The thin line between non-inferiority clinical trials and type II errors

La delgada línea de ensayos clínicos de no inferioridad y el error tipo II

We welcome a randomized clinical trial (RCT) evaluating the sedation strategies for low-risk patients requiring spinal anesthesia. The authors conclude that there is no difference between groups except for higher withdrawal reflex and/or pain from puncture in the group that only received midazolam. In a purely academic spirit, we would like to underscore a few ideas.

1. Ideally, an RCT requires one person to administer the medication and a second one to assess the outcomes. If this is not possible, the effect of the intervention may be overestimated (around 40%). However, we empathize with those authors that sacrifice their own resources for the sake of science.

2. The primary outcome variable – sample size calculation – should be explicit. This is a usual issue with RCT.

3. When designing the essay: were the authors looking for the advantages of combination therapy versus the use of midazolam or on the contrary, were they looking for equivalence among interventions? – equivalence trials require hundreds and some times thousands of participants to avoid type II errors (assuming no difference when in fact there was a difference).

4. We don’t want to look heartless, but would it be unreasonable to consider a placebo group (no sedation) or background music for patients who just need a spinal injection?… sedation enhances the tolerance to the procedure but may deteriorate patient’s cooperation for positioning.

Funding

The authors did not receive sponsorship to undertake this article.

Conflicts of interest

The authors have no conflicts of interest to declare.

REFERENCES


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Please cite this article as: Chaparro LE, Girón-Arango L. La delgada línea de ensayos clínicos de no inferioridad y el error tipo II. Rev Colomb Anestesiol. 2016;44:73.