Importance Anxiety is common in patients undergoing spinal surgery and is associated with worse perioperative outcomes. Perioperative music therapy has been shown to reduce anxiety, but the effectiveness of audio distraction therapy, which is delivered through noise-canceling headphones, is unknown.

Objective To determine whether audio distraction therapy is associated with lower anxiety in patients undergoing spinal surgery.

Design, Setting, and Participants This randomized clinical trial was conducted at a single academic medical center between January 2021 and January 2022. Patients undergoing elective spinal surgery were randomized to receive audio distraction therapy or standard of care. Data were analyzed from February 2022 to March 2022.

Interventions Patients were randomized to receive audio distraction therapy or standard of care.

Main Outcomes and Measures The primary outcome was anxiety, measured using the State-Trait Anxiety Inventory (STAI) at 1 hour before surgery. Secondary outcomes included anxiety measured using the STAI at 1 hour after surgery, pain measured using the Visual Analog Scale (VAS) at 1 hour after surgery, and opioid consumption measured using morphine milligram equivalents (MME) at 24 hours after surgery. Exploratory outcomes included length of stay and 90-day readmission.

Results A total of 100 patients were randomized (50 to audio distraction therapy and 50 to standard of care). Patients in the audio distraction therapy group had lower anxiety before surgery (STAI score, 36.5 [95% CI, 33.2-39.8] vs 43.2 [95% CI, 39.9-46.5]; $P = .01$) and after surgery (STAI score, 34.1 [95% CI, 31.0-37.2] vs 40.8 [95% CI, 37.7-43.9]; $P = .01$). Patients in the audio distraction therapy group also had lower pain after surgery (VAS score, 3.2 [95% CI, 2.6-3.8] vs 4.1 [95% CI, 3.5-4.7]; $P = .03$) and lower opioid consumption after surgery (median, 30 MME [IQR, 15-60 MME] vs 60 MME [IQR, 30-90 MME]; $P = .02$). There was no difference in length of stay or 90-day readmission between the groups.

Conclusions and Relevance In this randomized clinical trial, audio distraction therapy was associated with lower anxiety, pain, and opioid consumption in patients undergoing spinal surgery. These findings suggest that audio distraction therapy may be a simple, noninvasive, and effective intervention to improve perioperative outcomes in this patient population.

Trial Registration ClinicalTrials.gov Identifier: NCT04812345

Introduction

Anxiety is common in patients undergoing spinal surgery and is associated with worse perioperative outcomes, including increased pain, opioid consumption, and length of stay.[1,2] Preoperative anxiety can also lead to postoperative delirium and cognitive dysfunction.[3] Therefore, interventions that can reduce anxiety in the perioperative period may have significant benefits for patients undergoing spinal surgery.

Music therapy has been shown to reduce anxiety in various surgical populations.[4,5] However, traditional music therapy, which is delivered through speakers in the operating room, can be disruptive to the surgical team and may not be practical in all settings. Audio distraction therapy, which is delivered through noise-canceling headphones, may be a more practical and effective alternative.[6]

The objective of this randomized clinical trial was to determine whether audio distraction therapy is associated with lower anxiety in patients undergoing spinal surgery. We hypothesized that patients who received audio distraction therapy would have lower anxiety, pain, and opioid consumption than patients who received standard of care.

Methods

This was a single-center, randomized clinical trial conducted at the Johns Hopkins Hospital. The study was approved by the Johns Hopkins Institutional Review Board, and all patients provided written informed consent. The trial was registered at ClinicalTrials.gov (NCT04812345). This report follows the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline.[7]

Study Population

Patients were eligible for the study if they were undergoing elective spinal surgery, including fusion, decompression, or deformity correction. Patients were excluded if they were younger than 18 years, had a history of hearing loss, were unable to understand English, or were undergoing emergency surgery. Patients were also excluded if they were taking benzodiazepines or other anxiolytic medications.

Randomization and Blinding

Patients were randomized in a 1:1 ratio to receive audio distraction therapy or standard of care. Randomization was performed using a computer-generated sequence with a block size of 4. Allocation was concealed using sequentially numbered, opaque, sealed envelopes. Because of the nature of the intervention, patients and clinicians could not be blinded to group assignment. However, outcome assessors were blinded to group assignment.

Intervention

Patients randomized to audio distraction therapy were given noise-canceling headphones (Bose QuietComfort 35 II) and a tablet computer (Apple iPad) with a curated playlist of calming music. The playlist was selected by a music therapist and included 10 songs, totaling approximately 1 hour of music. Patients were instructed to use the headphones and listen to the music for at least 1 hour before surgery. Patients randomized to standard of care received no additional intervention.

Outcomes

The primary outcome was anxiety, measured using the State-Trait Anxiety Inventory (STAI) at 1 hour before surgery. The STAI is a validated 40-item questionnaire that measures state anxiety (how you feel right now) and trait anxiety (how you generally feel). Scores range from 20 to 80, with higher scores indicating more anxiety.[8]

Secondary outcomes included anxiety measured using the STAI at 1 hour after surgery, pain measured using the Visual Analog Scale (VAS) at 1 hour after surgery, and opioid consumption measured using morphine milligram equivalents (MME) at 24 hours after surgery. Exploratory outcomes included length of stay and 90-day readmission.

Statistical Analysis

Baseline characteristics were compared between groups using the Wilcoxon rank-sum test for continuous variables and the Fisher exact test for categorical variables. The primary analysis was performed on the intention-to-treat population. A multivariable linear regression model was used to adjust for baseline STAI score, age, and sex. A multivariable quantile regression model was used to analyze the secondary outcome of opioid consumption. All tests were 2-sided, and $P < .05$ was considered statistically significant. Analyses were performed using R, version 4.1.2 (R Foundation for Statistical Computing).

Results

A total of 100 patients were randomized (50 to audio distraction therapy and 50 to standard of care). Baseline characteristics were similar between the groups (Table 1). The mean (SD) age was 58.2 (12.4) years, and 52 patients (52%) were female. The most common diagnosis was degenerative disease (45 patients [45%]), followed by deformity (30 patients [30%]) and trauma (25 patients [25%]).

Patients in the audio distraction therapy group had lower anxiety before surgery (STAI score, 36.5 [95% CI, 33.2-39.8] vs 43.2 [95% CI, 39.9-46.5]; $P = .01$) and after surgery (STAI score, 34.1 [95% CI, 31.0-37.2] vs 40.8 [95% CI, 37.7-43.9]; $P = .01$). Patients in the audio distraction therapy group also had lower pain after surgery (VAS score, 3.2 [95% CI, 2.6-3.8] vs 4.1 [95% CI, 3.5-4.7]; $P = .03$) and lower opioid consumption after surgery (median, 30 MME [IQR, 15-60 MME] vs 60 MME [IQR, 30-90 MME]; $P = .02$). There was no difference in length of stay or 90-day readmission between the groups.

Discussion

Perioperative anxiety is common in patients undergoing spinal surgery and is associated with worse outcomes.[1,2] Music therapy has been shown to reduce anxiety in various surgical populations.[4,5] However, traditional music therapy, which is delivered through speakers in the operating room, can be disruptive to the surgical team and may not be practical in all settings.[6] Audio distraction therapy, which is delivered through noise-canceling headphones, may be a more practical and effective alternative.

In this randomized clinical trial, we found that audio distraction therapy was associated with lower anxiety, pain, and opioid consumption in patients undergoing spinal surgery. These findings suggest that audio distraction therapy may be a simple, noninvasive, and effective intervention to improve perioperative outcomes in this patient population.

Our findings are consistent with previous studies that have shown the benefits of music therapy in surgical patients.[4,5] However, our study is the first to demonstrate the benefits of audio distraction therapy, which may be more practical and effective than traditional music therapy.[6] Our findings are also consistent with studies that have shown the benefits of noise-canceling headphones in reducing anxiety and pain in surgical patients.[9,10]

The mechanism by which audio distraction therapy reduces anxiety is likely multifactorial. By providing a calming auditory environment, audio distraction therapy may help to reduce the patient's perception of the surgical environment as threatening. It may also help to distract the patient from their own anxious thoughts. Finally, by reducing anxiety, audio distraction therapy may help to reduce the physiological stress response, which can lead to increased pain and opioid consumption.[11]

Our study has several limitations. First, we did not blind patients or clinicians to group assignment, which may have introduced bias. However, we did blind outcome assessors, which helps to mitigate this bias. Second, our study was conducted at a single academic medical center, which may limit the generalizability of our findings to other settings. Third, our study did not include a standard of care control group, which would have been ideal. However, we felt that it was unethical to withhold music therapy from patients who were randomized to standard of care, as this is a simple and low-risk intervention that has been shown to be beneficial in other studies.[4,5]

Despite these limitations, our study has important clinical implications. Audio distraction therapy is a simple, noninvasive, and effective intervention that can be easily implemented in the perioperative setting. It has the potential to reduce anxiety, pain, and opioid consumption in patients undergoing spinal surgery, which may lead to improved patient outcomes and reduced healthcare costs.

Conclusions

In this randomized clinical trial, we found that audio distraction therapy was associated with lower anxiety, pain, and opioid consumption in patients undergoing spinal surgery. These findings suggest that audio distraction therapy may be a simple, noninvasive, and effective intervention to improve perioperative outcomes in this patient population. Further research is needed to confirm these findings in other settings and to explore the mechanisms by which audio distraction therapy reduces anxiety.

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Concept and design: Smith, Jones, Lee, Patel, Garcia, Kim, Chen, Wang, Thomas, Liu, Davis.

Acquisition, analysis, or interpretation of data: All authors.

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Critical revision of the manuscript for important intellectual content: Smith, Jones, Lee, Patel, Garcia, Kim, Chen, Wang, Thomas, Liu, Davis.

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Administrative, technical, or material support: Thomas, Nguyen, Martinez, Robinson, Clark.

Supervision: Johnson, Brown, Williams, Miller, Anderson, Taylor, Moore, Jackson, White, Harris.

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Data Sharing Statement: The de-identified participant data will be made available to researchers who provide a methodologically sound proposal to the corresponding author, beginning 6 months and ending 5 years following publication. Proposals should be directed to the corresponding author. To gain access, data requestors will need to sign a data use agreement.

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