CARDIAC



Randomized controlled trial of relaxation music to reduce heart rate in patients undergoing cardiac CT

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Received: 14 July 2015 / Revised: 22 October 2015 / Accepted: 13 January 2016 / Published online: 27 January 2016 © European Society of Radiology 2016

Abstract

Objectives To evaluate the heart rate lowering effect of relaxation music in patients undergoing coronary CT angiography (CCTA), pulmonary vein CT (PVCT) and coronary calcium score CT (CCS).

Methods Patients were randomised to a control group (i.e. standard of care protocol) or to a relaxation music group (ie. standard of care protocol with music). The groups were compared for heart rate, radiation dose, image quality and dose of IV metoprolol. Both groups completed State-Trait Anxiety Inventory anxiety questionnaires to assess patient experience. Results One hundred and ninety-seven patients were recruited (61.9 % males); mean age 56y (19-86 y); 127 CCTA, 17 PVCT, 53 CCS. No significant difference in heart rate, radiation dose, image quality, metoprolol dose and anxiety scores. 86 % of patients enjoyed the music. 90 % of patients in the music group expressed a strong preference to have music for future examinations. The patient cohort demonstrated low anxiety levels prior to CT.

Conclusion Relaxation music in CCTA, PVCT and CCS does not reduce heart rate or IV metoprolol use. Patients showed low levels of anxiety indicating that anxiolytics may not have

Electronic supplementary material The online version of this article (doi:10.1007/s00330-016-4215-8) contains supplementary material, which is available to authorized users.

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a significant role in lowering heart rate. Music can be used in cardiac CT to improve patient experience.

Key Points

- Relaxation music does not reduce heart rate in cardiac CT
- Relaxation music does not reduce beta-blocker use in cardiac CT
- Relaxation music has no effect on cardiac CT image quality
- Low levels of anxiety are present in patients prior to cardiac CT
- Patients enjoyed the relaxation music and this results in improved patient experience

Keywords Coronary computed tomography angiography · Heart rate · Calcium score · Beta-blocker · Pulmonary vein CT

Coronary calcium score computed tomography

Abbreviations

kV

mA

MDCT

Kilovoltage

Milliampere

CCS	Coronary carcium score computed tomography
CCTA	Coronary computed tomography angiography
CT	Computed tomography
DLP	Dose length product
DTA	Descending thoracic aorta
EW	Exposure window
HR	Heart rate
HR_B	Heart rate during final breathhold during ECG
	calibration
HR_{I}	Heart rate during image acquisition
$HR_{I\text{-}W}$	The change in heart rate between HR _I and HR _W
HR_T	Heart rate on first arrival at the CT table
HR_{W}	Heart rate in the waiting room prior to
	randomisation
HU	Hounsfield units

Multidetector computed tomography



PVCT Pulmonary vein computed tomography

RRI ECG R-R interval

STAI State-trait anxiety inventory

Introduction

Beta-blockers are given prior in cardiac computed tomography (CT) in order to achieve low and steady heart rates that are important for obtaining good quality diagnostic images at the lowest radiation dose [1]. However, some patients do not respond to oral or IV beta-blockers even at high doses [2]. This lack of response has been attributed to genetic variation in beta receptors and patient anxiety [2]. Different strategies have been considered such as the use of benzodiazepines to reduce patient anxiety [3].

Relaxation music has been used to reduce anxiety and improve physiological responses such as lowering the patient heart rate and respiratory rate for a variety of clinical scenarios [4–8]. Music has been successfully used in paediatric CT examinations to eliminate the use of sedation [9], but there is no published research on the potential heart rate lowering effect of music prior to cardiac CT. Based on previous findings, it could be theorized that music could provide an adjunct to beta-blockers in lowering heart rate especially for patients who show little or no response to beta-blockers. Other hypothetical benefits of music are the potential to decrease the amount of beta-blocker required and a reduction in dose related side effects (e.g., bronchospasm, dizziness, and headache) and improved patient experience. To the best of our knowledge, these potential benefits have not been studied in the context of cardiac CT.

The primary aim of this study was to test whether relaxation music lowers heart rate during cardiac CT, and whether this action is synergistic with use of beta-blockers. For the purposes of this study, we selected patients scheduled for 1) coronary CT angiography (CCTA), during which beta-blockers are routinely administered, and 2) pulmonary vein CT (PVCT) and coronary calcium score CT (CCS), for which beta-blockers are not routinely given. The secondary aims were to evaluate differences in radiation dose, metoprolol dose, image quality, patient experience and patient anxiety levels with the use of relaxation music.

Materials and methods

The local institutional review board approved this single blinded prospective randomised control trial (Clinicaltrials.gov - NCT02069405). The patients were recruited from January 2014 to May 2014 at a single centre.



Study criteria

All patients clinically referred to our institution for CCTA, PVCT, or CCS were included. Exclusion criteria were: hearing impairment, poor English literacy, pacemaker, automatic implantable cardioverter defibrillator, status post-coronary artery bypass grafting, prior heart transplant, and patients with congenital heart disease.

Study workflow (Fig. 1)

Consecutive eligible patients were approached by a study coordinator on arrival in the department and written informed consent was obtained from each participant. The patients were asked to complete a validated short-form State-Trait Anxiety Inventory (STAI) questionnaire [10] prior to randomisation. The randomisation sheet was concealed from the investigators, and the group to which the patient was randomised was only revealed to the investigators and patient on completion of the STAI questionnaire. The patient was randomly allocated to either a control group, which utilized a standard of care protocol, or to the music group, which added the use of relaxation music to the standard protocol. Patients randomised to the music group were provided with disposable ear phones and a small digital music player pre-loaded with 32 relaxation music tracks. The patients were instructed on how to use the music player and listened to relaxation music in the waiting room and during the CT scan until the scan was completed. The patients were given breathing instructions before and during the cardiac CT examination with instructions not to perform a Valsalva manoeuvre. As part of the study protocol, the CT technologist verified that the patients were able to hear the music over the background noise of the CT scanner. The patient's heart rate was recorded at several time points as follows: in the waiting room prior to randomisation (HR_W); when first lying on the CT table (HR_T), during the final breath hold ECG calibration (HR_B), and during image acquisition (HR_I). The change in heart rate (HR_{I-W}) was calculated from the difference between HR_I and HR_W. The X-ray tube kV and mA were recorded. The dose of intravenous metoprolol and sublingual nitroglycerin was noted. Post-cardiac CT, the patient completed a duplicate STAI questionnaire and additional questions on their experience during cardiac CT (see Fig. 1).

Sample size calculation

A sample size calculation was performed based on previously published data [2]. The sample size calculation was set with a power of 0.8, standard deviation of 12, minimum expected difference of 5 bpm in the $HR_{\rm I}$, and α error of 0.05 giving a sample size of 180 patients.

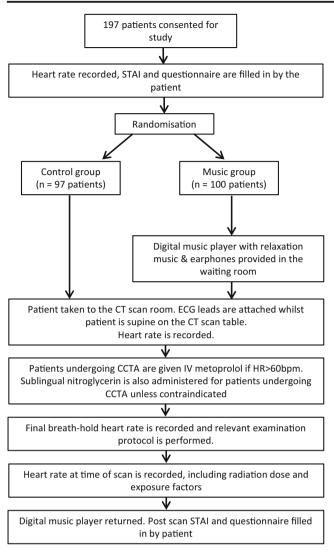


Fig. 1 Study workflow. CCTA – Coronary Computed Tomography Angiography; STAI – State-Trait Anxiety Inventory

Imaging protocol

All scans were acquired using a 320 multidetector CT (MDCT) Aquilion One, Toshiba Medical Systems, Otawara, Japan) using a beam collimation of 320×0.5 mm and gantry rotation time of 0.35 sec. The scans were all acquired using established clinical protocols with prospective ECG gating.

CCTA

CT dose reduction software (SureExposure) was employed to minimize patient exposure by maximizing X-ray tube current to a peak of 550 mA and minimize X-ray tube potential in the following clinically established settings of tube potential (kV); standard deviation of image noise (SD, HU) and trigger threshold (HU) for image acquisition in the descending thoracic aorta (DTA) respectively: (1) 80 kV, 46 HU, 240 HU; (2) 100 kV, 44 HU, 220 HU; (3) 120 kV, 40 HU, 200 HU; and (4)

135 kV, 38 HU, 200 HU. Iodinated contrast medium, iopromide 370 mg/ml (Bayer Healthcare), was injected into the antecubital vein. The volume and rate were titrated to the X-ray potential as follows: 80 kV, 50 mls at 4.0 mls/sec; 100 kV, 60 mls at 4.5 mls/sec; 120 kV, 70 mls at 5.0 mls/sec and 135 kV, 90 mls at 6.0 ml/sec. 20 ml of 0.9 % saline were injected at 5-7 ml/sec as a flush. The X-ray exposure window (EW) was adjusted to the heart rate (HR) as follows: HR \leq 59 bpm, EW=70-80 % of the R-R interval (RRI); HR \approx 59 bpm, EW=40-80 % of the RRI.

Intravenous metoprolol was administered slowly in 5 mg boluses up to a maximum of 50 mg to lower the heart rate ≤60 bpm. Sublingual nitroglycerin 300 µg (Nitrostat, Pfizer Inc, New York, USA) was administered 5 minutes before the start of the CCTA scan unless contraindicated. Trans-axial images were reconstructed at 0.5/0.3 mm slice thickness/ reconstruction interval.

Pulmonary vein CT

The X-ray tube potential was 100 kV, the tube current was 100-300 mA and the EW = 75 % of the RRI. Iodinated contrast agent, iopromide 370 mg/ml (Bayer Healthcare), was injected at 5-7 ml/sec using 60-105 ml and a 0.9 % saline flush of 20 ml at 5-7 ml/sec. Trans-axial images were reconstructed at 1.0 mm slice thickness. No beta-blockers or other medications were given.

Calcium score

Volumetric prospective ECG gated acquisition with 0.5 cm slice thickness was reconstructed into contiguous 3.0 mm trans-axial images. X-ray exposure settings were set at 120 kV and 250-550 mA depending on body habitus. No IV contrast, beta-blockers or other medications were administered.

Image quality analysis

Two level-3 trained cardiac radiologists with 17 years and 8 years experience of reading cardiac CT independently reviewed anonymized images, to assess image quality. The radiologists were blinded to group allocation for each patient. Where relevant, the reformatted or volume-rendered images were used to help with the assessment.

Each CCTA was assessed on a 4-point Likert scale for image quality based on coronary artery motion artefacts as follows: 1=severe resulting in a non-diagnostic scan; 2=moderate severity; 3=mild severity; and 4=no artefact [11].

The PVCT was also rated using a similar 4-point rating scale but focused on the pulmonary veins.

CCS was rated using a 3-point scoring scale for image quality based on coronary artery motion artefacts as follows: 1 = severe resulting in a non-diagnostic scan; 2 = mild/ moderate severity; and 3 = no motion artefact [12].



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The radiologists' image quality scores were averaged to obtain a composite mean quality score.

STAI and questionnaire

As patient anxiety was a secondary endpoint, the validated 6-item short form of STAI [10] was used to maximize completion rates and increase patient compliance. The cut-off used to indicate high anxiety for the 6-item short form correlates with a score of >13 [13, 14]. The STAI tool was used at the time of consent and post-scan. After completing the post-scan STAI tool, the patients were asked additional questions to rate their comfort in terms of: a) noise, b) body position, and c) room temperature; and preference for music: a) usual use of music for relaxation, b) whether they would like to have music for future CT examinations, and c) whether they enjoyed the music provided during the visit, using a 5-point Likert scale.

Music

Thirty-two music tracks were placed on 3 digital music players. The compilation included classical, new age, and jazz music (see supplement file 1).

Statistical analyses

Analysis was performed with IBM SPSS statistics for Windows version 20.0. The distributions of key parameters were investigated by examining plots, skewness, kurtosis, and using the Kolmogorov-Smirnov test for normality, as the parameters were not found to be normally distributed. The Mann-Whitney U test was used to compare the two patient cohorts for the following parameters: HR in the waiting room prior to randomisation (HR_W); HR when first lying on the CT table (HR_T), HR during the final breath hold ECG calibration (HR_B) and HR during image acquisition (HR_I); radiation dose, metoprolol dose, and patient experience via a State-Trait Anxiety Inventory (STAI). A Wilcoxon Signed Rank test was used to compare pre- and post-anxiety scores between the control group and the music group. A result of p < 0.05 was classed as a significant result.

Results

Characteristics of the participants

One hundred and ninety-seven patients were recruited (control group n = 97, music group n = 100). Patient demographics can be seen in Table 1.



Table 1 Baseline characteristics of patients recruited to the study. CCTA – Coronary Computed Tomography Angiography; PVCT – Pulmonary Vein Computed Tomography; CCS – Coronary Calcium Score Computed Tomography

Characteristic	Music Group N = 100	Control group N = 97	p-value
Mean Age in Years (SD)	55.5 (10.7)	56.5 (10.1)	0.495
No. of Male/ Female	61/39	61/36	0.883
Ethnicity (no./total (%))			0.20
White	82/100 (82 %)	69/97 (71 %)	
South Asian	7/100 (7 %)	11/97 (11 %)	
Other	11/100 (11 %)	17/97 (18 %)	
Exam Type (no./total (%))			0.221
CCTA	63/100 (63 %)	64/97 (66 %)	
CCS	25/100 (25 %)	28/97 (29 %)	
PVCT	12/100 (12 %)	5/97 (5 %)	
Oral Beta-Blocker Use			0.803
Yes	21	18	
No	69	71	
Unknown	10	8	

Heart rate

The median H_W was 75.5 bpm (Interquartile range (IQR) 64-83 bpm) in the music group and 70 bpm (IQR 59-79 bpm) in the control group ($p\!=\!0.017$, see Table 2 and Fig. 2). Analysis of patients as a whole or by CT protocol; CCTA, CCS and PVCT (see Table 2), demonstrated no significant difference in HR_I and $HR_{i\text{-w}}$ (i.e., change in heart rate). As a whole the music group and control group had a median $HR_{i\text{-w}}$ of 12.27 (IQR 4-20 bpm) and 10.11 (IQR 3-17.5 bpm), respectively.

IV metoprolol dose and radiation dose

There was no significant difference in the amount of IV metoprolol used for CCTA in the music and the control group (median of 15 mg (IQR 0-30 mg) and 10 mg (IQR 0-30), respectively, p = 0.757). Similarly, there was no significant difference in the radiation dose between both groups (median of music group=165 mGycm (IQR 100.5-233) and control group=149 mGycm (IQR 93-218.25), p = 0.398) even when allowing for scan protocol.

Image quality

There was no difference in the image quality scores for CCTA, CCS, and PVCT (see Table 2). The median image quality score for the music group and the control group for CCTA was 3 (IQR 2.5-3) and 3 (IQR 2.5-3). The median score for the music group and control group for CCS was 2 (IQR 2-2) and 2

 Table 2
 Mean, median, standard deviation, and p-values of the music and control group for primary outcome and secondary outcome measures. HR – Heart Rate, DLP – Dose Length Product, CCTA – Coronary CA – Coronary Calcium Score CT, PVCT – Pulmonary Vein CT

		Group		p-value	CCTA		p-value	CCS		p-value	PVCT		p-value
		$\begin{array}{l} Music \\ (n=100) \end{array}$	Control $(n=97)$		Music $(n=63)$	Control $(n = 64)$		$\begin{array}{c} Music \\ (n=25) \end{array}$	Control $(n = 28)$		Music $(n = 12)$	Control $(n=5)$	
Heart Rate at rest (HRw)	Median IQR	75.5 64, 83	70 59, 79	0.017	76.00 63, 83	71.00 60.25, 79	0.153	77.00 68.5, 86.5	69.5 59.25, 79	0.45	64.50 55.25, 80.75	57.00 55.5, 61.5	0.160
Hear Rate on table (HR $_{\mathrm{T}}$)	Median IQR	66 60, 74.75	65 57, 75	0.486	66.00 59, 73	65.00 57,75	0.864	68.00 63, 75.5	66.00 57, 76	0.379	59.00 54, 78.5	59.00 52.5, 64.5	0.799
Final breath-hold (HR _B)	Median IQR	57.75 54, 63	57.5 51.5, 63.5	0.508	56.00 54, 60	56.00 52, 62	0.938	62.00 57, 74	62.50 51.25, 77.25	0.464	55.50 49, 73	54.00 47.5, 57	0.506
Heart Rate during scan (HR _I)	Median IQR	60 56, 65.75	58 53, 63	0.055	59.00 55, 62	57.00 53, 61.75	0.168	64.00 58, 74	63.00 51.5, 78	0.402		55.00 50, 57	0.234
Change in Heart Rate (HR _{I-W)})	Median IQR	12.27 4, 20	10.11 3, 17.5	0.187	14.00 7, 22	13.00 5,25, 20	0.401	9.00 3, 16.5	5.00 1.5, 10	0.054		6.00	0.879
Anxiety pre-scan	Median IQR	10 7, 13	10 8, 13	0.812	10 8, 14	11 9, 14	0.296	11 7.5, 13	9 6.25, 11	0.129		6 6, 11	0.328
Anxiety post-scan	Median IQR	8 6, 10	9 6, 12.5	0.215	8 6, 10	9 6.25, 13	0.067	7 6, 10	7 6,9	0.993	8 7, 10.75	6 6, 15.5	0.721
Anxiety difference	Median IQR	- 4, 0,	-1 -3, 0	0.285		-1 -3, 0	0.536	-2 -4, 10	-0.5 -2.75, 0	0.124		0 0, 4.5	0.506
Exam DLP (mGycm)	Median IQR	165 100.5, 233	149 93, 218.25	0.398	179.00 107.5, 295.5	135.00 87, 238.75	0.099	176.00 149.25, 199	176.00 149, 194	0.529	86.00 76.25, 86	80.00 66, 86	0.328
IV Metoprolol dose (mg)	Median IQR	N/A	N/A	N/A		10.00 0, 30	0.757	N/A	N/A	N/A		N/A	N/A
Image Quality Score	Median IQR	2.5 2, 3	2,3	0.645	3 2.5, 3	3 2.5, 3	0.369	2, 2	2, 2.5	0.303	3.50 3.5, 4	4 3.25, 4	0.383



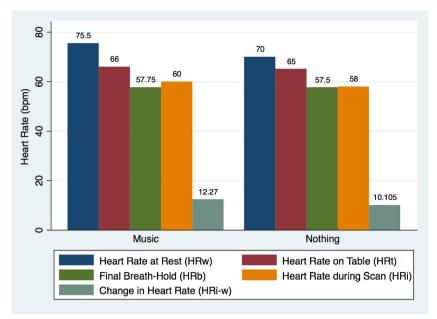


Fig. 2 A bar chart comparing the music group and control group. The bars represent the median values at the different time intervals where the heart rates were measured

(IQR 2-2). The median score for the music group and the control group for PVCT was 3.5 (SD 0.52) and 3.8 (SD 0.45).

STAI and questionnaire

The STAI questionnaire has a minimum score of 6 points and a maximum score of 24 points. The pre-scan median anxiety score was similar between the two groups with a score of 10 (IQR 7-13) for the music group and 10 (IQR 8-13) for the control group (p=0.812). The post-scan median anxiety score was 8 (IQR 6-10) in the music group and 9 (IQR 6-12.5) in the control group giving an median score change of -1 for the music group and -1 for the control group. The post-scan anxiety score and anxiety score change were not significantly different (p=0.215) and p=0.285, respectively).

The questionnaire revealed that >80 % of patients agreed or strongly agreed that they were comfortable with the level of

Table 3 Number of patients who agreed or strongly agreed with the above questions. Percentage in ()

	Music	Control	Total
Comfortable Noise Level	86 (86.9 %)	82 (84.5 %)	168 (85.7 %)
Comfortable Body Position	84 (85.7 %)	79 (81.4 %)	163 (83.6 %)
Confortable Temperature	87 (87.9 %)	82 (84.5 %)	169 (86.2 %)
Listening to Music Helps Me Relax	79 (79.8 %)	73 (78.9 %)	152 (78.3 %)
Would Like to Listen to Music in the Future	89 (89.9 %)	74 (76.3 %)	163 (83.2 %)
Enjoyed the Music Provided	85 (85.9 %)	N/A	N/A

noise, their body position, and the temperature in the CT room (see Table 3). Almost 80 % of patients said that the music helped them to relax and 83.2 % of patients said they preferred to listen to music during cardiac CT in the future. There was a significant difference in how this question was answered in the music and control groups (89.9 % and 76.3 %, respectively, p=0.008). In addition, 85.9 % of patients in the music group agreed or strongly agreed that they enjoyed the music provided.

Discussion

To the best of our knowledge, this is the first study to investigate the influence of music on the heart rate of patients having cardiac CT. Our study revealed no significant heart rate lowering effect with the use of music for the total study population who received music.

There are several possible explanations as to why the music group did not demonstrate a significant heart rate lowering effect for the total patient population.

One could look at the underlying mechanism of how music affects human psychophysiology resulting in a lower heart rate, but the process is highly complex and poorly understood [15]. A study by Okada et al. [16], showed that patients undergoing music therapy had increased parasympathetic and decreased sympathetic nervous system activity compared to a control group not given music. The music therapy patients also had a lower heart rate compared to the control group. Based on this mechanism of action, one would expect a reduction in heart rate when music is combined with beta-



blockers due to the music acting on the parasympathetic nervous system, which complements the beta-blockers action of inhibiting the sympathetic pathway [17].

Previous publications that demonstrated a significant reduction in heart rate with use of music were performed in more controlled environments with a fewer number of procedural steps [5, 18]. Interestingly, in studies where there was likely significant physician/ nursing-patient interaction while listening to music there was no significant difference in heart rate [6, 19].

The initial heart rate at the time of consent was significantly higher in the music group than the control group, although this became less significant when patients on oral beta-blockers were removed from analysis. However, the number of patients on beta-blockers was similar in both groups. The cause for a higher baseline heart rate in the music group prior to administering music is probably due to chance. In addition, a stratified randomisation was not performed. This higher heart rate in the music group was consistent when the patient arrived at the CT table, during the breath-hold for scan preparation, and at the time of image acquisition.

If we look at the different examination groups for possible explanations for a lack of response, the patients referred for pulmonary vein CT are a group where all patients have a history of refractory atrial fibrillation or other arrhythmias, which have failed medical therapy such as beta-blockers. Therefore, this group may be less responsive to music. In addition, the large variability in heart rate would also make it harder to determine a statistical difference in heart rate change with music. Our analysis of CCS patients reveals that there was a larger, although not statistically significant, heart rate lowering effect for patients using music, which may be due to the fewer procedural steps and patient interactions. Intravenous cannulation and the sensation of IV contrast injection during CCTA and PVCT has the potential to be anxiety provoking, especially if the patient has needle phobia, or feels uncomfortable during the IV contrast injection. In addition, CCTA requires use of sublingual nitroglycerin [20–22], which causes arterial and venous dilatation resulting in a reflex tachycardia [23]. These resultant increases in heart rate, therefore, may reduce the effectiveness of music. As the change in heart rate in the calcium score patients was not statistically significant, a larger study would be required with a sample size of 90 patients using an α error of 0.05 and power of 0.8. This possible significance has to be tempered by the statistically significant difference in the heart rate at rest which likely influenced this result.

Our study results show that anxiety levels were low in both groups of patients prior to the scan as indicated by the mean scores being <13. In addition, the anxiety scores post-scan were only slightly lower than the pre-scan scores. Therefore, anxiety prior to the scan is unlikely to be the explanation for a lack of response to music or even beta-blockers which has

been suggested in the past [2]. Consequently, the findings from this study suggest that anxiolytic medication may not have a significant role in lowering heart rate during cardiac CT, but further research would be required to confirm this. It is important to note, that there are no published studies on anxiety levels or the effects of benzodiazepines on patients undergoing cardiac CT. It has previously been acknowledged that research in this area is lacking [1].

The secondary outcome measures such as radiation dose to the patient, CT image quality for interpretation and IV metoprolol used did not show a statistically significant difference between the two groups, and this is most likely explained by similar heart rates at the time of the scan.

Of importance, the vast majority of patients enjoyed the music, had a positive experience and wished to have music available for future examinations. Our results demonstrate no disadvantage to incorporating music routinely for our cardiac CT protocols.

There are several limitations of the study. Firstly, the amount of time patients listened to the music was not measured and; therefore, it could be argued that an increased amount of time listening to music would have reduced the heart rates more significantly. However, the study was designed to make music easily applicable in the clinical environment with minimal disruption to workflow. Therefore, this is more representative of a real clinical environment. In addition, patients were provided with music close to the time of registration until the end of the CT scan, which would have resulted in a reasonable length of time listening to the music taking into account the extra preparation required for most cardiac CTs. Secondly, the music compilation was not heard in its entirety due to limited waiting room time and most patients would have heard only a subset of the entire list. We did not record the specifics of which tracks were used by each patient to determine which type of relaxation music seemed to have greater heart rate lowering effect. We chose to have a set music compilation as previous studies indicate that a wide selection choice results in a large variability in physiological response [4]. Thirdly, we did not record the level of background noise from the CT scanner before or during scanning, but it was routine to establish that the patients were able to hear the music at all times prior to scanning. Meditation tracks or verbal recordings intended for hypnosis were not used in our study but could be investigated in future studies. A direct comparison between music and beta-blocker use in the context of CCTA was also not performed, as the CCS and PVCT protocols do not require routine use of oral beta-blockers and could provide similar information. In addition, our results do not demonstrate a significant overall heart rate lowering effect with the use of music, so it is unlikely that music on its own would outperform IV beta-blockade. Finally, our patient cohort was predominantly Caucasian; this is reflective of our referral population for cardiac CT. Previous studies



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investigating the effects of music have shown that results may not be applicable to other ethnic populations [24, 25].

Conclusion

Our study shows that the use of relaxation music does not reduce heart rate for patients undergoing cardiac CT (CCTA, PVCT, or CCS) or IV metoprolol use in patients undergoing CCTA but does lead to improved patient experience. In addition, self-reported anxiety was generally low for the total patient population. Therefore, routine use of anxiolytic medication may not be beneficial in patients undergoing cardiac CT.

Acknowledgments The scientific guarantor of this publication is Elsie Thao Nguyen. The authors of this manuscript declare no relationships with any companies, whose products or services may be related to the subject matter of the article. This study has received funding by a Peter Munk Cardiac Centre Innovation Grant. Dr Ravi Menezes kindly provided statistical advice for this manuscript. Institutional Review Board approval was obtained. Written informed consent was obtained from all subjects (patients) in this study. Methodology: prospective, randomised controlled trial, performed at one institution.

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