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A COMPARATIVE STUDY OF INTRAOCULAR PRESSURE BETWEEN DIABETICS AND NON-DIABETICS IN A TERTIARY CARE HOSPITAL

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Abstract
In this study, we wanted to compare IOP among diabetic population with that of an age-sex matched control population.

Methods
This was a hospital-based cross-sectional descriptive study conducted among patients who were randomly selected into diabetic group and non-diabetic group after taking detailed history, in the outpatient departments of Ophthalmology and Medicine in Burdwan Medical College & Hospital, Burdwan, West Bengal, for 18 months from June 2015 to May 2016 after obtaining clearance from the institutional ethics committee and written informed consent from the study participants.

Results
There were more number of people who were either current smokers or had a significant history of smoking in the past among the diabetic population in comparison to the control population and the difference was statistically significant. Similarly, the diabetic population were dyslipidemic in comparison to control group. The difference was statistically significant. The average central corneal thickness among the males in the diabetic population was 558.38±14.1 microns compared to 528.24±16.8 microns among those in the control group. The difference was extremely significant. Similarly, the average central corneal thickness amongst the females was higher in the diabetic population than in the non-diabetic population and the difference was extremely significant. In the same manner, the mean CCT adjusted IOP among the males was higher in the diabetic population as compared to non-diabetic population. The difference was highly significant. Among the females

too similar findings were found. The mean CCT corrected IOP among the study population in the age group of 30-50 years, 50-70 years, and more than 70 years was 14.20±04 mmHg, 14.8±0.03 mmHg, 15.8±0.03 mmHg in comparison to 13.9±0.03 mmHg, 14.4±0.04 mmHg, 15.0±0.04 mmHg respectively in the control population. The difference in each age group was highly significant. The mean CCT adjusted IOP value among the patients with NPDR was 15.4±0.05 mm Hg and that among the patients with PDR the difference was extremely significant.

Conclusion
The CCT adjusted mean IOP level was significantly higher among the diabetic group as compared to the control population.

Keywords: Intraocular Pressure, Diabetics, Non-Diabetics.

INTRODUCTION

Whether diabetic patients are more prone to develop raised intraocular pressure and subsequently suffer irreversible visual loss from glaucomatous optic nerve damage is still a matter of debate. The need to routinely measure IOP in diabetic patients is debatable. There is no comprehensive data regarding the association of raised IOP in diabetic patients not only in Indian subcontinent but worldwide. The present study intended to investigate any co-relation between CCT adjusted IOP and diabetes mellitus. The data analysed from this study may help researchers in future to formulate guidelines to prevent and manage glaucoma especially among diabetic population.

AIMS AND OBJECTIVES

To have a comparative assessment of IOP among diabetic population and an age-sex matched control population in Burdwan Medical College and Hospital.
To measure the mean IOP among diabetic population and compare that with the age-sex matched control population.
To measure the distribution of IOP according to gender among diabetic population and compare that with the age-sex matched control population.
To measure the distribution of IOP according to age among diabetic population and compare that with the age-sex matched control population
To assess the effect of BMI on progression of diabetic retinopathy.
To study the relationship of IOP and HbA1C among the diabetic population.

MATERIALS & METHODS

This was a hospital-based cross-sectional descriptive study conducted among the patients who were randomly selected into diabetic group and non-diabetic group after taking detailed history, in the outpatient departments of ophthalmology and medicine in Burdwan Medical College & Hospital, Burdwan, West Bengal, for 18 months from June 2015 to May 2016 after obtaining clearance from the institutional ethics committee and written informed consent from the study participants.

Inclusion Criteria

All diabetic patients above the age of 30 years who were attending the outpatient departments of Ophthalmology, and Medicine in Burdwan Medical College & Hospital and their age and sex matched control subjects.
All diabetic patients and control subjects who gave informed consent.

Exclusion Criteria

Patients who were less than 30 years old.
Patients having pre-existing corneal diseases, uveitis, ocular inflammatory disease.
Patients who had any fundus diseases including hypertensive retinopathy except diabetic retinopathy.

Patients who were hypertensive.
Patients who had any form of glaucoma & glaucoma suspects or under IOP lowering agents.
Patients who were on oral and systemic steroids or other drugs that influence IOP.
Patients who had significant lental opacity such that fundus was not clearly discernible.
Patients who had undergone any intraocular surgery including cataract extraction.
Patients who had refused to give valid informed consent.

Statistical Methods
The collected data were analysed using standard statistical method.

RESULTS

Mean	**Diabetic (N-305)**	**Non-diabetic (N-309)**	**P-Value**
Age (in yrs.)	52.4±-2.5	52.2±2.2	P=0.29,t=1.05,SED=0.19
Male (%)	203(66.56%)	210(66.96)%	P=0.73
Smoking History	92(30.16%)	71(22.98%)	P=0.04
Dyslipidaemia	113(37.05%)	89(28.80%)	P=0.03
BMI (kg/m^2)	28.9 ±2.3	23.7±2.5	P<0.00,t=26.81,SED=0.27
FBS (mg/dl)	166±3.2	102±3.6	P<0.00,t=232.72,SED=0.27
PPBS(mg/dl)	220±3.6	134±13.1	P<0.00,t=317.32,SED=0.27
HbA1C (%)	7.8±0.6	5.6±0.4	P<0.00,t=58.52,SED=0.04
Socio-demographic, clinical and laboratory parameters between the study group and the control group			
Mean	**Diabetic (N-305)**	**Non-diabetic (N-309)**	**P-Value**
CCT (microns)	556.26 ±13.3	532.84±20.1	P<0.00, t= 17.00 SED= 1.38
CCT adjusted IOP (mm/Hg)	15.4 ±0.05	13.8±0.04	P<0.00, t=438.13 SED=0.00
The mean central corneal thickness and central corneal thickness adjusted mean IOP among the study and control population			
Table 1			

The mean age group of the diabetic population was 52.4±-2.5 years and that of the control population was 52.2±2.2 years and they were comparable (P=0.29, t=1.05, SED=0.19). 66.56% of the diabetic population were males in comparison to 66.96% in the control population. The gender distribution between the two groups was comparable (P=0.73).
There were more number of people who were either current smokers or had a significant history of smoking in the past among the diabetic population in comparison to the control population (30.16% vs 22.98%, P=0.04) and the difference was statistically significant.
Similarly, 37.05% of the diabetic population were dyslipidemic in comparison to 28.80% in the control group. The difference was statistically significant (P=0.03).
The mean age group of the diabetic population was 52.4±-2.5 years and that of the control population was 52.2±2.2 years and they were comparable (P=0.29, t=1.05, SED=0.19). 66.56% of the diabetic population were males in comparison to 66.96% in the control population. The gender distribution between the two groups was comparable (P=0.73).
The mean Central Corneal Thickness in the diabetic group was 556.26 ±13.3 microns in comparison to 532.84±20.1 microns in the control group. The difference was extremely significant (P<0.00, t= 17.00, SED= 1.38).

The mean CCT adjusted IOP among the diabetic group was 15.4 ±0.05 mmHg as compared to 13.8±0.04 mmHg in the control group. The difference was extremely significant (P<0.00, t=438.13, SED=0.00).

Mean	**Male(n=413)**			**Female(n=201)**		
CCT (microns)	Diabetic (N=203)	Non-diabetic (n=210)	P-value	Diabetic (N=102)	Non-diabetic (n=99)	P-value
	558.38±14.1	528.24±16.8	P<0.00 t=24.06 SED=0.00	552.86±15.6	532.48±19.4	P<0.00 t=14.33 SED=1.42
CCT adjusted IOP (mm Hg)	15.6±0.03	13.6±0.04	P<0.00 t=573.36 SED=0.00	15.4±0.05	13.5±0.06	P<0.00 T=244.18 SED=0.01

Table 2: The distribution of mean central corneal thickness values and CCT adjusted mean IOP values among the study and control population according to gender

The average central corneal thickness among the males in the diabetic population was 558.38±14.1 microns compared to 528.24±16.8 microns among the males in the control group. The difference was extremely significant (P<0.00, t=24.06, SED=0.00). Similarly, the average central corneal thickness amongst the females was higher in the diabetic population than in the non-diabetic population (552.86±15.6 vs 532.48±19.4 microns) and the difference was extremely significant (P<0.00, t=14.33, SED=1.42).

In the same manner, the mean CCT adjusted IOP among the males was higher in the diabetic population as compared to non-diabetic population (15.6±0.03 vs 13.6±0.04). The difference was highly significant (P<0.00, t=573.36, SED=0.00). Among the females too similar findings were found (P<0.00, t=244.18, SED=0.0).

Age(yrs.)	**Mean IOP**		**P-Value**
	Diabetic (N-305)	**Non-diabetic (N-309)**	
30-50	14.20. ±04	13.9±0.03	P<0.00, t=45.74, SED=0.01
50-70	14.8±0.03	14.4±0.04	P<0.00, t=103.68, SED=0.00
>70	15.8±0.03	15.0±0.04	P<0.00, t=77.63, SED=0.01

Table 3: Distribution of mean CCT adjusted IOP values among the study and control population according to age

The mean CCT corrected IOP among the study population in the age group of 30-50 years, 50-70 years, and more than 70 years was 14.20±04 mm Hg, 14.8±0.03 mm Hg,15.8±0.03 mmHg in comparison to 13.9±0.03 mmHg, 14.4±0.04 mmHg, 15.0±0.04 mmHg respectively in the control population. The difference in each age group was highly significant (P<0.00).

Diabetic retinopathy	**Mean IOP**	**P-Value**
NPDR	15.4±0.05	P<0.00,t=20.55,SED=0.02
PDR	15.8±0.04	

Mean CCT adjusted IOP values among the patients with Diabetic Retinopathy

BMI	NO DR(n-272)	NPDR(n-25)	PDR(n-8)	P-Value
<24.99	182(66.92%)	5(20%)	1(12.50%)	P<0.00 Chi-sq.=42.94
<25-29.99	56(20.58%)	7(28%)	2(25%)	
>30.00	34(12.50%)	13(52%)	5(62.50%)	

The prevalence of Diabetic Retinopathy according to Body Mass Index among the study population		
HbA1C (%)	CCT adjusted mean IOP (mm Hg)	P-value
<6.5	13.6±0.07	<0.00
6.5-8	14.5±0.06	
>8	15.9±0.05	
The distribution of CCT adjusted mean IOP values among the study population and control population		
Table 4		

The mean CCT adjusted IOP value among the patients with NPDR was 15.4±0.05 mm Hg and that among the patients with PDR was 15.8±0.04 mm Hg. The difference was extremely significant (P<0.00, t=20.55, SED=0.02).
Majority (66.92%) of the study population who did not have any evidence of diabetic retinopathy had BMI less than 24.99 kg/m^2 whereas both in NPDR and PDR subgroups majority had BMI more than 30 kg/m^2. The distribution was significantly skewed (P<0.00, Chi-sq. =42.94). The CCT adjusted mean IOP was 13.6±0.07 mmHg among subjects with less than 6.5% HbA1C levels whereas it was significantly higher in subjects with HbA1c levels of 6.5-8% (14.5±0.06 mmHg) and more than 8% (15.9±0.05 mm Hg) respectively. The distribution was extremely skewed towards higher HbA1C levels (P<0.00).

DISCUSSION

In the present study, among the diabetic population, majority were males (66.56%) whereas among the control population only 32.04% were females. (p=0.77, Chi-sq=0.08). However, in study conducted by Matsuoka M et al[1] there were more males (67.96%) among the diabetic population but among the non- diabetic population majority were females (57.75%). On the other hand, in the study conducted by Ellis J et al[2] the sex distribution of the two populations differed significantly (diabetic population 51.9% male, non-diabetic population 45.7% females, p<0.001).
In another study conducted by Pimentel L et al,[3] majority of both the diabetic and non-diabetic population, were females (64.7%, 60% respectively).
Among the diabetic group, majority belonged to the age group of 50-70 years (76.07%) in agreement with that of the control group (70.87%). 16.72% of diabetic population belonged to the age group of 30-50 years whereas 20.39% of control group belonged to the same age group. Only 7.21% of the diabetic population were above 70 years in comparison to 8.74% of the control population.
The mean age group of the diabetic population was 52.4±-2.5 years and that of the control population was 52.2±2.2 years and they were comparable (P=0.29, t=1.05, SED=0.19). In contrast, the mean (±standard deviation) age of diabetes patients was 61.4 ± 11.9 years, with a range of 21 to 85 years, according to a research by Matsuoka M et al. The patients who did not have diabetes ranged from 21 to 95 years old, with a mean age of 61.7 ± 15.6 years. In another study conducted by Pimentel L et al, the mean age of diabetic population was 61.0 ± 9.9 and the mean age of non-diabetic population was 55.2 ± 18.2 yrs. In another study conducted by Ozdamar et al,[4] in the diabetes group, the individuals' mean age ranged from 42–79 years, whereas in the non-diabetic group, it was 57.3 ± 4.7 years, with an age range of 50–60 years. There were more number of people who were either current smokers or had a significant history of smoking in the past among the diabetic population in comparison to the control population (30.16% vs 22.98%, P=0.04) and the difference was statistically significant. However, in the study conducted by Venkatachalam J et al,[5] smokers among diabetic population were 54% in comparison to the control population (19.34%) and the difference was statistically significant (p=0.001).
In the present study, 37.05% of the diabetic population were dyslipidemic in comparison to 28.80% in the control group. The difference was statistically significant (P=0.03). However, study conducted by Mathur A et al[6] showed raised levels of TG, LDL and cholesterol in the diabetic subjects as compared to the control group which was highly significant (p<0.0001).

Majority of the diabetic patients were diagnosed about 5-10 years back (54.75%). About 17.38% of the study population were diagnosed with diabetes mellitus 10-20 years back. Recently diagnosed (<5 years) were about 26.23%. Only 1.64% of the study population were diagnosed with diabetes mellitus for more than 20 years back. However, in the study conducted by Abdel Ghaffar W et al,[7] duration of diabetes was less than 5 years in 25% of the patients, between 6 and 10 years in 22% and more than 10 years in 53% of them, the patients' duration of diabetes was between 1 and 39 years (mean = 20 ± 9.3).
The average body mass index of the diabetic population was 28.9 ±2.3 kg/m^2 as compared to 23.7±2.5 kg/m^2 in the control group. The difference was extremely significant statistically (P<0.00, t=26.81, SED=0.27). However, study conducted by Pai S et al.[8] showed the average body mass index of the diabetic population as 23.13±3.05 kg/m^2 as compared to 21.31±2.37 kg/m^2 in the non-diabetic population. In another study conducted by Srikanth S et al[9] the mean BMI in diabetics was 26.4 kg/m2 and the mean BMI was 25.6 kg/m2 in non -diabetics. In another study conducted by Siddiqui F et al,[10] the mean BMI in the diabetics with hypertension was 29.86 ± 5.87 while in diabetics without hypertension was 27.49 ± 4.99 with a p-value of 0.027.

The mean central corneal thickness in the diabetic group was 556.26 ±13.3 microns in comparison to 532.84±20.1 microns in the control group. The difference was extremely significant (P<0.00, t= 17.00, SED= 1.38). According to a research by Abdul Ghani Y et al.,[11] diabetic individuals had an average central corneal thickness of 541.61± 22.92 microns, with a range of 513 to 586 microns. Among the patients without diabetes, the average central corneal thickness was 518.41 ± 34.09 microns, with a range of 448 to 555. A statistically significant (p<0.005) increase in central corneal thickness was seen in individuals with diabetes as compared to non-diabetic subjects.

In a different research by Mathebula S et al[12] the average CCT for individuals with diabetes was 567.14 mm ± 14.63 mm, whereas the CCT for those without diabetes was 531 ±43.4 mm. A statistically significant (p < 0.005) increase in CCT was seen in diabetes individuals as compared to non-diabetic patients.
On the other hand, study conducted by Pimentel L et al, among the diabetic patients, the average CCT was 516.2 ± 18.2, and non-diabetic patients, CCT was 519.8 ± 18.2.(p= 0.568). The average central corneal thickness among the males in the diabetic population was 558.38±14.1 microns compared to 528.24±16.8 microns among those in the control group. The difference was extremely significant (P<0.00, t=24.06, SED=0.00). Similarly, the average central corneal thickness amongst the females was higher in the diabetic population than in the non-diabetic population (552.86±15.6 vs 532.48±19.4 microns) and the difference was extremely significant (P<0.00, t=14.33, SED=1.42). In the same manner, the mean CCT adjusted IOP among the males was higher in the diabetic population as compared to non-diabetic population (15.6±0.03 vs 13.6±0.04). The difference was highly significant (P<0.00, t=573.36, SED=0.00). Among the females too similar findings were found (P<0.00, t=244.18, SED=0.0).

The mean CCT adjusted IOP among the diabetic group was 15.4 ±0.05 mmHg as compared to 13.8±0.04 mmHg in the control group. The difference was extremely significant (P<0.00, t=438.13, SED=0.00). On the other hand, in the research by Matsuoka M et al,[1] the group without diabetes had a mean IOP of 14.0 ± 0.1 mmHg, while the group with diabetes had a mean IOP of 15.5 ± 0.2 mmHg. People with diabetes had considerably higher IOPs than people without diabetes (P<0.0001). In another study conducted by Baisakhiya S et al,[13] the mean IOP of the non-diabetic participants was 14.56 ± 0.23 and the mean IOP of the diabetic patients was 17.71 ± 0.11 ($P < 0.005$).

In another study conducted by Siddiqui F et al,[10] the mean IOP of both eyes in diabetics with hypertension was 16.34 ± 0.34, while in diabetics without hypertension, it was 15.98 ± 0.43 with a p-value of 0.579.

A majority (89.19%) of the diabetic population did not have any evidence of diabetic retinopathy. 8.20% had non-proliferative diabetic retinopathy and the rest (2.62%) had proliferative diabetic retinopathy (P<0.00). However, in the study conducted by Matsuoka M et al,[1] among diabetic population, 46.12% patients had no retinopathy, mild to moderate NPDR (22.33%), severe NPDR (19.90%), and the rest (11.65%) had PDR. In another study conducted by Kaštelan S et al,[14] among diabetic population, 54.32% patients had no retinopathy, mild to moderate NPDR (21.65%), severe NPDR or PDR (24.03%) were seen.

The mean CCT adjusted IOP value among the patients with NPDR was 15.4±0.05 mm Hg and that among the patients with PDR was 15.8±0.04 mm Hg. The difference was extremely significant (P<0.00, t=20.55, SED=0.02). However, in the study conducted by Arora VK et al,[19] the mean IOP was significantly lesser in PDR group (15.98%) than NPDR group (22.18%).

A majority (66.92%) of the study population who did not have any evidence of Diabetic Retinopathy had BMI less than 24.99 kg/m^2 whereas both in NPDR and PDR subgroups, majority had BMI more than 30 kg/m^2. The distribution was significantly skewed (P<0.00, Chi-sq.=42.94). However, in the study conducted by Kaštelan S et al,[14] 54.31% of the population who did not have any evidence of Diabetic Retinopathy had BMI 26.50 ± 2.7 kg/m2, whereas mild to moderate NPDR had BMI 28.11±3.0 and severe NPDR or PDR had BMI 28.69± 2.5. P<0.01.

The CCT adjusted mean IOP was 13.6±0.07 mmHg among subjects with less than 6.5% HbA1C levels whereas it was significantly higher in subjects with HbA1c levels of 6.5-8% (14.5±0.06 mm Hg) and more than 8% (15.9±0.05 mm Hg) respectively. The distribution was extremely skewed towards higher HbA1C levels (P<0.00). However, in the study conducted by Baisakhiya S et al, the mean IOP of diabetic subjects with HBA1C<7% was 16.9±0.43 mmHg, with HBA1C 7-8% was 17.6±0.62 mm of Hg and with HBA1C>8% was 18.62±0.22 mm of Hg (*P*<0.005). In another study conducted by Hymowitz et al,[15] IOP was < 14.5 mmHg among the patients with mean HbA1c of 8.1±1.1, while IOP was 14.5 mmHg among the patients with mean HbA1c of 9.0±2.1. Regression analysis revealed a significant difference (P = 0.01) in the mean HbA1c level between the two groups, despite overlap in the confidence intervals. Crucially, lower IOP levels were seldom (<1%) seen in diabetic patients with increased HbA1c values.

IOP was inversely but substantially linked with the glycosylated haemoglobin (HbA1c) level (r = 0.142; P = 0.058) in the group of patients with diabetic retinopathy in a different research by Matsuoka M et al.[1] There was a significant correlation (r = 0.240, P = 0.015) between IOP and HbA1c level in patients with diabetic retinopathy (patients with mild to moderate non-proliferative diabetic retinopathy, severe non-proliferative diabetic retinopathy, and proliferative diabetic retinopathy).
Patients having diabetes with mild hyperglycaemia (glycosylated haemoglobin A1c) < or = 6.5%), moderate hyperglycaemia (6.5% < HbA1c < 8.0), and severe hyperglycaemia (HbA1c > or = 8.0%) had their IOP assessed in a different study by Oshitari T et al.[16] The moderate group's mean intracranial pressure (IOP) was 15.5 +/- 2.5 mm Hg, a statistically significant difference from the severe group's 16.6 +/- 2.4 mm Hg (P =.013).

CONCLUSION
The CCT adjusted mean IOP level was significantly higher among the diabetic group as compared to the control population. The CCT adjusted mean IOP levels were higher among both sexes in the diabetic group when compared to their non-diabetic counterparts. The CCT adjusted mean IOP levels showed an increasing trend with an increasing age among both the study and control population. The CCT adjusted mean IOP levels were significantly higher among diabetic subjects with evidence of Diabetic Retinopathy. The CCT adjusted mean IOP showed an increasing trend with worsening stages of diabetic retinopathy. When the CCT adjusted mean IOP was correlated

with the HbA1C levels it was found that mean IOP was higher with worsening state of glycaemic control. It was also found that though a minor proportion of diabetic patients had evidence of diabetic retinopathy, the body mass index was significantly higher in patients with diabetic retinopathy than the patients without diabetic retinopathy.

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