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## COMPARATIVE ASSESSMENT OF THE ANESTHETIC EFFICACY OF EMLA (EUTECTIC MIXTURE OF LOCAL ANESTHETICS) TO DORSAL PENILE NERVE BLOCK IN SUBJECTS UNDERGOING CIRCUMCISION

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### ABSTRACT

**Background:** Objective circumcision is a common procedure performed on newborns, and it is associated with considerable discomfort that necessitates anesthesia. While topical medications are said to have equivalent efficacy and reduced morbidity, infiltration of local anesthetics for various procedures in neonates is linked to a number of problems.

**Aim:** The purpose of this study was to compare the anesthetic effectiveness of dorsal penile nerve block (DPNB) and eutectic mixture of local anesthetics (EMLA) in participants undergoing circumcision.

**Methods:** Based on the type of anesthesia utilized prior to the procedure, two groups of 68 male newborns undergoing circumcision at the institute were created. The four steps of clamping, crushing, tying, and foreskin cutting with NIPS (neonatal infant pain scale) pain measurement were used to compare the anesthetic efficacy. Heart rate, transcutaneous SpO<sub>2</sub> change, and salivary cortisol levels were measured prior to and following surgery. After a day, the subjects were evaluated for any problems.

**Results:** During tying and cutting ( $p=0.01$  and  $0.03$ , respectively), individuals from the EMLA cream group showed significantly higher NIPS ratings. The EMLA group's heart rate increased significantly from baseline to the end of the operation. With  $p=0.93$  and  $0.17$ , respectively, there was no discernible rise in heart rate in the DPNB group during crushing and cutting. Both groups showed a considerable drop in SpO<sub>2</sub> from baseline. In both groups, salivary cortisol levels increased significantly. In any group, no serious complications were observed.

**Conclusions:** Compared to EMLA cream, dorsal penile nerve block with lidocaine provides superior pain management for newborns undergoing circumcision. Nonetheless, dorsal penile nerve blocks and EMLA cream are both safe treatments for newborns.

**Keywords:** newborns, EMLA, dorsal penile nerve block, circumcision.

## INTRODUCTION

The phrase "circumcision" refers to the surgical removal of the prepuce, one of the earliest and most popular surgical procedures done on newborns. There are several reasons why people get circumcised, including social, religious, and medical ones. Usually, circumcision is carried out on healthy newborns when it is done for social or religious reasons. Nonetheless, in certain civilizations, nurses and medical personnel may participate in public health campaigns to recommend against routinely circumcising neonates.<sup>1</sup>

Infants' suffering during the circumcision process is rarely considered in circumcision procedures. Research and discussion are still needed about the selection and application of anaesthetic during circumcision. The majority of clinical settings in India where circumcision is carried out lack anaesthesia and anaesthetic care.

The notion that the pain from the anesthetic injection is as unpleasant as the circumcision itself, the unfamiliarity with side effects and the use of anesthetic and analgesics in neonates, and the presumption that pain awareness is absent in neonates are some of the reasons why anesthesia is not used during circumcision.<sup>2</sup>

It is unknown if the subcortical and cortical areas, which are linked to painful inputs and where pain is sensed, are functional from birth. The basis for pain evaluation is the physiological alterations linked to neonatal circumcision, as well as behavioral abnormalities linked to pain sensitivity and adrenal cortical response. In response to these symptoms, a number of grading schemes for measuring newborn pain were created.<sup>3</sup>

The Neonatal Infant Pain Scale (NIPS) was utilized in the majority of research assessing the effectiveness of local anaesthetic drugs for circumcision in neonates. The NIPS included six markers of pain, including state of arousal, legs, arms, respiratory pattern, cry, and facial expressions. In particular, because salivary levels of cortisol are readily measured, it is an essential biochemical stress marker in neonates. Its level also rises in 5 minutes after being exposed to a stressor, making it a trustworthy biomarker for determining the severity of acute pain in both term and preterm newborns.<sup>4</sup>

Topical anaesthetics such as EMLA (eutectic mixture of local anaesthetics), which is composed of 2.5% prilocaine hydrochloride and 2.5% lidocaine, DPNB (dorsal penile nerve block), the use of sucrose pacifiers, immediate postoperative administration of acetaminophen or systemic opioids, and other techniques are used to provide analgesia during circumcision. It is still difficult for the operating staff to infiltrate local anaesthetics for surgeries on neonates. On the other hand, topical medications have been shown to have comparable effectiveness to local anaesthetics with less side effects.<sup>5</sup> In order to determine which method would be best for newborns in the Indian context, the dorsal penile nerve block with lidocaine and EMLA cream during circumcision were compared in the current study.

Heart rate (HR), NIPS ratings, variations in SpO<sub>2</sub> (oxygen saturation) throughout the treatment, and preoperative and postoperative salivary cortisol level changes are used as outcome measures for evaluating the anaesthetic efficacy of these techniques. According to the study's null hypothesis, there was no statistically significant difference in the anaesthetic effectiveness of DPNB with lidocaine and EMLA cream during neonatal circumcision.

## MATERIALS AND METHODS

In order to evaluate the anesthetic efficacy of dorsal penile nerve block (DPNB) versus eutectic mixture of local anesthetics (EMLA) in participants undergoing circumcision, a prospective comparative clinical trial was conducted. The study's participants came from the Institute's Department of Pediatric Surgery. Prior to participation, each participant's parents or guardians provided their verbal and written informed consent.

Preterm or infants with a corrected gestational age of  $\geq 37$  weeks, neonates without preputial or penile abnormalities, and patients whose guardians or parents were willing to participate in the study were all considered for inclusion.

Subjects having skin disorders affecting the groin or genital area, abrasions, signs of dermatitis, newborns circumcised using methods other than Platisbell, and newborns whose parents or guardians did not provide informed consent were all excluded from the study.

Before being circumcised, every newborn who voluntarily attended for the procedure had a clinical evaluation. The study enrolled the neonates in succession who met the inclusion criteria. Two hours prior to the circumcision, mothers were asked to nurse their newborns. The included neonates were then randomly assigned to one of two groups to undergo

circumcision under a lidocaine-infused DPNB block or under EMLA as a local anesthetic. Ampules of lidocaine and EMLA cream with a 5% concentration were utilized in the investigation.

Sociodemographic information and each subject's weight were recorded on the day of the circumcision. Every subject's baseline SpO<sub>2</sub> and heart rate were noted, in addition to their NIPS score. One gram of EMLA cream was applied to each newborn according to a randomization process one hour before to circumcision. To stop the spread of the cream when voiding prior to the treatment, the cream was applied directly to the prepuce and distal half of the penis and covered with an occlusive bandage provided by the manufacturer.

Each newborn received cream and an occlusive dressing on the penis one hour prior to circumcision, with the other group receiving the same jelly as a placebo. This was done to blind the examiner who was assessing the pain. Both EMLA and placebo jelly looked the same once the dressing was removed. Following this, newborns' saliva was collected using a light plastic pipette that was handed to the mother to insert inside the cheeks for 10–20 minutes over the course of an hour to collect 0.5–1 ml of saliva. This was done in order to estimate the cortisol levels in the babies. Before being taken to the lab, the collected sample was promptly chilled.

To prevent bias, the same pathologist estimated cortisol in each individual using an identical ELISA kit. Neonates applied with jelly received 1 milliliter of 1% lidocaine as DPNB one hour after the application of EMLA and jelly, whereas those treated with EMLA received 1% of normal saline in the anaesthetic room. The neonates were then taken to the operating room for circumcision. The newborns' mobility was supervised by assistance, and they were wrapped in warm clothing. After three minutes of DPNB, an aid stretched apart the lower limbs and performed a circumcision using the Platisbell method, following four typical stages for circumcision facilitation. A pulse oximeter probe was applied to the foot.

These procedures included clamping, which involved applying artery forceps to separate adhesions between the prepuce and glans penis, crushing, which involved using a hemostat and making a dorsal preputial incision, tying, which involved inserting the Plastibell and tightening the surrounding ligature, and cutting, which involved removing the prepuce. A team member who stayed in the operating room for the administration of DPNB and cream scored and evaluated the patient's pain during the procedure. Using NIPS scores, this team member was blind to the patient's group. The NIPS scale includes six pain indicators: alert state, legs, arms, breathing pattern, cry, and facial expression. There are five behavioral and one physiological pain indicators.<sup>6</sup>

Everything was rated 0–1, with the exception of the cry, which was rated 0-2. A score of four indicated severe pain. The five components of the NIPS were changed for the current study to include level of arousal, leg movement, breathing pattern, cry, and facial expression; arm movement was not included because the arms were bound with swaddle cloth. Excluding leg motions caused by tying, in accordance with another literature review.<sup>7</sup>

Therefore, during each routine procedural step and the entire duration of the surgery, heart rate, SpO<sub>2</sub>, and modified NIPS scores were recorded in the current investigation.

Following the treatment, the individuals were brought to a recovery room where they had an hour of careful observation. After 20 minutes of the surgery, a second saliva sample was taken using the same preoperative technique in order to measure the postoperative cortisol level. Every neonate received paracetamol at discharge. After a day, the babies were evaluated, and any difficulties were noted. Neonatals who had issues were called back for additional review. The collected data were statistically evaluated using the one-way ANOVA (analysis of variance) and SPSS software version 21.0 (IBM Corp., Armonk, NY, USA). The two groups' NIPS scores and physiological data were compared using an independent t-test. For both normally distributed and non-normally distributed continuous variables, the data were expressed as mean and standard deviation; for categorical variables, they were expressed as frequency and percentage. An acceptable p-value for statistical significance was <0.05.

## RESULTS

In order to evaluate the anaesthetic efficacy of dorsal penile nerve block (DPNB) versus eutectic mixture of local anaesthetics (EMLA) in participants undergoing circumcision, a prospective comparative clinical trial was conducted. Using a straightforward randomization technique, 68 participants were split into two groups and circumcised under either DPNB block with lidocaine or with EMLA as a local anaesthetic. Ampules of lidocaine and EMLA cream with a 5%

concentration were utilized in the investigation. In the DPNB and EMLA groups, the mean age of the neonates was  $13.66 \pm 5.44$  and  $15.25 \pm 6.70$  days, respectively. These differences were statistically not significant ( $p=0.14$ ).

The age range of 8–14 days accounted for the bulk of research participants, with 15–21 days following closely behind. This range was statistically equivalent ( $p=0.122$ ). With a p-value of 0.36, the mean gestation age in the DPNB and EMLA groups was statistically comparable at  $38.11 \pm 1.96$  and  $37.82 \pm 1.94$  weeks, respectively. With  $p=0.08$ , the proportions of term and preterm infants were similar in the two groups. Neonates weighed  $2.87 \pm 0.16$  and  $2.88 \pm 0.13$  kg on average, which was equivalent ( $p=0.74$ ). Table 1 displays the circumcision time in the DPNB and EMLA groups, which were  $7.79 \pm 1.64$  and  $7.55 \pm 0.71$  minutes, respectively. These results were statistically non-significant with  $p=0.26$ .

After analyzing the average changes in the NIPS scores of research participants from the DPNB and EMLA groups at each of the procedure's four steps, it was observed that the DPNB group's mean NIPS scores over the course of the procedure were 2.969, while the EMLA group's mean NIPS score was 3.550, indicating no statistically significant difference. With a score of less than three, the mean NIPS score in the dorsal penile nerve block represented pain sensation. On the other hand, the EMLA group experienced mild to moderate pain, with NIPS classification scores of 3–4.

According to the study's findings, there was a statistically significant rise in heart rate over the baseline values at every stage of the process.

The mean heart rate in the dorsal penile nerve block group increased significantly only during the clamping and tying phases, at 9.57 beats per minute and 6.41 beats per minute, respectively, with p values of 0.02 and 0.03. With regard to the variations in SpO<sub>2</sub> levels, there was a statistically significant difference observed in the mean SpO<sub>2</sub> throughout baseline values and all phases of the circumcision in both groups.

The EMLA and dorsal penile nerve block groups both showed higher mean cortisol levels. After circumcision, the EMLA group's mean salivary cortisol levels were  $6.931 \pm 6.206$  ng/ml, with a mean difference of 4.956 ng/ml, indicating statistical significance with  $p < 0.001$ .

Comparing the mean cortisol levels in the two groups after the surgery, the DPNB group showed similar results:  $6.292 \pm 5.847$  ng/ml and a mean difference of 5.451, indicating statistical significance with  $p < 0.0001$ . With  $p=0.533$ , the difference was not statistically significant. Regarding the problems in the two study subject groups, it was observed that 2.94% ( $n=1$ ) of the patients in the EMLA group and no subjects in the DPNB group had penile erythema. 5.88% ( $n=2$ ) of the participants in the dorsal penile nerve block group and 2.94% ( $n=1$ ) of the subjects in the EMLA group both had penile edema. 94.11% ( $n=32$ ) of the individuals in the dorsal penile nerve block group and 97.05% ( $n=33$ ) of the subjects in the EMLA group did not have any complications.

The difference between the two groups was statistically non-significant in the DPNB and EMLA groups with  $p=0.66$  as summarized in Table 3.

## DISCUSSION

Using a straightforward randomization technique, 68 participants in the study were split into two groups and had their circumcisions either under DPNB block with lidocaine or with EMLA as a local anaesthetic. Ampules of lidocaine and EMLA cream with a 5% concentration were utilized in the investigation. In the DPNB and EMLA groups, the mean age of the neonates was  $13.66 \pm 5.44$  and  $15.25 \pm 6.70$  days, respectively. These differences were statistically not significant ( $p=0.14$ ). The age range of 8–14 days accounted for the bulk of research participants, with 15–21 days following closely behind. This range was statistically equivalent ( $p=0.122$ ). With a p-value of 0.36, the mean gestation age in the DPNB and EMLA groups was statistically comparable at  $38.11 \pm 1.96$  and  $37.82 \pm 1.94$  weeks, respectively.

With  $p=0.08$ , the proportions of term and preterm infants were similar in the two groups. Neonates weighed  $2.87 \pm 0.16$  and  $2.88 \pm 0.13$  kg on average, which was equivalent ( $p=0.74$ ). With a p-value of 0.26, the circumcision duration in the DPNB and EMLA groups was found to be  $7.79 \pm 1.64$  and  $7.55 \pm 0.71$  minutes, respectively, not statistically significant. These findings were in line with research conducted in 2005 by Diatchenko L et al. and in 2017 by Sharara Chami R et al., in which the authors evaluated participants whose demographic information was similar to that of the current study.

According to study results, when mean changes in NIPS scores of research subjects from DPNB and EMLA groups were evaluated at four stages of the procedure, it was observed that the DPNB group's mean NIPS scores during the entire

procedure were 2.969, while the EMLS group's mean NIPS score was 3.550, indicating no statistical difference. With a score of less than three, the mean NIPS score in the dorsal penile nerve block represented pain sensation. On the other hand, the EMLA group experienced mild to moderate pain, with NIPS classification scores of 3–4. These findings aligned with those of Labban M et al. (10 in 2021) and Field T et al. (11) in 2017, whose research also produced results comparable to the current investigation.

Every stage of the process showed a statistically significant rise in heart rate when compared to the baseline values. The mean heart rate in the dorsal penile nerve block group increased significantly only during the clamping and tying phases, at 9.57 beats per minute and 6.41 beats per minute, respectively, with p values of 0.02 and 0.03. With regard to the variations in SpO<sub>2</sub> levels, there was a statistically significant difference observed in the mean SpO<sub>2</sub> throughout baseline values and all phases of the circumcision in both groups.

The present study's results were consistent with those of investigations conducted by Banik PP et al. (12) in 2020 and Van Gastel M et al. (13), who revealed comparable findings regarding SpO<sub>2</sub> and heart rate in male circumcisers. The study's findings demonstrated that both the EMLA and dorsal penile nerve block groups had an increase in mean cortisol levels. After circumcision, the EMLA group's mean salivary cortisol levels were 6.931±6.206 ng/ml, with a mean difference of 4.956 ng/ml, indicating statistical significance with p<0.001. Cortisol levels after circumcision in the DPNB group were 6.292±5.847 ng/ml on average, with a mean difference of 5.451 ng/ml indicating statistical significance with p<0.0001. The two groups' mean cortisol levels after the surgery were compared. With p=0.533, the difference was not statistically significant. These investigations supported the findings of Jin H et al. (2018) and Cabral DM et al. (2013), who similarly found that stress in neonates was associated with elevated cortisol levels.

Regarding the complications in the two study subject groups, it was also noted that 2.94% (n=1) of the patients in the EMLA group and no subjects in the DPNB group had penile erythema. 5.88% (n=2) of the participants in the dorsal penile nerve block group and 2.94% (n=1) of the subjects in the EMLA group both had penile edema.

No complication was seen in 94.11% (n=32) subjects from the dorsal penile nerve block group and in 97.05% (n=33) subjects from the EMLA group. The difference in the two groups was statistically non-significant in the DPNB and EMLA groups with p=0.66. These findings coincided with Okeke L et al<sup>16</sup> in 2006 and Ademuyiwa AO et al<sup>17</sup> in 2009 where authors reported similar complications following neonatal circumcision as seen in the present study.

## CONCLUSION

Considering its limitations, the present study concludes that better pain control in neonates undergoing circumcision is seen with dorsal penile nerve block with lidocaine compared to EMLA cream. However, both EMLA cream and dorsal penile nerve block are safe methods in neonates. Further longitudinal studies with a larger sample size are needed to reach a definitive conclusion.

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Indicator	Behavioral scores		
	0	1	
State of arousal	Awake and quiet/sleeping	Irritable, thrashing. Restless, alert	-
Legs	Relaxed. No muscle rigidity, occasional rando movements	Flexed/extended tense	-
Breathing patterns	Relaxed	Changes in breathing, breath holding, faster than usual, irregular breathing	-
Cry	Quiet-not crying	Intermittent cry, mild moaning	Continuous cry, rising shrill, scream
Facial expression	Relaxed muscles Natural expression	Furrowed brow, jaw, or chin Tight facial muscles	

**Table 1: Modified NIPS scores utilized in the present study**

Characteristics	DPNB group (n=34)		EMLA group (n=34)		p-value
	n	%	n	%	
Mean age (days)	13.66±5.44		15.25±6.70		0.14
Age range (days)					0.122
1-7	4	11.76	6	17.64	
8-14	20	58.82	15	44.11	
15-21	8	23.52	8	23.52	
22-28	2	5.88	5	14.70	
Mean gestational age (weeks)	38.11±1.96		37.82±1.94		0.36
Gestational age group (weeks)					0.08
Preterm	2	5.88	6	17.64	
Term	32	94.11s	28	82.35	
Mean weight (kgs)	2.87±0.16		2.88±0.13		0.74
Circumcision duration (min)	7.79±1.64		7.55±0.71		0.26

**Table 2: Demographic data of study participants in two groups**

Characteristics	DPNB group (n=34)		EMLA group (n=34)		p-value
	n	%	n	%	
Penile erythema	0	-	1	2.94	0.66
Penile edema	2	5.88	1	2.94	
None	32	94.11	33	97.05	

**Table 3: complications seen in two groups of study subjects**