

Vital Parameters Variations in Patients Undergoing Music Therapy During Cardiac Catheterization Procedures: A Preliminary Study

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Abstract

Background: Invasive cardiac procedures, such as coronary angiography, are known to induce patient stress and alter physiological parameters by triggering the sympathetic nervous system. While music is recognized to reduce anxiety, insufficient data exists regarding its specific physiological impact during these interventions. Unlike previous studies, which often utilized pre-selected tracks administered by non-specialized staff, this preliminary study investigates

whether a personalized music therapy intervention, managed by a qualified therapist, has a positive impact on vital parameters.

Methods: This prospective, single-center study compared 36 patients receiving personalized music therapy (experimental group) versus 36 controls (final cohort). The intervention involved a pre-procedural meeting for the therapist to assess musical preferences, establish rapport, and conduct a shared listening session. Vital parameters (Blood Pressure, Heart Rate,

Heart Rate Variability, and O₂ Peripheral Saturation) were analyzed across four distinct procedural phases.

Results: A statistically significant reduction in sedation requirements was observed in the music therapy group (11.8%) compared to the control group (44%) ($p < 0.0001$). The experimental group also demonstrated significantly higher SpO₂ levels compared to the non-sedated control subgroup. Conversely, BP and HRV showed no significant inter-group differences, indicating comparable hemodynamic stability. The observed increase in HR within the experimental group, occurring alongside stable HRV, correlated with specific musical parameters (e.g., stronger dynamics) and is interpreted as a state of positive arousal and emotional engagement rather than physiological distress.

Conclusions: Personalized music therapy demonstrates clinical value during invasive cardiac procedures. It significantly reduces the need for sedation and is associated with improved oxygen saturation while maintaining hemodynamic stability.

Keywords: Music therapy; Coronary angiography; Percutaneous coronary intervention (PCI); Cardiac catheterization; Cath lab

Introduction

Invasive diagnostic procedures, such as diagnostic coronary angiography and percutaneous angioplasty, may alter physiological parameters, inducing stress and triggering the sympathetic nervous system, while music, in general, has the potential to influence individual physiological response [1]. Scientific studies have involved the "administration" of pre-selected musical tracks by non-specialized personnel without prior knowledge of the patient, an essential premise for establishing a correct music-therapy relationship [2]. From these analyses, it has been possible to highlight that music and music therapy are able to reduce patients' anxiety levels in the cathlab. However, there is still insufficient data regarding changes in physiological parameters such as heart rate, blood

pressure, respiratory rate, and oxygen saturation. The psychological and emotional benefits of music are undeniable, both in non-invasive and invasive procedures, but the precise and scientific measurement of the parametric variations associated with music therapy remains incomplete. This study aims to investigate whether music therapy positively impacts the reactions that invasive coronary angiography and eventually percutaneous angioplasty may elicit in patients, by analyzing vital parameters.

Materials and Methods

This is a prospective single-center study in which 101 patients were enrolled between June 2022 and May 2023. Patients aged >18 years admitted to the Fondazione Policlinico Universitario Campus Bio-Medico in Rome to undergo a diagnostic coronary angiography procedure and eventually percutaneous angioplasty were included. All patients over 18 years old but hospitalized for a structural interventional procedure were excluded. Out of the 101 participants, 51 underwent an invasive procedure with music therapy support, while the other 50, who did not receive music therapy during the intervention, constituted the control group.

Patients who met the inclusion criteria were initially selected and enrolled. Eligible patients were contacted by the medical staff the day before the procedure. After the explanation phase, patients who decided to participate signed the informed consent. During this first contact, the medical staff also assessed the patients' musical preferences to provide useful information to the music therapist for song selection. This study complies with the Declaration of Helsinki and was approved by the local ethics committee. On the day of the procedure, the enrolled patients met with the music therapist to develop the most appropriate and effective therapeutic plan. All the pieces used were familiar or familiarizable, characterized by serene and open tonality, often modal, with non-syncopated tempos, not emotionally intense in lyrics or sonority,

tending to be static but not trivial. The next phase took place directly in the Hemodynamics Unit, where the single patients were welcomed again by the music therapist, ensuring continuity from the previous stage. In this pre-coronary angiography phase, the shared listening phase began: the music therapist played some of the previously selected tracks, and the patient expressed their opinion. This shared listening stage was crucial, as it helped confirm the most suitable musical orientation to use during the procedure and further strengthened the therapeutic and human relationship. However, not all the selected tracks were played; some remained new to the patient during the intervention. It was established that the preoperative phase should last between 15 and 30 minutes [3]. No musical parameters were recorded during this phase. From a clinical perspective, the patients' initial physiological data were accurately recorded: Blood Pressure (BP), Heart Rate (HR), and Peripheral Oxygen Saturation (SpO2). More specifically, the measurement methods for each parameter throughout the procedure were as follows:

Blood Pressure (BP) was recorded using a sphygmomanometer both before entering and after leaving the hemodynamics room. During the coronary angiography procedure, BP was measured invasively by connecting the arterial introducer to a pressure transducer, which allowed continuous recording via the polygraph.

Heart Rate (HR) was measured using a cardio-frequency meter (optical heart rate reading via photoplethysmography) before and after the procedure. Inside the room, HR was monitored using transthoracic electrodes for continuous ECG recording by the polygraph.

Peripheral Oxygen Saturation (SpO2) was measured using a pulse oximeter before and after the procedure. During the interventional procedure, a pulse oximeter was placed to enable continuous data recording by the polygraph.

Once inside the hemodynamics laboratory, patients wore audio headphones with disposable covers,

allowing them to communicate with the music therapist. Through these devices, the receptive musical therapy plan with pre-selected tracks was administered. Unlike the patient's headphones, the music therapist's set included a microphone, enabling vocal interaction when needed to maintain relational continuity. Throughout all phases, the physiological parameters were repeatedly recorded alongside the musical parameters corresponding to the track the patient was listening to. Close collaboration and coordination among team members were essential throughout the entire process. At the end of the procedure, the headphones were removed, and patients were transferred back to the pre-room area. In this phase, the final physiological parameters (BP, HR, SpO2) were recorded.

After the entire process, the music therapist contacted the patient for a final personal exchange, marking the end of the operational phase.

Musical Parameters

From a musical standpoint, the following key aspects were investigated: Agogics (specifically **BPM**), Genre, Tempo, Key, Dynamics, Register, **whether the piece was** vocal and/or instrumental, **and whether there was a** vocal intervention by the music therapist.

Descriptions of these aspects:

- **AGOGICS:** refers to the movement or pace of a piece.

| Term | BPM |
|-------------|------------|
| Largo | 40–59 |
| Larghetto | 60–66 |
| Adagio | 67–76 |
| Andante | 77–108 |
| Moderato | 109–120 |
| Allegro | 121–168 |
| Presto | 169–200 |
| Prestissimo | 201–208 |

Most selected tracks ranged from 47 to 89.67 BPM.

- **GENRE:** refers to the style or method of musical performance. Categories:
 - Classical
 - Light-Pop
 - Jazz-Latin
 - New Age-Celtic
 - Rock
 - Filmmusic
- **TEMPO:** refers to the time signature of the piece. The pieces used featured:
 - 4/4
 - 3/4
 - 2/4
 - 12/8
- **VOCAL/INSTRUMENTAL:** Tracks were either vocal (with lyrics) or instrumental (no lyrics).
- **DYNAMICS:** refers to sound intensity. The prevailing dynamics in the selected pieces were:
 - Mezzo-piano (moderately soft)
 - Mezzo-forte (moderatelyloud)
- **REGISTER:** refers to the pitch range. The prevailing registers in selected tracks were:
 - Low
 - Medium
- **THERAPIST'S VOICE:** The therapist's voice was not always involved, only when needed, and this variable was also recorded for analysis.

Most tracks featured a 4/4 tempo, while other time signatures were too infrequent for a significant comparative analysis.

The steps of physiological and musical parameters recordings are summarized in [Table 1](#).

Table 1: Steps of Physiological and Musical Parameters.

| | SETTING | PARAMETERS RECORDED |
|---------------|---|--------------------------------------|
| STEP 1 | UPON THE PATIENT ARRIVES AT THE WAITING ROOM | PHYSIOLOGICAL PARAMETERS |
| STEP 2 | UPON THE PATIENT ENTRY INTO THE HEMODYNAMICS ROOM | PHYSIOLOGICAL AND MUSICAL PARAMETERS |
| STEP 3 | FOLLOWING ARTERIAL INTRODUCER PLACEMENT | PHYSIOLOGICAL AND MUSICAL PARAMETERS |
| STEP 4 | FOLLOWING CONTRAST MEDIUM INJECTION | PHYSIOLOGICAL AND MUSICAL PARAMETERS |
| STEP 5 | OTHER INTRAPROCEDURAL EVENTS/ COMPLICATIONS | PHYSIOLOGICAL AND MUSICAL PARAMETERS |
| STEP 6 | REMOVAL OF ARTERIAL INTRODUCER | PHYSIOLOGICAL AND MUSICAL PARAMETERS |
| STEP 7 | PATIENT IN THE RECOVERY ROOM | PHYSIOLOGICAL PARAMETERS |

Statistics

Continuous variables were expressed as mean and standard error, and categorical variables expressed as number and percentage. The significance of differences between the means of the two groups was assessed by ANOVA, and a difference corresponding to a pvalue ≤ 0.05 was considered significant. Pearson's coefficient

was used to obtain the linear dependence between two variables, and a correlation greater than 0.3 in absolute value was considered significant. The analysis of musical parameters was performed in two stages. First, the correlation between each musical parameter and the mean physiological values (averaged across the four windows) was calculated. Subsequently, any

correlations found to be significant were then analyzed for their relationship within each time window. A superiority test was conducted to compare patients treated with music therapy to the control group, assessing whether the reduction in sedation requirements, potentially reflecting stress reduction, was statistically significant.

Data Analysis

The following steps were taken for parameter analysis. Four time windows of varying sizes were selected for the analysis of ECG data (7 leads) and pressure curves (obtained from invasive monitoring). The characteristics of the windows were as follows:

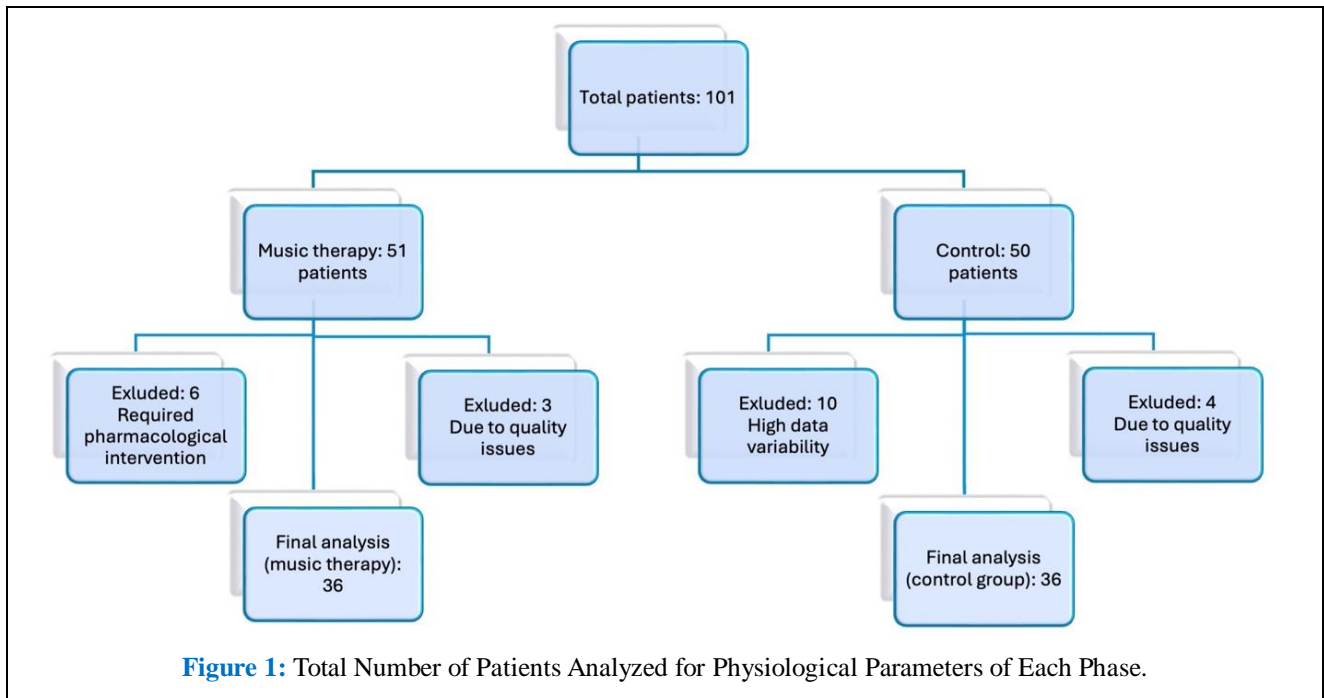
- **Stage 1:** first time window that, in most patients, started when the introducer was inserted until the first administration of contrast medium.
- **Stage 2 and 3:** these time windows were taken in the middle part of the tracing according to signal quality.
- **Stage 4:** last time window covering the parameters from the last administration of contrast medium until the removal of the introducer.

For each of these windows, the following analyses were performed: the mean Heart Rate (HR) and Heart Rate Variability (HRV) were calculated during the ECG evaluation through the rMSSD (Root Mean Square of Successive Differences). For the blood pressure data, mean Systolic Arterial Pressure (sAP) and mean Diastolic Arterial Pressure (dAP) were calculated. Of all the above parameters, the standard deviation was also calculated. Saturation data, having

very low variability, were compared by extrapolating only one value for each time window previously described. All variables were then compared between the two study groups, specifically:

- ✓ The experimental/test group that received music therapy support;
- ✓ Control group, consisting of both sedated and non-sedated patients, which later allowed for further investigation.

Comparisons were first conducted by evaluating the mean physiological parameters of each phase and subsequently re-evaluated using data derived from the intraprocedural relative variability, which was calculated by comparing the mean values of the subsequent windows to the first window. First, 6 patients from the experimental group who required pharmacological intervention (5 receiving opioids and/or benzodiazepines and 1 receiving atropine) were excluded. Second, patients who demonstrated high data variability (a standard deviation greater than 20% of the relative value for at least 5 measures) were excluded, which included 6 patients from the experimental group and 10 from the control group. Third, an additional 3 patients from the experimental group and 4 from the control group were excluded because they did not meet the inclusion criteria or due to data quality issues identified by an expert during the pre-analytical phase. The final cohort subjected to analysis, therefore, consisted of 36 patients in the experimental group and 36 in the control group (**Figure 1**).



The O2 saturation analysis was carried out separately from the primary analysis. This cohort included 38 patients from the experimental group and 46 from the control group. The control group (n=46) was composed of 27 sedated and 19 non-sedated patients. The exclusion criteria for this specific analysis differed: patients in the experimental group were excluded for receiving sedation and/or oxygen or for data quality issues, whereas control group patients were excluded only for data quality. Further investigation was conducted using a smaller sample of patients in whom normal coronary angiography was followed by a percutaneous angioplasty procedure, who were 10 patients in the test group and 25 in the control group. The patients who did not meet the criteria of either inclusion or standard deviation characteristics previously described were excluded. In the end, the final group consisted of 6 patients in the experimental group and 18 in the control group, of whom 6 received sedation while 12 did not. The aspects concerning SpO2 were also evaluated in this subgroup: 6 patients were analyzed for the experimental group and 22 for the control group, of whom 7 were sedated and 15 were not.

Results

The total population consisted of 101 patients; 51 were administered music therapy, while 50 made up the control group. The average age of the population treated with music therapy was 69 years, and 72 years for the control group. 74% of the music therapy group and 60% of the control group were male subjects. The group undergoing music therapy consisted of 58% residents in Lazio region, 26% in the rest of central Italy, 14% in southern Italy, and 2% in northern Italy. The analysis of the questionnaires showed that 56% of the patients listen to music often, 14% very often, 28% sometimes, and 2% rarely; while 64% of the subject listen to pop music, 24% prefer classical music, 10% rock music, and only 2% jazz music; 92% do not play any instruments, 2% play piano, 2% play trombone, and a 4% play guitar; 96% have no annoying noise that they would like to avoid, 4% experience annoyance when listening to jarring sounds; 48% have never heard of music therapy, while 52% know about it: specifically, among patients who previously know about music therapy, 79% learned about it through TV and media, 12% through school or non-profit organizations, and 8% learned about it in the hospital. The post-intervention questionnaire on music therapy activity showed that 96% of participants believed that the expectations about music therapy they had before

the intervention were met, for the 4% of the patients they were not met; 42% felt that the music therapy support was very helpful, 56% helpful, 2% not very helpful; 34% felt that music therapy supported relaxation a lot, 62% quite a lot, 2% a little, 2% not at all; 60% felt that music therapy helped them a lot in turning their thoughts to other things, 36% quite a lot,

2% a little, 2% not at all; 44% most appreciated music therapy during the procedure, 28% in the preoperative, 28% at both times; 100% would recommend music therapy support to other people. Average parametric values, obtained at four time windows, are shown in **Table 2**.

Table 2: Variation of PAS, PAD, HR, HRV, and SpO2 in Different Phases in Music Therapy Group, Control Group, and Sedated Group.

| PHASE | Music Therapy Group (n=51) | Control Group (n=25) | Control Group Sedated (n=25) | p |
|-----------------------|-----------------------------------|-----------------------------|-------------------------------------|----------|
| 1 | | | | |
| sAP, mmHg ± SD | 136,97 ± 1,57 | 141,89 ± 2,16 | 145,61 ± 4,61 | 0,38 |
| dAP, mmHg ± SD | 70,19 ± 1,35 | 70,83 ± 0,96 | 69,65 ± 2,22 | 0,82 |
| HR, bpm | 76,77 ± 1,44 | 71,02 ± 1,40 | 69,76 ± 1,77 | 0,03 |
| HRV | 95,12 ± 15,85 | 108,30 ± 23,09 | 110,13 ± 29,70 | 0,93 |
| SpO2 (%) | 96,31 ± 0,48 | 95,29 ± 0,40 | 96,63 ± 0,41 | 0,08 |
| PHASE 2 | | | | |
| sAP, mmHg ± SD | 127,90 ± 1,57 | 135,00 ± 2,58 | 135,74 ± 4,26 | 0,36 |
| dAP, mmHg± SD | 71,59 ± 1,50 | 70,22 ± 2,07 | 70,19 ± 1,75 | 0,55 |
| HR, bpm | 77,55 ± 1,13 | 71,27 ± 1,27 | 70,59 ± 1,38 | 0,02 |
| HRV | 76,49, ± 12,75 | 95,99 ± 20,49 | 86,47 ± 23,24 | 0,71 |
| SpO2 (%) | 96,45 ± 0,36 | 94,59 ± 0,48 | 95,74 ± 0,54 | 0,004 |

| | | | | |
|-------------------------------|------------------|------------------|-------------------|-------|
| PHASE 3 | | | | |
| sAP, mmHg ± SD | 125,08 ± 1,68 | 136,14 ± 1,65 | 131,02 ± 1,84 | 0,19 |
| dAP, mmHg± SD | 70,51 ± 1,05 | 72,45 ± 1,08 | 68,38 ± 1,25 | 0,94 |
| HR, bpm | 78,42 ± 1,22 | 71,00 ± 1,29 | 68,54 ± 1,56 | 0,007 |
| HRV | 85,30 ± 14,22 | 92,47 ± 19,72 | 102,42 ± 27,37 | 0,54 |
| SpO2 (%) | 96,13 ± 0,32 | 94,52± 0,49 | 95,84± 0,49 | 0,05 |
| PHASE 4 | | | | |
| sAP, mmHg± SD | 125,56± 1,6 | 135,33± 1,83 | 132,60 ± 2,73 | 0,11 |
| dAP, mmHg± SD | 71,14 ± 1,02 | 73,42 ± 0,88 | 69,74 ± 1,34 | 0,53 |
| HR, bpm | 78.75 ± 1,41 | 72,65± 1,33 | 69,19 ± 1,67 | 0,02 |
| HRV | 95,48 ± 15,91 | 92,46 ± 19,71 | 95,78 ± 25,60 | 0,90 |
| SpO2 (%) | 96,47± 0,30 | 95,52± 0,46 | 96,42 ± 0,65 | 0,26 |

Comparison of Arterial Pressure, Heart Rate, and Heart Rate Variability Groups

The analysis was carried out by evaluating the differences between the two groups in two different ways: the first by comparing the average physiological parameters of the individual phases of each patient. The second one was based on the comparison of the data obtained by calculating the relative change in the mean values of the subsequent windows to the first window. The comparison of the mean physiological parameters of the individual phases showed that for

both mean sAP and dAP parameters, there was no significant variability between the experimental group and the control group from Phase 1 to Phase 4. In the analysis of Heart Rate (HR), comparisons with both Mean Heart Rate and Heart Rate Variability (HRV) data were evaluated. Concerning HRV, no significant differences were observed between the experimental (test) group and the control group at any stage. However, the comparison of the data about mean HRV showed that patients in the experimental group presented higher values than patients belonging to the

control group. In particular, this significance is to be related to the sedated group rather than the non-sedated

one (Figure 2).

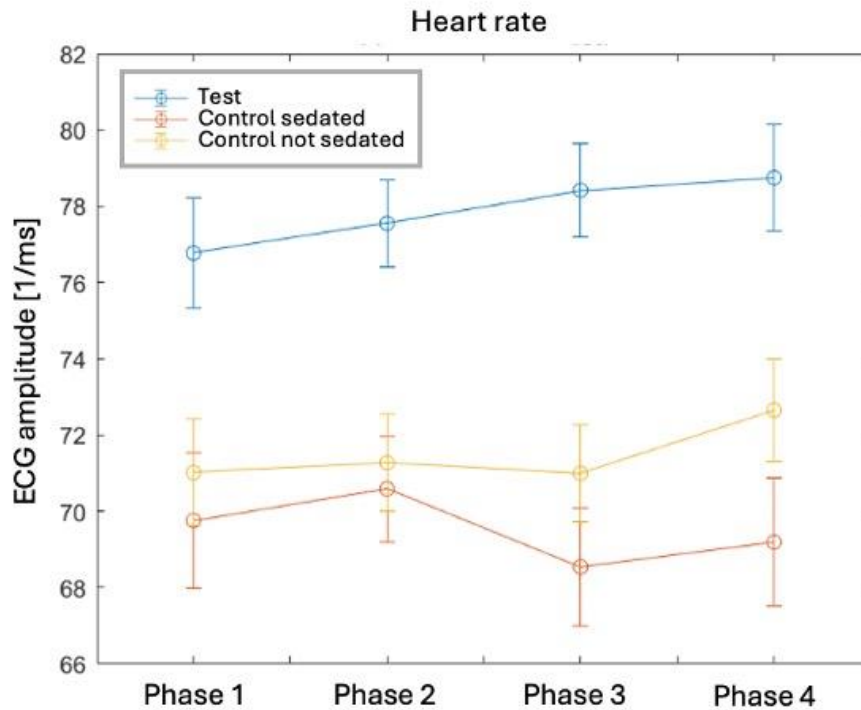


Figure 2: Comparison of Mean HRV between Groups.

The analysis of relative intra-procedural variability, which compared the changes in subsequent stages relative to the first stage, revealed no significant differences for either mean sAP or mean dAP. The same result was found in the evaluation of mean HR and HRV.

O2 Saturation Analysis and Comparison

The evaluation of O2 saturation parameters and group comparisons is detailed in Table 3. Absolute saturation levels were higher in the test group than in the control group; specifically, this increase was significant when compared to the non-sedated control subgroup.

Table 3: Comparison of HR and SpO2 between Groups.

| | Music Therapy Group (n=51) | Control Group (Not Sedated Pts) (n=25) | Control Group (Sedated Pts) (n=25) | P (Sedated Pts and Not Pts) | P (Music Therapy and Sedated Pts) | P (Music Therapy and Not Sedated Pts) | P (3 groups) | P (Test and Control Group) |
|----------|----------------------------|--|------------------------------------|-----------------------------|-----------------------------------|---------------------------------------|--------------|----------------------------|
| HR (bpm) | 77,55 ± 1,13 | 71,27 ± 1,27 | 70,59 ± 1,38 | 0,58 | 0,04 | 0,11 | 0,07 | 0,03 |
| HR (bpm) | 77,55 ± 1,13 | 71,27 ± 1,27 | 70,59 ± 1,38 | 0,72 | 0,03 | 0,06 | 0,05 | 0,02 |
| HR | 78,42± | 71,00 ± | 68,54 ± | 0,036 | 0,01 | 0,06 | 0,02 | 0,02 |

| | | | | | | | | |
|-------------|---|---|---|--|--|--|-------------------------|---|
| (bpm) | 1,22 | 1,29 | 1,56 | | | | | |
| HR | 78,75 ± | 72,65 ± | 69,19± | 0,13 | 0,01 | 0,12 | 0,02 | 0,02 |
| (bpm) | 1,41 | 1,33 | 1,67 | | | | | |
| | Music Therapy Group (n=51) | Control Group (Not Sedated Pts) (n=25) | Control Group (Sedated Pts) (n=25) | p (Sedated Pts and Not Pts) | p (Music Therapy and Sedated Pts) | p (Music Therapy and Not Sedated Pts) | p (3 groups) | p (Test and Control Group) |
| SpO2 | 96,31 ± | 95,29 ± | 96,63 ± | 0,03 | 0,94 | 0,01 | 0,02 | 0,08 |
| (%) | 0,48 | 0,40 | 0,41 | | | | | |
| SpO2 | 96,45 ± | 94,59 ± | 95,47 ± | 0,22 | 0,11 | 0,002 | 0,01 | 0,004 |
| (%) | 0,36 | 0,48 | 0,54 | | | | | |
| SpO2 | 96,13 ± | 94,52 ± | 95,84 ± | 0,08 | 0,66 | 0,01 | 0,03 | 0,05 |
| (%) | 0,32 | 0,49 | 0,49 | | | | | |
| SpO2 | 96,47 ± | 95,52 ± | 96,42 ± | 0,29 | 0,87 | 0,12 | 0,29 | 0,26 |
| (%) | 0,30 | 0,46 | 0,65 | | | | | |

HR: Heart Rate, SpO2: Peripheral Arterial Oxygen Saturation.

A separate analysis of the relative intra-procedural variability of SpO2 (comparing values after the first window to the last one) found no significant variability overall. The only exception noted in this variability analysis was in Phase 2, where a significant difference emerged between the test patients and the sedated control subgroup.

Percutaneous Coronary Angioplasty Group Sub analysis

The analysis included 6 patients from the experimental group and 18 from the control group. The control group was further composed of 6 sedated and 12 non-sedated patients. Considering the mean values of the various phases, no significant variations emerged regarding HR and HVR. In contrast, significant differences were observed between the values of sAP and dAP, which were higher in the test group than in the control group. Specifically, sAP was found to be significantly higher in Phases 1 and 2, particularly compared with the non-sedated control group. On the other hand, dAP was found to be increased in the experimental group compared with the control group,

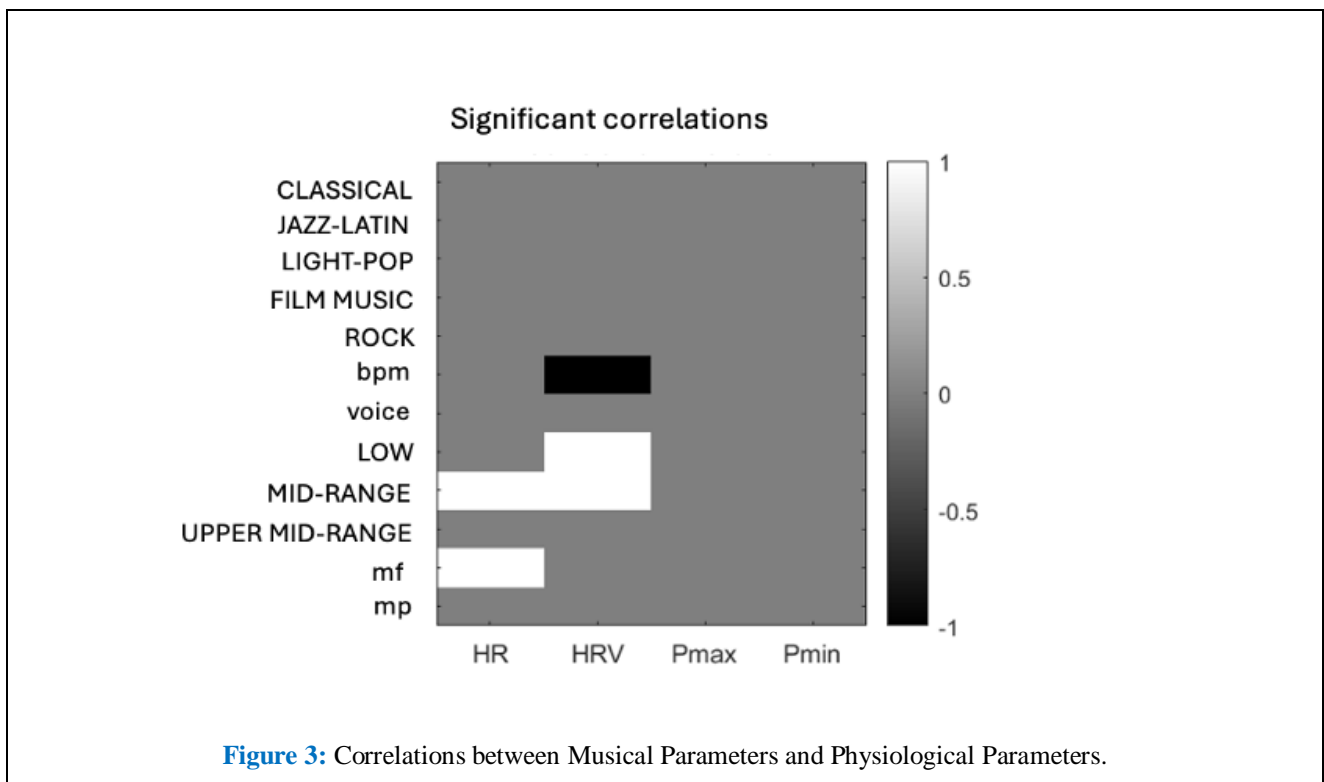
particularly compared with the non-sedated group in Phase 2. Comparison of the data obtained by calculating the relative intraprocedural variability between the stages after the first with the latter showed that there were no significant differences for either pressor values or HVR. HR, however, was higher between test patients and sedated control patients. This alteration was also observed within the same control group, where there was a significant difference between sedated and non-sedated patients in Phases 3 and 4. About the evaluation of SpO2 data, there were 6 patients analyzed in the experimental group and 22 in the control group, including 7 sedated and 15 non-sedated patients. The comparison showed that there was a significant difference in Phase 1 between the test group and control group, especially with the non-sedated subgroup. In contrast, the between-group comparison of relative intra-procedural variability revealed no significant variations.

Music Data

To assess the relationship between music and physiology, each musical parameter was first correlated

with the mean physiological values (averaged across the four windows). Subsequently, any correlations identified as significant were then analyzed in greater detail to determine their relationship within each of the individual windows. The Pearson correlation coefficient was used to determine the linear dependency between two variables, and a correlation was considered significant if it was greater than 0.3 in absolute value. From this analysis, it emerged that there is a significant correlation between bpm and HRV (Pearson coefficient = -0.38). Specifically, this relationship links higher bpm with lower HRV and vice versa. A clear association was observed in all stages,

particularly in the middle ones. Another significant correlation was found between dynamics and HR (Pearson coefficient = 0.49). Specifically, tracks with stronger dynamics were correlated with an increase in HR. This relationship was stronger in the central phases, Phases 2 and 3. Regarding the register, a significant correlation with HRV was observed (Pearson coefficient = 0.37 and 0.34). Lower registers were associated with an increase in HRV, while higher registers were linked to a decrease in HRV. No statistically significant differences emerged from the analysis and comparison of the other musical parameters (Figure 3).



Sedation During Intervention

A test for superiority was performed between the group of patients treated with music therapy and the control group in order to understand whether the reduction of the need for sedation, which could be a direct expression of stress reduction, was statistically significant. The result showed that there was a

statistically significant decrease in sedation between the control group (44%) and the music therapy group (11.8%), with a Confidence Interval (CI 95 percent) found to be -11.6 % to -43.3%. This significance is evidenced by the χ^2 test, which gave a p-value <0.0001 (Table 4).

Table 4: Comparison of Pharmacological Sedation Requirements between the Music Therapy Group and the Control Group, with Results from the Superiority (χ^2) Test.

| Group | Percentage of Sedated Patients | Absolute Reduction in Sedation | 95% CI (Wilson Interval) | p (χ^2 test) |
|---------------|--------------------------------|--------------------------------|--------------------------|--------------------|
| Music Therapy | 6/51 (11.8%) | -32.2% (11.8% - 44%) | From -11.6% to -43.3% | 0.000097 |
| Control | 22/50 (44%) | | | |

Discussion

Music therapy is defined by the use of music and/or its elements (sound, rhythm, melody, and harmony) by a qualified music therapist, who actively involves patients in listening to and expressing music. It is defined as an organized process carried out by the music therapist, aiming at specific goals through a series of sessions that lead to a gradual change in the patient, using different techniques depending on the reference mode, but with a common element: the use of sound within the relationship. Music therapy does not aim to acquire musical skills, nor does it refer to universally recognized musical aesthetic rules. Conversely, it aims to reduce tension, remove inhibitions, facilitate communication, stimulate activity, and improve relational possibilities. Additionally, music therapy attempts to establish a process that facilitates and encourages communication and the expression of emotions, in order to meet the patient's physical, emotional, social, and cognitive needs [5]. Finally, it aims to develop the potential or residual functions of the individual, so that the patient can improve quality of life through preventive, rehabilitative, and therapeutic processes [6]. Music affects every cognitive ability, not only the auditory and motor systems involved in musical perception and production, but also multisensory interactions, including physical parameters. Specifically, the main effects of music on the human body have been largely described [7]. In particular, musical rhythm is known to influence heart rate and blood pressure; for instance, HR tends to accelerate with fast-paced music and

decelerate with slower tracks. Slower beats reduce body tension, anxiety, and worries [8]. Also, body temperature, because some disturbing sounds are capable of creating cold shivers down the spine, while loud music can even raise body temperature by a few degrees [9]. Music also impacts respiration; listening to particularly rhythmic music can make breathing more dynamic, while slower rhythms tend to lead to deeper breaths, inducing a state of relaxation [10]. Studies have also shown that listening to relaxing music reduces the secretion of stress hormones such as cortisol [11]. Music is also able to regulate the release of oxytocin, another hormone that helps control stress and anxiety [12]. Current research has found that reduced oxygen levels in the blood can trigger neurodegenerative diseases, and listening to music can oxygenate cells, promoting the release of hormones that slow disease progression (immune system effect) [13]. Music may also influence the cognitive and behavioral system. As a structured form of communication with its own language, its decoding is largely handled by the left hemisphere (responsible for logical processes), while its emotional aspects are perceived by the right hemisphere [14].

The music therapy approach employed was based on receptive music listening, grounded in established music therapy reference models, integrated with neuroscientific evidence, and the theoretical framework proposed by K. Bruscia [15]. The auditory experience has the potential to modulate physiological, emotional, and cognitive dimensions, eliciting therapeutic responses through relaxation, meditation, structured or

spontaneous movement, free association, storytelling, and vocal expression. The efficacy of the intervention is contingent upon the precise alignment between the patient's therapeutic needs, the intrinsic properties of the selected musical stimuli, and their neuropsychological effects [16]. The selection of musical pieces follows rigorously defined criteria, encompassing a diverse range of musical genres, from classical to jazz, and from pop to new age. A critical determinant in the selection process is represented by the ISO (Identity Sound) principle formulated by R. O. Benenzon, which suggests the existence of a unique and subjective sonic identity, shaped by an individual's lifetime of auditory-musical experiences. This principle currently represents the most widely adopted theoretical model in clinical music therapy on an international scale [17]. Patients undergoing coronary angiography or percutaneous angioplasty procedures may manifest altered emotional reactivity with changes in vital parameters, brought about by fear or anxiety, which could affect the successful outcome of the procedure [18]. Building on evidence from previous studies demonstrating that music can reduce anxiety and influence physiological responses, there is a growing effort to integrate it into clinical practice to provide emotional support for patients and, when possible, reduce the need for medications such as benzodiazepines and opioids [19]. Most of the current literature has involved the "administration" of pre-selected music tracks, listened to by patients undifferentiatedly, chosen by non-specialized staff, and without prior knowledge of the candidate. In addition, insufficient data regarding the change in physiological parameters have not been reported so far.

Therefore, this study was created to enrich such evidence through the analysis of changes in the above-mentioned vital parameters (BP, HR, SpO₂). These parameters were collected during coronary angiography and percutaneous angioplasty procedures from patients treated with music therapy through a shared listening system in the Hemodynamics Unit. The

songs were carefully selected by the music therapist based on both the patient's musical tastes and his or her sensitivity and emotionality. A total of 101 patients were studied: 51 received music therapy, and 50 did not receive music (control group). Patients were followed before the procedure by the clinical team and the therapist to get to know them and make the musical support as personalized as possible. Physiological parameters were recorded before, during, and after the coronary examination and/or percutaneous angioplasty, while musical parameters were assessed only during the procedure. In the analysis of the recorded parameters, the changes in mean PAS, mean PAD, mean HR, and SpO₂ from Phase 1 to Phase 4 were calculated, and these data were then compared between the two study groups. Next, the relative intra-procedural variability of these parameters was assessed by comparing the windows after the first versus the latter, then making the comparison with the control group. From an analytical point of view, the first aspect that emerged from the evaluation of the study population was as follows: in the control group (50 patients), 44% (22 patients) needed pharmacological intervention compared with 11.8% (6 patients) in the experimental group (51 patients). This finding provides evidence that the treatment reduced the need for pharmacological intervention. From the superiority test, it has been demonstrated that this reduction was statistically significant. About the between-group comparison of the mean physiological parameters of the individual phases, it was found that there were no significant differences between either the mean PAS or mean PAD values in each phase, thus indicating hemodynamic stability equal to the control group. HVR showed no significant differences as well. However, the interpretation of this parameter is complex and must be contextualized, taking into account that there are several factors that can influence it, such as the HR. Evaluation of mean HR showed that there was a significant increase in the latter compared to the control group, specifically compared to the

sedated subgroup, while compared to the non-sedated subgroup, the values were borderline (with higher HR always in the test group). As previously noted, HR and HRV are interdependent, making an isolated analysis of either parameter reductive. Although HRV is considered a valuable non-invasive index of vagal autonomic activation, accurately using it for this purpose requires correcting the value relative to the concurrent HR. Therefore, a more complete interpretation of the current findings, specifically the observed increase in HR alongside stable HRV, is offered by the correlations found between the musical parameters and both the HR and HRV values. A significant correlation emerged between the dynamics of a song (medium or loud) and HR; in particular, louder songs would correlate with a greater increase in HR. It is appropriate from a scientific point of view to speak of Arousal: a temporary condition of bodily, psychological, and mental activation, involving a heightened attentional-cognitive state of vigilance, indicative of the intensity of psychophysiological activity related to emotional involvement [20]. Listening to pleasant music activates cortical and subcortical brain areas in which emotions are processed and from which increased arousal arises. It could also be pointed out that this parameter remains constant throughout the intervention [21]; in fact, from the assessment of the relative intra-procedural variability between the stages following the first and the latter, there are no significant differences to be pointed out. About the analytical evaluation of SpO₂ parameters, it was found that there was a significant difference between the test and control groups, specifically with the non-sedated subgroup. Indeed, SpO₂ was found to be increased in the experimental group. Some studies have highlighted the effects of music on breathing and how it tends to reduce the frequency of respiratory movements [22]. This data could be linked to the increase in SpO₂, which may arise from an increase in breathing depth. Undoubtedly, this evaluation could be supported by further investigations. However, even

with the data related to SpO₂ alone, it is evident that it was not only significantly increased compared to the non-sedated control subgroup but also that this benefit remained constant throughout the procedure. In particular, another aspect could be emphasized: in the experimental group, compared to the sedated control subgroup, the initial drop in SpO₂ between Phases 1 and 2, which was caused by the sedation itself, was also absent. The SpO₂ data were analyzed for a cohort of 6 patients in the experimental group and 15 in the control group (of which 7 were sedated and 8 were non-sedated). The analysis revealed that in Phase 1, the experimental group showed an increase in SpO₂ compared to the non-sedated control group. This benefit, however, seemed to disappear in the subsequent phases. Once again, for a better evaluation, the analysis group should be expanded. Finally, an additional sub-analysis was performed in the smaller sample of patients who continued the procedure with a percutaneous angioplasty: experimental group (6 patients) and control group (18 patients), of which 6 were sedated and 12 were not. This sub-analysis is only intended as a pilot study and should therefore be evaluated considering the small sample size, which could be expanded in the future. By analyzing the mean data of each phase, it emerged that, compared to the non-sedated controls, patients with music therapy tended to have higher Systolic Blood Pressure (sBP) values in Phases 1 and 2 and higher Diastolic Blood Pressure (DBP) values in Phase 2. Considering this sample as a subgroup of the previous one, and given that these phases (both 1 and 2) are more closely related to the coronary angiography procedure performed before percutaneous angioplasty, one possible interpretation could be that this evidence is mainly due to the small number of patients in the experimental group. The same assessment could be made regarding Phase 2, where a concurrent increase in DBP was observed. It should also be noted that, in this context, both Heart Rate Variability (HRV) and Heart Rate (HR) did not show significant changes. From the

data obtained by comparing the groups and assessing intra-procedural variations, between the phases following the first and the first phase itself, all parameters were not significant, except for the mean Heart Rate (HR), which was increased in the experimental group compared to the sedated control group, but not compared to the non-sedated control group. This data was significant in Phases 3 and 4. These phases, which are more closely related to the angioplasty procedure, might reflect an increased patient engagement, as they have now been informed and the intervention has become more complex. However, it should still be emphasized that this change is comparable to that of the non-sedated control group, and thus not relevant from a procedural risk perspective. This aspect should certainly be further explored by expanding the sample size.

Conclusions

In this study, the continuous dialogue between the various team members and their integration was fundamental.

The preliminary interview before the procedure, conducted by the music therapist, played a crucial role both in establishing the trust relationship with the patient, thereby making the therapeutic intervention more comprehensive, and in selecting the most suitable music tracks. Moreover, there was a shared listening experience between the music therapist and the patient, of the tracks considered appropriate, so as to constantly monitor the patient's experience. Another innovative aspect of the study was the use of the music therapist's voice, which was maintained even during the invasive procedure. This analysis highlighted that, in addition to an undeniable human value, music therapy can also have a clinical value: indeed, a reduction in pharmacological use was observed during diagnostic coronary angiography and/or percutaneous angioplasty procedures. This evidence was statistically validated through a superiority test, which yielded positive results. From a parametric perspective, a significant

benefit regarding SpO₂ levels was observed in comparison to the non-sedated control group, with stability throughout the procedure. Other parameters did not show significant variations, except for HR, which was increased in the experimental group compared to the controls. However, it is important to emphasize that HRV did not show significant changes. A possible interpretative key, based on the previous considerations, could be the arousal: a temporary state of bodily, psychological, and mental activation that leads to a heightened attentional-cognitive vigilance, indicating the intensity of the psychophysiological activity linked to emotional involvement. From a qualitative perspective, all this must be considered in the context where the post-procedure evaluation by the patient was excellent in most cases. As for the musical data, significant correlations emerged between tempo and HRV, predominant dynamics and HR, and predominant register and HRV. Rather than being absolute data, these results could be seen as further confirmation of the scientific evidence supporting the music therapist's choice of tracks to achieve the therapeutic objective.

Study Limitations

Undoubtedly, there is still much to investigate, and these data could be further enriched. For example, the respiratory rate could be investigated and correlated with SpO₂ values, or parametric data could be assessed between the pre-surgery phase and the phase just before the introducer placement, which is when the puncture occurs, representing a particularly delicate moment for the patient. In addition, more complex statistical analyses using the existing data could provide a better interpretive understanding, and enriching the sample with more patients treated with coronary angioplasty would allow for additional evaluations.

Authors Contribution Statement

All authors have provided significant contributions to the preparation of the enclosed manuscript as follows:

- Luca D'Antonio: conceptualization, project administration and supervision;
- Marina Bartucca: conceptualization, data and methodology curation;
- Maria Pia Di Bitonto: conceptualization, visualization, data curation, original draft preparation;
- Luisa Vicchio: conceptualization, visualization, formal analysis and original draft preparation;
- Valeria Cammalleri: conceptualization and supervision;
- Mariolina Rossi: conceptualization, data curation and resources finding;
- Myriam Carpenito: conceptualization and data curation;
- Rossana Alloni: funding acquisition, conceptualization and project administration;
- Gian Paolo Ussia: project administration and supervision.

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This study was conducted in accordance with the principles stated in the Declaration of Helsinki and was approved by the Ethics Committee of the Fondazione Policlinico Universitario Campus Bio-Medico in Rome. All participants provided written informed consent after receiving a full explanation of the procedure and prior to any study-related activities.

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