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REVIEW

Effects of cycle ergometer use in the postoperative period on functional capacity and hospitalization time in adults undergoing cardiac surgery: systematic review protocol

Efeitos do cicloergômetro no pós-operatório sobre a capacidade funcional e o tempo de hospitalização em adultos submetidos a cirurgia cardíaca: protocolo de revisão sistemática

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Abstract

Introduction: Among patients undergoing cardiac surgery, some pulmonary and cardiac complications can be observed, which can increase the length of hospital stay. The cycle ergometer is used to try to improve this clinical scenario. However, some inconsistencies can be observed in the literature. **Objective:** To synthesize evidence on the effects of cycle ergometer use in the in-hospital postoperative period in relation to control therapy without cycle ergometer use on functional capacity and length of hospital stay in adults

undergoing cardiac surgery. *Methods*: Systematic review of randomized clinical trials with patients undergoing cardiac surgery, to evaluate the effects of cycle ergometer use compared to control without cycle ergometer use. Primary outcomes: functional capacity and length of hospital stay. Searches: Medline, EMBASE, PEDro, Pubmed, Allied and AMED, Cinahl, Lilacs, Scielo, Scopus and Cochrane Central, ClinicalTrials.gov, ReBEC, and the references of included studies. Study selection will be conducted by three authors. The risk of bias will be assessed by two independent authors using the Cochrane Risk of Bias 2 (RoB 2) tool and conflicts will be resolved through consensus (in the absence of consensus, a third author will make the decision). The inverse variance method and random effects model will be considered in the meta-analysis. Continuous variables will be analyzed by weighted mean difference and dichotomous variables by relative risk (RR). We will use I² statistics to estimate the amount of heterogeneity between studies. *Discussion*: Different cardiac surgeries are performed all over the world, and have been widely investigated. However, some gaps and controversies can be observed. Therefore, a systematic review is essential to clarify existing gaps.

Keywords: aerobic exercise; cardiac surgery; postoperative period.

Resumo

Introdução: Entre os pacientes submetidos à cirurgia cardíaca, pode-se observar algumas complicações pulmonares e cardíacas, o que pode aumentar o tempo de hospitalização. O cicloergômetro é usado para tentar melhorar esse cenário clínico. Contudo, algumas inconsistências podem ser observadas na literatura. *Objetivo:* Sintetizar as evidências sobre os efeitos do cicloergômetro no pós-operatório intra-hospitalar em relação a terapia de controle sem cicloergômetro na capacidade funcional e tempo de hospitalização em adultos submetidos à cirurgia cardíaca. *Métodos:* Revisão sistemática de ensaios clínicos randomizados com pacientes submetidos a cirurgias cardíacas avaliando os efeitos do ciclo ergômetro comparado a controle sem ciclo ergômetro. *Desfechos primários:* capacidade funcional e tempo de hospitalização. *Buscas:* Medline, EMBASE, PEDro, Pubmed, Allied e AMED, Cinahl, Lilacs, Scielo, Scopus e Cochrane Central, ClinicalTrials.gov, ReBEC e nas referências dos estudos incluídos. A seleção do estudo será conduzida por três autores. O risco de viés será avaliado por dois autores independentes por meio da ferramenta Cochrane Risk of Bias 2 (RoB 2) e os conflitos serão sanados mediante consenso (na falta de consenso, um terceiro autor tomará a decisão). O método de variância inversa e modelo de efeitos aleatórios serão considerados na metanálise. As variáveis contínuas serão analisadas pela diferença de média ponderada e as dicotômicas através do risco relativo (RR).

Usaremos estatística de I² para estimar a quantidade de heterogeneidade entre os estudos. *Discussão*: Diferentes cirurgias cardíacas são realizadas em todo o mundo, sendo amplamente investigadas. No entanto, algumas lacunas e controvérsias são observadas. Portanto, uma revisão sistemática é essencial para esclarecer as lacunas existentes.

Palavras-chave: exercício aeróbico; cirurgia cardíaca; período pós-operatório.

Introduction

Cardiac surgeries are often highly complex surgical procedures and are therefore concentrated in well-developed urban areas and in low- and middle-income countries. In general, there are three types of cardiac surgery: corrective, reconstructive, and substitutive. Approximately 2.5 million people with cardiovascular disease require heart surgery [1]. This demand for heart surgery appears to increase year on year, for example, in 2020 in Germany there was a 2.1% increase in heart transplants compared to 2019 [2]. In Brazil, in the last three years, 874 heart transplants, 5,222 myocardial revascularizations using cardiopulmonary bypass, and 6,104 valve repairs and/or multiple valve replacement were performed [3].

Among patients who undergo cardiac surgery, 66.6% develop postoperative complications, 47.3% require blood products, 32% have atrial fibrillation complications, 0.9% have cardiac arrest, and 2.7% present pneumonia [4]. Postoperative hospital stays of 21 days in the intensive care unit and 24.6 days in the ward were reported [5].

In addition, loss of functional capacity, person's ability to exercise self-care and live independently [6], has been observed after cardiac surgery, being greatest on the seventh postoperative day [7]. When the patient presents associated complications, this functional loss is even greater, with reductions in muscle strength of the lower limbs and handgrip strength, which may further increase the hospitalization time [8].

In an attempt to reduce these complications and hospitalization time, as well as to improve the functional capacity of the patient, some treatment strategies are used in the postoperative period [9,10], for example, the cycle ergometer, which represents an alternative treatment used in upper and lower limbs, that appears to make therapy more attractive and engaging for the patient undergoing cardiac surgery [11]. However, some inconsistencies can be observed in the literature, regarding the relationship between the use of a cycle ergometer and physical activity, safety [10], cardiac autonomic modulation, length of hospital stay, and functionality [12-14]. These inconsistencies show the need for a systematic review to clarify these doubts. At least two clinical trials evaluating the

effects of the cycle ergometer in the postoperative period of cardiac surgery have already been published, making this systematic review feasible [15,16].

Therefore, it is necessary to address these questions about the use of the cycle ergometer in the postoperative period of cardiac surgery, in order to conduct the treatment appropriately, with safety, and above all, knowing what to expect when this therapy is used in clinical practice while the patient is hospitalized. After conducting a search of PROSPERO, Cochrane Library, Pubmed and JBI Evidence Synthesis, ongoing or published reviews on the review topic were found. Therefore, this review aims to answer the following research question: - Is the cycle ergometer more effective than control therapy without a cycle ergometer in the in-hospital postoperative period (phase I of cardiovascular rehabilitation) of cardiac surgery in adults on functional capacity, hospitalization time, cardiac and pulmonary complications, heart rate, blood pressure, perception of exertion, and adverse events?

Methods

Design

We report this protocol in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) [17]. This review protocol was previously registered in the International Prospective Register of Systematic Reviews (PROSPERO) under CRD42022378883.

Eligibility criteria

The eligibility criteria were prepared according to the PICO (Population, Intervention, Comparison, end Outcome) mnemonic.

Types of studies, language, and year of publication: Only randomized controlled trials published in any language and in any year will be included in this review.

Types of participants: Included studies are required to have been conducted with adult participants (at least 18 years of age) undergoing cardiac surgery.

Types of intervention: Clinical trials that evaluated the effect of the cycle ergometer in the in-hospital postoperative period (phase I of cardiovascular rehabilitation) of cardiac surgery will be included. The cycle ergometer could be used alone or in combination with other techniques, for at least 2 days.

Types of comparatives: Comparative therapy was required to be usual care Control without a cycle ergometer (Breathing exercises, non-invasive ventilation, and conventional physical therapy).

Investigated outcome: Having assessed at least one of the outcomes investigated by this systematic review

Primary outcomes

Functional capacity: Functional capacity will be recorded regardless of the method or scale used to measure this outcome after cardiac surgery, e.g., six-minute walk test [18], Incremental Shuttle Walk Test, one-minute sit-to-stand test [19], among others.

Hospitalization time: The total number of days the patient stays in the hospital will be recorded. In the case of studies reporting intensive care unit length of stay and ward length of stay separately, the sum of days will be performed to obtain the total hospitalization time.

Secondary outcomes

Cardiac (e.g. cardiac arrhythmia, acute myocardial infarction, orthostatic hypotension, and pneumopericardium) and pulmonary (e.g. acute respiratory failure, pleural effusion, hypoxemia, pneumonia, and atelectasis) complications: A complication is an unfavorable result after heart surgery. Complications may adversely affect the outcome of surgical procedure. The number of events (complications) will be recorded.

Heart rate: The number of heart beats in each minute after cardiac surgery will be recorded. Patients undergoing cycle ergometer training show variability in heart rate and blood pressure, which is also considered a way to detect autonomic instability in the postoperative phase, thus allowing to predict or prompt-diagnose postoperative complications [20]. All forms of heart rate monitoring will be accepted.

Systolic, diastolic, and mean blood pressure: Systolic blood pressure, diastolic blood pressure, and mean blood pressure measured using digital or analogue devices after cardiac surgery will be recorded.

Perception of effort: A rational notion of how arduous and exhausting it is to perform a given physical task [21] will be recorded. Studies that measured the perception

of exertion by measuring instruments such as the modified Borg scale, but not limited to it, will be considered.

Adverse events: Adverse healthcare-related events are incidents that occur during medical care and harm a patient, producing an injury, suffering, disability, or death [22]. Adverse events related to the use of the cycle ergometer, such as muscle pain, fatigue, nausea, among others, will be considered and recorded.

Information sources

The following databases will be searched: Medline (Through the EBSCOhost Research Platform), EMBASE, PEDro, Pubmed, AMED, Cinahl, Lilacs, Scielo, Scopus, and Central. The search will also be conducted in two clinical trial registry bases: ClinicalTrials.gov and ensaiosclinicos.gov.br. Finally, we will perform a search in the references of the studies included through the Snowballing technique and search for citations of studies selected for the synthesis through the Forward Citation Searching technique. Related descriptors and synonyms will be used, to adapt the search to the conditions of each source.

Search strategy

Terms related to the problem of interest and the therapeutic technique will be used. The terms are described in Table I. The search strategy below will be used in Medline via Pubmed and will be adapted to the specifications of each database.

Selection of studies

Three authors will independently select studies for inclusion in this systematic review (AM, ICB, and ECS). Two authors will extract possible studies identified based on the eligibility criteria (ICB and ECS). The authors will read the studies in the following order: titles, abstracts, and, if necessary, the texts will be read in full 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 between the two authors, and if the inconsistency persists, the inclusion of the study will be resolved by the third author (AM). Studies that do not meet the criteria will be excluded. In addition, studies in more than one database (duplicates), and studies with a smaller sample size with the same participants, the same outcome measures, and the same follow-up time for evaluations (duplicate reporting), will be excluded. Rayyan

software [23] will be used to streamline the screening and selection of studies. The flowchart that will be followed to report the selection process of this systematic review is shown in Figure 1.

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))
2	Intervention	((Cycle Ergometer) OR (Cycle Ergometer Exercises) OR (Bicycle Ergometer) OR (Hydraulic Circuit Training) OR (Ergometer Exercise Bike) OR (Bedside Cycle Ergometer) OR (Ergometer bike) OR (Leg Cycle Ergometry) OR (Bicycle Ergometer Exercise) OR (Bicycle Ergometer Exercise) OR (Arm Ergometer) OR (Upright bicycle) OR (Upright Bicycle Ergometry) OR (Exercise Bike ergometer) OR (Ergometer Exercise) OR (Leg Ergometer) OR (Exercise Bike OR (Bicycle ergometry) OR (Leg Bicycle Ergometer) OR (Ergometer Upright Bike) OR (Stationary Exercise Bicycle OR (Exercise Bike with Ergometer) OR (Agro stationary Bicycle) OR (Dynamic Bicycle Exercise) OR (Eccentric Cycling Exercise) OR (Passive Cycle Ergometer) OR (Early Cycle Ergometry) OR (Cycling) OR (Early Cycle Ergometry) OR (Cycle Sessions) OR (Stationary Cycle) OR (MR Ergometer) OR (In-Bed Cycling) OR (Cicloergómetro) OR (Bicicleta Ergométrica) OR (Cicloergómetro) OR (Bicicleta Estática) OR (Bicicleta Spinning))
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

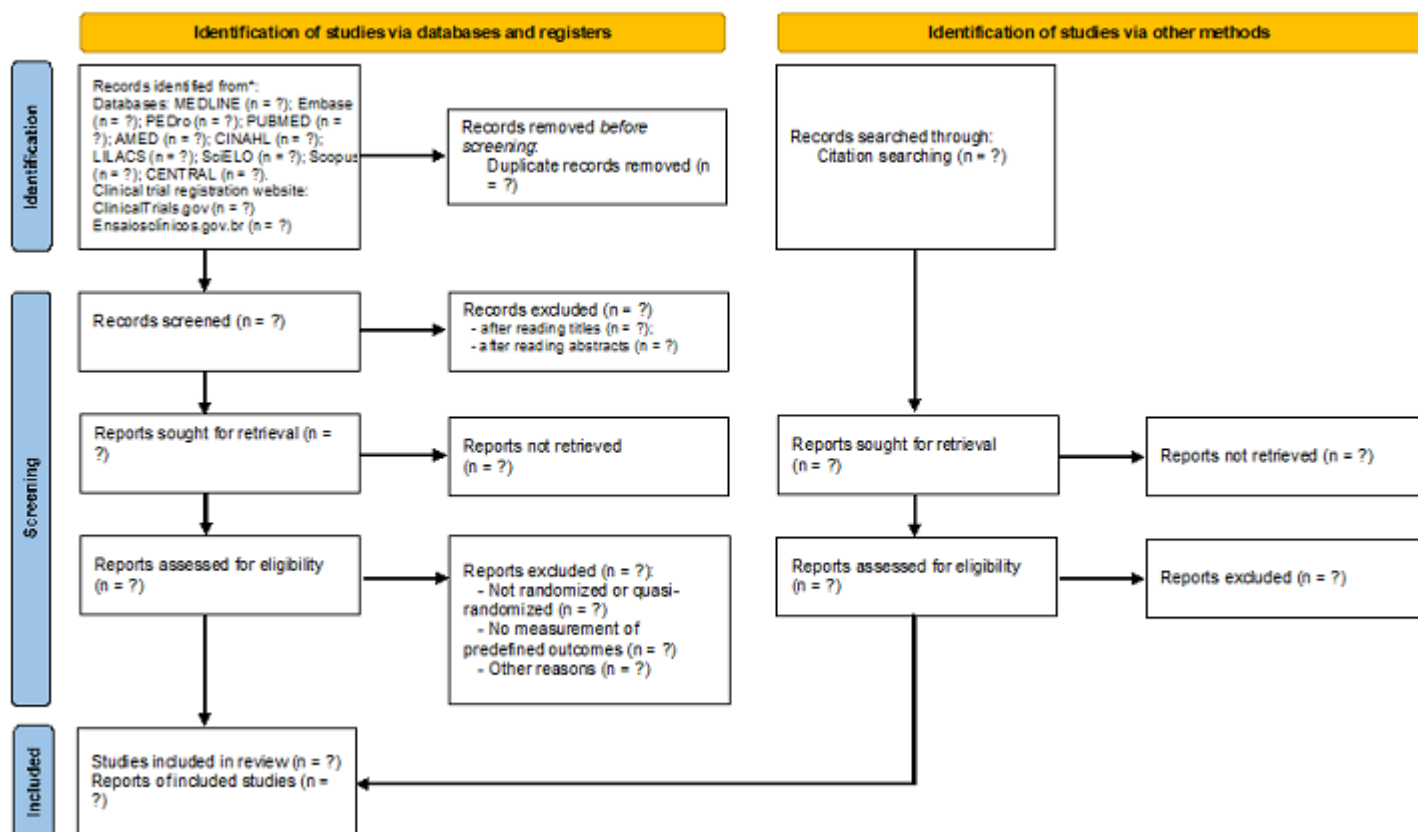


Figure 1 - Flowchart of the systematic review

Extraction of data from studies

Using a previously standardized method, two independent authors (JPRP and EPC) will extract data from the selected studies. A third author (ACNP) will monitor possible discrepancies in relation to the extracted data. If there is a discrepancy, this third author will make the final decision. A spreadsheet in the Excel application (Elaborated by the authors) will be used to record the extracted data, such as general characteristics of the studies (Authors, year and language of publication, and study design), patients involved (Sample size, sex, age, and clinical characteristics), surgical procedures included (Type of surgery, duration of surgery and use or not of extracorporeal membrane oxygenation), and outcomes of interest (Mean, standard deviation, median, the smallest value (Minimum), the largest value (Maximum), confidence interval, estimated population standard deviation, p value, and standard error will be extracted) in this systematic review.

Methodological robustness of included clinical trials and certainty of evidence

Two independent authors (JRFFM and LMDM) will assess the risk of bias. A third author (ACL) will monitor possible inconsistencies in the assessment. If there is inconsistency, an agreement on the decision in the evaluation will be prioritized between the two authors (JRFFM and LMDM). If there is no agreement, the final decision will be made by the third author (ACL).

The risk of bias will be assessed according to the RoB 2 tool, which consists of five levels. Within each level, RoB 2 users answer one or more signaling questions. Assessment responses are rated as low risk of bias, some concerns, or high risk of bias. Assessments at each level result in an overall risk of bias assessment for the judged outcome, which allows RoB 2 users to stratify meta-analyses by risk of bias [24,25]. Briefly, details of the randomization method with sequence generation, allocation concealment, degree of blinding, inclusion and exclusion criteria, study dropouts or withdrawals, intent to treat, and detailed statistical analysis will be examined.

Unexplained dropouts or an uneven number of dropouts across treatment groups will be considered a potential risk of bias. Likewise, the lack of important information, for example missing data, statistical methods, etc., will also be considered a potential risk of bias. Studies with low methodological robustness will not be excluded from the review. We will assess the quality of evidence using GRADE (Grading of Recommendations, Assessment, Development and Evaluations), using GRADEpro GDT [26]. GRADE is an accessible and comprehensive approach that guides assessments on the certainty of evidence. The GRADE assessment is based on the overall risk of bias, consistency of results, objectivity of evidence, publication bias, and accuracy of each outcome [27].

Evaluation of the quality of description of clinical trials

The reporting quality of the included studies will be assessed using the TIDieR (Template for intervention description and replication) checklist. The TIDieR was developed with the aim of improving the reporting of interventions in randomized controlled trials [28,29]. The checklist contains 12 items, including: intervention name, rationale, intervention materials, details of intervention providers, mode of intervention delivery, intervention delivery location and infrastructure, details of the number, duration, intensity and dose of interventions, intervention sessions, details of adaptations of any intervention, any modifications throughout the study, assessment of fidelity, monitoring and level reached [28,29]. We will perform the sum of each item for the control and intervention groups, and each item will be evaluated on a three-point Likert scale

according to the following categorizations, with their respective points: not reported (0), partially reported (1) and adequately reported (2). Thus, summary scores range from 0 (bad report) to 24 (good report) points [28].

Meta-analysis and heterogeneity

The meta-analysis will be performed using the inverse variance method and the random effects model in RevMan 5 [30]. Continuous variables will be analyzed by the weighted mean difference with 95% CI. Dichotomous variables will be analyzed through the RR with 95% CI.

When at least two studies are sufficiently homogeneous in terms of participants, interventions, and outcome measures, the results will be pooled in a meta-analysis. Separate meta-analyses will be performed for studies evaluating short-term (up to 2 months), medium-term (2 months to 6 months), and long-term (more than 6 months) outcomes. If a study has more than one measure, for example, in the short term (e.g. if evaluated in the second week and in the fourth week), we will consider the latest evaluation.

In case of selection of studies with insufficient data, the study authors will be contacted to request access to the missing data. If, for the same outcome, there are at least 10 studies, the publication bias will be evaluated, and for studies with a small sample size or in situations when there is doubt in the definition of this bias, we will use the Egger's test.

We will use the Higgins and Thompson inconsistency test (I²) to estimate the amount of heterogeneity between studies in each meta-analysis. I² values range from 0 to 100%. Values from 0% to 40% may not be important, values from 30 to 60% may represent moderate heterogeneity, values from 50% to 90% may represent substantial heterogeneity, and values from 75% to 100% considerable heterogeneity between studies [31]. In case of considerable heterogeneity, we will investigate possible causes by performing subgroup/sensitivity analyses. We will consider the following subgroups when investigating their effect on heterogeneity: sex, type of surgery, use of cardiopulmonary bypass, intervention details such as use of different types of devices (cycle ergometer for upper and lower limbs), frequency, duration, and start time of the intervention. We will consider the following information for sensitivity analysis: no blinding or inadequate blinding of outcome assessors, inadequate randomization methods, and large numbers (> 20%) of patients lost to follow-up.

Discussion

Different heart surgeries are performed worldwide and are often complex, for example, coronary, valve, aortic, and heart failure surgery and therefore, in the last decade, they have been widely investigated [32]. Regardless of the cause that leads to the need for cardiac surgery, the physical therapy treatment offered in the postoperative period should be properly managed to prevent and treat complications and reduce hospitalization time.

With this objective, the cycle ergometer is a device that has been used in the postoperative period of cardiac surgery in clinical practice, in different hospitals, and in different phases of cardiovascular rehabilitation, including phase I. In addition, some clinical trials have investigated its effects, showing conflicting results [11,33]. Therefore, a systematic review with a methodologically well-constructed protocol is essential to clarify existing knowledge gaps around the use of a cycle ergometer in the postoperative period of cardiac surgery.

Conflicts of interest

The authors declare no conflict of interest.

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Author contributions

Conception and design of the study: Pacheco JPR, Leão EP, Pinto APNP, Matias LMD, Santos EC; *Manuscript writing:* Pinto APNP, Lunardi AC, Santos EC; *Critical review of the manuscript for important intellectual content:* Mendes A, Pinto APNP, Boca IC, Macedo JRFF, Lunardi AC, Santos EC

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