Author's response to reviews

Title: Comparison of the efficacy and safety of URSL, RPLU, and MPCNL for treatment of large upper impacted ureteral stones: A Randomized Controlled Trial

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Response to Reviewers' comments

Dear Dr. De Nunzio,

We thank you for your careful consideration of our manuscript. We appreciate your response and overall positive initial feedback, and made modifications to improve the manuscript. After carefully reviewing the comments made by the Reviewers, we have modified the manuscript to improve the presentation of our results and their discussion, therefore providing a more complete context for the research that may be of interest to your readers.

We hope that you will find the revised paper suitable for publication, and we look forward to contributing to your journal. Please do not hesitate to contact us with other questions or concerns regarding the manuscript.
Reviewer #1

The present manuscript has the aim of comparing three different surgical procedures in patients with large upper impacted ureteral stones. The trial is interesting and not present in the actual litterature. It is a Randomised Clinical Trial.

The Title is informative and clearly states the aim of the study and the type of study.

Response: We thank the Reviewer for taking time to review our manuscript and for the comments.

Abstract: The abstract should state the main objective of the study in the backround. In the methods it should be stated that the patients were allocated with a 1:1:1 ratio. Trial registration is missing.

Response: We added the objective to the background. We added the randomization to the Methods. Since all three interventions are already approved by health care authorities all over the globe and all three are generally considered suitable for large upper impacted ureteral stones, the trial was not registered.

Background:

In this section the authors should explain the rational of the study. It is not clear why making a three way comparaison? The authors should better describe the need of this RCT. They should mainly concentrate on the results of the trials comparing these techniques and systematic reviews.

Response: We agree with the Reviewer. We improved the rationale of the study.

Methods:

I have some concerns regarding the methodology of the study. Number of men and women should be in the results section.
Response: It was moved to the Results.

Line 112 the last phrase of the paragraph is not needed.

Response: It was deleted.

Including patients with radiolucent stones may be a bias.

Response: The Reviewer is right. In fact, these patients were not included in our study because they are not eligible to these procedures at our center. It was clarified.

I have some concern regarding the use of a KUB to define stone free patients, why was 4 mm used as a cut off?

Response: We thank the Reviewer for the comment. In fact, according to the Chinese guidelines of medicine, stones of <4 mm are considered to be able to pass by themselves. Therefore, obtaining fragments <4 mm was considered successful.

How was the patient reevaluated at 6-12 months?

Response: The patients were followed-up at 6 and 12 months to ensure that no novel stone was forming and that there was no stenosis.

Some information are missing:

- Who performed the procedures.
  
  Response: All procedures were performed by the same physician.

- Describe when and how stents and tubes were removed.
  
  Response: One month after surgery, the patient returned to the hospital to remove the double-J stent and to be reexamined by KUB film.

- Sample size calculation and Power analysis of the study is missing.
  
  Response: Indeed, no power calculation was performed before beginning the trial and the sample size was based on convenience. Nevertheless, a post hoc power analysis based on the primary outcome revealed that our experiment had a 95% power to detect the differences in the primary outcome with a two-tailed α=0.05.

- Blinding data is missing? Radiologist, operator doing the follow up visit?
  
  Response: We thank the Reviewer for the comment. Radiologists were blind to patient data during all follow-up examinations. It was added to the Methods.
Give the definition of Stone Free rate only success rate has been defined.

Response: Stone clearance was defined as the absence of stone debris on the KUB film, and the stone clearance rate was calculated.

Results

Results are well written and tables are clear. These are my concerns:

- In table 2 MPCNL group how come 48/50 are stone free but 3/50 had auxiliary ESWL?

Response: The clearance rate was calculated based on the results after ESWL. It was clarified in the Methods.

- Data on number of patients followed at 6 and 12 months should be included as well as the data obtained from these patients as already mentioned earlier.

Response: All patients were followed up at 6 and 12 months.

Discussion

The authors describe each single procedure with pro and cos. In this section it would be useful to describe the different comparisons present in the literature. A recent meta-analysis has been published by Torricelli et al and should be included in the discussion.

Response: We agree with the Reviewer. It was added.

In the limitation part I would add the lack of a postoperative CT.

Response: We agree with the Reviewer. It was added as a limitation.

Reviewer #2

The p values even not significant (NS) have to be reported in the paper.

Response: We now provide the exact P-values.

Tables have to be uploaded a part not in the main text-file.

Response: The tables are now in a separate file.
The conclusion of the study must be correctly written giving the summary of the study results. The conclusions did not clearly support any procedure, and the reader cannot evaluate which is the better solution in case of large upper impacted ureteral stones.

Response: We agree with the Reviewer. The conclusion was edited.

I suggest a minor essential manuscript revision in the light of my comments.

Response: The manuscript was proofread.

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Declarations

- Ethics approval and consent to participate
- Consent to publish
- Availability of data and materials
- Competing interests
- Funding
- Authors' Contributions

- Acknowledgements

  Response: The declarations are already presented at the end of the manuscript.