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Safety and Acceptability of PrePex™ Circumcision among Adolescents in Kisumu, Kenya

Kawango Agot[1], Julie Ambia[1], Risper Bosire[1], David Muhuaya[1], Joshua Juma[1], Abraham Bitok[1], Ohaga Spala[1], Benard Ayieko[1], Maurice Onyango[1]

[1]Impact Research and Development and Organization

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Background

- PrePex™, as nonsurgical circumcision device, presents an alternative to surgical procedure for the scale up of voluntary medical male circumcision (VMMC) services, where health infrastructure and resources are limited.
- Despite PrePex™ circumcision being safe and acceptable to men seeking VMMC services[1], information on the safety and acceptability of PrePex™ procedures in adolescent boys below 13 years old and those with contraindications is lacking.
- Concerns related to odor, pain, tetanus infection, wound care, and healing time have also arisen[2] suggesting the need for more research to further optimize PrePex™ uptake.
- A modified PrePex™ procedure where the foreskin is removed on day 0 (Day0 Foreskin Removal Procedure (Day0 FRP)) has been proposed to address these concerns.

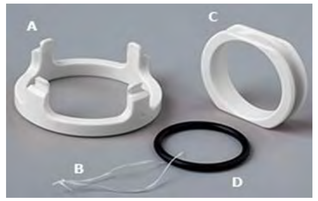
Objective

- To assess the safety and acceptability of Day0 FRP and Standard PrePex circumcisions performed by clinical and nursing officers on healthy and contraindicated adolescent boys aged 10 to 12 years.

Mechanism of action

PrePex ™ works by compressing the foreskin, between an inner ring (C) placed between glans and foreskin and outer elastic band (D) applied externally using applicator (A), leading to distal tissue necrosis. Necrotic foreskin together with the device is removed after 7 days (Fig.1)

Fig. 1. PrePex ™ device



Methods

Study Design: *P*hase IV, open-label, single-centre, single-arm trial.

Recruitment: We targeted approximately 200 adolescent males ages 10-12 years seeking VMMC services at Tuungane Youth Centre in Kisumu, one of the high HIV burden counties nationally (Fig 2).

Study Procedures: Participants were given tetanus toxoid vaccination, and offered either standard or Day 0 FRP PrePex™ circumcision. Participants with a contraindication to PrePex ™ circumcision went through appropriate preparation maneuvers before device placement.

Follow-up visits: Done weekly for 56 days.

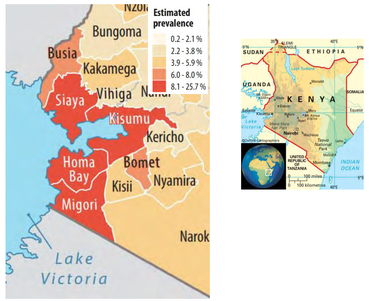
Analysis: Percentages were used to summarise study outcomes.

Results

Table 1. Characteristics of adolescent males in the study

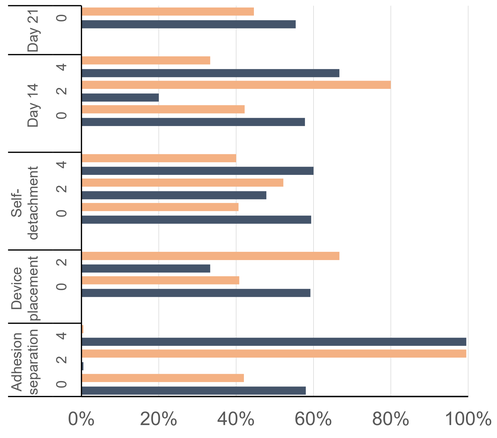
Parameter	n (%)	Age (years)		
		10	11	12
PrePex™ procedure	214 (100%)	95 (44.4%)	72(33.6%)	47 (21.9%)
Day 0 FRP	126 (58.9%)	59 (46.8%)	37 (29.4%)	30 (23.8%)
Standard	88 (41.1%)	36 (40.9%)	35 (39.8%)	17 (19.3%)
Contraindications	74 (34.6%)	29 (39.2%)	26 (35.1%)	21 (28.4%)
Preputial adhesions	44 (59.5%)	19 (43.2%)	13 (29.6%)	12 (27.3%)
Narrow foreskin	9 (12.2%)	0	2 (22.2%)	7 (77.8%)
Preputial adhesions and narrow foreskin	21 (28.4%)	11 (52.4%)	8 (38.1%)	2 (9.5%)

Fig. 2. Map of estimated HIV prevalence in Nyanza region, Kenya *



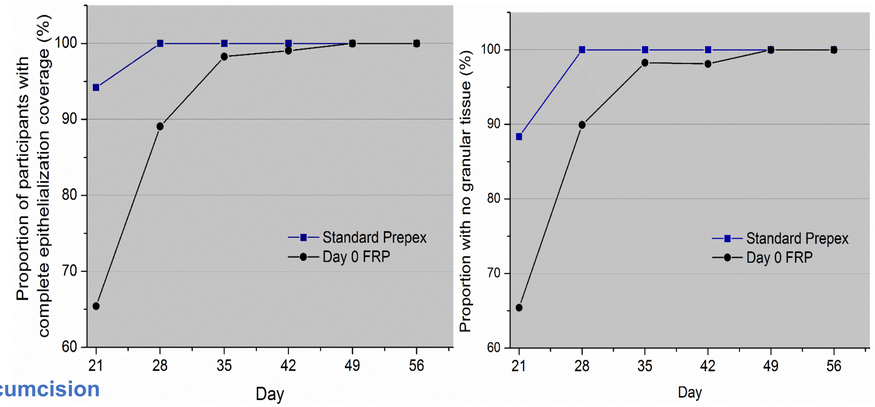
* Kisumu is one of counties in the Nyanza region with high HIV prevalence and home to the Luo community that constitute approximately 70% of Kenya's traditionally non-circumcising ethnic group.

Fig. 3. VAS pain levels during the circumcision and follow ups*



* Visual analog score (VAS): 0 - No pain; 2 – hurts just a little; and 4 – hurts just a little more

Fig 4. Comparison of the wound healing time assessed by epithelialization and granular tissue formation



Summary of results

Survey findings (Table 1)

- 214 boys enrolled between Apr and Nov 2017; 34.6% had contraindications to PrePex™ circumcision; 59% (126/214) underwent Day0 FRP.

Pain during circumcision phases (Fig. 3)

- Pain was not associated with the PrePex procedure.

Wound healing (Fig. 4)

- Participants who underwent standard PrePex™ device circumcision had shorter time to complete healing as compared to Day 0 FRP.

Adverse events (AE), satisfaction and acceptability

- 1 moderate adverse event (1/214, 0.5%) - bleeding due to device displacement reported in a Day0 FRP participant; AE corrected by surgical intervention.
- Majority (>90%) of participants and parents were satisfied with the outcome of the circumcision and showed willingness to recommend to their peers.

Conclusion

Circumcision using PrePex device was safe and acceptable among adolescent aged 10-12 years and should be considered for the scale up of VMMC services.

PREPEX™ For an AIDS FREE World

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References

1. Feldblum et al. PLoS One. 2014
2. Gelukande et al. PLoS One. 2014