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Evaluation of Loop-Mediated Isothermal Amplification Test Kit (TB-LAMP) for the Diagnosis of Pulmonary Tuberculosis in a Tertiary Hospital in Iloilo City: A Retrospective Study

Dr. Rollin Palermo Tabuena[1], Dr. Jiggy Leonard Flores Landong[2], Dr. Earl Joshua Gabasa Alcantara[3], Dr. Ma. Daisy Pedroso Tabuena[4], Dr. Ma. Theresa Crisanta Lim Anayan[5]

[1,2,3,4,5]Physician, Internal Medicine, Iloilo Mission Hospital

ABSTRACT

BACKGROUND. One of the leading infectious diseases in the world, tuberculosis (TB) has serious public health ramifications, particularly in low- and middle-income nations. The global End TB Strategy highlights the importance of early detection and successful treatment, emphasizing that the key of lowering transmission and enhancing patient outcomes is universal access to a precise diagnostic tool. Molecular tools such as GeneXpert MTB/RIF offer improved accuracy but are costly. The Loop-Mediated Isothermal Amplification (TB-LAMP) assay offers a promising alternative, balancing affordability, sensitivity, and ease of use.

OBJECTIVE. The purpose of this study was to assess the diagnostic efficacy of the TB-LAMP Test Kit in identifying pulmonary tuberculosis in patients who were admitted to Mission Hospital, located in Iloilo City, Philippines.

METHOD. A retrospective, cross-sectional analysis of adult patients with a clinical diagnosis of pulmonary tuberculosis who were admitted to Iloilo Mission Hospital was carried out. Patients had to have completed all three diagnostic tests (DSSM, GeneXpert, and TB-LAMP). Diagnostic yields were examined for agreement using Cramer's V, chi-square tests, and cross-tabulations.

RESULTS. A study found a moderate association between DSSM and LAMP in 106 patients, with 80% generating positive results. The concordance between TB-LAMP and GeneXpert was 59.4% ($\chi^2(4) = 45.399$, $p < .001$, Cramer's $V = 0.463$), suggesting a slight but significant correlation.

CONCLUSION. The results indicate that the TB-LAMP assay, which shows comparable diagnostic accuracy to GeneXpert and superior sensitivity to DSSM, is a promising diagnostic alternative for the detection of pulmonary tuberculosis. TB-LAMP is a useful supplement to diagnostic algorithms due to its ability to detect a significant percentage of GeneXpert cases and its simplicity of use, especially in settings with limited resources where access to molecular diagnostics is still restricted. Incorporating TB-LAMP into diagnostic procedures could firmly establish its role in national TB prevention, more studies evaluating clinical outcomes and cost-effectiveness are necessary.

Keywords: TB-LAMP, Tuberculosis, Loop-mediated Isothermal amplification, DSSM, GeneXpert

INTRODUCTION

The second-leading cause of death globally, after COVID-19, is tuberculosis (TB), which continues to pose a serious threat to global health. Nearly 10 million people are afflicted with TB annually, according to the World Health Organization's (WHO) 2023 Global Tuberculosis Report, highlighting the need for more aggressive global response tactics. By 2030, the WHO wants all UN members to work together to eradicate the tuberculosis epidemic. Underfunding in diagnostics, treatments, and vaccine research has hindered progress despite these efforts; in 2021, global funding for TB initiatives was only USD $1.0 billion. [13]

By shifting from conventional diagnostic methods to more sensitive and specific techniques, rapid molecular diagnostics, which has been available since 2011, has significantly improved TB detection and management. [13] The confirmation of TB infection and drug resistance has been made possible by phenotypic susceptibility testing, genome sequencing, and nucleic acid-based molecular assays. However, in high-burden, low-resource regions, adoption of these tools is significantly hampered by their high cost and technological complexity.[7]

The most widely used technique for pulmonary tuberculosis diagnosis at the moment is acid-fast bacillus (AFB) smear microscopy. Despite being inexpensive, it has low sensitivity and is heavily operator-dependent. Although polymerase chain reaction (PCR) and other nucleic acid amplification tests (NAATs) are being used more and more to diagnose lymph node tuberculosis (LNTB), their widespread use in peripheral settings is limited by the need for specialized laboratory infrastructure and trained personnel.[3]

The field of TB diagnostics has seen tremendous growth in recent years. These include computer-aided detection systems that use digital chest radiography, aerosol-capture technologies, biomarker-based diagnostic platforms, sophisticated molecular tests for TB disease detection, and interferon-gamma release assays (IGRAs) for latent TB infection.[13] Because of its simplicity, effectiveness, and specificity, the loop-mediated isothermal amplification (LAMP) assay has become well-known among them. With pooled sensitivity and specificity ranging from 74.1% to 78.0%, TB-LAMP has been approved by the WHO for use in diagnosing adult pulmonary tuberculosis, especially in smear-negative individuals.[5]

To improve the accessibility of molecular diagnostics, Eiken Chemical Co., Ltd. has created a commercially available TB-LAMP kit. The assay uses strand displacement DNA synthesis in an isothermal environment to target the *gyrB* and *insertion sequence (IS)* regions of the *Mycobacterium tuberculosis (MTB)* genome. Thermal cyclers are not necessary because results can be visually interpreted through fluorescence or turbidity in 15 to 60 minutes.[12]

The WHO formally approved TB-LAMP in 2016 as a follow-up test for adults with smear-negative pulmonary tuberculosis and as a substitute for smear microscopy.[10] The reference standard is still culture-based testing, but its drawbacks, such as its variable sensitivity and lengthy turnaround time (14–24 days), have prompted a move toward NAATs as the recommended first diagnostic method for respiratory specimens.[15] Nonetheless, there are still issues with assessing the precision of extrapulmonary TB (EPTB) diagnostics, and some research suggests that culture is a less-than-ideal reference standard. To increase classification accuracy in EPTB research, Kohli et al. (2018) recommended using a composite reference standard (CRS), which combines findings from several diagnostics.[9, 1]

The use of specially created primers, quick amplification at a consistent temperature, and shorter testing times make LAMP technology unique. Because of these characteristics, it is particularly useful for TB

detection in low-resource environments where traditional PCR might not be practical.[8, 2] Furthermore, it is appropriate for widespread use in national TB programs due to its reproducibility, cost-effectiveness, and simplicity.

Research has shown that TB-LAMP's diagnostic accuracy varies. While pooled analyses suggest sensitivity rates ranging from 95.2% to 96.6%, individual studies show sensitivity levels ranging from 66% to 82%. When compared to WHO Standards 1 and 3, specificity has varied between 90% and 99%.[14] TB-LAMP has demonstrated consistent specificity in the majority of studies and sensitivity ranging from 19% to 81%, depending on the diagnostic standard used, when used as an adjunct test after smear microscopy.

To treat TB cases, doctors around the world still use a mix of clinical judgment and diagnostic instruments. 7.5 million new cases of tuberculosis were reported in 2022, with high-income nations having the highest bacteriological confirmation rates. But an excessive dependence on smear microscopy is still problematic and can lead to overdiagnosis, especially in low-income environments. Systemic limitations in diagnostic coverage are evident in the Philippines, where bacteriological confirmation rates continue to fall below 50%.[13]

Significantly, 71% of the global discrepancy between estimated TB incidence and diagnosed cases is caused by 11 countries, including the Philippines. More than half of this disparity is accounted for by five nations alone: Nigeria, Pakistan, Indonesia, the Philippines, and India.[13] This highlights the need for more accurate and easily accessible diagnostic technologies.

This study aims to assess the efficacy and dependability of the TB-LAMP assay for pulmonary TB diagnosis in a tertiary hospital setting in light of these ongoing diagnostic and implementation issues. Particularly in resource-constrained environments like the Philippines, this study seeks to supplement the expanding global data on TB diagnostics and offer local insights that could guide future implementation strategies.

OBJECTIVE OF THE STUDY

This study's main goal was to assess how well the Loop-Mediated Isothermal Amplification Test Kit (TB-LAMP) would diagnose pulmonary tuberculosis (PTB) in patients who were admitted to a tertiary care facility in Iloilo City, Philippines. Given the need for easily available, reasonably priced, and precise diagnostic instruments in areas with a high TB burden, the study sought to produce empirical data regarding TB-LAMP's effectiveness in actual clinical settings.

Specifically, the study sought to:

- Assess the TB-LAMP assay's diagnostic sensitivity and specificity by contrasting it with the GeneXpert MTB/RIF assay, which was used as the molecular reference standard. This required evaluating how well TB-LAMP detected true positive and true negative cases in patients with suspected PTB.
- To put the diagnostic yield and disease burden in the context of tertiary hospitals, quantify the percentage of hospitalized patients who received a clinical diagnosis of pulmonary tuberculosis during the study period.
- Describe the clinicodemographic characteristics of patients with pulmonary tuberculosis, taking into account factors like age, sex, history of smoking, and comorbidities (e.g., HIV status, diabetes mellitus, hypertension, COPD, and asthma). The purpose of this analysis was to help guide local clinical decision-making by identifying potential clinical or demographic predictors of diagnostic outcomes.

- Test whether patient characteristics affected test concordance or diagnostic accuracy by examining the relationship between diagnostic test results (TB-LAMP, DSSM, and GeneXpert) and clinical or demographic factors using the proper statistical measures.

With these goals, the study sought to support evidence-based suggestions for TB-LAMP integration into TB diagnostic algorithms, especially in healthcare settings with limited resources.

METHODOLOGY

STUDY DESIGN AND SETTING. A retrospective, cross-sectional analytical design was used in this study to evaluate the clinicodemographic traits and diagnostic results of patients with pulmonary tuberculosis (PTB) who were admitted to Iloilo Mission Hospital. The study design was chosen to investigate statistical relationships between patient profiles and test results over a specified time period and to allow for the assessment of diagnostic test performance across a well-defined hospital population.

SAMPLE SIZE AND SAMPLING DESIGN. All hospitalized adults with a diagnosis of pulmonary tuberculosis who were 19 years of age or older and diagnosed between 2019 to year 2021, were purposefully included in the study. Patients had to have a complete medical record that included their demographics, clinical presentation, results of diagnostic tests (such as DSSM, TB-LAMP, and/or GeneXpert, if applicable), treatment plans, and final clinical outcomes in order to meet the inclusion criteria. Patients who did not have enough documentation to support a confirmed diagnosis of PTB or whose records were incomplete were not included in the analysis.

In order to preserve the reliability and integrity of the data, only clinically verified cases were included using this non-probability sampling technique. 106 patients who fulfilled all eligibility requirements and for whom at least one TB diagnostic technique was documented made up the final sample size.

STUDY PROCEDURES. The researchers gathered data by methodically reviewing laboratory and medical records after receiving official approval from the institution's ethics review board. Key variables covered by data abstraction included age, sex, smoking history, comorbidities (diabetes mellitus, hypertension, chronic obstructive pulmonary disease, and asthma), the main complaints at admission, the results of diagnostic tests (DSSM, TB-LAMP, GeneXpert), the type and duration of anti-TB therapy, the course of the ward, and the final clinical outcome (e.g., discharged improved, transferred, deceased).

To ensure consistent data collection and reduce transcription errors, the researchers used a standardized data extraction sheet. At least two impartial reviewers with training in medical data handling and ethical confidentiality procedures cross-checked the abstraction to guarantee data reliability.

STATISTICAL ANALYSIS. The sociodemographic and clinical characteristics of the patient population were described using descriptive statistics, such as frequencies, means, and percentages. Cross-tabulation matrices were used to assess test concordance, and the diagnostic yield of TB-LAMP was contrasted with that of traditional and molecular tools (DSSM and GeneXpert).

Chi-square (χ^2) tests for independence were used to assess the degree and significance of correlations between TB-LAMP results and clinical or demographic factors. To determine the effect size and interpret the strength of the association, Cramer's V coefficient was computed. For all inferential analyses, a significance threshold of $p < 0.05$ was applied. A validated software program that was authorized by the institutional research team was used for all statistical analysis.

ETHICAL CONSIDERATIONS. The Iloilo Mission Hospital Technical Review Board and the West Visayas State University Unified Research Ethics Review Committee (WVSU-URERC) examined and

approved this study. Prior to data collection, the Health Information and Records Section and the hospital administrator formally granted institutional permissions.

Every patient record that was gathered was handled carefully and in compliance with the Data Privacy Act of 2012 (Republic Act No. 10173), which strictly adheres to the ethical principles of confidentiality, anonymity, and responsible data stewardship. Prior to analysis, patient identifiers were anonymized, and after statistical processing and manuscript submission were finished, all data used in this study were permanently erased.

RESULTS

Table 1. Diagnostic Tools

Tool	Result	*N*	%
DSSM *n=105*	Positive	85	80.2%
	Negative	20	18.9%
	Not Requested	1	.9%
GX *n=41*	Positive	23	21.7%
	Negative	18	17.0%
	Not Requested	65	61.3
LAMP *n=75*	Positive	63	59.4%
	Negative	12	11.3%
	Not Requested	31	29.2%

- **DSSM (Direct Sputum Smear Microscopy):**
  - Test requested for almost all patients (99.1%)
  - Positive in 85 out of 106 (80.2%)
  - Only 1 case (0.9%) was not tested

  This shows DSSM remains the most utilized frontline diagnostic tool.
- **GeneXpert (GX):**
  - Performed on only 41 patients (38.7%)
  - Detected MTB in 23 cases (21.7%), while 18 cases (17.0%) tested negative

  A large portion (61.3%) of cases were not tested with GX, likely due to accessibility, cost, or clinical discretion.
- **TB-LAMP:**
  - Conducted on 75 patients (70.8%)
  - Positive in 63 patients (59.4%), negative in 12 (11.3%)

  TB-LAMP had high positivity and broader usage than GX, reflecting growing trust in its diagnostic value.

Table 2. LAMP * DSSM Sensitivity and Specificity

			DSSM			
			Positive	Negative	Not Requested	Total
LAMP	Positive	Count	63	0	0	63
		% within LAMP	100.0%	0.0%	0.0%	100.0%

		% within DSSM	74.1%	0.0%	0.0%	59.4%
		% of Total	59.4%	0.0%	0.0%	59.4%
	Negative	Count	0	12	0	12
		% within LAMP	0.0%	100.0%	0.0%	100.0%
		% within DSSM	0.0%	60.0%	0.0%	11.3%
		% of Total	0.0%	11.3%	0.0%	11.3%
	Not Requested	Count	22	8	1	31
		% within LAMP	71.0%	25.8%	3.2%	100.0%
		% within DSSM	25.9%	40.0%	100.0%	29.2%
		% of Total	20.8%	7.5%	0.9%	29.2%
Total		Count	85	20	1	106
		% within LAMP	80.2%	18.9%	0.9%	100.0%
		% within DSSM	100.0%	100.0%	100.0%	100.0%
		% of Total	80.2%	18.9%	0.9%	100.0%

TB-LAMP vs. DSSM

- TB-LAMP showed **100% sensitivity and specificity** relative to DSSM in the 75 patients tested with both tools.
- *Interpretation: Every patient who tested positive or negative on TB-LAMP had a matching DSSM result.*
- Chi-square analysis: **$\chi^2(4) = 69.996$, $p < .001$, Cramer's V = 0.575** → *Moderate association This supports strong internal validity and diagnostic alignment.*

Table 3. LAMP * GX Sensitivity and Specificity

			GX			
			Positive	Negative	Not Requested	Total
LAMP	Positive	Count	18	0	45	63
		% within LAMP	28.6%	0.0%	71.4%	100.0%
		% within GX	78.3%	0.0%	69.2%	59.4%
		% of Total	17.0%	0.0%	42.5%	59.4%
	Negative	Count	0	9	3	12
		% within LAMP	0.0%	75.0%	25.0%	100.0%
		% within GX	0.0%	50.0%	4.6%	11.3%
		% of Total	0.0%	8.5%	2.8%	11.3%
	Not Requested	Count	5	9	17	31
		% within LAMP	16.1%	29.0%	54.8%	100.0%
		% within GX	21.7%	50.0%	26.2%	29.2%
		% of Total	4.7%	8.5%	16.0%	29.2%
Total		Count	23	18	65	106
		% within LAMP	21.7%	17.0%	61.3%	100.0%
		% within GX	100.0%	100.0%	100.0%	100.0%

	% of Total	21.7%	17.0%	61.3%	100.0%

TB-LAMP vs. GeneXpert

- Among TB-LAMP-positive patients, **18 were GX-positive**, and **none tested GX-negative**
- Chi-square analysis: **$\chi^2(4) = 45.399$, $p < .001$, Cramer's V = 0.463** → *Modest association*
  No discordant positive-negative pairs were observed, emphasizing TB-LAMP's reliability.

Table 4. Association of Demographic Profile and LAMP, DSSM & GX

Demographics	LAMP *n*=76			DSSM Result, *n*=106			GX Result, *n*=41		
	X^2	Sig.	Cramer's V	X^2	Sig.	Cramer's V	X^2	Sig.	Cramer's V
Age	13.234	.352	.250	10.117	.606	.218	19.871	.070	.306
Sex	2.372	.305	.150	1.357	.507	.113	2.203	.332	.144
Comorbidity									
Smoking	.524	.769	.070	1.113	.573	.102	3.728	.155	.188
Diabetes	.648	.723	.078	1.158	.673	.086	1.699	.428	.127
Hypertension	2.062	.357	.139	1.479	.477	.118	1.103	.576	.102
COPD	1.058	.589	.100	.112	.946	.032	.077	.962	.027
Pneumonia	.258	.879	.049	1.057	.589	.100	.372	.830	.059
Asthma	3.036	.219	.169	1.617	.446	.123	4.119	.128	.197
HIV	.689	.709	.081	.249	.883	.049	3.643	.162	.185
# of comorbidities	17.497	.064	.287	11.993	.285	.238	4.939	.895	.153

Table 4 no significant association was found for **age, sex, smoking, comorbidities (e.g., diabetes, hypertension, asthma, pneumonia, HIV)** with LAMP, DSSM, or GX results

All Cramer's V values were **weak (< 0.3)**, and p-values were consistently above **.05**, indicating **no demographic subgroup was more likely to test positive or negative across tools**. This suggests TB diagnostic patterns were not influenced by demographic factors in this cohort.

Gray et al.'s 2016 study in China found the TB-LAMP assay to have 92.1% sensitivity for smear-positive, culture-positive sputum specimens, 53.8% sensitivity for culture-negative specimens, and 98.3% specificity for culture-negative samples.[13]

KEY CLINICAL AND PRACTICAL INSIGHTS

- The accuracy of TB-LAMP is on par with or better than that of conventional diagnostics, with especially strong agreement to DSSM and GX results.
- TB-LAMP is positioned as a strategic bridge between high-cost GX and low-cost DSSM due to its operational simplicity, high specificity, and quicker turnaround times.
- Without sacrificing result reliability, TB-LAMP may fill diagnostic gaps in situations where GX capacity is constrained.

DISCUSSION

PATIENT DEMOGRAPHICS. A total of 106 patients with a diagnosis of pulmonary tuberculosis were included in the study. Of them, 60% (n = 64) were 60 years of age or older, and 40% (n = 42) were under

60. The gender distribution was fairly balanced, despite a slight male preponderance. Comorbid conditions such as diabetes mellitus, hypertension, or chronic obstructive pulmonary disease (COPD) were documented in just 3.8% (n = 4) of the patients. Most patients reported neither a history of smoking nor a history of coexisting respiratory conditions (like pneumonia or asthma).

DIAGNOSTIC TEST RESULTS. 80.2% (n = 85) of patients had positive results from their initial Direct Sputum Smear Microscopy (DSSM) tests. GeneXpert MTB/RIF testing identified Mycobacterium tuberculosis in 21.7% (n = 23) of the cases. Furthermore, TB-LAMP results were positive in 59.4% of patients (n = 63).

When compared to DSSM, TB-LAMP demonstrated 100% sensitivity and 100% specificity, indicating perfect concordance between the two tests. This implies that all negative results matched and that all patients who tested positive for TB-LAMP also tested positive for DSSM. Cross-tabulation analysis confirmed a significant association between DSSM and TB-LAMP, $\chi^2(4) = 69.996$, $p < .001$, with a moderate correlation (Cramer's V = 0.575).

Additionally, the TB-LAMP and GeneXpert comparison yielded 100% sensitivity and specificity, demonstrating perfect agreement between the two tests' positive and negative results. With a Cramer's V of 0.463, a p-value of less than.001, and $\chi^2(4) = 45.399$, the GeneXpert and TB-LAMP results were shown to be significantly correlated.

Table 5. Association Result of the Diagnostics Tools

Demographics	X^2	*df*	Asymptotic Significance Sig. (2-sided)	Cramer's V	Approximate. Sig.
LAMP & DSSM	69.996	4	.000	.575	.000
LAMP & GX	45.399	4	.000	.463	.000

CLINICAL OUTCOMES AND DIAGNOSTIC UTILITY. There was no appreciable difference in test results (positive or negative) when demographic factors like age or sex were taken into account. This suggests that all three methods performed consistently in terms of diagnosis across patient subgroups.

The high accuracy of TB-LAMP, particularly its complete concordance with DSSM and GeneXpert, highlights its diagnostic reliability. LAMP technology amplifies DNA with high efficiency and specificity by focusing on eight different regions of the Mycobacterium tuberculosis genome. Although TB-LAMP is more expensive per unit than conventional smear microscopy, its rapid turnaround, ease of use, and operational simplicity make it a more cost-effective alternative to culture-based testing in settings with limited resources.

The combined diagnostic performance of TB-LAMP in this study is in line with global estimates (sensitivity: 74.1%–78.0%; specificity: 98.2%–98.9%) cited in WHO evaluations. These findings support its value in improving TB diagnostic capacities in high-burden, underfunded health systems.

Summary of Associations

- TB-LAMP vs. DSSM: $\chi^2(4) = 69.996$, $p < .001$; Cramer's V = 0.575 (moderate association)
- TB-LAMP vs. GeneXpert: $\chi^2(4) = 45.399$, $p < .001$; Cramer's V = 0.463 (modest association)

LIMITATIONS

During the peak of the COVID-19 pandemic, which created significant obstacles for data retrieval and record accessibility, the current study was carried out. Consequently, full clinical and diagnostic records

were not readily available. The study's capacity to identify possible correlations between TB-LAMP results and different comorbid conditions may have been limited by the lack of a more comprehensive sampling framework, even though a purposive sampling technique was used to include all eligible patients with available data. Furthermore, although the statistical tests used were suitable for the data structure, it's possible that they lacked the capacity to confirm more complex relationships that might have been discovered through randomized sampling. Notwithstanding these drawbacks, the study's results are in line with those found in other countries, enhancing TB-LAMP's legitimacy as a reliable diagnostic method for pulmonary tuberculosis in the community healthcare setting.

CONCLUSION

This study compared the diagnostic performance of the Loop-Mediated Isothermal Amplification (TB-LAMP) assay to Direct Sputum Smear Microscopy (DSSM) and the GeneXpert MTB/RIF assay for the detection of pulmonary tuberculosis in patients who were admitted to a tertiary hospital in Iloilo City. A high degree of diagnostic concordance between TB-LAMP and DSSM was found by the analysis; in the subset of patients tested using both techniques, TB-LAMP showed 100% sensitivity and specificity in comparison to smear microscopy. The assay's diagnostic reliability was further confirmed by a parallel analysis that revealed that TB-LAMP results were completely consistent with GeneXpert results—patients who tested positive or negative on TB-LAMP showed identical results on GeneXpert.

Importantly, the study did not discover any statistically significant correlations between TB-LAMP outcomes and important demographic factors like age, sex, or the existence of common comorbidities (e.g., diabetes, hypertension, chronic obstructive pulmonary disease). This research implies that TB-LAMP retains a constant level of diagnostic precision in a variety of patient subgroups, which increases its suitability for use in a range of clinical contexts. These findings are strong not only because of TB-LAMP's technical capabilities but also because of its potential to be a reliable substitute for more well-known but resource-intensive techniques like GeneXpert, especially in low-resource settings with restricted access to molecular diagnostics.

When combined, these findings add to the expanding corpus of global data demonstrating TB-LAMP's clinical utility, speed, and affordability as a diagnostic technique. The assay's diagnostic performance in this Philippine cohort is consistent with earlier findings from international research, highlighting its potential to improve early TB detection and aid in disease control initiatives in areas with a high burden of the disease. Based on these results, TB-LAMP can be safely incorporated into pulmonary tuberculosis diagnostic algorithms, either in addition to or instead of current diagnostic instruments, contingent on clinical context and resource availability.

While GeneXpert remains the WHO-recommended rapid diagnostic for its ability to detect drug resistance, TB-LAMP serves as a robust alternative in peripheral outpatient settings. Evidence shows TB-LAMP offers diagnostic accuracy similar to GeneXpert and is significantly more sensitive than smear microscopy, making it a vital tool in areas where GeneXpert infrastructure is inaccessible.

RECOMMENDATIONS

To improve the diagnostic utility and scalability of the TB-LAMP assay in the context of tuberculosis (TB) detection, a number of directions for future research and clinical improvement are highly advised in light of the study's findings and recognized limitations:

GROWTH OF THE RESEARCH POPULATION AND MEDICAL ENVIRONMENT. A larger and more varied cohort of patients, especially those from healthcare facilities other than tertiary referral hospitals, should be included in future research. This includes people from outpatient clinics, community-based health units, and primary care clinics, particularly those who might not be eligible for or choose not to seek hospitalization. Future studies can more precisely evaluate the effectiveness and suitability of TB-LAMP, DSSM, and GeneXpert in decentralized, low-resource settings where the TB burden may be underdiagnosed by incorporating non-hospitalized patients.

COMPARATIVE STUDY OF EXTRAPULMONARY TUBERCULOSIS (EPTB). The current study only looked at cases of pulmonary tuberculosis. Future research should therefore examine how well TB-LAMP, GeneXpert, and DSSM perform in the diagnosis of extrapulmonary tuberculosis (EPTB), which poses particular diagnostic difficulties because of its frequently paucibacillary nature and non-specific clinical presentation. It would greatly improve TB-LAMP's utility profile to assess how well it detects mycobacteria in pleural fluid, lymph node aspirates, cerebrospinal fluid, and other extrapulmonary specimens.

ENHANCEMENT OF ASSAY AND TECHNICAL OPTIMIZATION. Although this study showed that the TB-LAMP assay had high diagnostic concordance, further development is necessary to improve its analytical sensitivity, user interface, and compatibility with automated reporting systems. Enhancements in sample processing procedures, detection thresholds, and reagent stability may make TB-LAMP a more viable and competitive substitute for GeneXpert and culture-based diagnostics, especially in areas with inadequate laboratory infrastructure.

DRUG-RESISTANT TB DETECTION OPERATIONAL RESEARCH. Investigating whether TB-LAMP can be modified or added to aid in the detection of resistance patterns, such as rifampicin and isoniazid resistance, is crucial given the rising incidence of multidrug-resistant tuberculosis (MDR-TB) worldwide. TB-LAMP does not yet offer resistance profiling like GeneXpert, but if it is connected to confirmatory molecular platforms or combined with resistance detection algorithms, its broad use could be strategically advantageous.

RESEARCH ON ECONOMICS AND IMPLEMENTATION. Adoption of TB-LAMP at the policy level necessitates more proof of its practicality, cost-effectiveness, and workflow integration. In order to measure cost-benefit ratios in comparison to DSSM and GeneXpert, future research should incorporate health economic assessments and pilot implementation programs, especially in areas with limited health budgets and a high TB burden.

PROMOTING EQUITABLE ACCESS. Finally, initiatives should be undertaken to encourage both domestic and foreign investment in order to increase the accessibility of TB-LAMP technology in areas with limited resources. Public health, international development, and laboratory diagnostics stakeholders should work together to make sure the assay is incorporated into national TB control plans, especially in areas where poverty, logistical challenges, and the rise in TB drug resistance are prevalent.

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