"A CLINICAL STUDY OF EFFECTIVENESS OF PROPHYLACTIC IV METHYLPREDNISOLONE IN PREVENTION OF SEROMA FORMATION IN CARCINOMA BREAST PATIENTS UNDERGOING MODIFIED RADICAL MASTECTOMY (MRM)"

BY
Dr. SANJANA G K

DISSERTATION SUBMITTED TO SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, TAMAKA, KOLAR-563103, KARNATAKA

In partial fulfillment of the requirements for the degree of

M.S. GENERAL SURGERY

UNDER THE GUIDANCE OF
Prof. Dr. KRISHNA PRASAD K
PROFESSOR
DEPARTMENT OF GENERAL SURGERY
SRI DEVARAJ URS MEDICAL COLLEGE
TAMAKA, KOLAR

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The Institutional Ethics Committee of Sri Devaraj Urs Medical College, Tamaka, Kolar has examined and unanimously approved the synopsis entitled **"A Clinical study of effectiveness of prophylactic IV methylprednisolone in prevention of seroma formation in carcinoma breast patients undergoing modified radical mastectomy (MRM)""** being investigated by **Dr.Sanjana G K** &Dr. Mohan Kumar K in the Department of General Surgery at Sri Devaraj Urs Medical College, Tamaka, Kolar. **Permission is granted by the Ethics Committee to start the study.**

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This study is carried out by **Dr. Sanjana GK [1], Dr. Mohan Kumar[1]** in the Departments of General Surgery[2] at Sri Devaraj Urs Medical College, and SDUAHER Tamaka, Kolar.

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ABSTRACT

BACKGROUND : Breast cancer is currently one of the leading causes of malignancy in women. Incidence of 'Breast Cancer' was estimated to be 28.2% of all female cancers with 216,108 cases by 2022 in India. 272,454 cases were seen in the United States in 2021. More than two million cases were noted worldwide in the year 2022. The incremental application of newer diagnostic tools, effective surgical and adjuvant medical treatments has substantially increased overall survival. The overall outcome regarding the prognosis after surgery is dependent on various factors like age, stage of carcinoma, estimated blood loss and comorbidities[1]. MRM is the most commonly performed surgery for "Breast Cancer", which has its own local complications. Among the various post op complications encountered, seroma formation is a common one. Various methods have been advocated by which post operative seroma formation can be reduced and they include quilting to eliminate dead space, local or topical application of various agents like steroids, gentamycin, platelet rich plasma, octreotide[2].

There is limited evidence from some studies that a single preoperative dose of steroids decreases seroma formation over the first 2 postoperative periods, but the difference is not maintained after this period[3]. More studies are needed because at present the available evidence does not support the use of steroids for prevention of seroma after MRM. Hence, we would like to study if administration of 120mg of IV methylprednisolone preoperatively, is really beneficial in reducing seroma formation post operatively in carcinoma breast patients undergoing MRM.

METHODOLOGY: All patients diagnosed to have carcinoma breast fulfilling inclusion and exclusion

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Last, but not the least, I would like to express my gratitude to the **Almighty** for all his blessings

DR. SANJANA G K

"A CLINICAL STUDY OF EFFECTIVENESS OF PROPHYLACTIC IV METHYLPREDNISOLONE IN PREVENTION OF SEROMA FORMATION IN CARCINOMA BREAST PATIENTS UNDERGOING MODIFIED RADICAL MASTECTOMY (MRM)"

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METHODOLOGY: All patients diagnosed to have carcinoma breast fulfilling inclusion and exclusion criteria and who underwent MRM at RL Jalappa Hospital and who volunteered for the study are being considered in the study. Patients were divided into group A or B by randomisation / odd and even method. Patients in group A were the study group. These patients received 120mg of methylprednisolone IV 1 hour before the surgery. Patients in group B are the control group who did not receive IV methylprednisolone. All patients underwent standard MRM. At the end of surgery, a closed suction drain was placed and the amount of drain was documented everyday till drains were removed. Wound was closely observed for seroma formation, fullness, redness, fluctuation. If any infection, culture and sensitivity of the wound was done and appropriate antibiotics was given. Results thus obtained was documented and analysed using statistical methods. Independent t-test was applied to calculate difference between means and a p-value <0.05 was considered as statistically significant level for all comparisons.

RESULTS: The mean age was 64 years. The mean drainage in group A was significantly reduced as compared to group B (163ml vs. 279ml). Total drainage days were reduced (5 days vs. 7 days). The mean post op hospital stay was reduced (10.18 days vs 15.25 days). VAS pain score on POD 3 was reduced (2.56 vs 5.43).

CONCLUSION: Findings of the study clearly establish a significant reduction in seroma formation and early removal of drain in patients who received IV Methylprednisolone pre operatively. There was significant reduction in duration of stay of patients in the hospital and reduction in post operative pain. There was no SSI noted during the study.

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LIST OF ABBREVIATIONS USED

IV – Intravenous

3D - 3 Dimensional

BC - Breast Cancer

BIRADS - Breast Imaging Reporting And Data System

CC - Cranio caudal

CT - Computed Tomography

FNAB - Fine needle aspiration biopsy

MBC - Male breast Cancer

MLO - Medial lateral oblique

MRI - Magnetic resonance imaging

SEM - Standard error of mean

SD - Standard deviation

TDLU - Terminal duct lobular unit

USG – Ultrasonogram

LCIS – Lobular carcinoma in situ

DCIS – Ductal carcinoma in situ

CBE – Clinical breast examination

BSE – Breast self examination

INTRODUCTION

INTRODUCTION

Breast lumps, which can be benign or malignant, are one of the commonest problemsin a surgical outpatient department (OPD). These lumps are usually ignored for a variety of reasons and are commonly found in young and middle-aged women. Breast cancer is one of the major causes of cancer-related mortality among women. Early cancer identificationis so essential to enhancing survival.

There were 685, 000 deaths worldwide. More than two million new cases of breast cancer in women were reported in 2020. By the end of 2020, it was found that breast cancer is the most common cancer. Around eight million women were diagnosed as breast cancer patients in the last five years. Globocan data for India (2020) shows breast cancer accounted for more than ten percent of all the deaths and more than thirteen percent of all the cancer cases.[1]

A significant fraction of the global population is impacted by breast cancer, a critical public health concern with a discernible rising trend. Over the past few years new and innovative surgical techniques have been advanced to treat breast cancer. New diagnostic procedures have been evolved to detect breast cancer at an early stage leading to considerable drop in the number of deaths attributable to breast cancer. The outcome has improved gradually.[2] Breast cancer is no longer a singular ailment. It is a complex illness made of various biological subtypes with unique natural histories. Many clinical, pathological, and genetic features of breast cancer may have distinct prognostic and therapeutic implications.

It is found that breast cancer is prevalent in 25.8 per one lakh women in India. The mortality rate is 12.7 per one lakh women. Accordingly, breast cancer has been listed as the carcinoma most commonly found in Indian women. “Delhi had the highest age-adjusted

incidence rate of breast cancer at 41 per 100,000 women, followed by Chennai (37.9), Bangalore (34.4), and Thiruvananthapuram District (33.7)". Significant rise in age adjusted incidence from 1982-2014 in all of the PBCRs. Bangalore PBCR recorded the highest annual percentage change of 2.84 and Mumbai PBCR the least percentage change of 1.24 The incidence to mortality rate is high in rural registries compared to urban registries with an incidence of 66 and 8 respectively. In addition, the incidence of risk factor for developing breast cancer is found to be significant among young Indian women.[3]

Globally, breast cancer is rapidly becoming a primary cause of oncologic morbidity and mortality for women. Advancements in the breast cancer screening program, growing public knowledge of the disease, and the groundbreaking development of breast cancer imaging have minimized rise in the number of people presenting with breast cancer at an early-stage. [4]

Breast conservative surgery (BCS) is a common course of procedure. However, patients from low-income and rural areas present with advanced disease, and BCS is unable to clear microscopic cancer. In these cases, Modified Radical Mastectomy (MRM) continues to be the mainstay of care, sometimes as a primary treatment and other times following neo-adjuvant chemotherapy to achieve tumor free margins.[5]

From 3% to 85%, seroma development is the most frequent and preventable consequence following axillary lymph node dissection and mastectomy. It is the buildup of serous fluid in the axillary region or beneath the skin flaps. The seventh post op day is found to be the normal day of beginning of seroma development. It would reach peak level on the eighth day, and then gradually subsides over the course of the following several days[6].

Seroma is responsible for reduced wound healing, extended hospital stays, and significant morbidity, all of which lower quality of life and ultimately cause adjuvant therapy to be delayed. Surgical trauma is found to be primarily a result of an initial inflammatory

exudative reaction, which is also thought to be a key factor in the pathophysiology of seroma production. [7]

This is corroborated by noticing growth hormones, cytokines, proteinases, and proteinase inhibitors in the the seroma fluid. With varying degrees of success, a several strategies are used in avoiding formation of seroma, including shoulder immobilization, extended suction drain use, flap fixation, and tranexamic acid use during surgery.[8]

With encouraging outcomes, the use of steroids to reduce the inflammatory response has been reported in head and neck, plastic, cardiac, and abdominal operations. Consequently, in the prophylactic treatment of post-MRM seroma development in breast cancer patients, steroids such as hydrocortisone may demonstrate to be effective anti-inflammatory medicines. Because they are safe, affordable, and easy to use, steroids are highly advised.[9]

The purpose of this research is to ascertain whether giving patients with breast cancer an intravenous dosage of hydrocortisone can effectively prevent the formation of post-MRM seromas. This can be readily included into our care plan and will be a straightforward and efficient strategy to prevent this mastectomy complication[10]. Preventing seroma formation would guarantee an early patient recovery and result in a considerable decrease in morbidity[11].

AIMS AND OBJECTIVES

AIMS AND OBJECTIVES

AIM:

To evaluate effectiveness of prophylactic IV methylprednisolone in prevention of seromaformation in carcinoma breast patients undergoing modified radical mastectomy.

OBJECTIVES OF THE STUDY:

1. To document the amount of seroma formation postoperatively following administration of 120mg of methylprednisolone in patients undergoing modified radical mastectomy.
2. Documenting the amount of seroma formation postoperatively in those who do not receiveany prophylactic medication.
3. To compare the final outcome in terms of amount of seroma formation.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Approximately 3000 BC, Egyptian literature contained the first accounts of breast cancer. The "Edwin Smith Papyrus" details eight occurrences of surgically excising breast tumors with the aid of a fire drill. Afterwards, breast tumors were labeled as an incurable illness. In the early fourth century B.C., Hippocrates was the first to describe the stages of breast cancer.

Benjamin Bell (1749–1806) was the pioneering surgeons to treat breast cancer by opening the breast parenchyma, the lymph nodes, and the muscle beneath. In the eighteenth century, John Hunter conjectured that cancers originate from lymph that the blood constantly excretes. In 1713, Bernardino Ramazzini observed that nuns had a high incidence of breast cancer, which he attributed to hormones. Lorenz Heister wrote a book in 1719 called Chirurgiein which he expressed his views on lumpectomies and mastectomy[12].

The radical mastectomy technique was created in 1882 by Johns Hopkins University surgeon William Stewart Halsted. He was especially concerned about cutting off the pectoralis major to prevent recurrence and removing all tissue to stop the spread.

The foundation for hormone therapy for breast cancer was laid by University of Edinburgh graduate Thomas Beatson, who wrote in 1896 about the link between oophorectomy and breast cancer. In the nineteenth century, Rudolf Virchow was the first to connect disease to microscopic pathology[14].

In the 1920s, methods for staging breast cancer were created. Late in the 1960s, mammography techniques were standardized. In America, a radical mastectomy was was commonly used for a long period. In the 1970s, modern clinical research demonstrated that less intrusive surgery was just as successful for most patients with Carcinoma Breast. In the 1990s, Breast Cancer was linked to the BRCA1 and BRCA2 genes[15].

Globally, Breast Cancer is a major disease and has become the major tumor deaths in women. Various combinations of surgery, radiation, chemotherapy, and hormone immunotherapy are applied to treat Breast Cancer. One of the greatest treatments for Breast Cancer is surgery.

The major severe side effect in MRM is development of seroma. Disruption of lymphatic pathways and formation of a dead space during flap elevation are considered to be the basic mechanisms of post-MRM seroma production. Seroma fluid contains significant concentrationsof leukocytes, granulocytes, proteinases, IgG, and numerous other cytokines. Strong anti- inflammatory characteristics of corticosteroids, including hydrocortisone, have been shown in literature to prevent fluid buildup at the surgery site[16].

The Okholm and Axelsson study found no corticosteroid-associated decrease in occurrence of post-MRM seroma. The inflammatory response that occurs following MRM is significantly more pronounced than it is after head and neck surgery, which could be the cause of the negative association observed between the use of corticosteroids and lower frequency of seroma

formation. The trial employed a lower dose of corticosteroid, which may have contributed to the lackof a noticeable impact and increased seroma formation[17].

One preoperative high-dose steroid had a beneficial anti-inflammatory impact on patients undergoing open colonic resection, according to a research by Schulze et al. Taghizadeh et al. have shown a similar level of success with seroma management. A single dosage of glucocorticoid resulted in significant reductions in both the overall (a) No. of aspirations (b) total volume of the aspirate.

Trials carried out by Khan, Qvamme et al., and Talha et al. yielded comparable results. According to the results of another Indian investigation, hydrocortisone injection dramatically decreased seroma development[18].

EPIDEMIOLOGY:

Breast Cancer is found to be the most prevalent cancer among women in the world. In 2020, more than two million women were diagnosed with Breast Cancer. About seven lakh died worldwide. In 2020, about eight million women in he world were diagnosed as Breast Cancer patients. This makes the Breast Cancer as the most common cancer globally. Breast Cancer is also the major cause of "lost disability-adjusted life years (DALYs)" for women in the world. Epidemiological studies predict the possibility of more than two million Breast Cancer cases globally by 2030.In India, there were 526000 prevalent cases (474000 to 574000) and 118000 incident cases, with more than ninety eight percent of the cases being female. Between 1990

and 2016 (9.5 to 85.5 percent confidence interval), the age wise incidence rate of Breast Cancer increased across all states in the country for females.

Breast Cancer has been responsible for more than ten percent of all deaths and more than thirteen percent of all cancer cases across India as of 2020[19].

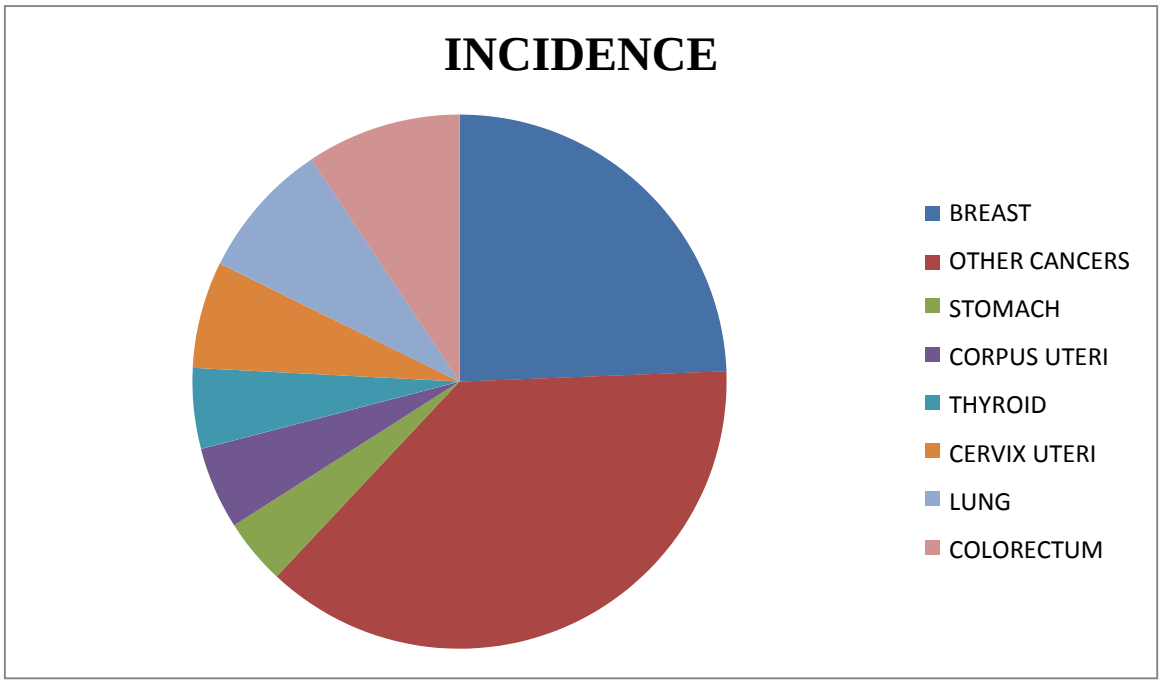


Fig 1:WHO : Number of new Cancer cases in the world in 2020 (estimate).

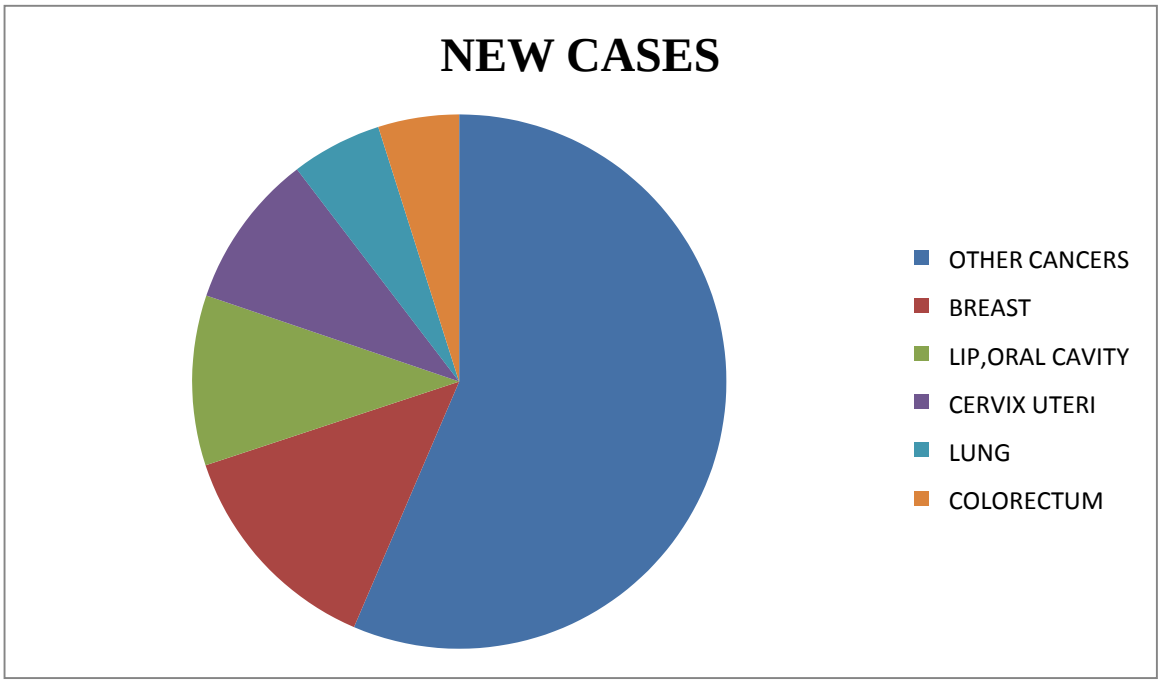


Figure 2: World Health Organization Globocan 2020 India

The World Cancer Report (2020) states that "The effective measures for controlling Breast Cancer are early identification and fast treatment. Patients with Breast Cancer in India have poorer survival rates compared to those in Western countries due to factors such as older age at diagnosis, advanced disease stage at presentation, delayed initiation of definitive therapy, and inadequate treatment".

Indian women are more likely to be affected by Breast Cancer at a younger age in comparison with the women in Western countries. A study found that "Patients in stage I had a 5-year overall survival rate of 95%, patients in stage II of 92%, patients in stage III of 70%, and patients in stage IV of just 21%. In order to identify women who are at a higher risk of developing breast cancer and to enable customized screening, it is critical to understand the genetic variations present in India". It is vital to identify

genetic and epigenetic biomarkers specific to India since these markers could be used as screeningtools for early detection[20].

EMBRYOLOGY OF BREAST

In utero is when breast development starts. Anatomically, a modified sweat gland arises from primordially generated breast tissue. Mammary parenchyma maturation is a trait unique to the mammalian species. It is made up of connective, lobular, and ductal tissues. The "milk line" refers to the location in embryology where the paired mammary glands develop concurrently.

The mammary ridge, colloquially called as the milk line is a line extending from the inguinal region to the primeval axilla in the area of development of the limb buds. However, in majority of the mammals, the number of mammary glands that develop maybe more than a pair, the exception being humans and primates, where a single pair develops on either side of this line in the region of the pectoralis major.

In males, the mammary gland usually experiences very little additional development throughout the postnatal period; whereas, in females, the mammary gland experiences significantgrowth and development due to hormonal stimuli[21].

The hormones that regulate reproduction are progesterone and estrogens. They can help in regulating postnatal development of the female mammary gland. This development is associated with the organ's pubertal development.

The breast ridge, two ventral bands of thicker ectoderm, begins to form in the 5^{th} or 6^{th} of fetal growth. They may disappear swiftly except for a little portion that may remain in the pectoral area.

The primary bud in each breast is produced by ectoderm ingrowth. This main bud

produces 15 to 20 secondary buds. Lactiferous ducts are produced when Epithelial Cords from the Secondary bud develop and penetrate the Mesenchyme. These Lactiferous Ducts open into the shallow Mammary pits. A nipple forms in the Mammary pit during infancy due to Mesenchyme development. Breasts of men and women are the same from birth.

The breast reaches its maximum development by the age of 20. As the ductal lobular matrix in the breast loses estrogenic support, atrophy starts in pre menopausal women around ages forty to forty five years. In Pregnancy and Lactation, there are noticeable changes in the amount of glandular tissue that is present as well as the breast's functional activity. Remodeling may also result from variations in the amounts of ovarian hormones (progesterone and estrogens) throughout menstruation cycles. Following menopause, the ovarian function's hormonal secretory activity rapidly decreases, causing the mammary gland to undergo involution, which is primarily packed with connective tissue and fat. This causes the mammary gland to lose structural volume, form, and contour[22].

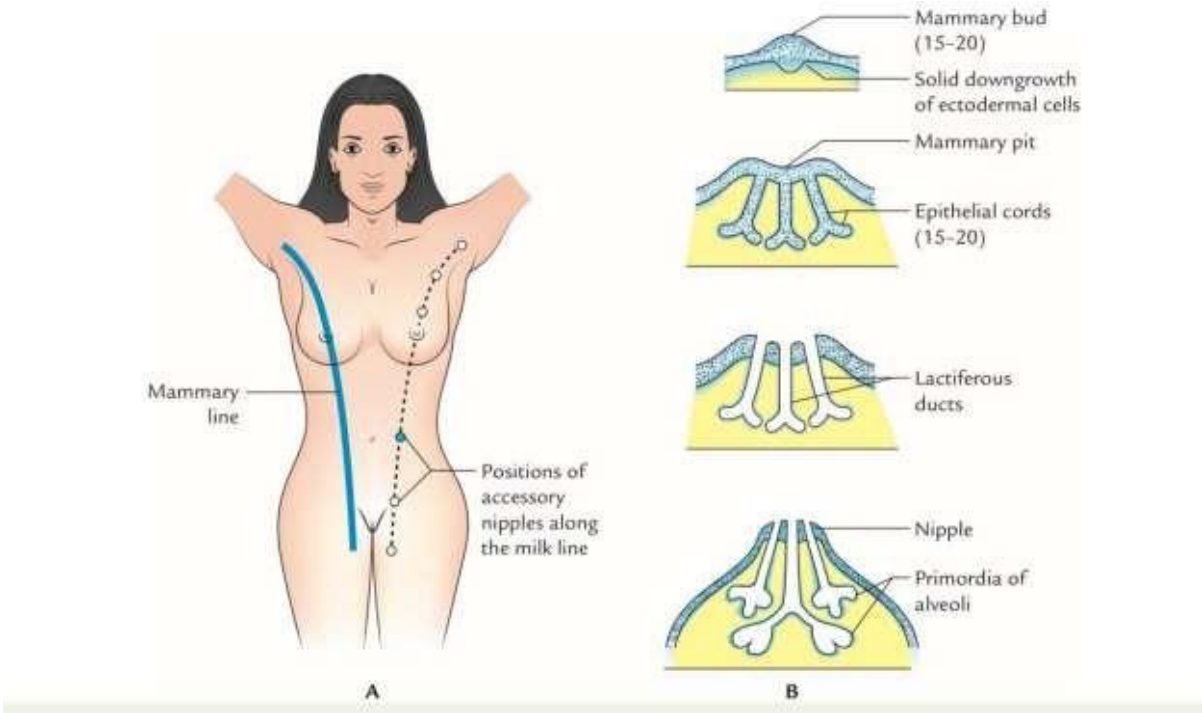


Fig ; Development of Mammary gland. Mammary Ridge (left side) and positions of AccessoryNipples (right side). B Stages of development of Mammary Gland.

ANATOMY OF BREAST

In the anterior chest wall, in the superficial fascial compartment is where the Breast Glands are located. Breast tissue is composed of Adipose tissue intercalated between the Lobules, Glandular tissue, and a Fibrous connective stroma that encloses and supports the Lobules.

The subcutaneous connective Tissue around breast components usually does not form a distinct capsule; rather, it spreads as laminae between the Lobes and lobules Connective Tissue, encircling the Gland and supporting the glandular elements. The result is a loss of structural volume, form, and contour in the Mammary Gland.

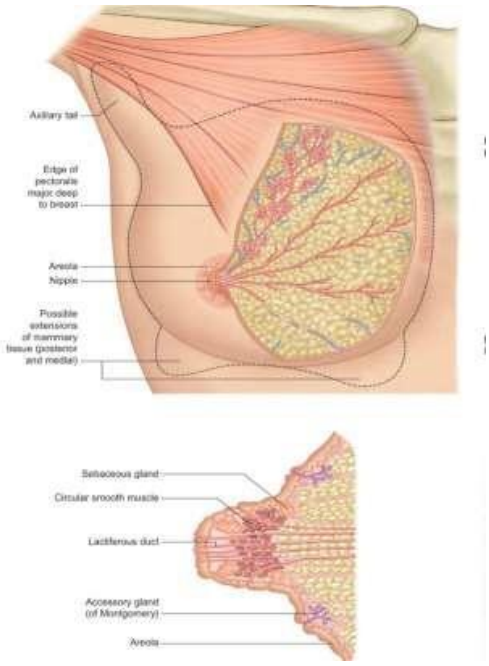


Fig : Mammary Gland

The Breast Tissue is extending usually from the second rib to the sixth rib in a cranio-caudal orientation. From the third to the fifth rib, sometimes. The breast extends transversely from the Anterior axillary line (lateral) to the Lateral sternal boundary (medial).

The ipsilateral pectorals major, serratus anterior, external oblique, rectus sheath fascia, and a superior portion of the rectus sheath are the muscles located posterior to the breast. The Pectoralis major fascia and the Breast's investing layer fascia are divided by the retromammary bursa.

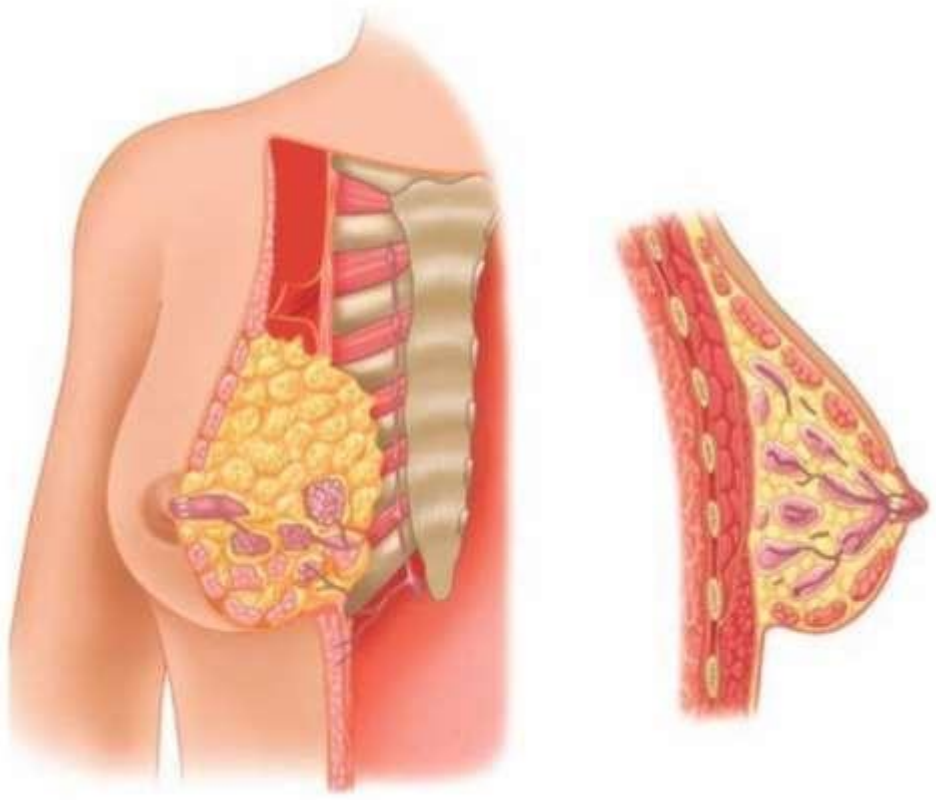


Fig : Anatomy of the Breast.

Pic courtesy: Schwart’z principles of surgery

The portion of the breast that extends across the Anterior axillary fold is referred as Axillary Tail of Spence. Retro Mammary bursa is responsible for the breast's flexibility and movement on the unyielding chest wall. The fibrous suspensory structures which are dense in nature are called “Cooper Ligaments” and are paralleled by finer dermal superficial fascial layers. These ligaments support theextraordinary movement of the gland and provide Breast structure with stability. The outer quadrant of the upper part of breast has more tissue in it compared to other quadrants[23].

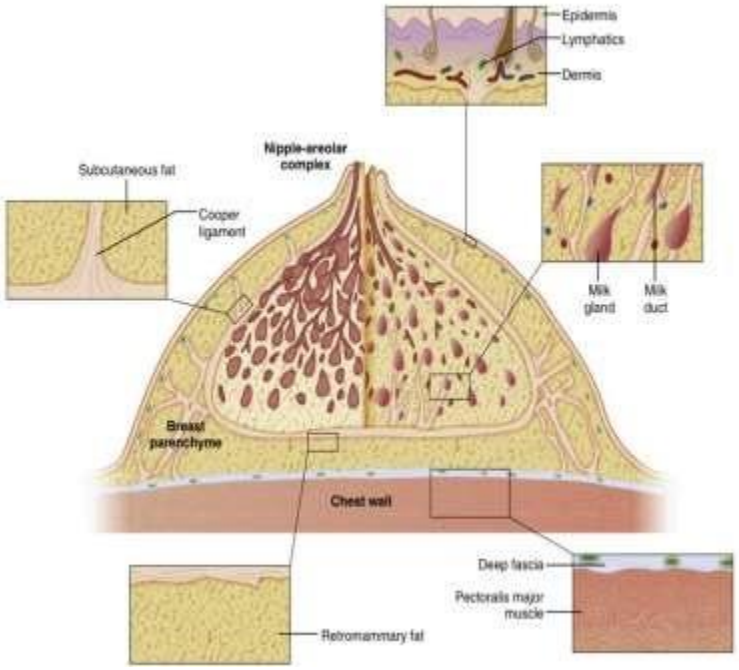


Fig : Mammary gland histology

Pic courtesy: Sabiston's textbook of surgery

NIPPLE AND AREOLA

The areola and nipple complex has pigmentation with channeling. During puberty, nipple darkens due to the pigmentation with an elevated shape. The areola expands and the pigmentation intensifies when the female is pregnant. Sweat, Sebaceous, and Auxiliary glands found in the areola cause Montgomery tubercles, which are little surface elevations. The nipple complex is circumference by thick connective tissue along the major ducts[24].

They control the nipple erection induced by various sensory stimulation. At the tip of the nipple are also Meissner's corpuscles and a large number of sensory nerve terminals. This sensory innervation triggers a sequence of neurohumoral events which causes milk to get ejected when the baby sucks[25].

INNERVATION:

Anterior and Lateral cutaneous branches of the 2nd through 6th intercostal nerves innervates the breast. Nipples are innervated by 4^{th} intercostal nerve.

THE ARTERIAL SUPPLY OF THE BREAST:

1. Thoracic Artery: "It is a division of the subclavian artery. The internal thoracic (or internal mammary) artery runs parallel to the sternum's lateral margin, located just behind the internal intercostal muscles.

2. Branches of the Axillary Artery: Four branches of the axillary artery that supply blood to the breast are:

a) The superior thoracic artery

b) The pectoral branches of the thoracoacromial artery

c) The lateral thoracic arteries

d) Unnamed mammary branches.

3. Intercostal Arteries: The third, fourth, and fifth intercostal arteries may also branch out intothe lateral portion of the breast.

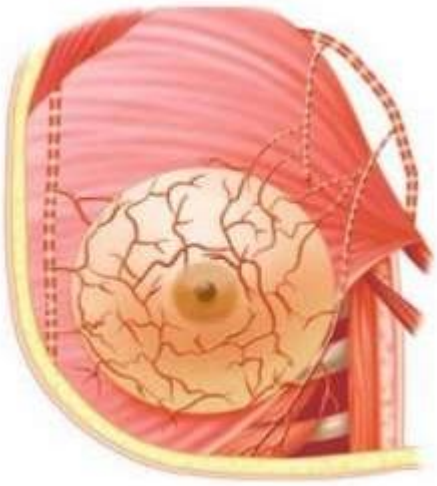


Figure: Arterial supply of breast, axilla and chest wall.

Pic courtesy: Schwart'z principles of surgery

VENOUS DRAINAGE SYSTEM OF BREAST

1. Internal thoracic vein branches that are perforated.
2. The perforating branches of posterior intercostal veins
3. The axillary vein's tributaries.
4. The Batson plexus: They are valve less. Thoracic veins and deep pelvis veins are connected to the internal vertebral venous plexus by these veins. They are the route for spread of metastasis from breast and pelvic organs to central nervous system[26].

AXILLA

The brachial plexus, axillary artery, lymph nodes, vein, fat, auxiliary breast tissue, skin, and subcutaneous glands are the constituents of the axilla.

A base and an apex are constituents of the boundaries. The axillary fascia, which resembles a buttress, is a dense, thick fascia that forms the curving longitudinal structure at the base of the axilla[27].

The anatomic boundaries are as follows:

a) Superiorly: the clavicle, scapula and first rib

b) Posteriorly: subscapular is, teres major and latissimus dorsi muscle

c) Anteriorly: pectoral is major and minor muscles.

d) Medially: serrates anterior and first four ribs

e) Lateral: curacao brachialis and short head of the biceps muscle

The cervicoaxillary canal is also known as axilla. This anatomic channel is where most structures that run between the neck and the upper extremities enter. The clavicle, the first rib in medicine, and the lateral scapular edge in posterior anatomy define the boundaries

of the cervicoaxillary canal. Both the pectoralis major and minor muscles, as well as the associated fascia, encircle the axilla anteriorly".

The posterior region of the axilla supports the location of subscapularis. Similarly, the axilla's lateral wall supports the location of bicipital groove. Teres Major insertion is on the lateral wall of bicipital groove, the Pectoralis insertion on the medial wall, and the Latissimus Dorsi insertion on the floor.

The lateral wall (axilla) contains the bicipital groove, a narrow area with closely spaced muscle between insertions of Anterior and Posterior compartment muscles. The subclavius and pectoralis minor muscles are encircled by the deep layer. It reaches the Axillary fascia in the floor of Axilla from the collarbone.

This structure is linked to 1st rib of the clavicle (medial aspect) and is primarily composed of the clavipectoral fascia. To reach the level III (cephalad) axillary dissection and properly expose the axillary vein anatomically, division of the halsted ligament is required. The axilla, encircled by loose connective tissue, contains arteries, veins and nerves which supply the upper extremities. Axillary sheath (investing layer of fascia) encloses the arteries and nerves[28].

Area of lymph nodes is divided into 3 levels:

a) "Level I: Lymph nodes lateral and inferior to the pectoralis minor muscle.

b) Level II: Lymph nodes beneath the pectoralis minor muscleLevel III: Lymph nodes deep and medial to the medial border of the pectoralis minormuscle".

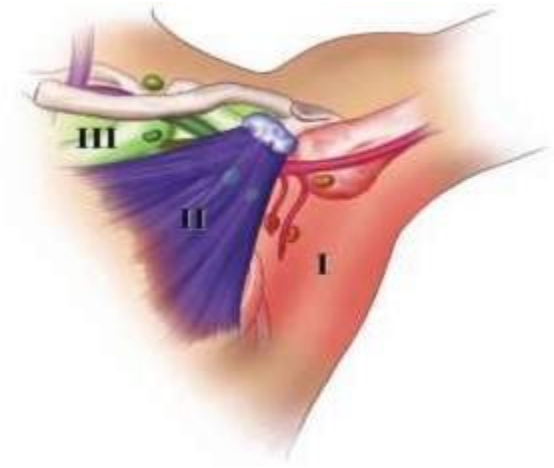


Fig : Levels of Axillary lymph nodes

Pic courtesy: Schwart'z principles of surger

LYMPHATIC DRAINAGE (BREAST)

1. Lateral / axillay group receives lymphatic drainage from upper extremities.
2. The anterior / pectoral group receives Lymphatic Drainage from the lateral aspect of Breast.
3. Subscapular (Posterior Group) receives lymphatics from posterior shoulder. They are situated along scapula's lateral edge[29].
4. The anterior, lateral and posterior groups drain to Central Group of Axillary Lymph Nodes. Central group receives lymphatic directly from the breast. They are present posterior to pectoralis minor muscle.
5. The subclavicular group collects lymphatics from the other axillary group of Lymph Nodes.
6. An important group of nodes (Interpectoral Nodes) are located between Pectorals Major and Minor muscle[30].

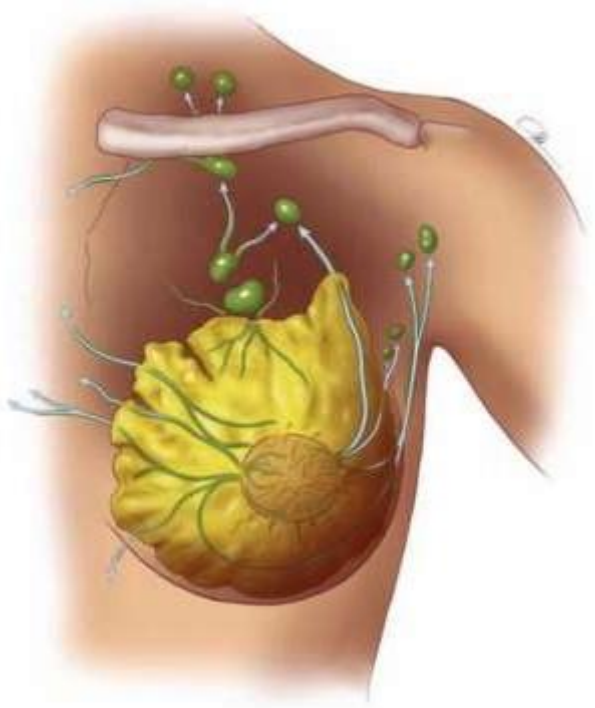


Fig : Lymphatics of the brest

Pic courtesy : Schwart'z principles of surgery

CARCINOMA BREAST:

RISK FACTORS:

FAMILIAL FACTORS

Carcinoma Breast is familial in origin in the range of 5-10%. Based on Gail model of risk scoring, there is a possibility of risk occurance in the range of 150-200% (1.5-3 times) for a person who has family history of a first degree relative.

GENETIC FACTORS

Mutations in the "BRCA 1 and BRCA 2" genes are a risk factor for Breast Carcinoma and Ovarian Carcinoma. It may cause Breast Cancer cases in the range of ten to five percent. Medullary tumors are often observed BRCA 1 mutations when examined histologically. Tubular and lobular alterations are primarily caused by BRCA 2 mutations.

RISK OF BREAST CANCER DUE TO HORMONAL FACTORS

- Enhanced endogenous oestrogen risk: risk of Carcinoma Breast is likely to more in women with early menarche, later menopause, nulliparity,and delayed age at full-term pregnancy.
- Hormone replacement therapy: hormonal replacement therapy in obesity and post-menopausal increases the risk of breastcancer.

LIFESTYLE AND DIET REALTED RISK FACTORS FOR CARCINOMA BREAST

- A diet filled with high-fat.
- Alcohol use
- Lower consumption of vitamin C, beta carotene, and folate also lead to high risk for carcinoma breast.[31]

ECOLOGICAL FACTORS

Early exposure to electromagnetic fields, ionizing radiation, and organochlorine pesticides before 15 years of age increases exposure fold to Breast Cancer.

It is important to do the physical examination without compromising the accuracy of the evaluation, all the while preserving the patient's privacy and comfort. First always is inspection. Examining the breasts in an upright position can identify any noticeable lumps, asymmetry, or skin abnormalities. Examining the 'Nipple Areolar Complex' for nipple retraction and ' Paget's Disease' (Nipple Destruction).

If there is retraction, we need to find out if it started recently or at birth.The patient is requested to place their arms on their waist in order to check their breasts. The pectoralis muscle will contract with this maneuver, highlighting the lump. By elevating the hand above the head, the Auchinclos approach examines the axilla and the inframammary fold.

This is to be followed by, bilateral palpation of the axillary nodal basins, cervical, supraclavicular, infraclavicular. Finally, supine position is recommended for the patient in the arm raised above head position. Patient is then upright, with relaxed arms, and the breast is palpated one at a time[32].

If a premenopausal woman has an area of nodules and there is any ambiguity regarding their importance in the absence of a noticeable lump, a second check at a different period of the menstrual cycle may shed further light. When women present with breast tenderness, breast palpation commonly elicits a discharge of the breasts. Documenting the type, location, and shadeof the discharging duct or ducts is crucial.

IMAGING MAMMOGRAPHY

The rise in the occurrence of Breast Cancer from 1980 and 1987 was observed to be caused by the increasing application of 'Screening Mammography'. Because 'Mammography' identifies micro lesions. Cancers can occur one to three years earlier than they otherwise would have.

The only method available to determine a female's breast density in the reproductive age range is mammography. By determining the ratio between the glandular and connective tissue components and the quantity of fat in the breast, an algorithm is used to determine it. Breast density influences the risk of developing Breast Cancer.

A Woman having higher 'breast density' stands to undergo large risk factor (4-6 times higher) in comparison to a woman with lower 'breast density'. High is categorized as category D and low as category A by BIRADS. Age, hormonal replacement therapy, and pregnancy are the following variables that impact breast density.

There is a hereditary preponderance in breast density. Taller and heavier women have higher densities due to their higher fat content.

It is known that individuals with thick breast tissue are less sensitive to breast cancer detection with mammography. For a woman who does show any signs of cancer, 'screening mammography' is used to identify the illness.

The 'American Cancer Society' has suggested:

- "Annual mammograms beginning at the age of 40
- Triannual clinical breast examination (CBE) for women in 3rd and 4th decade and annual for women above the age of 40 years
- Breast self-examination (BSE)".

Mammography continues as the "gold standard," in evaluating Breast Cancer. However, 'Magnetic Resonance Imaging (MRI)' emerges as a popular method as a valuable method for evaluating breast disease. During an MRI, the patient is not exposed to ionizing radiation. For screening young women found to be in the risk zone of getting Breast Cancer, MRI will be preferred because it is not limited by breast density[33].

FINE NEEDLE ASPIRATION BIOPSY

FNAB can quickly examine a solid mass cytologically, and the patient is often notified of the results the same day. Palpation or imaging technology can be employed to carry out the procedure. By FNA biopsy, breast masses can be diagnosed with an accuracy of about 80%.When a trained cytopathologist handles and examines the specimen, the probability of false positive results are found to be zero. A core biopsy is required to investigate a lesion with clinical or radiological suspicion since false-negative results occur frequently—14–17% of instances.

More than 95% of lesion outcomes are benign when imaging, FNA, and physical examination results are all positive[34].

CORE BIOPSY

For acquiring tissue for histology, small cores of tissue are extracted from breast lesions using small hollow trocars. However, the drawbacks of core biopsy are that they only offer a tiny amount of tissue, they cannot reveal any information about the tumor's margins or degree of invasiveness, and they might overlook small lesions of the breast. Trocar biopsy accompanied by ultrasonography has increased this test's accuracy in more recent years.

INCISION BIOPSY

For the detection of malignancy of carcinoma breast, it is found that incision biopsy and frozen section are more accurate. For detecting malignancy, some surgeons may prefer to incise the lesion and send a small amount of tissue. Incision biopsy is usually a part of preliminary procedure of definitive surgery.

EXCISION BIOPSY

Excision biopsy entails removing the entire tumour of the breast under anaesthesia in the operating room. If properly done with appropriate margin clearance, it serves as both a therapeutic and a diagnostic tool. Excision biopsy and histopathology are the most popular in evaluating breast lumps and are considered absolute gold standard[35].

To assess the prognosis and biological margin of the disease, core biopsy is preferred over FNAC. Further, core biopsy scores over FNAC in determining 'Hormone Receptor' and 'HER2 Status' critical in chemotherapy and radiation therapy.

MODIFIED TRIPLE ASSESSMENT

Previously, open biopsy was utilized to find cancer in the early stages of diagnosis.

A triple test comprising FNAC, mammography, and clinical examination was launched in the mid- 1970s, which improved breast cancer diagnosis. Subsequently, an ultrasonogram of the breast took the role of mammography. This is known as the modified triple test. The accuracy of diagnosis will be approximately 99% when correlation between these three modalities is similar.

The diagnostic yield of the triple test is similar to that of a palpable lesion, even in non- palpable lesions. A frozen section after excision was routinely applied to ensure presence of Breast Cancer. Identification of malignancy pre operatively is made simpler by using fine needle aspiration cytology tests. Because it directs the planning of surgical choices, a sound preoperative diagnosis is crucial. It might stop needless, extreme dissections[36].

A curative surgery can be scheduled sooner if a triple test indicates malignancy, avoiding the requirement for two surgeries - one for a biopsy and the second to treat the ailment.

In today's patient-centered breast cancer therapy, patients actively choose the type of surgery they will have. The type of lesion and the diagnosis of metastases are important considerations because this calls for advance planning. The triple test and its variations are essential to the workup of breast cancer. Medical literature from a few years ago advised that every breast lump be removed. This has now been updated to emphasize the need for an analysis and explanation of each breast lump[37].

Table 17-10

TNM staging system for breast cancer

Primary tumor (T)

The T classification of the primary tumor is the same regardless of whether it is based on clinical or pathologic criteria, or both. Size should be measured to the nearest millimeter. If the tumor size is slightly less than or greater than a cutoff for a given T classification, it is recommended that the size be rounded to the millimeter reading that is closest to the cutoff. For example, a reported size of 1.1 mm is reported as 1 mm, or a size of 2.01 cm is reported as 2.0 cm. Designation should be made with the subscript "c" or "p" modifier to indicate whether the T classification was determined by clinical (physical examination or radiologic) or pathologic measurements, respectively. In general, pathologic determination should take precedence over clinical determination of T size.

TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
Tis	Carcinoma in situ
Tis (DCIS)	Ductal carcinoma in situ
Tis (LCIS)	Lobular carcinoma in situ
Tis (Paget's)	Paget's disease of the nipple NOT associated with invasive carcinoma and/or carcinoma in situ (DCIS and/or LCIS) in the underlying breast parenchyma. Carcinomas in the breast parenchyma associated with Paget's disease are categorized based on the size and characteristics of the parenchymal disease, although the presence of Paget's disease should still be noted
T1	Tumor ≤20 mm in greatest dimension
T1mi	Tumor ≤1 mm in greatest dimension
T1a	Tumor >1 mm but ≤5 mm in greatest dimension
T1b	Tumor >5 mm but ≤10 mm in greatest dimension
T1c	Tumor >10 mm but ≤20 mm in greatest dimension
T2	Tumor >20 mm but ≤5 cm in greatest dimension
T3	Tumor >50 mm in greatest dimension
T4	Tumor of any size with direct extension to the chest wall and/or to the skin (ulceration or skin nodules)*
T4a	Extension to chest wall, not including only pectoralis muscle adherence/invasion
T4b	Ulceration and/or ipsilateral satellite nodules and/or edema (including peaud'orange) of the skin, which do not meet the criteria for inflammatory carcinoma
T4c	Both T4a and T4b
T4d	Inflammatory carcinoma**
	*Note: Invasion of the dermis alone does not qualify as T4
	**Note: Inflammatory carcinoma is restricted to cases with typical skin changes involving a third or more of the skin of the breast. While the histologic presence of invasive carcinoma invading dermal lymphatics is supportive of the diagnosis, it is not required, nor is dermal lymphatic invasion without typical clinical findings sufficient for a diagnosis of inflammatory breast cancer.

Regional lymph nodes—Clinical (N)

NX	Regional lymph nodes cannot be assessed (e.g., previously removed)
N0	No regional lymph node metastases
N1	Metastases to movable ipsilateral level I, II axillary lymph node(s)
N2	Metastases in ipsilateral level I, II axillary lymph nodes that are clinically fixed or matted; or in clinically detected* ipsilateral internal mammary nodes in the absence of clinically evident axillary lymph node metastases
N2a	Metastases in ipsilateral level I, II axillary lymph nodes fixed to one another (matted) or to other structures
N2b	Metastases only in clinically detected* ipsilateral internal mammary nodes and in the absence of clinically evident level I, II axillary lymph node metastases
N3	Metastasis in ipsilateral infraclavicular (level III axillary) lymph node(s) with or without level I, II axillary lymph node involvement; or in clinically detected* ipsilateral internal mammary lymph node(s) with clinically evident level I, II axillary lymph node metastases; or metastases in ipsilateral supraclavicular lymph node(s) with or without axillary or internal mammary lymph node involvement
N3a	Metastasis in ipsilateral infraclavicular lymph node(s)
N3b	Metastasis in ipsilateral internal mammary lymph nodes(s) and axillary lymph node(s)
N3c	Metastasis in ipsilateral supraclavicular lymph node(s)
	*Notes: "Clinically detected" is defined as detected by imaging studies (excluding lymphoscintigraphy) or by clinical examination and having characteristics highly suspicious for malignancy or a presumed pathologic macrometastasis based on fine needle aspiration biopsy with cytologic examination. Confirmation of clinically detected metastatic disease by fine needle aspiration without excision biopsy is designated with an (f) suffix, e.g., cN3a(f). Excisional biopsy of a lymph node or biopsy of a sentinel node, in the absence of assignment of a pT, is classified as a clinical N, e.g., cN1. Information regarding the confirmation of the nodal status will be designated in site-specific factors as clinical, fine needle aspiration, core biopsy, or sentinel lymph node biopsy. Pathologic classification (pN) is used for excision or sentinel lymph node biopsy only in conjunction with a pathologic T assignment.

Figure : TNM staging for carcinoma breast Pic courtesy : Schwart'z principles of surgery

TABLE 54.2 TNM Breast Cancer Stages

Stage Grouping			
Stage 0	Tis	N0	M0
Stage IA	T1*	N0	M0
Stage IB	T0	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
NOTES	T1 includes T1mi **T0 and T1 tumors with nodal micrometastases only are excluded from Stage IIA and are classified Stage 1B		

Source: Modified from American Joint Committee on Cancer. *AJCC Cancer Staging Manual.* 7th ed. New York: Springer; 2010:349-60.

Figure : Staging for carcinoma breast based on TNM classificationPic courtesy : Fischer's master of surgery 7th edition

BREAST CANCER SURGERY - HISTORY

The 2nd century AD surgeon, Claude has observed that: "We have often seen in the breast a tumor closely resembling the animal, the crab. The veins that emerge from the abnormal growth in this disease resemble the legs of a crab, much as a crab has legs on both sides of his body.This disease has been cured by us in its early stages, but no one has been able to cure it once it has grown to a significant size"[39].

Surgical resections, including the first efforts at mastectomy and axillary dissection, wereperformed more regularly as per the 18th-century recommendations of Morgagni, the

father of modern pathology. Henri le Dran, a surgeon who lived in the 18th century, proposed that breast cancer began locally and gradually moved to the axillary lymph nodes through the skin and breastlymphatics. Le Dran routinely excised any swollen axillary lymph nodes en bloc when performing surgery for breast cancer.

Moore has reiterated the importance of "total resection of the breast in cases of cancer by removing Palpable axillary lymph nodes. Banks supported Moore's ideas in recommending systematic removal of axillary lymph nodes even in cases where palpable lymphadenopathy was not obvious". William S. Halsted and Willy Meyer published a report on their radical breast cancer therapy procedures in 1894.

These surgeons set the standard procedure for radical mastectomy (RM) at that time by showcasing better locoregional control rates with RM. The removal of 'axillary lymph nodes level I, II and III' supported by Meyer and Halsted are considered to be the standard procedure to excise the 'Thoracodorsal Neurovascular bundle', axillary contents and 'long thoracic nerve'.

"Grave-Signs in breast cancer as identified by Haagensen and Stout are:

(a) edema of the breast surface;

(b) skin ulceration;

(c) fixation of the chest wall;

(d) an axillary lymph node larger than 2.5 cm in diameter; and/or

(e) fixed axillary lymph nodes".

Women who displayed two or more symptoms had a 2% 5-year disease-free survival

rate and a 42% local recurrence rate. These findings of the study lead the researchers to conclude that severe cases could not be cured by drastic surgery. In support of this idea, about 25% of women were turned away from surgery due to inoperability issues. Approximately 10% of women with complete mammography screening are discovered to have advanced breast cancer[38].

London based surgeons Patey and Dyson made important contribution in treating operable Breast Cancer. This resulted in proposal for modified radical mastectomy. Patey and Dyson advocated a procedure 'Axillary lymph nodes' and the Breast are removed by using MRM. This minimizes the loss of 'Pectoralis Major' muscle. Patey and Dyson have also recommended excision of the 'Pectoralis Minor' muscle to approach anatomical dissection of 'Axillary Lymph nodes levels I through III'. This is known as Patey modification.

Scapula's coracoid process that involves severing the pectoralis major muscle is an alternative process used in recent days. MRM has been promoted that would maintain Pectoralis Major and Minor muscles.

MRM which found wide spread application in 1980s prompted American surgeons to use it commonly in the treating Breast Cancer. Preferring MRM over Halsted RM is based on the recognition of 2 facts (a) "lack of consistency in achieving locoregional control in stage I and stage II of breast cancer (b) excision of the pectoralis major muscle as recommended by Halsted found not necessary for locoregional control in stage I and stage II Breast Cancer"[39].

Following that, Bernard Fischer and associates undertook the 'National Surgical Adjuvant Breast and Bowel Project B-04 (NSABP B-04)', which evaluated local along with regional breast cancer treatments.

Trial study involving a sample of 1,665 women resulted in life table estimations of 8141 mean value of 120 months. Women with 'Clinically node-negative' disease were randomized in this study as:

(a) "Halsted RM,

(b) Total mastectomy plus radiation therapy (TM+RT), and

(c) Total mastectomy (TM) alone".

Patients having clinical nodes were subjected to treatment with 'RM or TM+RT'. Survival rate of women with 'node-positive' disease did not differ significantly from survival rate of women with 'node-negative' disease after a median follow-up of ten years[40].

The trials that compared the MRM with Halsted RM were carried out by scholars at the University of Alabama Trial (Madddox et al., 2013) and the Manchester trial (Turner et al., 2014). These trials established the fact that the type of surgical method will not have significant impact on the rates of recurrence for patients with stage I and stage II Breast Cancer. 'Alabama Breast Cancer Project (1975– 1978)' required 'T1–T3 breast tumors' without clinically detectable distant metastases in order tobe eligible for accrual[41].

Patients had either a modified or a radical RM. 'Adjuvant Melphalan or adjuvant chemotherapy with cyclophosphamide, methotrexate, and 5-fluorouracil (CMF)' was given to women who tested + for nodes. The study covering a long period of 15 years found insignificant impact of either chemotherapy or surgical type on locoregional disease-free or overall survival. The combination of surgery, radiation therapy, and chemotherapy has advanced significantly since the 1970s in order to improve longevity, manage locoregional illness, and raise the likelihood of breast conservation[41].

MASTECTOMY INDICATIONS

The women patients's survival rates suffering from Breast Cancer between 2003 - 2009 are being computed using statistics from 'Surveillance, Epidemiology and End Results (SEER) Program'. Patients suffering from advanced stage of breast cancer found to have lower five year survival rate. Race is highly correlative for the adverse effect and decreased survival of the underserved populations of American culture[42].

PROPHYLACTIC MASTECTOMY

Retrospective studies of woman who are at the risk for the disease found that 'prophylactic mastectomy' lowers the risk of Breast Cancer by almost 90%. Research on women with 'BRCA-1 or BRCA-2' mutations revealed the relevance of preventive mastectomy. These studies varied depending on the mutation's specific contribution to breast cancer risk.

Familial risk of disease determines the rate of survival for patients who are subjected prophylactic mastectomy. It is fount that prophylactic mastectomy added more than five years to survival to patients with a lifetime risk of 85%, whereas it increases to three years to life for patients with a lifetime risk of 40% (approximately four times the population risk).

IN SITU BREAST CANCER VARIANTS

Pathologists know that sometimes it can be challenging to differentiate among 'Lobular Carcinoma In Situ (LCIS') or 'Ductal Carcinoma In Situ (DCIS)' on pathological grounds and atypia, 'Atypical Hyperplasia', or 'Malignancies with micro-invasion'. In every case, skilled pathologic assessment will be necessary.

As LCIS is viewed as "marker" in elevated risk condition and not in unavoidable

prelude to 'Invasive Disease', surveillance observation, either with or without antiestrogen therapy, is the current treatment for LCIS. The aim of treatment is to stop or identify the progressed cancer that eventually appears in more than 25 and less than 35 percent of patients at an early stage. Women who have multicentric illness (involvement of two or more breast quadrants) or multifocal DCIS, which is not treatable with a lumpectomy, need to have a mastectomy.

Women who have minor disease are encouraged to get a 'Lumpectomy and Radiation Therapy'. "Sentinel lymph node biopsy is recommended for women with

(a) Multifocal DCIS,

(b) Multicentric DCIS, or

(c) DCIS with comedonecrosis and tumor size ≥2.5 cm".

Every scenario is addressed with regard to antiestrogen medication[43].

BREAST CANCER (STAGE I - II B)

'Prospective trial NSABP B-06' compared TM and lumpectomy for the treating of stage I and II Breast Cancer patients. Trial concluded similar survival rates for the the methods. However, it found higher rate of 'ipsilateral breast cancer recurrence' for the patients that underwent lumpectomy but did not receive 'Radiation Therapy'.

The results of the study validated standard prescription for radiation therapy and lumpectomy in managing stage I and II breast cancer. For treating stage I and II Breast Cancer patients, the following procedures are recommended :

(a)Breast conservation (lumpectomy and radiation therapy with sentinel lymph node biopsy)

(b) Breast conservation (lumpectomy and radiation therapy with axillary lymph node dissection)

(c)Mastectomy with sentinel lymph node biopsy.

Because 'Breast Conservation' offers significant functional cosmetic benefits without compromising overall cancer-related survival, it should be the first consideration for all patients. "Breast conservation treatment is not suggested in the following:

(a) Radiation therapy to the breast or chest wall in the past;

(b) Surgical margins implicated or unclear after reexcision

(c) Multicentric disease; and

(d) Scleroderma or other connective tissue disorders".

This suggestion relates to the probably unfeasible use of postoperative radiation therapy.

Both adjuvant approaches may be applicable in extranodal axillary metastases. "Axillary lymph node dissection (levels I, II) and / or regional node irradiation for disease control is required in:

a) Three or more positive nodes

(b) Lymphadenopathy

(c) Metastatic disease in a sentinel lymph node".

'Adjuvant Chemotherapy' along with antiestrogen treatment are regularly evaluated forsituations involving tumor size greater than 0.5 cm[44].

REGIONAL BREAST CANCER (STAGE IIIA OR IIB)

Stge III and IIIb Breast Cancer may cause regional Breast Cancer called ‘Advanced Regional Breast Cancer’. This may be the case when the patient is not diagnosed with distant metastasis applying radiography or clinical tests. To provide the best possible locoregional and ‘distant disease-free survival’ of such patients, radiation treatment and chemotherapy are combined with surgery.

Patients in Stage IIIa are classified as having either an operable or an inoperable disease. For female patients with operable stage IIIa illness, adjuvant chemotherapy and radiation therapy are typically administered after surgery in the form of a modified RM. Radiation therapy is utilized to maximize locoregional control of breast cancer while adjuvant chemotherapy is intended to maximize survival rate of patient.

In order to improve primary cancer cytoreduction and enable conserving surgery, initial (neoadjuvant) chemotherapy is increasingly used in a subset of select stage IIIa patients. For reducing the locoregional cancer burden for ‘Inoperable Stage IIIa and Stage IIIb Breast Cancer’, Neo adjuvant chemotheray is suggested. ‘Adjuvant Chemotherapy’ and ‘Radiation Therapy’ are administered after MRM, along ‘Patey modification’, or the rare (<2%) ‘Halsted Radical Mastectomy’ in this clinical setting[45].

LOCOREGIONAL RECURRENCE OF BREAST CANCER

When ipsilateral chest wall has not previously underwent breast irradiation, Chemotherapy and/or Antiestrogen therapy are considered. The best way to categorize therapeutic options for a patient with recurrence locally of Breast Cancer for separation into:

(a) “Those who had mastectomy completion and

(b) Those who had conservation surgery (lumpectomy)".

Resection with reconstruction is suggested for patients who were diagnosed having prior mastectomy. Mastectomy along suitable reconstruction treatment is recommended who were diagnosed previously having 'Breast Conserving Surgery'. Consideration is given to chemotherapy and/or antiestrogen treatment. When a woman experiences a regional recurrence of her disease, she needs to have her axillary lymph nodes removed and then receive adjuvant chemotherapy[46].

MODIFIED RADICAL MASTECTOMY SURGERY STEPS:

"The patient was positioned in a supine posture, supported on an arm board, with the arm abducted (less than 90 degrees). The skin incision was marked, and the breast was dissected off the deep fascia from above downward, with various bleeding vessels secured. The top flap was lifted until the clavicle, followed by the lower flap being elevated until the infra mammary crease and the plane coming down onto the deep fascia. The pectoralis major's lateral boundary was identified, and the fascia was cut along its length to enter the axilla.

After retracting the contents of the axilla downward, the fat was gently cut across and parallel to the axillary vein until the vein could be seen. This marked the supero-lateral border of the axilla dissection, where the tributaries from the axillary fat that entered the axillary vein were split, ligated, and secured. The vein is cleared until the thoracodorsal vessels, which have a fascia that is sliced along its length to enter the axilla, are visible. These vessels are located on the muscles of the posterior wall of the axilla.

Just medial to the thoracodorsal vessels, the axillary vein gives way to the thoracodorsal nerve, which emerges and runs obliquely towards the vessels. The nerve and the vessels

remain intact, but all of the fat and nodes are removed from them. The infero-lateral limit of the dissection is the lateral border of the latissimus dorsi. The pectoralis minor muscle is then firmly retracted to obtain sufficient access to do a level III clearance once the vein has been cleaned up towards the axilla's apex. The pectoral nerves and accompanying vessels are encountered, crossing the upper axilla to the anterior axillary wall.

Once the pectoral nerves and related vessels traverse the upper axilla and reach the anterior axillary wall, they are confronted. Dissection along the medial wall involves removing the axillary contents from the serratus anterior muscle, with the goal of preserving the lateral and medial pectoral nerves, if at all possible. The intercostobrachial nerve, a substantial lateral branch of the second intercostal nerve, enters the axillary fat on the medial axillary wall and is attempted to be preserved

More posteriorly, the axillary contents are carefully released and allowed to fall back, allowing the nerve to the serratus anterior to be raised off the muscle. The residual apical fat and lymphatics are split and dissected off after this dissection combines with the posterior wall dissection. Ultimately, the fat that connects the specimen to the inferolateral skin incision is separated. Hemostasis is reached, two suction drains are placed—one under the skin flap and the other in the axilla—and an aseptic dressing is applied".

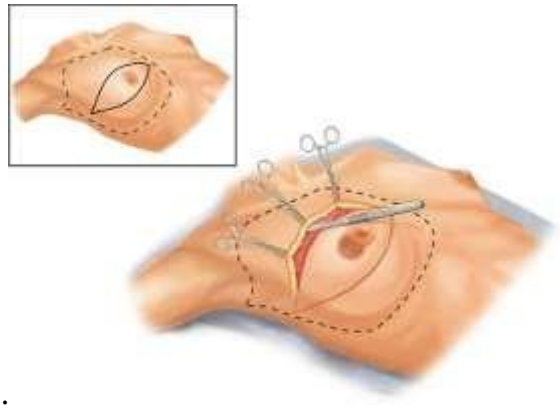


Figure: Limits of MRM

Pic courtesy: Fischer's master of surgery 7th edition

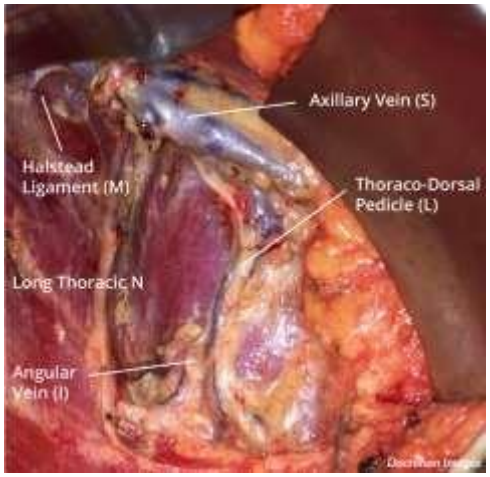


Figure: Limits of axillary dissection in MRM Pic courtesy: Fischer's master of surgery 7th edition

WOUND CLOSURE

Two flat 10-mm Jackson-Pratt closed suction catheters are inserted into the flap's inferior margin for approximate ‘anterior axillary line’ through separate incisions. Second ‘lateral catheter’ will be positioned about two centimeter below ‘axillary vein’. Drains are fastened with 3-0 nonabsorbable nylon sutures at the skin's surface. It is not advisable to fasten suction catheters onto the ‘chest wall’ to prevent possible cause of damage to muscles and bleeding during removal.

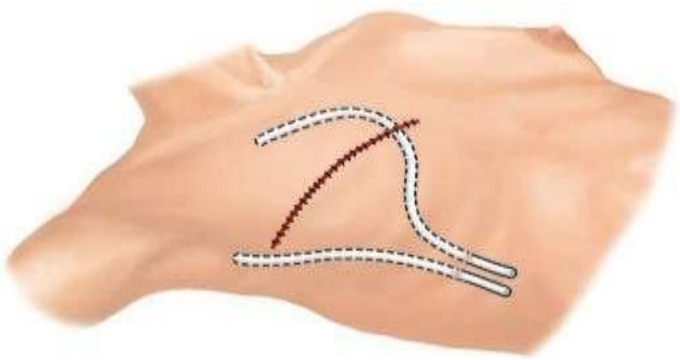
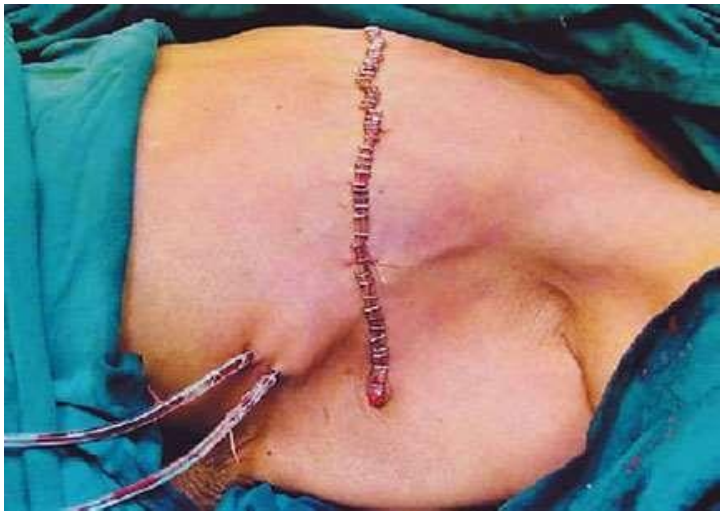


Figure : Drain placement

Pic courtesy : Fischer’s master of surgery 7th edition



- “The wound is closed in two layers.
- Subcutaneous tissue closed using vicryl 2-0.
- Skin is closed using non absorbable mattress sutures or staples.
- Sterile dressing is applied”.

COMPLICATIONS OF MRMSEROMA FORMATION

Seroma is a common postoperative sequel after Breast Surgery with an incidence of 10-85 percent. It can develop rarely after any surgical operation. It can cause severe morbidity and discomfort and may even postpone adjuvant therapy. Numerous factors have been suggested as causes of seroma, including fibrinolysis's disruption of lymphatic drainage and surgical methods, particularly the use of electrocautery as opposed to knife dissection.

Oertli *et al*. carried out a randomized double blind trial. This involved administering tranexamic acid at a dose of 1 g three times daily during the preoperative and postoperative phases. They arrived at a conclusion that procedure resulted reduction not only in the seroma formation but also in the volume of postoperative drainage. Nevertheless, postoperative patient compliance may be required, which is not always achieved because patients typically prefer to be on a lower medication load after surgery[47].

Knight et al.'s study examined the effectiveness of shoulder immobilization. While the recovery of normal shoulder mobility was delayed due to seroma, no patient experienced long- term musculoskeletal problems. Given that the developed seroma typically goes away with aspiration, keeping the drain in place for a longer amount of time seems like a sensible course of action[48].

Estes and Glover came to the conclusion that adhesion is facilitated when a suction

drain is maintained in place for an extended amount of time because it keeps adjacent surfaces in physical contact[49]. According to Conveney et al. when 'dead space' was eliminated by 'suturing the skin flaps to muscle', there was a significant decrease in both drainage and seroma production[50].

Chilson et al. supported a flap tacking technique that is similar and has been shown to be effective in preventing seroma[51]. In a Sprague-Dawley rat model, Lindsey et al. used topical fibrin glue at the surgical site, which likewise reduced the incidence of seroma after mastectomy[52,53].

Therefore, seroma should not be taken as a buildup of serum. It is most likely an inflammatory reaction that occurs during the first stage of wound healing. According to McCaul et al., fluid accumulation following axillary clearance and breast cancer surgery represents the exudative stage of wound healing[54].

For patients with open colon resection, Schulze et al. found a single 'preoperative infusion' with high-dose steroid could suppress the inflammatory response. Recently, Taghizadeh et al. reported remarkable progress in the treatment of seroma[55].

The findings from earlier head and neck surgery trials were used to determine the 125 mgsingle-dose methyl-prednisolone sodium succinate level. The inflammatory response following a mastectomy is likely more pronounced after 'Head and Neck Surgery. Low dose of glucocorticoid or the fact that glucocorticoid was given very soon after surgery could be the reason for the lack of a significant effect being reported.

Compared to other major surgical procedures, cardiopulmonary bypass causes a far more dramatic inflammatory response after cardiac surgery. This could be due to the over-activation of inflammatory mediators, which in turn causes postoperative atrial fibrillation. Several studies on heart surgery have documented a preventive effect of 15–30 mg/kg hydrocortisone intravenously one hour prior to surgery and up to 0.3 mg/kg every six hours

continuing for three days. This could be the ideal glucocorticoid dosage plan for seroma prophylaxis[56].

80 mg of triamcinolone (Kenolog; E.R. Squibb, Middlesex, UK) has been used therapeutically in patients with seroma production following autologous latissimus dorsi breast reconstruction , according to Taghizadeh et al. Shortly after the seroma was aspirated, the glucocorticoid was injected into the cavity. They demonstrated that a single dose reduced considerably:

a) "Additional aspirations

b) The total number of aspirations

c) The total volume aspirated, and

d) The total time to dryness".

To compare preventative anti-inflammatory regimens with therapeutic regimens, more research is required. A high preoperative single dose of 'Methylprednisolone Sodium Succinate (30 mg/kg)' was found to reduce immunofunction, the inflammatory response, the plasma cascade system activation, and the normal IL-6 and CRP response following colonic resection. However, it had no negative effects on wound healing[53].

Some have contended that glucocorticoids limit inflammation by forming lipocortin, a phospholipase inhibitor that reduces the amount of 'Arachidonic Acid' obtained in creating 'Prostaglandins' and 'Leukotrienes'. This leads to fibroblast and collagen deposition, edema, leukocyte migration, and subsequently symptoms of capillary proliferation. It also inhibits capillary permeability. The risk of infection and difficult wound healing is one of the negative effects of corticosteroid use.

Patients undergoing various forms of axillary surgery made up the case material for

the study conducted by Okholm and Axelsson. In each group, one third got sentinel lymph nodebiopsy and two thirds subjected to axillary clearing of 'Levels I and II' after surgery. The fact that the axillary surgeries were performed differently might have an impact on the outcomes. It might be argued that a combination of mastectomy and sentinel lymph node biopsy would result in less surgical trauma and, thus, less seroma formation and a reduced postoperative inflammatory response.

The case data includes patients who had undergone both forms of axillary surgery[57]. We eliminate this possible confounding factor in our analysis by standardizing the procedure, since all of our patients had 'Modified Radical Mastectomy' after receiving 'Level I and II' axillaryclearance.

LYMPHEDEMA

'Lymphedema', a long lasting edema due to interstitial accumulation of fluid. This is caused by lymphatic method's insufficient and reduced ability to move lymph fluid. Lymphedema may become a permanent risk that significantly impairs nature of life.

Advancements in surgical techniques have significantly reduced lymphedema in patients who were treated for Breast Cancer. Patients who undergo SLNB have an incidence rate of 5-8%, while those who were treated with 'Axillary Lymph Node Dissection (ALND)', which only includes patients at levels I and II, have an incidence rate of 14–16%[58].

Pramod et al. found that 231 patients who were treated with 'Axillary Lymph Node Dissection' at 'Amrita Hospital' in India between January 2004 and December 2007 had a cumulative incidence of lymphedema at the surgical region of 41.1%, or 95 individuals. He cameto the conclusion that individuals with lymphedema can have significant enduring and consistent consequences to their 'Quality Of Life' from both physical and psychological

assistance[59].

Post-operative radiation therapy both exacerbates and raises the risk of lymphedema, while some studies dispute this. Edward et al. observed that "incidence of lymphedema after breast cancer treatment using the volumetric technique and a subjective assessment of swelling. They found no evidence of a significant relationship between axillary irradiation and lymphedema"[60].

INFECTION

According to published data, 3–15% of individuals exhibit postoperative wound infection. The most prevalent microorganisms are often gram-positive (species of streptococcal or staphylococcal bacteria), and they can be treated with the right oral medications. In order to guide antibiotic treatment, any underlying seroma should be aspirated and cultured[61,62].

HEMATOMA – Around 2-10% of cases develop hematoma during the post-operative periodand early recognition and management are necessary.

INJURY TO THE NERVES - There is a 1% chance of suffering a serious motor nerve injury. The scapula wings when the long thoracic nerve is injured. Internal rotation and shoulder abduction are weakened by thoracodorsal nerve injury. When there is injury to 'Intercostobrachial nerve', there is numbness and paresthesia of inner upper arm[63,64].

METHYL PREDNISOLONE

Methyl prednisolone is slightly more potent and more selective than prednisolone. It is used in ulcerative colitis, arthritis, renal transplant, pemphigus to minimize the suppression of pituitary adrenal axis. The initial effect of 'Methylprednisolone' is probably on account of its 'Anti-inflammatory action' [65].

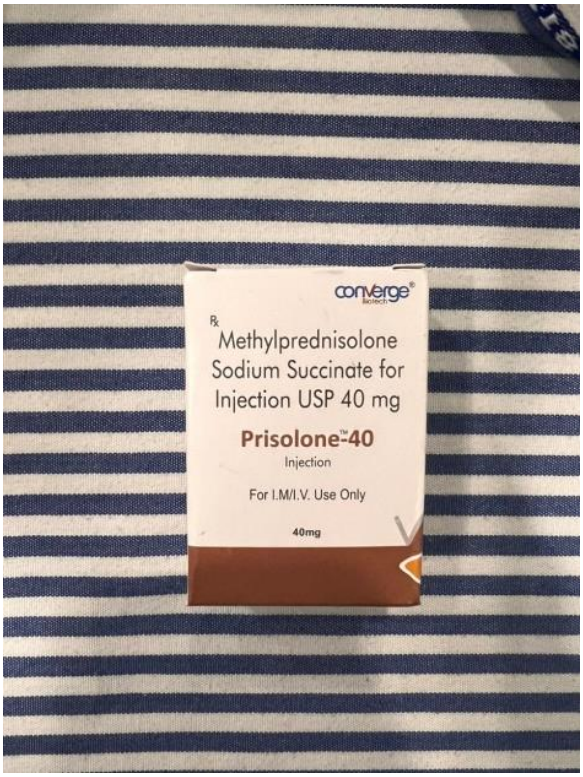


Fig – Inj IV Methylprednisolone 40 mg

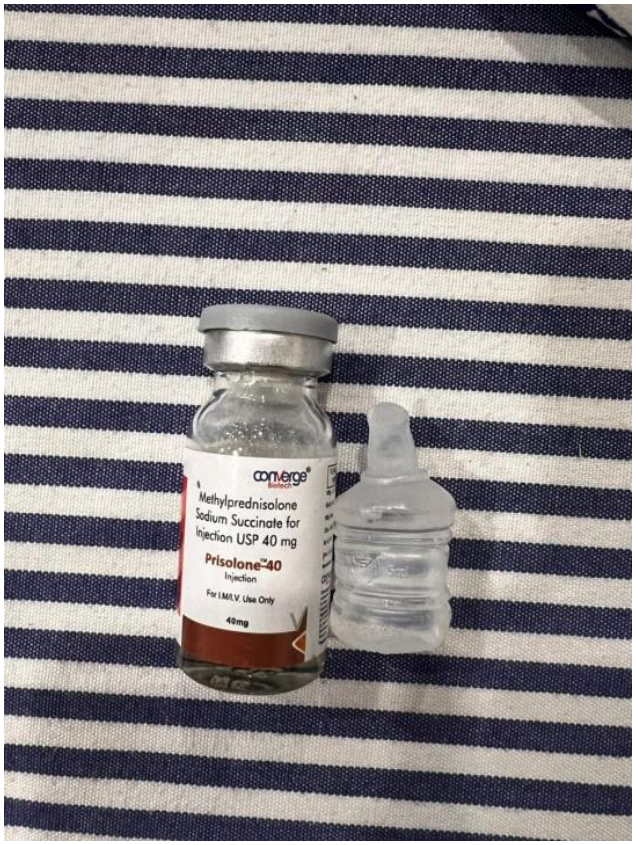


Fig - Inj IV Methylprednisolone 40 mg

MECHANISM OF ACTION:

Here is a summary of the mechanism of action of methylprednisolone, a synthetic glucocorticoid that predominantly acts through contact with glucocorticoid receptors.

1. **Glucocorticoid Receptor Binding:** Methylprednisolone enters cells and binds to glucocorticoid receptors (GR) present in the cytoplasm.
2. **Formation of GR Complex:** The glucocorticoid receptor translocates into the nucleus after binding, causing a conformational change in the receptor. Regulation of Gene Transcription: Target gene promoter regions contain particular DNA sequences known as 'Glucocorticoid Response Elements (GREs)', which are bound by the 'activated glucocorticoid receptor complex' in the nucleus.
3. **Gene Transcription Regulation:** Target gene promoter regions contain particular DNA sequences known as 'Glucocorticoid Response Elements (GREs)', which are bound by the 'activated glucocorticoid receptor complex' in the nucleus.
4. **Transactivation and Trans repression:** This binding can lead to either transactivation (activation of gene transcription) or trans repression (inhibition of gene transcription), depending on the specific target gene. Methylprednisolone predominantly exerts its anti-inflammatory effects through trans repression mechanisms, where it inhibits the transcription of 'pro-inflammatory genes' such as 'cytokines (e.g., IL-1, IL-2, IL-6, TNF-alpha),chemokines', and enzymes involved in the inflammatory pathway.
5. **Secondary Effects:** Methylprednisolone also influences cellular functions indirectly by modulating other signaling pathways, such as inhibiting phospholipase A2 (PLA2) activity, which decreases the production of arachidonic acid and subsequently reduces the inflammatory mediators like 'Prostaglandins' and 'Leukotrienes'.

Overall, methylprednisolone's primary mode of action involves altering gene transcription patterns in immune cells and other tissues, leading to potent anti-inflammatory,

immunosuppressive, and anti-allergic effects[66].

ADVERSE EFFECTS

1. **Gastrointestinal Effects:** These can include stomach irritation, ulcers, and gastrointestinal bleeding.
2. **Endocrine Effects:** Corticosteroids like methylprednisolone can reduce the adrenal glands'natural production of cortisol, resulting in adrenal insufficiency.
3. **Metabolic Effects:** Increased appetite, weight gain, and fluid retention are common. But it is subjected to a risk of elevated blood sugar levels leading to diabetes.
4. **Cardiovascular Effects:** its long term usage could increase blood pressure and the risk of cardiovascular disease.
5. **Musculoskeletal Effects:** Muscle weakness and loss of bone density (osteoporosis) arepossible adverse effects.
6. **Neurological Effects:** Mood changes, insomnia, and even psychiatric reactions such as euphoria or depression can occur.
7. **Immune System Effects:** Prolonged use can suppress the immune system, increasing susceptibility to infections.
8. **Ophthalmic Effects:** Increased intraocular pressure and the development of cataracts havebeen reported with long-term use.
9. **Skin Effects:** Thinning of the skin and delayed wound healing are possible.
10. **Other Effects:** may result in increased possibility of fungal infections, menstrual irregularities, and enhanced exposure growth of certain types of cancers are also concerns.

It's crucial to use methylprednisolone under medical supervision and follow the prescribed regimen to minimize these risks. Short courses are generally associated with fewer adverse effects compared to long-term or high-dose therapy[67,68].

MATERIALS AND METHODS

MATERIALS ANDMETHODS

Study Population: All patients diagnosed to have carcinoma breast fulfilling inclusion and exclusion criteria and undergoing MRM at RL Jalappa Hospital who volunteer to be part of the study.

Inclusion Criteria: All female patients between age group 18 and 70 diagnosed with carcinoma breast undergoing MRM.

Exclusion Criteria:

1. Patients who have received steroid for any illness in the recent past (3-6 months)
2. Previous surgery in the axilla
3. Previous exposure to radiation in the chest or axilla

Duration of study: September 2022 to June 2024. The study is based on a sample size of 32 patients.

Study Design: This is a prospective and case control study.

SAMPLE SIZE ESTIMATION FORMULA:

$$N = \frac{2\,SD^2(Z_{\alpha/2} + Z_{\beta})^2}{d^2}$$

Where "$Z_{\alpha/2}$ is the critical value of the Normal distribution at $_{\alpha/2}$ (e.g., for a confidence level of 95%, α is 0.05 and the critical value is 1.96).

$Z\underline{\beta}$ is the critical value of the Normal distribution at β (e.g., for a power of 90%, ß is 0.1 and the critical value is 1.28), SD is the standard deviation from previous study population

variance, and d is the difference between two means".

Method of Data Collection:

Method: Details of patients will be documented in a standard proforma. All patients diagnosedto have carcinoma breast fulfilling inclusion and exclusion criteria and undergoing MRM at RL Jalappa Hospital who volunteer for the study were included.

Patients were divided into group A or B by randomisation / odd and even method. Patients in group A are the study group. These patients received 120mg of methylprednisolone IV 1 hour before the surgery. Patients in group B are the control group who did not receive IV methylprednisolone. All patients underwent standard MRM. After surgery, a 'closed suction drain' was placed and the amount of drain was documented everyday untill the removal of drains. The removal of drains drains was done in case the output was ≤30ml for 3 consecutive days. Wound will be closely observed for seroma formation, fullness, redness, fluctuation and ultrasound of breast and axilla will be performed as and when required. Aspiration or Ultrasound guided aspiration will be done when it is significant and will be documented till discharge is nil or insignificant. If any infection, culture and sensitivity of the wound will be done and appropriate antibiotics will be given. Results thus obtained will be documented and analysed using statistical methods. The t-test is used to calculate means and 'p-value'. The 'p-value' of <0.05 was determined as 'statistically significant' level for comparing the results.

Figure – injecting IV Methylprednisolone 120mg to the patient in pre operative room half hour before shifting on the table.

All patients underwent the following investigations:

1. "CBC

2. Renal function tests
3. Liver function tests
4. Serum electrolytes
5. Chest radiograph/ CT thorax
6. FNAC/TRUCUT biopsy of breast tissue with ER, PR, and Her2neu Status.
7. USG/MAMMOGRAPHY of breast and axilla".

Financial burden: All the investigations involved were part of the routine management of breast carcinoma. Hence it was borne by the patient party. The costs for the drug were borne by the investigator.

STATISTICAL TOOLS :

A Microsoft Excel data sheet will be used to record the data, and SPSS version 22 software will be used for analysis. Frequencies and proportions will be used to depict categorical data. The significance test that was used is chi-square. The 'Mean' and 'Standard Deviation' were used to record continuous data. The test of Significance for determining the 'Mean Difference' between two Groups as independent t test. A 'p-value' of less than 0.05 is deemed statistically consistent.

SIZE OF THE SAMPLE STUDY:

Difference in Mean Duration of drainage between Group A (with steroid) and Group B (without steroid) is estimated on the basis of Maryam Alam khan et. al. as 10.2 ± 2.2 days and 6.5 ± 1.6 days. A sample size of 14 patients was obtained for each group. This was done on the basis a defined formula and application of 'Med Calc Sample Size Software'. Assuming nonresponse rate of ten percent, sample size of 14 + 1.4 ≈ 16 minimum

subjects are being considered in each of Group A and Group B.

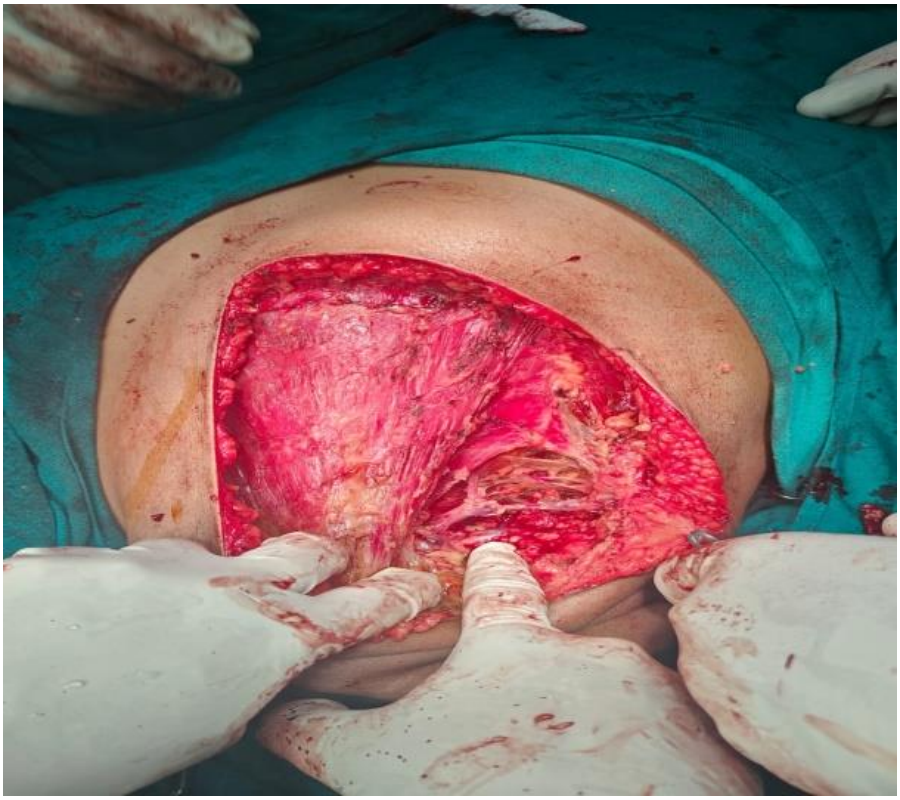
FORMULA FOR ESTIMATING SAMPLE SIZE:

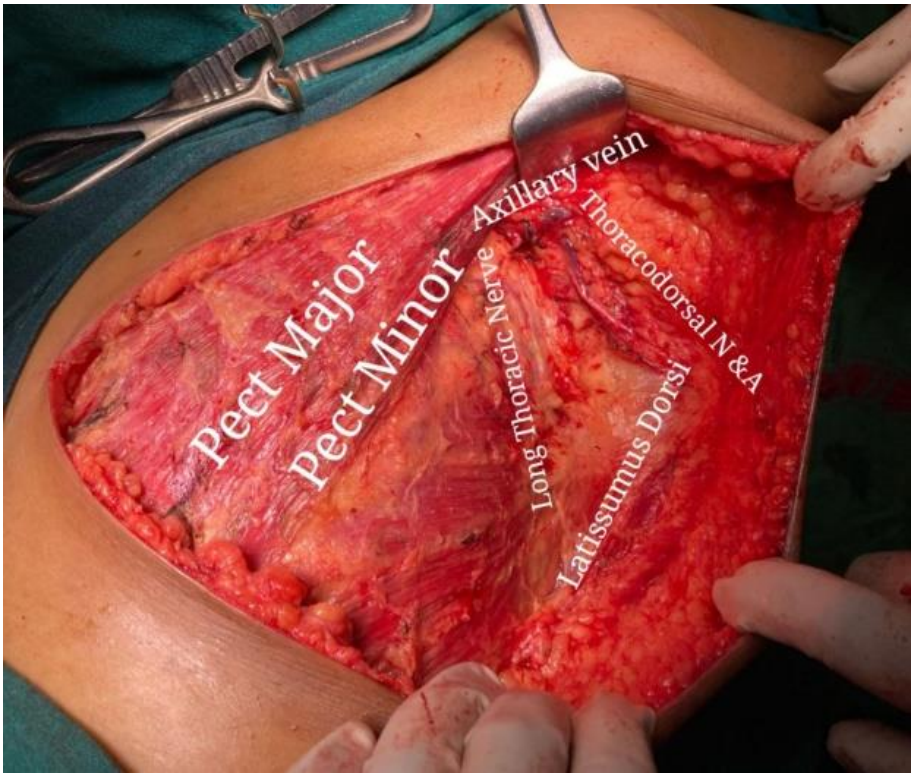
$$N = \frac{2\,SD^2(Z\alpha/2 + Z\beta)^2}{d^2}$$

Where "$Z\alpha/2$ is the critical value of the Normal distribution at $\alpha/2$ (e.g., for a confidence level of 95%, α is 0.05 and the critical value is 1.96). $Z\beta$ is the critical value of the Normal distribution at β (e.g., for a power of 90%, ß is 0.1 and the critical value is 1.28), SD is the standard deviation from previous study population variance, and d is the difference between two means".

Ethical consideration:

1. Institutional ethical approval was acquired well before the research starts.
2. Before the trial began, every patient who was included provided their informed permission.
3. Throughout the research and follow-up, all patients received the Standard of Care.




Pect Major
Pect Minor
Axillary vein
Thoracodorsal N &A
Long Thoracic Nerve
Latissumus Dorsi

RESULTS

RESULTS:

TABLE 1 : AGE DISTRIBUTION

		COUNT	PERCENTAGE
AGE	30 – 40	3	9 %
	41 - 50	6	19 %
	51 – 60	9	28 %
	61 – 70	10	31 %
	71 – 80	4	13 %
	TOTAL	32	100 %

The mean age was 64.13 years. Larger proportion of patients were in the age Group 61 to 70 years (31 %).

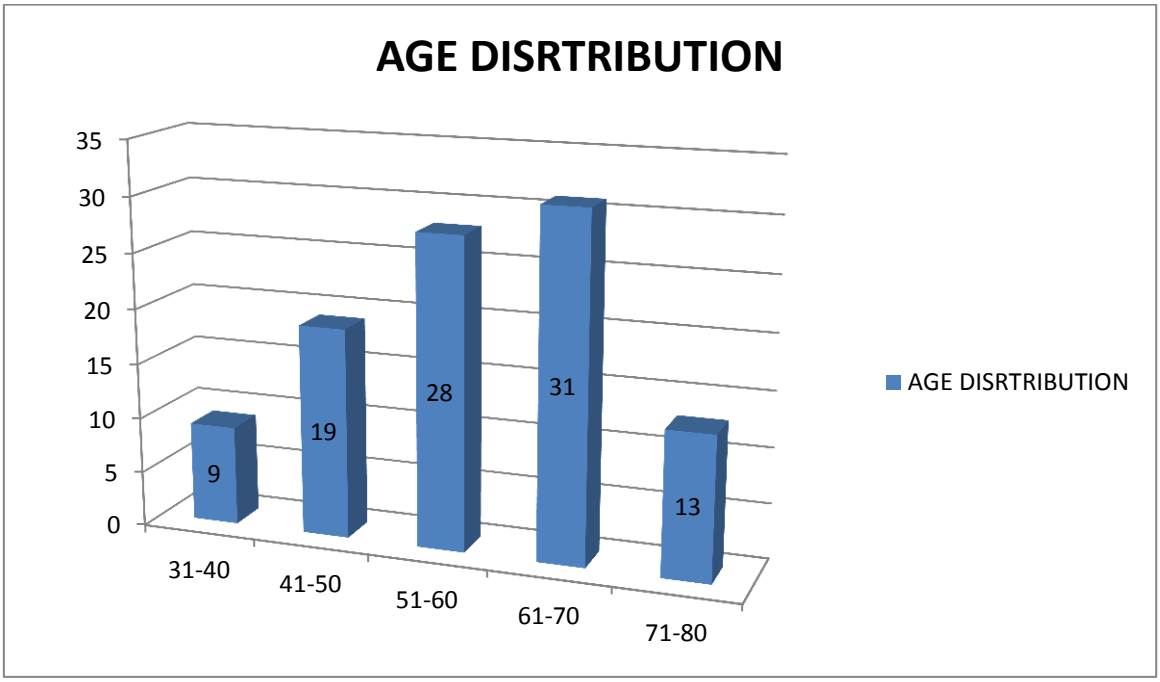


Fig : Bar diagram showing the Age distribution

TABLE 2 : OCCUPATION DISTRIBUTION

		COUNT	PERCENTAGE
	LABOURER	6	18.75%
	HOUSEWIFE	26	81.25 %
	TOTAL	32	100 %

In the study, 81.25% were housewives, and 18.75% were labourers

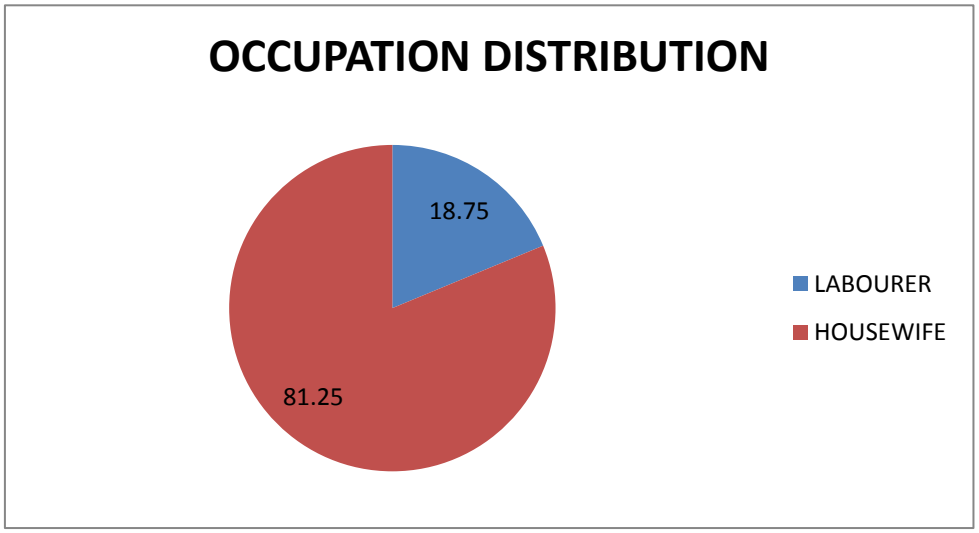


Fig : Pie diagram showing Occupation distribution

TABLE 3: PRESENTING COMPLAINT DISTRIBUTION

		COUNT	PERCENTAGE
PRESENTING COMPLAINTS	LUMP IN LEFT BREAST	15	46.87%
	LUMP IN RIGHT BREAST	17	53.12%
	TOTAL	32	100%

In the study majority of them had Lumps in the right breast (53.12%), and 46.87% had a lump in the Left breast

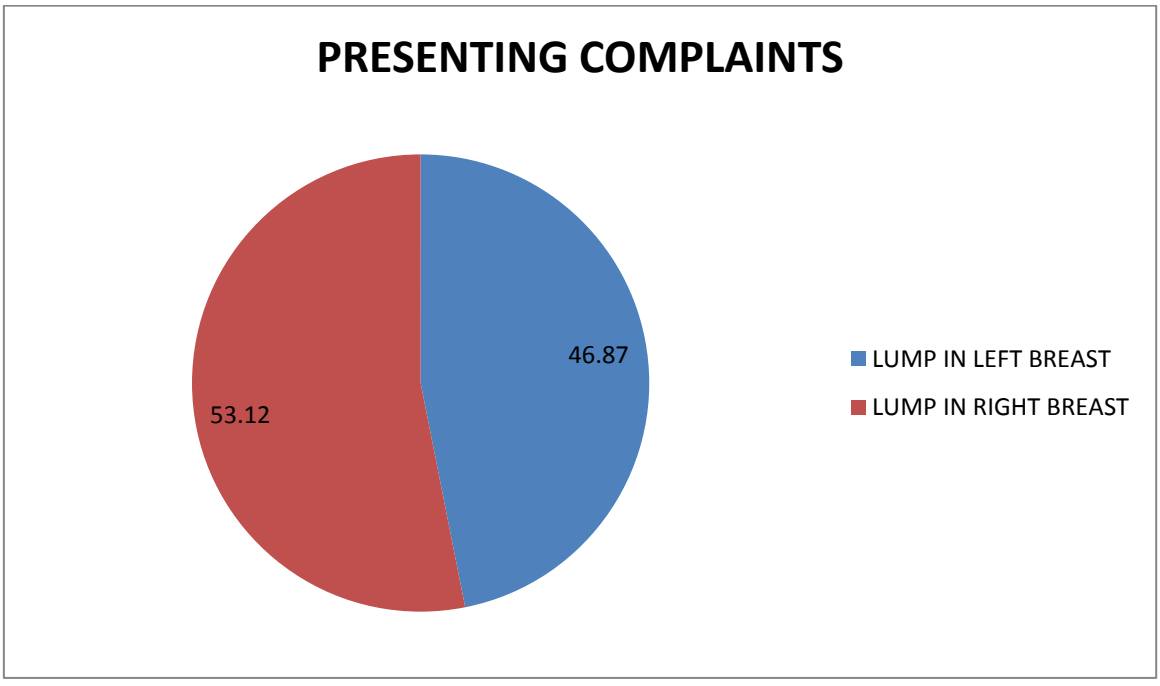


Fig : Bar diagram showing Presenting Complaint distribution

TABLE 4: ASSOCIATED COMPLAINTS DISTRIBUTION

		COUNT	PERCENTAGE
ASSOCIATED COMPLAINTS	PAIN	4	12.5%
	NIL	28	87.5%
	TOTAL	32	100%

In the study, 12.5% had pain.

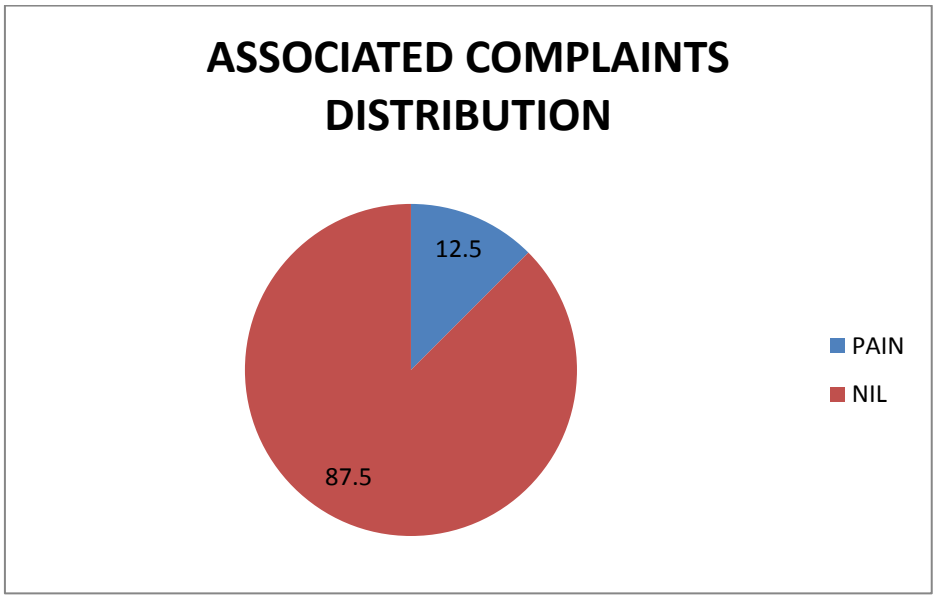


Fig : Pie diagram showing Associated Complaints distribution.

TABLE 5: PAST HISTORY DISTRIBUTION

		COUNT	PERCENTAGE
PAST HISTORY	HTN	3	9.3%
	DM	2	6.2%
	HTN AND DM	1	3.12%
	NIL	26	81.25%
	TOTAL	32	100%

In the study, 6.2% had DM, 9.3% had HTN, and 3.12% had HTN/DM

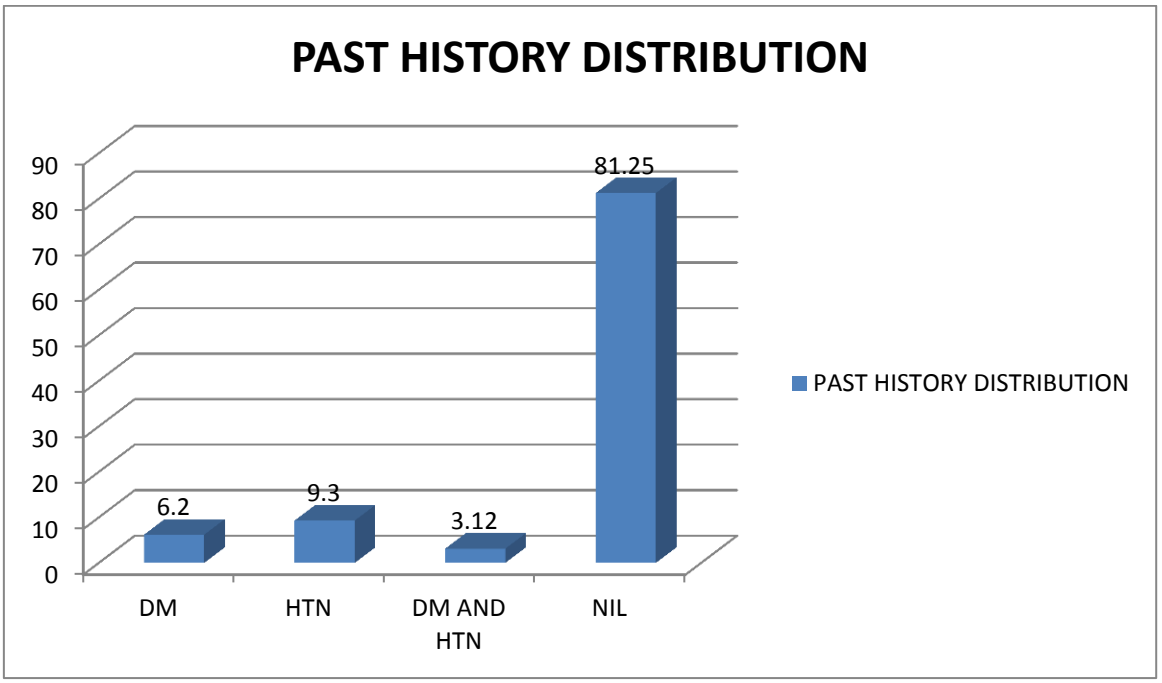


Fig : Bar diagram showing Past History distribution

TABLE 6: MENSTRUAL HISTORY DISTRIBUTION

MENSTRUAL HISTORY	POST MENOPAUSAL	22	68.75
	REGULAR CYCLES	6	18.75
	IRREGULAR CYCLES	4	12.5
	TOTAL	32	100%

In the study, 12.5% had irregular cycles, 68.75% were post-menopausal, and 18.75% had a regular cycle.

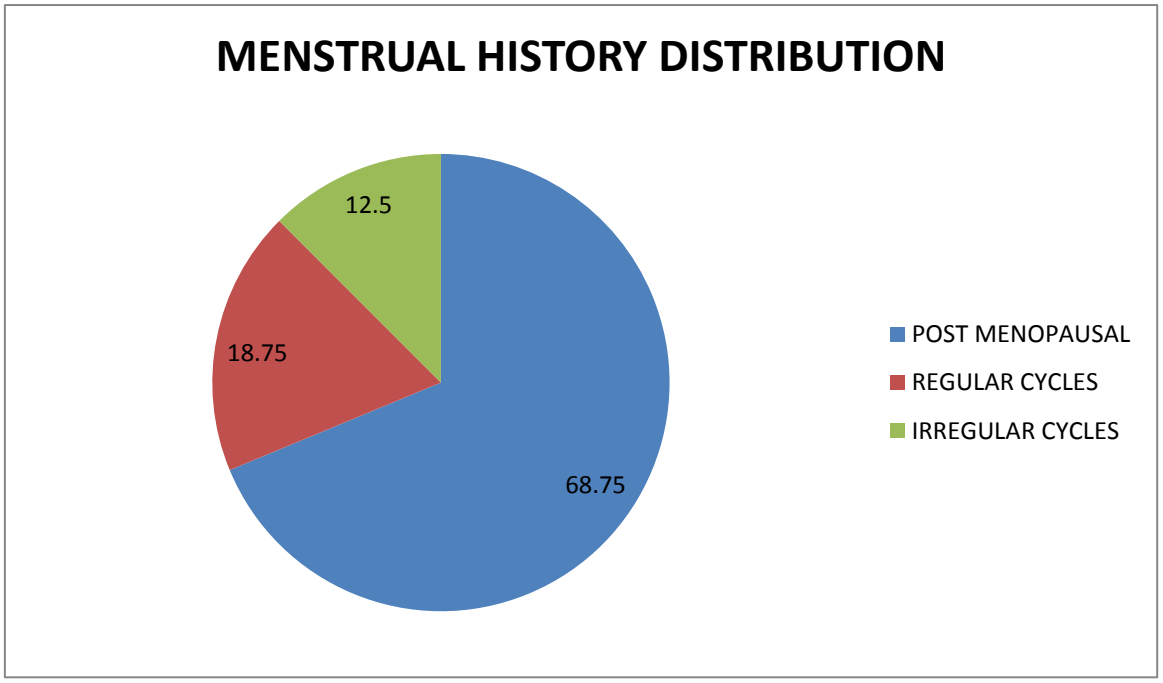


Fig : Pie diagram showing Menstrual History distribution

TABLE 7 : BUILT AND NOURISHMENT DISTRIBUTION

		COUNT	PERCENTAGE
BUILT	MODERATE	32	100%
NOURISHMENT	MODERATE	32	100%

In the study, 100% had moderate built and nourishment.

TABLE 8 : LUMP SIZE DISTRIBUTION

LUMP SIZE	COUNT	PERCENTAGE
4X3CM	7	21.8
3X2CM	5	15.6
5X4CM	7	21.8
6X5CM	1	3.1
6X4CM	3	9.3
7X5CM	5	15.6
8X6CM	4	12.5
TOTAL	**32**	**100%**

In the study, most patients (21.8%) had lump size of 4x3cm or 5x4cm, and 15.6% had 7x5cm and 3x2cm.

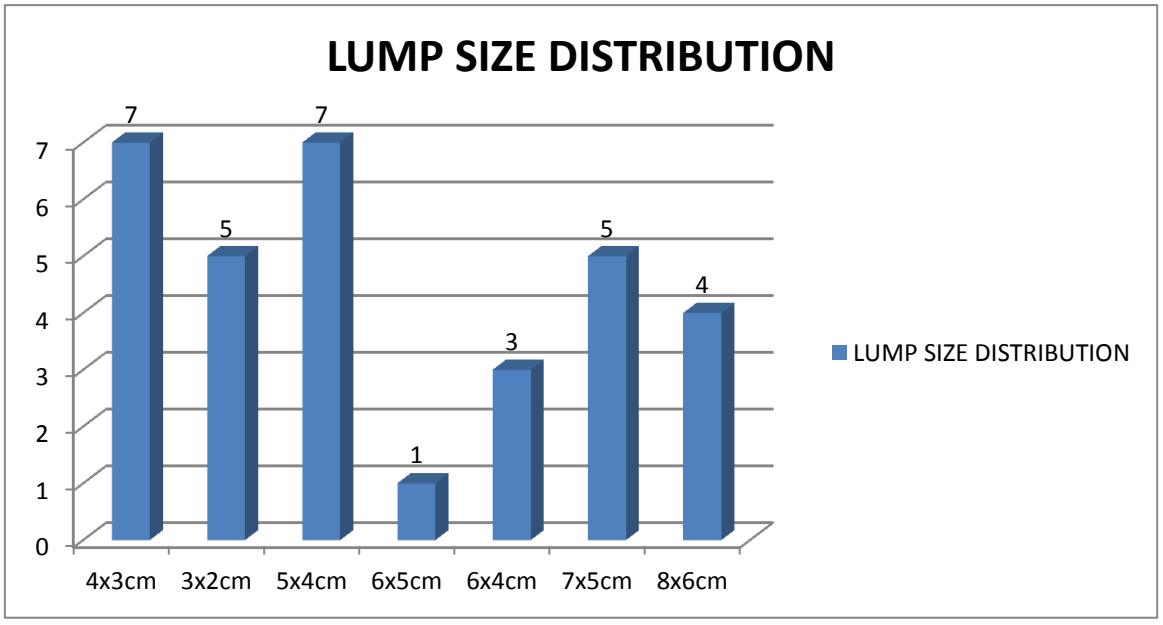


Fig: Bar diagram showing lump size distribution

In the study, 10 (31.25) patients had nipple retraction, 5 (15.6%) had nipple discharge and 20 (62.5%) had axillary lymphadenopathy.

TABLE 9 : DIAGNOSIS

		COUNT	PERCENTAGE
DIAGNOSIS	CA LEFT BREAST	15	46.87%
	CA RIGHT BREAST	17	53.12%
	TOTAL	32	100%

In the study, 53.12% had Carcinoma Right breast, and 46.87% had Carcinoma left breast.

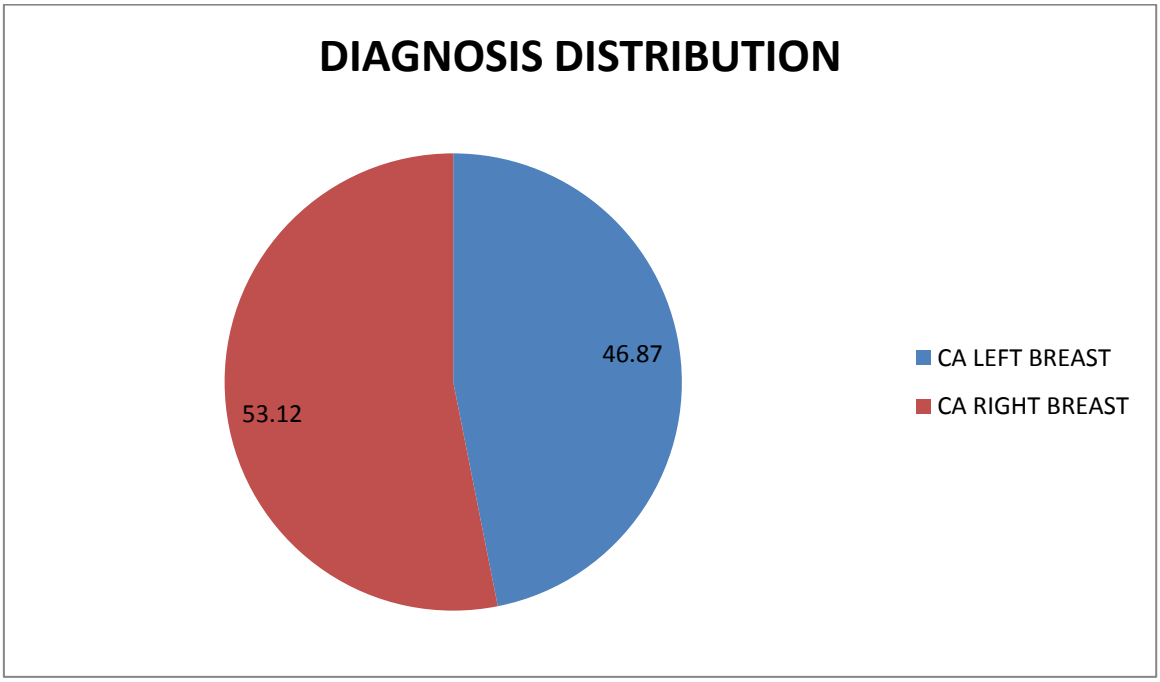


Fig : Pie diagram showing Diagnosis distribution

TABLE 10 : CLINICAL STAGING DISTRIBUTION

STAGING	COUNT	PERCENTAGE
T2N1	10	31.2
T2N0	8	25
T3N2a	3	9.3
T3N1	3	9.3
T3N2b	5	15.6
T3N0	3	9.3
TOTAL	**32**	**100%**

In the study, 10 (31.25%) of patients were diagnosed as T2N1 disease, 8 (25%) as T2N0 disease, 3 (9.3%) as T3N2a, T3N1, T3N0 and 5 (15.6%) as T3N2b disease.

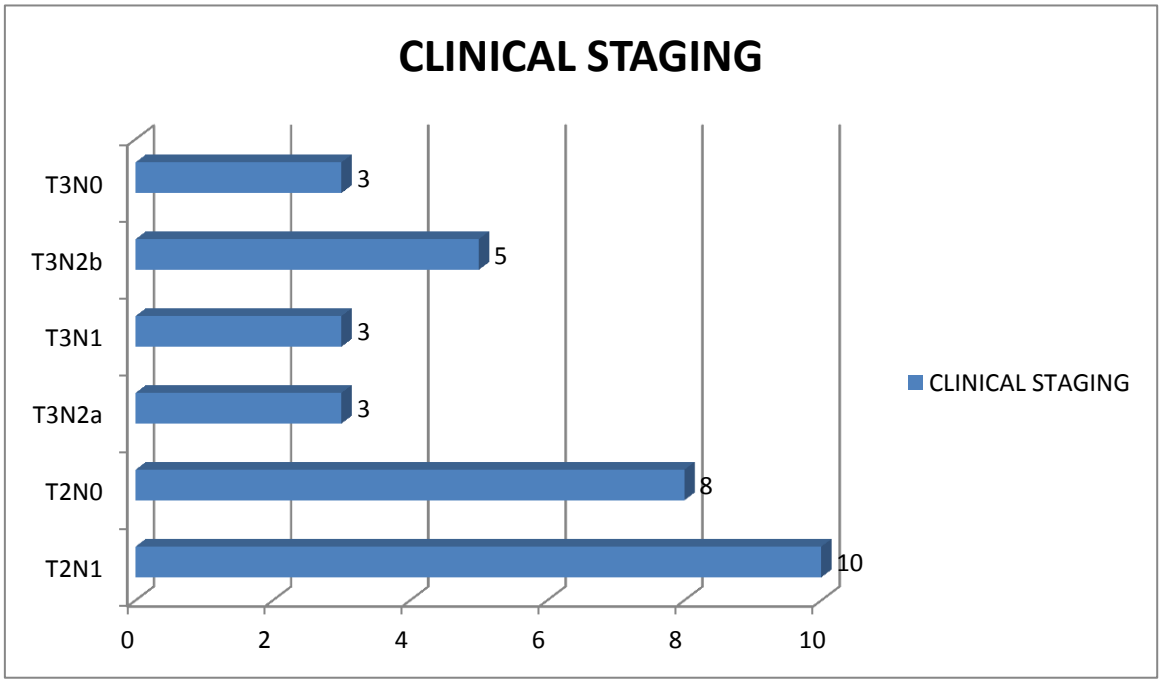


Fig : Bar diagram showing distribution of clinical staging

In the study, 27 (84.3%) patients were diagnosed with ductal carcinoma and 4 (12.5%) with lobular carcinoma and 1 (3%) with medullary carcinoma.

TABLE 11 : AVERAGE AMOUNT OF DRAINAGE ON POD 1

		AMOUNT
AVERAGE AMOUNT OF DRAINAGE ON POD 1	GROUP A	55ML
	GROUP B	75.62ML

In this study, group A had 55ml as average amount of drainage on POD 1 and group B had 75.62ml.

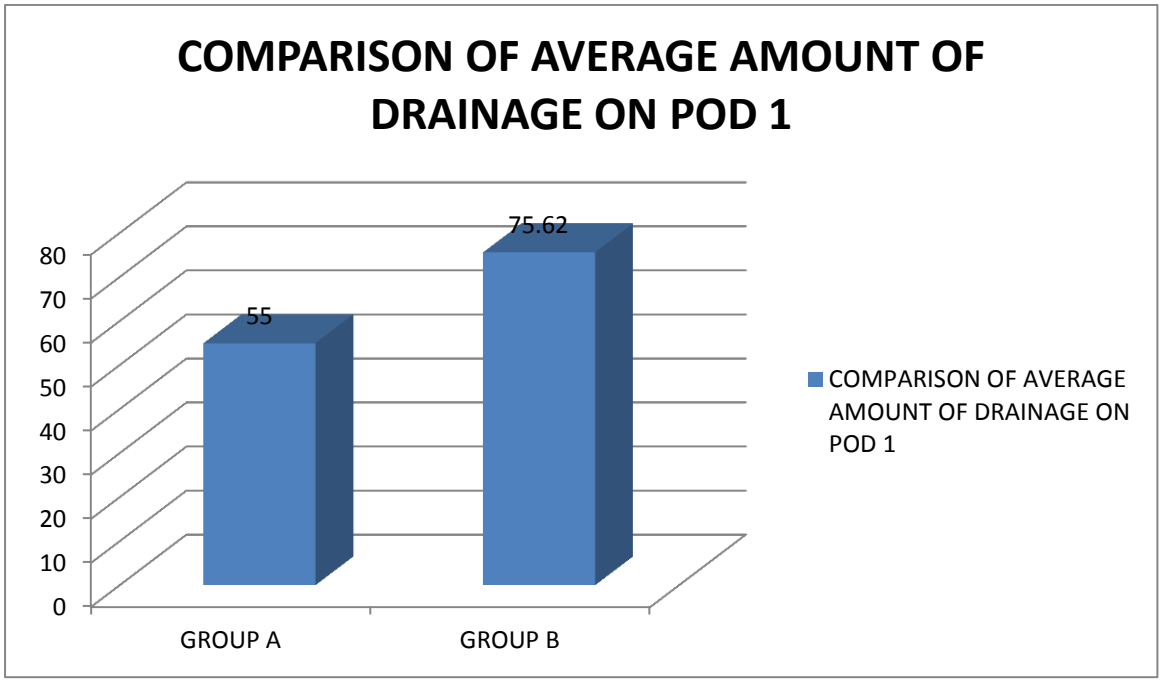


TABLE 12 : AVERAGE DRAIN REMOVAL

		DRAIN REMOVAL ON	
	GROUP A	**POD 5**	
	GROUP B	**POD 7**	

In this study, drain was removed for group A on an average of POD 5 and on POD 7 for group B.

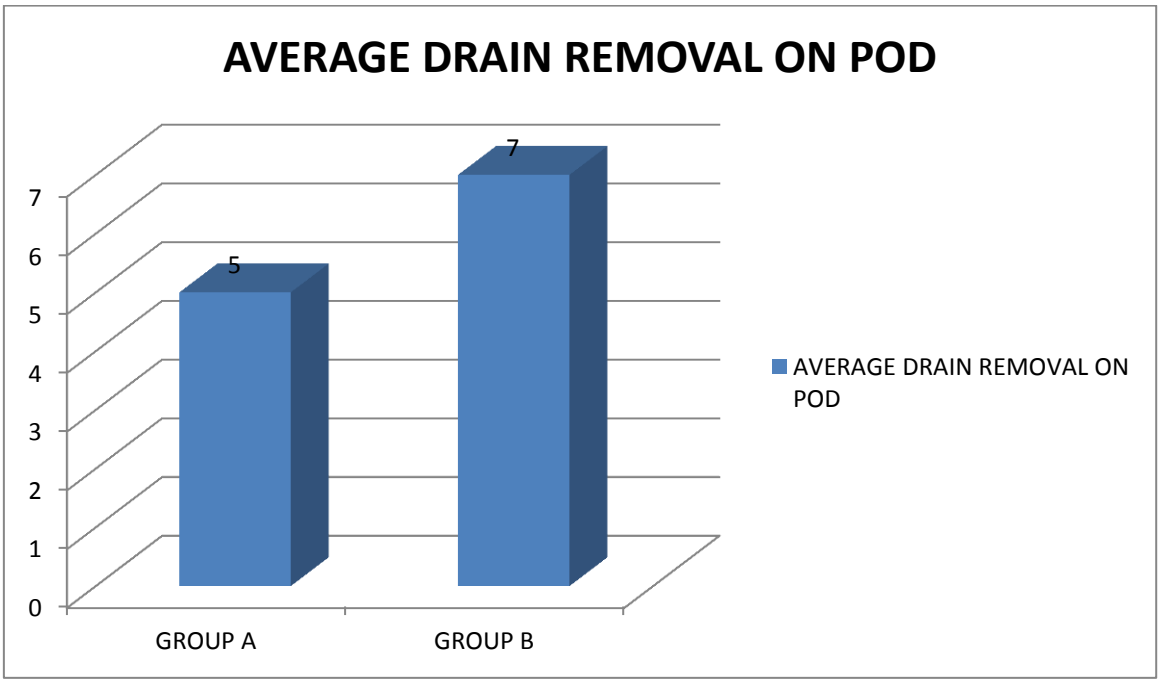


TABLE 13 : AVEARGE AMOUNT OF DRAINAGE

	AVERAGE AMOUNT OF DRAINAGE
GROUP A	163.3 ml
GROUP B	279.87 ml

In this study, average amount of drainage for group A was 163.3ml and 279.87 ml for group B.

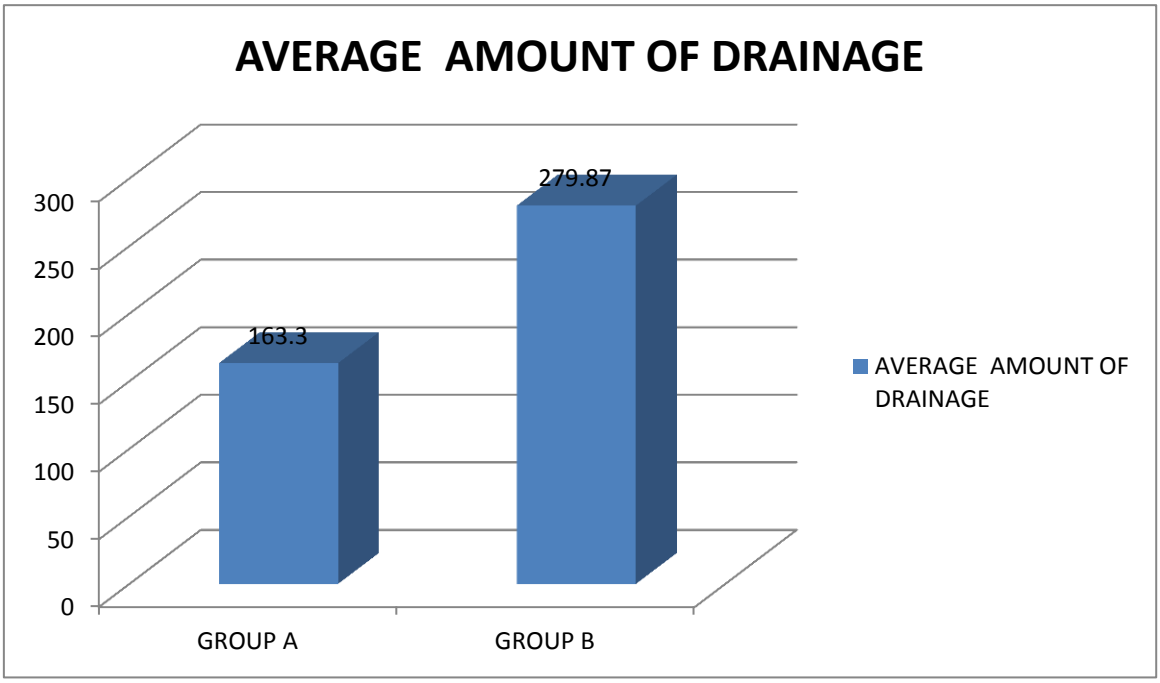


TABLE 14 : QUALITY OF DRAINAGE

QUALITY	COUNT	PERCENTAGE
SEROSANGUINEOUS	19	59.3%
SEROUS	13	40.6%
TOTAL	32	100%

In this study, 59.3% had serosanguineous drain quality and 40.6% had serous drain quality.

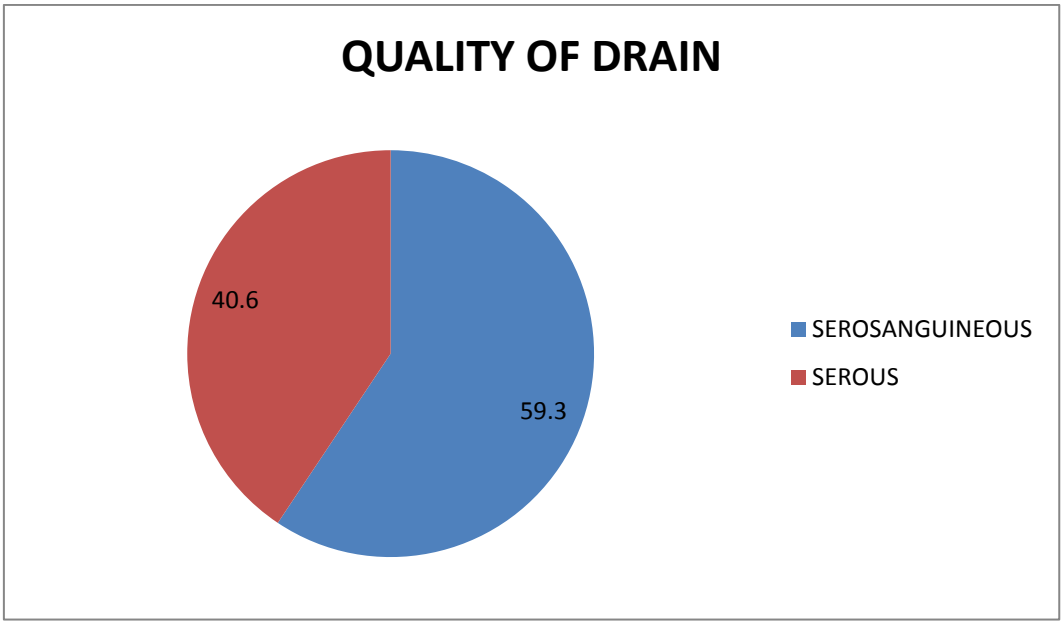


TABLE 15 : TOTAL AMOUNT OF DRAINAGE

		NUMBER	MEAN	STD DEVIATION	Std. Error Mean
TOTAL DRAINAGE	GROUP A	16	163.3125	38.71902	9.67975
	GROUP B	16	279.8750	75.59619	18.89905

TABLE 16 : INDEPENDENT SAMPLES TEST

	t-test for Equality of Means			
	t	df	Sig. (2-tailed)	Mean Difference
TOTAL_DRAINAGE	-5.489	30	.000	-116.56250

p value – 0.0001 (significant)

TABLE 17 : DRAIN REMOVAL

Group Statistics

		N	Mean	Std. Deviation	Std. Error Mean
DRAIN REMOVAL	GROUP A	16	5.1875	.65511	.16378
	GROUP B	16	6.7500	1.18322	.29580

TABLE 18 : INDEPENDENT SAMPLES TEST

	t-test for Equality of Means			
	T	df	Sig. (2-tailed)	Mean Difference
DRAIN REMOVAL	-4.621	30	.000	-1.56250

p value – 0.0001 (significant)

TABLE 19 : DURATION OF POST OP HOSPITAL STAY

		N	Mean	Std. Deviation
STAY DURATION	GROUP A	16	10.18	1.514
	GROUP B	16	15.25	5.67

p value – 0.0013 (significant)

In this study, Group A had mean post op hospital stay for 10.18 days and Group B had 15.25 days with a p-value of 0.0013 which is significant.

TABLE 20 : VAS PAIN SCORING ON POD 3

	N	MEAN	Std. Deviation
GROUP A	16	2.5625	3.16
GROUP B	16	5.4375	1.402

p value – 0.0029 (significant)

In this study, VAS pain scoring was done on POD 3. Mean score of 2.5625 for Group A and mean score of 5.43 for Group B was noted with a significant p value of 0.0029.

DISCUSSION

DISCUSSION

The most frequent and serious MRM consequence is seroma development. Disruption of lymphatic pathways and formation of a dead space during flap elevation are considered to be the basic mechanisms of post-MRM seroma production. Seroma fluid contains significant concentrations of leukocytes, granulocytes, proteinases, IgG, and numerous other cytokines[69]. Strong anti-inflammatory characteristics of corticosteroids, including hydrocortisone, have been shown in literature to prevent fluid buildup at the surgery site[70].

The pathophysiology of seroma production is still being studied, however a number of triggering events have been linked to it. After dissection, serous fluid fills the dead space that is left behind. In the days that follow surgery, the makeup of this fluid changes. It initially looks like lymph with blood clots, a sign of blood vessel and lymph breakage during the dissection. After few days, it changed as exudate with the body healing from surgically-induced 'Acute Inflammatory State'. The patient's damaged lymphatic and blood vessels begin to leak blood and lymph as she moves her arm again, contributing to the seroma. As a result, surgery appears to be the trigger for a complex pathophysiology of seroma production.

Since steroids are anti-inflammatory medications, they are a great choice for research on reducing seroma production, which is an inflammatory process from a pathophysiological perspective.

Therefore a Prospective study was carried out involving 32 women who were diagnosed as carcinoma patients undergoing MRM aged above 18 years at the Department of General Surgery, R.L. Jalappa Hospital and Research Centre, Sri Devaraj Urs Medical College, Tamaka, Kolar. This research was carried out for 2 years. First, before research began,

institutional ethics review committee approval was acquired. Prior to the study's commencement, the consent of the patient and their care taker was duly taken as per the ethical norms of the medical profession.

General Profile:

The average age profile of the patients 64.13 years. The major portion of patients under study found to be in the age group 61 to 70 years (31 %), 81.25% were housewives, and 18.75% were labourers.

Symptoms:

In the study majority of them had Lumps in the right breast (53.12%), and 46.87% had a lump in the Left breast and 12.5% had pain

Comorbidities and history

In the study, 6.2% had DM, 9.3% had HTN, and 3.12% had HTN/DM and 12.5% had irregular cycles, 68.75% were post-menopausal, and 18.75% had a regular cycle.

In the study, 100% had moderate built and nourished. In the study, 53.12% had Ca Right breast, and 46.87% had Ca left breast.

In the study, most patients (21.8%) had lump size of 4x3cm or 5x4cm, and 15.6% had 7x5cm and 3x2cm. In the study, 10 (31.25) patients had nipple retraction, 5 (15.6%) had nipple discharge and 20 (62.5%) had axillary lymphadenopathy. In the study, 10 (31.25%) of patients were diagnosed as T2N1 disease, 8 (25%) as T2N0 disease, 3 (9.3%) as T3N2a, T3N1, T3N0 and 5 (15.6%) as T3N2b disease. In the study, 27 (84.3%) patients were diagnosed with ductal carcinoma and 4 (12.5%) with lobular carcinoma and 1 (3%) with

medullary carcinoma.

In this study, 59.3% had serosanguineous drain quality and 40.6% had serous drain quality.

In this study, group A had 55ml as average amount of drainage on POD 1 and group B had 75.62ml. In this study, drain was removed for group A on an average of POD 5 and on POD 7 for group B with p-value of 0.0001 which is statistically significant.

Total amount of drainage average for Group A was 163 and Group B was 279 with p-value of 0.0001 which is statistically significant.

In this study, Group A had mean post op hospital stay for 10.18 days and Group B had 15.25 days with a p-value of 0.0013 which is significant. In this study, VAS pain scoring was done on POD 3. Mean score of 2.5625 for Group A and mean score of 5.43 for Group B was noted with a significant p value of 0.0029.

During the study, it was found that all wounds were healthy and SSI was not seen in any of them.

LIMITATIONS

LIMITATIONS

Limitations of our study include small sample size, study being conducted in a single hospital setting and different pain tolerance levels in patients. A larger sample size and a large scale study is needed for validation of efficacy IV Methylprednisolone for prevention of seroma in carcinoma breast patients undergoing MRM.

CONCLUSION

CONCLUSION

Findings of the study clearly establish a significant reduction in seroma formation and early removal of drain in patients who received IV Methylprednisolone pre operatively. There was significant reduction in duration of stay of patients in the hospital and reduction in post operative pain. There was no SSI noted during the study. Steroid treatment appears to be the most economical and efficient strategy for reducing the frequency of seroma development, which is the most frequent complication following mastectomy. It is advised to use it regularly in all cases while treating wounds and using adequate antibiotic coverage.

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ANNEXURE

ANNEXURE I

PROFORMA:

Name:

Age:

Sex:

Occupation:

UHID number:

Phone number:

Address:

DOA:

DOS:

DOD:

Presenting complaints:

Past history:

Drug history:

Family history:

Menstrual history:

GENERAL PHYSICAL EXAMINATION:

· Built and nourishment:

· Pallor/Cyanosis/Icterus/Clubbing/edema/Generalized lymphadenopathy

VITAL DATA:

· Pulse:

· Temperature:

· BP:

· Respiration rate:

SYSTEMIC EXAMINATION

· Per abdomen:

· Respiratory system:

· Cardio vascular system:

· Central nervous system:

LOCAL EXAMINATION:

Inspection :

· Site:

· Size:

· Symmetry: symmetrical/asymmetrical

· Number:

· Borders: well defined/ill defined

· Surface: smooth/irregular

· Skin changes:

o Peau d'orange: yes / no

o Dimpling: yes / no

o Ulceration and fungation: yes / no

· Nipple discharge: yes / no

· Scars: yes / no

Palpation:

· Local rise of temperature: present / absent

· Tenderness: present / absent

· Number:

· Size:

· Borders: well defined / ill defined

· Consistency: soft / firm / hard

· Fluctuation: present / absent

· Transillumination: present / absent

· Surface: smooth / irregular

· Axillary lymphadenopathy:

o Location:

o Number:

o Consistency:

o Fixity

· Supraclavicular lymphadenopathy:

o Number

o Consistency

o Fixity

Diagnosis: Carcinoma breast

POST OPERATIVE MONITORING:

PRIMARY OUTCOMES:

Amount of drainage on POD 1

Quality of drain

Cumulative drainage amount for all days before drain removal

POD on which drain was removed

Wound status

SECONDARY OUTCOMES:

VAS pain scoring on POD 3

SSI

Post op duration of hospital stay

ANNEXURE II

INFORMATION SHEET:

Study title: "A clinical study of effectiveness of prophylactic IV methylprednisolone 120mg in prevention of seroma formation in carcinoma breast patients undergoing modified radical mastectomy (MRM)"

GUIDE: DR. K KRISHNA PRASAD

STUDY CONDUCTED BY DR. SANJANA G.K

Study location: R L Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar.

The purpose of the study is explained in detail to us and all information collected is for study purpose only. The data collected is submitted to the department of surgery, SDUMC, Kolar and confidentiality ensured. The merits and demerits explained briefly to us.

All Patients diagnosed with carcinoma breast and planned for MRM will be included in this study. Patients in this study will be divided into 2 groups. Group A will receive IV methylprednisolone preoperatively and group B will not receive IV methylprednisolone. Post operatively both the groups will be assessed for seroma formation and USG guided aspiration of seroma will be done if required. Complications of this study include infection, mood changes, aggression, increase in blood sugar level, blurred vision, urinary retention, headache, etc.

Please read the following information and discuss with your family members. You can ask any question regarding the study. If you agree to participate in the study, we will collect information (as per proforma) from you or a person responsible for you or both. Relevant history will be taken. This information collected will be used only for dissertation and

publication.

All information collected from you will be kept confidential and will not be disclosed to any outsider. Your identity will not be revealed.

There is no compulsion to agree to this study. The care you will get will not change if you don't wish to participate. You are required to sign/ provide thumb impression only if you voluntarily agree to participate in this study. I will bear the cost of the study required materials.

For further information contact:

Dr. Sanjana G.K [post graduate]
Department of General Surgery
SDUMC, Kolar
Phone number: 9663146379.
Email : sanjanagkk@gmail.com

left thumb impression/signature of the patient

left thumb impression / signature of the witness

ಮಾಹಿತಿ ಶೀಟ್

ಅಧ್ಯಯನ ಶೀರ್ಷಿಕೆ : ಮಾರ್ಪಾಡಿತ ಬದಲಾಯಿತ ರ್ಯಾಡಿಕಲ್ ಮಾಸ್ಟೆಕ್ಟೊಮಿಯಲ್ಲಿ
ಸೆರೋಮ ಸಂಗ್ರಹ ತಡೆಗಾಗಿ ಕ್ಯಾರ್ಗಿನೋಮದ ಬೆಸ್ಟ್ ಕ್ಯಾನ್ಸರ್ ರೋಗಿಗಳಲ್ಲಿ ಪೊಫಿಲ್ಯಾಕ್ಟಿಕ್ 173
ಮೆಥೆಲ್ ಪ್ರೆಡ್ನಿಸೊಲೋನ್ 120 ಮಿಲಿಗ್ರಾಂ ಪರಿಣಾಮಕಾರಿತೆಯ ವೈದ್ಯಕೀಯ ಅಧ್ಯಯನ

ಮಾರ್ಗದರ್ಶಿ : ಡಾ| ಕೆ.ಕೃಷ್ಣಪಸಾದ್
ಅಧ್ಯಯನ ನಡೆಸಿದವರು : ಡಾ| ಜಿ.ಕೆ. ಸಂಜನ
ಅಧ್ಯಯನ ಸ್ಥಳ: ಆರ್.ಎಲ್. ಜಾಲಪ್ಪ ಆಸ್ಪತ್ರೆ ಮತ್ತು ಸಂಶೋಧನಾ ಕೇಂದ್ರ - ಶ್ರೀ
ದೇವರಾಜ ಅರಸು ಮೆಡಿಕಲ್ ಕಾಲೇಜು, ತಮಕ, ಕೋಲಾರ.
ಅಧ್ಯಯನದ ಉದ್ದೇಶವನ್ನು ವಿವರವಾಗಿ ನಮಗೆ ವಿವರಿಸಲಾಗಿದೆ ಮತ್ತು ಸಂಗ್ರಹಿಸಿದ ಎಲ್ಲಾ ಮಾಹಿತಿಯೂ ಅಧ್ಯಯನಕ್ಕಾಗಿ ಮಾತ್ರ ಎಂದು ತಿಳಿಸಲಾಗಿದೆ. ಸೇರಿಸಿದ ಡೇಟಾವನ್ನು ಸರ್ಜರಿ ವಿಭಾಗ, 80ಲ11ಲ ಕೋಲಾರ ಇಲ್ಲಿಗೆ ಸಲ್ಲಿಸಲಾಗಿದೆ. ಮತ್ತು ಗುಪ್ತತೆ ಖಚಿತ ಪಡಿಸಲಾಗಿದೆ. ಗುಣ ಮತ್ತು ಅವಗುಣಗಳನ್ನು ನಮಗೆ ಸಂಕ್ಷಿಪ್ತವಾಗಿ ವಿವರಿಸಲಾಗಿದೆ. ಕಾರ್ಸಿನೋಮ ಬೆಸ್ಟ್ ರೋಗ ನಿರ್ಣಯ ಮಾಡಿದ ಎಲ್ಲಾ ರೋಗಿಗಳನ್ನು ಯೋಜಿತ 1/81 ಗೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಸೇರಿಸಲಾಗಿದೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ರೋಗಿಗಳನ್ನು ಗುಂಪುಗಳಾಗಿ ವಿಭಾಗಿಸಲಾಗುತ್ತದೆ... ಗುಂಪು ಎ ಪೂರ್ವ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ 1.1 ಮೆಥಿಲ್‌ಪ್ರೆಡ್ನಿಸೋನ್ ಪಡೆಯುತ್ತದೆ ಮತ್ತು ಗುಂಪು ಬಿ 1.ಳ. ಮೆಥಿಲ್ ಪ್ರೆಡ್ನಿಸೊನ್ ಪಡೆದಿಲ್ಲ. ಶಸ್ತ್ರ ಚಿಕಿತ್ಸೆಯ ನಂತರ ದ್ವಿಗುಂಪುಗಳು ಎರಡೂ ಸಮರ್ಥವಾಗಿ ಸಿರೋಮಾ ರಚನೆಯ ವಿಮರ್ಶಿಸಲ್ಪಡುವುದು ಮತ್ತು ಅವಶ್ಯಕತೆಯಿದ್ದಲ್ಲಿ ಸಿರೋಮಾವನ್ನು 056 ಮಾರ್ಗದರ್ಶಿತ ಆಸ್ಪಿರೇಷನ್ ಸೆರೋಮ ಮಾಡಲಾಗುವುದು. ಈ ಅಧ್ಯಯನದ ಜಟಲತೆಗಳಲ್ಲಿ ಸಂಕ್ರಮಣ, ಮನೋದೈಹಿಕ ಬದಲಾವಣೆ. ಕೋಪಗೊಳಿಸುವ ಸ್ವಭಾವ, ರಕ್ತದ ಶರೀರದ ಮಟ್ಟ ಹೆಚ್ಚಾಗಲಿಕೆ, ಕಣ್ಣು ಕತ್ತರಿಸಿದ ದೃಷ್ಟಿ, ಮೂತ್ರವಹನದೆ ತಡೆ, ತಲೆನೋವು ಇವು ಸೇರಿವೆ.
ದಯವಿಟ್ಟು ಕೆಳಗಿನ ಮಾಹಿತಿಯನ್ನು ಓದಿ ನಿಮ್ಮ ಕುಟುಂಬದ ಸದಸ್ಯರೊಂದಿಗೆ ಚರ್ಚಿಸಿ. ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಯಾವುದೇ ಪ್ರಶ್ನೆ ಕೇಳಬಹುದು. ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳಲು ಒಪ್ಪಿಗೆ ನೀಡುವಿರಾದರೆ. ನಿಮ್ಮಿಂದ. ಅಥವಾ ನಿಮ್ಮಿಂದ ಉತ್ತರವಾಗಿ ಉಳಿದವರಿಂದ ಮಾಹಿತಿಯನ್ನು ಸಂಗ್ರಹಿಸುವೆವು.. (ಪ್ರೊಫಾರ್ಮದಲ್ಲಿ ್ಹನಿರೀಕ್ಷಿಸಿದಂತೆ). ಸಂಬಂಧಿತ ಹಿನ್ನೆಲೆ ತೆಗೆದುಕೊಳ್ಳಲಾಗುವುದು. ಈ ಮಾಹಿತಿಯನ್ನು ಕೇವಲ ಡಿಸರ್ಟೇಷನ್ ಮತ್ತು ಪ್ರಕಟಣೆಗಳಿಗೆ ಮಾತ್ರ ಬಳಸಲಾಗುವುದು.
ನೀವು ನೀಡಿದ ಎಲ್ಲಾ ಮಾಹಿತಿಯನ್ನು ಗುಪ್ತವಾಗಿ ಇಡಲಾಗುತ್ತದೆ ಮತ್ತು ಯಾವ ಹೊರಗಿನವರಿಗೂ ಹೇಳಲಾಗುವುದಿಲ್ಲ. ನಿಮ್ಮ ಗುರುತು ಬಯಲಾಗುದಂತೆ ನೋಡಿಕೊಳ್ಳಲಾಗುತ್ತದೆ.
ಈ ಅಧ್ಯಯನಕ್ಕೆ ಒಪ್ಪಿಗೆ ನೀಡುವುದು. ಬಲವಂತವಿಲ್ಲ. ನೀವು ಭಾಗವಹಿಸಲು ಇಷ್ಟಪಡದಿದ್ದರೆ ನಿಮ್ಮ ವೈದ್ಯಕೀಯ ಕಾಳಜಿನಲ್ಲಿ ವ್ಯತ್ಯಾಸ ಇರುವುದಿಲ್ಲ. ನೀವು ಸ್ವಯಂ ಪ್ರೇರಿತರಾಗಿ ಈ ಅಧ್ಯಯನಕ್ಕೆ ಒಪ್ಪಿಗೆ ನೀಡಿದರೆ ಮಾತ್ರ ನೀವು ಸಹಿ ಮಾಡಬೇಕಾಗುತ್ತದೆ.
ಅಧ್ಯಯನಕ್ಕೆ ಅಗತ್ಯವಾದ ಸಾಮಗ್ರಿಗಳ ಖರ್ಚನ್ನು ನಾನು ವಹಿಸುತ್ತೇನೆ.
ಹೆಚ್ಚಿನ ಮಾಹಿತಿಗಾಗಿ ಸಂಪರ್ಕಿಸಿ: ರೋಗಿಯ ಸಹಿ ಹೆಬ್ಬಟ್ಟು ಗುರುತು
ಡಾ| ಸಂಜನ ಜಿ.ಕೆ (ಸ್ನಾತಕೋತ್ತರ)
ಶಸ್ತ್ರಚಿಕಿತ್ಸಾ ವಿಭಾಗ
ಕೋಲಾರ ಸಾಕ್ಷಿಯ ಸಹಿ/ಹೆಬ್ಬೆಟ್ಟು ಗುರುತು
ಮೊ: 9663146379

ANNEXURE III
CONSENT FORM:

Title: "A clinical study of effectiveness of prophylactic IV methylprednisolone 120mg in prevention of seroma formation in carcinoma breast patients undergoing modified radical mastectomy (MRM)"

Principal investigator: Dr. Sanjana GK

I, Mrs. …….. have been explained in my own understandable language, that I will be included in a study which is EFFECT OF PREOPERATIVE INTRAVENOUS STEROIDS ON SEROMA FORMATION AFTER MRM IN CARCINOMA BREAST being conducted in RL JALAPPA HOSPITAL.

I have been explained that my clinical findings, investigations, preoperative and post-operative findings will be assessed and documented for study purpose.
I have been explained my participation in this study is entirely voluntary and I can withdraw from the study any time and this will not affect my relation with my doctor or treatment for my ailment.
I understand that the medical information produced by this study will become part of institutional records and will be kept confidential by my said institute.
I agree not to restrict the use of any data or result that arise from this study provided such a use is only for scientific purpose(s).
I have principal investigator mobile number for enquiries.
I have been informed that standard of care will be maintained throughout the treatment period.
I in my sound mind give full consent to be added in the part of this study.

Investigator: Dr. Sanjana GK

Participant's signature/ thumb impression
Name:

Signature/thumb impression of the witness: Date:
Name: Relation to patient:

ಒಪ್ಪಿಗೆ ಪತ್ರ

ಅಧ್ಯಯನ ಶೀರ್ಷಿಕೆ : ಮಾರ್ಪಾಡಿತ ರ್ಯಾಡಿಕಲ್ ಮಾಸ್ಟೆಕ್ಟೊಮಿಯಲ್ಲಿ ಸೆರೋಮ
ಸಂಗ್ರಹ ತಡೆಗಾಗಿ ಕ್ಯಾರಿನೋಮದ ಬೆಸ್ಟ್ ಕ್ಯಾನ್ಸರ್ ರೋಗಿಗಳಲ್ಲಿ ಪೊಫಿಲ್ಯಾಕ್ಟಿಕ್ 7 ಮೆಥೆಲ್
ಪ್ರೆಡ್ನಿಸೊಲೋನ್ 120 ಮಿಲಿಗ್ರಾಂ ಪರಿಣಾಮಕಾರಿತೆಯ ವೈದ್ಯಕೀಯ ಅಧ್ಯಯನ.
ಶ್ರೀಮತಿ ಆದ ನನಗೆ ನನ್ನದೇ ಅರ್ಥವಾಗುವ ಭಾಷೆಯಲ್ಲಿ
ಆರ್.ಎಲ್.ಜಾಲಪ್ಪ ಆಸ್ಪತ್ರೆಯಲ್ಲಿ ನಡೆಸಿದ ಎಂ.ಆರ್.ಎಂ ಕಾರ್ಸಿನೋಮು ಜೆಸ್ಟ್ ರೋಗಕ್ಕೆ
ಸಂಬಂಧಿಸಿದ ಅಧ್ಯಯನಕ್ಕೆ ನನ್ನನ್ನು ಒಳಪಡಿಸಿರುವುದನ್ನು ತಿಳಿಸಲಾಗಿದೆ. ನನ್ನ ವೈದ್ಯಕೀಯ ಪರಿಶೀಲನೆಗೆ ಸಂಬಂಧಿಸಿದ ಪೂರ್ವ ಮತ್ತು ಶಸ್ತ್ರಚಿಕಿತ್ಸೆ ಪರಿಣಾಮಗಳನ್ನು ಅಧ್ಯಯನಕ್ಕೆಂದು ವಿವರಿಸಲಾಗಿದೆ. ಮತ್ತು ಅವುಗಳನ್ನು ದಾಖಲಿಸಲಾಗಿದೆ. ನನ್ನ ಈ ಅಧ್ಯಯನಕ್ಕೆ ಒಪ್ಪಿಗೆ ಸಂಪೂರ್ಣ ಸ್ವತಂತ್ರವಾಗಿದೆ ಮತ್ತು ನಾನು ಯಾವಾಗಲಾದರೂ ಅದರಿಂದ ಹೊರಬರಬಹುದು ಮತ್ತು ಅದರಿಂದ ನನ್ನ ಮತ್ತು ವೈದ್ಯರ ಸಂಬಂಧಕ್ಕಾಗಲೀ ಅಥವಾ ನನ್ನ ಚಿಕಿತ್ಸೆಗಾಗಲೀ ಯಾವುದೇ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ.
ಈ ಅಧ್ಯಯನದಿಂದ ಉಂಟಗುವ ಯಾವುದೇ ಡೇಟಾ ಅಥವಾ ಫಲಿತಾಂಶವನ್ನು ಬಳಸುವುದಕ್ಕೆ ಅಧಿಕೃತರನ್ನು ನಿರ್ಬಂಧಿಸುವುದಿಲ್ಲ ಮತ್ತು ನಾನು ಸೂಕ್ತವಾಗಿ ಸಂಶೋಧನೆಯ ಮೂಲಕ ಉಂಟಾಗುವ ಯಾವುದೇ ಡೇಟಾ ಅಥವಾ ಫಲಿತಾಂಶಗಳ ಬಳಕೆಯನ್ನು ನಿರ್ಬಂಧಿಸುವುದಿಲ್ಲ ಎಂದು ನಾನು ಒಪ್ಪಿಕೊಳ್ಳುತ್ತೇನೆ. ಈ ಅಧ್ಯಯನದಿಂದ ಉಂಟಾಗುವ ವೈದ್ಯಕೀಯ ಮಾಹಿತಿ ಸಂಬಂಧಿತ ಇನ್‌ಸ್ಟಿಟ್ಯೂಷನ್ ರೆಕಾರ್ಡ್ಸ್ ಒಂದರ ಭಾಗವಾಗುವುದಕ್ಕೆ ನನ್ನ ಅಭ್ಯಂತರವಿರುವುದಿಲ್ಲ. ನಾನು ಅಧ್ಯಯನ ನಡೆಸಿದ ಡಾಕ್ಟರ್‌ರ ದೂರವಾಣಿ ಸಂಖ್ಯೆ ಹೊಂದಿದ್ದೇನೆ. ಅಧ್ಯಯನ ಮುಗಿಯುವವರೆಗೂ ಗುಣಮಟ್ಟದ ಚಿಕಿತ್ಸೆ ಖಾತರಿಪಡಿಸಲಾಗಿದೆ. ಈ ಅಧ್ಯಯನಕ್ಕೆ ನನ್ನ ಸಂಪೂರ್ಣ ಒಪ್ಪಿಗೆ ಇದೆ.

ಅಧ್ಯಯನ ನಡೆಸಿದವರು ಡಾ| ಸಂಜನ ಜಿ.ಕೆ

ರೋಗಿಯ ಸಹಿ ಹೆಬ್ಬಟ್ಟು ಗುರುತು
ದಿನಾಂಕ :

ಸಾಕ್ಷಿಯ ಸಹಿ/ಹೆಬ್ಬೆಟ್ಟು ಗುರುತು
ರೋಗಿಯೊಂದಿಗಿನ ಸಂಬಂಧ

MASTER CHART

SL.NO	UHID	AGE	OCCUPATION	CHIEF COMPLAINT	ASSOCIATED COMPLAINTS	PAST HISTORY	MENSTRUAL HISTORY	BUILT	NOURISHMENT	BREAST EXAMINATION				MAMMOGRAPHY	HISTOPATHOLOGICAL REPORT	CLINICAL TNM STAGING	DIAGNOSIS	IV METHYL PREDNISOLONE		AMOUNT OF DRAINAGE								TOTAL	QUALITY	DRAIN REMOVAL	WOUND	POST OP HOSPITAL STAY	SSI	VAS SCORE ON POST OP DAY 3
										LUMP SIZE	NIPPLE RETRACTION	NIPPLE DISCHARGE	AXILLARY LYMPHADENOPATHY							POD1	POD2	POD3	POD4	POD5	POD6	POD7	POD8	POD9							
1	77136	75	HOUSEWIFE	LUMP IN LEFT BREAST	PAIN	NIL	POST MENOPAUSAL	MODERATE	MODERATE	4X3CM	ABSENT	PRESENT	PRESENT	SPICULATED SOFT TISSUE LESION WITH SKIN THICKENING IN THE UOQ BIRADS-V	DUCTAL CARCINOMA	T2N1	CA LEFT BREAST	GIVEN	GROUP A	40ML	30ML	20ml	20ml	10ml					128ML	SEROSANGUINEOUS	POD5	HEALTHY	11 DAYS	NO	4
2	196309	45	LABOURER	LUMP IN LEFT BREAST	NIL	DM	IRREGULAR CYCLES	MODERATE	MODERATE	3X2CM	PRESENT	ABSENT	ABSENT	NOT DONE	DUCTAL CARCINOMA	T2N0	CA LEFT BREAST	NOT GIVEN	GROUP B	60ML	50ML	50ML	40ML	40ml	30ML	30ML	20ML		348ML	SEROUS	POD8	HEALTHY	16 DAYS	NO	6
3	73975	60	HOUSEWIFE	LUMP IN RIGHT BREAST	NIL	NIL	POST MENOPAUSAL	MODERATE	MODERATE	5X4CM	ABSENT	ABSENT	ABSENT	SPICULATED SOFT TISSUE LESION WITH SKIN THICKENING IN THE UOQ BIRADS-V	DUCTAL CARCINOMA	T2N0	CA RIGHT BREAST	GIVEN	GROUP A	55ml	40ML	30ml	30ML	20ml	20ml				199ML	SEROUS	POD6	HEALTHY	12 DAYS	NO	3
4	137723	49	HOUSEWIFE	LUMP IN LEFT BREAST	NIL	NIL	REGULAR CYCLES	MODERATE	MODERATE	3X2CM	ABSENT	ABSENT	PRESENT	NOT DONE	DUCTAL CARCINOMA	T2N1	CA LEFT BREAST	NOT GIVEN	GROUP B	80ML	60ml	50ML	40ml	30ml	30ml				290ML	SEROSANGUINEOUS	POD6	HEALTHY	15 DAYS	NO	4
5	185625	40	LABOURER	LUMP IN LEFT BREAST	PAIN	NIL	REGULAR CYCLES	MODERATE	MODERATE	6X5CM	PRESENT	ABSENT	PRESENT	NOT DONE	DUCTAL CARCINOMA	T3N2a	CA LEFT BREAST	GIVEN	GROUP A	40ML	30ml	20ml	10ml	MIN					102ML	SEROUS	POD 5	HEALTHY	10 DAYS	NO	2
6	65320	41	HOUSEWIFE	LUMP IN RIGHT BREAST	NIL	NIL	REGULAR CYCLES	MODERATE	MODERATE	6X4CM	ABSENT	ABSENT	PRESENT	NOT DONE	DUCTAL CARCINOMA	T3N1	CA RIGHT BREAST	NOT GIVEN	GROUP B	100ML	90ML	65ml	60ml	45ml	30ml	20ml			410 ML	SEROUS	POD 7	HEALTHY	17 DAYS	NO	6
7	143627	55	HOUSEWIFE	LUMP IN LEFT BREAST	NIL	HTN	POST MENOPAUSAL	MODERATE	MODERATE	4X3CM	ABSENT	ABSENT	ABSENT	SPICULATED SOFT TISSUE LESION WITH SKIN THICKENING IN THE UOQ BIRADS-V	LOBULAR CARCINOMA	T2N0	CA LEFT BREAST	NOT GIVEN	GROUP B	120ML	80ML	60ML	60ML	40ML					360 ML	SEROUS	POD 8	HEALTHY	15 DAYS	NO	5
8	81315	63	HOUSEWIFE	LUMP IN LEFT BREAST	NIL	NIL	POST MENOPAUSAL	MODERATE	MODERATE	7X5CM	PRESENT	PRESENT	PRESENT	NOT DONE	DUCTAL CARCINOMA	T3N2b	CA LEFT BREAST	NOT GIVEN	GROUP B	90ML	80ml	75ML	60ml	55ml	50ML	40ML	35ML	25ml	208ML	SEROSANGUINEOUS	POD9	HEALTHY	16 DAYS	NO	6
9	177274	42	HOUSEWIFE	LUMP IN LEFT BREAST	NIL	NIL	IRREGULAR CYCLES	MODERATE	MODERATE	8X6CM	ABSENT	ABSENT	ABSENT	NOT DONE	DUCTAL CARCINOMA	T3N0	CA LEFT BREAST	NOT GIVEN	GROUP B	80ML	70ML	50ml	40ML	40ML	30ml	30ml	15ml		375ML	SEROUS	POD 8	HEALTHY	15 DAYS	NO	6
10	170705	58	HOUSEWIFE	LUMP IN RIGHT BREAST	NIL	NIL	POST MENOPAUSAL	MODERATE	MODERATE	4X3CM	ABSENT	ABSENT	PRESENT	NOT DONE	DUCTAL CARCINOMA	T2N1	CA RIGHT BREAST	GIVEN	GROUP A	60ML	45ML	20ML	10ML	10ML					145 ML	SEROUS	POD 6	HEALTHY	10 DAYS	NO	3
11	227525	55	LABOURER	LUMP IN LEFT BREAST	NIL	NIL	POST MENOPAUSAL	MODERATE	MODERATE	5X4CM	ABSENT	ABSENT	PRESENT	NOT DONE	DUCTAL CARCINOMA	T2N1	CA LEFT BREAST	NOT GIVEN	GROUP B	70ML	60ML	30ML	30ML	20ML					270ML	SEROSANGUINEOUS	POD5	HEALTHY	16 DAYS	NO	7
12	241407	40	HOUSEWIFE	LUMP IN RIGHT BREAST	NIL	NIL	REGULAR CYCLES	MODERATE	MODERATE	3X2CM	ABSENT	ABSENT	PRESENT	SPICULATED SOFT TISSUE LESION WITH SKIN THICKENING IN THE UOQ BIRADS-V	DUCTAL CARCINOMA	T2N1	CA RIGHT BREAST	GIVEN	GROUP A	50ML	40ML	30ML	20ML	15ML					155ML	SEROUS	POD5	HEALTHY	9 DAYS	NO	1
13	229831	52	HOUSEWIFE	LUMP IN LEFT BREAST	NIL	DM AND HTN	IRREGULAR CYCLES	MODERATE	MODERATE	8X6CM	PRESENT	ABSENT	ABSENT	SPICULATED SOFT TISSUE LESION WITH SKIN THICKENING IN THE UOQ BIRADS-V	DUCTAL CARCINOMA	T3N2b	CA LEFT BREAST	GIVEN	GROUP A	70ml	60ml	50ML	40ml	30ml	30ml				272ML	SEROSANGUINEOUS	POD6	HEALTHY	11 DAYS	NO	3
14	267367	32	HOUSEWIFE	LUMP IN LEFT BREAST	PAIN	NIL	REGULAR CYCLES	MODERATE	MODERATE	7X5CM	PRESENT	ABSENT	PRESENT	NOT DONE	LOBULAR CARCINOMA	T3N2a	CA LEFT BREAST	NOT GIVEN	GROUP B	60ml	50ML	40ML	40ML	40ml	30ML	30ML			322ML	SEROSANGUINEOUS	POD7	HEALTHY	15 DAYS	NO	5
15	218496	63	HOUSEWIFE	LUMP IN RIGHT BREAST	NIL	NIL	POST MENOPAUSAL	MODERATE	MODERATE	5X4CM	ABSENT	ABSENT	ABSENT	NOT DONE	DUCTAL CARCINOMA	T2N0	CA RIGHT BREAST	GIVEN	GROUP A	55ml	40ML	30ml	20ML						159ML	SEROUS	POD4	HEALTHY	10 DAYS	NO	4
16	290102	45	LABOURER	LUMP IN LEFT BREAST	NIL	NIL	REGULAR CYCLES	MODERATE	MODERATE	7X5CM	ABSENT	PRESENT	PRESENT	SPICULATED SOFT TISSUE LESION WITH SKIN THICKENING IN THE UOQ BIRADS-V	DUCTAL CARCINOMA	T3N2b	CA LEFT BREAST	GIVEN	GROUP A	50ML	30ML	30ML	30ML	20ML					160ML	SEEROUS	POD5	HEALTHY	11 DAYS	NO	3
17	251719	65	HOUSEWIFE	LUMP IN RIGHT BREAST	NIL	NIL	POST MENOPAUSAL	MODERATE	MODERATE	6X4CM	ABSENT	ABSENT	PRESENT	SPICULATED SOFT TISSUE LESION WITH SKIN THICKENING IN THE UOQ BIRADS-V	DUCTAL CARCINOMA	T3N1	CA RIGHT BREAST	GIVEN	GROUP A	45ML	30ML	20ml	20ml	10ml	10ML				138ML	SEROSANGUINEOUS	POD6	HEALTHY	12 DAYS	NO	2
18	163720	72	HOUSEWIFE	LUMP IN RIGHT BREAST	NIL	HTN	POST MENOPAUSAL	MODERATE	MODERATE	5X4CM	PRESENT	ABSENT	PRESENT	SPICULATED SOFT TISSUE LESION WITH SKIN THICKENING IN THE UOQ BIRADS-V	DUCTAL CARCINOMA	T2N1	CA RIGHT BREAST	GIVEN	GROUP A	55ML	40ML	30ML	30ML	20ML					175ML	SEROSANGUINEOUS	POD5	HEALTHY	10 DAYS	NO	3
19	237991	48	HOUSEWIFE	LUMP IN RIGHT BREAST	NIL	NIL	IRREGULAR CYCLES	MODERATE	MODERATE	4X3CM	PRESENT	ABSENT	ABSENT	SPICULATED SOFT TISSUE LESION WITH SKIN THICKENING IN THE UOQ BIRADS-V	DUCTAL CARCINOMA	T2N0	CA RIGHT BREAST	NOT GIVEN	GROUP B	80ML	70ML	50ml	40ML	35ML	30ml	30ml	15ml		370ML	SEROSANGUINEOUS	POD8	HEALTHY	15 DAYS	NO	6
20	272010	65	HOUSEWIFE	LUMP IN RIGHT BREAST	NIL	NIL	POST MENOPAUSAL	MODERATE	MODERATE	3X2CM	ABSENT	ABSENT	ABSENT	NOT DONE	DUCTAL CARCINOMA	T2N0	CA RIGHT BREAST	GIVEN	GROUP A	50ML	40ML	30ML	30ML	20ML					170ML	SEROSANGUINEOUS	POD5	HEALTHY	9 DAYS	NO	2
21	346649	72	LABOURER	LUMP IN LEFT BREAST	NIL	NIL	POST MENOPAUSAL	MODERATE	MODERATE	8X6CM	PRESENT	ABSENT	ABSENT	NOT DONE	DUCTAL CARCINOMA	T3N0	CA LEFT BREAST	GIVEN	GROUP A	60ML	40ML	20ML	20ML	20ML					160ML	SEROSANGUINEOUS	POD5	HEALTHY	10 DAYS	NO	3
22	301994	58	HOUSEWIFE	LUMP IN RIGHT BREAST	NIL	NIL	POST MENOPAUSAL	MODERATE	MODERATE	7X5CM	ABSENT	PRESENT	PRESENT	SPICULATED SOFT TISSUE LESION WITH SKIN THICKENING IN THE UOQ BIRADS-IV	DUCTAL CARCINOMA	T3N2b	CA RIGHT BREAST	NOT GIVEN	GROUP B	60ML	50ML	20ML	20ML	20ML	20ML				190ML	SEROUS	POD6	HEALTHY	14 DAYS	NO	6
23	295740	66	HOUSEWIFE	LUMP IN RIGHT BREAST	NIL	DM	POST MENOPAUSAL	MODERATE	MODERATE	5X4CM	ABSENT	PRESENT	PRESENT	NOT DONE	LOBULAR CARCINOMA	T2N1	CA RIGHT BREAST	GIVEN	GROUP A	40ML	40ML	30ML	30ML						140ML	SEROUS	POD4	HEALTHY	6 DAYS	NO	3
24	313209	69	HOUSEWIFE	LUMP IN RIGHT BREAST	NIL	NIL	POST MENOPAUSAL	MODERATE	MODERATE	5X4CM	ABSENT	ABSENT	ABSENT	NOT DONE	DUCTAL CARCINOMA	T2N0	CA RIGHT BREAST	NOT GIVEN	GROUP B	60ML	40ML	30ML	20ML	20ML					170ML	SEROSANGUINEOUS	POD5	HEALTHY	14 DAYS	NO	6
25	310904	65	HOUSEWIFE	LUMP IN RIGHT BREAST	NIL	NIL	POST MENOPAUSAL	MODERATE	MODERATE	4X3CM	PRESENT	ABSENT	PRESENT	SPICULATED SOFT TISSUE LESION WITH SKIN THICKENING IN THE UOQ BIRADS-V	DUCTAL CARCINOMA	T2N1	CA RIGHT BREAST	NOT GIVEN	GROUP B	70ML	50ML	30ML	30ML	30ML	20ML				230ML	SEROSANGUINEOUS	POD6	HEALTHY	18 DAYS	NO	5
26	108664	59	HOUSEWIFE	LUMP IN RIGHT BREAST	NIL	NIL	POST MENOPAUSAL	MODERATE	MODERATE	6X4CM	PRESENT	ABSENT	PRESENT	SPICULATED SOFT TISSUE LESION WITH SKIN THICKENING IN THE UOQ BIRADS-V	DUCTAL CARCINOMA	T3N2b	CA RIGHT BREAST	NOT GIVEN	GROUP B	70ML	50ML	40ML	30ML	30ML	20ML	20ML			260ML	SEROSANGUINEOUS	POD7	HEALTHY	7 DAYS	NO	5
27	325993	54	LABOURER	LUMP IN LEFT BREAST	PAIN	NIL	POST MENOPAUSAL	MODERATE	MODERATE	7X5CM	ABSENT	ABSENT	ABSENT	SPICULATED SOFT TISSUE LESION WITH SKIN THICKENING IN THE UOQ BIRADS-IV	DUCTAL CARCINOMA	T3N0	CA LEFT BREAST	GIVEN	GROUP A	70ML	30ML	20ML	20ML	15ML					155ML	SEROSANGUINEOUS	POD5	HEALTHY	9 DAYS	NO	1
28	237790	67	HOUSEWIFE	LUMP IN RIGHT BREAST	NIL	HTN	POST MENOPAUSAL	MODERATE	MODERATE	8X6CM	ABSENT	ABSENT	PRESENT	NOT DONE	DUCTAL CARCINOMA	T3N2a	CA RIGHT BREAST	NOT GIVEN	GROUP B	60ML	40ML	30ML	30ML	20ML	15ML				195ML	SEROSANGUINEOUS	POD6	HEALTHY	16 DAYS	NO	4
29	350383	74	HOUSEWIFE	LUMP IN LEFT BREAST	NIL	NIL	POST MENOPAUSAL	MODERATE	MODERATE	5X4CM	ABSENT	ABSENT	PRESENT	NOT DONE	DUCTAL CARCINOMA	T2N1	CA LEFT BREAST	GIVEN	GROUP A	60ML	30ML	20ML	20ML	15ML	MIN				145ML	SEROUS	POD6	HEALTHY	30 DAYS	NO	2
30	299550	63	HOUSEWIFE	LUMP IN LEFT BREAST	NIL	NIL	POST MENOPAUSAL	MODERATE	MODERATE	4X3CM	PRESENT	ABSENT	ABSENT	NOT DONE	LOBULAR CARCINOMA	T2N0	CA LEFT BREAST	NOT GIVEN	GROUP B	80ML	50ML	30ML	40ML	20ML	20ML				240ML	SEROSANGUINEOUS	POD6	HEALTHY	19 DAYS	NO	5
31	325672	56	HOUSEWIFE	LUMP IN LEFT BREAST	NIL	NIL	POST MENOPAUSAL	MODERATE	MODERATE	3X2CM	ABSENT	ABSENT	PRESENT	NOT DONE	MEDULLARY CARCINOMA	T2N1	CA LEFT BREAST	GIVEN	GROUP A	80ML	60ML	30ML	30ML	20ML					210ML	SEROSANGUINEOUS	POD5	HEALTHY	12 DAYS	NO	2
32	334291	66	HOUSEWIFE	LUMP IN RIGHT BREAST	NIL	NIL	POST MENOPAUSAL	MODERATE	MODERATE	5X4CM	ABSENT	ABSENT	PRESENT	NOT DONE	DUCTAL CARCINOMA	T2N1	CA RIGHT BREAST	NOT GIVEN	GROUP B	70ML	50ML	40ML	30ML	30ML	20ML				240ML	SEROSANGUINEOUS	POD6	HEALTHY	16 DAYS	NO	5