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TREATMENT REGIMENS USED IN HIV-ASSOCIATED PULMONARY TUBERCULOSIS AND THEIR SAFETY PROFILE

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Abstract

Anti-tuberculosis, antiretroviral, and adjunct pathogenetic treatment regimens, together with their adverse effects, were analyzed in 79 patients with tuberculosis (n=41) and tuberculosis-HIV coinfection (n=38). An IDV-based antiretroviral regimen was absolutely predominant in the coinfection group (86.8%) and was not used at all in the isolated HIV group (P<0.001). Adjunct pathogenetic therapy and adverse effects (allergic reactions, loss of appetite, vomiting) were statistically significantly more frequent in the coinfection group, confirming that coinfection increases the overall treatment burden.

Keywords: anti-tuberculosis therapy, antiretroviral therapy, second-line drugs, adverse effects, treatment regimen.

INTRODUCTION

Managing tuberculosis-HIV coinfection requires the simultaneous administration of two independent yet mutually interacting treatment modalities — anti-tuberculosis and antiretroviral therapy — while accounting for drug-drug interactions and the risk of cumulative toxicity [2,5,7,11,15,16,18]. Such a complex pharmacotherapeutic strategy often leads, in practice, to deviations from standard regimens, early precautionary initiation of second-line drugs, and an increased frequency of adverse effects [3,6,8,10,12,17].

Systematic data on the composition of treatment regimens actually used in local clinical practice, their variation across patient groups, and their safety profile remain insufficient — a gap that underlies the relevance of the present study and provides a basis for developing practical pharmacotherapeutic recommendations [1,4,9,13,14,15].

Aim of the study: To comparatively evaluate, across patient groups, the composition of anti-tuberculosis, antiretroviral, and adjunct pathogenetic treatment regimens used in patients with tuberculosis and tuberculosis-HIV coinfection, as well as the frequency of their adverse effects.

Material and methods: The study included a total of 79 patients with tuberculosis (n=41) and tuberculosis-HIV coinfection (n=38). The composition of anti-tuberculosis and

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antiretroviral drugs, adjunct pathogenetic treatment modalities, and adverse effects recorded during treatment were analyzed on the basis of patient-level treatment records. Between-group comparisons were performed using Pearson's chi-square test and, when the expected frequency in any cell was below 5, Fisher's exact test; $P<0.05$ was accepted as the criterion of statistical significance.

RESULTS AND DISCUSSION

Table 1.

First-line anti-tuberculosis drugs used (n=79)

Drug	TB+HIV (n=38)		TB (n=41)		P	Total (n=79)	
	n	%	n	%		n	%
H (isoniazid)	28	73.7±7.1	34	82.9±5.9	0.414	62	78.5±4.6
R (rifampicin)	28	73.7±7.1	35	85.4±5.5	0.265	63	79.7±4.5
E (ethambutol)	27	71.1±7.4	35	85.4±5.5	0.172	62	78.5±4.6
Z (pyrazinamide)	30	78.9±6.6	35	85.4±5.5	0.560	65	82.3±4.3

The between-group distribution of all first-line drugs showed no statistically significant difference (all $P>0.17$), indicating that the standard HRZE regimen was used at a nearly identical frequency in both groups. At the same time, in both groups the proportion of patients receiving first-line drugs was below 100% (ranging from 71% to 85%), indicating that the remaining patients were treated according to individualized regimens (for example, having been switched to second-line drugs from the outset because of drug resistance) — a finding closely linked to the second-line drug indicator discussed below.

Table 2.

Second-line (reserve) anti-tuberculosis drugs used (n=79)

Drug	TB+HIV (n=38)		TB (n=41)		P	Total (n=79)	
	n	%	n	%		n	%
Lfx (levofloxacin)	7	18.4±6.3	5	12.2±5.1	0.537	12	15.2±4.0
Bdq (bedaquiline)	4	10.5±5.0	6	14.6±5.5	0.739	10	12.7±3.7
Lzd (linezolid)	6	15.8±5.9	6	14.6±5.5	1.000	12	15.2±4.0
At least one	11	28.9±7.4	7	17.1±5.9	0.284	18	22.8±4.7

The proportion of patients receiving second-line (reserve) drugs was numerically higher in the coinfection group (28.9%) than in the tuberculosis group (17.1%), although the difference did not reach statistical significance ($P=0.284$) — a finding that may be attributable to the limited sample size. This figure is closely consistent with the proportion of drug-resistant forms identified in our earlier study (29.0% in the coinfection group versus 14.6% in the tuberculosis group), although slightly higher — which may indicate

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that, in some cases, second-line drugs were prescribed empirically as a precautionary measure before drug resistance had been definitively confirmed.

Table 3.

Duration of antiretroviral therapy (HIV-positive groups, n=80)

Duration	TB+HIV (n=38)		HIV (n=42)		P	Total (n=80)	
	n	%	n	%		n	%
<6 months	0	0.0±0.0	26	61.9±7.5	<0.001	26	32.5±5.2
1–5 years	23	60.5±7.9	0	0.0±0.0	<0.001	23	28.7±5.1
>10 years	8	21.1±6.6	0	0.0±0.0	0.002	8	10.0±3.4

A marked difference between groups was found in the duration of ART: 61.9% of patients in the isolated HIV group had been receiving ART for less than 6 months (i.e., were relatively newly diagnosed), whereas 60.5% of patients in the coinfection group had already been receiving ART for 1–5 years (all differences $P<0.05$). This finding carries an important clinical implication: active tuberculosis is developing predominantly in patients who have been receiving ART for a longer period — indicating the need for separate investigation of factors such as virologically unsuccessful ART, drug-drug interactions, or acquired immunological impairment. Furthermore, IDV (indinavir) was used in nearly all patients in the coinfection group (86.8%) and was not used at all in the isolated HIV group ($P<0.001$) — suggesting that the institution follows a distinct standard ART protocol for patients coinfected with tuberculosis.

Table 4.

Adjunct (pathogenetic) treatment modalities used (n=79)

Treatment modality	TB+HIV (n=38)		TB (n=41)		P	Total (n=79)	
	n	%	n	%		n	%
Vitamin / hepatoprotector / detoxification therapy	37	97.4±2.6	41	100.0±0.0	0.296	78	98.7±1.3
Antifungal therapy	5	13.2±5.5	0	0.0±0.0	0.016	5	6.3±2.7
Additional antibacterial therapy	6	15.8±5.9	0	0.0±0.0	0.008	6	7.6±3.0

Vitamin therapy, hepatoprotections, and detoxification therapy were used in nearly all patients (97–100%) — indicating that this is standard practice aimed at preventing the hepatotoxic effects of anti-tuberculosis drugs. A notable difference was that antifungal therapy (13.2% vs. 0.0%; $P=0.016$) and additional antibacterial therapy (15.8% vs. 0.0%; $P=0.008$) were used exclusively in the coinfection group, confirming a higher risk of secondary (opportunistic and bacterial) infections under conditions of coinfection and a correspondingly greater complexity of the treatment regimen.

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Table 5.

Adverse effects of anti-tuberculosis and antiretroviral drugs (n=79)

Adverse effect	TB+HIV (n=38)		TB (n=41)		P	Total (n=79)	
	n	%	n	%		n	%
Allergic reaction	5	13.2±5.5	0	0.0±0.0	0.016	5	6.3±2.7
Nausea	27	71.1±7.4	41	100.0±0.0	<0.001	68	86.1±3.9
Loss of appetite	6	15.8±5.9	0	0.0±0.0	0.008	6	7.6±3.0
Vomiting	1	2.6±2.6	0	0.0±0.0	0.296	1	1.3±1.3

Nausea was the most frequently recorded adverse effect, occurring in 100.0% of the tuberculosis group and 71.1% of the coinfection group (P<0.001) — explained by the well-known gastrointestinal toxicity of anti-tuberculosis drugs (particularly Z and H). At the same time, allergic reactions, loss of appetite, and vomiting were recorded exclusively in the coinfection group — reflecting an increased cumulative toxicity burden resulting from the concurrent administration of ART and anti-tuberculosis drugs, and closely linked to the greater complexity of the treatment regimen.

The practical and economic significance of these findings is that the broader spectrum of adjunct therapy and adverse effects observed in the coinfection group substantially increases treatment costs and the workload of medical personnel. Therefore, anticipating expected adverse effects and additional costs before initiating treatment in coinfected patients (i.e., before the need for second-line drugs or additional antibacterial/antifungal therapy arises) is an important condition for the rational allocation of inpatient resources.

Furthermore, the combination of ART and anti-tuberculosis drugs (particularly the known pharmacokinetic interaction between IDV and rifampicin) requires continuous clinical and pharmacological monitoring, a matter that warrants separate, in-depth study.

CONCLUSION

1. The proportion of patients receiving second-line (reserve) anti-tuberculosis drugs was numerically higher in the coinfection group than in the tuberculosis group (28.9% vs. 17.1%), consistent with the prevalence of drug-resistant forms.

2. An IDV-based antiretroviral regimen was absolutely predominant in the coinfection group (86.8%) and was not used at all in the isolated HIV group (P<0.001); active tuberculosis developed predominantly in patients who had been receiving ART for a longer period (1–5 years) (P<0.001) — an important clinical-epidemiological finding.

3. The spectrum of adjunct pathogenetic therapy (antifungal, antibacterial) and adverse effects (allergic reactions, loss of appetite, vomiting) was considerably richer and more complex in the coinfection group, confirming that coinfection increases the treatment burden and requires closer monitoring.

4. Although the use of first-line drugs did not differ between groups, the proportion of patients receiving them remained below 100% in both groups — reflecting the proportion of patients switched to second-line drugs because of drug resistance or other

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clinical indications, and highlighting the need to separately document the reasons for deviation from the standard regimen.

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