Not All Sounds Have Negative Effects on Children Undergoing Cardiac Surgery

Sayed Kaoud Abd-Elshafy, MD,* Ghada Shalaby Khalaf,† Mohamed Zackareia Abo-Kerisha,‡ Nadia Taha Ahmed,§ Mervat Anwer Abd El-Aziz,† and Mona Aly Mohamed†

Objective: **This study was designed to evaluate the role of music therapy on the level of stress in children undergoing repair of congenital heart disease.**

Design: **Prospective, randomized, double-blind, controlled clinical trial.**

Setting: **Children's university hospital.**

Participants: **Fifty children aged 4 to 12 years undergoing repair of congenital heart disease.**

Interventions: **Patients were randomized into 2 equal groups (control group and music group); in the control group, patients listened to a blank CD, and in the music group, patients listened to a recorded CD of music and songs preferred by the child. Demographic data, clinical data, and preoperative vital signs were recorded. Baseline stress markers (blood glucose and cortisol levels) were sampled. Patients were assessed intraoperatively until extubation for vital signs and stress markers and after extubation for pain and sedation scales. An interview was conducted within the first postoperative week with the patients and their parents for assessment of post-traumatic stress disorder and negative postoperative behavior changes.**

Measurements and Main Results: **There were no significant differences in demographic characteristics, clinical data, vital signs, preoperative and at-extubation blood glucose levels, and preoperative blood cortisol levels between groups. Significant differences were found between groups in blood glucose levels and cortisol levels at all intraoperative times, but only in cortisol blood levels at extubation. Significant differences were found in pain score, sedation score, occurrence of child post-traumatic stress disorder, and occurrence of negative postoperative behavior.**

Conclusion: **Listening to favorable music by children undergoing repair for congenital heart disease resulted in less stress and more relaxation.**

KEY WORDS: children, congenital heart disease, music, cortisol, stress, behavior

CARDIAC SURGERY is a common interventional procedure for ischemic, valvular, and congenital heart disease (CHD). Cardiac surgery is accompanied by postoperative pain and anxiety. The use of music therapy has been shown to reduce pain, anxiety, and physiologic parameters in patients having surgical procedures.[1] The stress response during surgery is an unconscious systemic reaction to tissue injury that reflects autonomic, hormonal, and metabolic changes.[2] It long has been recognized that surgery can be a very stressful experience for children. In fact, this phenomenon has piqued the interest of clinical researchers for more than 60 years.[3] Physiologically extreme stress response causse the release of catecholamines, which, in turn, cause impaired cellular metabolism, myocardial irritation, ischemia, and global increase in oxygen consumption.[4] Psychological or neurologic alterations often are observed in patients after cardiac surgery. Children exposed to traumatic events can develop post-traumatic stress disorder (PTSD).[5,6] Over the past few decades, there has been a growing interest in the use of music to relieve pain and improve (balance) some physiologic parameters, such as blood pressure, heart rate, respiratory rate, and oxygen saturation in the postoperative period.[7] Music can be used therapeutically as an independent event or in combination with other therapeutic elements of relaxation.[8] Also, music has an analgesic effect,[9] makes patients relaxed,[10] and directs attention away from negative experience, thus helping patients cope with emotional stress.[11] The purpose of this study was to assess the effect of music therapy on physiologic and psychosocial behaviors of children undergoing repair of congenital heart disease.

MATERIALS AND METHODS

Written informed consent was obtained from all parents of the children undergoing cardiac surgery. Consent was given after a detailed description of the study was discussed with the parents and their children. The study was approved by the research ethics board of Assiut University hospitals.

Fifty patients aged 4 to 12 years were allocated randomly into 2 equal groups (control group and music group) by using computer-generated random numbers contained in an opaque sealed envelope. Patients with previous cardiac surgery, diabetes mellitus, hearing impairment, and psychiatric or neurologic illness were excluded from this study. Blood samples for assessment of baseline stress markers (blood glucose and plasma cortisol) were taken the morning before scheduled surgery. One researcher interviewed the patients and their parents before surgery; he collected the questionnaire regarding sociodemographic characteristics (age, sex, weight, and height), patient's clinical data (medical diagnosis and American Society of Anesthesiologists physical status), and vital signs (blood pressure, heart rate, oxygen saturation on room air, and temperature). In addition, the researcher asked the patients and their parents about the most popular songs or music that the child loved, including its tone and intensity. The preferred songs or music (commercially available) were

*From the *Anesthesia and Intensive Care Department, Faculty of Medicine; †Critical Care Nursing Department, Department of Nursing; ‡Clinical Pathology Department, Faculty of Medicine; and §Critical Care and Emergency Nursing Department; Faculty of Nursing, Assiut University, Hospital, Assiut Egypt.*

Address reprint requests to Sayed Kaoud Abd-Elshafy, MD, Department of Anesthesia and Intensive Care, Faculty of Medicine, Assiut University Hospital, Assiut 74111, Egypt. E-mail: sayed_k_72@yahoo.com and sayed.k.72@gmail.com

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recorded by the child to be used during the intraoperative and postoperative period until extubation in the music group.

On the morning of surgery (all patients were on the morning schedule), a nurse anesthetist (second observer), who was unaware of the preoperative interview and would not be observing the patients, opened the closed envelope before the surgery to know the group randomization; and a CD player was connected to the patient's ears before induction of anesthesia and continued during the intraoperative and postoperative periods until extubation. Patients in the music group listened to the recorded music and songs CD, and patients in the control group listened to a blank CD.

Standard anesthetic technique was used, in the form of standardized premedication with 0.5 mg/kg of oral midazolam and 10 μg/kg of atropine. Anesthesia was induced with sevoflurane plus fentanyl, 5.0 μg/kg, and cisatracurium, 0.1 mg/kg, and maintained with sevoflurane, fentanyl, 1.0 μg/kg/h, and cisatracurium, 0.05 μg/kg/dose. Electrocardiogram, invasive blood pressure, heart rate, temperature, oxygen saturation, exhaled CO_2 (end-tidal capnography), and train-of-4 of peripheral nerve stimulator for muscle relaxation monitoring were monitored continuously during the procedure. Management strategy of cardiopulmonary bypass (CPB) was standardized for all patients in each group. The CPB circuit was primed with mannitol, sodium bicarbonate, and packed red cells to obtain a hematocrit of 26%. Heparin, 400 IU/kg, was given to the patient, and once activated clotting time reached $\geq$450 seconds, CPB was initiated. The aorta was clamped, and cold blood cardioplegia was administered into the aortic root and the patient cooled to 30°C to 32°C. The cardioplegia solution was repeated every 20 minutes. The alpha-stat method of acid-base management was used. A mean arterial pressure was maintained between 30 to 60 mmHg during CPB. At the end of the intracardiac procedure, rewarming was started, the aortic cross-clamp was removed, and if spontaneous normal sinus rhythm was not present, pacing or defibrillation was performed depending on heart rate and rhythm. Ventilation was started, hemodynamics and arterial blood gases were stabilized, and patients were weaned from CPB at 37°C. Protamine was administered to reverse heparin in a dose of 1 mg of protamine for every 100 IU of heparin. Intraoperatively, the patients were assessed for vital signs and stress markers (blood glucose and plasma cortisol levels) at sternotomy, after 10 minutes of cross-clamping during CPB, and during rewarming. Intraoperative times (ischemic time, total CPB time, and duration of surgery) were recorded.

After the end of the surgery, the patients were transported to the intensive care unit (ICU). The criteria for extubation were the standards for postoperative cardiac patients, including adequate level of consciousness, hemodynamic stability, absence of arrhythmias, adequate airway reflexes, normothermia, acceptable mediastinal drainage blood loss, and acceptable blood gas analysis (appropriate for specific congenital heart defect lesion). Fentanyl infusion (0.5 μg/kg/h) continued until endotracheal extubation. Continuous blood glucose monitoring was used in both groups with no set target range for blood glucose management; patients were treated according to the preference of the attending cardiac intensivist. Grading of blood glucose (normal, prediabetes, and diabetes) was done according to the American Diabetes Association's standards.[12] The patients were assessed postoperatively for their vital signs (immediately at arrival in the ICU and immediately after extubation). Stress markers were assessed immediately after extubation from mechanical ventilation. After extubation, the patients were assessed for pain by the objective pain scale;[13] intravenous paracetamol (15 mg/kg) per dose was used as rescue analgesia if the objective pain scale was >4 (Appendix 1). Also, after extubation, the patients were assessed for sedation by using the Richmond Agitation Sedation Scale (Appendix 2).[14] An interview was conducted with the patients and their parents within the first postoperative week by a researcher blinded to the group randomization and using a PTSD (Appendix 3) and posthospital behavior questionnaire (Appendix 4).

The primary outcomes were plasma cortisol and blood glucose level measurements, and secondary outcomes were pain and sedation assessment, PTSD and posthospital behavior questionnaire, vital signs, duration of mechanical ventilation, the length of stay in the cardiac ICU, and the length of stay in the hospital.

Based on the preliminary study, a power analysis was done to find a sufficient sample size to determine a significant difference in plasma cortisol and blood glucose levels by using an alpha value of 0.05 and a power of 80%. This established that a sample size of 24 patients was adequate per group, so 25 patients were enrolled in each group.

STATISTICAL ANALYSIS

Data were computerized and analyzed using the SPSS (SPSS 16.0 software, Chicago, IL) computer program. The normality of the data was assessed by Kolmogorov-Smirnov test. Data are presented as mean ± SD or numbers and percentages when appropriate. Comparison between groups was by Student's *t*-test or Mann-Whitney U test when appropriate. Fischer's exact test of χ^2 test was used to assess group differences for categoric variables; $p < 0.05$ was considered significant.

RESULTS

Patients' general characteristics and different intraoperative times were summarized in Table 1; there were no statistically significant differences between groups. There also were no statistically significant differences between the control and music groups regarding mean blood pressure, heart rate, SPO_2, and temperature (Table 2). There were statistically significant differences in plasma cortisol levels between groups at sternotomy, at cross-clamping, at rewarming, and at extubation; not at preoperative baseline readings (Table 3). Serum glucose level preoperatively and at extubation showed no statistically significant differences between groups, but significant statistical differences at sternotomy, at cross-clamping, and at rewarming (Table 4). Sedation scale at extubation found that a high percentage of patients (13 [52%]) in the music group were restless; whereas, in the control group, results showed that most patients (21 [84%]) were agitated and combative, with statistically significant difference when comparing the control group with the music group (Table 5). The number of patients with a