

**TITLE: Effect of music on anxiety levels in patients undergoing Refractive surgery.**

**MANUSCRIPT TYPE:** Original article

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TITLE: Effect of music on anxiety levels in patients undergoing Refractive surgery

**ABSTRACT:**

**AIM:** To evaluate the effect of music on the anxiety levels and vital parameters of patients undergoing refractive surgery under topical anaesthesia.

**METHODS:** After screening for inclusion and exclusion criteria, we included 100 participants undergoing refractive surgery for the study. The participants were randomly assigned into music group and control group with 50 participants each. Anxiety levels were assessed using State-Trait Anxiety Inventory (STAI) questionnaire before and after the music therapy. Vital parameters (heart rate and blood pressure) was recorded pre-operatively and intraoperatively. The data was compared and analysed.

**RESULTS:** There were 50 patients each in music and control group with similar demographic profile and baseline STAI-S score. The music group reported a reduction in anxiety score following 1-hour of pre-operative music therapy, but the difference was not statistically significant (P-value = 1.18). Mean heart rate during surgery was lower in music group ( $91.7 \pm 24.75$ ) compared to control group ( $97 \pm 7.07$ ) and this difference was statistically significant (P-value < 0.05). No significant difference was found between groups in blood pressure.

**CONCLUSION:** Listening to music preoperatively can alleviate patient's anxiety and improve the patient satisfaction with the procedure.

**KEY-WORDS:** Music; Refractive surgery; STAI-S; anxiety;

## **INTRODUCTION:**

Refractive surgery has now been established as fairly safe procedure that produces excellent visual outcomes for patients with ametropia.<sup>1</sup>

Surgical experience is an anxiety-provoking event. Reports suggest that a significant number of patients experience high levels of anxiety before undergoing surgery.<sup>2</sup> This phenomenon of perioperative anxiety may be related to strangeness of the hospital environment, lack of knowledge regarding the procedure, uncertainty of the outcome, fear of pain and death and worry of recovery process. High levels of anxiety may result in need for sedative and analgesics, more difficult procedure and increased likelihood of medication-related complications.<sup>3-4</sup>

Currently various modalities are being used to reduce anxiety including psychological preparation, anxiolytic pre-medication, use of intraoperative sedatives and hypnotics to supplement local or regional anaesthesia.<sup>5</sup> Many studies have examined how music affects people's thought processes and physical functions.

Music has well established psychological effects, including the induction and modification of moods and emotions and healing is considered its natural quality.<sup>6</sup> Neuroscientific studies have shown that music is capable of influencing complex neurobiological processes in the brain and thus it can potentially play a role in treatment. Clinical studies provide some evidence that music therapy can be used as an alternative therapy in treating depression, autism, schizophrenia as well as problems of anxiety, agitation and insomnia.<sup>7</sup> During the Second World War, Harriet Ayer Seymour implemented music therapy visits in hospitals and trained more than 500 doctors for this purpose.<sup>3</sup>

The role of music in the treatment of preoperative anxiety has been well documented. Evidence shows that music can substitute anaesthetic medicines during surgeries. Various reports have shown that introduction of relaxing music at the pre-operative stage significantly reduces anxiety in patients undergoing minor surgical procedures compared with administration of midazolam.<sup>8</sup>

Since loss of vision is one of the most feared disabilities, people are highly concerned about the procedures involving their eyes. Also, patient cooperation is an uncompromisable factor in ophthalmic surgeries. Studies on the effects of music in patients undergoing Ophthalmic surgeries have shown varied outcomes. Bellan et al reported a large-scale study of 144 patients undergoing cataract surgery and found that listening to music before surgery was associated with decreased anxiety.<sup>5</sup> Cruise et al found similar results in a cohort of 121 patients undergoing cataract surgery under retrobulbar block who were more satisfied with their experience if they listened to relaxing music rather than operating room noise alone during the surgical procedure.<sup>9</sup>

## **METHODOLOGY:**

This two-armed, parallel design randomized control trial was approved by the institutional ethics committee and adhered to the tenets of the Declaration of Helsinki. During the study period September 2020 to December 2020, patients attending for scheduled, elective refractive surgery were identified and given information on the study. The persons included in the study were those who showed willingness to listen to music. A written consent was

obtained from the study participants. The persons with hearing disorders, communication problems, on sedatives and anxiolytic medications, presence of other ocular disorders and unwilling to participate were excluded from the study.

Participants were randomized using computer-generated random numbers to either the interventional group (“Music group”) or the control group. This design is guided by the CONSORT checklist. (Figure 1).

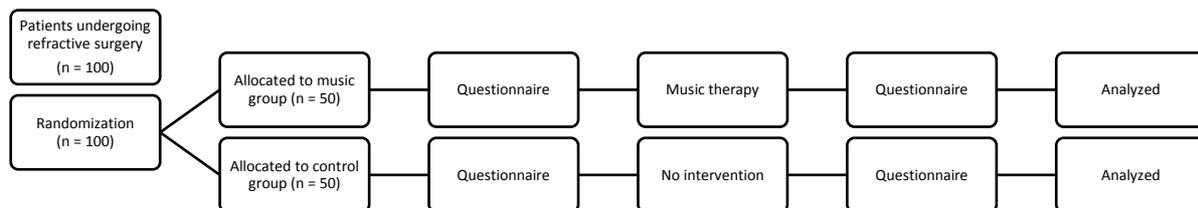


Figure 1: Consolidated Standards of Reporting Trials (CONSORT) flowchart of participant involvement.

Anxiety scores were determined by the traditional validated tool, the State-Trait Anxiety Inventory (STAI). All patients completed a baseline state-portion of STAI assessment 1 hour prior to the surgery. The participants of music group were made to listen to music of their choice at a self-selected volume through their personal headphones for a duration of one hour. Participants of both the groups completed another set of STAI-S questionnaire just before entering the Operating room (OR). The average score before and after the intervention will be compared and analysed between the two groups.

The State-Trait Anxiety Inventory (STAI) is a 40-item self-report measure that contains 20 items measuring state anxiety and 20 items measuring trait anxiety<sup>(10)</sup>. (Figure 2) Total scores for state and trait sections separately range from 20 to 80, with higher scores denoting higher levels of anxiety.

#### State-Trait Anxiety Inventory (state portion)

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then *circle* the appropriate number to the right of the statement to indicate *how you feel right now*, that is, *at this moment*. There is no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

Statement	Not at all	Some what	Moderately so	Very much so
(1) I feel calm	1	2	3	4
(2) I feel secure	1	2	3	4
(3) I am tense	1	2	3	4
(4) I feel strained	1	2	3	4
(5) I feel at ease	1	2	3	4
(6) I feel upset	1	2	3	4
(7) I am presently worrying over possible misfortunes	1	2	3	4
(8) I feel satisfied	1	2	3	4
(9) I feel frightened	1	2	3	4
(10) I feel comfortable	1	2	3	4
(11) I feel self-confident	1	2	3	4
(12) I feel nervous	1	2	3	4
(13) I am jittery	1	2	3	4
(14) I feel indecisive	1	2	3	4
(15) I am relaxed	1	2	3	4
(16) I feel content	1	2	3	4
(17) I am worried	1	2	3	4
(18) I feel confused	1	2	3	4
(19) I feel steady	1	2	3	4
(20) I feel pleasant	1	2	3	4

## Figure 2: State portion of Spielberger State-Trait Anxiety Inventory (STAI-S)

The secondary outcome measures are vital parameters (heart rate, systolic blood pressure and diastolic blood pressure) recorded by a monitor. Data was collected just before entering the OR and during the procedure.

All the participants of the study underwent the refractive surgery according to Standard care. All procedures were performed by a single surgeon utilizing topical anaesthesia. No systemic drugs (Ex. Anxiolytics) were administered as adjuvant therapy.

The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0. Categorical variables are presented in number and percentage (%) and continuous variables are presented as mean  $\pm$  SD and median. Normality of data was tested by Kolmogorov-Smirnov test.

Quantitative variables was compared using paired t-test between pre and post. Qualitative variables was compared using Chi-Square test. A p value of  $<0.05$  was considered statistically significant.

### **RESULTS:**

A total of 100 participants (50 music versus 50 control) completed the study. The mean age of the participants for the music and control group were  $24.5 \pm 2.12$  and  $20.5 \pm 0.71$  respectively. Demographics can be found in Table 1. Statistical analysis of these values shows that the groups were similar.

TABLE 1: Demographics and type of surgery

	Study Group	Control Group	P-value
Mean age	$24.5 \pm 2.12$	$20.5 \pm 0.71$	0.22 <sup>#</sup>
Male: Female	24:26	21:29	0.55*
Type of refractive surgery			0.90*
SMILE	15	14	
LASIK	30	32	
PRK	5	4	
TOTAL	50	50	

# Paired t-test

\*Chi-square test

The baseline STAI-S score for the music and control group were  $51.18 \pm 6.36$  and  $48.88 \pm 7.11$ . No significant difference was noted between the two groups. The baseline heart rate, systolic blood pressure (SBP) and diastolic blood pressure (DBP) in the music and control group were  $76 \pm 11.31$  and  $77 \pm 7.07$  per minute,  $111 \pm 12.73$  and  $120 \pm 14.14$  mm Hg,  $74 \pm 2.83$  and  $80 \pm 14.14$  mm Hg, respectively, with no significant difference between the two groups. (Table 2)

TABLE 2: Baseline parameters

Parameter	Study group	Control group	P-Value
(a) Mean pulse rate	$76 \pm 11.31$	$77 \pm 7.07$	2.01

(b) Mean SBP	111 ± 12.73	120 ± 14.14	0.20
(c) Mean DBP	74 ± 2.83	80 ± 14.14	0.36
(d) STAI-S score	51.18 ± 6.36	48.88 ± 7.11	0.07

After music intervention, lesser anxiety was reported by the music group compared to the control group ( $37.5 \pm 4.95$  versus  $49.36 \pm 7.73$ ), although the difference was not statistically significant ( $p=1.18$ ). (Table 3) The mean heart rate during the procedure in the music and control group were  $91.7 \pm 24.75$  and  $97 \pm 7.07$  per minute, respectively. The heart rate is statistically lower ( $p = 0.02$ ) in the music group than the control group during the surgery.

No statistical difference was noted between the mean SBP and mean DBP values between the two groups during the surgery. (Table 3)

Table 3: Comparison of outcomes

Parameter	Study group	Control group	P-value
(a) Post-intervention STAI-S score	$37.5 \pm 4.95$	$49.36 \pm 7.73$	1.18
(b) Intra-operative parameters			
Mean heart rate	$91.7 \pm 24.75$	$97 \pm 7.07$	0.02
Mean SBP	$116 \pm 5.66$	$131 \pm 12.73$	0.35
Mean DBP	$82 \pm 2.83$	$86 \pm 5.66$	0.12

### **DISCUSSION:**

Compared with the control group, the patients in the music group reported a significantly higher level of satisfaction. The results were consistent with the previously conducted studies. Although there was no statistical difference in the mean state anxiety levels between the two groups after music therapy, a trend of reducing level of anxiety was observed in the music group, which was consistent with other studies showing a reduction of anxiety when patients were offered to listen to music pre-operatively.

Lorne Bellan et al, performed a prospective randomized study to compare environmental factors around the time of cataract surgery in order to identify interventions that would minimize stress for patients. They found that oral sedation and listening to music showed decreased level of anxiety and increased level of stress.<sup>9</sup>

Chan et al, conducted a similar study at Grantham Hospital, Hong Kong to study the effect of music on anxiety level and pain during the intravitreal injections and concluded that there was a high satisfaction rate and a large number of subjects preferred having music played, although not significant.<sup>10</sup>

A similar study from Camara et al. points out that elderly patients who had undergone cataract surgery felt more satisfied because they were able to listen to relaxing music. The authors indicated a significant decrease in the preoperative blood pressure and heart rate of patients exposed to live piano music during ophthalmic surgery.<sup>11</sup>

Shue B et al, conducted a study to evaluate the effect of Mozart music on the performance of glaucoma patients on automated perimetry. They found that rate of fixation losses, false positives and false negatives did not improve in subjects with glaucoma after they listened to Mozart music.<sup>12</sup>

Several randomized control trials show that music intervention would lower the desire for analgesic and sedative medication use. Bringman et al, enrolled 372 patients undergoing elective surgery to compare the effect of pre-operative music with 0.05 – 0.1 mg/kg of oral midazolam and concluded that relaxing music decreases the level of anxiety in a pre-operative setting to a greater extent than orally administered midazolam. Higher effectiveness and absence of apparent adverse effects makes pre-operative relaxing music a useful alternative to midazolam for pre-medication.<sup>13</sup>

Nadiye Özer et al, conducted a quasiexperimental study on 87 patients who underwent open heart surgery where the music group was made to listen to music of their choice for 30 minutes while the control group had to rest in their beds. The study concluded with evidence in favour of music. In the music group, there was a statistically significant increase in oxygen saturation and a lower pain score than in the control group. There was no difference between the groups in the other physiologic parameters such as blood pressure, heart rate and respiratory rate.<sup>14</sup>

In summary, music can be used pre-operatively to alleviate anxiety in patients undergoing ophthalmic procedures and the use of music as an adjuvant to minimal sedation could enhance patients' satisfaction and potentially reduce drug-related complications. Especially in countries with limited resources and substantial decreases in the health budget, every intervention with cost-saving potential is not only welcome but also necessary.

## CONCLUSIONS:

The above study provides some evidence to support the use of music as a simple, non-medical anxiolytic in routine care of patients preoperatively to improve the patient's satisfaction.

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