Author’s response to reviews

Title: Effect of Female genital cutting/mutilation; Types I and II on sexual function: case-controlled study

Authors:

Sahar Ismail (saharsotohy@gmail.com)
Ahmad Abbas (bmr90@hotmail.com)
Dina habib (dina.habib50@aun.edu.eg)
Hanan Morsy (hanan_morsy2003@yahoo.com)
Medhat Saleh (medhatelaraby75@yahoo.com)
Mustafa Bahloul (bahloolmm@yahoo.com)

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Author’s response to reviews:

Response to Editors:

Dear Dr. Miller:

Thank you for considering our paper. We revised the manuscript and did all the requested changes and we hope to get our chance in your prestigious journal.

Comment # 1: Particularly important to revise is to mention in both discussion and conclusions how difficult it is to generalize from such as a small sample.

Reply: Done (page 11 line 18 & page 12 line 12)

Comment # 2: There is a question of repetition of words/phrases/sentences from a published article: Alexandria Journal of Medicine (2016) 52, 55. So if you used this as a source, please be sure to note similarities and change or use direct quotes and cite.

Reply: Done
Response to reviewers

Thank you for your valuable notes, we did address them all:

Reviewer #1 comments:

Comment # 1: You should stated that you include only women who knows to read and write as you obtained written consent from all. Non inclusion of illiterate women may be form a bias as high percent of women in Upper Egypt are illiterate.

Reply: a- You are right. We did exclude illiterate women from the study. Not because of the consent but because FSFI questionnaire needs to be answered by the women themselves. (this is not only a basic feature of the questionnaire (Rosen R, et al. J Sex Marital Ther. 2000;26:191-208) but also we believe that we will get the closest answers to truth if the women answered the questions by themselves; because of the sensitive issue of the study. However one of the female investigators was available at the interview room in case women need to clarify anything.

b- We believe that exclusion of illiterate women did not affect our results significantly because: 1- The prevalence of FGM is not our research question. 2- The decision of FGM is taken by the parents of the women and not the women themselves, so illiteracy of the parents is the affecting factor (beyond the scope of this paper).

- We added a clarification of this exclusion in the methods section (page 6 line 9).

Comment # 2: I think that inclusion of type III and IV; in comparison with type I and II will enrich your study (as I know that type 3 is common in upper Egypt).

Reply: Actually we didn’t meet any case with type III or IV in the study sample. Those types are found rarely in Egypt in the present time (3) (already mentioned in the background section page 5 line 2). We think there may be few cases in the south of Egypt (Aswan and Nubba) which is 500 km south of Assiut.

Comment # 3: In result section, table 3 why you did not use post Hoc test with One Way Anova and just comment on findings of post Hoc??

Reply: According to our statistician; the principle of Post Hoc test is the same as t-test; both aim to compare two means of quantitative parametric variables. They both give the same results.

Comment # 4: In discussion section please remove all paragraphs that correlate between this act and Islam.(page 8,9 and 12)
Reply: We think that the religious thoughts in our population are one of the strong reasons to continue this practice up till now. We did remove the requested paragraphs (page 9 line 3 and page 12 line 6). However, this point could be left to the editor if she feels that removal of those paragraphs will not affect the readability of the paper.

Reviewer #2 comments:

Comment # 1: Did these women give their informed consent to be examined or to fill the questionnaire or both?

Reply: The informed consent was for both items; questionnaire and examination.

Comment # 2: Is there a unit or clinic for routine checkups at your Hospital!!!!!!!!!!!!!!

Reply: No, we don't have units specific for routine check up in our hospital, but check up is usually occurring in several different clinics such as: internal medicine clinics, vaccination clinics and family planning clinics…etc. Participants were recruited from all these clinics in addition to the dermatology clinic.

Comment # 3: How many women have been invited to participate in the study? How many women out of these agreed to participate?

Reply: We invited 245 women in the FGM group during the period of the study, 197 women agreed to participate (80.4% response rate). We invited 233 women in the control group during the period of the study until equal number of women (197) agreed to participate (84.5% response rate).

- We added this clarifying sentence in the results section (page 7 line 6).

Comment # 4: What is the role of the gynecologists in the study if women were recruited from Dermatology clinics?

Reply: The main role of gynecologists was vaginal examination of all women to detect the type of FGM, which is one of the strength points of this paper as several previous studies depend on the history only. Some of them also helped in women recruitment, in addition to their role in the data analysis and paper drafting. (A detailed description of the author contributions has been already provided, page 13 line 13)
Comment # 5: I do think that this is an analytical cross sectional study and not a case control study.

Reply: According to our statistician: the study design is case control, as cases were defined as circumcised woman while controls were defined as non circumcised women, so from the start definition of cases and control were clear. After recruitment of cases according to the pre-determined inclusion criteria and genital examination to confirm the type of circumcision as mentioned in the methodology, a matching group of non circumcised control was enrolled, and then we collected data retrospectively in both groups, to compare sexual functions between the two groups. This design is the typical design for case control study which is analytical study design and not descriptive as cross sectional design. Also in cross sectional design we first recruit study participants without any concern who is circumcised or not and then divide them into circumcised and non-circumcised. This is not the situation in our study as from the start we recruited participants as cases and control.

Comment # 6: Authors did not mention on what basis did they estimate the sample size. Why did they chose 197 in each arm of the study?

Reply: Sample size was calculated by Open Epi Info (Kelsey et al., 1996) for case control study design with two sided confidence interval 95%, power 80 %, ratio of controls to cases 1, controls exposure 55 %, cases exposure 75% and odds ratio 2.45.(Elnashar et al. 2007; Hassanin et al. 2010; Ismail et al. 2012; Ibrahim et al. 2013). The calculated sample size by Fleiss with continuity correction (CC) is 99 for cases and equal number 99 for control with total number 198, but we raised the sample to 394 women (197 in each limb) to get more informative data and increase the power of the study.

- Elnashar M et al., Female sexual dysfunctions in lower Egypt. BJOG 2007; 114(2):201–6.
- We added a paragraph in the methods section to clarify sample size determination and their references were added (page 5 line 23)

Comment # 7: In addition, if they manage to recruit 197 women who had FGM/C in a period of six months (duration of the study), it would be very very difficult to recruit the same number of women without FGC/M during the same period. According to the latest EDHS in 2014, 92% have been circumcised. This means that <10% of women did not have FGM. This means that they will need at least 2 years to find this 197 women without FGM

Reply: Recruiting non-circumcised women was actually more difficult than recruiting circumcised women because of their limited number. (This was already mentioned in the discussion: page 11 line 20). However, group focused efforts were done to recruit them in seven months (December 2015 to June 2016) which is not short period putting in mind that Assiut University Hospitals are a group of referral hospitals that serve several governorates with hundreds of patients attending the outpatient clinics daily.

Comment # 8: I think it is better if the authors can put/mention the items of Female Sexual Function index in the manuscript.

Reply: There is already a paragraph in the methods section (page 6 line14) mentioning the 6 domains of the FSFI questionnaire and a reference to its Arabic version used in the study. Putting the detailed items will be too long.

Comment # 9: It is not clear if the FSFI was self filled or was interview filled? If it was interview filled, who did the interview?

Reply: The FSFI was self filled (It is not only a basic feature of the questionnaire (Rosen R, et al. J Sex Marital Ther. 2000;26:191-208) but also we believe that we will get the closest answers to truth if the women answered the questions by themselves; because of the sensitive issue of the study) However one of the female investigators was available at the interview room in case women need to clarify anything and to make sure all items were answered.

- A clarifying sentence was added to the methods section (page 6 line 13)

Comment # 10: It is very surprising to find FSD in about 2 thirds (64.5%) of the study population who had no FGM (N. women) compared to 83.8% in the study group. This brings us back to how accurate was the FSFI filled? and did these women actually understand that questionnaire?

Reply: 1-This high prevalence of FSD is not surprising as it is consistent with the prevalence reported in several previous studies in Egypt and Saudia Arabia [15-18].
2- We did all the precautions to guarantee getting the closest answers to truth and thus getting the most accurate scores:

a- We used FSFI which is a standard validated questionnaire used worldwide.

b- A detailed explanation of the study and the questionnaire items was given to all participants before filling the questionnaire.

c- Women answered the questions by themselves in a private room without mentioning their names or any identifying information

d- One of the female researchers (SI, HM) was available to answer any question, and to make sure all items were fulfilled without any interference in the answers of participating women.

3- It is worth mentioning that one explanation of the high FSD % is that FSFI total score divide participants into women with FSD and women without FSD. But it doesn’t help classifying women with FSD into grades (e.g. Mild FSD or severe FSD). So all women even with mild dysfunction will be included in FSD percentage. However FSFI is the most acceptable standardized validated questionnaire that is used worldwide (besides, criticism of FSFI is beyond the scope of this paper)

4- We do agree that the questionnaire answers may be somewhat subjective and this problem usually present in any questionnaire based research. – This limitation was already discussed in detail in the discussion section (Page 11 line 23)

Comment # 11: It was also surprising not to find a difference between type 1 and type 2 in FSFI
Reply: This finding is one of the very important findings in our study. We don’t however find it surprising. The main differences between Type I and II FGM (according to the WHO) are involving labia minora and labia majora, while the clitoris injury is involved in both types. Other factors included in the process of FGM as psychic trauma and infection are also present in both types.

Comment # 12: I urge the authors to review their results that 39% of women with FGN 22.8% of the control have a frequency of intercourse < once per week. The need to check that was this due to absentee of the husband or actually due to FGM. If such women actually do suffer, the male partners have their own needs.
Reply: We appreciate your advice however, these percentages are correct for ≤1 time/week. Similar results were found in two earlier studies in apparently healthy women in Egypt: Elnashar et al. 2007, reported that 26.2% had sexual intercourse for ≤1 time/week, while Hassanin et al. 2010, reported that 29.28% of women had sexual intercourse for <1 time/week, and 46.76% of women had sexual intercourse for 1-2 times/week.

Comment # 13: Tests of Significance should be mentioned below figures and tables 1,2.

Reply: Done

Comment # 14: It is quite difficult to withdraw conclusions from such a very small sample. It is good brainstorming study that draws attention to a very sensitive issue.

Reply: Although we included double the calculated sample to increase the power of the study, which should be good enough to answer the research question, we do agree that larger sample and rather, multiple centers' study will better address the problem.

- We added this sentence to the conclusion: Although it is difficult to withdraw generalized conclusions, the findings of this brainstorming study draw attention to a very sensitive issue (page 12 line 12).