Reply to the Letter to the Editor: Evidence based clinical practice manual: Patient preparation for surgery and transfer to the operating room theater☆

Réplica a la Carta al Editor: Manual de práctica clínica basado en la evidencia: preparación del paciente para el acto quirúrgico y traslado al quirófano

At the end of 2014 the Colombian Society of Anesthesiology and Reanimation (Sociedad Colombiana de Anestesiología y Reanimación – S.C.A.R.E.) undertook a project that culminated with the publication of four evidenced-based manuals, resulting from a systematic adaptation process.[1–4] Mainly, these manuals aimed to provide a base for clinics and hospitals who did not have access to these documents or the operative capacity to developed them. This was done in order to comply with Colombian regulations.[5] Our goal was never to replace documents previously developed by other health institutions.

Ibarra and collaborators disagree with two recommendations published on the manual on preparing the patient for surgical procedures.[6] Those disagreements are related to preoperative evaluation and correspond to only one of the eight sections of the manual.[1]

The development and writing to the manual was carried out through a process of systematic adaptation that follows Colombian[7] and international guidelines,[8] as adequately specified in the method section of the manual.[1]

We found no justification to disqualify the protocol used for the adaptation[9] based on the (lack of) recognition of the institution that endorsed it, the authors' work experience or publishing background or the lack of support from a scientific society of any particular country. In fact, tools used for the methodological evaluation in terms of validity and risk of bias in primary[10,11] and secondary[12,13] do not take these aspects into account as a source of methodological shortcomings.

To our knowledge, there is no published classification that shows that the American College of Cardiology/American Heart Association (ACC/AHA) 2014 guides[14] are the most relevant academically. This arbitrarily ignores the scientific value of other publications,[15,16] even more so when some authors have criticized the ACC/AHA guides base done empirical evidence.[17,18]

It is very important that the recommendations of the manual be interpreted and applied in the context of the level of evidence and the strength of recommendation following the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) classification.[19]

In the case of preoperative request of electrolytes the manual recommends it while warning that the level of evidence is very low and the strength of recommendation is weak. Nevertheless, other publications make similar recommendations.[16,20] Furthermore, there is evidence of the independent association of electrolyte disorders (hypernatremia and hyponatremia) and mortality after 30 days in patients undergoing elective surgery.[21]

The use of a 12-lead preoperative electrocardiogram (EKG) has been the object of intense debate.[20] The manual recommends[1] adjusting the paraclinical request for cardiovascular assessment to one of the guides currently used internationally.[14,15] Though the 2014 ACC/AHA guides[14] and the 2012 American Society of Anesthesiologists (ASA) guide[16] do not take preoperative EKGs based on age into account, the 2014 European Society of Cardiology/European Society of Anaesthesiology (ESC/ESA) guidelines recommend it in patients over the age of 65, even when risk factors are not present, in patients scheduled for surgeries of intermediate risk.[15] This is based on observational evidence[22] and on the idea that the usefulness of preoperative EKGs goes beyond preoperative risk-determination, as it can be useful to have a base pattern to correctly interpret abnormalities detected during or after surgery that could be interpreted incorrectly as new findings.[23] Furthermore, apart from age, an abnormal preoperative EKG is associated independently with perioperative complications (OR 2.8; CI 95% 1.4–5.8).[24] In patients with coronary disease, the prognostic utility of the EKG is independent from findings in the health record.[25]

As such, this manual continues to be available, and surgical services of health institutions that require it are invited to take it into account as an option to be adopted or adapted.

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Conflict of interest

The authors declare having no conflicts of interest.

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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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