

Music interventions in patients during coronary angiographic procedures: A randomized controlled study of the effect on patients' anxiety and well-being

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Received 24 February 2010; received in revised form 30 June 2010; accepted 2 July 2010
Available online 3 August 2010

Abstract

Background: A cardiac catheterization laboratory can be a frightening environment and music can be a supportive source of environmental sound that stimulates and maintains relaxation.

Aim: To test the effects of patient focused music versus loudspeaker music versus standard sound on patient's experiences of anxiety and well-being during coronary angiographic procedures.

Methods: A prospective, randomized, controlled trial of 98 subjects undergoing elective coronary angiogram and/or percutaneous coronary intervention. The subjects were randomly allocated to three different groups of sound environments: a control group (the usual sound environment), a patient focused music group (audio pillow) or to a loudspeaker music group.

Results: Anxiety decreased significantly and well-being increased significantly in the two music groups compared to the control group. There was a significantly more positive impression of the sound environment in the patient focused music group compared to the two other groups.

Conclusion: This study showed that the use of a specially designed music reduced anxiety and increased well-being in patients during coronary angiographic procedures. However, patient focused music seemed to be more preferable. The sound environment was rated more positively by the subjects listening to music via audio pillow. The music delivered via loudspeakers seemed to distract the staff during the examination at the cardiac catheterization laboratory.

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Keywords: Music; Anxiety; Well-being; Coronary angiographic procedure

1. Introduction

A cardiac catheterization laboratory (cath lab) can be a frightening environment with highly technical equipment and unfamiliar sounds [1]. Nurses have the responsibility to establish a healing and stress-reducing environment for the patient. One feature of such an environment can be soothing music, an intervention that can help patients focus their

awareness on the music, to promote relaxation [2]. Music intervention is a nursing intervention to facilitate healing through pre-recorded music, defined as “a supportive source of environmental sound that stimulates and maintains relaxation and reduces or controls distress by a self-management technique” [3]. The use of listening to pre-recorded music has also been defined as “Music medicine” in contradiction to “Music therapy” that includes an in-person music therapy treatment by a music therapist [4].

Music intervention as a single session intervention can reduce anxiety in patients admitted to the hospital [3,5,6]. Evidence suggests that music listening modulates emotional

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arousal as indexed by changes in cardiovascular and respiratory activity [7]. It has also been suggested that music directs attention away from negative experiences, thus helping an individual cope with emotional stress [3,8,9]. In a recent Cochrane review it has been reported that music listening may have a beneficial effect on blood pressure, heart rate, respiratory rate, anxiety, and pain in subjects with coronary heart disease. However, the quality of the evidence is not strong and the clinical significance unclear [5].

Several previous studies have evaluated music interventions prior to and during coronary angiography and percutaneous coronary intervention (PCI) [1,2,10–15]. Buffum et al. [12] reported lower levels of anxiety and reduced heart rate when patients listened to self-selected music prior to vascular angiography. The self-selected music included five categories of music; classical, jazz, rock, country western, and easy listening [12]. Two other studies found no effect of music prior to cardiac catheterization with respect to anxiety, heart rate, and respiratory rate [13,14] or uncertainty and mood [14]. The study by Hamel et al. [13] used Trance–Zendance music by Halpern and in Taylor Piliaes study [14] the subjects selected New Age, Chinese instrumental, or Western classical music. In a study by Bally et al. [11] they reported no effect of music on post-procedural pain and anxiety. The subjects listened to a self-selected audiocassette tape with music prior to, during, and after coronary angiography. It is unclear if the subjects selected the music completely on their own or from a list; as well as what musical genres were used in the study.

Music interventions during coronary angiography have shown both positive [1,5,10] and no effects [2]. A study by Argstatter et al. [10] on music interventions during coronary angiography found a reduction in subjective anxiety in a subgroup of patients with higher than average psychological strain, but no effects on physiological variables or medication. The music “Relaxation” by Martin Rummel was used in this study, which was designed for relaxation based on music psychological principles [10]. In addition, Moradipناه et al. documented decreased anxiety, stress and depression after listening to three different relaxing pieces of music (“Canon in D” by J. Pachelbel, the theme from “Love story” by R. Clayderman and “Dance of the iguana” by S. Pasero) [15]. Using specially designed music, MusiCure®, [16] seems to have positive effects on well-being and patients’ experiences of environmental sounds during coronary angiographic procedures [1]. However, Nilsson et al. [2] found no effects of the music by MusiCure® [16] on puncture pain and the related discomfort, angina and the related discomfort, or anxiety. In addition, the researchers found no significant effects on the experience of the sound environment, discomfort of lying still, or the doses of anxiolytics and analgesics [2].

To summarize, there is no clear evidence showing that soothing music has a positive effect on patients prior to or during coronary angiographic procedures. Furthermore, the

studies mentioned above included different types of soft and relaxing music with 60 to 80 beats per minutes (bpm). A clear picture has not emerged regarding, which genre is most beneficial [3,4].

Kolcaba’s theory of comfort proposes that there is an important relationship between patient comfort and subsequent outcomes of well-being and recovery. Therefore, when the professional caregivers address comfort needs of patients, the patients will experience favourable outcomes like reduced anxiety and stress as well as increased feelings of well-being [17]. In this study well-being is defined as the sense of satisfaction in the present moment [18] and anxiety as a transient experience of an unpleasant sensation that arouses worry and discomfort and is caused by intrinsic and extrinsic stimulation [19].

2. Purpose

The objective of this study was to test the effects of three different sound environments, two of which involved adjunctive music intervention on patient’s experiences of anxiety and well-being during coronary angiographic procedures.

3. Methods

3.1. Participants and setting

A convenience sampling method was used to recruit participants for this study. The study was designed as a prospective, randomized, controlled trial including a sample of 102 subjects undergoing elective coronary angiogram and/or percutaneous coronary intervention. The experimental design was tested in a U.S. community hospital with an active regional cardiac catheterization laboratory program. The patients were consecutively enrolled into the study between April and November of 2005. Approval to conduct the study was obtained from the research committee of the hospital and from the Institutional Review Board (IRB). Subjects were enrolled on the day of the procedure during the pre-procedure evaluation, and the investigator obtained written informed consent. The enrollment criteria for the subjects included outpatients, age 18 years or older, who could understand and speak sufficient English and had no difficulties in cooperating during measurements. The exclusion criteria for the subjects were significant hearing loss, uncontrolled psychiatric illness, and severe cases of dementia as documented in the medical records.

All the participants were scheduled outpatients from the same day surgical unit. Subjects were stratified into groups to obtain equal representation for gender after randomization. The same cath lab room was used throughout the study. The investigators were blinded to the treatment selected for the individual subjects until after the subjects were consented.

3.2. Intervention

The subjects were stratified into gender, and thereafter randomly allocated to one of three groups, based on sealed envelopes. Subjects randomized to the control group received standard care, and subjects in the music groups received standard care and music intervention. In the loudspeaker music group (LS music), the music was delivered to the patient via ceiling suspended loudspeakers. In the patient focused music group (PF music), the subjects received music from an audio pillow, which was made of foam material with specially built-in loudspeakers [20]. This system created a patient focused sound environment, minimally affecting the ambient sound environment of the cath lab for the health care providers.

The music used in the study, MusiCure® [16], was a specifically designed therapeutic music composed by Niels Eije according to the classical composing technique, however, without a specific genre appearance, characterized as “genreless” and as “soundpheres”. The music was designed to provide a calming influence without emotional triggering and included different melodies of 60 to 80 bpm. MusiCure® music has previously been tested in relation to patients’ pain, well-being, anxiety and/or relaxation with both positive [18,21,22] and neutral effects [2,23].

3.3. Devices and material approval

The materials, the audio pillow, and associated devices were checked and approved by the biomedical engineering department and the infectious disease control department. The audio pillow with integrated MP3 player was battery operated. The outside of the audio pillow was covered by a pillowcase. The audio pillow itself was covered by a special plastic cover for disinfection purposes between subjects. The standard disinfection procedure and policy was performed as approved for the institution and by the infectious disease department.

3.4. Procedures

The study personnel applied the music in a randomized fashion. The music was pre-set and standardized at a fixed low volume for the loud speakers, which was a standard sound system with the speakers in the ceiling positioned over the subject’s head. The audio pillow sound volume was pre-set and standardized by the staff to a setting on the MP3 player at two levels below maximum for all the subjects, with an option to increase or decrease the volume per patient preference. The LS music was set at a volume just below standard spoken volume i.e. 60 dB. The music was just audible to the staff when the audio speakers were on in the cath lab. The PF music was barely audible to the staff when on and only audible when standing very close to the head of the subject. The volume was at a set volume so the subjects could communicate and easily engage with the staff, as well

as relax into the music sound environment. The personnel were trained in the use of the audio pillow and loud speakers, and the standard volume settings of each for the study.

The music intervention started as the subject was placed on the procedure table and ended when the subject was transferred to the hospital bed after the procedure in the cath lab. In the music intervention groups, the music could be interrupted upon the request of the patient, nurse, physician, or technician. The reason for any interruption and the time of the interruption were documented. Likewise, any requested adjustments were recorded regarding the level of the music volume, to which level, and at which time. A music operation manual was created for the study and distributed to the same day surgical unit and the cath lab. The manual ensured uniform data collection and standardization for the application of the interventions.

3.5. Measurements

Before the procedure subject-related demographics were documented. The outcome measurements were collected when the subject was placed in the bed following the procedure. Anxiety (“What was the degree of anxiety that you experienced during your procedure?”) was measured on a numeric rating scale (NRS) scoring from 0 = *no anxiety* to 10 = *worst possible anxiety*. The NRS for anxiety has been psychometrically tested and found reliable, $r=0.64$ [24]. The NRS has been used frequently as an outcome assessment for pain and anxiety in studies testing music [3].

The questionnaire measuring well-being and sound environment was study-specific and included the following issues:

“Which effect has the sound environment had on your feeling of well-being during your stay in our cath lab?” Assessed by: “Very positive”, “Positive”, “Neutral”, “Negative” and “Don’t know.”

“How was your experience of the sound environment during your stay in our cath lab?” Assessed by: “Very pleasant”, “Pleasant”, “Unpleasant”, “Very unpleasant” and “Don’t know.”

3.6. Data analysis

Statistical analyses were performed using Statistical Package for the Social Sciences (SPSS) program 16.0. Statistics are presented as means, standard deviation, median, and range. Kruskal–Wallis one-way analysis following by a Mann–Whitney test was used to compare the data among the three groups. Analysis of variance of a given variable was made by the Friedman test as modified by Conover [25] for pair wise comparison, if an overall difference was found. A p-value below 0.05 was considered to indicate a statistically significant difference.

4. Results

The music intervention was prematurely stopped by request in four subjects—all from the music intervention group using ceiling suspended loudspeakers. The request to stop the music was in one case stated by the subject, in two cases by the technician, and in one case by the physician. The demographic data for the 98 participants (after exclusion of the four patients in which the music was stopped) did not show any significant difference among the three patient groups with respect to age, gender, procedures, anxiolytics (Midazolam®), and analgesics (Fentanyl®) during the procedure (Table 1).

A significantly higher anxiety score was measured in the control group 5 (range: 1–10) when compared to group LS music group 2 (range 1–9), $p < 0.05$ and PF music group: 2 (range: 1–8), $p < 0.05$. No significant difference was measured between the anxiety score between the two music groups. Furthermore, a significantly more positive well-being response was measured in the two groups exposed to the music intervention as compared to the group with the basic sound environment. However, there was no difference between the two music intervention groups (Table 2).

A significantly ($p < 0.05$) more positive impression of the sound environment was measured in the patient focused music group compared to the two other groups. No difference was found between the music intervention group with ceiling suspended loudspeakers and the control group (Table 3).

5. Discussion

The present study documented that music intervention induced a significant reduction in the anxiety level of the subjects. A more positive impression was found in the sound

Table 1
Comparison of patients' characteristics, procedures, anxiolytic and analgesic medications between among the groups.

| | | Control group n=34 | LP music group n=30 | PF music group n=34 |
|---------------------------------|----------------|-----------------------|------------------------|------------------------|
| Age (yr) | Mean (range) | 68.7 (41–81) | 66.9(48–84) | 66.7(50–79) |
| Gender | n | 17/17 | 17/13 | 17/17 |
| Female/male | | | | |
| Procedures: | n | 26/8 | 23/7 | 23/11 |
| CA; CA and PCI | | | | |
| Duration of the procedure (min) | Mean (min–max) | 51 (10–164) | 52 (19–217) | 51 (14–141) |
| Midazolam (mg) | Median (range) | 2 (1–3) | 2 (1–4) | 2 (1–4) |
| Fentanyl (µg) | Median (range) | 50 (25–75) | 50 (0–100) | 50 (0–75) |

Abbreviations: LP = Loud speaker; PF = Patient focus; CA = coronary angiogram; PCI = percutaneous coronary intervention.

Table 2
Patients' ratings of sound environments' effect on their well-being.

| | Very positive % (n) | Positive % (n) | Neutral % (n) | Negative % (n) | Don't know % (n) |
|------------------------|------------------------|-------------------|------------------|-------------------|---------------------|
| Control group n=34 | 12% (4) | 26% (9) | 50% (17) | 3% (1) | 9% (3) |
| LP music group n=30 | 30%* (9) | 53%* (16) | 7%* (2) | 0 | 10% (3) |
| PF music group n=34 | 26%* (9) | 53%* (18) | 15%* (5) | 0 | 6% (2) |

Abbreviations: LP = Loud speaker; PF = Patient focus.

* $p < 0.05$ compared to the control group.

environment's effect on well-being in the two groups exposed to music intervention. It was expected that the patient focused music would be the most effective and least obtrusive method of providing a music environment. However, the reduction in anxiety level for patient focused music intervention was not significantly different from music intervention via ceiling suspended loudspeakers. The reason for this is unclear, but a contributing factor was the very low anxiety level obtained by both interventions. Our results are in line with previous studies on music interventions during coronary angiography, which have shown decreased anxiety [10,15] and increased well-being [1]. The mechanism behind the effect of relaxing music is not clearly understood. It has been reported that the relaxing effect of music is related to an increased release of plasma oxytocin [22], and a reduction in plasma cytokine and catecholamine levels [26]. These responses to music convey emotions through autonomic arousal, likely in a bidirectional way [27]. A strong positive correlation exists between the pleasurable aspects of music listening and emotional arousal [28]. Furthermore, enhanced comfort leads to increased perceptions of well-being and decreased perception of stress [17]. Music intervention could therefore be called a comfort intervention in accordance with the findings of the present study.

Table 3
Patients ratings of the three sound environments.

| | Very pleasant % (n) | Pleasant % (n) | Unpleasant % (n) | Very unpleasant % (n) | Don't know % (n) |
|------------------------|------------------------|-------------------|---------------------|--------------------------|---------------------|
| Control group n=34 | 18% (6) | 70% (24) | 6% (2) | 0 | 6% (2) |
| LP music group n=30 | 30% (9) | 60% (18) | 3% (1) | 0 | 7% (2) |
| PF music group n=34 | 53%* (18) | 44%* (15) | 3% (1) | 0 | 0 |

Abbreviations: LP = Loud speaker; PF = Patient focus.

* $p < 0.05$ compared to the control group.

It is of great importance that the music listening equipment is of good quality, easy to use, and hygienic. Health care associated infections such as methicillin-resistant *Staphylococcus aureus* (MRSA) can be transmitted indirectly by sharing items that contain the organism [29]. Therefore, allowing patients to use equipment such as headphones can increase the risk of cross infection. In the present study the patient focused music was distributed through an audio pillow covered with a pillowcase that was changed between the patients. The audio pillow [20] offers an adjustable patient focused sound environment without “shutting off the external world”; as well as it enables the patient to rest in any position without the inconvenience induced by some types of headphones. In the loudspeaker music group, the music intervention was prematurely stopped by request in one case stated by the subject, in two cases by the technician, and in one case by the physician. It appears that the delivery of patient focused music during the procedures is preferable, as the loudspeaker music may disturb the staff in performing the procedure.

Florence Nightingale proposed that it was the responsibility of nursing to control the patient’s environment in order for healing to take place. She recognized the power of music as a part of the healing process. She recommended wind instrumental pieces with continuous sound or air as generally having a beneficial effect on the sick. She also observed that instruments, which do not produce continuous sounds, would have the opposite effect [3]. Descriptions of music perceived as relaxing are: “quiet”, “peaceful”, “soft”, “dreamy”, “soothing”, “serene”, “un-dramatic”, “slow speed”, “regular rhythm”, “pleasant combination of instruments”, and “low volume” [30]. However, no clear picture has emerged regarding which genre is superior, or if research selected versus patient-selected music is most beneficial [3,4]. In the present study, the music selected by the researchers was MusiCure® [16], which is specifically designed music composed according to the classical composing technique, characterized as “genreless” and as “soundpheres.”

5.1. Limitation of the study

There are some limitations to the present study. First, a Hawthorne effect [31] could have occurred because the participants were aware of the interventions. Studies which are un-blinded can overestimate the treatment effects by about 17% [3]. Second, anxiety and well-being were measured only by subjective anxiety and well-being levels and without measuring any pre-test values. Finally, we did not calculate any sample size. The Consolidated Standard of Reporting Trials (CONSORT) proclaims that the method for determining sample size should be identified in publications [32]. The idea behind a sample size calculation is to maximize the chance of detecting a statistically and clinically significant difference between the interventions, when a difference really exists [32]. However, even with a small sample, and without a sample size calculation, we detected significant differences.

5.2. Implication for further research

As proclaimed in a recent article, further research is required into the development and effectiveness of nursing interventions for patients who are anxious about coronary angiography and/or PCI [33]. Music intervention is a nursing intervention to facilitate healing through pre-recorded music [3]. Research following the CONSORT statement including sample size calculation, should continue to test the effects on anxiety and well-being pre, during, and post coronary angiographic procedures. In addition, researchers should measure the respiratory rate, hemodynamic parameters, oxygen saturation, oxytocin levels, and levels of relaxation. However, we cannot exclude the possibility of a Hawthorne effect in our subjects, because they were aware of the study design. Given the ethical requirements for informed consent, the Hawthorne effect cannot be tested.

6. Conclusion

This study showed that the use of a specially designed music reduced anxiety and increased well-being in patients during coronary angiographic procedures. However, patient focused music appeared to be more preferable. The sound environment was rated more positively by those listening to music via audio pillows as well as the music delivered via loudspeakers seemed to distract the staff during the examination. The ability of nurses to use music listening as an intervention for patients undergoing coronary angiographic procedures promotes nursing autonomy and the notion that nurses can influence the patient’s environment.

Acknowledgements

The authors gratefully acknowledge Per Thorgaard, MD, Aarhus University Hospital, Aalborg, Denmark, Katharine Kolcaba, PhD, RN, C, Akron University, and Kathy Bell, MD, University of Washington, for support and assistance. We also thank the cardiac catheterization laboratory and same day surgical unit staff at Northwest Hospital & Medical Center, who fully supported our study. Finally, we are especially grateful to the patients who participated in the study.

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