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ESTIMATION OF DIAGNOSTIC ACCURACY OF ULTRASOUND, (USING BREAST IMAGING REPORTING AND DATA SYSTEM) IN EVALUATING PALPABLE BREAST MASS, COMPARED TO CYTOPATHOLOGY (USING INTERNATIONAL ACADEMY OF CYTOLOGY YOKOHAMA SYSTEM) IN A TERTIARY CARE CENTRE, INDIA.

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Abstract:

Introduction: Imaging techniques in evaluating palpable breast masses is an initial point in multidisciplinary approach. Ultrasound is a cost-effective technique and is useful in the detection of breast masses as well as in the differentiation of masses seen on mammography as solid or cystic. This study was done to evaluate palpable breast masses using Breast Imaging-Reporting and Data System (BI-RADS) and compare it with cytopathology which is gold standard categorized based on The International Academy of Cytology Yokohama System (IAC) for Reporting Breast Fine-Needle Aspiration Biopsy Cytopathology.

Material and methods: A longitudinal study was done in 100 adult female patients with palpable breast mass attending a tertiary care center during May 2022 to May 2023. After obtaining ethical committee clearance and patient's informed consent, study was done. Convenient sampling method was executed to enroll the patients in to study. Palpable breast masses were examined for benign and malignant features using ultrasound (BIRADS) and cytopathology (IAC Yokohama system). Statistical analysis done with chi-square test with $P<0.05$. Sensitivity, specificity, positive and negative predictive value as well as accuracy of ultrasound were calculated compared with cytopathology.

Results: Mean ± SD of age was 32.5± 23.3 with a range of 18- 65 years. The IAC Cytopathology showed 16% patients have malignant lesions (which is C5) and 84% patients have benign lesions (which is C2,C3,C4). Ultrasound diagnosed 97.7% of malignant lesions and 94% of benign lesions with a significant association between BI-RADS and IAC

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Yokohama system (X^2- 58.1, $p \leq 0.001$). Diagnostic accuracy of ultrasound was 93.1% at 95% CI (83.4% to 95.76%).

Conclusions: Breast neoplasms were 16% and benign were 84%, Sensitivity and specificity of ultrasound in diagnosing palpable breast mass at 95% CI was 87.5% (61.65% to 98.45%) and 94.05% (86.65% to 98.04%) with accuracy of 93.1% at 95% CI (83.4% to 95.76%).

Keywords: Palpable Breast Mass, Ultrasound, Cytopathology, BI-RADS, IAC Yokohama system.

INTRODUCTION

Palpable breast mass is one of the common presenting complaints of breast cancer which is 2nd most common cancer affecting women of reproductive age group.[1]A palpable breast mass is defined as a dominant mass if it is 3-dimensional, distinct from surrounding tissues, and asymmetrical relative to the other breast, with will persist throughout a menstrual cycle. Smooth, well-demarcated dominant masses that are mobile are often benign. Features that are suggestive of neoplasm includes poorly defined margins, irregular edges, immobility, or fixation to the surrounding tissue. Skin changes such as dimpling, retraction of the nipple, nipple scaling, or bloody nipple discharge are other findings suggestive of malignancy. [2]

Imaging techniques in evaluating palpable breast masses is an initial point in multidisciplinary approach. [3]Ultrasound is a cost effective technique and is useful in the detection of breast masses as well as in the differentiation of masses seen on mammography (whether solid or cystic), assessment of peripheral masses located outside the field of view of a mammogram and can detect lesions in women with dense breasts, as well as in pregnant and lactating women.[4,5]Ultrasonography can guide interventional procedures as the exact location of the mass can be identified, which ensures an adequate sample retrieval. Differentiation between benign and malignant breast masses and as such is an adjunct to clinical examination and mammography.[6,7,8,9]Breast Imaging-Reporting and Data System (BI-RADS) is a risk assessment and quality assurance tool developed by American College of Radiology that provides a widely accepted lexicon and reporting scheme for imaging of the breast with 7 assessment categories (BI-RADS 0-6).[10,11]

Fine needle aspiration cytology, fine needle biopsy, core needle biopsy, or tru-cut biopsy and open surgical biopsy are the different methods of breast biopsy done to obtain tissue for cytopathological diagnosis which is considered as gold standard currently. Various cytopathology classification systems are in use, one such is The International Academy of Cytology Yokohama System for Reporting Breast Fine-Needle Aspiration Biopsy Cytopathology which have 5 categories (C1,C2,C3,C4,C5).[12,13,14]

The purpose of our study was to evaluate the diagnostic performance of breast Ultrasound as the primary imaging modality in the evaluation of palpable breast masses using BI-RADS and compare it with cytopathology which is gold standard categorized based on IAC Yokohama System.

MATERIAL AND METHODS

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A longitudinal study was done in 100 adult female patients with palpable breast mass attending a tertiary care center during May 2022 to May 2023. After obtaining ethical committee clearance and patient's informed consent, study was done. Convenient sampling method was executed to enroll the patients in to study.

Findings were recorded in a semi-structured questionnaire which includes patient's details, history on presenting symptoms and risk factors, family history, personal history, marital history, findings of ultrasonography of breast mass and cytopathology. Ultrasound examination and cytopathologywas done in all the participants by single radiologist and pathologist. BI-RADS classification was used to describe the palpable breast mass as per ultrasound with categories 0-6 which are 0 - incomplete evaluation,1-negative,2-benign,3-probably benign, 4-suspicious, 5-highly suggestive of malignancy, 6-pathology proven malignancy. The IAC Yokohama System for Reporting Breast Fine-Needle Aspiration Biopsy Cytopathology, was used for cytopathology reporting. It has 5 categories Inadequate/C1, Benign/C2, Atypia/C3, Suspicious/C4, Malignant/C5.

Patients not willing to participate, known breast and malignancy with metastasis in breast, with breast mass categorized as BI-RADS 0,1 and 6 and cytology categorization C1 were not included in the study. The diagnostic accuracy of ultrasound was estimated considering cytopathological categorization as gold standard.

Figure 1: Algorithm to evaluate a palpable breast mass [2]

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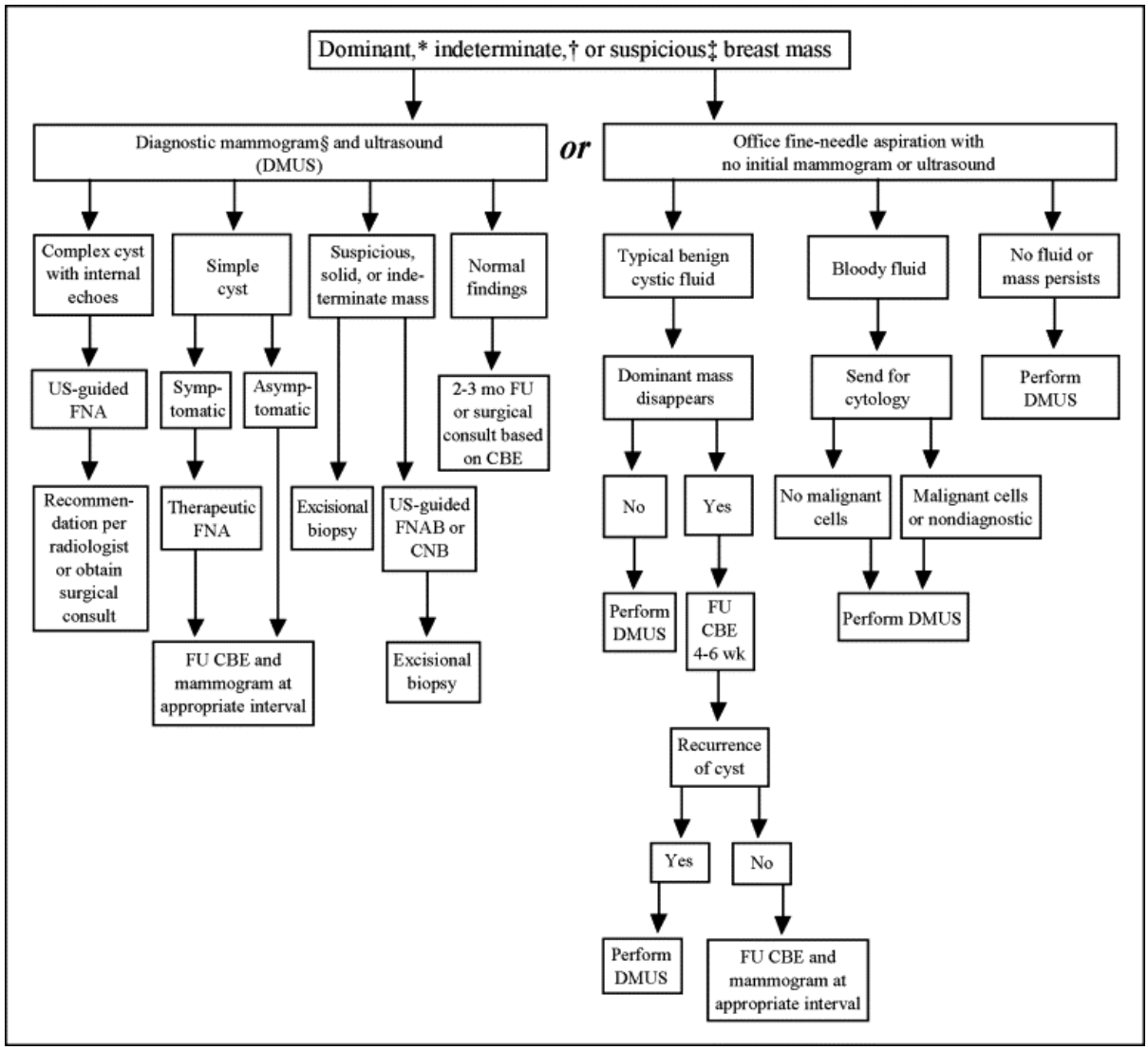

Figure 1=Algorithm to evaluate a palpable breast mass. CBE = clinical breast examination; CNB = core needle biopsy; consult = consultation; FNA = fine-needle aspiration; FNAB = FNA biopsy; FU = follow-up; US = ultrasonography.[2]

Source: Sandhya Pruthi. Detection and Evaluation of a Palpable Breast Mass. Mayo clinical proceedings. Concise review for clinicians. 2001;76(6);641-648. Available from; https://www.mayoclinicproceedings.org/article/S0025-6196(11)62416-6/fulltext#:~:text=A%20palpable%20breast%20mass%20is,are%20mobile%20are%20often%20benign.

Procedure: Ultrasound imaging of the palpable breast mass was performed with a linear-array transducer (5–12 MHz) on a Philips US scanner (Philips Healthcare Affiniti 70 G, USA) by the single radiologist.With the patients in supine position radial/ antiradial images of the breast with palpable mass were taken. Evaluation was done with respect to size, shape, margins, echogenicity, vascularity, presence of calcification, and posterior acoustic enhancement or shadowing as per BI-RADS.

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Echogenicity 1. Anechoic- Mass contained no internal echoes.

2. hypoechoic- low-level echoes were present

3. isoechoic - echogenicity was similar to that of fat

4. hyperechoic - echogenicity was greater than that of adjacent tissue

Palpable breast masses were examined for benign and malignant features. Malignant characteristics of a breast mass were - marked hypoechogenicity, angular or spiculated margins, posterior acoustical shadowing, micro calcifications, ductal extension, and microlobulation. The presence of any malignant feature excluded a nodule from benign classification.

A nodule was classified as benign if one of the following three combinations was present: intense and uniform hyperechogenicity, ellipsoid shape with a thin echogenic capsule, or three or fewer gentle macrolobulations associated with a thin echogenic capsule.

After undergoing ultrasound of breast mass, cytopathological examination was done (either fine needle aspiration or biopsy whichever is appropriate) as per guidelines of detection and evaluation of a palpable breast mass, under ultrasound guidance when needed.[2]

The breast mass were classified as BI-RADS 2,3 and 4 for benign, probably benign appearing and indeterminate or suspicious of neoplasm respectively. These were compared to the benign palpable breast masses of cytology C2, C3 and C4. Nodules that were classified as BI-RADS 5 which was highly suggestive of malignancy were compared to the C5 category which was malignant as per cytopathology.

Operational definitions:

Definitions

- *Sensitivity*: probability that a test result will be positive when the disease is present (true positive rate).

  = ***a / (a+b)***

- *Specificity*: probability that a test result will be negative when the disease is not present (true negative rate).

  = ***d / (c+d)***

- *Positive likelihood ratio*: ratio between the probability of a positive test result given the *presence* of the disease and the probability of a positive test result given the *absence* of the disease, i.e.

  = ***True positive rate / False positive rate = Sensitivity / (1-Specificity)***

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- *Negative likelihood ratio*: ratio between the probability of a negative test result given the *presence* of the disease and the probability of a negative test result given the *absence* of the disease, i.e.

  = ***False negative rate / True negative rate = (1-Sensitivity) / Specificity***

- *Positive predictive value*: probability that the disease is present when the test is positive.

$$PPV = \frac{sensitivity \times prevalence}{sensitivity \times prevalence + (1 - specificity) \times (1 - prevalence)}$$

- *Negative predictive value*: probability that the disease is not present when the test is negative.

$$NPV = \frac{specificity \times (1 - prevalence)}{(1 - sensitivity) \times prevalence + specificity \times (1 - prevalence)}$$

- *Accuracy*: overall probability that a patient is correctly classified.

  = ***Sensitivity × Prevalence + Specificity × (1 − Prevalence)***

Sensitivity, specificity, disease prevalence, positive and negative predictive value as well as accuracy are expressed as percentages with 95% confidence intervals. [15]

StatisticalAnalysis

Data entered in SPSS version 22 package.Data represented in frequencies, mean and standard deviation (SD) and median for non-normal distributed parameters**. C**hi-square test was used for statistical analysis.P <0.05 was consideredto besignificant statistically. Sensitivity and specificity, positive and negative predictive value as well as accuracy of BI-RADS in comparison with cytopathology as gold standard was estimated.

RESULTS

Out of 100 adult female patients enrolled in to the study mean age was 34.5± 23.3 with a range of 18- 65 years. Most of the patients were in the age group of 18-40 years (60%) followed by 41-60 years (32%) and >60 years (8%). Most common presenting feature was change in size and texture (56%) followed by relation to menstrual cycle (43%) and pain (23%). Nipple discharge was seen in only 12% of patients. Risk factors identified were family history of breast cancer or ovarian cancer in 18%, first-degree relative (mother, sister, or daughter) affected with breast cancer in 5%, median parity 2, mean age at first live birth 25.7±7.8, median age at menarche 12, median of cessation of menses was 45 in 36% of patients, use of hormone replacement therapy in 25% patients. Palpable breast mass identified were cyst in 16%, fibroadenomas in 34%, fibrocystic changes in 25%, intraductal papilloma in 9%, invasive breast carcinoma of no special type in 6% and lobular carcinoma in 10%. Thus, breast neoplasms were 16% and benign were 84%. (Table 1)

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Table 1: Distribution by Patient's characteristics

Patient characteristic	Group	Frequency
Age	18-40 Years	60 (60%)
	41-60 Years	32 (32%)
	>60 years	8 (8%)
	Mean ±SD	34.5±23.3
Presenting complaints	pain	23 (23%)
	change in size or texture over time	56 (56%)
	relationship to menstrual cycle	43(43%)
	nipple discharge	12 (12%)
risk factors for breast cancer	family history of breast cancer or ovarian cancer	18(18%)
	first-degree relative (mother, sister, or daughter) was affected with breast cancer	5(5%)
	Median parity	2
	Mean age at first live birth	25.7±7.8
	Median age at menarche	12
	Median late cessation of menses	45
	use of hormone replacement therapy	25 (25%)
Palpable breast mass on final diagnosis	Cyst	16%
	Fibroadenomas	34%
	Fibrocystic changes	25%
	intraductal papilloma	9%
	Invasive breast carcinoma of no special type	6%
	Lobular carcinoma	10%

Ultrasound imaging categorized palpable breast mass as BIRADS 2,3,4 and 5 in 64%, 16%, 1% and 19% respectively. Cytology findings shows C2 (benign) in 67%, C3 (atypical) in 14%, C4 (suspicious) in 3% and C5 (malignant) in 16%. (table2)

Table 2: Ultrasound and cytology findings

Ultrasound findings BI-RADS	Percentage	Cytology findings	Percentage
BI-RADS 2: Benign findings	64%	Category II (benign)	67%
BI-RADS 3: Probably benign findings	16%	Category III (atypical)	14%
BI-RADS 4: Suspicious abnormality	1%	Category IV (suspicious)	3%
BI-RADS 5: Highly suggestive of malignancy.	19%	Category V (malignant)	16%

The IAC cytopathology showed 16% patients have malignant lesions (which is C5) and 84% patients have benign lesions (which is C2,C3,C4). Whereas BI-RADS on ultrasound showed

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19% patients with neoplastic masses (BI-RADS 5) and 81% patients with benign pathology (BI-RADS 2,3,4). Thus, ultrasound diagnosed 97.7% of malignant lesions and 94% of benign lesions with a significant association between BI-RADS and IAC Yokohama system (X^2-58.1, $p \leq 0.001$). (Table 3)

Table 3: Ultrasound finding versus cytopathological finding

Ultrasound Finding	**Cytopathological Finding**		**X^2/ P value**
	Malignant (C5) (n=16)	**Benign (C2, C3, C4) (n=84)**	58.1/ P <0.00001
BI-RADS≥ 5 (n=19)	14 True Positive (97.7%)	5 False positive (16%)	
BI-RADS <5 (n= 81)	2 False Negative (2.3%)	79 True Negative (94%)	

Sensitivity and specificity of ultrasound in diagnosing palpable breast mass at 95% CI was 87.5% (61.65% to 98.45%) and 94.05% (86.65% to 98.04%). Positive and negative predictive value was 73.68% (53.98% to 99.3%) and 93% (86.1% to 97.1%) with accuracy of 93.1% at 95% CI (83.4% to 95.76%). (Table 4)

Table 4: Diagnostic accuracy of ultrasound (BI-RADS) with cytopathology (Yokohama system) as gold standard

Statistic	Value	95% CI
Sensitivity	87.5%	61.65% to 98.45%
Specificity	94.05%	86.65% to 98.04%
Positive Likelihood Ratio	14.70	6.16 to 35.09
Negative Likelihood Ratio	0.13	0.04 to 0.49
Disease prevalence (*)	16%	9.43% to 24.68%
Positive Predictive Value (*)	73.68%	54% to 99.3%
Negative Predictive Value (*)	93%	86.1% to 97.1%
Accuracy (*)	90.91%	83.44% to 95.76%

DISCUSSION

This study compared ultrasound findings of palpable breast mass over cytopathology findings using BI-RADS and the IAC yokohama System.

In the current study age range was 18- 65 years with mean age 34.5± 23.3 years, which was similar compared to study by Bello N et al where the mean age of the patients was 34.66 ± 13.99 (range 18–69) years, [16] and lower to study done in Zaria by Yusufu *et al*.[17] with mean age of 36.4 (range 13–80) years. In study by Devi R G et al, mean age was 41.84±9.1 years. [18] This was due to difference in age groups included in the study.

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In the current study out of 100 patients with breast mass 60% of patients were in the age group of 18-40 years followed by 32% and 18% in 41-60 years and >60 years respectively. In study by Bello N et al, age distribution of subjects presenting with palpable breast masses in the age group 18–27 had the highest incidence of breast lump with 39 (39%) subjects followed by the 28–37 age group that had 23 subjects.[16] This is similar to a study by Singh et al, which had the highest incidence of breast lumps in the age group of 20–29 years (44%).[19] Unlike in study by Ahmed et al most common age group suffering from the disease was 50-70 years followed by 30-50 with mean age 50.9 years (range 26-81 years).

In this study Most common presenting feature was change in size and texture (56%) followed by relation to menstrual cycle (43%) and pain (23%). Nipple discharge was seen in only 12% of patients. In study by Akinnibosun Raju HO et al 46 (28.7%) patients had associated breast pain, whereas only 8 (5.0%) had associated nipple discharge.[20]

In this study, palpable breast mass identified were cyst in 16%, fibroadenomas in 34%, fibrocystic changes in 25%, intraductal papilloma in 9%, invasive breast carcinoma of no special type in 6% and lobular carcinoma in 10%. Thus, breast neoplasms were 16% and benign were 84%. In study by Bello N et al, there were more benign masses (63%) than malignant masses (29%).[16] In study by Sankaye SB et al, of the 225 cases, 131 were in the benign category and 65 belonged to the malignant category.[21]In study by Akinnibosun Raju HO et al fibroadenoma was found in 49.4% of the patients and had the highest occurrence, followed by cysts (8.8%) and abscesses (8.8%). [20] Study by Muddegowda *et al*.,[22]found that benign breast lesions occurred more frequently with fibroadenoma being the most common benign breast lesion followed by fibrocystic diseases. Naz and Malik [23] found more cysts (37.5%) than fibroadenoma (28.5%) in their study.

In this study Cytology findings shows C2 Category II(benign) in 67%, C3 Category III (atypical) in 14%, C4 Category IV (suspicious) in 3% and C5 Category V (malignant) in 16%. Study by Dixit N et al found Category I (insufficient material) in 7.4%, Category II (benign) in 74%, Category III (atypical) in 5.7%, Category IV (suspicious) in 1.4%, and Category V (malignant) in 11.5%. [24]

In this study ultrasound diagnosed 97.7% of malignant lesions and 94% of benign lesions with a significant association between BI-RADS and IAC Yokohama system (X^2- 58.1, $p \leq 0.001$). In study by Akinnibosun Raju HO et al majority of the study participants with benign mass [78 (64.5%)] were within the 15–30 years age group, and 101 (83.5%) had benign outcome on histology with BI-RADS category of 2 (benign finding) on ultrasound. This was statistically significant ($P = 0.000$).[20]

In the current study sensitivity and specificity of ultrasound in diagnosing palpable breast mass at 95% CI was 87.5% (61.65% to 98.45%) and 94.05% (86.65% to 98.04%). Positive and negative predictive value was 73.68% (53.98% to 99.3%) and 93% (86.1% to 97.1%) with accuracy of 93.1% at 95% CI (83.4% to 95.76%). In study by Bello N et al, on comparing the final diagnosis of ultrasound to that of histology, it was found to have a sensitivity of 89%; specificity of 94%; positive predictive value of 89%; negative predictive value of 94%; and accuracy of 92%.[16] In study by Akinnibosun Raju HO et al, Sensitivity,

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specificity, positive predictive value, negative predictive value, and accuracy were found to be 79.5%, 98.3%, 93.9%, 93.7%, and 93.8%, respectively.[20]

The accuracy of this study (91%) in differentiating between benign and malignant masses was similar to that of study by Bello N et al (92%),[16] and lower than Irurhe *et al*.[25] and Pande *et al*.,[26] which recorded 97% and 94%, respectively, and higher than 71% recorded by Costantini *et al*.[27] Thus ultrasound is comparable to cytopathology and can be considered as a safe and primary imaging modality

CONCLUSION

In this study breast neoplasms were 16% and benign were 84%, ultrasound diagnosed 97.7% of malignant lesions and 94% of benign lesions with a significant association between BI-RADS and IAC Yokohama system (X^2- 58.1, $p \leq 0.001$). Sensitivity and specificity of ultrasound in diagnosing palpable breast mass at 95% CI was 87.5% (61.65% to 98.45%) and 94.05% (86.65% to 98.04%) with diagnostic accuracy of 93.1%. Thus ultrasound can be considered as cost effective and safe initial imaging modality.

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