

**“ROLE OF ELASTOGRAPHY IN EVALUATING
BREAST LESIONS”**

By

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Under the guidance of

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ABSTRACT

BACKGROUND AND OBJECTIVES:

Breast cancer is one of the most common cancers affecting women of all ages. Timely and correct diagnosis of breast lesions is of utmost significance. Equally vital is to avoid unnecessary interventions. For a better aid in diagnosing breast lesions which are confusing on ultrasonography, a new technique called Elastography was introduced. The two methods of Elastography, Strain and Shear wave velocity measurement have recently come into practise and have been included in BIRADs classification as well. Since these novel techniques are increasingly being used in recent times, our study aimed to assess its practicability and accuracy.

AIMS & OBJECTIVES OF THE STUDY:

1. To assess the role of Elastography as an added imaging modality to USG B scan in differentiating benign and malignant lesions of breast.
2. To assess the advantages and disadvantages of strain and shear wave elastography.

SOURCE OF DATA:

The patients attending / referred to the Radiology OPD or admitted to B.L.D.E.U's Shri B. M. Patil Medical College, Hospital and Research Centre, Vijayapur; who fulfill the inclusion criteria between November 2015 to June 2017.

METHOD OF COLLECTION OF DATA:

A brief history, physical examination, ultrasonographic and elastographic evaluation will be performed on all patients who fulfill the inclusion criteria who are attending / referred to the Radiology department or admitted in BLDEU'S Shri B M Patil

Medical college hospital and research center, Vijayapur between November 2015 to June 2017.

RESULTS:

64% of our cases were benign and 36% malignant. Common benign lesions were fibroadenomas and cysts whereas most malignant lesions were invasive/infiltrating ductal carcinomas. Sensitivity of ES and specificity of SR was better in our study. Both strain ratio and shear wave elastography showed a statistically significant difference between benign and malignant lesions. The sensitivity and specificity of shear-wave and strain elastography were different according to lesion histologic profile, tumor grade, and breast thickness.

INTERPRETATION:

USG is a good modality for breast lesion identification but has a limited predicting malignancy. The diagnostic performance of shear-wave and strain elastography was similar. Breast cancer screening plays a very important role in early cancer detection and helps in good prognosis.

Elastography is not a method that can replace conventional breast ultrasound for detecting breast cancer; however it may be an adjunct to conventional ultrasound by increasing its diagnostic capacity.

INTRODUCTION

Breast diseases, both benign and malignant, affect many women worldwide. Women presenting to the doctor with a positive family history and self-examination results are anxious to rule out malignancy. Characterization of breast lesions as benign and malignant is a very important task assigned to the radiologist and the pathologist. Many a times, women undergo unnecessary painful biopsies of which a large proportion turns out to be benign.

In India, during the year 2012, 144,937 women were reported to have newly detected breast cancer, of whom, 70,218 women died of breast cancer as released by Breast Cancer India. So roughly, in India, for every 2 women newly detected with breast cancer, one woman is dying of it.

What is worrisome about the trend of rising breast cancer in India is that more number of younger women are being affected and more aggressive cancers are occurring in young along with rising numbers of breast cancers. Late presentation and lack of awareness and screening are the major shortcomings. Screening is the single most important factor responsible for better survival of patients in the west.

Breast Imaging Reporting and Data System (BI-RADS) helps differentiate benign from malignant lesions and includes Ultrasonographic criteria of shape, margin, orientation, echo pattern, posterior acoustic features, lesion boundary, and vascularization. This helps us identify lesions in breast but characterization is sometimes difficult on Sonomammography (B mode) scans alone. Conventional ultrasound and

Doppler allow characterization of focal lesions, histological confirmation remains indispensable in inconclusive cases.

Mammography and ultrasonography (US) are highly sensitive in breast cancer detection. But both techniques have some restrictions. Mammography may often yield false-negative results in dense breasts.

Doppler imaging that depicts differential motion of tissue types. This technique provides good correlation for tissues that have a large difference.

Ultrasonographic Elastography (Sonoelastography) is a promising new modality. It is a non-invasive imaging technique that can be used to depict relative tissue stiffness or displacement (strain) in response to an imparted force. Elastography imaging has the potential to reduce the need for biopsy in patients with low risk lesions in the breast.

Its most important role is in differentiating between benign and malignant breast lesions. The main image acquisition techniques are compression Sonoelastography and vibration Sonoelastography. Tumours are usually stiffer. This phenomenon is responsible for tissue contrast on Elastograms.

The aim of this study is to evaluate whether the new method of Elastography improves the differentiation and characterization of benign and malignant breast lesions, especially in patients with inconclusive findings or potentially malignant lesions of BI-RADS categories III or IV, compared with B-mode ultrasound and the gold standard of histology.

This may grant a large group of patients diagnosed with breast masses to be comforted with a USG diagnosis of higher accuracy and confidence level. Hence this will reduce the number of biopsy or short-term follow-up.

AIMS & OBJECTIVE OF STUDY:

1. To assess the role of Elastography as an added imaging modality to USG B scan in differentiating benign and malignant lesions of breast.
2. To assess the advantages and disadvantages of strain and shear wave elastography.

MATERIALS AND METHODS

Machine which is used in the study is Siemens ACUSON s3000 USG machine equipped with Elastography software (compression and vibration) with linear high frequency transducer. Machine has an excellent B-mode, with a good cine-loop facility so that one can scroll back frame by frame and capture the frame of interest. The spatial and temporal resolution for these machines is good. Qualitative imaging or quantitative shear wave tissue measurements across multiple transducers and study types can be done.

The system also has a Color Doppler, Pulsed Doppler, and Continuous wave Doppler, M-mode & B-mode imaging capabilities.

SOURCE OF DATA:

The patients attending/referred to the Radiology OPD or admitted to _____ ; who fulfill the inclusion criteria between November 2015 to June 2017.

SAMPLE SIZE:

With sensitivity of detecting breast lesions 97 %, at 95 % confidence level and at ± 5 margin of error, the sample size is 45.

$$n = \frac{z^2 p(100-p)}{D^2}$$

Where z – z value at level

p - sensitivity for breast lesions

d - margin of error

Hence minimum 45 cases were included in the study.

STATISTICAL ANALYSIS:

Data was presented diagrammatically, Mean \pm SD and sensitivity and specificity by Fischer's, Chi square tests. Association with p values and AUROC were calculated.

METHOD OF COLLECTION OF DATA

STUDY DESIGN

A prospective cross sectional study design was used.

METHOD OF COLLECTION OF DATA

A brief history, physical examination, ultrasonographic and elastographic evaluation was performed on all patients who fulfill the inclusion criteria who are attending / referred to the Radiology department or admitted _____
_____ between November 2015 to June
2017.

INCLUSION CRITERIA:

1. All patients presenting with breast lump, breast pain or any other breast related complaints and have an ultrasonographically detectable mass.

EXCLUSION CRITERIA:

1. Patients who have already been operated.
2. Patients who do not consent to the examination.
3. Patients in who Fine needle aspiration cytology (FNAC) / Histo-pathology Report (HPR) follow-up is not possible.

REVIEW OF LITERATURE

History

A practitioner's hands feeling for the stiffness of a patient's tissues is referred to as palpation. Beginning around 1500 BC, with the Egyptian Ebers Papyrus and Edwin Smith Papyrus ^[1], palpation took off as a major diagnostic tool. Hippocrates of Greece also gave instructions on how to use palpation as a beneficial diagnostic tool, including in tissues like breasts, wounds, bowels, ulcers, uterus, skin and tumours. In modern medicine, palpation has become an irreplaceable method of diagnosis.

Several important limitations of manual palpation are that: it is limited to tissues that are accessible to the examiner's hand, it tends to become distorted by the intervening tissue in between, and it is qualitative but not quantitative.

Elastography, the measurement of tissue stiffness, seeks to address these challenges. Tactile imaging, also called "Mechanical imaging", "Stress imaging" or "Computerized palpation", is a medical imaging modality that translates the sense of touch into a digital image.

Ultrasonic Elasticity Imaging

One of the preliminary researches that was pertaining to elasticity imaging was carried on in late 1970s and in 1980s by Kit Hill of Royal Marsden Hospital, UK.

In 1976, Rob Dickinson tried to develop an ultrasonographic technique of analyzing tissue motion.

Maria Tristam and Jeff Bamber^[2] proved that the time rate of decorrelation between successive A-mode scans may help to discriminate between hard and soft tissues when subjected to either secondary or externally induced movement.

Mechanical Imaging

Mechanical Imaging is also called ‘tactile imaging’ and closely resembles manual palpation. The elasticity imaging techniques which are based on estimating static or dynamic strain in the tissue are called “strain imaging” techniques. Mechanical imaging uses estimates of the surface stress pattern and reconstructs tissue’s mechanical structure and hence, is also called as “stress imaging”.

Mechanical imaging records surface stress data and provides information regarding elasticity of tissue. This enables 2D and 3D reconstruction of elasticity modulus of the soft tissues. This information also gives knowledge about characteristics of breast masses such as size, shape, nodularity, consistency/hardness, and mobility. Mechanical imaging provides up to 30–40% local deformations of tissue similar to nonlinear quasi-static elastography and manual palpation.

There are different mechanical imaging systems that are used for breast imaging. It is shown that mechanical imaging helps in cancer recognition. ^[3]

Sonoelastography

Sonoelastography involves mechanical generation of harmonic shear waves and measurement of the wave propagation with Doppler or ultrasound imaging techniques.

Muthupillai^[4] used external actuators to give out a harmonic signal and induce shear waves in tissues so that shear wave speed can be measured to calculate Young's modulus.

Krouskop^[5] used a motorized actuator placed on the medial side of the thigh which induced shear waves into the muscle tissue. Another laterally placed ultrasound transducer measured the induced motion with the help of Doppler mode. The elastic modulus of the muscle was measured in both contracted and relaxed positions.

Lerner^[6] used colour Doppler to measure the motion resulting from an acoustic horn that was used to induce waves in phantoms and excised tissue.

Lately, customized USG machines include both actuators in one transducer. Then it was used to make images of shear wave velocities distribution in phantoms, human prostate and skeletal muscle.

Sonoelastography in Breast

In 1983 Fujimoto was one of the first researchers to illustrate use of ultrasonic dynamic tests to assess the compressibility and mobility of breast tumours which was done by applying pressure with the USG transducer.

He concluded that breast masses which are freely movable and deformable turn out to be fibroadenomas. However, the breast masses which are compressible and fixed are usually cystic in nature. Finally, the lesions which are both incompressible and fixed are almost undoubtedly malignant lesions.

In 1997, Garra^[7] showed elastography is practicable and can be performed by pressing against the chest wall when the patient is lying down. He also concluded that malignant lesions largely are harder than benign ones and the surrounding breast tissue.

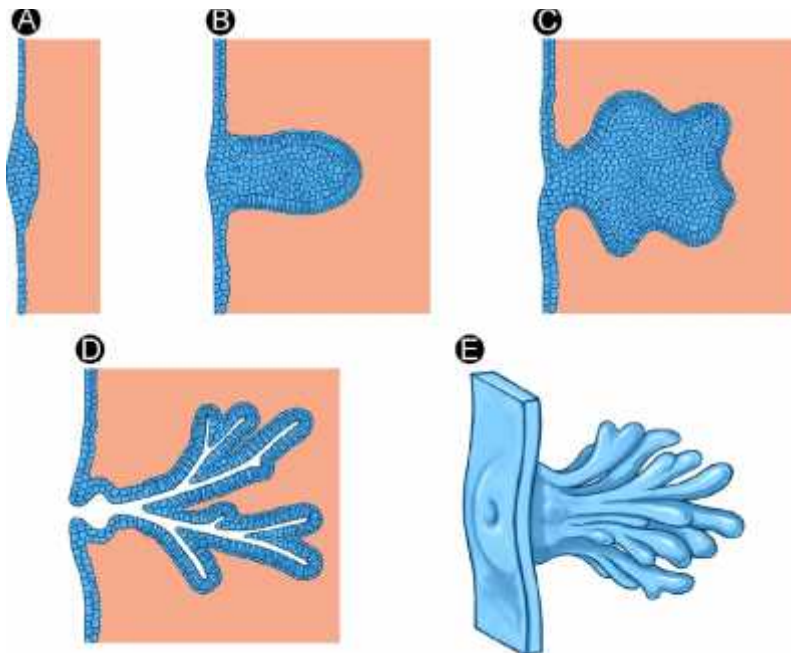
Anatomy and Embryology

The animal kingdom has a vast number of species. Mammals have come to evolve into highly functional beings. Presence of mammary glands makes mammals unique. ^[8]

Breast Embryology

Genetic and hormonal influences by the ectoderm control the development of the human breast.

Picture 1 depicting embryogenesis of breast:^[9]



Development of the mammary glands

At around the fourth week of embryological development, two ectodermal thickening called the mammary ridges start to grow along the midclavicular-pubic lines i.e., the milk lines. In the fifth intrauterine week, the mammary ridges form primary buds which grow in the underlying dermis. Around the twelfth week of development, several secondary buds develop from the primary buds which subsequently branch into ducts (around 15-24 in number) that converge towards the mammary dimple.

The nipple and the areola develop from the mammary dimple. The areola contains the Montgomery glands, which are considered to be rudimentary milk ducts.

One or more supernumerary nipples (polythelia) or supernumerary breasts (polymastia) may form along the course of the mammary ridges. At birth it is nothing but a rudimentary ductal system and before puberty it simply grows along with the overall body development.

During puberty the female breast gland undergoes an expansive proliferation due to the hormonal and growth factors influence. The pubertal breast consists of an extensive mammary tree that includes primary ducts and secondary branches that occupy the mammary fat pad. The secondary lateral ductal branches end in terminal ducts that give rise to terminal ductal-lobular units comprising numerous blind-ended ductules which are known as the “acini”. These are embedded in fibroblast-rich intra-lobular stroma. On the other hand, at the onset of puberty in males, testosterone acts on the mesenchymal cells to inhibit further growth of the mammary gland upon limited development.

The mammary gland undergoes many changes to prepare for lactation during pregnancy. These changes require both new glandular cells and their maturation which are primarily under the control of progesterone and prolactin.

Firstly, the gland shows an increase in ductal branching; next, there is development of the alveoli, which are capable of secreting milk during lactation. Thereafter, increased vascularisation occurs and by second trimester each alveolus gets surrounded by capillaries.

By late pregnancy and during lactation, the breast tissue is mainly composed of the alveoli which actively secrete milk. Alveoli are inactive and appear as acini until lactation begins.

Progesterone levels fall post delivery which leads to cortisol binding and lactogenesis. Suckling stimulates sensory receptors in the nipple which further on activates nerve impulses. These impulses are transmitted to the hypothalamus. Additionally, it also initiates the synthesis and release of prolactin. Lactation is not possible without prolactin. Oxytocin causes the myoepithelial cells to contract, resulting in release of milk into the lactiferous ducts and sinuses so that the baby can suckle it out.

After weaning, milk accumulates in the mammary ductal system which marks the beginning of involution process that leads to apoptosis of milk-producing epithelial cells and modifies the epithelial tree to return to its simple ductal architecture. At menopause, breast experiences an intense change which involves fatty substitution of glandular epithelium and interlobular connective tissues. In the aged female breast, only a few acini and ducts remain embedded in thin strands of collagen. ^[10]

Normal anatomy of the female breast

Breast is a symmetrical organ located on the front of the chest on both sides of the midline. It occupies an area that stretches from the third to the seventh rib and from edge of the sternum to the armpit. The volume, shape and degree of development are very variable in relation to various factors such as age, gland development, and amount of fat and relative influence of endocrine stimulation.

Before puberty, the mammary region is flat, but upon full development it assumes in females a hemispherical profile. Normal breast glands may be conical-shaped, pear-shaped or discoid.

At the centre of the breast are areola and nipple. Areola is a flat hyperpigmented region of skin with a round or oval shape and of variable diameter, usually, between 3.5 and 6 cm. The nipple stays at centre of the areola and has a variable size and shape (conical, cylindrical). At its apex there are several small depressions that represent the outlets of the ducts. The areolar surface is irregular due to the presence of the 8-12 tubercles of Morgagni, representing sebaceous glands.

The mammary gland is made of three components: glandular, adipose and fibrous tissues. Functionally, it can be considered a modified apocrine sweat gland, in relation to breast-feeding.

The glandular structure is composed by 15-20 lobes arranged in clusters with an irregular radial pattern around and behind the nipple.

Each lobe is an independent glandular entity made of numerous lobules, constituted by alveoli, which are the secreting units. The alveolar ducts converge into the lobular ducts which in turn converge into the milk ducts. The milk ducts, then, converge to the nipple with an ampullary dilatation, the lactiferous sinus. The stroma is composed of dense fibrous and adipose tissues that surround the entire gland and penetrate between the lobes. It may be divided in three portions: a subcutaneous part lies between the skin and the gland, an intraparenchymal portion, located between lobes and lobules, and a retromammary portion, located behind the gland.

The breast parenchyma is contained by a two-layer fold of the subcutaneous superficial fascia, may be divided in two parts: the superficial layer that covers the gland and contains fibrous septa, known as Cooper's ligaments. These ligaments intersperse between glandular tissue and form support structure of the parenchyma and divide it into lobes. The deep layer covers the posterior portion of the gland and separates it from the underlying superficial fascia of the pectoralis major muscle.

Normal ultrasound anatomy of the breast

The breast has alternating hyper and hypo-echoic layers as follows:

1. Skin – hyperechoic
2. Subcutaneous fat – hypoechoic
3. Fibroglandular parenchyma – hyperechoic
4. Retromammary fat – hypoechoic
5. Muscle, mainly the pectoralis major – hyperechoic ^[11]

Skin: The skin can be seen as two to three hyperechoic lines separated by another hypoechoic line that represents the dermis and has a variable thickness between 0.5 and 2 mm, not exceeding 3 mm.

The areola and nipple generally determine an attenuation of the acoustic signal and are hypoechoic. The nipple produces a strong attenuation of the acoustic signal that partially mask the underlying structures. Palpable cutaneous and subcutaneous lesions like sebaceous cysts are common.

Cooper's ligaments: The subcutaneous fat tissue is interspersed by Cooper's ligaments which are thin hyperechoic bands of supportive fibrous septae that extend from the skin to the glandular region. They look like segmental echogenic arcs bordering fatty lobules in superficial mammary layer and can produce focal linear shadowing in the orthogonal plane scans.

Fat lobules: The subcutaneous region or pre-mammary region is situated between skin and mammary fascia and it contains mostly adipose tissue, which is less echogenic than the glandular tissue. The thickness of this fatty region can vary up to 2-3 cm. Oval shaped mildly echogenic fat lobules sometimes comprising linear and punctate more echogenic foci (fibrous tissue) are seen continuously criss-crossing without a sudden border giving heterogeneous appearing mammary layer. Any breast lesion / mass echogenicity is compared with the echogenicity of this layer.

Fibrous tissue: It is the echogenic part of the mammary layer, mainly comprised of fibro-glandular tissue and is dependent on the hormonal status and age of the female.

Ducts: Under the nipple, the lactiferous ducts branch and course radially into the breast parenchyma. They appear to be paralleling the chest wall when patient is supine. They are anechoic or moderately echogenic tubular structures, depending on the content. They have a diameter of 2-3 mm, which gradually decreases going towards the periphery. Lumen of the duct contains fluid and the wall may appear like a thin echogenic line in a collapsed lumen. Radial and anti-radial scans help visualize the entire breast tissue.

Some patients can depict a globular shaped, blunt-ending projection of the duct running in an oblique perpendicular orientation. They are the terminal ducto-lobular units and have a widely varied appearance. As long as the ducts look like they are tapering and no focal dilatation is noted, it can safely be considered as normal.

Glandular region: It is located between the pre-mammary region and the retromammary region, is shaped like a triangle with its apex towards the areolar region and its base towards pectoral muscle and is enfolded by the mammary fascia that appears as a thin echogenic line. Echogenicity of the glandular region varies in relation to the percentages of glandular and adipose tissues. Fatty tissue in breast is hypoechoic, while the glandular tissue and stroma are echogenic. The most superficial part of this region shows some hyperechoic “pyramids” from which the Cooper ligaments, or ridges of Duret, branch.

Sonographically, breasts having larger quantity of fibroglandular component are more echogenic, while predominantly adipose breasts are diffusely hypoechoic. The breast gland shows constant changes in echogenicity due to factors such as age, menstrual cycle, pregnancy and lactation.

Retromammary region: The region of Chassaignac (retromammary area) is located behind the gland; it is made up of hypoechoic retromammary fat.

Chest wall: Pectoralis muscle and underlying serratus anterior muscle overlie ribs and intercostal muscles. These muscles are slightly more echogenic than the retromammary fat.

More deeply, the ribs show attenuation of the acoustic signal and appear as hypoechoic structures, and the parietal pleura can be displayed as a hyperechoic line.

Lymph nodes & Lymphatics: Lymph nodes are spread in entire breast tissue and can be seen as hypoechoic bean-shaped masses with echogenic centres. The shape, size, and appearance of normal lymph nodes are variable. Reactive and infiltrated nodes become conspicuous when they become larger, rounder, and more uniformly hypoechoic. ^[12]

Breast lymphatics are seen in the superficial areas of the breast, mainly between the skin and subcutaneous tissues and also along ducts but are only visualised when dilated. They are seen as hypo to anechoic, thin web like lines due to inflammation or tumoral infiltration as in inflammatory carcinoma.

Vascular network: It is made of arterial vessels proceeding from the deep portion of the gland to the Cooper's ligaments. Venous network accompanies the arteries which can be easily visualised by Doppler.

Changes in breast anatomy with age

The fibrous and glandular tissues show variable echogenicity, whereas fat is hypoechoic. Hence the USG appearance changes with age and also individually. Moreover, breast tissue is inhomogeneous.

Glandular tissue is seen in abundance in younger population. At puberty, estrogen stimulation leads to development of ducts, glandular and connective tissue. With progressing age, the glandular component gets replaced with fatty tissue.

Appropriate visualization of Breast on USG

Radial scans around the nipple is the most appropriate method of scanning breast as ducts are easily visualized when they branch into glandular tissue. The ducts are the widest (3 mm) in the subareolar region. The identification of pectoralis muscle ensures that we are examining the gland in its whole depth. Rib is seen as an oval, hypoechoic structure. This should not be mistaken for a nodule. The cartilaginous part of the ribs resembles a target and produces minimal shadowing too. Because it is located underneath the muscle, ribs can be easily distinguished from the nodules.^[13]

The intercostal, internal and external mammary arteries and subscapular arteries contribute towards most of the blood supply to breast. Even slow flow can be easily picked up with the help of Power Doppler in cases of minute arteries which is more intense at the time of ovulation. Veins are more compressible and are nearer to the skin surface almost paralleling it. The arteries are deeper and have an echogenic wall on B mode imaging.

The visualization of the axillary vessels requires adequate scanning of the axilla. The internal mammary artery and vein can be visualized through longitudinal scans of the 1st and 2nd intercostal spaces, parallel to the sternum.

Nipple-Areolar Complex

The nipple-areolar complex is comprised mainly of Montgomery glands. These are a subtype of sebaceous glands (mix of sweat glands and mammary glands) and can secrete milk. These glands open on the areola. These tiny openings are small (1–2-mm-diameter), raised papules and are called Morgagni tubercles. This complex also contains numerous sensory nerve endings, smooth muscle, and an abundant lymphatic system (Sappey's plexus).

Because of the continuation of the skin of nipple with epithelium of ducts, ductal cancer can spread to nipple.

Variant Anatomy

Sometimes, the normal anatomical variants can mimic a mass.

When there is incomplete involution of the milk line, an accessory nipple or nipples results. This is referred to as Polythelia and it is the most common abnormal variant. Accessory nipples and breast tissue develop along the embryologic milk line, most commonly in the axilla or inframammary fold, but can occur anywhere from the axilla to the groin. Accessory nipples may be mistaken for moles as they are pigmented.

Polymastia (formation of an accessory true mammary gland) also may occur when involution of the milk line is incomplete, but it is rare.

Nipple Retraction or Inversion

Retraction is a term used when only a slit-like area is pulled inward, whereas *inversion* is used in cases where entire nipple is pulled inward and it comes to lie below the surface of the breast. These conditions can be congenital or acquired and either unilateral or bilateral. Retraction is likely to be benign when it is bilateral and slowly progressive or long-standing nipple. An acquired unilateral nipple inversion may indicate an underlying malignancy or inflammatory condition such as duct ectasia (common), periductal mastitis, and tuberculosis.

Central, symmetric, slitlike retraction usually points towards benignity, whereas inversion of whole nipple accompanied by distortion of areola results from malignancy.

[14]

Gross anatomy of the lactating breast

Initial descriptions of standard human mammary gland were based on Cooper's dissections conducted on women who died during lactation. [8]

Ramsay and colleagues used high-resolution ultrasound in a study and concluded that there were fewer main ducts (mean 9; range 4–18) compared with the previously assumed number (15–20). Ductal branches get fused into one main collecting duct near the nipple. The milk ducts are distended only at the time of milk ejection, facilitating the transport of milk to the infant.

Proportion of glandular and fat tissues was highly variable from 50 to 80% of the breast composed of glandular tissue, the rest being composed of fat.

Ultrasonographically, lactating breast is similar to the non-lactating breast in most instances. The milk ducts of the lactating breast are on average relatively smaller (0.9-10 mm, on an average 2 mm) and branch just below nipple. On relatively little pressure application, the ducts get compressed. At ejection, ducts expand and milk flow can be observed within the duct which is seen as echogenic flecks. Breast milk comprises high amount of fat which reflects the ultrasound rays. As increasing amounts milk is synthesised and stored in breast, echogenicity of the glandular tissue increases.

There is increased mammary blood flow (almost double) during pregnancy and lactation. Along with increased arterial blood supply, the superficial veins of the breast also become more prominent. There is a wide variation noted in asymmetry and source of increased blood supply during this period. ^[15]

Male breast

It is mainly made up of adipose tissue. A small, flattened, disc-shaped body of grayish, fibrous glandular tissue is noted normally. This body consists of 15-25 lactiferous ducts which open at the apex of nipple. There are no lobular formations or Cooper's ligaments.

On ultrasound, there is a small volume of hypoechoic glandular tissue. There is hyperechoic overlying skin, hypoechoic subcutaneous fat tissue with hyperechoic streaks of fibrous striae. ^[16]

Benign breast lesions

Classification of benign breast lesions according to histological origin is as follows:

Terminal and lobular ducts

- a. Cysts
- b. Fibroadenoma
- c. Phyllodes tumor
- d. Hamartoma

Ductal system

- a. Ductal ectasia
- b. Intraductal papilloma

Lesions of miscellaneous origin

- a. Lipoma
- b. Hemangioma
- c. Mastitis/abscess

Lymph node origin

- a. Intramammary lymph nodes

USG of breast has long been considered as just an additional examination for identifying the nature of any abnormalities detected at physical examination or

atmammography. However, USG plays a much more important role as micro calcifications are better picked up on it.

Breast USG commonly reveals one of the following appearances:

- Normal tissue
- Simple cyst
- Complicated or complex cyst
- Indeterminate solid or cystic lesion
- Solid lesion

Simple cysts and some solid lesions have a few typical characteristics, so characterization of these breast lesions as benign (BI-RADS Category 2) can be made accurately with confidence.

There are certain parameters that help determine the benignity in most solid lesions:

- elliptical shape and horizontal orientation;
- well-defined curvilinear or only slightly lobulated margins;
- the presence of a complete, thin echogenic capsule;
- Echotexture almost completely hyperechoic. ^[17]

Cysts

Cysts occur when there is over-distension of the terminal duct lobular units (TDLU) because of gradual filling with liquid which eventually amalgamate into single

tensive cyst. There is also fibrosclerosis of the loose connective intralobular tissue giving appearance of a polylobated mass.

Cysts are of three types as follows: simple, complicated and complex cysts.

Typical features of simple cysts are: well circumscribed appearance, anechoic contents, thin echogenic external capsule, enhanced through-transmission and edges shadowing. Such cysts occur commonly in 30 to 50 years of age. Unless the patient is symptomatic, evacuation or monitoring is not warranted. Sometimes echoes in cysts maybe visualised due to technical artefacts or inappropriate gain adjustment or due to overt compression of probe, and can be decreased by using harmonic imaging technique.

The contents are not purely anechoic in complicated cysts, which show diffuse low level echoes due to the presence of amorphous material with cellular debris, blood cells and macrophages with foamy cytoplasm or liquid- liquid levels (e.g. galactocele). Sometimes, high-grade invasive ductal and medullary carcinomas and extra mammary metastatic lesions appear as rounded, hypoechoic lesions with increased through-transmission, and mimics complicated cyst. However, Doppler evaluation along with shape and contour assessment of the lesion may help in diagnosis. Complex cysts of breast are usually not a cause of worry.

Features which should raise a suspicion of malignancy in cystic lesions are thick isoechoic intracystic septations, mural nodules, fibrovascular stalk in the solid components and a microcystic appearance or microlobulated contour. However, most of these turn out to be benign intracystic papilloma and very few papillary lesions with atypia or intracystic papillary carcinoma.

Fibrocystic breast condition

This goes by many names: fibrocystic disease, fibrocystic change, cystic disease, chronic cystic mastitis or mammary dysphasia. Ultrasonographically, in the early stages, breast may appear normal, although clinically palpable mass maybe present. Focal parenchymal thickening along with patchy hyperechogenicity maybe noted. Cysts maybe seen occurring as clusters or can occur a discretely single entity. Focal changes in fibrocystic disease may mimic solid masses sometimes. Almost 50% of such lesions are usually termed as indeterminate which may necessitate further evaluation and characterization.

Duct ectasia

When a single tubular structure filled with fluid is seen it is termed as duct ectasia. Sometimes it may appear as multiple such structures. Echogenic content maybe noted within indicating old cellular debris. Sometimes these are misjudged as solid lesions tubular lesions when the lumen is debris filled.

Lipoma

Lipomas are well-defined, thinly capsulated, slow-growing, soft and compressible echogenic benign tumours. They may show a stippled or lamellar appearance. There may be absence of palpable lump with patient presenting only with increase in size of the involved breast.^[18]

Mastitis

Inflammation of the breast can be because of infectious and non-infectious causes. Non-infective mastitis results from blocked ducts. The breast gets engorged owing to localized inflammatory response. Infective mastitis results from a pathogenic invasion of the breast, most commonly by *Staphylococcus aureus*, -haemolytic streptococci, *Streptococcus faecalis* and *Escherichia coli*. These organisms enter the tissue via a nipple fissure due to trauma. Ultrasonographic appearances vary depending on the duration and extent of inflammation. In acute early phases, no discernable ultrasonographic changes may be noted. Gradually, skin thickens and becomes more hyperechoic. Furthermore, the Cooper's ligaments and stromal fibrous tissue become hypoechoic and become indistinguishable from surrounding adipose tissue. There is increased vascularity in the inflamed. In advanced stages the entire breast tissue appears similar, breast thickness is prominent and skin is conspicuously thickened which can be better visualised with a low frequency (5 MHz) probe. Resolution can be picked up with a decrease in blood flow. Inflammatory carcinoma which is a rare occurrence may appear like mastitis. In such cases, follow-up is required to make sure there is resolution.^[15]

Abscess

Abscesses occur when subareolar ducts and / or pre-existing galactocele get infected (puerperal mastitis), or ectatic ducts or cysts rupture. Initially, there is chemical inflammation and subsequently bacterial superinfection occurs.

Acutely occurring puerperal mastitis may have lobar or sublobar origin, but the whole organ may appear inflamed. If infective mastitis is improperly / incompletely treated, it results in abscess formation. There may be necrotic tissue and denatured milk products floating within the abscess cavity which has pus. In a pre-existing galactocele, the abscess develops much earlier and is more demarcated giving an oval or multilobulated shape. The confluence of several small abscesses gives it a multiloculated appearance with involvement of subareolar ducts.

When there is a focal chemical mastitis caused by rupture of ducts or cysts, a consequent release of lipid-rich secretions occurs. Large ducts are inflamed along with ductal ectasia in perimenopausal women quite often. This frequently leads to subareolar abscesses formation which show multilobulated appearance. Bilateral involvement with episodes of focal periductal mastitis is also encountered commonly. Bacterial infection results from repeated aspiration attempts or infected ductal communication or hematogenous seeding.

Ultrasonographically, abscess shows an elongated appearance and occurs along the axis of the original duct, with markedly thickened walls, early involvement of the nipple and pronounced surrounding inflammation.

Non puerperal abscesses recur easily and tend to become chronic with formation of cutaneous fistula. It may be difficult to treat. There occurs evident fibrotic reaction causing permanent nipple retraction. Neoplastic disorders should always be ruled out in such instances.

Galactocele

A painless lump developing during or a few weeks after breast feeding has ended, is generally diagnosed as galactocele. Ultrasonographic monitoring reveals spontaneous resolution. A guided aspiration may also be done to ease the clinical symptoms.

A galactocele is a cystic dilatation of the terminal ducts and ductules containing milk, so the appearance of a galactocele may vary during the monitoring. Initially, an anechoic cyst with or without septations is seen, as fresh milk has homogeneously emulsified fat globules in a liquid state. Further on, unevenly distributed fat tends to appear more echogenic, which may be floating sometimes forming the classic fat-fluid level. The galactocele mimics a solid nodule when the milk is curdled. However, distinguishing it from a solid nodule is easy because it is easily compressed, with no vascularity on Doppler, and movable contents. A chronic galactocele, where liquid part is completely absorbed, simulates a simple or complex lipid cyst.

Fibroadenoma

Uncoordinated proliferation of the epithelial and stromal tissue in a terminal duct lobular unit due to estrogen stimulation leads to formation of benign solid tumours called fibroadenomas. The surrounding tissues are partially compressed by the extensive growth of fibroadenomas, forming a pseudocapsule.

Internal structure is made up of stromal and epithelial elements. There can be myxoid degeneration, sclerosis, hyalinization and calcification of the stromal element. The epithelial component may progress to apocrine metaplasia, ductal hyperplasia, sclerosing and florid adenosis. Complex fibroadenomas typically show apocrine metaplasia, ductal hyperplasia, sclerosing adenosis or cysts.

Fibroadenomas have two peaks of incidence: in the third and in the fifth decade of life.

They usually grow rapidly and reach a size of 2 to 3 cm. Giant and juvenile fibroadenomas may reach 6 to 10 cm. The highly cellular stroma is similar to benign phyllodes tumour. They can be multiple and bilateral in upto 20% to 25% patients. Episodic infarctions occur during pregnancy and breast feeding making these lesions more irregular and can simulate carcinomas. However, carcinomas rarely develop from a fibroadenoma. "Complex" fibroadenomas have increased risk (1 out of 1000 cases) to malignant transformation with CIS being more common than infiltrating carcinomas. At USG, classic fibroadenomas are mobile and smooth, elliptical or slightly lobulated with a thin, echogenic capsule, horizontal orientation (wider than taller), isoechoic or mildly hypoechoic with no changes in the surrounding parenchyma.

Histological analysis is warranted when there is a microlobulated appearance, microcalcifications, ductal hyperplasia or when there is "Complex" fibroadenoma.

Fibroadenoma variants include tubular adenomas and lactating adenomas. There is evident epithelial hyperplasia and a very little stromal component in these variants. The lactating adenomas occur during breast feeding and in the third trimester of pregnancy;

sometimes may acquire quite a big size and oval in shape, but are very elastic and compressible mimicking a lipoma. They are scattered in the breast parenchyma, show micro-lobulations and milk filled cysts and rarely show pseudocapsules, almost always have increased vascularity. The echotexture varies depending on the emulsification level of the milk.

Seroma and hematoma

Seromas commonly occur unpredictably after interventional procedures, surgical resection or breast augmentation. They are basically collections of serous fluid. The collection is proportional to the extension of the operation located at the level of the surgical wound / resection site. Axillary seromas are truly lymphoceles located at the site of lymph node dissection. In patients on anticoagulant therapy, hemorrhagic extravasation may result in consequent hematoma formation. These collections may be round or oval shaped if they are distended, or angular and flat if undistended. Initially they are anechoic or markedly hypoechoic, with few internal echoes or thin fibrin septations. When there are blood clots, hyperechoic sediments, pseudonodule, wall thickening and coarse septa formation showing no vascularity at power Doppler are noted.

Hematoma may resolve spontaneously or become chronic, eventually simulating a solid nodule. It may develop liponecrosis with possible wall calcification. In cases of blunt trauma, an edema in the adipose tissue may be seen. In cases of superficial skin bruising, there may not be a real pseudocystic hematoma.

Intramammary lymph node

They are most frequently encountered in upper outer peripheral quadrant toward the axillary tail, but occur anywhere in the breast. The classic appearance of an oval or lobulated, isoechoic or hypoechoic nodule with well-circumscribed margins and a hyperechoic central fatty hilum irrevocably indicates a benign lymph node.

Gynecomastia

Gynecomastia is the enlargement of the male breast where the benign glandular ducts and stroma proliferate. It is the most frequently encountered breast swelling in males and are mostly physiological or paraphysiological. Transplacental exposure to maternal estrogens causes male breast enlargement immediately after birth. Hormonal instability during puberty can also cause gynecomastia. Diminished androgen secretion among senile males can result in gynecomastia.

Leydig cell tumors of the testis, adrenal tumors, ectopic production of gonadotropin by tumors of the lung, liver, or kidney, liver or renal failure and hyperthyroidism can also be associated with gynecomastia. It can result from an adverse effect of drugs like steroid hormones, cimetidine, thiazide diuretics, cardiac glucosides, antihypertensives, antidepressants, and narcotics.

Clinically, an occasionally painful, soft, elastic, nodular mass in retroareolar region is seen with no changes in the overlying skin.

The types of gynecomastia are: Nodular, dendritic and diffuse glandular. Each has a different degree of ductal and stromal proliferation. The nodular and dendritic forms are

the florid and fibrous stages respectively, and diffuse glandular type corresponds to epithelial proliferation and is often associated with exogenous usage of hormones.

USG in nodular gynecomastia shows subareolar nodular hypoechoic mass that parallels the skin. Occasionally, it is in the shape of a triangle with radiating extensions into the subareolar fat i.e., dendritic gynecomastia. Rarely, it resembles a female breast in cases of diffuse gynecomastia. Colour Doppler is unremarkable and shows vascularity reflecting that particular stage.

In male breast, gynecomastia occurs more frequently than malignancy.^[16]

Malignant breast lesions on USG

Ductal Carcinoma In Situ (DCIS)

Identifying and localizing a breast lesion primarily identified on mammography as DCIS on USG enables the radiologist to guide in interventional procedures (eg, needle biopsy, needle localization). Ultrasound also helps to detect DCIS without any calcifications and in detecting breast lesions in dense breasts.^[19] USG has often been shown to be more sensitive than mammography. Breast cancers are frequently detected by USG.^[20]

DCIS has typically a microlobulated appearance with ill-defined margins, mildly hypoechoic, extension to ducts, parallel orientation and normal acoustic transmission on USG. Invasion is indicated by spiculated margins, marked hypoechoicity, a thick echogenic rim, and posterior acoustic shadowing.

DCIS features were classified as follows: cystic or solid mass (hypoechoic or solid mass with clear margins, spherical in shape or up to 4 scant nicks), ill-defined hypoechoic mass (horned), microlobulated mass (mammary duct appears dilated, inner structure with a hypoechoic pattern), duct dilatation (one mammary duct is dilated), calcification (presence of echogenic spots that appear to be calcifications; however, background changes of the mammary gland are not helpful). Most were ovoid in shape, and the margins were circumscribed or microlobulated, making it difficult to differentiate from benign lesions. There can also be heterogeneous internal echoes.

Wang divided their study results into calcified and non-calcified DCIS. Malignant calcifications are more conspicuous at USG than benign ones, because they get masked by echogenicity of breast tissue. Calcifications seen with a mass is more likely to be invasive cancer. Also, calcifications are more commonly seen in high-grade than low-grade DCIS.

Ductal changes are commonly seen in tandem with microcalcifications of high-grade DCIS. Less commonly, calcifications may just appear as echogenic foci without a mass or significant change in duct. Associated findings to consider are an increase in the number of ducts and duct distention. Microlobulations may represent spread of tumor into the distended ducts which are seen projecting radially, being oriented parallel or antiparallel. Heterogeneous echotexture may be encountered due to calcifications with associated internal vascularity on Doppler. Posterior acoustic shadowing is noted in few cases of high-grade comedo-type DCIS.

Calcified DCIS, ultrasonographically, resembles benign lesions like sclerosing adenosis, atypical ductal hyperplasia, intraductal papilloma, fibroadenoma, and ductal epithelial hyperplasia.

Noncalcified DCIS are heterogeneous masses which are often hypoechoic and irregular in shape with microlobulated, indistinct margins being oriented parallel or antiparallel. Usually no posterior acoustic enhancement or shadowing is noted. Distention of the lobular portion of the terminal ductal lobular unit by DCIS along with ductal extension may be present giving it a “pseudomicrocystic” appearance. Since DCIS can arise in preexisting pathologic entities such as papillomas or radial scars, any gross changes in the surrounding is always suspicious for malignancy because of periductal lymphocytic reaction or periductal desmoplasia. Internal vascularity is frequently oriented perpendicular rather than parallel to the wall of mass in cases of cystic type of non-calcified DCIS mass. In a postmenopausal age group, clustered microcysts should raise concern for possible DCIS with recommended HPR for any solid component. Any abnormality of ducts in the form of neoductogenesis or an abnormal appearance should raise possibility of DCIS and this can be seen presenting with nipple discharge. Duct enlargement is typically proportional to grading of the tumour mass.

Non-calcified DCIS mimics benign lesions like fibrocystic change, microcysts, apocrine metaplasia, papillary duct hyperplasia, adenosis, and secretory change. ^[21]

Histological grading in DCIS was correlated with USG by Joelle M. Schoonjans^[22] in 2000.

The histological grading system which was used was proposed by Elston^[23] in 1991.

Grade 1 DCIS presented as round or oval well defined hypoechoic mass with no posterior enhancement or shadowing. Grade 2 DCIS lesions were round, oval, or irregular masses with circumscribed, microlobulated, or poorly defined margins. Three grade 2 DCIS lesions presented as hypoechoic complex cystic or solid mass. Posterior through transmission features (shadowing) was seen in 1 of 4 lesions and no posterior enhancement or shadowing in 3 of 4 lesions. Grade 3 DCIS lesions appeared as irregular, hypoechoic or complex masses with posterior acoustic shadowing.

Invasive breast cancers

Invasive breast cancers are epithelial tumors of ductal or lobular origin. Invasive ductal carcinoma is the most common form of breast cancer and accounts for 50% to 70% of invasive breast carcinomas. It usually presents as a hard palpable mass but is diagnosed much earlier with increasing usage of screening mammography. It is called infiltrating ductal carcinoma NOS (not otherwise specified) type when no specific features are noted and it accounts for 50%-70% of all IDC. When infiltrating ductal carcinomas takes on specific features, they are named according to the features that they display: infiltrating tubular carcinoma (2%-3%), mucinous or colloid carcinoma (2%-3%), medullary carcinoma (5%), invasive cribriform carcinoma (1%-3%), invasive papillary carcinoma (1%-2%), adenoid cystic carcinoma (1%) and metaplastic carcinoma (1%).

Infiltrating lobular carcinoma is less common and comprises about 15% of invasive breast cancers and is usually more multifocal.

Other invasive histologies of nonepithelial origin, such as breast lymphoma are much less common and together account for less than 10% of all invasive breast cancers. [24]

Invasive Ductal Carcinoma

They are usually irregular, ill-defined, or microlobulated “taller-than-wide” mass typically showing posterior shadowing and a thick echogenic rim with echogenic foci representing microcalcifications.

Grade 3 lesions were more likely to display posterior enhancement rather than shadowing which can cause confusion in diagnosis as it seen more often in benign lesions. [25]

Rotstein and Neerhut^[26] characterized the margins of breast masses evaluated by ultrasound as aggressive (“spiculated”, “microlobulated,” or “angular”), nonaggressive (“well-defined smooth”), and as indeterminate. Circumscribed tumors were significantly more likely to be high grade (compared with lower grade). [27]

With respect to echogenicity, no significant difference was noted among the different grades, and most lesions (82%) appeared hypoechoic.

Invasive Lobular Carcinoma

The reported prevalence of invasive lobular carcinoma (ILC) is variable, with more recent studies indicating that ILC accounts for 10%–15% of all invasive breast carcinomas.^[28]

This is the second most common breast malignancy and may be seen in elderly women. It is often missed on mammography. On USG, its appearances are variable, typically a large, ill-defined, isoechoic with picket-fence shadowing. Lesions similar to ductal carcinomas and show barely visualized areas of architectural distortion.

The most common sonographic appearance of ILC is an irregular or angular mass hypoechoic mass with heterogeneous internal echoes, ill-defined or spiculated margins, posterior acoustic shadowing, occurring in up to 60 % of cases and lacking in up to 20 % of cases. Lobular tumors can also manifest merely as an area of posterior acoustic shadowing without an associated visibly distinct mass. In Selinko's series^[29], 15 % of ILC tumors were described as an ill-defined area of altered, hypoechoic, inhomogeneous echotexture without identifiable margins and without frank shadowing or focal shadowing without a discrete mass. ILC is rarely seen as a well-circumscribed mass, reported in only 2 to 12 % of lobular tumors.^[30]

All subtypes of ILC have similar USG appearances. However, classic ILC presents as focal shadowing without a discrete mass, whereas pleomorphic type ILC presents as a mass with shadowing. Signet ring, alveolar, and solid subtypes of ILC are more likely to present as a lobulated, well-circumscribed mass.

Medullary Carcinoma

Typical sonographic features of malignancy include irregular shape, irregular margin, marked hypoechogenicity, a surrounding echogenic rim or halo and posterior acoustic shadowing.

Medullary carcinomas are uncommon, well-circumscribed, benign looking lesions, which may be homogenous/inhomogeneous, hypoechoic and with posterior enhancement on USG.

The typical sonographic features of benign tumors include round or oval shape with a smooth border or a pseudocapsule and homogeneous internal echoes with posterior enhancement. There is considerable overlap of sonographic features between medullary carcinomas and benign tumors; thus, medullary carcinomas are frequently misdiagnosed as benign tumors according to their sonographic features.

Larger masses with a greater L/AP ratio, which are round or lobular in shape, with a focally thick wall and anechoic cystic space, and enlarged axillary lymph nodes are more common findings in patients with medullary carcinoma than in patients with fibroadenoma. These sonographic findings help to differentiate medullary carcinoma from fibroadenoma. ^[31]

It may be due to that fact that malignant masses grow across normal tissue planes, which are horizontally oriented in patients who are scanned in the supine position, whereas fibroadenomas grow along the natural tissue planes.

An internal echo pattern is often considered to be a sonographic feature that is not specific. A homogeneous echo pattern is found in 71% to 89% of fibroadenomas and in 12% to 59% of malignant breast tumors.

Mucinous Carcinoma

Mucinous (colloid) carcinoma of breast is quite uncommon and accounts for 1–7% of all invasive mammary carcinomas and is mostly age-related. It is more common in older rather than younger women.^[32]

These are divided into pure or mixed type mucinous carcinomas depending on the mucinous content of the carcinoma. Mucinous carcinomas mostly present as a complex mass with solid and cystic components and rarely present as a homogeneous mass, either isoechoic or hypoechoic to the subcutaneous fat. Tumors with less than 40% mucin content do not show any distal enhancement. For tumors with 50% or more mucin content, show distal acoustic enhancement. Vascularity in both the periphery and the center of the lesion can be noted.

It is usually well-circumscribed microlobulated on USG with echogenic internal mucinous contents and posterior enhancement. Sometimes it can be misdiagnosed as a papillary tumor.^[33]

Male Breast Cancer

About 1% of all breast cancers occur in males. USG findings are similar to those of female breast cancer.

Breast malignancies in males are very rare. They usually present as localized, painful masses and at the subareolar level or in the upper outer quadrant of the breast. In contrast with gynecomastia, carcinomas are often eccentric with respect to the nipple. ^[16]

The mass may be attached to the skin or the pectoral muscle. Other clinical presentations include nipple retraction and bloody discharge from the nipple. Several risk factors have been identified for male breast cancer including age, family history (BRCA2), exposure to radiation, cryptorchidism, testicular injury, Klinefelter syndrome, liver dysfunction, and chest trauma. The most common forms are invasive ductal carcinoma (85% of cases), papillary carcinoma (5%), and lymphoma. USG wise, invasive ductal carcinoma appears as a solid hypervascular mass, which is usually hypoechoic and has irregular margins with intense posterior attenuation. Less commonly it may appear as a complex cyst.

Papillary carcinoma presents as a thick walled solid or complex cystic mass.

Whereas, primary breast lymphoma can present as a solid, rounded, hypoechoic hypervascular mass with irregular, lobulated margins.

BIRADS CATEGORIZATION ^[34]

The Breast Imaging Reporting and Data System® (BI-RADS®) initiative, instituted by the ACR, was begun in the late 1980s to address a lack of standardization and uniformity in mammography practice reporting.

During the early days of mammography, the American Medical Association specifically complained that mammography interpretation was often indecisive and

confusing. In response, the BIRADS Committee recommended that final impressions be summarized by choosing only one among several standardized final assessment categories at the end of a report, each of which included a matched, also standardized management recommendation. These categories currently are as follows:

Category 1: negative;

Category 2: benign finding(s);

Category 3: probably benign finding—initial short-interval follow-up suggested;

Category 4: suspicious abnormality— biopsy should be considered;

Category 5: highly suggestive of malignancy—appropriate action should be taken; and

Category 6: known biopsy-proven malignancy—appropriate action should be taken.

An incomplete category was also provided,

Category 0: need additional imaging evaluation and/or prior mammograms for comparison.

These categories also took an evidence-based approach. The “probably benign” category was based on literature demonstrating that follow-up rather than biopsy is safe and effective management for a clearly defined subset of findings that are very likely benign. The final assessment of “highly suggestive for malignancy” was included at the request of representatives of the American College of Surgeons. Thus, the “highly suggestive” category implied a “classic” finding for malignancy, which enabled women

living in underserved areas (without expertise in image-guided diagnosis) to be scheduled for operative diagnosis, using frozen section, and immediate surgical management.

PHYSICS OF ELASTOGRAPHY

The ability of a tissue to resume its original size and shape when an external force is applied is called elasticity. Cystic lesions which contain fluid which can assume any shape but do not vary in volume. Solids are rigid and can neither change their shape nor volume. Shear and volume elasticity is an inherent property of the solids. Any force acting on unit area produces change in size or shape which is called as strain (expressed as ratio) and the applied force is called as stress.

For a homogeneous isotropic solid just like the biological tissues, the ratio of stress / strain remains constant and is called the modulus of elasticity. ^[35]

The mechanical properties of tissues when assessed in vivo and in vitro vary drastically owing to the difference in architecture of tissue in the human body. Hence in vivo studies are more reliable and help in clinical decision making. Young's modulus typically ranges from about 2-3 m/s in fatty tissues to about 5-8 m/s in malignant lesions.

ELASTOGRAPHY

Introduction

Changes in tissue elasticity are generally correlated with its pathological state. In many instances, the lesions evade getting diagnosed by palpation even though changes in elasticity have occurred because of size of a lesion being small or its location being deep

in the body. As such these lesions are also ultrasonographically undetectable. A need for a technique that resolves this dilemma is highly necessitated.

Elastography is a method to evaluate elasticity of tissues by estimating local longitudinal strain of tissue elements by ultrasonically assessing the one dimensional local displacements. The elasticity information is displayed in the form of a gray scale image called an elastogram^[1].

Moreover, lesions look bigger on elastograms than on the analogous sonograms. Hence both stiffness or elasticity and size should be taken into account to rule out malignancy. Few authors have used colour maps to depict tissue stiffness and this has over the years become a standard method of grading breast lesions.

Initially, only qualitative evaluation of relative hardness was done but in recent times, both quantitative and semi-quantitative evaluation of masses is the norm. Current trend includes strain ratio measurement between the mass and surrounding normal tissue and the assessment of shear wave velocity within masses. This provides an assessment of shear modulus which is compared with overall stiffness of the breast tissue. Clinical studies employing quantitative elastography have only materialised in 2010s.^[36]

Need for Elastography

Hui Zhi^[37] conducted a study in 2004 – 2005 to assess the role of ultrasound elastography (UE) in differentiating benign versus malignant lesions in the breast and compare it with conventional sonography and mammography. They evaluated solid breast lesions by mammography, sonography and UE and classified them as benign and malignant. The diagnostic results were compared with histopathologic findings. They

revealed thatultrasound elastography was the most specific (95.7%) and had the lowest false-positive rate (4.3%) of the 3 modalities. The accuracy (88.2%) and positive predictive value (87.1%) of UE were higher than those of sonography (72.6% and 52.5%, respectively). The sensitivity values, negative predictive values, and false negative rates of the 3 modalities had no differences.

A combination of UE and sonography had the best sensitivity (89.7%) and accuracy (93.9%) and the lowest false-negative rate (9.2%). The specificity (95.7%) and positive predictive value (89.7%) of the combination were better, and the false-positive rate (4.3%) of the combination was lower than those of mammography and sonography.

They concluded that a combination of UE and sonography had the best results in detecting cancer and potentially could reduce unnecessary biopsy. Ultrasound elastography is a promising technique for evaluating breast lesions.

A study done by A. Thomas^[38] in 2006 revealed B-mode ultrasound had a sensitivity of 91.8% and a specificity of 78%, compared with sensitivities of 77.6% and 79.6% and specificity of 91.5% and 84.7%, respectively, for the two observers evaluating Elastography. Agreement between B-mode ultrasound and Elastography was good, yielding a weighted kappa of 0.67. Their results suggest that elastography in conjunction with B-mode sonography is a reliable method for the confirmation of benign breast lesions and that the differentiation of malignancy categories with elastography is comparable to that of conventional ultrasound.

The results of Thomas's study showed that realtime elastography improves the specificity of breast lesion diagnosis and is a promising new approach for the diagnosis of breast cancer.

According to Kumm^[39], although breast biopsy remains the gold standard for diagnosis of suspicious lesions, a large proportion of biopsy specimens reveal a benign result. Therefore, in 2010, they assessed the application and diagnostic performance of elastography for the characterization of breast lesions in patients referred for biopsy.

Elastography scoring (ES) and for strain ratio (SR) measurement were done in the detected mass lesions. Sensitivity, specificity, and positive and negative predictive values were determined using pathologic results from 14-gauge core needle biopsy as the reference standard. 72% lesions were benign and 28% lesions were malignant.

Sensitivity was 0.76 for ES and 0.79 for SR.

Specificity was 0.81 for ES and 0.76 for SR.

Positive predictive value was 0.60 for ES and 0.57 for SR.

Negative predictive value was 0.90 for ES and 0.90 for SR.

SR values for malignant lesions were significantly higher (median ratios 10.5 and 2.7, respectively, $P < .001$).

Kumm concluded that while the initial clinical performance of elastography imaging shows potential to reduce biopsy of low-risk lesions, a large-scale trial addressing appropriate patient selection, diagnostic parameters, and practical application of this technique is necessary prior to widespread clinical use.

Navarro^[40] conducted a study in 2010-11 with the aim of evaluating the diagnostic utility of elastography in differentiating benign from malignant breast lesions and comparing it with conventional sonography.

Of 124 breast lesions (59 malignant and 65 benign) which were examined with B-mode sonography and subsequently with elastography, elastography showed less sensitivity but higher specificity than conventional sonography.

Conventional sonographic findings were classified according to the American College of Radiology Breast Imaging Reporting and Data System for sonography, and elastographic images were assigned an elasticity score of 1 to 5 (1–3, benign; 4 and 5, malignant) according to the Ueno classification. Cytologic diagnoses obtained from fine-needle aspiration and histopathologic results from a core-needle biopsy or surgical biopsy were used as reference standards. Statistical analysis included sensitivity, specificity, and positive and negative predictive values for both elastography and conventional sonography.

Their results clearly depicted that elastography may be useful as a complementary technique in addition to conventional sonography in the characterization of breast lesions because it increases the diagnostic specificity, thus reducing the false-positive rate.

In a prospective study conducted by Cho^[41] in 2012 to investigate the effect of the combined use of ultrasonographic (US) elastography and colour Doppler US in breast lesions, a cohort of 367 biopsy-proved cases in 319 women with B-mode US, US elastographic, and Doppler US images were included.

Five blinded readers independently scored the likelihood of malignancy for four data sets (i.e., B-mode US alone, B-mode US and elastography, B-mode US and Doppler US, and B-mode US, US elastography, and Doppler US). The area under the receiver operating characteristic curve (A_z) values, sensitivities, and specificities of each data set were compared.

Cho et al concluded that combined use of US elastography and color Doppler US increases both the accuracy in distinguishing benign from malignant masses and the specificity in decision-making for biopsy recommendation at B-mode US.

Ya tu^[42] in 2013-14 did a retrospective study to assess role of ultrasonographic elastography. Breast masses were evaluated ultrasonography and classified according to BIRADS and then the Elastographic evaluation was done between January and December 2013 in Turkey. Findings were compared with pathological outcomes.

The mean strain ratio of benign masses was 2.48 ± 1.605 and strain score was 2.307 ± 1.327 . The mean strain ratio of malignant masses was 5.546 ± 1.434 and strain score was 4.458 ± 0.721 . The most frequent benign masses were fibroadenoma and fibrocystic lesions. The most common malignant lesion was invasive ductal carcinoma. When the cut-off value for strain ratio was accepted as 4.009 in receiver operating curve (ROC) analysis for the differential diagnosis of malignant breast masses, the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated as 83.8%, 76.9%, 62.3%, and 90.7%, respectively. When the limit value of strain patterns was accepted as scores 4 and 5, the sensitivity, specificity, PPV, and NPV were calculated as 42.7%, 94.2%, 77.2%, and 78%, respectively. When conventional

ultrasonography (U.S.) findings were considered together with the elastographic strain ratios the sensitivity, specificity, PPV and NPV were 87.5%, 71.1%, 58.3% and 92.5%, respectively.

They concluded that Elastography is not a method that can replace conventional breast ultrasound for detecting breast cancer; however it may be an adjunct to conventional ultrasound by increasing its diagnostic power.

In an Asian study conducted by Owvass Hamied Dar, Pankaj Sharma, Shaheen Hassan Dar and Maqsood Ahmad Dar^[43] in 2014, the sensitivity of US Elastography was found to be 88.57% with specificity of 90.32% and positive predictive value of 91.18%. Thus, they concluded Ultrasound Elastography can be used in early diagnosis and differentiation of breast masses into benign and malignant and hence can be influential in reducing the number of breast biopsies.

Types of elastography methods

A study conducted in 2012 by A. Goddi, M. Bonardi and S. Alessi^[44] did a review of elastographic studies to determine the usefulness of breast elastography. It also iterated the advantage of shear wave technology over strain elastography.

This study concluded that Elastography has a potential to reduce the need for biopsy in lesions classified by BIRADS into category 3 on US and postpone follow-up in cases which are definitely diagnosed as benign. Elastography findings are significant in the taking a call on subcentrimetric lesions picked up on US. Considering that these two technical solutions can complete each other they should be combined to overcome the limitations of both.

According to a study done in 2012 by Andrew Evans^[45], Shear wave Elastography versus greyscale BI-RADS performance figures were sensitivity: 97% versus 87%, specificity: 83% versus 78%, positive predictive value (PPV): 88% versus 84%, negative predictive value (NPV): 95% versus 82% and accuracy: 91% versus 83% respectively.

Evans also stated that shear wave elastography gives quantitative and reproducible information on solid breast lesions with diagnostic accuracy at least as good as greyscale ultrasound with BI-RADS classification. The study also suggested that elastography classification is at least as accurate as BI-RADS in separating benign and malignant lesions, but this requires a large scale research for confirmation.

Chang^[46] in 2013 compared the diagnostic values of shear wave and strain elastography for the differentiation of benign and malignant breast lesions.

They did B-mode ultrasound and shear-wave and strain elastography in 150 breast lesions; of which 71 were malignant. BI-RADS assessment, shear elasticity values in kilopascals, and elasticity 5-point score a scale were done before subjecting the patient to biopsy. Their results were compared using the area under the receiver operating characteristic curve (AUC).

They found that the AUC for shear-wave elastography was similar to that of strain elastography (0.928 vs 0.943). The combined use of B-mode ultrasound and either elastography technique improved diagnostic performance in the differentiation of benign and malignant breast lesions compared with the use of B-mode ultrasound alone (B-mode

alone, AUC = 0.851; B mode plus shear-wave elastography, AUC = 0.964; B-mode plus strain elastography, AUC =0.965; $p < 0.001$).

With the best cut off points of 80 kPa on shear-wave elastography and a score between 3 and 4 on strain elastography, the sensitivity was higher in shear-wave elastography, and specificity was higher in strain elastography (95.8% vs 81.7%, $p = 0.002$; 93.7% vs 84.8%, $p = 0.016$).

In cases of infiltrating ductal carcinoma, mean elasticity scores were lower in grade 3 than in grade 1 and 2 cancers ($p = 0.017$) with strain elastography causing false-negative findings.

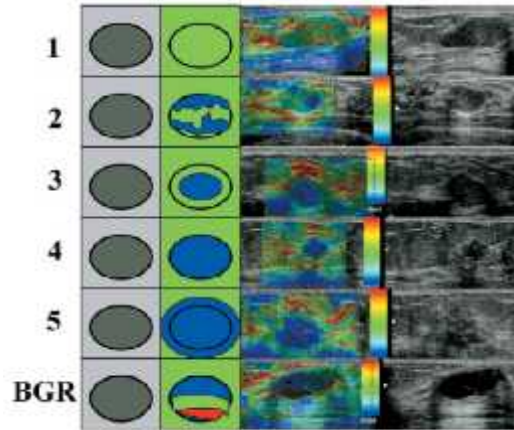
Hence, they concluded that the diagnostic performance of shear-wave and strain elastography was similar. Either elastography technique can improve overall diagnostic performance in the differentiation of benign and malignant lesions when combined with B-mode ultrasound.

However, the sensitivity and specificity of shear-wave and strain elastography were different according to lesion histologic profile, tumour grade, and breast thickness.

Differentiation between benign and malignant lesions

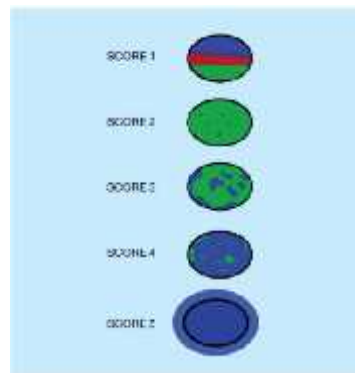
Ako Itoh^[47] from Hitachi general hospital in Japan proposed the revolutionary elastography scoring system in 2006 which is still followed and is given below:

Picture 2 depicting Tsukuba Elastography scoring by Itoh.



The Italians headed by Giorgio Rizzatto^[48] in 2007 published a similar scoring system similar to Itoh's where cysts were given a score of 1.

Picture 3 depicting Rizzato's Elastography scoring system.



Fleury^[49] in an attempt to categorize cystic breast lesions by elastography conducted a study in 2008 on 150 patients referred for percutaneous breast biopsy of 175 lesions. Histologically diagnosed solid lesions (153 lesions) were excluded; lesions histologically diagnosed as cystic (22 lesions), including complicated cysts, papillary lesions, inflammatory lesions, typical columnar cell hyperplasia and duct ectasia were retrospectively classified by means of elastography, according to a scoring system

developed by the authors, with categories ranging between 1 and 4. All of the cysts histologically diagnosed were sonographically characterized as indeterminate nodules, and assigned score 2, benign by elastography. Cysts with inflammatory content and ductal ectasia were sonographically characterized as complicated cysts, also with score 2 by elastography. These lesions presented a low malignancy potential and biopsies could be avoided if the features at ultrasound elastography had been taken into consideration.

One of the limitations for cystic lesions evaluation by elastography is the serial compressions intensity. The higher the intensity, the more the superficial tension of the internal fluid content is increased, determining the characterization as solid lesion according to the color scoring. The advantage is that, as a real-time method, the investigator is allowed to measure the compression intensity during the examination according to the different types of breast and lesion to be evaluated. This increase in the superficial tension of the intracystic fluid also can be observed in secretory lesions, like in the case of the columnar cell hyperplasia and also in some inflammatory cysts.

Hence Fleury concluded that different features of cystic breast lesions are demonstrated by elastography according to histological results, representing a useful and easily applicable method for differentiating benign from malignant breast lesions.

Dan-Dan Li, Hui-Xiong Xu, Bo-Ji Liu, Xiao-Wan Bo, Xiao-Long Li & Rong Wu^[50] from September 2014 to February 2015 conducted a study aimed to identify the associated factors for quality measurement (QM) of shear wave speed (SWS) imaging. Conventional ultrasound and SWS imaging were performed in 338 women with 361 breast lesions. Sensitivity, specificity and the area under receiver operating characteristic

(ROC) curve (AUC) among maximum SWS, QM and SWS+QM were compared to validate additional value of QM. Pathology confirmed 263 (72.9%) benign lesions and 98 (27.1%) malignancies. Factors like depth and posterior features were identified as associated factors aiding in diagnosis. Compared with SWS and QM, the sensitivity of SWS+QM increased from 67.3%, 64.3% to 83.7% whereas the specificity decreased from 90.5%, 72.6% to 65.4% (all $P < 0.05$). SWS had the highest AUC in comparison with QM and SWS+QM (0.849 vs. 0.685 vs. 0.745; $P < 0.05$).

They concluded that adding QM to SWS is useful for breast cancer screening and SWS alone is useful for breast cancer differentiation.

Michael Golatta^[51] in 2014 evaluated virtual touch tissue imaging quantification (VTIQ) which is based on ARFI shear wave technology of SIEMENS as a new elastography method. Both USG and Shear wave elastography were performed in 103 women with 104 lesions of which 54 were malignant. The mean values in malignant lesions were significantly higher than those in benign ($7.73 \text{ m/s} \pm 1.02$ versus $4.46 \text{ m/s} \pm 1.87$; $p < 0.0001$). The combination of BIRADS and shear wave technology led to improved test validity as it is highly reliable and reproducible.

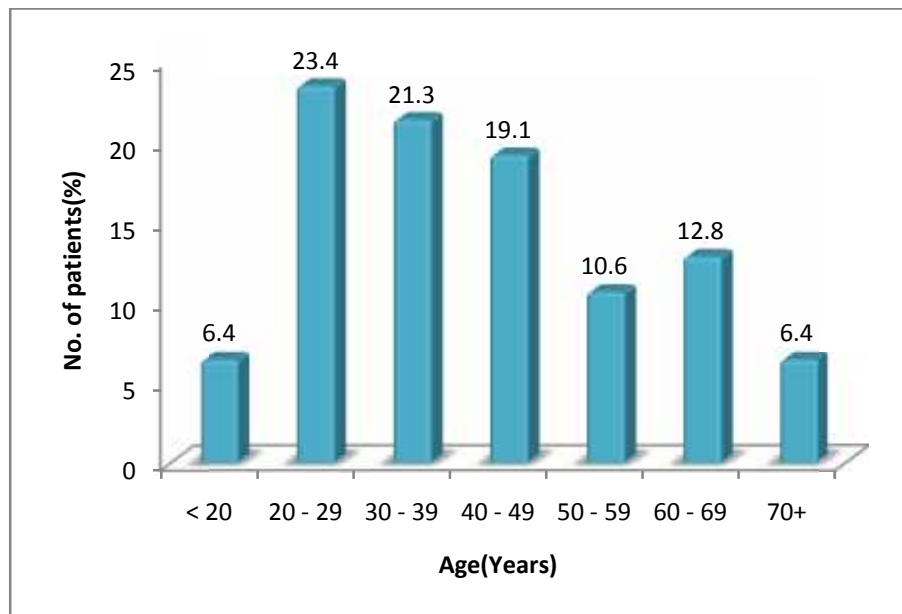
RESULTS

The total number of cases studied was 47 in a time period of approximately two years.

Few of the variables that decide add quality value to the diagnosis breast lesions by BIRADS are described below:

Age distribution:

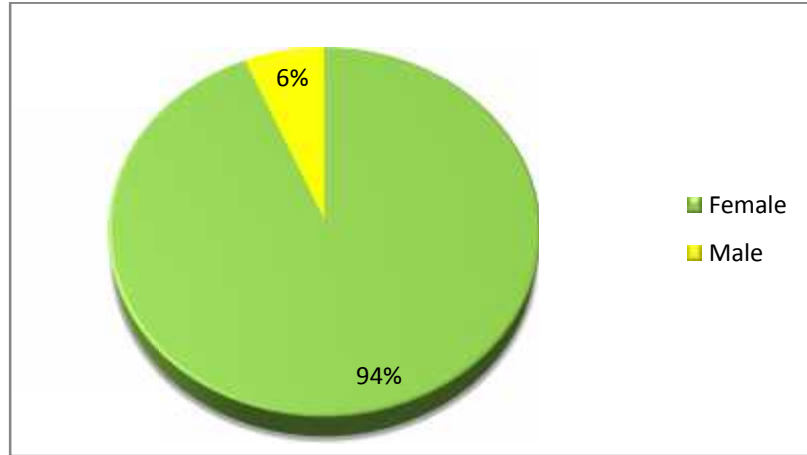
Picture 4 depicting Bar diagram of age distribution of patients in our study:



The age distribution of the patients in our study ranged from 11 to 80 years with the mean age being 40.87 ± 17.16 years. Most of the patients in our study were in the third decade of life followed by fourth, fifth and seventh decades.

Gender distribution:

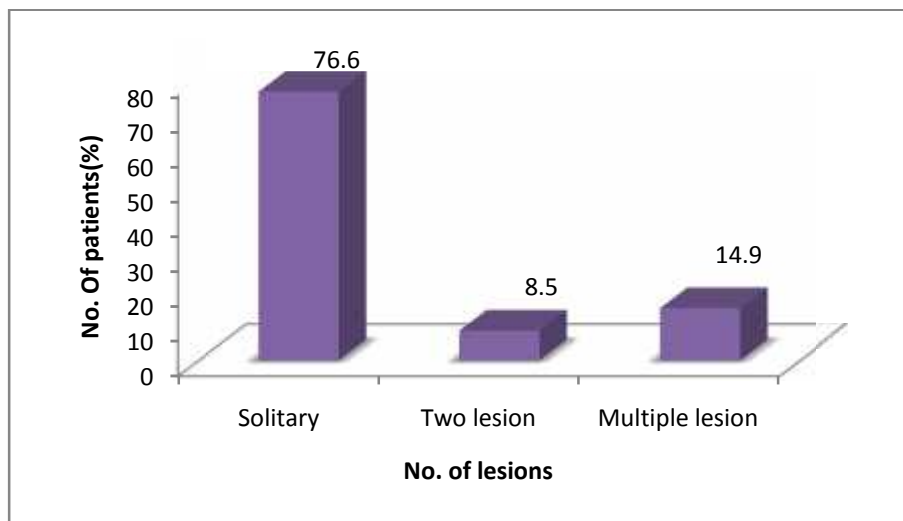
Picture 5 depicting Pie chart of distribution of patients according to gender:



Only three male patients were encountered in our study.

Number of lesions:

Picture 6 depicting Bar diagram of the number of lesions occurring in a single patient:



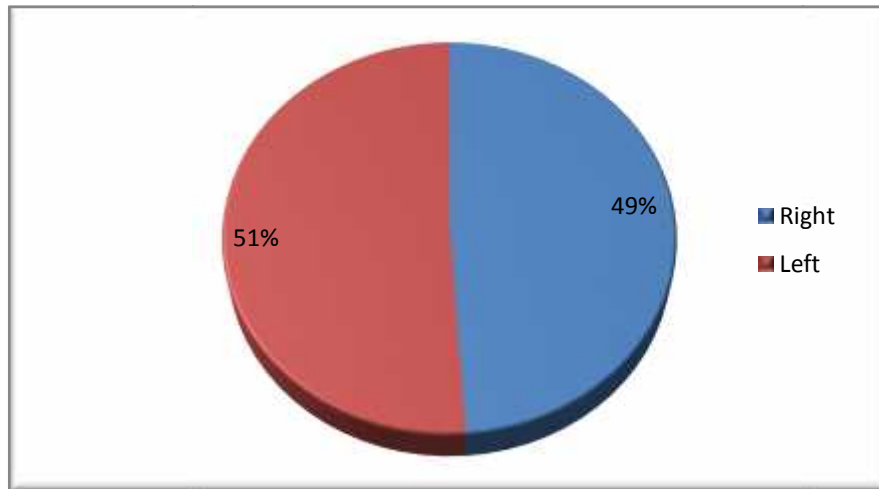
Mostly, solitary lesions were encountered. 7 cases of multiple lesions were seen followed by 4 cases of 2 lesions.

Size and shape of the lesions:

All the malignant lesions were taller than wider in our study. The length of the lesions ranged from 4 to 46 mm and width ranged from 1.4 to 48 mm with mean length being 21.25 ± 11.8 mm and mean width being 20.20 ± 11.7 mm.

Side affected (breast):

Picture 7 depicting Pie diagram of the distribution of breast lesions on the basis of side:

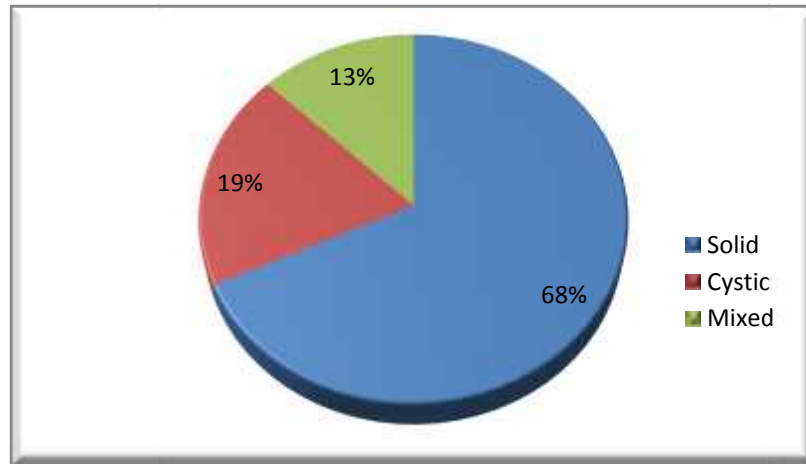


There was no significant side predilection noted with respect to breast affected by lesions in our study.

Types of lesions found:

Picture 8 depicting Pie diagram of distribution and frequency of lesions as follows

(Solid, cystic or Mixed):

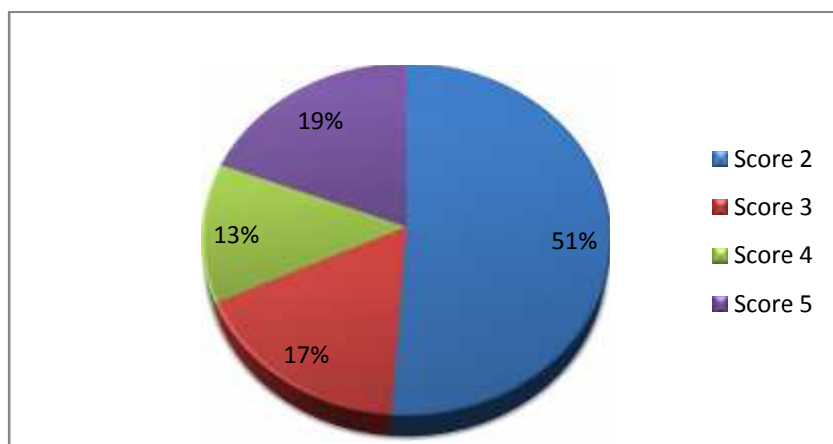


Most of the lesions found in our study were solid where Elastography is most beneficial since it has a limited role in cystic lesions.

BIRADS distribution:

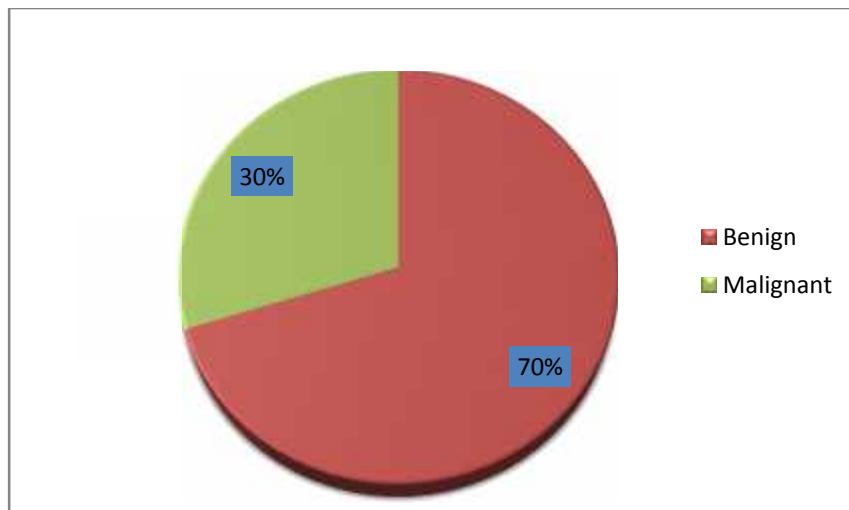
Picture 9 depicting Pie diagram of frequency and distribution of lesions according to

BIRADS categorization:



BIRADS categorization was done for all the lesions in our study. Most of the lesions (51%) fell under category 2 as they were purely “benign”. It was followed by “highly suggestive of malignancy” which accounted for 19%, “probably benign” being 17% and “suspicious abnormality” being 13%.

Picture 10 depicting Pie diagram of frequency of benign and malignant lesions according to USG (B mode):



33 cases were diagnosed to be benign and 14 cases as malignant on Ultrasound B-mode imaging in our study.

Table no. 1 Depicting distribution of lesions according to Strain Elastography

Colour:

| Strain colour | Frequency | Percentage |
|----------------------|------------------|-------------------|
| BGR | 9 | 19.1 |
| Blue | 2 | 4.3 |
| Green | 1 | 2.1 |
| Green -red | 6 | 12.8 |
| Green-blue | 15 | 31.9 |
| Red | 13 | 27.7 |
| Yellow-Red | 1 | 2.1 |

Table no. 2 depicting distribution of lesions according to Elastography scores:

| Score | Frequency | Percentage |
|--------------|------------------|-------------------|
| 1 | 4 | 8.5 |
| 2 | 17 | 34.0 |
| 3 | 3 | 6.4 |
| 4 | 1 | 2.8 |
| 5 | 13 | 27 |
| BGR | 9 | 19.1 |

According to Itoh's scoring system, the colour based evaluation of breast lesions gave an elastography scores for all the lesions. The minimum scoring given was 1 and maximum being 5 with mean score valuing at 3.73 ± 1.07 .

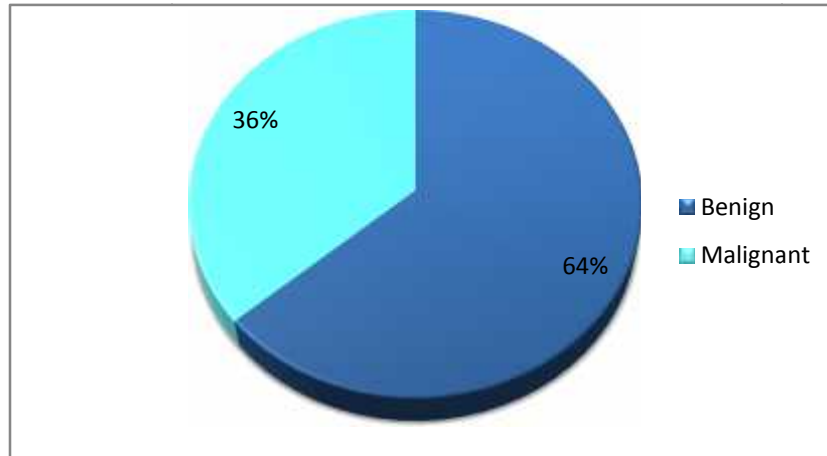
Strain ratio was calculated for all the lesions keeping the first region of interest in the lesion and the second region of interest in the surrounding normal soft tissue not at more depth than the first in the elastography field box. The values obtained in our study ranged from 0.4 to 12 with mean value being 3.6 ± 4.7 .

The shear wave elastography scores were calculated either on the basis of a single best measurement taken repeatedly for smaller lesions giving an average that was used for tabulations or by taking multiple samplings in a larger lesion over a superimposed colour map. These values ranged from 1.9 to 7 m/s with mean value being 3.2 ± 2.3 m/s.

Table no. 3 depicting classification of lesions as benign and malignant on the basis of different Elastography techniques:

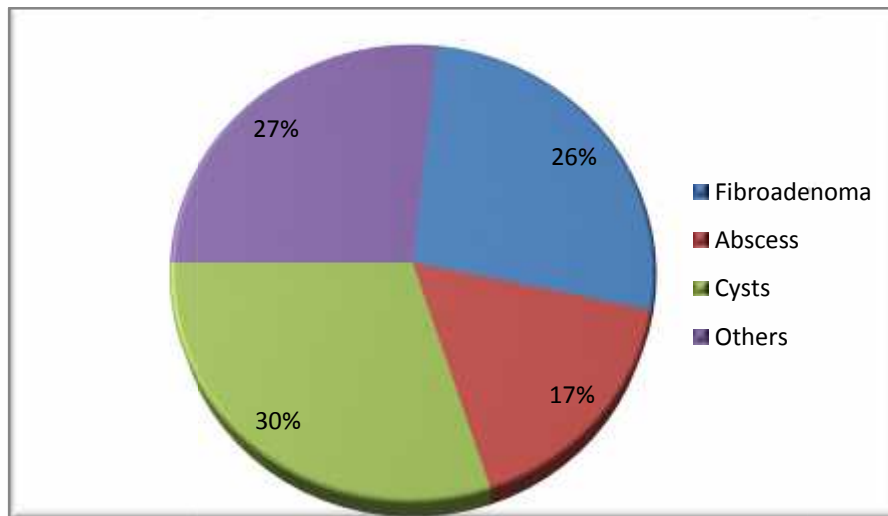
| | Elastography Score | Strain ratio | Shear wave elastography |
|-----------|--------------------|--------------|-------------------------|
| Benign | 32 | 31 | 31 |
| Malignant | 15 | 16 | 16 |

Picture 11 depicting Pie diagram of frequency of benign and malignant lesions according to pathology report:



30 cases were diagnosed to be benign and 17 cases as malignant according to pathology reports.

Picture 12 depicting Pie diagram of types of benign breast lesions (pathologically) encountered in our study:



The most commonly found benign entity was fibroadenoma, cysts and fibrocystic disease followed by abscess. Others included mastitis (3), lipoma (2), haematoma (1), fibroglandular tissue of gynaecomastia (1) and unclassified benign (1).

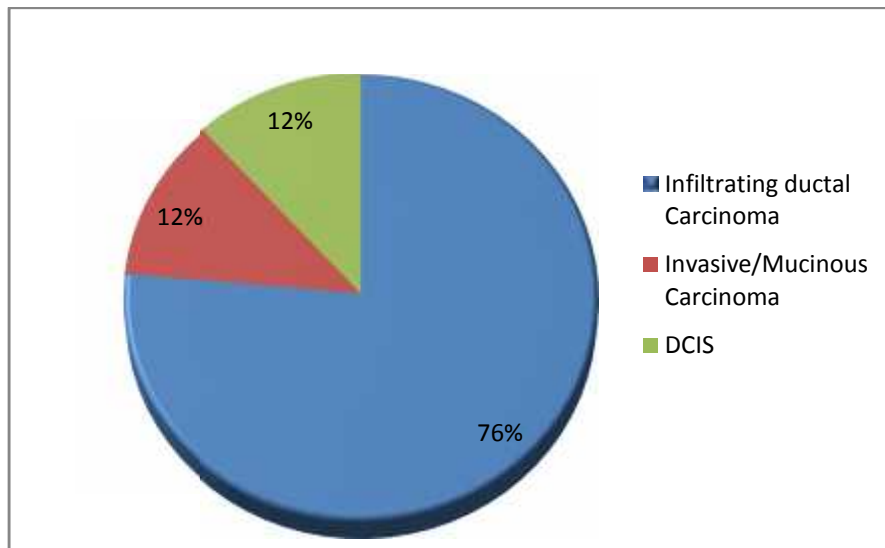
Additionally, we found that in our study that each the benign lesions had a few characteristic elastographic values. These were as follows:

Table no. 4 depicting the unique elastographic findings pertaining to each of the benign lesions:

| | Lipoma | Fibroadenoma | Cysts/Fibrocystic disease | Abscess |
|-------------------------------|---------|--------------|---------------------------|---------|
| Colour Elastography | 1-2 | 2-3 | BGR | 2 |
| Strain ratio | 0.4-1.3 | 0.4-1.6 | Very high | 2 |
| Shear wave Elastography (m/s) | 2 | 1.9-3.3 | Not applicable | 2.5-3 |

We found that cystic lesions displayed properties that were in tandem with the findings of Fleury^[49].

Picture 13 depicting Pie diagram of the distribution of malignant cases (pathologically) in our study:

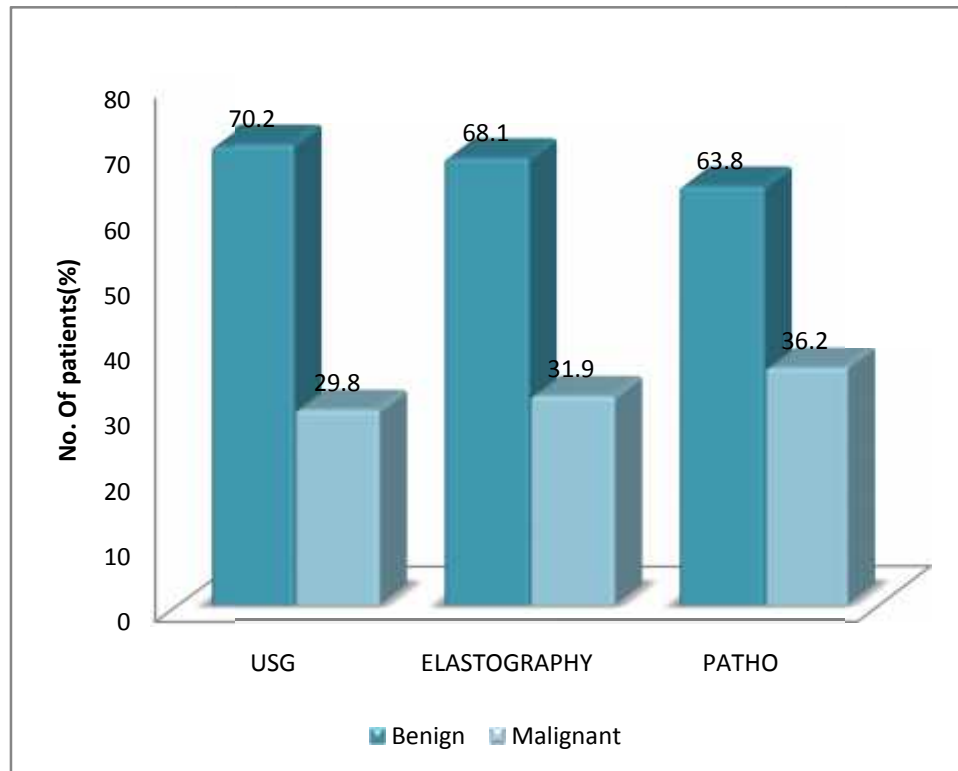


The most common condition was Infiltrating ductal carcinoma (13). Only two cases of Invasive/Mucinous Carcinoma and DCIS each were found.

Table no. 5 showing the distribution of benign and malignant lesions on different modalities including USG (B-mode), Elastography and Pathology:

| | USG | Elastography | Pathology |
|-----------|-----|--------------|-----------|
| Benign | 33 | 31 | 30 |
| Malignant | 14 | 16 | 17 |

Picture 14 depicting Bar diagram of the distribution of benign and malignant lesions on different modalities including USG (B-mode), Elastography and Pathology:



On the basis of these findings, an association table, ROC graph and sensitivity, specificity, positive predictive and negative predictive values were calculated which were as follows:

1. The relation between B-mode scanning and Pathological outcomes were of good value as described below:

With a p value of 0.0001, we found a significant co-relation between USG (B-mode) and Pathological outcome. Hence, our study proves that USG is a good modality of choice for breast cancer screening.

Table no. 6 showing Cross-tabulation between USG outcome and Pathological outcome

| USG | HPR | | Total | Chi square test |
|-----------|--------------|--------------|--------------|-----------------|
| | Benign | Malignant | | |
| Benign | 30 100.0% | 3 17.6% | 33 70.2% | P=0.0001 * |
| Malignant | 0 .0% | 14 82.4% | 14 29.8% | |
| Total | 30 100.0% | 17 100.0% | 47 100.0% | |

2. The relation between Strain Elastography colour scoring system and Pathological outcomes were of good value as described below:

With a p value of 0.0001, we found a significant co-relation between Strain Elastography colour scoring system and Pathological outcome.

Table no. 7 showing Cross-tabulation between Elastography Scoring and Pathological outcome

| Elastography Scoring | Pathology result | | Total | Chi square test |
|----------------------|------------------|--------------|--------------|-----------------|
| | Benign | Malignant | | p=0.0001* |
| Benign | 30 P=0.0001* | 2 11.8% | 32 68.1% | |
| Malignant | 0 .0% | 15 88.2% | 15 31.9% | |
| Total | 30 100.0% | 17 100.0% | 47 100.0% | |

3. The relation between Strain Ratio and Pathological outcomes were of good value as described below:

With a p value of 0.0001, we found a significant co-relation between Strain Ratio and Pathological outcome.

Table no. 8 showing Cross-tabulation between Strain Ratio and Pathological outcome

| Strain Ratio | Pathology outcome | | Total | Chi square test |
|--------------|-------------------|--------------|--------------|-----------------|
| | Benign | Malignant | | p=0.0001* |
| Benign | 29 96.7% | 2 11.8% | 31 66.0% | |
| Malignant | 1 3.3% | 15 88.2% | 16 34.0% | |
| Total | 30 100.0% | 17 100.0% | 47 100.0% | |

4. The relation between Shear wave elastography and Pathological outcomes were of good value as described below:

With a p value of 0.0001, we found a significant co-relation between Strain Ratio and Pathological outcome.

Table no. 9 showing Cross-tabulation between Shear wave elastography and Pathological outcome

| SW | Pathology outcome | | Total | Chi square test |
|----------|-------------------|--------------|--------------|-----------------|
| | Benign | Malignant | | |
| Benign | 30 100.0% | 1 5.9% | 31 66.0% | P=0.0001 * |
| Malignar | 0 .0% | 16 94.1% | 16 34.0% | |
| Total | 30 100.0% | 17 100.0% | 47 100.0% | |

Table no. 10 showing sensitivity, specificity PPV and NPV for following:

| USG | Pathology (95% CI) |
|---------------------------|--------------------|
| Sensitivity | 100% (88-100) |
| Specificity | 82% (57-96) |
| Positive predictive value | 91% (75-98) |
| Negative predictive value | 100% (77-100) |

| | ES vs Patho (95% CI) | SR vs Patho (95% CI) | SW vs Patho (95% CI) |
|---------------------------|-------------------------|-------------------------|-------------------------|
| Sensitivity | 100% (88-100) | 97% (83-99) | 100% (88-100) |
| Specificity | 88% (64-98) | 88% (64-98) | 94% (71-99) |
| Positive predictive value | 94% (79-99) | 94% (78-99) | 97% (83-99) |
| Negative predictive value | 100% (78-100) | 94% (70-99) | 100% (79-100) |

Table no. 11 showing mean benign and malignant shear wave and strain ratio values with standard deviation:

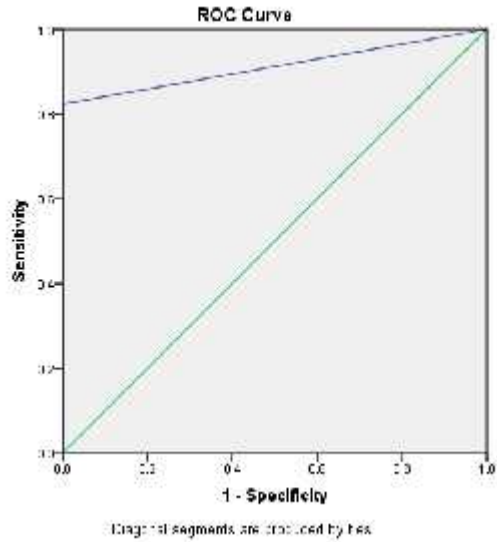
| | Mean \pm SD | | Mann Whitney U test |
|---------------------------|-----------------|---------------|---------------------|
| | Benign | Malignant | |
| Shear wave Elastography | 1.71 \pm 1.21 | 5.8 \pm 1.3 | P<0.0001* |
| Strain Elastography Ratio | 1.26 \pm 0.82 | 6.9 \pm 4.2 | P<0.0001* |

On shear wave elastography, malignant lesions had a mean elasticity values of 5.8 \pm 1.3 m/s (n=17), where as benign lesions had a mean elasticity values of 1.71 \pm 1.21 m/s (n=30). Statistically there is a significant difference between shear wave elasticity values of malignant and benign (p<0.0001).

On strain ratio elastography, the mean elasticity score for malignant lesions was 6.9 \pm 4.2 m/s (n= 17), and that for 1.26 \pm 0.82 m/s benign was (n= 30). Statistically significant difference found between strain ratio elasticity values of malignant and benign (p<0.0001).

The following depicts the Receiver operating curves for the multi-modality comparison used in our study to see whether the elastography techniques add diagnostic value to B-mode scanning.

Picture 15 showing graph of USG as a test curve represented in blue and pathology outcomes the standard value curve represented in green.



The area under this curve was inconclusive.

Picture 16 showing graph of Elastography colour scoring as a test curve represented in blue and pathology as the standard value curve represented in green.

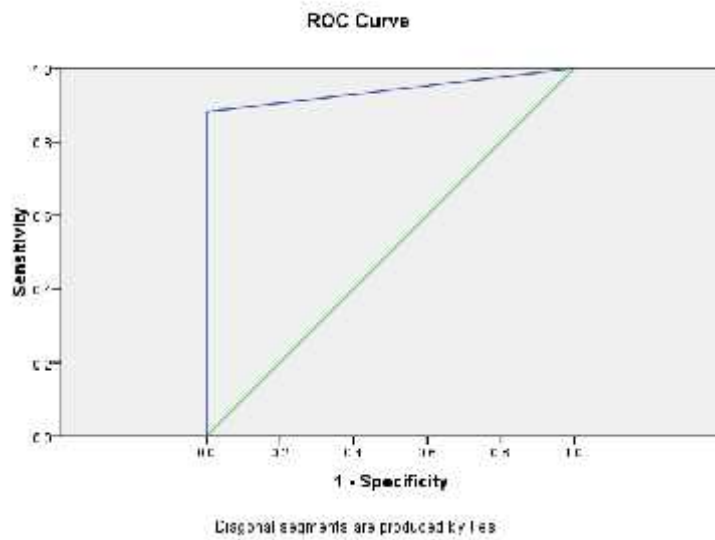


Table no. 12 depicting the Area Under the Receiver Operating Curve for ES vs Pathological outcome

Test Result Variable(s):ES

| Area | Std. Error ^a | p value* | Asymptotic 95% Confidence Interval | |
|------|-------------------------|----------|------------------------------------|-------------|
| | | | Lower Bound | Upper Bound |
| .941 | .047 | 0.0001 | .000 | 1.000 |

The table reveals that the AUROC is significant and is more than USG proving that the Elastography colour scoring system adds diagnostic value to USG in breast cancer evaluation.

Picture 17 showing graph of Strain Ratio as a test curve represented in blue and pathology as the standard value curve represented in green.

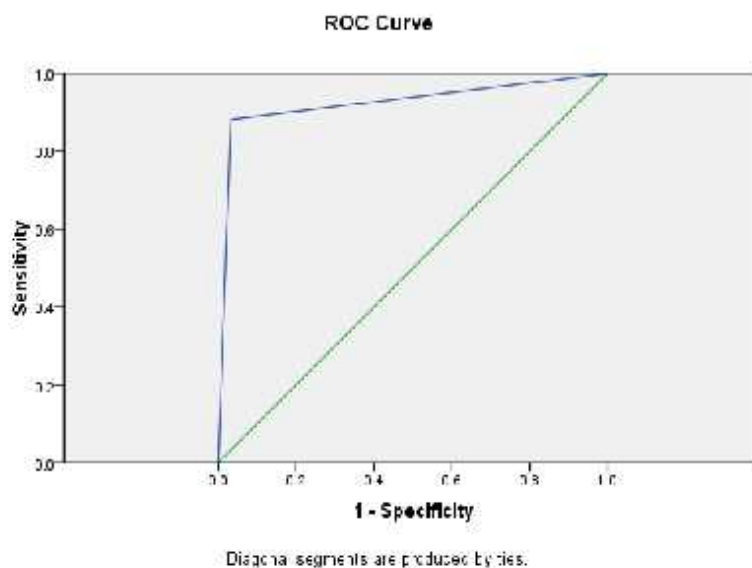


Table no. 13 showing Area Under the Receiver Operating Curve of SR vs pathology outcome

Test Result Variable(s):SR

| Area | Std. Error ^a | p value* | Asymptotic 95% Confidence Interval | |
|------|-------------------------|----------|------------------------------------|-------------|
| | | | Lower Bound | Upper Bound |
| .925 | .050 | 0.0001 | .000 | 1.000 |

The table reveals that the AUROC is significant and is more than USG proving that the Strain ratio adds diagnostic value to USG in breast cancer evaluation.

Picture 18 showing graph of Shear wave elastography as a test curve represented in blue and pathology as the standard value curve represented in green.

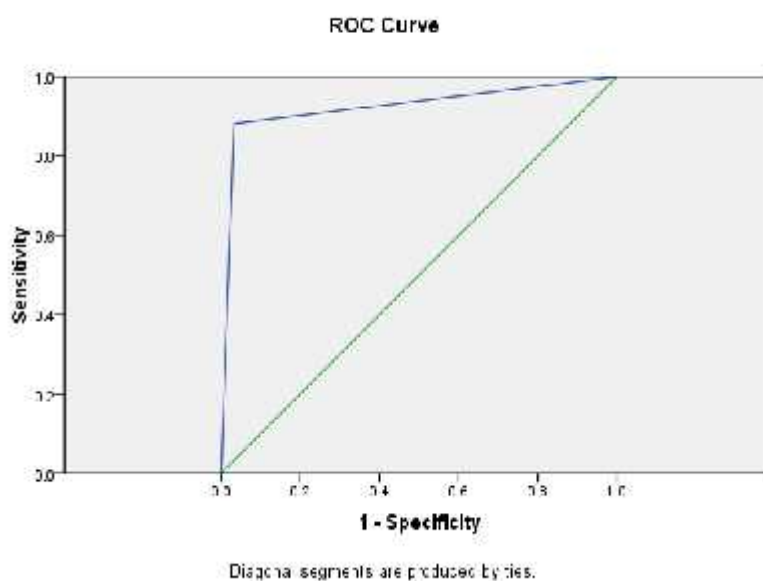


Table no. 14 showing Area Under the Receiver Operating Curve of SW vs pathology outcome

Test Result Variable(s):SW

| Area | Std. Error | p value | Asymptotic 95% Confidence Interval | |
|------|------------|---------|------------------------------------|-------------|
| | | | Lower Bound | Upper Bound |
| .971 | .034 | 0.0001* | .000 | 1.000 |

The table reveals that the AUROC is significant and is more than USG proving that the Shear wave elastography adds diagnostic value to USG in breast cancer evaluation.

Picture 19 showing graph of all the three elastography techniques as a test curves represented in yellow, blue and green (SW, ES & SR respectively) and pathology as the standard value curve represented in purple.

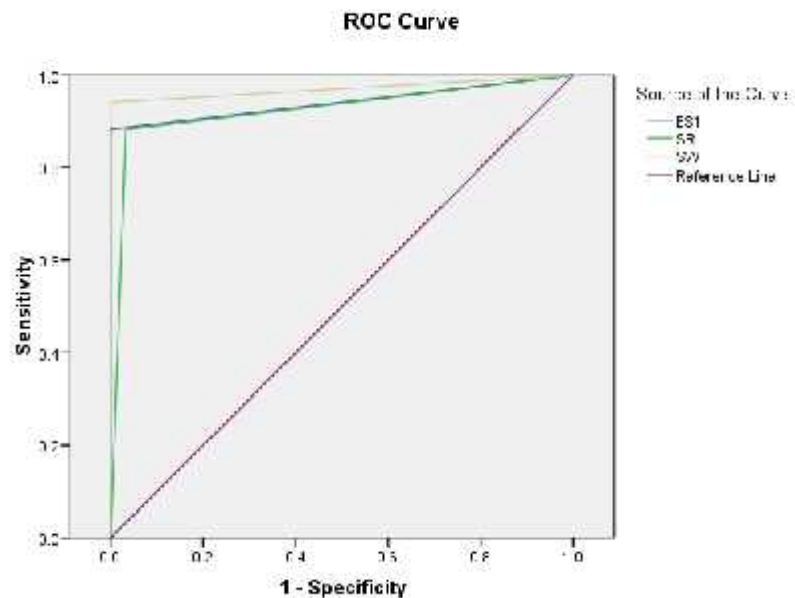


Table no. 15 showing Area Under the Receiver Operating Curve of ES,SR & SW vs Pathology outcome

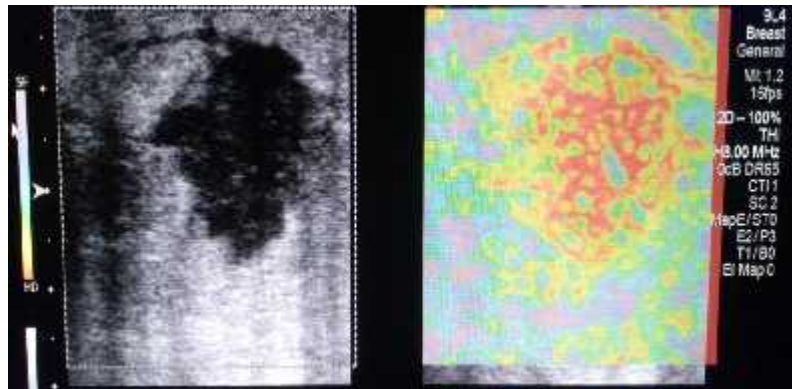
| Test Result Variable(s) | Area | Std. Error ^a | p value | Asymptotic 95% Confidence Interval | |
|-------------------------|------|-------------------------|---------|------------------------------------|-------------|
| | | | | Lower Bound | Upper Bound |
| ES | .941 | .047 | 0.0001 | .000 | 1.000 |
| SR | .925 | .050 | 0.0001 | .000 | 1.000 |
| SW | .971 | .034 | 0.0001 | .000 | 1.000 |

The table reveals that the AUROC is significant for all the elastography modalities and is more than USG. The best AUROC is for Shear wave elastography followed by Elastography colour coring and Strain ratio. The above findings prove that elastography adds diagnostic value to USG in breast cancer evaluation irrespective of the type of elastography.

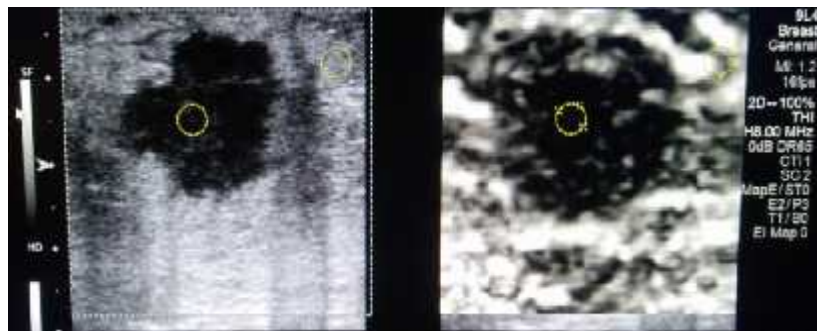
IMAGING GALLERY

CASE 1: INFILTRATING DUCTAL CARCINOMA WITH NODAL METASTASIS

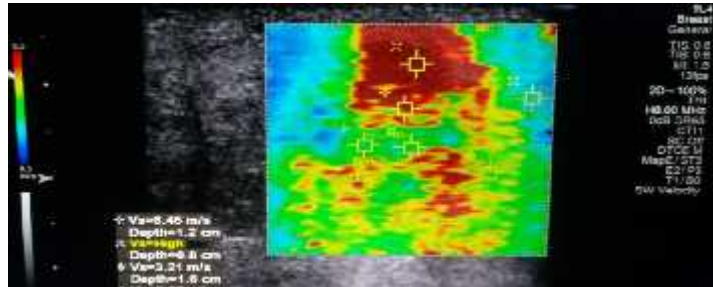
PICTURE 20 depicting irregular taller than wider hypoechoic lesion with posterior acoustic enhancement in the upper outer quadrant of right breast (BIRADS 4). Elastography Colour mapping (Red=Hard) in this lesion : SCORE 5



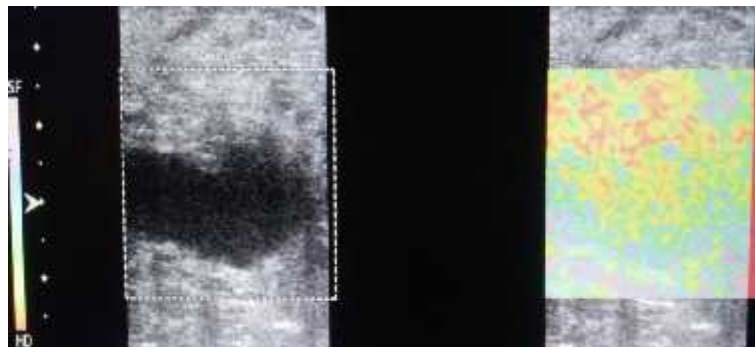
PICTURE 21 depicting Strain Ratio acquirement by ROI 1 in the lesion and ROI 2 in the surrounding soft tissue – 13.65



PICTURE 22 depicting multiple Shear Wave value acquisitions overlapping colour map image (6.45 m/s)



PICTURE 23 depicting an irregular hypoechoic lesion in the right axilla with no central echogenicity or recognizable hilar architecture of this malignant lymph nodal mass. predominantly hard on colour mapping : SCORE 4

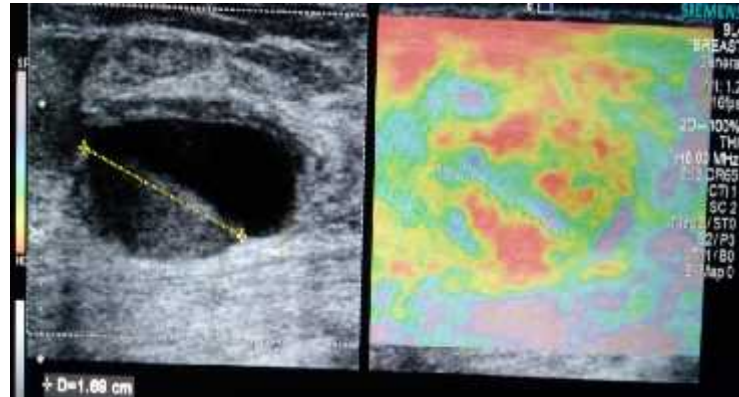


PICTURE 24 depicting Strain Ratio acquisition in the same lesion (SR=3.88)



CASE 2: COMPLEX CYST

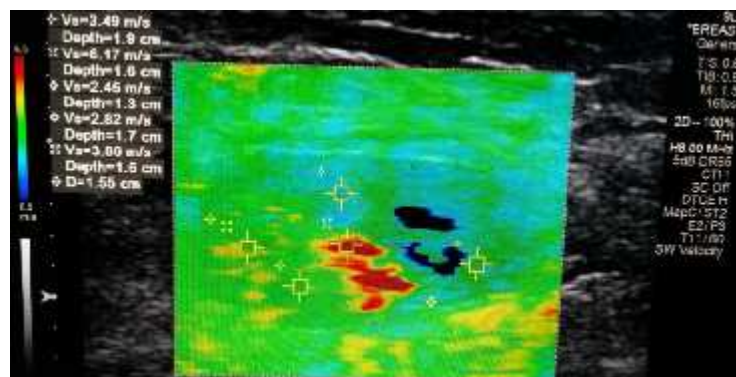
PICTURE 25 showing a well-defined wider than taller hypo to anechoic lesion with a small soft tissue component in the left breast at 3 o'clock position (BIRADS 3). Elastography Colour pattern - soft lesion-possibly debris/clot of old bleed (predominantly blue-green with central hardness) : Score 3 and BGR pattern indicating cystic nature of the lesion.



PICTURE 26 depicting Strain Ratio acquirement in the solid part of lesion (0.47)

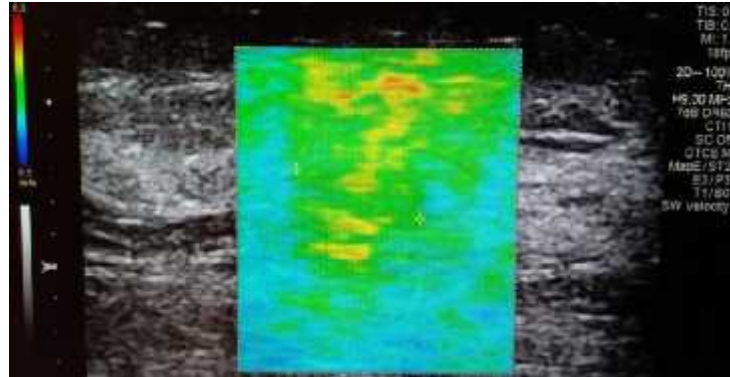


PICTURE 27 depicting Shear Wave acquirement in this lesion (3.4 m/s in solid part)



CASE 3: FIBROADENOMA

PICTURE 28 showing Elastography Colour pattern - soft lesion (predominantly green) :
SCORE 1



PICTURE 29 depicting Strain Ratio acquirement in this lesion (SR=1.07)



PICTURE 30 depicting a rounded well defined hypoechoic lesion in the glandular region of right breast with a central calcific focus (BIRADS 2). Shear Wave velocity acquirement is shown. (2.17 m/s)

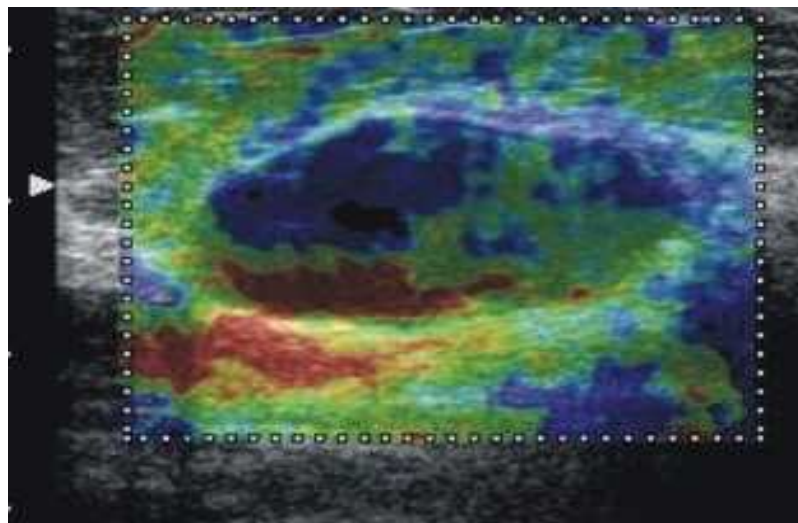


CASE 4: SIMPLE CYST

PICTURE 31 depicting a round to oval simple cystic lesion in the right breast at 9 o'clock position with typical posterior acoustic enhancement. (BIRADS 2)

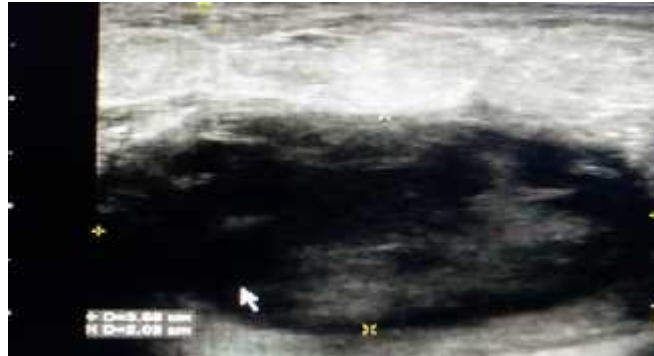


PICTURE 32 depicting typical BGR pattern on Colour Mapping Elastography

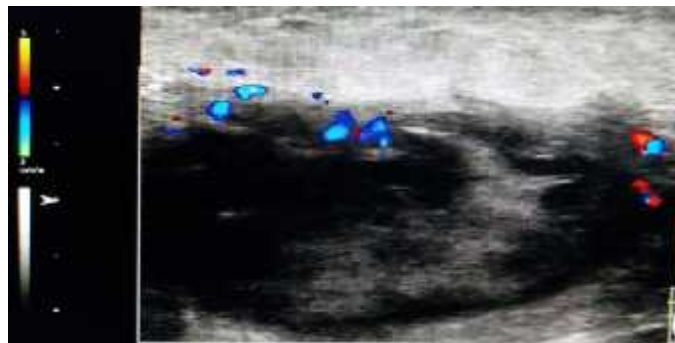


CASE 5: ABSCESS

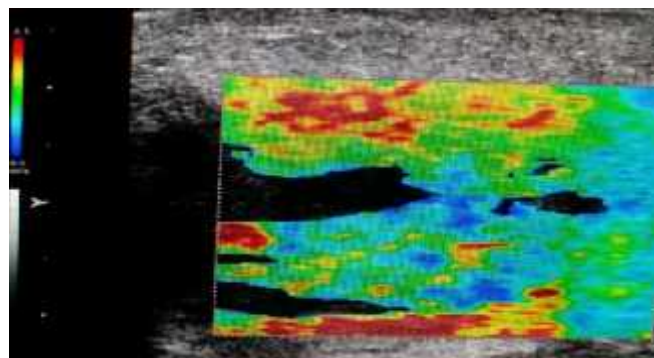
PICTURE 33 depicting a well-defined wider than taller hypoechoic lesion in the right breast in a young lactating female with echogenic contents within. (BIRADS 2)



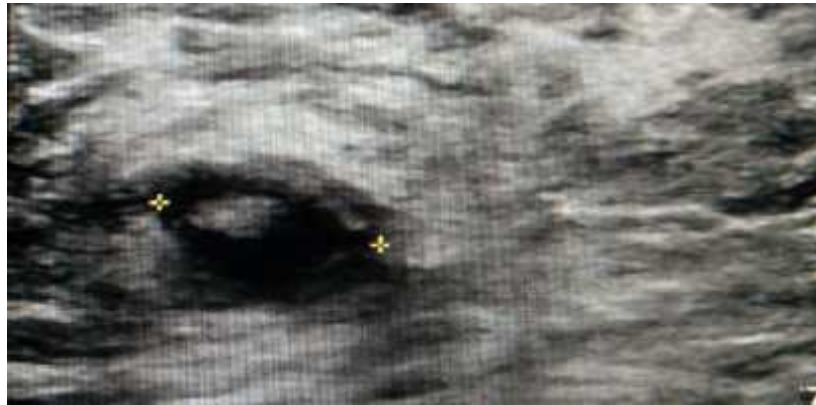
PICTURE 34 depicting the same lesion with increased peripheral vascularity typical of abscess



PICTURE 35 depicting Colour Mapping of this abscess showing predominantly green-red pattern indicating medium softness. SCORE: 3.

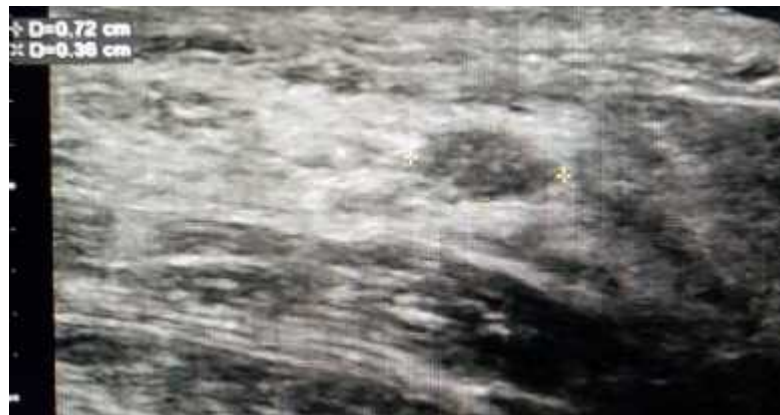


PICTURE 36 depicting a well-defined lymph node in the right axilla with central echogenicity and maintained fatty hilum indicative of benign reactive lymph node

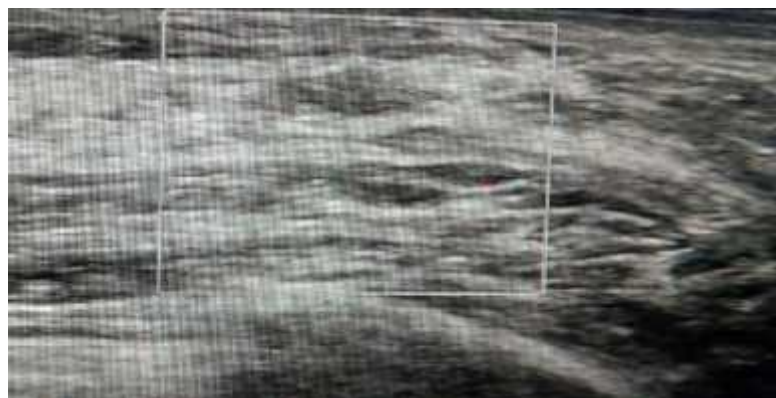


CASE 6: LIPOMA

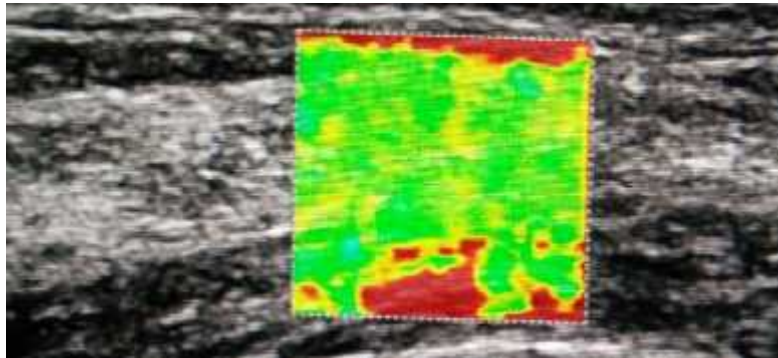
PICTURE 37 depicting a small well defined wider than taller hypoechoic lesion with no posterior through-transmission in the left breast at 6 o'clock position. (BIRADS 2)



PICTURE 38 depicting no significant colour uptake on Doppler



PICTURE 39 depicting uniform green colour mapping in the lesion and surrounding it
(SCORE: 1)



PICTURE 40 depicting a Strain Ratio of 0.41 in the lesion compared to the surrounding tissue



PICTURE 41 depicting Shear Wave value acquisition of 3.1 m/s in the lesion

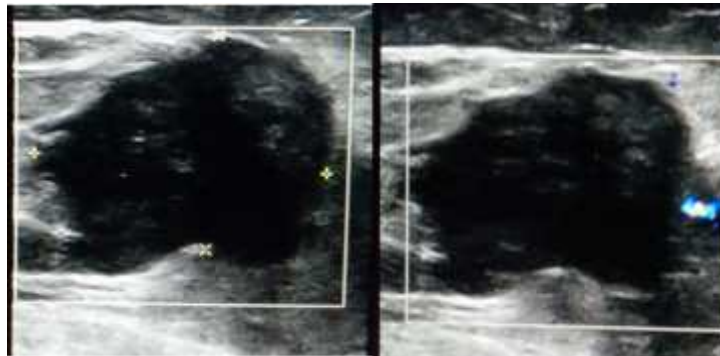


PICTURE 42 depicting a small non-reactive lymph node incidentally found in the same patient with normal hilar vascularity.

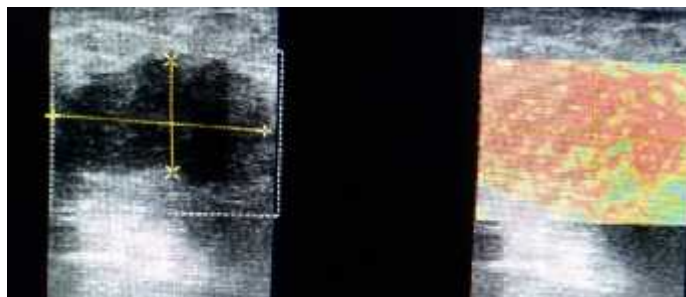


CASE 7: INVASIVE DUCTAL/MUCINOUS CARCINOMA

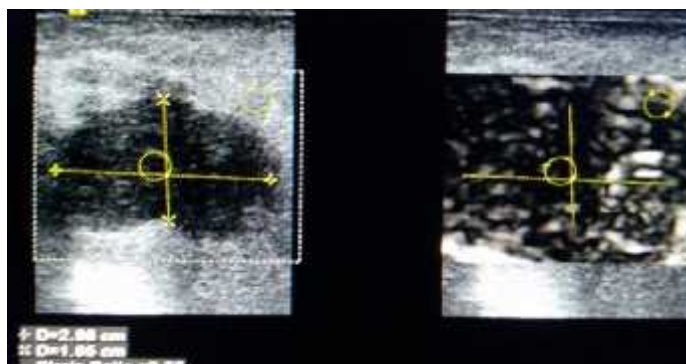
PICTURE 43 depicting an ill-defined and irregularly shaped hypoechoic lesion with peripheral hyper echogenicity in the right breast at 5 o'clock position with a peripheral feeding artery on Doppler. However, no particular through transmission is seen. (BIRADS 4)



PICTURE 44 depicting complete hardness (red) in the lesion and its surrounding
SCORE 5



PICTURE 45 depicting high Strain Ratio of the lesion (12.5)



PICTURE 46 depicting high Shear Wave velocity in the centre of the lesion (4.05)

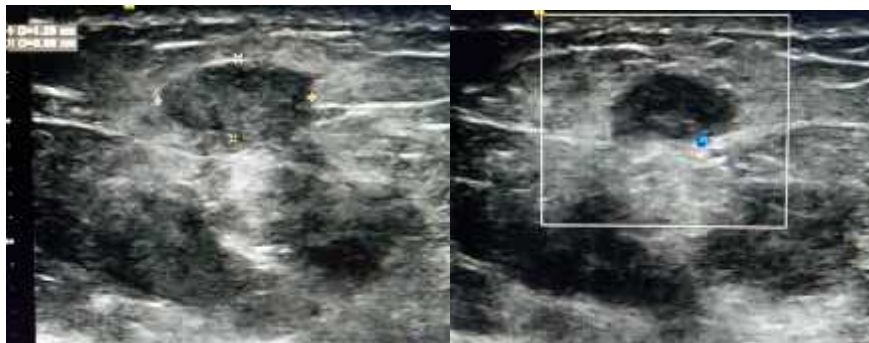


PICTURE 47 depicting an ill-defined, irregular lymph nodal mass in the right axilla with mild distortion of architectural pattern.

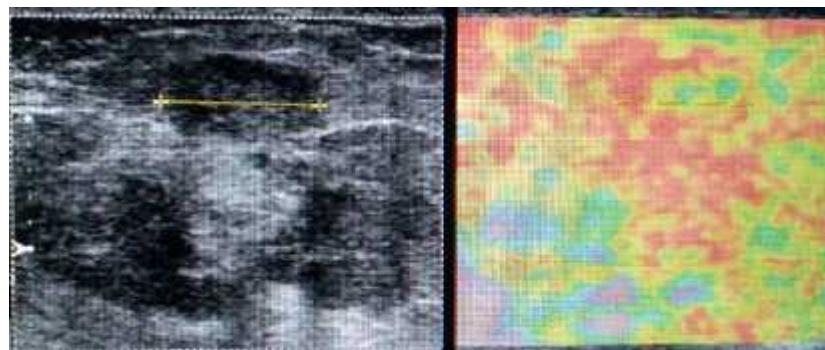


CASE 8: MULTIPLE RECURRENT FIBROADENOMAS IN A YOUNG FEMALE

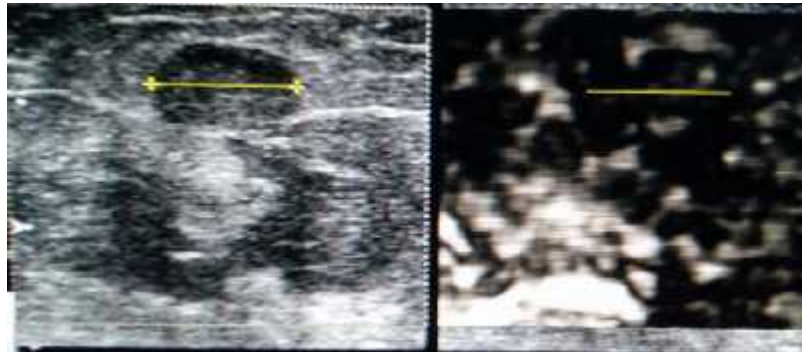
PICTURE 48 depicting multiple small well defined wider than taller hypoechoic lesion in the left breast with minimal peripheral vascularity. (BIRADS 2)



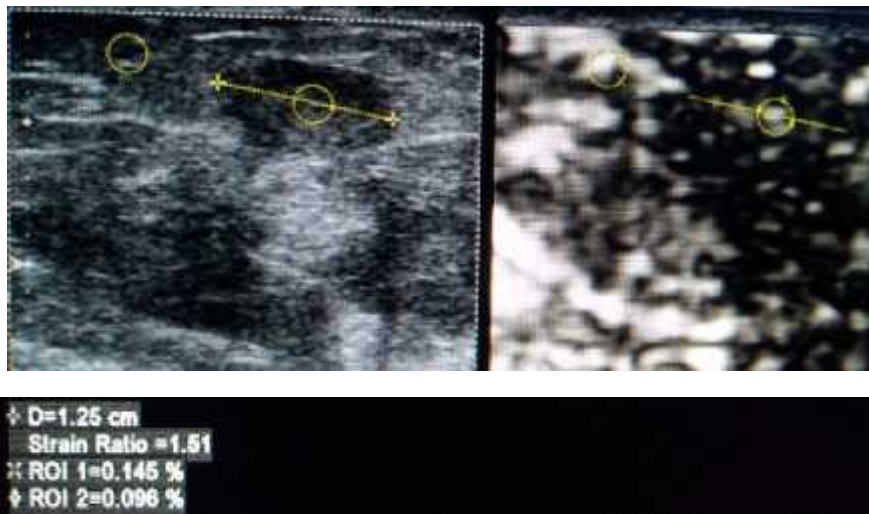
PICTURE 49 depicting soft centre (green) and peripheral, surrounding hardness (red):SCORE 3



PICTURE 50 depicting black and white Strain Mapping showing that the lesion is larger than seen on B mode scan.



PICTURE 51 depicting a Strain Ratio of benign lesion (1.51)

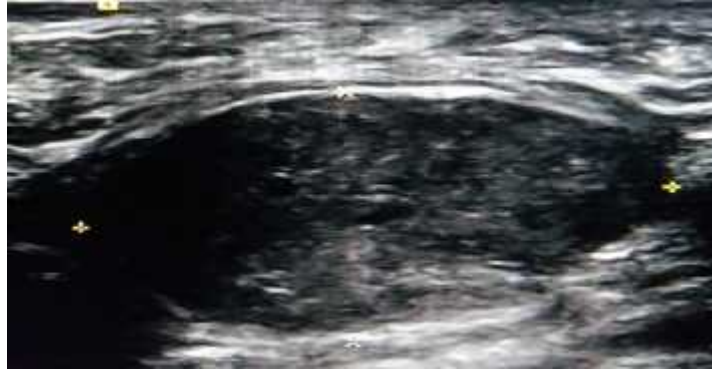


PICTURE 52 depicting Shear Wave velocity calculation of 1.06 m/s indicating benignity

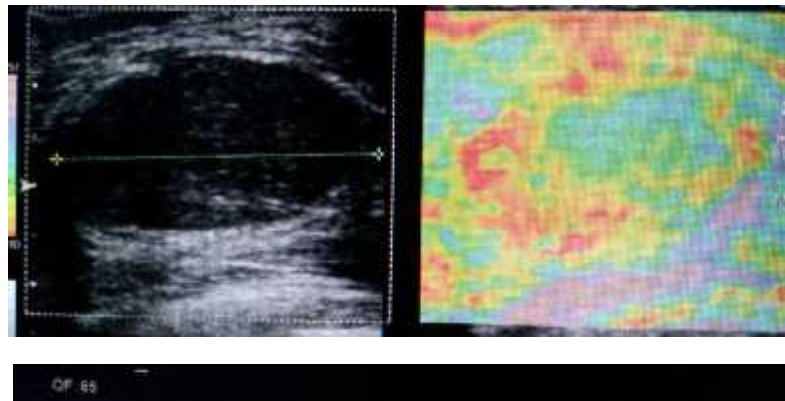


CASE 9: GIANT FIBROADENOMA

PICTURE 53 depicting a large well defined wider than taller encapsulated hypoechoic lesion in the right breast with peripheral mild hyper echogenicity and few cystic areas in the centre. (BIRADS 2)



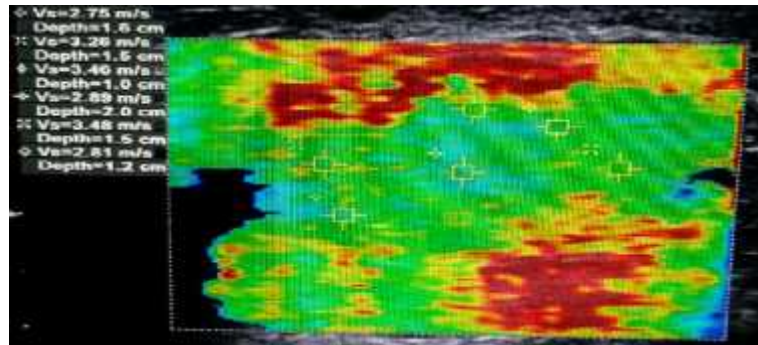
PICTURE 54 depicting a predominantly soft lesion (greenish blue) with peripheral subtle hardness (red) taken at a good quality index of 65. SCORE: 2



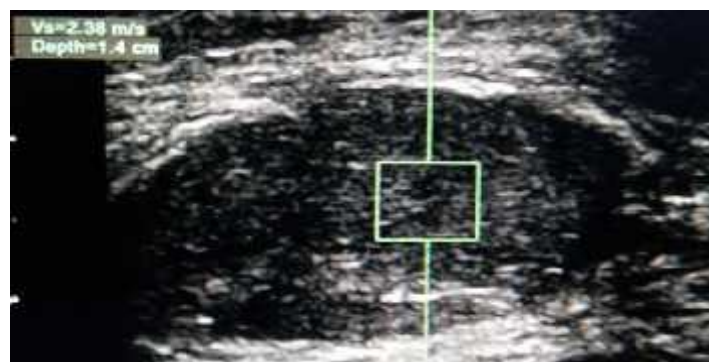
PICTURE 55 depicting a Strain Ratio of 2.1 indicative of benignity of the lesion



PICTURE 56 depicting Shear Wave velocity indices ranging from 2.7 to 3.5 m/s suggesting benign lesion

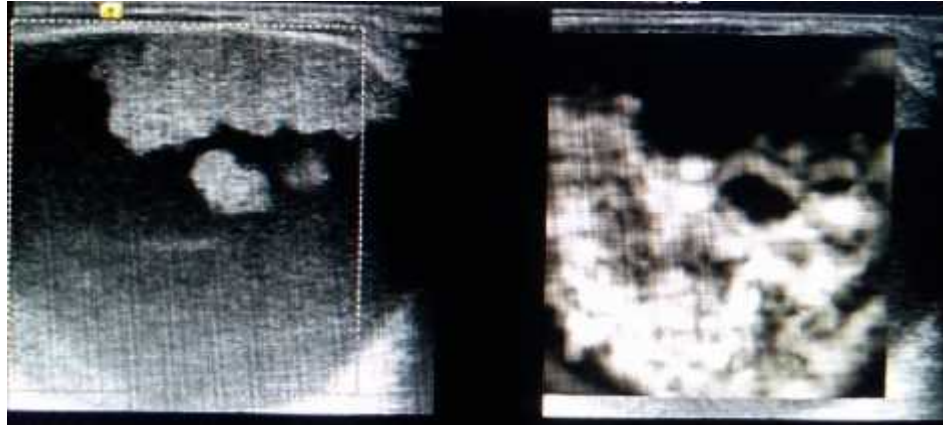


PICTURE 57 depicting a Shear Wave velocity of 2.3 m/s at the centre of the lesion.

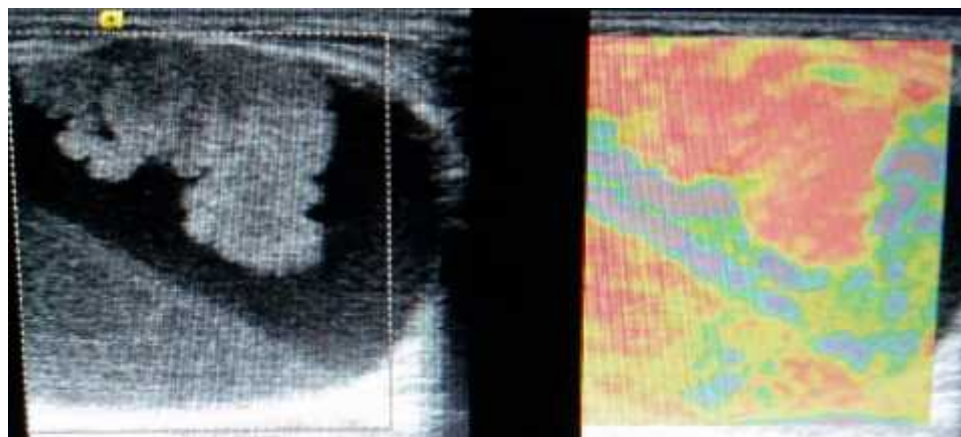


CASE 10: COMPLEX CYST WITH SOLID COMPONENT IN A MALE PATIENT POST TRAUMA

PICTURE 58 depicting a well-defined cystic lesion with layering of debris and an irregular nondependent solid component which resembles papilloma. (BIRADS 3)



PICTURE 59 depicting hard solid component and typical BGR pattern in the cystic part of the lesion.



PICTURE 60 depicting a Strain Ratio of 2.58 in the solid part of the lesion indicating benignity



PICTURE 61 depicting a Shear Wave velocity of 1.13 m/s in the solid component



DISCUSSION

Age distribution:

The age distribution of the patients in our study ranged from 11 to 80 years with the mean age being 40.87 ± 17.16 years. Most of the patients in our study were in the third decade of life followed by fourth, fifth and seventh decades. This goes on to say that breast lesions can occur at any age, mostly post menarche to old age and predominantly in the third decade of life.

Side predilection:

There was no side predilection noted in our study which was hand in hand with findings of Shu Yi Tan^[52] and Steven D. Allen^[53].

Distribution of cases as solid, cystic or mixed:

Most of the lesions found in our study were solid (32 cases) followed by cystic (9 cases) and lastly mixed type which included haematoma and abscesses (6 cases). Elastography is most beneficial and accurate in characterization of solid lesions and has a limited role in cystic type of lesions.

Distribution of cases into benign and malignant:

30 cases (64%) were diagnosed to be benign and 17 cases (36%) as malignant according to pathology reports. This coincided with the theory discussed in the introduction that most of the lesions turn out to be benign as stated by Kumm^[39],

Navarro^[40] and Chang^[46] whose results also revealed more benign lesions than malignant in a standard urban tertiary care centre.

Distribution of both benign and malignant Pathologies:

The most frequently encountered benign masses were fibroadenoma and fibrocystic lesions in our study. The most common malignant lesion found was invasive/infiltrating ductal carcinoma followed by DCIS. These findings were in keeping with the study conducted by Ya tu^[42].

Role of B-mode USG in diagnosis of breast lesions:

Ultrasound structure of breast is often homogeneous with a large variability of echogenicity depending on the type of breast tissue, age and the menstrual cycle. Vascularization is also variable and dependent on the same as above. USG is very sensitive in case of picking up lesions but not as much in characterization as described above in literature review and our study results. However, features like size, shape, presence of calcifications, posterior acoustic features, vascularity and location have a very important role in diagnosis as these features are the basis of BIRADS classification [34].

Malignant lesions usually present with features such as acoustic shadow, spicules, indented margins, hyperechogenic halo with desmoplastic reaction around the lesion, calcifications, spreading along the ducts and significant vascularization. Cancer can also have nonspecific features such as uneven architecture and gland oedema.

Most of the times, USG is the screening modality more than mammography because of its ionising radiation. As a screening modality, USG is a very good choice as its sensitivity is high. However, it falls short in characterization of the so called borderline lesions which fall under BIRADS 3 and 4 categories as the ultrasonographic features are not enough to confidently put off biopsy and follow up. Elastography can come to play an important role in such instances because of their predictability towards malignancy is higher and more accurate (higher sensitivity and specificity than USG alone as shown in results). An unnecessary biopsy/FNAC and constant need for follow up which causes anxiety in women can be accurately predicted.

Diagnostic value of BIRADS and Elastographic scoring and Strain ratio:

BIRADS classification is the most widely used way of reporting in breast lesions and used by almost all the authors which were reviewed in our literature with few studies undertaking elastography correlation using different techniques like Elastography colour scoring proposed by Itoh^[47] which is considered to be the primary and most reliable colour scoring system. However, few authors like Navarro^[40] scored their colour elastographic images according to the Ueno classification as 1 to 5 (1–3, benign; 4 and 5, malignant).

A significant co-relation between USG (B-mode) with Doppler and Pathological outcome was noted in our study with sensitivity and NPV of 100% and specificity and PPV of 82% and 91% respectively. This goes on to underline the fact that USG is a good modality of choice for breast cancer screening as stated by Andrew Evans^[45]. Although

lesions are picked up on USG, due to its limited specificity, predicting malignancy takes a back seat.

The relation between Strain Elastography colour scoring system and Pathological outcomes were of good value with sensitivity and NPV being 100%. A good specificity and PPV was also noted. This was in keeping with the opinion of Hui Zhi^[37] A. Thomas^[38].

The relation between Strain ratio and Pathological outcomes were of good value too with sensitivity being 97% and NPV being 94%. A specificity 88% and PPV 94% with AUROC for ES being 0.94 and SR being 0.92 indicating Specificity and PPV of both the modalities are equal. However, sensitivity and NPV of ES is more than SR in our study.

Kumm^[39] differinglly stated that sensitivity of SR and specificity of ES was better although both of these modalities are highly user dependent and both the studies were undertaken by inexperienced operators.

Advantages and disadvantages of the Strain and Shear wave Elastography techniques:

Goddi^[44] stated that Strain imaging elastography is useful in the assessment of elastic tissue properties owing to its short examination time required, real-time display, immediate interpretation and limited cost. Also, the criteria adopted in the image interpretation i.e. Colour scoring proposed by various pioneers like Itoh and Ueno have proven to be adequate in clinical practice.

However, the limitation lies in the fact that it is an exclusively qualitative method and may depend on histotype and lesion size. Additionally, it is an operator dependent technique which requires special training and the use of semi-quantitative indices like strain ratio does not improve the performance of the method and does not reduce interoperator variability.

These limitations of real-time elastography can be compensated by shear wave elastography, which is a quantitative method providing a more accurate assessment of the spatial distribution of tissue stiffness. However, shear wave elastography faces problems in measuring shear wave velocity in very stiff breast lesions where the velocity is depicted as very high. In these types of tumors strain elastography has demonstrated a high sensitivity which can compensate for the limitations of shear wave elastography.

Diagnostic value of Shear wave velocity:

The relation between Shear wave elastography and Pathological outcomes were of good value with sensitivity and NPV being 100%. A good specificity and PPV of 94% and 97% was also noted. This was keeping in opinion of Evans^[45] and Michael Golatta^[51].

However, as Dan-Dan Li, Hui-Xiong Xu, Bo-Ji Liu, Xiao-Wan Bo, Xiao-Long Li & Rong Wu^[50] concluded that factors like depth and posterior features help in a better diagnosis rather than using elastographic techniques alone.

Both strain ratio and shear wave elastography showed a statistically significant difference between benign and malignant lesions. The above findings prove that

elastography adds diagnostic value to USG in breast cancer evaluation irrespective of the type of elastography.

Our conclusion was in keeping with Cho et al that the diagnostic performance of shear-wave and strain elastography was similar. Either elastography technique can improve overall diagnostic performance in the differentiation of benign and malignant lesions when combined with B-mode ultrasound.

However, the sensitivity and specificity of shear-wave and strain elastography were different according to lesion histologic profile, tumour grade, and breast thickness.

Role of Elastography in diagnosis of breast lesions at present times- Advances and Limitations:

Elastography is most useful in uncertain breast lesions which are usually classified as BI-RADS 3 and 4 by upgrading a mass of low suspicion that would otherwise be sent for biopsy (BI-RADS 3) or downgrading a lesion classified as BI-RADS 4A. Hence it increases confidence of diagnosis with its higher specificity. However, it does not change protocol in cases of BI-RADS 1, 2, and 5 lesions. ^[54]

Moreover, elastography only has an ancillary role of elastography in the differentiation of benign and malignant breast masses of any size. Hence, it is recommended to start investigating a breast lesion with high-quality conventional breast B-mode ultrasound and to apply then elastography if clinically needed. ^[55,56]

Tumour stiffness is a characteristic feature of extracellular matrix which is dependent on collagen cross-linking. Hence, malignant lesions which have high

unchecked cellularity and less matrix show poor deformation by pressure than normal breast tissue and have a more complex elastic modulus.

Softer malignant lesions like medullary, mucinous, papillary, cystic and some necrotic infiltrating ductal carcinomas, are uncommon^[31,32] and are difficult to characterize on the basis of qualitative elastography due to their lack of characteristic features and variable contents. Also there have been no studies dedicated to defining elastographic features of these lesions yet.

The settings where Elastography has a limited role or falls short of its usual benefit over B-mode USG are when examining different types of breasts where gland components vary are as follows:

1. Absence of a capsule that allows containing compressing tissues makes the lesion seem softer than it is like in the case of a lipoma where there is only a pseudocapsule making it difficult to differentiate from the surrounding fatty parenchyma.
2. When characteristics of different lesions are highly variable, it is often difficult to differentiate features of benignity or malignancy especially when they do not match to their elasticity as in cases of cysts, necrosis and fibroadenomas.^[57]
3. Cysts are often hard in appearance and show low deformability, commonly represented with a blue green red pattern at the colour map and with a high strain ratio because of their low compressibility and hence were not quantified in our study.
4. The elastographic properties of fibroadenomas are usually variable, because of a substantial difference of fibrotic components in the lesion itself and the surrounding

breast tissue. Hyalinized and necrotic giant fibroadenomas are examples of such cases. Sometimes, fibroadenomas are difficult to evaluate by colour map because of similar elasticity to the breast tissue. Strain ratio usually ranges around 2.1 ± 0.8 for fibroadenomas.^[58] Fibroadenomas with larger fibrotic component and poor cellularity can have a suspicious colour map, but in all cases the strain ratio is lower than malignant forms.

There is ambiguity on reference parameters and the vague guidelines particularly regarding the need for adequate surrounding healthy parenchyma (vessels, fluid lesions including cysts, bone structures, etc.) that must be localized at the same depth of lesions to gain a right comparison in the region of interest. Few studies report any patient-specific lesion depth from breast surface, lesion size, and palpability to acquire reproducible and reliable results. Even quantification of static compressions influence and the influence it has on diagnostic accuracy is lacking due to which a failure to capture shear wave may occur. For example, the deformation or hardness ratios between two regions are usually not proportional to the theoretical ratios. Hence, only a numerical grading is inadequate. Instead analysis that allows classification as greater than 1 (harder) and less than 1 (softer) could be used as a NPV for malignant lesions and could prove to be more reliable.^[59]

On the other hand, there is no indisputable correlation between ratios of the diameter of the nodule in B mode and its diameter measured on the elastogram and also does not help in clear demarcation between soft and hard lesions.

There is also no consensus as to the best technique or classification of elastography.

Elastography like other ultrasound techniques is operator dependent and it requires some experience to obtain reproducible results i.e., it has a learning curve.

Finally, only a few studies described correlation between histological features and elastographic patterns, so the diagnostic and clinical performance of elastography in different kinds of lesions is not completely known to date.

Findings unique to our study:

We found that lipomas were the softest benign lesions, almost comparable and undisguishable from the surrounding breast parenchyma.

Fibroadenomas and abscesses had nearly comparable elastographic scores and values. The measurements in cases of abscesses which are primarily cystic areas were taken in the solid component or debris. If abscess is to be considered as cystic, then the SR and SW values should be very high. But they were the same as fibroadenomas. This could not be explained as it was in contradiction to the fact that abscesses are harder because their thick surrounding inflammation and capsules. Fibroadenomas are softer due to presence of a pseudo capsule. Even if abscesses are considered as predominantly cystic lesions, their quantitative values should have been higher than the fibroadenomas.

Limitations of the study:

Ya tu^[42] concluded that Elastography is not a method that can replace conventional breast ultrasound for detecting breast cancer, however it may be an adjunct to conventional ultrasound by increasing its diagnostic power.

Keeping in view the greater good and desire for a more accurate result, pathological interventions were recommended for most of the patients in our study so that a correlative study helps in recognising the role of Elastography in a small population set. Since ours was a pilot study with an inexperienced operator, there was a learning curve in which the initial cases were discarded as the results were thought to be inaccurate. Moreover, our exclusion criteria stated that cases without pathological evaluation would be discarded.

Future needs:

Rigorously designed and adequately powered large scale studies regarding Elastography is needed to seal its role in breast cancer evaluation by determining most appropriate cut-off points of strain or velocity in ultrasound systems by different manufacturers, and finally to assess the test performance across different lesion sizes and depths from breast surface. These efforts have taken off in the recent years and are progressing at a good pace.

CONCLUSION

1. 30 cases (64%) were diagnosed to be benign and 17 cases (36%) as malignant in our study.
2. The most common benign lesions were fibroadenoma and malignant lesion was invasive/infiltrating ductal carcinoma.
3. USG is a good modality of choice for breast lesion identification but has a limited role in predicting malignancy.
4. Sensitivity of ES and specificity of SR was better in our study.
5. Advantages of Strain imaging elastography are: lesser time consumption, real-time display, immediate interpretation and limited cost. It is better than shear wave technique in very stiff breast lesions.
6. The disadvantages of Strain imaging elastography are: it is an operator dependent technique which requires special training and is an exclusively qualitative method.
7. Advantages of shear wave elastography are: It is a quantitative method providing a more accurate assessment of the spatial distribution of tissue stiffness, non-operator dependent and is reproducible.
8. The disadvantages of shear wave elastography are: depending on histotype and lesion size, very high velocity values especially in stiffer lesions are not calculated.
9. B-mode factors like depth and posterior features help in a better diagnosis rather than using elastographic techniques alone.
10. Both strain ratio and shear wave elastography showed a statistically significant difference between benign and malignant lesions.
11. The diagnostic performance of shear-wave and strain elastography was similar.

12. The sensitivity and specificity of shear-wave and strain elastography were different according to lesion histologic profile, tumour grade, and breast thickness.

SUMMARY

The basic objective of breast cancer screening is to detect cancer in its early stages for a better prognosis. Equally important is the need to avoid unnecessary biopsies. Both the strain elastography techniques (ES and SR) are of comparable value but are qualitative and operator dependent. The diagnostic performance and accuracy of shear-wave and strain elastography was similar. B-mode factors like depth and posterior acoustic features help in a better diagnosis rather than using elastographic techniques alone.

Elastography is not a method that can replace conventional breast ultrasound for detecting breast cancer; however it may be an adjunct to conventional ultrasound by increasing its diagnostic capacity. Elastography helps reduce the need for biopsy in most of the breast lesions identified on US image and postpone follow-up.

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ETHICAL COMMITTEE CLEARANCE CERTIFICATE

PROFORMA

“Role of Elastography in evaluating breast lesions”

Hospital Number:

1. Name:

2. Age:

3. Sex:

4. Relevant history & physical examination:

5. Ultrasound Findings:

Benign/Malignant

BIRADS-

6. Elastography findings:

Elastography Score-

Strain Ratio-

Shear wave-

7. Pathology Report (FNAC/HPR):

CONSENT FORM

TITLE OF RESEARCH:

“Role of Elastography in evaluating breast lesions”

GUIDE : _____

P.G. STUDENT : _____

PURPOSE OF RESEARCH:

I have been informed that the purpose of this study is to assess the role of Elastography in differentiating benign and malignant breast lesions.

PROCEDURE:

I understand that I will undergo history, clinical examination, ultrasonographic/elastographic examination and FNAC/Histopathological follow up.

RISKS AND DISCOMFORTS:

I understand that there is no risk involved and I may experience mild pain during the above mentioned procedures.

BENEFITS:

I understand that my participation in this study will help to assess the role of Elastography in evaluating breast lesions.

CONFIDENTIALITY:

I understand that the medical information produced by the study will become a part of hospital record and will be subjected to confidentiality and privacy regulations of hospital. If the data is used for publications the identity of the patient will not be revealed.

REQUEST FOR MORE INFORMATION:

I understand that I may ask for more information about the study at any time.

REFUSAL OR WITHDRAWAL OF PARTICIPATION:

I understand that my participation is voluntary and I may refuse to participate or withdraw from study at any time

INJURY STATEMENT:

I understand in the unlikely event of injury to me during the study I will get medical treatment but no further compensations. I will not hold the hospital and its staff responsible for any untoward incidence during the course of study.

I have read the foregoing information, or it has been explained to me in my own language. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant_____

Signature of Participant / *Thumb print of participant*

KEY TO MASTER CHART

USG : ULTRASONOGRAPHY

FOR USG, ELASTOGRAPHY AND PATHO:

1 : BENIGN

2 : MALIGNANT

M : MALE

F : FEMALE

NUMBER OF LESIONS :

1-ONE

2-TWO

3-MULTIPLE

ES : ELASTOGRAPHY SCORE

SR : STRAIN RATIO

SW : SHEAR WAVE

BGR : BLUE GREEN RED

PATHO : HISTOPATHOLOGY REPORT/FNAC

UE : ULTRASOUND ELASTOGRAPHY

MASTERCHART

| Serial NO. | Pt Name | OP/IP No. | Age (years) | Sex | Side | Size (mm) | No. of lesions | BIRADS | USG | ES | SR | SW | Patho |
|------------|----------------|-----------|-------------|-----|------|-----------|----------------|--------|-----|----|----|----|-------|
| 1 | Sharanawwa K C | 27304 | 60 | F | R | 12 x 6 | 1 | 4 | 1 | 1 | 2 | 2 | 2 |
| 2 | Kanyakumari | 239299 | 17 | F | L | 30 x 29 | 3 | 2 | 1 | 1 | 1 | 1 | 1 |
| 3 | Basayya H | 24649 | 60 | M | R | 26 x 28 | 1 | 3 | 1 | 1 | 1 | 1 | 1 |
| 4 | Pramila | 257794 | 51 | F | L | 30 x 22 | 2 | 4 | 2 | 2 | 2 | 2 | 2 |
| 5 | Seema M | 71137 | 46 | F | R | 6 x 90 | 1 | 2 | 1 | 1 | 1 | 1 | 1 |
| 6 | Jayashree C | 429631 | 50 | F | R | 4 x 90 | 3 | 2 | 1 | 1 | 1 | 1 | 1 |
| 7 | Dr Renuka | 14536 | 35 | F | R | 20 x 35 | 1 | 2 | 1 | 1 | 1 | 1 | 1 |
| 8 | Shobha G | 67617 | 36 | F | R | 16 x 20 | 2 | 2 | 1 | 1 | 1 | 1 | 1 |
| 9 | Kamlesh H | 69829 | 55 | F | R | 33 x 28 | 1 | 4 | 2 | 2 | 2 | 2 | 2 |
| 10 | Bharti B | 73878 | 26 | F | L | 9 x 8 | 2 | 2 | 1 | 1 | 1 | 1 | 1 |
| 11 | Sangamma | 75374 | 48 | F | L | 34 x 42 | 1 | 4 | 2 | 2 | 2 | 2 | 2 |
| 12 | Sujata S | 80373 | 25 | F | L | 22 x 13 | 1 | 3 | 1 | 1 | 1 | 1 | 1 |

| | | | | | | | | | | | | | |
|----|---------------|--------|----|---|---|---------|---|---|---|---|---|---|---|
| 13 | Vidya S | 95085 | 23 | F | L | 23 x 25 | 1 | 3 | 1 | 1 | 1 | 1 | 1 |
| 14 | Gangabai | 9087 | 66 | F | R | 46 x 42 | 1 | 5 | 2 | 2 | 2 | 2 | 2 |
| 15 | Sunanda K | 105005 | 40 | F | L | 22 x 13 | 1 | 3 | 1 | 1 | 1 | 1 | 2 |
| 16 | Sharanamma N | 108875 | 80 | F | R | 14 x 18 | 1 | 2 | 1 | 1 | 1 | 1 | 1 |
| 17 | Gangawati | 114626 | 46 | F | L | 42 x 33 | 1 | 5 | 2 | 2 | 2 | 2 | 2 |
| 18 | Shirin | 20449 | 31 | F | R | 16 x 20 | 1 | 2 | 1 | 1 | 1 | 1 | 1 |
| 19 | Sushila K | 176654 | 48 | F | L | 38 x 34 | 1 | 5 | 2 | 2 | 2 | 2 | 2 |
| 20 | Shakuntala K | 31266 | 46 | F | R | 17 x 18 | 3 | 2 | 1 | 1 | 1 | 1 | 1 |
| 21 | Neelamma | 324972 | 60 | F | L | 26 x 21 | 1 | 3 | 1 | 2 | 1 | 2 | 2 |
| 22 | Vijayalaxmi A | 32979 | 20 | F | L | 40 x 48 | 3 | 3 | 1 | 1 | 1 | 1 | 1 |
| 23 | Sumangala | 5793 | 32 | F | L | 8 x 4 | 1 | 3 | 1 | 1 | 1 | 1 | 1 |
| 24 | Nirmala | 62899 | 38 | F | R | 20 x 19 | 1 | 5 | 2 | 2 | 2 | 2 | 2 |
| 25 | Rubina | 46378 | 38 | F | R | 26 x 32 | 1 | 5 | 2 | 2 | 2 | 2 | 2 |
| 26 | Indrabai | 8472 | 80 | F | R | 12 x 22 | 1 | 4 | 2 | 2 | 2 | 2 | 2 |
| 27 | Jyoti R | 10963 | 28 | F | L | 26 x 17 | 1 | 5 | 2 | 2 | 2 | 2 | 2 |

| | | | | | | | | | | | | | |
|----|----------------|--------|----|---|---|-----------|---|---|---|---|---|---|---|
| 28 | Gourabai K | 25617 | 60 | F | L | 32 x 28 | 1 | 5 | 2 | 2 | 2 | 2 | 2 |
| 29 | Kamalavva | 162155 | 38 | F | L | 36 x 27 | 1 | 5 | 2 | 2 | 2 | 2 | 2 |
| 30 | Parveen | 161984 | 25 | F | R | 25 x 23 | 1 | 2 | 1 | 1 | 1 | 1 | 1 |
| 31 | Dr I R Kumari | 146237 | 54 | F | L | 9 x 4 | 2 | 2 | 1 | 1 | 1 | 1 | 1 |
| 32 | Parvati D | 13038 | 45 | F | R | 22 x 12 | 1 | 3 | 1 | 1 | 1 | 1 | 1 |
| 33 | Jayalaxmi | 253146 | 50 | F | L | 8 x 9 | 3 | 2 | 1 | 1 | 1 | 1 | 1 |
| 34 | Reshmabanu | 238696 | 21 | F | L | 18 x 19 | 1 | 2 | 1 | 1 | 1 | 1 | 1 |
| 35 | Roshan | 14994 | 25 | F | R | 28 x 29 | 3 | 2 | 1 | 1 | 1 | 1 | 1 |
| 36 | Shailashree | 244822 | 35 | F | R | 26 x 28 | 1 | 2 | 1 | 1 | 1 | 1 | 1 |
| 37 | Shanta | 380107 | 38 | F | L | 23 x 25 | 1 | 2 | 1 | 1 | 1 | 1 | 1 |
| 38 | Sumitra | 98770 | 43 | F | L | 11 x 13 | 3 | 2 | 1 | 1 | 1 | 1 | 1 |
| 39 | Kundan | 237944 | 40 | F | R | 15 x 16 | 1 | 2 | 1 | 1 | 1 | 1 | 1 |
| 40 | Chandrashekhar | 266574 | 73 | M | R | 8 x 8 | 1 | 2 | 1 | 1 | 1 | 1 | 1 |
| 41 | Somnath | 242787 | 16 | M | L | 9 x 8 | 1 | 2 | 1 | 1 | 1 | 1 | 1 |
| 42 | Revati | 131456 | 11 | F | L | 5.5 x 1.4 | 1 | 2 | 1 | 1 | 1 | 1 | 1 |

| | | | | | | | | | | | | | |
|----|-------------|--------|----|---|---|-----------|---|---|---|---|---|---|---|
| 43 | Nagamma | 223654 | 21 | F | R | 9 x 6.5 | 1 | 2 | 1 | 1 | 2 | 1 | 1 |
| 44 | TanujaDilip | 266544 | 21 | F | R | 4.9 x 3.2 | 1 | 2 | 1 | 1 | 1 | 1 | 1 |
| 45 | Lalita | 175239 | 20 | F | L | 5.5 x 1.4 | 1 | 2 | 1 | 1 | 1 | 1 | 1 |
| 46 | Sattewwa | 178954 | 65 | F | L | 42 x 33 | 1 | 4 | 2 | 2 | 2 | 2 | 2 |
| 47 | Mamataj | 32358 | 35 | F | R | 44 x 38 | 1 | 5 | 2 | 2 | 2 | 2 | 2 |