"A PROSPECTIVE STUDY OF FACTORS INFLUENCING SEROMA FORMATION IN MODIFIED RADICAL MASTECTOMY "

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MAY - 2020

CERTIFICATE

This is to certify that this dissertation tilted **"A PROSPECTIVE STUDY OF FACTORS INFLUENCING SEROMA FORMATION IN MODIFIED RADICAL MASTECTOMY"** is bonafide record of work done by **Dr R SARAVANAN**, during the period of his post graduate study from May 2017 – April 2020 under guidance and supervision in the department of general surgery, Kilpauk medical college, Chennai, in partial fulfillment of the requirement for **M.S. General surgery** degree Examination of the Tamilnadu Dr MGR Medical University to be held in MAY 2020.

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DECLARATION

I, Dr R SARAVANAN hereby declare that this dissertation "A STUDY OF FACTORS PROSPECTIVE **INFLUENCING SEROMA** FORMATION IN MODIFIED RADICAL MASTECTOMY" is a bonafide, genuine research done by guidance work me under the of Dr.V.VIJAYALAKSHMI, PROFESSOR OF DEPARTMENT THE OF GENERAL SURGERY, GOVT. KILPAUK MEDICAL COLLEGE, Chennai

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Dr. R SARAVANAN

ABBREVIATIONS

ALND	-	Axillary Lymph node dissection
BCS	-	Breast Conservation Surgery
MRM	-	Modified radical mastectomy
DCIS	-	Ductal carcinoma in situ
EC	-	Electrocautery
ER	-	Estrogen Receptor
FAL	-	Functional Lympadenectomy
IDC	-	Infiltrating Ductal Carcinoma
ILC	-	Infiltrating Lobular Carcinoma
LCIS	-	Lobular carcinoma in situ
LN	-	Lymph nodes
LVI	-	Lymphovascular Invasion
MRM	-	Modified Radical Mastectomy
NAC	-	Neoadjuvant Chemotherapy
NS	-	Not Significant
PR	-	Progesterone Receptor
RCT	-	Randomized Control Trial
SLNB	-	Sentinel Lymph node Biopsy
US	-	Ultrasonic Scalpel
PM	-	Pectoralis major

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The Proposal is APPROVED.

The Institutional Ethical Committee expects to be informed about the progress of the study any Adverse Drug Reaction Occurring in the Course of the study any change in the protocol and patient information /informed consent and asks to be provided a copy of the final report.

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Instances where selected sources appear:

EVOLUTION OF SURGICAL TECHNIQUE

Hippocrates : associated breast cancer with cessation of menstruation, **Leon ides** is acknowledged to be the 1 st operative treatment for breast malignancy.

Andreas Vesalius (b. 1514), Flemish physician, advised mastectomy for breast cancer and practiced the use of sutures than cautery to control bleeding.Servetus, advised that the underlying muscles (pectoralis major & minor) to be removed as well as the axillary glands.

Wilhelm Fabry (b. 1560), the, Father of German Surgery, devised an instrument for mastectomy as shown in figure 1.

Mitchell Banks of Liverpool, in 1877 practised removal of axillary glands in all cases of breast cancer.

Dr. Joseph Pancoast, was first **to show** enblock removal of axillary glands as shown in figure 2

The rationale for the Halsted radical mastectomy was largely to achieve loco regional control of the breast malignancy.

In contrast to the Halsted radical mastectomy, the modified radical mastectomy defines a surgery of complete breast removal, with the inclusion of the tumour, overlying skin, and axillary lymphatics, with preservation of the pectoralis major muscle.

Murphy in 1912 had stopped Halsted radical mastectomy and started preserving pectoral muscles. This was based on the experiences of **Bryant**.

The Consensus Development. Conference on the management of breast malignancy in 1979 stated that the modified radical mastectomy was the standard of treatment for women with stages I and II breast cancer⁴

Figure 1: Mastectomy instruments of Fabry von Hilden in late. sixteenth century.

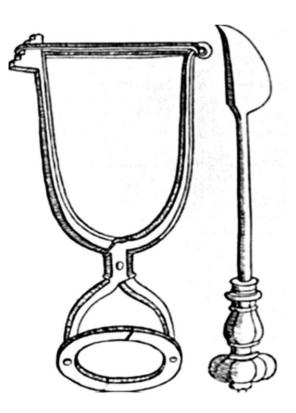


Figure 2: Mastectomy (1844) of Dr. Joseph Pancoast in the preanesthetic and pre antiseptic era En bloc removal with axillary lymphatic drainage



INTRODUCTION

The term breast is derived from **latin** word mamma (cf. mammal from latin mammalis "of the breast "). Breast are modified sudoriferous glands, composed of glandular, adipose, and connective. tissues.

Breast cancer is the commonest malignancy in women affecting one out of eight women worldwide and ranks among the top ten causes of death in women.^{1,2} Breast cancer ranked number one cancer among indian females with age adjusted rate as high as 25.8 per 100,000 women and mortality 12.7 per 100,000 women.

More than a million cases are diagnosed each year, rise in incidence is due to increased life span, life style changes and improved survival from other illness, and better investigation to diagnose early breast malignancy. It forms thirty three percent of all female cancers and for twenty percent of cancer related deaths in women.

Almost half of all patients with a palpable primary breast cancer will have lymph node metastases at presentation compared with only one fifth of those with a non palpable cancer detected on mammography.² In majority of patients with breast malignancy, excision of the tumour with (ALND) remains the standard treatment for invasive breast cancer³ Metastases in axillary lymph nodes is the most determinant of prognostic factor in patients with primary breast malignancy.

Almost all patients develop patches of numbress or paraesthesia and many patients develop reduced shoulder mobility and chronic lymphoedema.⁴ Seroma is an abnormal accumulation of serous fluid in the dead space of axilla, the breast following breast-conserving(BCT) surgery and is the commonest sequel.

The incidence of seroma formation varies between 5 and eighty five per cent.^{4, 9, 14-20} Seroma can increase the morbidity, prolong the hospital stay, need for multiple aspirations, wound gaping, erythema, delay the chemotherapy cycles.⁴

The type of surgery, the operating surgeon, preoperative radiation or chemotherapy, the amount of post operative physical activity, use of electrocautery, use of closed suction drains and closure of dead space have been implicated as potential factors influencing the likelihood of seroma formation.⁴⁻⁷

Constant chest wall movement due to respiration and shoulder use creates shearing forces that delay flap adhesion.⁵ For this, several techniques of

flap fixation or wound drainage, limitation of postoperative shoulder movement and the use of adhesive glue have been investigated to improve primary healing and minimize seroma formation.⁶

To reduce the incidence of seroma formation, it is essential to estimate individual risk for seroma formation, and future trials should be aimed at identifying predictive variables and thus reduce the incidence of seroma.

REVIEW OF LITERATURE

DEFINITION

There are various definitions for seroma as published in many article ,**Classe et al**⁷ defined axillary seroma as a palpable fluid accumulation causing discomfort and needing aspiration.

Woodworth et al⁸ during a retrospective analysis defined seroma as a clinically identifiable collection of serous fluid within a surgical cavity. They treatedseromas with serial aspirations until no further fluid collections are detected.

Nadkarni et al⁹ defined the presence of postoperative seroma as a need to aspirate serous fluid from the axillary cavity more than once,or, 2 or more times after removal of the axillary drain.

Benjasirichai et al¹¹defined postoperative seroma as any collection in the axilla that was detected by ultrasonography 2 weeks after the patient was discharged.

Hashemi et al¹⁰ defined axillary seroma as any clinically apparent fluid collection in the axilla or under skin flaps .

SEROMA INCIDENCE

Seroma frequency varies between 5 & 85%.^{3, 9, 14-20}

Table 1: SEROMA INCIDENCE

Authors	Study Type	Surgery	Patients(n)	Incidence (%)
Chen et. al, 1998 ¹⁵	RCT	MRM,BCS	40	4.8
Gupta et. al, 2001 ¹⁶	RCT	MRM	121	48
Purshotham .et al, 2002 ¹⁷	RCT	MRM,BCS	375	51
Jain. et al, 2004 ¹⁸	RCT	MRM,BCS	116	26
Lumachi .et al, 2004 ¹⁹	RCT	MRM,BCS	92	40
Unalp. et al, 2007 ²⁰	Retrospective	MRM,BCS	119	14.3
Nadkarni .et al, 2007 ⁹	RCT	MRM,BCS	160	84.7

PATHO PHYSIOLOGY

Seromas are collection of lymph exudates or "serum" in cavities, invariably due to surgery and healing process of inflammation.^{14,22} Continuous chest wall and shoulder movements disrupt the flap opposition to chest wall.²⁴

Bonnema et al²⁵ showed that the fibrinogen level in seroma was very low compared with plasma on day 1 but on day 5 and 10 post operatively it was virtually undetectable, and that peripheral lymph does not clot and contains only a trace amount of fibrinogen.

Oertli et al¹⁴presumed that fibrinolytic process leads to seroma formation. **Tadych and Donegan²¹**believed that seroma is due to the leakage of lymph from disrupted lymphatics in the axilla. Extensive manipulation and to the tissues creating a raw area in (MRM) leads to seroma formation from severed blood vessels & lymphatics and compared to (BCT) which produces less seroma.²² Ideal closure of wound will reduce lymph spillage& serum ooze, will approximate flaps to the underlying structures appropriately thus eliminating the dead space.³

FACTORS AFFECTING SEROMA FORMATION

Seroma is considered to be a side effect of surgery than a complication ,it can lead to significant morbidity like wound dehiscence, delay in initiation of adjuvant chemotherapy. **Kuroi et al²⁸**, review included one Meta analysis, 51 RCTs, 7 prospective & retrospective. They divided the risk factors for seroma formation into four categories: Patient and tumor characteristics, Surgical Factors, Post operative management, Non Surgical Modalities.

PATIENT AND DISEASE FACTORS

The incidence of seroma has been shown to correlate with patient's age,breast size, and hypertension, presence of malignant nodes in the axilla,number of malignant nodes, previous surgical biopsyand use of heparin^{19, 28, 29} patients who received chemotherapy before surgery had problems of wound healing and increased seroma occurence.⁸

Gonzalez et al²⁷observed that neo adjuvant chemotherapy did not affect seroma occurrence.

Kumar et al²⁹ found a significant association b/w BW and HTN with seroma but no association between nodal status or positivity of lymph nodes, hormone receptor status and stage with seroma formation there was no corelation with other factors such as ,DM , size of the breast, grade of the tumour side

Table 2: Association of Patient and Disease factors with Seroma formation²⁸

Patient Factors	Association	Disease Factors	Association
Age	Inconclusive.	Disease Stage	
Menstrual Status		LN Status.	_
Side/Tumor location		Tumor size	Inconclusive
Hypertension		.Histological type	—
Diabetes		Grade	—
Body weight	**- -\$-	Specimen size/weight.	—
Anemia.	_	Pathological Tumor size LN positivity.	 Inconclusive
Breast size	—	Hormone Receptor Status	—
NAC/ Prior Biopsy/RT	_		
BMI/Obesity	Inconclusive		

- # = Increases seroma formation
 - = No definite association

SURGICAL FACTORS

Type of Surgery

Seroma incidence is lower after BCS than MRM^{9,27} sentinel lymph node biopsy has prevented larger dissections thus in BCS seroma is less.

Woodworth et al⁸proved that reconstruction following MRM decreased seroma formation. There was no correlation seen with preserving pectoral fascia ³⁰.

AXILLARY DISSECTION

Time and again large number of studies have proved there is no correlation with number of axillary lymph nodes removed and seroma.^{27, 31-33}

Purushotham et al³² in the RCT involving 298 patients with early breast cancer who were clinically node negative, patients were randomly allocated to undergo ALND (control group) or SLNB followed by ALND if subsequently. found to be lymph node positive (study group) (SLNB) is associated with very less seroma & morbidity than ALND.

Its been demonstrated that a long procedure time and diagonal skin incision as compared to vertical skin incision increased seroma .^{28,34}

Table 3: Association of operational factors with seroma formation²⁸

Increases Seroma	Decreases Seroma	No Association	Inconclusive Evidence
Extended RM	Ultrasonic	Extent of LN	Surgeon
Diagonal Skin Incision	Dissection Immediate Breast. Reconstruction	Dissection Removal of pectoral Fascia	Pressure. Garment/ Compression dressing
Operation time	Suture Flap fixation	Type of Anesthesia	MRM Vs BCS
Electrocautery	SLNB Vs ALND	Laser Scalpel	Skin graft
		Adhesive Glue Blood loss	

SURGICAL TECHNIQUE/ INSTRUMENT

Tissue handling & dissection play a vital role in determining the occurrence of seroma. It is learnt that proper tissue handling and to minimize the bleeding and trauma to lymphatics can prevent seroma formation.³

Electro cautery has its own advantages of short duration, with less amount of blood loss but has its own problems of wound complications & seroma as shown by **Porter et al**³⁵ and **Keogh et al**³⁶ through RCTs However, studies **by Unalp and Onal**²⁰ **and Nadkarni et** al⁹ have failed to show any statistically significant difference in seroma formation between knife dissection and electrocautery dissection **Irshad and** .**Campbell**³⁷said harmonic scalpel reduced seroma formation.

Lumachi et al¹⁹ randomized ninety-two women to undergo axillary dissection by either using ultrasound scissors (Group A, 45 patients) or not (Group B, 47 patients). Twenty-eight patients developed wound seroma In patients with ultrasonic dissection drains were removed earlier.

Kontos et al³⁹prospectively randomized 32 patients who underwent modified radical mastectomy to either HS or electrocautery (EC) First 48 h drainage, total drained volume, aspirated volume, complications and required analgesia were comparable in the two groups and concluded that no significant reduction in seroma formation or wound complications and pain could be found with the use of HS.

Kerin et al⁴¹ failed to show the difference in postoperative seroma drainage between argon-enhanced electro surgery and conventional diathermy.

Table 4: comparative studies between , electrocautery and Ultrasonic

dissection

Authors	Type of Study	Total Patients	Surgical Technique. (No. of patients with seroma)	P value
Porter et al, 1998 ³⁵	RCT	80	EC(38) Vs .Sharp(13)	0.01
Galatius et .al, 20030 ⁴²	Comparative	59	Sharp(69) . Vs US(67)	NS
Lumachi. et al, 2004 ¹⁹	RCT	92	Sharp. (42) Vs US(20)	NS
Nadkarni .et al, 2007 ⁹	RCT	158	EC(68) Vs .Sharp(59)	NS
Unalp et. al, 2007 ²⁰	Retrospectiv e	119	EC(12) Vs. Sharp(5)	NS

Sharp = dissection with sharp scissors Laser = dissection with argon laser

DRAINS

Frequently drains are used after breast cancer surgery with the understanding that it will reduce seroma formation. The mechanism proposed is that the suction helps skin flaps to adhere to the underlying structure & axilla sealing off all leaking lymphatics. And thus, may facilitate wound healing, decrease wound infection, flap necrosis and prevent seroma formation.³

Drain Vs. No Drain.

Talbot and agarey⁴³ evaluated prospectively three groups of consecutive patients with breast cancer having axillary lymph node clearance. In the delayed removal group, 30 patients had total or partial mastectomy with axillary dissection, followed by closed suction drainage until the fluid output was < 50 mL in 24 h. In the early removal group, 30 patients had the same procedures, except that the drains were removed 2 days postoperatively, irrespective of the volume of drainage. In the 'no drain' group, 30 patients underwent partial mastectomy and axillary clearance without inserting any drain. Patients without drain needed more serial aspiration. The aspiration in each group being 2.1, 2.9, and 3.9, respectively. The observed that earlier removal of drain following ALND got discharged earlier with not much of wound infections.

Jain et al¹⁸ randomized 116 patients undergoing MRM to receive suction drainage or no drain . There was a significant reduction in hospital stay and postoperative pain scores in patients who did not have a drain. Following mastectomy without a drain, the use of fibrin sealant reduced seroma formation(P< 0.012). They observed that drains did not prevent seroma formation.

Single vs many Drains.

Terrell and Singer in 1992⁴⁴randomized 84 women undergoing (MRM). 37 patients had one axillary drain and 47 had two drains placed postoperatively, one in the axilla and the other beneath the pectoral flaps. The average total drainage was 870.4 mL per patient in the group with single drain and 997.4 mL per patient in the group with two drains and the overall complication rate was 35.0 percent and 31.9 for single drain group and two drain groups respectively. These differences did not reach statistical significance. They concluded that use of a single axillary drain after MRM seems to result in no increase in postoperative complications, may reduce the incidence of flap necrosis.

Petrek et al⁴⁵ in their study randomized 65 patients with carcinoma to two groups, single or multiple drains. For axillary dissection, randomization to multiple drains meant placement of four catheters in the axilla, and randomized to the single drain, one catheter in the axilla. Multiple drains didn't confer any added advantage to single drain over amount & duration of .fluid drainage.

Suction vs Passive drain

Traditionally, wound drainage was done using static drains, such as tube or Penrose drains. However, since the development of continuous closed suction drainage in 1947 by Murphy⁴⁶, closed suction drainage has superseded static wound drainage, as this increases freedom of movement, decreases need for bulky dressings and the incidence of infection is drastically reduced and requires less time for nursing care.

Nadkarni et al⁹ randomized 160 patients with breast malignancy, This enabled them to know the effect of 2 different factors use of scissors/electro cautery and suction/corrugated drains on the occurence of postop seroma formation. They concluded that the use of different surgical methods or drainage has no effect on the postop seroma formation.

Low pressure Suction vs High-pressure drain

The negative pressure on the suction drainage has been found to be significantly influence postoperative drain output , a high negative suction drain may disrupt the severed lymph vessels from sealing off thus leading to prolonged drainage leading to increased hospital stay.⁴⁷

Wedderburn et al⁴⁸ compared the use of low pressure and high pressure drains in 69 patients following mastectomy and axillary clearance. The results revealed no statistically significant difference between the two groups of patients (P>0.05) in terms of daily drainage. **Bonnema etal**⁴⁹ compared effect of negative pressure on fluid production RCT in 141 patient. Not much difference noticed b/w the low & the high Vacuum group in volume and duration 9.5 vs 10 days of seroma production, There was **a positive correlation b/w BMI and seroma**.

Early Drain removal vs Late Drain removal

Many surgeons removed drain when it is less than 20–50 mL in the preceding 24 hr , which delayed their discharge, causes discomfort to the patient, and increased the overall costs.^{16,21,51-55} This also delays starting on adjuvant radiotherapy or chemotherapy and wound healing Prolonged. drainage may also increase the hospital stay and the risk of infection by allowing retrograde migration of bacteria. Indiscriminate or premature withdrawal of postoperative drains irrespective of the amount of fluid drained may be accompanied by an increase in the incidence of axillary seromas.⁵¹⁻⁵⁴

Gupta. et al¹⁶ randomized121 patients into five-day group (n=64) and eight- day group (n=57). They concluded that 5-day post-operative drainage is as safe as 8-day post-operative drainage in the management of patients undergoing major breast surgery, but results in an increase in seroma aspiration and aspiration volume

Parikh et al⁵²randomized 100 patients having undergone (MRM) to either drain removal at 3 or at 6 days. post-operatively more seroma occurred in the group whose drain was left in situ longer.

Liu and McFadden⁵³ studied 50 consecutive patients undergoing a standard breast conservation surgery & ALND for breast cancer. The axilla drained with 7-Fr suction drain drains were removed after POD 1 & prior to discharge from the outpatient surgical center. No complications were seen in all 50 patients This short-term method reduced the incidence & the morbidity of seroma formation.

Baas-Vrancken Peeters et al⁵⁴ conducted an RCT comparing twenty fourhr to long-term drainage. Mainly duration in hospital stayed was taken into account and followed by seroma and its complications. Each group had 50 patients.In 24 h drainage , short stay in hospital noted(2.5 vs., 4.6 , P < 0.001). They observed that 24 h drainage following ALND is economical and free of wound complications and seroma formation compared to long term drainage.

Dalberg et al³⁰ studied the results from a multicentre randomized trial which included 247 patients had undergone (MRM) five Swedish hospitals between 1993 and 1997. Of these 247 patients a total of 198 patients were supposed to have the drain removed 24 h later or to keep the drain till < 40 ml / day discharge. earlyremoval had more chances of seroma formation(48% vs. 20% P < 0.001) and a shorter stay in hospital(2.8 days vs. 4 days, P < 0.001)

The evidence in established works opined in favour of early drain removal with less wound complications .

EXTERNAL COMPRESSION DRESSING

The use of pressure garment or compression dressings is to reduce the dead space by giving an external force onto the flaps and to facilitate flap attachment to underlying muscle, and thus reduces the seroma formation.

Chaturvedi⁵⁷used external compression and found less seroma occurence. He used 6" crepe bandages, which were applied circumferentially around the chest wall, immediately after the operation with the opposite breast was included in it.

Chen et al¹⁵ in their study randomized 41 patients with breast cancer to get pressure garment to be used after surgery or not. The garment was worn from the 1st post-op day up to 14 days. They found no added advantage in post-op drainage with the use of a pressure garment. More problems were seen with the patients without pressure garments seroma occurred in patients not using the garment. The use of the pressure garment appeared to increase the duration of use of the drain (6.8 vs. 6.1 days), these differences in the two groups was not significant.

O'Hea et al⁵⁸ in an RCT randomized 135 patients undergoing surgical treatment for breast malignancy to receive a external compression or conventional dressing. Dressing remained till postop day 4 Patients in the standard dressing were done with a front-fastening Surgibra only. Drains were taken out when the drainage was < 50 cc only. Duration of drains in both the groups were almost **similar**. The external compression dressing did not give any additional **advantage to prevent seroma formation**, frequent use of a compression in all cases to reduce postoperative drainage after ALND for breast cancer is not warranted.

Kontos et al⁵⁹ compared 200 patients who had undergone MRM were given external compression on the skin flaps and the axilla immediately (group A) with a patients of no external dressing group (B). Drains were removed when drain output< 30 ml per day, or on post op day 8. Mean time with drains kept in situ were 4.9 and 5.5 days in groups A and B. The differences seen were significant. They concluded that these findings are supportive of pressure dressing as an effective method to reduce seroma formation .

Unalp and Onal²⁰, in their retrospective analysis of 119 patients observed out of 101 patients who were given compression dressing postoperatively, 12 developed seroma whereas five patients developed seroma out of the 18 patients who did not use compression dressing. The P value of 0.158 was not significant and they concluded that compression dressing was not a factor that reduces seroma formation

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Figure3 : Application of Compression Bandage – Technique

Sterile gauze pads kept over the surgical wounds

Authors	Type of Study	Patients (n)	Study Method	P value
Chen. et al, 1998 ¹⁵	RCT	40	Pressure Garment (0) Vs None (5%)	NS.
O'Hea. et al,1999 ⁵⁸	RCT	135	CD Vs .Normal Dressing	CD > Normal. (P<0.01)
Unalp. et al,2007 ²⁰	Retrospect	119	Pressure Garment (12%) Vs None (28%)	NS.
Kontos. et al, 2008 ⁵⁹	Comparati ve	400	Pressure Garment (2.5%) Vs None (16%)	Significant.

 Table 5: Obliteration of dead space by external pressure

NS = Not Significant

CD = Compression Dressing



Elastoplast bandages applied with pressure covering Ipsilateral Hemithorax in

layers



Post application of Compression dressing

SUTURING OF SKIN FLAPS

Larsen .et al⁶¹ used subcutaneous suture to fix the flaps to the deep muscles and fascia with 35 to 50 fine cotton sutures after (MRM) with external pressure dressing. This procedure gave good cosmetic result and with less morbidity and faster recovery and drastically reduced seroma formationand drains were removed earlier than other patients.

<u>Chilson</u>et al³¹ used a flap tacking Procedure that closes the axillary fossa dead space and tacks the mastectomy flaps to the chest wall. This study in (MRM) demonstrated a significant decrease (25.4% vs. 38.6%, P = 0.038) in the incidence of seroma when flap tacking was performed. They opined that the flap tacking procedure reduced post mastectomy seromas, (P < 0.0001).

Schuijtvlot et al^{62} in a prospective audit 97 patients following breastconserving surgery for carcinoma with axillary dissection found that the use of an additional buttress suture inserted between the axillary skin and the chest wall decreased the occurrence of seroma from 52% to 24% (P<0.007). The buttress suture was a no. 1 size prolene suture was placed through the axillary skin, passed into the Serratus Anterior muscle on the chest wall, thus obliterating the axillary space.

In the RCT by **Hamy et al**⁶³, axillary padding with FAL gave satisfactory cosmesis, reduced seroma occurrence (27% vs. 80%, P<0.001) in patients undergoing BCS without axillary drainage.

Prospective study by **Classe et al**⁷,100 women were randomly allocated to two groups, axillary padding without drain (n=47) or axillary suction drain (n=51). In the axillary padding group, the length of hospital stay was significantly reduced from $4.5(\pm 2)$ days to $1.8(\pm 1)$ days (P <0.001).

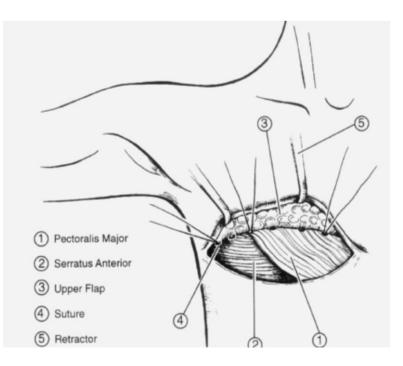
Coveney et al⁶⁴ in RCT involving 39 patients undergoing (MRM) were randomized to undergo flap fixation to underlying muscle or conventional skin closure. Drainage had reduced significantly than in skin closure patients (P < 0.05) in the group with flaps fixed ,in flap sutured group few developed seromas, 5 (25%) vs. 17 (85%), P < 0.001. They concluded that suturing skin flaps to underlying muscle reduces local morbidity

In the RCT by **Purushotham et al** ¹⁷, 375 patients undergoing surgery for breast malignancy were segregated to conventional surgery or suturing of flaps with no drain Patients segregated to control arm had 2 suction drains mastectomy flap which were removed, once volume was<fifty ml/day or at post op day 5, whichever occurred earlier. In the study arm, the flaps were fixed to the underlying PM muscle and Serratus anterior muscles with multiple 3 - 0 Vicryl sutures , starting at the apex of the axilla and cephalic aspect of upper flap Long thoracic nerve was secured. No sutures were inserted in the cavity of the breast following wide local excision. The results revealed a significant reduction in hospital stay.

Subscapularis m.

Figure 4: Dead space after Axillary dissection¹¹

Figure 5: Suturing of dead space after mastectomy¹⁷



POST OPERATIVE FACTORS

Shoulder Exercise

Shamley et. al ²³, in a study of delayed vs early postoperative exercise following (MRM), showed that evidence from 12 RCT recommend the use of delayed exercise (P = 0.00001) to reduce seroma formation. Delayed shoulder exercise is much more better than immediate post operative exercise at reducing seroma and there is no evidence that it will derange shoulder movements .

Drain Output.

Barwell et al⁵¹ compared 63 patients after BCS (n = 37) or MRM (n=26). Suction drains were removed after a median of 4 days . In all, 32 patients (51%) later developed seroma requiring needle aspiration. Seroma formation was associated with a larger total suction drain volume. The median yield of axillary lymph nodes was significantly greater in those who developed seromas (11 vs. 8; P< 0.002). There was not much change in the volume drained 24 h preceding drain removal (mean 60 ml vs. 50 ml). Thus, they observed that longer in situ drains was not much useful to prevent seroma formation.

Kopelman et al⁴⁷in a RCT trial defined the correct time to remove the drain after MRM 90 patients 42 were randomized to have the drain removed on postoperative day 3, and the rest to keep it till <35 ml/24 hours. Main outcome measure are the formation of seroma, wound infections, need to reinsert the

drain, and duration of hospital stay. Earlier the drain removed, carried a risk of seroma formation (9/42 compared with 2/48, p = 0.02) unless the total amount of fluid drained during the first 3 postop days was less than 250 ml.

Unalp and Onal²⁰ from their retrospective analysis of 119 patients conclude that later removal of drains didn't increase seroma occurence rate. They observed that a drain volume > 50 mL/ day for 2 days following surgery affected seroma development. They recommend drainage to be continued till flow rate at 48 hours is seen and daily drainage is lower than acceptable limit (up to 25 mL/ days).

Loo and Chow¹² in their retrospective analysis of 119 patients identified drain output exceeding 500 ml in first three postoperative days and drainage more than eight days as significant risk factors for seroma formation. Lumachi et al¹⁹ observed that total drainage is a predictor for seroma formation.

ADJUVANT THERAPY

Seroma can delay the initiation of adjuvant therapy in patients after MRM. However, adjuvant chemotherapy and radiotherapy can contribute to seroma formation **Sultan and Madhere**⁶⁵reported a case of seroma formation 4 years after breast reconstructive procedure and while on docetaxel.

NON-SURGICAL MODALITIES

Due to the associated complications and time constraints associated with the surgical management, Fibrin glue was used which interacted with the damaged tissues and favouring the fibroblasts growth and in wound healing. It favors haemostasis by preventing hematomas, which delay the surgical healing processes, blocks the lymphatic channels and thus reducing seroma formation; closes the dead spaces through tissue adhesion.

Table 6: Recent randomized trials using tissue sealants

Author	Total Patients	Sclerosant used	Seroma with / without sealant (%)	P value
Ulusoy. et al, 2003 ⁶⁸	54	Fibrin glue	18/11	NS
Jain et .al, 2004 ¹⁸	58	Fibrin glue	34/41	0.01
Mustenan. et al, 2004 ⁶⁹	40	Fibrin glue + aproptinin	20/26	NS
Johnson. et al, 2005 ⁷⁰	82	Fibrin glue	37/45	NS
Ruggiero. et al, 2008^{71}	50	Fibrin glue + collagen	11/16	0.02

NS = Not Significant.

Bonnema et al^{25} noted that seroma contained less amount of fibrinogen. Thus use of fibrin glue with its clot forming properties reduced seroma formation.

Jain et al¹⁸ showed that there was a positive correlation with the use of fibrin sealant on seroma occurence, consequent use of drains led to clot disruption and not adding to much advantage .

Johnson et al^{70} found no reduction in seroma formation and concluded that the fibrin glue was not cost effective, technique involved in its application is difficult indicated that it has no added advantage over normal suction drains

Ruggiero et al⁷¹conducted an RCT randomized 50 patients who underwent MRM. Fibrin glue spray and a collagen patch were applied to the axillary fossa in half of the patients, the other half were treated conventionally. Suction drainage was removed b/w post op days 3 & 4. Seroma amount and duration were significantly reduced and seroma aspiration and multiple hospital visits drastically reduced .

Mustenan et al⁷⁵ studied the use of fibrin glue & fibrinolysis inhibitor, he demonstrated that there was not much effect on seroma formation. Still further randomized control studies are needed to effectively point out the causative factors for seroma formation and it is difficult to identify patients who will suffer from seroma.

AIMS AND OBJECTIVES

Aim:

To study an association between various risk factors of seroma formation

Objectives:

- To estimate the incidence of seroma in KMCH
- To assess the risk factors like pre-operative status of patients, intra operative techniques, and post-operative observations of patients undergoing MRM for seroma formation
- To predict high-risk individuals for seroma formation and to recommend measures that can reduce the occurrence of seroma formation

SURGICAL ANATOMY

Gross Anatomy

Breast is situated in superficial fascia of anterior thoracic wall .it consists of 15 to 20 lobes wit fibrous tissue and adipose tissues Deep layer of superficial fascia covers the posterior aspect of breast, the retro mammary bursa is situated between deep layer of superficial fascia and clavipectoral fascia .⁴

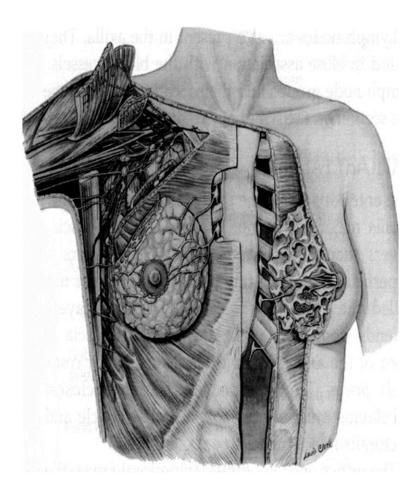
Axilla

Pyramidal shaped between the upper extremity and thoracic wall .it consists of 4 walls, an apex ,& a base . Base is made up of axillary fascia and skin . Apex is an aperture and extends into neck through cervicoaxillary canal. The anterior wall is made up of pectoralis major(PM) and minor muscle(Pm) .posterior wall is made up of subscapularis muscle , lateral wall is made up of humerus , medial wall is made up of serratus anterior muscle .

Breast is located just deep to dermis, suspensory ligaments of cooper pass from the septa that divides the breast into multiple lobules .

components of the brachial plexus, and axillary LN groups are seen. On the left side, the breast is cut to expose its structure in saggital view.

Figure 6: The contents of the axilla, axillary artery & vein



BLOOD SUPPLY

Breast is supplied by

- 1. Branches of internal mammary artery
- 2. Branches of posterior intercostal arteries
- 3. axillary, lateral thoracic, & thoracoacromial artery.

Venous Drainage

- 1. Drain into internal thoracic vein
- 2. Tributaries of axillary vein
- 3. Perforating branches of posterior intercostal veins

Bastons plexus of veins provide a route for metastatic emboli to reach the vertebral bodies, ribs and CNS.

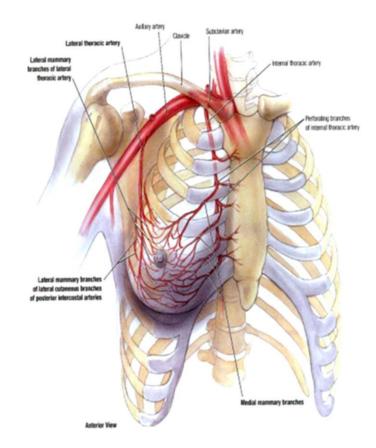


Figure 7: Diagrammatic Presentation of blood supply to breast

LYMPHATIC DRAINAGE OF THE BREAST

- 1. The lateral group, made up of 4 to 6 LN that lie near to axillary vein
- 2. The anterior group consists of 4 or 5LN major portion of the drainage of lymph from breast is to this group . Lymph drains primarily from these lymph nodes into the central LN
- 3. The posterior group, made up of 6 to 7 LN that lie along the subscapular vessels.
- 4. The central group made up of 3 to 4 lymph nodes that are present in the axilary pad of fat usually behind to the pectoralis muscle. Lymph from the central nodes passes directly to the sub clavicular (apical) nodes.
- 5. The apical group, made up of 6 to 12 LN located partly posterior to the upper border of the Pm. and partly superior to it. They may receive lymph directly or indirectly from all the other groups of axillary lymph nodes.
- 6. The Rotter's group, consists of 1 to 4 small LN that are located Between the PM and minor muscles in association with the pectoral branches of the thoraco acromial vessels Internal mammary group is situated in retrosternal spaces, the right internal mammary group drains into right lymphatic duct, and the left enters the main thoracic duct. Cross communication between lymphatics from each breast, explains the metastatic involvement of opposite breast and axilla. Sub areolar plexus plays no important in lymphatic drainage of breast.

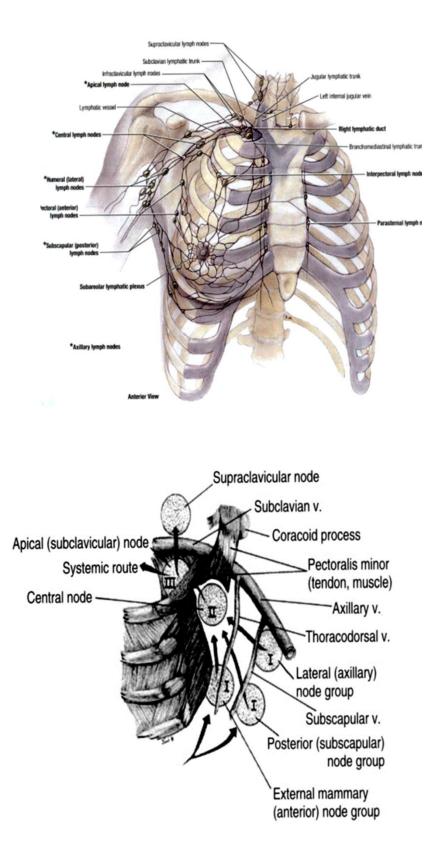


Figure 8: diagrammatic representation of lymphatic supply of breast.

Figure 9: Level I lymph nodes include the anterior, lateral &scapular groups; level II, the central group; and level III, the apical. There are three levels or groups of lymph nodes that are defined by their location relative to the pectoralis minor. The direction indicates the general direction of lymph flow. The axillary vein and its major tributaries associated with the pectoralis minor are included

CLASSIFICATION OF BREAST TUMORS

Table 7: Histological Classification of Breast Tumors

1 EPITHELIAL TUMOURS.

- A. Benign
 - 1. Intraductal papilloma
 - 2. Adenoma of the nipple
 - 3. Adenoma
 - a. Tubular
 - b. Lactating

B. Malignant

- 1. Non invasive
 - a. DCIS
 - b. LCIS

- 2. Invasive
 - a. Invasive ductal carcinoma(IDC)
 - b. IDC with predominant Intra ductal component
 - c. Invasive lobular carcinoma.
 - d. Mucinous carcinoma.
 - e. Medullary carcinoma.
 - f. Papillary carcinoma.
 - g. Tubular carcinoma.
 - h. Adenoid cystic carcinoma.
 - i. Secretory carcinoma.
 - j. Apocrine.
 - k. Carcinoma with metaplasia
- 3. Squamous type
- 4. Spindle cell type.
- 5. Cartilaginous and osseous type.
 - a. Mixed type.
 - b. Others.

II Mixed connective tissue and Epithelial tumors

- a. Fibro adenoma.
- b. Phyllodes tumour.
- c. Carcino sarcoma.

- III. Miscellaneous tumours.
- a. Soft tissue tumours.
- b. Skin tumours.
- c. Tumours of haematopoietic and lymphoid tissues.
- IV. Unclassified tumours.

STAGING OF BREAST CANCER

TNM staging system requires microscopic confirmation and histological typing of the tumour before attempting any stage classification.

TUMOUR(T)	
Tx	Primary tumour cannot be assessed
то	No evidence of primary tumour
Tis	Carcinoma in situ
Tis (DCIS)	DCIS
Tis(LCIS)	LCIS

 Table 8: AJCC/TNM Clinical Staging System

Tis pagets disease	Pagets disease of the nipple with no tumour
T1	Tumours <2cm in greatest dimension
T2	Tumour > 2cm and not more than 5 cm in greatest dimension.
Т3	Tumour > 5cm in greatest dimension
T4	Tumour of any size with direct extension to
T4a	Extension to chest wall , not including Pectoralis muscle
T4b	Oedema or ulceration of the skin of the breast or satellite nodules confined to the same breast.
T4c	Both T4a and T4b.
T4d	Inflammatory carcinoma.

REGIONAL LYMPH NODES.

Regional lymph nodes cannot be assessed
No regional lymph node metastasis
Metastasis to movable axillary lymph node
Metastasis in ipsilateral axillary lymph nodes fixed or matted or clinically apparent ipsilateral internal mammary nodes in the absence of clinically evident axillary lymph node metastasis.
Metastasis to ipsilateral axillary lymph nodes fixed to one another or to other structure
Metastasis only in clinically apparent ipsilateral internal mammary nodes and in the absence of clinically evidentaxillary lymph node metastasis

N3	Metastasis in ipsilateral infraclavicular lymph nodes or
	clinically apparent ipsilateral internal mammary nodes and in the presence of clinically evident axillary lymph nodes metastasis or metastasis in ipsilateral supraclavicular lymph nodes with or without axillary or internal mammary lymph nodes involvement
N3a	Metastasis in ips ilateral infra clavicular lymph nodes and axillary lymph Nodes
N3b	Metastasis in ipsilateral internal mammary nodes and axillary lymph nodes
N3c	Metastasis in ipsilateral supra clavicular lymph nodes
Mx	Distant metastasis cannot be assessed
M0	No distant metastasis.
M1	Distant metastasis.

Table 9: Staging of Breast Cancer

Stage 0	Tis N0M0.
Stage1	T1 N0M0.
Stage IIA	T0 N1 M0. T1 N1 M0. T2 N0 M0.
Stage II B	T2 N1 M0. T3 N0 M0.
Stage III A	T0 N2 M0. T1 N2 M0. T2 N2 M0. T3 N1 M0. T3 N2 M0

Stage III B	T4 N0 M0. T4 N1 M0 .T4 N2 M0.
Stage III C	Any T N3 M0
Stage IV	Any T Any N M1

MATERIALS AND METHODS

Study design	:	Prospective study.
Study Place	:	Department of General Surgery.
		Kilpauk medical college and .
		Government Royapettah Hospital
Duration of Study :		April 2019 to October 2019
Number of patients:		49 Patients.

Ethical committee clearance obtained.

Written informed consent obtained

Inclusion criteria.

> All cases of breast cancer undergoing Modified Radical Mastectomy.

Exclusion criteria.

- Cases of Mastectomy and Axillary dissection for indications other than carcinoma
- Cases undergoing palliative mastectomies and incomplete axillary dissection.
- Cases of breast cancer surgery in males
- Previous surgical procedures in and around the axilla

- Bilateral breast cancer
- Simultaneous reconstructive surgery
- Other serious underlying medical illness(es) precluding full study participation

OPERATIVE TECHNIQUE.

All patients underwent a complete clinical examination and relevant investigations required for diagnosis and staging. All participating women were informed about their diagnosis, the surgery to be performed and about the study before the surgery.

The surgery was performed under general anesthesia with patient supine on the operating table with both arms abducted. A third generation cephalosporin Cefotaxime was used as perioperative antibiotic and perioperative analgesics were used as per standard protocol. The operated side was painted and draped as per protocol. The operative technique was same throughout the study period in patients undergoing mastectomy, a horizontal elliptical incision was used which included the tumor with at least 2 cm skin margin. The flaps were raised using electrocautery medially up to mid sternum, superiorly up to the clavicle and inferiorly 2 cm below the infra mammary crease. Skin was closed with ethilon. Axillary node dissection consisted of an en bloc removal of level I& II lymph nodes. Flaps were raised using electrocautery. The axillary contents were cleared from the the axillary vein extending from the chest wall to the anterior border of latissimus dorsi muscle posteriorly & anteriorly lateral border of PM muscle. The inferiorly extended up to 5th intercostal space. The ipsilateral arm was then flexed, the PM and Pm muscles were retracted, and elevated and axillary contents dissected to the apex of the axillary cavity. Care was taken to preserve the nerve to Serratus anterior and thoracodorsal nerves and vessels. A 14 to 16 Fr closed suction drain was placed in the axilla. The wounds were dressed with sterile gauze pads.

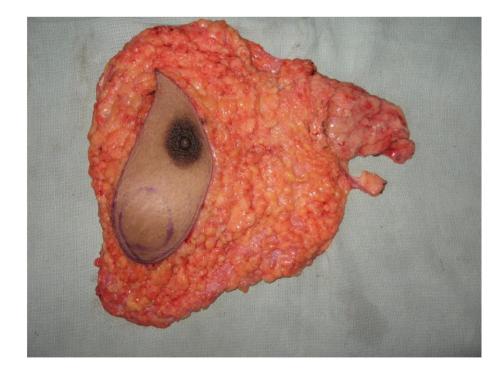


Figure 10 : Specimen of breast and axillary pad of fat after MRM

Figure 11 : axillary vein and thoracodorsal trunk seen after axillary lymph node dissection



Figure 12: exposed pectoralis major muscle after MRM



Definitions

- A seroma is defined as any palpable fluid collection in the axilla. Any seroma aspirated once a week or earlier if required and a sample sent for culture and sensitivity.
- 2. Wound infection was defined as erythema, cellulitis, purulent drainage, wound gaping, skin necrosis, or positive. microbiology at the incision site that needed antibiotics.

All patients were followed up in the outpatient clinics. Data was collected and recorded longitudinally output, cumulative postoperative day 7 drain output, total drain output, duration of drainage,

Outcome Measures.

The primary endpoint of the study was the incidence of seroma formation. The other parameters that were measured were postoperative day 1 drain output, cumulative postoperative day three drain, Operative details like; use of electro-cautery, suction drains ,axillary padding were also noted, implementation of upper limb (on the side operated) physiotherapy were noted. The number of lymph nodes removed & wound Complications were noted. Analysis of risk factors for seroma formation was also done. Seroma was managed by regular aspirations under aseptic precautions and the drain removal was delayed until the resolution of seroma

Figure 13 : flap necrosis after MRM



Figure 14: post mastectomy seroma collection in left breast



METHOD OF STATISTICAL ANALYSIS

Descriptive statistical analysis has been carried out in the present study. The collected data were analysed with IBM.SPSS statistics software 23.0 Version. To describe about the data descriptive statistics frequency analysis, percentage analysis were used for categorical variables and the mean & S.D were used for continuous variables. To find the significant difference between the bivariate samples in Independent groups the Unpaired sample t-test was used To find the significance in categorical data Chi-Square test was used similarly if the expected cell frequency is less than 5 in 2×2 tables then the Fisher's Exact was used. In all the above statistical tools the probability value .05 is considered as significant level.

RESULTS

DEMOGRAPHIC DATA

49 consecutively admitted female patients with the diagnosis of carcinoma breast counseled for MRM were included in the study 15 out of 49 patients, accounting for 30.6 percent, developed seroma

	Frequency	Percent	
No	34	69.4	
Yes	15	30.6	
Total	49	100.0	

Table 10 : Distribution of seroma. in study population

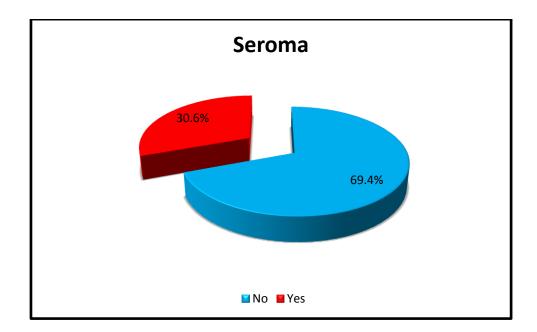
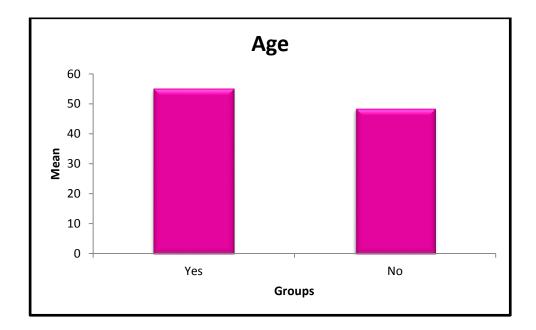


TABLE 11: DISTRIBUTION OF MEAN AGE IN THE STUDY POPULATION

Age comparison by Unpaired T-Test						
Seroma		N	Mean	S.D	t-value	P- value
Age	Yes	15	55	6.80	2.121	0.039
0	No	34	48	11.30	-	*
* Statistical Significance at P < 0.05 level						

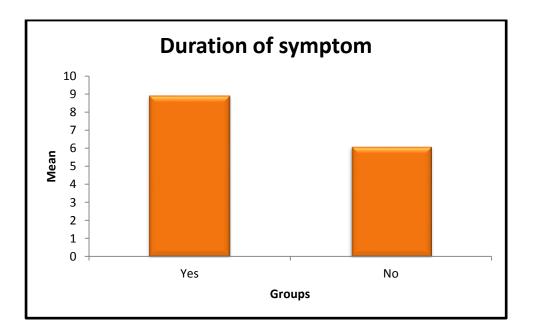


The mean age of patients who developed seroma was 55 + 6.80, whereas the mean age of those without seroma was 48 + 11.30 years. P value was statistically Significant 0,039

TABLE 12: MEAN DURATION OF SYMPTOM IN THE STUDY

POPULATION

Duration of symptom comparison by Unpaired T-Test						
Seroma		N	Mean	S.D	t-value	P- value
Duration	Yes	15	9	4.10		0.023
of symptom	No	34	6	2.44	2.488	*
* Statistical Significance at P < 0.05 level						



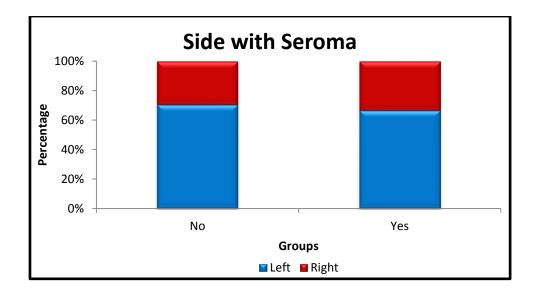
The mean duration of symptom in seroma group was 9 + 4.10 and in noseroma group was 6 + 2.44 days, **P value is 0.023, statistically significant**

TABLE 13:DISTRIBUTION OF TUMOUR SIDE IN STUDY

POPULATION

Comparison between Side with Seroma							
		Seroma		Total	2 -	P-	
			No	Yes	Total	value	value
	Left	Count	24	10	34		
Side		%	70.6%	66.7%	69.4%	0.075	1.000 #
	Right	Count	10	5	15		
		%	29.4%	33.3%	30.6%		
Total Count %		34	15	49			
		%	100.0%	100.0%	100.0%		
# No Statistical Significance at P>0.05 level							

	No	Yes
Left	70.6%	66.7%
Right	29.4%	33.3%

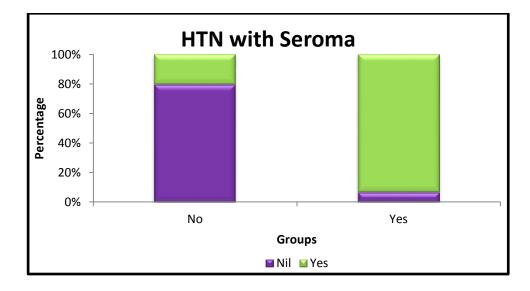


5 among the seroma group were found to be right sided tumors accounting for 33.3%, 10 among the seroma were found to be left sided tumors (66.7%).P value was insignificant 1.000

TABLE 14: DISTRIBUTION OF HYPERTENSION IN STUDYPOPULATION

Comparison between HTN with Seroma								
			Seroma		Total	2 -	P-	
			No	Yes	Total	value	value	
	No	Count	27	1	28		0.0005 **	
HTN		%	79.4%	6.7%	57.1%			
ΠΙΝ	Yes	Count	7	14	21	22.490		
		%	20.6%	93.3%	42.9%			
Total –		Count	34	15	49			
		%	100.0%	100.0%	100.0%			
** Highly Significant at P < 0.01 level								

	No	Yes
No	79.4%	6.7%
Yes	20.6%	93.3%

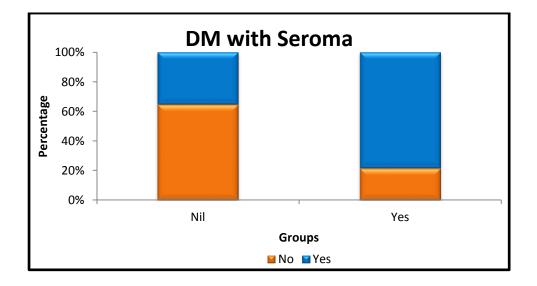


14 among the seroma group were found to be hypertensive accounting for 93.3%; 7 among the non-seroma group were hypertensive, 20.6%.**P value** was significant. 0.0005

Comparison between DM with Seroma							
			Seroma		Total	□ 2 -	P-
			No	Yes	Total	value	value
	No	Count	29	7	36		0.011
DM		%	85.3%	46.7%	73.5%		
DIVI	Yes	Count	5	8	13	7.967	
		%	14.7%	53.3%	26.5%		
Total —		Count	34	15	49		
		%	100.0%	100.0%	100.0%		
* Statistical Significance at P < 0.05 level							

TABLE 15 : DISTRIBUTION OF DIABETES IN STUDY POPULATION

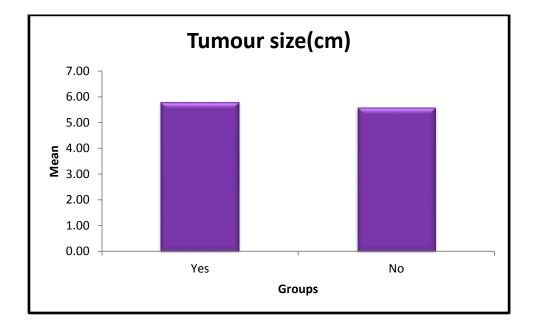
	No	Yes
No	85.3%	46.7%
Yes	14.7%	53.3%



8 among the seroma group were found to be diabetic accounting for 53.3%; 5 among the non-seroma group were dibetic, 14.7%.**P value was significant**. **0.011**

.POPULATION

Tumour size(cm) comparison by Unpaired T-Test								
Sero	ma	Ν	Mean	S.D	t-value	P- value		
Tumour	Yes	15	5.80	1.57	0.321	0.749		
size(cm)	No	34	5.59	2.32	0.521	#		
# No Statistical Significance at P>0.05 level								



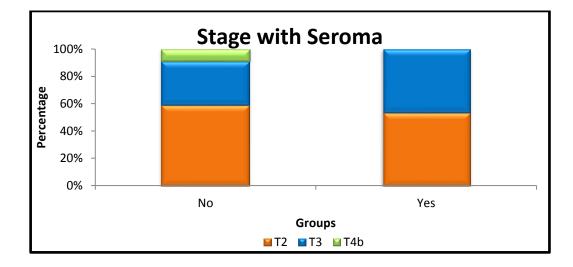
The mean tumour size of patients who developed seroma was **5.80** + **1.57**, whereas the mean tumour size of those without seroma was **5.59**+**2.32 cm.** P value was 0.749, statistically insignificant.

TABLE 17 : DISTRIBUTION OF STAGING OF TUMOUR IN STUDY

POPULATION

Comparison between Stage with Seroma								
	Seroma		Total	□ 2 -	P-			
			No	Yes	Total	value	value	
	T2	Count	20	8	28			
	12	%	58.8%	53.3%	57.1%			
Stogo	T3	T2 Count	11	7	18			
Stage	15	%	32.4%	46.7%	36.7%	1.959	0.376	
	T4b	Count	3	0	3	1.939	#	
	140	%	8.8%	0.0%	6.1%			
To	tol	Count	34	15	49			
10	lai	%	100.0%	100.0%	100.0%			
	#]	No Statist	ical Signi	ficance at	P>0.05 le	vel		

	No	Yes
T2	58.8%	53.3%
T3	32.4%	46.7%
T4b	8.8%	0.0%

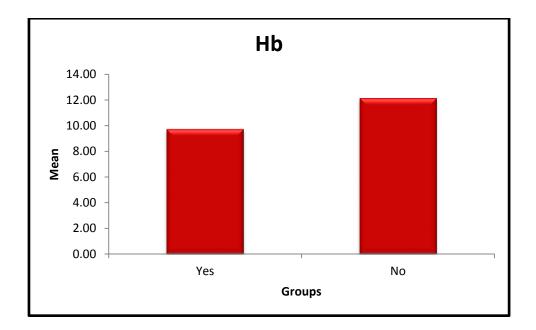


15 among the seroma group were found to be T2 -53.3%, T3-46.7%,

T4b - 0% . P value was 0.376 statistically insignificant.

TABLE 18: MEAN HAEMOGLOIN IN THE STUDY POPULATION

Hb comparison by Unpaired T-Test								
Ser	oma	Ν	Mean	S.D	t-value	P- value		
TTP	Yes	15	9.74	0.93	1.367	0.178		
Hb	No	34	12.15	6.77	1.307	#		
	# No Statistical Significance at P>0.05 level							

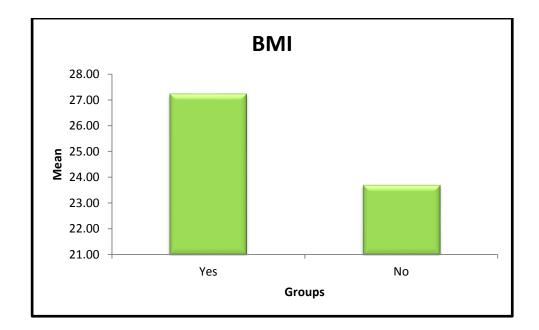


The mean haemoglobin in seroma group was 9.74 + 0.93 and in no seroma group was 12.15 + 6.77 gm/dl P value is 0.0178, statistically insignificant.

TABLE 19: DISTRIBUTION OFMEAN BMI (KG/M²) IN THE STUDY

POPULATION

	BMI comparison by Unpaired T-Test								
Ser	roma	Ν	Mean	S.D	t-value	P- value			
DMI	Yes	15	27.25	2.45	3.990	0.0005			
BMI	No	34	23.72	3.01	5.990	**			
	** Highly Significant at P < 0.01 level								



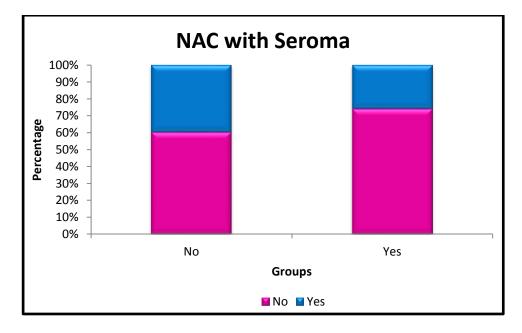
The mean BMI of those with seroma was 27.25 + 2.45; the BMI for patients without seroma was 23.72 + 3.01 kg/m2. **P value was highly significant 0.0005**

TABLE 20: DISTRIBUTION OF NEOADJUVANT CHEMOTHERAPY

Comparison between NAC with Seroma								
			Ser	Seroma		□ 2 -	P-	
			No	Yes	Total	value	value	
	No	Count	24	8	32			
NAC	NO	%	70.6%	53.3%	65.3%			
NAC	Yes	Count	10	7	17	1.368	0.331	
	168	%	29.4%	46.7%	34.7%	1.308	#	
Та	tal	Count	34	15	49			
10	Total		100.0%	100.0%	100.0%			
	#1	No Statist	ical Signi	ficance at	P>0.05 le	vel		

IN STUDY POPULATION

	No	Yes
No	100.0%	100.0%
Yes	65.3%	34.7%

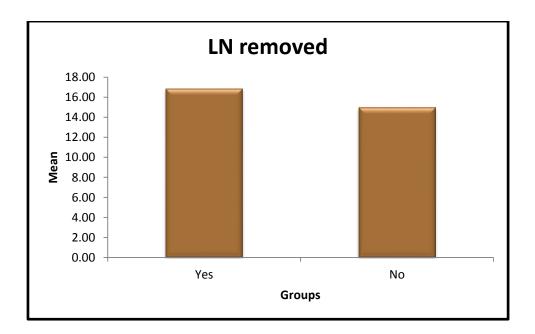


7 patients who had received neoadjuvant chemotherapy developed seroma, and 8 patients who received no neoadjuvant chemotherapy developed seroma. P value was 0.331, statistically Insignificant

TABLE 21: MEAN NUMBER OF LYMPH NODES REMOVED IN THE

STUDY POPULATION

LN removed comparison by Unpaired T-Test								
Seroi	ma	Ν	Mean	S.D	t-value	P- value		
LN	Yes	15	16.87	7.96	0.857	0.403		
removed	No	34	15.00	4.19	0.837	#		
	# No Statistical Significance at P>0.05 level							



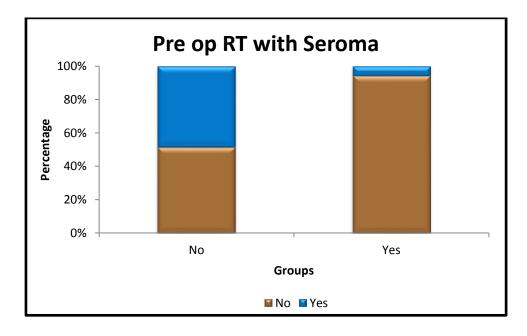
The mean number of lymph nodes removed in the seroma group was 16.87+7.96, whereas in no seroma group was 15 + 4.19 P value was insignificant 0.403

TABLE 22: DISTRIBUTION OF PREOPERATIVE RADIOTHERAPY

IN STUDY POPULATION

Comparison between Pre op RT with Seroma							
				oma	Total	□ 2 -	P-
			No	Yes	Total	value	value
	No	Count	32	14	46		
Pre op	No	%	94.1%	93.3%	93.9%		
RT	Yes	Count	2	1	3	0.11	1.000
	res	%	5.9%	6.7%	6.1%	0.11	#
Та	4.01	Count	34	15	49		
То	tai	%	100.0%	100.0%	100.0%		
	#]	No Statist	ical Signi	ficance at	P>0.05 le	vel	

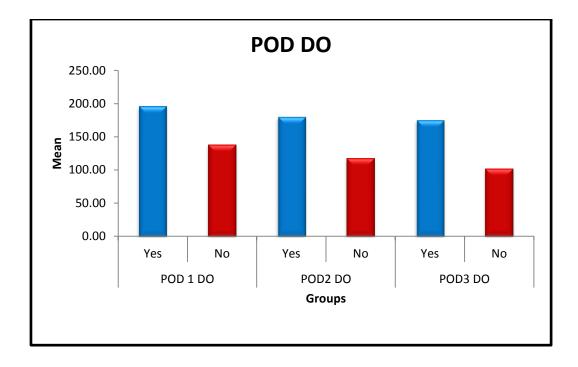
	No	Yes
No	100.0%	100.0%
Yes	93.9%	6.1%

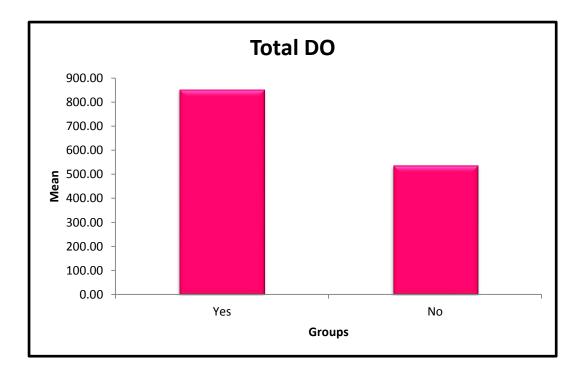


Out of 3 patients, who received preop radiotherapy only 1 developed seroma,14 patients who had not received radiotherapy developed seroma. P value was 1.000, statistically insignificant

TABLE 23 : MEAN DRAIN OUTPUT IN STUDY POPULATION

	POD DO comparison by Unpaired T-Test								
Ser	Seroma		Mean	S.D	t-value	P- value			
POD 1	Yes	15	196.33	30.03	6.404	0.0005			
DO	No	34	138.53 28.72	28.72	0.404	**			
POD2	Yes	15	180.00	24.49	- 1	0.0005 **			
DO	No	34	117.35	35.19	7.166				
POD3	Yes	15	175.33	18.46	9.492	0.0005			
DO	No	34	101.76	35.63	9.492	**			
Total	Yes	15	851.67	79.86	8.871	0.0005			
DO	No	34	538.09	167.43	0.071	**			
	** Highly Significant at P < 0.01 level								





The mean drain output on day 1 in seroma group was 196.33+30.03- and in no seroma group was 138.53 + 28.72 milliliters (ml), P value is 0.0005, statistically highly significant.

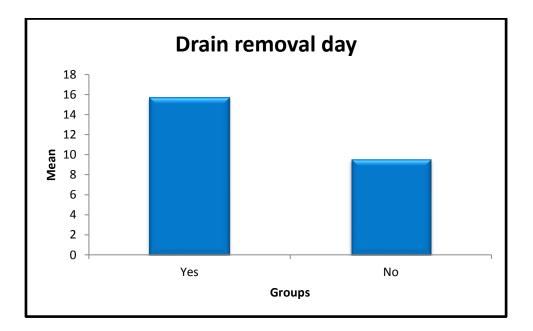
The mean drain output on day 2 in seroma group was 180 +24.49 and in no seroma group was 117.35+ 35.19 milliliters (ml), P value is 0.0005, statistically highly significant.

The mean drain output on day 3 in seroma group was 175.33 + 18.46and in no seroma group was 101.76 + 35.63 milliliters (ml), P value is 0.0005, statistically highly significant

The mean total drain output in seroma group was 851.67 + 79.86 and in no seroma group was 538.09 + 167.43 milliliters (ml), P value is 0.0005, statistically highly significant.

TABLE 24 : MEAN DRAIN REMOVAL DAY IN STUDY POPULATION

Drain removal day comparison by Unpaired T-Test								
Seroma		N	Mean	S.D	t-value	P- value		
drain	Yes	15	16	1.49	0.005	0.0005		
removal day	No	34	10	2.19	9.925	**		
** Highly Significant at P < 0.01 level								



The mean drain removal day in seroma group was 16 + 1.49 and in no seroma group was 10 + 2.19 days. **P value is 0.0006 statistically highly significant**.

DISCUSSION

Breast cancer is the most common cancer in women and surgical management remains the main line of management. The most common types of breast surgeries are MRM and BCS. Seroma is the commonest sequel following breast cancer surgery.

Seroma accumulation elevates the flaps from the chest wall and axilla thereby hampers their adherence to the tissue bed. Although it usually resolves within a few weeks, excessive fluid accumulation will stretch the skin and cause it to sag, resulting in patient discomfort and prolongation of the hospital stay.

It can thus lead to significant morbidity such as wound hematoma, wound infection, flap necrosis, wound break down, prolonged hospitalization, psychological distress, delayed recovery, & delay in starting chemotherapy.²²

Thus, although a number of factors have been correlated with seroma formation, strong data on factors associated with seroma formation are still rare, and it is difficult to identify patients who will ultimately suffer from seroma. Various studies have shown that suturing of skin flaps is a successful means of reducing seroma formation.^{7, 17, 60-64}

The success of external compression dressings have not yet been validated adequately through randomized studies.^{15,58,59} Early drain removal has also been shown not to significantly affect seroma formation while reducing duration of drainage and other postoperative morbidity. Complications due to these methods are not much different from the standard drain method and are not frequent or serious.

Our study included 49 randomly selected patients with the diagnosis of Carcinoma breast undergoing modified radical mastectomy. In our study, 30.6 % of patients developed Seroma . E. Hashemi et al in their study on 158 patients with breast cancer undergoing either modified radical mastectomy or breast preservation, overall seroma rate was 35%. Gonzalez E. A. et al in their study on 359 patients undergoing either modified radical mastectomy or wide local excision and axillary lymph node dissection showed overall seroma rate of 15.8%, 19.9% in modified radical mastectomy group and 9.2% in breast-conserving group. Seroma rate in a study by Unalp H. R. et al. was 14.28%.

In our study the mean age of presentation was 55 + 6.80 years, p value was 0.039 significant association was established between age of the patient and seroma formation. Menton M. et al opine that seroma formation increases with increasing age of the patient. On the contrary, K. Kuroi et al quoted that existing evidence was inconclusive for age with respect to seroma formation, as did E. Hashemi et al. The mean age in E. Hashemi et al study was 46.3 years

(SD+11.9). Unalp et al reported a mean age of 53.13 years (SD+13.26), which is comparable to the mean age of patients in studies from India like Nadkarni et al⁹ and Chintamani et al.⁵⁰ The mean age is lower than patients in studies from other parts of the world like Gupta et al¹⁶, Purushottam. et al ^{17,32}, Jain et al¹⁸, Lumachi et al ¹⁹, Galatius et al⁴², O'Hea et al⁵⁹ and Ruggerio et al.⁷³ This underlines the fact that breast cancer occurs at an earlier age in India than in the western countries.

In our study the mean duration of symptom in seroma group was 9 + 4.10 and in no seroma group was 6 + 2.44 days, **P value is 0.023, statistically significant**

In our study, mean BMI was 27.25 kg/mm²(SD+ 2.45).In our study BMI of patients from No seroma group had a lower BMI (23.72), the difference was statistically significant. Our study opines that there is association between BMI and seroma formation.

In our study among the seroma group ,14 of 15 patients (93.3%), were hypertensive, while in non seroma group , 7 of 34 patients were known hypertensives. There was significant association between seroma formation and history of arterial hypertension in the patient. Literature shows that high BMI and arterial hypertension are considered risk factors , Douay et al, Kumar et al²⁹ found a significant association b/w BW. and HTN with seroma.

In our study 8 among the seroma group were found to be diabetic accounting for 53.3%; 5 among the non-seroma group were dibetic, 14.7%.**P** value was significant. 0.011

In our study the mean haemoglobin in seroma group was 9.74 + 0.93and in no seroma group was 12.15 + 6.77 gm/dl P value is 0.0178, statistically insignificant.

In our study, 7 of the seroma group patients received neo adjuvant Chemotherapy, Whereas 10 patients who had not received neoadjuvant chemotherapy developed seroma significant reduction in seroma rate could not be demonstrated from the study as similarly concluded by Unalp H. R. et al

The mean drain output on day 1 in seroma group was 196.33+30.03- and in no seroma group was 138.53 + 28.72 milliliters (ml), P value is 0.0005, statistically highly significant.

The mean drain output on day 2 in seroma group was 180 + 24.49 and in no seroma group was 117.35 + 35.19 milliliters (ml), P value is 0.0005, statistically highly significant. The mean drain output on day 3 in seroma group was 175.33 + 18.46and in no seroma group was 101.76 + 35.63 milliliters (ml), P value is 0.0005, statistically highly significant

In our study the mean total drain output in seroma group was 851.67 + 79.86 and in no seroma group was 538.09 + 167.43 milliliters (ml), P value is 0.0005, statistically highly significant suggesting the probability of seroma formation in those patients with higher drain output on post op Day 3.k.kuroi et al , suggested that a positive association between drainage volume during the initial 72 hrs and seroma formation was consistent.

In the study the mean number of lymph nodes removed in the seroma group was 16.87+7.96, whereas in no seroma group was 15 + 4.19 P value was insignificant 0.403

In the study the mean drain removal day in seroma group was 16 + 1.49 and in no seroma group was 10 + 2.19 days. **P value is 0.0006 statistically highly significant**. Although k.kuroi et al showed that seroma formation rate was significantly high in patients following drain removal on post op day 5 when. compared to drain removal on post op day 8.

CONCLUSION

The factors influencing seroma formation following modified radical mastectomy for carcinoma breast are as follows;

The following factors has significant association for seroma formation.

- ≻ Age
- Duration of Symptom
- ≻ BMI
- ➢ Hypertension
- ➤ Diabetes
- > Drain output
- Drain removal

The following factors has no significant association for seroma formation.

- ➢ Side of the tumour
- ➢ Size of the tumour
- New adjuvant chemotheraphy
- Pre Op Radiotheraphy
- ➢ Haemoglobin status
- Lymph node removal status

Hypertension and High Body Mass Index has strong association for seroma formation. Higher drain output on post operative day 1, pod 2 and pod 3 is likely to predict the increased possibility of seroma formation. Delayed removal of drain showed increased seroma formation. Age, duration of symptom, Diabetes are associated with increased seroma formation.

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ANNEXURE

PROFORMA

Name :		Age :		
Study No.:	D.O.A	:	D.O.Sx:	D.O.D.:
Presenting History				
Duration and side of swe	elling/lump:			
Past and Personal histo	ory.			
Co morbid illness	: a.	diabetes me	llitus	
	b. h	ypertension		
Past Surgical/drug histor	y.			
Prior Therapy				
1. Chemotherapy		2. Radio	otherapy	
General examination				
Height (cm):	Weight (kg):	BMI :	Pulse:	BP:
Local examination				
Lump (SIZE, skin and n	ipple areola) Lymp	h Nodes (Lo	cation, number	& fixity)
1. Axillary				

2. Internal mammary/ Supra clavicular/Infra clavicular::

3. Hb% (g/dL):

Course and Events in Hospital

Surgery Performed Electro Cautery Used

Use of suction drain

Axillary padding

Upper Limb Exercise

Number of Lymph Nodes Removed:

Drain output:

POD	1	2	3	4	5	6	7	8	9	10
Drain output (ml)										
POD	11	12	13	14	15	16	17	18	19	20
Drain output (ml)										
POD	21	22	23	24	25	26	27	28	29	30
Drain output (ml)										

Date of drain removal:

Total duration of drainage (days):

Total volume of drainage (mL):

KEY TO MASTER CHART

Sl No	Serial number
R	RIGHT
L	LEFT
Y	YES
NAC	NEO ADJUVANT CHEMOTHERAPY
BMI	BODY MASS INDEX
PRE OP RT	PREOPERATIVE RADIOTHERAPY
MRM	MODIFIED RADICAL MASTECTOMY
POD	POSTOPERATIVE DAY

சுய ஒப்புதல் படிவம் (Consent Form)

ஆய்வு செய்யப்படும் தலைப்பு

"A prospective study of factors influencing seroma formation in modified radical mastectomy in Government Kilpauk Medical college"

ஆய்வு செய்யபடும் துறை : பொது அறுவைச்சிகிச்சை துறை ஆய்வு செய்யபடும் மருத்துவமனை : அரசு கீழ்பாக்கம் மருத்துவக்கல்லூரி மருத்துவமனையில்

பங்கு பெறுபவரின் பெயர் : பங்கு பெறுபவரின் வயது : பங்கு பெறுபவரின் மருத்துவமனை எண் : பங்கு பெறுபவர் இதனை (🗸)குறிக்கவும் :

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும் அதற்கான தகுந்த விளக்கங்களைப் பெறவும் வாய்ப்பளிக்கப்பட்டது.

நான் இவ்வாய்வில் தன்னிச்சையாகத்தான் பங்கேற்கிறேன். எந்தக் காரணத்தினாலோ எந்தக் கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகிக் கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.

ஆய்வு சம்மந்தமாகவும், மேலும் இந்த இது ஆய்வில் சார்ந்த ஆய்வு மேற்கொள்ளும்போதும், இந்த பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளைப் பார்ப்பதற்கு அனுமதி என் ട്ടേബെലിல്லെ அறிந்துகொள்கிறேன். நான் என

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ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன்

ஆய்வின் மூலம் கிடைக்கும் இந்த தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தகவல்களையும் தொடர்பான மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக் கொள்ளவும், பிரசுரிக்கவும் முழு என் மனதுடன் அதைப் சம்மதிக்கிறேன்.

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்குக் கொடுக்கப்பட்ட அறிவுரைகளின் படி நடந்துகொள்வதுடன், இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதியளிக்கிறேன். என் உடல் நலம் பாதிக்கப்பட்டாலோ அல்லது எதிர்பாராத வழக்கத்திற்கு மாறாக நோய்க்குறி தென்பட்டாலோ உடனே அதை மருத்துவ அணியிடம் தெரிவிப்பேன் என உறுதி அளிக்கிறேன்.

இந்த ஆய்வில் எனக்கு மருத்துவப் பரிசோதனை மற்றும் ஆய்வு குறித்து ஆராய்ச்சி செய்து கொள்ள நான் முழு மனதுடன் சம்மதிக்கிறேன்.

பங்கேற்பவரின் கையொப்பம்	கட்டைவிரல்													
ரேகை:														
இடம்														
தேதி														
பங்கேற்பவரின் பெயர் மற்றும் விலாசம்														
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ஆய்வாளரின் கையொப்பம்														
ஆய்வாளரின் பெயர்														
இடம்														
தேதி														

			1	duration			I	_															upper limb	drain	
sno	name	age	ip no	of	side	HTN	DM	Tumour	Stage	height	weight	BMI	NAC	Pre op	Hb	surgery	LN	electro	POD 1	POD2	POD3	Total DO	physio	removal	seroma
0.10	namo	age		symptom	0.00		2	size(cm)	elage	noigin	noigin	2		RT		cargory	removed	cautry	DO	DO	DO	. old. D O	theraphy	day	ooronna
1	lakshmi	52	24132	8	1	Y	Y	6	T3	1.5	60.6	26.9333	N	Ν	7.6	mrm	14	V	210	180	170	800	V	16	Y
2	valli	44	27184	5	L	NIL	NIL	5	T2	1.61	53	20.3355	N	N	10	mrm	17	V	120	90	90	365	Ý	8	N
3	devaki	54	14738	9	L	Y	NIL	7	T3	1.63	73	27.4756	N	N	9.4	mrm	20	Y	265	240	210	800	Y	19	Y
4	rajeshwari	63	18044	12	R	NIL	NIL	5	T2	1.53	66	28.1943	Y	N	9.2	mrm	18	Y	190	180	190	910	Y	13	N
5	sairabee	65	29429	12		Y	Y	5	T2	1.58	68.6	27.4796	Y		9.2 8.9	mrm	23	V	180	180	190	810	Y	17	Y
6	panjalai	44	23406	8	L	NIL	NIL	8	T3	1.56	64	27.4790	N	N	13.8	mrm	12	V I	120	110	120	440	Y	9	N
7	, , , , , , , , , , , , , , , , , , ,	60	23408 39147	0 7	L	NIL	Y	0 7	T3	1.59	67.4	26.6603	N	N	13.8		12	T V	120	130	90	515	Y	9	N
8	sarojadevi karpagani	48	29654	4	L	Y	r NIL	5	T2	1.59	59.6	25.1307	N	N N	10.2	mrm mrm	14	ř Y	150	130	90 120	610	Y	8 9	N
9	1 0	40 66	29654 31032	4 5	L	NIL	NIL	5	T2	1.34	59.0 54.7	24.6385	N	N	9.2		19	Y	170	140	120	765	Y	9 14	Y
9 10	saraswathy thulasi	55	21124	8		Y	NIL	4	T2	1.49	68.6	24.0305	N	N	9.2	mrm	19	T V	210	180	150	920	Y	14	T Y
11		48	31366	6	R	NIL	NIL	3	T2	1.39	43	19.8991	N	N	9.9 10.6		7	T V	190	120	110	920 640	Y	10	T N
	mary	40		5	R	NIL	Y	10	T4b		43 59		N	N		mrm	10	Y	150	120	130	720	Y	10	N
12	selvi	42 58	37893		_	Y	Y			1.48		26.9357 24.2874			12.6	mrm		T V					Y	-	Y
13	saroja	58 40	31843	4	R	Y NIL	Y NIL	6 7	<u>T3</u> T3	1.54	57.6 56	24.2874	Y N	N N	10.6 10.2	mrm	13 15	Y Y	180 140	170 150	190 130	1040 710	Y	15 12	
14	tamilarasi	40 50	28014 32044	5	_	NIL Y	NIL	7	T3	1.56 1.59	72	23.0112	N	N N	-	mrm	-	ĭ V	140	160	130	920	Y	12	N Y
15	narayani	50 60		5	L	Y Y	NIL	v					Y	N N	11	mrm	10 11	Y Y	180	160		920 400	Y Y	16	
16 17	rani	60 45	34459	4	L	Y NIL	NIL	5	T2 T2	1.42	46 53	22.8129		N N	12.2	mrm		Y Y	110		60		Y Y	-	N N
17	thangammal varalakshmi	45 37	32274 30134	4	R	NIL	NIL	4	T2	1.51 1.56	53 56.9	23.2446 23.381	N N	N N	10.6	mrm	13 10	T V	120	100 120	90 80	440 415	Y Y	7	N
19	varalakshmi	50	29323	4	L	Y	Y	5	T2	1.50	54	23.301	Y	N	11.2 10.2	mrm	10	Y	170	120	180	770	Y	7 15	Y
	muniammal				_			-		-	-			N	-	mrm			-			-	Y	-	
20 21	vijaya kasthuri	49 56	31355 43004	6 17	L R	NIL Y	NIL Y	3	T2 T2	1.59 1.54	56.7 56.4	22.4279 23.7814	N Y		11.6 9.6	mrm	15 21	Y	150 190	100 160	80 160	500 815	Y	9 15	N Y
_					ĸ	NIL	r NIL	5 8		-				n N		mrm		ř Y					Y	-	
22	baby	42	36981	8				-	T3	1.56	48.9	20.0937	Y		12.6	mrm	19	ř Y	150	100	90	620	Y Y	10	N
23 24	devi	48 53	33482	11	L R	NIL Y	NIL Y	4 8	T2 T3	1.53 1.46	51 58	21.7865 27.2096	Y Y	N N	9 8.6	mrm	17 9	Y Y	120 160	100 170	80 170	345 745	Y Y	11 14	N Y
	lakshmi		36021		ĸ	NIL	r NIL	-		-						mrm		ř Y		-		-	Y	-	
25	kumari	62	35288	10				7	T3	1.6	57.6	22.5	Y	Y	7.8	mrm	15	ř	150	140	150	595	ř Y	9	N
26 27	malliga	30 75	34215	3		NIL	Y NIL	4	T2 T2	1.52	54 51	23.3726	N N	N N	13.1 9.4	mrm	17	ř Y	190 100	170	150	860	Y	17 10	N N
	kurshid begum	-	22885	-	_					1.53	. .					mrm	15			90	100	390	Y Y		
28	bhavani	70	35838	6	L	Y Y	Y	5	T2	1.5	48.2	21.4222	N	N	8.8	mrm	14	Y	110	80	70	340	Y Y	9	N Y
29	vanaja	46	32141	5	R		NIL	4	T2	1.54	76	32.0459	N	N	9.9	mrm	39	Y Y	220	190	180	865		14	
30	sudha	26	5552	2	R	NIL	NIL	3	T2	1.52	57	24.6711	N	N	49.2	mrm	18	ř V	120	100	80	340	Y Y	9	N
31 32	ponnammal	55 56	29917 31017	10 9	R	NIL Y		6	T4b T3	1.5	74.5 63	33.1111	N Y	N Y	8.8 11.6	mrm	13 25	ř Y	170 130	130 90	100	625 675	Y	10 8	N
	rajalakshmi	56 69		9 14	L	Y	Y	9	T3	1.54 1.47		26.5643 30.5428	N N	r N	-	mrm	25 8	ř Y	250	230	110 190	870	Y Y	8 16	N Y
33	valasal		29177		_			-	-		66				10	mrm	-	ř V					Y	-	-
34 35	ragini qandhimathi	60 40	32226 33178	8.5 6	L R	NIL	NIL NIL	6 11	T3 T3	1.58 1.54	59 63	23.634 26.5643	Y N	N N	9.8 15.2	mrm	15 12	T V	100 110	70 60	60 50	520 500	Y Y	9	N N
35	ganonimatni sundari	40	293178	6 4	R L	Y	NIL	4	T2	1.54	63 46	26.5643	N	N N	15.2		12	Y Y	110	60 90	50 60	500 450	Y Y	8	N
36		47		4 5		Y NIL	NIL	4	T3		-				-	mrm		Y Y	-				Y Y	8	
37	latha chinnaponnu	41 60	36806 35677	3		Y	NIL	6 8	T3	1.48 1.5	51 65.6	23.2834 29.1556	N Y	N N	9.8 11.2	mrm mrm	18 28	T V	120 110	70 190	60 170	390 870	Y Y	8 14	N N
38	achammal	50	39773	3 11	R	Y		8 5	T2	1.5	64.4	29.1556	Y	N	10.2	mrm	 19	T V	180	190	170	840	ř V	14	N Y
39 40		50 48	29889	11	<u>г</u> х 1	Y NIL	NIL	5 12	T4b	1.52	64.4 50.7	21.6583	Y N	N N	10.2		9	T V	90	80	60	340	Y Y	15	Y N
40	shanthi	48	29889 41204	10	R	NIL	NIL	3	T2	1.53	50.7	21.6583	N	N N	11.6	mrm mrm	9 14	Y Y	90 110	80 80	80	290	Y Y	8	N
41	sahayarani	40 60		3				-	T2			-	Y	N	-			T V	-				Y Y	-	
42	dilshad lakshmi	60 54	31195 21302	3		NIL Y	NIL Y	5 4	T2	1.5 1.52	54 70	24	Y N	N N	8.9 11.2	mrm	16 9	Y Y	160 200	110 180	80 180	560 865	Y Y	10 17	N Y
43		54 45	19288	8 5	R	Y NIL	Y NIL	4	T3	1.52	61	30.2978 24.4352	N	N N	11.2	mrm	9 15	Y Y	140	180	80	365	Y Y	17	Y N
	shanthi	-						-	T2		-					mrm	-	Y Y	-	-			Y Y	v	
45	sundari	40	21431	7	L	Y	NIL NIL	5	T2 T3	1.54 1.62	45.4	19.1432	N	N	12	mrm	18	Y Y	170 180	160	170 200	780 950	Y Y	13	N Y
46	padmavathy	48	34394	6				÷	-	-	69.6		Y	N	9.8	mrm	21	ř V		160			Y	18	-
47	sumathy	40	24307	6	L	NIL	Y	4	T2 T2	1.5	59.4	26.4	N	N	10.6	mrm	19	Y V	190	140	130	535	Y	8	N
48	thasilim	30	36970	4	L	NIL	NIL	3		1.54	50	21.0828	N	N	14.6	mrm	13	Ý	170	130	120	600		9	N
49	kungumayee	50	38057	2	R	NIL	NIL	5	T2	1.51	53	23.2446	Y	N	10.2	mrm	10	Y	150	190	120	640	Y	11	N
50	poumali	55	27001	5	R	Y	Y	4	T2	1.56	57.9	23.7919	Ν	Ν	9.6	mrm	9	Ŷ	110	180	210	880	Y	16	Ϋ́