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Time needed to complete: 33m

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Lessening Glaucoma Treatment Burden: Sustained-Release Therapies (Part 1)

Announcer:
Welcome to CME on ReachMD. This episode is part of our MinuteCME curriculum.

Prior to beginning the activity, please be sure to review the faculty and commercial support disclosure statements as well as the learning objectives.

Dr. Cui:
This is CME on ReachMD, and I'm Dr. Qi Cui. The bimatoprost implant is a novel treatment option providing durable IOP [intraocular pressure] lowering. Let's take a look at the clinical data for this implant and its use in patients with early- to moderate-stage glaucoma.

The efficacy and safety of 2 doses of bimatoprost biodegradable drug-eluting implant compared to topical timolol was examined in two 20-month, phase 3, randomized clinical trials. The ARTEMIS studies enrolled adults with open-angle glaucoma and ocular hypertension who were known responders to topical beta-blockers and prostaglandin analogs.

Inclusion criteria also included baseline intraocular pressures between 22 and 32 mmHg at 8:00 AM and between 19 and 32 mmHg 2 hours thereafter, when topical timolol might be expected to reach peak efficacy. Another inclusion criteria was central corneal endothelial density of greater or equal to 1,800 cells per mm2. Participants were randomized to implants containing either 10 or 15 µg of bimatoprost or to topical timolol, 0.5%, administered twice daily. Implants were injected into the interior chamber on day 1, then again on weeks 16 and 32. Primary endpoints were IOP and IOP changes from baseline at weeks 2, 6, and 12. Long-term efficacy and safety profiles, after repeated administration, was evaluated through month 20.

By week 12, patients randomized to both strengths of the bimatoprost implant achieved IOP reductions from approximately 24 to 17 mmHg, representing a 30% reduction from baseline. In both trials, both strength of the bimatoprost implant met predefined criteria of not inferiority compared to timolol. The implant demonstrated statistical noninferiority of timolol with respect to IOP lowering in the 12 weeks after the second and the third injections. A Kaplan-Meier survival analysis estimated a probability of not requiring additional treatment for 1 year after the last implant injection to be in the range of 70%-75% for participants.

The most common treatment emergent adverse events were conjunctival hyperemia, ocular irritation, foreign body sensation, and conjunctival hemorrhages, most of which were thought to be related to the injection protocol and the use of Povidone-iodine antiseptic on the ocular surface. Corneal endothelial cell loss, edema and iritis were more frequent following bimatoprost implant administration compared to topical timolol. In particular, corneal endothelial cell density showed time-dependent loss in study eyes in the bimatoprost implant groups, with greater loss in the 15- compared to the 10-µg group. This difference was thought to be in part related to the larger size of the 15-µg implant.

Based on trial results, the bimatoprost implant 10 µg is approved for a single intracameral administration for IOP control in patients with open-angle glaucoma and ocular hypertension. It was shown to be noninferior to timolol with respect to IOP lowering after 12 weeks, and endothelial cell loss was reported to be in the range of 5% after repeat injections in 20 months of follow-up.

In summary, the bimatoprost implant is a good option for decreasing the burden of daily medication administration and has the potential to minimize ocular surface adverse effects in prostaglandin responders.

It is contraindicated in individuals with active or suspected ocular or periocular infections, corneal endothelial cell dystrophy, prior corneal transplantation, absent or ruptured posterior lens capsules, and in individuals with a history of hypersensitivity to bimatoprost.

Well, that's all the time we have for today. Thank you for joining me.

Announcer:
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