Original Article

Diagnostic Accuracy of a Sonographic Scoring System in Predicting the Malignant Potential of a Soft-tissue Swelling

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Abstract

Background: Soft-tissue masses usually present as painless palpable lumps. Although histopathologic examination (HPE) is diagnostic, ultrasonography (USG), being cost-effective, is the preferred screening modality. However, as it is operator dependent, the diagnostic accuracy might be affected. Thus, this study was planned to determine the diagnostic accuracy of USG with Doppler in identifying the malignant nature of soft-tissue swellings and also to develop a scoring system with a valid cutoff to help differentiate malignant lesions from the benign ones. **Methods:** This analytical study with longitudinal design was conducted from July 2022 to June 2024 on patients with soft-tissue swelling selected by systematic random sampling. Data were collected by face-to-face interview, USG with Doppler, and histopathological examination. Data were presented with the help of descriptive and inferential statistics. **Results:** USG had 83.3% sensitivity, 89.5% specificity, 71.4% positive predictive value, 94.4% negative predictive value, and 88.0% accuracy in differentiating between benign and malignant soft-tissue swelling. The interrater reliability between USG and HPE indicated "substantial agreement" (Cohen's Kappa 0.689, $P = 0.000$). Using the scoring system, the swelling could be categorized into benign (score <3.50), indeterminate (score 3.50–6.50), and malignant (score ≥6.50). **Conclusion:** USG with Doppler can accurately differentiate between benign and malignant soft-tissue swelling. USG with Doppler-based scoring system could increase the sensitivity and specificity of this imaging modality.

Keywords: Doppler, histopathological examination, scoring method, soft-tissue neoplasm, ultrasonography

Introduction

"Soft-tissue swelling" usually presents as painless palpable lumps without constitutional symptoms.[1-3] Most swellings are benign, with a benign to malignant incidence ratio of 150:1.[4] Laboratory investigations are usually nonspecific, whereas histopathological assessment could be technically challenging.[2] Thus, ultrasonography (USG) is preferred.[5] However, owing to its operator dependence, the diagnostic accuracy is greatly affected.[6] Developing a scoring system would help in identifying soft-tissue masses as malignant or benign. Thus, our study was planned to determine the diagnostic accuracy of USG with Doppler in identifying malignant soft-tissue swellings and to develop a scoring system for the identification of malignancy.

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Materials and Methods

Study type, design, settings and duration

This analytical study with the longitudinal design was conducted in the Departments of Radiodiagnosis, Surgery and Pathology of a Tertiary Care Hospital in Darjeeling from July 2022 to June 2024.

Study population and selection criteria

The participants in this research were patients with soft-tissue swelling referred to the Department of Radiodiagnosis of the institute. Patients with discrete and palpable soft-tissue

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Abbreviations

AUC	Area under the curve
CI	Confidence Interval
HPE	Histopathological Examination
OR	Odds Ratio
aOR	Adjusted Odds Ratio
ROC	Receiver Operator Characteristic
USG	Ultrasonography

swelling in any part of the body were included, whereas those with multiple soft-tissue masses; prior histopathological diagnosis; masses have seen evidently arising from viscera, joints, bones, central nervous system or lymphoid tissues on USG, and masses that appeared as vascular malformations, hematoma, abscess, or thickened subcutaneous fat on USG were excluded.

Sample size estimation and sampling technique

The minimum sample size was calculated as 48 using Buderer's formula,[7] $[(Z_{1-\alpha})^2 \times S_N \times (1 - S_N)]/(L^2 \times P)$ where, $Z_{1-\alpha} = 1.96$ at 95% level of confidence, $S_N = 0.92$ (Sensitivity of USG with color Doppler in diagnosing malignant soft-tissue swelling as per Shu *et al*.[8]), $L^2 = 10\%$ absolute error (0.10), $P = 0.59$ (prevalence of malignant soft-tissue swelling in the study by Shu *et al*.[8]). Taking an additional 20% for nonresponse and for those unable to undergo surgical excision/histopathological examination due to unavoidable reasons, the final sample size was 58. These patients were selected by systematic random sampling.

Study tools and techniques

Data were collected by face-to-face interview using a predesigned, pretested, and structured schedule; USG with Doppler (GE LogiqP9 USG machine with linear [8–12 MHz] and curvilinear probes [3–5 MHz] depending on the size of the lesion) and histopathological examination (after surgical excision) of the swelling.

Method of data collection

A total of 58 participants satisfying the eligibility criteria were selected by systematic random sampling following approval from the Institutional Ethics Committee. After explaining the proceedings of the study and ensuring them about the anonymity and confidentiality of the data provided by them, they were requested to give written informed consent to participate. Data were collected from the consenting participants by face-to-face interview followed by USG and Doppler examination of the soft-tissue swelling by a single trained radiologist. Then, a tissue sample was collected (excisional/incisional/core needle biopsy), and histopathological examination (HPE) was performed by a single senior pathologist, blinded to the ultrasound results. The results of the histopathological examination were collected and compared with the findings of USG with Doppler.

Study variables

Data on sociodemographic characteristics of the patients and features of the swelling on USG were acquired. The test variable in this study was diagnosis based on USG with Doppler, which compared with the diagnosis on histopathological examination (gold standard investigation).[9]

Method of data analysis

After data collection, it was edited and entered into Microsoft Office Excel 2016 (Microsoft Corp, Redmond, WA, USA), analyzed using Statistical Package for the Social Sciences Version 25.0 (IBM, New York City, USA) and presented using descriptive and inferential statistics. Kolmogorov–Smirnov test was done to test the normality of the data. The association between features of the swelling on USG and histopathological diagnosis was assessed through binary logistic regression. Initially, univariable binary logistic regression (for calculation of odds ratio [OR]) was done between these variables, where $P < 0.2$ was considered biologically plausible. This was followed by multivariable binary logistic regression (for calculation of adjusted OR [aOR]) including all the biologically plausible variables. $P < 0.05$ was considered statistically significant. Sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of USG with Doppler in identifying malignant lesions were calculated with reference to the diagnosis on histopathologic examination (HPE). Kappa statistics was employed to measure the degree of agreement (interrater reliability) between these two diagnostic modalities.

Scoring system (based on the parameters studied by Li *et al*.,[6] Chung and Cho,[5] Nepal *et al*.,[10] and Vanhoenacker *et al*.[11]).

Features of the swelling on Ultrasonography with score

i. Echotexture
   a. Homogeneous (0)
   b. Heterogeneous (1)
ii. Margins
   a. Smooth, well-defined (0)
   b. Infiltrative (1)
iii. Lobulations
   a. Absent (0)
   b. Present (1)
iv. Size
   a. Less than 5 cm (0)
   b. More than or equal to 5 cm (1)
v. Relation with investing fascia
   a. Superficial, no contact with investing fascia (0)
   b. Acute angle with investing fascia (1)
   c. Obtuse angle with investing fascia (2)
   d. Deep to investing fascia (whole or part) (3).

Features of the swelling on Doppler with score

A. Absent color Doppler signal (0)
B. Linear color Doppler signal (1)
C. Disorganized color Doppler signal (2).

The total USG with Doppler score was calculated by adding all these parameters. The scores could range from 0 to 9. The receiver operating characteristic (ROC) curve with area under

the curve (AUC) and Youden's J were used to determine the cutoff score to differentiate between benign and malignant swellings.

Ethical clearance

The study was conducted with prior approval from the Institutional Ethical Committee (IEC/NBMC/M-04/49/2022). Besides, written informed consent was taken from all participants before their enrolment. The study abided by the Declaration of Helsinki and the Indian Council of Medical Research (ICMR) ethical guidelines for biomedical research on human subjects.

Results

A total of 58 patients with soft-tissue swelling were enrolled in the study, of which 8 (13.8%) were either lost to follow-up (6) or refused surgery/biopsy (2). Thus, the final analysis included 50 participants. The mean age (±SD) of the participants was 39.5 (±17.4) years with most participants in the age group of 30–44 years (17, 34.0%). More number of females (26, 52.0%) than males (24, 48.0%) had participated in this study.

In most cases, the swelling had a smooth, well-defined margin (39, 78.0%), without lobulations (37, 74.0%), with a size <5 cm (40, 80.0%), at an acute angle to the investing fascia (22, 44.0%) and without color Doppler signal (33, 66.0%). As per the findings of ultrasound with Doppler, 36 (72.0%) swellings were benign. Sonographically malignant lesions usually had a heterogenous echotexture (12, 85.7%), with lobulations (9, 64.3%). In most cases, the swellings diagnosed as malignant on USG were located deep to the investing fascia (12, 85.7%) and presented with disorganized color Doppler signal (11, 78.6%).

As per the results of HPE, 38 (76.0%) patients had a benign lesion, whereas 12 (24.0%) lesions were malignant. Univariable binary logistic regression revealed heterogeneous echotexture (OR: 18.857, 95% confidence interval [CI]: 2.195–161.985, $P = 0.00$), infiltrative margins (OR: 11.900, 95% CI: 2.536–55.848, $P = 0.00$), presence of lobulations (OR: 7.467, 95% CI: 1.767–31.556, $P = 0.00$), and size ≥5 cm (OR: 4.714, 95% CI: 1.069–20.789, $P = 0.04$) were significantly associated with histopathologically diagnosed malignant swellings. On multivariate binary logistic regression, heterogeneous echotexture (aOR: 13.777, 95% CI: 1.357–139.836, $P = 0.027$) and infiltrative margin (aOR: 7.642, 95% CI: 1.017–57.400, $P = 0.048$) were significant predictors of malignancy [Table 1].

In most cases, sonographically benign lesions [Figures 1-5] were histopathologically benign [Figures 1-4] with a few exceptions [Figure 5]. Similarly, most lesions with ultrasound diagnosis of malignancy [Figures 6-10] were histopathologically confirmed as malignant [Figures 6-9] except for a handful of cases [Figure 10]. Representative histopathological images of some of the lesions have been included in Supplementary Figures 1-5. The discrepancy between USG and HPE in a couple of cases was due to their atypical sonographic appearance. The scoring details of certain prototype benign and malignant lesions have been described in Supplementary Table 1.

USG had 83.3% sensitivity, 89.5% specificity, 71.4% positive predictive value, 94.4% negative predictive value, and 88.0% accuracy in differentiating between benign and malignant soft-tissue swelling [Table 2]. The interrater reliability of the two modalities was assessed using Cohen's Kappa, which yielded a value of 0.689 (Standard error 0.117, $P = 0.000$) indicating "substantial agreement."

USG with Doppler (AUC = 0.948 [95% CI 0.889–1.000]) was able to identify patients with malignant swelling with an optimal cutoff score of ≥4.50 (max Youden's J 0.759), with a sensitivity of 91.7% and specificity of 84.2%**.** However, it was observed there was some degree of inaccuracy in the diagnosis of lesions with scores of 5 and 6. Thus, lesions were

Table 1: Multivariable binary logistic regression of ultrasonography features on histopathologically confirmed malignant lesions ($n = 50$)

Feature	aOR	*P*	95% CI
Echotexture			
Homogeneous	1	0.027	1.357–139.836
Heterogeneous	13.777		
Margins			
Smooth, well defined	1	0.048	1.017–57.400
Infiltrative	7.642		
Lobulations			
Absent	1	0.548	0.243–14.378
Present	1.868		
Size (cm)			
<5	1	0.3	0.310–28.448
≥5	2.968		

Omnibus test $P<0.05$, Hosmer Lemeshow test P 0.538, Nagelkerke R^2 0.537. aOR: Adjusted odds ratio, CI: Confidence interval

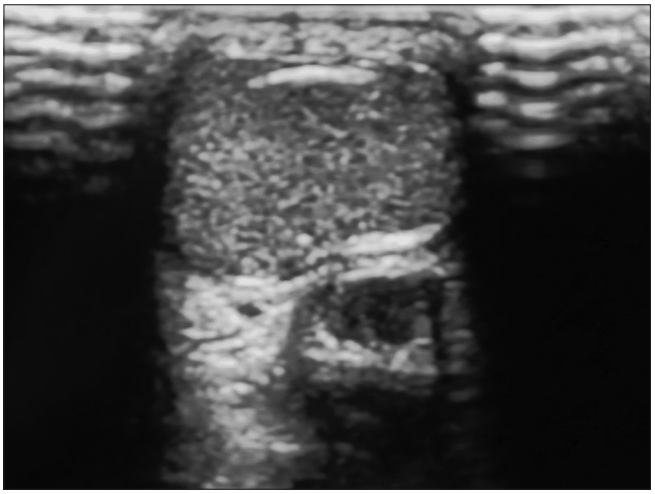

Figure 1: Grayscale ultrasound of a lesion in the nape of the neck with a total score 0 and USG diagnosis of benign lesion which was confirmed on HPE (epidermal inclusion cyst)

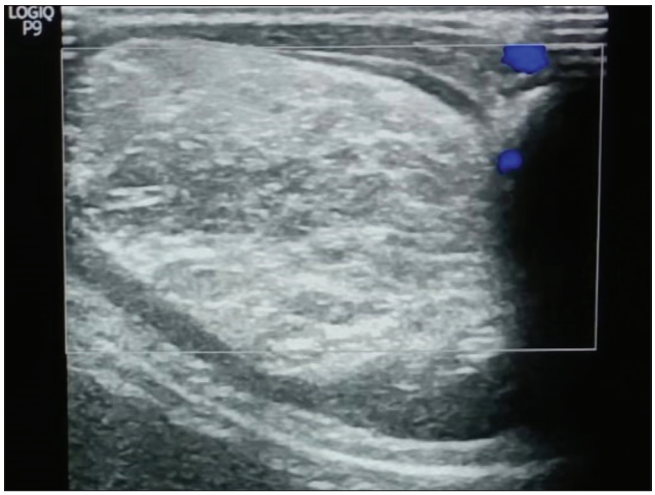

Figure 2: Grayscale and Doppler ultrasound of a thenar swelling with a score of 3/9 on USG with the diagnosis of benign lesion on USG and also on HPE (lipoma)

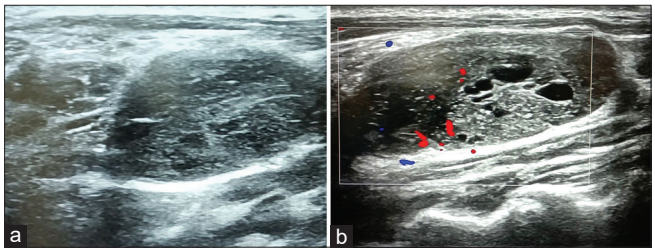

Figure 4: (a) Grayscale ultrasound of a neck swelling with (b) color Doppler with a score of 6/9 and USG and histopathological diagnosis of benign lesion (schwannoma)

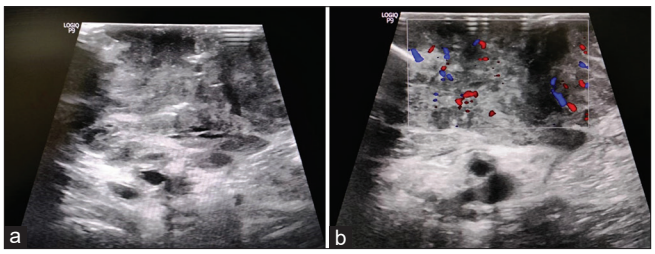

Figure 6: (a) Grayscale ultrasound of an inguinal lesion with (b) color Doppler and a total score of 9/9. The sonographic and histopathological diagnosis was of a malignant lesion (squamous cell carcinoma)

reclassified as benign (<3.50), indeterminate (3.50–6.50), and malignant (≥6.50) based on the coordinates of the ROC curve [Figure 11, Table 3]. Thus, we can consider lesions with scores 0–3 as benign, scores 4–6 as indeterminate, and scores 7–9 as malignant. The inclusion of an indeterminate category with a lowering of the upper limit of benign lesions from 4.50 to 3.50 helped us send more patients for diagnostic testing and thus achieve a confirmatory diagnosis regarding the malignant potential of their swelling.

Discussion

Our study revealed the impressive sensitivity (83.3%),

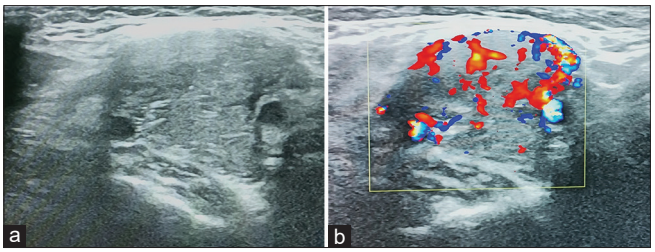

Figure 3: (a) Grayscale ultrasound of a neck mass with (b) color Doppler with a total score of 5/9 and a USG diagnosis of a benign lesion. HPE revealed benign lesion (carotid body tumor)

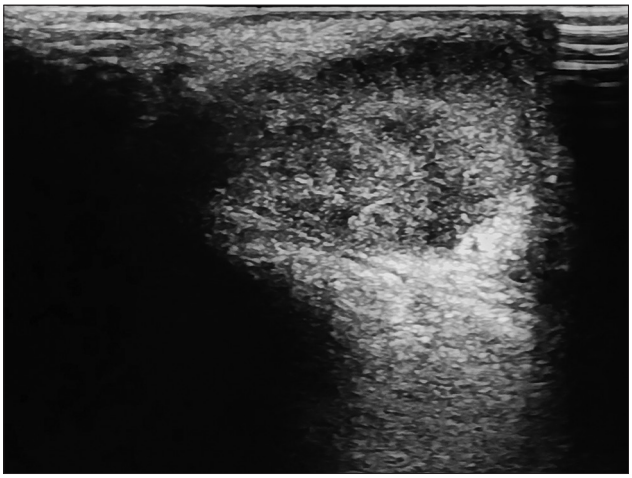

Figure 5: Grayscale ultrasound of a right postauricular swelling with a score of 3/9. USG diagnosis was of a benign lesion but HPE revealed malignancy (deposit of squamous cell carcinoma in lymph node)

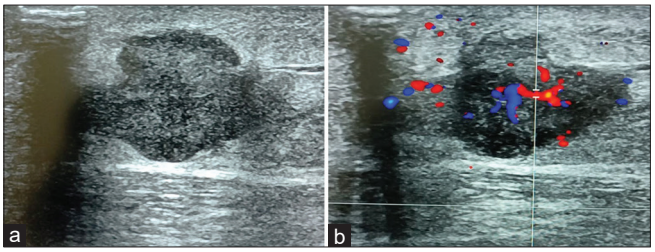

Figure 7: (a) Grayscale ultrasound of a pigmented left leg swelling with (b) color Doppler and a score of 6/9 and USG diagnosis of a malignant lesion. HPE confirmed malignancy (malignant melanoma)

specificity (89.5%), positive predictive value (71.4%), negative predictive value (94.4%), and accuracy (88.0%) of USG with Doppler in differentiating between benign and malignant soft-tissue swelling with "substantial agreement" between USG and HPE, establishing USG with Doppler as a suitable screening modality for differentiating between benign and malignant soft-tissue swelling. The study identified heterogeneous echotexture and infiltrative margins as independent predictors of malignancy, thus radiologists should give more significance to these features for diagnosing malignant lesions. This research also introduced a scoring system with scores ranging from 0 to 9 and a valid single cutoff of 4.50 to differentiate between benign and malignant lesions.

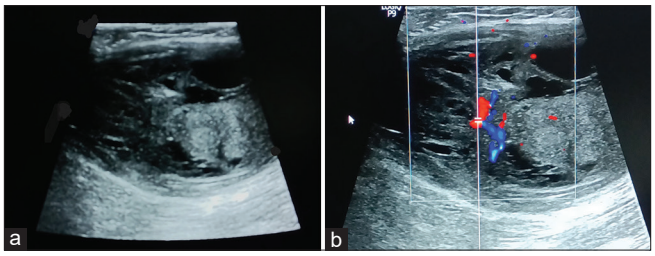

Figure 8: (a) Grayscale ultrasound of a right thigh mass and (b) color Doppler signal with a total score of 6/9 and sonographic diagnosis of malignancy which was confirmed on HPE (pleomorphic sarcoma)

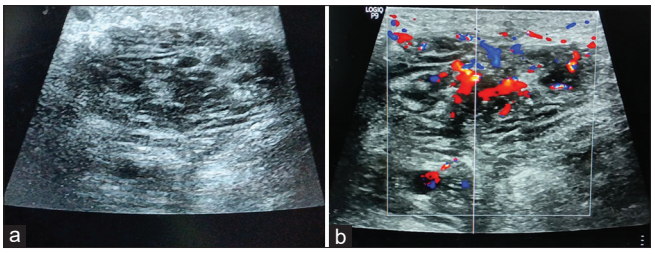

Figure 9: (a) Grayscale ultrasound of swelling in the left thigh and (b) color Doppler with a total score of 8/9 and a USG diagnosis of a malignant lesion. HPE revealed malignancy (muscle lymphoma)

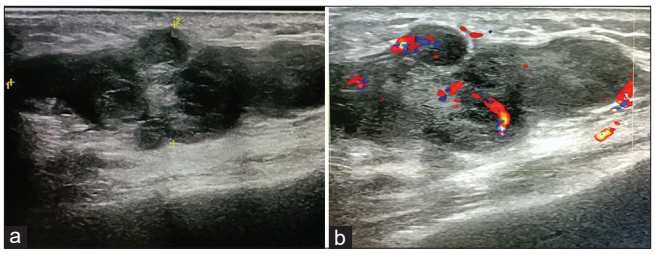

Figure 10: (a) Grayscale ultrasound of swelling over the right scapular region and (b) colour Doppler with a score of 7/9 and USG diagnosis of a malignant lesion. HPE suggested a benign (giant cell tumor of soft tissues)

Table 2: Comparison between the diagnosis of ultrasound with Doppler and histopathologic examination (n=50)

USG with Doppler	HPE		Total
	Malignant	Benign	
Malignant	10 (true positive)	4 (false positive)	14
Benign	2 (false negative)	34 (true negative)	36
Total	12	38	50

HPE: Histopathologic examination, USG: Ultrasonography

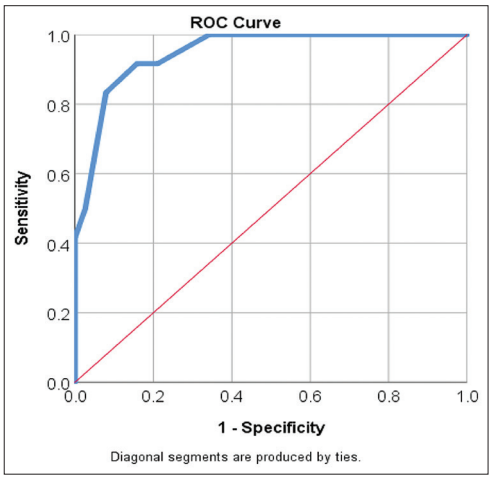

Figure 11: Receiver operating characteristic (ROC) curve comparing the efficacy of USG to HPE (n = 50)

To further refine the stratification, categories of benign (<3.50), indeterminate (3.50–6.50), and malignant lesions (≥6.50) based on the scoring system have been introduced, thus helping radiologists and clinicians to better predict the malignant potential of a soft-tissue swelling and select cases to be sent for further diagnostic evaluation.

The present research included 50 participants which was much less than the studies by Hung *et al*.[12] in Prince of Wales Hospital, Hong Kong; Morii *et al*.[13] in Kyorin University in Japan; Li *et al*.[6] and Shu *et al*.[8] in Nanjing Medical University, China, and the research by Li *et al*.[14] in pediatric patients of West China Second University Hospital of Sichuan University. However, unlike our study, there was no mention of sample size calculation using appropriate formulas in these studies.

Our scoring system included parameters such as echotexture, margins, lobulations, size, relation with investing fascia, and features on Doppler. Relation with investing fascia was graded more extensively in our scale, as described by Chung and Cho[5] in their study. Of all the studies conducted in the past, only those by Morii *et al*.[13] and Shu *et al*.[8] included a scoring system to differentiate between benign and malignant lesions.

Morii *et al*.[13] considered only the longest diameter, margin, and vascularity, whereas we considered many additional parameters for scoring after referring to numerous studies that have been mentioned previously. Shu *et al*.[8] considered bone destruction, but due to the low sensitivity of USG in identifying bone involvement owing to limited penetration, we decided to preclude this parameter from our scoring system to avoid inconsistencies in lesion characterization. Description of the lesion as cystic or solid was not included in the scoring system as it requires consideration of echogenicity and Doppler characteristics of the lesion which were already considered. While other scrutinized features are largely objective, categorizing a lesion as solid or cystic is often difficult, especially in lesions with heterogeneous debris, absent color Doppler flow, absence of anechoic component, or those with mixed solid and cystic components. Similar to cystic lesions, very homogeneous and hypoechoic solid lesions such as peripheral nerve sheath tumors and lymphoma may exhibit posterior enhancement. Besides, the majority of the studies in available literature did not consider this feature. We preferred the vascular patterns described by Li *et al*.[6] to Giovagnorio's criteria,[15] essentially described for lymph nodes, used by these two studies.

In our study, multivariable binary logistic regression revealed heterogeneous echotexture and infiltrative margins as

Table 3: Categorization of the swelling into benign, indeterminate, and malignant based on the coordinates of the receiver operating characteristic curve comparing the efficacy of ultrasonography to histopathologic examination (*n*=50)

Coordinates of the curve					
Test result variable(s)					
Positive if greater than or equal to[a]	Sensitivity	1 - Specificity	Specificity	Youden's J	Category
−1.00	1.000	1.000	0.000	0.000	Benign (<3.50)
0.50	1.000	0.974	0.026	0.026	
1.50	1.000	0.632	0.368	0.368	
2.50	1.000	0.342	0.658	0.658	
3.50	0.917	0.211	0.789	0.706	Indeterminate (3.50–6.50)
4.50	0.917	0.158	0.842	0.759	
5.50	0.833	0.079	0.921	0.754	
6.50	0.500	0.026	0.974	0.474	
7.50	0.417	0.000	1.000	0.417	Malignant (≥6.50)
8.50	0.167	0.000	1.000	0.167	
10.00	0.000	0.000	1.000	0.000	

independent predictors of malignancy. Similar to our study, Shu *et al*.,[8] Li *et al*.,[6] Morii *et al*.,[13] and Li *et al*.[14] also found margin to be an important differentiator between benign and malignant lesions. However, in contrast to our observations, echotexture was not an important predictor in other studies, though few had considered this parameter initially for the characterization of lesions. Vascularity on Doppler was an independent predictor in studies by Shu *et al*.[8] and Morii *et al*.,[13] but not in our study, possibly due to the use of different grading system. Shu *et al*.,[8] Li *et al*.,[6] and Morii *et al*.[13] also found size as a significant criterion for prediction of malignancy by multivariate binary logistic regression, whereas we found size ≥5 cm to be significantly associated with malignancy on univariable binary logistic regression which lost its significance in multivariable analysis and was not an important predictor of malignancy. Echogenicity was a significant differentiator in studies by Shu *et al*.[8] and Li *et al*.,[14] but not in our study as we did not consider echogenicity during the characterisation of lesions. This was done to avoid confusion in deciding the dominant echogenicity in heterogeneous lesions. Hence, we considered only echotexture and not echogenicity.

In the current work, as per HPE, 76.0% of patients had a benign lesion compared to the findings of ultrasound with Doppler, which identified 72.0% of swellings as benign. The sensitivity of USG in our study (83.3%) was higher than that by Li *et al*.[6] (71.4%) but less than the sensitivity observed by Hung *et al*.[12] (94.1%). Our observed specificity (89.5%) was superior to the specificity by Li *et al*.[6] (86.7%) but inferior to that by Hung *et al*.[12] (99.7%). Li *et al*.[6] reported lower positive and negative predictive values (65.2% and 89.7%, respectively) than in our study (71.4% and 94.4%). Hung *et al*.[12] did not calculate predictive values. The accuracy of USG in our study (88.0%) was superior to those in the other two studies that calculated this parameter, namely Li *et al*.[6] (75.4%) and Shu *et al*.[8] (86%). Li *et al*.[14] reported three sensitivity and specificity values based on the performance of three radiologists, the maximum reported sensitivity (96%) being superior to ours and the maximum reported specificity (77.2%) being lower than our observed value. Shu *et al*.[8] and Morii *et al*.[13] calculated some of these parameters only for their scoring system and not for USG as a screening tool in general. We found "substantial agreement" between USG and HPE (standard error: 0.117, *P* 0.000). To the best of our knowledge, none of the articles published in the past have expressed the accuracy of USG as the degree of agreement with HPE.

In the current study, USG with Doppler (ROC AUC = 0.948 [95% CI 0.889–1.000]) based optimal cutoff score was fixed at ≥4.50 (max Youden's J 0.759), with a sensitivity of 91.7% (0.917) and specificity of 84.2% (0.842) in identifying malignant swellings using a scoring system with scores ranging from 0 to 9. Despite an extensive review of existing literature, we could not find a USG-based scoring system with distinct benign (<3.50), indeterminate (3.50–6.50), and malignant (≥6.50) categories. The cutoff was 3.5 (area of ROC curve of 0.86) in the study by Shu *et al*.,[8] with a sensitivity and specificity of 0.92 and 0.72, respectively, with scores ranging from 0 to 6. Morii *et al*.[13] had set a cutoff value of 3 out of 4 (maximum score) to distinguish between benign and malignant lesions (ROC AUC 0.85), with a sensitivity of 0.825 and specificity of 0.732. Thus, the sensitivity of our scoring system was superior to that of Morii *et al*.[13] and quite similar to the sensitivity of the scoring system of Shu *et al*.[8] Our specificity was significantly superior to those of the scoring systems mentioned above, possibly due to more number of parameters considered for scoring.

Strengths

While being a completely novel subject of research for the country where this study was conducted, the inclusion of an adequate number of subjects, employment of rational exclusion criteria to minimize confounders, formulation of a scoring system combining statistically significant parameters of various previously conducted studies for predicting the possibility of malignancy, and comparison with a gold standard investigation

like histopathology using the degree of agreement as a measure of the accuracy of USG as a screening tool contributed in enhancing the validity of the study data. This study established a USG-based scoring system with distinct benign, indeterminate, and malignant categories, with the indeterminate category considered in none of the studies in the past.

Limitations

This research had a few limitations such as inadequate exclusion of sonographically atypical cases and nonconsideration of clinical parameters (rate of growth and age of the patient) as it focussed on the accuracy of USG with Doppler, the clinical context was consciously ignored which is not advisable in real life.

Conclusion

Interpretation and implications

USG with Doppler is highly sensitive, specific, and accurate in differentiating between benign and malignant soft-tissue swelling. It has considerably sound positive and negative predictive value. There is substantial agreement between USG with Doppler and HPE. Heterogeneous echotexture and infiltrative margins on USG are independent predictors of malignancy. USG with a Doppler cutoff score of ≥4.50 has a high sensitivity and specificity in identifying malignant soft-tissue swelling. Besides, the scoring system can be employed to classify lesions into benign, indeterminate, and malignant categories, thus imparting a more pragmatic approach to diagnostic categorization. With the introduction of an indeterminate category, such lesions can be sent for further evaluation without passing them off as benign (thus missing out on malignant lesions) or instantly stamping them as malignant (causing untimely mental agony to the patient).

Future research direction

This study successfully laid the foundation of a reliable scoring system with a valid cut-off based on USG with Doppler features which can predict the malignant potential of soft-tissue swelling.

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Conflicts of interest

There are no conflicts of interest.

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