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Systematic Review

Diagnostic accuracy of the TimBre acoustic device for detecting pulmonary tuberculosis: a systematic review and meta-analysis

S. Tejesh[1]*, Arijita Manna[1], Rovena Yazhini[1], Amatullah S. Qadeer[1], Zawata Afnan[2], Nirupama A. Y.[3]

[1]Indian Institute of Public Health, Hyderabad, Telangana, India
[2]HTAIn Regional Resource Centre, Indian Institute of Public Health, Hyderabad, Telangana, India
[3]PANPREP, Dr. Cyrus Poonawalla Centre for Infectious Diseases, Indian Institute of Public Health, Hyderabad, Telangana, India

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***Correspondence:**
Dr. S. Tejesh,
E-mail: tejeshreddy79898@gmail.com

ABSTRACT

Tuberculosis (TB) remains a major cause of infectious disease mortality worldwide, with India accounting for 26% of global cases. Conventional screening methods often miss asymptomatic or minimally symptomatic cases, highlighting the need for rapid, non-invasive detection tools. The TimBre acoustic system uses machine learning algorithms to analyze cough sounds for pulmonary TB (PTB) screening. A systematic review and meta-analysis were conducted following PRISMA 2020 guidelines to evaluate TimBre's diagnostic accuracy. Studies comparing TimBre with reference standards such as Xpert MTB/RIF, Xpert Ultra, TrueNat, or culture were identified from PubMed, Google Scholar, company sources, and grey literature. Pooled sensitivity and specificity were calculated using a random-effects model, and study quality was assessed with QUADAS-2. Three studies met inclusion criteria, encompassing populations from India, Vietnam, the Philippines, Uganda, and South Africa, with over 700,000 cough recordings analyzed. The pooled sensitivity was 71% (95% CI: 68-75%) and pooled specificity 76% (95% CI: 60-87%), with notable heterogeneity across studies. TimBre demonstrates moderate diagnostic performance as a rapid, low-cost, and non-invasive PTB screening tool. Its scalability and ease of deployment make it a promising triage solution for early TB detection, particularly in resource-limited settings. Larger multi-center validations and cost-effectiveness studies are warranted to guide programmatic integration.

Keywords: Tuberculosis, TimBre, Diagnostic accuracy, Cough acoustics, Artificial intelligence

INTRODUCTION

Tuberculosis (TB) remains one of the leading causes of morbidity and mortality from infectious diseases globally. India accounted for 26% of the global TB burden in 2023, with a mortality rate of 22 deaths per lakh population.[1] Despite this, approximately 2.5 lakh TB cases were missed in 2023.[1] India reported screening 94% (3.16 million) of household contacts, surpassing the global average of 84%[2]. However, conventional symptom-based screening approaches may fail to detect a considerable proportion of asymptomatic or minimally symptomatic cases, underscoring the need for improved and more sensitive detection strategies.[2] Early and accurate diagnosis of pulmonary tuberculosis (PTB) is essential for timely treatment initiation and reducing transmission.

The World Health Organization (WHO) recommends systematic screening of populations in regions with TB prevalence above 0.5% and targeted screening of high-risk groups through active case finding (ACF).[3] Cost-effective approaches often combine symptom assessment and chest X-ray (CXR), followed by confirmatory molecular diagnostic tests. Yet, conventional methods may miss

cases in community settings, emphasizing the importance of exploring novel and scalable detection strategies.[4]

Cough, a common symptom of PTB, has recently emerged as a promising non-invasive biomarker for screening, particularly with the advent of machine learning (ML) and artificial intelligence (AI).[5] Acoustic analysis of cough sounds captured via mobile phones or specialized microphone arrays has shown potential for identifying PTB and differentiating it from other respiratory conditions such as pneumonia, COPD, and COVID-19.[6]

The TimBre system, developed by Docturnal Private Limited, leverages ML algorithms to integrate cough acoustic data with clinical and demographic features for PTB screening.[7] Several primary studies have assessed its diagnostic performance across diverse populations and settings, reporting varying sensitivity and specificity. However, no comprehensive synthesis of these findings currently exists.[8-10]

This systematic review and meta-analysis aim to synthesize the available evidence on the diagnostic effectiveness of the TimBre system for PTB detection.

Specifically, it seeks to estimate pooled sensitivity and specificity and to evaluate the utility of acoustic-based TB screening tools to inform future research, validation, and programmatic implementation strategies.

METHODS

This systematic review and meta-analysis were conducted in accordance with the PRISMA 2020 guidelines. This review was prospectively registered with PROSPERO (Registration ID: CRD420251186413).

Inclusion criteria

Population (P)

Individuals being evaluated for pulmonary tuberculosis (PTB).

Intervention (I)

TimBre acoustic device (AI/ML-based cough sound analysis) used for TB detection.

Comparator (C)

Recognized reference standards such as Xpert MTB/RIF, Xpert Ultra, culture, or TrueNat.

Outcome (O)

Diagnostic accuracy measures such as sensitivity, specificity, true positive rate, true negative rate.

Study designs

Diagnostic accuracy studies, cross-sectional studies, and clinical validation studies.

Exclusion criteria

Studies without sufficient data to reconstruct a 2×2 contingency table were excluded.

Information sources and search strategy

A systematic search was conducted in PubMed, Google Scholar, company websites, and grey literature. Search terms combined keywords and MeSH terms related to "acoustic," "cough sound," "AI-based diagnosis," and "pulmonary tuberculosis."

Study selection and data extraction

Two reviewers independently screened titles and abstracts, followed by full-text review. Disagreements were resolved through discussion or consultation with a third reviewer. Data were extracted on study characteristics, sample size, participant demographics, device/algorithm type, reference standard, and diagnostic accuracy measures.

For studies that did not report true positives (TP), false negatives (FN), true negatives (TN), or false positives (FP), these values were reconstructed using reported sensitivity, specificity, and prevalence.

Risk of bias assessment

The methodological quality of included studies was assessed using QUADAS-2, covering four domains: patient selection, index test, reference standard, and flow and timing. Disagreements were resolved by consensus.

Data synthesis and statistical analysis

Given the limited number of studies and small sample sizes, a univariate random-effects model was used to pool sensitivity and specificity separately. Pooled estimates with 95% confidence intervals were calculated using the DerSimonian-Laird method. Heterogeneity was assessed using I^2 statistics, and forest plots were generated for both sensitivity and specificity. Analyses were performed in RStudio Desktop 2025.09.1+401 using the mada package.

RESULTS

Study selection

A systematic search across multiple sources identified 103 records: Google Scholar (n=94), grey literature (n=1), company websites (n=6), and free search (n=2). After removing 3 duplicates, 100 records were screened by title and abstract, excluding 93 and leaving 7 for full-text assessment. Of these, 5 were excluded (1 for different

outcome, 4 for wrong study design), resulting in 3 studies included in the final systematic review and meta-analysis. The PRISMA flow diagram illustrates the process of study selection (Figure 1).

Study characteristics

The included studies assessed the diagnostic performance of the TimBre acoustic device for pulmonary tuberculosis across diverse settings and sample sizes (Table 1). Early studies (2022) were small, with 126-474 participants, sensitivities of 59-80%, and specificities of 60-92%. Later multi-country pilot and Phase II studies (2023-2025) included over 700,000 cough recordings, reporting sensitivities of 68.8-91.7% and specificities of 69.5-71.3%. Prevalence varied from 1.05% to 45%, reflecting differences in study populations and settings.

Risk of bias

As shown in Table 2, the TimBre studies demonstrated some concerns regarding risk of bias, particularly in participant selection, internal validation of the index test, and limited reporting on flow and timing. The reference standard was appropriate, and while these studies provide encouraging preliminary evidence, further externally validated research is needed to enhance confidence in the findings.

Outcomes

Sensitivity

Figure 2 illustrates the diagnostic sensitivity across the four studies. Early, smaller studies display wide confidence intervals, with the 2022-NH/MSMF study reporting 0.80 [0.28-0.99], whereas the two Phase 2 studies, with substantially larger sample sizes, provide more precise estimates of 0.69 and 0.74. The overall pooled sensitivity, estimated using a random-effects model, is 0.71 (95% CI: 0.68-0.75). Considerable heterogeneity (I^2=99.7%) reflects differences in study size and event counts across the included studies.

Specificity

Figure 3 shows the diagnostic specificity across the four studies. The smaller early studies exhibit wide confidence intervals, reflecting greater uncertainty, while the two large Phase 2 studies provide precise estimates of 0.70 and 0.69. The pooled specificity from the random-effects model is 0.76 (95% CI: 0.60-0.87). Substantial heterogeneity (I^2=98.5%) highlights considerable differences in specificity among the studies, indicating that performance may vary depending on study size and setting.

Table 1: Characteristics of included studies.

S. no.	Authors (year)	Country/sites	Sample size	Index test	Reference standard	Sensitivity (%)	Specificity (%)	Prevalence (%)
1	Pathri et al (2022)	NH/MSMF	474	TimBre	Smear, Xpert, CXR	80	92	1.05
		Gadwal	126	TimBre	CXR	59	60	1.05
2	Pathri et al (2023)	India	1,191	TimBre	GeneXpert	75.4	68.3	NR
3	Pathri et al (2025)	India, Vietnam, Philippines, Uganda, South Africa	724,694 cough recordings	TimBre	MRS	68.8	70.4	25
		India, Vietnam, Philippines, Uganda, South Africa	724,694 cough recordings	TimBre	Xpert Ultra	73.8	69.5	22
		India	724,694 cough recordings	TimBre	MRS	91.7	71.3	9

Table 2: Quality assessment of included studies using QUADAS 2.

Domain	Pathri et al (2022)	Pathri et al (2023)	Pathri et al (2025)
Patient selection	Unclear	High	High
Index test	Unclear	High	High
Reference standard	Low	Low	Unclear
Flow and timing	Unclear	High	High
Overall risk of bias	Unclear	High	High

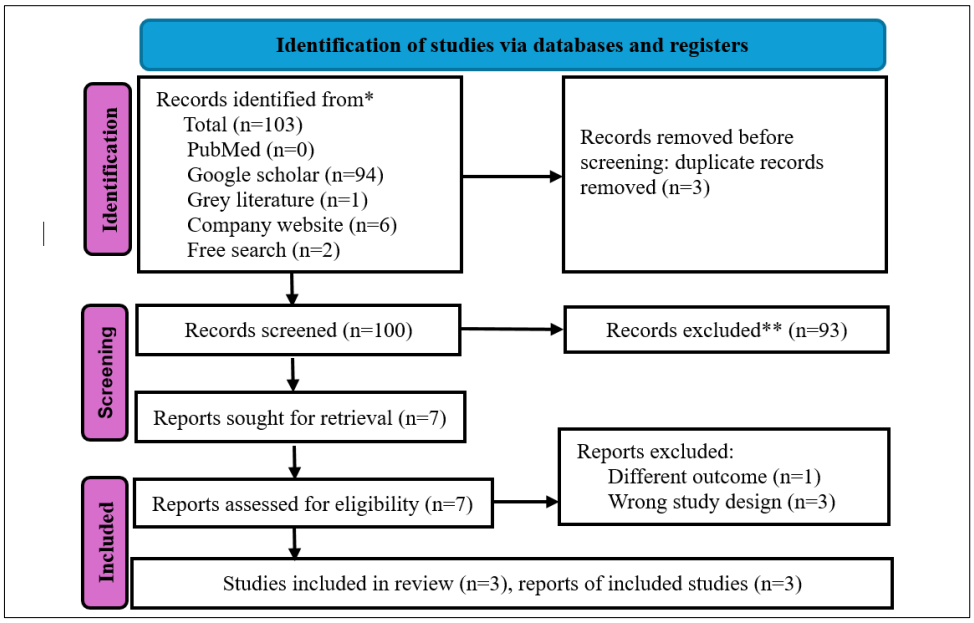

Figure 1: PRISMA flow diagram of study selection process.

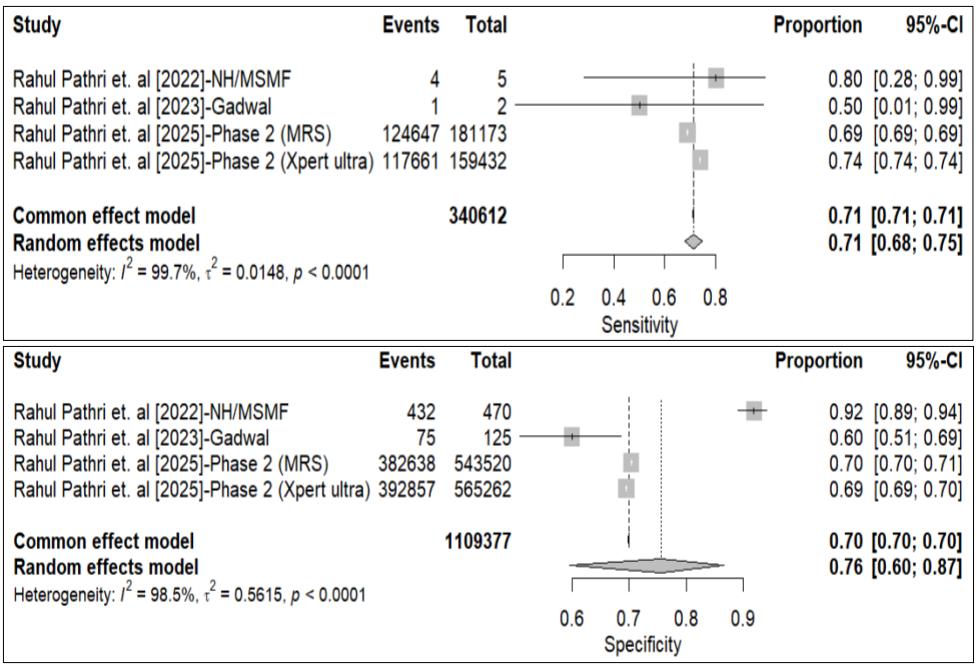

Figure 2: Forest plot of diagnostic sensitivity.

DISCUSSION

This systematic review and meta-analysis evaluated the diagnostic performance of the TimBre acoustic device for PTB across multiple settings and populations. Three studies were included, collectively covering multiple sites and diverse populations.[8-10] The 2022 study provided data from NH/MSMF and Gadwal, while the 2023-2025 Phase II studies included over 700,000 cough recordings across India, Vietnam, Philippines, Uganda, and South Africa. Pooled sensitivity was 71% (95% CI: 68-75%) and pooled specificity 76% (95% CI: 60-87%). Smaller, early datasets displayed wide confidence intervals, whereas the large multi-country datasets provided precise estimates. High heterogeneity for both sensitivity (I^2=99.7%) and specificity (I^2=98.5%) reflects differences in population characteristics, prevalence, reference standards, and recording methodologies.

Compared with molecular diagnostics such as Truenat and Xpert MTB/RIF, TimBre showed moderately lower accuracy but important operational benefits. While molecular assays achieve 86–94% sensitivity and 77-92% specificity, they require sputum samples, laboratory setup,

and trained personnel.[11] TimBre's pooled 71% sensitivity and 76% specificity reflect its non-invasive, acoustic-based approach that is simpler, faster, and more scalable for community-level use. Similarly, chest X-ray (CXR) screening reported by Giridharan et al had 86.4% sensitivity but poor 42.1% specificity, resulting in many false positives.[12] TimBre provides a more balanced accuracy without radiation exposure or imaging infrastructure needs.

Symptom-based screening, particularly prolonged cough, performs even worse, with 41.6% sensitivity and 72.8% specificity, missing nearly 60% of cases.[12] TimBre's AI-driven cough analysis improves detection, especially among asymptomatic or pauci-symptomatic individuals. Compared with blood-based biomarkers, which showed 64-79% sensitivity and 68-85% specificity, TimBre offers similar performance without laboratory processing.[13] Likewise, AI-based radiologic tools such as CAD4TB v7 achieved 90% sensitivity and 70% specificity but depend on X-ray imaging. Overall, TimBre performs comparably to other emerging triage tools while being non-invasive, low-cost, and operationally practical for large-scale TB screening.[14]

Despite this, TimBre offers key advantages as a rapid, low-cost, and non-invasive screening tool suitable for large-scale and resource-limited settings. It can function as a triage tool to identify individuals requiring confirmatory molecular testing, thereby optimizing TB case detection and reducing delays. These findings highlight the potential utility of TimBre across diverse populations and settings, but they also emphasize the need for further research. Future studies should include independent multi-center evaluations to confirm diagnostic performance across heterogeneous populations. Additionally, economic evaluations are warranted to assess cost-effectiveness, feasibility, and the potential impact on TB screening programs at scale.

Limitations

Limitations include the small number of included studies, high heterogeneity, differences in study design, reference standards, and prevalence across sites. Some sensitivity and specificity values were reconstructed from reported measures, which may introduce minor inaccuracies.

CONCLUSION

TimBre demonstrates moderate diagnostic performance for pulmonary tuberculosis, with pooled sensitivity and specificity of 71% and 76%, respectively. While molecular diagnostics such as Truenat provide higher accuracy, TimBre offers a non-invasive, rapid, and scalable screening solution that can be applied across diverse populations and settings. Further large-scale, independent, multi-center studies are required to validate its diagnostic performance and evaluate real-world feasibility. Incorporating TimBre as a triage tool in combination with confirmatory molecular testing has the potential to improve early TB detection, optimize resource utilization, and strengthen TB control efforts.

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