"A STUDY ON ROLE OF CONTINUOUS SUCTION DRAIN TUBE IN POST-MASTECTOMY SEROMA COLLECTION IN CARCINOMA BREAST"

Dissertation submitted in partial fulfilment of the regulations of

M.S. DEGREE EXAMINATION

BRANCH 1 GENERAL SURGERY

Department of General Surgery

GOVT.STANLEY MEDICAL COLLEGE AND HOSPITAL

CHENNAI – 600001

THE TAMILADU DR.M.G.R MEDICAL UNIVERSITY

CHENNAI

APRIL 2017

CERTIFICATE

This is to certify that this dissertation titled

"**A STUDY ON ROLE OF CONTINUOUS SUCTION DRAIN TUBE IN POST-MASTECTOMY SEROMA COLLECTION IN CARCINOMA BREAST**"

It is the bonafide work done by Dr.R.vinoth, Post Graduate student(2014-2017) in the department of General Surgery, Government Stanley Medical College and Hospital, Chennai under my guidance and supervision, in partial fulfilment of the regulations of The Tamilnadu Dr.M.G.R Medical University, Chennai for the award of M.S. Degree(General Surgery) Branch – I, Examination to be held in April 2017.

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DECLARATION

I, DR.R.Vinoth solemnly declare that this dissertation titled "**A STUDY ON ROLE OF CONTINUOUS SUCTION DRAIN TUBE IN POST-MASTECTOMY SEROMA COLLECTION IN CARCINOMA BREAST**" is a bonafide work done by me in the Department of General Surgery, Government Stanley Medical College and Hospital, Chennai under the guidance and supervision of my unit chief.

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Professor of Surgery

This dissertation is submitted to the Tamilnadu Dr.M.G.R. Medical University, Chennai in partial fulfilment of the university regulations for the award of M.S., Degree (General Surgery) Branch – I, Examination to be held in April 2017.

Place: Chennai

Date: September 2016 Dr.R.vinoth

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It is my earnest duty to thank my parents without whom accomplishing this task would have been impossible.

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Introduction

According to the reports obtained,female breast carcinoma was considered to be the first tumour from the times of Egyptian civilization. Hippocrates ,father of modern medicine considered surgery as the only option to treat this condition .During celsus period a prototype for radical mastectomy was made.Metastatic nature of the disease was recognized by Le Dran who suggested the removal of primary and axillary groups in continuity.

For the past 80 years surgery was the main modality of treatment.A detailed description of radical mastectomy was made by Halstead of Baltimore in 1894. Various improvisations have been made in the field of medicine due to recent advances. The essential part of surgical management are breast conservation surgery and modified radical mastectomy of Auchincloss.

Seroma is the most common complication following surgery of the breast.By creating negative pressure and obliterating dead space will encourage adhesions of the flaps to the underlying muscles.

The continuous suction drain tube procedure has been suggested as one potential technique to reduce the incidence of seroma in breast surgery by creating negative pressure. The aim is to study the effect of continuous suction drain tube in reducing seroma and to compare with standard closed suction drain.

AIMS AND OBJECTIVES:

- To study the effect of continuous suction drain tube in modified radical mastectomy patients of carcinoma breast
- To compare the role of continuous suction drain tube with that of standard wound closure and standard closed suction drain in reducing post-mastectomy seroma.

MATERIALS AND METHODS:

PLACE OF STUDY:

Department of General Surgery, Govt. Stanley Medical College & Hospital,Chennai

DURATION: JAN 2016 TO SEP 2016

STUDY DESIGN: Prospective study

SAMPLE SIZE : 30

INCLUSION CRITERIA:

Patients undergoing Modified Radical Mastectomy for Carcinoma Breast

EXCLUSION CRITERIA:

Patients undergoing - Breast Conservation Surgery

-Breast Reconstruction

-Previously operated Patients

METHODOLOGY:

In our department, patients undergoing modified radical mastectomy for breast carcinoma are included in this study.

- During closure,the wound is closed with a closed-suction drain.
- suction drain end is connected with suction pump which is available in the wards .

- The amount of seroma collected in vacuum is calculated in a standard measuring jar everyday.
- Suction drain is disconnected from pump for every three hours with one hour interval. .
- The volume of seroma are compared to those patients undergoing closed suction drain.

- when the total daily amount was less than 30ml, drains were removed.
- For each patients,Total days with drain, postoperative drainage volume, and day of drain removal were recorded
- Observations are tabulated and results were analysed according to pre designed proforma

LITERATURE REVIEW

Mammary tissues,the unique feature of mammals,represents modified sweat glands. Embryologically , the mammary gland forms along the midline, its an extension from the primordial axilla upto the inguinal region distally. Humans and most primates have only one pair of glands,one gland on each side develops in pectoral area, but the number of glands differ widely among different mammalian species. Polymastia(supernumerary breasts) , polythelia(nipples) may develop in approximately 1% of the females. The development of these supernumerary structures occur along milk line. During postnatal life ,extensive growth and development of mammary glands are seen in females, where as in males normally minimal development of the gland is seen.The growth of mammary gland in females is mainly regulated by hormones(estrogens) and is also related to age. Around 20 years of age,

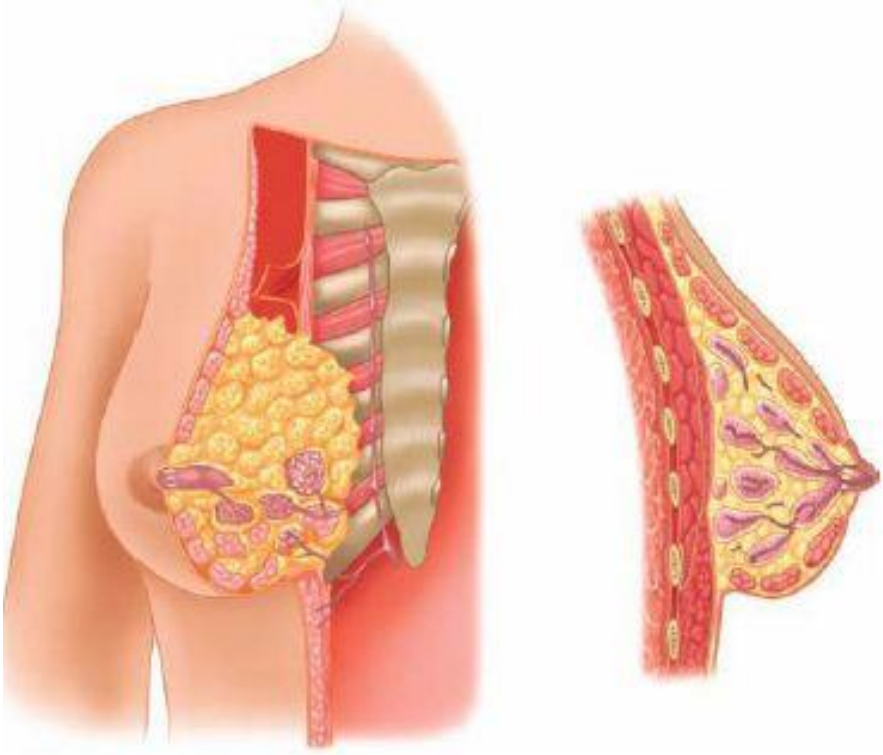
the breasts are very well developed and at around 40 years of age atrophy begins premenopausally.striking changes noted in the volume and the functional activity of the breast tissue at the time of pregnancy and lactation. Due to variations in ovarian hormone levels, menstrual cycles also show structural changes. Hormonal changes and mammary gland involuntary changes occur during menopause. The gland diminishes its structural volume, contour and form and is replaced by fat and connective tissue.

ANATOMY OF BREAST:

Mammary glands are situated within the superficial fascia. It consists of fibrous connective tissue supporting 15 to 20 lobes of tubuloalveolar glandular tissue and the adipose tissue between the lobes. There is no distinctive capsule around breast components in the

subcutaneous connective tissue, rather this tissue extends as septa between the lobules providing gravitational support to the gland. The pectoral fascia of chest wall fuses with the deep layers of the superficial fascia. Retromammary bursa, a distinct space is present between the deep layers of superficial fascia and the pectoral fascia.Mobility of the breast is contributed by retromammary bursa.

Figure 1 Anatomy of breast



Cooper's ligaments are the suspensory structures that interdigitate between the parenchymal tissue of the breast permits remarkable mobility of the breast. It extends from the deep layer of the superficial fascia to the skin dermis. Cooper's ligament provides breast contour and structural support. Extension of female breast is from the level of second or third rib to the sixth or seventh rib. Lateral border of sternum and the anterior or midaxillary line forms the lateral extent.

ANATOMY OF THE AXILLA:

The compartment located between the thoracic wall and the upper limbs represents axilla, which is a pyramidal structure with four boundaries. It has a base and an apex. Axillary fascia forms the base. Apex extends into posterior triangle of neck through the cervicoaxillary canal.This anatomic passage permit most of the structures to pass between neck and the upper extremity, is bounded by clavicle anteriorly. Scapula forms the posterior border. First rib lies medially. Axilla is

bounded by pectoralis major and minor muscles with their fasciae in its anterior wall. Subscapularis muscle,teres major and latissimus dorsi muscles forms the posterior wall. Medial wall bounded by serratus anterior and lateral wall by bicipital groove.

The two distinct planes of the fascia of the pectoralis major and minor muscles include superficial layer and deep layer. Superficial invests the pectoralis major muscle called pectoral fascia. Deep layer invests subclavius and pectoralis minor muscle, extends from the clavicle to axillary floor called the clavipectoral fascia. The cephalic vein, branches of thoraco acromial trunk and lateral pectoral nerve pierces the upper portion of clavipectoral fascia.

The medial pectoral nerve does not penetrate it, but supplies the pectoralis major muscle by passing through the pectoralis minor muscle and its anterior investing fascia. The clavipectoral fascia in its lower portion below the pectoralis minor is sometimes referred to as the coracoaxillary fascia or the suspensory ligament of the axilla.

A dense condensation of clavipectoral fascia called halsted ligament have an extension from the medial region of the clavicle investing subclavian artery and vein is an anatomic landmark.

A loose connective tissue in the axilla encircles great vessels and nerves of upper extremity, together with other axillary contents. Axillary sheath encloses these anatomically contiguous vessels and nerves.

The three parts of the axillary artery are:

1) The portion medial to the pectoralis minor forms the first part, a single branch the supreme thoracic supplying first and second intercostals spaces arises from it.
2) The second part, lies posterior to pectoralis minor, gives rise to lateral thoracic artery and thoraco acromial trunk. Pectoral branches of these arteries supply the pectoralis major and minor. During surgical dissection, identification of these vessels make the procedure safer. Lateral mammary branches originate from lateral thoracic artery.

3) Lateral to the pectoralis minor lies the third part, the three branches are anterior and posterior humeral circumflex arteries and subscapular artery. Subscapular artery is the largest branch within the axilla. The terminal branches of the subscapular artery are subscapular circumflex and the thoracodorsal arteries. The thoracodorsal artery runs with its corresponding nerve and vein provides substantial blood supply.

Axillary vein tributaries, in the form of venae comitantes follow the course of axillary artery branches. The cephalic vein passes in the deltopectoral groove, thereafter it pierces the clavipectoral fascia and enters the axillary vein. The axillary artery and various parts of the brachial plexus are anatomically contiguous throughout the course in the axilla. Depending on the positional and structural relationship with axillary artery cords of brachial plexus are named as medial, lateral and posterior.

The three nerves in which surgeons interested are

1)The long thoracic nerve enters axilla via cervicoaxillary canal. This medially placed nerve is invested by the serratus fascia aas it lies on the lateral most surface of the serratus anterior. During sampling of axillary lymphatics, there are chances of accidental injury to the nerve with the resection of the fascia. Division of this nerve results in the winged scapula deformity due to the denervation of the serratus anterior and so shoulder fixation is affected.

2) The thoracodorsal nerve, a branch from the posterior cord of the brachial plexus supplies latissimus dorsi muscle. Injury to this nerve doesn't affect primary shoulder function, since the nerve is useful for musculocutaneous reconstruction of latissimus dorsi with the use of myocutaneous flap, the nerve is preserved.

3) The medial cutaneous nerve of arm along with the second intercostals nerve(lateral cutaneouas branch) forms intercostobrachial nerve. The sensory innervation to the skin of upper inner aspect of the

arm, lateral axilla and apex of the axilla is by this nerve. Third lateral cutaneous nerve is formed by the second intercostobrachial nerve.

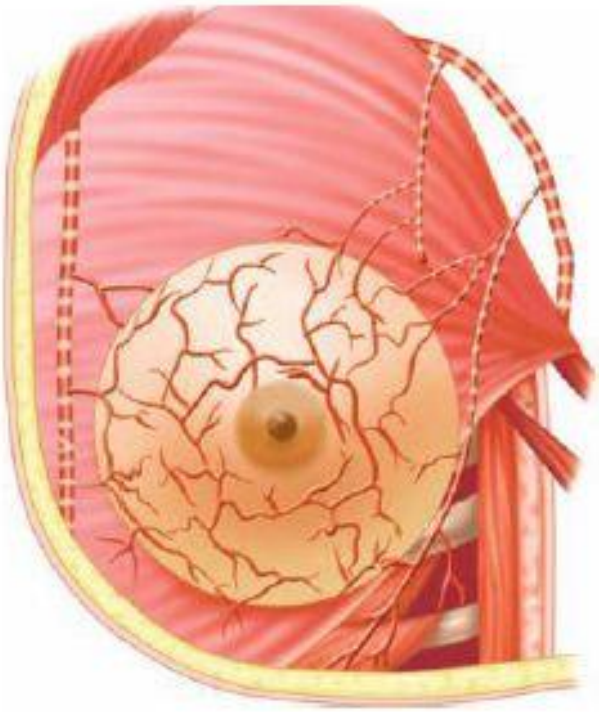
BLOOD SUPPLY OF THE BREAST:

Internal mammary artery with its perforating branches, axillary artery branches,and branches of the posterior intercostal arteries. Axillary artery branches include pectoral branches of the thoraco acromial artery, lateral and highest thoracic arteries.

Medial mammary arteries are contributed by the branches emerging from second to fourth anterior perforating arteries. The branches of the lateral thoracic artery supplies serratus anterior, subscapularis, pectoralis muscles, axillary lymphatics and fatty tissues supporting the breast.

Mammary branches in the intercostals spaces arise from posterior intercostal arteries. Thoracodorsal branch of the subscapular artery doesn’t primarily supply the breast, but is closely associated with the scapular and central lymph node groups.

Figure 2 Arterial supply of breast



During axillary node dissection, if there is injury to any one of the perforating branches of this vessel, it is very difficult to control bleeding from the veins of axilla that parallel the path of the distribution of the arteries showing preferential venous flow towards axilla.

The extensive anastomoses of the superficial venous plexus is evident through the overlying skin. Circulus venosus, an anastomotic circle formed by the superficial veins is seen around the nipple. Veins initially converge to the periphery of the breast to drain blood and thereafter terminate in the internal mammary,internal jugular and axillary veins.

Perforating branches of the internal mammary vein and posterior intercostals veins and tributaries of the axillary veins are the principal groups of veins involved in the venous drainage of the breast. The posterior intercostals veins and Batson's plexus lie in direct continuity and that have an extension from the skull base to the sacrum.

Batson's plexus provides an important pathway for metastases to vertebrae, pelvic bones, skull, and central nervous system through hematogenous dissemination.

INNERVATION OF THE BREAST:

Anterior and lateral cutaneous branches of second to sixth intercostal nerves primarily provides sensory innervation to the breast. Among these principal contribution is by fourth, fifth, and sixth intercostal

nerves. Upper portion of the breast is supplied by the cervical plexus, which is formed by the branches of the supraclavicular nerve. Sympathetic fibres to breast and overlying skin are conveyed by these nerves.The branches of the intercostals nerves exit the serratus anterior muscle and divide into anterior and posterior branches. Anterolateral thoracic wall is supplied by the anterior branches. Majority of breast surface are supplied by lateral mammary branches.

A large and constant sensory nerve from the second intercostals nerve is the intercostal brachial nerve. This nerve joins the medial cutaneous nerve of arm by coursing through the axillary floor.

If the intercostal brachial nerve is injured during axillary dissection, no motor loss is evident, instead the patient will be having paresthesia and/or hypoesthesia. The anterior branches of intercostals nerves allow arborization of branches over the thoracic wall when it exit near the lateral sterna border. These lateral branches are called medial mammary branches as they supply the medial aspect of the breast.

LYMPHATIC DRAINAGE OF BREAST:

Axillary lymphnode groups are the main route of lymphatic drainage of the breast. Surgeons usually describe six groups at three different anatomic levels. Anatomists typically identify four groups of axillary lymphnodes. These variations are due to the fact that nodal group boundaries are not well demarcated. Axillary nodes are divided as follows:The lateral group of lymphnodes consisting of four to six lies in association with axillary vein. It is identified at the junction of lateral vein with latissimus dorsi. This group receives largest lymphatic supply compared to others exception is the deltopectoral lymphnode drainage, also called as infraclavicular nodes.

According to the anatomists, external mammary nodes consisting of four or five lymphnodes are referred as pectoral or anterior group because of its location around pectoralis minor muscle . This group mainly drains breast parenchyma. From here, lymph drains into central lymphnodes. But there are also lymphatics draining directly to the subclavicular lymphnodes from the external mammary nodes.

The posterior group of lymphnodes consisting of six or seven lymphnodes identified by the anatomists as the subscapular group , which lies near the lateral border of scapula and near the floor of the axilla, it lies contiguous with the subscapular vessels. Lower portions of neck, posterior region of shoulder, skin and subcutaneous tissues of trunk are drained by this group. Lymph from this group in turn drains into subclavicular and central nodes.

The central group consisting of three or four large lymphnodes lies behind pectoralis minor is embedded in axillary fat pad.The central group, not only receives lymph from the preceding group but also receives direct lymph supply from afferent lymphatic vessels. This central group drains into subclavicular nodes. Its location is between anterior and posterior axillary folds.

Because of its superficial position, this is the most palpable group of axillary lymphatics, there by helps in accurate assessment of metastatic disease clinically.

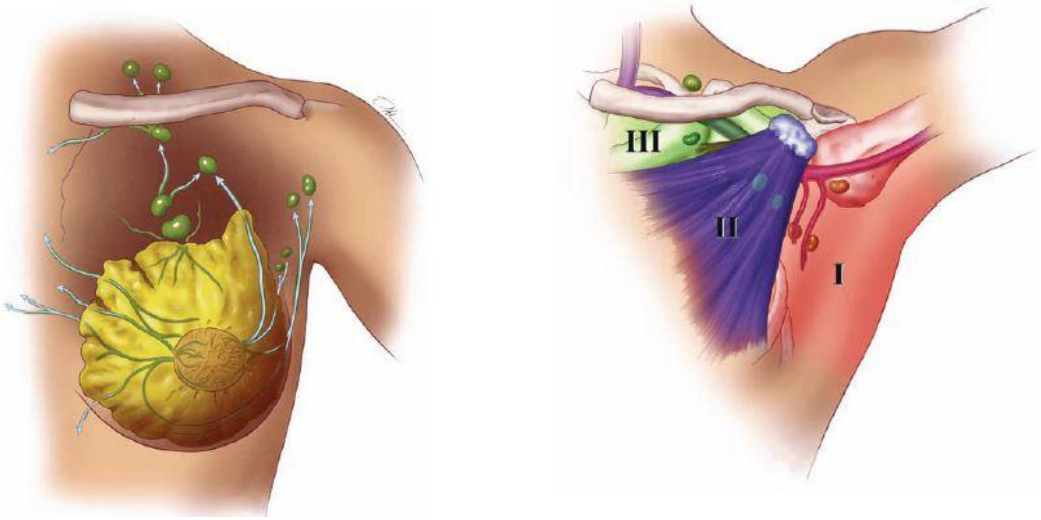
Apical group consisting of six to twelve lymphnodes are identified the anatomists is located posterior to the pectoralis minor muscle. It has an extension into the apex of the axilla. It receives lymph supply from all other groups also. Later these vessels unite to form the subclavian trunk.

During the course, it may directly enter subclavian vein or internal jugular vein. It confluences with thoracic duct on its left side and right lymphatic duct joins it on the right side.

Rotters group consisting of one to four small lymphnodes is present between the pectoralis major and minor muscles. From here lymph drains into central and subclavian nodes. Rotter's nodes are located along pectoral branches of the thoracoacromial vessels.

According to W.Sampson Handley, the british surgeon primary route of lymphatic dissemination are the internal mammary nodes. Central and medial lymphatics terminate in the internal mammary nodes by coursing along major blood vessels and perforating through pectoralis major, which is confirmed by the extensive clinical research.

Figure 3-4 lymphatic drainage and lymph nodes



Along the internal mammary vessels, internal mammary nodes are located in the retrosternal intercostals spaces. Endothoracic fascia invests these nodes, which terminate in the subclavian nodes.

Main thoracic duct receives left internal mammary nodes and the right lymphatic duct receives right internal mammary nodes.

Three groups of lymphatic vessels draining the breast include:

- Vessels that originate in the interlobar spaces of the breast parallel the lactiferous ducts are referred as primary group.
- Subareolar plexus receives vessels draining the skin of the central region of breast and the glandular tissue.
- Deep surface of breast contains rich lymphatic plexus that anastomose with vessels of parasternal nodes.

Axillary lymphnodes receive 75% of the lymph, where as the remaining drains into parasternal nodes. This is the reason for sampling axillary node to determine the histologic status, and hence we get valid pathologic staging. So axillary lymphnode is referred as the sentinel lymph node.

This allows surgeons to use axillary nodes for biopsy regardless of the quadrant of the tumour. Axillary lymphnodes also receive superficial lymphatic vessels that drains skin of the breast.

The chest and the upper abdomen cephalad to the umbilicus shows unidirectional lymph flow towards axilla. Lymph vessels near lateral

sternal margin pass to the parasternal lymphnodes by passing through the intercostals spaces. In the upper pectoral region, few lymphatic vessels drain into inferior deep cervical lymphnodes.

There are three groups of lymphnodes drained by the lymphatic vessels of deeper structures of thorax. They are parasternal, diaphragmatic and intercostal lymphnodes.

Parasternal lymphnodes are located 1cm lateral to the sternum along the internal mammary vessels. These nodes reside in the areolar tissue positioned in the intercostal spaces.

Each intercostals space contains one or more intercostals lymphnodes in relationship with the intercostal vessels. Lymphatics from breast and posterolateral wall of thorax drains into these nodes.

Right lymphatic duct receives afferent lymphatics from right sided intercostal lymphnodes. Thoracic duct receives efferent lymphatics from left sided intercostal lymphnodes.

The three groups of diaphragmatic lymphnodes are:

- The anterior group, also known as prepericardial nodes are located at the base of the xiphoid process. From this group, efferents pass to the parasternal nodes.
- On each side of diaphragm, two to three small nodes, diaphragmatic lymphnodes are located adjacent to the pericardial sac. These nodes are located near venacava and esophageal hiatus on the right and left respectively.
- Few lymphnodes located near the crura of the diaphragm are the posterior set of nodes, that drains into posterior mediastinal and lateral aortic nodes.

MICROSCOPIC ANATOMY OF BREAST:

15-20 irregular lobes of tubuloalveolar glands are present in the mammary gland parenchyma, separated by fibrous bands that radiate from nipple are further divided into multiple lobules.

Cooper's ligaments are the fibrous bands that attach to the cutis reticularis of the dermis. Lactiferous duct defines the termination of each

lobe of the gland,which gets emptied into the subareolar ampulla, at the terminus of nipple.

Lactiferous sinus, a dilated portion at the terminus of each duct is located beneath the areola. These ducts are lined by stratified squamous epithelium.

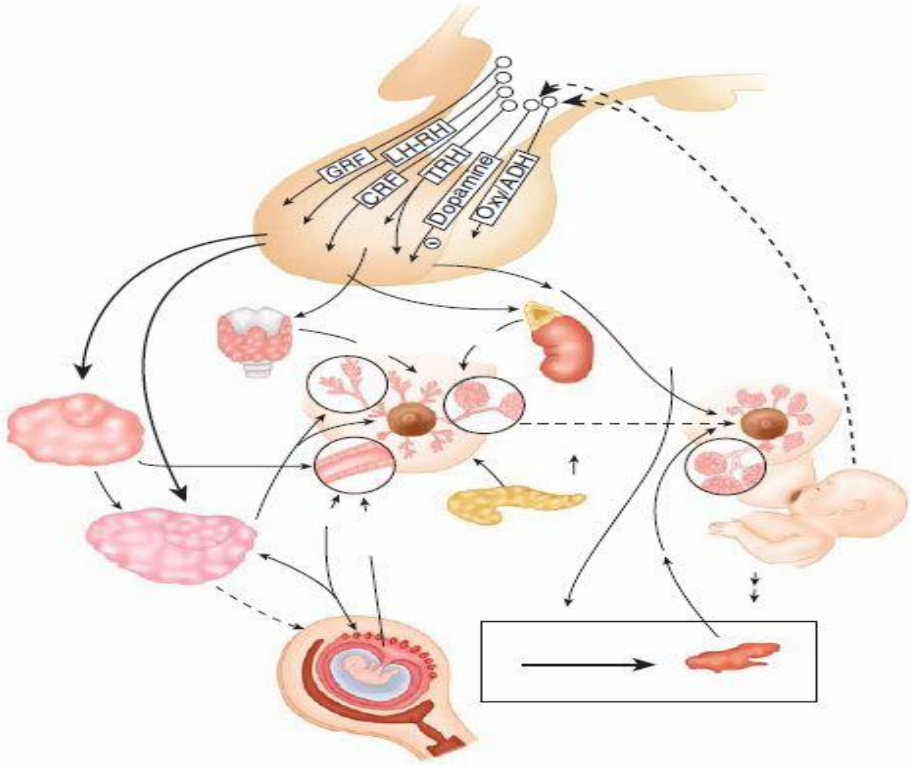
Gradual transition occurs in the epithelial lining from two layers of cuboidal cells to single layer of columnar cells, distributed throughout ductal system.

With age, the secretory portion of the mammary gland shows changes with pregnancy and lactation. Ducts are the predominant structures in the non pregnant gland, where as glandular component is sparse.

Throughout the menstrual cycle, slight cyclical changes are evident. Dramatic proliferation of mammary glands occur during pregnancy and so connective and adipose tissue diminishes in volume.Deep pigmentation and corrugation occurs in the nipple and areola during pregnancy. Thereafter , it has covering with keratinized,stratified squamous epithelium. Structures intermediate between sweat glands and

the true mammary glands present in the areola are sebaceous glands and accessory areolar glands of Montgomery.

Numerous free nerve endings and tactile corpuscles are present in the tip of the nipple, where as few of these are present in the areola. Peripheral to areola, neuronal plexus are located around hair follicle.Glandular tissue and dermis also contains pacinian corpuscles. During lactation, the essential component is the rich sensory innervation of the breast.



EPIDEMIOLOGY:

India tops among others in having number of DALY'S lost due to breast cancer. This is because of the late visits to the hospitals ,they do not survive long,irrespective of the qualified treatment, the mortality is fairly high.Shyness, lack of awareness,social stigma are the main reasons for late presentation.

NON-MODIFIABLE RISK FACTORS:

- Female gender
- Early age at menarche,late menopause
- Increasing age
- Nulliparity
- Genetic predisposition
- Family history
- History of radiation exposure

Incidence of familial,sporadic and hereditary breast cancer:

STK 11/LKB 1a <1%

P53a 1%

Hereditary breast cancer 5-10%

BRCA1a 45%

BRCA2 35%

HISTOLOGICAL CLASSIFICATION OF BREAST CANCER:

Invasive epithelial cancers:

Invasive lobular	10%
Invasive ductal(NOS)	50-70%
tubular	2-3%
papillary	1-2%
cribriform	1-3%
medullary	5%
Mucinous or colloid	2-3%
Adenoid cystic	1%
Metaplastic	1%

Non invasive epithelial cancers:

- DCIS
- LCIS
- Phyllodes tumor
- Mixed connective and epithelial tumors
- Angiosarcoma
- Adenocarcinoma
- angiosarcoma

BREAST CANCER STAGING:

AJCC-american joint committee on cancer

T - primary tumour

N - lymph node status

M - distant metastasis

Definition of tumour size

Tx	Cannot be assessed
T0	no tumor
Tis	In situ tumor
T1	Tumor less than or equal to two cm
T2	Tumor between two to five cm
T3	More than five cm
T4	Any size with extension
4a	Involvement of chest wall
4b	Involvement of skin
4c	Both 4a and 4b
4d	Inflammatory disease

Definition of regional lymph nodes

Nx	Cannot be assessed
N0	Nodes not present

N1	Ipsilateral mobile node
N2	
N2a	Ipsilateral fixed or matted node
N2b	Ipsilateral internal mammary node
N3	
N3a	Ipsilateral infraclavicular node
N3b	Ipsilateral internal mammary and axillary node
N3c	Ipsilateral supraclavicular node

Definition of metastasis

Mx	Cannot be assessed
M0	Metastasis not present
M1	Distant metastasis present

STAGING OF BREAST CARCINOMA

STAGE I	T1NOMO
STAGE IIa	T1NIM0 T0N1M0 T2N0M0
STAGE IIb	T3N0M0 T2N1M0
STAGE IIIa	T2N2MO T3N1M0 T1N2M0 T0N2M0 T3N2M0
STAGE IIIb	T4N2M0 T4N1M0 T4N0M0
STAGE IIIC	Any T,N3M0

STAGE IV	Any T,any N,M1

GRADING

stage 0 - In situ breast cancer

stage I,IIA,IIB- Early invasive breast cancer

stage IIIA or IIIB- Advanced locoregional cancer

stage IV- Metastatic cancer

Tumor stage determines the 5 year survival rate

- stage 0 ,98-100%
- stage I,96-100%
- stage II,87%
- stage III,58%
- stage IV,20%

For clinical stage I,IIA,or IIB or T3N1MO

- Lumpectomy with surgical axillary staging

  Depending on nodal status, radiotherapy following chemotherapy

Or

- Total mastectomy with surgical axillary staging +/- reconstruction.depending on nodal status, radiotherapy following chemotherapy

Or

- If T2 or T3 fullfills criteria for breast conservation surgery except for size- consider preop systemic therapy

Locally advanced breast cancer

- Operable
- Inoperable

Operable : surgery and

Adjuvant CT+RT/+- hormonal/+- transtuzumab

Inoperable: Neo adjuvant CT

Responders : surgery, CT+RT/+- hormonal/+- transtuzumab

Non responders:

If operable: surgery,CT+RT/+-hormonal/+- transtuzumab

If inoperable-taxane based CT

- Operable-surgery,CT+RT/+-hormonal/+- transtuzumab
- Inoperable –primary RT.

  If resectable- surgery

  If unresectable-continue CT/RT

Chemoradiation is the initial treatment of choice for most of the inoperable tumours. Induction chemotherapy includes anthracycline and taxane based chemotherapy.

Axillary clearance and total mastectomy can be done if the tumor size reduces. According to the receptor status, tamoxifen and transtuzumab are added. 5 year survival rate is only 25-30% inspite of multimodality therapy.

SURGICAL TECHNIQUE OF MODIFIED RADICAL MASTECTOMY:

Skin sparing mastectomy has a recurrence rate of <2% if used for T1 to T3 cancers. Removal of all breast tissue, necessary skin and nipple areolar complex is simple mastectomy. In addition to these structures, if level I axillary lymphnodes are removed, it is referred to as an extended simple mastectomy.

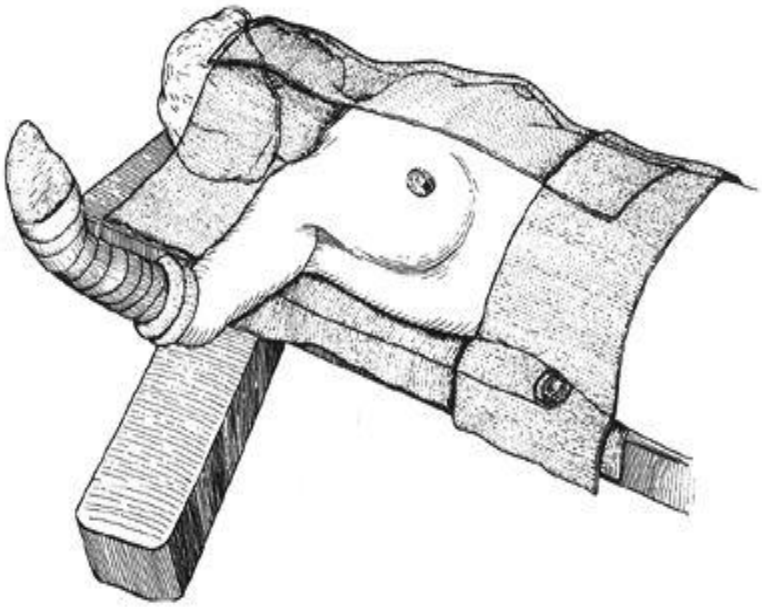
If level I and II axillary lymphnodes are removed in addition to the above structures, it is modified radical mastectomy.

A rolled sheet placed under shoulder to provide modest elevation . Also patient is placed at the edge of the table that avoids undue retraction on the brachial plexus or the pectoralis muscles.

Folded towels are used to expose the operative field, and are secured with surgical staples. Arm is placed perpendicular to the operating field in the arm board.

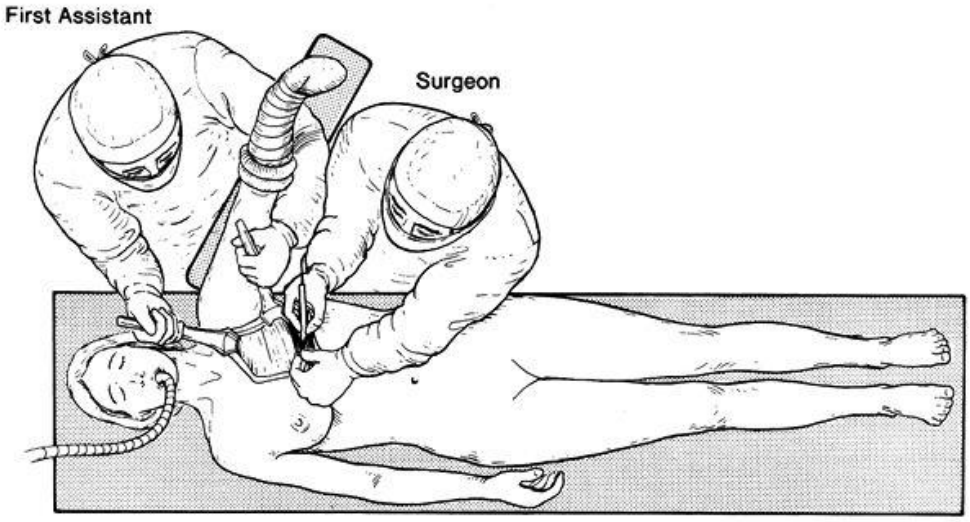
Occlusive cotton dressing (stockinette) is an another alternative method for isolation of the hand and forearm. Cephalad to the arm board, over the shoulder of the ipsilateral breast, first surgical assistant is positioned at the commencement of the surgery. This position helps the surgeon to retract the pectoral muscles during axillary dissection.

Preparing patient for MRM



Second surgical assistant is needed to assist with the axilla exposure in case of obese patient with large breasts.

Positioning of surgical team



The nipple-areolar complex and the overlying skin are removed enbloc by the elliptical incision. Using cautery or scalpel, skin flaps are developed and the boundaries of dissection are extended, that includes,

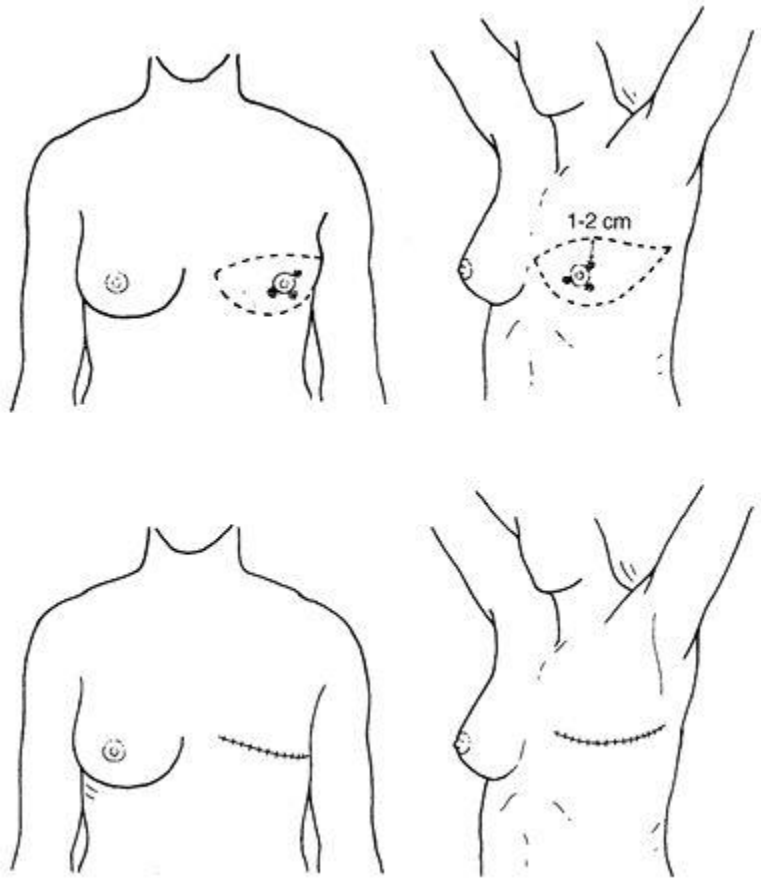
a) Medial boundary by sterna midline

b) Laterally by Latissimus dorsi

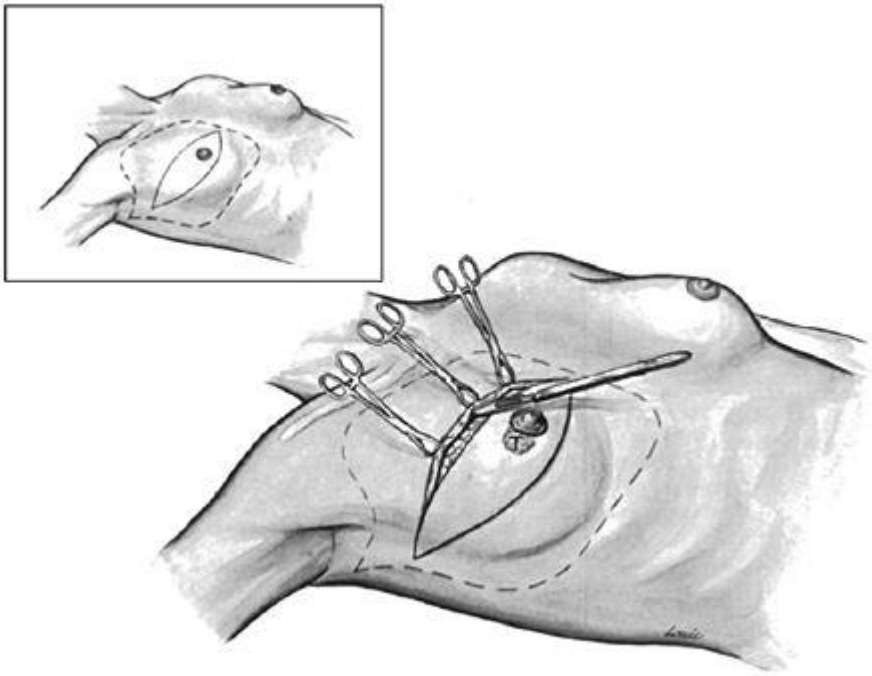
c) Superiorly by subclavius muscle

d) Inferiorly 3-4 cm below inframammary fold

The classic stewart elliptical incision



To expose the superficial fascia, the skin edges are elevated. The skin flaps differ in thickness based on body habitus.



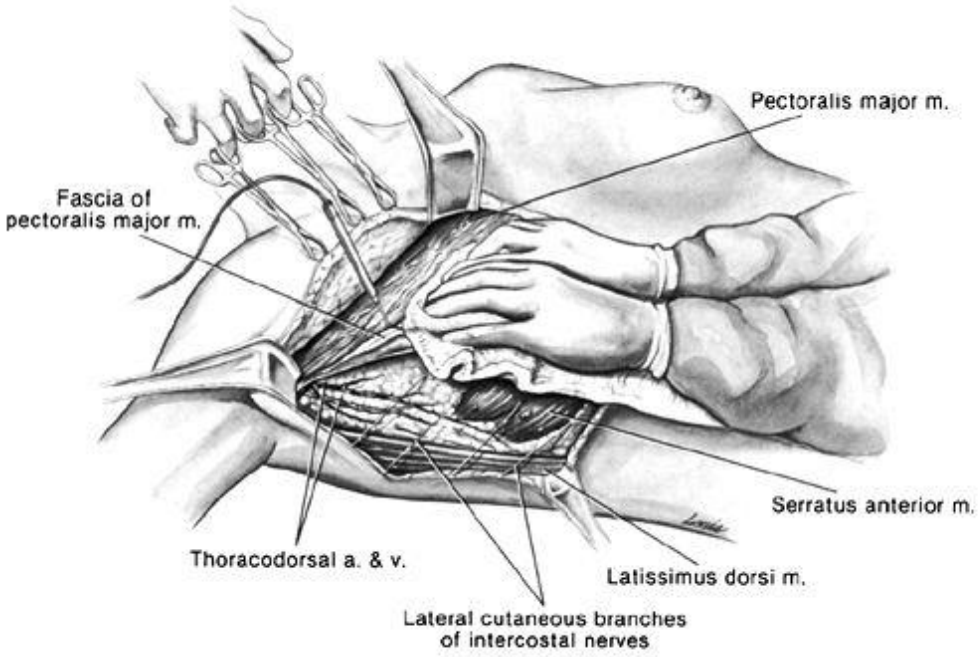
Superficial to the vessels of parenchyma of the breast and deep to the vasculature of the subcutaneous tissue lies the appropriate plane of dissection for taking skin flaps.

Consistent thickness of skin flaps should be maintained to avoid devascularisation which in turn leads to skin necrosis, flap retraction and seroma.

Parenchyma of breast and the fascia of the pectoralis major are elevated, once the skin flaps are developed. During elevation perforating vessels of anterior intercostals arteries are regularly encountered.

So it is essential to identify and secure them with 2-0 or 3-0 non absorbable sutures. This elevation is continued laterally to get the exposure of pectoralis major and minor muscle.

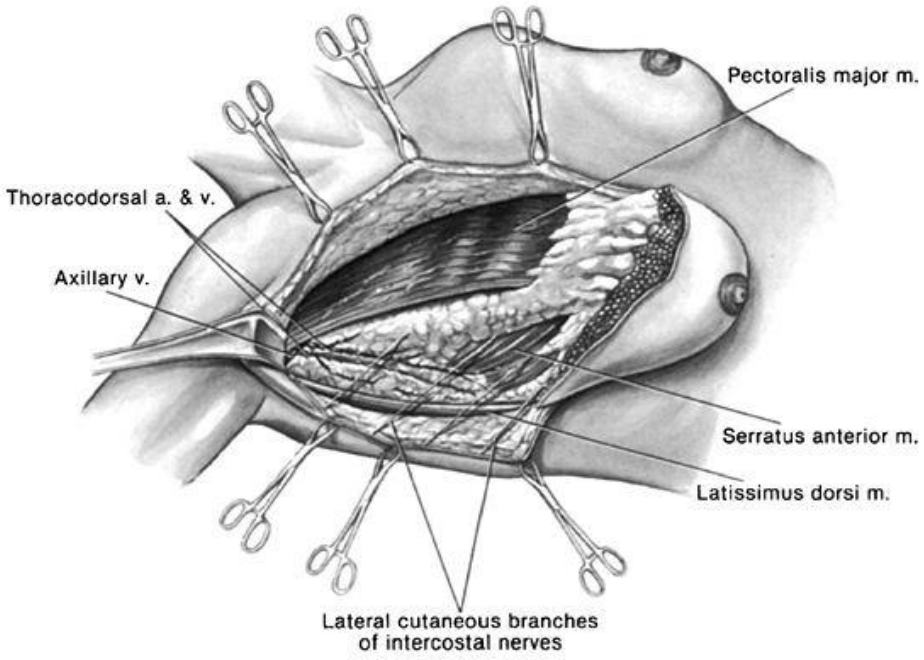
The surgeon should be aware of the course of the medial pectoral nerve and it is essential to preserve it to prevent lateral head of pectoralis major getting atrophied. So that significant functional and cosmetic defect can be avoided.



An incontinuity axillary node dissection is performed if elevation of parenchyma of breast and pectoralis major fascia is completed.

On dividing the investing fascia of the axillary space, the pectoralis minor muscle,lymph nodes like rotter nodes are cleared.

With the identification of the axillary vein and its course lateral axillary space is elevated, as the axillary node dissection proceeds.



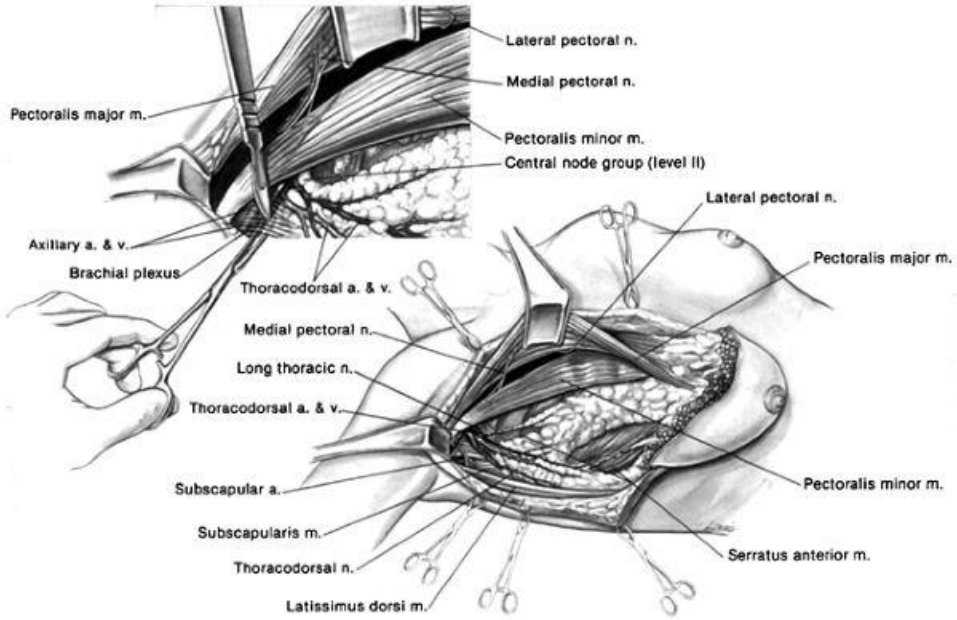
The anterior surface of the vein is completely visualized while dissecting the investing layer of the axillary vein. Intervening venous tributaries are ligated and divided.

Lateral pectoral nerve is exposed by retracting pectoralis major, and is protected to preserve pectoralis major medial head.

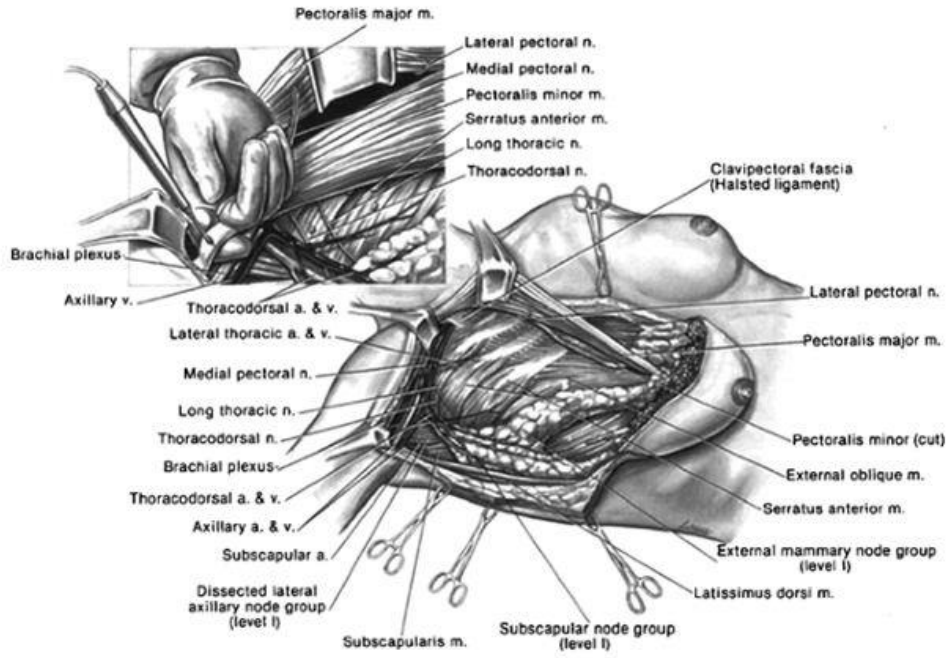
Dissection continues medially towards the axillary vein to include lateral group of axillary nodes.

The superior trunk of the intercostobrachial nerves courses through level II axillary nodes below the axillary vein, usually no attempt is made to save this nerve.

Incision of investing fascia of axilla



Lymph node dissection of axilla



Deep in the axillary space , thoracodorsal artery and vein are located, the surgeon makes attempt to preserve this.

The thoracodorsal nerve from the posterior cord is protected along its course to the latissimus dorsi muscle.

Lateral axillary lymphnode group is dissected en bloc along with level I subscapular group of nodes.

Posterior boundary of axilla is exposed during posterior axillary space dissection that helps in visualizing subscapularis muscle medially and teres major laterally. Then dissection proceeds with the removal of the central group.

To provide anatomic orientation metallic marker is used to identify the superomedial aspect of the specimen.

With medial dissection, long thoracic nerve is identified and preserved.

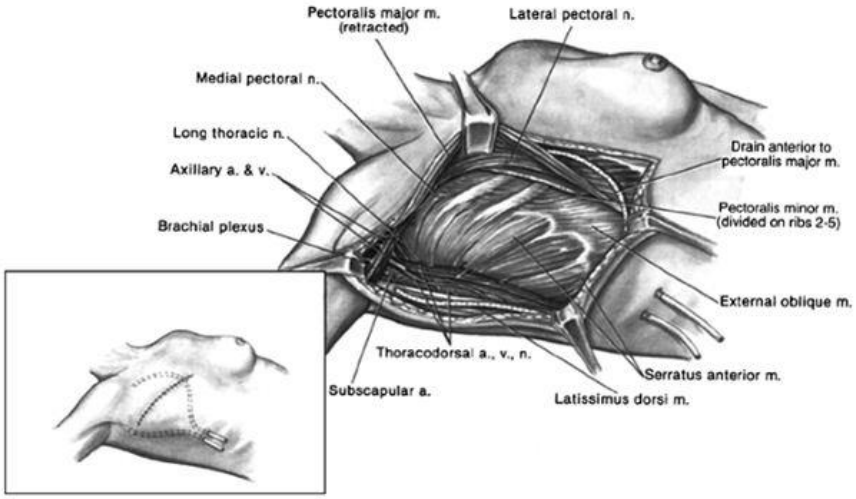
Dissection of the long thoracic nerve is done along its course. If there is injury to the nerve, winged scapula deformity occurs due to the denervation of serratus anterior muscle.

The axillary contents anteromedial to the nerve are swept inferomedially. Before dividing the inferior extent, the

thoracodorsal and long thoracic nerves are completely visualized during axillary dissection.

Patey's modified radical mastectomy is employed in case of level III lymphadenopathy.

Completed axillary lymph node dissection



During dissection along pectoralis major lateral margin, pectoralis minor insertion on the coracoid process of scapula is visualized.

Division of pectoralis minor near its insertion to access apical axillary nodes is done in patey's modification.

Also in this procedure the complete extent of the axillary vein is seen as it courses to confluence with the subclavian vein beneath the halsted ligament.

Immunohistochemistry (Her2-neu,ki67,PR,ER) and histological status is obtained with the resected specimen.

The residual tissue,serum,blood clots are evacuated when saline or sterile water irrigation either ligation or cauterization of bleeding points are done.

To avoid exfoliated cancer cells implantation, clean surgical instruments and fresh gloves are used.

Continuous suction sialistic catheters are placed just prior to closure and are brought out through separate stab wounds inferiorly.

In the subcutaneous tissues 3-0 absorbable sutures are placed to close the wound in two layers.

Either 4-0 absorbable subcuticular sutures or staples are used for approximation of skin edges.

For close approximation short steri-strips are placed perpendicular to the skin.Sterile dressings were made.

Anatomic complications of the modified radical mastectomy:

Vascular injury:

Ligation of the first and second perforating vessels are done, as they are too large for cautery.Repair is done for the torn axillary vein because ligation causes chronic edema.

Nerve injury:

Intercostobrachial nerve:

When severed, numbness occurs over the ipsilateral upper arm medial aspect.

Long thoracic nerve:

Winged scapular deformity occurs during its injury.

Medial and lateral thoracic nerves:

If severed, pectoralis muscle atrophy occurs.

Most frequent complication of the surgery is seroma formation beneath the skin flaps or in the axilla.

Seroma formation occurs in about 30% of the cases.

Wound infections in majority is secondary to skin flap necrosis, but are infrequent after mastectomy. Its management includes culture of the wound, debridement and appropriate antibiotics.

Hemorrhage in post operative period is very rare, which is managed in operating room by early exploration and re-establishment of drainage.

The incidence of lymphedema is around 10% after a modified radical mastectomy.

Lymphedema incidence increases in case of extended axillary node dissection, obesity, presence of pathologic lymphnodes and adjuvant radiation therapy.

The extent of lymphedema can be reduced by using intermittent compression devices and compressive sleeves.

Seroma:

Enbloc resection of lymphatics and fatty tissues are done during surgical ablation of breast. Accumulation of blood and lymph transudation are expected.

The pathophysiology behind seroma formation is not fully understood. Sagging of skin and hence delay in adjuvant therapy initiation occurs if excessive accumulation occurs.

Future trials involving identification of predictive variables are important to assess individual risk of seroma formation which helps in reducing the incidence of seroma.

Seroma occurs in most patients after surgery but all patients are not clinically symptomatic.

Its incidence ranges between 2.5% to 51%. Flap necrosis,sepsis,prolonged recovery period are some of the morbidity caused by seroma formation.

According to E.Hashemi et al retrospective cross sectional study, 158 patients who had breast preservation surgery and modified radical mastectomy showed significant seroma formation.

Other factors like age, surgical instrument, pre op chemotherapy,etc was not considered. So the type of surgery was found to significantly effect the occurrence of seroma.

Lumachi F et al conducted a prospectively randomized study on 92 women considering tumor size and total quantity of drainage.

This study also concluded the incidence of seroma formation is lowered in axillary dissection with the use of ultrasound scissors.

According to Douay N et al, the risk factors isolated were high volume drainage for the first 3 days, arterial hypertension and high body mass index.

He also found frequency of seroma formation is not based on axillary technique of surgery.

In seroma reduction, axillary drainage, axillary padding and sentinel node biopsy showed benefits.

According to the study of Unalph r et al, drainage flow rate more than 50ml/day after 2 days of breast surgery was the important predictive factor in seroma formation. He noted this finding by studying the following risk factors:

Tumor size

Age of patient

Lymph nodal metastases

Number of lymphnodes removed

Preference for surgery

Drainage duration

Type of surgical equipments used

Dead volume reduction

Drainage duration

Neo adjuvant chemotherapy

Following thermal trauma in electrocautery dissection, an increase in seroma incidence is noted by Agrawal A et al.

According to the study made by Burak W E Jr et al factors like age, initial 72 hour wound drainage and patient's weight are considered to be significant.

Drainage of significantly more fluid have an association with seroma formation was showed by Menton M et al. generally seroma formation starts on 7^{th} day, attains peak on 8^{th} day and slows down upto 16^{th} postoperative day.

Also according to him age is considered to be an important factor as the frequency of occurrence increases with age.

According to the study by Jain P K et al with 116 patients, drains did not prevent formation of seroma, instead they caused longer post operative stay.

According to Nadkarni M S prospective randomized study on 160 patients with breast cancer showed 90% incidence of seroma in those who underwent surgery.

Incidence changes to 82.2% if scissors are used for dissection and ligatures to achieve haemostasis.

Also suction drain or corrugated drain doesn't have any influence on seroma formation.

Seroma formation was considered as a necessary evil and not influenced by any of the above factors was the statement made by Gonzalez E.A. et al with his retrospective study of 359 patients.

Retrospective studies by katsumasa kuroi et al concluded that sentinel lymphnode biopsy shows reduction in seroma formation.

This conclusion is made from one meta-analysis, 7 prospective studies, 51 randomised control trials, 7 retrospective studies.

Pathophysiology of seroma:

Serous fluid collection in the axillary dead space or under the skin flaps following mastectomy and axillary dissection is defined as seroma.

Age

Co-morbid conditions

Size of tumour

Number of axillary malignant nodes

Use of drugs

Previous surgical biopsy are considered to be the risk factors.

Seroma is defined as an exudates that forms in response to inflammatory reaction due to increased fibrinolytic activity following surgery.

Either patient factors or surgical factors influence seroma formation.

Factors related to surgery:

Techniques:

Due to recent advances, there is a change in the surgical treatment for breast cancer from halsted's radical mastectomy to breast conservation surgeries. According to studies, increased incidence of seroma formation occurs in radical mastectomy, but no evidence of increased seroma formation with increased number of removal of lymphnodes.

It was said that significantly higher incidence of seroma formation is seen with conventional axillary dissection compared to sentinel lymphnode biopsy.

Surgical devices:

Devices like,

Argon diathermy

Electrocautery

Vessel sealer

Ultrasonic scissors

Laser scalpel

Ultrasonic scalpel are used to decrease time and blood loss during surgery.

Seroma formation is inversely proportional to the use of surgical scissors with ligation but directly proportional with the use of electrocautery.

Patient factors:

-hormone receptor status

-stage and grade of disease

-axillary nodal status and positivity

-body mass index

Seroma formation is influenced by certain factors that lack statistical evidence are

-smoking

-Disease site

-Diabetes mellitus

-Type of histology

-Anemia

-Breast size

Techniques for mechanical closure of dead space:

Following Modified Radical Mastectectomy ,techniques for dead space closure include

-Suction drain

-Fixation of Flap with sutures

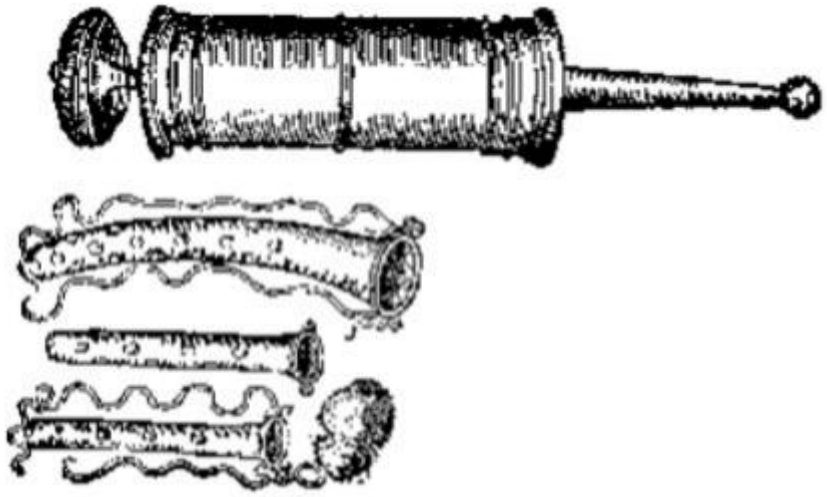
-External pressure Compression

Adhesion of flap to the underlying muscles is enhanced by these techniques by the dead space obliteration between the chest wall and flaps by suction drain, suturing and external compression..The complications associated with above mentioned methods are

infection,

pain and focal pressure necrosis.

Use of Drains favours closure of dead space and thus decreasing seroma. In earlier periods, static drains were used and now superseded by suction drainage.closed drainage systems are preferable to open system.Chururgia who used drain by cutting linen into pieces and served as wick to prevent premature closure of wound.



Ambroise who used drains to keep war wounds draining.johann schultetus who first recommended to use wick into a draining tube to increase its efficacy.lorenz heister who used penrose drain..

Raffl described the practical method of insuring adequate drainage of seroma and adherence of skin flaps to chest wall following radical mastectomy..following surgical procedures,pressure dressings always become satured with serum,causing maceration of skin,foul odour.skin flap tacking are time consuming,causes pain and focal necrosis.Frequent dressings increases risk of infection.These are eliminated by use of continuous suction negative pressure.Divino and gustave noted drains prevents seroma after axillary dissection. It was hypothesized that daily aspiration of seromas would keep wound cavity dry and allow wound flaps to adhere to chest wall preventing fluid accumulation resulting in more rapid resolution.

The advantages of drainages are reduced use of dressings, reduced incidence of tissue breakdown and infection and patient comfortness is improved post-operatively. (34,35).

Studies were also done to analyse the usefulness in tacking subcutaneous tissues to secure the flaps.use of tissue glue to close dead space remains controversial .But dead space in axilla is the potientially larger one which needs to be obliterated. Studies performing Functional ALND , limited ALND, were conducted to observe the effect on reduction of axillary space and its effect on seroma formation.(32,33)

Effect of suction drain on seroma

Suction drains has been found in various studies, superior to other methods of fluid evacuation to minimize the dead space. Mechanism proposed is that the suction helps to adhere skin flaps with chest wall and sealing off all leaking lymphatics in axilla.This reduces the incidence of post operative hematomas,seromas,flap necrosis..when no suction drain were used,seroma incidence was found to be unacceptably high in various studies.

Prolonged drainage ,may increase hospital stay and risk of infection will be high by allowing retrograde migration of bacteria.

Premature withdrawal of suction drains irrespective of amount of drained fluid may be accompanied by increase in axillary seroma incidence.

OBSERVATIONS AND RESULTS

This study was conducted in the Department of General Surgery,Govt. Stanley Medical College & Hospital, Chennai for a period of nine months.

After obtaining an informed consent from Patients and who fulfilled the inclusion criteria ,were included in this study,

Total Number of patients enrolled in this study – 30

Total Number of patients underwent continuous suction drain– 15

The quantity of seroma in the post operative period was measured on 3^{rd} day,7^{th} day,10^{th} day,12^{th} day and 15^{th} day and tabulated.

Figure 1.Total number of patients participated in study

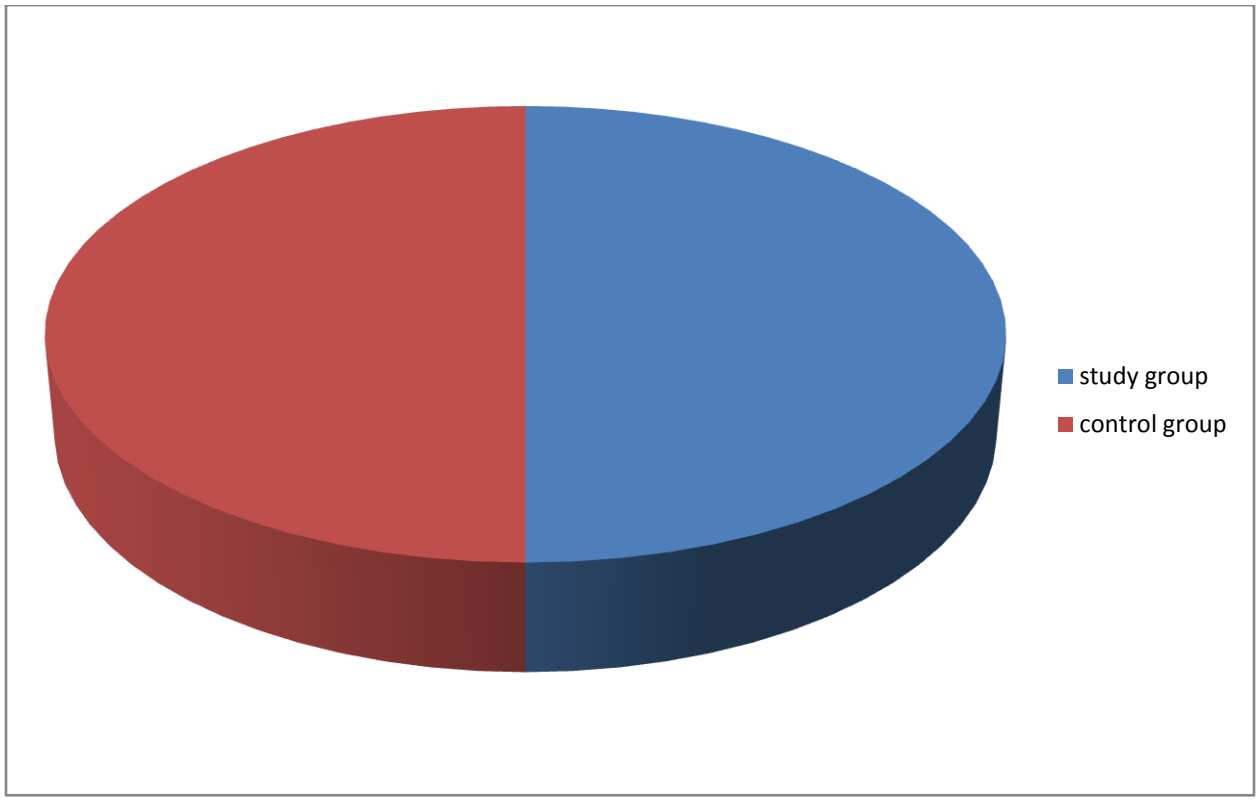


Table 1 Age wise Distribution

Age Group	Number of Patients	Percentage
31-40	2	6.6%
41-50	15	50%
51-60	7	23.3%
61-70	5	16.6%
71-80	1	0.03%

The age of patients with peak incidence in the 4th decade of life ranging from 35 years to 80 years

FIGURE NO 2: AGE-WISE DISTRIBUTION

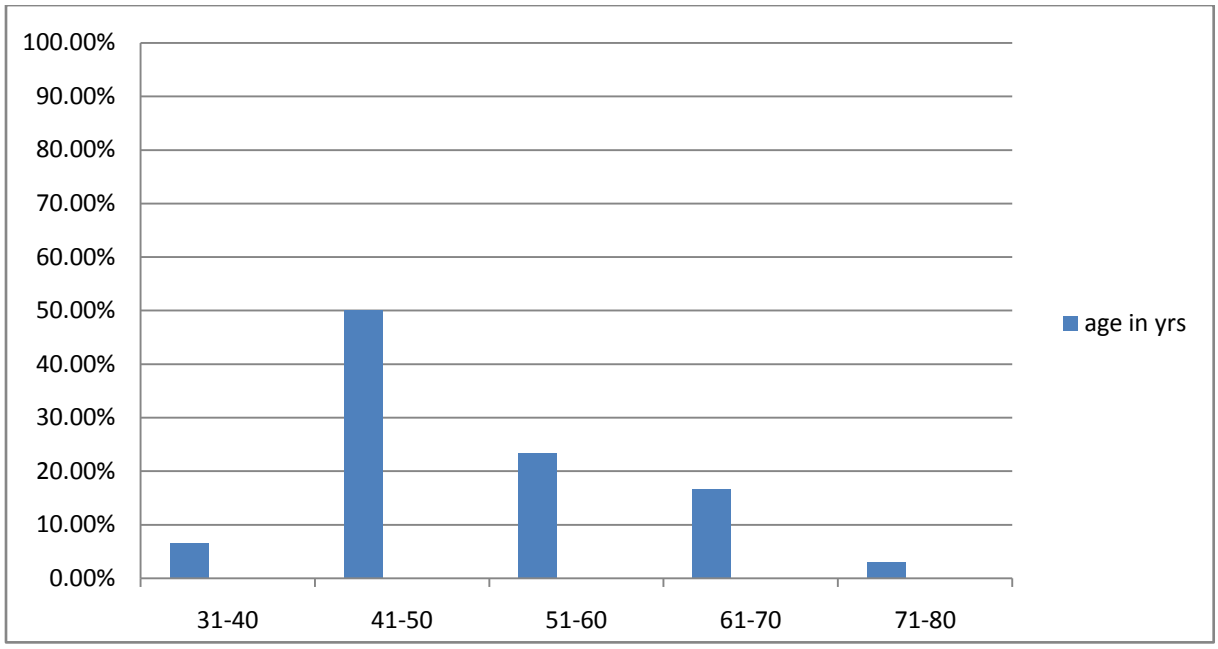
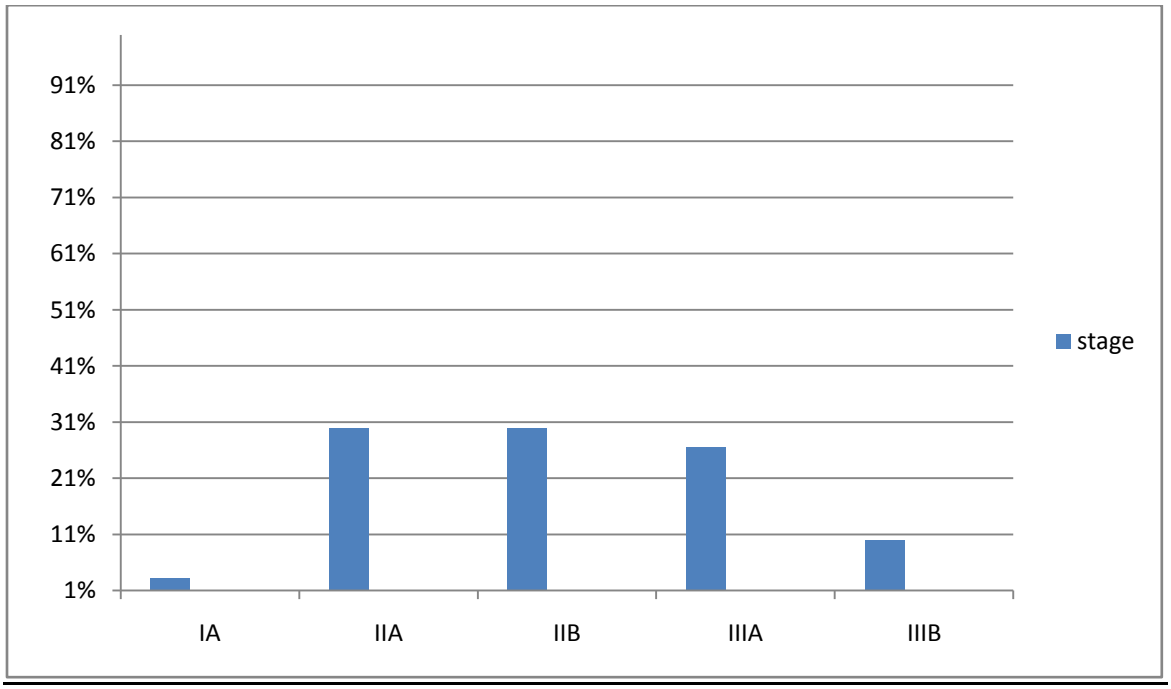


Table 2:Stage wise distribution:

STAGE	NUMBER OF PATIENT	PERCENTAGE
IA	1	3.3%
IIA	9	30%
IIB	9	30%
IIIA	8	26.6%
IIIB	3	10%

Figure No 3. STAGE WISE DISTRIBUTION



Between the two groups,there was a significant difference in the seroma quantity post operatively, thus permitting an earlier removal of drain tube in the study group.

Table 3 Average Quantity of Seroma

Day	Study Group	Control Group
POD 3	75ml	100ml
POD 7	30ml	55ml
POD 10	<5ml	25ml
POD 12	Nil	10ml
POD 15	Nil	Nil

There is a Significant reduction of seroma in study group compared to control group

Figure 1 Average Quantity of Seroma in ml

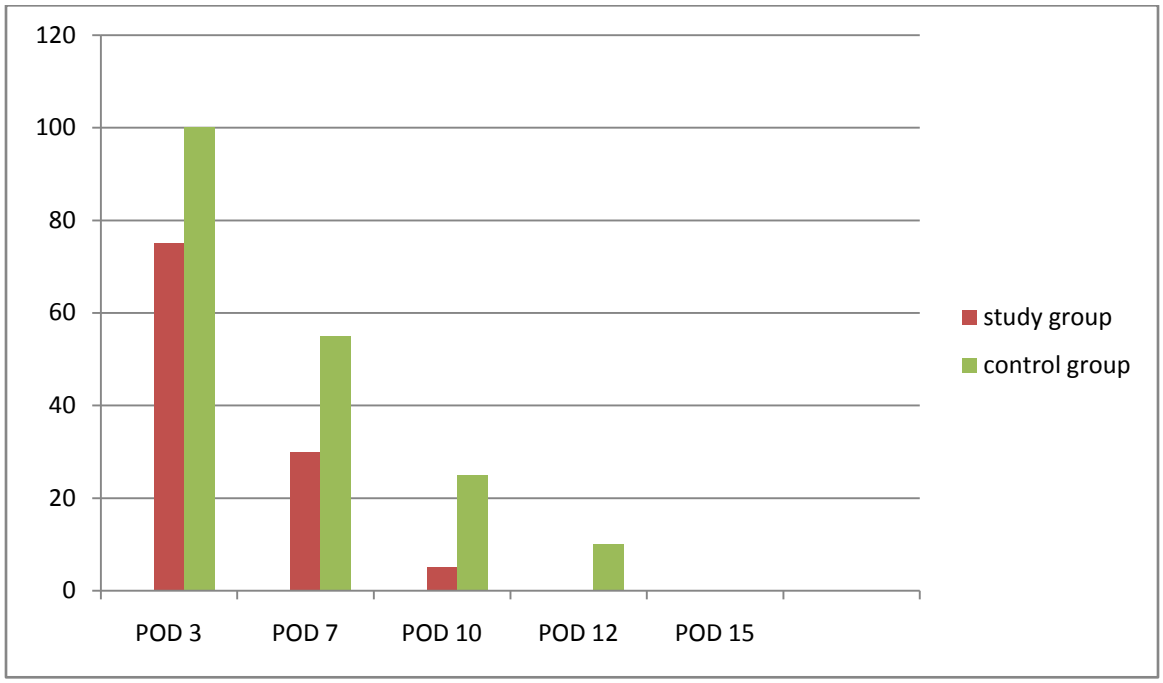


Table 4 Average Days Of suction Drain Tube Removal

Study Group	Control Group
7.9 Days	**12 Days**

Test of Statistical Significance

To compare sample proportion, 2-sample z-test was used. Test of statistical significance was calculated as follows:

Inputs

	Sample 1	Sample 2
Sample Proportion	1	0.06
Sample size	15	15
Significance level	0.05	
1- or 2-tailed test	1-tailed	

Results

	Sample 1	Sample 2	Difference
Sample proportion	1	0.06	0.94
95% CI (asymptotic)	1 - 1	-0.0409 - 0.1609	0.6402 - 1.2398
z-value	5.2		
P-value	<0.0001		
Interpretation	Statistically significant, reject null hypothesis that sample proportions are equal		
n by pi	n * pi <=5, test inappropriate		

SUMMARY

- Total number of patients involved in the study period – **30**
- Total number of patients on continuous suction drain tube– **15**
- Total number of patients on standard wound closure and closed suction drain tube– **15**
- Age of presentation with Peak incidence at 4th decade.
- Predominate stages were Stage II A and II B disease
- The seroma quantity were almost less than half of the control group in the study group on the corresponding days
- The average day of suction Drain removal

  Study group:8 days

  Control group:12 days

Using z-test ,by analyzing the above results, null hypothesis is rejected .so the test is statistically significant.

Conclusion:

- The role of continuous suction drain tube in Modified Radical Mastectomy has reduced the formation of seroma significantly
- Has led to early removal of drains,
- Instituition of 1st cycle of chemotherapy before discharging the patient and thus reducing the hospital stay.
- It has also led to low incidence of flap necrosis post operatively.
- However, further studies are needed to know whether co-morbid illness like Diabetes,Hypertension and instituition of Neo-Adjuvant Chemotherapy has any confounding effect on the formation of seroma

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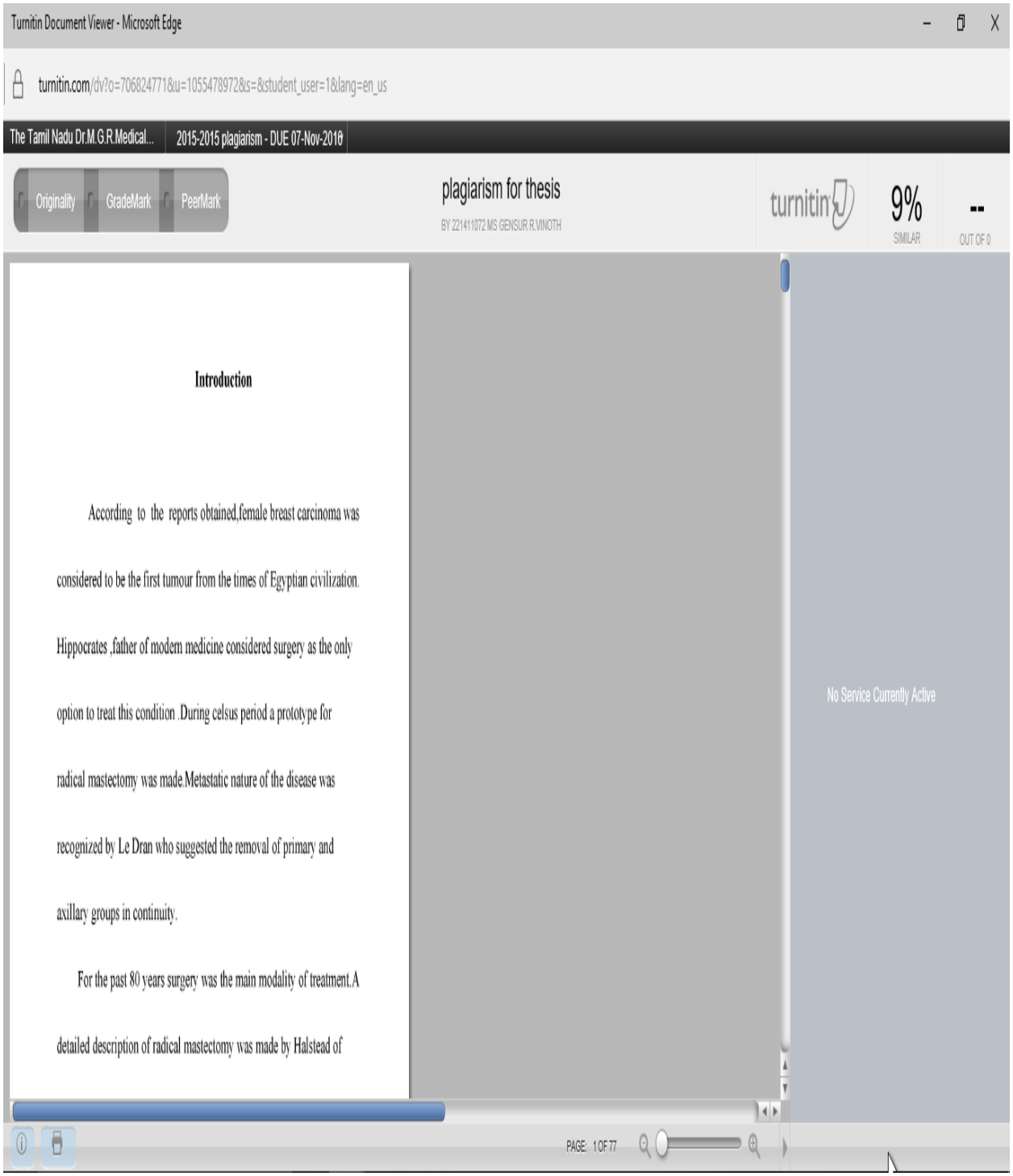
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Introduction
According to the reports obtained,female breast carcinoma was considered to be the first tumour from the times of Egyptian civilization. Hippocrates ,father of modern medicine considered surgery as the only option to treat this condition .During celsus period a prototype for radical mastectomy was made.Metastatic nature of the disease was recognized by Le Dran who suggested the removal of primary and axillary groups in continuity.
For the past 80 years surgery was the main modality of treatment.A detailed description of radical mastectomy was made by Halstead of
No Service Currently Active
PAGE: 1 OF 77

NAME	AGE	I.P NO	DIAGNOSIS	STAGING	PROCEDURE	SEROMA DAY3	DAY7	DAY 10	DAY 12	DAY 15	DT removal	continuous suction
chandra	45	1639222	ca RT breast	IIB	Rt MRM	70ml	20ml				8th POD	Y
singari	50	1623941	ca LT breast	IIA	Lt MRM	80ml	30ml				8th POD	y
SUMATHI	60	1639045	ca LT breast	IIB	Lt MRM	100ml	40ml	20ml			12th POD	N
Umadevi	52	1630004	ca LT breast	IIB	Lt MRM	75ml	30ml	10ml			10th POD	Y
valliyammal	50	1605259	ca LT breast	IIA	Lt MRM	100ml	60ml	30ml	10ml		12th POD	N
Geetha	50	1643177	ca LT breast	IIIA	Lt MRM	80ml	30ml	10ml			10th POD	y
VASANTHI	53	1637193	ca RT breast	IIA	Rt MRM	110ml	60ml	30ml	20ml		14th POD	N
kumudha	67	1548868	ca LT breast	IIA	Lt MRM	75ml	20ml				8th POD	Y
gomathi	37	1634756	ca RT breast	IIIB	Rt MRM	90ml	50ml	30ml	20ml		13th POD	N
Gnanamani	69	1563662	ca RT breast	IIB	Rt MRM	85ml	35ml	10ml			10th POD	Y
sagunthala	47	1571497	ca LT breast	IIIA	Lt MRM	75ml	25ml				7th POD	Y
Jayalakshmi	43	1608380	ca RT breast	IIIA	Rt MRM	70ml	20ml				7th POD	Y
thamaraiselvi	48	1608973	ca RT breast	IIIA	Rt MRM	110ml	60ml	30ml	10ml		13th POD	N
saroja	50	1634270	caRT breast	IIIB	Rt MRM	110ml	70ml	40ml	20ml		13th POD	N
lakshmi	65	1543465	ca LT breast	IA	Lt MRM	60ml	25ml				7th POD	y
prema	45	1515395	ca LT breast	IIIA	Lt MRM	65ml	20ml				7th POD	y
meenakshi	45	1512621	ca LT breast	IIA	Lt MRM	70ml	30ml				7th POD	y
Jothy	67	1629115	ca LT breast	IIB	Lt MRM	75ml	25ml				7th POD	y
valarmathy	48	1546415	ca LT breast	IIIA	Lt MRM	70ml	30ml				8th POD	Y
malliga	53	1618324	ca LT breast	IIIB	Lt MRM	75ml	25ml				7th POD	y
Rukmani	55	1604596	ca LT breast	IIB	Lt MRM	90ml	45ml	30ml	10ml		13th POD	N
seehithangam	49	1632249	ca LT breast	IIB	Lt MRM	110ml	60ml	35ml	20ml		13th POD	N
Anitha gloria	52	1639779	ca RT breast	IIA	Rt MRM	100ml	70ml	30ml	10ml		12th POD	N
maragadham	52	1634759	ca RT breast	IIB	Rt MRM	110ml	60ml	40ml	10ml		13th POD	N
kashali	38	1614818	ca RT breast	IIA	Rt MRM	75ml	30ml				7th POD	Y
mary	48	1639033	ca LT breast	IIA	Lt MRM	100ml	60ml	30ml	5ml		12th POD	N
abitha begum	45	1636625	ca RT breast	IIIA	Lt MRM	90ml	30ml				8th POD	N
vijayalakshmi	62	1569249	ca LT breast	IIB	Lt MRM	100ml	60ml	20ml			11th day	N
meena	45	1610242	ca RT breast	IIIA	Rt MRM	110ml	65ml	30ml			12th day	N
shantha	80	1604282	ca LT breast	IIA	Lt MRM	100ml	60ml	20ml			11th day	N

PROFORMA

SL. NO:

- **NAME :** **AGE /SEX:** **IP NO:**
- **ADDRESS WITH CONTACT NUMBER:**

- **DATE OF ADMISSION:** **DATE OF DISCHARGE/ DEATH:**

HISTORY OF PRESENTING ILLNESS:

H/O lump in breast Onset,site,location

Progression

Associated symptoms

Nipple Discharge

Nipple Retraction

Trauma,Fever

H/o abdominal pain,jaundice

H/o headache,back pain

H/o Loss of Weight,Loss of Appettite

PAST HISTORY:

Whether a known case of DM/hypertension/asthma/TB/epilepsy/cardiac illness

H/o similar episodes of cancer or lump breast in the past, if any:

H/o major illness/ hospital admissions, if any:

H/o drug intake/hormonal manupulation usage,if any:

PERSONAL HISTORY:

Age of menarche Marital status Consanguinity No.of. Children

Breast fed: Yes/No If Yes,Duration of feed: Age of menopause:

FAMILY HISTORY:

H/o similar complaints in mother,grandmother,female siblings,if any

H/o Prostatic illness in father,if any

CLINICAL EXAMINATION:

General examination:(after getting consent, with female attender by side)

Local Examination: Breast and Axilla

Arm,Chest wall,Supraclavicular fossa/infraclavicular fossa

Systemic examination:

CVS

RS

CNS

Abdomen

Spine and Cranium

Provisional diagnosis:

Staging:

Risk factors:

Comorbid disease:

INVESTIGATIONS:

CBC:

RFT:

HIV:

HBsAg:

Anti-HCV:

Blood Grouping & Typing:

BT/CT:

Chest X-Ray:

ECG:

USG Breast/Mammogram:

FNAC/Trucut Biopsy:

USG ABDOMEN:

CT Thorax/Bone scan

:**FINAL DIAGNOSIS:**

Revised staging:

GOVT.STANLEY MEDICAL COLLEGE, CHENNAI- 600 001

INFORMED CONSENT

DISSERTATION TOPIC: "A STUDY ON ROLE OF CONTINUOUS SUCTION DRAIN TUBE IN POST-MASTECTOMY SEROMA COLLECTION IN CARCINOMA BREAST"

PLACE OF STUDY: GOVT. STANLEY MEDICAL COLLEGE, CHENNAI

NAME AND ADDRESS OF PATIENT:

I, _____ have been informed about the details of the study in my own language.

I have completely understood the details of the study.

I am aware of the possible risks and benefits, while taking part in the study.

I understand that I can withdraw from the study at any point of time and even then, I will continue to receive the medical treatment as usual.
I understand that I will not get any payment for taking part in this study.

I will not object if the results of this study are getting published in any medical journal, provided my personal identity is not revealed.

I know what I am supposed to do by taking part in this study and I assure that I would extend my full co-operation for this study.

Name and Address of the Volunteer:

Signature/Thumb impression of the Volunteer

Date:

Witnesses:

(Signature, Name & Address)

Date:

Name and signature of investigator: **(Dr .VINOTH.R)**

சுயஒப்புதல் படிவம்

அரசு ஸ்டான்லி மருத்துவ கல்லூரி

சென்னை – 1

ஆராய்ச்சியின் பெயர் : மார்பக புற்றுநோய்க்கான மார்பக நீக்கம் அறுவை சிகிச்சைக்கு பிறகு சீரோமா சேகரிப்பில் தொடர்ச்சியான உறிஞ்சும் வடிகால் குழாய் பங்கு பற்றிய ஆய்வு

ஆய்வு இடம் : அரசு ஸ்டான்லி மருத்துவ கல்லூரி

_____ என்கிற எனக்கு இந்த ஆராய்ச்சி பற்றிய முழு விவரங்களும் என் தாய்மொழியில் தரப்பட்டன.

இந்த ஆராய்ச்சி பற்றி முழுமையாக புரிந்து கொண்டேன்.

இதில் நான் பங்கு பெறுவதினால் ஏற்படக்கூடிய அசௌகரியங்கள் மற்றும் நன்மைகள் பற்றியும் தெரிந்து கொண்டேன்.

இந்த ஆராய்ச்சியிலிருந்து என் சுய விருப்பபடி ,எந்த நேரமும் விலகி கொள்ள முடியும் என்றும், அதனால்

இம்மருத்துவமனையில் எனக்கு கிடைக்க வேண்டிய மருத்துவ உதவிகள் அனைத்தும் எந்த பாரபட்சமும் இல்லாமல் தொடர்ந்து கிடைக்கும் என்றும் தெரிந்து கொண்டேன்.

இதில் பங்கு பெற எந்தவித சன்மானமும் தர பட மாட்டாது என்று புரிந்து கொண்டேன்.

இந்த ஆராய்ச்சியின் முடிவுகள், என்னை பற்றிய தனிப்பட்ட தகவல் ஏதும் தராமல் இருந்தால், மருத்துவம் சார்ந்த பத்திரிக்கைகளில் பிரசுரமாவதற்கு எதிர்ப்பு தெரிவிக்க மாட்டேன்.

இந்த ஆராய்ச்சியில் பங்கு பெற நான் என்ன செய்ய வேண்டும் என்று தெரிந்து கொண்டேன். அதன்படி முழு ஒத்துழைப்பு கொடுக்க தயாராக உள்ளேன்.

பங்கு பெறுபவரின் கையொப்பம்_____

தேதி_____

முகவரி_____
_____
_____

சாட்சியாளரின் கையொப்பம்_____

தேதி_____

முகவரி_____
_____
_____

ஆராய்ச்சியாளரின் கையொப்பம்_____

தேதி_____

நோயாளி தகவல் தாள்

மார்பக புற்றுநோய்க்கான மார்பக நீக்கம் அறுவை சிகிச்சைக்கு பிறகு சீரோமா சேகரிப்பில் தொடர்ச்சியான உறிஞ்சும் வடிகால் குழாய் பங்கு பற்றிய - **ஓர் ஆய்வு**

ஆய்வின் நோக்கம் : மார்பக புற்றுநோய்க்கான மார்பக நீக்கம் அறுவை சிகிச்சைக்கு பிறகு சீரோமா சேகரிப்பில் தொடர்ச்சியான உறிஞ்சும் வடிகால் குழாய் பங்கு பற்றிய ஆய்வு

உண்டாக கூடிய இடர்கள்:

அனைத்து முறைகளிலும் இருப்பது போலவே இந்த முறையிலும் சில எதிர்பாராத இடர்கள் சம்மந்தபட்டுள்ளுன. சிலருக்கு சீரோமா தொற்று ஏற்படலாம்.

அந்தரங்க தன்மை :

உங்கள் மருத்துவ பதிவேடுகள் மிகவும் அந்தரங்கமாக வைத்து கொள்ள படும். பிற மருத்துவர்கள் / விஞ்ஞானிகள், இந்த ஆய்வின் தணிக்கையாளர் அல்லது ஆராய்ச்சி ஆதரவாளர்களின் பிரதிநிதிகள் ஆகியோரிடம் அவை வெளிப்படும்.

பத்திரிக்கைகளில் பிரசுரிக்கபடலாம். ஆனால் பெயரை வெளியிடுவது மூலம் நீங்கள் அடையாளம் காட்ட பட மாட்டீர்கள்.

ஆய்வில் பங்கேற்கும் நோயாளியின் கடமைகள் :

உங்களை கவனித்து கொள்ளும் மருத்துவருடன் நீங்கள் முழுமையாக ஒத்துழைக்க வேண்டும். என்னென்ன செய்ய வேண்டும் , என்னென்ன செய்யக்கூடாது என்றும் கூறப்பட்டுள்ளவற்றிலிருந்து சற்றும் விலக கூடாது என்றும் நீங்கள் எதிர்பார்க்கப்படுகிறீர்கள்.

<u>ஆய்வில் உங்கள் பங்கேற்பு மற்றும் உங்கள் உரிமைகள்</u>:

இந்த ஆய்வில் உங்கள் பங்கேற்பு தன்னிச்சையானது. காரணங்கள் எதையும் கூறாமலேயே நீங்கள் இந்த ஆய்விலிருந்து எந்த நேரத்திலும் விலகி கொள்ளலாம். எந்த ஒரு நேரத்திலும் உங்களுக்கு திருப்திகரமாக இல்லை என்று உணர்ந்தாலோ அல்லது வேறு ஏதேனும் உடல் நல குறைவு உண்டானாலோ , உங்களை கவனித்து வரும் மருத்துவரிடம் உடனடியாக தெரிவிக்கவும். சிகிச்சை உங்களுக்கு பொறுத்தமாக இருக்காது என்று தோன்றினால் உடனடியாக நிறுத்தப்படும் . உங்கள் சம்மதம் இன்றியே கூட ஆய்வு நிறுத்தப்படுவது சாத்தியமே .

INSTITUTIONAL ETHICAL COMMITTEE,
STANLEY MEDICAL COLLEGE, CHENNAI-1

Title of the Work : A Study on role of continuous suction drain tube in post mastectomy seroma collection in carcinoma breast.

Principal Investigator : Dr. Vinoth.R

Designation : PG MS (General Surgery)

Department : Department of General Surgery
Government Stanley Medical College,
Chennai-01

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 24.03.2016 at the Council Hall, Stanley Medical College, Chennai-1 at 2PM

The members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

The Principal investigator and their team are directed to adhere to the guidelines given below:

1. You should inform the IEC in case of changes in study procedure, site investigator investigation or guide or any other changes.
2. You should not deviate from the area of the work for which you applied for ethical clearance.
3. You should inform the IEC immediately, in case of any adverse events or serious adverse reaction.
4. You should abide to the rules and regulation of the institution(s).
5. You should complete the work within the specified period and if any extension of time is required, you should apply for permission again and do the work.
6. You should submit the summary of the work to the ethical committee on completion of the work.

MEMBER SECRETARY,
IEC, SMC, CHENNAI

MEMBER SECRETARY
ETHICAL COMMITTEE,
STANLEY MEDICAL COLLEGE
CHENNAI-600 001.