

## ORIGINAL ARTICLE

## A video study of pain relief during newborn male circumcision

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**Objective:** The purpose of this investigation was to compare the effectiveness of dorsal penile nerve block and topical lidocaine–prilocaine anesthesia techniques for pain relief during circumcision.

**Methods:** In total, 18 healthy term newborn males were divided based on anesthesia. The topical lidocaine–prilocaine group had six males undergoing circumcision and three males undergoing a sham procedure. The dorsal penile nerve block group had six males undergoing circumcision and three males undergoing a sham procedure. The procedures were videotaped and viewed by 90 noninvestigator reviewers who scored the infants' pain using the Neonatal Infant Pain Scale and a numeric pain scale. Statistical analysis utilized a  $P$ -value of  $<0.05$  as significant.

**Results:** The median Neonatal Infant Pain Scale and numeric pain scores were significantly lower in the dorsal penile nerve block group than in the topical lidocaine–prilocaine group or the sham group (Neonatal Infant Pain Scale: 1.0 (range 0–6) versus 6.0 (range 2–6) versus 4.0 (range 0–6),  $P<0.001$ , respectively; numeric pain scale: 2.0 (range 0–10) versus 8.0 (range 1–10) versus 4.0 (range 0–10),  $P<0.001$ , respectively). In the sham group, procedures with the dorsal penile nerve block had significantly lower pain scores than those with topical lidocaine–prilocaine (Neonatal Infant Pain Scale: 1.0 (range 0–6) versus 5.0 (range 2–6),  $P<0.001$ ; numeric pain scale: 1.0 (0–8) versus 6.0 (range 0–10),  $P<0.001$ ). When reviewers were divided by medical background, gender or parental status, no differences in pain scores were observed.

**Conclusion:** The dorsal penile nerve block anesthesia technique for newborn male circumcision was significantly more effective for pain relief than topical lidocaine–prilocaine.

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**Keywords:** dorsal penile nerve block; lidocaine–prilocaine; gomco clamp

**Introduction**

Newborn male circumcision has existed for more than 6000 years.<sup>1</sup> Currently an estimated 25% of males undergo this procedure worldwide.<sup>2</sup> In the USA, circumcision is the most commonly performed surgical procedure with more than 60% of newborn males circumcised annually.<sup>3,4</sup> The techniques for performing circumcisions have been reviewed and summarized by Litman.<sup>5</sup> Recently, studies have shown that infants do experience pain as evidenced through behavioral and physiological parameters and therefore anesthesia should be utilized.<sup>6</sup> Thus, the American Academy of Pediatrics and the International Evidence-based Group for Neonatal Pain both recently recommended the use of one of the following anesthetic techniques during newborn male circumcision: the dorsal penile nerve block, topical lidocaine–prilocaine, or subcutaneous ring block.<sup>3,6</sup> However, the literature remains mixed regarding the optimal anesthetic method for circumcision.

Pain scales have been used to evaluate the infant's behavioral components of pain. These behavioral components have been videotaped for the investigators to complete analysis.<sup>7–14</sup> Video studies have only been reviewed by the study investigators and never reviewed by noninvestigators or by nonmedical persons. In addition, no studies have used sham procedures in comparing anesthesia techniques or evaluate baseline levels of pain. A baseline level of neonatal pain, associated with either administration of anesthesia or positioning of the newborn, is present prior to a circumcision in which use of a sham procedure may prove beneficial in evaluation.

The purpose of this investigation was to compare the effectiveness of the dorsal penile nerve block and topical lidocaine–prilocaine anesthesia techniques utilized for newborn male circumcision to provide pain relief. A secondary outcome was comparison of medical and nonmedical scoring of pain associated with the circumcision procedure.

**Methods**

The study was a prospective, randomized, reviewer blinded comparison of anesthetic methods used in neonatal male circumcision. The Institutional Review Board approved the protocol

and informed consent was obtained for the circumcision procedure and for participation in the study.

Over a 3-week period, 18 term male newborns were recruited for study participation after parental consent was obtained for a videotaped circumcision. The number of newborns was limited to 18 secondary to the estimated length of a videotape that reviewers would subsequently view and score pain. A video greater than 45 min of continuous reviewing or which required a break during viewing process might have been a potential confounding variable. Exclusion criteria for the newborns were a gestational age <37 weeks, any contraindication to circumcision, use of sedative or pain medication, and parental refusal to participate. All circumcisions were carried out within 36 h of delivery with Gomco clamps (Allied Healthcare Products Inc., Saint Louis, MO, USA) and were performed by one of two physicians, who were not investigators in this study. Only leg restraints were utilized during the circumcision procedures.

One of the following anesthesia techniques was used for circumcision. The dorsal penile nerve block was performed with 0.3–0.5 ml of 1% lidocaine injected at 2 and 10 o'clock positions at the base of the penis 5 min before the procedure. A topical mixture of lidocaine (2.5%) and prilocaine (2.5%) cream (EMLA anesthetic cream, AstraZeneca Pharmaceuticals, Wilmington, DE, USA) was applied to the shaft of the penis with an occlusive dressing 1 h before the procedure.

A sham procedure was administration of anesthesia with the usual draping followed by gentle manipulation with touch and no circumcision performed. The neonates undergoing the sham procedures had the circumcision performed immediately after the videotaping was completed. A randomized listing was followed for determination of the sham procedure versus the actual circumcision.

This divided the neonates into three groups based on anesthesia and procedure. Group 1 was six newborns undergoing circumcision after a dorsal penile nerve block. Group 2 was six newborns undergoing circumcision after topical lidocaine–prilocaine. Group 3 was six newborns undergoing a sham procedure with three having dorsal penile nerve block and three having topical lidocaine–prilocaine.

The videotaping of the procedure started after anesthesia was administered and the newborn properly prepped and draped in a sterile manner. The video imaging included a letter identifier and only the newborn features above the umbilicus: the newborn's torso, arms, head, and face. Sound was included with the video and at the completion of the circumcision the video was discontinued. A sham procedure video was 2–2.5 min in length, the approximate length of an actual circumcision procedure. The circumcision video segments were edited into a 45 min video for viewing.

The composite videotape of the 18 procedures was distributed to 90 reviewers for pain scoring. The reviewers were recruited based on medical or nonmedical background. Nonmedical background

was defined as having no training in any healthcare related field. A predetermined randomly generated list was used to select the reviewer gender sequence. Basic demographic data were obtained from the reviewers including age, gender, attitudes towards newborn circumcision, parental status, whether their male child was circumcised, and opinions after viewing the video. Reviewers were blinded to the type of anesthesia used, whether an actual or sham procedure was performed. All scoring sheets were completed anonymously.

Two pain scales were given to the reviewers to complete while viewing the video: the Neonatal Infant Pain Scale<sup>7,15–17</sup> and a numeric pain scale. The Neonatal Infant Pain Scale consists of six components that evaluate facial expression, cry, breathing pattern, arm movements, leg movements, and state of arousal. In the procedure, the newborn legs were restrained and thus omitted from evaluation. The scoring was adjusted to a minimum pain score of 0 and the maximum pain score of 6. A numeric pain scale was also utilized with 0 representing no pain and 10 representing worst pain.

Statistic analysis utilized SPSS (Chicago, IL, USA) for analysis of data. Pain scores are not normally distributed and a two-tailed Mann–Whitney U nonparametric test was used for evaluation. The student's *t*-test, two-way analysis of variance (ANOVA), and  $\chi^2$  testing were used for comparison of demographics. A *P*-value of <0.05 was considered significant. Assessment of reliability between observers was measured using the intraclass correlation coefficient.<sup>18</sup> Power analysis using an alpha of 0.05 and a beta of 80% required six neonates in each group to detect a 50% difference in Neonatal Infant Pain Scale scores. A total sample size of 90 pain reviewers was required to achieve a power of 0.90 to detect a mean difference in Neonatal Infant Pain Scale scores of –2.5 with an alpha of 0.05 between medical and nonmedical cohorts.<sup>7,8,10</sup>

## Results

The dorsal penile nerve block and topical lidocaine–prilocaine anesthesia groups were similar with respect to gestational age (39.3±1.0 versus 39.2±0.89 week; *P* = 0.31), maternal age (31.6±4.1 versus 28.1±3.8 year; *P* = 0.09), and birth weight (3452±372 versus 3449±287 g; *P* = 0.30). No complications occurred secondary to the anesthetic method used (hematoma, rash, skin sloughing, urinary retention, or seizures).<sup>9</sup>

The median Neonatal Infant Pain Scale scores were significantly lower in the dorsal penile nerve block group than in the topical lidocaine–prilocaine group or the sham group (1.0 (range 0–6) versus 6.0 (range 2–6) versus 4.0 (range 0–6), *P*<0.001, respectively) (Table 1). The mean numeric pain scale scores were also significantly lower in the dorsal penile nerve block group than in the topical lidocaine–prilocaine group or the sham group (2.0 (range 0–10) versus 8.0 (range 1–10) versus 4.0 (range 0–10), *P*<0.001, respectively). Neonatal Infant Pain Scale

**Table 1** Circumcision pain evaluation divided by anesthesia type and procedure group

Characteristic	DPNB group	TLP group	Sham group	P-value
<i>Overall scores</i>	(n = 9)	(n = 9)		
NIPS score	1.0 (0–6)	6.0 (2–6)		<0.001
Numeric pain score	2.0 (0–10)	8.0 (1–10)		<0.001
<i>Anesthesia specific scores</i>				
DPNB	(n = 6)		(n = 3)	
NIPS score	1.0 (0–6)		1.0 (0–6)*	<0.001
Numeric pain score	2.0 (0–10)		1.0 (0–8)	<0.001
TLP		(n = 6)	(n = 3)	
NIPS score		6.0 (2–6)	5.0 (2–6)**	<0.001
Numeric pain score		8.0 (1–10)	6.0 (0–10)**	<0.001

Values presented as median (range).

\*Lower median value.

\*\*P-value = 0.03 when sham groups are compared: DPNB sham group versus TLP sham group.

NIPS = Neonatal Infant Pain Scale, TLP = topical lidocaine–prilocaine,

DPNB = dorsal penile nerve block.

scores, when using a dorsal penile nerve block, were significantly greater in newborns undergoing circumcision compared with those having a sham procedure (1.0 (range 0–6) versus 1.0 (range 0–6),  $P < 0.001$ ) and numeric pain scale scores were also greater in the dorsal penile nerve block group compared with the sham group (2.0 (range 0–10) versus 1.0 (range 0–8),  $P < 0.001$ ). Neonatal Infant Pain Scale scores, when using topical lidocaine–prilocaine, were significantly higher in newborns undergoing circumcision versus those having a sham procedure (6.0 (range 2–6) versus 5.0 (2–6),  $P < 0.001$ ). In the sham group, when evaluating the two anesthetic techniques, newborns with a dorsal penile nerve block had significantly lower pain scores than those newborns having topical lidocaine–prilocaine (Neonatal Infant Pain Scale: 1.0 (range 0–6) versus 5.0 (range 2–6),  $P = 0.03$ ; numeric pain scale: 1.0 (range 0–8) versus 6.0 (range 0–10),  $P < 0.001$ ). The intraclass correlation coefficient assessment of reliability between observers was 0.99 indicating excellent agreement between reviewers' scores.

The reviewer characteristics, when compared by medical background, were similar with respect to age, gender, parental status, and prior male child circumcised (Table 2). The only difference was that 71% (32/45) of the reviewers with a medical background had previously witnessed a circumcision compared to only 13% (6/45) in the nonmedical background group ( $P < 0.001$ ). Despite this difference, the Neonatal Infant Pain Scale scores and numeric pain scores were similar between reviewers with and without a medical background. Pain scores remained significantly lower in the dorsal penile nerve block group when compared with the topical lidocaine–prilocaine group or the sham group irrespective of the medical background of the reviewer.

**Table 2** Video reviewer characteristics and pain scoring when evaluated by medical background

Characteristic	Medical (n = 45)	Non-medical (n = 45)	P-value
Age (mean year $\pm$ s.d.)	34.4 $\pm$ 8.1	37.1 $\pm$ 10.3	0.23
Male gender (%)	20 (44%)	20 (44%)	0.83
Parent (%)	23 (51%)	26 (58%)	0.67
Male child (%)	18/23 (78%)	19/26 (73%)	0.92
Male child circumcised (%)	15/18 (83%)	18/19 (95%)	0.55
Have previously witnessed circumcision (%)	32 (71%)	6 (13%)	<0.001
Believe circumcision beneficial (%)	41 (91%)	40 (89%)	0.95
Neonatal Infant Pain Scale score			
TLP	6.0 (2–6)	6.0 (1–6)	0.18
DPNB	1.0 (0–6)	1.0 (0–6)	0.26
Sham	3.0 (0–6)	4.0 (0–6)	0.75
Numeric pain score			
TLP	8.0 (4–10)	8.0 (2–10)	0.63
DPNB	2.0 (0–9)	2.0 (0–10)	0.19
Sham	4.0 (0–10)	4.0 (0–10)	0.59

Values presented as *N* (%) or median (range).

NIPS = Neonatal Infant Pain Scale, TLP = topical lidocaine–prilocaine,

DPNB = dorsal penile nerve block.

**Table 3** Video reviewer characteristics and pain scoring when evaluated by parental status

Characteristic	Parent (n = 49)	Non-parent (n = 41)	P-value
Age (mean year $\pm$ s.d.)	39.6 $\pm$ 9.3	30.5 $\pm$ 6.0	0.02
Male gender (%)	17 (37%)	16 (39%)	0.84
Neonatal Infant Pain Scale score			
TLP	6.0 (2–6)	6.0 (3–6)	0.32
DPNB	1.0 (0–6)	1.0 (0–6)	0.48
Sham	4.0 (0–6)	3.0 (0–6)	0.65
Numeric pain score			
TLP	8.0 (4–10)	8.0 (0–10)	0.23
DPNB	2.0 (0–9)	2.0 (0–10)	0.71
Sham	5.0 (0–10)	4.0 (0–10)	0.54

Values presented as *N* (%) or median (range).

NIPS = Neonatal Infant Pain Scale, TLP = topical lidocaine–prilocaine,

DPNB = dorsal penile nerve block.

The Neonatal Infant Pain Scale scores and numeric pain scores were similar when compared by parental status (Table 3) or when compared by the reviewer gender (Table 4). The pain scores remained significantly lower in the dorsal penile nerve block group compared to the topical lidocaine–prilocaine group or the sham group irrespective of the parental status or gender. Reviewers that were parents were more likely to have been older than the

**Table 4** Video reviewer characteristics and pain scoring when evaluated by gender

Characteristic	Male (n = 40)	Female (n = 50)	P-value
Age (mean year ±s.d.)	34.4±9.2	36.7±9.1	0.86
Parent (%)	17 (43%)	32 (64%)	0.07
<i>Neonatal Infant Pain Scale score</i>			
TLP	6.0 (2–6)	6.0 (3–6)	0.08
DPNB	1.0 (0–6)	2.0 (0–6)	0.32
Sham	3.0 (0–6)	4.0 (0–6)	0.76
<i>Numeric pain score</i>			
TLP	8.0 (0–10)	8.0 (4–10)	0.09
DPNB	2.0 (0–9)	2.0 (0–10)	0.63
Sham	4.0 (0–6)	5.0 (0–10)	0.76

Values presented as *N* (%) or median (range).

NIPS = Neonatal Infant Pain Scale, TLP = topical lidocaine–prilocaine,

DPNB = dorsal penile nerve block.

nonparental video reviewers (39.6±9.3 year versus 30.5±6.0 year,  $P = 0.02$ ; respectively). There were no age differences when reviewers were compared by gender (male 34.4±9.2 versus 36.7±9.1 year;  $P = 0.86$ ).

## Discussion

The dorsal penile nerve block is superior to topical lidocaine–prilocaine for pain management during newborn male circumcision. The dorsal penile nerve block, compared with topical lidocaine–prilocaine, had significantly lower pain scores when actual procedures were performed and reduced pain scores when sham procedures were performed. The American Academy of Pediatrics recommends that adequate pain relief should be provided when newborn male circumcision is performed.<sup>3</sup> Topical lidocaine–prilocaine should be abandoned as the primary method of pain relief for circumcision since dorsal penile nerve block is a more effective anesthetic as shown by our study and several others.<sup>7–10</sup> The combination of topical lidocaine–prilocaine with dorsal penile nerve block has been shown to be safe with less pain than topical lidocaine–prilocaine alone.<sup>14</sup> The utilization of topical lidocaine–prilocaine cream at the base of the penis prior to injection to reduce injection site pain during dorsal penile nerve blockade seems sensible, but has only been studied in older children undergoing circumcision.<sup>19</sup>

Pain scores were similar when comparing reviewers with a medical background and those having no medical background. Lawrence *et al.*<sup>16</sup> originally used video of newborns experiencing needle-insertion procedures using the Neonatal Infant Pain Scale. The videos were scored before, during and postprocedure providing

a measurement of intensity of pain response by the newborn. Hudson-Barr *et al.*<sup>15</sup> utilized the Neonatal Infant Pain Scale and a Pain Assessment in Neonates (PAIN) in studying the intensity of painful response of neonates to various procedures which occur in the nursery, including circumcision. The nurses at the bedside in the unit scored observed pain using the scale provided during their shift. Only medically trained persons have evaluated pain during circumcision procedures and no study intervention has been able to completely eliminate circumcision pain response.<sup>10</sup> All video reviewers were blinded to anesthesia method and whether there was an actual procedure: circumcision versus sham. The reviewers clearly differentiated the pain difference between dorsal penile nerve block and topical lidocaine–prilocaine. More importantly, they were able to distinguish between actual and sham procedures.

Robinson and Wise<sup>20</sup> demonstrated female video reviewers rated observed pain 8–10% higher than their male counterparts observing the same video. In our study, there was no difference in the pain scoring based on reviewer gender. In addition, there was no difference in the pain scoring based on parental status. This validates that the Neonatal Infant Pain Scale and numeric pain scale were easily understood by all reviewers participating.

Prior studies evaluating topical and local anesthetics have not adequately demonstrated that there is a departure from a baseline pain when performing circumcisions.<sup>21</sup> In this study, sham procedures demonstrated that there is a minimal level of a painful response associated with simple touch and manipulation of the newborn penis. Hudson-Barr *et al.*<sup>15</sup> also described a baseline painful response when scoring nonpainful procedures in newborns. This may exist due to observer bias, obliged to score the pain. Interestingly, when evaluating the sham group, the level of the painful response through manipulation was significantly greater in the topical lidocaine–prilocaine group than the dorsal penile nerve block group. This may result from either the dorsal penile nerve block better preventing the sensation of touch and manipulation or when using topical lidocaine–prilocaine, the sensation of touch and manipulation is perceived as pain by the neonate. Sham procedures have resulted in many ethical arguments,<sup>22</sup> however, in this study all neonates ultimately had their circumcisions performed with a minimal delay.

One limitation of this study was the possible effect of the order in which the procedures were viewed. All viewers received the same sequence of newborns, which may have an affect on the scoring as the viewer proceeded through the videotape. Utilizing multiple presentation orders would have possibly balanced the order effects.<sup>23</sup> Another limitation was the number of newborns undergoing circumcision which was limited to 18 newborns. The number of newborns was determined based on the estimated length of a videotape that reviewers would score. More than 45 min of continuous video observation or requiring a break during reviewing process would further add confounding variables.

This study demonstrates that dorsal penile nerve block significantly reduces neonatal pain sensation during male circumcision when compared with topical lidocaine–prilocaine. Pain scores for the dorsal penile nerve block are lower than neonates having no procedure performed. The Neonatal Infant Pain Scale can be reliably used for evaluators and similar results obtained with and without a medical background. Despite many statements regarding the usage of anesthesia during newborn circumcision, individuals continue to ignore the medical evidence.

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