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Soothing Pain-Elicited Distress in Chinese Neonates

Luk Kar Bo, RN, BN, MN*, and Patrick Callaghan, RN, BSc, MSc‡

ABSTRACT. ***Objective.*** **To test the effect of nonnutritive sucking (NNS), music therapy (MT), and combined NNS and MT (NNS + MT), versus no intervention, on heart rate, transcutaneous oxygen ($TcPaO_2$) levels, and pain behavior of neonates in intensive care units having blood taken by a heel-stick procedure.**

Methodology. **A within-subjects, counter-balancing, repeated-measures design conducted in a government-funded hospital in Hong Kong, comparing $TcPaO_2$ levels, heart rate, and pain behavior outcomes in 27 neonates.**

Results. **Repeated-measures multivariate analysis of variance revealed statistically significant differences in outcomes across all interventions (Wilk's λ = .142; *F* [3,27] = 31.82; $\eta 2$ = .47). One-way analysis of variance revealed that the 3 comfort interventions significantly reduced neonates' heart rate (Wilk's λ = .647; *F* [2,27] = 18.93; $\eta 2$ = .35), improved their $TcPaO_2$ levels (Wilk's λ = .481; *F* [2,27] = 37.42; $\eta 2$ = .51), and reduced their pain behavior (Wilk's λ = .312; *F* [2,27] = 76.42; $\eta 2$ = .68). Posthoc scheffe tests revealed that NNS + MT had the strongest effect on neonates' $TcPaO_2$ levels and pain behavior; MT alone had the strongest effect on neonates' heart rate.**

Conclusions. **Health professionals using NNS + MT when doing heel-sticks can improve the $TcPaO_2$ levels of neonates and reduce their pain. Using MT alone can improve the heart rate of neonates. *Pediatrics* 2000;105(4). URL: http://www.pediatrics.org/cgi/content/full/105/4/e49; *psychological interventions, neonates, pain.***

ABBREVIATIONS. NNS, nonnutritive sucking; $TcPaO_2$, transcutaneous oxygen; MT, music therapy; CI, confidence interval; NIPS, Neonatal Infant Pain Scale; VAS, Visual Analog Scale.

Neonates in intensive care units are often exposed to painful invasive procedures such as heel-sticks to draw blood.[1] Previous randomized, controlled trials of the effects of interventions to comfort neonates during these procedures show inconclusive effects on various clinical outcomes. Neonates having heel-sticks and randomly assigned to nonnutritive sucking (NNS; pacifier) had less psychological distress but similar heart and respiratory rates than neonates receiving no intervention.[2] Control mechanisms were weak in this study with regard to the effects of the age and health status of the neonates on outcomes.

Neonates on assisted mechanical ventilation randomly assigned to receive NNS to soothe the distress of intravenous catheter insertion had lower heart rates and exhibited fewer restlessness and crying behaviors than did neonates having no intervention.[3] However, the small sample size[10] and the failure to control for the effects of age, birth weight, and experience of the person inserting the catheter weakened the study. NNS given for 3 minutes decreased heart rate and crying—although the effects were not sustained—in 2-week-old neonates having heel-sticks but not in 2-month-old neonates.[4]

Using music, intrauterine sounds, pacifiers, music plus pacifiers, intrauterine sounds plus pacifiers, or no intervention had similar effects on heart rate, blood pressure, and transcutaneous oxygen ($TcPaO_2$) levels of healthy neonates having circumcision without anesthetic.[5] The researchers' failure to take baseline and follow-up measures of the outcome variables renders it difficult to detect the effect of the interventions. Intrauterine sounds with female singing or music seem to significantly improve oxygen levels and reduce distress in premature neonates in studies that eschewed randomization and control and used samples sizes with insufficient statistical power.[6,7]

A meta-analysis of 10 studies published over 30 years showed that NNS decreased heart rate and increased $TcPaO_2$ levels. The effect size on heart rate was small, the effect size on $TcPaO_2$ levels was large. Larger effect sizes were found in premature neonates than were found in term neonates.[8] However, more independent studies are needed that test the effect of NNS on various clinical outcomes to truly determine the effect of NNS. Few studies tested the effect of NNS on physiologic indicators. None of the studies reviewed in this meta-analysis used random sampling or tested the effects of combined NNS + music therapy (MT) on neonates' clinical outcomes. Therefore, our aim was to test the effects of NNS, MT, and combined NNS + MT, versus no intervention, on heart rate, $TcPaO_2$ levels, and pain behavior of Chinese neonates in intensive care units having blood taken by a heel-stick procedure. We were particularly interested to measure the size of the effect of each intervention on each outcome as well as associated confidence intervals (CIs). Most of the previous studies rely on significance testing and few studies reported effect sizes or CIs. We hypothesized that neonates' $TcPaO_2$ levels, heart rate, and pain behavior would differ significantly after the use of comfort interventions versus no intervention.

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METHODS

Design and Sample

The researchers used a within-subjects, repeated-measures, counter-balancing design. Twenty-seven neonates in the special care baby unit of a government-funded general hospital in Hong Kong received NNS, MT, combined NNS and MT, and no intervention in a random order each time after a heel-stick procedure. Previous studies suggest we could expect a medium effect size in outcomes between the interventions. A sample of 27 is sufficient to detect a medium effect size with a statistical power of .80 at the 5% significance level in a 4-condition, within-subjects, repeated-measures design.[9]

Neonates were excluded if they had a 5-minute Apgar score under 6, a gestational age below 28 weeks, birth anomalies associated with neurological problems, or were receiving medication for pain or sedation. Table 1 shows the characteristics of the sample. The hospital involved in this study does not use the Score of Neonatal Acute Physiology (SNAP) index. The neonates were admitted to the special care as a precautionary measure and so their condition could be more closely monitored.

Outcome Measures

Pain behavior was measured by the Neonatal Infant Pain Scale[10] (NIPS). The NIPS is a standard tool to assess neonates' pain behavior. The vertical axis of the scale lists 6 behavioral groupings along with descriptors and potential scores. The horizontal axis lists periods and permitted scoring at 1-minute intervals before, during, and after a procedure such as heel-stick. The scores for each behavioral indicator are summed along the horizontal axis to provide a total score for each minute ranging from 0 to 7. A high score indicates a high level of pain behavior. We used the NIPS because it permits scoring at several intervals and it allows a more detailed assessment of neonates' pain, making it more advantageous than the Visual Analog Scale (VAS). The VAS has more advantages with adults able to report their own pain levels. Concurrent validity correlation between the NIPS and the VAS is .84, interrater reliability is .97 and Cronbach's α is .95.[10] The researchers used a Hewlett–Packard cardiac monitor (Hewlett-Packard, Hong Kong, China) to measure the neonates' heart rate and a Kontron microgas monitor probe (Kontron, Zurich, Switzerland) to measure $TcPao_2$ levels. One of the researchers (L.K.B.) calibrated the monitors before use.

Procedure

Ethical Issues

One of the researchers (L.K.B.) explained the nature of the study to each of the neonates' parents and obtained their written consent for their child to participate in the study. The hospital chief executive granted access to the study site and the clinical research ethics committee of the Chinese University of Hong Kong granted ethical approval.

Pilot Study

Two nurses were trained in the use of the NIPS, 1 of whom was a researcher (L.K.B.). After this, each nurse used the NIPS to independently rate the pain behaviors of 8 neonates. A κ-coefficient of .92 indicated a very high level of interrater reliability.

Primary Study

The neonates participated in each of the 4 conditions. Each trial consisted of 3 periods of data collection: a baseline 1 minute before the heel-stick procedure, each minute during 5 minutes of intervention, and each minute for 8 minutes after the heel-stick. The researchers monitored time intervals using a stopwatch. The researcher exposed each neonate to each intervention successively after the heel-stick. Each intervention lasted for 5 minutes after which it was withdrawn. We used a 1-minute baseline in line with protocols from other studies. We used a 5-minute intervention period based on previous work[4] suggesting that this was the minimum time needed to offset arousal. We continued collecting data for an additional 8 minutes after the withdrawal of each intervention. We used an 8-minute follow-up to test whether length of follow-up influenced outcomes compared with previous studies that used shorter follow-up.

During the NNS intervention the researcher gave each neonate a standard, small, short, hollow soft latex nipple (Enfamil, Philadelphia, PA) applying gentle pressure to maintain it in the neonate's mouth. During the MT intervention the researcher played intrauterine maternal pulse sounds with soothing music through a cassette recorder placed near the neonate's head using the same volume each time. In the combined MT + NNS intervention, the neonates had the intrauterine sounds and the latex nipple. During the no intervention condition, neonates were put in the supine position.

The researchers standardized all interventions for each neonate. The researcher did each heel-stick. Neonates were attached to the cardiac and microgas monitors throughout the entire test. $TcPao_2$ and heart rate were recorded from monitors next to the neonate's incubator. The nurses trained and used in the pilot study collected the pain behavior data using the NIPS.

The researchers imposed control to maintain constancy in the research environment to minimize possible effects on the emotions and behavior of the neonates. We kept temperature and noise levels consistent. All monitor alarms were silent and the ward door was closed to minimize outside noise. Each neonate was undressed for easy observation and nursed in an incubator with the temperature set at 34°C. The same nurse performed each heel-stick and a different nurse recorded the readings from the monitors.

RESULTS

Repeated-measures multivariate analysis of variance revealed statistically significant differences in outcomes across all interventions (Wilk's λ = .142; F [3,27] = 31.82; $\eta 2$ = .47; P < .0001). One-way analysis of variance revealed that the 3 comfort interventions significantly reduced the heart rate of neonates (Wilk's λ = .647; F [2,27] = 18.93; $\eta 2$ = .35; P < .0001), improved their $TcPao_2$ levels (Wilk's λ = .481; F [2,27] = 37.42; $\eta 2$ = .51; P < .0001), and reduced

TABLE 1. Sample Characteristics

	Mean (Standard Deviation)	Minimum	Maximum	Frequency	Percentage
Characteristic					
Gestation age (wk)	37 (3.43)	30	41		
Birth weight (kg)	2.74 (.62)	1.67	3.88		
Apgar score (1-min)	8.48 (1.05)	6	10		
Apgar score (5-min)	9.44 (.89)	6	10		
Male				17	63
Female				10	57
Diagnosis					
Respiratory distress				12	44
Pneumonia				10	37
Neonatal jaundice				2	7
Meconium aspirated				2	7
Abdominal distention				1	3

their pain behavior (Wilk's $\lambda = .312$; $F\ [2,27] = 76.42$; $\eta 2 = .68$; $P < .0001$). Figures 1–3 show the effect of each intervention on each outcome measure at each interval of data collection.

Heart Rate

There were no statistically significant differences in the heart rate of neonates at the baseline period of each intervention ($F\ [3,27] = .58$; $P > .62$). Posthoc scheffe tests showed that the heart rate of neonates was lowest during the MT intervention at 2 minutes (159 ± 6.88; 95% CI: 157–162; $F\ [3,27] = 15.67$; $\eta 2 = .31$; $P < .001$), 3 minutes (161 ± 6.12; 95% CI: 159–163; $F\ [3,27] = 31.95$; $\eta 2 = .47$; $P < .001$), 4 minutes (152 ± 6.87; 95% CI: 149–155; $F\ [3,27] = 78.80$; $\eta 2 = .69$; $P < .001$) and 6 minutes (137 ± 10.10; 95% CI: 133–141; $F\ [3,27] = 71.89$; $\eta 2 = .67$; $P < .001$). At 5 minutes, the neonates' heart rate was the same during the MT (143 ± 8.72; 95% CI: 140–146; $F\ [3,27] = 78.55$; $P < .001$) and the combined MT and NNS (143 ± 8.46; 95% CI: 140–146; $F\ [3,27] = 78.55$; $P < .001$) interventions.

Posthoc scheffe tests showed the heart rate of the neonates was lowest during each minute of the period after the heel-stick in the MT intervention. These data are as follows:

Minute	Mean (Standard Deviation) Heart Rate	95% CI	F(3,27) Ratio	$\eta 2$	P
7	133 ± 9.63	129–137	45.09	.56	.001
8	130 ± 10.25	126–134	23.17	.40	.001
9	128 ± 10.16	124–132	18.69	.35	.001
10	126 ± 10.11	122–130	17.15	.33	.001
11	125 ± 10.59	121–129	10.49	.23	.001
12	124 ± 10.83	120–128	8.66	.20	.001
13	123 ± 11.40	119–127	6.53	.15	.001
14	122 ± 11.56	118–126	4.58	.11	.004

$TcPaO_2$ Levels

There were no statistically significant differences in the $TcPao_2$ levels of neonates at the baseline period of each intervention ($F\ [3,27] = 2.17$; $P > .09$). Posthoc scheffe tests showed the $TcPao_2$ levels of the neonates were highest during the MT intervention at 4 minutes (66 ± 7.93; 95% CI: 65–69; $F\ [3,27] = 17.82$; $\eta 2 = .33$; $P < .001$), and 5 minutes (65 ± 7.88; 95% CI: 62–68; $F\ [3,27] = 26.33$; $\eta 2 = .43$; $P < .001$). At 2, 3, and 6 minutes, the $TcPao_2$ levels of the neonates were the same during the MT and the combined MT and NNS. In the follow-up period after the heel-stick and the removal of the intervention, the $TcPao_2$ levels of the neonates were highest when they had the combined MT and NNS. These data are as follows:

Minute	Mean (Standard Deviation) $TcPao_2$ Levels	95% CI	F(3,27) Ratio	$\eta 2$	P
7	71 ± 6.17	69–73	80.09	.69	.001
8	74 ± 5.88	72–76	101.08	.74	.001
9	75 ± 5.59	73–77	94.56	.73	.001
10	78 ± 5.58	76–80	79.53	.69	.001
11	78 ± 5.77	76–80	56.88	.62	.001
12	81 ± 5.86	79–83	34.64	.49	.001
13	82 ± 6.19	80–84	22.25	.39	.001
14	83 ± 6.20	81–85	13.22	.27	.001

Pain Behavior

Posthoc scheffe tests showed that the pain behavior of the neonates was lowest during the combined MT and NNS intervention at 4 minutes (.7 ± 1.18; 95% CI: .3–1.1; $F\ [3,27] = 135.60$; $\eta 2 = .79$; $P < .001$), 5 minutes (0 ± 0; 95% CI: 0; $F\ [3,27] = 134.84$; $\eta 2 = .97$; $P < .001$), and 6 minutes (0 ± 0; 95% CI: 0; $F\ [3,27] = 82.75$; $\eta 2 = .95$; $P < .001$). At 3 minutes, the NIPS scores of the neonates were the same during the MT (4 ± 1.18; 95% CI: 3.6–4.4; $F\ [3,27] = 48.95$; $P < .001$) and the combined MT and NNS interventions (4 ± 1.22; 95% CI: 3.6–4.4; $F\ [3,27] = 48.95$; $P < .001$). In the follow-up period after the heel-stick, the pain behavior of the neonates was lowest after they had the MT intervention at 7 minutes (0 ± 0; 95% CI: 0; $F\ [3,27] = 117.57$; $\eta 2 = .77$; $P < .001$), 8 minutes (0 ± 0; 95% CI: 0; $F\ [3,27] = 24.328$; $\eta 2 = .41$; $P < .001$), and 9 minutes (0 ± 0; 95% CI: 0; $F\ [3,27] = 32.55$; $\eta 2 = .48$; $P < .001$). The pain behavior of the neonates was highest when they had no intervention at 10 minutes (1 ± 1.50; 95% CI: .5–1.5; $F\ [3,27] = 17.85$; $\eta 2 = .34$; $P < .001$), and 11 minutes (.4 ± 1.12; 95% CI: 0-.8; $F\ [3,27] = 4.24$; $\eta 2 = .10$; $P < .007$). There were no statistically significant differences in the NIPS scores of the neonates during the follow-up period from 12 to 14 minutes for each intervention.

DISCUSSION

In this study, we improved on existing literature by measuring the magnitude as well as the direction

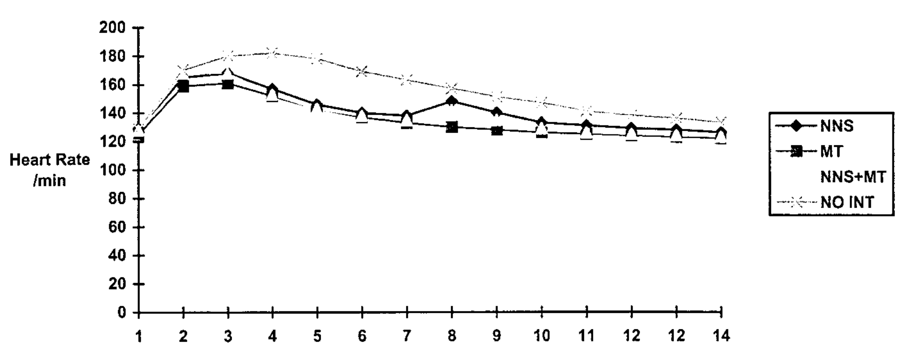

Fig 1. The effect of each intervention on heart rate.

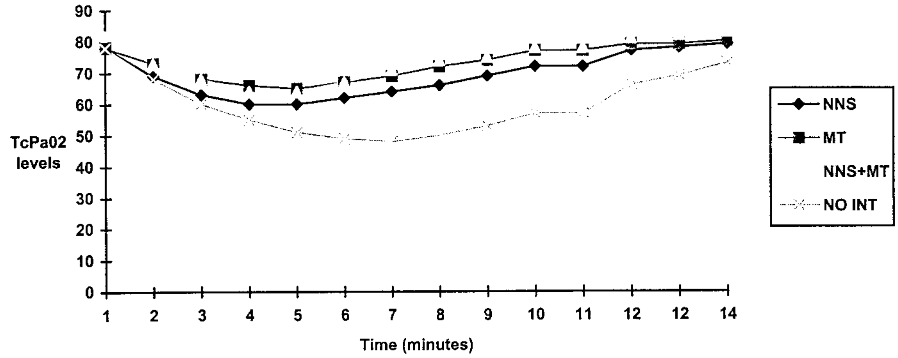

Fig 2. The effect of each intervention on $TcPaO_2$ levels.

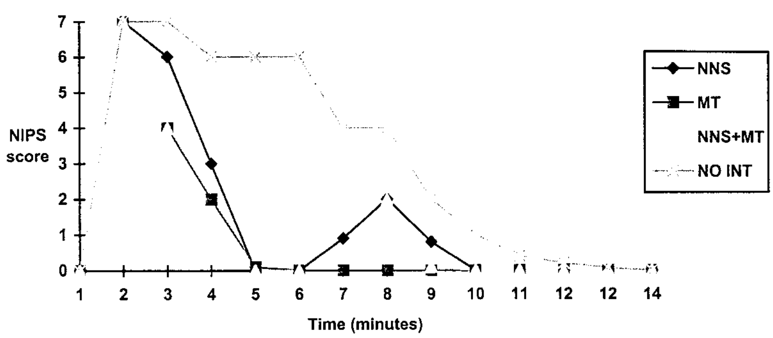

Fig 3. The effect of each intervention on NIPS score.

of the effect of 3 comfort interventions on the clinical outcomes of neonates.

MT had a better effect than the other interventions on heart rate and this effect was sustained even when the intervention was withdrawn. The effect sizes in heart rate differences during the MT intervention are large compared with the estimate by Cohen.[14] The large effect sizes and the narrow CIs are evidence of the strength of the effect. Our results show that MT will improve the physiologic outcomes of neonates after a heel-stick, and these effects are likely to be sustained for up to 8 minutes after the removal of the intervention. Combined MT + NNS may better soothe the pain behavior of the neonates but the effect may not be sustained once the intervention is removed. Our hypothesis that the $TcPaO_2$ levels, heart rate, and pain behavior of the neonates would differ significantly after the use of comfort interventions versus no intervention is supported.

The $TcPaO_2$ levels, heart rate, and pain behavior of the neonates changed significantly at the most invasive phase; maximum heart rate and pain score increased from baseline to 2 to 3 minutes after heel-stick. The biggest change in $TcPaO_2$ levels occurred at 4 to 6 minutes after the heel-stick. This delay could be attributable to the time delay required for the $TcPaO_2$ electrode to record the change. However, these findings are consistent with the responses of neonates described in other studies.[11,12]

Several investigators credited soothing music with decreasing distress and anxiety in hospitalized neonates. In 1 study,[6] intubated premature neonates who heard intrauterine sounds had a significant increase in oxygen saturation and a decrease in agitated behaviors compared with baseline observations without auditory input. Other researchers[7] also observed that intrauterine sounds were effective in reducing agitation and physiologic instability after a stressful intervention (suctioning). Our findings are consistent with these observations and support the use of intrauterine sounds to soothe neonates during stressful procedures. It has been reported that intrauterine sounds elicited soothing responses from fussy neonates but had minimal influence on infants who were awake and calm. We found that both fussy and calm neonates responded to these familiar sounds.

We were interested to study the effect of removal of the interventions. Consistent with previous findings,[4,13] removal of a pacifier was followed by increased arousal reflected in crying and increased heart rate. One researcher[4] reported that 3 minutes of sucking on a pacifier was insufficient to produce a sleep state before the pain-induced arousal was completely offset. Hence, removal of the pacifier might result in resumption of heightened arousal. When the intervention time is lengthened to 5 minutes as in our study, neonates remained alert and frustrated after removal of the pacifier. This suggests that the intervention should continue until the neonate falls asleep. This pattern of upset during the post intervention phase was also evident during the combined NNS and MT intervention. In contrast, this rebound in arousal did not occur after the termination of MT as the neonates' arousal state remained stable.

Nonpharmacological interventions proved surprisingly powerful in this study; they greatly reduced the pain of the neonates possibly by distracting them from the pain sensation and focusing their attention elsewhere. These findings suggest that these interventions are best when helping neonates deal with pain of a relatively short duration, such as that invoked by the heel-stick procedure. Among the 3 comfort interventions, MT had the strongest and most consistent comforting effects. NNS also proved to be an effective intervention for reducing pain stress, although less so than the combined NNS and MT. The results of this study illustrated the important role of psychological interventions in reducing pain-elicited distress. These interventions increased the amount of time neonates had normal heart rate and optimal oxygenated state and decreased the amount of time the neonates spent in a highly agitated state. This results in less energy expenditure and fewer stress-responses. This may also allow neonates to conserve energy for growth and healing.

Several strategies are available for dealing with neonates' discomfort when they are subjected to painful procedures such as heel-sticks. This study has shown that psychological interventions are effective in comforting neonates when they face painful procedures like heel-sticks. These interventions are simple, feasible, and accessible and can be easily given by those caring for neonates in hospital, such as pediatric nurses, doctors, or parents. Using these interventions may also be cost-effective because they involve minimal effort and time and may reduce or obviate the need for analgesics.

In this study, we compared the physiologic and behavioral responses of neonates to an acute, painful stimulus and investigated the soothing effects of 3 comfort interventions on these responses. No attempt was made to address how these interventions would work in neonates who required ventilator support in neonates of different postnatal ages or in neonates who were experiencing different painful events. Future studies need to address these issues and, in particular, these studies need to pay attention to the pattern of responses in neonates of multiple births, those on high levels of ventilation, those who had received analgesics or sedatives, and those with congenital abnormalities. Studies that address these issues will further clarify the effectiveness of psychological interventions in managing the responses of neonates to painful procedures.

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