ORIGINAL RESEARCH

Evaluating the Socioeconomic impact of Mammography and Ultrasound in palpable breast lesions and their potential application as a screening tool in a limited resource country

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ABSTRACT

Introduction: Breast cancer is a global problem accounting for 2.5 million cases per year worldwide. The younger women have a reported lower survival rate with cancers being detected at an advanced stage, while earlier detection improves survival rates by 27% to 47%.Health of a rural women and her access to health facility is further compromised due to socio-cultural, economical, and environmental factors. **Objective:** Evaluation of Mammography and Ultrasound in palpable and symptomatic breast lesions, observe concordance with histopathological findings (BIRADS IV and above) and evaluate usefulness of Ultrasound breast in young women with dense breasts as an alternative screening tool in rural areas. **Methods:** A total of 150 patients, more than 30 years of age withpalpable breast abnormality, underwent both Mammography and Ultrasound. Imaging characteristics of lesion evaluated and categorized using BIRADS-criteria. Cases with> BIRADS IV were further evaluated using Histopathological correlation. Statistical analysis was done using SPSS software version 25.0. Significance level of *p* was considered 0.05 or lower. **Results:** Mean age was 46.7 years, 51.3% were younger than 45 years of age and 89% of these had dense breasts. Ultrasound showed a higher detection rate in mammographically dense breasts. For Mammography, Sensitivity, Specificity, Positive and Negative predictive value were 85.%, 87.8%, 91.2% and 79.6% respectively; while for Ultrasound they were 100%, 68.3% , 82.5% and 100% respectively. There was concordance between imaging and pathology reports with morphological findings from Ultrasoundshowingbetter concordance with pathology. **Conclusion:** Ultrasound able to detect more lesions (than mammography) in women with dense breasts. Hence, proved to be more sensitivein early detection and can be promoted as a cost-effective screening initiative where mammography is not available. **Advances in knowledge:** Ultrasound appears to be superior for early diagnosis of breast lesions in dense breasts of young women and likely to have more compliance hence must be promoted as a screening tool.

Keywords: Ultrasound, Mammography, BI-RADS, Breast lesions, sensitivity, concordance, histopathology.

INTRODUCTION

Breast cancer is a global problem accounting for 2.5 million cases per year worldwide. Breast cancer has ranked number one cancer among Indian females with an age adjusted rate as high as 25.8 per 100,000 women and mortality of 12.7 per 100,000 women.(1) It is most common cause of cancer death in women and overall, fifth common cause of cancer deaths in the world. As per the Globocan data 2020, in India, breast cancer accounted for 13.5% (1,78,361) of all cancer cases and 10.6% (90,408) of all deaths.(1) The younger women have a reported lower survival rate with cancers being detected at an advanced stage, while earlierdetection improves survival rates by 27% to 47%.(2) There is evidence to suggest that a shift towards early stages may be achieved at considerably lower costs by health education and improved awareness, as revealed by the findings from Sweden and Barshi, India.(1) Health of a rural women and her access to health facility is further compromised due to

sociocultural, economical, and environmental factors. Nearly 68-72% of India's population stays in rural area. [i, ii]In a study on cancer awareness, only 4.59% women who said cancer is curable, knew correctly that it is possible only when early diagnosis and right treatment for right duration is provided. This study suggests that for information to reach rural women they need discussions conducted by the people in whom they have **faith**, for example, local doctors, Accredited Social Health Activist (ASHA), auxiliary nurse midwife (ANM). Awareness spread through mass media alone may not be sufficient in changing attitude or practice. Our study aims to make use of Mammography and Ultrasound as tools for early detection of breast cancer in palpable and symptomatic breast lesions, observe the concordance with histopathological findings (cases given BIRADS IV and above)and evaluate the usefulness of Ultrasound breast in young women with dense breasts as an alternative screening tool in rural areas where availability of dedicated mammography machines and expertiseare almost scarce to non-existent.

MATERIALS AND METHODS:

In this cross-sectional observational study, we included 150 patients, more than 30 years of age who had palpable breast abnormality, underwent both Mammography and Ultrasound in the Department of Radio-diagnosis at a large Tertiary care Government Medical college and Hospital between January to June 2023. All patients who underwent diagnostic mammography followed by high resolution Ultrasound after taking an Informed written consent. Mammography was performed by using SIEMENS Mammomat Select Mammography model equipment in two views (i.e., cranio-caudal and medio-lateral oblique views) and high kVp and low mAs exposures varying with the thickness of the breasts with minimum kVp 23.0 to max kVp 32.0. Ultrasound was performed by using a linear transducer with a 50-mm width and a frequency of 12 MHz, using Philips models affinity 50 and 70G. Imaging characteristics of the lesions were evaluated and categorization of the lesions was done using BIRADS-criteria. Final BIRADS was assigned to each case depending on imaging findings of Mammography and Ultrasound. The results were analysed and categorized according to BIRADS (Breast Imaging Reporting and Data System) score. (ACR BI-RADS ® Atlas Fifth Edition).[3] Results were coordinated with history and physical examination of the patients. Indeterminate/suspicious imaging findings were given > BIRADS IV which were further evaluated using FNAC or core needle biopsy and Histopathological correlation was done. The Ethical Committee and Review Board of our Institution approved the study.

INCLUSION CRITERIA

All women above 30 years of age, who presented with palpable breast abnormality either on self-examination or on clinical examination, evaluated with Mammography and Ultrasound of the breast, were included.

EXCLUSION CRITERIA

1. Patients below 30 years age
2. Pregnant and lactating women
3. Women with breast implants
4. Patients already undergone surgery or received Radiotherapy/ Chemotherapy.
5. Women who did not give consent for Mammography
6. Asymptomatic/ screening patients.

STATISTICAL ANALYSIS

Demographic data in addition to Mammography, Ultrasound and the pathologic reports were used for analysis and interpretation. Sensitivity, specificity, Positive Predictive Value (PPV), Negative Predicative Value (NPV) and Accuracy of Mammography and Ultrasound were calculated using SPSS software version 25.0. Fisher exact test and Chi-square test were used to examine the association of the variables. The significance level of *p* was considered 0.05 or lower.

KEY MESSAGES

- Sensitivity of USG is higher for Young women with dense breast parenchyma.
- Ultrasound has a higher accuracy of detecting breast cancer compared with mammography.
- Screening USG to promote Health equity amongst Rural women for early diagnosis will help reduce the economic and emotional burden.

RESULTS

A total of 150 patients were enrolled in the study, of which 148 were females and 2 were male. The mean age was 46.7 years, with an age range of 30 years to 78 years (Figure 1). Since our institute is a Tertiary care centre in a large district, the patients coming from rural areas (N= 96) was significantly more than from urban areas (N= 54). A total of 76 patients (50.6%) showed right-sided while 74 patients (49.3%) had left-sided pathology. The upper outer quadrant was most commonly involved in 54 (36 %) cases followed by Central region in 24 (16%) cases. On Mammography, 21 patients were given BIRADS-I, 15 were BIRADS-II, 46 were BIRADS-III, 44 were BIRADS-IV (IVA=12, IVB=23, IVC=9); and 24 were BIRADS-V. On Ultrasound, 5 patients were BIRADS-I, 21 were BIRADS-II, 30 were BIRADS-III, 64 were BIRADS-IV (IVA=31, IVB=23, IVC=10); and 30 were BIRADS-V (Figure 2). For BIRADS IV the *p*-value is 0.031849 which is significant, this means that ultrasound helped diagnose more concordant BIRADS IV cases as compared to mammography. For BIRADS V, the *p*-value is 0.816244, which was not significant at $p < .05$, this means that mammography and ultrasound are

individually both able to diagnose high grade BIRADS V cases well. Sensitivity, Specificity, Positive predictive value (PPV) and Negative predictive value (NPV) for Mammography and Ultrasound are shown in Table 1. The *p* value at <0.05 was taken as significant and those for Sensitivity was *p*= 0.0014 and Specificity was *p*= 0.0042. Study showed relative concordance between Mammography and Ultrasound when compared to histopathology findings(Table 2).It also revealed morphological findings from Ultrasound had higher overall concordance with pathology in palpable breast lesions as compared to Mammography.

Table 1: Accuracy of Mammography and Ultrasound in diagnosing Palpable malignant lesions.

Modality	Sensitivity	Specificity	PPV	NPV	Accuracy
1. Mammography	85%,	87.8%	91.2%	79.6%	86%
2. Ultrasound	100%	68.3%	82.5%	100%	87.5%

PPV=Positive predictive value, NPV=Negative predictive value

Table 2: Concordance of mammography and Ultrasound results with histopathology for BIRADS 4 and above lesions

	Mammography			Ultrasound		
BIRADS	Benign	Malignant	Total	Benign	Malignant	Total
4	9	35	44	25	39	64
5	2	22	24	2	28	30
Total	11	57	68	27	67	94

The proportion of malignant lesions identified by Mammography and Ultrasound were 38 % (N=57) and 44.66 % (N=67) respectively. Out of 94 patients given BIRADS 4 and above, 67 (71.2%) showed concordance and 27 (28.7%) showed discordance with Histopathology findings. Out of 27 discordance, ultrasound (27) overestimated the BIRADS as compared to mammography by 16 (17%) cases. On Mammography, out of 68 patients given BIRADS 4 and above, 57 (83.8%) showed concordance and 11 (16.1%) showed discordance with Histopathology findings (Figure 3).The histopathological distribution of malignant cases is as shown in Figure 4. A total of 77 patients (51.3%) were younger than 45 years with palpable breast findings, out of which 68 patients (89%) had type C (N=33) or D (N=35) dense breasts. Out of 77 young patients, Twenty were found to have positive histopathological findings, Four of these patients with dense breasts on Mammography were False negative.

FIGURES & LEGENDS

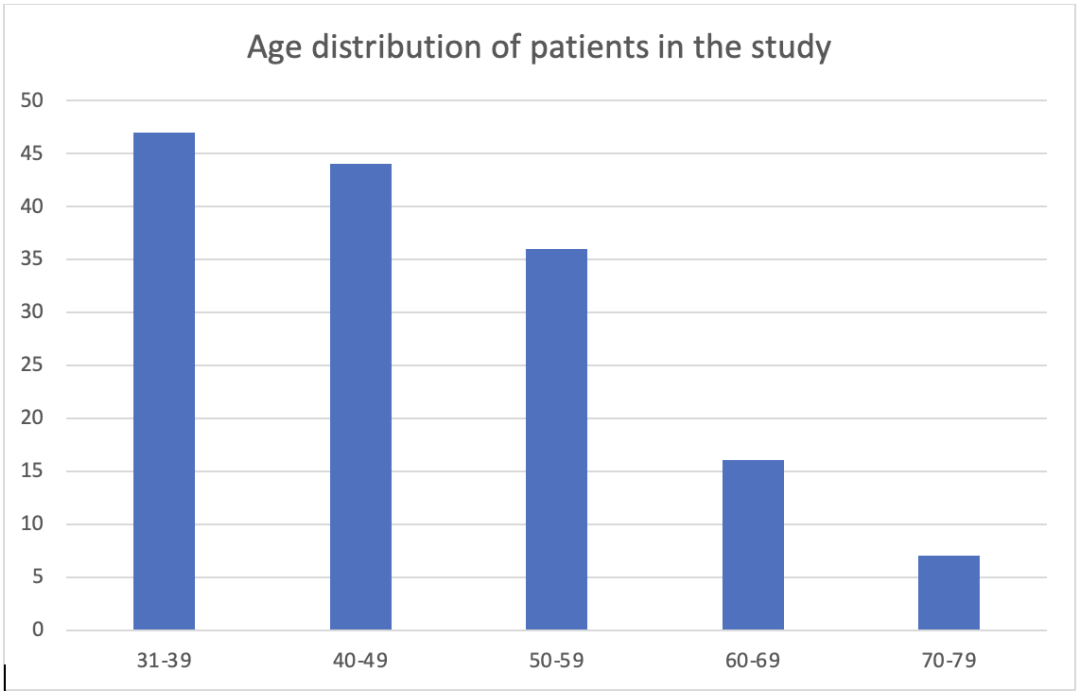

Figure 1: Age distribution of patients in the study.

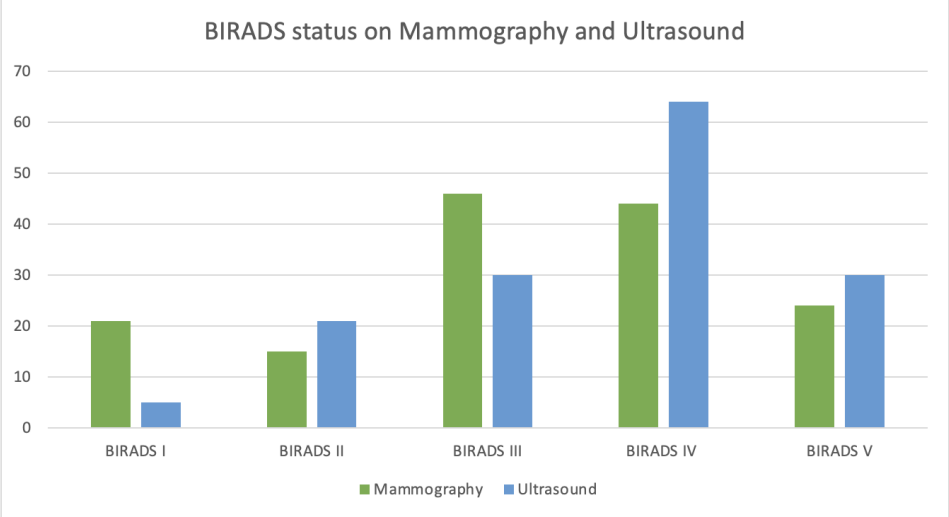

Figure 2: BIRADS status on Mammography and Ultrasound

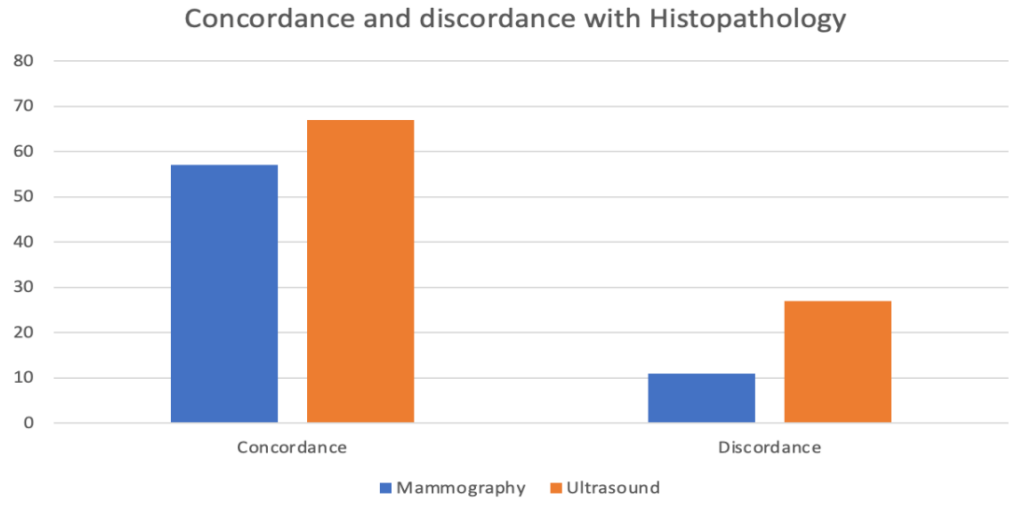

Figure 3:Concordance and discordance with Histopathology

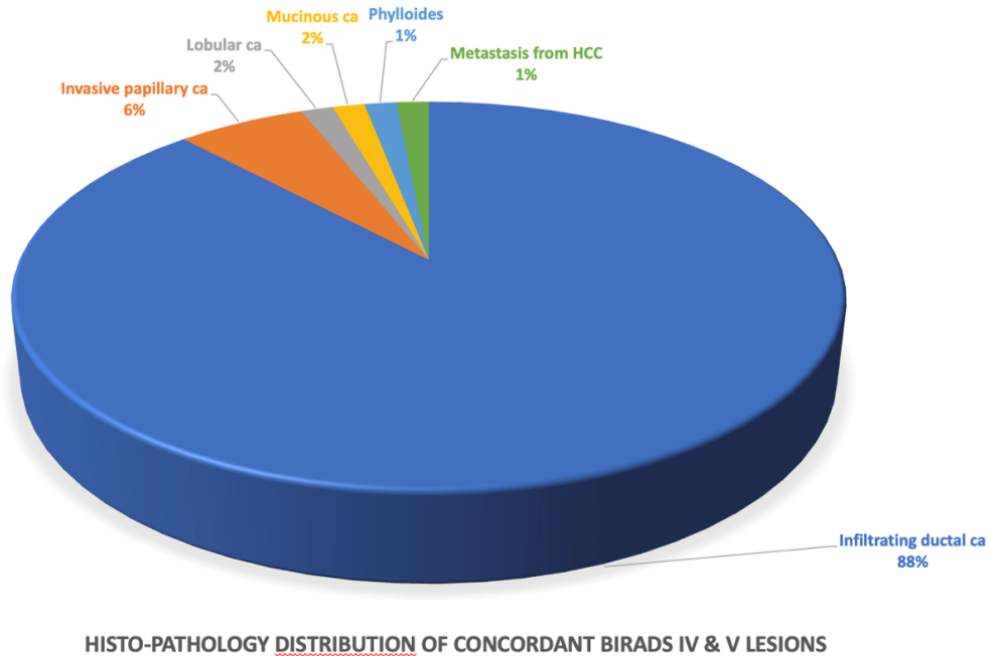

Figure 4: Histopathology distribution of concordant BIRADS IV & V lesions.

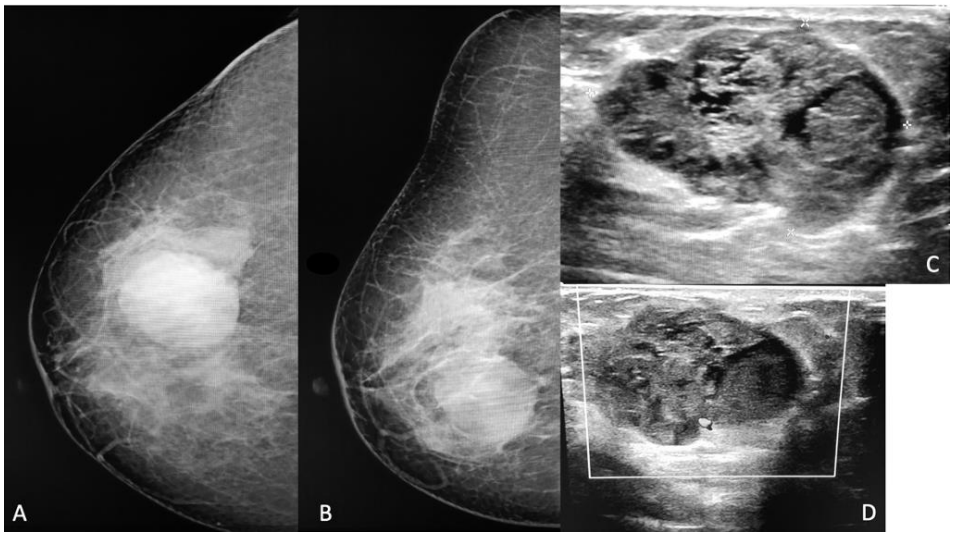

Figure 5: A 44-year-old female with non-mobile lump in right breast. (A & B) Mammography revealed a circumscribed, round high-density lesion. (C & D) On USG corresponding a hypoechoic soft tissue lesion with few micro lobulations and cystic changes and mild vascularity (ACR BIRADS IVB). Histopathology revealed Mucinous breast cancer.

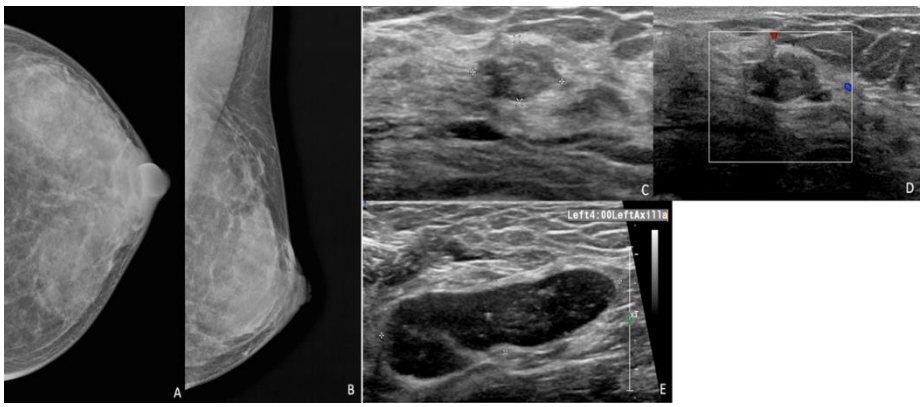

Figure 6: A 33-year-old Female presented with lump in left breast, had dense type D breasts on mammography (A), this did not reveal any obvious abnormality. (B & C) On ultrasound, a hypoechoic, micro lobulated and angulated lesion with mild vascularity. (D) An enlarged lymph node with thickened cortex (ACR BIRADS IVB). Histopathology was suggestive of Infiltrating ductal carcinoma.

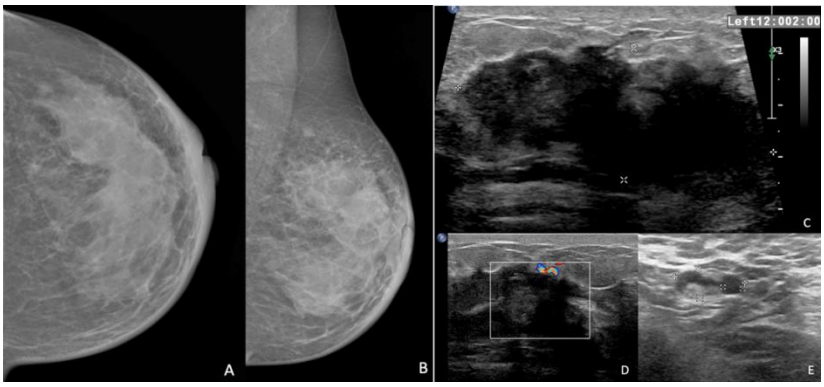

Figure 7: A 55-year-old female with palpable mass in left breast with nipple retraction. (A & B) Mammography revealed an irregular high-density mass with ill-defined margin in upper central and upper outer quadrant of left breast with multiple pleomorphic microcalcifications within and beyond the lesion with associated skin thickening and nipple retraction. (C, D&E) Ultrasound showed an irregular hypoechoic soft tissue lesion in upper central and upper outer quadrant of left breast, showing mild internal vascularity on colour doppler and multiple foci of calcifications within (ACR BIRADS V). Histopathology was suggestive Invasive ductal carcinoma. Patient underwent Mastectomy due to advanced stage of the disease.

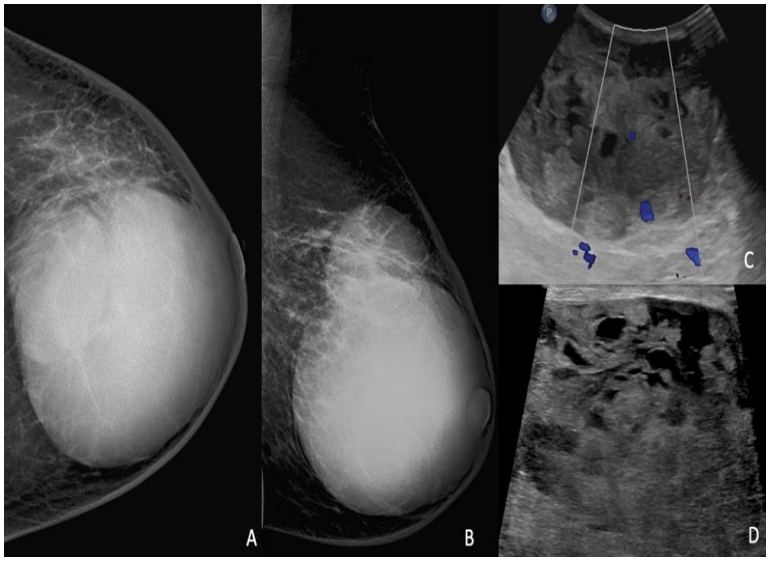

Figure 8: A 42-year-old female with swelling in left breast since 1 year, now presented with recent increased size and pain. (A & B) Mammography revealed two large high density lobulated lesions overlapping over each other with circumscribed margins with associated skin and Nipple areolar complexthickening, (C & D) USG corresponding to a large solid lobulated mixed echogenicity lesion with multiple cystic spaces lesion with posterior acoustic enhancement and significant internal vascularity within (ACR BIRADS IVA). Histopathology revealed Phyllodes tumour.

DISCUSSION

Studies comparing the Socioeconomic impact of Mammography and Ultrasound in palpable breast lesions and their potential application as a screening tool arelacking in Indian settings and hence the present study was planned. This study examined diagnostic accuracy and concordance of US and Mammography in 150 patients stratified by BI-RADS and considering pathology reports as the gold standard. Mammography is more accurate than physical examination to find masses and detect micro-calcification. In our study, the specificity in detection of palpable malignant breast lesion was higher with mammography, However the Sensitivity, NPV and accuracy were higher for Ultrasound(Figure 5).Moreover, both the modalities when combined gave better outcomes overall. Hence, combination of Mammography and Ultrasound was more sensitive, specific, and accurate in diagnosing malignant breast lesion**.** Mammography can establish the benign cause of palpable lesion and avoid further investigation but false negativity in case of mammography has been noted to be high, up to 16.5% in studies.[iii]This was similar to our study, wherein false negative was higher with mammography versus Ultrasound, though only marginally (6.7%). In our study, the US results were accompanied with over 17% overestimation of the benign lesions as malignant. We prospectively assessed the accuracy of high resolution breast ultrasonography in the diagnosis of palpable breast masses in comparison to clinical palpation and Mammography. In few studies, Ultrasound was able to detect incidental cancers that were clinically and mammographically occult[iv,v]. Similar to our study, Ultrasound showed a higher detection rate in mammographically dense breasts[vi,vii]since hyperechoic dense glandular tissue helped form an excellent contrasting back-ground for the detection of usually hypoechoic cancers(Figure 6). In a study by Khanduri, S. et al, [viii], the majority of patients were < 40 years of age. The accuracy of Ultrasound alone (85.8%) was higher as compared to Mammography alone (81.4%). This is in concordance with our results where 51.3% of patients in our study group were below 45 years of age with dense breast parenchyma where sensitivity of USG was higher. Ultrasound is widely accessible and affordable and is presently utilized as an adjunct to mammography. It does not utilize ionising radiation, which in itself induces more cancers. In a study by Omidiji et al., [ix] Ultrasound had high sensitivity in detecting breast cancer (100%) but very low specificity (22%). Mammography had reduced sensitivity (85.7%) compared with ultrasound but was more specific (55.4%). Positive predictive value was also low in ultrasound (33.3%) compared with mammography (42.8%). Negative predictive value (100%) was however higher in ultrasound compared with mammography (90.9%). Ultrasound also had a higher accuracy of detecting breast cancer (84%) compared with mammography (56%). This trend was found similar to our study. The accuracy of ultrasound is also higher than that of mammography, as seen in a study by Berg, W.A. et al., in which ultrasound was able to 4.2 cancers per 1000 patientsthan were detected by mammography alone [x]. Our findings were in agreement with the study by Lister, D. et al., [xi] where ultrasound was found to be superior to mammography in the detection of invasive carcinoma when indeterminate and malignant imaging findings are taken as positive.

The diagnostic accuracy of sonography was similar to that of palpation-guided FNA for not missing the malignancy [xii]. Clinical application of FNA results can be difficult, especially when the result is insufficiency or atypical cells. Moreover, FNA is invasive and overlaps other procedures. Therefore, this study concluded that sonography can replace palpation-guided FNA in peripheral setups for diagnosis of palpable lesions of the breast when the BI-RADS sonographic final assessment system is used appropriately.

India is a country, where despite rapid urbanization, more than two-thirds of the population (68.8%) still live in villages [vi]. This is similar to our study observation of Rural and Urban population distribution in our study group (64% and 36% respectively) . The screening facility for breast cancer detection in rural areas is jeopardized and, without exaggerating its status, has sometimes been termed as a non-existent reality. There are studies citing the barriers for early cancer detection amongst Indian rural women[xiii], as well as highlighting the lack of proper diagnostic services for late presentation of rural women.

It is known that lower education and income are important causes of delay in the diagnosis of breast cancer in women in developing countries [xiv]. In a study by Sen, S. et al., the proportion of cancer screening had a strong economic gradient. The screening for breast cancer was 378 among women in the poorest wealth quintile compared to 1331 among women in the richest wealth quintile. [xv] In a country like India, Mammography is not as easily available (for majority of our population) or as affordable compared to ultrasound, there is increased risk of false negativeas the majority of breast cancer patients are younger women leading to increased morbidity. As we know the yield of cancer diagnosed in women under the age of 40 years is considerably lower since younger women have denser breasts which decreases the test sensitivity. There are therefore major concerns to the value of Mass mammographic screenings, since cancer detection will be lower with mammographic screening (in India) when compared to other countries [xvi,xvii]. In a limited resource setting, clinical examination along with breast ultrasound is a useful diagnostic work-up. Fine-needle aspiration or core needle biopsies along with proper follow-up are the prerequisites for prompt detection and treatment.

We observed in our study group that majority of the patients with malignant breast lesions presented with advanced stage of disease (Figure 7) which was likely due to impact of recent COVID19 pandemic and other barriers for early detection of cancer amongst Indian rural women such as lack of awareness (Figure 8), inadequate knowledge, economic barrier (time and money), logistic barriers (child care, transportation, waiting times, etc.). [v] These barriers can be overcome through developing structural screening ultrasound programs at the town and village levels through increased awareness.

In a study by Yang et al.,[xviii]found that the specificity for combined clinical palpation and ultrasonography was higher (99%) than that for combined clinical palpation and mammography (96%). Mammography in addition did not significantly improve the sensitivity, specificity, or positive predictive value. This then raises the question whether mammography should be eliminated in the workup of a palpable mass. It has advantage in the detection of extended foci of DCIS (Ductal carcinoma in situ) related to a palpable mass, often undetected by ultrasonography. They found that sensitivity and specificity of Ultrasound was higher for patients with palpable breast abnormality nearing the results of combined study with mammography. This observation is important in a country like India where there is a lack of mammography infrastructure and diagnostic expertisein peripheries, however Ultrasound machines are quantitatively more easily available with better knowledge of breast USG among radiologist for symptomatic/ palpable breast lesions over Mammography. Patients with suspicious findings can be further referred to tertiary care centres for additional work up.

The ultrasound technology for breast imaging has greatly improved in the past decade. The negative predictive value of this technique can reach 100%, whereby the required confidence for follow-up will be provided, and the need for biopsy in patients with breast lesions will be minimized.[xix]Our study confirms, combined use of mammography and sonography is appropriate in most instances to better characterize palpable lesions and thus helps to reduce unnecessary interventions in those cases in which imaging findings are unequivocally benign. Mammography is better in detecting microcalcifications, spiculations, detecting focal asymmetries, architectural distortion and is a useful tool for screening, however, Ultrasound is the preferred modality for evaluation of palpable abnormalities of breast and dense breast. Hence, we believe that Ultrasound as an individual imaging modality can be confidently relied upon in palpable breast lesions in limited resources.Our study had a few limitations. Firstly, the sample size was limited, and the study was conducted at only one centre. Second, the histopathological correlation was available only for BIRADS 4 and above lesions. Finally, due to limited duration of the study, follow up of all the BIRADS III could not be considered in the data, hence the lesions showing upgrade of BIRADS were not included in the study. These limitations can be overcome by undertaking Future studies with a larger sample size, longer duration of the study availing follow up of BIRADS III lesions and multicentric setups to validate our study findings in the Indian context. The importance of screening cannot be overemphasized. The Central, State and

Local government should develop policies and guidelines that would ensure routine screening of all women for breast cancer. We recommend that Annual breast screening should commence from the age of 30 years, using ultrasound as a first line screening tool, especially in peripheral and rural areas of the country.

CONCLUSION

Ultrasound was able to detect more lesions than mammography especially in women with dense breasts and was able to characterise cystic from solid lesions. The results suggest that Ultrasound, showing high sensitivity and an early detection rate, holds promise to achieve cost-effective screening initiatives where mammography is not available. Since mammography is less effective in younger women and women with dense breasts, we suggest that USG should be put forward as a primary screening tool where mammography is not readily available. In a limited resource setting, the most appropriate screening method for Indian women is clinical breast examination by female physicians or trained health workers followed by Ultrasound. Timely diagnosis and treatment will reduce the social, emotional and economic burden over the families and help increase Female workforce for the overall Development of our Country.

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