“ROLE OF ULTRASOUND ELASTOGRAPHY IN CHARACTERIZATION OF BREAST LESIONS AS BENIGN AND MALIGNANT: ONE YEAR HOSPITAL BASED OBSERVATIONAL STUDY”

BY

REG. NO. BS0122002

Dissertation

Submitted to the

KLE Academy of Higher Education and Research, Belagavi, Karnataka

In partial fulfillment
of the requirements for the degree of

M.D.
IN
RADIO-DIAGNOSIS

DEPARTMENT OF RADIO-DIAGNOSIS,
J. N. MEDICAL COLLEGE,
BELAGAVI -590010. KARNATAKA

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH,

BELAGAVI, KARNATAKA

Endorsement by the HOD/Principal/ Head of the Institution

This is to certify that the dissertation entitled **"ROLE OF ULTRASOUND ELASTOGRAPHY IN CHARACTERIZATION OF BREAST LESIONS AS BENIGN AND MALIGNANT: ONE YEAR HOSPITAL BASED OBSERVATIONAL STUDY"** is a bonafide research work done by **REGISTRATION NO. BS0122002,**

KAHER J.N. MEDICAL COLLEGE BELAGAVI

Dr. SANTOSH D PATIL

M.D. RADIO-DIAGNOSIS

Professor and Head,
Department of Radio Diagnosis,
J. N. Medical College,
Nehru Nagar, Belagavi – 590010

Dr. SANTOSH D. PATIL
M.D. (Radio-Diagnosis)
Professor & HOD
Dept. of Radio-diagnosis
J.N. Medical College, BELAGAVI-10.
KMC Reg No. 58456

Date:
Place: Belagavi

Dr. N.S. MAHANTASHETTI

M. D. PEDIATRICS

Principal,
J. N. Medical College,
Nehru Nagar, Belagavi – 590010

PRINCIPAL
Jawaharlal Nehru Medical College
BELAGAVI

Date:
Place: Belagavi

UNDERTAKING

I, **Reg. No BS0122002,** hereby declare that the information and the data mentioned in my dissertation entitled **"ROLE OF ULTRASOUND ELASTOGRAPHY IN CHARACTERIZATION OF BREAST LESIONS AS BENIGN AND MALIGNANT: ONE YEAR HOSPITAL BASED OBSERVATIONAL STUDY"** belongs to me and is original. I am aware of the definition of plagiarism as detailed below:

- An act or instance of using or closely imitating the language and thoughts of another author without authorization and the representation of that author's work as one's own, as by not crediting the original author.
- A piece of writing or other work reflecting such unauthorized use or imitation.
- The deliberate or reckless representation of another's words, thoughts or ideas as one's own without attribution in connection with submission of academic work, whether graded or otherwise.

I hereby declare that the dissertation prepared by me is original one and does not involve plagiarism anywhere. In case at a later stage, it is found that I have indulged in plagiarism, then I am solely responsible for the same and the institution is at liberty to take any disciplinary action against me including cancellation of dissertation or any other penalties imposed by the University.

Date:

Place: Belagavi **(REG. NO. BS0122002)**

PLAGIARISM ACCEPTANCE LETTER

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH

JAWAHARLAL NEHRU MEDICAL COLLEGE

(A constituent unit of KLE Academy of Higher Education & Research Deemed-to-be-University)

(Recognized by National Medical Commission, New Delhi)

Accredited 'A+' Grade by NAAC (3rd Cycle) **Placed in Category 'A' by MoE (GoI)**

Nehru Nagar, Belagavi- 590 010, Karnataka, INDIA

0831 - 2471350 0831 - 2470759 www.jnmc.edu principal@jnmc.edu

Ref No: MDC/PG/ Date: 15-03-2025

"ACCEPTANCE LETTER"

The softcopy of thesis entitled: **"ROLE OF ULTRASOUND ELASTOGRAPHY IN CHARACTERIZATION OF BREAST LESIONS AS BENIGN AND MALIGNANT: ONE YEAR HOSPITAL BASED OBSERVATIONAL STUDY"** has been submitted for anti-plagiarism check through Turnitin software. The scan has been carried out and the scanned output reveals a match percentage of **09%** which is within the acceptable limits of **10%** as per the guidelines given by UGC.

Guide.

KAHER J. N. MEDICAL COLLEGE BELAGAVI

Dr. (Mrs.) N.S. Mahantashetti.
Chairperson-Antiplagiarism Committee &
Principal,
J. N. Medical College, Belagavi.

To,
Reg. No. BS0122002
Postgraduate Student,
2022-23 Batch,
Department of Radio-Diagnosis
J. N. Medical College, Belagavi.

ETHICAL CLEARANCE LETTER

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed – to- be- University)
Accredited 'A+' Grade by NAAC in (3rd Cycle) · Placed in Category 'A' by MHRD (GoI)
JNMC INSTITUTIONAL ETHICS COMMITTEE
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu
Phone: (+ 91-(0)831 Office : 2472550
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref No.MDC/JNMCIEC/ 194 **Date: 12/05/2023**

To.
BS0122002
PG Student in Radio-Diagnosis
J. N. Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"ROLE OF ULTRASOUND ELASTOGRAPHY IN CHARACTERIZATION OF BREAST LESIONS AS BENIGN AND MALIGNANT: ONE YEAR HOSPITAL BASED CROSS-SECTIONAL STUDY"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee.

(Dr. Smita Sonoli)
Member Secretary
JNMC Institutional Ethics Committee
J.N.Medical College, Belagavi.

(Dr. Harsha Hegde)
Chairman,
JNMC Institutional Ethics Committee
J.N.Medical College, Belagavi

LIST OF ABBREVIATIONS

AIUM	American Institute of Ultrasound in Medicine
AUC	Area Under the Curve
BIRADS	Breast Imaging-Reporting and Data System
BRCA	Breast Cancer Gene
BGR	Blue, Green, Red (color artifacts)
B-mode	Brightness Mode
CI	Confidence Interval
CRF	Case Record Form
E/B	Elasticity/Background Ratio
FNAC	Fine-Needle Aspiration Cytology
IDC	Invasive Ductal Carcinoma
kPa	Kilopascals
LIQ	Lower Inner Quadrant
LOQ	Lower Outer Quadrant
MHz	Megahertz
M-STB index	Motion stability index
NA	Not Available
NICPR	National Institute of Cancer Prevention and Research
NPV	Negative Predictive Value
PPV	Positive Predictive Value
ROI	Region of Interest
SD	Standard Deviation
SR	Strain Ratio
SWE	Shear Wave Elastography
UIQ	Upper Inner Quadrant
UOQ	Upper Outer Quadrant
US	Ultrasound
USG	Ultrasonography

ABSTRACT

Background: Breast ultrasonography (US) plays a vital role in diagnosing both palpable and incidental screening-detected breast masses. With the use of a high-frequency transducer, it provides an accurate, non-invasive method for identifying cystic and solid lesions. The theory that works here is it images the gradient of tissue displacement that occurs during compression. In recent years, elastography has gained prominence as a valuable imaging tool for differentiating benign from malignant breast lesions. This study evaluates the effectiveness of various elastography techniques, including Strain Ratio, Shear Wave Elastography (SWE), and BIRADS classification, in improving breast cancer diagnosis and reducing the need for unnecessary biopsies. ***Objectives:*** To determine the role of ultrasound elastography in characterizing malignant and benign breast lesions.

Methodology: 74 patients with breast cancer were recruited. Patients demographic details, history, clinical symptoms and investigations were noted. Data is analyzed using SPSS software version 21

Results: All elastography methods exhibited high specificity, with Strain Ratio and BIRADS achieving 100% specificity. The strain ratio cutoff of ≥4.5 resulted in a sensitivity of 66.67% and specificity of 100%. SWE, using a threshold of >98.66 kPa, demonstrated a sensitivity of 66.67% and specificity of 76.92%. Combining elastography techniques with conventional BIRADS assessment significantly improved diagnostic accuracy, with BIRADS classification achieving 94.44% accuracy. Additionally, malignancies were predominantly located in the Upper Outer Quadrant, accounting for 80% of cases. Axillary lymphadenopathy was strongly associated with malignancy, present in 88.9% of malignant cases.

Conclusion: Elastography plays a significant role in enhancing diagnostic accuracy compared to the standalone use of ultrasound. This study highlights the clinical importance of elastography in breast cancer detection. Combining Strain Ratio and Shear Wave Elastography (SWE) with BIRADS improves diagnostic accuracy and helps reduce unnecessary biopsies. These findings advocate for the integration of elastography into standard breast imaging protocols to enhance patient management and facilitate early cancer detection. Further research is needed to investigate the utility of elastography parameters in real-time elastography and elastography-guided breast biopsies, particularly in breast cancer screening programs.

Keywords: BIRADS, breast cancer, Elastography, Shear Wave, Strain ratio, E/B ratio

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF GRAPHS

INTRODUCTION

Breast disease is one of the most prominent health disorders impacting females across all age categories. A breast lump can be a symptom of different breast disorders, ranging from benign cysts to malignancies. For patients who require the right care and treatment, it is essential to recognize benign and malignant lumps. The most common benign breast lesion is fibroadenoma, whereas the most common malignant variety is invasive ductal carcinoma[1]

Breast cancer is the most common cancer among women, as reported by the National Institute of Cancer Prevention and Research (NICPR). India, along with China and the United States, accounts for a third of global breast cancer cases. The incidence of breast cancer is increasing in India, where it constitutes 27% of all cancers in women. Alarmingly, for every two women diagnosed with breast cancer in the country, one succumbs to the disease. [2]

In India, breast cancer incidence begins to rise in the early forties and reaches its highest rates between the ages of 50 and 64. [3] The lifetime risk of breast cancer is higher in urban areas, where one in twenty-two women is affected, compared to one in sixty women in rural regions. [4] India experiences a higher breast cancer mortality rate compared to both developed and other emerging nations. [5]

In India, breast cancer incidence begins to increase in the early forties and reaches its highest levels between the ages of 50 and 64. [3] The likelihood of developing breast cancer is greater in urban areas, where one in twenty-two women is affected, whereas in rural regions, the risk is lower at one in sixty. [4] India also has a higher breast cancer mortality rate compared to other developing and developed countries. [5]

Approximately 1.2 million breast cancer cases are reported globally each year. [6] Since mortality rates vary depending on the stage at diagnosis, early detection is essential for improving survival outcomes. The five-year survival rates differ significantly by stage, with 99% for stage 0, 92% for stage 1, around 82% for stage 2a, approximately 65% for stage 2b, and nearly 47% for stage 3a. In comparison, the survival rates drop further to about 44% for stage 3b and only 14% for stage 4. These figures emphasize the critical role of early diagnosis in increasing survival chances and ensuring timely treatment.

A significant number of breast cancer patients are diagnosed at an advanced stage, making treatment more difficult. The leading causes of breast cancer-related mortality include both locally aggressive tumors and distant metastases. [7] Clinical palpation has been used since the time of the ancient Greeks and Egyptians to evaluate the stiffness of lesions. [8] Rigid and immobile breast lesions may indicate malignancy. However, in vitro studies have shown that while there is some overlap, the stiffness of benign and malignant breast tumors varies considerably. [9] Therefore, elastography serves as an effective technique for accurately characterizing breast lesions.

Pathologic examination is the primary method for differentiating between benign and malignant breast masses. However, since it is an invasive procedure and nearly 75% of patients are diagnosed with benign conditions, its application in cancer screening is challenging. [7] Treatment strategies vary based on the stage of the disease. Imaging modalities such as mammography, ultrasound, and magnetic resonance imaging assist in assessing breast tissue. [10] Due to the high prevalence of breast cancer and the prolonged time to diagnosis, research has focused on developing more advanced diagnostic techniques. In recent years, the introduction of elastography has enhanced the specificity of ultrasound, aiding in the early detection of breast cancer. In cases where the Stavros criteria are ambiguous, incorporating quantitative elastography with strain ratio (SR) improves diagnostic accuracy, particularly in BIRADS stages 3 and 4. [11]

Elastography enhances the specificity of breast sonography by differentiating between benign and malignant masses, thereby reducing the number of unnecessary benign biopsies. To evaluate elastography metrics, including the strain ratio and modified color score, trichromatic blue, green, and red (BGR) artifacts were utilized for comparison. This approach is effective as it visualizes the gradient of tissue displacement following compression. Consequently, this study proposed a new modified color score, along with a mean strain score of 3:2, to improve the differentiation between benign and malignant tumors.

Malignant lesions tend to be less elastic and firmer compared to the surrounding tissues, whereas benign lesions exhibit elasticity similar to that of adjacent tissues. Additionally, due to the presence of a desmoplastic reaction, malignant lesions appear larger on elastography, whereas benign lesions appear smaller on elastography than on B-mode ultrasonography. [11]

OBJECTIVE OF THE STUDY

Determining the role of ultrasound elastography in characterizing malignant and benign breast lesions

REVIEW OF LITERATURE

DEVELOPMENT OF BREAST: [12]

The initial sign of mammary gland development is the emergence of a “band” like thickening in the epidermal layer, known as mammary line / ridge. By the seventh week of gestational period, this ridge will extend along both sides of the body, stretching from the base of the forelimb till hind limb region. Although most of mammary line regresses soon after its formation, small section in thoracic region remains and invades the mesenchyme, giving rise to sixteen to twenty-four sprouts. These sprouts eventually develop into small, solid buds.

By the end of the prenatal development, canalization of the epithelial sprouts is seen, forming the lactiferous ducts. The buds form small ducts and alveoli within the gland. Initially, lactiferous ducts open into a shallow epithelial pit. However, soon after the birth, proliferation of underlying mesenchyme causes this pit to elevate, transforming it into the nipple.

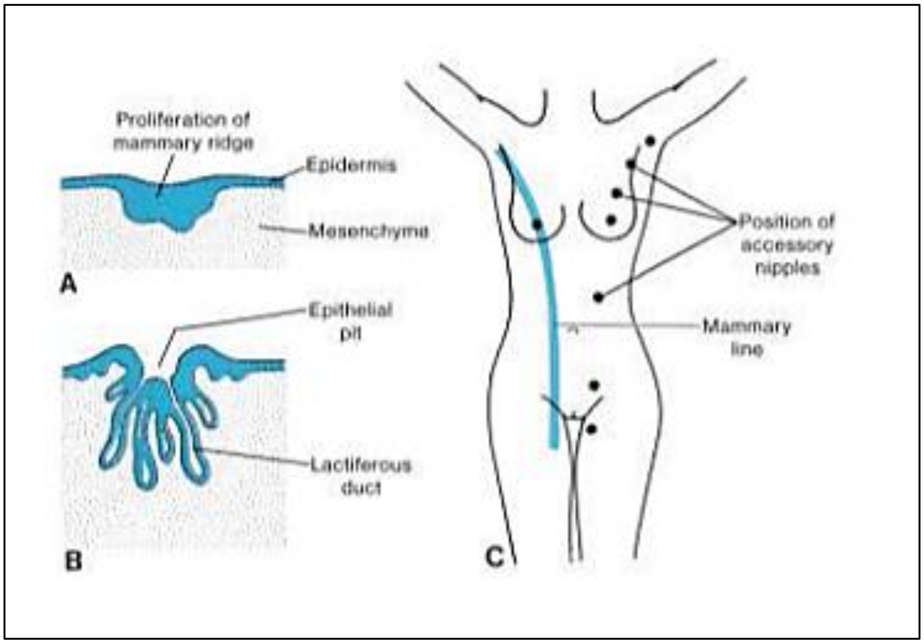


Fig 1: Development of breast: A and B. Sections through the developing mammary gland at the third and eighth months, respectively. C. Positions of accessory nipples (blue line, mammary line)[12]

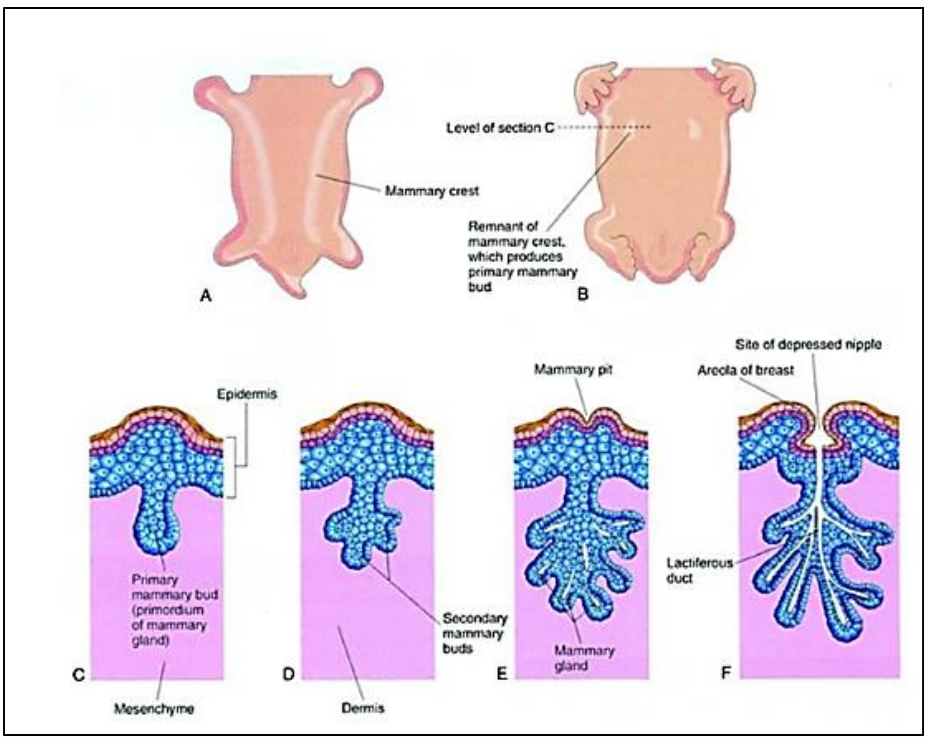


Fig 2: Embryology of breast[13]

ANATOMY OF BREAST: [13,14]

The initial sign of mammary gland development is the emergence of a "band" like thickening in the epidermal layer, known as mammary line / ridge. By the seventh week of gestational period, this ridge will extend along both sides of the body, stretching from the base of the forelimb till hind limb region. Although most of mammary line regresses soon after its formation, small section in thoracic region remains and invades the mesenchyme, giving rise to sixteen to twenty-four sprouts. These sprouts eventually develop into small, solid buds.

By the end of the prenatal development, canalization of the epithelial sprouts is seen, forming the lactiferous ducts. The buds form small ducts and alveoli within the gland. Initially, lactiferous ducts open into a shallow epithelial pit. However, soon after the birth, proliferation of underlying mesenchyme causes this pit to elevate, transforming it into the nipple.

The Pectoralis Major muscle covers the medial two-thirds of the breast, while the Serratus Anterior and External Oblique muscles lie beneath the lateral portion. The superolateral quadrant extends toward the axilla along the inferolateral border of the Pectoralis Major and may penetrate the deep fascia, reaching the axillary apex, forming the axillary tail of Spence.

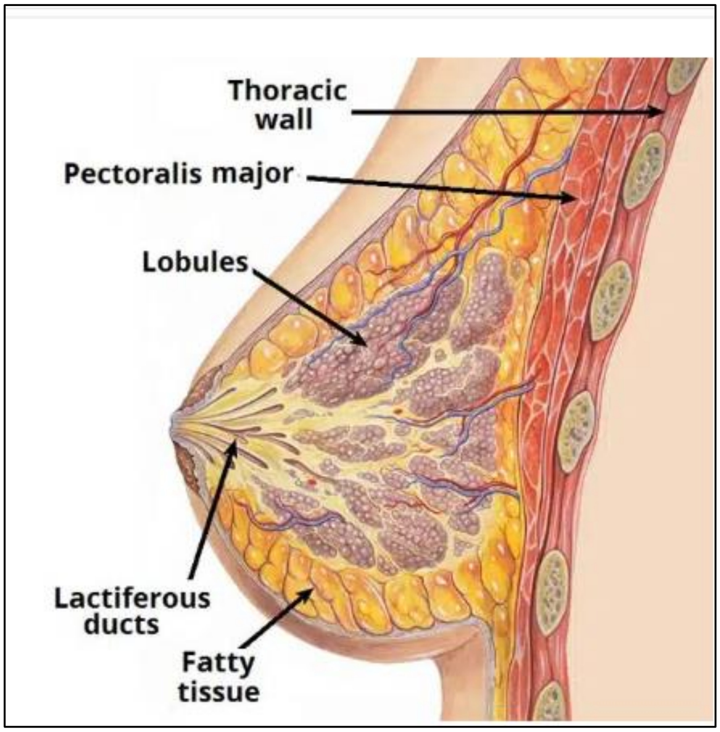


Fig 3: Anatomy of breast[13]

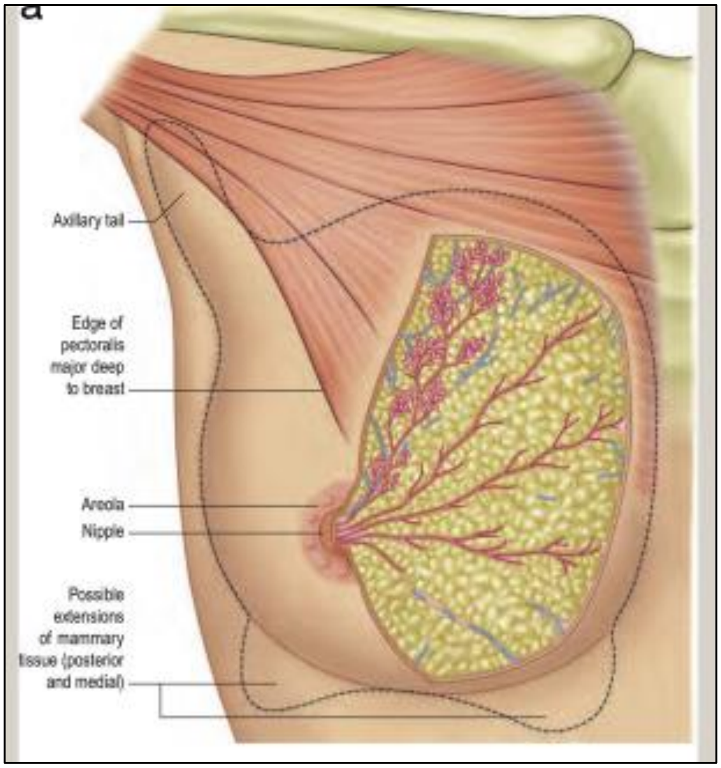


Figure 4. Physiological Development of Breast: Sagittal image showing the changes in breast during lactation [13]

AREOLA:

Sweat and sebaceous glands are abundant in the pigment tissues of areola. The skin overlying the areola is thicker than other parts of the breast skin and taper down to areolar limbus. Morgagni's tubercles are tiny, elevated nodular formations that are dispersed throughout the areola and indicate Montgomery's gland openings.

NIPPLE:

On the nipple, eight to twenty main ducts open. Each duct is 0.5-2 mm wide. A breast lobe is defined by ducts and their tributaries. The primary ducts expand into the Ampullary sections (lactiferous sinuses) beneath the nipple apertures. The deeper segmental ducts divide into sub-segmental structures & may branch further until they form the terminal ducts that enters the lobule. The term "terminal duct lobular unit," or TDLU, refers to a terminal duct and its lobule. They are not necessarily at the periphery and can also be found as direct branches of the primary ducts. [13]

Arterial supply:

The upper outer quadrant of the breast is supplied by the superior thoracic artery, lateral thoracic artery, pectoral branches of the thoracoacromial artery, and subscapular branches of axillary artery.

The centre & medial regions of the breast are supplied by internal mammary arteries and perforating branches.

The lateral breast tissue receives its blood supply from the perforating branches of the 2nd to 4th anterior intercostal arteries.

Nipple, areola, upper breast region, and surrounding breast tissue are supplied by the greatest perforating artery, the second one.

Venous Drainage:

The base of the nipple is surrounded by an anastomotic venous plexus. Branching from this plexus and the glandular tissue, the blood circulates around the gland and reaches axillary, internal thoracic, lateral thoracic, and intercostal veins.

Lymphatic Drainage:

The 2 layers of lymphatics—the superficial & deep levels—form interconnected networks. The major lymphatics drain into the axillary nodes via superficial sub-areolar plexus of Sappey and the deep communicating lymphatic plexus in interlobular connective tissue. Pectoral (anterior), subscapular (posterior), central, apical, and lateral groups comprise the 20–40 nodes. The nodes are described surgically with respect to Pectoralis minor muscle. The nodes at level I are inferolateral, level II are deep, and level III are supero-medial to the muscle. The majority of the rest from the medial and lateral breast regions drains to parasternal nodes.

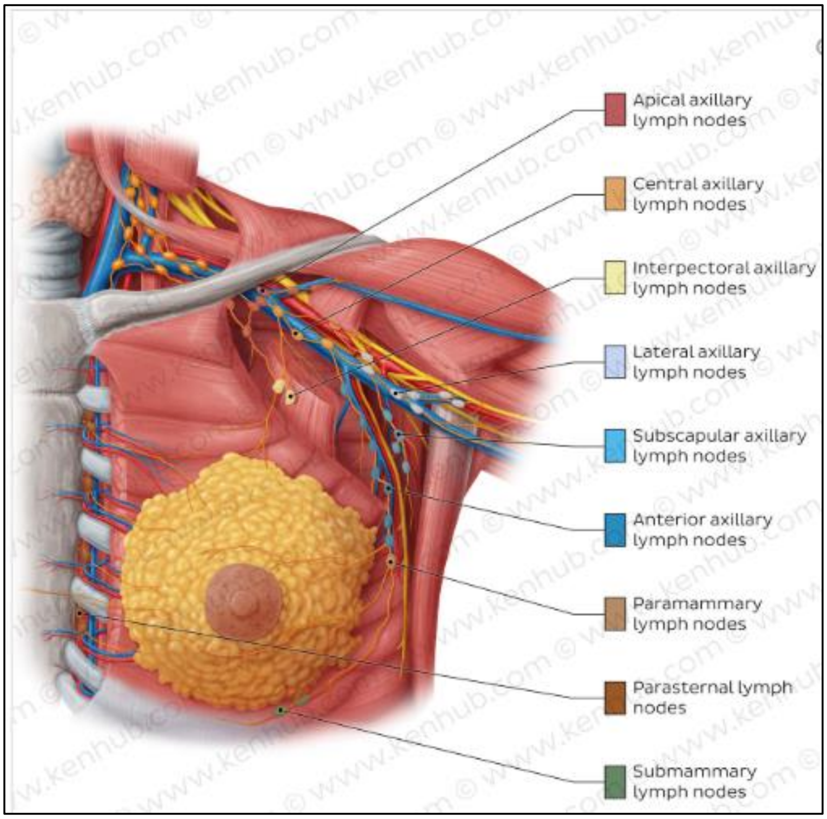


Fig 5: Lymphatic drainage of breast [13]

Nerve supply:

Breast is innervated by the intercostal nerves with superior portion of breast receiving additional innervation by branches of the supraclavicular nerves.

PHYSIOLOGICAL DEVELOPMENT OF BREAST: [15,16]

Pre-puberty: The breast consists primarily of up of dense fibrous stroma with scattered lactiferous ducts which are lined by epithelium and lack alveoli.

Puberty: Thelarche, or hormone-dependent maturation, occurs between the ages of 9 and 12 and is characterized by increased fat deposition, the elongation and branching of new ducts, and the development of lobular units.

Post-pubertal: Lobular units, lactiferous ducts, stroma, and fat are present in a mature or resting breast.

Menstruation:

<u>Proliferative phase</u>: Rising estrogen stimulates ductal cell proliferation and development throughout the menstrual cycles.

<u>Secretory phase</u>: Progesterone enhances terminal duct and stromal cell proliferation, leading to vacuolization and increase in mitotic activity. In late luteal phase, fluid accumulation and intralobular edema cause breast engorgement and pain.

<u>Menstruation</u>: A drop in estrogen and progesterone leads to epithelial desquamation, stromal atrophy, reduced edema, gland bud regression, and lymphocyte accumulation in periductal tissue.

Pregnancy: There is decrease in fibrous stroma with formation of new acini or lobules, known as ‘adenosis’.

Lactation**:** The loss of placental hormones, combined with raised prolactin levels, triggers lactation by stimulating myoepithelial contraction and milk expulsion.

Menopause**:** Involution reduces epithelial elements, increases fat deposition, decreases connective tissues, and causes lobular unit disappearance.

RADIOLOGICAL ANATOMY OF BREAST:

For women under 30, breast ultrasonography is frequently the initial modality of choice for imaging. Although it has mediocre specificity and a decent sensitivity, it is helpful for focused evaluations. It might be useful for screening people with denser breasts or those at a higher risk.

Breast cancer typically appears as a mass with irregular borders, spiculated margins on mammograms, and an irregular shape with microlobulated or angular margins on ultrasound, often indicating a suspicious lesion that may require further investigation; on MRI, breast cancer can manifest as a mass with heterogeneous enhancement and irregular borders, highlighting the importance of considering the imaging modality and specific features for accurate diagnosis. [17]

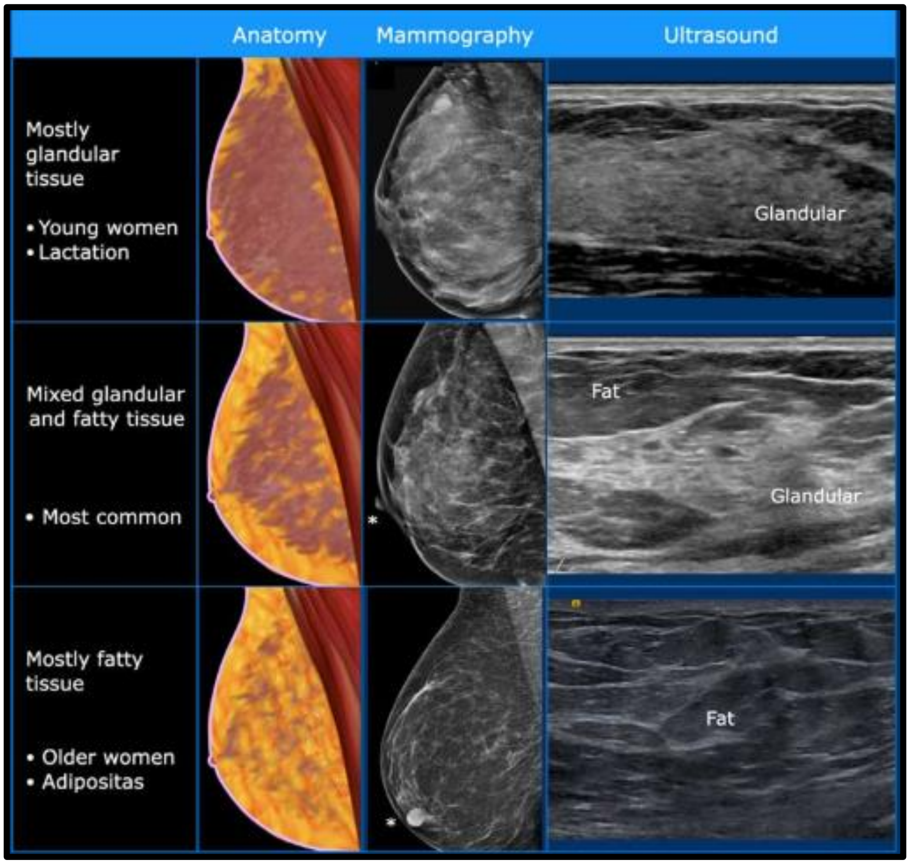


Fig 6 : Radiological anatomy of breast

DESCRIPTION OF A NORMAL BREAST ULTRASOUND:

Skin & Subcutaneous Layer: The skin appears as thin, echogenic layer.

The subcutaneous fat appears hypoechoic with echogenic Cooper's ligaments.

Glandular Tissue: It appears as heterogeneous echogenic fibroglandular tissue.

More prominent in younger women, with elderly women who have higher fat replacement.

Ducts & Lobules: Anechoic lactiferous ducts (<2 mm) within glandular structures.

Retromammary Layer: Situated between the pectoral muscles and glandular tissue. It appears as a thin hypoechoic zone with loose connective tissue, facilitating breast mobility.

Pectoral Muscles & Chest Wall: Pectoralis major and minor are seen as hypoechoic layers underneath the breast tissue.

The ribs are oval, hypoechoic structures with posterior acoustic shadowing.

Vascularity: Normal breast tissue has negligible vascular flow.

Increased or abnormal blood flow may be indicative of pathologies

Age Variations:

Young women have dense, echogenic fibroglandular tissue with little fat.

Postmenopausal women exhibit higher fat content and reduced fibroglandular echogenicity.

Pregnancy/lactation causes enlarged ducts and glandular growth.

PATHOLOGIES IN BREAST:

CONGENITAL ANOMALIES [18]

Ectopic breast/mammary heterotopias

Along the ‘milk line’, abnormal or supernumerary breast tissue is visible. The most common locations are the axilla and chest wall, and they are typically identified during pregnancy or puberty when accessory breast tissue begins to form alongside the normal breast tissue. This auxiliary breast tissue is prone to typical changes and pathologies that may be found in regular breast tissue.

Amastia:

Amastia is complete lack of breast tissue and nipple-areola complex, whereas, Amasia is the absence of only breast tissue.

Asymmetry of the Breast:

Aplasia, or the absence or hypoplasia of one breast, can happen alone or in conjunction with deformity in one or both Pectoral muscles (Poland's syndrome).

Congenital Abnormalities of Nipple:

It includes congenital nipple inversion, congenital absence of one or both nipples (Athelia), or accessory nipples (Polythelia) along nipple line.

INFLAMMATORY DISORDERS [19]

Ductal ectasia / Peri-ductal mastitis

Mammary duct ectasia typically affects duct in the retro-areolar area. it appears as tubular anechoic dilated duct with internal echoes on ultrasonography.

Acute mastitis:

Usually occurring during lactation, acute mastitis can develop into an abscess. Clinically, it is typically a palpable tender mass that is either well or poorly defined, with thickening of the overlying skin. On ultrasound, an abscess is seen as a complex irregular mass with solid/cystic components, with surrounding increased vascularity

Granulomatous mastitis:

The breast may be affected by granulomatous reactions caused by an infectious cause, foreign objects, or systemic autoimmune disorders including sarcoidosis and Wegener's granulomatosis. Breast tuberculosis is an extremely uncommon condition. Skin thickening, sinuses, duct ectasia, and a hypoechoic mass or abscess are nonspecific ultrasound manifestations of breast tuberculosis.

BENIGN PROLIFERATIVE BREAST DISEASE [20,21]

Fibrocystic Disease:

During the normal menstrual cycle, hormonal fluctuations can cause fibrocystic breast changes, primarily affecting premenopausal women. These alterations may be multifocal or occur in both breasts. Common in women aged 35 to 50, they are rare after menopause. The common symptoms include premenstrual cyclical breast pain and tenderness that enlarge before menstruation. In some cases, nipple discharge may also occur.

Imaging findings may vary and include complex solid-cystic lesions with posterior shadowing, along with a heterogeneous echotexture of the breast on sonomammography.

Breast cysts: [22]

Cysts are common in women aged 35 to 50 and appear as well-defined, round or ovoid anechoic areas. They are classified as benign lesions under the BIRADS 2 category.

Pathophysiology:

Breast cysts form when terminal acini become blocked, leading to ductal dilation. They are usually bilateral and multifocal but can also be unilateral. Large single cysts may appear as isolated masses. In larger cysts, the cuboidal to columnar epithelium flattens or may become atrophic. Epithelial proliferation can lead to mass formation, while apocrine-lined cysts often show epithelial overgrowth and papillary projections. The surrounding stroma consists of fibrous tissue.

Classification by size:

- **Microcyst:** Less than 3 mm
- **Macrocyst:** Greater than 3 m

A breast cyst is classified as a complicated cyst if it deviates from the typical features of a simple cyst or contains internal echoes. In all cases, cysts are anechoic with posterior acoustic enhancement. Simple cysts are well-defined with smooth internal margins. According to Stavros AT18, a cyst must meet specific sonographic criteria to be considered simple: it should be anechoic, well defined, have a thin hyperechoic capsule, exhibit posterior acoustic enhancement, and display thin edge shadows. Complex cysts, especially those that contain solid internal components, may have malignant potential on histopathology.

Fibroadenoma:

They are most prevalent benign tumors in young women. On palpation, these non-tender solid, spherical lumps are mobile and move easily within the breast. The average age group is in the 20–30 age range. It arises from the lobule's stromal connective tissue proliferation. It can be unilateral, bilateral, single or numerous and range in size from a few millimeters to a large in size, though its diameter is typically less than 3 cm. It is typically oval, broader than tall, homogeneous, well-defined, hypoechoic, and may or may not have posterior acoustic enhancement on USG.

Papilloma:

Papilloma form due to proliferation of ductal epithelium extending into ductal lumen, commonly affecting women aged 45 to 50. Clinically, it often presents with bloody nipple discharge. Pathologically, papillomas are classified as central or peripheral. Central papillomas are solitary, located in the subareolar region within a main duct, while peripheral papillomas are multiple and arise within terminal duct lobular units, carrying a higher risk of malignancy. On ultrasound, they appear as solid, round, or oval intraductal masses (2–3 mm in size), often presenting as broad based or pedunculated polypoid lesions that obstruct the duct, leading to cyst formation.

Phyllodes Tumour:

Similar to fibroadenoma, cystosarcoma phyllodes is a big, benign tumor made up of the epithelium of connective tissue stroma. Its malignant potential ranges from benign to completely malignant sarcoma and can show lung metastasis. They appear as thick, round or oval, lobulated, non-calcified mass with smooth margins that may contain cystic areas producing posterior acoustic enhancement. On mammography and USG, they are indistinguishable from fibroadenomas.

Lipoma:

The majority of lipomas are palpable masses that are superficial. They are hypoechoic on USG, much like a typical breast.

Fat Necrosis:

Saponification of fat from a prior history of trauma or surgery results in fat necrosis. One particular ultrasonographic sign of fat necrosis has been identified as mass with internal hyperchoic bands that change orientation when the patient's position varies.

Galactocele:

It is cyst containing inspissated milk. Features of solid mass with posterior acoustic enhancement or a simple or complex cyst can be seen on ultrasound.

Radial Scar:

It is also known as ‘sclerosing duct hyperplasia’, this lesion has an uncertain cause but may be associated with chronic inflammation or obliterative vascular changes. A central mass may or may not be present, and its ultrasound findings closely resemble those of malignancy.

Hamartoma:

Fibroadenolipoma, also known as hamartoma, is a rare lesion caused by fibrous and adenomatous growth. In a well-defined lesion, USG reveals both hypoechoic and hyperechoic regions.

Lymph Node:

The upper quadrant of breast and axillary tail region are frequent site to an intramammary lymph node. To make the diagnosis, a fatty hilum or hilar notch must be visible.

Adenomyoepithelioma:

A rare benign breast tumor, this condition is characterized by proliferation of epithelial and myo-epithelial cells. It typically presents as a palpable lesion. On sonomammography, it often appears as an abnormal lesion, raising suspicion for malignancy. A definitive diagnosis is made through immunohistochemistry, confirming the tumor's biphasic cellular composition. Although considered as benign, it has the potential for hematogenous spread and local recurrences.

Adenosis:

Adenosis is often undetectable on ultrasonography. It is marked by proliferation of intra-lobular ductules and the expansion of epithelial & connective tissue element within the lobule. When more connective tissue proliferation is seen, it is referred to as sclerosing adenosis. On mammography, sclerosing adenosis may present as a palpable lump, a suspicious lesion, or occasionally as a solitary clustered microcalcifications

MALIGNANT LESIONS OF THE BREAST [23]

ETIOLOGY:

Breast carcinoma has no single definitive cause, making it a complex disease. Epidemiological studies identified various risk factors that increase a woman's likelihood of developing cancer [14]

Strong relative risk factors (greater than 4) for breast cancer include: [24]

1. Advancing age
2. Raised blood levels of Insulin-like growth factor (IGF-1) before menopause
3. Increased estrogen levels post-menopause
4. Family history of breast cancer, particularly in a mother or sister

Factors associated with relative risk of 2 to 3.99 (Moderate risk) :

1. Higher socioeconomic status
2. First full-term pregnancy after the age of 30
3. Previous history of carcinoma in one breast
4. Presence of breast carcinoma in a first-degree relative
5. History of benign proliferative tumours, dysplastic changes on sonomammography, or high-dose ionizing radiation exposure to the chest

Factors associated with a relative risk of 1.25 to 1.99 (Modest risk):

1. History of nulliparity
2. Early onset of menstruation – menarche before the age of age 11 years
3. Late menopause - after the age of 55 years
4. Obesity after menopause
5. Diet rich in fat or saturated fats
6. Personal history of ovarian or endometrial cancer

GENETICS [24]

Hereditary breast cancers account for only 5–10% of all cases. However, recent data suggests that genetic factors may contribute to up to 27% of breast cancer cases, based on studies comparing identical and non-identical twins. Mutations in the BRCA1 & BRCA2 genes being responsible for approximately 30–40% of inherited breast cancers is noted.

PATHOPHYSIOLOGY [25,26]

Under normal conditions, cells divide in response to external signals that promote proliferation, aiding in functions like cell replacement and tissue repair. Once the task is completed, inhibitory signals are activated to halt further growth. These signals allow cells to exit the proliferation cycle (cell cycle) and enter a dormant state (G0) through differentiation or programmed cell death (apoptosis). This process is regulated by a complex network of interacting proteins. However, mutations or genetic alterations that lead to continuous activation of proliferation system results in an uncontrolled cell growth.

An oncogene is a gene that remains continuously active, driving cell proliferation. Conversely, if a gene responsible for suppressing cell growth is lost due to mutation or deletion, the cell cycle cannot be halted, leading to unchecked proliferation and potentially cancer. This lost gene is known as a tumor suppressor gene. Likewise, constant activation of anti-apoptotic genes can render a cell immortal, increasing the likelihood of further genetic mutations and cancer development. Similarly, the loss of pro-apoptotic genes can have comparable effects.

TYPES OF BREAST CANCER: [27]

Breast cancer is classified based on its origin, whether from ducts or lobules, its invasion pattern, and microscopic appearance. [27]

Carcinoma in situ:

Here, malignant cells remain within the ducts or lobules, without spreading to surrounding fatty tissue or other organs. Carcinoma in situ makes up 15% of all breast cancer cases.

Ductal Carcinoma in Situ:

DCIS falls within a spectrum of pre-invasive breast lesions. While ultrasound (USG) is not ideal for detecting microcalcifications, it can identify soft tissue component as a hypoechoic mass within the duct walls. On mammography, it is characterized by linear branching calcifications.

Invasive (infiltrating) breast cancer:

They typically spreads beyond the duct or lobule membrane, invading surrounding tissues and potentially affecting areas like lymph nodes.

Lobular Carcinoma in situ:

It is considered a pre-malignant condition rather than actual cancer. Typically, asymptomatic, it is often found incidentally during a breast biopsy. Around 25% women develop breast cancer within 30 years.

Invasive Ductal Carcinoma:

This type accounts for 70% of all breast carcinomas and often appears as a palpable, firm mass lesion. On sonomammography, these lesions are typically irregular, poorly defined, micro-lobulated, and heterogeneous, with infiltrative, spiculated margins. They may be taller than wide, and echogenic foci within the lesion suggestive of microcalcifications.

Invasive Lobular Carcinoma:

Invasive breast cancer is the 2^{nd} most common type, making up 5–10% of cases. It tends to present at a later age compared to invasive ductal carcinoma. Clinically, it appears as a poorly defined, tender, and indurated mass, with calcifications being rare. When mammography reveals an asymmetric density, ultrasound (USG) can help detect the underlying mass.

<u>Pathology</u>: Under a microscope, ILC is characterized by malignant monomorphic cells arranged in loosely distributed, linear invasive columns, unlike IDC, which typically forms a distinct mass. ILC lacks the strong desmoplastic reaction seen in IDC when invading normal tissue. Instead of directly invading ducts, ILC cells often surround them, preserving the ductal architecture.

Medullary carcinoma:

These rare, rapidly growing, high-grade breast tumors primarily affect young women, making up 3–6% of all breast cancers. Women with a hereditary predisposition are at significantly higher risk. Studies indicate that medullary carcinomas account for 13–19% of malignancies in those with a BRCA gene mutation. On sonography, they appear as homogeneous, hypoechoic lesions with well-defined borders, sometimes with posterior acoustic enhancements. As compared to other types of invasive ductal or lobular carcinoma, medullary carcinoma generally has a better prognosis.

Paget's disease:

It is a rare type of breast cancer that accounts for only 3% of cases. It primarily affects the nipple-areola region, often presenting with abnormal skin changes such as redness in these areas. Itching and burning sensations may also occur. Paget's disease can be associated with either invasive or in situ carcinoma. The prognosis is favourable in absence of palpable lump or if ductal carcinoma in situ is detected on biopsy.

Inflammatory breast cancer:

This is a rare type of breast cancer accounting for only 1% of cases and is named after its initial symptoms, which include breast skin swelling, redness, and warmth, often occurring without a distinct lump. These symptoms arise when cancer cells block lymphatic vessels in the breast skin, mimicking infection or inflammation. Based on the TNM staging system, inflammatory breast cancer is categorized as a T4 tumor.

Mucinous or colloid carcinoma:

Accounting for 3% of breast cancer cases, this rare type primarily affects older women and is slow-growing with well-differentiated characteristics. On ultrasound, it appears as a distinct hypoechoic lesion with micro-lobulated edges and posterior acoustic enhancement. In rare cases, it presents as a complex solid-cystic mass.

Tubular Carcinoma:

Tubular carcinoma is a rare, well-differentiated, slow-growing invasive breast cancer, comprising 1% of breast malignancies. On sonomammography, it appears as ill-defined lesion, with calcifications being uncommon. Compared to the more common invasive ductal carcinoma or lobular carcinoma, the prognosis for both mucinous and tubular carcinomas is more favourable.

Papillary Carcinoma:

Papillary carcinoma may present as an intra-cystic lesion, though the cyst is often a dilated duct. Sonographically, it typically appears as a complex solid-cystic lesion or an intra-cystic tumor with multiple projections (frond-like) into the cyst lumen.

Metastases:

Breast metastases are rare with primary cancers in the stomach, cervix, ovary, lung, or melanoma. On ultrasound (USG), they typically appear as one or more nonspecific solid masses, often bilateral, with either well-defined or poorly defined margins.

Calcifications and spiculations are rarely observed. Adenoid cystic breast carcinoma account for 0.4% of all cases, while carcino-sarcoma is exceptionally rare, comprising only 0.1% of all cases.

MALIGNANT CHARACTERISTICS (WITH POSITIVE PREDICTIVE VALUES):[28]

In 1995, Stavros et al. outlined the ultrasound characteristics of breast pathologies, distinguishing them as benign, intermediate, or malignant based on specific imaging features. [28]

1) **Sonographic spiculation** (87-90%): appears as alternating hypo- & hyperechoic lines radiating perpendicularly from the nodule's surface. Echogenic strands are visible when the lesion is surrounded by fat, while hypoechoic linear strands appear when surrounded by echogenic tissue.

2) **Taller than wide** (74-80%): Except in some invasive ductal carcinomas of grade III

3) **Microlobulations** (75%): Lobulations measuring 1–2mm on the surface increase the likelihood of malignancy as their number increases. Key sonographic features include angular margins (70%), a hyperechoic halo (74%), and a distinctly hypoechoic nodule (70%). Larger tumors often exhibit posterior acoustic shadowing (50%), a branching pattern (30%), and multiple projections extending from the nodule within or around ducts radiating from the nipple.

4) **Punctate calcifications (25%):** which usually do not show posterior shadowing

5) Duct extension (25%): seen as a projections from the nodule that extend radially inside or around the duct in the direction of the nipple.

6) Heterogeneous echotexture

7) Compressibility: Elastography operates on the principle that benign lesions compresses under transducer pressure, whereas malignant lesions displaces breast tissue without altering its height.

BENIGN CHARACTERISTICS (WITH NEGATIVE PREDICTIVE VALUES)

1. Well-defined hyperechoic tissue: 100%
2. 99% of cases are wider than tall
3. Smooth, gently curved lobulations (fewer than three in a nodule with a depth-to-width ratio <1): 99%
4. A thin echogenic pseudo-capsule in a nodule deeper than wide: 99%, typically indicating compressed normal tissue linked to a non-infiltrative process, best seen along anterior or posterior borders perpendicular to ultrasound beam.

USG FINDINGS FOR DIFFERENT BREAST CARCINOMA PATHOLOGIES [29,30]

Depending on the type and stage of the breast cancer, additional features may include ductal extension, branch pattern, and increase in vascularity on Doppler imaging. On ultrasound (USG), breast carcinoma usually manifests as irregular spiculated lesion with poorly defined borders, a "taller-than-wide" orientation, marked hypoechogenicity, posterior acoustic shadowing, and occasionally microcalcifications.

Infiltrating Ductal Carcinoma (IDC):

Commonly shows microcalcifications within it and typically manifests as a hypoechoic lesion with irregular margins, spiculated borders, and posterior acoustic shadowing.

Lobular Carcinoma:

On ultrasound, distinguishing it from benign lesions can be more difficult, as it may appear as an ill-defined mass with a "halo" effect, indistinct margins, and sometimes a "clustered" presentation due to multifocal involvement.

Medullary Carcinoma:

Typically a bigger, well-defined, hypoechoic mass that shows a lot of internal blood flow on Doppler and is frequently linked to lymphocytic infiltration.

Inflammatory Breast Carcinoma:

Edema, diffuse skin thickening, increased vascularity on Doppler, and multiple small hypoechoic nodules within the breast parenchyma, often resembling the appearance of skin.

Ductal Carcinoma In Situ (DCIS):

It may present as subtle architectural distortion or microcalcifications within the ducts, though it may not be easily detectable on USG alone.

PHYSICS OF ELASTOGRAPHY

US elastography is a newly developed dynamic imaging technique that evaluates tissue deformation under compression, based on the principle that softer tissues deform more easily than harder ones. This method enables an objective assessment of tissue stiffness when an external force is applied. [31, 32] In recent years, this rapidly advancing field has focused on the noninvasive imaging of the mechanical properties of various body tissues. [33]

Ultrasound elastography can detect certain abnormalities and clinical conditions that may not be visible using conventional ultrasound techniques. [34, 35] In homogeneous organs like the liver, mechanical properties can be represented as an average value, while in more heterogeneous tissues, they are displayed as a parametric map highlighting relative tissue characteristics, typically strain or Young's modulus. [36–39]

This approach offers additional diagnostic insights beyond conventional imaging by distinguishing between normal and pathological stages, depending on the specific technology and clinical application. [36–38] To simulate clinical scenarios, ultrasound imaging utilizes test objects that mimic tissue properties. These simulated lesions improve QA/QC processes, assess measurement accuracy, and support the advancement of new ultrasound techniques. [40]

ELASTOGRAPHY TECHNIQUES [40]

The main elastographic techniques include static, dynamic, transient, and remote elastography. Among these, static, remote, and transient elastography have been effectively used in clinical practice. A brief overview of these methods is provided here.

Static elastography:

Static elastography assesses tissue response to compression by comparing ultrasound signals before and after compression. Various manufacturers, including General Electric, Hitachi, Philips, Siemens, and Toshiba, have incorporated this technique into ultrasound scanners, primarily for breast, prostate, and thyroid imaging. Compression is usually applied manually, though some systems utilize natural patient movements like respiration or cardiac motion.

The intravascular ultrasound (IVUS) system (EndoSonics, USA) evaluates coronary wall and plaque structure by measuring strain in vascular tissue under varying pressures. While effective for IVUS, static elastography is less suitable for deep organs like the liver due to challenges in achieving controlled compression.

As a result, its use remains largely limited to breast, thyroid, and prostate imaging. Test objects should be designed accordingly. Since static elastography primarily evaluates relative elasticity in small areas, suitable test objects must feature inserts with varying stiffness and sizes, mimicking the mechanical properties of the targeted tissue.

Remote Elastography:

Remote elastography, or acoustic radiation force elastography, uses acoustic waves to induce localized tissue displacements via momentum transfer. This technique supports strain imaging and shear wave generation for stiffness quantification.

Mechanical strain in tissue is assessed through ultrasonic correlation-based methods or strain imaging, a static elastography technique using focused ultrasound. Siemens (Germany) applies this clinically as "Virtual Touch™ Tissue Imaging."

Acoustic radiation force impulse imaging (ARFI), based on this approach, is promising for liver lesion ablation. A suitable ARFI test phantom, like in static elastography, should include inserts of varying stiffness and sizes within a low-background tissue-mimicking material (TMM).

ARFI assesses tissue stiffness by measuring the shear wave velocity caused by acoustic radiation impulse. Siemens' "Virtual Touch Tissue Quantification" uses this to diagnose chronic liver illness by comparing shear wave velocity to liver fibrosis. ARFI test phantoms should contain homogeneous regions with varying shear wave velocities to imitate relevant tissue properties.

Supersonic shear imaging (SSI) by Supersonic Imagine (France) uses acoustic radiation force but displays tissue elasticity as a color-coded map overlayed on a B-mode image. SSI is a quantitative assessment of liver stiffness that also includes breast, prostate, and thyroid imaging.

Test objects for SSI should include inserts with varied stiffnesses within tissue-mimicking material. When used for homogeneous tissue assessment, such as liver stiffness measurement, phantoms should include regions with increasing stiffness to calibrate system accuracy in measuring Young's modulus.

Transient Elastography:

Transient elastography applies low-frequency, short-duration pulses to stimulate the target tissue. This mechanical stimulation generates low-frequency shear waves, which travel through the tissue at a speed that reflects its stiffness. The wave propagation is then measured using an ultrasonic pulse-echo technique. A modern commercial application of this method is Echosens' Fibroscan technology, specifically designed to evaluate liver fibrosis. Fibroscan estimates hepatic stiffness using a shear elasticity probe, which has been shown to correlate with the severity of fibrosis.

Shear wave Elastography

Shear wave elastography, a method of elastography in the ultrasound system, is used in clinical practice for evaluating breast masses. The integration of imaging findings from conventional ultrasound with elastography, which assesses tissue hardness—a feature that often differentiates benign from malignant masses—enhances the accuracy of breast mass evaluations [41,42]. The advantages of shear wave elastography include its technological simplicity, high sensitivity, and strong reproducibility. A low-frequency vibrator with ultrasonic single-element transducer generates a shear wave, which is then tracked, and its velocity is measured. This system operates under the assumption that the liver is a uniform medium, providing an average single measurement over a specific area of the patient. Consequently, to ensure accurate system evaluation, the phantom should be homogeneous rather than containing small targets, as seen in spatially resolved techniques.

Strain ratio elastography [43]

Strain elastograms are generated by physiological patient movements, such as heartbeat and breathing, or by applying pressure with the imaging transducer. Since both images can be displayed simultaneously, this method serves as a natural extension of B-mode imaging evaluation. The most useful frames for interpreting strain images with a high signal-to-noise ratio are those captured during consistent displacement, either in the transducer's upward or downward motion. Due to the viscoelastic nature of soft tissue, image quality is at its lowest—or may be entirely absent—when the compressive force is released, allowing the tissue to return to its original shape. Based on a cutoff value of 4.5, sensitivity is 90.47%, specificity is 98.24%, positive predictive value (PPV) is 95%, negative predictive value (NPV) is 96.55%, and overall accuracy is 96.15%.

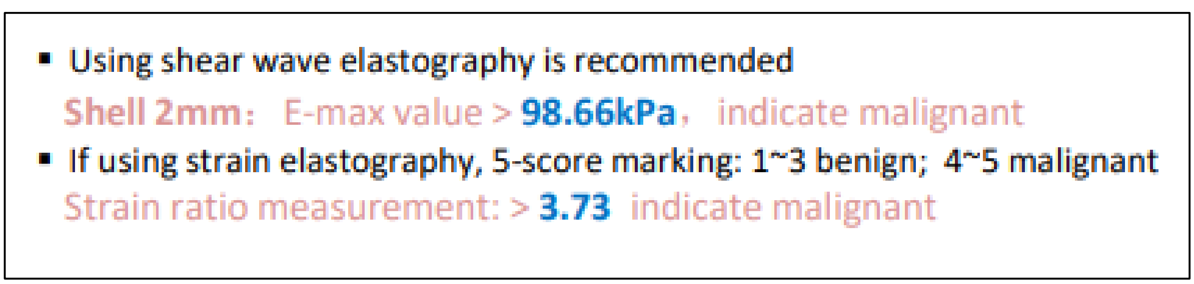


Fig 7: Elastography for breast [44]

E/B Ratio elastography [45]

The "E/B ratio" represents the extent to which a lesion appears larger on the elastogram compared to its actual size. A higher E/B ratio indicates increased stiffness, which may suggest malignancy. Generally, an E/B ratio greater than 1 raises suspicion for malignancy, whereas a ratio below 1 is typically associated with benign lesions.

A higher E/B ratio suggests that the lesion appears larger on the elastogram compared to the B-mode image, often indicating increased tissue stiffness and a potential malignancy. To calculate the E/B ratio, measure the lesion's diameter on the elastogram and divide it by its diameter on the B-mode ultrasound image. Elastography, combined with E/B ratio analysis, can help differentiate between benign and malignant breast tumors, particularly when conventional ultrasound results are inconclusive. [46] With a cutoff size ratio of 1.2, the sensitivity is 90.47%, specificity is 100%, positive predictive value (PPV) is 100%, negative predictive value (NPV) is 96.61%, and overall accuracy is 97.43% [47]

RELEVANT STANDARDS AND DESIGN CRITERIA [48]

Ultrasound phantoms play a crucial role in quality control (QC), performance testing, and clinical training for ultrasound imaging. To ensure accurate results, QC test phantoms must have tissue-like acoustic properties. According to IEC 1390 and AIUM 1990 standards, traditional B-mode ultrasound tissue-mimicking materials (TMMs) should have an acoustic velocity of 1540 m/s, attenuation coefficients between 0.5–0.7 dB/cm/MHz (for 2–15 MHz), and a linear attenuation response to frequency.

Although no official mechanical standards exist for ultrasound elastography TMMs, applying IEC and AIUM guidelines while incorporating mechanical properties of both healthy and diseased tissues is considered appropriate. Both commercial and research-based elastography TMMs are designed to match soft tissue acoustics while integrating mechanical features. Research indicates that background stiffness represents normal tissue, while target stiffness corresponds to malignant lesions. In cases of liver fibrosis, stiffness levels vary based on disease progression, affecting the entire liver.

TABLE 1. Suggested mechanical properties for tissue-mimicking materials include background and target stiffness values, elastic contrast, and standard target dimensions tailored to specific clinical applications.

Clinical applications	**Mechanical properties**			**Typical range of target dimensions(mm)**
	Background (kPa)	Target(kPa)	Elastic contrast	
Breast	25	30 -200	1.2-8	1-20
Prostate	15	10-40	0.7-2.7	5-40
Thyroid	10	15-180	1.5-18	10-40
Liver	3	3-16	1-5.3	10-80
Liver parenchyma	3-30	-	-	-

COLOR MAPPING & STIFFNESS SCORE [49]

PRINCIPLE OF ULTRASOUND ELASTOGRAPHY

1. Strain elastography evaluates tissue elasticity by detecting displacement caused by compression, with softer tissue displaying more movement than harder tissue.
2. Shear wave elastography measures elasticity by analyzing the speed of transverse shear waves, which travel faster through harder tissue compared to softer tissue.

QUALITATIVE ASSESSMENT OF STRAIN ELASTOGRAPHY: [50]

Elasticity allows a material to deform under force and return to its original shape once the force is removed. Different tissues respond based on their elastic modulus—adipose tissue deforms more easily, while fibrous tissue recovers more slowly. Strain elastography compares lesion strain to background adipose tissue, generating a visual elastogram that highlights relative stiffness. This stiffness helps assess malignancy likelihood.

Tsukuba Score: A five-point scale assessing cancer likelihood based on elasticity.

- **Score 1**: Benign hypoechoic lesion with uniform strain throughout.
- **Score 2**: Mostly strained benign lesion with some areas lacking strain.
- **Score 3**: Likely benign lesion with strain at the perimeter but absent in the center.
- **Score 4**: Malignant lesion with no strain throughout the hypoechoic area.
- **Score 5**: Malignant lesion with no strain in both the lesion and surrounding region.

  Simple cystic lesions with a score of 0 exhibit an aliasing artifact as a blue-green-red (BGR) pattern.

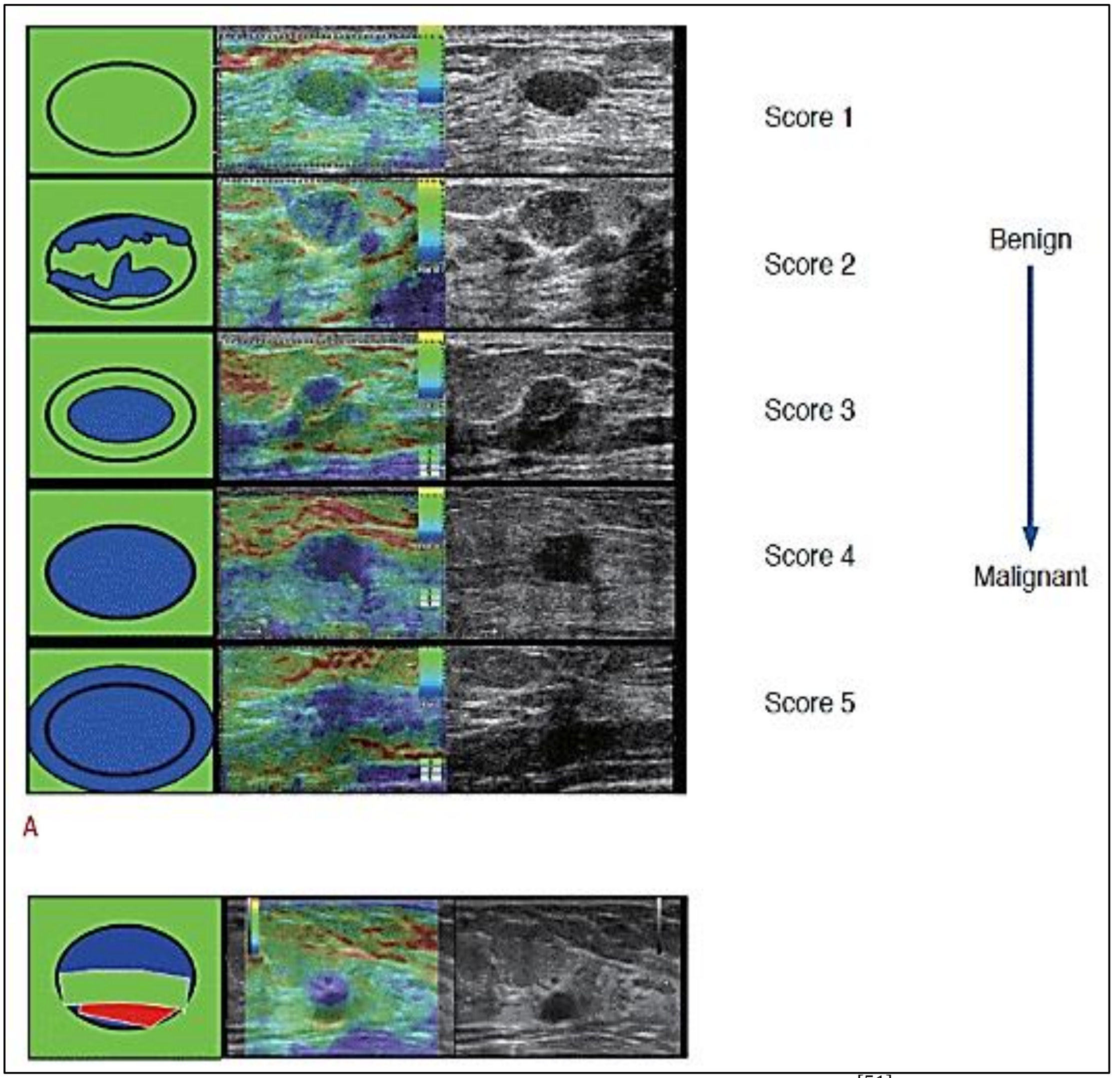


Figure 8: Elastography scoring system [51]

STRAIN RATIO MEASUREMENT:

Kumm et al. [52] introduced a semi-quantitative method for evaluating lesions known as strain ratio (SR) measurement. The SR value is determined by comparing the average strain within a lesion to that of a corresponding region of fatty tissue in the surrounding breast tissue. Using specialized software, a region of interest (ROI) is selected around the lesion to calculate its average strain. The lesion's ROI is labeled as **ST-ave LESION**, while the surrounding adipose tissue's ROI is labeled as **ST-ave FAT**. The strain ratio is then calculated using the formula: **Ratio = ST-ave FAT / ST-ave LESION**.

As the relative stiffness of the target lesion increases, the strain ratio value also rises. A higher strain ratio correlates with a greater risk of invasive breast cancer. While clinical experience with strain ratio imaging for breast cancer diagnosis is still limited, combining it with color elastography may improve overall diagnostic accuracy. Strain imaging could be particularly beneficial for assessing small and dense breasts, as well as reducing subjective factors in color image interpretation. [52]

QUALITATIVE ASSESSMENT OF SHEAR WAVE ELASTOGRAPHY [53]

Shear wave elastography (SWE) for breast cancer can be qualitatively assessed by comparing the relative stiffness of a suspicious mass to the surrounding normal tissue on the elastography image, without relying solely on numerical values. Malignant lesions, which tend to be stiffer, typically appear in warmer colors like red, indicating a higher likelihood of cancer, while softer, benign tissue is represented by cooler colors - blue.

ASSESSMENT FOR BREAST CANCER: [54]

Color-coded visualization:

The main technique for qualitative evaluation is to look at the color distribution on the SWE picture, where blue/green indicates softer tissue (probably benign) and red/yellow indicates stiffer tissue (possibly cancerous).

Region of interest (ROI) selection:

The radiologist focuses on the stiffest portion of the lesion and chooses a particular region inside the breast mass to examine.

Comparison to surrounding tissue:

To determine the relative stiffness difference, the color intensity inside the ROI is contrasted with the color of the surrounding normal breast tissue.

Subjective interpretation:

While qualitative shear wave elastography (SWE) provides valuable insights, its interpretation can be subjective, relying on the radiologist's expertise and color scale assessment. To reduce operator dependence and improve specificity, quantitative SWE is often used. This approach offers an objective evaluation of tissue elasticity by measuring stiffness in kilopascals (kPa), based on the speed of shear wave propagation within the region of interest (ROI).

EVIDENCES SUGGESTING THE ROLE OF ULTRASOUND ELASTOGRAPHY IN CHARACTERIZATION OF BREAST LESIONS AS BENIGN AND MALIGNANT

In 2024, Vikas Kumar Gupta et al. [5] evaluated the effectiveness of elastography and conventional B-mode ultrasonography in differentiating between benign and malignant breast lesions. Their prospective observational study involved 80 cases with 100 clinically palpable breast lumps in female patients who underwent both B-mode ultrasound and elastography. The final diagnosis was compared with sonographic features, modified color score, and mean strain ratio.

The study found that ultrasound had a sensitivity of 88.9%, specificity of 95.23%, a positive predictive value (PPV) of 94.42%, a negative predictive value (NPV) of 90.45%, and an overall diagnostic accuracy of 92.67%. The newly modified dual color score demonstrated a sensitivity of 96.4%, specificity of 85.78%, PPV of 85.92%, NPV of 86.87%, and diagnostic accuracy of 91.67%, with only a 2.2% chance of missing a malignant case. The mean strain ratio achieved the highest accuracy, with a sensitivity of 100%, specificity of 97.27%, PPV of 96.78%, NPV of 99.67%, and an overall diagnostic accuracy of 99.23%. The study underscored the reliability of elastography in detecting potential breast malignancies, helping reduce unnecessary invasive procedures.

In 2024, Daisy et al. [55] conducted prospective cross-sectional observational study to correlate the effectiveness of elastography in breast lesion diagnosis. The study included patients who underwent ultrasound examinations, focusing on both conventional ultrasound and elastography techniques.

Their findings highlighted the diagnostic capabilities of multiple imaging modalities. B-mode ultrasonography, utilizing the BI-RADS scoring system, achieved a sensitivity of 97.83%, specificity of 88.89%, and overall accuracy of 93%. Elastoscan, with a Tsukuba score cutoff of ≥4.0, demonstrated 95.65% sensitivity, 90.74% specificity, and 93% accuracy. E-strain elastography, using a strain ratio cutoff of >2.80, showed 94.0% sensitivity, 86.0% specificity, and 90.0% accuracy. Shear wave elastography, with a cutoff of >92.80 kPa, yielded 95.65% sensitivity, 90.74% specificity, and 93% accuracy. All imaging methods had an area under the curve (AUC) exceeding 0.947, with a statistically significant p-value of 0.001, indicating their strong ability to differentiate between benign and malignant breast lesions. The study concluded that elastography provides excellent diagnostic performance in distinguishing malignant from benign breast masses.

In 2022, **Xue et al in 2022**, [56] explored the role of elastography and BI-RADS classification in evaluating breast lesions located within the superficial fat layer. Their study included 75 such masses, with histopathology serving as the gold standard for comparison. They retrospectively analysed whether ultrasound elastography and BI-RADS classification aligned with histopathological results.

Histological analysis revealed that 73 of the lesions were benign, while only 2 were malignant. According to BI-RADS classification and treatment guidelines, 60% (45/75) of the masses were categorized as BI-RADS 4, warranting biopsy. However, only 4.4% (2/45) of these masses were actually malignant, meaning 95.6% (43/45) were unnecessarily biopsied. The study proposed that masses with well-defined margins within the fat layer, situated above the breast gland, are likely benign (BI-RADS 3), with a malignancy risk of just 1.4%, which aligns with the BI-RADS malignancy probability. Following this classification, only 1.3% (1/75) of patients would have required a biopsy

Anil kumar et al in 2022, [57] evaluated the effectiveness of elastography and conventional B-mode ultrasonography in distinguishing benign versus malignant breast masses, correlating their findings with pathology results. Their prospective observational study included 86 patients with 101 clinically palpable breast lumps who underwent both imaging modalities.

Sonography demonstrated a sensitivity of 89.8%, specificity of 96.15%, positive predictive value (PPV) of 95.65%, negative predictive value (NPV) of 90.91%, and an overall diagnostic accuracy of 93.07%. The newly modified dual-color score achieved a sensitivity of 97.8%, specificity of 87.0%, PPV of 86.79%, and NPV of 87.08%, with a diagnostic accuracy of 92.08%. The risk of missing a malignant case using this method was 2.1%.possible breast malignancies, thus preventing unnecessary invasive procedures. The mean strain ratio showed excellent diagnostic performance, with a sensitivity of 100%, specificity of 98.11%, PPV of 97.96%, NPV of 100%, and an overall accuracy of 99.01%. Their study highlighted the promise of elastography in accurately identifying potential breast malignancies, reducing the need for unnecessary invasive procedures.

In 2021, **Sinha R et al in 2021**, [58] assessed the sensitivity and specificity of ultrasound elastography in detecting and characterizing breast masses, aiming to differentiate between benign and malignant lesions. Their prospective study included 120 patients with breast lesions, all evaluated using ultrasonography (USG), with simultaneous B-mode and elastography examinations.

They found that when an elasticity score cutoff of 3 was used, sensitivity reached 97.0% and specificity was 86.7%. For strain ratio (SR), a cutoff of 3.8 resulted in a sensitivity of 93.3% and specificity of 95.5%. In all cases, ultrasound elastography findings regarding the extent of pathology, local or contiguous spread, and vascular involvement aligned well with cytological results. Their study concluded that ultrasound elastography is a quick and effective method that enhances the sensitivity and specificity of ultrasonography for evaluating focal breast lesions, thereby reducing unnecessary biopsies. The combination of ultrasound and elastography demonstrated high diagnostic accuracy, improving diagnostic confidence in assessing breast masses.

In 2021, **Priya Ram et al** [59] conducted a study on ultrasound elastography to assess tissue stiffness (elasticity) and its role in evaluating breast lesions. Their prospective observational study included female patients with suspected breast lesions identified through ultrasound or clinical examination, who were referred for breast elastography. A total of 90 female patients underwent ultrasound elastography, followed by core needle or surgical biopsy for histopathological analysis.

Histopathological results showed that 78.89% of lesions were benign, while 21.11% were malignant. The ultrasound elastography score distribution included scores of 1 (40%), 2 (23.56%), 3 (12.22%), 4 (8.89%), and 5 (13.33%), with scores 1 to 3 classified as benign and scores 4 and 5 as malignant. Statistical analysis revealed a sensitivity of 86.05%, specificity of 93.60%, positive predictive value of 88.1%, negative predictive value of 92.86%, and overall accuracy of 91.27% when compared with histopathological findings. The study concluded that ultrasound elastography is a valuable non-invasive diagnostic tool for distinguishing benign from malignant breast lesions, reducing the need for biopsies, thereby minimizing waiting time, cost, discomfort, and patient anxiety

Sinha et al.in 2022, [60] found that mammography was less effective in detecting breast cancer in women with dense breast tissue. Ultrasonography, especially with elastography, proved more effective as dense tissue appears hyperechoic, while most breast cancers are hypoechoic. Unlike mammography, ultrasound elastography poses no radiation risks. The study showed that elastography, based on strain ratios, provided higher specificity (92%) in differentiating benign from malignant lesions, reducing unnecessary biopsies, especially in BIRADS III and IV cases. Combining elastography with B-mode ultrasound significantly improved diagnostic accuracy.

In a single-center study by Ahmed (2020), [61] 100 female patients with 132 solid breast masses were included. Each patient underwent medical history evaluation, clinical examination, B-mode ultrasound using the BI-RADS system, and both strain and shear wave elastography. The strain ratio, mean elasticity value, and stiffness ratio were calculated, and all lesions were biopsied for comparison with histopathological findings. The results showed that ultrasound elastography, both strain and shear wave, demonstrated high sensitivity (94%) and specificity (88%) in evaluating breast masses. The study found that both elastography techniques provided similar diagnostic performance, which was further improved when combined with B-mode ultrasound. This combination significantly reduced unnecessary biopsies, highlighting elastography as a highly sensitive, non-invasive tool for assessing breast lesions

In a study by Yang et al. [62] (2020), women with breast lesions underwent conventional ultrasound (US) and shear wave elastography (SWE). Elastic values of the lesion's peripheral tissue were assessed based on shell size. The results showed that the combination of Emax-3shell (maximum elasticity value) and Emin-3shell (minimum elasticity value) significantly enhanced the diagnostic accuracy for breast lesion evaluation. The study found that this combination had a sensitivity of 92% and specificity of 85%, making SWE a valuable tool in differentiating benign from malignant lesions. The study concluded that integrating SWE features, particularly Emax-3shell and Emin-3shell, improves the precision of breast cancer diagnostics

Khamis et al. [63] (2017) studied 120 histopathologically confirmed solid breast masses in 120 females (mean age 38.2 years). Each mass was evaluated using an elastography score and strain ratio (SR), and a receiver operating characteristic (ROC) curve was plotted for both methods. The results revealed that the strain ratio (SR) demonstrated high diagnostic accuracy in distinguishing malignant from benign breast masses, with an area under the curve (AUC) of 0.91. However, no statistically significant difference was observed between SR and the elasticity score, suggesting that both methods offer similar diagnostic performance. The study concluded that SR is a reliable parameter for breast mass characterization, though the elasticity score can also provide comparable diagnostic value.

Singh et al. [64] (2020) conducted a study on 78 female patients to evaluate the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of ultrasound elastography (USE) in detecting and characterizing breast masses. The findings were compared with mammography, conventional ultrasound (USG), fine-needle aspiration cytology (FNAC), and histopathology. The results showed that USE demonstrated high specificity (92%) and NPV (95%), making it an effective tool in differentiating benign from malignant lesions. The study concluded that when combined with ultrasound, elastography significantly enhances diagnostic accuracy, particularly for lesions classified as BI-RADS 3. This approach helps reduce unnecessary biopsies and supports a more conservative follow-up strategy.

Chudasama et al. [65] (2019) conducted a study on 19 patients with breast lumps, first evaluating them with conventional ultrasonography followed by shear wave elastography. The ultrasound findings were classified using the BI-RADS grading system, while elastography results were assigned an elasticity score ranging from 1 to 5. The final diagnosis was confirmed through histopathological analysis via fine-needle aspiration cytology (FNAC) or biopsy. The results showed that elastography, when combined with B-mode ultrasound, enhanced specificity and diagnostic accuracy in differentiating benign from malignant breast lesions. The study found that elastography had a sensitivity of 90%

and a specificity of 85%. It concluded that integrating elastography with B-mode ultrasound helps reduce unnecessary biopsies, false positives, and associated morbidity, making it an effective tool for better breast lesion characterization.

Zhou et al. [66] investigated the effectiveness of ultrasound elastography in differentiating benign and malignant breast lesions. The study compared various elastography parameters with conventional ultrasound findings to assess diagnostic accuracy. The results showed that elastography significantly enhanced the characterization of breast lesions, with elastography improving sensitivity (93%) and specificity (85%) in detecting malignancies. The study concluded that elastography, when used alongside traditional ultrasound, not only enhances breast cancer diagnosis but also helps in reducing unnecessary biopsies and false-positive results, making it a valuable non-invasive imaging tool for clinical practice.

MATERIAL & METHODS

- **Study Duration**: They study was done for a period of 12 months (June 2023 to May 2024)
- **Source of Data**: Patients attending outpatient department and in patient department of KLE'S Dr. Prabhakar Kore hospital, Belagavi referred to the department of Radiodiagnosis were included
- **Study Design**: This was a prospective observational study done in 74 patients
- **Sample Size**:

$$n = \frac{Z^2_{(1-\frac{\alpha}{2})} pq}{d^2}$$

$$n = \frac{1.96^2 X\ 25.8\ X\ 74.2}{10^2}$$

Where,

n = sample size,
Z = statistic corresponding to level of confidence,
p = expected prevalence, and
q = 100 – p
d = desired precision

n = 73.5 ~ 74

Thus, 95% confidence interval, the proposed sample size for the study is **74.**

Patients underwent an ultrasonography of breast using an ultrasound machine - Mindray Resona i9. Both greyscale and elastography images were acquired as follows:

SCANNING TECHNIQUE

- Positioning of Patient: Supine.
- Probe: Proper depth and focus zone using linear array (7–13 MHz).
- Imaging techniques include clock-face reference and radial/antiradial scanning.
- Elastography images were acquired for shearwave and strain wave with Motion Stability (M-STB) index : >4

INCLUSION CRITERIA

1. Patient with symptoms such as breast lump and nipple discharge.
2. Asymptomatic women undergoing screening, with incidentally detected lesion.
3. Patient with family history of breast carcinoma
4. No previous history of breast chemotherapy, radiotherapy or surgery

EXCLUSION CRITERIA

1. Normal findings on Ultrasonography
2. Pregnant and lactating women
3. Known or operated case of breast malignancy
4. Patients with breast implants.
5. Unwilling to participate in the study

METHODS OF DATA COLLECTION

Institutional Ethical Review Board approval was obtained prior to initiation of the study. All the patients fulfilling the inclusion criteria were included in the study after their consent of participating and willingness to undergo required investigations as a part of the study.

The data was captured in the case record form that were broadly classified into

A. Demographic Characteristics: Name, age, sex, address, contact details.

B. Patient history – Medical history, family history, obstetric hstory and breast feeding details was noted

C. Clinical symptoms –Presence of Breast lump, its position, tenderness, nipple discharge, skin changes, duration of symptoms were noted down.

D. Investigations –BIRADs and elastography values were obtained and Hisptopathological reports were collected wherever possible.

STATISTICAL ANALYSIS

Data is analyzed using SPSS software version 21 and Excel. Categorical variables are given in the form of frequency table. Continuous variables are given in Mean ± SD/ Median (Min, Max) form. Chi square test is used to check the association of categorical variables with groups. Normality of variable is checked by Shapiro Wilk test and QQ plot. If data follows normal distribution, parametric tests like independent t test will be used. Otherwise, non-parametric test like Mann Whitney U test will be used. Sensitivity and specificity tests are done to evaluate the accuracy of a diagnostic test.P-value less than or equal to 0.05 indicates statistical significance.

RESULTS:

Data contains measurements of 74 women, presenting symptoms such as breast lump and nipple discharge.

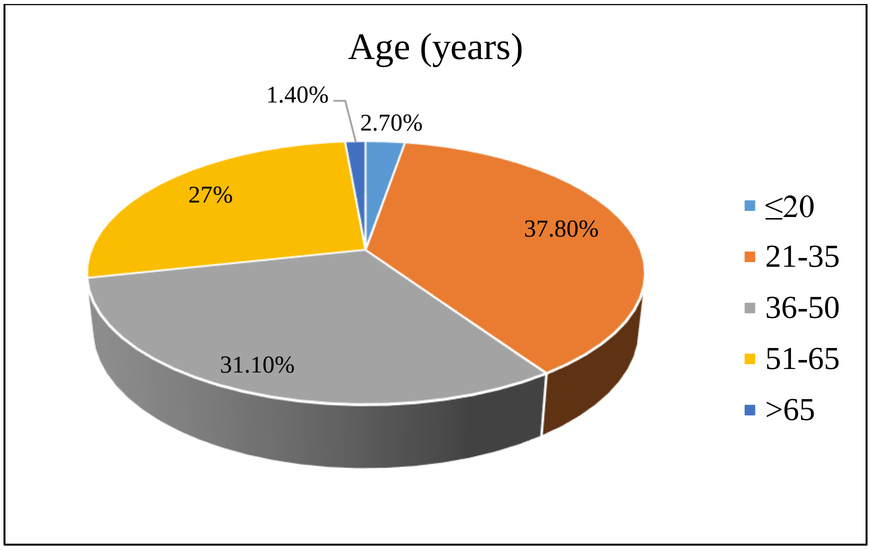
The following tables provides the details.

1. **DISTRIBUTION OF SUBJECTS ACCORDING TO AGE:**

Table 2: Distribution of subjects according to age.

Variable	Subcategory	Number of subjects (%)
Age (years)	≤20	2 (2.7%)
	21-35	28 (37.8%)
	36-50	23 (31.1%)
	51-65	20 (27%)
	>65	1 (1.4%)
	Mean ± SD Median (Min, max)	40.62 ± 12.08 37.5 (18, 67)

Out of 74 (100%) subjects, 28 (37.8%) were in age group 21-35 years, 23 (31.1%) were in between 36-50 years, 20 (27%) in between 51-65 years. The mean of ages was 40.62 ± 12.08 years.



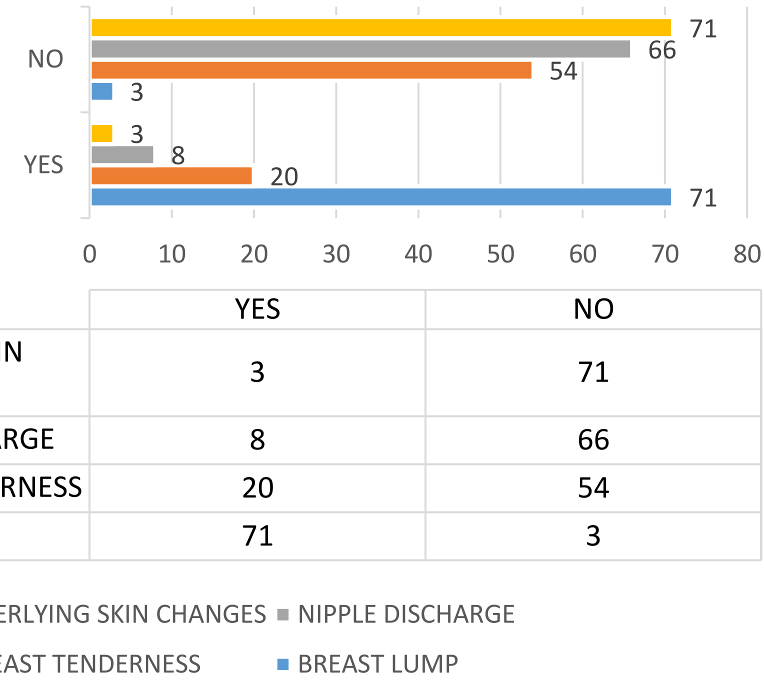
Graph 1: Distribution of subjects according to age (years).

2. DISTRIBUTION OF SUBJECTS ACCORDING TO PRESENTING COMPLAINTS:

Table 3: Distribution of subjects according to presenting complaints.

Variable	Subcategory	Number of subjects (%)
Breast lump	Yes	71 (95.9%)
	No	3 (4.1%)
Breast tenderness	Yes	20 (27%)
	No	54 (73%)
Nipple discharge	Yes	8 (10.8%)
	No	66 (89.2%)
Overlying skin changes	Yes	3 (4.1%)
	No	71 (95.9%)

Graph 2: Distribution of subjects according to presenting complaints.



	YES	NO
OVERLYING SKIN CHANGES	3	71
NIPPLE DISCHARGE	8	66
BREAST TENDERNESS	20	54
BREAST LUMP	71	3

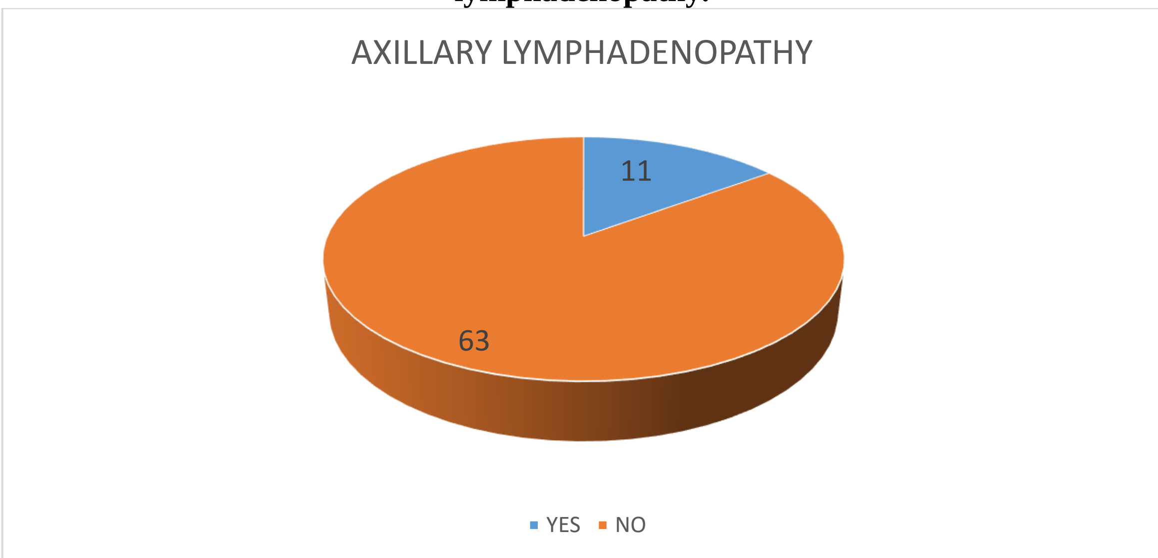
In the study, the majority of subjects presented with a breast lump, with 95.9% reporting its presence. Breast tenderness was reported by 27% of the participants, while 73% did not experience it. Nipple discharge was less common, with only 10.8% of subjects reporting it. Overlying skin changes were rare, occurring in just 4.1% of participants. Overall, most individuals did not exhibit the symptoms such as nipple discharge or skin changes.

3. DISTRIBUTION OF SUBJECTS ACCORDING TO USG FINDINGS:

Table 4: Distribution of subjects according to USG findings.

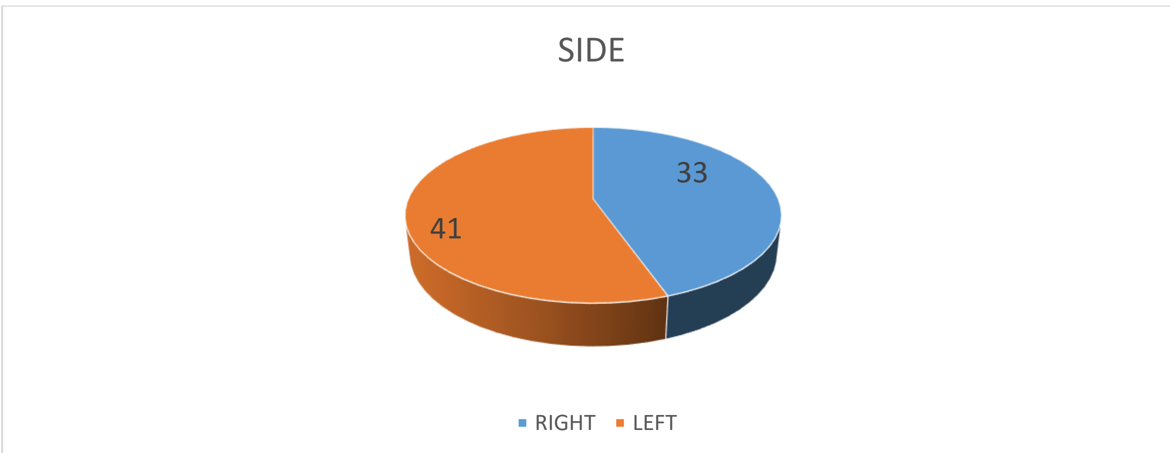
Variable	Subcategory	Number of subjects (%)
Axillary Lymphadenopathy	Yes	11 (14.9%)
	No	63 (85.1%)
Side	Right	33 (44.6%)
	Left	41 (55.4%)
Quadrant involved	LIQ	25 (33.7%)
	LOQ	18 (24.3%)
	UIQ	13 (17.5%)
	UOQ	18 (24.3%)

Graph 3: Distribution of subjects based on USG findings – Axillary lymphadenopathy.



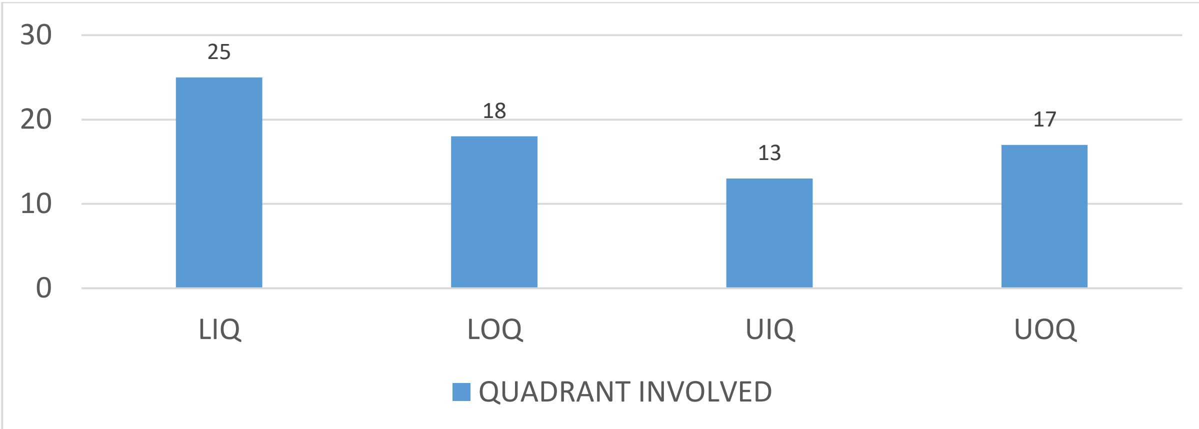
In this study, axillary lymphadenopathy was observed in 11 individuals, accounting for 14.9% of the total sample, while 63 individuals, or 85.1%, did not exhibit any signs of lymphadenopathy.

Graph 4: Distribution of subjects according to USG findings – Side.



Out of the total cases, 33 individuals (44.6%) had breast lesion on the right side, while 41 individuals (55.4%) had it on the left side. This indicates a slightly higher incidence of breast lesions on the left side compared to the right side within the sample.

Graph 5: Distribution of subjects according to USG findings – Quadrant involved.



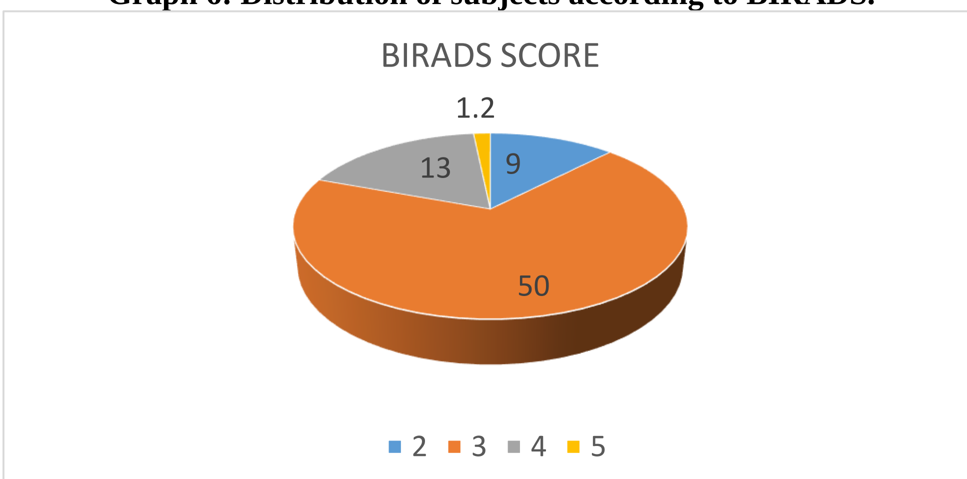
In terms of the quadrant involved, breast lesions were most commonly observed in the Lower Inner Quadrant (LIQ) with 25 cases, representing 33.7% of the total. This was followed by the Lower Outer Quadrant (LOQ) with 18 cases (24.3%), the Upper Inner Quadrant (UIQ) with 13 cases (17.5%), and the Upper Outer Quadrant (UOQ) with 17 cases (24.3%). These findings suggest that the LIQ was the most frequently affected in this study.

4. DISTRIBUTION OF SUBJECTS ACCORDING TO BIRADS:

Table 5: Distribution of subjects according to BIRADS.

Variable	Subcategory	Number of subjects (%)
BIRADS	2	9 (12.2%)
	3	50 (67.6%)
	4	13 (17.6%)
	5	2 (2.7%)

Graph 6: Distribution of subjects according to BIRADS.



The BIRADS (Breast Imaging-Reporting and Data System) scores in the study were distributed as follows: 9 cases (12.2%) were classified as BIRADS 2, indicating benign findings; 50 cases (67.6%) were classified as BIRADS 3, suggesting a probably benign condition; 13 cases (17.6%) were categorized as BIRADS 4, indicating suspicious findings that may require biopsy; and 2 cases (2.7%) were assigned a BIRADS 5, which indicates highly suspicious findings for malignancy. The majority of cases fell into the BIRADS 3 category.

5. DISTRIBUTION OF SUBJECTS ACCORDING TO ELASTOGRAPHY FINDINGS:

Table 6: Distribution of subjects according to Elastography findings.

Variable	Subcategory	Number of subjects (%)
BGR Artefact	Yes	7 (9.5%)
	No	67 (90.5%)
SHEARWAVE (kPa)	Mean ± SD Median (Min, max)	73.45 ± 32.05 74 (20, 178)
Strain Ratio#	Mean ± SD Median (Min, max)	2.51 ± 1.11 2.4 (0.9, 6)
E/B Ration#	Mean ± SD Median (Min, max)	0.80 ± 0.241 0.8 (0.3, 1.5)

In the study, the presence of a BGR (B-mode Real-time Grayscale) artifact was noted in 7 cases (9.5%), while 67 cases (90.5%) showed no such artefact.

The Shearwave measurements, expressed in kilopascals (kPa), had a mean value of 73.45 ± 32.05, with a median of 74 and a range from 20 to 178.

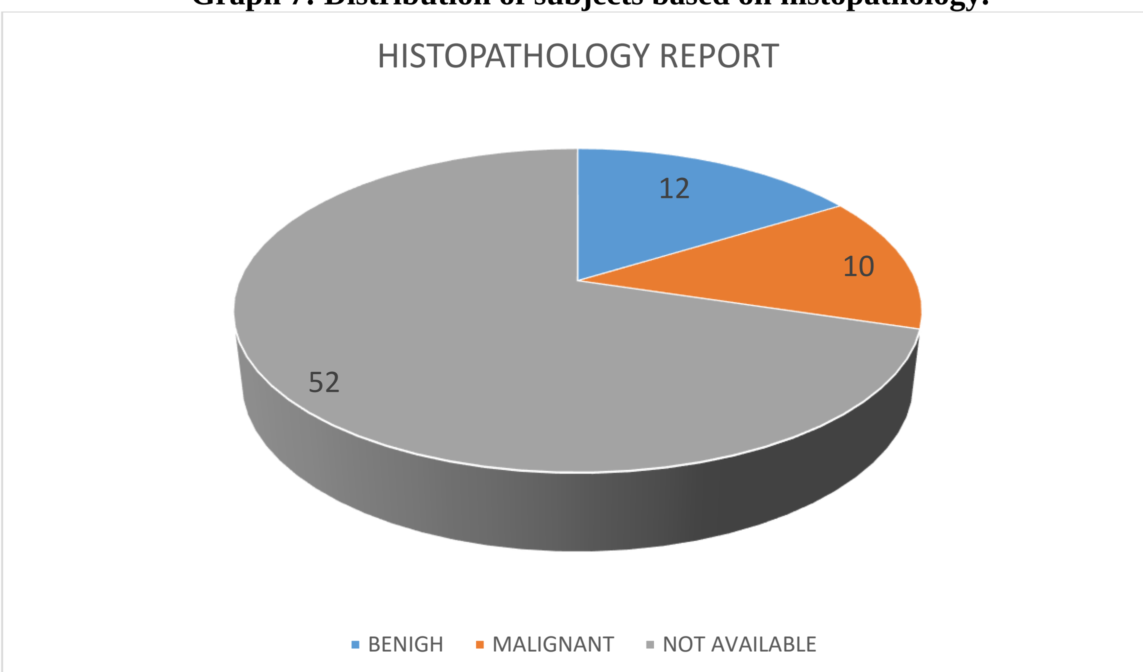
The strain ratio showed a mean of 2.51 ± 1.11, with a median of 2.4 and a range from 0.9 to 6. Finally, the E/B ratio had a mean of 0.80 ± 0.241, with a median of 0.8 and a range from 0.3 to 1.5.

6. Distribution of subjects according to histopathology:

Table 7: Distribution of subjects according to histopathology.

Variable	**Subcategory**	**Number of subjects (%)**
Histopathological report	Benign	12 (16.2%)
	Malignant	10 (13.5%)
	NA	52 (70.3%)

Graph 7: Distribution of subjects based on histopathology.



Out of 74 subjects, only 22 underwent histopathology examination. The histopathological reports indicated that 12 cases (16.2%) were diagnosed as benign, while 10 cases (13.5%) were classified as malignant. Additionally, 52 cases (70.3%) had no available histopathological data (NA).

Table 8: Distribution of subjects according to different variables over Benign and malignant groups.

Variable	Subcategory	Groups (Histopathology Report)		Total	p-value
		Benign (n=13)	Malignant (n=9)		
		Number of subjects (%)			
Breast lump	Yes	13 (59.1%)	9 (40.9%)	22 (100%)	-
Breast tenderness	Yes	0	9 (100%)	9 (100%)	**<0.001*C**
	No	13 (100%)	0	13 (100%)	
Nipple discharge	Yes	0	6 (100%)	6 (100%)	**<0.001*C**
	No	13 (81.3%)	3 (18.8%)	16 (100%)	
Overlying skin changes	Yes	0	3 (100%)	3 (100%)	**0.025*C**
	No	13 (68.4%)	6 (31.6%)	19 (100%)	
Axillary Lymphadenopathy	Yes	1 (11.1%)	8 (88.9%)	9 (100%)	**<0.001*C**
	No	12 (92.3%)	1 (7.7%)	13 (100%)	
Side	Right	4 (44.4%)	5 (55.6%)	9 (100%)	0.245C
	Left	9 (69.2%)	4 (30.8%)	13 (100%)	
Quadrant Position	LIQ	7 (77.8%)	2 (22.2%)	9 (100%)	0.150C
	LOQ	2 (50%)	2 (50%)	4 (100%)	
	UIQ	2 (100%)	0	2 (100%)	
	UOQ	2 (25%)	5(62.5%)	7 (100%)	
BGR Artefact	No	13 (59.1%)	9 (40.9%)	22 (100%)	-
BIRADS	3.0	13 (92.9%)	1 (7.1%)	14 (100%)	**<0.001*C**
	4.0	0	6 (100%)	6 (100%)	
	5.0	0	2 (100%)	2 (100%)	
Duration of symptoms (months)	Mean ± SD	4.92 ± 1.55 5 (3,7)	2.88 ± 0.781 3 (2,4)	3.90 ± 1.23 4 (2, 7)	**0.002*t**
SHEARWAVE (kPa)	Mean ± SD	78.3 ± 23.4 81 (44.7, 115)	111.54 ± 30.67 100 (78, 178)	94.92 ± 27.29 98 (44.7, 178)	**0.015*MW**
Strain Ratio	Mean ± SD	2.23 ± 0.92 2.4 (1.1, 3.9)	4.24 ± 0.74 4.5 (3.5, 5)	3.24 ± 0.83 2.95 (1.1, 5)	**<0.001*MW**
E/B Ration	Mean ± SD	0.8 ± 0.115 0.8 (0.6, 0.9)	1.18 ± 0.164 1.1 (1, 1.5)	0.99 ± 0.14 0.9 (0.6, 1.5)	**<0.001*MW**

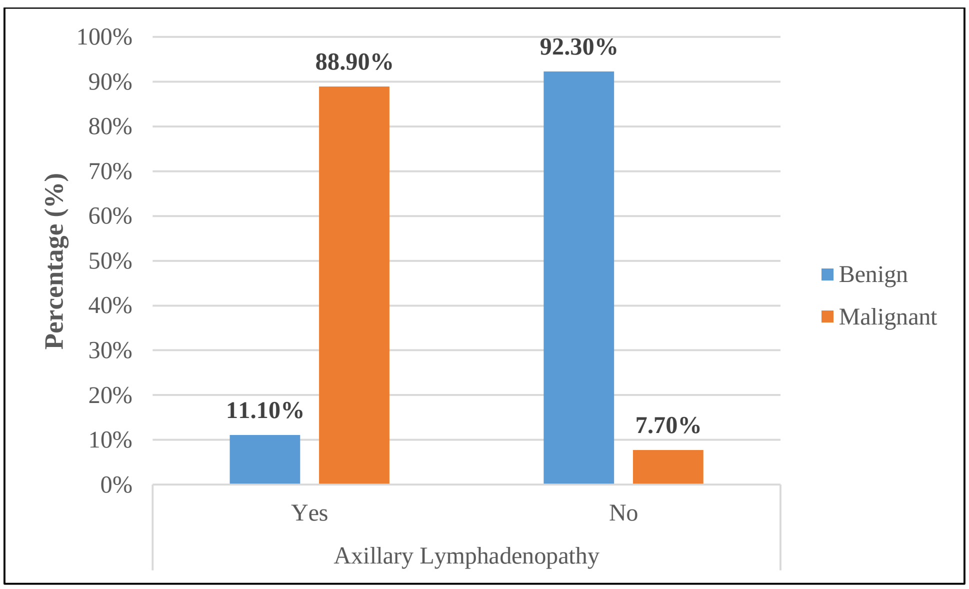
*Abbreviation: C- Chi square test, t- independent t test, MW- Mann Whitney U test, *- indicates statistical significance*

From Chi square test, it can be seen that there is significant association between breast tenderness, nipple discharge, overlying skin changes, Axillary Lymphadenopathy, BIRADS over benign and malignant groups. However, there was no association between sides, quadrant over groups in this study.

From independent t test, it can be observed that there is significant difference in the means of duration of symptoms over groups.

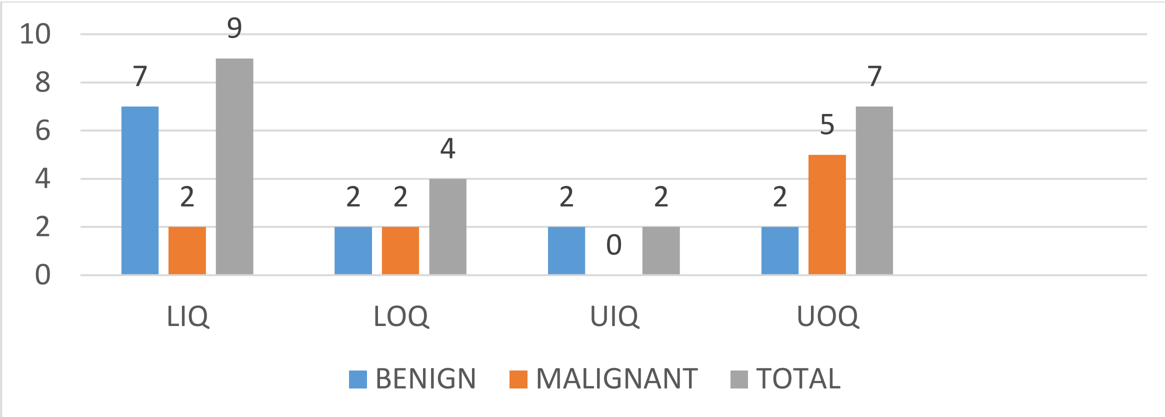
From Mann Whitney U t test, it can be observed that there is significant difference in the means of Shearwave (kpa), Strain ratio, E/B ratio over groups.

Graph 8: Distribution based on axillary lymphadenopathy in subjects who underwent histopathology examination



In the study, axillary lymphadenopathy was present in 11.1% in benign and 88.9% in malignant cases

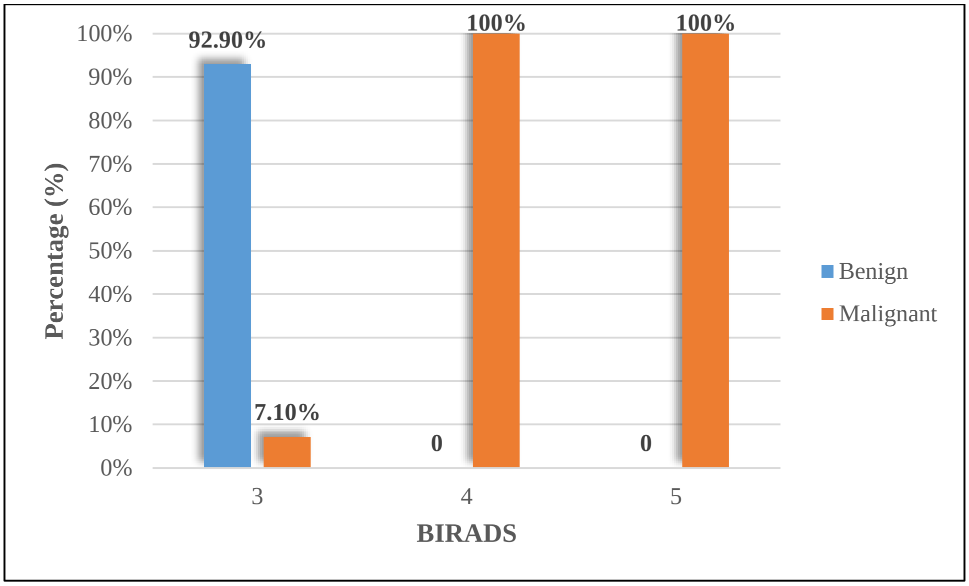
Graph 9: Distribution based on Quadrant/Position in subjects who underwent histopathology examination



The chart shows the distribution of benign and malignant cases across four breast quadrants. The LIQ has the highest total cases (9), with 77.8% benign and 22.2% malignant. The UOQ has 71.4% malignant cases, the highest malignancy rate, while 28.6% are benign. The LOQ has an equal 50-50% split, and the UIQ has the fewest cases (2), both benign (0% malignancy).

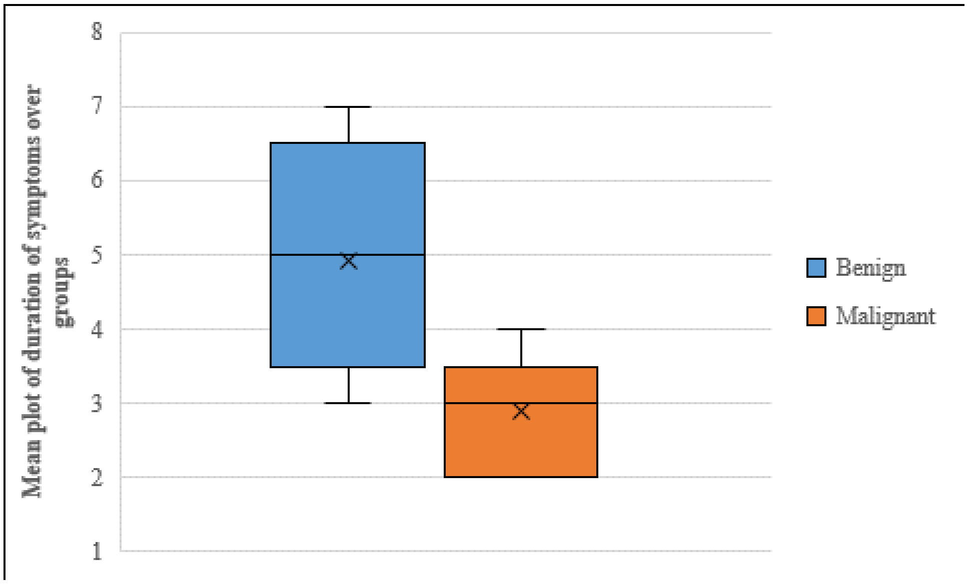
Malignancy is most common in the UOQ, making it a key area for clinical focus whereas LIQ, despite having the most cases, is predominantly benign.

Graph 10: Distribution of subjects based on BIRADS over groups



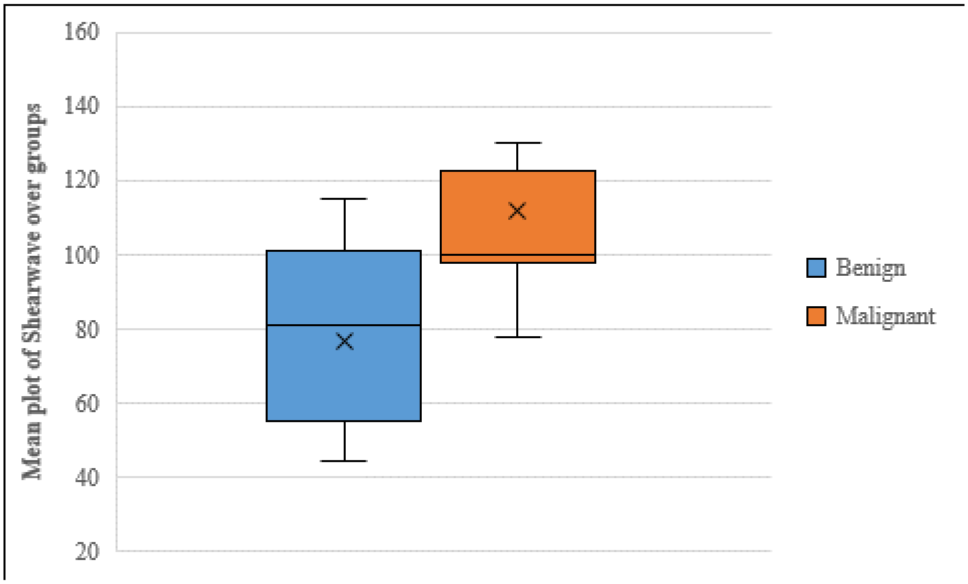
In this study, the bar chart illustrates the relationship between BIRADS scores and the percentage of benign versus malignant findings. The x-axis represents three BIRADS categories (3, 4, and 5), while the y-axis shows percentages. For BIRADS 3, 92.9% of cases were benign and 7.1% were malignant, indicating "probably benign" findings. In contrast, both BIRADS 4 ("suspicious") and BIRADS 5 ("highly suggestive of malignancy") showed 0% benign cases and 100% malignant cases. These results highlight the effectiveness of the BIRADS system in predicting malignancy risk, with higher BIRADS scores correlating strongly with increased malignancy.

Graph 11: Mean plot of duration of symptoms (months) over groups

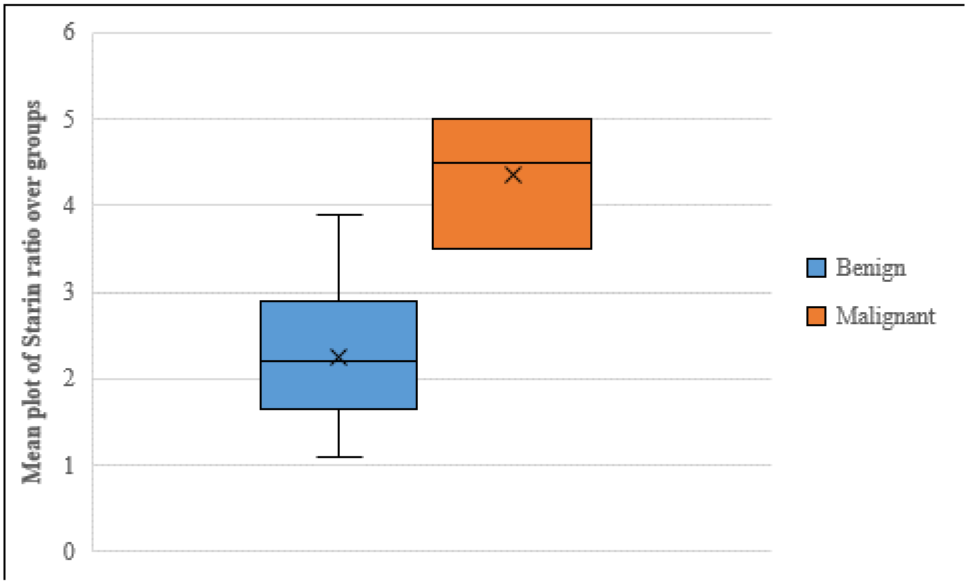


In this study, benign conditions had a longer symptom duration compared to malignant ones.

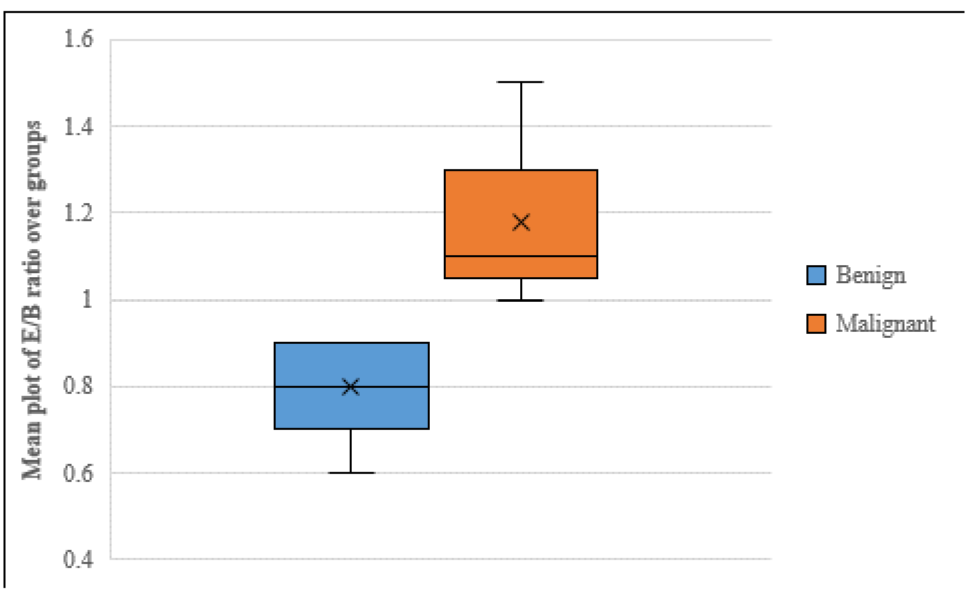
Graph 12: Mean plot of SHEARWAVE (kPa) over groups



Graph 13 : Mean plot of Strain ratio over groups



Graph 14 : Mean plot of E/B ratio over groups



In this study, the elastography results were as follows:

- **Shearwave (kPa)**: Benign cases had a mean of 78.3, while malignant cases had a mean of 111.54, with a significant difference (p=0.015).
- **Strain Ratio**: Benign cases had a mean of 2.23, while malignant cases had a mean of 4.24, showing a highly significant difference (p<0.001).
- **E/B Ratio**: Benign cases had a mean of 0.8, while malignant cases had a mean of 1.18, also showing a highly significant difference (p<0.001).

These findings suggest that malignant lesions have higher stiffness values across all measurements, supporting the use of elastography techniques for differentiating benign from malignant lesions.

Table 9: Sensitivity and Specificity for predicting malignancy with strain ratio

Variable	**Subcategory**	**Histopathology**	
		Benign	**Malignant**
Strain Ratio	**Negative (Benign)**	13 (81.3%)	3 (18.8%)
	Positive (Malignant)	0	6 (100%)

	Value	**95% CI**
Cut off	**≥4.5**	
Sensitivity	66.67%	29.93% to 92.51%
Specificity	100.00%	73.54% to 100.00%
Positive Predictive Value	100.00%	54.07% to 100.00%
Negative Predictive Value	75.00%	54.36% to 88.31%
Accuracy	83.33%	60.83% to 95.81%
p-value	**<0.001**	

Table 10: Sensitivity and Specificity for predicting malignancy with BIRADS

Variable	Subcategory	Histopathology	
		Benign	**Malignant**
BIRADS	**Negative (Benign)**	13 (92.9%)	1 (7.1%)
	Positive (Malignant)	0	8 (100%)

	Value	**95% CI**
Cutoff	**>3**	
Sensitivity	88.89%	51.75% to 99.72%
Specificity	100.00%	75.29% to 100.00%
Positive Predictive Value	100.00%	63.06% to 100.00%
Negative Predictive Value	90.00%	58.65% to 98.28%
Accuracy	94.44%	75.69% to 99.75%
p-value	**<0.001**	

Table 11: Sensitivity and Specificity for predicting malignancy with E/B ratio

Variable	Subcategory	Histopathology	
		Benign	**Malignant**
E/B Ratio	**Negative (Benign)**	13 (72.2%)	5 (27.8%)
	Positive (Malignant)	0	4 (100%)
		0.0%	4 (100%)

	Value	**95% CI**
Cutoff	**≥1.2**	
Sensitivity	44.44%	13.70% to 78.80%
Specificity	100.00%	75.29% to 100.00%
Positive Predictive Value	100.00%	39.76% to 100.00%
Negative Predictive Value	64.29%	50.09% to 76.35%
Accuracy	72.22%	49.25% to 88.93%
p-value	**0.008**	

Table 12: Sensitivity and Specificity for predicting malignancy with Shaerwave

Variable	Subcategory	Histopathology	
		Benign	Malignant
Shearwave (kpa)	**Negative (Benign)**	10 (76.9%)	3 (23.1%)
	Positive (Malignant)	3 (33.3%)	6 (66.7%)

	Value	95% CI
Cutoff	**>98.66**	
Sensitivity	66.67%	29.93% to 92.51%
Specificity	76.92%	46.19% to 94.96%
Positive Predictive Value	74.29%	49.15% to 89.62%
Negative Predictive Value	69.77%	46.64% to 85.90%
Accuracy	71.79%	48.81% to 88.65%
p-value	**0.041**	

In this study, all techniques showed good specificity and positive predictive value, with Strain Ratio and BIRADS showing the best performance for identifying malignancy.

1. The Strain Ratio results show that 81.3% of benign cases were negative and 18.8% positive, while all malignant cases (100%) were positive. Using a cutoff of ≥4.5, the diagnostic performance metrics were:

- Sensitivity: 66.67% (95% CI: 29.93% to 92.51%)
- Specificity: 100% (95% CI: 73.54% to 100%)
- Positive Predictive Value: 100% (95% CI: 54.07% to 100%)
- Accuracy: 83.33% (95% CI: 60.83% to 95.81%)
- p-value: <0.001

2. The BIRADS results showed 92.9% of benign cases were negative, and 100% of malignant cases were positive. Using a cutoff of >3, the diagnostic metrics were:

   - Sensitivity: 88.89% (95% CI: 51.75% to 99.72%)
   - Specificity: 100% (95% CI: 75.29% to 100%)
   - Accuracy: 94.44% (95% CI: 75.69% to 99.75%)
   - p-value: <0.001

3. The E/B Ratio results showed 72.2% of benign cases were negative, and 100% of malignant cases were positive. Using a cutoff of ≥1.2, the metrics were:

   - Sensitivity: 44.44% (95% CI: 13.70% to 78.80%)
   - Specificity: 100% (95% CI: 75.29% to 100%)
   - Accuracy: 72.22% (95% CI: 49.25% to 88.93%)
   - p-value: 0.008

4. The Shearwave (kPa) results showed 76.9% of benign cases were negative, and 66.7% of malignant cases were positive. Using a cutoff of >98.66, the metrics were:

   - Sensitivity: 66.67% (95% CI: 29.93% to 92.51%)
   - Specificity: 76.92% (95% CI: 46.19% to 94.96%)
   - Accuracy: 71.79% (95% CI: 48.81% to 88.65%)
   - p-value: 0.041

DISCUSSION:

Our study found that all elastography methods exhibited strong specificity, with Strain Ratio and BIRADS achieving perfect specificity (100%). This aligns with previous research. For instance, Daisy et al. [53] (2024) found elastoscan to have 90.74% specificity, while strain elastography showed 86% specificity. Anil Kumar et al. [55] (2022) documented a mean strain ratio specificity of 98.11%, and Sinha R et al. [56] (2021) observed 95.5% specificity for the strain ratio. Additionally, Singh et al. [62] (2020) reported a specificity of 92% for ultrasound elastography (USE). The consistently high specificity reported across multiple studies highlights elastography's effectiveness in minimizing false positives.

Strain Ratio Cutoff Values

The study applied a strain ratio threshold of ≥4.5, yielding a sensitivity of 66.67% and a specificity of 100%. In comparison, Daisy et al. [53] (2024) used a cutoff of >2.80, achieving 94.0% sensitivity and 86.0% specificity, while Sinha R et al. [56] (2021) reported 93.3% sensitivity and 95.5% specificity with a threshold of 3.8. Additionally, Khamis et al. [61] (2017) highlighted the high diagnostic accuracy of the strain ratio, with an AUC of 0.91. The variation in cutoff values suggests that optimal thresholds may depend on factors such as equipment, methodology, and patient characteristics. Nevertheless, the consistently high specificity of the strain ratio reinforces its reliability in the characterization of breast lesions.

Shear Wave Elastography Performance

In this study, shear wave elastography (SWE) with a cutoff of >98.66 kPa demonstrated a sensitivity of 66.67% and a specificity of 76.92%. This aligns with previous research, such as Daisy et al. [53] (2024), who used a threshold of >92.80 kPa and reported 95.65% sensitivity and 90.74% specificity. Similarly, Yang et al. [60] (2020) found SWE to have 92% sensitivity and 85% specificity. The variations in diagnostic performance across studies may be influenced by differences in equipment, methodology, or patient populations. Nevertheless, the consistently strong diagnostic accuracy reinforces SWE as a valuable tool for evaluating breast lesions.

Combined Approaches

This study assessed multiple parameters, including Strain Ratio, BIRADS, E/B ratio, and Shear Wave Elastography (SWE), adopting a multi-parameter approach that aligns with previous research. Ahmed [59] (2020) found that integrating elastography with B-mode ultrasound improved diagnostic performance, while Chudasama et al. [63] (2019) demonstrated that this combination enhanced specificity. Similarly, Zhou et al. [64] reported that using elastography alongside traditional ultrasound increased diagnostic accuracy. The consistent findings across these studies highlight the effectiveness of a multi-modality approach in achieving optimal breast lesion characterization.

Clinical Implications for Reducing Unnecessary Biopsies

Like previous studies, the current research highlights elastography's potential to reduce unnecessary biopsies. Xue et al. [54] (2022) reported that 95.6% of masses classified as BI-RADS 4 were unnecessarily biopsied, while Priya Ram et al. [57] (2021) concluded that elastography helped minimize the need for biopsies. Additionally, a study at NRI General Hospital found that elastography improved specificity to 92% in distinguishing benign from malignant lesions, thereby reducing unnecessary procedures. With this study demonstrating 100% specificity for Strain Ratio and BIRADS >3, the findings further support elastography's role in clinical decision-making, particularly for BI-RADS 3 and 4 lesions, where biopsy decisions can be challenging.

Anatomical Distribution Patterns

This study observed variations in malignancy rates across different breast quadrants, with the Upper Outer Quadrant (UOQ) accounting for 80% of malignant cases. This anatomical distribution pattern was not a major focus in the previous studies reviewed, suggesting that the current research may offer a unique contribution to understanding malignancy distribution in breast cancer.

CONCLUSION

This study demonstrates the significant clinical value of elastography techniques in differentiating benign from malignant breast lesions. The findings confirm that malignant lesions consistently exhibit higher stiffness values across all elastography measurements (Shearwave, Strain Ratio, and E/B Ratio), with statistically significant differences between benign and malignant groups.

The BIRADS classification system showed excellent diagnostic performance (94.44% accuracy), while the Strain Ratio measurement demonstrated perfect specificity and positive predictive value (100%). These results suggest that combining conventional BIRADS assessment with elastography techniques, particularly Strain Ratio, can substantially improve diagnostic accuracy and potentially reduce unnecessary biopsies.

The study also identified important clinical correlations, including the association between axillary lymphadenopathy and malignancy (present in 88.9% of malignant cases), and the varying distribution of malignancies across different breast quadrants, with the Right Upper Quadrant showing the highest malignancy rate.

This research supports the integration of elastography into standard breast imaging protocols to enhance diagnostic precision and improve patient management in breast cancer screening and diagnosis.

LIMITATIONS OF THE STUDY:

Like previous studies, this research has certain limitations.

- The sample size was relatively small, with only 74 patients.
- Histopathology examination was performed on only 22 cases.
- Future studies with larger sample sizes and standardized measurement protocols are needed.
- Expanding research in this area would help strengthen the evidence for elastography in breast lesion characterization.

SUMMARY

1. In the present study, 74 women with breast symptoms such as breast lump and nipple discharge were studied.

2. Majority of cases (37.8%) were in the age group of 21-35 years, followed by 31.1% in 36-50 years and 27% in 51-65 years, with a mean age of 40.62 ± 12.08 years.

3. This study showed left-sided breast lesion predominance (55.4% vs 44.6% right-sided).

4. Breast lump was the most common presenting complaint (95.9%), followed by breast tenderness (27%), nipple discharge (10.8%), and overlying skin changes (4.1%).

5. On radiographic assessment, 67.6% of cases were classified as BIRADS 3, 17.6% as BIRADS 4, 12.2% as BIRADS 2, and 2.7% as BIRADS 5.

6. Out of 74 patients, 22 underwent histopathology examination with 12 (16.2%) diagnosed as benign and 10 (13.5%) as malignant.

7. Significant correlation was observed between malignancy and breast tenderness, nipple discharge, overlying skin changes, axillary lymphadenopathy, and higher BIRADS scores ($p<0.001$).

8. For elastography measurements, malignant lesions showed significantly higher values compared to benign lesions:

- Shearwave values: 111.54 kPa in malignant cases and 78.3 kPa in benign cases (p=0.015)
- Strain ratio: 4.24 in malignant cases and 2.23 in benign cases (p<0.001)
- E/B ratio: 1.18 in malignant cases and 0.8 in benign cases (p<0.001)

9. Diagnostic performance for malignancy prediction was highest with BIRADS >3 (sensitivity 88.89%, specificity 100%, accuracy 94.44%), followed by Strain ratio ≥ 4.5 (sensitivity 66.67%, specificity 100%, accuracy 83.33%).

10. The Upper Outer Quadrant showed the highest malignancy rate (62.5%) despite Lower Inner Quadrant having the most lesions overall (33.7%).

The findings suggest that combining BIRADS with elastography techniques, particularly Strain Ratio, can improve diagnostic accuracy and potentially reduce unnecessary biopsies.

REFERENCES

1. Susan Klein. Evaluation of palpable breast masses. Am Fam Physician 2005; 71(9):1731-1738.
2. Ferlay J, Soerjomataram I, Ervik M, et al. Cancer Incidence and Mortality Worldwide: IARC Cancer Base No. 11 GLOBOCAN 2012 v1.0, Lyon, France: International Agency for Research on Cancer; 2013.
3. Bray F, Ren JS, Masuyer E, et al. Estimates of global cancer prevalence for 27 sites in the adult population in 2008.; 2013; Int J Cancer.; 132(5):1133-45
4. National Cancer Registry Programme. Consolidated report of the population based cancer registries1990-1996. New Delhi: Indian Counc Med Res; 2001.
5. Dr. Vikash Kumar Gupta, Dr. Parveen Kumar Kaushik, Dr. Tarun Kumar Chaudhari. The role of ultrasound elastography in characterization of breast lesion as benign and malignant. European Journal of Cardiovascular Medicine. 2024; 14(1):339-344.
6. Malich A, Boehm T, Facius M, Freesmeyer MG, Fleck M, Anderson R et al. Differentiation of mammographically suspicious lesions: evaluation of breast ultrasound, MRI mammography and electrical impedance scanning as adjunctive technologies in breast cancer detection. Clin Radiol. 2001Apr 1;56(4):278-83.
7. Malvia S, Bagadi SA, Dubey US, Saxena S: Epidemiology of breast cancer in Indian women. Asia Pac J ClinOncol 2017;13(4):289–295.

8. Tanter M, Bercoff J, Athanasiou A, Deffieux T, Gennisson JL, Montaldo G, et al. Quantitative assessment of breast lesion viscoelasticity: initial clinical results using supersonic shear imaging. Ultrasound Med Biol 2008;34:1373-1386
9. Krouskop TA, Wheeler TM, Kallel F, Garra BS, Hall T. Elastic moduli of breast and prostate tissues under compression. Ultrason Imaging 1998;20:260-274
10. Chalasani P, Downey L, Stopeck AT. Caring for the breast cancer survivor: A guide for primary care physician s. Am J Med. 2010;123(6):489-95.
11. Gheonea IA, Stoica Z, Bondari S, et al. Differential diagnosis of breast lesions using ultrasound elastography. Indian J Radiol Imaging 2011;21(4):301-5
12. Beller F. Development and anatomy of the breast. In Mitchell GW Jr,Bassett LW. The Female Breast and Its disorders. Baltimore: Williams &Wilkins; 1990
13. Susan S. Gray's Anatomy: The Anatomical Basis of Clinical Practice. 39thed. Churchill Livingstone; 2005.
14. Chaurasia V, Pal S. A Novel Approach for Breast Cancer Detection using Data Mining Techniques. International Journal of Innovative Research in Computer and Communication Engineering 2014. 2(1); 2456-65
15. Rosen PR. Rosen's Breast Pathology. 2nd ed. Philadelphia: LippincottWilliams & Wilkins; 2001.
16. Hartmann LC, Sellers TA, Frost MH. Benign breast disease and the risk ofbreast cancer. N Engl J Med 2005;353:229-37.
17. Alhaidary, A.A., Al-Qudimat, A.R., Arabi, H. et al. Imaging Patterns in Breast Cancer for Women Under 40 Years: A Descriptive Cohort Study. J Epidemiol Glob Health 14, 63–71 (2024)

18. Sadove AM, Van Aalst JA. Congenital and acquired pediatric breastanomalies: a review of 20 years experience. Plast Reconstr Surg. 2005 Apr1;115(4):1039-50.
19. Leong PW, Chotai NC, Kulkarni S. Imaging features of inflammatory breast disorders: a pictorial essay. Korean J Radiol. 2018 Feb 1;19(1):5-14.
20. Saraswat S, Kumar A. The study of different presentations of breast lumps in radiographic imaging. Acta Medica International 2014;1(1):45-51.
21. Cho, Park. Mimickers of Breast Malignancy on Breast Sonography. J Ultrasound Med 2013;32:2029-36
22. Jennifer A Harvey. Unusual Breast Cancers: Useful Clues to Expanding the Differential Diagnosis. Radiology. 2007 Mar; 242(3).
23. National Breast and Ovarian Cancer Centre. Breast cancer risk factors: a review of the evidence. National Breast and Ovarian Cancer Centre, Surry Hills, NSW, 2009. ISBN Online: 978-1-74127-141-6
24. Ferlay J, Soerjomataram I, Ervik M, et al. Cancer Incidence and Mortality Worldwide: IARC Cancer Base No. 11 GLOBOCAN 2012 v1.0, Lyon, France: International Agency for Research on Cancer; 2013.
25. Li CI, Uribe DJ, Daling JR. Clinical characteristics of different histologic types of breast cancer. Br J Cancer . 2005 Oct;93(9):1046.
26. Schnitt SJ et al. Pathology of invasive breast cancer in diseases of the breast .3rd edi. Lippincott, William and Wilkins.Philadelphia 2004;393.
27. Pam Stephen et al. Types of breast cancer: Ductal, lobular, inflammatory and Pagets. Jan 30 2019.

28. Stavros AT, Thickman D, Rapp CL et al. Solid breast nodules: use of sonography to distinguish benign and malignant .Radiology. 1995;196:123-34
29. Tsunoda H, Moon WK. Beyond BI-RADS: Nonmass Abnormalities on Breast Ultrasound. Korean J Radiol. 2024 Feb;25(2):134-145.
30. Cha H, Chang YW, Lee EJ, Hwang JY, Kim HJ, Lee EH, Ryu JK. Ultrasonographic features of pure ductal carcinoma in situ of the breast: correlations with pathologic features and biological markers. Ultrasonography. 2018 Oct;37(4):307-314.
31. Lerner RM, Huang SR, Parker KJ . Sonoelasticity images derived from ultrasound signals in mechanically vibrated tissues. Ultrasound Med Biol. 1990;16:231–239
32. Ophir J, Alam SK, Garra B, Kallel F, Knofagou E, Krouskop T et al. Elastography: Ultrasonic estimation and imaging of the elastic properties of tissues. Proc Inst Mech Eng. 1999 ; 213:203–233
33. Bamber J, Cosgrove D, Dietrich CF, Fromageau J, Bojunga J, Calliada F et al. EFSUMB guidelines and recommendations on the clinical use of ultrasound elastography. Part 1: Basic principles and technology. Ultraschall Med - Eur J Ultrasound. 2023 Apr;34(02):169-84.
34. AD, Ahuja AJ.et al. Post grad. Medical Journal. 1997; 73(861):412-414.
35. Caremeri C., Jeffery FB et al. Thyroid. 1998 April; 8(4):283-89.
36. Shimamoto , Sataka H.et al. Eur J Radiol . 1998 Nov; 29(1)4-10.
37. Pratap K,Ultrasound in Obstetrics and Gynecology Arya Book Depot;1995:1
38. Yamakara K, Naito S. Proceedings of first international conference of prognostic ultrasound.1965:41.
39. Vitti P, Rago T et al. J Clin Endocrinol Metabolism. 1994;(2):600-603.

40. Lin .J.D., Weng HF et al. Acta Cytol. 1997;41(3):687-91.
41. Cournane S, Fagan AJ, Browne JE. Review of ultrasound elastography quality control and training test phantoms. Ultrasound. 2022 Feb;20(1):16-23.
42. J.H. Youk, H.M. Gweon, E.J. Son, K.H. Han, J.A. Kim, Diagnostic value of commercially available shear-wave elastography for breast cancers: integration into BI-RADS classification with subcategories of category 4, Eur. Radiol. 23 (10) (2013) 2695–2704.
43. B. Liu, Y. Zheng, G. Huang, M. Lin, Q. Shan, Y. Lu, et al., Breast lesions:quantitative diagnosis using ultrasound shear wave elastography–a systematic review and meta–analysis, Ultrasound Med. Biol. 42 (4) (2016) 835–847.
44. Dietrich CF, Barr RG, Farrokh A, Dighe M, Hocke M, Jenssen C, Dong Y, Saftoiu A, Havre RF. Strain Elastography - How To Do It? Ultrasound Int Open. 2017 Sep;3(4):E137-E149.
45. Ian Wei Ming Tay, Llewellyn Shao-jen Sim, Tammy Hui Lin Moey, Karen Pei Pei Tan, Lily Mei San Lai, Lester Chee Hao Leong. Shear wave versus strain elastography of breast lesions—The value of incorporating boundary tissue assessment, Clinical Imaging, Volume 82, 2022, Pages 228-233.
46. Richard G Barr. Breast Elastography: How to Perform and Integrate Into a "Best-Practice" Patient Treatment Algorithm. Journal of ultrasound medicine. 2020;39(1):7-17.
47. Mamata Singh1, Dilleswari Pradhan2, Banita Kumari Sahu3, Panchanana Panigrahy4, Basanta Manjari Swain5, Jayashree Mohanty. Evaluation of Diagnostic Accuracy of Ultrasound Elastography in Differentiating benign and Malignant Solid

Breast Masses in Correlation with Mammography, Fine Needle Aspiration Cytology (FNAC) and Biopsy. International Journal of Contemporary Medical Research.2020;7(9):H4-H10.

48. Nightingale K, Soo MS, Nightingale R, Bentley R, Stutz D, Palmeri M etal. Acoustic radiation force impulse imaging: remote palpation of themechanical properties of tissue. In Ultrasonics Symposium, 2002.Proceedings. 2002 IEEE 2002 Oct 8 (Vol. 2, pp. 1821-1830). IEEE.
49. Kumm TR, Szabunio MM. Elastography for the characterization of breast lesions: initial clinical experience. Cancer Control. 2010 Jul;17(3):156-61
50. Itoh A, Ueno E, Tohno E, Kamma H, Takahashi H, Shiina T, YamakawaM, Matsumura T. Breast disease: clinical application of US elastographyfor diagnosis. Radiology. 2006 May;239(2):341-50.
51. Bercoff J, Chaffai S, Tanter M, Sandrin L, Catheline S, Fink M et al. In vivo breast tumor detection using transient elastography. Ultrasound MedBiol. 2003 Oct 1;29(10):1387-96.
52. Marukatat, P. Parklug, S. Issaragrisil, C. Sumanasrethakul, Shear wave elastography for solid breast masses evaluation: Quantitative measurement of mean elasticity value and elasticity ratio, European Journal of Radiology Open, Volume 12, 2024, 100573, ISSN 2352-0477,
53. Daisy gupta, Viyay Pal, Permeet Kaur, Poonam Ohri.role of ultrasound elastography in breast lesions with FNAC, histopahtologocal correlation. International Journal of Life Sciences, Biotechnology and Pharma Research. 2024;13(8): 119-128.

54. Xue N, Zhang S. Analysis of the accuracy of ultrasound elastography and BI-RADS classification of breast masses located within the superficial fat layer of the glands. Gland Surg 2022;11(10):1722-1729

55. Sakalecha, A. K., Parameshwar, K. B. H., Savagave, S. G., & Naik, B. R. (2022b). The role of ultrasonography and elastography in differentiating benign from malignant breast masses with pathologic correlation. *Journal of Diagnostic Medical Sonography*, *38*(3), 226–234.

56. Sinha R, Ali Z, Jaiswal M, et al. Evaluation of focal breast lesions using ultrasound elastography with FNAC and/or histopathological correlation – a prospective observational study in the region of Katihar, Bihar. J Evid Based Med Healthc 2021;8(25):2143-2148.

57. Priya Raman Bhole, Vijay Indal Naik. Radiological study of ultrasound elastography in the evaluation of breastlesions at a tertiary hospital. MedPulse International Journal of Radiology. December 2021; 20(3): 73-78.

58. Accuracy of Ultrasound Elastography in Characterization of Breast Lesions. Eur J Mol Clin Med, 2022; 9(7): 791-804

59. Ahmed, A.T. Diagnostic utility of strain and shear wave ultrasound elastography in differentiation of benign and malignant solid breast lesions. Egypt J Radiol Nucl Med 51, 70 (2020).

60. Yang, H., Xu, Y., Zhao, Y. et al. The role of tissue elasticity in the differential diagnosis of benign and malignant breast lesions using shear wave elastography. BMC Cancer 20, 930 (2020).

61. Khamis MEM, El-deen AMA, Ismail AAA. The diagnostic value of sonoelastographic strain ratio in discriminating malignant from benign solid breast masses. Egypt J Radiol Nucl Med. 2017;48:1149–57.

62. Mamata Singh, Dilleswari Pradhan, Banita Kumari Sahu, Panchanana Panigrahy, Basanta Manjari Swain, Jayashree Mohanty, Evaluation of Diagnostic Accuracy of Ultrasound Elastography in Differentiating benign and Malignant Solid Breast Masses in Correlation with Mammography, Fine Needle Aspiration Cytology (FNAC) and Biopsy, Int J Contemp Med Res Aug 2020, vol. 7(8)

63. Shilpa Chudasama11, Jay K Satapara2*, Nandini Bahri3,1Associate Professor, 2Resident, 3Professor and HOD, Department of Radiodiagnosis, Shri M.P. Shah Government Medical College and Shri Gurugobind Singh Government Hospital, Jamnagar Gujarat, INDIA, Role of elastography in evaluation of benign Vs malignant breast lesions, Med Int J of Medicine, vol. 12(3) Dec 2019

64. JianQiao Zhou, WeiWei Zhan, Cai Chang , XiaoXiao Zhang, Yi Jia, YiJie Dong, Chun Zhou, Jing Sun, Edward G. Grant.

ANNEXURES – I

KAHERs JNMC

BELAGAVI

INFORMED CONSENT FORM

"EVALUATION OF ROLE OF ULTRASOUND ELASTOGRAPHY IN CHARACTERIZATION OF BREAST LESIONS AS BENIGN AND MALIGNANT: ONE YEAR HOSPITAL BASED OBSERVATIONAL STUDY"

Roll no: BS0122002

Introduction:

Breast lesions are quite common in women. These lesions can be classified as benign or malignant. Breast cancer is the second most common cancer However; majority of the breast lesions are benign. Early diagnosis of malignant breast lesions helps in improving the treatment outcomes of the patients.

Modalities used commonly for diagnosing these cancers used now are ultrasonography, mammography and biopsy

Ultrasound elastography is a newer modality which is safer with less radiation exposure and is a non-invasive procedure, with cost similar to a biopsy.

Explanation of procedure:

After proper informed, written consent, patients coming for breast ultrasonography and fitting the inclusion criteria will be selected.

Patients will fill the pre-designed questionnaire.

Findings will be noted and grading of the lesion will be done on Ultrasonography (MINDRAY RESONA I9).

The lesion will also be seen on elastography with the help of MINDRAY RESONA i9 and findings will be noted.

Withdrawal from participation in the study:

Participation in this study in voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

Possible benefits from participating in the study:

You will/will not get any benefits by participating in this study.

Possible risks from participating in the study:

There are no risks involved in participating in this study.

Privacy and confidentiality:

The information collected from you will be coded, to prevent any person to identify you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication.

Financial incentives: You will not receive any payment for participating in this study.

Cost of investigations done during the course of study will be paid by the Participant**.**

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purpose and or presented to scientific groups.

However, your identity will never be revealed.

If you have any question or complaints with regard to your right as study participant you may contact Dr Harsha Hegde, Chairperson, Ethical committee of JNMC, 0831-2473777 Extension 4052.

Legal rights: By signing this consent form, we are not waving any of your legal rights

CONSENT STATEMENT

I am making a voluntary decision to participate in the study **“**EVALUATION OF ROLE OF ULTRASOUND ELASTOGRAPHY IN CHARACTERIZATION OF BREAST LESIONS AS BENIGN AND MALIGNANT: ONE YEAR HOSPITAL BASED OBSERVATIONAL STUDY”

My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the participant:

Signature or left thumb impression of the participant:

Name of the witness:

Signature or left thumb impression of the witness:

Name of the investigator: BS0122002

Signature of the investigator:

ANNEXURES – II

PROFORMA

TITLE:

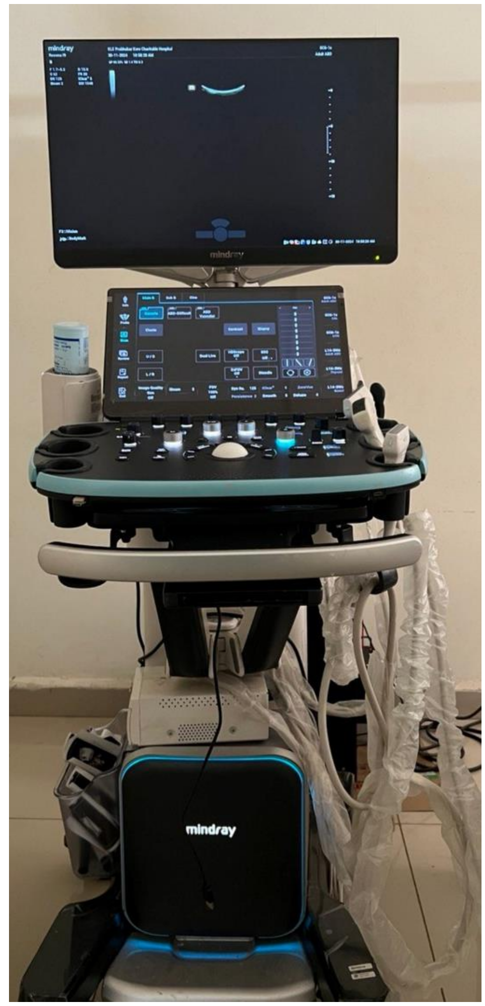
"EVALUATION OF ROLE OF ULTRASOUND ELASTOGRAPHY IN CHARACTERIZATION OF BREAST LESIONS AS BENIGN AND MALIGNANT: ONE YEAR HOSPITAL BASED CROSS-SECTIONAL STUDY"

- Name of patient:
- Age:
- Address:
- Relevant family history (if any):
- Obstetric history:
- Breast feeding (+/-):

<table>
<tr><th colspan="4">CLINICAL SYMPTOMS:</th></tr>
<tr><td></td><td colspan="2">YES</td><td>NO</td></tr>
<tr><td rowspan="2">BREAST LUMP:</td><td>UNILATERAL:</td><td>BILATERAL</td><td></td></tr>
<tr><td colspan="2">QUADRANT(S) INVOLVED:</td><td></td></tr>
<tr><td>BREAST TENDERNESS:</td><td colspan="2"></td><td></td></tr>
<tr><td>NIPPLE DISCHARGE:</td><td colspan="2"></td><td></td></tr>
<tr><td>OVERLYING SKIN CHANGES</td><td colspan="2"></td><td></td></tr>
<tr><td>DURATION OF SYMPTOMS:</td><td colspan="3"></td></tr>
</table>

ANNEXURE III: IMAGES / FIGURES PHOTOGRAPHS OF CASES

ULTRASONOGRAPHY LINEAR PROBE

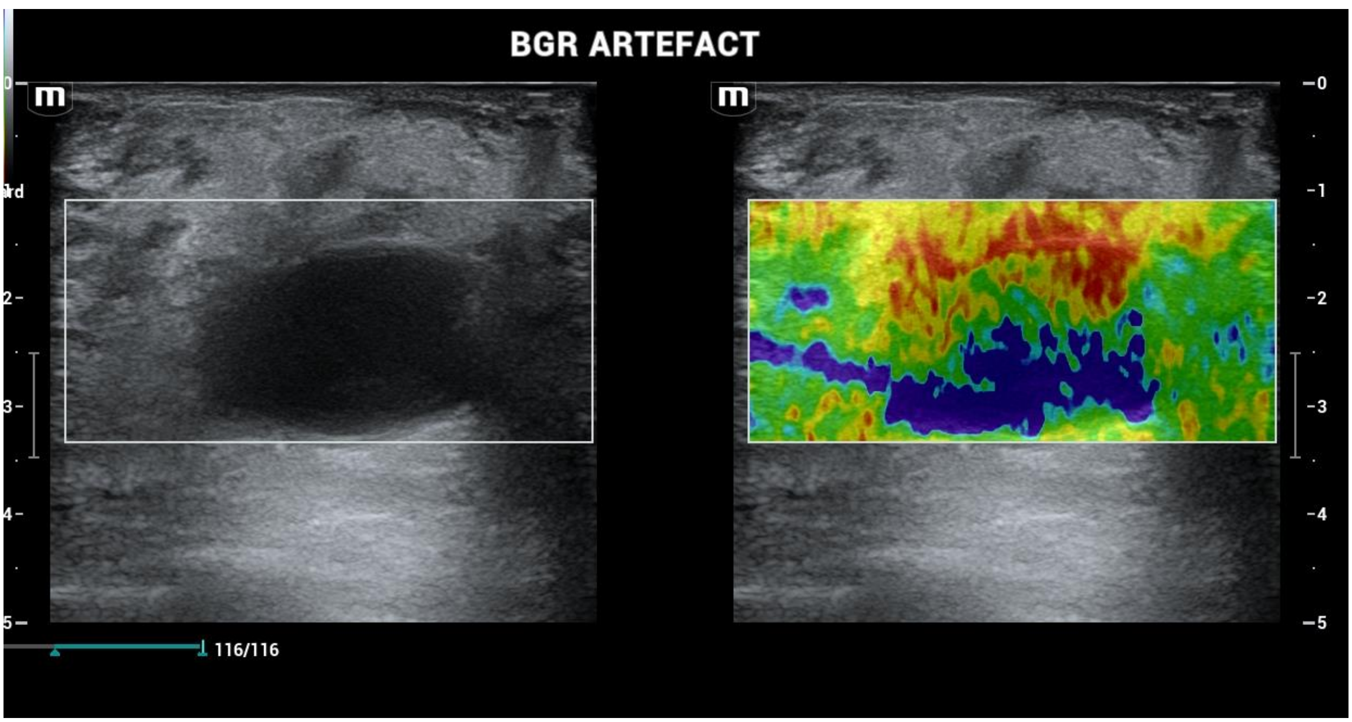


ULTRASONOGRAPHY MACHINE –
MINDRAY RESONA i9

CASE 1: Grey scale image showing a well-defined anechoic area in the mammary zone with posterior acoustic enhancement.

On elastography, the lesion shows blue-green-red (BGR) artifacts.

Above mentioned features suggestive of benign etiology –Breast cyst



CASE 2: Grey scale image showing a fairly well defined hypoechoic area with speculated margin in the mammary zone with posterior acoustic shadowing & internal vascularity on color doppler study.

On elastography, the findings are as follows:

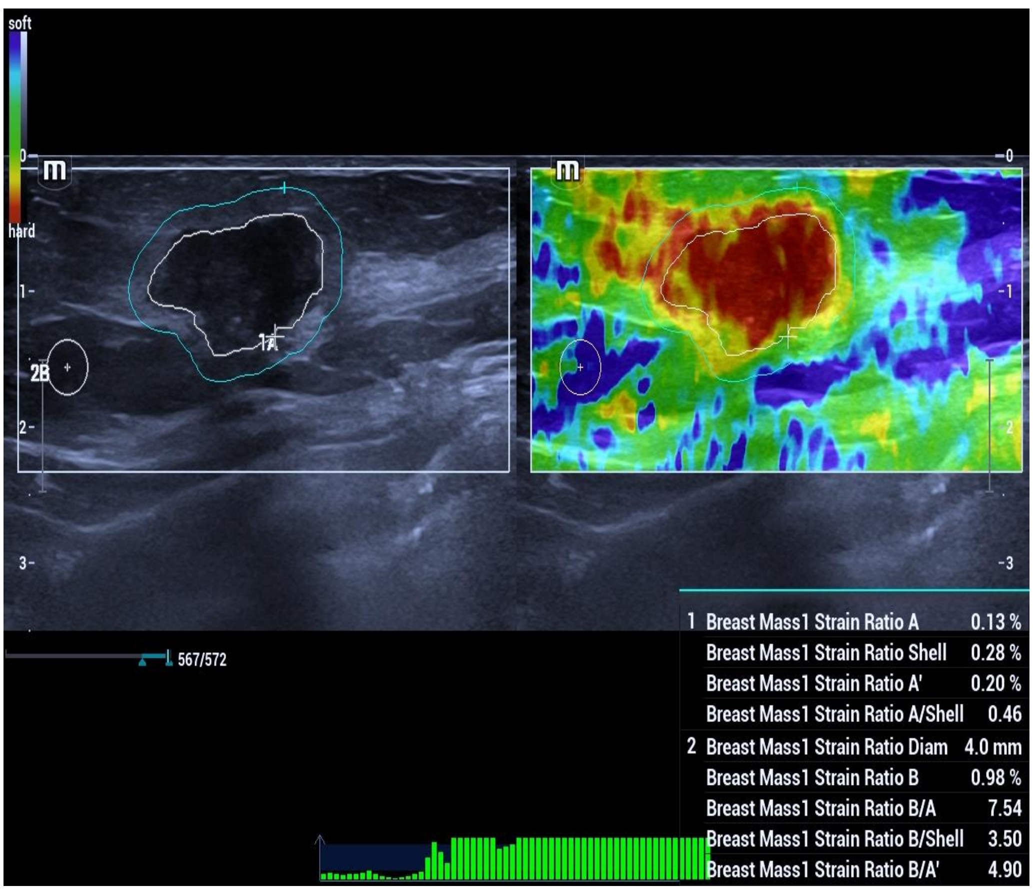
Shearwave – 107 kPa

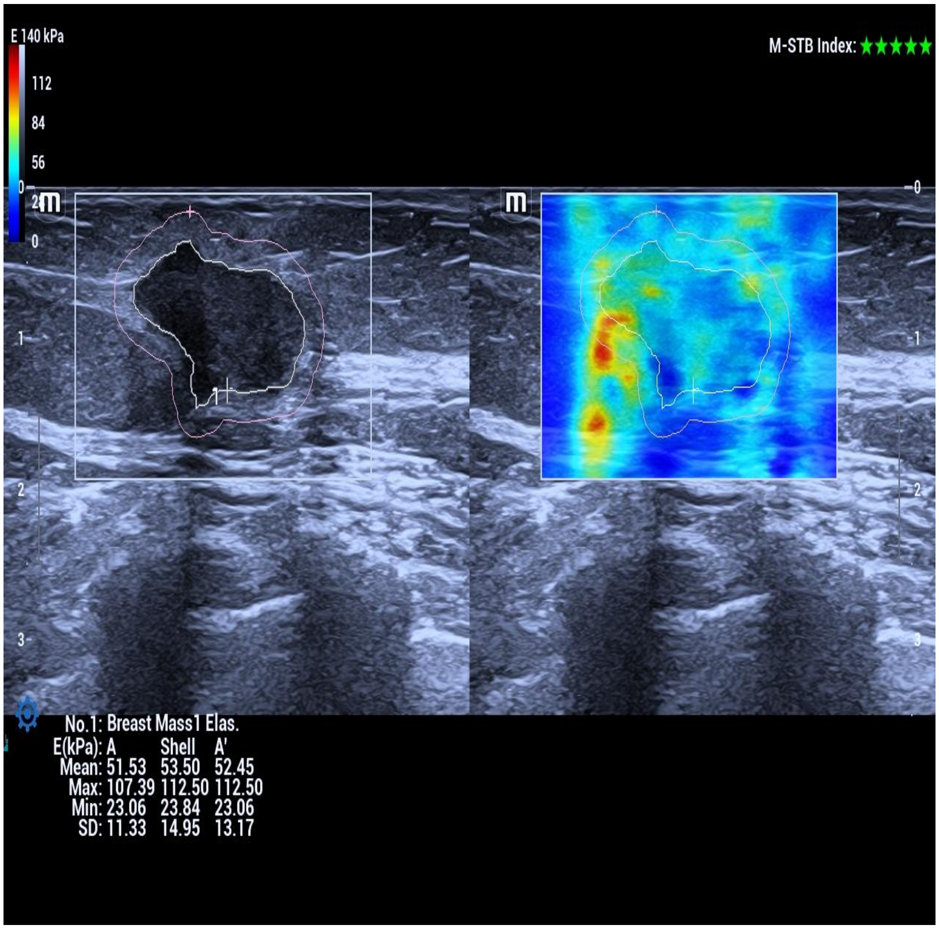
Strain ratio – 4.9

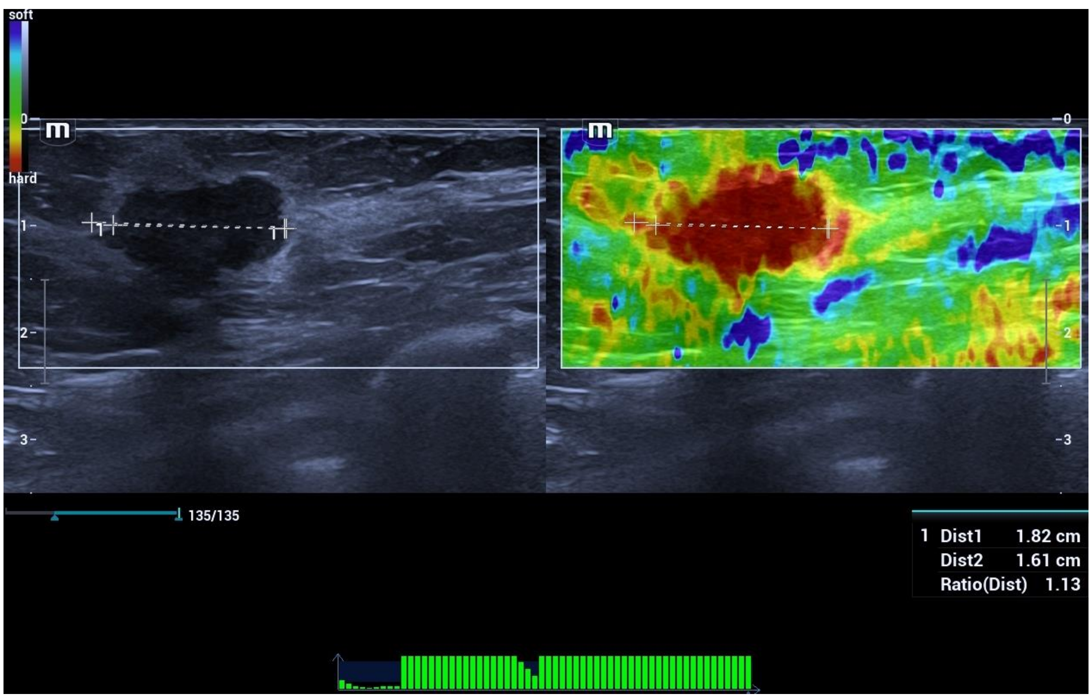
E/B ratio – 1.1

BIRADS score – 4

Above mentioned features are suggestive of a malignant lesion




E 140 kPa
112
84
56
28
0
M-STB Index:
No.1: Breast Mass1 Elas.
E(kPa): A Shell A'
Mean: 51.53 53.50 52.45
Max: 107.39 112.50 112.50
Min: 23.06 23.84 23.06
SD: 11.33 14.95 13.17


soft
hard
135/135
1 Dist1 1.82 cm
Dist2 1.61 cm
Ratio(Dist) 1.13

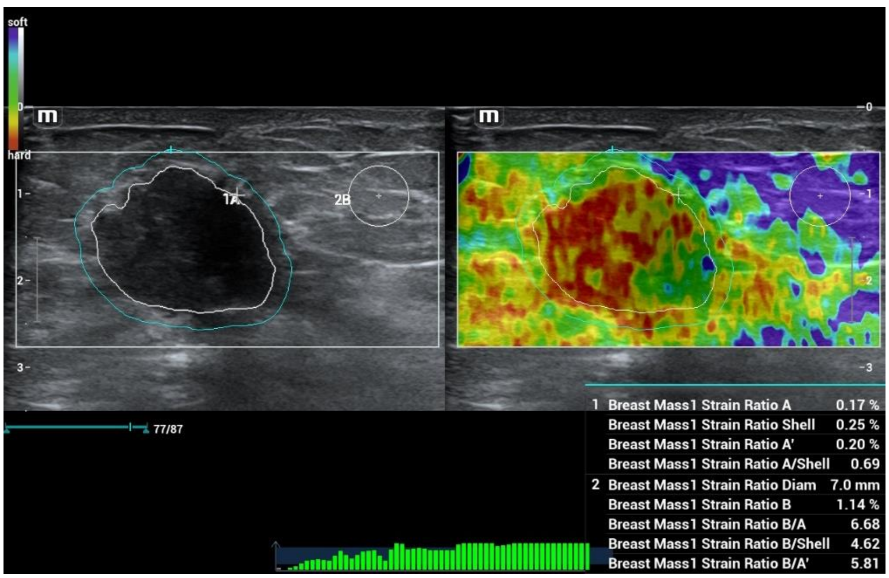
CASE 3: Grey scale image showing a fairly well defined hypoechoic area in the mammary zone with few specks of internal calcifications and vascularity on color doppler study.

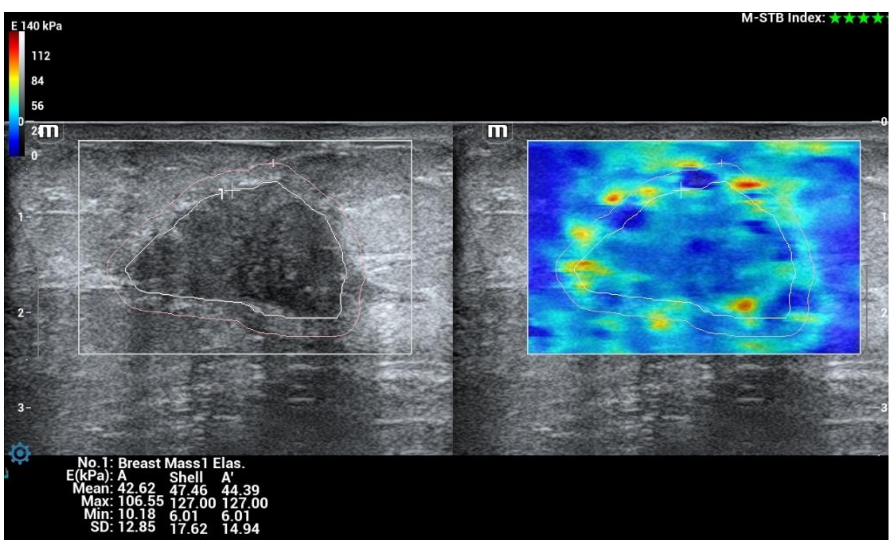
On elastography, the findings are as follows:

Shearwave – 106 kPa

Strain ratio – 5.8

BIRADS score – 4





CASE 4:

Grey scale image showing a well-defined hypoechoic area in the mammary zone with posterior acoustic shadowing and no evidence of vascularity on color doppler study.

On elastography, the findings are as follows:

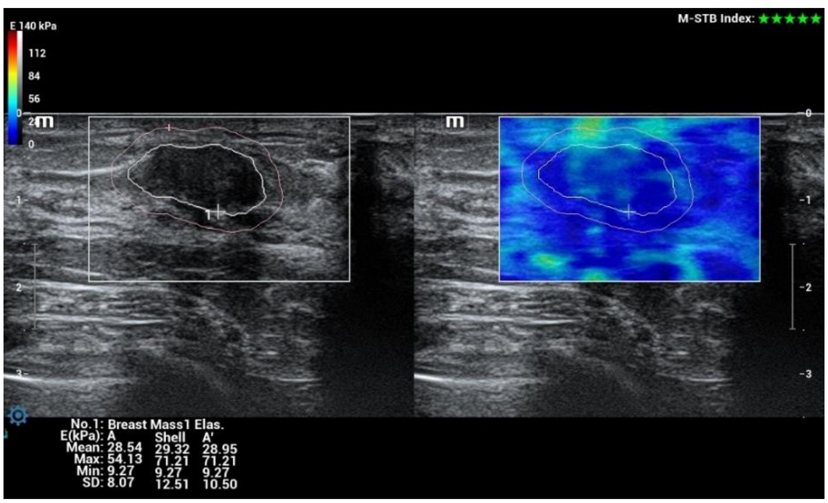
Shearwave – 54 kPa

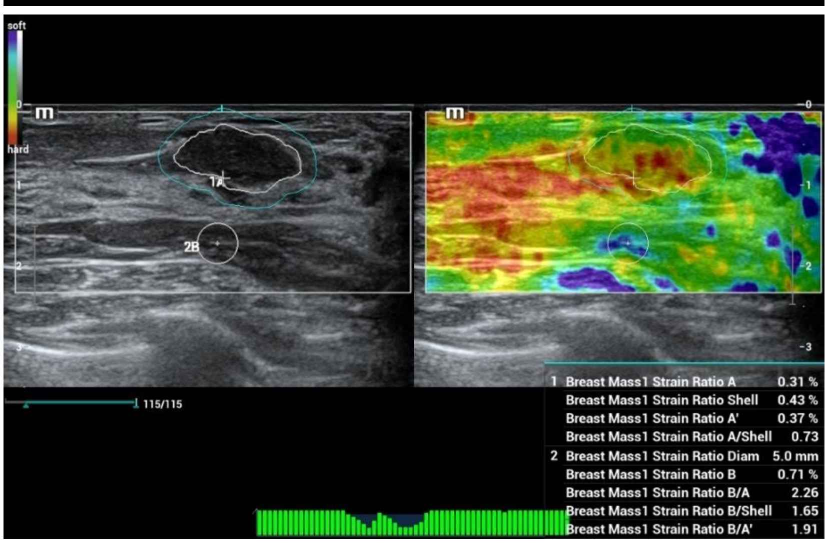
Strain ratio – 1.9

BIRADS score – 3

Above mentioned features suggestive of benign etiology

Histopathology report – Fibroadenoma





CASE 5:

Grey scale image showing an ill-defined hypoechoic area in the mammary zone with speculated margins and posterior acoustic shadowing and evidence of vascularity on color doppler study. The lesion also shows internal specks of calcifications.

On elastography, the findings are as follows:

Shearwave – 98 kPa

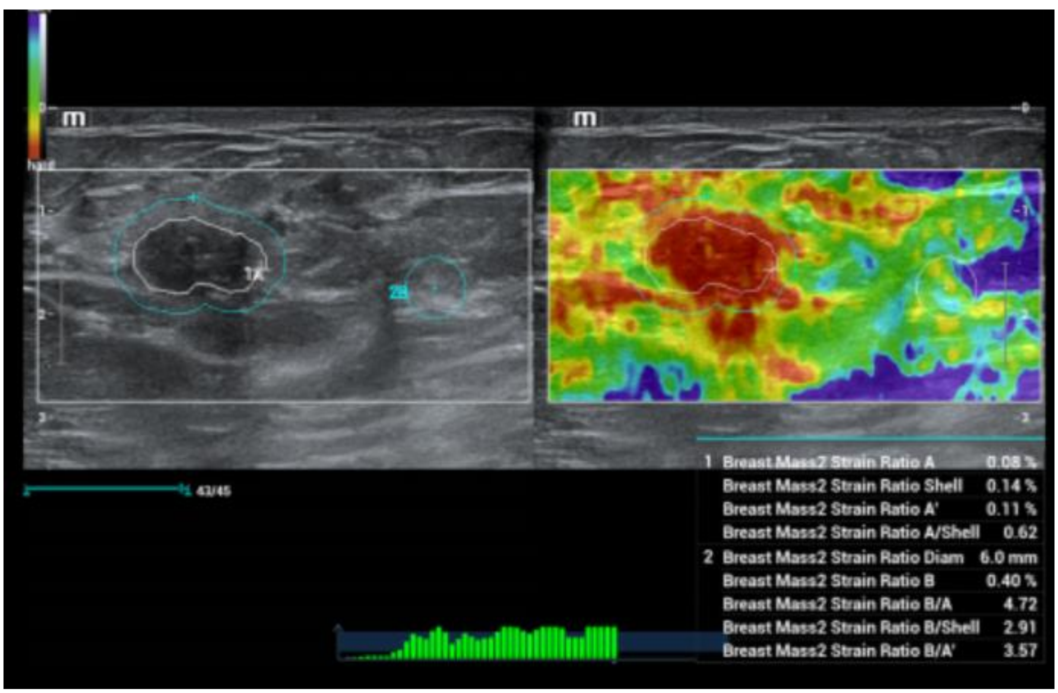
Strain ratio – 4.7

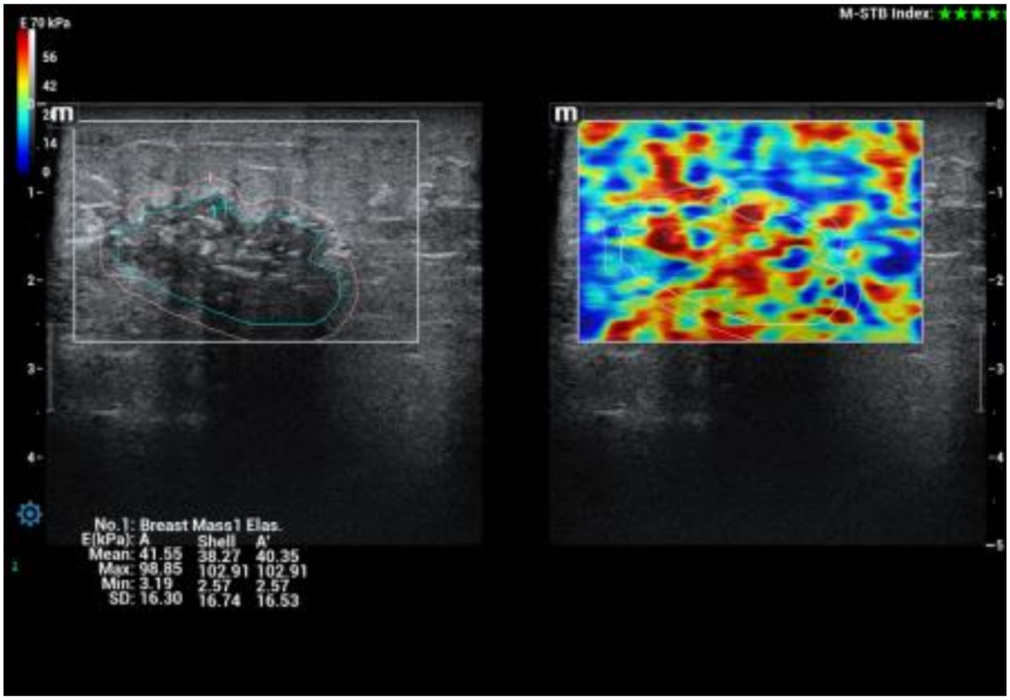
E/B ratio – 1.3

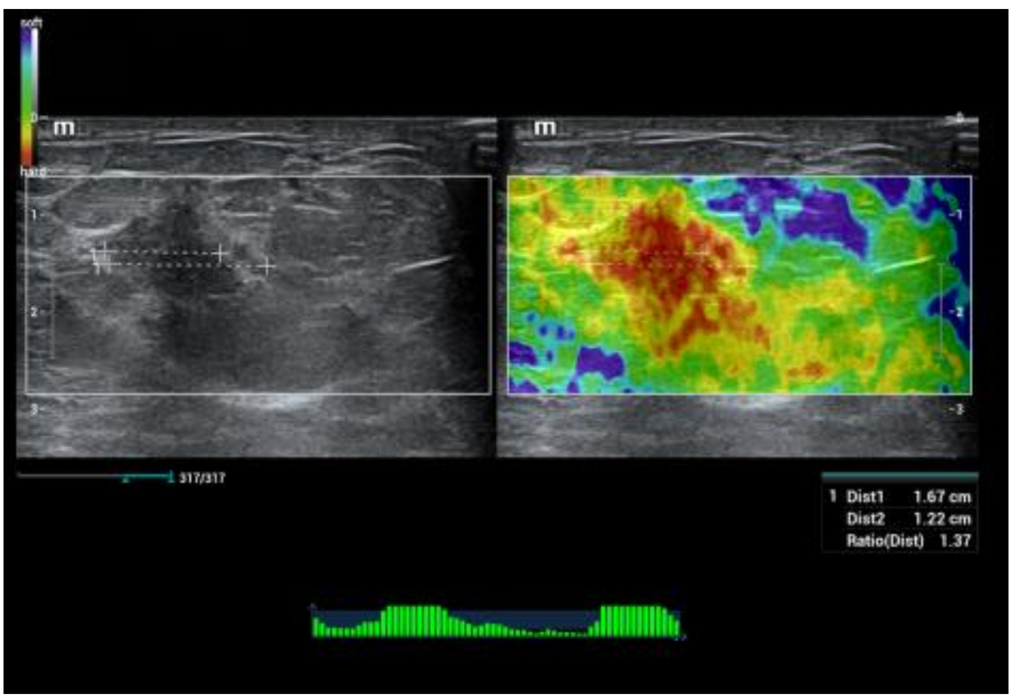
BIRADS score – 4

Above mentioned features suggestive of malignant lesion.

Histopathology report – Infiltrating ductal carcinoma




M-STB Index:
E 70 kPa
No.1: Breast Mass1 Elas.
E(kPa): A Shell A'
Mean: 41.55 38.27 40.35
Max: 98.85 102.91 102.91
Min: 3.19 2.57 2.57
SD: 16.30 16.74 16.53


soft
hard
317/317
1 Dist1 1.67 cm
Dist2 1.22 cm
Ratio(Dist) 1.37

ANNEXURE–IV–KEY TO MASTERCHART

BREAST LUMP	**YES – Y**
	NO – N
BREAST TENDERNESS	**YES – Y**
	NO – N
NIPPLE DISCHARGE	**YES – Y**
	NO – N
OVERLYING SKIN CHANGES	**YES – Y**
	NO – N
AXILLARY LYMPHADENOPATHY	**YES – Y**
	NO – N
QUADRANT POSITION	**LOWER INNER QUADRANT – LIQ**
	LOWER OUTER QUADRANT – LOQ
	UPPER INNER QUADRANT – UIQ
	UPPER OUTER QUADRANT – UOQ
SIDE	**RIGHT – R**
	LEFT – L
BGR ARTEFACTS	**YES – Y**
	NO – N
HPR (HISTOPATHOLOGY REPORT) - NA	**NOT APPLICABLE – NA**
	MALIGNANT – YM
	BENIGN – YB

MASTERCHART

S NO.	AGE (YRS)	BREAST LUMP	BREAST TENDERNESS	NIPPLE DIS-CHARGE	OVER-LYING SKIN CHANGES	AXILLARY LYMPH-ADENOPATHY	SIDE	QUADRANT/ POSITION	DURATION OF SYMPTOMS (MONTHS)	SHEARWAVE (kPa)	STRAIN RATIO	E/B RATION	BGR ARTEFACT	BIRADS	HPR (IF DONE)
1	29	Y	Y	N	N	N	R	LOQ	3	87.4	2.4	0.7	N	3	NA
2	39	Y	Y	N	N	N	R	LOQ	6	30.24	1.2	0.8	N	3	NA
3	30	Y	N	N	N	N	L	LOQ	5	54.1	1.9	0.9	N	3	NA
4	54	Y	N	N	N	N	L	LOQ	6	50.2	3.2	0.8	N	3	NA
5	43	Y	Y	Y	Y	Y	R	UOQ	2	78	3.5	1	N	3	YM
6	55	Y	Y	N	N	N	L	UOQ	3	117	3.9	1	N	4	NA
7	65	Y	N	N	N	N	R	LIQ	7	85	2.4	0.6	N	3	NA
8	60	Y	N	N	N	N	L	UOQ	5	118	1.5	1	N	3	NA
9	54	Y	N	Y	N	N	R	UOQ	2	78.5	3.2	1	N	4	NA
10	25	Y	N	N	N	N	R	UOQ	3	93.9	3.3	1	N	3	NA
11	34	Y	N	N	N	N	L	UOQ	6	56.5	1.7	0.8	N	3	NA
12	37	Y	N	N	N	N	R	UIQ	5	143.2	4	1	N	4	NA
13	55	Y	Y	Y	N	N	L	LOQ	2	70	3.1	0.8	N	4	NA
14	36	Y	N	N	N	N	R	LOQ	4	28	1.9	0.5	N	3	NA
15	36	Y	N	N	N	N	L	LOQ	4	22	0.9	0.3	N	3	NA
16	34	Y	N	N	N	N	L	LIQ	5	49.9	3.1	0.3	N	2	NA
17	54	Y	N	N	N	N	R	UOQ	6	27	1.9	0.5	Y	2	NA
18	47	Y	Y	Y	Y	Y	R	LOQ	2	114.9	5	1.5	N	5	YM
19	56	Y	N	N	N	N	L	LIQ	5	45	2	0.7	N	3	NA
20	35	Y	N	N	N	N	R	UOQ	5	74	2.4	0.6	Y	2	NA
21	54	Y	Y	N	N	Y	L	UOQ	2	98	4.5	1.1	N	4	YM
22	37	Y	N	N	N	Y	R	LIQ	4	115	2.9	0.8	N	3	YB
23	44	Y	N	N	N	N	L	UOQ	4	33	1.9	0.5	Y	2	NA
24	57	Y	N	N	N	N	R	LOQ	3	55	1.9	0.7	N	3	YB
25	56	Y	N	N	N	N	L	LIQ	3	55	2.4	0.7	N	3	YB
26	28	Y	N	N	N	N	L	LIQ	6	44.7	1.5	0.6	N	3	YB
27	58	Y	Y	Y	N	Y	R	LIQ	3	178	5	1.1	N	4	YM
28	51	Y	N	N	N	N	R	UOQ	6	82	2.4	1	N	3	NA
29	18	Y	N	N	N	N	L	UIQ	7	83.9	2.5	0.9	N	3	YB
30	18	Y	N	N	N	N	L	UIQ	7	64	2.9	0.8	N	3	YB
31	27	Y	N	N	N	N	R	LIQ	5	66.8	2.6	0.6	N	3	NA
32	38	Y	N	N	N	N	L	UIQ	3	42	2.7	0.5	N	3	NA
33	23	Y	N	N	N	N	R	LOQ	5	59	1	0.6	N	3	NA
34	21	Y	N	N	N	N	R	LIQ	4	81	1.1	0.6	N	3	YB
35	39	Y	N	N	N	N	L	LIQ	5	104	1.8	0.9	N	3	YB
36	28	Y	N	N	N	N	R	UIQ	7	38	1.2	0.6	N	3	NA
37	36	Y	N	N	N	N	L	LIQ	5	45	1.2	0.7	N	3	NA
38	54	Y	N	N	N	N	L	LIQ	5	98.2	2.9	0.8	N	3	NA
39	23	Y	N	N	N	N	R	UIQ	4	104	2.2	0.9	N	3	NA
40	44	Y	N	N	N	N	L	LIQ	6	74	1.6	0.6	N	3	NA
41	32	Y	N	N	N	N	R	LOQ	7	74	2	1	N	3	NA
42	30	Y	N	N	N	N	L	UOQ	5	84	1.2	0.9	N	3	YB
43	38	Y	N	N	N	N	L	LOQ	8	68	1.4	0.5	N	2	NA
44	52	Y	N	N	N	N	R	LOQ	5	71	1.2	0.5	N	2	NA
45	33	Y	N	N	N	N	L	LIQ	6	87	2.4	0.8	N	3	NA
46	35	Y	N	N	N	N	L	UIQ	7	116	2.4	1	N	3	NA
47	44	Y	N	N	N	N	L	LIQ	4	98	3.9	0.9	N	3	YB
48	45	Y	Y	N	N	Y	L	UOQ	4	109	4.5	1	N	4	YM
49	33	Y	N	N	N	N	R	LIQ	6	30	1.3	0.7	N	3	NA
50	45	Y	Y	Y	N	Y	L	UOQ	3	98	4.7	1.3	N	4	YM
51	25	Y	N	N	N	N	L	UOQ	5	82	3.2	0.7	N	3	NA
52	34	Y	Y	N	N	N	R	LIQ	6	45	2.4	0.6	Y	2	NA
53	29	Y	N	N	N	N	L	LIQ	6	104	3	0.9	N	3	YB
54	67	Y	Y	Y	Y	Y	R	UOQ	3	100	5	1.2	N	5	YM
55	56	Y	Y	N	N	Y	L	LIQ	4	107	6	1.1	N	4	NA
56	63	Y	N	N	N	N	R	UIQ	5	90	3.2	1	N	3	NA
57	34	Y	N	N	N	N	L	LIQ	5	56	2.9	0.9	N	3	NA
58	30	Y	N	N	N	N	R	UOQ	3	58	2	0.8	N	3	YB
59	55	Y	Y	N	N	N	R	LOQ	4	130	3.5	1.3	N	4	YM
60	45	Y	Y	Y	N	Y	L	LIQ	3	100	3.5	1.1	N	4	YM
61	42	Y	N	N	N	N	L	UIQ	6	42	1	0.9	N	3	NA
62	33	Y	N	N	N	N	L	LIQ	4	35	2.8	0.6	N	3	NA
63	38	Y	N	N	N	N	L	LOQ	7	54	2.2	0.9	N	3	YB
64	44	Y	N	N	N	N	R	LOQ	6	76	2.7	1	N	3	NA
65	60	Y	Y	N	N	Y	R	UIQ	8	121	3.9	1.2	N	4	NA
66	34	N	Y	N	N	N	L	LIQ	5	20	1.1	0.3	Y	2	NA
67	36	Y	N	N	N	N	L	LIQ	4	34	2.3	0.9	N	3	NA
68	35	N	Y	N	N	N	R	LIQ	7	23	2.2	0.5	Y	2	NA
69	34	Y	N	N	N	N	L	LOQ	5	65.7	2.7	0.9	N	3	NA
70	45	Y	N	N	N	N	R	UIQ	4	75.9	3.1	1	N	3	NA
71	54	Y	Y	N	N	N	L	UOQ	5	98	3.9	1.1	N	4	NA
72	34	Y	N	N	N	N	L	UIQ	7	56.4	2.9	0.8	N	3	NA
73	37	N	Y	N	N	N	R	UIQ	3	38.9	2.4	0.7	Y	3	NA
74	23	Y	N	N	N	N	L	LOQ	4	45	2.2	0.8	N	3	NA