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Diagnostic Accuracy of Mammography and Ultrasonography Screening for Breast Cancer in Pregnant and Lactating Women

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ABSTRACT

Breast cancer was of significant health concern affecting women worldwide. **Objective:** To assess diagnostic accuracy of mammography and ultrasonography in differentiating malignant and benign breast lesions in pregnant and lactating women. **Methods:** A cross sectional retrospective study was conducted at Radiology department of Shahida Islam Medical Complex, Lodhran from May 2023 to April 2024. A sample size of 242 females was calculated. Electronic medical records were reviewed for radiological examination including screening ultrasound and mammography. All those pregnant and lactating females on which ultrasound and mammograms were performed were included. SPSS version 23.0 was used for data analysis. Diagnostic accuracy of both ultrasound and mammography were calculated in terms of malignant or benign and sensitivity and specificity. Mann-Whitney U test was applied between mammography, ultrasonography and BI-RADS categories. **Results:** Of 242 females, 110 underwent mammography and 132 underwent ultrasound. Negative mammography was observed in 71 females in which at biopsy, 24 were benign. Negative ultrasound with only benign lesion was seen in 68 females and 10 of which were confirmed at biopsy. Specificity of ultrasonography was 100 %, sensitivity 85.7 %, positive predictive value of 100 % while negative predictive value of 25 %. Specificity of mammography was 100 %, sensitivity 92.3 %, positive predictive value of 100 % while negative predictive value of 42.8 % ($p<0.001$). **Conclusions:** Although both ultrasound and mammography were found to be specific, use of mammography was considered better in terms of sensitivity and diagnostic accuracy.

INTRODUCTION

Worldwide, breast cancers have been regarded as the most common, having significant health concern affecting women worldwide, and presents unique challenges due to fetal radiation exposure concerns [1]. Radiological screening has a crucial role in early detecting breast cancer, but traditional modalities like mammography may pose risk to fetus as well as in breastfeeding infant. Hence, developing effective and safe screening strategies tailored to pregnant and lactating women is imperative [2]. Mammography is gold standard screening test for cancers of the breast in non-lactating or non-pregnant females. However, its use in pregnant and lactating women is limited because of potential risks linked to exposure of radiation to fetus [3]. Evidence-based guidelines were established by American College of Radiology (ACR) for various clinical disorders, however for screening of cancers of breast, limited published evidence persists in support of it for females that are either lactating or pregnant [4]. Nonetheless, screening for breast cancers through mammography is not contra-indicated amid pregnancy, especially for females that are prone to cancers of the breast [5]. If ultrasonography or biopsy of solid lesion reveals malignancy in pregnant or lactating females, digital breast tomosynthesis and mammography are recommended to be performed [6]. Thorough evaluation via mammography is advised in order to stage breast cancers in pregnant females loco regionally [7]. Another modality for evaluating lesions of the breast in pregnancy

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and lactation is ultrasonography, having the added benefit of no exposure to radiation and is a sensitive imaging technique [8]. Diffuse hypo-echogenicity along with increase in vascularity and fibro-glandular enlargement are observed in the breast in pregnancy. Conversely, diffuse hyper-echogenicity along with increased vascularity and prominent ductal systems are reported during lactation [9]. Ultrasound is an initial imaging test of choice in under 30-year-old pregnant and lactating females, given lack of radiation exposure. Females that are lactating and are 30 years and older are mostly imaged via both mammography and ultrasonography [10]. For reducing overall breast density, lactating females are advised to secrete milk immediately before imaging [11]. Magnetic Resonance Imaging (MRI) is not typically used for breast cancer screening in pregnant or lactating women due to the physiological increases in breast vascularity during pregnancy and lactation, which result in markedly increased background parenchymal enhancement. These changes may limit the sensitivity of MRI, and its use is generally reserved for delineating disease extent in lactating women with breast cancer [12, 13]. In conclusion, logical screening strategies for breast cancer in pregnant and lactating women involve the use of ultrasonography as the initial imaging modality, with mammography reserved for pregnant women with suspicious findings on ultrasonography or biopsy of a solid lesion revealing malignancy [14]. MRI is generally not used for breast cancer screening in pregnant or lactating women due to the physiological increases in breast vascularity during pregnancy and lactation. The evaluation of breast imaging studies during pregnancy and lactation is challenging and the ACR Appropriateness Criteria recommend that pregnant women with palpable masses or pathological nipple discharge should be initially evaluated by ultrasonography [15]. Mammography can be used as a supplement to ultrasonography for breast evaluations in pregnant women with palpable masses or pathological nipple discharge. Overall, the goal of breast cancer screening in pregnant and lactating women is to balance maternal and fetal well-being while ensuring timely and appropriate care [16]. In majority of pregnant and lactating females, screening for breast cancer is carried out using either ultrasonography or mammography, seldom are both strategies employed for proper and complete screening of females. Due to high economic burden and patient's inflow, both strategies are not always used for screening. Therefore, this study has been undertaken to compare and determine as to which of the two screening are better suited for breast cancer in pregnant and lactating women.

The objective of this study was to assess the diagnostic accuracy of mammography and ultrasonography in differentiating between malignant and benign breast lesions in pregnant and lactating women.

METHODS

A retrospective cross sectional study was carried out after ethical approval from the Ethical Review Committee of Shahida Islam Medical Complex, Lodhran IRB no. SIMC/H.R./7729/23. Since this was a retrospective study, therefore need for informed consent was waived. All the breast ultrasounds and screening mammograms that were performed for pregnant and lactating women during the study time period May 2023 to April 2024 at Radiology department of Shahida Islam Medical Complex, Lodhran, Pakistan were included in the study. Pregnant (any trimester) or lactating mothers (within first year postpartum) between ages 18 to 45 years and presenting with clinical signs or symptoms suggestive of breast cancer (e.g. palpable breast mass, nipple discharge or skin changes etc.) and willing to undergo mammography or ultrasonography as part of screening process were included in the study while females with a previous history of breast cancer or any other malignancy with last 5 years were excluded from the study. In addition, females having co-morbid conditions which might affect participation or interpretation of imaging results were also excluded. Sample size calculation was carried out using online software for sample size calculation (web) using sensitivity/specificity estimation (https://wnarifin.github.io/ssc/sssnsp.html) in accordance with a reference for formula [17]. Keeping 92.5 % sensitivity and 76.47 % specificity as reported in a local study and prevalence of breast cancer at 50 % as reported in another local research with 85 % confidence level, the sample size calculated was 245 [18, 19]. This study included a total of 242 patients. Patient's medical files were manually reviewed for complete history, clinical examination and radiological examination including screening ultrasound, mammography, diagnostic imaging and pathological results (if available), clinical outcome after follow up were recorded. Biopsy-proven lesions having pathological abnormality for over 3 months of radiologic or clinical follow up were included in the study while biopsy-proven lesions having pathological abnormality for less than 3 months of radiologic or clinical follow up were excluded and regarded as lost to follow up. Mammograms performed at the hospital used either digital technique (DMR and D2000, GE Healthcare) or standard film screen. Breast ultrasound was carried out by interpreting radiologist (GE Healthcare, GE Logiz 700 and ATL HDI 5000, Philips Healthcare). In case of focal problem such as focal thickening, lump or palpable mass, erythema etc. directed ultrasonography was done. In cases suspected of generalized breast involvement, entire breast underwent ultrasonography. For evaluation of symptomatic women, National Comprehensive Cancer Network's guidelines were taken into account. Generally,

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females below 30 years of age underwent ultrasonography only and only if clinical symptoms or imaging findings were inconclusive, then mammography was done. In females 30 years and above, both ultrasonography and mammography were performed. Nonetheless it was on the discretion of the consulting clinician to modify the protocol. Mammography Quality Standards Act (MQSA) was used by radiologist for interpretation of each examination. BI-RADS assessment was used for both ultrasonography and mammography examinations. If any specific BI-RADS assessment was not included, radiologist reviewed the reports and assigned ultrasound BI-RADS category based on the standard criteria viz. 1-3 as negative and 4-5 as positive [20]. For calculation of diagnostic accuracy overall and sensitivity, specificity, Positive Predictive Value (PPV) and Negative Predictive Value (NPV), the following formulas were used.

$$\text{Diagnostic Accuracy: } \frac{TP + TN}{TP+TN+FP+FN}$$

True Position (TP)	False Positive (FP)	**PPV:** TP/ (TP+FP)
False Negative (TN)	True Negative (TN)	**NPV:** TN/ (TN+FN)
Sensitivity: TP/(TP+FN)	**Sensitivity:** TN/(FP+TN)	

Data were entered into Microsoft Excel and analyzed using SPSS version 23.0. Sensitivity and specificity of both ultrasound and mammography were calculated. Mann-Whitney U test was applied between mammography and ultrasonography and between BI-RADS categories. $P<0.05$ was considered as statistically significant.

RESULTS

Amongst the 242 female patients included in the study 27 were asymptomatic while 217 were symptomatic. The chief presenting complaint in 16 (6.72 %) females had a family history of breast cancer and attended OPD for checkup. Nine (3.73 %) were called back from screening and 02 (0.75 %) came for follow up with a previous lesion of BI-RADS 3. Palpable mass was present in 155 (64.01 %) females, 22 (9.01 %)) had erythema, 13 (5.37 %)) pain, 08 (3.3%) thickening, 05 (2.01 %) bloody nipple discharge, 02 (0.83 %) dimpling while breast firmness was reported in 04 (1.49 %), milk rejection and clear, yellow or milky discharge in 03 (1.24 %) each female (Table 1).

Table 1: Chief Presenting Complaint of Females with Breast Lesion (n=242)

Chief Presenting Complaint	Frequency (%)
Asymptomatic	
Family History of Breast Cancer	16 (6.72%)
Call Back from Screening	9 (3.73%)
Short Term follow up (Lesion Previously BI-RADS-3)	2 (0.75%)
Symptomatic	
Palpable Mass	155 (64.01%)
Erythema	22 (9.01%)
Pain	13 (5.37%)
Thickening	8 (3.3%)
Bloody Nipple Discharge	5 (2.01%)
Breast Firmness	4 (1.65%)
Milk Ejection	3 (1.24%)
Clear, yellow or milky discharge	3 (1.24%)
Dimpling	2 (0.83%)

A total of 110 females had undergone mammography and 132 had undergone ultrasound. Some females had undergone both. A negative mammography was observed in 71 (64.54%) females in. Benign calcifications were reported in 13 (11.81%) females while malignant in 03 (2.72%). Other benign / malignant findings were reported in Table 2. A negative ultrasound with only benign lesion was seen in 68 (51.51%) females. Solid mass (benign) was observed in 26 (19.69%) while malignant in 03 (2.27%) females. Other findings, their benign and malignant nature were reported in table 2.

Table 2: Baseline Characteristics of Lesions Evaluated using Ultrasonography and Mammography (n=242)

Techniques / Findings	Benign N (%)	Malignant N (%)
Mammography		
Negative	71 (64.54%)	0
Calcification	13 (11.81%)	3 (2.72%)
Mass	10 (9.09%)	0
Mass and Calcification	1 (0.91%)	1 (0.9%)
Architectural Distortion	0	1 (0.9%)
Focal Symmetry	9	0
Dense Lymph Nodes	0	1 (0.9%)
Others (Air-Fluid Level)	1 (0.91%)	0
Ultrasound		
Negative	68 (51.5%)	0
Solid Mass	26 (19.69%)	3 (2.27%)
Simple Cyst	10 (7.57%)	0
Complication Cyst	3 (2.27%)	0
Complex Cyst	5 (3.78%)	0
Dilated Ducts	6 (4.54%)	1 (0.75%)
Dilated Ducts with Solid Intra-Ductal Component	0	1 (0.75%)
Ill-Defined Attenuation	3 (2.27%)	1 (0.75%)
Subcutaneous Edema	2 (1.51%)	0
Sebaceous Cyst	2 (1.51%)	0
Inflammatory Lymph Mode	1 (0.75%)	0

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Figure 1 showed the graphical representation of both mammography and ultrasonography assessments in terms of their outcomes using BI-RADS. Outcome was regarded by clinical follow up or pathological analysis (biopsy confirmation). Specificity of ultrasonography was 100%, sensitivity 85.7%, positive predictive value of 100% while negative predictive value of 25%. Specificity of mammography was 100%, sensitivity 92.3%, positive predictive value of 100% while negative predictive value of 42.8%. A significant difference between both mammography and ultrasonography with the outcomes were observed ($p<0.001$).

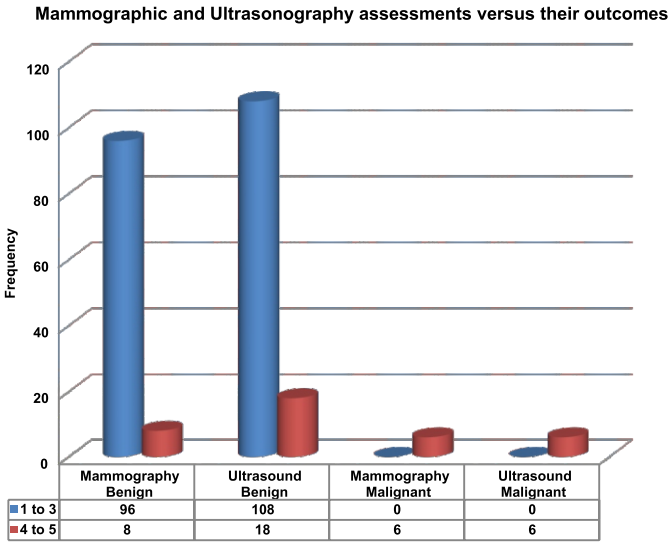

Figure 1: Graphical Representation of Mammographic and Ultrasonography Assessments versus Their Outcomes Using BI-RADS [$p<0.001$] (n=242)

This diagnostic test shows an accuracy of 92.7%. It correctly identified 96 cases as benign (true positives) with no false positives. However, it missed 8 malignant cases (false negatives), while correctly identifying 6 cases as malignant (true negatives). While the test was highly accurate, the presence of false negatives suggests some malignant cases were not detected (Table 3).

Table 3: Diagnostic Accuracy of Mammography (n=110)

Diagnostic Accuracy	Benign	Malignant
Positive Result	96 (True Positive)	0 (False Positive)
Negative Result	08 (False Negative)	06 (True Negative)
Diagnostic Accuracy	92.7 %	

This diagnostic test achieved an accuracy of 81.8%. It correctly identified 108 cases as benign (true positives) without any false positives. However, it failed to detect 18 malignant cases (false negatives) and correctly identified only 6 cases as malignant (true negatives). While the test effectively avoids misclassifying benign cases as malignant, the higher number of false negatives indicates a significant limitation in detecting all malignant cases (Table 4).

Table 4: Diagnostic Accuracy of Ultrasonography (n=132)

Diagnostic Accuracy	Benign	Malignant
Positive Result	108 (True Positive)	0 (False Positive)
Negative Result	18 (False Negative)	06 (True Negative)
Diagnostic Accuracy	81.8%	

DISCUSSION

The findings of this reported that both mammography and ultrasonography were safe, effective and accurate in terms of lesion identifying as well as keeping maternal and fetal/neonatal/infant health safe. Even though both screening techniques demonstrated 100% specificity and 100% PPV, sensitivity of mammography was higher than that of ultrasonography (92.3% vs 85.7%). Negative predictive value of mammography was also found to be higher than that of ultrasonography (42.8% vs 25%). Diagnostic accuracy of mammography was found to be higher than that of ultrasonography in our study (92.7% vs 81.8%). In a meta-analysis assessing the risk-benefit ratio of mammography in pregnant women with high-risk factors for breast cancer, it was observed that moderate sensitivity with low fetal radiation exposure risk was reported in pregnant women. The paper concluded that mammography many only be considered in high-risk cases after thorough risk assessment and shared-decision making [19]. Another retrospective comparative analysis of ultrasonography versus mammography in pregnant women reported that ultrasound demonstrated higher sensitivity (89 %) as compared with mammography (72 %) in detection of breast lesion without any fetal radiation exposure. The study concluded that ultrasound ought to be used as primary imaging modality for screening of breast lesions among pregnant women [20]. A study on the safety of contrast-enhanced MRI in lactating women observed that it was safely performed during lactation, even enhancing the diagnostic accuracy in breast cancer screening, however the study only included lactating women and not currently pregnant women [21]. Literature suggests that screening of pregnant and lactating females using ultrasonography or mammography has its advantages and disadvantages, for instance ultrasound was regarded as safe, accurate, versatile and easily accessible while on the down side, it has limited sensitivity, operator dependency and sometimes show inconclusive results [22, 23]. On the other hand, mammography can he highly sensitive, detect even micro calcifications, has well-established standardized protocols and complements ultrasound [24]. However, with mammography, risk of fetal radiation exposure was a major drawback coupled with the decreased sensitivity during pregnancy and lactation of the breast and was sometimes discomforting as it requires manual compressions [25]. In summary, both ultrasound and mammography have roles to play in breast cancer screening for pregnant and lactating women, but their use

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should be tailored to individual circumstances and risk factors. Ultrasound was generally preferred due to its safety and versatility, while mammography may be considered in specific cases where it can provide additional diagnostic information without undue risk to the fetus. Shared decision-making between patients and healthcare providers was essential to ensure that screening strategies prioritize both efficacy and safety [26-28]. Additionally, ongoing research and technological advancements may further improve the diagnostic accuracy and safety of breast cancer screening in this population. Although this study compared that two screening strategies among pregnant and lactating women, however this study was not free from limitations. The retrospective nature of the study and selection criteria of patients might have led to selection bias. In addition, limited sample size and the fact that this was a single centered study, cannot be authentically be generalized for the larger population. Further larger scale studies were required to generalize the findings reported in this study.

CONCLUSIONS

Although both ultrasound and mammography were found to be specific, use of mammography was considered better in terms of sensitivity and diagnostic accuracy. Further researches would be enlightening to the findings reported in this study.

Authors Contribution

Conceptualization: NM

Methodology: WA

Formal analysis: SB, MH

Writing, review and editing: NM, FU, SH, SB, ZUA, MH

All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

The authors declare no conflict of interest.

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