Effect of uneventful phacoemulsification cataract surgery in diabetic and non-diabetic patients on central macular thickness: A comparative study

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Abstract Background: Phacoemulsification surgery with implantation of a foldable intraocular lens (IOL) is the currently preferred technique. The procedure is efficient, and uneventful surgery is generally associated with good visual results. Postoperative cystoid macular edema is a complication of eventful or complicated cataract surgery, can also develop after uneventful cataract surgery. Aims and objective: To study the effect of uneventful phacoemulsification cataract surgery in diabetic and non-diabetic patients on central macular thickness. Materials and method: In this study 64 eyes were assessed by optical coherence tomography preoperatively and postoperatively day 1, week 1, week 4 and 12 week after uncomplicated phacoemulsification cataract surgery with foldable intraocular lens (IOL) implantation in the capsular bag under peribulbar anesthesia. The study included 32 eyes of non-diabetic patients (Group I) and 32 eyes of diabetic patients (Group II). Results: This study included 64 adult patients divided into 32 patients who were non -diabetic (group I) and 32 (group II) patients having diabetes undergone uncomplicated phacoemulsification surgery. Among 64 patients 44 were males (69%) and 20 were (31%) females. In our study among the 64 patients 60 patients were in the age group of 50-79 yrs. The postoperative percent change in central macular thickness was significantly different from baseline at 1 week between both the groups. The postoperative central macular thickness increase was statistically significant in diabetic group as compared to non -diabetics group after Phacoemulsification. Conclusion: Thus we conclude that majority of the patients were male with more than 50 years of age with posterior subscapular cataract as common type. This study has demonstrated change in central macular thickness, change in macular cube thickness, change in average macular cube thickness, and appearance/ worsening of cystoid macular edema in both non-diabetic and diabetic patients.

Key Word: phacoemulsification, diabetes, central macular thickness

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INTRODUCTION

Cataract extraction is one of the most commonly performed surgeries. Over recent years, the outcome of cataract surgery has improved due to consistent innovations in instrumentation, lens design, and surgical technique.¹ Phacoemulsification implantation of a foldable intraocular lens (IOL) is the currently preferred technique.² The procedure is efficient, and uneventful surgery is generally associated with good visual results.^{3,4,5} Postoperative cystoid macular edema is

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generally developed after complicated cataract surgery but can also developed after uneventful cataract surgery. Though enhanced surgical procedures have diminished the frequency of cystoid macular edema, it remains a reason for ominous visual outcomes post-surgery. Nevertheless, cystoid macular edema (CME) may develop, and this can result in suboptimal postoperative vision.^{6,7,8}Cystoid macular edema (CME) is a primary cause of reduced vision following both cataract and successful vitreoretinal surgery. The incidence of clinical CME following modern cataract surgery is 0.1-2.35%.9Cystoid macular edema can occur after uncomplicated surgery in patients with otherwise healthy eyes. After complicated surgery, or after surgery in patients with ocular diseases such uveitis or diabetic retinopathy.¹⁰ Among these, the improvement of CME taking after cataract surgery in diabetic patients is absolutely a matter of worry with steadily increasing cases of diabetes in the populace and especially in India. While the development of CME in patients with diabetic retinopathy (DR) is a well-established certainty, the development of the same in eyes without DR is absolutely a matter of intrigue and alert.

MATERIALS AND METHOD

The present comparative study was conducted in the department of Ophthalmology of Deenanath Mangeshkar Hospital and Research Centre, Erandwane, Pune. All adult patients who underwent uncomplicated phacoemulsification surgery were enrolled in the present study. The patients were divided in to two groups.

- **Group I:** Patients with no diabetes mellitus. (n: 32)
- **Group II:** Patients with type 2 diabetes mellitus with some of them having pre-existing nonproliferative diabetic retinopathy (n: 32)

Total sample size of 64 eyes of patients with 32 cases (patients with diabetes mellitus) with 32 controls (patients without diabetes mellitus) was needed to detect increase in the incidence of CME (cystoid macular edema) after cataract surgery among patients with pre-existing diabetic retinopathy $(25\%)^{11,12}$ as compared to that (2%) among patients without diabetes mellitus, based on previous studies, with 80% power at a significance level of $\alpha = 5\%$ (one-sided).Following inclusion and exclusion criteria was used to select the study subjects.

Inclusion criteria

• Patients with Age >18 years and who were, scheduled for phacoemulsification cataract surgery within at the most 28 days after the first evaluation and some of them are having type 2 diabetes mellitus with some of them having nonproliferative diabetic retinopathy.

- Patients with, Best corrected visual acuity perception of light or more
- Patients with, Central macular thickness measured on cirrus OCT ≤ 310 microns at baseline.

Exclusion criteria

- Patients with, Type 1 diabetes Mellitus and Eyes underwent any major intraocular surgery in past 6 months.
- Eyes with any significant extra-lenticular media opacity e.g. corneal opacity, vitreous hemorrhage etc. that interfered with patient's vision and was not going to be addressed as a part of present protocol strategy.
- Eyes of Patients harboring any serious systemic comorbidity e.g. End stage renal failure, Ischemic heart disease, uncontrolled hypertension etc. that had prevented the patient from attending the scheduled follow-up visits.
- Patients with, any other ocular co-morbidity that is likely to confound the results of the current study e.g. glaucoma, retinal vascular occlusions etc.
- Patients with posterior capsular rent during cataract surgery.
- Patients with, proliferative diabetic retinopathy

All the enrolled patients underwent detail history taking and clinical examination after proper Informed written consent. The collected information was recorded in aprestructured proforma. Optical coherence tomography done preoperatively and postoperatively at day1, week1, week4 and 12week after uncomplicated phacoemulsification with foldable intraocular lens (IOL) implantation under peribulbar anaesthesia. Optical coherence tomography was done using the Zeiss Stratus OCT scanners after dilating pupils fully with tropicamide (0.08%) and phenylephrine (5%) evedropsin every patient using macular cube 512×128 and macular thickness was noted. The central macular thickness was defined as the distance between the innermost foveolar surface and the outermost foveolar surface and was measured using the manually assisted technique of the program with the OCT system software, with the fixation point regarded as the foveal center. The preoperative and post operative changes in central macular(sub-field) thickness (CMT), macular cube volume thickness (MCV), average macular cube thickness (AMT) and development of cystoid macular edema on OCT of each group were noted and compared.

Table 1: Distri	bution accordi	ng to baselir	ne informatio	n
		Gr	Total	
	Age group	Group I	Group II	Total
	≤ 50	3	1	4
	51 - 60	9	9	18
Age group	61 - 70	10	18	28
	71 - 80	10	1	11
	> 80	0	3	3
Cov	Male	21	23	44
Sex	Female	11	9	20
	NS PSC	0	1	1
	NS2	6	1	7
Grade of Cataract	NS3	10	9	19
	NS4	0	1	1
	PSC	16	20	36
	Total	32	32	64

RESULTS

Majority of the subjects (44.0%) belonged to age group 61 - 70 years followed by 51 - 60 years (28%) and age group 71 - 80 years (17.0%). In the study in group I65% were males and 35% were females, while group II, 72% were males and 28% were females. It was observed that majority of the patients hadPSC among the both groups (group I=16, Group||=20) followed by NS3 (group I=10, Group=9)

Table 2: Comparisons of mean macular thickness between the study groups on OCT						
СМТ		Group I (n= 32)		Group II (n= 32)		Inter group
CIVIT		Mean	SD	Mean	SD	p-value
	Pre op	249.38	19.64	257.66	23.65	0.133
	Day 1	254.47	19.88	271.31	58.76	0.133
Central macular (subfield) thickness	week 1	264.53	30.29	295.81	80.53	0.046
	week 4	270.88	63.97	281.25	60.20	0.507
	week 12	264.09	67.26	258.50	23.96	0.66
	Pre op	9.44	0.38	9.67	0.55	0.062
	Day 1	9.51	0.39	9.48	1.53	0.92
Mean macular cube volume	week 1	9.60	0.44	9.94	0.81	0.042
	week 4	9.60	0.48	9.92	0.83	0.067
	week 12	9.58	0.66	9.40	1.77	0.59
	Pre op	267.94	12.70	274.34	13.92	0.059
	Day 1	271.28	12.38	278.09	16.52	0.067
Average macular thickness	week 1	274.94	13.29	282.66	19.98	0.074
	week 4	273.56	13.81	281.06	20.88	0.096
	week 12	272.78	18.78	277.28	16.07	0.307

The mean value of central macular (sub-field) thickness (CMT) before surgery in group I was $249.38\pm19.64 \mu m$ and in group II was $257.66\pm23.65 \mu m$ but the difference was not statistically significant. The mean value of central (sub-field) macular thickness on day 1 after surgery in group I was $254.47\pm19.88\mu m$. and in group II was $271.31\pm58.76\mu m$. The mean value of mean central macular (sub-field) thickness on 1 week after surgery in group I was $264.53\pm30.29\mu m$ and in group II was $295.81\pm80.53\mu m$ and the difference was statistically significant. The difference observed in the mean value of central macular (subfield) thickness at 4 week after surgery and 12 week after surgery among group I and group II was not statistically significant. The mean value of macular cube volume (CV) before surgery in group I was $9.44\pm0.38mm^3$ and in group II was $9.67\pm0.55mm^3$ and the difference was not statistically significant. It was seen that the mean difference in value of macular cube volume in group I and group II on day 1, on week 4 and week 12 after surgery was $9.60\pm0.44mm^3$ and in group II was $9.94\pm0.81mm^3$ and the difference was statistically significant. The mean average macular thickness (AMT) between the study groups was compared and it was seen that the difference observed in group I and group II before surgery, on day 1, week1, week4 and week12 after surgery was statistically not significant.

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Cystoid Macular Edema		Group		Total	n voluo	
		Group I	Group II	TOLA	p-value	
Day 1	Present	1	2	3	0.999	
	Absent	31	30	61		
Week 1	Present	2	9	11	0.043	
	Absent	30	23	53		
week 4	Present	2	10	12	0.022	
	Absent	30	22	52		
week 12	Present	1	0	1	0.990	
	Absent	31	32	63		

Table 3: Comparison of Cystoid Macular Edema between study group I and group II on OCT

The development of cystoid macular edema at day 1 in group I subjects was 3% and in group II it was 6%. At postoperative follow up at 1 week, in group I it was 6% and in group II it was 28% and the difference was statistically significant between two groups. At post-operative follow up 4 week, the cystoid macular edema developed 6% in group I and 31% in group II and the difference was statistically significant at 4 week also. The development of cystoid macular edema in our study at 12 week in group I was 3% and in group II none of the subject was having cystoid macular edema but the difference was not statically significant at 12 week.



DISCUSSION

The present prospective comparative study was conducted at Deenanath Mangeshkar Hospital Pune. Sixty four eyes of patients fulfilling the inclusion criteria attending the Ophthalmology Department. Sixty four eyes of patients underwent uncomplicated phacoemulsification of which Thirty two eyes of non-diabetic patients(group I) and remaining thirty two eyes of patients were having diabetic (group II). In the present study among 64 eyes of patients included 44 were males (68.75%) and 20 were females (31.25%). The sex distribution was skewed and similar studies have been done in past with unequal distribution of gender. Study done by Hayashi et al¹³examined 39 were male and 29 women. They carried out study to quantitatively examine changes in macular oedema after phacoemulsification surgery in eyes with diabetic retinopathy (DR) and in eyes without DR. They concluded that the degree of diabetic macular edema increases up to 3 months after cataract surgery, but there after decreases gradually. Grade of diabetic macular edema also worsens up to 3 months, but certain percent of macular edema that occurs after surgery resolves spontaneously. These changes are more prominent in eyes

with DR than in eyes with no DR. there were also no statistically significant differences between sex distributions like in present study. So the unequal gender distribution not going to affect the outcome of the study. The present study involved patients with senile cataract of various lens opacification and sclerosis grades- majority were Posterior subscapular cataract PSC(56%) followed by nuclear sclerosis (42%). It was noted that with grades advanced of cataract undergoing phacoemulsification, there were higher chances of postoperative intraocular inflammation and consequently higher incidence of post-operative cystoid macular edema. Such was not the case with present study as was reflected with similar studies by Biro Z et al14 who assessed change of foveal and perifoveal thickness measured by OCT after phacoemulsification and Intraocular lens implantation all the cases were of senile cataract from nuclear sclerosis grade I to III. Use of OCT to detect post cataract surgery cystoid macular edema is well validated by plethora of studies in literature. In a study done by Chingetal¹⁵, 131 eyes of 131 patient's presence of senile cataract in patients older than 50 years old Cataract extraction required because of visual

impairment clear fundal examination before cataract surgery were studied in an ophthalmology clinic. They also concluded that OCT was useful in detecting and confirming clinical CMO after cataract surgery. Many studies done in past assessing the change in macular thickness in diabetic patients perioperatively only compute the absolute increase in Central macular thickness[CMT], and in our opinion, disregard the baseline anatomical variation. In our study we accounted for the baseline variation in Central macular thickness of diabetic and non-diabetic patients by computing a percent change in Central Macular Thickness over baseline thickness- in our study, central macular (sub-field) thickness [CMT] at 1 week in diabetic patients was significantly higher than in non-diabetic patients. The percent change in central macular thickness at 1 week in group I was (non -diabetic group) 6% where as it was 13 % in group II(diabetic group). In a study with similar approach by Degenring *et al*¹⁶ which assessed 108 eves by optical coherence tomography preoperatively and 1 day, 1 week and 4 weeks after phacoemulsification showed significantly increased Minimal Foveal Thickness measurement in diabetic patients showing a tendency towards increase in retinal thickness than non-diabetic subjects. The percent changein minimal foveal thickness in non-diabetics at day 1, 1 week and 4 week it was 4.8%, 32% and 24% respectively whereas in diabetic subject at day 1, 1 week and 4 week it was 17.4%, 21.7% and 33.3 % respectively. They also concluded that, the foveal thickness at and volume demonstrated increase within 4 weeks after uncomplicated cataract surgery. In present study the significant increase in macular thickness was at 1 week and thereafter the difference between the two groups lost statistical significance, although the trend in diabetic patients of having higher CME continued through the study period. Different studies show different time patterns of having peak macular thickness. The study done by Kwon S II et al^{17} carried out evaluation of changes of macular thickness in diabetic retinopathy after cataract surgery ,in 104 eyes of diabetic patients in which Macular edema occurred in 19 eyes (18%) ,among 19 eyes 12 eyes (63%)developed macular edema developed at 1 month after surgery. The incidence of macular edema after cataract surgery in diabetic patients was 18%, which was having peak incidence at 1 month post-surgery. Such clinical observations may have impact on the perioperative monitoring strategies for macular oedema and time patterns and a spontaneous resolution, as was seen in our study would influence a choice for more aggressive therapies of macular oedema, e.g. intravitreal steroids. It was observed that the macular cube volume [CV] in group I and group II, the % increase from baseline at 1 week in group I was 1.6% and group II was

3%, the difference between two groups was statistically significant. Previously there were very few studies done which also study changes in macular cube volume. A similar study was done by Degenring *et al*¹⁶ which assessed 108 eyes by optical coherence tomography preoperatively and 1 day, 1 week and 4 weeks after phacoemulsification and also studied central foveal thickness change and macular volume change after phacoemulsification. They also concluded that in nondiabetic group at week 1 there was 9.9% increase in volume whereas in diabetics it was 16.7%(105), similar to our study. We propose that having macular cube volume calculation in addition to central macular thickness has high functional implications. In the present study there was no statistically significant difference in average macular cube thickness [AMT] between the two groups, at any time of post-operative follow up to 12 week. However in diabetic group there is a trend in terms of increase in AMT, up to postoperative 4 week. Most of the studies done in past studied mainly central macular thickness [CMT] only and similar studies which included average macular cube thickness are few in number. A study done by Saxena Set al^{18} concluded that cube average thickness provides a global perspective of defining DME within the macular cube It was observed that in present study the incidence of cystoid macular edema, in group I at1weekwas 6% which was also same at 4 week whereas in group II it was found to be 28% at 1 week and 31 % at 4 week ,the incidence of cystoid macular oedema in group II (diabetics) was more compared to group I(non-diabetic), these finding are corroborated by the study done by Katsimpris *et al*¹⁹ in which central foveal thickness was studied before and after cataract surgery using OCT in 49 eves from normal patients and 49 eyes diabetic patients. The incidence of cystoid macular edema (CME) was 4.0 % and 28.6 % for the control group and the diabetic group, respectively. They also concluded that eyes of diabetic patients present higher CFT and a higher incidence of CME after cataract surgery on OCT examination compared to eyes of healthy controls. In study done by Kim S J *et al*²⁰, the incidence of macular edema on OCT was 22%, which at follow up period of 1 month in Diabetic eyes which also have a high incidence of increased center macular thickness on OCT after cataract surgery. The patient having presence of more cystoid spaces and more increased in central macular thickness, as was seen in our study would influence choice for more aggressive therapies of macular oedema, e.g. intravitreal steroids.

CONCLUSION

Thus we conclude that majority of the patients were male with more than 50 years of age with Posterior subscapular cataract as common type. This study has demonstrated change in central macular thickness, change in macular cube thickness, change in average macular cube thickness, and appearance/ worsening of cystoid macular edema in both non –diabetic and diabetic patients. The incidence of optical coherence tomographically evident cystoid macular edema was 28% at 1 week and 31% at 4 week among the diabetic patients. The incidence of substantial increase in macular thickness was associated with impaired visual acuity. This study has demonstrated that the increase in the macular thickness and macular edema is more prominent in diabetic eyes than nondiabetic eye after surgery.

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