

Comparative Effectiveness of Three Prophylactic Strategies to Prevent Clinical Macular Edema after Phacoemulsification Surgery

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Purpose: To study the relationship of chemoprophylaxis and other factors with the occurrence of acute, clinical, postoperative macular edema.

Design: Retrospective cohort study. The drug regimens consisted of postoperative topical prednisolone acetate (PA) alone or with a nonsteroidal anti-inflammatory drug (NSAID) or intraoperative subconjunctival injection of 2 mg triamcinolone acetonide (TA) alone.

Participants: Patients undergoing phacoemulsification at Kaiser Permanente, Diablo Service Area, Northern California, from 2007 through 2013.

Methods: We identified incident macular edema diagnoses that had been recorded 5 to 120 days after phacoemulsification with visual acuity 20/40 or worse and evidence of macular thickening by optical coherence tomography. Odds ratios (ORs) and 95% confidence intervals (CIs) were obtained from logistic regression analysis, conditioned on the surgeon and adjusted for year, patient age and race, diabetic retinopathy status, other ocular comorbidities, systemic comorbidities, and posterior capsular rupture status.

Main Outcome Measures: Incident rates of acute, clinical, postoperative macular edema.

Results: We confirmed 118 cases among 16 070 cataract surgeries (incidence, 0.73%). Compared with PA alone, the OR for the relationship of macular edema with PA+NSAID was 0.45 (95% CI, 0.21–0.95) and that for TA injection was 1.21 (95% CI, 0.48–3.06). The frequency of intraocular pressure spikes of 30 mmHg or more between postoperative days 16 and 45 was 0.6% in the topical PA group, 0.3% in the topical PA+NSAID group ($P = 0.13$), and 0.8% for the TA group ($P = 0.52$). Black race was associated with a risk of macular edema (OR, 2.86; 95% CI, 1.41–5.79).

Conclusions: Adding a prophylactic NSAID to PA treatment was associated with a reduced risk of macular edema with visual acuity of 20/40 or worse. The risk and safety of TA injection were similar to those of PA alone. Further research is needed on the prognostic significance of postoperative macular edema, the role of prophylaxis, the risk among black people, and the effectiveness of depot medications. *Ophthalmology* 2015;■:1–7 © 2015 by the American Academy of Ophthalmology.

Cataract surgery is one of the most common surgical procedures in the United States, with more than 3 million surgeries performed annually.¹ Postoperative macular edema is one of the most common complications.^{2,3} The sensitivity and rate of detection have risen with the advent of optical coherence tomography (OCT).⁴ Moderate to severe postoperative macular edema may have an effect on long-term vision,⁵ although there is a paucity of evidence from well-controlled studies demonstrating a benefit of any chemoprophylaxis regimen on long-term postoperative visual acuity. In addition, the Food and Drug Administration has not approved any drug for prophylaxis of macular edema after cataract surgery.

We compared the effectiveness of 3 prophylactic strategies used in our department for preventing acute, clinical, postoperative macular edema with visual acuity of 20/40 or worse: topical prednisolone acetate (PA) alone, PA plus a

topical nonsteroidal anti-inflammatory drug (NSAID), and subconjunctival injection of 2 mg triamcinolone acetonide (TA) alone.

Methods

The institutional review board of the Kaiser Foundation Research Institute approved this study.

Setting

Kaiser Permanente is a prepaid, integrated, closed-panel health care organization with staffed physicians. The Diablo Service Area includes 17 cataract surgeons who practice at 3 medical offices and operate at a single center. Time-domain (TD) OCT (Zeiss-Meditec, Dublin, CA) and the more recent, higher-resolution spectral-domain (SD) OCT (Heidelberg Engineering, Heidelberg, Germany) were deployed at each medical office at different times

during the study. Access to eye care services for the service area's 380 000 members was at the initiation and discretion of the patient. Postoperative examinations were booked for the ophthalmologist at 1 day and 1 week and for an optometrist at 1 month; in 2011, the routine 1-week postoperative examination was discontinued. In addition, patients could telephone or send electronic mail to the operating surgeon.

The predominant surgery performed for cataract extraction was clear cornea phacoemulsification. Some aspects of perioperative clinical practice were standardized; however, the choice of prophylactic regimen varied based on surgeon preference, with choices including topical prednisolone alone, topical prednisolone with NSAIDs, or injected TA. Topical NSAIDs on the Kaiser Permanente formulary included the following generic eye drops: diclofenac sodium (Nexus Pharma, Karachi, Pakistan), flurbiprofen sodium (Bausch & Lomb, Rochester, NY), and ketorolac tromethamine (Hospira, San Jose, CA; Fresenius-Kabi, Lake Zurich, IL). Beginning in 2008, 2 of the cataract surgeons began injecting TA (Kenalog 40 mg/ml; Bristol-Myers Squibb, New York, NY), 2 mg (0.05 ml) in the subconjunctival space, 6 mm below the inferior limbus, at the conclusion of surgery. In 2013, 0.2 ml of a 10-mg/ml solution (also 2 mg) was used instead, allowing for a wider surface area for the depot. Eyes with a cup-to-disc ratio of 0.7 or more or with demonstrated glaucomatous visual field loss were excluded from injection.

Study Population

The study included health plan members who underwent a phacoemulsification surgery (Current Procedural Terminology [CPT] code 66984; International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9-CM], codes 13.41 and 13.71) from 2007 through 2013 at the Diablo Service Area and had at least 12 months of enrollment in Kaiser Permanente preceding the surgery. The study excluded patients who, in the 12 months before phacoemulsification, were diagnosed with cystoid macular edema (ICD-9-CM code, 362.53), retinal edema (ICD-9-CM code, 362.83), or diabetic macular edema (ICD-9-CM code, 362.07). We also excluded patients with a history of retinal detachment or defect (ICD-9-CM code, 361), a history of retinal surgery (ICD-9-CM codes, 14.0–14.9; CPT codes, 66852 and 67040–67228), or a history of trabeculectomy (ICD-9-CM code, 12.64; or CPT codes, 66170, 66172, and 66250) preceding their first phacoemulsification date.

Optical coherence tomography has become an important tool for diagnosing macular edema.⁶ To ensure that ascertainment of postoperative macular edema was comparable over the course of the study and across the 3 medical offices, we included only those eyes that underwent phacoemulsification after the date of installation of an OCT machine at each office.

We treated the diagnoses of cystoid macular edema (ICD-9-CM code, 362.53), retinal edema (ICD-9-CM code, 362.83), and diabetic macular edema (ICD-9-CM code, 362.07) as synonyms because hyporeflective spaces can occur on OCT in nondiabetic or diabetic macular edema.⁷ To focus the study on the incidence of postoperative macular edema, we excluded patients with a diagnosis of macular edema in either eye recorded during the 6 months preceding their first phacoemulsification procedure.

Definition of Postoperative Macular Edema

Patients with ICD-9-CM diagnosis codes 362.53, 362.83, or 362.07 recorded in outpatient data from 5 to 120 days after phacoemulsification were defined as preliminary macular edema cases. We counted only the first macular edema diagnosis per patient because eyes are not independent within persons, and

counting only the first occurrence removed bias related to within-person factors such as diabetes mellitus.⁸

The study ophthalmologist (N.H.S.) validated all preliminary macular edema cases by manually reviewing each patient's office notes and OCT images. Validation required a distance visual acuity of 20/40 or worse on the day of diagnosis of macular edema, OCT confirmation of retinal thickening, and correct laterality. The best Snellen visual acuity recorded by the medical assistant or optometrist on the day of diagnosis was used, be it corrected, uncorrected, or with pinhole. We defined, a priori, OCT cut points to define macular edema using published reports: TD OCT (fast macular thickness map) central subfield thickness (CST) of more than 250 μm ⁹ or SD OCT CST of more than 320 μm .¹⁰ Differences between TD and SD OCT cut points resulted from differences in resolution between the 2 methods, with SD OCT including more retinal layers in the measurement, from the internal limiting membrane to the retinal pigment epithelium–choriocapillaris complex.¹⁰ Preliminary cases with CST less than the cut points were validated individually with review of juxtafoveal thickening and foveal intraretinal hyporeflective cavities.

Data Collection

The dates of installation of each OCT machine were obtained from biomedical engineering records. Eye drops ordered and dispensed during the period from 120 days before to 4 days after phacoemulsification surgery were determined from gold standard inpatient and outpatient pharmacy information. In addition, surgeons were surveyed to determine their prescribing instructions for topical agents.

Intraoperative subconjunctival injection of TA was ascertained using a natural language processing algorithm of the operative notes. The final algorithm was validated through medical record review of 400 phacoemulsification cases, selected without regard to macular edema status, including 200 that were selected randomly from algorithm-positive eyes and 200 that were selected randomly from algorithm-negative eyes. The surgical complication posterior capsular rupture (PCR) was ascertained and validated similarly.

Other variables extracted for the study included the identity of the surgeon, patient demographics, systemic and ocular comorbidity recorded as diagnosis codes during the 6 months preceding phacoemulsification, and operative time. Systemic comorbidities included hypertension as well as elements of the Charlson comorbidity index (Deyo modification).¹¹ Ocular comorbidities included diabetic retinopathy (ICD-9-CM codes, 362.00–362.06), epiretinal membrane or macular pucker (ICD-9-CM code, 362.56), iritis or uveitis (ICD-9-CM code, 364.00, 364.02, 364.04, 364.10, 364.23, 364.3, 053.22, 054.44), age-related macular degeneration (ICD-9-CM code, 362.50), and glaucoma (ICD-9-CM code, 365).

Adverse Events

Corneal melt and globe perforation were ascertained from ICD-9-CM codes (370.00, 370.03, 370.06, 370.55, 370.9, and 371.89; and 360.89, 360.9, and 871.X or V45.69, respectively) recorded during the 120-day postoperative period. Postoperative intraocular pressure (IOP), measured by applanation or pneumotonometry, was obtained from values at the 3 office visits occurring on days 1 through 3, 4 through 15 (2007–2010), and 16 through 45. We analyzed IOP recorded for each patient's first phacoemulsification only to avoid estimating a *P* value that failed to account for the nonindependence of eyes. We also analyzed the number of IOP spikes, defined as 30 mmHg or more, the threshold above which the surgeons in the department add topical antihypertensive treatment to the postoperative regimen. The periods were chosen to separate early postoperative IOP spikes, which may

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