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A Randomized Noninferiority Trial of AccuCirc Device Versus Mogen Clamp for Early Infant Male Circumcision in Zimbabwe

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Background: Early infant male circumcision (EIMC) is a potential key HIV prevention intervention, providing it can be safely and efficiently implemented in sub-Saharan Africa. Here, we present results of a randomized noninferiority trial of EIMC comparing the AccuCirc device with Mogen clamp in Zimbabwe.

Methods: Between January and June 2013, eligible infants were randomized to EIMC through either AccuCirc or Mogen clamp conducted by a doctor, using a 2:1 allocation ratio. Participants were followed for 14 days post-EIMC. Primary outcomes for the trial were EIMC safety and acceptability.

Results: One hundred fifty male infants were enrolled in the trial and circumcised between 6 and 54 days postpartum (n = 100 AccuCirc; n = 50 Mogen clamp). Twenty-six infants (17%) were born to HIV-infected mothers. We observed 2 moderate adverse events (AEs) [2%, 95% confidence interval (CI): 0.2 to 7.0] in the AccuCirc arm and none (95% CI: 0.0 to 7.1) in the Mogen clamp arm. The cumulative incident risk of AEs was 2.0% higher in the AccuCirc arm compared with the Mogen Clamp arm (95% CI: −0.7 to 4.7). As the 95% CI excludes the predefined noninferiority margin of 6%, the result provides evidence of noninferiority of AccuCirc compared with the Mogen clamp. Nearly all mothers (99.5%) reported great satisfaction with the outcome. All mothers, regardless of arm said they would recommend EIMC to other parents, and would circumcise their next son.

Conclusions: This first randomized trial of AccuCirc versus Mogen clamp for EIMC demonstrated that EIMC using these devices is safe and acceptable to parents. There was no difference in the rate of AEs by device.

Key Words: AccuCirc, early infant male circumcision, HIV, Mogen clamp, Zimbabwe

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INTRODUCTION

Early infant male circumcision (EIMC, performed within the first 60 days of life) is recommended by the World Health Organization (WHO) and UNICEF for prevention of HIV.[1,2] Although EIMC's effects on HIV will take longer to realize, infant circumcision is likely to ultimately be more effective at preventing HIV acquisition than adult voluntary medical male circumcision (VMMC) as the procedure is performed long before the individual becomes sexually active. This eliminates the possibility of resuming sexual activity before complete wound healing and the associated risk of HIV acquisition or transmission.[3] Resumption of sex before the recommended postcircumcision abstinence period (6 weeks) is a major issue with adult men.[4–7] In the 3 randomized controlled trials conducted in sub-Saharan Africa, 3.9% of participants reported early sex in Kenya, 5.4% in Uganda, and 22.5% in South Africa.[4,7–9] More recently in an observational study conducted in Zambia, 24% of circumcised men reported resuming sex earlier than the recommended postcircumcision abstinence period (6 weeks).[5]

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Research has shown that VMMC is a cost-saving intervention, with modeling studies conducted between 2009 and 2011 estimating that if 80% of males aged 15–49 years were circumcised in 14 priority countries within 5 years and that coverage was sustained at this rate thereafter, 3.4 million new HIV infections could be averted within 15 years, in addition to yielding savings of US $16.5 billion in care and treatment costs.[10–12] A modeling study conducted in Rwanda in 2008 suggested that infant male circumcision is less costly than adolescent and adult VMMC and renders greater dividends despite the time lag between the procedure and averted infections.[13,14] It has been concluded that providing universal access to male circumcision, including infant MC, in conjunction with other effective HIV prevention interventions, will reduce the overall cost of HIV epidemics driven by heterosexual transmission.[13]

There are currently 3 circumcision devices that have been prequalified by WHO for use in infants: Gomco clamp, Mogen clamp, and Plastibell.[15] Each of these devices is characterized by rare, but potentially serious complications: (1) a mismatch in sizes of the separate pieces of the Gomco clamp can result in laceration of the glans penis,[15,16] (2) circumcision using the Mogen clamp can result in partial or total amputation of the glans penis or removal of too little foreskin (in which case the remaining foreskin remains vulnerable to infection with HIV),[15,17–19] and (3) migration of the Plastibell during circumcision can result in necrosis of the glans and other injuries; this risk is increased if the incorrect size of "bell" is used.[15,20–22] A relatively new EIMC device, AccuCirc, has the potential to address some of these shortcomings in that it comes prepackaged and does not require assembly. It has a shielding ring that protects the glans penis preventing laceration or amputation.[16] In addition, AccuCirc is disposable negating the need for device sterilization and facilitating its use at remote health care centers.[16] In addition, AccuCirc can be safely applied by non–surgically trained nurse-midwives.[16]

Here, we present results of a randomized noninferiority trial of EIMC comparing the AccuCirc device with Mogen clamp conducted in Zimbabwe. Because the cost and logistics of the AccuCirc device were perceived to be superior to the Mogen Clamp, a noninferiority trial design was chosen to determine whether AccuCirc was no worse with respect to adverse events (AEs). The results of this trial are part of a series of studies to determine safety, acceptability, and feasibility of using AccuCirc in resource-limited settings and will be used to inform device prequalification with WHO and EIMC scale-up in Zimbabwe and the wider region.

METHODS

Study Design

This individually randomized noninferiority trial evaluated the hypothesis that the AccuCirc device was as safe as that of a WHO prequalified EIMC device—Mogen clamp. The study design was based on the WHO Framework for Clinical Evaluation of Male Circumcision Devices.[23] Participants were randomized to AccuCirc or Mogen clamp in a 2:1 ratio and were followed for 2 weeks postcircumcision. Primary outcomes for the trial were EIMC safety and acceptability.

Recruitment and Training of EIMC Providers

Between November and December 2012, 4 doctors were recruited and trained in the use of the AccuCirc and Mogen clamp devices by 2 expert trainers. The trainers previously helped with drafting of the WHO *Manual for Early Infant Male Circumcision under Local Anaesthesia*[15] and oversaw training and field-testing of EIMC devices (including Mogen clamp and AccuCirc) in Nigeria and Botswana. The Zimbabwe training curriculum consisted of didactic lectures, practical skill sessions, use of an EIMC anatomic model, written assessment, and practical evaluation. Trainees were required to score 100% on the written assessment and show competency using the anatomic model. Each provider then had to demonstrate competency while performing 5 supervised circumcisions with each device.

Participants

Mothers and infants were enrolled between January and June 2013 at Edith Opperman, a Harare polyclinic with approximately 400 deliveries per month.[24] Sensitization on EIMC and participant recruitment took place at the antenatal clinic and after delivery in the maternity ward. Educational materials (posters and pamphlets) and demand creation activities (road shows, dramas, group and interpersonal discussions) were used to educate and sensitize the community about the trial. Before discharge postdelivery, mothers who were interested in having their male infants circumcised were asked to (1) provide locator information and consent for an outreach worker to physically verify their address, (2) complete an interviewer-administered questionnaire (asked among others: sociodemographic information, HIV and MC knowledge), and (3) discuss the procedure with their male partner (if relevant) before attending for EIMC at their first postnatal visit. Information on the number of eligible mothers approached about EIMC was recorded.

Locator data were physically verified on all potential trial participants between recruitment and enrollment. Maternal eligibility criteria were ability to attend follow-up appointments at study clinic until 2 weeks postpartum, preparedness to provide locator information and to be visited at home between delivery and circumcision, and provision of written informed consent. Mothers who were incarcerated were excluded. Initially, only infants aged 6–10 days were eligible for inclusion. However, after recruiting 108 babies, eligibility was extended to include babies aged 6–60 days in line with WHO guidance.[15] Additional infant eligibility criteria were as follows: male, gestational age ≥36 weeks, birth weight ≥2500 g, no evidence of neonatal infection/sepsis or other illness requiring hospitalization, no family history of bleeding disorder, and no genital abnormality representing a contraindication to EIMC. These eligibility criteria had been used previously in trials that compared Mogen clamp with other devices in Botswana and Zambia.[20,25] Data on eligibility criteria were collected from all

mothers and infants. Data on mother's HIV status were also collected. All infants who were ineligible due to genital abnormalities were referred to a specialist.

Sample Size

The sample size of 150 subjects (100 in AccuCirc arm; 50 in Mogen clamp arm) was guided by the WHO Framework for Clinical Evaluation of Male Circumcision Devices.[23] This sample size provides 80% power to detect noninferiority, based on a 2-sided 95% confidence interval (CI) approach, a 2% risk of AE in the Mogen clamp arm, and a noninferiority margin of 6% failure between the 2 arms. A noninferiority margin of 6% was chosen because this was deemed the maximum difference in safety that would be acceptable in terms of public health.

Randomization

Infants who met the trial inclusion criteria were randomized to infant male circumcision using either the AccuCirc device or the Mogen clamp in a 2:1 ratio (sample size 100 AccuCirc; 50 Mogen clamp). Randomization was conducted using randomly selected block sizes of 3, 6, or 9 generated off site in Stata version 13 (College Station, TX). Randomization codes were kept at the study site in sequentially numbered opaque envelopes.

Intervention

Before enrollment, study staff performed a physical examination to exclude infants with abnormalities precluding circumcision. All circumcisions were performed by the 4 trained doctors on a rotational basis. They were assisted by 3 nurse-midwives. All procedures were conducted under aseptic conditions (using sterile devices, gloves, drapes, swabs). All infants received vitamin K to minimize bleeding; vitamin K should be routinely administered at birth but was out of stock nationally at the time of the trial and therefore had to be imported specifically for that purpose. In addition, all infants had approximately 1 g of EMLA cream (eutectic mixture of local anesthetics containing 2.5% lidocaine and 2.5% prilocaine) applied to the outer foreskin and shaft of the penis about 45 minutes before the procedure. When EMLA cream had achieved anesthetic effect, the surgical area was cleaned with povidone–iodine. Achievement of anesthetic effect was determined by clamping the foreskin using artery forceps. If there was no pain response from the infant, subsequent steps would commence. Otherwise, providers would wait until the EMLA cream had achieved anesthetic effect (additional 10–15 minutes). The circumcision site (around the corona) was then marked using a surgical pen mark. The surgical pen mark served to minimize excessive or insufficient skin removal. Physiologic adhesions between the foreskin and the glans were released.

Device-specific procedures were used to expose the penile glans. During the procedure, glucose water was given using a gloved finger as per previous recommendations.[26–28] EIMC using AccuCirc was performed in line with manufacturer's recommendations (www.accucirc.com), and as recommended by the study previously conducted in Botswana.[16] The 2 AccuCirc sizes (1.1 and 1.3 cm penile diameter) were used. EIMC using Mogen clamp was performed as outlined in the WHO manual[15] and as recommended by the studies previously conducted in Botswana,[20] Kenya,[17] and Zambia.[25] After the procedure, the circumcision wound was dressed and infants were checked for postprocedure bleeding or other immediate complications. Mothers were given detailed postprocedure care instructions (how to deal with dressing, bleeding, and signs of infection) and emergency contact information. Mothers were encouraged to phone the nurse coordinator or attend the clinic in the event of any worries or unanticipated events that occurred between scheduled visits.

Follow-up and Evaluation

Follow-up appointments at the clinic took place at days 2, 7, and 14 postcircumcision. At these visits, parents were asked about complications. The infants also had a physical exam, including inspection of the circumcision site, by the EIMC doctors.

Outcomes

Primary end points for the comparative trial were EIMC safety and acceptability. These outcomes have been previously measured in trials that compared Mogen clamp with other devices in Botswana and Zambia.[20,25] Safety was measured by the number of moderate and severe AEs related to each EIMC technique. EIMC-related AEs were categorized as bleeding, infection, inadequate or excessive skin removal, and penile injury (glans, urethra, or shaft) (Table 1). Minor events such as bleeding that could be stopped with simple compression were recorded but excluded from analyses. EIMC acceptability was defined as the proportion of parents (1) who adopted EIMC for their son, (2) who reported being satisfied with the procedure by EIMC technique, and (3) who expressed willingness to adopt EIMC for a future son. A numerical scale (0–10) was used to evaluate the level of parental satisfaction; this was analyzed as a binary outcome with not satisfied defined as a score of <6. A numerical scale (0–10) was also used to record parental recommendations about circumcision to friends or relatives; a score of 0 was classified as "would not recommend" and 10 as "would definitely recommend." Secondary outcomes were as follows: (1) time required for each EIMC technique (measured using a stopwatch plus video recording of each procedure), (2) proportion with complete wound healing at 14 days postcircumcision for each EIMC technique, and (3) safety stratified by infant HIV exposure status.

Statistical Analyses

Statistical analyses were performed using Stata 13. Noninferiority was evaluated for the cumulative incident risk of AEs. The difference in cumulative incident risk of AEs for the 2 treatment arms was calculated and so was an associated 2-sided 95% CI to assess noninferiority of the AccuCirc

TABLE 1. Classification of Moderate and Severe AEs (Adapted with permission From VMMC AE Action Guide)

	Moderate	Severe
Bleeding	Bleeding that is not controlled by new dressings or 5–10 min of manual pressure, and requires a special return to the clinic for a pressure dressing, additional skin sutures, or vitamin K administration without surgical re-exploration of the wound	Bleeding that requires surgical re-exploration, hospitalization, or transfer to another facility or any case where blood transfusion or intravenous fluid is necessary
Infection	Discharge from the wound, painful swelling with erythema, or elevated temperature or use of oral antibiotics	Cellulitis or abscess of the wound, or infection severe enough to require surgical intervention, hospitalization, or intravenous or intramuscular antibiotic therapy
Inadequate skin removal	Prepuce partially covers glans when flaccid but surgical correction is not necessary	Prepuce partially covers glans when flaccid and surgical correction is necessary
Excess skin removal	Tightness of the skin discernible and additional sutures or skin mobilization needed for wound closure, but no other intervention needed	Reoperation or referral/ transfer to another facility required
Injury to penis	Significant laceration requiring prolonged follow-up, care and attention, or repeated/ additional dressings	Significant injury including laceration or severed portion of glans, damage to the urethra or shaft laceration with ongoing bleeding that requires hospitalization, transfer, or transfusion

procedure. The primary analyses were intention to treat. Superiority in the AccuCirc arm compared with the Mogen clamp arm was evaluated for (1) AEs resulting from the procedure, (2) time taken to perform the procedure, (3) wound healing, and (4) parental assessment of the procedure and its consequences (including satisfaction with the cosmetic result). The effect estimate for AEs (outcome 1) and time for procedure (outcome 2) was the mean difference, and 95% CIs were calculated. For binary outcomes (wound healing and parental satisfaction), the proportion in each study arm was calculated and compared. Logistic regression was used to calculate an odds ratio and associated 95% CI. Differences in participant characteristics were compared between arms.

Ethical Considerations

The study was approved by the Medical Research Council of Zimbabwe and the ethics committees of University College London and the London School of Hygiene and Tropical Medicine. Written informed consent was obtained from the infant's mother and verbal consent from infant's father (if relevant) before participant enrollment. After the procedure, mothers received a 20-L plastic bucket, 2 bars of washing soap, a 100-mL bottle of Vaseline (for wound care), and 3 disposable nappies (total value US $8). In addition, at each scheduled clinic visit, mothers received US $5 for bus fare reimbursement.

RESULTS

Participant Flow

To enroll 150 babies in the comparative trial, we approached 1151 parents of newborn male infants, corresponding to a 13% uptake of EIMC. A total 984 (85%) parents declined for their son to participate. Parental reasons for nonadoption of EIMC included fear of harm and sociocultural considerations.[29] A further 17 male infants were excluded after assessing their eligibility for inclusion (Fig. 1). One hundred fifty male infants aged 6–54 days were circumcised between January and June 2013. All were circumcised according to their allocated intervention (n = 100 AccuCirc; n = 50 Mogen clamp). All participants attended the 3 scheduled follow-up visits on days 2, 7, and 14.

Infant and Mothers Characteristics

The median gestation, birth weight, and body temperature were 40 weeks, 3.2 kg, and 36.4°C respectively, and similar by trial arm (Table 2). Twenty-six infants (17%) were born to HIV-infected mothers. The mean age at circumcision was 8 days and was similar in both arms. The majority of mothers (63%) were aged 25 years or older, married (93%), and had completed secondary education (80%); these characteristics were similar between trial arms.

Adverse Events

The AccuCirc device was deemed to be of correct size in all 100 AccuCirc procedures. There were 2 moderate AEs in the AccuCirc arm (2%; 95% CI: 0.2 to 7.0) (Table 3). These were 1 case of excess skin removal (hydrocortisone cream applied and wound was completely healed 4 months post-EIMC); and 1 case of inadequate skin removal, which warranted corrective surgery and was completely healed 20 days postcorrective surgery. No AEs occurred in the Mogen clamp arm. The cumulative incident risk of AEs was thus 2.0% higher in the AccuCirc arm compared with the Mogen Clamp arm (95% CI: −0.7 to 4.7). As the 95% CI excludes the noninferiority margin of 6%, the result provides evidence of noninferiority of AccuCirc compared with the Mogen clamp. Furthermore, the 95% CI includes zero, providing little evidence that Mogen clamp is superior to AccuCirc. The comparative safety of the AccuCirc and Mogen devices was similar in those infants either exposed to HIV or not (P = 0.42), although there was low power for this comparison.

During provider training, on 1 occasion, the AccuCirc device made only a partial incision (cut approximately 70% of

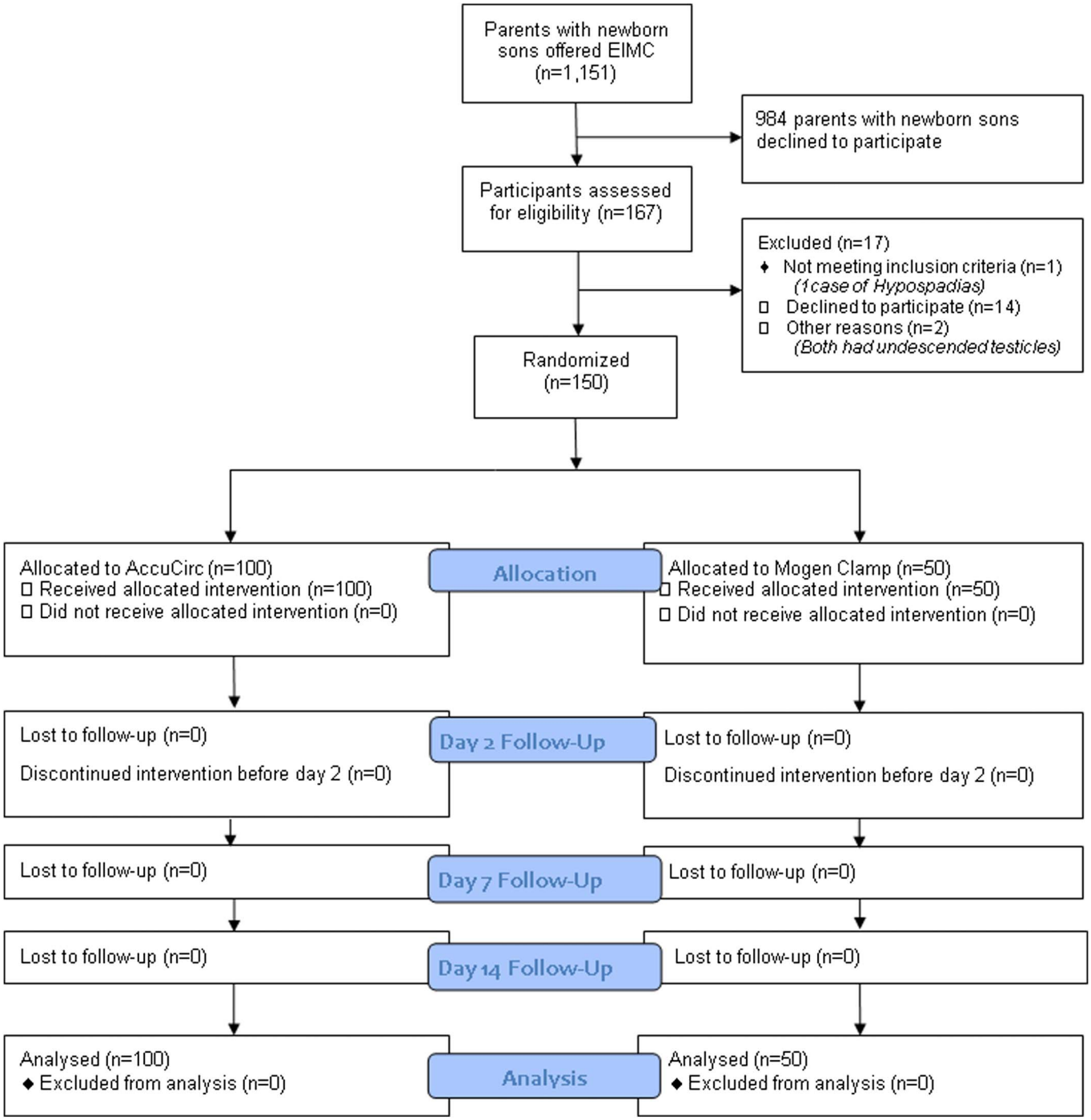

FIGURE 1. Trial participants recruitment and follow-up.

prepuce circumference), which was successfully completed using a pair of sterile surgical scissors. No partial cuts were encountered during the comparative trial. Because the partial cut occurred during training rather than during the trial, it was not included in trial analyses (although it was recorded and reported as an "incident").

Wound healing was complete in 144/150 boys by day 14 postcircumcision; 94% of the infants circumcised by the AccuCirc device and all infants circumcised by Mogen clamp had healed by day 14 (Table 3). The 6 infants with incomplete wound healing at day 14 included the 2 infants with moderate AEs, 2 infants with minor adhesions, which occurred post-EIMC, and 2 infants with delayed wound healing due to poor wound care. The mean time taken to perform the procedure was 15.5 minutes and was similar in both arms [mean difference = 0.1 minute (95% CI: −1.2 to 1.4)].

TABLE 2. Infant and Mothers Characteristics

	AccuCirc Device (N = 100)	Mogen Clamp (N = 50)
Infant characteristics		
Median baby's weight in kilograms (min–max)	3.2 (2.5–4.8)	3.2 (2.5–4.4)
Median gestational age in weeks (min–max)	40 (36–41)	40 (37–41)
Median baby temperature in degree Celsius (min–max)	36.4 (36–37.2)	36.4 (36–37.3)
Infant exposure to HIV, %	18 (18)	8 (16)
Age of baby, d		
Median (min–max)	8 (6–54)	8 (6–52)
6–10, %	83 (83)	41 (82)
11–30, %	12 (12)	7 (14)
31–54, %	5 (5)	2 (4)
Mothers characteristics, %		
Mothers age, yrs		
<25	37 (37)	18 (36)
≥25	63 (63)	32 (64)
Married	91 (91)	48 (96)
Live with male partner	89 (89)	47 (94)
Completed secondary level education	83 (83)	37 (74)
Ethnic group, %		
Shona	91 (91)	46 (92)
Non-Shona	9 (9)	4 (8)

Parental Satisfaction

Parental satisfaction with the circumcision procedure was assessed at the 2-day postcircumcision visit. The mother was present at this visit in 100% of cases, and in addition, the father attended this visit for 17% of boys (Table 3). Nearly all mothers (99.5%) reported being satisfied with the outcome (score 6–10), and this was similar between arms. The most common reasons for dissatisfaction among mothers were wound care requirements (n = 5, 3%), pain (n = 3, 2%), and babies crying (n = 3, 2%). All mothers who answered the relevant questions, regardless of arm said they would recommend EIMC to other parents and would circumcise their next newborn son (response rate at least 98%). Among the 25 fathers who reported satisfaction with the procedure, 100% gave a score of 6–10. Wound care requirement was the most common reason for dissatisfaction among fathers. All fathers would recommend the procedure to a friend and all fathers would have a future son circumcised.

DISCUSSION

We have conducted the first randomized trial of AccuCirc versus Mogen clamp for EIMC and found that EIMC using these devices is safe, feasible, and acceptable to parents. There was no difference in the rate of AEs by device.

We observed 2 moderate AEs (2%, 95% CI: 0.4 to 7.7) in the AccuCirc arm and none (95% CI: 0.0 to 7.1) in the Mogen clamp arm during the trial. The 2 AEs resolved quickly and without any lasting disability. Furthermore, because the 95% CI for the mean difference in AE percentages (−0.7 to 4.7) excludes the noninferiority margin of 6%, we conclude that the AccuCirc device is noninferior compared with the Mogen clamp. In the single-arm study conducted with the AccuCirc device in Botswana, researchers also observed 1 moderate AE (post-EIMC bleeding that lasted 90 minutes).[16] Moreover, these AEs were experienced earlier on in the trial and so it is possible that they were due to doctors' relatively limited experience of using the AccuCirc device at this stage. We have learnt from the VMMC program that the rate of AEs falls as providers gain greater proficiency.[30] The AccuCirc device AE rate will be more accurately quantified in a larger (n = 500) follow-up field study that has been conducted in the same study population. Nonetheless, the fact that AccuCirc poses the potential for partial circumcisions warrants further investigation.

Acceptability of the procedure by actual uptake was lower than previously suggested by hypothetical acceptability studies (13% versus 60%),[31,32] although the latter was among all adults and not necessarily those who are actually going to have children in the future. Our findings on the mismatch between hypothetical and actual EIMC acceptability are consistent with those from another regional setting. In a study conducted in Zambia, although 97% of mothers who participated in a quantitative survey indicated that they definitely or probably planned to have their newborn son circumcised, only 11% of participants subsequently brought their newborn sons for infant circumcision.[33] However, in both Zambia and Zimbabwe, EIMC was offered within a research setting. EIMC uptake within a research setting, and in Zimbabwe in the context of a trial, may be different from that when EIMC is offered as part of a programme. In addition, Zimbabwean parents were informed that the trial was comparing 2 EIMC devices. Parents may therefore, have felt this indicated that the devices were "experimental"; this thought may have exacerbated their fear of harm. Furthermore, the hesitancy of some cultural groups to participate in research has been documented.[34,35]

Of note, Zimbabwe is traditionally a noncircumcising country. It is inevitable that it will take time and the programme will need to earn the trust of parents before EIMC—a novel and invasive procedure—becomes accepted. Nonetheless, culturally appropriate demand–creation activities to promote EIMC need to be developed and introduced if EIMC is to become universal.[36] In practice, however, sustained acceptability and uptake will depend on perceptions of the safety and aesthetic aspects of the procedure.[37] Encouragingly, in this trial, nearly all mothers (99.5%) reported satisfaction with the outcome. These findings are consistent with those from other regional settings (Botswana,[20] Kenya,[38] and Zambia[25]) that have also shown high levels of satisfaction with the EIMC outcome (>90%).[16,25] With specific reference to satisfaction with EIMC performed through AccuCirc, the findings are consistent with those from Botswana where 91% of mothers reported high or complete satisfaction with the outcome.[16] To maintain these high levels of satisfaction within EIMC programs, EIMC provision will

TABLE 3. Primary and Secondary Outcomes After Circumcision and Time Taken for the Procedure

	AccuCirc Device (N = 100), n (%)	Mogen Clamp (N = 50), n (%)	Crude Effect Estimate (95% CI)
AEs, wound healing, and time of procedure, %			
All AEs*	2 (2)	0 (0)	Mean difference = 2.0 (−0.7 to 4.7)
All AEs stratified by infant HIV exposure status†			
Infant not exposed to HIV	1/81 (1.2)	0/42 (0)	Mean difference = 1.2 (−2.1 to 4.6)
Infant exposed to HIV	1/18 (5.6)	0/8 (0)	Mean difference = 5.5 (−11.8 to 23.0)
Complete wound healing at day 14	94 (94)	50 (100)	Inestimable
Time taken to perform procedure	15.6 min	15.5 min	Mean difference = 0.1 min (−1.2 to 1.4)
Mothers satisfaction, %			
Mothers satisfied with procedure‡	99 (99)	50 (100)	Inestimable
Satisfaction score (0–10)			
≤5	1 (1)	0 (0)	
6–8	2 (2)	3 (6)	
9	7 (7)	2 (4)	
10	90 (90)	45 (90)	
Reasons for dissatisfaction			
Appearance	0 (0)	0 (0)	
Wound care requirements	3 (3)	2 (4)	
Complication	0 (0)	0 (0)	
Delay in discharge	0 (0)	0 (0)	
Other reason§	7 (7)	3 (3)	
Mother would recommend MC‖	98 (100)	50 (100)	Inestimable
Mother would have next son circumcised¶	99 (100)	50 (100)	Inestimable
Fathers satisfaction, %			
Father present at the 2-day follow-up visit#	19 (19)	6 (12)	
Fathers satisfied with procedure**	19 (100)	6 (100)	Inestimable
Father satisfaction score			
7	1 (5)	1 (17)	
8	2 (11)	0 (0)	
10	16 (84)	5 (83)	
Reason for dissatisfaction			
Wound care	0	1	
Incomplete wound healing	1	0	
Father would definitely recommend MC	19 (100)	6 (100)	
Would have a future son circumcised	19 (100)	6 (100)	

*Adverse events included: severe bleeding, infection, inadequate or excessive skin removal, and penile injury.
†HIV exposure status unknown for 1 infant in the AccuCirc arm who was delivered at home.
‡Satisfaction score of 6–10.
§In the AccuCirc arm, reasons were baby cried (n = 2), pain (n = 2), wound not completely healed (n = 1), minimal pain (n = 1), and not sure (n = 1). In the Mogen clamp arm, reasons were fear (n = 1), baby cried (n = 1), and pain (n = 1).
‖Two mothers did not answer this question in the AccuCirc arm.
¶One mother did not answer this question in the AccuCirc arm.
#The number and % fathers that were present at the 2-day follow-up visit and responded to questions about satisfaction himself; others responses about the fathers satisfaction came from the mothers or another person in attendance (ie, not the baby's father himself).
**Among the 25 fathers who reported their satisfaction.

need to be carefully supervised and monitored to ensure (1) a good cosmetic result and (2) that AEs are prevented.[32]

Limitations

Although the trial sample size was guided by the WHO Framework for Clinical Evaluation of Male Circumcision Devices,[23] it was small. It is therefore possible that we did not detect all potential AEs that might occur during EIMC rollout. The follow-up field study undertaken in 500 infants will enhance our understanding of AEs associated with the procedure. Also, we only explored actual acceptability of doctor-led EIMC. Because it is likely that EIMC rollout will be through nurse-midwives, it is unclear how or whether this will affect uptake. Future research needs to explore actual acceptability of nurse-midwife delivered EIMC to effectively inform EIMC programming and rollout.

CONCLUSIONS

We safely circumcised 150 infants in a randomized trial of AccuCirc versus Mogen clamp for EIMC in Zimbabwe.

The AccuCirc device has the potential to facilitate widespread scale-up of safe EIMC in sub-Saharan Africa.

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