Beyond Dorsal Penile Nerve Block: A More Humane Circumcision

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ABSTRACT. *Objective.* **To explore techniques that can be utilized in addition to the dorsal penile nerve block (DPNB) to further reduce the neonate's stress and pain from routine circumcision, and thus make the procedure more humane.**

Setting. **Level 1 nursery at a community hospital.**

Subjects. **Eighty healthy, term, newborn male infants scheduled for routine neonatal circumcision.**

Study Design. **Prospective and randomized; double blind and placebo controlled for the study solutions.**

Methods. **Four statistically similar groups of 20 were studied. The control group included infants circumcised using: a) a rigid plastic restraint board; b) standard DPNB; and c) a pacifier dipped in water to comfort the infant. Each study group differed from the controls in one variable including: 1) using a specially designed, physiologic circumcision restraint chair; 2) pH buffering of lidocaine hydrochloride used for DPNB; and 3) offering a pacifier dipped in a 24% sucrose solution during the DPNB and circumcision. Behavioral observations were recorded and compared for each group starting before the injection of lidocaine hydrochloride and continuing through the completion of the circumcision. Plasma for cortisol levels were collected 30 minutes after the circumcision.**

Results. **Neonates circumcised on the new restraint chair showed a significant decrease in distress scores (>50%) compared with the control group on the rigid molded-plastic restraint. The pacifier dipped in sucrose had a distress-reducing effect during both the post-DPNB injection and circumcision periods. The infants who were injected with the buffered lidocaine showed no differences in distress from the controls. The plasma cortisol levels were not significantly affected by any additional technique and were comparable to the levels previously reported.**

Conclusions. **When neonatal circumcisions are performed routinely, they should be done as humanely as possible. This study demonstrates that, when used in conjunction with DPNB, a pacifier dipped in 24% sucrose and a more comfortable, padded, and physiologic restraint can be useful in decreasing distress and pain.** *Pediatrics* **1997;100(2). URL: http://www.pediatrics.org/cgi/content/full/100/2/e3;** ***dorsal penile nerve block, circumcision, neonatal pain.***

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ABBREVIATIONS. DPNB, dorsal penile nerve block; EMLA, eutectic mixture of local anesthetics; GHI, Group Health, Inc.; ANOVA, analysis of variance.

Routine neonatal circumcision, when performed without anesthesia, is a painful and stressful operation.[1–6] There is still a pervasive belief that infants do not experience pain, or if they do, they do not experience it in the same manner as seen in adults.[7] The physiologic effects of this pain have been well documented and have been widely utilized to study the effects of techniques to decrease the pain and stress.[2,3,5,8–14]

The rate of circumcision in the United States is unlikely to decrease, particularly after the 1989 American Academy of Pediatrics Task Force on Circumcision statement that found evidence of advantages and disadvantages to this most commonly performed operation[15,16] which is quick, safe, and has low morbidity.[17] It is incumbent upon physicians to continue to search for safe and effective methods of analgesia/anesthesia.

The dorsal penile nerve block (DPNB) was first described for use in the neonatal circumcision in 1978.[18] Since then, multiple studies have demonstrated both its safety and efficacy.[5,8–14] In a recent prospective report of short-term complications, no significant complications were noted with the use of DPNB in more than 7000 infants during an 8-year period.[19]

Other methods of anesthesia and analgesia have been reported such as eutectic mixture of local anesthetics (EMLA, Astra Pharmaceutical Products, Inc, Westborough, MA),[20] acetaminophen,[21] music,[22] oral sucrose,[23] topical lidocaine,[24,25] and local foreskin injection of lidocaine.[26] However, none of these methods has been shown to be statistically superior to DPNB in decreasing distress. In addition, reported studies with these techniques have been too small to answer questions of safety.

The DPNB is the most utilized procedure, despite its shortcomings of adding time, the additional discomfort of a needle injection, and the associated learning curve. For these reasons, this study focused on improving this technique rather than pursuing other methods of anesthesia. As stated in 1988,[5] if "circumcisions are still to be performed, we owe it to our children to perform them as humanely as possible."

Three additional techniques were studied to assess their contribution to decreasing the neonate's pain

and distress during circumcision as measured by behavioral scores and plasma cortisol.

METHODS

Male newborn infants from Group Health, Inc (GHI) who were already scheduled for a routine neonatal circumcision at Fairview Riverside Medical Center, a community hospital in Minneapolis, were screened for study entry in 1993 to 1994. GHI is a prepaid staff-model health maintenance organization with more than 240 000 members in the Twin City area.

Inclusion criteria included: 1) age greater than 20 hours; 2) uncomplicated vaginal or caesarean birth; 3) weight between 3000 and 4000 grams at birth; 4) a 5-minute Apgar score of greater than or equal to 8; 5) a full-term infant defined as a greater than or equal to 37-weeks-postconception age by the Ballard assessment;[27] 6) a normal range score on the Littman-Parmelee Obstetric Complication Scale[28]; and 7) a normal physical exam by a pediatrician.

Informed consent was obtained from the parents of all infants and the study was approved by the Institutional Review Boards of GHI, Fairview Riverside Medical Center, and the University of Minnesota. There were no added charges to the parents who agreed to participate, nor were there any incentives offered. The study was funded by the Group Health Foundation.

Due to a change in methodology from 1988[5] in preparing the infant, injecting the anesthetic, and soothing the neonate, a pilot project of five infants was completed. Several routine techniques were studied to determine their effect on modifying the stress and pain during circumcision: 1) all injections were given with the infant lying in their bassinet, 2) the iodine antiseptic solution was warmed to body temperature, and 3) there was no forced prolonged fasting. The restraint device that was used remained the Circumstraint (Olympic Medical Corporation, Seattle, WA), a rigid molded-plastic platform that restrains the infants' extremities in a position of extension. The infants were repeatedly offered a pacifier by an attendant nurse, and the infants' arms were swaddled against their chest with a soft receiving blanket.

The data obtained from this first pilot study failed to demonstrate a significant reduction in behavioral scores or cortisol levels compared with 1988 data.[5] Therefore, a second pilot of seven infants was performed utilizing standard DPNB in conjunction with a new restraint device, offering a pacifier dipped in sucrose, and buffering the lidocaine with sodium bicarbonate. The results from the second pilot study did show a significant reduction in behavioral distress and a tendency toward lower cortisol levels. A study was then undertaken to determine which of these three additive techniques was responsible for the reduction in distress.

Eighty infants were randomized to four equal groups of 20. (A fifth arm of the study [24% sucrose pacification without DPNB] was abandoned after enrolling only 3 patients due to high behavioral distress scores in the 3 infants, parents' concern about the lack of pain control, and the fact that DPNB is so well an accepted practice in the study hospital that it made enrollment into the study very difficult.) All subjects were injected for the DPNB in the bassinet, were prepared with warmed iodine solution, and had no forced fasting period preoperatively.

Group 1 (DPNB with new restraint, see Table 1) received a nonbuffered lidocaine injection, a pacifier dipped in water, and then were circumcised on a newly designed restraint chair (US Patent #5 160 185). This restraint differs from the Circumstraint in that: 1) all areas that contact the infant are soft, cushion padded, and adjustable to the size of the infant; 2) it allows free movement of the infant's extremities without compromising the surgical field; and 3) it allows the infant to sit with his hips abducted and flexed, knees flexed, and head/trunk elevated to 30 to 45 degrees with all its joints variably hinged for adjustability for size of the infant and exposure to the perineum. The positioning of the baby in the restraint is more physiologic as it allows for the innate hypertonicity and flexion of the neurologically immature neonate, and the velcro attached cushions allow accommodation to various sized infants (Fig 1 and Fig 2).

Group 2 (DPNB with sucrose) infants were continually offered a pacifier dipped in a 24% solution of sucrose (visually indistinguishable from water) beginning 2 minutes before the nonbuff-

TABLE 1. Study Group Designations

Study Group Number	Restraint Type	DPNB Solution	Pacifier Solution
1	New padded chair	0.8 mL Lidocaine 0.2 mL Saline	Water
2	Rigid plastic	0.8 mL Lidocaine 0.2 mL Sodium bicarbonate	Water
3	Rigid plastic	0.8 mL Lidocaine 0.2 mL Saline	24% Sucrose
4	Rigid plastic	0.8 mL Lidocaine 0.2 mL Saline	Water

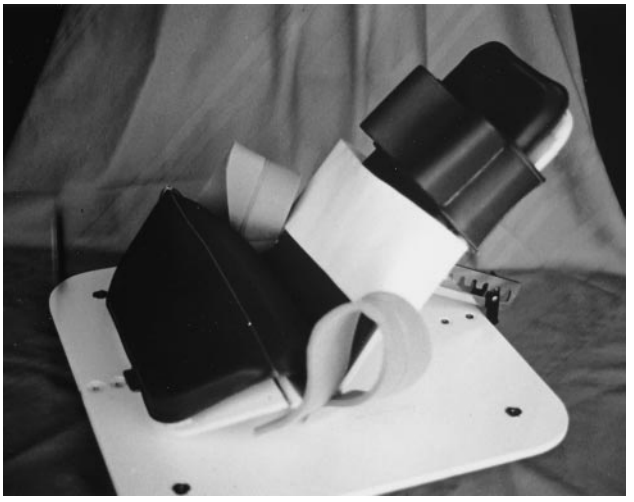

Fig 1. Cushioned circumcision restraint chair with adjustable Velcro cushions and hinged joints.

Fig 2. Neonate restrained in physiological position allowing access to surgical field.

ered lidocaine injection, and continuing until the infant was removed from the rigid restraint.

Group 3 (DPNB with buffered lidocaine) infants were given a water dipped pacifier and then were injected with .8 mL of 1% lidocaine hydrochloride mixed just before the procedure with .2 mL of sodium bicarbonate (1 milliequivalent per mL) to obtain a final pH of 7.4. The circumcision was performed on the Circumstraint.

Group 4 (control) served as the control group and infants were given a water-dipped pacifier, injected with nonbuffered lidocaine for the DPNB, and circumcised on the Circumstraint.

Both the study research assistant (L.B.) and the operator were blinded to the solution (water versus sucrose pacifier) and to which infants received the buffered lidocaine. Five different experienced pediatricians performed the 80 circumcisions. The technique of DPNB injection utilized is described elsewhere.[5,29]

All manipulations (eg, bathing, physical examinations, blood tests) known to stimulate the hypothalamic-pituitary axis were avoided for 1 hour before the circumcision.[30] Beginning 2 minutes before the DPNB injection, each infant's behavior was recorded every 30 seconds by a research assistant (L.B.) trained to 94% (by Cohen's κ) observer agreement using the Brazelton's behavioral state scale[31] to score behavioral arousal and a second scale for behavioral distress (see Table 2).

Five scoring periods were defined: 1) baseline preinjection: the 2 minutes immediately before injection of the DPNB; 2) injection: the 30 second intervals during which the DPNB injection was given; 3) immediate postinjection: the 2 minutes after the injection; 4) delayed postinjection: the next 2 minutes after injection; and 5) circumcision. Note, that there was a 5-minute waiting period between the injection and the circumcision; however, in the last minute the infants were being placed on the restraint and the surgical instruments were prepared. Because these scoring periods were of unequal duration, percent occurrence for each code in each scoring period was calculated. Distress scores for each scoring period were computed by multiplying these percentages by the code's weight shown in Table 2 and dividing by 100. A score of three indicated continuous, sustained crying throughout that period, although a score of zero indicated no fussing or crying during that interval. The percentage of coding intervals asleep was calculated for the circumcision scoring period by summing the quiet and active sleep codes from the scale.

Thirty minutes after the beginning of the circumcision, a plasma cortisol sample was collected by heel stick puncture (.5 mL) at the same time as the required metabolic newborn screening test. The blood was centrifuged, plasma extracted, and it was stored at −20 degrees Centigrade until assayed. The plasma was analyzed using a cortisol radioimmunoassay kit (Pantex Corporation, Santa Monica, CA. *Note: Pantex Corporation is now known as Bio Analysis Corporation*). This assay is highly specific for cortisol with the interassay and intraassay coefficients of variation both below 11%.

The distribution of sample characteristics across groups were examined using one-way analysis of variance (ANOVA) and χ^2 statistics, as appropriate. The distress scale data were analyzed using four (groups) by five (scoring periods) ANOVA with repeated measures on the second factor. Plasma cortisol and sleep data were examined using one-way ANOVAs. Post hoc tests were computed using Newman-Keuls formula. All findings described as statistically significant had P values of less than .05.

RESULTS

Subjects in all four groups were comparable with regard to age at time of circumcision (mean = 35.1 hours), gestational age (mean = 39.5 weeks), birth weight (mean = 3.65 kilograms), maternal age (mean = 29.9 years), 5-minute Apgar score (mean = 8.94), obstetrical complication score[28] (mean = 83.9), time since last feeding (mean = 1.19 hours), and duration of circumcision procedure (mean = 11.2 minutes). There were no significant statistical differences amongst the four study group means for any of these eight variables.

Fifty-two (65%) circumcisions were performed by the Gomco method and 28 (35%) by Plastibell (Hollister, Inc, Libertyville, IL) with the distribution being similar across the four groups by the χ^2 statistical analysis (P = .93). Sixty (75%) of the infants were delivered by caesarean section and 20 (25%) vaginally; there was no bias for any study group. Early discharge of vaginally delivered infants impacted their availability for the study.

There was no statistical difference in the distribution of subjects from the four study groups performed by any one pediatrician.

Seventy-five (94%) of the study infants were white, 3 (4%) were black, and 2 (2%) were Hispanic.

Because morphine-based anesthetic might influence the effects of sucrose, the use of morphine-based medications during labor and delivery were examined by group. There were no group differences for use of meperidine hydrochloride (n = 3), nalbuphine (n = 17), or intrathecal morphine (n = 24); 8 infants received naloxone hydrochloride at delivery. Results for behavioral and hormonal data were similar with and without these infants included in the analyses.

Behavioral Data

Table 3 displays the behavioral distress scores for each study group during each scoring period. The groups differed in the degree of behavioral distress they demonstrated ($P < .05$), with both the new restraint and the sucrose groups showing less distress than the other two groups ($P < .05$) overall. The scoring periods in which less distress was shown differed by group. Infants in all groups showed an increase in crying from preinjection baseline to the injection. Both the buffered lidocaine and sucrose were expected to decrease distress during the injection and/or allow the infants to calm more rapidly in the minutes after injection. The results demonstrate this effect for sucrose ($P < .05$) but not for buffered lidocaine. In the sucrose group, an effect was observed in the first 2 minutes after injection ($P < .05$) and not during the injections. Both the infants on the new restraint and those given sucrose were less behaviorally distressed during circumcision ($P < .05$). In fact, infants in these groups were not significantly more distressed during circumcision than they had been during the preinjection baseline period ($P > .10$).

Analysis of the percentage of time asleep during the circumcision, demonstrated a significant benefi-

TABLE 2. Behavioral Distress Scale

Weight	Description	Definition
0	Neutral	Brazelton Behavioral States 1–4[31]
1	Minimal fuss	Fuss slightly, no more than two times during a 30 second interval
2	Moderate fuss	Three or more fusses during a 30-second interval or a light rolling cry
3	Sustained cry	Brazelton Behavioral State 6[31]

TABLE 3. Mean Behavioral Scores* (SD) for Study Groups by Study Period [*P* value of Group Mean Compared With Group 4 Control]

Study Period	Group 1 Restraint Chair	Group 2 Buffered Lidocaine	Group 3 Sucrose	Group 4 Control	All groups (*P* Value for Period)
Preinjection	.23 (.51) [NS]	.10 (.26) [NS]	.05 (.16) [NS]	.12 (.25)	.125 (.32) [NS]
Injection	1.74 (1.15) [NS]	1.40 (.82) [NS]	1.37 (.93) [NS]	1.65 (1.06)	1.54 (.99) [NS]
2-Minute postinjection	.53 (.80) [NS]	.34 (.42) [NS]	.16 (.65) [.003]	.66 (.35)	.42 (.60) [.04]
4-Minute postinjection	.33 (.73) [NS]	.20 (.62) [NS]	.03 (.61) [NS]	.23 (.11)	.20 (.57) [NS]
Circumcision	.49 (.52) [.007]	1.22 (.78) [NS]	.45 (.80) [.002]	1.12 (.48)	.83 (.74) [<.001]

* Behavioral scoring assignments: neutral = 0, minimal fuss = 1, fussy cry = 2, sustained cry = 3.

cial effect for both the new restraint and sucrose groups. Infants in the new restraint group slept through 57% and those in the sucrose group slept through 48% of the circumcision scoring intervals, compared with 29% and 26% for the buffered lidocaine and water control groups, respectively.

Cortisol Data

In previous work examining the effects of DPNB on cortisol responses in circumcision,[5] the average cortisol level 30 minutes after the beginning of circumcision was 386 nmol/L (14.0 μg/dL), with a standard error of the mean (SEM) of 36 nmol/L. In the present study, the groups did not differ in plasma cortisol levels 30 minutes after the beginning of circumcision ($P > .10$) (Table 4). The mean cortisol level averaging throughout groups was comparable to the earlier study results, 403.4 nmol/L (14.6 μg/dL) with a SEM of 24.8 nmol/L.

DISCUSSION

Substantial clinical experience and basic research documents that neonates are capable of experiencing and perceiving pain.[1–26] Frequently, physicians who perform neonatal procedures deny their patients anesthesia and analgesia even though it has been strongly recommended by the American Academy of Pediatrics.[32]

DPNB has been utilized since 1978 to decrease the pain and stress of neonatal circumcision. It has been shown to be effective and safe.[5,8–14] Since the mid-1980's, DPNB has been used by the pediatricians at GHI for more than 10 000 neonatal circumcisions. Despite the definite decrease in pain and stress for most infants, an occasional infant does not get significant relief from DPNB alone and many seem more uncomfortable than the physician and parents would like. For these reasons, this study was undertaken in an attempt to document other techniques that would lessen the distress of circumcision and thus make it more humane.

Oral sucrose for analgesia in neonatal circumcisions was first explored by Blass and Hoffmeyer[23] in 1989. They demonstrated more than a 50% reduction in crying with infants sucking on a 24% solution of sucrose during the circumcision. Reproducing the earlier findings of Gunnar et al,[33] they found that nonnutritive pacifier sucking also attenuates the distress. Blass and Smith[34] later went on to show that sucrose is superior to other sugars (lactose, glucose, and fructose) in calming crying infants. It is felt that the calming/analgesia effect is not at the molecular blood-brain barrier, but rather that sucrose stimulates the opioid pathways in the brain by its sweet taste.

In this study, sucrose was helpful and additive to the analgesic and anesthetic effects of the DPNB during the immediate postinjection period and the circumcision itself. Although initially included, the arm of the study using sucrose alone for pain relief without DPNB, had to be abandoned attributable to parent and research assistant concerns with the lack of adequate anesthetic effect. Based on this experience and the results of this study, the use of sucrose as an adjunct to DPNB seems to be an effective use of this modality that is acceptable to care givers and parents.

Our group has now adopted the routine use of sucrose with all circumcisions. A practical formula to prepare a 24% to 25% sucrose solution involves mixing one packet of table sugar (commonly found in restaurants, hospital cafeterias, and doctors' lounges) with 10 mL of tap water. The sugar packets can be kept in the nursery, facilitating the mixing of solution just before the circumcision. A piece of gauze or a pacifier can then be dipped into the solution and repeatedly offered to the infant before and during the DPNB injection and circumcision.

We decided to study the effect of buffered lidocaine based on experience with adults in the emergency room setting showing lowered pain scores when local anesthetics were buffered with sodium bicarbonate before injection for laceration repair.[35] The pain of the injection was reduced but there was no reduction in anesthetic efficacy or onset of action. Buffering the usually acidic lidocaine hydrochloride (pH = 6.5) dramatically shortens its shelf life, thus the recommendation to add the buffer solution just before its use.[36] Unfortunately, the infants in the study did not seem to respond to this technique as

TABLE 4. Mean (SD) Plasma Cortisol Levels: nmol/dL [μg/dL] for Study Groups

Group 1 Restraint Chair	Group 2 Buffered Lidocaine	Group 3 Sucrose	Group 4 Control	All Study Infants	*P* Value
391.5 (217.8) [14.2 (7.9)]	408.0 (270.2) [14.8 (9.8)]	441.1 (217.8) [16.0 (7.9)]	372.2 (176.4) [13.5 (6.4)]	402.5 (220.6) [14.6 (8.0)]	NS NS

did the adults, thus reflecting the difficulty in extrapolating from the adult pain experience.

Any physician or nurse who has attempted to extend the arms and legs of a term neonate to strap them into a rigid restraint, realizes the resistance to extension that all neonates possess. This is attributable to their neurologically immature unmyelinated long tracts causing their inherent hypertonicity. In an attempt to overcome this problem, one of the authors (H.J.S.) designed a new restraint that is more physiologically adapted to the neonate's tone, obviates the need to impale the perineum to prevent movement, and eliminates the cold hard plastic. Previous work by Malone et al[37] did not demonstrate that limb restraint was particularly aversive, but data from this study clearly demonstrate a 50% reduction of distress during the procedure from the use of a physiologically designed, cushioned soft circumcision chair over the rigid plastic restraint (Circumstraint).

Although DPNB has the most extensive literature and experience supporting its use in neonatal circumcision, other modalities have been studied. EMLA can be a useful agent for pain management[20] in circumcision, but concerns about safety in newborns may limit its use. EMLA is not approved by the Food and Drug Administration for neonates because of the presence of prilocaine (one of the two anesthetics in the cream) which has been shown to induce methemoglobinemia in newborns. In addition, EMLA requires a prolonged (45 to 60 minutes) application that may not fit the schedule of a busy practitioner or nursery service. The only comparison of EMLA to DPNB was in a small study of bupivacaine .5% used for DPNB compared with EMLA for postoperative analgesia for circumcision in boys 2 to 10 years old.[38] The conclusion was that EMLA was not as effective as DPNB for postcircumcision analgesia.

Oral acetaminophen was found to provide some relief of pain after the immediate postoperative period, but does not ameliorate either the intraoperative or immediate postoperative pain.[21] Both classical music and intrauterine sounds have also failed to reduce pain as measured by behavioral and physiologic parameters.[22]

Topical lidocaine has also been shown to be efficacious and safe,[24,25] but has not been directly compared with DPNB. However, Mudge et al[24] found that infants treated with topical lidocaine cried 74% as much of the time as those treated with placebo. In contrast, Stang et al[5] showed that infants receiving DPNB cried only 33% as much as those given placebo. In addition, topical lidocaine also has the same practical problems as EMLA. The application must occur 20 to 120 minutes before the procedure making timing such an issue that it would be impractical in a busy practice or nursery.

Local anesthetic injection into the foreskin itself as described by Masciello[26] in 1989 was shown to be effective in attenuating pain responses, but his data on a small number of patients has not been substantiated.

The Jewish ritual circumcision (brit milah) acknowledges the pain of this operation by assigning an attendant (the sandek) to hold and soothe the infant with sweet wine, which may have a similar effect to sucrose by stimulating opioid pathways (the 12% alcohol may also benefit the infant with some sedation). Further study of the procedures utilized in the Jewish brit is warranted.

Surprisingly, our cortisol levels did not decrease as we had expected from examining preliminary data from our second pilot. With a baseline cortisol of 5.2 micrograms per deciliter under the exact same study preconditions,[39] an unanesthetized infant raises its cortisol to a mean of 17.0 whereas the level is decreased to 14.0 with DPNB alone.[5] In this study, the mean cortisol was 14.6 micrograms per deciliter for the entire 80 infants, but there was no significant difference between the study groups (see Table 3). This probably represents the fact that these manipulations help modify the stress and pain of circumcision but do not eliminate it.

In conclusion, if physicians are to continue to perform circumcisions, they should attempt to minimize the pain and stress of the procedure. In addition to the DPNB, allowing infants to suck on a sucrose dipped pacifier, and placing them on a more comfortable physiologically designed restraint can result in a reduction in crying and increase in sleep behavior. By adopting these techniques and encouraging their use by others, physicians can move beyond DPNB toward a more humane circumcision.

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