Sir,

A Comparison of the Efficacy of Tropicamide Applied Topically using a Novel Ophthalmic Delivery System versus a Phenylephrine-Tropicamide Drop Preparation in Insulin-Independent Diabetics

A novel ophthalmic delivery system (NODS) has been developed for the administration of topical medication. NODS incorporate the drug into a soluble polyvinyl alcohol flag which is attached to a water-soluble handle film via a thin soluble membrane. When placed in the inferior fornix the segment containing the drug detaches from the carrier and gradually dissolves releasing the drug. This delivery system overcomes the disadvantages of topical drop preparations, being preservative free, allowing longer corneal contact time and higher tear film concentration of the drug resulting in greater bioavailability.[1] A lower concentration of the drug can be used, thus there is decreased systemic absorption and less risk of systemic side-effects.[2]

The efficacy of topical medication in dilating the diabetic pupil is not entirely predictable. This unpredictability is due to the variable effects of a number of factors on pupil dilation capability.[3–6]

The aim of this study was to compare the efficacy of tropicamide NODS (125 μg) to a drop combination of phenylephrine 2.5% (875–1250 μg per drop) and tropicamide 1% (350–500 μg per drop) for pupil dilation in a group of insulin-independent diabetics.

Thirty patients were enrolled into the study (13 women and 17 men) all of whom were Caucasian; their average age was 55 years (range 30–71 years). All patients were insulin-independent diabetics with a mean of 9.5 years since diagnosis (range 2–35 years) and had a range of grades of retinopathy. Exclusion criteria for entry into the study were previous laser treatment or ocular surgery, known diabetic neuropathy, topical antiglaucoma treatment and the use of any medication likely to interfere with the ocular autonomic system.

One eye of each patient was randomly assigned to receive a NODS and the other the drop combination. Pupil diameter was measured in the vertical meridian using the millimetre scale of a Haag-Streit 900 slit lamp under the same dim background lighting conditions in a black-walled laser room. Measurements were taken pre-topical application and then at 10 minutes and 30 minutes post-dilation. The increase in pupil size at each examination interval and the final pupil size were calculated. All measurements were performed by one of the authors who was masked as to which eye received which preparation. As a statistical analysis a two-tailed Wilcoxon signed rank test was applied to the results.

The mean increase in pupil diameter at 10 minutes was 2.43 mm for the drop combination and 1.33 mm for the NODS ($p = 0.0002$). From 10 to 30 minutes the size increase was 1.54 mm for the drops and 2.13 mm for the NODS ($p = 0.0007$). The final diameter was increased by 3.97 mm for the drops and 3.16 mm for the NODS ($p<0.02$). There was no relation between the initial and final sizes of the pupil. The drop preparation showed a statistically significant ($p = 0.0063$) better dilating effect in blue eyes but no significant difference in other iris colours. A comparison of pupil dilation associated with type of retinopathy did not show any statistical difference between NODS and the drop combination.

This study has shown that there is no statistically significant difference in the extent of dilation of diabetic pupils produced by the drop combination and the NODS, 30 minutes following their instillation into the conjunctival fornix (except in blue irides). There were, however, statistically significant differences between the pupil dilation produced in the 0–10 and the 10–30 minute intervals: in the former interval the greater dilation was with the drop preparation, while in the latter interval it was with the NODS.

There was no obvious difference in subjective symptoms from the two preparations, although the drops tended to produce a stinging sensation whereas the NODS produced a foreign body sensation.

A tropicamide NOD costs 17.7p as compared with 29.5p for each minim of either 1% tropicamide or 2.5% phenylephrine. Assuming a separate minim is used for each patient, this represents quite a difference in total costs per clinic.

In conclusion, we did not show any advantage of one study preparation over the other in the extent of dilation of pupils in insulin-independent diabetics. The selection of one preparation over the other when considered in terms of the difference in cost and the decreased likelihood of potential side-effects must favour the NODS preparation.

N. P. O'Donnell, FRCOphth
W. Gillibrand, RGN, OND

St Paul's Eye Unit
Royal Liverpool University Hospital
Prescot Street
Liverpool L7 8XP, UK

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