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## REVIEW

### Effect of incentive spirometry after cardiac surgery: protocol for a systematic review *Efeito da espirometria de incentivo no pós-operatório de cirurgia cardíaca: protocolo para uma revisão sistemática*

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## Abstract

**Introduction:** Patients receiving cardiac surgeries present high risk of developing postoperative complications. Incentive spirometry (IS) is used for the prevention and treatment of postoperative pulmonary complications in patients undergoing cardiac surgeries. Publications have suggested that IS is ineffective. In contrast, some studies have shown that when IS is adequately used, it may lead to beneficial outcomes. **Objectives:** To assess the effect of IS in patients undergoing cardiac surgeries. **Methods/design:** Systematic Reviews with randomised and quasi-randomised trials with adult patients undergoing cardiac surgeries, evaluating the effect of flow or volume-oriented IS. **Outcome measures:** postoperative pulmonary complications; adverse events; mortality; length of hospital stay; length of intensive care unit stay; reintubation rate; pulmonary function; antibiotic use; oxygenation; and respiratory muscle strength. **Search:** MEDLINE, EMBASE, CENTRAL, PEDro, CINAHL, LILACS, SCIELO, Allied, AMED, Scopus, Open Grey database, the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP), ClinicalTrials.gov, clinicaltrialsregister.eu, and ReBec. Two authors will independently extract data. PEDro scale will be used to evaluate the methodological quality of the studies. Meta-analysis will be performed using the inverse variance method and the random effects model in RevMan 5.3. We will use the I<sup>2</sup> statistic to estimate the amount of heterogeneity across studies in each meta-analysis. **Ethics and dissemination:** The approval of an ethical committee is not required. Only clinical trials that have complied with ethical guidelines and followed the Declaration of Helsinki, will be included in this systematic review. The findings of this study will help clarify uncertainties about the effects of incentive spirometry in the postoperative period of cardiac surgery and may be disseminated to clinicians, assisting in decision making and including the best evidence in the treatment of their patients. **Discussion:** This review will clarify the uncertainty over whether IS is a useful technique for patients undergoing cardiac surgeries. While good quality studies have shown IS is an effective prophylactic technique, other studies have suggested that there is no evidence to support IS utilization.

**Keywords:** incentive spirometry, cardiac surgery, postoperative

## Resumo

**Introdução:** Pacientes submetidos a cirurgias cardíacas apresentam alto risco de desenvolver complicações pós-operatórias. A espirometria de incentivo (EI) é utilizada para a prevenção e

tratamento de complicações pulmonares pós-operatórias em pacientes submetidos a cirurgias cardíacas. As publicações têm sugerido que a EI é inefetiva. Em contrapartida, alguns estudos têm demonstrado que quando a EI é utilizada adequadamente, pode levar a resultados benéficos. **Objetivos:** Avaliar o efeito da EI em pacientes submetidos a cirurgias cardíacas. **Métodos/desenho:** Revisões sistemática de estudos randomizados e quase randomizados com pacientes adultos submetidos a cirurgias cardíacas, avaliando o efeito da EI a fluxo ou a volume. **Medidas de desfecho:** complicações pulmonares pós-operatórias; eventos adversos; mortalidade; tempo de internação hospitalar; tempo de internação na unidade de terapia intensiva; taxa de reintubação; função pulmonar; uso de antibióticos; oxigenação e força muscular respiratória. **Busca:** MEDLINE, EMBASE, CENTRAL, PEDro, CINAHL, LILACS, SCIELO, Allied, AMED, Scopus, Open Grey database, World Health Organization International Clinical Trials Registry Platform (WHO ICTRP), ClinicalTrials.gov, clinicaltrialsregister.eu, e ReBec. Dois autores irão extrair dados de forma independente. A escala PEDro será utilizada para avaliar a qualidade metodológica dos estudos. A meta-análise será realizada utilizando o método do inverso da variância e o modelo de efeitos aleatórios no RevMan 5.3. Será utilizada a estatística  $I^2$  para estimar a heterogeneidade entre os estudos em cada meta-análise. **Ética e disseminação:** A aprovação de um comitê de ética não é necessária. Somente estudos clínicos que tenham cumprido as diretrizes éticas e seguido a Declaração de Helsinque serão incluídos nesta revisão sistemática. Os resultados deste estudo ajudarão a esclarecer incertezas sobre os efeitos da espirometria de incentivo no período pós-operatório de cirurgia cardíaca e poderão ser divulgados aos clínicos, auxiliando na tomada de decisões e incluindo as melhores evidências no tratamento de seus pacientes. **Discussão:** Esta revisão esclarecerá a incerteza sobre a utilidade da EI para pacientes submetidos à cirurgia cardíaca. Embora estudos de boa qualidade tenham demonstrado que a EI é uma técnica profilática eficaz, outros estudos sugeriram que não há evidências que apoiem a utilização da EI.

**Palavras-chave:** espirometria de incentivo, cirurgia cardíaca, pós-operatório.

## Introduction

Worldwide, nearly two million patients undergo cardiac surgeries annually [1]. The patients receiving cardiac surgeries present high risk of developing postoperative complications [2]. Mortality rates may vary from 2.94% [3] to 6.50% [4]. The postoperative time, the type of cardiac surgery and the type of care received by the patients during the postoperative period are factors that may influence the mortality rates [5,6]. The costs of cardiac surgeries are high [5,6] and may increase when the patients receive low quality healthcare [7].

Incentive spirometry (IS) is a low-cost technique used for the prevention and treatment of postoperative pulmonary complications in patients undergoing cardiac surgeries [8]. IS comprises the use of volume or flow oriented devices, designed to provide visual feedback and to stimulate deep, slow and sustained inspirations [9]. Studies evaluating the effectiveness of IS have shown conflicting results. Several publications have suggested that IS is ineffective [8,10]. Nevertheless, nearly 42% of physiotherapists keep using IS after thoracic surgical procedures [11]. In contrast, some studies have shown that when IS is adequately used, it may lead to beneficial outcomes [12,13]. These studies have suggested that IS may improve blood arterial gas parameters and prevent and treat atelectasis [13]. Further well-conducted studies are needed to guide clinical decision making and avoid ineffective practices [15].

To our knowledge, there are no systematic reviews exclusively evaluating the effect of IS in patients undergoing cardiac surgeries, with extensive search of databases and no language or time of publication limitations. Thus, we designed this systematic review to answer the question: - Is IS safe and more effective than sham IS, nothing, or other therapies for reducing postoperative pulmonary complications, mortality, length of hospital and/or intensive care unit (ICU) stay, reintubation rate, pulmonary function, respiratory muscle strength, oxygenation and antibiotic use in patients undergoing cardiac surgery?

## Methods/Design

### Design

We will perform a systematic review following the recommendations proposed by the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) [16]. This review

protocol will be prospectively registered in the International Prospective Register of Systematic Reviews (PROSPERO)

## Eligibility criteria

### *Types of studies*

Randomized and quasi-randomized trials will be included in this systematic review. We will consider that quasi-randomized study are controlled trials in which participants are allocated to different groups using a not trully random method of allocation (eg, medical record number, or date of birth) [17].

### *Types of participants*

Trials including patients aged 18 years and over undergoing cardiac surgeries.

### *Types of interventions*

We will include trials evaluating the effect of postoperative flow or volume-oriented IS [18] in patients who have undergone cardiac surgeries. The IS may have been used alone, or combined with other techniques, after cardiac surgeries. Comparison groups can be: nothing, sham IS, other therapies or other comparisons in which IS effect can be exclusively evaluated, such as: IS + usual care versus usual care alone; IS + oxygen therapy versus oxygen therapy alone; IS + continuous positive airway pressure (CPAP) versus CPAP alone; and so on.

## Outcome measures

### - Primary outcomes

- Postoperative pulmonary complications, including independent analysis of the outcomes:
- Atelectasis: radiologic, bronchoscopic or clinical diagnosis.
- Respiratory infection (pneumonia): radiologic or clinical diagnosis.
- Adverse events: any reaction, harm, or complication associated with IS reported in the included studies.
- Mortality: any mortality cause will be accepted.

### - Secondary outcomes

- Length of hospital stay: the number of days spent in hospital after the cardiac surgical procedure will be registered.
- Length of intensive care unit stay: the number of days spent in ICU after the cardiac surgical procedure will be registered.
- Reintubation rate: the number of intubation events following planned extubation will be registered.
- Pulmonary function: all pulmonary function variables will be accepted.
- Antibiotic use: the number of antibiotics and the number of days using antibiotics will be registered.
- Oxygenation: arterial oxygen partial pressure (PaO<sub>2</sub>), oxygenation index (OI), and peripheric and central arterial oxygen saturation (SaO<sub>2</sub>) will be accepted.
- Respiratory muscle strength: Maximal inspiratory and expiratory pressures measured with digital or analog manovacuometer or manometer will be accepted.

## Report characteristics

We will include studies performed in any year. No language restrictions will be used in the selection. We will also include grey literature data.

## Data Sources and Searches

We will search MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL), PEDro, CINAHL, LILACS, SCIELO, Allied and Complementary Medicine Database (AMED) and Scopus using relevant descriptors and synonyms, adapting the search to the requirements of each database.

We will also search the Open Grey database, the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP), ClinicalTrials.gov, clinicaltrialsregister.eu, and ReBec (Brazilian Register of Clinical Trials) to identify published, ongoing, and unpublished studies. We will hand search abstracts from scientific meetings, including the International Conference on Cardiovascular and Thoracic surgery, International Conference on Cardiovascular Medicine and Cardiac Surgery, International Symposium of Cardiopulmonary Physiotherapy and Intensive Care Physiotherapy, European Society of Cardiology Congress, and European Association for Cardio-Thoracic Surgery Annual Meeting. We will contact authors of relevant studies to identify additional studies. Finally, we will use the technique of snowballing, searching the lists of references of the included studies.

## Search strategy

We will use the terms related to the problem of interest and to the therapeutic technique. The terms are described in Table I.

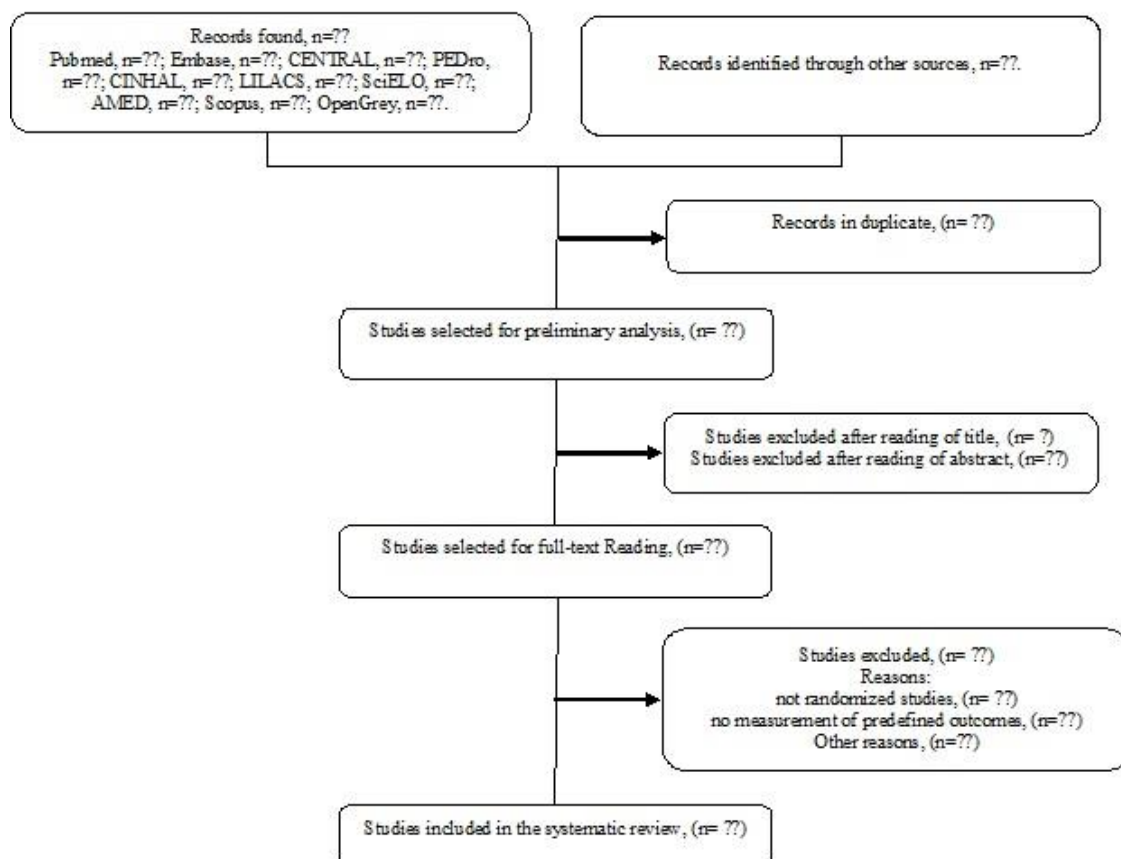
**Table I - Systematic review Search Strategy.**

Number	Combiners	Terms
1	Problem of interest	((("Cardiac Surgical Procedures"[Mesh]) OR (Heart Surgical Procedures) OR (Cardiac Surgical Procedure) OR (Cardiac Surgery) OR (Heart Surgery) OR (Cardiovascular Surgery) OR ("Coronary Artery Bypass"[Mesh]) OR (Coronary Artery Bypass Grafting) OR CABG OR (Heart Bypass) OR (Coronary Bypass) OR (Aortocoronary Bypass) OR (Myocardial Revascularization) OR ("Cardiopulmonary Bypass"[Mesh]) OR (Heart-Lung Bypass) OR (Cardiology Robotic Surgery) OR ("Angioplasty"[Mesh]) OR ("Balloon Valvuloplasty"[Mesh]) OR (Valve Repair) OR (Valvular Surgery) OR (Valve Surgery) OR ("Cardiac Valve Annuloplasty"[Mesh]) OR (Valvular Annuloplasty) OR (Heart Valve Annuloplasty) OR (Cardiac Valve Annulus Repair) OR (Heart Valve Annulus Repair) OR (Cardiac Valve Annular Reduction) OR (Cardiac Valve Annulus Shortening) OR (Cardiac Valve Annulus Reduction) OR (Valve Replacement) OR ("Transcatheter Aortic Valve Replacement"[Mesh]) OR TAVR OR ("Heart Valve Prosthesis Implantation"[Mesh]) OR (Insertion of Pacemaker) OR (Insertion of implantable cardioverter defibrillator) OR (Maze Surgery) OR (Aneurysm Repair) OR ("Heart Transplantation"[Mesh]) OR (Heart Transplant) OR (Heart Grafting) OR (Cardiac Transplantation) OR (Cardiac Transplant) OR (Insertion of Ventricular Assist Device) OR (VAD Surgery) OR (Insertion of Total Artificial Heart) OR TAH OR ("Thoracic Surgical Procedures"[Mesh]) OR (Thoracic Surgical Procedure) OR (Thoracic Surgery) OR (Arrhythmia Surgery) OR (Aortic Aneurysm Repair) OR (Aortic Surgery) OR (Left Ventricular Assist Device) OR LVAD OR (Left Ventricular Remodeling) OR (Surgical Ventricular Restoration) OR (Heart Myectomy) OR (Heart Myotomy) OR (Transmyocardial Revascularization) OR TMR OR (Atrial Fibrillation Surgery) OR (Hypertrophic Cardiomyopathy Surgery) OR (Thoracoscopic Surgical Procedures) OR (Thoracoscopic Surgeries) OR ("Thoracotomy"[Mesh]) OR Thoracotomies OR Thoracostomy OR ("Thoracic Surgery, Video-Assisted"[Mesh]) OR (Video-Assisted Thoracic Surgery) OR VATS))("Breathing Exercises"[Mesh]) OR
2	Intervention	(Incentive Spirometry) OR (Flow-Incentive Spirometer) OR (Incentive Spirometer) OR Coach OR (Coach 2) OR Triflo OR (Triflow Device) OR Voldyne))))
3	Type of study	(((((clinical[Title/Abstract] AND trial[Title/Abstract]) OR clinical trials as topic[MeSH Terms] OR clinical trial[Publication Type] OR random*[Title/Abstract] OR random allocation[MeSH Terms] OR therapeutic use[MeSH Subheading])))
4		#1 AND #2 AND #3

The search strategy above will be used in Medline via Pubmed and will be adapted to the specifications of each database.

## Study selection

Three authors will independently select the studies for inclusion in this review (ECS, JRFFM e ACPNP). Two authors will select potential studies identified by the search strategy based on the pre-specified eligibility criteria. First, duplicated studies (found in more than one database) will be excluded. When duplicated reports are found (studies with the same participants, with the same outcome measurements and using the same time points for the assessments), the report with the smaller sample size will be excluded. If reports with the same participants but different outcome measurements or using different time points for the assessments are found, both the reports will be included (the two reports will be considered as parts of only one study). Second, the authors will read the study titles and abstracts; and, if necessary, they will finally read the full texts. Studies that do not match the inclusion criteria for this review will be excluded. The reasons for exclusion of the studies that are fully read will be presented. Disagreements between authors regarding study inclusion will be resolved by the third author (ACPNP). We will use Rayyan app [19] to optimize the process of screening and selection of studies. The flow chart of this systematic review is shown in figure 1.



**Figure 1 - Flow chart of systematic review.**

### Data Extraction and management

Data will be managed and stored on Dropbox. Two authors (ECS e JRFFM) will independently extract data. Discrepancies or disagreements will be solved by a third author (ACPNP). The authors of the relevant studies will be contacted in the case of missing study details. We will use a predefined form to extract data from included studies. The form will have information related to: - the patients (demographic and clinical characteristics); - the surgery (the type of surgery: elective, urgency, or emergency; surgery duration; type of surgical incision; use of extracorporeal circulation); - intervention characteristics (time of the intervention commencing, type of device, training details: volume, frequency, recovery, duration, use of co-interventions,

adherence to training); - time points used for the assessments; - number of patients lost to follow up (in each group); - reasons for loss to follow up; - approach for handling missing data (data imputation/how data imputation was performed, use of intention-to-treat approach); - sources of funding; - possibility of conflict of interests; - adverse events; - outcome measures; - protocol deviations.

To assess the feasibility of performing a meta-analysis, we will also extract the following data for each primary and secondary outcome measure: - total number of patients (in each group); - number of events in each group (for dichotomous outcomes); - mean, standard deviation, standard error, median, interquartile range, minimum, maximum, 95% confidence interval (CI) (for continuous outcomes); - p value.

### **Assessment of Methodological Quality in included studies and quality of the body of evidence**

We will assess the methodological characteristics of included studies with PEDro [20] scale, as it is reliable [20], acceptable among assessors [20], and presents strong correlation with Cochrane Risk of Bias Tool [21]. We will evaluate the quality of evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) [22]. GRADE is a simple and integral approach that guides the judgement on the quality of the body of evidence. GRADE judgement is based on the overall risk of bias, consistency of the results, directness of the evidence, publication bias and precision of the results for each outcome. The GRADE profiler software, available online, will be used to summarize our findings on the quality of evidence [23]. Assessment of risk of bias, and assessment of the quality of evidence will be performed by two previously trained review authors (ECS and JRFFM) independently. All the disagreements in the assessment of the risk of bias or quality of evidence will be solved through discussion or, if required, by consulting with a third author (ACPNP).

### **Data synthesis and analysis**

When at least two studies are sufficiently homogeneous in terms of participants, interventions and outcome measurements, we will pool their results into meta-analysis. When insufficient data is presented in the primary studies to enter into meta-analysis, study authors will be contacted to request access to the missing data.

Meta-analysis will be performed using the inverse variance method and the random effects model in Review Manager version 5.3 [24]. Continuous variables will be analyzed using the weighted mean difference with 95% CI. Dichotomous variables will be analyzed using relative risk (RR) with 95% CI.

### **Dealing with missing data**

If a trial does not provide the standard deviation and after contacting the authors, they do not provide this measure, we will impute it using data from another trial which has evaluated the same outcome at an identical follow-up time point. This method is recommended in the Cochrane Handbook for Systematic Reviews of Interventions [17]. If insufficient data is provided following contact with the author, the results of the trial will be summarized only in qualitative synthesis.

### **Assessment of heterogeneity**

We will use the  $I^2$  statistic to estimate the amount of heterogeneity across studies in each meta-analysis. As suggested in Cochrane Handbook for Systematic Reviews of Interventions, if heterogeneity is substantial ( $I^2 \geq 50\%$ ), a subgroup or sensitivity analysis will be considered [17]. These analyses will involve the exclusion of one pre-determined study (subgroup) from the meta-analysis. The  $I^2$  of the remaining studies in the meta-analysis will be calculated to investigate if the excluded study was one potential source of heterogeneity. We will consider the following subgroups when investigating their effect on heterogeneity: age, sex, body mass index, type of surgery, utilization of extracorporeal circulation: severity of the disease, details of intervention, such as the use of different types of devices, frequency, duration, and time of the intervention commencing. We will consider the following information for sensitivity analysis: no blinding or inappropriate blinding of outcome assessors, inappropriate randomization methods, large number

(>20%) of patients lost to follow up, imputation of standard deviation or when adherence is not reported.

### Assessment of reporting biases

When at least 10 studies are included in a meta-analysis we will explore the likelihood of reporting biases visually inspecting funnel plots. For continuous outcomes, Egger's test will be used to detect possible small study bias as recommended in Cochrane Handbook for Systematic Reviews of Interventions [17].

## Discussion

This systematic review aims to assess the effect of IS in patients undergoing cardiac surgeries. To ensure that this systematic review of interventions is of high quality, we will follow Cochrane Handbook of Systematic Reviews recommendations [17]. We believe this scientifically rigorous review with transparent methods will provide a deep critical appraisal on the current evidence. While some studies have shown IS is an effective prophylactic technique [12-14], other studies have suggested that IS is only as effective as cough and deep breathing regimens [25], and that there is no evidence to support its utilization in clinical practice [8,10]. Our review will clarify the uncertainty over whether this widely used technique is useful for patients undergoing cardiac surgeries.

### Limitations and strengths

#### *Limitations*

This study aims to complete a comprehensive systematic review on the effect of IS in patients who have undergone cardiac surgeries, and if possible, to pool data into meta-analysis for reducing the probability of type 2 error in the comparisons. Potential limitations for this study include the possibility of finding: biased studies, such as those with lack of blindness of outcome assessors, or without proper randomization; substantial heterogeneity across studies which make them unsuitable for clustering or meta-analysis: or small sample studies that do not allow us to provide precise estimates of the effects.

#### *Strengths*

We believe that the strengths of this systematic review include the transparency, the strict methods, the evaluation of the quality of evidence for each outcome and the extensive and careful searches, without language or date of publication restrictions. We will be able to identify grey literature data and ongoing studies, to include important updated supplementary insights on this topic and to perform rigorous critical appraisal on the current body of evidence. Furthermore, we will include patients undergoing only cardiac surgeries. We anticipate this will provide more clinical homogeneity than in previous reviews [8,10,15].

### Reporting standards

This systematic review protocol was written as per the PRISMA-P guidelines [26].

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