ORIGINAL ARTICLE

Minimally invasive circumcision with a novel plastic clamp technique: a review of 7,500 cases

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Abstract

Purpose We aimed to analyze the outcome of circumcisions performed with a new minimally invasive circumcision device.

Methods This is the first study, which reports the results of 7,500 children circumcised with minimally invasive technique utilizing a plastic clamp device (Ali's clamp®) in our country. The results of this technique are compared to those of 5,700 children who underwent conventional circumcision.

Results The most common complication encountered after minimally invasive circumcision technique was found to be buried penis (1.04%). The second complication observed was infection (0.6%), which was significantly lower than the conventional group (p < 0.001). The third complication in plastic clamp group was bleeding with a rate of 0.4%. Bleeding was found to be the most common complication seen after conventional circumcision (5%) and was significantly higher than that of the plastic clamp group (p < 0.001). Total number of complications seen after plastic clamp technique was 2% when compared with 10.4% complication rate occurred after conventional circumcision (p < 0.001). The mean duration of circumcision time with plastic clamp technique was 4.5 ± 1.5 min whereas with conventional circumcision it was 23 \pm 4 min (p < 0.0001).

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Conclusion Minimally invasive circumcision technique utilizing plastic clamp significantly reduced the complication rates. The cosmetic appearance after circumcisions performed with this technique was observed to be better than the conventional circumcisions. Due to reduced complications, as well as short duration and ease of application, the minimally invasive technique is suggested as the circumcision procedure of choice.

Keywords Circumcision · Minimally invasive · Complications · Ali's clamp technique

Introduction

Circumcision is one of the oldest operations with a history of more than 15 thousand years. In our country, circumcision is a routine surgical procedure mainly performed for religious reasons. Circumcision became popular also in countries such as United States where more than 50% of newborns are being circumcised due to its therapeutic benefit or social reasons [1, 2]. On the other hand, in some countries such as England circumcision rate is reported to be very low (5%) [3].

There are various circumcision techniques, but in general, can be classified in two major groups depending on the material used to adhere the cut edges and maintain the haemostasis independent of the foreskin excision technique. In conventional circumcision, the cut edges of the wound are held together by suturing. The other technique known as minimally invasive circumcision utilises a device, which approximates the wound edges and maintains haemostasis. Each surgical technique has its own limitations and risk-benefit ratios. Although the therapeutic benefits of circumcision seem to be significantly high,



complications related to conventional circumcision technique cannot be underestimated [4–7]. Bleeding and wound infection are the most common complications of the circumcision [7–9]. In order to minimize the rate of complications and shorten the duration of the procedure, various minimally invasive techniques were developed. Following the introduction of Gomco clamp in 1935, a number of minimally invasive techniques performed with plastic devices have been reported [10-12]. These new devices made it possible to perform circumcision more easily within a short period of time. The ease of application, duration of the procedure and the rate of complications are the most important parameters in making decision of the technique to be used. This is the first report from our country analyzing the outcome of circumcisions performed with a new minimally invasive circumcision device. Furthermore, these results have been compared to those of conventional circumcision.

Materials and methods

Subjects

In our country where 99% of the population is Muslim, circumcision is performed mainly for religious reasons to all male children. A retrospective analysis of the complication rates among 7,500 children who were circumcised in three separate clinics utilizing a new plastic disposable device (Ali's clamp®) over a 6-year period (between January 2003 and February 2009) was performed. The rate of complications was compared to 5,700 children who were circumcised with conventional method using a suturing technique performed between June 1999 and November 2002. The age of children varied between first day of the life to 15 years. All of the circumcised children were followed up to 1 month for the possible complications such as infection, bleeding and buried penis. None of the patients were lost to follow up as this period was relatively short as well as circumcision is accepted as one of the most important surgical procedures in our country. Families do not satisfy unless the penis is totally healed without any problem, which is confirmed by their doctor.

Technique

Technique for conventional circumcision has been well defined elsewhere [13]. Ali's clamp[®] includes two plastic components and there are various sizes depending on the diameter of the inner tube (Fig. 1a, b). Number 10 and 12 clamps are usually used for the newborn and infant circumcisions, and number 14–20 clamps for older children. After sterile cleaning of the penis, local infiltrative

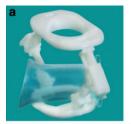




Fig. 1 Ali's clamp[®] **a** Includes two plastic components. An inner tube that is placed on the glans and an outer white plastic ring placed over the inner tube. **b** There are various sizes of the clamps between numbers 10–22 depending on the diameter of the inner tube

anaesthesia (dorsal penile nerve block) was applied with 0.8–2 mL of 1% lidocain. Circumcision with Ali's clamp® started after duration of 10–20 min following application of the local anaesthesia (Fig. 2a–i). There was no bleeding due to adequate haemostasis obtained with the pressure of the ring. Wound care and dressing was not necessary after the procedure. Children were allowed to wear their daily clothes and take a shower any time after the circumcision. The plastic apparatus was removed between 24 h and 5 days depending on the age of the child. Any difficulty was not experienced during the removal of the clamp. Children were called for routine follow-up visits, 1 week and 1 month after removal of the clamp.

Statistics

Age, duration of the circumcision and rate of complications such as infection, bleeding and buried penis among the children circumcised either with conventional or plastic clamp techniques were compared by utilizing Student's *t* test and the Chi-square test. PASW Statistics 18 for Windows was utilized for the data analysis and the significance level was accepted as 0.05.

Results

A total number of 7,500 children were circumcised utilizing Ali's clamp and 5,700 children with conventional circumcision method. The mean age was 7.2 ± 2.4 among the children who underwent conventional circumcision and 5.8 ± 1.8 in children who were circumcised with the plastic clamp technique. The number of children using diapers was 798 (14%) in conventional circumcision group



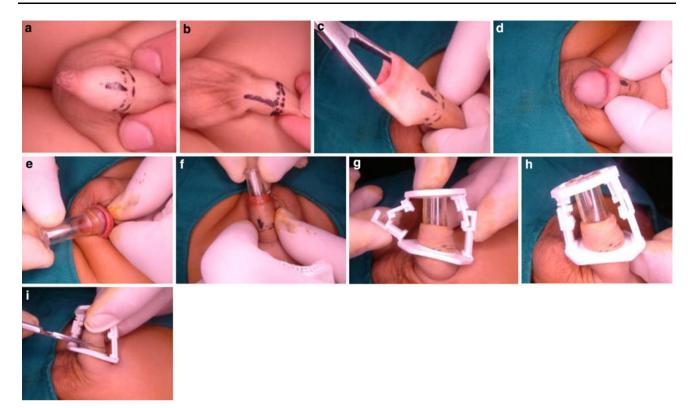


Fig. 2 Circumcision with Ali's clamp[®]. a Initially the penile skin which will be excised is marked with a sterile marking pen. b Ventral part of the penis was marked so as to leave longer skin at this region. c-d After completion of the marking, the foreskin is dilated with a hemostate and retracted completely to expose the glans. e According to size of the glans, an appropriate size of inner plastic tube is placed. f Following the placement of the inner tube, retracted foreskin is pulled over this tube to let the foreskin lie on the outer side and

leaving the glans inside of the tube. **g** A second white outer plastic ring was then placed over the foreskin and placed exactly at the border which was initially marked. **h** The outer plastic ring was locked after being sure that it was exactly covering the previously marked border. **i** The foreskin being squeezed between the inner tube and the outer ring was consequently excised with a number 15 surgical blade

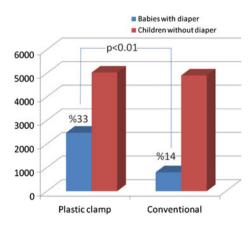


Fig. 3 The percentage of children using diapers in the plastic clamp group (33%, n 2,475) was significantly higher than the children in conventional circumcision group (14%, n 798) (p < 0.01)

whereas in plastic clamp group it was 2,475 (33%) (p < 0.01, Fig. 3).

The most common complication encountered after minimally invasive circumcision technique was buried penis, which was accepted as healing of wound edges above the glans penis and causing a constrictive ring at this level resulting in phimosis. This complication occured at similar rate in both circumcision groups. The children below 2 years age, and over 95 percentile weight were found to be under the risk of buried penis. Among the children circumcised with plastic clamp technique, the incidence of buried penis was 1.04% (n = 78, 60 of them under age of 2). Three out of 78 children underwent surgical revision in the plastic clamp group (3.8%). Two of the children requiring surgical revision were under 2 years of age and one older than 2 years. Buried penis was observed in 68 children who underwent conventional circumcision (1.2%), which was similar to the percentage observed after plastic clamp technique (p > 0.05). On the other hand, the number of children requiring surgical revision was 50 (74%) in the conventional circumcision group which was significantly higher than that of the plastic clamp group (p < 0.001).

The second complication observed after plastic clamp circumcision was infection. Pain around the wound 3 days after the circumcision, as well as hyperaemia and oedema



more than anticipated were considered as wound infection. The infection rate in plastic clamp group was found to be 0.6% whilst in the conventional circumcision group it was 4.2% (p < 0.001). Age of the child was found not to affect this rate. Among the children who underwent minimally invasive circumcision only 5 out of 45 (11%) of the children experienced a wound infection, which required administration of oral antibiotics (Table 1).

The third complication observed among the children circumcised with plastic clamp was bleeding, which occured within 24 h after disconnection of the clamp. The rate of bleeding in this group of children was found to be 0.4% (n = 30). Ten of these cases were due to a major trauma to penis such as a kick from older brother. Twelve cases occurred after a frictional force caused by the diaper or underwear, and eight of the bleedings occurred spontaneously (most of them started after urination). Fourteen children with bleeding (46.6%) required suturing to maintain haemostasis. Bleeding with a rate of 5% (n = 285) was the most common complication seen after conventional circumcision and was significantly higher than that of the minimally invasive circumcision (p < 0.001) (Table 1). Nearly half of them were major bleeding cases, which required suturing (n = 125, 43.8%). Age of the child was found not to affect the bleeding rate in both groups.

Total number of complications seen after plastic clamp technique was 153 (2%) whereas with the conventional circumcision it was 592 (10.4%) (Table 1). Results of this study demonstrate that minimally invasive circumcision has five times lower complication rate than that of the conventional circumcision technique. Duration of the circumcision time was also significantly lower than that of the conventional circumcision. The mean duration of circumcision time with the plastic clamp technique was 4.5 ± 1.5 min whilst for conventional circumcision it was 23 ± 4 min (p < 0.0001) (Table 1).

Cosmetic appearance of the incision line looked better in the plastic clamp group, being smooth and regular (Fig. 4a). Among the children circumcised with

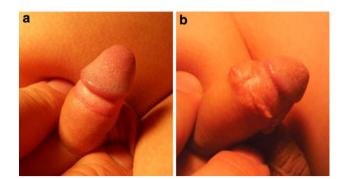


Fig. 4 a Cosmetic appearance of the penis circumcised with plastic clamp technique. The incision line was smooth and regular. b Among the children circumcised with conventional method, the incision line appeared slightly irregular and suture marks were remarkable

conventional method, the incision line appeared slightly irregular and suture marks were remarkable (Fig. 4b). There was a significant difference among the costs of either technique. The mean cost of plastic clamp technique was US \$6 where it was US \$14 for conventional circumcision. This difference was attributed to the high cost of the sutures utilized in the conventional method. At least one polyglactin suture were utilized for hemostasis and for wound stitches in conventional circumcision.

Discussion

Circumcision, with a history of at least 15 thousand years is accepted as the most common worldwide surgical procedure [14]. In our country, where 99% of the population is Muslim, circumcision is performed to only male children and mainly for religious reasons. Decreased incidence of urinary tract infections, and penile cancer among the circumcised men are accepted as the health benefits of circumcision [15, 16]. Recently, it was reported that circumcision significantly decreased the risk of HIV incidence [17]. Despite various benefits, a number of complications are related with circumcision. Conventional circumcision has overall complication rate between 2 and

Table 1 The comparison of the age of the children, complication rates and duration of plastic clamp and conventional circumcision procedures

	Plastic clamp (n 7,500)	%	Conventional (n 5,700)	%	p
Age	5.8 ± 1.8		7.2 ± 2.4		< 0.05
Infection	45	0.6	239	4.2	< 0.001
Bleeding	30	0.4	285	5	< 0.001
Bleeding required suturing	14/30	47	125/285	44	>0.05
Buried penis	78	1	68	1.2	>0.05
Buried penis required surgical revision	3/78	3.8	50/68	74	< 0.001
Total complications	153	2	592	10.4	< 0.001
Duration	4.5 ± 1.5 min		$23 \pm 4 \text{ min}$		< 0.001



10%, bleeding being the most common [7]. In order to minimize the complication rates of the conventional circumcision such as bleeding, wound infection, sepsis, penile injury and painful erection, there is a search for an ideal minimally invasive circumcision technique. This is the first study from our country analyzing the outcome of circumcisions performed with an easy applied plastic disposable device, Ali's clamp[®] in regard to complication rate and duration period in comparison to conventional circumcision technique.

Buried penis is a serious complication observed after circumcision, which has been reported as 2% after the minimally invasive circumcision [18]. The rate of buried penis found in our study was nearly half of this rate. Although it has been reported that redundant foreskin would be the main reason for the buried penis [19], in our study this complication did not seem to correlate with the amount of the foreskin left. The percentile weight of the child and age were found to be the main factors affecting the rate of this complication. Children with an exaggerated pre-pubic subcutaneous adipose tissue and a penis with small glans diameter were accepted as the risk groups for buried penis. In the plastic clamp group, only 3.8% of the children with buried penis required surgical revision in contrary to 74% requiring revision in the conventional group. This significant difference seen after conventional circumcision was attributed to the massive fibrosis occurring at the wound site, which anchored the wound edges and made it very difficult to retract. The low rate of necessity for surgical revision among the children with buried penis was accepted as an important advantage of plastic clamp technique. Children who underwent surgical revision in the plastic clamp group were those who missed their routine follow-up visit and were seen 1 month after the circumcision where retraction was not possible. Rest of the children with buried penis, were diagnosed within the first month where the active wound healing was in process. All of them were managed without surgical intervention by performing a penile massage. Penile massage was performed by retracting the penile skin by applying compression on the pre-pubic adipose tissue. This massage applied by the family at least three times a day for 4 weeks allowed healing without any surgical revision with a satisfactory cosmetic result.

Bleeding after plastic clamp circumcision was found to be the lowest complication in our study. On the other hand, bleeding was the main complication of conventional circumcision (5%), which is in accordance with the previously reported data [8, 9, 20, 21]. This rate was significantly higher than the bleeding rate seen after minimally invasive circumcision (0.4%). A bleeding rate of 0.4% is acceptable compared to the previously reported rates (0.2–0.7%) utilizing similar techniques [22, 23]. Most

of the previous studies included neonatals in which the wound healing is faster, and expected rate of bleeding is lower compared to older children. Whereas in our study, low bleeding risk was encountered in all age groups, which signifies one of the main advantages of Ali's clamp[®].

Bleeding usually occurred within 24 h after disconnection of the clamp due to unexpected detachment of the crust before the completion of appropriate healing. Main reason for the detachment of the crust was a frictional trauma applied to the wound. Other reason of detachment was softening of the crust with urine which caused spontaneous bleeding occurring after urination. In order to reduce the risk of trauma we suggest using a disposable foam glass placed around the penis under the diaper. This also relieves the pain which is aggravated by the friction of the diaper. For older children, we recommend special underwear with a concave plastic protection on the front side.

Infection was an uncommon complication of minimally invasive circumcision (0.6%) and was significantly lower than that of the conventional circumcision group (4.2%). Only 0.2% of the children experienced a wound infection requiring administration of oral antibiotics. This infection rate is lower than the previous studies which vary between 0.4 and 2.8% [14, 24]. Symptoms due to infection were relieved in all children within 3 days following the initiation of a penicillin group of antibiotics. The reason for a low infection rate is due to the fact that skin is clamped and the cut edge has no connection with the healthy tissue. Thus, the wound is not exposed to outside environment during the first 2-5 days after the circumcision, which avoids possible contamination and infection. As there is not open wound exposed to outer environment, this technique makes the dressing unnecessary. Avoidance of dressing improves the quality of post-circumcision life of the child. This was an important advantage of the technique especially for the infants. Families easily wiped the babies and were able to wash them in case of contamination of the penis and the apparatus. These advantages of minimally invasive circumcision made it a preferred technique for infants.

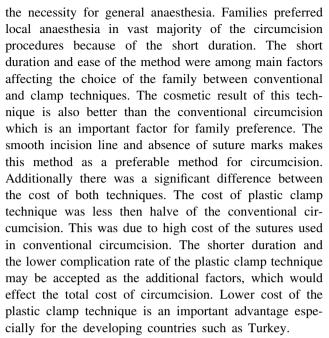
Serious complications such as urethral fistula, penile injury and necrosis were not encountered in the current study. There were complaints related to redundant foreskin (36 in plastic clamp group and 24 in conventional group). Most of these complaints were seen among children circumcised below age one or in those older children who were accepted as obese. The skin folds around the penile shaft due to compression of the thick pre-pubic adipose tissue were misinterpreted by the families as redundant skin. Revision or recircumcision was not needed in any of these children.

According to our results, there was a significant increase in number of infant circumcisions after utilization of the



plastic clamp technique. This is an important finding as most of the circumcisions are performed in older children in our country. We believe that the circumcision procedure in older children may cause highly big psychological stress. Despite the possible adverse psychological effects of the procedure in older children, most of the families did not prefer circumcision before age of two while only suggested method was the conventional circumcision technique (before January 2003). During this period, only 14% of the families preferred circumcision for their babies as it might require special care to protect the wound from infection and friction caused by the diaper as well as the long duration of the circumcision time (23 \pm 4 min). Most of the families were not able to use diapers during the first 48 h following circumcision because of these concerns. Difficulty in using diapers made baby care more difficult and reduced life quality of the mother. On the other hand, there was not any problem in using diapers after circumcisions performed by plastic clamp technique. It was also possible to wash the baby immediately after circumcision as there was not any open wound. Ability to use diaper and no need for wound care were important factors for family decision in the circumcision age. After application of the plastic clamp technique, there was an increase in the number of families who preferred circumcision in early infancy period as it did not required special care. This reflected to our results as an increase in baby circumcision from 14 to 33% after utilization of minimally invasive technique. We strongly suggest circumcision in early infancy period as the wound healing is significantly faster and it does not cause any psychological disturbances afterwards. This is especially important for Muslim countries such as Turkey where most of the children are circumcised at pre-school or school age.

Another advantage of the clamp technique was the short duration and ease of application of the procedure. This method can be performed at any age as there are various sizes of the device, which are suitable for a wide range of penile width. Ease of the procedure is an important factor for country-wide utilization of the technique. The learning curve of this technique is much shorter than that of the conventional technique. There is not any risk of penile injury in minimally invasive technique where major injuries may be encountered in conventional circumcisions especially performed by local circumcisers [8, 21]. In the current study, the mean duration of circumcision with plastic clamp technique was 4.5 min, which was significantly shorter than the mean duration of conventional circumcision p < 0.001). The main advantage of this short duration was reduction of the psychological stress of the children thus reducing the anxiety of the family and increasing the satisfaction rate. This was an important factor in avoiding



Despite the remarking results obtained in the current study there are some limitations. The study design was retrospective, not randomized and circumcisions were performed by separate teams, which might effect the homogeneity of the complication rates. All three surgical teams were experienced in plastic clamp technique and performed similar number of circumcisions. This minimized the possibility of variation of results among the separate surgical equipes. Currently, a prospective outcome study is ongoing for more precise evaluation of the complication rates, degree of post-circumcision pain, cosmetic results as well as the family satisfaction after the plastic clamp technique.

As a conclusion, the current study documented that minimally invasive circumcision utilizing Ali's clamp® is superior to conventional circumcision technique due to short duration, easy application at any age and significant lower complication rates and lower cost as well as satisfactory cosmetic results. We suggest the minimally invasive circumcision technique as the circumcision procedure of choice.

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