Review Article



Enhancing Diagnostic Accuracy in Breast Pathology: Insights from a Meta-Analyses of FNAC and TCB

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Abstract

Background: The Fine Needle Aspiration Cytology (FNAC) and Tru-Cut Biopsy (TCB) are significant investigative techniques used to differentiate breast issues. There is much research done on how well the two techniques complement each other. <u>Aim and objective:</u> The systematic review and meta-analyses aimed to compare the diagnostic accuracy, sensitivity, and specificity of FNAC with TCB in breast pathology by conducting a meta-analysis of ten studies from 2017 to 2024 and answer the question: "How far we can trust FNAC alone in the diagnosis of breast lump alone? What are the cases when we can opt for FNAC alone or combine it with TCB and how do we individualize each case?". <u>Methods:</u> The systematic literature review and meta-analyses using various databases, including PubMed, Scopus, and Embase were performed. Predesigned criteria-based studies were retrieved, with special emphasis on comparing FNAC with TCB in breast lesions. Data were retrieved for sample size evaluation, diagnosis outcomes, and tissue analysis correlations. Finally, ten studies were included. <u>Results:</u> The research found that TCB was more sensitive (average %) and specific (average %) compared with FNAC (average sensitivity %, specificity %). TCB also indicated fewer unsatisfactory specimens and misdiagnoses, especially with ductal carcinoma in situ (DCIS). <u>Conclusions:</u> TCB is more precise than FNAC in the diagnosis of breast lesions, especially regarding sensitivity and specificity. The evidence is in favor of recommending TCB as a first-line diagnostic test in clinical practice, especially in suspicious breast masses. However, the two techniques complement each other and proved to be crucial in the effective diagnosis of the condition.

Keywords: FNAC, Tru-Cut Biopsy, Breast Cancer, Diagnostic Accuracy, Systematic Review.

Introduction

Breast cancer is the most frequent cancer among women globally, resulting in mortality (Azamjah N *et al.*, 2019). Early diagnosis is extremely critical for improved treatment and survival. For the diagnosis of breast abnormalities, physicians most often employ a combination of physical examination, imaging procedures, and laboratory examinations. Two of the most frequent methods of obtaining tissue samples from breast abnormalities are Fine Needle Aspiration Cytology (FNAC) and Tru-Cut Biopsy (TCB).

FNAC is a straightforward test that involves the use of a fine needle to remove cells from a lump (Yip SW *et al.*, 2022). It is popular because it is easy, quick, and inexpensive. FNAC, however, is not without its issues, such as increased risk of being unable to obtain a sample and not being able to distinguish between in situ and invasive cancer. A substitute is TCB, or core needle biopsy, which removes a greater sample of tissue (Falah SQ *et al.*, 2021). This means that it permits the tissue to be examined further. It is increasing in popularity because it aids in making diagnoses more clearly and identifying receptor status, which is extremely helpful when planning treatment.

Although TCB has its advantages, FNAC remains the universally applied initial test in most medical conditions. Between the two procedures, the decision is usually made depending on the type of lesion, patient preference, and equipment availability. This review examines existing literature comparing FNAC and TCB, with an emphasis on their accuracy, sensitivity, and specificity in breast disease. Finally, the results came out and answered our queries regarding FNAC and TCB in the diagnosis of breast lump.

Methodology

This systematic review and meta-analyses followed the Preferred Reporting Item for Systematic Review and Meta-Analyses (PRISMA) guidelines (Page MJ *et al.*, 2022) (**Figure 1 a**). The risk of bias was also analysed (**Figure 1 b**).

Literature search

A comprehensive literature search was done to find out studies published between 2017 to 2024 on the comparison of FNAC vs TCB in diagnosis of breast lesion. Electronic database search was done in PubMed, Scopus and Embase using the keywords "Comparative study", "FNAC", "Tru-cut biopsy" and "Breast lesion".

Inclusion criteria

- 1. Comparisons between FNAC and TCB in breast lesions.
- 2. Published between 2017 and 2024.
- 3. Adult patients with palpable breast masses.
- 4. Reports with sensitivity and specificity measures.
- 5. English peer-reviewed articles.

Exclusion criteria

- 1. Studies not involving human subjects.
- 2. Editorials, reviews, and case reports.
- 3. Investigations of non-palpable lesions.
- 4. Studies with inadequate data for analysis.
- 5. Non-English publications.

Data extraction

The eligibility of the article based on criteria search was completed by two authors (S.K. and V.M.) and the full text of the studies was analyzed by using Microsoft Excel 2016. The two authors assessed the methodology and the quality of the articles by using the New Castle Ottawa assessment scale (Wells GA *et al.*, 2022). Finally, a total of ten studies met the quality of assessment (**Figure 1 b**). The first author name with year of publication, study design, sample size and study characteristics were tabulated (**Table 1**).

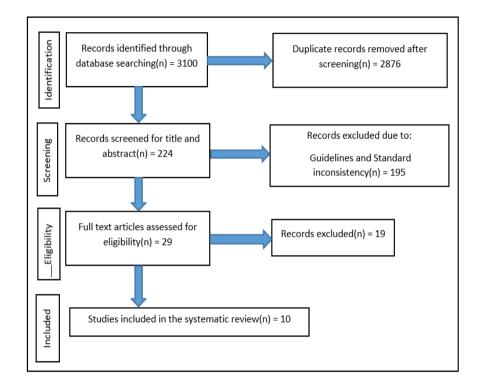


Figure 1 a: Flowchart for the selection of studies

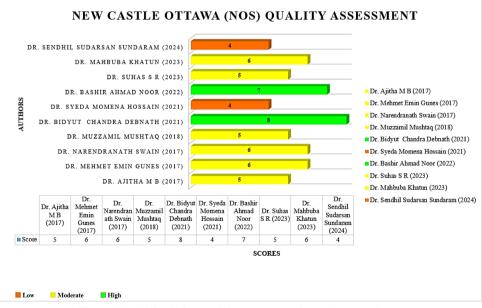


Figure 1 b: Risk of bias quality assessment for various studies

Results

A total of 3100 articles were retrieved from the electronic databases of PubMed, Scopus and Embase of which 2876 articles were excluded. During the title and abstract screening phase, a total of 195 articles were removed from 224 articles. About 19 articles were excluded from 29 articles during full text screening and finally 10 articles were included in the systematic review and meta-analyses.

The average sensitivity for FNAC and TCB were noted as 80.26% and 94.05% respectively while the average specificity for FNAC and TCB were noted as 95.86% and 97.89% respectively (**Table 2**)

The forest plots for sensitivity and specificity were plotted for FNAC vs TCB based on random effects model (REML). The pooled estimate came out to be 0.78(95% CI: 0.66-0.90) and 0.92(95% CI: 0.85-0.99) for sensitivity for FNAC vs TCB (Figure 2 a), respectively (I2 = 91.285% vs 91.376%). While the pooled estimate came out to be 0.92 (95% CI: 0.85-0.99) and 0.96 (95% CI: 0.94-0.98) respectively (I2 = 91.376% vs 0%) for specificity for FNAC vs TCB (**Figure 2 b**).

Funnel's and Egger's Test:

The funnel's test showed asymmetry for all plots attributed to the chronological and geographic variations (Figure 3 a and b). However, the Egger's test p values for sensitivity for FNAC and TCB were 0.15 and 0.45 respectively while the p values for specificity for FNAC and TCB were 0.30 and 0.70 respectively showing that there was no publication bias.

The bubble meta regression graphs for sensitivity and specificity for FNAC vs TCB were plotted (Figure 4 a and b).

S	First author	Study Design	Sample	Study Characteristics		
No	(Year)		Size			
1	Ajitha M B (2017)	Prospective Study	70	Out of a total 70 breast lump aspirations, 36 breast lumps were benign and 34 breast lumps were malignant lumps. Of 36 breast lumps with benign lesions, 24(66.6) were married. Maximum incidence in this group was in the 3rd decade. Whereas in 34 malignant breast lumps, 32 were married, peak age was in forth decade.		
2	Mehmet Emin Gunes (2018)	Retrospective Study	140	The mean age of 140 patients included this study was 51.26±15.83, and age ranged from 17 to 83 years. USG guided tru-cut biopsy was performed in 114 patients and tru-cut biopsy with palpation guidance was applied in 26 patients.		
3	Narendranath Swain (2017)	Prospective Study	64	60 (93.75%) patients are female and 4 (6.25%) patients are male, with female to male ratio 15:1. The age range varied from 11-70yrs. In female the average age is 40.5yrs and in males the average age is 40.5yrs.		
4	Muzzamil Mushtaq (2018)	Prospective Study	55	The patients ranged in age from 16 to 76 years. Lesions ranged in size from 2 to 12 cm grossly. 46 patients (83.63%) had a single lump in either breast. 9 patients (16.36%) had multiple lumps, out of which 8 patients had multiple lumps in a single breast while 1 patient had multiple lumps inboth the breasts		
5	Bidyut Chandra Debnath (2021)	Cross-Sectional Study	200	The mean age with standard deviation was 33.85±7.969 years. The male and female ratio was 1:19.		
6	Syeda Momena Hossain (2021)	Cross-Sectional Study	60	Thirty percent of the patients were middle-aged (40-50 years old), 26.7% late middle-aged (50-60 years old) and 23.3% early middle-aged (30-40 years). While elderly patients (60 or > 60 years old) comprised of 11.7%, younger patients (< 30 years old) formed of 8.3% cases only. The mean age of the patients were 44.4 \pm 11.9 years with youngest and the oldest patients being 19 and 80 years old respectively.		
7	Bashir Ahmad Noor (2022)	Cross-Sectional Study	190	56.84% of 108 participants were between the ages of 18 and 40, while 43.16% of the n=82 participants were between the ages of 41 and 60. The mean+sd was computed as 40.31+8.62 years of age.		
8	Suhas S R (2023)	Prospective Study	80	The prevalence of breast lumps was highest in the age group of 38-47 years, with 18 (36.00%) cases being benign and 8 (26.67%) cases being malignant. The second highest prevalence was in the age group of 18-27 years, with 23 (46.00%) cases being benign and 1 (3.33%) case being malignant. In the age group of 28-37 years, 7 (14.00%) cases were benign and 9 (30.00%) cases were malignant. There was a significant association between age and the study groups (p<0.05). The mean age was 32 ± 13 years in the benign group and 44 ± 11 years in the malignant group, with a significant difference between the two groups (p<0.05).		
9	Mahbuba Khatun (2023)	Cross-Sectional Study	100	The majority of the patients (30%) were in the age group of 41-50 years followed by 24% in the age group of 51-60 years, 20% in the age group of 31-40 years, 14% in the age group of 21-30		
10	Sendhil Sudarsan Sundaram (2024)	Prospective study	36	The mean age of the study patients was 41 ± 13.99 years, ranging from 22 to 84 years.		

Table 1: Study characteristics of various studies

Table 2: Sensitivity and specificity comparison between FNAC and TCB

First Author Name	Sample Size	FNAC	FNAC	ТСВ	ТСВ
		Sensitivity (%)	Specificity (%)	Sensitivity (%)	Specificity (%)
Narendranath Swain (2017)	70	93.33	97.05	100	100
Mehmet Emin Gunes (2017)	140	N/A	N/A	93.5	95.4
Muzzamil Mushtaq (2017)	64	63.63	100	95.45	100
Ajitha M B (2017)	55	86.84	100	97.14	100
Bidyut Chandra Debnath (2021)	200	70.49	93.8	80.33	96.12
Syeda Momena Hossain (2021)	60	65	100	98.1	100

Bashir Ahmad Noor (2022)	190	70.49	93.8	80.33	96.12
Suhas S (2023)	80	92.31	88.89	100	94.34
Mahbuba Khatun (2023)	100	N/A	N/A	95.65	96.88
Sendhil Sudarsan Sundaram (2024)	36	100	93.33	100	100

Table 3: Important findings of various studies

Sl No	First author (Year)	Important Findings
1	Ajitha M B (2017)	Trucut biopsy could also yield histological diagnosis and results were 100% concordant with the final histopathological report. It is also more specific in terms of tumour type, grade, receptor status, and
		lymphovascular invasion. FNAC to assess a breast lump has a high sensitivity, precision and specificity but
		trucut always provides a better histological diagnosis and more accurate.
2	Mehmet Emin	During preoperative time tru-cut biopsy is widely accepted as a diagnostic tool for high positive predictive
2	Gunes (2018)	value breast lesions and low false negativity. Triple assessment accordance which includes clinical,
	Guiles (2010)	radiological and pathological results also increase its diagnostic accuracy.
3	Narendranath Swain	in cases clinically suspicious if FNAC is unfavorable, we may go ahead with TCNB which is 100%
·	(2017)	specific. When TCNB is inconclusive we can go ahead with incision biopsy and ICstudy and then definite
		surgery undertaken. Intraoperative IC enhances diagnostic accuracy of FNAC, TCNB and all have good
		correlation with each other and, by HP research and their collective usage plays a very crucial role in
		successful management breast lumps in hospitals that lack equipment for frozen section examinations.
4	Muzzamil Mushtaq	Trucut biopsy detected more breast carcinomas as compared FNAC with a sensitivity of 95.45% as
	(2018)	opposed to 63.63%. Though both the techniques were equally specific, Trucut biopsy was able to correctly
		categorize borderline / inadequate lesions into definitely benign and malignant categories.
5	Bidyut Chandra	The use of tru-cut also lessens the propensity of complicated surgical procedures and minimizes patient
	Debnath (2021)	stress. In patients with malignant lesions, in addition to having diagnostic significance, TCB also provides
		adequate tissue for the evaluation of molecular markers which have extreme therapeutic value, there is a
		significant difference between FNAC and tru-cut biopsy for the detection of breast pathology.
6	Syeda Momena	Tru-cut biopsy is fairly comparable to that of histopathology in terms of its diagnostic accuracy and could
	Hossain (2021)	be used as a useful screening tool in the evaluation of clinically palpable breast lump. FNAC, although has
		appreciably higher specificity, its sensitivity is inappreciably lower and cannot be reliably used as a
		screening tool for differentiation of malignant from benign breast lesions. Besides, the test of agreement
		(kappa-test) between the two diagnostic modalities revealed a moderate agreement (in 50% cases there was
		an agreement) suggesting that one test cannot be replaced by the other. In such cases the test that has both
		higher sensitivity and higher specificity (Tru-cut biopsy) could be selected as a test of choice for screening
		of clinically palpable breast lump.
7	Bashir Ahmad Noor	Tru-cut biopsy is superior to FNAC in terms of diagnostic accuracy for the diagnosis of cancer in patients
	(2022)	with palpable breast lumps. There is no reason not to use this method, which protects patients' rights while
		reducing the financial burden of diagnosing and treating breast cancer.
8	Suhas S R (2023)	Tru-Cut should be preferred over FNAC for the diagnosis of palpable breast lumps with FNAC being
		reserved for definitely benign lesions. Freehand Tru-Cut detects more breast carcinomas as compared to
		FNAC in palpable breast lumps. and correctly categorizes borderline/ inadequate breast lumps on FNAC
		into benign & malignant categories, thus reducing indeterminate results and treatment delays. It can
0		therefore be used as an alternative to open biopsy.
9	Mahbuba Khatun	TCB is an accurate, reliable and a safe method of establishing the diagnosis of cancer in patients with
	(2023)	breast lesions. Our results yielded a high sensitivity of 95.65% with 96.88% specificity when compared with ENAC in the diagnostic of breast as a gracially when and islamy is not diagnostic. Thus, trunt
		with FNAC in the diagnosis of breast cancer especially when radiology is not diagnostic. Thus, trucut
10	Sandhil Sud-mean	biopsy should replace fine needle aspiration in the preoperative assessment of suspicious breast lumps.
10	Sendhil Sudarsan	FNAC and trucut biopsy proved complementary and vital in diagnosing breast lumps, showcasing
	Sundaram (2024)	substantial correlation with postoperative histopathological outcomes. The study underscores the
		importance of these diagnostic methods in guiding appropriate surgical interventions for accurate diagnosis and management of breast lumps.
		and management of oreast tumps.

Table 4: Merits and gaps for various studies

S No	First author (Year)	Merits	Gaps	
1	Ajitha M B (2017)	Prospective nature of study helped in real	Data collected over one year might not may	
		time collection of data	not capture long term trends	
2	Mehmet Emin Gunes (2018)	Strong statistical analysis	Retrospective design	
3	Narendranath Swain (2017)	Prospective design enhanced reliability	Limited male representation (four cases)	
			with small sample size	
4	Muzzamil Mushtaq (2018)	Robust conclusions with appropriate use of	Bias may be there due to subjective	
		statistical methods	interpretation of biopsy results	
5	Bidyut Chandra Debnath (2021)	Robust dataset	Cross-sectional study failed to establish	
			cause and effect relationship	

6	Syeda Momena Hossain (2021)	One of the few studies to compare	Small sample size
		consecutive sampling of breast lesions	
7	Bashir Ahmad Noor (2022)	Detailed diagnostic accuracy established in	Single center study
		terms of FNAC and TCB to detect cancer	
8	Suhas S R (2023)	Benefits and limitations of both the	Small sample size
		techniques were depicted in detail	
9	Mahbuba Khatun (2023)	High sensitivity and specificity of TCB were	Cross-sectional study
		reported when radiology was not diagnostic	
10	Sendhil Sudarsan Sundaram (2024)	Comprehensive triple assessment approach	Small sample size

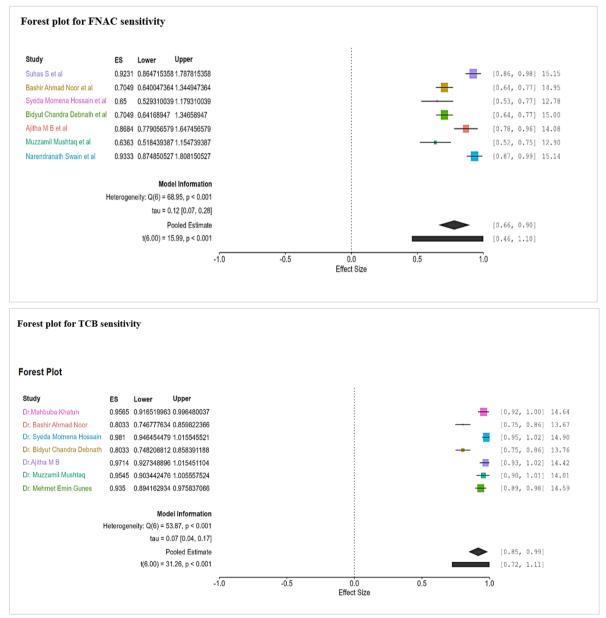


Figure 2 a: Forest plot for sensitivity FNAC vs TCB

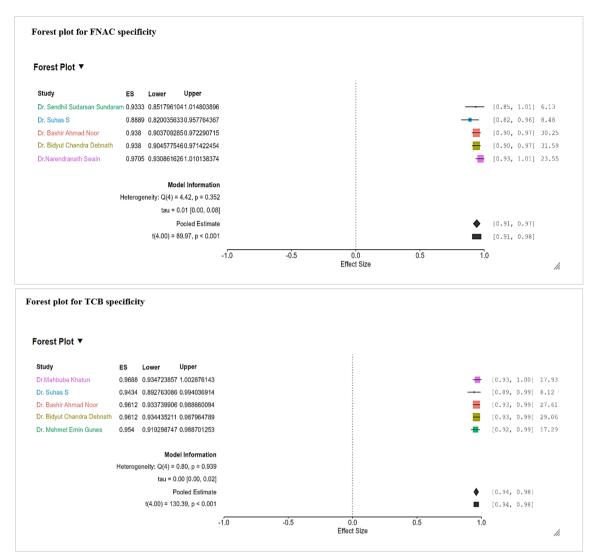
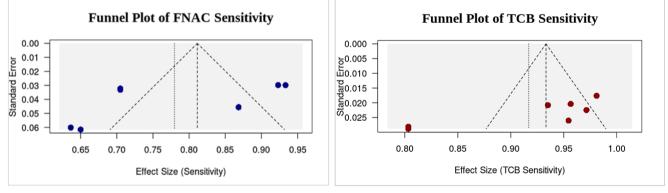
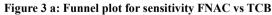


Figure 2 b: Forest plot for sensitivity FNAC vs TCB





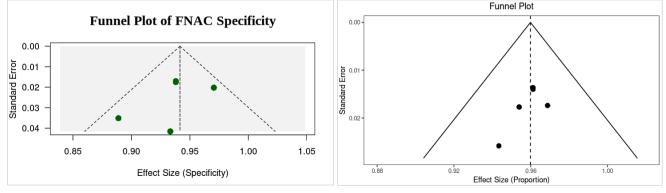


Figure 3 b: Funnel plot for specificity FNAC vs TCB

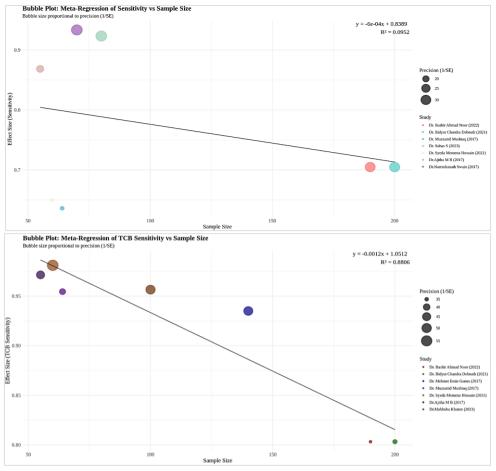


Figure 4 a: Bubble meta-regression analyses plot for sensitivity FNAC vs TCB

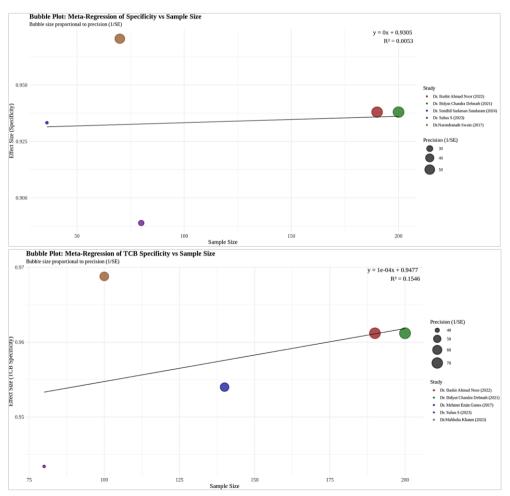


Figure 4 b: Bubble meta-regression analyses plot for specificity FNAC vs TCB

Discussion

A study identified the significant advantage of Tru-Cut biopsy (TCB) over Fine Needle Aspiration Cytology (FNAC) in providing a confirmatory histological diagnosis (Ajitha M *et al.*, 2017). The study showed TCB findings to be 100% in agreement with final histopathological reports, testifying to its reliability in accurately diagnosing breast lesions. The findings showed that TCB is superior in assessing tumor characteristics, including type, grade, and receptor status, which were significant in planning treatment. This was corroborated in another study (Memisoglu E *et al.*, 2022).

TCB in another research showed high positive predictive values and low false negativity rates, thereby emerging as a sought-after diagnostic tool in the preoperative setting (Günes ME, 2018). The research also endorsed the utility of a triad approach in testing, comprising clinical, radiological, and pathological tests, to enhance diagnostic yield, as recommended by another author in her report of the wide utility of TCB (Ajitha M *et al.*, 2017). This was further elucidated upon in another study (Iqbal S *et al.*, 2023).

Another author's results confirmed the application of TCB in situations where FNAC findings are not conclusive (Swain N *et al.*, 2017). He indicated that TCB was 100% specific, thus making it a sure bet for further examination. His research also indicated the application of intraoperative imprint cytology (IC) in the enhanced diagnostic accuracy of FNAC and TCB, thus suggesting that the two can complement each other to attain enhanced patient outcomes. Another author reported similar findings (Vinod K *et al.*, 2022).

Research done by another author discovered the sensitivity of detecting breast carcinomas by TCB to be up to 95.45% compared to just 63.63% that of FNAC (Mushtaq M *et al.*, 2018). This study indicated that TCB had a greater scope to classify correctly borderline lesions and thus further recommended TCB as a better alternative in clinical practice involving breast lump diagnosis. This was further reported in another study (Swadi FM, 2022).

Another author's research highlighted the fact that TCB not only reduces the need for intricate surgical procedures but also destresses the patient (Debnath BC *et al.*, 2021). His research indicated that TCB provides adequate tissue for the evaluation of molecular markers, which are important for therapeutic interventions. The research highlighted a striking difference in diagnostic accuracy between FNAC and TCB, which further testified the superiority of the latter. Similar findings were echoed in another study (Acar HZ, Özer N, 2021).

Yet another research showed that TCB was as diagnostic as histopathology and that FNAC was far more specific but less sensitive (Hossain SM *et al.*, 2021). The kappa-test also identified that there was moderate agreement between the two but that they were both useful and that TCB was better due to its greater sensitivity and specificity in distinguishing between malignant and benign lesions. This was further depicted in another study (Tripathi K *et al.*, 2022)

Yet another study established that TCB is more accurate than FNAC in breast cancer diagnosis with the main focus being on guarding patient rights and lowering the diagnosis and treatment cost (Noor BA *et al.*, 2022). His work supported the regular use of TCB in the clinical setting, as suggested by the previous authors of our study. This was further supported by another study (Agarwal NK *et al.*, 2023).

Another author endorsed the superiority of TCB in comparison to FNAC for the diagnosis of palpable breast lumps, highlighting that TCB is more proficient at identifying breast carcinomas and provided precise classification of borderline lesions (Suhas SR *et al.*, 2023). The results indicated that TCB had the potential to minimize indeterminate findings and prevent delays in treatment, thereby strengthening the general agreement regarding its clinical efficacy.

Yet another author's study was in concurrence with the findings of the previous studies taken in our systematic review stating that TCB was a sensitive and reliable technique of diagnosing breast cancer with a sensitivity of 95.65% and a specificity of 96.88% when compared to FNAC (Khatun M *et al.*, 2023). This again determined the position of TCB as a first-line diagnostic tool in the preoperative diagnosis of suspicious breast lumps. This was further demonstrated in another study (Butt MJ *et al.*, 2023).

Another author concluded FNAC and TCB to be complementary in breast lump diagnosis with high correlation with postoperative histopathological diagnoses (Sundaram SS *et al.*, 2024). The author's study emphasized the value of these diagnostic methods in surgical procedure, confirming the superiority of TCB over FNAC in diagnosing breast lump. However, one study reported that needle core biopsy (NCB) proved to be beneficial in comparison to FNAC before definitive treatment to differentiate between benign and malignant lesions (Siddiqui *et al.*, 2022).

The combined findings of these studies suggested that the use of Tru-Cut biopsy was superior to Fine Needle Aspiration Cytology diagnostic procedure in the diagnosis of palpable breast tumors due to its precision, reliability, and clinical relevance in the management of breast cancer.

The important findings and merits, and gaps were tabulated (Table 3 and 4).

Conclusion

As far as the diagnostic accuracy is concerned, for fine needle aspiration (FNAC) and tru-cut biopsy (TCB), TCB is superior, especially where malignancy is suspected. Also, it is a cost-effective treatment that we can rely on most of the time.

TCB surmounts these shortcomings by providing adequate tissue samples for detailed histological assessment, including tumor type, grade, and receptor status.

In the future, the development of new diagnostic tools such as liquid biopsy, which evaluates circulating tumor cells and cellfree DNA; molecular imaging modalities such as PET-CT and MRI; Optical Coherence Tomography (OCT); artificial intelligence-based image analysis tools; and genomic profiling by next-generation sequencing shows promising potential for the improvement of breast cancer diagnosis.

It is necessary to have definite protocols and diagnostic outcomes in order to draw conclusions so as to ultimately declare the final results.

Declaration

Ethical approval

Not required because the study was systematic review and meta analyses including the studies published between 2017 to 2024.

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Conflicts of interests

The authors report no conflict of interest.

Consent to publication

Not applicable

Availability of supporting data

Not applicable as the study is a systematic review and metaanalyses.

Author contributions

Conceptualization and methodology, S.K, V.M, S.H.; Formal analysis, S.K, V.M, S.H.; Visualization and writing – original draft S.K, V.M, S.H.; Writing – review and editing, S.K, V.M, S.H. and J.H. All authors have read and agreed to the final version of the manuscript.

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