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

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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.

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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 explaines 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 paruparu 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.

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LIST OF ABBREVIATIONS

| ABS | - | Acrylonitrile butadiene styrene |
|---------|---|--|
| ADC | - | Analogue to digital converter |
| am | - | Ante meridiem |
| ANOVA | - | Analysis of variance |
| BE-IS | - | Bartlett-Edwards incentive spirometer |
| BMI | - | Body mass index |
| CABG | - | Coronary artery bypass grafting |
| CI | - | Confidence interval |
| CICU | - | Cardiothoracic intensive care unit |
| Cindex | - | Condition index |
| CPAP | - | Continuous positive airway pressure |
| CPB | - | Cardiopulmonary bypass |
| DBE | - | Deep breathing exercise |
| df | - | Degree of freedom |
| FEV_1 | - | Force expiratory volume in first second |
| FIS | - | Flow-rate oriented incentive spirometer |
| FRC | - | Functional residual capacity |
| FVC | - | Forced vital capacity |
| GRC | - | Goal-recording counter |
| HSAJB | - | Hospital SultanahAminah Johor Bahru |
| IC | - | Inspiratory capacity |
| IPPB | - | Intermittent positive pressure breathing |
| IR | - | Infrared |
| IS | - | Incentive spirometry |
| ISDCD | - | Incentive spirometrydata collection device |
| | | |

| 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 |
| ISvc | - | Cumulative ISv |
| ISv _{rel} | - | Relative ISv |
| LCD | - | Liquid crystal display |
| LED | - | Light emitting diode |
| LET | - | Lung expansion therapy |
| MAPE | - | Mean absolute percentage error |
| NIV | - | Noninasive ventilation |
| NRS | - | Numeric rating scale |
| OHS | - | Open heart surgery |
| Palv | - | Alveolar pressure |
| PC | - | Personal computer |
| PEP | - | Positive expiratory pressure |
| PIC | - | Predictive inspiratory capacity |
| \mathbf{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 |

| V/Q | - | Ventilation-perfusion |
|-----|---|--------------------------------------|
| VAS | - | Visual analogue scale |
| VC | - | Vital capacity |
| VIS | - | Volume-oriented incentive spirometry |

LIST OF SYMBOLS

| α | - | Statistical significance level |
|---------------------------|---|-------------------------------------|
| β | - | Rate of type II error |
| % | - | Percentage |
| | - | Change |
| В | - | B- value or coefficient |
| $\mathbf{B}_{\mathbf{s}}$ | - | Standardized B-value or coefficient |
| cm | - | centimetre |
| D | - | Distance |
| f | - | G*power effect size |
| F | - | F-score in ANOVA |
| g | - | gram |
| Н | - | Height |
| kg | - | kilogram |
| L | - | Length |
| m | - | metre |
| ml | - | millilitre |
| Ν | - | 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 |
| | | |

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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:

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

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.
- 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.

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