Review Article

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Prophylactic noninvasive ventilation in patients undergoing cardiac surgery: protocol for an umbrella review

Ventilação não invasiva profilática em pacientes submetidos a cirurgia cardíaca: protocolo para uma revisão guarda-chuva

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Abstract

Background: Evidence on the effects of prophylactic non-invasive ventilation (NIV) in the postoperative period of cardiac surgery is still inconsistent, despite evidence derived from systematic reviews with meta-analyses of randomized clinical trials. **Aim**: To synthesize the evidence produced by systematic reviews on the effects of prophylactic postoperative NIV in adults undergoing cardiac surgery, on outcomes pulmonary complications, reintubation, length of stay in the intensive care unit (ICU), length of hospital stay, mortality, and oxygenation. **Methods**: Protocol for umbrella review that will include randomized trials, with patients undergoing cardiac surgery. Primary outcome: Pulmonary complication. Sources of information: various databases, in the *International Prospective Register Of Systematic Reviews* database, gray literature, and references and citations from the selected reviews. The search will be conducted by an independent author and two authors will select systematic reviews. The information extracted from the studies will be stored in a pre-structured database. The AMSTAR-2 tool will be used to assess the quality of the systematic reviews. The outcome measures will be presented in a descriptive format, with tables and meta-analyses. **Results**: This review will help to clarify which of these outcomes are consistent and inconsistent regarding the use of NIV in post-operative cardiac surgery and to investigate the possible causes of the outcome. **Conclusion**: By mapping the literature previously, we found at least four systematic reviews that can be analyzed and provide more consistent answers to these questions. In addition, future findings can support more accurate research, help in the formulation of policies and clinical practices.

Keywords: Respiratory Therapy; Thoracic Surgery; Review.

Resumo

Introdução: as evidências sobre os efeitos da ventilação não invasiva (VNI) profilática no pós-operatório de cirurgia cardíaca ainda são inconsistentes, apesar das evidências de revisões sistemáticas com meta-análises de ensaios clínicos randomizados. **Objetivo**: sintetizar as evidências produzidas por revisões sistemáticas sobre os efeitos da VNI profilática no pós-operatório em adultos submetidos à cirurgia cardíaca, sobre os desfechos complicações pulmonares, reintubação, tempo de internação na unidade de terapia intensiva, tempo de internação hospitalar, mortalidade e oxigenação. **Métodos**: protocolo para revisão guarda-chuva que incluirão ensaios randomizados, com pacientes submetidos à cirurgia cardíaca. Desfecho primário: complicação pulmonar. Fontes de informação: diversas bases de dados, na base de dados International Prospective Register Of Systematic Reviews, literatura cinzenta, referências e citações das revisões selecionadas. A busca será conduzida por um autor independente e dois autores selecionarão as revisões sistemáticas. As informações extraídas dos estudos serão armazenadas em um banco de dados pré-estruturado. A ferramenta AMSTAR-2 será utilizada para avaliar a qualidade das revisões sistemáticas. As medidas de desfecho serão apresentadas em um formato descritivo, tabelas e meta-análises. **Resultados**: esta revisão ajudará a esclarecer quais desses resultados são consistentes e inconsistentes em relação ao uso de VNI em cirurgia cardíaca pós-operatória e a investigar as possíveis causas do resultado. **Conclusão**: ao mapear a literatura previamente, encontramos pelo menos quatro revisões sistemáticas que podem ser analisadas e fornecer respostas mais consistentes a essas perguntas. Além disso, descobertas futuras podem apoiar pesquisas mais precisas, ajudar na formulação de políticas e práticas clínicas.

Plalavras-chave: Terapia Respiratória; Cirurgia Torácica; Revisão de Literatura.

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INTRODUCTION

Over the years, cardiac surgery has become consolidated as a worldwide surgical procedure[1]. Thus, therapeutic interventions that have been tested and proven to be effective, through robust studies, are required, with the aim of preventing and treating complications. Through this approach, it will be possible to achieve benefits, such as reducing the need for reintubation, the length of stay, and mortality[1].

Prophylactic noninvasive ventilation (NIV) is one therapeutic intervention used in the postoperative period of cardiac surgery that has been extensively investigated through different randomized clinical trials and at least three systematic reviews of controlled trials[2-4]. However, even in these reviews it is possible to observe inconsistencies, for example, there is a report that NIV is probably the most effective non-invasive respiratory approach to prevent pulmonary complications, while another record shows that NIV does not reduce these complications[2-4]. Inconsistencies are also observed regarding the length of stay, for example, a systematic review with meta-analysis indicates that NIV reduces the length of stay in the ICU, as well as the total length of stay in the hospital, while another review, also with meta-analysis, shows no reduction in these outcomes with the use of NIV[3,4].

Given these inconsistencies and concerns found in the abovementioned systematic reviews, as well as in others that may not have been identified, the need to group these findings in an umbrella review is clear, in order to reduce (perhaps eliminate) inconsistencies and allow clinicians to use NIV with awareness and safety in the postoperative period of cardiac surgeries[2-4].

With this in mind, a preliminary search in the JBI database of Systematic Reviews and Implementation Reports, Cochrane Library, PROSPERO, PubMed, and CINAHL concluded that no umbrella reviews have been performed on this theme. This type of review is relevant to discover the best possible evidence; evaluate its quality; and provide state-of-the-art knowledge on the effects of noninvasive ventilation in patients undergoing cardiac surgery on outcomes such as, pulmonary complications (atelectasis, pneumonia, respiratory distress, hypoxemia and pulmonary aspiration), reintubation, length of stay in the ICU, length of hospital stay, mortality, and oxygenation.

METHODS

Design

An umbrella review will be performed in accordance with the Reporting guideline for overviews of reviews of healthcare interventions: development of the PRIOR statement[5].-Register PROSPERO: CRD42024530048.

Eligibility criteria

The following inclusion criteria will be adopted:

Type of study: Systematic reviews with or without meta-analyses, focusing on controlled and randomized trials, published in a peer-reviewed journal. Studies will be considered a systematic review if they correspond to the description proposed by the Cochrane Collaboration Handbook[6];

Publication period: there will be no limitation on the year of publication;

Language: There will be no limitation on the publication language;

Participants: Studies with adult patients, aged 18 or over, undergoing cardiac surgery will be included;

Intervention: Systematic reviews that evaluate the effects of prophylactic NIV in the postoperative period of cardiac surgery;

Comparator: This umbrella review will include systematic reviews that compared an intervention with usual care, oxygen therapy, and control without NIV. In this study, usual care will be defined as the routine therapy of each hospital, for example chest physiotherapy techniques for removing secretions, breathing exercises, mobilization, and incentive spirometry, among others;

Outcomes of interest: The primary outcome will be "pulmonary complications (atelectasis, pneumonia, respiratory distress, hypoxemia and pulmonary aspiration)". The secondary outcomes will be (i) "reintubation", (ii) "ICU length of stay", (iii) "hospitalization time", (iii) "mortality", and (iv) oxygenation.

The exclusion criteria will be as follows:

Duplicates: Studies found in more than one database;

Duplicate reporting: Studies with a smaller sample size including the same participants, the same outcome measures, and the same follow-up time for assessments;

Studies in which outcomes are not directly related to the use of NIV in the postoperative period of cardiac surgery;

Studies that do not meet the minimum criteria for a systematic review;

Systematic reviews of other types of studies, such as experimental, observational, laboratory research, abstracts, case reports, protocols, personal opinions, letters, and posters;

Full text not available.

Information sources

Comprehensive searches will be conducted in the following electronic databases: MEDLINE (through the EBSCOhost search platform), PubMed, CINAHL, EMBASE, Scopus, Web of Science, Cochrane Database of

Systematic Reviews, JBI database of Systematic Reviews and Implementation Reports, JBI Evidence Synthesis, Epistemonikos database, and PDQ ("pretty darn quick") Evidence. The search will also be carried out in a database of systematic reviews: PROSPERO and in the gray literature, in the EThOS (e-theses online service) databases. Finally, we will search the references of the included studies using the Snowballing technique and search for citations of the studies selected for synthesis using the Forward Citation Searching technique.

These searches will be updated during data synthesis to identify any relevant systematic reviews that have been published in this period.

Search strategy

The search will be conducted by an independent author, using terms related to the problem of interest and therapeutic technique. The terms are described in Table 1. The following search strategy will be used in Medline via PubMed and will be adapted for each source of information, whenever necessary.

Selection of studies

Two authors will independently select studies for inclusion in this umbrella review, based on the eligibility criteria. The authors will read the studies in the following order: (i) title, (ii) abstract, and, if necessary, (iii) full text, to decide on the study's eligibility for inclusion. In the case of inconsistency between the two authors about the inclusion of the study in this review, an attempt will be made to reach an agreement, and if the inconsistency persists, the inclusion of the study will be resolved by a third author. Rayyan software will be used to streamline the screening and selection of studies[7].

The flowchart that will be followed to report the selection process of this umbrella review is shown in Figure 1.

Data extraction from included studies

Data extraction will be carried out in three stages. In the first stage, two independent authors will extract information from identical databases. After the first stage is completed, the second stage will begin, in which

Table 1. Umbrella 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))
2	Intervention	(((CPAP) OR (Continuous Positive Airway Pressure) OR (BIPAP) OR (Bilevel) OR (Bilevel Positive Airway Pressure) OR (IPPB) OR (Intermittent Positive Airway Pressure Breathing) OR (Intermittent Positive Pressure Breathing) OR (Non-invasive Positive Pressure) OR (Noninvasive Positive Pressure) OR (Non Invasive Positive Pressure) OR (Non-invasive Ventilation) OR (Noninvasive Ventilation) OR (Non Invasive Ventilation) OR (Intermittent Positive Pressure) OR (Intermittent Positive Pressure Ventilation) OR (Intermittent Positive Pressure Hyperventilation)
3	Type of study	((((systematic[Title/Abstract] AND review[Title/Abstract]) OR systematic reviews as topic[MeSH Terms] OR systematic review[Publication Type] OR systematic literature review[Title/Abstract] OR root cause analysis[MeSH Terms]))
4		#1 AND #2 AND #3

Source: Prepared by the authors of the protocol.

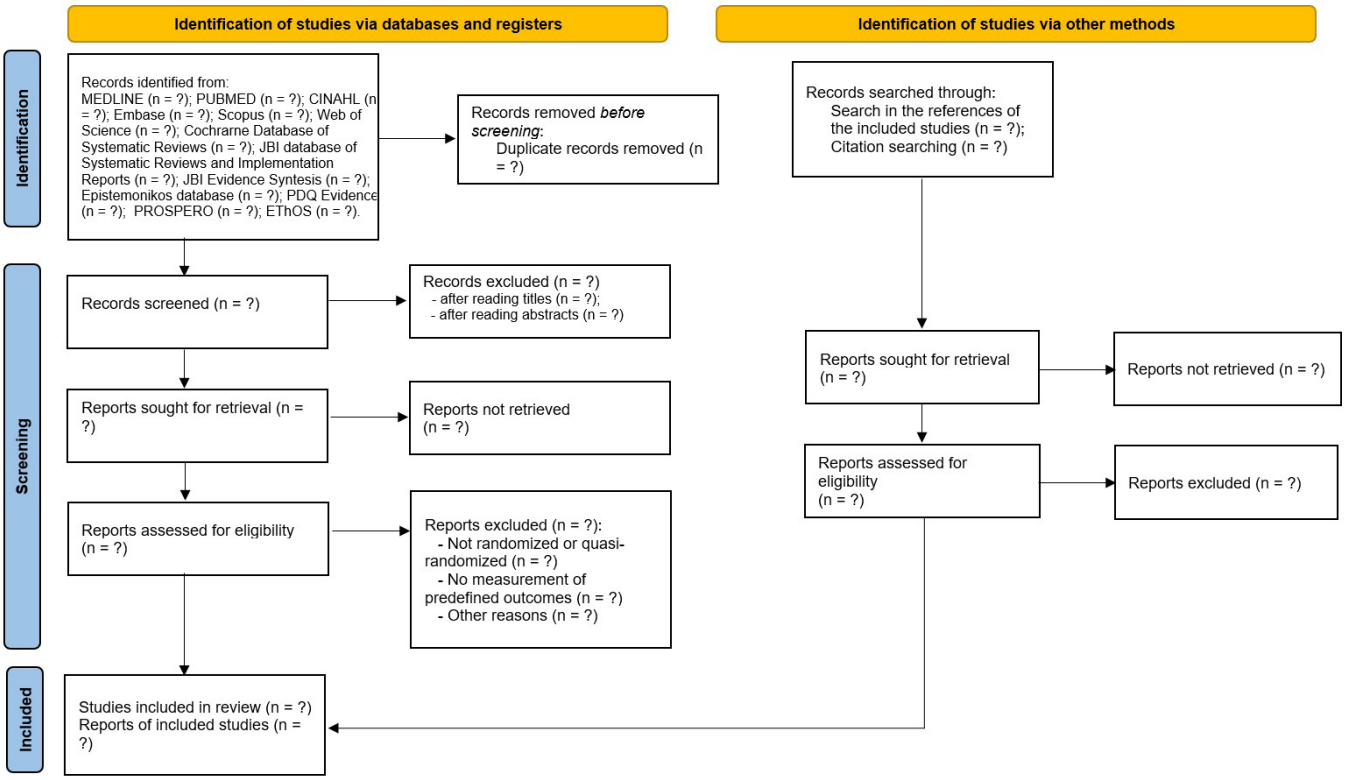

Figure 1. Flow diagram of the systematic review.

a third author will monitor the databases to try to identify inconsistencies. If inconsistencies are found, the third author will contact the two authors from the first stage to reach a consensus. In the absence of consensus between the two authors, the third stage will be carried out, in which the third author will make the final decision on the inconsistency.

The information will be extracted and stored in a spreadsheet created by the authors in the Excel application. The information extracted will include:

(i) Characteristics of the studies included: First author of the review, year of publication of the review, design of the review (whether systematic review without meta-analysis or with meta-analysis), objective, number of trials included in the review, time interval (year) of publication of the trials (year of publication of the oldest trial and year of publication of the most recent trial) of the included review, total number of participants in the review and its respective interval (trial with smaller sample size and trial with larger sample size), design of studies (if randomized or quasi-randomized clinical trial) included in the systematic review included in the umbrella review, clinical setting (whether in the ICU or on a ward), symptom or phenomenon of interest (e.g., mortality), reported positive outcome of the symptom or phenomenon (e.g., mortality reduction), summary of the assessment of methodological robustness or risk of bias (for example, assessment using tools such as Risk of Bias, PEDro Scale[8,9], or others), and characteristics of the intervention with NIV (author/year, type of NIV, duration, number of times/scenario, comparator, symptom, others);

(ii) Characteristics of the cardiac surgeries: Surgical procedures, average surgery time with interval (shortest time and longest duration), use of extracorporeal circulation (ECC) (yes or no), ECC time (in minutes), number of grafts, and need for transfusion, among others;

(iii) Characteristics of intervention with NIV: Time in days of protocol applied, type of NIV, dosage in cmH2O or equivalent unit, duration of therapy in each session in minutes or equivalent, and number of times per day, among others;

(iv) Characteristics of the control intervention: Time in days of the applied protocol, type of control intervention used (for example, exercise in inspiratory times, use of inspiratory encouragement, others), dosage, duration of each session in minutes or equivalent, and number of times per day, among others;

(v) Outcome of interest: The outcomes analyzed will include pulmonary complications (atelectasis, pneumonia, respiratory distress, hypoxemia, and pulmonary aspiration), reintubation, length of stay in the ICU, length of hospital stay, mortality, and oxygenation. Data related to outcomes, such as odds ratio (OR), risk ratio (RR), mean difference (MD), standard mean difference (SMD), mean,

standard deviation, median, the smallest value (Minimum), the largest value (Maximum), 95% confidence interval (CI), estimated population standard deviation, p value, and standard error will be extracted.

Systematic review quality assessment

The quality assessment of the selected systematic reviews will be carried out by two independent authors using the AMSTAR-2 tool, which assesses the methodological quality of systematic reviews of randomized clinical trials. In case of inconsistencies between the two authors, there will be a first attempt at agreement between the pair. If there is no agreement, the decision will be made by a third author. In this tool, most domains are classified as 'Yes' or 'No', although they may have the additional option of 'Partial Yes'[10].

Assessment is made through 16 domains, including: (1) Whether the research question and inclusion criteria for the review included the PICO components (P: Population; I: Intervention; C: Comparison; O: Outcome); (2) Whether the review report contains an explicit statement that the review methods were established prior to conducting the review and whether the report justifies any significant deviations from the protocol; (3) Whether the review authors explain their selection of study designs for inclusion in the review; (4) Whether the review authors use a comprehensive literature search strategy; (5) Whether the review authors perform the study selection in duplicate; (6) Whether the review authors perform data extraction in duplicate; (7) Whether the review authors provide a list of excluded studies and justify the exclusions; (8) Whether the review authors describe the included studies in adequate detail; (9) Whether the review authors use a satisfactory technique to assess the risk of bias in the individual studies included in the review; (10) Whether the review authors report sources of funding for the studies included in the review; (11) In cases where a meta-analysis was performed, whether the review authors use appropriate methods for statistical combination of results; (12) In cases where a meta-analysis was performed, whether the review authors assess the potential impact of risk of bias in individual studies on the results of the meta-analysis or other evidence synthesis; (13) Whether the review authors consider the risk of bias in individual studies when interpreting/discussing the review results; (14) Whether the review authors provide a satisfactory explanation and discussion of any observed heterogeneity in the review results; (15) In cases where they performed quantitative synthesis, whether the review authors perform an adequate investigation of publication bias and discussed its likely impact on the review results; (16) Whether the review authors report any potential sources of conflict of interest, including any funding they received to conduct the review. Quality of evidence will be measured with Grade of Recommendations Assessment, Development and Evaluation (GRADE).

Synthesis and statistical analysis of data

Considering the possible differences between the designs of studies included in the umbrella review, such as different inclusion criteria, synthesis methods, and outcome measures, the results will also be presented in narrative format. Furthermore, the general outcome measures, as well as descriptions of the characteristics and assessment of the quality of the review, will be summarized in tables.

If the extracted data are sufficient to conduct a meta-analysis, we intend to estimate the pooled effect size, using specific effect estimates (OR, RR, RD, MD, SMD, or others) with relevant uncertainty estimates (standard error or CI) and sample sizes of meta-analyses of systematic reviews. Another alternative is to use the data (mean, standard deviation, and number of participants in experimental and control groups for continuous data; and number of participants with events and total number of participants in experimental and control groups for dichotomous data) from the primary studies included in the systematic reviews that are selected for inclusion in the umbrella review[11].

The Cochrane I^2 and Q inconsistency tests will be applied to detect heterogeneity, and the I^2 value > 50% or $p < 0.1$ for the Q test will be considered as heterogeneity. If heterogeneity is detected, a subgroup analysis, considering sex, type of surgery, use of cardiopulmonary bypass, intervention details, such as use of different types of therapy (types/modalities of VIN), frequency, duration, and start time of the intervention, or sensitivity analysis, considering no blinding or inadequate blinding of outcome assessors, inadequate randomization methods, and large numbers (> 20%) of patients lost to follow-up, will be conducted to try to justify the heterogeneity. If each meta-analysis contains at least ten studies, publication bias will be assessed using funnel plots. We intend to use RevMan 5.4 software to perform the statistical analysis[12].

RESULTS

We believe that grouping of the best evidence found by systematic reviews and meta-analyses of controlled trials on the use of NIV in the postoperative period of cardiac surgery will help to reduce gaps and inconsistencies on the topic. Furthermore, it will provide an objective compilation on the effects of NIV on pulmonary complications, reintubation, length of stay in the ICU, length of hospital stay, mortality, and oxygenation.

This umbrella review will help to clarify which of these outcomes are consistent and inconsistent regarding the use of NIV in post-operative cardiac surgery and to investigate the possible causes of the outcome. Furthermore, it will be possible to provide robust guidance for decisions in clinical practice and perhaps offer support to strengthen public policies aimed at this field[13].

Strengths and limitations of this study

- This will be the first study that systematically summarises the effects of noninvasive ventilation in patients undergoing cardiac surgery on pulmonary complications, reintubation, length of stay in the ICU, length of hospital stay, mortality, and oxygenation.
- Anticipated limitations of our study are the heterogeneity of the included systematic reviews.
- Another limitation of this umbrella review will be the potential for study overlap across reviews

CONCLUSION

The objective of this umbrella review is to clarify the inconsistencies regarding the use of NIV in the postoperative period of cardiac surgery. By mapping the literature previously, we found at least four systematic reviews that can be analyzed and provide more consistent answers to these questions. In addition, future findings can support more accurate research, help in the formulation of public policies and clinical practices.

FUNDING

Nothing to declare.

CONFLICT OF INTEREST

Nothing to declare.

RESEARCH DATA AVAILABILITY

No research data was used.

AUTHOR CONTRIBUTIONS

JPRP: Conceptualization, Methodology, Supervision, Visualization, Writing – review & editing; HVCS: Methodology, Visualization; DOS: Methodology, Visualization; ACL: Conceptualization, Project administration, Methodology, Visualization, Writing – original draft, Writing – review & editing; ECS: Conceptualization, Project administration, Methodology, Supervision, Visualization, Writing – original draft, Writing – review & editing.

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