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Original Research Article

A prospective hospital based study of relation between carotid artery intimal medial thickness in patients with type 1 diabetes

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ABSTRACT

Background: The aim of this study was to found association between Type 1 Diabetes Mellitus and Carotid Arterial Intimal Thickness (CIMT).
Methods: Study design: It was a prospective case control hospital-based study. One hundred type 1 diabetes patient between the age group 3-36 years were taken. The association between type 1 diabetes with CIMT was studied. All the measurements were standardized. 50 age and sex matched controls were taken for comparison.
Results: There is positive correlation between type 1 diabetes and CIMT ($p<0.0001$). The correlation further extends between duration of diabetes, glycemic control, age of onset, frequency and severity of diabetic related complication with CIMT.
Conclusions: Carotid atherosclerosis as measured by CIMT has definite association with type 1 diabetes.

Keywords: Carotid arterial intimal thickness, Cases, Controls, Prospective hospital based study, Type 1 diabetes mellitus

INTRODUCTION

Type 1 Diabetes Mellitus is accompanied by increased risk of cardiovascular complications. Increased carotid intima- media thickness is a well-established index of structural atherosclerosis that correlates with prevalent and incident coronary artery disease. A look at the carotid arteries intimal thickness provides a window to the status of coronary arteries.[1] Measurement of carotid intima-media thickness with a B-mode ultrasound is a valid, non-invasive, simple, sensitive and reproducible technique with low inter and intra-observer variability and serves as a surrogate marker for future cardiovascular risk.[2] There are limited studies available on CIMT in patients with type 1 diabetes mellitus from India. This prospective hospital-based study was conducted in tertiary super speciality Hospital from Kashmir, India. In order to meet purpose, B-mode colour Doppler ultrasound was used for measurement of carotid intima-media thickness in 100 type 1 diabetic group. 50 age and sex matched controls to rule of intra and inter observer variability.

METHODS

One hundred type 1 diabetes mellitus patients were studied. Fifty age and sex-matched healthy individuals were recruited as controls, these included consenting non-diabetic siblings of the subjects. Ethical approval from the hospital committee was sought. Recruitment of the study subjects was done from January 2013 till October 2014. A written informed consent was obtained from all

the adult study subjects or the parents of subjects younger than 18 years.

Clinical assessment

The subjects found eligible were asked relevant history and physical examination as per the pre-formed proforma. Body weight was measured by an electronic scale (Filzola) to the nearest 0.1 kg with barefoot. Height was measured by a portable Seca stadiometer to the nearest 0.1 cm. BMI was calculated and converted to percentiles for age and gender. On the basis of Body Mass Index (BMI) subjects were classified as normal (BMI=18-22.9 kg/m^2), overweight (BMI=23-24.9 kg/m^2), or obese (BMI≥25 kg/m^2).[3] Waist circumference was measured in standing position midway between the costal margin and the iliac crest in mid expiration and Hip circumference was measured in standing position at the maximum circumference over the buttocks by using a millimetric non extensible and non-elastic measuring tape (Sanny).[4]

Investigations

Routine investigations which included kidney and liver function tests, uric acid, and lipid profile using Beckman Coulter AU680; glycosylated hemoglobin (HbA1c) was measured using PDQ Plus analyzer (Primus Corporation). USG Abdomen was performed in all patients to look for presence of fatty infiltration of liver and pancreatic calcification. For the diagnosis of nephropathy, the patients were asked to collect urine for 24 hours and estimation of protein and creatinine. Authors considered <150 mg/day as normal, 150-500 mg/day as microproteinuria, and >500 mg/day as macroproteinuria fundus examination was done for presence and type of retinopathy.[5] NCV study was done for presence and type of neuropathy

Carotid artery intimal - media thickness measurements

The intima-media thickness of the carotid artery was determined using a high-resolution B-mode ultrasonography system (Aloka Prosound SSD-3500SX) having an electronic linear transducer (high frequency probe of 7-10 MHz). The ultrasound examinations were made and evaluated by one radiologist who was unaware of the participant's clinical status. Patients were examined in the supine position with the neck slightly extended and the head turned 45º toward the side opposite that being examined. The place of measurement was standardized in every study. The carotid artery was scanned in its long axis with multiple scanning angles. The near and far-walls of the common carotid artery, the carotid bulb, and the internal carotid artery were scanned for the presence of atherosclerotic plaques or any area of stenosis. At each of the three segments, for far-walls in the left and right carotid arteries, intima-media thickness was defined as the distance between the leading edge of the lumen-intima interface and the leading edge of the media-adventitia interface.[6,7] Maximum thickness of the wall was calculated at each side. Overall mean of CIMT measurements on both the right and left side (six for each subject) was calculated and recorded.

Statistical analysis

Data analysis was performed using the statistical package for social sciences version 25. Continuous variables were expressed as mean±SD. Two-sided unpaired t test was performed for continuous variables and x2 test for discrete variables. Multivariate stepwise regression analysis was performed for continuous variables to detect independent predictors of CIMT using factors that had significant relation in univariate analysis. A value of $p<0.05$ was taken significant.

RESULTS

Age distribution between patients with type 1 diabetes and CIMT in the study population. Maximum number of patients were in age group 10-20 years and minimum number in age group >30 years (Table 1).

Table 1: Distribution of mean CIMT in type 1 diabetic in different age groups.

	Age (yrs)	No.	Mean±SD (mm)
Mean CIMT	1 - 10	22	0.39±0.08
	10 - 20	55	0.63±0.14
	20 - 30	21	0.87±0.12
	≥30	5	0.91±0.12
	Total	100	0.64±0.21

Significant relation between CIMT and duration of type 1 diabetes in the study population. As the duration of diabetes increases the severity of CIMT also increases as is shown after 15-20 years the CIMT is 0.89 mm versus in less than 5 years is 0.58 mm (Table 2).

Table 2: Distribution of mean CIMT in type 1 diabetic in duration of disease.

	Duration of DM (yrs)	No.	Mean±SD (mm)	p value
Mean CIMT	0.1-5	69	0.58±0.19	0.0001
	5-10	18	0.76±0.16	
	10-15	9	0.77±0.25	
	15-20	4	0.89±0.08	
	Total	100	0.64±0.21	

Correlation of CIMT with different clinical variables. The correlation with age, duration of diabetes, diabetic neuropathy, diabetic nephropathy, and diabetic retinopathy was found to be significant. It means that as number of years with diabetes increases more chances of CIMT is present. Similarly, with diabetic complications like diabetic neuropathy, nephropathy and retinopathy more chance of occurrence of CIMT is present. The

above association between the said variables is statistically significant (Table 3).

Table 3: Distribution of different parameters with CIMT in type 1 diabetes.

Variable	Sub variable	No.	CIMT (mm)	Std. deviation	p value
Age	Years	100	0.64	0.21	<0.0001
Sex	Female	58	0.63	0.21	0.494
	Male	42	0.66	0.21	
Locality	Rural	81	0.65	0.22	0.728
	Urban	19	0.63	0.20	
Se status	Middle	56	0.62	0.20	0.225
	Low	44	0.67	0.22	
Duration of diabetes	Years	100	0.64	0.21	<0.0001
HBA1C	<9%	15	0.69	0.25	0.293
	>9%	85	0.63	0.21	
Diabetic neuropathy	DSMN	19	0.74	0.18	<0.0001
	DSN	7	0.80	0.29	
	MN	3	0.82	0.08	
	Normal	71	0.59	0.18	
Diabetic retinopathy	Normal	82	0.59	0.19	<0.0001
	NPDR	13	0.89	0.16	
	PDR	5	0.71	0.21	
Diabetic nephropathy	Normal	70	0.58	0.19	<0.0001
	Microalbum	17	0.74	0.20	
	Macroalbumi	13	0.81	0.21	

Comparison of separate left and right carotid intima-media thickness between cases and controls. All the parameters of CIMT viz., CCA, bulb, ICA as well as overall mean value are higher in cases than in controls. The values of CIMT were more in left side than right side (Table 4).

Table 4: Comparison of CIMT between type 1 diabetics and matched controls.

Parameter	Cases	Controls	p
CIMT (L) CCA (MM) CIMT (R) CCA (MM)	0.66±0.22 (0.022) 0.62±0.21 (0.020)	0.43±0.11 (0.016) 0.37±0.10 (0.014)	0.0001
CIMT (L)BULB (MM) CIMT (R)BULB (MM)	0.74±0.23 (0.023) 0.70±0.23 (0.023)	0.48±0.12 (0.017) 0.44±0.11 (0.015)	0.0001
CIMT (L) ICA (MM) CIMT (R) ICA (MM)	0.59±0.20 (0.020) 0.55±0.21 (0.020)	0.36±0.12 (0.017) 0.33±0.11 (0.016)	0.0001
MEAN(L) CIMT (MM) MEAN(R) CIMT (MM)	0.66±0.22 (0.021) 0.62±0.21 (0.021)	0.42±0.11 (0.016) 0.38±0.10 (0.014)	0.0001

Correlation of overall mean CIMT with microvascular complications (Neuropathy, Nephropathy and Retinopathy) in patients with type 1 DM. Sixty-two patients did not have any evidence of diabetic microvascular complication. Thirteen patients had one complication; 6 patients had two complications while as 19 patients had evidence of all the three microvascular complications (tripathy). The overall mean CIMT in patients with no microvascular complication was 0.58 mm. The overall mean CIMT in patients with one, two and three microvascular complication was 0.59 mm, 0.69 mm and 0.86 mm respectively. All the values were statistically significant ($p< 0.0001$) (Table 5).

Multiple regression analysis of overall mean CIMT and various parameters included in the present study. The overall mean CIMT is the dependent variable and the studied parameters are independent variables. The blood

pressure and BMI have significant predictable value (Table 6).

Table 5: Distribution of number of complications with CIMT in type 1 diabetics.

Diabetic complications	Number	Mean CIMT	Std. Deviation	p value
None	62	0.58	0.19	
Monopathy	13	0.59	0.17	
Dipathy	6	0.69	0.16	≤0.0001
Tripathy	19	0.86	0.18	
Total	100	0.64	0.21	

Authors did a cohort study of one hundred type 1 diabetic patients and fifty age and sex matched controls. The maximum number of patients fell in age group 10-20 years (Table 1). With respect to duration of diabetes ,as the duration of diabetes increased the value of carotid intimal thickness progressively increased; for duration up to 5 years mean CIMT was 0.58±0.19 mm, and subsequently for 5-10 years, 10-15 years and 15-20 years the values were 0.76±0.16 mm, 0.77±0.25 mm and 0.89±0.08 mm respectively (Table 2). The values for right and left mean CIMT were as follows: up to 10 years of age 0.52 mm and 0.55 mm, between 10-20 years 0.64 mm and 0.68 mm, between 20-30 years 0.87 mm and 0.89 mm, and above 30 years 0.86 mm and 0.96 mm respectively. All the parameters were statistically significant (p=0.0001). The relation of HbA1c with CIMT was analyzed both at first time presentation (HbA1c onset) and repeated during enrolment in the study (HbA1c present). This study showed positive correlation between CIMT and HbA1c at onset and at present. In this study, the mean CIMT progressively increased in diabetic patients as the number of microvascular complications increased. Mean CIMT was 0.59±0.17 mm, 0.69±0.16 mm, and 0.86±0.18 mm in diabetic subjects who had one, two or three microvascular complications respectively (p<0.0001). Mean CIMT was 0.59±0.17 mm, 0.69±0.16 mm, and 0.86±0.18 mm in diabetic subjects who had one, two or three microvascular complications respectively (p<0.0001). In comparison, the mean CIMT patients without any evidence of complications (n=62) was 0.58±0.19 mm. In patients with diabetic nephropathy, the mean CIMT of microproteinuria (n=17) and macroproteinuria (n=13) were 0.74±0.20 mm and 0.81±0.21 mm respectively. These CIMT measurements were significantly more than those without proteinuria (0.58±0.19 mm; p-<0.0001) as well as healthy controls. Diabetic retinopathy occurred in 18 patients (NPDR in13 and PDR in 5). The mean CIMT in patients with NPDR (0.89±0.16 mm) and those with PDR (0.71±0.21 mm) was significantly higher than patients without diabetic retinopathy (0.59±0.19 mm) and healthy controls. The distal sensorimotor neuropathy (n=19) with CIMT value 0.74±0.18 followed by distal sensory neuropathy in 0.80±0.29 while distal motor neuropathy 0.82±0.08. All the subtypes of neuropathy were associated with higher CIMT as compared to patients without clinical neuropathy as well as healthy controls (p<0.001) (table 3).

Table 6: Multiple regression analysis of possible risk factors of overall mean CIMT in type I diabetic patients.

Dependent variable: CIMT					
Independent variables	Unstandardized coefficients		Standardized coefficients	T	p value
	B	Std. Error	Beta		
(Constant)	-3.385	2.836	S	-1.194	0.237
BG onset f	3.872	0.000	0.019	0.225	0.823
BG onset pp	-7.566	0.000	-0.052	-0.623	0.535
BMI	-0.049	0.051	-2.126	-0.952	0.344
WH ratio	4.117	4.125	0.732	0.998	0.322
BP	0.003	0.002	0.258	2.237	0.028
Creatinine	0.035	0.143	0.050	0.247	0.806
Bilirubin	-0.014	0.049	-0.029	-0.294	0.770
AST	0.000	0.001	-0.121	-0.287	0.775
ALT	0.000	0.001	0.145	0.346	0.730
ALP	0.000	0.000	0.125	1.439	0.154
Albumin	-0.013	0.038	-0.033	-0.352	0.726
Uric acid	0.016	0.015	0.118	1.080	0.284
Calcium	0.025	0.020	0.107	1.281	0.204
Phosphorus	0.007	0.024	0.027	0.300	0.765
Cholesterol	0.001	0.001	0.205	1.440	0.154
LDL	0.000	0.001	-0.047	-0.386	0.701
HDL	0.001	0.002	0.045	0.491	0.625
TG	2.522	0.000	0.007	0.064	0.949

The values of common carotid artery, internal carotid artery, bulb and mean CIMT where higher in diabetic patients as compared to matched controls and the difference were statistically significant (Table 4). Furthermore, with respect to sidedness, the mean left CIMT (0.66±0.22 mm) was greater than mean right CIMT (0.62±0.21 mm). Left sided CIMT values were higher than right side. CIMT values were higher in male diabetic patients as compared to female subjects and sex-matched controls in this study but the difference was not statistically significant. The values of common carotid artery, internal carotid artery, bulb and mean CIMT where higher in diabetic patients as compared to matched controls and the difference were statistically significant (Table 4).

DISCUSSION

Dyslipidemia has been reported to occur in 34-60% of patients with type 1 DM.[8] All the lipid parameters tested in this study population were higher in diabetic patients with statistically significant difference than those with matched controls. The DCCT research group also reported that lipid abnormalities were more frequently in young diabetics as compared to healthy controls.[9] The correlation of dyslipidemia with CIMT was statistically significant in this study. Various studies have shown significant correlation of CIMT with different lipid parameters.

The main thrust of this study was to find the relation of type 1 diabetes with carotid intimal media thickness. Longitudinal studies have demonstrated that increased CIMT in young adults is associated with the presence of cardiovascular risk factors in childhood.[10-12] CIMT is recommended by the American Heart Association as a non-invasive imaging method for detecting atherosclerosis.[13] Atherogenic plaques in type 1 diabetes tend to be more eccentric, softer, more fibrous, lipid rich thrombotic, unstable and rupture prone.[14] The atherosclerotic plaque size and corresponding CIMT measurements are increased in type 1 diabetes relative to age and sex matched apparently healthy born diabetic individuals.[15]

The standardization practice for measurement of CIMT includes the mean far-wall CIMT from six sites (the distal CCA, carotid bulb and ICA on both the right and left side).[16] CIMT values were higher in male diabetic patients as compared to female subjects and sex-matched controls in this study but the difference was not statistically significant. One study has reported higher CIMT in male patients with DM (0.052±0.09mm) as compared to females (0.45±0.1mm; p=0.017).[17] At any given age, the diabetic subjects had higher values than the non-diabetic subjects (Table 1).

The values of common carotid artery, internal carotid artery, bulb and mean CIMT where higher in diabetic patients as compared to matched controls and the difference were statistically significant (Table 4). Several research groups have found a positive association between type 1 DM and CIMT.[18,19] Furthermore with respect to sidedness, the mean left CIMT (0.66±0.22 mm) was greater than mean right CIMT (0.62±0.21 mm). Left sided CIMT values were higher than right side.[20]

The other domain of this study was to find relation of duration of diabetes and age at onset of diabetes with thickness of carotid artery. In this study with respect to duration of diabetes the carotid intimal thickness showed a linear relationship. As the duration of diabetes increased the value of carotid intimal thickness progressively increased; for duration up to 5 years mean CIMT was 0.58±0.19 mm, and subsequently for 5-10 years, 10-15 years and 15-20 years the values were 0.76±0.16 mm, 0.77±0.25 mm and 0.89±0.08 mm respectively (p=0.0001). Even children with duration of diabetes less than 5 years showed significantly increased CIMT when compared to healthy controls (p=0.0001) in the current study. As the age of onset of diabetes increased, the value of CIMT progressively increased. The values for right and left mean CIMT were as follows: up to 10 years of age 0.52 mm and 0.55 mm, between 10-20 years 0.64 mm and 0.68 mm, between 20-30 years 0.87 mm and 0.89 mm, and above 30 years 0.86 mm and 0.96 mm respectively. All the parameters were statistically significant (p=0.0001). A direct relation between CIMT in children with type 1 DM and age at onset and duration of DM has also been reported by several researchers.[21,22]

In order to find out the association between glycemic control and atherogenesis authors correlated the HbA1c with CIMT. The relation of HbA1c with CIMT was analyzed both at first time presentation (HbA1c onset) and repeated during enrolment in the study (HbA1c present). This study showed positive correlation between CIMT and HbA1c at onset and at present. Recent data in type 1 diabetes suggest little, if any, effect of HbA1c on cardiovascular disease.[23] The Diabetes Control and Complications Trial (DCCT) which compared intensive and standard therapies in patients with type 1 DM showed that although intensive therapy reduced the risk of development and progression of microvascular and neuropathic complications from 76 to 35 percent, the incidence of cardiovascular events was not significantly different. However, in EDIC study, no association was demonstrated with HbA1c level and CIMT of diabetic children.[24] On the contrary, in several studies, a positive correlation has been shown between HbA1c and CIMT.[25] These findings indicate that blood glucose level on its own is not a major risk factor for the development of atherosclerosis in type 1 DM.

In this study, the mean CIMT progressively increased in diabetic patients as the number of microvascular complications increased. Mean CIMT was 0.59±0.17 mm, 0.69±0.16 mm, and 0.86±0.18 mm in diabetic subjects who had one, two or three microvascular

complications respectively (p<0.0001). In comparison, the mean CIMT patients without any evidence of complications (n=62) was 0.58±0.19 mm. Similar results have been reported by other authors suggesting that diabetic microangiopathy is related with macroangiopathy.[26,27] Furthermore authors analyzed the relation between the CIMT and type of diabetic microvascular complications. In patients with diabetic nephropathy, the mean CIMT of microproteinuria (n=17) and macroproteinuria (n=13) were 0.74±0.20 mm and 0.81±0.21 mm respectively. These CIMT measurements were significantly more than those without proteinuria (0.58±0.19 mm; p-<0.0001) as well as healthy controls. Diabetic retinopathy occurred in 18 patients (NPDR in 13 and PDR in 5). The mean CIMT in patients with NPDR (0.89±0.16 mm) and those with PDR (0.71±0.21 mm) was significantly higher than patients without diabetic retinopathy (0.59±0.19 mm) and healthy controls. The distal sensorimotor neuropathy (n=19) with CIMT value 0.74±0.18 followed by distal sensory neuropathy in 0.80±0.29 while distal motor neuropathy 0.82±0.08. All the subtypes of neuropathy were associated with higher CIMT as compared to patients without clinical neuropathy as well as healthy controls (p<0.001).

CONCLUSION

Type 1 diabetic patients have higher incidence of dyslipidemia as compared to normal age and sex matched controls. CIMT is invaluable test for checking atherogenicity in Type 1 diabetic patients. Screening Type 1 diabetic patients for atherogenicity by USG Doppler can provide a reliable, affordable and early detectable diagnostic test for atherogenicity in Type 1 diabetic patients.

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