Effect of music on patients' anxiety during lower limb arthroplasty procedures under spinal anaesthesia: a prospective randomised controlled study

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Abstract

Background

Perioperative anxiety is a common entity that can present as a challenge to the anaesthetist, and can also negatively affect the surgical outcome and functional recovery. The use of music in a medical setting is becoming increasingly popular. Literature indicates promising outcomes on the use of music to reduce anxiety. The aim of this study was to determine the effects of listening to music on the anxiety of patients undergoing knee and hip arthroplasty procedures under spinal anaesthesia in a South African context.

Methods

This randomised, controlled study included 58 adult patients scheduled to receive lower limb arthroplasty surgery. Patients in the intervention group (music group) received one of five genres of music via headphones. The control group did not receive music. Both groups received a standardised neuraxial anaesthetic. Patients' anxiety in both groups was measured using a visual analogue scale for anxiety (VAS-A). Anxiety scores were measured at the preoperative visit, the morning prior to surgery, at skin incision and in the post-anaesthesia care unit.

Results

Each group contained 29 patients. There was no difference in the baseline anxiety scores recorded at the preoperative visit between the two groups (1.8 cm vs 1.9 cm; $p = 0.422$). The anxiety scores were significantly lower in the music group compared to the control group at skin incision (0.9 cm vs 1.9 cm; $p < 0.001$). The music group also experienced a greater decrease in their anxiety from prior to surgery to skin incision (1.4 cm vs 0.2 cm; $p = 0.002$).

Conclusion

Music is an effective, cheap, safe, non-pharmacological adjunct that can be used to reduce perioperative anxiety in patients undergoing lower limb arthroplasty procedures under spinal anaesthesia.

Level of evidence: Level 2

Keywords: music, anxiety, spinal anaesthesia, arthroplasty

Introduction

The increase in the ageing population has resulted in a greater prevalence of age-related diseases such as osteoarthritis and osteoporosis.[1] Developments in the field of arthroplasty have resulted in more favourable outcomes and the demand for these procedures is expected to rise exponentially over the next ten years.[2] These projections are likely to burden existing hospital resources. The elderly population have significant medical comorbidities and unique requirements which increase both the surgical and anaesthetic risk, and place further strain on resources. Perioperative assessment and management of these factors is imperative in order to reduce complications and improve patient outcomes.[1]

Optimisation of the anaesthetic technique can substantially reduce the risk of adverse events in these patients.[3] Neuraxial anaesthesia (provided there is no contraindication to its use) has been shown to be superior to general anaesthesia for both total hip and total knee arthroplasty procedures, and thus the International Consensus on Anaesthesia-Related Outcomes after Surgery (ICAROS) group recommend its use.[4] Despite the numerous advantages over general anaesthesia, patients often have increased fear and anxiety towards neuraxial anaesthesia.[5] This can lead to the complete disregard of this advised anaesthetic technique.

Perioperative anxiety is a complex, multifactorial entity that can be related to the fear of the unknown anaesthetic and surgical procedure.[6] As patients under neuraxial anaesthesia are awake during the procedure they are exposed to unusual stimuli, including bright lights, cold temperatures and noise, which can enhance fear and anxiety.[7] The excessive noise levels during orthopaedic procedures further add to this anxiety.[8] Not only is perioperative

anxiety a challenge to the anaesthetist but it can also negatively affect the surgical outcome and functional recovery.[9,10]

Existing preoperative anxiety coupled with the harsh theatre environment often leads to patients feeling uncomfortable. In order to ensure patient comfort during the surgical procedure, sedation is often combined with the regional anaesthetic modality.[11] The choice of sedative agent or the level of sedation is often not standardised. Sedation is not without risks or complications, particularly in the elderly population.[11]

Pharmacological treatment of anxiety is widespread practice, with alternative, non-pharmacological treatments available. Music is a simple, readily available, non-pharmacological technique that can be used as an adjunct to treat anxiety as well as other medical disorders.[12] Music has been used to treat anxiety in a large array of both medical and surgical patients, including patients with Alzheimer's disease,[13] cancer,[14] burns[15] and critically ill patients[16,17] in intensive care units.

The use of music in theatre dates to 1914. Kane was the first person to use music intraoperatively 'as a means of calming and distracting patients' undergoing surgical procedures performed using local anaesthetic.[18] The use of music in theatre has become more popular; however, it is sporadic and not targeted to patient care. In the developed world, music has been used for patients undergoing spinal anaesthesia as a method of reducing intraoperative anxiety and decreasing sedative requirements.[12,19-21]

In a resource-constrained environment, such as in South Africa, every effort needs to be made to avoid placing further burden onto existing fragile infrastructure. Music has shown promise in the developed world; however, there is a lack of evidence on its use in a setting similar to South Africa. Evolving technology has resulted in a large variety of music being readily available and it may be considered a cheap, safe, non-pharmacological intervention that could easily be implemented as an adjunct to spinal anaesthesia.[19] The aim of this study was to determine the effects of listening to music on patients' anxiety, during knee and hip arthroplasty procedures under spinal anaesthesia in two South African academic hospitals.

Materials and methods

This prospective, randomised controlled study was approved by the ethics committee and registered on clinicaltrials.gov (NCT05491707) and SANCTR (DOH-27-012023-8787). It was conducted at two academic hospitals in South Africa between January and June 2022. All patients 18 years and older, with the mental capacity to consent to the study and of American Society of Anaesthesiologists (ASA) class I to III, undergoing primary hip or knee arthroplasty surgery were assessed for eligibility. Patients were excluded if they had pre-existing visual or hearing loss, contraindications to spinal anaesthesia or moderate sedation, and pre-existing, diagnosed, anxiety disorders.

After assessment for eligibility, 58 patients were enrolled for the study (*Figure 1*). The study was explained and informed consent obtained (in the patients' preferred language; a translator was used where necessary). Patients were randomised in a 1:1 ratio, using a sealed envelope randomisation technique, into either the music group (intervention group) or the no music group (control group). Patients in the music group pre-selected their preferred genre of music at the preoperative assessment visit from the following list: classical, gospel, soul, pop and jazz. Anxiety scores were measured using the validated visual analogue scale for anxiety (VAS-A) (*Figure 2*). Patients used the faces as a visual guide and marked the level of anxiety along the ruler. Anxiety was measured

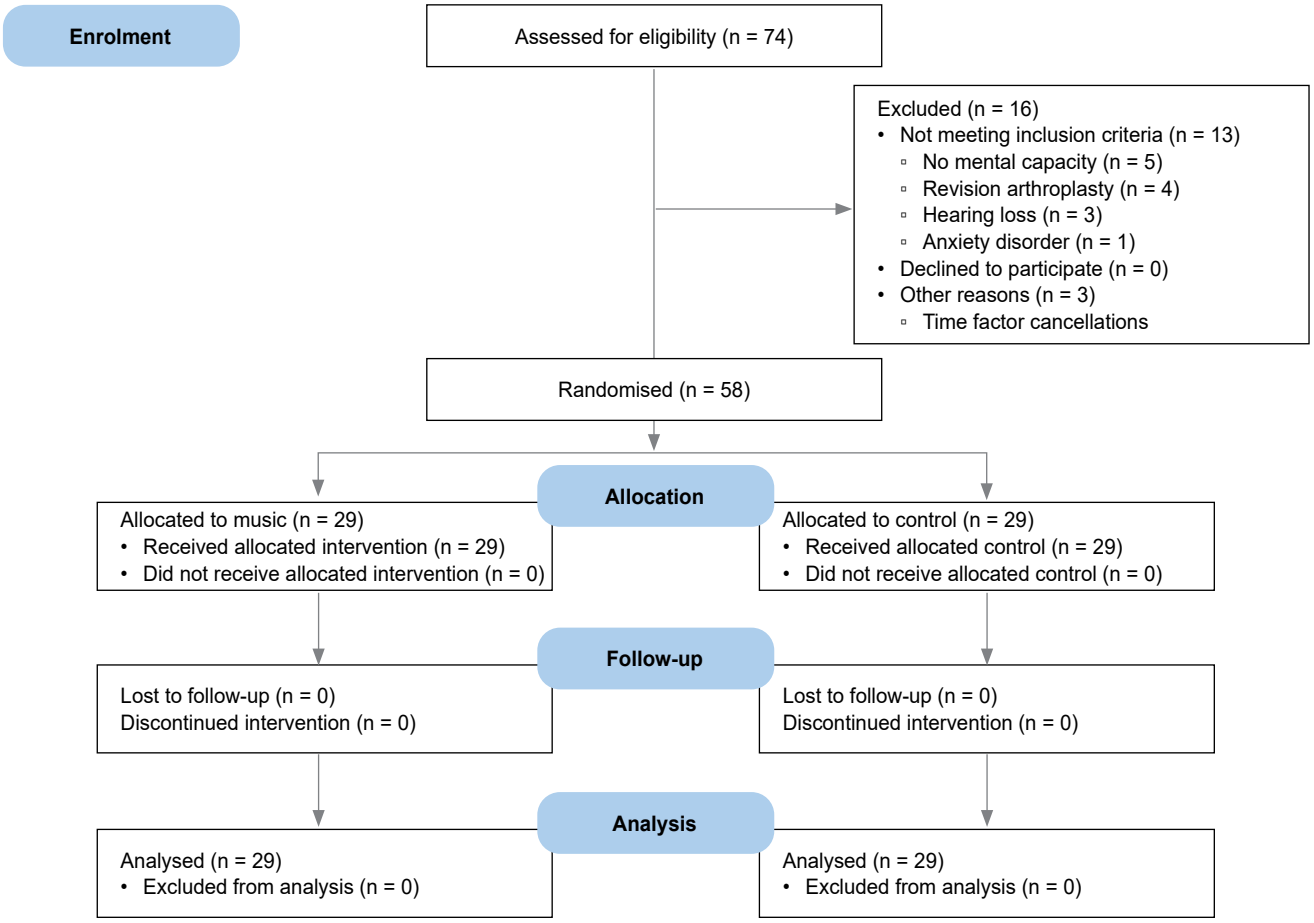

Figure 1. Consolidated Standards of Reporting Trials (CONSORT)[39] flowchart of participant involvement

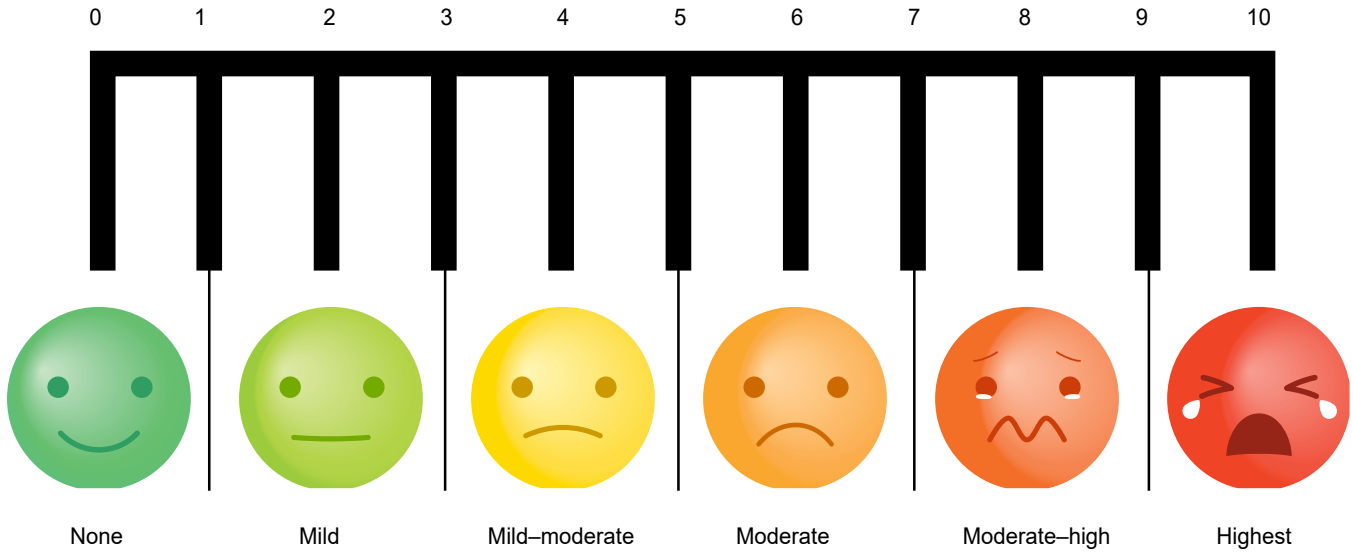

Figure 2. A combined visual analogue scale[36,40]

and recorded both in centimetres (0 cm indicating no anxiety and 10 cm indicating maximum anxiety) and by the faces categories. All participating patients completed a baseline anxiety assessment using the VAS-A at the preoperative assessment visit (T1) (*Figure 3*). The VAS-A was completed again on the day of surgery before the patient was taken into the operating room (T2). Patients in the intervention group received music after ASA monitors were applied. The music was played at a self-selected volume, on Pro Bass Swagger Series Aux disposable earphones, and was played for the duration of the surgical procedure. The music was played from an iPhone which was placed in a plastic bag for infection control purposes. The control group did not receive music.

The following anaesthetic technique was undertaken for all patients: routine ASA monitors were applied, including noninvasive blood pressure, electrocardiogram, oxygen saturation and capnography; supplemental oxygen was supplied by nasal cannula; and intravenous access was obtained. Spinal anaesthesia was performed using 13–15 mg plain bupivacaine 0.5% and 10–20 µg fentanyl intrathecally. A propofol target-controlled infusion (TCI) was used for sedation. The South African Society of Anaesthesiologists (SASA) guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in adults: 2020–2025 were followed.[22] The Marsh model was used for the propofol TCI, and a target concentration of 1–2 µg/ml was used; this was adjusted in the elderly patients (over 65 years of age) to 0.6–0.8 µg/ml as per the SASA guidelines.[22] Moderate sedation was used, and this was measured using the University of Michigan Sedation Scale (UMSS).[22]

Patients' anxiety levels were assessed again at skin incision (T3). At the end of the procedure the music was stopped, and the earphones removed prior to the transport of the patient to the post-anaesthesia care unit (PACU). In the PACU, patients completed the final VAS-A measurement (T4) and the patient satisfaction questionnaire.

Audit data was used to calculate the sample size. Assuming a statistical power of 90% and alpha of 5%, 29 patients were required in each group to reach a level of significance. Data was analysed using SPSS version 26. Continuous variables (age, length of surgery and total propofol dose) were described with medians and interquartile ranges (IQR) since variables were non-normally distributed and compared using the Mann-Whitney U test. Categorical variables (sex, ASA class, STOPBANG score, surgery side and type) were described as frequency and percentages and compared using the chi-squared test. The Wilcoxon signed-rank test was used to assess within-group differences for continuous variables. A p-value of 0.05 or less was considered statistically significant.

Results

A total of 58 patients were investigated (29 in the music group and 29 in the control group). Both groups were comparable in terms of sex, age, ASA class, STOPBANG score (a bedside screening tool for obstructive sleep apnoea), surgical side, surgical procedure, and surgery duration. Summary data are provided in *Table I.* The median propofol dose was slightly greater in the control group than the music group; however, this was not statistically significant (140 mg vs 110 mg; p = 0.503). The most popular choice of music genre was gospel (19 of 29; 65%).

A Mann-Whitney U test showed no difference in the baseline anxiety scores between the groups at the preoperative visit (T1) (p = 0.422, *Table II*). There was a general increase in anxiety from the preoperative visit (T1) to prior to surgery (T2) in both groups.

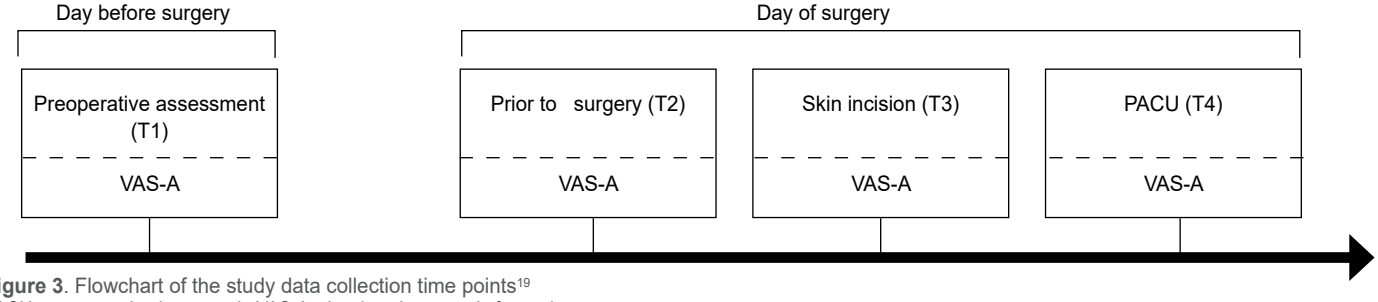

Figure 3. Flowchart of the study data collection time points[19]
PACU: postanaesthesia care unit; VAS-A: visual analogue scale for anxiety

Table I: Demographic and surgical characteristics

	Control n = 29[a]	Music n = 29[a]	Test statistics	p-value
Sex				
Female	19 (65.5)	24 (82.8)		0.134
Male	10 (34.5)	5 (17.2)		
Age (years)	66 (52–72)	65 (52.5–73)		0.913
ASA class				
1	2 (6.9)	1 (3.4)		0.495
2	19 (65.5)	23 (79.3)		
3	8 (27.6)	5 (17.2)		
STOPBANG score				
0	2 (6.9)	3 (10.3)		0.299
1	6 (20.7)	11 (37.9)		
2	12 (41.4)	6 (20.7)		
3	9 (31)	8 (27.6)		
4	0 (0)	1 (3.4)		
Surgical side				
Left	15 (51.7)	12 (41.4)		0.430
Right	14 (48.3)	17 (58.6)		
Surgical procedure				
Knee	14 (48.3)	9 (31)		0.180
Hip	15 (51.7)	20 (69)		
Surgery duration (minutes)	80 (45–147)	85 (35–110)		0.301
Total propofol dose (mg)	140 (85–215)	110 (70–200)		0.503

[a] n (%): Median (IQR)

Table II: Anxiety scores between control and music group

	Control group (n = 29)		Music group (n = 29)		Test statistics	
	Median	IQR	Median	IQR	z	p
VAS (cm)						
Preop (T1)	1.8	0.85–4.45	1.9	0.75–2.75	−0.80	0.422
Prior to surgery (T2)	2.7	1.55–4	2.5	1.75–3.6	−0.69	0.493
Skin incision (T3)	1.9	1.4–3.65	0.9	0.6–1.5	−4.06	**< 0.001***
PACU (T4)	0.5	0.4–0.8	0.5	0.4–0.5	−1.86	0.063
Change in VAS						
T4–T1	−1.2	−3.75–(−0.3)	−1	−2.4–(−0.35)	0.44	0.663
T4–T2	−2.1	−3.6–(−1.15)	−2.1	−3.05–(−1.35)	0.27	0.791
T4–T3	−1.2	−3.15–(−0.75)	−0.4	−1–(−0.1)	3.86	**< 0.001***
T3–T2	−0.2	−1.5–0.05	−1.4	−2.6–(−0.75)	−3.04	**0.002***
T3–T1	0	−0.95–0.45	−0.5	−2.25–0	−1.75	0.081
T2–T1	0.6	0–1.3	0.7	0–1.7	0.80	0.426

* statistically significant p-values

Thereafter anxiety levels decreased from prior to surgery (T2) until the PACU (T4) in both groups (*Figure 4*).

There was a significant difference in the median anxiety scores between the control and music group at skin incision (T3) (1.9 vs 0.9 cm; p < 0.001; *Table II, Figure 4*). There was also a significant difference in the change in anxiety scores from prior to surgery (T2) to skin incision (T3) between the control and the music group (p = 0.002; *Table II*). Patients in the music group showed a significantly larger decrease in anxiety (*Figure 4*). A significant difference in the change in anxiety scores from skin incision (T3) to those measured in the PACU (T4) (p < 0.001, *Table II*) between the control and music group was also noted. Patients in the control group showed a significantly larger decrease in anxiety over this period (*Figure 4*).

Both groups showed low levels of anxiety at the preoperative visit (T1). The median VAS-A measurement at T1 was 1.8 cm (IQR 0.85 to 4.45 cm) in the control group and 1.9 cm (IQR 0.75 to 2.75 cm) in the music group (p = 0.422, *Table II)*. The majority of patients, in both the control and music groups, experienced no to moderate anxiety at the preoperative visit (T1) (26 of 29; 90%

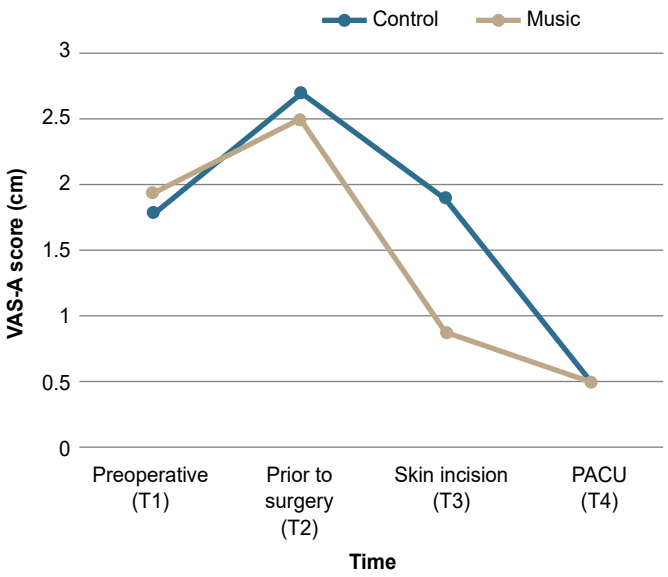

Figure 4. Anxiety scores (cm) from T1 to T4 in the control and music groups

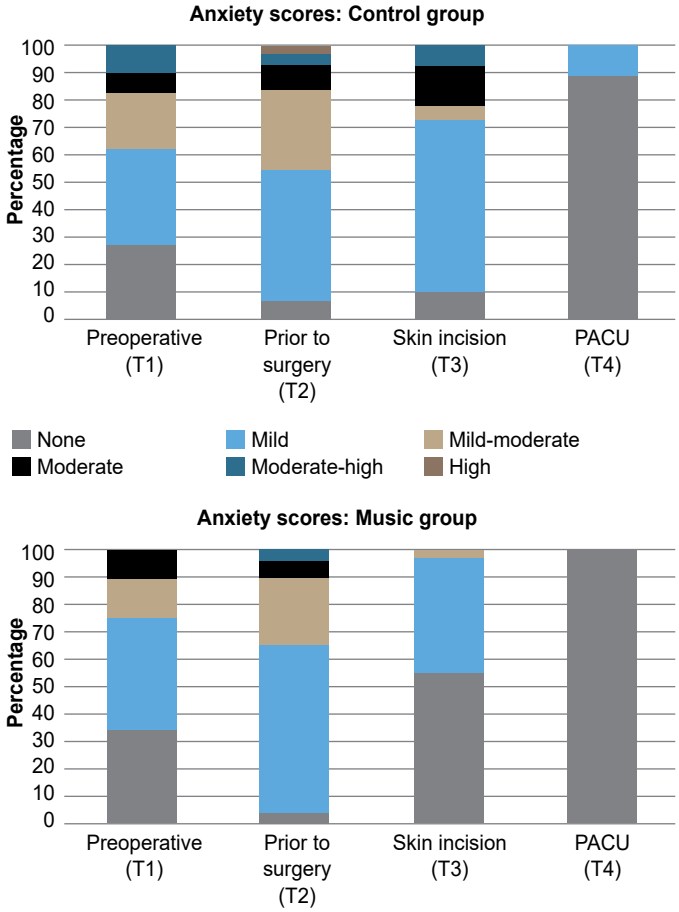

Figure 5. Anxiety scores (categories) from T1 to T4 in the control and music groups

and 29 of 29;100% respectively). Only 10% (3 of 29) of the control group reported moderate to high anxiety. There were no reports of high levels of anxiety in either group (*Figure 5*).

There was no statistically significant difference in anxiety scores between male and female patients (*Table III*), and between patients who had knee versus hip surgery (*Table IV*) at any time point (T1–T4).

Patient satisfaction within the music group was high (*Figure 6*). Most patients (28 of 29; 96%) felt that the music decreased their anxiety and provided calmness (questions 1 and 2). Of the patients in the music group, 86% (25 of 29) felt they experienced less pain (question 3). Eighty-six per cent (25 of 29) of these patients would request music again if coming for a similar procedure (question 4) and 89% (26 of 29) would recommend listening to music to their family and friends (question 5) (*Figure 6*).

Discussion

Perioperative anxiety is associated with multiple physiological consequences as a result of sympathetic, parasympathetic and endocrine stimulation.[23] This may cause additional risk to the patient intraoperatively and can worsen patient outcomes.[9,10] The findings of this study have provided insight into the effects of music on patients' anxiety under spinal anaesthesia for lower limb arthroplasty procedures. Overall, this study shows the anxiety-reducing effects of music among these patients in the perioperative period.

Patients in the music group had lower VAS-A scores at skin incision (T3), with a greater decrease in their level of anxiety from prior to surgery (T2) to skin incision (T3). Multiple studies have

Table III: Anxiety scores between male and female patients

	Male (n = 15)		Female (n = 43)		Test statistics	
	Median	IQR	Median	IQR	z	p
VAS (cm)						
Preop (T1)	1.8	0.9–4	1.9	0.7–4	−0.34	0.735
Prior to surgery (T2)	2.5	1.2–4	2.5	2–4	0.48	0.631
Skin incision (T3)	1.4	0.9–2	1.4	0.7–2.5	0.04	0.972
PACU (T4)	0.5	0.4–0.6	0.5	0.4–0.6	−0.71	0.480
Change in VAS						
T4–T1	−1.3	−3.5–(−0.3)	−1	−3.5–(−0.3)	0.25	0.803
T4–T2	−2.1	−3.5–(−0.8)	−2.1	−3.6–(−1.4)	−0.60	0.546
T4–T3	−0.8	−1.7–(−0.4)	−1	−2–(−0.3)	−0.31	0.756
T3–T2	−1.1	−2–0	−1	−2–(−0.2)	−0.63	0.528
T3–T1	−0.2	−1.1–0.1	−0.1	−1.6–0.2	0.38	0.702
T2–T1	0.2	0–0.8	0.9	0–1.7	1.38	0.167

Table IV: Anxiety scores between patients with knee and hip arthroplasty

	Knee arthroplasty (n = 23)		Hip arthroplasty (n = 35)		Test statistics	
	Median	IQR	Median	IQR	z	p
VAS (cm)						
Preop (T1)	2.0	0.7–2.1	1.8	0.8–4	0.51	0.610
Prior to surgery (T2)	2.5	2–4	2.5	1.5–4	−0.11	0.911
Skin incision (T3)	1.9	0.9–2.6	1.3	0.7–2	−1.59	0.111
PACU (T4)	0.5	0.4–0.8	0.5	0.3–0.5	−1.91	0.056
Change in VAS						
T4–T1	−0.9	−1.7–(−0.2)	−1.3	−3.5–(−0.6)	−1.29	0.197
T4–T2	−0.2	−3.6–(−1.4)	−2.2	−3.5–(−1.3)	−0.37	0.714
T4–T3	−1.1	−2.1–(−0.4)	−0.8	−1.4–(−0.3)	1.04	0.297
T3–T2	−0.8	−1.7–(−0.1)	−1.1	−2–(−0.1)	−1.08	0.279
T3–T1	−0.1	−1.1–0.8	−0.1	−2.1–0.1	−1.47	0.140
T2–T1	0.7	0–1.7	0.6	0–1.6	−0.46	0.644

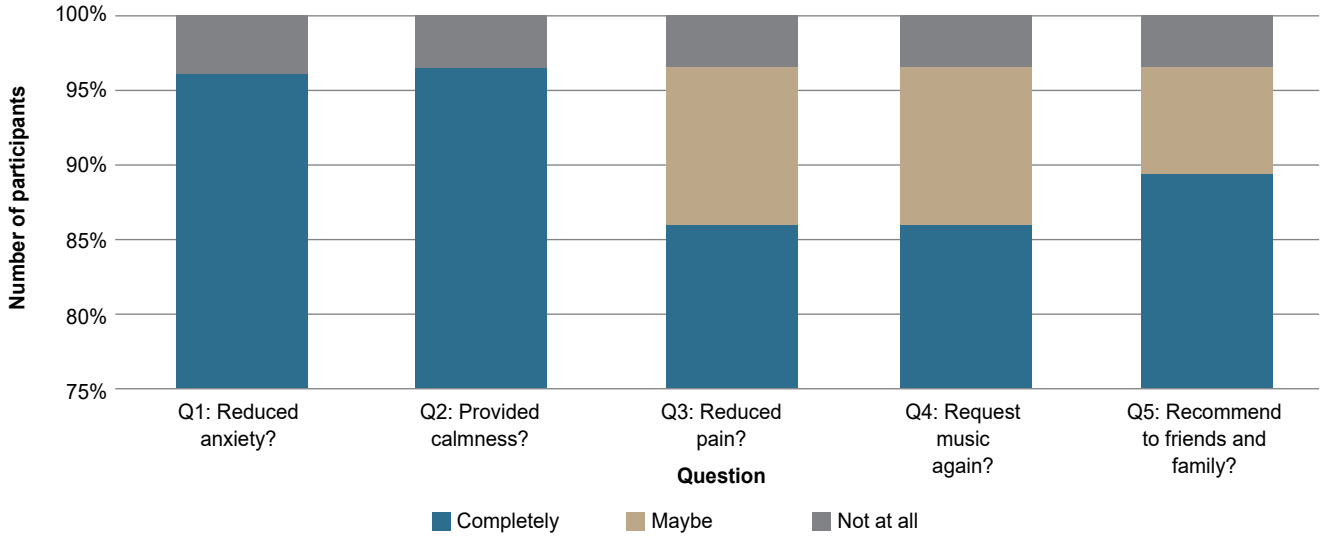

Figure 6. Patient satisfaction questionnaire scores in the music group

demonstrated the positive effects of music on patients' anxiety under spinal anaesthesia.[19,20,24-27] Hepp et al.[19] and Sarkar et al.[26] both reported significantly lower levels of anxiety in the music group compared to the control group in patients undergoing spinal anaesthesia for Caesarean section. A systematic review and meta-analysis evaluating the effect of music on anxiety in patients undergoing Caesarean delivery found that music is associated with reduced intraoperative anxiety.[27]

The results of our study are similar to those obtained by Ilkkaya et al.[25] who examined the effects of music, white noise and ambient noise on sedation and anxiety in patients under spinal anaesthesia during surgery. They found a significant reduction in the VAS-A scores reported in the music group as compared to the white noise and ambient noise groups. Their study looked at surgical, urological and orthopaedic operations and was not specific to arthroplasty procedures.

It has been shown that auditory pathways are connected to numerous areas within the central nervous system, including the limbic system, hypothalamus, hippocampus and reticular activating system. Listening to music modifies these neuronal connections, resulting in relaxing and sedative effects.[28] This could explain the significant reduction in anxiety experienced in the music group compared to the control group.

It is possible that the effects of music on patient anxiety demonstrated in our study are due to the masking of ambient theatre noise. Arthroplasty procedures are known to be extremely noisy.[8] It is understood that noise can have an impact on stress hormones and produce or worsen anxiety.[29] Tran et al.[12] compared the effect of noise cancellation to music on sedation requirements during total knee replacements. They found that there was no statistically significant difference in the amount of sedation used between the two groups. However, their study did not measure patient anxiety levels, making this an area for further investigation.

Our study identified a notable difference in the reporting of preoperative anxiety levels compared to prior research.[10,30] Both groups (music and control) reported low levels of anxiety at the preoperative assessment visit on the day prior to surgery (T1). Most patients reported no to moderate anxiety (55 of 58; 95%) with no reports of high anxiety. Additionally, there was no difference in the anxiety scores between male and female patients on the day prior to surgery (T1). A study published by Jlala et al.[30] contradicts this. It showed that one-third of patients having surgery under regional anaesthesia are highly anxious.[30] It further explained that the incidence of preoperative anxiety was higher among the female population.[30] Götz et al.[10] looked specifically at patients undergoing total hip and knee surgery. They found that 9.5% (520 of 5 447) of

patients were very or extremely anxious at the time of surgery.[10]

Preoperative anxiety is a complex entity experienced differently by different patients. There are multiple factors that may impact upon the nature in which anxiety is perceived. These include, but are not limited to, age, sex, cultural beliefs, marital status, education, level of income, support structure, previous surgeries, uncertainty of the exact day of surgery, and patients' ability to understand the events surrounding the surgery and anaesthesia.[23,31,32] Marlow et al.[32] expressed the importance of cultural adaptation of diagnostic tools in order to ensure accurate diagnosis and reporting of mental health disorders. Further investigation and questioning, with the aid of culturally adapted and validated tools, around these risk factors could provide more information on the low levels of preoperative anxiety reported in a South African setting.

Anxiety is described as a vague, ambiguous feeling which is often nonspecific and unfamiliar to the individual.[33] Patients may be unaccustomed to such feelings, which could result in underreporting. The use of objective measures, such as haemodynamic changes, plasma cortisol and urinary catecholamine levels, may provide further insight. A comparison of subjective responses to objective results could add more perspective.

The waiting lists for total hip and knee arthroplasty in our hospitals are in excess of four years. During data collection for this study, numerous delays and cancellations were experienced due to the COVID-19 pandemic, linen shortages, bed shortages, and the burden of acute orthopaedic injuries. As a result, these patients wait a considerable length of time before receiving their arthroplasty procedure. In this time their disease progresses, further limiting their range of function, and increasing pain is experienced. The relief of finally obtaining their joint replacement could potentially allay any potential fears that these patients may otherwise have had. Investigating preoperative anxiety in different surgical populations within our hospitals and patient interviews could provide us with a clearer understanding of this issue.

Kukreja et al.[20] studied the effects of music therapy during total knee arthroplasty under spinal anaesthesia. Their study found that there was no statistically significant difference in the amount of propofol used between the music (investigational) and the control (no music) groups. Our results echoed this finding. Patients in the control group required more propofol sedation compared to the music group; however, these results were not statistically significant.

The use of sedation can result in complications including respiratory depression, haemodynamic instability and uncontrolled movements.[11] Cognitive morbidity, including postoperative delirium, is another significant complication of sedation, especially in the geriatric population.[34] These complications have major consequences for both medical practitioners and patients and can result in significant cost implications.[34] Any reduction in sedation requirements would be advantageous in our setting and further research into this aspect should be considered.

Despite the measured effects of music on patients' anxiety, the considerable level of patient satisfaction needs to be highlighted. Ninety-six per cent of patients within the music group felt that music reduced their anxiety, and most of these patients would request music again if returning for a similar procedure. This is in keeping with a study conducted in Germany which also showed similar levels of patient satisfaction after receiving music during Caesarean sections under spinal anaesthesia.[19] Improved patient satisfaction is associated with greater adherence to prevention and treatment protocols, improved clinical outcomes, improved patient safety within hospitals and less healthcare utilisation.[35] The overwhelmingly positive response from patients regarding music is rewarding and supports its use.

A limitation of this study is that only one tool was used to measure anxiety. Despite the Spielberger State-Trait Anxiety Inventory (STAI) being the gold standard tool in measuring anxiety, this involves a lengthy questionnaire leading to concerns about language barriers. For these reasons the VAS-A was chosen as the measuring tool in this trial, which is validated against the STAI as accurate.[6,36] The graphic nature and the simplicity of the analogue scale was easier for patients to describe their honest feelings, which might not have been the case with a long questionnaire.

Multiple models of the doctor–patient relationship exist; however, they are all based on mutual trust, loyalty and regard.[37] Patients' fear of compromising this relationship may have resulted in bias in completing the VAS-A and the patient satisfaction questionnaire. Although this was explained to the patients, perhaps future studies could consider using an independent research assistant to help ensure the data collection is kept anonymous from the healthcare provider.

Another limitation is the lack of blinding of the researcher as this trial was conducted by a single researcher. This was compensated for by using group blinded data analysis. Blinding of participants was not possible due to the nature of the trial, and knowing about the lack of music may be a confounding factor.

The use of sedation intraoperatively may reduce anxiety levels in patients. This has been compensated for by using a standardised anaesthetic technique for all participants in the trial, as well as a propofol TCI model. The propofol TCI model was adjusted for elderly patients as per the SASA sedation guidelines[22] to ensure that these patients were not overly sedated. The UMSS was used to assess the level of sedation to allow for standardisation of the level of sedation between all patients. A bispectral index (BIS) monitor would have provided an objective measure of the level of sedation but this is not freely available in our setting, and the UMSS was used as recommended by the SASA sedation guidelines.[22] It has been recently shown that the use of BIS for the monitoring of depth of sedation is not completely reliable.[38] Combining a BIS monitor with the UMSS could provide more accurate results, and would be recommended in future studies.

The majority of available literature has been conducted in developed world countries, with a paucity of data from settings similar to South Africa. The results of this study could be used to ignite further research in this field and provide meaningful change to clinical practice, which would offer multiple advantages within our resource-constrained setting.

Conclusion

Music is an effective, cheap, safe, non-pharmacological adjunct in reducing perioperative anxiety in patients undergoing lower limb arthroplasty procedures under spinal anaesthesia. Music reduces anxiety and provides high levels of patient satisfaction. In view of the results of this study, consideration should be given to incorporating music as part of the anaesthetic care of these patients.

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Ethics statement

The authors declare that this submission is in accordance with the principles laid down by the Responsible Research Publication Position Statements as developed at the 2nd World Conference on Research Integrity in Singapore, 2010.

Prior to the commencement of the study ethical approval was obtained from the following ethical review board: Human Research Ethics Committee (Medical), University of the Witwatersrand (certificate number: M210702).

All procedures were in accordance with the ethical standards of the responsible

committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. Informed written consent was obtained from all patients for being included in the study.

Declaration

The authors declare authorship of this article and that they have followed sound scientific research practice. This research is original and does not transgress plagiarism policies.

Author contributions

SAB: conceptualisation and design, data collection, data analysis, and manuscript preparation
GD: conceptualisation and design, data analysis, manuscript preparation, critical revision, final approval of article
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