

Author's response to reviews

Title: Effectiveness of Vasectomy Using Cautery

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Response to reviewers' comments

Original manuscript title: Failure Rate of Vasectomy Using Cautery

Revised manuscript title: Effectiveness of Vasectomy Using Cautery

Authors: Barone, et. al.

Reviewer: David J Handelsman

1. Fascial interposition is already part of the Cox model, since site is part of the model. Given that the sites used different occlusion procedures, and that there might be other differences among the sites, a site variable is a better variable to assess any effect differences among the 4 study sites. One can interpret the results associated with site as related to fascial interposition, but this is speculative. We have revised what was the second to last paragraph in the discussion in order to include more on this.

2. We had explored using four age groups for the Cox models and the Kaplan-Meier estimates, but in the end choose the two age group split we presented in the manuscript. There was little additional information gained by adding the extra subgroups and the results become more complex to present/read with the additional subgroups and it seemed unnecessary. Also, the split at 35 is in line with other papers we have presented which allows for easier comparisons among papers. We added a sentence to the statistical methods to explain why we chose the two age groups.

3. We were not clear what was meant by 'baseline rates' in this comment. We interpreted the comment to be suggesting that some specific examples (such as risk at particular times say 12 and 24 weeks) be added. For age, detailed information is found in table 2. We added some text to the results to help clarify this. "We have also added a sentence on the HRs for the centers."

It is not readily feasible to add any illustrative examples for cumulative number of ejaculations. There are no K-M estimates associated with this variable because this was included in the model as a time dependent covariate. Participants cannot be split into groups in a simple manner as for age and center. The groups are re-defined at each time point depending on their number of ejaculations each time.

Finally, we have clarified that HR is hazard ratio, not hazard rate.

4. We have added a final paragraph to the discussion section to address the issue of possible recruitment bias.

Regarding the 12 week recommendation presented in the discussion section, we are unable to comment on how specific aspects of the occlusion techniques used in the study (use of fascial interposition for example) might impact on this for the reasons described in the response to the first comment above.

5. Although in general semen analysis data are non-monotonic, we used these data as a dichotomous outcome for this study. The decision rule to define success was once a study participant reached severe oligozoospermia (or azoospermia). Once a participant was declared a success or failure they could not go back. So, in essence the semen analysis data were used in a monotonic way.

6. We have changed the title to: “Effectiveness of Vasectomy Using Cautery.”

Reviewer: Ilpo Huhtaniemi

1. We have changed the title of the manuscript as noted above.

2. Figure 1 has been revised to include mention of which centers used fascial interposition, and the legend has been edited to include a description of the technique.

3. The overall success rate is actually not better for younger men, but rather they reach success sooner than older men. We added some clarifying text to the results paragraph on the covariate analysis.

4. We have decided not to include the additional information on sperm counts in relation to number of ejaculations.

5. We revised the last paragraph of the discussion section to include mention of the WHO study and added the citation in the reference section.

Reviewer: Jay Sandlow

1. There was no attempt to standardize the occlusion method used at the sites as this was an observational study. We have made this clearer in the methods section under “Vasectomy Procedures and Follow-up”.

2. The difference in failure rates between the fascial interposition RCT we conducted and the failure rates reported here is presumably due to the fact that cautery is a more effective occlusion technique compared to ligation and excision (either with or without fascial interposition). We have recently submitted a manuscript applying the same definition of failure across the two studies in order to compare failure rates for ligation and excision with fascial interposition to cautery.

3. Both references #1 and #8 are now published. The citations have been updated.

