A COMPARATIVE STUDY ON PAIN SCORE, ANXIETY LEVEL AND VITAL SIGNS DURING PRE AND POST PHACOEMULSIFICATION USING COMBINATION OF TOPICAL ANAESTHESIA AND BINAURAL BEATS AUDIO VERSUS TOPICAL ANAESTHESIA

BY

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DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTER OF MEDICINE (OPHTHALMOLOGY)

SCHOOL OF MEDICAL SCIENCES

UNIVERSITI SAINS MALAYSIA

2018

DISCLAIMER

I hereby certify that the work of this dissertation is of my own except for the quotations and summaries which have been duly acknowledged.

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DECLARATION

This is to certify that this work by Dr Ling Jiunn Loong has been reviewed and we, the undersigned are satisfied and have accepted it as a dissertation for the Doctor of Ophthalmology, 2018.

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ACKNOWLEDGEMENTS

Firstly and foremost, I would like to express my sincere thanks and gratitude to my supervisor Ass. Prof Dr Adil Hussein, senior lecturer in the Department of Ophthalmology, School of Medical Sciences, Universiti Sains Malaysia for his continuous support and guidance throughout the duration of my Master program and particularly in completing my dissertation.

My deepest appreciation to Dr Julieana binti Muhamed, lecturer in the Department of Ophthalmology, Universiti Sains Malaysia for her guidance as my co-supervisor for this dissertation. My earnest gratitude to all the lecturers in the Department of Ophthalmology, School of Medical Sciences, Universiti Sains Malaysia for their advice and encouragement throughout my course. And my foremost gratitude to Dr Punitan Rajendran, general ophthalmologist who has been a great senior in guiding and assisting me in this research.

I would like to thank my colleagues and staffs of the Department of Ophthalmology for their kind assistance in helping me to complete my dissertation. My deep appreciation to Mr Lim Kuang Hock, statistician, for his invaluable advises and teaching in the analysis of data.

I am deeply thankful to have the support, encouragement and unceasing love from my late father Mejar (Rtd) Ling To Tiong, my mother Madam Ooi Yeok Chooi, my sisters Dr Liza Ling Ping and Dr Lina Ling Chooi, my brother Dr Ling Jian Loong and my soul partner Dr Koh Koon Ling, who have enabled me to accomplish my ambition.

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ABSTRAK

Pengenalan: Bius topikal telah menjadi pilihan bius setempat yang popular untuk pembedahan ‘phacoemulsification’ kerana ia tidak mempunyai risiko seperti teknik suntikan bius. ‘Phacoemulsification’ yang dilaksanakan dengan bius topikal memberi tahap kesakitan yang boleh diterima tetapi ada di kalangan pesakit yang masih mengalami kesakitan semasa pembedahan. Kini, terdapat kajian kajian yang sedang dijalankan untuk mencari tambahan kepada bius topikal untuk meningkatkan tahap keselesaan pesakit semasa ‘phacoemulsification’. Penggunaan audio ‘Binaural Beats’ adalah menggunakan frekuensi bunyi untuk mengurangkan kesakitan. Setakat ini, tiada kajian tentang kesan audio ‘Binaural Beats’ sebagai tambahan kepada bius topical dalam mengurangkan tahap kesakitan dan kebimbangan semasa ‘phacoemulsification’.

Objektif: Untuk menilai kesan audio ‘Binaural Beats’ sebagai tambahan kepada bius topikal terhadap tahap kesakitan, tahap kebimbangan dan tanda vital semasa ‘phacoemulsification’.

Metodologi: Seramai 61 pesakit yang mempunyai katarak berkaitan penuaan dan memenuhi syarat kemasukan dan pengecualian telah dipilih. Pesakit dirawakkan kepada dua kumpulan- 30 pesakit dalam kumpulan bius topikal sahaja (kumpulan kawalan) dan 31 pesakit dalam kumpulan kombinasi bius topikal dan penggunaan audio ‘Binaural Beats’(kumpulan kajian). Sebelum pembedahan bermulan, tekanan darah, kadar nadi dan tahap kebimbangan pesakit dinilai.

‘Phacoemulsification’ dilaksanakan oleh seorang pakar bedah mata. Kumpulan yang menggunakan bius topikal sahaja diletakkan alat pendengar telinga tanpa audio pada kedua dua telinga. Kumpulan yang menggunakan kombinasi bius topikal dan penggunaan audio “Binaural Beats’ menerima audio muzik ‘Binaural Beats’ frekuensi ‘alpha’ melalui alat pendengar telinga pada kedua dua telinga sepanjang tempoh pembedahan. Penilaian tahap kesakitan dibuat serta merta selepas pembedahan. Tekanan darah, kadar nadi dan tahap kebimbangan pesakit dinilai semula selepas pembedahan.

Keputusan: Tahap kesakitan dan kebimbangan selepas pembedahan ‘phacoemulsification’ adalah lebih rendah dari sebelum pembedahan ‘phacoemulsification’ dari segi statistik di antara kumpulan ($p<0.05$). Manakala, bacaan tekanan darah distolik, kadar denyutan jantung didapati lebih rendah dari segi statistik dalam kumpulan kajian ($p<0.05$) selepas pembedahan ‘phacoemulsification’. Bagi bacaan tekanan darah sistolik pula, ia didapati lebih rendah selepas pembedahan ‘phacoemulsification’ di antara kumpulan tetapi tidak ketara dari segi statistik ($p= 0.068$)

Kesimpulan: ‘Phacoemulsification’ yang dilaksanakan dengan kombinasi bius topikal dan penggunaan audio ‘Binaural Beats’ secara ketara menurunkan tahap kesakitan pesakit. Tambahan penggunaan audio ‘Binaural Beats’ kepada bius topikal masih memberi respon sistemik fisiologikal yang selamat (tahap kebimbangan, tekanan darah dan kadar nadi).

ABSTRACT

Introduction: Topical anaesthesia has become a popular choice of anaesthesia during phacoemulsification as it has no risk of the needle techniques. Phacoemulsification performed using topical anaesthesia has acceptable pain control. However, a certain percentage of patients still perceive pain during the procedure. There are ongoing studies to find additions to the topical anaesthesia to increase patient's level of comfort during phacoemulsification. Binaural beats audio is the usage of certain audio frequency wavelength to relief pain and anxiety. There is no reported data on the effect of usage of Binaural Beats audio as an adjunct to topical anaesthesia on pain and anxiety control during phacoemulsification so far.

Objective: To evaluate the effect of Binaural Beats audio as an adjunct to topical anaesthesia on pain score, anxiety level and vital signs during phacoemulsification.

Methodology: 61 patients with senile cataract planned for phacoemulsification who met the inclusion and exclusion criteria were recruited. Patients were randomised into two groups- topical anaesthesia only (control group) and topical anaesthesia with the usage of Binaural Beats audio (study group). Before the start of surgery, patient's blood pressure, heart rate and anxiety level were assessed. Phacoemulsification was performed by a single Ophthalmologists. The group using topical anaesthesia only were given earphones without audio.

The group using topical anaesthesia with usage of Binaural Beats audio were given alpha wave frequency through the earphones throughout the surgery. Patients rated intraoperative pain score immediately after the surgery. Patient's blood pressure, heart rate and anxiety level were assessed again postoperatively.

Result: Postoperatively, statistically significant reduction of pain score and anxiety level between groups were seen ($p<0.05$). Diastolic blood pressure, mean arterial blood pressure and heart rate at the end of the surgery were also lower in the study group ($p<0.05$). However, systolic blood pressure was comparatively lower postoperatively but was not statistically significant ($p=0.068$)

Conclusion: Phacoemulsification using topical anaesthesia with Binaural Beats audio has significantly improved patient's level of pain. Addition of binaural beats to topical anaesthesia still produces a safe systemic physiological stress response (anxiety level, blood pressure and heart rate).

CHAPTER 1

INTRODUCTION

1.1 CATARACT SURGERY

Cataract surgery has been one of the most frequent outpatient procedures (Ryu *et al., 2009).* Over the last few decades, improved surgical techniques of cataract surgery have promoted it to become one of the safest and most successful ophthalmic procedures. Phacoemulsification, which was first introduced by Kelman in 1967, has become the mainstay of cataract surgical treatment worldwide. In Malaysia, there is a shift from extracapsular cataract extraction (ECCE) to phacoemulsification as the method of choice for cataract removal over the years, where ECCE had shown a reduction from 54.0% in 2002 to 6.8% in 2016 (Salowi, M. A., 2018). Since 2003, phacoemulsification with intraocular lens implantation has emerged as the most common type of cataract surgery performed in Malaysia (Lee *et al.*, 2014). Phacoemulsification has shown to be the method of choice as evidenced by a significant increase in phacoemulsification rate from 39.7% (2002) to 89.6%% (2016), reported by the Tenth Report of the National Eye Database 2016 (Salowi, M. A., 2018).

1.2 LOCAL ANAESTHESIA IN PHACOEMULSIFICATION

Advancement in phacoemulsification with new surgical technologies has contributed to more controlled, quicker and smaller incisional corneal wound. Anaesthesia techniques for cataract extraction have also made significant advances following that. An ideal anaesthetic should provide adequate analgesia, easy to administer with minimum systemic and local complication and cost effective (Duguid *et al*., 1995). The options for anaesthesia available for cataract surgery are local anaesthesia and general anaesthesia. Local anaesthesia includes topical anaesthesia, intracameral local anaesthesia and sub-Tenon, retrobulbar, peribulbar, or subconjunctival injections.

1.2.1 Topical Anaesthesia

In 1992, topical anaesthesia was administered for the first time in phacoemulsification by Fichman (Fichman, 1996). This technique eliminates the possible complications of injectable techniques. As phacoemulsification techniques have advanced, incision size has decreased, the need for iris manipulation has diminished and operative time has lessened. These changes have resulted in a decrease in the need for complete akinesia, long duration of ocular anaesthesia and intensity of iris and ciliary body sensory block. Topical anaesthesia alone can provide adequate anterior segment anaesthesia for non-complex phacoemulsification. It has since become a popular choice of anaesthesia during phacoemulsification and the preferred choice of anaesthesia by patients who are undergoing phacoemulsification (Li Quan Zhao *et al*., 2011). In Malaysia, 93.5% of patients who underwent phacoemulsification in 2016 were mostly done under local anaesthesia and 73.5% of them were performed under topical anaesthesia (Salowi, M. A., 2018).

Topical anaesthesia has no risks of the needle techniques including global perforation, no rise in orbital pressure, and no need for globe compression, causes minimal pain during application and allows quicker postoperative recovery (Ugur *et al*., 2007). In addition, topical anaesthesia allows for quick visual recovery. As compared with sub-Tenon technique, the absence of chemosis and subconjunctival haemorrhage are the advantages of topical anaesthesia. Topical anaesthesia by itself leads to a good analgesia but up to 30% of patients feel uncomfortable or even experience pain during the surgery (Pham and Castello, 2010). There was evidence that intraoperative pain score was higher in the topical anaesthesia group (Davison *et al*., 2007). In a recent review and update on local anaesthesia for cataract surgery, it was reported that the relative qualitative rating of patient-perceived pain during intraoperative cataract is higher in

patients given topical anaesthesia compared to those who received retrobulbar, peribulbar or sub-Tenon anaesthesia (Malik *et al*., 2010)

Thus, there are emerging studies on finding adjuncts to topical anaesthesia which can increase patient's comfort level during phacoemulsification and yet retained its safety profile. Among the methods explored include additional analgesic and sedative intravenous drugs, intracameral anaesthesia, viscoanaesthesia, cryoanalgesia, music therapy and even acupuncture. The use of additional analgesics and intravenous sedative drugs carries risks, especially in the elderly population. Intracameral anaesthesia and viscoanesthesia are the methods being studied currently. The long term effects of intracameral anaesthesia are yet to be determined in full (Malik et al., 2010). It was reported that viscoanaesthesia may have an increased of cornea oedema postoperatively (Valimaki and Tornblom, 2009). The application of acupuncture requires trained personnel and may not be available widely. Cryoanalgesia otherwise, it is not suitable for all cataracts and all patients (Rikin Shah, 2010).

Binaural beats audio, on the other hand is among the technique which in feasible.

1.3 BINAURAL BEATS AUDIO

1.3.1 Definition and concept of Binaural Beats Audio

By definition, Binaural Beats occurs when 2 different frequencies of sounds are played in a headset each in one ear and the brain which acts like a mixer makes the frequency difference between the two sounds. The brain which is able to process a difference of 1000Hz maximum frequency sound will then create the third sound called Binaural Beats. This sound which doesn't exceed 30Hz will induce a desirable positive cerebral wavelength.

For a normal person, the audible sound wave frequency ranges from 30 to 15000 vibrations per second and anything below than 30 Hz will not be perceived. This technique comes in necessary to 'trick' the ears (Filimon, 2010)

Binaural Beats are brain's auditory responses from the interaction of the sounds from the two ears which occurs at the brain centre namely the superior olivary nucleus- the first centre in the brain to receive sound signals from both ears and also considered as the likely site for the neural processing of low frequency sound impulses (Hutchison, 1973).

The brain is always in a permanent flow of electric and chemical activity. It releases electric impulses called brain waves: Delta, Theta, Alpha, Beta, and Gamma. The combinations of these waves will determine an individual's different state of conscience and is measured in Hz (Filimon, 2010).

Alpha waves ranges from 8Hz to 14Hz and characterise the vivid yet relaxed (while awake), calm and receptive mind, dreams, pre-sleep and pre-wake drowsiness. Beta waves ranging from 14Hz to 30 Hz comprises of our fundamental activities related to survival, brain's alert intellectual activity, active, busy and anxious thinking. As for Gamma waves which is above 40Hz involve with higher mental activity. Theta waves 4-7Hz, on the other hand involves in deep meditation, relaxation and for Delta waves which is below 4Hz characterise deep dreamless sleep, loss of body awareness.

Cerebral synchronisation occurs naturally on a daily basis but only incidentally and for a brief period of time (Filimon, 2010). The majority of people in current society use the vigil state of their brains which leads to Beta wave predominance (Filimon, 2010).

In geriatric population, hearing generally deteriorates with age but according to Gerald Oster, was found that older people are able to detect binaural beats and ability to locate sounds almost as good as the young (Hutchison, 1973).

In conclusion, Binaural Beats are in fact a subliminal aural message because they are unable to be captured by the human ear but will be perceived unconsciously in brain level (Filimon, 2010).

Surgery produces anxiety in most patients particularly in geriatric population. It often is accompanied by loss of control, expectations of pain and disfigurement, and unknown prognoses. The significance of preoperative anxiety is greater than that of a transient unpleasant emotion. Severe anxiety can negatively affect the patient's postoperative recovery. Stress associated with surgery can be intensified when surgery is performed on an outpatient basis. For patients undergoing outpatient surgery under local or regional anaesthesia, awareness of the harsh reality of the operating room extends for a long period of time. Without the benefit of sedation, the environment may appear threatening. Anxiety also may be intensified when the patient sees himself or herself in the physical position required for surgery. Music is an excellent outlet to provide enjoyment, relaxation, relief from pain, and anxiety and binaural beats can serve as a tool for the therapy.

Binaural beats were used in day case surgery patients undergoing surgery under general anaesthesia a day prior to their procedure might serve to reduced anxiety in majority of the patients without impacting adversely on postoperative functions (R. Padmanabhan *et al*., 2005). Binaural beats efficacy was tested on comparison to hypnotherapeutic techniques on the level of perceived pain reported to have lower levels of perceived pain compared to those who did not receive any treatments but have similar effect as the hypnotic therapy (Balăn, S *et al*., 2014) In treatment of anxiety, auditory and binaural beats were both used in anxious adults seeking treatment for anxiety show significant effect on the Journal Anxiety Scale (Le Scouamec *et al*., 2001)

In management of bruxism and myofascial pain-dysfunction syndrome with audio adjunct therapy showed reduced temporomandibular joint pain and muscle spasm in areas of the head and neck (Manns, 1981).

1.4 PAIN

1.4.1 Definition of Pain

According to the International Association for the Study of Pain (IASP), pain is defined as "unpleasant sensory and emotional experience associated with actual or potential tissue damage and described in terms of such damage" (Ong and Seymour, 2004). Pain is defined in terms of human experience and pain measurement relies on communication. Clinician can measure pain by patient's self-report, observation of resultant behaviour and physiologic parameters to be characteristic of patient in pain (Ong and Seymour, 2004). Assessment of pain generally built upon self-report by patients. There is no objective unit and no external "golden standard" for measurement of clinical pain (De Conno *et al*., 1994). Pain is a subjective matter and self-report gives the most valid measure of the pain experience (Ong and Seymour, 2004). Use of tools to quantify the subjective pain has given scientific and clinical results.

1.4.2 Assessment of Pain

An ideal pain measurement instrument should be simple to administer, accurate, reliable and understandable by most patients (Ong and Seymour, 2004). There are a large number of pain measurement instruments that have been developed for use. Currently, there is no single tool that is perfect in evaluating all pain properties. Clinicians and researchers should select the tool that best serve their purposes.

The rapidly administered unidimensional pain scales includes Verbal Rating Scale (VRS), Numerical Rating Scale (NRS), Visual Analog Scale (VAS), Picture Scale, Pain Diary, Pain Drawings and behavioural pain measures. Whereas, the multidimensional pain scale include many questionnaires that are directed to assess different properties of pain. Among the multidimensional pain scales include McGill Pain Questionnaire, Minnesota multiphasic personality inventory, Beck Depression inventory, Spielberger state trait anxiety inventory, pain disability index, coping strategies questionnaires and others.

VAS is a common tool used in quantifying pain. It was found to be the most frequently used scale in reviewed study. Its simplicity, reliability, validity and its ratio scale properties make it an optimal tool for describing pain severity and intensity (Katz and Melzack, 1999). VAS is widely used and is independent of language. It is easily understood and readily reproducible (Ong and Seymour, 2004). VAS is sensitive to pharmacological and non-pharmacological experiences that alter pain (Ong and Seymour, 2004). It correlates highly with pain measure on NRS and VRS. There is evidence to suggest that VAS tend to be more valid than pain rating scales with relatively few response options (Jensen *et al*., 2002). VAS is a valid measurement tool in the immediate post-operative period (DeLoach *et al*., 1998)

1.5 ANXIETY

1.5.1 Definition of Anxiety

Surgery causes stress and consistently elicits anxiety in patients (Habib *et al*., 2004). The incidence of preoperative anxiety varies from 10%-80%, depending mainly on the mode of assessment (McCleane and Cooper, 1990). Preoperative anxiety denotes an unpleasant state of

uneasiness or tension due to patient fear of the disease, hospitalization, anaesthesia or surgery (Habib *et al*., 2004).

There is a positive relationship between anxiety and pain. Anxiety levels have been demonstrated to predict pain sensation, intensity and pain behaviour. It was reported that pain-related anxiety can heighten perceived intensity of pain (Ploghaus *et al*., 2001). Patients who are anxious are more likely to feel discomfort or pain during medical or surgical procedures. At the same time, pain sensation can increase anxiety level and a vicious cycle follows.

1.5.2 Assessment of Anxiety

The State Trait Anxiety Inventory (STAI) is a self-report instrument which is capable of differentiating between feeling of anxiety – trait anxiety, and the current feelings of anxiety – state anxiety (Marteau and Bekker, 1992). It is a widely used questionnaire to measure state anxiety and trait anxiety. The original STAI has 40 items. Its disadvantage is the lengthy scales which make it time consuming. The six items, short form of STAI has been shown to produce similar scores as the full form and has acceptable reliability (Marteau and Bakker, 1992; Tluczek *et al*., 2009).

In the local context, the STAI has been reported to be reliable, valid and sensitive to clinical change in a sample of Malaysian patients with urological symptoms (Quek *et al*., 2004). The Malay version of STAI has been used in our local context. Mohad Anizu in his study on Psychological Predictors of Injury among Malaysian Professional Football Players used the Malay version of STAI (Mohad Anizu, 2006). The English version of STAI was translated into the Malay by language experts. Back translation of the questionnaire was also done in order to establish its reliability. The translated version was also distributed to two psychiatrists to determine face validity. Then, he did a pilot study on 50 players. The Cronbach's Alpha for the

state anxiety was 0.78 and test retest 0.71 while the Cronbach's Alpha was 0.79 and test-retest was 0.84 for trait anxiety.

Subjective criteria in assessing anxiety include the observer's impressions such as tremor, unsteady voice, sweating and lack of attention (Habib *et al*., 2004). Objective criteria for assessing anxiety measure physiological variables such as pulse rate, blood pressure, respiratory rate and hormone levels (Habib *et al*., 2004). These are considered to be reasonably good indicators, although they may give false results in patients with systemic disease (e.g. hypertension, cardiac rhythm disturbance) or with some endocrine disorders (Badner *et al*., 1990)

1.6 VITAL SIGN

1.6.1 Assessment of vital signs during phacoemulsification

Blood pressure and heart rate of patient during cataract surgery are stable though there are observed changes preoperatively and postoperatively (Suzuki *et al*., 1997). Increase in blood pressure and heart rate can be attributed to either anxiety or pain or both during cataract surgery. Fichman reported that 80% of his 600 patients who underwent cataract surgery under topical anaesthesia have mild pain, 8% had moderate pain and 3% reported to have severe pain. He also monitored the blood pressure of 100 patients and noted 1% had raised blood pressure (Fichman, 1996).

PK Argawal et al. studied the effect of perioperative blood pressure on intraoperative complications during phacoemulsification under local anaesthesia and noted there was no significant difference in the blood pressure between the hypertensive and the normotensive at

pre-assessment, admission, holding area, and at discharge (Agarwal *et al*., 2010). In another study, the rise in systolic blood pressure between intraoperative readings and those at pre-assessment and anaesthesia room was highly statistically significant (Yap *et al*., 2009).

Blood pressure and heart rate can be affected by the types of local anaesthesia administered. Patient who received retrobulbar anaesthesia was reported to have higher mean arterial pressure and heart rate during and just after the regional block (Ryu *et al*., 2009). Gombos et al. noted that the intraoperative systolic blood pressure was higher in the topical anaesthesia group compared to the retrobulbar anaesthesia group but decreased to their baseline at the end of the surgery (Gombos *et al*., 2007).

1.7 RATIONALE OF STUDY

Phacoemulsification performed using topical anaesthesia has acceptable pain control. However, a certain percentage of patients still perceive discomfort during the procedure. The rationale of this study is to evaluate the effectiveness of binaural beats audio as an adjunct to topical anaesthesia in reducing pain during phacoemulsification. As the topical anaesthesia has advantages over the needle techniques of anaesthesia, we hope to find an adjunct which could offer more comfort especially to patients who still perceive discomfort during phacoemulsification under topical anaesthesia. Patient's anxiety level and vital signs will also be evaluated during phacoemulsification using topical anaesthesia and in conjunction with the use of binaural beats.

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CHAPTER 2

OBJECTIVES OF THE STUDY

2.1 General Objective

To evaluate the effect of binaural beats as an adjunct to topical anaesthesia on pain score, anxiety level and vital signs during phacoemulsification.

2.2 Specific Objectives

2.2.1 To compare pain level between the group using topical anaesthesia with binaural beats and the group using topical anaesthesia only.

2.2.2 To compare anxiety level between the group using topical anaesthesia with binaural beats and the group using topical anaesthesia only.

2.2.3 To compare blood pressure between the group using topical anaesthesia with binaural beats and the group using topical anaesthesia only.

2.2.4 To compare heart rate between the group using topical anaesthesia with binaural beats and the group using topical anaesthesia only.

CHAPTER 3

MANUSCRIPT

EVALUATION OF BINAURAL BEATS AS AN ADJUNCT THERAPY TO TOPICAL ANAESTHESIA IN CATARACT SURGERY

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