ARTÍCULO DESTACADO DEL MES

Six-Month Intraocular Pressure Reduction with a Topical Bimatoprost Ocular Insert

Results of a Phase II Randomized Controlled Study

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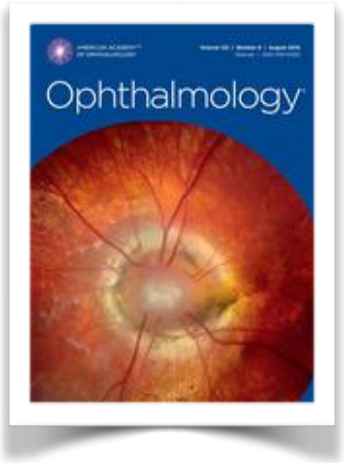
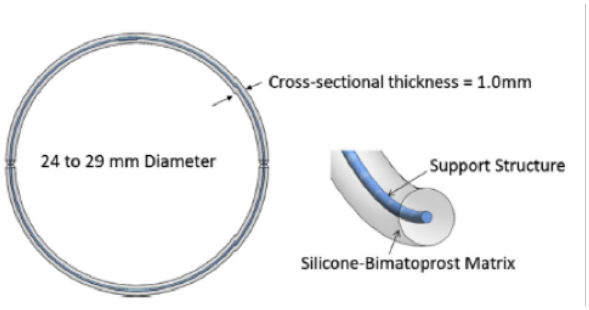


COMENTARIOS

Estudio multicéntrico, randomizado y a doble ciego cuyo propósito es comparar la eficacia y seguridad de un implante conjuntival de bimatoprost frente a la administración cada 12 horas de timolol 0.5%. Se incluyeron 130 pacientes hipertensos oculares o con glaucoma, bien controlados con una monoterapia o sin tratamiento pero con la expectativa de alcanzar un buen control tensional con una monoterapia.

El implante de bimatoprost es un dispositivo flexible en forma de anillo en el que el principio activo sin conservantes se encuentra embebido en una matriz de silicona que permite una adecuada tasa de liberación. Esta matriz de silicona rodea a una estructura interna anular de polipropileno que aporta consistencia. Existen diferentes tamaños de implante, entre 24 y 29 mm de diámetro, para una adecuada adaptación a los fondos de saco conjuntivales sobre los que se apoya.



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Ambos grupos mostraron descensos tensionales medios entre 4-6 mmHg (≥ 20%) frente a la basal durante los 6 meses de seguimiento. Sin embargo, la aplicación tópica de timolol 0.5% mostró reducciones de presión entre 0 y 1.5 mmHg de media mayores que el implante de bimatoprost. El dispositivo mostró una buena tolerancia, siendo la secreción debido al roce conjuntival el efecto adverso más destacable, y una tasa de dislocaciones del 12% a los 6 meses.

Interesante estudio por ser hasta la fecha el primero que demuestra que se pueden obtener descensos significativos de presión con dispositivos tópicos de lenta liberación de fármacos hipotensores.

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ABSTRACT

PURPOSE
Improving adherence to manage elevated intraocular pressure (IOP) remains an unmet need. A topical bimatoprost ocular insert was compared with twice-daily timolol eye drops in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT) treated for 6 months.

DESIGN
Parallel-arm, multicenter, double-masked, randomized, controlled trial.

PARTICIPANTS
One hundred thirty adult OAG or OHT patients.

METHODS
Eligible patients were randomized 1:1 to receive a bimatoprost insert plus artificial tears twice daily or a placebo insert plus timolol (0.5% solution) twice daily for 6 months after a screening washout period. Diurnal IOP measurements (at 0, 2, and 8 hours) were obtained at baseline; weeks 2, 6, and 12; and months 4, 5, and 6. Key eligibility included washout IOP of 23 mmHg or more at time 0, IOP of 20 mmHg or more at 2 and 8 hours, and IOP of 34 mmHg or less at all time points; no prior incisional surgery for OAG or OHT; and no known nonresponders to prostaglandins.

MAIN OUTCOME MEASURES

The primary efficacy end point examined the difference in mean change from baseline in diurnal IOPs (point estimate, 95% confidence interval) across 9 coprimary end points at weeks 2, 6, and 12 comparing the bimatoprost arm with the timolol arm using a noninferiority margin of 1.5 mmHg. Secondary end points were diurnal IOP measurements at months 4, 5, and 6 and adverse events (AEs).

RESULTS

A mean reduction from baseline IOP of -3.2 to -6.4 mmHg was observed for the bimatoprost group compared with -4.2 to -6.4 mmHg for the timolol group over 6 months. The study met the noninferiority definition at 2 of 9 time points but was underpowered for the observed treatment effect. Adverse events were consistent with bimatoprost or timolol exposure; no unexpected ocular AEs were observed. Primary retention rate of the insert was 88.5% of patients at 6 months.

CONCLUSIONS

Clinically relevant reduction in mean IOP was observed over 6 months with a bimatoprost ocular insert and seems to be safe and well tolerated. The topically applied bimatoprost insert may provide an alternative to daily eye drops to improve adherence, consistency of delivery, and reduction of elevated IOP.