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Evaluation of HbA1c, serum Magnesium (Mg) and Lipid Profile Among type 2 Diabetic Foot Ulcer and without Foot Ulcer Patients

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Abstract

Background: Diabetic foot ulcers are the major macrovascular complication of diabetes resulting in significant morbidity associated with diabetes and a leading cause of hospital admission in developed countries. [6] About 1-4% of people with type 2 diabetes develop foot ulcer every year and it results in gangrene and lower extremity amputation associated with socioeconomic impact. The aim of this study was to evaluate the HbA1c, serum Magnesium (Mg) and lipid profile among type 2 diabetic foot ulcer and without foot ulcer patients. **Materials & Methods:** This was a cross-sectional study and was conducted in the Department of Biochemistry and Molecular Biology, BIRDEM Academy, Dhaka, Bangladesh during the period from January 2018 to December 2018. In our study, we included 120 patients divided into two groups – Group I (Type 2 diabetic patients with foot ulcer) and Group II (Type 2 diabetic patients without foot ulcer). **Results:** The mean age of the study subjects was 49 years and most of them were male. The high hemoglobin A1c (HbA1c ≥7.5%) was significantly more affected by diabetic foot ulcer than compared with near normal HbA1c (61.6% vs 31.9%). The percentage of hypomagnesemia was 69.6% and 30.4% respectively. It was also observed that the percentage of hypomagnesemia was significantly higher in the diabetic foot ulcer group. The mean value of TC, TAG, LDL-c were significantly higher in foot ulcer group whereas HDL-c was significantly lower in diabetic foot ulcer group than in the without foot ulcer group. **Conclusion:** In conclusion, magnesium level should be maintained in DM patients, whether they have or do not have foot ulcer, and magnesium supplementation may be helpful for these individuals.

Keywords:- Diabetes mellitus, Foot ulcer, HbA1c, Serum Magnesium.

INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disease caused by inherited and/or acquired deficiency in the production of insulin by the pancreas or by the ineffectiveness of insulin action. Such a deficiency results in increased concentration of glucose in the blood, which in turn damage many of the body systems, in particular the blood vessels and nerves.[1] It is a global public health problem and one of the commonest endocrine disorders across the world.[2,3] According to International Diabetic Federation (IDF) Diabetic Atlas 2017, around 425 million people live with diabetes worldwide. In Bangladesh, the diabetic population was about 7.1 million in 2015 which

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is projected to increase to about 13.6 million by 2040. Among all types of Diabetes Mellitus, Type 1 DM (Insulin-dependent Diabetes mellitus) accounts for about 5%, and Type 2 DM (Non-Insulin-dependent Diabetes mellitus) accounts for approximately 90-95%.[4] Several pathogenic processes are involved in the development of Diabetes. Type 1 occurs due to autoimmune destruction of ß - cells of Pancreas whereas Type 2 DM occurs due to progressive defects in insulin secretion on the background of insulin resistance.[5]

Diabetic foot ulcers are the major macrovascular complication of diabetes resulting in significant morbidity associated with diabetes and a leading cause of hospital admission in developed countries.[6] About 1-4% of people with type 2 diabetes develop a foot ulcer every year and it results in gangrene and lower extremity amputation associated with socioeconomic impact.[7,8] The pathophysiology of chronic diabetic foot ulcer is complex and incompletely understood; however, micro and macro angiopathy as well as peripheral neuropathy and ischemia are the major contributing risk factors that strongly contribute to the development and delayed healing of diabetic wounds.[9] According to international consensus guidelines' protocols, such a complex pathology necessitates the participation of a multidisciplinary team, including the diabetologist, the podiatrist, the vascular surgeon, the radiologist, and the infectious disease specialist to manage and address all the various aspects and presentations of the pathology.[10] Previous studies have shown that diabetic patients have up to a 25% lifetime risk of developing diabetic foot ulcer.[11]

Glycated haemoglobin (HbA1c) is a form of haemoglobin used primarily to identify the average plasma glucose concentration which clearly shows control of diabetes mellitus for the last 2-3 months. The usage of HbA1c for the monitoring of control degree for glucose metabolism of patients with diabetes was first proposed in 1976.[12] The expert committee of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) recommended HbA1c level ≥6.5% as a diagnostic criteria for Diabetes.[13] Measurement of both blood glucose and HbA1c are now used as a routine management of diabetes. A strong association is observed between the risk of diabetic complications and the level of glycemia.[14] Good glycaemic control is shown to reduce the risk of microvascular and perhaps macrovascular complications of diabetes.[15] Uncontrolled diabetes mellitus may lead to elevated level of HbA1c which is associated with the development of diabetic complications like retinopathy, neuropathy, and foot ulcer.[16]

Magnesium is an intracellular cation and plays an important role in carbohydrate metabolism.[17] It is the fourth most abundant cation in human body and has a critical role in the actions of important enzymes.[18] It regulates ion channels and also plays an important role in neuromuscular transmission. It acts as a cofactor for every enzymatic reaction that requires kinases.[19] A low magnesium level can impair glucose homeostasis and insulin sensitivity in type 2 diabetes mellitus.[20] The various causes of low magnesium in diabetes include diet low in magnesium, osmotic diuresis causing high renal excretion of magnesium, insensitivity of insulin affecting

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intracellular magnesium transport and thereby causing increased loss of the extracellular magnesium, rampant use of loop and thiazide diuretics promoting magnesium wasting and reduced tubular reabsorption due to insulin resistance.[17,21,22,23] Low intracellular magnesium level negatively affect the transportation of cellular glucose, tyrosine kinase activity, post-receptor insulin action, and secretion of insulin from the pancreas.[23,24] Considering the pathophysiological mechanism it can be said that low serum Mg level is a risk factor for developing type 2 DM and type 2 DM is one of the causes of hypomagnesemia. Hypomagnesaemia can worsen glycaemic control in DM and both micro and macrovascular complications of diabetes are strongly associated with hyperglycaemia and/or uncontrolled glycaemia.[25] However, the association of hypomagnesemia with poorly controlled diabetes and also various chronic diabetic complications e.g. neuropathy and diabetic foot ulcer have been reported.[26] Previous studies have also shown that there is a high incidence rate of diabetic foot ulcer with hypomagnesemia in comparison to without foot ulcer diabetic patients.[20] Magnesium level should be controlled in DFU patients and magnesium supplementation can be a complimentary treatment of these patients to reduce mortality rate.[27]

Objective of the study

The main objective of the study was to evaluate the HbA1c, serum Magnesium (Mg) and lipid profile among type 2 diabetic foot ulcer and without foot ulcer patients.

MATERIALS AND METHODS

This was a cross-sectional study conducted in the Department of Biochemistry and Molecular Biology, BIRDEM Academy, Dhaka, Bangladesh during the period from January 2018 to December 2018. In the study, we included 120 patients and they were divided into two groups – Group I (Type 2 diabetic foot ulcer patients) and Group II (Type 2 diabetic patients without foot ulcer).

These are the following criteria to be eligible for the enrollment as our study participants: a) Patients aged 30-60 years; b) Patients with type 2 diabetes mellitus; c) Patients having type 2 diabetes with foot ulcer as case; d) Patients having type 2 diabetes without foot ulcer as control; e) Patients who were willing to participate were included in the study and a) Patients with endocrine disorder, e.g. hypothyroidism; b) Patients with history of cerebrovascular accident; c) Patients taking medications like diuretics or other drugs that can alter magnesium level or any lipid-lowering agents for last six months; d) Patients having peripheral arterial disease, e.g. Buerger's disease; e) Patients with any history acute illness (e.g., renal or pancreatic diseases, ischemic heart disease etc.) were excluded from our study.

Blood sample collection: At first 5 ml blood sample was collected from each study subjects after an overnight fasting of 10-12 hours. From this blood sample, 2 ml was delivered into EDTA tube for estimation of HbA1c. The remaining 3 ml was delivered into red tube for measurement of fasting plasma glucose, serum magnesium and lipid profile.

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Statistical Analysis: All data were recorded systematically in preformed data collection form and quantitative data was expressed as mean and standard deviation and qualitative data was expressed as frequency distribution and percentage. Statistical analysis was performed by using SPSS 23 (Statistical Package for Social Sciences) for windows version 10. Probability value <0.05 was considered as level of significance. The study was approved by Ethical Review Committee of BIRDEM Academy, Dhaka, Bangladesh.

RESULTS

[Table 1] showed the frequency and percentage distribution of age in Group I and Group II. In Group I most of the study participants were more than 50 yrs age group (56.7%) and in Group II the study participants belonging to the age group (41-50 yr) were more prevalent (58.3%).

The details of the socio-demographic characteristics of the study participants in Group I and Group II were shown in [Table 2]. Among the total study subjects, in Group I, 40 (66.7%) were male and 20 (33.3%) were female and in Group II, 31 (51.7%) were male and 29 (48.3%) were female. The highest participants in Group I were secondarily educated (28.3%) whereas in Group II the highest participants were higher secondarily educated (26.7%). Occupational status revealed that most of the study participants belonged to service holder group in Group I (45.0%) and housewife in Group II (38.3%). Most of the study participants were from urban areas in both groups (55.0% and 46.6% respectively). Family history of DM was higher in both groups (61.7% and 58.3% respectively). In Group I, 63.3% of the study subjects did physical exercise whereas the percentage was a little bit higher in Group II (70%).

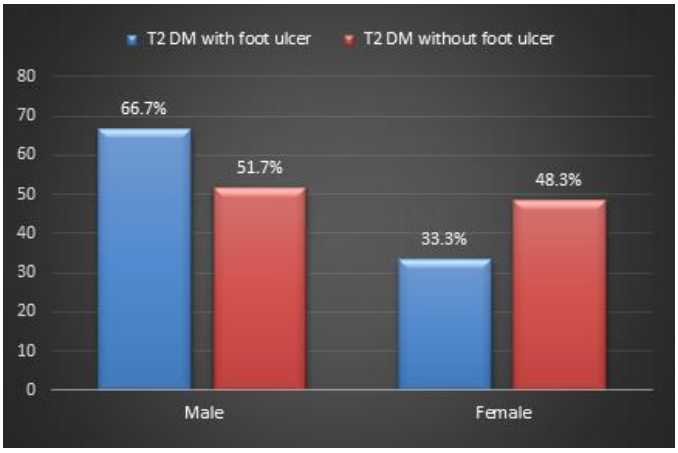

Figure 1: Gender distribution of Group I (type 2 diabetes with foot ulcer) and Group II (type 2 diabetes without foot ulcer) of the study subjects.

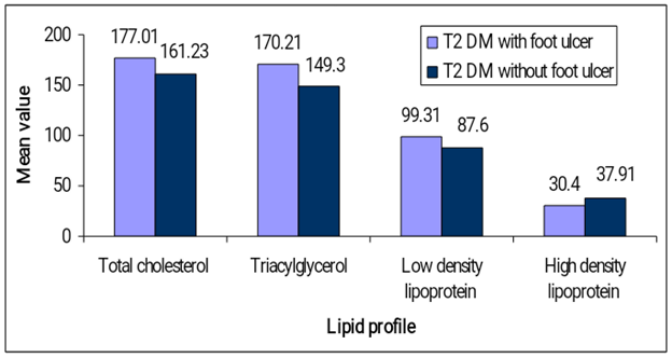

Figure 2: Lipid profile of Group I (type 2 diabetes with foot ulcer) and Group II (type 2 diabetes without foot ulcer) of the study subjects.

[Figure 1] showed the gender distribution of study subjects of Group I and Group II. This study found that in Group I, percentage of male and female participants were 66.7% and 33.3% respectively. In Group II the percentage of male

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participants was also more prevalent than female participants (51.7% vs 48.3%).

[Table 3] showed the distribution of BMI among Group I and Group II of study subjects. In Group I most of the study participants were overweight (56.7%) whereas in Group II the percentage of normal BMI distribution was more prevalent (58.3%).

[Table 4] showed that the high haemoglobin A1c (HbA1c ≥7.5%) was significantly more affected by diabetic foot ulcer than compared with near normal HbA1c (61.6% vs 31.9%; X2=10.10; p-value <0.001). On the other hand, normal HbA1c was found in the majority (68.1%) of patients in Group II compared to uncontrolled HbA1c (38.4%).

[Table 5] showed that among participants of Group I and Group II, the percentage of hypomagnesemia was 69.6% and 30.4% respectively. It was also observed that the percentage of hypomagnesemia was significantly higher in Group I than in Group II (p<0.001).

[Figure 2] showed the comparison of Lipid profile among Group I and Group II. Findings of this study revealed that the mean value of TC, TAG, LDL-c, and HDL-c in Group I were (177.01 ± 27.83, 170.21 ±56.01, 99.31 ± 32.31 and 30.40 ± 9.93 mg/dl respectively); whereas the mean value of TC, TAG, LDL-c, and HDL-c in Group II was (161.23 ± 28.35, 149.30 ± 46.95, 87.60 ± 21.44 and 37.91 ± 7.48 mg/dl respectively).

Table 1: Distribution of age in Group I (type 2 diabetes with foot ulcer) and Group II (type 2 diabetes without foot ulcer) of the study subjects.

Age	Group I (n=60)		Group II (n=60)	
	Frequency	Percentage	Frequency	Percentage
30-40 years	8	13.3	12	20.0
41-50 years	18	30.0	35	58.3
>50 years	34	56.7	13	21.7

Table 2: Characteristics of the study subjects.

Characteristics	Group I (n=60)		Group II (n=60)	
	Frequency	Percentage	Frequency	Percentage
Age (in years)	51.95±8.63		46.03±6.15	
Gender				
Male	40	66.7	31	51.7
Female	20	33.3	29	48.3
Residence				
Urban	33	55.0	28	46.6
Suburban	19	31.7	16	26.7
Rural	8	13.3	16	26.7
Educational status				
No education	12	20.0	6	10.0
Primary	16	26.7	11	18.3

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Secondary	17	28.3	15	25.0
Higher Secondary	12	20.0	16	26.7
Graduation	3	5.0	12	20.0
Occupational status				
Service holder	27	45.0	22	36.7
Housewife	15	25.0	23	38.3
Businessman	10	16.7	5	8.3
Others	8	13.3	10	16.7
Family history of DM				
Yes	37	61.7	35	58.3
No	23	38.3	25	41.7
Physical exercise				
Yes	38	63.3	42	70.0
No	22	36.7	18	30.0

Table 3: Distribution of BMI in Group I and Group II of the study subjects (N=120).

BMI (kg/m^2)	**Group I(n=60)**		**Group II (n=60)**	
	Frequency	**Percentage**	**Frequency**	**Percentage**
Normal (18.5-24.9)	26	43.3	35	58.3
Overweight (25-29.9)	34	56.7	25	41.7

Table 4: HbA1c status in type 2 diabetic patients with foot ulcer and type 2 diabetic patients without foot ulcer in the study subjects (n=120).

HbA1c	**Group I n (%)**	**Group II n (%)**	**X2**	**P-value**
Within reference (<7.5%)	15 (31.9%)	32 (68.1%)	10.10	0.001
Uncontrolled (≥7.5%)	45 (61.6%)	28 (38.4%)		

Table 5: Serum magnesium status in Group I (type 2 diabetes with foot ulcer) and Group II (type 2 diabetes without foot ulcer) in the study subjects (N=120).

Serum magnesium	**Group I n(%)**	**Group II n(%)**	**X2**	**P-value**
Hypomagnesaemia (<0.70 mg/dl)	39 (69.6%)	17 (30.4%)	16.10	0.001***
Within reference (≥0.70 mg/dl)	21 (32.8%	43 (67.2%		

DISCUSSION

Many studies have been done to estimate the serum magnesium level in T2DM patients and its correlation with HbA1c, but in Bangladesh, very few data are available regarding the serum magnesium level in diabetic patients, and to the best of our knowledge, this study was the first to evaluate the serum magnesium level with HbA1c & lipid profile in type 2 diabetic foot ulcer patients in Bangladesh.

In our study, the mean age of our patients was 49 years, others found the mean age was 54 & 55 years.[28,29] In the study, the ratio of male was greater than female which is inconsistent with

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many studies reported in different countries.[30,31]

Magnesium is an essential element that plays an important role in many biological functions, and low magnesium level is associated with insulin resistance, type 2 DM, dyslipidemia, and hypertension.[32,33] Many studies have shown that the plasma levels of magnesium are lower in patients with type 2 DM.[34,35]

In our study, the percentage of hypomagnesemia was 69.6% and 30.4% respectively. It was also observed that the percentage of hypomagnesemia was significantly higher in the foot ulcer Group than in without foot ulcer group. Masood et al. and Walter et al. reported the normal Mg level in both T2DM patients and healthy controls.[36,37] But Wälti et al. showed that serum Mg concentrations of 37.6% of the diabetics were below the reference range and the findings of many studies reported low magnesium serum level in T2DM.[28,34]

Considering the pathophysiological mechanism, it can be said that low serum magnesium concentration is a risk factor for developing type 2 DM, and that type 2 DM is one of the causes of hypomagnesemia. Hypomagnesaemia can worsen glycaemic control in DM, and both micro and macrovascular complications of diabetes are strongly associated with hyperglycemia and/or uncontrolled glycemia.[29]

In our study, the high hemoglobin A1c (HbA1c ≥7.5%) was significantly more affected by diabetic foot ulcer than compared with near normal HbA1c. Many studies reported high HbA1c levels in T2DM.[38,39]

Our results showed no correlation between serum Mg level and HbA1c level in contrast to many studies that reported an inverse correlation between serum Mg level and HbA1c, some studies showed normal Mg level in T2DM but lack of data correlation to HbA1c. Siddique et al. found that hypomagnesemia is associated with a higher level of HbA1c.[40]

When compared to the control group, the triacylglycerol level was high and the HDL-c level was low in the study group. HDL-c is connected with magnesium level as a cardiovascular risk factor, and a subsequent study by Guerrero-Romero and Rodriguez-Moran discovered a link between low magnesium and HDL-c level.[41] We assumed that insulin resistance, hyperglycemia, or uncontrolled diabetes mellitus brought on by hypomagnesemia were the causes of the high HbA1c percentage and triacylglycerol level in the current investigation. The Srinivasan et al. study found low magnesium level and high HbA1c percentage in patients with diabetes mellitus, further supporting this association.[42] Additionally, Rodriguez-Moran et al. reported high HbA1c percentage and triacylglycerol level in patients with diabetic foot ulcer, and low serum magnesium level when compared to the control; however, these results did not reach statistical significance.[43]

Our study findings indicate that, when compared to the length of DM, serum glucose level and HbA1c percentage are significantly associated with complications of diabetes. As a result, we concluded that low magnesium level is linked to high glucose, high HbA1c ratio, and low HDL-c level. Low HDL-c level and uncontrolled diabetes are significant risk factors for atherosclerosis, which can result in foot

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ulcer. High glucose level brought on by a magnesium deficit can lead to neuropathy, which is also at risk for developing foot ulcers.[29] Our study's findings are supported by earlier research, such as that of Rodriguez-Moran et al., who found a high correlation between type 2 diabetes and foot ulcer in patients with serum magnesium deficits.[43] In the Dasgupta et al. study, a high incidence of foot ulcer in patients with hypomagnesemia was seen when compared to the control (58.8% vs. 22.5%).[20] We investigated the serum magnesium level, lipid profile, and HbA1c in diabetic foot ulcer and without foot ulcer patients.

Limitations of the study: Our study was a single-center study. We took a small sample size due to our short study period. After evaluating those patients, we did not follow up them for the long term and have not known other possible interference that may happen in the long term with these patients.

CONCLUSIONS

In conclusion, magnesium level should be controlled in DM patients, whether they have or do not they have foot ulcer and magnesium supplementation may be helpful for these individuals. Additionally, giving magnesium supplementation to individuals with type 2 diabetes who are critically ill can lower their fatality rate.

So further study with a prospective and longitudinal study design including a larger sample size needs to be done to determine whether there is a correlation between serum Mg level and HbA1c level in T2DM.

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