

# No-Needle Local Anesthesia for Adult Male Circumcision

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## Abbreviations and Acronyms

MC = male circumcision  
SR = Shang ring

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**Purpose:** We used a local anesthetic jet injection technique for adult male circumcision. This method eliminates needle use and may decrease the fear of local anesthetic injection used for male circumcision.

**Materials and Methods:** We recruited 60 men seeking voluntary adult male circumcision into the study from June to September 2009. We used a MadaJet® Medical Injector to deliver a high pressure spray of 0.1 ml 2% plain lidocaine solution directly through the penile skin circumferentially around the proximal third of the penis. All men underwent circumcision using the Shang Ring™ and were evaluated for anesthetic safety, efficacy and acceptability. Pain was measured on a visual analog scale.

**Results:** The average volume of 2% lidocaine anesthetic solution delivered by jet injection was 0.1 ml with a mean total of 0.9 ml per circumcision procedure. More than 85% of men did not require supplemental anesthesia. Anesthetic onset required approximately 45 seconds from the time that injections were completed. Mean pain scores for immediate postoperative, 24-hour postoperative, ring removal and post-ring removal events were 0.1, 6.8, 2.2 and 0.9, respectively. In 4 patients (6.67%) mild urethral bleeding resolved with pressure, resulting in technique modification.

**Conclusions:** No-needle jet injection is safe and effective for adult MC. The technique efficiently delivers local anesthesia with rapid onset in men undergoing circumcision. This needle-free approach may enhance the popularity of adult male circumcision.

**Key Words:** penis; circumcision, male; injections, jet; equipment and supplies; lidocaine

MALE circumcision is one of the most common surgical procedures with a prevalence of approximately 70% in the United States and 30% world wide.<sup>1-3</sup> Adult MC has recently gained renewed interest in international public health circles since several clinical trials have shown that circumcision protects men from HIV as well as human papillomavirus and herpes simplex virus.<sup>4-7</sup> The complication rate of adult MC is about

2% to 4% under optimal conditions.<sup>3,8,9</sup> However, in nonclinical and resource poor settings the complication rate is significantly higher, at 35.2% and 17.7%, respectively.<sup>10,11</sup> Standardization of adult MC is an ongoing issue.

Adult circumcision is usually done using a dorsal slit, forceps guided or sleeve resection technique and it requires 4 to 6 weeks of abstinence from sexual activity to enable complete

wound healing.<sup>12,13</sup> To facilitate adult MC standardization, several devices have recently appeared on the market that show promise in clinical trials. One novel device is the Chinese SR, which has been used effectively to circumcise several thousand men in China since 2005.<sup>14</sup> The SR consists of 2 concentric plastic rings and a soft silicone pad that entraps the penile foreskin, allowing it to be cut away without stitches or significant bleeding. While conventional MC requires approximately 30 to 40 minutes, the SR has decreased operative time to 3 to 5 minutes, enabling substantially more procedures to be performed daily.

MC can be done using local anesthesia but a substantial number of adult MCs in the United States are performed using general anesthesia due to the fear of pain and concern about inadequate local anesthetic technique.<sup>15</sup> Local anesthesia for adult circumcision is usually given by a dorsal penile nerve block and/or a ring block. Specifically lidocaine without epinephrine is injected at the penile base deep into Buck's fascia, where the dorsal nerves emerge from under the pubic bone. The injection sites are at the 10 to 11 and 1 to 2 o'clock positions relative to the penile base. A 24 gauge needle is typically inserted and directed ventral. Initially a wheal is raised at the skin surface and the needle is then advanced deep and proximal along the penile shaft while injecting 3 to 5 ml anesthetic solution. Multiple circumferential injection block anesthesia is another common method. Potential complications are rare but include hematoma and intravascular injection of local anesthesia.<sup>16</sup> Good local anesthetic technique is essential to achieve a pain-free procedure and prevent these complications. Conventional local anesthetic administration usually requires 10 to 15 minutes to take effect and can be the most anxiety provoking aspect of the procedure in men.

Historically some men have refused surgical procedures such as vasectomy since they fear pain and possible complications of needle injection. To mitigate these fears a no-needle technique has been

successfully used using a MadaJet jet injector. Anesthetic solution is sprayed through the scrotal skin using a high pressure injector that patients have described as a gentle snap of a rubber band. Users of this device for vasectomy have documented an excellent safety and efficacy profile along with excellent patient acceptability.<sup>17</sup>

In this pilot study we examined the safety, efficacy and acceptability of a no-needle anesthetic technique for MC. This approach may decrease fear of the pain associated with the needle puncture, facilitating further adult MC endeavors world wide.

## MATERIALS AND METHODS

### Study Eligibility Criteria

This phase I clinical trial was designed as a collaborative effort between the Department of Sexual Medicine at Yijishan Hospital-Wannan Medical College, Wuhu, People's Republic of China, and the Department of Urology, Center for Male Reproductive Medicine and Microsurgery, New York Presbyterian-Weill Cornell Medical Center, New York, New York. All patients were screened from June to September 2009 by the principal investigator (YFP). The study protocol was approved by the Yijishan Hospital-Wannan Medical College institutional review board and informed consent was obtained from all study participants or their guardians. Eligible patients had phimosis or elected circumcision. Contraindications for study inclusion were acute inflammation, uncontrolled diabetes mellitus and penile phimosis secondary to balanitis xerotica obliterans. Any patient with congenital penile abnormalities such as hypospadias was excluded from study. Patients were informed that the anesthetic technique was investigational and, although it had been used for other urological procedures, it had never been used for MC.

### Anesthesia

**Preparation.** The MadaJet brand was used for all jet injections in this study. The jet injector was assembled and prepared in the standard manner, as previously described.<sup>17</sup> Approximately 4.5 ml of anesthetic solution (2% lidocaine without epinephrine) were loaded into the filling chamber (fig. 1, A). The main injector was fired several

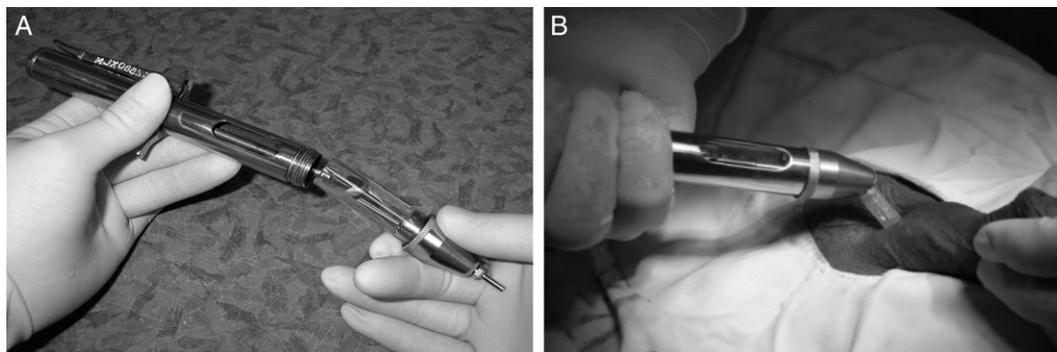


Figure 1. A and B, no-needle setup and technique

times to prime the mechanism before first use. This action also cleared any potential debris or contaminants from the tip. After use the injector was fully autoclavable for instrumental sterilization.

**Injection.** All patients underwent penile disinfection with iodophor or 0.05% chlorhexidine solution and were draped in standard surgical fashion for circumcision. The penis was grasped and the jet injector was placed at the penile base or the proximal third of the shaft. The spacer on the jet injector tip was positioned firmly over the penile skin and 1 spray of anesthesia was applied. Each spray was applied approximately 8 to 10 mm apart in circumferential fashion around the proximal third of the penis (fig. 1, B).

The jet injector was held perpendicular to the skin while administering anesthesia to the penile dorsal and lateral aspects. On the penile ventral aspect the jet injector was angled transversely 30 degrees away from the urethra to minimize injury to the penile urethra. After all 8 to 10 sprays at 0.1 ml per spray were administered to achieve a ring block throughout the penile base, we tested the distal penis and foreskin to ensure the penetration of appropriate local anesthesia.

### Circumcision

SR was used for all circumcisions. SR consists of an inner and an outer ring, a silicone rubber gasket and a fastener. Penile diameter is first measured to determine appropriate ring size (fig. 2, A). After anesthetic administration the inner ring is placed around the penis to the level of the

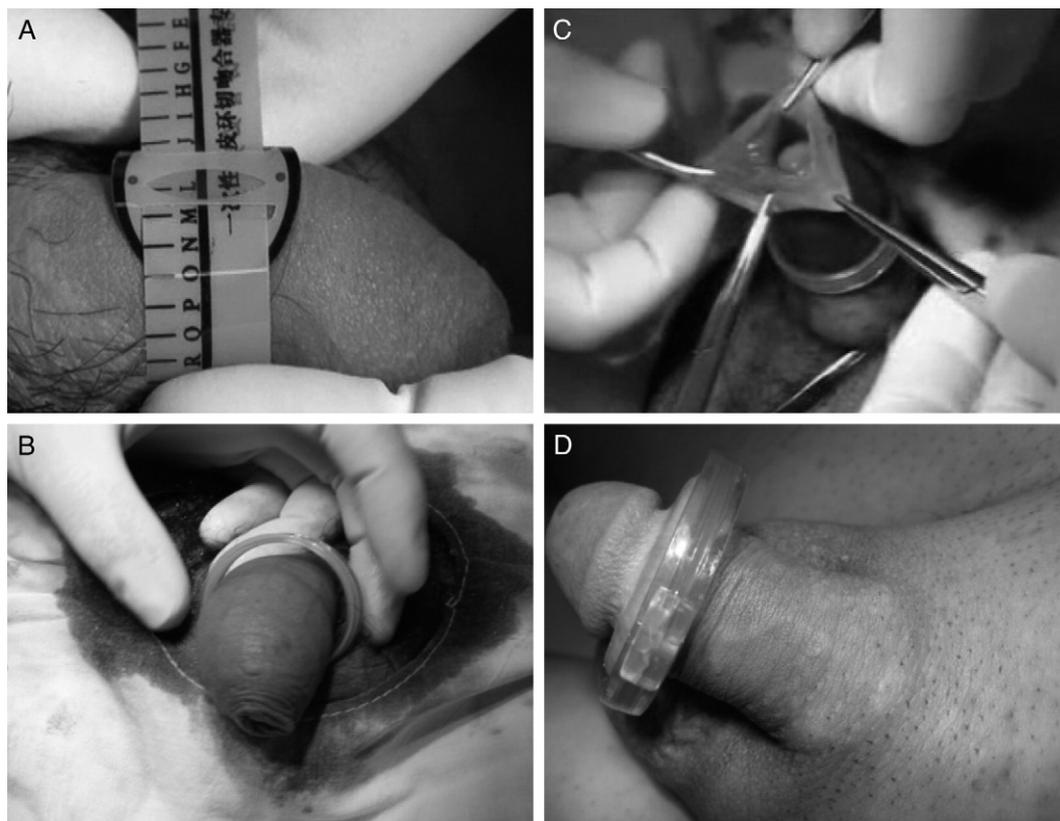
coronal sulcus (fig. 2, B). The foreskin is carefully everted over the inner ring (fig. 2, C). The outer ring is placed over the inner ring to sandwich the foreskin (fig. 2, D). The outer ring is tightened over the inner ring and the excess foreskin is excised using suture scissors. Three to 5 slits are then made in the foreskin on the underside of the ring using a scalpel blade. These slits are needed to enable the skin to spread as healing occurs and allow scab expansion.<sup>10</sup> The SR is left in place for 7 to 10 days and removed at a followup visit. A detailed description of a standardized surgical protocol for SR application has been previously published.<sup>18</sup>

### Ring Removal

In all patients the SR was removed on postoperative day 7. All patients were instructed to ingest 1 tablet of a nonsteroidal anti-inflammatory drug in the 30 minutes before SR removal. To further decrease any discomfort and soften the scab 2% lidocaine was sprayed on the wound. The outer ring was then removed. The inner ring was carefully separated from the wound margin and cut at the 3 and 9 o'clock positions using special scissors with a blunt tip and recessed cutting edges. The wound was wrapped with a bandage and the patient was instructed to change the bandage once daily for 7 days.

### Pain Assessment

All patients were asked to complete a visual analog scale pain questionnaire, which has been validated in other



**Figure 2.** A to D, SR surgical technique

clinical trials as an effective tool to evaluate patient pain perception.<sup>19,20</sup> We assessed information on operative and postoperative pain with the no-needle injection. Patients were asked to rate pain on a scale of 0—no to 10—severe pain at 4 points, including during MC, within 24 hours after MC, during SR removal and after SR removal. For pain scores after MC and after removal the men were contacted by telephone approximately 24 hours postoperatively.

## RESULTS

A total of 60 men were enrolled in the study. Mean patient age was 25.4 years and most patients were 21 to 30 years old (see [table](#)). All patients underwent MC with the SR, as described.

Each anesthetic jet injection delivered approximately 0.1 ml anesthetic solution. A median of 8 sprays were used with a median of 9 mm between spray sites (see [table](#)). Before proceeding with MC 9 of the 60 men (15%) who received the jet injection required supplemental needle anesthesia, consisting of a penile ring block of 3 to 5 ml 2% lidocaine.

Anesthetic onset was defined as the interval from the last dose of jet injected anesthesia to MC. Adequate pain control was assessed before proceeding with the operation. In the 51 cases with only jet

anesthesia median time to onset was 42 seconds (see [table](#)).

Four patients experienced mild urethral bleeding after jet injection, including 2 adults (3.9%) and 2 pediatric patients (25%) (Fisher's 2-tailed exact test  $p = 0.16$ ). Bleeding resolved spontaneously with mild pressure at the jet injector site in all cases. Other listed complications were related MC and not to the no-needle technique. In 4 patients mild wound erythema suggestive of superficial infection was treated with a brief course of oral antibiotics. Four patients with mild wound dehiscence were treated conservatively. Mild to moderate edema at the surgical site in 18 patients resolved spontaneously in all.

The mean intraoperative pain score reported by patients was 0.10 but within 24 hours after surgery the average pain score was 6.83. When patients presented for SR removal, they reported an average pain score of 2.23 during SR removal. The post-ring removal pain score was 0.90. No patients required supplemental anesthesia during SR ring removal other than 2% lidocaine spray.

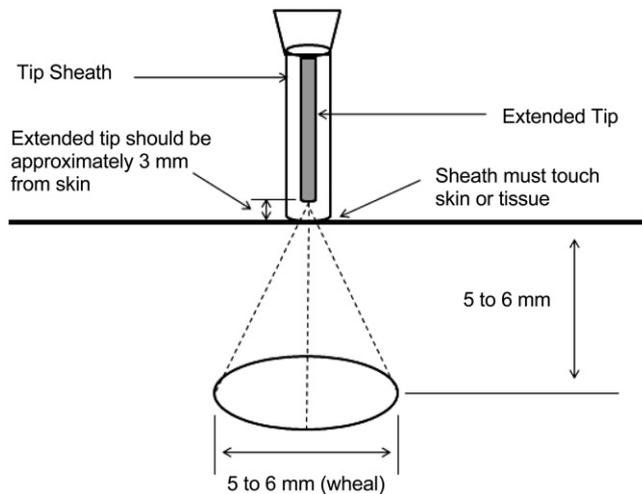
## DISCUSSION

Jet injection anesthesia may minimize the fear of needles in men seeking circumcision. Anesthesia using a high pressure jet injection device has been extensively used in dermatology, cosmetic and plastic surgery, gynecology, urology, dentistry and immunization.<sup>17,21–23</sup> The jet injection technique generates a high pressure spray, which creates a precise anesthetic mist that behaves as a virtual needle, passing through the penile skin and producing a numbing effect without requiring a needle. The jet stream exerts its anesthetic effect in a cone-shaped distribution, penetrating local tissue adjacent to the injection site ([fig. 3](#)). The stream penetrates approximately 4 to 4.5 mm into the tissue and disperses approximately 5 to 6 mm in diameter. Most men describe the sensation of the no-needle technique as a snap of a rubber band. In this study the no-needle technique was safe, efficacious and well tolerated in men seeking MC. In 85% of study patients the no-needle technique was the only anesthetic technique used. The anesthetic effect was rapid and easy to apply, which should be advantageous at high volume centers.

Our previous urological experience with the MadaJet System includes its use for no-needle, no-scalpel vasectomy, for which it was a safe, virtually painless, effective anesthetic technique.<sup>17,24</sup> Jet injection leads to a substantial decrease in the volume of anesthetic solution used, minimizing local swelling at the surgical site and significantly decreasing the time needed to achieve effective local anesthesia. The jet injector may also provide significant cost

*Patient demographics, anesthetic characteristics and no-needle anesthetic time*

	No. Pts
Ages (yrs):	60
7–14	8
15–20	12
21–30	27
31–40	8
41–50	3
Greater than 0	2
Indication:	
Redundant prepuce	51
Phimosis	9
No sprays:	
6 or Less	3
7	8
8	24
9	12
10	12
11	1
Distance between sprays (mm):	
8	13
9	25
10	17
11	5
Supplemental needle anesthesia	9
Time to surgery (secs):	51
0–30	10
31–40	12
41–50	16
51–60	10
Greater than 60	3



**Figure 3.** Anesthesia soft tissue penetration with jet injector

savings in high volume practices as a result of 1) decreased demand for lidocaine, 2) a minimal need for needles and syringes, and 3) decreased medical waste, ie needles, syringes and vials. Our study shows favorable results using jet injection anesthesia in men seeking voluntary circumcision. At a median of 9 sprays of anesthesia per procedure less than 1 ml 2% lidocaine is used per MC. Moreover, after it is loaded with 2% lidocaine, the device can be used for 3 to 4 MCs before reloading the anesthetic solution. The medical injector cost of \$568 to \$662 per set must be factored into the cost equation. Jet injectors also require regular maintenance and inspection to ensure a properly functioning unit.

Despite the relative intraoperative painlessness of the no-needle technique, the 24-hour postoperative pain score is of concern. Our study population reported a mean pain score of 6.83 approximately 24 hours after surgery. None of our patients were prescribed any specific postoperative analgesia but were advised to use over-the-counter medication. Patients who undergo adult MC in the United States are typically sent home with oral narcotic analgesics, which many require for 2 or 3 days postoperatively. In contrast to pain scores reported by Cheng et al,<sup>18</sup> this population reported more pain 24 hours

after surgery. However, this may have been due to methodological differences between the 2 studies. Cheng et al asked the men about pain when they returned for ring removal 7 days postoperatively while we contacted the men approximately 24 hours after surgery to minimize recall bias.

We recommend providing prescription analgesics postoperatively. Minimal pain was experienced during SR removal with almost negligible removal discomfort. To our knowledge we report the first study of no-needle anesthesia in men undergoing circumcision. The results of this pilot study suggest that the jet injector is a promising technique for anesthetic delivery for adult MC. This clinical experience is being used to drive future randomized, controlled trials comparing the no-needle technique to conventional needle delivery anesthesia.

Complications of no-needle anesthesia were minimal and minor. The mild urethral bleeding experienced by 4 adults and 2 children led to a modification of the anesthetic technique with the jet injector intentionally aimed at a 30-degree angle away from the urethra when anesthetizing the penile ventral aspect to minimize the risk of penetrating the penile urethra. The number of pediatric patients treated was small in this study and the difference was not statistically significant but pediatric patients appeared to have a higher rate of urethral bleeding and further research may be needed.

## CONCLUSIONS

No-needle anesthesia using the jet injector is safe and effective for adult MC. Complications are rare and minor. With the increased demand for adult MC worldwide no needle anesthesia offers high volume centers the possibility of a safe, virtually painless technique with rapid onset of effective anesthesia. Further studies are planned to prospectively compare the no-needle technique vs traditional needle injection of anesthesia.

## ACKNOWLEDGMENTS

An English translation of a standardized surgical protocol for SR application is available.<sup>18</sup>

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