TO THE EDITOR: We read with interest the article by Singh et al. that presented separate and pooled data from 2 large prospective (studies 1 and 2), randomized, parallel, phase III clinical trials demonstrating that nepafenac 0.3% once daily reduced the risk of macular edema (ME) after cataract surgery in patients with diabetic retinopathy (DR). The study has several notable strengths including its large size (>600 eyes enrolled in each study), rigorous design, and use of an objective definition of ME (30% change from baseline). However, we have several comments regarding the study’s results.

A significant reduction in ME (the study’s primary outcome) observed in nepafenac-treated eyes in study 2, did not translate into a significant improvement of 15 letters at day 60 or 90. This lack of robust correspondence between ME and visual acuity suggests that postoperative ME, particularly when mild, may not uniformly detriment vision. This finding supports recommendations from a recent report by the American Academy of Ophthalmology that visual acuity rather than ME should be the primary outcome in interventional trials assessing a therapeutic effect of topical nonsteroidal anti-inflammatory drugs in cataract surgery. When focusing on visual acuity instead of ME, the pooled results are less robust and in fact show no significant difference in 15-letter improvement at 90 days between nepafenac-treated and control eyes.

Importantly, no control eyes in this study were pretreated with any anti-inflammatory medication, whereas nepafenac-treated eyes seem to have received a total of 3 doses of nepafenac before surgery. Anti-inflammatory pretreatment before cataract surgery can significantly reduce postoperative retinal thickening and hasten visual recovery. This pretreatment may explain some of the reduced ME observed in nepafenac-treated eyes and raises the obvious question of whether pretreatment of the control group with prednisolone acetate 1% would have had similar effects. Although nonsteroidal anti-inflammatory drugs have the distinct clinical advantage of not increasing intraocular pressure, a large retrospective analysis of >16000 cataract surgeries by Shorstein et al. reported only a 0.6% incidence of elevated intraocular pressure of >30 mmHg observed after monotherapy with topical prednisolone acetate 1% and the absence of any other major adverse events related to its topical use.

Finally, eyes with moderate nonproliferative DR accounted for an overwhelming majority (84%–90%) of enrolled patients and are known to have an increased risk of ME when compared with eyes with less severe DR. Up to 20% of all cataract procedures are estimated to be performed for diabetic patients, but the great majority of these eyes have either no or mild retinopathy. Consequently, the findings of this study are not directly applicable to the majority of diabetic patients with less severe DR who are undergoing cataract surgery.

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