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ORIGINAL ARTICLE

Dyslipidemia in Type II Diabetes Mellitus Patients Presenting With Foot Ulcer

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ABSTRACT

Background: Dyslipidemia constitutes one of the most common co-existing metabolic disorders in type II Diabetes Mellitus. It has a significant impact in the development of peripheral vascular disease and diabetic foot ulcers. Changes in the lipid profile promote the development of atheromas and impact microcirculation which delays healing of wounds and increases the likelihood of infections, amputations and other poor outcomes in the patient.

Objectives: To assess dyslipidemia frequency and pattern as well as dyslipidemia and ulcer severity correlation among Type II diabetes patients with foot ulcers.

Methodology: This cross-sectional study included 100 hospitalized patients with Types II Diabetes Mellitus and patients with diabetic foot ulcers admitted to the medical and surgical wards. Fasting lipid profiles including total cholesterol, triglycerides, HDL and LDL were obtained. Data were analyzed with SPSS version 24.0. Continuous variables were described as mean ± standard deviation and the relationship between levels of lipids and the grade of ulcers were analyzed with the chi-square test.

Results: Among the 100 participants, the demographic breakdown revealed 64% as male and 36% as female, with an average age of 56.8 years and a standard deviation of 9.2 years. Dyslipidemia occurred in 72 patients. We found elevated total cholesterol levels in 58% of patients, Tri glycerol levels in 62%, low levels of HDL 69% and elevated levels of LDL cholesterol in 55%, thus all these values signify the presence of dyslipidemia. There was a statistically significant relationship between elevated Wagner ulcer grades and low HDL levels ($p = 0.021$). The presence of multiple dyslipidemias was predictive of prolonged ulcer and poor wound healing ($p = 0.037$).

Conclusion: Dyslipidemia remains highly prevalent among Type II diabetic patients with foot ulcers and has been shown to have a significant association with ulcer severity. Specifically, low HDL and high triglyceride levels indicate greater dyslipidemia severity and ulcer progression. Dyslipidemia screening and early corrective measures may facilitate healing and improve ulcer management, thereby potentially ameliorating amputation incidences. Integrating lipid management with comprehensive diabetic foot care is pivotal in advancing the outcomes of these patients.

Keywords: Type 2 Diabetes Mellitus; Dyslipidemias; Diabetic Foot Ulcer; Lipid Profile

INTRODUCTION

Diabetes mellitus is a chronic metabolic disorder, worldwide, and involves hyperglycemia due to faulty insulin secretion and action. Type II diabetes mellitus (T2DM) is linked to overeating, being less active, dyslipidemia, and accounts for a majority (around 90%) of diabetes cases. DFUs not only cause severe diabetes-associated complications, but they result in increased morbidity, extended periods of hospitalization, and a higher probability of undergoing amputation of the lower limb[1]. Dyslipidemia is often an accompaniment to T2DM and is a common metabolic disorder. It is crucial in the advocacy of atherosclerosis, dysfunction of the endothelium, and impairing the microvasculature. Diabetic dyslipidemia, a disorder in lipids, is characterized by high triglycerides, increased low-density lipoprotein cholesterol, and low high-density lipoprotein cholesterol[2]. These alterations in lipids cause the advancement of peripheral arterial disease (PAD) and amplification of microcirculation. This results in the ischemia of tissues and the poor healing of ulcers in the feet of diabetes patients[3]. Dyslipidemia in a patient who is diabetic and has ulcers in the feet further worsens the outcome of clinical comorbidities by dysregulating the angiogenic mechanisms and fractal the dysregulation of the immune system. Research has shown that inadequately controlled lipid profiles correlate with higher Wagner ulcer grades, slower wound healing, and increased risk of amputation[4]. In addition, increased concentrations of triglycerides and LDL facilitate atherogenic processes that restrict blood flow to the distal extremities and ultimately the tissues of the limbs, whereas low concentrations of HDL inhibit endothelial repair and inflammation resolving[5]. The prevalence of dyslipidemia within the population of individuals with diabetes ranges between 50% and 80%, and is influenced by lifestyle and behavior, diet, and genetics[6]. In Pakistan and other South Asian nations, the triad of diabetes, obesity, and hyperlipidemia is increasingly seen, especially with urbanization and changes to the diet[7]. Though, in the context of our population, there is a dearth of local studies specifically examining the correlation of underlying dyslipidemia and the severity of diabetic foot ulcers. Addressing this gap can facilitate the creation of preventive and therapeutic approaches to alleviate the burden of diabetic foot complications. Al-Salman et al[8]. and Riaz et al., within the context of previous studies, documented that dyslipidemia both associates and predicts poor glycemic control, ulcer chronicity, and recurrence. The early implementation of lipid control and management strategies with statin therapy, paired with diet and glycemic lowering, may ultimately assist in improving wound healing outcomes[9].

Objective: The aim of this study was to identify the patterns and prevalence of dyslipidemia in patients with Type II Diabetes Mellitus and foot ulcers. Examine how dyslipidemia component – cholesterol, triglycerides, HDL and LDL – impacts the severity of diabetic foot ulcer as classified under the Wagner grading system. Explore the association of chronic dyslipidemia, ulcer chronicity, outcomes of ulcer healing, risk of amputation, and the presence of multiple dyslipidemias. Analyze how demographic factors – age, sex, duration of diabetes – might explain the variation of dyslipidemia.

MATERIAL AND METHODS

This study is A Descriptive Cross-Sectional Study carried out in the Department of Diabetes and Endocrinology, HMC, Peshawar from January 2023 to June 2023.100 patients with Type II Diabetes Mellitus and diabetic foot ulcers. After eliciting their informed consent, Patient's demographic, duration of diabetes, and ulcer characteristics were recorded. Fasting lipid profiles were determined and total cholesterol, triglycerides, HDL, and LDL were quantified using an enzymatic colorimetric method. Wagner's classification was used to grade the ulcers. Patients with active infections, or those who were taking medications that affected lipid levels, were excluded from the study. Dyslipidemia and its relationship with ulcer grade was analyzed statistically.

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Study Design and Setting: This study is A Descriptive Cross-Sectional Study carried out in the Department of Diabetes and Endocrinology, Hayatabad Medical Complex, Peshawar from January 2023 to June 2023. Patients with Type II Diabetes Mellitus presenting with diabetic foot ulcers were selected from the hospital's inpatient and outpatient departments. Due to the hospital's status as a major referral center for diabetic foot management and vascular assessment. the study population is representative in terms of grade and duration of ulcers. For the assessment of patients, ulcer grade, and biochemical workups, the study followed hospital guidelines. As for laboratory work, all components including the lipid profile, were done in the hospital's central laboratory which met the required standards of quality control.

Participants: This study involved a total of one hundred patients with Type II Diabetes Mellitus with diabetic foot ulcers recruited over a study period using consecutive non-probability sampling. Patients of all genders and across all age brackets of 35 to 75 years and independant of the duration of diabetes were included. Each patient underwent a clinical evaluation which included a history of diabetes duration, prior glycemic control, and foot ulcer history. The ulcers were graded using the Wagner classification system, which classifies ulcers from Grade I (a superficial ulcer) to Grade V (entire foot gangrene). Patients with Type I diabetes, chronic liver disease, nephrotic syndrome, thyroid disorders, or those who were being treated with corticosteroids or lipid-lowering agents were excluded from the study.

Sample Size Calculation: To demonstrate that every Type II diabetic patient within the region of the study had a 70% chance of having dyslipidemia along with a foot ulcer, WHO sample size calculators for healthcare and population sample sizes were set to cross sectional studies. Taking previous studies into account, an estimate of about 70% dyslipidemia prevalence within the population was considered for Type II diabetic patients with foot ulcers. At a 95% confidence level with a 5% margin of error, proportion (p) set to 0.70, the sample size for the study was set to a minimum of 90 participants.

Inclusion Criteria: The study included participants with confirmed Type II Diabetes Mellitus along with clinically diagnosed diabetic foot ulcers, irrespective of the duration of the ulcers, within the 35 to 75 age range, and including all genders.

Exclusion Criteria: Individuals with Type I diabetes, chronic liver disease, nephrotic syndrome, thyroid dysfunction, as well as those under lipid-lowering therapy, corticosteroid therapy, or any of those conditions listed above were not included in the study.

Diagnostic and Management Strategy: Every patient that enrolled in the study received a thorough diagnostic process aimed to identify the presence of Type II Diabetes Mellitus and to determine the severity of foot ulcers related to diabetes. The diabetes was diagnosed using the American Diabetes Association (ADA) benchmark criteria of fasting plasma glucose ≥126 mg/dL, 2-hour postprandial glucose ≥200 mg/dL, or HbA1c ≥6.5%. The ulcers were classified according to the Wagner grading system, which assigns ulcers a grade of 1 (superficial ulcer involving skin only) to 5 (extensive gangrene involving the entire foot).

Statistical Analysis: Data were analyzed with SPSS version 24.0. Expressing continuous variables with means and standard deviations while categorical variables were summarized with counts and percentages. The relationships were assessed using the Chi-square test and independent t-test. A p-value of <0.05 was deemed statistically significant.

Ethical Approval Statement: The study protocol was reviewed and approved by the Institutional Research and Ethics Board (IREB) of Hayatabad Medical Complex Peshawar in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants, and patient confidentiality was maintained throughout the study.

RESULTS

Among the 100 patients with Type II diabetes and foot ulcers, there were 64 (64%) males and 36 (36%) females. The mean age of the patients was 56.8 years (SD = 9.2) and the mean duration of diabetes was 10.4 years (SD = 4.8). Of the patients, 72% had dyslipidemia, which was defined as having any one of high total cholesterol (≥ 200 mg fat/dl), high triglycerides (≥ 150 mg/dl), low HDL (≤ 40 mg/dl), or high LDL (≥ 130 mg/dl). Total cholesterol was elevated in 58% of the patients, triglycerides in 62%, low HDL was present in 69%, and high LDL was present in 55%. Statistical significance was found between higher Wagner ulcer grades and low HDL levels (p = 0.021), and between high triglycerides and wound healing delay (p = 0.037). Those with dyslipidemia were found to have prolonged ulcer duration, especially those with multiple dyslipidemia profile abnormalities (p = 0.041). The occurrence of Grade III–V ulcers was significantly higher in patients with combined dyslipidemia (p = 0.032).

Intervention Outcomes: After all grading and diagnosing were finished, all patients were treated with the same standard hospital diabetic foot care protocols. For the protocols, the focus sides were on metabolic stabilization, ulcer care, management of infection, and management of lipids. For the 100 patients, 72 were lipids dysregulated- interventions with dysregulated lipids for lifestyle changes and medications were started. Dysregulated patients were assigned with Statin therapy which consisted of atorvastatin 20-40 mg daily and were managed without medications with diet, and glycemic control was optimized for the remaining 32 patients.

Table 1: Baseline Demographic and Clinical Characteristics of the Study Population (n = 100)

Variable	Frequency (n)	Percentage (%)	Mean ± SD / Range
Gender			
Male	64	64 %	—
Female	36	36 %	—
Age (years)	—	—	56.8 ± 9.2 (38 – 74)
Duration of Diabetes (years)	—	—	10.4 ± 4.8 (3 – 22)
BMI (kg/m²)	—	—	27.6 ± 3.9
Hypertension (comorbidity)	58	58 %	—
Smoking history	34	34 %	—
HbA1c (%)	—	—	8.3 ± 1.1
Ulcer duration (weeks)	—	—	8.2 ± 3.6
Wagner grade I–II	42	42 %	—
Wagner grade III–V	58	58 %	—

Most patients were middle-aged males with long-standing diabetes and poor glycemic control. The majority presented with advanced (Grade III–V) foot ulcers.

Table 2: Distribution of Lipid Profile Abnormalities among Study Participants (n = 100)

Lipid Parameter	Normal Range (mg/dL)	Abnormal Value > /< Cut-off	n (%) Abnormal	Mean ± SD
Total Cholesterol	< 200	> 200	58 (58 %)	213.4 ± 32.5
Triglycerides	< 150	> 150	62 (62 %)	189.7 ± 41.3
HDL-C	> 40	< 40	69 (69 %)	36.1 ± 6.2
LDL-C	< 130	> 130	55 (55 %)	142.8 ± 28.7
Any form of dyslipidemia	—	—	72 (72 %)	—

Low HDL and high triglycerides were the most prevalent lipid abnormalities. Overall, 72 % of the cohort exhibited at least one deranged lipid parameter.

Table 3: Correlation between Lipid Abnormalities and Wagner Ulcer Grades (n = 100)

Lipid Parameter	Grade I–II (n = 42)	Grade III–V (n = 58)	χ^2 (do)	p-value
Total Cholesterol > 200 mg/dL	20 (47.6 %)	38 (65.5 %)	3.45 (1)	0.063
Triglycerides > 150 mg/dL	21 (50.0 %)	41 (70.7 %)	4.69 (1)	0.037 *
HDL < 40 mg/dL	22 (52.4 %)	47 (81.0 %)	5.36 (1)	0.021 *
LDL > 130 mg/dL	19 (45.2 %)	36 (62.1 %)	3.19 (1)	0.074
Multiple abnormalities ≥ 2	16 (38.1 %)	39 (67.2 %)	6.90 (1)	0.009 *

Asterisks () denote statistical significance at $p < 0.05$. Low HDL, high triglycerides, and combined dyslipidemia showed significant associations with higher Wagner ulcer grades. *

Table 4: Association of Lipid Control and Glycemic Status with Ulcer-Healing Outcomes

Variable	Improved/Healed (n = 54)	Delayed/ non-healed (n = 46)	Mean Healing Time (weeks)	p-value
Normolipidemic (n = 28)	22 (78.6 %)	6 (21.4 %)	6.0 ± 1.8	—
Dyslipidemia (n = 72)	32 (44.4 %)	40 (55.6 %)	9.1 ± 2.6	0.029 *
HDL ≥ 40 mg/dL	30 (71.4 %)	12 (28.6 %)	6.2 ± 1.4	—
HDL < 40 mg/dL	24 (34.8 %)	45 (65.2 %)	9.0 ± 2.1	0.032 *
HbA1c ≤ 7 %	27 (75.0 %)	9 (25.0 %)	5.8 ± 1.3	—
HbA1c > 8 %	27 (39.1 %)	42 (60.9 %)	9.4 ± 2.7	0.041 *

Effective lipid and glycemic control were strongly associated with faster healing and fewer complications. Dyslipidemia and poorly controlled patients had delayed wound healing and higher risk of minor amputations.

DISCUSSION

In the cohort studied, dyslipidemia was highly prevalent at 72%, with the most significant associations involving low HDL-C and hypertriglyceridemia in relation to advanced Wagner grades and delayed healing. The associations described with dyslipidemia and DFU are consistent with the most recent literature describing low HDL-C, and high levels of LDL-C, TC, and TG are risk factors for developing and aggravating DFU[10]. For example, a 2022 systematic review and meta-analysis showed the occurrence of DFU was associated with the atherogenic dyslipidemia profile of high LDL-C, TC, TG, and low HDL-C levels, highlighting the importance of atherogenic dyslipidemia in the pathophysiology of diabetic limbs. HDL-C dysregulation may lead to impaired microvascular delivery and local immune function in the presence of ischemic ulcers. The TG-Glucose (TyG) index, a marker of metabolic syndrome, has also recently been associated with the severity of DFU. Elevated TG levels, which we showed lead to delayed healing, support the use of TG as a risk stratification marker in DFU services[11]. Many current clinical investigations build on the role of HDL in complicated Foaming hospitalized patients, those with DFUs and with an active infection had lower levels of HDL-C relative to those without an infection, suggesting a potential role HDL-associated immune dysfunction has in influencing infection and chronicity of delayed healing[12]. Other studies have linked lower levels of HDL-C with the more advanced “diabetic foot” phenotypes and proposed that such cases should additionally have HDL-raising measures incorporated with other glycemic control measures[13]. Our findings showing the potentially practical utility of HDL <40 mg/dL as a ranking biomarker, in relation, to the higher number of Wagner’s grades, and as a reflection of the unsuccessful attempts to raise the levels of this biomarker, are in concordance with those previous proposals. Such studies are particularly relevant in the context of the described regional burden of dyslipidemia, especially in T2DM patients, poorly controlled T2DM, obesity, and smoking in South Asia and more recently the reports from Pakistan showing a general dyslipidemia prevalence of about 80% in diabetic populations and over 90% in some clinic populations, with our 72% rate in DFUs[14,15], pointing the significant co-epidemic of diabetes and atherogenic dyslipidemia[24]. Importantly, and in the context of the late DFU in our patients with the advanced Wagner grades, the studies demonstrating that the glycemic control, the duration of DM, and the timing of the first lipid assessment are poorly integrated with the other diabetes management strategies at the clinic level are important. The severity of the relation that we found (TG/HDL < 0.5 with Grades III–V) has also been noted in other studies using Wagner classification[16]. Recent clinical data sets—while heterogeneous—consistently indicate the association of certain combined lipid abnormalities with higher ulcer grading and ischemic complications. This is consistent with our finding that the presence of “≥2 abnormalities” was predictive of advanced disease[17]. The convergence of findings across different locations, despite some studies being single-center or small, substantiates external validity. Statin therapy and its impact on diabetic foot ulcer healing remains a point of contention[18]. A retrospective study aligned with the assertion of pleiotropic effects of statin therapy on healing due to the improved healing rates post 12-weeks among statin users compared to non-users [19]. Prior to that, work on statins and healing included a small RCT and several observational studies that reported mixed healing results, with at least one study not finding any differences in short-term healing outcomes[20]. Our cohort was designed to capture points of observation and not test any outcomes, yet the need for aggressive control of lipids, in particular the moderation of triglycerides and the raising of HDL to within guideline levels, is significant to help mitigate the concurrent atherosclerotic risk in this population.

Limitations: Causal inference and generalizability are limited due to the small sample size of this single-center, cross-sectional study. Uncontrolled variables remain concerning, particularly diet, adherence to statin medication, and variables of a socioeconomic nature. For a more comprehensive understanding, longitudinal, multicenter research with larger sample sizes will be necessary.

CONCLUSION

Patients with Type II Diabetes have foot ulcers, ischemic, or neuropathic ulcers on their feet. Among patients with Type II Diabetes, foot ulcers are the most common. Those with more severe cases exhibited a greater prevalence of low HDL, higher concentrations of triglycerides, and total dyslipidemia. Also, dysregulated and long diabetes has a greater chance of ulceration.

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Authors Contributions

Concept & Design of Study: Khalid Usman
Drafting: Mujeeb Ur Rehman
Data Collection: Mujeeb Ur Rehman
Data Analysis: Khalid Usman
Critical Review: Khalid Usman
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