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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[1] strategies for low-risk patients requiring spinal anesthesia.[2] 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%).[3] However, we empathize with those authors that sacrifice their own resources for the sake of science.[4]
2. The primary outcome variable – sample size calculation – should be explicit. This is a usual issue with RCT.[5]
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).[6]
4. We don't want to look heartless, but would it be unreasonable to consider a placebo group (no sedation) or background music[7] for patients who just need a spinal injection?... sedation enhances the tolerance to the procedure but may deteriorate patient's cooperation for positioning.

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Conflicts of interest

The authors have no conflicts of interest to declare.

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