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EFFECT OF MUSIC THERAPY IN PATIENTS UNDERGOING CAESAREAN DELIVERY UNDER SPINAL ANAESTHESIA

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ABSTRACT: Background: Increased anxiety in patients undergoing caesarean delivery has a negative impact on fetus and mother. Music therapy can have beneficial effects. The aim of our study was to determine the effects of preoperative and intraoperative music therapy on anxiety, pain, patient satisfaction and postoperative nausea and vomiting in patients undergoing caesarean delivery under spinal anaesthesia. Methods: A prospective randomised study was conducted on 100 patients, 18-40 years of age, ASA Grade I-III posted for caesarean delivery under spinal anaesthesia. Patients were randomly divided into two groups (50 each). Group M patients listened to soothing meditative flute music, and Group C patients had no music but headphones until the end of the surgery. Observations were recorded and analysed statistically: mean blood pressure (MBP), heart rate (HR), visual analogue score (VAS) for pain, visual analogue score for anxiety (VASA), and patient satisfaction score (PSS). Results: Compared to Group C, HR and MBP in Group M started falling after 10 minutes of spinal anaesthesia, and the difference was significant (p<0.05). Compared to Group C, the median VASA-2 in Group M was significantly lower than the median VASA-1 (p<0.01) in Group M. Group M patients reported a significantly lower median VAS than Group C patients at 30 minutes (p<0.01) and at the 1st hour (p<0.01) postoperatively. PSS was significantly higher in Group M compared to Group C (p<0.01). Conclusion: Music therapy is a useful adjunct for patients undergoing caesarean delivery under spinal anaesthesia, leading to reduced pain, anxiety scores and improved patient satisfaction.

INTRODUCTION: Pain and postoperative nausea and vomiting (PONV) are the most common symptoms of distress following surgery and anaesthesia, especially in women undergoing caesarean delivery (CD).



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Also, preoperative anxiety mixed with feelings of joy and fear can cause significant levels of stress in them, leading to detrimental effects on the mother due to hemodynamic fluctuations, poor wound healing, an increased incidence of postoperative infections, postpartum depression, and adverse foetal outcomes.

The overall incidence of moderate to severe postoperative pain after caesarean delivery has been reported to be 30% despite the use of postoperative opioid analgesics ¹. Pregnant patients are also considered to have a full stomach and may

require urgent caesarean delivery, and the side effects of uterotonic agents may predispose them to postoperative nausea and vomiting. Most of the time, pregnant women undergoing caesarean delivery experience considerable anxiety, which is manifested by changes in heart rate, blood pressure, and respiratory rate. Anxiety leads to psychological distress and delays postoperative recovery. It also leads to high levels of endogenous catecholamines, cortisol, and natural killer lymphocytes, which can lead to disturbed hemodynamics, delayed wound healing, decreased immunity, a high incidence of infection, and therefore delayed recovery Therefore, finding a safe way to reduce postoperative pain, nausea, vomiting, and anxiety in obstetric anaesthesia patients is a challenge. Among non-pharmacological and therapeutic interventions, music is an inexpensive and noninvasive way to affect the limbic system and induce conditioned relaxation, releasing natural endorphins and opioids from the pituitary gland, thereby reducing anxiety and decreasing pain and analgesic demands, aiding in breastfeeding and infant intimacy in some studies³.

Music therapy decreases patient anxiety and improves cardiorespiratory parameters through its effect on the autonomic and central nervous systems ⁴. Music can help reduce stress hormones such as cortisol, corticotropin, and catecholamines and can increase serotonin and oxytocin levels, reducing postoperative pain and stress improving mental health ⁵. Therefore, the aim of this study was to evaluate the effect of music intervention therapy in patients undergoing elective and urgent CD under spinal anaesthesia. The primary objective was to observe hemodynamic parameters, postoperative pain, anxiety, patient satisfaction, and postoperative nausea and vomiting.

MATERIALS & **METHOD:** Following institutional ethics approval (Reg. No.-PDUMCR/IEC/107/2021), this prospective randomised case-control study was performed in accordance with the Declaration of Helsinki at a tertiary care hospital from August 2022 onwards till completion of the data point on 100 female patients between 18 and 40 years of age with an American Society of Anaesthesiologists (ASA) Grade I, II, or III uncomplicated singleton pregnancy with at least 36 weeks of gestation undergoing elective or urgent CD under spinal anaesthesia. **Patients** with cognitive/psychological/memory disorders, hearing impairment or ear deformity, chronic treatment with analgesics and drug addicts, drug allergies, hemodynamic instability, cardiac, respiratory, hepatic impairment, neuromuscular disorder, and bleeding disorder were excluded from the study. A pre-anaesthetic evaluation was done, and written informed consent was taken after explaining the role of music therapy. All patients were informed about the benefits of music and the complications of spinal anaesthesia. They were also explained about the Visual Analogue Scale (VAS) for pain and the VASA for anxiety. VASA consists of horizontal lines ranging from 0 to 10 cm, where 0 represents no anxiety and 10 represents the worst computerised randomization Using software, randomization was done using sealed, opaque envelopes that contained computergenerated numbers.

An odd number indicated Group M (music or experimental group), and an even number indicated Group C (control group, who wore headphones but no music was played). Patients were kept nil per oral for 6 hours for solid food and 2 hours for clear oral fluids before induction of anaesthesia (except for urgency). Urgency, or Category 2 of the modified version of the RCOG classification by Lucas et al., is defined as maternal or foetal compromise that is not immediately threatening. In the preoperative room. hemodynamic parameters of patients were measured, including HR, SBP, DBP, MBP, and SpO2.

An investigator played pre-recorded soothing meditative flute music in the preoperative room for 30 mins and continued in the operating room (OR) (discontinued only during induction) to participants of Group M using headphones, while Group C patients wore the headphones but no music was played. The music was played with a standardised volume determined on the device and measured at the Group M participant's head at 80 dB (A). The investigator recorded second observations throughout the study. Anxiety was measured using the Visual Analogue Scale for Anxiety (VASA). The anxiety score was recorded as VASA-1 before

the spinal anaesthesia was given, while the anxiety score recorded in the recovery room after the completion of surgery was considered as VASA 2. In the operation theatre, standard monitoring was done, like non-invasive blood pressure (NIBP), pulse oximetry, and electrocardiography (ECG). A 20G IV cannula was used to secure the venous line. patients were premedicated with Ondansetron 4mg IV. Under aseptic precautions, a 25G spinal needle was used to administer spinal anaesthesia in sitting or lateral position, and 2-2.4 ml of hyperbaric bupivacaine (0.5%) was injected in between L2-3 or L3-4 space after confirming clear and free flow of CSF. Surgery was allowed to proceed after achieving T6 level of pinprick sensation. Parameters such as HR, SBP, DBP, MBP, ECG, and SpO2 were recorded. Tachycardia was defined as HR ≥120 beats per minute. If blood pressure drops more than 20%, Inj. Mephentermine 6 mg IV was administered. Inj. Oxytocin 10 units IV was administered soon after the baby was delivered in the form of an infusion. Appropriate fluid therapy was maintained throughout the surgery. Music was continued till the end of surgery (until the last stitches of wound closure and dressing), and after that, music was stopped and the headphones were removed. After surgery, patients were transferred to the recovery room and observed for their VAS score for pain, VAS scale for anxiety

(VASA 2), patient satisfaction score, postoperative nausea and vomiting. We collected demographic profile, data related to surgery, and hemodynamic parameters (HR, SBP, DBP, and MBP) at the entrance to operation room, immediately after induction of anaesthesia, and every 10 mins until the end of the procedure. We assessed the severity of pain by visual analogue scale (VAS) just after surgery, 30 min, 1 hr, 2 hrs, 4 hrs and 6 hrs after surgery. Inj. Tramadol by intravenous route was given as a rescue analgesic if the VAS score was more than 3 or the patient demanded analgesia, whichever came first, and time was noted. All the patients were monitored for PONV (till 6 hrs) and anxiety score (VASA 2) in the postoperative recovery room. Metoclopramide 0.15 mg/kg IV was administered to the patients if they complained of nausea and vomiting postoperatively. Patient Satisfaction Score (PSS) was recorded after 6 hours postoperatively by PSS Scale (1 - very good, 2 good, 3 - neither good nor bad, 4 - bad and 5 - very bad).

Statistical Analysis: To estimate the sample size for our study, we took the standard deviation of VAS reported by Sarkar *et al.* ² in their study as 2.57 and assumed a mean difference of VAS of 1.5 between the experimental and control groups.

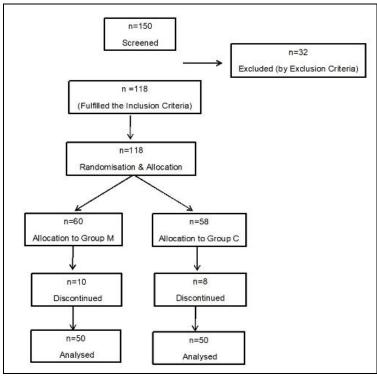


FIG. 1: CONSORT FLOW DIAGRAM OF THE RANDOMISATION, ALLOCATION AND ANALYSED

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Based on α -error of 5%, 95% confidence interval, and power of study 80%, we arrived at a sample size of 46, and an additional 10% of sample was taken to compensate for incomplete data, dropouts, and non-responses. Hence, the final sample size calculated was 50 in each group. All statistical analysis was performed using Statistical Packages for Social Science version 19 (SPSS Inc., Chicago, IL, USA). Mann Whitney U test was used to test the significance of differences for quantitative variables (HR, BP) (data following a nonnormative distribution), and the Chi-square Test was used to compare nominal categorical data between the groups. A probability value (p-value) <0.05 was considered statistically significant.

RESULTS: 5 patients (3 in Group M and 2 in Group C) removed theirheadphones in the preoperative period, while 6 patients (3 in Group M

and 3 in Group C) did so in the intraoperative period. 5 patients (2 in Group M and 3 in Group C) were converted to general anaesthesia (GA), and music failed to start in 2 patients (Group M).

The median age in Group M is 24 years and in Group C is 25 years, and the difference was not statistically significant. Likewise, the median weight and duration of surgery were also comparable between the two groups.

In Group M, 62% of patients underwent elective surgery and 38% had urgent surgery, while in Group C, the ratio was 58% and 42%, respectively. Analysis of baseline characteristics showed that there was no statistically significant difference in age group (p = 0.15), ASA grade (p = 0.28), weight (p = 1), type, or duration of surgery between Group M and Group C **Table 1.**

TABLE 1: COMPARISON OF DEMOGRAPHIC CHARACTERISTICS

V	ariables	Group M	Group M (N=50)		Group C (N=50)		
		Median	IQR		Median	IQR	p value
Ag	ge (Years)	24	6		25	7	0.28
We	eight (Kg)	68.5	15		68	10	0.47
Duration o	of Surgery (Mins)	70	22.5		70	20	0.58
Variables		Group M (N=50)			Group C (N=50)		p value
		No.	%		No.	%	
ASA	ASA II	36	72		31	62	p = 0.28
Grade	ASA III	14	28		19	38	
Type of	Elective	31	62		29	58	p = 0.68
Surgery	Urgency	19	38	21		42	

^{*}ASA: American Society of Anaesthesiology, IQR: Interquartile Range.

On comparing the hemodynamic parameters, HR, SBP, DBP, and MBP in both groups were comparable preoperatively and just after administering spinal anaesthesia (p>0.05). However, these parameters started falling more

significantly 10 minutes after induction in group M as compared to group C, and the difference was found to be significant till the end of surgery (p <0.05) **Fig. 2 and 3.**

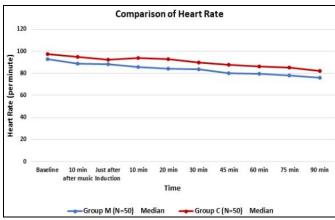


FIG. 2: COMPARISON OF HEART RATE

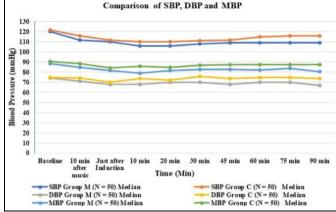


FIG. 3: COMPARISON OF SYSTOLIC, DIASTOLIC AND MEAN BLOOD PRESSURE

VAS score of patients in Group M was significantly lower than the Group C at 30 min (p <0.01) and at 1st hour (p <0.01) after surgery. Median VAS in Group M was lower in Group M than in Group C at 2nd hr, 4th hr and 6th hr after surgery, but it was statistically not significant. Median patient satisfaction score is higher in Group M group (p <0.01). Visual analogue scale for anxiety (VASA) was studied for both groups. After the application of music of choice in Group M, median VASA-2 fell to a much lower value than VASA-1. Median VASA-1 was 2 and fell to 1 (VASA-2) in Group M. However, in Group C,

median VASA-1 was found to be 2, and it remained the same after the completion of surgery (median VASA-2 = 2). On comparing VASA between two groups, we found that VASA was lower in Group M after surgery (VASA-2) as compared to Group C. This difference was found to be significant between both groups (p<0.01). First rescue analgesia was required at 155 min in patients with music, which is significantly later than the control group (p <0.01). **Table 2** there is no difference in postoperative nausea and vomiting till 6 hrs postoperatively in both the groups (p = 0.79) **Table 3.**

TABLE 2: COMPARISON OF VAS, PSS, VASA AND TIME OF FIRST RESCUE ANALGESIA

Variables	Group M (N=50)		Group C	Group C (N=50)		
		Median	IQR	Median	IQR	p value
Visual Analogue Score	0 hr	0	0	0	0	< 0.01
(VAS)	30 min	0	0	0	1	< 0.01
	1 hr	0	1	2	1	< 0.01
	2 hr	2.5	2	3	2	0.73
	4 hr	3	2	4	2	0.09
	6 hr	2	0	2	0	0.89
Patient Satisfaction Score (PSS)		1	1	2	0.25	< 0.01
Anxiety score (Pre-Op) VASA 1		2	1	2	1	0.8
Anxiety score (post-Op) VASA 2		1	0	2	1	< 0.01
Time of First Rescue Analgesia (Min)		155	72.5	130	72.5	< 0.05

^{*}VAS: Visual Analogue Score, PSS: Patient Satisfaction Score, VASA: Visual Analogue Score for Anxiety.

TABLE 3: COMPARISON OF POST-OPERATIVE NAUSEA AND VOMITING (PONV)

PONV	Group N	M (N=50)	Group C	p value	
	No.	%	No.	%	_
Yes	8	16	9	18	0.79
No	42	84	41	82	

DISCUSSION: Literature shows that the level of preoperative anxiety in the obstetric population is high, especially in those undergoing caesarean delivery ⁶. Parturient with pre-existing anxiety has significantly higher pain scores following CD, which may in turn increase their risk of developing persistent pain and postpartum depression ⁷. Anxiety before CD can increase the demand of analgesic medications and length of the hospital stay ⁸.

Non-pharmacological interventions like interviews with patients by healthcare providers, communicating strategies, spiritual or music therapy, visits from relatives, acupuncture, using distractions, and patient education also plays a very important role in allaying anxiety ⁹. Premedications like anxiolytics and sedatives are given to relieve anxiety but can harm the circulatory and

respiratory systems of the mother as well as baby. Suction machine sounds, monitor alarms, and communication & discussion amongst OT staff are some of the visual and auditory stimuli that can increase the anxiety of parturient undergoing CD. Music is a very important way to reduce anxiety and depression among the patients undergoing surgery ¹⁰. Listening to music leads to the activation of auditory pathways, the limbic system, and neuronal interconnections and attenuates excitatory neurotransmitters, resulting in relaxation, sedative effects, and reduced anxiety due to activation of the parasympathetic system ¹¹.

There are few studies in the literature regarding the use of different forms of perioperative music (instrumental, meditation, jazz, classical, alone or in combinations) in patients undergoing caesarean delivery. However, loud volume and fast music

played in OR may hamper proper communication among the staff, activate sympathetic response, and it might not be of patient's choice. While soft and slow instrumental music relaxes and calms the body, hence in our study we preferred soothing meditative flute music, which gives positive reinforcement to neurohormonal activity and leads to reduced needs of sedatives and analgesics 12. Studies have demonstrated the role of patientchosen music in relieving anxiety and improving relaxation in unfamiliar situations ^{13, 14, 15}. Also, the use of headphones has been suggested as an effective solution ^{16, 17}. In this study, we compared the effects of meditative flute music on elective and urgent caesarean deliveries by applying the music in one group using headphones and no music in the other group. Various hemodynamic parameters were assessed, along with the visual analogue scale (VAS), anxiety score, patient satisfaction score, time to request first rescue analgesia, postoperative nausea and vomiting.

In our study, the patients who underwent elective, scheduled, or urgent caesarean delivery were comparable in terms of age, weight, and duration of surgery. Music has a direct impact on the dopaminergic mesolimbic reward centre, and there is an interaction of the external musical rhythm with the internal body rhythms of the heart and respiratory rate. Systolic blood pressure and heart rate values are well documented as objective parameters reflecting stress and anxiety ¹⁸.

Laopaiboon M et al. 19 also found significant decrease in mean HR after using intraoperative music intervention in caesarean section under spinal anaesthesia. Similar to our study, Bansal GL et al.²⁰ compared HR and MBP between the two groups and observed significant decline in heart rate and MBP in music group compared to the control group from 10 min after induction till the end of surgery (p <0.005). Similarly, Hojati et al.²¹ observed that the rate of change of heart rate and DBP was significantly lower in music group as compared to the control group in patients underwent CD. Anxiety causes activation of the sympathetic system in elderly patients, which stimulates the hypothalamic autonomic system and increases heart rate. Music intervention in such patients undergoing spinal anaesthesia leads to reduction in anxiety and slowing of the heart rate,

as observed by Wang Y. et al 22. No significant changes in heart rate after music therapy was observed by Shu-Ming Wang et al. Ebneshahidi et al. 24, which was contrary to our study. This might be due to individual autonomic responsiveness to a stressful condition. Similarly, Studies by Bansal P et al. 13 and Mandel SF et al. 25 too, observed no significant reduction in blood pressure in the music intervention group in comparison to the control group. A better hemodynamic stability in patients administered music as compared to control group was observed in a prospective study done by Kahloul *et al.* ²⁶ on 140 patients undergoing abdominal surgery under general anaesthesia. Similar to our study, a perioperative music intervention infemales underwent mastectomy surgery for breast cancer, significantly reduced MAP, anxiety; and pain as observed by Binns-Turner et al ²⁷.

Post-caesarean delivery pain relief is important to improve mobilisation, reduce the risk of thromboembolism, and strengthen the mother-baby bond. Kurdi *et al* ²⁸ observed that the mean pain scores of M (Meditative music) and B (Binaural beat meditative music) groups were statistically comparable at the 1st, 6th, and 24th h, while the mean pain scores of M and B groups compared with C (No music) group decreased significantly at the 6th and 24th h. The mean time required for the first rescue analgesic in M and B groups was statistically comparable, whereas the mean time required for the first rescue analgesic in the M and B groups compared with the C group increased significantly.

Preoperative relaxing music is a useful alternative to decrease anxiety and fear in elective ambulatory surgeries in comparison to anxiolytic drugs. Bringman H *et al.* ²⁹ observed a decline in STAI-state anxiety scores that was significantly greater in music group compared to the midazolam group. Also, the importance of preoperative visit and counselling by an anaesthetist plays an important role in allaying anxiety ³⁰. In our study, the median VASA 2 in Group M was of a much lower value than in Group C, with a statistically significant difference (p <0.01). Bansal GL *et al.* ²⁰ observed a fall in VASA values in Group M and Group C at the end of surgery. However, on comparison, VASA was significantly lower in Group M (Music)

after surgery (VASA 2) as compared to Group N (No Music) (p = 0.004). The fall in VASA 2 in Group N could be due to the silencing of OR noises by the application of headphones, even though music was not switched on. Khaity *et al.* ³¹ conducted a meta-analysis of 1513 patients undergoing CD and came to the conclusion that the music has a beneficial effect on DBP and intraoperative heart rate changes in patients who underwent CD, but it doesn't differ significantly from the placebo in preoperative anxiety, postoperative heart rate and SBP.

Wang SM et al. 23 and Palmer et al. 11 did a study and found a significant reduction in anxiety scores in patients receiving music. Kurdi M et al. 28 observed on patients with caesarean sections that mean anxiety scores (VASA) were statistically comparable between the music and control groups at 1st, 6th and 24th hr between Group M (meditative music) and Group C (no music). Also, VASA in Group M and Group B (binaural beat meditation music) differed significantly at the 1st, 6th, and 24th hr compared with Group C. Kakde et al. analysed 108 parturient patients and observed reduced postoperative anxiety (VAS-A score) and lower pain catastrophizing (PCS total score and PCS sub-scores) due to perioperative music therapy.

The Benson relaxation technique (BRT) and music common nonpharmacological therapy are relaxation techniques that have been recognised as one of the most appropriate and cost-effective methods for reducing many illnesses. In a study done by Abarghoee et al. 33, the BRT and MT both helped to reduce anxiety among primiparous female patients before CD; however, the BRT was shown to be more effective. Hepp et al.³⁴, in their randomised controlled study among 304 patients, observed significantly lower anxiety levels in the experimental group regarding STAI-state anxiety (p = 0.004) and VASA (p = 0.018) at the end of surgery. The VASA score was still significantly lower in the experimental group two hours after the surgery (p = 0.018). Jule et al.³⁵, in their randomised controlled study among 49 patients, observed that the STAI anxiety score of the music group (35.88±5.39) was found to be statistically significantly lower than the control (42.14 ± 3.75) (p < 0.001) after the surgery.

Laopaiboom *et al.*¹⁹ found in their systemic review that patient satisfaction score increased by 3.4 points on a 35-point scale with the use of music score. Bansal GL *et al.*²⁰ and Sarkar *et al.*²¹ observeda higher patient satisfaction score inmusic group as compared to control group among the patients underwent CD. Sarkar *et al.*²¹ in his study found that maternal satisfaction score was very high in their music group as compared to the silence group in patients undergoing caesarean sections.

Few studies have observed that music is highly desirable in patients undergoing conscious sedation and RA by reducing sedative consumption and improving the patient's satisfaction ^{18, 36}. Also contrary to our study, Palmer *et al.*¹¹ observed no significant difference in patient satisfaction score in the music group compared to no music group in patients undergoing ambulatory surgery for breast cancer. In our study, there was no difference in postoperative nausea and vomiting between both groups till 6 hrs postoperatively. (p=0.79). **Table 3** Similar to our study, Kurdi *et al.* ²⁸ observed that mean PONV scores in M, B, and C groups were statistically comparable at 1st, 6th, and 24th hr postoperatively.

Preoperative and intraoperative music played probably led to improvement in the psychological wellbeing of patients, leading to a positive frame of mind and decrease in neurohormonal stress in patients undergoing caesarean delivery, and hence they could feel less pain and require less antiemetic in the postoperative period. Our study had few limitations. Expectant mothers might not be able to report exactly how anxious they felt during intraoperative surgery or whether they were already experiencing relief with the baby's birth, as they may be anxious about the postpartum period. So, the process of determining the level of anxiety in such patients is quite subjective, and the level of anxiety could have been measured just before the entry of patient in the preoperative room. Also, we could not assess the changes in various hormone levels involved in the stress response of patients under music therapy. The study was conducted among a small number of subjects, and hence, randomised controlled double-blind studies with a large sample size incorporating the perioperative effect of different types of music or according to

the choice of the patient and also the impact of music therapy on the entire surgical team are needed to further substantiate or refute the results of the study.

CONCLUSION: We conclude that preoperative and intraoperative music therapy is a useful adjunct in patients undergoing caesarean delivery under spinal anaesthesia. The patients had better intraoperative hemodynamic stability, reduced pain, anxiety, and higher satisfaction as compared to those with no music therapy.

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