



Original Article



The Frequency of Raised Liver Enzyme in Patients on Anti-Tuberculosis Drugs

Tariq Abdullah¹, Abdul Khalid¹, Mehwish Mumtaz², Mazhar Hamdani¹ and Muhammad Ali Shahid³¹Department of Medicine, Abbas Institute of Medical Sciences, Muzaffarabad, Pakistan²Department of Medicine, Combined Military Hospital, Rawalakot, Pakistan³Department of Pulmonology, Abbas Institute of Medical Sciences, Muzaffarabad, Pakistan

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***Corresponding Author:**

Tariq Abdullah
 Department of Medicine, AIMS Hospital,
 Muzaffarabad, Pakistan
khawajatarqabdullah93@gmail.com

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ABSTRACT

Anti-tuberculosis therapy is associated with hepatotoxicity, which may manifest as elevation of liver enzymes and can affect treatment adherence and outcome. **Objective:** To determine the frequency of raised liver enzymes in patients receiving anti-tuberculosis therapy. **Methods:** This prospective observational study was conducted at the Department of Medicine, AIMS Muzaffarabad, from May 2025 to December 2025. A total of 200 patients aged 18 to 70 years with pulmonary tuberculosis were enrolled through consecutive non-probability sampling. Patients with pre-existing liver disease, viral hepatitis, HIV, pregnancy, alcohol use, or concurrent hepatotoxic medications were excluded. All patients received standard first-line anti-tuberculosis therapy. Liver function tests were performed at baseline, 2 weeks, 4 weeks, 2 months, 4 months, and 6 months. Data were analyzed using SPSS version 30. **Results:** The mean age was 44.17 ± 15.55 years, and 59% were male. Elevated ALT was observed in 29.0%, AST in 39.0%, and ALP in 7.0% patients. Overall, hepatotoxicity was observed in 57% patients. Elevated enzyme concentration was more common among subjects aged over 50 and subjects with a BMI over 25 kg/m²; nevertheless, no statistical significance was reached for these observations. The levels of enzymes significantly increased during the follow-up periods ($p < 0.001$). **Conclusion:** Antitubercular therapy is commonly associated with a considerable frequency of raised liver enzymes, emphasizing the need for proper monitoring in antitubercular therapy.

INTRODUCTION

Anti-tuberculosis drugs form the cornerstone of tuberculosis management, a chronic and potentially life-threatening infectious disease caused by *Mycobacterium tuberculosis* [1]. If left untreated, tuberculosis can severely damage the lungs and other organs, and its ability to spread through airborne droplets makes it a major public health concern worldwide [2]. The standard treatment regimen generally consists of a carefully designed combination of drugs such as isoniazid, rifampicin, pyrazinamide, and ethambutol [3]. These drugs act on the bacterium in different ways, and their combined effect works synergistically in eliminating the bacterium from causing infections, while at the same time avoiding the formation of

resistant strains [4]. Like all powerful drugs, there is a risk involved when using antituberculosis drugs. This is due to their side effects, which can affect different body organs. While some of the adverse effects are lesser and include gastrointestinal symptoms, vomiting, and dermatitis, other severe side effects are also common [5]. Adverse effects associated with these important medications should be carefully considered. These include the aspect of hepatotoxicity, which is well-known and common, especially when the medicines are either isoniazid, rifampicin, or pyrazinamide [6]. These medications, which are highly effective, cause considerable liver distress and can disrupt the metabolism of the liver. This adverse effect



is particularly common among patients having underlying factors such as advanced age, existing liver disease, excessive alcohol intake, malnutrition, and exposure to additional liver-toxic medications [7]. Hepatotoxicity as a result of an elevation in liver enzymes is a major sign of toxicity in patients receiving anti-TB medications, and it signifies damage or distress to the liver [8]. In some patients, the level of ALT, AST, and bilirubin is noted to be elevated [9]. In mild cases, there are no symptoms, but the elevation is reversible upon adjustment of the medication dose and termination of the therapy. In more severe cases, there might be rapid progression of hepatotoxicity, which can result in jaundice and an inability of the liver to work effectively. It can even cause liver failure in some cases. This would hamper the efficiency and success of the tuberculosis control program. Improper adjustment of the anti-TB drugs would reduce efficacy [10]. This is why the routine testing of liver functions should be done periodically, especially in the intensive stage of treatment. The study conducted by Shaikh et al revealed the incidence rate of ALT elevation was 29.6%, AST elevation was 39%, and ALP elevation was 7.4% in patients taking anti-tuberculosis drugs [11].

TB has been one of the health issues in Muzaffarabad for many years, with a high number of patients who need treatment with TB medicines. It should be noted that although it is very effective, its side effect is that this treatment produces adverse effects on the liver, especially an increase in enzyme levels in the liver. Since little literature is available in this regard locally, it becomes difficult to calculate the risk involved. This study, which has been carried out in Muzaffarabad, will be of great help in that respect.

METHODS

This Prospective observational study was carried out in the Department of Medicine, AIMS Muzaffarabad, Azad Jammu and Kashmir, from May 2025 to December 2025. A total of 200 patients diagnosed with pulmonary tuberculosis were included. The sample size was calculated through the WHO sample size determination software, applying a 95% confidence interval, a 3.7% margin of error, and an anticipated frequency of raised alkaline phosphatase of 7.4% among individuals receiving anti-tuberculosis therapy [11]. A non-probability consecutive sampling technique was employed for patient recruitment. Ethical approval for the study was obtained from the Institutional Review Board of AIMS Muzaffarabad (IRB No. 8810/AIMS/2025). The subjects selected had to be within the age range of 18 to 70 years of either gender, and must have satisfied the diagnosis requirements of tuberculosis. Diagnosis of tuberculosis was based on the presence of pulmonary consolidation on the chest radiographs and

Mantoux reaction positivity with induration of ≥ 10 mm recorded after 48-72 hours. Individuals suffering from pre-existing hepatic disorders, associated infections like hepatitis B, hepatitis C, or HIV, alcoholism, use of hepatotoxic drugs, pregnancy, or lactation amongst women were excluded from the study. Informed consent was obtained from all the subjects before the commencement of the experiment. Basic demographic details were noted, such as age, gender, body mass index, socioeconomic status, education, residency, and the duration of presenting complaints. Detailed history and physical examination were performed, and standardized anti-tuberculosis therapy was initiated. During the intensive phases, the patients were put on isoniazid (5 mg/kg, maximum 300 mg/day), rifampin (10 mg/kg, maximum 600 mg/day), pyrazinamide (25 mg/kg/day), and ethambutol (15 mg/kg, maximum 1.5 g/day) for two months. This was followed by the continuation phase, which was continued for four months and involved the administration of isoniazid and rifampin at the same doses. The doses were individualized based on age and weight. Liver function test was planned at the start of the therapy during the second week, fourth week, and the second and fourth months. After the sixth month of therapy, 5 mL of venous blood was taken using Vacutainer tubes by an experienced fourth-year resident and analyzed for biochemical values. ALT >42 U/L, AST >42 U/L, and ALP >120 U/L were considered elevated based on standard laboratory reference ranges [12]. Elevated levels were considered to be raised liver enzymes.

All of the data were entered and analyzed using SPSS 30.0. Quantitative variables like age, BMI, and duration of symptoms were expressed as mean and standard deviation. Categorical data, including sex, socioeconomic class, residence, educational background, and frequency of raised liver enzymes, were expressed as frequencies and percentages. Raised ALT, AST, and ALP were stratified against demographic and clinical variables, and statistical significance was determined using chi-square or Fisher's exact test where appropriate, with a p-value ≤ 0.005 considered significant.

RESULTS

In this study evaluating the frequency of raised liver enzymes in patients on anti-tuberculosis therapy, the mean age was 44.17 ± 15.55 years, and the mean BMI was 23.22 ± 2.98 kg/m² (as shown in Table-1). Of the 200 patients, 118 (59.0%) were male, and 82 (41.0%) females; 138 (69.0%) were rural residents, and 62 (31.0%) were urban dwellers. Socioeconomically, 120 (60.0%) belonged to the low-income group, 58 (29.0%) to the middle-income group, and 22 (11.0%) to the high-income group (Table 1).

Table 1: Patient Demographics

Demographics	Mean ± SD
Age (Years)	44.17 ± 15.55
BMI (kg/m ²)	23.22 ± 2.98
Gender	
Male n (%)	118 (59%)
Female n (%)	82 (41%)
Residence	
Rural n (%)	138 (69%)
Urban n (%)	62 (31%)
Socioeconomic Status	
Low n (%)	120 (60%)
Middle n (%)	58 (29%)
High n (%)	22 (11%)

The mean ALT, AST, and ALP levels were 41.42 ± 29.69, 48.90 ± 34.43, and 91.56 ± 35.71 U/L, respectively. Among 200 patients on anti-tuberculosis drugs, raised ALT was observed in 58 (29%), raised AST in 78 (39%), and raised ALP in 14 (7%) patients. Overall hepatotoxicity was recorded in 114 (57%) patients (Table-2).

Table 2: Frequency of Raised Liver Enzymes in Patients on Anti-tuberculosis Drugs

Liver Enzyme	Mean ± SD
ALT (U/L)	41.42 ± 29.69
AST (U/L)	48.90 ± 34.43
ALP (U/L)	91.56 ± 35.71
Liver Enzyme	n (%)
Raised ALT	58 (29%)
Raised AST	78 (39%)
Raised ALP	14 (7%)
Overall Hepatotoxicity	114 (57%)

Stratified analysis of raised ALT showed that among patients aged ≤50 years, 30 (24.2%) had raised ALT compared to 94 (75.8%) without, while in those >50 years, 28 (36.8%) had raised ALT versus 48 (63.2%) normal (OR=1.83, p=0.077). Among males, 34 (28.8%) had raised ALT and 84 (71.2%) normal, while among females, 24 (29.3%) had raised ALT and 58 (70.7%) normal (OR=0.98, p=0.944). In patients with BMI ≤25, 40 (26.3%) had raised ALT compared to 112 (73.7%) normal, while patients with BMI > 25 had 18 (37.5%) raised versus 30 (62.5%) normal (OR=1.68, p=0.137). By residence, 38 (27.5%) rural patients had raised ALT and 100 (72.5%) normal, compared to 20 (32.3%) urban patients with raised and 42 (67.7%) normal (OR=1.25, p=0.496). According to socioeconomic status, 36 (30.0%) low-income patients had raised ALT, while 84 (70.0%) were normal, 16 (27.6%) middle-income raised vs. 42 (72.4%) normal, and 6 (27.3%) high-income raised vs. 16 (72.7%) normal (OR=1.14 for low vs high, p=0.929). For AST, among ≤50 years, 46 (37.1%) patients had raised levels, while 78 (62.9%) were normal, compared to >50 years,

where 32 (42.1%) had raised levels, and 44 (57.9%) were normal (OR=1.23, p=0.481). Male patients had 46 (39.0%) raised AST vs. 72 (61.0%) normal, and females had 32 (39.0%) raised vs. 50 (61.0%) normal (OR=1.00, p=0.995). In the BMI ≤25 group, 56 (36.8%) had raised AST vs. 96 (63.2%) normal, while the BMI >25 group had 22 (45.8%) raised vs. 26 (54.2%) normal (OR=1.45, p=0.266). By residence, 56 (40.6%) rural patients had raised AST, and 82 (59.4%) had normal, compared to 22 (35.5%) urban patients raised and 40 (64.5%) normal (OR=0.80, p=0.494). Socioeconomic status showed 50 (41.7%) raised vs. 70 (58.3%) normal in low, 18 (31.0%) raised vs. 40 (69.0%) normal in middle, and 10 (45.5%) raised vs. 12 (54.5%) normal in high group (OR=0.86 for low vs high, p=0.318). For ALP, among ≤50 years, 8 (6.5%) had raised ALP vs. 116 (93.5%) normal, while >50 years had 6 (7.9%) raised vs. 70 (92.1%) normal (OR=1.24, p=0.698). Male patients showed 8 (6.8%) raised vs. 110 (93.2%) normal, while females had 6 (7.3%) raised vs. 76 (92.7%) normal (OR=0.92, p=0.884). In the BMI ≤25 group, 8 (5.3%) had raised ALP vs. 144 (94.7%) normal, compared to the BMI >25 group with 6 (12.5%) raised vs. 42 (87.5%) normal (OR=2.57, p=0.087). By residence, 12 (8.7%) rural patients had raised ALP vs. 126 (91.3%) normal, while only 2 (3.2%) urban patients had raised vs. 60 (96.8%) normal (OR=0.35, p=0.233). Socioeconomic differences were significant: 6 (5.0%) low-income patients had raised ALP vs. 114 (95.0%) normal, 8 (13.8%) middle-income raised vs. 50 (86.2%) normal, and none in the high-income group (0.0% vs. 100%) (OR=3.04 for middle vs low, p=0.040) (Table-3).

Table 3: Association of Raised Liver Enzymes with Demographic Factors

Demographic Factors		Raised ALT			OR	p-value
		Yes, n (%)	No, n (%)	Total		
Age (years)	≤50	30 (24.2%)	94 (75.8%)	124	1.83	0.077
	>50	28 (36.8%)	48 (63.2%)	76		
Gender	Male	34 (28.8%)	84 (71.2%)	118	0.98	0.944
	Female	24 (29.3%)	58 (70.7%)	82		
BMI (Kg/m ²)	≤25	40 (26.3%)	112 (73.7%)	152	1.68	0.137
	>25	18 (37.5%)	30 (62.5%)	48		
Residential Status	Rural	38 (27.5%)	100 (72.5%)	138	1.25	0.496
	Urban	20 (32.3%)	42 (67.7%)	62		
Socioeconomic Status	Low	36 (30.0%)	84 (70.0%)	120	1.14	0.929
	Middle	16 (27.6%)	42 (72.4%)	58		
	High	6 (27.3%)	16 (72.7%)	22		
Raised AST						
Age (years)	≤50	46 (37.1%)	78 (62.9%)	124	1.23	0.481
	>50	32 (42.1%)	44 (57.9%)	76		
Gender	Male	46 (39.0%)	72 (61.0%)	118	1.00	0.995
	Female	32 (39.0%)	50 (61.0%)	82		
BMI (Kg/m ²)	≤25	56 (36.8%)	96 (63.2%)	152	1.45	0.266
	>25	22 (45.8%)	26 (54.2%)	48		
Residential Status	Rural	56 (40.6%)	82 (59.4%)	138	0.80	0.494
	Urban	22 (35.5%)	40 (64.5%)	62		

Socioeconomic Status	Low	50 (41.7%)	70 (58.3%)	120	0.86	0.318
	Middle	18 (31.0%)	40 (69.0%)	58		
	High	10 (45.5%)	12 (54.5%)	22		
Raised ALP						
Age (years)	≤50	8 (6.5%)	116 (93.5%)	124	1.24	0.698
	>50	6 (7.9%)	70 (92.1%)	76		
Gender	Male	8 (6.8%)	110 (93.2%)	118	0.92	0.884
	Female	6 (7.3%)	76 (92.7%)	82		
BMI (Kg/m ²)	≤25	8 (5.3%)	144 (94.7%)	152	2.57	0.087
	>25	6 (12.5%)	42 (87.5%)	48		
Residential Status	Rural	12 (8.7%)	126 (91.3%)	138	0.35	0.233*
	Urban	2 (3.2%)	60 (96.8%)	62		
Socioeconomic Status	Low	6 (5.0%)	114 (95.0%)	120	3.04	0.040*
	Middle	8 (13.8%)	50 (86.2%)	58		
	High	0 (0.0%)	22 (100.0%)	22		

*Fisher's Exact Test

Binary logistic regression analysis demonstrated no statistically significant interaction between gender and duration of therapy in relation to overall hepatotoxicity ($p = 0.238$) (Table 4).

Table 4: Logistic Regression Analysis for Interaction Between Gender and Duration of Therapy in Relation to Overall Hepatotoxicity

Variables	B	SE	OR (Exp B)	p-value
Gender	1.402	1.186	4.063	0.237
Duration	3.563	1.066	35.265	<0.001
Gender × Duration	-0.827	0.701	0.438	0.238

DISCUSSION

Present study values are similar proportions as recorded by Sehar *et al.* which were 11.33%, which were lower compared to our study, possibly because the study had strictly applied their biochemical abnormality definition ($>3 \times$ ULN) compared to our study that recorded elevated enzymes despite modest elevations [13]. Our findings are more aligned with the study conducted by Malik *et al.* which revealed the presence of hepatotoxicity in 36.8% of patients, corresponding to the total percentage of enzyme elevation observed in our study [14]. This correspondence could be due to similarities possibly existing between both study populations, mainly the preponderance of middle-aged patients on standard therapy. However, the study conducted by Shahid *et al.* observed an alarming proportion of 55%, especially in patients undergoing thrice-weekly combination therapy of INH, RIF, and PZA, which produced 100% hepatotoxicity [15]. This observed discrepancy could be attributed to the smaller study population and possibly the use of more hepatotoxic drug combinations, as well as regional factors. Mansoor *et al.* observed marked increases in levels of ALT, AST, bilirubin, and alkaline phosphatases during the intensive phase, thus validating the corresponding observation that subclinical

hepatotoxicity occurs commonly and the monitoring of enzymes is necessary. Compared to Akkahadsee *et al.* who had an incidence of 14.45% for anti-tuberculosis drug-induced liver injury (ATDILI) in Thailand, our study had significantly higher figures for the elevation of enzymes [16, 17]. This may be attributed to the fact that Akkahadsee *et al.* included participants with normal baseline liver function and applied stricter diagnostic criteria, unlike the present study, which looked for any increase above the normal values. Furthermore, their identification of malnutrition, comorbidities, and alcohol as key risk factors is consistent with our observation of higher risk in patients with older age and higher BMI, suggesting that multiple patient-related factors contribute to susceptibility [17]. Tariq *et al.* reported 8% hepatotoxicity with only 0.2% mortality, which is much lower than our observed frequency, which may again be attributed to regional variation and difference in case definition [18]. Memon *et al.* demonstrated a 16.93% frequency of hepatotoxicity in patients with HCV co-infection, a lower rate compared to ours, but their much higher ALT and AST values at peak toxicity suggest more severe liver injury likely due to underlying hepatic compromise [19]. Overall, our findings are comparable with regional data that demonstrate a higher burden of ATT-related hepatotoxicity compared to international reports, which may reflect population-based risk factors, including nutritional status, comorbidities, and monitoring practice [16-18]. This association of longer duration of therapy and elevated enzymes observed in our study further emphasizes the significance of liver function monitoring, which has been advised in various investigations [20]. No significant interactions between gender and duration were observed, indicating that the effects of treatment duration on hepatotoxicity do not differ between males and females. The study was a single center study using an observational prospective study design that may limit the applicability of the findings in the general population. The prospective observational design allowed assessment of temporal changes in liver enzyme levels during therapy; however, it does not permit inference of causal relationships, and the findings should be interpreted as associations only. Importantly, important confounders like nutritional factors, pre-existing subclinical hepatic dysfunction, and genetic factors were not considered in the study design. The study has extensively used biochemical markers, but has not clinically validated the degree of liver toxicity suffered by patients. The duration of therapy was not quantitatively analyzed, which limits understanding of time-dependent hepatotoxic effects.

There are some limitations that need to be considered in this study. This is a single-center prospective

observational study done in a tertiary care hospital, and this could limit its applicability to a larger population. As an observational study, it can only determine associations but cannot prove any cause and effect, and the temporality in the exposure to drugs and the increase in enzyme levels must not be assumed as being causal. Some confounders, such as nutrition, the presence of asymptomatic liver disease, and genetic predisposition, which may have affected the outcome of the study, were not determined in this study. No relation to the biochemical indices was made to the clinical manifestations of hepatotoxicity. In addition, no quantitative correlation of the cumulative duration of treatment with increased enzyme levels was made in this study. Therefore, it may not be concluded from this study that there is a drug-related effect, since uncontrolled confounding variables might have influenced the outcome of this study.

CONCLUSIONS

The study found that patients on anti-tuberculous medication developed frequent abnormal liver enzymes. This was associated with those who have had long-term treatment, older patients, higher body mass index, and low socioeconomic class, though there is no cause-and-effect relationship. Monitoring of the liver function during medication is very necessary.

Authors' Contribution

Conceptualization: AT

Methodology: MM, MAS

Formal analysis: AT, AK, MH

Writing and Drafting: AT

Review and Editing: AT, AK, MM, MH, MAS

All authors approved the final manuscript and take responsibility for the integrity of the work

Conflicts of Interest

All the authors declare no conflict of interest.

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