Erectile function in circumcised men: Lusaka, Zambia

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MMED-Family Medicine

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Declaration

I, Dr Evans Chinkoyo the undersigned, hereby declare that the work contained in this assignment is my original work and that I have not previously submitted it, in its entirety or in part, at any university for a degree. I also declare that ethical approval for the study was obtained from the Health Research Ethics Committee of Stellenbosch University (Reference number: N10/11/387).

Signed:

Date:

Abstract:

Introduction*:* Evidence from 3 randomized controlled trials in South Africa, Uganda and Kenya showing that male circumcision can reduce heterosexual transmission of HIV from infected females to their male sexual partners by up to 60% has led to a dramatic increase in the demand for circumcision in most African countries hard-hit by the HIV pandemic. Among communities where circumcision is not routinely practiced, this has created anxieties around possible deleterious effects of circumcision on erectile function. Most studies that have been conducted to explore the relationship between male circumcision and erectile function have yielded conflicting results (6-8, 14, 15). This study aimed to compare erectile function in circumcised and uncircumcised men in Lusaka, Zambia.

Aim/objectives*:* To compare erectile function in circumcised and uncircumcised adult men aged 18 years and above in Lusaka, Zambia.

Methods:

Design: In this cross sectional survey, a total of 478 participants (242 circumcised and 236 uncircumcised) comprising patients, health workers and other men visiting the 4 study sites between 1/6/13 and 30/9/13 were handed the IIEF-5 questionnaire to complete.

Information about participants' age, relationship status, education level, smoking, alcohol use and medication use was also collected. The study included sexually active men older than 18 years living in Lusaka, Zambia. Males younger than 18 years, those lacking sexual experience and, those with serious mental and physical conditions were excluded from the study. *Setting*: Outpatient departments of 4 primary health care facilities in Lusaka, Zambia.

Main Outcome Measure: Erectile function scores were calculated for the 2 groups. Normal erectile function was defined as an IIEF-5 score ≥22 (out of a possible maximum score of 25) points.

Results: Circumcised men had higher average erectile function scores compared to their uncircumcised counterparts, U=23062.50, Z=3.64, p<0.001. The prevalence of ED was lower in circumcised men (56%) compared to that in uncircumcised ones (68%), χ^2 (N182) =7.52, df=1, p<0.05. Erectile function scores were similar in those circumcised in childhood compared to

those circumcised in adulthood, χ^2 (*N*242) =0.29, df=1, *p*=0.59. The groups did not differ significantly in age, relationship status, smoking, alcohol use and medication use. However, a statistically significant difference was observed in education levels with the circumcision group showing higher levels, χ^2 (*N*478)=19.05, df=6, *p*<0.005.

Conclusion: The higher erectile function scores in circumcised men observed in this study show that circumcision does not confer adverse effects on erectile function in men. Circumcision can thus be considered without concern about worsening erectile function. However, a prospective study in a similar cultural context is needed to confirm these findings.

Introduction

Male circumcision is increasingly being accepted as an additional viable strategy for the prevention of Human Immunodeficiency Virus (HIV) transmission from infected females to their uninfected male partners. Three randomized clinical trials in South Africa, Kenya and Uganda have demonstrated that male circumcision can provide partial protection for heterosexual men against HIV infection from infected female sexual partners [1]. This has prompted Ministries of Health in most countries hard-hit by the HIV pandemic to consider male circumcision as an additional strategy for prevention of HIV infection. In Zambia, a strategy to circumcise up to 2.5 million males between the ages of 13 and 39 by the year 2020 has been launched and measures put in place to ensure its success [2]. Most countries in Sub-Saharan Africa have also introduced plans to circumcise up to 80% of eligible males in their populations [3]. The expected outcome of these interventions is a reduction in new HIV infections.

While emphasis is currently on prevention of HIV infection, there are several ongoing debates around the safety, relevance and human rights aspects of male circumcision [4, 5]. Most of the discussions are centred around children who are unable to consent to the procedure on their own but have to rely on their parents or guardians to make decisions on their behalf.

Questions are also being asked about the effect of circumcision on sexual function and the ability of a circumcised man to initiate and maintain a satisfactory erection for normal sexual intercourse. Normal sexual function requires intact genitalia, good blood flow to pelvic organs, an intact neuro-endocrine system and a healthy psychological state [6]. Male circumcision interferes with the integrity of the genitalia by removing the foreskin together with its nerves and

blood vessels. This partial denervation of the penis and the subsequent keratinisation of the exposed glans can potentially cause sensory changes resulting in altered ability to experience tactile stimulation, which is necessary for initiation and maintenance of a penile erection. There have been several attempts to explore the relationship between male circumcision and sexual function but they have yielded disparate results. In a study of the effect of circumcision on erectile function, penile sensitivity, sexual activity and satisfaction, Fink [7] observed, among other findings, that adult circumcision appeared to result in worsened erectile function and decreased penile sensitivity. Several studies of this nature have been published and they have yielded similar results [8-10]. Other studies also reported reduced glans sensitivity following circumcision but without any difference in erectile function [11, 12]. A review of international evidence for benefits and risks of infant circumcision [13] concluded that male circumcision had no adverse effect on sexual function, penile sensation or satisfaction. In a randomized controlled study conducted in Uganda [14], circumcision did not appear to have any adverse effects on sexual function and satisfaction in men. However, this study had limitations in that blinding was not possible and therefore there was a possibility of both interviewer and reporting bias by participants.

Another study that was looking at the effect of circumcision on male sexual function [15] also observed that circumcision did not have clinically important adverse effects on male sexual function in sexually active adults who underwent the procedure. This same result was echoed by systematic reviews and a meta-analysis of scientific literature on this subject which concluded that male circumcision has no adverse effect on sexual function, sensitivity, sexual sensation, or satisfaction [16, 17]. This lack of consensus at international level called for local exploration of the subject in order to establish whether similar results could be reproduced in Zambia, a country with a different cultural context. Since there had not been any formal studies to establish the prevalence of erectile dysfunction among Zambian men, the survey aimed to simultaneously measure the prevalence of erectile dysfunction among circumcised and uncircumcised men in order to compare the 2 results. The study also sought to determine whether there was any difference in erectile function in those circumcised in childhood compared to those circumcised in adulthood.

Aim and objectives

The aim of this study was to compare erectile function in circumcised and uncircumcised adult men aged 18 years and above in Lusaka, Zambia. Objectives of the study were:

1. To determine the prevalence of erectile dysfunction among circumcised and uncircumcised men aged 18 years and above
2. To compare the prevalence of erectile dysfunction in circumcised and uncircumcised men aged 18 years and above
3. To determine whether the age at which circumcision was performed in study participants had any effect on erectile function in adulthood
4. To make recommendations on how to respond to concerns regarding erectile function following circumcision.

The aims and objectives of the study were derived from the hypothesis that there was no significant difference in erectile function between circumcised and uncircumcised males.

Methods

Design

This was a descriptive cross-sectional survey. This study design was adequate for the main aim and objectives of the survey. In order to strengthen internal validity of this cross sectional survey, some predictor and confounding variables such as age, sexual partner relationship status, alcohol use and smoking habits were also included in the questionnaire (Appendix A). The measure used (IIEF-5) is a well-known instrument with proven reliability and discriminant validity at international level but has never been validated in Zambia. Four research assistants (1 from each participating site) were adequately oriented on the ethics (Appendix B) and techniques of conducting the survey and were contacted at regular intervals to find out about issues arising from the activity, and to provide them with guidance. Specifically, they were introduced to the aims and objectives of the study, the targeted group of participants, inclusion and exclusion criteria, research ethics issues and how to administer the questionnaire. Data were captured on paper-based questionnaires which were kept in locked cabinets. These data were subsequently entered into an Excel data set on a password-protected computer.

Setting

The study was conducted in outpatient departments of 4 primary health care facilities in Lusaka, Zambia between 1/6/13 and 30/9/13. These were Matero, George, Kanyama and Chilenje Health Centres.

ParticipantsThe population of interest for this study comprised circumcised and uncircumcised sexually active males older than 18 years living in Lusaka, Zambia.

Inclusion criteria

The survey included all sexually active men older than 18 years who were visiting the study sites for various reasons, and those who had responded to requests to participate in the study (e.g. patients with minor ailments, men accompanying patients, employees and their partners, men previously circumcised at the centres).

Exclusion criteria

- Males younger than 18 years
- Men with mental and physical conditions that would have made it difficult for them to participate in the study (e.g. clinical depression, psychosis, serious physical illness, alcohol or other drug intoxication)
- Lack of sexual experience
- Refusal to participate in the study.

A convenience sample of an equal number of circumcised and uncircumcised men totalling a minimum of 460 individuals was chosen for the study. The sample size was calculated based on the assumption of 25% disease in the uncircumcised group and 37.5% in the circumcised one; two-sided confidence level 95%, power 80%. A total of 242 circumcised and 236 uncircumcised men took part in the study. The population that was accessible to the study consisted of all eligible adult males visiting Chilenje, Matero, Kanyama and George Health Centres during the study period. Since all the study sites also serve as circumcision centres, circumcision records with contact details dating back to the last few years were also used as sampling frames to recruit willing participants into the study. Such candidates were non-randomly contacted by telephone with requests to participate in the study. Participants were also requested to encourage their peers and family members to participate. The 4 participating sites are scattered across Lusaka and generally receive people from different sections of society and can therefore be reasonably

considered representative of the population of interest. Chilenje Health Centre is located in a peri-urban township that has relatively higher education levels and income per household than Kanyama and George compounds. Matero community falls somewhere in between Chilenje and Kanyama or George compounds in terms of socio-economic development. The sampling frame was also representative of males who had undergone circumcision under the programme that stimulated interest for this study.

Measures

The measure used in this study (IIEF-5 questionnaire) [18] is a well-known abridged version of the International Index of Erectile Function questionnaire (IIEF) [19]. The IIEF-5 questionnaire was administered to study participants as part of a structured interview during which other demographic data was also captured, e.g. age, level of education, relationship status, smoking habits, alcohol use, and use of medications, including sexual enhancers. This questionnaire comprises 4 questions from the erectile function domain and 1 question from the intercourse satisfaction domain of the IIEF. Each of the five items of the questionnaire can be scored from a minimum of 1 to a maximum of 5. The IIEF-5 score [18] is the sum of the ordinal responses to the 5 items in the questionnaire. The following are the possible scores with their interpretation:

- 22-25: No erectile dysfunction
- 17-21: Mild erectile dysfunction
- 12-16: Mild to moderate erectile dysfunction
- 8-11: Moderate erectile dysfunction
- 5-7: Severe erectile dysfunction

The IIEF-5 (Appendix A) has been validated in several cultures and languages, and has been shown to have good reliability and discriminant validity [19, 20]. Participants were divided into 2 groups, i.e. circumcised and uncircumcised groups. All participants received the same IIEF-5 questionnaire and those who could not read and/or write were assisted to answer it in private. They were assured of confidentiality and each one of them was only surveyed once.

Procedure

Adult men visiting Matero, Kanyama, George and Chilenje Health Centres during the study period were approached with requests to participate in the survey. This included circumcised and uncircumcised male patients, employees, partners of female employees, men previously circumcised at the centres and others referred by participants themselves. Eligibility for the survey was ascertained first and the purpose of the study explained before requesting them to participate in the study. Those who agreed to participate were given participant information sheets containing details of the study (Appendix C). They were assured confidentiality (Appendix C) and each one of them gave written informed consent (Appendix D) before enrolling into the study. All participants were given the freedom to decline to participate and to withdraw from the study at any point without fear of any reprisals. They were then handed the IIEF-5 questionnaire with 7 demographic questions to complete.

Bias

The convenience sampling method used to recruit participants did not allow randomization and therefore might not be representative of the male population in Lusaka. Although the IIEF-5 assessment tool for this survey had never been validated in Zambia, it had demonstrated strong reliability and validity in previous studies conducted at international level. Its primary weakness was its subjective nature and reliance on self-reporting by participants. The quota sampling that was used to select some participants in the circumcised group was prone to recall bias in favour of reporting only socially acceptable outcomes. Circumcision status was not verified through physical examination.

Conflict of interest/ Financial gain

I had no financial conflicts of interest during the study. I had, however, previously served as a male circumcision technical advisor and had participated in drafting the WHO circumcision course notebook for trainers (22).

Ethical considerations

For this research project, the researcher adhered to all the principles for ethical research (Appendix B).

Results

The aim of the study was to compare erectile function between circumcised and uncircumcised males older than 18 years. IIEF-5 scores were analyzed to assess erectile function while demographic data was evaluated to screen for confounding factors. Chi-square tests were used to examine differences in some categorical variables (alcohol use, cigarette smoking, relationship status and education level) while Mann-Whitney U tests were used for comparison of the 2 groups by age, medication use and erectile function scores. Calculated probabilities of <0.05 were considered to be significant and are quoted to 3 decimal places. All other statistical results are quoted to 2 decimal places.

There were 478 participants in this study; 242 in the circumcised group and 236 in the uncircumcised one. There were very few differences in terms of age, relationship status, alcohol use, smoking and medication use between the 2 groups of participants. However, significant differences were observed in participants' levels of education and erectile function scores.

Demographic characteristics

Age of participants

A review of participants' age ranges was conducted for all the 478 patients in the study (Table 1). The mean age of the 2 groups did not differ significantly, U=26944.50, Z=1-066976, p=0.286.

Table 1: Two-way summary table of observed frequencies of age.

Age range	Circumcised	Uncircumcised
<20	8	15
20-29	98	100
30-39	92	80
40-49	41	38
50-59	3	3
Total	**242**	**236**

Relationship status

The majority of participants were either married (58%) or single (37%). No statistically significant difference was observed between the 2 groups in this respect, χ^2 (*N*478) =6.69, df=4, *p*=0.153.

Alcohol use

About 53% of participants from the circumcision group admitted to using alcohol while in the uncircumcised group, 51% reported alcohol use. No statistically significant difference was found in the use of alcohol between the 2 groups, χ^2 (*N*247) =0.10, df=1, *p*=0.758.

Smoking

Smokers represented 18% and 23% in the circumcised and uncircumcised groups respectively. There was no statistically significant difference under this category between these 2 groups, χ^2 (*N*97) =1.41, df=1, *p*=0.235.

Medication use

From the circumcised group, 7% reported use of anti-hypertensive drugs while less than 1% indicated use of anti-diabetic medications. Almost 2% and less than 1% of participants from the uncircumcised group reported use of anti-hypertensive medications and anti-diabetic medications respectively. None of the participants reported use of medications for erectile dysfunction. These results did not present any significant difference between the 2 groups, *U*=26932.00, *Z*=0.99, *p*=0.318.

Education level

As can be seen from Table 2, the circumcised group had significantly more participants with higher education levels than those from the uncircumcised group, χ^2 (*N*478) =19.05, df=6, *p*<0.005.

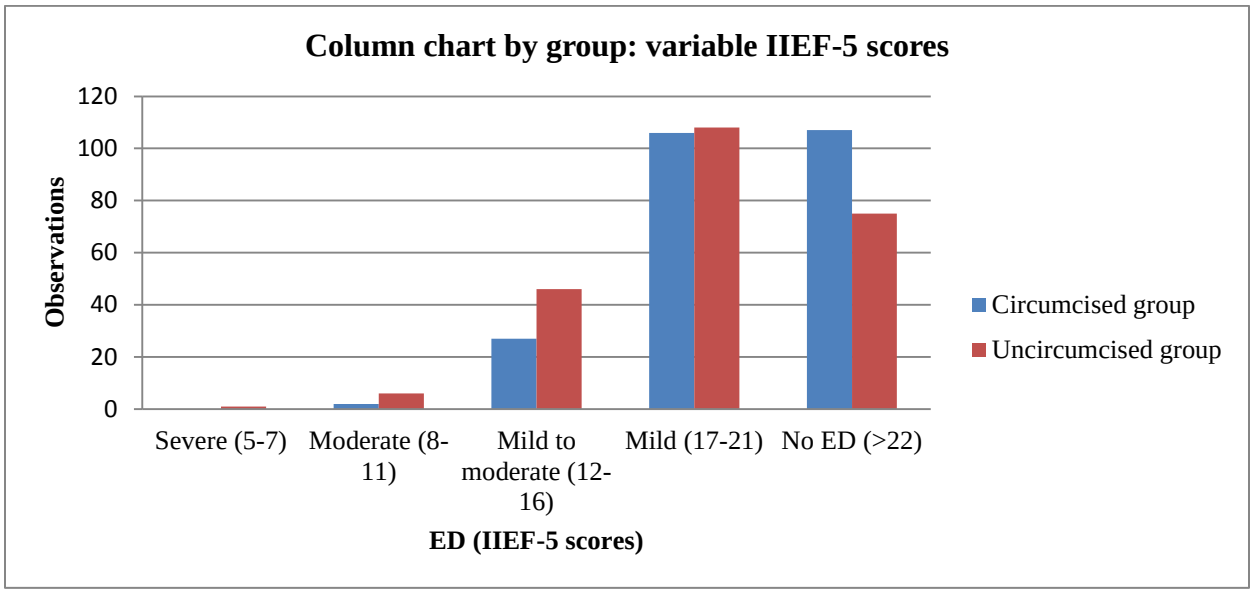
Table 2: Two-way summary table of observed frequencies of the level of education.

Education level	Group-Circumcised	Group Uncircumcised	Row-Totals
None	3	3	**6**
Column %	1.24%	1.28%	
Primary (Grade 1-7))	20	29	**49**
Column %	8.26%	12.34%	
Junior Secondary (Grade 8-9	26	52	**78**
Column %	10.74%	22.13%	
Senior Secondary (Grade 10-12)	76	70	**146**
Column %	31.40%	29.79%	
College certificate or diploma	96	70	**166**
Column %	39.67%	29.79%	
Undergraduate degree	20	9	**29**
Column %	8.26%	3.83%	
Postgraduate degree	1	2	**3**
Column %	0.41%	0.85%	
Missing	0	1	**1**
Column %	0%	0.42%	
Totals	**242**	**236**	**478**

Erectile function evaluation

Figure 1 below depicts IIEF-5 scores by group. Most of the scores for both groups (92%) were between 16 and 25, i.e. in the mild to no erectile dysfunction (ED) range.

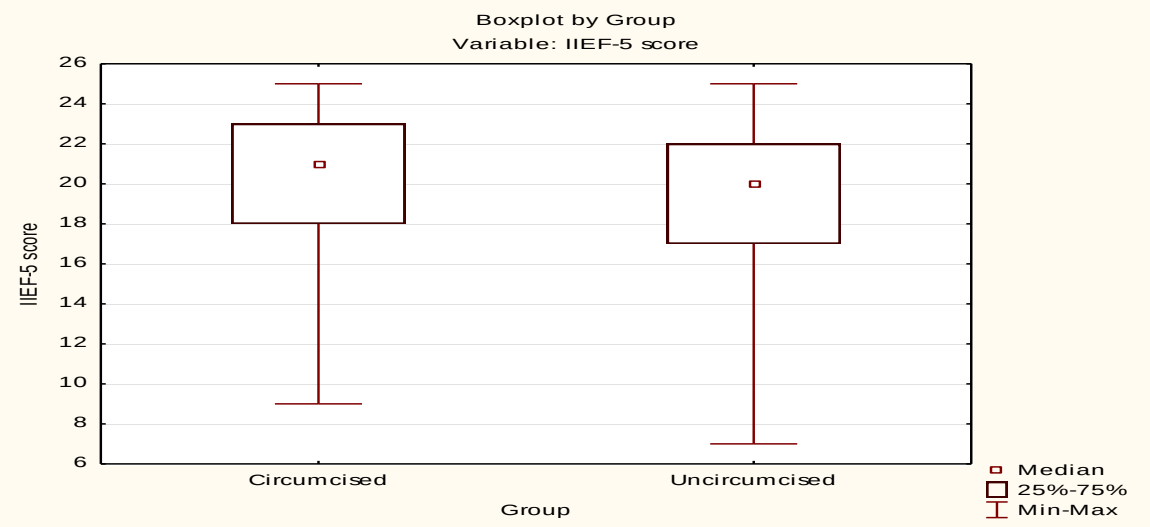
Figure 1: Column chart of IIEF-5 scores by group



Comparison of erectile function scores

Figure 2 shows IIEF-5 scores plotted against groups. The median in circumcised men was higher than in uncircumcised men. The 2 groups showed statistically significant differences from each other with higher average scores observed in the circumcised group, U=23062.50, Z=3.64, p<0.001.

Figure 2: Boxplot by group plotted against IIEF-5 scores.



Prevalence of erectile dysfunction

The prevalence of erectile dysfunction in all participants surveyed was around 62%. Among circumcised participants 44% registered normal erectile function compared to 32% in the uncircumcised group. These results imply that 56% of circumcised and 68% of uncircumcised participants had varying degrees of erectile dysfunction (Table 3).

Table 3: Two-way summary table of observed frequencies of IIEF-5 scores > or <22.

IIEF-5 score	**Circumcision group**	**Uncircumcised group**
≥22	107 (44.2%)	75 (31.8%)
<22	135 (55.8%)	161 (68.2%)
Total	**242 (100%)**	**236 (100%)**

Comparison of erectile dysfunction in the 2 groups

The observed difference in the prevalence of erectile dysfunction in the 2 groups was statistically significant, χ^2 (N182) =7.83, df=1, p<0.05. More participants in the circumcised group had normal erectile function than participants in the uncircumcised group.

Relationship between age at circumcision and erectile function

Table 4 below represents the distribution of participants who were circumcised in childhood and those circumcised in adulthood. The prevalence of erectile dysfunction was around 58% and 56% in those circumcised in childhood and adulthood respectively. These results did not show any statistically significant difference between the 2 subgroups, χ^2 (N242) =0.29, df=1, p=0.59.

Table 4: Frequency table of age at circumcision

Category	**Count**	**Percent**
Circumcised in childhood (<18 years old)	107	44.2%
Circumcised in adulthood (>18 years old)	135	55.8%
Total	**242**	**100%**

Discussion

The results of this study showed higher average erectile function scores in circumcised men compared to uncircumcised ones. The prevalence of erectile dysfunction was correspondingly lower in circumcised participants than in uncircumcised ones. No difference was observed in the prevalence of erectile dysfunction between those circumcised in childhood and their counterparts who were circumcised in adulthood. There were no statistically significant differences between the groups in age, relationship status, smoking, alcohol use and medication use categories. However, a significant difference was observed in the education level category which demonstrated more participants with higher levels in the circumcision group.

The higher IIEF-5 scores that were observed in the circumcised group imply that circumcision did not have significant adverse effects that could have worsened participants' erectile function. Demographic characteristics of the 2 groups that were being compared were similar and only differed in the education level category where circumcised men indicated higher education levels than their counterparts in the uncircumcised group. This observation cancels out most of the factors that could have confounded the results of the study. The observed differences in education levels between the 2 groups could not have had much impact on study results as research assistants were at hand to help participants with difficulties completing the questionnaire.

The finding in this research that circumcision does not worsen erectile function replicate the findings of Collins [11] which stated that the procedure did not appear to present any clinically important effects on erectile function in adults who underwent the procedure. Observed higher average IIEF-5 scores in the circumcised group present a different picture from what was observed in the study by Fink [7] in which it was suggested that circumcision appeared to worsen erectile function. Similarities in erectile function scores in those circumcised in childhood and adulthood agree with the findings of Aydur [21].

There are several possible explanations of what was observed from this study. First, even if all efforts were made to assist participants with challenges completing the questionnaire, it seems possible that the higher education levels observed in the circumcised group might have made it easier for them to understand instructions in the questionnaire and to answer them more

objectively. Participants with lower education levels might have misread the questions and provided incorrect responses. It is also plausible that the opposite might have happened with more literate participants providing misleading responses. This is especially so because the IIEF-5 tool is subjective in nature and can be reported differently by different individuals. Even if the questionnaire had been validated in other languages and cultures, it had not been done so in Zambia and this could have affected participants' interpretation of the tool. The other explanations for these results could be recall bias with participants self-selecting the importance of their groups or only reporting those behaviours that they considered socially acceptable.

The clinical relevance of these findings is that they demonstrate that circumcised men have normal erectile function with high average IIEF-5 scores. These findings may help clinicians to better counsel those wishing to undergo circumcision.

The limitations of this study are that the study design does not allow making conclusions about cause and effect, and it is prone to selection and measurement bias. The method used to recruit participants did not allow randomization and the quota sampling employed for selection of some members of the circumcised group can increase recall bias in favour of reporting positive outcomes only. Participants were requested to state their circumcision status but were not physically examined to confirm their status. Literacy levels also differed and this can lead to poor understanding of instructions in the IIEF-5 questionnaire, resulting in misleading responses.

One area that remains to be explored is the response of female partners of circumcised men to gauge their assessment of their partners' erectile function. Considering that the IIEF-5 questionnaire was applied for the first time in Zambia, I would also be interested in validating it locally before using it for future studies.

Conclusions

The findings of this study show that circumcision does not confer adverse effects that could cause erectile dysfunction in men. Going by these results, circumcision can be considered safe in terms of erectile function. However, a prospective study in a similar cultural context is needed to confirm these findings.

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Appendices

Appendix A. Erectile Function Survey Questionnaire (includes IIEF-5)

My name is _____, your facilitator for this session. I would like to welcome you to participate in this very important study that is exploring erectile function in men aged 18 years and older. Please read the questions carefully and answer them to the best of your ability by placing an "X" in the box with the appropriate response. If you have any questions, please feel free to direct them to me.

Shaded part below is for official use only

Participant ID number: _____ Facility code: _____ Date: ____/_____/_____

Circumcision code: _____

1. What is your age range?

Less than 20 ☐

20-29 ☐

30-39 ☐

40-49 ☐

50-59 ☐

60-69 ☐

70-79 ☐

80+ ☐

2. What is your relationship status?

Single ☐

Married ☐

Divorced ☐

Separated ☐

Widowed ☐

3. What is your highest level of education?

None ☐

Primary (Grade 1-7) ☐

Junior Secondary (Grade 8-9) ☐

Senior Secondary (Grade 10-12) ☐

College certificate or diploma ☐

Undergraduate degree ☐

Post-graduate degree ☐

4. Do you drink alcohol?

Yes ☐ No ☐

5. Do you smoke cigarettes?

Yes ☐ No ☐

6. When were you circumcised?

Not applicable ☐

In childhood (0-18 years old) ☐

In adulthood (older than 18 years) ☐

7. Mark in the appropriate box if you are taking medications for any of the following conditions:

Hypertension ☐

Diabetes ☐

Mental illness (e.g. depression) ☐

Erectile dysfunction ☐

8. Please choose the appropriate response for each question about your sexual abilities over the past 4 weeks. (Put an "X" next to the appropriate response)

Question	**Response**	**Points**
(1) How do you rate your confidence that you could get and keep an erection?	very low or none at all	1
	low	2
	moderate	3
	high	4
	very high	5
(2) When you had erections with sexual stimulation how often were your erections hard enough for penetration?	almost never or never	1
	a few times (much less than half the time)	2
	sometimes (about half the time)	3

	most times (much more than half the time)	4
	almost always or always	5
(3) During sexual intercourse how often were you able to maintain your erection after you had penetrated (entered) your partner?	almost never or never	1
	a few times (much less than half the time)	2
	sometimes (about half the time)	3
	most times (much more than half the time)	4
	almost always or always	5
(4) During sexual intercourse how difficult was it to maintain your erection to completion of intercourse?	extremely difficult	1
	very difficult	2
	difficult	3
	slightly difficult	4
	not difficult	5
(5) When you attempted sexual intercourse how often was it satisfactory for you?	almost never or never	1
	a few times (much less than half the time)	2
	sometimes (about half the time)	3
	most times (much more than half the time)	4
	almost always or always	5
Total Points based on 5 questions		

Appendix B. Ethical considerations

1. Respect for persons-
    a. Participants were treated with respect as autonomous individuals on equal terms with the investigator. All participants took part in the study voluntarily and interactions occurred in a non-threatening environment. Those unable to freely read or write in English were assisted to complete the questionnaire and interaction with them took place in the language of their choice. All questionnaires were in plain and easy-to-understand English language, and were administered in a culturally appropriate manner.
    b. Participants were adequately informed of the aims, methods, sources of funding, institutional affiliations of investigators and anticipated benefits and risks of the study. Informed consent was given freely and in writing by all study participants before taking part in the study. For those unable to read and/or write, a provision was made for them to give it orally and to use a thumb print in place of a signature in the presence of a literate witness. The witness then certified in writing that informed verbal consent was given by the participant. Participants were informed of their right to abstain from the study or to withdraw consent to participate without reprisal. They were also informed of the size and nature of the two groups taking part in the study, and circumstances that could lead to termination of their participation.
    c. All identifiable private information obtained from participants was kept private and confidential. Participants were identified by codes that were matched against securely kept files to ensure anonymity.
2. Beneficence-participants were not subjected to any harmful interventions. All interactions with them were in the form of verbal interviews and assistance with completion of questionnaires in some cases.
3. Justice-participants were selected solely on their eligibility to take part in the study. No person was inappropriately excluded based on their race, age, disability, education, religion, marital status, ethnic or social origin, belief or language.

Appendix C. Participant information

Title of the research project: Erectile function in circumcised men: Lusaka, Zambia

University of Zambia Biomedical Research Ethics Committee Reference Number: 005-11-12

Stellenbosch University Health Research Ethics Committee Reference Number: N10/11/387

Principal Investigator: Dr Evans Chinkoyo

Address: Plot 222, Meanwood-Ibex Hill, Lusaka, Zambia

Contact number: +260977230473

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. It will take you approximately 30 minutes to complete the questionnaire. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part initially.

This study has been approved by the **Health Research Ethics Committee (HREC) at Stellenbosch University** and the **University of Zambia Biomedical Research Ethics Committee,** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki.

What is this research study all about?

- ✓ This study will be conducted in Lusaka at Chilenje , Matero, George and Kanyama Health Centres. Approximately, 115 participants will be recruited at your site leading to a total of 460 participants recruited from all sites for this study.
- ✓ The project aims to establish whether male circumcision has any effect on the ability of men to achieve satisfactory erections for normal sexual function. The study is being conducted in view of the increasing number of circumcisions that are being offered to Zambian men in the context of reducing HIV transmission from infected female sexual partners to their uninfected male counterparts.

Why have you been invited to participate?

- ✓ You are selected to participate because you have met the following requirements needed to take part in the study as a participant:
  - You are a man aged 18 years and older;
  - You are sexually active;
  - You do not have any serious mental or physical problems that would make it difficult for you to participate in the survey;
  - You have agreed to participate in the survey
- ✓ Based on your circumcision status, you will be put in either the circumcised or the uncircumcised group. A questionnaire will then be administered to you with a list of questions that will help you to understand your erectile function. If you are able to read and write, you will be allowed to complete the questionnaire on your own but an assistant will be available to assist you should you require help. If you are unable to read and/or write, an assistant will also be at hand to read the questionnaire to you in a local language of your choice and to help you answer the whole questionnaire.

What will your responsibilities be?

Your responsibilities in this study will include providing proof of your age and identification, and completing the questionnaire.

Will you benefit from taking part in this research?

There are no direct benefits from the study for you if you are already circumcised as the findings will mainly help to provide information for uncircumcised persons planning to undergo male circumcision in future. Should you be found with a sexual condition requiring treatment, you will be referred to doctors with the expertise to manage it. Results of the study will be reviewed by the Department of Family Medicine at Stellenbosch University in South Africa and may be made available for public use.

Are there any risks involved in your taking part in this research?

There are no risks involved in taking part in this study.

Who will have access to your medical records?

All information collected from you will be treated as confidential and protected. Only senior members of the research team will have access to your personal information and your identity will remain anonymous in all publications that will follow this study.

Will you be paid to take part in this study and are there any costs involved?

No, you will not be paid to take part in the study and there will be no costs involved for you, if you do take part.

Is there anything else that you should know or do?

- ✓ You can contact **Dr Evans Chinkoyo** on mobile number **+260977230473** if you have any further queries or encounter any problems.
- ✓ You can contact the Biomedical **Research Ethics Committee** at the **University of Zambia at the School of Medicine, Dean's Office, P.O. Box 50110, Nationalist Road, Ridgeway Campus, Lusaka, Zambia** if you have any concerns or complaints that have not been adequately addressed by your study doctor.
- ✓ You will receive a copy of this information and consent form for your own records.

Appendix D. Consent

Declaration by participant

By signing below, I ……..…… agree to take part in a research study entitled ***"Erectile function in circumcised men: Lusaka, Zambia"***

I declare that:

- I have read or had read to me this information and consent form and it is written or explained to me in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.

- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) .....…..……. on (*date*) ……...…….. 2013.

....

Signature of participant (or thumb print) **Signature of witness (or thumb print)**