Sonographic Evaluation of Spectrum of Breast Diseases-A Study in a Tertiary Care Hospital of Southern Tamil Nadu.

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ABSTRACT

Background: Breast carcinoma has become one of the leading causes of death among women. Early clinical detection of breast carcinoma through screening has led to the detection of the tumor at a relatively earlier clinical stage, which definitely reduced the mortality. Breast ultrasonography (US) has gained widespread acceptance as a diagnostic tool for the evaluation of human breast disease and the ultrasound guided fine needle aspiration biopsy (FNAB) as the preferred method of tissue sampling. The present study aims to observe the diagnostic accuracy of US, in the assessment of breast masses compared to pathologic findings. **Methods:** This analytical, retrospective study was conducted on 246 patients that were referred for US scan in a tertiary care hospital of southern Tamilnadu, between January to December 2017. 110 breast masses from 246 patients were evaluated with US & US guided FNAB. BI-RADS US criteria combined with pathological findings were correlated in differentiation between benign and malignant masses. Sensitivity, Specificity & Accuracy were derived for US. **Results:**In our study the Sensitivity, Specificity, Positive predictive value (PPV) & Negative predictive value (NPV) of US, in detecting malignant breast nodule, was found to be 94%, 97.67%, 98.43% and 91.30% respectively. The overall accuracy of US in detection of benign & malignant breast nodule was found to be 95.45%. **Conclusions:** BI-RADS criteria combined with US guided FNAB, well correlated with pathological findings, increases the rate of detection of Breast cancer and reduces the number of unnecessary surgical & radiological procedures and the overall cost of medical care.

Keywords:Breast disease, Breast Carcinoma, BI-RADS, Mammography, Sonomammography, Ultrasonography.

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INTRODUCTION

Breast lumps are common problem affecting females, which require proper workup, early diagnosis and treatment. Although most detected masses are benign, every woman presenting with breast mass should be evaluated to exclude or establish diagnosis of carcinoma.

Over 100,000 new breast cancer patients are diagnosed annually in India and according to WHO (2012) an estimated 70218 women died due to breast cancer.[1-3]

The established management of palpable breast lesions includes the triple assessment, which includes Physical examination, Imaging and Fine needle aspiration or core biopsy.[4]

US is currently considered the first-line examination in the detection and characterization of breast lesions including the evaluation of breast cancer.[5]

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For symptomatic women, US is the primary modality for the evaluation of palpable masses in younger women. In pathologic nipple discharge, for detection of intraductal mass or hypoechoic irregular subareolar mass, differentiating between intraductal papillomas and carcinoma in situ and invasive cancer, US is a useful diagnostic tool, superior to mammography and may be worth including in the routine evaluation.[6]

According to a multicenter trial of combined screening with mammography and US (ACRIN 6666),[7] that reported higher cancer detection in high risk women who underwent annual US screening in addition to mammography compared to those that underwent mammography alone, the combined screening detected an additional 4.2 cancers per 1000 women.[8]

High-resolution US, is a useful modality that helps to additionally evaluate breast lesions and also helps to characterize a mammographically non-detected palpable abnormality in dense breast.[9] Women with dense breasts run a four- to six-fold higher risk of developing breast cancer than other women.[10]

The high-prevalence of US-only detected carcinoma and tolerance of US scanning in women makes US screening implementation possible. Furthermore, the standardized scanning and BI-RADS interpretive criteria proved to be practicable for independent performance and interpretation and could be used for further implementation.

Hence, the aim of this study is to assess the value of US & US guided FNAB in evaluating breast masses, to compare it with Pathology results, and to evaluate its potential role in differentiating benign from malignant breast disease.

MATERIALS & METHODS

An electronic medical record search in Hospital Information System (HIS) at Velammal Institute of Medical Sciences and Research Institute hospital, Madurai, southern Tamilnadu, India, a large tertiary care referral hospital for patients referred for US to rule out Breast lesions, between January 2017 to December 2017, identified 246 patients.

All Patients irrespective of age and sex with clinically suspected breast lesions, palpable lump, breast complaints like nipple discharge, retraction, skin thickening were included in the study. Of the study group of 246 patients, 243 were female and 3 male. 2 male patients aged 24 & 30 years with BIRADS category 1 and another 76 years male patient who had proliferative breast disease (BIRADS 2) was eliminated from the study. Age of the patients ranged from 17 years to 82 years. The mean age of the patients was 47 years.

Among the 243 patients, 133 patients whose US were normal (BI-RADS category 1) or who did not undergo FNAC/ HPE were excluded from the study. The study was approved by the Ethics Committee and informed written consent was obtained from all patients.

One hundred & ten patients with one or more breast mass (BIRADS 2-6), who underwent US and US guided FNAB were enrolled in this retrospective study. Findings of Clinical examination, US examination and US guided FNAB were recorded for each participant.

All of the US examinations and US guided FNAB were performed by qualified radiologist using a linear array transducer 4-12 MHz (Voluson S6, S8 GE). Certain aspects of sonographic technique are unique to US examination of the breast, such as proper application of compression, transducer positioning, and image labeling. In order to stabilize, center, and thin out the breast tissue, the conventional position for breast US examination places the patient supine with the arm of the side being examined raised above the head. With larger breasts, a degree of elevation under the shoulder blade may be required in order to center the breast. This can best be accomplished with a foam wedge or roll of towels or sheets.

Scanning is performed with the degree of compression necessary to penetrate to the area of interest and eliminate superficial artifact. Scanning in the plane of ductal anatomy can be achieved by scanning in the radial and antiradial planes. Radial scanning is performed with the long axis of the transducer oriented along the long axis of the ductal and lobar anatomy (nipple to periphery of the breast in a branching pattern) and antiradial in the orthogonal plane (from the periphery of the breast inward toward the nipple).

Transverse and sagittal plane scanning are acceptable in the initial survey, and if a lesion is detected, radial and antiradial scanning are recommended, as the margins and extension of the mass may be better displayed and this approach increases the potential for finding other masses within the same ductal system . The position of the lesion should be labeled on the image according to the mammographic clock, noting distance from the nipple or areolar margin. It is important that this information be labeled on each image to ensure appropriate follow-up or localization for biopsy.

US findings were categorized according to the Breast Imaging Report and Data System (BI-RADS) lexicon using the following tumour classification,[11]: Shape (oval, round or irregular), orientation (parallel to the skin surface or not), margin (circumscribed or not, indistinct, angular, spiculated or microlobulated), echo pattern (anechoic, hypoechoic, hyperechoic or complex), posterior acoustic features (none, enhancement or shadowing), surrounding tissue change (absent or present), vascularity (none, focal or penetrating flow, or diffusely increased flow), presence of associated calcifications (none or microcalcifications in or out of a mass).

The BI-RADS lexicon requires the breast imaging report be summarized into 1 of 7 possible categories,[12]

BI-RADS 0 - Further assessment required;

BI-RADS 1 -Negative study;

BI-RADS 2- Benign finding (risk of malignancy similar to that of the surrounding parenchyma);

BI-RADS 3- Probably Benign finding (less than 2% risk of malignancies should be followed up at 6, 12, and 24 months, and then classified as benign category 2 after showing stability for 24 months or biopsied if concerning changes or growth are seen);

BI-RADS 4- lesion is Suspicious for Malignancy (biopsy is offered);

BI-RADS 5- lesions are Highly suggestive of Malignancy; and

BI-RADS 6- lesions are Biopsy-proven Malignant before surgery is obtained (it is suggested that appropriate actions should be taken for these categories).

“Positive” category were all those who had BI-RADS assessment category 4, 5 and 6. “Negative” category were all those with BIRADS assessment category 0, 1, 2 and 3.

All patients underwent pathological assessment either by FNAC or biopsy or both. Biopsies included either core biopsy or surgical excision biopsy. Surgical specimens had been fixed in 10% formaldehyde solution and cut into serial 5-mm thick slices. Histo-pathological slides in each tumor were reviewed by a pathologist independently. The cytology reports were classified as benign, suspicious for carcinoma, malignant, or inadequate. Histology was performed if cytology was suspicious or suggestive of malignancy.

BI-RADS criteria combined with US guided FNAB, were correlated with pathological findings to determine the Sensitivity, Specificity and Accuracy of the Sonographic examinations.

After the pathological assessment patients were reviewed in the out patients clinic with their pathology report to plan any further treatment.

RESULTS

In present study 243 breasts were examined amongst which 110 cases were included, rest of the cases were normal or failed to follow-up and refused for consent. Of the remaining consecutive 110 cases (BIRADS 2 to 6) were evaluated clinically, by sonomammography & FNAB. In this study the age range of patients presenting with breast lesions was 17–82 years with mean age 49.6 years. BIRADS Category score of patients in the study with reference to Age is depicted [Table1].

Table 1: BIRADS Category score of patients in the study with reference to Age.

Birads Score	Age group in years								Total
	10-19	20-29	30-39	40-49	50-59	60-69	70-79	>80	
0	0	0	0	0	0	0	0	0	0
1	1	18	33	31	24	21	5	0	133
2	1	3	8	9	4	4	2	0	31
3	1	1	2	5	3	0	0	0	12
4	1	1	0	4	2	0	1	0	09
5	0	1	3	20	12	10	9	2	57
6	0	0	0	1	0	0	0	0	01
Total	4	24	46	70	45	35	17	2	243

Age prevalence showed less than 2.7 % of patients in the age group of 10-19 years and 10.9 % of patients above the age group of 70 years were affected. Our study showed that 80% of breast lesions occurred in the age group of 40 years & above, the remaining were younger than 40 years. Most lesions were found in the upper outer quadrant and the right breast was affected more than the left in 55 lesions (50%) & bilateral lesions (19%) were detected in 21 women. Amorphous micro-calcifications were detected in 1 US test (0.9%).

Fifty seven lesions (51.81%) were assigned BI-RADS 5 category. The second most common category was BI-RADS 2 in 31 lesions (28.18%).

The patients with malignant disease underwent surgery. The surgical & histo-pathological findings were positive for carcinoma breast in 64 patients (58.18%) [Table2].

Table 2: Sonographic diagnosis of Carcinoma Breast compared with pathologic findings.

Sonography	Pathology		Total
	Negative	Positive	
Positive	4	63	67
Negative	42	01	43
Total	46	64	110

Among the total patients, 55 were diagnosed histopathologically as Infiltrating ductal carcinomas (IDC), 5 Poorly differentiated carcinoma, 2 Invasive mucinous carcinomas (IMC) & 2 Metaplastic carcinoma [Figure 1-3].

There were total of 46 benign (41.81%) cases, Fibroadenoma (17) being the commonest, followed by Fibrocystic disease (12), Mastitis (6), simple Cysts (4), Duct ectasia (2), Phylloides (2),Galactocele (2) and least being Papilloma (1) [Figure 4-6]. On pathological examination 1 benign case of fibroadenoma turned out to be malignant. A case of papilloma and 3 cases of fibroadenoma were misdiagnosed as malignant.

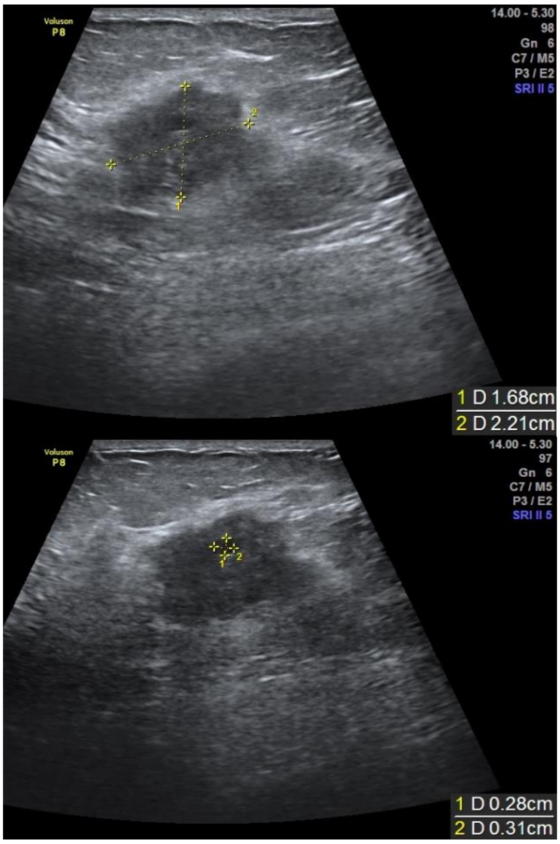

Figure 1(a,b): 40 years old female with infiltrating ductal carcinoma (IDC). US image reveals a hypoechoic mass that is Wider than taller, lobulated borders, internal tiny cystic component, peripheral marginal acoustic shadowing & no evidence of echogenic capsule.

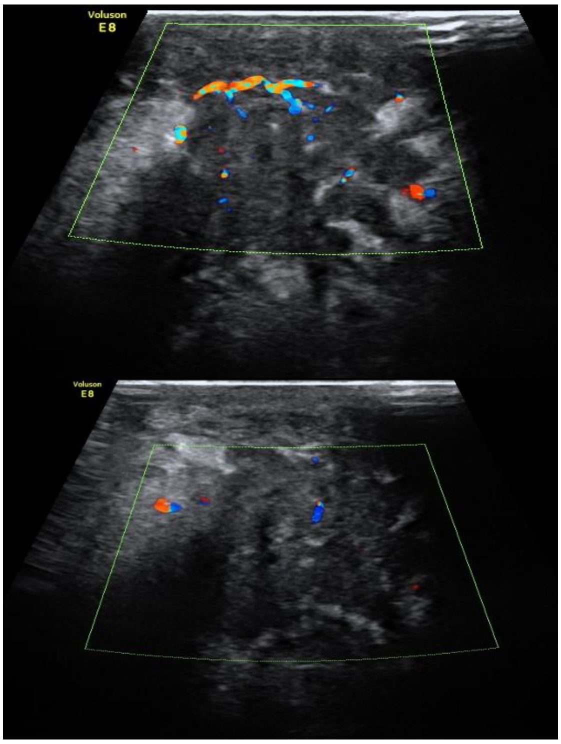

Figure 2(a,b): 71 years old female with Infiltrating ductal carcinoma. CDUS shows an irregular hypoechoic mass lesion with increased peripheral & central vascularity.

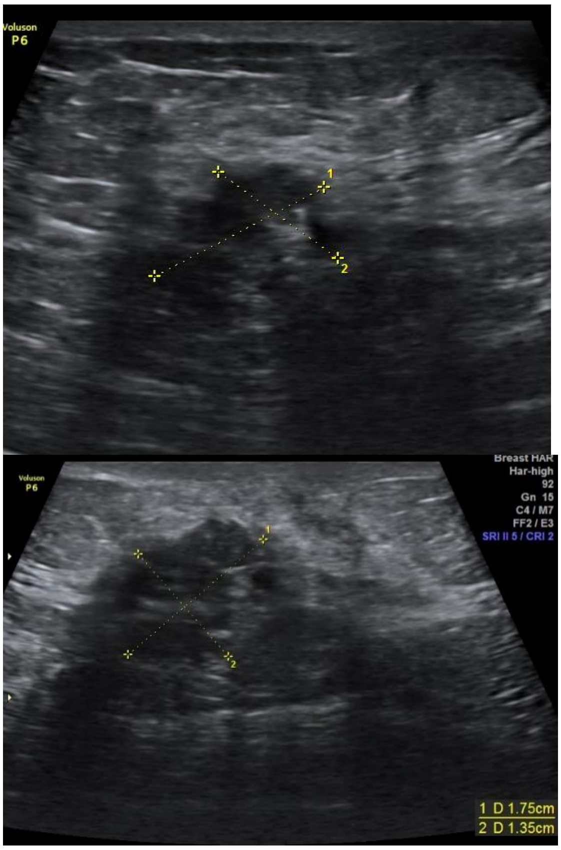

Figure 3 (a,b): 74 years old female with Infiltrating mucinous carcinoma(IMC). US shows lobulated heterogenous hypoechoic solid mass with tiny eccentric cystic components and peripheral acoustic shadowing.

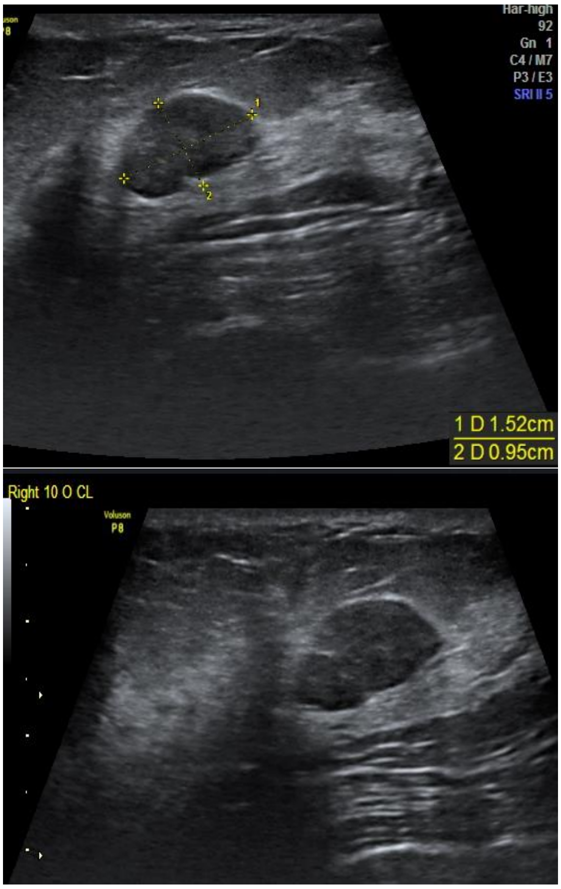

Figure 4 (a,b): 31 years old female with Fibroadenosis. Transverse sonographic image, showing an oval shape, hypoechoic mass with thin, echogenic capsule in right upper outer quadrant at 10'o clock position.

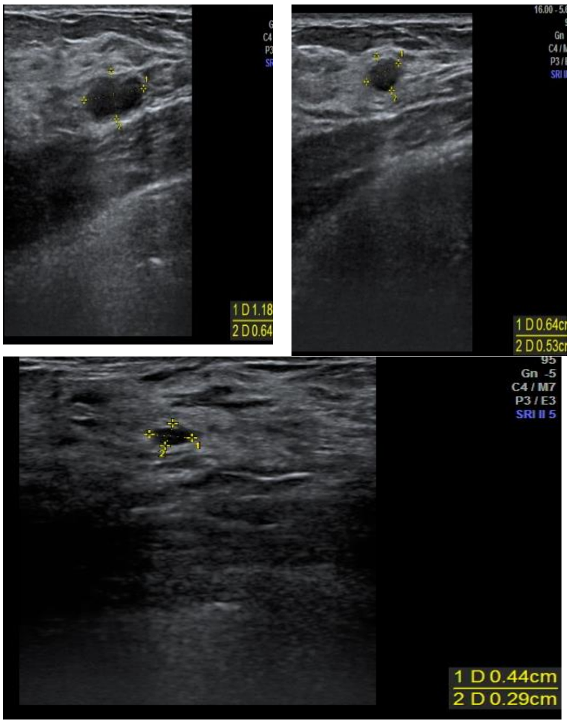

Figure 5 (a,b,c): 37 years old female with Fibrocystic disease.US images shows multiple tiny hypoechoic solid lesions & anechoic cysts.

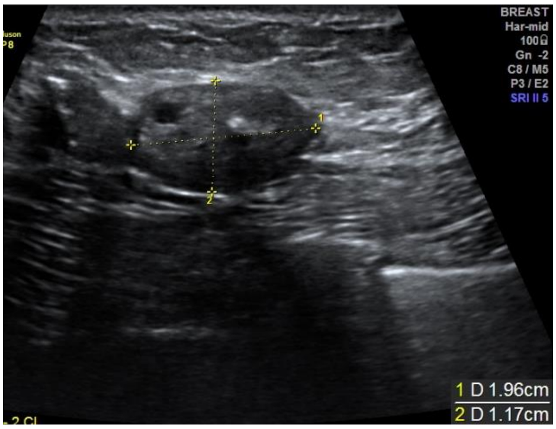

Figure 6: 44 years old female with Fibroadenoma. Transverse sonographic image, showing an oval shape, hypoechoic mass with thin echogenic capsule.

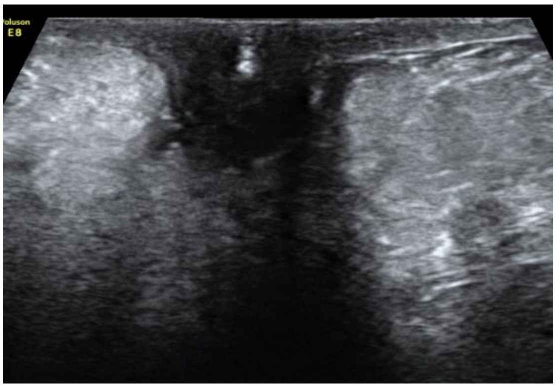

Figure 7: 57 years old female with acute suppurative inflammation. Transverse US image shows hypoecoic collection with thickened overlying skin & subcutaneous tissues.

Diagnostic role of US was evaluated by calculating Sensitivity, Specificity, Positive predictive value, Negative predictive value and overall diagnostic Accuracy using standard formulae and values obtained [Table 3 &4].

Table 3: Results of Sonographic studies in diagnosis of Breast Disease.

Breast disease	Proven on Histopathology	Sonography			
		True Positive	True Negative	False Positive	False Negative
Benign	46	42	63	4	1
Malignant	64	63	42	1	4

Table 4: Parameters depicting comparison of Benign & Malignant lesions by Sonography.

Sonography	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)	Accuracy (%)
Benign	97.67	94	91.30	98.43	95.45
Malignant	94	97.67	98.43	91.30	95.45

On the basis of the final diagnosis, the Sensitivity, Specificity & Positive predictive value of Sonography in detection of Malignant breast disease were 94 %, 97.67 % & 98.43 % respectively and Prevalence of 60.9% [Table4 & 5].

Table 5: Comparison of Sonomammographic results in different studies.

Study	Sensitivity (%)	Specificity (%)	Accuracy (%)
Texidor HS et al [13]	95.7	89.2	-
Taori K et al 2013 [15]	-	86.9	92.7
R E Mohamed et al 2014 [14]	92	90.24	91.03
Kumar et al 2016	85.45	89.31	82.7
Present study 2017	94	97.67	95.45

In conclusion, in our study Sonography was found to have a high Negative Predictive Value of 91.3 % for the exclusion of Carcinoma breast & Accuracy of 95.45% [Table4 & 5].

DISCUSSION

Breast cancer, the most frequently diagnosed and leading cause of death among women accounts for 23% of all cancer cases and 14% of cancer deaths globally,[17,18]whereas breast cancer in men accounts for only 0.7% with tremendous socio-economic, emotional,[19] and public health implications.

Benign breast disease is far more common than breast cancer. 50% of women will develop some form of benign breast disease during their lifetime. However, 1 in 9 of those presenting with a breast lump will be diagnosed as breast cancer.[20] Since it is not as yet preventable, its early detection gives the patient the best chance of a cure. Hence, breast screening programs have been implemented in many parts of the world.

The risk factors for breast cancer are numerous and can essentially be divided into hormonal, non-hormonal and genetic risk factors.[21] Patients with a benign lump but having a family history of breast cancer also have an associated increased relative risk for cancer. 50% of breast cancer patients do not have any specific risk factors.[21]

In our study, the enrolled women were with a wide age range between 17 and 82. The mean age was 49.6 years old. This study is similar to study by starves et al,[34] were mean age of the women was 47 years, with a range of 18-88 years and near similar to studies of Ayoade BA et al & Siddiqui MS et al,[22,23] were age range of 14-70 and mean age of 41years were reported.

In our study eighty eight women (80%), were aged 40 years and above & the remaining were younger than 40 years. Most of the patients with benign lesions (32.55 %) and malignant breast lesions (37.31%) according to BI-RADS assessment were within the age range of 40-49 years. This finding is in agreement with the results of Okobia et al,[24] where they found patients with malignancy to be from the 4th decade of life.

The mean age of patients in the two benign and malignant groups in our study were 43.41 years and 54 years respectively , which is similar to study by Ozdemir A et alwho have reported significantly older age among the malignant breast lesions compared with the benign group.[31]

Patients with palpable breast lesion commonly present for radiology evaluation. Various imaging techniques like Mammography, Ultrasonography, MRI, Scintimammography, CT and PET are now available.

Mammography is primary method of detection and diagnosis of breast disease with sensitivity of 85%-95%.[25] The specific mammographic features of the breast mass help in diagnosis. Benign lesions show round to oval shape, well defined margins, few lobulations, low soft tissue density and fat containing lesions. Malignant lesions are high soft tissue density, irregular margins, multiple lobulations and spiculations with or without microcalcifications.[26]

Mammography is nearly 87% accurate in detecting cancer,[27,28] its specificity is 88% and its positive predictive value may be as high as 22%.[28] But the false negative findings in mammography in evaluation of palpable breast mass is high, estimated between 4% & 12%.[29,30] Hence many of the times, other modalities are needed to compliment the primary diagnosis given on mammography. A study has shown that using ultrasound in addition to mammography increases the sensitivity to 77.5% compared to that of mammography alone (50%) in women with dense breasts and increased risk of breast cancer.[31]

However, for screening, US is increasingly used to detect early breast cancer worldwide. The success of supplementary screening US might be attributed to the low cancer detection rate of conventional mammography in the dense breast population. Several studies have already shown that US can demonstrate small, non-palpable, invasive cancers that are not seen on mammography.[32-34] US is less sensitive, however, than mammography or MRI in the detection of ductal carcinoma in situ.[35-37]

Breast cancer in women younger than 40 years is rare and typically presents symptomatically. For symptomatic women, US is the primary modality for the evaluation of palpable masses in younger women.

Previous studies demonstrated that the following US features such as oval or round shape, parallel orientation, circumscribed margins, abrupt interface, enhancement or absence of posterior acoustic features, absence of surrounding tissue alterations represented a benign breast lesion [Figure 4-6], whereas, irregular shape, non-parallel orientation, echogenic halo, posterior acoustic shadowing and abnormalities of the surrounding tissue regardless of echo pattern were considered to be consistent with a malignant lesion [Figure 1-3].[38,39] It is also true that not all carcinomas fulfill these criteria and some do only partially.[39]

The BI-RADS in this study accurately predicted 43 benign breast lesions (39%) and 67 malignant lesions (60.9%), while histopathology identified 46 benign breast lesion (41.8%) and 64 malignant lesions (58.18%). The difference may be attributed to the limitation of relying purely on morphological appearances.

Infiltrating ductal carcinoma (IDC) and ductal carcinoma in situ (DCIS) represent 85% of malignant breast tumors.[40]Typically, infiltrating ductal carcinoma presents as a spiculate, irregular or focal asymmetrical mass, while ductal carcinoma in situ presents as pleomorphic or linear microcalcifications.[41]In our study IDC represented 85.93%, similar to the study by Khomsi F et al.[40]

Prognosis is unfavorable in cases of isolated IDC. Some histological types of breast tumors such as medullary carcinoma, mucinous carcinoma and tubular carcinoma are associated with a better prognosis.

US BI-RADS assessment from our study, has Sensitivity of 94%, Specificity of 97.67%, Positive predictive value (PPV) of 98.43%, Negative predictive value (NPV) of 91.10% and Accuracy of 95.45% in detection of breast carcinoma, which were similar to the results of R E Mohamed et al of 92%, 90.24%, 87.88%, 93.67% and 91.03% respectively and comparable to the results of Texidor HS et al with sensitivity 95.7%, specificity of 89.2% and accuracy of 92.7% by Taori K et al [Table5].

In a study by Jaipal R Beerappa et al,[42] the overall sensitivity, specificity & accuracy of US was 89.45%, 90.31% & 88.17%, which nearly correlates with our study of 95.83%, 95.83% & 95.45% respectively [Table5]. High prevalence (60.9%) of malignant breast disease in this region may be attributed to low socio-economic status of the population. Sensitivity of sonomammography in detecting benign lesions were high because small cysts and fibroadenomas are better seen even in dense breasts and US differentiates cyst from solid lesions. Specificity of US in detecting malignant lesions was less as microcalcifications were not well seen in US. These observations are similar to results of Texidor SH et al [Table5]. When histopathology results were compared with that of BI-RADS predictions in this study, no statistically significant difference was observed.

The use of color Doppler ultrasonography (CDUS) for characterizing breast lesions has increased in recent years. The presence and distribution of blood vessels associated with malignant lesions is visualized by CDUS [Figure 2]. Doppler criteria such as resistive index (RI), pulsatility index (PI), and flow velocity are used to distinguish benign from malignant lesions.

Real-time ultrasound elastography (RTE) is a non-invasive dynamic imaging technique that assesses the strain of soft tissues and provides structural information other than the morphologic features shown by conventional B-mode US.[38] It can differentiate between benign and malignant lesions based on their elasticity. Benign lesions have elasticity similar to the surrounding tissue, while malignant lesions are harder than the adjacent tissue.[43] A 5-score system was described by Itoh et al,[43]to classify elastographic findings that can be easily correlated to the American College of Radiology (ACR) BI-RADS.

Contrast US seems to be a reliable method to differentiate breast lesions, because it provides typical enhancement patterns and perfusion curves, correlate well with MRI wash in & wash out curves. Rapid contrast uptake and rapid washout distinguishes benign from malignant lesions.[44]

New technical developments, such as three-dimensional (3D) US, computer-aided diagnosis (CAD) & automated breast US (ABUS) are now available on some machines.

Several new minimally invasive procedures, including radiofrequency ablation, interstitial laser ablation, focused US ablation, cryotherapy, and vacuum-assisted devices are currently under investigation and may provide treatment options that are comparable with that of traditional surgical therapies.[45]

US has a significant role in the postoperative assessment of patients with breast cancer. It is helpful in evaluating postoperative recurrent breast masses and postsurgical complications, such as seroma, infection and fat necrosis, as well as exclusion of recurrent disease.

MR Mammography can be useful in detecting distant, multifocal, or multicentric lesions when there is no clinical sign or suspicious mammographic finding. For diagnosis and evaluation of tumors of the nipple and retroareolar tumors, MR imaging has higher sensitivity than mammography. It also shows nipple involvement even when it is clinically unsuspected.[46] Contrast-enhanced breast MR imaging is known to help identify foci of cancer that are not detectable at physical examination, mammography or US.

CT & MRI has a major role in staging of locally advanced breast cancers. US is limited to detect the lesions with less than 1 mm in diameter ,whereas combined modalities such as US, CT and MRI increase the accuracy of detection from 86.4 to 93.8%.[47] Therefore, it has become very important that a variety of imaging modalities has been used for examining tumor extension and multifocality in breast cancer patients.

Scintimammography using 99mTc-sestamibi is a noninvasive and painless diagnostic imaging method that is used to detect breast cancer when mammography is inconclusive.

2-[fluorine-18]fluoro-2-deoxy-d-glucose (FDG) positron emission tomography (PET) / CT may have limited diagnostic value for detecting small primary breast tumors, well-differentiated breast cancer, or regional lymph node involvement, but it is superior to conventional imaging modalities for detecting distant metastases and recurrences and for monitoring the response to therapy. The most important advantage of FDG PET or PET/CT compared with other imaging modalities is the capability of detecting unsuspected distant metastases during a single whole-body examination.[48]

The American Joint Committee on Cancer (AJCC) staging system for breast cancer (7th edition) provides a tumor-node-metastasis (TNM) classification scheme for breast cancer that is important for determining prognosis and treatment.

Radiologic information that may alter stage, prognosis, or treatment includes tumor size; number of tumor lesions; total span of disease; regional nodal status (axillary levels I–III, internal mammary, supraclavicular); locoregional invasion (involvement of the pectoralis muscle, skin, nipple, or chest wall); and distant metastases to bone, lung, brain, and liver, among other anatomic structures. High-risk patients are screened for occult metastases with chest radiography, abdominal US, and bone scintigraphy, although the use of CT, MR imaging, and FDG PET is increasing .The staging information will help in choosing between breast conservation and mastectomy, preoperative and postoperative chemotherapy or hormonal therapy, sentinel lymph node biopsy (SLNB) and axillary lymph node dissection (ALND), and radiation therapy.[49]

Limitations

The study was done in a tertiary referral hospital, as a result some of the cases were already advanced at the time of evaluation. There was more number of malignant cases than benign for the same reason. Only patients attending the hospital were enrolled. It is not possible to know how many patients with a lump did not attend the hospital. It was not possible to do statistical analysis for all risk factor variables in this study. Despite these caveats the major aims and objectives of the study was achieved.

CONCLUSION

Ultrasound (US) has a significant role in diagnostic breast imaging. It is most commonly used as an adjunctive test in characterizing lesions detected by other imaging modalities or by clinical examination. US is recognized as the modality of choice in the evaluation of women who are symptomatic and younger than 30 years of age, pregnant, or lactating and for guiding interventional breast procedures.

BIRADS US criteria combined with US guided FNAB, well correlated with pathological findings, increases the rate of detection of Breast cancer and reduces the number of unnecessary surgical & radiological procedures and the overall cost of medical care.

Elastography, 3D, CAD US, and automated whole-breast screening US are techniques that may have an impact on future clinical performance.

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