Original Article

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Efficacy and Safety of Intra-operative Posterior Sub-Tenon's Triamcinolone Injection in Cataract Surgery Associated with Diabetic Retinopathy

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Abstract

Background: Diabetes mellitus increases the probability of developing cataract. There is growing evidence that diabetic retinopathy (DR) progresses more rapidly after cataract surgery.

Purpose: To study the effect of single posterior sub-Tenon's triamcinolone acetonide on occurrence and progression of macular edema and visual outcome following cataract surgery in diabetic patients.

Materials and Methods: This is a prospective interventional comparative study conducted on 36 eyes of 26 patients with DR and cataract. Patients were randomly assigned to Group I, triamcinolone acetonide (TA) (triamcinolone group) receiving a single posterior sub-Tenon's TA injection 1 ml (40 mg), at the end of small incision cataract surgery and Group II (control group) who underwent only cataract surgery. Best corrected visual acuity (BCVA) and intra-ocular pressure (IOP) were recorded at baseline and at each follow-up. Fundus fluorescein angiography and optical coherence tomography were done at baseline and 3 months postoperatively.

Results: The macular thickness in the control group increased by 71 microns (30.45%) at 3 months post-operatively and was statistically significant (P = 0.006). However, there was no statistically significant difference in the foveal thickness between the groups either at baseline (P = 0.07) or at 3 months (P = 0.63). At 6 months, there was no significant difference in the mean change in foveal thickness between the 2 Groups. There were no statistically significant differences between the groups in BCVA at 1 month (P = 0.38) and 6 months (P = 0.66) post-operatively.

Conclusions: The results of our study suggest that a sub-Tenon's injection of triamcinolone reduced the incidence of cystoid macular edema after cataract surgery in diabetic patients. In addition, it reduced the central macular thickness and improved visual acuity in the short term However, sub-Tenon's injection of TA did not affect DR progression or visual acuity at 6 months post-operatively which was determined by the pre-operative metabolic status.

Key words: Cataract, Macular edema, Macular thickness, Sub-Tenon's triamcinolone, Visual acuity

INTRODUCTION

The probability of developing early cataract is more in patients with diabetes mellitus.[1] This also increases the risk of reduced visual outcome.[2] Cataract and diabetic retinopathy (DR) are the leading causes of blindness.[1] DR is the progressive dysfunction of the retinal vasculature due to chronic hyperglycemia. Macular edema is an important cause of poor post-operative visual gain following cataract surgery. Patients with DR are more prone to develop post-operative macular edema following cataract surgery than normal subjects. This is because cataract surgery facilitates inflammation and breakdown of blood-retinal barrier, especially in patients with DR with dysfunctional retinal vasculature.[3]

Poor visual outcome of cataract surgery in diabetic patients is linked to severity of retinopathy and maculopathy existing prior to cataract surgery.[4-6] DR progression after

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cataract surgery is known to be influenced by the severity of pre-operative DR, duration of diabetes, and the adequacy of glycemic control.

Diabetic macular edema (DME) is defined as retinal thickening from the accumulation of fluid within one disc diameter of the center of the macula. DME can be classified as focal, diffuse, ischemic, and mixed types. Macular edema can be treated with macular photocoagulation, intra-vitreal/peribulbar steroids or anti-vascular endothelial growth factor (VEGF) agents.[7-9] Based on the observations of early treatment DR group (ETDRS), focal or grid laser photocoagulation is the gold standard treatment for DME.[3] However in the ETDRS, only 17% of the eyes had an improvement in visual acuity and <3% had a visual improvement of three or more ETDRS lines following laser. Moreover, a significant number of patients with DME, especially the DME of the diffuse type, remain refractory to focal or grid laser treatments. Among alternative treatments, pharmacotherapeutic agents such as triamcinolone acetonide (TA), a long-acting synthetic corticosteroid, when given by the intravitreal route or posterior sub-Tenon's route has been reported to be efficacious.[9-12]

The effect of cataract surgery on the progression of DR remains an issue of debate. Krepler *et al.*,[13] in a prospective study on 42 eyes showed that cataract surgery seems to have no influence on the progression of DR. A visual improvement is achieved in the majority of patients with non-proliferative DR (NPDR), but poorer visual outcome is observed in patients developing macular edema. Mittra *et al.*[14] showed that NPDR and surgical inexperience resulted in an increased rate of retinopathy progression.

Kato *et al.*[15] found that diabetic patients who did not have preoperative DR were more susceptible to postoperative DR progression after surgical intervention. Moreover, cataract surgery may facilitate inflammation and breakdown of the blood-retinal barrier, especially in patients with DR.

TA for ophthalmic use is available as a suspension. TA is a corticosteroid that in addition to its anti-inflammatory effects, causes down-regulation of VEGF.[16] Intravitreal triamcinolone may be associated with various complications such as glaucoma, cataract, endophthalmitis, retinal detachment, and scleritis.[17]

Peribulbar injection of corticosteroids appears a good alternative way of delivering the drug intravitreally. This route appears a less invasive approach than intravitreal injection and may deliver equivalent therapeutic concentrations to the retina.

Aim

To study the effect of single posterior sub-Tenon's triamcinolone acetonide on occurrence and progression of macular edema and visual outcome following cataract surgery in diabetic patients. The objectives are:

a. To compare the change in the central macular thickness (CMT) between the 2 Groups.
b. To compare the best corrected visual acuity (BCVA) scores between the 2 Groups.
c. To study steroid related complications.

MATERIALS AND METHODS

This is a prospective interventional comparative study conducted on 26 patients with DR and cataract who attended vitreo-retina outpatient development at Sarojini Devi Eye Hospital, from April 2012 to November 2013.

Inclusion Criteria

1. Diabetes with NPDR/mild PDR
2. Uneventful cataract surgery
3. In the bag placement of IOL.

Exclusion Criteria

1. DR with high-risk characters
2. Diabetes with other macular pathologies such as ARMD and macular holes
3. Patients with glaucoma
4. Intraoperative complications of cataract surgery such as posterior capsular rupture and iris damage.

Diagnosis, prognosis, various treatment options, and possible complications were explained to the patients and their informed consent was taken before enrolment. All the patients underwent a comprehensive ophthalmological examination.

BCVA and intraocular pressure (IOP) were recorded at baseline and at each follow-up. Fundus fluorescein angiography (FFA) and optical coherence tomography (OCT) were done at baseline and 3 months postoperatively. Patients were investigated for blood and urine sugars, glycosylated hemoglobin, Hb%, serum lipids, serum creatinine, and blood urea. Patients with deranged systemic parameters were referred to a general physician for the control before they were taken up for cataract surgery.

Patients were randomly assigned to Group I (TA group) receiving a single posterior sub-Tenon's TA injection 1 ml

(40 mg), at the end of small incision cataract surgery, Group II (control group) underwent only cataract surgery.

Postoperatively, patients were instructed to use topical antibiotic eye drops 4 times a day, steroid eye drop 6 times a day, and cycloplegics 2 times a day for 1-week. After 1-week, only steroid drops were used in tapering doses for 6 weeks, the minimum period of follow-up was 6 months. Patients were re-examined at 1-day, 1-week, 1-month, 3 months, and 6 months after the injection. The data thus collected were subjected to statistical analysis. The data were statistically evaluated using the Wilcoxon signed rank test, Mann–Whitney test, and t-tests wherever applicable. The analysis was performed using SPSS (Version 17) windows software ($P < 0.05$).

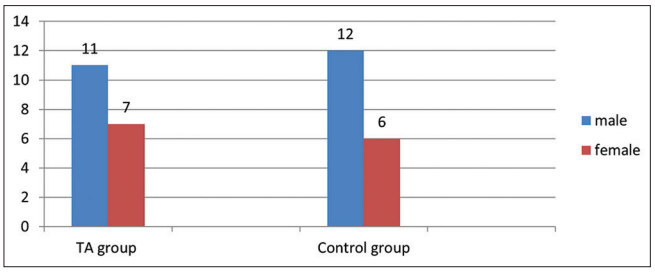
RESULTS

Patients with diabetes are more likely than patients without diabetes to develop macular edema after cataract surgery, the major vision-threatening form of DR in addition to PDR.

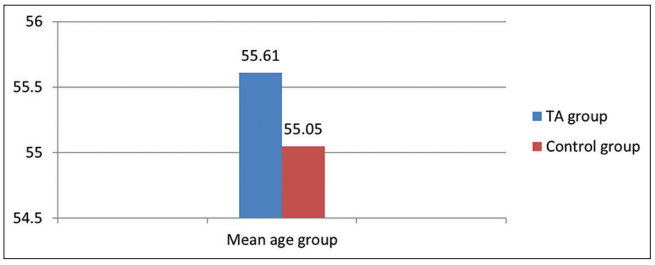
The mean patient age was 55.6 ± 6.2 (range 45-70) in TA group and 55.0 ± 6.5 in the control group. Eleven patients (61.1%) were men and seven patients (38.9%) were women in TA Group and 12 patients (66.7%) were men and 6 patients (33.3%) were women in control group (Graphs 1 and 2).

The mean ± SD value of the duration of diabetes was 11.61 ± 6.11 years in the TA group and 11.50 ± 6.08 years in the control group (Graph 3). The mean glycosylated Hb% was above 9 in both the groups (TA Group - 9.35%, control Group - 9.26%) (Graph 4). Patients with deranged systemic parameters were referred to a general physician for the control before they were taken up for cataract surgery.

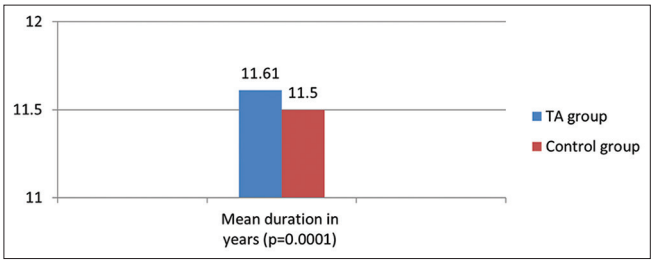
The mean preoperative CMT on OCT was 231.16 ± 40.86 µm in the control group and 288.83 ± 115.87 µm in the TA group ($P = 0.07$) (Graph 5). The mean CMT was 304.33 ± 115.38 µm and 281.50 ± 163.74 µm, respectively ($P = 0.63$), postoperatively, at the end of 3 months. The mean change in CMT at 3 months was statistically significantly greater in the control group ($P = 0.006$) in our study. The macular thickness in the control group increased by 71 microns (30.45%) at 3 months postoperatively and was statistically significant ($P = 0.006$). However, there was no statistically significant difference in the foveal thickness between the groups either at baseline ($P = 0.07$) or at 3 months ($P = 0.63$). At 6 months, there was no significant difference in the



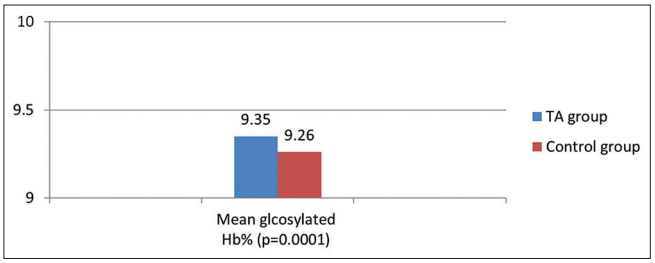
Graph 1: Demographic profile: Gender distribution



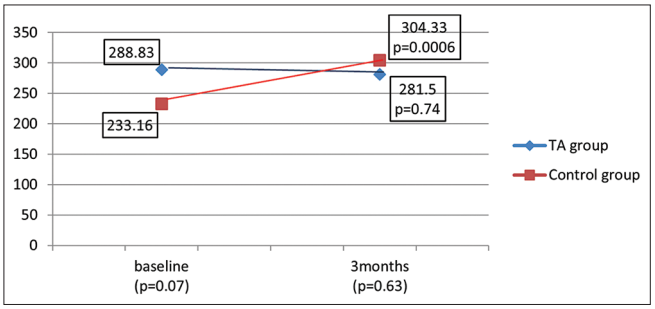
Graph 2: Age distribution



Graph 3: Duration of diabetes



Graph 4: Glycosylated Hb%



Graph 5: Macular thickness comparison

mean change in CMT between the 2 groups. In our study, four (22.2%) eyes in the control group showed CME on OCT and FFA and none in TA group. Patients with good metabolic control showed lesser CMT than the patients with poor metabolic control irrespective of the group, thus emphasizing the importance of good preoperative metabolic control on the occurrence of postoperative macular edema. A case with poor metabolic control is shown in Figure 1a-c with increased foveal thickness and diffused leakage on fluorescein angiography. Post cataract surgery with PST, there is no respite in foveal thickness and diffuse leakage on FFA, at 3 months (Figure 1d-f). Another case with good metabolic control (Figure 1a-c) shows stable fovea on OCT and no foveal leakage on FFA (Figure 1d-f).

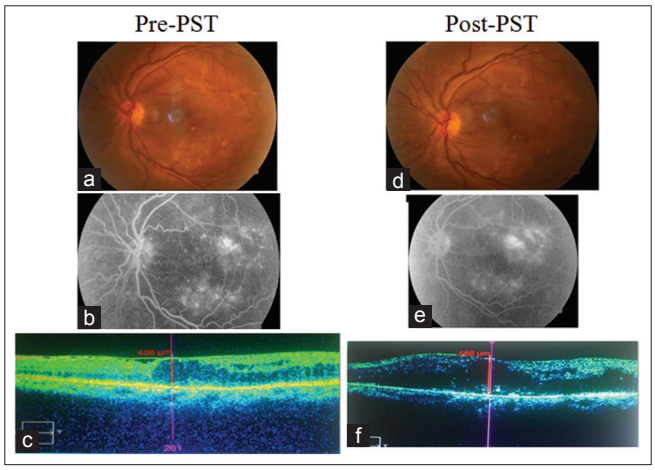


Figure 1: (a-c) Pre-triamcinolone injection with cataract surgery and (d-f) Post injection, show no respite in diffuse leakage on fundus fluorescein angiography and persisting increased foveal thickness on optical coherence tomography, after 3 months

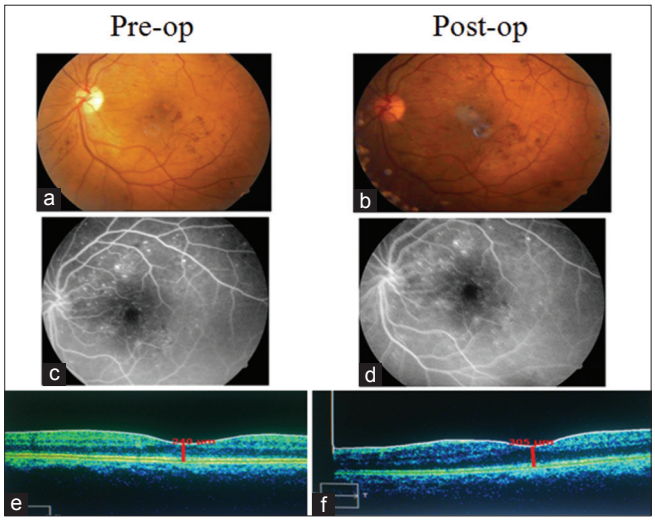


Figure 2: (a,c,e) Control group. Preoperative pictures of a case with good metabolic control, (b,d,f) 3 months post cataract surgery pictures with stable macula, no leakage on fundus fluorescein angiography, and no increase in foveal thickness on optical coherence tomography

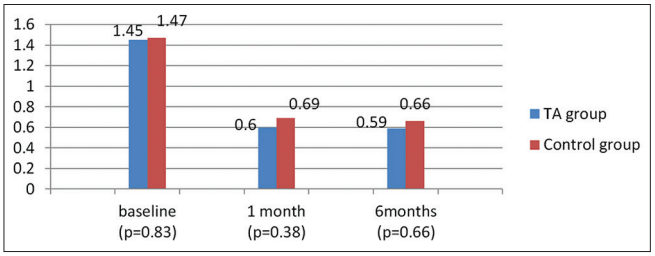
The mean change in BCVA at 1-month postoperatively was greater in TA than in control group. There were no statistical significant differences between the groups in BCVA at 1-month (P = 0.38) and 6 months (P = 0.66) postoperatively (Graph 6).

The IOP rise from baseline to 1-month postoperatively was greater in TA group than in control group but the rise was not statistically significant (P = 0.12) (Graph 7).

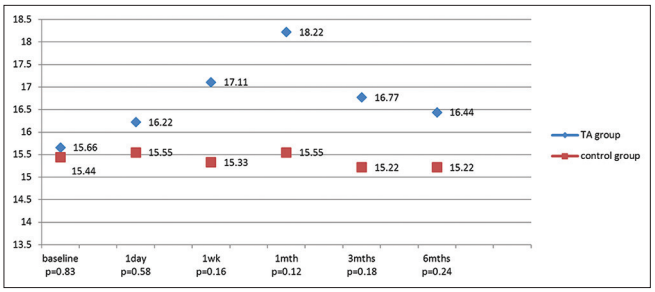
DISCUSSION

This study shows that the average CMT in the control group increased by 71 microns at 3 months and this was statistically significant, but there was no statistically significant difference between the 2 Groups. In a similar study by Kim *et al.*[18] reported in their study that the mean preoperative CMT on OCT was 204.93 ± 39.08 μm in the control group and 228.24 ± 43.34 μm in the triamcinolone group (P = 0.130). One month postoperatively, the mean CMT was 273.93 ± 91.00 μm and 238.76 ± 48.20 μm, respectively (P = 0.469). The mean change in CMT at 1-month was statistically significantly greater in the control group (P = 0.015), but the difference was not statistically significant at the end of 6 months.

In our study, we observed that mean change in visual acuity (log MAR) in TA group was 1.45 log MAR (P = 0.0001), 0.6 log MAR (P = 0.0001), and 0.59 log MAR (P = 0.0001)



Graph 6: Best corrected visual acuity (log MAR) comparison



Graph 7: Intraocular pressure rise comparison

at baseline, 1, and 6 months, respectively. While in the Control group it was 1.47 log MAR ($P = 0.0001$), 0.69 log MAR ($P = 0.0001$), and 0.64 log MAR ($P = 0.0001$) at baseline, 1, and 6 months, respectively. The mean change at 1-month postoperatively was greater in TA than in control group. There were no statistically significant differences between the groups in BCVA at 1-month ($P = 0.38$) and 6 months ($P = 0.66$) postoperatively. Kim *et al.*[18] reported that there were no statistically significant differences between the groups in BCVA at 1-month and 6 months postoperatively ($P > 0.05$). The mean change in the lines of BCVA (log MAR) from baseline to 1-month postoperatively was significantly greater in the TA group than in the control group ($P = 0.045$). However, mean change at 6 months was not statistically significant between the groups. In a study by Ahmadabadi *et al.*,[19] intravitreal injection of TA reduced the amount of central point thickness after phacoemulsification in eyes of diabetic patients. It also reduced the incidence of cystoid macular edema but it had no effect on visual acuity gain.

Potential side effects of injecting TA into the posterior sub-Tenon's capsule include IOP elevation, globe perforation (rare), occlusion of the central retinal artery, blepharoptosis, and infection. In our study, we did not encounter any complication in the TA group.

In our study, IOP rise from baseline to 1-month postoperatively was greater in TA group than in control group but the rise was not statistically significant ($P = 0.12$). IOP rise in between the groups was never statistically significant with $P = 0.12$, 0.18, 0.24 at 1, 3, and 6 months, respectively, in our study.

Chew *et al.* (DRCR Net)[20] reported that anterior peribulbar triamcinolone injections were associated with an increased risk of IOP elevation and cataract development compared to posterior sub-Tenon's triamcinolone injections.

The limitation of this study is that the number of patients was relatively small. Further study with a larger sample size will be necessary to elucidate our results.

CONCLUSION

The results of our study suggest that a sub-Tenon's injection of triamcinolone reduced the incidence of cystoid macular edema after cataract surgery in diabetic patients. In addition, it reduced the CMT and improved visual acuity in the short term. However, sub-Tenon's injection of TA did not affect DR progression or visual acuity at 6 months postoperatively which was determined by the preoperative metabolic status.

Rate of DR progression after cataract surgery is influenced by the severity of pre-operative DR, duration of diabetes, adequacy of glycemic control, and other associated systemic factors such as hypertension and hyperlipidemia.

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