DISSERTATION ON

"A PROSPECTIVE STUDY OF POST MASTECTOMY SKIN FLAP ANCHORING AND SEROMA MONITORING"

BY

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DISSERTATION SUBMITTED FOR THE DEGREE OF

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CERTIFICATE

This is to certify that the dissertation titled ***"A PROSPECTIVE STUDY OF POST MASTECTOMY SKIN FLAP ANCHORING AND SEROMA MONITORING"*** is the bonafide work done by **Dr. A.SALEEM**, during his M.S. General Surgery course 2015-18, under my guidance and supervision in partial fulfilment of the rules and regulations laid down by The TamilNadu Dr. M.G.R. Medical University, Chennai for M.S. (Branch-I) general surgery Examination, MAY2018.

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DECLARATION

I, **Dr. A. SALEEM,** certainly declare that this dissertation titled ***"A PROSPECTIVE STUDY OF POST MASTECTOMY SKIN FLAP ANCHORING AND SEROMA MONITORING"*** represents a genuine work of mine. The contributions of any supervisors to the research are consistent with normal supervisory practice and are acknowledged. I also affirm that this bonafide work or part of this work was not submitted by me or any others for any award, degree or diploma to any other university board, either in India or abroad. This is submitted to the Tamil Nadu Dr. M.G.R. Medical University, Chennai in partial fulfilment of the rules and regulations for the award of Master of Surgery degree Branch I (General Surgery)

Date: **Dr. A. SALEEM**

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Dr. A.SALEEM

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Dear Dr.A.Saleem.,

The Institutional Ethics Committee has considered your request and approved your study titled "**A PROSPECTIVE STUDY OF POST MASTECTOMY SKIN FLAP ANCHORING AND SEROMA MONITORING" - NO.26012017 (III).**

The following members of Ethics Committee were present in the meeting hold on **24.01.2017** conducted at Madras Medical College, Chennai 3

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We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

14/2/17

Member Secretary - Ethics Committee

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This is to certify that this dissertation work titled ***"A PROSPECTIVE STUDY OF POST MASTECTOMY SKIN FLAP ANCHORING AND SEROMA MONITORING"*** of the candidate **Dr.SALEEM, M.B.B.S.,** with registration Number **221511008** for the award of **MS Branch-I,** in **General Surgery.** I personally verified the urkund.com website for the purpose of plagiarism Check. I found that the upload thesis file contains from introduction to conclusion pages and result shows 0% (Zero percentage) of plagiarism in the dissertation.

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INTRODUCTION

INTRODUCTION

Breast cancer has remained the second leading cause of cancer death among women worldwide over the past three decades and contributes significantly to cancer surgical load. Surgical treatment for breast cancer includes breast conservation surgery and mastectomy with or without axillary dissection depending on disease stage. Seroma formation is the most frequent postoperative complication seen after mastectomy and axillary surgery with an incidence of 3% to 85%.

It is so common that it is now believed to be a side effect of surgery rather than a complication. Associated morbidity in the form of prolonged drainage is not only troublesome to the patient but can also significantly impact treatment by delaying adjuvant therapy and increasing the risk for infection. A reoperation may be necessary for cases of longstanding persistent seroma.

This review updates the various factors thought to contribute to seroma formation and the probable interventions that may be of help to reduce the incidence. In this study, we assess the role of skin flap

anchoring and seroma monitoring. This study was conducted at the Institute of General Surgery, Madras Medical College and Rajiv Gandhi Government General Hospital.

AIM AND OBJECTIVES

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AIM

To assess the role of skin flap anchoring and seroma monitoring in modified radical mastectomy.

OBJECTIVES

1. To study outcome of skin flap anchoring in modified radical mastectomy
2. To study the positive effect of be skin flap anchoring on seroma formation.
3. To study relation between skin flap anchoring and early drain removal.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Aetiology

Carcinoma breast is more common in developed, western countries. In African-American women, it is more aggressive. It is less common in Japan, Taiwan.

It is second most common carcinoma in females. Incidence is 19-34%. Median age is 47 years. Carcinoma in one breast increases the risk of developing carcinoma on opposite breast by 3-4 times. Incidence of bilateral carcinoma is 2%. It is more common after middle age, but can occur at any age group, after 20 years. It can be familial in 2-5% cases. Mutation of tumour suppressor genes BRCA1/BRCA2 is related to high-risk of breast carcinoma.

Occasionally mutation of BRCA3 gene and p53 tumor suppressor gene is also relevant. It is mainly in nulliparous woman. Attaining early menarche and late menopause have related high-risk of breast malignancy. It is common in obese persons. Breast cancer relative risk is calculated as relative risk .If relative risk is 2.0 then risk is twice the

normal population. If the relative risk is 0.5 then risk is 50% less than normal population. Risk is 3-5 times more and strong if first degree relative is having breast cancer.

Risk is more if first degree relative is younger /premenopausal / having bilateral breast cancers. Previous radiation may predispose carcinoma breast Particularly when radiation is given at small larage for lymphoma.

It is common in people who using OCP and hormone replacement therapy for five years or even more.

Presently carcinoma breast is considered as a systemic disease. *Halsted concept* of spread is *sequential spread*. Breast—axillary lymph node systemic spread. *Fischer concept* is early to begin with itself, there is distant blood spread because of *micrometastasis* without nodal disease. Only tumour lesser than 1 cm size can be sequential. *Spectrum concept* is new one where disease spreads loco-regionally as well as systemically

which makes it to aim at both locoregional disease control as well as systemic disease control.

Pathology

Breast carcinoma arising from lactiferous ducts is called as *ductal carcinoma*.

Breast carcinoma arising from lobules is called as *lobular carcinoma*. It is 10% common.

In situ carcinoma is pre invasive carcinoma which has not breached the epithelial basement membrane.

Classifications

I. Ductal carcinoma breast and Lobular carcinoma breast.

II. (a) *In situ* carcinoma (Noninvasive carcinoma)

DCIS (Ductal carcinoma breast *in situ*).

LCIS (Lobular carcinoma breast *in situ*).

(b) Invasive.

Invasive ductal carcinoma—most common type. Adenocarcinoma with *no special type* (80%) is more common. 60% of this will show micro or macroscopic spread to axillary nodes. Invasive type can be special type or no special type. Invasive lobular carcinoma. It is commonly multifocal and often bilateral.

III. Unilateral, Bilateral—2-5% common.

IV. Unifocal.

Multifocal—tumour tissues within the same quadrant atmultiple foci.

Multicentric—tumour tissues within the same breast butin different quadrant.

Types of Carcinoma Breast

1**.** ***Scirrhous carcinoma****:* It is 60% common. It is hard, whitish, or whitish yellow, noncapsulated, irregular, with *cartilaginous* consistency. It contains malignant cells with fibrousstroma.

2. ***Medullary carcinoma (5%):*** Also called as encephalloid type because of its brain like consistency. It contains malignantcells with dispersed lymphocytes.

Medullary variant with some features of pure form show suniformly high grade aggressive tumour cells with negative ER, PR, HER2 NEU cell surface receptors (triple negative). They express molecular markers of basal/ myoepithelial cells and so now termed as *basal-likebreast cancers.*

3. Inflammatory carcinoma/Lactating carcinoma/Mastitis carcinomatosis:

Most aggressive type of carcinoma breast. It is 2% common. It is common in lactating women or pregnancy. It mimics acute mastitis because of its short duration, pain, warmth and tenderness. Clinically, it is a rapidly

progressive tumour of short duration, diffuse, painful, warm often involving whole of breast tissue with occurrence of peau d' orange, often extending to the skin of chest wall also.

4. Colloid carcinoma: *It produces abundant mucin, both intra and extra cellularly carrying better prognosis.*

5. Paget's disease of the nipple: *It is superficial manifestation of an intra ductal carcinoma. The malignancy spreads within the duct up to the skinof the nipple and down into the sub stance of the breast.It mimics eczema of nipple and areola.*

6. Tubular, papillary, cribriform are other types of duct carcinomas.

7. Atrophic scirrhous carcinoma:

Seen in elderly females. It is a slow growing tumour which has got better prognosis.

8. Lobular carcinoma in situ: *It originates in terminal duct lobular unit only of female breast showing its distension and distortion. It is 12 times more common in white females. Predominantly perimenopausal. It is multifocal, bilateral (50%). 50% cancers can develop in the contralateral breast.* ***9. Disease of Reclus:*** *It is a rare intracystic papil liferous carcinoma of breast presenting as a cystic swelling with bloody discharge from the nipple.*

Grading of the Tumour

It is based on nuclear pleomorphism; tubule formation; mitotic rate.

It can be—well-differentiated (grade 1); moderately differentiated (grade 2) and poorly differentiated (grade 3). Tumour doubling occurs in 6 months with reaching 1 cm in size in 30 doublings. Breast cancer more than 1 cm has its own blood supply and so high chances of systemic spread and so systemic therapy is a must.

Biological Behaviour and Clinical Features of Carcinoma Breast

Most common site is upper outer quadrant (60%) because breast tissue is more in this quadrant.

Cutaneous Manifestations of Carcinoma Breast

Peau d'orange: Due to obstruction of dermal lymphatics, openings of the sebaceous glands and hair follicles getburied in the oedema giving rise to orange peel appearance. Dimpling of skin due to infiltration of ligament of Cooper. Retraction of nipple due to infiltration of lactiferousduct. Ulceration, discharge from the nipple and areola. Skin ulceration and fungation. Cancer-en-cuirasse: Skin over the chest wall and breastis studded with cancer nodules appearing like an armourcoat. Tethering to skin.

Spread into the Deeper Plane

Into pectoralis major muscle (is confirmed by observing the restricted mobility of the swelling while contracting the PM muscle). Into latissimus dorsi muscle (extending the shoulder against resistance). Into serratus anterior (by pushing the wall with hands without flexing the elbow). Into the chest wall (breast will not fall forward when leaning forward, and while raising the arm above the shoulder, breast will not move upwards as it is fixed to the chest wall).

Lymphatic Spread

It occurs through:

Subareolar Sappey's lymphatic plexus Cutaneous lymphatics.

Intramammary lymphatics.

Lymphatic drainage of the breast is predominantly through axillary (75%) and internal mammary lymph nodes.

Axillary group of nodes are:

1. Anterior along lateral thoracic vessels (Pectoral).

2. Central embedded in fat in the centre of the axilla.

3. Posterior along subscapular vessels.

4. Lateral along axillary vein.

5. Apical lies above pectoralis minor tendon in continuity with the lateral nodes and receive efferents from all the groups. Spread to these lymph nodes occur by lymphatic permeation. Interpectoral, lies between pectoralis major and minor muscle (Rotter's nodes). Presently involvement of these lymph nodes are considered due to retrograde spread. These lymph nodes are cleared during Patey's mastectomy From

axillary lymph nodes spread occurs to supraclavicular lymph nodes by lymphatic embolisation. Through dermal lymphatics, it may spread to opposite breast or to opposite axillary lymph nodes.

Spread restricted to level I nodes carries better prognosis. Spread to level II has poor prognosis. Spread to level III indicates worst prognosis. Spread may occur into internal mammary lymph nodes of same side and then to mediastinal lymph nodes.

Contralateral internal mammary lymph nodes can also get involved by retrograde spread. Fixed enlarged axillary nodes can cause lymphoedema due to lymphatic block; venous thrombosis and venous oedemadue to venous block; and severe excruciating pain along thedistribution of the median and ulnar nerves (rare in radialnerve) with often significant sensory and motor deficits due to tumour infiltration of the cords of brachial plexus (medialcord often lateral cord).Once axillary lymph nodes get fixed, it can result in lymphoedema of the upper limb. .

It develops gradually. Compression of nodes on axillary vein can cause sudden onset of venous oedema of upper limb (Venous edema develops faster, and is more proximal with bluish discolouration of the skin of the upper limb. It may lead to venous, gangrene and so the compression has to be relieved early by radiotherapy).

Breast is in subcutaneous plane, but its extension, axillary tail of Spence passes through an opening in the deep fascia (foramen of Langer). Often it is difficult to differentiate between lymph node in pectoral region and tumour invasion of axillary tail. Mobility will be indepen dent if it is a lymph node, but if it is an axillary tail tumour, it is along with the primary tumour in the breast.

Haematogenous Spread

Bone (most common) (70%) Lumbar vertebrae, femur, ends of long bones, thoracicvertebrae, ribs, skull, in order. They are osteolytic lesion often with pathological fracture. Presents with painful, tender, hard,

nonmobile swelling, with disability.70% of secondaries in bone in a women is due to carcinomabreast.

Spine secondaries can cause paraplegia.

Liver—either through blood, occasionally through transcoelomic spread.

Lung—causes malignant pleural effusion and cannon ball like secondaries.

Brain—causes increased intracranial pressure, coning. Adrenals and ovaries.

Transcoelomic Spread

Through mediastinal lymph nodes, it may spread into peritoneal cavity causing secondaries in liver, peritoneum, ovary (Krukenberg secondaries-

occurs in menstruatingage groups. During ovulation, cells get attached over the ovarian capsule).

Staging of Carcinoma Breast (Manchester and TNM Staging)

Manchester Staging

1. Tumour in the breast, not involving pectoral or deeper plane. Skin involvement if present, it is lesser than the size of tumour. Lymph nodes are not palpable.

2. Same as stage I but with mobile, discrete lymph nodes palpable in the ipsilateral axilla.

3. Tumour fixed to pectoral muscle, or skin involvement more than the tumour size or ipsilateral axillary lymph nodes adherent to each other or fixed.

4. Tumour fixed to the chest wall, skin involvement wider than that of the breast, involvement ofipsilateral or contralateral supra clavicular lymph nodes oropposite breast or opposite axillary lymph nodes,

TNM STAGING

Primary Tumor (T)

TX Primary tumor can't be assessed .

T0 No evidence of primary tumor

Tis Carcinoma breast in situ.

Tis (DCIS) Ductal carcinoma breast in situ

Tis (LCIS) Lobular carcinoma breast in situ

Tis Paget's disease of the nipple no association with invasive carcinoma and carcinoma in situ in the underlying breast parenchyma.

T1 Tumor ≤ 20 millimeter in longest dimension.

T1mi Tumor ≤ 1 mm in longestdimension.

T1a Tumor > 1 mm but ≤ 5 mm in longest dimension.

T1b Tumor > 5 mm but ≤ 10 mm in longestdimension.

T1c Tumor > 10 mm but ≤ 20 mm in longest dimension.

T2 Tumor > 20 mm but ≤ 50 mm in longest dimension .

T3 Tumor > 50 mm in longest dimension.

T4 Tumor of any size with direct extension to the chest wall and/ or with the skin.

T4b Ulceration and/or ipsilateral satellite nodules with edema (including peau d'orange) of the skin, which dont fulfil the criteria for inflammatory carcinoma.

T4c Both T4a and T4b.

T4d Inflammatory carcinoma of breast.

Regional Lymph Nodes (N)

NX Regional lymph nodes can't be assessed

N0 No metastasis to regional lymph node

N1 Metastases to mobile ipsilateral level I, II axillary lymph node

N2 Metastases in ipsilateral level I, II axillary lymph nodes that are fixed ipsilateral internal mammary nodes in the absence of axillary lymph node metastases.

N2a Metastases in ipsilateral level I, II axillary lymph nodes fixed

N2b Metastases only in clinically identified ipsilateral internal mammary nodes and in the absence of level I, II axillary lymph node metastases

N3 Metastases in ipsilateral infraclavicular lymph node with or without level I, II axillary lymph node involvement or in clinically identified ipsilateral internal mammary lymph node with clinically evident level I, II axillary lymph node metastases or metastases in ipsilateral supraclavicular lymph node with or without axillary or internal mammary lymph node

N3a Metastases in ipsilateral infraclavicular lymph node

N3b Metastases in ipsilateral internal mammary lymph node and axillary lymph node

N3c Metastases in ipsilateral supraclavicular lymph node

Distant Metastases (M)

M0 No clinical or radiological evidence of distant metastases.

cM0(i+) No clinical or radiological evidence of distant metastases, but deposits of microscopically detected tumor cells in circulating blood, bone marrow, or other nonregional nodal tissue area that are no larger than 0.2 mm in a person without symptoms or signs of metastases.

M1 Distant detectable metastases as determined by clinical and Radiological means andhistologically proven larger than 0.2 mm.

Stage 0 Tis N0 M0

Stage IA T1* N0 M0

Stage IB T0 N1mi M0 T1* N1mi M0

Stage IIA T0 N1** M0 T1* N1** M0 T2 N0 M0

Stage IIB T2 N1 M0 T3 N0 M0

Stage IIIA T0 N2 M0 T1* N2 M0 T2 N2 M0 T3 N1 M0 T3 N2 M0

Stage IIIB T4 N0 M0 T4 N1 M0 T4 N2 M0

Stage IIIC Any T N3 M0

Stage IV Any T Any N M1

Investigations in Carcinoma Breast

<u>Mammography:</u>

Bilateral mammography is done to identify multicentricity,to have guideline for assessing eventual chemotherapy orRT in LABC.

<u>Ultrasound of breast:</u>

To find out whether the lesion is solid or cystic.

<u>FNAC:</u>

It is very useful in diagnosingthe carcinoma breast. U/S guided FNAC is also used. But negative results are difficult to interpret because it maybe due to sampling errors and so requires further diagnostic methods. FNAC of opposite breast, lymph nodes, opposite axillary lymph nodes are also often required.

Corecut/Trucut biopsy:

It is done under local anaesthesia. It gives clear histological evidence and also confirms DCIS (FNAC can not confirm DCIS). This allows proper neoadjuvant /primary chemotherapy, receptor status of the tumour. Wide boreneedle biopsy with vacuum is also used.

Excision biopsy:

It is done only when FNAC is inconclusive and a facility for frozen section is not available. Incision should be planned in such a way that it will be included in eventual mastectomy.

Chest X-ray:

To look for pleural effusion, cannon ball secondariesin lungs, mediastinal lymph nodes, secondaries in rib.

CT chest:

It is more reliable method to see lung secondaries.

Ultrasound abdomen:

To look for liver secondaries, ascites, Krukenbergs tumour.

X-ray spine shows osteolytic secondaries.

Oestrogen receptor study:

They are oestrogen sensitive receptors, which are cytosolic, glycoprotein present in the breast and tumour issue. It is an important indicator of prognosis of carcinomabreast.

Progesterone receptor (PR status) study or Her 2 Neu receptor status or cErb

B2 (growth factor receptor study) are other studies done at present to plan the therapy and assess the prognosis.

MRI of breast:

To differentiate scar from recurrence.

To image breasts of women with implants.

To evaluate the management of axilla and recurrent disease.

Edge biopsy:

Done only when there is ulceration and fungation.

Diathermy should be avoided in incision biopsy as it may distort the histology of tumour and study of hormone receptor status may not be possible.

Tumour markers:

CA 15/3 (normal value < 40 U/ml of serum) are used mainly during follow-up period. CEA, CA15-3, CA 27-29 may be useful.

PET scan:

It may be an effective single scan for bone, soft tissue or visceral metastases in patients with symptoms or signs of metastatic disease.

Sentinel lymph node biopsy (SLNB):

The first axillary node draining the breast (by direct drainage) is designated as the sentinel node (SLN). SLN is first node involved by tumour cells and presence or absence of its histological involvement, when assessed will give a predictive idea about the further spread of tumour to other nodes. The incidence of involvement of other nodes without SLN is less than 3% and so if SLNB is negative nodal dissection can be avoided but regular follow-up is needed. SLNB is done in all cases of early breast cancers, T1 and T2 without clinically palpable node.

CT scan of chest:

Abdomen and brain whenever needed. CT is said to be more useful to detect secondaries in these regions.

Ductography:

It is contrast study of ducts of breast in case of unilateral nipple discharge.

Fine cannula is passed under vision carefully through the duct opening into the duct and 0.2 ml of dilute water-soluble contrast media is injected

into the duct. Craniocaudal and medio lateral X-ray films are taken. Contrast irregular f lling defect may be observed.

Breast ductal endoscopy:

It is useful in direct visualisation of the tumour in DCIS and invasive ductal carcinomas. But it is technically difficult and demanding. Blood count, complete liver function tests are needed.

Treatment

It is usually through a combined approach

Surgery

Radiotherapy

Hormone therapy

Chemotherapy.

<u>Surgeries for Carcinoma Breast</u>

MANAGEMENT OF EARLY CARCINOMA BREAST

Early breast cancer is the one diagnosed by mammography or stage I carcinoma breast.

Usually chest X-ray, blood count and liver functions are sufficient to screen the early breast cancer patients.

Aims of Treatment

To achieve possible curative level.

Control of local disease in breast and axilla.

Breast conservation, i.e. breast form and function.

Prevention of distant metastasis.

To prevent local recurrence.

<u>Indications</u>

Lump < 4 cm

Clinically negative axillary nodes

Mammographically detected lesion

Well-differentiated tumour with low S phase

Adequate sized breast to allow proper RT to breast

Breast of adequate size and volume

Feasibility of axillary dissection and radiotherapy to intact breast

Contraindications

Tumour > 4 cm

Positive axillary nodes > N1

Tumour margin is not free of tumour after breastconservative surgery needs MRM

Poorly differentiated tumour

Multicentric tumour

Earlier breast irradiation

Tumour/breast size ratio is more (centeral tumour)

Tumour beneath the nipple

Extensive intraductal carcinoma

Modalities of Treatment

Breast conservative surgery (BCS)—ideally done as wide local excision with axillary dissection with RT to breast and chest wall. Quadrantectomy as a part of QUART therapy may be used only in selected patients. RT is given to the entire breast with 4500 cGy dose.

Patey's operation or simple mastectomy with axillaryclearance.

Postoperative radiotherapy in high-risk patients.

Hormone therapy, i.e. tamoxifen 10 mg BID or 20 mg OD.

Sentinel node biopsy when required.

Regular follow-up often with radioisotope bone scan and CEA tumour marker.

In early breast cancer, breast conservative surgery like wide local

excision/quadrantectomy, axillary dissection (level Iand II) and postoperative radiotherapy (to the breast) is usedwhich prevents the disfi gurement and psychological traumaof mastectomy to the patient. Tumour is removed with a rimof normal tissue. Wide excision and QUART therapy are different procedures. Wide local excision is ideal and betterwhere clearance margin is 1 cm. In quadrantectomy entiresegment with ductal system with 2-3 cm clearance margin isachieved. But it is not advocated now as there is no benefit inoutcome (survival/recurrence rate) by quadrantectomy over wide local excision.

Principles of Conservative Breast Surgery

Curvilinear nonradial incisions (radial incisions should not be placed, because if there is a need to convert into total mastectomy, then incision plan may be difficult).

Separate incision for axillary dissection.

Undermining of the skin flap must be avoided.

Confirm tumour clearance by frozen section. It may be often difficult and so tumour is cut and only margin which is close and doubtful is advocated for frozen section.

Radiotherapy is a must to breast and chest wall region (locally).

QUART Therapy

It is quadrantectomy, axillary dissection of level I and II nodes with separate axillary incision and postoperative radiotherapy to breast (5000 cGy) and axilla (1000 cGy). First it was started by Umberto Veronesi from Milan. Now Quart therapy is only occasionally used.

Skin Sparing Mastectomy (SSM)

It is like a key-hole surgery of breast.

Skin sparing/limited skin excision (5-10%) will not alter/affect the recurrence rate.

Marginal skin excision over the tumour/biopsy site.

Total glandular mastectomy.

Axillary dissection using either same (extension of SSM incision) or separate incision in the axilla.

Indications for Total Mastectomy in EarlyBreast Cancer

When tumour is more than 4 cm.

Multicentric tumour.

Poorly differentiated tumour—high grade.

Tumour margin is not clear of tumour after breast conservative surgery.

Principles of Axillary Dissection/Axillary Clearance

Indications:

Axillary dissection is done when there is clinical involvement of nodes; when FNAC of lymph nodenor sentinel node biopsy proved malignancy; when in a large tumour where reconstruction is needed so that 2nd eventual axillary surgery is difficult at a later period.

It is removal of fat, fascia, nodes in the axilla. Usually level I and II nodes are removed. Nodes below the axillary vein are only removed. Level III dissection increases the chances of lymphoedema. Risk of lymphoedema further rises if RT is given later along with level III dissection.

Dissection is done through an individual crease transverse incision in the axilla, when it is advocated with breast conservative surgery. When it is advocated along with total mastectomy it is done like modified radical mastectomy—Auchincloss iscommonly used.

<u>Total or simple mastectomy:</u>

In simple mastectomy the tumour, whole breast, areola, nipple, skinof breast, With axillary tail are removed. Therewill no axillary dissection. Often the patient is subjectedto radiotherapy later on axilla. Pectoral fascia is removed with breast and breast tissue superficial to axillary fascia is removed.

Total mastectomy with axillary clearance:

Commonly procedure in practice. Total mastectomy is done with removal of axillary fat, fascia and lymph nodes. Level I and II axillary nodes are removed with simple mastectomy.

Modified radical mastectomy [MRM]:

Patey's operation: *It is total mastectomy with clearance of all the three levels of axillary nodes and removal of pectoralis minor too. . An elliptical incision is made from medial aspect of the second and third intercostal space enclosing the nipple, areola and tumour extending laterally into the axilla along the anterior axillary fold. Upper and lower skin flaps are raised. Breast with tumour is raised from the medial aspect of the pectoralis major muscle. Dissection is proceeded laterally with ligating pectoral vessels. Once dissection reaches axilla, lateral border of pectoralis major muscle is cleared with level I nodes.*

Pectoralis minor is divided from coracoid process to clear level II nodes. Medial and lateral pectoral nerves should be preserved (otherwise atrophy of pectoralis minor muscle occurs). Later from the apex of axilla level III nodes are cleared.

Nerve to serratus anterior, nerve to latissimus dorsi, intercostobrachial nerve, axillary vein, cephalic vein and pectoralis major muscle are preserved. Wound is closed with a suction drain.

Scanlon's operation:

Is a modified Patey's operation instead of removing pectoralis minor, it is incised for approaching the affected level III lymph nodes.

Auchincloss modified radical mastectomy:

Here pectoralis minor muscle is not removed and level III lymph nodes are not dissected

Halsted Radical Mastectomy (Complete Halsted) (RM):

Structures removed are:

Tumour.

Entire breast, nipple, areola, skin over the tumour with margin.

Pectoralis major and minor muscles.

Fat, fascia, lymph nodes of axilla.

Few digitations of serratus anterior.

Conservative breast surgeries:

Wide local excision

Quadrantectomy

Toilet mastectomy

Extended radical mastectomies

Skin sparing mastectomy

Lumpectomy/partial mastectomy is better called as wide local excision

Complications of MRM/mastectomy

Injury/thrombosis of axillary vein

Seroma—50-70%

Shoulder dysfunction 10%

Pain (30%) and numbness (70%)

Flap necrosis/infection

Lymphoedema (15%) and its problems

Axillary hyperaesthesia (0.5-1%)

Winged scapula

Occasionally if on table injury occurs to axillary vein, it shouldbe repaired by vascular suturing using 5 zero polypropylene Numbness over the medial upper part of the arm can occurdue to intercostobrachial nerve injury Pectoral muscles atrophy if medial and lateral pectoral nervesare injured Weakening of internal rotation and abduction of shoulderoccurs due to injury to thoracodorsal nerve.

Lymphangiosarcoma (Stewart-Treve's syndrome) of upper limb can develop in patients who have developed lymphoedemaafter mastectomy with axillary clearance. Usually it occurs 3-5years after development of

lymphoedema. Such patient mayrequire fore-quarter amputation. It has got poor prognosis.

Itpresents as multiple subcutaneous nodules.

Radiotherapy in Carcinoma Breast

Indications:

Patient who underwent conservative breast surgery, breast is irradiated after surgery. After total mastectomy, external radiation is given to axilla.

Patients with higher risk of relapse after surgery:

a. Invasive breast carcinoma.

b. aggresive in situ carcinoma of breast.

c. Patients below 35 years.

d. With multifocal disease.

In bone secondaries, to palliate pain and swelling. If there is pathological fracture is present, internal fixation has to be done along with external irradiation.

Inflammatory carcinoma of breast.

In scirrhous carcinoma of breast, curativeradiotherapy can be helpful.

As preoperative radiotherapy, to reduce the tumour sizeand downstage the tumour, so that the operability and accessability is better.More than 4 positive lymph nodes in the axilla, pectoral fasciaspread, positive surgical margins, extranodal spread and in patients with axillary status not assessed.

Hormone Therapy in Carcinoma Breast Principles:

It is utilised in ER and PR positive persons in all age groups .It is safe, easy to administer. It gives prophylaxis against carcinoma of other breast also.

It is very useful in metastatic breast carcinoma.

Hormone therapy is used in breast cancer in elderly (positive ER) after wide local excision It is now not used in ER negative persons.

Menopausal statu, nodal status,chemotherapy used are no more factors to defer the use of hormone therapy.

Hormone therapy reduces the recurrence rate and so improves the life span.

Oestrogen receptor antagonists—tamoxifen.

Ovarian ablation by surgery (Bilateral oophorec tomy) orby radiation.

LHRH agonists (Medical oophorectomy).

Oral aromatase inhibitors for postmenopausal women.

Adrenalectomy or pituitary ablation.

Progesterone receptor antagonist.

Aminoglutethimide—blocks the synthesis of steroids byinhibiting conversion of cholesterol to pregnenolonemedical adrenalectomy.

Progestogens, e.g. medroxyprogesterone acetate.

Chemotherapy in Carcinoma Breast

Adjuvant chemotherapy is administration of chemo drugs to women after breast surgery to removeo clinically undetectable distant spread. Reduced recurrence rate and improved survival rate is observed in all women with invasive breast cancer. Chemotherapy is usually not indicated in DCIS.

Neoadjuvant chemotherapy *is administration of chemo drugs in a large operable tumour to reduce the tumour size to make it better approachable for surgical resection, usually after 3 doses. It downstages the disease*

early systemic control is achieved.

Palliative chemotherapy is used in advanced carcinoma breast.

Indications:

All node positive persons. Primary tumour of breast is more than 1 cm in size. Presence of poor prognostic signs vascular and lymphatic Invasion high nuclear and histologic grade; Her 2/Neu overexpression negative hormone receptor status.

In advanced carcinoma breast In postoperative period after total mastectomy in stage III carcinoma breast with fixed axillary nodes.

In inflammatory carcinoma of the breast.

In stage IV carcinoma breast with secondaries in lungs,bones, liver.

In premenopausal age with poorly differentiated tumour.

1st line drugs—anthracyclines—FEC regimen (better); CAF; CMF

2nd line drugs—taxanes

3rd line—gemcitabine

MATERIALS AND METHODS

MATERIALS AND METHODS

PLACE OF STUDY:

Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai-600003.

STUDY DESIGN

Interventional study (Prospective)

PERIOD OF STUDY:

February 2017 to September 2017 (8 months)

Sample Size:

50 (25 test vs 25 control){Sample size N=Z^2P(1-P)/d^2 where

Z=1.96,P=10%,d=10%}

Inclusion Criteria:

Patients posted for modified radical mastectomy in Rajiv Gandhi Government General Hospital, Chennai-600003.

Exclusion Criteria:

Patient unfit for surgery, Advanced disease

Background

Breast cancer is the second most common in women, and it was estimated approximately 167 million of new cases in breast cancer in 2012 (25% of total cancer). The breast cancer in Asia is escalating more rapidly than in the west, for instance, in Singapore the Age-Standardized Incidence Rate (ASR) of breast cancer had increased from 202 per 100,000/year between 1968 and 1972 to 549 per 100,000/year between 1998 and 2002 [1]. Breast cancer is also a common cancer in women in India. The incidence of breast cancer in India in 2012 amounted to 48,998 people (30.5%) of the total 160,833 people affected by cancer. The mortality of 19,750 people or 21.5% of total mortality caused by cancer are 92,821 people. The prevalence of breast cancer in Indonesia for the last 5 years was

171,005 (41.7%) [2]. Although several non-invasive techniques have been developed for the treatment of cancers, surgery is the gold standard for most of the life-threatening diseases. Surgery for operable breast cancer has evolved a long way since W. Halsted first described this malignancy

[3]. The type of surgery depends on the stage of the breast cancer at the time of presentation and surgeon's choice. The different surgical treatment options available include simple mastectomy, modified radical mastectomy and breast conservation surgery. Among these procedures, modified radical mastectomy (MRM) is the most commonly performed procedure (in about 70% women) [4]. Seroma, an accumulation of fluid can infrequently occur after any surgical procedure and is the most prevalent postoperative sequel after breast surgery, with an incident of 10% to 85% leading to significant morbidity and discomfort and possibly delayed adjuvant therapy [5]. An ideal skin flap fixation will minimize the intrusion of lymph fluid and serum leakage and provide a way of holding the skin flaps safely to the structure of the chest wall thereby obliterating the dead space. It allows the lymph that is formed to drain more quickly . A number of fixation techniques of skin flaps or wound drainage necessary to be conducted, as well as restriction of shoulder movement of post-operative and the using of glue, have been studied to

improve primary healing and to minimize the production of seroma [6]. The study was to evaluate the effect of obliteration of dead space with suture fixation of mastectomy skin flaps on chest wall so as to prevent the incidence of seroma formation.

Seroma :

Seroma is defined as a serous fluid collection that develops under the skin flaps during mastectomy or in the axillary dead space after axillary dissection (Pogson et al, 2003). Seroma formation generally begins on the seventh day post surgery, reaches a peak rate of growth on the eighth day and slows continuously until the sixteenth day when it generally resolves (Menton and Roemer, 1990). Watt-Boolsen et al (1989) found that the composition of the fluid and aspirates and the time-related changes of the investigated criteria suggested that Seroma is not an accumulation of serum, but an exudates. Exudate is an element in an acute inflammatory reaction, i.e. the first phase of wound repair Seroma formation reflects an increased intensity and a prolongation of this repair phase. Watt-Boolsen et al (1989) also posited that the predominant white cells present in a seroma were granulocytes rather than lymphocytes, indicating that the fluid is likely to be exudate. The protein concentration in seromas was found to be more consistent with that of an exudate produced as a result of acute inflammation during wound healing (Watt-Boolsen et al, 1989). Gardner et al (2005) suggests that there are seven causative factors contributing to seroma formation Poor adherence of flaps to chest wall Division of several larger lymph trunks Large dead space/large raw area in the axilla Pump action of upper limb increasing

lymph flow Local inflammatory mediators, Irregular shape of chest wall and axilla Shear forces during respiration. Although seromas are not lifethreatening, they can lead to significant morbidity (e.g. flap necrosis, wound dehiscence, predisposition to sepsis, impaired shoulder function [muscle strength weakness], prolonged recovery period and multiple physician visits) and may delay adjuvant therapy (Budd et al, 1978; Aitkin and Minton, 1983; Gardner et al, 2005). Extensive dissection generates a considerable potential space as breast tissue is removed and lymphatic vessels are severed allowing lymph to pass into the dead space.

The distensibility of the skin flaps raised during the surgery further establishes a potential space in which fluid can collect. In addition, axillary lymph node dissection results in the division of several larger lymph trunks, and when the arm is mobilised post-operatively, the upper-limb musculature acts as a pump, increasing lymph flow (Gardner et al, 2005). It is common for people who have had their lymph nodes removed to experience fullness under the arm after the drain(s) has been removed. Evidence on the effect of drains on seroma formation is inconclusive (Gardner et al, 2005). Following a modified radical mastectomy it is also possible to develop seroma on the chest wall. As with a haematoma, this fluid is reabsorbed by the body over time. Persistent seromas have

traditionally been treated with repeated aspirations, local pressure dressings, and occasionally surgical ablation (Gardner et al, 2005). Seromas should only be aspiratedwhen symptomatic (Anand et al, 2002).

In some cases, the fluid collection may recur so this may need to be done more than once (Cancer Society of New Zealand, 2003). Seromas can generally be managed by one to six aspirations (Gonzalez et al, 2003). However, the use of fine needle aspiration to assess changes in an oedematous breast can be problematic and may, in itself, produce additional inflammation and oedema (Williams, 2006).

Although seromas are not life-threatening, they can lead to significant morbidity (e.g. flap necrosis, wound dehiscence, predisposition to sepsis, impaired shoulder function [muscle strength weakness], prolonged recovery period and multiple physician visits) and may delay adjuvant therapy.

Several interventions have been reported with the aim of reducing seroma formation including the use of pressure garment and prolonged limitation of arm activity. However, it has been suggested that the use of these interventions not only reduces seroma formation, but may also

increase the incidence of seroma formation after removal of the drain (O'Hea et al, 1999), and even might cause shoulder dysfunction (Dawson et al, 1989). Seroma formation after breast cancer surgery occurs independently of drainage duration, compression dressing and other known prognostic factors in breast cancer patients except the type of surgery, i.e. there is a 2.5 times higher risk of seroma formation in patients who undergo a modified radical mastectomy compared to breast-conserving surgery (Hashemi et al, 2004). Schultz et al (1997) were able to show that immobilisation of the shoulder until day seven postoperatively significantly reduced the incidence of seroma.

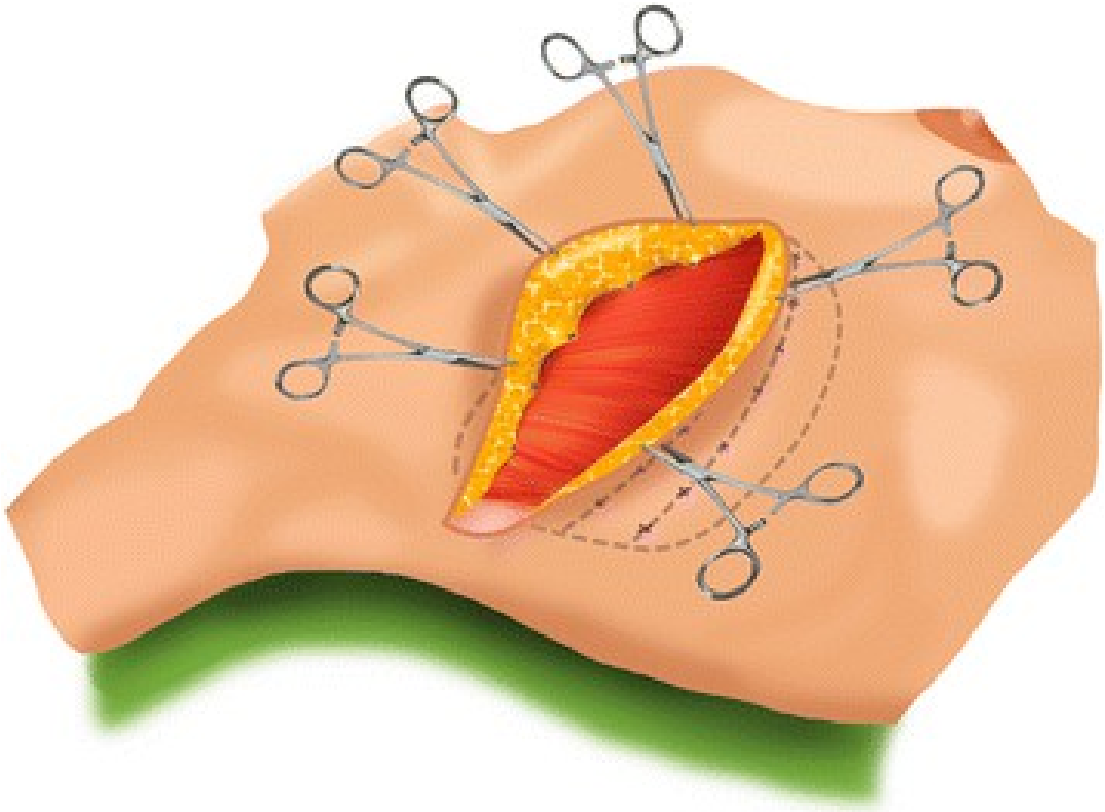
However, other authors describe how immobilisation of the upper limb generated unacceptable rates of frozen shoulder and, therefore, advise early shoulder exercises. Evidence for a clear role of immobilisation in seroma prevention is still lacking (Gardner et al, 2005). Postoperative breast seroma, therefore, is an important cause of morbidity that continues to cause difficulties for surgeons and for which the best treatment has long been debated (Gardner et al, 2005).

METHODS:

Patients undergoing flap fixation had flaps anchored to the underlying muscle using multiple rows of interrupted 2/0 polyglactin (vicryl) sutures. Sutures were placed approximately 2.5 cm apart and all sutures were buried . Care was taken not to include the long thoracic nerve in the suture when anchoring the axillary flaps. Patients having drainage had one or two suction drains sited beneath the mastectomy flaps and in the axilla (if axillary dissection was performed). Drains were removed when draining less than 20 ml of serous fluid for two consecutive days.

The effect of flap fixation over early drain removal and seroma formation are studied.

Schematic depiction of points of flap fixation



STATISTICAL ANALYSIS

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.

OBSERVATION AND ANALYSIS

OBSERVATION AND INFERENCE

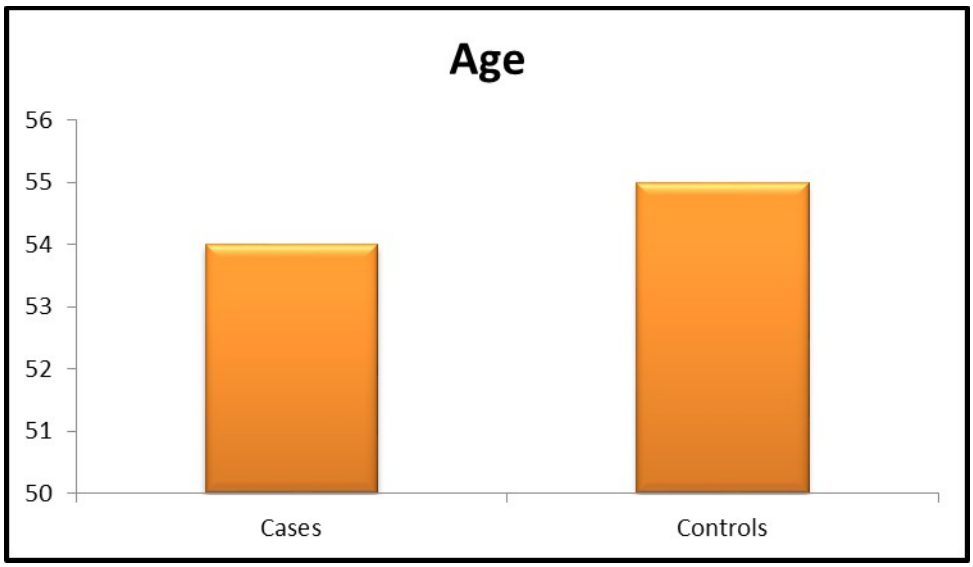
50 (25 +25) consecutive patients admitted to the Institute of General Surgery, RGGGH were studied.

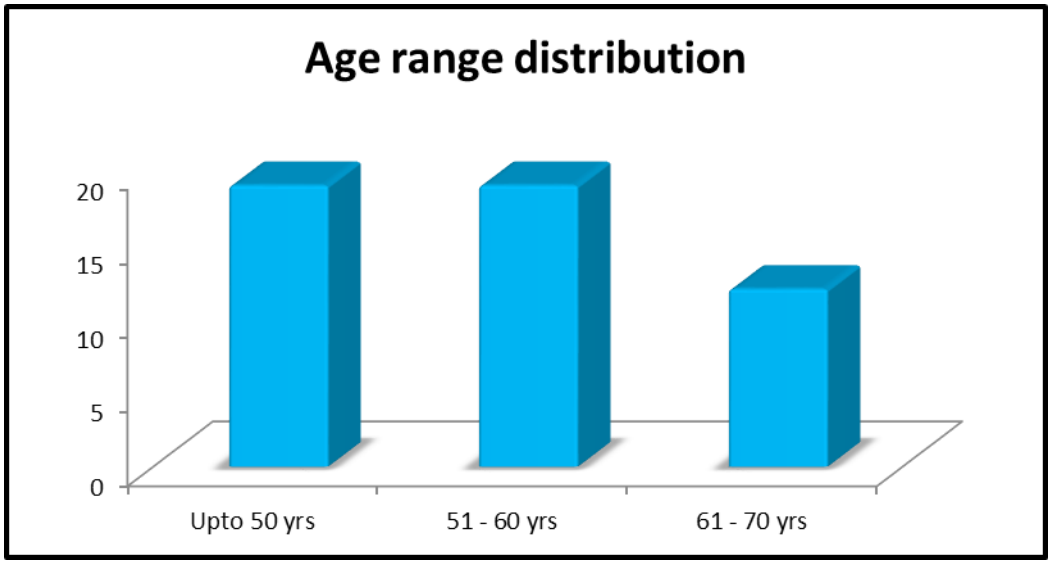
The post operative day of drain removal done for cases : about 4% in 3rd pod , 76% in 4th pod, 20% in 5th pod.

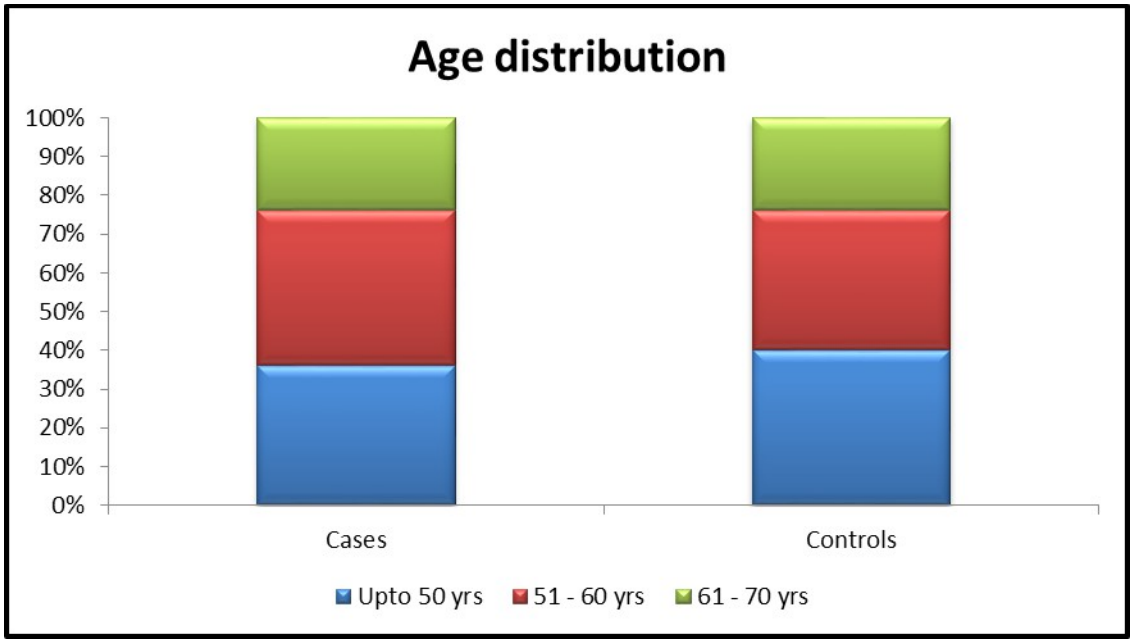
The post operative day of drain removal for controls : about 4% on 4th pod, 20% on 5th pod 28% on 6th pod 36% on 7th pod 12%on 8th pod.

About 8% cases developed seroma.

About 20% controls developed seroma.


Age
56
55
54
53
52
51
50
Cases
Controls


Age range distribution
20
15
10
5
0
Upto 50 yrs
51 - 60 yrs
61 - 70 yrs


Age distribution
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
Cases
Controls
Upto 50 yrs
51 - 60 yrs
61 - 70 yrs

AGERANGE

		Frequency	Percent
Valid	Upto 50 yrs	19	38.0
	51 - 60 yrs	19	38.0
	61 - 70 yrs	12	24.0
	Total	50	100.0

MEAN AND SD

CC		N	Mean	Std. Deviation	Std. Error Mean
AGE	Cases	25	54	8.189	1.638
	Controls	25	55	9.193	1.839

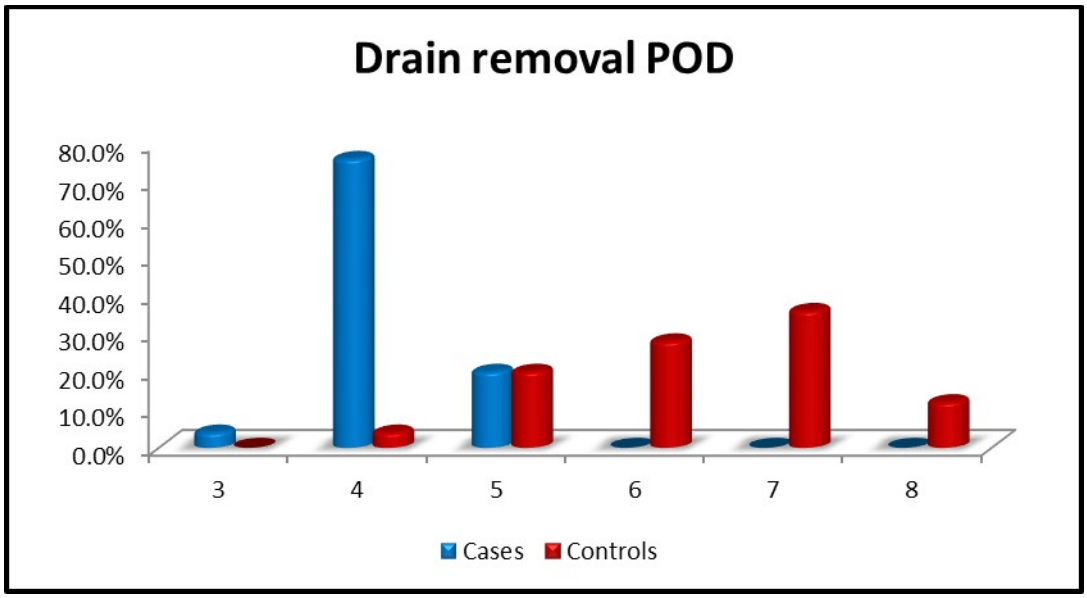
GROUP STATISTICS

CC		N	Mean	Std. Deviation	Std. Error Mean
Day 1	Cases	25	135.20	37.873	7.575
	Controls	25	190.00	43.301	8.660
Day 2	Cases	25	72.40	32.440	6.488
	Controls	25	130.00	40.620	8.124
Day 3	Cases	25	29.60	25.573	5.115
	Controls	25	96.00	42.230	8.446
Day 4	Cases	24	17.50	5.108	1.043
	Controls	25	63.60	33.774	6.755
Day 5	Cases	5	16.00	5.477	2.449
	Controls	24	37.92	29.040	5.928
Day 6	Cases	0[a]			
	Controls	19	21.05	11.002	2.524
Day 7	Cases	0[a]			
	Controls	12	16.67	4.924	1.421
Day 8	Cases	0[a]			
	Controls	3	13.33	5.774	3.333

t cannot be computed because at least one of the groups is empty.

INDEPENDENT SAMPLE TEST

	t-test for Equality of Means		
	t	df	Sig. (2-tailed)
Day1	-4.763	48	.0005
Day2	-5.540	48	.0005
Day3	-6.725	48	.0005
Day4	-6.612	47	.0005
Day5	-3.417	27	.002



DRAIN REMOVAL POD CROSS TAB

			CC		Total
			Cases	Controls	
DRAIN	3	Count	1	0	1

REMOVAL		% within CC	4.0%	0.0%	2.0%
POD	4	Count	19	1	20
		% within CC	76.0%	4.0%	40.0%
	5	Count	5	5	10
		% within CC	20.0%	20.0%	20.0%
	6	Count	0	7	7
		% within CC	0.0%	28.0%	14.0%
	7	Count	0	9	9
		% within CC	0.0%	36.0%	18.0%
	8	Count	0	3	3
		% within CC	0.0%	12.0%	6.0%
Total		Count	25	25	50
		% within CC	100.0%	100.0%	100.0%

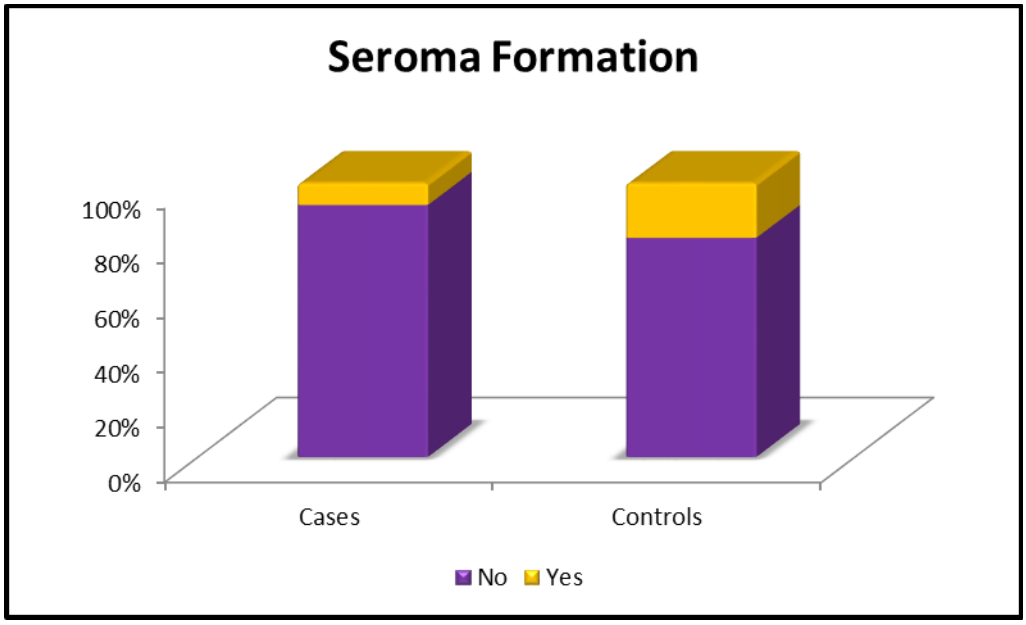
DRAIN REMOVAL POD

	Cases	**Controls**
3RD	4.0%	0.0%
4TH	76.0%	4.0%
5TH	20.0%	20.0%
6TH	0.0%	28.0%
7TH	0.0%	36.0%

8TH	0.0%	12.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	36.200[a]	5	.0005
Likelihood Ratio	47.511	5	.000
Linear-by-Linear Association	31.362	1	.000
N of Valid Cases	50		

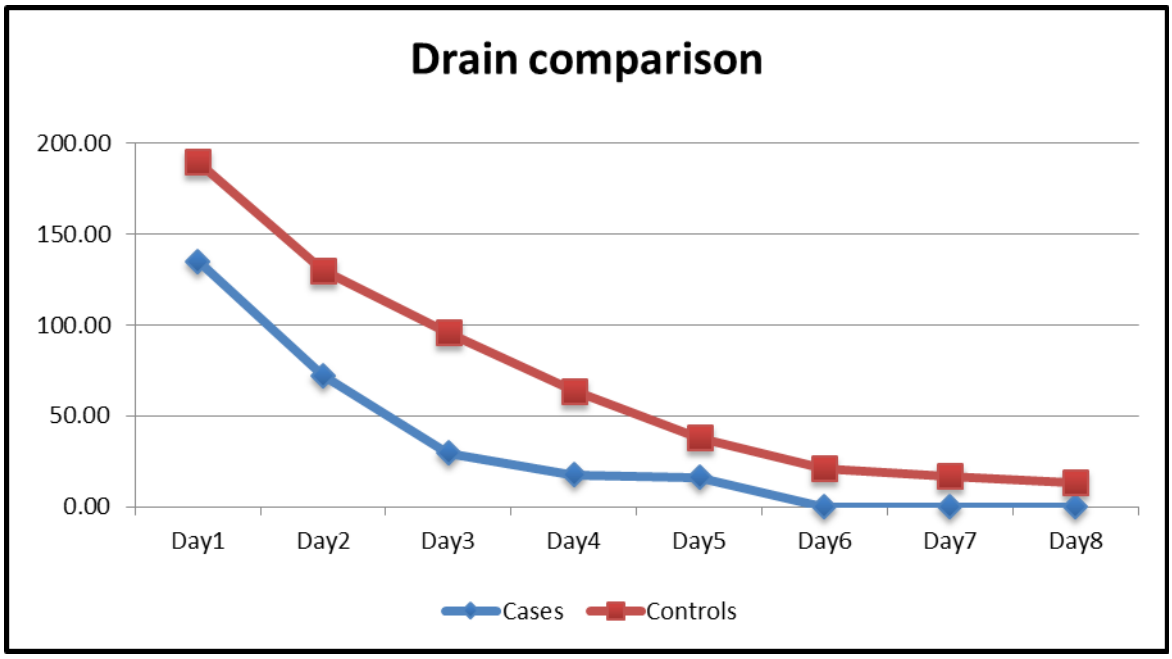


Crosstab

	CC		
	Cases	**Controls**	**Total**

SEROMA FORMATION	N	Count	23	20	43
		% within CC	92.0%	80.0%	86.0%
	Y	Count	2	5	7
		% within CC	8.0%	20.0%	14.0%
Total		Count	25	25	50
		% within CC	100.0%	100.0%	100.0%

	Cases	**Controls**
No	92.0%	80.0%
Yes	8.0%	20.0%


Drain comparison
200.00
150.00
100.00
50.00
0.00
Day1
Day2
Day3
Day4
Day5
Day6
Day7
Day8
Cases
Controls

DISCUSSION

DISCUSSION

This study demonstrates that reduction of the dead space after mastectomy using flap fixation reduces seroma formation and seroma aspirations. For many decades, breast surgeons have used closed suction drainage to reduce dead space. However, seroma formation and its sequelae continued to cause postoperative problems in these patients, proving that wound drainage is insufficient in combating seroma. Flap fixation combined with low suction drainage significantly reduces seroma formation and the need for seroma aspiration after mastectomy.

The key to reducing seroma formation seems to partly lie in the obliteration of dead space. However, the techniques used to achieve this goal are subject of much controversy and debate . In a randomised controlled study, it was difficult to elucidate whether reducing the dead space or ligation of lymphatics or a combination of both were responsible for reduction of seroma formation.

The extent of the dissection plane seems to be an important factor in seroma formation, and therefore, obliteration of dead space in patients undergoing mastectomy or modified radical mastectomy seems to be

pivotal. Pressure garments or compression bandages are not effective in combating seroma; however, quilting of the skin flaps or skin flap fixation seems to be much more effective.

Different techniques have been employed to obliterate the dead space (under flaps and the axilla) to reduce seroma formation. Halsted first advocated creating a short superior flap and suturing it with interrupted silk to the fascia below the first rib and skin grafting the remaining part of the defect.

In 1951, Orr used tension sutures tied over rubber tubing bolsters to tack flaps to the chest wall. In 1953, Keyes et al. used through and through sutures to attach the skin flaps to the chest wall. Besides these techniques, suturing of flaps with subcutaneous tissue , avoiding use of axillary drains following breast conservation therapy , and obliterating axillary dead space by muscle approximation have all been tried for reducing seroma formation. Coveney et al. compared suturing skin flaps to underlying muscle with conventional skin closure and observed a lower incidence of seroma formation in the flap suture group, although flap suturing did add to total operating time. A recent randomized study

compared a combination of skin flap suturing, ligation of lymphatics and obliteration of axillary dead space to conventional skin closure after mastectomy.

As a result, the incidence of seroma formation decreased to 2% with the combination of techniques. Although effective, the authors stated that it was impossible to determine which of the three techniques, or any combination, actually produced the observed effect. Mechanical pressure has also been applied to obliterate dead space following surgery. The use of a pressure garment does not reduce postoperative drainage and has low tolerance and a higher complication rate.

CONCLUSION

CONCLUSION

Flap fixation is a surgical technique that reduces the dead space in patients undergoing mastectomy for invasive breast cancer or DCIS. It

appears to reduce the occurrence of seroma and the need for seroma aspirations.

ANNEXURE

MASTER SHEET CASES

S.NO	IP NO	AGE	SEX	DT DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	DAY 8	DAY 9	DRAIN REMO	SEROMA FORMATIO
1	24270	55	F	150	70	20	20						4	N
2	28468	55	F	100	50	20	20						4	N
3	34735	52	F	200	100	20	20						4	N
4	35497	57	F	100	50	10	5						4	N
5	37492	48	F	150	70	20	20						4	N
6	47395	65	F	200	150	100	20	20					5	Y
7	55023	53	F	100	50	20	20						4	N
8	52312	61	F	150	100	20	20						4	N
9	52364	70	F	150	80	20	20						4	N
10	69121	45	F	100	70	20	20						4	N
11	69765	45	F	200	100	80	20	20					5	N
12	70114	51	F	150	80	20	20						4	N
13	70318	65	F	100	40	20	20						4	N
14	70712	53	F	100	30	10	10						4	N
15	70918	42	F	150	80	50	10	10					5	N
16	71579	60	F	100	30	10	5						4	N
17	72462	50	F	150	70	40	10	10					5	N
18	74852	70	F	100	70	20	20						4	N
19	75648	65	F	150	100	20	20						4	N
20	86640	42	F	80	20	20							3	N
21	88012	50	F	100	50	20	20						4	N
22	89117	55	F	150	80	20	20						4	N
23	90417	45	F	100	50	20	20						4	N
24	91142	49	F	200	150	100	20	20					5	Y
25	91268	55	F	150	70	20	20						4	N

MASTER SHEET CONTROLS

S.NO	IP.NO	AGE	SEX	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	DAY 8	DAY 9	DRAIN	SEROMA
1	20591	57	F	200	150	100	80	50	20	20			7	N
2	29183	61	F	150	80	50	20	20					5	N
3	27712	57	F	200	100	70	40	10	10				6	N
4	44398	52	F	100	50	20	10						4	N
5	45492	47	F	200	150	100	70	20	10				6	N
6	46035	50	F	250	200	100	80	30	10	10			7	Y
7	47263	60	F	150	80	50	20	10					5	N
8	52264	75	F	250	180	150	100	100	50	20	10		8	Y
9	58421	62	F	200	150	100	100	10	10				6	N
10	68917	45	F	200	150	100	40	10	10				6	N
11	69697	53	F	150	80	40	20	20					5	N
12	69912	50	F	100	70	50	20	10					5	N
13	70417	65	F	250	150	150	100	70	20	10			7	N
14	70655	60	F	200	150	100	80	40	20	10			7	N
15	70867	48	F	200	100	40	10	10					5	N
16	71727	42	F	150	100	80	50	20	20				6	N
17	71895	60	F	200	160	120	100	80	20	20			7	N
18	74912	48	F	200	150	100	80	50	20	20			7	N
19	74820	80	F	250	150	150	100	40	20	10			7	Y
20	86918	43	F	150	100	80	40	20	20				6	N
21	87645	54	F	200	150	150	100	100	40	20	10		8	Y
22	90746	57	F	200	150	100	50	20	20				6	N
23	90917	49	F	150	100	100	80	40	20	20			7	N
24	91485	61	F	200	150	100	100	50	20	20			7	N
25	91347	50	F	250	200	200	100	80	40	20	20		8	Y

INFORMATION SHEET

TITLE: ***"A PROSPECTIVE STUDY OF POST MASTECTOMY SKIN FLAP ANCHORING AND SEROMA FORMATION"***

Name of Investigator: Dr.A.SALEEM.

Name of Participant:

Purpose of Research: To study about advantages of skin anchoring in MRM

Study Design: Prospective Observational Study

Study Procedures: Patient will be subjected to routine investigations, Xray, Usg, CECT Abdomen, complete hemogram, as indicated, and the data analysed

Possible Risks: No risks to the patient

Possible benefits

To patient : A better understanding of their problem so has to devise a plan of management which suits their needs.

To doctor & to other people: If this study gives positive results, it can help determine the role of quilting sutures in MRM. This will help in providing better and complete treatment to other patients in future.

Confidentiality of the information obtained from you: The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared

Can you decide to stop participating in the study: Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time

How will your decision to not participate in the study affect you: Your decision will not result in any loss of benefits to which you are otherwise entitled.

Signature of Investigator **Signature of Participant**

Date & Place:

PATIENT CONSENT FORM

Study Detail : ***"A PROSPECTIVE STUDY OF POST MASTECTOMY SKIN FLAP ANCHORING AND SEROMA FORMATION"***

Study Centre : Rajiv Gandhi Government General Hospital, Chennai.

Patient's Name :

Patient's Age :

In Patient Number :

Patient may check (☑) these boxes

I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction. ❑

I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving reason, without my legal rights being affected. ❑

I understand that sponsor of the clinical study, others working on the sponsor's behalf, the Ethics committee and the regulatory authorities will not need my permission to look at my health records, both in respect of current study and any further research that may be conducted in relation to it, even if I withdraw from the study I agree to this access. However, I understand that my identity will not be revealeds in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study. ❑

I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well being or any unexpected or unusual symptoms. ❑

I hereby consent to participate in this study ❑

I hereby give permission to undergo complete clinical examination and diagnostic tests including hematological, biochemical, radiological tests and to undergo treatment ❑

Signature/thumb impression Signature of Investigator

Patient's Name and Address: Study Investigator's Name: Dr.A.SALEEM

PROFORMA

Name TEST/CONTROL

Age

Sex

IP no

DOA

Weight

Procedure done

Post operative complications

- Pain
- Wound infection

Co-morbid illness

Past Surgical

- Procedure done
- Type of incision
- Operative duration
- Post operative period

Medical history

- Diabetes
- Thyroid
- Hypertensive
- Asthma

Steroid intake Chronic constipation or difficulty micturition

DRAIN

DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7

SEROMA FORMATION : YES / NO

DAY OF DRAIN REMOVAL(POD) :

BIBLIOGRAPHY

BIBLIOGRAPHY

1. Kumar S, et al. Post-mastectomy seroma: a new look into the aetiology old an old problem. J R Coll Surg Edinb. 1995;40:292–4. [PubMed]

2. Tadych K, et al. Postmastectomy seromas and wound drainage. Surg Gynecol Obstet. 1987;165(6):483–7. [PubMed]

3. Hashemi E, et al. Seroma formation after surgery for breast cancer. World J Surg Oncol. 2004;9(2):44. doi: 10.1186/1477-7819-2-44. [PMC free article] [PubMed] [Cross Ref]

4. Gonzalez EA, et al. Seroma formation following breast cancer surgery. Breast J. 2003;9(5):385–8. doi: 10.1046/j.1524-4741.2003.09504.x. [PubMed] [Cross Ref]

5. Porter KA, et al. Electrocautery as a factor in seroma formation following mastectomy. Am J Surg. 1998;176:8–11. doi: 10.1016/S0002-9610(98)00093-2. [PubMed] [Cross Ref]

6. Srivastava V, et al. Seroma formation after breast cancer surgery: what we have learned in the last two decades. J Breast Cancer. 2012;15(4):373–380. doi: 10.4048/jbc.2012.15.4.373. [PMC free article] [PubMed] [Cross Ref]

7. Van Bemmel AJM. Prevention of seroma formation after axillary dissection in breast cancer: a systemic review. Eur J Sur Oncol. 2011;37(10):829–35. doi: 10.1016/j.ejso.2011.04.012. [PubMed] [Cross Ref]

8. Almond LM, et al. Flap anchoring following primary breast cancer surgery facilitates early hospital discharge and reduces costs. Breast Care. 2010;5:97–101. doi: 10.1159/000301586. [PMC free article] [PubMed] [Cross Ref]

9. Sakkary MA. The value of mastectomy flap fixation in reducing fluid drainage and seroma formation in breast cancer patients. World J Surg Oncol. 2012;10:8. doi: 10.1186/1477-7819-10-8. [PMC free article] [PubMed] [Cross Ref]

10. Ten Wolde B, et al. Quilting prevents seroma formation following breast cancer surgery: closing the dead space by quilting prevents seroma following axillary lymph node dissection and mastectomy. Ann Surg Oncol. 2014;21:802–807. doi: 10.1245/s10434-013-3359-x. [PubMed] [Cross Ref]

11. Lee K-T, et al. Fibrin Sealants and quilting suture for prevention of seroma formation following latissimus dorsi muscle harvest: a systematic

review and meta-analysis. Aesth Plast Surg. 2015;39:399–409. doi: 10.1007/s00266-015-0476-x. [PubMed] [Cross Ref]

12. Charlson M, et al. Validation of a combined comorbidity index. J Clin Epidemiol. 1994;47(11):1245–51. doi: 10.1016/0895-4356(94)90129-5. [PubMed] [Cross Ref]

13. Gong Y, et al. Prevention of seroma formation after mastectomy and axillary dissection by lymph vessel ligation and dead space closure: a randomized trial. Am J Surg. 2010;200:352–6. doi: 10.1016/j.amjsurg.2009.10.013. [PubMed] [Cross Ref]

14. Kuroi K, et al. Effect of mechanical closure of dead space on seroma formation after breast surgery. Breast Cancer. 2006;13(3):260–5. doi: 10.2325/jbcs.13.260. [PubMed] [Cross Ref]

15. Iovino F, et al. Preventing seroma formation after axillary dissection for breast cancer: a randomized clinical trial. Am J Surg. 2012;203(6):708–14. doi: 10.1016/j.amjsurg.2011.06.051. [PubMed] [Cross Ref]

16. Cortadellas T, et al. Electrothermal bipolar vessel sealing system in axillary dissection: a prospective randomized clinical study. Int J Surg. 2011;9(8):636–40. doi: 10.1016/j.ijsu.2011.08.002. [PubMed] [Cross Ref]

17. Degnim AC, et al. Surgical site infection (SSI) after breast surgery: impact of 2010 CDC Reporting Guidelines. Ann Surg Oncol. 2012;19(13):4099–4103. doi: 10.1245/s10434-012-2448-6. [PMC free article] [PubMed] [Cross Ref]

18. Pogson CJ, et al. Seroma following breast cancer surgery. Eur J Surg Oncol. 2003;29:711–717. doi: 10.1016/S0748-7983(03)00096-9. [PubMed] [Cross Ref]

19. Holcombe C, et al. The satisfaction and savings of early discharge with drain in situ following axillary lymphadenectomy in the treatment of breast cancer. Eur J Surg Oncol. 1995;21(6):604–6. doi: 10.1016/S0748-7983(95)95133-4. [PubMed] [Cross Ref].