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ORIGINAL ARTICLE

Diagnostic Accuracy of Ultrasonography in Differentiating Benign and Malignant Breast Masses with Histopathological Correlation

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ABSTRACT

Introduction: *Breast cancer remains the most common malignancy in women worldwide, with a rise in incidence in younger populations. Early and accurate diagnosis is critical for the improvement of outcomes. Ultrasonography (USG), a non-surgical modality with extensive availability, is a useful technique in assessing breast masses, albeit histopathology being the gold standard.* ***Objectives:*** *The aim of this study was to assess the diagnostic accuracy of ultrasonography in differentiating between benign and malignant breast lesions by histopathological correlation.* ***Methods & Materials:*** *This cross-sectional observational study was conducted in the Department of Radiology and Imaging, Community Based Medical College Bangladesh,* Mymensingh, *Bangladesh Jan 2020 to Dec 2020. Total 116 patients who presented with palpable or clinically suspected breast masses and were referred for ultrasonography were included in the study.* ***Results:*** *The age of the patient was on average 36.5 ± 12.6 years, with most cases falling in the 35–44 years age group. Histopathology confirmed 60.3% benign and 39.7% malignant lesions. Ultrasonographic BI-RADS classification placed 47.6% of the lesions in suspicious or malignant categories (BI-RADS 4 and 5). Compared with histopathology, ultrasonography correctly diagnosed 42 out of 46 malignant and 62 out of 70 benign lesions, with statistically significant correlation ($p < 0.001$). Diagnostic accuracy was 91.3% sensitive, 88.6% specific, 84.0% PPV, 93.9% NPV, and 89.7% overall accuracy.* ***Conclusion:*** *Ultrasonography is very accurate in diagnosis and correlates well with histopathology in the evaluation of breast masses, warranting its status as a useful diagnostic modality in practice.*

Keywords: *Diagnostic Accuracy, Ultrasonography, Benign and Malignant Breast Masses, and Histopathological Correlation*

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INTRODUCTION

Breast cancer remains the most common malignancy in females worldwide and remains a key public health challenge. Latest estimates by the GLOBOCAN 2020 and projections for 2025 reveal that breast cancer accounts for more than 2.3 million new diagnoses and about 685,000 annual deaths and is the leading cause of cancer-related death among females worldwide.[1] It is not uniformly distributed and has a disproportionately high prevalence and mortality rate in low- and middle-income nations (LMICs), where access to early detection and treatment services remains suboptimal.[2,3] Of most concern, however, is a disconcerting rise in the number of cases of breast cancer among young women, particularly in LMICs, whose premature age of onset renders screening and treatment all the more difficult.[4,5] Such trends emphasize the global need for effective diagnostic and early detection methods.

Early detection of breast cancer will be crucial to reducing morbidity, mortality, and the economic burden of advanced-stage treatment. Imaging technologies form the cornerstone of early detection strategies, and mammography is employed widely in organized screening programs. However, mammography has age-old limitations in dense breast tissue, i.e., more so in younger women, hence necessitating adjunct or alternative imaging modalities.[6] In such situations, ultrasonography (USG) has emerged as a vital adjunctive diagnostic modality.

Ultrasonography has been universally used to be a safe, cheap, and non-invasive method for the evaluation of breast masses. Its non-ionizing properties and accessibility render it of

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particular utility in LMICs, as well as in populations with dense breast parenchyma whose sensitivity for mammography is low.[7,8] Conventional ultrasonographic assessment relies on firmly established morphological features like lesion shape, borders, echotexture, posterior acoustic features, calcification patterns, vascularity, and BI-RADS classification, which in combination refine the process of decision-making in diagnosis.[9,10] Studies have demonstrated that ultrasound enhances cancer detection rates when used as an adjunct modality in dense breasts, thereby solidifying its place in today's diagnostic algorithms.[6,11]

Despite these advantages, ultrasonography has its limitations. Its diagnostic performance is typically plagued by operator dependence, variation in image acquisition and interpretation having a bearing on accuracy. Besides, substantial overlap of sonographic features of benign and malignant breast lesions can reduce specificity and lead to unnecessary biopsies or misclassification.[7] While advances such as Doppler imaging and elastography have been introduced into practice to improve characterization of lesions, their use and accessibility are unequal within healthcare systems, particularly in resource-limited settings.[9] Hence, ultrasound alone cannot be a routine accurate definite diagnostic method.

Histopathology is still the gold standard for determining the nature of breast tumors. Imaging findings, regardless of modality, must ultimately be correlated with histological observations to achieve diagnostic accuracy.[9,10] Several studies evaluating the diagnostic accuracy of ultrasonography have produced variable outcomes with sample size, research design, population characteristics, and ultrasonographic equipment employed influencing sensitivity and specificity.[2] These discrepancies necessitate establishing region-specific evidence reflecting local demographic and clinical environments.

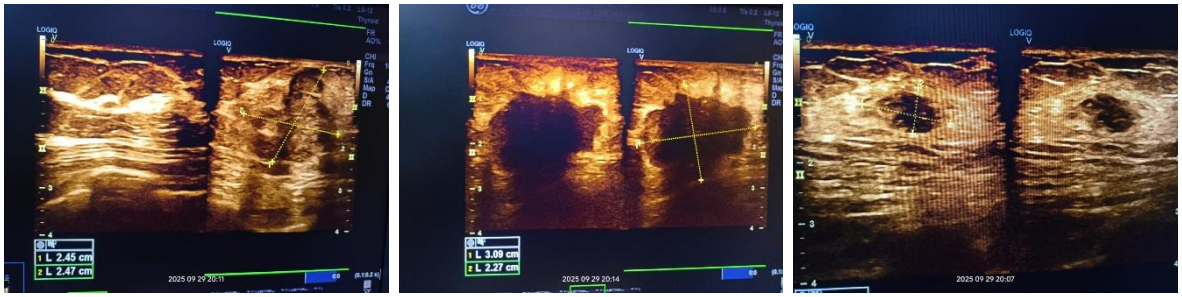
In the context of the ongoing global disease burden of breast cancer, the inadequacies of current diagnostic methods, and the need for strong correlation with histopathological data, the present study aims to validate the diagnostic accuracy of ultrasonography in differentiation between malignant and benign breast masses.

OBJECTIVES

To assess the diagnostic accuracy of ultrasonography in differentiating between benign and malignant breast lesions by histopathological correlation.

METHODS & MATERIALS

This cross-sectional observational study was conducted in the Department of Radiology and Imaging, Community Based Medical College Bangladesh, Mymensingh, Bangladesh Jan 2020 to Dec 2020. Total 116 patients who presented with palpable or clinically suspected breast masses and were referred for ultrasonography were included in the study. Inclusion criteria comprised patients aged between 15 to 65 years who underwent breast ultrasonography followed by histopathological examination of the same lesion. Patients with incomplete clinical or histopathological records, those who had undergone prior breast surgery for the same lesion, or those who received neoadjuvant chemotherapy or radiotherapy before ultrasonography were excluded to avoid confounding results. All patients underwent high-resolution ultrasonography using a linear-array transducer with a frequency range of 7–12 MHz. Imaging was performed by experienced radiologists, and the lesions were assessed systematically based on established sonographic parameters, including size, shape, margin characteristics, echotexture, posterior acoustic features, calcification patterns, and vascularity on Doppler evaluation. Each lesion was categorized according to the Breast Imaging Reporting and Data System (BI-RADS) classification to stratify the likelihood of malignancy. Subsequently, all patients underwent histopathological examination of the breast lesion, which served as the reference standard for diagnosis. Biopsy samples were analyzed by the Department of Pathology of the same institution, and histopathological outcomes were recorded. The diagnostic performance of ultrasonography was then evaluated by comparing the BI-RADS-based categorization with the histopathological diagnosis. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy of ultrasonography in differentiating benign from malignant breast masses were calculated using standard statistical methods. Ethical approval was obtained from the Institutional Review Board of Community Based Medical College, Bangladesh, and written informed consent was collected from all patients prior to their participation. All collected data were systematically recorded and subsequently analyzed using Statistical Package for the Social Sciences (SPSS) version 23. A p-value <0.05 was considered statistically significant for all analyses.



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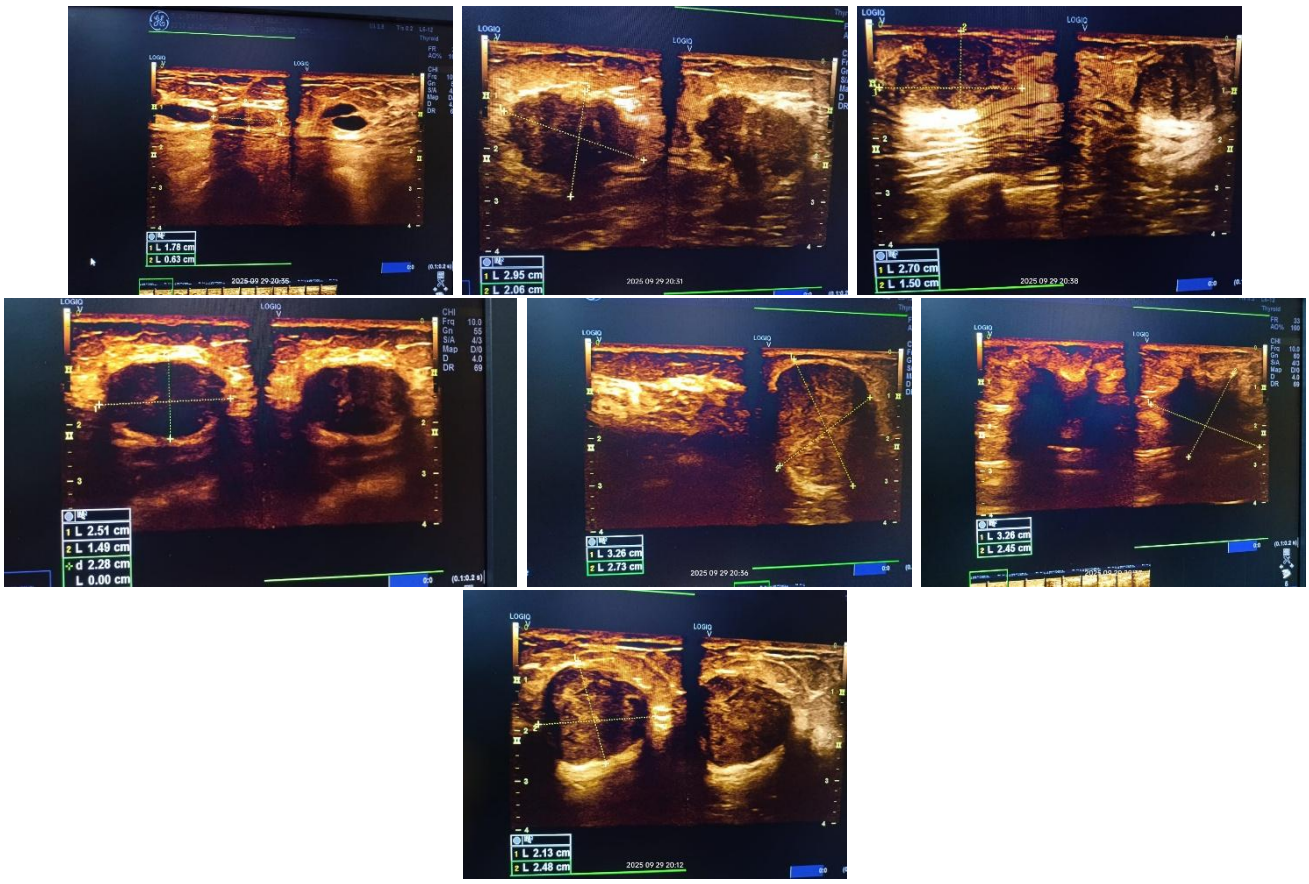

Figure 1: Ultrasonographic appearances of breast masses in the study population

RESULTS

The baseline profile of the study cohort is summarized in Table I. The age of the patients ranged from 15 to 65 years, with a mean age of 36.5 ± 12.6 years. The majority of patients (27.59%) were within the 35–44-year age group, followed by 24.14% in the 25–34-year group, 21.55% in the 45–54-year group, 16.38% in the 15–24-year group, and 10.34% in the 55–65-year group. Most of the participants were married (84.48%), while 15.52% were unmarried. The mean duration of breast mass before presentation was 13.2 ± 2.5 months. Histopathological distribution of lesions (Figure 2) demonstrated that 60.3% of the masses were benign and 39.7% were malignant.

Table II presents the distribution of patients according to BI-RADS classification on ultrasonography. Out of 116 patients, 25.9% were categorized as BI-RADS 2 (benign), 21.6% as BI-RADS 3 (probably benign), 34.5% as BI-RADS 4 (suspicious), and 18.1% as BI-RADS 5 (highly suggestive of malignancy). This distribution highlights that more than half of the lesions fell into suspicious or malignant categories on ultrasound.

The diagnostic correlation between ultrasonography and histopathology is detailed in Table III. Among the 46 histopathologically confirmed malignant cases, 42 were correctly identified as malignant by ultrasonography, while 4 were misclassified as benign. Conversely, out of 70 histopathologically benign lesions, 62 were accurately identified as benign on ultrasound, and 8 were incorrectly classified as malignant. The association between ultrasonography findings and histopathology was statistically significant ($p < 0.001$), indicating strong diagnostic correlation.

Table IV summarizes the diagnostic performance indices of ultrasonography when compared with histopathology as the gold standard. Ultrasonography demonstrated a sensitivity of 91.3% (95% CI: 79.2–97.6) and a specificity of 88.6% (95% CI: 78.7–95.0). The positive predictive value (PPV) was 84.0% (95% CI: 70.9–92.8), while the negative predictive value (NPV) was 93.9% (95% CI: 85.2–98.3). The overall diagnostic accuracy of ultrasonography in differentiating benign and malignant breast masses was 89.7% (95% CI: 83.2–94.5).

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Table – I: Baseline characteristics of the study patients (*n*=116)

Characteristics	Number of patients	Percentage (%)
Age group (years)		
15-24	19	16.38
25-34	28	24.14
35-44	32	27.59
45-54	25	21.55
55-65	12	10.34
Mean± SD	36.5±12.6	
Marital status		
Married	98	84.48
Unmarried	18	15.52
Duration of mass (months)		
Mean± SD	13.2±2.5	

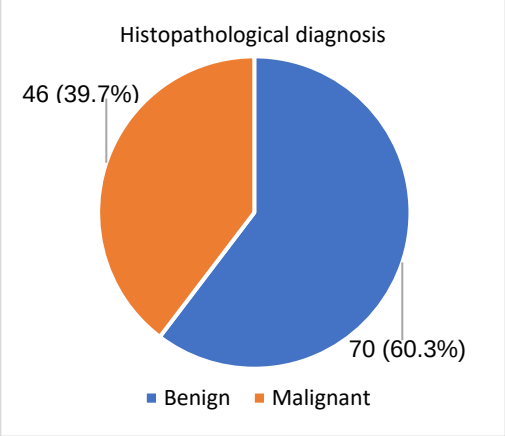

Figure – 2: Distribution of lesions by histopathology

Table – II: Ultrasonographic BI-RADS classification

BI-RADS Category	Number of patients	Percentage (%)
2 (Benign)	30	25.9
3 (Probably Benign)	25	21.6
4 (Suspicious)	40	34.5
5 (Highly Suggestive of Malignancy)	21	18.1

Table – III: Correlation of ultrasonography findings with histopathology

Ultrasonography findings	Histopathology Positive (Malignant)	Histopathology Negative (Benign)	p-value*
USG Positive (Malignant)	42	8	<0.001
USG Negative (Benign)	4	62	
Total	46	70	116

*=significant

Table – IV: Diagnostic performance of ultrasonography (*n*=116)

Parameter	Value (%)	95% CI
Sensitivity	91.3	79.2 – 97.6
Specificity	88.6	78.7 – 95.0
Positive Predictive Value (PPV)	84.0	70.9 – 92.8
Negative Predictive Value (NPV)	93.9	85.2 – 98.3
Overall Accuracy	89.7	83.2 – 94.5

DISCUSSION

The present study evaluated the diagnostic accuracy of ultrasonography in differentiating benign and malignant breast lesions, with histopathology serving as the gold standard. The mean age of the patients in this study was 36.5 years, with the majority falling between 35 and 44 years of age. This finding is consistent with earlier studies from South Asia, which have also reported that breast cancer tends to present at a relatively younger age compared to Western populations.[4] The predominance of younger women in our cohort highlights the importance of incorporating ultrasonography into diagnostic pathways, as mammography has reduced sensitivity in dense breast tissue commonly found in this age group.[12]

Histopathological evaluation in this study revealed that 39.7% of lesions were malignant and 60.3% were benign. This distribution is similar to the findings of Malik et al.[13], who reported 38% malignant lesions in a study conducted on females with palpable breast lumps. Begum et al.[14] also observed a comparable ratio of benign to malignant lesions in their retrospective analysis, reinforcing the utility of ultrasonography as a frontline tool for preliminary categorization before histopathological confirmation.

Ultrasonographic evaluation using BI-RADS classification demonstrated that the majority of patients were categorized into BI-RADS 4 and 5, together accounting for more than half of the cases. This distribution reflects the high proportion of suspicious lesions encountered in clinical practice and is supported by previous studies that have validated the predictive value of BI-RADS classification. Aziz et al.[15] found a statistically significant correlation between BI-RADS scores and histopathological outcomes, confirming the reliability of this structured reporting system. Our findings align with those observations, particularly in highlighting BI-RADS 4 as the most frequent suspicious category.

Correlation of ultrasonographic findings with histopathology in this study revealed a strong diagnostic association, with 42 of 46 malignant cases correctly identified and 62 of 70 benign lesions accurately classified. The statistical significance of this association ($p < 0.001$) emphasizes the robustness of ultrasonography when applied systematically. Comparable results have been reported by Rehman et al.[16], who demonstrated an overall diagnostic accuracy of 87% for ultrasound elastography against histopathology, and by Schaefer et al.[17], who found sensitivity and specificity values of 88% and 90%, respectively, in their prospective study. Similarly, Liew et al. [18] reported sensitivity of 92% and specificity of 86%, closely mirroring the present findings.

The diagnostic performance indices in our study further underscore the effectiveness of ultrasonography. Sensitivity was found to be 91.3%, specificity 88.6%, PPV 84.0%, NPV 93.9%, and overall accuracy 89.7%. These values are highly comparable with those reported in earlier studies. For instance, Sadigh et al.[19] in their meta-analysis observed pooled sensitivity and specificity of 91% and 82%, respectively, for ultrasound elastography, while Wang et al.[20] highlighted improved diagnostic accuracy when non-mass-like sonographic features were correlated with histology. Such consistency across diverse populations suggests that ultrasonography remains a robust diagnostic modality for breast lesions across varying clinical settings.

The slightly lower PPV observed in our study may reflect the overlap of sonographic features between benign and malignant lesions, a limitation acknowledged by several authors.[21] Nonetheless, the high NPV underscores the role of ultrasonography in confidently excluding malignancy in many cases, thereby reducing unnecessary biopsies and interventions.

In summary, the findings of this study corroborate existing literature that ultrasonography, when interpreted using BI-RADS and correlated with histopathology, provides high diagnostic accuracy in differentiating breast lesions. While operator dependence and lesion overlap remain challenges, the integration of adjunct modalities such as elastography and Doppler may further enhance accuracy in future practice.

CONCLUSION

This study establishes that ultrasonography is a highly reliable, safe, and low-cost modality in the differentiation of benign and malignant breast lesions when compared with histopathology, the gold standard. Ultrasonography, with 91.3% sensitivity, 88.6% specificity, and 89.7% overall accuracy, has fair diagnostic concordance with histopathological findings. Despite limitations such as operator dependence and overlapping imaging features, its high negative predictive value vindicates its role as a useful diagnostic modality, particularly in young women and dense breast populations.

Conflict of Interest Statement: None.

REFERENCE

1. *Kim J, Harper A, McCormack V, Sung H, Houssami N. Global patterns and trends in breast cancer incidence and mortality across 185 countries. Nat Med. 2025;*
2. *Heer E, Harper A, Escandor N, Sung H. Global burden and trends in premenopausal and postmenopausal breast cancer: a population-based study. Lancet Glob Health. 2020;8(8):e1027–37.*
3. *Lima SM, Kehm RD, Terry MB. Global breast cancer incidence and mortality trends by region, age-groups, and fertility patterns. EClinicalMedicine. 2021;38:100985.*
4. *Hughes T, Harper A, Gupta S, Frazier AL. The current and future global burden of cancer among adolescents and young adults: a population-based study. Lancet Oncol. 2024;25(9):1183–95.*
5. *Sopik V. International variation in breast cancer incidence and mortality in young women. Breast Cancer Res Treat. 2021;186(2):325–33.*
6. *Yuan WH, Hsu HC, Chen YY, Wu CH. Supplemental breast cancer-screening ultrasonography in women with dense breasts: a systematic review and meta-analysis. Br J Cancer. 2020;123(5):673–88.*
7. *Cerdas MG, Farhat J, Elshafie SI, Mariyam F, James L. Exploring the evolution of breast cancer imaging: a review of conventional and emerging modalities. Cureus. 2025;17(4):e58023.*
8. *Bicchierai G, Di Naro F, De Benedetto D. A review of breast imaging for timely diagnosis of disease. Int J Environ Res Public Health. 2021;18(11):5509.*
9. *Philadelpho F, Calas MJG, Carneiro GAC. Comparison of automated breast ultrasound and hand-held breast ultrasound in the*

screening of dense breasts. Rev Bras Ginecol Obstet. 2021;43(11):807–14.

10. *Kim SY, Han BK, Kim EK, Choi WJ, Choi Y, Kim HH. Breast cancer detected at screening ultrasonography: survival rates and clinical-pathologic and imaging factors associated with recurrence. Radiology. 2017;284(2):354–63.*
11. *Melnikow J, Fenton JJ, Whitlock EP. Supplemental screening for breast cancer in women with dense breasts: a systematic review for the US Preventive Services Task Force. Ann Intern Med. 2016;164(4):268–78.*
12. *Ghaemian N, Tehrani NHG. Accuracy of mammography and ultrasonography and their BI-RADS in detection of breast malignancy. Caspian J Intern Med. 2021;12(4):573–9.*
13. *Malik N, Rauf M, Malik G. Diagnostic accuracy of ultrasound BI-RADS classification among females having breast lumps, taking histopathology as gold standard. J Soc Obstet Gynaecol Pak. 2020;10(1):29–33.*
14. *Begum S, Krishnamurthy B, Banu N. Correlation of diagnostic accuracy of BI-RADS scoring with cyto-histological features of breast lesions – a retrospective study. J Adv Med Pharm Sci. 2024;6(4):1175–80.*
15. *Aziz S, Mohamad MA, Zin RRM. Histopathological correlation of breast carcinoma with BI-RADS classification. Med J Malaysia. 2022;77(4):479–84.*
16. *Rehman H, Raza S, Aziz S, Ahmad AM. Diagnostic accuracy of sonoelastography in the non-invasive diagnosis of malignant breast cancer compared to histopathology as a gold standard. Int J Contemp Med Res. 2017;4(7):1423–7.*
17. *Schaefer FKW, Heer I, Schaefer PJ, Mundhenke C, Osterholz S, Order BM, et al. Breast ultrasound elastography—results of 193 breast lesions in a prospective study with histopathologic correlation. Eur J Radiol. 2011;77(3):450–6.*
18. *Liew PL, Liu TJ, Hsieh MC, Lin HP, Lu CF, Yao MS. Rapid staining and immediate interpretation of fine-needle aspiration cytology for palpable breast lesions: diagnostic accuracy, mammographic, ultrasonographic and histopathologic correlations. Acta Cytol. 2011;55(1):30–6.*
19. *Sadigh G, Carlos RC, Neal CH, Dwamena BA. Accuracy of quantitative ultrasound elastography for differentiation of malignant and benign breast abnormalities: a meta-analysis. Breast Cancer Res Treat. 2012;134(3):923–31.*
20. *Wang ZL, Li N, Li M, Wan WB. Non-mass-like lesions on breast ultrasound: classification and correlation with histology. Radiol Med. 2015;120(8):745–52.*
21. *Sultan A, Rizvi S, Cioni D. Diagnostic accuracy of combined mammography and ultrasound in the detection of malignant breast lesions using BI-RADS classification taking histopathology as the reference standard. Acad J Surg Med. 2024;6(1):45–50.*