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MALE CIRCUMCISION

HEALTH TECHNOLOGY ASSESSMENT SECTION
MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA
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DISCLAIMER

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DISCLOSURE

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EXECUTIVE SUMMARY

Background

Conventional open surgery (forceps-guided, dorsal slit, sleeve resection, and guillotine) is the standard procedure currently used as recommended by World Health Organization (WHO). However, it is time consuming, painful, requires stitches, and its operative incision visibility lacks controllability. Furthermore, evidence suggested that practitioners must complete an average of 100 circumcisions before they are considered adequately trained to perform it safely and effectively. In recent years, there has been increased in the use of device assisted circumcision that do not require suturing. There are at least 20 identified devices which include non-disposable and disposable. Two commonly used non-disposable devices are the Gomco clamp and the Mogen clamp whereas Plastibell is the most popular disposable device. Other disposable device assisted circumcision include Alisklamp, Ismail Klamp, Tara KLamp, SmartClamp, AccuCirc, Unicirc, circular stapler, and Sunathrone. Recently, the WHO has prequalified two adult disposable devices: PrePex and Shang Ring. The emergence of such devices has been claimed to reduce operative time and complications rate, hence enhance the recovery process. In addition, less surgical skill is required, and highly cosmetic results are achieved. Circumcision using laser is relatively new and few data using this technique are available in the literature. Nevertheless, controversy exist as to whether the efficacy and safety of this new devices are superior to the conventional techniques. With more types of device being manufactured, albeit with the same mechanism, it is important to categorically compare the efficacy of device assisted circumcision with the conventional techniques. To date there is no guideline that defines which technique is safer to be implemented as a standard of care. Hence, there is a need to further evaluate and compare these techniques with respect to its benefits and harms. This technology review was conducted following a request from the Director of Medical Development Division, Ministry of Health Malaysia to provide evidence as an input for the development of a guideline to ensure male circumcision (MC) practice in Malaysia is safe and conforms to acceptable standards for the benefits of the public.

Objective/aim

The objective of this technology review was to assess the effectiveness, safety and cost-effectiveness of different circumcision techniques for male circumcision.

Results and conclusions

The search strategies yielded 262 articles through the Ovid interface and PubMed. This systematic review included 13 articles related to the effectiveness and safety of male circumcision whereas four on the economic evaluations. Articles consists of two systematic review and meta-analysis, six randomised controlled trials (RCTs), four non-RCTs, one cohort study, and four cost-analysis. The studies were conducted in United States, Turkey, South Africa, Zimbabwe, Zambia, Mozambique, Uganda, Rwanda, Iran, China, India, and Singapore.

(1) Effectiveness:

Device assisted circumcision (non-disposable) versus conventional
There was good level of retrievable evidence to suggest that:

a. Intraoperative time was less with the Gomco clamp compared with dorsal slit technique ($p<0.001$).
b. Pain scores were low and there was less pain in the Gomco clamp as compared with dorsal slit technique ($p=0.008$).
c. The cosmetic result was superior in the Gomco clamp when compared with dorsal slit technique.

Device assisted circumcision (disposable) versus conventional
There was limited good level of retrievable evidence to suggest that:

a. Shang Ring and circular stapler were associated with shorter operative time, lower pain scores, shorter wound healing time, and excellent penile cosmetic appearance relative to dorsal slit or sleeve resection technique. PrePex, Plastibell, and SmartClamp also tends to have short surgery time while Unicirc resulted in less pain and shorter wound healing time.
b. Compared with dorsal slit, Plastibell required greater use of analgesics ($p<0.0001$).
c. No significant differences were encountered in cosmetic displeasure ($p=0.109$) for SmartClamp as compared with sleeve resection technique.
d. Less favourable outcomes were associated with Tara KLamp as compared with forceps-guided method including higher pain score ($p=0.003$), delayed wound healing ($p=0.004$), and problems with penis appearance ($p=0.001$).

Laser circumcision versus conventional
There was limited fair to good level of retrievable evidence to suggest that:

a. Laser circumcision technique was associated with a decrease in operative time ($p<0.05$) and less postoperative pain ($p<0.05$) as compared with dorsal slit and guillotine techniques.
b. Follow-up visit demonstrated excellent cosmetic result both for laser and conventional techniques.

(2) Safety:

Device assisted circumcision (non-disposable) versus conventional
There was good level of retrievable evidence to suggest that:

a. There was no significant difference between Gomco clamp and dorsal slit in terms of bleeding, haematoma or infection.
b. Wound disruption was greater in Gomco clamp at one week ($p=0.04$) and two weeks ($p<0.001$) compared with dorsal slit.

Device assisted circumcision (disposable) versus conventional

There was good level of retrievable evidence to suggest that:

a. A lower AE rates was observed in the Shang Ring group in comparison with the conventional group ($p<0.001$).
b. Bleeding was the only complication which occurred in sleeve resection technique while in Plastibell, delayed separation of ring was the most common complication followed by bleeding, excess mucosa, infection, disposition, and haematoma.
c. SmartClamp device seemed to carry the disadvantages of longer mucosal length ($p<0.001$) and penile oedema ($p=0.039$) compared to sleeve resection technique.
d. Participants circumcised with the Tara KLamp were significantly more likely to report bleeding, lesions to the penis, infection, swelling, haematoma, and problems with urinating ($p<0.001$) as compared with forceps-guided method.
e. Circumcision using circular stapler device was associated with less complications (haematoma, incision bleeding, infection) compared with sleeve resection approach.

Laser circumcision versus conventional

There was limited fair to good level of retrievable evidence to suggest that:

a. The overall incidence of postoperative complications (bleeding, infection, and oedema) was less in the laser group compared with dorsal slit ($p<0.05$).
b. There were no significant difference in the rate of haematoma, wound dehiscence, and haemorrhage between the laser group and guillotine technique ($p>0.5$).

(3) Psychological/social/ethical:

Device assisted circumcision (disposable) versus conventional

There was fair to good level of retrievable evidence to suggest that:

a. Parents whose children was circumcised using Plastibell were significantly more concerned about swelling and satisfied with the aesthetic results compared with parents whose children was circumcised using dorsal slit technique.
b. Parental anxiety in the SmartClamp group was statistically higher than sleeve resection group ($p<0.001$).
c. Similarly, more patients were fully satisfied with the cosmetic penis appearances when using circular stapler device compared to sleeve resection technique ($p=0000$).

Laser circumcision versus conventional

There was limited fair to good level of retrievable evidence to suggest that parents of the patients in laser and guillotine group were satisfied with the aesthetic results.

(4) Organization:

Conventional technique

There was fair to good level of retrievable evidence to suggest that:

a. There were no overall difference in operative duration between physicians and clinical officers, but physicians required less time to perform the sleeve procedure. This shorter operative duration by physicians, however, was less marked and was inconstant for the dorsal slit procedure.
b. A total of 20 circumcision procedures (sleeve resection or dorsal slit) as an increase in surgical experience of the provider reduced operative duration by 1.5 minutes ($p<0.001$).

Device assisted circumcision (non-disposable versus disposable)

There was fair to good level of retrievable evidence to suggest that:

a. The mean number of procedures to competency was 10.3 (SD=63.3) for Gomco clamp, 10.3 (SD=63.7) for Plastibell, and 8.9 (SD=62.9) for the Mogen clamp. All providers were competent in each circumcision method by 15 procedures.
b. In general, nurses took longer to train than the other providers, but this was not statistically significant.

(5) Economic: cost-analysis

There was evidence to suggest that:

a. Total cost savings per circumcision done by laser was S$31.00 compared with those done by the conventional guillotine method in Singapore.
b. The direct cost of one circumcision using dorsal slit was US$17.67 while the cost was US$18.21 using the Shang Ring in a scale-up voluntary medical male circumcision programme in Zambia.
c. A meaningful cost-savings can be achieved in Rwanda with nonsurgical male circumcision performed by nurses using the PrePex device (US$35.50) in place of dorsal slit surgical performed by physicians (US$53.50).
d. Early infant male circumcision scale-up in Zimbabwe has a lower unit cost when using AccuCirc (US$49.53) compared with Mogen clamp (US$55.93).

Methods

Electronic databases were searched through the Ovid interface: Ovid MEDLINE® In-process and other Non-indexed citations and Ovid MEDLINE® 1946 to present, EBM Reviews - Cochrane Central Register of Controlled Trials - November 2016, EBM Reviews - Cochrane Database of Systematic Reviews - 2005 to January 2017, EBM Reviews - Health Technology Assessment – 4th Quarter 2016, EBM Reviews - Database of Abstracts of Reviews of Effects – 1st Quarter 2016, EBM Reviews – NHS Economic Evaluation Database 1st Quarter 2016. Searches were also run in PubMed. Google was used to search for additional web-based materials and information. No limits were applied. Additional articles were identified from reviewing the references of retrieved articles. Last search was conducted on 16th January 2017.

MALE CIRCUMCISION

1.0 BACKGROUND

The circumcision of males is arguably the oldest and the most commonly performed surgical procedure in history. Circumcision is the removal of some or the entire prepuce (foreskin) from the penis. It has been practiced since antiquity. The first record of male circumcision (MC) dates from the Sixth Dynasty of the Egyptian pharaohs, around 2420 BC.[1]

In 2007, the World Health Organization (WHO) estimated that globally one-third of males aged 15 years and over is circumcised, with almost 70% of those being Muslims. Male circumcision is nearly universal in the Muslim world and in Israel due to the religious requirements of the majority of Muslims and Jews. It is prevalent in some Islamic countries in South East Asia such as Indonesia and Malaysia; however, the WHO states that there is little non-religious circumcision in Asia, with the exceptions of the Republic of Korea and the Philippines.[2-3] In parts of Africa it is often practiced as part of tribal or religious customs. The prevalence of circumcision is also high in the United States, although there has reportedly been a decrease in routine neonatal circumcision in recent years. In contrast, it is relatively rare in most of Europe, parts of southern Africa, most of Asia, Oceania and Latin America, constituting South America, Central America, the Caribbean and Mexico.[4] Australia, Canada, Ireland, New Zealand and the United Kingdom are examples of countries that have seen a significant decline in MC in recent decades, while there have been indications of increasing demand in southern Africa, partly for preventative reasons due to the human immunodeficiency virus (HIV) epidemic there.[5]

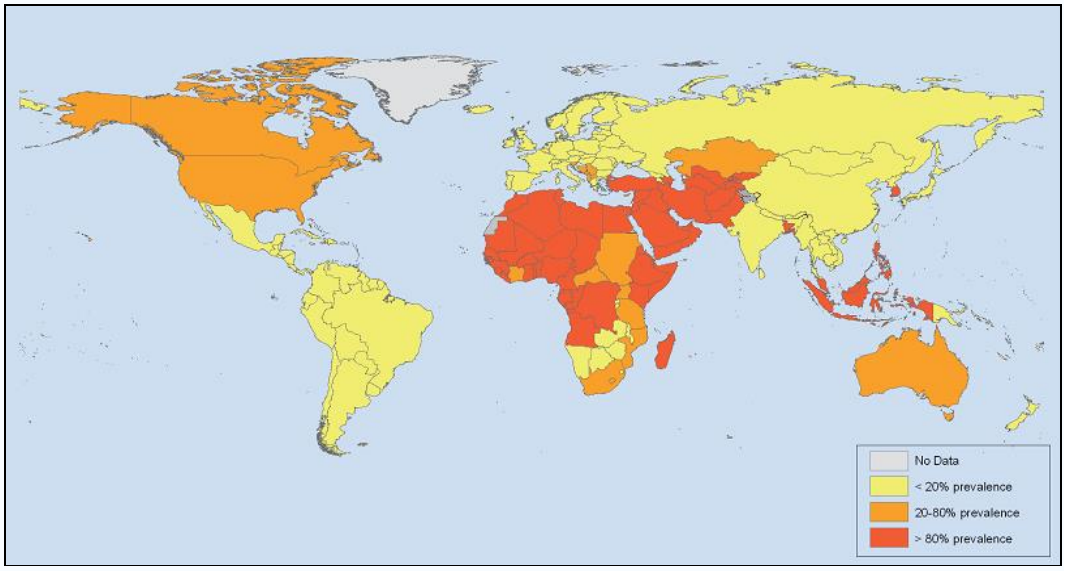


Figure 1: Global prevalence of male circumcision

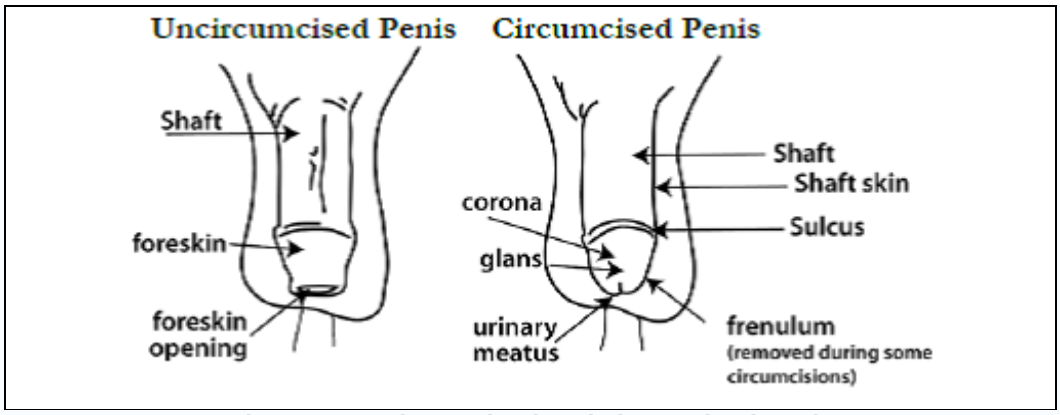


Figure 2: Uncircumcised and circumcised penis

While religious and cultural considerations are a major reason behind the practice, a growing volume of research attests to the significant medical and public health benefits of MC. Circumcision has been demonstrated to reduce various sexually transmitted infections, such as HIV, human papillomavirus (HPV), and herpes simplex virus type 2.[6-9] Moreover, it is associated with the prevention of urinary tract infections, penile cancer, prostate cancer, and cervical cancer of female partners.[10-14] In Western societies, circumcision is mostly performed for medical reasons, the most common of which is phimosis (a stricture of the foreskin that narrows the opening and prevents it from being retracted to uncover the glans).[15-17] Other medical indications are paraphimosis (in which the foreskin is trapped behind the corona and forms a tight band of constricting tissue, causing swelling of the glans and foreskin), balanitis (inflammation of the foreskin), posthitis (inflammation of the glans), localized condylomata acuminata, and localized carcinoma.[17-19]

In light of the protection that MC affords against HIV infection in particular[20], major health bodies such as WHO, the Joint United Nations Program on HIV/AIDS (UNAIDS), and the US Centers for Disease Control and Prevention (CDC) have endorsed and currently promote voluntary medical male circumcision (VMMC) in HIV-1 epidemic settings in which the major route of HIV transmission is through heterosexual intercourse[21-22]. In sub-Saharan African countries, 13 were prioritized by WHO and UNAIDS for VMMC for HIV prevention in 2007, with Ethiopia's Gambella province, the Central African Republic, and South Sudan added subsequently[23]. Implementation is well underway in the original 13 countries, with over 10 million VMMC performed since 2009.[24]

The principals of circumcision are asepsis, adequate excision of outer and inner preputial skin layers, proper haemostasis, protection of glans and urethra, and cosmesis. Circumcision may be complete or partial. Complete circumcision may be performed in the newborn period by using the Gomco clamp or Mogen clamp, and the PlastiBell. After the newborn period, surgical circumcision is recommended. General surgical guidelines

include complete sterile dissection, complete separation of the glanular adhesions, and exclusion of hypospadias.[16,18] For adult males, conventional open surgery or dissection-based circumcision is recommended by WHO as the standard procedure. The forceps-guided, dorsal slit, sleeve resection, and guillotine are the commonly used and remain predominant open method of circumcision. However, conventional circumcision (CC) has some limitations: it is time consuming, painful, requires stitches, and its operative incision visibility lacks controllability.[25-26] In addition, adequate training (an average of 100 circumcisions) is required for practitioners to perform CC safely and effectively.[27]

Recently, a substantial new device assisted such as disposable clamps have been introduced for circumcision. It is claimed to reduce complications, bleeding, surgical time, enhance the recovery process, and improve cosmetic appearance.[28] Several proprietary devices have been designed to improve MC surgery.[29] Circumcision using laser on the other hand is relatively new and there is very few data using this technique available in the literature.[30-31] In Malaysia, besides all the techniques mentioned, traditional method of circumcision is still commonly practiced. It is performed by a traditional healer who practices the art of circumcision and is popularly known as "*Tok Mudim*". However, there is no data on prevalence or trends of circumcision available in Malaysia or the methods adopted by the "*Tok Mudim*".[32]

Despite growing evidence regarding the benefits of currently available device assisted circumcision, there is a continuing need to improve the safety of the circumcision procedure. Therefore, an effective, safe, and inexpensive method or technique of circumcision would assist to ease any burden. With more types of devices being manufactured, albeit with the same mechanism, it is important to categorically compare the efficacy of device assisted circumcision with the conventional technique. To date there is no guideline that defines which technique is safer to implement as a standard of care. Hence, there is a need for further evaluation and comparison of these techniques with respect to its benefits and harms.

This technology review was conducted following a request from the Director of Medical Development Division, Ministry of Health Malaysia to provide evidence as an input for the development of a guideline to ensure male circumcision (MC) practice in Malaysia is safe and conforms to acceptable standards for the benefits of the public.

2.0 OBJECTIVE/AIM

The objective of this technology review was to assess the effectiveness, safety and cost-effectiveness of different circumcision technique for male circumcision.

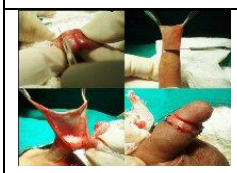
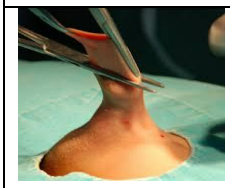
3.0 TECHNICAL FEATURES

There are several methods of MC and each of the methods has its merits and demerits. The basic principle in circumcision is to ensure that safety and morbidity should be kept to the minimum, no matter what technique is employed. [33] Circumcision methods can be classified into one of three types or combinations: dorsal slit, shield and clamp, and excision. Many of the methods in use today fall in to one of these major classes. Shield and clamp adopts the use of device to effect circumcision obviating the use of knife in majority of cases. Both conventional and device are commonly used depending on institution and surgeon preference.[16, 18]

3.1 Conventional open surgery/dissection-based circumcision

Conventional MC as recommended by the WHO includes forceps-guided, dorsal slit, sleeve resection, and guillotine. A summary of these techniques is shown in Table 1.[34]

Table 1: Conventional open surgery/dissection-based circumcision

	**Forceps-guided** The foreskin was pulled through a pair of bone cutters, which (usually) protected the glans, and the exposed foreskin cut along the clamp's edge.
	**Dorsal slit** ▪ Involves the crushing and division of the two layers of the prepucial dorsum to enable the operator to free the prepuce circumferentially down to the corona. The slit is then extended to the corona and the prepuce is excised under direct vision, leaving a 2–3 mm skirt of prepucial rim. ▪ Can be performed in any hospital or clinic equipped with standard surgical instruments. ▪ Requires more surgical skill than other methods.
	**Sleeve resection** Performed by excising each of the two layers of the prepuce under direct vision, starting with the outer layer to allow effective haemostasis as the bleeding vessels are ligated.
	**Guillotine** Entails a circumferential release of the adherent prepuce, which is then pulled taut over the glans. The penis is retracted as far as possible, and a bone cutter or strong pair of artery forceps applied to crush the prepuce distal to the retracted glans penis for up to 10 minutes before the skin distal to the crush is trimmed off. It is a blind procedure.

3.2 Device assisted circumcision (non-disposable and disposable)

The basis of device assisted circumcision (irrespective of the individual type of device) is crushing of the foreskin at the proposed tissue apposition line and simultaneously obtaining haemostasis. The foreskin is then excised or allowed to slough off by ischaemic necrosis. The crushed apposed edges can then be sutured reinforced, glued or are sometimes left alone.[35]

There are at least 20 identified devices for MC.[36-37] Two commonly used non-disposable devices are Gomco clamp and Mogen clamp whereas Plastibell™ is the most popular disposable device. [21] Recently, the WHO has prequalified two adult devices: PrePex™ and Shang Ring. Device assisted circumcision can be further classified as ligature devices (i.e. they allow the foreskin to slough off by ischaemic necrosis with no suturing apposition needed) or crush devices (i.e. they provide crushing haemostasis and simultaneous apposition, foreskin is excised and edges are suture reinforced).[37]

All the device assisted circumcision has been previously described. [38] Briefly, a summary of the two most common non-disposable devices is shown in Table 2, whereas some of disposable devices for use in both paediatric and adults circumcision is shown in Table 3.[39-40]

Table 2: Summary of the non-disposable device assisted circumcision

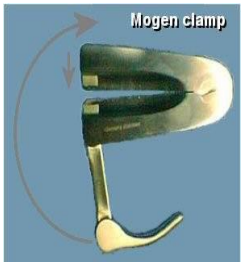
Devices	Advantages	Disadvantages	Comment
Gomco clamp 	Simple technique; can be performed with EMLA anaesthesia. Produces a circular crushed welded edge that does not need suturing.	Needs to have a set of Gomco clamps with different bell sizes. Multipart device, with risk that parts will be lost or damaged. Parts not readily interchangeable between different clamp sets.	Although suturing is not usually needed, it may be on occasion, thus surgical skills must be available in clinics where these devices are used.
Mogen clamp 	Technique using one piece instrument, which is simple to use; simple to teach. Produces a crushed welded edge, which does not need suturing.	Risk of partial amputation of glans if device is not applied carefully. Risk of glans being buried by cross-adhesions.	

Table 3: Summary of disposable device assisted circumcision

Device		Country of origin	Ages	Duration of clamp for haemostasis
Plastibell		USA	Infant to adult	4 to 7 days
AccuCirc		USA	Infant	-
Alisklamp		Turkey	Infant to adult	Several days
Circular stapler		China	Adult	8 to 10 days
Ismail clamp		Malaysia	Infant to adult	5 to 10 days
PrePex		USA	Infant to adult	5 to 10 days
Shang Ring		China	Five years to adult	7 days
SmartClamp		Netherlands	Infant to adult	5 days
Sunathrone		Malaysia	Infant to adult	8 to 12 days
Tara KLamp		Malaysia	Infant to adult	5 days
Unicirc		South Africa	Children to adult	-

3.3 Laser circumcision

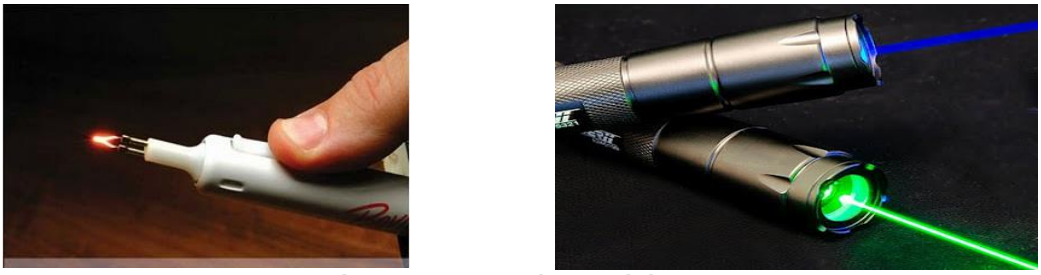


Figure 3: Laser circumcision

Carbon dioxide (CO_2) and neodymium:yttrium aluminium garnet (Nd:YAG) lasers have been frequently used as first-line therapy for MC with reasonable response rates, good cosmetic and functional results. This laser beam cuts and controls bleeding through the skin that result in the

highly tidy wound. It is the technique which allows the exact proportions of the skin as well as the membrane of the mucous to get removed. Moreover, laser circumcision is basically the technique of option for the children circumcision and it can even get applied to the adult patients as well. In the laser circumcision, some of the stitches are placed at end of the surgery and it helps to bring edges of wound to be together. Such sutures will also dissolve in about 7-10 days.[31, 41-42]

4.0 METHODS

4.1. Searching

Electronic databases searched through the Ovid interface:

- MEDLINE(R) In-Process and Other Non-Indexed Citations and Ovid MEDLINE (R) 1946 to present
- EBM Reviews – Cochrane Central Registered of Controlled Trials – November 2016
- EBM Reviews – Database of Abstracts of Review of Effects – 1st Quarter 2016
- EBM Reviews – Cochrane Database of Systematic Reviews – 2005 to January 2017
- EBM Reviews – Health Technology Assessment – 4th Quarter 2016
- EBM Reviews - NHS Economic Evaluation Database – 1st Quarter 2016

Other databases:

- PubMed
- Horizon Scanning database (National Horizon Scanning Centre, Australia and New Zealand Horizon Scanning Network, National Horizon Scanning Birmingham)
- Other websites: US FDA, INAHTA, MHRA

General databases such as Google and Yahoo were used to search for additional web-based materials and information. Additional articles retrieved from reviewing the references of retrieved articles. The search was limited to articles on human. There was no language limitation in the search. Appendix 1 showed the detailed search strategies. The last search was conducted on 16th January 2017.

4.2. Selection

A reviewer screened the titles and abstracts against the inclusion and exclusion criteria and then evaluated the selected full-text articles for final article selection. The inclusion and exclusion criteria were:

Inclusion criteria:

Population	Male of any ages; neonates, newborns, infants, children, adolescents, adults
Interventions	a. Device assisted circumcision: - Non-disposable such as Gomco clamp and Mogen clamp - Disposable such as Plastibell, AccuCirc, Alisklamp, circular stapler, Ismail Klamp, PrePex, Shang Ring, Tara KLamp, SmartClamp, Sunathrone, Unicirc b. Laser circumcision
Comparators	Conventional open surgery, dissection-based circumcision, any recognized dissection technique: forcep-guided, dorsal slit, sleeve resection, guillotine
Outcomes	a. Efficacy/effectiveness: operative time, wound healing, pain, cosmetic appearance b. Safety: adverse events/complications such as bleeding/blood loss, haematoma, infection, swelling, adhesion, disruption, dehiscence, oedema, dysuria, lesions, scars c. Psychological/social/ethical: stress, trauma, anxiety, preference, acceptance, simplify technique, satisfaction d. Organizational: training e. Economic: cost-effectiveness
Study design	Systematic review (SR), randomised controlled trial (RCT), cross-sectional study, cohort study, case control study, case series
	English, full text articles

Exclusion criteria:

Study design	Case report, survey, anecdotal, animal studies
	Non-English full text articles

Relevant articles were critically appraised using Critical Appraisal Skills Programme (CASP) checklist and evidence graded according to the US/Canadian Preventive Services Task Force (Appendix 2). Data were extracted from included studies using a pre-designed data extraction form (evidence table as shown in Appendix 3) and presented in tabulated format with narrative summaries. No meta-analysis was conducted for this review.

5.0 RESULTS AND DISCUSSION

The search strategies yielded 262 articles through the Ovid interface and PubMed. This systematic review included 13 articles related to the effectiveness and safety of male circumcision whereas four on the economic evaluations. Articles consists of two systematic review and meta-analysis, six randomised controlled trials (RCTs), four non-RCTs, one cohort study, and four cost-analysis. The studies were conducted in United States, Turkey, South Africa, Zimbabwe, Zambia, Mozambique, Uganda, Rwanda, Iran, China, India, and Singapore.

Risk of bias

One of the tools that are being used by MaHTAS to assess the risk of bias is the CASP checklist which consists of eight critical appraisal tools designed for SR, RCT, cohort studies, case control studies, economic evaluations, diagnostic studies, qualitative studies, and clinical prediction rule. This is achieved by answering a pre-specified question of those criteria assessed and assigning a judgement relating to the risk of bias as either:

+	Indicates YES (low risk of bias)
?	indicates UNKNOWN risk of bias
-	Indicates NO (high risk of bias)

The assessment of risk of bias revealed that the two SR are considered to have low risk of bias, similar with the non-RCT and cohort study. However, there was no blinding in five of the RCT whereas most of the economic evaluation studies did not mentioned about discounting and sensitivity analysis.

The results of risk of bias of included studies are summarised in Table 4-8

Table 4: Assessment of risk of bias of SR (CASP)

Criteria assessed	Authors look for the right type of papers?	Selection of studies (all relevant studies included?)	Assessment of quality of included studies?	If the results of the review have been combined, is it reasonable to do so (heterogeneity)?
Cao D et al.[26]	+	+	+	+
Fan Y et al.[44]	+	+	+	+

Table 5: Assessment of risk of bias of RCT (CASP)

Criteria assessed	Adequate sequence generation	Allocation concealment	Blinding of participants and personnel	Incomplete outcome data addressed	Free of selective reporting	Free of other bias
Millard P et al.[43]	+	+	-	+	+	+
Nagdeve N et al.[45]	+	+	-	+	+	+
Lagarde E et al.[47]	+	+	-	+	+	+
Wang J et al.[48]	+	+	-	+	+	+
Mousavi SA et al.[50]	+	?	?	+	+	+
Xu Y et al.[51]	+	+	+	+	+	+

Table 6: Assessment of risk of bias of quasi experimental studies (non-RCT) (JBI)

Criteria assessed	Karadag M et al.[46]	Zhang Z et al.[49]	Gorgulu T et al.[52]	Bowa K et al.[54]
Clear what is the cause and what is the effect?	+	+	+	+
Participants included in any comparisons similar?	+	+	+	+
Participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?	+	+	+	+
Was there a control group?	+	+	+	-
Multiple measurements of outcome pre and post the intervention/ exposure?	?	?	?	?
Follow-up complete, and if not was follow-up adequately reported and strategies to deal with the loss to follow-up employed?	+	+	+	+
Outcomes of participants included in any comparisons measured in the same way?	+	+	+	+
Outcome measure in reliable way?	+	+	+	+
Appropriate statistical analysis used?	+	+	+	+

Table 7: Assessment of risk of bias of cohort (CASP)

Criteria assessed	Selection of cohort	Exposure accurately measured	Outcome accurately measured	Confounding factors	Follow-up of subjects
Buwembo D et al.[53]	+	?	-	+	?

Table 8: Assessment of risk of bias of economic evaluation (CASP)

Criteria assessed	How AC et al.[55]	Bratt J et al.[56]	Mutabazi V et al.[57]	Mangenah C et al.[58]
A well-define question posed?	+	+	+	+
Comprehensive description of competing alternative given?	+	+	+	+
Effectiveness established?	+	+	+	+
Effects of intervention identified, measured and valued appropriately?	+	+	+	+
All important and relevant resources required and health outcome costs for each alternative identified, measured in appropriate units and valued credibly?	+	+	+	+
Costs and consequences adjusted for different times at which they occurred (discounting)?	-	-	-	-
Results of the evaluation?	+	+	+	+
Incremental analysis of the consequences and costs of alternatives performed?	-	+	+	+
Sensitivity analysis performed?	-	-	-	+

5.1 Effectiveness

5.1.1 Device assisted circumcision (non-disposable) versus conventional

Millard PS et al. 2013 compared a minimally invasive technique using the Gomco circumcision clamp plus tissue adhesive with conventional open surgical circumcision with suturing (dorsal slit) in 200 healthy uncircumcised men (>18 years). This was a single-centre non-blinded RCT with allocation in balanced blocks of 10 using a random number table. The primary outcome was intraoperative time while secondary outcomes included ease of performance, AEs, post-operative pain, time to healing, patient satisfaction, and cosmetic result. A 10-point visual analogue scale was used for pain evaluation in the first 48 hours after circumcision and a 5-point Likert scale to grade satisfaction. Follow-up examination occurred at two days, seven days, two weeks, and four weeks. The study demonstrated that intraoperative time were less with the Gomco plus tissue adhesive technique (mean 12.8 minutes versus 22.5 minutes; $p<0.001$). Pain scores were low and there was less pain in the Gomco group during the first 48 hours (1.8 versus 2.5 on a 10-point scale; $p=0.008$). There were no differences in healing at four weeks or in patient satisfaction. The cosmetic result was superior in the Gomco group, a regular scar line developing in 98.9% versus 58.5% ($p<0.001$) of patients. The authors concluded that removal of the foreskin with the Gomco instrument and sealing the wound with tissue adhesive required much less operative time, was easier to perform, and had much better cosmetic results over traditional open surgical circumcision.[43, level I]

5.1.2 Device assisted circumcision (disposable) versus conventional

Cao D et al. 2015 conducted a systematic review and meta-analysis to compare the efficacy and safety of Shang Ring circumcision (SRC) with conventional circumcision (CC) for male patients. A systematic literature search using the MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, and Google Scholar databases were performed. All the selected trials were RCTs. Study selection was based on Preferred Reporting Items for Systematic Reviews and Meta-analysis criteria (PRISMA). Two reviewers independently evaluated study quality using the Jadad scale score. The following outcome measures were defined from the included studies: operative time, intraoperative pain score, penile appearance (PA)/cosmetic results, wound healing time, blood loss, and adverse event rate (AER). Statistical analysis of dichotomous variables (PA, AER, wound bleeding rate, wound oedema rate, wound infection rate, and wound dehiscence rate) was performed using the risk ratio (RR) as the summary analysis, whereas continuous variables (operative time, intraoperative pain score, wound healing time, and blood loss) were analysed using the mean difference (MD); accompanying 95% confidence

intervals (CIs) and p values were reported. For these results, p<0.05 was considered statistically significant. The Mantel-Haenszel chi-square test for heterogeneity was conducted. Heterogeneity was assessed using the I^2 statistic: I^2 values ≤50% were defined as acceptable, whereas those >50% indicated high levels of heterogeneity. When there was a lack of heterogeneity, a fixed-effects model was applied. Otherwise, a random-effects model was applied when heterogeneity was >50%. Overall, there were 3,314 male patients in the eight study trials; 1,815 who received SRC and 1,499 who received CC. Although these RCTs were inadequate in allocation concealment and blinding because of ethical issues and properties of surgery studies, quality assessment revealed that the included studies were of high quality. The comparison outcomes between SRC group and CC group are summarized in Table 9.[26, level I]

Table 9: Comparison of outcomes between SRC and CC group

		SRC/CC						
					Heterogeneity			
Outcomes	No. of Studies	No. of Patients	*P* Value	MD or RR (95% CI)	Chi-square	df	*P* Value	I^2 (%)
Operative time	7	1749/1427	<.001	−17.44 (−21.61 to −13.27)	1251.25	6	<.001	100
Intraoperative pain score	4	1403/1110	<.001	−3.13 (−3.79 to −2.47)	100.21	3	<.001	97
Penile appearance satisfaction rate	5	1458/1263	.007	1.29 (1.07 to 1.56)	128.67	4	<.001	97
Wound healing time	4	1392/1191	.14	2.55 (−0.80 to 5.91)	282.33	3	<.001	99
Intraoperative blood loss	6	1552/1226	<.001	−8.09 (−10.70 to −5.48)	904.72	5	<.001	99
Adverse event rate	3	756/504	<.001	0.54 (0.39 to 0.74)	2.95	2	.23	32
Wound bleeding rate	6	1541/1307	<.001	0.06 (0.02 to 0.14)	3.56	5	.61	0
Wound edema rate	7	1749/1427	.75	0.92 (0.55 to 1.53)	33.25	6	<.001	82
Wound infection rate	7	1607/1379	.26	0.43 (0.10 to 1.83)	42.76	6	<.001	86
Wound dehiscence rate	7	1749/1427	.96	1.01 (0.66 to 1.55)	1.59	6	.95	0

Operative time (minutes):

In the meta-analysis of the seven studies (n=3,176) using the random-effects model, the pooled estimates showed that there was a statistically significant difference between the two groups (MD, -17.44; 95% CI: -21.61, -13.27; p<0.001), with the SRC group showing a markedly shorter operative time relative to the CC group.[26, level I]

Intraoperative pain score:

In the pooled estimates (four studies, n=2,513), using a random-effects model, a statistically significant difference was observed in favour of the SRC group, which showed significantly lower intraoperative pain scores in comparison with the CC group (MD, -3.13; 95% CI: -3.79, -2.47; p<0.001).[26, level I]

Penile appearance:

Participant satisfaction rate was measured in five studies (n=2,721). A random-effects model was used in the pooled analysis. The data from meta-analysis demonstrated that patients in the SRC group reported higher satisfaction with PA compared with patients in the CC group (RR, 1.29; 95% CI: 1.07, 1.56; p=0.007).[26, level I]

Wound healing time (days):
Data on wound healing time were extracted for forest plot analysis from four studies (n=2,583). There was no significant difference in wound healing time between the SRC and CC groups (MD, 2.55; 95% CI: -0.80, 5.91; p=0.14).[26, level I]

Limitation:
Heterogeneity may have resulted from a number of factors, including: (1) differences in operator skill level and proficiency, as well as follow-up periods, (2) objective differences among patients such as visual analogue scale scores and satisfaction rates for PA, and (3) subjective assessment of bleeding volume and wound healing time by the surgeon. In addition, insufficient or unclear allocation concealment and blinding might increase heterogeneity. Furthermore, insufficient data of the included studies may introduce bias into the analysis, especially with regard to wound healing time.[26, level I]

Author conclusion:
Shang Ring circumcision was associated with shorter operative time, lower intraoperative pain score, and higher satisfaction with PA relative to CC. Thus, it seems that SRC is a more effective choice than CC for conducting MC.[26, level I]

More recently, Fan Y et al. 2016 conducted a systematic review and meta-analysis to assess the efficacy and safety of in situ device (ISD) and circular disposable device (CDD), and to evaluate the characteristics of these devices for optimizing MC. A systematic literature search of PubMed, Embase, and the Cochrane Library databases (the Cochrane Central Register of Controlled Trials and the Cochrane database of Systematic Reviews) of Ovid was done for RCTs that reported using disposable devices to complete adult MCs. The methodological quality of each selected trial was assessed according to the Cochrane Collaboration Risk of Bias Tool in Review Manager 5.3. Men were divided into different groups according to the principle of the operation, irrespective of the brand names of devices used. Shang Ring and PrePex were classified as ISD; circular stapler and Unicirc were classified as CDD; and all non-device MCs were classified as CC (e.g., sleeve resection and dorsal slit). The comparisons were between at least two of ISD, CDD, and CC. The outcomes measured in this review included the following: intraoperative blood loss (IB), operative time (OT), mean pain score on the operation day (PO), mean pain score of postoperative days (PP), overall incidence of complication (COM), wound healing time (WHT), satisfaction rate (SR), incidence of wound adverse event (WAE), incidence of wound bleeding (WB), incidence of wound dehiscence (WD), incidence of wound edema (WE), incidence of wound infection (WI), and overall expenditure (cost). Meta-analysis was processed in Stata 13.0.[44, level I]

Description of studies:

These trials were conducted in China and some countries in Africa. The methodological quality of RCTs was moderate due to inadequacies in allocation concealment and blinding because of ethical issues and properties of the surgical studies (Figure 4). Ten RCTs involving 4,649 men were identified and included in the meta-analysis. Five studies compared CDD versus CC, six compared ISD versus CC, and one compared CDD versus ISD directly. However, the numbers of comparisons were variable and less than ten in each of the analysed outcomes - considered the publication bias in each comparison.[44, level I]

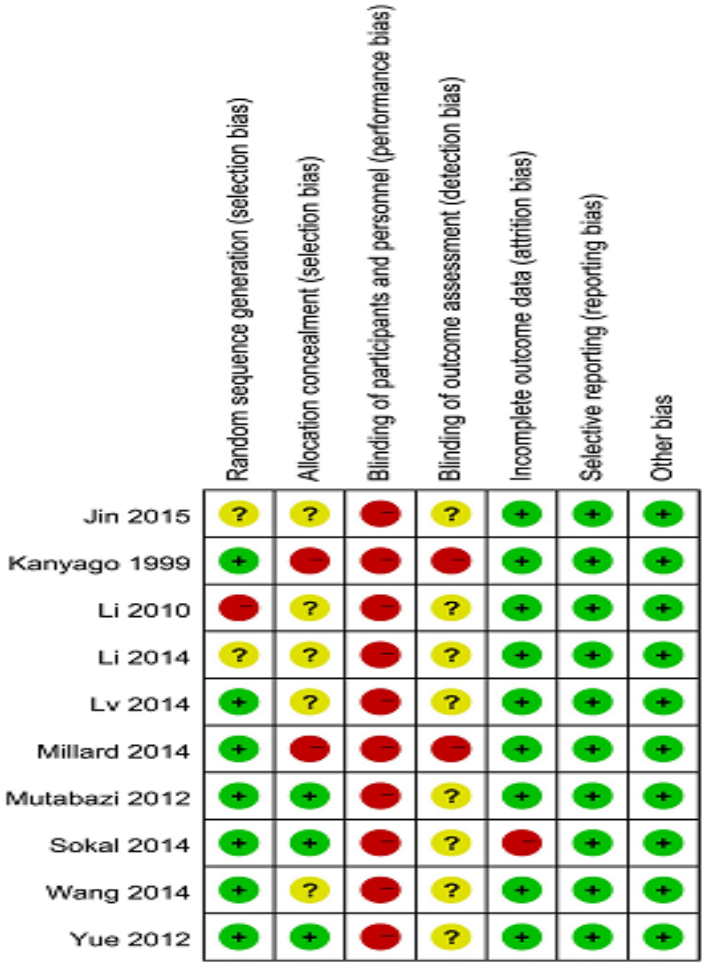


Figure 4: Risk of bias summary of included studies: (+) Low risk of bias; (-) High risk of bias; (?) Unclear risk of bias

Comparisons between CDD and CC:
Five studies involving 2,026 men were included in the meta-analysis (Table 10). The statistically significant outcomes were IB, OT, PO, PP, and WHT. Circular disposable device showed less IB [standard mean difference (SMD): −3.12 (−4.32, −1.92)], less OT [SMD: −4.33 (−6.43, −2.23)], less PO [SMD: −1.51 (−2.55, −0.46)], less PP [SMD: −1.38 (−2.28, −0.48)], and less WHT [SMD: −0.88 (−1.18, −0.58)] compared with CC.[44, level I]

Comparisons between ISD and CC:
Five studies involving 2,937 men were included in the meta-analysis (Table 10). The statistically significant outcomes were IB, OT, SR, WB, and WE. In situ device showed less IB [SMD: −3.25 (−3.65, −2.85)], less OT [SMD: −5.72 (−7.11, −4.33)], a higher SR [risk ratios (RR): 1.17 (1.02, 1.35)], less WB [RR: 0.16 (0.03, 0.76)] and WE [RR: 0.69 (0.53, 0.88)] compared with CC.[44, level I]

Comparisons between CDD and ISD:
Only one study involving 628 men was included in the meta-analysis (Table 10). The statistically significant outcomes were observed for IB, OT, PO, PP, SR, WAE, WB, WE, WHT, and WI. Circular disposable device showed more IB [SMD: 0.33 (0.17, 0.48)], more OT [SMD: 0.48 (0.32, 0.63)], less PO [SMD: −2.23 (−2.43, −2.03)], less PP [SMD: −2.39 (−2.59, −2.18)], a higher SR [RR: 1.57 (1.39, 1.78)], less WAE [RR: 0.30 (0.20, 0.45)], more WB [RR: 21.0 (1.24, 357)], less WE [RR: 0.10 (0.05, 0.24)], less WHT [SMD: −0.74 (−0.90, −0.58)], and less WI [RR: 0.04 (0.002, 0.62)] compared with ISD.[44, level I]

Limitation:
The authors failed to contact missing data and had a limited number of studies (10 RCTs), and only one comparison between CDD and ISD implies the possibility of a publication bias. Some of the outcomes measured in this meta-analysis were only based on two studies. Studies often report their outcomes in different ways, such as follow-up periods, pain score, and definition of complications. Therefore, all of the results from this meta-analysis should be considered with caution.[44, level I]

Author conclusion:
The clinical performance of disposable devices used in adult MC exceeded that of CC. Circular disposable device (CDD) circumcision tends to have the best wound healing condition and the least pain experience. In situ device (ISD) circumcision tends to have the lowest operative time, least intraoperative blood loss, least incidence of wound bleeding, and highest satisfaction rate. Each device has its own advantages and these should be discussed with men prior to their circumcision.[44, level I]

Table 10: Outcomes of meta-analysis *p<0.05, RR: relative risk, SMD: standard mean difference, CI: confident intervals

Comparisons	Outcomes	No. of comparisons	RR&SMD	2.5%CI	97.5%CI
CDD vs CC	Com	3	0.75	0.21	2.68
	Cost	2	64.1	−2.62	130
	IB*	5	**−3.12**	**−4.32**	**−1.92**
	OT*	5	**−4.33**	**−6.43**	**−2.23**
	PO*	4	**−1.51**	**−2.55**	**−0.46**
	PP*	4	**−1.38**	**−2.28**	**−0.48**
	SR	5	1.12	0.96	1.30
	WAE	5	1.00	0.30	3.39
	WB	5	1.24	0.52	2.97
	WD	5	1.13	0.42	3.03
	WE	3	0.35	0.06	2.02
	WHT*	3	**−0.88**	**−1.18**	**−0.58**
	WI	5	0.67	0.32	1.44
ISD vs CC	Com	4	0.87	0.34	2.25
	Cost	2	0.34	−11.5	12.2
	IB*	3	**−3.25**	**−3.65**	**−2.85**
	OT*	5	**−5.72**	**−7.11**	**−4.33**
	PO	6	−1.15	−2.37	0.08
	PP	5	−0.95	−3.09	1.19
	SR*	6	**1.17**	**1.02**	**1.35**
	WAE	6	0.77	0.47	1.26
	WB*	6	**0.16**	**0.03**	**0.76**
	WD	5	1.04	0.66	1.64
	WE*	6	**0.69**	**0.53**	**0.88**
	WHT	6	0.59	−0.11	1.30
	WI	6	0.49	0.12	2.05
CDD vs ISD	IB*	1	**0.33**	**0.17**	**0.48**
	OT*	1	**0.48**	**0.32**	**0.63**
	PO*	1	**−2.23**	**−2.43**	**−2.03**
	PP*	1	**−2.39**	**−2.59**	**−2.18**
	SR*	1	**1.57**	**1.39**	**1.78**
	WAE*	1	**0.30**	**0.20**	**0.45**
	WB*	1	**21.0**	**1.24**	**357**
	WD	1	0.63	0.29	1.36
	WE*	1	**0.10**	**0.05**	**0.24**
	WHT*	1	**−0.74**	**−0.90**	**−0.58**
	WI*	1	**0.04**	**0.002**	**0.62**

Nagdeve N et al. 2013 evaluated and compared parental satisfaction after Plastibell (PD) and conventional dissection circumcision (CDS - dorsal slit technique) in 198 children younger than 12 years (including neonates) who required circumcision for various indications. All the parents whose

children belonged to the PD group were told to note the day of separation of the PD. The study showed that surgical duration was significantly shorter for the PD group as compared to the CDS group (5.91 ± 1.74 versus 23.52 ± 5.94 minutes; p<0.0001). The time taken for separation of the Plastibell device ranged from seven to 20 days with a mean of 10.85 ± 2.49 days. Furthermore, Kaplan-Meier analysis showed that the bell separated earlier in younger children (p<0.0001). Children in the PD group used analgesics after surgery 2.79 fold more than those in the CDS group (5.14 ± 1.88 versus 2.21 ± 0.84 days (hazard ratio: 2.79; 95% CI: 1.61, 4.83; p<0.0001). The authors concluded that PD use has comparable outcomes to the conventional dissection technique for paediatric circumcision and has an obvious advantage of shorter surgical duration. However, it is less comfortable in the postoperative period due to greater use of analgesics.[45, level I]

A prospective clinical study by Karadag MA et al. 2015 analysed parental anxiety and outcomes of 125 children (aged two to 10 years) who were circumcised by the conventional dissection technique (CDT - sleeve resection) and the remaining children were operated by the SmartClamp. All children in both groups were compared in terms of bleeding, infection, penile oedema, operative time, cosmetic result, length of the inner mucosal layer, and parental anxiety. Cosmetic result and length of the inner mucosal layer were evaluated by a blinded urologist after six weeks. A state-trait anxiety inventory (STAI) form was used to measure the impact of circumcision on parental anxiety. This form was completed by parents on postoperative day two. The study indicated that the operative time of the SmartClamp group was statistically shorter than for the CDT group (6.93 ± 2.58 versus 18.08 ± 3.55 minutes; p<0.001). No significant differences were encountered in cosmetic displeasure (p=0.109).[46, level II-1]

In a study by Lagarde E et al. 2009, participants of the control group of the male circumcision randomised controlled trial (MCRCT) conducted in South Africa (on 3,274 uncircumcised men aged 18 to 24) were asked to participate in a randomised sub-trial to compare the safety of the Tara KLamp (TK) technique with the conventional forceps-guided (FG) method. Men were recruited from among the 1,654 control group of the MCRCT participants who had been offered circumcision at the end of the follow-up, 21 months after inclusion in the MCRCT. For randomisation, each participant chose an envelope containing the group name from a basket of 10 envelopes. Neither GPs, participants nor investigators were blinded to the randomisation group. At interview, the nurse was not aware of the method used but on examination could conclude which technique was used. Assessment criteria included: (1) comparison of circumcision methods according to the number and nature of adverse events reported by the GP who performed the procedure; (2) the nurse's clinical assessment, which included any signs of adverse events, observed penile

infection or delay in wound healing, problem with penis appearance, excessive or insufficient skin removed and any erectile dysfunction; and (3) participants' reports, which included pain score, bleeding within the two weeks following the procedure, lesions to the penis, swelling or haematoma within the two weeks following the procedure, any problem when urinating, and satisfaction with penis appearance. Participants were asked to visit the GP for a clinical follow-up three days and six weeks after surgery. The post-circumcision visit was attended by 91% (29/32) of those circumcised by the FG method and 79% (19/24) of those circumcised with the TK method. No statistical differences were found related to socio-demographic characteristics, sexual experience, health-related behaviour or history of medical problems (hospitalisations and ulcerations). The mean scores for pain were 6.1 and 9.5 among those circumcised by the FG and TK methods respectively, which was statistically significant. On clinical examination by nurse, men circumcised by the TK method were significantly more likely to have delayed wound healing (21% versus 3%; p=0.004) and problems with penis appearance (31% versus 3%; p=0.001). This study provides compelling evidence that strongly cautions against use of the TK method on young adults.[47, level I]

Wang J et al. 2014 conducted a RCT to evaluate the efficacy and safety of circular stapler device for MC. A multi-centre pilot clinical trial was conducted at two Chinese hospitals to compare intra- and postoperative outcomes of MC using this device with conventional sleeve resection technique. Adult male patients (n=120; mean age 26.6 years) with redundant foreskin and/or phimosis were randomly divided into two groups using a computerized random table method generated by SAS 8.0 (SAS, Cary, NC). Intraoperative bleeding, surgery duration, pain, healing, and satisfaction with penis appearance were assessed. Adverse events (AEs) were also noted. Follow-up was conducted on day one, three, seven, and 14 following surgery. Each patient underwent follow-up examinations in-clinic, where they completed a written assessment of surgery. There was no significant differences (in age, height or weight, clinical baseline parameters, clinical examination results, routine blood test results or ECG) were observed between the groups ($p>0.05$). Significantly different mean surgical times of 7.6 ± 4.5 (2–23) minutes and 23.6 ± 4.4 (15–35) minutes in the Device Group and the Control Group, respectively, were observed ($p<0.01$). Surgical success rates were 96.7% (58/60) in the Device Group and 100% (60/60) in the Control Group. The majority of patients in both groups reported acceptable healing by day seven (88%, 53/60 Control Group patients; 84%, 49/58 Device Group patients). By day 14, all patients reported complete covering of the wound by epithelium, consistent with the acceptable healing designation.[48, level I]

Zhang Z et al. 2016 compared the surgical effects, postoperative complications, and patient experience of two circumcision methods in a prospective non-RCT. A total of 520 cases of excess foreskin and 62 phimosis patients underwent circumcision in a single centre using circular stapler device (n=295; mean age 30.4 years) and conventional sleeve resection approach (n=287; mean age 28.6 years). During the surgery, intraoperative blood loss was calculated by weighing the gauzes. A visual scale (0–10) was used to assess the pain level. At their visit at one month after the operation, the recovery duration and incision healing time for each patient were collected. Patients were also asked whether they were satisfied with their cosmetic penis appearances at one month visit. The incidence of complications was also recorded at the follow-up. Multivariate logistic regression with likelihood ratio test was used to observe the significant predictors of oedema occurrence postoperatively. The study revealed that all surgery procedures in the two groups were completed well, with no intraoperative complications occurred. The operation time (minute) in the device group was significantly shorter than that in the conventional group (10.2 ± 1.2 versus 28.4 ± 2.4; p=0.000). Similar trend was found in the comparison of intraoperative pain scores (2.2 ± 0.8 versus 6.6 ± 1.0; p=0.022). At follow-up, patients in the device group experienced a shorter incision healing time (day) (14.5 ± 2.2 versus 20.8 ± 3.4; p=0.034) and recovery time (day) (3.4 ± 0.8 versus 8.7 ± 2.0; p=0.041) when compared to the conventional group. The comparison of postoperative pain score at one week yielded significant results as well (p=0.021). They concluded that circumcision using circular stapler device is associated with short operative time, rapid recovery, and less pain experience.[49, level II-1]

Mousavi SA and Salehifar E conducted a RCT to compare the various complications of two methods of circumcision in infantile age. A total of 586 infants were randomised in one of two techniques: the Plastibell device (PD) or conventional dissection surgery (CDS - sleeve resection). All children were followed up until the wound was healed, along with observing them for any associated complications. An obvious advantage of using the Plastibell was the short surgery time. Average procedure duration with the PD group was 3.4 minutes, compared with 9.2 minutes with the sleeve resection. There was a significant positive correlation between the age and weight of subjects within the time of ring separation (p<0.001). This indicates that the ring separated faster in younger children. The results of this study suggest the use of Plastibell method for neonates and low-weight infants with thin prepuce while the CDS for other infants.[50, level I]

5.1.3 Laser circumcision versus conventional

Xu Y et al. 2013 conducted a RCT to investigate the efficacy and safety of a modified CO_2 laser technique for circumcision in 300 adult males (>18 years) with the indications of phimosis, recurrent balanoposthitis, and patient requests. Participants were randomised to the laser group or the conventional dorsal slit technique using computer generated, sequentially numbered, opaque sealed envelopes. Operating time and intraoperative blood loss were recorded during the surgery. As for pain assessment, participants were asked to rate their postoperative pain at one day and seven days using a visual analogue scale (VAS) displaying numbers and words describing levels of pain from 0=no pain to 10=worst pain possible. Side effects were monitored closely during the postoperative period. In order to rule out the subjective bias, the people recording the intraoperative data, VAS score, and postoperative complications were blinded to the techniques. Comparison of the patients in the two groups demonstrated a 10 minutes decrease in the operative time in the laser-treated group (10.5 ± 0.9 versus 21.1 ± 2.7 minutes, $p<0.05$). The CO_2 laser technique was associated with much less pain at both one day (2.9 ± 1.9 versus 4.9 ± 2.5, $p<0.05$) and seven days (1.2 ± 0.5 versus 1.9 ± 1.3, $p<0.05$) postoperatively. In both groups, follow-up visits demonstrated excellent cosmetic results, and no secondary operations were performed because of unacceptable appearance. The authors concluded that the modified CO_2 laser technique offers a simple, faster, and effective alternative method to the conventional technique in adult MC.[51, level I]

A non-RCT by Gorgulu T et al. 2016 examined the combined use of a CO_2 laser and cyanoacrylate for shortening the operating time and reducing complications related to bleeding. Circumcisions were performed under general anaesthesia in 75 boys (aged 6-9 years) only for religious reasons. As a control, they compared them retrospectively with 75 age-matched patients who were circumcised using the conventional guillotine technique. Patients were followed postoperatively for 12 months on average. The study showed that in a CO_2 laser and cyanoacrylate combination, wound healing took one week. The median operating time was seven minutes (range 6–9) using the CO_2 laser and 22 minutes (range 20-26) in the conventional guillotine group. The difference in surgical time was significant ($p<0.001$).[52, level II-1]

5.2 Safety

The three most commonly used devices; Gomco, Mogen and Plastibell were classified under Regulatory Class II by United States Food and Drug Administration (US FDA) and received approval for marketing. SmartClamp received US FDA approval, 510(k) premarket notification in 2004 because of substantial equivalence of the device to a legally

marketed predicate Gomco circumcision clamp, Mogen circumcision clamp, and Hollister Plastibell. Tara KLamp is classified under Class I sterile and received CE mark. It is also classified under Class II by US FDA and is in the US FDA Device Listing Database. However, there were no retrievable evidence on approval by US FDA or CE mark for other circumcision devices such as Ismail Clamp, Alisklamp, and Shang Ring. Sunathrone™, a new disposable plastic circumcision clamp is registered under the Malaysian Voluntary Medical Devices Establishment Registration (MeDVER).[38]

5.2.1 Device assisted circumcision (non-disposable) versus conventional

In a non-blinded RCT by Millard PS et al. 2013 comprising 200 male volunteers (>18 years), it was reported that there was no significant difference between Gomco circumcision clamp plus tissue adhesive group and the open surgical technique group (dorsal slit) in terms of bleeding, haematoma or infection, either taken individually or as a composite. The rate of wound infection was 6.9% prior to the use of prophylactic antibiotics and 1.4% after initiation of cloxacillin prophylaxis. Wound disruptions were greater in the Gomco circumcisions; >2 cm occurred 1.0% at two days, 10.1% at one week, and 20.8% at two weeks. Wound disruptions, however, were not more than 5 mm in width, and none required surgical closure. They concluded that Gomco instrument was potentially safer, can greatly facilitate scale-up of mass circumcision programmes, and a disposable plastic Gomco- like device should be produced and evaluated for use in resource-limited settings.[43, level I]

5.2.2 Device assisted circumcision (disposable) versus conventional

In a systematic review and meta-analysis of circumcision with Shang Ring (SRC) versus conventional circumcision (CC), a lower adverse event rate (AER) was observed in the SRC group in comparison with the CC group (RR, 0.54; 95% CI: 0.39, 0.74; p<0.001; I^2=32%). Wound bleeding rate and intraoperative blood loss (ml), which are the most common complications, was observed less frequently in the SRC group than in the CC group (RR, 0.06; 95% CI: 0.02, 0.14; p<0.001; I^2=0% and MD, -8.09; 95% CI: -10.70, -5.48; p<0.001), respectively. Other complications showed no significant difference between the two groups: wound oedema rate (RR, 0.92; 95% CI: 0.55, 1.53; p=0.75; I^2=82%), wound infection rate (RR, 0.43; 95% CI: 0.10, 1.83; p=0.26; I^2=86%), and wound dehiscence rate (RR, 1.01; 95% CI, 0.66, 1.55; p=0.96; I^2=0%) (Table 9). The authors concluded that SRC is a safer choice than CC for conducting MC.[26, level I]

A RCT comparing Plastibell device (PD) and conventional dissection surgery (CDS - dorsal slit technique) among 198 children (<12 years, including neonates) reported that swelling, dysuria and infection were the

prominent problems noted in both groups (p=0.070) in the first seven days. At second follow-up, there were significantly more complications in the CDS group than the PD group (20.85% versus 4.25%; p<0.05), which included irregular cicatrical scars (16.66% versus 0%; p<0.001) and postoperative adhesions (25.04% versus 6.38%; p<0.001). The authors concluded that although PD use has comparable outcomes to the conventional dissection technique, it is less comfortable in the postoperative period due to swelling, and requires greater use of analgesics.[45, level I]

In the clinical study by Karadag MA et al. 2015, they analysed parental anxiety and outcomes for the SmartClamp circumcision and the classic surgical dissection technique (CDT – sleeve resection) in 250 boys aged two to 10 years. It was reported that there were no statistically significant differences among the two groups in terms of bleeding and infection (p>0.05). Penile oedema was significantly more common in the SmartClamp group (p=0.039) and the inner mucosal length was longer compared to CDT (14.10 ± 3.46 versus 5.09 ± 1.22 mm; p<0.001). The authors concluded that complication rates were similar in both techniques. Unfortunately, SmartClamp device seemed to carry the disadvantages of longer mucosal length and penile oedema. These points should be kept in mind by the urologists before choosing this technique.[46, level II-1]

In a study by Lagarde E et al. 2009 comparing the safety of the Tara KLamp (TK) with the conventional forceps-guided (FG) method, a total of 12 adverse events were reported by the GPs during the course of the study, all corresponding to participants initially randomised to the TK group. Two participants were eventually circumcised by the FG method, as the TK method had failed. Participants circumcised by the TK method were significantly more likely to report bleeding, lesions to the penis, infection, swelling, haematoma and problems with urinating (p<0.001). On clinical examination by nurse, men circumcised by the TK method were significantly more likely to have at least one sign of an adverse event (37% versus 3%; p=0.004). No participants were reported with a current infection, excessive or insufficient skin removed or erectile dysfunction. Given the high rate of adverse events and low number of available studies, this study provides compelling evidence that strongly cautions against use of the TK method on young adults.[47, level I]

A multi-centre RCT by Wang J et al. 2014 among 120 adult male patients with redundant foreskin and/or phimosis was conducted to compare intra- and postoperative outcomes of MC using circular stapler device with conventional sleeve resection technique. Intraoperative bleeding and AEs were assessed. Follow-up was conducted on day one, three, seven, and 14 following surgery. Lower estimated intraoperative bleeding was observed in the Device Group (mean 3.5 ± 2.7 ml, ranging 15–35 ml)

compared with the Control Group (mean 13.1 ± 6.1 ml, range 4–25 ml) ($p<0.01$), and no AEs due to postoperative bleeding or haematoma formation were reported in either group. Notably, no device-related accidents causing patient injury, post-surgical wound bleeding, dehiscence, infection, or other AEs were observed in any group. The authors concluded that MC using circular stapler device provided equivalent outcomes with current CDT and may be a valid alternative treatment.[48, level I]

A prospective non-RCT by Zhang Z et al. 2016 compared the postoperative complications of two circumcision methods; circular stapler device versus conventional sleeve resection technique in 520 cases of excess foreskin and 62 phimosis Chinese patients. It was reported that the incidence of wound dehiscence, scar, oedema, and reoperation were similar between the two groups. Two patients (2/295, 0.67%) had haematoma in the device group. By contrast, a higher percentage of patients in the conventional group experienced haematoma (16/287, 5.6%). Notably, the incidences of incision bleeding and infection were also significantly lower in the device group. A multivariate logistic regression with likelihood ratio test revealed that phimosis was the significant predictor of oedema occurrence postoperatively (Chi square of likelihood ratio=9.88, df=1, p=0.025). Of the total 30 phimosis patients in device group, 18 (60%) developed postoperative oedema. By contrast, 20 out of 32 (62.5%) phimosis patients in the conventional group had oedema postoperatively. Notably, they failed to identify the positive role of surgical options in the prediction of oedema. They concluded that although circumcision using circular stapler device was associated with less complications, phimosis patients should be notified that they had a great possibility to develop oedema postoperatively regardless of the surgical options.[49, level II-1]

Mousavi SA and Salehifar E conducted a RCT to compare the various complications of two methods of circumcision in 586 infants: the Plastibell device (PD) method and conventional dissection surgery (CDS - sleeve resection). All children were followed up until the wound was healed, along with observing them for any associated complications. They found that overall complication rate of conventional surgical method was less than that of the Plastibell method (1.95% versus 7.08%). In conventional dissection group, bleeding was the only complication and stopped with compress dressing. In Plastibell method, delayed separation of ring was the most common complication (2.6%) followed by bleeding, excess mucosa, infection, disposition, and haematoma.[50, level I]

5.2.3 Laser circumcision versus conventional

Xu Y et al. 2013 conducted a RCT to investigate the safety of a modified CO_2 laser technique for circumcision in 300 adult males as compared with the conventional dorsal slit method. They found that the incidence of postoperative bleeding was 2.7%, and occurred only in the conventional group (four cases), within the 24 hours after the removal of the wound dressing. These patients were treated conservatively with compressive management, and none required a second operation to control the haemorrhage. There was almost no blood lost during the operation using the CO_2 laser whereas the mean blood loss was 7.2 ± 1.5 g in the conventional group ($p<0.05$). In the laser-treated group, wound dehiscence requiring re-suturing was observed in one patient after intercourse at 23 days postoperatively. No patients in the conventional group developed wound dehiscence. The incidence of postoperative oedema was less in the laser group (2.0% versus 8.0%, $p<0.05$), none of these patients required any further treatment, and the oedema disappeared gradually within two to four weeks. The overall incidence of complications was less in the laser group (2.7% versus 10.7%, $p<0.05$). No patients developed late complications, such as adhesion, secondary phimosis, buried penis, or scar. The authors concluded that the modified CO_2 laser technique offers a simple and safe alternative method to the conventional technique in adult MC with less complications.[51, level I]

A non-RCT by Gorgulu T et al. 2016 which examined the combined use of a CO_2 laser and cyanoacrylate for reducing complications among 150 boys (aged six to nine years) found that there were no haematomas, bleeding, or wound infections observed. Dehiscence occurred in one child (1.3%) during the early postoperative period but healed spontaneously within one week. In the conventional guillotine group, one haematoma (1.3%), two wound dehiscences (2.6%), and two haemorrhages (2.6%) were recorded. The difference in the rate of complications, however, was not significant ($p>0.5$) between the two groups.[52, level II-1]

5.3 Psychological/social/ethical

5.3.1 Device assisted circumcision (disposable) versus conventional

Nagdeve N et al. 2013 evaluated and compared parental satisfaction after Plastibell (PD) and conventional dissection circumcision (CDS – dorsal slit technique) in 198 children including neonates. Written questionnaires were given to parents at time of discharge, and they were told to complete and return at the 15th and 90th day of follow-up visits. The questionnaire consisted of two parts. The first part was related to the problems faced by the parents/patients in the early postoperative period. The second part of the questionnaire was about the parents' satisfaction regarding aesthetic

outcome. The study revealed no statistical difference with regard to parental concern about pain (managed with analgesics) (p=0.164), infection (p=0.632), and dysuria (p=0.140). However, PD group parents were statistically significantly more concerned about swelling. Parental responses about aesthetic outcome following circumcision revealed that 97.9% of the PD group parents and 80.2% of the CDS group parents claimed satisfactory aesthetic results.[45, level I]

A prospective clinical study by Karadag MA et al. 2015 which analysed parental anxiety of 125 children who were circumcised by SmartClamp and the conventional dissection technique (CDT - sleeve resection) indicated that parental anxiety in the SmartClamp group was statistically higher; the state-trait anxiety inventory (STAI) scores were nearly 10 points higher than CDT group (p<0.001). These points should be kept in mind by the urologists before choosing this technique.[46, level II-1]

Wang J et al. 2014 conducted a RCT to compare intra- and postoperative outcomes of MC using circular stapler device with conventional sleeve resection technique in 120 adult patients with redundant foreskin and/or phimosis. Each patient underwent follow-up examinations in-clinic, where they completed a written assessment of surgery. The study revealed that by day 14, 97% (56/58) Device Group patients and 95% (57/60) Control Group patients reported full satisfaction with MC outcomes. Notably, only two (3%) and three (5%) patients of the Device Group and Control Group, respectively, reported moderate satisfaction. No patient reported poor satisfaction in any group. No significant differences were observed in any outcomes between the two groups.[48, level I]

A prospective non-RCT by Zhang Z et al. 2016 compared the patient satisfaction of two circumcision methods; circular stapler device versus conventional sleeve resection technique in 520 cases of excess foreskin and 62 phimosis. Patients were asked whether they were satisfied with their cosmetic penis appearances at one month visit. They found that only five patients in the device group were dissatisfied with their penile cosmetic appearance while 75 in 287 patients using conventional circumcision method were dissatisfied, which indicated a statistical significance (p=0.000).[49, level II-]

5.3.2 Laser circumcision versus conventional

Gorgulu T et al. 2016 examined the combined use of a CO_2 laser and cyanoacrylate for reducing complications among 150 boys (aged 6-9 years). As a control, they compared them retrospectively with 75 age-matched patients who were circumcised using the conventional guillotine technique. The study showed that parents of the patients in both groups were satisfied with the aesthetic results.[52, level II-1]

5.4 Organizational

5.4.1 Conventional technique

Buwembo D et al. 2011 conducted a prospective cohort study to assess the efficiency (the time required for the MC procedure) of the dorsal slit and sleeve technique, performed by trained physicians and clinical officers (COs) after completion of a randomised trial of MC for HIV prevention in Rakai District, Uganda. A total of 5,152 male aged 12 to 71 years were involved. Univariate and multiple regressions with robust variance estimation were used to assess factors associated with operative duration (linear). The patients were followed-up at 24 to 48 hours, seven to nine days, and at four weeks after MC. Six general physicians and eight COs conducted 1,934 (1,511 sleeve and 423 dorsal slit) and 3,218 (1,170 sleeve and 2,048 dorsal slit) MC procedures, respectively. The study indicated that there were no overall difference in operative duration between physicians and COs, but physicians required less time to perform the sleeve procedure. This shorter operative duration by physicians was less marked and inconstant for the dorsal slit procedure. In multivariate analysis, there were no significant differences in adjusted surgical durations between physicians and COs. Dorsal slit required 2.7 minutes less time than sleeve resection ($p<0.001$). Use of bipolar cautery to control bleeding significantly reduced operative duration by ≈4 minutes compared with ligation ($p=0.008$), and ≈20 MC procedures as an increase in surgical experience of the provider reduced operative duration by 1.5 minutes ($p<0.001$) (surgical experience is expressed in sequence of bins of 20 surgeries for the first 100 and then bins of 100 surgeries thereafter). After performing 100 surgeries, dorsal slit took an average of 22.5 minutes compared with 25.3 minutes for the sleeve method. They concluded that dorsal slit technique requires less time to perform than the sleeve resection, and can be performed equally efficient by COs and physicians.[53, level II-2]

5.4.2 Device assisted circumcision (non-disposable versus disposable)

A study by Bowa K et al. 2013 to determine the acceptability and feasibility of national scale-up NMC among 640 infants using one of the three NMC methods indicated that the mean number of procedures to competency was 10.3 (SD=63.3) for Gomco clamp, 10.3 (SD=63.7) for Plastibell, and 8.9 (SD=62.9) for the Mogen clamp. All providers were competent in each circumcision method by 15 procedures. In general, nurses took longer to train than the other providers, but this was not statistically significant. The authors concluded that Mogen clamp was the preferred device for most providers.[54, level II-1]

5.5 Economic: cost-analysis

How AC et al. 2003 evaluated their experience with CO_2 laser circumcision for 60 children and its cost-analysis as compared to conventional guillotine technique in Department of Paediatric Surgery, Women's & Children's Hospital, Singapore. The total cost of use of the laser machine was calculated, taking into account maintenance costs, estimated life span of laser machines (10 years) and costs of disposables used during each circumcision. The study revealed that the operating time for patients who underwent circumcision by CO_2 laser was shorter by five minutes as compared to that for patients who had circumcision by the conventional [median time 15 (95% CI: 13, 17) versus 20 (95% CI: 16, 21); p=0.002]. The cost of a CO_2 laser machine was S$105,000. If estimated life-span for each machine is 10 years, with consideration of maintenance charges of S$5,000 per year, machine costs would make up to S$15,500 per year. Approximately 1,000 circumcisions were done in their institution every year. Hence, the cost of machine per circumcision would be S$15.50. Other cost considerations in a laser circumcision would be the cost of disposables used which comes up to S$3.50 for a sterile plastic camera sleeve, which is unnecessary in a circumcision done by the conventional technique. Therefore, the total cost of each circumcision would be S$19.00. With regards to the reduced operating time by five minutes per circumcision done by laser; there is a concomitant reduction in operating theatre facility charge by S$50.00. This makes the total cost savings per circumcision done by laser S$31.00. The authors concluded that CO_2 laser offers a simple and cost-effective method of circumcision as demonstrated from its reduced operating time and favourable morbidity rates compared with those done by the conventional technique.[55]

Bratt J and Zyambo Z compared direct costs of the Shang Ring and dorsal slit technique for delivery of voluntary medical male circumcision (VMMC) in the context of a randomised controlled trial carried out in Zambia in 2011 (n=191). Information on direct costs of clinician time, disposable supplies, and reusable medical instruments were collected by study staff. "Clinician time" was measured from administration of anaesthetic until the end of the procedure, and a cost per minute of US$0.09 was used (US$5.30 per hour). "Disposable medical supplies" included surgical blades, caps, masks, gloves, and drapes; disinfectants, injection equipment, local anaesthetics', and postoperative analgesics; sutures and dressings; the Shang Ring device itself; and cleaning supplies to prepare the surgical workspace between cases. "Reusable instruments" included assorted clamps, forceps, scissors, blade handles, and the Shang Ring removal set consisting of a scissors and key. The study indicated that using dorsal slit, the direct cost of one circumcision was US$17.67, whereas the direct cost of one circumcision using the Shang Ring was US$18.21. Although total direct costs of the two techniques are similar,

components of direct cost are slightly different. Cost of clinician time was higher with dorsal slit, reflecting the longer duration of the procedure (24.3 minutes on average, versus 13.4 minutes for the Shang Ring). Cost of disposable medical supplies was higher with the Shang Ring, where the unit cost of the device and associated supplies outweighed the costs of scalpel, sutures, and dressings used in the dorsal slit technique. The cost of reusable instruments was similar for the two techniques. The authors suggested that at levels of demand lower than the maximum output per session for standard surgery, substituting the Shang Ring would not affect the average total cost of the procedure.[56]

Mutabazi V et al. 2014 compared the costs associated with nonsurgical adult MC performed in a standard examination room by a team of two trained nurses using the PrePex device versus surgical MC performed in a sterile environment by a physician-nurse team using the WHO approved dorsal slit method. Cost categories included in the analysis reflect ongoing expenses that are specific to each method such as supplies (tools, devices, and other consumables), laboratory tests, and salaries for the clinicians performing the procedures, and treatment of procedure-related adverse events (AEs). All subjects in both groups achieved successful circumcision and healing (epithelialization with no drain-age from the site). Adverse events requiring treatment were documented in six subjects from the surgical group (8%) but none from the PrePex group. The study showed that the mean total of ongoing costs specific to each method of performing MC was US$22.73 (US$22.38 for supplies, US$0.00 for laboratory testing, US$0.35 for salaries, US$0.00 for treatment of AEs) for PrePex device performed in a standard examination room by nurse teams; and US$40.85 (US$29, US$6, US$4.36, US$1.49) for dorsal slit surgical MC performed in a sterile setting by physician-nurse teams. This study suggests that meaningful cost-savings can be achieved in Rwanda with nonsurgical MC performed by nurses using the PrePex device in place of surgical MC performed by physicians.[57]

Mangenah C et al. 2015 presented results on a relative cost-analysis within a randomised noninferiority trial of early infant male circumcision (EIMC) comparing the AccuCirc device with Mogen clamp in Zimbabwe. Trial methods are described in detail elsewhere. [48] The overall unit cost plus the key cost drivers of EIMC using both AccuCirc and Mogen clamp were evaluated. Direct costs included consumable and nonconsumable supplies, device, personnel, associated staff training, and environmental costs. Indirect costs comprised capital and support personnel costs. This analysis adopted the perspective of the Zimbabwe Ministry of Health as a health care payer. Client costs such as transport to and from the EIMC facility, opportunity costs of time spent seeking EIMC services and caregiver costs were therefore excluded. As this cost-analysis is based on a pilot EIMC study, they estimated the costs based on the assumption of a

vertical EIMC program. They present costs in 2013 constant US dollar prices and assume an exchange rate of US$1=US$1 because Zimbabwe officially adopted the US dollar as its principal currency in 2009. The study demonstrated that it would cost US$49.53 to perform an EIMC procedure in Zimbabwe using AccuCirc compared with US$55.93 using Mogen clamp. The key cost drivers were consumable supplies, capacity utilization, personnel costs, and device price. One-way sensitivity analysis showed that unit prices were likely to be lowest at full capacity utilization and increase as capacity utilization decreases. Unit prices also fall with lower personnel salaries and increase with higher device prices.[58]

5.6 Limitation

Our review has several limitations. The selection of the studies and appraisal was done by one reviewer. Although there was no restriction in language during the search, only the full text articles in English published in peer-reviewed journals were included in the report, which may have excluded some relevant articles and further limited our study numbers. The most important limitation was the methodological quality of the included studies, particularly in terms of risk of bias. Most studies were limited by the lack of blinding because of ethical issues and properties of surgery studies. While the GPs, nurse, patients and investigator were not blinded to the randomisation group, it was likely impossible to perform parental blinding to operative technique as parents know if a device is present or not. Similarly, some of the questionnaires are subjective and non-validated. There were also no retrievable evidences related to the cost-effectiveness analysis or cost-utility analysis of different circumcision technique for male circumcision. The only limitation of the cost-analysis studies included in this review was the need to include the discounting and to perform sensitivity analysis.

6.0 CONCLUSION

6.1 Effectiveness:

6.1.1 Device assisted circumcision (non-disposable) versus conventional

There was good level of retrievable evidence to suggest that:

a. Intraoperative time was less with the Gomco clamp compared with dorsal slit technique.
b. Pain scores were low and there was less pain in the Gomco clamp as compared with dorsal slit technique.
c. The cosmetic result was superior in the Gomco clamp when compared with dorsal slit technique.

6.1.2 Device assisted circumcision (disposable) versus conventional

There was limited good level of retrievable evidence to suggest that:

a. Shang Ring and circular stapler were associated with shorter operative time, lower pain scores, shorter wound healing time, and excellent penile cosmetic appearance relative to dorsal slit or sleeve resection technique. PrePex, Plastibell, and SmartClamp also tends to have short surgery time while Unicirc resulted in less pain and shorter wound healing time.
b. Compared with dorsal slit, Plastibell required greater use of analgesics.
c. No significant differences were encountered in cosmetic displeasure for SmartClamp as compared with sleeve resection technique.
d. Less favourable outcomes were associated with Tara KLamp as compared with forceps-guided method including higher pain score, delayed wound healing, and problems with penis appearance.

6.1.3 Laser circumcision versus conventional

There was limited fair to good level of retrievable evidence to suggest that:

a. Laser circumcision technique was associated with a decrease in operative time and less postoperative pain as compared with dorsal slit and guillotine techniques.
b. Follow-up visit demonstrated excellent cosmetic result both for laser and conventional techniques.

6.2 Safety:

6.2.1 Device assisted circumcision (non-disposable) versus conventional

There was good level of retrievable evidence to suggest that:

a. There was no significant difference between Gomco clamp and dorsal slit in terms of bleeding, haematoma or infection.
b. Wound disruption was greater in Gomco clamp at one and two weeks compared with dorsal slit.

6.2.2 Device assisted circumcision (disposable) versus conventional

There was good level of retrievable evidence to suggest that:

a. A lower AE rates was observed in the Shang Ring group in comparison with the conventional group.

b. Bleeding was the only complication which occurred in sleeve resection technique while in Plastibell, delayed separation of ring was the most common complication followed by bleeding, excess mucosa, infection, disposition, and haematoma.
c. SmartClamp device seemed to carry the disadvantages of longer mucosal length and penile oedema compared to sleeve resection technique.
d. Participants circumcised with the Tara KLamp were significantly more likely to report bleeding, lesions to the penis, infection, swelling, haematoma, and problems with urinating as compared with forceps-guided method.
e. Circumcision using circular stapler device was associated with less complications (haematoma, incision bleeding, infection) compared with sleeve resection approach.

6.2.3 Laser circumcision versus conventional

There was limited fair to good level of retrievable evidence to suggest that:

a. The overall incidence of postoperative complications was less in the laser group compared with dorsal slit.
b. There were no significant difference in the rate of haematoma, wound dehiscence, and haemorrhage between the laser group and guillotine technique.

6.3 Psychological/social/ethical:

6.3.1 Device assisted circumcision (disposable) versus conventional

There was fair to good level of retrievable evidence to suggest that:

a. Parents whose children was circumcised using Plastibell were significantly more concerned about swelling and satisfied with the aesthetic results compared with parents whose children was circumcised using dorsal slit technique.
b. Parental anxiety in the SmartClamp group was statistically higher than sleeve resection group.
c. Similarly, more patients were fully satisfied with the cosmetic penis appearances when using circular stapler device compared to sleeve resection technique.

6.3.2 Laser circumcision versus conventional

There was limited fair to good level of retrievable evidence to suggest that parents of the patients in laser and guillotine group were satisfied with the aesthetic results.

6.4 Organization:

6.4.1 Conventional technique

There was fair to good level of retrievable evidence to suggest that:

a. There were no overall difference in operative duration between physicians and clinical officers, but physicians required less time to perform the sleeve procedure. This shorter operative duration by physicians, however, was less marked and was inconstant for the dorsal slit procedure.
b. A total of 20 circumcision procedures (sleeve resection or dorsal slit) as an increase in surgical experience of the provider reduced operative duration by 1.5 minutes ($p<0.001$).

6.4.2 Device assisted circumcision (non-disposable versus disposable)

There was fair to good level of retrievable evidence to suggest that:

a. The mean number of procedures to competency was 10.3 (SD=63.3) for Gomco clamp, 10.3 (SD=63.7) for Plastibell, and 8.9 (SD=62.9) for the Mogen clamp. All providers were competent in each circumcision method by 15 procedures.
b. In general, nurses took longer to train than the other providers, but this was not statistically significant.

6.5 Economic: cost-analysis

There was evidence to suggest that:

a. Total cost savings per circumcision done by laser was S$31.00 compared with those done by the conventional guillotine method in Singapore.
b. The direct cost of one circumcision using dorsal slit was US$17.67 while the cost was US$18.21 using the Shang Ring in a scale-up voluntary medical male circumcision programme in Zambia.
c. A meaningful cost-savings can be achieved in Rwanda with nonsurgical male circumcision performed by nurses using the PrePex device (US$35.50) in place of dorsal slit surgical performed by physicians (US$53.50).
d. Early infant male circumcision scale-up in Zimbabwe has a lower unit cost when using AccuCirc (US$49.53) compared with Mogen clamp (US$55.93).

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44. Fan Y, Cao D, Wei Q et al. The characteristics of circular disposable devices and in situ devices for optimizing male circumcision: a network meta-analysis. Sci Rep. 2016; 9:6: 25514
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8.0 APPENDIX

8.1 Appendix 1: LITERATURE SEARCH STRATEGY

Ovid MEDLINE® In-Process & Other Non-indexed Citations and Ovid MEDLINE® 1946 to present

1.	Circumcision, Male/
2.	Male circumcision*.tw.
3.	1 or 2
4.	"Equipment and Supplies"/
5.	Apparatus.tw.
6.	Instruments.tw.
7.	Device*, medical.tw.
8.	Medical device*.tw.
9.	Device*.tw.
10.	Equipment.tw.
11.	4 or 5 or 6 or 7 or 8 or 9 or 10
12.	Gomco.mp.
13	Mogen.mp.
14.	Plastibell.mp.
15.	Alisklamp.mp.
16.	PrePex.mp.
17.	Shang ring.mp.
18.	Tara Klamp.mp.
19.	12 or 13 or 14 or 15 or 16 or 17 or 18
20.	Laser circumcision.mp.
21.	Dorsal slit.mp.
22.	Sleeve.mp.
23.	Guillotine.mp.
24.	21 or 22 or 23
25.	3 and 11
26.	3 and 19
27.	3 and 20
28.	3 and 24
29.	25 or 26 or 27 or 28
30.	limit 29 to (male and yr="2000 -Current")

OTHER DATABASES	
EBM Reviews – Cochrane Central Registered of Controlled Trials	Same MeSH, keywords, limits used as per MEDLINE search
EBM Reviews – Database of Abstracts of Review of Effects	
EBM Reviews – Cochrane database of systematic reviews	
EBM Reviews – Health Technology Assessment	
NHS economic evaluation database	
PubMed	Same MeSH, keywords, limits used as per MEDLINE search
INAHTA	
US FDA	

8.2 Appendix 2

HIERARCHY OF EVIDENCE FOR EFFECTIVENESS STUDIES

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)

Evidence Table : Effectiveness
Question : What is the most ideal/appropriate method for male circumcisions in term of their efficiency? (**NON-DISPOSABLE DEVICES VS CONVENTIONAL: IN ADOLESCENT/ADULTS**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
1. Millard PS, Wilson HR, Veldkamp PJ et al. Rapid, minimally invasive adult voluntary male circumcision: A randomised trial. S Afr Med J 2013; 103(10): 736-742	**Randomised controlled trial** To compare a minimally invasive technique using the Gomco circumcision clamp plus tissue adhesive with conventional open surgical circumcision with suturing. This was a single-centre non-blinded RCT with allocation in balanced blocks of 10 using a random number table. The slip of paper with the group assignment was folded and placed in sealed, opaque envelopes. Each envelope was opened only at the time of surgery. **Primary outcome**: Intraoperative time **Secondary outcomes**: Doctor-described ease in performing the technique, operative and post-operative complications, post-operative pain, time to healing, patient satisfaction, and cosmetic result. A 10-point visual analogue scale was used for pain evaluation in the first 48 hours after circumcision and a 5-point Likert scale to grade satisfaction.	**I**	A total of 200 healthy uncircumcised men (>18 years)	Gomco circumcision clamp with cyanoacrylate skin adhesive (n=100)	Open surgical technique - dorsal slit (n=100)	At two days, seven days, two weeks, and four weeks	Intraoperative time were less with the Gomco/tissue adhesive technique (mean 12.8 versus 22.5 minutes; p<0.001). Pain scores were low and there was less pain in the Gomco group during the first 48 hours (1.8 versus 2.5 on a 10-point scale; p=0.008). There were no differences in healing at four weeks or in patient satisfaction. The cosmetic result was superior in the Gomco group, a regular scar line developing in 98.9% versus 58.5% of patients (p<0.001). **Author conclusion:** This study has important implications for the scale-up of voluntary medical male circumcision (VMMC) services. Removal of the foreskin with the Gomco instrument and sealing the wound with tissue adhesive had several advantages over traditional open surgical circumcision: it required much less operative time, was easier to perform, and had much better cosmetic results.	

Evidence Table : Effectiveness
Question : What is the most ideal/appropriate method for male circumcisions in term of their efficiency? (**DISPOSABLE DEVICES VS CONVENTIONAL: IN MEN**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
2. Cao D, Liu L, Hu Y et al. A systematic review and meta-analysis of circumcision with Shang Ring vs conventional circumcision. Urology. 2015; 85(4): 799-804	**Systematic review and meta-analysis** A systematic literature search using the MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, and Google Scholar databases were performed. All the selected trials were RCTs. Study selection was based on Preferred Reporting Items for Systematic Reviews and Meta-analysis criteria (PRISMA). Two reviewers independently evaluated study quality using the Jadad scale score. The following outcome measures were defined from the included studies: operative time, intraoperative pain score, penile appearance (PA)/cosmetic results, wound healing time, blood loss, and adverse event rate (AER). Statistical analysis of dichotomous variables (PA, AER, wound bleeding rate, wound oedema rate, wound infection rate, and wound dehiscence rate) was performed using the risk ratio (RR) as the summary analysis, whereas continuous variables (operative time, intraoperative pain score, wound healing time, and blood loss) were analysed using the mean difference (MD); accompanying 95% confidence intervals (CIs) and p values were reported. For these results, $p<0.05$ was considered statistically significant. The Mantel-Haenszel chi-square test for heterogeneity was conducted. Heterogeneity was assessed using the I^2 statistic. I^2 values ≤50% were defined as acceptable, whereas those >50% indicated high levels of heterogeneity. When there was a lack of heterogeneity, a fixed-effects model was applied. Otherwise, a random-effects model was applied when heterogeneity was >50%.	**I**	A total of 3,314 male patients in the 8 study trials; 1,815 who received SRC and 1,499 who received CC.	Shang Ring circumcision	Conventional circumcision		**Operative time (minutes)** In the meta-analysis of the seven studies (n=3,176) using the random-effects model, the pooled estimates showed that there was a statistically significant difference between the two groups (MD, -17.44; 95% CI: -21.61, -13.27; $p<0.001$), with the SRC group showing a markedly shorter operative time relative to the CC group. **Intraoperative pain score** In the pooled estimates (four studies, n=2,513), using a random-effects model, a statistically significant difference was observed in favour of the SRC group, which showed significantly lower intraoperative pain scores in comparison with the CC group (MD, -3.13; 95% CI: -3.79, -2.47; $p<0.001$). **Penile appearance** Participant satisfaction rate was measured in five studies (n=2,721). A random-effects model was used in the pooled analysis. The data from meta-analysis demonstrated that patients in the SRC group reported higher satisfaction with PA compared with patients in the CC group (RR, 1.29; 95% CI: 1.07, 1.56; $p=0.007$). **Wound healing time (days)** Data on wound healing time were extracted for forest plot analysis from four studies (n=2,583). There was no significant difference in wound healing time between the SRC and CC groups (MD, 2.55; 95% CI: -0.80, 5.91; $p=0.14$)	

Evidence Table : Effectiveness and safety
Question : What is the most ideal/appropriate method for male circumcisions in term of their efficiency and safety? (**DISPOSABLE DEVICES VS CONVENTIONAL: IN MEN**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
3. Fan Y, Cao D, Wei Q et al. The characteristics of circular disposable devices and in situ devices for optimizing male circumcision: a network meta-analysis. Sci Rep. 2016; 9:6: 25514	**Systematic review and network meta-analysis** **Objective**: To assess the safety and efficacy of in situ device (ISD) and circular disposable device (CDD) and to evaluate the characteristics of these devices for optimizing male circumcision (MC). **Data sources**: A systematic bibliographic search of PubMed, Embase, and the Cochrane Library databases (the Cochrane Central Register of Controlled Trials and the Cochrane database of Systematic Reviews) of Ovid was done for RCTs that reported using disposable devices to complete adult MCs. The methodological quality of each selected trial was assessed according to the Cochrane Collaboration Risk of Bias Tool in Review Manager 5.3. **Outcome measures**: Intraoperative blood loss (IB), operative time (OT), mean pain score on the operation day (PO), mean pain score of postoperative days (PP), overall incidence of complication, wound healing time (WHT), satisfaction rate (SR), incidence of wound adverse event (WAE), incidence of wound bleeding (WB), incidence of wound dehiscence (WD), incidence of wound edema (WE), incidence of wound infection (WI), and overall expenditure (cost).	**I**	Ten RCTs involving 4,649 men were identified and included in the meta-analysis	ISD (Shang Ring and PrePex) CDD (circular stapler and Unicirc)	Conventional circumcision (CC) – all non-device (e.g., sleeve and dorsal slit) *The comparisons were between at least two of ISD, CDD, and CC.*	Between 14 and 90 days	These trials were conducted in China and some countries in Africa. The methodological quality of RCTs was moderate due to inadequacies in allocation concealment and blinding because of ethical issues and properties of the surgical studies. Five studies compared CDD versus CC, six compared ISD versus CC, and one compared CDD versus ISD directly. However, the numbers of comparisons were variable and less than ten in each of the analysed outcomes - considered the publication bias in each comparison. **Comparisons between CDD and CC** Five studies involving 2,026 men were included in the meta-analysis. The statistically significant outcomes were IB, OT, PO, PP, and WHT. CDD showed less IB [standard mean difference (SMD): −3.12 (−4.32, −1.92)], less OT [SMD: −4.33 (−6.43, −2.23)], less WHT [SMD: −0.88 (−1.18, −0.58)], less PO [SMD: −1.51 (−2.55, −0.46)], and less PP [SMD: −1.38 (−2.28, −0.48)] compared with CC. **Comparisons between ISD and CC** Five studies involving 2,937 men were included in the meta-analysis. The statistically significant outcomes were IB, OT, SR, WB, and WE. ISD showed less IB [SMD: −3.25 (−3.65, −2.85)], less OT [SMD: −5.72 (−7.11, −4.33)], a higher SR [risk ratios (RR): 1.17 (1.02, 1.35)], less WB [RR: 0.16 (0.03, 0.76)], and less WE [RR: 0.69 (0.53, 0.88)] compared with CC. **Comparisons between CDD and ISD** Only one study involving 628 men was included in the meta-analysis. The statistically significant outcomes were observed for IB, OT, PO, PP, SR, WAE, WB, WE, WHT, and	

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
							WI. CDD showed more IB [SMD: 0.33 (0.17, 0.48)], more OT [SMD: 0.48 (0.32, 0.63)], less PO [SMD: −2.23 (−2.43, −2.03)], less PP [SMD: −2.39 (−2.59, −2.18)], a higher SR [RR: 1.57 (1.39, 1.78)], less WAE [RR: 0.30 (0.20, 0.45)], more WB [RR: 21.0 (1.24, 357)], less WE [RR: 0.10 (0.05, 0.24)], less WHT [SMD: −0.74 (−0.90, −0.58)], and less WI [RR: 0.04 (0.002, 0.62)] compared with ISD. **Authors conclusion:** The clinical performance of disposable devices used in adult MC exceeded that of CC. CDD circumcision tends to have the best wound healing condition and the least pain experience. ISD circumcision tends to have the lowest operative time, least intraoperative blood loss, least incidence of wound bleeding, and highest satisfaction rate. Each device has its own advantages and these should be discussed with men prior to their circumcision.	

Evidence Table : Effectiveness
Question : What is the most ideal/appropriate method for male circumcisions in term of their efficiency? (**DISPOSABLE DEVICES VS CONVENTIONAL: IN CHILDREN**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
4. Nagdeve NG, Naik H, Bhingare PD et al. Parental evaluation of postoperative outcome of circumcision with Plastibell or conventional dissection by dorsal slit technique: a randomized controlled trial. J Pediatr Urol. 2013; 9(5): 675-682	**Randomised controlled trial** To evaluate and compare parental satisfaction after Plastibell (PD) and conventional dissection circumcision (CDS). A block randomisation scheme was used with equal allocation of subjects to the PD and CDS groups. Written questionnaires were given to parents at time of discharge, and they were told to complete and return them. The questionnaire consisted of two parts. The first part was related to the problems faced by the parents/patients in the early postoperative period. The second part of the questionnaire was about the parents' satisfaction regarding aesthetic outcome. All the parents whose children belonged to the Plastibell group were told to note the day of separation of the Plastibell. After the first postoperative visit, all parents were instructed to perform repetitive traction of the remaining prepuce twice a day to avoid adhesions and retraction of the surgical scar. Parents were told to report if their child experienced increased bleeding, dysuria and discharge of pus from surgical wound, proximal migration of the Plastibell, or device not separating for 20 days.	**I**	A total of 198 children younger than 12 years (including neonates) who required circumcision for various indications were randomised and allocated into two groups: PD and CDS	Plastibell device	Conventional dissection circumcision – dorsal slit technique	7th, 15th (or after separation of Plastibell; whichever later) and 90th day after surgery	The two groups were comparable with respect to age, weight, indications for circumcision and Kayaba's classification of the prepuce. Surgical duration was significantly shorter for the PD group as compared to the CDS group (5.91 ± 1.74 versus 23.52 ± 5.94 minutes; p<0.0001). The time taken for separation of the Plastibell device ranged from seven to 20 days with a mean of 10.85 ± 2.49 days. Furthermore, Kaplan-Meier analysis showed that the bell separated earlier in younger children (p<0.0001). Children in the PD group used analgesics after surgery 2.79 fold more than those in the CDS group (5.14 ± 1.88 versus 2.21 ± 0.84 days (hazard ratio: 2.79; 95% CI: 1.61, 4.83; p<0.0001).	

Evidence Table : Effectiveness
Question : What is the most ideal/appropriate method for male circumcisions in term of their efficiency? (**DISPOSABLE DEVICES VS CONVENTIONAL: IN CHILDREN**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
5. Karadag MA, Cecen K, Demir A et al. SmartClamp circumcision versus conventional dissection technique in terms of parental anxiety and outcomes: A prospective clinical study. Can Urol Assoc J. 2015; 9(1-2):E10-3	**Non-randomised clinical trial** They analysed parental anxiety and outcomes for the SmartClamp circumcision and the classic surgical dissection technique. After clinical and preoperative evaluation, the first 125 children were circumcised by the conventional dissection technique (CDT; sleeve technique) and the remaining children were operated by the SmartClamp method. All children in both groups were compared in terms of bleeding, infection, penile oedema, operative time, cosmetic result, length of the inner mucosal layer, and parental anxiety. Cosmetic result and length of the inner mucosal layer were evaluated by a blinded urologist after 6-weeks. A state-trait anxiety inventory (STAI) form was used to measure the impact of circumcision on parental anxiety. This form was completed by parents on postoperative day two.	**II-1**	A total of 250 boys aged two to 10 years. Children with hypospadias, buried penis, ventral chordae or other genital anomalies and bleeding disorders were excluded from the study.	SmartClamp (SC)	Classic surgical dissection – sleeve resection		The operative time of the SmartClamp group was statistically shorter than for the CDT group (6.93 ± 2.58 versus 18.08 ± 3.55 minutes; p<0.001). No significant differences were encountered in cosmetic displeasure (p=0.109). **Authors conclusion:** Circumcision with SC device was faster, when compared to CDT. Cosmetic results and complication rates were similar.	

Evidence Table : Effectiveness
Question : What is the most ideal/appropriate method for male circumcisions in term of their efficiency? (**DISPOSABLE DEVICES VS CONVENTIONAL: IN ADOLESCENT & ADULTS**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
6. Lagarde E, Taljaard D, Puren A et al. High rate of adverse events following circumcision of young male adults with the Tara KLamp technique: a randomised trial in South Africa. S Afr Med J. 2009; 99(3): 163-169	**Randomised controlled trial** This RCT compared two methods of male circumcision. Participants of the control group of the male circumcision randomised controlled trial (MCRCT) conducted in South Africa on 3,274 uncircumcised men aged 18 to 24 were asked to participate in a randomised sub-trial to compare the safety of the Tara KLamp (TK) technique with the conventional forceps-guided (FG) method. Men were recruited from among the 1,654 control group of the MCRCT participants who had been offered circumcision at the end of the follow-up, 21 months after inclusion in the MCRCT. For randomisation, each participant chose an envelope containing the group name from a basket of 10 envelopes. Assessment criteria included: (1) comparison of circumcision methods according to the number and nature of adverse events reported by the GP who performed the procedure; (2) the nurse's clinical assessment, which included any signs of adverse events, observed penile infection or delay in wound healing, problem with penis appearance, excessive or insufficient skin removed and any erectile dysfunction; and (3) participants' reports, which included pain score, bleeding within the two weeks following the procedure, lesions to the penis, swelling or haematoma within the two weeks following the procedure, any problem when urinating, and satisfaction with penis appearance	**I**	A total of 166 men (uncircumcised, no contraindication to circumcision, good general health with normal physical and genital condition) were asked to participate	Tara KLamp (TK) technique	Conventional forceps-guided (FG) method	Three days and 6-weeks after surgery	Of the 166 patients asked to participate in the study, 97 refused; all agreed to give reasons for refusal, most (n=94) saying that they did not want to be circumcised by the TK technique. Of the 69 participants who agreed to participate, 34 were randomised to the FG group and 35 to the TK group; four participants in the TK group were eventually circumcised by the FG method (cross-over). All FG group participants were circumcised with the FG method. Among the 69 randomised participants, six from the FG group and seven from the TK group did not visit the GP for circumcision and were excluded from the analysis. The post-circumcision visit was attended by 91% (29/32) of those circumcised by the FG method and 79% (19/24) of those circumcised with the TK method. No statistical differences were found related to socio-demographic characteristics, sexual experience, health-related behaviour or history of medical problems (hospitalisations and ulcerations). The mean scores for pain were 6.1 and 9.5 among those circumcised by the FG and TK methods respectively, which was statistically significant. Almost all participants were satisfied with the appearance of their penis. On clinical examination by nurse, men circumcised by the TK method were significantly more likely to have at least one sign of an adverse event (37% vs. 3%; p=0.004), delayed wound healing (21% vs. 3%; p=0.004) and problems with penis appearance (31% vs. 3%; p=0.001).	Neither GPs, participants nor investigators were blinded to the randomisation group. At interview, the nurse was not aware of the method used but on examination could conclude which technique was used.

Evidence Table : Effectiveness
Question : What is the most ideal/appropriate method for male circumcisions in term of their efficiency? (**DISPOSABLE DEVICES VS CONVENTIONAL: IN ADOLESCENT & ADULTS**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
7. Wang J, Zhou Y, Xia S et al. Safety and efficacy of a novel disposable circumcision device: A pilot randomized controlled clinical trial at 2 centers. Med Sci Monit. 2014; 20: 454-462	**Randomised controlled trial** To evaluate the safety and efficacy of a circular stapler device for male circumcision (MC). A multi-center pilot clinical trial was conducted at two Chinese hospitals to compare intra- and postoperative outcomes of MC using this device with conventional dissection technique (CDT). Patients were randomly divided into two groups using a computerized random table method generated by SAS 8.0 (SAS, Cary, NC). Intraoperative bleeding, surgery duration, pain, healing, and satisfaction with penis appearance were assessed. Adverse events (AEs) were noted.	**I**	Adult male patients (n=120; mean age, 26.6 years) with redundant foreskin and/or phimosis. Patients were divided into two groups and subjected to MC with a circular stapler device (n=60) or to CDT (n=60).	Circular stapler device	Conventional dissection technique (CDT) (sleeve resection)	One, three, seven, and 14 days following surgery	**Clinical characteristics:** No significant differences (in age, height or weight, clinical baseline parameters, clinical examination results, routine blood test results or ECG) were observed between the groups ($p>0.05$). No significant variations of body temperature, pulse, respiration, systolic blood pressure, and diastolic blood pressure were observed between the Device and Control Groups at pre-surgical examinations or at follow-up day 1, 3, 7, or 15 ($p>0.05$). **Intraoperative time** Significantly different mean surgical times of 7.6 ± 4.5 (2–23) min and 23.6 ± 4.4 (15–35) min in the Device Group and the Control Group, respectively, were observed ($p<0.01$). **Surgical success rates:** Surgical success rates of 96.7% (58/60) and 100% (60/60) were observed in the Device Group and Control Group, respectively. **Outcomes of surgical MC treatments:** The majority of patients in both groups reported acceptable healing by day seven (88%, 53/60 Control Group patients; 84%, 49/58 Device Group patients). By day 14, all patients reported complete covering of the wound by epithelium, consistent with the acceptable healing designation.	

Evidence Table : Effectiveness
Question : What is the most ideal/appropriate method for male circumcisions in term of their efficiency? (**DISPOSABLE DEVICES VS CONVENTIONAL: IN ADOLESCENT & ADULTS**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
8. Zhang Z, Yang B, Yu W et al. Application of a novel disposable suture device in circumcision: a prospective non‐randomized controlled study. Int Urol Nephrol. 2016; 48: 465–473	**Prospective non-randomised controlled trial** To compare the surgical effects and postoperative complications and patient experience of two circumcision methods in Chinese excess foreskin or phimosis patients. The duration of each operation in minute and the total cost of each patient were recorded. During the surgery, intraoperative blood loss was calculated by weighing the gauzes. A visual scale (0–10) was used to assess the pain level. Intraoperative pain score was collected immediately after the surgery. Postoperative assessment at one week included postoperative pain score. At their visit at one month after the operation, the recovery duration (from the date of discharging to the date of getting back to work) and incision healing time for each patient were collected. The incision healing time was determined based on the check of the wound and the inquiry of the patients by the doctors at 1-week and 1-month follow-up. Patients were also asked whether they were satisfied with their cosmetic penis appearances at 1-month visit. The incidence of complications was also recorded at the follow-up. Multivariate logistic regression with likelihood ratio test was used to observe the significant predictors of oedema occurrence postoperatively.	**II-1**	A total of 520 cases of excess foreskin and 62 phimosis patients underwent circumcision in a single centre using circular stapler device (n=295; mean age 30.4 years, range 18–44 years) and conventional suture approach (n=287; mean age 28.6 years, range 16–41 years)	Circular stapler device	Conventional suture approach (sleeve resection)	At 1-week and 1-months after operation	Circumcision using circular stapler device was performed in 295 patients (excess foreskin, n=265; phimosis, n=30). Circumcision with conventional suture procedure was conducted on 287 patients (excess foreskin, n=255; phimosis, n=32). The patient age, percentage of excess foreskin patients, the marital status, and the educational level between the two groups were similar. All surgery procedures in the two groups were completed well, with no intraoperative complications occurred. The operation time (minutes) in the disposable suture group was significantly shorter than that in the conventional group (10.2 ± 1.2 versus 28.4 ± 2.4; p=0.000). Similar trend was found in intraoperative pain score (2.2 ± 0.8 versus 6.6 ± 1.0; p=0.022). At follow-up, patients in the disposable suture device group experienced a shorter incision healing time (days) (14.5 ± 2.2 versus 20.8 ± 3.4; p=0.034) and recovery time (days) (3.4 ± 0.8 versus 8.7 ± 2.0; p=0.041) when compared to the conventional circumcision group. The comparison of postoperative pain score at 1-week yielded significant results as well (p=0.021).	

Evidence Table : Effectiveness
Question : What is the most ideal/appropriate method for male circumcisions in term of their efficiency? (**DISPOSABLE DEVICES VS CONVENTIONAL: IN INFANTS**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
9. Mousavi SA, Salehifar E. Circumcision complications associated with the Plastibell device and conventional dissection surgery: a trial of 586 infants of ages up to 12 months. Adv Urol. 2008: 606123	**Randomised controlled trial** To compare the various complications of two methods of circumcision in infantile age. Infants were randomised in one of two groups unless the parents insisted on a particular circumcision method. Acetaminophen drop was used as an analgesic for children in both operations. All children were followed up until the wound was healed, along with observing them for any associated complications. The complications are, for example, infection, bleeding or haematoma, excess mucosa, bell disposition (entrapping the ring), and delayed falling. Data were analysed by SPSS 11.5 software, and p-value of <0.05 was considered as a significant difference. The frequency of complications between two groups was assessed by chi square test. Correlations between age and weight of cases with the separation time of the Plastibell method were investigated by Pearson correlation test.	**I**	A total of 586 infants equal to or less than 12 months; full-term healthy males without any medical indication or urological anomaly	Plastibell method (n=381)	Conventional dissection surgery (CDS) (sleeve resection) (n=205)		The mean age of both groups was less than six months. Considering the age and weight of the children, more than 90% had a normal weight. There was a significant positive correlation between the age and weight of subjects within the time of ring separation ($p<0.001$). This indicates that the ring separated faster in younger children. An obvious advantage of using the Plastibell was the short surgery time. Average procedure duration with the PD group was 3.4 minutes, compared with 9.2 minutes with the sleeve resection. **Authors conclusion:** The bell separation time directly correlates with the age and weight of infants. The results of this study suggest the Plastibell method for neonates and low-weight infants with thin prepuce, and the CDS for other infants.	

Evidence Table : Effectiveness
Question : What is the most ideal/appropriate method for male circumcisions in term of their efficiency? (**LASER VS CONVENTIONAL: IN ADOLESCENT & ADULTS**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
10. Xu Y, Li F, Li Z et al. A prospective, randomized controlled trial of circumcision in adult males using the CO2 laser: modified technique compared with the conventional dorsal-slit technique. Photomedicine and Laser Surgery. 2013; 31(9): 422-427	**Randomised controlled trial** To investigate the safety and efficacy of a modified CO_2 laser technique for circumcision in adult males as compared with the conventional dorsal-slit method. Participants were randomised to the laser group or the conventional group using computer generated, sequentially numbered, opaque sealed envelopes (patient-blinded study). The following parameters were recorded during the surgery: operating time and intraoperative blood loss. As for pain assessment, participants were asked to rate their postoperative pain at 1-day and 7-days using a visual analogue scale (VAS) displaying numbers and words describing levels of pain from 0=no pain to 10=worst pain possible. Side effects were monitored closely during the postoperative period. In order to rule out the subjective bias, the people recording the intraoperative data, VAS score, and postoperative complications were blinded to the techniques.	**I**	A total of 300 patients >18 years of age were recruited for circumcision with the indications of phimosis, recurrent balanoposthitis, and patient requests.	Modified CO_2 laser technique	Conventional dorsal-slit method	At 1-day, 1-week, 2-weeks, 1-month, and 3-months post-operatively	Patients in both groups had similar age distribution and indications for circumcision. Comparison of the patients in the two groups demonstrated a 10 minutes decrease in the operative time in the laser-treated group (10.5 ± 0.9 versus 21.1 ± 2.7 minutes, $p<0.05$). The CO_2 laser technique was associated with much less pain at both 1-day (2.9 ± 1.9 versus 4.9 ± 2.5, $p<0.05$) and 7-days (1.2 ± 0.5 versus 1.9 ± 1.3, $p<0.05$) postoperatively. In both groups, follow-up visits demonstrated excellent cosmetic results, and no secondary operations were performed because of unacceptable appearance. **Authors conclusion:** The modified CO_2 laser technique offers a simple, faster, and effective alternative method to the conventional technique in adult male circumcision with decreased pain experience.	

Evidence Table : Effectiveness
Question : What is the most ideal/appropriate method for male circumcisions in term of their efficiency? (**LASER VS CONVENTIONAL: IN CHILDREN**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
11. Gorgulu T, Olgun A, Torun M et al. A fast, easy circumcision procedure combining a CO2 laser and cyanoacrylate adhesive: a non-randomized comparative trial. Int Braz J Urol. 2016; 42: 113-117	**Non-randomised comparative trial** This study examined the combined use of a CO_2 laser and cyanoacrylate for shortening the operating time and reducing complications related to bleeding.	**II-1**	A total of 75 boys, aged 6–9 (median 7) years. As a control, they compared them retrospectively with 75 age-matched patients who were circumcised using the conventional guillotine method. In all cases, the parents had requested circumcision for religious reasons.	A CO_2 laser and cyanoacrylate combination	Conventional guillotine method	12 (range 4–18) months on average.	In a CO_2 laser and cyanoacrylate combination, wound healing took one week. The median operating time was seven minutes (range 6–9) using the CO_2 laser and 22 minutes (range 20-26) in the conventional guillotine group. The difference in surgical time was significant ($p<0.001$). **Authors conclusion:** The combined CO_2 laser and cyanoacrylate procedure overcomes the disadvantages observed with each circumcision procedure alone and shortening the operating time.	

Evidence Table : Safety
Question : What is the most ideal/appropriate method for male circumcisions in term of their safety? (**NON-DISPOSABLE DEVICES VS CONVENTIONAL: IN ADOLESCENT/ADULTS**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
1. Millard PS, Wilson HR, Veldkamp PJ et al. Rapid, minimally invasive adult voluntary male circumcision: A randomised trial. S Afr Med J 2013; 103(10): 736-742	**Randomised controlled trial** To compare a minimally invasive technique using the Gomco circumcision clamp plus tissue adhesive with conventional open surgical circumcision with suturing. This was a single-centre non-blinded RCT with allocation in balanced blocks of 10 using a random number table. The slip of paper with the group assignment was folded and placed in sealed, opaque envelopes. Each envelope was opened only at the time of surgery. **Primary outcome**: Intraoperative time **Secondary outcomes**: Doctor-described ease in performing the technique, operative and post-operative complications, post-operative pain, time to healing, patient satisfaction, and cosmetic result. A 10-point visual analogue scale was used for pain evaluation in the first 48 hours after circumcision and a 5-point Likert scale to grade satisfaction.	**I**	A total of 200 healthy uncircumcised men (>18 years)	Gomco circumcision clamp with cyanoacrylate skin adhesive (n=100)	Open surgical technique - dorsal slit (n=100)	At two days, seven days, two weeks, and four weeks	There was no significant difference between the two groups in terms of bleeding, haematoma or infection, either taken individually or as a composite. The rate of wound infection was 6.9% prior to the use of prophylactic antibiotics and 1.4% after initiation of cloxacillin prophylaxis. Wound disruptions >2 cm occurred in 1% of the Gomco circumcisions at 2-days, 10.1% at 1-week, and 20.8% at 2-weeks. Wound disruptions were not more than 5 mm in width, and none required surgical closure. The rate of >2 cm wound length disruption was 24.4% using adherent dressing and 18.2% after it was discontinued. **Author conclusion:** Removal of the foreskin with the Gomco instrument and sealing the wound with tissue adhesive was potentially safer over traditional open surgical circumcision. This method can greatly facilitate scale-up of mass circumcision programmes. A disposable plastic, Gomco- like device should be produced and evaluated for use in resource-limited settings.	

Evidence Table : Safety
Question : What is the most ideal/appropriate method for male circumcisions in term of their safety? (**DISPOSABLE DEVICES VS CONVENTIONAL: IN MEN**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
2. Cao D, Liu L, Hu Y et al. A systematic review and meta-analysis of circumcision with Shang Ring vs conventional circumcision. Urology. 2015; 85(4): 799-804	**Systematic review and meta-analysis** To compare the safety and efficacy of Shang Ring circumcision (SRC) with conventional circumcision (CC) for male patients. A systematic literature search using the MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, and Google Scholar databases were performed. All the selected trials were RCTs. Study selection was based on Preferred Reporting Items for Systematic Reviews and Meta-analysis criteria (PRISMA). Two reviewers independently evaluated study quality using the Jadad scale score. The following outcome measures were defined from the included studies: operative time, intraoperative pain score, penile appearance (PA)/cosmetic results, wound healing time, blood loss, and adverse event rate (AER). Statistical analysis of dichotomous variables (PA, AER, wound bleeding rate, wound edema rate, wound infection rate, and wound dehiscence rate) was performed using the risk ratio (RR) as the summary analysis, whereas continuous variables (operative time, intraoperative pain score, wound healing time, and blood loss) were analysed using the mean difference (MD); accompanying 95% confidence intervals (CIs) and p values were reported. For these results, $p<0.05$ was considered statistically significant. The Mantel-Haenszel chi-square test for heterogeneity was conducted. Heterogeneity was assessed using the I^2 statistic. I^2 values ≤50% were defined as acceptable, whereas those >50% indicated high levels of heterogeneity. When there was a lack of heterogeneity, a fixed-effects model was applied. Otherwise, a random-effects model was applied when heterogeneity was >50%.	**I**	A total of 3,314 male patients in the 8 study trials; 1,815 who received SRC and 1,499 who received CC.	Shang Ring circumcision	Conventional circumcision		**Adverse event rate** A lower AER was observed in the SRC group in comparison with the CC group (RR, 0.54; 95% CI: 0.39, 0.74; $p<0.001$; $I^2=32\%$). Wound bleeding rate, which is one of the most common complication, was observed less frequently in the SRC group than in the CC group (RR, 0.06; 95% CI: 0.02, 0.14;$p<0.001$; $I^2=0\%$). Other complications showed no significant difference between the 2 groups: wound oedema rate (RR, 0.92; 95% CI: 0.55, 1.53; $p=0.75$; $I^2=82\%$), wound infection rate (RR, 0.43; 95% CI: 0.10, 1.83; $p=0.26$; $I^2=86\%$), and wound dehiscence rate (RR, 1.01; 95% CI, 0.66, 1.55; $p=0.96$; $I^2=0\%$). **Authors conclusions:** SRC is associated with less intraoperative blood loss, lower AER, and lower wound bleeding rate relative to CC. Thus, it seems that SRC is a safer and more effective choice than CC for conducting MC.	

Evidence Table : Safety
Question : What is the most ideal/appropriate method for male circumcisions in term of their safety? (**DISPOSABLE DEVICES VS CONVENTIONAL: IN CHILDREN**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
3. Nagdeve NG, Naik H, Bhingare PD et al. Parental evaluation of postoperative outcome of circumcision with Plastibell or conventional dissection by dorsal slit technique: a randomized controlled trial. J Pediatr Urol. 2013; 9(5): 675-682	**Randomised controlled trial** To evaluate and compare parental satisfaction after Plastibell (PD) and conventional dissection circumcision (CDS). A block randomisation scheme was used with equal allocation of subjects to the PD and CDS groups. Written questionnaires were given to parents at time of discharge, and they were told to complete and return them. The questionnaire consisted of two parts. The first part was related to the problems faced by the parents/patients in the early postoperative period. The second part of the questionnaire was about the parents' satisfaction regarding aesthetic outcome. All the parents whose children belonged to the Plastibell group were told to note the day of separation of the Plastibell. After the first postoperative visit, all parents were instructed to perform repetitive traction of the remaining prepuce twice a day to avoid adhesions and retraction of the surgical scar. Parents were told to report if their child experienced increased bleeding, dysuria and discharge of pus from surgical wound, proximal migration of the Plastibell, or device not separating for 20 days.	**I**	A total of 198 children younger than 12 years (including neonates) who required circumcision for various indications were randomised and allocated into two groups: PD and CDS	Plastibell device	Conventional dissection circumcision – dorsal slit technique	7th, 15th (or after separation of Plastibell; whichever later) and 90th day after surgery	Swelling, dysuria and infection were the prominent problems noted in both groups (p=0.070) in the first 7-days. At second follow-up, there were significantly more complications in the CDS group than the PD group (20.85% versus 4.25%; p<0.05), which included irregular cicatrical scars (16.66% versus 0%; p<0.001) and postoperative adhesions (25.04% versus 6.38%; p<0.001).	

Evidence Table : Safety
Question : What is the most ideal/appropriate method for male circumcisions in term of their safety? (**DISPOSABLE DEVICES VS CONVENTIONAL: IN CHILDREN**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
4. Karadag MA, Cecen K, Demir A et al. SmartClamp circumcision versus conventional dissection technique in terms of parental anxiety and outcomes: A prospective clinical study. Can Urol Assoc J. 2015; 9(1-2):E10-3	**Non-randomised clinical trial** They analysed parental anxiety and outcomes for the SmartClamp circumcision and the classic surgical dissection technique. After clinical and preoperative evaluation, the first 125 children were circumcised by the conventional dissection technique (CDT; sleeve technique) and the remaining children were operated by the SmartClamp method. All children in both groups were compared in terms of bleeding, infection, penile edema, operative time, cosmetic result, length of the inner mucosal layer, and parental anxiety. Cosmetic result and length of the inner mucosal layer were evaluated by a blinded urologist after 6-weeks. A state-trait anxiety inventory (STAI) form was used to measure the impact of circumcision on parental anxiety. This form was completed by parents on postoperative day 2.	**II-1**	A total of 250 boys aged two to 10 years. Children with hypospadias, buried penis, ventral chordae or other genital anomalies and bleeding disorders were excluded from the study.	SmartClamp	Classic surgical dissection – sleeve resection		There were no statistically significant differences among the two groups in terms of age, bleeding, and infection ($p>0.05$). Penile oedema was significantly more common in the SmartClamp group ($p=0.039$) and the inner mucosal length (mm) was longer compared to CDT (14.10 ± 3.46 versus 5.09 ± 1.22; $p<0.001$). **Authors conclusion:** SmartClamp seemed to carry the disadvantages of longer mucosal length and penile oedema. These points should be kept in mind by the urologists before choosing this technique.	

Evidence Table : Safety
Question : What is the most ideal/appropriate method for male circumcisions in term of their safety? (**DISPOSABLE DEVICES VS CONVENTIONAL: IN ADOLESCENT & ADULTS**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
5. Lagarde E, Taljaard D, Puren A et al. High rate of adverse events following circumcision of young male adults with the Tara KLamp technique: a randomised trial in South Africa. S Afr Med J. 2009; 99(3): 163-169	**Randomised controlled trial** This RCT compared two methods of male circumcision. Participants of the control group of the male circumcision randomised controlled trial (MCRCT) conducted in South Africa on 3,274 uncircumcised men aged 18 to 24 were asked to participate in a randomised sub-trial to compare the safety of the Tara KLamp (TK) technique with the conventional forceps-guided (FG) method. Men were recruited from among the 1,654 control group of the MCRCT participants who had been offered circumcision at the end of the follow-up, 21 months after inclusion in the MCRCT. For randomisation, each participant chose an envelope containing the group name from a basket of 10 envelopes. Neither GPs, participants nor investigators were blinded to the randomisation group. At interview, the nurse was not aware of the method used but on examination could conclude which technique was used. Assessment criteria included: (1) comparison of circumcision methods according to the number and nature of adverse events reported by the GP who performed the procedure; (2) the nurse's clinical assessment, which included any signs of adverse events, observed penile infection or delay in wound healing, problem with penis appearance, excessive or insufficient skin removed and any erectile dysfunction; and (3) participants' reports, which included pain score, bleeding within the 2 weeks following the procedure, lesions to the penis, swelling or haematoma within the 2 weeks following the procedure, any problem when urinating, and satisfaction with penis appearance	**I**	A total of 166 men (uncircumcised, no contraindication to circumcision, good general health with normal physical and genital condition) were asked to participate	Tara KLamp (TK) technique	Conventional forceps-guided (FG) method	Three days and 6-weeks after surgery	A total of 12 adverse events were reported by the GPs during the course of the study, all corresponding to participants initially randomised to the TK group. Two participants were eventually circumcised by the FG method, as the TK method had failed. The mean and median intervals between circumcision and the post-circumcision visit were longer among those circumcised by the FG method. Participants circumcised by the TK method were significantly more likely to report bleeding, lesions to the penis, infection, swelling, haematoma and problems with urinating ($p<0.001$). On clinical examination by nurse, men circumcised by the TK method were significantly more likely to have at least one sign of an adverse event (37% vs. 3%; $p=0.004$), delayed wound healing (21% vs. 3%; $p=0.004$) and problems with penis appearance (31% vs. 3%; $p=0.001$). No participants were reported with a current infection, excessive or insufficient skin removed or erectile dysfunction. **Authors conclusion:** Given the high rate of adverse events and low number of available studies, this study provides compelling evidence that strongly cautions against use of the TK method on young adults.	

Evidence table : Safety
Question : What is the most ideal/appropriate method for male circumcisions in term of their safety? (**DISPOSABLE DEVICES VS CONVENTIONAL: IN ADOLESCENT & ADULTS**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
6. Wang J, Zhou Y, Xia S et al. Safety and efficacy of a novel disposable circumcision device: A pilot randomized controlled clinical trial at 2 centers. Med Sci Monit. 2014; 20: 454-462	**Randomised controlled trial** To evaluate the safety and efficacy of a circular stapler device for male circumcision (MC). A multi-center pilot clinical trial was conducted at two Chinese hospitals to compare intra- and postoperative outcomes of MC using this device with conventional dissection technique (CDT). Patients were randomly divided into two groups using a computerized random table method generated by SAS 8.0 (SAS, Cary, NC). Intraoperative bleeding, surgery duration, pain, healing, and satisfaction with penis appearance were assessed. Adverse events (AEs) were noted.	**I**	Adult male patients (n=120; mean age, 26.6 years) with redundant foreskin and/or phimosis. Patients were divided into two groups and subjected to MC with circular stapler device (n=60) or to CDT (n=60).	Circular stapler device	Conventional dissection technique (CDT) (sleeve resection)	One, three, seven, and 14 days following surgery	B**leeding results:** Significantly lower estimated intraoperative bleeding was observed in the Device Group (mean 3.5 ± 2.7 ml, ranging 15–35 ml) compared with the Control Group (mean 13.1 ± 6.1 ml, range 4–25 ml) ($p<0.01$), and no AEs due to postoperative bleeding or haematoma formation were reported in either group. **Adverse events:** Notably, no device-related accidents causing patient injury, post-surgical wound bleeding, dehiscence, infection, or other AEs were observed in any group. **Authors conclusion:** Notably, MC using circular stapler device resulted in reduced bleeding compared with CTD treatment.	

Evidence Table : Safety
Question : What is the most ideal/appropriate method for male circumcisions in term of their safety? (**DISPOSABLE DEVICES VS CONVENTIONAL: IN ADOLESCENT & ADULTS**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
7. Zhang Z, Yang B, Yu W et al. Application of a novel disposable suture device in circumcision: a prospective non‐randomized controlled study. Int Urol Nephrol. 2016; 48: 465–473	**Prospective non-randomised controlled trial** To compare the surgical effects and postoperative complications and patient experience of two circumcision methods in Chinese excess foreskin or phimosis patients. The duration of each operation in minute and the total cost of each patient were recorded. During the surgery, intraoperative blood loss was calculated by weighing the gauzes. A visual scale (0–10) was used to assess the pain level. Intraoperative pain score was collected immediately after the surgery. Postoperative assessment at 1-week included postoperative pain score. At their visit at 1-month after the operation, the recovery duration (from the date of discharging to the date of getting back to work) and incision healing time for each patient were collected. The incision healing time was determined based on the check of the wound and the inquiry of the patients by the doctors at 1-week and 1-month follow-up. Patients were also asked whether they were satisfied with their cosmetic penis appearances at 1-month visit. The incidence of complications was also recorded at the follow-up. Multivariate logistic regression with likelihood ratio test was used to observe the significant predictors of oedema occurrence postoperatively.	**II-1**	A total of 520 cases of excess foreskin and 62 phimosis patients underwent circumcision in a single centre using circular stapler device (n=295; mean age 30.4 years, range 18–44 years) and conventional suture approach (n=287; mean age 28.6 years, range 16–41 years)	Circular stapler device	Conventional suture approach – sleeve resection	At 1-week and 1-months after operation	The incidence of wound dehiscence, scar, oedema, and reoperation were similar between the two groups. Two patients (0.67%) had haematoma in the disposable suture device group. By contrast, a higher percentage of patients in the conventional group experienced haematoma (16/287, 5.6%). Notably, the incidences of incision bleeding and infection were also significantly lower in the disposable suture device group. A multivariate logistic regression with likelihood ratio test revealed that phimosis was the significant predictor of oedema occurrence postoperatively (Chi square of likelihood ratio=9.88, df=1, p=0.025). Of the total 30 phimosis patients in disposable suture device group, 18 (60%) developed postoperative oedema. By contrast, 20/32 (62.5%) phimosis patients in the conventional suture group had oedema postoperatively. Notably, they failed to identify the positive role of surgical options in the prediction of oedema. **Authors conclusion:** Circumcision using circular stapler device is associated with less complications. Phimosis patients should be notified that they had a great possibility to develop oedema postoperatively regardless of the surgical options.	

Evidence Table : Safety
Question : What is the most ideal/appropriate method for male circumcisions in term of their safety? (**DISPOSABLE DEVICES VS CONVENTIONAL: IN INFANTS**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
8. Mousavi SA, Salehifar E. Circumcision complications associated with the Plastibell device and conventional dissection surgery: a trial of 586 infants of ages up to 12 months. Adv Urol. 2008: 606123	**Randomised controlled trial** To compare the various complications of two methods of circumcision in infantile age. Infants were randomised in one of two groups unless the parents insisted on a particular circumcision method. Acetaminophen drop was used as an analgesic for children in both operations. All children were followed up until the wound was healed, along with observing them for any associated complications. The complications are, for example, infection, bleeding or haematoma, excess mucosa, bell disposition (entrapping the ring), and delayed falling. Data were analysed by SPSS 11.5 software, and p-value of <0.05 was considered as a significant difference. The frequency of complications between two groups was assessed by chi square test. Correlations between age and weight of cases with the separation time of the Plastibell method were investigated by Pearson correlation test.	**I**	A total of 586 infants equal to or less than 12 months; full-term healthy males without any medical indication or urological anomaly	Plastibell method (n=381)	Conventional dissection surgery (CDS) (sleeve resection) (n=205)		The overall complication rate of conventional surgical method was less than that of the Plastibell method (1.95% versus 7.08%). Although the p value of complication comparison between PD and CDS groups was a little more than 0.05, the hazard ratio is so high (7.08/1.95=3.6). In conventional dissection group, bleeding was the only complication and stopped with compress dressing. In Plastibell method, delayed separation of ring was the most common complication (2.6%) followed by bleeding, excess mucosa, infection, disposition, and hematoma. **Authors conclusion:** The overall complication rate of CDS is less than that of the Plastibell method. The results of this study suggest the Plastibell method for neonates and low-weight infants with thin prepuce, and the CDS for other infants.	

Evidence Table : Safety
Question : What is the most ideal/appropriate method for male circumcisions in term of their safety? (**LASER VS CONVENTIONAL: IN ADOLESCENT & ADULTS**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
9. Xu Y, Li F, Li Z et al. A prospective, randomized controlled trial of circumcision in adult males using the CO2 laser: modified technique compared with the conventional dorsal-slit technique. Photomed Laser Surg. 2013; 31(9): 422-427	**Randomised controlled trial** To investigate the safety and efficacy of a modified CO_2 laser technique for circumcision in adult males as compared with the conventional dorsal-slit method. Participants were randomised to the laser group or the conventional group using computer generated, sequentially numbered, opaque sealed envelopes (patient-blinded study). The following parameters were recorded during the surgery: operating time and intraoperative blood loss. As for pain assessment, participants were asked to rate their postoperative pain at 1-day and 7-days using a visual analogue scale (VAS) displaying numbers and words describing levels of pain from 0=no pain to 10=worst pain possible. Side effects were monitored closely during the postoperative period. In order to rule out the subjective bias, the people recording the intraoperative data, VAS score, and postoperative complications were blinded to the techniques.	**I**	A total of 300 patients >18 years of age were recruited for circumcision with the indications of phimosis, recurrent balanoposthitis, and patient requests.	Modified CO_2 laser technique	Conventional dorsal-slit method	At 1-day, 1-week, 2-weeks, 1-month, and 3-months post-operatively	The incidence of postoperative bleeding was 2.7%, and occurred only in the conventional group (four cases), within the 24 hours after the removal of the wound dressing. These patients were treated conservatively with compressive management, and none required a second operation to control the haemorrhage. In the laser-treated group, wound dehiscence requiring re-suturing was observed in one patient after intercourse at 23 days postoperatively. No patients in the conventional group developed wound dehiscence. The incidence of postoperative oedema was less in the laser group (2.0% versus 8.0%, $p<0.05$), none of these patients required any further treatment, and the oedema disappeared gradually within two to four weeks. The overall incidence of complications was less in the laser group (2.7% versus 10.7%, $p<0.05$). No patients developed late complications, such as adhesion, secondary phimosis, buried penis, or scar.	

Evidence Table : Safety
Question : What is the most ideal/appropriate method for male circumcisions in term of their safety? (**LASER VS CONVENTIONAL: IN CHILDREN**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
10. Gorgulu T, Olgun A, Torun M et al. A fast, easy circumcision procedure combining a CO2 laser and cyanoacrylate adhesive: a non-randomized comparative trial. Int Braz J Urol. 2016; 42: 113-117	**Non-randomised comparative trial** This study examined the combined use of a CO_2 laser and cyanoacrylate for shortening the operating time and reducing complications related to bleeding.	**II-1**	A total of 75 boys, aged 6–9 (median 7) years. As a control, they compared them retrospectively with 75 age-matched patients who were circumcised using the conventional guillotine method. In all cases, the parents had requested circumcision for religious reasons.	A CO_2 laser and cyanoacrylate combination	Conventional guillotine method	12 (range 4–18) months on average.	No haematomas, bleeding, or wound infections were observed. Dehiscence occurred in one child (1.3%) during the early postoperative period but healed spontaneously within one week. Six months postoperatively, the cases were similar in appearance to those who underwent the conventional procedure. In the conventional guillotine group, one haematoma (1.3%), two wound dehiscences (2.6%), and two haemorrhages (2.6%) were recorded, with no significant difference in the rate of complications between the two groups (p>0.5).	

Evidence Table : Psychological/social/ethical
Question : What is the ideal/appropriate method for male circumcisions from the social aspect? (**DISPOSABLE DEVICES VS CONVENTIONAL: IN CHILDREN**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
1. Nagdeve NG, Naik H, Bhingare PD et al. Parental evaluation of postoperative outcome of circumcision with Plastibell or conventional dissection by dorsal slit technique: a randomized controlled trial. J Pediatr Urol. 2013; 9(5): 675-682	**Randomised controlled trial** To evaluate and compare parental satisfaction after Plastibell (PD) and conventional dissection circumcision (CDS). A block randomisation scheme was used with equal allocation of subjects to the PD and CDS groups. Written questionnaires were given to parents at time of discharge, and they were told to complete and return them. The questionnaire consisted of two parts. The first part was related to the problems faced by the parents/patients in the early postoperative period. The second part of the questionnaire was about the parents' satisfaction regarding aesthetic outcome. All the parents whose children belonged to the Plastibell group were told to note the day of separation of the Plastibell. After the first postoperative visit, all parents were instructed to perform repetitive traction of the remaining prepuce twice a day to avoid adhesions and retraction of the surgical scar. Parents were told to report if their child experienced increased bleeding, dysuria and discharge of pus from surgical wound, proximal migration of the Plastibell, or device not separating for 20 days.	**I**	A total of 198 children younger than 12 years (including neonates) who required circumcision for various indications were randomised and allocated into two groups: PD and CDS	Plastibell device	Conventional dissection circumcision – dorsal slit technique	7th, 15th (or after separation of Plastibell; whichever later) and 90th day after surgery	**Evaluation of parental questionnaire:** There was no statistical difference with regard to parental concern about pain (managed with analgesics) (p=0.164), infection (p=0.632), and dysuria (p=0.140). However, PD group parents were statistically significantly more concerned about swelling. Parental responses about aesthetic outcome following circumcision revealed that 97.9% of the PD group parents and 80.2% of the CDS group parents claimed satisfactory aesthetic results.	

Evidence Table : Psychological/social/ethical
Question : What is the ideal/appropriate method for male circumcisions from the social aspect? (**DISPOSABLE DEVICES VS CONVENTIONAL: IN CHILDREN**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
2. Karadag MA, Cecen K, Demir A et al. SmartClamp circumcision versus conventional dissection technique in terms of parental anxiety and outcomes: A prospective clinical study. Can Urol Assoc J. 2015; 9(1-2):E10-3	**Non-randomised clinical trial** They analysed parental anxiety and outcomes for the SmartClamp circumcision and the classic surgical dissection technique. After clinical and preoperative evaluation, the first 125 children were circumcised by the conventional dissection technique (CDT; sleeve technique) and the remaining children were operated by the SmartClamp method. All children in both groups were compared in terms of bleeding, infection, penile oedema, operative time, cosmetic result, length of the inner mucosal layer, and parental anxiety. Cosmetic result and length of the inner mucosal layer were evaluated by a blinded urologist after 6-weeks. A state-trait anxiety inventory (STAI) form was used to measure the impact of circumcision on parental anxiety. This form was completed by parents on postoperative day 2.	**II-1**	A total of 250 boys aged two to 10 years. Children with hypospadias, buried penis, ventral chordae or other genital anomalies and bleeding disorders were excluded from the study.	SmartClamp (SC)	Classic surgical dissection – sleeve resection		Parental anxiety in the SmartClamp group was statistically higher; the STAI scores were nearly 10 points higher than CDT group ($p<0.001$). **Authors conclusion:** Circumcision with SC device seemed to carry the disadvantages of higher parental anxiety. These points should be kept in mind by the urologists before choosing this technique	

Evidence table : Psychological/social/ethical
Question : What is the ideal/appropriate method for male circumcisions from the social aspect? (**DISPOSABLE DEVICES VS CONVENTIONAL: IN ADOLESCENT & ADULTS**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
3. Wang J, Zhou Y, Xia S et al. Safety and efficacy of a novel disposable circumcision device: A pilot randomized controlled clinical trial at 2 centers. Med Sci Monit. 2014; 20: 454-462	**Randomised controlled trial** To evaluate the safety and efficacy of circular stapler device for male circumcision (MC). A multi-center pilot clinical trial was conducted at two Chinese hospitals to compare intra- and postoperative outcomes of MC using this device with conventional dissection technique (CDT). Patients were randomly divided into two groups using a computerized random table method generated by SAS 8.0 (SAS, Cary, NC). Intraoperative bleeding, surgery duration, pain, healing, and satisfaction with penis appearance were assessed. Adverse events (AEs) were noted.	**I**	Adult male patients (n=120; mean age, 26.6 years) with redundant foreskin and/or phimosis. Patients were divided into two groups and subjected to MC with circular stapler device (n=60) or to CDT (n=60).	Circular stapler device	Conventional dissection technique (CDT) (sleeve resection)	One, three, seven, and 14 days following surgery	By day 14, 56/58 (97%) Device Group patients and 57/60 (95%) Control Group patients reported full satisfaction with MC outcomes. Notably, only 2 (3%) and 3 (5%) patients of the Device Group and Control Group, respectively, reported moderate satisfaction. No patient reported poor satisfaction in any group. No significant differences were observed in any outcomes between the two groups.	

Evidence Table : Psychological/social/ethical
Question : What is the ideal/appropriate method for male circumcisions from the social aspect? (**DISPOSABLE DEVICES VS CONVENTIONAL: IN ADOLESCENT & ADULTS**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
4. Zhang Z, Yang B, Yu W et al. Application of a novel disposable suture device in circumcision: a prospective non‐randomized controlled study. Int Urol Nephrol. 2016; 48: 465–473	**Prospective non-randomised controlled trial** To compare the surgical effects and postoperative complications and patient experience of two circumcision methods in Chinese excess foreskin or phimosis patients. The duration of each operation in minute and the total cost of each patient were recorded. During the surgery, intraoperative blood loss was calculated by weighing the gauzes. A visual scale (0–10) was used to assess the pain level. Intraoperative pain score was collected immediately after the surgery. Postoperative assessment at 1-week included postoperative pain score. At their visit at 1-month after the operation, the recovery duration (from the date of discharging to the date of getting back to work) and incision healing time for each patient were collected. The incision healing time was determined based on the check of the wound and the inquiry of the patients by the doctors at 1-week and 1-month follow-up. Patients were also asked whether they were satisfied with their cosmetic penis appearances at 1-month visit. The incidence of complications was also recorded at the follow-up. Multivariate logistic regression with likelihood ratio test was used to observe the significant predictors of oedema occurrence postoperatively.	**II-1**	A total of 520 cases of excess foreskin and 62 phimosis patients underwent circumcision in a single centre using circular stapler device (n=295; mean age 30.4 years, range 18–44 years) and conventional suture approach (n=287; mean age 28.6 years, range 16–41 years)	Circular stapler device	Conventional suture approach – sleeve resection	At 1-week and 1-months after operation	At 1-month visit, only five persons in the disposable suture device group were dissatisfied with their penile cosmetic appearance while 75 in 287 patients using conventional circumcision method were dissatisfied, which indicated a statistical significance (p=0.000).	

Evidence Table : Psychological/social/ethical
Question : What is the ideal/appropriate method for male circumcisions from the social aspect? (**LASER VS CONVENTIONAL: IN CHILDREN**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
5. Gorgulu T, Olgun A, Torun M et al. A fast, easy circumcision procedure combining a CO2 laser and cyanoacrylate adhesive: a non-randomized comparative trial. Int Braz J Urol. 2016; 42: 113-117	**Non-randomised comparative trial** This study examined the combined use of a CO_2 laser and cyanoacrylate for shortening the operating time and reducing complications related to bleeding.	**II-1**	A total of 75 boys, aged 6–9 (median 7) years. As a control, they compared them retrospectively with 75 age-matched patients who were circumcised using the conventional guillotine method. In all cases, the parents had requested circumcision for religious reasons.	A CO_2 laser and cyanoacrylate combination	Conventional guillotine method	12 (range 4–18) months on average.	The parents of the patients in both groups were satisfied with the aesthetic results.	

Evidence Table : Organizational
Question : What is the ideal/appropriate method for male circumcisions from the organizational aspect? (**NON-DISPOSABLE VS DISPOSABLE DEVICES: IN NEONATES**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
1. Bowa K, Li MS, Mugisa B et al. A controlled trial of three methods for neonatal circumcision in Lusaka, Zambia. J Acquir Immune Defic Syndr. 2013; 62:e1–e6	**Non-randomised controlled trial** To determine the acceptability, feasibility, and safety of three different neonatal male circumcisions (NMC) – to advise the Zambian Ministry of Health on the best method for national scale up. Infants were circumcised using one of the three NMC methods being trained (Mogen, Gomco, or Plastibell). The method performed on a given infant was determined based on which method was being practiced by the attending 17 provider (five physicians, nine nurses or midwives, and three clinical officers) at the time of the procedure. Study staff performed a detailed physical exam on all infants at one and six weeks after the procedure. At infants' 6-week visits, parents completed a satisfaction survey during which they were asked to rate their level of satisfaction with the procedure. Any observed complication was referred to study staff and recorded on an adverse events form.	**II-1**	A total of 640 healthy male infants of gestational age >37 weeks at birth, aged 0–28 days, and between 2,500 and 5,000 g. Infants with urethral or penile shaft abnormality, local infection, any current illness, or family history of bleeding disorder were excluded.	Mogen (n=216) Gomco (n=206) Plastibell (n=218)		At one and six weeks after the procedure.	The mean number of procedures to competency was 10.3 (SD=63.3) for Gomco, 10.3 (SD=63.7) for Plastibell, and 8.9 (SD=62.9) for the Mogen clamp. All providers were competent in each circumcision method by fifteen procedures. In general, nurses took longer to train than the other providers, but this was not statistically significant.	

Evidence Table : Organizational
Question : What is the ideal/appropriate method for male circumcisions from the organizational aspect? (**AMONG CONVENTIONAL TECHNIQUES: IN ADOLESCENT & ADULTS**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
2. Buwembo D; Musoke R; Kigozi G et al. Evaluation of the safety and efficiency of the dorsal slit and sleeve methods of male circumcision provided by physicians and clinical officers in Rakai, Uganda. BJU Int. 2011; 109(1): 104-108	**Prospective cohort** To assess the safety [adverse events (AEs)] and efficiency [the time required for the male circumcision (MC) procedure] of the dorsal slit and sleeve MC procedures, performed by trained physicians and clinical officers (COs) after completion of a randomised trial of MC for HIV prevention in Rakai District, Uganda. Univariate and multiple regressions with robust variance estimation were used to assess factors associated with operative duration (linear) and odds ratio (OR) of AEs was estimated by logistic regression with robust variance.	**II-2**	A total of 5,152 male aged 12-71 years. During the study period, 1,934 service surgeries were performed by general physicians (1,511 sleeve and 423 dorsal slit) and 3,218 MCs were performed by COs (1,170 sleeve and 2,048 dorsal slit).	**Procedure method:** -Dorsal slit -Sleeve resection **Provider:** -Physicians -COs		24–48 hours, 7–9 days and at 4-weeks after MC	Irrespective of experience, the time required for sleeve resection was consistently longer than for dorsal slit and this differential was particularly marked for the first 100 procedures performed. There were no overall difference in operative duration between physicians and COs, but physicians required less time to perform the sleeve procedure. This shorter operative duration by physicians was less marked and inconstant for the dorsal slit procedure. In multivariate analyses, there were no significant differences in adjusted surgical durations between physicians and COs. Dorsal slit required 2.7 min ($p<0.001$) less time than sleeve resection. Use of bipolar cautery to control bleeding significantly reduced operative duration by ≈4 min compared with ligation ($p=0.008$), and ≈20 MC procedures as an increase in surgical experience of the provider reduced operative duration by 1.5 min ($p<0.001$). After performing 100 surgeries, dorsal slit took an average of 22.5 min compared with 25.3 min for the sleeve method. **Authors conclusion:** Dorsal slit method of MC requires less time to perform than the sleeve resection method, and can be performed equally efficiently by COs and physicians. **Surgical experience is expressed in sequence of bins of 20 surgeries for the first 100 and then bins of100 surgeries thereafter.*	

Evidence Table : Economic evaluation
Question : What is the most cost-effective method for male circumcisions? (**LASER VS CONVENTIONAL: IN CHILDREN**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
1. How A, Ong C, Jacobsen A et al. Carbon dioxide laser circumcisions for children. Pediatr Surg Int. 2003; 19: 11–13	**Cost-analysis** A retrospective case review was carried out in Department of Paediatric Surgery, Women's & Children's Hospital, Singapore **Aim**: to review their experience with laser circumcision for children and to evaluate its cost-effectiveness as compared to conventional methods. The operating times in both groups were compared. The total cost of use of the laser machine was calculated, taking into account maintenance costs, estimated life span of laser machines (10 years) and costs of disposables used during each circumcision. This was weighed against the cost savings from shorter operating times and reduced operating theatre facility charges. Statistical analysis was performed using the Statistical package for Windows Version 5.0 and the level of statistical significance set at $p<0.05$.		Thirty male patients (aged 1-11 years) who underwent conventional circumcision in 1985 and another 30 patients (aged 2-10 years) who underwent laser circumcision in 1995 was undertaken. Patients in both groups had similar indications for circumcision, that is phimosis, balanitis or religious reasons	Carbon dioxide laser probe	Guillotine method with the knife		A total of 60 patients were studied. The operating time for patients who underwent circumcision by carbon dioxide laser was shorter by five minutes as compared to that for patients who had circumcision by the conventional method [median time 15 (95% CI: 13, 17) versus 20 (95% CI: 16, 21); p=0.002]. The cost of a carbon dioxide laser machine was S$105,000. If estimated life-span for each machine is 10 years, with consideration of maintenance charges of S$5,000 per year, machine costs would make up to S$15,500 per year. Approximately 1,000 circumcisions are done in their institution every year. Hence, the cost of machine per circumcision would be S$15.50. Other cost considerations in a laser circumcision would be the cost of disposables used which comes up to S$3.50 for a sterile plastic camera sleeve, which is unnecessary in a circumcision done by the conventional method. Therefore, the total cost of each circumcision would be S$19.00. With regards to the reduced operating time by five minutes per circumcision done by laser; there is a concomitant reduction in operating theatre facility charge by S$50.00. This makes the total cost savings per circumcision done by laser S$31.00. **Authors conclusion:** The carbon dioxide laser offers a simple and cost-effective method of circumcision as demonstrated from its reduced operating time and favourable morbidity rates compared with those done by the conventional method.	

Evidence Table : Economic evaluation
Question : What is the most cost-effective method for male circumcisions? (**DISPOSABLE DEVICE VS CONVENTIONAL: IN ADOLESCENT & ADULTS**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
2. Bratt J, Zyambo Z. Comparing direct costs of facility-based Shang ring provision versus a standard surgical technique for voluntary medical male circumcision in Zambia. J Acquir Immune Defic Syndr 2013; 63: e109–e112	**Cost-analysis** They compared direct costs of the Shang Ring and dorsal slit techniques for delivery of voluntary medical male circumcision (VMMC) in the context of a randomised controlled trial carried out in Zambia in 2011. Information on direct costs of clinician time, disposable supplies, and reusable medical instruments were collected by study staff. "Clinician time" was measured from administration of anaesthetic until the end of the procedure, and a cost per minute of US$0.09 was used (US$5.30 per hour). "Disposable medical supplies" included surgical blades, caps, masks, gloves, and drapes; disinfectants, injection equipment, local anaesthetics', and postoperative analgesics; sutures and dressings; the Shang Ring device itself; and cleaning supplies to prepare the surgical workspace between cases. "Reusable instruments" included assorted clamps, forceps, scissors, blade handles, and the Shang Ring removal set consisting of a scissors and key. Costs denominated in Zambian Kwacha were converted into dollars using an exchange rate of 4500 Kwacha to 1 US dollar.		A total of 191 men (n=96 for Shang Ring, n=95 for dorsal slit)	Shang Ring	Dorsal slit		Using dorsal slit, the direct cost of one circumcision was US$17.67, whereas the direct cost of one circumcision using the Shang Ring was US$18.21 Although total direct costs of the two techniques are similar, components of direct cost are slightly different. Cost of clinician time was higher with dorsal slit, reflecting the longer duration of the procedure (24.3 minutes on average, versus 13.4 minutes for the Shang ring). Cost of disposable medical supplies was higher with the Shang ring, where the unit cost of the device and associated supplies outweighed the costs of scalpel, sutures, and dressings used in the dorsal slit technique. The cost of reusable instruments was similar for the two techniques. **Authors conclusion:** Although direct costs were roughly equivalent during this small-scale trial, with the increased demand from scaling up VMMC, a Shang ring team could provide services at a substantially lower average total cost due to the potential for more intensive use of staff and other fixed resources.	

Evidence Table : Economic evaluation
Question : What is the most cost-effective method for male circumcisions? (**DISPOSABLE DEVICE VS CONVENTIONAL: IN ADOLESCENT & ADULTS**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
3. Mutabazi V, Bitega J, Ngeruka L et al. Cost analysis of adult male circumcision with the PrePex™ device versus surgery in Rwanda. Urologic Nursing. 2014; 34(6): 303-311	**Cost-analysis** This single-centre non-blinded randomised controlled trial compared the costs associated with nonsurgical adult male circumcision (MC) performed in a standard examination room by a team of two trained nurses using the PrePex device versus surgical MC performed in a sterile environment by a physician-nurse team using the WHO approved dorsal-slit method. Cost categories included in the analysis reflect ongoing expenses that are specific to each method: supplies (tools, devices, and other consumables), laboratory tests, salaries for the clinicians performing the procedures, and treatment of procedure-related adverse events (AEs). With both methods, supplies accounted for the greatest portion of ongoing costs. The present study generated primary data on the cost of supplies for the PrePex procedure (in U.S. dollars, to the nearest $0.01). The cost of supplies for surgical MC (to the nearest $1.00) was taken from a previously		The study population was composed of 217 adult male (aged 21 to 54 years) Rwandan volunteers randomised in a 2:1 ratio to have either nonsurgical MC with the PrePex device performed by teams of two nurses (n=144) or dorsal-slit surgical MC performed by teams of one physician and one nurse (n=73).	PrePex device	Dorsal-slit method		All subjects in both groups achieved successful circumcision (defined as full exposure of the glans) and healing (epithelialization with no drain-age from the site). AEs requiring treatment were documented in six subjects from the surgical group (8%) but none from the PrePex group. In the following cost summaries, all amounts are given in U.S. dollars: **Supplies:** The total cost of supplies needed for a single PrePex MC procedure was $22.38. The mean total cost of supplies for dorsal-slit surgical MC in an adult in Rwanda was assessed by Binagwaho et al. (2010) at $29 ($21 for consumables, $8 for the surgical kit including costs for sterilization and amortization); in addition, surgical MC incurred a $6 cost per procedure for laboratory testing (haematology profile) as a safety precaution, whereas such testing was not required with the PrePex procedure. **Salaries for clinicians performing MC:** For both PrePex and surgical MC, ongoing costs for staff time reflect the combined time required for preparation and for the procedure itself, as previously reported (Mutabazi et al. 2012), and the mean hourly salaries for staff physicians and for professional nurses with six years of training in Rwanda. PrePex procedure time is the combined time required for device placement (from positioning of the placement ring over the penis to removal of the verification thread and patient standing up) and device removal (from the first cut of dry foreskin to detachment of the device). Surgical procedure time is measured from first cut to last suture. The mean total per-procedure costs for associated staff salaries for the time spent by clinical personnel involved in performing MC with the PrePex device was $0.35 and $4.36 by dorsal slit surgery. **Treatment of adverse events:** The cost of treating AEs was based on the time spent by clinicians, the materials and medications used (based on the type of AE), and the incidence of each type of AE	

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
	published report by Binagwaho et al. (2010), which modelled the cost-effectiveness of surgical MC in Rwanda in a large hypothetical cohort of males in different age groups (adults, n=150,000). These differences in data sources, population characteristics, and the precision of cost data precluded formal statistical comparisons.						reported. Among the 217 MC procedures performed by nurses using the PrePex procedure or by physicians using dorsal slit surgery, there were no reported cases of infection following either type of procedure. However, a small number of cases of bleeding serious enough to require suturing (apart from routine suturing during the surgical procedure), edema, and exudate were reported among subjects who underwent surgical MC. Treatment of AEs added a mean of $1.49 per procedure to the cost of surgical MC; however, among subjects who had MC performed with the PrePex device, there were no AEs reported and therefore no additional costs in this category. **Mean total costs per procedure:** The mean total of ongoing costs specific to each method of performing MC was $22.73 ($22.38 for supplies, $0.00 for laboratory testing, $0.35 for salaries, $0.00 for treatment of AEs) for nonsurgical MC with the PrePex device performed in a standard examination room by nurse teams; and $40.85 ($29, $6, $4.36, $1.49) for dorsal slit surgical MC performed in a sterile setting by physician-nurse teams. To provide additional perspective for these differences in ongoing costs specific to each method of performing MC, the expenditures common to both methods must also be considered. As previously reported by Binagwaho et al. (2010), these costs include approximately $3.50 for wide-scale promotion of the MC program and $9.20 for HIV counselling and testing. Thus, the total ongoing cost for adult MC in Rwanda would be approximately $35.50 with PrePex versus $53.50 with surgery (a difference of 33%). **Authors conclusion:** This study suggests that meaningful cost-savings can be achieved in Rwanda with nonsurgical MC performed by nurses using the PrePex device in place of surgical MC performed by physicians. The speed, safety, and acceptability of the PrePex nonsurgical method may also contribute to the attainment of Rwanda's national goals for scale-up voluntary MC programs designed to reduce the heterosexual transmission of HIV.	

Evidence Table : Economic evaluation
Question : What is the most cost-effective method for male circumcisions? (**DISPOSABLE DEVICE VS CONVENTIONAL: IN INFANTS**)

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
4. Mangenah C, Mavhu W, Hatzold K et al. Estimating the cost of early infant male circumcision in Zimbabwe: Results from a randomized noninferiority trial of AccuCirc device versus Mogen clamp. J Acquir Immune Defic Syndr. 2015; 69: 560–566	**Cost analysis** They present results on a relative cost-analysis within a randomised noninferiority trial of early infant male circumcision (EIMC) comparing the AccuCirc device with Mogen clamp in Zimbabwe. Trial methods are described in detail elsewhere. The overall unit cost plus the key cost drivers of EIMC using both AccuCirc and Mogen clamp were evaluated. Direct costs included consumable and nonconsumable supplies, device, personnel, associated staff training, and environmental costs. Indirect costs comprised capital and support personnel costs. This analysis adopted the perspective of the Zimbabwe Ministry of Health as a health care payer. Client costs such as transport to and from the EIMC facility, opportunity costs of time spent seeking EIMC services and caregiver costs were therefore excluded. As this cost analysis is based on a pilot EIMC study, they estimated the costs based on the assumption of a vertical EIMC program. They present costs in 2013 constant US dollar prices and assume an exchange rate of US$1=US$1 because		A total of 150 infants (male, gestational age ≥36 weeks, birth weight ≥2,500 g, no evidence of neonatal infection/sepsis or other illness requiring hospitalization, no family history of bleeding disorder, and no genital abnormality representing a contraindication to EIMC)	AccuCirc device (n=100)	Mogen clamp (n=50)	At 14 days post-circumcision	The mean time taken to perform the procedure was 15.5 minutes and was similar in both arms (mean difference=0.1 minute 95% CI: -1.2, 1.4). Two moderate AEs (2%, 95% CI: 0.2, 7.0) were observed in the AccuCirc arm. No AEs occurred in the Mogen clamp arm. Nearly all mothers (99.5%) reported great satisfaction with the outcome. All mothers, regardless of arm, said they would recommend EIMC to other parents and would circumcise their next son. Trial outcomes are described in detail elsewhere. The unit costs of EIMC using AccuCirc and Mogen clamp were $49.53 and $55.93, respectively. Costs of consumable supplies were higher for Mogen clamp ($30.18 compared with $13.48). This large difference is explained by the fact that the prepackaged AccuCirc kit comes with a number of consumable supplies required for an EIMC procedure, and because AccuCirc is disposable, it does not require the sterilization supplies required for the Mogen clamp. The contribution of device cost was higher for AccuCirc, at $10, compared with $0.21 for the reusable Mogen clamp. Key cost contributors to the unit cost of AccuCirc were consumable supplies, device price, and personnel costs. For AccuCirc, consumable supplies ($13.48), device price ($10), and personnel costs ($19.11) accounted for a combined 86.2% of EIMC unit cost. For Mogen clamp, key cost contributors were consumable supplies ($30.18) and personnel costs ($19.11), which together contributed 88% to the unit cost. The wide difference in consumable supplies costs between the two devices reflects the cost-savings due to the lower number of supplies costed for the AccuCirc procedure, as a number of EIMC supplies come prepacked in the AccuCirc kit already priced at $10. Overall, other direct costs (training and environmental costs) and indirect costs (capital equipment and support personnel costs) had a smaller contribution to the total costs of EIMC for both devices.	

Bibliographic citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
	Zimbabwe officially adopted the US dollar as its principal currency in 2009. In 1-way sensitivity analyses, they assessed potential changes in unit costs due to variations in main parameters, one at a time, holding all other values constant.						**1-way sensitivity analysis results:** Demonstrates unit cost impacts for AccuCirc when the main parameters (AccuCirc device price, capacity utilization, and personnel salaries) are varied and when capital equipment is excluded. They explored EIMC unit cost impacts in an integrated EIMC program where personnel time is shared with other medical services in addition to EIMC. Results show EIMC unit cost for AccuCirc rising from $49.53 to $64.53 as device price increases from $10 to $25. They also varied capacity utilization between 2 and 6 procedures per day to study the impact of low EIMC uptake (low capacity utilization). While at maximum capacity utilization EIMC unit cost is $49.53, when only 2 EIMC procedures are performed per day, EIMC unit cost rises to $59.25. As EIMC scale-up is likely to use government facilities, in sensitivity analyses they tested the impact on unit cost if lower civil service salaries were used rather than research staff salaries. Results show that EIMC unit cost decreases from $49.53 in the base case to $43.71 in the public sector. Furthermore, as durable equipment required for EIMC already exists in Zimbabwe's public health facilities, they also tested EIMC unit cost impacts when durable equipment is excluded. However, as durable equipment has a relatively low contribution to EIMC unit cost, excluding equipment costs does not have a large impact on EIMC unit costs. **Authors conclusion:** EIMC has a lower unit cost when using AccuCirc compared with Mogen clamp. To minimize unit costs, countries planning to scale-up EIMC using AccuCirc need to control costs of consumables and personnel. There is also need to negotiate a reasonable device price and maximize capacity utilization.	