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Research Paper

A Comparative Evaluation of The Effect of Music Therapy, Noise Occlusion and Ambient Noise on Anxiety and Sedation Levels in Patients Undergoing Elective Lower Limb Orthopaedic Surgeries Under Combined Spinal Epidural Anaesthesia

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ABSTRACT

The purpose of the study was to determine the effect of music therapy on anxiety and sedation level of patients undergoing elective lower limb orthopaedic surgeries under combined spinal epidural anaesthesia in Deen Dayal Upadhyay Hospital, New Delhi. The study was designed as a prospective, randomised comparative study. The subjects consisted of 75 patients randomised into control group (C = 25), music group (M = 25) and noise occlusion group (N= 25). Data was collected over a period of one and half years from August 2017 to Feb 2019. After completion of the study a comparison of the haemodynamic parameters, respiratory rate, anxiety and sedation scores was done at different time intervals among the three groups to study the anxiolytic and sedative effects of music therapy. The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0. The hypothesis that patients who received Music therapy had less anxiety and higher sedation level than those who did not (group C and N) was supported ($p<0.05$). The second hypothesis that patients who were occluded from ambient OT noise (group N) had lesser anxiety was refuted ($p>0.05$) but higher sedation was supported ($p<0.05$). Hence our study concluded that patients scheduled to undergo elective surgery experience anxiety preoperatively. Listening to pre-selected slow rhythm music intraoperatively is effective in lowering the anxiety of patients and helps them fall asleep. Blocking ambient OT noise aids sedation but has no effect on anxiety of patients whereas exposure to ambient OT noise increases their anxiety as they may be aware of the OT proceedings throughout the surgery.

Keywords: *Evaluation, Music Therapy, Noise Occlusion, Ambient Noise, Anxiety, Sedation Levels, Lower Limb, Orthopaedic Surgeries, Spinal Epidural, Anaesthesia*

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A Comparative Evaluation of The Effect of Music Therapy, Noise Occlusion and Ambient Noise on Anxiety and Sedation Levels in Patients Undergoing Elective Lower Limb Orthopaedic Surgeries Under Combined Spinal Epidural Anaesthesia

Anxiety is an unpleasant emotional experience which may be defined as feelings of tension, apprehension and fear characterised by high autonomic activity. It varies in intensity and degree of fluctuation from time to time[1,2].

Anxiety influences the sympathetic nervous system which is manifested in the form of change in respiratory rate, heart rate and blood pressure[3-6]. Extreme forms of anxiety prior to surgical procedure lead to cardiovascular disturbances such as tachycardia, hypertension, arrhythmia, dizziness, nausea, headache and increase in postoperative pain. Studies have also demonstrated that pre and post-operative anxiety increase the requirement of anaesthetic drugs. Previous studies have shown that anxiety levels may lower the pain threshold, alter perception of pain and increase postoperative analgesic consumption. It has been reported that higher number of medical complications develop and post-operative hospital stay is prolonged in patients with a high level of preoperative anxiety. It causes elevation in the level of endogenous catecholamines, cortisol and natural killer (NK) cells which delays wound healing and recovery [7-12].

Anxiety in a patient scheduled to undergo surgery may be due to fear of acute pain, concern about treatment regimens, surgical failure, anaesthesia, financial burdens of care, disruption of personal / professional life and fear of death. The operating room environment, conversation between the staff, noise of operating instruments being assembled and intraoperative sawing, nailing etc. may further contribute to the anxiety of patients undergoing surgery especially under regional anaesthesia[13]. Patients in orthopaedic operation theatre (OT) are especially exposed to significant noise pollution due to the use of power instruments. Noise especially unexpected high intensity sound acts as biological stressor producing startle response and activates fight or flight response of the autonomic and endocrine system. Exposure to noise can also cause psychological stress and anxiety[14,15].

Efforts have to be made towards alleviating anxiety in perioperative period. Pharmacological agents like benzodiazepenes and opioids are employed to alleviate this anxiety. They help in calming the patients but their doses are kept low to avoid side effects. Opioids may cause cardiovascular and respiratory depression, constipation, biliary colic, retention of urine, nausea and vomiting and the like. Benzodiazepenes may cause fatigue, decreased motor coordination, impairment of cognition and gait abnormalities [16, 17].

A number of non-pharmacological means like meditation, acupuncture, naturopathy, lifestyle modifications and music are now being evaluated for relieving anxiety, stress and pain during perioperative period as they are safe and non-interfering with the normal physiology of the body[18]. Continuous information and opportunity to ask questions also reduces patient's anxiety[19].

Music is one such inexpensive, non-invasive, non-pharmacological method for anxiety reduction with characteristic calming, soothing effects and no major side effects. Music has found its application during various outpatient and minor procedures, intensive care units, cancer wards, labour rooms and has been seen to reduce the stress and anxiety in patients. Music therapy has decreased sedative and analgesic requirement pre and post operatively. Many branches in medicine especially neurology and psychology have compared music with low dose anti-anxiety medication in efficacy. Besides elimination of ambient noise using ear

plugs or sound cancellation devices has also been observed to be effective in lowering the anxiety of patients [20-25]

Aim and Objectives

Aim:

To compare the anxiety and sedation levels in patients undergoing elective lower limb orthopaedic surgeries under combined spinal epidural anaesthesia exposed to ambient noises, with patients occluded from ambient noises via noise cancelling headphones and with patients receiving music therapy via noise cancelling headphones.

Objectives:

Primary objectives

1. To measure the anxiety and sedation scores in patients of all three groups.
2. To observe the haemodynamic parameters in patients of all three groups.

Secondary objective

- To observe untoward incidents if any.

MATERIALS AND METHODS

Design, Setting and Participants

A three group Prospective, Randomised, Comparative Study design was used. Participants were 75 patients scheduled for elective lower limb orthopaedic surgeries at Deen Dayal Upadhyay Hospital (DDUH), Hari Nagar, New Delhi**.** The participants were randomised into three groups.

- Group M : Receiving music therapy via noise cancellation headphones
- Group N : Occluded from ambient OR noises by noise cancellation headphones.
- Group C : Exposed to ambient noises.

Inclusion criteria were patients of age 18-65 years, both sexes, ASA grade I and II. Patients not giving consent for participation, Patients with history of difficulty in hearing, Patients with previous diagnosis of anxiety or depression and on psychiatry treatment, Patients with cognitive impairment, Patients with any contraindication to neuraxial anaesthesia, Patients with a dislike for music, Acute trauma patients with duration of injury less than 7 days, Patients being converted to general anaesthesia from combined spinal epidural anaesthesia, Patients with haemodynamic instability arising from surgical complications intraoperatively were excluded from the study.

Pre Anaesthesia Check-Up Protocol:

Asa per institutional guidelines

Special study requirements:

- Portable music player (Philips Go Gear mix Mp3 player).
- Noise cancellation headphones (Sony MDR-ZX110NC on-ear noise cancellation head phones)
- Music of patient's choice from given options (selection of devotional music or instrumental music played on loop).

METHODOLOGY

The patients were explained the procedure of the study in the pre-operative area where they were told that noise cancellation headphones may or may not be applied to their ears during the surgery in which they may or may not hear music. They were also made to hear pre-determined different kinds of music to allow them to decide their preferred choice of music and volume in case they fall in the music group. The music largely comprised of devotional songs or soft and soothing instrumental music Allocation of groups was done by computer generated randomization table into group M (music group), group N(noise occluded group)and group C (control group exposed to ambient noises). Preoperative vitals, anxiety scores (As per the State Trait Anxiety Inventory) and sedation scores (As per the Observer's Assessment of Alertness/Sedation Score) were recorded in preoperative area by me, henceforth referred to as the observer, after receiving training for the same by a qualified Psychiatrist of the hospital. The STAI[31,32] is a self-report measure consisting of a 20 items in state portion which assesses how the patient feels at a particular moment about an event. In the state portion of STAI, ten statements express anxiety(item number 3,4,6,7,9,12,13,14,17 and 18) while the remaining 10 statements (item number 1,2,5,8,10,11,15,16,19 and 20)represent the relaxed and pleasant state of the patient. These statements are arranged randomly and each statement has responses rating patient's state of mind on a 4 point scale (1=not at all, 2= somewhat, 3= moderately so, 4= very much so). Patients were asked to pick any one response for each statement. Scoring was done manually. During scoring points were given between 1 and -1 or 4 and -4 depending on the positive or negative characteristic of the item, and an extra 50 points were added to the total score. The score of STAI ranges from a maximum of 80 to a minimum score of 20. High final score (STAI score $\geq$ 44) indicates intense anxiety whereas low score (STAI score <44) reflects no anxiety.

The observer's assessment of alertness/sedation score[49] reflects the decreasing response of patients to increasing intensity of stimulus as the sedation level increases which is scored between a maximum of 5(fully alert) and a minimum of 0(fully sedated).

The observer recorded the hemodynamic parameters and respiratory rate of the patient till patient was positioned for surgery. Once the positioning for surgery was done the observer assessed the STAI and OAA/S score before onset of surgery. All patients, irrespective of the group to which they belonged, were given 0.1 mg/kg dose of Inj. Midazolam, Inj. Ondansetron 0.08mg/kg and Inj. Ranitidine 1mg/kg. Thereafter, on the basis of the group assigned to the patient as per computer generated randomization, the observer applied headphones to patients of group M in which pre-decided music of choice played at a volume adjusted according to patient's comfort pre-decided in the preoperative area by the patient himself/ herself. Noise cancellation headphones were applied to group N to eliminate the ambient noises but no music was started. Group C patients received standard OT care. No headphones were applied and they were exposed to all ambient OT noises. Thus, the observer was not blinded to group assignment. Surgery was initiated. Appropriate IV fluids were given as per the individual requirements. The observer recorded the intraoperative haemodynamic parameters at the predecided intervals.

The Noise cancellation headphones with or without music were applied to the intervention groups M and N only after administration of neuraxial block and appropriate positioning till the completion of surgery. Same noise cancellation headphones and Mp3 player was used in all patients of group N and group M.

All the groups received the standard OT care during surgery. Epidural test dose with inj lignocaine + adrenaline and top up with 0.5%-0.125% bupivacaine (isobaric) was given as per routine protocol of the hospital for efficient analgesia throughout surgery.

At the end of surgery noise cancellation-headphones were removed ensuring minimal stimulation and the observer assessed the sedation score and the anxiety score of the patient were recorded before shifting the patient out of the OT.

Evaluating Parameters

After completion of the study a comparison of the haemodynamic parameters, respiratory rate, anxiety and sedation scores was done at different time intervals among the three groups to study the anxiolytic and sedative effects of music therapy.

Statistical Analysis

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean ± SD and median. Normality of data was tested by Kolmogorov-Smirnov test. If the normality were rejected then non parametric test was used. Statistical tests applied were as follows-

1. Quantitative variables were compared using unpaired t-test/Mann-Whitney Test (when the data sets were not normally distributed) among the three groups and Paired t-test/ Wilcoxon test within the groups across follow-ups.
2. Qualitative variables were compared using Chi-Square test /Fisher's exact test.

A p-value of < 0.05 was considered statistically significant.

The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

RESULTS

Baseline data

Table 1: Patient distribution.

Study Group	Sample Size	%
M	25	33.33
N	25	33.33
C	25	33.33

The data is expressed in numbers and percentage

Table 2: Comparison of mean age (in years)

Variable	Group			Total	p-value
Age	**M**	**N**	**C**		
Mean ± SD	41.6 ± 14.91	45.64 ± 13.46	43.2 ± 14.15	43.48 ± 14.09	0.600

The table is expressed in Mean ±SD, p-value <0.05 is significant

Table 3:-Comparison of gender

Variable	Group			Total	p-value
Gender	**M**	**N**	**C**		
Female	10	5	6	21	0.249
Male	15	20	19	54	
Total	25	25	25	75	

The table is expressed in number of patients, p-value <0.05 is significant

Vital parameters

Heart Rate

Figure 1 show the comparison of the mean heart rate between groups.

Patients of group M showed a statistically significant decrease in the mean heart rate starting from 30 minutes after the application of intervention till the end of surgery at all time intervals (p-value <0.05) in comparison to group N and C. However no statistically significant difference was observed in the mean heart rate on comparing groups N and C at any time interval (p-value >0.05).

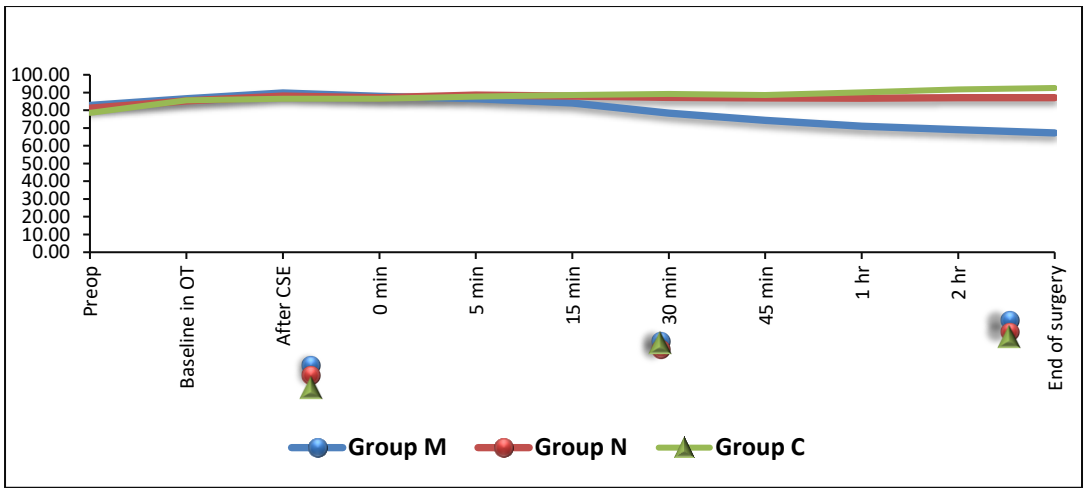

Figure 1 Comparison of mean heart rate trend between groups

Figure 2 shows the comparison of mean SBP between the groups.

A statistically significant reduction in the mean SBP of group M was observed starting from 30 minutes after intervention till the end of surgery at all time intervals as compared to group C (p-value < 0.05). On comparing group M with group N the reduction in mean SBP of group N was statistically significant after 45 minutes at all time intervals till the end of surgery (p-value < 0.05). The mean SBP of group N was lower than that of group C starting from 45 minutes after intervention till the end of surgery at all time intervals and the difference was statistically significant (p-value <0.05)

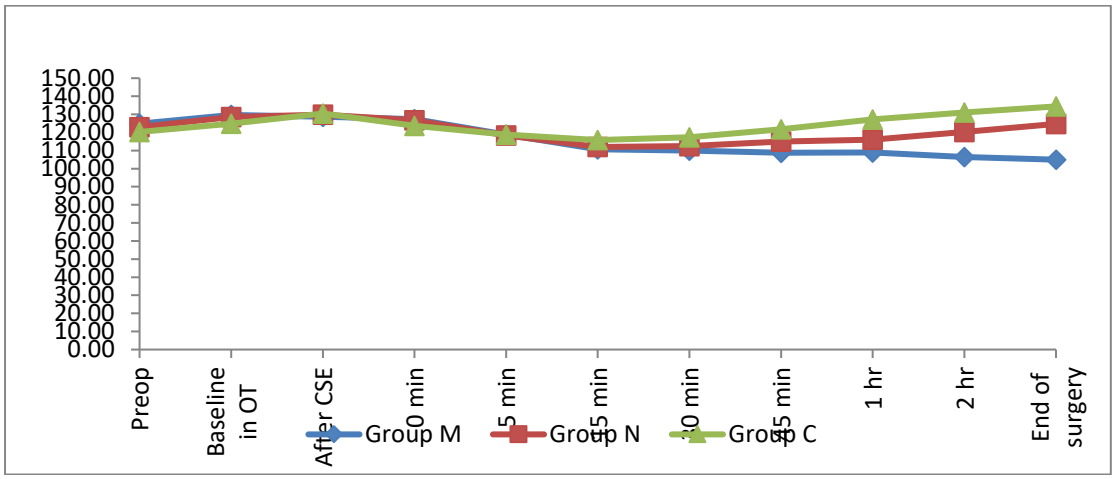

Figure 2 comparison of mean SBP trend between groups

Figure 3 show the comparison of mean DBP between groups.
A statistically significant reduction in the mean DBP of group M was observed starting from 30 minutes after intervention till the end of surgery at all time intervals as compared to group C (p-value < 0.05). On comparing group M with group N the reduction in mean DBP of group N was statistically significant starting from 45 minutes after intervention till the end of surgery at all time intervals (p-value < 0.05). The mean DBP of group N was lower than that of group C starting from 30 minutes after intervention till the end of surgery at all time intervals and the difference was statistically significant (p-value <0.05)

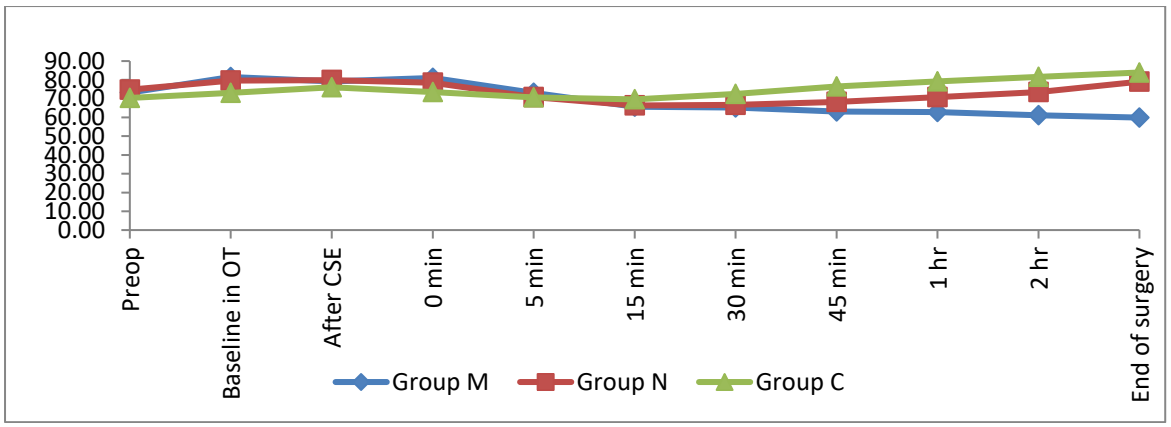

Figure 3 comparison of mean DBP trend between groups

Figure 4 shows the comparison of mean MAP between groups.
A statistically significant reduction in the mean MAP of group M was observed starting from 30 minutes after intervention till the end of surgery at all time intervals as compared to group C (p-value < 0.05). On comparing group M with group N the reduction in mean MAP of group N was statistically significant 45 minutes after intervention at all time intervals till the end of surgery p-value < 0.05). The mean MAP of group N was lower than that of group C starting from 30 minutes after intervention till the end of surgery at all time intervals and the difference was statistically significant (p-value <0.05)

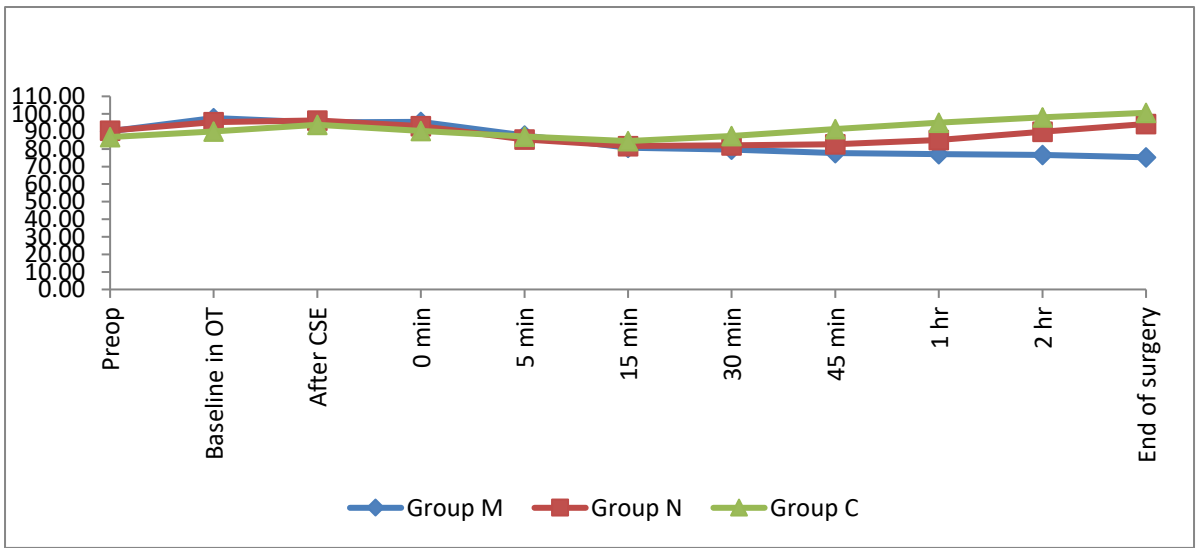

Figure 4 comparison of mean MAP trend between groups

Figure 5 show the comparison of mean RR between groups.
A statistically significant reduction in the mean RR of group M was observed starting from 15 minutes after intervention till the end of surgery at all time intervals as compared to both group N and group C (p-value < 0.05). The mean RR of group N was lower than that of group C starting from 15 minutes after intervention till the end of surgery at all time intervals and the difference was statistically significant (p-value <0.05)

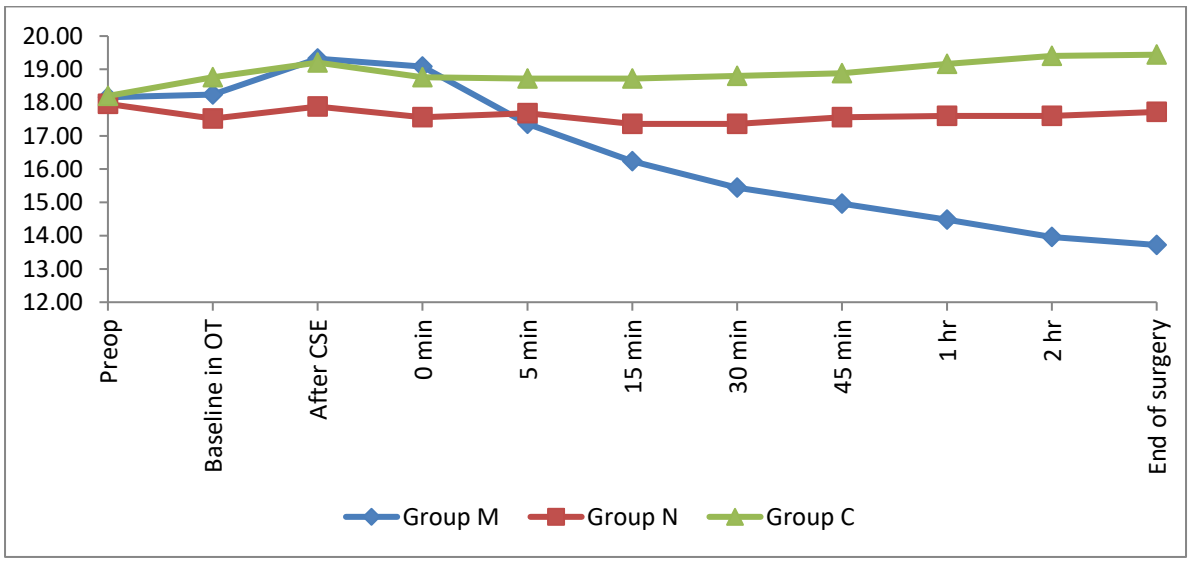

Figure 5 comparison of mean RR trend between groups

Figure 6 shows the comparison of mean STAI score between groups.
The STAI score is a self-report measure of anxiety. It consists of 20 items on a 4 point likert scale. On calculating the total score if its value is ≥ 44 then the patient is said to have anxiety whereas if the total score is <44 then there is no anxiety.

Preoperatively the mean STAI score was 52.16 ± 5.19 for group M, 50.64 ± 4.76 for group N and 51.2 ± 5.72 for group C. Thus, all the patients in the three groups were anxious and the difference between groups was not statistically significant (p-value >0.05)

The mean STAI score inside the OT just prior to onset of surgery was 52.16 ± 5.19 for group M, 50.64±4.76 for group N and 52±5.52 for group C. Thus, all the patients were anxious but the difference between groups was not statistically significant (p-value >0.05).

The mean STAI score just prior to completion of surgery was 42.2±3.67 for group M, 50.76±4.77 for group N and 53.72±5.71for group C. There was statistically significant reduction in the mean STAI score of group M as compared to group N and C (p-value <0.05). However there was no statistically significant difference in the mean STAI score between group N and group C (p-value >0.05).

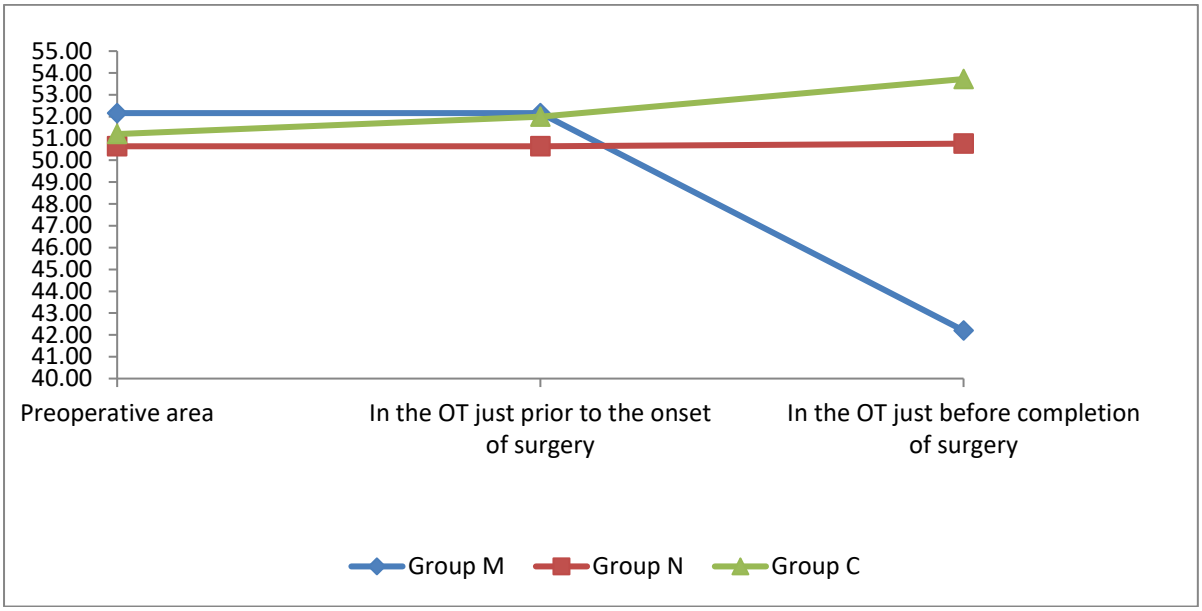

Figure 6 Comparison of mean STAI score trend between groups

Figure 7 shows the comparison of mean OAA/S score between groups. Figure 8 shows the mean OAA/S scores of patients in OT just before completion of surgery.

Just before completion of surgery the OAA/S score of group N was 4 in 28% patients and 5 in 72% patients. The reduction in the score was statistically significant (p-value <0.05) in comparison to group C. The reduction in the mean OAA/S score of group N just before the completion of surgery in comparison to the preoperative mean OAA/S score was statistically significant (pvalue <0.05).

In patients of group C the OAA/S score remained unchanged (score = 5) in 100% patients till just before completion of surgery.

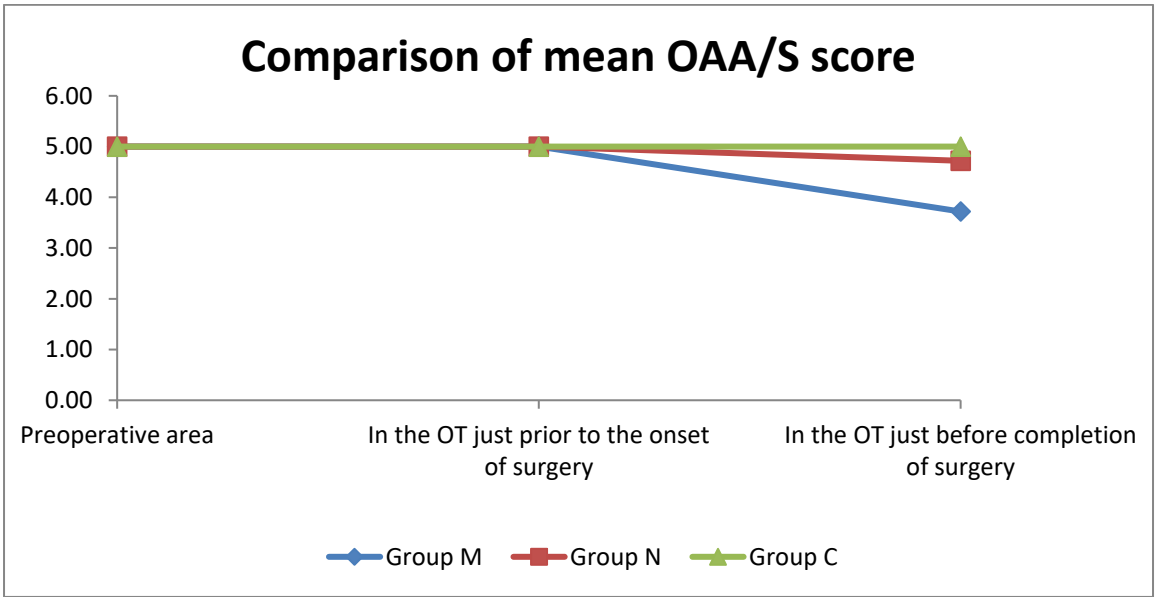

Figure7 comparison of mean OAA/S score trend

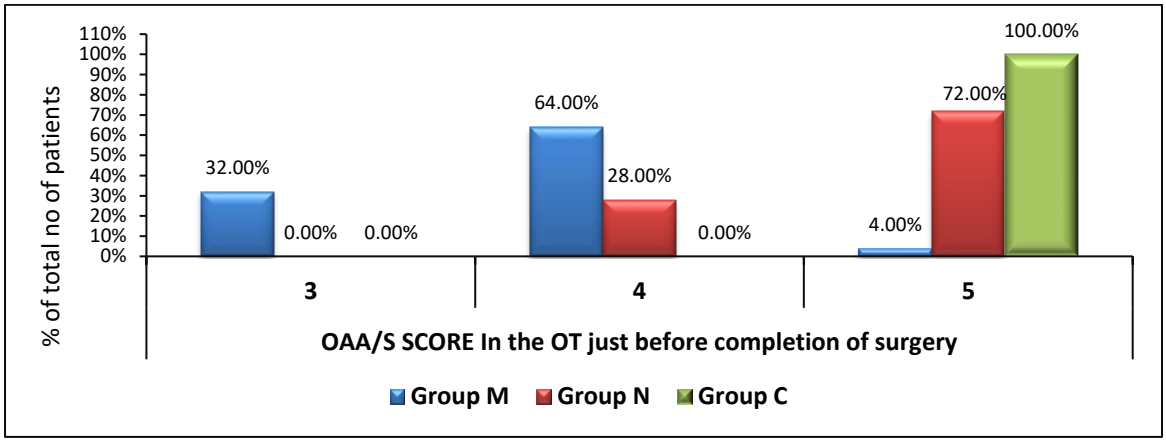

Figure 8 mean OAA/S scores of patients in OT just before completion of surgery.

DISCUSSION

Perioperative period is stressful for patients and induces intense anxiety among them as has been demonstrated by various studies. This anxiety has been related to several factors that include fear of pain, fear of complications during surgery, NPO status and concerns about outcome of surgery. The patients undergoing orthopaedic surgeries are especially distressed due to their bed ridden status which hampers their daily living.

Most of the orthopaedic surgeries of lower limb are done under neuraxial blockade. The intraoperative sounds of conversations of the OT staff or the noise of power operated machinery like sawing or drilling and hammering may further increase their anxiety leading to increased requirement of pharmacological agents for anxiolysis and sedation. Most frequently used pharmacological agents are benzodiazepenes and opioids which have a number of side effects. Opiods may cause cardiovascular and respiratory depression, constipation, biliary colic, retention of urine, nausea and vomiting and the like. Benzodiazepenes may cause fatigue, decreased motor coordination, impairment of cognition and gait abnormalities[16,17].

It has been postulated that non pharmacological means of anxiolysis and sedation like accupuncture, meditation, yoga, music therapy etc can be effective alternatives to the pharmacological methods. Music has been an integral part of our culture over centuries. It has been an ancient means of entertainment and relaxation which is still not outdated. Music provides pleasure, soothes the mind and creates a distraction that interrupts the negative thoughts of patients scheduled for surgery. It creates a positive frame of mind among patients and hence lowers their anxiety.Various studies have been done in the past to demonstrate anxiety among patients and the positive effect of music therapy on the this anxiety. [18-24].

In our study we compared the effect of music therapy and noise occlusion on the anxiety and sedation levels of patients undergoing lower limb orthopaedic surgeries under CSE with those exposed to ambient OT noise while undergoing the same type of surgeries under CSE. Seventy five patients scheduled for elective lower limb surgeries to be done under CSE were randomised in three groups of 25 patients each. One group received music therapy intraoperatively, one group received noise occlusion and the third group was exposed to ambient OT noise.

Demographic data

In our study the demographic data was comparable for age, sex and education between the groups and the differences were statistically not significant (p-value >0.05).

Choice of music

In our study we used either devotional songs (chosen by patients according to their religious faith Gayatri Mantra, Hey Ram, Ik Omkar, Silent Night) or instrumental music which played on loop throughout the surgery. All the songs on the playlist had a slow rhythm and low beats. Goel N *et a*l[39] conducted a study on effects of devotional music on the cardiovascular system and proved that devotional music has a positive effect on human psychology as compared to rock, pop, jazz or disco music. Syal K *et al*[45] conducted a study to study the effects of music therapy in relieving anxiety in patients undergoing surgery and used three types of music (spiritual, folk or Bollywood songs) and the music was selected by patients as per their preference.

Vital parameters

When the hemodynamic parameters were studied, we found a statistically significant reduction in the HR, SBP, DBP, MAP and RR (p-value <0.05) of group M 30 minutes after intervention at all time intervals till the end of surgery. This indicated a reduction in anxiety and increased sedation in patients of group M. The parameters like HR, SBP, DBP, MAP and RR were higher at the end of surgery for group N and C as compared to preoperative values and this difference was statistically significant (p-value <0.05)

Bansal P *et al*[41] conducted a study on patients undergoing surgery under SAB to assess the effect of music therapy hemodynamic parameters. They observed that SBP and DBP were comparable between the music and control group (p-value >0.05).

Pamela G binis *et al*[46] conducted a study on the effects of music therapy on hemodynamics of women undergoing mastectomy and observed there was a significant reduction in MAP of music group patients (98.7± 15.7 to 83.6± 13.0, p-value <0.05) but the difference of HR was not statistically significant (p-value >0.05).

Drubajyoti *et al*[47] studied the effect of music therapy on patients undergoing orthopaedic surgery under SAB. They compared two groups - music intervention and control. No statistically significant change was observed in hemodynamic parameters (p-value >0.05) . Syal K *et al*[45] studied the effect of preoperative music therapy on patients and found that there was a significant reduction in heart rate (85.28 ±8.432 to 79.42±7.262, p-value <0.05) and MAP (84.70±8.428 to 80.20±7.557, p-value <0.05) in the intervention group as compared to control group.

Mustafa Karalar *et al*[48] conducted a study to assess the effects of music and noise-canceling headphones (NCHs) on perceived patient pain and anxiety from extracorporeal shockwave lithotripsy (SWL). Respiratory parameters were recorded before and just after the SWL session. They found no statistical difference with respect to heart rate etween the groups.

We found a statistically significant reduction in the mean RR of group M while there was a statistically significant increase in the mean RR of the other two groups. This can be attributed to the calming effect of music.

Anxiety scores

In our study we recorded the anxiety score of patients in the preoperative area using STAI. It was observed that all the patients had anxiety irrespective of the group they belonged to and the differences between the mean anxiety score of the three groups were not statistically significant (p-value >0.05).

The patients were taken to OT and after successful administration of anaesthesia and positioning for surgery the anxiety score was assessed again. No statistical difference was observed in the mean anxiety score from the preoperative value for any group (p-value >0.05). Thereafter the anxiety score was assessed just before completion of surgery. It was found that the mean anxiety score of group M was significantly lowered (52.16 ± 5.19 to 42.2 ± 3.67, p-value <0.05), remained similar for group N (50.64 ± 4.76 versus 50.76 ± 4.77, p-value>0.05) and was significantly higher for group C (51.2 ± 5.72 to 53.72 ± 5.71, p-value <0.05) as compared to preoperative mean anxiety score.

A N Karanci *et al*[26] conducted a study to compare the preoperative and post-operative anxiety among patients scheduled for surgery using the STAI score and found that patients had significant anxiety in preoperative area (49.52±11.3) which was higher than in the post-operative area(42.99±5.9). They concluded that the reduction in mean anxiety score of patients in the post-operative period may be due to the feeling of relief experienced by patients on completion of the procedure. Keeping this in mind we planned our study in a such a manner that we assessed the anxiety scores just before the completion of surgery when the patient was not aware that the surgery is ending. In this way we could study the isolated effect of intervention on the anxiety level of patients and eliminate the effect of relief experienced on completion of surgery by the patients. We found that there was a statistically significant reduction in the anxiety of patients belonging to group M (p-value <0.05).

Y M Chan *et al*[40] studied the impact of music on anxiety in patients undergoing colposcopic examination. The patients were divided into two groups (music and control). In the music group music was played during examination. They concluded that patients experienced lower anxiety (mean STAI 39.36 versus 44.16, p-value <0.05) if they were in the music group as compared to control group. Thus the results of our study are consistent with this study.

Kartik syal et al[43] studied the effect of music therapy on patient's anxiety using the visual analogue scale indicating the intensity of anxiety on a scale of 1 to 4. They administered music to patients in the intervention group atleast 30 minutes prior to surgery. The patients were shifted to OT while listening to music and listening continued during administration of spinal anaesthesia till the end of surgery. They found that there was a significant reduction in anxiety of patients belonging to music group (2.88±0.627 to 1.76 ± 0.59. p-value <0.05) as compared to control group in which an increase in anxiety was observed (2.74± 0.487 to 2.92 ±0.52, p-value <0.05). These results are consistent with our study.

Pamela G binis *et al*[44] conducted a study on the effects of music therapy on the anxiety level of women undergoing mastectomy. Music was applied to patients in the music group throughout the preoperative, intraoperative and postoperative period. They found that there

was a significant reduction in mean anxiety scores of music group (41.5± 15.8 to 30.7± 12.3, p-value <0.05) as compared to the control group. These results are consistent with our study.

Drubajyoti *et al*[45] studied the effect of music therapy on patients undergoing orthopaedic surgery under SAB and compared music intervention and control group where music was initiated after successful administration of spinal anaesthesia and lasted till the end of surgery. They observed the Visual analogue scale for anxiety (VASA) in preoperative (VASA 1) and postoperative period (VASA 2). As per their results there was a statistically significant reduction in anxiety among music group patients (VASA1 verses VASA 2 p-value <0.05). These results are consistent with our study.

In our study the intervention was applied in the intraoperative period after successful administration of CSE and positioning of patient. Intervention was discontinued just before the completion of surgery. This was done to avoid disruption in the intervention during patient transport to OT and during administration of anaesthesia which requires conversation with the patient.

Sedation scores

We used the Observer's assessment of alertness and sedation score (OAA/S) to assess the level of sedation. In the preoperative area and in the OT just before onset of surgery all the patients were alert having a mean OAA/S score of 5. Thereafter intervention was applied in group M and group N while group C was given standard OT care. To maintain uniformity all the patients were given weight adjusted dose of inj. Midazolam as an institutional protocol.

A statistically significant reduction in the mean OAA/S score was observed in group M (5 ± 0 to 3.72 ± 0.54, p-value <0.05) but none of the patient was so sedated that he/she was unable to report the anxiety score assessed soon after. In our study the lowered mean OAA/S score in group M indicates the sedative effect of music. A statistically significant reduction in the mean OAA/S score was observed in group N as well (5± 0 to 4.72 ±0.46, p-value <0.05). In group C no statistically, significant change was observed in the mean OAA/S score (p-value >0.05).

Vijay sharma[13] studied the efficacy of music therapy in lowering intraoperative sedative requirement. He found that the mean dose of midazolam needed in the control group was 2.91± 0.54 mg which was higher as compared to 1.13± 0.36 mg required in the music group and this difference was statistically significant (p-value <0.05) concluding that the sedative requirement is lowered in the music group.

Bansal P et al[41] conducted a study on patients undergoing surgery under SAB to assess the effect of music therapy on sedation requirements. They demonstrated that the requirement of midazolam in patients listening to music intraoperatively was lower to maintain a desired level of sedation (2.17± 0.53 mg versus 3.25± 0.77mg; p-value <0.05). The results of these studies are consistent with our study.

A statistically significant reduction in the mean OAA/S score was observed in group N as well (5± 0 to 4.72 ±0.46, p-value <0.05) indicating that occlusion of noise also made the patient comfortable enough to fall asleep during surgery. We could not come across any

study which observed the effect of noise occlusion on the sedation in regional anaesthesia cases. JG kang[25] conducted a study on 63 patients undergoing total knee replacement under CSE with propofol sedation maintaining a desired sedation level to determine the effect of music, silence and OT noise on the BIS score of patients. They found that sound level was highest when the saw (T3,80.25 dB) and the impact device (T4,80.98 dB) were in use. Bispectral index scores in the silence group during those times (T3, 68.5 vs 76.9, P = 0.025, and T4, 67.6 vs 78, P = 0.005) were lower than in the noise group. However, BIS scores were similar in the noise and music groups. They concluded that it was more effective to block noise than playing music in reducing BIS scores during propofol sedation in a noisy environment.

CONCLUSION

In this prospective, randomised, comparative study on the evaluation of the effect of music therapy, noise occlusion and ambient OT noise on the anxiety and sedation level of patients undergoing elective lower limb orthopaedic surgeries, we conclude the following:

- Patients in all the three groups experienced anxiety preoperatively.
- The level of anxiety at the end of surgery was significantly lower in group M as compared to group N and C. However no significant difference was observed between group N and group C.
- On comparing it's value with preoperative score, the level of anxiety at the end of surgery was significantly lower in group M, similar in group N and significantly increased in group C.
- The level of sedation was enhanced in group M and N at the end of surgery as compared to preoperative observation.
- The haemodynamic and respiratory parameters were significantly lowered in group M at the end of surgery as compared to preoperative values. Significant increase was observed with respect to these parameters in group N and C

Thus, we conclude that intraoperative music therapy via noise cancelling headphones is an effective, inexpensive, safe and easily available non pharmacological alternative to anxiolytics and sedatives. Blocking the ambient noise aids in sedation but is not an effective alternative for anxiolysis.

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Conflict of Interest
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