EFFECTS OF PERIOPERATIVE MUSIC THERAPY ON PAIN, ANXIETY AND HEMODYNAMICS IN PATIENTS UNDERGOING UPPER LIMB SURGERY

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TABLE OF CONTENTS

		PAGE
TITLE		i
ACKNOWLEDGEMENT		ii
TABLE OF CONTENTS		iii
LIST OF TABLES AND FIGURES		vi
LIST OF SYMBOLS AND ABBREVIATIONS		vii
ABSTRAK (BAHASA MALAYSIA)		ix
ABSTRACT (ENGLISH)		xi
CHAPTER 1: INTRODUCTION		
1.1	Background	1
1.2	Problem Statement	3
1.3	Benefit of Study	4
1.4	Justification of Study	4
1.5	References for Introduction	5
CHAPTER 2: OBJECTIVES OF THE STUDY		
2.1	General Objectives	6
2.2	Specific Objectives	6

2.3	Study Hypothesis	7

CHAPTER 3: MANUSCRIPT

3.1	Title Page	8
3.2	Abstract	10
3.3	Introduction	12
3.4	Methodology	14
3.5	Result	17
3.6	Discussion	20
3.7	Conclusion	22
3.8	References	23
3.9	Tables and Figures	25
3.10	Guidelines/ Instruction of Malaysia Journal of Medical Sciences	31

CHAPTER 4: STUDY PROTOCOL

4.1	Study Protocol Submitted for Ethical Approval	50
4.2	Ethical Approval Letter from JePEM	80

CHAPTER 5: APPENDICES

5.1	Data Collection Forms	84
5.2	Borang Maklumat dan Keizinan Pesakit	90
5.3	Patient Information and Consent Forms	95
5.4	Pain Score Assessment Tools	99
5.5	Good Clinical Practice (GCP) Certificate	100
5.6	Raw Data in Software in CD	101

LIST OF TABLES AND FIGURES

		Page
Table 1.0:	Description of demographic characteristic for Control and Intervention group	26
Table 2.0:	Description of baseline data	27
Table 3.0:	Pain score between Control and Intervention group	28
Table 4.0:	Level of anxiety in Control and Music intervention group	29
Table 5.0:	Pre-operative, intra-operative and post-operative measurement of MAP and HR for Control and Intervention group	30
Table 6.0:	Description of clinical data (secondary outcomes)	31

LIST OF SYMBOLS AND ABBREVIATIONS

%	Percent
µg	Microgram
kg	Kilogram
mg	Milligram
min	Minutes
sec	Seconds
ANOVA	Analysis of variance
ASA	American Society of Anaesthesiologists
BMI	Body mass index
ERAS	Enhanced Recovery after Surgery
GCP	Good Clinical Practice
HADS	Hospital Anxiety and Depression scale
HR	Heart rate
HUSM	Hospital Universiti Sains Malaysia
IQR	Interquartile range
IV	Intravenous
JePEM	Jawatankuasa Etika Penyelidikan (Manusia) of USM
MAC	Minimum alveolar concentration
MAC	Monitored anaesthesia care
MAP	Mean arterial pressure
MD	Doctor of Medicine
MJMS	Malaysian Journal of Medical Sciences
MMC	Malaysian Medical Council
NRS	Numerical rating scale
PACU	Post-anaesthesia Care Unit
PCA	Patient-controlled analgesia
PPSK	Pusat Perubatan Sains Kesihatan
SD	Standard deviation

SpO_2	Peripheral saturation of Oxygen
UK	United Kingdom
USM	Universiti Sains Malaysia
VAS	Visual analogue scale

ABSTRAK

***Tajuk*: Kesan Perioperatif Terapi Muzik Kepada Tahap Kesakitan, Kebimbangan Dan Hemodinamik Di Kalangan Pesakit Yang Menjalani Pembedahan Anggota Tangan**

***Latar Belakang*:** Pada masa kini, terdapat penambahan kajian dalam perioperatif terapi muzik sebagai salah satu cara bukan-ubatan dalam rawatan tahap kesakitan dan kebimbangan, dan menunjukkan hasil yang menjanjikan. Kajian ini dijalankan untuk mengkaji kesan perioperatif lagu berunsur keagamaan kepada tahap kesakitan, kebimbangan dan tanda vital dalam populasi tempatan Malaysia.

Tujuan: Untuk mengkaji kesan perioperatif terapi muzik kepada tahap kesakitan, kebimbangan dan hemodinamik di kalangan pesakit yang menjalani pembedahan anggota tangan dengan menggunakan lagu berunsur keagamaan atau zikir di hospital USM.

Kaedah: Kajian ini dijalankan secara rawak sebelah pihak di Dewan Bedah hospital USM. Seramai 81 orang pesakit terlibat dan dibahagikan secara rawak kepada kumpulan Kawalan (n=40) atau kumpulan Muzik (n=41). Kedua-dua kumpulan Kawalan dan Muzik menerima rawatan standard. Kumpulan Intervensi dimainkan zikir pilihan sendiri sebelum pembedahan dan sepanjang pembedahan dijalankan. Manakala, kumpulan Kawalan mendengar lagu "White noise" sebelum dan sepanjang pembedahan. Pembolehubah utama yang dikaji termasuk tahap kesakitan (semasa rehat dan dinamik),

tahap kebimbangan, hemodinamik (purata tekanan darah dan denyutan nadi). Pembolehubah sekunder termasuk keperluan fentanyl sepanjang pembedahan, masa kepada keperluan dos morphine pertama dan dos morphine terakhir selepas ketibaan di PACU dan tempoh pemerhatian di PACU.

Keputusan: Secara statistik, kumpulan Muzik menunjukkan penurunan yang drastik dalam tahap kebimbangan ($p<0.05$) dan purata tekanan darah di dalam kumpulan ($p<0.05$). Selain itu, penurunan sebanyak lebih daripada 50% didapati dalam keperluan fentanyl semasa pembedahan, kumpulan Kawalan 79.17µg (SD 45.87), manakala kumpulan Muzik 36.11µg (SD13.18), $p=0.01$. Tempoh pemerhatian di PACU di kalangan pesakit kumpulan Muzik lebih pendek berbanding kumpulan Kawalan ($p=0.02$). Walau bagaimanapun, tiada perbezaan didapati dalam tahap kesakitan dan pembolehubah sekunder yang lain.

Kesimpulan: Hasil kajian menyokong applikasi terapi muzik berunsur keagamaan dalam rawatan pesakit untuk mengurangkan tahap kebimbangan semasa pembedahan dan dalam mengekalkan purata tekanan darah yang lebih stabil sepanjang pembedahan. Selain itu, terapi muzik juga mempercepatkan pesakit didiscaj dari PACU.

ABSTRACT

Title: Effects of Perioperative Music Therapy on Pain, Anxiety and Hemodynamics in Patients Undergoing Upper Limb Surgery

***Background*:** There are growing studies of music therapy recent years as a non-pharmacological method in perioperative management of anxiety and pain with promising result. This study was conducted to investigate the effect of perioperative religious-based music on pain, anxiety and hemodynamic parameters targeted specific in our local population.

Objective: To examine the effectiveness of perioperative music intervention on pain, anxiety, and vital signs among patients undergoing upper limb surgery using religious-based music in Hospital Universiti Sains Malaysia (HUSM).

Methods: A randomized single-blinded controlled clinical trial was conducted in the Operation Theatre in HUSM, Kelantan. 81 patients were recruited and randomly assigned to either Control (n = 40) or Music (n = 41) group respectively. Standard care was given to both Control and Music group. The Intervention group listened to patient-selected religious-based music preoperatively and throughout the surgery, while Control group were played with White noise sound preoperatively and throughout the surgery. Primary measures include pain score (at rest and dynamic), anxiety level, and vital signs, i.e. mean arterial pressure (MAP) and heart rate. Secondary outcomes include total fentanyl requirement intraoperatively, time to first morphine requirement after arrival in

PACU, time to last morphine requirement in PACU and duration of stay in PACU before discharge.

Results: The Music group showed remarkable reduction in anxiety level and MAP reduction within group ($p<0.05$ respectively). Statistically significant secondary outcomes include more than 50% reduction in total fentanyl requirement intraoperatively, with Control group 79.17µg (SD 45.87), while Music group 36.11µg (SD13.18) with $p=0.01$. Subjects in Music group have shorter duration of PACU stays compared to Control group ($p=0.02$). There was no significance difference between groups were identified in pain score and other secondary measures.

Conclusion: The study findings provide new evidence to support the application of religious-based music intervention in reducing anxiety level, maintain more stable MAP intraoperatively and hastened discharge from PACU after upper limb surgery

CHAPTER 1

INTRODUCTION

1.1 Background

Our Ministry of Health is promoting on Pain-Free Hospital (1), parallel with the Declaration of Montreal, International Pain Summit 2010 - "Access to Pain Management is a basic human right". Various approaches have been proposed in advanced medicine and up-to-date is ERAS (Enhanced Recovery after Surgery). One of the vital components of Enhanced Recovery After Surgery (ERAS) is optimal management of postoperative pain using multimodal analgesia.(2)

Opioids use in postoperative analgesic regimens may result in adverse effects, such as postoperative nausea and vomiting, urinary retention, paralytic ileus, sedation, and respiratory depression, which may delay PACU discharge, prolonged the time to recovery milestones and length of hospital stay.(2) Therefore, multimodal analgesia, i.e. the use of more than one analgesic modality to achieve effectual pain control while minimizing opioid-related side effects, has become the cornerstone of enhanced recovery.

There is a wide heterogeneity of analgesic techniques available for multimodal postoperative analgesia. These modalities are divided into

pharmacological and non-pharmacological methods. Systemic pharmacological modalities involve opioids and non-opioids such as acetaminophen, non-steroidal anti-inflammatory drugs, N-methyl-D-aspartate receptor antagonists, anticonvulsants groups, alpha-2-agonists, sodium channel blocking agents, and glucocorticoids. Other pharmacological modalities include surgical-site local infiltration, central neuraxial techniques, and regional analgesia. Adjunctive non-pharmacological techniques for pain management include acupuncture, music intervention, transcutaneous electrical nerve stimulation, and hypnosis. There is mixed evidence regarding such modalities, although a lack of harm is associated with their use.

Music is an important keynote for research in different fields of Anaesthesiology. In postoperative pain management and post-anaesthesia care, music can be a complementary mean for reducing pain, anxiety, and stress.(3) Anxiety associated with surgery in adult is reported to be as high as 11-80%.(4) Patient with high level of preoperative anxiety level may experience insomnia, delayed wound healing, more cardiorespiratory complications, impaired immunity and lower self-confidence.

Moreover, music is inexpensive, non-invasive, and free of adverse effects, and as such, can serve as a complementary method for managing perioperative stress and for acute and chronic pain management.(5) Although there are growing studies of music therapy in recent years, the quantity and quality of the studies are sparse and might not be accurately extrapolated into local settings in

view of different races, ethnicity, preference and cultures. This study was conducted to investigate the effectiveness of religious-based music on patients' postoperative pain, anxiety, and vital signs after upper limb surgery in our local population.

1.2 Problem Statement

Music therapy is a non-invasive and low-cost intervention that can be conveniently implemented in the perioperative setting. Self-report and physiological measures on post-surgical patients indicate that music stimulation reduces the perception of pain, both alone or as a part of multimodal pain management regime, and can reduce the need for pharmaceutical interventions.(6) However, non-pharmacological interventions after surgery, is still rare in medical practice, especially in our country.

Most of the studies found in the journals selected music from a variety of genre, e.g. Classical, New Age, Jazz, slow instrumental, etc.(3) However, no study has look into the use of religious-based music. Furthermore, a systemic review conducted by Ulrica Nilsson suggested that, the differences in the effect of music interventions related to patient age, gender, and ethnicity should be further explored.(3) There have been limited trials looking into the use of religious-based music in recent study.

Religious-based music has calming and soothing effect, (7) which may provide positive outcomes on relaxation and pain relief. A study by Abdala GA et.al showed that higher level of intrinsic religiousness was associated with better physical and mental performance. (8-9) In this multi-racial and multi-religious country of Malaysia, this aspect can be further explored. In turn, these findings will allow medical researchers and practitioners to design guidelines and standardized applications for this promising method of pain management in modern medicine.

1.3 Benefit of Study

To explore the potential of music therapy as one of the non-pharmacological intervention in reducing pain, anxiety and cause more stable hemodynamics intraoperatively

1.4 Justification of Study

Music therapy had positive effects in reducing anxiety level, patients' pain and vital signs in approximately half of the reviewed studies. (3) Further research into music intervention is justified in light of the low cost of implementation and the potential capability of music as non-pharmacological therapy.

1.5 References for Introduction

1. MOH. Pelaksanaan Tahap Kesakitan Sebagai Tanda Vital Kelima (Pain As Fifth Vital Sign).2008;120. Available from: http://www.iasppain.org/files/Content/NavigationMenu/Advocacy/InternationalPainSummit/Malaysia_PainAs5thVitalSign.pdf

2. Tan M, Law LS-C, Gan TJ. Optimizing pain management to facilitate Enhanced Recovery After Surgery pathways. Can J Anesth Can d'anesthésie [Internet]. 2015;62(2):203–18. Available from: http://link.springer.com/10.1007/s12630-014-0275-x

3. Nilsson U. Effects of Music Interventions : A Systematic Review. 2008;87(4).

4. Caumo W, Schmidt AP, Schneider CN, Bergmann J, Iwamoto CW, Bandeir D, Ferreira MBC: Risk factors for preoperative anxiety in adults. *Acta Anaesthesiol Scand* 2001, **45:**298-307.

5. Matsota P, Christodoulopoulou T, Smyrnioti ME, Pandazi A, Kanellopoulos I, Koursoumi E, et al. Music's Use for Anesthesia and Analgesia. J Altern Complement Med [Internet].2013;19(4):298307. Available from: http://online.liebertpub.com/doi/abs/10.1089/acm.2010.0235

6. Binns-Turner PG, Wilson LL, Pryor ER, Boyd GL, Prickett CA. Perioperative music and its effects on anxiety, hemodynamics, and pain in women undergoing mastectomy. AANA J. 2011;79(SUPPL. 4):20–7.

7. Hakak S, Kamsin A, Lubis A, Prasetyo Y, Amin G. Effects of Salat on Health. 2016;63:1–6.

8. Peteet JR, Balboni MJ. Spirituality and religion in oncology. CA Cancer J Clin [Internet]. 2013;63(4):280–9. Available from: http://doi.wiley.com/10.3322/caac.21187

9. Abdala G. Religiosity and Quality of Life in Older Adults : Literature Review Religiosidade e qualidade de vida em pesssoas com idade avançada : revisão de literatura. 2015;25–51.

CHAPTER 2

OBJECTIVES OF THE STUDY

2.1 General Objectives

To evaluate the effect of perioperative music therapy on pain, anxiety, and hemodynamics in patients undergoing upper limb surgery

2.2 Specific Objectives

1. To compare the pain score at rest and movement (dynamic pain) as assessed by Numerical Rating Scale (NRS) between group with music and without music therapy
2. To compare the changes in pain between group with music and without music therapy as determined by
   - Total rescue fentanyl requirement during intraoperative
   - Total morphine requirement in PACU
3. To determine anxiety-reducing effect of music therapy between Control and Intervention group as assessed by Hospital Anxiety and Depression Scale (HADS) – Malay Version
4. To determine the change in mean arterial pressure (MAP) and heart rate (HR) between group with music and without music therapy

2.3 STUDY HYPOTHESIS

H_0: Perioperative music therapy has no effect in reducing pain, anxiety level, MAP and HR among patients undergoing upper limb surgery

H_1: Perioperative music therapy is effective in reducing pain, anxiety level, MAP and HR among patients undergoing upper limb surgery

CHAPTER 3

MANUSCRIPT

3.1 TITLE PAGE

Article Title: Effects of Perioperative Music Therapy on Pain, Anxiety and Hemodynamics in Patients Undergoing Upper Limb Surgery

Running Head:

Effectiveness of Perioperative Music Therapy and White Music on Pain, Anxiety and Hemodynamics

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- The results of this study have not been presented in another form such as a poster or abstract, or at a symposium.
- There is no conflict of interest and no source of financial support in this study.

3.2 ABSTRACT

***Title*: Effects of Perioperative Music Therapy on Pain, Anxiety and Hemodynamic in Patients Undergoing Upper Limb Surgery**

***Background*:** There are growing studies of music therapy recent years as a non-pharmacological method in perioperative management of anxiety and pain with promising result. This study was conducted to investigate the effect of perioperative religious-based music on pain, anxiety and hemodynamic parameters targeted specific in our local population.

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PACU, time to last morphine requirement in PACU and duration of stay in PACU before discharge.

Results: The Music group showed remarkable reduction in anxiety level and MAP reduction within group ($p<0.05$ respectively). Statistically significant secondary outcomes include more than 50% reduction in total fentanyl requirement intraoperatively, with Control group 79.17µg (SD 45.87), while Music group 36.11µg (SD13.18) with $p=0.01$. Subjects in Music group have shorter duration of PACU stays compared to Control group ($p=0.02$). There was no significance difference between groups were identified in pain score and other secondary measures.

Conclusion: The study findings provide new evidence to support the application of religious-based music intervention in reducing anxiety level, maintain more stable MAP intraoperatively and hastened discharge from PACU after upper limb surgery.

Keywords**:** *music therapy, perioperative, pain, anxiety, hemodynamics*

3.3 INTRODUCTION

Worldwide, it is estimated 240 million patients undergo surgery each year and 40-60% reported clinically significant pain in the immediate post-operative period.(1) Orthopaedic surgery is a common procedure irrespective of age group and is performed on a daily basis. A study conducted by Ekstein and Weinbroum 2011 showed that orthopaedic surgery is associated with a two-fold higher incidence of severe pain in the immediate (0–3 hour) postoperative period compared with laparotomy and require more analgesia than standard protocolized regimen. (2)

Anxiety usually accompanies pain and intensified especially before surgical procedure. Anxiety is a psychological disorder that may lead to adverse outcomes. Traditional means of reducing anxiety in patients going for surgery have been focused primarily on the use of pharmacological interventions, e.g. benzodiazepine. However, such medications may result in paradoxical disinhibition, delayed recovery and discharge from postoperative care. A non-pharmacologic intervention such as music therapy may improve postoperative outcomes by minimizing potential adverse effects of the pharmacologic agents.

Music consists of “a complex web of expressively organized sounds” and includes the basic elements of duration, tone, loudness, and pitch. (3) Few studies have indicated significant effects of music on selected outcomes, such as heart rate, blood pressure, anxiety, and pain. In addition, religious citation

is bread and butter in Malaysian population with a soothing and calming effect. Studies have shown inverse relationship between religiosity and intensity of anxiety. (4) Because of the limitations of existing studies, there is a need for further investigations to evaluate the use of religious music during the perioperative period. The purpose of this study was to examine the effects of a perioperative music intervention, i.e. religious music (provided continuously throughout the preoperative, intraoperative, and postoperative periods) on changes in vital signs, anxiety, and pain in patients undergoing upper limb surgery in our local population.

3.4 METHODOLOGY

After obtaining ethical approval from the Research Ethics Committee (Human) (JePEM) of HUSM, a total of 81 subjects scheduled for elective upper limb surgery were recruited. Informed consent taken and subjects were randomly assigned to either Control or Music group. Muslim subjects were randomized into Music or Control group, while non-Muslim subjects were allocated into Control group to render music intervention standard to ease data interpretation.

The Music group listened to patient-selected religious-based music, while Control group listened to White noise sound. 4 types of religious-base music were provided for selection by subjects in Music group after consulted religious expertise from Pusat Agama Islam, HUSM. On the other hand, white noise is a noise whose amplitude is uniform throughout the audible frequency range. White noise is used as a universal description for any type of constant, unchanging background noise. (8) It includes a diverse variety of sounds, e.g.:

- nature sounds – rain, sea/waves, wind blowing, birds chirping, jungle
- machinery noises – washing machine, air conditioning units
- ambient soundscapes – crackling campfire, crowd noise

The use of white noise in this study may reduced bias and sense of inferiority in study subjects.

Music intervention was delivered using iPod/MP3 player with headphones. For blinding purposes as to subjects' assignment allocation, iPod/MP3 player was enclosed in a carrying case covering the display. Subjects were allowed to adjust

volume to own comfortable range, which still allow ambient surrounding sound to be heard. Music was played to both subject groups for 30minutes preoperatively, throughout the surgery and during PACU stay, until subjects requested to have headphones removed or until they were fit for discharged from PACU, in order to standardize the treatment dose.

Intraoperatively, both groups received standard care under general anaesthesia. All subjects received same dose of morphine boluses based on weight calculation and additional fentanyl rescue dose were given at the discretion of anaesthetist incharged based on clinical judgement and documented. Vital signs were charted throughout surgery and during recovery. In the PACU, pain score at rest and on movement were assessed at regular interval using Numerical Rating Scale. Additional morphine boluses were given if pain score more than 3 and charted. Besides, time to first morphine and last morphine requirement and duration to PACU discharged were noted. Subjects were discharged from PACU after fulfilled discharge criteria as judged by anaesthetist incharged.

At the end of the study, subjects in Music group were asked to rate the preference and familiarity scale (from 1 to 10) as researchers have suggested that patient's familiarity and preference towards a certain music is particularly potent determinants in determining the effectiveness of music therapy. (9-10) All subjects in Music group documented familiarity and preference scale of 7 or more in this study.

Data were entered and analysed using Prism Software version 7 and checked for missing data and outliers (none were found). Descriptive statistics were used to

summarise the socio-demographic characteristics of subjects and between-condition differences in baseline data were assessed using Fisher's Exact test. Numerical data were presented as mean (SD) or median (IQR) based on their normality of distribution. Categorical data were presented as frequency (percentage). The statistical analysis of the response variables are based on a Linear regression analysis accounting for group and time differences and adjusting for covariates (age, height, weight) if necessary

- Comparison between groups of the main study variables (MAP, HR, pain and anxiety level) analyzed using One-way and Repeated Measure ANOVA
- Comparison between groups of others secondary outcomes analyzed using Mann Whitney test or Unpaired Student's t-test

$P<0.05$ was considered significant. Values are mean (SD) unless otherwise stated.

3.5 RESULT

A total of 81 subjects were recruited into this study. There was no significant difference between groups, i.e. gender, nationality, marital status, educational level, previous surgery, age, BMI and total fluids given intraoperatively. There is a marginal differences in physical status in ASA level between groups (P-value=0.03) with 87.8% of subjects in Music group was ASA 1 and 5% was ASA2, while 67.5% of Control group was ASA1 and 13% was ASA2. All subjects were Muslim in the Intervention group in view of nature of religious music in this study. The groups were examined for differences in other intraoperative and postoperative variables that may have affected results, e.g. duration of surgery and duration of anaesthesia. Insignificance in duration of surgery and anaesthesia indirectly implies no difference in treatment dose between study groups.

3.5.1 Primary Outcomes: Pain, Anxiety Level, Hemodynamic Parameters

Subjects in Control group reported a mean pain score at rest of 2.42 (SD1.64) and mean dynamic pain score of 2.82 (SD1.73) post-operatively. While in Music group, mean pain score at rest was 2.80 (SD1.78) and mean dynamic pain score was 3.19 (SD1.89). These result show no significant difference between Control and Music groups in term of pain score at rest and dynamic pain score (pain with movement) with p-value of >0.05.

In the Control group, the mean anxiety score preoperatively was 11.37 (SD6.04) and mean anxiety score postoperatively was 8.67 (SD4.78) with T2-T1 reduction in anxiety level of 2.70 (SD3.38). On the other hand, in the Music group, the mean anxiety score preoperatively was 11.39 (SD 5.80) and postoperatively was 7.26 (SD 4.43) with T2-T1 changes in anxiety score of 4.12 (SD3.91). Comparison between Control and Music group showed no statistically difference in anxiety level reduction post-intervention (p-value = 0.40). However, comparison made within group showed significant reduction in anxiety level postoperatively when compared with baseline anxiety level before surgery with p-value of <0.05.

In this study, hemodynamic parameters in term of MAP and HR changes were investigated. Table 5.0 shows the mean MAP and HR changes preoperatively, intraoperatively and postoperatively between 2 groups. One-way ANOVA showed no significant difference between Control and Music groups in mean MAP changes. However, it is found out that there was significance reduction in mean MAP in Music group postoperatively compared to intraoperative mean MAP. There was also statistically significance reduction in mean MAP within Music group intraoperatively compared to preoperative mean MAP value. Both at a significant probability level of <0.05. In addition to statistical significance, there was clinical significance supporting music intervention because the MAP for the Music group decreased as much as a mean of 10mmHg intraoperatively, compared to Control group with a mean reduction of 7mmHg.

3.5.2 Secondary Outcomes

There was clinically significant reduction in total fentanyl requirement intraoperatively between Control and Music groups. The mean total fentanyl requirement in Control group was 79.17µg (SD45.87), as compared to Music group which required only half of the requirement with mean total requirement of 36.11µg (SD13.18), which is statistically very significant findings (p=0.01). Furthermore, duration of PACU stay was shorter in Music group with mean 3003 seconds (SD 218), compared with subjects in Control group with a mean duration of 3276 seconds (SD321) with a p=0.02.

This study revealed shorter time to first morphine requirement after arrival in PACU in Music group with mean 1304 seconds (SD 224) compared with Control group with mean of 1550 seconds (SD474) with p-value 0.02, not in favour of music intervention. The Control and Music groups did not differ in the mean time to last morphine requirement before discharged from PACU or in total morphine requirement in PACU with p=0.09 and p=0.18, respectively.

3.6 DISCUSSION

The study findings indicated that levels of anxiety, intraoperative MAP within group and the total requirement of fentanyl intraoperatively were significantly lowered or improved in the Music group compared with the Control group. Furthermore, the duration of PACU stay was significantly shorter in the Intervention group, indicating faster PACU discharge. Nevertheless, the mean pain score at rest and dynamic pain score showed no significance difference between 2 groups, not supporting the study hypothesis.

Interestingly, with regard to MAP, subjects in Music group showed clinically significant within group reduction in MAP intraoperatively compared to preoperative MAP with a mean of 10mmHg. This is also parallel with the findings of lesser total fentanyl required intraoperatively with nearly 50% reduction. This is a new finding that was discovered unique to religious-based music used in this study that worth for further exploration in the future.

The effect of music on human's brain is a potential field for ongoing exploration. Up to date, it is still not clear how music affects cerebral impulse transmission and neuronal activity. It is hypothesized that it involves modulation of neurotransmitters such a dopamine, norepinephrine and glutamate, thus influences emotions, mood and memories (11–12) and may cause a decline in neurohumoral response to surgery. (13)

A number of previously reported researches have evaluated the effects of music interventions during the perioperative period on 1 or more of the 4 dependent variables investigated in this study (pain, anxiety, MAP and HR) both in adult and paediatric subjects. (14-18) The review of the existing literature indicates considerable variability in findings related to the effects of music, as a vast majority of studies involve different patient population, heterogeneous types of musical selection and different time and duration of implementation. Because of these differences, it is difficult to compare findings across studies and extrapolate the findings.

Many of the existing studies have limitations that preclude generalizing their findings. The design of the present study addressed many of these limitations, including random allocation to Intervention and Control groups, and the use of religious-based music selected by the patient rather than the researcher. A study sample that consist of only patients undergoing upper limb surgical procedure (more than 1 hour duration) was selected to produce a relatively homogenous study population to control selected extraneous variables.

It must be acknowledged, however, that there were no measures to the control of other potential confounding variables such as socioeconomic status, baseline medications, differences in outcomes based on the operating surgeon or perioperative environment (e.g. background noise and cold temperature). In addition, because subjects knew that their levels of pain and anxiety were being studied, there may be the influence of a Hawthorne effect (Observer

effect) because of the nature of the self-reported assessment tools used and may have created an element of response bias. The Hawthorne effect is a type of reactivity in which individuals modify an aspect of their behaviour in response to their awareness of being observed.

3.7 CONCLUSION

The findings from this study provide new evidence about the effects of perioperative religious-based music on MAP, anxiety, and pain. Most previous studies have examined music that was provided only during the preoperative, intraoperative, or postoperative period and, rarely, throughout the perioperative period. The findings of this research are not only statistically significant, but they also demonstrate clinical significance.

Future research is recommended to determine whether perioperative religious-based music interventions might be helpful for patients undergoing other types of surgery, therapeutic or diagnostic procedure and other types of anaesthesia, e.g. in monitored anaesthesia care (MAC). Besides, further study may be done to explore the effect of religious-based music on awareness or depth of anaesthesia guided by BIS monitoring. Additional research is also needed to more specifically examine the mechanisms by which music produces beneficial effects, possibly at the level of cortical electrophysiology or neuronal cellular level.

3.8 REFERENCES

1. Zaslansky R, Rothaug J, Chapman RC, Backström R, Brill S, Engel C, et al. PAIN OUT: An international acute pain registry supporting clinicians in decision making and in quality improvement activities. J Eval Clin Pract. 2014;20(6):1090–8.

2. Ekstein MP, Weinbroum AA. Immediate Postoperative Pain in Orthopedic Patients Is More Intense and Requires More Analgesia than in Post-Laparotomy Patients. Pain Med. 2011;12(2):308–13.

3. Binns-Turner PG, Wilson LL, Pryor ER, Boyd GL, Prickett CA. Perioperative music and its effects on anxiety, hemodynamics, and pain in women undergoing mastectomy. AANA J. 2011;79(SUPPL. 4):20–7.

4. Aghamohammadi Kalkhoran M, Karimollahi M. Religiousness and preoperative anxiety: A correlational study. Ann Gen Psychiatry. 2007;6:1–5.

5. Fernell J. Listening to music during ambulatory ophthalmic surgery reduced blood pressure, heart rate, and perceived stress. Evid Based Nurs [Internet]. 2002;5(1):16–16. Available from: http://ebn.bmj.com/cgi/doi/10.1136/ebn.5.1.16

6. Ikonomidou E, Naesh O. Effect of Music. 2004;80(2).

7. Wong M. Effects of Music on Patient Anxiety. 2003;77(2).

8. Spencer J, Moran D, Lee A, Talber D. White noise and sleep induction. Arch Dis Child. 1990;65(1):135–7.

9. Terry P, Karageorghis C, Queensland S. Music in sport and exercise. 2016: (January 2011).

10. Schubert E. The influence of emotion, locus of emotion and familiarity upon preference in music. Psychol Music. 2007;35(3):499–515.

11. Särkämö T, Soto D. Music listening after stroke: Beneficial effects and potential neural mechanisms. Ann N Y Acad Sci. 2012;1252(1):266–81.

12. Särkämö T, Tervaniemi M, Laitinen S, Forsblom A, Soinila S, Mikkonen M, et al. Music listening enhances cognitive recovery and mood after middle cerebral artery stroke. Brain. 2008;131(3):866–76.

13. Chan MF, Chan EA, Mok E. Effects of music on depression and sleep quality in elderly people: A randomised controlled trial. Complement Ther Med. 2010;18(3–4):150–9.

14. Liu Y, Petrini MA. Effects of music therapy on pain, anxiety, and vital signs in patients after thoracic surgery. Complement Ther Med [Internet]. Elsevier Ltd; 2015;23(5):714–8. Available from: http://dx.doi.org/10.1016/j.ctim.2015.08.002

15. Garza-Villarreal, Eduardo; Pando, Victor; Vuust, Peter; Parsons C. Music-Induced Analgesia in Chronic Pain Conditions: A Systematic Review and MetaAnalysis. Pain Physician [Internet]. 2017;20:597–610. Available from: http://www.painphysicianjournal.com/current/pdf?article=NDcwMw%3D%3D&journal=108

16. Ottaviani S, Jean-Luc B, Thomas B, Pascal R. Effect of music on anxiety and pain during joint lavage for knee osteoarthritis. Clin Rheumatol. 2012;31(3):531–4.

17. van der Heijden MJE, Oliai Araghi S, van Dijk M, Jeekel J, Hunink MGM. The Effects of Perioperative Music Interventions in Pediatric Surgery: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. PLoS One [Internet]. 2015;10(8):e0133608. Available from: http://dx.plos.org/10.1371/journal.pone.0133608

18. Kain ZN, Caldwell-Andrews AA, Krivutza DM, Weinberg ME, Gaal D, Wang S-M, et al. Interactive Music Therapy as a Treatment for Preoperative Anxiety in Children: A Randomized Controlled Trial. Anesth Analg [Internet]. 2004;(12):1260–6. Available from: http://content.wkhealth.com/linkback/openurl?sid=WKPTLP:landingpage&an=00000539-200405000-00013