INCENTIVE SPIROMETRY PRESCRIPTION AND INSPIRATORY CAPACITY RECOVERY GUIDELINE FOR THE EARLY PERIOD AFTER OPEN HEART SURGERY

LEELA A/P T. NARAYANAN

A thesis submitted in fulfilment of the requirements for the award of the degree of Doctor of Philosophy (Health Science)

Faculty of Biosciences and Medical Engineering
Universiti Teknologi Malaysia

MARCH 2018
This thesis is dedicated to the cherished memory of my loving parents, the late Mr. T. Narayanan and Madam Hamalatha Narayanan.

Amma and Acha, I am who I am because of you.

I also dedicate this work to my dear husband, Syed Rasul Bin G. Syed Hamid.

Ji, you are the wind beneath my wings.
ACKNOWLEDGEMENT

First and foremost, I would like to express my heartfelt gratitude to my thesis supervisor, Prof. Ir. Ing. Dr. Eko Supriyanto (Faculty of Biosciences and Medical Engineering (FBME), UTM), for his immense support and guidance all throughout my PhD journey. “The best teachers are those who show you where to look, but don’t tell you what to see” – Alexandra Trenfor.

I would also like to thank Norayati Nordin (Biomedical Engineering Masters student, FBME) and Muhammad Akmal Ayob (Research Officer, FBME) for their participation and contribution in the development and validation of the data collection device used in this study. Without their unwavering and enthusiastic support, this research would not have been successfully conducted. Finally, my profound gratitude to Rumaisa Abu Hasan (Research Assistant, FBME), whose valuable insights and comments made my thesis preparation an exhilarating and enlightening experience.

To all of you, Thank you.
ABSTRACT

Incentive spirometry (IS) is often used as lung expansion therapy for increasing postoperative IS inspiratory capacity (ISIC) in open heart surgery (OHS) patients. However, currently there is a lack of guidelines and prescription on how this therapy should be administered for these patients. Although there is some information on several patient- and surgery-related factors associated with ISIC volumes after OHS, the role of IS performance variables such as IS inspiration volumes (ISv) and IS inspiration frequency (ISf) has not been investigated. In order to formulate evidence-based IS therapy guidelines and prescription, this study investigated factors, which included ISv and ISf, to identify predictors of ISIC recovery in a cohort of OHS patients in Hospital Sultanah Aminah, Johor Bahru (HSAJB). This study involved collection of objective and precise IS performance data of 95 OHS patients using a newly developed and validated multisensor data collection device (ISDCD) for five consecutive postoperative days (POD). Data analysis identified ISv as the sole predictor of ISIC recovery which explains 23%, 24%, 17% and 25% of variances for ISIC recovery on POD2, POD3, POD4 and POD5 respectively. Three pathways for postoperative ISIC recovery were also identified, namely for patients following the fastest pathway having the highest ISIC recovery rate of 19% for each POD, followed by 16% for the middle pathway and 12% for slowest. The findings facilitated the formulation of evidence-based IS therapy prescription and ISIC recovery guidelines from POD1 to POD4. However, these findings need to be verified further through research involving comprehensive and objective evaluation of IS performance using appropriate technology devices.
ABSTRAK

Alat insentif spirometer (IS) sering digunakan untuk mengembangkan paru-paru dan meningkatkan keupayaan inspirasi IS (ISIC) selepas pembedahan jantung terbuka (OHS). Walau bagaimanapun, pada masa ini terdapat kekurangan garis panduan dan preskripsi bagaimana terapi ini perlu diberikan untuk pesakit-pesakit ini. Walaupun terdapat maklumat mengenai beberapa faktor berkaitan dengan pesakit dan pembedahan yang dikaitkan dengan pemulihan ISIC selepas OHS, peranan faktor-fator dan peramal prestasi IS seperti isipadu inspirasi IS (ISv) dan frekuensi inspirasi IS (ISf) belum disiasat. Untuk merumuskan garis panduan terapi dan preskripsi terapi IS yang berasaskan bukti, kajian ini menyiasat faktor, termasuk ISv dan ISf, untuk mengenal pasti peramal pemulihan ISIC dalam kohort pesakit OHS di Hospital Sultanah Aminah, Johor Bahru (HSAJB). Kajian ini melibatkan pengumpulan data prestasi IS yang objektif dan tepat bagi pesakit 95 OHS menggunakan alat pengumpulan data multisensor yang baru dihasilkan dan disahkan (ISDCD) berturut-turut selama lima hari pasca-pembedahan (POD). Analisis data mengenal pasti ISv sebagai peramal tunggal pemulihan ISIC yang menjelaskan 23%, 24%, 17% dan 25% variasi untuk pemulihan ISIC pada POD2, POD3, POD4 dan POD5 masing-masing. Tiga laluan untuk pemulihan ISIC pasca-pembedahan juga dikenalpasti, yaitu pesakit yang mengikuti laluan terpantas mempunyai kadar pemulihan tertinggi ISIC sebanyak 19% untuk setiap POD, diikuti oleh 16% untuk laluan tengah dan 12% untuk yang paling lambat. Penemuan penemuan ini memudahkan penggubalan preskripsi terapi IS berasaskan bukti dan garis panduan pemulihan ISIC dari POD1 hingga POD4. Walau bagaimanapun, penemuan ini perlu disahkan menerusi penyelidikan yang melibatkan penilaian komprehensif dan objektif prestasi IS menggunakan peranti teknologi yang sesuai.
TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>CHAPTER</th>
<th>TITLE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>DECLARATION</td>
<td>ii</td>
</tr>
<tr>
<td></td>
<td>DEDICATION</td>
<td>iii</td>
</tr>
<tr>
<td></td>
<td>ACKNOWLEDGEMENT</td>
<td>iv</td>
</tr>
<tr>
<td></td>
<td>ABSTRACT</td>
<td>v</td>
</tr>
<tr>
<td></td>
<td>ABSTRAK</td>
<td>vi</td>
</tr>
<tr>
<td></td>
<td>TABLE OF CONTENTS</td>
<td>vii</td>
</tr>
<tr>
<td></td>
<td>LIST OF TABLES</td>
<td>xiii</td>
</tr>
<tr>
<td></td>
<td>LIST OF FIGURES</td>
<td>xvi</td>
</tr>
<tr>
<td></td>
<td>LIST OF ABBREVIATIONS</td>
<td>xx</td>
</tr>
<tr>
<td></td>
<td>LIST OF SYMBOLS</td>
<td>xxiii</td>
</tr>
<tr>
<td></td>
<td>LIST OF APPENDICES</td>
<td>xxiv</td>
</tr>
<tr>
<td>1</td>
<td>INTRODUCTION</td>
<td>1</td>
</tr>
<tr>
<td>1.1</td>
<td>Background of Study</td>
<td>1</td>
</tr>
<tr>
<td>1.2</td>
<td>Problem Statement</td>
<td>3</td>
</tr>
<tr>
<td>1.3</td>
<td>Study Objectives</td>
<td>4</td>
</tr>
<tr>
<td>1.4</td>
<td>Research Questions and Hypothesis</td>
<td>5</td>
</tr>
<tr>
<td>1.5</td>
<td>Scope of Study</td>
<td>5</td>
</tr>
<tr>
<td>1.6</td>
<td>Significance of Study</td>
<td>7</td>
</tr>
<tr>
<td>2</td>
<td>LITERATURE REVIEW</td>
<td>8</td>
</tr>
<tr>
<td>2.1</td>
<td>Introduction</td>
<td>8</td>
</tr>
<tr>
<td>2.2</td>
<td>Overview of Postoperative Atelectasis</td>
<td>9</td>
</tr>
</tbody>
</table>
2.2.1 Lung Volumes after OHS

2.2.2 Factors and Predictors Affecting Lung Volumes after OHS

2.2.3 Postoperative Lung Expansion Therapy

2.3 Incentive Spirometry as LET for Facilitating Postoperative Lung Expansion

2.3.1 Other Clinical Applications of IS

2.3.2 Brief History of Incentive Spirometry Equipment

2.3.3 Effects of Volume and Flow-oriented Incentive Spirometers on Thoracoabdominal Dynamics and Pulmonary Volume

2.4 Evidence Base for Therapeutic Efficacy of Incentive Spirometry Following OHS

2.4.1 Caveats in the Evidence Base Assessing Therapeutic Efficacy of Incentive Spirometry

2.4.1.1 Compliance-related Issues in Incentive Spirometry Interventions

2.4.1.2 Lack of Evaluation on Outcomes of IS from the Perspective of Lung Volume Recovery after OHS

2.4.2 Issues Pertaining to Monitoring and Tracking IS Performance and Usage

2.5 Rationale for Current Study

2.6 Summary of Chapter Two

3 METHODOLOGY

3.1 Overview

3.2 Ethics Approval
3.3 Organization of Study

3.3.1 Phase One: Materials and Methods

3.3.1.1 Rationale for Selecting Levento Spiro-Ball VIS

3.3.1.2 ISDCD Model

3.3.1.3 ISDCD Casing

3.3.1.4 ISDCD Evaluation before Field Study

3.3.2 Phase Two: Main Study Involving IS-related Data Collection

3.3.2.1 Research Design Consideration and Justifications

3.3.2.2 Venue of Study

3.3.2.3 Study Population

3.3.2.4 Definition of IS Volumes and Performance Variables Studied

3.3.2.5 Measurement of Key Study Variables

3.3.2.6 Data Collection Procedures

3.3.2.7 Ethical Considerations for Data Collection and Storage Procedures

3.3.2.8 Postoperative Physiotherapy

3.3.2.9 Analysis of Data

3.4 Summary of Methodology

4 RESULTS AND DISCUSSION

4.1 Introduction

4.2 ISDCD Validation

4.2.1 Electrical Safety of ISDCD

4.2.2 ISDCD Data Accuracy Analysis

4.2.3 Ability of ISDCD to Display ‘Quick Review’ Data Correctly; and to Track
and Store IS Data Accurately in Memory
Card along a Timeline

4.2.4 Reliability and Validity of Data
Collected

4.3 Sample Characteristics

4.4 ISIC Volume Changes from Preoperative Value
to POD5

4.4.1 Preoperative and Postoperative ISIC
Volumes

4.4.2 ISIC Volumes Achieved on POD5

4.4.2.1 Comparison of Sample
Characteristics between
Subgroups

4.4.2.2 Comparison of ISIC Volumes
between Subgroups

4.4.3 Implications of Findings on
Postoperative ISIC Volume Changes

4.5 IS Performance from POD1 to POD4 for Whole
Cohort and Subgroups

4.5.1 ISf of Whole Cohort and Subgroups

4.5.1.1 Distribution of ISf on POD 1, 2, 3
and 4

4.5.2 ISv of Whole Cohort and Subgroups

4.5.3 IS Compliance of Study Sample

4.5.3.1 Comparison between PODi ISf
with ISf=100 for each POD

4.5.3.2 IS Usage across Four Categories
of Timeline

4.5.3.3 Comparison between PODi ISv
with Corresponding PODi ISIC
for Whole Cohort and Subgroups

4.5.4 Relationship of ISv on Subsequent
Postoperative ISIC Volumes
4.5.5 Compliance and IS performance of the Study Cohort

4.6 NRS for Pain Evaluation

4.6.1 Relationship between Pain and IS Performance

4.6.1.1 Correlation between Pain and Corresponding POD$i$ IS$v$ in Absolute and Relative Values for Whole Cohort and Subgroups.

4.6.1.2 Correlation between Pain and Subsequent POD$i$ ISIC for Whole Cohort and Subgroups

4.6.2 Association between Postoperative Pain, ISIC Volumes and IS Performance

4.7 Predictive Strength of Patient, Surgery and IS Performance –Related Variables associated with ISIC$_{rel}$ Volumes

4.7.1 Predictive Strength of Variables Associated with Percentage ISIC Reduction from Preoperative to POD1

4.7.2 Predictive strength of variables associated with ISIC$_{rel}$ from POD1 to POD5

4.7.2.1 Predictive Strength of IS Performance and Pain of each POD$i$ on Subsequent POD$i$ ISIC$_{rel}$

4.7.2.2 Predictive Strength of Baseline Characteristics Variables and ISIC Reduction from Preoperative Value to POD1 on POD5 ISIC$_{rel}$
4.7.3 Factors and Predictors of Postoperative ISIC

4.7.3.1 Patient- and Surgery-related Factors and Predictors of Postoperative ISIC 112

4.7.3.2 IS Performance Predictors of Postoperative ISIC 114

4.7.3.3 Proposal for IS Therapy Prescription from POD1 to POD4 116

4.7.3.4 ISIC Recovery Goals from POD2 to POD5 118

4.7.3.5 Post-hoc Power Analysis 121

4.8 Summary of Key Findings 121

5 CONCLUSION AND RECOMMENDATIONS 123

5.1 Conclusion 123

5.1.1 Outline of Research Problems and Procedures 123

5.1.2 Implications of Significant Findings 124

5.2 Study Limitations 126

5.3 Recommendation for Future Research 127

REFERENCES 129

Appendices A-F 144-172
# LIST OF TABLES

<table>
<thead>
<tr>
<th>TABLE NO.</th>
<th>TITLE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Brief summary of reviewed papers with details on IS prescription and compliance evaluation; IS – incentive spirometry</td>
<td>28</td>
</tr>
<tr>
<td>3.1</td>
<td>Overall features and technical description of the ISDCD</td>
<td>46</td>
</tr>
<tr>
<td>3.2</td>
<td>Parameters compared from the datasets of the three sources: volunteer log sheet, LCD and memory card</td>
<td>52</td>
</tr>
<tr>
<td>4.1</td>
<td>Summary of safety check results of the ISDCD during phase one and two based on IEC 6000-1-1</td>
<td>77</td>
</tr>
<tr>
<td>4.2</td>
<td>RMSE and MAPE results for the ISDCD</td>
<td>78</td>
</tr>
<tr>
<td>4.3</td>
<td>Details on the IS performance of volunteers A, B and C</td>
<td>79</td>
</tr>
<tr>
<td>4.4</td>
<td>Baseline characteristics of the study sample</td>
<td>81</td>
</tr>
<tr>
<td>4.5</td>
<td>Postoperative ISIC volume changes in both absolute and relative values for whole cohort</td>
<td>82</td>
</tr>
<tr>
<td>4.6</td>
<td>Comparison between PODi ISIC and preop ISIC$_{abs}$ for whole cohort</td>
<td>83</td>
</tr>
<tr>
<td>4.7</td>
<td>Comparison of PODi ISIC with subsequent PODi ISIC in absolute and relative values for whole cohort</td>
<td>83</td>
</tr>
<tr>
<td>4.8</td>
<td>Comparison of sample characteristics between subgroups</td>
<td>85</td>
</tr>
<tr>
<td>4.9</td>
<td>Comparison of ISf between subgroups for each postoperative day</td>
<td>91</td>
</tr>
<tr>
<td>4.10</td>
<td>ISv on each postoperative day from POD1 to POD4 for whole cohort and subgroups in both absolute and relative values</td>
<td>93</td>
</tr>
</tbody>
</table>
4.11 Comparison of IS\textsubscript{v} between subgroups for each postoperative day in both absolute and relative values  
4.12 IS\textsubscript{v,c} on each postoperative day for whole cohort and subgroups  
4.13 Comparison of IS\textsubscript{v,c} between subgroups for each POD  
4.14 Comparison between POD\textsubscript{i} IS\textsubscript{f} and IS\textsubscript{f}=100 for whole cohort  
4.15 Comparison between POD\textsubscript{i} IS\textsubscript{f} and IS\textsubscript{f}=100 for subgroups  
4.16 IS usage across four categories of timeline for the whole cohort  
4.17 IS usage across four categories of timeline for subgroups  
4.18 Comparison between POD\textsubscript{i} IS\textsubscript{v} with the corresponding POD\textsubscript{i} ISIC for whole cohort in both absolute and relative values  
4.19 Comparison between POD\textsubscript{i} IS\textsubscript{v} with the corresponding POD\textsubscript{i} ISIC for subgroups in both absolute and relative values  
4.20 Correlation between each POD\textsubscript{i} IS\textsubscript{v,abs} and subsequent POD\textsubscript{i} ISIC\textsubscript{abs} for whole cohort  
4.21 Correlation between each POD\textsubscript{i} IS\textsubscript{v,rel} and subsequent POD\textsubscript{i} ISIC\textsubscript{rel} for whole cohort  
4.22 Correlation between each POD\textsubscript{i} IS\textsubscript{f} and subsequent POD\textsubscript{i} ISIC in absolute and relative values for whole cohort  
4.23 Comparison between daily mean pain levels of NRS between subgroups  
4.24 Correlation between each POD\textsubscript{i} pain scores and subsequent POD\textsubscript{i} IS\textsubscript{f} for whole cohort and subgroups  
4.25 Correlation between each POD\textsubscript{i} pain scores and corresponding POD\textsubscript{i} IS\textsubscript{v} in absolute and relative values for whole cohort and subgroups
4.26 Correlation between each POD$i$ pain scores and subsequent POD$i$ ISIC in absolute and relative values for whole cohort and subgroups

4.27 Univariate analysis to identify potential predictors for ISIC reduction from preoperative to POD1 values

4.28 Univariate analysis to identify potential predictors for subsequent POD$i$ ISIC$_{rel}$

4.29 Univariate analysis to identify potential predictors for POD5 ISIC$_{rel}$

4.30 Volume changes in POD5 ISIC$_{rel}$ as a result of mean ISV$_{rel}$, preopISIC$_{abs}$ and smoking status

4.31 Volume changes in POD$i$ ISIC$_{rel}$ as a result of POD$i$ ISV$_{rel}$

4.32 Guideline for ISIC recovery goals for the three different pathways

4.33 Recovery rate of ISIC for usual, accelerated and slower pathways
# LIST OF FIGURES

<table>
<thead>
<tr>
<th>FIGURE NO.</th>
<th>TITLE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>(A) During normal tidal volume inspiration (typically 500ml), only 350 ml enters the alveolar spaces to participate in gaseous exchange. The last 150 ml of this inspired air remains in the conducting airways or anatomical dead space where no gaseous exchange occurs; (B) If a person inspires only 150 ml of air during shallow breathing, theoretically, no fresh air enters the alveolar spaces as the 150 ml of inspired air is likely to remain in the conducting airways</td>
<td>10</td>
</tr>
<tr>
<td>2.2</td>
<td>(A) Normal – Alveoli perfused and ventilated; (B) mismatch of alveolar blood flow and ventilation caused by mucus plugging; (C) mismatch of alveolar blood flow and ventilation caused by low tidal volume breathing</td>
<td>12</td>
</tr>
<tr>
<td>2.3</td>
<td>(A) Pleural pressure decreases relative to alveolar pressure due to thoracic expansion during spontaneous inspiration. Transpulmonary pressure gradient increases resulting in alveolar expansion. (B) Alveolar pressure increases relative to pleural pressure due to positive pressure application. Transpulmonary pressure gradient increases resulting in alveolar expansion</td>
<td>17</td>
</tr>
<tr>
<td>2.4</td>
<td>Schematic diagram of the BE IS</td>
<td>21</td>
</tr>
<tr>
<td>2.5</td>
<td>Spirocare incentive breathing exerciser</td>
<td>22</td>
</tr>
<tr>
<td>2.6</td>
<td>Triflo: a flow-rate oriented incentive spirometer; (A) actual unit and (B) schematic diagram</td>
<td>23</td>
</tr>
</tbody>
</table>
2.7 Spiroball: a volume oriented incentive spirometer 24
2.8 Performing inspirations using the volume-oriented incentive spirometer 24
3.1 Flowchart of study methodology 39
3.2 Spiro-ball IS 40
3.3 The hollow spot at the base of the Spiro-ball IS volume chamber 41
3.4 Functional block diagram of the ISDCD 42
3.5 Display for total number of inspirations on the LCD intended for quick review 43
3.6 Volume markings on the Spiro-ball IS 44
3.7 The measured distances of the Spiro-ball IS and ISDCD sensor 44
3.8 Warning sign on the ISDCD’s LCD when the tilt sensor is activated 45
3.9 Sliding-in slot for Spiro-ball IS atop the ISDCD 46
3.10 Three dimensional design of the ISDCD with actual dimensions in mm 47
3.11 The Spiro-ball IS attached to the ISDCD 47
3.12 Summary of the testing procedure 49
3.13 Experimental setup for test one 50
3.14(A) Diagram depicting procedures used for descriptive statistics in phase two. Rectangles shaded in grey indicate the new emerging variables which were not previously defined in the objectives. 69
3.14(B) Flowchart depicting procedures and statistical tests used in comparative and correlational analyses (phase two) 70
3.14(C) Flowchart depicting procedures and statistical tests that were used in regression analyses (phase two) 71
4.1 Screenshot of the raw data in .txt file from the ISDCD memory card showing (a) date of IS performance (b) time of each inspiration (c) target volume set (d) volume of performed inspiration. 79
4.2 Sample selection process and reasons for excluding data of 51 patients

4.3 Categorization of patients into subgroups based on their achievement of 100% of preop ISIC_{abs} by POD5

4.4 Comparison POD{i} ISIC in (A) absolute and (B) relative values between subgroups

4.5 Comparison of POD{i} ISIC_{rel} with preop ISIC_{abs} (100%) within subgroups

4.6 Comparison of POD{i} ISIC_{abs} with subsequent POD{i} ISIC_{abs} within subgroups

4.7 Comparison of POD{i} ISIC_{rel} with subsequent POD{i} ISIC_{rel} within subgroups

4.8 ISf for each postoperative day from POD1 to POD4 for the whole cohort and subgroups

4.9 Distribution of ISf for whole cohort and sub-groups on (A) POD1, (B) POD2, (C) POD3 and (D) POD4

4.10 Multiple regression analysis to identify potential predictors for ISIC reduction from preoperative to POD1 values

4.11 Graphical representation for best predictive model for ISIC reduction from preoperative to POD1 values

4.12 Multiple regression analysis to identify potential predictors for subsequent ISIC_{rel} on (A) POD2, (B) POD3, (C) POD4 and (D) POD5

4.13 Graphical representations for predictive model for ISIC_{rel} from POD2 to POD5

4.14 Multiple regression analysis process of identifying predictors for POD5 ISIC_{rel}

4.15 Graphical representation of best predictive model for POD5 ISIC_{rel}

4.16 Contribution of predictors to POD5 ISIC_{rel} predictive model
4.17 ISIC recovery for usual (N = 95), accelerated (n = 53) and slower (n = 42) recovery pathways
**LIST OF ABBREVIATIONS**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABS</td>
<td>Acrylonitrile butadiene styrene</td>
</tr>
<tr>
<td>ADC</td>
<td>Analogue to digital converter</td>
</tr>
<tr>
<td>am</td>
<td>Ante meridiem</td>
</tr>
<tr>
<td>ANOVA</td>
<td>Analysis of variance</td>
</tr>
<tr>
<td>BE-IS</td>
<td>Bartlett-Edwards incentive spirometer</td>
</tr>
<tr>
<td>BMI</td>
<td>Body mass index</td>
</tr>
<tr>
<td>CABG</td>
<td>Coronary artery bypass grafting</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence interval</td>
</tr>
<tr>
<td>CICU</td>
<td>Cardiothoracic intensive care unit</td>
</tr>
<tr>
<td>C_index</td>
<td>Condition index</td>
</tr>
<tr>
<td>CPAP</td>
<td>Continuous positive airway pressure</td>
</tr>
<tr>
<td>CPB</td>
<td>Cardiopulmonary bypass</td>
</tr>
<tr>
<td>DBE</td>
<td>Deep breathing exercise</td>
</tr>
<tr>
<td>df</td>
<td>Degree of freedom</td>
</tr>
<tr>
<td>FEV₁</td>
<td>Force expiratory volume in first second</td>
</tr>
<tr>
<td>FIS</td>
<td>Flow-rate oriented incentive spirometer</td>
</tr>
<tr>
<td>FRC</td>
<td>Functional residual capacity</td>
</tr>
<tr>
<td>FVC</td>
<td>Forced vital capacity</td>
</tr>
<tr>
<td>GRC</td>
<td>Goal-recording counter</td>
</tr>
<tr>
<td>HSAJB</td>
<td>Hospital SultanahAminah Johor Bahru</td>
</tr>
<tr>
<td>IC</td>
<td>Inspiratory capacity</td>
</tr>
<tr>
<td>IPPB</td>
<td>Intermittent positive pressure breathing</td>
</tr>
<tr>
<td>IR</td>
<td>Infrared</td>
</tr>
<tr>
<td>IS</td>
<td>Incentive spirometry</td>
</tr>
<tr>
<td>ISDCD</td>
<td>Incentive spirometry data collection device</td>
</tr>
</tbody>
</table>
ISf - Incentive spirometry inspiration frequency
ISIC - Incentive spirometry inspiratory capacity
ISIC_{abs} - Absolute value of ISIC
ISIC_{rel} - Relative value of ISIC
ISv - Incentive spirometry inspiration volume
ISv_{abs} - Absolute ISv
ISv_{c} - Cumulative ISv
ISv_{rel} - Relative ISv
LCD - Liquid crystal display
LED - Light emitting diode
LET - Lung expansion therapy
MAPE - Mean absolute percentage error
NIV - Noninvasive ventilation
NRS - Numeric rating scale
OHS - Open heart surgery
Palv - Alveolar pressure
PC - Personal computer
PEP - Positive expiratory pressure
PIC - Predictive inspiratory capacity
P_{L} - Transpulmonary pressure gradient
pm - Post meridiem
POD - Postoperative days
P-P - Probability-probability
PPC - Postoperative pulmonary complication
Ppl - Pleural pressure
PreopISIC_{abs} - Absolute value of preoperative ISIC
RCT - Randomized controlled trial
RMSE - Root mean square error
SD - Standard deviation
SDHC - Secure digital high capacity
se - Standard error
SPSS - Statistical package for social science software
TLC - Total lung capacity
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>V/Q</td>
<td>Ventilation-perfusion</td>
</tr>
<tr>
<td>VAS</td>
<td>Visual analogue scale</td>
</tr>
<tr>
<td>VC</td>
<td>Vital capacity</td>
</tr>
<tr>
<td>VIS</td>
<td>Volume-oriented incentive spirometry</td>
</tr>
</tbody>
</table>
LIST OF SYMBOLS

$\alpha$ - Statistical significance level
$\beta$ - Rate of type II error
$\%$ - Percentage
- Change
B - B-value or coefficient
$B_s$ - Standardized B-value or coefficient
cm - centimetre
D - Distance
$f$ - G*power effect size
F - F-score in ANOVA
g - gram
H - Height
kg - kilogram
L - Length
m - metre
ml - millilitre
N - Sample size of whole cohort
n - Sample size of subgroup
p-value - Probability value
r - Effect size
R - Pearson correlation coefficient
$s$ - Infrared sensor output
t - t-score in t-test
V - volt
Vol - Inspired volume
W - Width
## LIST OF APPENDICES

<table>
<thead>
<tr>
<th>APPENDIX</th>
<th>TITLE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Drugs.com Image</td>
<td>144</td>
</tr>
<tr>
<td>B</td>
<td>Ethics Approval Forms</td>
<td>145</td>
</tr>
<tr>
<td>C</td>
<td>Informed Consent Forms</td>
<td>148</td>
</tr>
<tr>
<td>D</td>
<td>HSAJB Field Study Data Collection Form</td>
<td>160</td>
</tr>
<tr>
<td>E</td>
<td>Incentive Spirometry Protocol</td>
<td>162</td>
</tr>
<tr>
<td>F</td>
<td>P-P Plot</td>
<td>163</td>
</tr>
</tbody>
</table>
CHAPTER 1

INTRODUCTION

1.1 Background of Study

This study investigates factors and predictors of changes that occur in incentive spirometry inspiratory capacity (ISIC) volumes in the first five postoperative days (PODs) after open heart surgery (OHS). ISIC are volumes of air inspired by patients using volume-oriented incentive spirometer (VIS) devices while OHS is a surgical procedure where access to the heart and its associated structures is obtained through a midline sternotomy incision. OHS patients are at high-risk for postoperative pulmonary complications (PPCs) due to various surgery and patient-related factors which cause diminished lung volumes, causing increased susceptibility to PPCs (Warner, 2000). This underscores the need for effective lung expansion therapies (LET) to improve lung volumes in the early postoperative period after OHS. One such commonly used LET for facilitating maximal inspiratory breaths in postoperative patients is incentive spirometry (IS),

The process of IS requires the patient to inspire to maximal inspiratory volumes on each postoperative day and these volumes are increased progressively throughout the course of IS therapy in order to achieve preoperative ISIC volumes
prior to discharge. However, there is not much information on ISIC volume changes that occur in the postoperative period after OHS. Current IS guidelines also do not specify the magnitude of increases in ISIC volume goals that should be targeted for OHS patients. This makes it difficult to ascertain suitable target volumes for achieving optimal outcomes for each postoperative day.

Several surgery and patient-related factors and predictors have been identified as risk factors for reduced lung volumes and increased propensity towards PPCs after OHS. However, patient-related factors such as compliance and performance of IS therapy has not been investigated comprehensively. Patient compliance with IS therapy is essential for maintaining and improving alveolar patency and pulmonary function (Fisher, 2013). Compliance, in clinical situations, is the extent to which therapeutic prescriptions or recommendations are followed by the patient (Martin, 2005) and in the context of IS, patient’s performance and self-administration of this therapy may be insufficient or vary throughout the course of intervention to cause an impact on outcomes. IS therapy is often based on prescriptions comprising several performance parameters such as the frequency at which the therapy should be done and the amount of volume that should be inspired during each inspiration. However, there is lack of supportive evidence on the relationship and effects of IS parameters on lung volume outcomes. Current guidelines on IS therapy (Restrepo et al., 2011) also reflect these uncertainties they do not specify optimal dosages for IS performance parameters.

Despite the lack of sufficient scientific evidence on its efficacy on clinical outcomes, ease and simplicity of use makes IS a favored option for postoperative LET in many healthcare settings (Fisher, 2013) and this practice has been deemed counterproductive, especially in the context of increasing healthcare costs (Branson, 2013). Hence, given the dearth of evidence on IS performance-related factors, there is a need for more research to explore these perspectives as well. In order to accomplish this, ISIC volume changes and IS performance-related variables need to be studied comprehensively in an objective manner. One of the constraints preventing such efforts may be the lack of data collection features in current IS
devices, which could be overcome using appropriate technological approaches. Hence this study aimed to conduct an objective longitudinal investigation into ISIC volume changes in relation to patient and surgery-related factors, as well as IS performance variables obtained using an appropriate technology device.

1.2 Problem Statement

Cardiothoracic surgery service is one of the major fast growing specialties in Malaysian Ministry of Health hospitals and the need for effective evidence-based interventions to optimize patient care and outcomes is espoused in its operational policy (Ministry of Health, Malaysia, 2011).

i. IS is routinely used to improve lung volumes in the early postoperative period for OHS patients in Hospital Sultanah Aminah, Johor Bahru (HSAJB), Malaysia. However, information on serial relative ISIC volume changes occurring after OHS, to be used as a guideline for ascertaining IS target volumes for each postoperative day, is not available. Additionally, factors and predictors of postoperative ISIC volume outcomes in a local OHS has not been investigated before.

ii. IS prescription used in HSAJB also comprises these two parameters, namely frequencies of usage and inspiratory volumes and therapy is performed with the goal of recovering postoperative ISIC volumes to preoperative values prior to discharge. However, the association between these two parameters and ISIC volume outcomes has not been investigated before.

iii. To address the above-mentioned issues, IS performance needs to be objectively monitored and tracked through the course of intervention to obtain precise data on patients’ compliance to the prescribed IS
parameters. However, the single-use disposable VIS devices used in this hospital lack the necessary features. Electronic technologies may be used for collecting such data but implications of cost has to be considered as any upgrade to the IS device itself is bound to increase its cost. Thus, an appropriate electronic technology capable of tracking and collecting such data, and at the same time does not increase the cost of the IS device, needs to be developed before these endeavors can be undertaken.

1.3 Study Objectives

The objectives of this study are as follows:

i. To identify relative changes in ISIC volumes from preoperative period to POD 5 and the IS compliance of an OHS study sample in HSAJB.

ii. To determine the relationship and predictive strength of age, gender, body mass index (BMI), smoking status, preoperative ISIC (preop ISIC), cardiopulmonary bypass (CPB) time, pain, IS frequency (ISf) and IS inspiration volumes (ISv) on postoperative ISIC outcomes in order to formulate and propose evidence-based IS prescription for this patient population.

iii. To develop and validate an appropriate IS data acquisition device capable of collecting and storing IS performance data which can be used to investigate relationship between IS performance and postoperative ISIC volume outcomes in these patients.
1.4 Research Questions and Hypothesis

i. What are the relative changes that occur in ISIC volumes from the preoperative period to POD 5 and the IS performance compliance of a sample of OHS patients in HSAJB?

ii. What evidence-based IS prescription can be formulated for these patients, based on the findings from the relationship and predictive strength of their age, gender, BMI, smoking status, preop ISIC, CPB time, pain, IS performance frequency and volumes on their postoperative ISIC volume outcomes?

iii. Is the newly-developed IS data collection device valid and reliable in collecting IS performance data?

For this study, a null hypothesis was postulated that there is no relationship between any factors or predictors which were studied on postoperative ISIC volume outcomes.

1.5 Scope of Study

To achieve the research objectives, this study was conducted in a cohort of OHS patients in HSAJB. The scope of the study was focused on the aspects outlined below:

i. Conduct power analysis to determine the sample size needed for the study.
ii. Collect data:
   a. Using manual methods for:
      – Sample characteristics and preop ISIC
      – Postoperative ISIC
   b. Using the newly developed IS data collection device for IS performance from POD 1 to POD 5.

iii. Conduct data analysis to:
   a. Examine and describe the relative changes in ISIC volumes from the preoperative period to POD 5.
   b. Examine and describe the IS performance compliance of these patients.
   c. Examine the relationship and test the predictive strength of pain, IS performance frequency and volumes on POD 1, 2, 3 and 4 on ISIC volume outcomes on POD 2, 3, 4 and 5 respectively.
   d. Examine the relationship and test the predictive strength of age, gender, BMI, smoking status, preop ISIC, CPB time, IS performance frequency and volumes on ISIC volume outcomes on POD 5.

iv. Formulate and propose IS therapy prescription for this patient population, based on the findings from this research.

v. Develop a suitable device capable of tracking, recording and storing IS-related data.

vi. Test the device in these following aspects:
   a. Electrical safety
   b. Functionality of the various features of the device
   c. Performance of the device in accurately tracking, recording and storing IS-related data.
1.6 Significance of Study

This study helps to:

i. Provide evidence on the relationship between age, gender, BMI, smoking status, preop ISIC, CPB time, pain, IS performance frequency and volumes on postoperative ISIC volume outcomes after OHS to formulate and propose suitable IS therapy prescription that can be potentially used for OHS patients in HSAJB.

ii. Provide insights on the clinical validity of IS therapy and facilitate care strategies that may improve outcomes for these patients.

iii. Provide a suitable technology option for fellow researchers in this field to conduct similar studies in different clinical populations.

iv. Catalyze a new direction in IS research by highlighting the need for including comprehensive and objective evaluation of IS performance frequency and volumes to determine best practices in IS therapy.
REFERENCES


