Safety of over Twelve Hundred Infant Male Circumcisions Using the Mogen Clamp in Kenya

Marisa Young, Emory University
Robert C. Bailey, University of Illinois
Elijah Odoyo-June, Nyanza Reproductive Health Society
Tracy E. Irwin, University of Illinois
Walter Obiero, Nyanza Reproductive Health Society
Dedan O. Ongong’a, New Nyanza Provincial General Hospital
Jacinta A. Badia, CARE International
Kawango Agot, Impact Research and Development Organisation
Sherry K. Nordstrom, University of Illinois

Journal Title: PLoS ONE
Volume: Volume 7, Number 10
Publisher: Public Library of Science | 2012-10-17, Pages e47395-e47395
Type of Work: Article | Final Publisher PDF
Publisher DOI: 10.1371/journal.pone.0047395
Permanent URL: https://pid.emory.edu/ark:/25593/tw1qm

Final published version: http://dx.doi.org/10.1371/journal.pone.0047395

Copyright information:
© 2012 Young et al.
This is an Open Access work distributed under the terms of the Creative Commons Attribution 4.0 International License (https://creativecommons.org/licenses/by/4.0/).

Accessed June 29, 2020 2:17 PM EDT
Safety of over Twelve Hundred Infant Male Circumcisions Using the Mogen Clamp in Kenya

Marisa R. Young1,*, Robert C. Bailey1,2, Elijah Odoyo-June2, Tracy E. Irwin3, Walter Obiero2, Dedan O. Ongong’a4, Jacinta A. Badia5, Kawango Agot6, Sherry K. Nordstrom3

1 Department of Epidemiology and Biostatistics, University of Illinois at Chicago School of Public Health, Chicago, Illinois, United States of America, 2 Nyanza Reproductive Health Society, Kisumu, Kenya, 3 Department of Obstetrics and Gynecology, University of Illinois at Chicago College of Medicine, Chicago, Illinois, United States of America, 4 Department of Surgery, Nyanza Provincial General Hospital, Kisumu, Kenya, 5 CARE International, Kisii, Kenya, 6 Impact Research and Development Organisation, Kisumu, Kenya

Abstract

Background: Several sub-Saharan African countries plan to scale-up infant male circumcision (IMC) for cost-efficient HIV prevention. Little data exist about the safety of IMC in East and southern Africa. We calculated adverse event (AE) rate and risks for AEs associated with introduction of IMC services at five government health facilities in western Kenya.

Methods: AE data were analyzed for IMC procedures performed between September, 2009 and November, 2011. Healthy infants aged ≤2 months and weighing ≥2.5 kg were eligible for IMC. Following parental consent, trained clinicians provided IMC services free of charge under local anesthesia using the Mogen clamp. Odds ratios and 95% confidence intervals were used to explore AE risk factors.

Findings: A total of 1,239 IMC procedures were performed. Median age of infants was 4 days (IQR = 1, 16). The overall AE rate among infants reviewed post-operatively was 2.7% (18/678; 95%CI: 1.4, 3.9). There was one severe AE involving excision of a small piece of the lateral aspect of the glans penis. Other AEs were mild or moderate and were treated conservatively. Babies one month of age or older were more likely to have an AE (OR 3.20; 95%CI: 1.23, 8.36). AE rate did not differ by nurse versus clinical officer or number of previous procedures performed.

Conclusion: IMC services provided in Kenyan Government hospitals in the context of routine IMC programming have AE rates comparable to those in developed countries. The optimal time for IMC is within the first month of life.
Methods

In partnership with the Kenyan Ministry of Health, we introduced infant male circumcision services in five Government health facilities in three Districts in Nyanza Province, western Kenya. The data for this analysis come from two sources: (1) a case/control study [24] examining factors associated with parental acceptance of IMC services where infants were actively followed-up postoperatively (research infants), and (2) routine monitoring of IMC services where post-operative follow-up was passive (non-research infants). In the research study, “case” parents were those who accepted IMC for a son and “control” parents had declined IMC services for an eligible son. We used safety data from babies who were circumcised. Information on demographic characteristics of parents and parental satisfaction with IMC was recorded for research infants but not for non-research infants. The following information was collected as part of routine monitoring of IMC services for all infants: date and location of procedure, name of parent/guardian, weight of baby, date of birth of baby, IMC provider and cadre, date of follow-up (if any), and type and severity of any intra-operative or post-operative adverse event. IMC services were available to term male neonates and infants, aged ≤2 months, weighing ≥2.5 kg, generally healthy (eg: absence of fever and jaundice) and without an anomaly of the genitals. All mothers (and fathers, if present) were counseled on the benefits and risks of IMC and provided written informed consent for the procedure prior to surgery.

IMC services were provided on a voluntary basis to all infants free of charge by a trained nurse or clinical officer (similar to a physician’s assistant) using the Mogen clamp method. A dorsal penile nerve block of 0.15 mg per kg of 2% lidocaine, diluted with an equal amount of water for injection, was administered for intra-operative analgesia. Parents were given verbal and written instructions on post-operative wound care in their language of choice (English, Kiswahili or DhoLuo), a 50 ml bottle of petroleum jelly to apply to the wound, a 50 ml bottle of acetaminophen (paracetamol) for post-operative analgesia, and one disposable diaper. All parents were asked to return to the health facility with the infant three to four days following IMC to assess progress of wound healing. Research participants were given a transport stipend (approximately 1.50 USD) upon return to the health facility for the post-operative review and were actively followed-up if they did not return. Active follow-up included calls to the parents, attempted tracing, and home visits to review the wound post-operatively. Non-research infants were not given a stipend and were not called or traced if they failed to return for review. We used a standardized data collection form for documenting AEs that was adapted from our earlier trial of adult male circumcision for HIV prevention in Kisumu [2] and was completed by an IMC-trained clinician. All parents were given the telephone number for an IMC hotline, staffed by an IMC-trained clinician and instructed to call with any questions or concerns.

This analysis is largely descriptive in nature. We report medians, inter-quartile ranges (IQR) and proportions, as appropriate. Differences in AE rates by provider type, provider experience level, and age of baby were computed using odds ratios (ORs).

Results

Between September 1, 2009 and November 29, 2011, 1,261 babies were registered for IMC at the five facilities where the procedure was offered. Of these, 22 infants (2%) were excluded from surgery due to contraindications discovered after entry into the surgical register: eleven with penile anomaly (nine hypospadias, one epispidias, one micropenis), five with dense foreskin adhesions, two with fever, two with impetigo, one with severe phimosis, and one missing reason. All but the last of these were referred to a pediatric surgeon who was a co-investigator in the study (DO) or to a nurse at the health facility where the IMC took place.

Fifty one providers performed 1,239 IMC procedures (three quarters of procedures were provided by 10 clinicians). Three hundred and eight infants (25%) were research infants and the remaining 931 infants were non-research infants. The median age of babies circumcised was four days (IQR 1–16). Among research infants, 294 of 308 infants (95%) were reviewed post-operatively. The post-operative review rate among non-research infants was 41% (384/931). Other characteristics of research and non-research infants are listed in Table 1.

Most post-operative reviews (96%) occurred within one week of surgery. The remaining 4% occurred up to 45 days following IMC. Seven research infants had an IMC-related adverse event (AE rate 2.4%, 95%CI: 0.6, 4.1). One research infant had two AEs, for a total of eight adverse events in this group. Among non-research infants returning for review, the AE rate was 2.9% (11/384, 95%CI: 1.2, 4.5). Therefore, there were a total of 19 AEs detected in 18 unique infants out of 678 infants reviewed post-operatively (Total AE rate 2.7%, 95%CI: 1.4, 3.9). Out of the total 1,239 infants circumcised, the AE rate was 1.5% (95%CI: 0.8, 2.1). We had one severe AE involving excision of a small piece of the dorso-lateral aspect of the glans penis. Other events were classified as mild or moderate and treated conservatively (see Table 2). These included: intra-operative or post-operative bleeding arrested with pressure (n = 7) or sutures (n = 3), post-operative abrasion (n = 3), and wound infection (n = 5).

AEs were more common in older babies; 7/205 babies aged one month or older (3.4%) experienced an adverse event, in comparison to 11/1,007 babies (1.1%) less than one month of age (OR = 3.20, p = 0.02). There was no difference in AE rate by type of provider or experience level of provider (Table 3). Nearly all (282/294, 96%) parents of research infants reported being ‘very satisfied’ with IMC services received. All parents of research infants returning for review who were asked said they would choose circumcision for their son, if they could do it again.
### Table 1. Characteristics of research and non-research IMC procedures.

|                        | Research Infants (active follow-up) n = 308 | Non-research Infants (passive follow-up) n = 931 |
|------------------------|---------------------------------------------|-------------------------------------------------|
| **Post-operative follow up** |                                             |                                                 |
| Yes                    | 294 (95.5)                                 | 384 (41.3)                                      |
| No                     | 14 (4.5)                                   | 547 (58.8)                                      |
| **Age, days [median (IQR)]** | 7 (1, 26)                                 | 4 (1, 10)                                       |
| **Provider type**      |                                             |                                                 |
| Nurse                  | 233 (75.7)                                 | 590 (63.4)                                      |
| Clinical Officer       | 75 (24.4)                                  | 326 (35.0)                                      |
| Missing                | 0 (0.0)                                    | 15 (1.6)                                        |
| **Experience level of provider** |                                         |                                                 |
| <10 procedures         | 73 (23.7)                                  | 221 (23.7)                                      |
| 10+ procedures         | 234 (76.0)                                 | 674 (72.4)                                      |
| Missing                | 1 (0.3)                                    | 36 (3.9)                                        |
| **Satisfaction with IMC at post-operative visit** |                                         |                                                 |
| Very satisfied         | 282 (95.9)                                 | N/A                                             |
| Somewhat satisfied     | 11 (3.7)                                   | N/A                                             |
| Somewhat dissatisfied  | 1 (0.3)                                    | N/A                                             |
| Very dissatisfied      | 0 (0.0)                                    | N/A                                             |
| **Would circumcise son again** |                                         |                                                 |
| Yes                    | 293 (99.7)                                 | N/A                                             |
| No                     | 0 (0.0)                                    | N/A                                             |
| Missing                | 1 (0.3)                                    | N/A                                             |

IQR, Inter-quartile range; N/A, Not applicable.

1Question wording: “If you were to do it again, would you circumcise your baby?”

doi:10.1371/journal.pone.0047395.t001

### Table 2. Type and frequency of adverse events and other events.

|                        | Research Infants n = 308 | Non-research Infants n = 931 |
|------------------------|--------------------------|-----------------------------|
| **IMC-related Adverse Events** |                          |                             |
| Severe AE              |                          |                             |
| Damage to the glans    | 0 (0.0)                  | 1 (0.1)                     |
| Mild/Moderate AE       |                          |                             |
| Intra-operative bleeding - suture required | 1 (0.3) | 2 (0.2) |
| Intra-operative bleeding - resolved with pressure | 2 (0.6) | 2 (0.2) |
| Post-operative bleeding - resolved with pressure | 1 (0.3) | 2 (0.2) |
| Infection              | 2 (0.6)                  | 3 (0.3)                     |
| Meatal abrasion         | 2 (0.6)                  | 1 (0.1)                     |
| Sub-total:             | 8 (2.6)                  | 11 (1.2)                    |
| **Other Events**       |                          |                             |
| Too little foreskin removed | 3 (1.0)    | 6 (0.6)                     |
| Impetigo/rash not involving genitals | 1 (0.3) | 2 (0.2) |
| Post-operative fever without other symptoms, not IMC related | 0 (0.0) | 2 (0.2) |
| Sub-total:             | 4 (1.3)                  | 10 (1.1)                    |

AE, adverse event; IMC, infant male circumcision.

doi:10.1371/journal.pone.0047395.t002
We did not ask non-research parents about satisfaction or the decision to circumcise again.

**Discussion**

There are few published reports on safety of IMC in developing country settings [12]. The available data show adverse event rates associated with IMC vary widely by setting, type of provider, method used and classification of what constitutes an AE. A recent review found that the median AE rate following neonatal and infant MC was 1.5% (range 0%-16%) among 16 prospective studies from 12 countries [19]. The median rate of serious AE was 0% (range 0%-2%). The review did not include any studies in which the Mogen clamp method was used. We are aware of only one other study reporting AE rates from East Africa, where IMC is rarely performed [25]. In that Tanzanian study, 368 infants were circumcised using the Plastibell device with an overall AE rate of 2.8% and no serious AEs. Our observed AE rate of 2.4% among research infants and 2.9% among non-research infants is consistent with the lower range of AEs reported from studies conducted in the developing world [25–29]. Lack of consistency in ascertainment and definition of AEs contributes to the wide range of published AE rates. For example, we elected not to include cases of too little foreskin removed (n=9) in our adverse event calculations because this is not a medical adverse event, per se. Others have chosen to include this type of event, because rebreaking of adhesions and corrective surgery may be necessary in the future. If we included these cases in our count of AEs, the overall AE rate among those returning for post-operative review would be 4.0% (27/678; 95%CI: 2.5, 5.5).

The wide variation in AE rates reported in the literature may be due to differences in experience and training of provider, traditional versus medical IMC, device used, location of procedure, and age of infant. In this study, IMC was provided in a health care setting by trained medical providers (nurses or clinical officers) using sterile equipment on neonates and young infants (<2 months of age); factors that likely contributed to our low observed adverse event rate. We found no difference in AE rates by provider type, a finding that supports the inclusion of trained nurses as IMC providers. Infants one month of age or older had over three times the odds of experiencing an AE and this result was statistically significant (p=0.02) despite the relatively small number of events, which suggests that the optimal time for IMC is in the first month of life. That IMC is safer at younger ages is consistent with the few published reports on this topic [30,31] and reinforces the WHO recommendation that IMC be performed within the first two months of life [32].

Early adverse events following neonatal or infant circumcision are generally minor and treatable. These include: bleeding resolved with conservative management or suturing, minor infection resolved with antibiotic therapy, pain that can be managed with analgesic therapy, problems with incomplete separation or retention of Plastibell or other disposable device used in circumcision, and parental dissatisfaction with appearance [33,34]. The AEs we observed in this study are consistent with these early, minor events. More rarely, severe or life threatening adverse events following IMC have been reported. These complications can be early or late and include: complete denudation of penile shaft skin, formation of skin bridges between the shaft and glans, damage to the penis including partial or complete amputation or necrosis, damage to the urethra, buried or trapped penis and meatal stenosis [34–37]. We did not actively follow infants after the initial review, usually occurring within one week of the procedure. Therefore, we cannot exclude the possibility of serious late AEs. However, we did not receive telephone calls or follow-up visits from parents with concerns about late complications and we offered treatment of adverse events free of charge.

This analysis has several limitations. We did not record information about the number or type of phone calls between study staff and parents who had questions or concerns about IMC. Our follow-up period was relatively short and the routine monitoring data did not collect several variables of interest potentially associated with AE risk (e.g. hygiene practices). Nevertheless, this study provides valuable data on AE rate and reinforces the WHO recommendation that IMC be performed within the first two months of life [32].

**Table 3.** Adverse event rate and risk factors for adverse events in research and non-research circumcisions.

| Provider type          | Research Infants (active follow-up) n = 308 | Non-research Infants (passive follow-up) n = 931 | Combined N = 1,239 |
|------------------------|---------------------------------------------|--------------------------------------------------|--------------------|
| AE rate (reviewed post-op) | 7/294 (2.4%; 95%CI: 0.6, 4.1)               | 11/384 (2.9%; 95%CI: 1.2, 4.5)                    | 18/678 (2.7%; 95%CI: 1.4, 3.9) |
| AE rate (all procedures) | 7/308 (2.3%; 95%CI: 0.6, 3.9)               | 11/931 (1.2%; 95%CI: 0.5, 1.9)                    | 18/1239 (1.5%; 95%CI: 0.8, 2.1) |
| **Provider type** | **AEs** | **IMCs** | **%** | **OR** | **p** | **AEs** | **IMCs** | **%** | **OR** | **p** | **AEs** | **IMCs** | **%** | **OR** | **p** |
| Nurse                  | 5       | 233     | 2.1   | 0.97   | 0.96  | 7       | 590     | 1.2   | 12     | 823   | 1.5   | 18     | 601     | 1.5   | 0.97 | 0.96 |
| Clinical Officer       | 2       | 75      | 2.7   | 1.15   | 0.84  | 4       | 326     | 1.2   | 6      | 401   | 1.5   | 10     | 531     | 1.5   | 0.96 | 0.96 |
| Experience level       | 2.46    | 0.25    | 1.15  | 0.84   | 1.56  | 0.38    | 2.46    | 0.25 | 1.15   | 0.84  | 1.56  | 0.38  |
| <10 procedures         | 3       | 73      | 4.1   | 3.27   | 0.06  | 8       | 674     | 1.2   | 12     | 908   | 1.3   | 3.20   | 0.02    | 3.20  | 0.02 |
| 10+ procedures         | 4       | 234     | 1.7   |        |       | 4       | 221     | 1.4   | 6      | 294   | 2.0   |        |         |       |
| Baby’s age             |         |         |       |        |       |         |         |       |        |       |       |         |         |       |
| Age 30+ days           | 3       | 68      | 4.4   |        |       | 4       | 137     | 2.9   | 7      | 205   | 3.4   |        |         |       |
| Age <30 days           | 4       | 240     | 1.7   |        |       | 7       | 767     | 0.9   | 11     | 1,007 | 1.1   |        |         |       |

AE, adverse event; CI, confidence interval; IMC, infant male circumcision; OR, odds ratio.
doi:10.1371/journal.pone.0047395.t003
rable to that among research infants (2.9% vs. 2.4%), and the latter group had a 93% follow-up rate. Review rates for IMC may be low in the absence of financial reimbursement for transport costs and active follow-up.

Our study shows IMC services can be provided safely by nurses and clinical officers and with high parental satisfaction in a developing country setting where infant circumcision is little-known and rarely practiced. These results are consistent with the developing country setting where infant circumcision is little-known and rarely practiced. These results are consistent with the

References

1. Alanis MC, Luciti CF (2004) Neonatal circumcision: a review of the world’s oldest and most controversial operation. Obstet Gynecol Surv 59: 379–395.
2. Bailey RC, Moses S, Parker CB, Agot K, Maclean I, et al. (2007) Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomised controlled trial. Lancet 369: 643–656.
3. Auvert B, Taljaard D, Lagarde E, Sobngwi-Tambekou J, Sitta R, et al. (2005) Randomized controlled intervention trial of male circumcision for reduction of HIV infection risk: the ANRS 1265 Trial. PLoS Med 2: e296.
4. Gray RH, Kigozi G, Serwadda D, Makumbi F, Wabwire-Mangen F, et al. (2007) Male circumcision for HIV prevention in men in Rakai, Uganda: a randomised trial. Lancet 369: 657–666.
5. Weiss HA, Quigley MA, Hayes RJ (2000) Male circumcision and risk of HIV infection in sub-Saharan Africa: a systematic review and meta-analysis. AIDS 14: 2361–2370.
6. Bailey RC, Flumma FA, Moses S (2001) Male circumcision and HIV prevention: current knowledge and future research directions. Lancet Infect Dis 1: 223–231.
7. Tobian AA, Gray RH (2011) Male foreskin and oncogenic human papillomavirus infection in men and their female partners. Future Microbiol 6: 739–745.
8. Gray RH, Kigozi G, Serwadda D, Makumbi F, Wabwire-Mangen F, et al. (2009) The effects of male circumcision on female partners’ genital tract symptoms and vaginal infections in a randomized trial in Rakai, Uganda. Am J Obstet Gynecol 200: 4 e1–47.
9. Wawer MJ, Tobian AA, Kigozi G, Kong X, Gravitt PE, et al. (2011) Effect of circumcision of HIV-negative men on transmission of human papillomavirus to HIV-negative women: a randomised trial in Rakai, Uganda. Lancet 377: 209–218.
10. Castlesague X, Bosch FX, Munoz N, Mejer CJ, Shah KV, et al. (2002) Male circumcision, penile human papillomavirus infection, and cervical cancer in female partners. N Engl J Med 346: 1105–1112.
11. Wisewell TE, Hachey WE (1993) Urinary tract infections and the uncircumcised state: an update. Cln Pediatr (Phila) 32: 130–134.
12. Weiss HA, Larke N, Halperin D, Schenker I (2010) Complications of circumcision in male neonates, infants and children: a systematic review. BMC Pediatr 10: 2.
13. Amiri M, Raja MH, Niaz WA (2000) Neonatal circumcision with Gomco clamp: a hospital-based retrospective study of 1000 cases. J Pak Med Assoc 50: 15–20.
14. Tobian AA, McConkey J, Binyamini J, Hardak B, Ben-Meir D, et al. (2005) Complications of circumcision in Israel: a one year multicenter survey. Isr Med Assoc J 7: 368–370.
15. Ben Chaim J, Livne PM, Binyamini J, Hardak B, Ben-Meir D, et al. (2005) Complications of circumcision in Israel: a one year multicenter survey. Isr Med Assoc J 7: 368–370.
16. de Bruyn G, Martimson NA, Gray GE (2010) Male circumcision for HIV prevention: developments from sub-Saharan Africa. Expert Rev Antivir Ther 8: 23–31.
17. Weiss HA, Larke N, Halperin D, Schenker I (2010) Complications of circumcision in male neonates, infants and children: a systematic review. BMC Pediatr 10: 2.
18. Wisewell TE, Gesche DW (1989) Risks from circumcision during the first month of life compared with those for uncircumcised boys. Pediatrics 83: 1011–1015.
19. Johnson KE, Quinn TG (2008) Update on male circumcision: prevention success and challenges ahead. Curr Infect Dis Rep 10: 243–251.
20. Banagahalo A, Pugari E, Muita J, Bertozi S (2010) Male circumcision at different ages in Rwanda: a cost-effectiveness study. PLoS Med 7: e1000211.
21. White RG, Glyn RR, Orroth KK, Freeman EE, Bakker R, et al. (2000) Male circumcision for HIV prevention in sub-Saharan Africa: who, what and when? AIDS 14: 2361–2370.
22. Young MR, Odoyo-June E, Nordstrom SK, Irvin TE, Ongong’a DO, et al. (2012) Factors Associated With Uptake of Infant Male Circumcision for HIV Prevention in Western Kenya. Pediatrics.
23. Manji KP (2006) Circumcision of the young infant in a developing country using the Plastibell. Ann Trop Paediatr 26: 101–104.
24. al-Samarrai AV, Mofit AB, Crankson SJ, Jawad A, Haque K, et al. (1988) A review of a Plastibell device in neonatal circumcision in 2,000 instances. Surg Gynecol Obstet 167: 341–345.
25. Amiri M, Raja MH, Niaz WA (2000) Neonatal circumcision with Gomco clamp: a hospital-based retrospective study of 1000 cases. J Pak Med Assoc 50: 224–227.
26. Banagahalo B (2000) Optimal time for neonatal circumcision: an observational based study. J Pediatr Urol 5: 359–362.
27. Ben Chaim J, Livne PM, Binyamini J, Hardak B, Ben-Meir D, et al. (2005) Complications of circumcision in Israel: a one year multicenter survey. Isr Med Assoc J 7: 368–370.
28. Horowitz M, Gershbein AB (2001) Gomco circumcision: When is it safe? J Pediatr Surg 36: 1047–1049.
29. Moosa FA, Khan FW, Rao MH (2010) Comparison of complications of circumcision by ‘Plastibell device technique’ in male neonates and infants. J Pak Med Assoc 60: 664–667.
30. World Health Organization and Jhpiego (2010) Male circumcision for HIV prevention: current knowledge and future research directions. Lancet Infect Dis 10: 243–251.
31. World Health Organization and Jhpiego (2010) Male circumcision for HIV prevention: current knowledge and future research directions. Lancet Infect Dis 10: 243–251.
32. World Health Organization and Jhpiego (2010) Male circumcision for HIV prevention: current knowledge and future research directions. Lancet Infect Dis 10: 243–251.
33. Palit V, Menebhi DK, Taylor I, Young M, Elmasry Y, et al. (2007) A unique complication of circumcision by ‘Plastibell device technique’ in male newborns. J Pediatr Surg 42: 153–157.
34. Krill AJ, Palmer LS, Palmer JS (2011) Complications of circumcision. ScientifcWorldJ 11: 2458–2468.
35. Sherman J, Borer JG, Horowitz M, Glassberg KJ (1996) Circumcision: successful glanular reconstruction and survival following traumatic amputation. J Urol 156: 942–944.
36. Pieretti RV, Goldstein AM, Pieretti-Vanmarcke R (2010) Late complications of male circumcision. Pediatr Clin North Am 57: 1205–1216.
37. Patel HI, Moriarty KP, Birson PA, Feins NR (2001) Genitourinary injuries in the newborn. J Pediatr Surg 36: 235–239.