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Original research

Role of combined phacoemulsification and intravitreal injection of Bevacizumab in prevention of postoperative macular edema in non-proliferative diabetic retinopathy

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Abstract

Purpose: To evaluate the role of combined phacoemulsification and intravitreal injection of Bevacizumab in prevention of postoperative diabetic macular edema (DME) in patients with no diabetic retinopathy or non-proliferative diabetic retinopathy (NPDR) and without macular edema.
Methods: In a prospective randomized clinical trial, 71 eyes from 71 diabetic patients with no diabetic retinopathy or mild NPDR and with central macular thickness (CMT) of less than 300 μm were enrolled and were randomized into two groups: combined phacoemulsification and intravitreal Bevacizumab injection group and only phacoemulsification group. Our primary outcome measures included best corrected visual acuity (BCVA), CMT, and total macular volume (TMV) before and after (1 month and 3 months) the cataract surgery.
Results: The two groups did not show any significant difference in terms of baseline BCVA, age, CMT, stage of diabetic retinopathy. While the Bevacizumab group showed lower CMT one month after the surgery compared to control group (267.3 ± 31.8 and 293.6 ± 53.7, respectively, $P = 0.019$), this difference did not remain significant 3 months after surgery (264.5 ± 21.9 and 291.4 ± 79.8, $P = 0.089$). The TMV and BCVA in the two groups showed no significant difference one month or 3 months after surgery. Considering our definition of post-cataract surgery diabetic macular edema (PME) in this study [CMT >300 μm using spectral domain optical coherence tomography (SD-OCT)], there was no significant difference between the incidence of PME at 1 month and at 3 months after surgery.
Conclusions: Although the intravitreal injection of Bevacizumab during phacoemulsification would result in decreased macular thickness in patients with no diabetic retinopathy or NPDR and without macular edema in the early postoperative period, this effect would no longer persistent at 3 months. In addition, the BCVA and TMV showed no significant difference between the two groups at any time during follow-up period.
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Keywords: Intravitreal Bevacizumab; Phacoemulsification; Postoperative macular edema

Introduction

Phacoemulsification is one of the most common surgical procedures which is being performed in diabetic patients through the world.[1] It has been shown that even an uncomplicated phacoemulsification may lead to macular edema in non-diabetic patients and those who are not predisposed to this complication.[2] In diabetic eyes, however, the increased level of vascular endothelial growth factor (VEGF) in aqueous humor has been observed at 1 day after surgery.[3] Considering the important role of angiogenic factors such as VEGF in progression of diabetic macular edema (DME), the advent of Anti-VEGF therapies in prophylaxis and treatment of post-cataract surgery diabetic macular edema (PME) has gained much interest.[4–6]

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Recently, numerous studies have investigated the role of Anti-VEGF therapies combined with phacoemulsification in progression of diabetic retinopathy.[4,7–9] However, all have included the patients with either preexisting DME or proliferative diabetic retinopathy (PDR) as well. There are only two studies available which have observed the role of Ranibizumab in prevention of PME in diabetic patients without DME.[10,11] Both have concluded that intravitreal Ranibizumab injection just after phacoemulsification would prevent PME in patients with diabetic retinopathy.

Bevacizumab is a full-length recombinant humanized monoclonal antibody that blocks all isoforms of VEGF and is routinely used as an off-label therapeutic modality in treating DME. Although several studies comparing the efficacy and safety of Bevacizumab and Ranibizumab in treating DME have not yielded robust evidence in terms of superiority of each option, it seems that Bevacizumab could be a rational option regarding its lower cost and more widespread availability compared to Ranibizumab.[12–14]

In the present study, we evaluated the efficacy of intravitreal injection of Bevacizumab immediately after the phacoemulsification in patients with stable non-proliferative diabetic retinopathy (NPDR) without a present or past history of DME.

Methods

Patients

In a prospective randomized clinical trial, we enrolled 71 eyes from 71 diabetic patients who were referred to Diabetic Retinopathy Clinic, Farabi Eye Hospital, Tehran University of Medical Sciences, Tehran, Iran, between May 2013 and February 2016. The patients had visually significant cataract which was not too severe to evaluate the posterior segment. At the first visit, all the patients were randomly assigned to one of the two groups by block randomization. While the patients in first group received intravitreal injection of Bevacizumab (1.25 mg) immediately at the end of phacoemulsification surgery, the patients in second group (the control group) received only phacoemulsification.

The inclusion criteria were as follows: 1) Patients with diabetes mellitus (DM) and visually significant cataract with best corrected visual acuity (BCVA) under 20/40, as determined by using the Snellen acuity chart; 2) No diabetic retinopathy or mild NPDR as defined by the Early Treatment Diabetic Retinopathy Study.

The exclusion criteria were as follows: 1) HbA1c >7.5; 2) Central macular thickness (CMT)>300 μm and/or any evidence of cystic spaces as determined by spectral domain optical coherence tomography (SD-OCT) (Spectralis SD-OCT; Heidelberg engineering; Germany); 3) Severe NPDR or PDR; 4) Complicated cataract surgery; 5) DM type 1; 6) Uncontrolled blood hypertension; 7) Previous retinal laser treatment or intraocular surgery.

Patient examination

At the screening visit, all patients underwent comprehensive anterior and posterior segment examination using slit-lamp and 90 D lens (Volk Optical, Inc, Mentor, OH), intraocular pressure determination using Goldmann applanation tonometry and SD-OCT. Grades of retinopathy were assessed according to the Wisconsin Epidemiology Study of Diabetic Retinopathy.[15] BCVA was converted to logarithm of the minimum angle of resolution (logMAR) visual acuity. After cataract surgery, postoperative complete ophthalmic examinations were performed at 1 day, 7 days, and 1 and 3 months later. SD-OCT was performed at one month and 3 months after surgery.

SD-OCT images were depicted using the 512 × 128 scan pattern with the center of the 6 × 6-mm scanning area positioned at the center of the fovea. CMT, namely the average retinal thickness in the central 1-mm subfield of the fovea, was measured. The total macular volume (TMV), namely the volume of the retina summed over all nine subfields of the Early Treatment Diabetic Retinopathy Study–type grid, was also calculated. In the present study, we used the Munk et al. methods to differentiate between the post-cataract surgery cystoid macular edema (CME) and PME.[16] Briefly, when we observed the absence of an epiretinal membrane and solely inner nuclear layer (INL)-cysts, we made the diagnosis of post-cataract surgery CME and excluded the patient from the study. However, when we noticed the absence of subretinal fluid, presence of hard exudates, microaneurysms, and ganglion cell layer and/or retinal nerve fiber layer cysts, we made the diagnosis of PME and included the patient in the study.

Surgical technique

Phacoemulsification was performed under topical anesthesia by a single surgeon (A.KH.). A temporal side clear corneal incision was made using a 3.2 mm keratome. After the anterior chamber was filled with an ophthalmic viscosurgical gel (VISICROM®2%, BinaChashm, Tehran, Iran), a continuous curvilinear capsulorhexis was made. Phacoemulsification was done using a phaco-machine (Constellation® vision system; Alcon Laboratories). After phacoemulsification, a foldable intraocular lens (Acrysof SN60AT; Alcon Laboratories) was injected in the capsular bag. At the end of cataract surgery in the Bevacizumab injection group, 0.1 mL of a solution containing 1.25 mg of Bevacizumab (Avastin®; Genentech; California; United States) was injected intravitreally through the sclera from 3.5 mm posterior to the limbus. No intraoperative complication including vitreous loss or iris manipulation was noted.

Outcome measures

The Bevacizumab injection and control groups were compared in terms of change in BCVA, CMT, and TMV at baseline and after cataract surgery. To better compare our study results with DRCR.net protocols, we defined clinically meaningful postoperative macular edema by CMT >300 μm using SD-OCT (Spectralis SD-OCT; Heidelberg engineering; Germany).

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