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Clinical and Care-Related Factors Associated with Unsuccessful All-Oral Treatment of Multidrug-Resistant Tuberculosis in Indonesia: A Multicentre Cohort

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ABSTRACT: Clinical disease burden and care-related barriers may influence multidrug-resistant tuberculosis (MDR-TB) treatment outcomes, yet evidence from Eastern Indonesia remains limited. This multicentre retrospective cohort included 473 patients with pulmonary MDR-TB receiving all-oral regimens in Makassar, Indonesia, during 2021–2025, with final outcomes documented by August 2026. Multivariable logistic regression examined nine baseline factors and an expanded model incorporating three treatment-period characteristics. Treatment was successful in 328 patients (69.3%), while 145 (30.7%) experienced unsuccessful outcomes. In the baseline model, unsuccessful treatment was associated with high bacillary burden (adjusted odds ratio [aOR] 3.27; 95% CI 2.07–5.17), extensive pulmonary lesions (2.46; 1.57–3.88), diagnostic delay ≥30 days (2.29; 1.27–4.15), low socioeconomic status (1.96; 1.25–3.06), underweight status (1.83; 1.18–2.85), and limited healthcare access (1.65; 1.01–2.70). In the expanded model, medication non-adherence (aOR 4.43; 95% CI 2.21–8.85), delayed or absent culture response (3.33; 2.01–5.52), and poor family support (3.07; 1.65–5.73) were independently associated with unsuccessful outcomes. These findings highlight the importance of integrating baseline clinical assessment with accessible, patient-centred care, adherence support, family involvement, and bacteriological monitoring throughout MDR-TB treatment. The observed associations should not be interpreted as causal.

1. INTRODUCTION

Multidrug- or rifampicin-resistant tuberculosis (MDR/RR-TB) remains a major challenge despite the transition toward shorter, injection-free treatment. In 2024, an estimated 390,000 people developed MDR/RR-TB worldwide, while treatment success reached 71% among patients enrolled in 2022 [1]. A randomized trial demonstrated favorable efficacy and safety of a six-month all-oral regimen [2], although regimen changes during routine nine-month treatment have been reported in Indonesia [3].

Clinical factors at treatment initiation remain relevant. An individual-participant meta-analysis associated low body mass index with unfavorable outcomes in rifampicin-resistant TB [4]. Undernutrition was also associated with delayed culture conversion and unsuccessful MDR-TB treatment in a systematic review and meta-analysis [5]. Baseline sputum smear grading and pulmonary cavitation have been linked to time to culture conversion [6]. In a multicentre Indonesian cohort including both drug-susceptible and MDR-TB patients, underweight status and higher smear grades were associated with unfavorable outcomes [7].

Challenges beyond clinical disease burden are also documented. MDR-TB treatment imposes substantial financial costs on affected households [8]. In Jakarta, patient- and health-system factors contributed to delays in treatment initiation [9], while a Bandung care-cascade study documented substantial attrition across diagnosis and treatment stages [10]. Timely drug-

susceptibility testing remains central to appropriate treatment selection [11]. How clinical severity, diagnostic delay, socioeconomic disadvantage, and healthcare access intersect in routine MDR-TB care in Eastern Indonesia is less well described. This multicentre retrospective cohort study examined their associations with unsuccessful treatment outcomes among patients with pulmonary MDR-TB in Makassar, with treatment-period factors assessed separately.

2. MATERIALS AND METHODS

2.1. Study Design and Setting

This multicentre retrospective cohort study was conducted at Dr. Wahidin Sudirohusodo General Hospital and affiliated teaching hospitals in Makassar, Indonesia. The participating centres provided routine MDR-TB care and contributed clinical, laboratory, and TB-RO/SITB records for eligible patients. The study included patients with pulmonary multidrug-resistant tuberculosis (MDR-TB) who initiated treatment between January 1, 2021, and December 31, 2025. Treatment outcomes were ascertained from available records up to August 31, 2026. Data were obtained retrospectively from medical records, the national Tuberculosis Information System (SITB), laboratory records, and treatment monitoring documentation. The study was reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations [12].

2.2. Study Population and Eligibility Criteria

Total sampling was applied to all eligible patients during the study period. Pulmonary MDR-TB was defined by documented resistance to at least rifampicin and isoniazid, established through drug-susceptibility testing or line probe assays. Patients were eligible if they had confirmed pulmonary MDR-TB and received an all-oral treatment regimen classified as BPaL/BPaLM, short-term regimen (STR), or long-term regimen (LTR), based on the TB-RO/SITB registry and medical records.

Exclusion criteria comprised rifampicin-resistant tuberculosis without documented isoniazid resistance, exclusively extrapulmonary tuberculosis, transfer to another facility or unavailable final treatment outcomes, incomplete essential records, and duplicate treatment episodes. Of 709 patient records screened, 473 met the eligibility criteria and were included in the analysis (Figure 1).

2.3. Clinical and Nonclinical Variables

Baseline variables included age (≥60 versus <60 years), sex, nutritional status, diabetes mellitus, pulmonary lesion extent, initial bacillary burden, healthcare access, socioeconomic status, and diagnostic delay.

Underweight was defined as body mass index (BMI) <18.5 kg/m². Extensive pulmonary lesions were identified from baseline radiological reports indicating involvement of more than one lung field, cavitation, or bilateral disease. High initial bacillary burden was defined as sputum smear microscopy grading of 2+ or 3+, compared with negative, scanty, or 1+ results.

Limited healthcare access was defined by a distance of ≥10 km from the treatment facility or residence outside Makassar; travel time ≥60 minutes was used when distance information was unavailable. Low socioeconomic status was classified using participation in the government-subsidized health insurance scheme (*Penerima Bantuan Iuran*, PBI) as a proxy. Diagnostic delay was defined as an interval of ≥30 days between symptom onset and MDR-TB diagnosis.

Three additional variables were assessed during treatment. Medication non-adherence was defined as receipt of <90% of scheduled doses, assessed through the sixth treatment month or before the recorded outcome, whichever occurred first. Poor family support was determined from documented inadequate involvement of family members in treatment supervision or follow-up, rather than a validated questionnaire. Culture response was categorized as early (<3 months, including sustained negative results among patients with negative baseline cultures) or delayed/absent (≥3 months, persistent positivity, or recurrent positivity). These variables were treated as treatment-period characteristics rather than baseline predictors.

2.4. Treatment Outcome Assessment

Treatment outcomes were classified according to World Health Organization definitions [13]. Successful treatment comprised cure and treatment completion. Cure required completion of the prescribed regimen, clinical improvement, and at least two consecutive negative sputum cultures collected at least seven days apart. Treatment completion indicated completion of the prescribed regimen without evidence of treatment failure but without sufficient bacteriological documentation to classify the

patient as cured. Unsuccessful treatment comprised treatment failure, loss to follow-up, and death. Treatment failure was defined by permanent discontinuation or replacement of at least two drugs because of inadequate clinical or bacteriological response, adverse drug reactions, or additional drug resistance. Loss to follow-up was defined as treatment interruption for at least two consecutive months, while death included death from any cause during treatment. Patients transferred to another facility without an ascertainable final outcome were excluded. The primary dependent variable was coded as 1 for unsuccessful and 0 for successful treatment outcomes.

2.5. Statistical Analysis

Data were analyzed using IBM SPSS Statistics version 30 (IBM Corp., Armonk, NY, USA). Categorical variables were summarized as frequencies and percentages. Between-group comparisons were performed using Pearson's chi-square test, with Fisher's exact test considered when expected cell counts were inadequate. Crude odds ratios (ORs) and 95% confidence intervals (CIs) were estimated from 2×2 contingency tables.

Two multivariable binary logistic regression models were constructed. The baseline model simultaneously included nine clinical and nonclinical variables: age, sex, underweight status, diabetes mellitus, extensive pulmonary lesions, high initial bacillary burden, limited healthcare access, low socioeconomic status, and diagnostic delay. The second model additionally incorporated family support, medication adherence, and culture response to assess associations involving treatment-period characteristics.

Results were expressed as adjusted odds ratios (aORs) with 95% CIs. Model fit was assessed using the Hosmer–Lemeshow test, and Nagelkerke pseudo-R^2 was reported. A complete-case approach was used. Records without an ascertainable final treatment outcome or complete essential variables were excluded before model fitting. All 473 patients retained in the analysis had complete data for the variables included in both regression models; therefore, no imputation was performed. Statistical significance was set at $p<0.05$.

3. RESULTS AND DISCUSSION

3.1. Baseline Characteristics of the Study Population

Of 709 patient records assessed for eligibility, 236 were excluded because of incomplete data or failure to meet the eligibility criteria. The remaining 473 patients were included in the analysis (Figure 1). Successful outcomes comprised cure in 155 patients (32.8%) and treatment completion in 173 (36.6%), whereas unsuccessful outcomes comprised treatment failure in 107 (22.6%), loss to follow-up in 19 (4.0%), and death in 19 (4.0%).

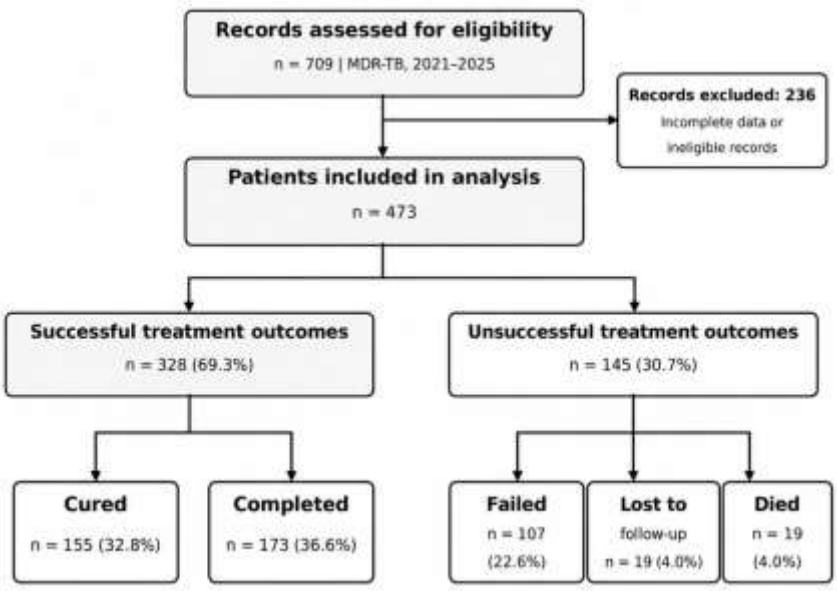

Figure 1. Study participant flow and treatment outcomes.

As shown in Table 1, patients with unsuccessful outcomes had significantly higher proportions of underweight nutritional status, extensive pulmonary lesions, high baseline bacillary burden, limited healthcare access, low socioeconomic status, and diagnostic delay of at least 30 days (all p<0.001). Age group, sex, and diabetes mellitus status did not differ significantly between the outcome groups.

Table 1. Baseline Characteristics of Patients According to Treatment Outcomes

Characteristics	Total (n=473)	Successful (n=328)	Unsuccessful (n=145)	p-value[a]
Age ≥60 years	65 (13.7)	43 (13.1)	22 (15.2)	0.548
Male sex	281 (59.4)	199 (60.7)	82 (56.6)	0.400
Underweight (BMI <18.5 kg/m²)	191 (40.4)	112 (34.1)	79 (54.5)	<0.001*
Diabetes mellitus	80 (16.9)	51 (15.5)	29 (20.0)	0.234
Extensive pulmonary lesions	230 (48.6)	132 (40.2)	98 (67.6)	<0.001*
High baseline bacillary burden	232 (49.0)	130 (39.6)	102 (70.3)	<0.001*
Limited healthcare access	139 (29.4)	81 (24.7)	58 (40.0)	<0.001*
Low socioeconomic status	236 (49.9)	147 (44.8)	89 (61.4)	<0.001*
Diagnostic delay ≥30 days	350 (74.0)	226 (68.9)	124 (85.5)	<0.001*

Notes: Data are presented as n (column %). [a] Pearson's chi-square test. *Statistically significant at p<0.05. BMI, body mass index. High bacillary burden indicates an initial sputum smear grade of 2+ or 3+. Low socioeconomic status was classified using the study's health insurance subsidy proxy.

3.2. Baseline Factors Associated with Unsuccessful Treatment Outcomes

In the univariable analysis, six baseline factors were significantly associated with unsuccessful treatment outcomes (Table 2). All six associations remained significant after multivariable adjustment. High baseline bacillary burden showed the strongest association (adjusted odds ratio [aOR] 3.27, 95% CI 2.07–5.17), followed by extensive pulmonary lesions (aOR 2.46, 95% CI 1.57–3.88) and diagnostic delay ≥30 days (aOR 2.29, 95% CI 1.27–4.15). Low socioeconomic status, underweight nutritional status, and limited healthcare access were also independently associated with unsuccessful outcomes. Age, sex, and diabetes mellitus were not significantly associated after adjustment.

Table 2. Baseline Factors Associated with Unsuccessful Treatment Outcomes

Factors	Crude OR (95% CI)	p[a]	Adjusted OR (95% CI)	p[b]
Age ≥60 years	1.19 (0.68–2.07)	0.548	1.36 (0.72–2.56)	0.343
Male sex	0.84 (0.57–1.25)	0.400	0.78 (0.50–1.23)	0.288
Underweight (BMI <18.5 kg/m²)	2.31 (1.55–3.44)	<0.001*	1.83 (1.18–2.85)	0.007*
Diabetes mellitus	1.36 (0.82–2.25)	0.234	1.72 (0.95–3.09)	0.072
Extensive pulmonary lesions	3.10 (2.05–4.67)	<0.001*	2.46 (1.57–3.88)	<0.001*
High baseline bacillary burden	3.61 (2.38–5.50)	<0.001*	3.27 (2.07–5.17)	<0.001*
Limited healthcare access	2.03 (1.34–3.08)	<0.001*	1.65 (1.01–2.70)	0.045*
Low socioeconomic status	1.96 (1.31–2.92)	<0.001*	1.96 (1.25–3.06)	0.003*
Diagnostic delay ≥30 days	2.67 (1.59–4.48)	<0.001*	2.29 (1.27–4.15)	0.006*

Notes: OR, odds ratio; CI, confidence interval; BMI, body mass index. [a] Pearson's chi-square test, with crude OR calculated from 2×2 tables. [b] Multivariable binary logistic regression (all nine factors entered simultaneously). *p<0.05. Reference categories were age <60 years, female sex, BMI ≥18.5 kg/m², no diabetes, minimal lesions, low bacillary burden, adequate healthcare access, higher socioeconomic status, and diagnostic delay <30 days.

The adjusted associations between baseline characteristics and unsuccessful treatment outcomes are illustrated in Figure 2. Six factors remained statistically significant after multivariable adjustment, with high baseline bacillary burden demonstrating the strongest association.

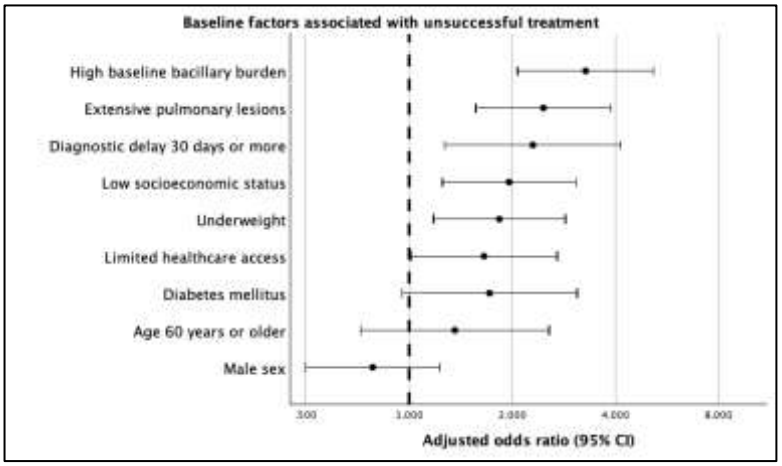

Figure 2. Forest plot of adjusted associations between baseline factors and unsuccessful treatment outcomes.

3.3. Treatment-Related Factors Associated with Unsuccessful Outcomes

Treatment-related factors were significantly associated with unsuccessful outcomes (Table 3). After adjustment for baseline clinical and socioeconomic characteristics, medication non-adherence showed the strongest association (adjusted odds ratio [aOR] 4.43, 95% CI 2.21–8.85), followed by delayed or absent culture response (aOR 3.33, 95% CI 2.01–5.52) and poor family support (aOR 3.07, 95% CI 1.65–5.73; all p<0.001). Adding treatment-period factors increased Nagelkerke's pseudo-R^2 from 0.269 in the baseline model to 0.413 in the expanded model. The baseline model showed a statistically significant Hosmer–Lemeshow test (χ^2=15.664, df=8, p=0.047), suggesting possible lack of fit, whereas the expanded model showed no statistically significant evidence of lack of fit (p=0.520).

Table 3. Treatment-Related Factors Associated with Unsuccessful Treatment Outcomes

Factors	Successful (n=328)	Unsuccessful (n=145)	Crude OR (95% CI)	Adjusted OR (95% CI)	p[a]
Poor family support	43 (13.1)	41 (28.3)	2.61 (1.61–4.24)	3.07 (1.65–5.73)	<0.001*
Medication non-adherence	27 (8.2)	34 (23.4)	3.41 (1.97–5.92)	4.43 (2.21–8.85)	<0.001*
Delayed or absent culture response	118 (36.0)	102 (70.3)	4.22 (2.77–6.44)	3.33 (2.01–5.52)	<0.001*

Notes: Data are presented as n (column %). OR, odds ratio; CI, confidence interval. [a] Multivariable binary logistic regression adjusted for nine baseline factors and the other treatment-related factors. Crude ORs were calculated from 2×2 tables. Reference categories: good family support, treatment adherence, and early culture response. *p<0.05.

3.4. Discussion

In this multicentre retrospective cohort, 69.3% of patients achieved successful treatment outcomes, approaching the 71% global success rate reported for the 2022 MDR/RR-TB cohort [1]. A previous Indonesian multicentre study reported 60.1% treatment

success among its MDR-TB subgroup [7]. A prospective Indonesian BPaL study reported successful outcomes in 82 of 84 patients with available outcomes (97.6%) [15]. These figures provide useful context, although differences in patient selection, disease severity, treatment regimens, and study periods limit direct comparisons. Treatment failure accounted for most unsuccessful outcomes in the present cohort (107 of 145 cases), highlighting the importance of understanding baseline disease burden and subsequent treatment response.

High baseline bacillary burden had the largest adjusted odds ratio among baseline characteristics (aOR 3.27; 95% CI 2.07–5.17), followed by extensive pulmonary lesions (aOR 2.46; 95% CI 1.57–3.88). These findings are consistent with Indonesian evidence associating higher sputum smear grades with unfavorable treatment outcomes [7]. A meta-analysis also linked baseline smear positivity and pulmonary cavitation to longer culture conversion times, although that outcome differs from final treatment success [6]. Underweight status was independently associated with unsuccessful treatment (aOR 1.83; 95% CI 1.18–2.85). This agrees with an individual-participant meta-analysis of rifampicin-resistant TB [4] and a systematic review showing associations between undernutrition, delayed culture conversion, and unsuccessful MDR-TB outcomes [5]. A Ugandan MDR-TB cohort reported similar findings using mid-upper arm circumference rather than BMI [16].

Nonclinical characteristics remained associated with unsuccessful outcomes after adjustment for baseline clinical factors. Diagnostic delay of at least 30 days (aOR 2.29), low socioeconomic status (aOR 1.96), and limited healthcare access (aOR 1.65) were independently associated with unfavorable outcomes. Our diagnostic-delay variable measured the interval from symptom onset to MDR-TB diagnosis. Research in Jakarta examined a different interval, from diagnosis to treatment initiation, and identified patient- and health-system barriers [9]. A Bandung care-cascade study similarly documented substantial delays and attrition across DR-TB services [10]. These findings complement evidence of the considerable financial burden faced by MDR-TB households [8]. An Indonesian study also associated economic limitations, insufficient social support, and dissatisfaction with healthcare services with loss to follow-up [17]. The socioeconomic association in our cohort should nevertheless be interpreted in relation to subsidized health insurance status, which served as a proxy rather than a direct measure of household income.

Treatment-period characteristics provided further insight. Medication non-adherence showed a strong association with unsuccessful outcomes (aOR 4.43; 95% CI 2.21–8.85), as did poor family support (aOR 3.07; 95% CI 1.65–5.73). A Southeast Asian meta-analysis reported a modest improvement in TB treatment completion following adherence-promoting interventions (RR 1.04; 95% CI 1.01–1.08), although it was not restricted to MDR-TB [18]. A mixed-methods review emphasized the importance of multidimensional, context-sensitive psychosocial support, while finding insufficient evidence that psychological support alone improves treatment outcomes [19]. Conversely, a cross-sectional study involving 79 Indonesian DR-TB patients found no significant relationship between questionnaire-assessed family support and medication compliance [20]. Differences in population, measurement, and outcomes may explain these findings. Our study assessed documented family involvement and final treatment outcomes, rather than perceived support and self-reported compliance.

Delayed or absent culture response was also strongly associated with unsuccessful treatment (aOR 3.33; 95% CI 2.01–5.52). In the multinational endTB cohort, longer time to initial culture conversion was associated with subsequent culture reversion [21]. Nevertheless, culture response requires careful interpretation in our study. The classification included patients with sustained negative baseline cultures, while persistent bacteriological positivity could also contribute to the definition of treatment failure. The observed association therefore reflects an important treatment-monitoring characteristic, rather than an independent predictor available at treatment initiation.

Age, sex, and diabetes mellitus were not significantly associated with unsuccessful outcomes after baseline adjustment. For diabetes, the adjusted estimate remained above unity (aOR 1.72; 95% CI 0.95–3.09). A meta-analysis of 25 studies reported higher odds of unsuccessful treatment among MDR-TB patients with diabetes (pooled OR 1.57; 95% CI 1.20–2.04) [22]. The present result is not necessarily inconsistent with this evidence, given its uncertainty and differences in patient characteristics. Although BPaL/BPaLM recipients showed a high observed success proportion, the small group size (n=22) and nonrandom regimen selection prevent conclusions about comparative effectiveness. The increase in Nagelkerke pseudo-R^2 from 0.269 to 0.413 after incorporating treatment-period characteristics indicates greater explanatory fit, not validated prognostic performance.

The multicentre setting and integration of clinical and programmatic records provide useful evidence from routine MDR-TB care in Eastern Indonesia. Retrospective documentation may introduce measurement error, particularly for symptom onset, adherence, and family involvement, while residual confounding and the temporal relationship between treatment-period variables and outcomes limit causal interpretation. Differences in patient characteristics and routine documentation across participating centres may also have contributed to unmeasured heterogeneity. Because inclusion required a documented final treatment outcome by August 31, 2026, patients who initiated longer regimens near the end of the recruitment period may have been underrepresented, potentially introducing selection bias. Reverse causation and time-dependent bias cannot be excluded for treatment-period characteristics because adherence, family involvement, and culture response were assessed after treatment initiation. An Indonesian patient-pathway study reported a median symptom-to-diagnosis interval of 62 days among patients with TB, illustrating the broader relevance of diagnostic delays, although it was not restricted to MDR-TB [23]. The present findings support integrated clinical and programmatic assessment, combining early evaluation of nutritional status, bacillary burden, and pulmonary involvement with attention to healthcare access, treatment adherence, family involvement, and bacteriological monitoring. Prospective multicentre studies with standardized assessments are warranted to further evaluate these associations.

4. CONCLUSION

In this multicentre retrospective cohort of patients with pulmonary MDR-TB receiving all-oral regimens, treatment success was achieved in 69.3% of patients. Unsuccessful outcomes were associated with both clinical disease burden and nonclinical barriers to care. High baseline bacillary burden emerged as the strongest baseline clinical correlate, while underweight status, extensive pulmonary lesions, diagnostic delay, limited healthcare access, and low socioeconomic status were also independently associated with unsuccessful outcomes. During treatment, medication non-adherence showed a particularly strong association, alongside poor family support and delayed or absent culture response. These findings highlight the importance of integrating baseline clinical assessment with accessible, patient-centred care, adherence support, family involvement, and bacteriological monitoring. Given the retrospective observational design and inclusion of treatment-period variables, these associations should not be interpreted as causal. An integrated approach addressing clinical vulnerability and barriers to continued treatment may support improvements in MDR-TB care in referral healthcare settings.

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AUTHOR CONTRIBUTIONS

AY: Conceptualization, Methodology, Investigation, Data Curation, Formal Analysis, Visualization, Project Administration, and Writing – Original Draft.

ID: Conceptualization, Methodology, Supervision, Validation, and Writing – Review & Editing.

MI: Conceptualization, Methodology, Supervision, Validation, and Writing – Review & Editing.

EA: Methodology, Validation, Supervision, and Writing – Review & Editing.

JM: Methodology, Validation, and Writing – Review & Editing.

SN: Methodology, Validation, and Writing – Review & Editing.

All authors critically reviewed the manuscript, approved the final version, and agreed to be accountable for the integrity and accuracy of the work.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

FUNDING

This research received no external funding.

ETHICS STATEMENT

This study was conducted in accordance with the ethical principles of the Declaration of Helsinki, as revised in 2024. Ethical approval was obtained from the Health Research Ethics Committee of the Faculty of Medicine, Hasanuddin University, Makassar, Indonesia (Protocol ID: UH26050619; Ethical Approval No. 752/UN4.6.4.5.31/PP36/2026), issued on June 17, 2026. The requirement for individual informed consent was waived in accordance with institutional ethical procedures because the study involved retrospective analysis of routinely collected medical records without direct patient contact. All patient information was de-identified, and confidentiality was maintained throughout the study.

DATA AVAILABILITY STATEMENT

The data supporting the findings of this study are available from the corresponding author upon reasonable request, subject to applicable ethical and institutional restrictions.

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