DOI: https://doi.org/10.5114/ait.2023.129007

The effect of Mozart music on patient satisfaction during caesarean delivery: a randomised controlled trial

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Abstract

Background: Music is a low-cost intervention that can improve patient satisfaction.

Methods: This was a prospective, randomised, controlled trial conducted at an urban tertiary care academic medical centre in the United States. Nulliparous women 18-50 years old with a healthy singleton pregnancy at ≥ 37 weeks gestational age undergoing elective caesarean delivery under neuraxial anaesthesia were randomised to the music group (Mozart sonatas) or control group (no music). Mozart sonatas were broadcast to the music group immediately prior to patient entry and maintained throughout the procedure. The primary outcome was patient satisfaction using the Maternal Satisfaction Scale for Caesarean Section (MSSCS). Secondary outcomes were changes in anxiety pre- and post-operatively and post-operative mean arterial pressure (MAP). Student's *t*-test, the Wilcoxon rank sum test, and the $\chi 2$ test were used where appropriate for statistical analyses.

Results: 27 parturients were evaluated for participation between 2018 and 2019, and 22 enrolled. The final study subject number was 20 due to two withdrawals. There were no clinically meaningful differences in baseline demographics, vital signs, and anxiety. The mean (SD) total patient satisfaction for music vs. control was 116 (16) vs. 120 (22), mean difference 4 (95% CI: –14.0 to 22.0), $P = 0.645$. The mean (SD) change in anxiety with music vs. control was 2.7 (2.7) vs. 2.5 (2.6), mean difference –0.4 (95% CI: –4.0 to 3.2), $P = 0.827$. The median (IQR) post-operative MAP with music vs. control was 77.7 (73.7–85.3) vs. 77.3 (72.0–87.3), $P = 0.678$.

Conclusions: The use of Mozart sonatas did not result in improvements in patient satisfaction, anxiety or MAP in parturients undergoing elective caesarean delivery.

Key words: Maternal Satisfaction Scale for Caesarean Section (MSSCS), mean arterial pressure (MAP), standard deviation (SD), interquartile range (IQR).

Clinical Trial Identification: clinicaltrials.gov (NCT03412019).

Anaesthesiol Intensive Ther 2023; 55, 2: 114–119

Received: 13.01.2023, **accepted:** 24.04.2023

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There is significant interest in the medical community in the use of music as a therapeutic modality to improve a wide variety of clinical outcomes [1, 2]. Patient satisfaction is often found to improve with music use in randomised trials, and a recent meta-analysis confirms the finding that music may have a strong effect on patient satisfaction [3]. In the US, the use of a cost-effective intervention to improve patient satisfaction is of interest to hospital administrations because a portion of Medicare (the US federal health insurance) reimbursements is based on the results of patient satisfaction surveys under the Hospital Value-based Purchasing programme of the Affordable Care Act (a US law that increases health insurance coverage) [4, 5].

Findings from a recent meta-analysis of 16 randomised controlled trials suggest that music increases patient satisfaction in a variety of clinical scenarios [3]. However, these clinical trials assessed overall patient satisfaction as a secondary outcome using only simple scales (e.g. numeric rating scale, verbal analogue scale, or Likert scale). Therefore, the evidence supporting the use of music to improve patient satisfaction could be enhanced by studies examining the types of procedures that may benefit, the choice of music that may have the greatest effects, and the circumstances under which the music is played (e.g., pre-operatively, intra-operatively, or post-operatively).

The purpose of this study was to understand the effects of music on patient satisfaction using

a rigorous scientific design. The composite score on the Maternal Satisfaction Scale for Caesarean Section (MSSCS), a previously validated survey instrument designed to specifically assess patient satisfaction in parturients undergoing caesarean delivery, was used as a comprehensive assessment of patient satisfaction [6]. The hypothesis was that there would be an improvement in patient satisfaction with the use of Mozart sonatas in parturients undergoing elective caesarean delivery.

METHODS

Study design

We conducted a prospective, randomised, controlled trial at an urban tertiary care academic medical centre approved by the Tufts Health Sciences Institutional Review Board (#12718) and submitted prior to patient enrolment at clinicaltrials.gov (NCT03412019, principal investigator: Dan Drzymalski, date of registration: January 12, 2018). Written informed consent was obtained from all study participants by one of the study co-investigators. This manuscript adheres to the applicable CONSORT guidelines.

Participants

Participants who were eligible for the study included women 18-50 years old with a healthy singleton pregnancy at ≥ 37 weeks gestational age undergoing elective caesarean delivery under neuraxial anaesthesia. Exclusion criteria were patient refusal, impaired hearing, prior extensive abdominal surgery, labour, contraindication to neuraxial anaesthesia, uncorrected coagulopathy, pre-existing infection at potential site for placement of neuraxial technique, increased intracranial pressure, haemodynamic instability, hypersensitivity to local anaesthetics, and anxiolytic use. Patients were not incentivised or remunerated in any manner.

Randomisation and blinding

Parturients were randomly assigned to either music or control, as previously described [7, 8]. Computer generated randomisation was in a 1 : 1 ratio in a single block using Research Randomizer version 4.0 (www.randomizer.org) [9]. The allocation was concealed to patients and investigators using sequentially numbered, sealed, opaque envelopes, until after parturients consented to participate in the study. The study was unblinded when participants entered the operating room for surgery, at which point they would hear the music if randomised to the intervention group. Follow-up was performed by a study investigator who was aware of the random assignment.

Intervention

For parturients randomised to music, an amplified speaker was used to broadcast music through an iPod (Apple, Cupertino, California). To decrease variability that might result from having patients listen to music with different qualities, the same set of Mozart sonatas, which have been previously shown to improve patient anxiety, an important determinant of patient satisfaction, was administered to participants [10, 11]. The sonatas were played in a loop in the following order: KV283, "Andante" (1775); KV311, "Andantino con espressione" (1777); KV330, "Andante cantabile" (1783); KV332, "Adagio" (early 1780s); KV333, "Andante cantabile" (1783); KV545, "Andante" (1788); KV570, "Adagio" (1789); and KV576, "Adagio" (1789). The control group did not listen to music, and any radio in the operating room was turned off prior to patient entry.

Music was initiated in the operating room immediately prior to the patient's entry into the operating room and maintained throughout the surgery. The music was played at a volume adjusted according to patient preference. Parturients underwent a standardised spinal technique at the L3–L4 or L4–L5 interspace using a 25-gauge Whitacre needle.

Outcomes

The primary outcome was patient satisfaction, using the MSSCS, a reliable and validated survey [6]. The responses were measured on a 7-point Likert scale anchored with "strongly disagree" to "strongly agree" to obtain a composite score in the range 22–154, representing the lowest to the highest satisfaction. Four major domains of the patient experience are assessed, including: interaction with family and staff, anaesthetic and technical effects, intra-operative and post-operative events, and side effects. The survey was administered on postoperative day one between 8:00 a.m. and 1:00 p.m.

Secondary outcomes included change in anxiety before and after surgery using a numeric rating scale of 0–10, with 0 representing no anxiety and 10 representing the greatest level of anxiety possible, as well as mean arterial pressure (MAP) immediately post-operatively.

Sample size calculation

The sample size was calculated based on a prior study in parturients who received midazolam vs. not, in which mean (standard deviation [SD]) patient satisfaction (using MSSCS) was 130.3 (10.5) vs. 113.6 (11.9), respectively [12]. To detect a similar difference in the present study with a power of 80% and α of 0.05, the total number of subjects needed

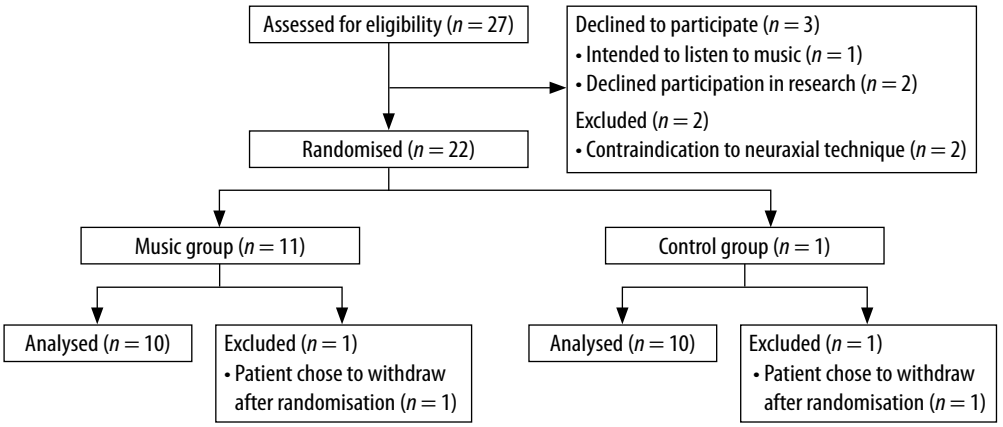

FIGURE 1. Trial profile

TABLE 1. Patient demographics and baseline characteristics

Factor	Music ($n = 10$)	Control ($n = 0$)	*P*-value
Age (years)	34 (31–36)	38 (32–39)	0.092
Body mass index (kg m^{-2})	28 (26–31)	31 (30–41)	0.123
Gravidity	3 (2)	5 (2)	0.091
Parity	1 (1)	2 (1)	0.465
Gestational age (weeks)	39 (38–39)	39 (38–39)	0.879
Ethnic origin			
White	7 (64%)	6 (55%)	0.999
Hispanic	2 (18%)	3 (27%)	
Asian	1 (9%)	0 (0%)	
Other	1 (9%)	2 (18%)	
Heart rate	86 (9)	93 (13)	0.176
Mean arterial pressure	87 (5)	93 (13)	0.206
Anxiety*	5 (1)	4 (3)	0.384

Data are presented as median (interquartile range), mean (standard deviation) or number (%).
*Anxiety was measured using a numeric rating scale from 0 to 10, with 0 representing no anxiety and 10 representing the greatest level of anxiety.

would be 18. To account for an approximate 20% attrition rate, a total of 22 subjects were enrolled. Sample size calculation was performed using G*Power 3.1.9.3 [13].

Statistical analysis

The Shapiro-Wilk test was used as a test of normality. For variables found to be normally distributed in the Shapiro-Wilk test, Student's *t*-test was performed and the results presented as mean (SD). For variables found to be non-normally distributed in the Shapiro-Wilk test, the Wilcoxon rank sum test was performed and the results presented as median (interquartile range [IQR]). Categorical variables were assessed using the χ^2 test and the results presented as number (percentage). The significance level for type I error was set at 0.05. All analyses were performed using STATA v.16.1 (StataCorp, College Station, TX, USA).

RESULTS

Between February 21, 2018 and August 6, 2019, a total of 27 parturients were evaluated for study participation, of whom 22 parturients were enrolled and randomised equally to either the music or control group (Figure 1). Two parturients were excluded from the final analysis because they withdrew prior to completing the study, resulting in the final number of analysed study subjects being 20. Baseline demographics, vital signs, and anxiety, which showed no clinically meaningful differences, are presented for the study groups in Table 1.

The mean (SD) total patient satisfaction as assessed by the MSSCS for music vs. control was 116 (16) vs. 120 (22), mean difference 4 (95% CI: –14 to 22), $P = 0.645$. The mean (SD) difference in anxiety with music vs. control was 2.7 (2.7) vs. 2.5 (2.6), mean difference –0.4 (95% CI: –4.0 to 3.2), $P = 0.827$. The median (IQR) post-operative MAP with music vs. control was 77.7 (73.7–85.3) vs. 77.3 (72.0–87.3), $P = 0.678$.

DISCUSSION

The present study found that parturients undergoing elective caesarean delivery while listening to Mozart sonatas did not have increased patient satisfaction as measured by the composite score of the MSSCS compared to control. Similarly, improvement in anxiety and post-operative MAP was not found.

The findings in this study were unexpected given multiple prior reports, suggesting significant improvement in patient satisfaction and other outcomes with music use in a wide variety of clinical settings [14–17]. The explanation that the lack of difference in outcomes may be due to type II error is unlikely as we had sufficient subjects enrol in the study based on our a priori performed sample size calculation. Instead, there are other plausible explanations for our study findings.

While the basis for the present study was a meta-analysis published in *The Lancet* with sound statistical analysis finding increased patient satisfaction with music use, the 16 randomised controlled trials analysed in that meta-analysis used a simple single-item tool to assess overall satisfaction [3]. However, there are several problems with using single-item tools to assess outcomes. First, single-item surveys are not reliable; when these questions are asked multiple times (test-retest), there is a high likelihood that the response will not be the same each time. Second, data obtained from single-item surveys commonly have a significant positive skew (in many cases, the median score is the top score), making it difficult to detect meaningful differences [18]. Therefore, it is likely that the meta-analysis by Hole *et al*. [3] overestimated the effect of music on patient satisfaction because the randomised controlled trials used a methodology to evaluate patient satisfaction that is very limited.

Given that Hole *et al*. [3] may have overestimated the effect of music on patient satisfaction, in this study patient satisfaction was pre-defined as the primary outcome, in order to decrease the risk of type I error and the risk of overestimating the intervention effect [19, 20]. Furthermore, the present study specifically used the MSSCS to evaluate patient satisfaction because multidimensional survey instruments yield more reliable results and can better differentiate between groups compared to single-item surveys [21]. The MSSCS is specifically designed to assess patient satisfaction with caesarean delivery, and it is a robustly developed and validated instrument with high reliability as assessed by a qualitative systematic review of over 3,000 articles assessing patient satisfaction tools [6, 22, 21]. The MSSCS assesses 4 major domains of the patient experience with caesarean delivery, and a composite score is calculated from the individual responses. Importantly, the MSSCS was developed using patient feedback, which is key to making a reliable survey because it makes the survey patient-focused and helps identify areas that are of importance to patients who have had an anaesthetic [23]. Therefore, not finding a difference in overall satisfaction as measured by the MSSCS is likely a more accurate estimate of the effect of music on patient satisfaction with caesarean delivery as compared to any single question.

Changes in MSSCS scores have been attributed to differences within the specific domains of the survey. For example, Morgan *et al*. [22] found that MSSCS scores were higher in parturients who underwent epidural vs. spinal anaesthesia for caesarean delivery. The authors explained that this finding was mainly due to changes in the domain assessing side effects, specifically pruritus, mood change, dry throat, and dry mouth at 24 hours. Such an explanation is supported by other studies, which have found similar differences in pruritus and other side effects with epidural vs. spinal anaesthesia [24, 25]. As such, the present study suggests that music does not affect those areas that are of importance to patients as assessed by the MSSCS.

In the present study, anxiety was a secondary outcome because anxiety reduction might lead to improved patient satisfaction. A prior study found that parturients who receive midazolam prior to caesarean delivery reported lower pre-operative anxiety and higher post-operative satisfaction (as assessed by the MSSCS tool) compared to those receiving placebo, suggesting an inverse relationship between anxiety and satisfaction [12]. While midazolam and music (in the right context) both function to reduce patient anxiety, midazolam has the additional property of impairing memory processing [26]. Higher patient satisfaction with midazolam use may be more related to amnesia of perioperative events (e.g. pain from needles) than anxiety reduction directly. Such an explanation could support the finding that pre-operative anxiolytic use in patients undergoing general anaesthesia was not associated with an increase in patient satisfaction, as such patients already have amnesia of perioperative events from the general anaesthetic and would not recall intra-operative pain [27]. While one explanation for not finding a difference in anxiety could be the choice of music used in our study, music use in general, as well as Mozart sonatas as used in this study, have been previously associated with a decrease in anxiety [3]. Nevertheless, not finding a change in patient satisfaction may be related to not finding a change in anxiety in the present study.

Importantly, the timing and context of music administration may play a key role in its effects on patient satisfaction and anxiety. Music is not always associated with an improvement in clinical outcomes [1]. In a prior study of music use during epidural catheter placement for labour analgesia, anxiety was higher and patient satisfaction lower when music was used compared to the control [8]. Similarly, patients undergoing carotid endarterectomy under cervical plexus block experienced higher intra-operative anxiety with music use than without [28]. These paradoxical findings suggest that music use during invasive procedures might actually be harmful to patients, particularly in cases where patients are asked to participate or provide feedback (e.g. during the epidural technique, parturients are often asked to indicate whether they feel pain on one side or the other). Increased anxiety could be due to the increased cognitive load in the context of background

music [29]. On the other hand, when Mozart sonatas were played during the pre-operative waiting period, patients reported decreased anxiety [7]. These studies suggest that the effects of music may differ in different portions of the perioperative period, thus proposing that timing and context of music administration may be important determinants of the effects on patient satisfaction and anxiety. At the same time, patient selection of music may influence the patient's reaction and therefore satisfaction with the overall experience. Future studies that examine the effects of music (as well as selection of music) on patient satisfaction and anxiety based on the timing of music administration should be performed.

As with all investigations, it is important to consider the limitations of the present study. First, the study was designed a priori as a superiority trial given the overwhelming evidence suggesting that music improves patient satisfaction, anxiety, and blood pressure across clinical settings [3, 14-17]. While a difference was not found based on our non-significant statistical results, the analysis does not indicate that no difference exists (in other words, we cannot conclude that using music is equivalent to no music). To reach such a conclusion, a statistical test of noninferiority or equivalence would be necessary [30]. However, noninferiority or equivalence studies are typically performed to test a new drug that might have the same clinical properties as an existing drug, but may be less expensive, have fewer side effects, or have some other advantage which would justify performing such a study. In our case, the most relevant clinical question was whether music use was better than no music, so a superiority trial was nevertheless the more relevant study design. Second, because we used a speaker to broadcast the music, patients and clinicians were unblinded as to treatment group the moment they entered the OR and could thus be biased in their responses. To minimise selection bias of patients who may have a preference for music or no music in the OR, the investigators and patients were blinded as to treatment allocation until after the patients agreed to participate by using sequentially numbered, sealed, opaque envelopes. Finally, we cannot determine from our results whether the patients found music use valuable, only that we did not find a difference in patient satisfaction as measured by MSSCS scores. In a study of parturients listening to music during labour epidural catheter placement, parturients who listened to music were more likely to report that they would request music for future placements, despite incongruent findings in patient satisfaction [8]. Therefore, to understand the value of music use in the perioperative area, specific survey questions should be developed and validated.

CONCLUSIONS

Despite several prior studies suggesting improved patient satisfaction with music use during invasive procedures, the present study did not find improvements in patient satisfaction, anxiety, or MAP, in parturients undergoing elective caesarean delivery listening to Mozart sonatas compared to the control group. The findings emphasise that patient satisfaction is complex and may not improve with the use of music during caesarean delivery. Perhaps the lack of effect in our study could be related to the parturient anxiously awaiting the sound of her baby crying and the music could be seen as a distraction from the aura of that moment. Regardless, the major strength of the present study was the rigorous methodology used to measure patient satisfaction. Future studies should further distinguish between the use of music during invasive vs. non-invasive procedures and between different types of invasive procedures. The effects of music may vary in different clinical settings, and therefore it is important to understand when and how to best use music to improve patient outcomes.

ACKNOWLEDGEMENTS

1. Assistance with the article: none.
2. Financial support and sponsorship: none.
3. Conflicts of interest: none.
4. Presentation: none.

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