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**“EFFECT OF INTRAOPERATIVE MUSIC THERAPY ON  
ANXIETY IN GERIATRIC PATIENTS UNDERGOING  
SURGERY UNDER SPINAL ANAESTHESIA: A ONE  
YEAR HOSPITAL BASED DOUBLE BLIND  
RANDOMIZED CONTROL TRIAL.”**

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**By**

**REG NO. BA0121018**

**Dissertation**

*Submitted to*

*KAHER, Belagavi, Karnataka,*

*In partial fulfilment of the requirements for the degree of*

**M.D.**

**In**

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**DEPARTMENT OF ANAESTHESIOLOGY,  
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**DECEMBER – 2024 / JANUARY 2025**

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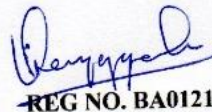
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With reference to the above, we wish to inform you that your proposed research project titled "EFFECT OF INTRAOPERATIVE MUSIC THERAPY ON ANXIETY IN GERIATRIC PATIENTS UNDERGOING SURGERY UNDER SPINAL ANAESTHESIA: A ONE YEAR HOSPITAL BASED DUBLE BLIND RANDOMIZED CONTROL TRIAL." is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee.

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## ABBREVIATIONS

|                  |   |  |
|------------------|---|--|
| ASA              | - | American Society of Anaesthesiologists |
| HR               | - | Heart Rate (bpm)                       |
| SBP              | - | Systolic Blood Pressure ( mm Hg )      |
| DBP              | - | Diastolic Blood Pressure ( mm Hg )     |
| SpO <sub>2</sub> | - | Saturation of peripheral oxygen ( % )  |
| L                | - | Lumbar sensory dermatomal level        |
| mcg.             | - | micrograms                             |
| min.             | - | minutes                                |
| kgs.             | - | kilograms                              |
| cms.             | - | centimeters                            |
| VASA             | - | Visual Analogue Score for Anxiety      |

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## **ABSTRACT-**

**TITLE-** Effect of intraoperative music therapy on anxiety in geriatric patients undergoing surgery under spinal anaesthesia: A one year hospital based double blind randomized control trial.

**CONTEXT** – Spinal anaesthesia is the most commonly used anaesthesia for infra umbilical surgeries. As a potential alternative to pharmaceutical interventions, this study aims to examine the effects of music therapy during spinal anaesthesia in geriatric patients, particularly focusing on whether intraoperative music therapy impacts patient anxiety, the amount of sedation required during surgery, and postoperative satisfaction.

**AIMS-** To compare anxiety between patients who were and who were not exposed to music during the surgery using Visual Analogue Scale for Anxiety (VASA). To evaluate whether music is linked to a reduction in intraoperative sedative requirements and to assess patient satisfaction.

**SETTING AND DESIGN-** A year hospital based randomized clinical trial

**MATERIALS AND METHODS-** A total of 82 Patients aged above 60 years, of either gender, belonging to ASA grade I-III, undergoing elective surgery in supine position under spinal anaesthesia were enrolled in the study and randomized into two groups. GROUP M: Patients listened to a chosen soundtrack using noise-cancelling headphones Group N: No Music Group: Patients wore headsets with turned off settings. Anxiety was measured with the VASA and every ten minutes, intraoperative hemodynamic parameters were watched over and noted until the end of the surgery.

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**RESULT-**Group-M had better VAS score for anxiety and better hemodynamic parameters as compared to the Group-N. The mean VAS score for anxiety scores and hemodynamic parameter were comparable between the groups.

**CONCLUSION-** Intraoperative music therapy significantly reduces anxiety in geriatric patients undergoing infraumbilical surgery under spinal anaesthesia. Intraoperative music therapy also leads to reduced requirement of intraoperative sedation.

**KEYWORDS-** Geriatric patients, Spinal anaesthesia, Music therapy, intra operative anxiety.

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## **INTRODUCTION-**

Spinal anaesthesia is the most commonly used anaesthesia for infra umbilical surgeries. Hence it is being utilized increasingly in geriatric patients undergoing lower limb surgery. But since hammers, drills, suction equipment, and cautery are frequently utilized in the operating room—especially for orthopaedic surgeries—the surroundings can be noisy. An orthopaedics oscillating saw's sound can reach 105 decibels (dB), which would induce significant anxiety. For elderly patients, being in an unfamiliar environment and knowing that their body is being operated on can be highly stressful and anxiety-inducing, often necessitating the use of additional sedative medications. Higher frequency of delirium particularly in the older population is linked to higher sedative needs during prolonged operations .

Many studies have shown that wearing headphones featuring patient-selected music can help to lower operating room anxiety and raise general patient satisfaction. Considered as a non-pharmacological intervention, music therapy has been utilized as an adjunct to help in postoperative recovery and also help to lower preoperative anxiety. Although this has not been specifically studied in geriatric patients undergoing spinal anesthesia, hearing to music during surgery has been shown to increase patient satisfaction and reduce the need for sedatives in other types of procedures.

As a potential alternative to pharmaceutical interventions, this study aims to examine the effects of music therapy during spinal anaesthesia in geriatric patients, particularly focusing on whether intraoperative music therapy impacts patient anxiety, the amount of sedation required during surgery, and postoperative satisfaction

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## **OBJECTIVE OF THE STUDY**

### **Primary objective**

1. To compare anxiety in between patients who were and who were not exposed to music during the surgery under spinal anaesthesia using Visual Analogue Scale for Anxiety(VASA)

### **Secondary objective**

2. To evaluate whether music is linked to a reduction in intraoperative sedative requirements.
3. To assess patient satisfaction.

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## **REVIEW OF LITERATURE.**

Music therapy a non pharmacological intervention has been found to reduce anxiety in patients undergoing various procedures. It has also been found to reduce anaesthetic requirement during general anaesthesia.

Kulkarni et al<sup>2</sup>. (2012) did a study looking at how music might affect anxiety, pain, and sedation during interventional radiological treatments. With just 42% of the patients in the music group needing sedation compared to 60% in the control group the data showed that patients in the music group needed less sedation. Additionally, the average requirement for midazolam, the mean need for fentanyl, was lesser in the music group compared to the control group. However, there were no significant differences in vital signs between the two groups.

In a recent study of Fu et al<sup>3</sup> (2020). looked at how perioperative music affected duration of hospital admission and medication needs. The results showed that postoperative opioids were needed less in the perioperative music group. While producing the same degree of sedation as the non-music group, the intraoperative needs for propofol and midazolam also significantly dropped.

Using music interventions in study group, Kühlmann et al<sup>4</sup>.s (2020) meta-analysis which comprised 81 randomized controlled trials and over 7,385 patients—showcased notable decreases in anxiety and pain. On a 100 mm visual analog scale, they noted specifically a drop of 24 mm in anxiety and 10 mm in discomfort. Furthermore, their meta regression study revealed no appreciable correlation between variables including age, sex, music choice, timing of the music, or kind of anaesthesia and the efficacy of music interventions.

Recent research by Bansal et al<sup>5</sup> (2019). looked at how music might help with reducing anxiety during caesarean procedures under spinal anaesthesia. Patients having past caesarean sections were part of the trial. The VASA scores were notably lesser in the music group than in the non-music group.

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Patients who heard music during the present procedure also reported far less anxiety than those who had a previous caesarean section without music.

Many studies have shown that music therapy can help lower the pre operative anxiety. For patients undergoing spinal anaesthesia, Lee et al<sup>7</sup>. found, that listening to music reduced anxiety and physiological stress responses with appreciable changes in HR, respiration rate, and BP as well as a marked decrease in State-Trait Anxiety Inventory (STAI) scores.

Thoma et al<sup>8</sup>. (2013) did a thorough meta-analysis looking at how music therapy might reduce anxiety in surgical patients. They discovered that for many different surgical operations, music greatly lowered anxiety. Their research comprised experiments using various patient demographics and forms of anaesthesia, implying that the anxiolytic effects of music are generally relevant

Chan et al<sup>9</sup>. (2012) investigated especially how music therapy affected patients under spinal anaesthesia for elective caesarean procedures. Those who listened to music reported reduced fear and more general happiness with their surgical experience, according to their data. Emphasizing the ongoing advantages of music therapy all through the surgical process, the decrease in anxiety was clear both preoperatively and intraoperatively.

Under regional anaesthesia—that is, spinal and epidural anaesthesia— Nilsson et al<sup>10</sup>. (2009) investigated how intraoperative music affected patients undergoing orthopedic surgery. In the music group, their study found notable drops in anxiety and improved patient satisfaction than the control group.

Bradt et al<sup>11</sup>. (2013) examined in surgical environments the psychological and physiological impacts of music treatments. Their results showed that music therapy not only lowers anxiety but also improves many physiological factors including HR, BP, and cortisol levels. These advantages improve general patient satisfaction and help to provide a more comfortable intraoperative environment (Bradt et al.,2013).

Hole et al. (2015) systematically reviewed and meta-analyzed how music can affect postoperative

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recovery. They found that music therapy greatly lowers anxiety and pain as well as increases patient satisfaction, the study underlined the need of including music therapy into regular surgical procedures.

Joke Bradt et al<sup>12</sup>(2016). performed a comprehensive study implying that music therapy might help cancer patients with anxiety, discomfort, exhaustion. The study emphasizes that music therapy may help cancer patients in improving their quality of life, discomfort, anxiety, and tiredness. Furthermore adding to an overall sense of well-being was the review's finding that music may have a effect on physiological indicators including HR, RR, and BP.

A 2020 systematic study by Cheryl Dileo et al<sup>13</sup>. found that listening to music helps people on mechanical ventilation reduce their anxiety. These results are similar with the findings of three other Cochrane<sup>23</sup> meta-analysis aimed at studying the effect of music therapy on anxiety in the medical patient. The review also shows that listening to music regularly reduces systolic blood pressure and respiratory rate.

Moreover, the results imply a possible decrease in the use of sedatives and analgesics. As such, we suggest that for mechanically ventilated patients, music therapies could be a good alternative for controlling anxiety.

Music therapy during LSCS has a positive effect on HR, RR, visual analog scale (VAS) scores, & the time until the demand for rescue analgesia during the postoperative period, according to Abhishek Halder et.al in a study done in 2022 on women undergoing elective LSCS. It does not, however, change SpO2 levels, BP, MAP, VRS, or NRS. Music is a type of intervention that efficiently increases hemodynamic stability, lowers pain (VAS), and prolongs the period to rescue analgesia in women having LSCS delivery. Furthermore established is the increase in the (PACU) cut-off time for a second dosage of analgesia. These results, together with the fact that music therapy is a cheap and simple approach, suggest that perioperatively for LSCS delivery music therapy could be advised.

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Although several studies have evaluated the effect of music therapy in the peri-operative period, very few studies have assessed the effect of music therapy on geriatric patients undergoing surgery under spinal anaesthesia. Hence this study is being undertaken to evaluate the same.

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## **BASIC SCIENCES-**

### **MUSIC IN MEDICINE**

Music in medicine <sup>1</sup>is the clinical and evidence-based use of music interventions to accomplish individualized goals within a therapeutic relationship by a medical professional (music medicine). In other words, music in medicine is a musical intervention to improve the comfort of patients. Music in medicine has various facets like physical, emotional, mental, social, aesthetic, and spiritual. Some common music in medicine usages is developmental work (communication/motor skills) for individuals with special needs, relaxation, physical rehabilitation, alcohol/drug recovery programs, etc. Music in medicine is also used for pain & depression management in palliative cancer care & psychiatric management. Music may be beneficial for everyone with either physical or mental disabilities. Music may improve heart rate, reduce anxiety, reduce CNS stimulation and improve learning. Music therapy/medicine is also applied for stress relief before and after surgery besides areas like memory loss viz., Alzheimer's disease, or severe dementia. A pediatric patient who listened to music during venipuncture shows less distress and less pain. Similarly, patients with mental disorders such as anxiety, depression, and schizophrenia have shown some improvement in their mental health following music therapy/medicine.

### **Historical perspective (global)**

Music-based experiences were used to address various domains of human functioning viz., cognitive, academic, emotional, psychological, behavioral, physiological (sensory, motor, neurological, and other physical systems), pathological (pain), spiritual, etc in the ancient world. Music in medicine is in place for long, but one can reliably trace around 500-400 BCE from Greek mythology (Apollo, Aesculapius, Plato, Aristotle, etc). Aesculapius,

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also known as the god of medicine in ancient Greek mythology, was a physician, who used to practice rejuvenation and healing aspects of the medical arts using various ways, including music. Similarly, Plato and Aristotle later relate music with healthy emotional responses and harmony between the three parts of the soul i.e., reason, spirit, and appetite. Later, the use of music in medicine can be traced to Al-Farabi (870-950 CE), also known as a second teacher (Aristotle was known as the first teacher), a renowned early Islamic (Persian/Turkic origin) philosopher and jurist. He also wrote a book on music (*Kitab al-Musiqa/The Book of Music*). Al-Farabi, in his book, describes philosophical principles about music, its cosmic qualities, and its influences on a human being. He also described music therapy and the effect of music on the soul.

Ancient Arab hospitals (650-1300 CE) used to have music rooms for patients as part of healing. The kings of the Persians used to divert the melancholic by listening to music, distracting the sick, and keeping away from negative thoughts. Music therapy was considered a broad philosophical approach toward harmony. Selection of music used to be carried out by a musician for the treatment of specific diseases, a unique concept in the history of music and medicine.

The next important book on music and medicine was found in the book of Robert Burton (*The Anatomy of Melancholy*, 1621-1628) where music was used to treat melancholia, and thereafter from the book of Athanasius Kircher as *Musurgia Universalis*, 1650 that described details of the effect of music on the brain (music invokes specific emotional responses in the listener). Later, in 1745 von Ernst Anton Nicolai, a medical professional from Germany published a book named 'Die Verbindung der Musik mit der Arzneygelahrtheit' where the author has shown an association of music with the science of medicine. Later, John Brown (1780) in his book on *Elementa Medicinae* (commonly known as the Brunonian system

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of medicine) described stimulation of the nerves by music could directly improve health. Peter Lichtenthal's (1807) book *Der musikalische Arzt* is similar to John Brown's book and describes the effects of music on the body. Lichtenthal mostly described "doses of music," which should be determined by using the Brunonian scale. Live music to hospital patients (by St. Cecilia Guild) was in use for the alleviation of acute pain; soft, slow music was used for the seriously ill, whereas brisk exhilarating dance music was reserved for convalescents. This was followed by a publication in the *Lancet* journal 1892 on music as a remedy for diseases. Music therapy was in use during world-war I (Wheeler et al. 1919) to heal wounded soldiers by music at Columbia University and world-war II to boost the morale besides physical and emotional rehabilitation of returning veterans.

### **HISTORICAL PERSPECTIVE (INDIAN)**

Sacred music therapy in north India was in place for a long (BCE) and can be traced from ancient Hindu mythology (goddess Saraswathi, God Krishna, Narad, etc), Vedic scripts, and local folk traditions. This book provides information on North Indian traditional music therapy as well as other indigenous music healing traditions. Ancient Hindu scripts describe the healing of illness by using hymns. Singing or listening to sacred hymns are believed to provide healing and improve mental health. It is just one of the examples of the ways that sound and music have been used for thousands of years to promote healing in India. Literature on the science of music (Gandharva tattva) in India dates back to the fourth century BCE. "Raga Chikitsa," one of the ancient texts elaborates on the therapeutic role (suitable for emotional healing, particularly anxiety and stress) of musical melodies. Swami Haridas, the guru of Tansen, a classical musician of 16 century India, is known to use music in treating illnesses. Historical records indicate that he treated & recovered one of the queens of Emperor. Ayurveda (a holistic approach rooted in Veda from the prehistoric era) also uses music (raga)

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to help balance the doshas. Musopathy (mapping music and its medicinal benefits) term was coined by an Indian musician Ravikiran in 1990. It is intended to understand how and why music is good for health besides mood. The Music Therapy Trust (of India) was founded by Dr. Margaret Lobo in 2005 to provide music therapy to those facing difficult psychosocial and physical challenges. The Indian Association of Music Therapy (IAMT) represents researchers, bio-musicologist, scientists, music therapists, etc to promote the use of music for the cure of various diseases and healthy life. IAMT was established in 2010. The objective was to establish music as a drug to cure disease and rehabilitate deformities. Later, in 2011 the association started its official peer-reviewed journal “International Journal of Music Therapy”. Thereafter, the Music Therapy Academy in India was founded by Australian cricketer Brett Lee in 2012 to train Indian musicians by offering a year-long post- graduate diploma in clinical music therapy.

### **MUSIC IN PERIOPERATIVE CARE.**

The earliest documentation of music therapy can be traced to 1789 in Columbia Magazine as Music Physically Considered (American Music Therapy Association/AMTA, 2011). The first music therapy intervention was reported in the 1800s but not until the 1900s, and in particular, during World War II, that music can have an on one’s sense of well-being (AMTA, 2011). Recorded music was first used in hospitals by treating doctors after the invention of phonograms. In 1914, Kane was the first person to provide intra-operative music via phonogram to distract the patient’s attention from the horror of the surgery. Ilsen advocated the use of music, often classical music to alleviate physical pain in surgical patients in World War I reconstruction hospitals besides using it for insomnia and terminal illness. Van de Wall began a career using music to treat and prevent mental illness. He also developed a therapeutic music program for Mental Disorders. The organism-as-a-whole concept (mind

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and body integration) is essential to understanding the therapeutic effects of music therapy. Use of magnetic recorder silent music during operation was reported by Light et al. in 1949.

In one experimental study Good et al, 1995 compared the effects of jaw relaxation and music, individually and combined, on sensory and affective pain following surgery and the author found the helpful nature of music for sensation and distress of pain. Researchers also evaluated the effect of peri-operative music listened to through headphones on pain and anxiety levels and found that music helped to relax and distract. In another study, researchers examined the effect of music on the level of patient pain in the immediate postoperative period but found no differences in the level of pain. Similarly, Cepeda et al (1998) did not find any beneficial effect of perioperative music in patients undergoing lithotripsy following an RCT study.

Another study using western music (tape recorded) in Taiwanese patients for its effectiveness in reducing postoperative pain did not find any differences and suggested the use of culturally acceptable music. In an RCT study researcher evaluated music influences on intraoperative sedative and analgesic requirements in awake patients and observed a decrease in sedative and analgesic requirements. Another study on self-selected perioperative music in ambulatory geriatric ophthalmic surgery can ameliorate stress and hypertensive response. Similarly, music in the intra-operative period under general anesthesia for hysterectomy can improve the recovery of patients. A study that evaluated the effect of relaxing music on the pain level of mechanically ventilated patients found that music therapy reduced pain scores and physiological findings.

Later, a group of surgeons studied the use of music and found that music has a calming effect on normally tense and nervous patients. Various studies examined the effect of music intervention on preoperative anxiety and/or physiologic parameters or perioperative anxiety,

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stress or pain, perioperative music in pediatric surgery, postoperative pain following gynecologic laparoscopy, or postoperative pain & stress in patients undergoing elective hysterectomy, intraoperative sedative requirements, etc. Similarly, it is also observed that music was effective in managing pain after a percutaneous coronary operation.

Another study that investigated the effect of preoperative music therapy on postoperative pain found a significant decrease in postoperative pain and analgesic consumption. Another study on music intervention following abdominal surgery observed milder pain & distress besides lower respiratory rate in the postoperative period. A study on the effect of music on comfort, anxiety, and pain in the intensive care unit found a significant decrease in the VAS pain scores of the patients in the ICU after listening to music, which indicates the positive effect of music on reducing pain. However, the study also suggests that there may not be a significant difference in the health care setting on the desired benefit of music interventions. Music therapy is used with almost all surgery with variable results, some with a negative outcome and many with either positive or marginally improved outcomes.

The principle of music in medicine is based on the fact that while pain stimuli are occurring, the central nervous system is also receiving other stimuli. The central nervous system processes a limited number of messages in a given time, and these sensations compete with pain stimuli. Therefore, if consciousness and awareness (attention) can be focused on a strong, positive stimulus such as music, then the perception of pain could be attenuated. Music reduces anxiety by activating auditory pathways and the limbic system. These communicate with the hypothalamus, reticular activating system, and hippocampus to attenuate excitatory neurotransmitters leading to relaxation. In addition, music also distracts the brain and also activates the parasympathetic system. Various author also have studied the level of hormones and neurotransmitters while listening to music. They showed that music lowers hormones like

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cortisol, adrenocorticotrophic hormone, and catecholamines but increases oxytocin as well as serotonin. Oxytocin has a boosting effect on psychology as well as emotion/bonding/ maternal behavior whereas serotonin lowers pain, stress, and anger. Music also induces alterations in endorphin levels, which have a role in relieving stress and pain. The experience of pain often shows inter-individual variability and linked with individual differences in biological and psychosocial variables. 70 Psychological factors like hypnotism, meditation, or distraction can alter the intensity of pain.

Surgery is an indispensable method of health care but it causes severe perioperative stress. Surgery is associated with significant pain in the postoperative period. Pain compromises a person's overall health and well-being. Surgery-induced tissue trauma induces sustained activation of the sympathetic autonomic nervous system thus impairing physiological homeostasis and causing psychological stress, as well as metabolic and immune dysfunction. This affects postoperative recovery.

Present interventions in use to attenuate perioperative stress are pharmacological and invariably associated with adverse effects. Non-pharmacologic interventions in the perioperative period to decrease stress and analgesic use are warranted. Perioperative Music Medicine (PMM) can be an efficacious, safe, and low-cost non-pharmacologic intervention.

The intact auditory pathway is a prerequisite for the effect of PMM. In rodent experiments, a shift from sympathetic to more parasympathetic autonomic activity, suppression of stress hormones, lowering heart rate, blood pressure, and anxiety, but increased immune functions were observed. 45 In human studies, there is a strong body of evidence supporting the efficacy of PMM in causing a reduction in pain and anxiety, and decreased opioid use. PMM impacts both intensity and quality of pain and lowers anxiety. PMM produces endogenous opioids and oxytocin as well as decreases cortisol and catecholamines.

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The effects of music on the ANS include reductions in heart rate. PMM can modulate the neurohormonal response to surgery during general anesthesia thus reducing postoperative pain, analgesic use, anxiety, respiratory rate, blood pressure, cortisol levels, postoperative nausea, and vomiting. 76 PMM decreases sympathetic activation and helps the homeostasis of stress metabolism and immune function through activating parasympathetic output. This parasympathetic cardiac cholinergic output can be quantitated by changes in heart rate variability. The interplay of the sympathetic & parasympathetic autonomic nervous system allows adaptation to stress (everyday challenges/surgery induced) via the hypothalamic-pituitary- adrenal axis leading to the release of corticosteroids and pro-inflammatory factors from the adrenal gland.

### **Psychological response to perioperative anxiety**

The extent of anxiety levels varies individually. It fluctuates over time; starting prior to the surgery and persists until the late postoperative period. Different patient react perioperative periods in different ways. Some find it as relief as they are going to have a disease free life. Other considered it as one of the stressful event of lifetime. They are preoccupied with their discomfort or concerned about the success of surgery, strong fear of failure combined with career and family problems, postoperative state of physical health and problems adapting to the changed situation.

The consequences of perioperative anxiety are tachycardia, increased blood pressure, change in the breathing pattern (hyper/hypoventilation), irritability, in some rare cases major cardiac events (acute myocardial infarction, heart failure, pulmonary edema), high readmission rate (1st 6 month, 1 years), poor quality of life and high rate of cardiac mortality.

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Perioperative anxiety is associated with high postoperative pain, increased analgesic and anesthetic consumption, prolonged hospital stay, adverse influence during anesthetic induction and patient recovery and decrease patient satisfaction with perioperative experience.

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## **MATERIALS AND METHODS.**

Source of data: Patients aged above 60 years, of either gender, belonging to ASA grade I and II, undergoing elective surgery in supine position under spinal anesthesia at “KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre and KLES charitable hospital Nehru Nagar, Belagavi -10” between September 2022 and August 2023.

1. Study design: Double blinded, one-year hospital based clinical trial
2. Sample Size: 82

“The minimum sample size formula based on mean and standard deviation is

$$n = \frac{(z_{\alpha} + z_{\beta})^2 (s_1^2 + s_2^2)}{(\bar{X}_1 - \bar{X}_2)^2}$$

$\bar{X}_1$  is the mean of the first group and  $\bar{X}_2$  is the mean for the second group.  $s_1$  is the standard deviation of the first group and  $s_2$  is the standard deviation of the second group where  $z_{\alpha}$  is linked with the level of significance and  $z_{\beta}$  is linked with the power of the test. For 5% level of the significance  $z_{\alpha} = 1.96$  and  $z_{\beta} = 0.84$  for 80% power of the test”

Ref: “Kukreja P et.al -Effects of Music Therapy During Total Knee Arthroplasty Under Spinal Anesthesia: A Prospective Randomized Controlled Study. Cureus. 2020 Mar 24;12(3):e7396. doi: 10.7759/cureus.7396. PMID: 32337122; PMCID: PMC7179990”.

With the above values the sample size obtained is 82

Each of the two groups will have minimum 41 cases.

### **SOURCE OF DATA-**

Patients aged above 60 years, of either gender, belonging to ASA grade I, II and III, who underwent elective surgery in supine position under spinal anesthesia at “KLE's Dr.

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Prabhakar Kore Hospital and Medical Research Centre and KLES charitable hospital Nehru Nagar, Belagavi -10”during the period from September 2022 to August 2023.

**Inclusion Criteria:**

- Patients with ASA I to III
- Age above 60 yrss.
- Patients undergoing elective surgeries under spinal anaesthesia in supine position
- Provides Consent

**Exclusion criteria**

- Patients with ASA grading more than III
- Patient refusal or who are unable to give consent.
- Patient undergoing emergency surgery.
- Patients with contraindication to spinal anesthesia.
- Patients with documented hearing loss.
- Patients with history of psychiatric illness.

After Approval of Ethical committee and CTRI registration 82 patients fulfilling the inclusion and exclusion criteria and who gave consent were selected for the study.

**Randomization & Group Assignment**

Using a computer-generated randomizing table, patients fulfilling the inclusion and exclusion criteria and giving consent were randomized into either one of two groups:

GROUP M: Patients listened to a chosen soundtrack using noise-cancelling headphones

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Group N: No Music Group: Patients wore headsets with turned off settings. After initial evaluation before operations Patients were asked to select the kind of music they would want to listen to during their surgery. Patients were also directed on evaluating their anxiety levels intraoperatively by using the Visual Analogue Scale for Anxiety (VASA).

### **Preoperative Preparation**

On the day of surgery the patients were shifted to the operating theatre after confirming they had been nil by mouth (NBM) for at least six hours. All standard monitors including pulse oximetry, non-invasive blood pressure monitoring and electrocardiogram were attached; baseline values were recorded. Maintenance fluid—IV Ringer's lactate solution—was delivered using an 18G peripheral venous cannula. Preoperatively baseline anxiety levels were evaluated.

### **Music Intervention and Anaesthesia**

Patients were administered, under strict aseptic precautions, spinal anaesthesia in the L2–L3 level with 0.5% bupivacaine heavy ten minutes following the administration of spinal anaesthesia:

Group M (music group)-Patients listened to their selected music at a volume fit for their taste but restricted to 60dB. They were advised that they could ask to have headphones taken off at any moment, there after excluding them from the study.

Group N (No Music Group): Headsets were worn but music was off-turned.

Anxiety at the following times was measured with the VASA:

#### **1. Baseline**

- 
2. Just before the music began to play.
  3. Every thirty minutes over the course of surgery.

Should a patient's VASA score be higher than five, they will be given 0.5 mg of midazolam, with a maximum dosage of 2 mg authorized.

Every ten minutes, intraoperative hemodynamic parameters were watched over and noted until the end of the surgery. Any fall in HR more than 20% of the baseline will be treated with Inj.Atropine 0.06mg i.v and fall in BP will be treated with Inj.Mephentermine 6mg i.v which may be repeated if required .

#### Assessment Following Surgery

Patient satisfaction was assessed in the recovery room.

This study intended to assess how well music therapy lowers anxiety levels in patients under spinal anaesthesia, therefore offering a more customized method of anxiety control during surgical operations.

Patients and the anaesthesiologist were asked to complete a questionnaire.

#### **METHODS:**

Data is analysed using statistical software “R version 4.4.0. and Microsoft Excel. Categorical variables given in the form of frequency tables. Continuous variables given in Mean  $\pm$  SD / Median (Min, Max) form. Chi square test is used to check the association of categorical variables with groups. Normality of variable is checked by Shapiro Wilk test and QQplot”. As the data followed a normal distribution, parametric tests were used; otherwise, non-parametric tests were employed. The two-sample t-test was used to compare the means of variables between groups. The Mann- Whitney U test compared the distribution of variables

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between groups, while the Friedman test was used to compare the distribution of variables over time. A p-value of 0.05 or less indicated statistical significance.

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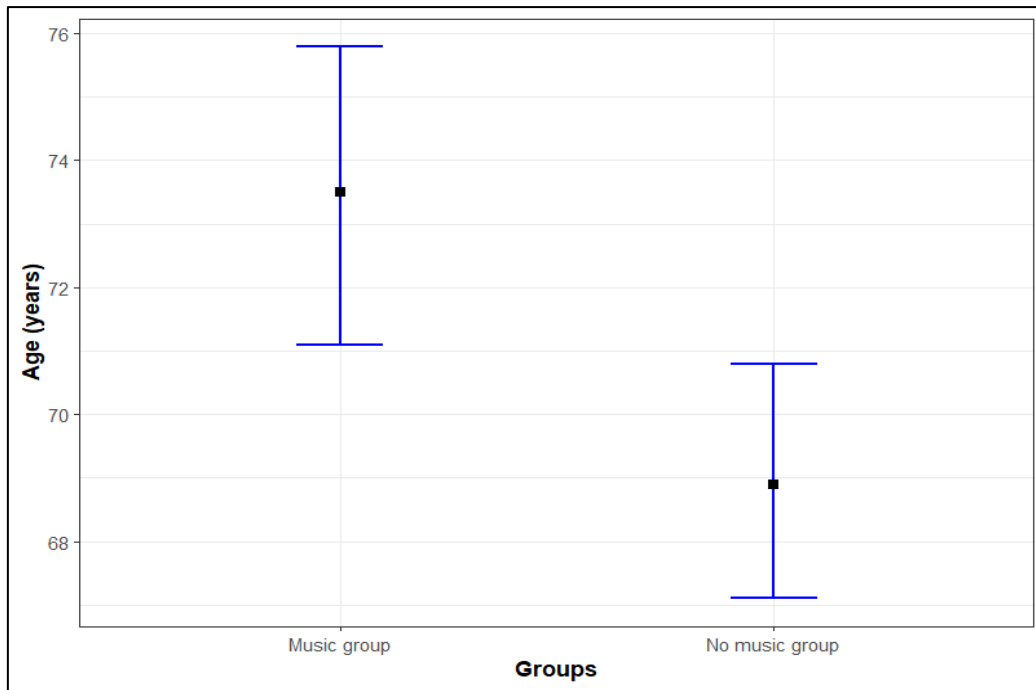
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## **RESULTS:**

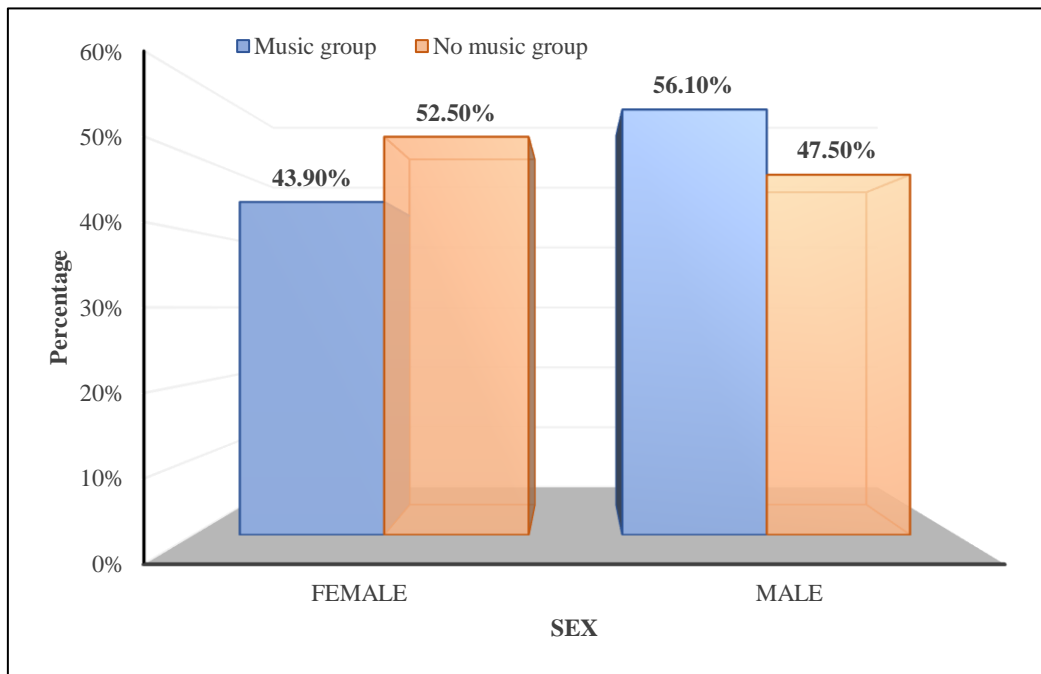
Data contains measurements on 82 subjects which are divided into Group M and N of 41 subjects in each group. The following table gives the comparison of demographic details over groups.

**Table 1: Comparison of demographic details over groups.**

| <b>Variables</b> | <b>Sub Category</b> | <b>Group-M</b>   | <b>Group-N</b>   | <b>p-value</b> |
|------------------|---------------------|------------------|------------------|----------------|
| Age (years)      | Mean $\pm$ SD       | 69.49 $\pm$ 7.48 | 68.92 $\pm$ 5.81 | 0.058          |
|                  | Median (Min, Max)   | 73 (61, 89)      | 67 (64, 87)      |                |
| Sex              | Female              | 18 (43.9%)       | 22 (53.5%)       | 0.4388         |
|                  | Male                | 23 (56.1%)       | 19 (46.3%)       |                |



**Figure 1: Mean plot of age over groups.**



**Figure 2: Distribution of gender over groups.**

The below table gives the comparison of HR over time and group.

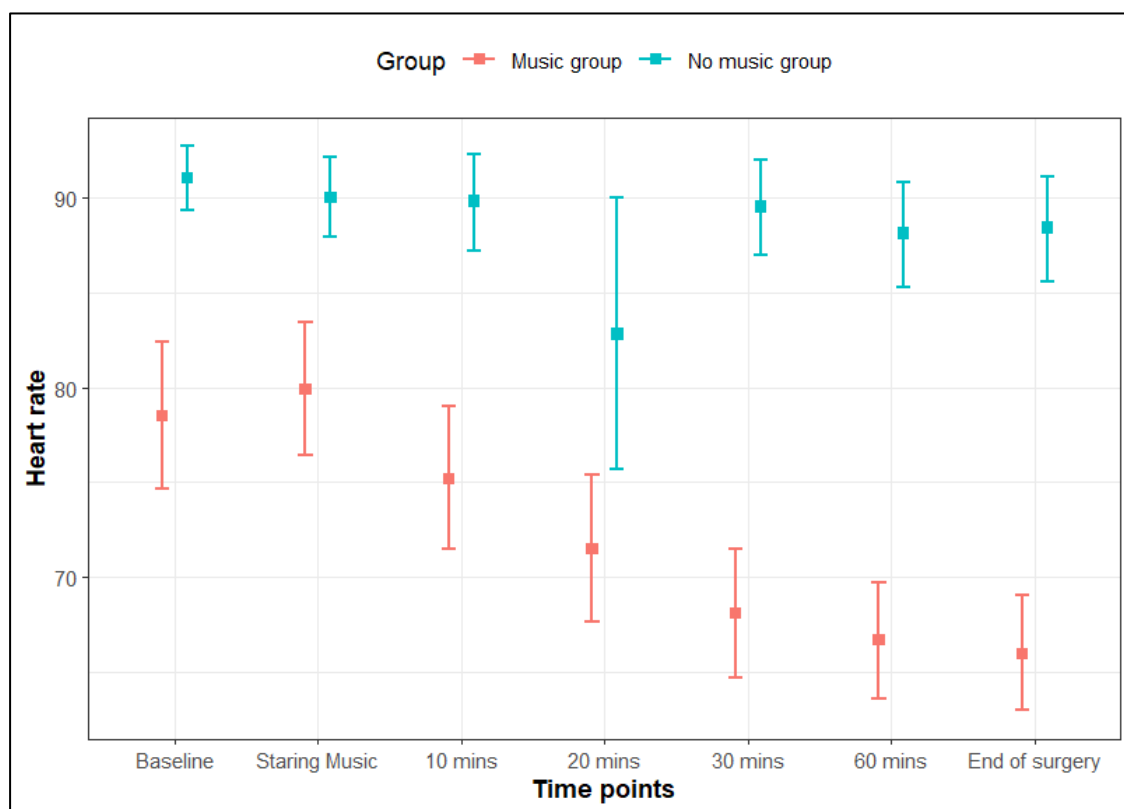
**Table 2: Comparison of HR over time and group.**

| <b>HR</b>         | <b>Group M</b>                | <b>Group N</b>                | <b>p-value</b>    |
|-------------------|-------------------------------|-------------------------------|-------------------|
| Baseline          | 78.54 ± 12.22<br>77 (60, 106) | 81.36± 5.26<br>84(82, 98)     | 0.056             |
| Starting of music | 78.88 ± 11.03<br>77(65, 106)  | 88± 6.64<br>89 (76, 98)       | 0.052             |
| 10 mins           | 75.24 ± 11.74<br>70 (60, 100) | 89.75 ± 8.11<br>88 (75, 98)   | <b>0.031</b>      |
| 20 mins           | 71.54 ± 12.28<br>64 (54, 95)  | 82.85 ± 22.3<br>88 (9, 98)    | <b>&lt; 0.001</b> |
| 30 mins           | 68.12 ± 10.76<br>62 (53, 90)  | 89.5 ± 7.89<br>86 (78, 100)   | <b>&lt; 0.001</b> |
| 60 mins           | 66.68 ± 9.66<br>62 (52, 90)   | 88.08 ± 8.56<br>85 (76, 98)   | <b>&lt; 0.001</b> |
| End of surgery    | 66.05 ± 9.68<br>60 (53, 88)   | 88.38 ± 8.62<br>89.5 (76, 98) | <b>&lt; 0.001</b> |
| p-value           | <b>&lt; 0.001</b>             | 0.06                          | -                 |

At baseline, the Music group had a mean HR of  $78.54 \pm 12.22$ , while the No music group had a mean HR of  $81 \pm 5.26$ . There were no much significant difference in HR at baseline and at the start of music, but significant difference were observed at subsequent time

points: at the 10 minutes, 20 minutes, 30 minutes, 60 minutes, and at the end of surgery, with the Music group consistently showing lower HRs compared to the No music group. Specifically, at the end of surgery, the Music group had a mean HR of  $66.05 \pm 9.78$  against to  $88.38 \pm 8.62$  in the No music group ( $p$ -value  $< 0.001$ ).

Using the Friedmans test , In the music group there is statistically significant fall in HR across time points within the group. In the nonmusic group HR fluctuated showing an increasing trend across time points



**Figure 3: Mean plot of HR over time and groups.**

The following table gives the comparison of SBP over time and group.

**Table 3: Comparison of SBP over time and group.**

| <b>SBP</b>        | <b>Group M</b>                  | <b>Group N</b>                   | <b>p-value</b>    |
|-------------------|---------------------------------|----------------------------------|-------------------|
| Baseline          | 133.61 ± 25.59<br>131 (93, 177) | 136.4 ± 15.34<br>140 (130, 176)  | 0.059             |
| Starting of music | 132.32 ± 8.88<br>130 (52, 82)   | 135.12 ± 9.89<br>142 (130, 165)  | 0.053             |
| 10 mins           | 128.22 ± 28.56<br>146 (92, 172) | 138.75 ± 10.47<br>138 (124, 160) | <b>0.034</b>      |
| 20 mins           | 127.05 ± 27.42<br>140 (88, 165) | 137.88 ± 9.2<br>137 (128, 155)   | <b>0.023</b>      |
| 30 mins           | 121.22 ± 27.39<br>132 (80, 160) | 129 ± 18.97<br>134 (98, 150)     | <b>0.015</b>      |
| 60 mins           | 114.93 ± 26.75<br>130 (74, 150) | 134.5 ± 14.81<br>138 (100, 150)  | <b>&lt; 0.001</b> |
| End of surgery    | 113.05 ± 27.82<br>128 (67, 148) | 134.25 ± 15.41<br>138 (98, 150)  | <b>&lt; 0.001</b> |
| p-value           | <b>&lt; 0.001</b>               | 0.051                            | -                 |

At baseline, the Music group had a mean SBP of 133.61 ± 25.59 mmHg, while the No music group had a mean SBP of 136.4 ± 15.34 mmHg (p-value = 0.059). When music started, the Music group's mean SBP was 130.32 ± 8.88 mmHg, whereas the No music group's mean

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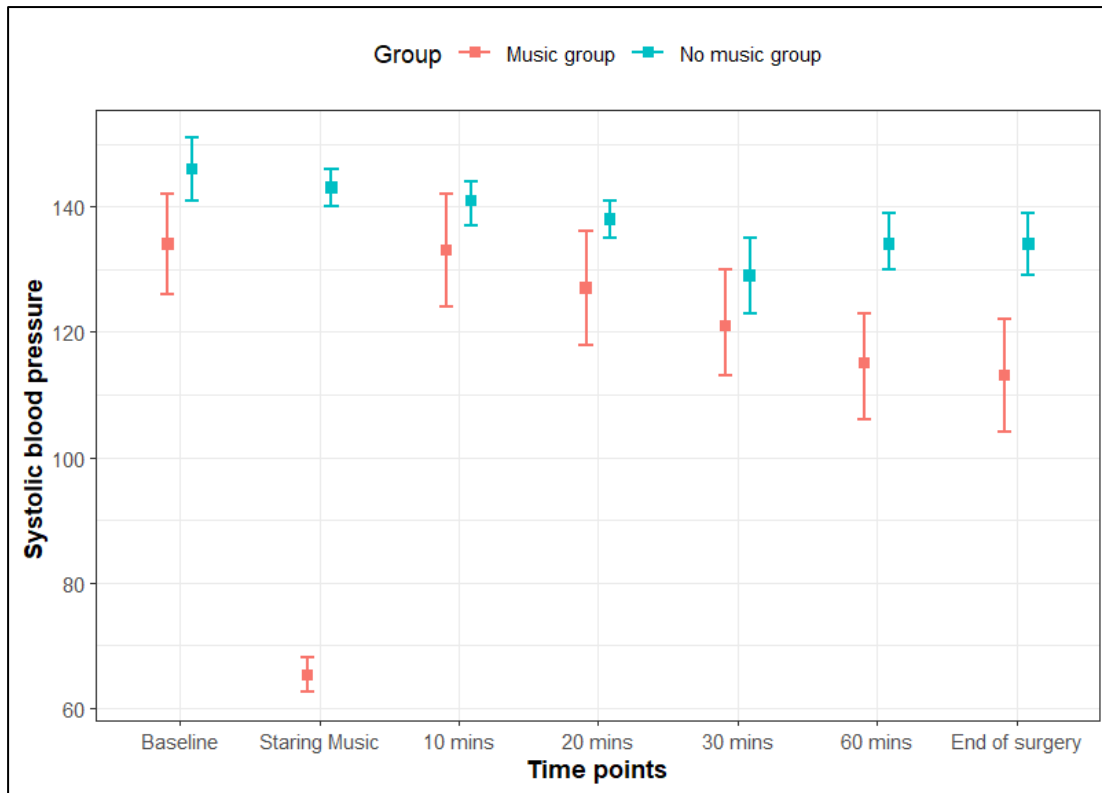
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SBP was  $135.12 \pm 9.89$  mmHg (p-value 0.03). The SBP was comparable between the two groups at baseline as well as when music was started,

Subsequently at 10mins,20mins,30mins SBP was significantly less in the music group with p values being 0.034,0.023,0.015 respectively as compared to the music group.

At 60 minutes and at the end of surgery, the group M had significantly lower mean SBPs v/s music group N. At 60 minutes, the Music group had a mean SBP of  $114.93 \pm 26.75$  mmHg compared to  $134.5 \pm 14.81$  mmHg in the No music group (p-value < 0.001). At the end of surgery, the Music group's mean SBP was  $113.05 \pm 27.82$  mmHg, whereas the No music group's mean SBP was  $134.25 \pm 15.41$  mmHg (p-value < 0.001).

Using the Friedmans test , in the music group there is statistically significant fall in SBP across time points with the group. In the nonmusic group SBP fluctuated showing an increasing trend across time points.



**Figure 4: Mean plot of SBP over time and groups**

The following table gives the comparison of DBP over time and group.

**Table 4: Comparison of DBP over time and group.**

| <b>DBP</b>        | <b>Group M</b>                | <b>Group N</b>               | <b>p-value</b> |
|-------------------|-------------------------------|------------------------------|----------------|
| Baseline          | 82.2 ± 16.64<br>81 (60, 116)  | 85.75 ± 6.83<br>83 (78, 94)  | 0.1339         |
| Starting of music | 83.54 ± 16.39<br>84 (62, 130) | 85.75 ± 6.83<br>83 (78, 94)  | 0.6339         |
| 10 mins           | 80.93 ± 15.3<br>82 (60, 120)  | 84.25 ± 6.67<br>83 (76, 92)  | 0.3666         |
| 20 mins           | 77.68 ± 14.72<br>76 (58, 110) | 83 ± 6.94<br>82 (74, 92)     | <b>0.0210</b>  |
| 30 mins           | 75.9 ± 13.59<br>74 (58, 104)  | 80.5 ± 10.11<br>81 (64, 92)  | 0.0866         |
| 60 mins           | 72.85 ± 13.71<br>76 (56, 102) | 80.88 ± 10.15<br>83 (60, 90) | <b>0.0095</b>  |
| End of surgery    | 72.54 ± 13.21<br>74 (56, 100) | 80.88 ± 10.15<br>83 (60, 90) | <b>0.0058</b>  |
| p-value           | <b>&lt; 0.001</b>             | <b>&lt; 0.001</b>            | -              |

Abbreviation: MW – Mann Whitney U test, F – Friedman’s test, \* indicates statistical significance.

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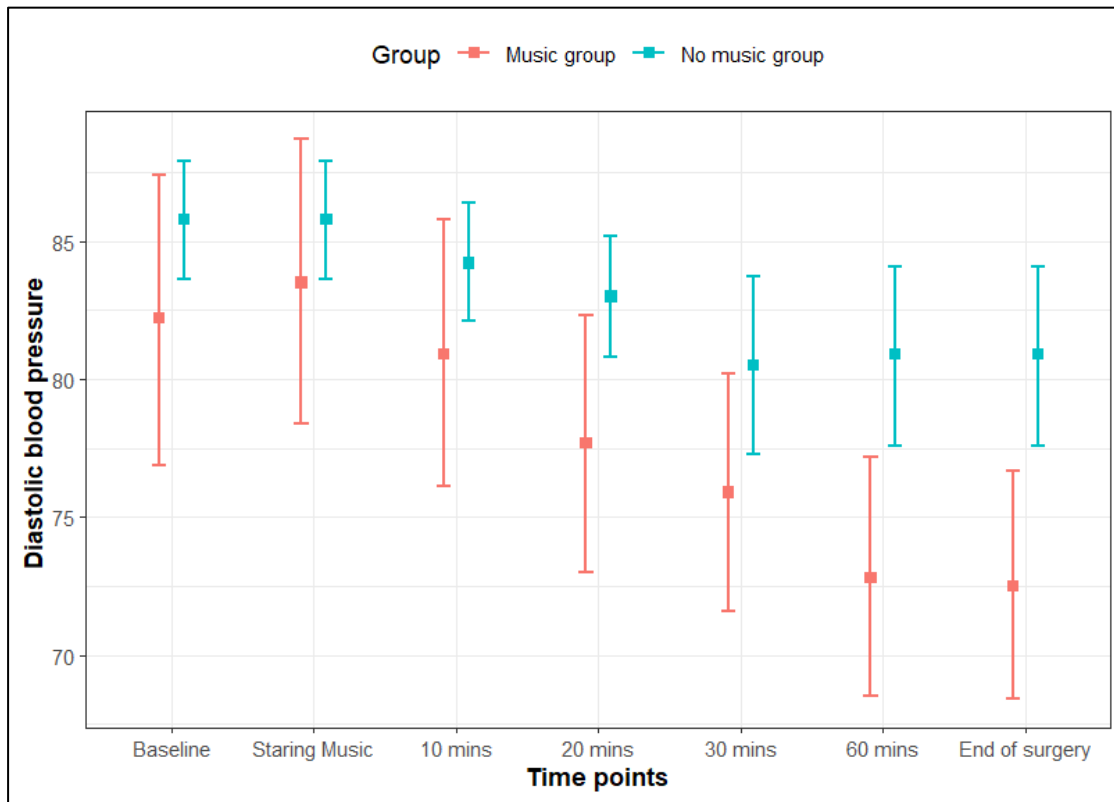
At baseline, the group M had a mean DBP of  $82.2 \pm 16.64$  mmHg, while the No music group had a slightly higher mean DBP of  $85.75 \pm 6.83$  mmHg; however, this variation was statistically not significant (p-value = 0.1339).

When music started, the mean DBP in the Music group was  $83.54 \pm 16.39$  mmHg, and in the No music group, it was  $85.75 \pm 6.83$  mmHg, also not a significant difference (p-value = 0.6339). At 10 minutes, the Music group had a mean DBP of  $80.93 \pm 15.3$  mmHg, compared to  $84.25 \pm 6.67$  mmHg in the No music group (p-value = 0.3666), again showing no significant difference.

At 20 minutes, the Music group's mean DBP decreased to  $77.68 \pm 14.72$  mmHg, which was significantly lower than the No music group's mean DBP of  $83 \pm 6.94$  mmHg (p-value = 0.0210). At 30 minutes, the Music group's mean DBP was  $75.9 \pm 13.59$  mmHg, while the No music group's mean DBP was  $80.5 \pm 10.11$  mmHg; this variation did not reach significant statistical value (p-value = 0.0866).

Significant differences were observed again at 60 minutes and at the end of surgery. At 60 minutes, the Music group's mean DBP was  $72.85 \pm 13.71$  mmHg, significantly lower than the No music group's mean DBP of  $80.88 \pm 10.15$  mmHg (p-value = 0.0095). At the end of surgery, the Music group's mean DBP was  $72.54 \pm 13.21$  mmHg, compared to  $80.88 \pm 10.15$  mmHg in the No music group (p-value = 0.0058).

Using the Friedman's test, it is seen that there is statistically significant difference in DBP across time points for both music and no music groups ( $p$ -value  $< 0.001$ )



**Figure 5: Mean plot of DBP over time and groups.**

The following table gives the comparison of MAP over time and group.

**Table 5: Comparison of MAP over time and group.**

| <b>MAP</b>        | <b>Group M</b>                | <b>Group N</b>               | <b>p-value</b> |
|-------------------|-------------------------------|------------------------------|----------------|
| Baseline          | 95.29 ± 14.81<br>95 (70, 127) | 88.7 ± 7.26<br>78 (68, 90)   | 0.056          |
| Starting of music | 91.93 ± 15.21<br>92 (70, 120) | 88 ± 11.14<br>86 (60, 94)    | 0.052          |
| 10 mins           | 88.02 ± 12.96<br>88 (70, 110) | 85.5 ± 12.06<br>75 (58, 94)  | 0.043          |
| 20 mins           | 85.12 ± 11.15<br>84 (70, 106) | 86.25 ± 11.02<br>75 (58, 90) | 0.038          |
| 30 mins           | 74.24 ± 11.14<br>82 (70, 104) | 84.75 ± 9.55<br>75 (64, 90)  | 0.024          |
| 60 mins           | 70.54 ± 10.84<br>82 (64, 100) | 76.12 ± 9.51<br>75 (62, 90)  | 0.002          |
| End of surgery    | 69.8 ± 10.68<br>80 (64, 100)  | 75 ± 8.89<br>75 (62, 90)     | 0.001          |
| p-value           | < 0.001                       | < 0.001                      | -              |

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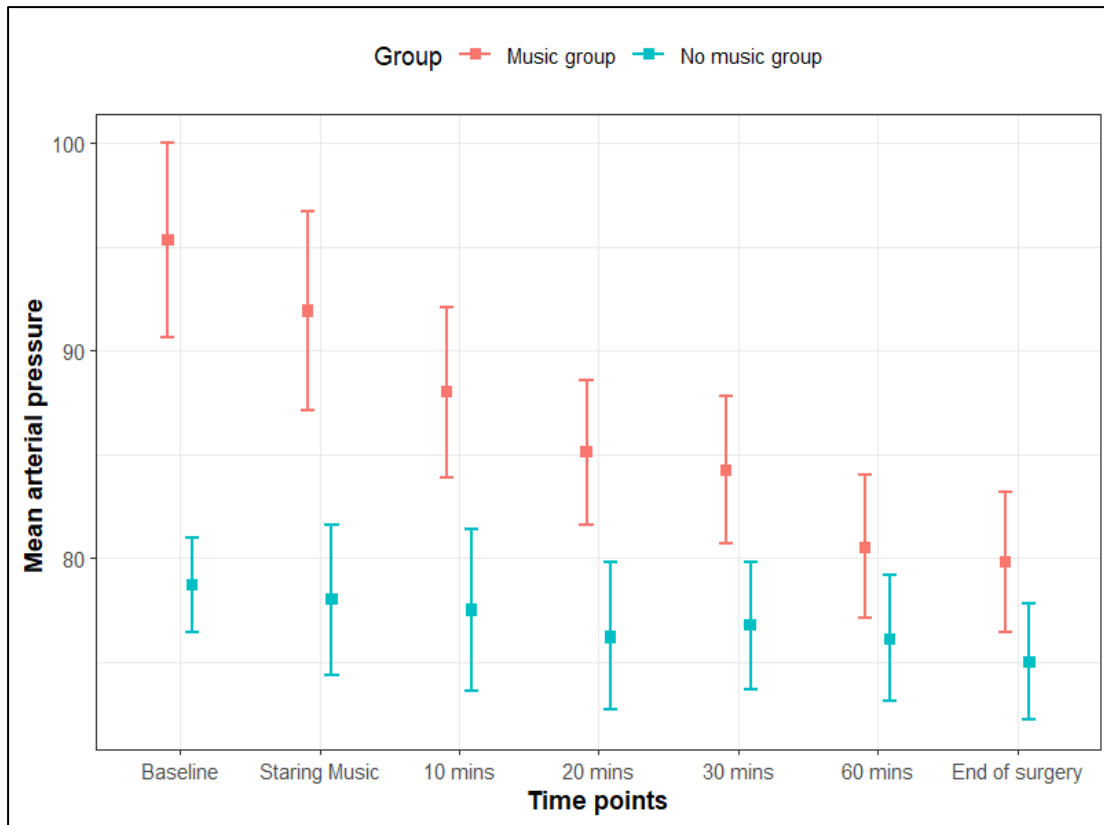
At baseline, the Music group had a mean MAP of  $95.29 \pm 14.81$  mmHg, wherein No music group's mean MAP of  $88.7 \pm 11.26$  mmHg (p-value - 0.056). At the start of music, Music group's mean MAP at  $91.93 \pm 15.21$  mmHg compared to  $88 \pm 11.14$  mmHg in the No music group (p-value - 0.052), with no much statistical significance.

At 10 minutes, the Music group had a mean MAP of  $88.02 \pm 12.96$  mmHg while No music group's mean MAP of  $75.5 \pm 12.06$  mmHg (p-value = 0.043) which showed significant difference.

Significant differences were noted at 20 minutes (Music:  $75.12 \pm 11.15$  mmHg, No music:  $86.25 \pm 11.02$  mmHg, p-value = 0.038) and 30 minutes (Music:  $84.24 \pm 11.14$  mmHg, No music:  $76.75 \pm 9.55$  mmHg, p-value = 0.0041).

At 60 minutes, the difference in MAP between the groups was also statistically significant (Music:  $70.54 \pm 10.84$  mmHg, No music:  $76.12 \pm 9.51$  mmHg, p-value = 0.0027). At the end of surgery, the Music group had a mean MAP of  $69.8 \pm 10.68$  mmHg, which was significantly lower than the No music group's mean MAP of  $75 \pm 8.89$  mmHg (p-value <0.001).

Using the Friedmans test , in the music group there is statistically significant fall in MAP across time points with the group. In the nonmusic group MAP fluctuated across time points .



**Figure 6: Mean plot of MAP over time and groups.**

The following table gives the comparison of VAS for anxiety over time and group.

**Table 6: Comparison of VAS for anxiety over time and group.**

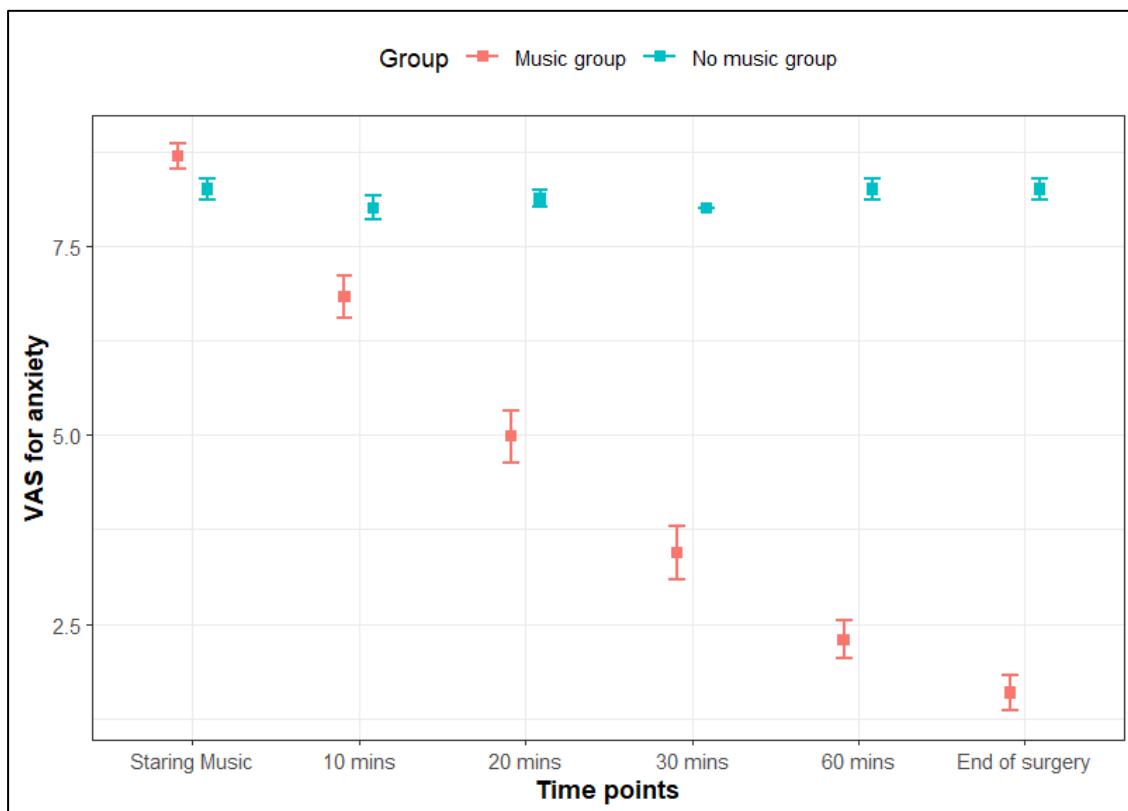
| VAS for anxiety         | Group M                 | Group N                 | p-value           |
|-------------------------|-------------------------|-------------------------|-------------------|
| Base line               | 8.68 ± 0.52<br>9 (7, 9) | 8.25 ± 0.44<br>8 (8, 9) | 0.063             |
| Placement of headphones | 8.68 ± 0.52<br>9 (7, 9) | 8.25 ± 0.44<br>8 (8, 9) | 0.063             |
| 10 mins                 | 7.83 ± 0.89<br>7 (5, 9) | 8 ± 0.51<br>8 (7, 9)    | 0.058             |
| 20 mins                 | 4.98 ± 1.08<br>5 (3, 7) | 8.12 ± 0.33<br>8 (8, 9) | <b>0.03</b>       |
| 30 mins                 | 3.44 ± 1.14<br>3 (2, 7) | 8 ± 0<br>8 (8, 8)       | <b>&lt;0.001</b>  |
| 60 mins                 | 2.29 ± 0.81<br>2 (1, 5) | 8.25 ± 0.44<br>8 (8, 9) | <b>&lt; 0.001</b> |
| End of surgery          | 1.59 ± 0.74<br>1 (1, 4) | 8.25 ± 0.44<br>8 (8, 9) | <b>&lt; 0.001</b> |
| p-value                 | <b>&lt; 0.001</b>       | 0.063                   | -                 |

At the placement of headphones, the Music group mean VAS score for anxiety was (8.68 ± 0.52) compared to the No music group (8.25 ± 0.44) (p-value=0.063). At the start of surgery both groups had almost similar VAS score for anxiety.

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At subsequent time points (20 mins, 30 mins, 60 mins, and end of surgery), the Music group consistently had significantly lower mean VAS scores for anxiety compared to the No music group ( p-values <0.001).

Using the Friedmans test , In the music group there is statistically significant fall in VASA across time points with the group. In the nonmusic group VASA fluctuated allowing an increasing trend across time points.



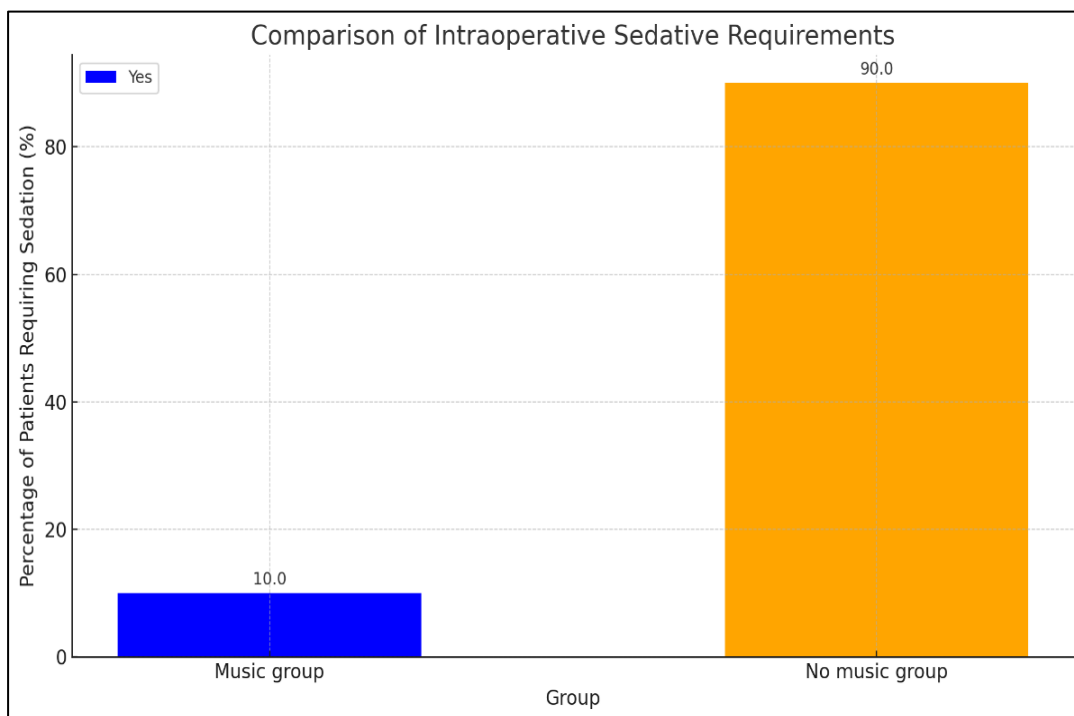
**Figure 7: Mean plot of VAS for anxiety over time and groups.**

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The following table gives the intraoperative sedative requirements.

**Table 7 Comparison of intraoperative sedative requirements of patients .**

| <b>Patients requiring intraoperative sedation</b> | <b>Music group</b> | <b>No music group</b> | <b>Total</b> |
|---|--------------------|-----------------------|--------------|
|   | 4 (10%)            | 36 (90%)              | 40 (50%)     |



**Figure 8: Comparison of intraoperative sedative requirements of patients.**

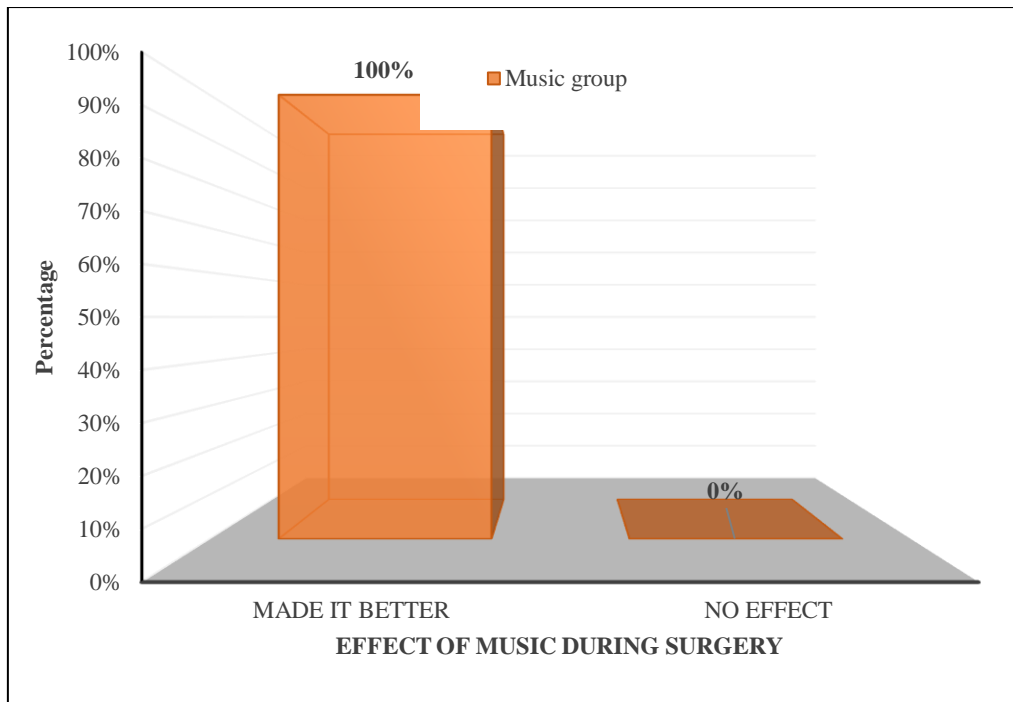
The table below presents the results of patient satisfaction among those in the music group.

**Table 8: Patient’s questionnaire for Group M .**

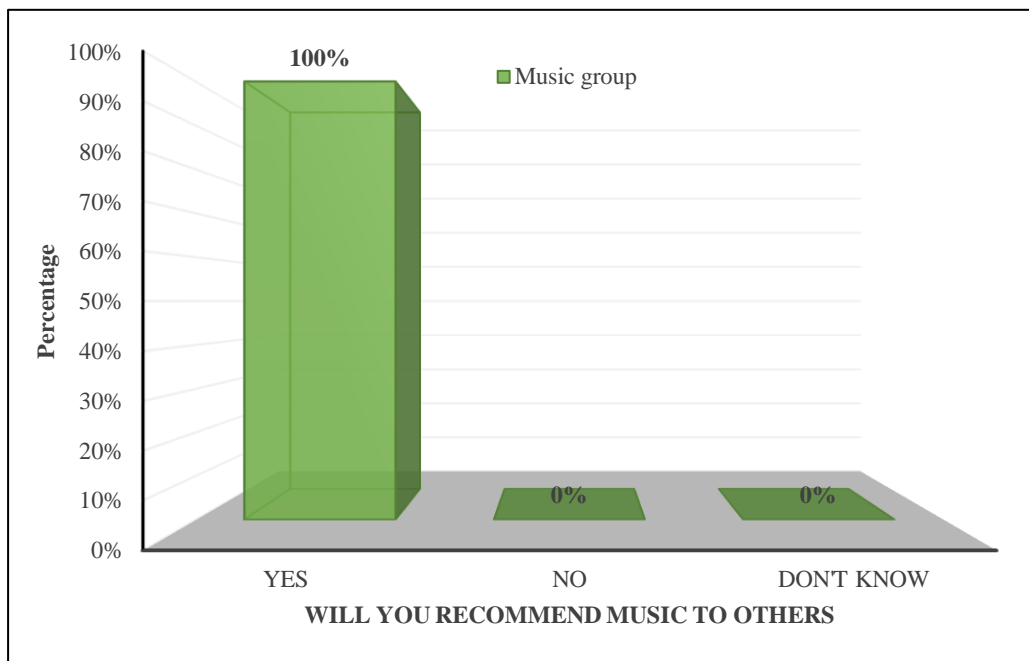
| <b>Variables</b>                   | <b>Sub Category</b> | <b>Music group</b> |
|------------------------------------|---------------------|--------------------|
| Effect of Music During Surgery     | Made it better      | 41 (100%)          |
|                                    | No effect           | 0 (0%)             |
| Will you recommend music to others | Yes                 | 41 (100%)          |
|                                    | No                  | 0 (0%)             |
|                                    | Don't know          | 0 (0%)             |

For the effect of music, all 41 (100%) patients in the Music group felt that music made their surgery experience better. Regarding the recommendation of music to others, all 41 (100%) patients in the Music group would recommend it.

| <b>Group M</b> | <b>Happy with the music</b> | <b>Not happy with music</b> |
|----------------|-----------------------------|-----------------------------|
| Males          | 23(100%)                    | 0(0%)                       |
| Females        | 18(100%)                    | 0(0%)                       |



**Figure 8: Distribution of opinion about ‘Effect of Music During Surgery’ over groups.**



**Figure 9: Distribution of response to ‘will you recommend music to others’ over groups.**

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The following table gives the comparison of doctor's questionnaire over groups.

**Table 9: Comparison of doctor's questionnaire over groups.**

| <b>Did placement of earphones<br/>cause any problem during<br/>surgery</b> | <b>Music group</b> | <b>No music group</b> | <b>Total</b> | <b>p-value</b> |
|--|--------------------|-----------------------|--------------|----------------|
| No   | 41 (100%)          | 41(100%)              | 82 (100%)    | 1 <sup>C</sup> |

*Abbreviation: C – Chi square test.*

There is unanimous agreement among anaesthetist in both the music and no music groups that placement of head phones did not cause any problems during surgery. From Chi-square test, it is concluded that, there is no significant difference in the opinion about music

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## **DISCUSSION**

The process of surgery imposes both physical and psychological strain on patients, especially in cases where spinal anesthetic is used and the patient remains awake. In order to alleviate the anxiety that is commonly experienced during surgery, pharmaceutical therapies have been employed, although they have their own drawbacks. We did a study to look into how music during surgery could help with sedation and reduce anxiety without using drugs. A lot of research has been done on how music therapy affects patients' anxiety levels and how their bodies react to it. Nevertheless, there is a scarcity of studies that examine the impact of music on geriatric patient undergoing surgery under spinal anesthesia and sedation requirement during surgery in geriatric patients.

Research has demonstrated that listening to music can effectively influence the mood, conduct, and psychology of individuals, leading to a more positive mental state. Studies have demonstrated that it can decrease anxiety levels while also positively affecting Hemodynamic factors. We assessed the impact of music therapy by measuring vital signs such as HR, SBP, DBP and MAP which serve as indirect indicators of anxiety when they increase. We also assessed patient anxiety using Visual Analogue Score for Anxiety (VASA).

In our study the observer who monitored patients and assessed intraoperative anxiety levels was unaware whether the patient belonged to music or the non-music group there by eliminating the observer bias. Hence patients in the non-music group were also wearing headphones but with no music to eliminate observer bias.

The neurophysiological mechanism underlying music therapy elucidates its impact on anxiety and stress. Listening to music stimulates the brain to release endorphins. This fosters an ambiance of serenity and calmness. Some studies have suggested that the release of

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endogenous endorphins can decrease pain and reduce the need for pain medication. The neurological connections between the auditory pathway and the limbic system regulate emotional reactions that are linked to listening to music. It is believed that the auditory connections with the hypothalamus, hippocampus, and the reticular activating system reduce the release of stimulating chemicals in the brain, resulting in relaxation and the calming effects of music.

Concerns are increasing over the usage of loud music played in the operating theater as patients are exposed to many anxiety-inducing visual and auditory stimuli during regional anesthesia. Music emanating from wall speakers adds to the total background noise, hindering efficient communication among staff members and diminishing the priority of patient's preferences. Therefore, the utilization of noise cancelling headphones is a more desirable method for addressing these issues in operating room environments. In our study the volume level was kept as per patient comfort with maximum of 60dB. This was done to provide patient a comfortable music hearing experience to the patient and avoid patient discomfort which may affect the study results.

In the current study, the analysis of demographic data between two groups of 41 patients each, mean age and gender distribution showed no significant variation between the groups. Their mean ages Group M 73.49 years and 68.92 years for Group N were comparable as our study population is geriatric population group. Overall, the analysis indicates that there were no statistically significant variations between the two group's mean ages and gender distributions.

In our study at baseline, music group had mean HR of 78.54 while, no music group had a mean HR of 84.56. The heart rate didn't show much difference soon after starting the music. Where in later subsequent time points like 20mins, 30mins, 60mins and at end of the

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surgery the HR in the music group was much lower compared the no music group. This variation was found to be of statistical significance. Within the group also the HR showed a significant decreasing trend probably due the calming effect of music.

At the beginning of our study, the music group had an average systolic blood pressure (SBP) of 131.6mmHg, whereas the non-music group had an average SBP of 146.4mmHg. The SBP did not exhibit significant variation at the baseline and shortly after the commencement of the music. At later time intervals such as 20 mins, 30 mins, 60 mins, and the completion of the procedure, the SBP in the music group exhibited a statistically significant decreasing tendency. Based on 2017 research on the effects of music therapy on anxiety and hemodynamic parameters, Syal et al. deduced that SBP was lower in the group M as compared to the group N. The findings of our study are consistent with those of Syal et al. Within the group the SBP, similar to the HR showed a significant decreasing trend probably due the calming effect of music which is an added advantage,

When music started, the mean DBP in the group M was 83.54mmHg, and in the No music group, it was 85.75mmHg, also not a significant difference. At 10 minutes, the Music group had a mean DBP of  $80.93 \pm 15.3$  mmHg, compared to 84.25mmHg in the No music group, again showing no significant difference. In later stages at 20mins, 60mins and end surgery there was significant statistical difference in the DBP. Within the group too the DBP showed a significant decreasing trend contributing to the stable intraoperative hemodynamics.

The fall in heart rate and blood pressure though statistically significant was clinically not significant and did not require any interventions for the same.

In 2018 Eren et al. <sup>[26]</sup> looked at how music affected several cesarean section births. The writers claim that music therapy helps patients undergoing cesarean sections to have less anxiety by means of physiological reactions. After 10 minutes of music intervention, MAP

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and HR,SDP in the music group began to decline compared to the nonmusical group, according to Bansal et al. this difference was noteworthy. The findings are similar to our study.

At the placement of headphones, the Music group had no significant different mean VAS score for anxiety (8.68) compared to the No music group (8.55) . At subsequent time points (10 mins, 20 mins, 30 mins, 60 mins, and end of surgery), the Music group consistently had significantly lower mean VAS scores for anxiety compared to the No music group , with VAS scores reducing significantly.

It is widely recognized that sedatives used during surgery might slow down patient recovery and have the potential to induce negative consequences such as excessive sedation and respiratory depression in the post operative period. The findings of our study demonstrated that that a significantly smaller percentage of patients in the music group required sedation (10%) compared to those in the no music group (90%).

Carolina Lepage et al<sup>27</sup> and Marc E. Koch<sup>28</sup> et al conducted studies that found a notable reduction in the dose of sedatives needed in the music cluster compared to the non-music group in order to achieve identical levels of sleepiness. In contrast, Tej Kaul<sup>29</sup> et al found that patients using occlusive headphones had comparable propofol requirements to those who listened to music during surgery. However, the use of headphones reduced ambient noise in the operating theater and decreased the need for sedatives in patients receiving regional anesthesia. The finding of our study are similar to study done by Carolina Lepage<sup>27</sup> et.al and Tej Kaul<sup>29</sup> et.al

For our research, we employed a visual analog scale to quantify anxiety. This scale involves assigning a score ranging from 0 to 10 on a line. The Visual Analogue Scale for anxiety(VASA) is a simple, yet effective tool used to measure an individual's level of anxiety.

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It typically consists of a horizontal line, usually 10 centimeters long, anchored by two descriptions at each end—such as "No anxiety" and "Extreme anxiety." The Visual Analogue Scale (VAS) for anxiety has several advantages that make it a valuable tool for assessing anxiety levels. Its easiness in understanding makes simpler to administer and , making it feasible to a broad group of individuals The scale's sensitivity allows it to detect small changes in anxiety levels, providing precise and nuanced measurements. Additionally, the VAS is non-verbal, which is particularly useful for individuals who may have difficulty articulating their feelings, such as those with language barriers, cognitive impairments, or other communication challenges. These attributes collectively make the VAS a practical and effective instrument for both clinical and research settings.

Our observation revealed that music was successful in decreasing patient anxiety, as there was a notable disparity in VASA scores between the music group and the nonmusic group through out the surgical procedure and at the conclusion of the procedure ( $1.59 \pm 0.74$  vs.  $8.25 \pm 0.44$ ).

In 2017, Syal et al<sup>30</sup>. did a extensive study that assessed the effect of music therapy on reducing anxiety in surgical patients. Their findings were similar to ours, as they discovered that the anxiety scores were lower in the group that received music therapy ( $1.66 \pm 0.69$  in the music group vs.  $1.92 \pm 0.52$  in the no music group,  $P < 0.001$ ). According to their study, the decrease in anxiety caused by music could be attributed to a fall in catecholamine levels.

In a study done by Bansal et al<sup>6</sup>. in 2019, the researchers investigated the use of music as an effective method to decrease anxiety during c-section procedures performed under SAB. Patients with a prior history of C-Section were chosen. The study found that the VASA score was significantly lower in the cluster of subjects who received music therapy against those who did not. The level of anxiety experienced by patients during current surgery was

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significantly reduced when music was included, in comparison to their previous experience of undergoing a cesarean section. None of the patients in our study had previous experience of undergoing surgery unlike in the above study where they compared intraoperative experience with and without music giving more credibility to the above study.

Kuhlmann<sup>(4)</sup> et al. when performed a meta-analysis that involved 81 randomized controlled studies. They discovered a noteworthy decrease in anxiety and discomfort when utilizing music intervention, against to the control group. They recorded a reduction of 0.22 cm for anxiety and 0.10cm for pain sensation on a 10cm VAS The meta regression analysis revealed non-significant correlation between the music intervention and variables such as age, sex, choice, or kind of anesthetic. In our study fall in the intraoperative anxiety levels was uniform across both the gender and we did the study in geriatric patients and the same study can be done in younger age group patients.

As a result of reduced anxiety due to music therapy in the intraoperative period, number of patients requiring sedation were markedly reduced in the Music group. Only 10%(4) of the patients in the Music group required sedation as against 90% (36) patients required sedation in the no music group. This is particularly advantageous in the geriatric patients where sedations can lead to post operative confusion, prolonged somnolence, and hence delayed discharge from hospital.

We also studied the patient's satisfaction with the intraoperative music therapy in the recovery room. The patients were asked to complete a questionnaire regarding the intraoperative experience and whether they would recommend the music therapy to others. 100%(41) patients in the music group said that music made the intraoperative surgical experience better and that they would definitely recommend intra operative music therapy to other patients.

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We also studied whether the anesthesiologist faced any problems intraoperatively in communicating with the patients due the presence of head phones and/or music. or any difficulties faced in managing these patients due to the presence of music therapy. None of the consultant anesthesiologists faced any difficulties in communicating with these patients. All of them expressed satisfaction with the calmness, better intraoperative hemodynamics seen in the patients due to music therapy and would definitely implement intraoperative music therapy in future.

Although our study clearly demonstrates the advantage of intraoperative music therapy, the sample size is quite limited. Larger multi centric trails would definitely be more useful. In addition, we did not measure serum cortisol levels which would validate the findings of our study.

We have studied the effect of music therapy in patients undergoing surgery under spinal anesthesia. Similar the effect of intraoperative music therapy on anesthetic requirement during general anesthesia can be studied.

Effect of intraoperative music therapy can also be studied in children where too; it is expected to have beneficial effects.

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## **CONCLUSION-**

Intraoperative music therapy significantly reduces anxiety in geriatric patients undergoing infraumbilical surgery under spinal anesthesia.

Intraoperative music therapy also leads to reduced requirement of intraoperative sedation.

100% of the patients who received therapy expressed satisfaction with the same and strongly recommended its use.

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## Summary-

Spinal anesthesia is the most commonly used anesthesia for infra umbilical surgeries. As a potential alternative to pharmaceutical interventions, this study aims to examine the effects of music therapy during spinal anesthesia in geriatric patients, particularly focusing on whether intraoperative music therapy impacts patient anxiety, the amount of sedation required during surgery, and postoperative satisfaction.

In our study we compared anxiety between patients who were and who were not exposed to music during the surgery using Visual Analogue Scale for Anxiety (VASA), and evaluated whether music is linked to a reduction in intraoperative sedative requirements and to assess patient satisfaction.

A total of 82 Patients aged above 60 years, of either gender, belonging to ASA grade I-II, undergoing elective surgery in supine position under spinal anesthesia were enrolled in the study and randomized into two groups. GROUP M: Patients listened to a chosen soundtrack using noise-cancelling headphones Group N: No Music Group: Patients wore headsets with turned off settings. Anxiety was measured with the Visual analogues score for Anxiety (VASA) and intraoperative hemodynamic parameters were watched over and noted until the end of the surgery.

Group-M had better Visual Analogue Score for Anxiety (VASA) and better hemodynamic parameters as compared to the Group-N.

Intraoperative music therapy significantly reduces anxiety in geriatric patients undergoing infraumbilical surgery under spinal anesthesia. Intraoperative music therapy also leads to reduced requirement of intraoperative sedation.

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## ANNEXURES

### ANNEXURE-I

#### INFORMED CONSENT FORM

**“EFFECTS OF INTRAOPERATIVE MUSIC THERAPY ON ANXIETY IN GERIATRIC PATIENTS  
UNDERGOING SURGERY UNDER SPINAL ANAESTHESIA: A ONE YEAR HOSPITAL BASED DOUBLE  
BLIND RANDOMIZED CONTROL TRIAL”**

**Name of Student/Principal Investigator: DR. VINAY G YADAV**

**Name of Guide/Co Investigators: DR. VANDANA A. GOGATE M.D.**

**Objective:**

1. The primary objective is to compare anxiety as assessed by **VISUAL ANALOGUE SCALE FOR ANXIETY** for patients who were or were not exposed to music during the surgery.
2. A secondary objective is to analyze whether the music is associated with decrease in intra operative sedative requirements.
3. To assess patient satisfaction

**Introduction:**

**Explanation of procedure:** If you agree to participate in our study, we will ask to present, past and past history. Then you will be clinically examined in detail you will be allotted into one of the two groups randomly using envelope method of randomization

**Withdrawal from participation in the study:** Participation in this study is voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case you

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decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

**Possible benefits from participating in the study:** You will/will not have nor get any benefits by participating in this study. The data gathered will help the population at large.

**Possible risks from participating in the study:** There are no risks involved in participating in this study.

**Privacy and confidentiality:** The information collected from you will be coded, to prevent any person from identifying you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication.

**Financial incentives:** You will not receive any payment for participating in this study.

**Authorization for publication of aggregated data:** Results obtained after processing of the aggregated data will be published for scientific purposes and or presented to scientific groups. However, your identity will never be revealed.

**Questions:** In case of any questions with regard to this study, you are free to contact: "Name of student/PI, mobile number, email ID" If you have any question or complaints with regard to your right as study participant you may contact Dr. Harsha Hegde, Chairperson, Ethical committee of JNMC, 0831-2473777 Extension 4052.

**Legal rights:** By signing this consent form, we are not waving any of your legal rights.

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**CONSENT STATEMENT**

I am making a voluntary decision to participate in the study **“EFFECTS OF INTRAOPERATIVE MUSIC THERAPY ON ANXIETY IN GERIATRIC PATIENTS UNDERGOING SURGERY UNDER SPINAL ANAESTHESIA: A ONE YEAR HOSPITAL BASED DOUBLE BLIND RANDOMIZED CONTROL TRIAL”**

My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the participant:

Signature or left thumb impression of the participant:

Name of the witness:

Signature or left thumb impression of the witness:

Name of the investigator:

Signature of the investigator:

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**ANNEXURE-II**

**PROFORMA**

**Title: “EFFECTS OF INTRAOPERATIVE MUSIC THERAPY ON ANXIETY IN GERIATRIC PATIENTS UNDERGOING SURGERY UNDER SPINAL ANAESTHESIA: A ONE YEAR HOSPITAL BASED DOUBLE BLIND RANDOMIZED CONTROL TRIAL”**

Patient’s Name :

I.P No. :

Age :

Date of Examination :

Gender :

Anaesthesiologist :

Address :

**Pre-anesthetic evaluation:**

**Chief complaints:**

**HOPi:**

**Past History:**

- H/o co-morbidities and drug intake :
- H/o previous surgery/(s) where difficult airway was encountered :
- Previous anesthetic experience:
- Contraindications to spinal anaesthesia.

**Family History:**

**General physical examination:**

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Height (cm) :                      Weight (Kg):                      BMI :

Pallor :                      Icterus :

Cyanosis :                      Clubbing :

PR :                      RR :

SpO2 :

**Systemic examination:**

**RS:** Breath sounds:                      **CVS:** Heart sounds:

**CNS:**                      **GIT:**

**Airway Assessment:**

**Teeth:**

**Jaw movements:**

**Investigations:**

Hb(gm/dl):                      TLC:                      Platelet count:

Serum Creatinine:                      FBS:

Chest x-ray:                      ECG:

**Preoperative physical status:** ASA Grade    I   II  

**Diagnosis:**

**Proposed surgery:**

**VISUAL ANALOGUE SCALE FOR ANXIETY**



| <u>VITALS</u>     | HR | SBP | DBP | MAP | SPO <sub>2</sub> |
|-------------------|----|-----|-----|-----|------------------|
| Starting of music |    |     |     |     |                  |
| 10min             |    |     |     |     |                  |
| 10min             |    |     |     |     |                  |
| 30min             |    |     |     |     |                  |
|                   |    |     |     |     |                  |
|                   |    |     |     |     |                  |
|                   |    |     |     |     |                  |
| End of surgery    |    |     |     |     |                  |

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**Questionnaire for postoperative assessment**

1) What effect do you think music had on your experience during surgery

- a. Made it better
- b. Made it worse
- c. No effect

2) Would you recommend listening to music during an operation to other people

- a. Yes
- b. No
- c. Don't know

**To anaesthetist**

1. Do you think music or head phones caused any problems during the operations

- a. Yes
- b. No
- c. Don't know

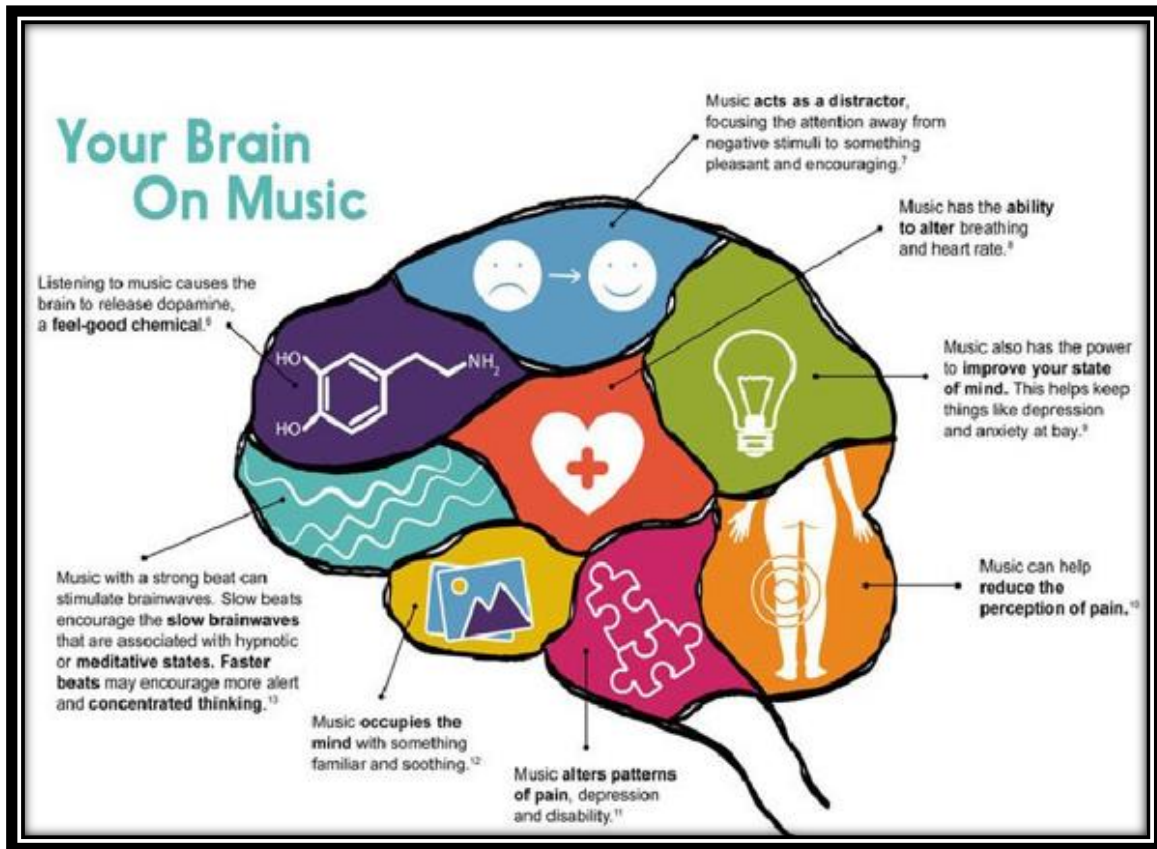
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**ANNEXURE-III**

**IMAGES**



**IMAGES 1: SHOWS MUSIC BEING ADMINSTERED TO THE PATIENT**



**IMAGES 2: : SHOWS THE PICTORIAL REPRESENTATION OF EFFECT OF MUSIC ON BRAIN**

ANNEXURE-IV MASTER CHART

| MUSIC GROUP |     |     |            |     |     |     |        |       |       |       |       |       |            |        |       |       |       |       |       |            |        |       |       |       |       |       |            |        |               |       |       |       |       |                              |                             |                            |            |       |                |       |       |
|-------------|-----|-----|------------|-----|-----|-----|--------|-------|-------|-------|-------|-------|------------|--------|-------|-------|-------|-------|-------|------------|--------|-------|-------|-------|-------|-------|------------|--------|---------------|-------|-------|-------|-------|------------------------------|-----------------------------|----------------------------|------------|-------|----------------|-------|-------|
| Sl. No.     | Age | Sex | MUSIC LINE |     |     |     | HR     |       |       |       |       |       |            | SEP    |       |       |       |       | OEP   |            |        |       |       | MOP   |       |       |            |        | VOCAL Ability |       |       |       |       | PASS WRIT & QUES. & COMPARIS | VALUATION OF MUSIC TEACHERS | REMARKS (CASE OR PROBLEMS) |            |       |                |       |       |
|             |     |     | HR         | SEP | OEP | MOP | SEP/HR | 10hrs | 20hrs | 30hrs | 40hrs | 60hrs | EMPLOYMENT | SEP/HR | 10hrs | 20hrs | 30hrs | 40hrs | 60hrs | EMPLOYMENT | SEP/HR | 10hrs | 20hrs | 30hrs | 40hrs | 60hrs | EMPLOYMENT | SEP/HR | 10hrs         | 20hrs | 30hrs | 40hrs | 60hrs |                              |                             |                            | EMPLOYMENT | 10hrs | 20hrs          | 30hrs | 40hrs |
| 1           | 72  | M   | 90         | 354 | 28  | 70  | 88     | 88    | 86    | 80    | 78    | 76    | 74         | 164    | 154   | 130   | 150   | 148   | 144   | 140        | 88     | 88    | 86    | 84    | 80    | 80    | 70         | 70     | 70            | 70    | 64    | 64    | 8     | 6                            | 4                           | 3                          | 2          | 2     | MADE IT BETTER | YES   | NO    |
| 2           | 66  | F   | 106        | 144 | 96  | 76  | 106    | 100   | 94    | 84    | 80    | 82    | 82         | 144    | 138   | 130   | 126   | 124   | 122   | 126        | 96     | 90    | 84    | 80    | 78    | 76    | 74         | 72     | 70            | 70    | 68    | 68    | 9     | 6                            | 4                           | 3                          | 1          | 1     | MADE IT BETTER | YES   | NO    |
| 3           | 64  | F   | 104        | 146 | 88  | 74  | 104    | 96    | 95    | 90    | 90    | 84    | 82         | 148    | 146   | 134   | 130   | 130   | 130   | 130        | 74     | 68    | 66    | 66    | 66    | 66    | 70         | 72     | 74            | 70    | 66    | 66    | 8     | 7                            | 7                           | 4                          | 3          | 1     | MADE IT BETTER | YES   | NO    |
| 4           | 70  | M   | 104        | 164 | 90  | 88  | 104    | 100   | 92    | 86    | 80    | 80    | 80         | 162    | 150   | 142   | 140   | 136   | 130   | 132        | 130    | 120   | 110   | 104   | 100   | 100   | 88         | 86     | 84            | 82    | 80    | 78    | 9     | 6                            | 5                           | 4                          | 2          | 1     | MADE IT BETTER | YES   | NO    |
| 5           | 62  | M   | 97         | 161 | 85  | 110 | 97     | 94    | 90    | 90    | 88    | 88    | 80         | 162    | 158   | 156   | 154   | 150   | 140   | 140        | 85     | 84    | 80    | 80    | 80    | 74    | 74         | 72     | 70            | 70    | 64    | 64    | 9     | 7                            | 7                           | 4                          | 2          | 1     | MADE IT BETTER | YES   | NO    |
| 6           | 64  | F   | 72         | 93  | 67  | 75  | 72     | 70    | 64    | 62    | 62    | 60    | 60         | 98     | 90    | 90    | 90    | 88    | 88    | 88         | 67     | 66    | 64    | 64    | 64    | 64    | 75         | 70     | 72            | 72    | 72    | 72    | 9     | 9                            | 5                           | 5                          | 2          | 2     | MADE IT BETTER | YES   | NO    |
| 7           | 73  | M   | 68         | 160 | 111 | 127 | 68     | 60    | 54    | 53    | 52    | 53    | 52         | 160    | 154   | 150   | 148   | 140   | 140   | 138        | 110    | 108   | 106   | 104   | 102   | 100   | 120        | 110    | 104           | 102   | 100   | 100   | 9     | 8                            | 7                           | 7                          | 5          | 4     | MADE IT BETTER | YES   | NO    |
| 8           | 80  | F   | 69         | 111 | 88  | 95  | 69     | 67    | 60    | 58    | 58    | 56    | 56         | 110    | 100   | 98    | 94    | 92    | 92    | 92         | 88     | 84    | 83    | 80    | 80    | 80    | 95         | 90     | 90            | 88    | 80    | 80    | 9     | 8                            | 7                           | 3                          | 2          | 2     | MADE IT BETTER | YES   | NO    |
| 9           | 82  | M   | 71         | 139 | 70  | 98  | 72     | 64    | 62    | 60    | 58    | 58    | 58         | 138    | 134   | 132   | 128   | 126   | 124   | 124        | 82     | 80    | 76    | 74    | 78    | 78    | 92         | 90     | 88            | 84    | 82    | 80    | 8     | 6                            | 4                           | 2                          | 2          | 1     | MADE IT BETTER | YES   | NO    |
| 10          | 72  | M   | 65         | 147 | 106 | 119 | 65     | 60    | 62    | 58    | 58    | 58    | 56         | 146    | 140   | 138   | 136   | 134   | 130   | 128        | 106    | 100   | 98    | 94    | 88    | 88    | 110        | 104    | 84            | 100   | 88    | 94    | 9     | 7                            | 4                           | 3                          | 2          | 1     | MADE IT BETTER | YES   | NO    |
| 11          | 76  | F   | 75         | 93  | 60  | 92  | 76     | 70    | 64    | 62    | 62    | 60    | 60         | 92     | 88    | 80    | 84    | 80    | 74    | 70         | 62     | 60    | 58    | 58    | 56    | 56    | 92         | 88     | 84            | 82    | 82    | 80    | 9     | 7                            | 5                           | 3                          | 3          | 1     | MADE IT BETTER | YES   | NO    |
| 12          | 68  | M   | 80         | 158 | 84  | 108 | 80     | 76    | 74    | 70    | 70    | 70    | 70         | 150    | 144   | 132   | 130   | 133   | 130   | 130        | 84     | 82    | 76    | 74    | 64    | 64    | 108        | 101    | 98            | 96    | 92    | 90    | 9     | 7                            | 5                           | 4                          | 2          | 2     | MADE IT BETTER | YES   | NO    |
| 13          | 75  | M   | 76         | 114 | 83  | 93  | 69     | 67    | 60    | 58    | 58    | 56    | 56         | 110    | 100   | 98    | 94    | 92    | 92    | 92         | 88     | 84    | 83    | 80    | 80    | 80    | 95         | 90     | 90            | 88    | 80    | 80    | 9     | 8                            | 7                           | 3                          | 2          | 2     | MADE IT BETTER | YES   | NO    |
| 14          | 73  | F   | 61         | 133 | 115 | 121 | 72     | 64    | 62    | 60    | 58    | 58    | 58         | 138    | 134   | 132   | 128   | 126   | 124   | 124        | 82     | 80    | 76    | 74    | 78    | 78    | 92         | 90     | 88            | 84    | 82    | 80    | 8     | 6                            | 4                           | 2                          | 2          | 1     | MADE IT BETTER | YES   | NO    |
| 15          | 76  | M   | 72         | 166 | 61  | 96  | 80     | 76    | 74    | 70    | 70    | 70    | 70         | 150    | 144   | 132   | 130   | 133   | 130   | 130        | 84     | 82    | 76    | 74    | 64    | 64    | 108        | 101    | 98            | 96    | 92    | 90    | 9     | 7                            | 5                           | 4                          | 2          | 2     | MADE IT BETTER | YES   | NO    |
| 16          | 89  | M   | 67         | 116 | 109 | 111 | 88     | 88    | 86    | 80    | 78    | 76    | 74         | 164    | 154   | 150   | 150   | 140   | 144   | 140        | 88     | 88    | 86    | 84    | 80    | 80    | 70         | 70     | 70            | 70    | 64    | 64    | 8     | 6                            | 4                           | 3                          | 2          | 2     | MADE IT BETTER | YES   | NO    |
| 17          | 73  | F   | 66         | 142 | 73  | 96  | 65     | 60    | 62    | 58    | 58    | 58    | 56         | 146    | 140   | 138   | 136   | 134   | 130   | 128        | 106    | 100   | 98    | 94    | 88    | 88    | 110        | 104    | 84            | 100   | 88    | 94    | 9     | 7                            | 4                           | 3                          | 2          | 1     | MADE IT BETTER | YES   | NO    |
| 18          | 77  | M   | 85         | 170 | 68  | 98  | 80     | 76    | 74    | 70    | 70    | 70    | 70         | 150    | 144   | 132   | 130   | 133   | 130   | 130        | 84     | 82    | 76    | 74    | 64    | 64    | 108        | 101    | 98            | 96    | 92    | 90    | 9     | 7                            | 5                           | 4                          | 2          | 2     | MADE IT BETTER | YES   | NO    |
| 19          | 69  | M   | 80         | 131 | 60  | 83  | 72     | 64    | 62    | 60    | 58    | 58    | 58         | 138    | 134   | 132   | 128   | 126   | 124   | 124        | 82     | 80    | 76    | 74    | 78    | 78    | 92         | 90     | 88            | 84    | 82    | 80    | 8     | 6                            | 4                           | 2                          | 2          | 1     | MADE IT BETTER | YES   | NO    |
| 20          | 88  | F   | 97         | 172 | 116 | 100 | 97     | 90    | 88    | 84    | 80    | 78    | 74         | 172    | 165   | 160   | 154   | 150   | 150   | 148        | 116    | 108   | 104   | 100   | 98    | 96    | 110        | 108    | 106           | 104   | 96    | 94    | 9     | 5                            | 4                           | 2                          | 1          | 1     | MADE IT BETTER | YES   | NO    |

| MUSIC GROUP |    |   |          |     |     |     |              |        |        |        |        |        |            |              |        |        |        |        |        |            |              |        |        |        |        |        |            |              |        |                |        |        |        |            |                        |                       |                          |                              |                |        |        |
|-------------|----|---|----------|-----|-----|-----|--------------|--------|--------|--------|--------|--------|------------|--------------|--------|--------|--------|--------|--------|------------|--------------|--------|--------|--------|--------|--------|------------|--------------|--------|----------------|--------|--------|--------|------------|------------------------|-----------------------|--------------------------|------------------------------|----------------|--------|--------|
| S/N         | A  | G | BASELINE |     |     | HR  |              |        |        |        |        | SEP    |            |              |        |        |        | OEP    |        |            |              |        |        | MOP    |        |        |            |              |        | MAGTA Activity |        |        |        |            |                        | PARENT/CLUB'S OPINION | WAS IT COMMENT/TEACHER'S | WAS THE STUD. QUIET/CLUBBERS |                |        |        |
|             |    |   | HR       | SEP | OEP | MOP | Starting Mus | 10Mins | 20Mins | 30Mins | 40Mins | 60Mins | EMPLOYMENT | Starting Mus | 10Mins | 20Mins | 30Mins | 40Mins | 60Mins | EMPLOYMENT | Starting Mus | 10Mins | 20Mins | 30Mins | 40Mins | 60Mins | EMPLOYMENT | Starting Mus | 10Mins | 20Mins         | 30Mins | 40Mins | 60Mins | EMPLOYMENT | PLACEMENT OF TEACHER'S |                       |                          |                              | 10Mins         | 20Mins | 30Mins |
| 21          | 82 | F | 78       | 105 | 73  | 88  | 76           | 70     | 64     | 62     | 60     | 60     | 92         | 88           | 80     | 84     | 80     | 74     | 70     | 62         | 60           | 58     | 58     | 56     | 56     | 92     | 88         | 84           | 82     | 82             | 80     | 9      | 7      | 5          | 3                      | 3                     | 1                        | MADE IT BETTER               | YES            | NO     |        |
| 22          | 74 | M | 80       | 154 | 66  | 95  | 68           | 60     | 54     | 53     | 52     | 53     | 160        | 154          | 150    | 148    | 140    | 140    | 138    | 110        | 108          | 106    | 104    | 102    | 100    | 120    | 110        | 104          | 102    | 100            | 100    | 9      | 8      | 7          | 7                      | 5                     | 4                        | MADE IT BETTER               | YES            | NO     |        |
| 23          | 63 | M | 71       | 158 | 112 | 127 | 80           | 76     | 74     | 70     | 70     | 70     | 130        | 144          | 132    | 130    | 133    | 130    | 130    | 84         | 82           | 76     | 74     | 64     | 64     | 108    | 101        | 98           | 96     | 92             | 90     | 9      | 7      | 5          | 4                      | 2                     | 2                        | MADE IT BETTER               | YES            | NO     |        |
| 24          | 71 | M | 88       | 115 | 81  | 92  | 88           | 88     | 86     | 80     | 74     | 76     | 164        | 154          | 150    | 150    | 144    | 144    | 140    | 88         | 88           | 86     | 84     | 80     | 80     | 70     | 70         | 70           | 70     | 64             | 64     | 8      | 6      | 4          | 3                      | 2                     | 2                        | MADE IT BETTER               | YES            | NO     |        |
| 25          | 62 | M | 89       | 177 | 66  | 103 | 80           | 76     | 74     | 70     | 70     | 70     | 130        | 144          | 132    | 130    | 133    | 130    | 130    | 84         | 82           | 76     | 74     | 64     | 64     | 108    | 101        | 98           | 96     | 92             | 90     | 9      | 7      | 5          | 4                      | 2                     | 2                        | MADE IT BETTER               | YES            | NO     |        |
| 26          | 61 | F | 74       | 97  | 62  | 73  | 76           | 70     | 64     | 62     | 62     | 60     | 60         | 92           | 88     | 80     | 84     | 80     | 74     | 70         | 62           | 60     | 58     | 58     | 56     | 56     | 92         | 88           | 84     | 82             | 82     | 80     | 9      | 7          | 5                      | 3                     | 3                        | 1                            | MADE IT BETTER | YES    | NO     |
| 27          | 62 | F | 64       | 116 | 72  | 86  | 88           | 88     | 86     | 80     | 72     | 76     | 164        | 154          | 150    | 149    | 142    | 144    | 140    | 88         | 88           | 86     | 84     | 80     | 80     | 70     | 70         | 70           | 70     | 64             | 64     | 8      | 6      | 4          | 3                      | 2                     | 2                        | MADE IT BETTER               | YES            | NO     |        |
| 28          | 73 | M | 85       | 115 | 87  | 96  | 76           | 70     | 64     | 62     | 62     | 60     | 60         | 92           | 88     | 80     | 84     | 80     | 74     | 70         | 62           | 60     | 58     | 58     | 56     | 56     | 92         | 88           | 84     | 82             | 82     | 80     | 9      | 7          | 5                      | 3                     | 3                        | 1                            | MADE IT BETTER | YES    | NO     |
| 29          | 70 | F | 83       | 112 | 81  | 91  | 76           | 70     | 64     | 62     | 62     | 60     | 60         | 92           | 88     | 80     | 78     | 80     | 74     | 70         | 62           | 60     | 58     | 58     | 56     | 56     | 92         | 88           | 84     | 82             | 82     | 80     | 9      | 7          | 5                      | 3                     | 3                        | 1                            | MADE IT BETTER | YES    | NO     |
| 30          | 82 | M | 90       | 99  | 71  | 80  | 72           | 70     | 64     | 62     | 62     | 60     | 60         | 98           | 90     | 90     | 98     | 88     | 88     | 88         | 67           | 66     | 64     | 64     | 64     | 64     | 75         | 70           | 72     | 72             | 72     | 72     | 9      | 9          | 5                      | 5                     | 2                        | 2                            | MADE IT BETTER | YES    | NO     |
| 31          | 83 | M | 92       | 157 | 67  | 97  | 80           | 76     | 74     | 70     | 70     | 70     | 130        | 144          | 132    | 128    | 133    | 130    | 130    | 84         | 82           | 76     | 74     | 64     | 64     | 108    | 101        | 98           | 96     | 92             | 90     | 9      | 7      | 5          | 4                      | 2                     | 2                        | MADE IT BETTER               | YES            | NO     |        |
| 32          | 78 | F | 82       | 113 | 73  | 86  | 88           | 88     | 86     | 80     | 76     | 76     | 164        | 154          | 150    | 141    | 142    | 144    | 140    | 88         | 88           | 86     | 84     | 80     | 80     | 70     | 70         | 70           | 70     | 64             | 64     | 8      | 6      | 4          | 3                      | 2                     | 2                        | MADE IT BETTER               | YES            | NO     |        |
| 33          | 67 | F | 73       | 117 | 68  | 84  | 76           | 70     | 64     | 62     | 62     | 60     | 60         | 92           | 88     | 80     | 78     | 80     | 74     | 70         | 62           | 60     | 58     | 58     | 56     | 56     | 92         | 88           | 84     | 82             | 82     | 80     | 9      | 7          | 5                      | 3                     | 3                        | 1                            | MADE IT BETTER | YES    | NO     |
| 34          | 82 | F | 69       | 127 | 71  | 89  | 69           | 67     | 60     | 58     | 58     | 56     | 56         | 130          | 100    | 98     | 98     | 92     | 92     | 92         | 88           | 84     | 83     | 80     | 80     | 80     | 95         | 90           | 90     | 88             | 80     | 80     | 9      | 8          | 7                      | 3                     | 2                        | 2                            | MADE IT BETTER | YES    | NO     |
| 35          | 89 | M | 67       | 147 | 72  | 97  | 76           | 70     | 64     | 62     | 62     | 60     | 60         | 92           | 88     | 80     | 84     | 80     | 74     | 70         | 62           | 60     | 58     | 58     | 56     | 56     | 92         | 88           | 84     | 82             | 82     | 80     | 9      | 7          | 5                      | 3                     | 3                        | 1                            | MADE IT BETTER | YES    | NO     |
| 36          | 73 | M | 82       | 173 | 103 | 126 | 80           | 76     | 74     | 70     | 70     | 70     | 130        | 144          | 132    | 128    | 133    | 130    | 130    | 84         | 82           | 76     | 74     | 64     | 64     | 108    | 101        | 98           | 96     | 92             | 90     | 9      | 7      | 5          | 4                      | 2                     | 2                        | MADE IT BETTER               | YES            | NO     |        |
| 37          | 76 | F | 61       | 128 | 80  | 96  | 88           | 88     | 86     | 80     | 72     | 76     | 164        | 154          | 150    | 144    | 126    | 144    | 140    | 88         | 88           | 86     | 84     | 80     | 80     | 70     | 70         | 70           | 70     | 64             | 64     | 8      | 6      | 4          | 3                      | 2                     | 2                        | MADE IT BETTER               | YES            | NO     |        |
| 38          | 78 | F | 60       | 98  | 90  | 92  | 76           | 70     | 64     | 62     | 62     | 60     | 60         | 92           | 88     | 80     | 88     | 80     | 74     | 70         | 62           | 60     | 58     | 58     | 56     | 56     | 92         | 88           | 84     | 82             | 82     | 80     | 9      | 7          | 5                      | 3                     | 3                        | 1                            | MADE IT BETTER | YES    | NO     |
| 39          | 76 | F | 77       | 122 | 96  | 104 | 72           | 64     | 62     | 60     | 58     | 58     | 58         | 138          | 134    | 132    | 122    | 126    | 124    | 124        | 82           | 80     | 76     | 74     | 78     | 78     | 92         | 90           | 88     | 84             | 82     | 80     | 8      | 6          | 4                      | 2                     | 2                        | 1                            | MADE IT BETTER | YES    | NO     |
| 40          | 72 | M | 68       | 124 | 99  | 107 | 68           | 60     | 54     | 53     | 52     | 53     | 55         | 124          | 118    | 116    | 108    | 102    | 102    | 102        | 90           | 84     | 80     | 78     | 74     | 70     | 100        | 96           | 94     | 92             | 88     | 88     | 7      | 5          | 3                      | 2                     | 1                        | 1                            | MADE IT BETTER | YES    | NO     |
| 41          | 70 | M | 84       | 100 | 67  | 78  | 98           | 88     | 86     | 80     | 78     | 75     | 75         | 100          | 94     | 90     | 88     | 84     | 84     | 67         | 64           | 62     | 60     | 58     | 60     | 60     | 78         | 74           | 72     | 70             | 68     | 68     | 9      | 7          | 6                      | 5                     | 2                        | 1                            | MADE IT BETTER | YES    | NO     |

| GROUP N |     |     |          |     |     |     |           |       |       |       |       |            |           |       |       |       |       |            |           |       |       |       |       |            |           |       |                 |       |       |            |           |                        |       |                             |       |            |                           |                         |                                |    |
|---------|-----|-----|----------|-----|-----|-----|-----------|-------|-------|-------|-------|------------|-----------|-------|-------|-------|-------|------------|-----------|-------|-------|-------|-------|------------|-----------|-------|-----------------|-------|-------|------------|-----------|------------------------|-------|-----------------------------|-------|------------|---------------------------|-------------------------|--------------------------------|----|
| Sl. No. | Age | Sex | BASELINE |     |     |     | HR        |       |       |       |       | SBP        |           |       |       |       | DBP   |            |           |       |       | MAP   |       |            |           |       | VAS for Anxiety |       |       |            |           | PATIENTS QUESTIONNAIRE |       | ANAESTHETISTS QUESTIONNAIRE |       |            |                           |                         |                                |    |
|         |     |     | HR       | SBP | DBP | MAP | Springhuk | 10Min | 20Min | 30Min | 40Min | ENDOBREVEY | Springhuk | 10Min | 20Min | 30Min | 40Min | ENDOBREVEY | Springhuk | 10Min | 20Min | 30Min | 40Min | ENDOBREVEY | Springhuk | 10Min | 20Min           | 30Min | 40Min | ENDOBREVEY | Springhuk | 10Min                  | 20Min | 30Min                       | 40Min | ENDOBREVEY | EFFECT ON DRUG DEPENDENCY | WELL YOUR COMORBIDITIES | DRUGS USE OR POSSIBLE COMORBID |    |
| 1       | 68  | M   | 98       | 136 | 94  | 75  | 98        | 98    | 96    | 96    | 96    | 96         | 148       | 148   | 140   | 140   | 140   | 140        | 94        | 92    | 92    | 92    | 90    | 90         | 76        | 76    | 76              | 76    | 76    | 76         | 8         | 8                      | 8     | 8                           | 8     | 8          | NO EFFECT                 | Don't know              | NO                             |    |
| 2       | 66  | M   | 96       | 138 | 86  | 68  | 88        | 95    | 94    | 94    | 94    | 94         | 138       | 138   | 138   | 138   | 138   | 138        | 86        | 86    | 86    | 84    | 88    | 88         | 68        | 68    | 68              | 68    | 68    | 68         | 8         | 8                      | 8     | 8                           | 8     | 8          | NO EFFECT                 | Don't know              | NO                             |    |
| 3       | 64  | F   | 96       | 144 | 78  | 76  | 96        | 98    | 98    | 98    | 98    | 98         | 144       | 148   | 148   | 148   | 148   | 148        | 78        | 78    | 78    | 74    | 76    | 76         | 76        | 74    | 74              | 74    | 74    | 74         | 8         | 8                      | 8     | 8                           | 8     | 8          | NO EFFECT                 | Don't know              | NO                             |    |
| 4       | 68  | F   | 88       | 140 | 94  | 72  | 96        | 98    | 96    | 100   | 98    | 98         | 140       | 138   | 136   | 98    | 134   | 134        | 94        | 92    | 92    | 92    | 90    | 90         | 72        | 70    | 68              | 68    | 68    | 68         | 8         | 9                      | 9     | 8                           | 8     | 8          | NO EFFECT                 | Don't know              | NO                             |    |
| 5       | 64  | M   | 90       | 130 | 80  | 90  | 90        | 88    | 88    | 86    | 85    | 85         | 130       | 132   | 130   | 130   | 138   | 138        | 80        | 76    | 74    | 70    | 75    | 75         | 90        | 94    | 90              | 90    | 90    | 90         | 9         | 8                      | 8     | 8                           | 8     | 9          | 8                         | NO EFFECT               | Don't know                     | NO |
| 6       | 65  | F   | 86       | 176 | 94  | 88  | 88        | 82    | 82    | 86    | 80    | 80         | 144       | 138   | 128   | 128   | 128   | 128        | 94        | 92    | 88    | 90    | 90    | 90         | 94        | 92    | 90              | 86    | 86    | 86         | 8         | 7                      | 8     | 8                           | 8     | 9          | 9                         | NO EFFECT               | Don't know                     | NO |
| 7       | 64  | F   | 92       | 164 | 80  | 80  | 88        | 86    | 84    | 80    | 80    | 80         | 165       | 160   | 155   | 150   | 150   | 150        | 80        | 80    | 78    | 78    | 78    | 78         | 88        | 88    | 86              | 88    | 85    | 76         | 8         | 8                      | 8     | 8                           | 8     | 8          | NO EFFECT                 | Don't know              | NO                             |    |
| 8       | 67  | M   | 82       | 136 | 80  | 78  | 76        | 75    | 79    | 78    | 76    | 76         | 136       | 124   | 128   | 100   | 100   | 98         | 80        | 78    | 76    | 64    | 60    | 60         | 60        | 58    | 58              | 64    | 62    | 62         | 9         | 8                      | 8     | 8                           | 8     | 9          | NO EFFECT                 | Don't know              | NO                             |    |
| 9       | 68  | M   | 98       | 136 | 94  | 75  | 98        | 98    | 96    | 96    | 96    | 96         | 148       | 148   | 140   | 140   | 140   | 140        | 94        | 92    | 92    | 92    | 90    | 90         | 76        | 76    | 76              | 76    | 76    | 76         | 8         | 8                      | 8     | 8                           | 8     | 8          | NO EFFECT                 | Don't know              | NO                             |    |
| 10      | 76  | F   | 96       | 138 | 86  | 68  | 88        | 95    | 94    | 94    | 94    | 94         | 138       | 138   | 138   | 138   | 138   | 138        | 86        | 86    | 86    | 84    | 88    | 88         | 68        | 68    | 68              | 68    | 68    | 68         | 8         | 8                      | 8     | 8                           | 8     | 8          | NO EFFECT                 | Don't know              | NO                             |    |
| 11      | 64  | F   | 96       | 144 | 78  | 76  | 96        | 98    | 98    | 98    | 98    | 98         | 144       | 148   | 148   | 148   | 148   | 148        | 78        | 78    | 78    | 74    | 76    | 76         | 76        | 74    | 74              | 74    | 74    | 74         | 8         | 8                      | 8     | 8                           | 8     | 8          | NO EFFECT                 | Don't know              | NO                             |    |
| 12      | 78  | M   | 88       | 166 | 94  | 72  | 96        | 98    | 96    | 100   | 98    | 98         | 140       | 138   | 136   | 98    | 134   | 134        | 94        | 92    | 92    | 92    | 90    | 90         | 72        | 70    | 68              | 68    | 68    | 68         | 8         | 9                      | 9     | 8                           | 8     | 8          | NO EFFECT                 | Don't know              | NO                             |    |
| 13      | 64  | M   | 90       | 130 | 80  | 90  | 90        | 88    | 88    | 86    | 85    | 85         | 130       | 132   | 130   | 130   | 138   | 138        | 80        | 76    | 74    | 70    | 75    | 75         | 90        | 94    | 90              | 90    | 90    | 90         | 9         | 8                      | 8     | 8                           | 8     | 9          | 8                         | NO EFFECT               | Don't know                     | NO |
| 14      | 65  | F   | 86       | 176 | 94  | 88  | 88        | 82    | 82    | 86    | 80    | 80         | 144       | 138   | 128   | 128   | 128   | 128        | 94        | 92    | 88    | 90    | 90    | 90         | 94        | 92    | 90              | 86    | 86    | 86         | 8         | 7                      | 8     | 8                           | 8     | 9          | 9                         | NO EFFECT               | Don't know                     | NO |
| 15      | 64  | F   | 92       | 164 | 80  | 80  | 88        | 86    | 84    | 80    | 80    | 80         | 165       | 160   | 155   | 150   | 150   | 150        | 80        | 80    | 78    | 78    | 78    | 78         | 88        | 88    | 86              | 88    | 85    | 76         | 8         | 8                      | 8     | 8                           | 8     | 8          | NO EFFECT                 | Don't know              | NO                             |    |
| 16      | 67  | M   | 82       | 136 | 80  | 78  | 76        | 75    | 79    | 78    | 76    | 76         | 136       | 124   | 128   | 100   | 100   | 98         | 80        | 78    | 76    | 64    | 60    | 60         | 60        | 58    | 58              | 64    | 62    | 62         | 9         | 8                      | 8     | 8                           | 8     | 9          | NO EFFECT                 | Don't know              | NO                             |    |
| 17      | 78  | M   | 98       | 146 | 94  | 88  | 98        | 88    | 86    | 86    | 84    | 96         | 148       | 148   | 140   | 140   | 140   | 140        | 94        | 92    | 92    | 92    | 90    | 90         | 76        | 76    | 76              | 76    | 76    | 76         | 8         | 8                      | 8     | 8                           | 8     | 8          | NO EFFECT                 | Don't know              | NO                             |    |
| 18      | 76  | M   | 96       | 138 | 86  | 68  | 88        | 95    | 94    | 94    | 94    | 94         | 138       | 138   | 138   | 138   | 138   | 138        | 86        | 86    | 86    | 84    | 88    | 88         | 68        | 68    | 68              | 68    | 68    | 68         | 8         | 8                      | 8     | 8                           | 8     | 8          | NO EFFECT                 | Don't know              | NO                             |    |
| 19      | 64  | F   | 96       | 144 | 78  | 76  | 96        | 98    | 98    | 98    | 98    | 98         | 144       | 148   | 148   | 148   | 148   | 148        | 78        | 78    | 78    | 74    | 76    | 76         | 76        | 74    | 74              | 74    | 74    | 74         | 8         | 8                      | 8     | 8                           | 8     | 8          | NO EFFECT                 | Don't know              | NO                             |    |
| 20      | 68  | M   | 88       | 140 | 94  | 72  | 96        | 98    | 9     | 100   | 98    | 98         | 140       | 138   | 136   | 98    | 134   | 134        | 94        | 92    | 92    | 92    | 90    | 90         | 72        | 70    | 68              | 68    | 68    | 68         | 8         | 9                      | 9     | 8                           | 8     | 8          | NO EFFECT                 | Don't know              | NO                             |    |

| Sl. No. | Age | SEX | GROUP N  |     |     |     |                |         |         |         |         |              |                |         |         |         |         |              |                |         |         |         |         |              |                |         |                 |         |         |              |                |                         | PATIENTS QUESTIONNAIRE      |                              |         | ANAESTHETISTS QUESTIONNAIRE |           |            |              |
|---------|-----|-----|----------|-----|-----|-----|----------------|---------|---------|---------|---------|--------------|----------------|---------|---------|---------|---------|--------------|----------------|---------|---------|---------|---------|--------------|----------------|---------|-----------------|---------|---------|--------------|----------------|-------------------------|-----------------------------|------------------------------|---------|-----------------------------|-----------|------------|--------------|
|         |     |     | BASELINE |     |     |     | HR             |         |         |         |         | SBP          |                |         |         |         | DBP     |              |                |         |         | MAP     |         |              |                |         | VAS for Anxiety |         |         |              |                | EFFECT OF NOK (DEPRESS) | VAS FOR COMBINATION THERAPY | REMARKS (USE AN PRELIMINARY) |         |                             |           |            |              |
|         |     |     | HR       | SBP | DBP | MAP | Start of study | 10 Mins | 20 Mins | 30 Mins | 40 Mins | END OF STUDY | Start of study | 10 Mins | 20 Mins | 30 Mins | 40 Mins | END OF STUDY | Start of study | 10 Mins | 20 Mins | 30 Mins | 40 Mins | END OF STUDY | Start of study | 10 Mins | 20 Mins         | 30 Mins | 40 Mins | END OF STUDY | Start of study |                         |                             |                              | 10 Mins | 20 Mins                     | 30 Mins   | 40 Mins    | END OF STUDY |
| 1       | 68  | M   | 98       | 136 | 94  | 75  | 98             | 98      | 96      | 96      | 96      | 96           | 148            | 148     | 140     | 140     | 140     | 140          | 94             | 92      | 92      | 92      | 90      | 90           | 76             | 76      | 76              | 76      | 76      | 76           | 8              | 8                       | 8                           | 8                            | 8       | 8                           | NO EFFECT | Don't know | NO           |
| 2       | 66  | M   | 96       | 138 | 86  | 68  | 88             | 95      | 94      | 94      | 94      | 94           | 138            | 138     | 138     | 138     | 138     | 138          | 86             | 86      | 86      | 84      | 88      | 88           | 68             | 68      | 68              | 68      | 68      | 68           | 8              | 8                       | 8                           | 8                            | 8       | 8                           | NO EFFECT | Don't know | NO           |
| 3       | 64  | F   | 96       | 144 | 78  | 76  | 96             | 98      | 98      | 98      | 98      | 98           | 144            | 148     | 148     | 148     | 148     | 148          | 78             | 78      | 78      | 74      | 76      | 76           | 76             | 74      | 74              | 74      | 74      | 74           | 8              | 8                       | 8                           | 8                            | 8       | 8                           | NO EFFECT | Don't know | NO           |
| 4       | 68  | F   | 88       | 140 | 94  | 72  | 96             | 98      | 96      | 100     | 98      | 98           | 140            | 138     | 136     | 98      | 134     | 134          | 94             | 92      | 92      | 92      | 90      | 90           | 72             | 70      | 68              | 68      | 68      | 68           | 8              | 9                       | 9                           | 8                            | 8       | 8                           | NO EFFECT | Don't know | NO           |
| 5       | 64  | M   | 90       | 130 | 80  | 90  | 90             | 88      | 88      | 86      | 85      | 85           | 130            | 132     | 130     | 130     | 138     | 138          | 80             | 76      | 74      | 70      | 75      | 75           | 90             | 94      | 90              | 90      | 90      | 90           | 9              | 8                       | 8                           | 8                            | 9       | 8                           | NO EFFECT | Don't know | NO           |
| 6       | 65  | F   | 86       | 176 | 94  | 88  | 88             | 82      | 82      | 86      | 80      | 80           | 144            | 138     | 128     | 128     | 128     | 128          | 94             | 92      | 88      | 90      | 90      | 90           | 94             | 92      | 90              | 86      | 86      | 86           | 8              | 7                       | 8                           | 8                            | 9       | 9                           | NO EFFECT | Don't know | NO           |
| 7       | 64  | F   | 92       | 164 | 80  | 80  | 88             | 86      | 84      | 80      | 80      | 80           | 165            | 160     | 155     | 150     | 150     | 150          | 80             | 80      | 78      | 78      | 78      | 78           | 88             | 88      | 86              | 88      | 85      | 76           | 8              | 8                       | 8                           | 8                            | 8       | 8                           | NO EFFECT | Don't know | NO           |
| 8       | 67  | M   | 82       | 136 | 80  | 78  | 76             | 75      | 79      | 78      | 76      | 76           | 136            | 124     | 128     | 300     | 100     | 98           | 80             | 78      | 76      | 64      | 60      | 60           | 60             | 58      | 58              | 64      | 62      | 62           | 9              | 8                       | 8                           | 8                            | 8       | 9                           | NO EFFECT | Don't know | NO           |
| 9       | 68  | M   | 98       | 136 | 94  | 75  | 98             | 98      | 96      | 96      | 96      | 96           | 148            | 148     | 140     | 140     | 140     | 140          | 94             | 92      | 92      | 92      | 90      | 90           | 76             | 76      | 76              | 76      | 76      | 76           | 8              | 8                       | 8                           | 8                            | 8       | 8                           | NO EFFECT | Don't know | NO           |
| 10      | 76  | F   | 96       | 138 | 86  | 68  | 88             | 95      | 94      | 94      | 94      | 94           | 138            | 138     | 138     | 138     | 138     | 138          | 86             | 86      | 86      | 84      | 88      | 88           | 68             | 68      | 68              | 68      | 68      | 68           | 8              | 8                       | 8                           | 8                            | 8       | 8                           | NO EFFECT | Don't know | NO           |
| 11      | 64  | F   | 96       | 144 | 78  | 76  | 96             | 98      | 98      | 98      | 98      | 98           | 144            | 148     | 148     | 148     | 148     | 148          | 78             | 78      | 78      | 74      | 76      | 76           | 76             | 74      | 74              | 74      | 74      | 74           | 8              | 8                       | 8                           | 8                            | 8       | 8                           | NO EFFECT | Don't know | NO           |
| 12      | 78  | M   | 88       | 166 | 94  | 72  | 96             | 98      | 96      | 100     | 98      | 98           | 140            | 138     | 136     | 98      | 134     | 134          | 94             | 92      | 92      | 92      | 90      | 90           | 72             | 70      | 68              | 68      | 68      | 68           | 8              | 9                       | 9                           | 8                            | 8       | 8                           | NO EFFECT | Don't know | NO           |
| 13      | 64  | M   | 90       | 130 | 80  | 90  | 90             | 88      | 88      | 86      | 85      | 85           | 130            | 132     | 130     | 130     | 138     | 138          | 80             | 76      | 74      | 70      | 75      | 75           | 90             | 94      | 90              | 90      | 90      | 90           | 9              | 8                       | 8                           | 8                            | 9       | 8                           | NO EFFECT | Don't know | NO           |
| 14      | 65  | F   | 86       | 176 | 94  | 88  | 88             | 82      | 82      | 86      | 80      | 80           | 144            | 138     | 128     | 128     | 128     | 128          | 94             | 92      | 88      | 90      | 90      | 90           | 94             | 92      | 90              | 86      | 86      | 86           | 8              | 7                       | 8                           | 8                            | 9       | 9                           | NO EFFECT | Don't know | NO           |
| 15      | 64  | F   | 92       | 164 | 80  | 80  | 88             | 86      | 84      | 80      | 80      | 80           | 165            | 160     | 155     | 150     | 150     | 150          | 80             | 80      | 78      | 78      | 78      | 78           | 88             | 88      | 86              | 88      | 85      | 76           | 8              | 8                       | 8                           | 8                            | 8       | 8                           | NO EFFECT | Don't know | NO           |
| 16      | 67  | M   | 82       | 136 | 80  | 78  | 76             | 75      | 79      | 78      | 76      | 76           | 136            | 124     | 128     | 300     | 100     | 98           | 80             | 78      | 76      | 64      | 60      | 60           | 60             | 58      | 58              | 64      | 62      | 62           | 9              | 8                       | 8                           | 8                            | 8       | 9                           | NO EFFECT | Don't know | NO           |
| 17      | 78  | M   | 98       | 146 | 94  | 88  | 98             | 88      | 86      | 86      | 84      | 96           | 148            | 148     | 140     | 140     | 140     | 140          | 94             | 92      | 92      | 92      | 90      | 90           | 76             | 76      | 76              | 76      | 76      | 76           | 8              | 8                       | 8                           | 8                            | 8       | 8                           | NO EFFECT | Don't know | NO           |
| 18      | 76  | M   | 96       | 138 | 86  | 68  | 88             | 95      | 94      | 94      | 94      | 94           | 138            | 138     | 138     | 138     | 138     | 138          | 86             | 86      | 86      | 84      | 88      | 88           | 68             | 68      | 68              | 68      | 68      | 68           | 8              | 8                       | 8                           | 8                            | 8       | 8                           | NO EFFECT | Don't know | NO           |
| 19      | 64  | F   | 96       | 144 | 78  | 76  | 96             | 98      | 98      | 98      | 98      | 98           | 144            | 148     | 148     | 148     | 148     | 148          | 78             | 78      | 78      | 74      | 76      | 76           | 76             | 74      | 74              | 74      | 74      | 74           | 8              | 8                       | 8                           | 8                            | 8       | 8                           | NO EFFECT | Don't know | NO           |
| 20      | 68  | M   | 88       | 140 | 94  | 72  | 96             | 98      | 9       | 100     | 98      | 98           | 140            | 138     | 136     | 98      | 134     | 134          | 94             | 92      | 92      | 92      | 90      | 90           | 72             | 70      | 68              | 68      | 68      | 68           | 8              | 9                       | 9                           | 8                            | 8       | 8                           | NO EFFECT | Don't know | NO           |