OPEN PEER REVIEW

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- More transparency, constructiveness and tactful comments of the peer review process: leads to an increase in the quality of reviews
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- Education of both authors and new students
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Anesthesiology and Pain Medicine
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Peer Review Report for "Efficacy and Safety of Pediatric Procedural Sedation Outside the Operating Room"

Author(s): Thitima Sirimontakan, Ninuma Artprom, Nattachai Anantasit

Review Timeline:

Submit Date: 16 Jun 2020
Revised Date: 25 Jul 2020
Accepted Date: 5 Aug 2020

Revision (0)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

REFEREE: Reviewer | Revision (0) — 26 Jun 2020

Dear AE,
The design and the topic of the study are such a useful and demanding one.
Also, it's worth an almost long time duration study. But there are some points that need more clarification and explanation.
1. I did not understand why you omitted the capnography as an important and valuable monitoring tool especially outside the operation room anesthesia?
2. Why the study took the age 20 as pediatric range?
3. How did you measure and evaluate sedating? what was the tool and scoring?
4. The Rocuronium is not a sedative medication actually.
5. It is recommended to use a variety of medications to lower the side effect and their doses since we also experience it in the practical field. In my opinion, considering multiple medications as a risk factor would be a bias and what actually impress these patients is their health and overall status not the number of medications.
Thank you

Reza Salehi: Reviewer | Revision (0) — 29 Jun 2020

Dear AE,

According to the article, out of 641 procedures performed
- 15 patients suffered of severe adverse events . It equals 2% .
- In line 127, 0.2% was reported.
- Of course, it is not clear why the number of patients with the complication (SAE) was compared with the total number of procedures, and it would have been better to report the number of SAEs .
With respect

REFEREE: Associate Editor | **Revision (0)** 11 Jul 2020

Dear EIC,
Based on the reviewer's comments this manuscript needs some corrections. Also, suggest to author for considering below reference:
- Pinto Filho W A, Silveira L D H J, Vale M L, Fernandes C R, Gomes J A. Gabapentin in Improvement of Procedural Sedation and Analgesia in Oncologic Pediatric Patients: A Clinical Trial, Anesth Pain Med. 2019; 9(5):e91197.
Kind regards

REFEREE: EIC | **Revision (0)** 11 Jul 2020

Dear Author,
Your article is reviewed by the reviewers carefully. According to their comments, this document needs minor revision. Please follow their comments as requested.
Thanks.

OPEN PEER REVIEW

Revision (1)

Reply to Reviewers

Ideally, the reviewing process can significantly improve the submitted manuscripts by allowing the authors to take into account the advice of reviewers. Author(s) must reply to all reviewers' comments in a separate Word file, point by point. A "**Reply to Reviewers**" document is submitted along with revised manuscript during submission of revised files, summarizing the changes that the authors made in response to the reviewers' comments. The responses to reviewers' comments specifies how the authors addressed each comment the reviewers made.

You can read the authors' responses to the reviewers' comments in the next page.

Response to reviewers' comments

Thank you for your constructive comments and your time in reviewing our manuscript. We really appreciate your suggestion. Red font indicates revised text.

Reviewer:1

Thank you for your comments

Q1. I did not understand why you omitted the capnography as an important and valuable monitoring tool especially during outside the operating room anesthesia?

R1. We agree that the capnography is an important monitoring tool during PSA. As the developing country and financial issue, we did not have capnography monitoring during the PSA at that time. However, all PSA patients were sedated under the certified sedative team with hemodynamic monitoring equipment (continuous SpO2, RR, HR and blood pressure). In addition, previously systematic review study showed no difference in cardiopulmonary complication between standard monitoring and the addition of capnography to standard monitoring for emergency department procedure sedation (ref 17).

We have added "Importantly, our sedation team comprises four staff with limited resources available. A recent guideline from the American Academy of Pediatrics recommends to use the end-tidal carbon dioxide monitor during pediatric PSA (5). However, the systematic review showed no difference in cardiorespiratory adverse events between standard monitoring and the addition of capnography to standard monitoring for emergency department procedural sedation (17). Virtual monitoring device such as capnography was not mandated in this study." in the discussion part. (page 13-14)

Q2: Why the study took the age 20 as pediatric range?

R2: Our center accepted patients from newborn period to the age of twenty. This study included the children which median age was 52 months (range 15 to 119 months).

Q3: How did you measure and evaluate sedating? What was the tool and scoring?

R3: We monitored level of consciousness and responsiveness in all PSA patients. We have also used the Pediatric Sedation State Scale since 2017.

We added "The depth of sedation was assessed by patient's level of consciousness, and responsiveness." in the method part. (page 10)

Q4: The rocuronium is not a sedative medication actually.

R4: We agree with your comment that rocuronium is not a sedative medication. We use rocuronium prior to laryngeal mask airway insertion in patient who underwent flexible bronchoscopy.
We deleted "rocuronium and atropine" in the result (page 11).

Q5: It is recommended to use variety of medication to lower the side effect and their doses since we also experience it in practical field. In my opinion considering multiple medication as a risk factor would be bias and what actually impress these patient's health and overall status not the number of medications.

R5: We agree with your comment. However, our result showed that patients who received more than three sedative medication had statistically significant higher serious adverse events than patients who received less medication after the multiple logistic regression analysis. This finding is similar with the prior study (Kamat PP, et al.) which have shown the risk factors associated with adverse events was number of adjunctive medications.

Reviewer:2

Thank you for your kind consideration and constructive comments

Q1: According to the article, out of 641 procedure performed 15 patients suffered of severe adverse events. It equals 2%. In line 127, 0.2% was reported. Of course, it is not clear why the number of patients with the complication (SAE) was compares with total number of procedures, and it would have been better to report the number of SAEs.

R1: We agree with your suggestion.

We edited "There were 15 children who experienced serious adverse events such as one patient with laryngospasm with cardiac arrest, 7 patients with significant desaturation requiring high flow nasal cannula, or noninvasive positive pressure ventilation, and 7 patients with hypotension (Figure 1)." In the result part (page 12).

We edited "The overall AE incidence was 3.9%, and the SAEs was only 2.7%." in the discussion part (page 13).

Associated Editor's Comments

Q: Based on reviewer's comments this manuscript need some corrections. Also, suggest to author for considering below reference:

Pinto Filho WA, Silveira LDHJ, Vale ML, Fernandes CR, Gomes JA. Gabapentin in Improvement of Procedural Sedation and Analgesia in Oncologic Pediatric Patients: A Clinical Trial, Anesth Pain Med.2019; 9(5):e91197.

R: Thank you for your correction. We have edited as your suggestion in reference part (page 21).

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Revision (1)

Here, you can see the **Reviewers**, **Associate Editors** and **EICs'** comments from the beginning to the end of the revision process.

REFEREE: Reviewer | **Revision** (1) 5 Aug 2020

Dear AE,
The revised manuscript was reviewed and the author has replied to the majority of requested items.
Sincerely

REFEREE: Associate Editor | **Revision** (1) 5 Aug 2020

Dear EIC,
Based on reviewers' comments the revised format ID#106493 was acceptable for publishing at Anesth Pain Med.
Regards

REFEREE: EIC | **Revision** (1) 5 Aug 2020

Dear Author,
The document is reviewed carefully by the reviewers. According to their comments and your revisions as requested, this manuscript is accepted.
Thanks.