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Research Article

Role of Music in Alleviating Procedural Pain in Neonates

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Abstract

Aim: To observe the effects of music therapy on pain relief in neonates and compare the effects of instrumental music and vocal music during IV cannulation in the NICU

Materials and Methods: This prospective interventional study enrolled 66 term neonates requiring IV cannulation. Neonates were randomly distributed into music intervention groups A and B (23 in each), where vocal music and instrumental (sitar) music were used, respectively, and control group C (20 neonates), where no music intervention was used. The Neonatal Infant Pain Scale was used for baseline and postprocedure pain scoring. The mean postprocedure scores and rise in pain scores were compared between the groups.

Results: The mean initial pain scores of the 3 groups were 1.2, 1.3, and 0.9, respectively, and the mean postprocedure pain scores were 4.5, 4.4, and 5.8, respectively. The mean postprocedure pain scores in both the music intervention groups were lower than that in the control group ($P < .05$). The mean rise in pain score in both the music intervention groups was significantly less than that in the control group. The mean postprocedure pain score in the vocal music group was higher than that in the instrumental music group, though the statistical significance could not be proven.

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Conclusion: Music is a very effective modality for pain management in neonates. Instrumental music appears to have more benefits over vocal music.

Key Words: Music therapy, procedural pain, intravenous cannulation, neonates, pain relief, nonpharmacologic pain reliever, instrumental music, vocal music

Introduction

Earlier, it was thought that neonates do not feel pain. Now, we have considerable evidence showing that neonates do feel pain, and it is measurable using different pain scales. Although neonates are nonverbal, they do show behavioral, physiological, metabolic, and hormonal responses to pain. Most scales use behavioral and physiological responses to analyze pain.[1] Even preterm neonates feel pain; in fact, it has been reported that they demonstrate an exaggerated response to pain.[2,3]

Painful stimuli, especially repeated exposure, is observed to cause short- and long-term hypersensitivity to pain due to the developing neurons and pain pathways.[4] The anxiety and stress caused by repeated exposure to painful stimuli can increase with each exposure. This can have long-term effects on the emotions and psychology of both the child and the family. The neurodevelopment in neonates is also affected due to exposure to painful stimuli as the nervous system is in the developing phase, especially in preterm neonates.[2,5]

A neonate in the NICU undergoes many painful procedures, and an Australian survey revealed that 25% of NICUs do not have a pain management program.[6] A similar scenario was found in other developed countries too. In 2005, the American Academy of Pediatrics and the Canadian Academy of Pediatrics made a policy for NICUs, which included minimizing painful procedures, assessing the pain, and preventing pain during invasive procedures.[7]

The pain management methods tried in neonates are pharmacologic and nonpharmacologic. Pharmacologic methods are used during surgical procedures but may not be safe in neonates for day-to-day use in the NICUs. Nonpharmacologic methods such as giving breast milk, nonnutritive sucking, administering sucrose, kangaroo mother care, and swaddling are found to be useful.

Over generations, in all the cultures and communities, mothers are known to sing lullabies to calm their babies. Of late, many studies have shown that music is beneficial in calming babies.[8,9] It is thought that the analgesic effects of music stems from its indirect effect on attention, where distraction averts concentration, enabling slower processing of painful stimuli.[9] All varieties of sounds used have been found to be useful. Chou et al[10] used a soundtrack—a combination of actual womb sounds and simulations of the sounds that an unborn child might hear as the mother sings. They played it during endotracheal suctioning and found it to be useful. Early auditory preferences have been observed in neonates, and it was found that they respond better to the maternal voice or a rhythm that was familiar to them in intrauterine life.[11] This gave us an idea that neonates may preferentially respond to vocal or instrumental music. To the best of our knowledge, hitherto there is no study that has compared the effects of vocal and instrumental music, separately, on procedural pain.

Aim

To observe the effects of music on pain relief in neonates and compare the effects of instrumental music and vocal music during IV cannulation in the NICU

Materials and Methods

Study design

This prospective, interventional study was conducted in the NICU of a tertiary care hospital (Acharya Vinoba

Bhave Rural Hospital, Wardha, Maharashtra, India) over 6 months (June to December 2018). Ethical clearance was sought for the study, and written informed consent was obtained from the parents. Totally, 66 neonates were enrolled into the study.

Inclusion criterion

Term neonates (N = 66) requiring IV cannulation were enrolled.

Exclusion criteria

Neonates who were syndromic, were on the ventilator, or had multiple anomalies or abnormal sensorium were excluded. Neonates with bilirubin in the high-risk zone were also excluded, as they would have hearing problems. It was also decided to exclude neonates who became irritable or started crying when music was played; however, there were no such neonates.

Study procedure

All neonates fulfilling the selection criteria were randomized into the following 3 groups:

Group A: Vocal music was used during the IV cannulation procedure (n = 23)

Group B: Instrumental music was used during the IV cannulation procedure (n = 23)

Group C: The IV cannulation procedure was done without music intervention (control group; n = 20)

The Neonatal Infant Pain Scale (NIPS), a behavioral scale that can be applied in both full-term and preterm neonates,[12] was used to score the pain response. This tool uses the behaviors that nurses have described as being indicative of neonatal pain or distress. It assesses 6 indicators, namely, facial expression, cry, breathing pattern, arms, legs, and state of arousal. Each behavioral indicator is scored 0 or 1 except "cry", which has 3 possible descriptors, and it is therefore scored as 0, 1, or 2. The neonates were observed for a minimum of 1 minute for fully assessing each indicator. The total pain scores range from 0 to 7. The higher the score, the greater is the pain and more evident is the neonate's response.

Three trained staff (2 nurses and 1 resident doctor) were present at the time of the IV cannulation procedure: 2 for scoring and 1 for doing the procedure. Once the neonate and the staff were ready for the procedure, the baseline information required for scoring was collected by both the scorers simultaneously.

For the control group (C), scoring was done before and after completing the procedure. For the experimental groups (A and B), after baseline scoring was done, music was played 3 minutes before the procedure. The second scoring was done as soon as the procedure was completed, and music continued to be played for a minimum of 3 minutes after the procedure. Each time, both the scorers simultaneously noted the scoring, and the mean was used as the final score.

The vocal music used was a recorded lullaby in the Marathi language. The instrumental music was a recorded sitar tune. The recorder was kept 1 meter away from the neonate, and using a sound meter, the volume was kept below 55 decibels.

Details of all the neonates including their clinical status was noted in a pretested, prevalidated proforma document. Scoring was done separately in a sheet, and the final score calculated was entered in the proforma document. The score sheet was attached to the proforma document after completion of all entries.

Outcome measures

The postprocedure pain score on the NIPS and the difference between the preprocedure pain scores and postprocedure pain scores were used as outcome measures.

Statistical analysis

The mean, standard deviations, and range of scores were calculated for each group. The mean pain scores of the music intervention groups (A and B) and the control group (C) were compared using the Student's t test. $P < .05$ was considered significant. SPSS version 20.0 (IBM Corp, Armonk, NY, USA) was used for statistical calculations.

Result

Sixty-six term neonates were enrolled. The music intervention groups (A and B) had 23 neonates each, and the control group (C) had 20 neonates. The mean age of the neonates was 3.9 days (range, 1–7 d), and the mean weight was 2.6 kg (range, 1.8–3.8 kg); 40 neonates (60.6%) were male, and 26 (39.4%) were female (male:female ratio, 1.53:1). The mean gestational age was 38.6 weeks (range, 37–40 wk). Lower segment cesarean section was the mode of delivery in 38 neonates (57.5%) and normal vaginal delivery in 28 (42.5%) neonates. The hands were the most common site for IV cannulation (52 [78.8%]; right hand in 47 neonates and left hand in 5 neonates) and the feet were the next most common site (11 [16.6%]). The cubital veins were the rarest site of cannulation (3 [4.6%]). All the 3 groups were comparable in all these aspects (Table 1).

Table 1. Characteristics of the Study Neonates

Characteristic	Group A (Vocal Music; *n* = 23)	Group B (Instrumental Music; *n* = 23)	Group C (Control; *n* = 20)	Total (*N* = 66)
Mean Age at Enrollment, d (Range)	3.8 (2–7)	3.6 (2–6)	4.0 (2–7)	3.9 (1–7)
Sex, Male:Female	1.5:1	1.6:1	1.5:1	1.5:1
Gestational Age, wk (Range)	38.6 (37–41.3)	38.5 (37–41.1)	38.3 (37.3–40.6)	38.6 (37–40)
Weight, kg (Range)	2.6 (2.1–3.2)	2.7 (2.2–3.4)	2.6 (2.1–3.4)	2.6 (1.8–3.8)
Mode of Delivery				
LSCS, %	40	36	30	57.5
NVD, %	60	64	70	42.5
Sequence of Cannulation, *n* (%)				
First	13 (56.6)	12 (52.2)	11 (55)	36 (54.5)
Second	9 (39.1)	9 (39.2)	9 (45)	27 (40.9)
Third	1 (4.3)	2 (8.6)	0 (0)	3 (4.6)

LSCS, lower segment cesarean section; NVD, normal vaginal delivery.

The mean initial pain score (before the cannulation procedure) for all the neonates was 1.1 (range, 0–3), and the mean postprocedure pain score was 4.8 (range, 3–7). The initial pain score in each group and the pain scores after the cannulation procedure are given in Table 2. The control group had the minimum initial pain score (0.9) and the maximum postprocedure pain score (5.8). The postprocedure pain scores in the instrumental and vocal music groups were significantly lower than that in the control group (no music). Although the mean postprocedure pain score in the vocal music group was higher than that in the instrumental music group, no statistical significance could be shown.

Table 2. The Mean Pain Scores Before and After the Cannulation Procedure in the 3 Groups

Intervention	Mean Pain Score, (SD; range)	
	Before	After
Vocal Music (Group A)	1.2 (± 0.8; 0–3)	4.5 (± 2.1; 2–7)
Instrumental Music (Group B)	1.3 (± 0.8; 0–3)	4.4 (± 2.2; 3–6)
No Music/Control (Group C)	0.9 (± 0.6; 0–2)	5.8 (± 1.8; 2–7)
All Groups	1.1 (± 0.8; 0–3)	4.8 (± 1.9; 3–7)

Vocal vs no music: *P* = .036, CI: 0.0857–2.5143; instrumental vs no music: *P* = .0291, CI: 0.1500–2.6500; vocal vs instrumental music: *P* = .8754, CI: - 1.3781–1.1781.

The mean difference between the preprocedure and postprocedure pain scores (postprocedure rise of score) in each group was compared (Table 3). The highest rise in pain scores were in the control group followed by the vocal music and the instrumental music groups. The mean rise in pain scores in both the music intervention groups were significantly lesser than that in the no music (control; C) group. There was no significant difference between the vocal music (A) and the instrumental music (B) groups, although the score rise was higher in the vocal music group (A). This emphasizes the usefulness of music in both forms during procedures.

Table 3. The Mean Rise in Pain Score After the Procedure

Intervention	Rise in Mean Score	SD
Vocal Music (Group A)	4.1	1.8
Instrumental Music (Group B)	3.3	1.8
No Music/Control (Group C)	5.2	1.7

Vocal vs no music: *P* = .0467; instrumental vs no music: *P* = .0010; instrumental vs vocal music: *P* = .1389.

In a majority of neonates, the cannulation procedure was done for the first time, but in a few, it was done for

the second or third time (repeat cannulations; Table 1). The rise in pain score after the first, second, and third cannulations was compared (Table 4). The mean pain score after the first cannulation was 3.4 (SD ± 2.2), and after the second, it was 4.0 (SD ± 1.8); there was no significant difference (P = .2679) in both the values. The mean pain score for the third cannulation was 3.1 (SD ± 1.9). The mean rise in pain score during the third cannulation procedure did not show any significant difference when compared with the first (P = .8791) and second (P = .4255) cannulations. The highest pain score was during the second cannulation procedure, and the lowest pain score was during the third cannulation procedure.

Table 4. Comparison of Sequence of Cannulation and Pain Scores

Sequence of Cannulation	Mean Pain Score	SD	*P* Value
First	3.4	2.2	.2679[a]
Second	4.0	1.8	.4259[b]
Third	3.1	1.9	.8791[c]

[a]Between cannulations 1 and 2; [b]Between cannulations 2 and 3; [c]Between cannulations 1 and 3.

None of the neonates showed irritability or restlessness and did not cry in the first 3 minutes of playing the music. This was taken as an indicator that music has no harmful effects on neonates.

Discussion

Pharmacologic therapy for pain prevention during procedures is not preferred in neonates as drug safety and pharmacokinetics are not well established. Moreover, the number of minor or major procedures neonates have to undergo in the NICU may be innumerable. Premature neonates undergo more procedures and are more vulnerable to adverse drug effects due to organ immaturity.

Thus, neonatologists use certain nonpharmacologic therapies for pain prevention, as repeated exposure to painful stimuli in these neonates has shown both short- and long-term effects including increased pain sensitivity, behavioral problems, and effect on neurodevelopment.[4] The commonly used nonpharmacologic methods are giving breast milk, kangaroo mother care, swaddling, and administering sucrose and glucose.[13-16] Oral administration of sucrose has become a standard pain relief method in many NICUs; however, Johnston et al[17] have shown that administration of sucrose more than 10 times in 24 hours is associated with poor motor activity and attention in neonates who are at 36 and 40 weeks' postmenstrual age. Music therapy is becoming popular of late, and many researchers have tried to compare its effect in common procedures along with other methods or with no music.[8,13] Many forms of music have been tried, for example, recorded vocal, live singing by the mother, womb sounds, and instrumental music, in both preterm and term neonates.[18-20] Our study was performed in term neonates using vocal music and instrumental music and compared with no music intervention.

Our study demonstrates that both kinds of music, vocal and instrumental, brought about significant pain relief compared with no music. Ramezani et al[20] compared warm compresses and flute music with no intervention during heel prick in neonates, and they found that both the nonpharmacologic methods were good, but the reduction in heart rate was better with music. Maryam et al[13] compared breast milk and music therapy with no intervention, and found that the effect of music was significantly better than that of breast milk, which was better than no intervention.[13] Pölkki and Korhonen,[21] in their systematic review, reported that live music was more beneficial than recorded music. In our study, both the music groups received only recorded music.

Haarika et al[22] conducted a trial comparing a recorded lullaby, mothers' recorded voice, and no intervention during venipuncture. They found that the recorded lullaby (music) and mothers' voice groups showed better physiological and behavioral response than the no music group; however, the recorded lullaby had a better effect than the recorded mother's voice.[22] Butt and Kisilevsky[8] used both vocal music and instrumental music by Brahms and compared them with a control group. They found music to have better effects than no music, but they could not show a difference between vocal and instrumental music, as both were together. In our study, the rise in pain score with instrumental

music was less, indicating a better response than vocal music, but a statistical difference was not found. Tramo et al[23] found that use of vocal music mixed with some instrumental music during heel prick improved physiological and behavioral pattern of neonates. They started music after the procedure, as they did not want music to become an indicator of heel prick. In our study, we started music 3 minutes before the cannulation procedure and continued it for 2 to 3 minutes after the procedure, till the neonate calmed down. Yilmaz and Yıldız[24] used classical music every day for a group of neonates and compared the effects with a control group. They found that music caused a reduction in stress behavior and peak heart rate, normalized respiratory parameters, and facilitated sleep.[24] Although the study by Yilmaz and Yıldız[24] did not observe the effects of music on procedural pain, it demonstrates the calming and soothing effects of music. Liaw JJ et al[25] showed that the combined use of nonpharmacologic methods is more useful. We wanted to observe the effects of music specifically, so did not combine other modalities. Yamada et al[26] conducted a structured review of all the systematic reviews where music was tried as the pain relief method, and they found that the magnitude of pain reduction was small, and hence the clinical benefit was uncertain. Our study shows a definite benefit of music compared with no music.

Invasiveness of the support system that the neonate is receiving in the NICU might also make a difference in the neonate's response. Moran et al[27] used music during physiotherapy in the NICU and compared it with no music therapy. There were 11 neonates on noninvasive ventilation and 15 on oxygen therapy. They measured the heart rate and respiratory rate variability and found music to be beneficial. This variability was lower in those neonates who received only oxygen as the support (less invasive support).[27] Williams et al[28] also showed that if the neonate is on mechanical ventilation, the pain response is attenuated. In our study, we excluded sick neonates.

Sudden, painful stimuli are known to increase heart rate, respiratory rate, and blood pressure and, at the same time, cause a fall in oxygen saturation, produce irritable cry, lead to facial grimacing, and limb activity.[28] Many scales are available to assess pain response in neonates, which use these vital parameters (oxygen saturation, respiratory rate, and heart rate) and behavior of neonates (cry, activity, sleep–wake state, and limb position). In our study, we used the NIPS, which is a behavioral scale and can be used at home also by mothers. Other scales that include only behavioral parameters are the Neonatal Facial Coding System (NFCS) and the Douleur Aiguë Nouveau-né (DAN) scale. The NFCS uses only facial expressions, and hence, requires very close observation of the neonate. The DAN scale uses vocal expression also apart from facial expression and limb movements, and hence, may need more training, especially to observe vocal expression.[29] We found the NIPS very simple and useful. It has been validated and adapted for regular use in Brazil.[30]

A neonate's pain response may change at subsequent times a similar procedure is done. Donia et al[31] noticed that with repeated painful experience, behavioral scores come down, but the physiological scores increase. In our study, we found that during the second cannulation procedure, the scores were higher than those of the first or third time procedures, though a statistical significance could not be shown. Maybe due to previous experience, the response was more, or as Tramo et al[23] suggested, starting the music before the procedure conditioned the neonate. We have not used physiologic parameters. Attenuation of pain response has been reported if the duration of NICU stay increased.[28] In our study, the mean pain scores of the third cannulation procedure were at minimum, maybe due to the long duration of stay or attenuation of response with repeated experience.

We did not observe any harmful effect of music, such as excessive irritability or cry. No adverse reaction during music therapy was reported. This confirms the safety and feasibility of this useful modality.

Limitations

In our study, we used only vocal music and a sitar tune. Varieties of melodies and instrumental music can be compared. We enrolled only term neonates; preterm

and sick neonates also need to be studied. A larger sample size will provide more assuring results, especially to demonstrate the effectiveness of vocal music versus instrumental music.

Conclusions

Music therapy is very useful for minor painful procedures in neonates. It is simple, easily available, and easy to implement, especially with widespread availability of mobile phones or small music recording devices. Both vocal music and instrumental music were found useful. They can be used alone or in combination, though we did not test this in our study. If used with proper sound intensity control, music is a safe, harmless, and a feasible modality. Besides, it is an effective and economical way to relieve procedural pain in neonates.

References

1. Anand KJS, et al. Summary proceedings from the neonatal pain-control group. *Pediatrics.* 2006;117(3 Pt 2):S9–S22.
2. Grunau RE, Holsti L, Peters JWB. Long-term consequences of pain in human neonates. *Semin Fetal Neonatal Med.* 2006;11(4):268–275.
3. Slater R, et al. Premature infants display increased noxious-evoked neuronal activity in the brain compared to healthy age-matched term-born infants. *Neuroimage.* 2010;52(2):583–589.
4. Hermann C, et al. Long-term alteration of pain sensitivity in school-aged children with early pain experiences. *Pain.* 2006;125(3):278–285.
5. Grunau RE, Holsti L, Peters JWB. Long-term consequences of pain in human neonates. *Semin Fetal Neonatal Med.* 2006;11(4):268–275.
6. Harrison D, Loughnan P, Johnston L. Pain assessment and procedural pain management practices in neonatal units in Australia. *J Paediatr Child Health.* 2006;42(1–2):6–9.
7. American Academy of Pediatrics Committee on Fetus and Newborn and Section on Surgery, Section on Anesthesiology and Pain Medicine, Canadian Paediatric Society, Fetus and Newborn Committee. Prevention and management of pain in the neonate: an update. *Pediatrics.* 2006;118(5):2231–2241.
8. Butt ML, Kisilevsky BS. Music modulates behavior of premature infants following heel lance. *Can J Nurs Res.* 2000;31(4):17–39.
9. Tsao JCI, et al. A review of CAM for procedural pain in infancy: Part II. Other interventions. *Evid Based Complement Alternat Med*. 2008;5:149354.
10. Chou LL, et al. Effects of music therapy on oxygen saturation in premature infants receiving endotracheal suctioning. *J Nur Res.* 2003;11(3):209–216.
11. Kinzler KD, Dupoux E, Spelke ES. The native language of social cognition. *Proc Natl Acad Sci USA*. 2007; 104(30):12577–12580.
12. Obiedat H, Al-Maaitah EI. Critique of the use of neonatal infant pain scale (NIPS). *Neonat Pediatr Med.* 2020;6(1).
13. Maryam M, et al. Comparing the effect of listening to melody vs. breast-feeding on neonates' pain intensity during heel-blood sampling in neonatal intensive care unit. *J Anesthesiol Pain*. 2015;5(3)45–54.
14. Johnston C, et al. Skin-to-skin care for procedural pain in neonates. *Cochrane Database Syst Rev.* 2017;2(2):CD008435.
15. Campos RG. Soothing pain-elicited distress in infants with swaddling and pacifiers. *Child Dev.* 1989;60(4):781–792.
16. Stevens B, et al. Sucrose for analgesia in newborn infants undergoing painful procedures. *Cochrane Database Syst Rev.* 2016;7(7):CD001069.
17. Johnston CC, et al. Routine sucrose analgesia during the first week of life in neonates younger than 31 weeks' postconceptional age. *Pediatrics.* 2002;110(3):523–528.
18. Johnston CC, Filion F, Nuyt AM. Recorded maternal voice for preterm neonates undergoing heel lance. *Adv Neonatal Care.* 2007;7(5):258–266.
19. Bo LK, Callaghan P. Soothing pain-elicited distress in Chinese neonates. *Pediatrics.* 2000;105(4):E49.
20. Ramezani Z, et al. Comparison of the effectiveness of warm compress and music on the pain caused by heel blood sampling in neonates: a single-blind, prospective, randomized controlled trial. *Crescent J Med Biol Sci.* 2020;7(1):138–139.
21. Pölkki T, Korhonen A. The effectiveness of music on pain among preterm infants in the neonatal intensive care unit: a systematic review. *JBI Libr Syst Rev.* 2012;10(58):4600–4609.
22. Haarika V, et al. The effectiveness of music and mother's voice on pain reduction during venepuncture in neonates—a randomized control trial. *Int J Adv Res.* 2017;5(2):2575–2579.
23. Tramo MJ, et al. Effects of music on physiological and behavioral indices of acute pain and stress in premature infants: clinical trial and literature review. *Music Med.* 2011;3(2):72–83.
24. Yilmaz D, Yıldız S. Effect of classical music on stress among preterm infants in a neonatal intensive care unit. *Healthmed.* 2012;6(9):3162–3168.
25. Liaw JJ, et al. Effects of combined use of non-nutritive sucking, oral sucrose, and facilitated tucking on infant behavioural states across heel-stick procedures: a prospective, randomized controlled trial. *Int J Nurs Stud.* 2013;50(7):883–894.

26. Yamada J, et al. A review of systematic reviews on pain interventions in hospitalized infants. *Pain Res Manag.* 2008;13(5):413–420.
27. Moran CA, et al. Use of music during physical therapy intervention in a neonatal intensive care unit: a randomized controlled trial. *J Hum Growth Dev.* 2015;25(2).
28. Williams AL, et al. The behavioral pain response to heel stick in preterm neonates studied longitudinally: description, development, determinants, and components. *Early Hum Dev.* 2009;85(6):369–374.
29. Witt N, et al. A guide to pain assessment and management in the neonate. *Curr Emerg Hosp Med Rep.* 2016;4:1–10.
30. Motta Gde C P da, Schardosim JM, Cunha MLC da C. Neonatal infant pain scale: cross-cultural adaptation and validation in Brazil. *J Pain Symptom Manage.* 2015;50(3):394–401.
31. Donia AES, Tolba OA. Effect of early procedural pain experience on subsequent pain responses among premature infants. *Egypt Paediatr Assoc Gaz.* 2016;64(2):74–80.

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