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Original Article

Pain in full term newborns submitted to music and swaddling during venipunctures

Dor em recém-nascidos a termo submetidos à intervenção música e enrolamento durante punção venosa

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ABSTRACT

Objective: to compare pain scores in term newborns submitted to music and swaddling interventions during venipuncture. **Methods:** pilot study of a clinical trial, carried out with 11 newborns in rooming-in care who received venipunctures. The newborns were randomly allocated into two groups: Experimental (20 minutes of music + swaddling) and Control (swaddling). Newborns were filmed and pain was assessed by the Neonatal Facial Coding System at baseline, procedure, and initial recovery phases. **Results**: the Experimental Group at baseline, procedure (antisepsis, puncture, and milking), and recovery showed less pain reactions and lower heart rate mean and variation ($p<0.05$) than the Control Group. **Conclusion**: newborns who received the intervention of music combined with swaddling had less pain reactions and less variations in heart rate during venipuncture. Brazilian Clinical Trial Registry: RBR-8x8v2r.

Descriptors: Infant, Newborn; Rooming-in Care; Pain; Music.

RESUMO

Objetivo: comparar a dor em recém-nascidos a termo submetidos à intervenção música e enrolamento durante punção venosa. **Métodos**: estudo piloto de ensaio clínico, realizado em alojamento conjunto com 11 recém-nascidos que receberam punção venosa. Alocados aleatoriamente em dois grupos: (Grupo Experimental (20 minutos música + enrolamento) e Grupo Controle (enrolamento). Recém-nascidos foram filmados e a dor avaliada pela *Neonatal Facial Coding System,* nos momentos basal, procedimento e recuperação inicial. **Resultados**: o Grupo Experimental nos momentos basal, procedimento (antissepsia, punção e ordenha) e recuperação apresentou menos reações de dor; menor média e variação da frequência cardíaca ($p<0,05$) que o Grupo Controle. **Conclusão**: recém-nascidos que receberam a intervenção música combinada ao enrolamento, apresentaram menos reações de dor e menores variações na frequência cardíaca durante a punção venosa. Registro Brasileiro de Ensaio Clínico: RBR-8x8v2r.

Descritores: Recém-Nascido; Alojamento Conjunto; Dor; Música.

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Introduction

Newborns experience several painful procedures, even in their first 24 hours of life. The procedures are part of the neonatal care routine and include several injections and blood collection[1]. The newborn's constant exposure to these procedures can, in the long term, compromise neurological and behavioral development. Evidence shows that pain control has benefits in the physiological, behavioral, and hormonal responses of the newborn. There are validated scoring systems for pain assessment, but there is not a standardized and universal approach[2].

In newborns, pain can be identified through the assessment of physiological and behavioral responses, observed during the painful procedure. Many scales evaluate such parameters, and, thus, for this study, the evaluation of facial expressions used the Neonatal Facial Coding System (NFCS) scale[3]. This scale can be combined with physiological parameters, such as heart and respiratory rates, saturation of oxygen and systolic blood pressure. The association of parameters contributes to the perception of pain by the nursing professional, and can assist their conduct in minimizing and preventing complications during painful procedures[4].

In order to minimize exposure to multiple medications and adverse effects on the newborn's immature organic systems[5], the nurse may use non-pharmacological measures, such as swaddling, comforting, touching, kangaroo position, cozy blanket embraces, warmth, holding[6], and music[7].

Music, when seen as a non-pharmacological measure, can have great therapeutic value and assist in holistic care, since it interferes with cells and organs, in addition to emotions and organic systems, causing a feeling of relaxation, reducing anxiety, changing the mood, reducing the perception of pain, and promoting comfort[8].

Thus, the following research question was made: what are the facial pain reactions of full term newborns submitted to venipuncture, after being exposed to music in combination with the swaddling?

It stands out that music is mentioned as having a potential calming effect, which may help to reduce the perception of pain in term newborns[9]. However, there is still a gap in national literature regarding the effect and use of music with other non-pharmacological methods in healthy newborns who are in rooming-in care and undergo painful procedures, such as venipunctures. Neonatal pain is a reality in neonatal units, an in low, medium, or high-risk patients. It should be considered part of the provision of care by the entire multidisciplinary team, especially by nurses, since they are the workers responsible for carrying out many of these painful procedures.

The aim of the study was to compare pain in term newborns submitted to music and swaddling during venipuncture.

Methods

Pilot study of a randomized clinical trial carried out in babies in rooming-in care in a philanthropic hospital in Ceará-Brazil, from January to June 2017.

The sample consisted of eleven newborns, randomly allocated in two groups, chosen randomly using sealed and numbered envelopes. The groups were: the Experimental Group, with six participants, which received 20 minutes of music combined with the swaddling; and the Control Group, with five patients, which received only the swaddling intervention.

Full term newborns with gestational age of ≥37 full weeks; Apgar ≥7 in the 5th minute of life; submitted to venipuncture to collect material for exams; and normal hearing neonatal screening were included. Those with a history of surgery, whose mothers were using medication that interfered with painful nociception responses, and children who were breastfeeding were excluded.

All newborns used headphones, but only those in the Experimental Group heard two instrumental lullabies, from the Musi Baby collection: Bonne Nuit (Sais-Tu Combien D'étoiles Brillent? And Le Marchand

de Sable), lasting for 2:42 and 3:15 minutes, respectively, and played successively on an MP3 player, with a volume of 40 decibels. The song was played for 20 minutes, after the baseline moment and before antisepsis for venipuncture, continuing until the moment of initial recovery. To avoid contamination among neonates, at each procedure, the headset was previously cleaned with 70% alcohol, wrapped in polyvinyl chloride film. The swaddling intervention, in the Experimental and Control Groups, started two minutes before the baseline, according to the institutional protocol of the unit. This intervention is performed with a sheet and involves the newborn's body[10].

For this article, pain assessment in newborns was considered at the following moments: baseline (when term newborns are kept at rest on a surface before venipuncture), procedure (they are submitted to antisepsis, puncture, aspirating blood, and compression); initial recovery (when the newborn rests after finishing the compression). In the original study, pain assessment was carried out according to the recommendation of the updated NFCS manual, in which the evaluation of the expressions of brow bulge, eye squeeze, naso-labial furrow, horizontal mouth, and taut tongue were sufficient for accurate identification of pain[11].

Three collection instruments were used: the first contained neonatal and therapeutic variables, extracted from the neonates' medical records: gender, type of delivery, gestational age at birth, birth weight, head circumference, Apgar at 5 minutes, hour of life. The second was the NFCS pain scale[11], showed through facial manifestations (brow bulge, eye squeeze, naso-labial furrow, horizontal mouth, and taut tongue). The signs are recorded as "present" (score 1) or "absent" (score 0), continuously, from second to second, as follows: in the interval of the first 20 seconds of the baseline moments and the initial recovery; during the procedure, second by second, while the antisepsis, puncture, aspiration, and compression procedures lasted.

The third instrument evaluated the physiological heart rate response. Values of 110-160 beats per minute were considered as the normal range of heart rate for the full term newborns. This variable was continuously recorded, second by second, through a cardiac monitor (Polar RS 200 model), adapted and connected to wire cables to two electrodes, both placed on the newborn's chest, similar to the NFCS, throughout all the stages of the procedure. For the baseline, the evaluation took place every 20 seconds, for 2 minutes.

The parents of the eligible newborns were informed about the research and signed the Free and Informed Consent Form. Newborn hearing screening was performed by the institution's speech therapist. With a positive sign of the auditory reflex, the newborns were directed to a room reserved for laboratory collection, using a cardiac monitor (Polar) and contained through the use of the non-pharmacological swaddling intervention. The nursing technician who cared for the newborn opened one of the envelopes and randomly selected the type of intervention that would be administered**.** This professional had received guidance about the research objectives and that they would not be filmed. Data collection took place in the morning and afternoon shifts, during all days of the week. The venipuncture was carried out on the dorsum of the hand or on the anterior part of the newborn's arm, by two laboratory technicians with more than two years of experience.

Two digital cameras were used, supported by tripods. One was directed to the face of the newborn; the second to the cardiac monitor. To mark the moments of the filming, a manual timer and verbal commands from one of the authors to the technician were used to start blood collections. Videos with facial reactions were evaluated by two trained nurses in a blinded analysis. Footage was viewed on an individual computer, after Kappa reached at least 80%[11].

The data were inserted in a Microsoft Excel for Windows 2007 spreadsheet, analyzed using the Statistical Package for the Social Sciences software (version 20), license No. 10101131007. Pearson's chi-

-square test and odds ratio were applied for the association of the facial mimics of the groups, considering a 95% confidence interval (p<0.05). For the heart rate, the mean and standard deviation between the intervals were calculated.

National and international research standards involving human beings were respected. The study was approved by the institution's Ethics and Research Committee, according to opinion No. 1,858,929/2016 and Certificate of Presentation for Ethical Appreciation No. 62424916.2.0000.5054.

Results

From the 11 newborns evaluated, six (54.5%) were female, seven (63.6%) were delivered by c-section, seven (63.6%) had 39-40 weeks gestational age, eight (72.7%) had a birth weight of 3000-3750g, and nine (81.8%) had a head circumference of 33-34.9 cm. All had Apgar scores from 7 to 10 in the fifth minute of life, and the venipuncture was performed between the 12th and 18th hours of life in 10 (90.9%) of them.

The results for the baseline and initial recovery stages are described in the text and the data on the procedure and heart rate are shown in Tables 1, 2, and 3. At baseline, newborns in the Control Group (swaddling) had more facial pain reactions than those in the Experimental Group (music for 20 minutes + swaddling). A p<0.05 was present in all facial reactions (brow bulge, eye squeeze, deep naso-labial furrow, horizontal mouth, and taut tongue) from the NFCS when the two groups were correlated. In the Control Group, regarding the percentage of facial expressions of the newborns for 20 seconds (n=600), the brow bulge were in 9.0% of the expressions, eye squeeze (6.0%), naso-labial furrow in 5.0%, and the horizontal mouth in 7.0%. In the Experimental Group (n=720), brow bulge and eye squeeze (0.8%) were identified.

During the procedure, according to Tables 1 and 2, newborns in the Control Group also had more facial pain reactions than those in the Experimental Group, particularly in the aspiration stage.

For the procedure (antisepsis and puncture), all p-values were statistically significant for all facial reactions studied (p<0.05), and the odds ratio for the absence of pain reactions (brow bulge and deep naso-labial furrow) was 17.1 times higher, at the time of antisepsis, for the Experimental Group.

Table 1 – Facial reactions observed at the time of the procedure (antisepsis and puncture), in the Experimental and Control Groups, using the NFCS scale. Fortaleza, CE, Brazil, 2017

Facial reactions	Experimental group n(%)	Control Group n(%)	*OD	†CI 95%	‡p-value
Antisepsis					
Brow Bulge					
Present	8 (6.5)	26(54.2)	17.1	6.8-42.7	0.000
Not present	116 (93.5)	22(45.8)			
Eye Squeeze					
Present	9(7.3)	26(54.2)	15.1	6.2-36.5	0.000
Not present	115(92.7)	22(45.8)			
Naso-labial Furrow					
Present	8(6.5)	26(54.2)	17.1	6.8-42.7	0.000
Not present	116(93.5)	22(45.8)			
Horizontal Mouth					
Present	0(0)	26(54.2)	6.6	4.5 – 9.7	0.000
Not present	124(100.0)	22(45.8)			
Taut Tongue					
Present	0(0)	26(54.2)	6.6	4.5 – 9.7	0.000
Not present	124(100.0)	22(45.8)			
Venipuncture					
Present	0(0)	3(60.0)	4.0	1.2-13.2	0.026
Not present	6(100.0)	2(40.0)			
Eye squeeze					
Present	0(0)	3(60.0)	4.0	1.2-13.2	0.026
Not present	6(100.0)	2(40.0)			
Naso-labial furrow					
Present	0(0)	3(60.0)	4.0	1.2-13.2	0.026
Not present	6(100.0)	2(40.0)			
Horizontal mouth					
Present	0(0)	3(60.0)	4.0	1.2-13.2	0.026
Not present	6(100.0)	2(40.0)			
Taut tongue					
Present	0(0)	3(60.0)	4.0	1.2-13.2	0.026
Not present	6(100.0)	2(40.0)			

*OR: Odds Ratio; †CI: Confidence Interval; ‡Pearson's chi-square test

For the procedure (aspiration), the p-values were statistically significant for all the facial reactions studied (p<0.000), and it was found that the Control Group had the highest amount of facial pain expressions. At the time of compression, only the brow bulge showed p<0.000, with odds ratio for all pain reactions ranging from 1-13.

Table 2 – Facial reactions observed during the procedure (aspiration and compression), in the Experimental and Control Groups, using the NFCS scale. Fortaleza, CE, Brazil, 2017

Facial reactions	Experimental group n(%)	Control Group n(%)	*OD	†CI 95%	‡p-value
Aspiration					
Brow bulge					
Present	12(2.5)	263(75.1)	115.6	62.0-215.4	0.000
Not present	459(97.5)	87(24.9)			
Eye squeeze					
Present	39(8.3)	251(71.7)	28.0	18.7-41.9	0.000
Not present	432(917)	99(28.3)			
Naso-labial furrow					
Present	14(3)	242(69.1)	73.1	40.0-130.3	0.000
Not present	457(97)	108(30.9)			
Horizontal mouth					
Present	24(5.1)	251(71.7)	47.2	29.4-75.7	0.000
Not present	447(94.9)	99(28.3)			
Taut tongue					
Present	16(3.4)	229(65.4)	53.8	31.2-92.8	0.000
Not present	455(96.6)	121(34.6)			
Compression					
Brow bulge					
Present	11(4)	100(35.3)	13.0	6.7-24.9	0.000
Not present	262(96)	183(64.7)			
Eye squeeze					
Present	99(33.6)	107(37.8)	1.0	0.7-1.5	0.706
Not present	174(66.7)	176(62.2)			
Naso-labial furrow					
Present	89(32.6)	97(34.3)	1.0	0.7-1.5	0.676
Not present	184(67.4)	186(65.7)			
Horizontal mouth					
Present	88(32.2)	101(35.7)	1.1	0.8-1.6	0.390
Not present	185(67.8)	182(64.3)			
Taut tongue					
Present	83(30.4)	104(36.7)	1.3	0.9 – 1.8	0.113
Not present	190(69.6)	179(63.3)			

*OR: Odds Ratio; †CI: Confidence Interval; ‡Pearson's chi-square test

The heart rate during the moments assessed was higher in the Control Group, when compared to the Experimental Group. During the procedure, the aspiration phase was the technique that presented the highest mean of beats per minute (bpm), followed by compression (Table 3).

Table 3 – Heart rate at baseline, procedure and initial recovery, in the Experimental and Control Groups. Fortaleza, CE, Brazil, 2017

Heart rate	Experimental group		Control group		Total	
	n	Mean ± standard deviation	n	Mean ± standard deviation	n	Mean ± standard deviation
Baseline	600	131.0±24.8	720	121.5±15.6	1320	125.8±20.9
Procedure/antisepsis	48	142.7±30.7	125	119.8±15.8	173	126.2±23.3
Venipuncture	5	141.0±34.5	6	118.1±11.1	11	128.5±26.0
Aspiration	350	164.9±34.7	471	124.7±15.6	821	141.9±32.4
Compression	283	150.0±24.374	273	146.8±34.348	556	148.4±29.708
Initial recovery	600	136.6±22.255	720	124.0±20.015	1320	129.7±21.977

Discussion

As a limitation of the study, it can be cited that it was carried out in only one health institution, in addition to the small sample size in each study group, even considering that this is a pilot study. However, the importance of evidencing the pain of full term newborns in rooming-in care is evident, since, since the baby in this sector is considered healthy, the sensitivity to pain is mistakenly overlooked or disregarded.

The results of this study show that the Experimental Group was effective, compared to the Control Group, when evaluated by facial expression scores (NFCS) and by physiological heart rate responses. These differences can be observed at baseline, procedure (Brow bulge, eye squeeze, naso-labial furrow, horizontal mouth, and taut tongue), and initial recovery stages, showing statistical significance.

A study carried out in a neonatal unit in Rio de Janeiro, Brazil, found that 19.0% of nursing assistants and technicians, 18.1% of nurses, 45.0% of doctors and 100.0% of physical therapists evaluated neonatal pain through vital signs only. Only 27.2% of nurses, 40.0% of doctors and 50.0% of physical therapists mentioned assessing the presence of pain through the association of vital signs and other methods[12].

A randomized clinical trial investigated the

effect of music and touch with a control group (touch only), at the beginning of hospitalization and two weeks later. They used the Premature Infant Pain Profile, in 62 premature infants undergoing painful daily procedures. The researchers observed that there was no significant difference in pain for the group that received the intervention and those who did not ($p>0.05$) at the beginning of hospitalization; after two weeks, the music and touch group had a significantly lower pain score (10.50 ± 0.85; $p<0.05$) when compared to the control group (13.00 ± 0.46)[13], confirming that music, when associated with other non-pharmacological methods, has an effect in minimizing pain in newborns.

When used during the venipuncture procedure, NFCS correlates with changes in other specific parameters that suffer variations in painful procedures. Changes like the variation in oxygen in hemoglobin, salivary cortisol and skin conductivity in the neonate can be observed, as shown in an observational, prospective study, developed in France with 113 full term newborns, during the venipuncture procedure. The results showed a high correlation between NFCS and total hemoglobin values ($r=0.41$, $p<0.001$) or oxygenated hemoglobin ($r=0.27$, $p<0.001$); moderate correlation with changes in salivary cortisol ($r=0.42$, $p<0.001$); and skin conductivity ($r=0.29$, $p<0.001$). Heart rate and oxygen saturation were not associated[14].

On the other hand, a similar study that assessed the newborns' pain response to arterial punctures, also using the NFCS, found that 96.1% of the newborns showed facial expressions compatible with the presence of pain. The most prevalent manifestations were horizontal mouth (96.1%); brow bulge (88.4%); and eye squeeze (76.9%). The only indicators that were seen in less than half the newborns were taut tongue and chin tremor, suggesting that it may be related to the use of mechanical ventilation in 23 babies. In addition, 50.0% of newborns also showed changes in heart rate[4]. These findings are similar to those in this study with regards to the most identified facial reactions, both in the experimental and control groups, with greater presence in those who did not use music. This reiterates that music is indicated to the care of newborns with acute pain.

A clinical trial conducted at the neonatal unit, with a sample of 48 footage of premature infants, 26 in the experimental group (music, 10 minutes), and 22 in the control group (glucose 25%), showed similarities between the groups, at baseline (newborns in rest), recovery 1 (compression with cotton after collection of arterial puncture), recovery 2 (resting of the premature infants after the end of compression). However, there was a statistically significant difference in the moments "treatment" (antisepsis) ($p=0.014$), and "painful" (needle introduction) ($p=0.029$) for the control group[15]. These results are similar to the present study, in which the newborns in the control group had more facial pain expressions at the time of the procedure.

Another clinical trial study that analyzed the song sang by parents for pain relief in newborns did not identify significant changes in the infant pain score. The use of music sung as an intervention, during venipuncture, in preterm and full term newborns, showed similar results for pain scores in the group of newborns who received only routine care from the institution. However, regular and calm breathing patterns were observed in newborns who heard the songs before the needle was inserted[16].

A study that used as interventions music by Mozart, Beethoven, heartbeat sounds, and a control group without music, showed a decrease in heart rate, reduction in pain perception and increase in oxygen saturation in all groups that were exposed to music[9]. This result was to the present study, in which there was a decrease in heart rate and pain perception.

As for the use of the swaddling technique as a non-pharmacological measure, it is used by nursing assistants/technicians (86.3%), nurses (100%), and physical therapists (100%) during the performance of painful procedures in newborns[12]. Literature, however, differs in many aspects regarding the use or not

of this technique. An integrative review that aimed to identify evidences about the risks and benefits of swaddling[17], found that it can calm and facilitate the newborn's sleep, in addition to not interfering with long-term breastfeeding. On the other hand, it was equally or less effective than other non-pharmacological methods for pain management.

Although other studies with the association of swaddling and music could not be identified in literature, it is observed that the use of swaddling with another non-pharmacological method can have beneficial effects on the reduction of neonatal pain, as was identified in this study.

Finally, non-pharmacological methods need to be considered as the first option during planning, assistance, and after pain management in children. Such methods can provide a reduction in the use of analgesics for pain or even their cessation, in some cases. In addition, non-pharmacological techniques are usually less expensive, easily accessible, reusable, and adaptable to any environment[18].

It is also noteworthy that the short- and long--term consequences of coexisting with pain and stress in neonates lead to changes in neurobiology and behavior, consequently affecting the deterioration of quality of life. Therefore, it is important to anticipate, prevent and deal with pain and stress in neonates, aiming to lead to a high quality of life in the future[19].

As a result, this research stands out as one of the pioneers with regards to comparing interventions that combine both music and swaddling with those that use only swaddling during venipunctures in full term newborns, considering that the swaddling is a routine non-pharmacological intervention.

Furthermore, in view of the results identified, the need for critical and holistic attention for the neonatal period is emphasized, in order to preserve the individual's full brain development, and the relevance of the evaluation not only of the physiological responses of newborns, but also that of behavioral aspects for conducting adequate nursing care.

Conclusion

Newborns submitted to music associated with the swaddling technique had less pain reactions during the procedure than those exposed only to swaddling, since they expressed a greater amount of facial pain reactions in the antisepsis, puncture, and blood aspiration stages.

It was also found that music, in association with swaddling, has a positive effect on heart rate, since the group that received the intervention had lower averages, as well as variation at all phases evaluated.

Collaborations

Viana TRF contributed with data interpretation, writing of the article, relevant critical review of the intellectual content and final approval of the version to be published. Melo GM and Cardoso MVLML collaborated with the conception and design, analysis and interpretation of data, writing of the article, relevant critical review of the intellectual content and final approval of the version to be published. Almeida PC, Oliveira LM and Santos DAS assisted in the approval of the final version to be published.

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