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Original Article

Role of Image-Guided Biopsy in Nonpalpable Breast Lesions: A Study in the Sub-Himalayan Region of North India

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Abstract

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Background Nonpalpable breast lesions pose a challenge in their early diagnosis. Image-guided biopsy is preferred in these cases so that a pathological diagnosis of breast carcinoma is reached timely for a better prognosis as the disease has an increased chance of successful outcome with early identification and treatment.

Objective The study aims at evaluating the role of stereotactic core needle biopsy (CNB) and percutaneous ultrasound-guided core needle biopsy (US-CNB) in diagnosing suspicious nonpalpable breast lesions.

Methods Our study included 35 patients with nonpalpable breast lesions and having a Breast Imaging Reporting and Data System (BI-RADS) risk assessment category IV or V on mammography or sonography. These 35 lesions were subjected to percutaneous image-guided (stereotactic or US) biopsy for histopathological analysis.

Results Out of a total of 35 cases, 17 were pathologically malignant (48.6%), with the most common subtype being invasive ductal carcinoma (82.3%). Twenty-nine cases underwent US-CNB, 16 (55.1%) of which were malignant and 13 (44.8%) were benign on histopathological evaluation (HPE). The remaining six cases, which on mammography showed no mass but suspicious malignant calcification only, were subjected to stereotactic CNB, out of which one (16.6%) was malignant and five (83.3%) were benign on HPE. Hence, the lesions visible on sonography were more likely to be malignant.

Conclusion Sonography and mammography play a complimentary role in detecting breast carcinoma. Percutaneous biopsy under image guidance can be used as an accurate diagnostic alternative to open surgical excisional biopsy to avoid diagnostic delay.

Keywords

- breast cancer
- ultrasound-guided core needle biopsy
- stereotactic core needle biopsy
- Breast Imaging Reporting and Data System
- histopathology

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Introduction

Breast cancer is the most common noncutaneous malignancy worldwide.[1] Given the increasing burden of new breast cancer cases and related morbidity and mortality, detecting it at an early preinvasive clinically nonpalpable stage can improve the cure rate and increase disease-free survival.[2] Surgical open excisional biopsy is the "gold standard" technique for the diagnosis of breast cancer. As the lesion is completely removed during excisional biopsy, there is very little chance of sampling error. However, nonpalpable breast lesions serve as a challenge in their diagnosis. In case of nonpalpable lesions, open excisional biopsy is performed after preoperative image-guided hook wire placement to guide the surgeon to the location of the lesion. Nevertheless, image-guided percutaneous core needle biopsy (CNB) and vacuum-assisted breast biopsy (VABB) have emerged as its reliable alternatives as they are easy, less invasive, cost-effective, highly accurate, and aesthetically better procedures with shorter recovery time and with few procedure-related complications.[3] Use of 14-gauge core needles has significantly improved the accuracy of breast CNB[3] with a false-negative rate of 0 to 9%.[4]

Most breast lesions are biopsied under ultrasound (US) guidance. Ultrasonography (USG) guided procedures are preferred as the patients tend to be more comfortable in the supine position, the breast is not compressed, and the procedure is fast and done in real time for better needle placement.[5] Lesions located close to the chest wall, in the axillary tail, or in the subareolar location are difficult to position under stereotactic biopsy but, these are easily targeted by US guidance. However, the major limitation of USG-guided biopsy that needs to be recognized is that detection of microcalcifications is only 23 to 45% even after correlation with mammograms.[6,7] Therefore, certain mammographic microcalcifications and small parenchymal deformities are not demonstrable on US and thus require stereotactic guidance for biopsy.

The aim of our study was to evaluate the diagnostic accuracy of image-guided biopsy (stereotactic and US-guided core needle biopsy [US-CNB]) in nonpalpable suspicious breast lesions and to establish the importance of screening mammography in early detection of breast cancer.

Methods

This was a prospective single-center study performed over a period of 1 year in the Department of Radiodiagnosis, Indira Gandhi Medical College and Hospital, Shimla, Himachal Pradesh, India. The institutional ethical board approved this study, which was conducted in accordance with the Helsinki Declaration, and written informed consent was taken from each patient. A total of 35 patients were selected for the study with an inclusion criterion of a nonpalpable breast lesion with a Breast Imaging Reporting and Data System (BI-RADS) IV or V risk assessment category on sonomammography. These patients were either symptomatic with vague breast pain or nipple discharge or asymptomatic, but patients in the high-risk group had either family history or previous history of breast cancer and patients in the low-risk group were referred for screening mammography. The exclusion criteria were patients with palpable masses and patients not giving consent for image-guided biopsy. Any significant personal and family history was taken from each patient. Clinical examinations and relevant blood investigations were also done.

All 35 patients underwent imaging, first on mammography and then on US on the same day. Mammography was performed on Amulet Innovality Digital Mammography machine (Fujifilm India). Standard craniocaudal (CC) and mediolateral oblique (MLO) views were obtained. Parenchymal density of the breasts was categorized according to BI-RADS composition grade into A (entirely fatty), B (scattered fibroglandular tissue), C (heterogeneously dense), and D (extremely dense).[8] Bilateral breasts were evaluated for masses, microcalcifications, architectural distortion, and asymmetry. The size, shape, outline, and density of the mass were recorded. Microcalcifications were evaluated for number, distribution, and morphologic type. Then the lesions were categorized into BI-RADS risk assessment category 0 to VI and subjected to sonography for final sonomammographic BI-RADS category allotment before biopsy.

US was performed on Lifecare GE Logiq P6 Premium with a linear probe having a frequency range of 5 to 12 MHz. Bilateral breasts were evaluated for any mass lesion, calcification, and duct dilatation on sonography. The size, shape, outline, height, width, echotexture, edge shadowing, posterior acoustic enhancement, vascularity, and microcalcifications of lesions were noted and given BI-RADS risk assessment category.[8]

All the BI-RADS category IV or V lesions, which were detected on sonography, underwent US-CNB and lesions not detected on US underwent stereotactic-guided CNB.

Ultrasound-Guided Core Needle Biopsy

Patients were positioned supine and the lesion was localized on sonography. Local anesthesia was injected around the lesion. A small skin incision (1–2 mm) was made at the biopsy site. Then under all aseptic conditions, US-guided biopsy was performed with a 14-gauge CNB gun. A total of four to five core biopsy samples were taken.

Stereotactic-Guided Core Needle Biopsy

Stereotactic breast biopsies are performed when suspicious lesions are seen on mammography but cannot be visualized with US. They are performed most commonly for microcalcifications, but also for areas of architectural distortion and some small mass lesions. The lesion is localized in three dimensions using two angled stereotactic images taken at 15 degrees to either side of the direction of the scout image. The computer software then calculates the target for correct placement of the needle. In our study, stereotactic biopsy was performed on Amulet Innovality Digital Mammography machine with add-on digital attachments in the upright position. The biopsy coordinates and depths were calculated from the image on the stereotactic breast biopsy unit. The

procedure was performed under local anesthesia without intravenous sedation. Small skin incision was made at the site of the needle entry through which a 14-gauge core needle was inserted. Stereotactic images were used to confirm the needle position and four to five core biopsy samples were taken from each lesion. Magnified breast biopsy specimen radiographs were obtained to confirm the presence of calcifications.

Specimens were preserved in formalin and sent for histopathological analysis for final diagnosis, which was taken as the gold standard. Histopathological diagnosis was then correlated with mammographic and sonographic diagnosis.

Follow-Up and Data Analysis

The clinical and imaging findings were reviewed, along with histopathological results for each biopsy. In cases of discordance, repeat biopsy or surgical excision of the breast lesion was done. Patients with concordant benign lesions underwent repeat mammography and US at 6 or at 12 months to confirm the benign nature of the lesions. Patients with high-risk lesions or histopathologically confirmed malignant lesions underwent surgical resection. Data were entered in Microsoft Excel spreadsheet, cleaned for errors, and analyzed using SPSS 16.0 for windows. We performed a descriptive analysis to characterize the baseline characteristics of study participants in terms of number and percentages.

Results

A total of 35 patients with nonpalpable breast lesions with BI-RADS categories IV and V on mammography or sonography underwent image-guided biopsy. The age of the patients ranged from 35 to 72 years, with a mean age of 51.2 years. The maximum number of patients were in the age group of 41 to 60 years (26, 74.2%). The average age of menarche was 13.2 years in the study population, with maximum age of 15 years and minimum age of 12 years. Out of these 35 patients, 21 patients were postmenopausal, while 14 patients were still in the menstruating phase. None of the patients in our study population received any kind of hormone replacement therapy after menopause. Five patients presented with vague breast pain and discomfort, while seven had nipple discharge. Twenty-three patients did not have any clinical complaints. Out of these, seven had a family history of breast cancer (►Fig. 1), 14 were above 40 years of age and undergoing screening mammography, and the remaining 2 patients had a history of breast cancer in the contralateral breast for which they had already undergone mastectomy and were on the high-risk screening protocol for the remaining breast.

The most common mammographic parenchymal density of breasts was type B (71.4%). Calcification was seen in 19 patients on mammography. All four cases of benign type of calcification were proven to be benign on HPE, whereas 10 of 15 (66%) cases of suspicious type of calcification were proven to be malignant on histopathology. So, the malignancy rate was higher in the cases with suspicious type of calcification (►Table 1). Architectural distortion was seen in 17 cases, out of which 13 (76.5%) were proven to be malignant on histopathology. Eighteen cases did not show any architectural distortion, out of which 4 (22.2%) were proven to be malignant. Hence, architectural distortion was significantly associated with the malignancy ($p = 0.001$).

On US, a total of 11 cases demonstrated calcification, of which 6 were classified as benign and 5 as malignant. Eight out of these 11 cases demonstrating calcification were proven to be malignant on histopathology. Out of the total six cases demonstrating benign type of calcification, four (66.6%) were proven to be malignant. While out of total five cases demonstrating suspicious type of calcification, four (80%) were proven to be malignant. The p-value was 0.139, which denoted no significant correlation between type of calcification on US and possibility of malignancy (►Table 2).

On combined sonomammography, 15 cases were categorized as BI-RADS IVa and 3 as IVb, all of which were proven benign on histopathology. Nine cases were classified as IVc and eight were classified as category V, all of which were malignant on histopathology. On mammography, lesions were detected in 28 of 35 cases, out of which mass with no calcification was seen in 9 cases, mass with calcification in 13 cases, and only calcification with no mass was present in 6 cases. On sonography, breast masses were visible in 28 cases, only architectural distortion with calcification was seen in 1, and no mass was seen in the remaining 6 cases even after correlating with mammographic microcalcification, which were seen in all these cases. So, all these 6 cases underwent stereotactic CNB (►Fig. 2) and the remaining 29 underwent US-CNB (►Fig. 3). No major complications were seen during the biopsy procedures. A few experienced little pain and slight bleeding from the biopsy site. On HPE, out of the total of 35 cases, 15 cases were malignant, 17 were benign, and 3 cases were inconclusive due to sampling error in the biopsy specimen. The mammograms and US images of all the benign ($n = 17$) and inconclusive ($n = 3$) cases were reviewed by two radiologists on consensus. On review, these three inconclusive cases were considered suspicious for malignancy and a repeat biopsy of these breast lesions was done. On repeat biopsy, two turned out to be malignant and one benign on HPE. Thus, in the final histopathological analysis, 17 of 35 lesions were malignant, out of which 14 were invasive ductal cell carcinoma (►Fig. 4), 2 were ductal carcinomas in situ (DCIS; ►Fig. 2), and 1 was invasive lobular carcinoma. The overall malignancy rate in our study was 48.6% (17/35). Invasive ductal cell carcinoma was the most common histopathologic subtype (82.3%) seen in these 17 malignant breast lesions. The remaining 18 cases, which were benign on HPE (►Figs. 5, 6), underwent follow-up mammography or sonography at 6 or 12 months, and no significant change in lesions was detected.

Discussion

Breast carcinoma is the most common malignancy diagnosed in women worldwide. The incidence was 2.26 million cases in 2020.[9] Deaths due to breast cancer account for 20% of global cancer deaths.[10] With the widespread introduction of

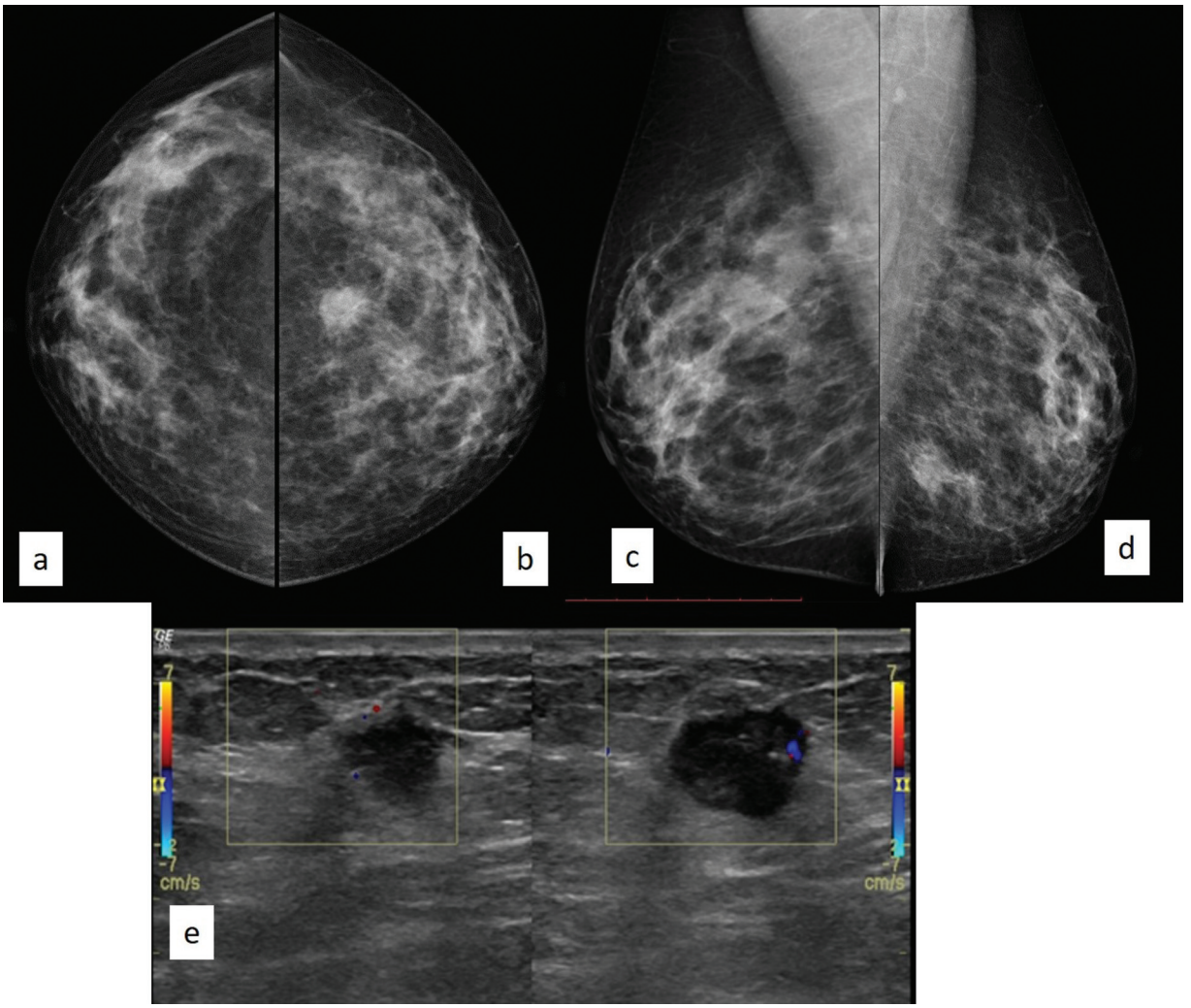

Fig. 1 A 45-year-old woman having a family history of breast carcinoma with duct cell carcinoma in situ of the left breast. (**a–d**) Mammography shows the presence of an oval high-density mass lesion with spiculated margins in the outer lower quadrant of left breast. (**e**) On ultrasound, a hypoechoic mass lesion with edge shadowing and moderate vascularity was present.

Table 1 Type of calcifications identified on mammography and its correlation with malignancy

		Histopathology		Total
	Calcification type (on mammography)	**Malignant**	**Benign**	
	Benign	0	4	4
	Suspicious	10	5	15
Total		10	9	19

Table 2 Type of calcifications identified on ultrasound and its correlation with malignancy

	Calcification type (on ultrasound)	**Histopathology**		**Total**
		Malignant	**Benign**	
	Benign type	4	2	6
	Suspicious type	4	1	5
Total		8	3	11

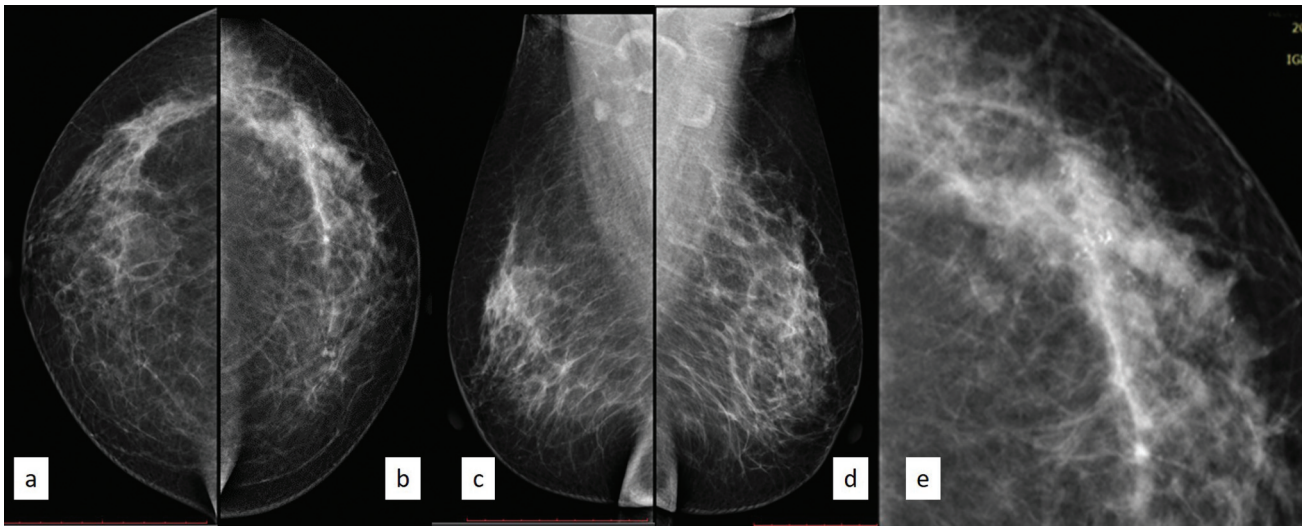

Fig. 2 A 52-year-old woman with ductal carcinoma in situ of the left breast. (**b**) Craniocaudal and (**d**) mediolateral oblique views of left breast show the presence of pleomorphic microcalcification in the upper outer quadrant of the left breast with surrounding asymmetry which is better depicted on magnified mammographic view (**e**). No lesion was identified on ultrasonography. (**a**) Craniocaudal and (**c**) mediolateral oblique views of right breast show normal breast parenchyma.

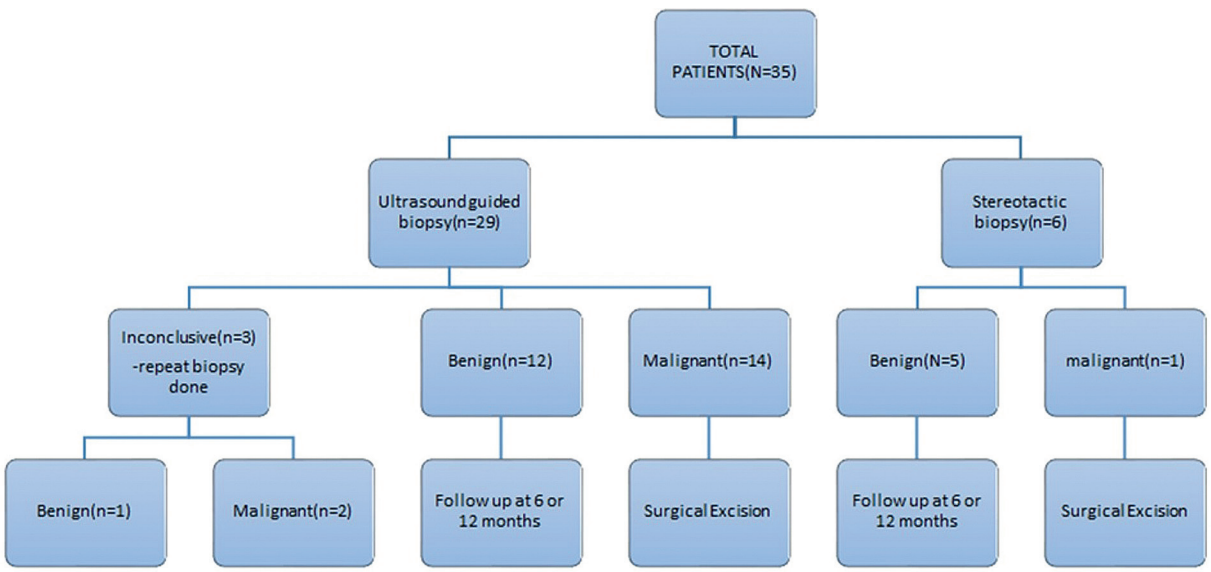

Fig. 3 The flow chart shown above needs n=6 in place of 29 in stereotactic biopsy box.

National Screening Program for breast cancer, there is significant increase in detection of clinically occult nonpalpable breast lesions.[5] Screening mammography plays an important role in the detection of early breast carcinoma. In addition, breast ultrasonography offers another effective imaging tool for early diagnosis of breast cancer. It is a better imaging modality than mammography for detecting lesions in mammographically dense breast. It is an easy, cost-effective, portable, ionizing radiation-free imaging modality widely available even in low-resource settings and remote areas.[11]

Different diagnostic imaging modalities are now available to guide for tissue retrieval for histopathological analysis, each with its own pros and cons. Palpable lesions are easily identified by clinical examination and undergo fine needle aspiration cytology (FNAC) or biopsy readily. However, FNAC is prone to sampling errors and thus unreliable giving false-negative results and lower accuracy rates. US-CNB was introduced by Parker et al in the 1990s.[3,12] Since then, it has gradually replaced FNAC as an option for initial diagnostic tissue sampling method.[13] US-CNB is considered less traumatic and safer than surgical open excisional biopsy. However, the limitation of this procedure, which is a matter of concern, is underestimation of malignant lesion that is, improper pathological characterization of lesion highly suspicious for malignancy.[3] Image-guided biopsies like CNB and VABB are considered more accurate for obtaining a truly representative tissue than palpation-guided biopsies.[14–17] VABB, with its introduction in 1995, has higher diagnostic accuracy as compared with CNB and provides 10 times larger tissue volume.[10] However, it is costlier and not easily available.[18]

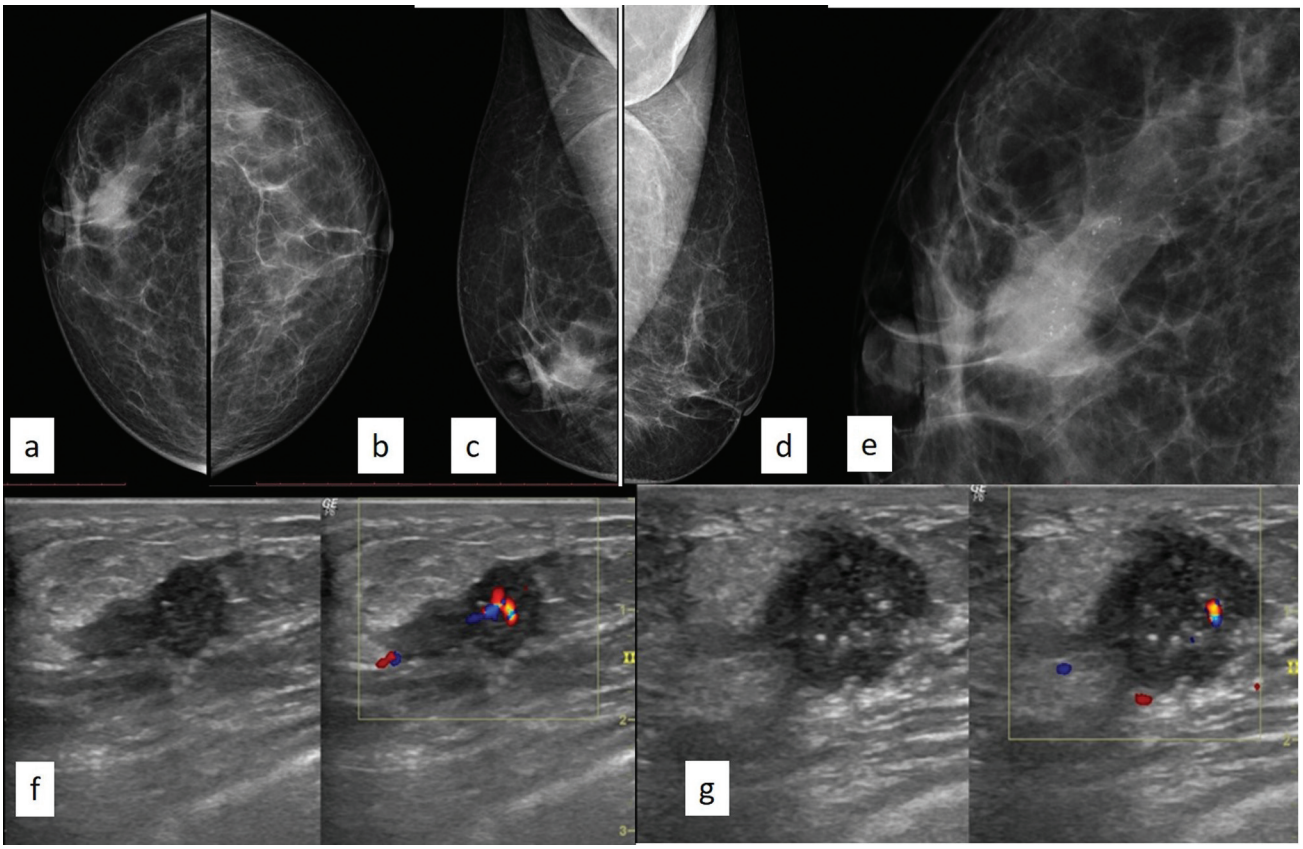

Fig. 4 A 63-year-old woman with infiltrating duct cell carcinoma of the right breast. (**a**) Craniocaudal, (**c**) mediolateral oblique, and (**e**) magnified mammographic view demonstrate focal area of asymmetric high density with surrounding architectural distortion with pleomorphic microcalcification in the lower outer quadrant of the right breast. (**f, g**) Ultrasound shows the presence of a hypoechoic mass of size 1.9×1.1 cm with microcalcifications and marked vascularity.(**b**) Craniocaudal and (**d**) mediolateral mammographic views of left breast show normal breast parenchyma.

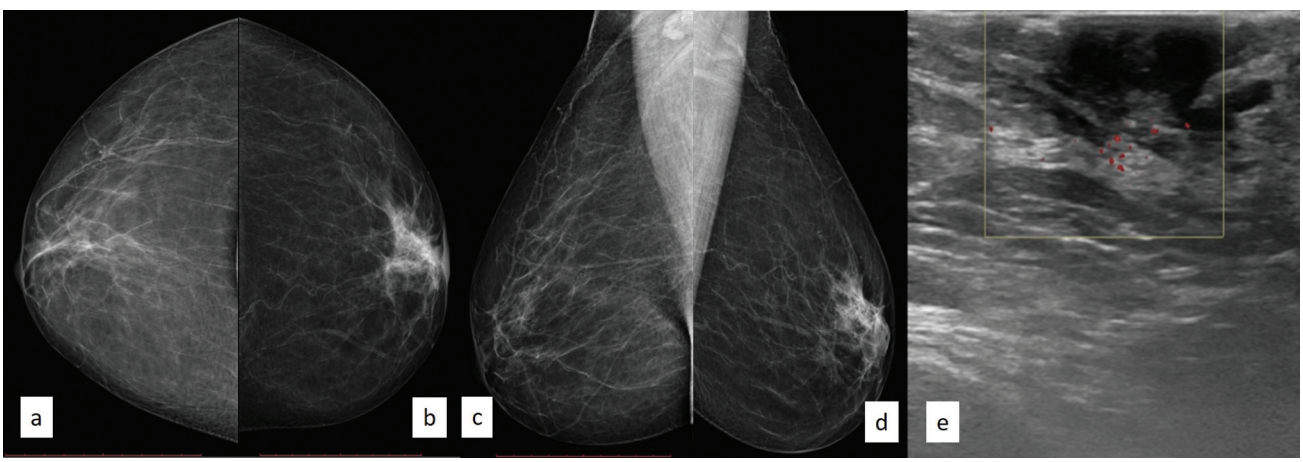

Fig. 5 A 60-year-old woman with granulomatous mastitis of the left breast. (**b**) Craniocaudal and (**d**) mediolateral Mammography views shows the presence of architectural distortion and focal asymmetry in the retroareolar region of the left breast. (**e**) Ultrasound shows hypoechoic lesion in the retroareolar region without any significant vascularity. (**a**)Craniocaudal and (**c**) mediolateral Mammography views of right breast show normal breast parenchyma.

Image-guided biopsy was performed on nonpalpable breast lesions, which were suspicious for malignancy in this prospective study. A total of four to five biopsy specimens were obtained from each breast lesion. The recommended number of biopsy specimen are also at least four[19] so that sufficient tissue is available for a complete histopathologic diagnosis and immunohistochemistry.

On mammography, 10 out of 19 calcification (52.6%) were of malignant pathology in the current study, which was in concordance with a study done by Kim et al.[20] They performed stereotactic biopsy in 62 cases with microcalcifications, out of which 29 were proven to be malignant on histopathology with a malignancy rate of 46.7%. A study by Bohan et al[21] found that 63.2% of calcification were

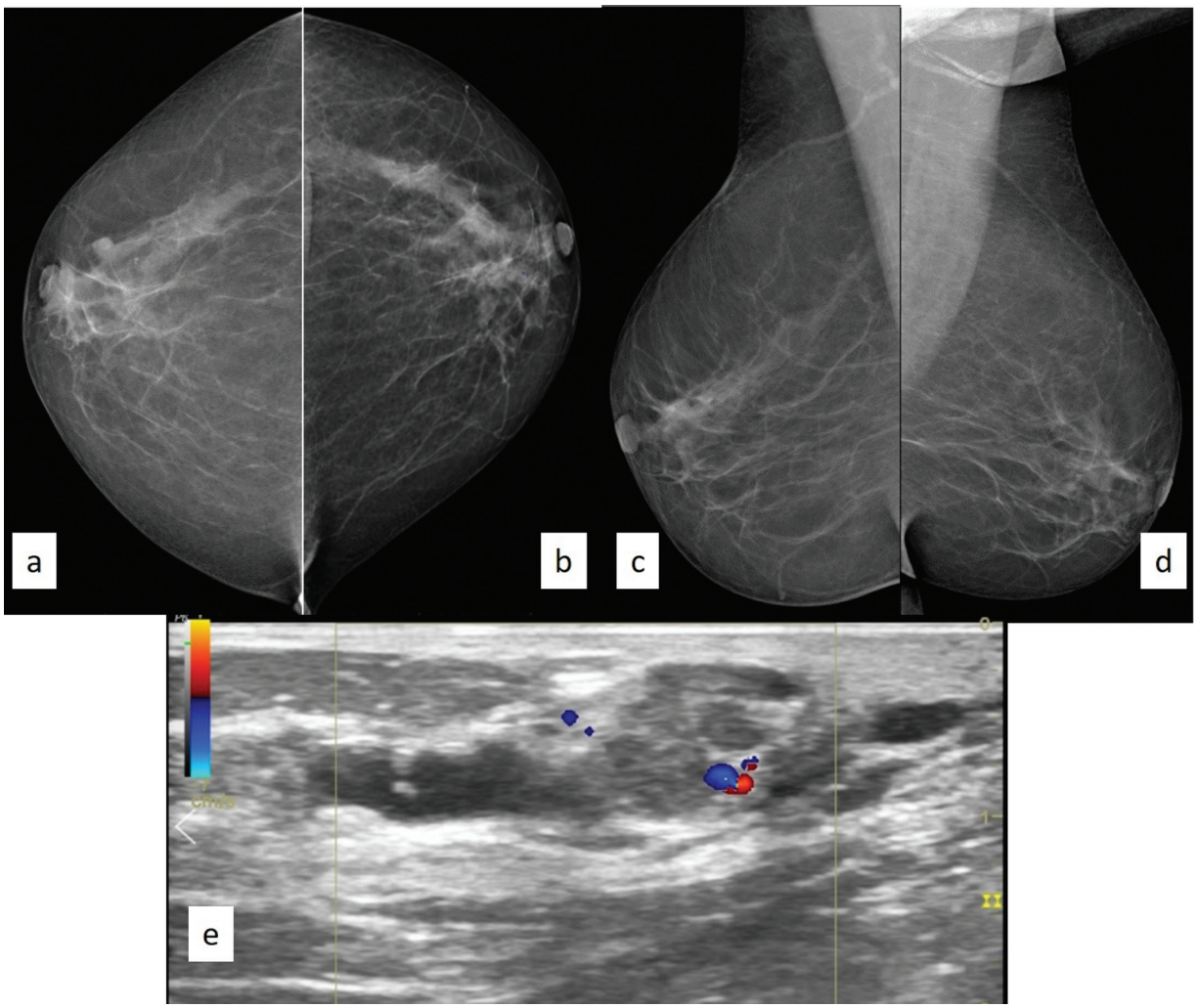

Fig. 6 A 57-year-old woman with fibrocystic disease of the right breast. (a, c) Mammography shows the presence of an intermediate density oval lesion in the upper outer quadrant of the right breast with foci of calcification and architectural distortion with obscured margins. (**e**) Ultrasound shows the presence of a hypoechoic lesion with well-defined margins and calcification. There is evidence of adjacent prominent ducts. (**b**) Craniocaudal and (**d**) mediolateral mammographic views of left breast show normal parenchyma.

associated with benign lesions. In our study, calcification was demonstrated in 11 cases on US, out of which 72.7% ($n = 8$) cases were proven to be malignant. This is similar to study by Bae et al in which 51 of 77 (66.2%) cases with sonographically visible calcification were proven to be malignant.[22]

On mammography, 76.5% of the masses showing architectural distortion were proven to be malignant, so there was a significantly high correlation of architectural distortion with malignancy. However, in a study by Park et al,[23] architectural distortion was seen in only five cases, out of which only one was malignant. Also, in the present study, 28 (80%) cases demonstrated a mass on US, and 57.1% of the masses ($n = 16$) were proven to be malignant on histopathology, whereas 12 were benign, similar to the study by Pijnappel et al in which mass was seen in 76% of the total cases on US.[24] The malignancy rate was significantly higher in the current study as compared with study by Rahbar et al in which 23.1% masses were proven to be malignant.[25] This was because only BI-RADS category IV and V lesions were included in our study.

The overall malignancy rate in the present study was 48.6% (17/35), and the most common histopathologic type was invasive duct carcinoma seen in 82.3% (14/ 17) of cases. The findings were consistent with the study done by Youk et al in 2008.[3] They conducted a study to establish diagnostic accuracy of US-CNB in a total of 2,420 cases of palpable and nonpalpable breast lesions. The pathologic malignancy was found in 52% (1,256) cases in their study, out of which invasive duct carcinoma was seen in 80.6% (1,013/1,256) cases. A study by Wiratkapun et al in 2012 showed 46% breast malignancy rate (334 cases) in a total of 733 lesions and invasive duct carcinoma in 72.5% (242/334),[19] again consistent with our study. However, another study done by Parmar et al[26] on women younger than 45 years and having a dense breast on mammogram revealed a breast cancer rate of 32.8% (44 of 134 lesions). This disparity in findings may be due to the older age of the study participants and inclusion of only BI-RADS IV and V categories in the present study, which gave a higher malignancy rate.

Also, in the present study, the malignancy rate was 0% in BI-RADS IVa and IVb categories, whereas it was 100% in BI-RADS IVc and V categories. Although the likelihood of malignancy increases with higher BI-RADS category, this bias could be attributed to the small sample size. In study by Bae et al, the malignancy rate in BI-RADS IVa, IVb, IVc, and V categories were 17.9, 53.2, 84.8, and 100%, respectively.[22]

Twenty-three patients underwent screening mammography in the current study. Out of this, malignancy was detected in 11 cases (47.8%). It has been proven in various studies that screening mammography helps in early detection of malignancy.[27]

Stereotactic biopsy was performed in six patients, out which only one (16.6%) was malignant (DCIS) on histopathology. There was calcification along with focal asymmetry in this patient on mammography, while the remaining five cases only had calcification and were benign on HPE. In a multicentric study done by Kettritz et al, stereotactic biopsy (VAB) was performed in 2,874 cases, out of which 784 (27%) were proven to be malignant.[28]

US-guided breast biopsy was performed in 29 of 35 cases in our study, which accounted for 82.5% of total cases. This was similar to the study by Pijnappel et al in which 85% of the cases underwent US-guided breast biopsy.[24] Out of 29 cases undergoing US-guided breast biopsy, 16 (55.1%) were proven to be malignant on histopathology. In a study by Schueller et al, US-CNB was performed in 1,061 cases using a 14-gauge CNB needle, which yielded 671 (63.2%) malignant, 86 (8.1%) high-risk, and 304 (28.7%) benign lesions.[29] In our study, the malignancy rate in sonographically visible lesion was 55.1%, while it was 16% in lesions that were only seen in mammography. This is very similar to the finding observed by Bae et al,[22] who concluded that sonographically detected lesions had a higher malignancy rate of 66.2% as compared with sonographically invisible lesions, which had a malignancy rate of 22.2%.

Eren et al[30] conducted a study in which 126 breast biopsies were included and histopathologically correlated with BI-RADS category. More than one-third (37%) cases were malignant. They concluded that histopathological verification was necessary, especially in patients with BI-RADS IV lesions to exclude malignancy. Kasliwal et al[31] retrospectively studied 26 percutaneous core biopsy specimens. Out of these, 15 (57.6%) were found to be malignant. The most common malignant histological variant was infiltrating ductal carcinoma (14 cases). All these findings were consistent with the present study. Shah et al[32] studied 449 breast biopsies, out of which 38.53% were malignant. The most common malignancy observed was of ductal carcinoma (94.21%). Also, the age group of 41 to 60 years contained the maximum number of malignant cases as was also seen in our study.

Chakrabarthi[33] in a review article calculated that the number of estimated stereotactic biopsies in India would be 174,865 per annum nationally, if one considered that only the eligible urban population participated in screening. In such a scenario, the number of annual mammograms would be approximately 43,716,303 and 0.4% of these would be recalled for biopsy, which was the minimum recalled for assessment of microcalcifications after screening mammograms.

Bhattacharya et al[34] in their metanalysis emphasized the role artificial intelligence–based breast cancer screening in patients having breast cancer. They mentioned that incidences of breast cancer and deaths were higher in rural locations than in urban areas due to multifactorial reasons like cultural factors, ignorance, delay in diagnosis, and cost of treatment.

Limitations

The limitations to be recognized in our study were small sample size and a relatively short follow-up period of 1 year for benign lesions, which may be insufficient to accurately depict the overall true picture of benignity.

Conclusion

Early detection of breast cancer can cause a paradigm change in its management and can shift the prognosis from a rather gloomy one to a better one. Image-guided biopsy has a proven merit and accepted standard of care over surgical excision biopsy for the early diagnosis of nonpalpable breast lesions to establish the imaging–histopathologic correlation.

Authors' Contributions

C.S.T. and S.M. developed the study concept and design. S.P.S., C.S.T., and N.S. contributed to data acquisition. S.P.S., S.K., and S.T. analyzed the data. S.T. and S.P.S. drafted the manuscript. A.J. and N.A. contributed to critical revision of the manuscript. All authors read and approved the final manuscript.

Conflict of Interest

None declared.

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