ผลของการสนับสนุนในการผ่าตัดผู้ป่วยต้อกระจกที่ศูนย์ต้อกระจกธรรมศาสตร์

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บทคัดย่อ:
วัตถุประสงค์: เพื่อศึกษาเปรียบเทียบประสิทธิภาพระหว่างการใช้เลเซอร์ดับเครื่องสำอางคอมพิวเตอร์กับการมีการคัดเลือกโดยผู้เชี่ยวชาญทางด้านดนตรี/การสนับสนุน เพื่อวิเคราะห์ความสัมพันธ์ตลอดการผ่าตัดสายตาต้อกระจกได้แตกต่างกันหรือไม่

วิธีการศึกษา: การศึกษาเปรียบเทียบแบบสุ่มลายทอด

ผลการศึกษา: จากผู้เข้าร่วมวิจัยทั้งหมด 83 คน โดยอยู่ในกลุ่ม researcher selected music 29 คน กลุ่ม music intervention 27 คน และกลุ่มที่ไม่ได้ฟังเพลง (control group) 27 คน ผลการวิเคราะห์พบว่า กลุ่ม music intervention และกลุ่มที่ไม่ได้ฟังเพลง (control group) อย่างไม่มีนัยสำคัญทางสถิติ (P<0.05) ที่ระดับ p = 0.05. ผลการวิเคราะห์发现了 กลุ่ม music intervention ที่ระดับ p = 0.02 สำหรับการศึกษาต่างวัดอื่นๆ ได้แก่ อัตราการผ่าตัดของต้อกระจก ความดันโลหิต และระดับความเจ็บปวด ซึ่งไม่ใช่อย่างที่คาดว่าจะมีขึ้นในกลุ่มการศึกษา และไม่มีนัยสำคัญทางสถิติ รวมถึง ข้อมูลด้านศิลปะและดนตรี/การสนับสนุน (researcher selected music) ยังสามารถลดความเจ็บปวด (pain score) ได้มากกว่ากลุ่มที่ไม่ได้รับการสนับสนุน

สรุป: จากการศึกษาพบว่าการฟังเพลงที่ผ่านการคัดเลือกจากผู้เชี่ยวชาญทางด้านดนตรี/การสนับสนุน (therapist selected) ในขณะที่ได้ผลที่ดีกว่าจากการมีการคัดเลือกโดยผู้มีประสบการณ์ทางด้านดนตรี/การสนับสนุน (music intervention) โดยมีการลดความเจ็บปวด (pain score) ได้มากกว่ากลุ่มการศึกษาที่ไม่ได้รับการสนับสนุน
The anxiolytic effect of researcher-selected music medicine on patients undergoing phacoemulsification cataract surgery with topical anesthesia, a randomised controlled trial

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Abstract

Objective: The anxiolytic effect of music medicine, comparing researcher-selected and popular relaxation music in patients undergoing phacoemulsification

Study design: Efficacy study, randomised controlled trial

Methods: Three groups were exposed to different music through loudspeakers in the operating theatre: 1. researcher-selected music based on literature-recommended musical parameters; 2. popular relaxation music; and 3. no music (control). The anxiolytic effect was measured for change in pre and post-operative values of State-Trait Anxiety Inventory (STAI), heart rate, blood pressure, and 10-point numerical rating pain score. All participants gave informed written consent.

Results: Researcher-selected music group had significantly reduced STAI postoperatively compared to the control group (9.10±8.51 versus 2.26±7.41 respectively, P<0.05). Researcher-selected music was significantly more effective in reducing postoperative STAI when compared to popular relaxation music (P<0.001). Other parameters (heart rate, blood pressure and pain scores) were not found to be significantly different between the three groups.


Keywords: phacoemulsification, music therapy, medical music intervention.

No Author has a financial or proprietary interest in material or method mentioned

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Introduction

Cataract is a condition where the lens becomes cloudy due to aging and various external factors resulting in reduced visual acuity, and is the leading cause of blindness, affecting up to 50% of the Thailand’s population. The World Health Organization’s Vision 2020 initiative advocates cataract surgeries for 100,000 eyes per year in Thailand, although there is a long waiting list.1-3

Phacoemulsification is an ubiquitous method of cataract surgery.4,5 The procedure has a short duration and surgeons often employ the use of topical anesthesia, enabling patients to recover at home after day-case surgery. Patients remain conscious during surgery with topical anesthesia and may experience anxiety peri-operatively. It is well-established that music interventions have an anxiolytic and mood uplifting effect through the mechanisms involving endorphins in the cerebral cortex, hypothalamus, limbic system and insula - resulting in reduced anxiety and pain reception.6

Numerous efficacy studies on music interventions have proven its effectiveness for reducing anxiety and distraction from noxious perioperative stimuli during awake surgery.6 The majority of existing studies focused on assessing pre and postoperative anxiety and pain states, the impracticality of measuring intraoperative states results in few studies with such data.7,8 Furthermore, each individual’s aural sensory reception is subject to biological differences and preferences to music genre and volume and may result in unfavourable outcomes during surgery.

An important distinction must be made in music intervention terminology. Music medicine in this study is defined as music prescribed by healthcare professionals to be passively listened by patients simultaneously and without interference to routine treatment. Conversely, music therapy is provided by qualified music therapists who actively engage with patients in listening and interacting with music during consultations - either in conjunction or separately from other routine treatment by other healthcare professionals.6 This study uses music medicine as it is more practical to integrate its use during cataract surgery.

Efficacy studies on the anxiolytic and anesthetic effects of music medicine showed conflicting data and assumptions on the mechanism of what components of a piece of music cause the anxiolytic and anesthetic effects for patients during surgery, which led to the rationale of researchers defining a criterion of musical parameters for selecting music aimed at maximising anxiolytic and anesthetic effects to be prescribed in music medicine.6

A previous anesthesiology-based study used researcher-selected music medicine for preoperative anxiolytic and anesthetic effects in combination with verbal relaxation suggestions during regional anesthesia day case surgical patients, comparing the effect to that of oral midazolam - and found that the music medicine intervention is significantly comparable to the pharmacological intervention.9

Our research team sees the importance of reducing patient anxiety during phacoemulsification cataract surgery, and previous studies have provided evidence for efficacy of music medicine in this respect but with no consensus on what characteristic of music should be used. Hence we use the criterion cited by Gooding et al6 in preselecting music medicine with the aid of music experts to provide evidence supporting the use of a standardised criterion for music selection for use at the Thammasat
Cataract Center, and to be applicable to any genre and culture of music medicine globally.

**Methods**

This is an efficacy study using a randomised controlled trial. Eighty three patients undergoing cataract surgery by phacoemulsification at Thammasat University Hospital between January and May 2017 were recruited and randomised into three groups (see Figure 1) and were exposed to music with different playlists through loudspeakers in the operating theatre. The researchers opted to use loudspeakers instead of headphones as headphones can disrupt the practicality and contaminate cataract surgery, in addition to allowing operating theatre staff to communicate with patients intraoperatively, which is more applicable to routine procedure.13

**Group 1: researcher-selected music.**

Instrumental music selected by a panel of three professionally and academically qualified musicians based on a criterion of musical parameters based from literature by Gooding et al.6 the following musical parameters in Figure 2 appear to be the most effective in achieving anxiolytic and anesthetic effects.

**Group 2: popular relaxation music**

Commonly found instrumental relaxation music (popular relaxation music) from Youtube with the title “คุณน่ะงงการเรียนเพื่อให้มีสมาธิ”. https://youtu.be/8p7WX14AfDE, it is popular for relaxation with 6.3 million views and is determined by qualified musical professionals that it does not fit with the musical parameters of Group 1.

**Group 3: controls.**

This group was exposed to no music during phacoemulsification cataract surgery. All participants gave written informed consent before undergoing block randomisation into the three groups. Both patients and researchers were blinded from which type of music was exposed as they are unable to distinguish one music type from another. Only the control group was not blinded by the patients as this was impractical.

Patients were excluded prior to randomisation if they had epilepsy, had a previous cataract surgery experience, had a baseline blood pressure of above 160 mm Hg systolic and 110 mm Hg diastolic, or had hearing problems or dementia. Patients were excluded after randomisation if their operation time was less than 20 minutes.10

The anxiolytic and anesthetic effect of the three intervention groups was measured for change pre and post operatively using the following criteria: State-Trait Anxiety Inventory;8,11,12 Heart rate and peripheral systolic and diastolic blood pressure; and 10-point numerical rating pain score (NRS).

**Preoperative phase**

Prior to each operation, participants were led to the waiting room for 15 minutes to receive baseline blood pressure and heart rate measurements and to assess STAI and pain score. Participants were also exposed to either researcher-selected music, popular relaxation music or controls, respectively, during this time.

Two audio speakers were placed on opposing walls in the preoperative waiting room operating within parameters which are believed to cause relaxation...
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**Figure 1** CONSORT flow diagram of the progress through phases of the study

- Tempo (music speed): slow; 60 to 80 beats per minute; stable, consistent tempo
- Dynamics (volume): low level with minimal changes
- Timbre (sound quality or tone color): gentle, without harsh contrasts
- Texture (combination of sounds/instruments): consistent; limited instrumentation and/or changes
- Melody (theme): legato or connected/smooth
- Rhythm (movement): stable rhythms, absence of percussive or accented rhythms
- Pitch (tone): simple harmonic or chord progressions

**Figure 2**
effects at 50-60 decibels (at the level of typical conversations) and at the frequency range of 200 - 2,650 hertz. This was measured using an Extech 407730 Digital Sound Level Meter. Tetracaine hydrochloride 0.5% was used for ophthalmic topical anesthesia and Tropicamide 1% (Mydriacyl®) and Phenylephrine hydrochloride 10% were used for dilatation of pupils.

**Intraoperative Phase**

The audio set up in the operating theatre was identical to that in the preoperative waiting room. Music was switched on for intervention groups 1 and 2 upon patient entry, repeating the playlist for 20 minutes in duration until completion of surgery. Participants were excluded from the study if the operation duration was less than 20 minutes. Bringman et al⁹ suggested that music medicine is effective if patients are exposed for a minimum of 15 minutes preoperatively and 20 minutes intraoperatively.

**Postoperative Phase**

After completion of surgery, participants were returned to the recovery area for 15 minutes, during which time the patient was reassessed for their STAI-S score (from 20-80 points), in addition to the numerical rating pain score (0-10 points) and have their heart rate and peripheral blood pressure measured, all within the first 5 minutes of recovery. Participants were also exposed to their respective music interventions during these 15 minutes.

**Statistical Analyses**

Sample size was estimated to detect a difference of two independent proportions for a one-sided test, alpha of 0.05 and power 0.80. Block randomisation was our method of choice. Outcomes were analysed for difference of means using one-way ANOVA and Bonferroni’s post hoc analysis.

**Results**

Of all 83 participants, 27 were randomised to the researcher-selected music group, 27 to the popular relaxation music group and 29 to the control group. Baseline characteristics of the participants included age, gender, pulse, blood pressure, STAI score and operation duration. There were no significant differences in any of these parameters for all three intervention groups post randomisation (Table 1).

Comparing between all three groups, participants exposed to researcher-selected music had significantly greater anxiety reduction than either the popular relaxation music group or the control group (Table 2). STAI-S scores were reduced (9.10±8.51, 6.0±11.58, 2.26±7.41 respectively, P<0.05, one-way ANOVA). The popular relaxation music group showed greater anxiety reductions compared to the control group, however this was statistically insignificant. The researcher-selected music group showed significantly greater anxiety reduction compared to the popular relaxation music group (P<0.001, post hoc analysis, Bonferonni).

**Discussion**

There has been a host of previous research on utilising music for therapeutic purposes, namely in treating anxiety, depression and reduction of pain during surgery in various specialities.¹⁰,¹⁴-¹⁹ Our research team selected music based on a literature recommended criterion of music parameters by Gooding et al⁶ with the aid of qualified music professionals. This music was provided as music medicine
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Table 1 Baseline characteristics of patients in different intervention groups

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>Control (N = 27)</th>
<th>PM (N = 27)</th>
<th>RM (N = 29)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>68.4 ± 7.9</td>
<td>67.4 ± 9.4</td>
<td>66.3 ± 8.5</td>
<td>0.202</td>
</tr>
<tr>
<td>Sex (Female ratio)</td>
<td>1.25 (12:15)</td>
<td>1.7 (10:17)</td>
<td>1.6 (11:18 )</td>
<td>0.542</td>
</tr>
<tr>
<td>Initial STAI-T score</td>
<td>39.2 ± 9.47</td>
<td>38.8 ± 11.6</td>
<td>37.0 ± 7.9</td>
<td>0.488</td>
</tr>
<tr>
<td>Initial STAI-S score</td>
<td>35.7 ± 7.7</td>
<td>33.2 ± 9.1</td>
<td>27.1 ± 4.4</td>
<td>0.117</td>
</tr>
<tr>
<td>Blood pressure (mm Hg)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>139.5 ± 19.3</td>
<td>143.0 ± 17.1</td>
<td>136.7 ± 12.8</td>
<td>0.489</td>
</tr>
<tr>
<td>Diastolic</td>
<td>79.5 ± 10.2</td>
<td>80.2 ± 12.0</td>
<td>73.7 ± 11.6</td>
<td>0.520</td>
</tr>
<tr>
<td>Heart rate (beats/min)</td>
<td>78.3 ± 12.4</td>
<td>74.7 ± 15.1</td>
<td>74.6 ± 13.2</td>
<td>0.166</td>
</tr>
<tr>
<td>Operative time (min)</td>
<td>28.7 ± 7.5</td>
<td>29.0 ± 7.7</td>
<td>29.7 ± 7.0</td>
<td>0.122</td>
</tr>
</tbody>
</table>

*Abbreviations: Control = No music; PM = Popular relaxation music; RM = Researcher-selected Music; STAI-S, State-Trait Anxiety Inventory-State; STAI-T, State-Trait Anxiety Inventory-Trait.
Values are mean±SD. *Blood pressure and heart rate on admission.

Table 2 Difference in pre and post-intervention STAI-S scores compared between groups by ANOVA analysis

<table>
<thead>
<tr>
<th>Control (n = 27)</th>
<th>PM (n =27)</th>
<th>RM (n = 29)</th>
<th>Control vs PM</th>
<th>Control vs RM</th>
<th>PM vs RM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (S.D.)</td>
<td></td>
<td></td>
<td>P-value</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Difference in pre and post STAI-S scores*</td>
<td>2.26 (7.41)</td>
<td>6.0 (11.58)</td>
<td>9.10 (8.51)</td>
<td>0.222</td>
<td>&lt; 0.05</td>
</tr>
</tbody>
</table>

*Abbreviations: Control = No music; PM = Popular relaxation music; RM = Researcher-selected Music; STAI-S, State-Trait Anxiety Inventory-State.
*Differences in STAI-S scores (Initial STAI-S score minus Post STAI-S score). Subjective measurement of decrease in anxiety

Table 3 Difference in pre and post-intervention Heart Rate compared between groups by ANOVA analysis

<table>
<thead>
<tr>
<th>Control (n = 27)</th>
<th>PM (n =27)</th>
<th>RM (n = 29)</th>
<th>Control vs PM</th>
<th>Control vs RM</th>
<th>PM vs RM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (S.D.)</td>
<td></td>
<td></td>
<td>P-value</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Difference in pre and post Heart Rate</td>
<td>7.85 (19.6)</td>
<td>6.73 (11.4)</td>
<td>7.79 (9.2)</td>
<td>0.059</td>
<td>0.297</td>
</tr>
</tbody>
</table>

*Abbreviations: Control = No music; PM = Popular relaxation music; RM = Researcher-selected Music; STAI-S, State-Trait Anxiety Inventory-State.
*Differences in Heart Rate (Initial Heart Rate minus Post Heart Rate
Table 4 Comparison of change in Blood pressure and Heart rate after surgery between groups (ANOVA)

<table>
<thead>
<tr>
<th></th>
<th>Control (n = 27)</th>
<th>PM (n = 27)</th>
<th>RM (n = 29)</th>
<th>Control vs PM</th>
<th>Control vs RM</th>
<th>PM vs RM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic blood pressure (mmHg)</td>
<td>-11.55(17.4)</td>
<td>-7.8(14.2)</td>
<td>-5.79(13.8)</td>
<td>0.236</td>
<td>0.624</td>
<td>0.473</td>
</tr>
<tr>
<td>Diastolic blood pressure (mmHg)</td>
<td>-4.11(10.99)</td>
<td>-4.6(10.7)</td>
<td>-7.7(14.0)</td>
<td>0.310</td>
<td>0.947</td>
<td>0.334</td>
</tr>
<tr>
<td>Heart rate (beats per minute)</td>
<td>+7.85(19.6)</td>
<td>+6.74(11.4)</td>
<td>+7.78(9.2)</td>
<td>0.059</td>
<td>0.297</td>
<td>0.371</td>
</tr>
</tbody>
</table>

*Abbreviations: Control = No music; PM = Popular relaxation music; RM = Researcher-selected Music; STAI-S, State-Trait Anxiety Inventory-State;
*Differences in Vital sign at the beginning of the operation minus vital sign at operation time 20 min.

for study participants before, during, and after undergoing phacoemulsification cataract surgery under topical anesthesia at our day case surgery center. We compared our researcher-selected music with popular relaxation music and no music (control). This study measured anxiolytic effects of music medicine interventions using the State-Trait Anxiety Inventory (STAI) created by Spilberger, a scoring system with a scale of 20-80 points, which is a widely used self-assessment tool in research revolving anxiety reduction interventions. When comparing the anxiolytic and anesthetic reduction outcomes for all 3 groups using one-way ANOVA, the researcher-selected music group was found to have the largest amount of anxiety reduction postoperatively at 9.10±8.51 points on the STAI scoring system, (P<0.05). Comparatively, the popular relaxation music group reduced anxiety by 6.0±11.58 and the control group reduced by 2.26±7.41 points on the STAI scoring system. Post hoc analysis found that the researcher-selected music was significantly more effective than popular relaxation music and control (P<0.001).

On the other hand, the reduction in heart rate among participants in the popular relaxation music group was non-significantly greater than the control group (P<0.059) (Table 3). With respect to other outcome parameters of anxiolytic effects, namely systolic and diastolic blood pressure in addition to pain score, no significant reduction in any of the parameters was found among all three groups (Table 4).

**Conclusions**

The study demonstrates the effectiveness of music medicine in alleviating anxiety during phacoemulsification cataract surgery with topical anesthesia. The effects of anxiolytic effects are even greater when the music is selected by qualified musical professionals according to the literature-recommended criteria.
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