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Original Article

Frequency of Elevated Serum Alanine Transaminase in Patients With Type 2 Diabetes Mellitus

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ABSTRACT

Background: Type 2 diabetes mellitus is a common metabolic disorder associated with systemic complications, including possible hepatic biochemical abnormalities. Serum alanine transaminase is a widely available marker of hepatocellular injury and may help identify diabetic patients who require further hepatic assessment, although ALT elevation alone does not confirm non-alcoholic fatty liver disease. Objective: To determine the frequency of elevated serum alanine transaminase among patients with type 2 diabetes mellitus presenting to a tertiary care hospital in Abbottabad, Pakistan, and to assess its association with gender and duration of diabetes. Methods: This hospital-based cross-sectional study was conducted at Medical Unit A, Ayub Teaching Hospital, Abbottabad, from January 2024 to June 2024. A total of 245 patients with type 2 diabetes mellitus were enrolled through non-probability convenience sampling. Patients aged more than 20 years were included, while those with alcohol intake, hepatotoxic drug use, chronic liver disease, viral hepatitis, or hepatic malignancy were excluded. Serum ALT ≥40 IU/L was considered elevated. Data were analyzed using SPSS version 22, and associations were assessed using the chi-square test. Results: The mean age was 54.3 ± 10.8 years, and the mean serum ALT level was 36.7 ± 14.5 IU/L. Elevated ALT was observed in 56 patients, giving a frequency of 22.9%. Elevated ALT was significantly more common in males than females (29.0% vs 15.0%; OR 2.32, 95% CI 1.22–4.43; p=0.011) and increased with longer diabetes duration, reaching 34.5% among patients with diabetes for more than 10 years (OR 3.03, 95% CI 1.34–6.86; p=0.004). Conclusion: Elevated serum ALT was common among patients with type 2 diabetes mellitus and was significantly associated with male gender and longer diabetes duration. Routine liver enzyme monitoring may help identify diabetic patients requiring further hepatic and metabolic evaluation. Keywords: Type 2 diabetes mellitus; Alanine transaminase; ALT; Liver function tests; Hepatic dysfunction; Non-alcoholic fatty liver disease; Pakistan.

INTRODUCTION

Diabetes mellitus is a major chronic metabolic disorder and one of the leading contributors to long-term cardiovascular, renal, neurological, and hepatic morbidity worldwide. The International Diabetes Federation estimated that approximately 537 million adults were living with diabetes in 2021, with projections suggesting a continued rise to 643 million by 2030 and 783 million by 2045, reflecting the expanding global impact of hyperglycemia, obesity, sedentary behavior, and population ageing (1). Type 2 diabetes mellitus accounts for the predominant proportion of diabetes cases and is strongly linked with insulin resistance, central adiposity, dyslipidemia, chronic low-grade inflammation, and progressive metabolic dysfunction, all of which contribute to multisystem complications beyond glycemic abnormalities alone (2). Earlier global estimates also showed a sustained increase in diabetes prevalence across regions, emphasizing that the disease burden is not confined to high-income countries but is increasingly concentrated in low- and middle-income populations where screening and long-term complication monitoring may be inconsistent (3).

Pakistan carries a particularly high burden of diabetes, with national epidemiological data indicating a substantial prevalence of diabetes and prediabetes among adults, alongside modifiable risk factors such as obesity, physical inactivity, hypertension, and adverse dietary patterns (4). In such settings, diabetic care often prioritizes glycemic control and vascular complications, while hepatic abnormalities may remain under-recognized despite the liver's central role in glucose regulation, glycogen storage, lipid metabolism, inflammatory signaling, and insulin clearance. Chronic hyperglycemia and insulin resistance can promote oxidative stress, mitochondrial dysfunction, lipid accumulation, and hepatocellular injury, providing a biological basis for abnormalities in liver enzymes among patients with type 2 diabetes mellitus (5). Serum alanine transaminase is commonly used as a biochemical indicator of hepatocellular injury because of its relatively greater liver specificity compared with several other aminotransferases, although its elevation should be interpreted as a marker of possible hepatic stress rather than a standalone diagnosis of any specific liver disease.

Abnormal liver enzymes have been repeatedly documented among patients with type 2 diabetes mellitus and are often associated with broader features of metabolic syndrome. Forlani et al. reported a notable prevalence of elevated liver enzymes in patients with type 2 diabetes mellitus and demonstrated their association with metabolic syndrome components, supporting the view that hepatic biochemical abnormalities may reflect systemic metabolic risk rather than isolated liver pathology (6). Similarly, studies evaluating liver function markers in relation to type 2 diabetes have suggested that abnormalities in aminotransferases may accompany the onset and progression of metabolic dysfunction, although reported frequencies vary according to population characteristics, laboratory cutoffs, and the degree to which obesity, glycemic control, viral hepatitis, alcohol exposure, and medication use are assessed (7). These variations highlight the need for local data using clearly defined operational criteria and transparent exclusion of alternative hepatic causes.

Non-alcoholic fatty liver disease is increasingly regarded as the hepatic manifestation of metabolic syndrome and is particularly common among individuals with type 2 diabetes mellitus. A global epidemiological analysis reported a high burden of NAFLD and non-alcoholic steatohepatitis among patients with type 2 diabetes, emphasizing the close relationship between hepatic steatosis and metabolic disease (8). Conversely, NAFLD itself has been associated with a higher risk of incident type 2 diabetes mellitus, suggesting a bidirectional relationship between liver fat accumulation and systemic insulin resistance (9). The clinical relevance of this association extends beyond the liver, as NAFLD in patients with type 2 diabetes has been linked with increased cardiovascular risk and adverse metabolic outcomes (10). Liver markers have also been investigated as predictors of future diabetes risk, further supporting the biological connection between hepatic injury, insulin resistance, and metabolic progression (11). However, serum alanine transaminase alone cannot confirm NAFLD, distinguish simple steatosis from steatohepatitis, or stage fibrosis; therefore, elevated ALT should be interpreted as a practical screening signal that may identify patients requiring further clinical, biochemical, or imaging-based evaluation.

The clinical importance of identifying elevated ALT in type 2 diabetes lies in its potential to detect patients with unrecognized hepatic dysfunction at an earlier stage, particularly in resource-limited settings where advanced liver imaging or fibrosis assessment may not be routinely available. Current literature emphasizes that patients with type 2 diabetes and suspected NAFLD require careful metabolic assessment, cardiovascular risk reduction, and attention to modifiable risk factors, while therapeutic strategies should be guided by the broader cardiometabolic profile rather than liver enzymes alone (12). Reviews on NAFLD and diabetes further indicate that their coexistence is associated with complex mechanisms involving hepatic insulin resistance, lipotoxicity, inflammation, adipokine imbalance, and progressive metabolic injury (13). NAFLD is also closely integrated with metabolic syndrome, reinforcing the need to consider liver enzyme abnormalities within the broader context of obesity, dyslipidemia, hypertension, and glycemic dysregulation (14). Nevertheless, published estimates of elevated ALT among diabetic populations differ widely, and one prior study reported elevated ALT in

19.8% of patients with type 2 diabetes mellitus, a frequency used to guide sample size estimation in the present study (15).

Despite the established relationship between type 2 diabetes mellitus and hepatic biochemical abnormalities, local evidence from Pakistan, particularly from Khyber Pakhtunkhwa, remains limited. Differences in population risk profiles, diabetes duration, access to routine biochemical monitoring, background prevalence of viral hepatitis, medication exposure, and patterns of obesity may influence the observed frequency of elevated ALT in local diabetic populations. Generating hospital-based data from Abbottabad may therefore help clinicians estimate the burden of ALT elevation among patients with type 2 diabetes mellitus and identify subgroups who may benefit from closer hepatic evaluation. This study was conducted to determine the frequency of elevated serum alanine transaminase among patients with type 2 diabetes mellitus presenting to a tertiary care hospital in Abbottabad, Pakistan, and to assess its association with selected clinical and demographic factors, particularly gender and duration of diabetes.

MATERIALS AND METHODS

This hospital-based cross-sectional observational study was conducted at Medical Unit A, Ayub Teaching Hospital, Abbottabad, Pakistan, over a six-month period from January 2024 to June 2024. The cross-sectional design was selected because the primary objective was to estimate the frequency of elevated serum alanine transaminase among patients with established type 2 diabetes mellitus at the time of clinical presentation and to assess its association with selected patient characteristics. The study population consisted of adult patients with diagnosed type 2 diabetes mellitus who presented to the study setting during the defined study period and fulfilled the eligibility criteria.

A total of 245 patients were included using non-probability convenience sampling. Patients aged more than 20 years, of either gender, with previously diagnosed type 2 diabetes mellitus were eligible for inclusion. Patients were excluded if they had a history of alcohol intake, current or recent use of hepatotoxic drugs, known chronic liver disease, viral hepatitis, or hepatic malignancy, because these conditions could independently elevate serum alanine transaminase and confound the interpretation of ALT abnormalities in relation to diabetes. Eligible patients were enrolled after informed consent, and demographic and clinical information was recorded on a predesigned data collection proforma. The collected variables included age, gender, duration of diabetes, serum ALT level, and ALT status according to the operational cutoff used in the study.

Serum alanine transaminase was measured using venous blood samples obtained under aseptic conditions. Five milliliters of venous blood were collected from each participant and sent to the hospital laboratory for biochemical analysis. The main outcome variable was elevated serum ALT, operationally defined as serum ALT ≥40 IU/L according to the cutoff applied in the study protocol. Participants with ALT values below this threshold were classified as having normal ALT. Duration of diabetes was recorded in years and categorized into clinically interpretable groups of less than 5 years, 5–10 years, and more than 10 years to assess whether longer disease duration was associated with a higher frequency of elevated ALT. Gender was recorded as male or female and analyzed as a categorical exposure variable.

The sample size was calculated using the WHO sample size calculator by taking an anticipated frequency of elevated serum ALT of 19.8%, a 95% confidence level, and an absolute precision of 5%, resulting in a required sample of 245 patients. To reduce measurement-related variability, all blood samples were processed through the same hospital laboratory system. Data were checked for completeness and internal consistency before analysis. Patients with predefined alternative causes of ALT elevation were excluded to reduce confounding by non-diabetic hepatic disease; however, because variables such as body mass index, HbA1c, lipid profile, waist circumference, and imaging-confirmed fatty liver status were not included in the dataset, these factors were considered important residual confounders when interpreting the findings.

Data were analyzed using SPSS version 22. Quantitative variables, including age, duration of diabetes, and serum ALT level, were summarized as mean and standard deviation. Categorical variables, including gender, ALT status, and duration-of-diabetes categories, were summarized as frequencies and percentages. The frequency of elevated ALT was calculated by dividing the number of participants with ALT ≥40 IU/L by the total sample size. Stratified analyses were performed for gender and duration of diabetes, and the chi-square test was applied to assess associations between categorical variables and elevated ALT status. A p-value of ≤0.05 was considered statistically significant. Where appropriate for strengthened reporting, association estimates such as odds ratios and 95% confidence intervals should be added in the final statistical tables to support clinical interpretation beyond p-values alone.

The study was conducted after approval from the Institutional Ethical Review Committee. Written informed consent was obtained from participants before enrolment, and patient information was handled confidentially. Data were recorded in an anonymized format for analysis, and access to study records was limited to the research team. The study followed the principles of ethical human-subject research, including voluntary participation, confidentiality, and use of collected information only for the stated research purpose.

These sections incorporate the review feedback by correcting the rationale, avoiding overdiagnosis of NAFLD from ALT alone, strengthening the local gap, clarifying the study design and operational definitions, and adding bias/confounding and reproducibility considerations while preserving the manuscript's original data.

RESULTS

A total of 245 patients with type 2 diabetes mellitus were included in the analysis. The mean age of the participants was 54.3 ± 10.8 years, and the mean duration of diabetes was 8.2 ± 4.9 years. The mean serum alanine transaminase level was 36.7 ± 14.5 IU/L. Of the total study population, 138 patients were male and 107 were female, representing 56.3% and 43.7% of the sample, respectively. The original manuscript reported elevated ALT in 56 of 245 patients and provided stratified results according to gender and duration of diabetes.

Table 1. Baseline Characteristics of the Study Population (n = 245)

Variable	Mean ± SD / Frequency (%)
Age, years	54.3 ± 10.8
Duration of diabetes, years	8.2 ± 4.9
Serum ALT, IU/L	36.7 ± 14.5
Male	138 (56.3%)
Female	107 (43.7%)

ALT: alanine transaminase; SD: standard deviation.

Elevated serum ALT, defined as ALT ≥40 IU/L, was observed in 56 patients, giving an overall frequency of 22.9% among patients with type 2 diabetes mellitus. The estimated 95% confidence interval for the observed frequency was 17.6% to 28.1%, indicating that approximately one in every four to five diabetic patients in this hospital-based sample had elevated serum ALT.

Table 2. Frequency of Elevated Serum Alanine Transaminase Among Patients With Type 2 Diabetes Mellitus

ALT Status	Frequency	Percentage	95% CI
Elevated ALT	56	22.9%	17.6–28.1%
Normal ALT	189	77.1%	71.9–82.4%
Total	245	100.0%	—

ALT: alanine transaminase; CI: confidence interval. Elevated ALT was defined as serum ALT ≥40 IU/L.

When stratified by gender, elevated ALT was more frequent among male patients than female patients. Among 138 male patients, 40 had elevated ALT, corresponding to a frequency of 29.0%. In comparison, 16 of 107 female patients had elevated ALT, corresponding to a frequency of 15.0%. The association

between gender and elevated ALT was statistically significant, with males showing approximately 2.32 times higher odds of elevated ALT compared with females.

Table 3. Association Between Gender and Elevated Serum Alanine Transaminase

Gender	Elevated ALT, n (%)	Normal ALT, n (%)	Odds Ratio (95% CI)	p-value
Female	16 (15.0%)	91 (85.0%)	Reference	—
Male	40 (29.0%)	98 (71.0%)	2.32 (1.22–4.43)	0.011
Total	56 (22.9%)	189 (77.1%)	—	—

ALT: alanine transaminase; CI: confidence interval. p-value retained from the manuscript's reported stratified analysis.

Duration of diabetes also showed a clinically meaningful gradient with elevated ALT. Among patients with diabetes duration of less than 5 years, 12 of 81 patients had elevated ALT, corresponding to 14.8%. This increased to 22.6% among patients with diabetes duration of 5–10 years and further increased to 34.5% among patients with diabetes duration greater than 10 years. Compared with patients having diabetes for less than 5 years, those with disease duration greater than 10 years had approximately 3.03 times higher odds of elevated ALT, indicating that longer exposure to metabolic dysregulation may be associated with greater hepatic biochemical abnormality.

Table 4. Association Between Duration of Diabetes and Elevated Serum Alanine Transaminase

Duration of Diabetes	Elevated ALT, n (%)	Normal ALT, n (%)	Odds Ratio (95% CI)	p-value
<5 years	12 (14.8%)	69 (85.2%)	Reference	—
5–10 years	24 (22.6%)	82 (77.4%)	1.68 (0.78–3.61)	—
>10 years	20 (34.5%)	38 (65.5%)	3.03 (1.34–6.86)	0.004
Total	56 (22.9%)	189 (77.1%)	—	—

ALT: alanine transaminase; CI: confidence interval. p-value retained from the manuscript's reported stratified analysis. Odds ratios were calculated using the <5 years group as the reference category.

Overall, the results demonstrate that elevated serum ALT was present in a substantial proportion of patients with type 2 diabetes mellitus. The frequency was notably higher among male patients and increased progressively with longer diabetes duration. These findings suggest that male gender and prolonged diabetes duration may identify subgroups of diabetic patients who warrant closer biochemical monitoring and further clinical evaluation for possible hepatic involvement, while avoiding the assumption that elevated ALT alone confirms non-alcoholic fatty liver disease.

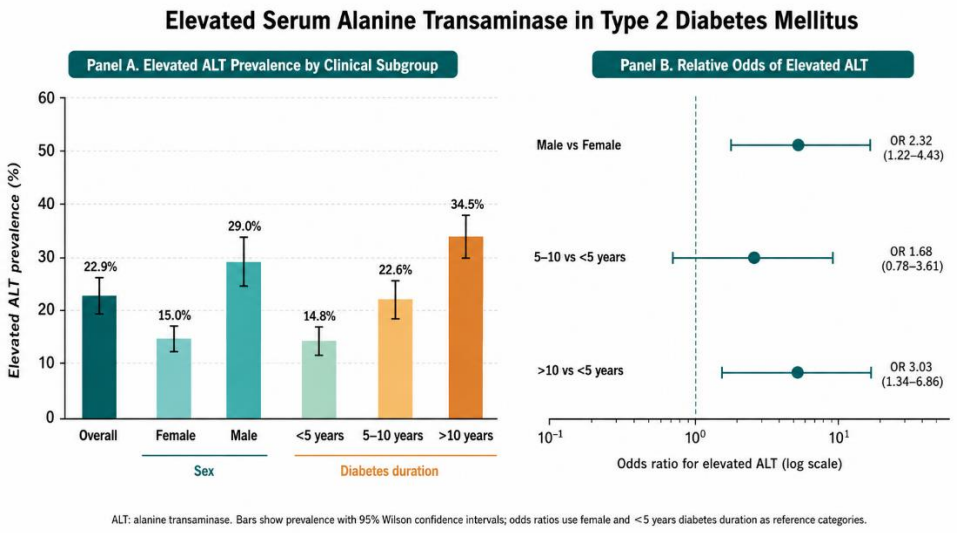

Figure 1. Elevated Serum Alanine Transaminase in Type 2 Diabetes Mellitus

The panelled figure summarizes clinically relevant patterns in elevated serum ALT using only the manuscript's aggregated data. Panel A shows that elevated ALT was present in 22.9% of the total sample,

with a higher prevalence in males than females (29.0% vs 15.0%) and a progressive increase across diabetes-duration categories from 14.8% in patients with diabetes for <5 years to 22.6% at 5–10 years and 34.5% after >10 years. Panel B demonstrates the corresponding effect-size pattern: male patients had 2.32-fold higher odds of elevated ALT compared with females, while patients with diabetes duration >10 years had 3.03-fold higher odds compared with those with duration <5 years. These findings indicate that prolonged diabetes duration and male gender may define subgroups requiring closer biochemical monitoring and further hepatic risk assessment, while ALT elevation alone should not be interpreted as diagnostic confirmation of NAFLD. Data were derived from the manuscript's reported tables.

DISCUSSION

The present study found that elevated serum alanine transaminase was present in 56 of 245 patients with type 2 diabetes mellitus, corresponding to an overall frequency of 22.9%. This finding indicates that nearly one in four patients with type 2 diabetes in this tertiary-care sample had biochemical evidence of possible hepatocellular stress. The observed frequency is clinically important because serum ALT is a widely available, low-cost marker that may help identify diabetic patients who require more detailed hepatic and metabolic evaluation. However, ALT elevation should be interpreted cautiously, because it is not diagnostic of non-alcoholic fatty liver disease by itself and cannot distinguish simple steatosis from steatohepatitis, fibrosis, or other forms of liver injury without additional clinical, biochemical, serological, and imaging-based assessment.

The frequency observed in this study is broadly consistent with previous research reporting liver enzyme abnormalities among patients with type 2 diabetes mellitus. Mathur et al. reported elevated ALT in 19.8% of patients with type 2 diabetes, which is close to the 22.9% frequency observed in the present study (15). Differences between studies may reflect variation in ALT cutoffs, patient age, duration of diabetes, obesity prevalence, glycemic control, medication exposure, viral hepatitis screening, alcohol history, and diagnostic methods used to identify underlying liver disease. Because the current study excluded known chronic liver disease, viral hepatitis, hepatotoxic drug use, hepatic malignancy, and alcohol intake, the findings are more likely to reflect metabolic or diabetes-associated hepatic biochemical abnormality; nevertheless, residual confounding remains possible because body mass index, waist circumference, HbA1c, lipid profile, and imaging-confirmed fatty liver status were not included.

Male patients in this study had a significantly higher frequency of elevated ALT than female patients, with elevated ALT observed in 29.0% of males compared with 15.0% of females. The calculated odds ratio showed that males had approximately 2.32 times higher odds of elevated ALT than females. This finding may be explained by sex-related differences in visceral adiposity, insulin resistance, hepatic fat distribution, lifestyle factors, and metabolic syndrome burden. Male predominance in ALT elevation has also been described in studies evaluating asymptomatic liver enzyme abnormalities and metabolic liver disease in clinical populations, where ALT levels may be influenced by body composition, hepatic fat accumulation, and cardiometabolic risk clustering (16). The present result therefore supports the need for clinicians to consider gender-specific metabolic risk patterns when interpreting abnormal liver enzymes in patients with type 2 diabetes.

A progressive increase in elevated ALT was also observed with longer duration of diabetes. Patients with diabetes duration less than 5 years had an elevated ALT frequency of 14.8%, which increased to 22.6% among those with diabetes for 5–10 years and 34.5% among those with diabetes for more than 10 years. Patients with diabetes duration greater than 10 years had approximately 3.03 times higher odds of elevated ALT compared with those with duration less than 5 years. This gradient is biologically plausible because prolonged exposure to hyperglycemia, insulin resistance, oxidative stress, dyslipidemia, and inflammatory pathways may contribute to progressive hepatocellular stress and hepatic fat accumulation. The economic and clinical burden of non-alcoholic steatohepatitis among patients with type 2 diabetes further supports the importance of identifying diabetic patients who may be at increased

hepatic risk, particularly when disease duration is long and metabolic risk factors are likely to accumulate over time (17).

The relationship between type 2 diabetes and hepatic dysfunction has broader clinical implications because NAFLD is increasingly recognized as a multisystem condition rather than an isolated liver disorder. Byrne and Targher emphasized that NAFLD is associated with adverse metabolic, cardiovascular, and extrahepatic outcomes, supporting the view that liver-related abnormalities in diabetic patients should be interpreted within the wider cardiometabolic risk profile (18). In addition, NAFLD has been linked with increased risk of extrahepatic cancers and other long-term complications, indicating that hepatic metabolic dysfunction may reflect systemic disease activity rather than a localized biochemical abnormality alone (19). Although the present study did not diagnose NAFLD radiologically, the observed ALT elevation in a substantial proportion of diabetic patients reinforces the importance of considering liver enzyme monitoring as part of comprehensive diabetes care.

From a public health perspective, the findings are relevant because the burden of NAFLD is expected to rise substantially in parallel with increasing obesity, diabetes, and metabolic syndrome. Modeling studies have demonstrated an expanding burden of NAFLD-related disease, including progressive liver disease, cirrhosis, and hepatocellular carcinoma, particularly in populations with high rates of metabolic risk factors (20). In Pakistan, where diabetes prevalence is high and advanced liver assessment may not be routinely accessible in all settings, a simple biochemical marker such as ALT may serve as an initial signal for further evaluation. Nevertheless, abnormal ALT should not be used as a sole screening or diagnostic strategy, because some patients with NAFLD or advanced fibrosis may have normal aminotransferase levels, while ALT elevation may occur due to several hepatic and non-hepatic causes.

Current practice guidance emphasizes that the diagnosis and management of NAFLD require a structured clinical approach involving exclusion of secondary causes, assessment of metabolic comorbidities, fibrosis risk stratification, lifestyle intervention, and appropriate referral when advanced disease is suspected (21). Therefore, the present findings should be interpreted as evidence of the frequency of elevated ALT among patients with type 2 diabetes rather than direct evidence of NAFLD prevalence. Patients with elevated ALT in diabetic clinics may benefit from additional evaluation, including repeat liver function testing, viral hepatitis screening where indicated, medication review, assessment of obesity and metabolic syndrome, ultrasound or elastography when available, and fibrosis risk scoring. Such an approach would allow clinicians to distinguish transient biochemical abnormalities from persistent hepatic disease requiring follow-up.

The study has several limitations. First, it was conducted at a single tertiary-care hospital using non-probability convenience sampling, which limits generalizability to the broader diabetic population. Second, the cross-sectional design prevents causal inference and does not determine whether longer diabetes duration directly caused ALT elevation. Third, the study did not include body mass index, waist circumference, HbA1c, lipid profile, medication history, viral hepatitis serology details, ultrasound findings, FibroScan assessment, or fibrosis scores, all of which could influence ALT levels and improve interpretation. Fourth, NAFLD was not radiologically confirmed; therefore, elevated ALT should be interpreted only as a biochemical abnormality suggesting possible hepatocellular injury. Fifth, the use of a single ALT cutoff of ≥40 IU/L may not account for sex-specific or laboratory-specific reference limits. Despite these limitations, the study provides useful local evidence showing that elevated ALT is common among patients with type 2 diabetes mellitus and is significantly associated with male gender and longer disease duration.

Future studies should use multicenter designs, probability or consecutive sampling, larger sample sizes, and more comprehensive metabolic profiling. Incorporating HbA1c, body mass index, waist circumference, lipid profile, medication exposure, hepatitis screening, liver ultrasound, non-invasive fibrosis scores, and elastography would allow stronger evaluation of the relationship between diabetes and hepatic involvement. Longitudinal studies would also be valuable to determine whether elevated

ALT predicts future NAFLD, fibrosis progression, cardiovascular outcomes, or diabetes-related complications. Evidence-based management strategies for NAFLD increasingly emphasize weight reduction, cardiometabolic risk control, diabetes optimization, and individualized therapeutic approaches, making early identification of at-risk diabetic patients clinically meaningful (22).

CONCLUSION

Elevated serum alanine transaminase was observed in 22.9% of patients with type 2 diabetes mellitus in this hospital-based cross-sectional study, with significantly higher frequencies among male patients and those with longer diabetes duration. These findings suggest that ALT elevation is a common biochemical abnormality in diabetic patients and may help identify individuals who require closer hepatic and metabolic evaluation. However, elevated ALT should not be interpreted as diagnostic confirmation of non-alcoholic fatty liver disease without further assessment. Routine liver enzyme monitoring, combined with evaluation of metabolic risk factors and appropriate imaging or fibrosis assessment when indicated, may improve early recognition of possible hepatic involvement in patients with type 2 diabetes mellitus.

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