Original Article

Evaluation of the Safety of the Taraklamp Male Circumcision Device in Zambia

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ABSTRACT

Background: Male circumcision has been proved to be an effective additional means of preventing transmission of the HIV virus from females to males in heterosexual relationships with efficacy of up to 60%. Many methods and devices for adult male circumcision have now been developed. However, there are still concerns on safety, duration of procedure, and public acceptability of these devices.

Objectives: to assess safety, duration of procedure, complications, pain and public acceptability of the Taraklamp, male circumcision device, in adolescents and adult male circumcision in Zambia.

Materials and Methods: we conducted a field study with 1,046 male adolescents and adults recruited from five district clinics. Prior to circumcision, participants were educated on benefits of circumcision while undergoing HIV counseling and screening. Duration of procedure was recorded, intra and postoperative pain was assessed and adverse events were documented for each participant. Levels of satisfaction with the procedure both from doctors' and participants' perspectives were also documented.

Results: A total of 794 participants were circumcised using the TARAKLAMP device**.** The median time for circumcision was 4 minutes (IQR: 3-6 minutes; range: 1-24 minutes). Approximately 5 (0.6%) of the participants experienced postoperative pain and 12 (1.5%) experienced adverse events following the procedure. Despite this all participants found the procedure safe and acceptable, as did the doctors who carried out the procedure.

Conclusions: the results from this study showed that the TARAKLAMP device is safe for medical male circumcision. Acceptability of the circumcision using the device was exceptional and it is possible to use the TARAKLAMP to roll out medical male circumcision in Zambia.

INTRODUCTION

Male circumcision is the removal of the foreskin of the penis and is one of the oldest recorded surgical procedures. It is carried out for a variety of reasons that range from religious to cultural, though lately it is increasingly being performed for medical purposes. Data from three randomized controlled trials conducted in Orange Farm, South Africa; Kisumu, Kenya and Rakai District, Uganda revealed that following male circumcision, the incidence of HIV infection in men was significantly reduced.[1,2,3] In addition at least one meta-analysis and one systematic review of studies on male circumcision and HIV infection have shown that circumcision reduces the risk of acquiring HIV in sexually active men.[4,5] The World Health Organization recommends as part of a comprehensive strategy against HIV infection voluntary medical male circumcision.[6] Zambia, like many other countries with high HIV prevalence and low circumcision rates has been working to develop implementation plans that will see a significant scale-up of male circumcision. A number of barriers to the roll-out of male circumcision have been identified in the

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country and include: cultural tradition, pain, and safety, as well as other barriers, such as cost and the concern that men would engage in more sex if they perceived themselves to be fully protected by circumcision. To address safety, cost and operative difficulty concerns, the country has been looking at the possible role of medical devices for circumcision.

Male circumcision devices have been successfully and safely utilized in babies and young boys particularly in the Asian region.[7] They have the potential to fuel an up scaling of male circumcision countrywide due to the advantages they have over the traditional surgical procedures for male circumcision. These advantages include: the potential to reduce the operation time, ease of use by non-surgeon practitioners, reduced complication rates and shorter healing times.[1,8]

The Taraklamp circumcision device is a disposable plastic clamp that was developed in Malaysia and has a long history of use in children and adolescents in Malaysia and Indonesia.[7] It's use in non-physician surgeons hands was reported to be favourable with no major complications and a good cosmetic result. Similar results were reported in a comparative study of the Taraklamp method and the conventional surgical circumcision in boys in the Netherlands.[9] Researchers in both studies stressed the importance of appropriate patient selection and adequate training in using the device prior to performing male circumcision using the Taraklamp disposable MC device.

Male circumcision devices have the potential to accelerate programme scale up because the procedure is faster, safer and simpler, requiring less highly trained providers and makes the procedure more acceptable by non-circumcising communities.[10,11] To date, the Shang-Ring®, PrePex® and Taraklamp are among some of the devices being marketed for use in Africa.[12,13] While circumcision devices have been successfully used in other populations, experience with their use among adolescents and adults in Africa have not been encouraging.[14] In addition there are reports that the use of such devices in an African setting is not cost effective.[15] Thus, the World Health Organization (WHO) has recommended that the scale up of male circumcision using these devices proceeds in a cautious yet progressive fashion, ensuring that the safety, effectiveness and acceptability of the devices in the population with good access to care are established before proceeding to a more widespread implementation.

This paper presents a field study by trained clinical personnel in a low resource setting of Zambia, reflecting anticipated conditions of intended use.

MATERIALS AND METHODS

Study design

This was a field study held in three clinics of Solwezi town in the North-Western Province and one clinic in Lusaka city, Lusaka Province of Zambia. Community mobilizers were used to recruit uncircumcised adolescent and adult males from Kazomba, Kimasala and Mitukutuku areas in Solwezi and Chawama area in Lusaka. The study was a scale up from an initial pilot study involving 177 participants conducted during the previous year in Ndola and Lusaka.

TARAKLAMP device

The Taraklamp device is a plastic disposable clamp developed in Malaysia by Dr. Gurchran Singh of TARAMEDIC pharmaceuticals (Fig 1). The device does not leave an open wound after circumcision and there is no need for sutures. It is reported to be easy to use and requires minimal training making it ideal for rural hospital settings where qualified doctors are usually scarce.

Surgical technique

The level of circumcision is marked on the penis preoperatively with a surgical pen. The correct clamp size is selected by use of a measuring card with several circular holes. The appropriate hole is the one whose diameter corresponds to diameter of the glans penis at the level of the corona. The prepuce is stretched and pulled over the rim of the clamp to the level previously marked. The frenulum is pulled up through the clamp to prevent postoperative urinary retention and pain during voiding. The foreskin is then cut circumferentially while the inner tube of the clamp protects the glans. The clamp is left in situ for approximately 6 days after which it is removed.

Data collection and procedure

Background information from the participants was obtained using a structured questionnaire administered by a qualified nurse before the Taraklamp procedure. Counselling on the benefits of male circumcision and HIV was provided to all the participants before the operations were carried out. Six medical doctors assessed participant suitability for circumcision before the procedure. Only participants above the age of 12 years were considered for circumcision. The procedures were carried out by the 6 medical doctors each with one assistant.

Circumcisions were carried out in phases with the first phase taking place from 7th to 11th April 2014. Clamp removal took place six days after the procedure provided doctors were satisfied with the outcome. Postoperative evaluations took place at two and six weeks post operation however, participants were advised to return to the clinics any time they noticed complications. The second phase took place from 1st to 6th December 2014 and was similar to the first phase in execution.

The duration of each circumcision was measured using a timer. After the procedure the doctors documented information on duration of the procedure, intra and postoperative complications, bleeding during procedure, safety, ease of use and acceptability. In addition doctors had to document information on pain, bleeding and complications at removal of the clamp, which took place approximately 6 days after the procedure. The clients filled out information on pain, bleeding, safety and approval of the method. This was done after the procedure and repeated during removal of the clamp. Participants were asked if they experienced pain during and after the operation.

Assessment Criteria

The assessment criteria was developed using, as a guide, the WHO's Framework for Clinical Evaluation of Devices for Male Circumcision.[16] From the provider perspective the criteria was based on the following clinical assessment of the procedure: penile infection, bleeding during and after the procedure, delayed wound healing, excessive or insufficient skin removal, erectile dysfunction acceptability of the procedure. From the participant's perspective the criteria was based on the following pain score, bleeding within two weeks following the procedure, lesions on the penis, swelling or hematomas, problems with urinating and overall satisfaction with penis appearance and circumcision procedure.

The data collected from the questionnaires filled in by clients and the Doctors and their Assistants were entered and assessed by the Data Monitoring team from the Surgical Society of Zambia (SSZ), Ministry of Health (MoH) and Ministry of Community Development Mother and Child Health (MCDMCH).

The duration of circumcision is expressed as an interquartile range. The rest of the variables are dichotomous and are expressed as percentages. Outcome variables included duration of the procedure, postoperative complications, bleeding and acceptability of the procedure by both participants and doctors. We used logistic regression to explore possible associations between postoperative complications and from circumcision and key variables including age, marital status, sexual activity, duration of the procedure, HIV status and previous sexually transmitted infections (STI). All analyses were conducted using Statistical Package for Social Sciences (SPSS) version 22.0.

Ethics Approval

The University of Zambia Biomedical Research Ethics Committee (UNZABREC) (reference number:022-06-10) approved the study on 10th February 2011 and all the activities were reported to the committee.

RESULTS

Background Characteristics of Participants

A total of 1,046 people volunteered to be circumcised however, only 794 participants met the inclusion criteria for circumcision. The distribution of the 794 participants was as follows: Chainama Clinic 173, Kazomba Clinic 258, Kimasala 176 and Mitukutuku 187. The characteristics of the participants are listed in table 1. The median age of participants was 16 years of age (Interquartile range [IQR]: 12-22 years of age; range: 10-56 years of age) (Table 1). At 602 (75.6%) the majority of participants were single and without sexual partners, 119

(14.9%) were in relationships, 68 (8.6%) were married and one participant was divorced while one other was cohabiting (0.1%). Approximately 351 (44%) of the participants were sexually active while 442 (56%) were not sexually active. Among the sexually active participants 253 (72%) used condoms to protect against sexually transmitted infections while 98 (28%) did not use condoms to protect against STIs. The vast majority of the participants 779 (98%) wanted to be circumcised as a means of protection against STIs. Other wanted to be circumcised for social, religious, traditional and medical reasons. Most 770 (97%) of the participants had not suffered an STI in the three months preceding the study. Twenty-four of the sexually active participants had suffered an STI within the previous 3 months equating to 6% of sexually active participants. For the purposes of this study STIs were reported as any one of the following genital warts, gential sores, urethral discharges, pain on urination and difficulties retracting foreskins. None of the participants had suffered from genital warts or sores. Three participants had urethral discharge complaints, 2 complained of pain on urination, 3 had difficulty retracting their foreskins while 4 had other complaints. None of the clients had Genital warts and Genital sore (ulcer) complaints. There were also a total of 79 (3.4%) Prepucial anomalies recorded. Out of the 79 anomalies: 27 (34.2%) were Adhesions; 25 (31.6%) were Phimosis; 21 (26.6%) were prepucial rings; 5 (6.3%) and 1(1.3%) Congenital partial circumcision.

Table 1: Baseline characteristics of participants

Age Years (Interquartile range)[Range]	16(12-22)[10-56]	
	Variable	**Number (%)**
Marital status	Single (no regular partner)	602(75.6)
	Single (with regular partner)	119(14.9)
	Married	68(8.6)
	Cohabiting	1(0.1)
	Divorced	1(0.1)
Sexual activity	Yes	351 (44)
	No	442 (56)
Use of protection (Among sexually active participants only)	Yes	243 (72)
	No	98 (28)
Reasons for circumcision	Partial protection against HIV/STIs	779 (98)
	Religious/social	3 (0.37)
	Traditional	11 (1.38)
	Medical	1 (0.12)
STI infections in last 3 months	Yes	770 (97)
	No	24 (3)

TARAKLAMP Procedure and Clamp Removal

Circumcision by Taraklamp took a median time of 4 minutes (IQR: 4-6 minutes; range 1-24 minutes) (Fig: 2). Twelve participants (1.5%) experienced postoperative complications after circumcision using the Taraklamp procedure. Only one (0.1%) participant reported bleeding after circumcision. The bleeding was effectively treated by application of haemostatic pressure or insertion of a solitary suture. A total of 5 participants (0.6%) experienced pain after the procedure (Table 2). Most of the participants (762 [96%]) said that they could move around freely while the device was attached to their penises. All the participants including the ones that had experienced postoperative complications felt that they would prefer this method for circumcision to the forceps guided method.

Figure 1: Taraklamp device and measuring device

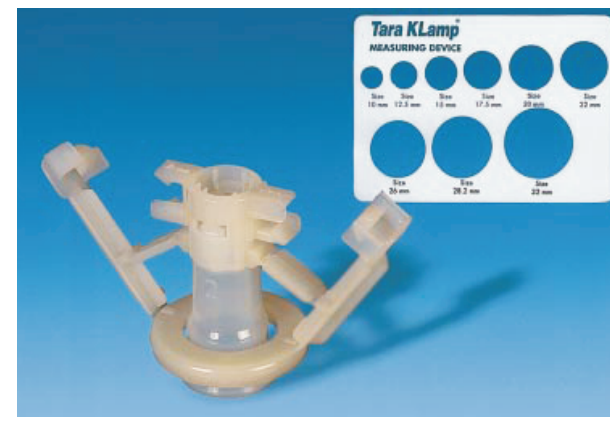

Figure 2: Duration of procedure

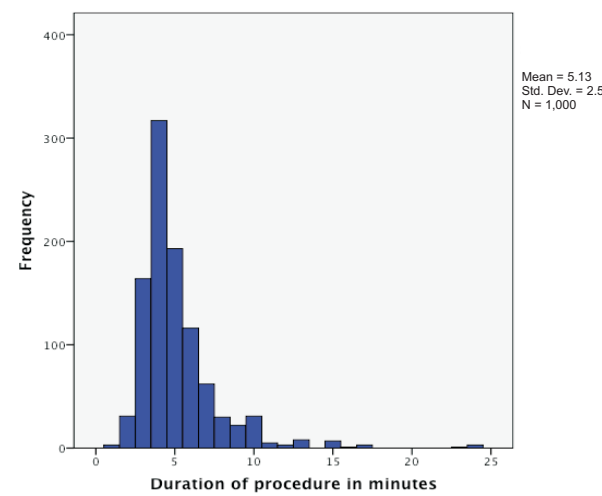

Table 2: Client perspective of procedure

	Number (794)	Percentage (100%)
Postoperative complications	12	1.5
Postoperative complications (time of clamp-removal)	158	20
Pain	5	0.6
Bleeding	1	0.1
Approval	794	100

The doctors reported that the procedure was easy and quick. According to the doctors none of the participants experienced complications during and after the procedure. The doctors also reported no significant postoperative complications resulting from the procedure.

Only HIV status is significantly associated with client reporting post-operative complications after circumcision using TARAKLAMP (TK) device. The odds of reporting post-operative complications after circumcision using the TK decreased by 0.16 (95% Confidence interval: 0.04-0.5, p-value<0.05) if the participant was HIV negative.

DISCUSSION

Our investigation revealed an apparent acceptability (100% among both participants and doctors) of male circumcision among the sexually active age group for whom the principal indication was protection against HIV infection.

There was an enthusiastic acceptance of being circumcised using a disposable MC device that clients associated with fewer complications in comparison with traditional surgical MC procedures. This is in keeping with previous authors who found that in Zambia there is no aversion toward male circumcision provided it was performed in a clinical setting with fewer chances of adverse complications and that there is widespread belief that circumcision reduces risk of acquisition of STI, including HIV.[5,17]

The procedure time from administration of anaesthesia to excision of the foreskin and application of the sterile dressing was relatively short. The median procedure time of 4 minutes compared favourably with other disposable devices and was significantly faster than traditional surgical procedures.

Twelve (1.5%) participants experienced adverse events while 5 (0.6%) complained of pain after circumcision using the device. These figures were significantly lower than those observed by Lagarde *et al* in their experience with the clamp.[18] The doctors felt that reported pain may have been a result of ineffective anaesthesia or excessive skin entrapment within the clamp. In some instances the duration took over 10 minutes, with one procedure taking as long as 24 minutes to complete. Protracted procedure times were attributed to the following: delay in anaesthesia taking effect, phimosis and faulty Taraklamp devices. In addition only one participant complained of bleeding after circumcision showing that effective haemostasis can be achieved in the majority of cases where the device is used.

The majority of staff performing the circumcisions found the procedure quick and easy to carry out. This was aided by the fact that the device presents as a single piece that does not require assembly, as is the case with other disposable devices.

The removal of the Taraklamp was the most problematic part of the procedure for patients. Though its proponents advise that the clamp can be removed easily with some discomfort, 20% of patients complained of complications on removal of the clamp. Fourteen percent complained of pain during and after removal while for 6% of patients, swelling and pus discharge complicated removal of the clamp. For optimal results, good genital hygiene was important to avoid infection and constant lubrication of the necrotic tissue allowed for its easy removal.

Although all the doctors who performed the procedure found it acceptable, there were complaints that related to the removal of the clamp and these included pain and the difficulty of removing the clamp by releasing the tube by cutting the thin plastic at the distal end of the Taraklamp using any other blade but a curved blade. This seemingly simple requirement made the process frustratingly difficult.

CONCLUSION

The results from this study of the Taraklamp device use in adolescent and adult male circumcision show that the device is safe for further study in Zambia. Acceptability of the Taraklamp device among participants was exceptional. The device appears to be easy to use and effortless in the hands of trained health personnel and this could facilitate rollout of male circumcision on a large scale. The WHO recommends a larger study with a bigger sample size before a male circumcision device is deemed acceptable for use in a developing country. We, therefore, suggest a sample size of between 1500 – 2000 adolescent and adult males, as recommended by the World Health Organization before the device is pronounced ready for use in a Zambian context.

CONFLICT OF INTEREST

There is no conflict of interest.

AUTHORS' CONTRIBUTIONS

John Kachimba is the principal investigator and James Munthali, Edward Chibwili and Mweene Cheelo are the Researchers on the study. All Authors designed the study and contributed to the draft report. Three University of Zambia students entered the data. All the authors contributed to data analysis, interpretation and the final report.

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TABLES AND FIGURES

List of tables and figures included in the manuscript with their detailed legends:

Table 1: Baseline demographic characteristics of participants

Table 2: Information on Taraklamp procedure participant perspective

Figure 1: Taraklamp device and measuring device

Figure 2: Histogram showing duration of circumcision by Taraklamp device.

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