

Analgesia for Neonatal Circumcision: A Randomized Controlled Trial of EMLA Cream Versus Dorsal Penile Nerve Block

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ABSTRACT. *Objective.* To compare the efficacy of the dorsal penile nerve block (DPNB) with a less invasive form of local anesthesia, eutectic mixture of local anesthetic (EMLA) cream, for reduction of pain during neonatal circumcision.

Design. Prospective, blinded, randomized, controlled trial.

Setting. Tertiary referral, neonatal intensive care nursery in a university teaching hospital.

Patients. Fifty infants $\geq 34\frac{1}{2}$ weeks postmenstrual age and stable for discharge at time of circumcision; gestational age at birth 25 to 41 weeks; birth weight 600 to 4390 g; age at study 3 to 105 days. An additional cohort of term newborns (n = 20), who were not randomized, were circumcised without anesthesia.

Interventions. Administration of either EMLA cream (0.5 g topically 1 hour before circumcision) or 1% lidocaine (0.7–1.0 mL subcutaneously 3 minutes before circumcision).

Outcome Measures. Primary: Neonatal Infant Pain Scale (NIPS) score; secondary: heart rate, respiratory rate. All outcome measures were assessed by an individual who was blinded to the group assignment and did not perform the circumcision.

Results. NIPS scores were significantly lower in the DPNB infants (2.3 ± 1.8) compared with the EMLA infants (4.8 ± 0.7). NIPS scores in patients circumcised without anesthesia indicated severe pain. There was a significantly greater increase in heart rate over the duration of the circumcision in the EMLA group than in the DPNB group (49 vs 9 beats per minute). Adverse effects included small hematomas at the site of injection in DPNB infants (10/23), mild erythema at 1 and/or 24 hours after circumcision in the EMLA infants (3/21), and penile edema noted 5 days after circumcision requiring removal of the circumcision bell in 1 DPNB infant.

Conclusions. DPNB provides better pain reduction during neonatal circumcision than EMLA cream. EMLA cream may provide pain reduction compared with no anesthesia during neonatal circumcision. *Pediatrics* 1998;101(4). URL: <http://www.pediatrics.org/cgi/content/full/101/4/e5>; *circumcision, dorsal penile nerve block, EMLA*.

ABBREVIATIONS. DPNB, dorsal penile nerve block; EMLA, eutectic mixture of local anesthetic; NICU, neonatal intensive care unit; NIPS, Neonatal Infant Pain Scale.

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Neonatal circumcision is one of the oldest and most frequently performed surgical procedures in the United States.¹ Most parents elect to circumcise their sons for religious or cultural reasons. Despite the current concern with pain responses and management in infants, many males are circumcised without the benefit of anesthesia. The neural pathways that relay painful stimuli, the cortical and subcortical centers that perceive pain, and the required neurotransmitters are all present and functioning at birth.² There is clear neurophysiologic and clinical evidence that neonates are capable of mature pain perception, even at relatively immature gestational ages.²

In light of the growing evidence that newborns experience pain, recent research has focused on the pain associated with circumcision.^{3–5} Neonatal circumcision produces both physiologic changes (increased heart rate, blood pressure, and plasma cortisol levels and decreased transcutaneous partial pressure of oxygen^{2,6}) and behavioral changes (facial expression, crying patterns, irritability, and level of attentiveness⁷).

Our clinical experience is that many health care providers perform neonatal circumcision without anesthesia. The health care providers who do provide anesthesia most frequently use the dorsal penile nerve block (DPNB). The DPNB, if administered properly, is a simple, safe, and effective measure to minimize the pain associated with neonatal circumcision and to decrease its physiological stresses.^{4,5} It is effective in decreasing crying, diminishing heart rate increases, and oxygen saturation decreases.^{3–5} Although local anesthesia is an effective means of decreasing pain during circumcision, the DPNB must be performed by a skilled individual to minimize the risk of injecting lidocaine into the blood stream and the possibility of hematoma formation. In addition, the injection of lidocaine itself may be painful. Because of these considerations, some health care providers have chosen not to use the DPNB.

A topical anesthetic, eutectic mixture of local anesthetic (EMLA) cream, is currently being used in the pediatric population for invasive procedures such as lumbar puncture, intravenous insertion, and central line insertion^{8,9}. The safety of topical application of EMLA has been established in the pediatric population. EMLA does not lead to measurable changes in methemoglobin levels and appears safe for use in both premature and term infants.⁹ However, very little is known about the effectiveness of EMLA

cream for neonatal circumcision. Benini et al¹⁰ and Taddio et al¹¹ found that EMLA cream for circumcision in full-term newborns was safe and effective in diminishing pain responses including smaller increases in heart rate, less decrease in oxygen saturation, fewer facial grimaces, and less crying when compared with unanesthetized control infants. They concluded that EMLA had significant anesthetic effect.^{10,11}

With the increasing awareness of the pain response of neonates to circumcision and the desire to improve neonatal care with the alleviation of pain, this study was designed to evaluate and compare the efficacy of two pharmacologic anesthetics, EMLA cream and the DPNB. To our knowledge, these two agents have not been compared in a randomized trial in this patient population. We hypothesized that EMLA cream and the DPNB would be equally effective in alleviating pain. By providing data that demonstrates the efficacy of EMLA cream, specifically to those who currently do not use anesthesia because of the potential risks associated with the DPNB, we would be improving the quality of care for male newborns undergoing circumcision. Because the current practice in our neonatal intensive care unit (NICU) is to provide anesthesia during neonatal circumcision, we did not feel justified in randomizing any infant to no anesthesia. For comparison purposes, data on infants circumcised without anesthesia or analgesia were obtained from 20 infants circumcised by two obstetricians who followed their usual practice.

METHODS

Study Design

This study was a prospective, randomized, controlled, blinded trial comparing two local anesthetic regimens for neonatal circumcision. Informed parental consent was obtained for circumcision and enrollment into the study. The protocol was approved by the Institutional Review Board.

Sample

Infants who had been admitted to the NICU of Strong Memorial Hospital and were $\geq 34\frac{1}{2}$ weeks postmenstrual age and stable for discharge to home at the time of circumcision were enrolled. Neonates were excluded from the study if they had evidence of bleeding diathesis, sedation or pain medication within the previous 48 hours, local infection, urethral or penile shaft abnormalities, or prenatal drug exposure.

The sample size was based on the primary outcome variable, the average Neonatal Infant Pain Scale (NIPS) scores. The assumption made was that infants receiving no anesthesia would score between 5 and 6, infants receiving a somewhat effective anesthetic would score between 3 and 4, and infants receiving very effective anesthetic would score between 0 and 2. To demonstrate a difference in the category of pain with a significance level of 5% and 80% power, our sample size was calculated to be 22 patients in each of the two randomized study groups.

Procedure

After informed consent was obtained, infants were randomized to receive either EMLA cream alone or placebo cream followed by the DPNB. This computerized randomization was performed by a randomized number generator in blocks of 10.

To assure that the bedside nurse remained blinded to group assignment, every infant had a cream and dressing applied to the penis 1 hour before the circumcision. Infants randomized to receive EMLA cream had EMLA cream (0.5 mL = 0.5 g) and Tegaderm dressing (Johnson & Johnson, Inc, Arlington, TX) applied 1

hour before the circumcision by the individual performing the circumcision.¹⁰ Infants randomized to receive the DPNB received vehicle (Moisturel cream; Westwood Pharmaceuticals) and Tegaderm dressing by the individual performing the circumcision 1 hour before the circumcision, followed by a DPNB (0.3–0.5 mL 1% lidocaine at 2 and 10 o'clock at the base of the penis) 3 minutes before the circumcision. Baseline vital signs, including heart rate and respiratory rate, were recorded 1 hour before the circumcision by the nurse caring for the infant. All infants had been fed 2 to 3 hours before the circumcision. The bedside nurse caring for the infant was not present during the circumcision. All infants in both groups were swaddled from the waist up, restrained in supine position on the circumcision board, and had sugar pacifiers placed before the start of the procedure. Circumcisions were performed by one individual (M.B.O.) using the Stuart Surgical circumcision tray (Olympic Medical, Seattle, WA) and the Hollister PlastiBell (Hollister Inc, Ontario, Canada). An audiovisual camera recorded the procedure beginning just before the circumcision. The camera captured the infant's face and torso, excluding the individual performing the circumcision and the field. The video camera recorded facial expression, crying time and intensity, breathing patterns, arm movements, and state of arousal. Also, during the procedure, after the anesthetic was administered, a continuous cardiorespiratory monitor (Athena Airshields 950, Athena Recorder 9741, Airshields, Hatboro, PA) recorded and printed a trend of the heart rate and respiratory rate. The nurse who assisted during the procedure indicated on the monitor each of the six circumcision events (see below) via an event marker. Physiologic parameters were again recorded at 1 hour and 4 hours after the circumcision by the bedside nurse caring for the infant.

All infants had Vaseline gauze wrapped around the penis for 24 hours after the circumcision. Documentation of the circumcision site was done by the individual performing the circumcision at the completion of the procedure, 24 hours after the circumcision, and as requested by the care delivery team. Side effects that were closely monitored and recorded included erythema, hematoma, pallor, bleeding, and blistering of the penis.

A third, nonrandomized group of full-term infants ($n = 20$), who were circumcised by an obstetrician without any anesthesia, were also circumcised with the Stuart Surgical circumcision tray and the Hollister PlastiBell. These infants were also videotaped and placed on a continuous cardiorespiratory monitor. The video camera captured the same parameters and the cardiorespiratory monitor recorded the same physiologic data as the randomized infants. No pre- or postcircumcision vital signs were recorded, nor could the site be evaluated at 24 hours.

Measures

The NIPS, a noninvasive, replicable, and objective tool for assessing pain responses, was chosen as a method of providing global pain assessment. Interobserver, construct validity, concurrent validity, and internal consistency are very high.¹² The pain scale consists of six behavioral components with a composite score of 0 to 6. Five of the six components were used in this study, including facial expression, crying, breathing patterns, arm movements, and state of arousal. Leg movements were omitted because the infant was restrained on the circumcision board (Table 1). The individual performing the circumcision called out six assigned events of the circumcision including clamping the foreskin, lysis of adhesions between the foreskin and glans, dorsal incision of the foreskin, lysis of adhesions between the foreskin and glans, tying the PlastiBell, and cutting of the foreskin. The videotapes were then reviewed by a second individual (C.L.) unaware of the infant's experimental group assignment. NIPS scores were assigned for each of the six events on all 44 randomized patients as well as the 20 full-term nonrandomized patients. A mean NIPS score for each infant was then calculated by taking the mean of the 6 measured events. Physiologic and behavioral data were collected and analyzed by a third individual (R.G.) who had not performed the circumcision nor scored the tapes.

Eleven of the sixty-five videotapes were randomly chosen and re-reviewed and scored a second time to determine internal consistency.

Statistical Analysis

Analysis was conducted using Systat 5.2.1 for Macintosh. Student's *t* tests were performed comparing the two randomized

TABLE 1. Modified NIPS Pain Assessment Scale

	Behavior Score		
	0	1	2
Facial expression	Relaxed muscles Neutral expression	Tight facial muscles Furrowed brow, chin, jaw	—
Cry	Quiet—not crying	Mild moaning—intermittent cry	Loud scream, rising shrill continuous
Breathing patterns	Relaxed	Changes in breathing; irregular, faster than usual, gagging, breath holding	—
Arms	Relaxed No muscular rigidity Occasional random Movements of arms	Flexed/extended tense, straight arms, rigid and/or rapid extension, flexion	—
State of arousal	Sleeping/awake Quiet, peaceful, sleeping, or alert and settled	Fussy Alert, restless, and thrashing	—

TABLE 2. Demographic Characteristics of the Randomized Infants (Mean \pm SD)

	EMLA <i>n</i> = 25	DPNB <i>n</i> = 25
Gestational age at birth (wk)	32.9 \pm 4.4	34.0 \pm 5.0
Postmenstrual age at circumcision (wk)	37.3 \pm 2.6	37.8 \pm 3.5
Birth weight (g)	2084 \pm 950	2118 \pm 877
Weight at circumcision (g)	2521 \pm 679	2515 \pm 689
Race		
White	56%	64%
African-American	28%	20%
Other	16%	16%
Duration of circumcision (min)	4.3 \pm 0.9 (<i>n</i> = 22)	4.5 \pm 1.1 (<i>n</i> = 23)

treatment groups. Mean values for heart rate and NIPS scores were analyzed separately. Significance was assigned if $P < .05$. A secondary analysis was performed comparing the infants who received EMLA cream with those who did not receive anesthesia before circumcision. Although demographic characteristics for these two groups differed, no correction was applied before analysis as there is little information regarding the influence of chronologic age, race, or weight at time of circumcision on pain perception.

RESULTS

Fifty patients who met the study criteria were enrolled. The mothers of 3 other infants refused consent and their infants were not randomized. Six infants (4 who received EMLA and 2 who received DPNB) were excluded from the complete analysis because of technical difficulties with the recording equipment. In addition, consent was obtained for all 20 term newborns whose parent was approached for permission to videotape and score an unanesthetized circumcision.

The sample characteristics were similar for the two randomized groups (Table 2). All of the nonrandomized infants were full-term and 24 to 60 hours of age at the time of circumcision.

Internal consistency of scoring in the present study was as reported in the literature.¹² The mean NIPS scores for the eleven infants reviewed a second time differed by 0.3 ± 0.3 (mean \pm SD).

Overall, the infants receiving EMLA demonstrated a greater pain response during circumcision than did the infants anesthetized using a dorsal penile nerve block (Table 3). Average NIPS scores were significantly lower in the DPNB infants compared with the EMLA infants ($P < .001$). All nonrandomized infants

TABLE 3. Outcome Variables (Mean \pm SD)

	EMLA <i>n</i> = 21	DPNB <i>n</i> = 23
Average NIPS score during circumcision	4.8 \pm 0.7	2.3 \pm 1.8
Heart rate (beats per minute)		
End of circumcision	196 \pm 20	162 \pm 19
Increase (before to end)	49 \pm 20	9 \pm 15
Adverse effects		
Erythema at 1 h (n, [%])	1 [4.8%]	0 [0%]
Erythema at 24 h (n, [%])	2 [9.5%]	0 [0%]
Hematoma at 24 h (n, [%])	0 [0%]	10 [43.5%]
Other (see text)	0 [0%]	1

who were circumcised without previous anesthesia had the maximum NIPS score of 6 throughout the entire procedure (Fig 1). There were variations in NIPS scores as a function of the element of the circumcision that was being performed for both of the experimental groups. In both groups, NIPS scores were higher during lysis of adhesions and tying of the PlastiBell than during clamping, dorsal incision, or cutting of the foreskin. However, at all events during the circumcision, NIPS scores were significantly lower in the group that had received DPNB compared with the group that had received EMLA cream (Fig. 2).

The increase in heart rate was more than five times greater for the EMLA group than the DPNB group ($P < .001$). There was no statistically significant difference between groups in heart rate 1 and 4 hours after the circumcision. Respiratory rates were variable and difficult to evaluate from the monitor output; there was no apparent difference between groups.

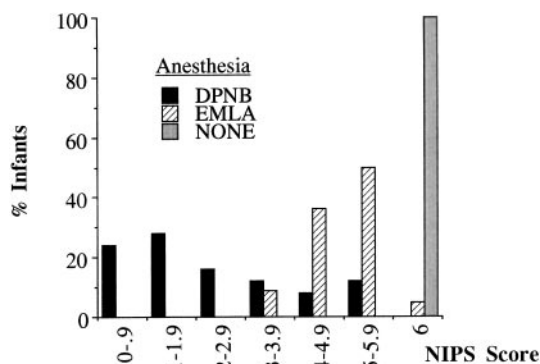


Fig 1. Graphic representation of the distribution of NIPS scores among the three treatment groups. Data are presented as the percent of infants in each treatment group receiving a NIPS score in the defined interval. All infants circumcised without anesthesia received a score of 6 throughout the procedure, whereas only 1 infant who received anesthesia before circumcision (EMLA) received a score of 6.

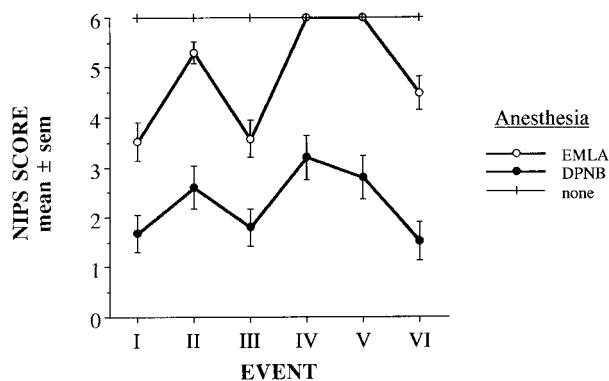


Fig 2. Mean NIPS scores during circumcision in three groups of infants, EMLA-treated (open circles), DPNB (closed circles), and no anesthesia (x with dotted line). Events during circumcision that were scored included: I, clamping of the foreskin; II, lysis of adhesions between foreskin and glans; III, dorsal incision of the foreskin; IV, lysis of adhesions between foreskin and glans; V, tying PlastiBell; and VI, cutting of the foreskin. The higher the score, the greater the behavioral manifestation of pain. Bars indicate \pm SEM.

Adverse effects referable to either the circumcision or the mode of anesthesia were evaluated at 1 and 24 hours after the procedure (Table 3). Of the 25 infants receiving EMLA, 1 developed slight erythema at the site 1 hour after the circumcision and 2 of 21 infants examined at 24 hours had mild to moderate erythema. Ten of the 23 infants who received DPNB and were available at 24 hours for examination had a small hematoma at the site. One infant who received DPNB was noted on the fifth day after the procedure to have developed penile edema and the circumcision bell was removed with resolution of the swelling.

DISCUSSION

Circumcision is a frequently performed neonatal procedure that is often done without benefit of anesthesia. We hypothesized that if we could demonstrate the efficacy of EMLA cream in providing pain relief, then more care providers would use local anesthesia when performing circumcisions. Our data showed that although EMLA may provide some

pain amelioration compared with no anesthesia, DPNB is a more effective method of providing local anesthesia.

The 20 infants who received no anesthesia for circumcision in our study cried loudly and vigorously, trembled, tightened facial muscles, breathed faster with occasional breathholding and gagging, rapidly extended and flexed their arms, and were in an overall state of thrashing and restlessness. There was no doubt that neonatal circumcision produced severe and persistent pain.¹³⁻¹⁵

Several studies have addressed pain-reducing interventions during circumcision including use of pacifiers, swaddling, and medication.^{3-5,10,11} The DPNB was first introduced in 1978 and was shown to be a safe and effective procedure for decreasing pain during neonatal circumcision.³ Additional studies, including the present one, indicate that the DPNB significantly decreases pain during circumcision as evidenced by decreasing physiologic and behavior distress associated with the procedure.³⁻⁵ We demonstrated in our study that the DPNB was extremely effective in reducing the pain of circumcision as indicated by a mean NIPS score of 2.3 and average rise in the heart rate of only 9 beats per minute.

Taddio et al¹¹ demonstrated that overall, EMLA cream decreased the pain of circumcision; however, the effectiveness was considerably less during phases involving extensive tissue damage. There was no difference in mean facial activity scores between EMLA and placebo groups except at forceps application, dorsal incision, application of the clamp, and foreskin cutting. In contrast, we showed that although the degree of pain amelioration was dependent on phase of the procedure, DPNB was more effective in reducing behavioral manifestations of pain at all phases of the circumcision, compared with both EMLA and no anesthesia.

Despite these findings, the tradition of performing neonatal circumcision without the benefit of anesthesia continues. The rationale for not using the DPNB includes lack of familiarity with the technique of DPNB, additional stress and pain caused by administration of the DPNB, concern over complications and adverse effects, and the assumption that the circumcision procedure is quick and, therefore, pain and side effects are minimal.

The DPNB has potential risks if not administered properly. The lidocaine can be injected into the circulation, hematomas can form at the site of injection, and the procedure is painful. Our measurement of pain scores began 3 minutes after the DPNB was given and, therefore, we have no behavioral data assessing the degree of pain associated with the DPNB procedure itself. However, heart rate data suggest that within 3 minutes after the administration of lidocaine, there was no difference in heart rates between the experimental groups.

Given some health care providers' reluctance to use the DPNB, we chose to compare the effectiveness of EMLA cream, a less invasive form of anesthesia, with the DPNB. Although administration of EMLA cream requires less skill than the DPNB procedure, 60 to 80 minutes are required for absorption of the

anesthetic. This time factor may be viewed as a constraint by some providers. The optimal dose of EMLA has not been determined. Amounts ranging from 0.5¹⁰-1.0¹¹ g have been used in neonates undergoing circumcision. In addition, there are no means of assuring uniform absorption of the EMLA cream given such factors as potential dilution by urine or differences in skin thickness in different neonatal populations.

Our results indicated that EMLA usage during circumcision is associated with an average NIPS score of 4.8 and an average increase in heart rate by almost 50 beats per minute. Although EMLA was not as effective as the DPNB, there was evidence suggesting that it may be better than no anesthesia at all. This comparison between the infants receiving EMLA and those receiving no anesthetic is weakened by the fact that the two groups were not drawn from the same population. Because it is our standard practice in the NICU to provide anesthesia during circumcision, we did not feel justified in randomly assigning infants to a no anesthesia group. Infants available to us for this comparison group were those whose circumcisions were performed by a private obstetrician using the same technique as that used in the experimental group. These infants were healthy, full term males in whom the circumcision was performed 1 to 4 days after birth. These infants all had NIPS scores of 6 throughout the procedure.

Although it is clear that DPNB is significantly better than EMLA in reducing the pain of circumcision acutely, there are no data regarding differential behaviors over the 24 hours after the procedure. Data suggest that after painful events, infants sleep for a prolonged periods of time and withdraw and become less available for social interactions. This has potential implications for developing relationships between the parent and child.^{1,4,6,8,16} We did not collect information on these parameters and thus cannot determine whether the degree of anesthesia provided by EMLA is sufficient to normalize postoperative behaviors. This data would be important in assessing the relative efficacy of this form of local anesthesia. In addition, there is evidence that unanesthetized neonatal circumcision in male infants is associated with an increased pain response to vaccination at 4 to 6 months of age. Taddio et al¹⁷ demonstrated that perioperative treatment with EMLA attenuated this pain response. We do not have comparable follow-up data for our population of infants.

The American Academy of Pediatrics encourages the use of anesthesia and analgesia in the neonate undergoing a painful procedure. The policy statement on neonatal anesthesia states that "local or systemic pharmacologic agents now available permit relatively safe administration of anesthesia or analgesia to neonates undergoing surgical procedures and that such administration is indicated according to the usual guidelines of the administration of anesthesia to high-risk, potentially unstable patients . . . the decision to withhold such medication should be based on the same medical criteria used for older

patients. The decision should not be based solely on the infant's age or perceived degree of cortical maturity." Although questioned in the past, the necessity for pain control in neonates undergoing painful procedures is beginning to receive adequate consideration.

In conclusion, our data indicate that the DPNB provides better pain reduction during neonatal circumcision than does EMLA cream. However, EMLA cream may provide some reduction in pain when compared with no anesthesia. Neonates in this study who received the DPNB had significantly lower NIPS scores and a significantly lesser rise in heart rate over the duration of the circumcision compared with infants who received EMLA cream or no anesthesia. We endorse the use of local anesthesia for neonatal circumcision and conclude that the DPNB is the more effective agent.

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