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To study the significance of glycosylated haemoglobin on wound healing in patients with diabetic foot.

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Abstract

Introduction*: Diabetes is a major health problem which is currently showing an alarming increase in its incidence and prevalence. Diabetic foot ulcers are a predominant complication of the disease. This has led to a growing interest in corelating HbA1c to wound healing in the management of diabetic foot ulcers.*

Objectives*: To correlate the influence of level of Glycosylated Haemoglobin on wound healing.*

Methods*: The study focused on assessing the clinical characteristics, treatment outcomes, and the correlation between proper glycaemic control (HbA1c) and the healing of diabetic foot ulcers (DFUs) in a population of diabetic patients in a single centre. The parameters which were explored included significant correlations between key clinical indicators, such as HbA1c levels, wound healing duration. 100 patients with diabetic foot ulcers were selected.*

Results*: The study found that the majority of participants were male (78%) and with a mean age of 61.48 years. A significant proportion of participants (59%) had Wagner Grade 2 ulcers. Poor glycaemic control, indicated by higher HbA1c levels, was strongly correlated with prolonged healing times, highlighting the importance of glycaemic management in DFU care.*

Conclusions*: The present study reaffirms the critical role of glycaemic control in managing diabetic foot ulcers. Higher HbA1c levels were associated with delayed healing, underscoring the need for aggressive management to improve wound healing. The study emphasizes the need for a comprehensive approach to managing diabetes incorporating strict glycaemic control, patient education and regular follow-up are necessary to enhance treatment outcomes and quality of life for diabetic patients.*

Article proper

Introduction

Diabetes is a major health problem which is currently showing an alarming increase in its incidence and prevalence. Diabetic foot ulcers are a predominant complication of the disease. It is estimated that around 19-34% of the patients with diabetes are likely to be affected by diabetic foot ulcers in their Lifetime. These foot ulcers become a significant proportion of patients presenting to the outpatient departments of Department of General Surgery across India. Diabetes mellitus is one of the commonest global non communicable health-care problem, carrying a predicted pandemic score of 366 million population by 2030.[1] According to the ICMR-INDIAB study, there are 62.4 million people living with diabetes in India alone, making it "diabetic capital" of the world.[2] About 15% of all such patients develop a foot ulcer in their lifetime.[3] Neuropathy and ischemia, two common complications of diabetes, have been implicated as the primary underlying risk-factors in the development of foot-ulcers while hyperglycaemia contributes to delayed and impaired wound healing.[4] Treatment of diabetic foot ulcers is challenging and one must employ a multidisciplinary approach in its treatment.

Glycosylated haemoglobin (HbA1c) is a measure of beta-N-1-deoxy fructosyl component of haemoglobin, which is formed by non-enzymatic glycation pathway, due to haemoglobin's exposure to plasma glucose, depicting the average blood glucose level over previous 2-3 months span.[5] American Diabetic Association has included HbA1c in the diagnosis of diabetes mellitus, with a cut-off value of 6.5.[6] Although it is clear from literature review that strict glycaemic control prevents complications, the relationship amongst HbA1c value, wound healing, vasculopathy and neuropathy in diabetic foot patients is less well defined.

A paucity of studies regarding a compelling association between DFU and HbA1c level has been observed. It has been reported that inconsistent HbA1c levels of diabetic patients have a greater influence on wound healing activity than a baseline control value. Moreover, after accommodating confounding factors, there has been no correlation between HbA1c level and healing of DFU. Contradicting these outcomes, a strong association between elevated HbA1c and delay in the healing of DFU has also been observed.

Objectives

To assess the Glycosylated Haemoglobin levels in patients with diabetic foot ulcers and to correlate the influence of level of Glycosylated Haemoglobin on wound healing.

Methods

The study design was a prospective observational study with a study duration of 18 months. Study population and source of data was from patients with diabetic foot ulcers grade 1 & 2 (Wagner Classification) presenting to the surgical outpatient department. Sampling Technique used was systematic random sampling where every 2nd patient with Diabetic foot ulcers grade 1 & 2 (Wagner Classification) attending surgical outpatient department were selected.

The study was conducted in the department of surgery, JSS Mysore. Patients presenting to, surgical outpatient department with lower limb ulcers were selected on the basis of clinical history, physical examination, blood investigation. Proper treatment in the form of local wound care, control of sepsis and control of diabetes was provided regularly and they were re-assessed at 12 weeks.

Duration and family history of diabetes, compliance to treatment, history of numbness, decreased sweating, corns/callosities and ulcer/abscess of lower limb. Clinical nutritional assessment, palpation of all peripheral pulses, ulcer evaluation was documented with haematological investigations such as hemogram, fasting and post-prandial blood sugar level, renal function test and HbA1c assessment.

Management done was under strict glycaemic control, patients were followed up at regular intervals and ulcers were debrided surgically. Appropriate antibiotic(s) were started as per the tissue culture-sensitivity report, and moist dressings applied. At 12th week of treatment, patients were re-assessed by history (for improvement in symptoms), clinical examination, and biochemical analysis (HbA1c value).

Inclusion criteria was diabetic foot ulcers grade 1 & 2 (Wagner Classification) and the exclusion criteria included pregnant women, age >80 years, patients with Serum creatinine > 2 mg/dl, diabetic foot ulcers grade 3, 4 and 5 (Wagner classification).

Data Analysis:

Data Entry will be done using Microsoft excel 2013 and analysis done using SPSS Version 16. Qualitative data will be expressed in frequencies and percentages and Quantitative data in mean and standard deviation. Parametric tests include unpaired t test for intergroup comparison will be used. Chi square test will be used for Qualitative variables. Bar diagrams and pie charts will be used to represent the data. p value of <0.05 will be considered statistically significant.

Results

Table 1. Distribution Of Study Subjects Based on Age

Age (Years)	Frequency	Percentage
<=40	3	3.0
41-50	14	14.0
51-60	31	31.0
61-70	27	27.0
71-80	25	25.0
Total	100	100.0

This table presents the distribution of study participants by age groups. The age range is divided into five categories: those aged 40 years or below (3%), 41-50 years (14%), 51-60 years (31%), 61-70 years (27%), and 71-80 years (25%). The data suggests that the majority of the participants fall within the 51–60-year range, making up 31% of the total, while the youngest group (≤40) represents only 3% of the population.

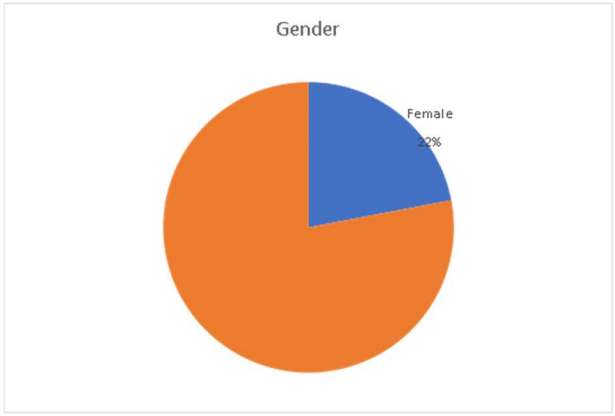

Figure 1- Pie Chart Showing Distribution of Subjects By Gender

Out of the 100 participants, 22% are female and 78% are male, indicating a significantly larger proportion of male participants in the study.

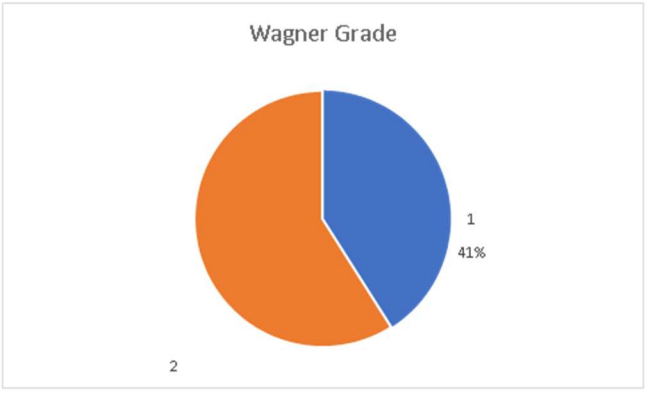

Figure 2 – Distribution Of Subjects By Wagner Grade

The study subjects are categorized by their Wagner grade, a classification used to assess the severity of diabetic foot ulcers. In this study, 41% of the participants fall under Wagner Grade 1, while 59% are classified under Wagner Grade 2. This indicates a higher prevalence of severe ulcer conditions among the participants.

Table 2: Descriptives

Variables	Minimum	Maximum	Mean± SD
Age	38	80	61.48±10.67
Urea	8	155	39.75±24.99
Creatinine	0.38	3.8	1.09±0.51

Haemoglobin	6.6	17.1	10.96±2.1
TLC	5100	32000	12948.43±5585.73
Platelet	0.45	9.87	3.28±1.51
HbA1c	4.5	15.1	9.13±2.52
FBS	57	417	150.79±73.72
PPBS	96	532	226.66±107.65
Duration (Years)	1	35	8.2±6.19
Wound Length	0.5	20	5.26±3.51
Wound Breadth	0.5	15	4.56±2.89
Area(cm^2)	0.25	200	30.66±38.49
SBP	90	190	130.14±16.89
DBP	60	100	82.12±9.71
Pulse Rate	66	116	86.38±11.36
Repeat HbA1c	5	13	7.9±1.84
Days of Healing	25	100	57.83±17.39

This table provides descriptive statistics (minimum, maximum, and mean ± standard deviation) for various variables. These include age (mean: 61.48 years), urea (mean: 39.75 mg/dL), creatinine (mean: 1.09 mg/dL), haemoglobin (mean: 10.96 g/dL), and several others such as total leukocyte count, platelet count, HbA1c, and fasting and postprandial blood sugar levels. Furthermore, it includes measurements like systolic and diastolic blood pressure as well as the wound characteristics such as length and breadth. 59% of patients had trivial trauma as the inciting event, while 41% had spontaneous development of DFU. The right limb is affected in 52% of the subjects, while the left limb is affected in 48%, showing an almost equal distribution between the two limbs.

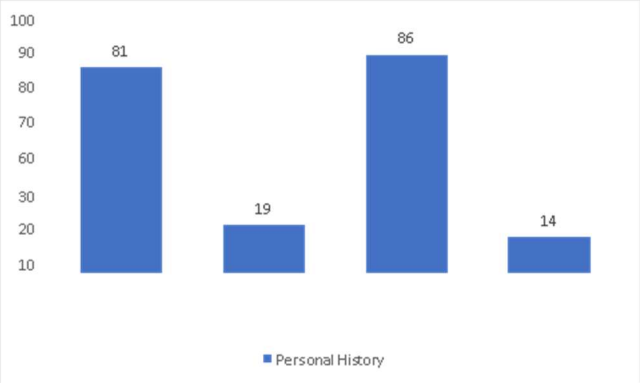

Figure 3 – Bar Graph Depicting Personal History of Deleterious Habits

This figure categorizes participants based on their personal habits, specifically alcohol consumption and smoking. The majority of participants (81%) did not consume alcohol, while 19% did. Similarly, 86% of participants are non-smokers, with only 14% identified as smokers.

Table 3: Distribution Of Study Population Based on Their Clinical History

		Frequency	Percentage
OHA/Insulin	OHA	54	54.0
	Insulin	46	46.0
Hypertension	Absent	44	44.0
	Present	56	56.0
Ischemic Heart Disease	Absent	72	72.0
	Present	28	28.0
Family History	Absent	47	47.0
	Present	53	53.0
Numbness	Absent	64	64.0
	Present	36	36.0
Peripheral Pulses	Absent	46	46.0

	Present	54	54.0

The clinical history of participants is broken down in this table. It shows that 54% of the participants are treated with oral hypoglycemic agents (OHA), while 46% are on insulin therapy. Additionally, 56% of participants have hypertension, 28% have ischemic heart disease, 53% have a family history of similar conditions, 36% experience numbness, and 54% have palpable peripheral pulses.

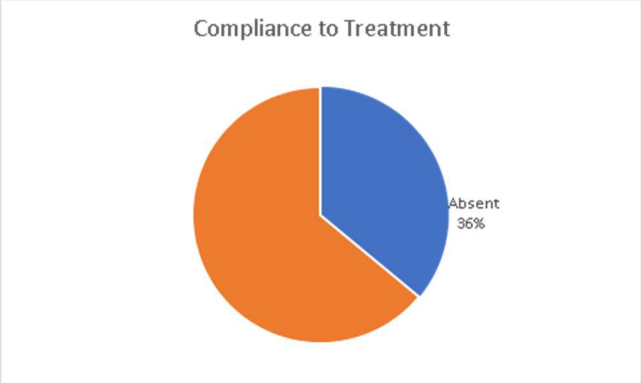

Figure 4 – Pie Chart Depicting the Compliance to Treatment

This table shows the compliance rate of participants with the prescribed treatment plan. 64% of participants were compliant with their treatment regimen, while 36% were not.

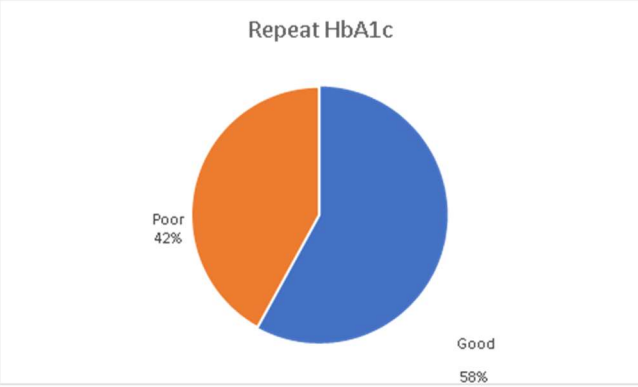

Figure 5 – Pie Chart Depicting Repeat Hba1c Values After 12 Weeks

The study population is divided based on their repeat HbA1c results, which measure long-term blood glucose control. In this study, 58% of participants achieved good control, while 42% had poor control of their blood glucose levels.

Table 4: Comparison Of Days of Healing and Repeat Hba1c

Repeat HbA1c	Days of Healing		t Value	p Value
	N	Mean ± SD		
Good	58	47.93±11.17	-8.58	**<0.001***
Poor	42	71.5±15.06		

This table compares the number of days required for wound healing between two groups of participants: those with good HbA1c control and those with poor control. Participants with good glycaemic control healed faster, with a mean healing time of 47.93 ± 11.17 days, compared to 71.5 ± 15.06 days for those with poor control. The t-value of -8.58 and a p-value of <0.001 indicate a statistically significant difference between the two groups.

Table 5: Correlation Between Repeat Hba1c and Days of Healing

Variables	Pearson Correlation Coefficient	p Value
Repeat HbA1c	0.797**	**<0.001***
Days of Healing		

This table presents the Pearson correlation coefficient between repeat HbA1c levels and the days required for healing. The correlation coefficient is 0.797 with a p-value of <0.001, indicating a strong and statistically significant positive correlation between higher HbA1c levels and longer healing times.

Table 6: Correlation Between Hba1c and Serum Creatinine

Variables	Pearson Correlation Coefficient	p Value
HbA1c	-0.26	**<0.001***
Serum creatinine		

This table examines the correlation between HbA1c and serum creatinine levels. The Pearson correlation coefficient is -0.26, with a p-value of <0.001, suggesting a weak but statistically significant negative correlation between the two variables.

Discussion

In the present study, the mean age of participants was 61.48 years, with a significant proportion (31%) in the 51-60 age group. This is consistent with a study by Kumar B et al. [9] (2016), where the mean age of patients presenting with diabetic foot ulcers was 53.4 years. In Study by Hegde et al.[7] (2022), the mean age was reported as 56.4 ± 11.41 years, with 28.89% of participants in the 51-60 age group. This indicates that diabetic foot ulcers are prevalent in individuals in their sixth decade of life, although the present study population was slightly older. The older mean age in the present study suggests that the population in this area may be experiencing complications later in life, potentially due to differences in healthcare access or disease progression. Both studies confirm a male predominance in diabetic foot cases, which was also observed in the present study, where 78% of participants were male.

Study suggests that diabetic foot ulcers may affect men more frequently, which could be related to behavioural factors such as higher rates of smoking and alcohol consumption. This consistency across studies highlights gender disparity in the occurrence of diabetic foot ulcers, suggesting that males are at a higher risk of developing such complications, possibly due to differences in lifestyle factors, healthcare engagement, or other socioeconomic factors.

In the present study, the study subjects were found to have Wagner grade 2 ulcers in 59% while 41% of the study subjects had Wagner grade 1 ulcers. This is in contrast to the findings of Kumar B et al. [9]. (2016), where Wagner grade 1 accounted for 84% and Wagner grade 2 for 16 %. Similarly, Ojing K. et al[10]. (2023) reported a more balanced distribution with 53.3% of subjects in Wagner Grade 1 foot ulcers and 46.7% in Wagner Grade 2. In Hegde et al.[7]. (2022) study 58.89% of participants were categorized as Wagner Grade 2 and 41.11% as Wagner Grade 1 ulcers. Both studies showed a higher prevalence of Wagner grade 2 ulcers emphasizing the prevalence of more severe conditions in the diabetic population. This discrepancy may be due to differences in the healthcare standards or socioeconomic or demographic characteristics in the present study. The higher proportion of Wagner Grade 2 cases in the present study suggests a more advanced stage of foot ulceration at presentation, possibly indicating delayed healthcare access or recognition of symptoms among the population. Thus, earlier detection and prompt intervention are needed to prevent progression to more severe stages of DFU. The elevated HbA1c levels in the present study underscore the importance of tighter glucose management in diabetic patients to promote better wound healing and reduce complications. Additionally, the mean creatinine level in the present study was 1.09 mg/dL, which is within the normal range, similar to findings by Kumar B et al.[9]. (2016), suggesting preserved renal function despite the advanced ulcerations.

Trivial trauma was noted as the inciting event in 59% of cases, which is slightly lower than the 70% reported by Kumar B et al.[9]. (2016). This suggests that trauma is a common trigger for ulcer formation across different populations, particularly in diabetic patients with neuropathy who may not be able to identify minor injuries. The lower percentage in the study could reflect differences in environmental, geographical or occupational factors, or it could suggest better preventive measures in place to avoid trauma among the diabetic population. Nonetheless, trauma remains a significant contributor to the onset of diabetic foot ulcers. Thus, the importance of need for increased patient education on foot care and injury prevention is necessary.

The right limb was the affected side in 52% of subjects, while the left limb was affected in 48%, showing somewhat equal distribution. This is similar to the findings of Kumar B et al.[9]. (2016), who observed no significant difference between the right and left limb involvement in diabetic foot ulcers. The near parity in limb involvement suggests that diabetic foot ulcers do not preferentially affect one limb over the other and that the distribution may largely be random. The present study findings align with the findings of Hegde et al.[7]. (2022), where 52.22% of ulcers were on the plantar side of the foot and 47.78% on the dorsum, reflecting no significant bias toward one side. This supports the understanding that factors such as trauma, peripheral neuropathy, and vascular complications are likely to affect both limbs equally in diabetic patients. Consequently, preventive measures and monitoring should be equally applied to both limbs in at-risk patients.

Our research found that 19% of subjects consumed alcohol and 14% smoked, indicating a lower prevalence of these risk factors compared to studies like that of Ojing K. et al [10]. (2023), where 36.7% of subjects had a history of smoking. The lower prevalence of smoking in the present study may reflect regional differences in lifestyle or the effectiveness of smoking cessation programs. The present study is similar to the study by Bansal et al [11]. (2014), which reported alcohol consumption in 24.9% of diabetic patients and smoking in 12.4%. Nevertheless, smoking and alcohol consumption are known risk factors that impair wound healing by reducing circulation and exacerbating oxidative stress, which could contribute to the slower healing rates observed in patients with these habits. These further underscores the importance of addressing lifestyle factors as part of a comprehensive diabetic foot management strategy.

54% of the patients were treated with oral hypoglycemic agents (OHA), and 46% were on insulin therapy for diabetes treatment. Similarly, Kumar B et al.[9]. (2016) also observed a comparable distribution in their study, where a significant portion of the patients were taking insulin therapy. The proportion of patients with systemic hypertension in the current study was 56%, which is slightly higher than the 44% reported by Ojing K. et al [10]. (2023). Additionally, 28% of the current study's population had ischemic heart disease, which is similar to findings from other studies such as Kumar B et al. [9]. (2016), where vasculopathy was present in 30% of the cases. The presence of these comorbidities is critical, as they are known to exacerbate diabetic foot ulcer outcomes by impairing circulation, delaying healing and further worsen quality of life to patients. Therefore, the results of the present study highlight the need for multidisciplinary approach to managing diabetes and its associated comorbidities to improve outcomes.

64% of patients were compliant with their diabetic treatment such as OHAs or insulin, whereas 36% were not. Compliance is a critical factor in the management of diabetic foot ulcers, as noted in Christman et al[8]. (2011), who stressed the importance of consistent treatment adherence to improve healing rates. In comparison, Ojing K. et al [10]. (2023) highlighted those patients with better compliance had more favourable outcomes, including faster healing times and fewer complications. The lower compliance rate in the present study may partly explain the prolonged healing times observed thus emphasizing the need for more robust patient education on diabetic foot care and support systems to improve adherence to prescribed regimens with regular monitoring.

58% of subjects had good glycemic control, with HbA1c levels considered favourable, while 42% had poor control of repeat HbA1c done after 12 weeks. This is similar to the findings in the study of Ojing K. et al [10]. (2023), where patients with lower HbA1c values had better outcomes in terms of wound healing and improved significantly. The results from the present study prove the critical role of maintaining good glycemic control in improving diabetic foot ulcer outcomes. Thus, the importance of strict glycaemic management is emphasized in diabetic foot ulcer care as lower HbA1c levels are consistently associated with better healing

rates.

Patients with good HbA1c control healed in an average of 47.93 days, while those with poor glycaemic control took significantly longer duration in terms of wound healing, with a mean of 71.5 days. These findings are in line with the results from the study of Christman et al[8]. (2011), where lower HbA1c levels were strongly correlated with faster wound healing rates. Ojing K. et al [10]. (2023) similarly found that patients with lower HbA1c levels healed more rapidly than those with poor glycemic control. Additionally, Bansal et al [11]. (2014) emphasized that poorly controlled blood sugar levels are associated with both delayed recovery in diabetic foot ulcers as well as a higher prevalence of diabetic complications. Thus, the critical impact of HbA1c on the healing process is reinforced. The strong correlation in the present study between better HbA1c levels and faster healing emphasizes the importance of aggressive glycemic control in reducing healing times for diabetic foot ulcers.

The study demonstrated a strong positive correlation (Pearson's coefficient of 0.797) between higher HbA1c levels and increased days of healing, with a significant p-value of <0.001. This strong correlation is supported by other studies such as that by Christman et al[8]. (2011), where each percentage increase in HbA1c was shown to slow the healing rate of diabetic wounds. Ojing K. et al [10]. (2023) also observed similar results, further corroborating the finding that poor glycemic control leads to prolonged healing times. These consistent findings across studies underscore the need for maintaining optimal HbA1c levels in diabetic patients to quicken wound healing and prevent further worsening condition of the patient by progression of complications.

In the present study, there was a weak negative correlation (Pearson's coefficient of - 0.26) between HbA1c and serum creatinine, with a significant p-value of <0.001. This result suggests that while HbA1c and renal function are related, the correlation is not as strong as with wound healing outcomes. Kumar B et al. [9]. (2016) also reported a weak relationship between glycemic control and renal function, though kidney impairment was not the focus of their study. The findings in the current study emphasize the multifactorial nature of diabetic complications, where HbA1c management is crucial not only for wound healing but also for preserving renal function, even if the correlation is weaker.

LIMITATIONS

Even though the study is consistent with the finding that good glycaemic control for the DFU healing, a larger study is required to consider the other factors which help in better treatment of DFU and prevention of the associated complications. There are confounding factors which affect wound healing in the study which have not been analysed such as anaemia, nutrition, co-morbidities and immunosuppression. Only Wagner grade 1 and 2 ulcers were studied. Patients with osteomyelitis and peripheral vascular disease were not included in the study. Further research is required into this. In current Indian scenario, the cost for HbA1c might not be affordable for all socioeconomic groups.

CONCLUSION

The present study reaffirms the critical role of glycaemic control in managing diabetic foot ulcers. Higher HbA1c levels were associated with delayed healing, underscoring the need for aggressive management of blood glucose levels to improve wound healing outcomes and reduce the risk of complications. The study also highlights the importance of patient compliance with treatment regimens, early detection, and intervention in managing DFUs. Given the high male predominance and older age of participants, targeted preventive measures for at-risk groups, particularly focusing on lifestyle modifications such as smoking cessation and

foot care education, are essential. While the correlation between HbA1c and renal function was weaker, the study emphasizes the need for a comprehensive approach to managing diabetes and its complications, incorporating strict glycaemic control, regular monitoring, and patient education regarding foot care, glycaemic control and regular follow-up are necessary to enhance treatment outcomes and quality of life for diabetic patients.

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