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The Effectiveness of Mother's Recorded Voice on the Pain and Anxiety in Pediatric Undergoing Surgery: A Randomized Clinical Trial Study

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Abstract

Background

Pain and anxiety are the common complications following surgery. The mother's recorded voice can be used to reduce the pain and anxiety. Current research aimed to investigate the effectiveness of the mother's recorded voice on the preoperative anxiety and postoperative pain in children undergoing surgery.

Materials and Methods: This clinical trial study was performed in two groups in the Ali Ebn Abitalib Hospital in Zahedan, Iran in 2019. Eighty children were selected using convenience sampling method and were randomly assigned into intervention group (n=40), and control group (n=40). In the intervention group, the mother's recorded voice was played through the TSCO TH 5335 wireless headphones for 10 min to the child. Anxiety was assessed by modified mYPAS. The pain was assessed 30 min after surgery by the FLACC and one hour after operation by TPPPS. Data were analyzed using software version 22.0.

Results: The mean anxiety in the intervention group after playing mother's voice (52.82 ± 6.90) was significantly lower than before playing the mother's voice (57.12 ± 6.59), (P <0.001). The mean pain 30 min after surgery in intervention group (2.35 ± 1.09) was significantly lower than that in control group (4.9 ± 0.81), (P <0.001). Also, the mean of pain one hour after surgery in the intervention group (2.72 ± 0.716) was significantly lower than that in the control group (4.42 ± 0.675), (P <0.001).

Conclusion

The results suggest that the mother's recorded voice reduced the anxiety before surgery and pain after surgery in children; therefore, we propose that nurses can use the mother's recorded voice to control the pain and anxiety in children.

Key Words: Anxiety, Mother, Pain, Pediatrics, Surgery, Voice.

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1- INTRODUCTION

Surgery is an adverse event, accompanied by adverse effects in children which will threaten their life (1, 2). Each year, approximately 3.3 million children are hospitalized in the United States for surgery (3, 4). Children undergoing surgery usually experience significant anxiety (5, 6). Anxiety increases in the surgical waiting room and before induction of anesthesia (7). Anxiety is the body's natural response to surgical stress (8). It is estimated that between 40–60% of children experience severe anxiety prior to undergoing surgery (2, 9). The level of preoperative anxiety may increase the duration of anesthesia (9). The inability to control anxiety may lead to maladaptive behaviors including general anxiety, regressive behaviors, crying, and bedwetting (10-12).

Sympathetic responses increase in anxious children and they receive more pain (5). 80% of patients who undergo surgery experience acute post-operative pain (1, 13-15). Complications of the postoperative pain include sympathetic nervous system activation, increased blood coagulation, and increased respiration rate (16, 17). Uncontrolled pain may contribute to maladaptive behaviors, increased costs, and have a negative impact on mental health (17, 18).

Careful consideration needs to be given to reduce a child's level of pain during care (19). Opioid analgesics are used to relieve the post-surgical pain (16). Opioids can lead to tolerance or withdrawal syndrome. Because of the complications of these drugs and their effects on the central nervous system, they are less commonly used (20). Nowadays, non-pharmacological techniques are used to reduce pain because they are simple, safe and effective interventions (18). Today, music therapy has been applied in many areas of medical science (21). Researchers report that vocal stimulation has analgesic and sedative effects on patients. Music can improve feelings of happiness and well-being (22). The mother's voice is considered as one of the powerful auditory stimuli which can activate certain areas in the brain (23). Maternal voice plays an important role in a child's brain and contributes greatly to several aspects of his/her development. The mother's voice leads to increasing the auditory attention and language development in child (24). Mother's voice increases brain cortical activity compared to hearing the voice of an unknown female and children exhibit intense neurotic reactions to the maternal voice (25). The mother's voice can be effective in decreasing unstable vital signs, the improvement of physiologic performance, and neural-behavioral development in neonates. Newborns exposed to the maternal voice showed a significant decrease in heart rate, and reduced apnea (20, 26).

Azarmnejad et al. (2015) found that mother's voice reduced the arterial blood sampling induced pain in neonates (20). Da Silva et al. (2017) found that listening to a mother's recorded voice can improve a child's cooperation during the cardiac catheterization (27). Kim et al. (2010) demonstrated that infants' anxiety before cardiac catheterization can be controlled by listening to recordings of their mother's voice (28). Considering the importance of mother's recorded voice and its effect on the pain and anxiety in pediatric undergoing surgery, and emphasizing a positive mother-child relationship, this study was conducted to investigate the effectiveness of the mother's recorded voice on the anxiety and pain in children undergoing surgery.

2- MATERIALS AND METHODS

2-1. Study and Samples

This clinical trial study was conducted on 80 children aged 1-6 years who were hospitalized in pediatric surgery ward of

Ali-Ebn Abi Talib Hospital of Zahedan, Iran, in 2019. The eligible subjects were selected by the convenience sampling and were randomly divided into two groups: 1. Intervention group (40 subjects), and 2. Control group (40 subjects). At first, a packet containing the group name was prepared and randomly arranged and one of the cards indicating an intervention group or a control group was assigned to either mother or child. Inclusion criteria were as follows: 1. aged 1-6 years; 2. lack of the use of anxiolytic and analgesic drugs at least two hours before and after intervention; and 3. candidate for elective lower abdominal surgery. Exclusion criteria were as follows: 1. emergency surgery; 2. a history of surgery over the past year; and 3. the presence of hearing disorders and psychiatric disorders.

Total sample size was calculated 34 per group based on the study of Babaei et al. (2016), (29) with 95% confidence interval and 90% power (10). Based on the formula ($Z_{1-\frac{\alpha}{2}}$ = 1.96, S_1 =0.5, $\overline{X_1}$=1.25, $Z_{1-\beta}$ =1.28, S_2= 1.93, $\overline{X_2}$= 2.37). To ensure the adequacy of the sample size and to consider the sample attrition in this study, 40 subjects were assigned in each group with a total of 80.

$$n = \frac{(Z_{1-\frac{\alpha}{2}}+Z_{1-\beta})^2(S_1{}^2+S_2{}^2)}{(\overline{X_1}-\overline{X_2})^2} = 34$$

2-2. Measurement

Data were collected through a demographic questionnaire, the modified Yale preoperative anxiety scale (mYPAS), the toddler-preschooler postoperative pain scale (TPPPS), and the FLACC behavioral pain scale. The demographic questionnaire included six questions (gender, age, history of hospitalization, ethnicity, birth order and maternal education). The modified Yale Preoperative Anxiety Scale (mYPAS) includes 22 items divided into five sub-scales (activity, speaking, emotional expressivity, state of arousal, and parental dependency). This scale is an observational measure, but not a self-report measure. Each of the five mYPAS sub-scales is scored with different behavioral levels related to that category. Some of mYPAS sub-scales contain four and six items, scored from 1 to 100. The level of behavior that the child has in each category is divided into the number of categories. For example, the total scores of a child who has 2 of the 5 categories, including 4 and 6 with a score of 1 in each category, is calculated as follows:

$$\text{Total adjusted score} = \frac{\left(\frac{1}{4}+\frac{1}{6}\right)*100}{2}$$

The validity and reliability of the mYPAS has been confirmed in some studies (28, 30). In Iran, Sadeghi et al. (2019), calculated the Cronbach's alpha of the mYPAS as 0.82 (30). In the present study, the inter-rater reliability was used to assess the reliability of the mYPAS. Pearson's correlation coefficient was obtained 0.71. The toddler-preschooler postoperative pain scale (TPPPS) included 7 items divided among three pain behavior categories: (1) vocal pain expression (verbal pain complaint/cry, scream, groan, moan and grunt), (2) facial pain expression (open mouth, lips pulled back at corners, squint, close eyes, furrowed forehead and brow bulge), and (3) bodily pain expression (such as restless motor behavior/rub or touch painful area). The 7 pain behavior items were scored as '1' if the behavior (s) was observed and as '0' if the behavior(s) was not observed. Scores on the scale may range from 0 to 7. In the study by Maroofi et al. (2015), the Cronbach's alpha was 0.88 (16). In the present study, the inter-rater reliability was applied to assess the reliability of TPPPS. Pearson's correlation coefficient was obtained 0.81 for reliability of the TPPPS. The Faces, Legs, Activity, Cry and Consolability (FLACC) behavioral pain scale is used to measure postoperative pain for children aged 2

months to 7 years and contains five behavioral items (face, legs, activity, cry, and consolability). This scale is scored in a range of 0–10, which are 0 = no pain, 1-3 = mild pain, 4-6 = moderate pain, and 7-10 = severe pain. In the study by Arab et al. (2015), the Cronbach's alpha of the FLACC was 0.85 (31). Babaei et al. (2016) confirmed the face and content validity of the tool (r = 0.70), (29). In the present study, the inter-rater reliability was used to assess the reliability of the FLACC. Pearson's correlation coefficient was obtained 0.79 for reliability of the FLACC.

2-3. Intervention

The present study was without blinding. So, one researcher performed interventions. The researcher selected the eligible participants from those admitted to the pediatric surgery ward of Ali-Ebn Abi Talib Hospital of Zahedan, Iran. Written and verbal mother's consent was obtained after adequate explanations to the mothers. The demographic questionnaire was completed by an interview conducted with the child's mother. An explanation for recording their sound was given to the mothers in the intervention group. In intervention group, the mother's voice was recorded in two stages; first, the recording of mother's voice to reduce the pre-surgery anxiety and in the second stage, it was recorded to relieve post-surgery pain.

On the request of the child or his / her mother, the recorded voice content was determined to be poetry, prayer, storytelling or ordinary conversation in order to reduce the child's anxiety. Then, a written text was given to the mother to read her own voice for the child's postoperative pain relief. The content of the text is as follows: "Call the child's name and open your eyes, your operation went very well. Everyone here is so kind and wants to help you get well soon". To assess a child's hearing status, the researcher spoke with him/her at a close distance. The recording of maternal voice was done on the smartphone (LG G4 Stylus) using the voice recorder software. The researcher before sound recording tested the voice recorder. The time of recording of mother's voice was when she had no anxiety about their child's surgery.

The recording of mother's voice was performed in a quiet room for 5 to 10 minutes. The mother was assured that her voice would remain confidential, and it would be deleted after the end of the study. Before playing the mother's voice for the child, the mother's voice was set to normal speech levels (50 to 60 dB) using the Sound Meter PRO installed on the Android device. The mother's recorded voice was played in two stages; first, when the child entered the operating room and in the second stage, after the surgery was completed through the TSCO TH 5335 wireless headphones. Child anxiety was assessed in two stages.

The first stage, the time the child entered the operating room before the playing of the mother's voice and the second stage, 15 minutes after playing the mother's voice using the mYPAS Questionnaire by researcher. The researcher used the FLACC 30 min after the end of the surgery in the recovery room (based on the study of Byun et al. (2018) (23), and after gaining partial consciousness; after the mother's voice was played for the second time pain level was measured. In addition, one hour after the surgery, while the child was present in the pediatric surgical ward, and once the child's condition was stabilized, pain level was measured using the TPPPS according to study of Pouy et al. (2017), (32). The control group did not receive any intervention except routine care. Postoperative anxiety and pain were assessed at specified times in control group as performed in the intervention group.

2-4. Ethical Considerations

The study protocol was approved by the Ethics Committee of Zahedan University of Medical Sciences (IRCT Code: 20181214041960N1), and ethical Code: (IR.ZAUMS.REC.1397.342). Informed consent was obtained verbally and in written form from the mothers.

2-5. Statistical Analysis

Data were analyzed using SPSS software version 22.0 (SPSS, USA, IBM), and by using independent t-test, chi-square test and paired t-test. Chi-square test was used to assess the demographic qualitative variables. T-test was used to compare the mean scores of pain and anxiety in each group and between the two groups before and after the intervention. Significance levels in this study were less than 0.05.

3- RESULTS

3-1. Demographic Characteristics

Our findings showed that the mean age of children was (4.08 ± 1.26) in the intervention group and (4.10± 1.46) in the control. **Table.1** shows the study variables in the two groups. No statistically significant differences were observed between the two groups in terms of demographic characteristics (P> 0.05).

Table-1: The Main Characteristics Studied in Both Groups.

Variables	Intervention group, n=40	Control group, n= 40	P-value
Age (Mean ± SD)	4.08±1.26	4.10±1.46	0.93 †
Gender			0.74 ‡
Girl	5 (12.5)	6 (15)	
Boy	35 (87.5)	34 (85)	
Birth order			0.74 †
1-2	23 (57.5)	24 (60)	
3-4	17 (42.5)	22 (55)	
Ethnicity			0.26 ‡
Baloch	23 (57.5)	18 (45)	
Fars	17 (42.5)	22 (55)	
Educational level of mother			0.62 ‡
Primary school	4(10)	5(12.5)	
Secondary school	15(37.5)	11(27.5)	
High school and university	21(52.5)	24(60)	

† t-test. ‡ Chi-square test. SD: Standard deviation.

3-2. Anxiety before Operation

The results in **Table.2** indicated the mean anxiety in the intervention group after playing mother's voice (52.82 ± 6.90) was significantly lower than before playing the mother's voice (57.12 ± 6.59) (P <0.001). While in the control group, mean anxiety after the care (57.84±6.10) was significantly increased to before the care (56.10±6.03). Independent t-test revealed that there was a significant difference between the intervention and control groups in terms of the mean anxiety scores following surgery and after playing mother's voice (P <0.001). The results also showed that the change in mean anxiety following surgery in the intervention group (4.3 ± 3.44) was significantly higher than that in the control group (-1.74 ±2.85), (P <0.001).

3-3. Pain after surgery

As can be seen from **Table.3**, results of pain 30 min after surgery by FLACC indicated that the mean pain in intervention group (2.35 ± 1.09) was

significantly lower than that in control group (4.9 ± 0.81) (P=0.001). Moreover, results of pain one hour after surgery by TPPPS indicated that the mean pain in the intervention group (2.72 ± 0.716) was significantly lower than that in the control group (4.42 ± 0.675), (P <0.001).

Table-2: Changes of the Mean in Anxiety before Operation in Both Groups.

Anxiety	Before intervention	After intervention	Changes of mean	P-value (Paired-test)
	Mean ± SD	Mean ± SD	Mean ± SD	
Intervention group	57.12 ±6.52	52.82±6.90	4.3±3.44	t= 7.89 df= 39‡ P=0.0001*
Control group	56.1± 6.03	57.84±6.10	-1.74±2.85	t=-3.8 df=39‡ P=0.0001*
P (t-Test) †	t=0.72 df=78‡ P=0.47	t=-3.44 df=39‡ P=0.0001*	t=4.1 df=78 P=0.0001*	

† Independent sample t-test. ‡ Degrees of freedom. * P< 0.05. SD: Standard deviation.

Table-3: The Mean in Pain after Operation in Both Groups.

Pain	Intervention group	Control group	P-value (t-Test) †
	Mean ± SD	Mean ± SD	
Pain 30 minutes after operation by FLACC	2.35±1.09	4.9±0.81	t=-11.812 df =78 ‡ P=0.0001*
Pain 1 hour after operation by TPPPS	2.72±0.716	4.42±0.675	t=-10.928 df =78 ‡ P=0.0001*

† Independent sample t-test. ‡ Degrees of freedom. * P< 0.05. SD: Standard deviation. FLACC: Faces, Legs, Activity, Cry and Consolability.

4- DISCUSSION

The aim of this study was to investigate the effectiveness of the mother's recorded voice on pain and anxiety in children undergoing surgery. Our findings showed that no statistically significant difference was observed in mean anxiety between the intervention and control groups before the intervention, but there was significant difference between the two groups after the intervention. Furthermore, the mean pain in the intervention group was significantly different from that in the control group, this indicates that listening to a mother's voice could be effective in reducing preoperative anxiety and postoperative pain in children. Researchers have made significant findings about the effectiveness of mother's recorded voice on the reduction of anxiety in children (23, 28). Byun et al. (2018) concluded that children who listened to mothers' voices in the intervention group experienced less anxiety and less pain compared to those who listened to the voice of an unknown female, and control group. Byun et al. (2018) wrote that children who listened to their mother's voice were intubated for significantly shorter periods and opened their eyes sooner than cases that listened to the voice of an unknown female (23). Some studies have been conducted to investigate the effect of parental presence on the preoperative anxiety of children (23), but parental presence in the operating room is not possible in all cities with different cultures. Parents' anxiety

can be transmitted to their children in the operating room, and parental presence during anesthesia induction can increase anxiety in the surgical team; therefore, the recording of the mother's voice when the mother is not anxious and playing it in the operating room can be a good solution (23). The results of a study conducted by Kim et al. (2010) showed that playing the maternal recorded voice-playing mother's voice to children reduced both children's anxiety in the operating room and the duration of recovery, but had no effect on consumption of ketamine. Kim et al. (2010) reported that the mother's recorded voice made mothers feel that they were involved in the medical care process for their child and also the mother's recorded voice reduced anxiety in the waiting room but did not affect mother's anxiety after their child's surgery (28). The findings of the study of Da Silva et al. (2017) revealed that after playing mother's voice during cardiac catheterization, the mean anxiety in intervention group was lower than the control group, but had no effect on the volume of anesthetic agent (27).

Most studies have examined the effect of maternal recorded voice on neonates. Considering that newborns have spent less time with their mothers compared to children, it is expected that children are more sensitive to hearing their mother's voice compared to neonates. Regarding the effect of mother's recorded voice on reduced post-operative pain in children, our study results are consistent with previous studies (20, 27, 29). The results of these studies (27, 28) show that distraction techniques like vocal stimulation can be utilized in the waiting room to reduce children's anxiety. The results of the study of Babaei et al. (2016) showed that the mean of pain in children who listened to their mother's voice was significantly different than control group (29). Azarmnejad et al. (2015) investigated the effect of mother's recorded voice on arterial blood sampling induced pain in neonates. The results of their study indicated that listening to mother's voice reduced the arterial blood sampling induced pain in neonates (20).

4-1. Study Limitations

The limitations in this study were as follows: (1) the lack of cooperation of some children in placing the headphone on their ears, and (2) the presence of environmental factors during recording of the mothers' voice, which led to a decrease in the quality of the mother recorded voice.

5- CONCLUSION

The findings of the present study demonstrated that listening to a mother's recorded voice for 5-10 minutes could be effective in reducing preoperative anxiety and 30 minutes and 1 hour postoperative pain. Nurses as members of the healthcare team, can use vocal stimulation with the mother's voice as a non-pharmacological method and it is cost-effective for children. It is recommended that a safe environment be provided for children in the waiting room and it seems that the audiovisual distraction may have a positive effect on children's anxiety.

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7- CONFLICT OF INTEREST: None.

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