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Subgroup analysis in the steroids for corneal ulcers trial-reply

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Dulku raises an important point and one that we fully agree with. A clinical trial has 1 primary outcome; all other analyses are either secondary prespecified or post hoc exploratory analyses and should be noted as such.

In our study, the subgroup analysis assessing the effect of corticosteroids in severe bacterial ulcers was prespecified prior to any of the results being available, so the cut points chosen for the subgroups were decided a priori based on clinical interest. We made an attempt to limit the number of subgroup analyses in an effort to reduce the chances of making a type I error. It is still possible that our finding that steroids are of benefit in patients with ulcers of greater severity is not true. However, the fact that this finding was corroborated across various subgroups representing different ways of measuring severity such as worse visual acuity, central location of the ulcer, deeper ulcer, and larger infiltrate increases the credibility of our finding. We completely agree that this result, along with any others that we subsequently find, will need to be confirmed in future randomized trials.

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