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Original Article

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Analgesic efficacy of using topical anesthetic before dorsal penile nerve block in infant circumcision: A randomized-controlled study

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Abstract

Objectives: The aim of this study was to investigate the effect of lidocaine-prilocaine cream (LPC) application on circumcision analgesia and algology before dorsal penile nerve block (DPNB).

Patients and methods: Between January 2024 and April 2024, a total of 128 healthy male infants aged 1 to 12 months, who were screened and underwent circumcision under local anesthesia in our clinic, were included in this randomized-controlled study. The patients were divided into two groups as the DPNB group (DPNB group, n=64) and the DPNB+LPC group (n=64). The heart rate (HR), respiratory rate (RR), peripheral arterial oxygen saturation (SpO_2) changes, and Neonatal Infant Pain Scale (NIPS) scores were measured during the surgical stages of the groups with and without topical analgesia before DPNB. The values at the time of DPNB injection, at the time of circumcision, and at 3 min after the end of the operation were recorded.

Results: There was no statistically significant difference in the mean age and body weight of the patients between the groups (p>0.05). There was also no statistically significant difference between the HR, RR, and SpO_2 of the groups before the operation (baseline), at the time of local analgesic needle insertion, during circumcision and after the operation (p>0.05). The NIPS scores at the time of local anesthetic needle insertion were significantly different (p=0.04), although there was no significant difference in the NIPS scores at the other time points (p>0.05).

Conclusion: Our study results suggest that LPC application before DPNB yields favorable effects in terms of local anesthesia and ease of surgery, and it is a safe technique to apply.

Keywords: Analgesics, dorsal penile nerve block, lidocaine-prilocaine cream, male circumcision.

Circumcision is the process of surgically cutting off the prepuce surrounding the glans penis and revealing the glans. It is a surgical procedure performed throughout history for religious and cultural reasons, to assist with hygiene and for medical purposes.[1] Circumcision is one of the most commonly performed surgical procedures particularly among Muslims and Jews.[2] About 30% of male population worldwide are circumcised.[3]

Numerous analgesic techniques for circumcision have been documented in modern medicine. These methods include local anesthesia, regional anesthesia, sedoanalgesia and general anesthesia, and each of them has certain advantages and disadvantages. Optimal analgesia helps to keep the patient calm and the surgeon more meticulous during the procedure, thereby improving the surgical outcome.[4] General anesthesia is effective, but has high relative risks. Regional techniques such as caudal and pudendal blocks are also effective, but rather invasive.[5] Dorsal penile nerve block (DPNB) and topical anesthetics such as lidocaine-prilocaine cream (LPC) are safe and commonly used technique.[6] Many studies have shown that DPNB is more effective than topical LPC.[7] However, there

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are painful steps in its use, as well as documented incomplete block up to 13% and complete block failures up to 7%.[8] The DPNB elicits pain at the time of administering the block due to the trauma of the needle prick. Additionally, it is significantly less effective during circumcision steps involving trauma to the ventral aspect of the penis, as this surface is partly supplied by the perineal nerve, which is not affected by the block.[9]

In our center, we previously used DPNB alone with similar anecdotal experience. In the present study, we hypothesized that LPC administered prior to DPNB for circumcision could provide more effective analgesia by reducing the pain of the block injection and obviating probable sources of block failure. It might also provide additional analgesia extending throughout the procedure and postoperatively up to 2 h or more after removing the cream,[10] despite its increased cost and waiting time. We, therefore, we aimed to determine the effectiveness of DPNB with or without LPC for infant circumcision analgesia using heart rate (HR), respiratory rate, (RR), peripheral arterial oxygen saturation (SpO_2) changes, and Neonatal Infant Pain Scale (NIPS) as indicators of pain (Table 1).

PATIENTS AND METHODS

This single-center, prospective, randomized-controlled study was conducted at Kızılcahamam State Hospital, Department of Urology between January 2024 and April 2024. A written informed consent was obtained from the parents and/or legal guardians of the patients. The study protocol was approved by the Sivas Cumhuriyet University Non-Interventional Clinical Research Ethics Committee (date: 21.12.2023, no: 2023-12/20). The study was conducted in accordance with the principles of the Declaration of Helsinki.

A total of 130 healthy male infants between the ages of 1 to 12 months were screened. Those with congenital anomaly of the phallus (n=1), preputial complications, dermatitis, untreated bleeding disorders, or postoperative bleeding (n=1) were excluded from the study. Finally, a total of 128 infants were included in the study. The patients who underwent circumcision under local anesthesia in our clinic were divided into two groups. The DPNB was applied to one group with 4 mg/kg of lidocaine 1% 15 min before the operation (DPNB group, n=64) using a 23-gauge needle at the 2 o'clock and 10 o'clock positions at a ratio of 50:50 and circumcision was performed. A total of 2 to 3 g of lidocaine (5%) + prilocaine (5%) topical cream was applied to the other group and the penis and scrotum were covered with a drape, waited for 1 h and, then, DPNB was performed in the same way as the other group (DPNB+LPC group, n=64).

Dorsal slit method was applied to all circumcisions. In both approaches, hemostasis was achieved using bipolar cautery attentively and the wound sides were approximated by single sutures using 5/0 polyglactin (Vicryl RAPIDE™, Ethicon LLC, Johnson & Johnson Inc., NJ, USA). The HR, RR, SpO_2 (%), NIPS[11] of all babies were recorded before the procedure (baseline). The values at the time of DPNB injection, the values at the time of circumcision with dorsal slit (circumcision), and

TABLE 1
Neonatal infant pain scale

	Behavioral score		
Indicator	0	1	2
Facial expression	Relaxed muscles Neutral expression	Tight facial muscles furrowed brow chin or jaw	-
Cry	Quiet-not crying	Mild moaning intermittent cry	Loud scream, rising shrill Continuous cry
Breathing patterns	Relaxed	Changes in breathing; irregular, faster than usual, breath holding	-
Legs	Relaxed. No muscular rigidity. Occasional random movements	Flexed/extended Tense	-
State of arousal	Awake and quiet or sleeping	Irritable. Alert, restless, and thrashing	-

the values at 3 min after the end of the operation were measured (postoperative). Data including demographic and clinical characteristics of the patients and postoperative follow-up data were evaluated.

Statistical analysis

Study power analysis and sample size calculation were performed using the G*Power version 3.1.9.7 software (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). Accordingly, 64 samples were required for each group with a moderate effect (d=0.5), alpha (α) of 0.05 (95% confidence level), and β of 0.80.

Statistical analysis was performed using the IBM SPSS version 21.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were expressed in mean ± standard deviation (SD), median (min-max) or number and frequency, where applicable. Independent samples t-test was used for two-group comparisons of normally distributed quantitative variables, while the Mann-Whitney U test was used for two-group comparisons of non-normally distributed quantitative variables. The Pearson chi-square test and Fisher exact probability test were used to compare qualitative data. A *p* value of <0.05 was considered statistically significant.

RESULTS

Of a total of 128 patients included in the study, there were 64 patients in each group. The mean ages of the DPNB group and DPNB+LPC group were 6.5±2.8 months and 6.1±3.0 months, respectively. Their average weight was 8.1±4.1 and 7.9±3.6 kilograms in the DPNB and DPNB+LPC groups, respectively. There was no statistically significant difference in the mean age and body weight of the patients between the groups (p>0.05). There was also no statistically significant difference between the HR, RR, and SpO_2 of the groups before the operation (baseline), at the time of local analgesic needle insertion, during circumcision and after the operation (p>0.05). The HR, RR, and SpO_2 changes between the groups are shown in Figures 1, 2 and 3, respectively.

While the NIPS scores of the DPNB group were 2.0, 5.6, 5.3, 4.4 at baseline, injection, circumcision and postoperative periods, respectively, they were 2.1, 3.8, 4.8, 4.2 in the DPNB+LPC group, respectively (Table 2). The NIPS scores at the time of local anesthetic needle insertion were significantly different (p=0.04); however, no significant difference was observed between the NIPS scores at the other time points (p>0.05) (Table 3). The changes in NIPS values of the groups are shown in Figure 4. No overall complications occurred due to local anesthesia in any patient. Penile edema and erythema due to DPNB developed in five patients in the DPNB group and in four

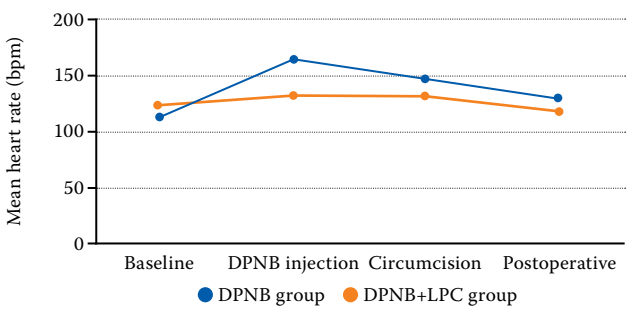

Figure 1. Mean heart rate flow chart.

DPNB: Dorsal penile nerve block; LPC: Lidocaine-prilocaine cream.

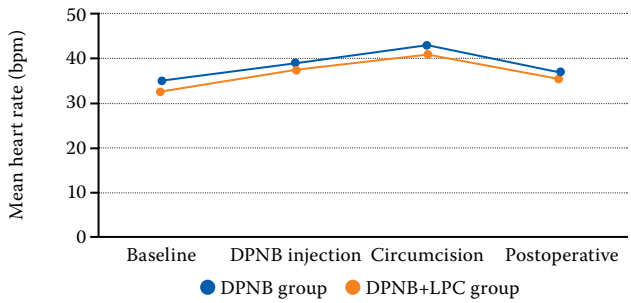

Figure 2. Respiratory rate flow chart.

DPNB: Dorsal penile nerve block; LPC: Lidocaine-prilocaine cream.

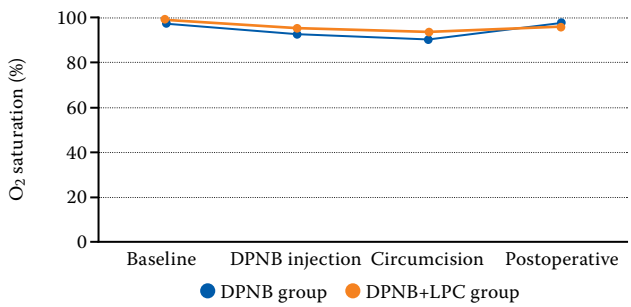

Figure 3. SpO_2 flow chart.

DPNB: Dorsal penile nerve block; LPC: Lidocaine-prilocaine cream; SpO_2: Peripheral arterial oxygen saturation.

TABLE 2
Statistical results of groups at different surgical stages

	Heart rate (n/min)			Respiratuar rate (n/min)			O_2 saturation (%)		
	DPNB	DPNB+LPC	*p*	DPNB	DPNB+LPC	*p*	DPNB	DPNB+LPC	*p*
Baseline	115	118	0.71	35	33	0.84	97	98	0.84
Injection	164	132	0.46	39	38	0.68	93	95	0.56
Circumcision	147	135	0.23	43	41	0.37	91	93	0.63
Postoperative	129	122	0.62	37	36	0.67	97	96	0.91

DPNB: Dorsal penile nerve block; LPC: Lidocaine-prilocaine cream.

patients in the DPNB+LPC group. No complications related to LPC were observed in any patient.

DISCUSSION

In the present study, we evaluated the effectiveness of DPNB with or without LPC for infant circumcision analgesia. The average HR, RR, SpO_2 and NIPS scores were compared in both groups at baseline, DPNB injection, circumcision, and postoperative stages. As expected, less pain was felt in the group where LPC was applied before DPNB, particularly at the time of DPNB application. Although only the NIPS score was found to be significantly different at the time of DPNB injection, the differences in the mean values of other variables indicated that algology was more effectively achieved in the group to which local topical anesthetic was added. During circumcision, although there was no statistically significant difference in terms of RR and HR among groups, these values were lower in the DPNB+LPC group.

TABLE 3
NIPS scores and statistical results of the groups in the surgical stages

	NIPS score		
	DPNB	DPNB+LPC	*p*
Baseline	2.0	2.1	0.22
Injection	5.6	3.8	0.04*
Circumcision	5.3	4.8	0.12
Postoperative	4.4	4.2	0.24

DPNB: Dorsal penile nerve block; LPC: Lidocaine-prilocaine cream.

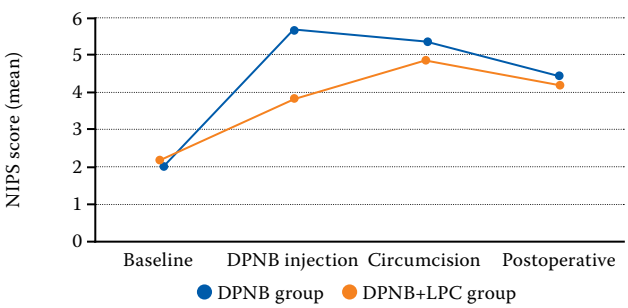

Figure 4. Neonatal infant pain scale flow chart.
NIPS: Neonatal infant pain scale; DPNB: Dorsal penile nerve block; LPC: Lidocaine-prilocaine cream.

The utilization of LPC before DPNB is three-layered. First, it aims to reduce the pain sensation caused by the needle during DPNB application, preventing the patient from crying and becoming restless before the procedure begins. Second, despite achieving penile block with DPNB, it aims to reach the sensory pathways of the perineal nerve. While the failure rate of DPNB is mentioned to be as low as 5%, there are studies suggesting an incomplete block of approximately 13%.[8,12] Evaluating these rates based on our clinical observations, it is clear that they cannot be disregarded. Third, it supports postoperative analgesia following circumcision.

Circumcision under local anesthesia in a pediatric patient is a process management. Apart from successfully applying local anesthesia, it is also very critical to consider the infant's comfort at all stages. In circumcisions where the comfort process is not disrupted at all, high NIPS scores are not expected to be obtained until the end of the circumcision. In our study, the situation that mostly triggered the crying during circumcisions was DPNB application, and the process was managed

more successfully with lower NIPS scores at the time of DPNB application in the LPC group.

In the current study, we investigated the effectiveness of adding LPC to DPNB. Similarly, in the study conducted by Modekwe et al.,[13] the anesthetic effectiveness of local anesthetic cream (EMLA®, Eczacıbaşı, İstanbul, Türkiye) and DPNB in neonatal circumcisions was compared.[13] The SpO_2, crying intensity, and NIPS scores showed significant differences between the groups during the stages of circumcision. In this study, the authors concluded that EMLA did not provide effective analgesia, but DPNB provided more effective anesthesia. In the study conducted by Emordi et al.,[14] DPNB with lidocaine yielded a more effective pain control compared to EMLA® cream during neonatal circumcision. Both methods are safe in neonates. Indeed, it is obvious that our study increases the positive effectiveness of both anesthesia techniques, providing a more successful analgesia and a comfortable operation. In a study conducted for similar purposes to our study, Ogundele et al.[15] evaluated serum cortisol level increase, SpO_2 decrease, and average HR parameters in the group in which LPC was added before DPNB in neonatal circumcisions, and they reported that LPC application before DPNB provided a more effective analgesia. In the study conducted by Mujeeb et al.,[16] they evaluated the circumcisions of patients with an average age of 2.3 months with the same variables as ours and found the HR and NIPS scores to be statistically significantly different in several different parts of the surgery, although not completely; however, it was interpreted as an external cost increase in the EMLA® group where the general pain control was the same. Although applying LPC for analgesia increases the cost, the success of the surgery can be achieved with an infant whose analgesia is provided and whose mobility is minimized. Most of the studies have included neonatal or low-month-old children and, therefore, our study shows superiority to these studies, as it shows the same algology success in older infants.

In a study conducted by Serour et al.,[9] other techniques would be needed since LPC application would not reach the dorsal penile nerve located under Buck's fascia in any way, and the authors reported that although LPC application reduced the pain at the time of needle insertion (penetration), it did not reduce the pain at the time of infiltration, and multiple (circular) injections were used. Numerous solution suggestions have been made so far, such as more superficial infiltration, slower injection of the anesthetic agent, and less injection of the anesthetic agent.[17] There are various studies showing that these application changes increase the success of analgesia.[17,18] Although all these mentioned changes in injection practice should be standardized in studies, they are not. Although this is a limitation to our study, we believe that performing circumcisions by a single physician can prevent these changes.

Another issue that should be taken into consideration in circumcision anesthesia is that oxidizing agents such as lidocaine and prilocaine may cause methemoglobinemia. This risk is much higher, particularly in the neonatal period, and it can be treated successfully with the help of intravenous methylene blue.[19] Young infants are more susceptible to developing methemoglobinemia, as fetal hemoglobin is more easily oxidized than adult-type hemoglobin. The United States National Library of Medicine (NLM) states that topical lidocaine/prilocaine should not be used in neonates with a gestational age <37 weeks. It also states that infants up to three months of age should be monitored for methemoglobin concentration before, during, and after administration.[20]

Although we investigated in our study that adding LPC to the circumcision protocol could increase success and provide a more comfortable surgery, the fact that we were unable to prove this statistically with all parameters can be considered as a limitation to our study. The fact that all parameters are not statistically different may be due to the lack of a standardized and precise method for understanding pain in this age group. Although there are studies published for similar purposes to our study, our study is shared as it does not contain statistically identical results and analgesia application techniques would affect the results.

In conclusion, LPC application before DPNB yields favorable effects in terms of local anesthesia and ease of surgery, and it is a safe technique to apply. Nonetheless, further multi-center, large-scale, prospective, randomized-controlled studies are needed to draw more reliable conclusions on this subject.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Concept: A.Ö., İ.E.E.; Design, analysis or interpretation: İ.E.E., H.S.; Data collection or processing: A.Ö., A.A.; Literature search: A.Ö., H.S.; Writing: A.Ö., A.A., İ.E.E.

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