Triple Preservative-Free Therapy for Glaucoma Promotes Efficacy and Ocular Surface Health

A triple preservative-free therapy for glaucoma yielded positive results in efficacy and ocular surface health compared with preserved latanoprost.

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April 20, 2018 - In patients with open-angle glaucoma, preservative-free (PF) tafluprost alone and in combination with PF dorzolamide/timolol improved intraocular pressure (IOP) control and ocular surface health compared with preserved latanoprost.

Anastasios-Georgios Konstas, MD, with the 1st University Department of Ophthalmology, at the Aristotle University of Thessaloniki, in Thessaloniki, Greece, and colleagues reported the findings in the December 2, 2016 online publication of Advances in Therapy.

"Branded or generic latanoprost 0.005% containing BAK [benzalkonium chloride] is currently the most popular first-choice monotherapy in Europe for patients with ocular hypertension or glaucoma," according to IMS (Intercontinental Marketing Services) Health, Inc.

"Lifelong topical antiglaucoma therapy with preserved medications has a detrimental effect on ocular surface health, especially when multiple agents are used," explained Dr. Konstas. Consequently, tolerability of various future treatments can diminish in patients, he continued.

"To the best of our knowledge this is the first study to compare the 24-h efficacy and ocular surface status with a triple PF regimen versus a popular monotherapy," the researchers noted of the current crossover, comparative study.

The prospective observer-masked trial included 43 consecutive patients who had uncontrolled IOP and ocular surface disease after a 3-month treatment of preserved branded or generic latanoprost. The mean 24-h baseline IOP of the selected patients was 22.2 $\pm$2.9 mmHg.

Patients were randomly assigned to receive daily either PF tafluprost 0.0015% (Saflutan®) or a combination of PF tafluprost and PF dorzolamide 2%/timolol 0.5% (Cosopt PF®). After 3 months of treatment, they were crossed over to the opposite therapy. After each treatment period, 24-h IOP measurements and 3 ocular surface tests, including tear film break-up time, corneal fluorescein staining, and the Schirmer I test, were completed.

Relative to preserved latanoprost, PF tafluprost monotherapy reduced the mean (21.9 vs 22.2 mmHg; $P = 0.006$), peak (23.9 vs 24.5 mmHg; $P = 0.001$), and fluctuation (3.9 vs 4.6 mmHg; $P = 0.001$) 24-h IOP parameters. In addition, the ocular surface tests improved significantly (all $P < 0.01$) in the PF tafluprost therapy compared with the latanoprost therapy.

The triple PF therapy was significantly lower both in mean (17.3 vs 22.2 mmHg; $P < 0.001$) and peak (19.8 vs 24.5 mmHg; $P < 0.001$) 24-h IOP parameters compared with preserved latanoprost. No improvements were noted for 24-h fluctuation (4.4 vs 4.6 mmHg; $P = 0.726$). Compared with preserved latanoprost, the corneal stain test significantly improved ($P < 0.001$) in the triple PF therapy, but the tear film break-up time and Schirmer I test did not significantly change.

The finding that the triple PF therapy with 3 active ingredients had a similar ocular surface profile to the preserved latanoprost monotherapy was, "surprising," according to Dr. Konstas and colleagues. "This is

likely due to the elimination of BAK, but could also be attributed to the relatively small sample size or the short duration of the study," they added.

Clinically adverse events were reported least by patients on PF tafluprost and equally by patients on either triple PF or preserved latanoprost. Symptoms of tired eyes or fluctuating vision occurred only in patients on preserved latanoprost. Burning, stinging, and bitter taste were the most common adverse events in the triple PF therapy. However, all 3 therapies were well tolerated.

PF medications for glaucoma can successfully control the IOP of patients and "can meaningfully improve tolerability in glaucoma patients with symptoms or signs of ocular surface disease," the researchers concluded.

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