International Journal of Research in Medical Sciences
Jamaiyar A et al. Int J Res Med Sci. 2023 Aug;11(8):2832-2836
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20232160

Original Research Article

A prospective study to evaluate changes in macular thickness after uncomplicated cataract surgery using optical coherence tomography in diabetic patients

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Received: 18 June 2023
Accepted: 03 July 2023

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ABSTRACT

Background: The objective of this study is to evaluate the alterations in macular thickness subsequent to cataract surgery in individuals diagnosed with diabetes, utilising optical coherence tomography (OCT) as the imaging modality.
Methods: In this prospective study, a cohort of 150 patients was divided into three equal groups based on their diabetic status and presence of retinopathy. Group 1 consisted of nondiabetic patients, Group 2 consisted of diabetic patients without retinopathy, and group 3 consisted of patients with diabetic retinopathy. All patients underwent cataract surgery using manual small incision cataract surgery (m-SICS) technique. A comprehensive ophthalmological assessment was conducted prior to the surgical procedure. The subjects were monitored on the first day following the surgical procedure, and at 2, 6 and 12 weeks after the operation. During each appointment, a comprehensive ophthalmic assessment and OCT of the macula were conducted.
Results: There was a notable augmentation in foveal thickness at the 6-week mark among individuals diagnosed with diabetic retinopathy, in contrast to those without retinopathy and the control group. In the study, it was observed that 26% of individuals diagnosed with diabetes experienced the occurrence of macular edoema, whereas only 4% of the control group exhibited the same condition.
Conclusions: The postoperative alteration in macular thickness and visual outcomes is contingent upon the individual's diabetic condition, duration of diabetes, and severity of retinopathy. A positive correlation was also observed between the alteration in macular thickness and the levels of HbA1C in individuals diagnosed with diabetes.

Keywords: OCT, Central macular thickness, Diabetic retinopathy, Cystoid macular edema

INTRODUCTION

High-resolution cross-sectional imaging of the retina is a valuable tool in the medical field for the identification, monitoring, and quantitative assessment of macular thickness. OCT is a cutting-edge medical diagnostic imaging modality that enables the acquisition of high-resolution, cross-sectional or tomographic images within biological tissues at the micron scale. Retinal cross-sectional images were acquired with a resolution of 10 microns.[1,2] OCT employs low coherence or white light-interferometry techniques to conduct precise measurements and imaging with enhanced resolution. The infrared light beam possesses a wavelength of 820 nm in accordance with medical and academic terminology.[3] Post-operative alterations in macular thickness manifest subsequent to cataract surgical intervention. Subclinical alterations in macular thickness, which do not impact visual acuity, manifest and can be evaluated using OCT.[1] Pseudophakic cystoid macular edoema (PCME) is a frequently encountered complication following cataract extraction and intraocular lens (IOL) implantation, characterised by the extravasation of fluid from the capillary network. Cystoid

spaces are known to develop in the macula as a result of accumulation of serous fluid within outer plexiform layer. This phenomenon typically exhibits self-limiting nature, resulting in spontaneous resolution. However, in some cases, it can result in significant impairment of central vision, which may persist chronically or permanently.[4,5]

The prevalence of macular edoema as observed through OCT was found to be 22% among diabetic patients who underwent cataract surgery, as reported in a previous study.[6] Distinguishing the aetiology of macular edoema following cataract surgery in individuals with diabetes poses a challenge, as it may arise from either the surgical intervention or the underlying diabetic condition. Despite advancements in surgical techniques, the occurrence of postoperative cystoid macular edoema continues to be a contributing factor to suboptimal visual results.[7,8] Furthermore, there is a scarcity of data pertaining to alterations in macular thickness subsequent to uneventful cataract surgery of various classifications. Fundus fluorescein angiography has been widely regarded as the established diagnostic method for subclinical PCME. However, non-invasive cross-sectional imaging of the retina using OCT has emerged as a promising alternative for effectively identifying this condition. Moreover, OCT offers the additional benefits of quantification and the ability to obtain repeatable results.[9] Given the aforementioned factors, the present study was undertaken with the objective of evaluating the alterations in macular thickness following cataract surgery using micro-incisional small-incision cataract surgery (m-SICS) technique in individuals with diabetes mellitus, utilising OCT as the imaging modality.

METHODS

Study design and location

This prospective, comparative study was conducted to evaluate the clinical outcome of individuals diagnosed with diabetes, both with and without diabetic retinopathy, who underwent cataract surgery. The present investigation was carried out from March 2022 to May 2023 at the Rajendra institute of medical sciences, Ranchi. Informed consent was duly obtained from all participants in the study.

Sample population

Study gathered total of 150 participants who categorised into 3 distinct groups. Group 1 consisted of 50 individuals without diabetes, while group 2 comprised 50 individuals with diabetes but without diabetic retinopathy. Lastly, group 3 consisted of 50 individuals with diabetes and diagnosed with diabetic retinopathy.

Inclusion criteria

Patients aged between 30-80 years of both sexes with T2DM with or without DR who underwent m-SICS were included as cases. Non-diabetic patients were included as controls.

Exclusion criteria

Patients with other retinopathies, pre-existing glaucoma and those having severe hypertension and nephropathies were excluded.

All participants exhibited clinically significant age-related cataract of LOCS III (Lens opacities classification system) grade N3. The diabetic group had comorbidity of diabetes mellitus type II, while the control group demonstrated absence of diabetes as confirmed by fasting blood glucose test. A comprehensive ophthalmic and systemic medical history was obtained. Every patient underwent best corrected distance visual acuity (VA) assessment using the logarithm of the minimum angle of resolution (LogMAR) equivalent of the standard Snellen's chart, as well as the Snellen's near vision chart, for both eyes. All the individuals underwent anterior segment examination, biomicroscopic evaluation with fundus non-contact +90D lens. Standard haematological and biochemical analyses, including assessment of blood and urine samples, were conducted upon initial examination. Additionally, the level of glycosylated haemoglobin (HbA1C) was measured. All subjects were administered topical gatifloxacin 0.3% one day prior to the surgical procedure in conjunction with Topical flurbiprofen sodium 0.03%. On the day of the surgical procedure, the patient received three applications of topical flurbiprofen sodium 0.03% at 10-minute intervals, in addition to three applications of topical mydriatics. The mydriatics consisted of a combination of two eye drops: 0.8% tropicamide and 5% phenylephrine, which were administered at 10-minute intervals. All surgical procedures were performed under peribulbar anaesthesia by a sole surgeon. Following aseptic technique, the procedure of manual MSICS was carried out. Following the surgical procedure, a postoperative regimen was implemented, which included the administration of topical flurbiprofen in conjunction with corticosteroid and antibiotic medications (specifically, gatifloxacin 0.3% and dexamethasone 0.1%). These medications were prescribed four times daily for a duration of six weeks across all three study groups.

The measurement of central macular thickness (CMT) was conducted using the stratus OCT machine model 3000, manufactured by Carl Zeiss Meditec Inc., equipped with software version 4.0. The Fast macular thickness (FMT) protocol was employed in the study. The study parameters were assessed on the preoperative day, which was considered as the baseline. A 30% augmentation in foveal thickness relative to the initial measurement (Preoperative) was deemed indicative of macular edoema. The subjects underwent postoperative follow-up assessments on day 1, and at 2 weeks, 6 weeks, and 12 weeks after the surgical procedure. A comprehensive

ophthalmic examination, which included OCT, was performed during each subsequent visit.

Statistical analysis

The data were presented as the mean ± standard deviation. Statistical differences during follow ups were assessed using a paired t-test. To find correlation between the variables Pearson's correlation of coefficient was applied. A p value of less than 0.05 was considered to be statistically significant.

RESULTS

There was a notable enhancement in visual acuity observed across all three experimental groups. The postoperative visual acuity on the first day was found to be superior in patients belonging to group 1, whereas it was comparatively inferior in group 2 patients when compared to those in group 3. The ultimate visual acuity at the end of the 12-week period demonstrated superior outcomes in patients belonging to group 1, while patients in group 3 exhibited comparatively poorer results (Table 1). Group 2 showed maximum range of improvement in visual acuity in post operative period.

Following surgical procedure, specifically on 1st day post-op there was marginal reduction in foveal thickness observed across all three groups. However, it is important to note that this decrease did not reach statistical significance ($p>0.5$). Observed average augmentation in foveal thickness in group 1 was 15.18 µm ($p=0.0010$, indicating an extremely significant result) after 6 weeks, in contrast to 21.79 µm in group 2 ($p=0.0282$, indicating a significant result), and 50.28 µm ($p<0.0001$, indicating an extremely significant result) in group 3 (Table 2).

Table 1: Corrected visual acuity in patients.

Groups	Pre-op	Day 1	2 weeks	6 weeks	12 weeks
Group 1	1.225±0.292	0.207±0.097	0.164±0.121	0.078±0.121	0.012±0.085
Group 2	1.390±0.414	0.415±0.155	0.195±0.191	0.153±0.196	0.09±0.161
Group 3	1.347±0.323	0.227±0.104	0.252±0.118	0.36±0.1607	0.185±0.161

Table 2: Foveal thickness (µm) in post operative period.

Groups	Pre-op	Day 1	2 weeks	6 weeks	12 weeks
Group 1	179.32±18.147	178.32±18.220	187.04±19.484	194.5±19.787	183.3±19.717
Group 2	196.26±42.2	194.74±41.526	201.14±41.795	218.05±37.354	201.6±30.354
Group 3	206.42±30.823	205.04±30.647	229.76±33.487	256.7±37.599	228.6±34.309

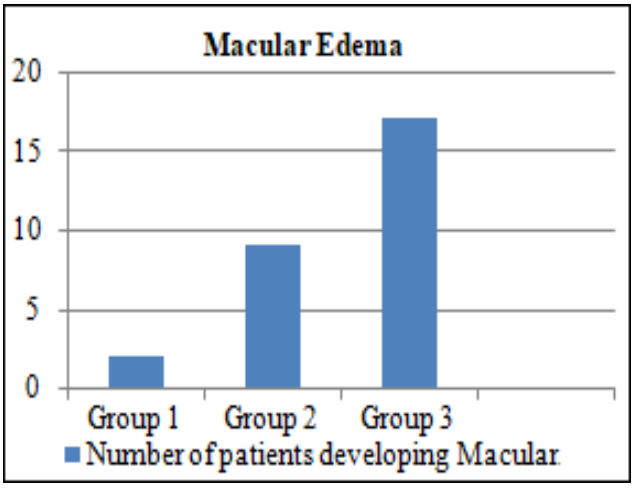

Figure 1: Number of patients developing macular edema.

In group 1, 2 eyes (4%) experienced the development of macular edoema after the operation at the 6-week mark. In group 2, this occurred in 9 eyes (18%), while in group 3, it was observed in 17 eyes (34%). Hence, a total of 26 individuals (26%) out of a cohort of 100 patients diagnosed with diabetes mellitus exhibited the occurrence of macular edoema following the surgical intervention, specifically at the 6-week postoperative period. Figure 1 shows that when the prevalence of macular edoema was compared between individuals with diabetes and those without diabetes using Fisher's exact test, the two-sided $p=0.0007$, indicating statistical significance. The relative risk was determined using the Katz approximation method, yielding a value of 1.531. Although the incidence of macular edoema in diabetic patients with retinopathy was higher compared to patients without retinopathy, the statistical analysis yielded a two-sided $p=0.1095$, indicating a lack of significance.

DISCUSSION

The study conducted by Gharbiya et al examined a cohort of 40 ocular specimens from 40 individuals (16 male and 24 female).[10] The mean best-corrected visual acuity (BCVA) of the surgically treated eyes demonstrated a statistically significant improvement compared to the BCVA of the non-operated fellow eyes. On the initial postoperative day, there was a notable reduction in the average retinal thickness across all macular subfields in the operated eyes when compared to the corresponding fellow eyes. Corneal mean thickness (CMT) of the surgically treated eyes exhibited a notable increase starting from the initial postoperative month, reaching its maximum at the second month. At the age of 6 months,

the retinal thickness in the outer macular region of the surgically treated eyes exhibited a statistically significant increase, while no notable disparity in retinal thickness was observed in the central fovea.

Wang et al conducted a study on a total of 159 eyes, comprising 58 eyes from individuals diagnosed with diabetes and 101 eyes from a control group.[11] The mean age of the study participants was 67.11 years, with a majority of 54.1% being of the male gender. There were notable enhancements in BCVA observed during all subsequent postoperative evaluation intervals. Within the non-diabetic cohort, a notable and statistically significant elevation in central retinal thickness (CRT) was observed during the second and fourth weeks following the surgical procedure. In the cohort of individuals with diabetes but without retinopathy, there was a notable and statistically significant increase in CRT at postoperative Week 4 when compared to the initial baseline measurement. There were no statistically significant disparities observed in the average CRT and BCVA among the study cohorts prior to surgery and during the first, second, and fourth weeks following the operation. There was no statistically significant correlation observed between CRT and glycated haemoglobin (HbA1c) levels, as well as between BCVA measured in logarithm of the minimum angle of resolution (logMAR) and HbA1c levels, both preoperatively and at week 1, 2 and 4.

Neumaier-Ammerer et al conducted a study on cohort of 25 patients, each with 25 eyes, which were divided into 2 distinct groups. Group 1 consisted of 10 individuals who did not exhibit any general internal disease, whereas group 2 comprised patients who presented with diabetes with or without hypertension. No statistically significant increase in foveal thickness was observed following uneventful phacoemulsification surgery in either of the study groups. Furthermore, there was no statistically significant difference observed between these groups. The incidence of foveal thickening was found to be significantly higher in group 2 compared to group 1, with a prevalence of 60% and 20% after 4 weeks, and 47% and 30% after 12 weeks post-surgery, respectively.

Stunf et al conducted a study on a sample of 28 eyes belonging to 28 patients. Among these patients, 10 were non-diabetic, while 18 had diabetes but did not exhibit any signs of diabetic retinopathy. Following the surgical removal of a cataract the average retinal thickness in the diabetic cohort exhibited a significant alteration, increasing from 238.6 µm prior to the surgical intervention to 255.2 µm ($p=0.02$) at the 6-month postoperative evaluation following cataract surgery. In the experimental cohort, the central field thickness exhibited a significant alteration from 247.6 µm prior to the surgical intervention to 261.7 µm ($p=0.03$) at the 6-month postoperative mark following cataract surgery.

Kwon et al conducted a study involving a cohort of 104 participants, consisting of 36 male and 68 female subjects.[14] The total count of individuals lacking diabetic retinopathy was 61, accounting for 58.65% of the patient population. Among these patients, 27 individuals (25.96%) exhibited mild to moderate non-proliferative diabetic retinopathy (NPDR), while 16 individuals (15.36%) displayed severe NPDR or proliferative diabetic retinopathy (PDR). The most prevalent complication observed was macular edoema, which manifested in 19 eyes (18.27%). This was closely followed by the progression of retinopathy, which occurred in 11.54% of cases. Among the 19 ocular cases exhibiting macular edoema, a total of 12 eyes (63%) manifested the presence of macular edoema one month following the surgical intervention. Furthermore, a majority of 13 eyes (68%) demonstrated a notable amelioration in the macular edoema by the sixth month post-surgery. The residual six ocular organs did not exhibit any significant improvement within the six-month timeframe.

In the current investigation, the mean BCVA of the surgically treated eyes exhibited a statistically significant improvement, consistent with the aforementioned studies. The prevalence of macular edoema subsequent to cataract surgery in individuals with diabetes was found to be 26%, with a higher occurrence observed among patients in group 3. Kwon et al reported a prevalence rate of 18.27% in their study. The foveal thickness of the eyes that underwent surgery exhibited a decrease on the first day following the procedure, which aligns with the findings of Gharbiya et al.[10] However, this decrease was not statistically significant. The CMT exhibited a subsequent increase and reached its maximum at 6 weeks, which is consistent with the findings of Gharbiya et al, where the foveal thickness reached its peak at 2 months post-surgery.[10] Similarly, Kwon et al reported that 63% of patients developed macular edoema at 1 month after the surgical procedure.[14] The final clinical measurement time (CMT) at 12 weeks exhibited a sustained elevation compared to the baseline, consistent with the aforementioned studies. A significant positive correlation was observed between alterations in foveal thickness as measured by OCT as well as the levels of glycated haemoglobin (HbA1C) in patients belonging to group 2 and 3.

CONCLUSION

Patients diagnosed with diabetes present a distinct challenge owing to their heightened susceptibility to the premature onset of cataracts, as well as their increased likelihood of experiencing macular edoema and the advancement of retinopathy subsequent to undergoing cataract surgery. The findings of this study indicate that the postoperative alteration in macular thickness and visual outcomes is closely associated with the diabetic condition, duration of the disease, and severity of retinopathy. A positive correlation was observed between the alteration in macular thickness and the levels of HbA1C in patients diagnosed with diabetes.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Jamaiyar A, Kumar S, Kiran N, Mahato RK, Anand M. A prospective study to evaluate changes in macular thickness after uncomplicated cataract surgery using optical coherence tomography in diabetic patients. Int J Res Med Sci 2023;11:2832-6.