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Micro-dosing of phenylephrine comparable to conventional dropper administration

Piezo-ejection micro-dosing of phenylephrine showed comparable results to traditional eyedropper administration in pupil dilation, as well as less systemic absorption, according to a study.

The phase 2, masked, nonrandomized, crossover study evaluated pupil dilation with topical phenylephrine in 12 eyes of 12 patients administered by a conventional 32-µL eyedropper (2.5% or 10% formulation) and in the second eye by an 8-µL electronic micro-dose ejection (10% formulation).

Pupil diameter was measured before dosing and 15, 30, 45, 50, 75, 120 and 180 minutes after dosing, while safety assessments including blood pressure and heart rate measurements were taken at 10, 15, 30, 45 and 60 minutes after dosing.

At 75 minutes, eyes dilated with the micro-dosing method produced the same dilation as eyes with the 10% formulation using the conventional method and superior results compared with eyes that received the 2.5% formulation using the conventional method.

To achieve the same biological effect, the total amount of drug needed was "markedly reduced," according to the study authors.

"Piezo-print is a rather sophisticated device, but we think it's time we start thinking about moving from the pipette and eyedrop paradigm to something that will give us a little bit more precise delivery, will help us eliminate some of the side effects," study author **Tsontcho "Sean" Ianchulev, MD,** founder and chairman of Iantech, said in a presentation at the American Academy of Ophthalmology meeting in New Orleans.

In the study, plasma phenylephrine levels were measured in blood samples drawn from patients 20 minutes after administration; eyes that had been micro-dosed had lower circulating phenylephrine concentration than those in the 10% conventional group.

Nine mild ocular adverse events occurred: one in the micro-dosing group, one in the 2.5% conventional group and seven in the 10% conventional group.

The study authors suggested the micro-therapeutic approach could be applicable in treating other diseases.

"We are building a pipeline of pharmaceuticals, starting with glaucoma. We have a phase 3 program that we are going to launch next year. We have one in dry eye with micro-tears, and also we are very excited about the opportunity to take an old drug that we know works very well for slowing the progression of myopia but that is hampered by the side effects. It works great in low dose, so micro-dose would be really amenable to therapeutic intervention," Ianchulev said at the meeting. – *by Rebecca L. Forand*

Reference:

Ianchulev S. High precision microdose delivery of topical medications. Presented at American Academy of Ophthalmology annual meeting; Nov. 11-14, 2017; New Orleans.

Disclosure s : Ianchulev reports he is a consultant for Eyenovia and is named on the device patent application. Please see the study for all other authors' relevant financial disclosures.

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