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A comparative study of changes in central macular thickness in diabetic and non-diabetic subjects following uncomplicated cataract surgery using optical coherence tomography

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ABSTRACT

Background: Diabetes mellitus is a chronic, multi-system metabolic disorder which gives rise to ernestful ocular complications. Cataract is believed to be the second most common of these complications, next to diabetic retinopathy, and it poses special challenges to the surgeon both in terms of management and post-operative outcomes. Materials and methods: This was a comparative, prospective, interventional study to assess and compare preoperative and postoperative central macular thickness at weeks 1 and 12 after uncomplicated cataract surgery among 50 well-controlled diabetic subjects with no evidence of diabetic retinopathy and 50 non-diabetic subjects, using Optical Coherence Tomography (OCT).Results: Majority patients of the diabetic group (42%) belonged to the age-group of 51 to 60 years, while the majority in the control group (36%) belonged to the age-group of 61 to 70 years. 54% of the patients had duration of diabetes between 5 to 10 years, while 44% of the patients had duration of diabetes less than 5 years. Significant increase in central macular thickness (CMT) from baseline was seen postoperatively at weeks 1 and 12 in both the groups, but while making inter-group comparison, the changes in macular thickness were not found to be significant. Also, the incidence of post-operative complications was observed to be higher in the diabetic group in comparison to the control group.Conclusion: Uncomplicated cataract surgery in diabetics with well-controlled glycaemic profile and without any evidence of diabetic retinopathy yielded similar outcomes as non-diabetics in terms of rise in post-operative macular thickness. However, in terms of post-operative complications, diabetic group showed a slightly higher incidence.

Keywords: OCT, CMT, Diabetes

INTRODUCTION

Cataract surgery is one of the most commonly performed procedures worldwide. It is also one of the oldest.[1] Recent innovations in instrumentation and surgical technique have dramatically improved the outcome of cataract surgery.Along with these advances have improved intraocular lens materials and designs, especially well-suited for use with smaller incisions.[2]

However, despite all the advancements, unwanted outcomes following cataract surgery are not uncommon. One such outcome is the development of cystoid macular edema (CME), which can lead to suboptimal postoperative vision.[3] CME is defined as retinal thickening of the macula due to a disruption of the normal blood-retinal barrier; this causes leakage from the perifoveal retinal capillaries and accumulation of fluid within the intracellular spaces of the retina, primarily in the outer plexiform layer.[4]

CME following cataract surgery was initially reported by Irvine in 1953 and demonstrated angiographically by Gass and Norton in 1966 and has come to be known as the Irvine Gass syndrome.Irvine-Gass syndrome (IGS) commonly known as pseudophakic cystoid macular edema (CME) is one of the leading causes of low visual acuity following cataract surgery.[5]

Although the exact pathophysiology of development of macular edema following cataract surgery is not completely understood, it is believed that surgical trauma along with the release of prostaglandins and blood–retinal barrier disruption might have an important role to play.[6] Light toxicity and vitreomacular traction might also have a role.[7] Using non-steroidal anti-inflammatory drugs preoperatively, and steroids and anti-inflammatory drugs in the postoperative period, is believed to reduce the incidence of postoperative CME.[8]Optical Coherence Tomography (OCT) is a non-invasive imaging test, which uses light waves to take cross-section pictures of the retina. It enables the ophthalmologist to see each of the retina's distinctive layers and to map and measure their thickness. Thus, invent of OCT was one of the biggest advances in ophthalmic imaging.[9]In patients suffering from diabetes mellitus, it has been observed that macular edema after cataract surgery occurs predominantly in those with concurrent pre-existing diabetic macular edema (DME) involving the center of the macula. Prior to the availability of OCT, the implication of pre-existing DME as a prominent risk factor in the development of postoperative macular edema was a matter of an inconclusive debate.[10] Using the data obtained from OCT, the dynamics of macular parameters can be studied quantitatively as well as qualitatively both prior to and after the cataract surgery so as to correlate and compare the changes in macula between non-diabetic and diabetic subjects. Therefore we conducted this study to evaluate the macular thickness changes using OCT in the preoperative and early postoperative course of twelve weeks in non-diabetic and diabetic subjects after uncomplicated cataract surgery with PC- IOL implantation.

MATERIALS AND METHODS

The present study was conducted to compare the macular thickness changes using OCT in the preoperative and early postoperative course of twelve weeks in non-diabetic and diabetic subjects after uncomplicated cataract surgery with PC- IOL implantation.

A prospective, comparative, interventional parallel-group study was conducted on a total of 100 patients. Data was collected from a total of 100 patients suffering from senile cataract attending Ophthalmology OPD of Government Medical College, Patiala. The patients were divided into 2 groups consisting of 50 diabetic and 50 non-diabetic subjects undergoing uncomplicated phacoemulsification surgery. Patients fulfilling the inclusion and exclusion criteria were enrolled in the study. A written informed consent was taken from the

patients after explaining to them the purpose of study. Patient data was collected according to the proforma.

Patients with age > 40 years were enrolled in the study who underwent uncomplicated phacoemulsification surgery, being performed in similar settings. In diabetic group, patients diagnosed with diabetes mellitus, controlled on oral hypoglycemic agents or added insulin therapy, random blood sugar <200 mg/dl, or fasting blood sugar <150mg/dl (All-India-Ophthalmological-Society Guidelines to Prevent Intraocular Infection) and HbA1C <8% were included, who did not have any evidence of diabetic retinopathy. In control group, non-diabetic subjects were enrolled.

Exclusion criteria were patients with complicated phacoemulsification surgery; patients with dense white cataract in whom OCT cannot be performed, or scans with Signal Strength Index (SSI) <5/10; patients suffering from any ocular disease that might influence central macular thickness (CMT), such as ocular hypertension, glaucoma, uveitis, and age-related macular degeneration or any other retinal pathology; patients with a history of previous eye surgery or a history of macular edema in the fellow eye; and patients with any other chronic systemic illness. In diabetic group, patients having evidence of presence of anemia [men (Hb<13 g/dl); women (Hb<12 g/dl)], pregnancy or diabetic nephropathy (abnormal kidney function test including serum electrolytes, microalbuminuria, serum creatinine, and serum urea) were also excluded.

Detailed history was taken including age, gender and chief complaints, previous ocular history, history of systemic diseases, history of diabetes, (if diabetic, duration of diabetes as well as type of treatment for diabetes), history of smoking, hypertension was recorded. History of fasting or random blood sugar and HbA1C was recorded.

During ocular examination, both corrected and uncorrected visual acuity were recorded by Snellen chart and IOP assessment was done using Goldmannapplanation tonometry. This was followed by slit lamp biomicroscopic examination to rule out any ocular or neurological abnormality, and to assess the severity, extent and type of cataract. Fundus examination using 90 D was performed on the slit lamp biomicroscope. Optic disc was examined for margins, colour, shape and size. Any abnormality in background was noted (any haemorrhage, soft exudate, microaneurysm, IRMA in background) to check for any evidence of diabetic retinopathy or other disorders that can possibly hamper with the study.

After pupillary dilation with eye drops tropicamide, OCT was performed and fundus photograph was taken using Nidek RS-330 SD-OCT machine. The subject was asked to sit comfortably on chair in front of the OCT device and to place his/her chin on the chin rest and the forehead against the head rest. The subject was asked to open both eyes and look at the green fixation target. The scan was performed over the posterior pole to achieve a high-quality image. Macular thickness was determined using the retinal thickness map analysis protocol, and represented in an Early Treatment Diabetic Retinopathy Study (ETDRS) grid. A traditional ETDRS grid, which contains three concentric rings of diameters 1, 3, and 6 mm, and two reticules to divide the macula into nine sections, was employed. Any obscure images and artifacts were not considered. Central macular thickness (CMT) was defined as the mean of thicknesses in nine sections and then used for comparisons in the study. The measurements were recorded preoperatively and postoperatively at weeks 1 and 12.

RESULTS

This was a comparative, prospective, interventional study conducted on a total of 100 patients, divided into a diabetic and a control group. Mean age of the patients of the diabetic group was 54.9 years and of the non-diabetic group 56.8 years. Majority patients of the diabetic group (42 percent) belonged to the age group of 51 to 60 years, while the majority in the control group (36 percent) belonged to the age group of 61 to 70 years. 52 percent of the

patients of the diabetic group were males and 48 percent were females. 56 percent of the patients of the non-diabetic group were males and 44 percent were females. 52 percent of the patients of the diabetic group were of urban residence and 54 percent of the patients of non-diabetic group were of urban residence. 48 percent of the patients of the diabetic group were of rural residence and 46 percent of the patients of non-diabetic group were of rural residence. Both the study groups were comparable in terms of age-wise (p=0.318), gender-wise (p=0.882), and residence-wise (p=0.812) distribution of patients.

Mean RBS among the patients of the diabetic group was 167.38 mg/dL and mean RBS among the patients non-diabetic group was 113.5 mg/dL. Mean HbA1c among the patients of the diabetic group was 7.1% and mean HbA1c among the patients of non-diabetic group was 5.2%. Glycaemic profile of the patients of the diabetic group was significantly higher in comparison to the patients of the non-diabetic group.

Mean duration of diabetes among the patients of the diabetic group was 5.4 years. 54 percent of the patients had duration of diabetes between 5 to 10 years, while 44 percent of the patients had duration of diabetes less than 5 years. Out of 50 patients of the diabetic group, 24 percent of the patients achieved glycaemic control with lifestyle modification only. 58 percent of the patients used oral hypoglycemic agents in addition to lifestyle modifications. 18 percent of the patients used additional insulin therapy. 52 percent of the patients of diabetic group and 54 percent of the patients of the non-diabetic group underwent cataract surgery in right eye. 48 percent of the patients of diabetic group and 46 percent of the patients of the non-diabetic group underwent cataract surgery in left eye. Both the groups were comparable in terms of laterality of the eye undergoing cataract surgery (p=0.425).

Mean CMT among the patients of the diabetic group was found to be 256.4 μm preoperatively, 264.4 μm at 1 week postoperative and 268.9 μm at 12 weeks postoperative. Mean CMT among the patients of the control group was found to be 255.3 μm preoperatively, 261.2 μm at 1 week postoperative and 267.4 μm at 12 weeks postoperative. Both the groups showed a significant increase in CMT at weeks 1 and 12 when compared to baseline, however, while comparing the mean CMT in between diabetic group and control group at baseline, 1 week postoperative and 12 weeks postoperative, non-significant results were obtained.

Post-operative complications were noted and compared between the two groups. Pigment dispersion was seen in 4 percent of the patients of the diabetic group and 2 percent of the patients of the control group. Striate keratopathy was seen in 4 percent of the patients of the diabetic group and 2 percent of the patients of the control group. Wound dehiscence was seen in 2 percent of the patients of the diabetic group. Corneal oedema was seen in 12 percent of the patients of the diabetic group and 8 percent of the patients of the control group. Anterior chamber reaction was seen in seen in 8 percent of the patients of the diabetic group and 6 percent of the patients of the control group.

Table 1: Demographic profile of all the patients comparing the diabetic and the control group

Variable	Diabetic group	Control group	p- value
Mean age (years)	54.9	56.8	0.318
Gender	F=24; M=26	F=22; M=28	0.882
Residence	Rural=24; Urban=26	Rural=23; Urban=27	0.812

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Graph 1: Age-wise distribution of patients

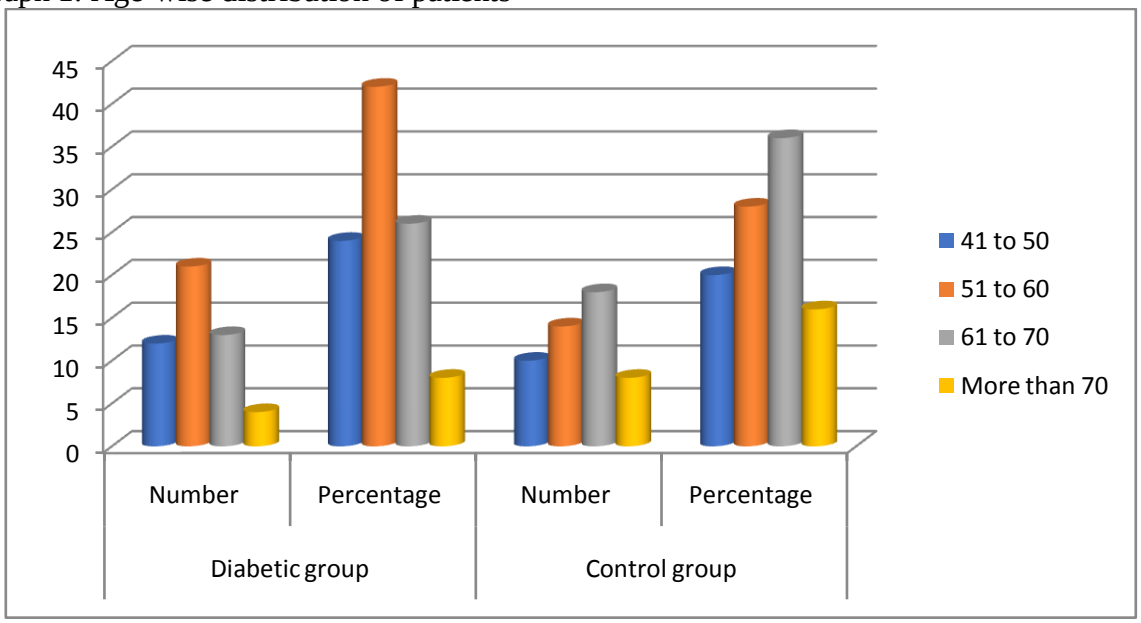
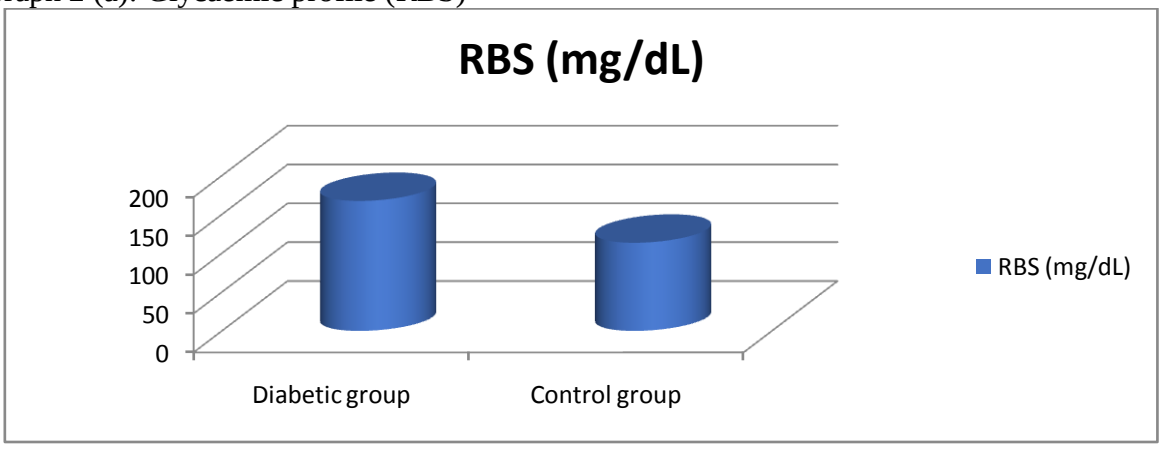


Table 2: Glycaemic profile

Glycaemic profile	Diabetic group		Control group		p- value
	Mean	SD	Mean	SD	
RBS (mg/dL)	167.38	13.54	113.5	10.8	0.001*
HbA1c (%)	7.1	0.49	5.2	1.3	0.020*

Graph 2 (a): Glycaemic profile (RBS)



Graph 2 (b): Glycaemic profile (HbA1c)

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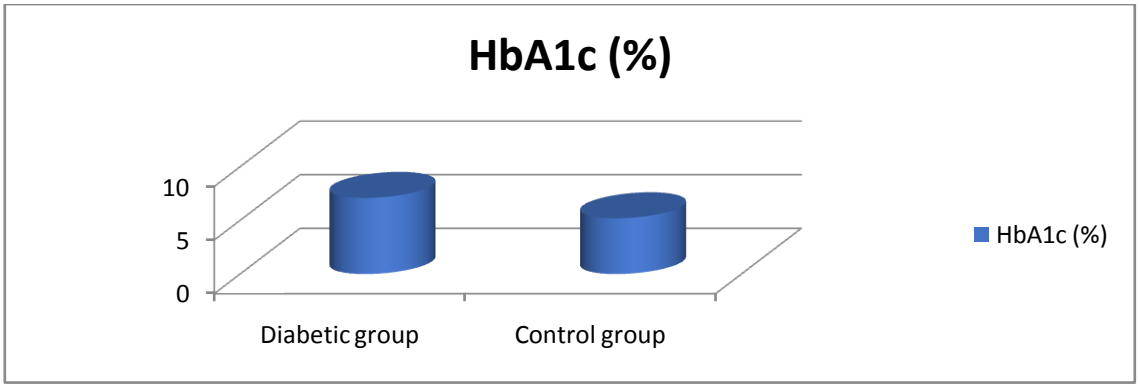

Table 3: Treatment of diabetes

Treatment	Number of patients	Percentage
Life style modifications	12	24
Oral hypoglycemic (s) + Life style modifications	29	58
Added insulin therapy	9	18
Total	50	100

Graph 3: Treatment of diabetes

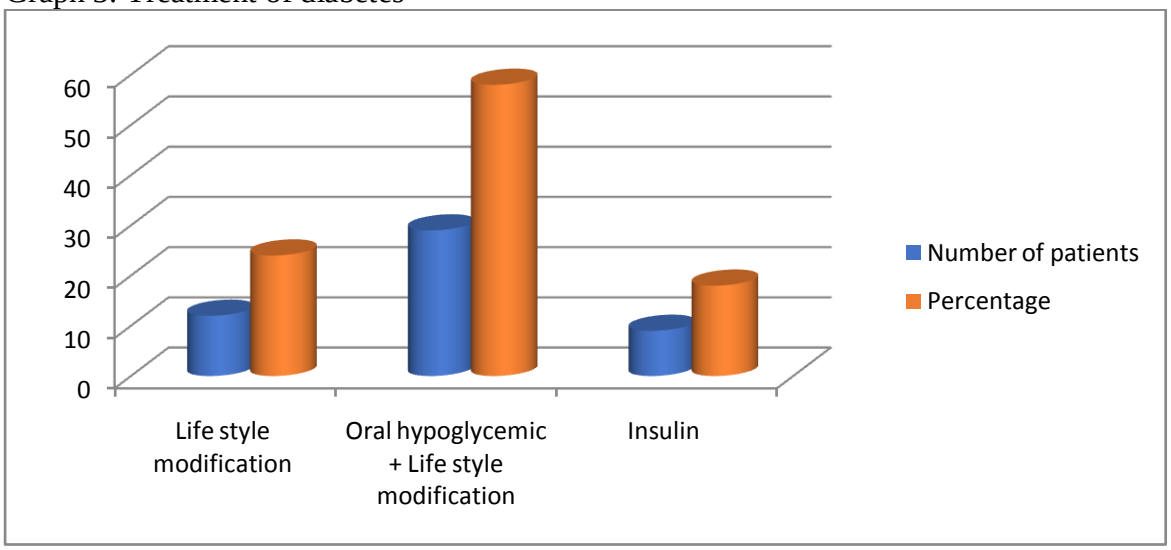

Table 4: Comparison of CMT between diabetic group and control group

CMT (µm)	Diabetic group		Control group		p- value
	Mean	SD	Mean	SD	
Baseline	256.4	8.5	255.3	5.6	0.42
1 week postoperative	264.4	5.5	261.2	5.4	0.38
12 weeks postoperative	268.9	6.7	267.4	5.9	0.82

Graph 4: Comparison of CMT in between diabetic group and control group

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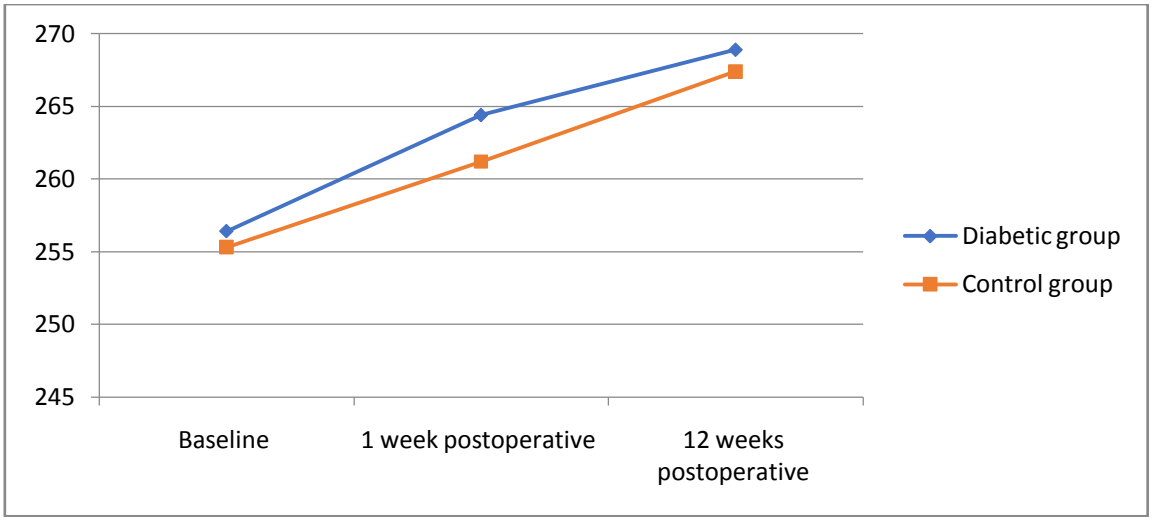


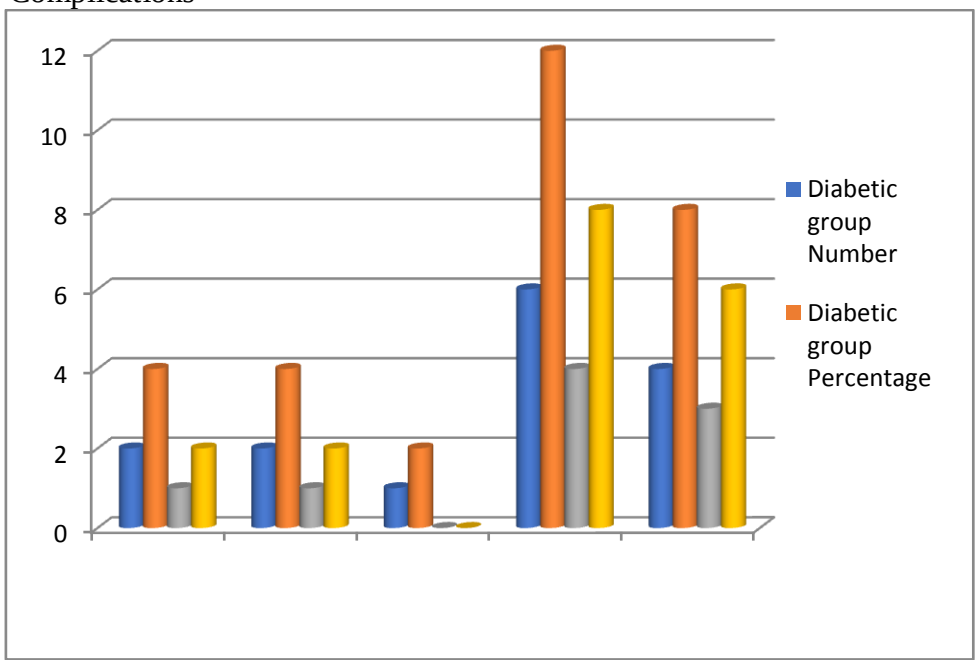
Table 5: Intragroup comparison of CMT

Comparison of CMT at different time intervals	Diabetic group	Control group
Baseline versus 1 week postoperative	0.001*	0.021*
Baseline versus 12 week postoperative	0.042*	0.034*
1 week versus 12 week postoperative	0.031*	0.028*

Table 6: Complications

Complications	Diabetic group		Control group	
	Number	Percentage	Number	Percentage
Pigment dispersion	2	4	1	2
Striate keratopathy	2	4	1	2
Wound dehiscence	1	2	0	0
Corneal oedema	6	12	4	8
ACR	4	8	3	6

Graph 5: Complications



DISCUSSION

Diabetes mellitus is one of the common systemic problems affecting a variety of people worldwide. Epidemiological data suggests that there is an increasing incidence of diabetes mellitus in developing countries.[11]

Cataract is the second most common ocular complication of diabetes mellitus after diabetic retinopathy. Diabetes mellitus influences the function and morphology of the lens. Cataracts occur at an early age in diabetics compared to non- diabetics. Apart from visual improvement, diabetic patients need cataract surgery for the assessment and treatment of posterior segment pathology. [11]

In India approximately 20% of all cataract surgery is performed in diabetics. Poor visual outcome after cataract surgery in diabetics is associated with the severity of pre-existing retinopathy and diabetic maculopathy prior to the surgery. In diabetics, there is an increased incidence of intra-operative complications including an increased risk of capsule rupture and vitreous loss. Diabetic patients are more prone to postoperative complications such as pigment dispersion, rubeosisiridis, neovascular glaucoma, macular edema, severe inflammation (iritis, uveitis), vitreous hemorrhage, synechiae to IOL, retinal detachment and corneal decompensation. Diabetics are more prone to develop posterior capsule opacification postoperatively. Higher incidence of diabetes in developing countries such as India necessitates an assessment of the outcome of cataract surgery in diabetic patients. [11]

In the present study, the mean age of the patients of the diabetic group was 54.9 years and of the non-diabetic group 56.8 years. In a study conducted by Sowmya CA et al, mean age of the patients of the diabetic group and control group was 56.5 years and 59.9 years. [11]In another study conducted by Guliani BP et al, mean age in control group was 58.30 years, while the mean age in diabetic group was 63.24 years. [12]

In the present study, mean RBS among the patients of the diabetic group was 167.38 mg/dL and mean RBS among the patients non-diabetic group was 113.5 mg/dL. Mean HbA1c among the patients of the diabetic group was 7.1% and mean HbA1c among the patients of non-diabetic group was 5.2%. Glycaemic profile of the patients of the diabetic group was significantly higher in comparison to the patients of the non-diabetic group.

In the present study, mean duration of diabetes among the patients of the diabetic group was 5.4 years. 54 percent of the patients of the diabetic group had duration of diabetes between 5 to 10 years, while 44 percent of the patients had duration of diabetes less than 5 years. In a previous study conducted by Sowmya CA et al, 55.2% patients were recently diagnosed diabetics with duration of disease being less than 3 years and about 13.8% patients had duration of disease more than 10 years. The risk for cataract formation and diabetic retinopathy was observed to be more in patients with longer duration of diabetes and in those with poor metabolic control.[11] The development of cataract secondary to hyperglycemia is probably due to modification of the lens proteins due to advanced glycation end products (AGEs), osmotic stress, depletion of ATP and generation of free radicals.

In the present study, mean CMT among the patients of the diabetic group was found to be 256.4 μm preoperatively, 264.4 μm at 1 week postoperative and 268.9 μm at 12 weeks postoperative. Mean CMT among the patients of the control group was found to be 255.3 μm preoperatively, 261.2 μm at 1 week postoperative and 267.4 μm at 12 weeks postoperative. While comparing the mean CMT between diabetic group and control group at baseline, 1 week postoperative and 12 weeks postoperatively, non-significant results were obtained. While making intra-group comparison, significant changes were seen in terms of CMT among both the diabetic group and control group.

In a study conducted by Guliani et al, the mean CMT changes in diabetic and control groups preoperatively versus postoperatively at week 1 and at week 6 were sound to be statistically significant. No significant difference was noted in the mean CMT values between

the two groups on any of the three occasions when CMT was measured. [12] In another study, conducted by Ikegami et al., it was observed that the postoperative CMT increased during follow-up in both the diabetic and control groups, and there was a significant increase compared to the preoperative value at 3 months after surgery in patients with diabetes, and at 1 and 3 months after surgery in patients without diabetes. The CMT values tended to be higher in patients with diabetes than in those without diabetes; however, there were no significant differences between the groups. [13]

Bannale et al. (2012), while comparing the control group with diabetic patients with no DR, reported that the phacoemulsification surgery had a stronger effect on the blood-aqueous barrier of diabetic patients. Surgery itself can cause inflammatory response by releasing prostaglandins, which plays an important role in the occurrence of macular thickening. [14] Eriksson et al. (2011) found that macular thickness increased significantly between the preoperative measurements and the 6-week follow up in both diabetics and controls. There was, however, no significant difference between the two groups. [15]

In the present study, pigment dispersion was seen in 4 percent of the patients of the diabetic group and 2 percent of the patients of the control group. Striate keratopathy was seen in 4 percent of the patients of the diabetic group and 2 percent of the patients of the control group. Wound dehiscence was seen in 2 percent of the patients of the diabetic group. Corneal edema was seen in 12 percent of the patients of the diabetic group and 8 percent of the patients of the control group. Anterior chamber reaction was seen in seen in 8 percent of the patients of the diabetic group and 6 percent of the patients of the control group.

Larsson et al have shown that diabetes has been associated with structural changes in corneal endothelial cells such as polymegathism and pleomorphism. Cataract extraction and IOL implantation causes trauma to the already compromised corneal endothelium and causes corneal edema. [16] In a study conducted by Sowmya CA et al, pigments over IOL were seen in 4 (6.9%) of the cases in diabetics as compared to 2 (3.4%) in the Nondiabetic group. A total of 6 (10.3%) eyes in the diabetic group and 5 (8.6%) eyes in the non-diabetic group had anterior chamber reaction. [11]

This study demonstrated that the influence of uncomplicated cataract surgery on CMT in well-controlled diabetic patients did not significantly differ from healthy non-diabetic subjects after uncomplicated cataract surgery. In other words, well-controlled diabetics and nondiabetic patients showed similar intragroup thickening of the central macula at weeks 1 and 12 after uncomplicated phacoemulsification, and the intergroup comparison was not statistically significant.

CONCLUSION

Under the light of results obtained from this prospective interventional study, it was concluded that uncomplicated cataract surgery in diabetics with well controlled glycaemic profile and without any evidence of diabetic retinopathy yields similar outcomes as non-diabetics in terms of rise in post-operative macular thickness. The number of people with diabetes mellitus is increasing exponentially. Diabetic patients with visually significant cataracts pose unique challenges and since there seems to be a higher incidence of postoperative complications among diabetics, so extra caution should be taken intra-operatively and during post-operative follow up.

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