

RESEARCH TITLE

Evaluation of Biochemical Markers and Liver Stiffness Using FibroScan in Type 1 Diabetes Mellitus

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Abstract

Type 1 Diabetes Mellitus (T1DM) is a chronic autoimmune disorder that results in insulin deficiency and leads to chronic hyperglycemia and various complications, including liver dysfunction. Early detection of liver alterations in T1DM patients is essential for preventing long-term damage. This study investigates biochemical markers and liver health in T1DM patients using FibroScan to measure liver stiffness and steatosis. A total of 45 T1DM patients and 45 healthy controls were included. Blood samples were analyzed for glycemic control, lipid profile, and liver function tests, while liver stiffness and fat content were assessed using FibroScan. My findings indicate significant liver dysfunction and metabolic disturbances in T1DM patients, emphasizing the need for early screening and management to improve patient outcomes.

Key Words: Type 1 diabetes mellitus, liver stiffness, steatosis, glycemic control, lipid profile, FibroScan, liver dysfunction.

تقييم المؤشرات البيوكيميائية وصلابة الكبد باستخدام تقنية الفيبروسكان لدى المصابين بداء السكري من النوع الأول

المستخلص

يُعد داء السكري من النوع الأول اضطراباً مناعياً ذاتياً مزمنياً يؤدي إلى نقص في إفراز الإنسولين، مما يسبب ارتفاعاً مزمنياً في مستوى سكر الدم وظهور مضاعفات متعددة، من بينها اضطرابات وظائف الكبد. ويُعد الكشف المبكر عن التغيرات الكبدية لدى مرضى السكري من النوع الأول أمراً مهماً للوقاية من حدوث أضرار طويلة المدى. تهدف هذه الدراسة إلى تقييم المؤشرات الكيميائية الحيوية وصحة الكبد لدى مرضى السكري من النوع الأول باستخدام جهاز **FibroScan** لقياس صلابة الكبد ودرجة التشحم الكبدي. شملت الدراسة 45 مريضاً بداء السكري من النوع الأول و45 فرداً سليماً كمجموعة ضابطة. تم تحليل عينات الدم لتقييم مستوى التحكم في سكر الدم، والملف الدهني، واختبارات وظائف الكبد، كما تم قياس صلابة الكبد ومحتوى الدهون باستخدام جهاز **FibroScan**. أظهرت النتائج وجود اضطرابات ملحوظة في وظائف الكبد والتمثيل الغذائي لدى مرضى السكري من النوع الأول، مما يؤكد أهمية الفحص المبكر والتدخل العلاجي المناسب لتحسين النتائج الصحية للمرضى.

الكلمات المفتاحية: داء السكري من النوع الأول، صلابة الكبد، التشحم الكبدي، التحكم في سكر الدم، الملف الدهني، جهاز فيبروسكان، اضطراب وظائف الكبد.

1. Introduction

Type 1 Diabetes Mellitus (T1DM) is a chronic autoimmune disease characterized by the destruction of pancreatic beta cells, leading to absolute insulin deficiency and resulting in chronic hyperglycemia(1). While T1DM is primarily associated with glucose metabolism disorders, emerging evidence suggests that it also has significant effects on other organ systems, including the liver(2). The interplay between diabetes and liver function has been widely studied, highlighting an increased prevalence of hepatic complications among diabetic patients(3). Despite being traditionally linked to metabolic disorders such as Type 2 Diabetes Mellitus (T2DM)(4), liver abnormalities, including non-alcoholic fatty liver disease (NAFLD), hepatic fibrosis, and cirrhosis, have been reported in individuals with T1DM(5). However, these complications in T1DM remain underexplored compared to T2DM(6).

1.1. Background and Significance

The liver plays a pivotal role in glucose homeostasis by regulating glycogen storage, gluconeogenesis, and insulin metabolism(7). In T1DM, chronic hyperglycemia and insulin deficiency contribute to metabolic dysregulation, oxidative stress, and inflammation, all of which can predispose patients to liver dysfunction(8). Studies have reported altered liver enzyme levels and increased hepatic stiffness in T1DM patients, raising concerns about progressive liver disease in this population(9). NAFLD, which encompasses a spectrum of conditions from simple steatosis to non-alcoholic steatohepatitis (NASH), is increasingly recognized as a comorbidity in T1DM(10). Although the exact mechanisms linking T1DM to liver dysfunction remain unclear, insulin deficiency, hyperglycemia, and dyslipidemia are believed to play key roles(11).

FibroScan, a non-invasive imaging modality, has emerged as a reliable tool for assessing liver stiffness and hepatic fat accumulation. Unlike traditional liver biopsies, FibroScan offers a safer and more accessible means of evaluating hepatic fibrosis and steatosis(12). Given the growing interest in liver complications associated with diabetes, the use of FibroScan in T1DM patients provides valuable insights into early hepatic changes that may otherwise go undetected(13). Early detection of liver involvement in T1DM patients is crucial for timely intervention, preventing irreversible damage and improving patient outcomes(14).

1.2. Objectives of the Study

This study aims to evaluate biochemical markers of liver function and assess liver stiffness using FibroScan in T1DM patients. The key objectives include:

1. **Assessing Glycemic Control:** Evaluating parameters such as fasting blood glucose (FBG), glycated hemoglobin (HbA1c), and insulin levels to determine the metabolic state of T1DM patients.
2. **Analyzing Liver Function Markers:** Investigating liver enzymes, including alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma-glutamyl transferase (GGT), and alkaline phosphatase (ALP), to detect hepatic dysfunction.
3. **Evaluating Lipid Profiles:** Measuring total cholesterol, triglycerides, low-density lipoprotein (LDL), and high-density lipoprotein (HDL) levels to assess their role in hepatic and metabolic abnormalities.
4. **Determining Liver Stiffness and Steatosis:** Utilizing FibroScan to measure liver stiffness and fat accumulation, providing insights into the potential development of NAFLD or hepatic fibrosis in T1DM patients.

5. Comparing Findings with Healthy Controls: Establishing differences in biochemical markers and FibroScan measurements between T1DM patients and non-diabetic individuals to highlight the impact of diabetes on liver health.

1.3. Expected Outcomes and Clinical Implications

Given the increasing recognition of liver complications in T1DM, this study aims to provide critical insights into the extent of hepatic involvement in diabetic patients. It is expected that T1DM patients will exhibit significant metabolic disturbances, including elevated liver enzymes, increased liver stiffness, and higher fat accumulation compared to healthy controls. The findings of this study could contribute to the development of early screening strategies for liver complications in T1DM patients, thereby facilitating early intervention and improving long-term health outcomes.

By emphasizing the need for regular liver function monitoring in T1DM patients, this research could inform clinical guidelines and encourage the incorporation of non-invasive tools such as FibroScan into routine diabetic care. Furthermore, understanding

2. Materials and Methods

2.1 Study Design

This study involves a cross-sectional analysis of 45 T1DM patients and 45 healthy control subjects. Blood samples are collected from all participants to assess biochemical markers, including glycemic control parameters, lipid profiles, and liver function tests. FibroScan measurements are performed to evaluate liver stiffness and hepatic fat content. The collected data are statistically analyzed to determine correlations between glycemic control, lipid metabolism, and liver health.

2.2 Biochemical Analysis

Blood samples were processed using a Cobas biochemical analyzer. The following biochemical markers were assessed:

- **Fasting Blood Glucose (FBS):** Enzymatic assay.
- **Glycated Hemoglobin (HbA1c):** Immunoturbidimetric assay.
- **Lipid Profile:** Including total cholesterol (T.C), triglycerides (T.G), low-density lipoprotein (LDL), and high-density lipoprotein (HDL).
- **Liver Enzymes:** Alanine aminotransferase (ALT), Aspartate aminotransferase (AST), and Alkaline phosphatase (ALP).

2.3 FibroScan Assessment

Liver stiffness and steatosis were evaluated using FibroScan, which provides quantitative assessments of liver stiffness (kPa) and fat content (CAP score). The results were interpreted based on liver stiffness scores (ranging from 2 to ≥ 14 kPa) and steatosis grades (S1-S3 based on CAP scores).

3. Results

3.1 Demographi Characteristics and FibroScan Results

A total of 90 participants were included in this study, divided equally into two groups: 45 patients with Type 1 Diabetes Mellitus (T1DM) and 45 healthy controls. The gender distribution was balanced in both groups, with 25 males (60%) and 20 females (40%) in each, ensuring that gender-related differences did not confound the findings (Table 3-1).

Table (3-1): Distribution of gender in T1DM patients and the control group.

Gender	Male	Female
Control (n=45)	25 (60%)	20 (40%)
Patients (n=45)	25 (60%)	20 (40%)

Age did not significantly differ between the two groups, with a mean of 15.11 ± 5.15 years in T1DM patients and 16.72 ± 5.02 years in healthy controls ($p = 0.2$), indicating comparability in terms of age distribution.

A comparative analysis of key demographi characteristics and fibroscan characteristics between T1DM patients and healthy controls is summarized in Table 3-2.

Table (3-2): Comparison of baseline Demographi Characteristics and FibroScan of T1DM patients and controls.

Characteristic	Patients (n=45)	Controls (n=45)	p-value
Age (years)	15.11 ± 5.15	16.72 ± 5.02	0.2
BMI (Kg/m ²)	18.61 ± 4.90	19.70 ± 4.51	0.0001*
Steatosis score (UAP, dB/m)	275.49 ± 36.80	184.64 ± 13.60	0.001*
Liver stiffness (kPa)	11.05 ± 3.11	7.38 ± 4.55	0.037*

(*Statistically significant at $p \leq 0.05$)

- **Body Mass Index (BMI):** T1DM patients exhibited a significantly lower BMI compared to the control group (18.61 ± 4.90 kg/m² vs. 19.70 ± 4.51 kg/m², $p = 0.0001$). This may reflect altered metabolic status and potential nutritional imbalances associated with T1DM.
- **Liver Stiffness:** The mean liver stiffness was significantly higher in T1DM patients (11.05 ± 3.11 kPa) than in healthy controls (7.38 ± 4.55 kPa, $p = 0.037$), suggesting early fibrotic changes or increased hepatic rigidity in diabetic patients.
- **Steatosis Score:** A significantly higher controlled attenuation parameter (CAP) score was observed in T1DM patients (275.49 ± 36.80 dB/m) compared to controls (184.64 ± 13.60 dB/m, $p = 0.001$), indicating a higher prevalence of hepatic steatosis.

These results highlight significant metabolic and hepatic alterations in T1DM patients. The increased liver stiffness and steatosis scores suggest early hepatic involvement, possibly due to chronic hyperglycemia and insulin deficiency. The findings emphasize the need for routine liver health assessments in T1DM patients to enable early detection and management of liver complications.

3.2 Biochemical Markers

The biochemical analysis included fasting blood sugar (FBS), glycated hemoglobin (HbA1c), and lipid profile parameters. The results, summarized in Tables 3-3 and 3-4, reveal significant metabolic alterations in T1DM patients compared to healthy controls.

3.2.1 Glycemic Control Markers

Table (3-3): Comparison of Fasting Blood Sugar (FBS) and Glycated Hemoglobin (HbA1c) between T1DM patients and healthy controls.

Variable	Patients (n=45) Mean ± S.D	Controls (n=45) Mean ± S.D	p-value
FBS (mg/dL)	305.92 ± 137.61	93.47 ± 9.19	< 0.0001*
HbA1c (%)	10.32 ± 1.99	4.67 ± 0.23	< 0.0001*

(*Statistically significant at $p \leq 0.05$)

- **Fasting Blood Sugar (FBS):** T1DM patients exhibited significantly higher FBS levels compared to the healthy group (305.92 ± 137.61 mg/dL vs. 93.47 ± 9.19 mg/dL, $p < 0.0001$), confirming the characteristic hyperglycemia associated with T1DM.
- **Glycated Hemoglobin (HbA1c):** A marked increase in HbA1c levels was observed in T1DM patients ($10.32 \pm 1.99\%$) compared to controls ($4.67 \pm 0.23\%$, $p < 0.0001$), indicating chronic poor glycemic control in diabetic individuals.

3.2.2 Lipid Profile

Table (3-4): Comparison of lipid profile parameters between T1DM patients and healthy controls.

Variable	Patients (n=45) Mean ± S.D	Controls (n=45) Mean ± S.D	p-value
Triglycerides (TG) (mg/dL)	124.70 ± 74.31	72.40 ± 15.46	0.0004*
Total Cholesterol (TC) (mg/dL)	172.00 ± 38.32	139.20 ± 37.60	< 0.0001*
High-Density Lipoprotein (HDL) (mg/dL)	22.15 ± 3.81	44.09 ± 13.89	< 0.0001*
Low-Density Lipoprotein (LDL) (mg/dL)	102.90 ± 33.01	73.15 ± 22.37	0.0004*

(*Statistically significant at $p \leq 0.05$)

- **Triglycerides (TG):** A significant elevation in triglyceride levels was observed in T1DM patients (124.70 ± 74.31 mg/dL) compared to controls (72.40 ± 15.46 mg/dL, $p = 0.0004$), suggesting altered lipid metabolism and increased cardiovascular risk.
- **Total Cholesterol (TC):** T1DM patients exhibited higher total cholesterol levels (172.00 ± 38.32 mg/dL) than healthy controls (139.20 ± 37.60 mg/dL, $p < 0.0001$), reinforcing the link between diabetes and dyslipidemia.
- **High-Density Lipoprotein (HDL):** Interestingly, HDL levels were significantly decreased in T1DM patients (22.15 ± 3.81 mg/dL) compared to controls (44.09 ± 13.89 mg/dL).

13.89 mg/dL, $p < 0.0001$). While HDL is generally considered beneficial, this unexpected increase may be attributed to compensatory metabolic responses or differences in insulin therapy.

- **Low-Density Lipoprotein (LDL):** LDL levels were significantly higher in T1DM patients (102.90 ± 33.01 mg/dL) compared to controls (73.15 ± 22.37 mg/dL, $p = 0.0004$), further indicating an increased risk for atherosclerosis and cardiovascular disease.

These findings confirm that T1DM patients exhibit significant dyslipidemia, which, combined with chronic hyperglycemia, may contribute to the progression of vascular complications.

3.3 Liver Function Tests

Liver function tests (LFTs) were evaluated in both T1DM patients and healthy controls to assess potential hepatic alterations. The results are summarized in Table 3-5.

Table (3-5): Comparison of liver function markers between T1DM patients and healthy controls.

Variable	Patients (n=45) Mean \pm S.D	Controls (n=45) Mean \pm S.D	p-value
Aspartate Aminotransferase (AST) (U/L)	21.28 ± 7.31	19.12 ± 6.91	0.15
Alanine Aminotransferase (ALT) (U/L)	16.54 ± 9.97	12.33 ± 3.75	0.02*
Alkaline Phosphatase (ALP) (U/L)	281.28 ± 197.92	144.43 ± 74.13	0.0001*

(*Statistically significant at $p \leq 0.05$)

- **Alanine Aminotransferase (ALT):** A statistically significant increase in ALT levels was observed in T1DM patients (16.54 ± 9.97 U/L) compared to controls (12.33 ± 3.75 U/L, $p = 0.02$), suggesting mild hepatocellular injury or early liver involvement in diabetes.
- **Alkaline Phosphatase (ALP):** T1DM patients exhibited a marked increase in ALP levels (281.28 ± 197.92 U/L) compared to healthy controls (144.43 ± 74.13 U/L, $p = 0.0001$), indicating possible biliary dysfunction or increased bone turnover.
- **Aspartate Aminotransferase (AST):** No significant difference in AST levels was observed between T1DM patients (21.28 ± 7.31 U/L) and controls (19.12 ± 6.91 U/L, $p = 0.15$), suggesting that AST is not a primary marker of liver dysfunction in these patients.

3.4 Interpretation of Liver Function Results

The significant increase in ALT and ALP levels among T1DM patients suggests potential hepatic stress, which may be attributed to chronic hyperglycemia, insulin resistance, or metabolic dysregulation. The absence of a significant difference in AST levels suggests that overt hepatic injury may not yet be present but could develop over time. These findings highlight the importance of liver function monitoring in T1DM patients to detect and manage early hepatic complications.

4. Discussion

The results of this study suggest that T1DM patients exhibit significant biochemical and hepatic disturbances, including poor glycemic control, dyslipidemia, and early signs of liver dysfunction(15). Elevated liver stiffness and steatosis, as assessed by FibroScan, indicate the presence of non-alcoholic fatty liver disease (NAFLD) and potentially early fibrosis in this population(16). The correlation between elevated FBS, HbA1c, and liver dysfunction further supports the hypothesis that poor glycemic control contributes to liver alterations in T1DM(11,17). These findings underscore the importance of regular monitoring of liver health in diabetic patients, as early detection of liver changes may help prevent severe liver damage, such as cirrhosis(18).

4.1 Demographic Characteristics and FibroScan Results

The study included a total of 90 participants, divided equally between 45 T1DM patients and 45 healthy controls, with an equal distribution of males and females in both groups. This balance minimizes potential gender-related confounding factors, ensuring that observed differences in metabolic and hepatic parameters are primarily due to the disease state rather than gender disparities(19).

The absence of a significant age difference between T1DM patients and controls ($p = 0.2$) strengthens the comparability of the groups. However, the significantly lower BMI in T1DM patients ($18.61 \pm 4.90 \text{ kg/m}^2$) compared to controls ($19.70 \pm 4.51 \text{ kg/m}^2$, $p = 0.0001$) suggests an altered metabolic state. This could be attributed to insulin deficiency, poor glycemic control, or increased catabolism commonly observed in T1DM patients(20).

FibroScan analysis revealed that liver stiffness was significantly higher in T1DM patients ($11.05 \pm 3.11 \text{ kPa}$) compared to controls ($7.38 \pm 4.55 \text{ kPa}$, $p = 0.037$), indicating early fibrotic changes in the liver. The increased controlled attenuation parameter (CAP) score in T1DM patients ($275.49 \pm 36.80 \text{ dB/m}$) compared to controls ($184.64 \pm 13.60 \text{ dB/m}$, $p = 0.001$) suggests a higher prevalence of hepatic steatosis in diabetic individuals. These findings align with previous studies linking T1DM with nonalcoholic fatty liver disease (NAFLD), reinforcing the need for routine liver assessments in diabetic patients(17,21).

4.2 Biochemical Markers

4.2.1 Glycemic Control

As expected, T1DM patients exhibited significantly elevated fasting blood sugar (FBS) levels ($305.92 \pm 137.61 \text{ mg/dL}$) compared to healthy controls ($93.47 \pm 9.19 \text{ mg/dL}$, $p < 0.0001$). The elevated glycated hemoglobin (HbA1c) levels in T1DM patients ($10.32 \pm 1.99\%$) compared to controls ($4.67 \pm 0.23\%$, $p < 0.0001$) confirm poor long-term glycemic control. These findings highlight the chronic hyperglycemia characteristic of T1DM,(22) which is a key driver of microvascular and macrovascular complications(23).

4.2.2 Lipid Profile Alterations

T1DM patients demonstrated significant dyslipidemia, characterized by elevated triglycerides ($124.70 \pm 74.31 \text{ mg/dL}$ vs. $72.40 \pm 15.46 \text{ mg/dL}$, $p = 0.0004$) and total cholesterol ($172.00 \pm 38.32 \text{ mg/dL}$ vs. $139.20 \pm 37.60 \text{ mg/dL}$, $p < 0.0001$). Elevated LDL levels ($102.90 \pm 33.01 \text{ mg/dL}$ vs. $73.15 \pm 22.37 \text{ mg/dL}$, $p = 0.0004$) further suggest an increased risk of cardiovascular disease in T1DM patients(24).

Interestingly, HDL levels were significantly decrease in T1DM patients ($22.15 \pm 3.81 \text{ mg/dL}$) compared to controls ($44.09 \pm 13.89 \text{ mg/dL}$, $p < 0.0001$). While HDL is generally considered cardioprotective (25), such an unexpected increase may result from altered lipid metabolism

due to insulin deficiency or compensatory mechanisms(26). Further studies are needed to evaluate the functional properties of HDL in T1DM patients, as dysfunctional HDL has been reported in diabetes despite elevated levels(27).

4.3 Liver Function Tests

Liver function parameters showed significant alterations in T1DM patients, with elevated alanine aminotransferase (ALT) levels (16.54 ± 9.97 U/L vs. 12.33 ± 3.75 U/L, $p = 0.02$) and alkaline phosphatase (ALP) levels (281.28 ± 197.92 U/L vs. 144.43 ± 74.13 U/L, $p = 0.0001$). These findings suggest early hepatic stress and possible biliary dysfunction in diabetic patients(28).

However, no significant difference was observed in aspartate aminotransferase (AST) levels (21.28 ± 7.31 U/L vs. 19.12 ± 6.91 U/L, $p = 0.15$), indicating that overt hepatocellular damage is not yet evident. The mild elevation of ALT and ALP suggests early hepatic involvement, possibly due to chronic hyperglycemia and metabolic stress(29). These findings warrant further investigation to assess the long-term impact of diabetes on liver function and the potential progression to more severe hepatic disorders(30).

4.4 Clinical Implications and Future Directions

The findings of this study highlight significant metabolic and hepatic disturbances in T1DM patients. The increased liver stiffness and steatosis scores suggest early liver involvement, reinforcing the need for regular hepatic monitoring in T1DM patients. Dyslipidemia and chronic hyperglycemia further contribute to an increased risk of cardiovascular and hepatic complications.

Future research should focus on exploring the mechanisms underlying these metabolic alterations and identifying potential therapeutic interventions to mitigate liver and cardiovascular risks in T1DM patients. Longitudinal studies assessing the progression of hepatic changes and their clinical consequences in diabetic patients would provide valuable insights into disease management and prevention strategies.

5. Conclusion

The relationship between T1DM and liver dysfunction is complex and multifaceted. With the use of advanced non-invasive diagnostic tools such as FibroScan, it is now possible to detect early hepatic alterations in diabetic patients, potentially mitigating long-term complications. This study underscores the importance of integrating liver health assessments into the standard care of T1DM patients to improve disease management and overall patient well-being. The findings will provide valuable data for clinicians and researchers working towards a deeper understanding of metabolic liver disease in the context of T1DM.

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