

## **Effect of Recorded Maternal Voice on Child's Cooperation During Cardiac Catheterization –A randomized controlled trial**

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*Received: February 03, 2016; Initial review: March 28, 2016; Accepted: January 11, 2017.*

**Objective:** To assess the effect of recorded maternal voice on child's cooperation during cardiac catheterization.

**Design:** Randomized placebo controlled trial.

**Setting:** Cardiac catheterization laboratory at a tertiary care hospital.

**Participants:** 90 children with congenital heart disease scheduled for cardiac catheterization between July 2014 and Dec 2014 randomized to maternal voice group and control group.

**Intervention:** During cardiac catheterization, children in maternal voice group listened to a 3-min audio-recording of their mother's voice, played in loop, using head-phones. Children in the other group wore headphones without auditory stimuli.

**Main outcome measures:** Child's cooperation during cardiac catheterization as assessed by Child Emotional Manifestation Scale.

**Results:** Children in the maternal voice group showed lower mean (SD) distress scores [13.2 (4.6) vs. 16 (5.6),  $P=0.01$ ]. The requirement of sedative agents during the procedure was not different ( $P=0.09$ ).

**Conclusions:** Allowing children to listen to recorded voice of their mother is an effective strategy to improve cooperation during cardiac catheterization.

**Keywords:** Anxiety, Cooperation, Distress, Congenital heart disease.

**Published online:** February 02, 2017. PII:S097475591600037

**A** well performed cardiac catheterization is important for management of a variety of congenital heart diseases (CHD). The accuracy of information obtained during cardiac catheterization relies heavily on achieving a steady hemodynamic state during the procedure and therefore the child's cooperation is mandatory. In most of the centers worldwide, cardiac catheterization is performed under conscious sedation. Pre-procedure counselling allay anxiety of most of the adolescents and adults. However, this is not an option in young children. It is not just fear of the procedure, but many other factors such as intravenous cannulation and physical restrain to achieve optimal position for vascular access during catheterization, that makes them anxious. To add to the woes children are separated from their parents. This anxiety and discomfort not only risks the validity of cardiac catheterization but also result in stressful hospital experience. These adverse hospital experiences are known to result in psychosocial adjustment problems in children [1,2].

Anxiety can partly be allayed by administration of intravenous analgesia and anesthesia before the procedure.

Child's cooperation; however, remains far from desired in the majority. Among other measures distracting child's attention away from unpleasant stimuli is effective in improving cooperation during painful invasive procedures [3-6]. Although the presence of the parents is arguably most reassuring to a distressed child, it involves the risk of radiation exposure to parents. In addition, the potential of interference with smooth functioning of healthcare professionals cannot be understated. The use of parental voice eliminates these problems while successfully distracting the child away from the stressful environment during various non-invasive procedures [7-10]. This has not been studied in the setting of cardiac catheterization. We undertook this randomized study to assess the effect of maternal voice on child's cooperation during cardiac catheterization.

### **METHODS**

Children aged 2-5 years, scheduled for cardiac catheterization between July 2014 and December 2014 were enrolled in this randomized control trial. Children were excluded from the study if they had significant hearing or learning deficits, or were not accompanied by

their mother. In addition, children who underwent the procedure under general anesthesia, or were deeply sedated during the procedure were also excluded from the analysis. The study was approved by the Institutional ethics committee of our institute, and a written informed consent was obtained from the parents. After enrolment, children were randomized to Maternal-voice group arm and Control group using a computer-generated sequence.

Mothers of children in the intervention group were interviewed and explained the process of voice-recording one day prior to the procedure. Mothers were encouraged to record conversation unrelated to the cardiac catheterization. Maternal voice was recorded for 3 minutes in their native language talking about pleasurable events or activities by which the child was most likely to be happy. The recording was performed in a quiet room using microphone and voice recorder function incorporated within Samsung Galaxy GT 15510 mobile smartphone (Seoul, South Korea) in which telecommunication was disabled temporarily. Both mother and the researcher assessed for the quality of the voice recorded. The voice recording was accepted when both mother and the researcher were satisfied of the quality and content of the recording. The voice recordings were then coded and saved within the recording device.

As per institutional policy, children scheduled for cardiac catheterization were fasting for at least four hours before the procedure. Approximately 10 minutes before the procedure, intravenous injection Morphine and Midazolam were administered at a dose of 0.1 mg/kg each for analgesia and sedation in the presence of either of the parents. Thereafter, once children were sleepy they were restrained on a radiolucent Bakelite board to obtain favorable position for femoral vascular access and to avoid unwanted movement of the child during cardiac catheterization. Children were then shifted inside the catheterization laboratory for cardiac catheterization.

The headphones were placed over ears of children soon after shifting inside the catheterization laboratory. The headphones were connected to the same device that was used for recording maternal voice. As per randomization, maternal voice was played in maternal voice group while headphones did not emit any sound in control group. The maternal voice was played in loop for continuous auditory stimulation. It was ensured that the headphones did not interfere with the interaction between the operator and the child. Pediatric cardiologist performing the procedure and nursing staff were not aware of the randomization.

During the procedure, children were administered additional doses of intravenous sedation if deemed

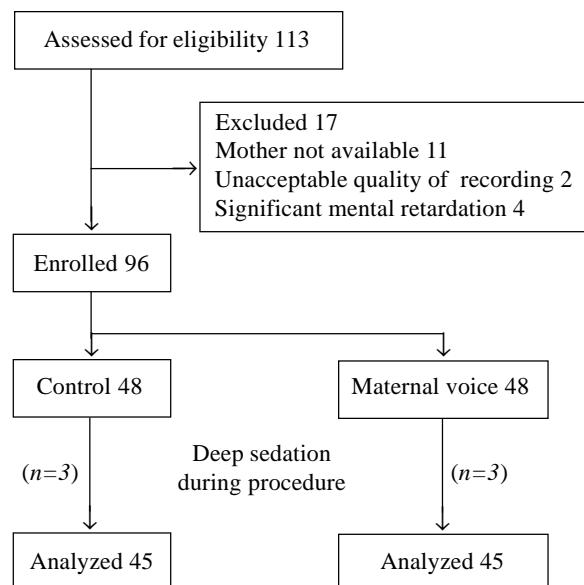
necessary by the operator. The dose and frequency of additional doses of sedation were at the discretion of the operator with no information to the person handling voice recordings and headphones inside the catheterization laboratory. The additional doses of intravenous sedation were recorded by staff nurse.

The child's cooperation was assessed using Children's Emotional Manifestation Scale (CEMS). CEMS is a simple, objective and consistent clinical tool to assess children's emotional behavior during stressful medical procedures [11]. This scale includes five components - facial expression, vocalization, activity, interaction and level of cooperation (*Web Fig. 1*). Each component is scored from 1- 5 with '1' being the most cooperative behavior and '5' being the least co-operative behavior thus giving a minimum score of 5 and a maximum score of 25 [11]. The pediatric cardiologist performing the procedure scored CEMS based on child's behavior in the initial 15 minutes of the procedure after obtaining vascular access.

**Statistical analysis:** A pilot study of ten patients showed mean (SD) distress score of 17.1 (6.2) in control group and 14 (4.3) in the maternal voice group. Considering 5% level of significance and 80% power, the required sample size was 45 in each group. Statistical data were analyzed using STATA version 11.1. For all the statistical tests, *P* value <0.05 was considered significant.

## RESULTS

Ninety consecutive children, who were scheduled for



**FIG. 1** Study flow chart.

cardiac catheterization were enrolled with 45 children in each group for analysis (**Fig. 1**). Various demographic and procedural characteristics are summarized in **Table I**. Children in both the groups were similar in age, sex and educational status of the mother. Majority of the procedures in both the groups were diagnostic catheterization.

Overall CEMS scores and scores for individual sectors were lower in the maternal voice group as compared to in the control group ( $P = 0.01$ ) (**Table II**). The heart rate and respiratory rate during the procedure in both the groups were comparable. Forty children in the control group and 34 in maternal voice group required administration of additional doses of intravenous sedation during the procedure ( $P=0.09$ ).

## DISCUSSION

In this randomized control trial, children who listened to the maternal voice during the procedure showed improved cooperation. Overall mean distress scores as well as scores in individual sector of CEMS were lower in children listening to recorded maternal voice.

Our findings are consistent with the previous studies on distraction techniques during other invasive medical procedures [9-12]. The requirement of additional doses

**TABLE I** DEMOGRAPHIC AND PROCEDURE-RELATED CHARACTERISTICS

	Maternal voice group (n = 45)	Control group (n = 45)
School going children, n (%)	21 (47)	25 (56)
Literate mother, n (%)	42 (93)	42 (93)
Area of residence, n (%) Rural	24 (53)	31 (69)
<i>Patient characteristics</i>		
Age (y), mean (SD)	3.5 (1.05)	3.9 (1.2)
Male sex	27 (60)	35 (78)
Height, mean (SD)	76.9 (4.8)	77.9 (4.3)
Weight, mean (SD)	11 (2.6)	11.9 (2.4)
Heart rate, mean (SD)	145 (13)	141 (12)
Respiratory rate, mean (SD)	40 (6)	39 (7)
*Acyanotic CHD, n (%)	23 (51)	33 (73)
<i>Procedural characteristics</i>		
Procedure duration (min) mean (SD)	27.6 (9.9)	24.8 (9.9)
Pre-procedure fasting time (h) mean (SD)	4.4 (0.8)	4.5 (1.2)
Time from injection of local anesthesia to puncture for vascular access (min) mean (SD)	3.04 (1.1)	2.8 (1.1)
*Diagnostic catheterization	33 (73)	41 (91)

\* $P<0.05$ .

**TABLE II** COMPARISON OF CHILD'S EMOTIONAL MANIFESTATION SCALE (CEMS) SCORES IN THE TWO GROUP

	Maternal voice group (n=45)	Control group (n=45)	P value
Facial expression	3 (1.1)	3.6 (1.4)	0.02
Vocalization	2.7 (1.2)	3.4 (1.3)	0.01
Activity	2.1 (1.0)	2.8 (1.2)	0.01
Interaction	2.7 (1.2)	3.2 (1.2)	0.01
Level of cooperation	2.4 (0.8)	2.9 (.02)	0.01
Total	13.2 (4.6)	16 (5.6)	0.01

Values in mean (SD).

of sedatives did not differ in two groups. This may be related to more number of therapeutic catheterizations in the maternal voice group. This is similar to the study by Kim, *et al.* [9] and colleagues while studying the effect of recorded maternal voice on perioperative anxiety in children. In their study maternal voice resulted in lower anxiety scores but did not result in reduction in the requirement of injection Ketamine [9]. During therapeutic procedures pediatric cardiologists tend to use more sedation to minimize unwanted movement of the child. This, however, is unlikely to affect CMES assessment as it was based on the child's behavior during first 15 minutes of the cardiac catheterization when majority of patients have not received top-up sedatives. Similar to the findings of Ozcetin, *et al.* [12] maternal voice did not change heart rate and respiratory rate of children in our study.

CEMS is a simple, reproducible and objective tool but overall evaluation in individual sectors is subjective [11]. The operators assessing child's cooperation were blinded to the randomization and therefore, the CEMS scores are unlikely to reflect bias. CEMS assessment was performed only once, although the child's cooperation varied throughout the procedure.

In conclusion, in this randomized trial involving children with CHD undergoing cardiac catheterization, use of recorded maternal voice achieved better cooperation of children than standard patient care in catheterization laboratory. This practice is expected to make cardiac catheterization more acceptable to children with CHD in addition to improving the yield of cardiac catheterization.

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**WHAT IS ALREADY KNOWN?**

- Use of distraction techniques improve child's cooperation during invasive procedures.

**WHAT THIS STUDY ADDS?**

- Recorded maternal voice improves child's cooperation during cardiac catheterization.

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