

Evaluation of the safety and efficiency of the dorsal slit and sleeve methods of male circumcision provided by physicians and clinical officers in Rakai, Uganda

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What's known on the subject? and What does the study add?

MC reduces heterosexual acquisition of HIV in men for safe and efficient rapid scale-up; task shifting from physicians to clinical officers is safe and the use of bipolar cautery will reduce operative time, but is associated with higher adverse events.

OBJECTIVE

- To assess the safety and efficiency of the dorsal slit and sleeve male circumcision (MC) procedures performed by physicians and clinical officers (COs).

PATIENTS AND METHODS

- We evaluated the time required for the MC procedure (efficiency) and moderate/severe adverse events (AEs) for MC (safety) by trained physicians and COs using the sleeve and dorsal slit MC methods in a service programme.
- Univariate and multiple regressions with robust variance estimation were used to assess factors associated with operative duration (linear) and AEs (logistic).

RESULTS

- Six physicians and eight COs conducted 1934 and 3218 MCs, respectively; there were 2471 dorsal slit and 2681 sleeve MC procedures. The overall mean operative duration was 33 min for newly trained providers, which decreased to ≈ 20 min after ≈ 100 MCs.
- The adjusted mean operative duration for dorsal slit MC was significantly shorter than that for the sleeve MC method ($\Delta - 2.7$ min, $P < 0.001$).
- The operative duration was longer for COs than physicians for the sleeve procedure, but not the dorsal slit procedure; however this difference reduced with increasing numbers of MCs completed.
- The unadjusted AE rates were 0.6% for dorsal slit MC and 1.4% for the sleeve method ($P = 0.006$) and 1.5% for physicians and 0.68% for COs ($P = 0.003$); however,

there were no significant differences after multivariate adjustment.

- Use of bipolar cautery significantly reduced operative duration ($\Delta - 4.0$ min, $P = 0.008$), but was associated with higher AE rates (adjusted odds ratio 2.13, 95% confidence interval 1.26–3.61, $P = 0.005$).

CONCLUSION

- The dorsal slit MC method is faster than sleeve resection, and can be safely performed by non-physicians; however, use of bipolar cautery may be inadvisable in this setting.

KEYWORDS

adult male circumcision, task shifting, adverse events, HIV, circumcision programmes, Uganda

INTRODUCTION

Male circumcision (MC) has been shown to reduce the risk of HIV, herpes simplex virus type 2, human papilloma virus infections, and

genital ulcer disease in men [1–4], and MC is now recommended by WHO/Joint United Nations Programme on HIV/AIDS (UNAID) for HIV prevention in men [5]. Modelling studies have shown that rapid initial scale-up efforts

can accrue direct and indirect effects on the HIV epidemic earlier, are considerably more cost-effective, and necessitate fewer MCs to avert one infection and more HIV infections particularly in sub-Saharan Africa [6], but

limited numbers of trained physicians present a constraint on provision of services [7]. Task shifting of procedures conventionally performed by physicians has been shown to be effective in overcoming human resource deficits [8,9]. Therefore, there is a need to assess task shifting of MC from physicians to other healthcare personnel. Also, it is important to evaluate MC procedures to determine which may be most appropriate for the African context in terms of safety and efficiency [7].

After completion of a randomized trial of MC for HIV prevention, we provided MC as a service to the trial control arm participants and to the general male population in Rakai District, Uganda. The surgeries were performed by physicians and clinical officers (COs), using two surgical resection methods: sleeve and dorsal slit. We report here the findings from an evaluation of this service programme for the time required to perform MC (efficiency) and associated rates of moderate and severe adverse events (AEs), by surgical procedure and type of provider (safety).

PATIENTS AND METHODS

Between May 2006 and May 2010 we provided MC services to males aged 12–71 years. For this programme evaluation, we considered MC procedures of providers that had performed between 100 to 700 (range 109–700) surgeries making a total of 5152. Adult men provided written informed consent for surgery; minors provided assent with parental consent. All patients were offered voluntary HIV counselling and testing, were instructed on postoperative wound care and the need to abstain from sexual intercourse until the wound was certified as completely healed. All patients were screened before surgery and if they had signs of penile pathology (e.g. balanitis or sexually transmitted infections), they were treated, and MC was delayed until the lesions resolved.

MCs were performed using either sleeve or dorsal slit resection methods on alternate days of the week, and were carried out by trained and certified physicians and COs. Because of prior trial protocol requirements, all trial control arm participants were circumcised by physicians using sleeve resection. Non-trial MC clients were circumcised by physicians and COs (physician

assistants equivalents) depending on provider availability, using the resection method set for that day.

At time of MC, the skin was prepared with 10% povidone-iodine. MC was performed under local anaesthesia using a dorsal penile nerve block with a mixture of equal volumes of 2% lidocaine and 0.5% bupivacaine.

For the sleeve resection method, the foreskin was retracted and a distal incision made 0.5–1 cm from the coronal sulcus, followed by a proximal incision following the coronal prominence of the unretracted foreskin. Bucks fascia was exposed and a sleeve of foreskin was freed and removed. For the dorsal slit method, the prepuce was secured by artery forceps at the 1 and 11 o'clock positions and an incision made at the 12 o'clock position between the two forceps. The foreskin was then removed using dissecting scissors. Haemostasis was secured by either bipolar electrocautery (mainly used by physicians), or by ligation (mainly used by COs). For both procedures, the skin edges were apposed with four mattress sutures and additional simple sutures. The operative duration was recorded from the time of the first skin incision to wound closure and dressing. In all, 2681 sleeve and 2471 dorsal slit procedures were performed.

Surgery during the trial was performed by trained general physicians, but to meet the increased demand for services, COs, who are equivalent to physicians' assistants in the USA, were trained by a consultant urologist (S.W.) to perform MCs. During the study period, 1934 service surgeries were performed by general physicians (1511 sleeve and 423 dorsal slit MCs) and 3218 MCs were performed by COs (1170 sleeve and 2048 dorsal slit MCs).

The patients were followed-up at 24–48 h; 7–9 days and at 4 weeks after MC to assess AEs related to surgery and wound healing. At each visit, the patients were interviewed to ascertain symptoms of MC-related complications and the penis was examined. Surgery-related AEs were predefined and graded into mild (requiring no treatment), moderate (requiring treatment) and severe (requiring surgical intervention, hospitalization or referral for specialized care). This assessment of safety was restricted to moderate and severe MC-related AEs.

The characteristics of the patients were assessed according to provider and resection method to evaluate comparability of the patient populations. The frequencies of moderate and severe surgery-related AEs were estimated per 100 surgeries, by provider and resection method. Univariate and multivariate generalized estimating equations (GEE) regression with robust variance estimation to account for repeated surgeries by the same provider were used to assess factors associated with operative duration using linear regression. The odds ratio (OR) of AEs was estimated by logistic regression with robust variance. Only variables with a univariate $P < 0.15$ were included in the multivariate analyses.

RESULTS

Table 1 shows the characteristics of the patients before surgery, stratified by provider and procedure. Dorsal slit recipients were younger than their sleeve method counterparts ($P < 0.001$); 29% compared with 20% were aged < 20 years, respectively. The patients receiving dorsal slit were predominantly unmarried (62% vs 52% for the sleeve method ($P < 0.001$)).

Figure 1a, shows the operative duration by the number of procedures performed. Irrespective of experience, the time required for sleeve resection was consistently longer than for dorsal slit and this differential was particularly marked for the first 100 procedures performed. With both procedures, the operative duration declined with the number of MCs performed by a provider as previously described [10]. There were no overall difference in operative duration between physicians and COs (Fig. 1b), but physicians required less time to perform the sleeve procedure (Fig. 1c). This shorter operative duration by physicians was less marked and inconstant for the dorsal slit procedure (Fig. 1c).

Table 2 shows factors associated with the operative duration. In multivariate analyses, there were no significant differences in adjusted surgical durations between physicians and COs. Dorsal slit required 2.7 min ($P < 0.001$) less time than sleeve resection, use of bipolar cautery to control bleeding reduced operative duration by ≈ 4 min compared with ligation ($P = 0.008$), and ≈ 20 MC procedures as an increase in surgical

TABLE 1 Characteristics of men before MC, stratified by provider and procedure method

Variable	Physician, n (%)			CO, n (%)		
	Sleeve	Dorsal slit	All	Sleeve	Dorsal slit	All
N	1511 (78.1)	423 (21.9)	1934 [100]	1170 (36.4)	2048 (63.6)	3218 [100]
Age, years						
<15	7 (0.5)	11 (2.6)	18 (0.9)	13 (1.1)	61 (3.0)	74 (2.3)
15–19	195 (12.9)	129 (30.5)	324 (16.8)	355 (30.3)	592 (28.9)	947 (29.4)
20–29	758 (50.2)	185 (43.7)	943 (48.8)	516 (44.1)	906 (44.2)	1422 (44.2)
30–39	406 (26.9)	71 (16.8)	477 (24.7)	209 (17.9)	350 (17.1)	559 (17.4)
≥40	145 (9.6)	27 (6.4)	172 (8.9)	77 (6.6)	139 (6.8)	216 (6.7)
Marital status:						
Married	831 (55.0)	159 (37.6)	990 (51.2)	467 (39.9)	770 (37.6)	1237 (38.4)
Unmarried	680 (45.0)	264 (62.4)	994 (48.8)	703 (60.1)	1278 (62.4)	1981 (61.6)

TABLE 2 Univariate and multivariate analyses of factors associated with operative duration (min)

	n/N	Unadjusted analysis coefficient (95% CI)	P	Adjusted analysis coefficient (95% CI)	P
All participants	5152/5152				
Provider:					
Physician	1934/5152	1.00 (referent)		1.00 (referent)	
CO	3218/5152	-1.62 (-4.35, 1.11)	0.25	-0.62 (-4.65, 3.4)	0.763
Surgical method:					
Sleeve	2681/5152	1.00 (referent)		1.00 (referent)	
Dorsal slit	2471/5152	-4.63 (-6.21, -3.40)	<0.001	-2.79 (-3.59, -1.98)	<0.001
Haemostasis:					
Ligation	3959/5152	1.00 (referent)		1.00 (referent)	
Bipolar cautery	1193/5152	4.37 (1.58, 7.16)	0.00	-3.99 (-6.95, -1.03)	0.008
Age of participant	5152/5152	-0.01 (-0.02, 0.00)	0.08	-0.01 (-0.02, -0.00)	0.007
Surgical experience*	5152/5152	-1.59 (-2.19, 0.99)	<0.001	-1.56 (-2.14, -0.99)	<0.001
Constant	5152/5152	-	-	33.14 (30.03, 36.24)	<0.001

*Surgical experience is expressed in sequence of bins of 20 surgeries for the first 100 and then bins of 100 surgeries thereafter.

TABLE 3 Moderate/severe AEs by provider, procedure, and method of haemostasis

	Provider		Procedure method		Method of haemostasis	
	Physician	CO	Sleeve	Dorsal slit	Bipolar cautery	Ligation
No. of MC procedures	1934	3218	2681	2471	1193	3959
Surgery related AEs, n (%):						
Infection	8 (0.41)	9 (0.28)	12 (0.45)	5 (0.20)	9 (0.75)	8 (0.2)
Bleeding	17 (0.88)	12 (0.37)	20 (0.75)	9 (0.36)	11 (0.92)	18 (0.45)
Wound dehiscence	1 (0.05)	0	1 (0.04)	0	2 (0.17)	0
Wound dehiscence + infection	1 (0.05)	0	1 (0.04)	0	1 (0.08)	0
Other	2 (1.50)	1 (0.03)	2 (0.07)	1 (0.04)	1 (0.08)	2 (0.05)
Total	29 (1.50)	22 (0.68)	36 (1.34)	15 (0.61)	23 (1.93)	28 (0.71)

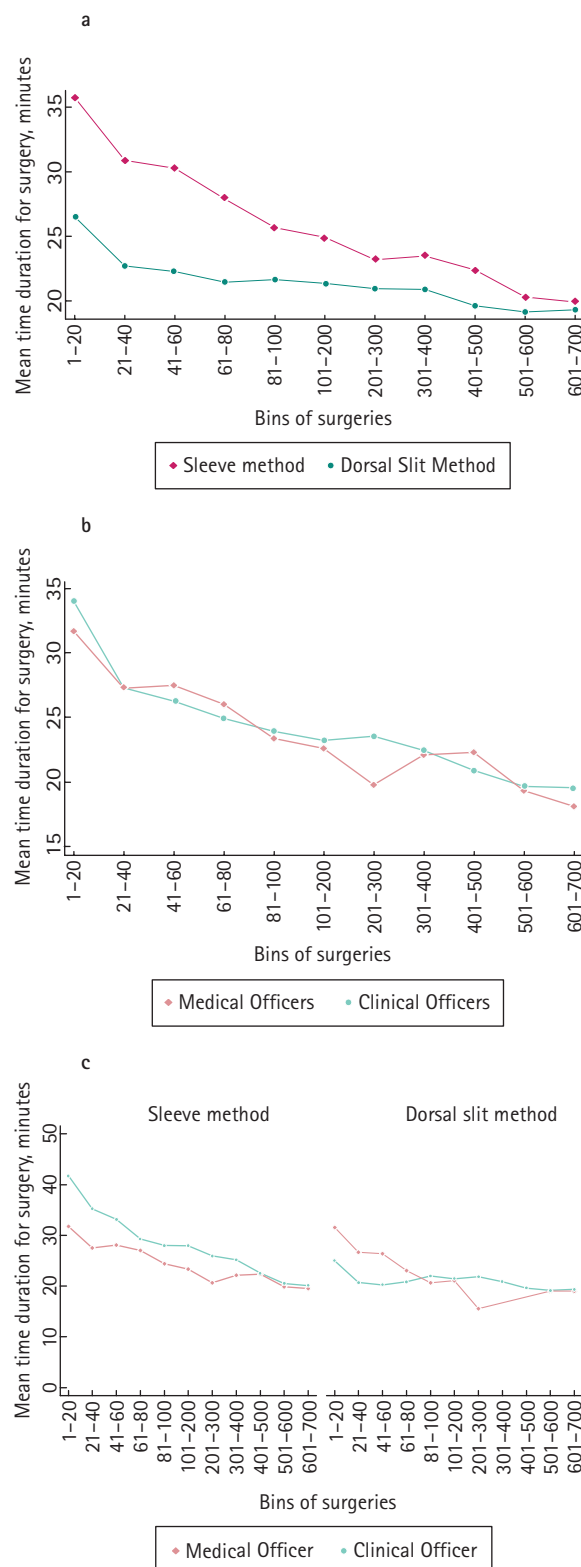
experience of the provider reduced operative duration by 1.5 min ($P < 0.001$). After performing 100 surgeries, dorsal slit took an average of 22.5 min compared with 25.3 min for the sleeve method.

Table 3 shows the rates of moderate and severe surgery-related AEs. Physicians had a higher rate of AEs (1.5%) than COs (0.6%, $P = 0.007$). AE rates were also higher with sleeve resection (1.34%) than dorsal slit

(0.6%, $P = 0.01$), and bipolar cautery was associated with higher AE rates (1.9%) than haemostasis by ligation (0.7%, $P < 0.00$). Both bleeding and dehiscence were more common with bipolar cautery (Table 3). In

FIG. 1.

The mean operative duration (min) for: **a**, sleeve and dorsal slit methods of MC; **b**, MCs performed by physicians and COs; and **c**, MC method and provider type.



univariate analyses, provider, procedure and mode of haemostasis were significantly associated with the risk of AEs (Table 4). However, in multivariate adjusted analyses,

only use of bipolar cautery was significantly associated with an increased odds of moderate/severe AEs (OR 2.13, 95%CI 1.26–3.61, $P = 0.005$).

DISCUSSION

This evaluation of MC for a HIV prevention service programme suggests that the dorsal slit method of MC requires less time to perform than the sleeve resection method (Fig. 1A), and can be performed equally efficiently by COs and physicians (Fig. 1C). Additionally, unadjusted AEs rates were lower with the dorsal slit than with the sleeve resection method (Tables 2 and 3). Although bipolar cautery reduced operative duration, it was associated with a higher rate of AEs compared with ligation for haemostasis (Table 4), the increased risk of moderate/severe AEs with bipolar cautery use was possibly due to inadequate bleeding control or cautery-related tissue necrosis leading to infection.

Because the dorsal slit method avoids the use of a scalpel leading to reduced costs and sharp instrument injury, we conclude that dorsal slit is the preferred procedure for MC in a rural, resource limited setting like Rakai and that it can be safely and efficiently provided by trained COs. Furthermore, bipolar electrocautery requires an electricity supply, a diathermy machine, additional maintenance costs, and is associated with higher AEs, hence using diathermy may be contraindicated in this setting.

This programme evaluation shows that task shifting from physicians to COs is safe and efficient in a resource-limited setting, will help alleviate the shortages of physicians, and will reduce MC costs. The present findings support those of the Kenyan MC Study [11] and the suggestion that non-physicians should be considered for MC programmes as has been shown in Zambia [12].

The rate of MC-related moderate/severe AEs was 1.0%, which is lower than previously reported in our randomized trial (3.5%) [13]. During the trial, the COs monitoring participants in this rural setting tended to be highly conservative and probably over-diagnosed possible AEs, over-estimated AE severity and over-prescribed antibiotics. For example, the 'infection' rate was 2.2% in the trial [11], compared with 0.35% in the present service programme. The definition of infection was unchanged, but provision of antibiotics automatically entailed a severity grade 2 (i.e. moderate) or higher, COs were prone to prescribe prophylactic antibiotics for

TABLE 4 The odds ratio of adverse events associated with age, provider, procedure, hemostasis, and surgeon's experience

	n/N	Unadjusted analysis		Adjusted analysis	
		OR (95% CI)	P	OR (95% CI)	P
All participants	51/5152				
Provider cadre					
Medical officer	29/1934	1.00 (referent)	0.003	1.00 (referent)	0.525
Clinical officer	22/3218	0.45 (0.26–0.76)		0.87 (0.57–1.33)	
Surgical method					
Sleeve method	36/2681	1.00 (referent)	0.004	1.00 (referent)	0.189
Dorsal slit	15/2471	0.46 (0.27–0.78)		0.72 (0.44–1.18)	
Blood control method					
Non cautery	28/3959	1.00 (referent)	<0.001	1.00 (referent)	0.005
Cautery	23/1193	2.91 (1.78–4.75)		2.13 (1.26–3.61)	
Surgical experience*	51/5152	0.92 (0.85–0.99)	0.018	0.94 (0.85–1.03)	0.177

*Surgical experience is expressed in sequence of bins of 20 surgeries for the first 100 and then bins of 100 surgeries thereafter.

any suspected infection during the trial but with increasing experience and training, this overuse of antibiotics diminished during the post-trial service provision. It is also possible that the severity of AEs may have been under-reported in this service programme, but we think this is unlikely.

There are limitations to the present findings. This was an evaluation of a service programme rather than a randomized trial or a pre-planned operations research study, so there is a possibility of bias and confounding. For example, physicians were over-represented among sleeve MC providers and were the predominant users of cautery. However, multivariate analysis adjusted for these differences. Although it might be desirable to conduct a randomized trial, we think that this programme evaluation is sufficient to provide guidance for planning MC services.

In summary, although differences were statistically significant, they were generally small, and probably not of clinical significance. But we think that the AEs associated with bipolar cautery use are clinically relevant to this African setting.

This evaluation of a MC programme suggests that the dorsal slit method is preferable to the sleeve method for efficiency, and that task shifting from physicians to COs is safe.

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CONFLICT OF INTEREST

None declared.

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Abbreviations: MC, male circumcision; CO, clinical officer; AE, adverse event; OR, odds ratio.