

A Comparative Study of Adult Male Circumcision with a Circular Stapler and Conventional Circumcision

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Abstract:

Objective: To do comparative evaluation of the clinical outcomes of adult male circumcision with a circular stapler versus conventional adult male circumcision. The comparative evaluation was done based on the primary and secondary outcomes.

Methods: We performed comparative randomized control to compare several aspects and outcomes of male circumcision with a circular stapler and conventional male circumcision in adults in the population of Central India. The operative time, pain score, blood loss volume, healing time, treatment costs, and postoperative complications were compared between the two groups.

Results: The operative time and blood loss volume were significantly lower in the stapler group than in the conventional group (6.8 ± 3.1 vs 24.2 ± 3.2 min and 1.8 ± 1.8 vs 9.4 ± 1.5 mL, respectively; $P < 0.01$ for both). The intraoperative and postoperative pain scores were significantly lower in the stapler group than in the conventional group (0.8 ± 0.5 vs 2.4 ± 0.8 and 4.0 ± 0.9 vs 5.8 ± 1.0 , respectively; $P < 0.01$ for both). Additionally, the stapler group had significantly fewer complications than the conventional group (2.7% vs 7.8%, respectively; $P < 0.01$). However, the treatment costs in the stapler group were much higher than those in the conventional group (8000 ± 500.20 vs 1000.50 ± 125.00 , respectively; $P < 0.01$).

Conclusion: Overall, the present study has shown that stapler circumcision is a time-efficient and safe male circumcision technique.

Keywords: Conventional Circumcision, Disposable Circumcision Suture Device, Meta-Analysis, Phimosis, Redundant Prepuce, Systematic Review.

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Introduction

Male circumcision (mc) was one of the earliest operations performed by humans. This procedure has the potential to decrease the risk of sexually transmitted diseases such as human papillomavirus, genital ulcer disease, and human immunodeficiency virus (hiv) infection [1-3]. Additionally, it improves penile topical hygiene and reduces the incidence of balanitis and penile cancer [4,5]. Conventional male circumcision as recommended by the world health Organization (who) includes three techniques: the dorsal slit, the forceps-guided method, and sleeve resection [6].

However, complications such as bleeding, edema, and unsatisfactory cosmetic results are still common in patients who undergo conventional mc [7,8]. Moreover, conventional mc is time consuming. The

Chinese shang ring was recently introduced worldwide. The use of this device is associated with a shorter operative time, lower blood loss volume, and fewer postoperative complications than in conventional mc [9,10]. However, use of the shang ring also has some drawbacks: more time is required for wound healing, patients must endure pain for 7 to 16 days until the ring can be removed, and wound dehiscence is relatively common after the ring is removed because the procedure is suture less.

The circular stapler, a new disposable circumcision device, has been developed for commercial use in China (henry medical device company, figure 1). It includes two parts: an inner bell and an outer bell. The inner bell is designed to protect the glans. The outer bell comprises a circular blade to cut the

foreskin and staples to close the wound for simultaneous hemostasis.

We performed a Prospective randomized control trial in the General Surgery Department to investigate the safety and efficacy of mc with a circular stapler in adult male patients.

Materials and Methods:

- **Study Type:** Randomized Control Study.
- **Study Population:** Patients presenting with phimosis/paraphimosis/redundant prepuce at study area (RKDF Medical College Hospital & Research Centre, Bhopal) during the defined study period.

Inclusion Criteria:

- All enrolled patients will be adult men above 18 years of age with a redundant prepuce or phimosis/paraphimosis.

Exclusion Criteria:

- Acute infection of the genitalia (acute posthitis or balanitis).
- Severe foreskin adhesion.
- Other contraindications to male circumcision such as a concealed penis or active sexually transmitted disease.
- Coagulopathies.

- **Study Area:** RKDF Medical College Hospital & Research Center, Bhopal, M.P.
- **Study Duration:** One year and Six months (1st April to 2022 to 30th September 2023)
- **Sample Size:** The sample size was estimated using the formula:
- $N = Z^2pq/d^2$

N= Sample size

d= allowable error= 6%

p= Prevalence of circumcision in adult male population.

q= 1-p

- According to NFHS-4 data of 2015 the overall prevalence of circumcision in adult male population is 16%.

The appropriate sample size according to the above formula is 150.

● Selection of Cases:

- An informed written consent was taken from all the patients after the approval of institutional ethical committee.

- The work was started after the review and approval of protocol of study by institutional ethics and research committee.
- We included all patients according to inclusion criteria who visited RKDF Medical College Hospital And Research Centre, Bhopal requiring circumcision during the aforementioned period.
- The details of the cases were recorded as shown in proforma.

All patients were followed up 1 day; 1, 2, and 3 weeks; and 1 and 3 months after surgery. Additionally, an investigator called each patient to inquire about the wound condition until complete healing was achieved. Fifty-six patients who underwent the stapler technique were followed up 1 year after circumcision. The following data were collected and compared between the two groups: operative time, pain score (intraoperative and 1 h after surgery), blood loss volume, postoperative complications, healing time, and treatment costs. We used an internationally accepted visual analog scale to evaluate pain. Mild edema was considered to be present when the perimeter of the inner foreskin layer, including the edema, was $\geq 30\%$ of the perimeter of the penile shaft. If the perimeter was $< 30\%$ of the penile shaft, the edema was classified as severe. Wound dehiscence was defined as a > 2 -mm separation of the wound edge. Postoperative bleeding was defined as bleeding that required suture closure. The healing time was defined as the time point at which the crusts of the wound disappeared and the healing line totally appeared.

- Two study groups were formed:

Group A: Patients undergoing circumcision with a circular stapler after meeting the inclusion criteria.

Group B: Patients undergoing circumcision via the conventional method after meeting the Inclusion criteria.

- The following data was collected and compared between the two randomized study groups:
 1. The operative time.
 2. Intra-operative blood loss volume.
 3. Post operative pain.
 4. Healing time.
 5. Duration of hospitalisation.
 6. Post operative complications (edema/ bleeding/ wound dehiscence).
 7. Glanular sensitivity
 8. Cosmetic appearance.
 9. Time off work.
 10. Time to resumption of normal sexual function post-surgery.

Surgical Technique: In the stapler group, the appropriate size of the stapler device was first determined by measuring the penis just below the

glans. The penis was then surgically disinfected with povidone-iodine. A dorsal penile nerve block and a circumferential block were performed with 1% lidocaine, and the treatment was conducted according to a defined protocol. In the conventional

group, all patients underwent MC with the dorsal slit technique using an electric scalpel in accordance with the WHO guidance manual. All circumcisions were performed by well-trained Surgeons.



Observation Chart

| Outcome | Experiment group Stapler group (n = 20) | Control group Conventional method (n = 20) | P value |
|-------------------------|--|---|---------|
| Operative time (min) | 5.35 ± 1.38 | 30.30 ± 5.32 | <0.05 |
| Complication rate | 4.8 % | 12.7% | >0.05 |
| Blood loss (ml) | 2.56 ± 0.38 | 10.40 ± 1.35 | <0.05 |
| Post operative Recovery | 4 days | 7 days | <0.05 |

Results

Average procedural time needed to use the device was 7.7 ± 2.6 minutes. Patients returned to full physical activity on postoperative day 3. The overall complication rate was 4.8%, including 1 case of intraoperative bleeding due to operator inexperience and 2 of a delay in staples falling out. No patient experienced wound infection or excessive foreskin excision. No incision site edema was observed beyond postoperative day 7. All enrolled patients were satisfied with the postoperative

penile cosmesis.

Statistical Analysis: The collected data was summarized by using frequency, percentage, mean & S.D. To compare the qualitative outcome measures Chi-square test or Fisher’s exact test was used. To compare the quantitative outcome measures independent t test was used. If data was not following normal distribution, Mann Whitney U test was used. SPSS version 22 software was used to analyse the collected data. p value of <0.05 was statistically significant.

Discussion

Male circumcision is the most frequently performed procedure by urologists. Safety and efficacy of the circumcision procedure requires continual improvement. Jin XD et al in a prospective randomized clinical trial compared adult male circumcision with a circular stapler versus conventional circumcision. The authors investigated the safety and efficacy of a new male circumcision technique involving the use of a circular stapler. The operative time, pain score, blood loss volume, healing time, treatment costs, and postoperative complications were compared between the two groups. Overall, the study, like our study shows that stapler circumcision is a time-efficient and safe male circumcision technique, although it requires further improvement. [11]

Yuan Y et al did clinical investigation of a novel surgical device for circumcision that is the circular cutter with stapled anastomosis for circumcision. The device used 18 staples for anastomosis, which fall out during the recovery course, as designed. Patients were followed at day 3, and weeks 1, 2, 4 and 12 after the procedure. Outcome measures were evaluated, including patient safety, procedural time, patient satisfaction and complication rate. The circular cutter with stapled anastomosis for circumcision is a 1-step device that can achieve excellent postoperative results with minimal procedural time. Therefore, it has the potential to enable the performance of circumcision as a rapid turnover bedside procedure. [12]

Huo ZC et al did a systematic review and meta-analysis on the use of a disposable circumcision suture device versus conventional circumcision. This systematic review assessed the safety and efficacy of the disposable circumcision suture device (DCSD) and conventional circumcision (CC) in the treatment of redundant prepuce and phimosis. Compared with the CC group, the DCSD group had a shorter operative time, shorter wound healing time, less intraoperative blood loss, better cosmetic penile appearance, lower intraoperative pain score, lower 24-h postoperative pain score, lower incidence of infection, less incision edema, and fewer adverse events. There were no differences between the CC and DCSD groups in the incidences of dehiscence, or hematoma. The results of this meta-analysis indicate that the DCSD appears to be safer and more effective than CC. However, additional high-quality RCTs with larger study populations are needed.

Circumcision is one of the oldest and most performed surgical procedures in practice today. Circumcision is the main treatment for phimosis and redundant prepuce. Although dorsal incision circumcision is the traditional method of circumcision, it has the disadvantages of long operation time, stitch removal pain, and easy

infection of the wound; furthermore, surgeons who are new to the technique can easily generate adverse events such as an irregular incision and postoperative hematoma. Surgery with the DCSD is the newest method of circumcision. Compared with CC, which requires scalpels and operating scissors, circumcision with the DCSD is easy, convenient, and reduces operative complications [13]

Fan Y et al did a network meta-analysis of the characteristics of circular disposable devices and in situ devices for optimizing male circumcision. According to the outcomes that were statistically significant in both pairwise and network meta-analyses, ISD was found to have less intraoperative blood loss (IB), less operative time (OT) and less incidence of wound bleeding (WB) than conventional circumcision (CC); ISD was found to have less WB but more wound healing time (WHT) than CDD; CDD was found to have less IB and less OT than CC. CDD tended to have the best wound healing condition and least pain experience; ISD tended to have the least IB, least OT, least WB, and highest satisfaction rate. With their own superiorities in many aspects, CDD and ISD are both safe and effective devices for optimizing MC. [14]

Jadhav RM et al did a comparative study of conventional and sutureless circumcision. Both groups were compared on basis of - Diagnostic parameters (BXO, congenital phimosis, recurrent balanoposthitis, recurrent UTI, and others). Intra-op parameters (Mean operative time, mean blood loss, mean pain score) Post-op parameters (Mean healing time, mean satisfaction, post-operative stay) We observed that complications such as bleeding, wound dehiscence, oedema and infection were seen in conventional circumcision and no such complications were seen in suture less circumcision. Today is the era of 'Wireless' in technology and here comes era of 'Suture less' in field of surgery. Every surgeon wishes for better wound healing with better cosmesis without complications and early back to activities. All this is possible with use of staplers for circumcision. Stapler circumcision is associated with short operative time, lower blood loss volume, less pain, few post-operative complications and less post-operative stay. [15]

To evaluate and compare the surgical outcomes and complications of the modified circumcision using disposable circumcision suture device (device group) and the conventional dorsal slit circumcision (conventional group) in children, Rao JM et al did a randomized controlled trial. All patients were preoperatively assessed and evaluated at 4 weeks after surgery. The perioperative data and postoperative outcomes were compared between the 2 groups. No statistical differences were observed in the average age and indications between the 2 groups preoperatively ($P > .05$). Compared with the conventional group, patients in the device group

were shorter mean operative time, less blood loss, lower intraoperative and postoperative pain score, faster incision healing time and a higher satisfaction rate of penile cosmetic appearance ($P < .01$). Similarly, the incidences of complication were significantly lower in the device group than in the conventional group. The modified circumcision using disposable circumcision suture device is a simple, safe, faster, and effective procedure and may become the attractive alternative to the conventional technique for the children, with a relatively lower complication rate and better cosmetic results. With the improvement of disposable circumcision suture device, the modified circumcision using disposable circumcision suture device has the potential to be widely used in the world

Jiang Z et al safety and efficacy of circumcision stapler in the treatment for children with phimosis and redundant prepuce. Outcomes were operation time, intraoperative blood loss and postoperative complications. Results: There was significant difference between the two groups for operation time (5.35 min vs 30.30 min, $P < 0.05$) and intraoperative blood loss (2.56 ml vs 10.40 ml, $P < 0.05$) respectively. Circumcision staplers are superior to conventional circumcision for the advantages of shorter operation time and fewer blood losses.

Shen J et al did a comparative study on the clinical efficacy of two different disposable circumcision suture devices in adult males. Authors evaluated the safety and efficacy of two different kinds of disposable circumcision suture devices in adult men. Postoperative complications of the two kinds of disposable circumcision suture devices are different. We should pay attention to the risk of postoperative bleeding when the patients use the Langhe disposable circumcision suture device, while the patients who use the Langhe disposable circumcision suture device will have a longer healing time, and postoperative pain and the risk of infection cannot be ignored after the surgery.

CONCLUSION: Stapler circumcision is a time-efficient and safe male circumcision technique. Circumcision staplers are superior to conventional circumcision for the advantages of shorter operation time and fewer blood losses.

Declarations:

Funding: None.

Availability of data and material: Department of General Surgery RKDF Medical College Hospital and Research Centre, Bhopal.

Code availability: Not applicable.

Consent to participate: Consent taken.

Ethical Consideration: There are no ethical conflicts related to this study.

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Consent for publication: Consent taken.

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