Author's response to reviews

Title: Vasectomy surgical techniques in South and South East Asia

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Re: MS 7922525945995184 - Vasectomy surgical techniques in South and South East Asia

Dear Editor,

We are pleased to provide an edited version of our manuscript entitled *vasectomy surgical techniques in South and South East Asia* taking in accounts the reviewers' comments. Our responses to reviewers' comments and details of the modifications made in the manuscript follow. We hope this revision will be to your convenience.

Responses to Robert Brannigan's comments

We first thank Robert Brannigan for his positive comments regarding our paper. As recommended we corrected the grammatical errors in Tables 3 and 4.

Responses to David J Handelsman's comments

We also want to thank David J Handelsman for his thoughtful review. We have responded to his compulsory revisions suggestions as follows:

General Comment

Handelsman commented that : "The manuscript is mainly a field progress report on a program to introduce variations on vasectomy methods… It is an uneven blend of observations…plus intervention…without evaluation of outcome."

We wish to clarify that although some non governmental organizations funded the project in part (see cover page of the article), this qualitative inquiry was not conducted as part of any current structured program and cannot be considered as a "progress report on a program". Furthermore, Handelsman's comment about "intervention…without evaluation of outcome" implies that we carried out trial(s) on the introduction of new vasectomy methods. Indeed (page 9) " Audio-visual material on vasectomy techniques using cautery and FI was presented and hands-on demonstrations were performed by one author (ML) according to the local situation and interest." and (page 15) "About 20 vasectomies were performed involving local providers using the cautery devices brought from America". However, our focus was on qualitatively assessing (page 7) "the factors that could facilitate or obstruct the introduction of vasectomy occlusion techniques using cautery and FI". In that sense, we performed a meticulous evaluation of the outcome of interest for this study.

Major Compulsory Revisions

1. Handelsman states that: "an important emerging concept …is making a consistent distinction between failure rates based on a pregnancy … and those based on sperm output… In several places, the manuscript blurs this important distinction and should be revised…"

In our initial submission, we were careful to make the distinction between occlusive and contraceptive efficacy whenever we wrote about vasectomy failure:

- "The risk of **occlusive** failure with this technique…" (p 4)
- "The risk of **contraceptive** failure may also be unacceptably high…" (p 4)
- "Using a **definition of failure** as > 5 million motile sperm / mL at 14 weeks…" (p5)
- "Using a definition of **early failure** as >10 million sperm / mL at 12 weeks..." (p5)
- "…from numerous large case series showing that the **occlusive** effectiveness of cautery…" (p5)
- "…one center reported a **pregnancy rate** as high as 4%." (p 15)
- "…In Nepal, **vasectomy was repeated** in 4 (1.6%) of 263 men…"(p 15)
- "…In India, 3 (1.2%) **pregnancies** were encountered in 258 vasectomies…"(p15)

However, we found in two instances that the distinction was not made and we corrected the manuscript:
"…the failure rate **based on repeated vasectomy** was said to be 2 to 3%" (p 15)
"…adding FI to LE resulted in **no repeated vasectomy** in 130 vasectomized men…" (p15).

We are appreciative of Handelsman noting the importance of being clear about how failure is defined.

Please note that we are aware of the literature on how to assess vasectomy failure[1-8], but the focus of this paper is not on vasectomy effectiveness. Some data on vasectomy effectiveness were indeed described but only as background information to explain relevance of the study (p 4 and 5), and to briefly describe which resources are available in centers visited regarding further evaluation of performance if introduction of thermal cautery and FI were to be considered (p 15).

2. Concerning the representativeness of sampling, Handelsman suggests that "some caveats on representative sampling within countries might be required". On page 18 and 19, we had highlighted the limits of our study related to our sample, however, as Handelsman recommended, we provided more details on this aspect of our study.

3. Regarding the issue of regret and reversibility is indeed a very important point. We are now conducting an assessment of the needs perceived by patients and physicians

for decision aids regarding male sterilization, based on the Ottawa Decision Support Framework (http://decisionaid.ohri.ca). However, regret and reversibility is not the focus of the present study, and we do not believe we should discuss this issue. Concerning open-end vasectomy, to our knowledge, there is insufficient evidence supporting the fact that open-end increases ease of vasectomy reversal. Moreover, FI is no much more compatible with open-end than cautery is. Testicular end may be left open with any technique of occlusion performed on abdominal end of the severed vas. The supporters of the open-end technique usually combined FI and cautery to occlude the lumen of the abdominal segment.[9, 10]

4. Concerning our enthusiasm for cautery which is said to be based on no real evidence, this is partially true. We agree that there is no randomized trial on the specific subject but there are methodology sound studies suggesting that combining thermal and FI is associated with the highest occlusive effectiveness.[6] In fact, we wrote: "Though the results are encouraging for the use of cautery in vasectomy, they must be interpreted with caution based on this non-randomized comparison. In addition, while FI was showed to be important in improving vasectomy occlusion success when LE are the primary occlusion method, this exploratory study of cautery cannot definitively confirm that FI is as useful when cautery is used as the primary occlusion method. However, these findings support the results from numerous large case series showing that the occlusive effectiveness of cautery, especially when combined with FI on the prostatic end, is high, with failures well below 1%."

We are fully aware of the limits of the evidence, and we believe that in fact we were not overenthusiastic about thermal cautery. We clearly stated:

"Further studies assessing the effectiveness, safety, and feasibility of implementation are needed before thermal cautery combined with FI is introduced in Asia on a large scale. Until thermal cautery is introduced in a country, vasectomy providers should practice LE with FI to maximize effectiveness of vasectomy procedure." (p 2)

"Although, cautery combined with FI appears to be much more effective than LE combined with FI, firm and conclusive evidence of the superiority of one technique over the other are still lacking.[6] Moreover, introducing cautery with FI may be associated with the same implementation barriers encountered with introducing FI on a large scale. In addition, new direct costs (cautery devices and batteries) and indirect costs (training, processing, and maintenance of the devices) would have to be considered before implementing cautery on a large scale."(p 19-20)

5. There is much difference between electro-cautery and thermal cautery regarding the devices and their utilization, and possibly the outcomes associated with these two types of occlusion technique[11]. We believe the adjective thermal should remain when describing this specific technique.

6. We corrected the errors in abstract, page 8, 12 and also 18 (not mentioned by the reviewer.

Discretionary revision

7. The results section is indeed longer than usual quantitative reports but considering the qualitative design of the study implying a lot of narrative, we believe the length and scope is appropriate. Narrative on reasons for low uptake of FI, for example, is indeed a result of this qualitative inquiry.

Details of the modifications in the article

Cover page, Jeevan Bhattarai[7], Ganesh D Bhatt[7],

P 2. Abstract methods: … 2004, 3 to 6 major vasectomy

P4 "…After more than 5 years of follow-up, a similar failure rate (4.1%) was also found in Vietnam.[7] In a study conducted in China, among 1,555 couples using vasectomy as a contraceptive method, the risk an unplanned pregnancy was 9.5% after 5 years.[8]"

P8 bottom …Visits to 3 to 6

P10 bottom …. On December 2002, 309 NSV courses had been organized …

P 10 bottom … annual basis by the NSV Surgeons of India (http://www.nsvsi.com).

P11 middle … due to increased access to other contraceptive…

P 12 top … Overall 21 vasectomy centers

P14 middle … mandatory step of vasectomy. There is no mention

P 14. bottom …, the failure rate based on repeat vasectomy was estimated to be 2 to 3%.

P15 to … resulted in no need to repeat vasectomy in 130 vasectomized

P15 bottom …was tested in a suburban mobile camp in Nepal and proved to be feasible.

P 18 ….South East Asia. However, we included two strategies that we believe were sufficient to achieve our objectives and to provide a sound basis for planning future operational research addressing the issues. First, in each country key-informants from various levels of the health care system related with male sterilization program were interviewed. To the exception of Thailand, this included the national authorities who are responsible for the vasectomy program, and who could provide an overview of the global situation in each country. Second, a convenience sample of about 21 urban and rural vasectomy centers from various Asian countries was visited, including participation in daily clinical activities in most centers. Although these centers many not be fully representative of all vasectomy centers in Asia, there were very strong national standards

regarding how family planning services must be provided in the countries visited. We thus expect much less variations in techniques used in the countries visited than in North American or European countries.

Table 2 Nepal 1 in FI column Yes instead of ±

Table 3 and 4 Belief that current techniques are effective

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