Reviewer’s report

Title: The Analgesic Efficacy and Safety of Peri-articular Injection Versus Intra-articular Injection in One-stage Bilateral Total Knee Arthroplasty: A Randomized Controlled Trial

Version: 0 Date: 29 Oct 2019

Reviewer: Jean-Pierre Estèbe

Reviewer's report:

The authors attempted to clarify whether intra-articular infiltration (IAI) was better than peri-articular infiltration (PAI) for the treatment and/or prevention of the postoperative pain after bilateral TKA. It was an RCT (n = 60).

There is a major ethical problem that the authors must clarify. Indeed, the date of IRB agreement was posterior (Dec 2018) to the study (Feb 2017 to July 2018).

The second major problem is statistical. How do the authors determine the NTT (n = 44) if literature does not report any significant difference? Did they perform preliminary study? What is the question asked; is IAI better than PAI? Hypothesis of non-inferiority? If the hypothesis was the superiority of IAI; why the study was not stopped because of inferiority?

Have the authors used VAS (0 to 100 mm) for the evaluation of pain or NRS (numeric scale 11 points)? Statistic tests are not the same for continuous Vs; discontinuous values.

Many preoperative factors are well known to be predictive of postoperative pain. Also, an ANOVA analysis would be useful (particularly for the preoperative pain.

Usually, IAI had a short duration of action. Discuss the prolongation of action more than 48hrs. Choose Figures 2-5 or tables 2 and 3.

Bilateral TKA surgery is not common practice in my country. We could ask the question of the confounding factor in this bilateral surgery. In the academic physiology of pain, it was said that one pain could reduce the other. So, the difference observed could be exaggerated. Discuss.

The problem with such mixture used for infiltration is too complex to allow to explain the mechanism of action. Such magic bullet cannot work everywhere in the same manner. A placebo group could be useful (particularly for intra-articular infiltration as previously used).
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Unable to assess

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Unable to assess

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
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