Title

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Comment on Non-Infectious Outcomes of Intravitreal Antibiotic-Steroid Injection and Topical NSAID Versus Triple Drop Therapy Post Cataract Surgery

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I found the report of Mian et al regarding the comparison of injected vs topical post-operative anti-inflammatory treatments to be thought provoking.[1] First and foremost, of all the treatments administered in this report, only the topical non-steroidal anti-inflammatory agents (NSAIDs) and topical corticosteroids are FDA approved products, each for reduction of post-operative inflammation. None of the products is approved for the prevention of cystoid macular edema. Further, the corticosteroid and antibiotic injected intraocularly is an unapproved product. The manufacturer of this product has been cited for this product by FDA for violations in its claims of safety and efficacy (https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/imprimis-pharmaceuticals-540678-12212017). Thus, it is not a surprise that the authors note that there is inadequate information existing on the safety and efficacy of this product. Furthermore, at a time when there is concern about contamination in ocular medications, compounded medications do not meet the same quality standards as approved products made by pharmaceutical manufacturers, and thus present a safety risk.[2, 3] The authors present a retrospective, non-randomized study of the intraocular product plus a topical NSAID vs the standard topical ocular use of an NSAID, a corticosteroid, and an antibiotic. There is no apparent explanation of the reason for the selection of one treatment regimen vs. the other for patients. The authors make no a priori power calculation, no definition of clinically significant differences, and no apparent adjustment for the multiple outcome measures (e.g. visual acuity, intraocular pressure, inflammation, etc.). Thus, it seems that this study does not meet the regulatory definition of a "well controlled study" as is required for an approved drug in the U.S. (21 CFR 314.126).

Given these design issues, as well as the differences between treatments in preoperative characteristics of 5%, it seems challenging to interpret the statistically ~5% difference in post-operative complication rate between treatment as “fewer complications”.

I suggest that readers interpret these results with caution.

Disclosure: The author consults for medical device and pharmaceutical firms, but has no stock or proprietary interests.

References

1. Mian OT, Asif H, Sandhu U, et al. Non-Infectious Outcomes of Intravitreal Antibiotic-Steroid Injection and Topical NSAID Versus Triple Drop Therapy Post Cataract Surgery. *Am J Ophthalmol* 2023.
2. Novack GD. Infections from Over-the-Counter Artificial Tears: Implications for Patients and Clinicians. *Ophthalmology* 2023;130 (11):1114-1117.
3. Kuo IC. Extensively Multi-drug-Resistant Pseudomonas aeruginosa in Artificial Tears: Public Health Sleuthing Success but Challenges Ahead. *Am J Ophthalmol* 2023;253:xii-xiv.