Utilization of the CONSORT checklist to enhance clinical trials reporting – A critical analysis

Dear Editor,

We read with interest the article titled "Comparative clinical trial of intracameral ropivacaine vs. lignocaine in subjects undergoing phacoemulsification under augmented topical anesthesia" by Sharma *et al*. published in your esteemed journal recently.[1] We have a few concerns regarding this article and request clarifications from the authors about some of the below-mentioned points.

Firstly, the primary and secondary outcome measures are unclear. As this is the metric based on which we design the entire trial, including sample size estimation, entire statistical plans and outcome interpretations, it is imperative that authors define this well. In our opinion, as this is an analgesia related trial, the visual analog scale (VAS) should have been the primary outcome. Yet, authors do not mention this. Moreover, they do not provide the VAS scores in the two treatment groups at all, either in the abstract or main results, which is unfortunate. We suggest that future studies on similar topics are done keeping in mind the VAS as the primary outcome.

Secondly, it is also not very clear as to whether this is a superiority trial or a non-inferiority trial, or a combination of both. This has implications on how the outcomes are interpreted and translated into patient care and need to be mentioned. The specific methods of randomization, allocation and masking have not been mentioned. Also, the type of anesthesia described during the surgery is augmented topical anesthesia; however, there is no mention in the methodology regarding the nature of topical drug that was used, or its dosage & frequency. This makes it difficult for the readers to understand the exact context of this study and how intracameral ropivacaine or lignocaine supplement topical anesthesia.

Thirdly, from a statistical perspective, we are not sure of how the sample size was arrived at. No previous study or statistic was quoted; the primary outcome on which sample size was calculated is missing and authors don't provide the alpha and beta errors used to calculate the sample size. In the results section, the authors say, "The average VAS scores recorded at the end of the surgery were 2.29 (SD 0.70, Range 2–4) and the distribution was not normal ($P < 0.001$)". What exactly is this *P* value for? What was being compared? Also, the VAS is a categorical variable and should be dealt with as such, where n, % of each of the VAS categories should have been provided. Additionally, as mentioned above, it was imperative to provide VAS in ropivacaine vs. lignocaine groups.

Fourthly, the correlation coefficient for endothelial cell loss in relation to EPT has been given suggesting that the EPT was the driver of the ECD and not the drug. Given that EPT is a strong confounder, multivariable regression analysis is needed to determine the individual effects of ropivacaine on ECD. It may be prudent for authors to consider regression analysis in their papers to neutralize confounders and uncover true associations.

Lastly, the authors mention that the maximum number of subjects felt pain during bisection of the nucleus in both the groups. However, it is somewhat difficult to fathom how patients would know what step was in progress when they felt the sudden burst of pain.

In our humble, opinion, adhering to the use of the CONSORT statement,[2] while presenting results from an RCT, would have gone a long way in improving the quality of the paper. We urge the readership, as well as the reviewers, to use checklists while writing and reviewing papers, so that manuscript quality is improved in years to come.

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Conflicts of interest

There are no conflicts of interest.

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