CIRCUMCISION CLAMPS

HEALTH TECHNOLOGY ASSESSMENT SECTION
MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA
009/2008

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July 2008

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EXECUTIVE SUMMARY

Circumcision is one of the oldest and commonest elective surgical procedure performed by man. Circumcision is the removal of some or all of the foreskin (prepuce) from the penis. The word "circumcision" comes from Latin *circum* (meaning "around") and *cædere* (meaning "to cut"). Problem faced with circumcision were mainly pain sensation, bleeding and infection. Deaths due to circumcision were not uncommon, and mainly attributable to bleeding and infection. With the advent of analgesia, septic technique, sutures, Anti Tetanus Toxoid and antibiotics, circumcisions done today are safe and relatively painless. However, with the free hand technique, accidental amputation of glans penis (partial or total) has been reported even in advanced and well medical centre.

In the early 20th century, Moskovich was the first to practice bloodless circumcision, when he invented circumcision forcep. The forcep was not popular, because of its poor cosmetic outcome and since then become obsolete. Subsequently, more clamps (disposable and non disposable) were invented, most of which were already obsolete.

Non disposable clamps that are popular today is the Gomco Clamp and Mogen clamp. Disposable circumcision clamps include Plastibell, Smart Klamp, Ali's Klamp, Hong-Kyo Clamp, Zhenxi Ring, Ismail Clamp, Tara Klamp and Sunathrone™ . Tara Klamp, Ismail Clamp and Sunathrone™ are manufactured in Malaysia.

Disposable circumcision clamps are becoming more popular because such clamps are claimed to be fast and relatively bloodless (the whole circumcision procedure can be completed in less than 10 minutes). Blood vessels are clamped, prior to excision of prepuce, making it relatively bloodless, also saving time to ligate vessels as opposed to conventional circumcision. It also claimed to be safe since the glans penis and frenulum are protected by inner tube and cannot be accidentally excised during circumcision.

There was fair level of evidence to support the safety of Gomco, Mogen, Plastibell and Tara KLamp. The evidence to support the safety of Sunathrone™ is still insufficient.

There was fair level of evidence to support the effectiveness of Gomco, Mogen, Plastibell and Tara KLamp. However, more randomized controlled trials should be conducted involving larger number of subjects. Currently, the evidence to support the effectiveness of Sunathrone™ is still insufficient.

There was no retrievable evidence on the cost-effectiveness of circumcision clamps.

Based on the above review, disposable circumcision clamps such as Tara KLamp, and Sunathrone™ can be used as a research tool. More clinical research such as randomized clinical trials is warranted to provide better quality evidence.

CIRCUMCISION CLAMPS

1. INTRODUCTION

Circumcision is one of the oldest and commonest elective surgical procedure performed by man. Circumcision is the removal of some or all of the foreskin (prepuce) from the penis. The word "circumcision" comes from Latin *circum* (meaning "around") and *cædere* (meaning "to cut"). Early depictions of circumcision are found in cave drawings and Ancient Egyptian tombs, though some pictures may be open to interpretation. Male circumcision is a commandment from God in Judaism. In Islam, though not discussed in the Quran, circumcision is widely practiced and most often considered to be a "*sunnah*". It is also customary in some Christian churches in Africa, including some Oriental Orthodox Churches.[1]

According to the World Health Organization (WHO), global estimates suggest that 30% of males are circumcised, of whom two thirds were Muslim. The prevalence of circumcision varies widely between different populations. For example, prevalence is reported to be nearly universal in the Middle East, but under 2% in Scandinavia. There is scientific evidence supporting both sides of the circumcision controversy. Routine neonatal circumcision advocators claimed circumcision provides important health advantages which outweigh the risks, has no substantial effects on sexual function. It has a complication rate of less than 0.5% when carried out by an experienced physician and is best performed during the neonatal period. Opponents of routine neonatal circumcision claimed circumcision violates the individual's bodily rights, is medically unnecessary, adversely affects sexual pleasure and performance, and is a practice defended through the use of myths.[1]

Problem faced with circumcision were mainly pain sensation, bleeding and infection. Deaths due to circumcision were not uncommon, and mainly attributable to bleeding and infection. With the advent of analgesia, septic technique, sutures, Anti Tetanus Toxoid and antibiotics, circumcisions done today are safe and relatively painless. However, with the free hand technique, accidental amputation of glans penis (partial or total) has been reported even in advanced and well medical centre. [2]

Attempts are made to ensure that circumcisions are safe and relatively bloodless. Bleeding is not only bad for the patient, but also messy, and obstructs surgeon's view, to the extent he may not be able to visualize what is going on. In the early 20th century, Moskovich was the first to practice bloodless circumcision, when he invented circumcision forcep. The forcep was not popular, because of its poor cosmetic outcome and since then become obsolete. [2]

Subsequently, more clamps (disposable and non disposable) were invented, most of which were already obsolete. Non disposable clamps that are popular today is the Gomco Clamp and Mogen clamp. Disposable circumcision clamps include Plastibell, Smart Klamp, Ali's Klamp, Hong-Kyo Clamp, Zhenxi Ring, Ismail Clamp, Tara Klamp and Sunathrone™ .[2] Tara Klamp, Ismail Clamp and Sunathrone™ are manufactured in

Malaysia. Disposable circumcision clamps are becoming popular because such clamps are claimed to be:

i. **Fast and relatively bloodless:**
The whole circumcision procedure can be completed in less than 10 minutes. Blood vessels are clamped, prior to excision of prepuce, making it relatively bloodless and also saves time to ligate vessels as opposed to conventional circumcision.

ii. Easy to use:
It needs minimal training

iii. Safe:
Glans penis and frenulum are protected by inner tube and cannot be accidentally excised during circumcision.

iv. Economical:
a). It does need an operating theatre
b). It does not need to acquire expensive medical equipment such as cautery set and laser scarpel set.
c). It does not need dressing and saves time and cost as dressing can be a painful and distressing experience.

v. Disposable:
It saves cost on sterilization apparatus and time on sterilization procedure.

vi. Decrease risk of cross infection:
It is pre sterilized. Its single use application eliminates risk of cross infection from inadequately sterilized reusable equipment.

vii. Normal physical activity not compromised:
Patient can resume normal activity immediately after circumcision. Patients are also advised to take regular bath, and not to indulge in strenuous and/or vigorous physical activity until circumcision wound has healed.

viii. Good cosmetic outcome:
Pleasant appearance with an even and uniform cut. No stitch mark

This technology review was conducted following a request from the office of Deputy Minister of Health, Malaysia. The request was assessment on Sunathrone™. In addition, Principal Assistant Director, Medical Development Division, Ministry of Health also requested technology assessment on Tara KLamp.

2. OBJECTIVE

The objective of this review is to determine the safety, effectiveness and cost-effectiveness of circumcision clamps.

3. TECHNICAL FEATURES

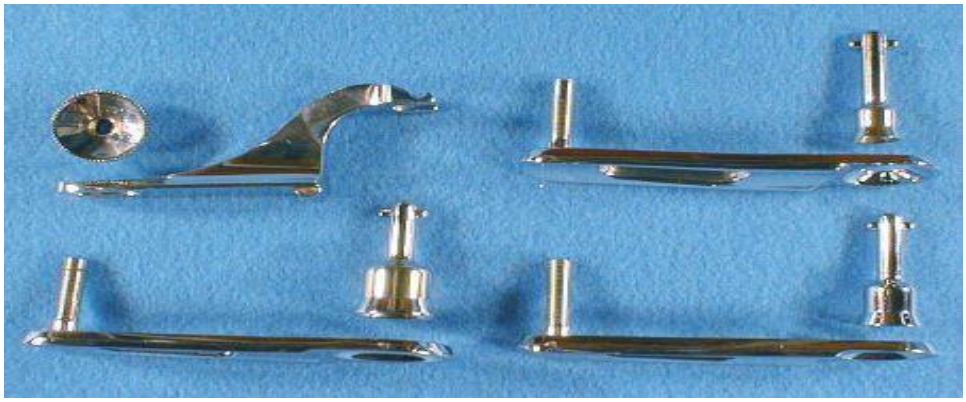
3.1. Non-disposable circumcision clamps

3..1.1 Gomco clamp

The introduction of the Gomco clamp and the development of the bloodless technique by Yellen in 1935 and Brodie in 1939 have encouraged the practice of routine circumcision.

The Gomco clamp is made up of 4 parts: a plate, a stud (bell), an arm (yoke), and a nut (to tighten the clamp). The bell is introduced into the preputial cavity (over the glans and under the foreskin) and the prepuce is drawn over it. The plate is then placed over the bell so that the prepuce is sandwiched between them. The arm is fitted into its proper place, and when the nut is screwed on tightly, it exerts a crushing force on the prepuce at the junction of the bell and plate. The clamp is left for 5 minutes to achieve hemostasis, and the prepuce is excised. [3]

The Gomco clamp comes in a wide variety of sizes for use on infants, boys and men of all ages and sizes. The following shows a standard youth set.



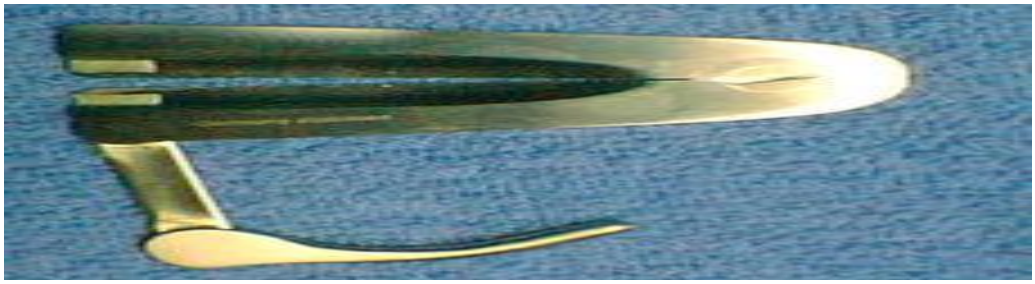
There are 3 sizes namely:-

- 1.3 - 1/2" Newborn
- 1.6 cm - 5/8" Child
- 2.1 cm - 13/16" Youth

This is a combination set. It contains 3 base Plates - 3 Bells - 1 Rocker - 1 Screw Down Wheel and can be put together to accommodate all three of the above sizes.

It is often used in newborns. This device should not be used to do a self-circumcision. Circumcision should always be performed by a trained and skilled healthcare provider.[3]

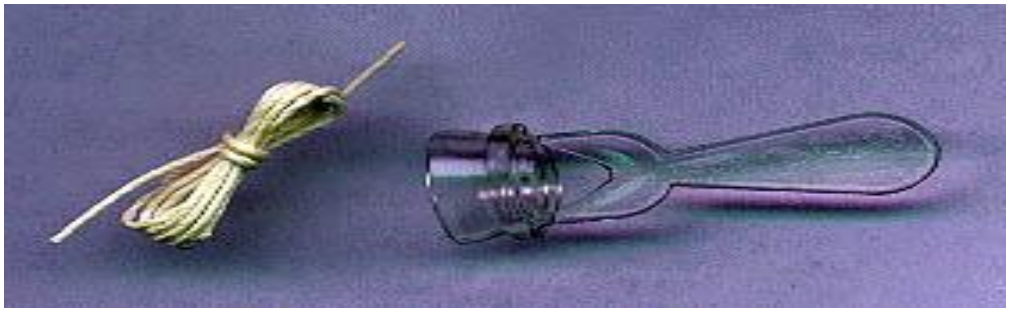
3.1.2. Mogen clamp



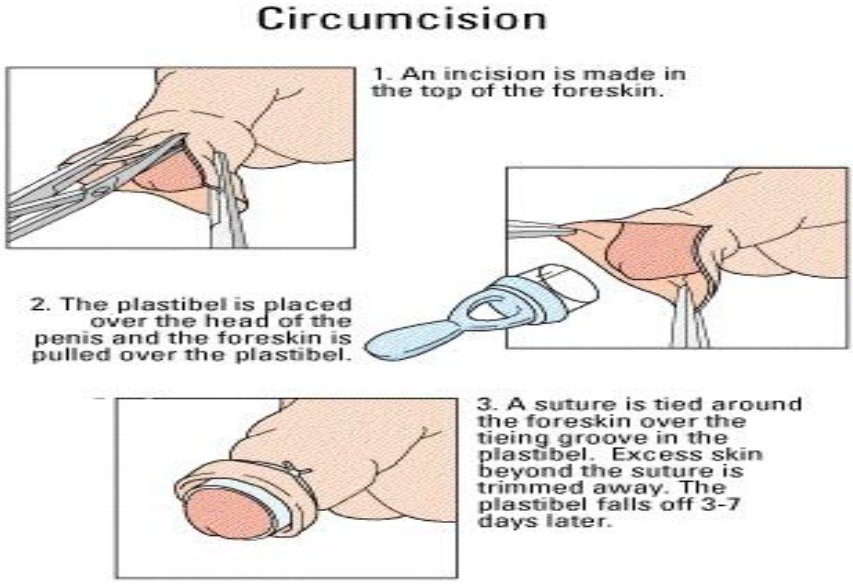
Bronstein, a Brooklyn Mohel (ritual circumcisor), who invented the Mogen Clamp, also invented the Nutech clamp. The Mogen Clamp is a variation of the Kantor clamp. Instead of crushing the tissue by the attached hemostat, the Mogen shield acts as the clamp. It has the shortcomings of the Kantor clamp, plus 1 uniquely its own: with the glans below completely out of sight, there is a chance that the tip of the glans might be caught in the clamp. However, this is the preferred device of the more modern Jewish Mohel.[4]

3.2. Disposable circumcision clamps

3.2.1. Plastibell



Hollister makes the Plastibell, which is a plastic bell with a groove close to the edge. It is a disposable plastic device. The bell is inserted into the preputial cavity (over the glans, and under the foreskin) and the foreskin (prepuce) is tied around it with a tight string. Blood flow to the prepuce is ceased, and the prepuce in front of the string is cut off. After several days, the prepuce caught under the string necrotizes and falls off, providing a bloodless circumcision, with no open wound to become irritated or infected.



Because of the danger of the plastic ring being pulled back behind the glans, only the foreskin that naturally covers the glans can be safely removed using the Plastibell. Hence it usually results in a looser, although a visually appealing, circumcision, unlike the newly developed Tara KLamp.

The Plastibell is primarily used on infants in the United States, although youth, teenages and adult models are sometimes used in Europe. [5]

3.2.2. Smart Klamp

This device is similar in operation to the Tara KLamp except that it is in two parts. The glans is first measured using the Size-O-Meter to determine which size device is required. Any adhesions are broken down and the tube part is inserted between the glans and the foreskin, which is pulled up onto the tube. The outer portion is passed over the tube and rotated half a turn to lock the tube to it. The locking arms are then half-closed to lightly hold the foreskin. The foreskin is adjusted over the tube so that it will be clamped at the desired place. The locking arms are clicked completely shut and the excess foreskin is removed from in front of the locking ring. The device can be left to fall off by itself in

about a week or the doctor can remove it after a few days. It was originally available only in sizes for infants and children. However, in March 2004 the company has announced the introduction of the adult sizes (XL (27mm) and XXL (35mm) with first distribution in Istanbul. This device should not be used to do a self-circumcision. Circumcision should always be performed by a trained and skilled healthcare provider. [6]

3.2.3. Ismail clamp

Components of Ismail clamp

1. Inner tube.
2. Clamp Holder
3. Screw nut

Ismail circumcision clamp is invented and produce in Malaysia. It has all the features of currently available disposable circumcision clamps, with added features of reversible clamping which the manufacturer claims make its removal on 5th to 10th day, easy, spontaneous and relatively painless. Ismail clamp comes in 4 sizes: 10 mm, 13 mm, 16 mm and 19 mm and measuring device is provided by the manufacturer.

Features unique to Ismail Clamp

i. Reversible clamping: Clamp can be removed just by turning screw nut anticlockwise

a. Clamp can be removed at home by family members. If family members are not able to do it, clamp can be removed by attending doctor.

b. In case of complication, it is easy to remove the clamp and proceed to conventional circumcision.

c. Prepuce can be adjusted, prior to its removal.

d. Removal of clamp on 5th day is easy, spontaneous and relatively painless.

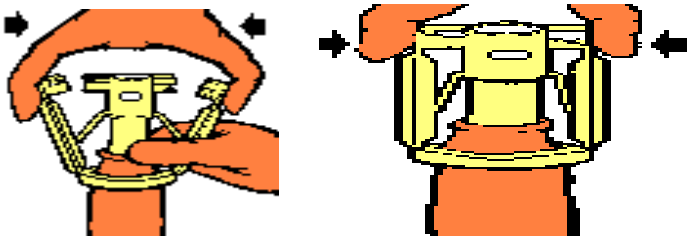
ii. Easy, spontaneous and relatively painless removal

To achieve this, the only active intervention required is to unscrew and remove the screw nut. Do not attempt to forcibly detach clamp from the penis. Allow patient to go home with clamp on (without screw nut) and advise patient to soak (1/2 to 1

hour) clamp and penis in water such as take long showers and the clamp will detach from the penis spontaneously an relatively painless.[7]

3.2.4. Tara KLamp

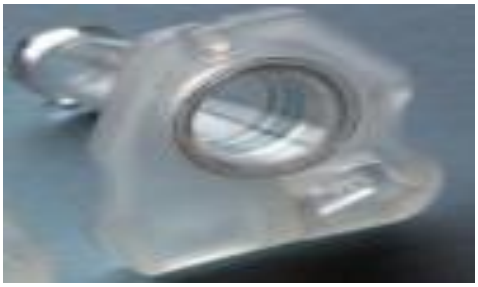
This is a Malaysian invention. The surgical steps used by this device are based on non-invasive surgery. The concepts that enable non-invasive surgery were discovered by [redacted] who invented the Tara KLamp. The device works in a very similar fashion to the Plastibell except that instead of having to tie suture material around a groove in the bell, plastic arms lock into place to force two surfaces into tight contact; with the foreskin trapped between them.**.** The device remains on the penis for 7 to 10 days until it falls off. If the foreskin is tight, a dorsal slit is required to gain access for the bell to be applied over the glans. The foreskin which is trapped in front of the clamping device is cut away after the clamp has been in place for 20 minutes or so. The glans and frenulum are protected and the frenulum is never cut during this procedure. Prior to surgery, at least a local anesthetic is used. Immediately after the surgery and for the next day or two, oral analgesics are required.

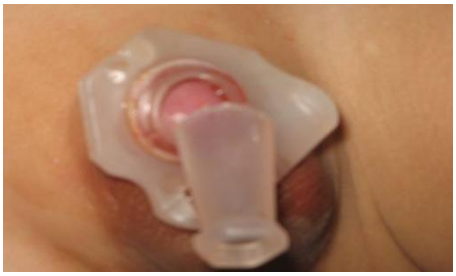


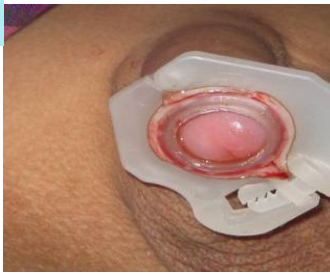
It has various sizes from 12.5 mm to 32 mm (infant to adult). Sizing guides are provided by the manufacturer. The device is pre-sterilized and is for single use only. [8,9]

The manufacturer claims that it enables male circumcisions to be performed
easily, safely and anywhere e.g. whether out there in the bush or open area. It is of unitary construction and does not require to be assembled before use, so that even para-medic can use it with ease, with minimal training. The device does not create an open wound and hence, it does not require any sutures, ligatures or bandages.[9]

3.2.5. Sunathrone™







Sunathrone is a new disposable plastic circumcision clamp. It is developed by [redacted] in Malaysia. Sunathrone™ prototype is designed by SIRIM. It is made from hypoallergenic food grade plastic which is completely transparent, which the manufacturer claims help in correct positioning of meatus urinae. They claim Sunathrone™ offers superior surgical advantages against any other existing plastic disposable devices. The principal advantage appears to be the size of the device remaining on the penis for the duration of the healing period, which is considerably shorter than the Tara KLamp and other similar clamps. (Once the tube has been detached, the super- lightweight device weighs 1.5 grams or less, depending on the size). It has a safe locking mechanism which can only be released by using a tool to cut through the plastic tongue of the lock. In most cases the Sunathrone clamp will fall off in the bath, in a manner similar to a Plastibell circumcision. The clamp comes in various sizes for use on males of all ages, from newborn to adults. It has a measuring device called Sunameter™. [10, 11]

4. Methodology

4.1. Searching

Electronic databases were searched, which included Pubmed, Ovid, Proquest, EBSCO Host, Medline, CINAHL, Cochrane database of systematic reviews, HTA Databases, Horizon scanning databases (CADTH, ASERNIP-S, Defra, euroscan), FDA website, MHRA and Google for published reports. Additional articles were identified from

reviewing the bibliographies of retrieved articles and from documents provided by Sunathrone Bio-medical Sdn Bhd and Taramedic Corporation Sdn Bhd. There was no limitation in the search. Personal communication was also carried out by telephone calls.

The search strategy used the terms, which are either used singly or in various combinations: Sunathrone, "plastic disposable circumcision clamp", "disposable circumcision", "sunathrone clamp", "Tara KLamp", "Ismail clamp", "Ali's clamp", Gomco clamp, Plastibell, "Mogen clamp" AND effectiveness OR efficacy, safety OR safe OR "adverse effect*" OR "harm* effect*" OR toxicity, "cost effectiveness" OR "cost analysis" OR econom*.

4.2. Selection

All articles published and unpublished related to safety, effectiveness and cost effectiveness of male circumcision clamps were selected. Critical appraisal of relevant literature was performed and evidence graded according to US/Canadian Preventive Services Task Force (Appendix 1)

5. RESULTS AND DISCUSSION

The search strategies yielded few published articles related to Gomco clamp, Mogen clamp, Plastibell, and Tara KLamp. The rest of the articles (unpublished) were provided by [redacted] and [redacted]

5.1. SAFETY

5.1.1. Gomco clamp

The device is classified under Regulatory Class II by US Food and Drug Administration (FDA). It received FDA approval for marketing.[12] Gomco clamp is used most commonly for neonatal circumcisions in the United States. Horowitz M and Gershbein AB conducted a review to determine the optimal age at which the procedure should be performed. Ninety-eight patients underwent Gomco circumcision as neonates or early infancy at a mean age of 17 days (range, 4 to 30 days) and 32 patients underwent circumcision after early infancy at a mean age of 6.5 months (range, 90 days to 8.5 months). The result showed that none of the 98 patients in the early infancy group had post circumcision complications. Of 32 patients in the older age group, 12 (30%) had post operative bleeding requiring suture repair of fulguration. The authors concluded that although safe and effective for circumcision in the neonatal period in early infancy, use of Gomco clamp for circumcision beyond early infancy (3 months of age) has substantial morbidity, and alternative methods of circumcision should be sought.[13]

The impact and safety of neonatal circumcision under a uniform policy using Gomco clamp was evaluated by Amir A, Raja MH and Niaz WA. They retrospectively analysed 1000 consecutive cases of neonatal circumcisions done using Gomco clamp at Armed Forces Hospital, Jubail, Saudi Arabia during the period of 1996 to 1998. There were 19 (1.9%) complications with mild to moderate bleeding in 6 cases which settled with

further compressive dressing, 4 cases of superficial sepsis, 2 frenular ulcers, 4 babies had soft preputial adhesions that were separated easily under topical anaesthesia and 3 cases of inadequate circumcisions.[14]

5.1.2. Mogen clamp

The device is classified under Regulatory Class II by US Food and Drug Administration (FDA). It received FDA approval for marketing.[12] Complications of circumcision using Mogen clamp were described by Kaweblum et al. In his study involving 313 circumcisions done among patients between 1 and 2 years of age with the exception of four patients, the complication rate was 1.6%. Two patients had local infection, one mild haemorrhage, one concealed penis and one post circumcision phimosis. The author concluded that circumcision using Mogen clamp is simple, quick and safe procedure.[15]

5.1.3. Plastibell

The device is classified under Regulatory Class II by US Food and Drug Administration (FDA). It received FDA approval for marketing.[12] Several studies were retrieved on complications related to plastibell circumcision device. Fraser et al. in his randomized controlled trial of routine circumcision using Plastibell device compared to a dissection suturing technique involving 100 children with a mean age 4.7 years, found that general discomfort was slightly less common after plastibell circumcision, but dysuria was more common with plastibell circumcision. He noted that no serious complication was encountered with either method and infection was slightly more common after the conventional procedure.[16] Similarly, Sorenson SM and Sorenson MR also noted that there were no serious complications encountered but dysuria was more prominent using the plastibell device. [17]

Owen ER and Kitson JL described complication caused by proximal dislocation of the plastibell ring, which failed to fall off at the usual time. In one case, a general anaesthesia was required to remove the ring.[18] Similarly, Datta NS and Zinner NR described the cases of four neonates with retained plastibell ring which need to be removed by wire cutters.[19] A review of 9-year results of plastibell circumcisions performed among 1,129 Muslim infants between 6 and 14 weeks old, demonstrated that common complications encountered were problems with the ring (3.6%) and bleeding (3%). [20] Duncan et al. showed that minor complications occurred in 2.4% of circumcisions.[21] Manji KP reported that plastibell circumcision was associated with minor, remediable complications in less than 3% of 386 young infants undergoing plastibell circumcisions between 1992 and 1998 in Tanzania.[22] However, Bliss et al. reported the occurrence of necrotizing fasciitis among two neonates after plastibell circumcisions.[23]

5.1.4. Smart Klamp

The device is classified under Regulatory Class II by US Food and Drug Administration (FDA). It received approval for marketing in United States of America, 510(k) premarket notification in 2004, because of substantial equivalence of the device to a legally marketed predicate Gomco Circumcision Clamp, Mogan Circumcision Clamp and Hollister Plastibell.[12]

5.1.5. Ismail clamp

No retrievable evidence on the safety of Ismail clamp. No retrievable evidence on approval by US FDA.

5.1.6. Tara KLamp

ECRI, a collaborating Center of the WHO, declared Tara KLamp as 'acceptable' and has been given a code which needs to be displayed on all packs of Tara KLamp. Tara KLamp circumcision device is classified under (Class I sterile) and received CE mark. It is classified under Class II by US FDA and is in the US FDA Device Listing Database but no retrievable evidence on the FDA approval.[24] Tara KLamp circumcision device are being marketed in European Union, Indonesia, Malaysia, Phillipines, China and South Afrika.[24] Schmitz et al. in his study involving 64 circumcisions of Muslim Boys using Tara KLamp performed by Medical Assistants supervised by Medical Doctors in a hall in Kuala Lumpur demonstrated that no major complications occurred and the boys generally experienced mild pain postoperatively.[25] Another study was conducted by Schmitz et al. involving 275 boys. He compared the results of circumcisions using Tara KLamp circumcision device (TCD) in a clinic with circumcisions using the conventional technique (CDT) in another clinic in Netherlands. The results showed that, there was no difference in complication rate (bleeding, 2 cases in TCD and 1 case in CDT) and infection (3 cases in TCD and 2 cases in CDT). Post operative pain was comparable in both groups.[26 level II-I.] Circumcision using Tara KLamp disposable circumcision device performed on 25 boys in Malacca Hospital demonstrated that there was minimal bleeding (a few drops) in cases of phimosis or nil in non-phimotic cases. There was also no infection.[27]

5.1.7. Sunathrone™

Sunathrone™ is registered under the Malaysian Voluntary Medical Devices Establishment Registration (MeDVER). Sunathrone™ circumcision device are being marketed in Indonesia, Malaysia, United Kingdom and Sweden. However, there was no retrievable evidence on approval by US FDA or CE mark. The result on the safety of the device was based on the raw data of 50 case series provided by the manufacturer. Circumcisions using Sunathrone™ were performed in 50 boys (3.5 to 12 years old), whereby 22 (44%) of the boys had mild to severe phimosis. Post operative complications included mild bleeding in one patient (2%) and bleeding release adhesion in another patient (2%). Two patients (4%) had infection.[28]

5.2. EFFECTIVENESS

5.2.1. Gomco clamp

Amir A, Raja MH and Niaz WA retrospectively analysed 1000 consecutive cases of neonatal circumcisions done using Gomco clamp at Armed Forces Hospital, Jubail, Saudi Arabia during the period of 1996 to 1998 and demonstrated that 99.7% parents were satisfied with the final cosmetic result. [14]

5.2.2. Mogen clamp

Study was conducted to compare pain experienced by neonates using Mogen and Gomco clamps circumcision devise by Kurtis et al. In his randomized, controlled unblinded study, involving 48 healthy full terms infants he found that the length of the procedure was associated with the type of circumcision device (mean time using Mogen = 81 seconds; mean time using Gomco = 209 seconds). Fifty six percent of infants circumcised with the Mogen clamp and dorsal penile nerve block did not cry at all during the procedure. He concluded that for a given anaesthe condition, the Mogen clamp is associated with a less painful procedure than the Gomco.[29]

Another study was performed by Taeusch et al. to compare pain experienced during circumcision using Mogen and Plastibell in 59 newborns. In this randomized, prospective but not blinded study, the authors concluded that circumcision using Mogen was associated with less pain and discomfort, took less time (20 versus 12 minutes) and was preferred by trainees when compared to Plastibell.[30 level I]

5.2.3. Plastibell

Fraser et al. in his randomized controlled trial of routine circumcision using Plastibell device compared to a dissection suturing technique, involving 100 children with a mean aged 4.7 years, found that cosmetic results were similar for both methods.[16] Duncan et al. in his study involving 205 Jamaican neonates, using Plastibell device, demonstrated that bell separation usually occurred within 10 days of the procedure and cosmetic results met with unanimous parental acceptance. [21] A follow-up study of surgery for phimosis with Plastibell among 53 boys noted that 31% experienced cosmetic complications, 21% claimed to have experienced psycho-social problems due to appearance of the penis after operation. Nonetheless, 44 patients (83%) were fully satisfied with the cosmetic result. Four patients (8%) claimed to have pain or discomfort on erection or intercourse. One patient (2%) was re-operated three years after the primary operation because of recurrence of symptoms.[31]

5.2.4. Smart Klamp

No retrievable evidence on the effectiveness of Smart KLamp

5.2.5. Ismail clamp

No retrievable evidence on the effectiveness of Ismail clamp.

5.2.6. Tara KLamp

Schmitz et al. in his study involving 64 circumcisions of Muslim Boys using Tara KLamp performed by Medical Assistants supervised by Medical Doctors in a hall in Kuala Lumpur showed that good cosmetic results were obtained in most patients and 90% of parents would recommend the new clamps to others.[25] Similarly, in another study conducted by Schmitz et al. involving 275 boys comparing the results of circumcisions using Tara KLamp circumcision device (TCD) in a clinic with circumcisions using the conventional technique (CDT) in another clinic in Netherlands, showed that the median operative duration was 8 minutes less for TCD (15 versus 7 min; $p < 0.001$). He also noted that the cosmetic results were better for the TCD group ($p < 0.001$) [26 level II-I]

Circumcision using Tara KLamp disposable circumcision device performed on 25 boys in Malacca Hospital demonstrated that some of the participants were able to do circumcision using Tara KLamp within 7 minutes compared to 30 minutes for dorsal slit.[27]

5.2.7. Sunathrone™

There was no retrievable evidence on the effectiveness of Sunathrone™. However, based on the on the raw data of 50 case series provided by the manufacturer, 49 patients (98%) had an uneventful recovery and 1 patient (2%) had acceptable recovery. [28]

5.3. COST-EFFECTIVENESS

There was no retrievable evidence on the cost-effectiveness of circumcision clamps. However, the price quoted by the manufacturer was as follows:-

i. Tara KLamp = [redacted] unit
ii. Sunathrone™ = [redacted] unit depending on the size.

6. CONCLUSION

6.1. SAFETY

There was fair level of evidence to support the safety of Gomco, Mogen, Plastibell and Tara KLamp. The evidence to support the safety of Sunathrone™ is still insufficient.

6.2. EFFECTIVENESS

There was fair level of evidence to support the effectiveness of Gomco, Mogen, Plastibell and Tara KLamp. However, more randomized controlled trials should be conducted involving larger number of subjects. Curently, there was poor quality evidence to support the effectiveness of Sunathrone™.

6.3. COST-EFFECTIVENESS

There was no retrievable evidence on the cost-effectiveness of circumcision clamps.

7. RECOMMENDATION

Based on the above review, disposable circumcision clamps such as Tara KLamp, and Sunathrone™ can be used as a research tool. More clinical research such as randomized clinical trials is warranted to provide better quality evidence.

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9. APPENDIX

9.1 Appendix 1

DESIGNATION OF LEVELS OF EVIDENCE

I Evidence obtained from at least one properly designed randomized controlled trial.

II-I Evidence obtained from well-designed controlled trials without randomization..

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

III Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

SOURCE: US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris 2001)