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Research Article

Correlation of Clinical Examination with Radiological Imaging in the Diagnosis of Painful Breast Lumps: A Prospective Study

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ABSTRACT

Painful breast lumps are a common reason for clinical visits among women leading to significant anxiety. Although triple assessment (clinical examination (CE), ultrasonography (USG), and tissue sampling) is considered the diagnostic gold standard test, routine biopsy may be unnecessary in these females with benign clinical feature and imaging. This study evaluates the diagnostic accuracy of CE and USG in women aged 18–35 years presenting with painful breast lumps and correlates findings with pathological results. This prospective observational study included 65 females aged 18–35 years with painful breast lumps. All participants underwent clinical examination, ultrasonomammography using BI-RADS classification, and fine-needle aspiration cytology (FNAC). Clinical and radiological diagnoses were correlated with histopathology findings. Sensitivity, specificity, predictive values, and diagnostic accuracy were calculated, and associations were analyzed using chi-square and Z-tests. The majority of lumps were benign on CE and USG. Histopathology confirmed benign lesions in 98.5% of patients, with fibroadenosis (56.9%) and fibroadenoma (29.2%) being most common. Only one patient (1.5%) had malignancy. CE demonstrated a sensitivity of 100%, specificity of 95.3%, and diagnostic accuracy of 95.3%. Ultrasonography showed 100% sensitivity, 100% specificity, and 100% diagnostic accuracy with perfect concordance with biopsy ($p < 0.0001$). Combined CE and USG accurately identified benign lesions in 95.3% of cases, and all BI-RADS IV lesions were malignant. Painful breast lumps in young women are overwhelmingly benign. Ultrasonography, combined with clinical examination, provides excellent diagnostic accuracy that can reliably identify benign lesions, potentially reducing the need for routine biopsy. Selective use of tissue sampling, reserved for suspicious CE or BI-RADS IV/V findings, may reduce patient anxiety, procedural risks, and healthcare costs without compromising cancer detection.

Keywords: Painful breast lump, Ultrasonography, Clinical examination, BI-RADS, fibroadenoma, Benign breast disease, Young females, Triple assessment.

INTRODUCTION

Breast diseases have long intrigued surgeons, with references to breast cancer dating back to the Smith Surgical Papyrus (3000–2500 B.C.) [1]. Among various breast complaints, a lump remains the most common and concerning symptom. While such lumps can arise from both benign and malignant causes, the fear of breast cancer often causes significant anxiety in women presenting with breast lumps, pain, or nipple discharge [2].

In India, the incidence of breast cancer is increasing, with a noticeable shift in the average age of onset from the 50s–60s to the 30s–40s [3]. However, studies indicate that the risk of malignancy in women under 30 presenting with focal breast symptoms is very low (around 0.4%) [4]. Fibroadenoma is the most common diagnosis in this age group [5], and the incidence of breast cancer in patients with breast pain alone is reported between 0 and 3.2% [6]. Thus, painful breast lumps in young females typically carry a low risk of malignancy.

The current gold standard for assessing breast lumps is the triple assessment, which includes clinical examination (CE), imaging (ultrasound or mammography), and tissue sampling via fine-needle aspiration (FNA) or core biopsy (CB) [7]. When all three modalities agree, the positive predictive value exceeds 99.9% [8], making it a reliable diagnostic approach. In young women, ultrasound is preferred due to denser breast tissue, but despite a low malignancy risk, many young patients undergo biopsy regardless of benign clinical or imaging features.

However, the triple assessment approach, particularly needle biopsy, is invasive, costly, and often distressing for patients [9,10]. It may lead to complications such as bleeding or infection and has

been shown to negatively affect quality of life. Recent advances in ultrasonography have significantly improved its diagnostic accuracy, with a reported sensitivity of 98% and a negative predictive value of 99.5% in identifying benign lesions [7]. Similarly, clinical examination has demonstrated high sensitivity (94.5%) and specificity (87.7%) [11].

While multiple studies from developed countries have explored the potential of clinical examination and ultrasound to reduce unnecessary biopsies [4,7,13], similar research is scarce in developing nations. Moreover, limited data exists specifically on painful breast lumps in young women.

This study aims to evaluate the diagnostic accuracy of clinical examination and ultrasonography in young females with painful breast lumps, correlate findings with biopsy results, and assess whether biopsy can be safely avoided in select cases to reduce invasive procedures, anxiety, and costs.

MATERIALS AND METHODS

This prospective observational study enrolled a total of 65 female patients aged 18–35 years presenting with painful breast lumps, who were included based on defined inclusion and exclusion criteria.

Clinical evaluation included history taking and breast examination to assess size, site, consistency, mobility, tenderness, and fixity. Radiological assessment was performed using ultrasonography with BIRADS classification, where BIRADS 2 and 3 were considered benign and BIRADS 4 and 5 were considered malignant. All patients underwent fine-needle aspiration cytology (FNAC); core needle biopsy was done when FNAC was inconclusive.

Data were recorded using a structured proforma. Clinical assessments were categorized as benign, suspicious, or malignant, with "suspicious" considered malignant for analysis. Final diagnosis was confirmed through pathological evaluation. Patients were treated according to NCCN guidelines based on findings.

Sample size (n=65) was calculated, assuming a 94.5% sensitivity of clinical examination. Data were analyzed using descriptive statistics, chi-square test, t-test, and Z-test. Sensitivity, specificity, and predictive values were calculated. Ethical clearance was obtained from the institutional ethics committee prior to the study.

RESULTS

A total of 65 women were included. The mean age was 28.04 ± 4.96 years. Baseline demographic and clinical characteristics are summarized in Table 1. Most patients were married (79.6%), presented with unilateral breast lumps, and had cyclical mastalgia (70.8%). Mean lump size was 2.30 ± 0.45 cm.On clinical examination, 61 patients (93.8%) were diagnosed as benign and 4 (6.2%) as suspicious. Ultrasonography categorized lesions as BI-RADS II in 45 patients (69.2%), BI-RADS III in 19 (29.2%), and

Table 1: Demographic and clinical characteristics (n = 65)

Parameter	Categories	Frequency (%)	Statistical test results
Age group (years)	<20	2 (4.1%)	Mean ± SD: 28.04 ± 4.96; Median: 29 Z=2.59; p=0.0096
	20–29	28 (57.1%)	
	30–35	19 (38.8%)	
Marital status	Married	39 (79.6%)	Z=8.37; p<0.0001
	Unmarried	10 (20.4%)	
Laterality of lump	Left	26 (40.0%)	Z=0.88; p=0.37
	Right	30 (46.2%)	
	Bilateral	9 (13.8%)	
Duration of symptoms (months)	1–3	52 (80.0%)	Z=8.48; p<0.0001
	4–5	13 (20.0%)	
Nipple discharge	Yes	1 (1.5%)	—
	No	64 (98.5%)	
Breast pain	Cyclical	46 (70.8%)	Z=5.88; p<0.0001
	Non-cyclical	19 (29.2%)	
VAS pain score	2–3	55 (84.6%)	Mean ± SD: 2.80 ± 0.79; Median: 3 Z=9.78; p <0.0001
	4–5	10 (15.4%)	
Skin changes	Present	4 (6.2%)	—
	Absent	61 (93.8%)	
Lump size (cm)	1.0–2.0	37 (56.9%)	Mean ± SD: 2.30 ± 0.45; Z=1.98; p = 0.047
	2.1–3.0	28 (43.1%)	
Axillary lymph node	Present	5 (7.7%)	—
	Absent	60 (92.3%)	

Table 2: Diagnostic Findings (n = 65)

Parameter	*Categories*	*Frequency (%)*	*Statistical test results*
Clinical Diagnosis	Benign	61 (93.8%)	Z=12.38; p <0.0001
	Suspicious for malignancy	4 (6.2%)	
Ultrasonomammography (USM)	BIRADS-II	45 (69.2%)	Z=5.65; p <0.0001
	BIRADS-III	19 (29.2%)	
	BIRADS-IV	1 (1.5%)	
Needle Biopsy Diagnosis	Fibroadenoma	19 (29.2%)	Z=3.95; p <0.0001
	Fibroadenosis	37 (56.9%)	
	Fibrocystic disease	5 (7.7%)	
	Infiltrating ductal carcinoma	1 (1.5%)	
	Sclerosing adenosis	3 (4.6%)	
Clinical vs Biopsy Concordance	Concordant	61 (93.8%)	Z=12.38; p <0.0001
	Discordant	4 (6.2%)	
Ultrasound vs Biopsy Concordance	Concordant	64 (98.5%)	Z=13.71; p <0.0001
	Discordant	1 (1.5%)	
Clinical vs Biopsy Comparison	TP: 1 (1.5%) TN: 61 (93.8%) FN: 0 FP: 3 (4.6%)	Diagnostic Accuracy: 95.3% Sensitivity: 100% Specificity: 95.3% PPV: 25.0% NPV: 100%	
USM vs Biopsy Comparison	TP: 1 (1.5%) TN: 64 (98.5%) FN/FP: 0	Diagnostic Accuracy: 100% Sensitivity: 100% Specificity: 100% PPV: 100% NPV: 100%	

Table 3: Correlation between Findings

Correlation Type	*Chi-square (χ^2)*	*p-value*	*Interpretation*
Clinical diagnosis vs Needle Biopsy	$\chi^2 = 18.38$	<0.0001	Significant correlation
USM findings vs Needle Biopsy	$\chi^2 = 104.29$	<0.0001	Significant correlation
Pain Score (VAS) vs Needle Biopsy	$\chi^2 = 10.13$	0.038	Significant correlation
Combined Correlation (Clinical + USM vs Needle Biopsy)	—	Descriptive	95.3% clinically benign confirmed benign; 100% BIRADS-IV was malignant

BI-RADS IV in 1 patient (1.5%) (Table 2).Pathological evaluation confirmed benign lesions in 64 patients (98.5%), with fibroadenosis (56.9%) and fibroadenoma (29.2%) being most common. One patient (1.5%) had infiltrating ductal carcinoma.Clinical examination showed a sensitivity of 100%, specificity of 95.3%, PPV of 25.0%, NPV of 100%, and diagnostic accuracy of 95.3%. Ultrasonography showed complete concordance with pathological diagnosis (Table 2). These values should be interpreted with caution due to the very low prevalence of malignancy.Correlation between clinical findings, ultrasonography, pain score, and pathological diagnosis was statistically significant (Table 3).

DISCUSSION

Breast lumps are one of the most common complaints in young and middle-aged females, with painful lumps constituting a significant proportion of cases. Differentiating between benign and malignant lesions is crucial to avoid unnecessary biopsies while ensuring timely detection of malignancy. In the present study, we prospectively evaluated the role of clinical examination and ultrasonography in diagnosing painful breast lumps and correlated them with pathological findings.

Clinical Examination and Mastalgia–Cancer Relationship

Our findings align with earlier studies, which emphasized that pain alone is rarely indicative of malignancy, although its presence cannot completely rule it out. Yıldırım et al. (2015) [14] demonstrated that mastalgia is most often associated with benign breast conditions, with cancer accounting for a very small proportion of cases. In our study, the majority of painful lumps were benign, reinforcing the fact that clinical mastalgia requires careful evaluation but is not an independent predictor of malignancy.

Efficacy of Clinical Examination in Diagnosis

Clinical breast examination (CBE) remains the first step in evaluating breast lumps. The diagnostic accuracy of CBE is variable and operator-dependent. In our study, CBE alone could differentiate benign from malignant lesions in a significant proportion of cases, but it showed limitations in small or deep-seated lumps. Similar results were reported by KharKwal et al. (2014) [15], who found that CBE as part of the "triple test" had good diagnostic efficacy but required adjunct radiological or pathological confirmation. Jan et al. (2010) [16] also highlighted that clinical examination alone can be misleading and recommended its use as part of a combined approach.

Role of Ultrasonography in Painful Breast Lumps

Ultrasound has emerged as a highly sensitive tool in evaluating palpable breast masses, especially in younger women with dense breast tissue, where mammography may be limited. Our results confirm the findings of Stavros et al. (1995) [17], who showed that specific sonographic features such as margin, echogenicity, and posterior acoustic pattern can reliably distinguish benign from malignant nodules. Similarly, Park et al. (2008) [18] suggested that palpable breast masses with benign morphology on ultrasound can be safely followed up without immediate biopsy, reducing unnecessary invasive procedures. In our study, ultrasonography was particularly useful in identifying fibroadenomas and cysts, which comprised the bulk of benign painful lumps.

Correlation of Clinical and Radiological Assessment with Pathology

The cornerstone of breast lump diagnosis remains the triple assessment, comprising clinical examination, imaging, and pathological confirmation. Our findings support this principle, as both clinical assessment and ultrasonography correlated well with histopathology when used in combination. Wai et al. (2013) [19] reported similar outcomes with a modified triple test where ultrasound and core biopsy significantly improved diagnostic accuracy compared to clinical and mammographic assessment alone. In the present study, combining CBE with ultrasonography markedly reduced false negatives, echoing the conclusions of Ackermann et al. (2016) [20] that integration of clinical data with imaging improves diagnostic precision, especially in indeterminate BI-RADS 3 lesions.

Appropriateness Criteria and Standardized Guidelines

The American College of Radiology (ACR) has laid down appropriateness criteria for the management of palpable breast masses. Harvey et al. (2013) [21] emphasized that ultrasonography is the preferred initial imaging modality for women under 30 years, while mammography gains importance in older women. Our study population, predominantly young females, benefited greatly from ultrasonographic evaluation, which corroborates ACR recommendations.

Pattern of Disease in Painful Breast Lumps

In terms of disease distribution, our study revealed that the majority of painful breast lumps were benign, with fibroadenomas and fibrocystic disease being the commonest findings. This is consistent with population-based data such as the SEER registry (2014) [22], which shows breast cancer incidence increases with age, with malignancy being relatively uncommon in younger age groups. Thus, while painful breast lumps in younger women are most often benign, vigilance is required to rule out malignancy.

The present study underscores the importance of a stepwise diagnostic approach. Clinical examination remains an essential first step, but its accuracy is enhanced when combined with ultrasonography. Pathological confirmation should be pursued when either clinical or sonographic findings are suspicious. Our findings reinforce the role of the triple assessment, which has consistently been validated in literature as the gold standard [15,16,19].

REFERENCES

REFERENCES

1. Hunt KK, Robertson JFR, Bland KI. The Breast. In: Brunicardi FC, Andersen DK, Billiar TR, Dunn DL, Hunter JG, Matthews JB, et al., editors. Schwartz's Principles of Surgery. 10th ed. New York, NY: McGraw-Hill Education; 2015.
2. Jaykar RD. A Study of Modified Triple Test Score for Assessment of Palpable Breast Masses in Young Females. 2013;7(2).
3. Rangarajan B, Shet T, Wadasadawala T, Nair NS, Sairam RM, Hingmire SS, et al. Breast cancer: An overview of published Indian data. South Asian J Cancer. 2016;5(3):86–92.
4. Loving VA, DeMartini WB, Eby PR, Gutierrez RL, Peacock S, Lehman CD. Targeted ultrasound in women younger than 30 years with focal breast signs or symptoms: outcomes analyses and management implications. AJR Am J Roentgenol. 2010 Dec;195(6):1472–7.
5. Surati K, Suthar K, Parekh B, Shah J. A study of accuracy of triple assessment as a clinical tool for the diagnosis of a palpable breast lump. Int J Med Sci Public Health. 2013;2(3):733.
6. Madjar H. Role of Breast Ultrasound for the Detection and Differentiation of Breast Lesions. Breast Care (Basel). 2010;5(2):109–14.
7. Yue D, Swinson C, Ravichandran D. Triple assessment is not necessary in most young women referred with breast symptoms. Ann R Coll Surg Engl. 2015 Sep;97(6):466–8.
8. Williams N, O'Connell PR, editors. Bailey & Love's Short Practice of Surgery. 25th ed. London: CRC Press; 2008. 1536 p.
9. Kamath J, Cruess DG, Claffey K, Wilson L, Phoenix N, Tannenbaum S. Symptom distress associated with biopsy in women with suspect breast lesions. ISRN Oncol. 2012;2012:898327.
10. Novy DM, Price M, Huynh PT, Schuetz A. Percutaneous core biopsy of the breast: correlates of anxiety. Acad Radiol. 2001 Jun;8(6):467–72.
11. Ravi C, Rodrigues G. Accuracy of Clinical Examination of Breast Lumps in Detecting Malignancy: A Retrospective Study. Indian J Surg Oncol. 2012 Jun;3(2):154–7.
12. Maxwell AJ, Pearson JM. Criteria for the safe avoidance of needle sampling in young women with solid breast masses. Clin Radiol. 2010 Mar;65(3):218–22.
13. Ha R, Kim H, Mango V, Wynn R, Comstock C. Ultrasonographic features and clinical implications of benign palpable breast lesions in young women. Ultrasonography. 2015 Jan;34(1):66–70.
14. Yıldırım AC, Yıldız P, Yıldız M, Kahramanca Ş, Kargıcı H. Mastalgia-Cancer Relationship: A Prospective Study. J Breast Health. 2015 Apr 1;11(2):88–91.
15. Kharkwal S, Sameer null, Mukherjee A. Triple test in carcinoma breast. J Clin Diagn Res. 2014 Oct;8(10):NC09-11.
16. Jan M, Mattoo JA, Salroo NA, Ahangar S. Triple assessment in the diagnosis of breast cancer in Kashmir. Indian J Surg. 2010 Apr;72(2):97–103.

17. Stavros AT, Thickman D, Rapp CL, Dennis MA, Parker SH, Sisney GA. Solid breast nodules: use of sonography to distinguish between benign and malignant lesions. Radiology. 1995 Jul;196(1):123–34.
18. Park YM, Kim EK, Lee JH, Ryu JH, Han SS, Choi SJ, et al. Palpable breast masses with probably benign morphology at sonography: can biopsy be deferred? Acta Radiol. 2008 Dec;49(10):1104–11.
19. Wai CJ, Al-Mubarak G, Homer MJ, Goldkamp A, Samenfeld-Specht M, Lee Y, et al. A modified triple test for palpable breast masses: the value of ultrasound and core needle biopsy. Ann Surg Oncol. 2013 Mar;20(3):850–5.
20. Ackermann S, Schoenenberger CA, Zanetti-Dällenbach R. Clinical Data as an Adjunct to Ultrasound Reduces the False-Negative Malignancy Rate in BI-RADS 3 Breast Lesions. Ultrasound Int Open. 2016 Sep;2(3):E83-89.
21. Mainiero MB, Lourenco A, Mahoney MC, Newell MS, Bailey L, Barke LD, et al. ACR Appropriateness Criteria Breast Cancer Screening. J Am Coll Radiol. 2013 Jan;10(1):11–4.
22. SEER. Cancer of the Breast (Female) - Cancer Stat Facts. Available from: https://seer.cancer.gov/statfacts/html/breast.html

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