Intraoperative stress and anxiety reduction with music therapy: A controlled randomized clinical trial of efficacy and safety

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Objective: The purpose of this study was to investigate the music therapy (MT) effect in levels of intraoperative anxiety in patients undergoing crossectomy with stripping of the great saphenous vein and to assess the efficacy, safety, and feasibility of this alternative therapy as a complement of standard intraoperative care.

Material and methods: The study is a simple blind, controlled, parallel groups, prospective randomized clinical trial. Patients were allocated by means of randomized controlled sampling. The study was performed in the surgery room of Getafe University Hospital in Madrid. The study was carried out in 40 patients, 20 randomized to the experimental group and 20 randomized to the control group, with an age range from 27 to 70 years. The control group was given intraoperative routine attention, and the experimental group was given an MT passive intervention that consisted of audition of musical fragments during varicose veins surgery. These pieces previously showed relaxing actions on the cardiovascular system. The anxiety levels were measured by means of pre- and postsurgical questionnaires by a blinded investigator for the study arm to which the patients had been randomized. Heart rate and systolic and diastolic blood pressures were determined during the intervention, and adrenaline and noradrenaline plasma levels were determined before and after the surgical procedure.

Results: The majority of the patients in the MT group (95%) and standard care group (90%) completed the study. There were no statistical differences between the control and experimental groups in heart rate gradient or systolic and diastolic blood pressures measured after the intervention. The anxiety state and the stress feeling scale score after surgery were significantly inferior in the MT group (94.7% vs 57.9% decrease in anxiety levels, P < .05, and stress score of 1.31 vs 2.36, P < .05, respectively). The adverse events ratio was low and occurred with similar frequency in both groups.

Conclusions: The MT intervention was easily implemented in the context of nursing care received during varicose vein surgery and was positively accepted and valued by the majority of the patients. MT is a safe procedure that is proved to reduce anxiety and stress in the study patients. (J Vasc Nurs 2013;31:101-106)

Anxiety is a common phenomenon among hospitalized patients. It is an emotional condition characterized by stress and unpleasant feelings, nervousness, concern, fear, and a higher activity of autonomous nervous system. Anxiety causes physical and psychologic effects. The physiologic response to stress implies the activation of the hypothalamic-pituitary-adrenal axis and sympathetic nervous system that causes an increase in heart rate, blood pressure, and cardiac output.²

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Intraoperative anxiety is strongly correlated with a higher incidence of postsurgery pain, an increase in the need for analgesics and anesthetics, and delayed recovery and discharge from hospital. Therefore, creative and supportive interventions for patients during these moments of discomfort and uncertainty may be relevant in ameliorating distress and improving health outcomes.³

According to the National Association for Music Therapy, music therapy (MT) consists of using music to achieve therapeutic objectives: restoration, maintenance, and increase in health, both physical and mental. Music can be used therapeutically as a perceptual focus and stimulus, exerting its effect through entrainment by means of synchronization of cardiovascular rhythms to achieve relaxation.4 Previous studies have demonstrated the entrainment of body rhythms with music to decrease sympathetic nervous system activity.⁵ These responses lead to a decrease in adrenergic activity and may produce altered states of consciousness and decreased neuromuscular arousal. This relaxation response is manifested as physiologic indicators of the relaxation response by decreases in heart rate, blood pressure, respiratory rate, metabolic rate, oxygen consumption, skeleton muscle tension, epinephrine levels, gastric acidity, and motility and sweat gland activity.6

The auditory stimulation of listening to music also influences the limbic system of the brain, the center of emotions and feelings, causes a reduction in the ability of the neurotransmitters to relay unpleasant and uncomfortable feelings, and triggers endorphin release.

Prior studies in different patient groups have shown that MT reduces psychologic stress and subjective anxiety. Yung et al demonstrated a reduction in physiologic anxiety signs, heart rate, and systolic blood pressure, yielded by an MT intervention. It was also found that the anxiety level after the intervention in patients who received MT decreased 16% compared with the pre-intervention level, whereas the anxiety level of the control group did not change significantly.

MT is an appealing technique for a nursing therapeutic intervention because it is innocuous and feasible. Providing music to patients is a low-cost intervention and does not require the use of additional human resources or other resources (eg, training or specialized equipment). Accordingly, MT could be integrated as a safe, effective, and viable nursing intervention within nursing intraoperative care.

The objective of this study was to evaluate the effect of MT on intraoperative anxiety levels in patients undergoing venous crossectomy and stripping of the great saphenous veins (GSVs). The current study was performed on the hypothesis that patients who listen to adequate music during surgery will have statistically significant lower levels of anxiety than patients who receive routine care.

MATERIALS AND METHODS

Trial design

A controlled randomized trial was used to determine the effect of selected music on intraoperative anxiety levels. The study sequentially included all of the patients who underwent elective varicose vein crossectomy with GSV stripping, under essential varicose vein diagnosis, during the recruitment period from December 2010 to March 2011.

All patients underwent surgery via the stripping method in a single lower limb because of chronic venous insufficiency with varicose veins GII-III on Clinical, Etiologic, Anatomic, and Pathologic classification under spinal anesthesia without sedation. This is the standard type of anesthesia for this procedure. No further informed consent was needed for the anesthesia type. Thus, patients remained awake and conscious during the intervention in all cases. All patients included were prospectively randomized to receive MT during the intervention (a passive audition of a musical piece) or standard care. In the MT group, this musical piece previously showed relaxing actions on vital constants and endothelial function.6 Heart rate, systolic and diastolic blood pressures, and anxiety level and stress feeling were determined by the State Trait Anxiety Inventory (STAI) questionnaire and surveys applied by an investigator blinded to the type of care received by the patient before and after surgery.

Selected music

The piece of music selected for the experimental intervention (Henry Gorecki, Symphony Number 3, Slow Cantabile Semplice) was specifically selected to comply with determined

pre-established requirements, providing reproducibility (external validity) to the study and meeting the musical characteristics of rhythm, phrasing, and emphasis. The music piece was a psychologically mental and emotionally positive stimulus that altered the hemodynamic, endothelial function, and cardiovascular variables in a well-established and predictable direction. A previous study showed this piece to improve endothelial function, reduce chronic systemic inflammatory markers, and improve arterial vasoreactivity (De Haro J, unpublished data, 2012).

As Bernardi et al⁴ concluded, these established parameters refer to characteristics of emphasis (uniformed emphasis vs progressive crescendos) and phrasing rhythm (6 cycles/min or 10-s duration phrases, ie, ~0.1 Hz, which is equivalent to fluctuations in rhythm of the blood pressure, ie, Mayer waves, which result from imperfect baroreceptor control caused by the interaction of a rapid vagal response in heart rate and a slow vascular response ruled by the sympathetic system). Bernardi et al⁴ demonstrated that the variables of emphasis and phrasing rhythm have a constant dynamic influence on cardio-hemodynamic variables, almost immediate, objective, and independent of subject, sex, age, training, or musical preferences.

Music was listened to through headphones via an MP3 player to minimize external noise from the surgery room during the surgical procedure and to increase concentration on music. The width of signal was preadjusted to obtain a comfortable volume to hear the complete dynamic range of the musical piece. This preadjustment was done by means of preliminary listening by 5 healthy volunteers and was maintained afterward for all of the auditions during the study.

Study population/participants

The study included 40 patients (30% were male; 20 in the experimental arm and 20 in the control group). The patients were recruited from the Angiology and Vascular Surgery department of Getafe University Hospital. Patients were eligible to participate if they met the inclusion and exclusion criteria.

The inclusion criteria were as follows: men and women aged 18 to 70 years, signed informed consent form to participate in the study, and crossectomy with stripping of the GSVs performed under intradural anesthesia without sedation.

The exclusion criteria were as follows: sensory disability, particularly auditory condition; psychiatric acute or deteriorating disorder; altered mental status; and cognitive impairment.

Study protocol

The study was a randomized controlled parallel groups clinical trial. The experimental intervention to study in the different arms consisted of an experimental group with a selected music audition during the surgical procedure and a control group with ambient noise and standard care during surgery.

Neither additional analgesic nor anxiolytic drugs, aside from those standard for intradural anesthesia (without sedation) used in all the cases, were administered to patients in both the MT and control groups.

The study variables were determined in each patient independently of the assigned group, before and after the experimental intervention, by a researcher blinded to the patient's group.

Randomization: Type, random allocation sequence, and allocation concealment method

A restrictive 4-person block randomization matched by genre was performed to secure that the number of patients in each group of treatment was the same in an attempt to minimize the probability of imbalance between both groups and temporal biases and homogeneity in genre distribution. Computer-generated randomized number sequences were used for group assignment.

Data-collection techniques

A structured preoperative personal interview was performed verbally with the patient 20 minutes before surgery. The interview was assessed using the State Anxiety and the Trait Anxiety with the STAI scale in the surgery waiting room. In addition, we administered a questionnaire of 27 closed questions with dichotomous and multiple choice answers specifically created for this study, as well as a visual-analogical scale of anxiety. The investigator who helped the patients complete the STAI survey and the specific questionnaire was blinded to group assignments.

The specific questionnaire was designed to discover the potential differences relevant to the current study, regarding the musical habits and training of the patient, demographic features, and particular levels of anxiety, specifically preoperative, both somatic and cognitive, between the groups. The test–retest reliability correlation of the entire questionnaire was 0.89, using the Pearson product moment correlation coefficients method.

A structured postoperative personal interview was performed directly with the patient in the post-anesthetic reanimation unit at least 10 minutes after surgery. The STAI survey and the same questionnaire of closed questions (multiple choice test) with dichotomous and multiple alternative answers were applied. There was a variation in the number of questions on the questionnaire depending on whether the patient had been treated with MT during surgery, because individuals in the control group were not asked about the level of satisfaction with the MT intervention.

Biophysiologic measures. In vivo: Hemodynamic monitoring was performed in each patient in the surgical room, obtaining a continuous evaluation and assessment of vital signs. Heart rate, blood pressure, breathing rate, and oxygen saturation were recorded every 5 minutes during surgery.

In vitro: Plasma levels of catecholamines (adrenaline, nor-adrenaline) were measured before and after the study intervention, MT versus standard intraoperative care. Samples of peripheral blood were previously processed after 15 minutes/1500 rpm centrifugation and stored at -80° C. Levels of catecholamine in plasma were analyzed using a high-resolution liquid chromatography routine technique with a Chromsystems kit (Munich, Germany) that allows a limit of detention and linearity of 10 to 1000 pg/mL in plasma with an intratest accuracy of 5%.

Informed consent

After providing patients with the necessary verbal information about the study and free acceptance to participate, an information and consent form to donate biological samples was obtained. All patients included in the study signed the informed consent and donation of biological samples forms. The specific intervention of this study did not have additional disturbance or risk for the patient.

Data-collection protocol

Data collection was performed in the following 3 phases:

In the surgery waiting room (preoperatively), the research team performed the following: checked that the patient met inclusion/exclusion criteria; provided all information about the study; after free acceptance to participate in the study, obtained patient's signature on the informed consent form; randomized the patients to the different arms of the study; a blinded investigator performed the structured interview with the patient before surgery.

In the surgery room (intraoperatively): The patient's vein blood was withdrawn after peripheral access setting; vital signs were monitored and registered every 5 minutes; once the patient was under intradural anesthesia, the experimental intervention in patients was performed, MT or ambient noise, and standard care.

In the post-anesthetic reanimation unit (postoperatively): Another venous peripheral blood sample was collected 20 minutes post-intervention, a postoperative interview was performed, and vital signs were monitored and registered 10 minutes after arrival of the patient.

Statistical analysis

Sample size. Sample size was estimated to show a 2-tailed null hypothesis. By assuming a statistical power of 80% and an alpha error of 5%, the size of the sample estimation resulted in 40 patients for the expected differences regarding the anxiety score reported by previous studies in a population similar to that in our study. To calculate the sample size, we used calculator software available online (http://calculators.stat.ncla.edu).

Data analysis. The Kolmogorov-Smirnoff test and Cochran test were used to analyze the homogeneity of variables and its normal distribution. Data were shown as mean \pm standard deviation in continuous variables and as percentage in dichotomous variables. Comparison of variables between the 2 study groups was performed using independent-samples Student t test for continuous variables and chi-square test with 2 × 2 contingency tables, applying the Fisher exact test when necessary for dichotomous variables. Lineal multiple regressions were performed for each dependent variable (anxiety score, adrenaline plasma levels, noradrenaline plasma levels, heart rate, and systolic and diastolic blood pressures), establishing the type of intervention as an independent variable: MT versus standard care. P values < .05 were considered statistically significant. Statistical analysis was performed using the Statistical Package for the Social Sciences version 15.0 (SPSS, Inc, Chicago, Ill).

Ethics

Informed consent was obtained from all study patients. All patients were informed that they could withdraw from the study at any time. The trial was approved by the local ethics committee.

RESULTS

Forty-eight patients who met inclusion/exclusion criteria were invited to participate in the study; 3 of them refused to participate, and 5 were excluded because they did not comply with

No.

DEMOGRAPHIC FEATURES, HEMODYNAMIC BASAL LEVELS, AND TRAIT ANXIETY BASAL LEVELS DID NOT SIGNIFICANTLY DIFFER BETWEEN MUSIC THERAPY AND CONTROL GROUPS

	MT Group	Control Group	P Value
A (0.5 0.75)	42.7 1 0	44.1 ± 9	.81
Age (M \pm SD)	43.7 ± 9		
Gender, male (%)	6 (30)	6 (30)	.99
Baseline SBP (M \pm SD)	121 ± 13	119 ± 12	.66
Baseline DBP (M \pm SD)	73 ± 11	71 ± 15	.72
Current smoking (%)	20	20	.99
DM (%)	5	5	.99
COPD (%)	0	0	.99
Baseline heart rate (M \pm SD)	69.2 ± 13	71 ± 11	.55
Baseline Trait Anxiety STAI score (M \pm SD)	33.7 ± 9.3	34.1 ± 10.0	.78
Previous surgical interventions (M \pm SD)	1.1 ± 0.7	0.9 ± 0.6	.63

COPD = chronic obstructive pulmonary disease; DBP = diastolic blood pressure; DM = diabetes mellitus; M = mean; MT = music therapy; SBP = systolic blood pressure; SD = standard deviation; STAI = State Trait Anxiety Inventory.

the study protocol. Forty patients were randomized in a 1:1 proportion to one of the study arms. Demographic features and comorbidity and basal anxiety levels did not differ significantly between the groups (Table 1). Some 95% of patients in the MT group and 90% of patients in the standard care group completed the study.

The structured interview analyzed the subjective control of anxiety and satisfaction degree with MT intervention. To the question "Do you think that music has helped you to relax?" 94.7% of patients in the MT group answered affirmatively. To the question "If you need undergone another surgical intervention, would you choose intraoperative MT?" 94% of patients who received this therapeutic option answered positively.

There were no significant statistical differences between groups regarding the postoperative minus the preoperative gradient in heart rate and systolic and diastolic blood pressures.

Anxiety, assessed in a specific test to evaluate the intraoperative anxiety, and the stress feeling scale score were significantly lower in the MT group (Table 2). Changes in catecholaminergic levels in plasma after intervention were significantly different between both groups: Patients in the MT group had a lower increase of adrenergic amine levels (Table 2). The ratio of complications was insignificant in both groups.

DISCUSSION

The results of the current study demonstrate that MT, used as a nursing intervention during surgery, reduces anxiety levels in patients undergoing varicose vein surgery compared with patients who receive standard care. The data suggest that music can be a feasible, cost-effective, and profitable treatment to manage intraoperative anxiety. Our results are consistent with those obtained in previous research, 1-3,10-18 confirming the efficacy of intraoperative MT.

The advantages of music intervention to control perioperative anxiety are numerous. The main benefit is that music does not cause adverse effects, versus anxiolytic drugs use. In addition, music can be a good alternative to reduce anxiety in patients allergic to benzodiazepine or those in whom it is contraindicated. None of the patients in the study had received any specific type of musical study or training.

Consistent with previous research, patients reported that they felt less stressed when music was present, and participants exposed to surgical stressor also reported lower levels of state anxiety in the presence of music than in its absence. The finding that music also prevents stress-induced changes in physiologic measures (catecholamine levels) is more noteworthy. Research in this area has been inconsistent, particularly with regard to blood pressure and heart rate indices. 5,16 Several factors may account for the effect observed in the current study. First, a moderate sample size was used, and the experimental setting, including a well-established effect of selected music applied to all patients, enabled consistency of conditions across participants. This reduced variability considerably provided the study a high internal validity. The proved effects by authors of the music pieces in previous studies predict a more stable and expected change in physiologic responses. Second, participants' baseline measures were entered as covariates in the analyses by means of the variable gradient analysis to control the potential confounding factors and biases associated with differential demographic features and musical training and preferences between groups through relativizing the absolute variables as a function of the baseline variables.

The current findings lend experimental support to a number of clinical studies and reviews that have reported that music reduced sympathetic nervous system indices of stress. 5,11,15,16,19

It was anticipated that factors such as familiarity and liking the piece, trait anxiety, and music training might have mediated the effect of music on stress reactivity. Previous research has

nadialis.

INTRAOPERATIVE ANXIETY AND THE SCALE OF STRESS FEELING SCORE WERE SIGNIFICANTLY LOWER IN THE MUSIC THERAPY GROUP

	MT Group $n = 20$	Control Group $n = 20$	P Value
▲ Heart rate gradient	-12.5 ± 3.1	-13.8 ± 4.2	.71
▲ SBP gradient	-18.7 ± 5.2	-26.3 ± 8.7	.65
▲ DBP gradient	-8.6 ± 6.0	-11.7 ± 7.6	.33
Control of intraoperative anxiety	94.7%	57.9%	.03
Intraoperative stress feeling scale	1.31 ± 0.3	2.36 ± 0.3	.02
▲ Adrenaline (pg/mL)	113.7 ± 21.0	520.5 ± 37.1	.02
▲ Noradrenaline (pg/mL)	77.2 ± 12.1	305.6 ± 23.9	.03

^{▲ =} differential postoperative value - preoperative value; DBP = diastolic blood pressure; MT = music therapy; SBP = systolic blood pressure.

Patients who received MT had a lower increase in adrenergic amines levels after intervention. No significant differences were found in hemodynamic parameter gradients.

indicated that the effect of music on physiologic responses is enhanced by familiarity, liking the piece, and musical training of the participant. Nevertheless, the current study evaluated the effects of the music by its own musical parameters and confirm the previous findings of Bernardi et al⁴ that intrinsic variables of music as emphasis and phrasing rhythm have a constant dynamic influence objective and independent of subject, sex, age, training, or musical preferences on cardio-hemodynamic variables. The influence of familiarity or preference of piece used in the present study is negligible because a small percentage of patients were familiar with or liked the selected piece. Nonetheless, it is interesting that these results suggest the reverse in this study, in that the effect of music seems to be more pronounced in participants who were unfamiliar with the music and had no musical training.

The observation that music prevents an increase in catecholamine plasma levels is consistent with previous research. In this context, it is of interest that the type of physiologic response to a stressor is to some extent dependent on the perceived degree of control one feels over the stressor. The only limitation in the application of MT during surgery is that the patient has to be conscious. Thus, surgical acts that require general anesthesia are excluded.

Study limitations

Our study has the limitation that it could not be performed double-blinded. In practice, it is not possible to blind the patient to the type of assigned intervention/arm. Answers to the structured questionnaire can be biased because of a possible placebo effect. However, the values obtained from catecholamine plasma level measurements are similar to those obtained by means of interviews and the gradation of the anxiety level score.

This research shows that music should become a routine component of the care provided to patients during varicose vein surgery. The objective must be to minimize anxiety associated with surgery. Music can be used as an independent nursing intervention to reduce this anxiety. Music could be offered to surgical patients before, during, and after surgery. This study is relevant for nursing practice because it provides evidence-based information on perioperative nurse interventions.

CONCLUSIONS

The results of this study showed that listening to selected music reduces intraoperative anxiety. Although the results are promising, they must be verified with large sample studies.

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