Reviewer's report

Title: A prospective, randomized, double-blind, and multicenter trial of prophylactic effects of ramosetron on postoperative nausea and vomiting (PONV) after craniotomy: comparison with ondansetron

Version: 1 Date: 13 April 2014

Reviewer: Mohamed Abdulatif

Reviewer's report:

A prospective, randomized, double-blind, and multicenter trial of prophylactic effects of ramosetron on postoperative nausea and vomiting (PONV) after craniotomy: comparison with ondansetron

A randomized double-blind multicenter study evaluating the prophylactic anti-emetic potentials of ramosetron with two dose levels of ondansetron in adult patients undergoing elective craniotomy. The study hypothesis is original and important. However, I have the following structured comments:

Abstract:
- The discrepancy between the number of patients in the methods and results sections is confusing. It is better to present in the abstract the number of patients who completed the study and were included in the final statistical analysis.
- The first sentence in the results section in the abstract is too long and is difficult to understand.

Methods:
- There is discrepancy between the ASA physical status in the abstract and in the methodology (I-III versus I-II).
- An intracranial pressure > 15 mm Hg was considered as an exclusion criterion. Please explain how you managed to measure precisely the intracranial pressure in all patients preoperatively.
- A Glasgow coma scale < 9 was considered as an exclusion criterion. Would a patient with a Glasgow coma scale of 9 be able to communicate effectively?
- “Temperature was monitored using an esophageal stethoscope maintained at 36 ± 1°C throughout surgery”. How come an esophageal stethoscope was used to monitor and maintain core temperature?!!
- Were patient kept NPO (nothing per os) postoperatively for the 48 hours study period?
- Why an alpha error of 0.0175 was chosen for sample size calculation?
- The minimum calculated sample size of 46 patients in each group was not finally achieved in any of the three study groups (Figure 1, CONSORT diagram).
Please specify the Post-hoc test used to find out which group is statistically different.

Results:
- The incidence of nausea and vomiting in different groups at different assessment time points is grossly duplicated in text and in table formats. It is desirable to point out to the main overall findings or trends in the text part of the results and refer to the appropriate table/s for the numerical values.
- The authors did not comment on the possible difference between the two dose levels of ondansetron.

Discussion:
- There is considerable duplication of results section.
- It is desirable to explain why ramosetron is more effective than ondansetron.
- It is important to specify in the final conclusion statement that patients were managed by total intravenous anesthesia using propofol and remifentanil.

References:
- This section needs careful revision to match the standard reference format adopted by most of the biomedical journals.

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests.