Incidence of Clinical and Subclinical Cystoid Macular Edema in Diabetic and Non-Diabetic Patients After Cataract Surgery by Means of Optical Coherence Tomography

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Abstract

Purpose: To evaluate the incidence of clinical and subclinical cystoid macular edema in diabetic and non-diabetic patients after cataract surgery by means of Optical Coherence Tomography (OCT).

Materials & Methods: A total of 30 eyes of 30 patients (15 diabetic and 15 non-diabetic) aged between 50 and 80 years diagnosed to have cataract were enrolled. Patients were investigated for absence of any evidence of macular edema with OCT before surgery. After undergoing cataract extraction by phacoemulsification with foldable IOL implant, OCT was again carried out at post-operative 1st week and 4th week to know the foveal thickness and total macular volume. Similarly distance visual acuity was recorded at post-operative 1st and 4th week on Snellen's visual acuity chart. The comparison was done between visual acuity and OCT readings obtained in non-diabetic and diabetic patients to know the incidence of cystoid macular edema (CME).

Results: There was no significant change found between foveal thickness measured pre-operatively and post-operatively at 1st and 4th week in diabetic and non-diabetic group but significant increase of total macular volume was found at post-operative 4 weeks when compared with baseline in non-diabetic \(p<0.001\) and diabetic group \(p=0.035\). There was a significant correlation found in foveal thickness and visual acuity in diabetic patients at 4th week of surgery.

Conclusions: This study has shown a low incidence of subclinical CME. OCT showed increased macular volume in both groups of patients in a small percentage of cases.

Introduction

Cystoid macular edema (CME) following uneventful phacoemulsification cataract surgery is recognized as the most common cause of decreased vision post-operatively. With intra capsular cataract surgery (ICCE), the rate of postoperative macular oedema was around 2–20%, whereas it decreased to 1–2% with the widespread use of extra capsular cataract extraction (ECCE) with intact posterior capsule. Modern cataract surgery with phacoemulsification, self-sealed corneal incision and implant of foldable intraocular lens (IOL) in the capsular sac seem to have reduced considerably the prevalence of angiographic as well as clinical CME.\(^1\)\(^2\) Although angiography with fluorescein is usually utilised to confirm the diagnosis of CME, it is a painful procedure, which can cause severe complications, and there is not always a co-relation between the degree of hyper-fluorescence and visual loss.\(^3\)\(^4\) The introduction of optical coherence tomography (OCT) which is non-invasive, comfortable method has enabled clinicians to reliably detect and measure small changes in macular thickness in case of clinical and sub-clinical pseudo-phakic CME and to quantitatively evaluate the efficacy of different therapeutic modalities. This may be important for establishing treatments to avoid the visual loss post-operatively.\(^5\)\(^6\)\(^7\)\(^8\)

Materials and Methodology

A total of 30 eyes of 30 subjects (15 diabetic and 15 non-diabetic) aged between 50 and 80 with a mean age of 63.62 ± 5.81 (for diabetic) and 65.08 ± 9.71 (for non diabetic) diagnosed to have cataract were enrolled in this prospective study. Permission was obtained from ethical committee of the institute. An informed consent was obtained from subjects willing to participate in the study. All subjects underwent baseline examination to rule out any abnormality in the eyes. Unaided, aided and pinhole visual acuity was recorded for distance with Snellen’s distant visual acuity chart at 6 meters. Refraction was performed objectively and subjectively with dilated and undilated state. Slit lamp evaluation was done to rule out any anterior segment abnormality and for grading of cataract. All the cases were senile cataract from grade II to III. IOP was measured by Goldman applanation tonometer. Detailed examination of the posterior segment was done with +90 D lens and indirect ophthalmoscope by using +20 D lens. All subjects were investigated for absence of any evidence of macular edema with the help of Optical Coherence Tomography (Stratus OCT [OCT3]; Carl Zeiss Meditec, Dublin, Calif) before cataract surgery. The foveal thickness and total macular volume were measured on the preoperative day. Phaco-emulsification cataract surgeries were performed under peribulbar anesthesia using a standard technique. The mean effective phaco time was calculated. Postoperative 1st week and 4th week distance visual acuity was recorded carefully on Snellen’s visual acuity chart. Objective and subjective refraction was done in both dilated and undilated pupil. Slit lamp evaluation was again carried out.
out to rule out any anterior segment abnormality. Similarly OCT readings of foveal thickness and total macular volume were recorded one week and four weeks post operatively in diabetic and non-diabetic patients respectively. Visual acuity was converted to equivalent decimal value for simplification in statistical analysis. The comparison was done between the VA and OCT readings obtained in non-diabetic and diabetic patients to know the incidence of CME. The inclusion criteria were patients having past or no history of diabetes, those who were diagnosed to have diabetes mellitus at least 2 years prior to cataract surgery with controlled blood sugar level and single handed operatory system with phacoemulsification and same type of IOL and anaesthesia. Exclusion criteria were patients having any signs or pathology associated with diabetes or any other systemic illness except diabetes, any other ocular abnormality and intraoperative complications. Selection Criteria for the study were: Clinical CME has historically been defined as a reduction in vision to 20/40 or less that is attributable to ophthalmoscopically or angiographically visible CME. Subclinical CME is an asymptomatic condition in which visual acuity is greater than or equal to 20/40 but seen small cystic spaces on OCT with increase in retinal thickness. Grading of cataract was decided according to the estimated impact on visual acuity and by using slit lamp biomicroscopy.8,9 The Feline Diabetes Message Board FAQ lists 60-120 mg/dL (3.3 - 6.7 mmol/L) as “normalized” when not receiving insulin, and 60-150 mg/dL (3.3-8.3) as “tightly regulated” when receiving insulin. Stratus OCT 3000 was used to measure both the foveal thickness and total macular volume. Each eye was dilated with Tropicamide 1% before recording the images and scans were performed with a minimum papillary diameter of 5 mm. The internal fixation target was used owing to its higher reproducibility. The examination was performed under mydriasis. Fast macular thickness protocol as well as Radial scan were used.

### Results

In this study, 30 eyes of 30 subjects (15 Diabetic and 15 Non-Diabetic) were examined for the evaluation of incidence of clinical and subclinical CME and following assessments were performed. Total 30 eyes were compared in this study. [Table 1] showed comparison of foveal thickness in diabetic and non-diabetic group. [Table 2] showed comparison of total macular volume (mm³) in diabetic and non-diabetic group. By using 2 independent sample t-test, p-value > 0.05 therefore there was no significant difference between diabetic and non-diabetic group of patients with respect to foveal thickness (measured in microns) and total macular volume. Diabetic [Table 3] and non diabetic [Table 4] group showed no significant difference between foveal thickness compared from baseline to that of post operatively 1st week and 4th week but when comparison was made between pre operative and post operative macular volume in diabetic and non-diabetic group, it was found to be not significant at 1st week and significant at 4th week in diabetic patients [Table 5] than non-diabetic patients. [Table 6]. Statistical analysis of foveal thickness and visual acuity showed no significant correlation in a group of non-diabetic patients at post operative

#### Table 1: Comparison of foveal thickness in diabetic and non-diabetic group.

| Foveal thickness at | Group   | p-value |
|---------------------|---------|---------|
|                     | Diabetic (n=15) | Non-diabetic (n=15) |
| Pre operative       | 195.27 ± 21.22  | 204.40 ± 21.81  | 0.255 |
| At 1st week         | 205.47 ± 27.04  | 196.60 ± 22.64  | 0.339 |
| At 4th week         | 203.27 ± 19.01  | 220.13 ± 34.75  | 0.113 |

#### Table 2: Comparison of total macular volume (mm³) in diabetic and non-diabetic group.

| Total Macular volume at | Group   | p-value |
|-------------------------|---------|---------|
|                         | Diabetic (n=15) | Non-diabetic (n=15) |
| Pre operative           | 6.39 ± 0.45   | 6.63 ± 0.40   | 0.124 |
| At 1st week             | 6.59 ± 0.50   | 6.67 ± 0.65   | 0.709 |
| At 4th week             | 6.69 ± 0.42   | 6.92 ± 0.62   | 0.234 |

#### Table 3: Comparison of foveal thickness at pre operative and 1st week and 4th week in diabetic patients.

| Foveal thickness at | Number of patients | Foveal thickness (mean ± SD) | p-value |
|---------------------|--------------------|------------------------------|---------|
| Pre operative       | 15                 | 195.27 ± 21.22               |         |
| At 1st week         | 15                 | 205.47 ± 27.04               | 0.295   |
| At 4th week         | 15                 | 203.27 ± 19.01               | 0.236   |
1st week [Correlation coefficient ($r$) = 0.270, p-value = 0.330] and at 4th week [Correlation coefficient ($r$) = 0.287, p-value = 0.330]. Similarly no co-relation was observed between total macular volume and visual acuity at postoperative 1st [Correlation coefficient ($r$) = -0.083, p-value = 0.769] & 4th week [Correlation coefficient ($r$) = 0.035, p-value = 0.900] in group of non diabetics. In case of diabetic group statistical analysis of foveal thickness and visual acuity showed no co-relation at post operative 1st week [Correlation coefficient ($r$) = -0.201, p-value = 0.401] but at postoperative 4th week [Correlation coefficient ($r$) = -0.604, p-value = 0.017] the change in foveal thickness caused change in visual acuity in diabetic patients. Total macular volume and visual acuity showed no significant relation in diabetic group of patients at post operative 1st week [Correlation coefficient ($r$) = -0.158, p-value = 0.574] and 4th week [Correlation coefficient ($r$) = -0.169, p-value = 0.547]. The occurrence of subclinical CME in diabetic and non diabetic group [Table 7] was found to be significantly less following phaco-emulsification cataract surgery as shown in the Image 1, 2, 3 and 4.

### Discussion

In recent years, we have seen great progress in cataract surgery, both in the surgical technique as well as with modern phacoemulsifiers, in addition to the design and construction of intraocular lenses which have allowed faster and cleaner surgery with much lower complication rates in comparison to intracapsular and even extra capsular techniques. Accordingly, pseudo-phakic CME, formerly a frequent complication, seems more uncommon at present although potentially serious in chronic cases. Referring only to clinical CME, the prevalence is of 2%-10% in intracapsular and of 1.2%-2% in extra capsular operations. In 1999, a publication showing data collected in 4 hospitals of four countries by the International Cataract Surgery Outcomes

### Table 4: Comparison of foveal thickness at pre operative and 1st week and 4th week in non-diabetic patients.

| Foveal thickness at | Number of patients | Foveal thickness (mean ± SD) | p-value |
|---------------------|--------------------|-----------------------------|---------|
| Baseline            | 15                 | 204.40 ± 21.81              |         |
| 1st week            | 15                 | 196.60 ± 22.64              | 0.252   |
| 4th week            | 15                 | 220.13 ± 34.75              | 0.104   |

### Table 5: Comparison of total macular volume (mm$^3$) at pre operative and 1st week and 4th week in diabetic patients.

| Total macular volume at | Number of patients | Total macular volume (mean ± SD) | p-value |
|-------------------------|--------------------|----------------------------------|---------|
| Baseline                | 15                 | 6.39 ± 0.45                     |         |
| 1st week                | 15                 | 6.59 ± 0.50                     | 0.106   |
| 4th week                | 15                 | 6.69 ± 0.42                     | < 0.001 |

### Table 6: Comparison of total macular volume (mm$^3$) at pre operative and 1st week and 4th week in non-diabetic patients.

| Total macular volume at | Number of patients | Total macular volume (mean ± SD) | p-value |
|-------------------------|--------------------|----------------------------------|---------|
| Baseline                | 15                 | 6.63 ± 0.40                      |         |
| 1st week                | 15                 | 6.67 ± 0.65                      | 0.795   |
| 4th week                | 15                 | 6.92 ± 0.62                      | 0.035   |

### Table 7: Comparison of total macular volume (mm$^3$) at pre operative and 1st week and 4th week in diabetic patients.

| Total macular volume at | Number of patients | Total macular volume (mean ± SD) | p-value |
|-------------------------|--------------------|----------------------------------|---------|
| Baseline                | 15                 | 6.63 ± 0.40                      |         |
| 1st week                | 15                 | 6.67 ± 0.65                      | 0.795   |
| 4th week                | 15                 | 6.92 ± 0.62                      | 0.035   |
Table 7: Incidence of subclinical CME in diabetic and non-diabetic patients.

| Group   | Total Macular Volume at 1st week | Total Macular Volume at 4th week | Subclinical CME | No CME | Total | p-value |
|---------|----------------------------------|----------------------------------|-----------------|--------|-------|---------|
| Diabetic | 6.70 mm³                         | 7.60 mm³                         | 1               | 14     | 15    | 1.000   |
| Non-diabetic | 7.5 mm³                        | 8.27 mm³                         | 1               | 14     | 15    | 1.000   |

Study, showed a prevalence of CME as a complication of cataract surgery with phacoemulsification of 0.3% in the United States, of 1.4% in Canada, of 0.0% in Denmark and of 0.6% in Spain. The mean prevalence of CME in this research is 0.4%. In this study, for the non diabetic group of patients with 15 eyes, we did not find any clinical CME case but we found one case of subclinical CME in 1st and 4th week of follow up. An increase of total macular volume (mean ± SD, 6.92 ± 0.62) was found at postoperative 4th week when compared with baseline (mean ± SD, 6.63 ± 0.40). However, in the group of diabetic patients with 15 eyes, we did not find any clinical CME case but we found one case of subclinical CME in 1st and 4th week of follow up. An increase of total macular volume (mean ± SD, 6.69 ± 0.42) was found at postoperative 4th week when compared with baseline. (mean ± SD, 6.39 ± 0.45). No significant change was found between foveal thickness compared pre-operatively and post-operatively 1st week and 4th week in diabetic and non-diabetic group. In uncomplicated phacoemulsification cataract surgery, total macular volume increased after 4th week of surgery compared to 1st week in both diabetic and non diabetic group and foveal thickness showed significant correlation with visual acuity in diabetic patients. The sensitive measurement possible with OCT suggests that the incidence of CME after routine cataract surgery is greater than previously thought. Lobo and colleagues measured retinal leakage with scanning laser ophthalmoscopy (CSLO, Carl Zeiss Meditec, Jena, Germany) and OCT (Humphrey Instruments) in 32 eyes at 3, 6, 12, and 30 weeks after uneventful cataract surgery. Almost all eyes (97%) showed evidence of retinal thickening compared with controls at some point during follow up. Increase in retinal thickness reached a peak at 6 weeks postoperative, when 41% of eyes showed increased retinal thickness, even with visual acuities better than 20/25. During the first 12 weeks, macular leakage was seen in 88% of eyes; this percentage decreased to 68% at 30 weeks, suggesting a trend toward recovery. At 30 weeks, visual acuity was good in all eyes, but retinal thickening was still seen in 22% of eyes. The result of ophthalmoscopy, fluorescein angiography, and ultrasound examination is supplemented by the possibility of the anatomic examination of the retina, which may facilitate diagnosis and therapy. FFA is also an invasive test, with side effects ranging from nausea (up to 20%) to its rarest complication, anaphylaxis and death. Therefore it is important to have alternative non invasive methods such as OCT. OCT is a quantitative measurement and enables the detection of minimal changes in retinal thickness and volume even after uncomplicated cataract surgery. The changes in the parameters may allow us to quantitatively assess progression of disease and success of therapy and helpful in patients not achieving log MAR unit 0.
Conclusion
The occurrence of subclinical CME in diabetic and non-diabetic group was found to be significantly less following phaco-emulsification cataract surgery.

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