



Research Article

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Correlation of Glycosylated Haemoglobin with Outcome in Diabetic Lower Limb Ulcer Patients

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Abstract

With a lifetime prevalence of 15–25% in the diabetic population, diabetic ulcers are among the most prevalent consequences of the disease. Over the last several decades, significant progress has been made in understanding the etiology and treatment of diabetic ulcers in the lower limbs, yet the therapeutic efficiency of these interventions remains inadequate.

Aims: To investigate the relationship between glycosylated hemoglobin and the prognosis of individuals with diabetic lower leg ulcers.

Materials and Methods: The following study is a prospective observational study conducted between May 2023 – April 2024 in the department of General surgery in Dr. B.R.A.M.H and Pt JNM medical college Raipur. The duration of the study was one year.

Result: The Most common age group was 51-60 years (Mean age - 58.18 +/- 9.215) with a male preponderance of 57.6%. There is no significant association found between age and gender with Hba1c. The majority of participants (54.8%) fell within the HbA1c range of 6.5-8, followed by 29.5% with HbA1c levels greater than 8 but less than 10, a smaller proportion had HbA1c levels below 6.5 (5.7%) or above 10 (10.0%). Out of the 210 cases, wounds healed by granulation tissue formation and epithelialisation in 57 (27.14%) and 32(15.24%) cases, respectively. While 64 patients (30.48%) needed grafting for the covering of the exposed raw area, 57 patients (27.14%) underwent amputations. The organisms that were found in the ulcer bed include different gram negative and gram-positive bacteria. Among the gram-negative bacteria, *E. coli* and Klebsiella were found in the majority of the cases. As the degree of the glycemic control worsens the leukocyte count is also increasing. There is a significant association between total leukocyte count and glycosylated hemoglobin (p<0.0001)

Conclusion: The study found that managing glycosylated hemoglobin is crucial for preventing complications in diabetic foot ulcers. Optimizing glycosylated hemoglobin levels can reduce the severity of diabetic foot ulcers, promote wound healing, and reduce amputation rates.

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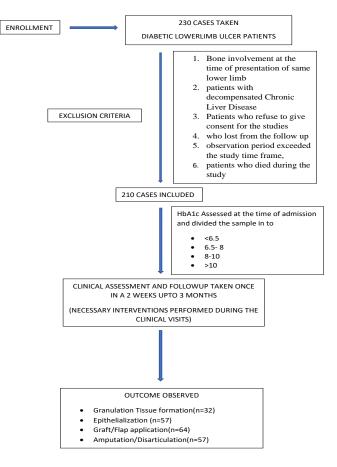
KEYWORDS: Diabetes Mellitus, Lower Limb Ulcers, Wound Healing and Diabetic Foot Ulcer.

1. INTRODUCTION

With an estimated lifetime frequency of 15-25% in the diabetic population, diabetic ulcers are among the most prevalent consequences of the disease ^[1]. Over the last several decades, significant progress has been made in understanding the etiology and treatment of diabetic ulcers in the lower limbs; nevertheless, the therapeutic effectiveness of these interventions is still lacking ^[2]. It was demonstrated that hyperglycemia and several other associated variables, including micro- and macrovascular problems, might be the causes preventing the ulcers from healing. Thus, blood glucose control is regarded as a fundamental part of treating lower limb diabetic ulcer patients' wounds ^[2]. A major global health problem is the rising prevalence of diabetes mellitus, a group of chronic disorders marked by elevated blood glucose levels due to deficiencies in insulin synthesis, action, or both. Diabetic foot ulcers are among the most prevalent consequences of diabetes affecting the lower extremities. According to estimates, 15% of diabetic individuals get lower extremity ulcers at some point in their illness ^[3]. One in five diabetic individuals may experience diabetic foot at some point in their lives. It is a complicated and diverse illness that has an impact on both lower limb survival and overall morbidity^[4]. A multidisciplinary team comprising a diabetologist, podiatrist, vascular surgeon, radiologist, and infectious disease specialist is required to manage and address all the different aspects and presentations of the pathology, as per the international consensus guidelines protocols ^[5]. Blood glucose levels are undoubtedly a significant factor in determining HbA1c values, which in turn indicate the degree of diabetes management during the previous three months ^[6].

2. MATERIALS AND METHODS

This prospective observational study was conducted at Dr. B.R.A.M.H and Pt JNM medical college Raipur, Chhattisgarh, India, between May 2023 – April 2024. Data were collected from outpatient and inpatient registries of general surgery. We included patients who visited and were admitted with a diagnosis of diabetes with lower limb ulcers. Patients with decompensated Chronic Liver Disease, Patients who refuse to give consent for the studies, who lost from the follow up, observation period exceeded the study time frame, patients who died during the study were excluded from the study. Two proportion methods calculated the sample size, and 210 cases were included. Informed consent is taken from the patient's attendant and/ patient. The institutional ethical committee approved the proposed study. In the selected patients, detailed particulars were recorded in a designed format, which included the clinical details like age, sex, duration of ulcer, type of diabetes mellitus, medication, foot deformity assessed by x-ray, infection, glycemic control (HbA1c) at the time of admission, and other comorbid conditions. Glycosylated hemoglobin values were divided into four ranges (< 6.4, 6.5-8, 8-10, > 10). Data recordings were done once in two weeks during clinical visits and continued up to 3 months. If any signs of moderate to severe infection were observed, readmission was considered. The outcome was evaluated as Granulation tissue formation, Epithelialisation, Graft procedure/flap application, and amputation. Data collected were charted onto an Excel sheet, and then correlations were made between Age, Size of ulcer, Wagener's grading, Total leukocyte count, bacteriological profile, Outcomes of diabetic lower limb ulcer patients, and angiopathy with HbA1c.



3. **RESULTS**

Our study found that 51-60 years of age (58.18 +/-9.215) was the most commonly observed age group, with a male preponderance of 57.6% (Table 1).

Demographic Parameter		Hba1c				Total		D Walaa
		<6.5	6.5-8	>8-10	>10	Total	Chi-square	P- Value
	<30	0	1	0	0	1	23.153	0.185
	31-40	0	0	2	0	2		
	41-50	6	28	13	0	47		
Age in group	51-60	3	51	23	13	90		
	61-70	2	28	19	5	54		
	71-80	1	5	5	2	13		
	>80	0	2	0	1	3		
Total		12	115	62	21	210		
Condon	Female	5	41	31	12	89	5.483	
Gender	Male	7	74	31	9	121		0.14
Total		12	115	62	21	210		

Table 1: Relation of Glycosylated haemoglobin and Age and Gender

We observed that larger ulcers often necessitate more invasive treatments such as grafting or amputation.

	Size of the ulcer (In Greatest diameter)							
Outcome	0-2	3-4	5-6	7-8	9-10	>12		
Epithelialisation	21	10	0	0	0	0		
Granulation Tissue	3	24	12	9	7	1		
Grafting	1	3	18	28	9	2		
Amputation	13	3	4	6	6	2		

In our study, most of the patients were presented at the stage of Wagner grade II (65.7%). 21 patients observed at Wagner grade III and 35 patients observed at Wagner grade IV. Cases were

observed less at the extremes of grading. We found that poorly controlled blood sugar levels are associated with more severe diabetic foot ulcers.

Table 3: Correlation of glycosylated hemoglobin with Wagner's grading

Demographic Parameter		HbA1c				Total	Chi-square	P-Value
		<6.5	6.5-8	>8–10	>10	Total	Ciii-square	r-value
	<30	0	1	0	0	1	23.153	0.185
	31–40	0	0	2	0	2		
	41–50	6	28	13	0	47		
Age in group	51-60	3	51	23	13	90		
	61–70	2	28	19	5	54		
	71–80	1	5	5	2	13		
	>80	0	2	0	1	3		
Total		12	115	62	21	210		
Gender	Female	5	41	31	12	89		
	Male	7	74	31	9	121	5.483	0.14
Total		12	115	62	21	210]	

As the degree of the glycemic control worsens the leukocyte count is also found increasing. There we got a significant

association between total leukocyte count and glycosylated haemoglobin (Table 4).

Table 4: Relation of Total leukocyte count and glycosylated hemoglobin

HbA1c								
Total Leukocyte Counts	<6.5	6.5-8.0	8.1-10.0	>10.1	Total	Chi-square	P-value	
<5000	1	18	0	2	21			
5000-9999	2	47	21	6	76			
10000-14999	8	53	14	2	77			
15000-19999	1	2	4	3	10	69.582	< 0.0001	
20000-25000	0	0	13	6	19			
>25000	0	1	4	2	7			
Grand Total	12	121	56	21	210			

While correlating the data with glycosylated hemoglobin, we got the finding that as the Hba1c increases need for intervention also increases. Among the 21 patients who had the value of Hba1c above 10, the majority ended up in lower extremity amputation (17 patients-80.95%), and the rest of the patients ended up in grafting for the healing of the diabetic foot. In patients whose HbA1c was less than 6.5, the wound healed with less intervention.

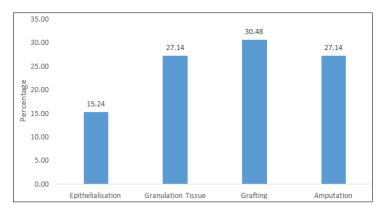


Figure 1: Outcome of diabetic lower limb ulcer patients



Hba1c	Outcome	Frequency	Percent
	Epithelialization	4	33.33
	Granulation Tissue	3	25
<6.5	Grafting	5	41.67
	Total	12	100
	Epithelialization	28	24.35
	Granulation Tissue	45	39.13
6.5-8	Grafting	35	30.43
	Amputation	7	6.09
	Total	115	100
	Granulation Tissue	9	14.52
8.1-10	Grafting	20	32.26
8.1-10	Amputation	33	50
	Total	62	100
	Grafting	4	19.05
>10	Amputation	17	80.95
	Total	21	100

In our study, 5 (2.39%) patients had Coagulase Negative Staphylococcus Aureus, 58 (27.62%) patients had Escherichia coli, 41 (19.53%) patients had Klebsiella pneumonia, 15 (7.15%)

patients had Proteus, 12 (5.72%) cases had Pseudomonas, 29 (13.81%) patients had Staphylococcus aureus, 7 (3.34%) cases had Acinetobacter, 43 (20.47%) cases and no growth (Fig. 1).

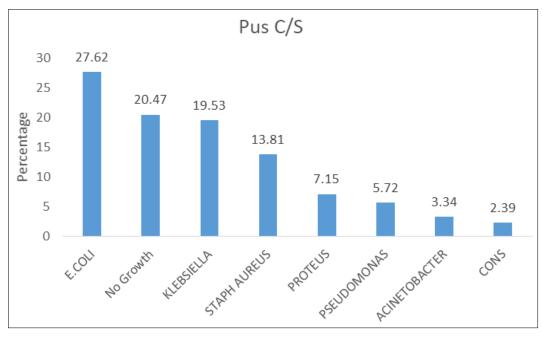


Figure 2: Distribution of bacteria

4. DISCUSSION

The study's mean age was 58.18 standard deviation was 9.215. People in the middle age group dominated the survey for the most part. Age and Hba1c readings did not appear to be significantly correlated in this study's data collection. Ghanbari A et al. (2023) ^[7] discovered that the patients' ages ranged from 38 to 71 years. The relation between age and Hba1c in our study justified the results of the Ghanbari A et al. (2023) ^[7]. In our study, there is male preponderance among the cases with 57.6% being Males and 42.3% being Females. Cheng et al. (2015)^[8] carried out a study with 54 research participants in total, in which, 55.6% were men and 44.4% were women. In our study, we categorised the glycosylated hemoglobin to 4 categories. Among these, recorded most of the patients within the mid ranges i.e; 6.5-8 and 8.1-10. Fesseha *et al.*, (2018) ^[10], study conducted at Johns Hopkins Multidisciplinary Diabetic Foot of 270 patients with HbA1C < 6.5% as many as 149 people, followed by 6.5-8.0% as many as 162 people, and the most >8%as many as 298 people In our study, we got that, the majority of participants (54.8%) fell within the HbA1c range of 6.5-8, followed by 29.5% with HbA1c levels greater than 8 but less than 10. A smaller proportion had HbA1c levels below 6.5 (5.7%) or above 10 (10.0%). As per Monisha G et al. [11], patients with high HbA1C>10 about 65% underwent major and minor amputation. In our study, as of the result mentioned in the Monisha G, et al. ^[11], HbA1c value more than 10 underwent minor and major amputations and in the range between 8.1 - 10 a total of 62 patients were encountered. Among these, 33 patients needed limb/digit scarifying interventions. In our study, we found that, in those patients who had HbA1c value <6.5 wound healed with less interventions. We also found that complete epithelialization occurred in 33% of cases in patients with HbA1c less than 6.5%. While in the 6.5% to 8% range, complete epithelialization was found in 24.35%. There were no cases of epithelialization observed in the range of more than 8. Granulation tissue formation was observed in 25% of patients whose Hba1c was below 6.5. Granulation tissue formation occurred more in the 6.5% -8% group. Only 14.5% of the wound showed granulation tissue formation when HbA1c was 8%-10%. As the value of HbA1c rises the percentage of epithelialization and granulation tissue formation is found decreasing. In contrast, the need for intervention increases with the high levels of HbA1c, i.e., 80% of the patients with Hba1c more than 10% required amputation. While 50% ended up with amputation when Hba1c was 8%-10%. There, we found a relation between HbA1C and the outcome of diabetic lower limb ulcer patients, as the value of HbA1c rises frequency of epithelialisation and granulation tissue formation decreases, and as the value of HbA1c rises need for more invasive intervention also increases. Shah et al. (2022) ^[12] also discovered a higher percentage of Grade II diabetic foot ulcers (42%), Grade III (34%), Grade IV (12%), Grade I (4 persons), and Grade V (up to 2 persons). We further found that as the Hba1c value rises, there is a significant rise in the Wagner grade (p = < 0.0001). In our study, most of the patients were presented with Grade II Wagner grading (65.7%).

In our study, the most common organisms found were gramnegative bacteria E. coli and Klebsiella. In high extreme HbA1c. Staphylococcus aureus and Pseudomonas are found in most of the cases. Other organisms like proteus, E. coli, Coagulase coagulase-negative staphylococcus aureus was also found in the ulcer bed. In 20.47% samples, we found no growth of bacteria in the ulcer. J Coll et al. (2016) ^[13] of the organisms that were identified, Staphylococcus aureus was the most common, accounting for 23.16% of the total. In our study, it was found that the minimum value of total leucocyte count was 3400 and the maximum of 35000, with a mean value of 11299.62. More the value of total leucocyte count presented in higher grades of diabetic foot. Shamima N. Anonna et al. (2021) [14] discovered that the WBC level in diabetes blood was higher in diabetic patients than in non-diabetic individuals. M. A Tresierra et al. (2017) ^[15] discovered that peripheral artery disease was present in 78% of individuals with diabetic foot ulcers. In our study, the relationship between the involvement of the type vessels and the glycosylated hemoglobin revealed there is a significant association between these two (p=<0.0001). As the value of HbA1c increases, we found a tendency of becoming more severe disease (Wagner grade) and the involvement of macro vessels of the limb. Abdulhussein et al. (2019) [9] found the following factors to have statistically significant relationships with diabetic foot ulcer healing: patient age, glycosylated hemoglobin, length of diabetes, peripheral neuropathy problems, and ulcer size. In our study, we observed that larger ulcers often necessitated more invasive treatments such as grafting or amputation.

5. CONCLUSION

According to the study, managing glycosylated hemoglobin is essential for reducing complications related to diabetic foot ulcers. We also concluded that, to maintain the grades of diabetic foot ulcers, increase the rate at which wounds heal as seen by epithelialization and granulation tissue production, and lower the rate at which amputations occur, glycosylated hemoglobin levels must be adjusted. Furthermore, we found that the range of microorganisms implicated in diabetic ulcer sepsis has changed from Gram-positive to Gram-negative (Klebsiella, *E. coli*). Therefore, we concluded that maintaining adequate blood sugar levels might lower the risk of ulcers, promote wound healing, lower the likelihood of amputations, and greatly enhance the quality of life for those with diabetic foot problems.

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