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SAFETY OF A DISPOSABLE MALE CIRCUMCISION KIT. RESULTS FROM A RANDOMIZED CONTROLLED TRIAL CONDUCTED IN SOUTH AFRICA

E. LAGARDE[1], D. TALJAARD[2], A. PUREN[3], G. SHILALUKE[6], B. GWALA[6], D. ZULU[6], G. GUMEDE[2] AND B. AUVERT[1,4,5]

[1]Inserm, U687, Saint-Maurice, France; [2]National Institute for Communicable Diseases, Johannesburg, South Africa; [3]Progressus CC, Johannesburg, South Africa; [4]Hôpital Ambroise Paré, AP-HP, Boulogne-Billancourt, France; [5]Université de Versailles - Saint-Quentin-en-Yvelines, UFR médicale Paris-Ile-de-France-Ouest, Garches, France; [6]Private General Practitioners, Orange Farm, South Africa.

Objective: 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). The objective of this study was to evaluate the safety of this new circumcision kit.

Patients and 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 practitioners already performing the circumcisions in the main trial on the impact of circumcision using the Forceps Guided method. The patients were randomized into two groups of equal size (using the Cir-Kit (CK group), or using conventional reusable instruments (RI group)). Adverse events were recorded by the general practitioners in charge of the follow-up to surgery, and the participants attended a check-up visit 6 weeks after surgery, during which they underwent a clinical examination performed by a nurse and answered a standardized questionnaire, including the assessment of pain using a visual pain analogue scale.

Results: Of the 513 men invited to participate, 511 consented 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 difference 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.

Conclusions: 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 follow up of the patients and access to medical facilities in case of serious complications are, however, also required.

Key Words: male circumcision, adults, Cir-Kit

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 unclean cutting equipment used on several patients, thus leading to complications and in particular to infections[4-8]. No complication rates associated with ritual circumcision performed in non-medical 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 [11,12]increase in the rate of such surgery

In response to this need for safer circumcision practices, a South African company recently designed 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 invite 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 using reusable conventional instruments in optimal safety conditions.

PATIENTS AND METHODS

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, between February and June 2005.

During their last visit as part of the MCRCT follow-up (month 21), MCRCT control group members were invited 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 did not 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, hematoma, infection, inadvertent damage to the glans, removal of too much or too little skin, esthetically unpleasant 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 behavior just like uncircumcised people. All participants who attended the center 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 randomization to one of the two groups, each participant was invited by the manager of the center 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 randomization group. Finally, participants were asked to come back to the center 6

weeks after surgery for a genital examination and completion of a short questionnaire. Participants who attended the center for this post-circumcision visit received a 40 Rand payment.

Eligibility criteria to participate in the study were to be:

- an uncircumcised man from the control group of the MCRCT trial and visiting the center 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 contact (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.

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 three general practitioners (GPs) 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 2103 intervention participants in the MCRCT. The procedure has been audited and standardized with a particular focus on safety and adverse event 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. Anesthesia was accomplished by administering a subcutaneous ring block[13]. The foreskin was pulled out forwards over the glans and a pair of stout artery 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.

The participants were asked to visit the GP one or two 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 event 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 a medical monitoring board.

A follow-up visit was arranged at the center 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 visual analogue pain scale (from 0 mm to 100 mm) which has been demonstrated to be reliable in assessing acute pain[14].

Table 1: Cir-Kit content.

CONTENTS*	Quantity
Syringe 10 ml N/N LS	1
Needle 23 G x 32 mm	1
Suture chromic catgut 3/0 cc needle 25 mm	1
Gauze swabs 100 x 100 x 8 ply 5'	3
Lignocaine 2% 5 ml	2
Paranet 10 x 10 1'	1
Sterile gloves large 1 pair	1
Sterile gloves medium 1 pair	1
Sterile drape with fenestration	1
Hemostatic clamp with lock metal	1
Needle holder	1
Forceps	1
Circumcision clamp 5 cm	1
Blade & blade holder	1
Hypo-allergenic paper tape 12.5 mm x 3 m N/S	1
Povidone Iodine solution 50 ml (5g) N/S	1

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

Participants who did not come to the center were visited at home and asked to come to the center. The nurse who performed the clinical examination and the interview was blind to the intervention group.

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 group 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. Adverse events during surgery and during the first postoperative month were classified into moderate or severe according to the form shown in Table 2. 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).

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 event forms were transmitted to a medical monitoring board for analysis.

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.

The baseline participant characteristics were compared between the two randomization groups. Only one cross-over occurred and further analyses were consequently

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 this	Moderate
	- Prepuce still covers the glans and re-operation is required to correct this	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

conducted "by treatment received", meaning that the outcomes of the procedures 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).

The 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.

The protocol had initially been designed to randomize the participants to three groups including an additional group of men circumcised with another method (the Tara KLamp method). Because of a delay in the availability of the Cir-Kit, the Tara KLamp was 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 had originally been planned to be performed exactly 6 weeks after surgery. No participant attended the visit before 6 weeks but the median [mean] duration between circumcision and visit was higher than 6 weeks (42 [22.9])

RESULTS

Of 513 men invited to participate in the study, 2 refused (Fig. 1). Among the 511 participants who agreed to participate, 259 were randomized to the RI group and 252 to the CK group. In the CK group, one 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 randomized 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 behavior 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 hematoma). Only the latter event was also reported by the participant 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 for the 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 complication 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

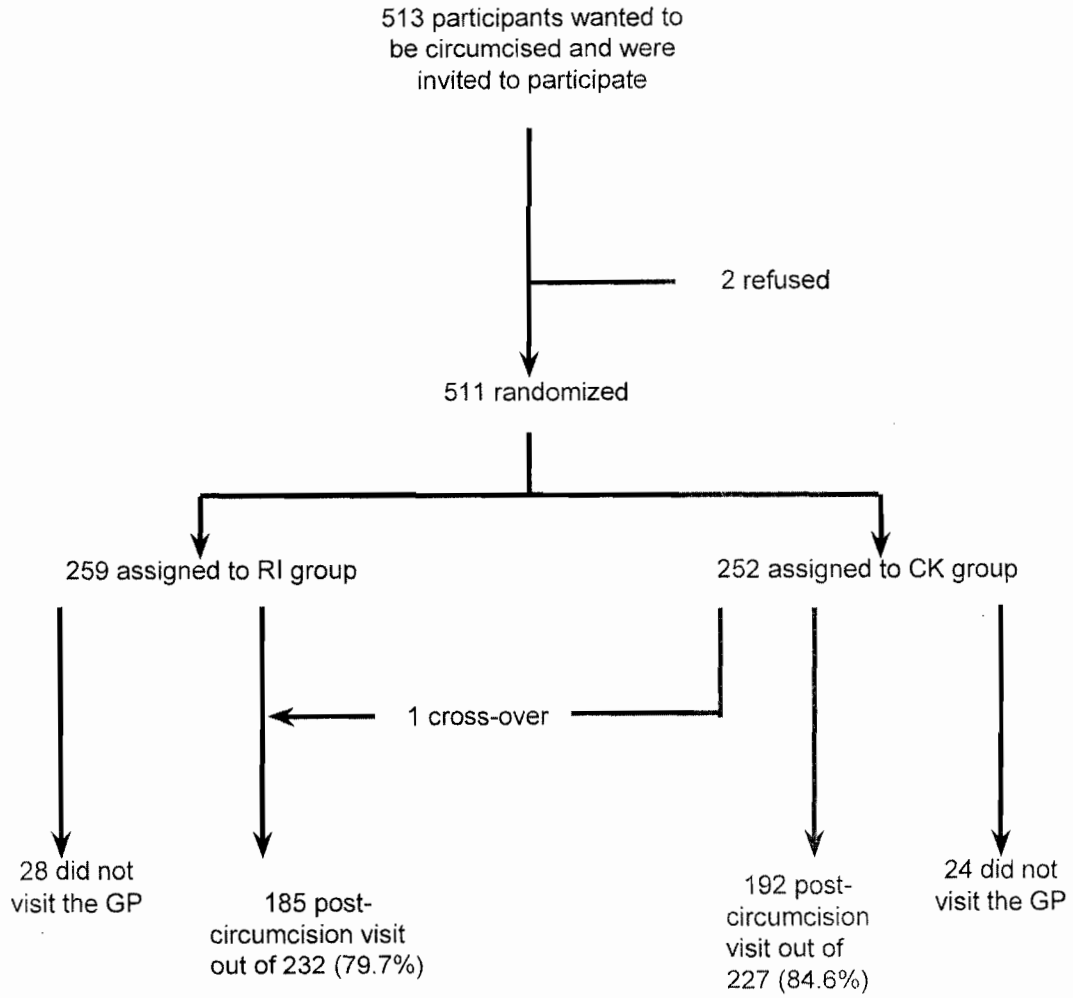

Fig. 1: Trial profile.

the penis (3 out of 377), swelling or hematoma 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%[1-3]. Hemorrhage[16-19] and infection[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

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%)	
Catholic	13 (5.0%)	
Muslim	0 (0.0%)	
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.

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 favorably 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.

Table 4: Comparison of circumcision outcomes between the two groups according to nurses' 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%)			
Sufficient 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 hematoma 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.

Comparison of baseline characteristics revealed no imbalance between the two randomization groups. There was an excess of 7 participants in the RI 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 had run out of Cir-Kit. Consequently, "by treatment received" and "intent-to-treat" analyses provided similar results (data not shown).

A 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 guarantee for a safe male circumcision. Practitioners must be also trained to perform the procedure and provide adequate counseling and follow-up to the patient. This also includes access to medical facilities in case of severe complications.

Contributors:

E. Lagarde designed the study, analyzed the data and wrote the first draft of the report. B. Auvert was the principal investigator and contributed to the 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.

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RESUME

Sécurié d'un kit de circoncision à usage unique. Résultats d'un essai contrôlé randomisé conduit en Afrique du Sud

Fond et objectif: Les instruments correctement stérilisés et les consommables appropriés sont nécessaires pour exécuter les procédures de circoncision dans des conditions de sécurité sanitaire satisfaisante. En réponse à ce besoin une compagnie sud-africaine a récemment préparé une trousse à usage unique (Cir-Kit) contenant tous les instruments jetables, les consommables et les produits pharmaceutiques requis pour exécuter une circoncision simple chez de jeunes adultes selon la technique la plus commune utilisée en Afrique du Sud (la technique guidée par forceps). L'objectif de cette étude était d'évaluer la sécurité sanitaire de ce nouveau kit de circoncision.
Patients et méthodes: À la suite d'un essai contrôlé randomisé sur l'impact de la circoncision sur la transmission d'HIV, 511 des 3274 participants ont accepté de participer à cet essai. Ils ont été circoncis par un des trois médecins généralistes déjà responsables des circoncisions dans l'essai principal sur l'impact de la circoncision, selon la méthode guidée par forceps , puis randomisés dans deux groupes de taille égale (utilisant le Cir-Kit (groupe de CK), ou à l'aide d'instruments réutilisables conventionnels (groupe de RI)). Les résultats ont été enregistrés par les médecins généralistes responsables de l'intervention chirurgicale et du suivi médical. Les participants ont assisté à une visite de contrôle pendant 6 semaines après la chirurgie pendant laquelle ils ont subi une recherche clinique réalisée par un infirmier et ont répondu à un questionnaire normalisé comprenant l'évaluation de la douleur en utilisant une échelle visuelle analogique d' estimation individuelle de douleur.
Résultats: Des 513 hommes qui ont été demandés à participer, 511 ont accepté dont 259 ont été randomisés au groupe de RI et 252 au groupe de CK. 80% de ceux circoncis par la méthode de RI et 85% de ceux circoncis par la méthode de CK ont assisté à la visite de post-circoncision, comme rapporté par l'examen génital réalisé par l'infirmier pendant la visite post-circoncision ou rapportés par des participants à l'infirmier. Aucune différence statistiquement significative de complication n'a été trouvée entre les deux groupes (avec type I error risk de 5%). Tous les tests d'équivalence étaient significatifs quand des limites inférieures et supérieures pour la différence ont été prises à D=±10% (±20 millimètre pour les points moyens de douleur). Avec D=±5% (±10 millimètre pour les points moyens de douleur), 7 sur 13 tests d'équivalence sont restés significatifs.
Conclusion: La trousse à outils de circoncision Cir-Kit s'est avérée équivalente aux instruments conventionnels réutilisables si utilisée d'une façon optimale. Ce produit sera utile quand utilisé dans les situations où la stérilisation des instruments réutilisables n'est pas facile ou où les consommables et les produits pharmaceutiques sont rares. La formation des praticiens, le suivi des patients appropriés et l'accès aux équipements médicaux en cas de complications sérieuses sont cependant également exigés.

Editorial Comment:

The study of Lagarde et al. in the current issue found that a disposable male circumcision kit was just as effective as reusable instruments, but had a greater potential for safety in areas where maintaining sterility is a problem. Further, they found that the costs were comparable, although no detailed data were given for the cost of reusable instruments (the kit cost was 8 Euros). The cost factor is important if circumcision has widespread adoption in Africa in the face of convincing evidence that circumcised men have about half the chance of acquiring HIV infection on heterosexual exposure as do those who are uncircumcised, a finding that has the potential for saving millions of lives.

The complication rate with experienced medical operators was found to be 10%. This figure seems high and might reflect the fact that findings such as short or long foreskin were considered to be surgical complications rather than imperfect surgical outcomes of questionable significance. I think it would be more realistic to limit complications to evidence of infection, bleeding and penile injury, which would result in a low rate, and be of more clinical importance. The fact that 96% of the patients were satisfied would suggest that the complication rate is much lower than suggested. The aim of circumcision in this setting is not to get a pleasing cosmetic effect, but rather to remove as much of the foreskin as practical and end up with a functional penis less likely to get infected with HIV.

It was not within the realm of this paper, but in my opinion any large scale circumcision program should include newborn circumcision. Newborn circumcision is quicker, safer, and has fewer complications (in the United States the complication rate is less than 1%). There are well-established, effective clamp methods (Mogen, Gomco and Plastibell), and with experienced operators the procedure takes less than 10 minutes. Because of the thin foreskin, sutures are not needed and healing is much quicker. Babies are more resilient and recover faster than adults. There are additional lifetime benefits to newborn circumcision, including protection against infant kidney infections, local foreskin problems and infections, dermatoses, penile cancer and cervical cancer in female partners. Published evidence shows a preventive effect against other sexually transmitted infections including human papilloma virus (HPV) and Chlamydia. Adult circumcision is necessitated by the dangers of the current HIV/AIDS epidemic, but the problem has been around for over 20 years. Had newborn circumcision become the standard of care in Africa when HIV/AIDS was first related to circumcision in the late 1980's there would now be an entire generation with a protection of 50% or more against acquiring HIV.

In trying to establish the safest and most effective way of performing circumcision on a large enough scale to help control the immediate HIV/AIDS crisis in Africa the authors have made a worthy contribution, which above all addresses HIV, but has the potential for preventing other disorders as well.

Edgar Schoen, M.D.
University of California, San Francisco and Kaiser Permanente, Oakland, USA

Corresponding author:

Emmanuel Lagarde
Equipe Avenir Santé et Insécurité Routière
INSERM Unité 593
Université Victor Segalen Bordeaux 2, Case 11
146, rue Léo-Saignat
F-33076 Bordeaux cedex
France

e-mail:emmanuel.lagarde@isped.u-bordeaux2.fr