

# Assessment of meatal stenosis in neonates undergoing circumcision using Plastibell Device with two different techniques

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**Purpose:** It was intended to compare meatal stenosis (MS) as a late complication of neonatal circumcision by using two different methods of Plastibell Device circumcision.

**Materials and methods:** A total of 2,307 healthy term newborns (6–36 hours) who were born between 2007 and 2009 in Niknafs Medical Center of Rafsanjan, Iran, were simply randomized into two groups in a controlled, nonblinded clinical trial. In group A (1,102 neonates), the frenulum was maintained intact without any manipulation, and in group B (1,205 neonates) frenular hemostasis was performed in all cases by thermal cautery. MS was assessed by follow-up visits that were made for all cases at the 24–72 hours, 60th day, 12th month, and 16th month after circumcision.

**Results:** At 2 months follow-up visit, the rate of MS in group A was 4.9% (54) and in group B was 5.9% (71), which was not statistically significant. After 12 months, MS in group A was 8.5% (94) and in group B was 13.7% (165), which was statistically significant ( $P<0.001$ ). At 16 months after circumcision, in the frenulum intact group, MS was 13.8% (152) and in the cautery group, it was 18.9% (228), which was compatible with significant difference ( $P=0.001$ ).

**Conclusion:** Our experience with large group of cases revealed that neonatal circumcision by using Plastibell Device with intact frenulum technique decreases the rate of delayed MS.

**Keywords:** neonatal circumcision, Plastibell device, meatal stenosis

## Introduction

Circumcision is one of the most common neonatal surgical procedures performed throughout the world. About one-sixth of total male populations of the world have undergone circumcision and most of them are performed for religious beliefs, not for medical reasons.<sup>1</sup> Circumcision, like other surgical procedures, has intraoperative and postoperative complications including bleeding, meatal stenosis (MS), and penile injury. MS is one of the late complications of circumcision that occurs in 5%–20% of circumcised cases.<sup>2</sup> Severe balanitis, ischemia due to frenular artery ligation, meatitis, and chemical dermatitis caused by urine are the possible etiologies for MS occurrence.<sup>3</sup> Circumcision using Plastibell Device is one of the most common techniques used for neonatal circumcision in outpatient clinics. Two to three percent of circumcised cases were complicated after Plastibell Device Circumcision.<sup>4</sup> Not all boys – particularly in non-Islamic countries – are circumcised. However, the risk of MS in non-circumcised boys is 10–26 times lower than circumcised boys.<sup>5</sup>

We designed this study to assess the rate of MS in two different methods of Plastibell Device Circumcision – intact frenulum and thermal cautery of frenulum – in large group of neonates.

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## Materials and methods

A total of 2,307 healthy term newborns (6–36 hours) who were born between January 2007 and December 2009 in NIKNAFS Medical Center of Rafsanjan were simply randomized into two groups in a controlled, nonblinded clinical trial. Mean birth weight was 3,180 g in group A and 3,150 g in group B; mean age of cases was similar between the two groups. Of the 2,307 cases that were included in this study, 1,102 cases were in group A and 1,205 in group B. The neonates underwent Plastibell circumcision which was conducted by a general urologist after a routine physical examination. Surgical procedure was performed after one trial of successful voiding. Scrotum, penis, and groin area were cleaned by using disinfecting solution and then evaluation for penile anatomic abnormalities was completed. Lidocaine 1% (2 mg/kg) was used for dorsal penile nerve block. In group A (1,102 neonates), the frenulum was maintained intact without any manipulation, and in group B (1,205 neonates) frenular hemostasis was performed by thermal cautery. An appropriate Plastibell Device was then positioned over the glans, and the Plastibell ring was overlaid by unnecessary preputial skin, and ligation was completed by a silk suture over the ring groove. After circumcision, 10 mg/kg oral acetaminophen was prescribed as analgesic immediately and their parents were informed about any complications. The neonates were observed 1 hour after circumcision, and then discharged without antibiotic prescription. Other blinded follow-up visits were made for all cases at the 24–72 hours, 2 months, 12 months, and 16 months post circumcision by the original urologist who had performed the procedure. At the second visit (24–72 hours), the neonates were examined for early complications and in the third and fourth visits the urinary calibration was performed for evaluation of MS. At this stage, urinary calibration was done by visual inspection for finding the pin-point urethral opening. At the last visit (16th month), the caliber of urine stream was estimated by visual inspection.

## Ethics statement

We declare that our study was approved by the ethical Committee of the Rafsanjan University of Medical Sciences. Additionally, written informed consent was provided by the parents or legal guardians of the babies for participation in our study, the safety of our procedure, and its probable complications.

## Results

MS was assessed at three follow-up visits: 2 months, 12 months, and 16 months post circumcision. At 2 months, the rate of MS in group A (frenulum intact group) was 4.9% (54 cases) and in group B (cautery group) was 5.9% (71 cases), which was not statistically significant. At 12 months after circumcision, MS

in the frenulum intact group was 8.5% (94 cases) and in the cautery group was 13.7% (165 cases), which was statistically significant ( $P<0.001$ ). At the 16th month post circumcision, the rate of MS was significantly higher ( $P=0.001$ ) in group B: 13.8% (152 cases) in the frenulum intact group and 18.9% (228 cases) in the cautery group (Table 1).

Follow-up visit at 16 months after circumcision revealed that MS increased significantly in both groups ( $P<0.001$ ).

## Discussion

Circumcision is one of the most common surgical procedures performed in the world. It can be performed at any age but usually is completed during the neonatal period.<sup>6</sup> Neonatal circumcision can be performed via different methods but three techniques are used routinely: the Mogen clamp, the Gomco clamp, and the Plastibell Device.<sup>7</sup> In the United States, most of the newborns are circumcised by the Gomco clamp or the Plastibell Device.<sup>7</sup> In one study, the complications due to the Plastibell Device were reported between 1.85% and 3%.<sup>9,10</sup> Another study reported a complication of 7.08% with this technique.<sup>11</sup>

Meatal Stenosis is one of the late complications of circumcision. Surgical intervention such as ventral meatotomy may be indicated in severe forms of MS. Some previous studies have investigated the prevalence of MS such as Reynolds RD et al<sup>8</sup> and ceylan et al<sup>12</sup>. They revealed that the prevalence of MS was 23% and 20.4%, respectively. Two main pathophysiologies suggested for MS are meatitis and meatal ischemia due to damage of the frenular artery following circumcision.<sup>3</sup>

Our study was designed to evaluate the effect of frenular artery manipulation on MS in Plastibell Device circumcision. In group A the frenulum remained intact, and in group B frenular hemostasis was performed by thermal cautery as previously described. Our results revealed that although MS incidence increased in both groups at the follow-up period, although it was less frequent in group A compared with group B, significantly. Assessment of infants for MS showed that the frequency of this complication declined in group A compared

**Table 1** Prevalence of meatal stenosis at different follow-up times after circumcision in two groups of cases (defined by visual inspection of meatus)

Time of visit	Group of patients	Meatal stenosis
2 months after circumcision	Group A	54 (4.9%)
	Group B	71 (5.9%)
12 months after circumcision	Group A	94 (8.5%)
	Group B	165 (13.7%)
16 months after circumcision	Group A	152 (13.8%)
	Group B	228 (18.9%)

with group B significantly except at the first visit (60th day). This decrease was 1% in 60th day post circumcision, which was not statistically significant. It may be from this hypothesis that MS is a late complication of circumcision, and the mean age of symptomatic presentation of stenosis in children is 3 months to 13 years, whereas the mean age of presentation of stenosis in one study was 1–2 years.<sup>13</sup>

Therefore, it can be concluded that symptomatic presentation of MS after neonatal circumcision may be very late and can be the cause of a low percentage of MS incidence in the 60th day in our study. There was a significant difference between the two groups regarding prevalence of MS at 12 and 16th month post circumcision visits and it seems that this difference may be from the effect of frenulum manipulation.

## Conclusion

MS is extremely rare in boys who are not circumcised. If parents request that the foreskin be removed from their son's penis for religious or cultural reasons, it is important for pediatric surgeons/urologists to perform circumcision with safety and minimal trauma to the glans and urethra of the neonate. The complication rate at the operating table of circumcision is low with the Plastibell Device. MS is one of the late complications of circumcision that is mainly seen 1–2 years later. The late occurrence of MS was significantly lower in our group of boys who were circumcised with preservation of the frenulum compared with those who underwent circumcision with thermal cautery of the frenular artery. These results indicate that non-manipulation of the frenulum decreases the risk of MS.

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## Disclosure

The authors report no conflicts of interest in this work.

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