CLINICOPATHOLOGICAL ANALYSIS OF BREAST LUMP IN FEMALES

By
Dr. KIRTANA S. SHAH

Dissertation Submitted to
SumandeepVidyapeeth, Pipariya, Vadodara.
In partial fulfilment
Of the requirements for the degree of

"MASTER OF SURGERY"

(BRANCH-I)

GENERAL SURGERY

Under the guidance of:

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I hereby declare that this dissertation/thesis entitled **"Clinicopathological Analysis of Breast lump in Females"** is a bonafide and genuine research work carried out by me under the guidance of **Dr.Rajesh P. Bharaney (Head and Professor).**

Date:
Place: Pipariya **DR. KIRTANA S. SHAH**

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It is certified that the study is original.

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Abstract

Introduction:

Breast is a glandular organ which is affected by hormones. Among all the disorders of breast, palpable lump in the breast is the second most common presentation, following pain which is the most common presentation. Being under hormonal control, breast tissue undergoes changes from birth till the end of the reproductive life. The changes in breast of a female are usually associated with inordinate anxiety and apprehension from the patient and her family. As such changes have array of presentations and pathological findings which according to the modern protocol demands a step-wise diagnostic approach involving clinical, radiological and pathological examination.

Materials and Methods:

This prospective study was conducted from October 2015 to September 2017 on female patients admitted to S.B.K.S. Medical Institute & Research Center, Dhiraj General Hospital, Pipariya, Vadodara. 100 female patients with breast lumps were enrolled in this study.

Results and Analysis:

Out of the 100 females having breast lumps that were studied, most presented in 5^{th} decade of life, with predominance towards malignant lesions. Majority of the benign lesions were seen in 3& 4^{th} decade while malignant in 5^{th} decade of life. The most common presenting complain was lump in breast associated with pain. Majority of the females had late presentation after onset of symptoms. Majority of the patient were multiparous. Most patients with benign lesions were premenopausal while most with

malignant were postmenopausal. History of Oral Contraceptive use and that of breast feeding was seen in most females. Approximately half of the females had lumps greater than 2 cms and were hard in consistency. Most common lesion on clinical examination was carcinoma of breast.The most common benign lesion on histopathology examination was fibroadenoma while the most common malignant lesion was invasive ductal carcinoma. Majority of the patients showed up for follow-up upto 1 year. 5 patients with carcinoma of breast had recuurence of ipsilateral breast on follow-up.1 patient each showed liver, lung and skeletal metastasis on follow-up.

Conclusion:

Analytical study of clinic-pathological features of 100 female patients having breast lumps showed that there is alarming high incidence of breast cancer out of which most presented with advanced stages at a later age. Benign diseases were common among the younger age group among which fibroadeomas were the most common. Certain findings on clinical examination allowed accurate differentiation between benign and malignant lumps. Risk factors for development of breast cancer showed strong association with our findings. Discrepancies among the findings established between clinical examination and laboratory findings suggest FNAC and histopathological examination are required investigation for the confirmation of the diagnosis.

Keywords:

Breast lump, FNAC, Fibroadenoma, Carcinoma Breast, Fibroadenosis

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Breast is a glandular organ which is affected by hormones. Among all the disorders of breast, palpable lump in the breast is the second most common presentation, following pain which is the most common presentation [1]. Being under hormonal control, breast tissue undergoes changes from birth till the end of the reproductive life.[2,3] The changes in breast of a female are usually associated with inordinate anxiety and apprehension from the patient and her family. As such changes have array of presentations and pathological findings which according to the modern protocol demands a step-wise diagnostic approach involving clinical, radiological and pathological examination.[5] Early diagnosis is the key to increase in survival rate but social, religious factors, unawareness regarding the fatality of the disease, false vanity and fear of infertility delay the diagnosis as well as the treatment.[6] In lactating females, inflammatory lesions are common while young adults have benign etiologies common for breast lump and malignant lumps are common in old females.[7] Benign breast lesions being the most common presentation in clinical examination accounts for 90% of patients presenting with breast lump.[4] Majority of patients presenting with breast lumps are eventually being diagnosed with benign breast disorders on histopathological examination. As for the many published studies, it has been observed that breast cancer is the most common malignancy in females leading to the assumption that all breast lumps are malignant unless proved otherwise. A proper evaluation of breast lump is required in cases of proliferative breast disease as they have high potential to become malignant and a mammographic evaluation is required even after histopathological diagnosis and excision. A higher risk of developing invasive breast cancer is imposed in patients having complex fibroadenomas. Family history of breast cancer adds up to the risk factor for developing carcinoma of breast.[5] Breast cancer is divided into carcinoma and sarcoma with incidence of

sarcoma being less than 1%. Urbanization and stress may lead to development of breast lesions usually in adults. Incidence of breast cancer is rising in western countries but the mortality rates have decreased due to improved screening and treatment. Gradual rise has been seen in incidence rates of carcinoma of breast in Asia and Africa in recent years leading to awareness among females for this major health issue.[6]

Aim

To analyse the array of presentation and pathology of breast lumps.

Objective

1. To review & study female patients who presented with breast lump.
2. To study the clinical profile of breast lump in females presenting in surgical Out Patient Department.
3. To do histopathological examination of the excised specimen for the confirmation of cytological and clinical diagnosis.
4. To study the management of breast lump according to histopathological diagnosis.
5. To evaluate the pattern of breast lumps in females with special reference to assess the correlation between tumor grade, lymphnodal metastasis and other prognostic factors like tumor size, angiogenesis and expression of estrogen, progesterone receptors and Her2/neu in case of malignant tumors following the cytology report.

History[8-16]

Tumors have existed in animals since prehistoric times even before men existed. The first evidence of cancer cells was found in dinosaur fossils dating back 70-80 million years. The first known malignant tumor was found in Homo Erectus, or Australopithecus which dates back 4.2-3.9 million years ago. Evidence of cancerous cells was found in mummies in Egypt in the Edwin Smith Papyrus which was written approximately 3000BC. In 1750 BC Babylion code of Hammurabi set standard fee for surgical removal of tumors (ten shekels) and penalties for failures. In 1600BC the Egyptians blamed cancer on Gods. Their scrolls describe 8 cases of breast tumors treated by cauterization. Hippocrates and his disciples believed that cancer was initiated by natural causes. They rationalized that excess or deprivation of blood, mucus, bile and other body secretions, particularly at old age, caused cancer. He regarded breast and cervical cancer with bloody discharge as life-threatening tumors and applied only palliative care. In 440 BC the first reported case of human breast tumor was by Greek Historian Herodotus, generally known as the “father of history”. He wrote about Atossa, daughter of Cyrus(Persian King, 600-530 BC) and the wife of Darius I (Persian King, 550-486 BC), stating she “had a tumor on her breast after some time it burst; and spread considerably. As long as it was small she concealed it, and from delicacy informed no one of it; when it became dangerous, she sent for Democedes, a famous doctor of medicine, and showed it to him. In Circa, 250 BC (China) there was first description of clinical picture of breast cancer including progression, metastasis and death and prognosis approximately after 10 years of its diagnosis in The Nei Chang which gave primarily description of tumors and five forms of therapy. In 50 AD, Celus recommended early and aggressive surgical therapy for cancers. He knew that advanced breast cancer have tendency to recur in

the axilla with or without the swelling of arm and by spreading to distant organs may cause death. Greek doctor Claudius Galen (100AD) excised some tumors but he generally believed that cancer was best left untreated. He believed melancholia to be the main factor causing breast cancer. And recommended special diets, exorcism and topical application. Treatment of breast cancer by mastectomy was introduced by Aetius of Amida (562AD), physician to Emperor Justinian in Constantinopole to Theodora. Females of Skoptsy sect in Tsarist Russia conducted mastectomy as a ritual along with castration for men for their belief that sexual desire was evil. La Franc in 13th century, gave the first finding on hoe to differentiate benign tumors of breast from cancer which till then were considered to be breast cancer. In 17th century, Dutch surgeon Adrian Helvetius performed both lumpectomy and mastectomy claiming it to be a cure for breast cancer. German surgeon Wilhelm Fabricium Hildanus removed enlarged lymph nodes in breast cancer surgery. Johann Scultetus performed total mastectomies. In 18th century, Le Dran recognized the spread of breast cancer to regional axillary lymph nodes which had poor prognosis. In 1713, Dr. Bernardino Ramazzini reported absence of cervical cancer and increased incidence of breast cancer in nuns which led to the identification of hormonal factors such as pregnancy and infections related to sexual contact in cancer risk indicating association of lifestyle with development of cancer. John Hunter stated tumors originated in lymphatic system and then migrated and deposited around the body. He suggested that some may be cured by surgery, especially those not invading nearby tissue. In 1890s Professor William Stewart Halsted developed radical mastectomy for breast cancer. In 19th century Dr. Thomas Beatson, by his experiments, on breasts of rabbits which stopped producing milk after removing ovaries, established control of one organ over the other which led him to test the effects of removal of ovaries in patients

with advanced breast cancer which resulted in improvement. Thus discovering the effect of estrogen on breast tumors long before the hormone was discovered which developed foundation of use of hormones and analogs in modern medicine for treating and preventing breast cancer. In 1926 Janet Lane Claypon from her study demonstrate risk factors for development of breast cancer such as nulliparous women, increased age at first pregnancy and not breastfeeding. In 1930-1950s, classification of breast cancer was introduced allowing planning of more individual based treatment. In 1970s Bernard Fisher, USA and Umberto Veronesi, Italy from their study to see whether lumpectomy followed by radiation therapy was an alternative to radical mastectomy in early breast cancer. The results concluded that total mastectomy, lumpectomy or lumpectomy plus radiation therapy had same results. Dr. G. Bonnadona, Milan (1981) conducted first study of adjuvant chemotherapy for carcinoma of breast using 5-fluorouracil, cyclophosphamide and methotrexate which resulted in decrease in recurrence of cancer. In 1994, BRCA1 first known breast and ovarian cancer predisposing gene was discovered.

Normal Anatomy of the Human Breast[17,18]

The breast overlies 2nd to 6th rib extending from lateral border of sternum to the anterior axillary line. The breast lies on the deep pectoral fascia and the fascia of serratus anterior. They are bounded by the clavicle superiorly, the lateral border of latissimus dorsi laterally, the sternum medially, and the inframammary fold inferiorly. The 'Tail of Spence' or axillary tail is an extension of breast tissue extending obliquely into medial wall of axilla.

The structural unit of mammary gland is the lobule. They vary in number and size. The lobules empty into lactiferous ducts through ductules. Each lactiferous duct is lined by a contractile myoepithelial cells and has terminal ampulla.

Ligament of Cooper are hollow conical projections which consist of fibrous tissue filled with breast tissue. The apices are firmly attached to superficial fascia and thereby to skin over the breast. As they are not taut they allow the natural motion of the breast. They relax with the age and hence result in breast ptosis.

The areola contains numerous sweat glands and sebaceous glands (Montgomery's tubercles).

The nipple is covered by thick skin with corrugations. Its apex has orifices of lactiferous ducts. The nipple lies above inframammary crease just lateral to mid-clavicular line.

The muscles that underlie and support the breast tissue are Pectoralis major, Serratus anterior, External oblique and Rectus Abdominis.

Arterial Supply

The blood supply of the breast depends in subdermal plexus which communicates with deeper vessels supplying the breast parenchyma. It is supplied by:

- Internal Mammary perforators (2^{nd} to 5^{th})
- Thoracoacromial artery
- Vessels to Serratus Anterior
- The lateral thoracic artery
- Terminal branches of 3^{rd} to 8^{th} intercostal perforators.

The superomedial perforator, branch of internal mammary vessels provide 60% of total blood supply to the breast.

Venous Drainage

The venous drainage is mainly into axillary vein. The other veins that drain the breast are subclavian, intercostal and internal thoracic veins.

Nerve Supply

- Sensory innervation is dermatomal in nature, mainly from anterolateral and anteromedial branches of thoracic intercostal nerves T3-T5.
- Upper and lateral portions of the breast is supplied by the Supraclavicular nerves from the lower fibres of cervical plexus.
- Nipple gets the innervation from lateral cutaneous branch of T4.

Lymphatic Drainage:

Breast predominantly drains into axillary (85%) and internal mammary lymph nodes.

The axillary Lymph nodes are arranged in the following groups:

- Lateral: along axillary vein
- Anterior: along lateral thoracic vessels
- Posterior: along subscapular vessels
- Central: embedded in fat in center of axilla
- Interpectoral: in between pectoralis major and minor muscles.
- Apical: above level of pectoralis minor tendon in continuation with lateral nodes which receive efferents of all other groups and also with supraclavicular nodes which further drain into subclavian lymph trunk entering the great veins directly or through thoracic duct or jugular trunk.

Sentinel node is the first lymph node which drains the tumor bearing area of the breast

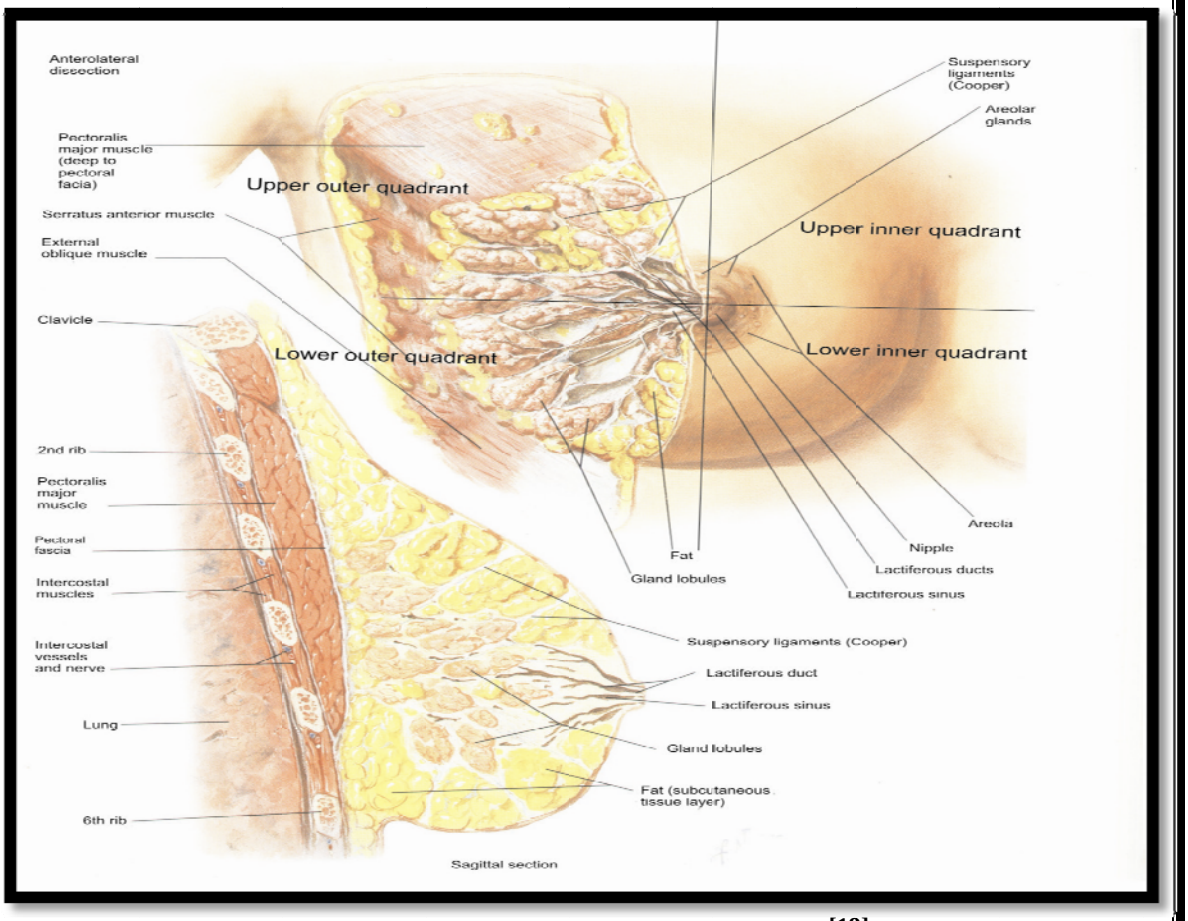


Fig 1. Normal Anatomy of the breast.[19]

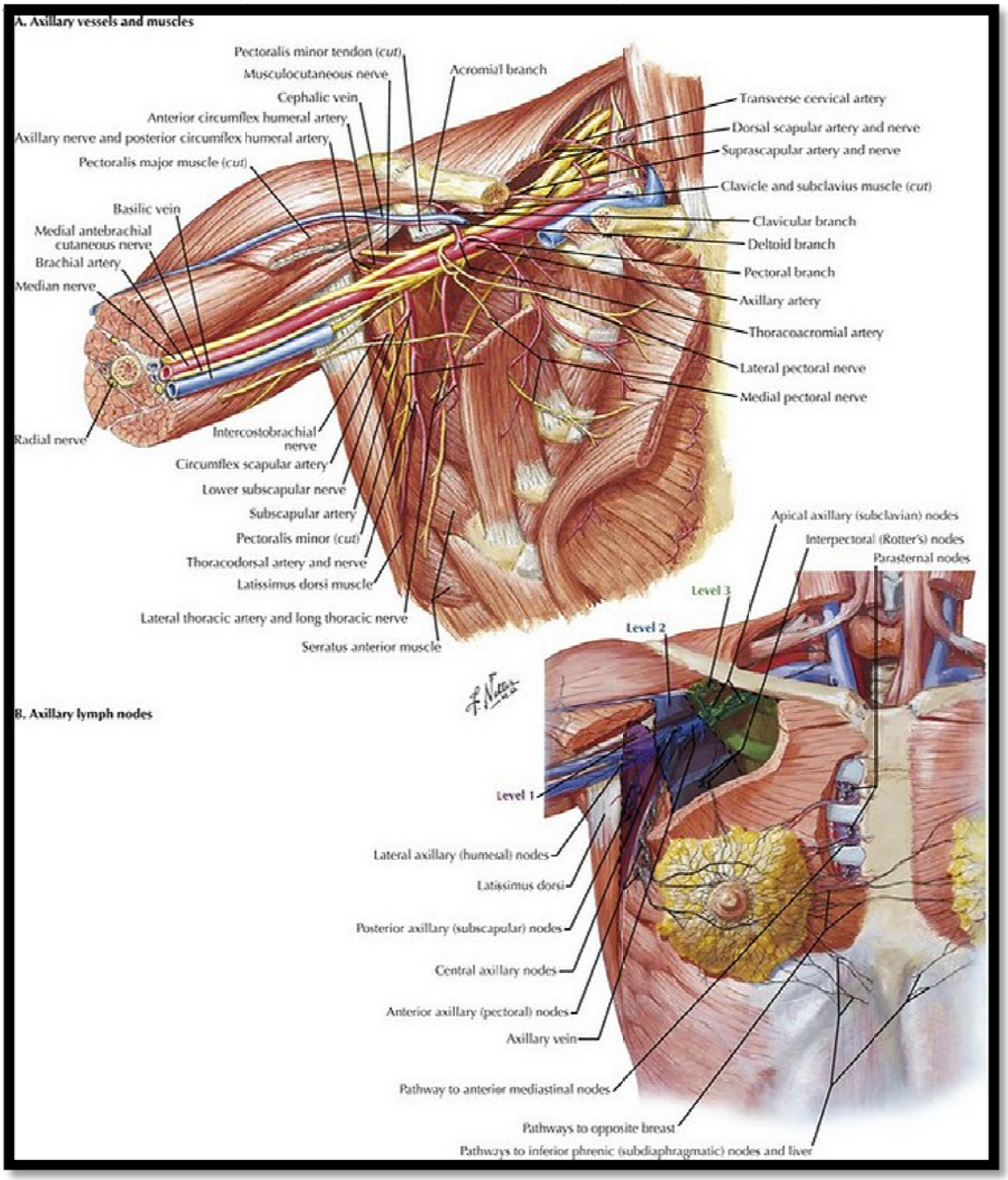


Fig 2. Blood supply and Lymphatic Drainage of the Breast.[19]

Histology[20,21]

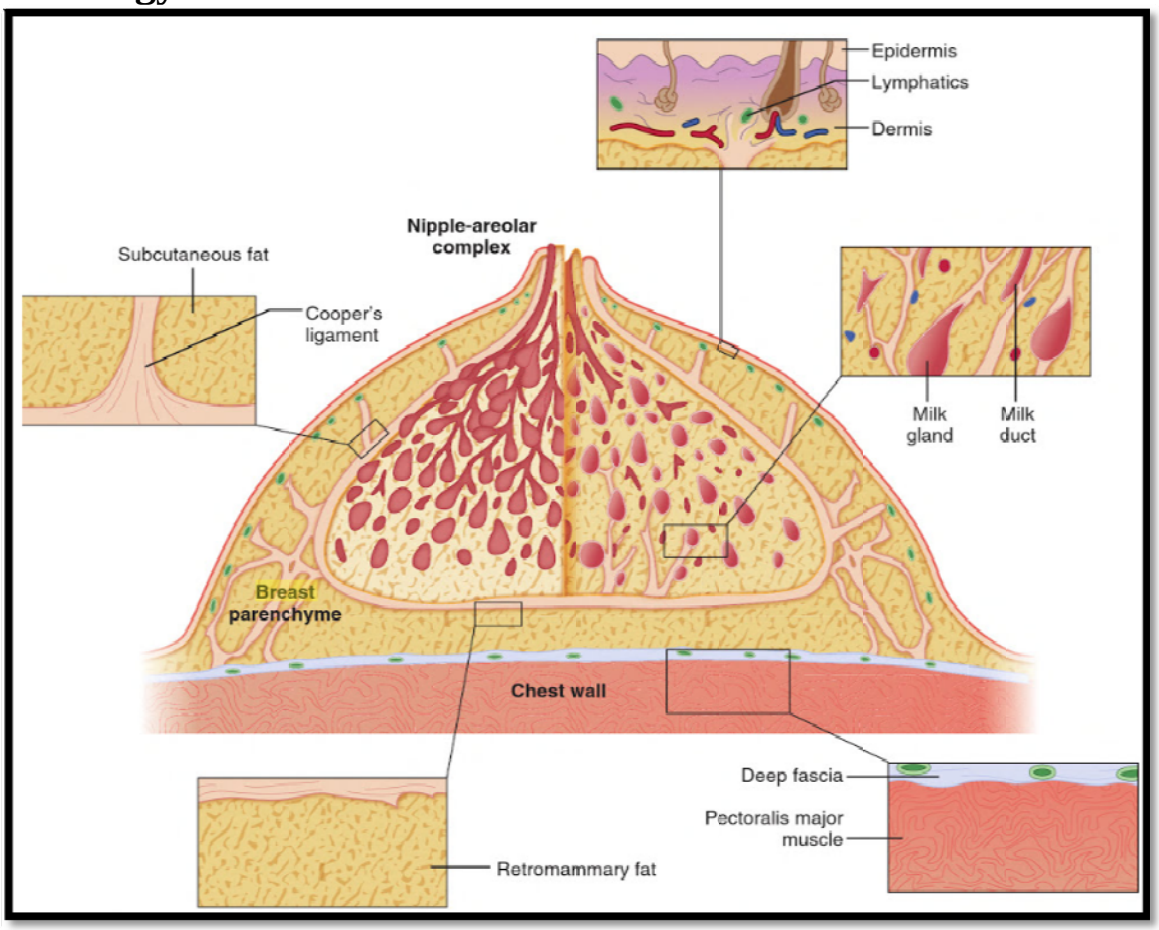


Fig 3 Cut-away diagram of a mature resting breast.[22]

Breast tissue comprises of epithelial as well as stromal components. Ductolobular system is composed of two layer of epithelia lying over a basement membrane ('Basal Lamina') and covered by stroma.

Epithelial Cells: Extralobular Pseudostratified columnar epithelium forms the inner layer of two-layered ductolobular system. The myoepithelium forming the outer layer rests on the basement membrane. This having contractile properties aids in propelling milk formed in lobules towards the nipple.

Basement Membrane: It is partially covered by contractile meshwork that contains type IV collagen, laminin and proteoglycans. It surrounds mammary ducts, ductules & acini separating ductal system from surrounding stroma. This layers is an important layer for differentiating in situ from invasive ductal carcinoma. In Cancinoma in situ

the integrity of the basement membrane is maintained while in invasive variant the membrane integrity of the membrane is disrupted and there is invasion of stroma.

The branching system of ducts organized in radical pattern spreading outward and downward from nipple-areolar complex, constitutes the glandular apparatus of the breast. This aids in cannulating individual ducts and visualize the lactiferous ducts with contrast agents. The dye only enters a single ductal system. It does not enhance the adjacent or intertwined branches from functionally independent ductal branches. There is a dilated portion of each ductal system below the nipple-areolar complex. The ducts converge through a orifice into ampulla of nipple.

Stroma:

Interlobular Stroma: It surrounds large ducts and terminal duct lobular units. It is dense and more collagenous than intralobular connective tissue.

Intralobular Stroma: It surrounds acini with terminal duct lobular units. Here the stroma is loose and contains fibroblasts, scattered lymphocytes, plasma cells, macrophages and vessels. It is responsive to hormones. There are no elastic fibres. It may appear myxoid.

Nipple Areolar Complex: It consists of dense fibrous stroma with bundles of smooth muscle tissue. It contains numerous sebaceous glands, devoid of hair follicles except at periphery of areola. Montgomery tubercles are sebaceous gland sharing an ostium with lactiferous duct. They may also contain apocrine glands. They also contain Toker cells which are clear cells basally located in epidermis.

Diagnosis:

The diagnosis of the patient with breast lump is best done by Tripple assessment:

Tripple assessment includes:

Physical examination

Mammography

Fine-needle aspiration cytology

Mammography[23,24]

Mammography is primary imaging modality for screening of asymptomatic women. During this screening mammography, breast is compressed between plates which reduces the thickness of tissue through which the radiation has to pass, separates the adjacent tissues and improves resolution. Here two views of each breast are taken- the mediolateral oblique and craniocaudal. To further evaluate the abnormalities which are detected on screening mammography, diagnostic mammography is done which helps evaluate calcifications on magnification views and gives additional information on compression views when mass lesion is suspected.

In 1913 Albert Salomom first tried to visualize tumors with the help of radiology and demonstrated their spread to axillary lymph nodes. In 1930s Stafford L Warren was the pioneer to use mammography for detection of breast cancer during pre-operative assessment. In 1931 Walter Vogel gave radiographic classification of benign breast lesions and described how X-rays could detect differences from malignant lesions. In 1938, Jacob Gershon Cohen and Albert Stickler described range of normal radiographic appearances of breast corresponding to age and menstrual status and described the use of mammography as a screening tool for healthy women for breast cancer.In 1949, Raul Leborgne reported finding microcalcification in upto 30% of patients with breast cancer. In late 1950s Robert Egan invented a new technique of

screening mammography which was high milliamperage- low kilovoltage technique. In 1960s, Mammography, as a screening tool, became widely popular. In 1963 to 1966, Philip Strax, Louis Venet and Sam Shapiro by their study, proved that mammography reduced breast cancer death by one-third. In 1969, first X-ray units dedicated for breast imaging became available. In 1973, in a study by National Cancer Institute, concluded that women having benign tumors and growths had undergone breast surgery which were unnecessary. In 1976, mammography as a screening device became a standard protocol. In 1992, Congress passed the Mammography Quality Standards Act, which made sure that all women have access to mammography for detection of breast cancer. In 1993, a common terminology was created by The American College of Radiology, known as Breast Imaging and Reporting and Data System.(BI-RADS). In 2000, FDA approved the first digital mammography system. In 2009, it was reported by The American cancer Society, that the deaths due to breast cancer are down by 30% due to early detection and treatment due to the use of mammography. In 2011, Hologic's 3D mammography technology was approved by FDA. In 2014, it was reported by Journal of American Medical Association that Hologic's 3D Mammography technology finds significantly more invasive cancers than the traditional mammogram.

The most recent and used advances in mammography involves:

Digital mammography or Full-field Digital mammography.

Computer aided Detection (CAD).

Fine Needle Aspiration Cytology[25]

In the 17th century in Holland and Italy first microscope which can be used practically was his d constructed. Anthony Van Leeuwenhoek improvised the instrument which provided the magnification of ×275. His observations have ranged from bacteria to spermatozoa. Robert Hooke, along with this instrument used a focusing adjustment in 1665 and observed that corks and sponges are composed of little boxes called cells. The significance of this observation was not understood for the next 200 years. Malpighi, Iltalian anatomist was considered the creator of histology. Invention of achromatic lenses gave the decisive knowledge of cell and tissue structure. In 1820s, in London (by Lister) and in Paris (by Chevalier) compound microscopes with such optics were developed. During the first half of 19th century all microscopic observations were done on the cells as techniques for tissue processing were very primitive. The most significant record of such findings was given by French Microscopist, Andre Francois Donne in 1845. It was based on the newly described technique given by Daguerre. Rudolf Virchow in the middle of the 19th century stated that each cell is derived from another cell. Lionel Beale in 1858, in his book "The Microscope in its Application to Practical Medicine" has stated the method of hardening of soft tissue samples by boiling, method of preparing transparent thin sections which can be used for microscopic examination and also hand-held cutting instruments. Later on, chromium salts, alcohol and finally formalin was put to use for tissue fixation. Around 1880 mechanical microtomes had replaced manual cutting instruments. By 1885, tissue embedding in wax or paraffin, use of microtome for cutting and use of hematoxylin and eosin stain for staining had become a standard practice. Significance and value of tissue pathology was enhanced by two events. First, the Ruge and Veit in 1877 first gave the concept of tissue biopsy for diagnosis

of carcinoma of cervix and entometrium. Second, In 1895, Cullen popularized the concept of frozen section which allowed rapid processing of the tissues. In 18th and 19th century when the autopsy pathology was the mainstay for classification of diseases, along with that histopathology became the dominant diagnostic tool of human pathology. French Physician Kun and German-Swiss pathologist Lebert, in 1847 and 1851, described the use of cannula to aspirate cell samples from palpable tumors and use of microscope to identify the pathology. Two British military surgeons, Greig and Gray in 1905, aspirate swollen lymph nodes with needle and syringe from patients with sleeping sickness to diagnose mobile trypanosoma. Hirschfeld in 1912 was the first person to use small caliber needle and gave first aspiration diagnosis of solid tumor of skin. James Ewing between 1910 and 1940 has made significant contribution in classification and identification of human cancer. Hayes Martin due to his aversion of operating without a tissue diagnosis started to aspirate palpable tumors of various organs with large bore needle and Record syringe. The tissue were processed according to the method given by Edward Ellis. Dr. Fred W Stewart, embedded tissue fragments in paraffin and processed them as cell blocks. Palpable lumps of lymph nodes, breast and thyroid were primary targets of aspiration. In 1933 in "The Diagnosis of Tumor by Aspiration" he has described his experience. Sixten Franzen and Josef Zajicek applied the use of thin needle technique first to prostate and then to broad range of body organs, from salivary glands to skeleton. Franzen described the syringe which allowed performance of aspiration with one hand while the other steadied the lesion. That technique has become the popular and is also being used in recent times.

WHO Classification of Epithelial Breast Tumors (Modified)[26]

A. Benign

1. Inraductal Papilloma
2. Adenoma of nipple
3. Adenoma
    a. Tubular
    b. Lactating
4. Fibroadeoma
5. Others

B. Malignant

1. Noninvasive
    a. Intraductal Carcinoma
    b. Lobular carcinoma in situ
2. Invasive
    a. Invasive ductal carcinoma
    b. Invasive ductal carcinoma with a predominant intraductal component
    c. Invasive lobular carcinoma with a predominant in situ component
    d. Mucinous carcinoma
    e. Medullary carcinoma
    f. Papillary carcinoma

g. Tubular carcinoma

h. Adenoid cystic carcinoma

i. Secretory or juvenilr carcinoma

j. Apocrine carcinoma

k. Carcinoma with metaplsia

1. Squamous type

2. Spindle cell type

3. Cartilaginious and osseous type

4. Mixed type

l. others

3. Paget’s disease of nipple

4. Phyllodes tumor

Breast Cancer can be graded cytologically by 3 systems[27]

I Hunt's cytological grading

II Modified Black grading system

III Simplified Black Grading System

The Simplified Black grading system; among the three correlates to a greater degree with Modified Scarff Bloom Richardson (Nottingham) histological grading.

Nottingham Modification of Scarff Bloom Richardson Grading System

A) MITOTIC COUNT

1 point- 0-5/hpf

2 points- 6-10/hpf

3 points- >11/hpf

B) TUBULE FORMATION

1 point- tubular formation in more than 75% of the tumor

2 points- tubular formation in 10-75% of the tumor

3 points- tubular formation in less than 10% of the tumor

C) NUCLEAR PLEOMORPHISM

1 point- nuclei with minimal variation in size and shape

2 points- nuclei with moderate variation in size and shape

3 points- nuclei with marked variation in size and shape

Grade I- 3 to 5 Points

Grade II- 6 to 7 Points

Grade III- 8 to 9 Points

Staging of Carcinoma Breast [28]

TNM staging (AJCC Cancer Staging Manual, 2002, Sixth Edition)

Tumor:

T_x- Tumor cannot be assessed.

T_o- No evidence of primary

T_{is}- Carcinoma in situ (DCIS or LCIS)

T_{is} Paget's- Paget's disease of nipple with no tumor (with tumor underneath is stage according to size)

$T_{1\ mic}$- Microinvasion <0.1cm

T_1- Tumor size <2cmin greatest diameter (T1a-0.1-0.5cm; T1b- 0.5-1.0cm; T1c-1-2cm)

T_2- Size 2-5cms

T_3- Size>5cms

T_4-Tumor fixed to chest wall or skin (T4a- fixed to chest wall, T4b- fixed to skin, T4c-T4a + T4b, T4d- inflammatory carcinoma breast)

Node:

N_x- Nodes cannot be assessed

N_0- No nodes

$N_{1\ mic}$- Node with micrometastasis

N_1- Axillary nodes- ipsilateral, mobile, discrete

N_2-

N_{2a}- Axillary nodes- ipsilateral fixed to one another and other structures.

N_{2b}- Clinically apparent and ipsilateral interal mammary nodes in the absence of clinically palpable axillary nodes.

N_3-

N_{3a}- Spread to ipsilateral infraclavicular lymph nodes with or without axillary nodes.

N_{3b}- Spread to ipsilateral internal mammary nodes and axillary nodes.

N_{3c}- Spread to ipsilateral supraclavicular lymph nodes with/without axillary or internal mammary nodes.

Metastasis:

M_x-Metastasis cannot be assessed.

M_0- No metastasis

M_1- Distant metastasis.

Stage I- $T_1N_0M_0$

Stage IIa- $T_0N_1M_0$; $T_1N_1M_0$; $T_2N_0M_0$

Stage IIb- $T_2N_1M_0$; $T_3N_0M_0$

Stage IIIa- $T_0N_2M_0$; $T_1N_2M_0$; $T_2N_2M_0$; $T_3N_1M_0$; $T_3N_2M_0$

Stage IIIb- $T_4N_0M_0$; $T_4N_1M_0$; $T_4N_2M_0$

Stage IIIc- any TN_3M_0

Stage IV- Any T, any N, M

Early breast cancer- Stage I and II; T_1N_1, T_2N_1; T_3N_0

Locally advanced breast cancer (LABC)- Stage IIIA, IIIB

Metastatic Breast Cancer- Stage IV

This prospective study was conducted between October 2015 to September 2017 on female patients admitted to Dhiraj General Hospital, S.B.K.S. Medical Institute & Research Center, Pipariya,Vadodara, with the presentation of breast lumps. A sample size of 100 patients was observed in this study.

INCLUSION AND EXCLUSION CRITERIA:

Inclusion criteria:

1. All the patients referred to or admitted under the departments of General Surgery with the presentation of breast lump.

Exclusion criteria:

1. Patient not willing for study.
2. Patient with immunocompromised status, comorbid factors like cardiac / respiratory diseases, organ failure were excluded.

METHOD OF COLLECTION OF DATA

On admission, history was collected and thorough physical examination was done. Data collection on admission including age, address and clinical presentation with respect to site /size/ onset duration and progress of lump was done. History of previous illnesses, admission surgeries and co-morbidities will be noted.Family history for breast lumps was extracted.

Clinical examination of lump with respect to exact location, size, consistency, fixity to skin/ deeper structures, nipple changes, presence of palpable axillary lymph nodes and examination of the opposite breast in case of unilateral lesions was done.Routine investigations like complete hemogram, Blood urea, Random blood sugar, Serum electrolytes and Serology was carried out.Ultrasonography of breast followed by FNAC was done.

The treatment plan was focused on initial diagnosis followed by wither medical or surgical management based on the diagnosis and if necessity with diagnosis neo-adjuvant chemo-radiotherapy based on histopathological report.

Data like clinical symptoms, results of investigations, complications, surgical procedures, duration of hospital stay was carefully recorded.

Patients will be asked to follow up on OPD basis 2 weeks and 3 months after discharge. Patients with fibroadenoma less than 5 cmsnot treated with surgical management were advised for follow up at regular intervals.

Proforma

- Name:
- Reg. No.:
- Age/Sex:
- Ward:
- Address:
- Date of Admission:
- Date of Surgery:
- Date of Discharge:
- Clinical History:
- Occupational History:

Presenting Complains:

- Lump in breast.
- History of Trauma
- Association with pain
- Nipple discharge
- Ulceration
- Retraction of nipple
- Menstrual history and its relation to lump
- Duration and Progress of lump
- History of Rapid Growth
- Associated swelling in Axilla
- Change in the size of the lump

Past History:

- History of similar complaints in association with its regression or not
- History of DM / HT / Trauma / Dietary Habits / Addiction.
- History of previous surgery.

Family History:

- History of Similar Complains
- History of Breast Cancer in mother, grandmother or daughter
- History of Gastrointestinal or Ovarian Malignancy
- History of any major illnesses.

Personal History:

- History of breast feeding:
- Diet:
- Lump discovered by:

Menstrual History:

- Menstruating/ Menopausal:
- Duration between the cycles
- Duration of menstruation
- Relation of swelling with menstruation
- Age of Menarche and Menopause.

Obstetric History:

- Total number of Pregnancies
- Age at first pregnancy
- Age of last pregnancy
- History of any abortions
- Mode of delivery
- Last child birth
- History of Oral Contraceptive Use/ hormone replacement therapy use
- Type of Oral Contraceptive Pills

CLINICAL EXAMINATION

Vitals:

- General Condition
- Blood Pressure
- Pulse
- Temperature
- Respiratory Rate
- Pallor / Icterus / Cyanosis / Clubbing / Oedema / Lymphadenopathy

Local examination:

Inspection: (diseased breast)

- Symmetry and position of breast in comparison to normal side
- Size and shape of the breast in comparison to normal side.

- Nipple: Position in comparison to normal side

  Size and shape

  Surface

  Displacement

  Retraction

  Ulceration

- Areola: Size

  Diminution in size due to retraction

  Texture

  Discharge

- Skin over the breast:
- Swelling in the breast: Position in relation to the quadrant

  Extent

  Size and Shape

  Surface and margin

  Skin over the swelling

- Edema of the arm:
- Done with arms raised above the head:
- Patient sitting and leaning forward:
- Patient sitting and pressing her waist with hands:
- Opposite breast:

Palpation:

Opposite breast

(diseased breast)

- Temperature
- Tenderness
- Any Palpable lump: position in relation to quadrant

  Sizeand Shape

  Surface and Margin

  Consistency

  Fixity to skin

  Fixity to breast tissue

  Fixity to underlying pectoral fascia and pectoralis major muscle

  Fixity to chest wall

  Fixity to serratus anterior

  Fluctuation and transillumination

Examination of the axilla: (For regional lymph nodes)

- Level I: anterior (pectoral) / lateral/ posterior
- Level II: central
- Level III: apical
- Examination of Supraclavicular lymph nodes:
- Examination of opposite axillary lymph nodes

Systemic Examination:

RS

CVS

CNS

Per Abdomen:

Clinical Diagnosis:

Investigations:
Mammography
USG breast
FNAC

Management:
Medical/Surgical

Histopathology report:

Final Diagnosis

Outcome:
Discharged/ Mortality

Follow up period:

Chemotherapy cycles taken: (if applicable)

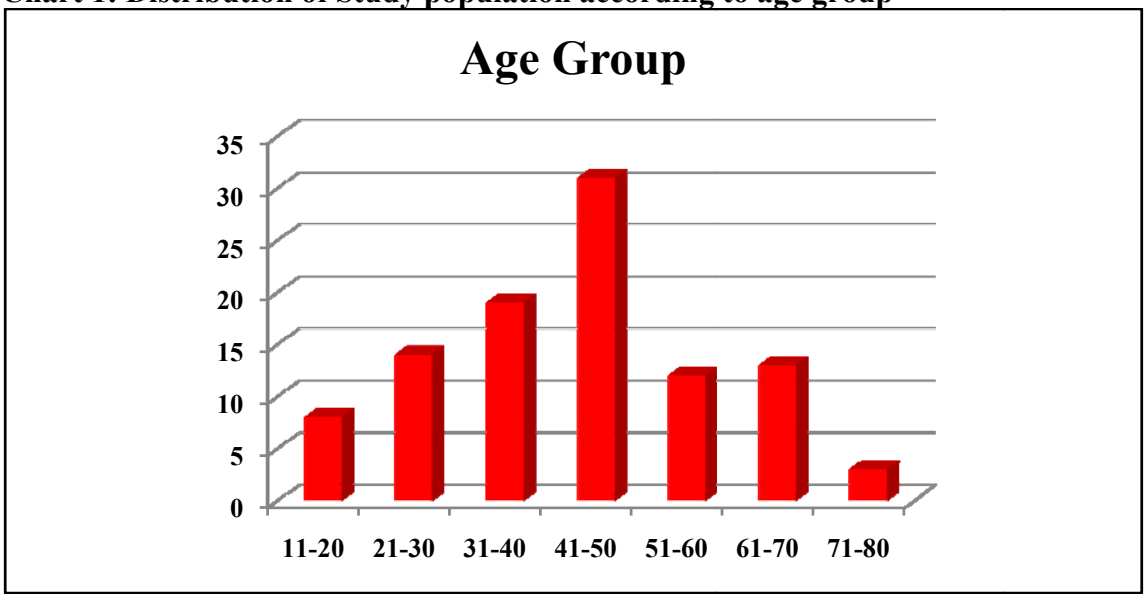
In the present study a total of 100 female patients were studied.

The youngest patient in this study was 16 years while the oldest patient was 80 years with a mean of 44.17 years. The maximum patients were in the age group of 41-50 years followed by the age group of 31-40 years.

Table 1: Distribution of Study population according to age group

Age	Frequency	Percentage
11-20	8	8
21-30	14	14
31-40	19	19
41-50	31	31
51-60	12	12
61-70	13	13
71-80	3	3
Total	100	100

Chart 1: Distribution of Study population according to age group

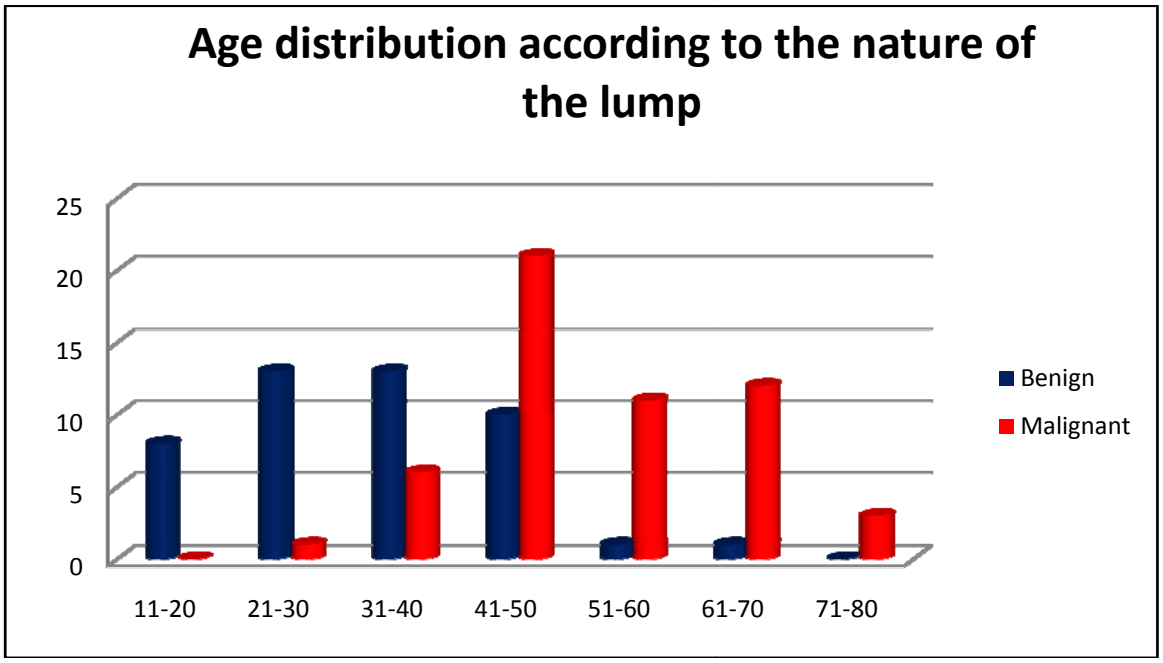


The malignant lumps were seen in the age range of 30 to 80 years, most between 41-50 years with a mean age of 53.03 years while benign lumps were seen in the age range of 16 to 65 years, most in 21-40 years with a mean age of 33.76 years.

Table 2: Distribution of study population according to the nature of the lump.

Age	Benign	Malignant	Total
11-20	8	0	8
21-30	13	1	13
31-40	13	6	20
41-50	10	21	31
51-60	1	11	12
61-70	1	12	13
71-80	0	3	3
Total	46	54	100

Chart 2: Distribution of study population according to the nature of the lump.

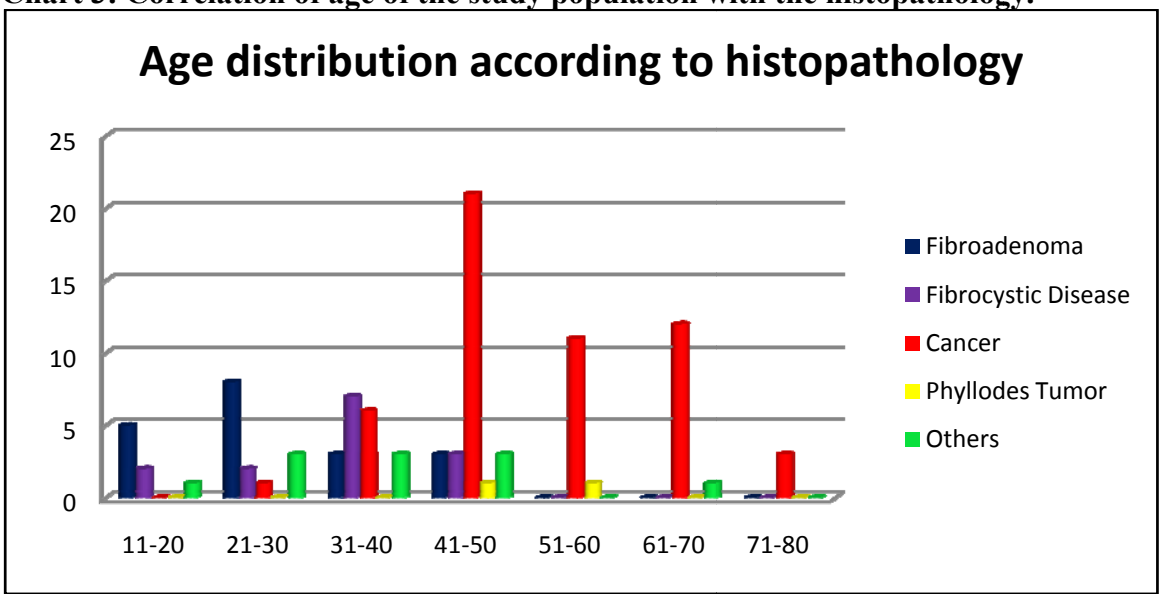


Fibroadenomas were mostly seen in younger age group (21-30), fibrocystic disease was seen in 31-40 year age group while carcinoma of the breast were mostly seen in older age group(41-50).

Table 3: Correlation of age of the study population with the histopathology.

Age range	Fibroadenoma	Fibrocystic Disease	Cancer	Phyllodes Tumor	Others	Total(%)
11-20	5	2	0	0	1	8
21-30	8	2	1	0	3	14
31-40	3	7	6	0	3	19
41-50	3	3	21	1	3	31
51-60	0	0	11	1	0	12
61-70	0	0	12	0	1	13
71-80	0	0	3	0	0	3
Total	18	13	54	2	13	100

Chart 3: Correlation of age of the study population with the histopathology.

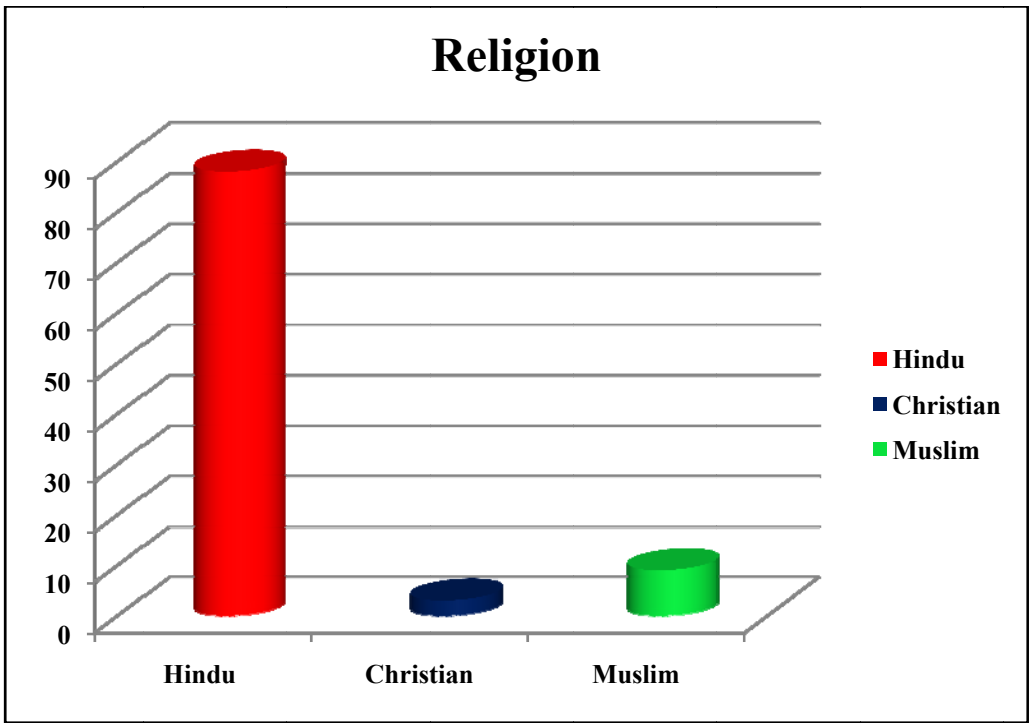


The majority of the females were Hindu (88%) followed by Muslim(9%).

Table 4 : Distribution of Study population according to religion

Religion	Frequency	Percentage
Hindu	88	88
Muslim	9	9
Christian	3	3
Total	100	100

Chart 4: Distribution of Study population according to religion

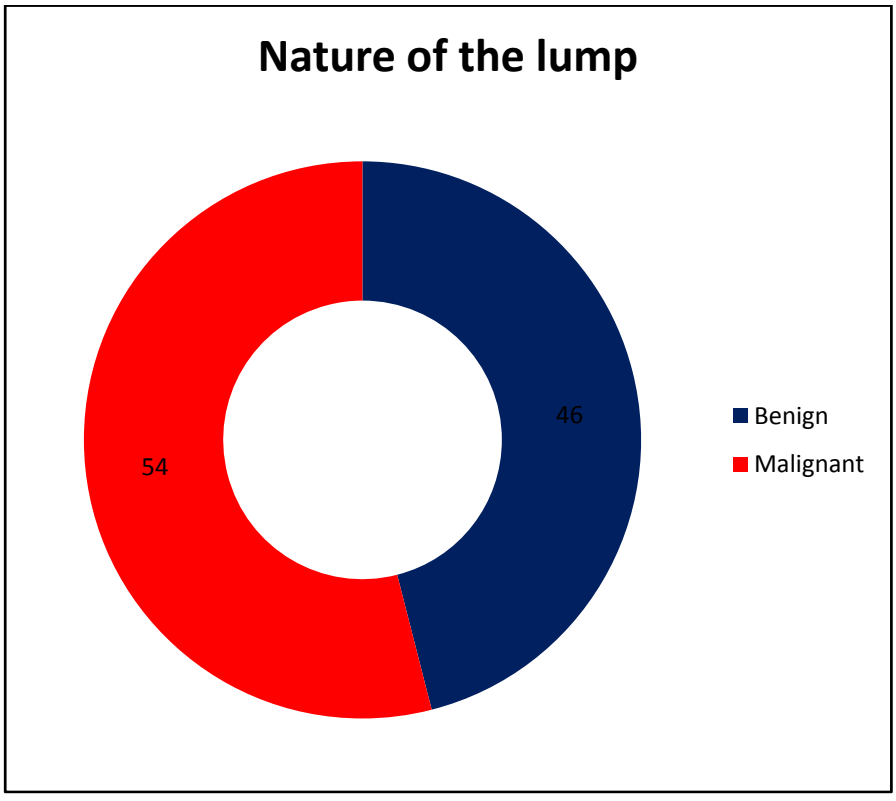


Out of the 100 patients studied 46 had benign breast lumps whereas 54 had malignant breast lumps, the ratio being 1:1.17 for benign to malignant.

Table 5: Distribution of the study population according the nature of breast lumps

Nature	Frequency	Percentage
Benign	46	46
Malignant	54	54
Total	100	100

Chart 5: Distribution of the study population according the nature of breast lumps

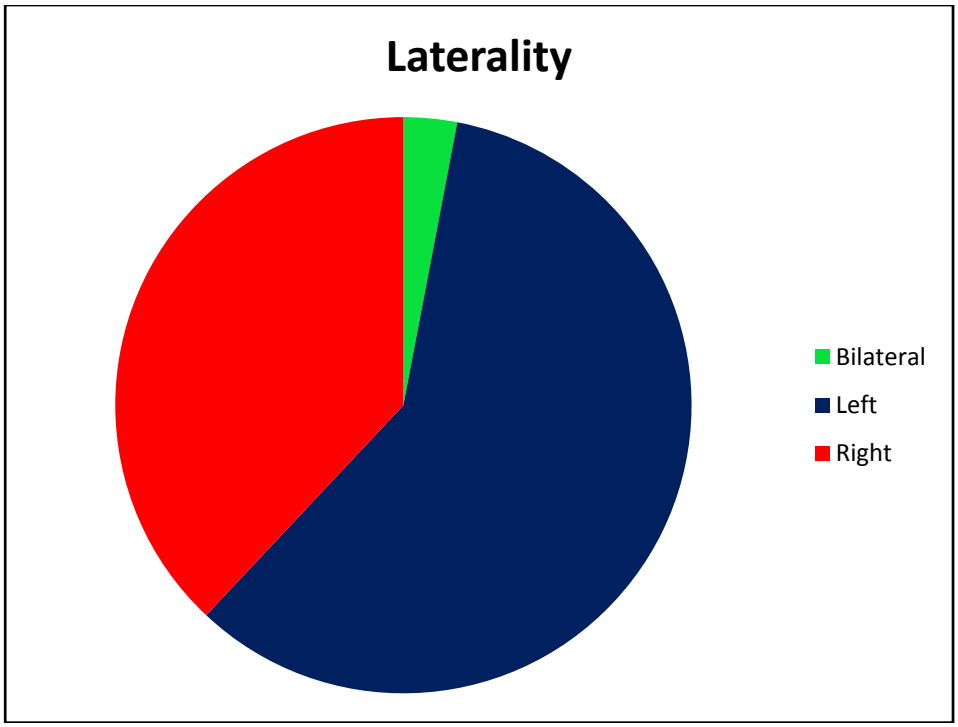


97 females had lump in one breast while 3 had lumps in both the breasts. 59 had breast lump in left breast while 38 had lumps in right breast.

Table 6: Distribution of the study population according to laterality.

Laterality	Frequency	Percentage
Left	59	59
Right	38	38
Bilateral	3	3
Total	100	100

Chart 6: Distribution of the study population according to laterality.

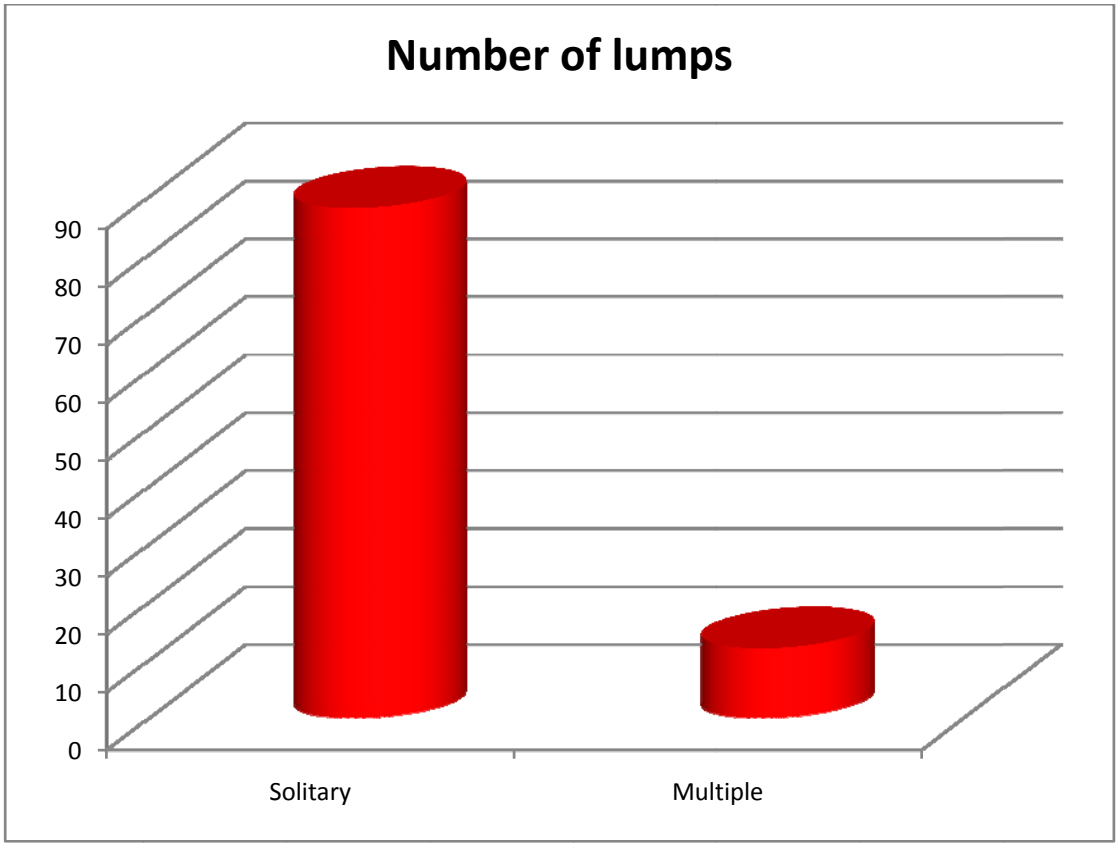


In the 100 females studied, 88 had solitary lumps, while 12 had multiple lumps. Out of the 12 females with multiple lumps, 9 had multiple lump in the same breast but different quadrants and 3 had lumps in different breasts. Those were the females with bilateral breast lumps.

Table 7: Distribution of study population on the basis of number of lumps.

Number of lumps	Frequency	Percentage
Solitary	88	88
Multiple	12	12
Total	100	100

Chart 7: Distribution of study population on the basis of number of lumps.

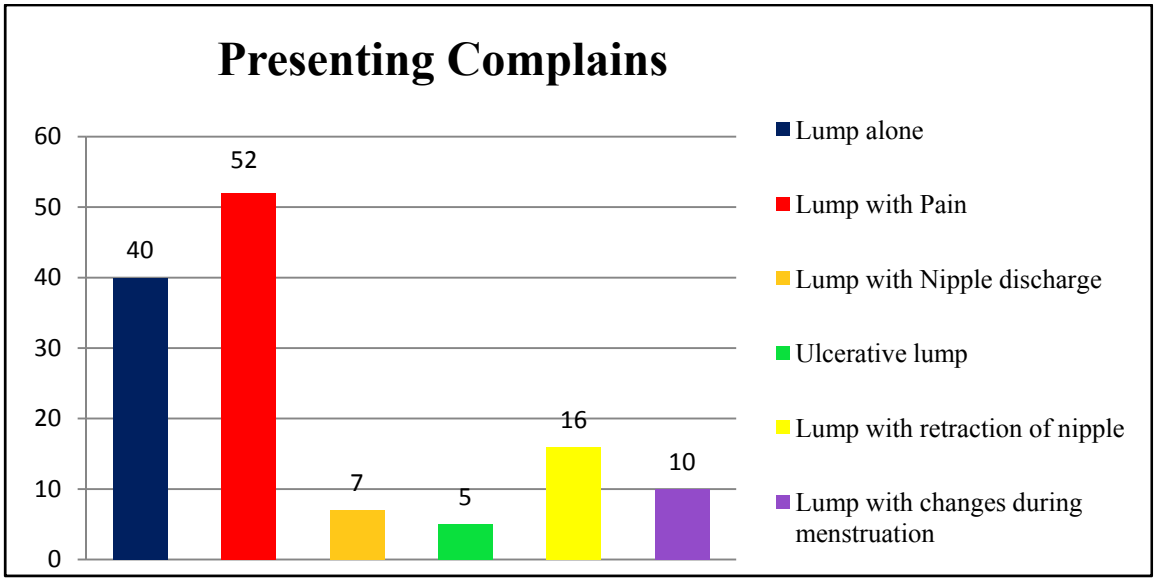


The females presented with complains ranging from lump in breast to ulcerative lump with bloody nipple discharge. Among the 100 females study, 40 females presented only with complains of lump in breast, 52 presented with complain of lump in breast with pain, 7 females presented with complains were of lump in breast with nipple discharge, 5 females had complains of ulcerative lump in breast.

Table 8: Distribution of study population according to presenting complains.

Complain	Frequency
Lump alone	40
Lump with Pain	52
Lump with Nipple discharge	7
Ulcerative lump	5
Lump with retraction of nipple	16
Lump with changes during menstruation	10

Chart 8: Distribution of study population according to presenting complains.

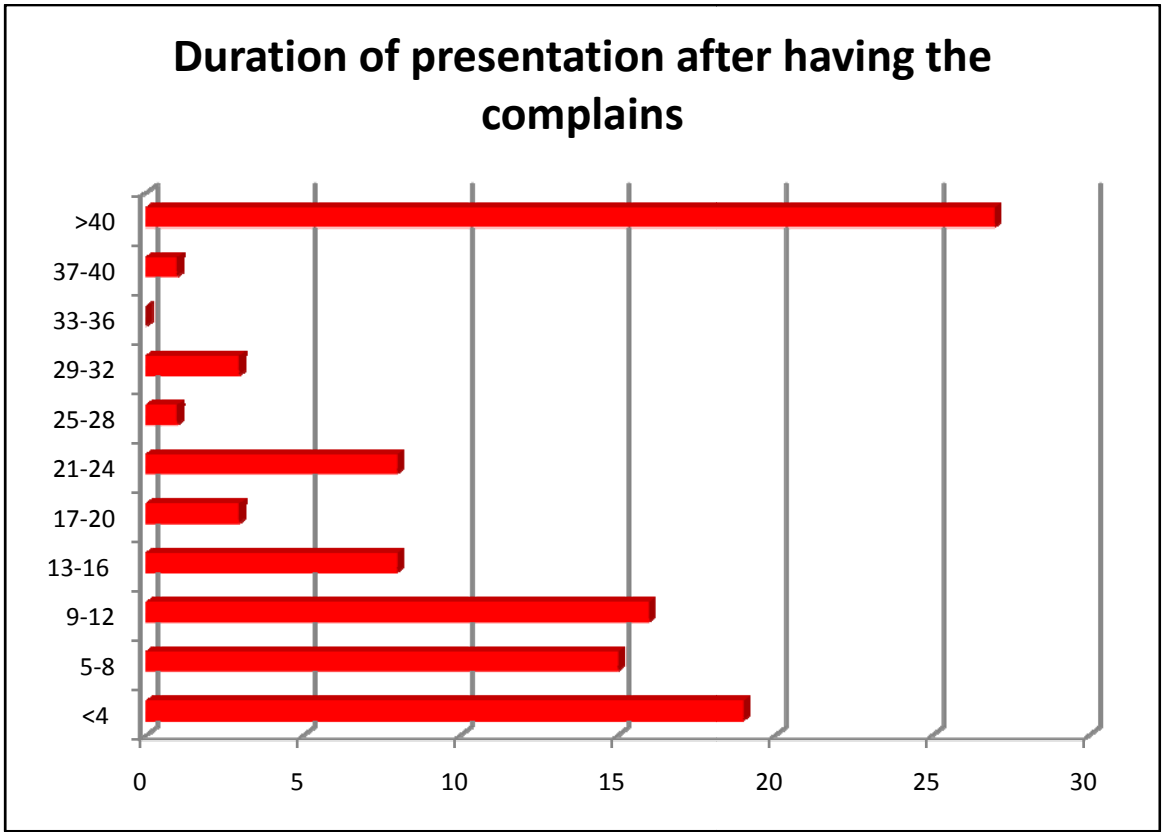


The duration of complains ranged from 1 week to 520 weeks having an average of 43.82 weeks. Only 19 patients presented before 4 weeks after having the complains. Most patients (81) showed late presentation (>4 weeks).

Table 9: Distribution of Study population based of duration of presentation after having the complain.

Duration (in weeks)	Frequency	Percentage
<4	19	19
5-8	15	15
9-12	16	16
13-16	8	8
17-20	3	3
21-24	8	8
25-28	1	1
29-32	3	3
33-36	0	0
37-40	1	1
>40	27	27
Total	100	100

Chart 9: Distribution of Study population based of duration of presentation after having the complain.



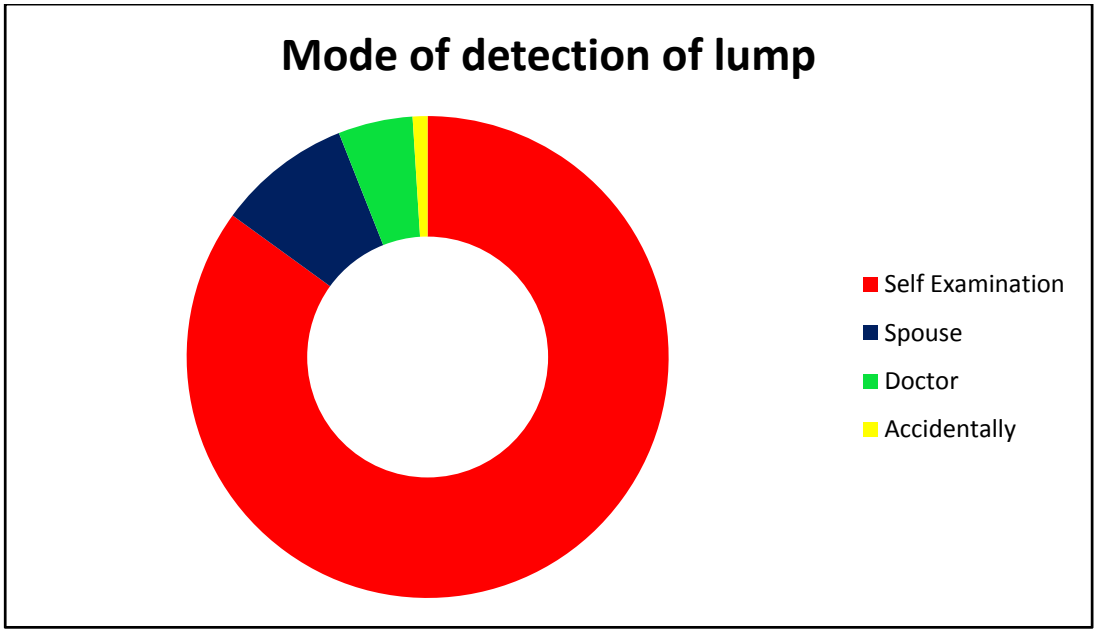
In the 100 females presenting with breast lumps, 5 patients had the history of trauma following which there was lump formation. All these females had benign pathologies for the development of the lump.

The breast lump was found by self examination in 85 females, while it was found by their spouses in 9 females. In 5 females the lump was discovered by the doctor and in 1 female the lump was accidentally been found.

Table 10: Distribution of study population on the basis of the discovery of the lump

Lump discovered by	Frequency	Percentage
Self Examination	85	85
Spouse	9	9
Doctor	5	5
Accidentally	1	1
Total	100	100

Chart 10: Distribution of study population on the basis of the discovery of the lump

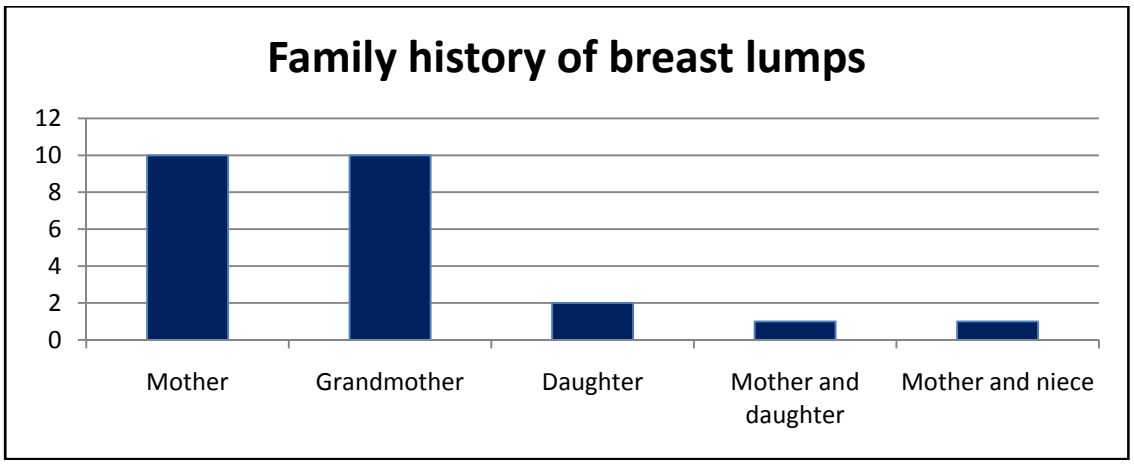


24 females had family history of breast lumps among the 100 females studied. Out of them 10 had mother with history of breast lumps, 10 had history of grandmother with breast lump and 2 had a daughter with a history of breast lump. 1 patient had a mother as well as a daughter with the history of breast lump. While one patient had a mother as well as a niece with the history of carcinoma of breast.

Table 11: Distribution of Study population on the basis of family history of breast lumps.

Relation	Frequency	Percentage
Mother	10	41.6
Grandmother	10	41.6
Daughter	2	8.4
Mother and daughter	1	4.2
Mother and niece	1	4.2
Total	24	100

Chart 11: Distribution of Study population on the basis of family history of breast lumps.



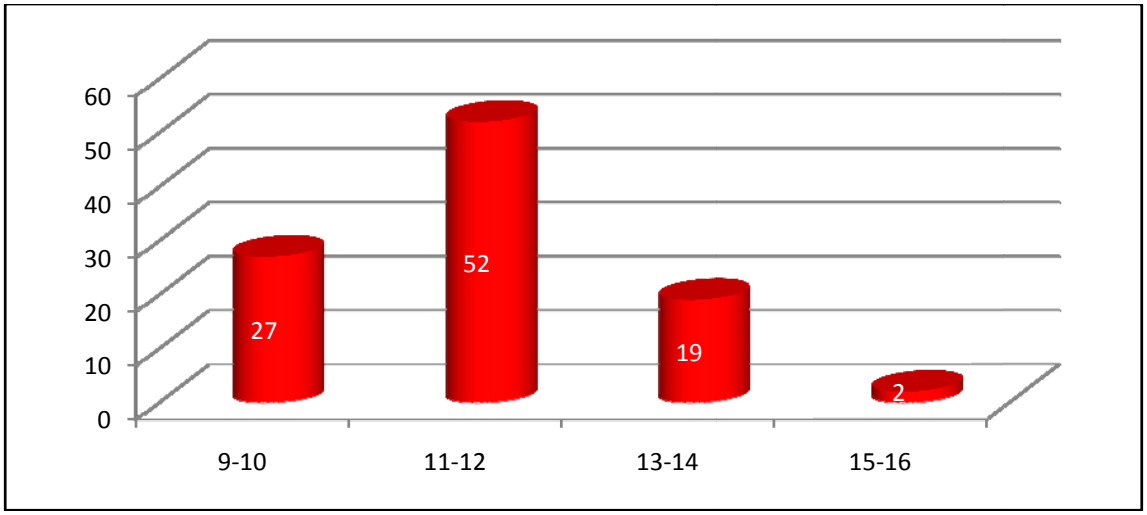
History of previous ovarian malignancy was seen in only 1 patients while 1 patient was treated for gastric malignancy earlier. Both these patients had malignant lumps. 5 patients earlier had breast lumps for which they were operated. Only 1 patient out of those 5 had malignant lump the rest had lumps with benign etiologies.

The onset of menarche was maximum between 11-12 years in 52 females, followed by 27 females in the age 9-10 years. Out of the 54 ptients having malignant lumps 47 patients had early menarche; i.e. till 12 years of age.

Table 12: Distribution of Study population according to age at menarche

Age	Frequency	Percentage
9-10	27	27
11-12	52	52
13-14	19	19
15-16	2	2
Total	100	100

Table 12: Distribution of Study population according to age at menarche



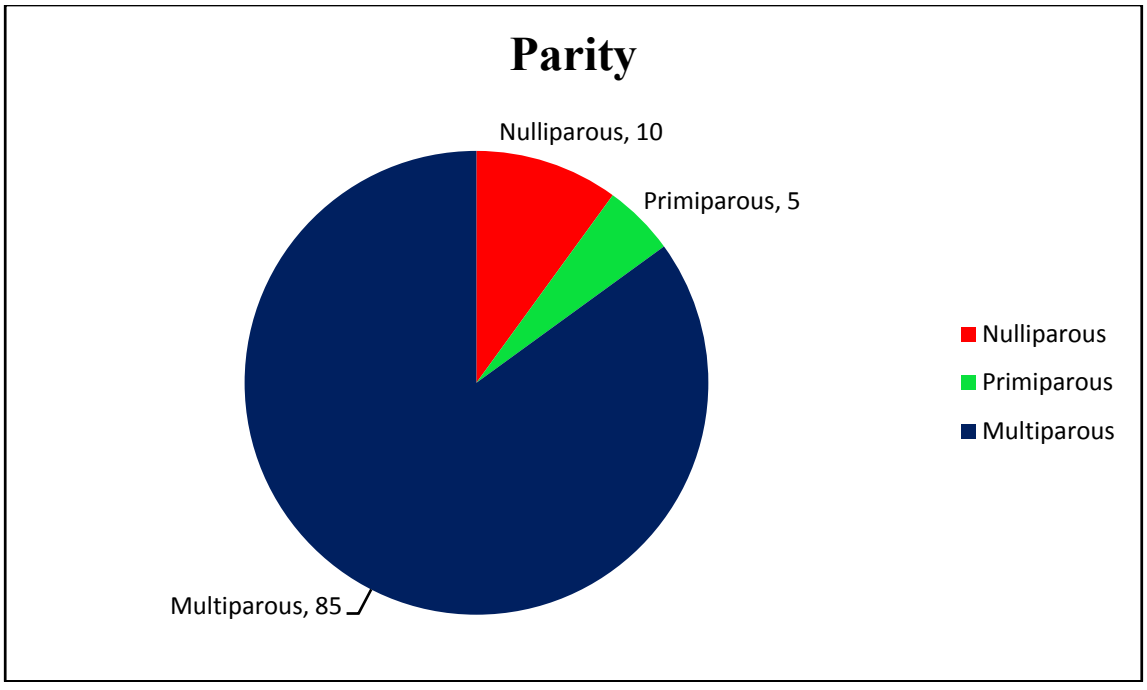
From the 100 female patients studied 10 were nulliparous while 85 were multiparous.

Out of the multiparous females, majority of the females had 2 children.

Table 13: Distribution of study population according to the parity.

Parity	Frequency	Percentage
Nulliparous	10	10
Primiparous	5	5
Multiparous	85	85
Total	100	100

Chart 13: Distribution of study population according to the parity.

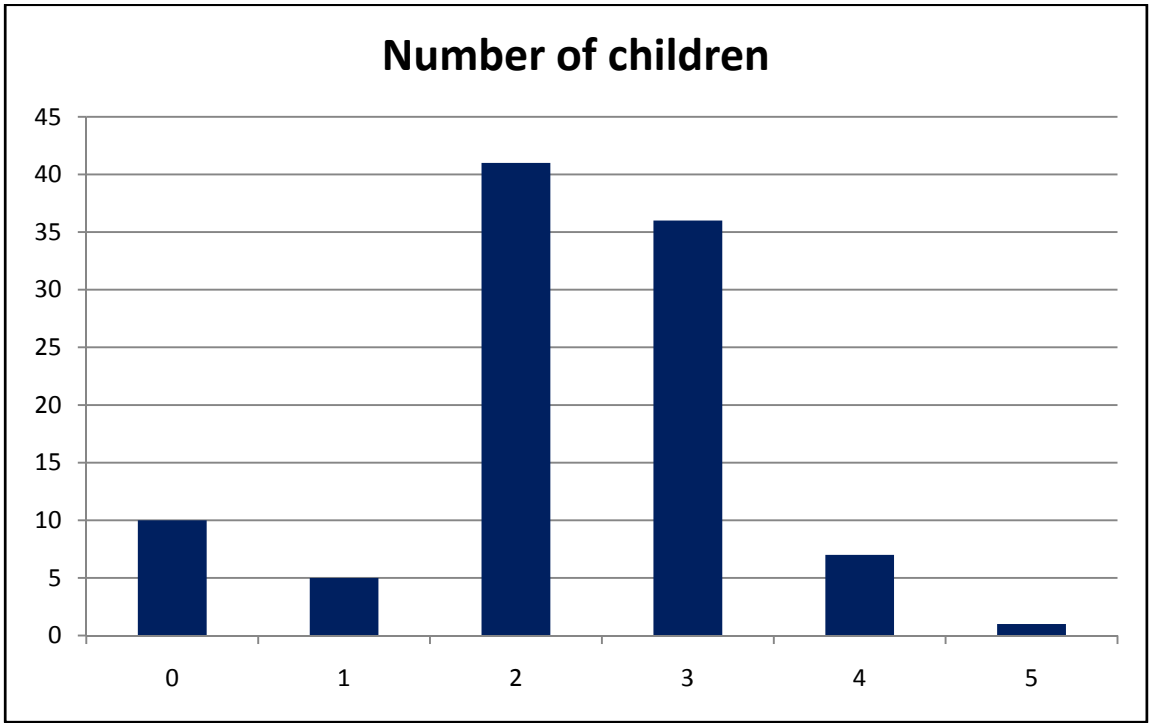


Among the 100 females studied 94 were married. Out of the 100 patients 90 had children. There were 44 females with 3 or more children.

Table 14: Distribution of study population according to number of children.

No of children	Frequency	Percentage
0	10	10
1	5	5
2	41	41
3	36	36
4	7	7
5	1	1
Total	100	100

Chart 14: Distribution of study population according to number of children.

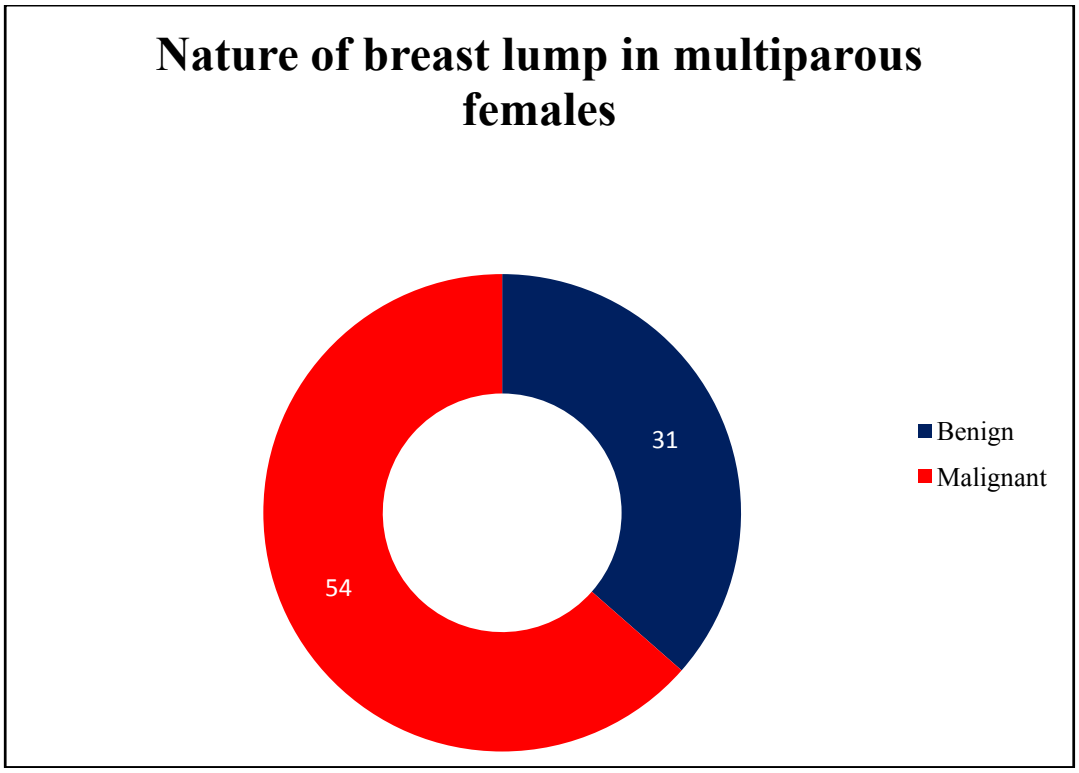


Among the females that were multiparous 31 had benign etiology while 54 had malignant etiology, 35 females had 3 or more than 3 children.

Table 15: Correlation of nature of the breast lump with multiparity.

Nature	Frequency	Percentage
Benign	31	36.47
Malignant	54	63.53
Total	85	100

Chart 15: Correlation of nature of the breast lump with multiparity.

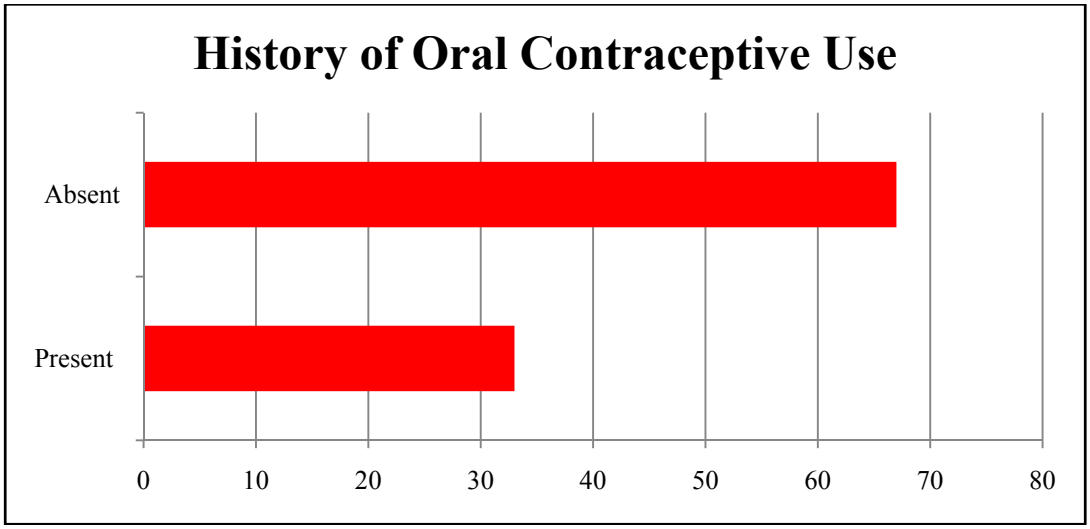


Oral contraceptive use was seen in 33 females while 67 females had no history of use of oral contraceptive pills. The majority females (18) with history of oral contraceptive use showed presence of malignant etiology while 15 were having benign lumps out of which most were under the age of 35 years.

Table 16: Distribution of study population on basis of oral contraceptive use

H/o oral contraceptive use	Frequency	Percentage
Present	33	33
Absent	67	67
Total	100	100

Chart 16: Distribution of study population on basis of oral contraceptive use

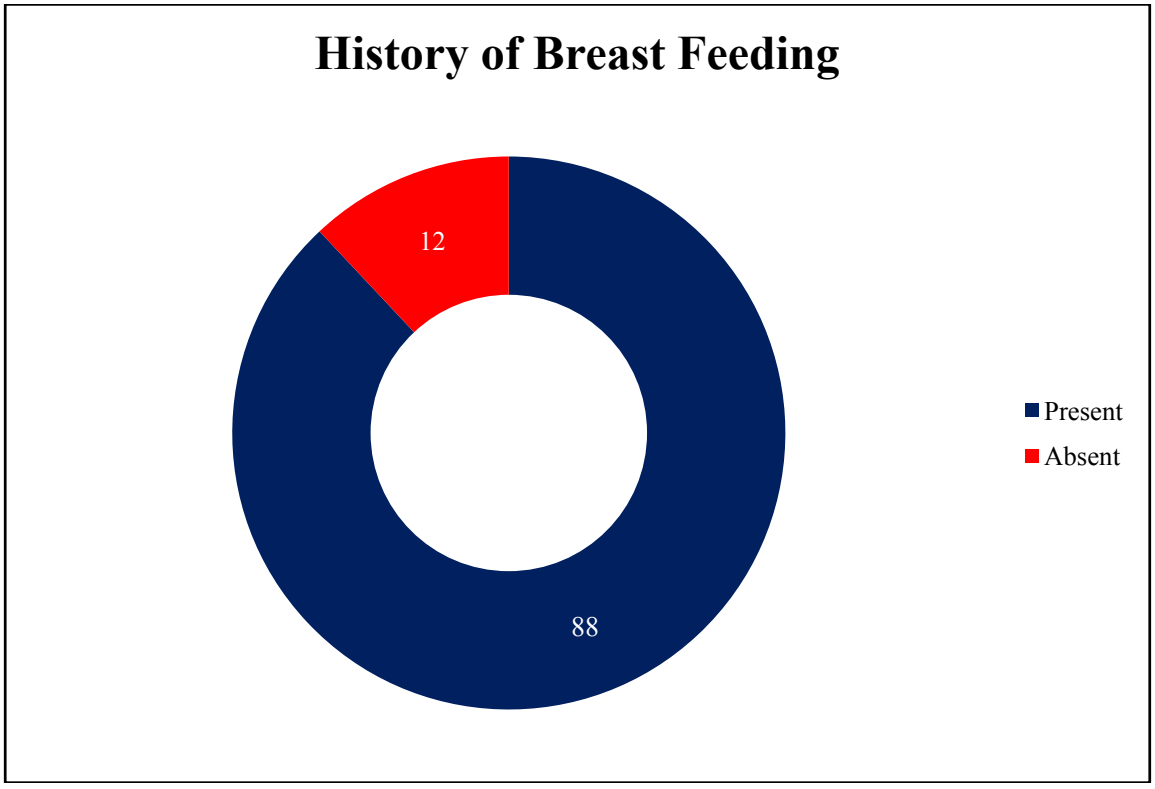


Out of the 100 females studied 88 females had the history of breast feeding while 12 had no history of breast feeding. Out of those 12, 9 were unmarried with benign lumps. Only 1 had malignant lump.

Table 17: Distribution of study population on the basis of history of breast feeding.

H/o Breast Feeding	Frequency	Percentage
Present	88	88
Absent	12	12
Total	100	100

Chart 17: Distribution of study population on the basis of history of breast feeding.

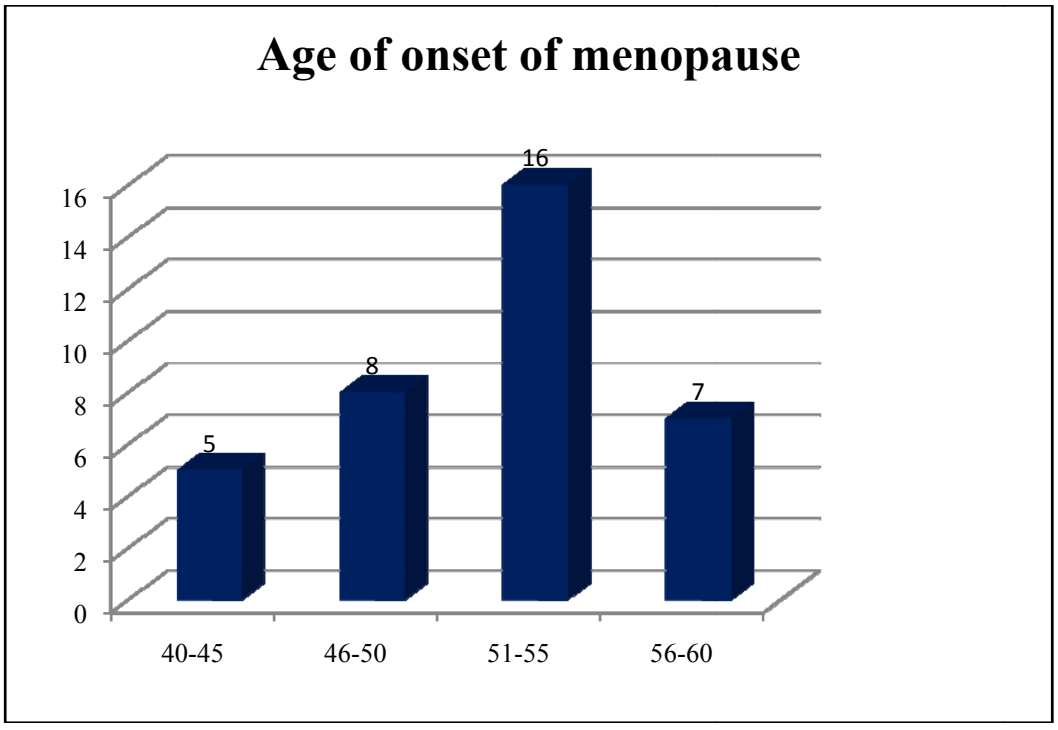


Only 36 females were postmenopausal. The onset of menopause was maximum between 51-55 years in 16 females, followed by 8 females in the age group 46-50 years. Among these women only 4 had benign etiologies for the lump, rest had malignant etiologies.

Table 18: Distribution of Study population according to age at menopause

Age	Frequency	Percentage
40-45	5	13.81
46-50	8	22.22
51-55	16	44.44
56-60	7	19.44
Total	36	100

Chart 18: Distribution of Study population according to age at menopause

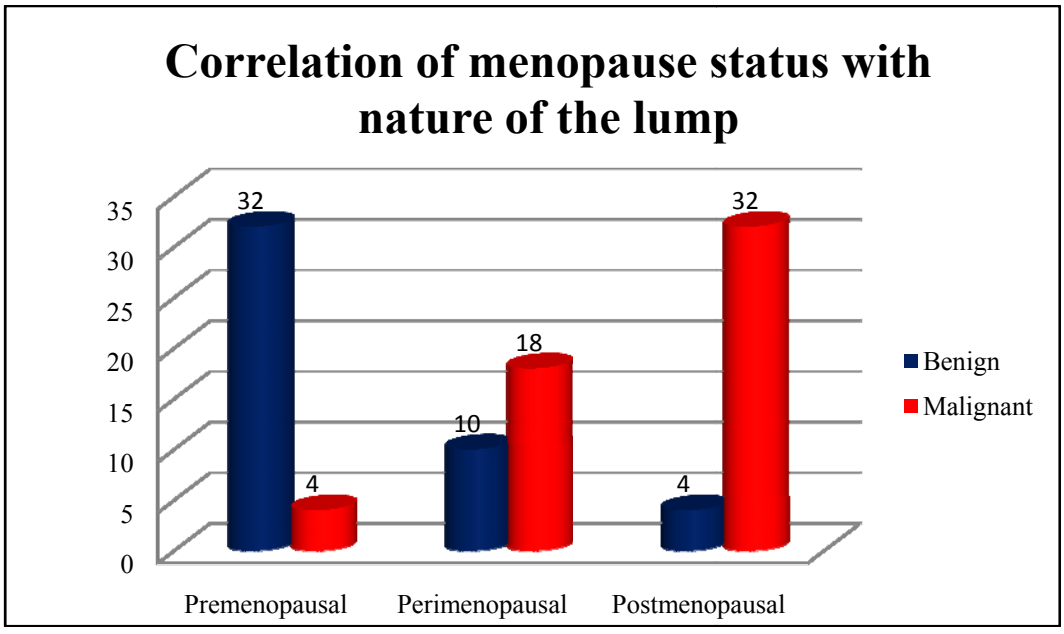


In this study 36 femlaes were premenopausal, 28 were perimenopausal and 36 were postmenopausal. Out of the 54 females that had malignant etiology 4 were premenopausal, 18 were perimenopausal and 32 were postmenopausal. Among the 46 females with benign breast lump 32 were premenopausal, 10 were perimenopausal and 4 were postmenopausal.

Table 19: Correlation of menopause status with nature of the lump

Menopausal Status	Nature of the Lump	Frequency	Percentage
Premenopausal	Benign	32	32
	Malignant	4	4
Perimenopausal	Benign	10	10
	Malignant	18	18
Postmenopausal	Benign	4	4
	Malignant	32	32
Total		100	100

Table 19: Correlation of menopause status with nature of the lump

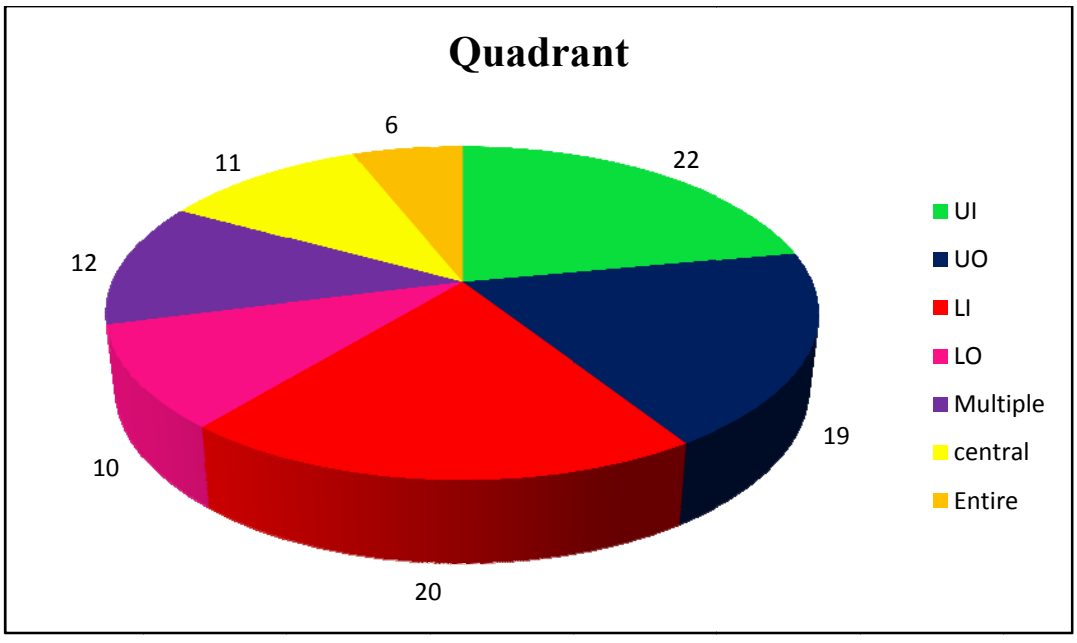


On assessing the location of the breast lump, maximum breast lumps (22) were found in upper inner quadrant while the least (6) were placed in multiple quadrants.

Table 20: Distribution of Study population based on the location of the breast lump.

Location	Frequency	Percentage
Upper inner	22	22
Upper Outer	19	19
Lower Inner	20	20
Lower Outer	10	10
Central	12	12
Entire	11	11
Multiple	6	6
Total	100	100

Chart 20: Distribution of Study population based on the location of the breast lump.



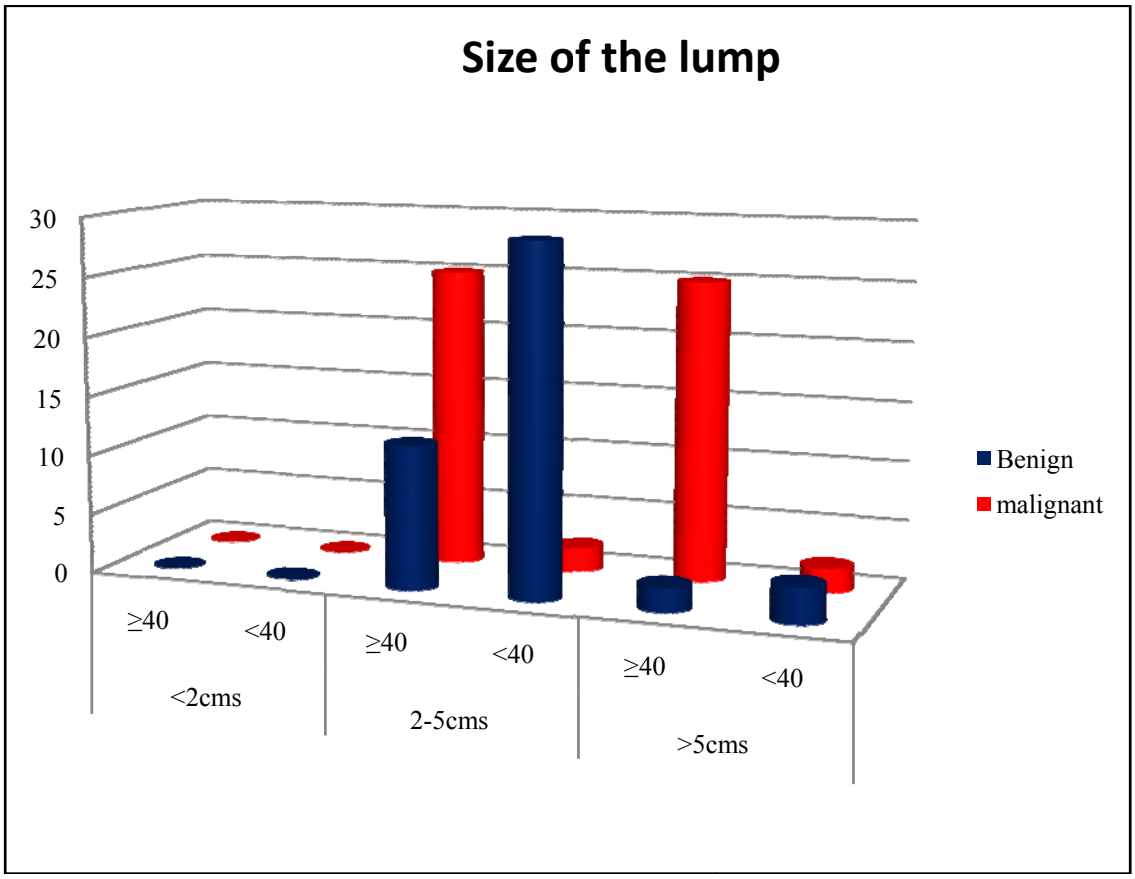
In this study the size of the lump ranged from 2 to 18 cms. With an average of 4.8 cms.

43 females had reported the increase in size of the lump over time while 11 had reported the decrease in size of the lump over time. Patients with malignant lump did not show any decrease in size while 11 females with benign pathlogy showed a decrease in size. All patients had lumps greater than the size of 2 cms. In 68 patients the size of the lump was 2-5cms mostly in the age greater than 40 years. Most of the lumps were benign in nature. In 32 patients the size of the lump was greater than 5 cms out of which 27 females were more than 40 years of age. Most of the lumps were malignant in nature. (In the case of lump in both the breast and females with multiple lumps, the largest dimension among all the lumps was considered).

Table 21: Distribution of Study population according to the size of the lump.

Size (in largest dimension)	Age	Nature	Frequency	Percentage
<2cms	≥40	Benign	0	0
		Malignant	0	0
	<40	Benign	0	0
		Malignant	0	0
2-5cms	≥40	Benign	12	12
		Malignant	25	25
	<40	Benign	29	29
		Malignant	2	2
>5cms	≥40	Benign	2	2
		Malignant	25	25
	<40	Benign	3	3
		Malignant	2	2
Total			100	100

Chart 21: Distribution of Study population according to the size of the lump.

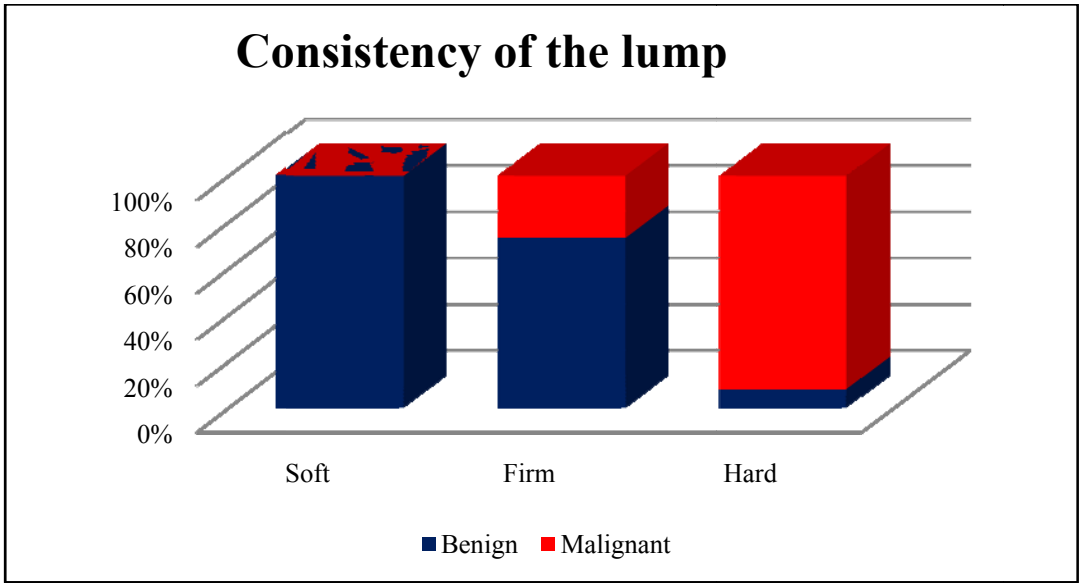


On examination 23 females had lump which were soft in consistency, 26 had firm consistency and 51 had hard consistency. Hard lumps were found in majority in females having malignant etiology. All lumps soft in consistency were benign.

Table 22: Distribution of Study population based on the consistency of the lump

Consistency	Nature	Frequency	Percentage
Soft	Benign	23	23
	Malignant	0	0
Firm	Benign	19	19
	Malignant	7	7
Hard	Benign	4	4
	Malignant	47	47
Total		100	100

Chart 22: Distribution of Study population based on the consistency of the lump

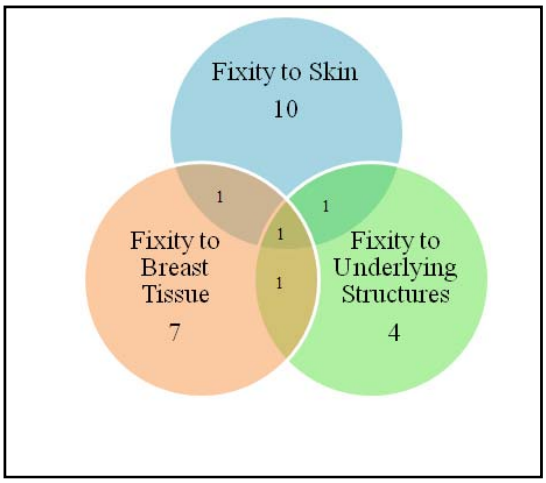


Furthermore on examination it was revealed that 16 females with malignant lumps showed fixity to surrounding structures. Out of that 7 females showed fixity to skin only, 1 female showed fixity to underlying structures only and 4 females showed fixity to the breast tissue only. 1 also showed fixity to skin and underlying structures and 1 showed fixity to the skin and breast tissue. 1 patient had fixity to the breast tissue, skin and underlying structures and 1 had fixity to breast tissue and underlying structures. No benign lumps showed fixity to the surrounding structures.

Table 23: Distribution of breast lumps according to fixity to surrounding structures

Fixity	Frequency	Percentage
Fixity to skin only	7	43.75
Fixity to underlying structures only	1	6.25
Fixity to Breast Tissue only	4	25
Fixity to Skin and Breast Tissue	1	6.25
Fixity to Skin and Underlying Structures	1	6.25
Fixity to Breast and Underlying tissue	1	6.25
Fixity to Skin, Breast and Underlying tissue	1	6.25
Total	16	100

Chart 23: Distribution of breast lumps according to fixity to surrounding structures



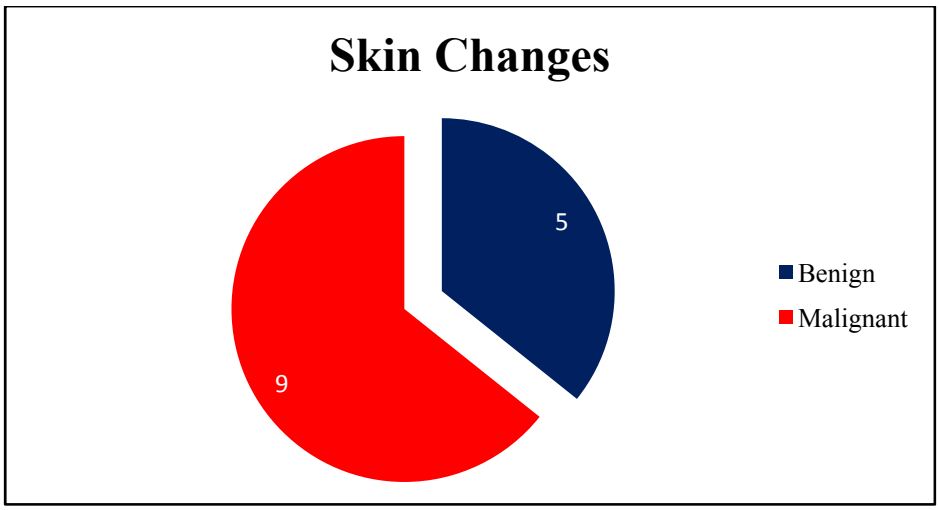
The mobility of the lump was observed in 16 patients all having benign etiologies.

Skin changes were seen in 14 females, out of which only 5 patients had benign etiologies for the lump while the rest had malignant lumps. In the patients with malignant lump the skin overlying the breast either showed peau d' orange appearance or had ulcerative or fungating growth. In the patients with benign etiologies, females either had scar from previous surgeries for the similar complain or the skin was inflamed showing redness due to inflammation with rise in local temperature.

Table 24: Correlation of nature of breast lump with the presence of skin changes.

Skin Changes	Frequency
Benign	5
Malignant	9
Total	14

Chart 24: Correlation of nature of breast lump with the presence of skin changes.

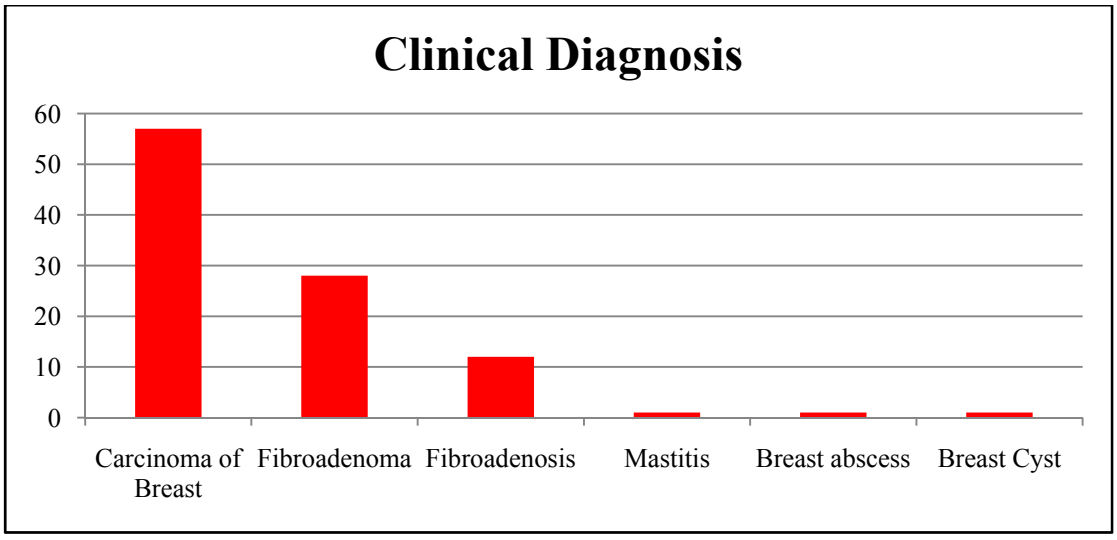


On Clinical Examination, 57 patients were suspected to have carcinoma of breast, 28 were suspected to have fibroadenoma, 12 were suspected to have fibroadenosis, 1 female to have mastitis, 1 with breast abscess and 1 with breast cyst.

Table 25: Distribution of study population of basis of diagnosis after clinical examination

Diagnosis	Frequency	Percentage
Carcinoma of Breast	57	57
Fibroadenoma	28	28
Fibroadenosis	12	12
Mastitis	1	1
Breast abscess	1	1
Breast Cyst	1	1
Total	100	100

Chart 25: Distribution of study population of basis of diagnosis after clinical examination

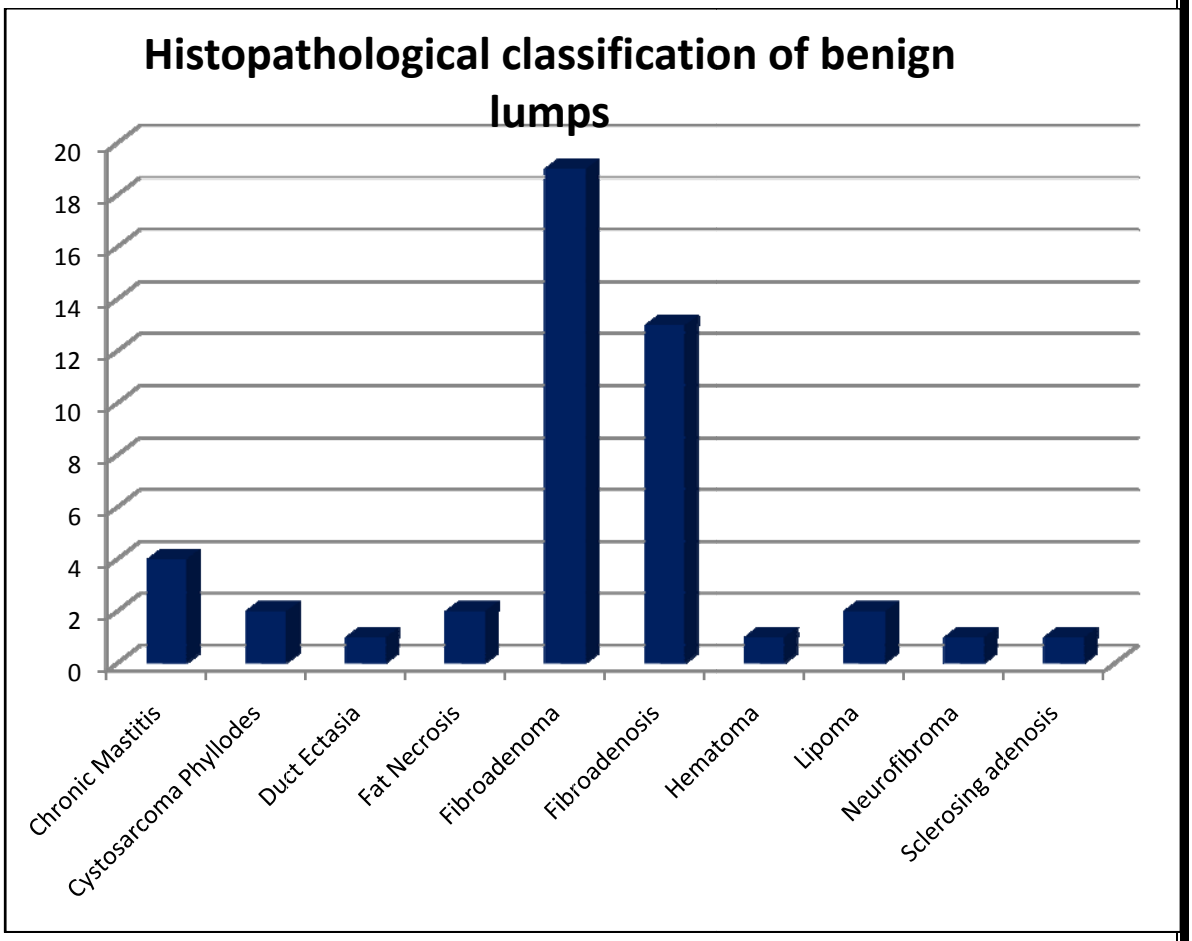


On histopathological examination, out of the 46 females having benign breast lumps, 19 were diagnosed to have fibroadenomas, 13 with fibroadenosis, 4 with chronic mastitis, 2 with cystosarcoma phyllodes, 2 with fat necrosis, 2 lipoma, 1 with duct ectasia, 1 with hematoma, 1 with neurofibroma and 1 with sclerosis adenosis.

Table 26: Distribution of benign breast lumps according to histopathology findings

Diagnosis	Frequency	Percentage
Chronic Mastitis	4	8.69
Cystosarcoma Phyllodes	2	4.35
Duct Ectasia	1	2.18
Fat Necrosis	2	4.34
Fibroadenoma	19	41.3
Fibroadenosis	13	28.26
Hematoma	1	2.18
Lipoma	2	4.34
Neurofibroma	1	2.18
Sclerosing adenosis	1	2.18
Total	46	100

Chart 26: Distribution of benign breast lumps according to histopathology findings

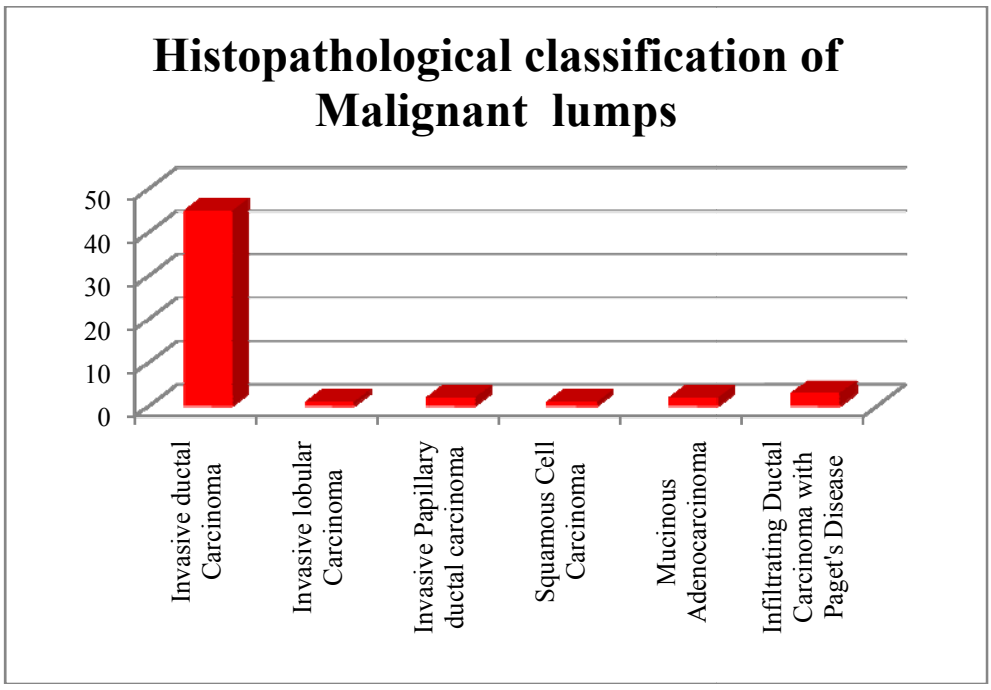


On histopathological examination, out of the 54 females having malignant breast lumps, 45 were diagnosed to have invasive ductal carcinoma, 3 with infiltrating ductal carcinoma with Paget's Disease, 2 with invasive papillary ductal carcinoma, 2 with mucinous adenocarcinoma, 1 with invasive lobular carcinoma and 1 with squamous cell carcinoma.

Table 27: Distribution of malignant breast lumps according to histopathology findings

Diagnosis	Frequency	Percentage
Invasive ductal Carcinoma	45	83.35
Invasive lobular Carcinoma	1	1.85
Invasive Papillary ductal carcinoma	2	3.7
Squamous Cell Carcinoma	1	1.85
Mucinous Adenocarcinoma	2	3.7
Infiltrating Ductal Carcinoma with Paget's Disease	3	5.55
Total	54	100

Chart 27: Distribution of malignant breast lumps according to histopathology findings

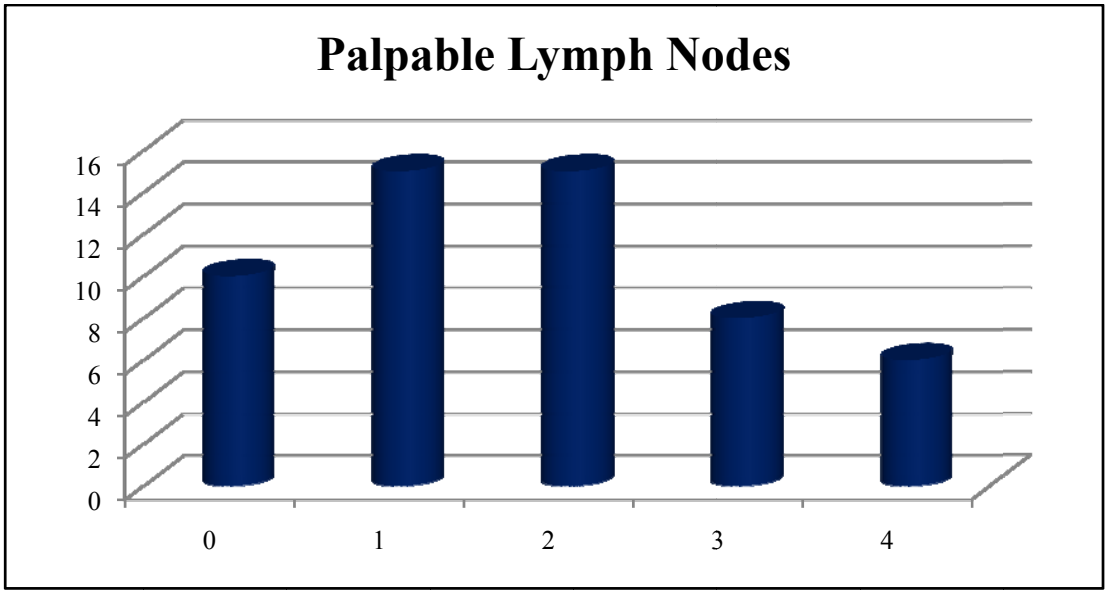


Among the females with malignant lumps, 11 patients did not have any axillary lymph nodes palpable, 1 lymph node was palpable in 15 patients, 2 lymph nodes were palpable in 15 patients, 9 patients had 3 lymph nodes palpable and 6 patients had 4 lymph nodes palpable.

Table 28: Distribution of study population on the basis of lymph nodes palpable.

Lymphnode palpable	Frequency	Percentage
0	10	18.52
1	15	27.78
2	15	27.78
3	8	14.81
4	6	11.11
Total	54	100

Chart 28: Distribution of study population on the basis of lymph nodes palpable.



Among the 46 patients with benign diseases 44 patients underwent excision of the lump. 1 having fibrocystic disease of breast having firm mass, initially underwent excision biopsy and then once diagnosis was made lumpectomy was done. In one another patient having a lump 18×12 cm, having cystosarcoma phyllodes, underwent modified radical mastectomy. In 54 cases with malignant lesions, 51 cases underwent modified radical mastectomy. For 2 out of them, initially excision biopsy was done, for which after confirmation of diagnosis modified radical mastectomy was done. And for 1, first lumpectomy was done and later on after confirmation of diagnosis modified radical mastectomy was done.

In 26 cases, the diagnosis varied on histopathological examination as compared to clinical examination and Fine needle aspiration cytology. In 7, Fine Needle Aspiration Cytology results were nonconclusive. Of that 7, 2 were suspected to have fibroadenoma on clinical examination, out of which 1 had neurofibroma and another had fibroadenosis. The other 5 were suspected to have fibroadenosis on clinical examination, out of which 2 had fibroadenosis, 2 had chronic mastitis and 1 had chronic granulomatous mastitis. In 4 patients suspected to have carcinoma of breast on clinical examination, 3 on FNAC were diagnosed with fibroadenosis, out of which on histopathological examination 1had fibroadenosis ,1 had chronic mastitis and 1 had fibrocytic changes with chronic mastitis. Among 6 patients in whom fibroadenoma was suspected on clinical examination, 2 patients had same results on FNAC but had fibroadenosis on histopathological examination. 1 had lipoma, 1 had fat necrosis and 2 other had fibroadenosis on histopathological examination. Among 5 patients suspected to have fibroadenosis on clinical examination, 2 had fat necrosis, 1 had phyllodes tumor, 1 had mucinous adenocarcinoma and 1 had fibroadenoma. One patient suspected to have mastitis on clinical examination was diagnosed with duct

ectasia with breast cyst on histopathological examination. Another suspected to have breast cyst was diagnosed with sclerosing adenosis and another with breast abscess was confirmed to have fibroadenosis.

In patients with no lymph nodes palpable one patient had 5 lymph nodes showing tumor invasion. In patients with 1 lymph node palpable, no lymph node to 12 lymph nodes showed tumor invasion. In patients with 2 lymph nodes palpable, no lymph nodes to 15 lymph nodes showed tumor invasion. In patients with 3 lymph nodes palpable, no lymph nodes to 22 lymph nodes showed tumor invasion. In patient with 4 lymph nodes palpable, 2 lymph nodes to 13 lymph nodes showed tumor invasion.

Table 29: Correlation between palpable lymph nodes- range of nodes with tumor invasion

Lymph node palpable	Minimum Lymph nodes positive	Frequency	Maximum Lymph nodes positive	Frequency
0	0	9	5	1
1	0	5	12	1
2	0	3	15	1
3	0	1	22	1
4	2	1	13	1

Chart 29: Correlation between palpable lymph nodes- range of nodes with tumor invasion

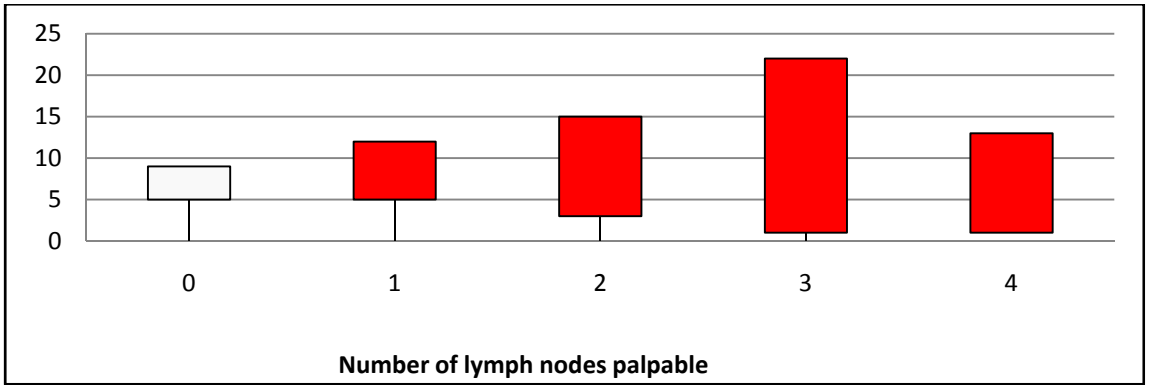
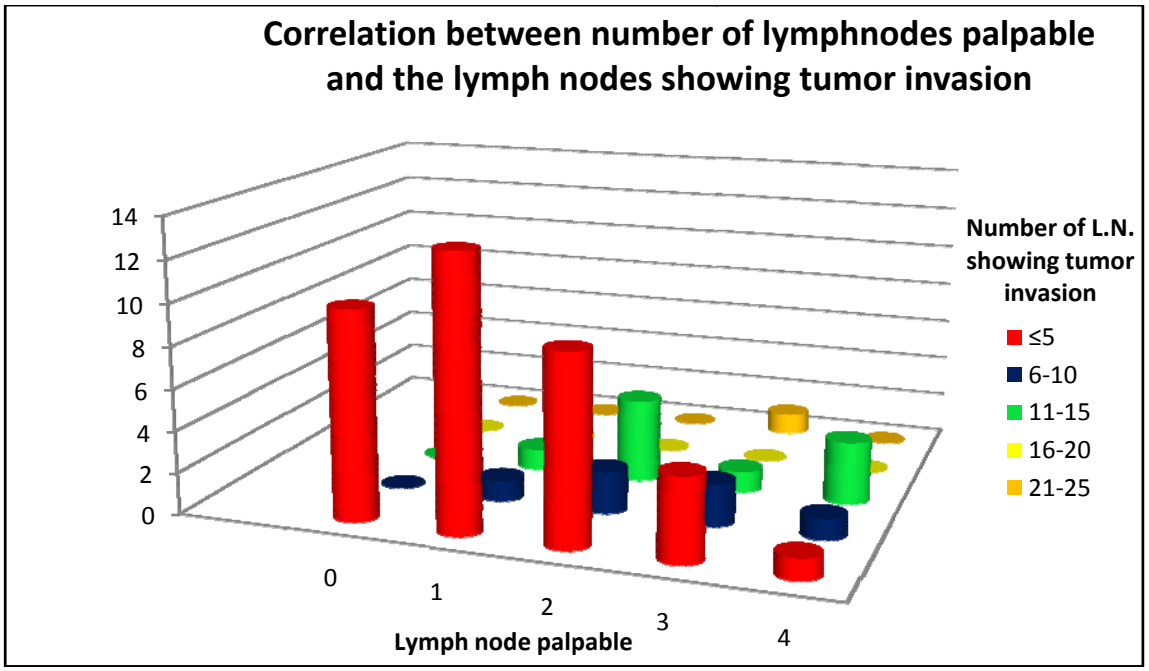


Table 30: Correlation between number of lymphnodes palpable and the lymph nodes showing tumor invasion

No. of nodes palpable→ No of nodes showing tumor invasion ↓	0	1	2	3	4
≤5	10	13	9	4	1
6-10	0	1	2	2	1
11-15	0	1	4	1	3
16-20	0	0	0	0	0
21-25	0	0	0	1	0

Chart 30: Correlation between number of lymphnodes palpable and the lymph nodes showing tumor invasion

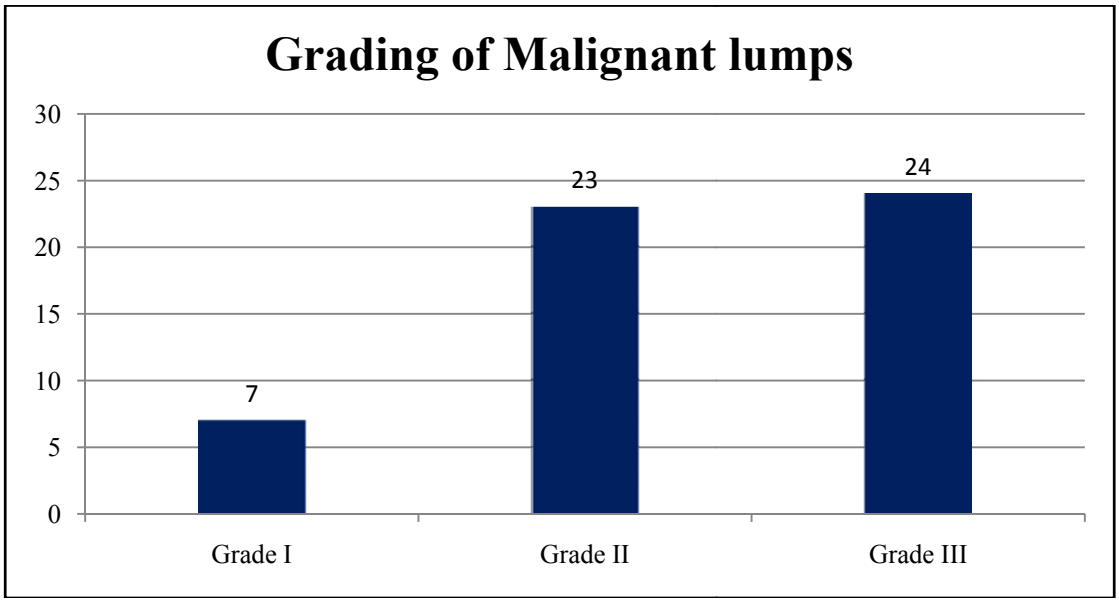


On histological examination of the malignant lumps, it was found that 7 patients had grade I tumor according to the Modified Scarff Bloom Richardson histological Grading, while 23 had grade II tumors and 24 had Grade III tumors.

Table 31: Distribution of Study population with malignant lump according to Modified Scarff Blood Richardson histological grading system

Grading of the tumor	Frequency	Percentage
Grade I	7	12.97
Grade II	23	42.59
Grade III	24	44.44
Total	54	100

Chart 31: Distribution of Study population with malignant lump according to Modified Scarff Blood Richardson histological grading system

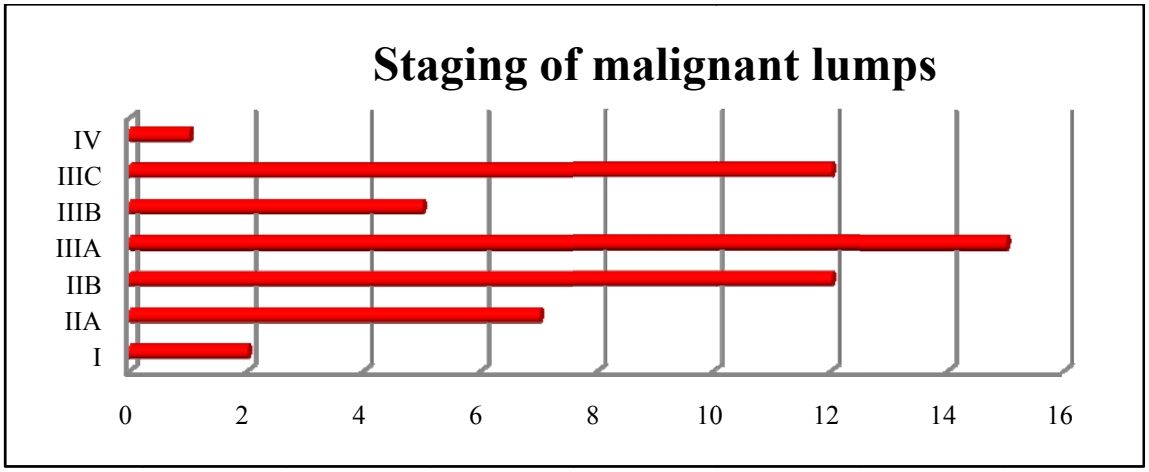


Of the 54 females with malignant lumps, after the histopathological examination of the excised lump, it was found that highest number of females (15) were in Stage IIIA according to the TNM classification of Carcinoma of breast followed by Stage IIB and IIIC having 12 females each. 7 females had stage IIA cancer, 5 having Stage IIIB, 2 having Stage I and 1 having Stage IV cancer.

Table 32: Distribution of study population with malignant lumps according to the TNM staging of the tumor

Staging of the tumor	Frequency	Percentage
I	2	3.7
IIA	7	12.97
IIB	12	22.22
IIIA	15	27.78
IIIB	5	9.25
IIIC	12	22.22
IV	1	1.86
Total	54	100

Chart 32: Distribution of study population with malignant lumps according to the TNM staging of the tumor



On immunohistochemistry, out of the 54 females with malignant lumps, 20 females had their Estrogen receptor positive, 17 had progesterone receptor positive while 25 had Her2/neu receptor status positive. Among them only 2 had only had estrogen receptor positive, only 1 had only progesterone receptor positive, 11 patients had only Her2/neu receptor positive, 4 patients had estrogen and progesterone receptor positive, 2 patients had estrogen and her2/neu receptor positive and 12 patients had all three receptor positive.

Table 33: Distribution of study population with malignant lumps on the basis of the positivity of the receptors.

Receptors positive	Frequency	Percentage
Estrogen Receptor	20	37.03
Progesterone Receptor	17	31.48
Her2/neu Receptor	25	46.29

Table 34: Correlation between different receptors and their positivity in study population with malignant lumps.

Receptor Positivity	Frequency	Percentage
ER +ve	2	3.7
PR +ve	1	1.85
Her2/neu +ve	11	20.37
ER,PR +ve	4	7.4
ER, Her2/neu +ve	2	3.7
ER, PR, Her2/Neu +ve	12	22.22

Chart 33: Distribution of study population with malignant lumps on the basis of the positivity of the receptors.

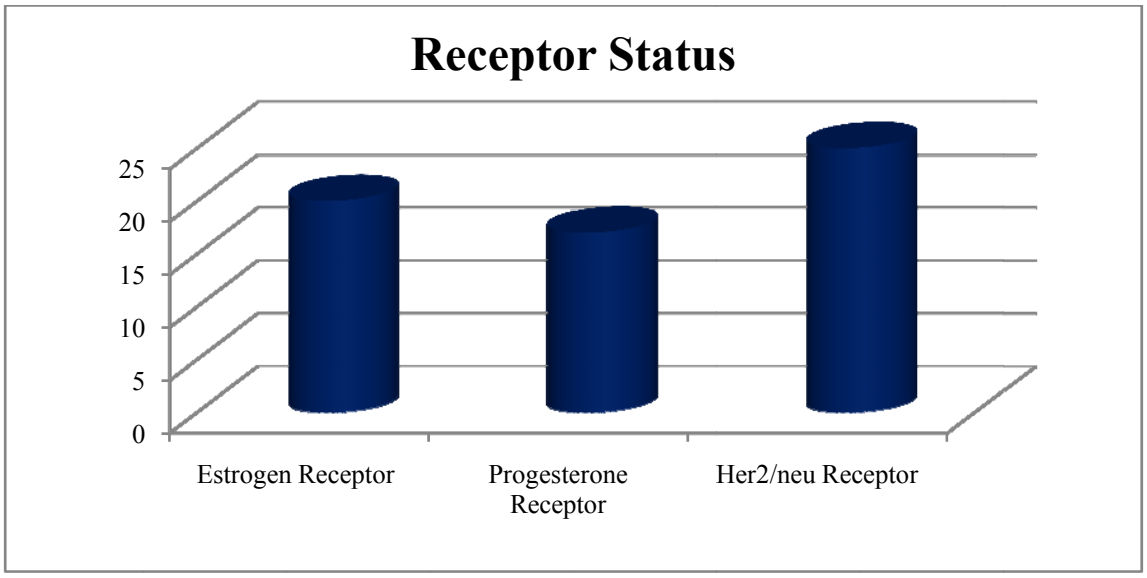
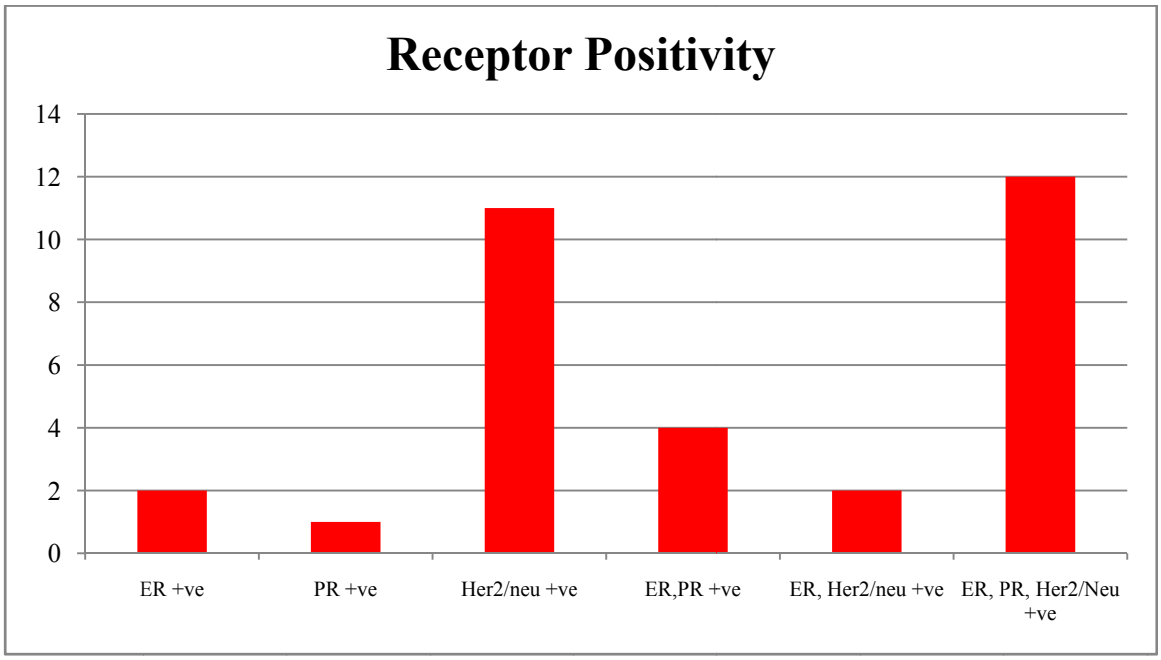


Chart 34: Correlation between different receptors and their positivity in study population with malignant lumps.

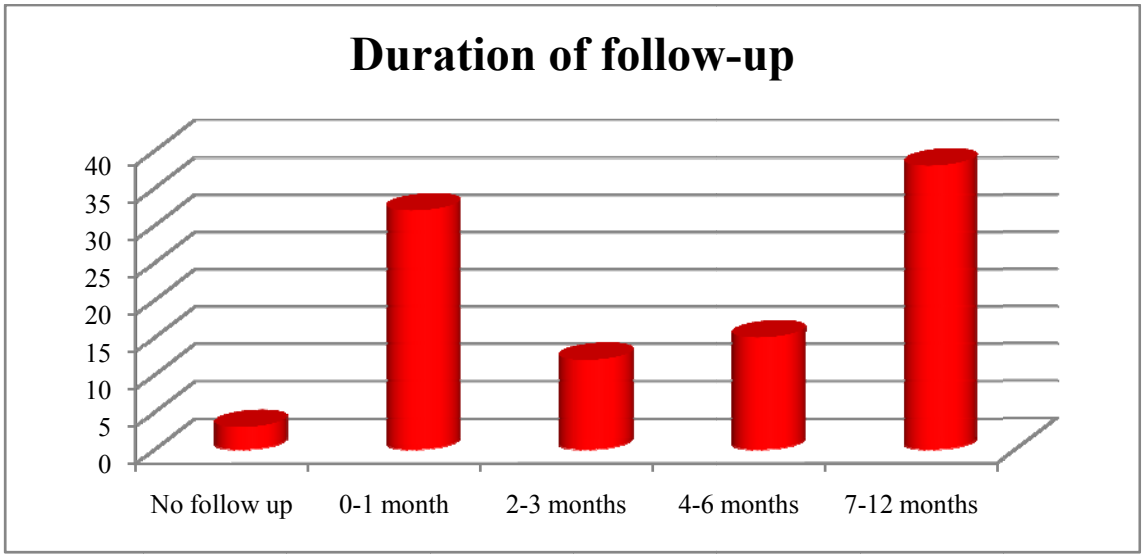


Among the 100 female patients, 97 were available for follow up at 1 month only ,65 were available for follow up till 3 months, 53 till 6 months and 38 were available for follow up till 12 months. 3 patients did not come up for follow up at all. The duration of follow up ranged from half a month upto 12 months with a median of 5 months. Most females with malignant lumps showed up for follow up for 6-12 months.

Table 35: Distribution of study population on the basis of duration of follow-up.

Duration of follow up	Frequency	Percentage
No follow up	3	3
0-1 month	32	32
2-3 months	12	12
4-6 months	15	15
7-12 months	38	38
Total	100	100

Chart 35: Distribution of study population on the basis of duration of follow-up.

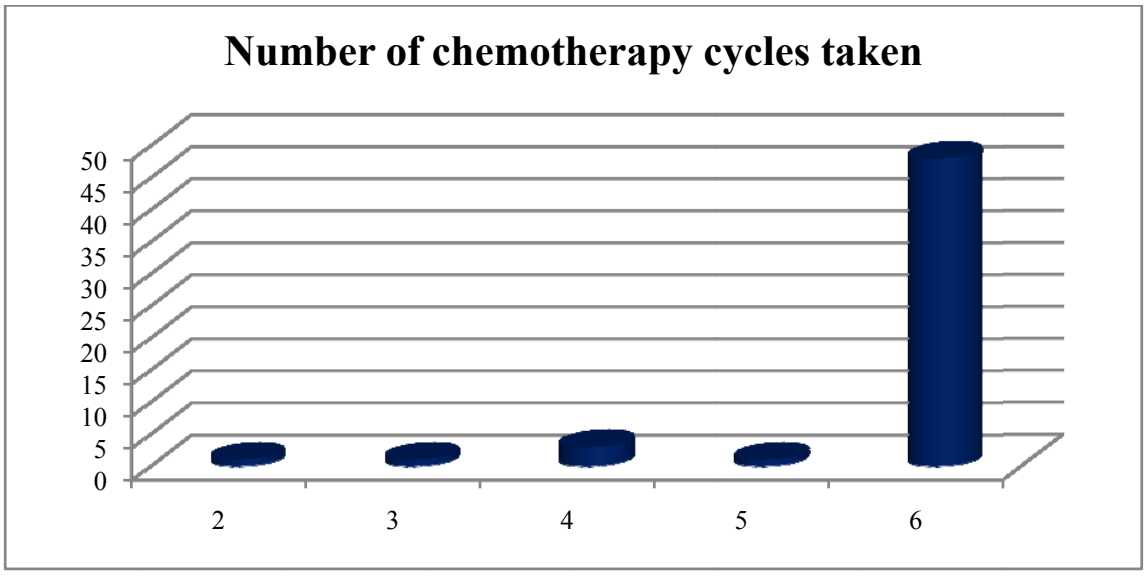


On an average 6 cycles of chemotherapy was given to the patients with Carcinoma of breast. 6 patients with malignant lumps were lost on follow-up and did not complete 6 cycles of chemotherapy. 48 patients received 6 cycles of chemotherapy. 1 patient only took 2 cycles of chemotherapy, 1 patients took 3 cycles of chemotherapy,3 patients took 4 cycles of chemotherapy and 1 took 5 cycles of chemotherapy. Out of the 48 patients who completed 6 cycles of chemotherapy only 38 patients were available for further follow up where treatment with tamoxifen was given.

Table 36: Distribution of study population with malignant lumps on basis of number of chemotherapy cycles received.

Number of chemotherapy cycles taken	Frequency	Percentage
2	1	1.85
3	1	1.85
4	3	5.56
5	1	1.85
6	48	88.89
Total	54	100

Chart 36: Distribution of study population with malignant lumps on basis of number of chemotherapy cycles received.

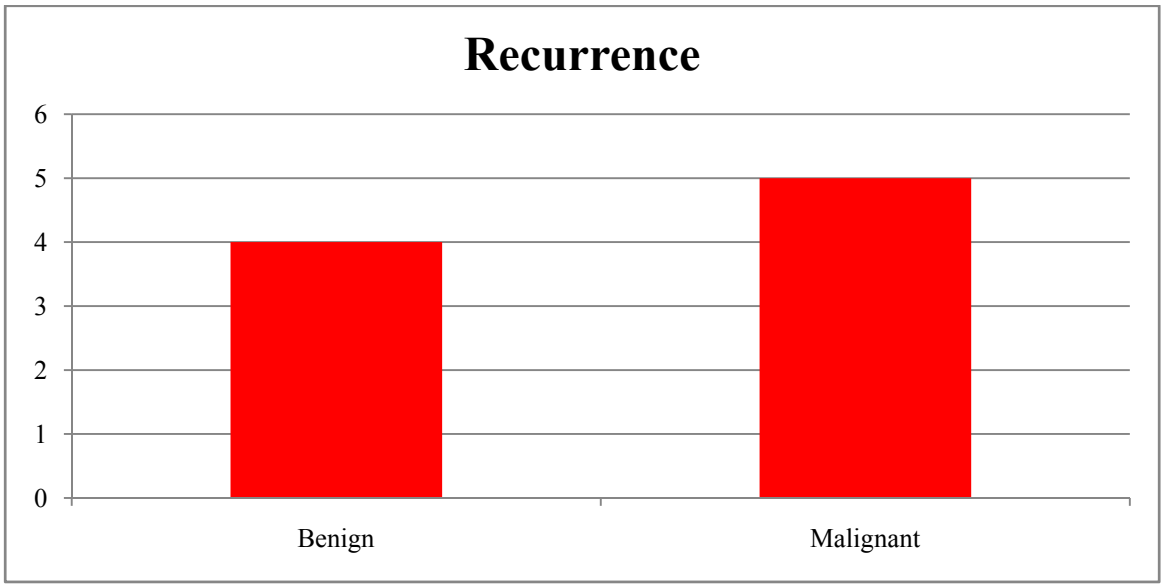


Out of the 100 patients 9 patients showed recurrence, out of which 4 patients had benign etiology while 5 patients had malignant etiology on primary assessment.

Table 37: Distribution of the study population on the basis of recurrence

Recurrence	Frequency
Benign	4
Malignant	5

Chart 37: Distribution of the study population on the basis of recurrence



In the cases with malignant lumps, 1 patient had developed lung metastasis while 1 patient had liver metastasis on follow up. 1 patient also had skeletal metastasis.

High levels of anxiety are associated with possibility of the diagnosis of carcinoma of breast which leads to the late presentation of the female to the clinics for examination. In our setup, majority of the females coming to the hospital with complains of breast lumps are around the age range of 40-50 years with preponderance towards malignant diseases. These results are not in agreement with the results from other studies. The variations are a result of difference in age group, race and study designs. Reports derived from western literature suggest that pre-menopausal status, delayed age at first live birth (>25 years) and low parity have an accelerated risk for development of invasive breast cancer. [5] Benign breast disease have also been reported as risk factor for development of carcinoma of breast attributed to atypical parenchymal lesions. Female sex hormone levels show a rise from 8 years of age and reach adult level by 17 years of age, which is a peak age for development of fibroadenoma. There is some similarity between risk factors for development of fibroadenoma and breast cancer. Fibroadenomas impose a long term risk for development of carcinoma of breast. This risk increases if females have complex fibroadenomas or ductal hyperplasia .[27]

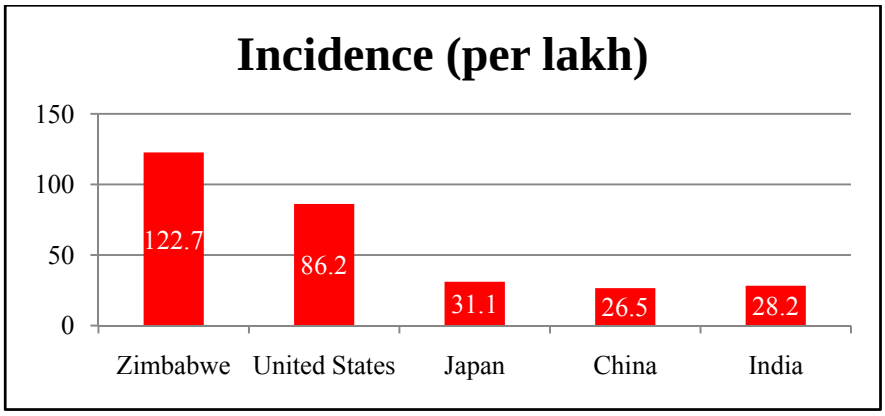
M. Kumar et al (2010) concluded that in Indian rural population the benign breast diseases are 5 to 10 times more common than breast cancers. He also studied that benign breast diseases varies according to different geographical areas but due to lack of basic education women disregard the breast lump. [31]Aisha Memon et al (2007) suggested in their study that benign breast lesions are 10 times more common than breast cancer in West[32]. In 1993, Kelsay et al concluded that breast cancer is 100 times more common in women than in men. There is an increase in incidence with age, urban population and higher socio-economic class. They also stated that other than the genetic causes, there is increase in incidence with change in lifestyle.[27]

In 2003, Balkrishna B Yeole et al in his epidemiological study has compared the incidence of breast cancer in various countries and he observed that incidence rates were very high in developed countries[33]. The highest incidence of breast cancer was seen in European population living in Zimbabwe. (122.7 per 1 lakh). In United states, Non-Hispanic Whites exhibited the incidence rate of breast lumps of 86.2 per 1 lakh while Asian population exhibited lower incidence. Japan showed 31.1 per 1 lakh, China 26.5 per lakh and India with the incidence rate of 28.2 per lakh. He also said that the life time risk (0 to 74 years) of Carcinoma of breast in Mumbai was 3.3% (1 in 30), Chennai 2.4% (1 in 42) and that in Trivandrum was 2.05% (1 in 50). In Us the life time risk of developing breast cancer during entire life time in 1 in 8 (12.5%) [Parkin et al 1997][34]

Table 38: Incidence of Breast Cancer in different countries

Country	Incidence (per lakh)
Zimbabwe	122.7
United States	86.2
Japan	31.1
China	26.5
India	28.2

Chart 38: Incidence of Breast Cancer in different countries

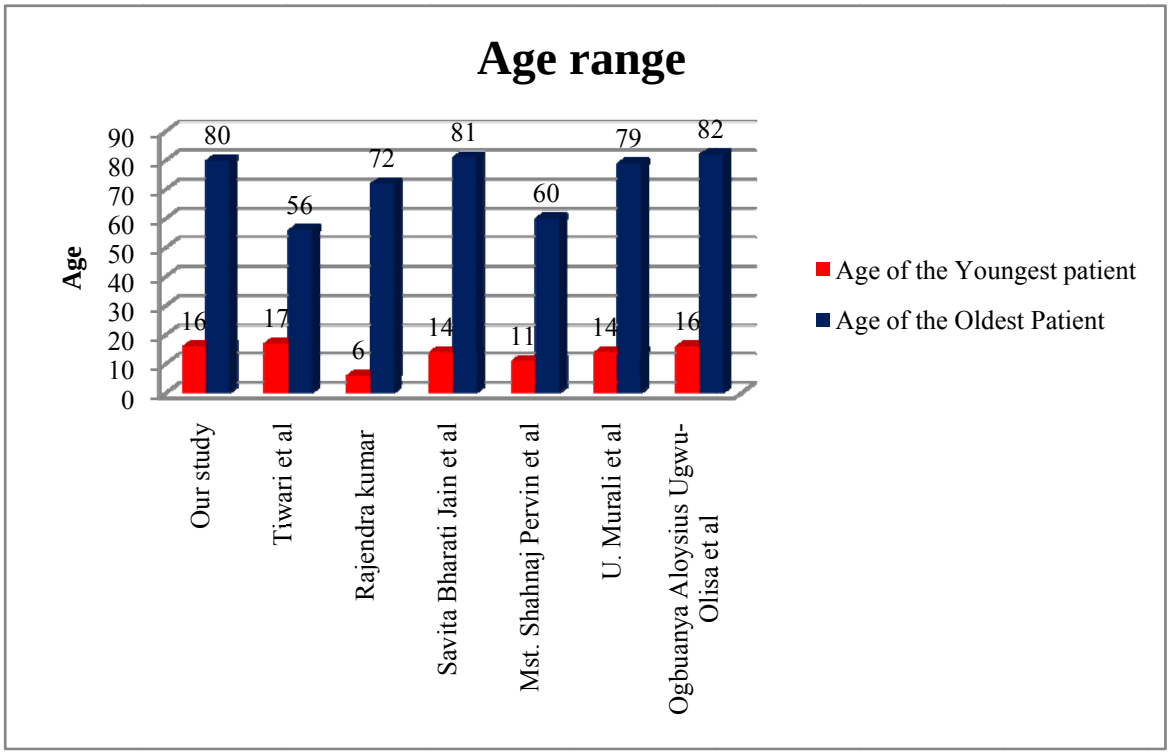


In our study the patients ranged from the age range of 16-80 years with a mean age of 44.17 years while in a study in Nepal by Tiwari in 2007 the patients ranged from 17-56 years. In another study in Bhairahwa, Nepal by Rajendra Kumar the patients enrolled were in the range of 6 to 72 years. [7]In Madhya Pradesh, India in 2015, another study by Savita Bharat jain et al. showed the study population between the age of 14-81 years.[29]Mst. Shahnaj Pervin et al in their study in Mymensingh, Bangladesh, studied the patient between the age range of 11 and 60 years.[6] In a study in mauratius, by U. Murali et al the youngest patient was 14 years while the eldest patient was of 79 years.[30] In a study in Nigeria, by Ogbuanya Aloysius Ugwu-Olisa et al the youngest patient was 16 years while the eldest patient was of 82 years.[5] Our study was similar to that of Savita Bharat Jain, Ogbuanya Aloysius Ugwu-Olisa et al and U. Murali.

Table 39: Comparison of age range of study population in different studies

Study	Age of the Youngest patient	Age of the Oldest Patient	Mean age
Our study	16	80	44.17
Tiwari et al	17	56	38
Rajendra kumar	6	72	34
Savita Bharati Jain et al	14	81	32
Mst. Shahnaj Pervin et al	11	60	27
U. Murali et al	14	79	40.5
Ogbuanya Aloysius Ugwu-Olisa et al	16	82	37

Chart 39: Comparison of age range of study population in different studies



Probably, the most important risk factor for development of carcinoma of breast is age. The age-adjusted incidence of Carcinoma of breast increases with advancing age. Carcinoma of breast is uncommon in females younger than 20 years of age. In our study most females have presented in 5th decade (31%) of life and only 8% of the females have presented before 20 years of age. Benign breast diseases are more common in young age. Most females presenting with benign lumps have presented before 40 years of age (73.9%). So our results showing inclination towards malignant lesions correlates with age as a risk factor.

Only a small proportion of study population (9%) is Muslim but majority of these females had malignant lumps. Though having high parity these females had malignant lesions in the advanced stages due to their religious and social customs which prevented them from presenting early after the onset of symptoms.

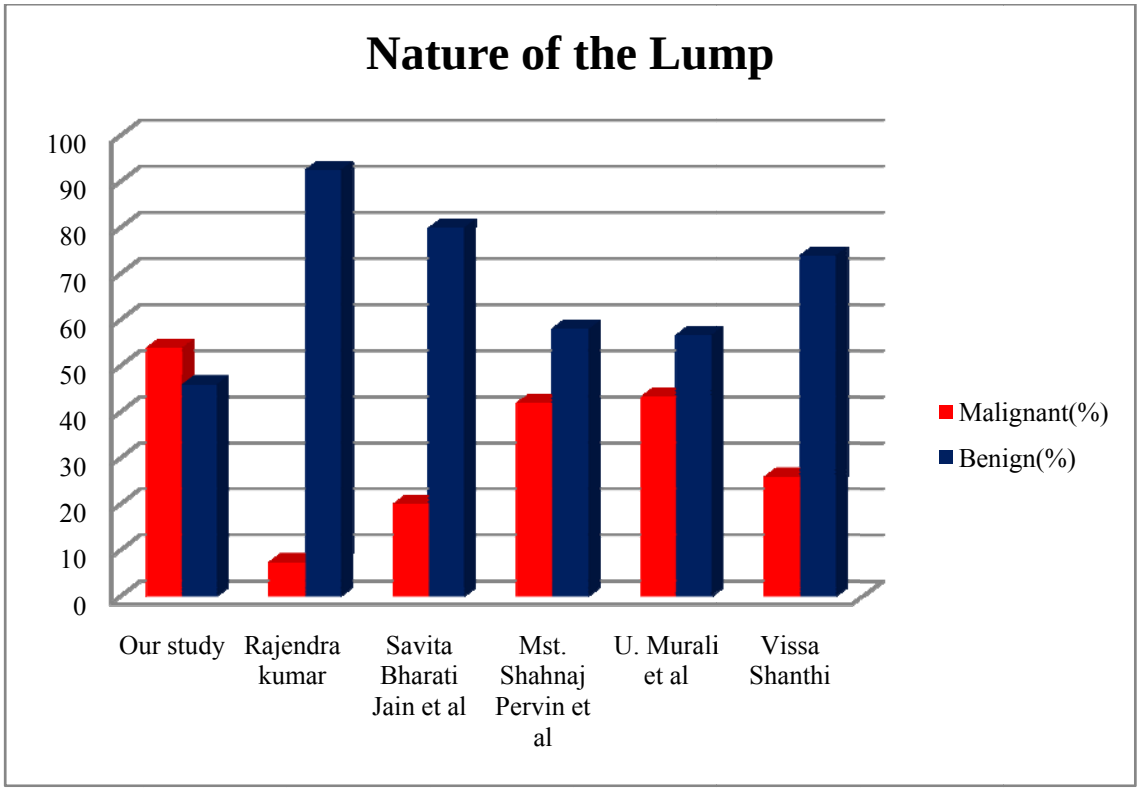
In our study 54% of the patients had malignant lumps while 46% of the patients had benign lumps. In the study by Rajendra Kumar 7.4% of the patients had malignant

lesions while 92.6 % of the patients had benign lesions. In a study by Savita Bharati Jain et al. 20% patients had mailgnant lumps and 80% patients had benign lumps. Mst. Shahnaj Pervin et al in his study showed that 42% of the patients had malignant lumps while 58% patients had benign lumps. 129(43.3%) patients had malignant lumps while 169(56.7%) patients had benign lumps in a study by U murali et al. In a study by Vissa Shanthi et al, 74% of the patients had benign lumps and 26% had malignant lumps. Our study coincides with the study of U. Murali and Mst. Shahnaj Pervin. In a study by Rajendra Kumar, out of the 243 females, 114 presented before the age of 30 years, all of which had benign lumps owing to greater percentage of benign lumps present among the study population. Breast cancer being more common than benign lesions, there is predominance of malignant lesions seen in our study as well due to selective referral of carcinoma of breast to tertiarry hospital like ours and management of benign lumps by private hospitals. As most of the patients presenting to our setup belonged to a rural population and were illiterate leading to the high levels of anxiety regarding the suspicion of cancer and unawareness regarding the severity of the symptoms leading them to present late after onset of symptoms, causing a higher incidence of malignant lesions. Moreover the patients presenting were in the age range of 40-50 years which has preponderance towards malignant lesions.

Table 40: Comparison of our study with other study according to the nature of the lump.

Study	Malignant(%)	Benign(%)
Our study	54	46
Rajendra kumar	7.4	92.6
Savita Bharati Jain et al	20	80
Mst. Shahnaj Pervin et al	42	58
U. Murali et al	43.3	56.7
Vissa Shanthi	26	74

Chart 40: Comparison of our study with other study according to the nature of the lump.

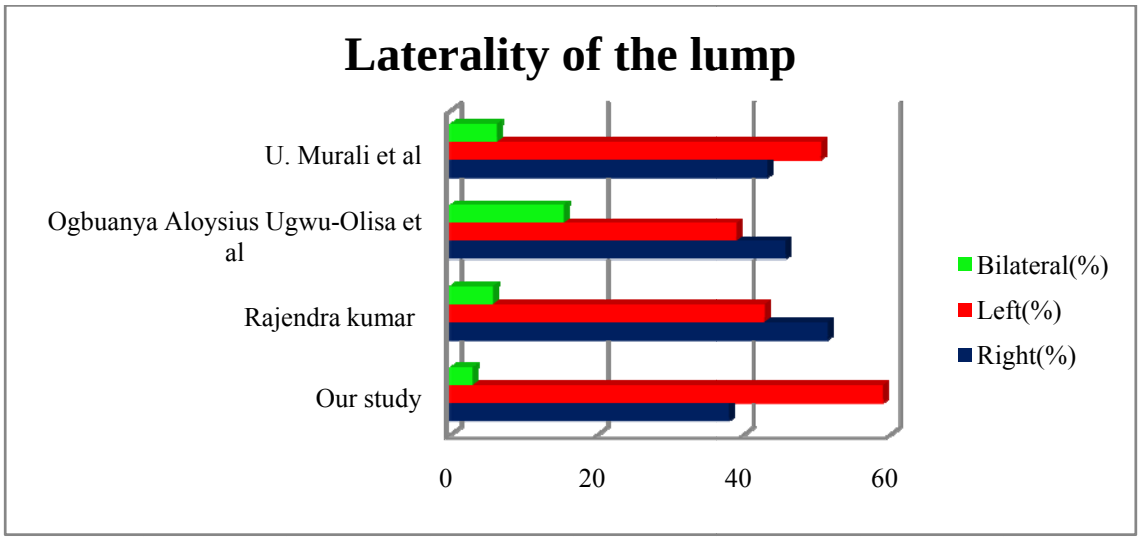


In our study, 59% of the patients had lump on the left, 38% in the right and 3% of the patients had bilateral lumps. In a study by Ogbuanya Aloysius Ugwu-Olisa in Nigeria, 164 patients(45.7%) had lumps in the right breast, 140 (39.0%) had lump in the left breast while 55 (15.3%) had lumps in bilateral breast. While in a study by U. Murali in Malaysia , 48 patients (50.5%) had lump in left breast, 41 (43.15%) had lump in right breast while 6 (6.3%) had lumps in both the breasts. Rajendra Kumar in his study stated that 51.4% patients had lesions in right breast while 42.8% patients had lesion in left breast while 5.76% patient had bilateral lesions. Ahmed et al in his study showed similar results. This results correlates with the results of the study by U. Murali. Predominance of involvement of left is assumed to be associated with physical and social grounds.

Table 41: Comparison of our study with other studies on the basis of the laterality of the lump.

Study	Right(%)	Left(%)	Bilateral(%)
Our study	38	59	3
Rajendra kumar	51.4	42.8	5.76
Ogbuanya Aloysius Ugwu-Olisa et al	45.7	39	15.3
U. Murali et al	43.15	50.5	6.3

Chart 41: Comparison of our study with other studies on the basis of the laterality of the lump.

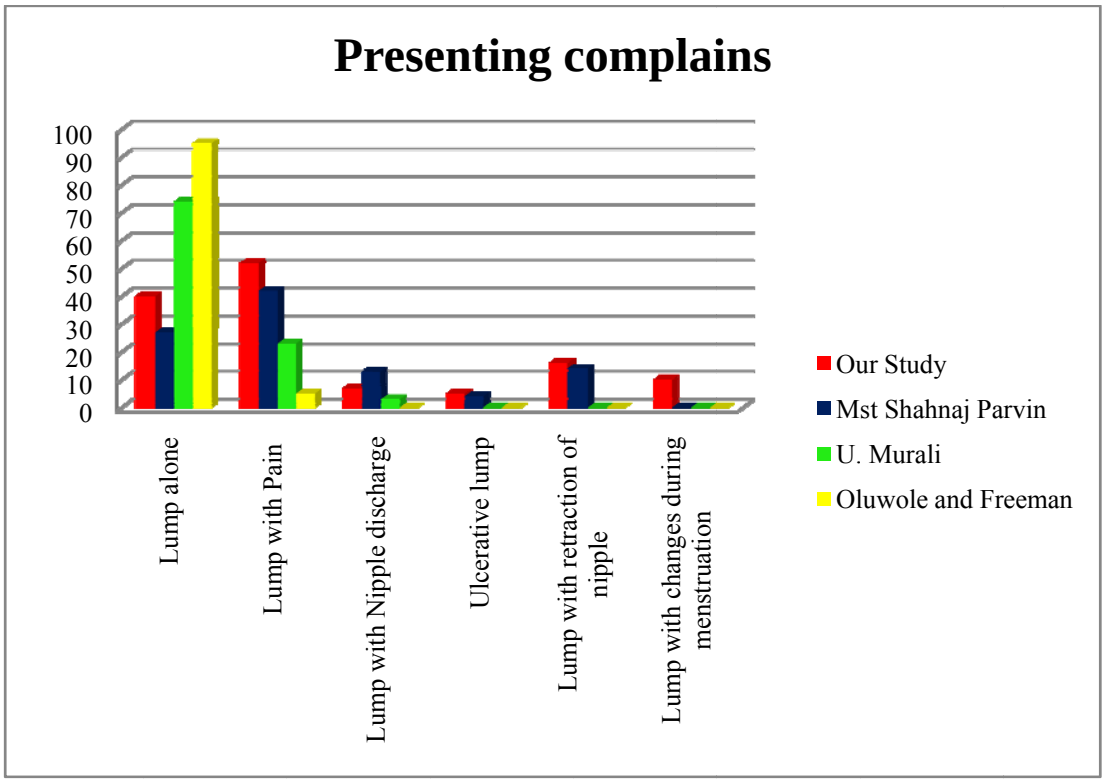


The females presented with complains ranging from lump in breast to ulcerative lump with bloody nipple discharge. Among the 100 females study, 40 females presented only with complains of lump in breast, 52 presented with complain of lump in breast with pain, 7 females presented with complains were of lump in breast with nipple discharge, 5 females had complains of ulcerative lump in breast. Majority of the females (42%) present with pain along with lump in a study by Mst Shahnaj Pervin followed by 27% of the females presenting only with lumps. In 1979, Oluwole and Freeman found that 95% of the patients presented only with breast lumps and 5% had associated complains of pain. U. Murali in his study stated that 74% of the females presented only with lump in the breast. There was association between lump in the breast and carcinoma of the breast (31.4%). Our study correlates with that of Mst. Shahnaj Pervin. Majority of maligant lumps had a longer duration of symptoms and had advanced stages of presentation. Correlation between nipple abnormalities and malignancy was seen in our study. The size of the lumps were larger in malignant lesions as compared to benign lesions. Mobility was seen in majority of the benign lesions except that in large inflammatory lesions.

Table 42: Comparison between different studies according to presenting complains.

Complain	Our Study	Mst Shahnaj Pervin	U. Murali	Oluwole and Freeman
Lump alone	40	27	74	95
Lump with Pain	52	42	23	5
Lump with Nipple discharge	7	13	3	0
Ulcerative lump	5	4	0	0
Lump with retraction of nipple	16	14	0	0
Lump with changes during menstruation	10	0	0	0

Chart 42: Comparison between different studies according to presenting complains.

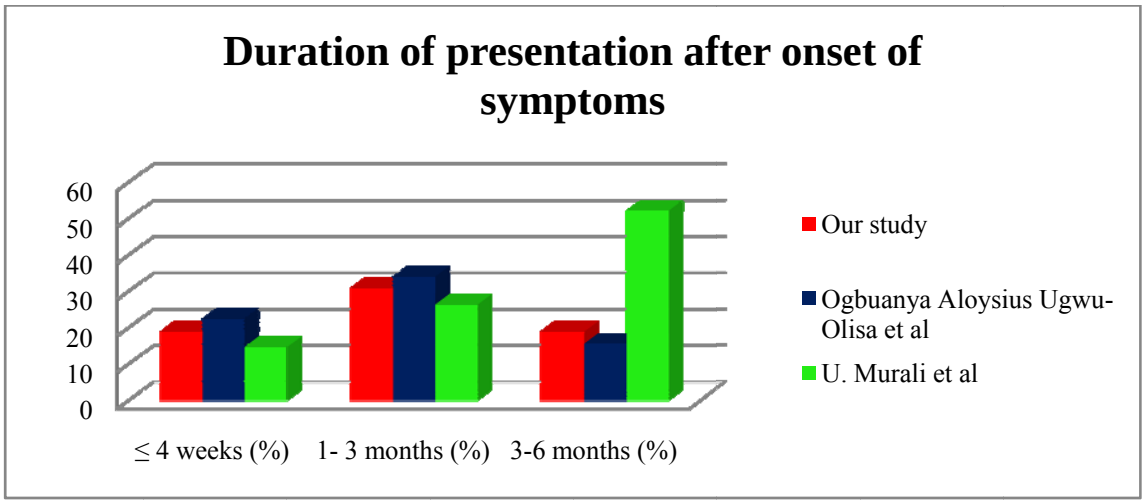


In our study only 19% of the patients presented before 4 weeks after presentation of the symptoms. 31% and 19% presented within 3 months and 6 months of development of symptoms. The duration of complains ranged from 1 week to 520 weeks having an average of 43.82 weeks. U. murali in his study had patients presenting between 1 to 156 weeks of development of symptoms with a mean of 18.6 weeks. 14.7% of the patients presented before 4 weeks after presention of complains. In a Study in Nigeria by Ogbuanya Aloysius Ugwu-Olisa patients presented between 4 days to 15 years with a mean of 2.8 years. 22.5% patients presented within 4 weeks of development of complains. 103 (34.1%) presented within 3 months of onset, 47(15.6%) within 3-6 months, 32 (10.6%) within 6-12 months and 120(39.7%) after 12 months of the onset of the symptoms. As in the study by U. Murali and Ogbuanya Aloysius Ugwu-Olisa et al in Mauratius and Nigeria respectively, and in our study, due to the study population belonging to a rural area and them being unaware regarding the seriousness of the complains and lack of tertiary health care center in their area, most of the patients (>75%) have presented later than 4 weeks after the onset of the symptoms. Low socio-economic background is one of the key- factors for the late presentation (>4 weeks) of the patients.

Table 43: Comparison between studies on the basis for duration of presentation after onset of symptoms

Study	≤ 4 weeks (%)	1- 3 months (%)	3-6 months(%)
Our study	19	31	19
Ogbuanya Aloysius Ugwu-Olisa et al	22.5	34.1	15.6
U. Murali et al	14.7	26.4	52.3

Chart 43: Comparison between studies on the basis for duration of presentation after onset of symptoms

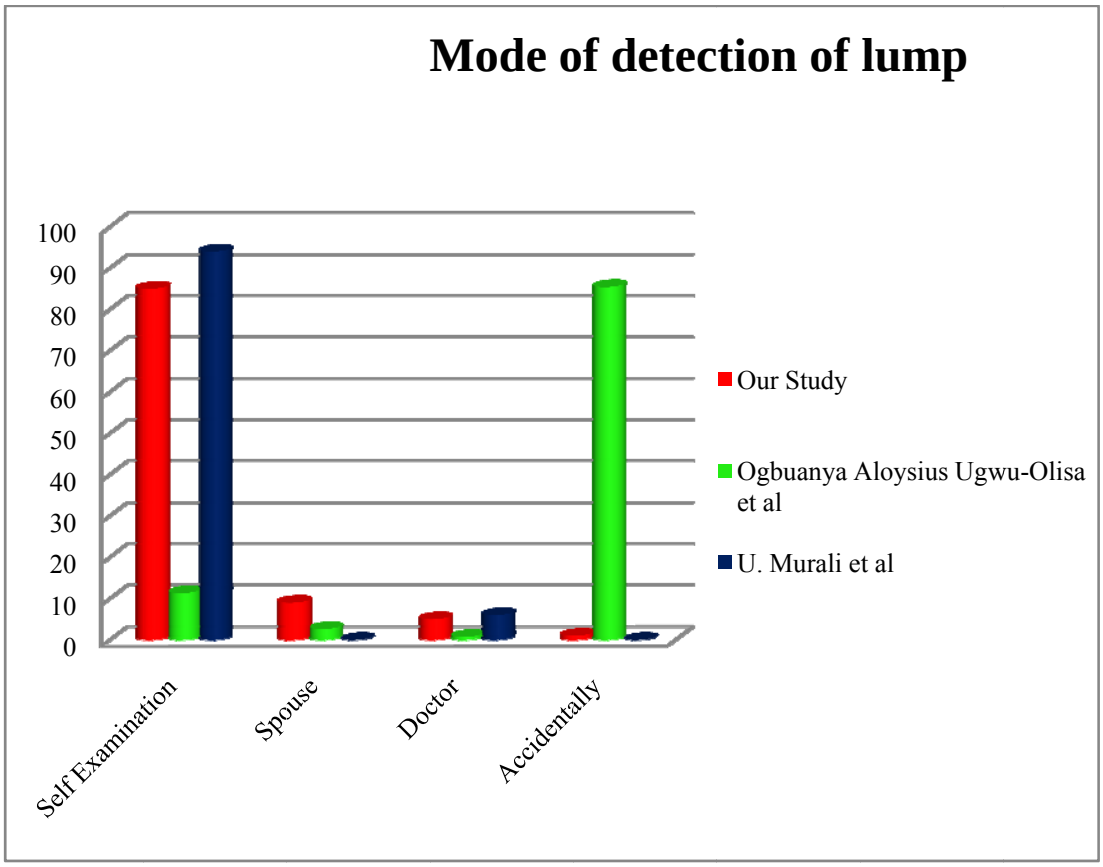


In our study, breast lump was found by self examination in 85 females, while it was found by their spouses in 9 females. In 5 females the lump was discovered by the doctor and in 1 female the lump was accidentally been found. In a study by Ogbuanya Aloysius Ugwu-Olisa et al breast lump was self detected by 11.3% females, in 85.4% of the cases it was an accidental discovery, 2.6 % females' spouses had detected the lump while in 0.7% females doctors had discovered the lump on clinical examination.[5] In a study by U. Murali 94% were self detected while 6% were detected by the doctor. Our results relate to results given by U. Murali. Our self-detection rates are very high as compared to 53% of in study given by Vargas et al in California[30]. In our study population, as the patients do not approach the doctor for regular check-up, most of the patients have detected the lump by self examination (88%).

Table 44: Comparison between studies on basis on detection of lump.

Lump discovered by	Our Study	Ogbuanya Aloysius Ugwu-Olisa et al	U. Murali et al
Self Examination	85	11.3	94
Spouse	9	2.6	0
Doctor	5	0.7	6
Accidentally	1	85.4	0

Chart 44: Comparison between studies on basis on detection of lump.

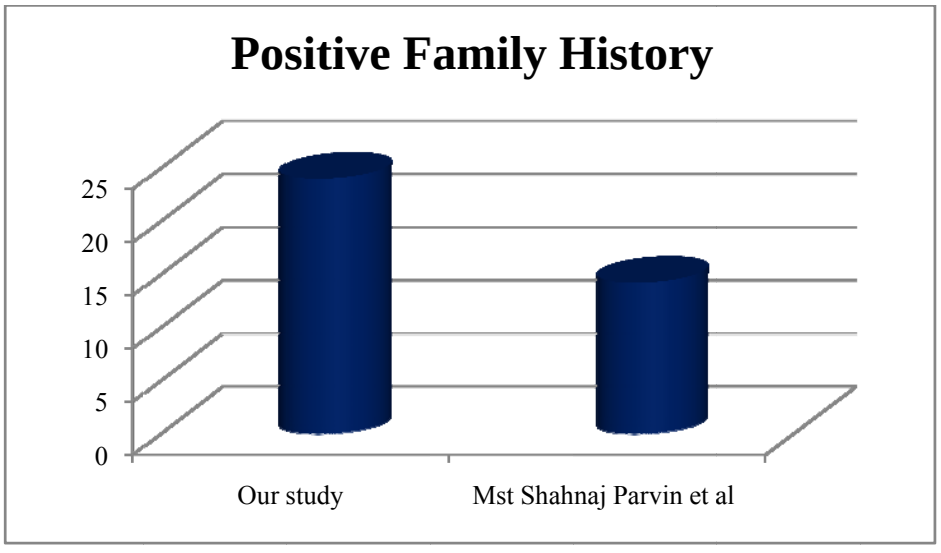


In our study the family history was positive for carcinoma of breast in 24 % of the patients. 14.2% of the patients gave positive family history for carcinoma of breast in the study by Mst. Shahnaj Pervin. The risk of developing carcinoma of breast increases two to three times in patient with first degree relatives(sister, mother and daughter) having carcinoma of breast. Our study shows strong association of carcinoma of breast with positive family history (44.44%). The risk increases if the relative has had the onset of disease before menopause or had bilateral carcinoma of breast. In such females the absolute risk is 50%, which is in compliance with autosomal mode of inheritance. The risk is superadded when the history of ovarian cancer is seen on same side of the family.

Table 45: Comparison of our study with another study on basis of family history.

Study	Positive Family History (%)
Our study	24
Mst Shahnaj Pervin et al	14.2

Chart 45: Comparison of our study with another study on basis of family history.

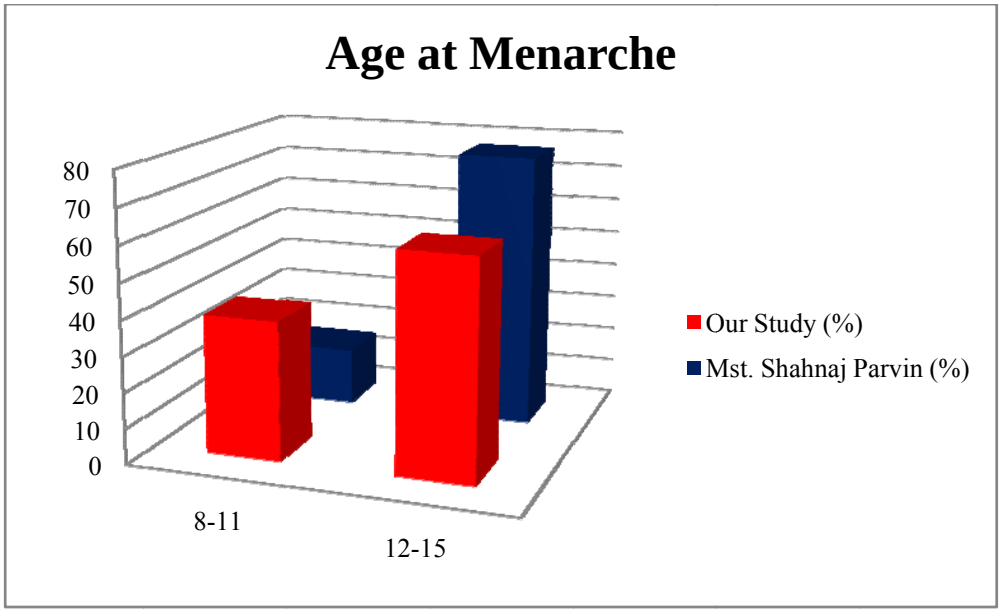


Reproductive milestones like onset of menarche before 12 years of age, first live child birth after 30 years of age, nulliparity and menopause after 55 years of age increases a women's life time exposure to estrogen which increases the risk of developing breast cancer. Majority of the females (67%) had their onset of menarche between 12-15 years, followed by 31 females in the age 8-11 years. In a study by Mst. Shahnaj Pervin 77% of the females had their onset on menarche between 12-15 years while 16% of the females had their onset of menarche between 8-11 years. Our results correlates with the results given by Mst. Shahnaj Pervin.

Table 46: Comparison between studies according to age at menarche

Age	Our Study (%)	Mst. Shahnaj Pervin (%)
8-11	39	16
12-15	61	77

Chart 46: Comparison between studies according to age at menarche

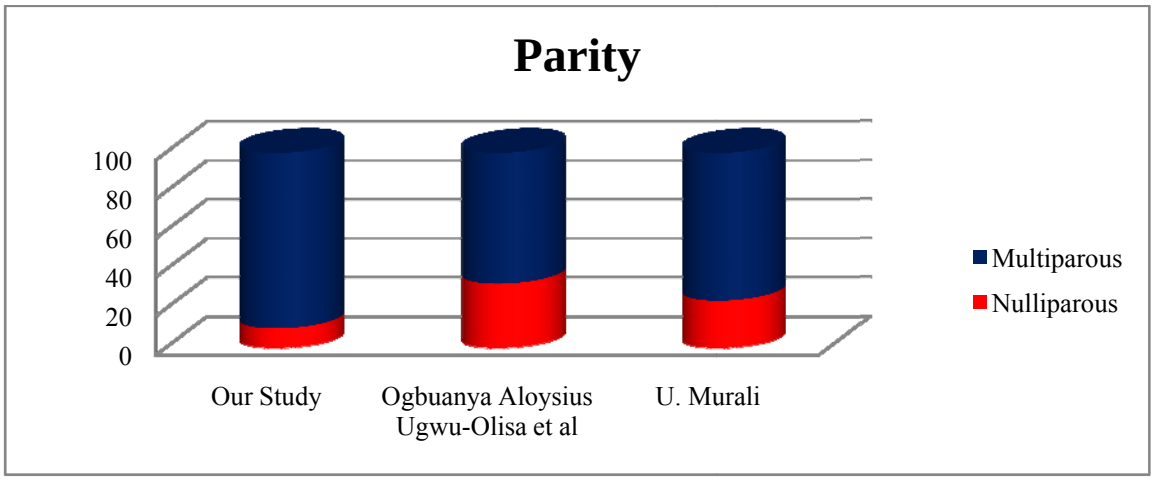


It has been observed and agreed upon that both benign and malignant lesions are more commonly seen in nulliparous women than in multiparous women having 3 or more than 3 children. Fibroadenosis is usually common in multiparous females. As our study has been done in a population where early mairrage is common, our results may vary from the standard results. In our Study among the 100 female patients, 10 were nulliparous while 90 were multiparous. In a study by Ogbuanya Aloysius Ugwu-Olisa et al 98 (32.9%) patients were nulliparous while 200 (67.1%) patients were multiparous.[5] In a study By U. Murali 18 (24.2%) of the patients were nulliparous while 72 (75.8%) patients were multiparous.[30] First full term pregnancy before the age of 18 years reduces the risk of developing breast cancer by half than the first pregnancy after the age of 30 years. In our study 30 patients had their first delivery before the age of 21 years out of which most had malignant lumps. The reason for our result is early marriages among the females of our study population and illiteracy.

Table 47: Comparison between different studies according to the parity.

Parity	Our Study	Ogbuanya Aloysius Ugwu-Olisa et al	U. Murali
Nulliparous	10	32.9	24.2
Multiparous	90	67.1	75.8

Chart 47: Comparison between different studies according to the parity.

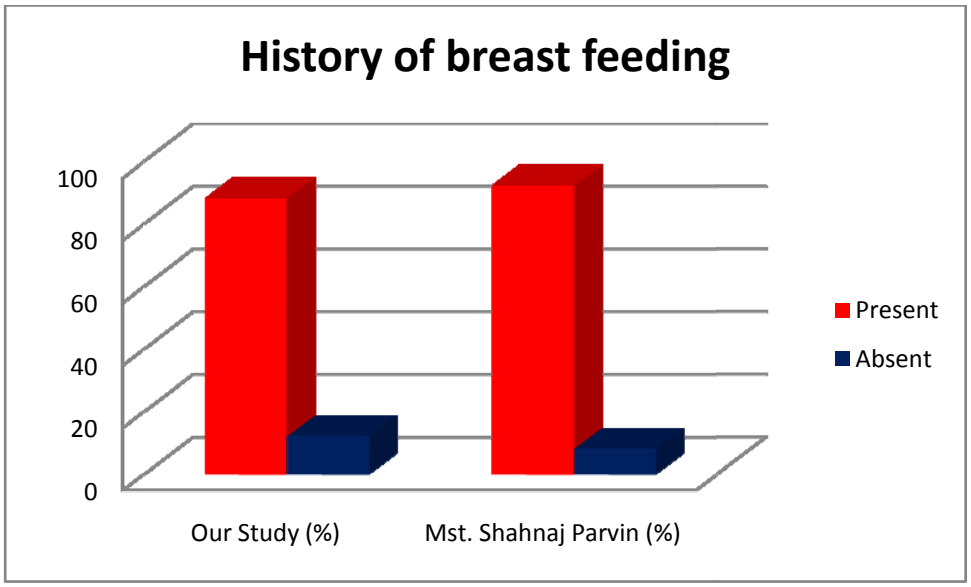


In our study, Out of the 100 females studied 88 females had the history of breast feeding while 12 had no history of breast feeding which is similar to the results given by Mst. Shahnaj Pervin which showed that 92% of the females had history of breast feeding. Interestingly enough, majority of the patients in our study though having the history of breast feeding presented with malignant lumps. The results were similar to that of Mst. Shahnaj Pervin et al. where in there is almost equal ratio of benign to malignant lumps. This finding donot correlate with the findings of breast feeding being a factor in reduction of risk of carcinoma of breast.

Table 48: Comparison between different studies on the basis of history of breast feeding.

H/o Breast Feeding	Our Study (%)	Mst. Shahnaj Pervin (%)
Present	88	92
Absent	12	8

Chart 48: Comparison between different studies on the basis of history of breast feeding.



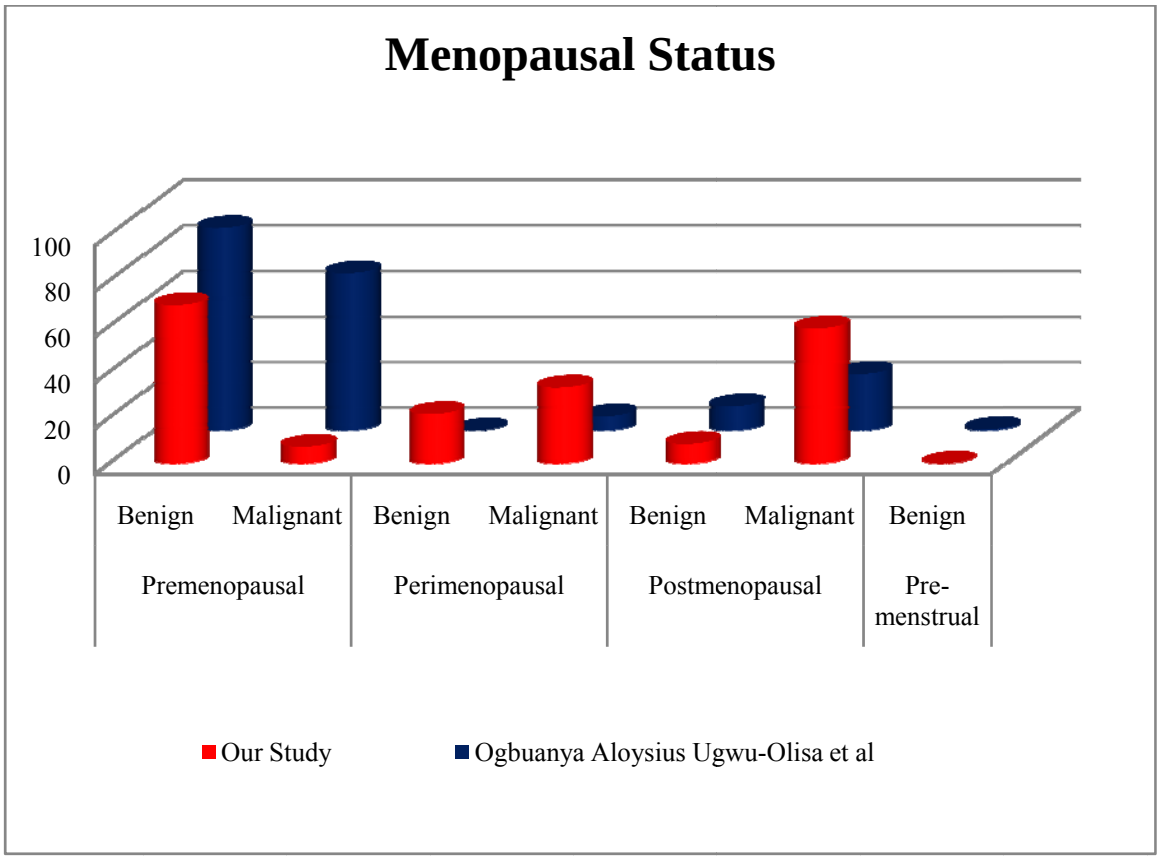
Use of therapeutic and supplemental estrogen or progesterone is most common in two cases, one as oral contraceptive in premenopausal and second as hormone replacement therapy in postmenopausal females. It is also used in menstrual irregularities, fertility treatment, polycystic ovaries and hormone insufficiency states. The risk for carcinoma of breast is high in patients currently using them or have used in the past, but the risk decreases as the duration after stopping the drug increases. It has been stated in a study that patients taking combination hormone replacement therapy with estrogen and progesterone for 5 years have 20% increase in risk for developing carcinoma of breast. In our study there is a strong correlation between the use of oral contraceptive and carcinoma of breast.

In this study 36 femlaes were premenopausal, 28 were perimenopausal and 36 were postmenopausal. Out of the 54 females that had malignant etiology 4 (7.4%) were premenopausal, 18 (33.33%) were perimenopausal and 32 (59.25%) were postmenopausal. Among the 46 females with benign breast lump 32 (69.5%) were premenopausal, 10 (21.7%)were perimenopausal and 4 (8.6%) were postmenopausal. In the study by Ogbuanya Aloysius Ugwu-Olisa et al, among females that had malignant etiology 69% were premenopausal, 6.2% were perimenopausal and 24.8% were postmenopausal. Among the 46 females with benign breast lump 88.88% were premenopausal, 10.6% were postmenopausal while 0.6% were pre-menstrual.

Table 49: Comparison between different studies correlation of menopausal status with nature of the lump

Menopausal Status	Nature of the Lump	Our Study	Ogbuanya Aloysius Ugwu-Olisa et al
Premenopausal	Benign	69.5	88.8
	Malignant	7.4	69
Perimenopausal	Benign	21.7	0
	Malignant	33.33	6.2
Postmenopausal	Benign	8.6	10.6
	Malignant	59.25	24.8
Pre-menstrual	Benign	0	0.6

Chart 49: Comparison between different studies correlation of menopausal status with nature of the lump



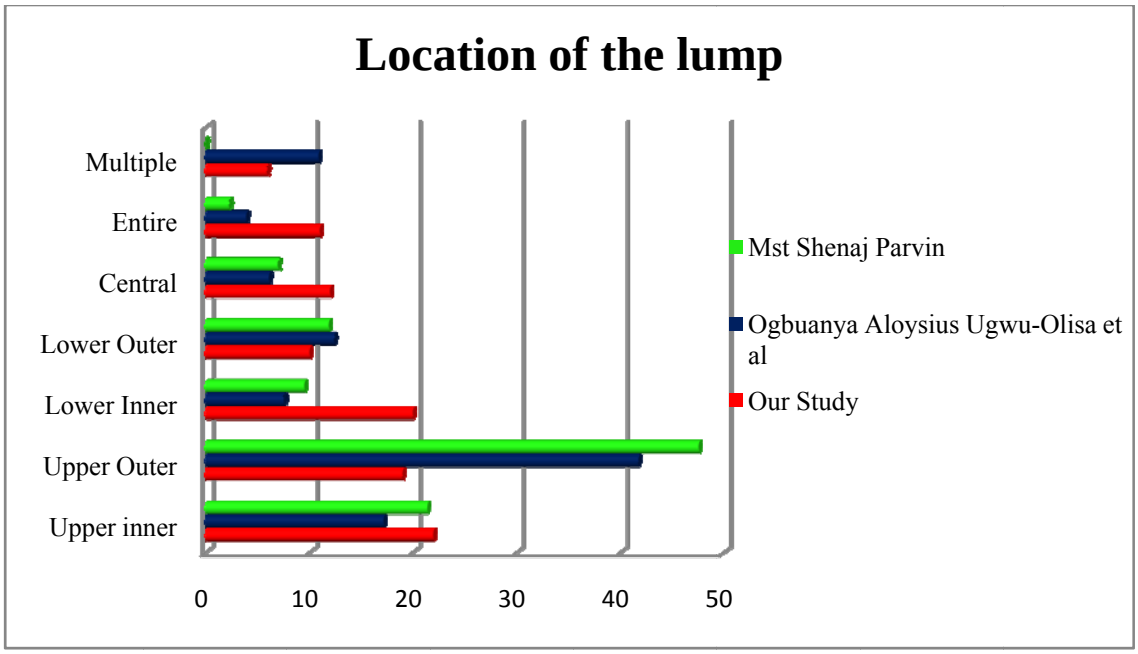
From studies in Africa, Yemen and Pakistan it has been seen that majority of females with breast lumps are premenopausal which causes a concern for development of invasive cancer in young women of these population. In our study also majority of the females with benign diseases are premenopausal, imposing a greater risk on them for development of breast cancer. It has also been noted that majority of the patients with malignant lumps are post menopausal which is consistent with the results of our study[5].

In our study maximum breast lumps (22) were found in upper inner quadrant while the least (6) were placed in multiple quadrants. Ogbuanya Aloysius Ugwu-Olisa et al and Mst. Shahnaj Pervin et al in their study had maximum lumps (41.72%) and (47.6%) in the upper outer quadrant respectively. Our findings almost correlate with the findings from the other studies.

Table 50: Comparison between different studies according to the location of the lump

Location	Our Study	Ogbuanya Aloysius Ugwu-Olisa et al	Mst Shenaj Pervin
Upper inner	22	17.2	21.4
Upper Outer	19	41.72	47.6
Lower Inner	20	7.61	9.5
Lower Outer	10	12.4	11.9
Central	12	6.2	7.1
Entire	11	3.97	2.3
Multiple	6	10.9	0

Chart 50: Comparison between different studies according to the location of the lump



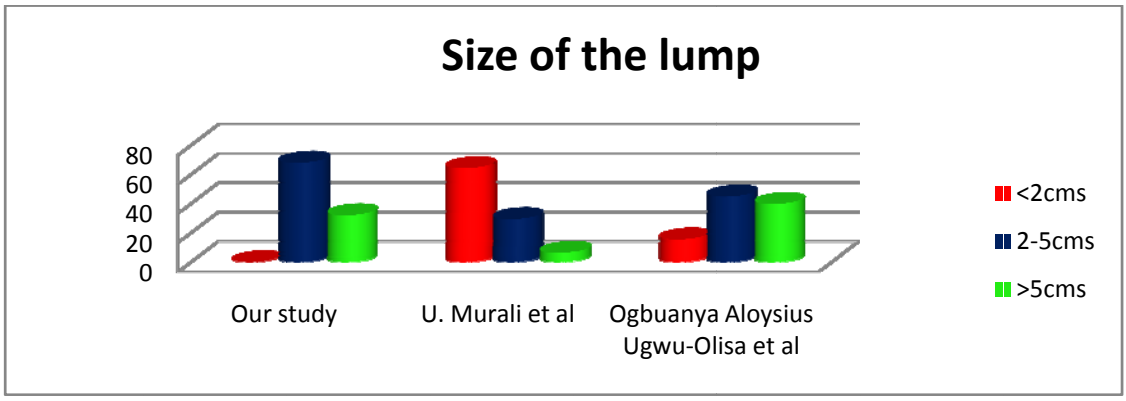
In this study the size of the lump ranged from 2 to 18 cms. With an average of 4.8 cms.

All patients had lumps greater than the size of 2 cms. In 68 patients the size of the lump was 2-5cms mostly in the age greater than 40 years. Most of the lumps were benign in nature. In 32 patients the size of the lump was greater than 5 cms out of which 27 females were more than 40 years of age. In a study by U. Murali et al, 64.2% of the patients had lump greater than 2 cm, 29.4% of the patients with lump in range of 2-5cms and 6.3% of the patients with lump greater than 5 cms. In a study by Ogbuanya Aloysius Ugwu-Olisa et al, 15.5% of the patients had lump greater than 2cms, 44.8% of the patients with lump in range of 2-5cms and 39.7% of the patients with lump greater than 5cms.

Table 51: Comparison between different studies according to the size of the lump.

Size (in largest dimension)	Our study	U. Murali et al	Ogbuanya Aloysius Ugwu-Olisa et al
<2cms	0	64.2	15.5
2-5cms	68	29.4	44.8
>5cms	32	6.3	39.7

Chart 51: Comparison between different studies according to the size of the lump.

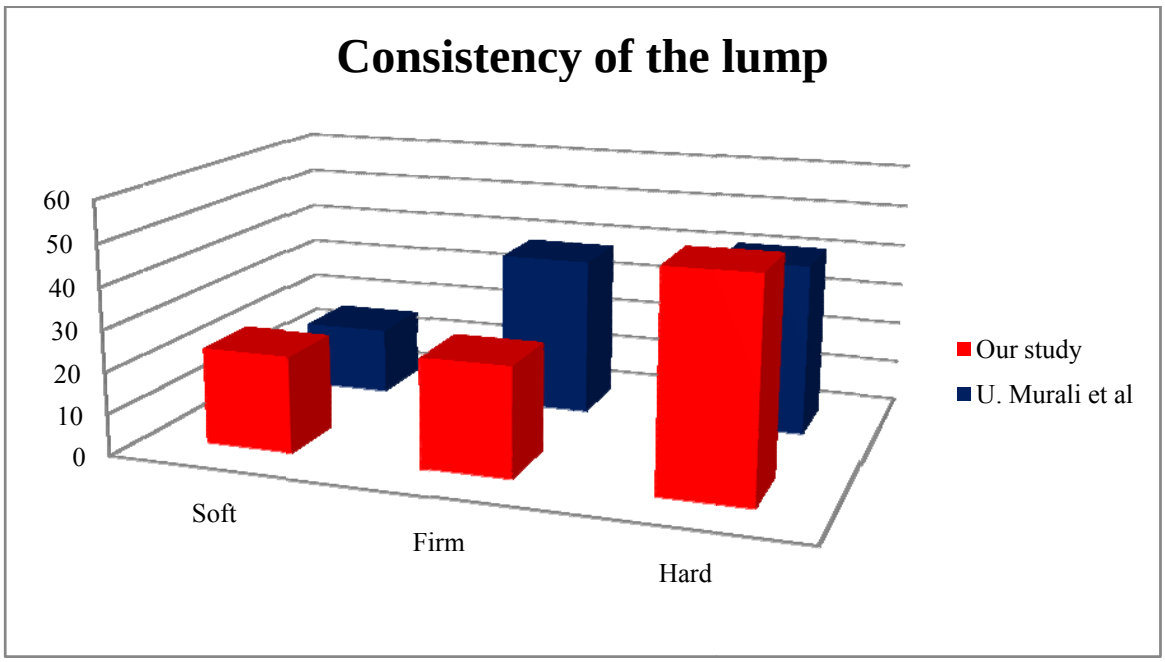


In our study, on examination 23 females had lump which were soft in consistency, 26 had firm consistency and 51 had hard consistency. Hard lumps were found in majority in females having malignant etiology. All lumps soft in consistency were benign. In a study by U. Murali et al, 16 females had lump which were soft in consistency, 38 had firm consistency and 41 had hard consistency. Our results support the data given by U.Murali which suggest that majority of the malignant breast lumps are hard in consistency while patients with fibroadenoma and fibrocystic diseases have lumps which are soft in consistency.

Table 52: Comparison different studies based on the consistency of the lump

Consistency	Our study	U. Murali et al
Soft	23	16
Firm	26	38
Hard	51	41

Chart 52: Comparison between different studies based on the consistency of the lump



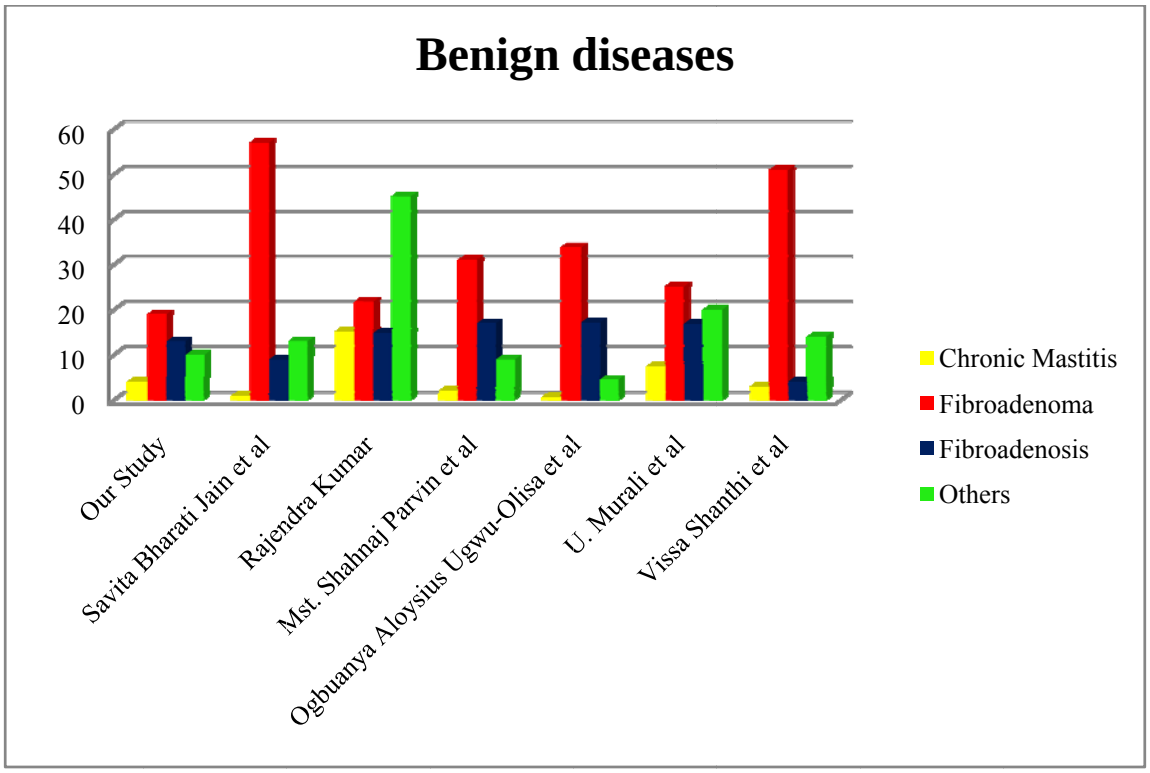
Furthermore on examination, in our study, it was revealed that 16 females with malignant lumps showed fixity to skin and surrounding structures. Skin changes were seen in 9 patients with malignant lumps. No benign lumps showed fixity to the surrounding structures. In a study by U. Murali et al, the similar result was seen in which fixity to skin and underlying structures was more evident in patients with malignant lumps. This made our clinical examination a good differentiating indicator from benign lesions.

In our study the most common histological diagnosis among benign lesions was fibroadenoma(19%), followed by fibroadenosis(13%) and then by chronic mastitis(4%). In a study by Savita Bharati et al, the most common benign lesion was fibroadenoma(57%), followed by fibroadenosis(9%). In a study by Rajendra Kumar the most common lesion was fibroadenoma(21.81%), followed by fibroadenosis(14.81%) and then by chronic mastitis(15.22%). In a study by Mst. Shahnaj Pervin et al, the most common benign lesion was fibroadenoma(37%), followed by fibroadenosis(17%). In a study by Ogbuanya Aloysius Ugwu-Olisa et al, the most common benign lesion was fibroadenoma(33.8%), followed by fibroadenosis(17.2%). In a study by U. Murali et al, the most common lesion was fibroadenoma(25.2%), followed by fibroadenosis(16.8%) and then by breast cyst(10.52%). In a study by Vissa Shanthi et al, the most common lesion was fibroadenoma(51%), followed by fibrosis(6%) . Our results are consistent with the results of other studies.

Table 53: Comparison between studies according to histological types of benign lumps

Diagnosis	Our Study	Savita Bharati Jain et al	Rajendra Kumar	Mst. Shahnaj Pervin et al	Ogbuanya Aloysius Ugwu-Olisa et al	U. Murali et al	Vissa Shanthi et al
Chronic Mastitis	4	1	15.22	2	0.7	7.4	3
Cystosarcoma Phyllodes	2	0	0	0	1.7	1.05	4
Duct Ectasia	1	0	1.23	0	1.0	1.05	0
Fat Necrosis	2	0	2.05	0	0	1.05	0
Fibroadenoma	19	57	21.81	31	33.8	25.2	51
Fibroadenosis	13	9	14.81	17	17.2	16.8	4
Hematoma	1	0	0.82	1	0	0	0
Lipoma	2	1	0.82	2	0.3	2.1	1
Neurofibroma	1	0	0	0	0.3	0	0
Sclerosing adenosis	1	0	1.64	1	0	2.1	0
Abscess	0	3	0	1	0	1.05	0
Gynaecomastia	0	3	2.46	1	0.3	0	0
Lactating adenoma	0	2	0	0	0.3	0	0
Tubercular abscess	0	2	3.29	0	0	0	2
Duct Papilloma	0	1	2.88	0	0	0	0
Atypical ductal hyperplasia	0	1	2.88	1	0	1.05	0
Galactocele	0	0	0.82	0	0	0	1
Breast Cyst	0	0	4.52	1	0	10.52	0
Fibrosis	0	0	8.23	0	0	0	6
Ductal hyperplasia	0	0	12.34	1	0	0	0
Adenoma	0	0	0.82	0	0	0	0
Sclerosing Fibrosis	0	0	0.41	0	0	0	0
Granula cell tumor	0	0	0	0	0.3	0	0
Reactive intramammary lymph node	0	0	0	0	0.3	0	0

Chart 53: Comparison between studies according to histological types of benign lumps



The rarity of minor breast tumors seen in our study in consistent with reports found in earlier studies in Maid Uguri, Nnewi. As in our study the case of duct ectasia was misdiagnosed as chronic mastitis, while a phyllodes tumor due to its large size and hard consistency was diagnosed to be malignant on clinical examination, but histological examination confirmed its benignity. Several similar cases were seen in this study. The clinical importance of these findings matter in the management of these lumps which show the necessity of step- wise diagnostic approach for dominant breast masses[5].

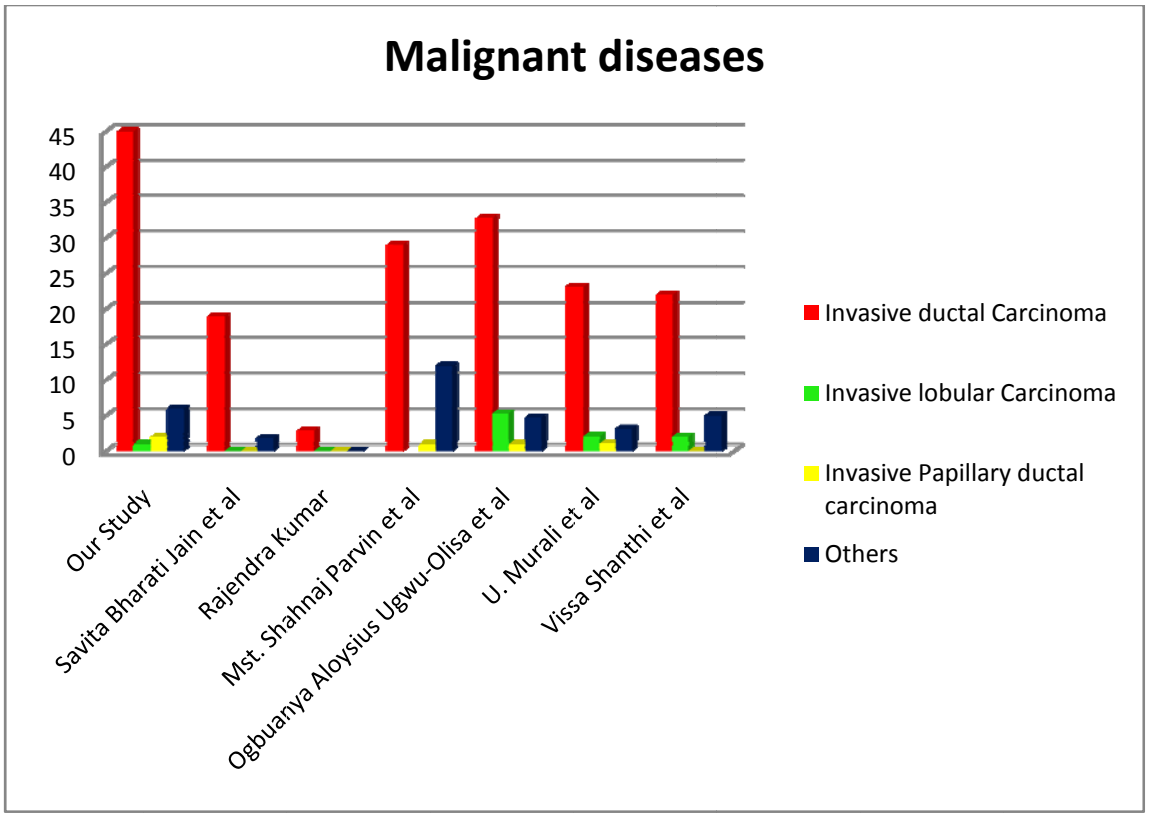
In our study the most common histological diagnosis among malignant lesions was Invasive ductal Carcinoma (45%), followed by Infiltrating Ductal Carcinoma with Paget's Disease (3%). In a study by Savita Bharati et al, the most common malignant lesion was Invasive ductal Carcinoma (57%) followed by apocrine carcinoma(1%).

In a study by Rajendra Kumar the only malignant lesion was Invasive ductal Carcinoma (2.88%). In a study by Mst. Shahnaj Pervin et al, the most common malignant lesion was Invasive ductal Carcinoma (29%), followed by mucinous adenocarcinoma (5%). In a study by Ogbuanya Aloysius Ugwu-Olisa et al, the most common malignant lesion was Invasive ductal Carcinoma (32.8%), followed by Invasive lobular Carcinoma(5.3%). In a study by U. Murali et al, the most common malignant lesion was Invasive ductal Carcinoma (23.15%), followed by Invasive lobular Carcinoma(2.10%). In a study by Vissa Shanthi et al, the most common lesion was the most common malignant lesion was Invasive ductal Carcinoma (22%), followed by Invasive lobular Carcinoma(2%). Our results are consistent with the results of other studies. The results coincide with data from Africa, Pakistan and India. The frequency of invasive ductal carcinoma (83.33%) among malignant lesions is similar to that in Sokoto (76.2%), Nigeria and Yemen (86.6%). This points out that difference in clinical profile in India and Western countries is not due to histological types but due to tumor biology, delayed presentation, poverty and social and cultural differences. Ali-Fehmi et al. in 2003; Skandarajah et al., in 2008 stated that intraductal papilloma, specifically multiple papilloma diagnosed on core biopsy were malignant on histopathology which is a marker for breast cancer risk. Multiple benign breast lesions are also a risk factor for carcinoma of breast as stated by Cheng et al in 2008.Khan et al stated that mortality and incidence is comparatively lower in developing countries and other countries as compared to western countries.

Table 54: Comparison between studies according to histological types of malignant lumps

Diagnosis	Our Study	Savita Bharati Jain et al	Rajendra Kumar	Mst. Shahnaj Pervin et al	Ogbuanya Aloysius Ugwu-Olisa et al	U. Murali et al	Vissa Shanthi et al
Invasive ductal Carcinoma	45	19	2.88	29	32.8	23.15	22
Invasive lobular Carcinoma	1	0	0		5.3	2.10	2
Invasive Papillary ductal carcinoma	2	0	0	1	1.0	1.05	0
Ductal Carcinoma in situ	0	0	0	0	0.7	1.05	0
Squamous Cell Carcinoma	1	0	0	0	0	0	0
Mucinous Adenocarcinoma	2	0	0	5	1.3	0	1
Infiltrating Ductal Carcinoma with Paget's Disease	3	0	0	0	0	1.05	0
Apocrine carcinoma	0	1	0	0	0	0	0
Comedocarcinoma	0	0.41	0	0	0	0	0
Schirrous	0	0.41	0	0	0	0	1
Medullary Carcinoma	0	0	0	2	2.0	0	1
Tubular Carcinoma	0	0	0	3	0	0	0
Malignant Phyllodes tumor	0	0	0	2	0	1.05	1
Burkitt's lymphoma	0	0	0	0	0.7	0	0
Hemangiendothelioma	0	0	0	0	0	0	1

Chart 54: Comparison between studies according to histological types of malignant lumps

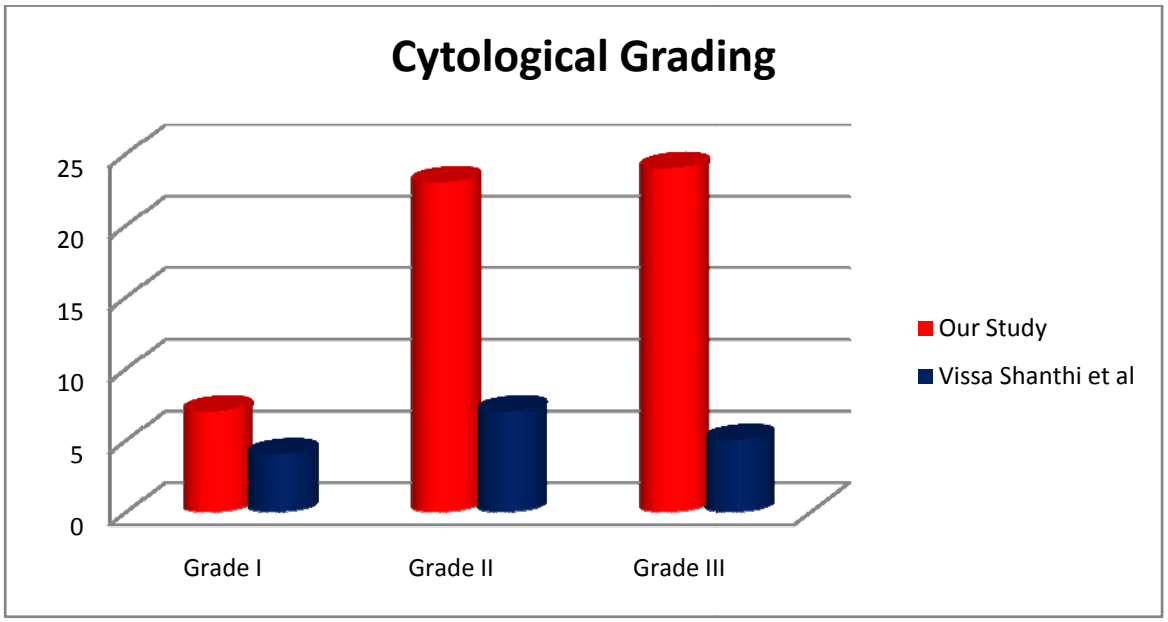


The clinical features of fibroadenomas overlap with that of localized dysplastic change of the breast. So few of the patients clinically diagnosed to have fibroadenomas had to be subjected to histopathological examination. For this Fine Needle Aspiration Cytology was performed. But in few cases it being nonconclusive, excision biopsy was conducted for confirmation of the report.[27] On cytological examination of the malignant lumps, in our study, it was found that 7 patients had grade I tumor according to the Modified Scarff Bloom Richardson histological Grading, while 23 had grade II tumors and 24 had Grade III tumors. In a study by Vissa Shanthi et al 4% of the patients had grade I tumor, 7% had grade II tumors and 5% had grade III tumors.

Table 55: Comparison between different studies in study population with malignant lump according to Modified Scarff Blood Richardson histological grading system

Grading of the tumor	Our Study	Vissa Shanthi et al
Grade I	7	4
Grade II	23	7
Grade III	24	5

Chart 55: Comparison between different studies in study population with malignant lump according to Modified Scarff Blood Richardson histological grading system



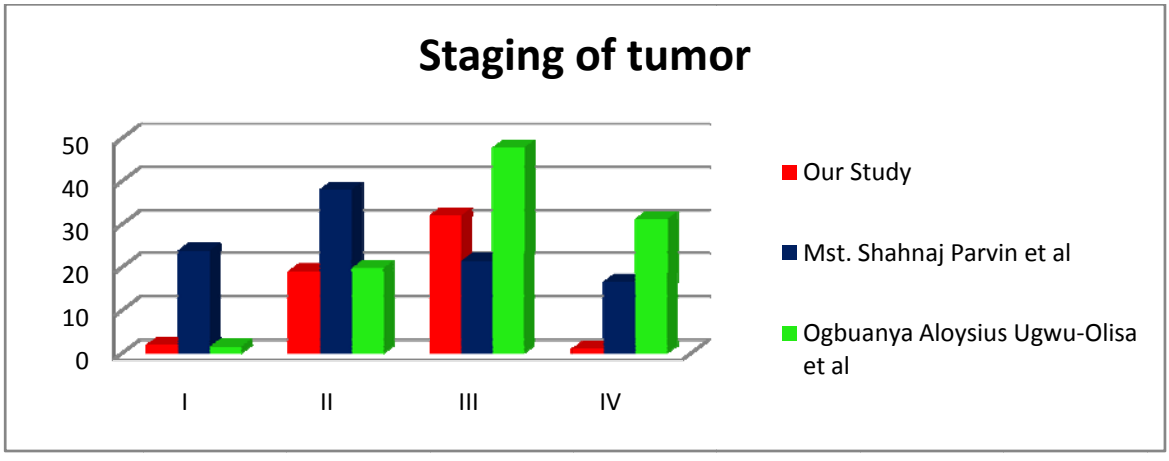
Of the 54 females with malignant lumps, in our study, after the histopathological examination of the excised lump, it was found that highest numbers of females (32) were in Stage III according to the TNM classification of Carcinoma of breast followed by Stage II. In a study by Mst. Shahnaj Pervin et al, it was found that highest numbers of females (38%) were in Stage II followed by Stage I (23.8%). In a study by

Ogbuanya Aloysius Ugwu-Olisa et al, it was found that highest numbers of females (47.7%) were in Stage III followed by Stage I (19.7%). Our results were consistent with that of Ogbuanya Aloysius Ugwu-Olisa et al.

Table 56: Comparison between different studies study population with malignant lumps according to the TNM staging of the tumor

Staging of the tumor	Our Study	Mst. Shahnaj Pervin et al	Ogbuanya Aloysius Ugwu-Olisa et al
I	2	23.8	1.5
II	19	38	19.7
III	32	21.4	47.7
IV	1	16.6	31.1

Chart 56: Comparison between different studies study population with malignant lumps according to the TNM staging of the tumor

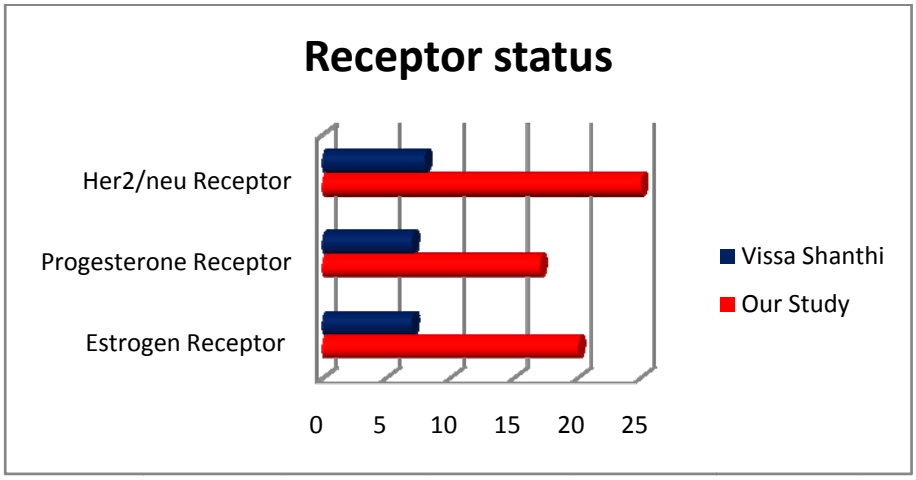


ER, PR and Her2/neu are important factors for estimating the prognosis of the patient. The tumors that are ER and PR positive have strong correlation with low grade nuclei while Her2/neu positive tumors have relation to high grade nuclei. Out of the 54 females with malignant lumps, 20 females had their Estrogen receptor positive, 17 had progesterone receptor positive while 25 had Her2/neu receptor status positive. In a study by Vissa Shanthi, 7 patients had Estrogen receptor positive, 7 had progesterone receptor positive and 8 patients had Her2/neu receptor positive.

Table 57: Comparison between different studies in study population with malignant lumps on the basis of the positivity of the receptors.

Receptors positive	Our Study	Vissa Shanthi et al
Estrogen Receptor	20	7
Progesterone Receptor	17	7
Her2/neu Receptor	25	8

Chart 57: Comparison between different studies in study population with malignant lumps on the basis of the positivity of the receptors.

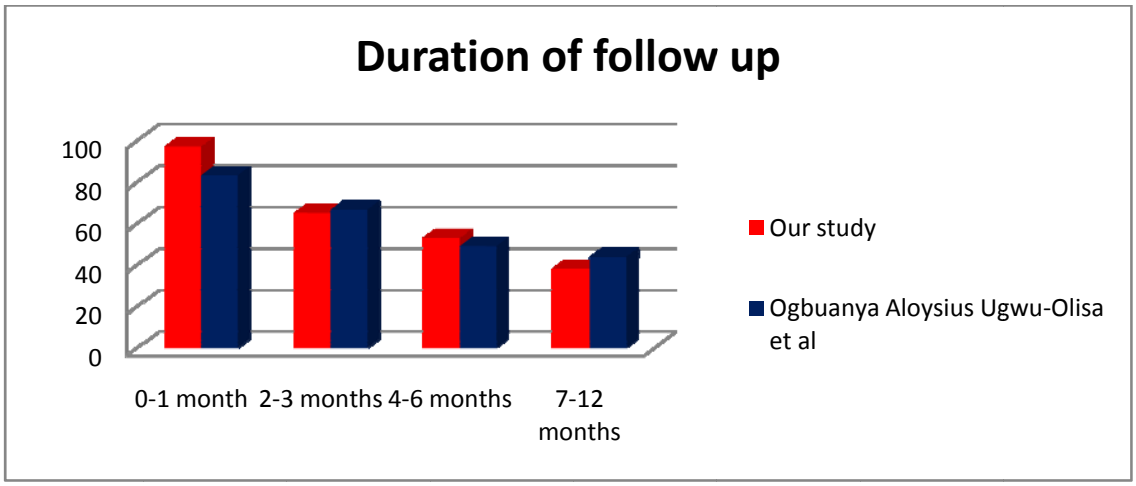


In our study, among the 100 female patients, 97 were available for follow up at 1 month ,65 were available for follow up till 3 months, 53 till 6 months and 38 were available for follow up till 12 months. 3 patients did not come up for follow up at all. The median of duration of follow up was 5 months. In a study by Ogbuanya Aloysius Ugwu-Olisa et al, 83.1% were available for follow up at 1 month ,66.6%were available for follow up till 3 months, 49% till 6 months and 44.0% were available for follow up till 12 months. The median of duration of follow up was 9 months. Our results were consistent with other studies. Most patient with malignant lumps showed follow-up for chemotherapy which was atleast given 6 times. Only a few patients with benign lumps showed follow up for more than 1 month resulting into a great decrease in follow-up past 1 month.

Table 58: Comparison between different studies on the basis of duration of follow-up.

Duration of follow up	Our study	Ogbuanya Aloysius Ugwu-Olisa et al
No follow up	3	-
0-1 month	97	83.1
2-3 months	65	66.6
4-6 months	53	49.0
7-12 months	38	44.0

Chart 58: Comparison between different studies on the basis of duration of follow-up.

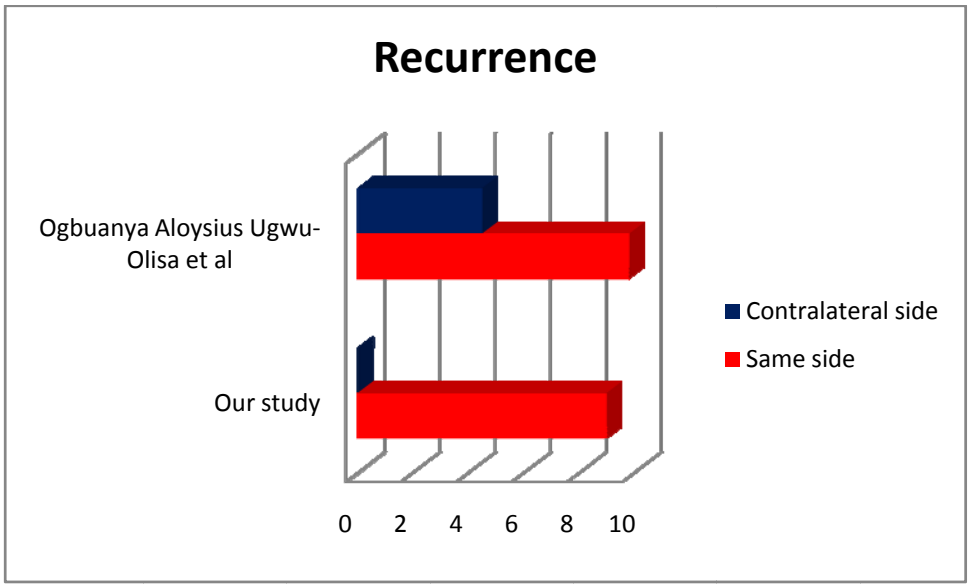


Out of the 100 patients in our study, 9 patients showed recurrence, out of which 4 patients had benign etiology while 5 patients had malignant etiology on primary assessment. All had recurrence on the same site. In a study by Ogbuanya Aloysius Ugwu-Olisa et al, 9.8% had recurrence on the same site and 4.5% had recurrence on the contralateral site. The likelihood of patient developing second primary cancer in contralatral breast increases in patient with history of breast carcinoma on one side. The intensity of risk is dependent on age at the diagnosis of previous primary cancer, status of estrogen receptor of previous carcinoma of breast and whether the patient had adjuvant systemic chemotherapy and endocrine therapy. In our study 5 patients have had recurrence of carcinoma of breast , all of which were on the ipsilateral breast.

Table 59: Comparison between different studies on the basis of recurrence

Recurrence	Our study	Ogbuanya Aloysius Ugwu-Olisa et al
Same side	9	9.8
Contralateral side	0	4.5

Chart 59: Comparison between different studies on the basis of recurrence

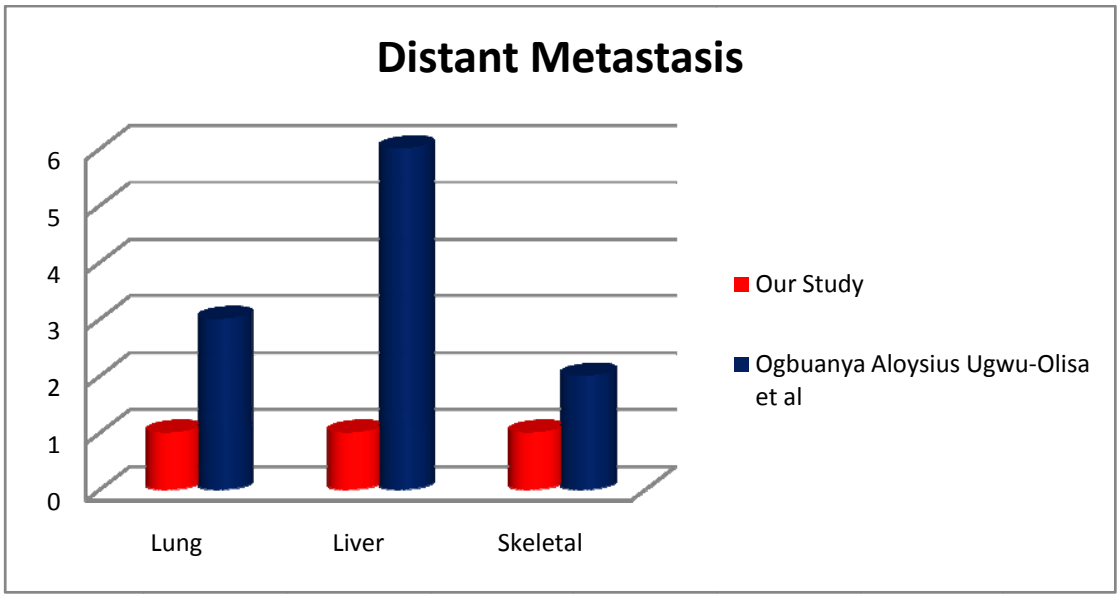


Following Carcinoma of breast metastasis is seen to bone which is most common followed by liver, lung, brain, adrenal and ovaries. They also have transcoelomic spread. In our study 1 patient had developed liver metastasis while 1 developed lung metastasis and 1 had skeletal metastasis. In a study by Mst. Shahnaj Pervin 3 patients had lung metastasis, 6 with liver metastasis and 2 with skeletal metastasis.

Table 60: Comparison between different studies on basis of distant metastasis.

Organ	Our Study	Mst. Shahnaj Pervin et al
Lung	1	3
Liver	1	6
Skeletal	1	2

Chart 60: Comparison between different studies on basis of distant metastasis.



Analytical study of clinic-pathological features was conducted on 100 female patients having breast lumps and following conclusion was made based on our findings:

Patients presenting with lump in breast alone or with pain along with lump, nipple retraction or ulceration were examined thoroughly and were admitted for further evaluation according to diagnostic protocol. After the clinical examination patients were subjected to Fine Needle Aspiration Cytology followed by Histopathological examination following surgery for the lump. All the 100 patients underwent this protocol and based on the histopathology report further treatment was carried out.

1. The maximum patients were in the 5^{th} decade of life followed by 4^{th} decade of life. Breast lumps usually occur after the age of 17 years owing to the peak of female sex hormones.
2. Patients presenting to our setup belonged to the rural areas of Gujarat and Madhya Pradesh. This resulted in late presentation of the patient after the onset of symptoms owing to the illiteracy and unawareness about the severity of the breast lumps. This also caused the increase in proportion of malignant lesions presenting to our setup.
3. Due to the social customs females from such population donot promptly approach the doctor when the develop symptoms which leads to self detection of lumps in majority of the females.
4. Though in Indian Rural population, benign breast diseases are more common than the malignant lesions, our findings shows almost equal proportion of benign as well as malignant lumps. As fibroadenomas, especially complex fibroadenomas and ductal hyperplasia impose a risk of developing breast cancer and the patients present late to our setup after onset of symptoms, could be the reason for preponderance towards malignant breast lesions in our study.

5. On basis of physical and social, there is a predominance of left side involvement in females which is consistent with our findings.
6. Most patients have presented with lump in breast pain out of which most are benign sparing a few having advanced stages of carcinoma of breast. Nipple discharge, retraction of nipple and ulcerative lump were consistent with malignant lesions.
7. The risk of developing carcinoma of breast increases two to three times in patient with first degree relatives(sister, mother and daughter) having carcinoma of breast. Our study shows strong association of carcinoma of breast with positive family history.
8. Reproductive milestones like onset of menarche before 12 years of age, first live child birth after 30 years of age, nulliparity and menopause after 55 years of age increases a women's life time exposure to estrogen which increases the risk of developing breast cancer. In our study, majority of the females had their onset of menarche between 12-15 years.
9. First full term pregnancy before the age of 18 years reduces the risk of developing breast cancer by half than the first pregnancy after the age of 30 years. In our study 30 patients had their first delivery before the age of 21 years out of which most had malignant lumps due to early marriages among the females of our study population and illiteracy.
10. Breast feeding decreases the risk for development of carcinoma of breast. But in our study there is no strong correlation between the two.
11. Majority of the females with benign diseases are premenopausal, imposing a greater risk on them for development of breast cancer. It has also been noted that majority of the patients with malignant lumps are post menopausal.

12. History of oral contraceptive and hormone replacement therapy use is one of the modifiable risk factor for carcinoma of breast. The present finding suggest the status of use of such treatment donot significantly increase the risk of carcinoma of breast but however our study points out that there is a correlation between the use of oral contraceptive pills and carcinoma of breast.
13. Most lumps were found in upper inner quadrant. Size of the lump, its fixity to surrounding structures, its mobility, the skin changes guides towards the diagnosis of the lump. In our study larger size of the lump was seen in malignant lesions, while mobility was observed in fibroadenomas and skin changes were seen more in malignant lesions.
14. Consistency of the lump is one of the diagnostic marker for clinical examination. Majority of the malignant breast lumps are hard in consistency while patients with fibroadenoma and fibrocystic diseases have lumps which are soft in consistency.
15. Fibroadenomas are among the most common benign lesions of the breast. While invasive ductal carcinoma is the most common of the malignant lesions of the breast. Our findings are consistent with this result.
16. Fine Needle Aspiration Cytology is a minimally invasive and cheap invesrtigaton. In our study it was not able to correctly diagnose the lump in 12 cases.
17. Grading of the tumor is done according to Modified Scarff Bloom Richardson grading system. Most of the patients due to late presentation were in Grade II and Grade III category.

18. TNM staging is a universally accepted staging for grading of carcinoma of breast on basis of histopathological examination. Most patient had Stage III tumors.
19. ER, PR and Her2/neu are important factors for estimating the prognosis of the patient. The tumors that are ER and PR positive have strong correlation with low grade nuclei while Her2/neu positive tumors have relation to high grade nuclei. In our study almost half of the females with malignant lesions had Her2/neu receptor positive showing bad prognosis.
20. Most patient with malignant lumps showed follow-up for chemotherapy which was atleast given 6 times. Only a few patients with benign lumps showed follow up for more than 1 month resulting into a great decrease in follow-up past 1 month.
21. The intensity of risk is dependent on age at the diagnosis of previous primary cancer, status of estrogen receptor of previous carcinoma of breast and whether the patient had adjuvant systemic chemotherapy and endocrine therapy. In our study 5 patients have had recurrence of carcinoma of breast , all of which were on the ipsilateral breast.

Study of 100 patients presenting with lump in breast:

1. All the patients studied were females.
2. 31% of the patients presented in the 5^{th} decade of life.
3. Patients with benign lesions were more commonly seen in 3^{rd} & 4^{th} decade of life (56.5%).
4. Majority of patients with malignant lesions were seen in 5^{th} decade of life (38.8%).
5. 88% of the females were Hindu by religion.
6. 54% of the lesions were malignant while 46% were benign.
7. 59% of patients had lump in left breast.
8. 88% of the patients had solitary lumps.
9. Majority of the patients (52%) presented with lump in breast associated with pain. Other presenting complains were lump alone, nipple retraction, ulcerative lump and nipple discharge.
10. Most of the patients (81%) showed up after 4 weeks of onset of symptoms.
11. 5 patients had history of trauma.
12. Majority of the patients (85%) found the lump of self examination of the breast.
13. 24 patients (24%) had positive family history of carcinoma of breast.
14. Past history of ovarian and gastrointestinal malignancy was seen in 1 patient each.
15. 79% of the patients had onset of menarche between 9-12 years.
16. 85% of the patient were multiparous with 41% having 2 children. Majority of them had malignant lumps (63.53%).
17. 67% of the patients had history of oral contraceptive use.

18. 88% of the patients had history of breast-feeding.
19. 44.44% of postmenopausal female had their onset of menopause between 51-55 years.
20. 32% of the females with benign lesions were premenopausal while 32% of females with malignant lumps were postmenopausal.
21. 22% of the female had lump in upper inner quadrant.
22. 68% of the patients had lump between 2-5cms.
23. 51% of the lumps were hard in consistency, 92.15% of which were malignant.
24. 16 patients with malignant lumps showed fixity to surrounding structures.
25. Skin changes were seen in 14 patients.
26. Most common lesion on clinical examination was carcinoma of breast (57%).
27. The most common benign lesion on histopathology examination was fibroadenoma(41.3%) while the most common malignant lesion was invasive ductal carcinoma (83.35%).
28. Majority of the patients with malignant lesions had 1 or 2 lymph nodes palpable.
29. Majority of the patients with benign lumps underwent excision while majority with malignant lesions underwent modified radical mastectomy.
30. 68.5% patients with malignant lesions showed tumor invasion in less than 5 lymph nodes.
31. 44.44% patients with malignant lumps had grade III tumors according to Modified Scarff Richardson cytological grading.
32. 59.25% of the patients had Stage III tumors.
33. Among the patients with malignant lumps, 20 had Estrogen receptors positive, 17 had Progesterone receptors positive and 25 had Her2/Neu receptor positive.
34. 38% of the patients showed up for follow-up upto 1 year.

35. 88.89% of patients with malignant lumps took 6 cycles of chemotherapy.
36. 5 patients with carcinoma of breast had recuurence of ipsilateral breast on follow-up.
37. 1 patient each showed liver, lung and skeletal metastasis on follow-up.

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ANNEXURE I
ABBREVIATIONS

BC- Before Christ

AD- After Death

BI-RADS- Breast Imaging Reporting and Data System

FDA- Food and Drug Association

FNAC- Fine Needle Aspiration Cytology

OPD- Out Patient Department

RS- Respiratory System

CVS- Cardiovascular System

CNS- Central Nervous System

USG- Ultra Sonography

ER- Estrogen Receptor

PR- Progesterone Receptor

Her2/Neu- Human Epidermal Growth Factor Receptor 2

ANNEXURE II

INFORMED CONSENT FORM

SUMANDEEP VIDYAPEETH UNIVERSITY

Piparia, Ta. Waghodia, Dist. Vadodara Pin: 391760

Informed Consent Form (ICF) for Participants in Research Programmes involving studies on human beings

Study Title: *Clinicopathological analysis of breast lump in females.*
Study No: SVU/SBKS/_____ /2015-_____
Participants Initials: _____ Participants Name: _____
Date of Birth: _____ Age: _____Years

1. I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions.

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

3. I understand that the investigator of this study, others working on the investigators behalf, the Ethics committee and the regulatory authorities will not need my permission to look at my health records, both in respect of the current study and further research that may be conducted in relation to it, even if I withdraw from the study. I agree to this access. However, I understand that my identity will not be revealed in any information related to the third party or get published.

4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

5. I agree to take part in the above study.

Signature/Thumb impression of the participant _____
Legally acceptable representative _____
Signatory's Name _____ Date _____
Signature of the investigator _____ Date _____
Study Investigator's Name _____ Date _____
Signature of the impartial witness _____Date _____
Name of the witness _____ Place_____

સુમનદીપવિદ્યાપીઠયુનીવર્સિટી

એસ.બી.કે.એસ. મેડિકલ ઈન્સ્ટટ્યુટ એન્ડ રીસર્ચ સેન્ટર

પીપરીયા, તા. વાઘોડીયા, જી. વડોદરા.

અભ્યાસમાંભાગલેવામાટે (સંશોધન) સહભાગીદ્વારાસમજીવિચારીનેઆપેલીપરવાનગીનુસંમતિપત્રક

અભ્યાસનું નામ:"ધિરજ જનરલ હોસ્પિટલ, પિપરિયા "***સ્ત્રીઓના સ્તનમાં થતી ગાંઠનો તબીબી અને રોગ વિજ્ઞાન વિષયકનો અભ્યાસ***"

અભ્યાસ ક્રમાંક :SVU/SBKS/ /૨૦૧૫-___

સહભાગીનું પુરૂ નામ:

સહભાગીનું ટુંકૂ નામ:

સહભાગીની જન્મ તારીખ :વર્ષ :_____/_____/ **ઉમર :**_____

૧) મેંઆ અભ્યાસ(સંશોધન)સંબંધી તારીખ: / /ની માહિતી પત્રિકા વાંચેલ અને સમજેલ છે તેમજ મને મારા ડોકટર (તપાસકર્તા) ને પ્રશ્નો પુછવાની અને ચર્ચા કરવાની પણ તક મળી છે.

૨) મને સમજાવેલ છે કે આ અભ્યાસ (સંશોધન)માં ભાગ લેવો એ સંપૂર્ણ મારી મરજી ઉપર છે તેમજ હું ગમે ત્યારે કારણ આપ્યા વગર પણ આમાંથી નીકળી શકું છું, અને આમ કરવાથી મારી તબીબી સારવાર કે કાયદેસરના હક્કોને કોઇ અસર નહીં થાય.

૩) હું જાણુ છું કે આ અભ્યાસ (સંશોધન)ના તપાસકર્તા, તેમના મદદનીશો, એથિકલટીમ અને તેના ઉપર દેખરેખ રાખતા અધિકારીઓને મારા સ્વાસ્થ્યની કોઇપણ જાતની માહિતી, સદર અભ્યાસ (સંશોધન)ને લગતી કે તે સિવાયની, મેળવવા માટે મારી પરવાનગીની જરૂર રહેશે નહીં, ભલે પછી હું અભ્યાસ (સંશોધન)માંથી ખસી જાઉં. હું જાણું છું કે મારી આ પ્રકારની માહિતી અન્ય કોઇને જાણ કે પ્રસિધ્ધ નહીં કરવામાં આવે.

૪) આ અભ્યાસ (સંશોધન) દરમ્યાન, અથવા તેના અંતે પ્રાપ્ત થતી માહિતી, કોઇપણ જાતની વૈજ્ઞાનિક શોધ માટે ઉપયોગ કરવા માટે હું સ્વૈચ્છિક રીતે છુટ આપું છું

૫) હું આ અભ્યાસ (સંશોધન)માં ભાગ લેવા/ જોડાવા માટે મારી સંમતિ આપું છું.

સહભાગીનું નામ:_____સહભાગીની સહી અથવા ડાબા અંગુઠાનું નિશાન:_____

સંમતિલેનારનું નામ:_____સંમતિલેનારની સહી:_____

સાક્ષીનું નામ:_____સાક્ષીની સહી અથવા ડાબા અંગુઠાનું નિશાન:_____

સ્થળ:_____તારીખ:_____

सुमनदीप विद्यापीठ

एस. बी. के. एस. मेडिकल इंस्टिट्यूट एंड रिसर्च सेण्टर

पिपरिया, ता. वाघोडिया, जी. वड़ोदरा३९१७६०

अभ्यासमें भाग लेने के लिए प्रतिभागी द्वारा सोच समाजके दी गयी सहमति का प्रपत्र

अभ्यास का नाम: धीरज जनरल हॉस्पिटल, पिपरियामें "*स्त्रीओमें स्तनकी गठनो का नैदानिक एवं विकृति विज्ञान का अभ्यास*"

अभ्यास का क्रमांक: SVU/SBKS/ /२०१५-

प्रतिभागी के नाम के आदि अक्षर:

प्रतिभागी का पूरा नाम:

प्रतिभागी की जन्म तारीख/ उम्र:_____ / _____वर्ष

१.में पुष्टि करता हूँ की मैंने अभ्यास के लिए सूचना पत्र दिनांक _____को ध्यानसे पढ़ा और समाज हैं और मुझे सवाल पूछने की तक दी गयी हैं.

२. में समझता हूँ की मेरा यह अभ्यासमें भाग लेना स्वैच्छिक हैं और मुझे जब इचहो तब यह अभ्यास में से निकलने का हक़ हैं, कोई कारन दिए बिना, मेरी सर्वरया क़ानूनी अधिकार को कोई हानि न हो वैसे.

३. में समझता हूँ की यह अभ्यास के चिकित्सक, उनके सहायकों, आचार समिति एवं नियामक अधिकारी को मेरे चिकित्सा सम्बन्धी रिकार्ड्स देखने के लिए मेरी परवांगी की ज़रूरत नहीं होगी, यह अभ्यास या आगे इस अभ्यास से होने वाले संशोधन के लिए, यदि में इस भागमें से बीचमें से निकल भी जाता हूँ तो. में इसके लिए मंज़ूरी देता हूँ. में यही भी जनता हूँ के मेरा परिचय गुप्त रखा जायेगा यदि इस अभ्यास में हुई कोई भी जानकारी प्रकाशित होती हैं तो.

४. में यही मंज़ूरी देता हूँ की इस अभ्यास से मिलने वाली कोई भी जानकारी के उपयोग की लिए में मना नहीं करूँगा जब तक यह जानकारी वैज्ञानिक तोरपे अपनायी जार ही हैं.

५. में यह अभ्यासमें भाग लेने की सहमति देता हूँ.

प्रतिभागी के हस्ताक्षर या अंगूठे का निशान _____

कानूनी तौर पर स्वीकार्य प्रतिनिधि _____

हस्ताक्षर कर्ता का नाम _____ तारीख _____

अन्वेषक के हस्ताक्षर _____ तारीख _____

अन्वेषक का नाम _____ तारीख _____

निष्पक्षगवाह के हस्ताक्षर _____तारीख _____

निष्पक्षगवाहका नाम _____ जगह_____

ANNEXURE III

PARTICIPANT INFORMATION SHEET

SumandeepVidyapeeth University

S.B.K.S Medical Institute and Research Centre

Piparia, Ta. Waghodia, Dist. Vadodara Pin 391760

PARTICIPANT INFORMATION SHEET

Study No. _____ Date_____

Invitation to participant

1.Introduction

This study entitles reviewing the patient coming in the out-patient department with the presentation of breast lumps and establishing the diagnosis on clinical examination and later confirming the diagnosis with pathological evaluation of the lump, (if required the lump shall be surgically removed) and comparing the difference between the two.

2. What is the purpose of this study?

The purpose of this study is to throw light upon the topic of *Clinico pathological analysis of breast lump in females* based on age distribution, incidence, presentation and diagnostic as well as their management.

3. Why have I been chosen?

The female patients having breast lump are selected.

4. Do I have to take part?

The participation in the study is totally voluntary and is to be decided by the patient if she is willing to give her support for the same.

5. How long will the study last?

This study will last from November 2015 to October 2017

6. What will happen to me if I take part?

This is an observational study.

When the patient approaches the doctor she will be examined, later investigated and then if required will undergo surgery or will be treated conservatively depending on the diagnosis and later the histopathology report of the removed lump shall be assessed.

7. What do I have to do?

The patient has to allow the treating doctor to examine her, get the required investigations done and if required for the treatment give consent to get operated for the same.

8. What are the benefits of the study?

This study has both individual and community benefits. This study will provide data about various breast lump its presentation, diagnostic modality and management.

9. What are the side effects of the treatment received during the study?
This is an observational study hence there are no side effects of this study.

10.What if new information becomes available?
After this study the information regarding the difference in the diagnosis after clinical examination and after pathological evaluation will be established.

11.What happens when the study stops?
When the study stops more information on diagnosing the patient based solely on clinical examination would be established.

12. What if something goes wrong?
If any type of threat or untoward event, consequent to present study, is met with, the patient will be provided every type of protection. Nature of this protection can be decided when such an event actually is faced with.

13. Will my taking part be kept confidential?
All the details of the patient including her identity, her disease and her further management will be kept totally confidential.

14. What else should I know?
In case additional information is required, the patient may be contacted to inquire about past, personal and family history. Also religious background, social customs, beliefs and other details can be inquired into.

15. Additional Precautions
No additional precautions are required for this study.

16. Who to call with questions?
If any problem develops, you can contact:
NAME: Dr.Kirtana S Shah
ADDRESS: Department of General Surgery, Dhiraj General Hospital.
Piparia. Tal: Waghodia. Dist: Vadodara.
MOBILE NO: 9924658185

સુમનદીપવિદ્યાપીઠયુનીવર્સિટી
એસ.બી.કે.એસ. મેડિકલ ઈન્સ્ટટ્યુટ એન્ડ રીસર્ચ સેન્ટર
પીપરીયા, તા. વાઘોડીયા, જી. વડોદરા **-391760**

અભ્યાસનુંનામ:"ધિરજ જનરલ હોસ્પિટલ, પિપરિયા ***સ્ત્રીઓના સ્તનમાં થતી ગાંઠનો તબીબી અને રોગ વિજ્ઞાન વિષયકનો અભ્યાસ***

અભ્યાસક્રમાંક:_____ **તારીખ:**_____

સહભાગીને આમંત્રણ

1. પરિચય

આ અભ્યાસમા ઑ.પી.ડી.મા આવતી મહિલાઓ જેને સ્તનમા ગાંઠ છે તેની તપાસ કરવામા આવશે જેના પરથી રોગનુ નિદાન કરવામા આવશે, પછી તે ગાંઠમાંથી સોઇ દ્વારા તપાસ લઈ લેબોરેટરીમા જાંચ થશે જેના ઉપરથી પણ નિદાન કરવામા આવશે (જરૂર પડતા ગાંઠને ઑપરેશન કરીને કાઢી નાખવામા આવશે) અને ત્યાર બાદ બન્ને નિદાનો વચ્ચેની તફાવત જોવામા આવશે.

2. આ અભ્યાસનો હેતુ શુ છે?

આ અભ્યાસનો હેતુ "ક્લિનિકોપથોલોગિક્લ અનલય્સિસ ઓફ બ્રેઅસ્ત લુમ્પ ઇન ફેમલેસ" ના વિષય પર વધારે જાણકારી મેળવવાનો છે.

3. આ અભ્યાસમા મારી પસંદગી કેમ થઈ છે?

જે મહિલાઓને સ્તનમા ગાંઠ હશે તે ઓની આ અભ્યાસ માટે પસંદગી થયેલ છે.

4. શુ મારે આ અભ્યાસમા ભાગ લેવો જરૂરી છે?

અભ્યાસમાં ભાગ લેવો સંપુર્ણ પણે મરજીયાત છે. અભ્યાસમાં ભાગ લેવા માટે સહમત થયા પછી સહભાગીએ તપાસ કર્તાને તમામ સુસંગતતથ્યો તેમજ તપાસમાં સંપુર્ણ સહકાર આપવો પડશે.

5. આ અભ્યાસ કેટલો સમય ચાલશે?

આ અભ્યાસ નવેમ્બર ૨૦૧૫ થી ઓક્ટોબર ૨૦૧૭ સુધી ચાલશે.

6. આ અભ્યાસમા ભાગ લીધા બાદ મારી સાથે શુ થશે?
આ અભ્યાસમા ફક્ત નિરીક્ષણ કરવામા આવશે. એકવાર અભ્યાસ માટે સંમતી આપ્યા બાદ દર્દીની તપાસ થશે, લેબોરેટરીમા જરૂરી તપાસ થશે, દવાઓ આપવામા આવશે અન જરૂર પડતા તે ગાંઠનિ કાડવા માટે ઑપરેશન કરવામા આવશે.

7. મારે શુ કરવાનુ આવશે?
દર્દીએ તેમની સારવાર કરતા ડોક્ટોરને તપાસ કરવાની પરવાંગી આપવાની થશે, જાંચ કરવી પડશે અને જો સાજા થવા જરૂર પડે તો ઑપરેશન કરવાની પરવાંગી આપવી જરૂરી છે.

8. આ અભ્યાસના શું ફાયદા છે?
આ અભ્યાસથી દર્દી તથા સમાજને ફાયદો થશે. આ અભ્યાસથી સ્તનની ગઠન વિષે માહિતી, તેના નિદાન માટેની તપાસ અને સારવાર માટે ની રીતો વિષે વધારે જાણકારી મડશે.

9. આ અભ્યાસમા થતી સારવારના શુ ગેરફાયદા છે?
આ અભ્યાસમા ફક્ત નિરીક્ષ થવાથી એના કાય ગેરફાયદા નથી.

10. જો આ અભ્યાસ પછી નવી જાણકારી મડશે તો એનુ શુ કરવાનુ?
આ અભ્યાસ પછી ખાલી તપાસ કરતા અન જાંચ કરીને જે નિદાનમા તફાવત આવ્વઈ જોવા મા આવશે જેનાથી વીલી અન અસરકારક સારવાર થઈ શકશે.

11.આ અભ્યાસ પતશે ત્યારે શુ થશે?
આ અભ્યાસ પતશે ત્યારે ખાલી પેહલી વાર દર્દીને તપાસીને નિદાન કરવા માટેની જાણકારી મડશે.

12. આ અભ્યાસ દરમિયાન કોઈ પણ અણબનાવ બને તો શુ થશે?
ઉપરોક્ત અભ્યાસને સુસંગત કોઇપણ પ્રકારના અણબનાવ સામે સહભાગીને યોગ્ય રક્ષણ પુરૂ પાડવામાં આવશે. રક્ષણનો પ્રકાર આવો કોઈ બનાવ બને ત્યારે નક્કિ કરવમા આવશે.

13.શુ મારૂ ભાગ લેવાનુ ગુપ્ત રેહશે?
દર્દીનીઓઢખ,
તેનીબિમારીઅનેતેનીસારવારવિષેનીજાણકારીસંપૂન્નપણેગુપ્તરાખવામાઆવશે.

14.મારે બિજુ શુ જાણવુ જરૂરી છે?

જો કંઈ વધારે જાણકારી દર્દીના પેહલાની બિમારી, તેના સગાની બિમારી કે તેના પોતાના વિષેની જાણકારી જો જોઇતી હશે તો દર્દીનો સંપર્ક કરવામા આવશે. તેમના ધર્મ, રીતિ-રિવાજ, માન્યતાઓ વિષેની જાણકારી મેદવવાની જરૂરી પાડી શકે છે.

15.બિજુ શુ ધ્યાન રાખવાની જરૂર છે?

આ અભ્યાસ માટે બિજુ કંઈ ધ્યાન રાખવાની જરૂર નથી.

16.કોઈ પણ સવાલ હોઈ તો કોનો સંપર્ક કરવો?

ડૉ. કિર્તનાશાહ

જનરલ સર્જરી વિભાગ, એસ.બી.કે.એસ. મેડિકલ ઈન્સ્ટટ્યુટ એન્ડ રીસર્ચ સેન્ટર

પીપરીયા, તા. વાઘોડીયા, જી. વડોદરા.

મોબાઇલ નંબર: ૯૯૨૪૬૫૮૧૮૫

सुमनदीप विद्यापीठ

एस. बी. के. एस. मेडिकल इंस्टिट्यूट एंड रिसर्च सेण्टर

पिपरिया, ता. वाघोडिया, जी. वड़ोदरा ३९१७६०

अभ्यासका नाम: धीरज जनरल हॉस्पिटल, पिपरियामें "स्त्रीओमें स्तनकी गठनो का नैदानिक अवं विकृति विग्नां का अभ्यास"

अभ्यासका क्रमांक: _____ तारीख:_____

अभ्यास के सहभागियो को आमंत्रण:

१. परिचय

यह अभ्यासमें ओ.पि. दी. में आनेवाली महिलायें जिनके स्तनमें गठन हैं उनकी जाँच की जाएगी और निदान बनाया जायेगा जिसके बाद गठन में से सुई दाल के जाँच के लिए टुकड़ लिया जायेगा और उसके तोर पे निदान किया जायेगा. फिर उन दोनों निदानो के बीच का अंतर देखा जायेगा.

२. अभ्यास का कारन क्या हैं?

यह अभ्यास का ध्येय हे की "स्त्रीओमें स्तनकी गठनो का नैदानिक अवं विकृति विग्नां का अभ्यास" के विषय पर ज़्यादा जानकारी लेना हैं.

३. इस अभ्यासमें मुझे पसंद क्यों किया गया हैं?

जिन स्त्रीओ को स्तनमें गठन होगी उनको इस अभ्यासमें चुना जायेगा.

४. क्या मुझे यह अभ्यासमें भाग लेना ज़रूरी हैं?

इस अभ्यासमें शामिल होना पूरी तरहसे अपनी मर्ज़ी पर हैं. अभ्यासमें शामिल होने की मंज़ूरी देने के बाद दर्दी को अपने चिकित्सक को जाँच करने देने की सहमति देनी होगी और इलाज करने के लिए पूरा सहयोग देना होगा.

५. यह अभ्यास कितने समय तक चलेगा?

यह अभ्यास नवंबर २०१५ से अक्टूबर २०१७ तक चलेगा.

६. यह अभ्यासमें भाग लेने के बाद मेरे साथ क्या होगा?

इस अभ्यासमें सिर्फ निरिक्षण किया जायेगा. एक बार अभ्यासमें शामिल होने के लिए समाती देने के बाद दर्दीको जांचा जायेगा, लेबोरेटरीमें जरुरी जाँच भेजी जाएगी, दवाई दी जाएगी और ज़रुरत पड़ने पर गठनको ऑपरेशन करके निकला जायेगा और उस गठनो को जाँचके लिए भेजा जायेगा.

७. मुझे क्या करना होगा?

दर्दीको अपने चिकित्सक को जाँच करने की मंज़ूरी देनी होगी, गठनमें सुई दालके जाँचकरनी पड़ेगी और अगर ज़रुरत पड़ती हैं तो ऑपरेशन करके गठनको निकलने की सहमति देनी पड़ेगी.

८. यह अभ्यास के क्या फायदे हैं?

यह अभ्यास से दर्दी और समाज दोनों को फायदा होगा. इस अभ्याससे स्तनके गठनके बारे मैं ज़्यादा माहिती मिलेगी, उनके निदानके लिए जाँच और इलाज के लिए ज़्यादा सफल तरीको के बारे में ज़्यादा जानकारी मिलेगी.

९. यह अभ्यास में होने वाली चिकित्सा के क्या गेरफायदे हैं?

यह अभ्यासमें सिर्फ निरिक्षण होगा जिसके चलते यह अभ्यासके कोई गेरफायदे नहीं हैं.

१०. यदि यह अभ्यास के बाद नयी जानकारी मिलेगी तो उसका क्या होगा?

यह अभ्यासके बाद दर्दी को जाँचके और गठनमें सुई दालके जाँचके निदानोमें जो अंतर अत है वो देखके निदान और सर्वर के नए तरीके मिलेंगे.

११. यह अभ्यास के अंत में क्या होगा?

यह अभ्यास ख़तम होने पर दर्दी को सिर्फ जंचके निदान मिल सके वैसे तरीकोकी जानकारी मिलेगी.

१२. अगर यह अभ्यासके दौरान कुछ णबनाव हुआ तो क्या होगा?

यह अभ्यासको लेके कोई भी अनबनाव बनता हैं तो दर्दीको उसके खिलाफ पूरी सुरक्षा दे जाएगी. सुरक्षा का प्रकार ऐसा बनाव बनने पर तै किया जायेगा.

१३. क्या मेरा परिचय गुप्त रहेगा?

दर्दी की पहचान, उनकी बीमारी और उनकी सर्वर की सारी जानकारी गुप्त राखी जाएगी.

१४. मुझे और क्या जानना ज़रूरी हैं?

अगर कुछ ज़्यादा जानकारी, जैसे की दर्दी की पहले की कोई बीमारी, उनके रिश्तेदारों की बीमारी या फिर उनके बारेमें कोई जानकारी चाहिए तो दर्दीसे संपर्क किया जायेगा. उनके धर्म, रीती-रिवाज़, मान्यताएं के बारेमें जानकारी लेनी पद सकती हैं.

१५. और क्या ध्यानमें रखना होगा?

इस अभ्यास के लिए और कुछ ध्यान मेंर रखना ज़रूरी नहीं हैं.

१६. अगर कुछ ज़्यादा जानकारी चाहिए तो किसका संपर्क करना होगा?

डॉ. कीर्तना शाह

जनरल सर्जरी विभाग,एस. बी. के. एस. मेडिकल इंस्टिट्यूट एंड रिसर्च सेण्टर

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मोबाइल नो.: ९९२४६५८१८५

ANNEXURE IV

Proforma

- Name:
- Reg. No.:
- Age/Sex:
- Ward:
- Address:
- Date of Admission:
- Date of Surgery:
- Date of Discharge:
- Clinical History:
- Occupational History:

Presenting Complains:

- Lump in breast.
- History of Trauma
- Association with pain
- Nipple discharge
- Ulceration
- Retraction of nipple
- Menstrual history and its relation to lump
- Duration and Progress of lump
- History of Rapid Growth
- Associated swelling in Axilla
- Change in the size of the lump

Past History:

- History of similar complaints in association with its regression or not
- History of DM / HT / Trauma / Dietary Habits / Addiction.
- History of previous surgery.

Family History:

- History of Similar Complains
- History of Breast Cancer in mother, grandmother or daughter
- History of Gastrointestinal or Ovarian Malignancy
- History of any major illnesses.

Personal History:

- History of breast feeding:
- Diet:
- Lump discovered by:

Menstrual History:

- Menstruating/ Menopausal:
- Duration between the cycles
- Duration of menstruation
- Relation of swelling with menstruation
- Age of Menarche and Menopause.

Obstetric History:

- Total number of Pregnancies
- Age at first pregnancy
- Age of last pregnancy
- History of any abortions
- Mode of delivery
- Last child birth
- History of Oral Contraceptive Use/ hormone replacement therapy use
- Type of Oral Contraceptive Pills

CLINICAL EXAMINATION

Vitals:

- General Condition
- Blood Pressure
- Pulse
- Temperature
- Respiratory Rate
- Pallor / Icterus / Cyanosis / Clubbing / Oedema / Lymphadenopathy

Local examination:

Inspection: (diseased breast)

- Symmetry and position of breast in comparison to normal side
- Size and shape of the breast in comparison to normal side.

- Nipple: Position in comparison to normal side

  Size and shape

  Surface

  Displacement

  Retraction

  Ulceration

- Areola: Size

  Diminution in size due to retraction

  Texture

  Discharge

- Skin over the breast:
- Swelling in the breast: Position in relation to the quadrant

  Extent

  Size and Shape

  Surface and margin

  Skin over the swelling

- Edema of the arm:
- Done with arms raised above the head:
- Patient sitting and leaning forward:
- Patient sitting and pressing her waist with hands:
- Opposite breast:

Palpation:

Opposite breast

(diseased breast)

- Temperature
- Tenderness
- Any Palpable lump: position in relation to quadrant

  Sizeand Shape

  Surface and Margin

  Consistency

  Fixity to skin

  Fixity to breast tissue

  Fixity to underlying pectoral fascia and pectoralis major muscle

  Fixity to chest wall

  Fixity to serratus anterior

  Fluctuation and transillumination

Examination of the axilla: (For regional lymph nodes)

- Level I: anterior (pectoral) / lateral/ posterior
- Level II: central
- Level III: apical
- Examination of Supraclavicular lymph nodes:
- Examination of opposite axillary lymph nodes

Systemic Examination:

RS

CVS

CNS

Per Abdomen:

Clinical Diagnosis:

Investigations:
Mammography
USG breast
FNAC

Management:
Medical/Surgical

Histopathology report:

Final Diagnosis

Outcome:
Discharged/ Mortality

Follow up period:

Chemotherapy cycles taken: (if applicable)

| | | |