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Correlation between Glycated Hemoglobin, Extra-cranial Carotid Artery Disease and Peripheral Arterial Disease in Type 2 Diabetic Patients with Coronary Artery Disease

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ABSTRACT

Background: Diabetes mellitus [DM] is the well-known endocrine problem where the body either doesn't deliver sufficient insulin or has a resistance to the circulating insulin. Atherosclerotic cardiovascular disease stays the chief reason of death and disability among diabetic patients, particularly in type II DM patients.

Aim of the work: To correlate between glycated Hemoglobin [HBA1C], carotid, peripheral and coronary artery disease in type II DM patients.

Patients and methods: This is an observational study of 122 type II DM patients who were admitted to National Institute of Diabetes and Endocrinology. A full history, a full clinical examination, 12 lead-ECG, Echocardiography, Carotid duplex, Ankle-brachial index [ABI] measurement, HbA1C and Invasive non emergent coronary angiography were done.

Results: Carotid intima-media thickness [IMT] in patients with HbA1C >7% was significantly higher than those with HbA1C<7, HbA1C had a significant positive correlation with carotid IMT, ABI was significantly lower in patients with HbA1C>7% compared to those with HbA1C<7%, Number of diseased coronary vessels was significantly higher in patients with higher HbA1C >7% compared to those with HbA1C>7%, ABI had a significant negative correlation with number of diseased coronary vessels and IMT had a significant positive correlation with number of diseased coronary vessels in patients with higher HbA1C >7% with no significant correlation in those with HbA1C<7%.

Conclusion: Our results showed a significant correlation between HbA1C and Carotid atherosclerosis, Peripheral artery disease [PAD] and Coronary Artery disease [CAD] severity based on number of diseased coronary vessels in uncontrolled T2DM patients.

Keywords: Glycated Hemoglobin; Carotid Artery; Carotid intima-media thickness; Ankle-brachial index; Diabetes Mellitus.

INTRODUCTION

Diabetes mellitus [DM] is the well-known endocrine problem where the body either doesn't deliver sufficient insulin or has a resistance to the circulating insulin, and is described by high glucose levels over prolonged periods [1].

DM is a developing worldwide medical problem. In 2000, DM affected an expected 171 million individuals in the entire world expanded on 2011 to in excess of 366 million individuals and expected to be in excess of 552 million by 2030 [2].

Atherosclerotic cardiovascular disease [ASCVD] stays the main cause of death and disability among DM patients, particularly in type II DM [T2DM] patients happening 14.6 years earlier, with greater seriousness, and with more diffuse dissemination than in people without DM [3].

Peripheral artery disease [PAD] is a chronic progressive atherosclerotic disease causing fractional or total peripheral vascular impediment. PAD regularly influences the abdominal aorta, iliac arteries, lower limbs, and sporadically the upper limbs [4].

The ankle-brachial index [ABI] is a cheap and reliable technique for evaluating lower limb hemodynamics with a sensitivity of distinguishing angiographically significant stenosis 94% to 97% [5].

Carotid arterial disease is a major macrovascular complication of DM linked to stroke and cardiovascular disease. It is generally evaluated by ultrasound which can discover atherosclerotic plaque and quantify intima-media thickness [IMT] [6].

Glycated hemoglobin [HbA1c] is the most utilized clinical test to assess mean blood glucose. It is utilized to diagnose DM and to screen the adequacy of treatment. HbA1C was the estimation studied in clinical preliminaries exhibiting the advantages of improved glycemic control on micro vascular and macro vascular results [7].

PATIENTS AND METHODS

It is an observational study was performed on 122 T2DM patients over 50 years' old who were admitted to National Institute of Diabetes and Endocrinology during the period from January 2019 to June 2021. According to the American diabetic association [ADA], reducing HbA1C below or around 7.0% has been found to reduce microvascular complications and macrovascular disease. The glycemic target for non-pregnant persons with diabetes is 7.0% [8]. So the patients were classified according to the HbA1C into: Group I which included 68 patients with HbA1C level >7 % and Group II which included 54 patients with HbA1C level <7 %. The patients were enrolled according to the following criteria:

Inclusion criteria: T2DM patients with documented coronary artery disease [CAD] diagnosed by non-emergent invasive coronary angiography were included.

Exclusion Criteria: non diabetic patients, type I diabetic patients, pregnant females, patients with lower limb amputation, patients with lower limb trauma and patients with chronic kidney disease.

Patients who were to be accepted in this study were selected after obtaining the ethical approval of the Faculty of Medicine, Al-Azhar university ethical committee.

All the patients were subjected to the following: personal, present, past and family history and the major coronary artery disease documented risk factors [Hypertension, DM, Smoking, Family history of CAD], clinical examination: Including general and local examination including blood pressure, body mass index, 12 leads surface ECG was done. Routine echocardiography study was performed with special emphasis on ejection fraction measured in parasternal long axis and apical 4 views using 2D eye-balling or Simpson's method by expert operators using a SIEMENS ACUSON x300 machine [9]. Routine laboratory testing: Hemoglobin, Serum creatinine, HbA1C, Lipid profile was done.

Invasive coronary Angiogram: using Seldinger's technique, Standard views of coronary angiogram were evaluated. With left-dominant, balanced or right-dominant circulations, three major coronary arteries: the left anterior descending [LAD], the circumflex, and the right coronary artery [RCA], were assessed [10]. The degree of disease characterized as one-vessel, two-vessel, three-vessel, or left main disease, with a significant stenosis as being narrowed by either a ≥ 70% decrease of the internal diameter of at least one major coronary artery or a ≥ 50% decrease of the internal diameter of the left main [LM] coronary artery [11]. All coronary angiograms were evaluated by an interventional cardiologist.

Carotid US: The intima-media thickness [IMT] of the common carotid artery was assessed by carotid US. An expert sonographer used a machine [ACUSON NX3 Elite; SIEMENS] to perform high resolution B-mode, color Doppler, and pulse Doppler US of both carotid arteries. Patients were examined while lying on their backs with their heads slightly cocked back. Transverse scans were used to find the carotid arteries, and then the probe was turned 90 degrees to capture and record longitudinal pictures of the bilateral carotid arteries. High-resolution photos were taken of the internal carotid arteries, carotid bulbs, and the distant wall of the bilateral common carotid arteries. IMT was defined as the space between the media-adventitia echo's leading edge and the lumen-intima echo's leading edge. For each common carotid artery, measurements were obtained over a 1-cm length and recorded from both sides [12].

Ankle brachial index [ABI] measurements by Doppler device: The patients were asked to lie in a supine position on an examination table with his arms and legs at one level with the heart, for at least 10 minutes before assessment, a suitable sized sphygmo-manometer cuff for both the ankle and the arms; the cuff width was at least 40% greater than the limb circumference. The cuff was placed on the leg with average 2-3 cm above the malleolus. Doppler device was used to check the brachial, dorsalis pedis, and posterior tibial pulses. The brachial systolic pressures of both arms were measured, and the higher was selected. Anterior tibial and posterior tibial systolic pressures of the lower limb were obtained, and we selected the higher of the 2 measurement as the ankle pressure value. Ankle pressure is divided by brachial artery pressure to produce the ABI value [13].

Ankle-Brachial Index Diagnostic Standards for PAD of the Lower limbs: 1.0 to 1.3: normal, 0.9 to 1.0: borderline, 0.7 to 0.9: mild PAD, 0.4 to 0.7: moderate PAD, < 0.4: severe PAD [5].

Statistical Analysis: The SPSS v26 statistical analysis programme was used [IBM Inc., Chicago, IL, USA]. The unpaired Student's t-test was used to compare quantitative data between the two groups. Quantitative variables were provided as mean and standard deviation [SD]. When appropriate, the Chi-square test or Fisher's exact test was used to analyse qualitative variables, which were provided as frequency and percentages [%]. A two tailed P value ≤ 0.05 was considered statistically significant, Pearson correlation was done to estimate the degree of correlation between two quantitative variables, a logistic regression analysis was performed to predict a dependent data variable by analyzing the relationship between one or more existing independent variables.

RESULTS

Patients were classified according to HbA1C level into two groups: group I: included 68 patients with HbA1C level >7 % and group II: included 54 patients with HbA1C level <7 %.

Age, sex, the incidence of HTN and smoking were insignificantly different between both groups. Group I's BMI was considerably greater than Group II's [P value<0.001] [Table 1].

Patients with HbA1C >7% had right carotid IMT that spanned from 0.6 to 1.5 mm, with an average of 1.01 ± 0.18 mm, which was substantially greater than the span for patients with HbA1C <7%, which was from 0.5 to 1.2 mm, with an average of 0.8 ± 0.15 mm. Patients with HbA1C >7% had left carotid IMT that spanned from 0.7 to 1.2 mm, with an average of 1.01 ± 0.15 mm, which was substantially greater than the span for patients with HbA1C <7%, which was from 0.7 to 1.1 mm, with an average of 0.84 ± 0.14 mm. Regarding plaque site in patients with HbA1C>7%, it was located in proximal ICA in 8 [11.8%] patients, in right CCA in 6 [8.8%] patients, in Lt CCA in 8 [11.8%], in Lt ICA origin in 8 [11.8%] patients and 6 [8.8%] patients had bifurcation calcific plaque. Regarding plaque site in patients with HbA1C<7%, it was located in proximal ICA in 1 [1.9%] patient, and in Lt ICA origin in 1 [1.9%] patient, therefore, plaque site was significantly different between both groups [P value<0.05]. Patients with HbA1C > 7% had plaque sizes that varied from 13.5 to 29.5 mm2, with a mean of 26.06 ± 4.52 mm2, which was considerably larger than the plaque sizes of patients with HbA1C<7%, which ranged from 5.6 to 21.2 mm2 and had a mean of 11.72 ± 8.35 mm^2 [Table 2].

Patients with HbA1C>7% had significantly lower ABI than those with HbA1C<7% [P value <0.001] [Table 3].

Patients with one vessel disease were 32 [47.06%], 42 [77.78%] in group I & II respectively, patients with two vessels disease were 15 [22.06%], 9 [16.67%] in group I &II respectively and patients with three vessels disease were 21 [30.88%], 3 [5.56%] in group I&II respectively. In comparison to patients with HbA1C <7%, the number of diseased coronary vessels was significantly greater in patients with higher HbA1C >7%. [P value<0.001] [Table 4].

HbA1C had a significant positive correlation with right and left carotid IMT [r=0.348, P<0.001], [r= 0.393, P<0.001] respectively [Table 5].

In patients with HbA1C>7%, ABI had a strong inverse relationship with number of vessels [r= -0.263, P= 0.03] while right and left IMT had a considerable positive relationship with number of affected vessels [r= 0.28, 0.27, P= 0.021, 0.026 respectively]. While in patients with HbA1C<7%, ABI, right and left IMT had no significant correlation with number of affected vessel [Table 6].

Table [1]: Demographic data of the studied groups

		Group I [n = 68]	Group II [n = 54]	P value
Age [years]	Mean ± SD Range	59.38 ± 6.23 50 - 71	57.96 ± 6.71 50 – 76	0.229
Sex	Male Female	44 [64.7%] 24 [35.3%]	32 [59.3%] 22 [40.7%]	0.538
BMI [kg/m^2]	Mean ± SD Range	29.91 ± 4.19 22 – 37	25.77 ± 2.84 22 – 35	**<0.001***
Hypertension		31 [45.6%]	29 [53.7%]	0.373
Smoking		25 [36.8%]	23 [42.6%]	0.512

BMI: Body Mass Index

Table [2]: Carotid duplex of the studied groups

		Group I [n = 68]	Group II [n = 54]	P value
RT carotid IMT [mm]	Mean ± SD Range	1.01 ± 0.18 0.6 - 1.5	0.8 ± 0.15 0.5 - 1.2	**<0.001***
LT carotid IMT [mm]	Mean ± SD Range	1.01 ± 0.15 0.7 - 1.2	0.84 ± 0.14 0.7 - 1.1	**<0.001***
Plaque site	Proximal ICA	8 [11.8%]	1 [1.9%]	**0.033***
	Rt CCA	6 [8.8%]	0 [0%]	**0.028***
	Lt CCA	7 [10.3%]	0 [0%]	**0.013***
	Lt ICA origin	8 [11.8%]	1 [1.9%]	**0.033***
	Bifurcation calcific plaque	6 [8.8%]	0 [0%]	**0.023***
Plaque size [mm^2]	Mean ± SD Range	26.06 ± 4.52 13.5 – 29.5	11.72 ± 8.35 5.6 – 21.2	**0.001***

IMT: Intima-Media Thickness.

Table [3]: ABI of the studied groups

	Group I [n = 68]	Group II [n = 54]	P value
Mean ± SD	**0.89 ± 0.22**	**1.08 ± 0.18**	**<0.001***
Range	**0.46 - 1.3**	**0.64 - 1.3**	

ABI: Ankle brachial index.

Table [4]: Coronary angiography of the studied groups

		Group I [n = 68]	Group II [n = 54]	P value
Number of affected vessels	**1 vessel**	**32 [47.06%]**	**42 [77.78%]**	**< 0.001***
	2 vessels	**15 [22.06%]**	**9 [16.67%]**	
	3 vessels	**21 [30.88%]**	**3 [5.56%]**	

Table [5]: Correlation between HbA1C, peripheral artery disease [ABI] and carotid artery disease [IMT]

	Rt Carotid IMT		Lt Carotid IMT	
	r	**P**	**r**	**P**
HbA1C	**0.348**	**<0.001***	**0.393**	**<0.001***

Table [6]: Correlation between coronary artery disease [number of affected vessels], peripheral artery disease [ABI] and carotid artery disease [IMT] in group I [patients with HbA1C >7%] and group II [patients with HbA1C <7%]

		ABI		Rt Carotid IMT		Lt Carotid IMT	
		r	**P**	**r**	**P**	**r**	**P**
Patients with HbA1c>7%	No. of affected vessels	-0.263	**0.03***	0.28	**0.021***	0.27	**0.026***
Patients with HbA1c<7%	No. of affected vessels	-0.055	0.658	0.212	0.084	0.205	0.096

DISCUSSION

Based on study findings and international diabetes recommendations, the HbA1c is considered as the key predictor of complications in diabetes since it shows a chronic hyperglycemic state [14].

According to the ADA, reducing HbA1C below or around 7.0% has been found to reduce microvascular complications and macrovascular disease. The glycemic target for non-pregnant persons with diabetes is 7.0%. Therefore, for the majority of persons with diabetes, a HbA1C level of 7.0% suggests glycemic control [8]. So the study population was divided into two groups [group I HbA1C>7 and group II HbA1C <7].

In the current study, Group I's BMI was considerably greater than Group II's [P value<0.001], the mean BMI of group I was 29.91kg/m^2 while mean BMI of group II was 25.77kg/m^2. In accordance with our results, a study conducted by **Boye *et al.*** [15] on 304073 diabetic patients reported that elevated BMI classification was linked to elevated HbA1c values.

In the current study, Carotid duplex findings [carotid intima media thickness and carotid plaque] were considerably greater in group I compared to group II [P values<0.05], HbA1C had a significant direct relationship with right [r=0.348, P<0.001] and left carotid IMT [r= 0.393, P<0.001].

Our findings were also compatible with the work of **Kanakaraju and Ranganathan** [16] who reported that a strong favourable relationship between both carotid IMT and HbA1c [p < 0.001 for both carotids].

Furthermore, another study conducted by **Singh *et al.*** [17] reported that HbA1c readings were greater in patients with high CIMT than in those with normal CIMT, and this difference was almost significant [P = 0.06].

Also **Lee *et al.*** [18] reported that HbA1c was independently linked to increase in CIMT [p = 0.045].

A multiethnic study by **McNeely *et al.*** [19] revealed that greater CIMT values are associated with higher HbA1c values [6 ± 0.3%] compared to lower HbA1c values [5 ± 0.2%] [0.87 vs. 0.85 mm, p = 0.003, respectively].

Several studies conducted on patients with DM found significant correlation between high HbA1c and increased CIMT [20-23].

On the contrary, HbA1c and CIMT results did not significantly correlate with one another, according to **Du *et al.*** [24] and **Olt *et al.*** [25]. Both of the previous authors disagree with our findings.

When it comes to the ABI, it had a significant negative correlation with HbA1c, Patients with HbA1C>7% had significantly lower ABI than those with HbA1C<7% [P value = 0.003]. This was compatible with the study by

Liu *et al*. [26] who reported that OR of HbA1C for low ABI was of statistical significance. HbA1c was freely straightly linked to left and right ABI [P < 0.001].

Another Egyptian study included 93 subjects, also reported the same significant negative correlation [r = -0.459 – p < 0.001] [27]. Furthermore, an additional Nigerean study conducting on 150 T2DM patients confirmed the same relationship [28].

In our study, HbA1c levels showed a significant positive correlation with the quantity of diseased coronary vessels. In comparison to patients with HbA1C <7%, the number of diseased coronary vessels was significantly greater in patients with higher HbA1C >7%. [P-value <0.001].

In accordance with our findings, a study conducted by **Dutta *et al*.** [29] reported that increase in HbA1c level was firmly related with CAD severity and higher SYNTAX score. A huge increment was noted in the mean number of affected vessels [p-value < 0.001] as HbA1c level increments.

Also **Hong *et al*.** [30] revealed an immediate connection between HbA1c levels and the seriousness of CAD in light of the quantity of affected vessels in patients with stable angina. They additionally observed that HbA1C was a free indicator of seriousness of CAD [p < 0.001].

In our study, ABI had a strong inverse relationship with number of affected coronary vessels [r= -0.263, P= 0.03] in group I [patients with HbA1C >7], while ABI did not significantly link to number of diseased coronary vessels in group II [patients with HbA1C<7]. In the same context, **Papamichael *et al*.** [31] reported that ABI was linked to the CAD severity as assessed by quantity of diseased coronaries [p = 0.04].

Another study conducted by **Benyakorn *et al*.** [32] showed that ABI was altogether adversely related with the seriousness of stenosis in CAD by utilizing Syntax score. Also **Chen *et al*.** [33] reported that ABI was freely connected to the numbers of affected coronary vessels [P = 0.025].

In our study, right and left IMT significantly correlated positively with quantity of affected coronary vessels [r= 0.28, 0.27, P= 0.021, 0.026 respectively] in group I [HbA1C >7], while in group II [HbA1C <7] right and left IMT did not significantly correlate with quantity of affected vessels.

In same line with our results, **Ciccone and his colleague** [34] conducted a study on 115 patients with significant stenosis at least in one major coronary artery, the study results showed a highly statistically significant relationship between the degree of the quantity of coronary artery with a critical impediment and the increment of carotid IMT [P < 0.001].

Lekakis *et al*. [35] reported that carotid and femoral IMT expanded fundamentally with an increment in CAD severity measured by the quantity of diseased coronaries and by Gensini score.

Also **Kablak-Ziembicka *et al*.** [36] reported that a significant, almost straight relationship among IMT and developing CAD was found [p, 0.0001].

The limitation of the current work included small sample size [126 patients] and single center. However, we could recommend good glycemic control in T2DM to delay DM complications such as PAD, carotid atherosclerosis and CAD. Further studies are needed to show the association between HbA1C, CAD, PAD and carotid Atherosclerosis with large sample size and multicenter involvement.

Conclusions: Our results showed a significant correlation between HbA1C and Carotid atherosclerosis, PAD and CAD severity based on number of diseased coronary vessels in uncontrolled T2DM patients.

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Declaration of Conflicting Interest: The authors declare that there is no conflict of interest.

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