Journal of Health Science
Volume 4 , Number 1 , February 2026
DOI: https://doi.org/10.54816/jhs.v4i1.1492

Submissions: January 14, 2026
Revision: February 8, 2026
Accepted: February 13, 2026
Available online: February 20, 2026

Xpert MTB/RIF Results among Presumptive Pulmonary Tuberculosis Patients by Treatment History at Sekayu Regional General Hospital, Indonesia

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ABSTRAK

Riwayat pengobatan tuberkulosis (TB) merupakan salah satu faktor risiko penting TB resistan obat. Penelitian ini bertujuan menggambarkan hasil Tes Cepat Molekuler (TCM) Xpert MTB/RIF pada pasien terduga TB paru menurut riwayat pengobatan dan membandingkan pasien baru dengan pasien yang pernah diobati. Penelitian potong lintang retrospektif berbasis register dengan analisis deskriptif dan komparatif ini menggunakan data register TCM dan Sistem Informasi Tuberkulosis (SITB) RSUD Sekayu periode Januari–Juni 2024. Perbandingan dilakukan dengan uji *Chi-square* Pearson, uji eksak Fisher, dan rasio prevalensi (RP) dengan interval kepercayaan (IK) 95%. Dari 320 pasien, 268 (83,8%) merupakan pasien baru dan 52 (16,2%) pernah diobati. *Mycobacterium tuberculosis* (MTB) terdeteksi pada 110 pasien (34,4%): 95 dengan resistansi rifampisin tidak terdeteksi, 12 resistan rifampisin (10,9% dari MTB terdeteksi), dan 3 *indeterminate*. MTB lebih sering terdeteksi pada pasien yang pernah diobati (28/52; 53,8% vs 82/268; 30,6%; RP 1,76; IK 95% 1,29–2,40). Di antara hasil rifampisin yang dapat ditentukan, resistansi lebih tinggi pada pasien yang pernah diobati (8/27; 29,6% vs 4/80; 5,0%; RP 5,93; IK 95% 1,94–18,13). Riwayat pengobatan berasosiasi secara kasar dengan proporsi MTB terdeteksi dan resistansi rifampisin yang lebih tinggi. Akses TCM bagi seluruh terduga TB dan kelengkapan pencatatan riwayat pengobatan perlu dipastikan.

Keywords: resistansi rifampisin; riwayat pengobatan; tes cepat molekuler; tuberkulosis paru

ABSTRACT

A history of previous tuberculosis (TB) treatment is an important risk factor for drug-resistant TB. This study aimed to describe Xpert MTB/RIF molecular rapid test results among presumptive pulmonary TB patients by treatment history and to compare new and previously treated patients. This register-based retrospective cross-sectional study with descriptive and comparative analyses used Xpert register and national TB information system (SITB) data from Sekayu Regional General Hospital for January–June 2024. Comparisons used Pearson's chi-square test, Fisher's exact test, and prevalence ratios (PR) with 95% confidence intervals (CI). Of 320 patients, 268 (83.8%) were new and 52 (16.2%) were previously treated. Mycobacterium tuberculosis *(MTB) was detected in 110 patients (34.4%): 95 with rifampicin resistance not detected, 12 with rifampicin resistance detected by Xpert (10.9% of MTB-detected results), and 3 indeterminate. MTB was detected more often in previously treated patients (28/52; 53.8% vs 82/268; 30.6%; PR 1.76; 95% CI 1.29–2.40). Among determinate rifampicin results, resistance was more frequent in previously treated patients (8/27; 29.6% vs 4/80; 5.0%; PR 5.93; 95% CI 1.94–18.13). Treatment history showed a crude association with higher MTB detection and rifampicin resistance. Access to Xpert testing for all presumptive TB patients and complete recording of treatment history should be ensured.*

Keywords : *molecular rapid test; previously treated; pulmonary tuberculosis; rifampicin resistance*

p-ISSN 2774-2938
e-ISSN 2775-7811

Introduction

Tuberculosis (TB) remains one of the leading causes of death from infectious diseases. The latest global TB report estimates that Indonesia will contribute around 10% of all incident TB cases worldwide by 2025, the second largest after India [1]. In the WHO report, rifampicin -resistant TB (*rifampicin-resistant TB) is a major cause of death. tuberculosis*, RR-TB) and multidrug - *resistant TB tuberculosis* MDR-TB), which is resistant to at least rifampicin and isoniazid, is combined as MDR/RR-TB [2]. Rifampicin resistance detected by molecular testing is not identical to evidence of resistance to isoniazid, so the term used in this study is rifampicin resistance.

The government is targeting TB elimination by 2030 through rapid case detection and treatment until cured [3]. Molecular Rapid Test (TCM) with cartridges Xpert MTB/RIF on the GeneXpert platform is the primary TB diagnostic tool in Indonesia because it detects *Mycobacterium DNA. tuberculosis (MTB) as well as rpoB* gene mutations associated with rifampicin resistance in about two hours [4]. The WHO recommends rapid molecular diagnostic tests as the initial screening for suspected TB [5], and a Cochrane systematic review demonstrated high accuracy of Xpert MTB/RIF for detecting pulmonary TB and rifampicin resistance [6].

A history of prior TB treatment is an important risk factor for drug-resistant TB. Globally, the proportion of MDR/RR-TB in 2024 is estimated to be 3.2% in new cases and 16% in previously treated cases [2]. For Indonesia, the WHO estimate for 2022 is 2.2% in new cases and 25% in previously treated cases [7]. These figures are estimates of the TB patient population, not of suspected TB patients examined at a single hospital. A study at seven drug-resistant TB referral hospitals in Indonesia also reported that combined MDR-TB and pre -XDR-TB were more frequently found in previously treated patients (52.5%) than in new patients (15%) [8]; these outcomes differ from the TCM-based rifampicin resistance measured in this study.

The proportion of MTB detected in suspected TB patients varies by facility type and population examined. At a provincial referral hospital in Aceh, MTB was detected in 32.8% of suspected pulmonary TB patients and 14.1% of confirmed rifampicin-resistant cases; the study also categorized treatment history, including relapse, failure, and discontinuation [9]. At Tugu Jaya Regional General Hospital, approximately 11.8% of 400 suspected patients tested positive [10], while at a community health center in Temanggung, the rate was only 1.7% [11]. This variation highlights the importance of local data for evaluating laboratory services.

Sekayu Regional General Hospital (RSUD Sekayu) is a referral hospital in Musi Banyuasin Regency, South Sumatra, which provides TCM examinations for suspected TB patients. A description of TCM results by treatment history category is required by the hospital to evaluate the pattern of examination results, the completeness of treatment history recording, and the need for follow-up of resistance results. This study aims to describe the results of TCM examinations in suspected pulmonary TB patients based on their treatment history at Sekayu Regional General Hospital from January–June 2024 and to compare the proportion of detected MTB and rifampicin resistance between new and previously treated patients.

Method

Design and location. This is a retrospective, register-based cross-sectional study with descriptive and comparative analyses between groups. Data were collected from the TCM Laboratory of Sekayu Regional Hospital, Musi Banyuasin Regency, South Sumatra, for the period January–June 2024. Data collection and analysis were conducted from September 2024–February 2025.

Population and sample. The population was all suspected pulmonary TB patients who underwent TCM examination during the study period. Suspected pulmonary TB patients were patients who were requested to undergo TCM sputum specimen examination by the clinician, with a statement of

suspected pulmonary TB on the TB examination request form and laboratory register. All patients who met the criteria were included (*total sampling*). Inclusion criteria were sputum specimens, recorded in the TCM register, and complete TCM results and treatment history. Exclusion criteria were non-sputum specimens, *error /invalid/ no* results. *results* without valid re-examination, repeat examinations on the same patient, and examinations for treatment monitoring. The unit of analysis is the patient: each patient contributes one diagnostic result. If the initial examination yields an *error /invalid/ no result results* and repeated, the valid results from the repeat examination were used. All patients analyzed were aged ≥15 years.

Laboratory examination. TCM examinations are performed by laboratory staff at Sekayu Regional Hospital as a routine service using cartridges. Xpert MTB/RIF according to national technical guidelines [4]. Researchers did not perform the examination, but reviewed the recorded results.

Variables and operational definitions. TCM results were categorized as undetected MTB, detected MTB with undetected rifampin resistance, detected MTB with detected rifampin resistance (rifampin resistant), or detected MTB with rifampin results. *indeterminate* [4]. The term "rifampicin resistance undetectable" is used as the equivalent of "rifampicin sensitivity" in the register and does not imply sensitivity to other anti-TB drugs. *Indeterminate results* are the final results recorded in the register. Treatment histories follow the program classification recorded in the SITB and the register [12,13]: new patients are those who have never received anti-TB drugs (OAT) or have taken OAT for less than one month; relapse patients are those previously declared cured or completed treatment and are currently diagnosed with TB again; treatment after failure is a patient whose last treatment result was declared a failure; and treatment after interruption is a patient whose treatment was interrupted for two consecutive months or more. Relapse, after failure, and after interruption are combined as previously treated patients. Researchers did not reclassify treatment histories. Gender and age group were recorded as patient characteristics.

Data collection and ethics. Data were collected from the TCM laboratory register, TB examination request forms, and the TB case report (SITB) using a data collection sheet. Treatment histories in the register were matched with the case report (SITB) data. Patient identities were used only for cross-source matching and were not stored in the analysis dataset. This study used secondary data from routine services without intervention or patient contact and was conducted with the permission of the Director of Sekayu Regional General Hospital.

Data analysis. Data were analyzed descriptively in the form of frequencies and percentages, overall and by treatment history category, with a 95% CI using the Wilson method. Comparisons were made between new patients and the pool of previously treated patients. The proportion of MTB detected (denominator: all suspected) was compared using the Pearson *Chi- square test* without continuity correction. The proportion of rifampin resistance was calculated among determinable rifampin results (*indeterminate results* were excluded) and compared using the two-sided Fisher's exact test because there were cells with an expected value less than 5. The magnitude of association was expressed as the crude prevalence ratio (RP) of previously treated patients to new patients, with a 95% CI using the logarithmic method. This RP was not adjusted for other variables. Details of the four treatment history categories are presented descriptively without statistical testing. The threshold for significance was $p < 0.05$.

Results and Discussion

A total of 320 suspected pulmonary TB patients met the inclusion criteria. The majority were male (61.3%) and new patients (83.8%), with the largest age group being 45–54 years (23.1%) (Table 1).

Table 1. Characteristics of suspected pulmonary TB patients (n = 320)

Characteristics	n	%
Gender		
Man	196	61.3
Woman	124	38.8
Age (years)		
15–24	38	11.9
25–34	52	16.3
35–44	61	19.1
45–54	74	23.1
55–64	59	18.4
≥65	36	11.3
Treatment history		
New patient	268	83.8
Relapsed	34	10.6
Treatment after failure	7	2.2
Treatment after stopping treatment	11	3.4

Source: secondary data from the TCM register and SITB of Sekayu Regional General Hospital, January–June 2024. Percentages are rounded to one decimal place so the total may not be exactly 100%.

Overall, MTB was detected in 110 patients (34.4%; 95% CI 29.4–39.7%) and undetectable in 210 patients (65.6%). Among the 110 patients with detected MTB, 95 had undetectable rifampin resistance, 12 had rifampin resistance, and 3 *were indeterminate*. Thus, rifampin resistance results accounted for 12/110 (10.9%; 95% CI 6.4–18.1%) of all detected MTB or 12/107 (11.2%; 95% CI 6.5–18.6%) of the determinable rifampin results (Table 2).

Table 2. TCM results by treatment history category

TCM Results	New	Relapsed	Fail	Discontinued treatment	Total
n	268	34	7	11	320
MTB not detected	186	17	1	6	210
MTB detected	82	17	6	5	110
Rif not detected	76	13	2	4	95
Rif resistance	4	3	4	1	12
Rif *indeterminate*	2	1	0	0	3
% MTB detected[a]	30.6	50.0	85.7	45.5	34.4
Rif resistance/ Rif results can be determined[b]	4/80	3/16	4/6	1/5	12/107

Source: secondary data from the TCM register and SITB of Sekayu Regional General Hospital, January–June 2024. Rif = rifampicin ; Rif undetectable = rifampicin resistance undetectable. [a]Denominator: all suspected cases in the category. [b]Denominator: determinable rifampicin results (*indeterminate results* excluded); the proportion of resistant cases among all MTB detected was 12/110 (10.9%). The treatment failure and discontinuation categories were small in number and presented descriptively.

MTB was detected in 82/268 (30.6%) new patients, 17/34 (50.0%) relapsed patients, 6/7 patients after treatment failure, and 5/11 (45.5%) patients after treatment interruption. Among those with detectable rifampin results, resistance was found in 4/80 new patients, 3/16 relapsed patients, 4/6 patients after treatment failure, and 1/5 patients after treatment interruption (Figure 1). Compared with new patients, previously treated patients had a significantly higher proportion of detectable MTB and rifampin resistance (Table 3).

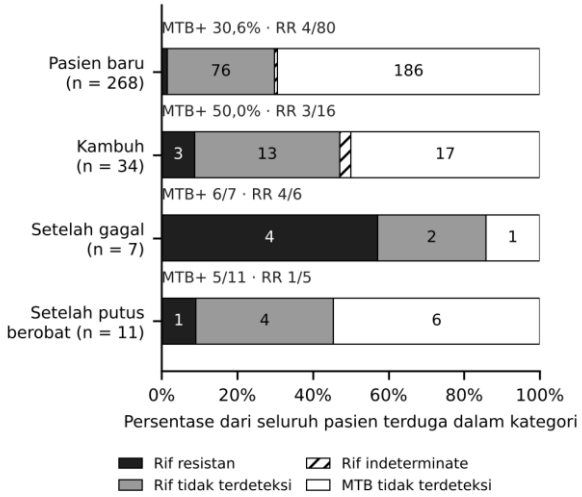

Figure 1. Composition of TCM results by treatment history category (n = 320)

Numbers in bars are the number of patients; bar lengths use the denominator of all suspects in the category. MTB+ = proportion of MTB detected. RR = number of rifampin- resistant cases /number of determinable rifampin results (*indeterminate results* excluded). Rif undetectable = rifampin resistance not detected. The categories after treatment failure (n = 7) and after treatment interruption (n = 11) are small, so their proportions should be interpreted with caution.

Table 3. Comparison of TCM results between new patients and previously treated patients

Indicator	New patients n/N (%)	Ever treated n/N (%)	RP (IK 95%)	p-value
MTB detected[a]	82/268 (30.6)	28/52 (53.8)	1.76 (1.29–2.40)	0.001[c]
MTB not detected	186/268 (69.4)	24/52 (46.2)	References	
Rif resistan[b]	4/80 (5.0)	8/27 (29.6)	5.93 (1.94–18.13)	0.002[d]
Rif not detected	76/80 (95.0)	19/27 (70.4)	References	

Source: secondary data from the TCM register and SITB of Sekayu Regional General Hospital, January–June 2024. RP = crude prevalence ratio (previously treated versus new patients), 95% CI logarithmic method; CI = confidence interval. [a]Denominator: all suspects. [b]Denominator: determinable rifampicin results; excluding 3 *indeterminate results* (2 new patients and 1 previously treated patient). [c]Pearson's *Chi- square test* without continuity correction (χ^2 = 10.43; df = 1). [d]Two-sided Fisher's exact test. This table compares

new patients with the combined previously treated patients and does not test for differences between categories of relapse, failure, and discontinuation.

MTB was detected in 34.4% of suspected pulmonary TB patients at Sekayu Regional Hospital. This figure is close to the findings at provincial referral hospitals in Aceh (32.8%) [9] and higher than at Tugu Jaya Regional Hospital (around 11.8%) [10] and at community health centers (1.7%) [11]. Differences in the spectrum of patients referred to hospitals may be one explanation, but the severity and origin of referrals were not measured in this study. Comparisons between facilities are also influenced by differences in period, suspected criteria, age, and type of examination. The proportion of positives at service facilities does not reflect the prevalence of TB in the community.

The male-dominated composition of suspected patients is consistent with data on suspected patients at Tugu Jaya Regional Hospital (257 out of 400 male patients) [10]. Research in Aceh reported that TB cases were more common in men and in the 45–54 year age group [9]. However, Table 1 depicts the composition of all suspected cases, not the proportion of positive cases by gender or age, so this composition cannot be interpreted as a difference in risk.

The proportion of MTB detected in previously treated patients was 1.76 times that in new patients. This difference may be related to differences in patient selection, disease recurrence, or the detection of residual DNA. TCM detects DNA and does not distinguish live from dead bacilli; specificity Xpert is lower in individuals with a history of TB [6]. Theron et al. reported that approximately one in seven positive Xpert results in retreatment patients were not culture-confirmed, with a higher risk of false positives when the interval from the previous treatment was shorter [14]. Because this study lacked culture data, clinical comparators, or time since last treatment, some positive results in the previously treated group could not be confirmed as active TB. Follow-up of positive results in this group requires consideration of the clinical context and the prevailing diagnostic pathway [4,5].

Among rifampin- determined outcomes, resistance was found in 29.6% of previously treated patients and 5.0% of new patients. The direction of this difference is consistent with WHO estimates for Indonesia (25% and 2.2%) [7], global estimates (16% and 3.2%) [2], and reports from referral hospitals in Indonesia [8,9]. However, the closeness of the figures does not indicate equivalence or representativeness because the national estimate, the study of drug-resistant TB referral hospitals, and this six-month hospital sample have different populations, selection processes, and outcomes; these differences were also not statistically tested. The wide 95% CI (1.94–18.13) reflects the small number of resistance outcomes (12 patients).

The literature suggests that inadequate treatment can select for resistant mutants, but resistance can also be present prior to treatment and lead to therapeutic failure [12]. Compliance, regimen adequacy, and pre-therapy resistance status were not measured in this study. With its cross-sectional design, this study cannot determine whether resistance was acquired during treatment or pre-existing, and treatment history cannot be considered an independent factor because confounders were not controlled.

The highest proportion of resistance descriptively was found in the post-failure group, with 4 of 6 patients with MTB detected (95% CI 30.0–90.3%) out of a total of 7 patients in that group. This number is so small that it cannot be used as a basis for meaningful comparison with the relapse or discontinuation categories or risk factor rankings. This finding is consistent with program regulations that direct patients with a history of treatment failure to undergo drug sensitivity testing [4].

Rifampin resistance was also found in 4 of 80 new patients with detectable rifampin results (5.0%; 95% CI 2.0–12.2%). This finding suggests that rifampin resistance can be detected without documented treatment history and is consistent with the possibility of transmitted resistance. However, the route of transmission is inconclusive because this study lacked contact tracing, epidemiological tracing, or genotyping data, and treatment history could have been misclassified.

Resistance results in patients with low pre - test probability, especially those with very low bacillary loads, may also be false positives and should be followed up according to the algorithm [5,15]. These findings support the policy of TCM screening for all TB suspects, not just previously treated patients [3–5].

This study has several limitations. First, the data were obtained from a single hospital within a six-month window, thus limiting generalizability. Second, the use of register data relies on completeness of records; exclusion of incomplete records and invalid results may introduce selection bias, and treatment histories may be misclassified. Third, without cultures or clinical comparators, the study did not assess the sensitivity, specificity, or validity of each positive result as active TB; time since previous treatment was also unavailable. Fourth, the reported associations are crude and have not been adjusted for age, sex, HIV status, diabetes mellitus, or referral source; with only 12 resistance results, multivariable analysis is inadequate. Fifth, the number of patients in the post-failure and post-discontinuation groups was small, resulting in unstable proportions.

Conclusion

In suspected pulmonary TB patients examined with TCM at Sekayu Regional Hospital during January–June 2024, MTB was detected in 34.4% of patients, and rifampin resistance was found in 10.9% of all detected MTB (11.2% of rifampin-determinable results). Previously treated patients had a higher proportion of detected MTB (53.8% vs. 30.6%) and rifampin resistance (29.6% vs. 5.0%) compared to new patients as a crude association. The highest proportion of resistance in the post-failure group represents a descriptive trend with a small number of patients.

Hospitals are advised to ensure access to TCM for all TB suspects, complete treatment history documentation, systematically record repeat and *indeterminate results, and follow up on resistance results according to guidelines. Medication support remains relevant as a programmatic measure to prevent treatment discontinuation, although its benefits were not tested in this study. Further research should document time since previous treatment,* regimen, referral source, comorbidities, and culture and susceptibility test results, and, where possible, use a cohort design to distinguish initial resistance from resistance that emerges during treatment.

Thank-you note

The authors would like to thank Kader Bangsa University Palembang for funding this research, as well as the Director and staff of the TCM Laboratory of Sekayu Regional Hospital for permission to use the data and assistance in data collection.

Conflict of Interest

The author declares no conflict of interest in this research.

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