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OPEN PEER REVIEW

Effect of Atropine Administration Before Induction of Anesthesia on the Incidence of Delirium and Other Complications in a Post-anesthesia Care Unit (PACU) Among Children Undergoing Surgery: A Randomized, Placebo-Controlled Clinical Trial

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About this report

This open peer review (OPR) report shows the public comments made on this article during peer review, by the reviewers, the associate editor and the editor-in-chief, for every revision round, together with the authors' replies. Comments appear only with the consent of the people who wrote them. Reviewers who chose to sign their report are named; the others are shown as "Referee". Comments are edited for language only, and confidential remarks to the editors are not included.

More about open peer review: brieflands.com/knowledgebase/opr

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1 Original submission

1 comment · 26 Nov 2022

Ana Dragoljub Mandras Reviewer

ACCEPT 26 Nov 2022

The author completed every step of writing in accordance with the proposed CONSORT guidelines. I would suggest that the author repeat the study with larger study groups.

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Revision 1

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Reviewers' Comments:

Reviewer 1:

Author did every step of writting in accordance to proposed CONSORT guidelines. I would suggest to author to repeat the study with a bigger study gorups.

We have written the manuscript according to CONSORT guidelines. Below is the CONSORT checklist.

Reported on page No	Checklist item	Item No	Section/Topic
Title and abstract			
Page 1; line 3.	Identification as a randomised trial in the title	1a	
Page 1; line 11.	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1b	
Introduction			
Page 2.	Scientific background and explanation of rationale	2a	Background and objectives
Page 2; lines 20-23.	Specific objectives or hypotheses	2b	
Methods			
Page 3; lines 2, 16, 17.	Description of trial design (such as parallel, factorial) including allocation ratio	3a	Trial design
Page 3; lines 8-12.	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	3b	
Page 3; lines 8-12.	Eligibility criteria for participants	4a	Participants
Page 3; lines 16-17.	Settings and locations where the data were collected	4b	
Page 3; lines 19-22. And Page 4; lines 3-9.	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5	Interventions
Page 3; line 18 Page 4; lines 10-17.	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6a	Outcomes
-	Any changes to trial outcomes after the trial commenced, with reasons	6b	
Page 3; lines 13-15.	How sample size was determined	7a	Sample size
-	When applicable, explanation of any interim analyses and stopping guidelines	7b	
			Randomisation:
Page 3; line 17.	Method used to generate the random allocation sequence	8a	Sequence generation
Page 3; line 17.	Type of randomisation; details of any restriction (such as blocking and block size)	8b	
Page 3; line 17. Page 4; lines 1, 2.	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9	Allocation concealment mechanism
Page 3; line 17. Page 4; lines 1, 2.	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	10	Implementation
Page 4; lines 1, 2.	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	11a	Blinding
-	If relevant, description of the similarity of interventions	11b	
Page 4; lines 19-22. Page 5; lines 1-2.	Statistical methods used to compare groups for primary and secondary outcomes	12a	Statistical methods
Page 4; lines 19-22. Page 5; lines 1-2.	Methods for additional analyses, such as subgroup analyses and adjusted analyses	12b	
Results			
Page 5; line 4	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	13a	Participant flow (a diagram is strongly recommended)
-	For each group, losses and exclusions after randomisation, together with reasons	13b	
-	Dates defining the periods of recruitment and follow-up	14a	Recruitment
-	Why the trial ended or was stopped	14b	
Tables 1-4.	A table showing baseline demographic and clinical characteristics for each group	15	Baseline data
Page 5; line 4.	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	16	Numbers analysed
Page 5; lines 9-22. Page 6; lines 1-16. Tables 1-4.	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	17a	Outcomes and estimation
Page 5; lines 4-5. Page 5; lines 9-22.	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	17b	
-	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	18	Ancillary analyses
Page 6; lines 5-16.	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	19	Harms
Discussion			
Page 9; lines 4-7.	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	20	Limitations
Page 9; line 8.	Generalisability (external validity, applicability) of the trial findings	21	Generalisability
Pages 7-9.	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	22	Interpretation
	Other information		
Page 3; line 7	Registration number and name of trial registry	23	Registration
Page 3; line 6	Where the full trial protocol can be accessed, if available	24	Protocol
Page 3; line 5	Sources of funding and other support (such as supply of drugs), role of funders	25	Funding

Reviewer 2:
Dear authors, thank you for choosing our journal for your submission. followings are my comments on your manuscript:

SUBJECT:
- The subject is interesting. However, it was better to study other parameters, such as the need for vasoactive drugs during surgery between groups.
We did not evaluate vasoactive drugs, and it was not part of the goals of our study, and unfortunately, we do not have any information to present in the manuscript.
TITLE:
- The title is too long. It's not necessary to mention the type of surgery in the title (lower abdominal surgery).
It has been removed. Page 1; line 1

- Add "other" before "complications" in the title: "… on the incidence of delirium and other complications in….".
It has been added. Page 1; line 2

ABSTRACT:
- The abstract did not convey the concept and findings of the research properly.
It has been rewrite. Page 1; abstract

- In "materials and methods" section of the abstract: it is correct to note that: "70 patients were randomly assigned between two groups" or "35 patients were randomly assigned to each group". It is also recommended to mention other studied parameters in this section (HR, BP, discharges and etc).
It has been revised. Also we added MAP and HR. Page 1; lines 12, 13 and 17-20.

- In "result" section of the abstract, mention other findings (especially changes in the HR) briefly.
It has been rewrite. Page 1; lines 17-22.

INTRODUCTION:
- The introduction clarifies the objectives properly.
Thanks

MATERIALS AND METHODS:
- line 61: Please mention what ASA stands for and give a brief explanation about ASA classification.
It has been revise. Page 3; line 9.

- Separate the inclusion criteria form exclusion criteria.
It has been revise. Page 3; lines 8-12.

- line 67: mention the route of administration of atropine and normal saline (apply this correction in abstract section too).
It has been added. Page 1; line 13 and Page 3; lines 18, 20.

- What was the method of randomization? Please explain more about the randomization, blinding and blocking method of your study.
We included patients in the study using convenience sampling. Then they were divided into two groups using the random allocation software. Page 3; lines 16, 17.

RESULTS:
*- lines 110 to 114 are not clear. In the manuscript, you mentioned that "Intragroup investigation showed significant reduction in delirium severity in both intervention and control groups in PACU (P<0.001 and P = 0.005, respectively)". However, in table 2, these values are written 0.42 and <0.001 respectively (P***). You also mentioned that the P.value of this finding is 0.24, but it is not mentioned in the table 2.*
This was a typo. P value was equal to 0.042. It was corrected. In addition, thanks to the accuracy of the respected reviewer, the explanations related to this table were completely rewritten in the text. Page 5; lines 14-22.

DISCUSSION:
- In line 165, “at the surgery site” should be omitted.
It has been removed. Page8; line 3.

- In line 177, it’s better to omit “as well as a reduction in the propofol dose”, as it was not a statistically significant finding.
It has been removed. Page 8; line 15.

- It is recommended to explain more about yours and others findings in this part.
We added the findings of the current study and their interpretation and comparison with other studies to the discussion section. Pages 7-9; discussion section.

REFERENCES:
- Where are references 11 to 16?! They are missed in this section!
We revised references and added these. Pages 11, 12.

TABLES:
- Please insert the “unit” of measurement in the “intervention and control groups” in tables 2 and 3. For example: N (%) or mean ± SD.
It has been added and highlighted. Pages 13-15; tables 1-4

- In table 3, "drop in spo2, vomiting and laryngospasm" are subsets of “complication”. In addition, “propofol” and “mean propofol dose” belong to a same finding, as well as “fentanyl” and “mean fentanyl dose”. It is recommended to merge these rows similar to what you did in “mean postoperative pain intensity” row.
We modified this table. Page 15;this table.

FIGURES:
- In figure 1, the number of “excluded” items should be 5 (not 0).
It has been edited. Page 13; Figure 1.

- Recheck the spell in the “allocation section, control group”.
It has been edited. Page 13; Figure 1.

OTHERS:
- The text needs substantial English language editing.
The whole text was checked.

> ***Associate Editor's Comments:***
Associate Editor 1:
Your paper has been examined by 2 external reviewers and then re-evaluated in-house.
The reviewers believe that your manuscript is interesting but not publishable in its current form. They have raised a number of points, listed below for your convenience.
Thanks to your valuable comments, the manuscript was revised and revised with great care and based on the opinions of the reviewers.

2 Revision 1

1 comment · 30 Jan 2023

Referee 1 Reviewer

MINOR REVISION 30 Jan 2023

Dear authors,
The manuscript has been edited properly based on previous comments.
Please correct the caption of table 3 --> "Comparison of mean and incidence of delirium between the two groups". It seems that this caption is better: "Comparison of severity and incidence of delirium between the two groups".

3

Revision 2

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

> Reviewers' Comments:

Reviewer 1:

Dear authors,

The manuscript have been edited properly based on previous comments.

Thanks a lot

Please correct the caption of table 3 --> "Comparison of mean and incidence of delirium between the two groups". It seems that this caption is better: "Comparison of severity and incidence of delirium between the two groups".

It has been revised. Page 13; table 3

> Associate Editor's Comments:

Associate Editor 1:

It is clear that the authors have gone to great lengths to improve their manuscript. Nevertheless, we still have a few remarks mainly concerning the paper.

The reviewer's comment was done. With thanks for your attention

3 Revision 2

0 comments

No public comments in this round.