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Brand vs. generic: Which is best cataract surgery medicine?

Why brand name medications considered treatments of choice due to safety, efficacy

May 01, 2014 By Cheryl Guttman Krader

Take home

Substituting generic products for brand name innovators in cataract surgery medication regimens can bring trade-offs in efficacy, safety, and convenience, perhaps with just modest savings in cost.

Dr. Donnenfield

By Cheryl Guttman Krader; Reviewed by Eric D. Donnenfeld, MD, Stephen S. Lane, MD, and Francis S. Mah, MD

Brand name medications may cost more than generic alternatives, but the extra money spent is well worthwhile considering the many other ways innovator products differ from generic pharmaceuticals, according to leading cataract surgeons.

Eric D. Donnenfeld, MD, Stephen S. Lane, MD, and Francis S. Mah, MD, discussed why they prefer to write prescriptions for brand name antimicrobial and anti-inflammatory products in their cataract surgery medication regimens.

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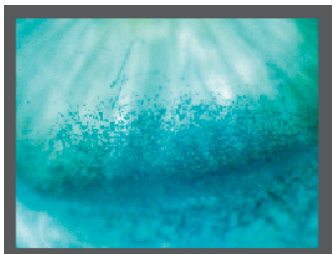
Dr. Mah acknowledged that generic products do provide a service by virtue of their lower upfront cost. However, he emphasized that decisions on medications should also take into account efficacy, safety, and dosing convenience.

Low cost not always most important



Inferior corneal staining following cataract surgery in a patient treated with topical generic ketorolac. *(Image courtesy of Eric D. Donnenfeld, MD)*

“You really can’t put a price on the benefits of better safety and efficacy,” said Dr. Mah, director, cornea and external disease, and co-director, refractive surgery, Scripps Clinic, La Jolla, CA.

The bottom line, Dr. Donnenfeld said, is that the branded products of the medications used in cataract surgery offer significant advantages over their generic counterparts, and the differences translate into better outcomes.

“Achieving premium outcomes with cataract surgery requires the use of premium pharmaceuticals,” said Dr. Donnenfeld, clinical professor of ophthalmology, New York University, New York, and founding partner, Ophthalmic Consultants of Long Island and Connecticut, Rockville Centre, NY.

Similarly, Dr. Lane— adjunct professor of ophthalmology, University of Minnesota, Minneapolis, and medical director, Associated Eye Care, Stillwater, MN— summed up his preference for prescribing brand name products as being based on a focus to provide the best possible care.

“Patients must be educated so that they understand that saving money is not as important as taking care of their problem,” he said. “Patients should be made aware that use of a less expensive generic medication may be done at some risk.”

Inequivalence of generic equivalents

Dr. lane

According to FDA policies, ophthalmic generic products introduced prior to 1992 did not have to match the inactive ingredients of the innovator. Beginning in 1992, newly approved generic ophthalmic solutions had to contain the same active and inactive ingredients as the innovator and in the same concentrations otherwise manufacturers had to demonstrate clinical bioequivalence. Demonstration of bioequivalence is also required for all generic ophthalmic products that are not solutions, regardless of whether the ingredients are the same as the innovator.

The key is that there are no requirements for generic manufacturers to conduct studies proving that their product is clinically equivalent to the innovator in terms of efficacy and safety. The unfortunate consequences of this situation are well-known to ophthalmologists through the experience with the generic topical diclofenac product that was responsible for corneal melts. Subsequently, reports have also emerged describing corneal melts and epithelial defects associated with the use of other generic nonsteroidal anti-inflammatory drugs (NSAIDs), the surgeons noted.

"I would almost guarantee that had these generic NSAIDs been tested in clinical trials, the [illegible] id Dr. Mah. "However, in the absence of clinical data, we have no idea how the efficacy and safety of generic products compare with the brand name medications."

Dr. Donnenfeld noted that he has seen many patients using a generic ketorolac product who complain of decreased vision following cataract surgery. Slit-lamp examination reveals the presence of superficial punctate keratitis in the visual axis, a problem that resolves upon cessation of the generic NSAID, he said.

Inferior substitutions

Due to patent protection, the latest brand name products have no generic equivalent. Therefore, when generic substitutions for these products are made at the pharmacy, the dispensed medication will be within the same broad class as the product prescribed (ie., corticosteroid, NSAID, antibiotic), but may represent an entirely different entity in a different, suboptimal vehicle and with different dosing directions.

Discussing NSAIDs, Dr. Donnenfeld noted that the most recent generation of products within this class—nepafenac 0.3% suspension (Ilevro, Alcon) and bromfenac 0.07% (Prolensa, Bausch + Lomb)—are safer, better tolerated, and have dosing regimens that are easier for patients to comply with relative to older brand name and generic NSAIDs.

"The newest agents offer once a day dosing," he said. "That is a tremendous convenience advantage that enables compliance and therefore increases efficacy. At the same time, the decreased drop burden reduces the risk of epithelial toxicity."

Dr. Mah also noted that the reduced dosing frequency with the newest NSAIDs has safety value because it minimizes ocular exposure to preservatives. In addition, the newest brand name ophthalmic products are more likely than the generic agents to be formulated with an advanced, "gentler" preservative or at least with a lower concentration of benzalkonium chloride, he said.

Dr. Lane mentioned that due to ingredient differences, the generic NSAIDs are associated with higher rates of stinging on instillation than the latest brand name products. That factor combined with their increased dosing frequency—up to 4 times a day—can compromise compliance and therefore the benefit of treatment.

"The consequences of not using an NSAID as directed after cataract surgery include increased anterior chamber inflammation and even cystoid macular edema," Dr. Lane said.

He noted that the problem of substituting one chemical entity for another is also an issue with generic substitutions for corticosteroids and antibiotics as the newest and best products within these classes have no generic equivalent.

"A branded drug like loteprednol etabonate 0.5% gel (Lotemax Gel, Bausch + Lomb) may be substituted with a generic prednisolone acetate. While both medications are steroids,

they are very different compounds with a different safety profile, and their formulations are markedly different," he explained.

Discussing antibiotics, Dr. Lane noted that when substituting for a branded fluoroquinolone, patients might be given a generic aminoglycoside or sulfonamide.

"The spectrum of antimicrobial coverage of these two antibiotic classes is vastly different than with the latest generation fluoroquinolones," he said.

Dr. Mah also highlighted concerns about antibiotic substitutions. He noted that compared with both non-fluoroquinolone antibiotics and earlier generation fluoroquinolones (ciprofloxacin, ofloxacin, and levofloxacin), the latest generation fluoroquinolones, besifloxacin 0.6% (Besivance, Bausch + Lomb), moxifloxacin 0.5% (Vigamox/Moxeza, Alcon), and gatifloxacin 0.5% (Zymaxid, Allergan), have more potent activity against important endophthalmitis pathogens along with an advantage of less frequent dosing. In addition, the propensity for development of bacterial resistance is lower using the newer fluoroquinolones than the older entities, and that is an important consideration recognizing that antimicrobial resistance is a growing global concern.

Minimal savings

The only potential benefit of a generic medication is lower cost, but Dr. Lane pointed out that significant savings usually only come when there is a substitution for an entirely different medication. Furthermore, the price of generic medications may be much higher than patients expect. Although generic manufacturers do not need to recoup drug development costs, the manufacturing process itself may be complex, and its expense will be reflected in price paid at the pharmacy counter, Dr. Lane said.

Furthermore, prices of generic medications have been on the rise recently, narrowing the cost difference between branded and generic medications, and that trend may continue if more rigorous FDA standards for generic medications are implemented, Dr. Mah said.

He noted that in his geographic region, patients without prescription insurance coverage could expect to pay between $40 and $50 for generic prednisolone acetate 1% and $100 for generic fluorometholone, if they can find it at all.

"With the use of manufacturer-supplied coupons, brand name products may actually be cheaper than the generic, and with branded products, we can sometimes provide patients with free samples," Dr. Mah said. "That is an opportunity that simply does not exist with generic products."

Patient education

As a bottom line, all three surgeons said that while they are sensitive to the costs of some brand name medications and leave the final decision to the patient, they still recommend the brand name products.

"My recommendation is based on what is best for the patient," Dr. Donnenfeld said. "That starts with safety and efficacy but also includes cost. However, I give patients the choice of deciding what they think is best for them."

Dr. Lane noted that patients in his practice receive written materials with information detailing why the branded medications are preferred.

"We encourage patients to fill their prescriptions as written, but at the end of the day, it is

the patients who choose what they want to use for their treatment," he said.

Dr. Mah said he also counsels patients about the concerns accompanying the use of generic products.

"I essentially have an informed consent discussion in which the patient is told the generic products may require more frequent dosing, have not been demonstrated safe and effective in FDA clinical trials, and do not have to defend product-specific safety information in their labeling since the label is taken from the branded drug without trials," he explained. "Therefore, I tell patients that I cannot guarantee the results they will get using a generic product. I offer patients the coupons for branded medications if the cost is an issue, and even have the patients call for samples if the coupons do not bring down the costs to a reasonable level."

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