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OPEN PEER REVIEW

Prophylactic Neostigmine Infusion After Radical Cystectomy; Phase I 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.

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1 Original submission

1 comment · 2 Dec 2024

Morteza Fallah Karkan Reviewer

MINOR REVISION 2 Dec 2024

It was a very interesting study and within the scope of the journal. The author(s) made a good attempt to share their experience in managing these cases. However, the following observations can be made:
1) The language and grammar would need to be corrected by someone who is a native English speaker.
2) Please summarize the introduction section of the manuscript.
3) Precisely define all clinical endpoints examined.
4) Complications should be detailed according to the Dindo Clavien system. The severe complication should be described in more detail.
5) How missing data were addressed is not explained.
6) Comment on how the sample size was calculated.
7) In the results, values already presented in the tables are repeated, making the text redundant.
8) The discussion section needs to be more detailed.

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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.

While thanking you for reviewing our manuscript, we appreciate the thoughtful comments provided by the reviewers and would like to address their concerns:

Reviweer1:

It was a very interesting study and within the scope of the journal. The author(s) had made a good attempt to share their experience in managing these cases. However, the following observations can be made:

Reviewer1 comment 1: The language and grammar would need to be corrected by someone who is a native English speaker.

Response: Thanks for your comment. The entire text of the article was checked and approved by a native English editor, and possible mistakes were corrected.

Reviewer1 comment 2: Please summarize the introduction section of the manuscript.

Response: It was corrected.

Reviewer1 comment 3: Precisely define all clinical endpoints examined.

Response:

The outcomes and complications were explained in detail.

Reviewer1 comment 4: Complications should be detailed according to Dindo Clavien system. The severe complication should be better detailed.

Response: Thanks for your valuable comment. We added a paragraph at the end of the “Results” section to categorize the primary therapeutic interventions associated with neostigmine administration using The Clavien-Dindo classification system.

Reviewer1 comment 5: How missing data were addressed is not explained.

Response:

As we selected a small sample size, we did not have any missing data or follow up information.

Reviewer1 comment 6: Comment about how sample size was calculated.

Response:

In Phase I clinical trial the methodologists suggest to select a small number of volunteers to evaluate safety of the intervention without burdening risk to patients. If we will be sure about the safety, we can run the phase II with a larger number of participants.

Reviewer1 comment 7: In results, there are described values that are already in the tables, making reading redundant.

Response: Only the average age of the patients was repeatedly mentioned in the table and text, which we removed from the text. We did not find any other duplicates to remove.

Reviewer1 comment 8: The discussion section needs to be more elaborative.

Response: Thank you for your valuable comment. We have added some sentences to the "Discussion" section to elaborate.

Reviweer2:

Reviewer2 comment 1: The abstract provides a clear summary of the trial, including the background, objectives, methods, results, and conclusions. It specifies the intervention (neostigmine administration), the patient population (post-radical cystectomy), and the main findings regarding safety.

The introduction provides a clear background on the issue of postoperative ileus (POI) and the rationale for using neostigmine. It highlights the gap in research regarding neostigmine's impact on POI after radical cystectomy.

The objective is clearly stated: to assess the safety of neostigmine administration after radical cystectomy and urinary diversion.

The methods section describes the intervention (1 mg of neostigmine administered intravenously 24 hours post-surgery) and the monitoring of drug-related complications. However, **the trial design (e.g., randomized, controlled) is not explicitly mentioned.**

Response: Thank you for your valuable and detailed comment. This study represents the first phase of a clinical trial so there was no control group or any randomization. To ensure it receives the necessary attention we highlighted the relevant sentence at the beginning of the "Methods" section.

Reviewer2 comment 2: The results section provides information on the number of participants (25), their average age, and the outcomes regarding safety.

The conclusion discusses the safety of neostigmine and suggests future research on its efficacy. **The generalizability is not explicitly addressed.** The abstract does not mention any funding or support for the trial.

Response: Thank you for your comment. By adding a paragraph at the end of the article, we explicitly mentioned the generalizability of the results.

We should emphasis that this project was not supported by any grant.

At the end, we would once again like to express our sincere gratitude to the reviewers for their valuable comments and suggestions, which have significantly contributed to the enhancement of our manuscript.

2 Revision 1

0 comments

No public comments in this round.