Biological Research for Nursing - Decision on Manuscript ID BRN-ROR-10-02-0007 Title: Evidence that Music Listening Reduces Preoperative Patients' Anxiety

Abstract

Background. Preoperatively, patients often exhibit fear and anxiety that may influence the process of induction and recovery from anesthesia. Music is thought to be an alternative to medication for relief of fear and anxiety.

Objectives.

The purpose of the present study was to explore the feasibility of using heart rate variability for evaluating the efficacy of music listening to relieve the patients' anxiety during their stay in the waiting area of the operation room and to compare the HRV measures with subjective visual analogue scale (VAS) scores.

Methods. In total, 140 patients were randomly assigned to the experimental group (n=64) or control group (n=76). The intervention consisted of a 10-min period of exposure to relaxing music delivered through headphones. Anxiety levels were measured by the VAS (a ten-point scale) and 5 min of monitoring of HRV before and after the music intervention.

Results. The music group demonstrated significant reductions in VAS scores, mean heart rate, low-frequency HRV, and low- to high-frequency ratio, and an increase in high-frequency HRV, while patients in the control group showed no changes. Listening to music before surgery can lower patients' anxiety levels, and the subjective results of patient's VAS anxiety scores were consistent with the objective results of HRV parameters.

Conclusions. Listening to music can significantly lower the anxiety levels of patients before surgery. The frequency-domain parameters of HRV can be indicators for monitoring the change in anxiety level of preoperative patients.

Key words: heart rate variability, music listening, preoperative anxiety

Introduction

Every year, 3.5 million patients receive surgery in Taiwan (Department of Health, 2009). The most common emotion felt by patients before surgery is anxiety about the unknown (Leach, Zernike, & Tanner, 2000; Rosén, Svensson, & Nillson, 2008). An unfamiliar environment, dependence on strangers, separation from family and friends (Gillen, Biley, & Allen, 2008), a perceived or actual physical risk, possible postoperative complications, and even the threat of death are factors that may cause patients to feel anxious in the waiting area before surgery (Mitchell, 2003). The waiting period is also the time during which patients are most likely to imagine any potential danger they may face (Cooke, Chaboyer, Schluter, & Hiratos, 2005; Haun, Mainous, & Looney, 2001). To date there has been little research conducted with the Taiwanese on their propensity to preoperative anxiety.

Anxiety can affect an individual's cognitive abilities and cause both mental and physical discomfort (Vaughn, Wichowski, & Bosworth, 2007). This, in turn, can increase postoperative pain, prolong postoperative recovery, and increase analgesic requirements. (Ozalp, Sarioglu, Tuncel, Aslan, & Kadiogullari, 2003; Katz et al., 2005; Rosén et al., 2008). Even though doctors usually provide prescribed anxiolytics or sedatives for patients, most patients still feel anxious (Duggan et al., 2002).

Research also indicates that patients do not want excessive medication to lower their anxiety, but would rather listen to music or read (Hyde, Bryden, & Asbury, 1998).

Music has been used since ancient times to influence human health (Nilsson, 2008). The common theory to explain the anxiety and stress-reducing effect of music is that music acts as a distracter, focusing the patient's attention away from negative stimuli to something pleasant and encouraging (Mitchell, 2003; Nilsson, 2008). Music involves patient's mind with something familiar and soothing, which allows a patient to escape into his or her "own world." Patients can focus their awareness on the music to aid relaxation. (Thorgaard et al., 2005; White, 2000; White, 2001). Research comparing music and diazepam (Berbel, Moix, & Quintana, 2007) showed that music had calming effects that could lower anxiety and relax patients before surgery. Therefore, music is an effective non-invasive method to reduce anxiety (Buffum et al., 2006; Nilsson, 2008).

Some have suggested that therapeutic music should have a slow tempo, low pitch, regular rhythm, and pleasing harmonics, and consist of string, flute, and piano selections (Nilsson, 2008; Pelletier, 2004). The genre and the duration of the soothing music did not seem to influence the effectiveness of music intervention. These results are confirmed both by a review that explored the use of music and its effect on

anxiety during short waiting periods and a Cochrane review that explored the effects of music on pain (Cooke, Chaboyer, & Hiratos, 2005).

Most of the studies measured anxiety by subjective scales, such as the State-Trait Anxiety Inventory (STAI) or visual analog scale (VAS) (Mitchell, 2003; Nilson, 2008). Their validity was limited by the clients' self-reporting ability and results were influenced by personal preference of music (Mitchell, 2003). As the medical profession has considerable concern about patient safety, effective anesthesia and what patients want, objective indicators are needed to monitor the level of anxiety in assessing and caring for patients.

In addition, though many studies showed that listening to music is effective, the physiological indicators were not consistent (Dijkstra, Pieterse, & Pruyn, 2006). Previous studies have also shown that anxiety scores were not related to blood pressure (Hamel, 2001; Yung, Chiu-Kam, Lau, & Chan, 2003), breathing (Buffum et al., 2006; Yung, Chui-Kam, French, & Chan, 2002; Taylor-Piliae, & Chair, 2002), electrodermal activity, or serum levels of cortisol and adrenaline (Wang, Kulkarni, Dolev, & Kain, 2002).

The purpose of this study was to explore the feasibility of using heart rate variability for evaluating the effects of music listening on relieving the anxiety of

patients during their stay in the waiting area of the operating theater, and to compare the HR variability measures with subjective visual analogue scale (VAS) scores.

Methods

Research Design and Setting

The present study was a randomized, clinical study that took place in the waiting area of an operating theater of a teaching hospital in northern Taiwan. There are ten rooms in this operating theater and the average number of surgeries is 1000/month. Patients are admitted to the hospital at least one day before the day of surgery. They are sent to the waiting area of the operating theater 30 min before the scheduled surgery time. Premedication will be given when they enter the operating room. The waiting room is nearly independent but not completely isolated from the nursing station. Its size is 1260 x 390 cm, and it can hold eight patients simultaneously. The temperature of the room was maintained at $19 \sim 21^{\circ}$ C.

Sampling and sample size

Patients who were sent to the waiting area between 07:00 and 16:00 were recruited for enrollment. The inclusion criteria were that the patient: (1) was conscious and aged 20~65 years, (2) had not consumed any medications for hypertension or heart disease, caffeine, sedatives, or operative premedication, (3) had not been diagnosed with hearing impairment, visual impairment, arrhythmias, or heart disease, (4) stayed at least 25 min in the waiting area, and (5) was willing to participate in the study and signed an informed consent form.

Group assignment was done by dividing subjects' by birthday according to even (experimental group) or odd days (control group). Sample size was determined by the assistance of G power software (Grant Devilly, Vistoria, Australia). We set alpha as 0.05, the effect size (t) for heart rate variability as 0.3 (small), and the power as 0.8 for our two group repeated level of two statistical procedures. A resulting sample size of 55 for both groups was obtained. Considering an attrition rate of 20% due to short stays in the waiting area, we decided on an expected sample size of 70 for both groups. <u>Intervention</u>

The patients in the experimental group listened to music via an MP3 player (Ergotech, ET-U31P, Taoyuan, Taiwan), while patients in the control group did not listen to music. Subjects were provided with a list of five kinds of music of 10 min duration to choose from. All five kinds of music were light music such as folk songs or pop music, played at a tempo of 60~80 beats per minute and a volume of 50~55 db. Measurements

In our study, we used a visual analog scale (VAS) instead of State-Trait Anxiety Inventory (STAI) which has been used in most studies of anxiety. This decision was made out of three concerns. First, the 40-item STAI takes several minutes to fill out.

This could cause unnecessary strain for patients waiting for surgery in the waiting area of the operating room and could make them more nervous. On the other hand, the VAS takes only five seconds for a patient to express his/her anxiety level. Second, a patient can remain lying down and still respond to the VAS, while the patient might need to change his/her posture to fill out the STAI questionnaire. Third, the VAS was routinely used in this hospital for pain and anxiety assessment. Subjects were used to responding to it.

The VAS is a ten-centimeter horizontal line marked by vertical lines at onecentimeter intervals to construct a scale. To use in measuring anxiety, subjects were asked to say a number or indicate with their finger to give the score from 0 (calm) to 10 (very anxious). It was reported that the VAS was significantly correlated with hospital anxiety (r= 0.28) (Ledowski, Bein, Hanss, Tonner, Roller, & Scholz, 2005) and STAI (r=0.5-0.6) (Abdul-Latif, Putland, McCluskey, Meadows, & Remington, 2001; Clan, 2004).

Heart rate was measured by a CheckMyHeart handheld HRV device (DailyCare BioMedical, Chungli, Taiwan). It is a handheld limb lead EKG (lead I) recorder with HR variability analytical software. To measure HR, the researchers placed the sensor on the radial area of the patient's forearm for 5 min. Participants were asked not to move around to ensure the quality of the readings. According to the user's manual, the CheckMyHeart is CE certified (Conformite Europeenne) and has passed electromagnetic interference and compatibility tests. Its sampling frequency is 250 samples/sec. The measurement heart rate range is 45-186 bpm and ST segment -3 to +3 mm, and operates stably at temperature of 50°F-104°F (10°C-40°C) and humidity of 25%-95%. It has been used in previous clinical studies of HR variability (Peng, Koo, & Yu, 2009; Wen, Chung-Kwe, Yang, & Yang, 2007).

The heart rate data was analyzed by the CheckMyHeart software and provided parameters of heart rate variability. In the time-domain analysis, the original normalto-normal intervals (NNIs) were subjected to a statistical analysis, and the variables included the mean of the NNIs (mean NNI), the standard deviation of the NNIs (SDNN), and the root mean square of successive differences in the NNIs (rMSSD). Prior literature has established that when an individual feels anxiety or pressure, these indicators decrease (Malik et al. 1996).

In the frequency-domain, a power spectral density analysis was utilized to analyze the distribution of HR variability at different frequencies. The total power is a short-term estimate of the total power of the spectral density in the range of frequencies between 0 and 0.4 Hz representing the overall activity of the autonomic nervous system (ANS). Very low frequencies (VLFs; frequencies between 0.0033 and 0.04 Hz) reflect the overall activity of slow mechanisms of sympathetic function. Low frequencies (LFs; frequencies between 0.04 and 0.15 Hz) reflect mixed sympathetic and parasympathetic activities. High frequencies (HFs; frequencies between 0.15 and 0.4 Hz) reflect parasympathetic activity. Deep, even breathing activates the parasympathetic and raises the HF amplitude (Malik et al. 1996; Musselman, Evans, & Nemeroff, 1998; Niskanen, Tarvainen, Ranta-aho, & Karjalainen, 2004). High values of the low-to high (LF/HF) ratio indicate a dominance of sympathetic activity while low values indicate a dominance of parasympathetic activity. Activation of the sympathetic nerves, as happens in anxiety, can cause the HR to increase, total power and high frequencies to decrease, and low frequencies and the low-to-high ratio to increase (Kamath & Fallen, 1993).

Data Collection Process

The research was approved by the Institutional Review Board of the study setting (approved code: CRC-03-09-07). The researcher (KJL) checked the operating schedule and met the potential participants in the waiting area of the operating theater. After an eligible participant entered the waiting room, the researcher explained the purpose and process of the study, helped the patient fill out a consent form, let the patient lie down on the gurney, and closed the curtains. After 5 min of rest, the VAS and 5-min HR were measured. Then, subjects of the experimental group listened to a 10-min session of music through headphones. Another VAS and 5-min HR were measured after the music session was finished. Subjects in the control group received the VAS and heart rate measurements by the researcher at a 10-min interval without a music intervention.

Statistical Analysis

Data was first examined for completeness. Incomplete data or data with too many noise signals were deleted for data processing. Data analysis was performed with SPSS 15.0 (SPSS, Chicago, IL). The major statistical procedures applied were descriptive statistics, the Chi-squared test, independent Student's *t*-test, and paired *t*test. If data was not normally distributed, nonparametric statistical procedure was applied. A value of p < 0.05 was taken as statistically significant.

Results

Between September and November 2009, 185 patients were contacted and 161 were enrolled in the study. Of these, six were unable to complete the study because they were sent to the operating suite before the 10-min of music or rest was finished, four refused the second measurement, and 11 were deleted due to poor EKG recording (incomplete or too many noise signals). Finally, there were 76 and 64 subjects in experimental group and control group, respectively, that provided useful data for statistical processing. The participation process is presented in Figure 1. There were no significant differences between the experimental and control group in terms of demographics. The average waiting time for the 140 participants was 27 min. Seventy percent to 80% of patients received general anesthesia, and 11%~15% underwent spinal anesthesia. The majority of subjects received obstetric and gynecological surgery, followed by orthopedic surgery. There were no significant differences between the two groups in age, gender, waiting time, methods of anesthesia, or types of surgery (Table 1).

Pre-surgical Anxiety

The VAS scores in both groups before and after music intervention are listed in Table 2, and the HR variability (HRV) data in both groups before and after music intervention is listed in Table 3.

According to the VAS scores, the initial mean anxiety level of all participants was 3.4 ± 2.7 . The mean anxiety levels of the experimental and control groups were 3.5 ± 2.9 and 3.2 ± 2.5 , respectively, and the difference was not significant (t=.61, p=.54, see Table 2). The mean HR of the subjects was 72.7 ± 11.6 beats/min (bpm). There were no significant differences in mean HR, mean NNI, SDNN, rMSSD, total power, %LF, %HF, or the LF/HF ratio between the two groups (Table 3).

The Effect of Music on Anxiety Levels

The VAS scores in both groups before and after music intervention are listed in Table 2. After listening to music, the mean VAS scores of the experimental group was decreased and the difference was statistically significant (3.5 ± 2.9 vs. 2.8 ± 2.3 , p < 0.001). Comparing the VAS score changes in the control group, the difference was not statistically significant (3.2 ± 2.5 vs. 3.3 ± 2.4 , p > 0.05).

The HR variability (HRV) data in both groups before and after music intervention are listed in Table 3. After listening to music, the heart rate of the experimental group was also decreased and the difference was statistically significant (73.1±10.7 vs. 72±10.6 bpm, p < 0.001). In terms of HRV parameters, the mean NNI significantly increased (p < 0.001), while SDNN, and rMSSD did not exhibit significant changes. Percent of low frequency (%LF) and the low-to-high ratio became significantly smaller after listening to music (p < 0.001), the percent of high frequency (%HF) showed a significant increase (39.5±17.3 vs. 46.1±19.3, p < 0.001), while the total power did not exhibit a significant change. Compared to changes in HRV data at 10-min intervals in the control group, none of the differences were statistically significant (p>.05).

Table 4 shows the changes between the pre- and post-test measures of the experimental and control groups. The mean difference in the VAS scores for the experimental and control groups were -0.72 ± 0.91 and 0.13 ± 0.95 , respectively. The

difference was statistically significant (p < 0.001). Additionally, the decrease in the HR was significantly greater in the experimental group ($1.1\pm2.3 \text{ vs}.0.3\pm1.5 \text{ bpm}$, p = 0.02). In terms of HRV parameters, the change in the mean NNI for the experimental group was significantly higher than that of the control group (p = 0.046). However, changes in the other parameters, including SDNN and rMSSD were not significant. Changes in the total power and low-to-high ratio were not significant between the two groups, but changes in %LFs and %HFs were (Table 4). Taken together, the change in anxiety levels measured by both the subjective and objective indicators in the experimental group between the pre- and post-test periods were significantly higher than those of the control group.

The Influence of Personal Differences on the Effect of Listening to Music

In the music intervention group, personal differences on the pre- and post-test mean difference in anxiety scores were examined. The results showed that no demographic background factor such as age, gender, anesthesia type, surgery type, or surgical experience had a significant influence on changes in anxiety level.

Discussion

In this study, the VAS level of the experimental group was reduced after the musical intervention, while the control group did not exhibit a significant change

(Table 2). The mean difference in the VAS score for the experimental group was significantly greater than that of the control group (Table 4). This finding was consistent with previous findings (Gillen et al., 2008), demonstrating the anxietyrelieving effect of music intervention on pre-surgical patients in waiting area of operating theater.

The anxiety-reliving effect was also reflected in the change in heart rates and part of heart rate variability parameters (Table 3, 4). The HR of the experimental group had significantly decreased after the music intervention. The mean difference in the HR in the experimental group was also significantly greater than that of the control group (p < 0.02). This was consistent with findings of past studies (Bringman, Giesecke, Thorne, & Bringman, 2009; Yung et al., 2003).

In our frequency-domain parameters of HR variability, low frequency and the low-to-high ratio of the experimental group showed significant decreases after the musical intervention, while the high frequency exhibited a significant increase (Table 3). Sheps and Sheffield (2001) stated that anxiety increases the activity of sympathetic nerves and decreases the activity of parasympathetic nerves, resulting in increased low frequency HR variability and lowered high frequency HR variability. Thus our findings indicate decreased activity of sympathetic nerves and increased activity of parasympathetic nerves after listening to music. In contrast, the HR variability parameters in the control group showed no significant changes (Table 3).

Chiu, Lin, Kuo, Chiang, and Hsu (2003) used an HRV analysis to evaluate the anxiety of 68 pre-procedure subjects, and found that low frequency and the low-tohigh ratio significantly decreased in patients who received music therapy. They also found that the HFs significantly increased, consistent with our findings. Ledowski et al. (2005) compared the anxiety level of 50 patients waiting for surgery with healthy individuals, and found that the patients' total power, low frequency, and high frequency were all lower than those of healthy individuals, indicating the less heart rate variability in anxious patients.

In terms of the time domain of HR variability parameters, the mean changes in the SDNN, and rMSSD were not significant. This phenomena indicates that 10 min of music listening did not cause significant changes in the scales of the variations, but the frequency of variation presented a significant change. In other words, the timedomain parameters were not as sensitive as frequency-domain parameters for indicating changes in anxiety levels of patients preoperatively.

Our study confirms the immediate effect of music intervention for anxiety reduction. However, the duration of this effect is unclear. It was reported that post operation music intervention not only reduced anxiety scores, but also pain scores and

the use of analgesics (Nilsson, 2008). Future studies need to determine if lowering the levels of anxiety in the preoperative patient has any lasting effect on outcomes during the intraoperative and postoperative stages. Using objective measurements such as HR variability evaluation, investigating the anxiety levels of patients intraoperatively and immediately post-operation becomes possible.

Limitations of this study are as follows: Both raters and subjects were not blinded, which may introduce bias. However, consistent results demonstrated by objective HR variability data may help eliminate the Hawthorn effect. In addition, subjects in the control group did not wear headphones as subjects in the experimental group did. Further study needs to distinguish the effect of wearing headphones from the effect of music intervention for relieving anxiety.

Conclusions

Listening to music is effective for reducing the anxiety of preoperative patients. Patient anxiety can be indicated by a decrease in VAS scores, a decrease in the HR, and a decrease in the low- and an increase in the high-frequency parameters of HR variability. With an HR variability evaluation as objective measurement, this can also be considered for assessing the impact of patients' preoperative anxiety on induction and recovery. In addition, nurses can become more sensitive at assessing patients' anxiety, even in situations where subjects are unable to express subjective feelings.

Effective interventions such as music listening can be delivered in a more timely

manner to help alleviate patients' anxiety.

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