The Journal of Maternal-Fetal & Neonatal Medicine

ISSN: 1476-7058 (Print) 1476-4954 (Online) Journal homepage: http://www.tandfonline.com/loi/ijmf20

"The Original Sound": a new non-pharmacological approach to the postnatal stress management of preterm infants

Francesco Tandoi, Gaia Francescato, Alessia Pagani, Giuliano Buzzetti, Eva Negri & Massimo Agosti

To cite this article: Francesco Tandoi, Gaia Francescato, Alessia Pagani, Giuliano Buzzetti, Eva Negri & Massimo Agosti (2015) "The Original Sound": a new non-pharmacological approach to the postnatal stress management of preterm infants, The Journal of Maternal-Fetal & Neonatal Medicine, 28:16, 1934-1938, DOI: 10.3109/14767058.2014.973392

To link to this article: http://dx.doi.org/10.3109/14767058.2014.973392

Accepted author version posted online: 06 Oct 2014.
Published online: 29 Oct 2014.

THE JOURNAL OF MATERNAL-FETAL & NEONATAL MEDICINE

http://informahealthcare.com/jmf
ISSN: 1476-7058 (print), 1476-4954 (electronic)

J Matern Fetal Neonatal Med, 2015; 28(16): 1934–1938
 DOI: 10.3109/14767058.2014.973392

informa healthcare

ORIGINAL ARTICLE

''The Original Sound'': a new non-pharmacological approach to the postnatal stress management of preterm infants

Francesco Tandoi[1], Gaia Francescato[2], Alessia Pagani[3], Giuliano Buzzetti[1], Eva Negri[4], and Massimo Agosti[1]

[1]Neonatology and NICU, Ospedale Del Ponte, Azienda Ospedaliera Di Circolo Fondazione Macchi, Varese, Italy, [2]Neonatology and NICU, Department of Clinical Sciences and Community Health, Fondazione IRCCS Cá Granda – Ospedale Maggiore Policlinico, Milano, Italy, [3]Pediatric Clinic, Major Hospital Charity, Novara, Italy, and [4]Department of Epidemiology, IRCCS Istituto di Ricerche Farmacologiche ''Mario Negri'', Milan, Italy

Abstract>

Objective: To evaluate the effect of the exposure to ''The Original Sound'' (TOS), an original track composed of different sounds such as fetal heartbeat, breathing, blood flow, and ambience sounds, specifically created for this study, on physiological stability of preterm infants during a 10-d hospitalization.

Methods: Thirty-four preterm infants (32–37 weeks of gestation) were randomized to receive either TOS or environmental noise. TOS was provided for a 20-min period, three times a day, using two speakers and a MP3 player placed in the cradle. Cardiorespiratory and behavioral parameters were recorded.

Results: Heart rate in the treated group was positively correlated with TOS exposure, showing a significant reduction on day 2 and lower values during the first day. A decrease in RR is also recorded on day two in the TOS group, although not significant.

Conclusion: This study provides preliminary evidence for short-term improvements in the physiological stability of preterm infants using TOS. Future studies are needed to investigate the potential of this non-pharmacological approach and its clinical relevance to postnatal stress management in neonatal intensive care units.

Keywords

Neonatal Care, preterm neonates, stress management

History

Received 10 December 2013
Accepted 02 October 2014
Published online 29 October 2014

Background

Among non-pharmacological methods used in attempt to reduce pain and stress perception in preterm and term neonates in Neonatal Intensive Care Units (NICUs), some such as maternal skin-to-skin contact [1] and non-nutritive sucking have been proven efficacious [2]. Music, as well, is gaining the interest of many units for recognized positive effects on pain response, as demonstrated by the regulation and reduction of heart rate (HR), rise in oxygen saturation [3,4] and improvement on behavioral state [5]. It is well recognized that low frequency maternal sounds, such as the mother's voice and heartbeat, are audible inside the womb early in gestation [6].

Exposure to maternal sounds may therefore be crucial for healthy fetal development [7]. However, the specific effects of maternal auditory stimulation on short-term physiological outcomes are still unclear and the role of exposure to maternal sounds as a developmental care strategy for preterm infants is still controversial [8].

By 25–26 weeks gestation preterm infants can already perceive and respond to sounds in their environment [9,10]. When a premature birth occurs, the low-frequency maternal sounds in the amniotic environment are replaced by loud background noises. Premature infants are therefore deprived of the physiological auditory stimulation needed for their normal maturation and development. This can interfere with auditory development and especially frequency discrimination. It could have consequences for the development of language skills, as well as for later socio-emotional development [11] and even impact on the cardiorespiratory regulation, particularly at younger gestational age [12,13].

Previous studies have attempted to address these issues by introducing maternal voice [14,15] in incubators in NICU. Lahav et al. have previously proposed a sample of biological sounds, consisting of voice and heartbeat, recorded from a mother of a premature infant [11] and afterwards demonstrated its efficacy on short-term improvements in cardiorespiratory regulation [16] and weight gain velocity [17] in extremely preterm infants.

Within this context, a multidisciplinary group of neonatologists, pharmacologists, sound engineers, artists, created The Original Sound (TOS), mixing together the idea of

Address for correspondence: Gaia Francescato, Gaia Francescato, Neonatology and NICU, Department of Clinical Sciences and Community Health, Fondazione IRCCS Cà Granda – Ospedale Maggiore Policlinico, University of Milan, via Della Commenda 1220122, Milano, Italy. Tel: +390255032234; +393382371583. E-mail: gaia.francescato@mangiagalli.it or gaia.francescato@yahoo.it

''care'' with the acoustic memory of a fetus during intrauterine life, in order to reinforce the ''calming effect'' of music. We hypothesize that reproducing sounds, rhythms, percussions that fetuses hear in the maternal womb can represent, particularly in preterm infants, a non-pharmacological approach able to reduce the resulting adaptive stress of birth.

Aim of the study

To evaluate the effect of TOS on HR in preterm infants during the hospitalization period at the NICU of the ''Filippo Del Ponte'' Hospital in Varese, Italy. Secondary evaluation endpoints were:

- respiratory rate (RR);
- O_2 saturation;
- behavior.

Data collection was performed with the help of the nursing staff of the department, trained on how to conduct the study.

Study design

Prospective open-label study, randomized, controlled parallel group. The study duration for each subject was established during the first 10 d of life.

Materials and methods

TOS is a musical track recording obtained with several specific audio equipments. The recording has been done using also special contact-microphones (membrane microphones), Doppler sensors and micro-vaginal microphones strictly in contact with the womb. Using hydrophones placed in water tanks and in contact with the womb of pregnant women, we have recorded sounds like fetal heartbeat, breathing, blood flow and other visceral sounds, potentially recreating those internal sources that fetus hears during the gestational period. In addition, TOS includes a series of sounds that fetus experienced during intrauterine life such as female and male voices, footsteps, electrical noises, traffic noises, TV and radio output, music, wind, chirping, ocean waves, traffic, TV and radio output recorded from inside a sheath with characteristics similar to uterine wall and filtered by calibrating the different sequences to reproduce what the fetus hears from external sources. TOS is faithfully replicating all intrauterine songs emphasizing all high frequencies and filtering the song output up to 70/80 decibels. With this method, we obtained a rhythm track that plays the music and melodies that help to create the first audio-sensory memory of the fetus. TOS can be spread through a normal audio system into the environment or, better, in the cradle of the infant through the use of a suitable acoustic speaker. Our sound diffusion has been done using two speakers and a MP3 player placed opposite the baby's head with a limited volume (max 70/80 decibels) and fixed upside down reproducing the sound within the cradle.

Selection criteria

All premature infants of both sexes, consecutively admitted in the Department of Neonatology and Neonatal Intensive Care Unit of the Hospital of Varese and who have responded to all the inclusion criteria were admitted up to the calculated sample size.

Inclusion criteria were: 1. birth within the previous 24 h; 2. gestational age greater than or equal to 32 weeks and less than 37 weeks; 3. birth weight greater than or equal to 1500 g; 4. absence of any major disease. 5. written informed consent of a parent.

Experimental sample

We enrolled a total of 34 evaluable subjects (17 per experimental group). This gave to our study an 80% probability to detect a difference of 15.0 bpm between the two groups with a significance of 5% two-way, assuming a standard deviation of the response of 15.0 bpm. Similar sample sizes have been found to be consistent with the assessment of a one standard deviation difference among groups, in a recent review on this topic [18]. Once verified the selection criteria an informed consent from parents was obtained.

Treatment (day 0: baseline)

The baseline visit was conducted after at least 6–12 h from birth. Each subject who met the selection criteria and for whom the parents have given written consent was detected for the following basal parameters:

- measurement of heart rate (b/min);
- measurement of respiratory rate (b/min);
- measurement of transcutaneous O_2 saturation by digital oximeter.

Behavior of each infant was measured using a scale with a score ranging from 1 to 7: (1) deep sleep; (2) light sleep; (3) drowsiness; (4) quiet awake or alert; (5) active awake and agitated; (6) markedly agitated, upset or crying; (7) prolonged respiratory pause$>$ 8 s.

The scale was previously used by Arnon et al. [5], and it was defined by Als [19].

Subsequently, the subject was assigned on the basis of a list of randomization to one of the two groups in the study:

(A) a study group given daily sessions of 30 min with TOS;
(B) a control group not subjected to TOS but only to the usual environmental noise.

Particular attention was dedicated to the detection of an apparently significant worsening of clinical parameters of the newborn.

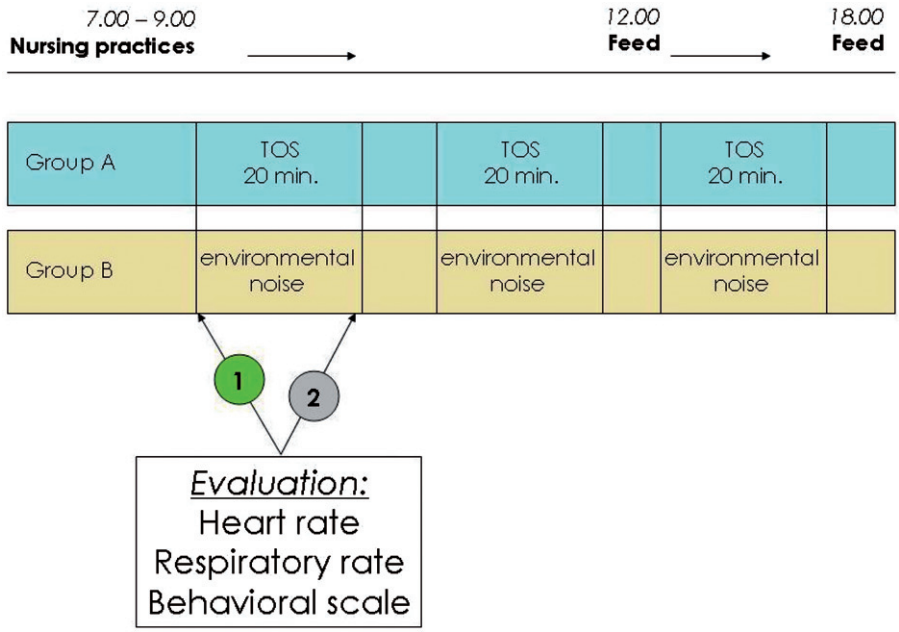
The scheme of the study is shown in Figure 1.

Each infant concluded the trial at discharge from the NICU and in any case after 10 d of hospitalization. The total duration of hospitalization was recorded on medical records.

The group (A) was subjected to treatment with TOS. The administration of TOS has taken account of the sleep–wake cycle and was detected immediately after the manoeuvers of nursing, including the possible withdrawal (7:00 to 9:00 h). The duration of each session was approximately 30 min. TOS was diffused through an audio equipment complying with CE dispositions, placed near the cradle, to a volume between 55 and 70 decibels.

The control group (B) was exposed only to environmental noise of the unit. After the manoeuvers of nursing in the

Figure 1. Study design.



morning for each infant were recorded the following parameters: heart rate and respiration, pulse oximetry and behavioral scale.

These measurements were programmed (see diagram):

(a) for the Group (A)
  (1) terminated as soon as the manoeuvers of nursing;
  (2) after the administration of music therapy;
(b) for group (B)
  (1) terminated as soon as the manoeuvers of nursing;
  (2) after at least 30 min from the previous survey.

Ethical issues

The study was conducted according to the Declaration of Helsinki and has been subjected to the binding opinion of the Ethics Committee of the Hospital of Varese.

Statistical analysis

A linear mixed-effect model for repeated measures using a first-order autoregressive correlation structure was fitted. The dependent variable was the difference from the value at day i and the baseline value, where $i = 1,2,3$. The variables included in the model were time, treatment and the time × treatment interaction. The parameter of interest was the time × treatment interaction, indicating a change over time of the difference between the two groups.

For the behavior score, which was measured on an ordinal scale, a generalized linear model for repeated measures using SAS s proc GENMOD (SAS Institute Inc., Cary, NC) was used to estimate the odds ratio (OR) of having lower values of behavioral score in the treatment group.

Results

Objectives, methods and content of the study were accepted without reservation by all parents at the time of its presentation and during the performance. It never became necessary to interrupt the treatment because of poor tolerance by the newborn.

Table 1. Baseline characteristics of the two groups.

Variable	The Original Sound (N=17)	Control (N=17)	p-value
Males %	53 (n=9)	59 (n=10)	0.73
Apgar 5, mean	9.4	9.1	0.32
Cardiac Frequency, mean	133.8	137.7	0.29
Respiratory Frequency, mean	41.4	43.1	0.35
Saturation, mean	96.6	96.2	0.61
Weight, mean grams	2048	2107	0.58
Behavioral score	2.1	2.3	0.78

The baseline characteristics of the two groups at enrollment are shown in Table 1. As shown, the basic outline for the parameters in question showed two completely overlapping populations and therefore comparable. Both groups were comparable as for type of deliveries (50% versus 55% caesarean section) and type of feeding (60 versus 55% breastfeeding, respectively).

Heart rate in the treated group was positively correlated with TOS exposure, showing a significant ($p = 0.05$) reduction on day 2 and lower values during the first day.

In parallel, although not significantly, a decrease in RR is seen (Table 2b) on day 2 in the TOS group, in agreement with the reduction of HR. No significant differences between the two groups emerged with respect to HR, RR and O_2 saturation during the other days of treatment.

The reduction of the HR and RR in the second day of life does not influence O_2 saturation as it might be expected to be improved in a condition of less stress.

Overall, this type of treatment, according to behavioral parameters, involves a ‘‘calming’’ effect about three times greater (OR [95% CI: 2.7 (1.1–6.6), $p = 0.04$] in the treated population (Table 3). No adverse events were reported at any time of TOS administration.

Table 2. Main vital parameters under study.

Day	TOS mean (SD)	Control mean (SD)	*p*-value
a) HR			
Baseline	133.8 (13.0)	137.7 (7.2)	0.29
1	131.1 (10.2)	137.7 (11.7)	0.09
2	130.8 (10.8)	137.5 (8.2)	0.05
3	132.9 (9.4)	131.4 (10.8)	0.65
b) RR			
Baseline	41.4 (6.2)	43.1 (4.0)	0.35
1	41.8 (6.4)	42.6 (6.29	0.71
2	40.8 (5.0)	43.4 (3.6)	0.09
3	40.8 (5.4)	41.2 (3.8)	0.80
c) O_2 Saturation			
Baseline	96.6 (2.1)	96.2 (2.0)	0.61
1	98.0 (2.0)	96.7 (1.8)	0.06
2	97.8 (1.7)	97.2 (1.7)	0.32
3	97.9 (1.3)	98.2 (1.3)	0.59

Table 3. Differences according to the scale of behavior adopted in the study.

Day	TOS mean (SD)	Control mean (SD)	*p*-value
Baseline	2.8 (1.3)	2.9 (1.1)	0.73
1	1.6 (0.6)	2.3 (0.8)	0.05
2	1.9 (0.6)	2.5 (0.8)	0.06
3	1.6 (0.5)	2.1 (0.8)	0.09
OR (95%CI)	2.7 (1.1–6.6)		0.04

Discussion

The most interesting results of our study, comparing the two populations, concerns behavior. Compared to baseline (2.8 versus 2.9 OS control), TOS showed a beneficial effect over the time. We can speculate that this result could be correlated with the trend in reduction of HR in the treated group, although below the limit of statistical significance. This effect is greatest in the first 2 d of life, to show how much sensitive the infant is to a series of familiar sounds, supposedly playing TOS, that environment which infants have experienced up to a few hours before delivery. We can also postulate that the time of administration of TOS, which we set at 30 min (as suggested by most studies that have preceded this one), can also be increased to boost the beneficial effects of treatment, since it was also well tolerated.

The treatment may also exert some of its positive effects, contrasting the ''background noise'' of NICU, characterized by voices, alarms and other auditory stimuli not controlled for volume and duration and widely documented as a cause of stress and fatigue. These considerations have constituted the basis for the creation of guidelines to reduce exposure to negative and completely unexpected stimuli for the preterm infant.

One of the possible future developments of this technology could reside in the ability to overdub the true voices and maternal/paternal or on the base track, making this experience even closer to the family identity of each child. The novelty of the track we have utilized lies not only in unusual structural complexity, in terms of technology, but from having two components fused together, environmental noise and sound, not usually considered together in previous experimental experiences, but which in reality are often associated. No significant differences emerged between the two groups during the first 3 d of life on HR, a parameter of significant interest given the circumstances of the experimental study. However, the trend in reduction of this parameter in the TOS group in the second and third day of life indicates that the study has probably lapped this result, described in other publications, as the more ''organic'' relevant effect of and probably could be confirmed with expansion of the series both in numbers and in a context of ''case mix''. A similar trend is shared by the RR. Moreover, the population selected with our criteria included only ''healthy'' preterm infants; for most of them nursing procedures (sampling, eye examination, etc.) that preceded the administration of the TOS did not provide significant stress, as opposed to subjects included in previous studies highlighting the effects of ''comforters'' [20,21].

Conclusions

TOS can be interpreted as a structured attempt to reduce stress conditions in preterms. Since our study was exploratory (1 SD difference as significant), we may have missed the numerosity and/or the length of treatment sufficient to detect greater differences between treatments. TOS, combined with other environmental stimuli, may prolong the bonding with the mother after birth while preparing the neonate to the next sound environments. Beside other environmental treatments, TOS could play a role in educational and other preparatory practices of care and somatosensory stimulation of preterm infants.

Declaration of interest

The authors report no conflicts of interest.

References

1. Johnston CC, Filion F, Campbell-Yeo M, et al. Kangaroo mother care diminishes pain from heel lance in very preterm neonates: a crossover trial. BMC Pediatr 2008;8:13.
2. Stevens B, Yamada J, Lee GY, Ohlsson A. Sucrose for analgesia in newborn infants undergoing painful procedures. Cochrane Database Syst Rev 2013;1:1–44.
3. Standley JM, Moore RS. Therapeutic effects of music and mother's voice on premature infants. Pediatr Nurs 1995;21:509–12, 574.
4. Collins SK, Kuck. Music therapy in the neonatal intensive care unit. Neonatal Network 1991;9:23–6.
5. Arnon S, Shapsa A, Forman, et al. Live music is beneficial to preterm infants in the neonatal intensive care unit environment. Birth 2006;33:131–6.
6. Graven SN, Browne JV. Auditory development in the fetus and infant. Newborn and Infant Nursing Rev 2008;8:187–93.
7. Fifer W, Moon C. The role of mother's voice in the organization of brain function in the newborn. Acta Paediatr 2008;83:86–93.
8. Diana ON, Linda LL. Music as a nursing intervention for preterm infants in the NICU. Neonatal Network: J Neonat Nurs 2008;27: 319–27.
9. Hall III JW. Development of the ear and hearing. J Perinatol 2000; 20:S12–20.
10. Graven SN, Browne JV. Auditory development in the fetus and infant. Newborn Infant Nurs Rev 2008;8:187–93.
11. Panagiotidis J, Lahav A. Simulation of prenatal maternal sounds in NICU incubators: a pilot safety and feasibility study. J Matern Fetal Neonatal Med 2010;23:106–9.

12. Anderssen SH, Nicolaisen RB, Gabrielsen GW. Autonomic response to auditory stimulation. Acta Paediatr 1993;82:913–18.
13. Wachman EM, Lahav A. The effects of noise on preterm infants in the NICU. Arch Dis Child Fetal Neonatal Ed 2011;96:F305–9.
14. Cevasco AM. The effects of mothers' singing on full-term and preterm infants and maternal emotional responses. J Music Ther 2008;45:273–306.
15. Krueger C, Parker L, Chiu SH, Theriaque D. Maternal voice and short-term outcomes in preterm infants. Dev Psychobiol 2010;52: 205–12.
16. Doheny L, Hurwitz S, Insoft R, et al. Exposure to biological maternal sounds improves cardiorespiratory regulation in extremely preterm infants. J Matern Fetal Neonatal Med 2012;25:1591–4.
17. Zimmerman E, Keunen K, Norton M, Lahav A. Weight gain velocity in very low-birth-weight infants: effects of exposure to biological maternal sounds. Am J Perinatol 2013;30:863–70. [epub ahead of print].
18. Hartling L, Shaik MS, Tjosvold L. Music for medical indications in the neonatal period: a systematic review of randomised controlled trials. Arch Dis Child Fetal Neonatal Ed (England), 2009;94: F349–54.
19. Als H. Manual for the naturalistic observation of newborn behavior (preterm and fullterm infants). Boston (MA): The Children's Hospital; 1984.
20. Standley JM. The effect of music and multimodal stimulation on physiological and developmental responses of premature infants in neonatal intensive care. J Pediatr Nurs 1998;24: 532–8.
21. JM Standley. A meta-analysis of the efficacy of the music therapy for premature infants. J Pediatr Nurs 2002;17:107–13.