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Study of Intraocular Pressure in Diabetes Mellitus Patients

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ABSTRACT

Objectives: Determination of intraocular pressure of diabetes and diabetic retinopathy patients and the normal population.
Methods: Six hundred sixty four patients (n=1328 eyes) of age 40 years or more were studied in five groups. Eyes of diabetic patients without diabetic retinopathy, mild/moderate nonproliferative diabetic retinopathy, severe nonproliferative diabetic retinopathy, proliferative diabetic retinopathy and control group on exclusion of ocular comorbidities. Data recorded were age, sex, intraocular pressure by noncontact tonometer and grades of diabetic retinopathy in each eye.
Results: The mean intraocular pressure was 18.24 ± 3.72 mmHg in the 908 diabetic eyes. Of the 908 eyes the intraocular pressure was 15.00 ± 2.61 mmHg in no apparent diabetic retinopathy (n = 495), 17.6 ± 2.8 mmHg in mild to moderate nonproliferative diabetic retinopathy (n=239), 19.4 ± 2.6 mmHg in severe diabetic retinopathy (n = 144), 20.9 ± 6.3 mmHg in eyes with proliferative diabetic retinopathy (n = 30) and 15.72±3.71 mmHg in the 420 nondiabetic control eyes.
The intraocular pressure of each diabetic group was considerably higher than the nondiabetic group ($p < 0.001$). One way ANOVA test showed the test as highly significant at 5% level and intraocular pressure values of all these five groups differ significantly.
Conclusions: The intraocular pressure is higher in diabetic patients than normal. Intraocular pressure increased significantly on increasing severity of diabetic retinopathy showing a positive correlation between intraocular pressure and grades of diabetic retinopathy.

Keywords: Intraocular pressure, Diabetic retinopathy, open-angle glaucoma.

INTRODUCTION

Diabetes mellitus (DM) is a major public health problem and disease burden increasing day by day. It has been estimated that there were 451 million people (Age 18-99 years) with diabetes in 2017 and this figure might increase to 693 million by 2045 globally. [1] Diabetes with chronic hyperglycemia is associated with long-term damage and dysfunction of multiple organs due to microangiopathic complications.

Diabetic retinopathy (DR) is a serious microangiopathic complication of diabetes mellitus and also prime cause of adult blindness. Besides diabetic retinopathy it is a known risk factor for development of raised intraocular pressure (IOP), cataract, rubeosis iridis causing decreased visual acuity during its course. [2-5] A number of studies have also shown the association of diabetes mellitus with glaucoma; where

elevated IOP is a major risk factor. [6-10] Many studies showed an increase in relative risk of development of ocular hypertension (OH) during the clinical cause of disease favouring emergence of open angle glaucoma. [3,4,11,12] Diabetic patients are twice likely to develop glaucoma compared to nondiabetics. Study also says significant raised IOP in uncontrolled diabetes than in controlled diabetes. There is association of diabetes with raised IOP and primary open-angle glaucoma (POAG) in many studies. [13-16] However some of the studies failed to establish a positive correlation between diabetes mellitus and open-angle glaucoma. [17,18] So individual IOP determination is an important factor. The only effective treatment is the IOP reduction therapy which prevents proven effective treat glaucoma blindness due to DM and DR on early detection and intervention.

The Goldmann applanation tonometer (GAT) is the gold standard for measurement of intraocular pressure. But IOP measurement by noncontact tonometer (NCT) is very popular and widely used for routine examination. It also correlates well with GAT. [8,13,17,19-21] Hence the study was conducted with the patients who were examined with an NCT on daily basis.

The objective of this study was to determine whether IOP is affected by diabetes and the grades of diabetic retinopathy. To establish a relation, the IOP of diabetes mellitus patients was compared to the IOP of the patients without diabetes mellitus.

MATERIALS AND METHODS

In the study period from January 2018 to December 2019, six hundred sixty-four patients were selected prospectively in accordance with Helsinki Declaration which is approved by institutional ethics committee. Informed consent, demographic data and risk-benefit of examination procedures were explained. Both nondiabetic and diabetic patients age more than 40 years were included.

Diabetic patients were reported by physicians diagnosis of fasting glucose above 120mg/ml or postprandial glucose >150mg/ml and under treatment. Healthy nondiabetic individuals were included attending ophthalmology OPD and self reported normal glucose level in previous 6 months.

Any history of systemic hypertension with or without treatment and other systemic diseases having ocular effect are excluded. Ocular co-morbidities like IOP not measured, diagnosis of glaucoma, steroid medication topical/oral, corneal opacity, refractive error of >5D or cylindrical >2D, ocular inflammatory conditions and retinal diseases except for diabetic retinopathy were excluded. Other diseases affecting IOP measurement i.e. cataract, nystagmus, squint, pterygium and severe trichiasis were not included. Similarly vitrectomy, glaucoma and buckling surgery, trauma or intraocular surgery for cataract were also excluded from the study. However mild cataract having fundus examination clarity were included.

Standard ocular examination includes best corrected visual acuity, slit-lamp examination. IOP measurement performed before pupil dilation between 8am to12noon by NCT (Topcon computerized tonometer CT-800, Topcon Corporation, Tokyo, Japan). IOP was measured thrice in each eye and average of three valid readings of right and left eye were documented for statistical analysis. Direct and indirect ophthalmoscopic and slit-lamp biomicroscopic examination were performed on each eye to detect presence or absence of any signs of diabetic retinopathy and clinically classified according to grades of severity as per International clinical diabetic retinopathy severity scale [2] and documented. No apparent signs shows no diabetic retinopathy (DR). In mild to moderate non-proliferative diabetic retinopathy (NPDR) searched for microaneurysms, retinal haemorrages, exudates, cotton wool spots, venous beading and intraretinal microvascular aneurysms.

Searched for significant venous beading, moderate intraretinal microvascular aneurysms and severe retinal haemorrheges in severe NPDR. In proliferative diabetic retinopathy (PDR) and diabetic macular edema looked for signs of new vessels on the optic disc and elsewhere and vitreous haemorrhage. Patients having PDR undergone routine gonioscopy to exclude neovascular glaucoma

Any retinal pathology not associated with diabetes mellitus such as retinal arteolar alterations, exudates, cotton wool spots, haemorrhage, extensive microvascular abnormalities and papilledema in hypertensive retinopathy and other lesions were excluded.

Statistical Methods

The mean intraocular pressure of the control (group -1) and its standard deviation were compared with that of the mean and standard deviation of IOP of Group-2 diabetes without retinopathy through unpaired t-test with t= 3.4316, d.f. = 913 and p=< 0.001 showing the test as highly statistically significant at 95% CI. Then the mean and SD of IOP of the control group were compared with that of the Group-3 diabetes with mild/ moderate NPDR through t-test with t=6.4452, d.f. = 657 and p< 0.0001 which indicates the test is extremely statistically significant at 95% CI. Further the mean and SD of the control goup were compared with that of Group -4 diabetes with severe NPDR through t-test and found to be extremely statistically significant at 95% CI with t=11.1152 df=562 and<0.0001. Finally the comparison between the control Group and Group-5 diabetes with PDR were made through t-test and the test was found to be highly statistically significant at 95% CI with t=6.9751, d.f. = 448, p < 0.0001.

Further a comparison of all the five groups were made through application and analysis of variance (ANOVA-one way) test in which F = 86.5313 with d.f. (between the groups) = 4 and d.f. (within the group) =1323. P value < 0.00001 showing the test as highly statistically significant at 5% level of significance. It is concluded that the mean IOP values of all these five groups differ significantly.

RESULT

There were 664 patients of male 330 (49.70%) and female 334 (50.30%) were enrolled in the study group. 484 patients were diagnosed with diabetes and 210 nondiabetes as control. The mean and standard deviation of 484 diabetic patients was 55.81 and 4.15 respectively with sample space of 40 to 82 years. The 484 diabetic patients consisted of 216 male (age 55.27 ± 4.01years) and 238 female (age 56.34 ± 4.25 years). The mean age of the 210 control patients was 55.57 ± 4.50 years with range of 40 to 79 years. In the group of 210 control patients 114 were male with age 54.70 ± 4.80 years and 96 female with age 56.41 ± 4.30 years. 1328 eyes of 664 male and female patients were divided into five groups as per retinopathy and nonretinopathy changes (Table 1).

Table 1: Classification of the studied population according to clinical ophthalmological diagnosis

Gr 1	Control group- Eyes of nondiabetic patients both Male and Female
Gr 2	Eyes of Diabetic patients without diabetic retinopathy (DR) both Male and Female
Gr 3	Eyes of Diabetic patients with mild to moderate non-proliferative diabetic retinopathy (NPDR) both Male and Female
Gr 4	Eyes of Diabetic patients with severe NPDR both Male and Female
Gr 5	Eyes of Diabetic patients with proliferative diabetic Retinopathy (PDR) both Male and Female

Table 2: IOP Values of each group of the studied population

Eyes Group	Mean IOP	Standard deviation	Minimum IOP value	Maximum IOP value	Sample size (No of Eyes)
1 – Control	15.72	3.71	8	29	420
2 – DM without DR	15.01	2.61	9	23	495
3 - DM with mild/mod NPDR	17.62	2.81	9	25	239
4 – DM with severe NPDR	19.45	2.67	13	28	144
5 – DM with PDR	20.91	6.32	13	26	30

The mean IOP was 15.72 ± 3.71 mmHg in the 420 eyes of 210 nondiabetic control group and 18.24 ± 3.72 mmHg in the 908 eyes of 454 diabetic group. In the nondiabetic patient group, the mean was 16.20 ± 3.75 mmHg in eyes of male patients (n = 228) and 15.10 ± 3.59 mmHg in eyes of female patients (n = 192). The intraocular pressure in the diabetic group was significantly higher as compared to nondiabetic group.

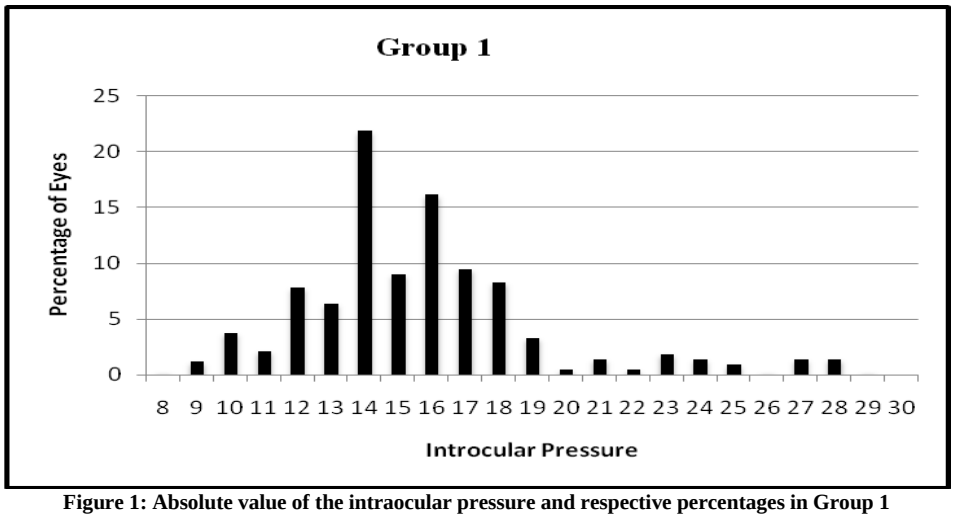

Figure 1: Absolute value of the intraocular pressure and respective percentages in Group 1

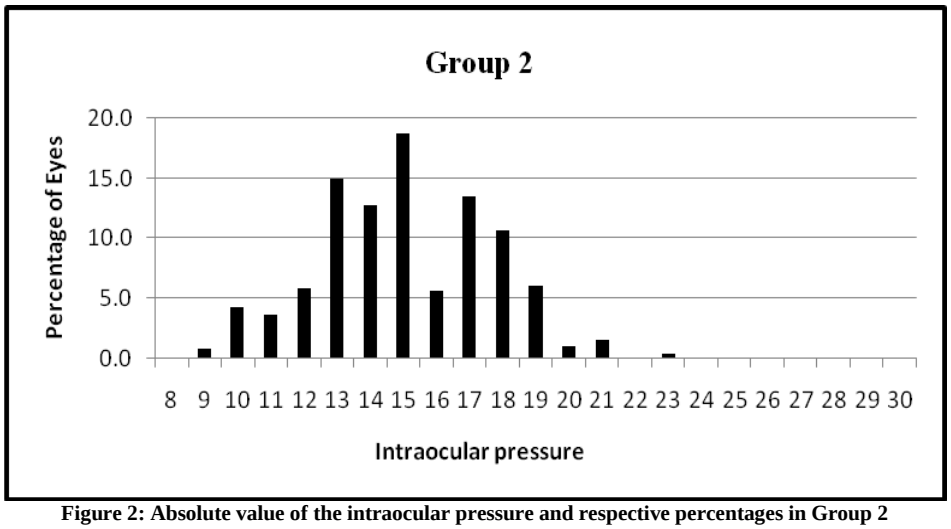

Figure 2: Absolute value of the intraocular pressure and respective percentages in Group 2

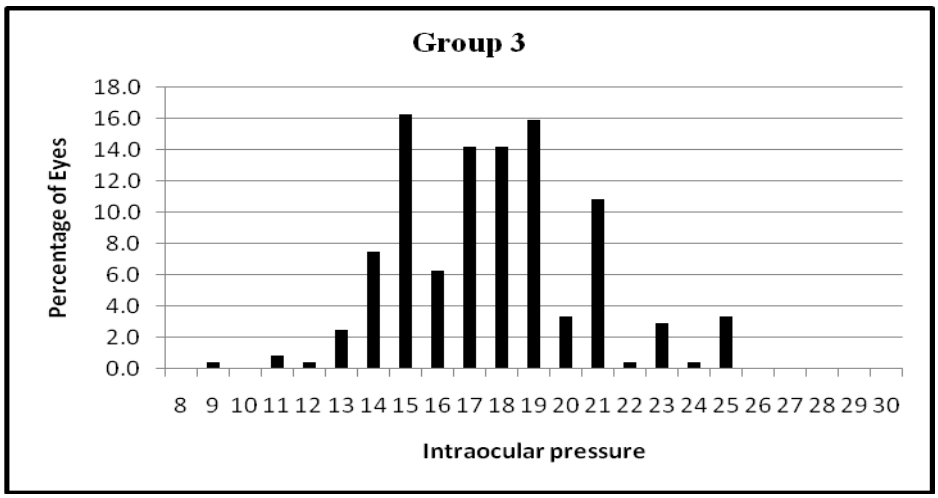

Figure 3: Absolute value of the intraocular pressure and respective percentages in Group 3

The IOP in the 908 eyes of 454 diabetes patients; without diabetic retinopathy, mild to moderate NPDR, severe NPDR and PDR were illustrated in Table 2. In the diabetic patients without retinopathy (n = 495) the intraocular pressure was 15.00 ± 2.61 mmHg , 17.6 ± 2.8 mmHg in eyes of patients with mild to moderate NPDR (n = 239), 19.4 ± 2.6 mmHg in eyes of patients with severe NPDR (n = 144) and 20.9 ± 6.3 mmHg in eyes of patients with PDR (n = 30). The intraocular pressure of each diabetic group was significantly higher than the IOP of nondiabetic group ($p < 0.001$). The IOP increased significantly in increasing severity of diabetic retinopathy. Figures 1-5 show the absolute values and respective percentages of IOP variations found in each of the 5 groups.

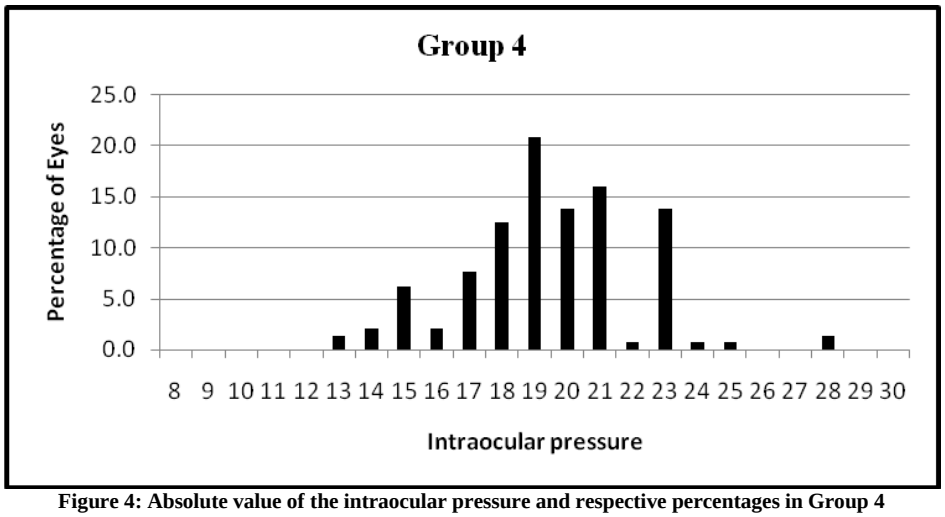

Figure 4: Absolute value of the intraocular pressure and respective percentages in Group 4

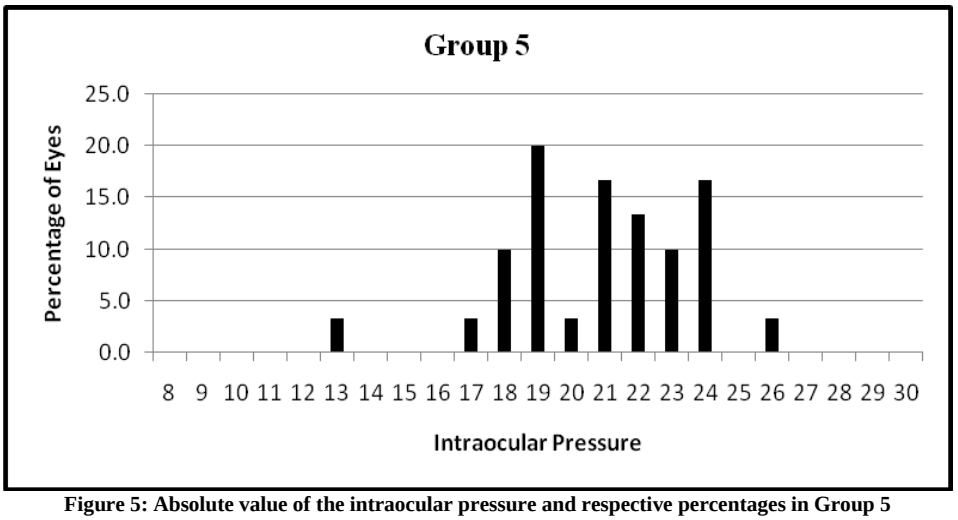

Figure 5: Absolute value of the intraocular pressure and respective percentages in Group 5

DISCUSSION

Diabetic retinopathy and glaucoma are major causes of irreversible blindness. Diabetes mellitus damages microvascular system affecting the autoregulatory mechanism of retinal blood vessels and optic nerve and associated with increase of intraocular pressure. Therefore diabetes is suggested to be a probable risk factor for glaucoma, specifically open-angle glaucoma. [13,15,16] However, the relationship between diabetes and glaucoma is inconlusive.

Los Angels Latino Eye study. [7] The Baltimore Eye Survey [18] and Barbados Eye Study [23] showed diabetes mellitus is a major risk factor associated with elevated IOP among other risk factors like,

hypertension, age, female sex, higher body mass index, higher central corneal thickness, darker colour iridis and cataract. Study shows glucose level are significantly associated with IOP changes in diabetic patients.[6] Diabetic patients exhibit higher IOP having high HbA1c than low HbA1c having mean baseline value of IOP 14.5 mmHg.[24] Other studies showed diabetes patients are at an increased risk of developing open-angle glaucoma significantly. [2,13,14,16] Studies like The Baltimore Eye Survey [18] and Singapore Malay Eye Study [11] reported that diabetes influences increase of intraocular pressure but not related with open-angle glaucoma development. The Beijing Eye Study [12] showed ocular hypertension was associated with diabetes but not with glaucomatous optic nerve damage. In a study by Sakata et al. [3] and Dongguan Eye Study [17] shows IOP values not associated with diabetes which disagree to this study. Although many patients are referred for an ophthalmological examination having diabetes for diabetic retinopathy, until it was doubtful on variation of intraocular pressure.

The Rotterdam study,[15] Beaver Dam Eye Study [9] and other studies [10,11,16,21,25] reported increased risk of open angle glaucoma in diabetes compared to those in the non-diabetic individuals. Diabetes shows a positive association with IOP in other studies [23,25] and the Singapore Epidemiology of Eye diseases Study [26] reported of increased IOP in diabetes in longterm hyperglycemia measured by Goldmann applanation tonometer. A study conducted by Matsuoka M et al. [8] on intraocular pressure measurement by noncontact tonometer in diabetic patients and found that diabetes patients had significantly has higher intraocular pressure by NCT than nondiabetes. Study by Zhao D et al. [27] and other study [14] showed diabetes, duration of diabetes and fasting glucose levels were associated with significant risk of glaucoma with slight increase of IOP. Another meta-analysis study by Zhao YX et al.[28] stated significant association of diabetes with primary open angle glaucoma.

In our study mean IOP in nondiabetic control group was 15.72±3.71 mmHg showed a normal distribution comparable to the Dongguan Eye Study [17] 15.55±3.53 and 15.60±3.08 in male and female respectively in general population. Our study also observed increase IOP in diabetic patients than general population agreed to studies The Blue Mountain Study [13], The Baltimore Eye Survey [18] and Barbados Eye Study.[23] The Shihpai Eye Study, [21] Kumejima study [25], Los Angeles Latino eye study [16] and Singapore Malay Eye Study [11] found glaucoma prevalence is higher in diabetes than without diabetes. A study by Khalaj M et al.[29] reported the mean IOP (16.71±1.96) in diabetes is more than non-diabetes (12.86±1.45). Contrary the Dongguan Eye Study [17] found that is not related to diabetes status suggesting diabetes mellitus may not be a risk factor of higher intraocular pressure or glaucoma. Baltimore Eye Survey, [18] Tajimi study group [10] and Singapore Malay Eye Study [11] studied higher IOP in diabetes patients than without diabetes (17.40 mmHg) but diabetes was not associated with POAG. Raised IOP can damage optic nerve on mechanical compression leading to optic neuropathy and death of retinal ganglion cells. Patients of long duration diabetes mellitus tends to develop diabetic retinopathy resulting to amaurosis, the correlation between diabetes and IOP increase, glaucoma is still controversial.

Intraocular pressure increased progressively from diabetes patients without retinopathy to with grades of retinopathy i.e. mild/moderate NPDR, severe NPDR and PDR. This shows relationship between ocular hypertension and evolution of diabetic retinopathy. Our study showed diabetic retinopathy patients had significantly higher intraocular pressure than that of nondiabetic patients. And the stages of diabetic retinopathy patient groups

were significantly associated with raised IOP than diabetes without retinopathy suggesting an association between IOP and diabetes without retinopathy and diabetic retinopathy groups. Study by Matsuoka M et al [8] revealed IOP measurement by NCT in diabetic patients without diabetic retinopathy, mild to moderate NPDR, severe NPDR and PDR found the stages of diabetic retinopathy group was significantly associated with raised IOP than nondiabetic group but no difference among diabetic retinopathy groups. But study by Sakata et al. [3] found no IOP increase in diabetes patients 16.50±4.15 mmHg (n-52), 16.10±2.02 mmHg (n-10) in diabetes without retinopathy and diabetes with retinopathy respectively. Risk factor for IOP increase in diabetic people might be related to grades and duration of diabetes.

Our study showed that intraocular pressure was not related with gender in both diabetic and non-diabetic groups. This is also in tandem with the results of Tajimi Study, [10] Kumejima Study [25] and Beijing Eye Study. [12] On a contrary IOP is revealed to be more in females than male in diabetes in Dongguan Eye Study, [17] Barbados Eye Study [23] and Shihpai Eye Study. [21]

Many studies reported the influence of age on increase of IOP Barbados Eye Study. [23] But Dongguan Eye Study, [17] Bejing study, [12] Tajimi Study [10] and study by Matsuoka M et al. [8] revealed IOP had not any significant correlation between IOP and age which is in agreement to our study. Singapore Malay Eye Study [11] showed diabetes is not a significant risk factor for glaucomatous optic neuropathy.

The underlying mechanism of IOP increase in diabetes might by different mechanisms by increased aqueous osmotic gradient and extracellular matrix components accumulation in trabecular meshwork in blockage of aqueous outflow leading to IOP increase and development of POAG. [3,17,30,31] It is also reasoned that diabetes is related to genetic factors and autonomic dysfunction. Normally IOP tends to depend on central corneal thickness (CCT). CCT of diabetic patients is reported to be higher due to corneal stiffening by glycation-induced corneal collagen cross link resulting to high IOP.[17,25,26,32]

However our study has some limitations need to be noted that: mean age of patients is 55.67±4.18 in such case IOP dependence on age is not considered as a contributory factor. Noncontact tonometer was used for measuring intraocular pressure instead of Goldmann applanation tonometer, results of IOP represent only during measuring period may not reflect circadian IOP fluctuations [33] and measurement of CCT was not carried out.

CONCLUSION

In conclusion our findings in this study showed of IOP distribution in general population is similar to that of other studies. Diabetic patients had significantly higher intraocular pressure than nondiabetics. Moreover, there was a considerable positive correlation between IOP with diabetes mellitus without retinopathy and diabetes mellitus with degrees of diabetic retinopathy which needs further study.

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