

A COMPARATIVE STUDY OF ADULT MALE CIRCUMCISION WITH A CIRCULAR STAPLER AND CONVENTIONAL CIRCUMCISION

Dr Sridhar Panda¹, Dr Niranjan Mohapatra², Dr Sanjay Choudhuri³

Assistant Professor, Department of Medicine, SCB Medical college and Hospital¹

Assistant Professor, Department of Medicine, SCB Medical college and Hospital²

Assistant Professor, Department of Urology, SCB Medical college and Hospital³

Corresponding Author

Dr Sridhar Panda

Assistant Professor, Department of Medicine, SCB Medical college and Hospital

drsridharpanda@gmail.com

7077843032

Abstract

Male circumcision (mc) was among the first surgeries done by mankind. This method has the ability to reduce the risk of sexually transmitted illnesses such as human papillomavirus (HPV), genital ulcer disease, and HIV infection. The Problems such as haemorrhage, edoema, and poor cosmetic outcomes remain prevalent in individuals who have traditional mc. Furthermore, traditional mc is time-consuming

Objective:

The objective of this study was to compare the clinical results of adult male circumcision using a circular stapler to traditional methods. Primary and secondary outcomes were used to conduct a comparative assessment.

Methods:

We used a comparative randomised control to examine numerous characteristics and results of male circumcision using a circular stapler vs traditional male circumcision in adults in Central India. The surgical time, pain score, blood loss volume, healing time, treatment expenses, and postoperative complications were compared in the two groups.

Results:

The stapler group had a considerably shorter operation time and lower blood loss volume compared to the traditional group (6.8 ± 3.1 vs 24.2 ± 3.2 min and 1.8 ± 1.8 vs 9.4 ± 1.5 mL, respectively; $P < 0.01$). The stapler group had substantially lower intraoperative and postoperative pain levels than the traditional group (0.8 ± 0.5 vs 2.4 ± 0.8 and 4.0 ± 0.9 vs 5.8 ± 1.0 , respectively; $P < 0.01$). Furthermore, the stapler group had considerably less problems than the traditional group (2.7% vs 7.8%, respectively; $P < 0.01$). However, the stapler group had significantly greater treatment expenses than the traditional group (8000 ± 500.20 vs

1000.50 ± 125.00, respectively; P<0.01).

Conclusion:

Overall, the current research demonstrated that stapler circumcision is a time-saving and safe male circumcision procedure.

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

INTRODUCTION

Male circumcision (mc) was among the first surgeries done by mankind. This method has the ability to reduce the risk of sexually transmitted illnesses such human papillomavirus (HPV), genital ulcer disease, and HIV infection [1-3]. Furthermore, it promotes penile topical cleanliness and lowers the risk of balanitis and penile cancer [4,5]. The World Health Organisation (WHO) recommends three procedures for male circumcision: dorsal slit, forceps-guided approach, and sleeve resection [6]. However, problems such as haemorrhage, edoema, and poor cosmetic outcomes remain prevalent in individuals who have traditional mc [7,8]. Furthermore, traditional mc is time-consuming.

The Chinese shang ring was recently introduced globally. This device is related with a quicker surgical time, lower blood loss volume, and less postoperative problems than traditional mc [9, 10]. However, there are several negatives to using the shang ring: wound healing takes longer, patients must suffer discomfort for 7 to 16 days before the ring can be removed, and wound dehiscence is prevalent when the ring is removed since the technique is sutureless.

The circular stapler, a novel disposable circumcision instrument, has been developed for commercial usage in China. It has two parts: an inner bell and an outer bell. The inner bell is intended to protect the glans. The outer bell has a circular blade that cuts the foreskin and staples are used to seal the incision and provide simultaneous hemostasis. We conducted a prospective randomised control study in the General Surgery Department to look at the safety and effectiveness of mc using 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 18years 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:** SCB Medical college and Hospital, cuttack
- **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 for one day, one, two, and three weeks, as well as one and three months following surgery. In addition, an investigator phoned each patient to ask about the wound's state until full healing occurred. Fifty-six individuals who underwent the stapling procedure were followed up one year following circumcision. The following variables were gathered and compared between the two groups: operating time, pain score (intraoperative and 1 hour after surgery), blood loss volume, postoperative problems, healing time, and treatment expenses. We evaluated pain using a widely known visual analogue scale. Mild edoema was deemed present when the inner foreskin layer, including the edoema, measured 30% of the penile shaft's circumference. If the perimeter of the penile shaft was 0.30%, the edoema was considered severe. Wound dehiscence was defined as the separation of the wound edge by more than 2 mm. Postoperative haemorrhage was defined as bleeding that needed to be sutured closed. The healing period was defined as the moment at which the wound's crusts removed and the healing line fully emerged.

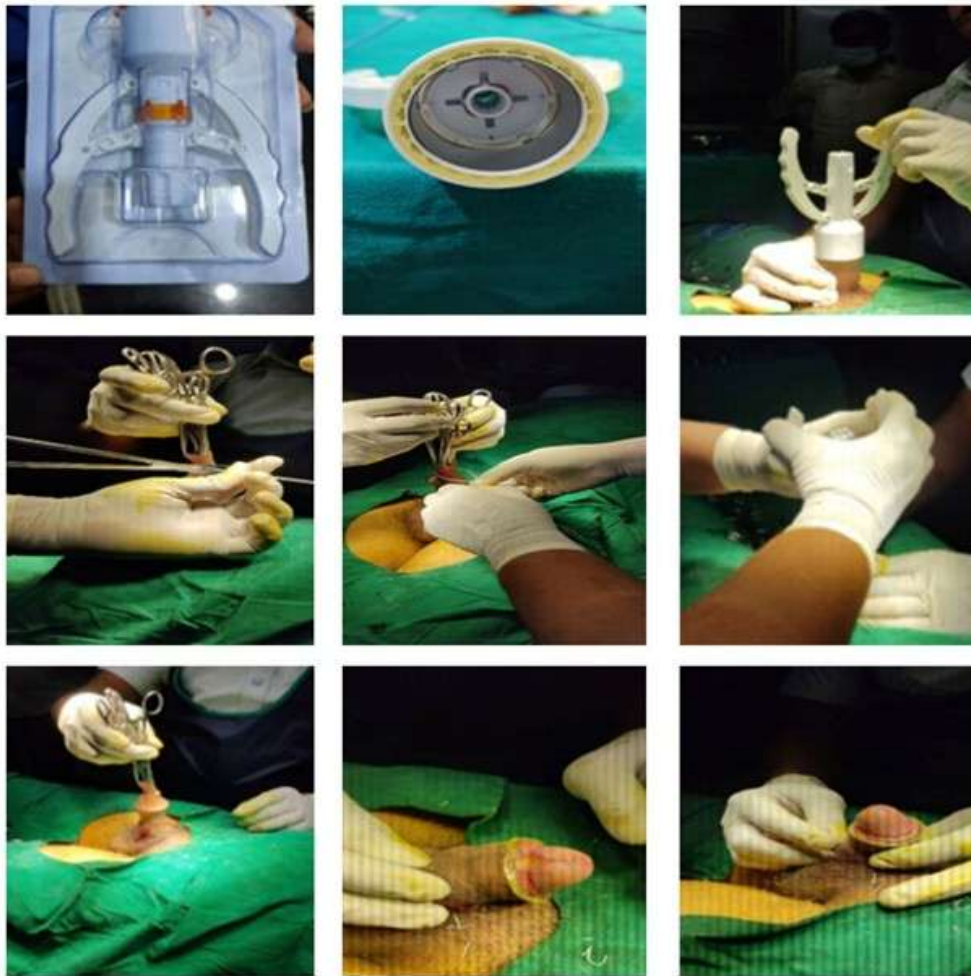
- Two study groups were formed:

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 Inclusioncriteria.

- 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 sensivity
 8. Cosmetic appearance.
 9. Time off work.
 10. Time to resumption of normal sexual functionpost-surgery.

Surgical Method: In the stapler group, the suitable size of the stapler device was first established by measuring the penis immediately below glans. The penis was then surgically disinfected with povidone-iodine. A dorsal penile nerve block and a circumferential block were done using 1% lidocaine, and the therapy followed a predefined procedure. In the usual all patients in the group underwent MC utilising the dorsal slit method with an electric scalpel, as per the WHO guideline handbook. All circumcisions were conducted by highly qualified 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

The device required an average procedure duration of 7.7 ± 2.6 minutes. Patients resumed full physical activity on the third postoperative day. The total complication rate was 4.8%, with one incidence of intraoperative haemorrhage owing to operator inexperience and two cases of staples not coming out on time. No patients had wound infections or had an excessive amount of foreskin removed. After surgical day 7, no edoema at the incision site

was noticed. All participating patients were happy with the postoperative care with Penile cosmesis.

Statistical Analysis: The acquired data was summarised using frequency, percentage, mean, and SD. To compare qualitative outcome measures, the Chi-square test or Fisher's exact test were utilised. To compare quantitative outcome measures, an independent t-test was performed. If the data did not follow a normal distribution, the Mann Whitney U test was used. The acquired data was analysed using the SPSS version 22 programme. A p value of <0.05 indicated statistical significance.

Discussion

Male circumcision is the most common operation done by urologists. The safety and effectiveness of circumcision need continuous improvement. Jin XD et al. conducted a prospective randomised clinical research comparing adult male circumcision using a circular stapler to traditional circumcision. The authors studied the safety and effectiveness of a novel male circumcision procedure that uses a circular stapler. The surgical time, pain score, blood loss volume, healing time, treatment expenses, and postoperative complications were compared in the two groups. Overall, the research, like ours, demonstrates that stapler circumcision is a time-saving and safe male circumcision procedure, while it still needs development. [11]

Yuan Y et al conducted clinical trials on a new surgical instrument for circumcision, the circular cutter with stapled anastomosis for circumcision. The device employed 18 staples for anastomosis, which fell out throughout the healing period, as intended. Following the operation, patients were observed on day 3, as well as weeks 1, 2, 4, and 12. Patient safety, procedure time, patient satisfaction, and complication rate were among the outcome metrics assessed. The circular cutter with stapled anastomosis for circumcision is a one-step device capable of producing outstanding postoperative outcomes in a short period of time. As a result, it has the potential to allow the conduct of circumcision as a quick turnaround bedside surgery. [12] Huo ZC et colleagues conducted a comprehensive study and meta-analysis comparing the use of a disposable circumcision suture device to traditional circumcision. This systematic study compared the safety and effectiveness of the disposable circumcision suture device (DCSD) to traditional circumcision (CC) in the treatment of superfluous prepuce and phimosis. Compared to the CC group, the DCSD group had a shorter operative time, a shorter wound healing time, less intraoperative blood loss, a better cosmetic penile appearance, a lower intraoperative pain score, a lower 24-hour postoperative pain score, a lower infection rate, less incision edoema, and fewer adverse events. The occurrences of dehiscence and hematoma were same in the CC and DCSD groups. The findings of this meta-analysis show that DCSD seems to be safer and more effective than CC. However, more high-quality RCTs with bigger sample sizes are required. Circumcision is one of the oldest and most common surgical procedures in use today. Circumcision is the primary therapy for phimosis and superfluous prepuce. Although dorsal incision circumcision is the conventional form of circumcision, it has the drawbacks of extended operation duration, discomfort during stitch removal, and easy

Infection of the wound; also, doctors who are unfamiliar with the method may easily cause unpleasant effects such as an uneven incision and postoperative hematoma. The DCSD is the newest technique of circumcision. Compared to CC, which needs scalpels and operating scissors, circumcision using the DCSD is simple, convenient, and decreases surgical complications. [13]

Fan Y et al. conducted a network meta-analysis of the features of circular disposable devices and in situ devices to optimise male circumcision. According to statistically significant outcomes in both pairwise and network meta-analyses, ISD had less intraoperative blood loss (IB), less operative time (OT), and less incidence of wound bleeding (WB) than conventional circumcision (CC); ISD had less WB but more wound healing time (WHT) than CDD; CDD had less IB and OT than CC. CDD had the greatest wound healing and the least pain experience, whereas ISD had the least IB, OT, WB, and highest satisfaction rating. CDD and ISD are both safe and effective technologies for optimising MC, and each has its own set of advantages. [14]

Jadhav RM et al conducted a comparative analysis of traditional and sutureless circumcision. Both groups were compared based on diagnostic criteria (BXO, congenital phimosis, recurrent balanoposthitis, recurrent UTI, and others). Intra-surgical parameters (mean operational time, mean blood loss, and mean pain score). Post-operative metrics (mean healing time, mean satisfaction, and postoperative stay) We discovered that traditional circumcision resulted in problems such as haemorrhage, wound dehiscence, oedema, and infection, while sutureless circumcision did not. Today is the age of 'Wireless' technology, and the era of 'Suture-less' surgery is on its way. Every surgeon strives for improved wound healing with greater cosmesis, fewer complications, and an early return to activity. All of this is feasible with the use of staplers during circumcision. Stapler circumcision is linked to a shorter operational time, lower blood loss volume, less discomfort, fewer post-surgical problems, and a shorter post-operative stay. [15]

Rao JM et colleagues conducted a randomised controlled study in children to assess and compare the surgical results and complications of modified circumcision utilising a disposable circumcision suture device (device group) to traditional dorsal slit circumcision (conventional group). All patients were preoperatively examined and reassessed four weeks following surgery. The perioperative data and postoperative results were compared in the two groups. There were no significant variations in average age or indications between the two groups preoperatively ($P > .05$). In contrast to the traditional group, patients in the device group

There was a shorter mean surgical time, less blood loss, lower intraoperative and postoperative pain scores, quicker incision healing time, and better satisfaction rate with penile cosmetic appearance ($P < .01$). Similarly, the device group had much reduced complication rates than the standard group. The modified circumcision employing a disposable circumcision suture device is a simple, safe, quicker, and more successful treatment that might become an appealing alternative to the traditional approach for children, with a reduced complication rate and better aesthetic outcomes. With the advancement of disposable circumcision suture device, the modified circumcision employing disposable

circumcision suture device has the potential to be extensively utilised globally. Jiang Z et al. investigated the safety and effectiveness of circumcision staplers in the treatment of children with phimosis and superfluous prepuce. The outcomes were surgery time, intraoperative blood loss, and postoperative problems. Results: The two groups differed significantly in terms of operation duration (5.35 min vs 30.30 min, $P < 0.05$) and intraoperative blood loss (2.56 ml vs 10.40 ml, $P < 0.05$). Circumcision staplers are better to traditional circumcision because they require less time to perform and result in fewer complications.

Shen J et al. conducted a comparative investigation of the clinical effectiveness of two disposable circumcision suture devices in adult men. The authors assessed the safety and effectiveness of two types of disposable circumcision suture devices in adult males. Postoperative problems for the two types of disposable circumcision suture devices vary. We should be aware of the risk of postoperative bleeding when patients use the Langhe disposable circumcision suture device, as this will result in a longer healing time, as well as postoperative pain and infection risk.

CONCLUSION:

Stapler circumcision is a time-saving and safe male circumcision procedure. Circumcision staplers are better to traditional circumcision because they require less time to perform and result in fewer complications.

References

1. Jin XD, Lu JJ, Liu WH, Zhou J, Yu RK, Yu B, Zhang XJ, Shen BH. Adult male circumcision with a circular stapler versus conventional circumcision: A prospective randomized clinical trial. *Brazilian Journal of Medical and Biological Research*. 2015 Mar 27;48:577-82.
2. Yuan Y, Zhang Z, Cui W, Gao B, Peng J, Xin Z, Guo Y. Clinical investigation of a novel surgical device for circumcision. *The Journal of urology*. 2014 May 1;191(5):1411-5.
3. Shen J, Shi J, Wang N, Tang J, Yu B, Wang W, Wang R. A Comparative Study on the Clinical Efficacy of Two Different Disposable Circumcision Suture Devices in Adult Males. *Urology Journal*. 2017 Sep 1;14(5).
4. Huo ZC, Liu G, Li XY, Liu F, Fan WJ, Guan RH, Li PF, Mo DY, He YZ. Use of a disposable circumcision suture device versus conventional circumcision: a systematic review and meta- analysis. *Asian journal of andrology*. 2017 May;19(3):362.
5. Fan Y, Cao D, Wei Q, Tang Z, Tan P, Yang L, Liu L, Liu Z, Li X, Xue W. The characteristics of circular disposable devices and in situ devices for optimizing male circumcision: a network meta-analysis. *Scientific Reports*. 2016 May 9;6(1):25514.
6. Jadhav RM, Nangare NR, Janugade HB. A comparative study of conventional and sutureless circumcision. *International Journal of Health Sciences*.(II):3018-28.
7. Rao JM, Huang H, Chen T, Yang CG, Pan CZ, Deng GC, Shen LJ, Qian XH, Peng MK, Zhou HD, Peng HL. Modified circumcision using the disposable circumcision suture device in children: a randomized controlled trial. *Urology*. 2020 Sep 1;143:206-

- 11.
8. Jiang Z, Chen H, Wu M, Li H, Jiang M, Cai X. Safety and Efficacy of Circumcision Stapler in the Treatment for Children with Phimosis and Redundant Prepuce. *Open Journal of Urology*. 2018 Aug 30;8(09):263.
9. Albero G, Castellsague X, Giuliano AR, Bosch FX. Male circumcision and genital human papillomavirus: a systematic review and meta- analysis. *Sex Transm Dis* 2012; 39:104-113.
10. Mehta SD, Moses S, Parker CB, Agot K, Maclean I, Bailey RC. Circumcision status and incident herpes simplex virus type 2 infection, genital ulcer disease, and HIV infection. *AIDS* 2012; 26: 1141-1149.
11. Bailey RC, Moses S, Parker CB, Agot K, Maclean I, Krieger JN, et al. Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomised controlled trial. *Lancet* 2007; 369: 643-656.
12. Hayashi Y, Kohri K. Circumcision related to urinary tract infections, sexually transmitted infections, human immuno-deficiency virus infections, and penile and cervical cancer. *Int JUrol*2013;20:769-775.
13. Larke NL, Thomas SL, dos Santos Silva I, Weiss HA. Male circumcision and penile cancer: a systematic review and meta-analysis. *Cancer Causes Control* 2011;22:1097-1110.

14. Hargreave T. Male circumcision: towards a World Health Organisation normative practice in resource limited settings. *Asian J Androl* 2010; 12: 628-638.
15. Ceylan K, Burhan K, Yilmaz Y, Can S, Kus A, Mustafa G. Severe complications of circumcision: an analysis of 48 cases. *J PediatrUrol.* 2007; 3: 32-35.