Introduction

Pre-operative anxiety is among the most unpleasant experiences associated with surgery. An unfamiliar environment, loss of control, perceived or actual physical risk, dependence on strangers, separation from family and friends (Gillen et al., 2008), the threat of death, and possible postoperative complications 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 et al., 2005; Haun et al. 2001). Preoperative anxiety is characterized by subjective, consciously perceived feelings, of apprehension and tension accompanied by autonomic nervous system arousal, which cause physical and psychological changes, including changes in heart rate, blood pressure, and respiratory rate, as well as feelings of pressure, fear, and uncertainty (Gail, 2005). Anxiety can affect an individual’s cognitive abilities and cause discomfort both mentally and physically (Vaughn et al., 2007). This, in turn, may increase postoperative pain, prolong postoperative recovery, and increase the potential for complications (Ozalp et al., 2003; Katz et al., 2005).

Given the potential effects of anxiety, there are strategies to limit patient anxiety and improve comfort levels when waiting for surgical and invasive procedures. It has been reported that even though doctors usually provide anxiolytics or sedatives for
patients, most still feel anxious (Duggan et al., 2002). Other research has revealed that patients do not want excessive medication to lower their anxiety, but would rather listen to music or read (Hyde et al., 1998). Among various non-pharmaceutical anxiety-relieving alternatives, music intervention had been reported to have a consistently positive and statistically significant effects on reducing pre-operative anxiety and post-operative pain (Nilsson, 2008). The common theory regarding 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 the patient’s mind with something familiar and soothing, which allows 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). Most prior studies used a compact-disk or cassette player with headphones to listen to music (Gillen et al., 2008). However, re-using headphones among patients raises a concern about nosocomial infection control. Since the organisms causing most nosocomial infections can come from contact with staff (cross-contamination), contaminated instruments and needles, and the environment (exogenous flora), WHO (2002) suggested highly-susceptible patients or protected areas such as operating suites need separate cleaning equipment. Though disposable headphones and small plastic sealable bags may help reduce nosocomial
infections (Short et al., 2010), it increased extra cost. Therefore, non-contact alternative music delivering devices other than headphones need to be considered out of concern for infection control. The purpose of the present research is to evaluate the effectiveness of broadcast music versus headphone music playing to relieve preoperative anxiety levels of patients in the waiting area of an operating theater.

Materials and Methods

Research design and setting
The present study is a randomized controlled clinical study that took place in the operating theater of a metropolitan teaching hospital in Taiwan. The aim of this study is to evaluate the effectiveness of broadcasting compared with headphone in delivering music intervention to reduce pre-operative anxiety of the patient in holding area of an operation theatre. To contrast the effect of music intervention in our study, control group was considered in addition to broadcasting and headphone groups. The study hospital is JCIA (Joint Commission International Accreditation) certified. It is required to assess patients’ anxiety and pain on admission and each significant events such as surgery and procedure. The waiting area is independent, but not completely isolated, from the nursing station. It is 12.6 x 3.9 m, and it can take seat eight patients simultaneously. The temperature of the room was maintained between 19 to 21°C.

Sampling and sample size
Patients who were sent to the waiting area between 07:00 and 14:00 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, or 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.

We applied random table to divide numbers 1 to 30 to three groups to determine each day of a month to be ‘headphone day,’ ‘broadcast day’ or ‘control day’. Subjects who were sent to the operating theater for surgery on ‘headphone day’ were assigned to the headphone group. The same rule was applied to recruit subjects into the broadcast and control groups.

Sample size was determined with G power software (Grant Devilly, Victoria, Australia). We set alpha as 0.05, the effect size (f) of one-way ANOVA of VAS scores and heart rate variability among the three groups as 0.3 (small), and the power as 0.8 for our three groups. The resulting sample size was 111 participants (37 for each group). Considering an attrition rate of 30% due to the short stay in the waiting area, we decided on an expected sample size of 50 for each group.

**Intervention**
It is recommended that therapeutic music should have a slow tempo, low pitch, regular rhythm, and pleasing harmonics, and should 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 et al., 2005).

Considering the short stay of patient in the waiting area and time spent for HRV and VAS measuring, a 10-min music was prepared for intervention. The kinds of music chosen to play in this study were light music of folk songs or pop music, played at a tempo of 60~80 beats per minute and a volume of 50~55 db. The patients in the headphone group listened to music via an MP3 player (Ergotech, ET-U31P, Taiwan). The headphone was put on when the subject agreed to participate. For the subjects in the broadcast group, they listened to music through an open speaker (Pioneer CD player, PD-M427, Japan). The music was played from 07:00 to 15:00 on the broadcast day. When subjects entered the waiting area, they were asked about participating by permitting VAS and HR measurements. The control group did not listen to music, and were asked if they would participate by having VAS and HR measurements.

Considering that music for the broadcast group was sent from open speaker
which make every person in the same area can hear, we decide to use pre-selected standard 10 pieces of music repeatedly, randomly played and not allow participants to make choice. To prepare music for intervention, we firstly chose 40 pieces of music which meet the recommended criteria. Then, we had 10 preoperative patients to elect the top ten relax ones. All the 10 pieces of music were stored in a MP3 player or CD disk and played randomly.

**Measurements**

We employed both subjective and objective measures for anxiety in our study.

**The visual analog scale**

We used a visual analog scale (VAS) instead of State-Trait Anxiety Inventory (STAI), which is used in most studies of anxiety. This decision was made out of three concerns. First, the 40-item STAI takes minutes to fill out. This could cause unnecessary strain for patients waiting for surgery in the waiting area of the operating room and make them more nervous. In contrast, the VAS takes only 5 s for the patient to communicate 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 position 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 10-cm horizontal line marked by vertical lines at 1 cm intervals to
construct a scale. The researcher gave oral instruction (in mandarin) of “Please point at the number line to show how anxious you feel at the moment”, and offered three examples: “A mark at the extreme left would show that you are feeling not anxious at all at the moment. A mark at the extreme right would show that you are feeling the most anxious you could ever imagine. A mark near the centre would show that you feel moderately anxious”.

To use for measuring anxiety, participants were asked to say a number or indicate with their finger a score from 0 (calm) to 10 (very anxious). It has been reported that the VAS was significantly correlated with hospital anxiety ($r=0.28$) (Ledowski et al., 2005) and STAI ($r=0.5-0.6$) (Abdul-Latif et al., 2001; Clan, 2004). Davey et al. (2007) showed the VAS correlation with STAI was 0.78, and claimed that VAS measures quickly and easily assess anxiety and may be useful for research purposes when researchers have very limited time or questionnaire.

**Heart rate variability**

Heart rate variability (HRV) is a well-established non-invasive tool which can be used to study the effect of mental stress on autonomic control of the heart rate (Acharya et al., 2006; Malik et al., 1996). Several studies have shown that analysis of heart rate variability is gaining acceptance as a tool to measure cardiac parasympathetic activity and its relation to anxiety (Friedman, 2007; Cohen and
Benjamin, 2006). In our previous study (Lee et al., 2010) evaluating the preoperative anxiety relieving effect of a music intervention, HR variability parameters correlated well with VAS scores, indicating that HR variability parameters can provide reliable evidence for measuring preoperative anxiety.

There were time-domain and frequency-domain parameters in HR variability analysis. In the time-domain analysis, 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). The past literature pointed out that when an individual feels anxiety or pressure, these indicators decrease (Malik et al., 1996).

In the frequency-domain, total power represents the overall activity of the autonomic nervous system (ANS). 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. 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 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 and Fallen, 1993).

In our study, 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. The participants were asked not to move around to ensure the quality of the readings. According to the user’s manual, the CheckMyHeart is CE (CONFORMITE EUROPEENNE) certified 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 it operates stably at temperatures of 50°F-104°F (10°C-40°C) and humidity of 25%-95%. It has been used in clinical studies of HR variability (Peng et al., 2009; Wen et al., 2007). Our heart rate data were analyzed by the CheckMyHeart software, and provided parameters of heart rate variability.

**Data Collection Process**

This 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 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 a gurney, and closed the curtains. Then, patients in the headphone
group listened to a 10-min session of music with an MP3 player and headphones.

Participants in the broadcast group listened to music from a CD player broadcast in the air. Subjects of the control group were told to rest and relax. After a 10-min session, participants received VAS and 5-min HR measurement

**Statistical Analysis**

Data were 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, and Chi-squared test were applied to evaluate the background differences among the three groups. One way ANOVA test was applied to examine the different in VAS and HR variability parameters among the three groups. If a significant difference was identified, a Sheffe test was further applied to examine the paired difference. A value of $p<.05$ was deemed statistically significant.

**Results**

Between May to June 2009, 186 patients were contacted and 180 were enrolled in the study. Of them, six were unable to complete the study due to being sent to the operating suite before the 10-min of music or rest was finished, three refused measurement, four were excluded due to poor EKG recording (incomplete or too much noise signal). Finally, we got useful data from 167 subjects for statistical
processing. The 167 subjects were 66 in the broadcast group, 48 in the headphone group and 53 in the control group. The participation process is presented in Figure 1. There were no significant differences between three groups in terms of demographics. The average waiting time for the 167 participants was 23 min. Seventy-six percent of patients received general anesthesia, and eighteen percent 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).

**VAS Anxiety levels**

According to the VAS scores, the mean anxiety level of all participants was 5.2±1.8. The mean anxiety score of the control group was 6.2 (SD=1.2), which was significantly higher than that of the headphone group (5.1±2.7) and the broadcast group (4.4±1.6) (p<.05). The anxiety score of the broadcast group was lower than that of the headphone group, but no statistically significant difference was found between the two groups (p=0.1) (Table 2).

**Heart rate variability parameters**

The average heart rates of the broadcast group, headphone group and control group were not significantly different (72.2 bpm, 76.2 bpm, and 74.6 bpm, respectively, F=1.8, p<.17). Time-domain heart rate variability parameters in the
broadcast group were all higher than those in the headphone and control groups (Table 2), but the differences were not significant. There was significant difference in high frequency HR variability among the three groups (F=4.8, p<.01). The Scheffe test showed that the significant difference was between the broadcast group and the control group (p<.01), while there was no difference between the broadcast group and the headphone group. There was also significant difference in low frequency HR variability among the three groups (F=4.9, p<.01). The Scheffe test showed that the significant difference was between the broadcast group and the control group (p<.01), while there was no difference between the broadcast group and the headphone group.

No significant differences in high frequency, low frequency and low-to-high frequency ratio of HR variability were found between the headphone group and the control group. Furthermore, the total power of the headphone group was higher than that of the broadcast group or the controls, though it was not statistically significant.

**Correlation of VAS scores and heart rate variability parameters**

The correlation between VAS scores and heart rate variability parameters were examined by Pearson correlation and the result was shown in Table 3. The VAS scores were significantly correlated with frequency-domain parameters of HR variability (p<.05) but not time-domain ones. The VAS score was positively correlated with low frequency and low-to-high frequency ratio of HR variability (r=.22, p<.01;
r = .21, p < .01 respectively) and was negatively correlated with high frequency of HR variability (r = .22, p < .01).

Discussion

There was no pretest-posttest comparison in this study. This was limited by the intervention for our broadcast group. When patients in the broadcast group entered the room, music might already be playing and this would make a pretest-posttest comparison meaningless. To provide reference in absence of pre-test, we include a control group for post intervention comparison. In our previous study on (Lee et al., 2010), we had demonstrated the effect of 10 minutes music on anxiety-relieving for patients awaiting surgery. Current study was to compare the anxiety-relieving effect of broadcast to headphone music playing for patients awaiting surgery. The finding of no difference between the broadcast group and the headphone group provide reference in considering using music broadcast system for anxiety-relieving effect.

In this study, the VAS levels of the two music listening groups were reduced after the music intervention, while the control group did not exhibit a significant change (p < 0.01). This finding, as expected, was consistent with previous findings (Cooke et al., 2005; Gillen et al., 2008; Hayes et al., 2003; Lee et al., 2004; Maranets and Kain, 1999; Padmanabhan et al., 2005; Wang et al., 2002). Similar findings have also been reported in the literature. Buffum et al., (2006) conducted a randomized
control trial of 170 patients waiting for vascular angiography procedures using a
boom-box style music player, and the result showed statistically significant
differences in anxiety reduction between the experimental group and the control
group. In addition, Kaemph and Amodei (1989) found a significant decrease in
anxiety among outpatients awaiting arthroscopic procedures for the group exposed to
music played on an audiocassette player a foot away. Our research also showed that
anxiety in the broadcast group was significantly lower than that of the control group.
This evidence indicates that when headphones are not available or not appropriate,
speakers can be an effective substitute.

The anxiety reliving effect was also indicated by a change in part of the heart
rate variability parameters. Our frequency-domain analysis showed that LF and HF
were statistically different among the broadcast group and the control group ($p <
0.01$). HF in the broadcast group was markedly higher than that in the control group,
indicating a greater modulation of HF by the parasympathetic nervous system in the
broadcast group than that in the control group upon listening to music. HF in the
headphone group was also higher than that in the control group. Moreover, our
findings that LF in the broadcast group was significantly lower than the control
group indicates there was less tension of the sympathetic nervous system in the
broadcast group. LF in the headphone group was also lower than that of the control
group. Sheps and Sheffield (2001) stated that anxiety increases the activity of sympathetic nerves and decreases the activity of parasympathetic nerves, resulting in increased LFs and lowered HFs. Thus our findings indicated a decreased activity of sympathetic nerves and an increased activity of parasympathetic nerves after listening to music. Our findings are similar to those by Chiu et al. (2003) where HF was markedly elevated and LF and LF/HF ratio significantly decreased after music therapy.

In contrast, the HR variability parameters in the control group showed less changes (Table 2). Comparing the HF and LF, the regulation of the sympathetic nervous system is superior in both the headphone and the broadcast groups to that of the control group. However, the difference was only significant between broadcast group and control group. One possible reason is that while listening to the music, patients in the waiting room can also monitor the progress in the environment by listening to the staff talking, which makes them feel more at ease. In patients listening to music with headphones, they were deprived from any information from the environment. Such effect of sensory deprivation resulting from wearing headphones requires further evaluation.

The HR values did not show a significant difference among the three groups. This is consistent with previous studies (Buffum et al., 2006; Kaempf and Amodei 1989). In
terms of the time domain of HR variability parameters, the differences among the three groups were not significant (Table 2) as well as the correlations with VAS scores (Table 3). Chiu et al. (2003) used HRV analysis to evaluate the anxiety of 68 pre-operative procedure subjects, and also found time-domain parameters, consistent with our findings. This phenomena indicates that 10 min of music listening did not cause significant changes in the scale of the variations, but the frequency of variation presented a significant change (Table 2 and Table 3). Our study found VAS scores is associated with frequency domain of HR variability parameters. The previous study showed high-frequency parameter of HR variability was significantly correlated with anxiety by using STAI (State–Trait Anxiety Inventory) (Shinba et al., 2008). However, Francis et al. (2009) showed anxiety score was associated with rMSSD in implantable cardioverter defibrillator patients. Their explanation is that time domain assessments collected over several hours are less vulnerable to ECG artifacts and ectopy than frequency domain. In other words, the time-domain parameters were not as sensitive as frequency-domain parameters for indicating changes in anxiety levels of patients preoperatively. Researchers have pointed out that temporal-domain analysis is optimal for analyzing long-term EKG recording (Chiu et al., 2003). Therefore, it is possible that the indicators in this short-term study were not suitable for time-domain analysis.

Though our data confirmed that listening to music has an immediate effect of
anxiety reduction, the retention of this effect is unclear. It has been reported that post operation music intervention not only reduced anxiety scores, but also pain scores and the use of analgesics (Nilsson, 2008). Therefore, 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. With the use of objective measurements such as HR variability used in this study, investigating the anxiety levels of patients intraoperatively and immediately postoperatively becomes possible.

Limitations

Although the present study has yielded findings that have both theoretical and practical implications, there are some limitations. First, there was no pretest-posttest comparison. Primarily without a pre-test it is impossible to determine the change. To provide reference in absence of pre-test, we include a control group for post intervention comparison. Second, in the present research, participants were not allowed to choose their favorite music. The waiting room in our study did not have individual partitions, so the participants in the broadcast group could not listen to music of their own choosing. Therefore, the participants in the headphone group listened to same music arrangement without personal choice. In future studies, a better research design or a more suitable testing location may provide better insight regarding this issue.
**Conclusion**

Listening to music is effective for reducing the anxiety of preoperative patients.

Such patient anxiety can be indicated by a decrease in VAS scores, and a decrease in the low- and an increase in the high-frequency parameters of HR variability. Both headphone and broadcast music are effective for reducing the preoperative patient’s anxiety in the waiting room.

**Relevance to clinical practice**

From an infection control perspective, broadcasting from speakers can be a substitute for headphones when playing music to lower the anxiety level of patients waiting for surgery.

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Contributions of the author

Study design: YFC, KCL; data analysis: YFC, KCL, PYC; Manuscript preparation: YFC, KCL, JJY, YHC.
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