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Establishing proof of concept for utility of Trueprep®-extracted DNA in line-probe assay testing

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SUMMARY

BACKGROUND AND OBJECTIVES: With an increased demand for rapid, diagnostic tools for TB and drug resistance detection, Truenat® MTB-RIF assay has proven to be a rapid point of care molecular test. The present study aimed to establish a proof of concept of using Trueprep-extracted DNA for line-probe assay (LPA) testing.

METHODS: A total of 150 sputum samples (MTB-positive at Truenat sites) were divided into two aliquots. One aliquot was used for DNA extraction using the Trueprep device and MTB testing. The second aliquot of the sample was subjected to GenoLyse® DNA extraction. DNA from both the Trueprep and GenoLyse methods was subjected to first-line (FL) and second-line (SL) LPA testing.

RESULTS: Of 139 Trueprep-extracted DNA, respectively 135 (97%) and 105 (75%) had interpretable results by FL and SL-LPA testing. Of 128 GenoLyse-extracted DNA, all 128 (100%) had interpretable FL-LPA results and 114 (89%) had interpretable SL-LPA results.

CONCLUSION: The results obtained in this study indicate that Trueprep-extracted DNA can be used in obtaining valid LPA results. However, the study needs to be conducted on a larger sample size before our recommendations can be used for policy-making decisions.

KEY WORDS: Trueprep DNA; line-probe assay; bacillary load; GenoLyse DNA; diagnostic algorithm

TB, which is caused by *Mycobacterium tuberculosis* (MTB), is a major public health menace. According to the 2022 WHO global TB report, an estimated 10.6 million people fell ill with TB worldwide in 2021 with an increase of 4.5% from 10.1 million in 2020. Of these, 71% (2.4/3.4 million) of bacteriologically confirmed pulmonary TB people were tested for rifampicin (RIF) resistance, similar to that in 2020 (2.1/3.0 million) and around 10% more than in 2019 (2.2/3.6 million, 61%).[1] Among these, 141,953 cases of multidrug-resistant/RIF-resistant TB (MDR/RR-TB) and 25,038 cases of pre-extensively drug-resistant TB (pre-XDR-TB) or XDR-TB were detected.[1] According to the 2022 India TB report, 20.5% (450,304/2,197,757) of the total number of MTB tests performed using Truenat® MTB-RIF assay (Molbio Diagnostics Pvt Ltd, Verna, India) were MTB-positive and 4.9% (21,927/452,181) had RIF resistance.[2,3] Early diagnosis, effective treatment and successful interruption of transmission are major strategies for TB control and prerequisites for treating TB patients.

The Truenat assay is a real-time polymerase chain reaction (PCR) based molecular test for the detection of TB and RIF resistance. This WHO-endorsed test has been extensively validated and its feasibility in field settings has been demonstrated for use at district and sub-district level globally.[4–7] In programmatic settings, molecular detection of resistance to drugs other than RIF (fluoroquinolone [FQ] and isoniazid [INH]) is done using line-probe assay (LPA).[8] Current LPA methods include GenoType MTBDR*plus* assay v2.0 (Hain Lifescience, Nehren, Germany) for testing susceptibility to first-line (FL) drugs (i.e., RIF and INH) and GenoType MTBDR*sl* v2.0 (Hain Lifescience) for second-line (SL) drugs (FQs and aminoglycosides [AGs]) from sputum samples of smear-positive patients and culture from smear-negative patients.[9–12]

As per India's National TB Elimination Programme (NTEP) diagnostic algorithm, two samples are collected from a presumptive TB patient for MTB diagnosis. Truenat testing is carried out with the first sample at the field-level; this involves the extraction of DNA from an automated Trueprep instrument, followed by MTB and RIF testing using a Truelab instrument. If the first sample turns out to be MTB-positive on a nucleic acid

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amplification test (NAAT) at a periphery-level facility, the second sample is transported to the linked reference laboratory for LPA testing; this involves sample processing, smear microscopy and DNA extraction using the manufacturer-recommended GenoLyse® kit (Hain Lifescience). Thus, for MTB-positive samples DNA is extracted twice – first at the Truenat site and then at the LPA laboratory. The total volume of DNA extracted is approximately 100 µl: around 12 µl of DNA is used for MTB (6 µl) and RIF resistance detection (6 µl), while 88 µl of DNA is kept for further use.[13] To optimise efficiency and resource utilisation, it is crucial to conduct a systematic assessment when utilising the remaining Trueprep-extracted DNA for LPA testing. By doing so, we can avoid unnecessary repetition of DNA extraction specifically for LPA testing, resulting in considerable time and resource savings. The study aimed to establish proof of concept for using Trueprep DNA for FL and SL-LPA testing and to determine a cut-off value of colony forming unit per ml (cfu/ml) of the Truenat MTB-positive results with valid FL and SL-LPA results.

METHODS

The study was jointly conceptualised by the Indian Council of Medical Research-National Institute for Research in Tuberculosis (ICMR-NIRT) and USAID's Infectious Disease Detection and Surveillance Project (IDDS) led by ICF Incorporated LLC, in consultation with the Central TB Division (CTD), Ministry of Health & Family Welfare (MoHFW) and WHO India. The study was carried out at the culture and drug susceptibility testing (DST) laboratory of the Bacteriology Department of NIRT Chennai (a supranational reference laboratory for TB) with linked Truenat sites at the Chennai, Thiruvallur, Kanchipuram and Vellore districts of Tamil Nadu State in southern India. Ethics approval for use of the remainder of the DNA and sputum samples was obtained from Institutional Ethics Committee, ICMR-NIRT, Chennai, India (IEC NO: 2021048).

A total of 150 sputum samples (MTB-positive on Truenat assay at Truenat sites) were included in the study and all the samples were divided into two aliquots. Aliquot 1 of the sample was used for DNA extraction using the Trueprep device and MTB testing was done using the Truelab equipment. Cycle threshold (Ct), cfu/ml and RIF resistance of all the MTB-positives were noted. Truenat testing was performed using three batches of Truenat test kits for all the samples to check the consistency of the results. The quantity and quality of DNA was assessed using QUBIT dsDNA (Thermo Fisher Scientific, Waltham, MA, USA) high sensitivity assay and subjected to FL-LPA and SL-LPA testing with MTBDR*plus* v2.0 and MTBDR*sl* v2.0 kits.

The second aliquot of sputum sample was subjected to FL-LPA and SL-LPA testing using Genolyse Kit. The sputum sample was decontaminated using the *N*-acetyl-L cysteine sodium hydroxide (NALC-NaOH) method,[14] and subjected to fluorescent microscopy (FM) assay. DNA was extracted the smear-positive samples using the GenoLyse reagent as per the manufacturer's protocol for LPA (FL and SL) testing. Unlike the NTEP diagnostic algorithm, where only smear-negative samples are subjected to culture, in this study, all 150 samples were subjected to liquid culture. All smear-negative samples were subjected to indirect LPA if the culture turned out to be positive. The FL and SL-LPA results of the DNA extracted using Trueprep and GenoLyse were compared (Figure 1). The discordance between Truenat and LPA results obtained by either of the DNA extraction methods was resolved through DNA sequencing for targeted gene regions for *rpo*B gene covering RIF drug resistance mutations.

Statistical analysis

Data were collected and entered into an MS Excel (Microsoft, Redmond, WA, USA) sheet with data validation checks. Data were analysed using Stata v15.0 (Stata Corp, College Station, TX, USA), and cross-tabulated by frequency and percentage. The *Z*-proportion test was used to determine whether two proportions are different from each other. Receiver operating characteristic (ROC) analyses was performed to determine the minimum cut-off value of cfu/mL with valid FL and SL-LPA data. All the tests were two-tailed and conducted at a significance level of 0.05.

RESULTS

A total of 150 Truenat MTB-positive sputum samples received from the peripheral sites were used to assess the feasibility of using remnant Truenat DNA for LPA testing. These samples were subjected again to Truenat testing at the NIRT, and 139 (92.6%) were found to be MTB-positive. While 133 (88.6%) were positive on all three batches of MTB kits tested, 6 (4%) were positive on either one or two batches. Of these 150 samples, 128 (85.3%) were found to be smear-positive and 22 (14.7%) were smear-negative in decontaminated sputum specimens following the NTEP laboratory's standard operating procedures. Of the smear-negative samples, 8 (36.4%) were positive for *M. tuberculosis* on liquid culture and 12 (54.5%) were positive on Truenat. DNA concentration of these 12 samples ranged from 50 to 100 ng/µl ($<10^{04}$ cfu/ml) to from 120 to 800 ng/µl ($\geq 10^{04}$ cfu/ml).

Feasibility of line-probe assay testing

DNA extracted from samples using both Trueprep ($n = 139$) and GenoLyse (128 smear-positives) were subjected to FL- and SL-LPA testing. Of 139 Trueprep-extracted DNA, 135 (97%) had interpretable results

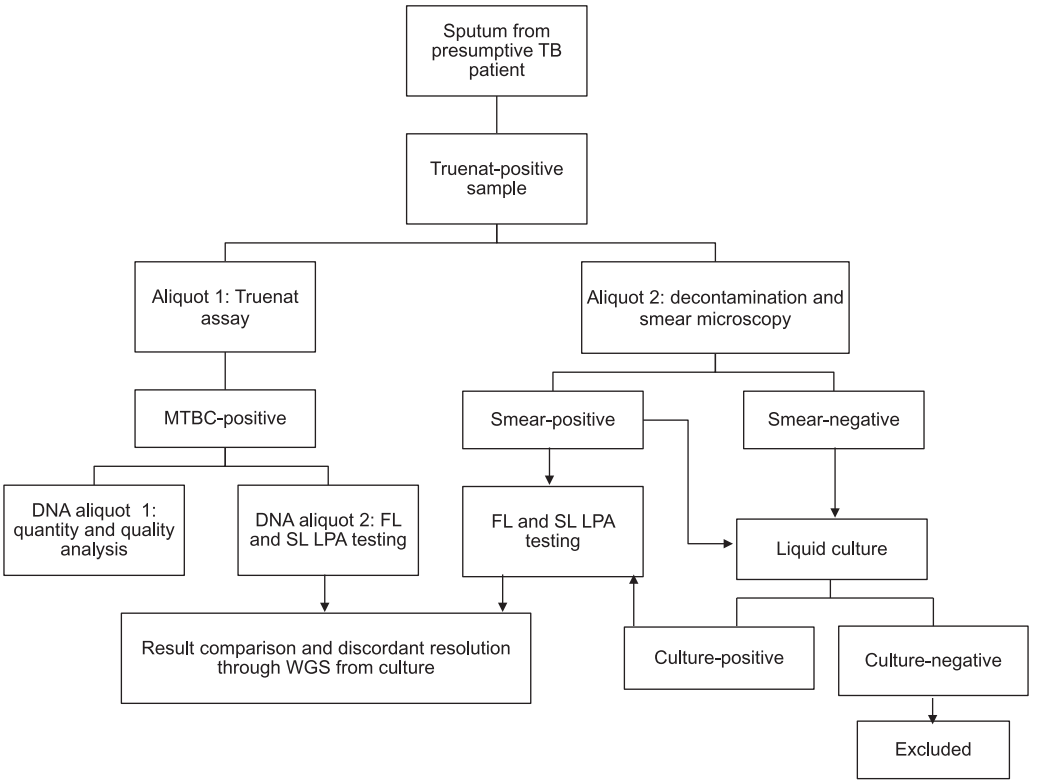

Figure 1 Workflow for the Truenat MTB-positive samples obtained from the Truenat site. MTBC = *Mycobacterium tuberculosis* complex; FL = first-line; LPA = line-probe assay; SL = second-line; WGS = whole-genome sequencing.

on FL-LPA and 105 (75%) had interpretable results on SL-LPA. Of the 128 samples of GenoLyse-extracted DNA, all 128 (100%) had interpretable FL-LPA results, while 114 (89%) had interpretable SL-LPA results (Figure 2). Among the 8 smear-negative cultures, respectively 7 and 5 cultures produced interpretable results when subjected to FL- and SL-LPA testing. Statistical analysis revealed no significant difference ($P = 0.238$) between the two extraction methods for FL-LPA. However, for SL-LPA testing, results were statistically significant, both when culture results were included ($P = 0.008$) and when these were excluded ($P = 0.004$).

On comparing DST results with FL-LPA between the two DNA extraction methods, 113 samples (75.3%) were found to be RIF-susceptible and INH-susceptible

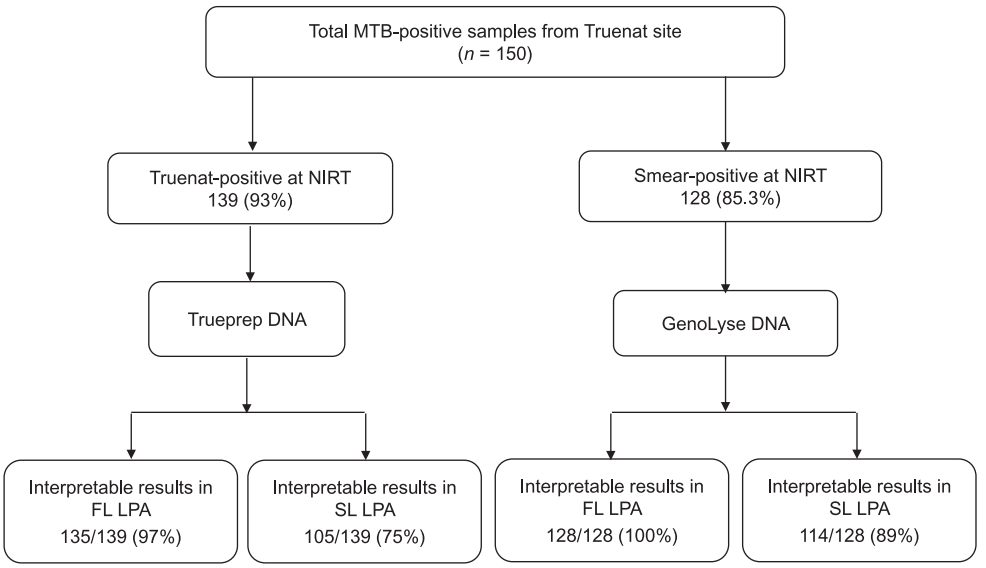

Figure 2 Interpretable FL- and SL-LPA results by Trueprep and Genolyse extracted DNA samples. MTB = *Mycobacterium tuberculosis*; NIRT = National Institute for Research in Tuberculosis; FL = first-line; LPA = line-probe assay; SL = second-line.

Table Bacillary load of Truenat MTB-positive (139/150) samples with valid FL- and SL-LPA results

Bacillary load on Truenat cfu/ml	MTB-positive samples *n/N* (%)	Samples with valid FL-LPA results *n/N* (%)	Samples with valid SL-LPA results *n/N* (%)
10^2	6/139 (4.3)	2/6 (33.3)	0
10^3	10/139 (7.2)	8/10 (0.8)	0
10^4	21/139 (15.1)	20/21 (95.2)	11/21 (52.4)
10^5	45/139 (32.4)	45/45 (100)	43/45 (95.5)
10^6	46/139 (33.1)	46/46 (100)	40/46 (87)
10^7	11/139 (7.9)	11/11 (100)	11/11 (100)

MTB = *Mycobacterium tuberculosis*; FL = first-line; SL = second-line; LPA = line-probe assay.

by both methods. Of the 15 resistant samples, 10 were RIF-susceptible and INH-resistant, 4 were RIF- and INH-resistant and 1 was RIF-resistant and INH-susceptible. One sample was found to be susceptible to both INH and RIF on FL-LPA when tested using Trueprep-extracted DNA, but resistant to both INH and RIF when tested using GenoLyse-extracted DNA. This discordance was resolved by sequencing and the discordant sample was found to be INH- and RIF-resistant. Sequencing was performed using the DNA extracted from the positive culture (from aliquot 2 of the sputum specimen).

In SL-LPA, 4 samples were found to be resistant when tested using GenoLyse DNA (3 were FQ-resistant and AG-susceptible and 1 was FQ- and AG-resistant) and 3 samples were found to be resistant when tested using Trueprep DNA (2 were FQ-resistant and AG-susceptible and 1 was FQ- and AG-resistant). One sample that was FQ-resistant and AG-susceptible on GenoLyse DNA turned out to be invalid on Trueprep DNA. The resistance pattern was further confirmed using sequencing of the DNA isolated from culture.

Determination of cut-off values

Of the total 139 samples that tested positive on Truenat, 103 samples (74.1%) had a bacillary load of $\geq$104 cfu/ml, 102 (99%) of which produced interpretable results when subjected to FL-LPA, while 94 samples (91%) produced interpretable results in SL-LPA. On rechecking the DNA concentration of the uninterpretable SL-LPA results, it was found that their concentrations ranged from 48.4 ng/µl to 598.6 ng/µl. These uninterpretable SL-LPA samples accounted for 9% of the total samples. In contrast, of the 37 samples (26.6%) that had a bacillary load of $\leq$104 cfu/ml, 30 (81%) produced interpretable results in FL-LPA, while only 11 samples (29.7%) produced interpretable results in SL-LPA (Table).

In the statistical analysis, the bacillary load of all 139 Truenat MTB-positive samples was included to establish the minimum cut-off value. The classification variable was deemed valid if it indicated susceptibility or resistance to the drugs that were tested. On the other hand, if any of these results were not obtained, the classification variable was considered invalid. The bacillary load (in cfu/ml) was used to determine the cut-off for valid and invalid results using receiver operating characteristic curve (ROC) analysis. In FL-LPA, a minimum cut-off bacillary load of greater than 10^2 cfu/ml had a sensitivity of 100% (95% CI 97–100) and a specificity of 100% (95% CI 3–100). In SL-LPA, a minimum cut-off bacillary load of greater than 10^5 cfu/ml had a sensitivity of 84% (95% CI 75–90) and a specificity of 78% (95% CI 56–93) (Figure 3).

DISCUSSION

India and several other countries have adopted Truenat testing as a point-of-care (POC) solution at peripheral healthcare centres in line with the 2020 WHO recommendations. Truenat testing allows for the use of the remnant DNA after extraction, and PCR amplification and detection can be carried out using two different methods. When transported under appropriate conditions, the remnant DNA extracted at peripheral-level centres can be used in reference laboratories to perform assays such as LPA. The stability of DNA at 4°C has been documented earlier,[15,16] indicating that DNA when transported under cool conditions can be used in reference laboratories for further testing.

In this study, we aimed to establish the proof of concept of using Trueprep-extracted DNA for LPA testing. Of the 139 Truenat-extracted DNA samples, 135 (97%) had interpretable FL-LPA results and 105 (75%) had interpretable SL-LPA results. While the proof of concept for using Trueprep-extracted DNA in FL- and SL-LPA testing has already been established, additional refinement and evidence are necessary to determine the minimum bacillary load values (in cfu/ml) for reliable SL-LPA testing. Moreover, it is evident that the reduction in bacillary load values is related to the reduction in sensitivity of SL-LPA. While the minimum cut-off bacillary load for obtaining valid FL-LPA results was $>10^2$ cfu/ml, this was higher ($>10^5$ cfu/ml) for obtaining valid SL-LPA results. This indicates that Trueprep-extracted DNA can be used for FL-LPA and for most SL-LPAs if transported under appropriate temperature conditions.

In a systematic review conducted on LPAs, the sensitivity of FL-LPA was found to be higher than that of

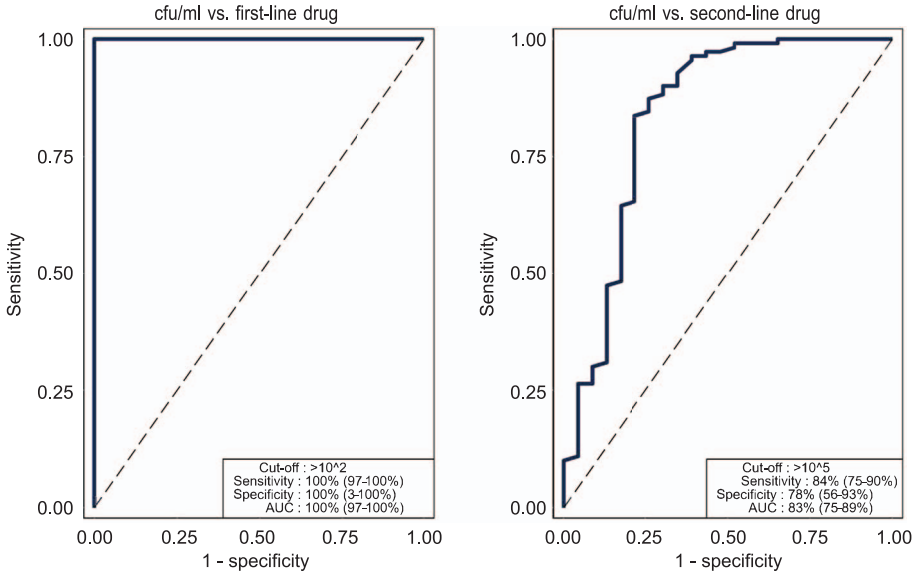

Figure 3 ROC analysis for the determination of the minimum cut-off value of cfu/ml with valid FL and SL-LPA results. cfu = colony-forming unit; AUC = area under the ROC curve; FL = first-line; LPA = line-probe assay; SL = second-line; ROC = receiver operating characteristic.

SL-LPA (96.2–96.7% vs. 86.2–87.2%). In addition, compared to FL-LPA, the number of indeterminate results was generally higher in SL-LPA, especially in case of the direct testing of sputum specimens.[17,18] The sensitivity of molecular methods is known to depend on the type of clinical specimen, smear grade, the homogenisation-decontamination method used and the principles of the PCR technique used.[19,20] In addition, PCR results could also be greatly influenced by the DNA extraction methods used, with sensitivity ranging from 11% to 81%.[21] In this study, while the GenoLyse extraction method was carried out with processed samples using NALC-NaOH decontamination, Trueprep extraction was carried out with raw samples. This difference in sample processing method could be an important factor affecting reduced sensitivity in SL-LPA of Trueprep-extracted DNA. Studies have shown that prior treatment of samples with proteinase K before DNA extraction improves DNA yield.[21–23] Implementation of such sample pretreatment methods before subjecting them to Trueprep DNA extraction could increase the DNA yield and this needs further exploration.

Study benefits

Presently, close to 70 laboratories in India are certified for performing FL- and SL-LPA. As per the current diagnostic algorithm, the second sample is transported for LPA testing to the linked reference laboratory after *M. tuberculosis* is detected in Truenat assay at peripheral laboratories. Direct LPA testing is dependent upon the results of sputum smear microscopy performed in the reference laboratory according to the NTEP's current diagnostic policy. Only specimens that are acid-fast bacilli-positive on smear microscopy are considered for direct LPA testing. This involves decontamination and DNA extraction using GenoLyse kits, which requires more time and resources (DNA extraction reagents/kits and labour). Sometimes patients are asked to return in order to collect a second sample, resulting in delays; on occasions, the cascade testing is not completed as the second sample is not collected. Our study shows the utility of Trueprep-extracted DNA for LPA testing, which will result in shorter turnaround time for LPA results (24–48 h instead of 72 h), reduce staff workload at reference laboratories and facilitate earlier treatment decisions for patients.

Study limitations

The feasibility of Trueprep DNA utility for LPA testing was assessed at a tertiary care setting and our results may not represent the effect of transport and temperature on the quality of the DNA transported. Multicentric field feasibility is planned to investigate the effects of transportation on the quality of DNA obtained from field settings for Phase II of this study.

CONCLUSION

According to the NTEP diagnostic algorithm, all samples detected as MTB-positive using NAATs are subjected to FL-LPA; samples that are INH- and/or RIF-resistant or both are further subjected to SL-LPA. The results obtained in Phase I (proof of concept) of this study have successfully shown that Truenat-extracted DNA can be used in obtaining valid FL-LPA and SL-LPA results. However, the low sensitivity of the SL-LPA assay led to reduced interpretability of valid SL-LPA results, especially for Trueprep-extracted DNA, which has a lower

bacillary load. The second phase of this study is expected to provide greater insight into cut-off values for interpretable and valid SL-LPA results, and facilitate the NTEP's policy-making decisions.

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References

1 World Health Organization. Global tuberculosis report, 2021. Geneva, Switzerland: WHO, 2021.
2 Government of India. India TB Annual Report, 2022. New Delhi, India: GoI, 2022.
3 Government of India. National Strategic Plan to End TB in India. New Delhi, India: GoI, 2020.
4 World Health Organization. WHO recommendations on Truenat MTB, MTB Plus and MTB-RIF Dx assays. Geneva, Switzerland: WHO, 2021.
5 Nikam C, et al. Evaluation of the Indian TrueNAT micro-RT-PCR device with GeneXpert for case detection of pulmonary tuberculosis. Int J Mycobacteriol 2014;3(3):205–210.
6 Gomathi NS, et al. Multicentric validation of indigenous molecular test Truenat™ MTB for detection of *Mycobacterium tuberculosis* in sputum samples from presumptive pulmonary tuberculosis patients in comparison with reference standards. Indian J Med Res 2020;152(4):378.
7 Penn-Nicholson A, et al. A prospective multicentre diagnostic accuracy study for the Truenat tuberculosis assays. Eur Respir J 2021;58(5):2100526
8 Central TB Division, Ministry of Health & Family Welfare, Government of India. Guidelines on programmatic management of drug-resistant TB in India. New Delhi, India: MoHFW, 2021.
9 Nguyen TN, et al. Molecular diagnosis of drug-resistant tuberculosis: a literature review. Front Microbiol 2019;10:794.
10 Gardee Y, et al. Evaluation of the genotype MTBDR*sl* version 2.0 assay for second-line drug resistance detection of *Mycobacterium tuberculosis* isolates in South Africa. J Clin Microbiol 2017;55(3):791–800.
11 Tomasicchio M, et al. The diagnostic accuracy of the MTBDR*plus* and MTBDR*sl* assays for drug-resistant TB detection when performed on sputum and culture isolates. Sci Rep 2016;6(1): 1–8.
12 Meaza A, et al. Evaluation of genotype MTBDR*plus* VER 2.0 line probe assay for the detection of MDR-TB in smear positive and negative sputum samples. BMC Infect Dis 2017;17(1): 1–8.
13 Rajsekar K, Tyagi K., Singh M. Rapid health technology assessment for incorporating TrueNat as a diagnostic tool for tuberculosis under RNTCP in India. New Delhi, India: Indian Council of Medical Research, 2019.
14 Srivastava S, Chapagain M, Gumbo T. Effect of specimen processing, growth supplement, and different metabolic population on Mycobacterium tuberculosis laboratory diagnosis. PLoS One 2020;15(4):e0230927.
15 Towne B, Devor EJ. Effect of storage time and temperature on DNA extracted from whole blood samples. Hum Biol 1990; 62(2):301–306.
16 Alrokayan SA. Effect of storage temperature on the quality and quantity of DNA extracted from blood. Pakistan J Biol Sci 2000;3(3):392–394.
17 Theron G, et al. GenoType® MTBDR*sl* assay for resistance to second-line anti-tuberculosis drugs. Cochrane Database Syst Rev 2016;(9):CD010705.
18 Nathavitharana RR, et al. Accuracy of line probe assays for the diagnosis of pulmonary and multidrug-resistant tuberculosis: a systematic review and meta-analysis. Eur Respir J 2017;49(1): 1601075.
19 Noordhoek GT, et al. Sensitivity and specificity of PCR for detection of *Mycobacterium tuberculosis*: a blind comparison study among seven laboratories. J Clin Microbiol 1994;32(2): 277–284.
20 Bennedsen J, et al. Utility of PCR in diagnosing pulmonary tuberculosis. J Clin Microbiol 1996;34(6):1407–1411.
21 Barani R, et al. Improved detection of *Mycobacterium tuberculosis* using two independent PCR targets in a tertiary care centre in South India. J Infect Dev Ctries 2012;6(01):46–52.
22 Tarhan G, et al. Evaluation of the efficacy of five DNA extraction methods for the detection of *Mycobacterium tuberculosis* DNA in direct and processed sputum by -an in-house PCR method. Turk J Med Sci 2009;39(2):253–257.
23 Jain A, et al. Qualitative evaluation of mycobacterial DNA extraction protocols for polymerase chain reaction. Mol Bio Today 2002;3:43–50.

RÉSUMÉ

CONTEXTE ET OBJECTIFS : Face à la demande croissante d'outils de diagnostic rapide pour la TB et la détection de la résistance aux médicaments, le test Truenat® MTB-RIF s'est avéré être un test moléculaire rapide sur le lieu de soins. La présente étude visait à établir une preuve de concept de l'utilisation de l'ADN extrait de Trueprep pour le test de la sonde de ligne (LPA, de l'anglais '*line-probe assay*').

MÉTHODES : Un total de 150 échantillons d'expectoration (MTB-positifs dans les sites Truenat) ont été divisés en deux aliquotes. Une aliquote a été utilisée pour l'extraction de l'ADN à l'aide du dispositif Trueprep et pour le test MTB. La seconde aliquote de l'échantillon a été soumise à l'extraction d'ADN par GenoLyse®. L'ADN issu des méthodes Trueprep et GenoLyse a été soumis à un test de LPA de première ligne (FL, de l'anglais '*first-line*') et de deuxième ligne (SL, de l'anglais '*second-line*').

RÉSULTATS : Sur 139 ADN extraits par la méthode Trueprep, 135 (97%) et 105 (75%) respectivement ont donné des résultats interprétables par les tests FL- et SL-LPA. Sur 128 ADN extraits par GenoLyse, les 128 (100%) ont obtenu des résultats interprétables par FL-LPA et 114 (89%) ont obtenu des résultats interprétables par SL-LPA.

CONCLUSION : Les résultats obtenus dans cette étude indiquent que l'ADN extrait par Trueprep peut être utilisé pour obtenir des résultats de LPA valides. Cependant, l'étude doit être menée sur un échantillon plus important avant que nos recommandations puissent être utilisées pour des décisions politiques.