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Ultrasound-guided penile block for circumcision instead of anatomical landmark method in newborn babies

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Abstract

Background: The primary objective of this study is to compare the effectiveness of the newborn's penile block performed by the surgeon using the classical landmark method and the penile block performed by the anesthesiologist with ultrasound guidance.

Results: This prospective, single-blinded, randomized clinical study included a total of forty newborn babies scheduled to undergo elective circumcision. The babies were randomized into two treatment groups of ultrasound (US)-guided penile block (group I; n = 20) and classical landmark method dorsal penile nerve block (DPNB) (group II; n = 20) group. Face, Legs, Activity, Cry, Consolability (FLACC) score was used to determine the block efficacy and postoperative pain and analgesic requirements. Intraoperative and postoperative FLACC scores, intraoperative analgesic needs, discharge time, complications, first oral intake time, and parent's satisfaction were also recorded.

FLACC scores were higher in group II than in group I during the intraoperative periods. Heart rate was higher in group II than in group I, at the incision, and during the procedure ($P < 0.05$). The number of patients requiring fentanyl was higher in group II than in group I ($P < 0.01$). FLACC scores were statistically higher in the landmark group at arrival in the PACU ($P < 0.01$) and after 30 min up to 2 h ($P < 0.01$). Parent's satisfaction was significantly higher in US group ($P < 0.01$)

Conclusions: Intraoperative analgesic needs and pain scores are lower in newborn babies who performed penile block with ultrasound-guided compared to the landmark method.

Keywords: Newborn circumcision, Ultrasound-guided penile block, Landmark method penile block, Intraoperative analgesic need, Parent's satisfaction

Background

Circumcision is a painful surgery and it is a very wrong belief that anesthesia and postoperative analgesia are not required in newborn babies. When we look at the place of circumcision in history, we see that it was generally performed for religious and hygienic reasons. Traditionally, newborn babies were circumcised without using general anesthesia. The most frequently used method is the

injection of local anesthetics into the base of the penis to block the dorsal penile nerve (DPNB) by surgeons (Dalens et al. 1989). This block was first described by Bateman in the 1970s and since then several variations of this method have been described (Bateman 1975).

With the widespread use of ultrasound, it has become popular to perform bilateral subpubic injections with ultrasound guidance. This method was first described in 2007 by Sandeman and Dilley (Sandeman and Dilley 2007). Although the dorsal penile nerve is very difficult to see directly with ultrasound, the spreading of the local anesthetic solution can be seen on both sides.

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It is important to know whether the block is performed effectively during circumcision in newborn babies. For this reason, it is necessary to see the effective spread of local anesthesia with the block performed with ultrasound and follow-up of the newborn during circumcision. Regardless of whether the circumcision is performed locally or regionally, the newborn should be followed by an anesthesiologist and intervened in case of insufficient anesthesia.

For this reason, in our study, we wanted to compare the ultrasound (US)-guided block, in which local anesthetic spread is made by seeing it, and the classical landmark method, which was made by not seeing local anesthetic spread.

The primary objective of this study is to compare the effectiveness of the penile block performed by the surgeon using the landmark method and the penile block performed by the anesthesiologist with ultrasound guidance. The secondary objective is the comparison of parent's satisfaction of blocks made by the landmark method and blocks made by the ultrasound guidance.

Methods

The study protocol was approved by the institutional Ethics Committee and written informed consent was obtained from each parent. The study was conducted in accordance with the principles of the Declaration of Helsinki.

This prospective, single-blinded, randomized clinical study included a total of 40 newborn babies scheduled to undergo elective circumcision surgery who had an American Society of Anesthesiologists (ASA) grade I, between May 2018 and January 2019. The babies were randomized into two treatment groups of ultrasound (US)-guided penile block group (group I; $n = 20$) and classical landmark method DPNB group (group II; $n = 20$). Randomization was performed with a closed envelope method. Premature and low-birth weight babies and the

babies with an allergy to an aminoamide local anesthetics or a general contraindication for penile nerve block were excluded from the study. All blocks were performed by the same anesthesiologist and surgeon.

Forty-five minutes before the block, topical anesthesia with lignocaine-prilocaine cream was administered to the block area in both groups. The penis and scrotum area were prepared with 0.5% chlorhexidine in 70% alcohol. Pulse oximetry, electrocardiography, and noninvasive blood pressure were monitored in the operating room. Intravenous access was performed before the block.

In US-guided group I, a linear ultrasound probe with 5 to 10 MHz (LogiQ P5, GE, Milwaukee, USA) was placed transversely along the base of the penis (Fig. 1). By using real-time ultrasound with the in-plane method, after determining the corpora cavernosa, dorsal artery and vein, and superficial and deep Buck's fascia, the needle was advanced through Buck's fascia laterally to the dorsal artery. After negative aspiration, plain 0.25% bupivacaine solution was injected 0.1 ml/kg under direct vision, while being careful to prevent neurovascular injury or intravascular injection. After the injection, the spread of the local anesthetic solution was seen as a black hypoechoic area (Fig. 2), and the same procedure was performed on the other side. Finally, 0.05 mg local anesthetic solution was injected at the scrotal penis basis to block the scrotal branches of the pudendal nerve. In group II, surgeons used the landmark method to block the dorsal penis and scrotal penis nerve with the same local anesthetic solution. The needle was inserted on either side of the midline just distal to the inferior ramus of the pubic bone then advanced slowly, in a slightly medial and caudal direction, until a "pop" was felt as it passed through Scarpa's fascia, and local anesthetic was injected. In both groups, 26-gauge needles were used.

The skin incision was started 10 min after the block performed. Face, Legs, Activity, Cry, Consolability (FLACC) (Voepel-Lewis et al. 1997) (Table 1) score

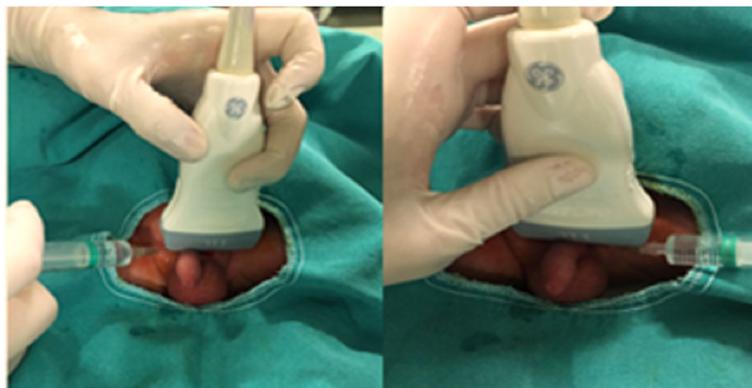


Fig. 1 Anesthesiologist approach: ultrasound-guided (in-plane method) penile block

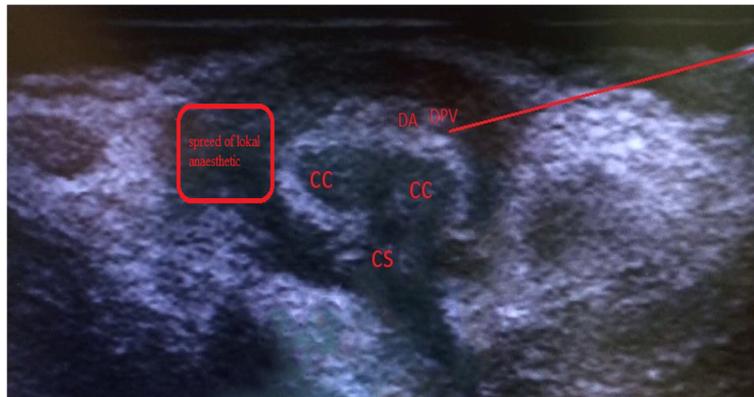


Fig. 2 Ultrasound-guided in-plane needle placement for dorsal penile nerve block. CC, corpus cavernosum; CS, corpus spongiosum; DA, dorsal artery; DPN, dorsal penile nerve; red arrow, 22-G needle

was used to determine the block efficacy and postoperative pain and analgesic requirement. FLACC score was recorded at the beginning, 10 min later, and every 30 min until day 1 at home. If the FLACC score was higher than 4, determined an increase in heart rate, and mean arterial pressure of more than 20% above the baseline, an ineffective block was defined. In case of failure fentanyl, 1 mcg kg was administered intravenously.

On arrival post-anesthesia care unit (PACU) and then every 30 min up to 3 h, FLACC score was recorded by the same trained nurse. When the FLACC score was higher than 4, paracetamol 15 mg kg iv was given as a first choice of rescue analgesic. One day after circumcision, the family was questioned for satisfaction. Answers were recorded as yes and no. Discharge time, complications, first oral intake time, and parent’s satisfaction was recorded also.

Table 1 FLACC score

FLACC Behavioral Scale

Categories	Scoring		
	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant frown, clenched jaw, quivering chin
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
Cry	No cry (awake or asleep)	Moans or whimpers, occasional complaint	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to, distractable	Difficult to console or comfort

Each of the five categories (F) Face; (L) Legs; (A) Activity; (C) Cry; (C) Consolability is scored from 0-2, which results in a total score between zero and ten.

Statistical analysis

Statistical analysis was performed with the Statistical Package for Social Sciences version 10 software (SPSS Inc., Chicago, IL, USA). Data were analyzed by using the Student's t-test, Mann-Whitney U test, and logistic regression tests. The results were assessed in the 95% safety interval and statistical significance was assumed when $p < 0.05$.

Sample size estimation

Assuming a 50% reduction in the number of patients receiving fentanyl and paracetamol to be clinically significant, it was estimated that a minimum of 20 patients would be required in each group to achieve a power of 80% at the 0.05 level of significance.

Results

The demographic characteristics of the babies were similar in both groups. No patients were excluded from the study. Group I median age is 6.5 (29) days, and weight 3.1 (2.9) kg. Group II median age is 4 (29) days, median weight 3.1 (1.3) kg. The number of patients requiring fentanyl was higher in group II than in group I ($P < 0.01$) (Table 2). We used fentanyl intraoperative for one patient in the US group and eight patients in the landmark group ($P < 0.01$). Only one patient received the paracetamol during the hospital stay (5%) in the US group and 8 (40%) in the landmark group during the postoperative periods ($P < 0.01$). FLACC scores were higher in group II than in group I during the intraoperative periods ($P < 0.05$) (Table 2). FLACC scores during the postoperative periods were shown in Table 3. FLACC scores were statistically higher in the landmark group at arrival in the PACU ($P < 0.01$) and after 30 min up to 2 h ($P < 0.01$). No significant differences were found in the FLACC score at the third hour of the hospital stay ($P > 0.05$). Heart rate was higher in group II than in group I at the incision and during the procedure ($P <$

0.05). The ultrasound method took longer to perform in group II than in group I ($P < 0.01$). There was a significant difference in first oral intake time between the groups ($P < 0.01$) but no significant differences were found in discharge time in the groups ($P > 0.05$). While the families of all babies in the US group answered yes to the questioning of satisfaction, 16 families in the landmark group answered yes.

Discussion

Circumcision is a routine procedure in neonate babies for religious or cultural reasons. Caudal anesthesia, topical anesthesia, and dorsal penile nerve block are the most common methods for pain relief (McGowan et al. 1998). Dorsal penile nerve block (DPNB), which is applied by injecting local anesthetic drugs close to the dorsal nerves of the penis, was first described in the 1970s (Dalens et al. 1989). The complication rates of the penile block are low. Reports of complications include swelling, hematoma, or edema; bruising at the injection site; and drug-related complications (Snellman and Stang 1995).

Since 1978, ultrasound-guided nerve block has been reported in the literature (Peterson et al. 2002). With the use of ultrasound in regional anesthesia, significant improvements have been made in pediatric regional anesthesia. Rubin et al. showed with their clinical studies that block made with ultrasound guidance provide some advantages over blocks made by traditional methods in children (Rubin et al. 2009). In DPNB performed with ultrasound guidance, it provides a two-dimensional evaluation of the subpubic space and penile structures, allowing the needle to be advanced directly into the subpubic area in real-time and to see the effective spread of the local anesthetic solution.

In this study, the US-guided method was compared with the classical landmark method. FLACC score was used to evaluate the pain and rescue analgesic needs. We wanted to show whether the block performed with

Table 2 Main result

	Ultrasound-guided (group I)	Anatomical landmark (group II)	P-value
Duration of the procedure (min)	20 (14; 24)	20 (10; 20)	0.1
Time to perform block (min)	8 (6; 12)	2 (1; 3)	0.01
Number of requiring fentanyl, n (%)	1 (5)	8 (40)	0.01
Number of required paracetamol, n (%)	1 (5)	8 (40)	0.01
Time to oral intake (min)	30 (10; 40)	41 (33; 60)	0.01
Time to discharge (h)	3	3	1
Number of failed block (%)	1 (5)	8 (40)	0.01
Heart rate at incision	124 (120; 154)	130 (125; 165)	0.04
Heart rate during procedure	125 (120; 158)	132 (128; 170)	0.04
Family satisfaction, n (%)	20 (100)	16 (80)	0.01
Number of patients FLACC score > 4	1	8	0.01

Table 3 FLACC score versus time

	Ultrasound-guided (group I)	Anatomical landmark (group II)	P-value
FLACC incision	1.15 (0; 2)	2.6 (2; 4)	0.002
FLACC 10 min	0.85 (0; 1)	1.9 (1; 2.5)	0.04
FLACC 30 min	0.2 (0; 2)	0.85 (0; 3)	0.001
FLACC 60 min	0 (0; 0)	0.5 (0.5; 2)	0.001
FLACC 120 min	0 (0; 0)	0.3 (0; 1)	0.001
FLACC 180 min	0 (0; 0)	0 (0; 0)	0.8
FLACC at discharge	0 (0; 0)	0 (0; 0)	0.8
FLACC day 1 at home	0 (0; 0)	0 (0; 0)	0.8

the use of ultrasound in newborn babies provides more effective analgesia.

Serious complications, like gangrene of the glans, intravascular local anesthetic injection, have been described in the literature. We found only one baby in group I and two babies in groups II that had swelling and edema on his penis during and after the surgery. In Soh and colleague's retrospective study, DPNB complication rate was 0.23% in 3909 boys (Sara and Lowry 1985). In Faraoni's study, they have a small group, compare the US and classical landmark methods, and found no minor or major complications (Faraoni et al. 2010).

O'Sullivan et al. compared the DPNB by anatomical landmark method with the ultrasound-guided method (O'Sullivan et al. 2011). The findings of this study do not support the routine use of ultrasound for the performance of DPNB in male pediatric circumcision compared with the anatomical landmark method. They found there is no significant difference in the fentanyl usage or in the initial pain scores between the "anatomical landmark" group and the "ultrasound" group. Unlike this study, in our study, our patients were newborn babies and intraoperative analgesic needs and postoperative pain scores were higher in the landmark group. Time to first need a rescue analgesic was also shorter in the landmark group. Parent's satisfaction rates were higher in the US group due to improved postoperative analgesia.

Faraoni et al. also compared the subpubic DPNB by anatomical landmark method with the ultrasound-guided method. Like our study, they concluded that ultrasound guidance does improve the efficacy of the procedure (Faraoni et al. 2010).

In Sandeman's study, they compared three different regional methods (landmark-based DPNB, US-guided DPNB, and caudal anesthesia) in pediatric circumcision (Sandeman and Dilley 2007). The authors found the landmark method needs more rescue analgesics in the recovery room but no other differences between other groups including hospital discharge time. Caudal analgesia was compared with DPNB in several trials, and no differences were found in the need for rescue analgesia

or the incidence of postoperative nausea and vomiting (Gauntlett 2003; White et al. 1983). However, the caudal group showed a higher incidence rate of motor block or leg weakness (Cyna and Middleton 2008). In our study, we found that the US-guided block in newborn babies provides better intraoperative and postoperative analgesia than the landmark method. Most anesthesiologists prefer penile block performed by the surgeon with the landmark method instead of the caudal block and general anesthesia in newborn babies because they are afraid of the technical difficulties and complications of the procedure. These studies are important to encourage the US-guided DPNB instead of caudal block.

In recent years, the use of ultrasound has become popular in the performance of regional anesthesia, and several studies have shown the benefit of ultrasound over the landmark method mostly in pediatric anesthesia. However, there are studies supporting the use of ultrasound not only in pediatric circumcision surgery but also in adult penile surgery. In Gurkan's study, they demonstrate the analgesic effect of US-guided DPNB in adult penile surgery (Gurkan et al. 2016). They showed that US-guided penile block improved postoperative analgesia and decreased morphine consumption in adults like our study.

Newborns have a special importance among pediatric circumcised patients. They are a difficult group of patients due to their fragility, immature systems, and different responses to pain. In these patients, postoperative and intraoperative pain can only be evaluated subjectively. It is not known whether the pain has a long-term effect on newborns. Therefore, we think that knowing that the use of ultrasound in neonatal circumcision provides a better postoperative and intraoperative analgesia is important for the routine use of ultrasound during the newborn penile block.

Our study has some limitations. The low number of patients decreases the statistical power, and this is an important limiting factor of our study. Therefore, multicentric studies with a much higher number of patients are needed. All pain scores used in neonates may not be

able to make an objective pain assessment, so we may not be able to determine effectively which patient's block is effective or not.

Conclusions

Ultrasound use improved the efficacy of the penile block compared to the classical landmark method in newborn circumcision.

Abbreviations

US: Ultrasound; FLACC: Face, Legs, Activity, Cry, Consolability; PACU: Post-anesthesia care unit; ASA: American Society of Anesthesiologists; DPNB: Dorsal penile nerve block

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Authors' contributions

SAY, HO, and AT designed the study. SAY drafted and modified the manuscript. SAY performed the study and collected data. AT performed the statistical analysis. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Ethical approval was obtained from the Regional Ethical Committee of Emsey Hospital Ethical Committee (protocol no. 2014/08) and therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. The written informed consent was obtained from all parents.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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