RESEARCH PAPER

Hemodynamic Responses to Recorded Maternal Voice Among Sedated Children in the Pediatric Intensive Care Unit: An Open-Label Randomized Controlled Trial

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Objective: To assess the effect of maternal audiotaped voice on clinical parameters of sedated children. **Methods:** A randomized controlled trial was conducted on 25 sedated critically ill children admitted to the pediatric intensive care unit. An audiotaped maternal voice was played to the children in the experimental group (*n*=13) via a headphone for 15 minutes, twice a day for 3 days. Children in the control group (*n*=12) received routine care without any additional auditory stimulation. Clinical and hemodynamic variables were recorded at 5 minutes interval three times. **Results:** Significant changes were observed in the mean (SD) heart rate (per minute) at 10 minutes [129.83 (19.14) vs 124.29 (14.90), *P*=0.051], respiratory rate at 5 minutes [44.38 (17.79) vs 34.65 (7.64), *P*=<0.001] and 10 minutes [42.79 (13.89) vs 35.44 (7.65) *P*=<0.001], systolic blood pressure at 5 minutes [95.24 (15.01) vs 101.02 (19.83) *P*=0.045], and mean blood pressure at 15 minutes [68.66 (13.61) vs 73.61 (17.59) *P*=0.051] mmHg between the experimental and the control group, respectively. **Conclusion:** Listening to recorded maternal voice had a positive effect on clinical parameters of sedated critically ill children.

Keywords: *Anxiety, Blood pressure, Comfort scale, Pain.*

Trial Registration: Clinical Trial Registry of India: CTRI/202/08/02378

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A critical illness subjects a child to extreme stress arising from highly invasive procedures, separation from family members, limited parental interaction, and varying intensity of light and noise levels in the pediatric intensive care unit (PICU) [1-3]. Many PICUs in India allow only brief visits by the parents and restrict visits by other family members for concerns of potential spread of infection, breach of confidentiality and privacy, undue emotional stress to the parents, and lack of space [2,3]. These restrictive policies undermine the importance of parental presence at the bedside, family-centered care and parental involvement in decision-making.

Maternal voice activates the prefrontal cortex of the child, affecting behavioral and neurological responses [4]. The effect of recorded maternal voice on anxiety and pain relief during procedures is well documented [5-7]. Recorded maternal voice has also been reported to decrease the emergence delirium in children recovering from anesthesia [8,9], but its effect on the clinical parameters of a sedated child has not been explored. This study aimed to assess the effect of audiotaped maternal voice on the clinical parameters of children admitted to the PICU. The secondary objectives were to assess its association on the duration of mechanical ventilation and length of PICU stay.

METHODS

This open-labelled randomized controlled trial was conducted at an 8-bedded PICU of a tertiary care center in northern India between September, 2020 and January, 2021. Ethical approval was obtained from the institutional ethics committee, and written informed consent was taken from the mothers.

Children from one month to 10 years of age, having a sedation score of 17-26 as per Comfort Sedation Scale (CSC) were included in the study [10]. Critically ill children with a history of hearing problems or ear discharge, children with developmental delay or neurological diseases, increased intracranial pressure, uncontrolled seizures or mental disorders, extremely sick children, children with shock, or an anticipated stay of less than 24 hours in PICU were excluded. Computer generated random number sequence was used for randomization.

Allocation concealment was ensured by the use of the sequentially numbered opaque sealed envelope (SNOSE) technique. It was done by a person not involved in the conduct of the study.

All mothers in the experimental group (EG) were assisted in the preparation and the recording of the individual script of 5-10 minutes considering the age of the child, language known to the child, and previous significant memorable events in the life of the child. After establishing rapport, she was made to listen to a sample of recorded voice of another mother. The time for the audio recording was fixed as per her convenience and done in a quiet area. The recording was checked for clarity before storing it for the use in researcher's mobile phone (Honor 7X model). The audio-recorded voice was played using a mobile phone with a wireless headphone having a wireless frequency of 2403 MHz -2480 MHz at 60 to 70 decibels. It was sweat proof and background noise-proof and had a sensitivity of 115 DB. It was played twice daily for 15 minutes in the morning (7 to 8 AM) and evening (5 to 6 PM) consecutively for 3 days.

The children in the control group (CG) did not receive any recorded auditory stimuli. Clinical parameters of including heart rate (HR), respiratory rate (RR), pulse oximetry (SpO_2) and blood pressure were recorded at baseline, intervention, at 5, 10, and 15 minutes after the intervention. After each intervention, the headphone was disinfected using a 70% alcohol swab and kept ready for the next use. Six observations were made per participant (twice a day for 3 days).

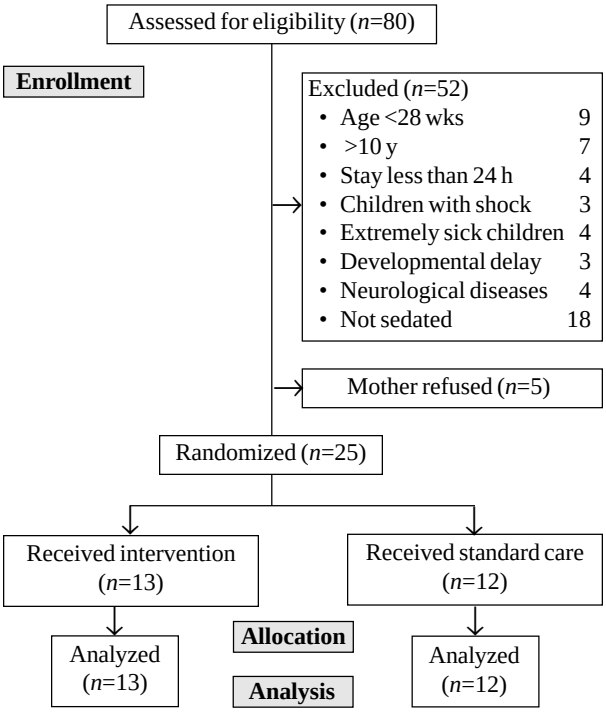

Fig. 1 Flow diagram for the study.

The tools used for data collection included the screening sheet to identify eligible children based on inclusion/exclusion criteria, demographic and clinical information sheet, pediatric Glasgow coma scale (GCS) and comfort sedation scale [10]. Patients with a comfort scale scores between 8-17 are considered over-sedated, a score between 17-26 adequately sedated, and scores between 27-40 under-sedated. The inter-rater reliability of the comfort scale ranges from 0.63-0.93 (kappa) [11].

To estimate a clinically relevant difference in the heart rate of 5 beats per minute, a pooled standard deviation of 10.2 based on previous study [5], with 80% power and 95% confidence was used to calculate a sample size of 66 in each group.

Statistical analysis: Data were entered in a Microsoft Excel spreadsheet and then imported to STATA software version 13.1 (Stata Corp). Descriptive statistics were used for the baseline characteristics. Independent sample *t* test was used to compare the means of variables between groups. Paired *t*-test was used to compare the means of related groups. Analysis of variance (ANOVA) was used to com-pare means across more than two measurement points. Non-parametric data were analyzed using the chi-square test, Fisher exact test, and Wilcoxon sign rank test. The set level of significance was 0.05.

RESULTS

A total of 80 children were assessed for eligibility; of which, 25 children were enrolled and randomized to the experimental group (EG, *n*=13) and the control group (CG, *n*=12) (**Fig. 1**). **Table I** shows the baseline characteristics of the enrolled children. All children were mechanically ventilated and also had arterial and central lines in place. None of the admitted children had COVID-19 infection.

Table I Baseline Characteristics of Hospitalized Children

Variable	*Experimental group (n=13)*	*Control group (n=12)*
Age (mo)	11 (1-96)	48 (1-120)
Girls[a]	4 (30.8)	5 (41.7)
Attending school[a]	1 (7.69)	5 (41.67)
Immunized for age[a]	8 (61.5)	9 (75)
Orotracheal tube[a]	12 (92.3)	12 (100)
Tracheostomy[a]	1 (7.69)	0
Length (cm)	64 (51-93)	97 (65.2-123)
Weight (kg)	4 (3-14)	12 (5-20)

Data expressed as median (IQR) or [a]no. (%). P>0.05 for all values.

Table II Effect of Maternal Audiotaped Voice on Primary Outcomes in the Experimental and Control Groups

Variables	*Experimental (n =13)*	*Control (n=12)*	*P value*
Heart rate (per min)			
Baseline	119.25 (19.57)	123.08 (14.71)	0.18
At 5 min	128.46 (22.12)	124.23 (15.06)	0.17
At 10 min	129.83 (19.14)	124.29 (14.90)	0.05
At 15 min	121.88 (19.63)[b]	123 (14.56)	0.69
Respiratory rate (per min)			
Baseline	37.11 (18.18)	34.36 (7.39)	0.23
At 5 min	44.38 (17.79)	34.65 (7.64)	<0.001
At 10 min	42.79 (13.89)	35.44 (7.65)	<0.001
At 15 min	38.58 (12.81)[b]	35.73 (10.38)	0.13
Oxygen saturation (%)			
Baseline	91.84 (12.88)	94.91 (12.58)	0.14
At 5 min	92.23 (14.46)	95.63 (9.74)	0.09
At 10 min	94.56 (8.72)	95.66 (9.22)	0.45
At 15 min	95.41 (10.14)	92.23 (14.46)	0.12
Glasgow coma score			
Before	8.23 (0.80)	8.19 (0.79)	0.78
After	10.10 (7.75)[b]	7.75 (0.43)	<0.001
Comfort score			
Before	18.0 (0.70)	17.92 (0.49)	0.4
After	23.37 (1.09)[b]	18.25 (0.62)[b]	<0.001
Systolic blood pressure (mm Hg)			
Baseline	104.34 (16.67)	102.13 (19.72)	0.45
At 5 min	95.24 (15.01)[a]	101.02 (19.83)	0.04
At 10 min	103.79 (18.63)	102.87 (19.33)	0.76
At 17 min	101.86 (15.16)	101.86 (19.63)	0.5
Diastolic blood pressure (mm Hg)			
Baseline	59.25 (19.22)	61.38 (19.91)	0.50
At 5 min	65.16 (18.43)	60.83 (18.71)	0.15
At 10 min	64.37 (17.53)	60.70 (19.17)	0.22
At 15 min	57.73 (14.39)[b]	59.59 (19.01)	0.49
Mean blood pressure (mm Hg)			
Baseline	68.75 (14.01)	72.68 (17.77)	0.13
At 5 min	76.57 (15.22)	74.54 (18.35)	0.45
At 10 min	75.43 (14.79)	75.80 (17.91)	0.89
At 15 min	68.66 (73.61)	73.61 (17.59)	0.05

Data expressed as mean (SD). [a]P value <0.05 or [b]P<0.001 for within group comparison.

A total of 150 observations were recorded and compared in EG *(n*=78) and CG (*n*=72) (**Table II**). No significant differences were observed in the sedation dosages, median duration of mechanical ventilation (14 vs 13 days), and the median length of PICU stay (19 vs 11 days) between the two groups.

DISCUSSION

In this trial, significant changes were observed in the heart rate, respiratory rate, systolic and mean arterial blood pressure of critically sick hospitalized children who were exposed to maternal voice. Change in vital signs is the first physiological response elicited in hospitalized patients and has a prognostic value [12]. The mother's voice is considered as non-noxious stimuli and the physiological changes induced by exposure to these familiar auditory stimuli are likely to be beneficial for the child [13].

The physical set-up of the PICU often minimizes the interaction of the child with his parents, with very little free space at the bedside. Evidence suggests that infants give more attention to their own mothers' voices as compared to unfamiliar voices present in the environment [4]. Hearing is one of the last senses to be lost in an unconscious individual [14]. Allowing frequent visits of mothers in PICU and encouraging them to talk to their sedated children, as a sensory stimulation can provide comfort to the sedated child, and can lead to improvement in their bio-physiological parameters. Several studies have reportedly shown the positive effect of maternal recorded voice on reduction in procedural pain, and anxiety, improvement in physiological parameters, and better cooperation [7,9,15].

This study observed few changes in the vital parameters of the children receiving the intervention. However, due to the small sample size, a significant improvement in the physiological parameters of children and difference in secondary outcomes could not be elicited following the intervention. The targeted sample size could not be achieved due to decreased admission rates in the PICU during the COVID-19 pandemic. The intervention could not be blinded, and that may have accounted for observer bias.

In the present study, structured, individualized and tailored communication via recorded maternal voice was used, which was safe and beneficial for the sedated children. These audios can be repeatedly played for sedated children in the PICUs in the absence of mothers, or when visitations are not practically feasible. Mothers who had agreed to the audio recordings had informally conveyed happiness and satisfaction to the researchers for playing those recordings for their children.

Therefore, healthcare providers should communicate with sedated patients during daily assignments and rounds and while giving care to them. They should also encourage the caregivers, like the mothers who play an important role for the emotional well-being and neurological development of her child. Our findings support the involvement of parents in the care of critically ill children.

Ethics clearance: EIC, All India Institute of Medical Sciences, New Delhi; No. IECPG-136, dated April 23, 2020.

WHAT THIS STUDY ADDS?

- Listening to recorded maternal voice had a positive effect on clinical hemodynamic parameters of sedated critically ill children.

Contributors: SM,PJ,LLM: conception and design, data collection, analysis and interpretation of data, drafting of manuscript, review and approval; RL: Conception and design, analysis, drafting of manuscript, review and approval.
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