https://doi.org/10.37939/jrmc.v28i2.2345

Diagnostic Accuracy Of Spectral Doppler Ultrasound In Diagnosis Of Malignant Breast Lesions Taking Histopathology As Gold Standard

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Abstract

Objective: To determine the diagnostic accuracy of Spectral Doppler Ultrasound in malignant breast lesions, taking histopathology as the gold standard.

Place and Duration of Study: This study was conducted at the Department of Diagnostic Radiology, Pak Emirates Military Hospital, Rawalpindi. The study duration was 06 months from 10th June 2020 to 10th December 2020.

Methods: The study design was Cross-sectional.Consecutive non-probability sampling technique was used for sample collection. A total of 165 women with breast lumps with a duration of lump >1 month and of any size and age 25-65 years were enrolled. Each patient was subject to spectral Doppler ultrasound using a high-resolution unit with a linear array probe centred at 7.5MHz. The findings were interpreted by a consultant radiologist for the presence or absence of malignant breast lesions. All patients underwent biopsy in the concerned ward and the histopathology report was compared with spectral Doppler USG findings.

Results: Sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of Spectral Doppler Ultrasound in diagnosing malignant breast lesions, taking histopathology as gold standard was 91.84%, 83.86%, 89.11%, 87.50% and 88.48% respectively. All spectral Doppler indices, including mean peak systolic velocity (PSV), resistive index (RI), and Pulsatility index (PI) were significantly higher in malignant tumours. The optimal cut-off points were PSV = 12.5 cm/s (sensitivity: 85%, specificity: 82%), RI = 0.68 (sensitivity = 92%, specificity = 85%), and PI = 0.93 (sensitivity = 91%, specificity = 88%).

Conclusion: The use of Doppler Ultrasound is a feasible, safer and non-invasive modality and has high sensitivity and specificity in the diagnosis of malignant breast lesions.

MeSH Keywords: Histopathology, Malignancy, Breast cancer, Biopsy, Ultrasound.

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Cite this Article: Tabassum M, Waseem R, Niazi M, Riaz Z, Shakil H, Anam W. Diagnostic Accuracy Of Spectral Doppler Ultrasound In Diagnosis Of Malignant Breast Lesions Taking Histopathology As Gold Standard. JRMC. 2024 Sep. 26;28(3).365-370. https://doi.org/10.37939/jrmc.v28i2.2345.

Received January 19, 2024; accepted September 11, 2024; published online September 26, 2024

1. Introduction

Breast carcinoma is attributed to be one of the most common malignancies, responsible for over 22 % of cancers among the female population globally.[1] Patients tend to be less inclined towards biopsies, as not only are they painful and invasive, but according to pathologic reports, they account for 75 % of benign cases.[2] Consequently, more accurate and less invasive procedures must be undertaken for cases of suspicious breast lesions. To determine whether breast masses are malignant or benign, imaging features on ultrasonography may be useful and consequently, may reduce the reliance on diagnostic biopsies over time.[3] Therefore, another procedure to come forth as a sonographic parameter to ascertain if the breast masses are malignant or benign is the spectral Doppler.

Although, a biopsy is considered the gold standard for these lesions large number of biopsies for benign breast abnormalities have long been recognized as a serious problem.[4] While biopsy is generally safe, it is not entirely free of risks. Infection, bleeding and swelling at the biopsy site are potential complications. Excessive biopsies have adverse effects on society (like healthcare costs, overburdened healthcare facilities, resource allocation etc) and on the women (like physical discomfort and pain, emotional distress and anxiety, scarring and cosmetic concerns etc) who undergo them.[5] These risks are typically low but can occur, especially in cases where the procedure is not performed by an experienced practitioner. Thus, the need is the utilization of less invasive and cost-effective method(s) of diagnosis without resorting to a more painful and invasive surgical biopsy.[6] Therefore, breast-imaging techniques have been developed as primary clinical methods for identifying early-stage breast cancers and differentiating them from benign breast tumours. At present, the main screening tests include mammography and ultrasonography.[7] Preliminary screening for breast cancer typically involves imaging of susceptible breast lesions by methods such as mammography X-ray examination, MRI and Doppler ultrasound.[7,8]

With the continued development and greater availability of colour Doppler and contrast-enhanced ultrasound technologies, ultrasound has become the preferred method for breast tissue examination, suitable for differential diagnosis of physical properties of solid and cystic mass lesions.[9] Colour Doppler USG is a non-invasive, repeatable and widely available diagnostic tool. Doppler ultrasound has a stronger prognostic impact on overall survival than most established factors, e.g. tumour size, age or grading.[10] High-frequency ultrasound probes with improved spatial and contrast resolution have been used to study both breast cancer and axillary nodes.[11] The available evidence on the diagnostic accuracy of Spectral Doppler Ultrasonography in malignant breast lesions has shown variable results.[12,13] So the rationale of this study is to determine the diagnostic accuracy of Spectral Doppler Ultrasound in diagnosing malignant breast lesions, taking histopathology as the gold standard in our clinical setup and also providing the local statistics. Based on these results, this imaging modality can be applied as a screening and diagnostic tool for breast cancer that may help the clinicians for selection of proper treatment options and reduce the number of pure diagnostic biopsies, so that patient anxiety can be reduced, and morbidity and mortality can be minimized.

2. Materials & Methods

This was a cross-sectional validation study conducted at the Department of Diagnostic Radiology, Pak Emirates Military Hospital, Rawalpindi, over 6 months. A sample size of 165 cases has been calculated with a 95 % Confidence level, prevalence of malignant breast lesions as 52%, 10% desired precision for the sensitivity of 75 % and 10% desired precision for the specificity of 71.4% of spectral Doppler ultrasound in diagnosing malignant breast lesions. The technique was non-probability, consecutive sampling. Female patients aged 25 to 65 years having breast lumps as per operational definitions with duration of lump >1 month and of any size based on clinical examination were included. Those excluded were patients with any chronic disease i.e. tuberculosis and diabetes mellitus (assessed on medical record), Recurrent lump at the same site of the previous operation and Women with trauma to breast tissue.

After obtaining approval from the institutional review board and ethical committee, 165 female patients meeting the inclusion criteria were recruited for the study. Informed consent was obtained from all participants, and the procedures were thoroughly explained to each individual. Spectral Doppler ultrasound was performed using a high-resolution unit with a linear array probe centred at 7.5MHz. The findings were interpreted by a consultant radiologist (with at least 3 years of post-fellowship experience) for the presence or absence of malignant breast lesions. All patients underwent biopsy in the relevant ward and the histopathology report was compared with spectral Doppler USG findings. All this data (age, duration of lesion, size of lesion, peak systolic velocity, resistive index, Pulsatility index of malignant breast lesions as reported on spectral Doppler USG and histopathology) was recorded on a specially designed proforma & categorization of patients was done according to age (25-45 years and 46-65 years), duration of disease (< 6 months and > 6 months) and size of breast lumps (< 3 cm or > 3cm).

Collected data was analysed through computer software SPSS version 25. Age, duration of lump, size of lump, peak systolic velocity, resistive index and Pulsatility index were presented as mean and standard deviation. Malignant breast lesions on spectral Doppler USG and histopathology (present/absent) were presented as frequency and percentage. 2×2 contingency tables were used to calculate sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of spectral Doppler USG in detecting malignant breast lesions, taking histopathology as the gold standard. The formulas/ equations that were used for calculation are as follows:

$$\textbf{Sensitivity} = \frac{\textbf{True Positive (TP)}}{\textbf{True Positives (TP)+ False Negatives (TN)}} \times \textbf{100} \quad \text{eq 1}$$

$$\textbf{Specificity} = \frac{\textbf{True Negatives (TN)}}{\textbf{True Negatives (TN)+ False Positives (FP)}} \times \textbf{100} \quad \text{eq 2}$$

$$\textbf{Positive Predictive Value} = \frac{\textbf{True Positive (TP)}}{\textbf{True Positives (TP)+ False Positive (FP)}} \times \textbf{100} \quad \text{eq 3}$$

$$\textbf{Negative Predictive Value} = \frac{\textbf{True Negatives (TN)}}{\textbf{True Negatives (TN)+ False Negatives (FN)}} \times \textbf{100} \quad \text{eq 4}$$

$$\textbf{Accuracy} = \frac{\textbf{True Positives (TP)+ True Negatives (TN)}}{\textbf{True Positives (TP)+ True Negatives (TN)+ False Positives (FP)+ False Negatives (FN)}} \times \textbf{100} \quad \text{eq 5}$$

ROC (receiver operating characteristic) curve and likelihood ratio were also calculated. Effect modifiers

like age, duration of disease, size of the lesion and spectral Doppler indices (PSV/RI/PI) were controlled by stratification. Post-stratification diagnostic accuracy was calculated.

3. Results

A total of 165 female patients with age between 25-65 years who had breast lesions of > 1-month duration were studied. Informed consent was taken from each patient. Spectral Doppler Ultrasound findings were compared with the Histopathology result.

Spectral Doppler supported the diagnosis of malignant breast lesions in 101 (61.21%) patients. Histopathology confirmed malignancy in 98 (59.39%) cases. In 101 Spectral Doppler Ultrasound positive patients, 90 patients (89.1%) had malignant breast lesions and 11 (10.8 %) had benign histopathology findings. Among, 64 Spectral Doppler Ultrasound negative patients, histopathology identified 08 patients (12.5 %) as positive and 56 patients (87.5 %) as negative, adhering to the criteria delineated within our operational framework.

Table 1: Cross-tabulation of Spectral Doppler Ultrasound and histopathology results

	A positive result on histopathology	A negative result on histopathology	p-value
Positive result on Doppler	90 (TP)*	11 (FP)**	0.0001
A negative result on Doppler	08 (FN)***	56 (TN)****	
Sensitivity (eq 1): 91.84%, Specificity (eq 2): 83.86%, PPV (eq 3): 89.11%, NPV (eq 4): 87.50%, Accuracy (eq 5): 88.48 %			

Analysis of these findings involved the construction of 2 x 2 contingency tables, which facilitated the enumeration of subjects meeting various criteria: those positively identified through spectral Doppler and confirmed as such by histopathology (true positives); those testing positive via spectral Doppler but demonstrating negativity during biopsy (false positive); those testing negative via Spectral Doppler but found to be positive during biopsy (false negatives); and those testing negative via spectral Doppler and confirmed as such on histopathology (true negatives). This tabular representation afforded a comprehensive overview of true and false positives, as well as true and false negatives.

Our study findings indicated that within the overall study Cohort, 54.5 % (n=90) were true positives, 33.9% (n=56) were true negatives, 6.66% (n=11) were false positives and 4.8 % (n=08) were false negatives. Overall sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of Spectral Doppler Ultrasound in diagnosing malignant breast lesions, taking histopathology as the gold standard was 91.84%, 83.86%, 89.11%, 87.50% and 88.48% respectively. The ROC Curve is shown in Figure I. All spectral Doppler indices, including mean peak systolic velocity (PSV), resistive index (RI), and Pulsatility index (PI) were significantly higher in malignant tumours. The optimal cut-off points were PSV = 12.5 cm/s (sensitivity: 85%, specificity: 82%), RI = 0.68 (sensitivity = 92%, specificity = 85%), and PI = 0.93 (sensitivity = 91%, specificity = 88%).

Stratification of diagnostic accuracy concerning age groups is shown in Table 2. Stratification of diagnostic accuracy with respect duration of disease is shown in III. Stratification of diagnostic accuracy concerning the size of the lesion is shown in Table 4.

Table 2: Stratification of diagnostic accuracy concerning age

Age	25-45 years (n=114)			46-65 years (n=51)		
	Positive on Histopathology	Negative on Histopathology	P-Value	Positive on Histopatholo gy	Negative on Histopatholo gy	P-Value
Positive on Spectral Doppler Ultrasound	64 (TP)	07 (FP)	0.001	26 (TP)	04 (FP)	0.001
Negative on Spectral Doppler Ultrasound	06 (FN)	37 (TN)		02 (FN)	19 (TN)	
Sensitivity		91.43%			92.86%	
Specificity		84.09%			82.61%	
Positive Predictive Value (PPV)		90.14%			86.67%	
Negative Predictive Value (NPV)		86.05%			90.48%	
Diagnostic Accuracy		88.60%			88.24%	

Table 3: Stratification of diagnostic accuracy concerning duration of disease

Duration of disease	≤ 6 months (n=102).			> 6 months (n=63).		
	Positive on Histopathology	Negative on Histopathology	P-Value	Positive on Histopathology	Negative on Histopathology	P-Value
Positive on Spectral Doppler Ultrasound	53 (TP)	09 (FP)	0.001	37 (TP)	02 (FP)	0.001
Negative on Spectral Doppler Ultrasound	04 (FN)	36 (TN)		04 (FN)	20 (TN)	
Sensitivity	92.98%			90.24%		
Specificity	80.0 %			90.91%		
Positive Predictive Value (PPV)	85.48%			94.87%		
Negative Predictive Value (NPV)	90.0%			83.33%		
Diagnostic Accuracy	87.25 %			90.48%		

Table 4: Stratification of diagnostic accuracy concerning size of the lesion

Size of lesion	Size of lesion ≤3 cm (n=64).			Size of lesion >3 cm (n=101).		
	Positive on Histopathology	Negative on Histopathology	P-Value	Positive on Histopathology	Negative on Histopathology	P-Value
Positive on Spectral Doppler Ultrasound	35 (TP)	06 (FP)	0.001	55 (TP)	05 (FP)	0.001
Negative on Spectral Doppler Ultrasound	01 (FN)	22 (TN)		07 (FN)	34 (TN)	
Sensitivity	97.22%			88.71%		
Specificity	78.57 %			87.18%		
Positive Predictive Value (PPV)	85.37%			91.67%		
Negative Predictive Value (NPV)	95.65%			82.93%		
Diagnostic Accuracy	89.06 %			88.12%		

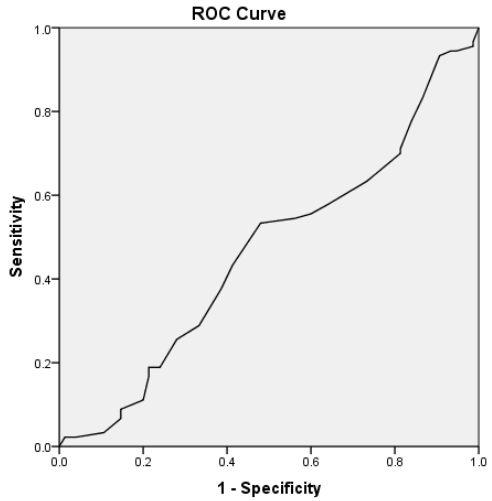

Figure 1: ROC curve

4. Discussion

Breast lesions often require accurate diagnostic evaluation to determine the appropriate management strategy.[14] Ultrasonography is a non-invasive and easily available basic valuable tool in this regard, but its diagnostic accuracy compared to biopsy and histopathology as the gold standard, remains a subject of interest and investigation.[15] This study aims to assess the diagnostic accuracy of spectral Doppler in the diagnosis of malignant breast lesions and its concordance with histopathology findings.

All spectral Doppler indices, including mean peak systolic velocity (PSV), resistive index (RI), and Pulsatility index (PI) were significantly higher in malignant tumours. The optimal cut-off points were PSV = 12.5 cm/s (sensitivity: 85%, specificity: 82%), RI = 0.68 (sensitivity = 92%, specificity = 85%), and PI = 0.93 (sensitivity = 91%, specificity = 88%). In a study, Jain et. al. found the sensitivity and specificity of Doppler USG to diagnose breast malignant lesions as 94.2% and 89.5% respectively.[13]

In a characterization of breast lesions, as malignant lesions has high RI and PI values. Chao et al. reported that PSV, RI, and PI are higher in carcinomas; however, they did not find any cut-off point to distinguish benign and malignant tumours.[16] Studying 70 breast masses, Stanzani et al. demonstrated that RI ≥ 0.73 is significantly predictive of malignancy.[17] Choi et al observed that, in more than 80% of malignant breast nodules, the RI exceeded 0.70 with a sensitivity of 80.9% and specificity of 89.1%.[18] However, they also concluded that this threshold could not be used alone and a biopsy is the gold standard for diagnosis. Zanoni et al

and Zing et al reported that a threshold of 0.75 and 0.7 were the suitable cut-offs respectively.[19,20] Keeping in view the results of this study women presenting with breast mass can be first investigated with Spectral Doppler followed by a biopsy if ultrasound parameters are suggestive of malignancy and taking pre-test probability into account which can potentially reduce the number of biopsies carried out for investigating breast masses.

In a local study,[21] By Arshad et. al., Doppler sonography (resistive index) had high sensitivity i.e. 94.2% and a high NPV of 93.4%. Specificity was found to be 89.5%, high PPV 90.7% and diagnostic accuracy was found to be 92%. Higher values of pulsatility index (PI), RI and maximum velocity were considered as indicators of malignancy.[22]

However, in the study of Ozdemir et al., neither morphologic nor spectral Doppler analysis proved to be successful on its own, but the information obtained could increase the diagnostic certainty of grayscale ultrasound and mammography.[23]

In a recent study, del Cura et al. suggested diagnostic criteria for Doppler sonography of breast lesions.[24] They performed spectral Doppler sonography in breast lesions to evaluate PSV, PI and RI of the lesions and correlated with histologic results. Although colour flow was more frequently seen in malignant than in benign lesions, the sensitivity, specificity, and positive- and negative-predictive values for this sign were low (68, 64, 58 and 73%, respectively).

The likelihood of malignancy varies significantly based on age, ranging from 2.4 % for individuals aged 20 to 30 years to a much higher 77.3 % for those aged 51 to 60 years.[25] Similarly, the size of the lesion is a crucial factor with a 2 – 3 cm lesion carrying a 4.9 % risk of malignancy, compared to a substantially higher risk of 55.3 % for lesions between 5.1 – 6 cm.[26] These factors can be effectively utilized to estimate the pre-test probability of malignancy.

Ultrasonography is a straightforward approach to diagnosing malignant breast lesions. It can be conducted as an outpatient procedure, is well-tolerated by the majority of patients, doesn't necessitate anesthesia, and provides immediate results.[27] While there are certain limitations associated with making precise predictions about specific lesions, combining Doppler Ultrasonography of breast lesions with a comprehensive clinical history and physical examination including clinical breast examination (CBE) can provide valuable insights to assist the surgeon in arriving at an accurate diagnosis and planning the subsequent course of treatment.

This study further suggests remarkable improvement in the differentiation of malignant from benign breast lesions with concomitant use of conventional ultrasound and Spectral Doppler. However, it's important to note that a definite and reliable diagnosis is ultimately established through histopathology. The study conducted on a limited sample size might not have provided a sufficiently extensive basis for forming all-encompassing conclusions. Additionally, the ultrasound reports were produced by different radiologists and pathologists, each possessing varying levels of expertise. To establish a more precise assessment of the validity of ultrasonography, it is advisable to conduct larger-scale studies on this topic.

5. Conclusion

Doppler Ultrasonography was observed to be an effective, non-invasive and reliable diagnostic tool for assessing malignant breast lesions. It has good sensitivity and specificity in the diagnosis of benign and malignant cases and can minimize the use of invasive biopsies for diagnosis, But, considering false positive and false negative findings on ultrasound and the overall satisfactory accuracy of biopsy followed by histopathology, highlights its practicality in clinical practice for diagnosing breast malignant lesions, making it a valuable and accessible option for clinicians.

INSTITUTIONAL REVIEW BOARD

RAD-2017-124-2389

CONFLICTS OF INTEREST- None

Financial support: None to report.
Potential competing interests: None to report

Contributions:

M.T, - Conception of study
M.T, M.N - Experimentation/Study Conduction
R.W, Z.R, H.S, W.A - Analysis/Interpretation/Discussion
M.T, R.W, H.S, W.A - Manuscript Writing
M.N, Z.R - Critical Review
All authors approved the final version to be published & agreed to be accountable for all aspects of the work.

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