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FACTORS AFFECTING TREATMENT OUTCOMES IN HIV-ASSOCIATED PULMONARY TUBERCULOSIS AND AN ALGORITHM FOR ASSESSING TREATMENT COMPLEXITY

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Abstract

Treatment outcomes and the factors affecting them were analyzed in 79 patients with tuberculosis (n=41) and tuberculosis-HIV coinfection (n=38). The overall cure rate was 87.3%; no deaths were recorded during the study period. Univariate analysis of 11 candidate factors found none with statistically significant predictive value (all P>0.05). A clinical scoring system combining risk factors identified in earlier studies was proposed, but its validation in this cohort showed no reliable association with outcome — a finding that is discussed openly.

Keywords: treatment outcomes, risk factors, univariate analysis, odds ratio, complexity scoring system.

INTRODUCTION

Identifying the factors that affect the final treatment outcome in tuberculosis-HIV coinfection forms the scientific basis for shaping individualized treatment tactics and directing limited resources toward the highest-risk group of patients [13,14,17]. At the same time, conducting such analyses in small- and medium-sized clinical samples requires particular methodological caution: when the number of “unfavorable” events in the sample is limited, multivariate regression models can produce spuriously precise, uninterpretable results [2,4,8,10,12].

In this article, while openly acknowledging this methodological limitation, we adopt the most reliable analytical approach available within the constraints of the data — univariate screening and calculation of the odds ratio (OR) — and present the results obtained, including statistically non-significant (“null”) findings, with full transparency.

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It should also be emphasized that improving treatment outcomes and shortening treatment duration in phthisiology practice carries not only clinical but also economic and social significance: every additional bed-day and every episode of retreatment places an additional financial burden on the system [3,6,11,16,18]. Therefore, attempting to identify factors associated with outcome — even when they are not individually statistically significant — forms the scientific basis for achieving long-term economic efficiency through early risk stratification and the planning of preventive measures [1,5,7,9,15].

Aim of the study: To comparatively evaluate the final treatment outcomes in patients with tuberculosis and tuberculosis-HIV coinfection, to identify clinical and laboratory factors potentially associated with outcome by means of univariate analysis, and to propose and perform a preliminary validation of a practical scoring system combining risk factors identified in earlier studies.

Material and methods: The study included a total of 79 patients with tuberculosis (n=41) and tuberculosis-HIV coinfection (n=38). Treatment outcomes were assessed according to the standard categories accepted in international practice (cured, treatment failure with persistent MTB, lost to follow-up, transferred to another facility, died). The category "unfavorable outcome" included all four outcomes other than cure. For 11 candidate factors (HIV status, age, sex, drug resistance, type of treatment episode, comorbidity burden, use of second-line drugs, selenium/CRP status, body mass index, CD4 count), Fisher's exact test and the odds ratio (OR) with 95% confidence interval were calculated. Because the number of events was insufficient for multivariate regression (per the rule of 10 events per variable), a formal multivariate model was not constructed.

RESULTS AND DISCUSSION

Table 1.

Treatment outcomes (n=79)

Outcome	*TB+HIV (n=38)*		*TB (n=41)*		*P*	*Total (n=79)*	
	n	**%**	**n**	**%**		**n**	**%**
Cured	36	94.7±3.6	33	80.5±6.2	0.089	69	87.3±3.7
Treatment failure (persistent MTB)	0	0.0±0.0	2	4.9±3.4	0.494	2	2.5±1.8
Lost to follow-up	0	0.0±0.0	3	7.3±4.1	0.241	3	3.8±2.2
Transferred to another facility	2	5.3±3.6	3	7.3±4.1	1.000	5	6.3±2.7

The final treatment outcome was characterized by a high overall success rate: 87.3% of patients achieved complete cure, and no deaths were recorded during the study period. Notably, the cure rate was numerically higher in the coinfection group (94.7%)

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than in the tuberculosis group (80.5%); although this difference did not reach the conventional threshold of statistical significance (P<0.05), it was recorded at the level of a trend (P=0.089) — which may be explained by HIV-positive patients being under continuous dispensary follow-up at the ART center and, accordingly, adhering more closely to treatment. Loss to follow-up and treatment failure with persistent MTB, conversely, were recorded exclusively in the tuberculosis group, although these differences did not reach statistical significance.

Table 2.

Univariate analysis of factors potentially associated with unfavorable outcome (n=79)

Factor	Present		Absent		OR (95% CI)	P
	n	M±m (%)	n	M±m (%)		
HIV coinfection present	2	5.3±3.6	8	19.5±6.2	0.23 (0.05–1.16)	0.089
Age ≥60 years	7	20.6±6.9	3	6.7±3.7	3.63 (0.86–15.26)	0.090
Male sex	5	10.9±4.6	5	15.2±6.2	0.68 (0.18–2.58)	0.734
Drug-resistant form	4	22.2±9.8	6	9.8±3.8	2.62 (0.65–10.56)	0.224
Retreatment case	1	7.7±7.4	9	13.6±4.2	0.53 (0.06–4.57)	1.000
Comorbidity burden ≥2	5	16.7±6.8	5	10.2±4.3	1.76 (0.46–6.68)	0.492
Second-line drug use	3	16.7±8.8	7	11.5±4.1	1.54 (0.36–6.70)	0.687
Selenium deficiency	4	10.3±4.9	6	15.0±5.7	0.65 (0.17–2.50)	0.737
Elevated CRP	3	12.5±6.8	7	12.7±4.5	0.98 (0.23–4.16)	1.000
BMI <18.5	2	18.2±11.6	8	11.8±3.9	1.67 (0.30–9.13)	0.624
CD4 <200 (in TB+HIV, n=38)	1	4.2±4.1	1	7.1±6.9	0.57 (0.03–9.81)	1.000

None of the 11 factors examined reached the strict threshold of statistical significance (P<0.05). Nevertheless, two indicators stood out at the level of a trend

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(P≈0.09): the presence of HIV coinfection was numerically associated with a reduced risk of unfavorable outcome (OR=0.23), whereas age ≥60 years was associated, conversely, with an increased risk (OR=3.63). In both cases the 95% confidence interval crosses the line of unity, so these should be regarded not as a definitive conclusion but as a clinical hypothesis warranting testing in a larger sample. For the remaining factors, no reliable difference was found in either direction or magnitude.

Table 3.

Proposed scoring system for assessing treatment complexity

Criterion	***Points***
HIV coinfection present	2
CD4 <200 cells/μL	2
MDR/XDR tuberculosis form	3
Abnormal selenium and/or CRP	1
BMI <18.5	1
Comorbidity burden ≥2	1
Retreatment case	1
At least one second-line drug	1

The maximum possible score is 12. This system was developed as a preliminary model, proposed on the basis of clinical experience, combining clinical and laboratory indicators that had each been individually confirmed as statistically significant in our earlier studies. When validated against actual outcome data (n=79, including 10 unfavorable outcomes), the mean score was 3.40 among patients with an unfavorable outcome and 3.83 among patients who achieved complete cure (Mann-Whitney test, P=0.800); rank-based ROC analysis yielded an AUC of 0.475 — which is, in practice, no different from random chance.

There are several plausible reasons why the validation of the scoring system yielded a lower-than-expected result: first, the limited number of unfavorable outcomes in the sample (n=10) was insufficient for adequate statistical power; second, since no deaths were recorded in this cohort, there is no discriminating data for the most severe outcome category; and third, the weighting coefficients were chosen on the basis of clinical judgment rather than statistical derivation. For these reasons, this scoring system should be regarded not as a ready-to-use clinical tool but as a preliminary model proposed on the basis of clinical experience, and it is recommended that it be re-tested in the future on a larger prospective sample with more unfavorable outcomes (with re-estimation of the weighting coefficients). In keeping with scientific integrity, rather than presenting a

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statistically non-significant result as positive, we chose to report it openly and to set a clear direction for future research.

CONCLUSION

1. The overall cure rate among patients with tuberculosis and tuberculosis-HIV coinfection was high (87.3%), and no deaths were recorded during the study period; the cure rate in the coinfection group was numerically higher than in the tuberculosis group, at the level of a trend (94.7% vs. 80.5%; P=0.089).

2. None of the 11 clinical and laboratory factors examined was individually a statistically significant predictor of unfavorable outcome (all P>0.05), although HIV coinfection and age ≥60 years stood out at the level of a trend (P≈0.09).

3. The proposed scoring system, which combines risk factors confirmed in earlier studies, showed no reliable association with outcome upon statistical validation in this cohort (P=0.800; AUC=0.475) — a finding that is reported openly and that substantiates the need to re-test the system in a larger sample in the future.

4. The limited number of unfavorable outcomes in the sample (n=10) and the complete absence of deaths made a formal multivariate regression analysis methodologically infeasible — a limitation that is openly acknowledged in both the dissertation and this article, and that points to the need for future, higher-event, multicenter studies.

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