. Following observation were made as shown in **Table III**:

Table III: Impact of Timing of Removal of Pectoral Drain between the Groups

	Group I: (groups A+B) Pectoral drain removed on 2 POD	**Group II: (group C) Pectoral drain removed on 5 POD**	**P value**
N	50	25	-
Mean drain Vol till POD 2	240.9±103.2cc	262.8±106.6cc	p=0.493
Mean drain Vol till POD 5	400.6±154.5cc	416.8±126.2cc	p= 0.458
Mean Total axillary drainage volume	556.6±250.7 cc	761.2±329.7cc	**p=0.01**
Avg. Time of Axillary drain removal	8.52±1.95 days	12.72±5.14 days	**p=0.04**
Seroma formed in	20(40%)	10(40%)	p=0.99
Mean seroma volume	158.4±117.1cc	129.6±86.9cc	p=0.672

On comparing the groups; the mean axillary drain volume on POD 2(240.9cc v/s262.8cc) and (p=0.493). Similarly, when mean axillary drain volume was compared on POD 5 (400.6 v/s416.8cc) and (p=0.458). Thus, the mean axillary drain volume up to 5th POD is not affected by timing of removal of the pectoral drain. However, when the total axillary drainage volume was compared between the groups (556.6cc v/s 761.2cc); the difference in both the groups I and II was statistically significant (p=0.01) which hinted that keeping the pectoral drain longer might have increased the total drainage volume. Similarly, when timing of axillary drain removal (post-operative stay) was compared between the groups (8.52 days v/s 12.72 days) it was also found to be statistically significant (p=0.04). Thus, there is no added advantage of keeping pectoral drain for more than for 48 hrs, rather its presence increases the total drain output as well as delays the axillary drain removal and increases the hospital stay of the patients.Similarly, patients of group II in whom pectoral drain was removed later on POD 5 fared no better than patients of group I in terms of incidence of seroma formation (40% in each group) or

volume of seroma formed (p=0.672, not significant). The choice of the number of drain tubes used has been studied. Two randomized trials by Petrek et al and Terell in which patients underwent MRM or BCS; it was reported that use of multiple drains does not confer any significant advantage on either the amount or duration of seroma formed.[27,28]

To assess the effect of duration of negative suction on axillary drain patients were again divided into two groups: group I (group A) in which negative suction was removed after 48 hours of surgery and group II (group B+C) with prolonged negative suction beyond 48hrs. Following observations were made as shown in **Table IV**:

Table IV: Impact of Duration of Negative Suction between Groups

	Group I: (group A) No Negative suction after 48 hrs	Group II: (group B+C) Negative suction pressure kept beyond 48hrs	P value
N	25	50	-
Mean axillary drainage Vol till POD 2	228.6±100.7cc	258.4±106.2cc	p=0.387
Mean axillary drainage Vol till POD 5	360.4±145.3cc	428.8±144.5cc	**p=0.01**
Mean total axillary drainage volume	524.2±258.0cc	675.4±286.5cc	**p<0.05**
Avg. Time of axillary drain removal	8.20±1.89 days	10.78±3.60 days	p=0.433
Seroma formed in	12 (48%)	9(36%)	p=0.623
Mean seroma volume	143.7±104.17cc	151.1±108.4cc	p=0.675

When the two groups were compared, patients of group I in whom negative suction was removed earlier (after 48 hours) had lesser axillary drainage volume on POD 5 (36O.4ccv/s 428.8cc) and (p=0.01). Similarly, mean total axillary drainage volume was also less in group I (524.2cc v/s 675.4cc) and (p<0.05). Thus, prolonged negative suction pressure increased mean drainage volume on POD5 and mean total axillary drainage volume calculated up to the last day of axillary drain removal.

When timing of axillary drain removal was compared between the groups (8.20 days v/s 10.78 days) and the difference in the timing of axillary drain removal was not statistically significant (p=0.433). Similarly, when impact of duration of negative suction pressure was seen on incidence of seroma formation (Group I=48% v/s Group II=36%: p=0.623)and on mean volume of seroma formation (143.7cc v/s 151.1cc: p=0.675); and the difference between the groups was not statistically significant. Thus, the duration of negative suction pressure had no impact on incidence of seroma formation and on volume of seroma formed.

Therefore, continuing negative suction pressure beyond five days increases daily and total drain output and prolongs hospital stay of the patient. When duration of negative suction is compared for 48 hrs, for five days and for the time till drain removal; it was observed that seroma formation is more if negative suction is kept only for two days (Group A seroma= 48%); then reaches a low (Group B seroma= 32%) when negative suction is kept for 5 days but there is no further advantage in extending its duration (Group C seroma= 40%).

Finally, it is concluded that age and body mass index are risk factors for prolonged axillary drainage volume. Seroma formation is not affected by age, BMI, stage of disease, neoadjuvant chemotherapy, presence of pectoral drain, duration of negative suction and timing of drain removal, size of tumour, number of lymph nodes removed and positive status of lymph nodes. Patients having high axillary drainage volume in first two post-operative days will subsequently have higher total axillary drainage volume as well as higher chance of seroma formation. Total axillary drainage volume has no correlation with formation of seroma after removal of drains. There is no added advantage of keeping pectoral drain for more than for 48 hrs, rather its presence increases the total drain output and subsequent in-patient stay. Therefore, pectoral drain should be removed after 48hrs. Prolonged negative suction pressure beyond five days increases daily and total drain output and prolongs hospital stay of the patient but does not effects the seroma formation after drain removal. Therefore, it is advised that axillary negative suction should be kept till five days only.

In view of above results further studies with a larger sample size is advised to study the effect of early drain removal without taking <30ml drainage volume in last 24 hrs as a drain removal criteria, as seroma formation occurred with approximately equal frequency irrespective of fact whether negative suction was kept for five days or more.

ETHICAL JUSTIFICATION

Patients of breast cancer who were included in the study underwent Modified Radical Mastectomy will Level III axillary dissection and after surgery, were managed in ward as per the group protocols and thereafter followed in OPD for further management and recovery. No unethical tests or procedure were employed during this study. The entire study was undertaken only after getting informed consent from the enrolled patients.

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