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Drug-Induced Liver Injury in Newly Diagnosed Patients with Tuberculosis on Anti-Tuberculous Therapy: A Prospective Cohort Study

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Article Info

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Date Received:
06th June, 2026
Date Revised:
08th July, 2026
Date Accepted:
23rd July, 2026

Check for updates

This article may be cited as:
Khan S, Rahman S, Rahim F, Fatima R, Saeed S, Amin S: Rug-Induced Liver Injury in Newly Diagnosed Patients with Tuberculosis on Anti-Tuberculous Therapy: A Prospective Cohort Study. J Postgrad Med Inst. 2026;40(3):184-90. http://doi.org/10.54079/jpmi.40.3.3960

Abstract

Objective: This study aimed to determine the cumulative incidence and clinical risk factors of Drug-induced liver injury (DILI) in patients on anti-tuberculous therapy (ATT).

Methodology: A single-arm prospective cohort study was conducted at Hayatabad Medical Complex, Peshawar, evaluating 222 newly diagnosed tuberculosis (TB) patients initiated on first-line ATT. Patients with abnormal baseline liver function tests (LFTs), pregnancy, alcohol use, or concurrent hepatotoxic medication use were excluded. Enrolled participants underwent clinical and biochemical follow-up at the end of the second, fourth, and eighth weeks, or at any time in case they developed symptoms of DILI. Drug-induced liver injury was diagnosed using the standardized American Thoracic Society (ATS) criteria. Associations between the risk factors and DILI were evaluated using Mann-Whitney U and Chi-square / Fisher's exact tests and multivariable logistic regression analysis.

Results: The cumulative incidence of DILI was 14% (n=31), with 90.3% (n=28) of cases occurring within the first four weeks of starting therapy. Symptomatic presentation occurred in 61.3% (n=19) of cases, with nausea (78.9%) and anorexia (63.2%) being the most frequent clinical manifestations. Age (AOR: 1.04, 95% CI: 1.01 – 1.07, p = 0.005), chronic liver disease (AOR: 3.82, 95% CI: 1.10 – 13.24, p = 0.034), and obesity (AOR: 2.48, 95% CI: 1.05 – 5.88, p = 0.039) were identified as independent predictors of DILI.

Conclusion: The cumulative incidence of ATT-induced DILI was 14%, with most cases presenting within the first month of treatment. Increasing age, chronic liver disease, and obesity were significant risk factors for DILI.

Keywords: anti-tuberculous treatment, chronic liver disease, cohort, drug induced liver injury

Introduction

Tuberculosis (TB) is an infectious disease caused by Mycobacterium tuberculosis, it is an important cause of morbidity and mortality worldwide.[1] Tuberculosis commonly affects the lungs, but extra-pulmonary involvement is also reported.[2,3] TB can either be present as a latent infection or active disease, with active disease being associated with the highest risk of transmission.[3,4] Globally, approximately 10.7 million cases of TB are diagnosed each year, resulting in approximately 1.23 million deaths annually. In Pakistan, approximately 600,000 new cases occur each year, with approximately 140 deaths daily due to TB. Pakistan is classified among the top five countries with significant TB prevalence, thus contributing a significant burden on the limited healthcare resources of the country.[1]

The management of TB includes the use of a multi-drug combination called anti-tuberculous therapy (ATT).[5] Anti-tuberculous therapy is one of the important causes of drug-induced liver injury (DILI).[6,7] The incidence of DILI secondary to ATT is reported to be approximately 3%-28%, and it varies widely as factors such as genetic predisposition, malnutrition, underlying liver diseases, and other comorbid conditions influence susceptibility to hepatotoxicity.[2,8] Traditionally, DILI is classified as intrinsic (or direct) and idiosyncratic.[8] Intrinsic DILI is due to drugs that are inherently toxic to the liver. This type of DILI is typically dose- related, predictable, and the onset is within hours to days. In contrast, Idiosyncratic DILI is due to drugs that are not inherently toxic to the liver. This type of DILI is dose-independent, unpredictable, and has variable latency, with onset of days to weeks to months. Anti-tuberculous therapy-induced DILI is of the idiosyncratic type, and it is the most common cause of idiosyncratic DILI worldwide.[8] DILI can either present as asymptomatic elevation of liver enzymes, symptomatic hepatitis, jaundice, or acute liver failure in severe cases.[2,5] The early detection of liver injury is crucial as it requires a change in, or interruption of, the ATT regimen depending on the type of TB and the severity of DILI.[1,5,9]

In Pakistan, previous studies have documented variable frequencies of ATT-induced DILI, ranging from 10.4% to 34.1%. Najam et al. reported a frequency of 10.3%, and was limited by its cross-sectional design, small sample size, absence of standardized DILI diagnostic criteria, lack of prospective follow-up, and limited assessment of independent risk factors.[10] Naqvi et al. reported a DILI frequency of 34.1% in a prospective cohort setting.[11] However, the study was limited by its single-center design and limited evaluation of established risk factors. Jathol et al. reported a DILI frequency of 10.4%, but their study was limited by a relatively small number of DILI cases, a short follow-up period, and limited assessment of predictors.[12] Shaikh et al. reported a DILI frequency of 24%. However, this study was limited by its small sample size, predominantly descriptive analysis, and unclear application of standard DILI diagnostic criteria.[13]

Our study is designed to fill this gap and aims to determine the cumulative incidence of DILI among all the newly diagnosed TB patients on ATT, and to explore the potential demographic and clinical risk factors associated with its occurrence. As performing baseline or serial liver function tests in every patient on ATT is not a standard recommendation, this study will provide insight into the need for routine monitoring in these patients.[14] It will also identify the demographic or clinical factors associated with DILI. Moreover, it will ensure the Pakistani population gets due representation in any future systematic reviews and meta-analyses on the topic.

Methodology

This was a single-arm prospective cohort study conducted Hayatabad Medical Complex, Peshawar, Pakistan. The institutional ethical review board of Khyber Girls Medical College / Hayatabad Medical Complex, Peshawar, approved the study. (Date=06/01/2025, No# 2434). The inclusion criteria were patients newly diagnosed with tuberculosis who were started on first-line anti-tuberculous therapy (rifampicin, pyrazinamide, ethambutol, and isoniazid). Patients with abnormal baseline liver function tests [serum alanine aminotransferase (ALT) or bilirubin], pregnancy and postpartum period, or those using alcohol and other hepatotoxic drugs were excluded from the study. Drug-induced liver injury was defined according to the American Thoracic Society (ATS) definition as the presence of at least one of the following: increase in serum ALT to more than three times the upper limit of normal (ULN) in symptomatic patients (anorexia, nausea, vomiting, or jaundice) or more than five times the ULN in asymptomatic patients or absolute rise in serum bilirubin to more than 1.5mg/dL after the initiation of ATT.[2,15] Chronic liver disease (CLD) was operationally defined as seropositivity for hepatitis B or hepatitis C or compensated liver cirrhosis/fibrosis with normal serum ALT and bilirubin at enrollment. Obesity was operationally defined as having BMI ≥ 27.5kg/m2. Taking 10.3% as the expected frequency of DILI, a confidence level of 95%, and a margin of error of 4%, the required sample size was 222.[10]

Patients presenting to the focal center for TB at Hayatabad Medical Complex, Peshawar for registration underwent clinical assessment and were advised baseline serum ALT and bilirubin after informed consent. Among them, those who met the inclusion and exclusion criteria were enrolled through a consecutive sampling technique. The following information was recorded on a pre-designed proforma: Age, gender, height, weight, site of tuberculosis (pulmonary or extrapulmonary), mode of TB diagnosis (microbiological confirmation, e.g., Gene Xpert, staining or culture positive, or diagnostic histopathology versus clinical diagnosis), presence of CLD, and the values of serum ALT and bilirubin at baseline.

All study participants were counseled and educated regarding the symptoms of DILI and regular follow-up after the second, fourth, and eighth weeks, or at any time in case they developed symptoms of DILI. At each visit, all patients were clinically assessed for symptoms (nausea, anorexia, jaundice, upper abdominal pain, pruritus) of DILI and were advised to have serum ALT and bilirubin checked. The presence or absence of symptoms, and the values of serum ALT and bilirubin were recorded at each follow-up visit on the proformas. The study was concluded after complete data were collected for 222 patients. Patients who developed DILI during the study were referred to the primary consultant for the management of DILI.

Statistical Package for Social Sciences (SPSS), version 21, was used for data analysis. Age, which has a non-normal distribution, is presented as median and interquartile range. Categorical variables are presented as frequencies and percentages. The significance of the age difference between patients with and without DILI was determined using the Mann-Whitney U test. Likewise, the association between DILI and gender, site of tuberculosis, mode of diagnosis, chronic liver disease, and obesity was evaluated by the Chi-square test / Fisher's Exact test. A p-value less than or equal to 0.05 was considered statistically significant.

Results

A total of 222 newly diagnosed TB patients, who were on anti-tuberculous therapy, were included in the study. The median age was 43.0 years (IQR 29.75–58). Out of the total, 114 (51.4%) were males, and 108 (48.6%) were females. The overall cumulative incidence of DILI was 14% (n=31). Most cases of DILI (n=19, 61.3%) were symptomatic, and most (n=28, 90.3%) were identified within the first month of starting ATT. Nausea (n=15, 78.9%) and anorexia (n=12, 63.2%) were the two most common reported symptoms of DILI. Table 1 summarizes the characteristics of the study participants.

A statistically significant association was observed between DILI and age, with patients with DILI having a higher median age than those without DILI [58 (IQR: 29 – 61) vs 41 (IQR: 30 – 55), p=0.038]. There was no significant association between DILI and gender, the site of tuberculosis, the mode of diagnosis, or the presence of chronic liver disease or obesity. (Table 2)

Multivariable logistic regression analysis showed that each one-year increase in age was associated with a 4% increase in the risk of DILI (AOR: 1.04, 95% CI: 1.01 – 1.07, p = 0.005). Similarly, chronic liver disease (AOR: 3.82, 95% CI: 1.10 – 13.24, p = 0.034) and obesity (AOR: 2.48, 95% CI: 1.05 – 5.88, p = 0.039), although not significant in univariate analysis, independently predicted the development of DILI after adjustment for other variables (Table 3).

Discussion

This study aimed to determine the cumulative incidence and associated risk factors of DILI among the newly diagnosed TB patients on ATT. In our cohort, the cumulative incidence of DILI was 14% (n=31). This is consistent with the published literature where ATT-induced DILI has been reported in 2 to 28% of patients.[5]

Table 1. Baseline characteristics of the study population (n=222)

Variables	Median (IQR) / No. (%)
Age (Years)	43.0 (29.75 – 58)
Gender	
Male	114 (51.4%)
Females	108 (48.6%)
Site of Tuberculosis	
Pulmonary TB	158 (71.2%)
Extra-Pulmonary TB	64 (28.8%)
Mode of diagnosis	
Microbiologically confirmed	130 (58.6%)
Clinically diagnosed	92 (41.4%)
Chronic Liver Disease	
No	205 (92.3%)
Yes	17 (7.7%)
Obesity	

J Postgrad Med Inst 2026;40(3):184-90.
http://doi.org/10.54079/jpmi.40.3.3960

No	154 (69.4%)
Yes	68 (30.6%)
Drug-induced liver injury	
No	191(86%)
Yes	31 (14%)
Symptomatic DILI*	
No	12 (38.7%)
Yes	19 (61.3%)
Symptoms of DILI#	
Nausea	15 (78.9%)
Anorexia	12 (63.2%)
Jaundice	10 (52.6%)
Abdominal Pain	08 (42.1%)
Pruritis	03 (15.8%)
DILI Onset*	
Within 4 weeks	28 (90.3%)
From 5th to 8th week	03 (9.7%)

IQR: Interquartile range; TB: Tuberculosis; DILI: Drug-induced liver injury

*Results for patients with DILI (n=31)

#Results for patients with symptomatic DILI (n=19)

Table 2. Association of risk factors with drug-induced liver injury (n=222)

Variables		Drug-induced liver injury		P-Value
		Yes (n=31)	No (n=191)	
Age (years)		58 (29 – 61)	41 (30 – 55)	0.038#
Gender	Male	17 (14.9%)	97 (85.1%)	0.675*
	Female	14 (13%)	94 (87%)	
Site of Tuberculosis	Pulmonary	20 (12.7%)	138 (87.3%)	0.378*
	Extra-pulmonary	11 (17.2%)	53 (82.8%)	
Mode of diagnosis	Microbiologically confirmed	15 (11.5%)	115 (88.5%)	0.215*
	Clinically diagnosed	16 (17.4%)	76 (82.6%)	
Chronic Liver Disease	No	26 (12.7%)	179 (87.3%)	0.069@
	Yes	05 (29.4%)	12 (70.6%)	
Obesity	No	18 (11.7%)	136 (88.3%)	0.141*
	Yes	13 (19.1%)	55 (80.9%)	

#Mann-Whitney U test; *Chi-square test; @Fisher Exact test

Table 3. Multivariable logistic regression analysis for the development of DILI

Risk factors		AOR	95% CI	P-value
Age		1.04	1.01 – 1.07	0.005
Gender	Female*			
	Male	1.63	0.71 – 3 .71	0.247
Site of Tuberculosis	Pulmonary*			
	Extra-pulmonary	1.21	0.51 – 2.84	0.666
Mode of diagnosis	Microbiologically confirmed*			
	Clinically diagnosed	1.36	0.62 – 3.01	0.445
Chronic Liver Disease	No*			
	Yes	3.82	1.10 – 13.24	0.034
Obesity	No*			
	Yes	2.48	1.05 – 5.88	0.039

*Reference category

AOR: Adjusted odds ratio; CI: Confidence interval

Among these studies, ATT-induced DILI was reported as 10.3% by Najam et al., 10.4% by Jathol et al., 24.0% by Shaikh et al., and 34.1% by Naqvi et al.[10–13] This wide range can be attributed to the idiosyncratic pathogenesis of DILI secondary to ATT, differences in the operational definition of DILI, demographic differences, and the monitoring patterns.[8,16]

Most patients (n=28, 90.3%) with DILI developed it within four weeks after starting ATT. This is similar to the pattern reported by Alvi et al. and Abbara et al., with DILI onset predominantly in the first month, extending up to 8 weeks after starting ATT.[17,18] This can be explained by hepatotoxic metabolites of anti-tuberculous drugs, oxidative stress, mitochondrial dysfunction, and immune-mediated reactions, processes that are most pronounced shortly after drug exposure. Although most cases are pooled within the first two weeks, hepatotoxicity can develop as late as week 8, which can be attributed to the idiosyncratic nature of ATT-induced DILI, cumulative drug effects, delayed presentation, or immune-mediated processes.[6]

In this study, 61.3% (n=19) of the ATT-induced DILI patients were symptomatic, with the most common symptoms being nausea (n=15, 78.9%) and anorexia (n=12, 63.2%). This is in agreement with the published literature, such as Abbara et al., in which most DILI patients reported nausea as the commonest symptom.[18] These non-specific symptoms represent the earliest clinical manifestations of hepatic injury, and are attributed to inflammatory cytokine release from damaged hepatocytes, impaired bile acid metabolism, and the direct gastrointestinal effects of anti-tuberculous medications. As overt jaundice and liver dysfunction are preceded by these non-specific symptoms, their recognition results in timely detection and management of ATT-induced DILI.

This study revealed a significant association of DILI with increasing age (p=0.038), and each one-year increase in age increased the odds of DILI by 4%. This is in line with some studies that have reported a significant association between ATT-induced DILI and increasing age.[6,19] Increasing age has been previously identified as an independent predictor of ATT-induced DILI, as reported in Gaude et al.[20] However, other studies have not identified significant associations among ATT-induced DILI and advancing age, such as Saha et al.[21] This inconsistency may be explained by differences in the age distribution of the study populations, prevalence of comorbid conditions, and the diagnostic criteria used for DILI. Age-related changes in hepatic blood flow, regenerative capacity, and drug metabolism may increase susceptibility to hepatotoxic injury.

The study did not find significant associations between ATT-induced DILI and gender (0.675), the site of TB (0.378), and the mode of diagnosis (0.215). However, previous literature such as Zhao et al. and Ali et al. have reported significant association among female gender and extra-pulmonary TB with ATT-induced DILI.[22,23] This contrasts with this study and can be attributed to variations in study designs, sample size, population characteristics, and diagnostic criteria of DILI. The lack of association in this study may reflect a relatively balanced distribution of other established risk factors between males and females, and suggests that gender alone might not be an independent predictor of hepatotoxicity. Extra-pulmonary TB is associated with greater disease burden, malnutrition, and systemic nature of illness; these factors in themselves might increase

J Postgrad Med Inst 2026;40(3):184-90.
http://doi.org/10.54079/jpmi.40.3.3960

the susceptibility to hepatotoxicity rather than extra-pulmonary TB alone in some studies. The relatively small sample of patients with extra-pulmonary TB in this study might have masked its association with DILI. The association between the mode of diagnosis of TB and DILI has not been previously studied in the literature. There is a common assumption that the risk of DILI is higher in patients who are clinically diagnosed as TB compared to those confirmed microbiologically. Further research designed specifically to explore this relationship might provide valuable insight into this association.

Although CLD and obesity were not significantly associated with DILI in univariate analysis, they became significant predictors of DILI in multivariable analysis. This might be because of the confounding effect of other variables, like age and gender, which was minimized by the multivariable model. This is consistent with previous studies which have reported an association between hepatitis B or C infection, pre-existing liver injury, and obesity with ATT-induced DILI.[2,24,25]

This study utilized a single arm prospective cohort design, observing temporal ATT exposure and the development of DILI. This design enabled the estimation of cumulative incidence (risk over time), providing a more robust epidemiological measure of DILI in this population. Additionally, addressing a notable gap, our study provides valuable insight into the Pakistani population. The use of standardized ATS criteria in defining DILI, and robust exclusion criteria add to the strengths of this study. Predefined clinical and biochemical monitoring enabled detection of both symptomatic and asymptomatic hepatotoxicity and improved accuracy in determining onset patterns.

The main limitations in our study that necessitates further research include an interval based follow up protocol to detect DILI, which may not accurately reflect the exact time of onset of DILI. Secondly, the relatively small DILI patient size may have reduced the statistical power of the study thus failing to identify associations. Moreover, residual confounding is possible as factors like HIV status, nutritional status, and history of smoking and alcoholism are not assessed. Lastly, being a single center study, the findings may not be generalizable to a broader population.

Conclusion

The cumulative incidence of ATT-related DILI in newly diagnosed TB patients was 14%. The median age of patients with DILI was higher than that of patients without DILI. Chronic liver disease and obesity were independent predictors of DILI. The development of DILI was not affected by gender, site of TB, or mode of diagnosis of TB. Although serial monitoring of LFTs in patients with normal liver function is not a standard recommendation, clinical and biochemical monitoring to detect DILI early is warranted in older patients and in patients with CLD or obesity, irrespective of baseline liver function.

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Authors' Contribution Statement

SK contributed to the conception, design, acquisition, analysis, interpretation of data, drafting of the manuscript, and critical review of the manuscript. SR contributed to the acquisition, analysis of data, and drafting of the manuscript. FR contributed to the acquisition, analysis, and interpretation of data. RF contributed to the acquisition, analysis, and interpretation of data. SS contributed to the acquisition, analysis, and interpretation of data. SA contributed to the conception, critical review of the manuscript, and final approval of the version to be published. All authors are accountable for their work and ensure the accuracy and integrity of the study.

Conflict of Interest

Authors declared no conflict of interest

Grant Support and Financial Disclosure

None

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.