



Experience with ShangRing Circumcision in Malawi Voluntary Medical Male Circumcision Program

Nandi Owuor¹, Martin Kapito², Chiwawa Nkhoma¹, Frackson Shaba¹, Kudakwashe Murombedzi¹, Kenneth Sikumbiri¹, Zacharia Kafuwa¹, Karin Hatzold³, James Odek⁴

1. PSI, Malawi
2. Ministry of Health, Malawi
3. PSI, Washington,
4. USAID, Malawi

Background

- Between 2012 and 2020 about 980,000 males aged between 10 and 49 years have been circumcised in Malawi through the national voluntary medical male circumcision (VMMC) program for HIV prevention.
- Most of these procedures were performed using conventional surgical techniques such as forceps guided and dorsal slit methods.
- Conventional surgical techniques have longer procedure time, less favourable cosmetic outcome and higher risk of glans injury, especially among younger adolescents, 15 years and below.
- WHO prequalified (PQ) ShangRing device, in 2015, for circumcision of males aged 13 years and above using injectable anesthesia as alternative to conventional surgical MC.
- The WHO amended the ShangRing PQ in 2018 to include No-flip ShangRing circumcision technique and the use of topical anaesthesia.
- ShangRing achieves circumcision by creating hemostasis through the pressure applied by two interlocking rings which minimizes bleeding and eliminates the need for sutures.
- MoH Malawi, in collaboration with partners, evaluated ShangRing as outlined in the WHO Framework for clinical evaluation of devices for male circumcision, and endorsed it for passive roll out.

Description

Device evaluation

- The ShangRing device was first introduced in Malawi in 2015, through implementation pilot to assess safety and acceptability among males 18 to 49 years, using injectable anesthesia, in one static (health facility) site.
- The device safety and acceptability were further evaluated in males 10 to 49 years under active adverse event(AE) surveillance(AAES) from April to September 2019 using injectable anesthesia, with 18 device sizes, in 10 static sites.
- All ShangRing circumcised clients came for clinic review and device removal on day 7.
- VMMC providers(nurses, clinical officers) were trained to provide ShangRing circumcision and to manage AEs related to ShangRing.
- After AAES, ShangRing circumcision was rolled out under passive AE surveillance(PAES) and services have been continuing since October 2020.

Table 1, Evaluation

Stage of device introduction	Objective	Sites	Timeframe	Number of circumcisions performed
Pilot	Assess safety and acceptability	1	2015	498
Active adverse event (AE) surveillance (AAES)	Evaluate safety and acceptability in routine health care settings	10	April-Sept 2019	1862
Passive/Routine AE surveillance	Endorsed for passive rollout	Static sites	Open ended	6750 (by Dec 2020)

Results

- During the pilot phase, the AE rate was 1.4% (7/498; moderate AE), and 98% (488/498) of males circumcised, separately interviewed, were happy with cosmetic outcome.
- During AAES, the AE rate was low (0.05%: 1/1862, Severe) compared to the national acceptable rate (1%), and 31(82%) out of 38 ShangRing clients separately interviewed were satisfied with placement and removal procedures because of less pain experienced.

Results-cont..

- Since passive roll out, 6750 ShangRing circumcisions were done by end of December 2020 with 0.1%(7/6750) AE rate reported(3 moderate & 4 severe AEs)
- All severe AEs reported were ring displacement that occurred within 1 day post-placement and were managed through surgical wound closure and hemostasis.
- ShangRing circumcision has short placement procedure time (7 minutes, AAES; 5 minutes, PAES) compared to time taken on conventional surgical techniques (15 minutes).
- Key challenge associated with ShangRing circumcision during the studies, is the requirement for multiple device sizes (15) leading to frequent site-specific stock outs.

Table 2, Results

Stage of device introduction	Adverse event	Remarks
Pilot	<ul style="list-style-type: none"> •Moderate (7), wound disruption; infections •Severe (0) •Rate: 1.4% (7/498) 	•Safe and effective
Active AE surveillance	<ul style="list-style-type: none"> •Moderate(0) •Severe(1): ring displacement requiring surgical intervention •Rate: 0.05% (1/1862) 	<ul style="list-style-type: none"> •Low AE rate than that of conventional surgical methods national accepted rate (1%) •Effective and well accepted Severe AE managed by hemostasis & wound closure
Passive AE surveillance, (open-ended)	<ul style="list-style-type: none"> •Moderate(3); wound disruptions •Severe(4); ring displacements requiring surgical intervention •Rate: 0.1% (7/6750) 	<ul style="list-style-type: none"> •Safe in Malawi context and scalable •6750 done as at 31st Dec 2020 under passive AE surveillance Severe AEs managed by Hemostasis & wound closure

Lessons learned

- ShangRing is safe, fast, and acceptable in Malawi context
- ShangRing prevents potential penile glans injuries and urethral fistulas commonly associated with deep stitches of conventional surgical techniques, especially among younger adolescents.

Conclusions/Next Steps

As ShangRing progresses through routine implementation, the following next steps will be essential to ensure safety and increased uptake in Malawi:

1. Train more providers and trainers of trainers on ShangRing circumcision
2. Promote ShangRing circumcision as an equivalent alternative to conventional surgical circumcision
3. Revise national circumcision communication strategy document and incorporate ShangRing communication materials
4. Address ShangRing sizes supply chain bottlenecks by identifying commonly used sizes and increase their availability
5. Scale up ShangRing circumcision among adolescent and adult males to accelerate achievement of national VMMC target and coverage

This research poster has been supported by the President's Emergency Plan for AIDS Relief (PEPFAR) through the U.S. Agency for International Development (USAID) under the terms of cooperative agreement number : 72061220CA00003. The findings and conclusions in this poster are those of the author(s) and do not necessarily represent the official position of USAID.