Probing with Mitomycin-C in Adults with Nasolacrimal Duct Obstruction

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Dear Editor:

WE READ WITH a great interest Sinha et al.'s article entitled "Efficacy of Probing with Mitomycin-C in Adults with Primary Acquired Nasolacrimal Duct Obstruction," published recently in the *Journal of Ocular Pharmacology and Therapeutics*.¹ They designed the study to determine the efficacy and safety of adjunctive mitomycin-c (MMC) in adults with nasolacrimal duct obstruction (NLDO) during probing. They concluded that "Use of intraoperative MMC improves the success of probing and the overall subjective improvement was in 65% of cases." Although this issue is an interesting topic in ocular pharmacology and therapeutics, there are some concerns in this study that undermine the reported results to make a definite conclusion.

The amount of cases is one the most important queries in this study. We can affirm that if differences between the 2 study groups (MMC and physiological saline) were not significant during follow-ups, it could be because of a small amount of the sample size. Therefore, a sample size was not estimated, and the author should estimate power of this study to rule out this query. Secondly, randomization in an experimental study is critical. The method of their randomization (e.g., computer-based randomization method or other) was not mentioned in their study by the authors. The authors demonstrated the equal distribution of men and women in their study, but they did not state the *P* value to confirm it. Thirdly, according to the Consolidated Standards of Reporting Trials (CONSORT) statement,^{2,3} a participation flow chart is necessary for clinical studies. The authors showed that they enrolled a total of 40 patients into their study, and they excluded those patients who had any history of previous trauma, surgery, recent dacryocystitis, and any factor leading to hyperlacrimation or any other cause for NLDO. However, in the analysis of data, we see 40 patients who enrolled at onset of the study, and no one was excluded, which makes it a necessity for the authors to show the participation flow chart.

In the preliminary study,⁴ the duration of follow-up was 9 months. Therefore, for confirming the conclusion about the efficacy of using MMC in probing of patients with a NLDO period for a 9-month follow-up or up to this period, is re-

quired. The authors performed this prospective study during the 3-month follow-up, which makes concerns to show a definite conclusion. Moreover, the duration of surgery should be equal for cases and controls, but they did not mention it in their study. Finally, the authors did not discuss about why a steady decline in the success rate of the probing was observed in the cases over the 3-month period. We suggest that a study with a larger sample size and with accurate and powerful methods according to the CONSORT statement is required for this topic.

References

1. Sinha, M.K., Bajaj, M.S., Pushker, N., Ghose, S., and Chandra, M. Efficacy of probing with mitomycin-c in adults with primary acquired nasolacrimal duct obstruction. *JOP* 2012 [Epub ahead of print]; DOI: 10.1089/jop.2012.0083.
2. Schulz, K.F., Altman, D.G., and Moher, D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *J. Clin. Epidemiol.* 63:834-840, 2010.
3. Begg, C., Cho, M., Eastwood, S., Horton, R., Moher, D., Olkin, I., et al. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. *JAMA* 276:637-639, 1996.
4. Tsai, C.C., Kau, H.C., Kao, S.C., Hsu, W.M., and Liu, J.H. Efficacy of probing the nasolacrimal duct with adjunctive mitomycin-C for epiphora in adults. *Ophthalmology* 109:172-174, 2002.

Received: January 11, 2013

Accepted: February 19, 2013

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Editor's Note: The corresponding author of the article referenced herein was contacted for a response, but did not reply.

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