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LETTER

A Randomized, Controlled Trial Comparing Tearcare® and Cyclosporine Ophthalmic Emulsion for the Treatment of Dry Eye Disease (SAHARA) [Letter]

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Dear editor

With interest, we read the article titled "A Randomized, Controlled Trial Comparing Tearcare® and Cyclosporine Ophthalmic Emulsion for the Treatment of Dry Eye Disease (SAHARA)" published by Ayres et al.[1] We congratulate the authors for their outstanding work. We do want to draw attention to specific areas in this study where more research is needed and where it would be possible to make improvements.

The study aimed to compare TearCare (TC) to cyclosporine ophthalmic emulsion 0.05% (CsA) for the treatment of dry eye disease (DED). The primary effectiveness endpoints were changes from baseline in tear break-up time (TBUT) and the Ocular Surface Disease Index (OSDI) at 6 months. While the study demonstrated the superiority of TC over CsA in improving TBUT, it did not show a statistically significant difference in OSDI between the two groups at the 6-month primary endpoint. The mean difference between groups was 2.35, with a p-value of 0.9843, indicating non-inferiority but not superiority.

A detailed explanation of the implications of this result is crucial for a comprehensive understanding of the study's primary objective.[2] The study design appears to have a hierarchical fixed sequence for testing the two primary outcomes (TBUT and OSDI). The study considered TBUT first, and if superiority of TC over CsA was established, then OSDI was evaluated. This design could introduce bias and limit the interpretation of results.[3]

The sample size estimation was based on a minimum of 175 subjects in each group to provide at least 90% power to detect a mean difference of 1 second in TBUT between TC and CsA. It's important to ensure that the sample size is adequate for all primary and secondary endpoints, and any deviations from the planned sample size could impact the study's power.[4] A more comprehensive sample size justification that includes both outcomes would enhance the study's robustness.

The statistical analysis used linear mixed effects (LME) models for TBUT and analysis of covariance (ANCOVA) models for OSDI. While these are common statistical methods,[5] the appropriateness of these models depends on the underlying assumptions and the distribution of the data. The exclusion of patients using various topical and systemic medications might limit the generalizability of the study findings to a broader population. The study should carefully justify these exclusions. Safety outcomes were assessed for adverse events, changes in intraocular pressure (IOP), and best-corrected visual acuity (BCVA). It's essential to ensure that the safety assessment is thorough, considering the nature and frequency of adverse events associated with each treatment.

While the study demonstrated superiority of TC over CsA in some secondary outcomes (eg, Meibomian Gland Secretion Score), the interpretation of these findings should be done cautiously, considering the overall study results and the primary effectiveness endpoints.[6] The provided text lacks detailed information on randomization procedures, patient blinding, and other crucial methodological aspects that are essential for evaluating the study's internal validity.[7]

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In conclusion, we believe that acknowledging and addressing this gap could not only enhance the quality and impact of research in this field but also benefit the broader scientific community and those who rely on this knowledge for decision-making and practice. We appreciate the authors and dedication to advancing knowledge in this field and encourage them to consider these suggestions for future research endeavors.

Disclosure

The authors report no conflicts of interest in this communication.

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