AOCOO-HNS 2023 Abstract

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Title:

Efficacy of Intracanalicular Dexamethasone Insert Placement in the Lower Versus Upper Punctum Following Cataract Surgery

Purpose:

FDA approval of intracanalicular dexamethasone insert (DEXTENZA [DEX]) for postop ocular inflammation & pain was based on three Phase 3 trials which evaluated DEX when inserted into the lower punctum after surgery. The objective of the current study was to evaluate the safety & effectiveness of lower compared to upper punctum placement of DEX.

Methods:

Prospective, randomized, controlled study. Eyes undergoing cataract surgery with or without iStent, Hydrus, or goniotomy were randomized to receive either DEX in the lower punctum (n=39) or upper punctum (n=40) on the day of surgery in the operating room. Primary endpoints were absence of anterior chamber (AC) cell at Day 14 and absence of ocular pain at Day 7. Other measurements collected include visual acuity (BCVA), ease of DEX insertion, and DEX retention throughout the 30-day follow-up period. Safety was assessed by adverse events (AEs) collection and IOP measurements.

Results:

Proportion of subjects with absence of AC cell on day 14 showed no statistically significant difference between lower and upper eyes (97.4% vs 92.3% respectively; p =0.615). Absence of pain on day 7 showed no statistically significant difference between lower and upper eyes (100% vs 97.5% respectively; p=1.0). DEX was easy to insert in 92.3% and 90% of the lower and upper groups, respectively and was inserted on the first attempt in 97.4% and 87.5% of the lower and upper groups, respectively. Incidence of ocular AEs were similar in both groups (4 AEs in each group) and all were mild or moderate. Additionally, there was no clinically significant changes in mean IOP observed in either DEX upper or lower insertion groups.

Conclusions:

Upper DEX insertion met its primary endpoint and demonstrated reduction in postop ocular inflammation and pain outcomes comparable to lower DEX insertion for up to 30 days. Upper DEX insertion was generally well tolerated with no serious or severe ocular AEs reported and no clinically significant differences in IOP compared to lower DEX insertion.