Safety of a disposable male circumcision kit. Results from a randomized controlled trial conducted in South Africa

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Abstract:

Background:
Properly sterilized instruments and appropriate consumables are needed to perform male circumcision procedures in safe conditions. In response to this need a South African company recently prepared a single-use sterilized toolkit (Cir-Kit) containing all disposable instruments, consumables and pharmaceutical products needed to perform one single male circumcision among young male adults according to the most common technique used in South Africa (the Forceps Guided technique).

Methods:
Following on from a randomized controlled trial on the impact of male circumcision on HIV transmission, 511 of 3274 participants agreed to take part in a trial on male circumcision methods. They were circumcised by one of the three general practitionners already in charge of the circumcisions in the main trial on the impact of circumcision, either using the Forceps Guided method, and then randomised into two groups of equal size (using the Cir-Kit (CK group), or using conventional reusable instruments (RI group)). Adverse events were recorded by general practitionners in charge of the medical follow-up to surgery and participants attended a check-up visit 6 weeks after surgery during which they underwent a clinical investigation performed by a nurse and answered a standardized questionnaire including the assessment of pain using a self-rating analog visual pain scale.

Findings:
Of the 513 men asked to participate, 511 accepted and 259 were randomized to the RI group and 252 to the CK group. Eighty per cent of those circumcised by the RI method and 85% of those circumcised by the CK method attended the post-circumcision visit, as reported by the nurse from genital examination performed during the post-circumcision visit or reported by participants to the nurse. No statistically significant differences in complication rates was found between the two groups (with type I error risk of 5%). All equivalence tests were significant when lower and upper bounds for difference were taken at D=±10% (±20 mm for mean pain score). With D=±5% (±10 mm for mean pain score), 7 out of 13 equivalence tests remained significant.

Conclusion:
The male circumcision Cir-Kit toolkit was found to be equivalent to re-usable conventional instruments as used in optimal safety conditions. This product will be useful when used in settings where sterilization of reusable instruments is not easy or where consumables and pharmaceutical products are scarce. Practitioners' training, proper patients' follow-up and access to medical facilities in case of serious complications are however also required.

INTRODUCTION

Male circumcision is by far the most prevalent surgical procedure. Each year about 10 million are performed worldwide, most in a non-medical setting. Although circumcision is considered a minor and safe procedure, the incidence of postoperative complications can be relatively high (1-3). Traditional surgeons throughout sub-Saharan Africa often perform circumcision with uncleaned cutting equipment used on several patients, leading to complications and in particular infections (4-8). No complication rates associated with ritual circumcision performed in non-medicalized settings have been reported, but most authors agree that such unsafe practices should be discouraged (6, 9, 10).

A comprehensive safety assessment of available male circumcision procedures is needed to identify the appropriate methods in each setting and to issue proper clinical guidelines. This has become all the more important as recent results on the protective impact of male circumcision against HIV transmission are likely to lead to an increase in the rate of such surgery (11, 12).

In response to this need for safer circumcision practices, a South African company recently prepared a single-use sterilized toolkit (Cir-Kit, Transaid, Pretoria, www.transfarm.co.za) containing all disposable instruments, consumables and pharmaceutical products needed to perform one single male circumcision according to the most common technique used in South Africa (the Forceps Guided technique).

We took advantage of the randomized controlled trial conducted in South Africa in 3274 uncircumcised men aged 18-24 (referred to here as the Male Circumcision Randomized Controlled Trial or MCRCT) to ask the participants of the control group to participate in a randomized sub-trial with the objective of assessing the safety of the Forceps Guided method when using this single-use sterilized disposable kit (Cir-Kit), as compared to when using reusable conventional instruments in optimal safety conditions.

METHODS

Population and setting

The study was carried out in Orange Farm and surrounding areas, a semi-urban region of the city of Johannesburg in the Gauteng province of South Africa in February-June 2005.

Inclusion and randomization

During their last visit of the MCRCT follow-up (month 21), MCRCT control group members were asked to participate in the study after being informed of its aim and procedures. In particular, we ensured that they understood that by consenting to participate they were agreeing to be circumcised free of charge by the Forceps Guided method, the practitioner using either the Cir-Kit (CK group) or his own reusable conventional instruments (RI group), and that the groups would be chosen at random. We explained the circumcision techniques and presented the Cir-Kit. If for some reason they didn't want to participate in the study, potential participants were informed that they would be offered free circumcision performed in the usual way. Potential participants were also told of the risks of bleeding, haematoma, infection, inadvertent damage to the glans, removal of too much or too little skin, aesthetically unpleasing results and a change of sensation during intercourse. Finally, the participants were informed that male circumcision provides only partial protection against AIDS/HIV and were urged to use condoms and adopt safe sexual behaviour just like uncircumcised people. All participants who attended the centre for their last visit of the MCRCT follow-up received a 150 Rand (20 euros) payment whether or not they agreed to participate in the study.

For randomisation to one of the two groups, each participant was invited by the manager of the centre to choose an envelope containing the group name from a basket of 10 envelopes. After each choice, a new envelope was added to the basket. This added envelope was taken sequentially from a set of envelopes prepared in such a way that each set of 10 envelopes contained the same number of 'Usual' and 'Cir-Kit'. Participants were invited to be circumcised within a week, with an appointment for surgery and free transportation. They were given a voucher for the general practitioner clearly indicating the randomisation group. Finally, participants were asked to come back to the centre 6 weeks after surgery for a genital examination and completion of a short questionnaire. Participants who attended the centre for this post-circumcision visit received a 40 Rand payment.

Eligibility criteria

Eligibility criteria to participate in the study were:

- to be an uncircumcised man from the control group of the MCRCT trial and visiting the centre for the final MCRCT visit;
- with no contraindication for circumcision;
- in good general health with normal physical and genital examinations;
- consenting to participate in the trial, and specifically:
- consenting to randomization of the circumcision method;
- consenting to avoid sexual contacts (except with condom protection) during the 6 weeks following the circumcision;
- consenting to a medical visit 6 weeks after circumcision;
- consenting to report any adverse events.

Circumcision procedure

All participants were prepared and circumcised following the same procedures. The only difference between the two groups was that practitioners used the Cir-Kit toolkit for the CK group (the detailed content of which is listed in Table 1) and used their conventional instruments and consumables for the RI group.

All 3 general practitioners (GP) had extensive experience with the Forceps Guided circumcision method which they had been performing on a regular basis for several decades. Before the start of the present study they had already employed this method to circumcise 2 103 intervention participants in the MCRCT. The procedure has been audited and standardized with a particular focus on safety and adverse events prevention.

Preparation of the surgical site included a thorough surgical scrub of the genital area with a povidone-iodine preparation. Sterile draping of the area was performed to identify the surgical field. Anaesthesia was accomplished by administering a subcutaneous ring block (13). The foreskin was pulled out in front of the glans and a pair of stout locking forceps was clamped across it, parallel to the corona of the glans and immediately in front of the glans. The scalpel was run across the face of the forceps furthest from the glans to remove the foreskin. The glans was protected by the forceps. The cut edges of the foreskin were closed using absorbable sutures. Excess bleeding was controlled with ligature, direct pressure or electrocautery.

Sterile paraffin Tulle Gras and sterile gauze were wrapped circumferentially around the sutured area, followed by paper tape. The dressing was removed 24 to 48 hours after surgery by the GP who performed it. At this point, no further dressing was necessary, and the patient was instructed to wear loose-fitting briefs. The patient was advised to gently wash the wound daily for the next five to seven days and that intercourse and masturbation should be avoided for four to six weeks after the procedure to prevent breakdown of the wound and HIV infection.

Follow-up

The participants were asked to visit the GP 1 or 2 days after surgery for a clinical follow-up. Complications noted on that occasion, later on or during the procedure were reported using a standardized adverse events sheet. Participants were also advised to contact the GP in the event of complications like bleeding, severe pain or infection. All serious adverse events were submitted to the Data Safety Monitoring Board.

A follow-up visit was arranged at the centre 6 weeks after surgery where participants underwent a genital examination by a male nurse. During the same visit, participants were also interviewed on circumcision-related and unrelated pathological events. They were also asked to rate the maximum pain suffered either during or after the intervention using a self rating visual analogue pain scale (from 0 mm to 100 mm) which has been demonstrated to be reliable in assessing acute pain (14). Participants who did not come to the centre were visited at home and asked to come to the centre. The nurse who performed the clinical examination and the interview was blind to the intervention group.

Sample size and course of the study

The sample size was initially calculated to be a total of 400 participants in order to obtain a power of 80% to detect a 100% increase in the proportion of adverse events in the CK groups with a level of significance of 5%, assuming a 6% prevalence of adverse events in the RI

group, as previously estimated among patients of the intervention group of the MCRCT who were all circumcised with the RI method. The randomization started on 19/02/2005 and stopped on 19/06/2005 after 511 inclusions (259 in the RI group and 252 in the CK group).

Ethics

The research protocol was reviewed and approved by the University of Witwatersrand Human Research Ethics Committee (Medical) on 29 April 2004 as an amendment to the protocol of the MCRCT study (protocol study no. M020104). All adverse events forms were transmitted to a Data Safety Monitoring Board in charge of analyzing them.

Data management

Data collected from questionnaires were entered twice in a database (Microsoft Access, Redmond, Washington, USA) by different people. The two entries were compared and discrepancies were corrected using source documents. Then, the data were checked again for inconsistencies using the source documents. After clean-up, data were imported into the statistical package SPSS for Windows version 13 (SPSS Inc., Chicago, USA) for comparison tests and NCSS Stat System 2005 (NCSS Inc., Kaysville, USA) for equivalence tests and PASS 2005 (NCSS Inc., Kaysville, USA) for statistical power analysis.

Statistical analysis

Baseline participant characteristics were compared between the two randomization groups. Only one cross-over occurred and further analyses were consequently conducted "by treatment received" meaning that procedures' outcomes were compared according to the actual method used for circumcision rather than according to the randomization groups. "Intent-to-treat" analysis was also performed but provided almost identical results (data not shown).

Circumcision outcomes were compared using the Chi-square test for proportions and the t-test for means. Equivalence tests (2-sided, alpha=5%) were performed with three different upper and lower bounds (D=±10% and ±5% for proportions; D=±20 mm and 10 mm for means). An estimate of the statistical power of each equivalence test was also computed.

Departure from protocol

The protocol was initially designed to randomize participants to three groups including an additional group of men circumcised with another method (the Tara KLamp method). Because of delay in the availability of the Cir- Kit, the Tara KLamp was first compared to the usual RI method in a first study. Then, a second randomization process was initiated in order to compare the FG method as used with RI or with CK.

The other deviation from the protocol was that the post-circumcision visit was originally planned to be performed exactly 6 weeks after surgery. No participant attended the visit before 6 weeks but median [mean] duration between circumcision and visit were higher than 6 weeks (42 [22.9]).

RESULTS

Of 513 men asked to participate in the study, 2 refused (see Figure 1). Among the 511 participants who agreed to participate, 259 were randomised to the RI group and 252 to the CK group. In the CK group, 1 participant was eventually circumcised by the RI method because the GP ran out of Cir-Kit. All participants from the RI group were circumcised with the RI method. Among the 511 randomised participants, 28 (5.5%) from the RI group and 24 (4.7%) from the CK group did not visit the GP to be circumcised and were excluded from the analysis. Eighty per cent of those circumcised with the RI method and 85% of those circumcised with the CK method attended the post-circumcision visit.

Table 3 shows the baseline characteristics of the two groups. No statistical differences were found related either to socio-demographic characteristics or to sexual experience, health-related behaviour or history of medical problems (hospitalizations and ulcerations). Similarly, the mean and median durations between circumcision and post-circumcision visit did not differ between the two groups.

Two complications were reported (by the same GP) during the course of the study, one in the RI group (infection with wound dehiscence) and one in the CK group (large haematoma). Only the latter event was also reported by the participants during the post-circumcision visit.

Table 4 compares data collected during the post-circumcision visit. With regard to complication rates, either reported by the nurse from the genital examination performed during the post-circumcision visit or reported by participants to the nurse, no statistically significant differences could be found between the two groups (with type I error risk of 5%). All equivalence tests were significant when lower and upper bounds for difference were taken at D=±10% (±20 mm for mean pain score). With D=±5% (±10 mm for mean pain score), 7 out of 13 equivalence tests remained significant while it should be noted that the statistical power of these latter equivalence tests was low.

DISCUSSION

As regard to post-circumcision complication rate, this trial showed equivalence of the use of a disposable toolkit when compared to conventional instruments, consumables and pharmaceutical products when used in optimal safety conditions.

The complications rate reported from post-circumcision clinical examination was about 10%, though most events were simply related to significant scarring and/or delayed wound healing. Infections (2 out of 377), damage to the penis (3 out of 377), swelling or haematoma in the 2 weeks following circumcision (3 out of 377) were rarely reported. Clinical examination revealed, however, that a significant proportion of men would need to be re-operated (14 out of 377), either for penis appearance problems or for insufficient skin removal. An exhaustive review of the literature on circumcision complications was published in 1993 (15). Complication rates range from 0.06% to 55% but a realistic figure is 2-10% (1) (2) (3). Haemorrhage (16-19) and sepsis (1, 20) are the main reported causes of morbidity, but complications include removal of insufficient skin (3) , removal of too much foreskin, laceration of the penis and scrotum (19), laceration of the penile shaft (21), total ablation (22), urethral fistula (23) (24), meatal stenosis (25) (26), sexual dysfunction (27) and psychological problems (28). This is consistent with our data except that delayed wound healing and scarring or cosmetic problems were reported frequently by the nurse who conducted the clinical examination during the post-circumcision visit. Delayed wound healing may not have been considered as a complication in previous studies. Unlike in other studies, cosmetic appearance of the scar was evaluated by an independent assessor and not by the GP who performed the surgery.

No significant difference was found in pain as rated using a visual analogue pain scale. A study conducted in an emergency medicine department (29) found that the minimum clinically significant difference in visual analogue scale pain scores is 9 mm. Differences of less than 9 mm , even if statistically significant, are unlikely to be of clinical relevance. This minimum value of 9 did not vary with gender, age or cause-of-pain group. When using ±9 as upper and lower bounds for difference, the test for equivalence of visual analogue scale pain scores between the two groups is statistically significant.

It is noteworthy that the investigators were not blind to the randomization group. As the deliberate rationale in designing the Cir-Kit was to enable safe circumcision in underserved areas, the investigators may have been favourably predisposed towards it. This may have influenced how the analyses were performed. The nurse in charge of the interview and of the clinical examination was, however, totally blind to the randomization group. Furthermore, as the same Forceps Guided method was employed, it was not possible from scar examination to guess whether or not the Cir-Kit had been used.

Comparison of baseline characteristics revealed no imbalance between the two randomization groups. There was an excess of 7 participants in the Reusable Instrument group which was not inconsistent with how the randomization process was designed. Only one cross-over occurred: one participant of the Cir-Kit group was eventually circumcised with reusable instruments because the GP ran out of Cir-Kit. Consequently, “by treatment received” and “intent-to-treat” analyses provided similar results (data not shown).

Potential bias could stem from a potential differential attendance at the post-circumcision visit according to occurrence of complications. We are, however, confident that this is unlikely to explain the results as (i) attendance rates were similar in the two groups; (ii) there were no participants' reports suggesting any preconceived idea of the most appropriate method.

The results of this trial show that with regard to complication rates, the Cir-Kit toolkit was equivalent to the optimal use of conventional instruments and consumables when performing male circumcision according to the Forceps Guided technique. It may therefore prove efficient in avoiding complications, and especially infections, when used in settings where sterilization is not easy or where consumables and pharmaceutical products are scarce. As far as costs are concerned, the Cir-Kit is sold at about 8 euros which is not more than the cost of consumables (needle, suture, gauze swabs, lignocaine, gloves, drape, paper tape and povidone iodine) when bought separately. Providing proper and sterilized instruments and consumables is however no guaranty for a safe male circumcision. Practitioners must be also trained to perform the procedure and provide adequate counselling and follow-up to the patient in the following days. This also includes the access to medical facilities in case of severe complications.

Contributors
E Lagarde designed the study, analysed the data and wrote the first draft of the report. B Auvert was the principal investigator and contributed to study design, A Puren and D Taljaard were the principal supervisors and contributed to study design and data collection. G Shilaluke, B Gwala and D Zulu performed all circumcisions and G Gumede conducted the clinical investigations. All authors contributed to data interpretation and critically revised the report.

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Data Safety Monitoring Board
Peter Cleaton-Jones, Mohamed Haffejee (University of Witwatersrand, South Africa), and Jonathan Levin (MRC, South Africa)

Conflict of interest
The Cir-Kit product is not patented. INSERM, NICD and Transaid signed collaboration and licensing agreements related to the Cir-Kit product. None of the authors is employed by Transaid, has received any remuneration or owns any shares in this company.

Table 1: Cir-Kit content

CONTENTS*:	Quantity
SYRINGE 10ml N/N LS	1
NEEDLE 23G x 32mm	1
SUTURE CHROMIC catgut 3/0 cc needle 25mm	1
GAUZE SWABS 100 x 100 x 8 ply 5'	3
LIGNOCAINE 2% 5ml	2
PARANET 10 x 10 1'	1
STERILE GLOVES Large 1 pair	1
STERILE GLOVES Medium 1 pair	1
STERILE DRAPE with FENESTRATION	1
HAEMOSTATIC CLAMP with LOCK Metal	1
NEEDLE HOLDER	1
FORCEPS	1
CIRCUMCISSION CLAMP 5cm	1
BLADE & BLADE Holder	1
HYPO-ALLERGENIC PAPER TAPE 12.5mm x 3m N/S	1
POVIDONE IODINE SOLUTION 50ml (5g) N/S	1

* to reduce costs, no pair of scissors was included. Sutures were cut using the blade.

Table 2. Adverse events sheet items as used by GPs who performed the surgery.

Adverse event type	Description of Adverse Event Type	Severity
During surgery		
Excessive bleeding	Bleeding that requires pressure dressing to control	Moderate
	Blood transfusion or transfer to another facility for management required	Severe
Anesthetic-related event	Reaction to anesthetic requiring medical treatment in study clinic but not transfer to another facility	Moderate
	Anaphylaxis or any reaction requiring transfer to another facility	Severe
Excessive skin removed	Skin is tight, but additional operative work not necessary	Moderate
	Requires re-operation or transfer to another facility to correct the problem	Severe
Damage to the penis	Bruise or abrasion to the glans or shaft of the penis requiring pressure dressing or additional surgery to control	Moderate
	Portion or all of the glans or shaft of the penis severed	Severe
First Month Post-Surgery		
Pain	5 or 6 on pain scale	Moderate
	7 on pain scale	Severe
Excessive bleeding	Bleeding that requires a special return to the clinic for medical attention	Moderate
	Bleeding that requires surgical re-exploration to control	Severe
Excessive skin removed	Skin is tight, but additional operative work not necessary	Moderate
	Requires re-operation or transfer to another facility to correct the problem	Severe
Insufficient skin removed	Prepuce still partially covers the glans and re-operation is required to correct	Moderate
	Prepuce still covers the glans and re-operation is required to correct	Severe
Swelling/Hematoma	Significant tenderness and discomfort, but surgical re-exploration not required	Moderate
	Surgical re-exploration required to correct	Severe
Damage to the penis	Bruise or abrasion to the glans or shaft of the penis requiring pressure dressing or additional surgery to control	Moderate
	Portion or all of the glans or shaft of the penis severed	Severe
Infection	Purulent discharge from the wound	Moderate
	Cellulitis or wound necrosis	Severe
Delayed wound healing	Additional non-operative treatment required	Moderate
	Requires re-operation to correct	Severe
Appearance	Significant wound disruption or scarring, but does not require re-operation	Moderate
	Requires re-operation to correct	Severe
Problems with voiding	Requires a special return to the clinic, but no additional treatment required	Moderate
	Requires referral to another facility for management	Severe

Figure 1: Trial profile

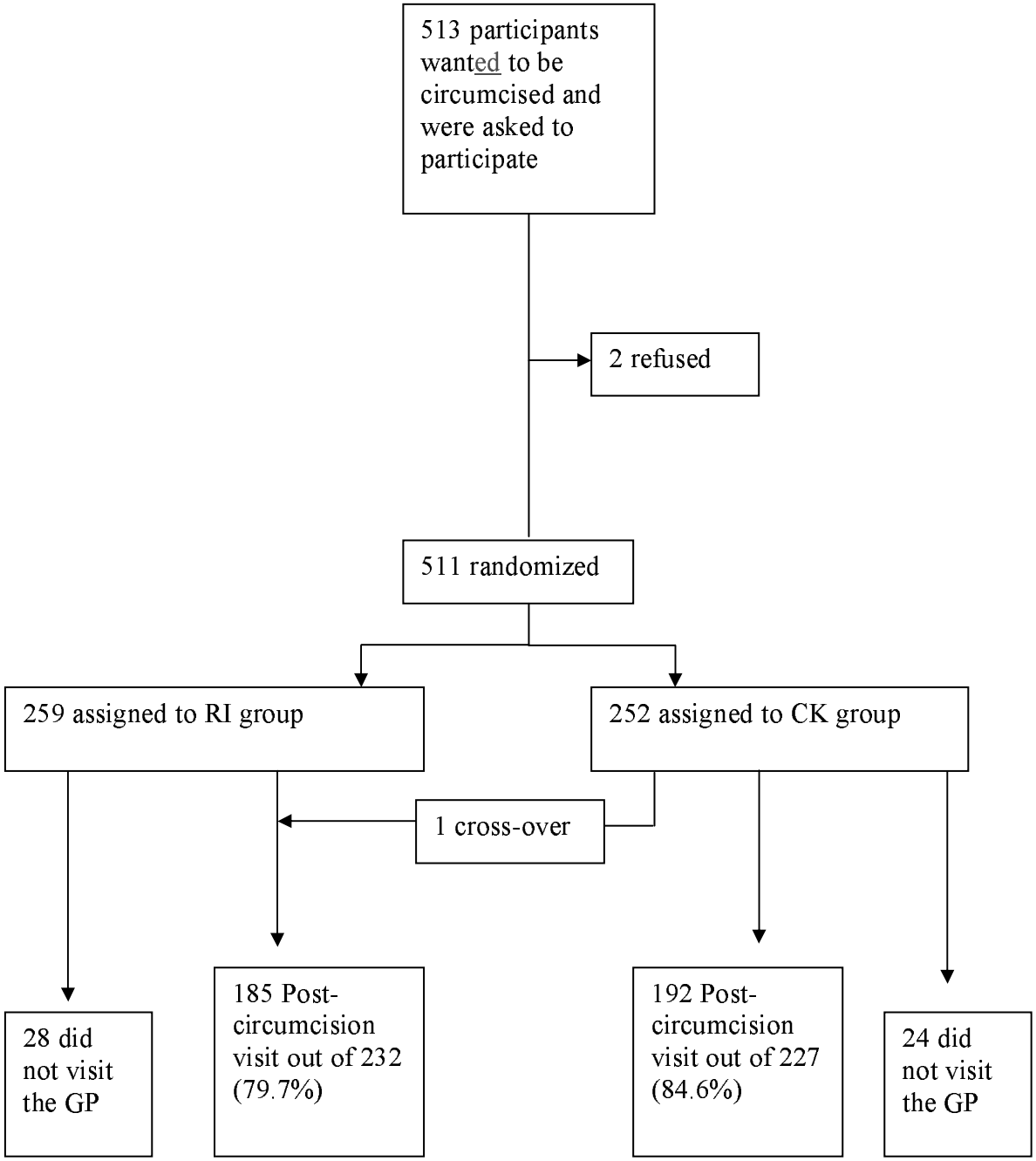

Table 3: Baseline characteristics of the sample*

	Reusable Instruments (n=259$)	Cir-Kit (n=252$)
Background characteristics		
Age at randomization (years)	22 (21 – 24)**	22 (21 – 24)**
Primary level of education completed	254 (98.1%)	250 (99.2%)
Religion (%)		
African Traditional	131 (50.6%)	129 (51.2%)
Other	90 (34.7%)	89 (35.3%)
Protestant	25 (9.7%)	20 (7.9%)
Catholic	13 (5.0%)	13 (5.2%)
Muslim	0 (0.0%)	1 (0.4%)
Ethnic group		
Sotho	146 (56.4%)	145 (57.5%)
Zulu	78 (30.1%)	68 (27.0%)
Xhosa	20 (7.7%)	26 (10.3%)
Tswana	12 (4.6%)	10 (4.0%)
Other	3 (1.2%)	3 (1.2%)
Sexually experienced	229 (88.4%)	227 (90.1%)
Washes genitals with soap every day or more often	193 (74.5%)	181 (71.8%)
Has been hospitalized in the past 5 years	31 (12.0%)	18 (7.1%)
Experienced genital ulcerations in the past 12 months	17 (6.6%)	19 (7.5%)
Attended post-circumcision visit	184 (71.0%)	193 (76.6%)
Duration between circumcision and visit (days)		
Mean	56.5	55.3
Median (IQR)	43 (42-48)	42 (42-51)

* None of the comparisons listed were statistically significant (p>0.05).
** Median (Inter quartile range IQR) .
$ except for duration between circumcision and visit

Table 4. Comparison of circumcision outcomes between the two groups according to nurse' clinical examination and participants' reports, both during post-circumcision visit.

	Reusable Instruments (n=185)	Cir-Kit (n=192)	p	p equivalence (1-β) D=±10%	p equivalence (1-β) D=±5%
Clinical examination					
Any sign of adverse event	18 (9.7%)	22 (11.5%)	0.59	0.006 (80%)	0.15 (0%)
Current infection	1 (0.5%)	1 (0.5%)	1.00	$<10^{-4}$ (17%)	0.002 (17%)
Delayed wound healing	9 (4.9%)	4 (2.1%)	0.16	0.002 (30%)	0.14 (5%)
Problem with appearance			0.89	0.003 (85%)	0.08 (0%)
- Significant scarring or other cosmetic problem, but does not require re-operation	18 (9.7%)	19 (9.9%)			
- Requires re-operation to correct	3 (1.6%)	2 (1.0%)			
- No problem with appearance	164 (88.6%)	171 (89.1%)			
Skin is tight, but additional operative work not necessary	3 (1.6%)	6 (3.1%)	0.50	0.0002 (63%)	0.03 (36%)
Insufficient skin removed			0.41	0.001 (83%)	0.11 (17%)
-Prepuce partially covers the glans only when extended	3 (1.6%)	6 (3.1%)			
-Prepuce still partially covers the glans and re-operation is required to correct	3 (1.6%)	6 (3.1%)			
-Prepuce still covers the glans	1 (0.5)	0 (0.0%)			
- No insufficient skin removed	178 (96.2%)	189 (93.8%)			
Participants report during post-circ visit					
Bleeding within the 2 next weeks*	2 (1.1%)	6 (3.1%)	0.28	0.0003 (67%)	0.05 (32%)
Damage to the penis	1 (0.5%)	2 (1.0%)	1.00	$<10^{-4}$ (30%)	0.003 (30%)
Infection following circumcision	1 (0.5%)	0 (0.0%)	0.49	$<10^{-4}$ (5%)	0.003 (5%)
Swelling or haematoma within the 2 next weeks**	1 (0.5%)	2* (1.0%)	1.00	$<10^{-4}$ (30%)	0.05 (5%)
Problem urinating	1 (0.5%)	0 (0.0%)	0.49	$<10^{-4}$ (5%)	0.003 (5%)
Satisfied with penis appearance	178 (96.2%)	182 (94.8%)	0.62	0.0005 (78%)	0.06 (30%)
Mean pain score	49 mm (SD=38)	53 mm (SD=37)	0.23	$<10^{-4}$ (99%) (D=±20)	0.059 (45%) (D=±10)

* One of these reports corresponded to one of the two adverse events reported by GP.
** Following circumcision procedure.

REFERENCES

1. Griffiths DM, Atwell JD, Freeman NV. A prospective survey of the indications and morbidity of circumcision in children. Eur Urol. 1985;11(3):184-7.
2. Speert H. Circumcision of the newborn; an appraisal of its present status. Obstet Gynecol. 1953 Aug;2(2):164-72.
3. Leitch IO. Circumcision. A continuing enigma. Aust Paediatr J. 1970 Jun;6(2):59-65.
4. Miles SH, Ololo H. Traditional surgeons in sub-Saharan Africa: images from south Sudan. Int J STD AIDS. 2003 Aug;14(8):505-8.
5. Sefara M. Is There Place for a Scalpel in the Bush? . The Sowetan. 2001 July 18.
6. Ahmed A, Mbibi NH, Dawam D, Kalayi GD. Complications of traditional male circumcision. Ann Trop Paediatr. 1999;19(1):113-7.
7. Menahem S. Complications arising from ritual circumcision: pathogenesis and possible prevention. Isr J Med Sci. 1981;17(1):45-8.
8. Ozdemir E. Significantly increased complication risks with mass circumcisions. Br J Urol. 1997;80(1):136-9.
9. Magoha GA. Circumcision in various Nigerian and Kenyan hospitals. East Afr Med J. 1999;76(10):583-6.
10. Growley. Ritual circumcision (Umkhwethta) among the Xhosa of the Ciskei. Br J Urol. 1979;55:521.
11. Auvert B, Taljaard D, Lagarde E, Sobngwi-Tambekou J, Sitta R, Puren A. Randomized, Controlled Intervention Trial of Male Circumcision for Reduction of HIV Infection Risk: The ANRS 1265 Trial. PLoS Med. 2005 Nov;2(11):e298.
12. WHO, UNAIDS, UNFPA, UNICEF. UNAIDS statement on South African trial findings regarding male circumcision and HIV. 26 July 2005 [cited 01/08/2005]; Available from: http://www.who.int/mediacentre/news/releases/2005/pr32/en/
13. Szmuk P, Ezri T, Ben Hur H, Caspi B, Priscu L, Priscu V. Regional anaesthesia for circumcision in adults: a comparative study. Can J Anaesth. 1994;41(12):1181-4.
14. Bijur PE, Silver W, Gallagher EJ. Reliability of the visual analog scale for measurement of acute pain. Acad Emerg Med. 2001 Dec;8(12):1153-7.
15. Williams N, Kapila L. Complications of circumcision. Br J Surg. 1993;80(10):1231-6.
16. Griffiths DM, Munro MF, Freeman NV. Who cares for the foreskin? Br J Clin Pract. 1986;40(10):414-6.
17. Kaplan GW. Complications of circumcision. Urol Clin North Am. 1983;10(3):543-9.
19. Gee WF, Ansell JS. Neonatal circumcision: a ten-year overview: with comparison of the Gomco clamp and the Plastibell device. Pediatrics. 1976;58(6):824-7.
19. Shulman J, Ben-Hur N, Neuman Z. Surgical Complications of Circumcision. Am J Dis Child. 1964 Feb;107:149-54.
20. Fraser IA, Allen MJ, Bagshaw PF, Johnstone M. A randomized trial to assess childhood circumcision with the Plastibell device compared to a conventional dissection technique. Br J Surg. 1981;68(8):593-5.
21. Byars LT, Trier WC. Some complications of circumcision and their surgical repair. AMA Arch Surg. 1958 Mar;76(3):477-82.
22. Gearhart JP, Rock JA. Total ablation of the penis after circumcision with electrocautery: a method of management and long-term followup. J Urol. 1989;142(3):799-801.
23. Lackey JT, Mannion RA, Kerr JE. Urethral fistula following circumcision. JAMA. 1968;206(10):2318.
24. Limaye RD, Hancock RA. Penile urethral fistula as a complication of circumcision. J Pediatr. 1968;72(1):105-6.
25. MacKenzie AR. Meatal ulceration following neonatal circumcision. Obstet Gynecol. 1966;28(2):221-3.
26. Gairdner D. The fate of the Foreskin. BMJ. 1949;ii:1433-7.
27. Harnes JR. The foreskin saga. Jama. 1971;217(9):1241-2.
28. Mohl PC, Adams R, Greer DM, Sheley KA. Prepuce restoration seekers: psychiatric aspects. Arch Sex Behav. 1981;10(4):383-93.
29. Kelly AM. Does the clinically significant difference in visual analog scale pain scores vary with gender, age, or cause of pain? Acad Emerg Med. 1998 Nov;5(11):1086-90.