POINT/COUNTERPOINT: A DISRUPTIVE INNOVATION OR A COSTLY DISRUPTION?

Two perceptions of one drug's impact on ophthalmology.

A First in Intraoperative Drug Delivery for Cataract Surgery

BY ERIC DONNENFELD, MD, AND ALLISON W. SHUREN, JD


The future of pharmaceuticals and cataract surgery is unequivocally drug delivery. Omidria (phenylephrine and ketorolac injection; Omeros) is the first FDA-approved medication for anterior segment surgery to be delivered intracamerally. Omidria, which contains the mydriatic phenylephrine 1% and the nonsteroidal anti-inflammatory drug (NSAID) ketorolac 0.3%, is added to 500 mL of balanced salt solution to irrigate the anterior chamber during cataract surgery. It is indicated to maintain the pupil's size by inhibiting intraoperative miosis and to reduce postoperative ocular pain.

Without a doubt, the future holds many more drug delivery products. This disruptive concept is exciting to most ophthalmologists and patients, but as with anything new, individuals have concerns about efficacy, risk, and cost, which this article addresses.

EFFICACY

The FDA trials show overwhelming efficacy with Omidria. It is important to note that all patients—both those treated with the drug and controls—in the phase 2 and 3 clinical trials had standard preoperative dilating medications. Only 4% of patients treated with Omidria had a pupillary diameter of less than 6 mm just prior to lens implantation compared with 23% of the placebo group ($P < .0001$).[1] Some might argue that the same

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An Unnecessary Financial Burden

BY KEITH A. WALTER, MD

The newly FDA-approved drug Omidria (Omeros) is injectable phenylephrine and ketorolac indicated for intraoperative mydriasis and postoperative pain. I have two concerns with this drug. First, I question if it is even necessary, and second, I wonder who is going to pay $465 for it.

Most surgeons use a nonsteroidal anti-inflammatory drug (NSAID) preoperatively to prevent miosis and cystoid macular edema. Dilating drops in the preoperative area work well and are relatively convenient. If a pupil does not dilate well, commercially available phenylephrine can be injected for about $4. Omidria contains ketorolac, and it is not clear how long this agent stays in the eye or if it will even help prevent cystoid macular edema, as no studies have been done.

Omidria received "pass-through" status from Medicare. This may seem beneficial because it will not cost ambulatory surgery centers, hospitals, or patients, but I worry about physicians' declining reimbursement from Medicare. Not all pass-throughs are bad; I am in favor of pass-through status for corneal transplants, because there are no alternatives (not to mention that the procedures are necessary) and transplants are a significant cost for ambulatory surgery centers and patients. With more than 3 million cataract procedures performed annually, however, Omidria has the potential to cost Medicare over $1 billion each year. What will the Centers for Medicare & Medicaid Services do? Will the agency cut our reimbursement for cataract surgery further? Where will the money come from to cover this new cost? As a taxpayer, I do not think federal dollars should be spent to make a drug

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results could be obtained with off-label epinephrine or phenylephrine, but this is an error. In the phase 2 FDA trial designed to show an improved combined effect of using phenylephrine with ketorolac versus phenylephrine or ketorolac alone, 22% of subjects receiving phenylephrine in the irrigation solution versus only 6% of subjects receiving Omidria in the irrigation solution had pupillary diameters less than 6 mm during the procedure ($P = .0216$). The addition of ketorolac inhibits prostaglandin production and helps prevent miosis, which a dilating agent alone cannot accomplish.

Physicians evaluate the success of cataract surgery in terms of visual rehabilitation, and patients want to be comfortable during this process. Omidria decreased postoperative pain for 10 to 12 hours after surgery.[1] During this important postoperative period, despite all study patients' having received standard-of-care preoperative topical anesthetic agents, the percentage in the control group reporting moderate to severe pain (Visual Analogue Scale pain score ≥ 40) was twice that in the Omidria-treated group (14% vs 7%; $P = .0027$), and those experiencing no pain (Visual Analogue Scale pain score = 0) throughout the early postoperative period comprised 26% of those treated with Omidria compared to 17% of control patients ($P = .0014$).[1] These pain data are impressive, given that the control group also received 40% more postoperative pain medications. Animal studies evaluating the intraoperative administration of Omidria during cataract surgery have shown ketorolac to achieve therapeutic levels in the retina that have not been demonstrated with topical NSAIDs, levels that are estimated to effectively block both COX-1 and COX-2 activity for at least 10 hours postoperatively (data on file with Omeros).

RISK

In the FDA trials, Omidria was safe and effective with no significant side effects; the incidence of the adverse events observed was similar to that of the placebo group. In our opinion, the only risk associated with Omidria is not using it. Ophthalmologists practice in a challenging environment today with a perfect storm of government intervention, compounding pharmacies' errors, shortages of preservative-free medications, and malpractice lawyers who create risk for our patients, practices, and surgicenters. Many surgicenters and hospitals now prohibit the use of off-label medications for fear of being closed down regardless of the benefits to patients' care. Using a medication off label (especially when a better alternative that is FDA approved is available) risks presumed culpability for any bad outcome that occurs. In addition, shortages of bisulfate-free epinephrine have been problematic for many ophthalmic surgicenters. The incidence of intraoperative floppy iris syndrome and pseudoexfoliation leading to intraoperative miosis and surgical complications is rising, and my (E.D.) initial experience is that Omidria may reduce the number of these challenging cases.

COST

Worries about cost include expenses to patients, surgeons, surgical facilities, and taxpayers. For Medicare part B patients, the first three concerns do not exist. There is no coinsurance payment for Omidria associated with procedures performed in hospital outpatient departments, and almost all Medicare patients have supplemental insurance that cover copayments. Omidria has "pass-through" status, which means Medicare pays the cost of this product above and beyond the normal facility fee for cataract surgery. In our opinion, this is a win-win-win opportunity for patients, surgeons, and surgical facilities.

The wholesale acquisition cost for Omidria is $465, and for Part B patients, Medicare reimburses at wholesale acquisition cost plus a 6% handling fee, followed later by the average selling price plus 6%. This reimbursement decision was determined by the Centers for Medicare & Medicaid Services (CMS) based on well-established criteria specified by federal regulations governing Medicare spending. Pass-through status for Omidria is expected to expire on December 31, 2017. Thereafter, the payment for the drug will most likely be incorporated into the facility fee for cataract surgery.

Concerns that the cost of Omidria will reduce reimbursement for physicians and/or facilities are misguided (for more on the current reimbursement climate and its impact on the field of ophthalmology, go to eyetube.net/?v=okune). Funds for pass-through products are set aside each year by Congress and administered by CMS to encourage the use of innovative new products across all of medicine, not just in ophthalmology. Each year, CMS estimates the total amount of spending for all pass-through drugs and devices. In the hospital outpatient departments and surgicenters, CMS "paid for" these pass-through payments by reducing the 2015 payment rates for facility services by 0.13%—a miniscule amount. Omidria accounts for a small fraction of that 0.13%, since the reduction covers all pass-through drugs and devices, not just those for cataract surgery or ophthalmology. Therefore, Omidria will have a negligible effect on cataract surgery reimbursement, and our hope is that, if Omidria is used extensively when the pass-through period ends, it may be incorporated into the facility fee for cataract surgery. The payment rate for cataract surgery may then rise over time, as the increased cost is incorporated into facility charges. Omidria and other pass-through products have no effect now or in the future on physicians' professional service fees.

CONCLUSION

Omidria gives ophthalmologists a unique opportunity to increase their control of cataract surgery, improve postoperative outcomes by reducing the risk of a small pupil, and enhance patients' comfort—all without changing the procedure or its economics for Medicare patients. This agent will help ophthalmologists to make cataract surgery safer and more predictable, and it represents the first FDA-approved approach to intraoperative drug delivery, another important step forward in refractive cataract surgery. ■

1. Lindstrom RL, Loden JC, Walters TR, et al. Intracameral phenylephrine and ketorolac injection (OMS302) for maintenance of intraoperative pupil diameter and reduction of postoperative pain in intraocular lens replacement with phacoemulsification. *Clin Ophthalmol.* 2014;8:1735-1744.

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company or its investors wealthy. I am vexed that Omeros is receiving almost the equivalent of the surgeon's fee for a drug that I believe is not even necessary. ■

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