

Visual Outcomes after Phacoemulsification with Lens Implant in Diabetic vs Non-diabetic Patients: A Prospective Comparative Study

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ABSTRACT

Background and Objective- More than 285 million people are affected worldwide by diabetes mellitus. According to the International Diabetes Federation, number is expected to increase to 439 million by 2030. Here, the aim of this study was to assess visual outcome of cataract surgery using phacoemulsification with intra ocular lens implant in diabetic patients with cataract as compared to non-diabetic patients with cataract.

Methodology- A prospective study conducted on 232 patients between January 2018 to May 2018. 116 consecutive diabetic patients with cataract and 116 non-diabetic patients with cataract and undergoing phacoemulsification cataract surgery were enrolled in this study after taking informed consent. Statistical analysis was performed using JASP (Version 0.8.6) and Microsoft Excel 2013.

Result- The mean age was 63.04 ± 8.11 in non-diabetic group and 63.64 ± 6.27 in diabetic group. Non-diabetic group had 48.28% males (56 males) and 51.72% females (60 females), whereas the diabetic group had 49.14% males (57 males) and 50.86% females (59 females). The overall mean duration of diabetes was seen to be 8.3 ± 5.1 years. The diabetic patients were found to be significantly associated with hypertension ($P = <.001$) and IHD ($P = 0.04$). At postoperative 6 weeks mean BCVA was 0.07 ± 0.1 in Non-Diabetics and 0.11 ± 0.13 in diabetics while difference in BCVA was statistically significant ($p = 0.04$).

Conclusion- Visual outcome after phacoemulsification surgery with intra ocular lens implant was comparable in diabetic and non-diabetic group.

Keywords- Phacoemulsification, Lens implant, Visual outcomes, Diabetics, Non-diabetics, diabetic retinopathy (DR).

INTRODUCTION

More than 285 million people are affected worldwide by diabetes mellitus. According to the International Diabetes Federation, number is expected to increase to 439 million by 2030. [1] Patients with diabetes mellitus (DM) have a higher prevalence of lens opacities and develop cataract at an earlier age than nondiabetics. [2]

Cataract is considered as a major cause of visual impairment in diabetic patients. Cataract in diabetic patients decreases the visual acuity, makes it difficult or nearly impossible to perform an adequate examination of the retina and to provide photocoagulation treatment. Therefore, it is important to perform cataract surgery for visual rehabilitation, and for diagnostic and therapeutic reasons in diabetic patients with cataract. The association between diabetes and cataract formation has been shown in clinical, epidemiological, and basic research studies. The incidence of diabetic cataracts has been rising steadily. (1,3,4) Fully describing the pathomechanisms that may help delay or prevent the development of cataract in diabetic patients remains a challenge. Although newer techniques have made cataract surgery safe and predictable, certain intrinsic problems in diabetes lead to poorer

visual outcomes in diabetics compared to non-diabetics.

Diabetics are vulnerable to intra- and post-operative complications, retinopathy (DR) progresses more rapidly in diabetic patients after cataract surgery; a ruptured capsule [5] can be a factor in rubeosis. Both diabetes and cataract pose an enormous health and economic burden, particularly in developing countries, where diabetes treatment is insufficient and cataract surgery often inaccessible. [1] Many previous studies have shown that either DR or level of DR severity, predicts worse postoperative visual outcomes in patients with diabetes. (6-11)

With the advent of modern phacoemulsification cataract surgery, the overall postoperative visual outcome has been found to have improved for the large majority of cataract surgical patients. (6,8,9,12,13) It remains unclear, however, whether patients with diabetes or with diabetic retinopathy achieve less visual acuity (VA) gain after phacoemulsification cataract surgery than patients without diabetes, and if so, how much less VA gain can be expected. [11]

This study aims to assess visual outcome of cataract surgery by an experienced and well-trained surgeon using phacoemulsification with intra ocular lens implant in diabetic patients with cataract as compared to non-diabetic patients with cataract. To the best of our knowledge, such comparison has not been done in a population sample from Central India.

METHODOLOGY

This is a hospital based, prospective, observational study about visual outcome in patients with or without diabetes having cataract and undergoing cataract by phacoemulsification surgery at Mahatma Eye Bank and Eye Hospital from January 2018 to May 2018. Patients were examined in the outpatient department and diagnosed having cataract in one eye. Approval of the study was taken from Institutional Ethics Committee. Patients undergoing cataract surgery were divided into two groups, first

group consisted of 116 patients with diabetes (116 eyes) and the second group consisted of 116 persons without diabetes (116 eyes) was enrolled after taking informed consent.

Inclusion criteria for Group A were diabetic patients with cataract was known diabetics with confirmed diagnosis of type 1 or type 2 diabetes mellitus, treatment with oral anti diabetic drugs or insulin were included as “diabetic”. While in Group B Non-diabetic patients with cataract was known normal person with random sugar \leq 140 mg/dl considered as non-diabetic.

Exclusion criteria were Small Pupil, Pseudo exfoliation Syndrome, Uveitis, Retinal artery/ vein occlusion, Glaucoma, Macular degeneration, Vision limiting Diabetic maculopathy, Intra or postoperative complications like vitreous loss or posterior capsule rupture and patients whose diabetes is controlled by diet only.

All the diabetic patients in our study turned out to be non-insulin dependent diabetic mellitus (NIDDM) i.e. type 2 DM, who were controlled with oral anti diabetic drugs. Detailed history regarding any pre-existing ocular inflammations and all the aforesaid ocular and systemic conditions in the inclusion and exclusion criteria was taken. Measurement of best corrected visual acuity (BCVA) for distance and near using LogMAR chart was done.

Visual acuity with Snellen chart at 6 meters (6/6), at 20 feet (20/20), 1.0 vision in decimal charts and 0.0 log MAR are considered equivalent. Visual acuity was grouped into three categories as normal vision (Log MAR 0.1 to 0.5); moderate vision (0.6 to 1.0) and poor vision (\geq 1.1) as recommended by International Council of Ophthalmology (ICO) Sydney, Australia, April 20, 2002. [3]

Dilated Fundus examination was done using +90D and +20D and results recorded on given Performa. Based on fundus findings, the number of patients with NO DR and MILD NPDR were merged into the group, and those with moderate NPDR, severe NPDR and laserd PDR were merged

into one group for further analysis, and we thus subdivided the diabetic group into two groups, i.e. Diabetics with NO or MILD DR and Diabetics with Advanced DR (moderate, severe and lasered PDR).

A grader assessed DR according to ETDRS (Early Treatment Diabetic Retinopathy study) criteria, [4] with adjudication provided by a retinal specialist. Only one eye of each patient was scheduled for cataract surgery. One experienced surgeon performed all procedures according to a standardised protocol. All surgeries were performed under Zeiss operating microscope. Phacoemulsification surgeries were performed with Appasamy Associates Galaxy pro Phaco machine.

All the patients were followed with a schedule of first postoperative day, one week and six weeks post operatively. On each post-operative visit, BCVA was checked on Log Mar and recorded. A complete ophthalmic examination, including slit lamp evaluation, fundus evaluation, and refraction, were performed at the final visit.

Statistical analysis was performed using JASP (Version 0.8.6) and Microsoft Excel 2013. Visual acuity was calculated using Logarithm of the Minimum Angle of Resolution (LogMAR) (converted from Snellen's equivalent) for statistical evaluation. Descriptive data are presented as percentages, means, and standard deviation. Data were checked for the assumption of normality using Shapiro Wilk test. Non-parametric tests such as Wilcoxon signed rank test were used to evaluate differences in variables between groups using null hypothesis testing. For comparison between more than 2 groups, analysis of variance was performed followed by pairwise comparisons. Contingency tables and Chi square test was used to test association between nominal variables. P values were considered statistically significant at <0.05 level.

RESULT

There were 232 patients in this study, 116 patients in each group; group 1

(diabetics) and group 2 (non-diabetics). The mean age was 63.04 ± 8.11 in non-diabetic group and 63.64 ± 6.27 in diabetic group. Non-diabetic group had 48.28% males (56 males) and 51.72% females (60 females), whereas the diabetic group had 49.14% males (57 males) and 50.86% females (59 females). Diabetic patients with no diabetic retinopathy had mean duration of 4.8 ± 2.96 years. Those diabetic patients with MILD NPDR had mean duration of 8 ± 2.35 years. The diabetic patients with moderate NPDR had mean duration of 13.4 ± 3.29 years and with severe NPDR had mean duration of 18.5 ± 0.71 years. Those with lasered PDR had mean duration of 19.0 ± 3.74 years. The overall mean duration in diabetic patients was 8.3 ± 5.1 years.

All patients taken in this study were senile immature cataracts out of which maximum were in the category of Nuclear sclerosis grade 2 with total 149 patients out of 232, (53% in diabetics and 47% in non-diabetics) i.e. 110 (44%), followed by Nuclear sclerosis grade 3 with total of 82 patients out of 232 (43.9% in diabetics and 56.1% in non-diabetics). There were 83 diabetic patients out of total 116 patients, who had associated hypertension, whereas there were only 7 non-diabetic patients who had associated hypertension. This was statistically significant with $p < 0.001$ using Chi square test.

There were 4 diabetic patients out of total 116 patients, who had associated IHD. $p = 0.04$ which was statistically significant.

232 patients with 232 eyes, 116 eyes in-group A (Diabetics) and 116 eyes in group B (non-diabetics) were included in this study. Mean BCVA at base line in diabetics was 0.90 ± 0.39 (6/60 Snellen's) and in the non-diabetic group was 0.94 ± 0.44 (6/48 Snellen's). The difference in best-corrected visual acuity (BCVA) between diabetics and non-diabetics was not statistically significant preoperatively ($P = 0.58$) and at postoperative day 1 ($P = 0.55$, Mann-

Whitney U Test). At postoperative 6 weeks mean BCVA was 0.07 ± 0.1 in Non-Diabetics, and 0.11 ± 0.13 in diabetics, and the difference in BCVA was statistically significant ($p = 0.04$). However, this difference was clinically not significant as it corresponds to visual acuity of 6/6 in non-diabetics vs 6/7.5 in diabetics as per the Snellen's scale.

Visual acuity is grouped into three categories as normal vision (Log MAR 0.1 to 0.5), moderate vision (0.6 to 1.0) and poor vision (≥ 1.1) as recommended by International Council of Ophthalmology (ICO) Sydney, Australia, April 20,2002 (5). Normal vision (Log Mar 0 to 0.5; $\geq 6/18$), was achieved by 93.1% diabetics, moderate vision (LogMAR 0.6 1 log Mar,) by 6.9% on the first postoperative day. By end of first week all, the diabetic achieved normal vision. Whereas 95.7% non- diabetics achieved normal vision on the first post-operative day and 4.3% achieved moderate vision. Diabetics as well non-diabetics maintained normal vision by the end of the study (six weeks post-operative).

In Non-diabetics, the mean baseline BCVA was 0.94 ± 0.44 LogMAR which improved

to 0.07 ± 0.1 LogMAR, $p = <0.001$ which was statistically insignificant, using Wilcoxon-Signed rank test. In Diabetic group, the mean baseline BCVA 0.90 ± 0.39 was LogMAR which improved to 0.11 ± 0.13 LogMAR at the end of the study which was also statistically insignificant, $p = <0.001$, using Wilcoxon-Signed rank test.

Diabetic patients with No DR (n=51) had mean pre -op BCVA 0.91 ± 0.4 LogMAR, which improved to 0.11 ± 0.1 LogMAR, post-op 6 weeks. In diabetic patients with Mild NPDR (n=35), the mean pre-op BCVA was 0.87 ± 0.4 LogMAR, which improved to 0.08 ± 0.1 LogMAR, post-op 6 weeks. The diabetic patients with Moderate NPDR (n=23), had mean pre-op BCVA of 0.89 ± 0.4 LogMAR, which improved to 0.13 ± 0.2 LogMAR, after post-op 6 weeks. In diabetic patients with Severe NPDR (n=2), the mean pre-op BCVA was 1.50 ± 0.7 LogMAR, which improved to 0.30 ± 0.0 LogMAR, after 6 weeks post-op. Diabetic patients with PDR who had been lasered pre-operatively for the same (n=5), had mean pre-op BCVA 0.94 ± 0.1 LogMAR, which improved to 0.25 ± 0.3 LogMAR, 6 weeks post- operatively.

Table 1: Best corrected visual acuity (VA) in diabetic patients with different stages of diabetic retinopathy (DR) and controls, before and after surgery. All values of VA are given as median (range).

	Non-Diabetic	Diabetic but No or Mild DR	Moderate to Severe DR	P-value*
Preoperative BCVA	0.94 ± 0.44	0.89 ± 0.39	0.94 ± 0.4	0.58
Postoperative Week 6 BCVA	0.07 ± 0.1	0.1 ± 0.12	0.16 ± 0.17	0.03
P-value within groups [^]	<.001	<.001	<.001	

[^] Wilcoxon-Signed rank test.

* One-way ANOVA, Kruskal Wallis test.

DISCUSSION

We observed that visual acuity goes on improving with time. Both the study groups were comparable in terms of BCVA 6 weeks post-operative.

At day 1 post operatively 108 (93.1%) patients in the diabetic group had visual acuity better than 6/18 while 111 (95.7%) patients in non-diabetic group had visual acuity of 6/18 or better, which was statistically similar.

Whereas, as mentioned above the vision improved significantly in diabetics and non-diabetics, the visual acuity

improvement at 6 weeks was statistically significant, but was not significant clinically. The difference was statistically significant by One-way ANOVA and Kruskal Wallis test (non parametric) with $p = 0.03$.

These findings are in agreement with the study conducted by Ostri et al, [15] Krepler et al, [16] Calvin Sze-un Fong et al, [11] Straatsma BR et al, [17] Mittra et al, [10] Shaikh et al, [5] Zaczek et al, [9] Dowler et al, [8] Henricsson et al. [7]

Ostri et al, [15] showed that the CDVA increased significantly after phaco-

emulsification cataract surgery in diabetic patients regardless of the degree of diabetic retinopathy. The apparent progression in diabetic retinopathy after modern cataract surgery seems to reflect the masking of low grades of diabetic retinopathy by preoperative lens opacities. Our study showed consistent results with this study. This study was limited by its retrospective design. There was no documentation of the preoperative degree of cataract and no available intraoperative data, and were not able to adjust for these factors in the analysis. On the contrast, our study was prospective and had all preoperative documentation.

In addition, the prospective nature of our study and its adjustment for age, gender and diabetes duration provide a more realistic estimate for postoperative VA in eyes with diabetic damage

Krepler et al ^[16] study showed that improved vision can be expected in a majority of patients with cataract and mild-to-moderate diabetic retinopathy after phacoemulsification and posterior chamber intraocular lens implantation. Our study was consistent with these results, but we also found significant improvement in visual outcome after cataract surgery in diabetic patients with PDR but without CSME.

Calvin Sze-un Fong et al ^[11] reported improvement of VA by an average two lines for patients both with and without diabetes, or with DR but no past laser treatment. No improvement was evident for patients who had preoperative DR and laser therapy. Our study in contrast to this showed that the results were comparable between diabetics and non-diabetics, irrespective of degree of retinopathy.

Straatsma BR ^[17] found no statistically significant difference in operative or postoperative complications in diabetics, with and without non-proliferative retinopathy and non-diabetics in extra capsular cataract extraction with posterior chamber intraocular lens.

Mitra et al ^[10] considers preoperative retinopathy and surgical inexperience an

important factor in postoperative progression of retinopathy and result irrespective of the techniques used.

These studies show that if diabetic eye does not have retinopathy, controlled diabetes and surgery is done by an experienced surgeon, the postoperative results are comparable to non-diabetic.

In our study, we evaluated patients visual acuity potential pre and post operatively with super pin hole test and most of the patients from both the groups improved to N6, 6 weeks post operatively. Somaiya et al ^[18] showed that visual potential testing is a useful method of estimating postoperative BCVA in diabetic patients being evaluated for cataract surgery. Our results were consistent with the study as we used super pinhole test for estimating pre and post-operative visual acuity potential in our study. These tests are often used in the preoperative evaluation of patients having cataract extraction as they provide some objective data for predicting possible postoperative visual outcomes. In this study, we quantified the amount of improvement by comparing the postoperative BCVA to the preoperative visual potential measured by the Super Pin-hole test.

Mozafferiah et al ^[19] study shows that even with a significant percentage of eyes displaying preoperative retinopathy of some type (74.6%), VA in the operated eye improved in a large proportion of diabetes patients (94.1%). The study also showed that, variables such as the patient's sex, age, duration of diagnosed diabetes, mean preoperative HbA1c (%) and insulin or antihypertensive treatment do not influence the patient's visual function greatly; however, the extent of the preoperative retinopathy is one of the more important factors influencing the patient's visual and functional outcome. This results were consistent with our study.

Our findings are similar to previous findings by Mozafferiah et al ^[19] and Somaiya et al, ^[18] who argued that one of the most important predictors of visual outcome in

diabetes patients is the extent of preoperative retinopathy. Their results of outcomes of surgery are based on the patient's VA.

In a retrospective study, Schatz et al [20] found that diabetic eyes that have cataract surgery have a poorer visual prognosis and more severe diabetic retinopathy than the fellow eye or a control group of diabetic patients without cataract. No patient in their study had a final visual acuity of better than 20/30, and 50% had an acuity of 20/100 or worse. However, there was no mention of the operative technique used or whether there were complications

In a study by Jaffe and Burton, [21] 8 patients had progression of NPDR after ECCE. Clinically significant macular edema (CSME) developed in all 8 patients and the final visual acuity in 6 was worse than preoperatively. No patient achieved an acuity better than 20/50.

Previous studies (7-10,22) report significant improvement in visual acuity after phacoemulsification cataract surgery in diabetic patients with all levels of diabetic retinopathy, which is consistent with findings of our study.

Several retrospective series found that diabetic eyes had a significant improvement in visual acuity postoperatively at all levels of preoperative retinopathy. (21,10) Therefore, diabetic patients should not be excluded from consideration for cataract surgery.

Sadiq et al [22] conclude that diabetic patients have a good chance of visual improvement, but to a level less than if they were not diabetic.

Dowler et al [8] found that postoperative visual acuity improved more after phacoemulsification than after ECCE, especially in eyes with retinopathy. They postulate that this finding may be a result of the lower postoperative inflammation after small-incision phacoemulsification. In our study, we evaluated the success of small-incision phacoemulsification in

diabetic and control patients as measured by postoperative BCVA.

We found that small-incision phacoemulsification led to improved BCVA in both groups.

Previous reports indicate that poor cataract surgery visual outcomes are related to the preoperative retinal status, particularly when PDR and CSME are present. (6,8-10) Our study findings show VA improvement in eyes that had undergone preoperative laser treatment (probably because of PDR but not CSME), than other eyes that had not had prior laser treatment. Despite the differences in VA in both study groups after cataract surgery, both groups, on average, had comparable VA improvement after the surgery. In our study, we found that even diabetic patients with proliferative retinopathy who had been lasered preoperatively had mean BCVA 0.94 ± 0.1 LogMAR, which increase to mean BCVA 0.25 ± 0.3 LogMAR, 6 weeks post-operative which was significant.

Surgical technique contributes to the incidence of postoperative complications in the anterior and the posterior segment of the eye.

The breakdown of blood-aqueous barrier (BAB) by surgical trauma produces postoperative inflammation [4] with a pigment dispersion, a fibrinoid reaction, and development of posterior synechiae. The advantage of phacoemulsification is that this technique with a small incision reduces the postoperative breakdown of BAB. [5] Therefore, significantly less fibrinoid reaction is found in the anterior chamber of diabetic eye during first postoperative week after phacoemulsification, compared with ECCE. [11]

The surgical procedure also may contribute to the progression of diabetic retinopathy, [23] and deterioration of pre-existing diabetic maculopathy. [24] CMO occurs more frequently in eyes with diabetes than in non-diabetics, [25] and more often in eyes with retinopathy than without retinopathy. Our study contributes to this, we found CMO in only 3 patients of 116 of

all diabetic patients. In addition, CMO was not recorded in eyes with no DR. The possible explanation for these results is that a phacoemulsification technique with a small incision was used. In addition, an IOL was implanted in the capsular bag, and these lenses may reduce postoperative inflammation.

CONCLUSION

We conclude that the final visual outcome after phacoemulsification surgery with intra ocular lens implant was comparable in diabetic and non-diabetic group.

In this era of modern cataract surgery, phacoemulsification is safe and efficacious procedure for diabetic cataracts, with excellent visual outcomes. As per our study 99.1% of patients achieved a visual acuity of 6/18 or better at 6 weeks postoperative follow up in both the diabetic as well as non-diabetic groups and the final visual outcome of phacoemulsification cataract surgery in diabetic and non-diabetic patients are comparable.

Conflict of Interest- No

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