High rate of adverse events following circumcision of young male adults with the Tara KLamp technique: A randomised trial in South Africa

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Background. The Tara KLamp (TK) device has been claimed to enable circumcisions to be performed safely and easily in medical and non-medical environments. Published evaluation studies have been conducted among young children only.

Methods. Following a randomised controlled trial (RCT) on 3 274 participants on the impact of male circumcision on HIV transmission, 69 control group members participated in this male circumcision methods trial and were randomised to a forceps-guided (FG) group and a TK group, and circumcised.

Results. Of the 166 men asked to participate, 97 declined, most (94) refusing circumcision by the TK technique; 34 men were randomised to the FG group and 35 to the TK group, and 32 and 24 patients were circumcised by the FG and TK methods respectively, of whom 29 and 19 respectively attended the post-circumcision visit. All 12 adverse event sheets corresponded to the TK group (p<0.001) and circumcisions by the TK method. Less favourable outcomes were associated with the TK method, including any sign of an adverse event (37% v. 3%; p=0.004), delayed wound healing (21% v. 3%; p=0.004) and problems with penis appearance (31% v. 3%; p=0.001).

Participants randomised to the TK method were significantly more likely to report bleeding (21% v. 0%; p=0.02), injury to the penis (21% v. 0%; p=0.02), infection (32% v. 0%; p=0.002), swelling (83% v. 0%; p<0.001), and problems with urinating (16% v. 0%; p=0.056). The mean score of self-estimated pain was 9.5 for participants circumcised by TK compared with 6.1 for other participants (adjusted p=0.003).

Conclusion. This study provides compelling evidence that strongly cautions against use of the TK method on young adults.

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Male circumcision is by far the most prevalent surgical procedure worldwide, with about 10 million performed each year, mostly in non-medical settings. Although circumcision is considered to be a minor and safe procedure, the incidence of postoperative complications can be high.[1-3] Traditional circumcisions throughout sub-Saharan Africa are usually performed with cutting tools that are used without intermediate cleaning on several patients in turn, leading to complications and, in particular, infections.[4-8] Complication rates associated with ritual circumcision performed in non-medical settings have not been widely reported, but most authors agree that such unsafe practices should be discouraged.[6,9,10]

A comprehensive safety assessment of current male circumcision procedures is necessary to identify appropriate methods for each setting and to issue proper clinical guidelines, as positive results on the protective effect of male circumcision against HIV transmission are likely to boost circumcision rates.[11,12]

According to the Malaysian inventor-manufacturer, the Tara KLamp (TK) '… enables circumcisions to be performed not only safely and easily but also enables circumcisions to be performed just as aseptically, at home, on the roadside or out there in the bush, as in an operating theater' (Tara KLamp brochure available at www.taraklamp.com.my, and www.circlist.com/instrstechs/taraklamp.html). Few data on its safety have been published.

A study in The Netherlands among children aged >2 years compared circumcision using a shield and knife method with the TK. Operation duration was 8 minutes less for the TK and its cosmetic results were better. There was no difference in complication rates, and parents' satisfaction scores were similar.[13] A study evaluating the TK among 64 Muslim children (no control group) reported no major complications.[14]

A study from Thailand on adolescent circumcisions (www.circlist.com/instrstechs/taraklamp.html) reported a 32% complication rate among 44 procedures performed with

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the TK, and a 1% complication rate among 476 surgical procedures, and warned that the TK technique leaves necrotic tissue attached to the penis for several days, and that most complications occurred with larger-size clamps.

We asked participants of the control group of the male circumcision randomised controlled trial (MCRCT)[11] conducted in South Africa on 3 274 uncircumcised men aged 18 - 24 to participate in a randomised sub-trial to compare the safety of the TK technique with the conventional forceps-guided (FG) method.

Methods

This randomised controlled trial compared two methods of male circumcision. Men were recruited from among the 1 654 control group MCRCT participants who had been offered circumcision at the end of the follow-up, 21 months after inclusion in the MCRCT.

Population and setting

The study was carried out in Orange Farm and surrounding areas, a semi-urban region of Johannesburg, from September to November 2004.

Inclusion and randomisation

During the last follow-up visit (month 21) in the MCRCT, control group participants were asked to participate after having been informed of the study's aim and procedures. We ensured that they understood that, by consenting to participate, they agreed to be circumcised free of charge either by the usual FG method (FG group) or by the TK method (TK group), and that the groups would be chosen at random. We described both techniques, a sample TK kit was available for demonstration, and they were also told of the risks of complications. If they did not want to participate in the study, potential participants were offered free circumcision by the usual FG technique. Participants were further informed that male circumcision provides only partial protection against AIDS/HIV and they were urged to use condoms and adopt safe sexual practices as if they were uncircumcised. All participants who attended the centre for their last visit of the MCRCT follow-up received a R150 (20 Euro) payment whether or not they participated in the study.

For randomisation, each participant chose an envelope containing the group name from a basket of 10 envelopes. After each choice, a new envelope 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 TK tokens, was added to the basket. Participants were invited to be circumcised within a week, with an appointment for surgery and free transportation. A voucher for the general practitioner clearly indicated the randomisation group. Participants were asked to return to the centre 6 weeks after surgery for a genital examination and completion of a short questionnaire. Participants who attended this post-circumcision visit were paid R40.

Eligibility criteria

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

Circumcision procedures

All three general practitioners (GPs) had extensive experience with the FG circumcision method. They were provided with TKs of different sizes and the instruction manual, asked whether they felt able and agreed to perform the procedure, and asked to record the actual method used. Two of the GPs had already used the TK on a few occasions.

Both groups went through the same pre-operative steps: preparation of the surgical site including a surgical scrub of the genital area with a povidone-iodine solution, sterile draping, and anaesthesia by a dorsal penile nerve block, with or without a ring block.[15]

Forceps-guided method

The FG method had already been employed for 1 855 participants in the MCRCT. The foreskin is pulled outwards in front of the glans, and forceps clamped across it, parallel to the corona of the glans and immediately in front of the glans. The scalpel is run across the face of the foreskin, and absorbable sutures are used to close the cut edges. Excess bleeding is controlled with ligature, direct pressure or cautery. The sutured area is covered with sterile paraffin tulle gras, sterile gauze and paper tape; this dressing is removed 24 - 48 hours after surgery by the GP who performed it. No further dressing is necessary.

Tara KLamp technique

The TK is a pre-sterilised disposable plastic device (Fig. 1); the size is chosen by using a measuring card with holes of various diameters, and the device is installed by the GP. The foreskin is pulled slightly forward over the rim of an inner tube and positioned inside an outer ring. Two plastic arms are locked into place to force two surfaces (the inner tube and the outer clamping ring) into tight contact with the foreskin trapped between them. If the foreskin is tight, a dorsal slit is required to gain access for the ring to be applied over the glans. Then the foreskin trapped forward of the clamping device is cut away.

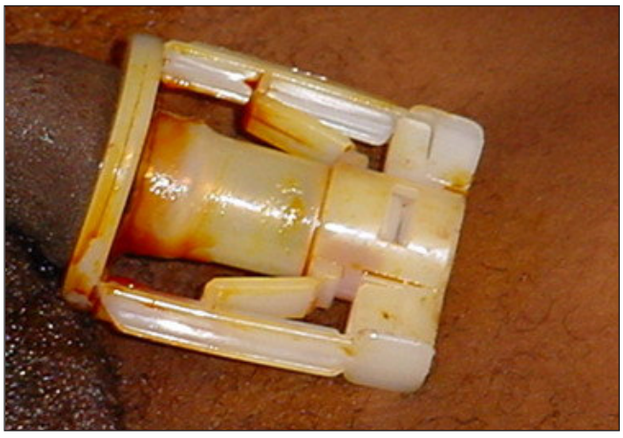

Fig. 1. The Tara KLamp device.

The device is intended to remain on the penis for 7 - 10 days until it is removed or falls off with the necrotised foreskin.

Follow-up

Participants were asked to visit the GP for a clinical follow-up 3 days after surgery. Adverse events were recorded using a standardised sheet. Participants were advised to contact the GP in the event of complications. All serious adverse events were submitted to the Data Safety Monitoring Board. At a follow-up visit 6 weeks after surgery, participants were interviewed on circumcision-related and unrelated pathological events and asked to rate the maximum pain suffered either during or after the intervention, using a reliable self-rating visual analogue pain scale.[16] At this visit, participants underwent a genital examination by a male nurse. Participants who did not come to the centre were visited at home and asked to come to the centre. The nurse who performed the interview and the clinical examination was blinded to the intervention group, but was obviously able to identify the group from seeing the scar.

Assessment criteria

Assessment criteria included: (*i*) comparison of circumcision methods according to the number and nature of adverse events reported by the GP who performed the procedure; (*ii*) the nurse's clinical assessment, which included any signs of adverse events, observed penile infection or delay in wound healing, problem with penis appearance, excessive or insufficient skin removed and any erectile dysfunction; and (*iii*) participants' reports, which included pain score, bleeding within the 2 weeks following the procedure, lesions to the penis, swelling or haematoma within the 2 weeks following the procedure, any problem when urinating, and satisfaction with penis appearance.

Neither GPs, participants nor investigators were blinded to the randomisation group. At interview, the nurse was not aware of the method used but on examination could conclude which technique was used.

Sample size and course of the study

The sample size was initially calculated to total 400 participants to obtain a power of 80% to detect a 100% increase in the proportion of adverse events in the TK group with a level of significance of 5%, assuming a 6% prevalence of adverse events in the FG group as previously estimated among patients of the intervention group of the MCRCT who were all circumcised by the FG method. The randomisation started on 17 September 2004 and was stopped on 23 October 2004 after 48 inclusions (24 in the FG group and 24 in the TK group) because of the high number of reported adverse events associated with the TK technique. A medical doctor was sent by the exclusive supplier of TK in South Africa to improve the three GPs' skills in performing the procedure. The study resumed on 9 November 2004 and stopped again on 29 November 2004 after a further 21 inclusions (10 in the FG group and 11 in the TK group) because the GPs once again requested a trial interruption as of an unacceptable rate of adverse events and difficulties with the procedure. The trial investigators informed the Data and Safety Monitoring Board and stopped the trial.

Ethics approval

The research protocol was approved by the University of the Witwatersrand Human Research Ethics Committee (Medical). Adverse events forms were transmitted to a Data Safety Monitoring Board.

Data management

Data collected from questionnaires were entered twice in a database (Microsoft Access, Redmond, Washington, USA) by different people; entries were compared and discrepancies corrected. Data were checked again for inconsistencies using the source documents. Data were analysed by the statistical package SPSS for Windows, version 13 (SPSS Inc., Chicago, USA).

Statistical analysis

Participant characteristics between the randomisation groups were compared. Analyses were compared 'by treatment received', meaning that procedure outcomes were according to the actual method used for circumcision rather than according to the randomisation groups. Because of the small sample size, circumcision outcomes were compared using Fisher's exact test for proportion and a *t*-test for means. The comparison of pain scores was further adjusted for the interval (as a categorical variable) between circumcision and post-circumcision visit, using linear regression.

Departure from protocol

The protocol was designed to randomise participants to three groups, including men circumcised with a single-use sterile surgery kit, but because of delay in its availability, the study

started with only two (the TK v. FG method with re-usable instruments). The planned number of participants of 400 in each group was not achieved because of trial interruption owing to a high number of adverse events in one group. The post-circumcision visit was originally planned to be exactly 6 weeks after surgery, but only 3 participants made the visit 1 - 3 days before 6 weeks. Median and mean intervals between circumcision and visit were more than 6 weeks.

Results

Of the 166 patients asked to participate in the study, 97 refused (Fig. 2); all agreed to give reasons for refusal, most (94) saying that they did not want to be circumcised by the TK technique. Of the 69 participants who agreed to participate, 34 were randomised to the FG group and 35 to the TK group; 4 participants in the TK group were eventually circumcised by the FG method. All FG group participants were circumcised with the FG method. Among the 69 randomised participants, 6 from the FG group and 7 from the TK group did not visit the GP for circumcision and were excluded from the analysis.

We shall now consider the actual method used for circumcision (FG or TK) rather than the initial randomisation groups (by treatment analyses).

The post-circumcision visit was attended by 91% of those circumcised by the FG method and 79% of those circumcised with the TK method. Table I shows the baseline characteristics of the two groups. No statistical differences were found related to socio-demographic characteristics, sexual experience, health-related behaviour or history of medical problems (hospitalisations and ulcerations).

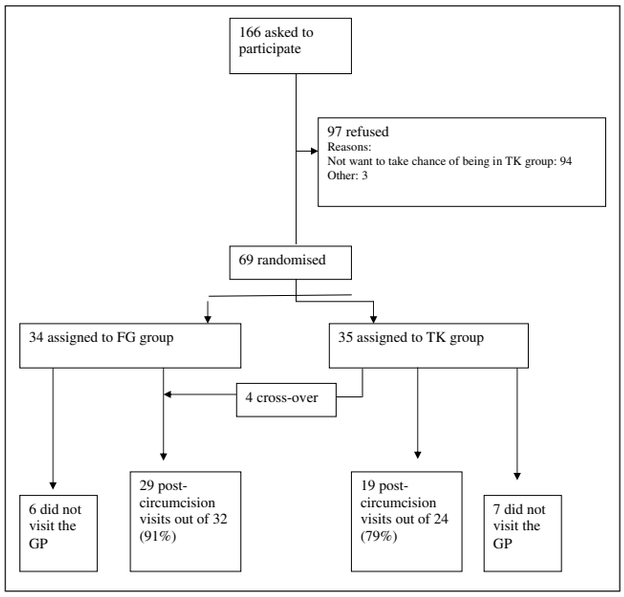

Fig. 2. Trial profile.

A total of 12 adverse events were reported by the GPs during the course of the study (Table II), all corresponding to participants initially randomised to the TK group. Two participants were eventually circumcised by the FG method, as the TK method had failed.

Table III compares data from post-circumcision visits. The mean and median intervals between circumcision and the post-circumcision visit were longer among those circumcised by the FG method. Participants circumcised by the TK method

Table I. Baseline characteristics of the sample*

Background characteristics	FG method randomisation group (*N*=34)	TK randomisation group (*N*=35)
Age at randomisation (years)	21.5 (20 - 23.25)†	22 (21 - 24)†
Primary level of education completed	28 (82%)	33 (94%)
Religion (%)		
Protestant	1 (2.9%)	3 (8.6%)
Catholic	1 (2.9%)	0 (0.0%)
Muslim	0 (0%)	0 (0%)
African traditional	16 (47%)	16 (46%)
Other	16 (47%)	16 (46%)
Ethnic group		
Sotho	10 (29%)	13 (37%)
Tswana	4 (12%)	5 (14%)
Xhosa	3 (8.8%)	4 (11%)
Zulu	17 (50%)	13 (37%)
Sexually experienced	33 (97%)	32 (91%)
Washes genitals with soap each day or more often	22 (65%)	24 (67%)
Hospitalised in the past 5 years	5 (15%)	4 (11%)
Genital ulcerations in the past 12 months	2 (6%)	2 (6%)

*Median (interquartile range).

†None of the comparisons listed were statistically significant ($p>0.05$).

were significantly more likely to report bleeding, lesions to the penis, infection, swelling, haematoma and problems with urinating. The mean scores for pain were 6.1 and 9.5 among those circumcised by the FG and TK methods respectively, which was statistically significant. Almost all participants were satisfied with the appearance of their penis.

Table II. Description of the 12 reported adverse events

Date of circumcision	Interval between circumcision and report (days)	General practitioner	Randomisation group	Circumcision method	Adverse events
29/09	0	Z	TK	FG	Procedure failed due to inexperience; resorted to FG method
11/10	0	Z	TK	FG	Excessive bleeding when using TK; resorted to FG method
12/10	10	S	TK	TK	Urticaria Cellulitis proximal to wound
14/10	5	G	TK	TK	TK remained in tissue for too long
15/10	10	G	TK	TK	TK remained in tissue for too long
18/10	5	S	TK	TK	Cellulitis proximal to wound
18/10	10	G	TK	TK	TK remained in tissue for too long Insufficient foreskin removed
18/10	12	S	TK	TK	Cellulitis proximal to wound
19/10	11	S	TK	TK	Swelling Septic wound
23/10	9	Z	TK	TK	Septic wound TK remained in tissue for too long
24/11	5	Z	TK	TK	Erythema Swelling TK removed but tube still adhering
24/11	5	Z	TK	TK	Erythema Swelling TK removed but tube still adhering

Table III. Comparison of circumcision outcomes between the two groups

	FG method (*N*=29)	TK (*N*=19)	*p*
Interval between circumcision and visit (days)			
Mean	95	83	
Median (IQR)	62 (42 - 109)	48 (42 - 67)	0.60
Clinical examination			
Any sign of adverse event	1 (3.4%)	7 (37%)	0.004
Current infection	0 (0%)	0 (0%)	0.072
Delayed wound healing	1 (3.4%)	4 (21%)	0.004
Problem with appearance	1 (3.4%)	6 (31.6%)	0.001
Excessive skin removed	0 (0%)	0 (0%)	-
Insufficient skin removed	0 (0%)	0 (0%)	-
Participants' report during postoperative visit			
Mean pain score (0 - 10)	6.1	9.5	0.003*
Bleeding within the 2 next weeks†	0 (0%)	4 (21%)	0.02
Lesion to the penis	0 (0%)	4 (21%)	0.02
Infection following circumcision	0 (0%)	6 (32%)	0.002
Swelling or haematoma within the 2 next weeks†	0 (0%)	15 (83%)‡	<0.001
Problem with urinating	0 (0%)	3 (16%)	0.056
Satisfied with penis appearance	29 (100%)	16 (84%)	0.056
Any reported erectile dysfunction	0 (0%)	0 (0%)	-

*Adjusted for interval between circumcision and using linear regression.

† Following circumcision procedure.

‡One answer was missing.

On clinical examination, men circumcised by the TK method were significantly more likely to have at least one sign of an adverse event, delayed wound healing, or a problem with penis appearance. No participants were reported with a current infection, excessive or insufficient skin removed or erectile dysfunction.

After the first interruption of the trial, the exclusive TK supplier in South Africa attributed the high number of adverse events to the GPs' inexperience, and they sent an experienced practitioner to provide additional training. Table IV shows data from participants who were circumcised by the FG method (*N*=7) and the TK method (*N*=8) in the period following the training and who attended the centre for a post-circumcision visit. Poor results continued for the TK method and remained statistically significant regarding participants' reports of bleeding within the next 2 weeks, and swelling or haematoma.

Of the 12 adverse events reported by the GPs, 10 occurred among patients who attended the post-circumcision visit. For 2 of those patients, the GP reported that the TK procedure failed and that he resorted to the FG method (first 2 lines of Table II) and no adverse event was reported either by the nurse or by the participant at the post-circumcision visit. Of the other 8 adverse events reported by the GPs, 4 were also reported by the nurse and all 8 by the participants during the post-circumcision visit.

Table IV. Comparison of circumcision outcomes between the two groups in the post-training period of the trial

	FG method (*N*=8)	TK (*N*=7)	*p*
Clinical examination			
Any sign of adverse event	0 (0%)	2 (29%)	0.20
Current infection	0 (0%)	0 (0%)	-
Delayed wound healing	0 (0%)	1 (14%)	0.47
Problem with appearance	0 (0%)	1 (14%)	0.47
Excessive skin removed	0 (0%)	0 (0%)	-
Insufficient skin removed	0 (0%)	0 (0%)	-
Participants' report during postoperative visit			
Mean pain score (0 - 10)	5.6	9.3	0.051*
Bleeding within the 2 next weeks†	0 (0%)	4 (57%)	0.026
Lesion to the penis	0 (0%)	3 (43%)	0.077
Infection following circumcision	0 (0%)	2 (29%)	0.20
Swelling or haematoma within the 2 next weeks†	0 (0%)	6 (86%)‡	<0.001
Problem with urinating	0 (0%)	1 (14%)	0.47
Satisfied with penis appearance	8 (100%)	6 (86%)	0.47
Any reported erectile dysfunction	0 (0%)	0 (0%)	-

*Adjusted for interval between circumcision and using linear regression.
†Following circumcision procedure.
‡One answer was missing.

Discussion

This trial showed that the TK method compared unfavourably with the FG method when performed among young adults. Unacceptably high rates of adverse events among the TK group resulted in an early interruption of the study.

Because of this early interruption, few participants (69) were included, compared with the 400 originally planned. Nevertheless, the very high rate of complications in the TK group led to statistically significant comparisons. Even among the small group (15) of participants who were circumcised and assessed after the additional training session, and when adjusted for the interval between surgery and the post-circumcision visit, the proportion of participants who reported swelling or haematoma was significantly higher among those circumcised by the TK method. Problems encountered could therefore not be entirely attributed to inexperience.

We also noted a high rate of participation refusal that was related to reluctance to be circumcised by the TK method. Anecdotal reports suggest that participants were put off by the size of the device and by considerations of discomfort and aesthetics.

The literature on circumcision complications has been exhaustively reviewed.[17] Complication rates range from 0.06% to 55% but a realistic figure is 2 - 10%.[1-3] Complication rates in our FG group were consistent with this 2 - 10% range, while the rate in the TK group was definitely abnormal. Haemorrhage[18-21] and sepsis[1,22] are the main reported causes of morbidity. In our study, the most frequent complications were swelling and haematoma.

Studies on the TK procedure performed on children[13,14] reported no abnormal complication rates. On the other hand, adolescent circumcisions with a 32% rate of complications for 44 participants using the TK compared with a 1% complication rate for 476 participants circumcised by a surgical method, was reported from Thailand (www.circlist.com/instrstechs/taraklamp.html). These data, consistent with our results, suggest that the TK is unsuitable for adolescents and adults but may prove useful for children.

Among the potential study limitations are that not all 69 randomised participants were eventually circumcised; 13 did not visit a GP in charge of the procedure and were lost to follow-up. These 13 men did not differ from the remaining 56 participants in terms of age, religion, ethnic group, sexual experience, genital hygiene, history of hospitalisation or genital ulcerations (data not shown). In addition, 8 of the 56 circumcised participants did not attend the post-circumcision visit, of whom only 2 were among the 12 participants with adverse events, as reported by the GPs.

Mean and median intervals between circumcision and the post-circumcision visit were shorter for TK participants. This fact is largely explained by the high rate of complications

in this group: excluding participants with reported adverse events, the mean (median) interval was 61 (89) days in the FG group and 56 (98) in the TK group.

The GPs, nurse, participants and investigators were not blinded to the randomisation group. It is, however, unlikely that a potential judgement bias could explain the results of this study because: (*i*) the TK method was not negatively perceived when the study started; (*ii*) assessments by participants, nurse and GPs were consistent; and (*iii*) differences in the rates of complications between the two groups were unusually high.

Intent-to-treat analyses are not shown in this paper. Among the 4 cross-over participants who were randomised to the TK group but were eventually circumcised by the FG method, 2 were listed among the 12 adverse events reported by GPs. In the first case, it appeared that the TK method failed because of the GP's inexperience and that he then resorted to the FG method. In the second case, the GP resorted to the FG method because of excessive bleeding when attempting to use the TK. Consequently, intent-to-treat analyses, which would have involved analysis of the 2 latter participants in the TK group, would have led to even worse outcome data for the TK method.

Conclusion

Given the high rate of adverse events in this study and the low number of available studies, we strongly caution against the use of the TK for young adults, and we recommend careful evaluation of the procedure when performed on children.

Authors' contributions. E Lagarde designed the study, analysed the data and wrote the first draft of the report. B Auvert was the principal investigator, 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 the circumcisions. All authors contributed to data interpretation and critical revising of the report.

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Conflict of interest. INSERM and the NICD signed collaboration and licensing agreements with a private South African company for providing all sterilised instruments and consumables for performing a single male circumcision according to the FG method.

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): 184-187.
2. Speert H. Circumcision of the newborn; an appraisal of its present status. *Obstet Gynecol* 1953; 2(2): 164-172.
3. Leitch IO. Circumcision. A continuing enigma. *Aust Paediatr J* 1970; 6(2): 59-65.
4. Miles SH, Ololo H. Traditional surgeons in sub-Saharan Africa: images from south Sudan. *Int J STD AIDS* 2003; 14(8): 505-508.
5. Sefara M. Is there place for a scalpel in the bush? *The Sowetan* 2001; 18 July.
6. Ahmed A, Mbibi NH, Dawam D, Kalayi GD. Complications of traditional male circumcision. *Ann Trop Paediatr* 1999; 19(1): 113-117.
7. Menahem S. Complications arising from ritual circumcision: pathogenesis and possible prevention. *Isr J Med Sci* 1981; 17(1): 45-48.
8. Ozdemir E. Significantly increased complication risks with mass circumcisions. *Br J Urol* 1997; 80(1): 136-139.
9. Magoha GA. Circumcision in various Nigerian and Kenyan hospitals. *East Afr Med J* 1999; 76(10): 583-586.
10. Crowley IR. 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; 2(11): e298.
12. WHO, UNAIDS, UNFPA, UNICEF. UNAIDS statement on South African trial findings regarding male circumcision and HIV. 26 July 2005. http://www.who.int/mediacentre/news/releases/2005/pr32/en (accessed 1 August 2005).
13. Schmitz RF, Schulpen TW, Redjopawiro MS, Liem MS, Madern GC, Van Der Werken C. Religious circumcision under local anaesthesia with a new disposable clamp. *BJU Int* 2001; 88(6): 581-585.
14. Schmitz RF, Abu Bakar MH, Omar ZH, Kamalanathan S, Schulpen TW, van der Werken C. Results of group-circumcision of Muslim boys in Malaysia with a new type of disposable clamp. *Trop Doct* 2001; 31(3): 152-154.
15. 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): 1181-1184.
16. Bijur PE, Silver W, Gallagher EJ. Reliability of the visual analog scale for measurement of acute pain. *Acad Emerg Med* 2001; 8(12): 1153-1157.
17. Williams N, Kapila L. Complications of circumcision. *Br J Surg* 1993; 80(10): 1231-1236.
18. Griffiths DM, Munro MF, Freeman NV. Who cares for the foreskin? *Br J Clin Pract* 1986; 40(10): 414-416.
19. Kaplan GW. Complications of circumcision. *Urol Clin North Am* 1983; 10(3): 543-549.
20. Gee WF, Ansell JS. Neonatal circumcision: a ten-year overview: with comparison of the Gomco clamp and the Plastibell device. *Pediatrics* 1976; 58(6): 824-827.
21. Shulman J, Ben-Hur N, Neuman Z. Surgical complications of circumcision. *Am J Dis Child* 1964; 107: 149-154.
22. 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): 593-595.

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