INTRODUCTION

• Voluntary medical male circumcision (VMMC) represents an important intervention toward reducing the rate of spread of HIV.

• Since 2008, VMMC has primarily targeted men above 18 years of age. This includes the use of circumcision devices, which reduce the time needed to carry out the circumcision procedure.

• However, circumcision in boys is simpler and less expensive, with lower risks of complication and faster healing than in adults.

• Currently, the devices recommended by the World Health Organization (WHO) for carrying out male circumcision in infants cannot be used in children older than 2 months of age, due to the higher risk of associated adverse events.

• No single circumcision device has been shown to be safe and acceptable across all age-groups, from infants to adults.

• The Shang Ring has been shown to be a safe, acceptable device for carrying out male circumcision among adults. It is commercially available in sizes for all ages, but its use in boys in Africa has not been previously reported.

STUDY METHODS

• The study aimed to recruit 80 clients, distributed equally into four childhood age-groups.

• Informed consent was obtained from the participants’ parents or a guardian. Assent was additionally obtained from clients who were above the age of 7 years old and could understand the study procedures.

• Clients were circumcised and scheduled for removal of the Shang Ring on days 5-7. Follow-up visits were scheduled every seven days until the client was observed to have healed completely.

• At every follow-up visit, clients were examined for healing, any reported complaints, and any adverse events.

• A completion interview was carried out when clients exited from the hospital on the day of recruitment.

Inclusion criteria

• Consent from parent or guardian

• Assent from participant >7 years of age

• Weight >2.5 kg; penile shaft >1 cm in length

• Good general health and free of sexually transmitted infections

• Assent from participant >7 years of age

• A completion interview was carried out when clients exited from the hospital on the day of recruitment.

Exclusion criteria

• Allergy to lidocaine

• Known bleeding disorder

• Active genital infection, anatomic abnormality or other condition preventing circumcision

RESULTS: DEMOGRAPHICS

A total of 80 clients were enrolled into the study.

• The youngest client was 3 months old.

• Recruitment of children in the <1-year-old was difficult, and we could not address this within the time frame of the study.

OBJECTIVES

Primary objective:

• To evaluate the safety, efficacy, and course of wound healing when using the Shang Ring in boys under 18 years of age.

Secondary objectives:

• To determine the acceptability of the Shang Ring device among the participants (or their parents).

• To evaluate the ease of use of using the Shang Ring as a device for male circumcision in boys.

RESULTS: SHANG RING CIRCUMCISION AND REMOVALS

CIRCUMCISION TIME

• The mean (SD) time taken for Shang Ring circumcision was 6.7 (2.41) minutes.

• No adverse events occurred during the circumcisions.

PAIN AT TIME OF DEVICE REMOVAL

ADVERSE EVENTS

<table>
<thead>
<tr>
<th>Age-group</th>
<th>Adverse event (AE)</th>
<th>Moderate event (%)</th>
<th>Severe event (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1 (n=6)</td>
<td>16.7</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>1–5 (n=30)</td>
<td>3.3</td>
<td>35.7</td>
<td>73.3</td>
</tr>
<tr>
<td>&gt;5–12 (n=22)</td>
<td>0</td>
<td>4.5</td>
<td>50.0</td>
</tr>
<tr>
<td>&gt;12–&lt;18 (n=15)</td>
<td>0</td>
<td>0</td>
<td>33.3</td>
</tr>
</tbody>
</table>

All moderate AEs healed with conservative management.

ACCEPTABILITY

<table>
<thead>
<tr>
<th>Things likely about circumcision</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved hygiene</td>
<td>74</td>
<td>92.5</td>
</tr>
<tr>
<td>Circumcision quick</td>
<td>61</td>
<td>76.3</td>
</tr>
<tr>
<td>Cosmetic appearance</td>
<td>57</td>
<td>73.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Circumcision outcome</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Better than expected</td>
<td>12</td>
<td>15.8</td>
</tr>
<tr>
<td>Circumcision took too long to heal</td>
<td>5</td>
<td>6.6</td>
</tr>
<tr>
<td>Wound care during healing was difficult</td>
<td>4</td>
<td>5.2</td>
</tr>
<tr>
<td>Not the best cosmetic appearance</td>
<td>1</td>
<td>1.1</td>
</tr>
</tbody>
</table>

Satisfaction with appearance of circumcised penis

<table>
<thead>
<tr>
<th>Satisfaction with appearance of circumcised penis</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very satisfied</td>
<td>72</td>
<td>94.7</td>
</tr>
<tr>
<td>Somewhat satisfied</td>
<td>4</td>
<td>5.3</td>
</tr>
</tbody>
</table>

CONCLUSIONS AND RECOMMENDATIONS

• The results of this pilot study suggest that the Shang Ring is a safe, effective, and acceptable technique for male circumcision in children below age 18.

• Since the Shang Ring is available in sizes suitable for infants to adults, its use would allow for easier, more cost-effective implementation of circumcision programs, by simplifying training and supply chain management.

• The Shang Ring has the potential as a single device to be implemented across all age-groups, including adults, adolescents, young boys, and infants.

• Larger prospective trials are required to further validate the use of the Shang Ring in the pediatric population.

Question or Comments?

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