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# Pilot study of viability in the use of cycle ergometer for upper limbs on the first postoperative day of cardiac surgery

# Estudo piloto da viabilidade no uso de cicloergômetro para membros superiores no primeiro dia pós-operatório de cirurgia cardíaca

**Giulliano Gardenghi[1], Celina Lumi Kushida[2], Abissay Francisco Dias[3], Jessyka Bueno Cruz[4], Kassiely Ribeiro de Lima[5], Artur Henrique de Souza[6]**

[1]Correspondent author. ENCORE Hospital (Aparecida de Goiânia). CEAFI College (Goiânia). São Cristóvão Hospital and Maternity (São Paulo). Goiás, São Paulo, Brazil. ORCID: 0000-0002-8763-561X. ggardenghi@encore.com.br
[2]ENCORE Hospital. Aparecida de Goiânia, Goiás, Brazil. ORCID: 0000-0002-7050-0014. clumi@encore.com.br
[3]ENCORE Hospital (Aparecida de Goiânia). CEAFI College (Goiânia). Goiás, Brazil. ORCID: 0000-0003-4266-4166. afdias@encore.com.br
[4]ENCORE Hospital. Aparecida de Goiânia, Goiás, Brazil. ORCID: 0000-0001-7829-3489. jbcruz@encore.com.br
[5]ENCORE Hospital. Aparecida de Goiânia, Goiás, Brazil. ORCID: 0000-0001-8922-944X. krlima@encore.com.br
[6]ENCORE Hospital. Aparecida de Goiânia, Goiás, Brazil. ORCID: 0000-0002-5835-1052. ahsouza@encore.com.br

**RESUMO | INTRODUÇÃO:** O uso do cicloergômetro para os membros superiores pode contribuir para manter a capacidade funcional em pacientes após cirurgia cardíaca (CC). **OBJETIVOS:** Investigar as respostas cardiorrespiratórias de pacientes após CC recebendo ou não drogas vasoativas (DVAs) durante a realização de cicloergômetro para membros superiores, verificando a incidência de perda de cateter arterial radial ou de fraturas de fios de aço no esterno. **MATERIAL E MÉTODOS:** Estudo piloto envolvendo 26 pacientes divididos em 2 grupos. Grupo CO: sem uso de DVAs (13 pacientes, idade: 57 ± 12 anos, 09 homens) e grupo DVA: (13 pacientes, idade: 61 ± 10 anos, 07 homens), submetidos à CC, que no 1ºPO realizaram o cicloergômetro para membros superiores. Os parâmetros avaliados durante o exercício foram frequência cardíaca (FC), saturação de oxigênio (SpO2), dispneia, fadiga de membros superiores e pressão arterial média (PAM). A incidência de perdas do cateter da artéria radial ou de fraturas de fios de aço no esterno foi avaliada. A análise estatística adotou análise de variância de um ou dois caminhos, com post hoc de Newman Kauls ou Scheffé, quando necessário. O valor de significância foi 0,05%. **RESULTADOS:** a FC aumentou nos dois grupos ao final do exercício (p = 0,00), sem diferença (p = 0,97); SpO2, dispneia e PAM não se alteraram do repouso para o final do exercício (p = 0,49; p = 0,78 e p = 0,25, respectivamente); A fadiga nos membros superiores aumentou em ambos os grupos (p = 0,04); Não houve eventos de perda do cateter de artéria radial ou de fraturas de fios de aço no esterno. **CONCLUSÃO:** A adoção do cicloergômetro para membros superiores mostrou-se segura no 1ºPO de CC, mesmo nos indivíduos que utilizaram DVAs. Não houve relação entre o uso do cicloergômetro dos membros superiores e a perda de cateteres arteriais ou de fraturas de fios de aço no esterno.

**PALAVRAS-CHAVE:** Cirurgia torácica. Terapia por exercício. Revascularização miocárdica.

**ABSTRACT | INTRODUCTION:** The use of a cycle ergometer for the upper limbs may contribute to maintain the functional capacity in patients after heart surgery (HS). **OBJECTIVES:** To investigate the cardiorespiratory responses of HS patients receiving or not vasoactive drugs (VADs) during the realizations of cycle ergometer for upper limbs, verifying the incidence of loss of radial arterial catheter or of steel wire fractures in the sternum. **MATERIAL AND METHODS:** A pilot study involving 26 patients divided in 2 groups. Group CO: no use of VADs (13 patients, age: 57±12 years, 09 male) and VAD group: (13 patients, age: 61±10 years, 07 male), submitted to HS, which on the first postoperative day (1stPO) performed the cycle ergometer for upper limbs. The parameters evaluated during the exercise were heart rate (HR), oxygen saturation (SpO2), dyspnea, fatigue of upper limbs and mean arterial pressure (MAP). The incidence of losses of the radial artery catheter and of steel wire fractures in the sternum was calculated. Statistical analysis adopted one-way or two-way analysis of variance, with post hoc from Newman Kauls or Scheffé, when necessary. The significance level was 0.05%. **RESULTS:** HR increased in both groups at the end of the exercise (p = 0.00), with no difference (p=0.97); SpO2, dyspnea and MAP did not change from rest to the end of exercise (p=0.49; p=0.78 and p=0.25, respectively); The fatigue in the upper limbs increased in both groups (p=0.04), without difference between groups (p=0.79); There was no event of loss of radial artery catheter or steel wire fractures in the sternum. **CONCLUSION:** The adoption of the cycle ergometer for upper limbs was safe in sthe 1stPO of HS, even in the individuals using VADs. There was no relationship between the use of the upper limbs cycle ergometer and losses of arterial catheters or steel wire fractures in the sternum.

**KEYWORDS:** Thoracic surgery. Exercise therapy. Myocardial revascularization.

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## Introduction

Cardiovascular rehabilitation programs in phase I (in-hospital) have as main objectives the reduction of the risks of pulmonary complications, improvement of pulmonary ventilation, reduction of pain in the postoperative period, prolongation of survival with quality, as well as a better recovery of activities of daily living (ADLs)[1]. Respiratory and motor disorders are described, mainly in the postoperative period, and physiotherapy can act to minimize such complications, since it has been highlighted as an important adjuvant in the care of individuals exposed to the surgical procedure[1]. A scientific study conducted in Switzerland that included 53 patients showed that early mobilization (between 12 and 24 hours postoperatively) in cardiac surgery patients is a safe procedure in an intensive care setting, with few adverse events, even though such intervention may be associated with significant hemodynamic changes[2].

The upper limb cycle ergometer comes as a device to assist the physiotherapist in increasing muscle training. This equipment allows cyclical rotations and can be used to perform passive, active and resisted exercises with patients[3]. Recent article describes that the use of the cycle ergometer can generate positive repercussions such as increased oxygen saturation, been still associated with changes in heart and respiratory rates, as well as physiological responses on blood pressure, with an increase in systolic pressure in parallel with the exertion performed[4].

Many surgeons still do not admit the widespread mobilization of the upper limbs after heart surgery, by the presence of artery catheterization (invasive blood pressure monitoring), the use of vasoactive drugs (VADs) and the fear of rupture of the steel wires used for fixation of the sternum, among other causes[5]. Many physiotherapists also avoid using the cycle ergometer for upper limbs in the early phase after cardiac surgery, motivated by the same reasons that were presented earlier in this paragraph, regarding the fear of medical surgeons for mobilization of upper limbs after thoracic surgeries. This type of restriction to early mobilization may lead to greater functional limitation in this population, complicating postoperative recovery and keeping coronary disease patients in a sedentary state of life after hospital discharge. Our hypothesis is that the exercise of cycle ergometry with upper limbs can be performed safely early after cardiac surgery, even in patients with arterial vascular accesses and in the use of VADs.

Considering this fact, the aim of this study is to perform a comparative study investigating the cardiorespiratory behavior of patients in the postoperative period of heart surgery receiving or not VADs during the cycle ergometer for upper limbs, and verify the safety in the use of the cycle ergometer for upper limbs and the occurrences related to the loss of the radial arterial catheter or of steel wire fractures in the sternum.

## Material and Methods

A pilot study the patients were evaluated in the intensive care unit (ICU) of Encore Hospital, in Aparecida de Goiânia/GO. Approved by the Ethics Committee indicated by the Brazil Platform, under CAAE number 08498819.8.0000.0033. All participants signed an informed consent form, in accordance with Resolution 466/2012 of the Ministry of Health. In order to carry out this work, in the sample acquisition, all patients who underwent cardiac surgery between January and March 2016 were consecutively submitted to the upper limb cycle ergometer on the first (1st) postoperative day, following eligibility criteria adopted by the physiotherapy team. The criteria for not performing the physiotherapeutic approach are described at the end of this section. The 26 individuals of both sexes were divided into two groups for analysis: control group (CO) without use of VADs (13 patients) and VAD group, using dobutamine, noradrenaline or both (in small doses by medical criteria) also with 13 patients. The patients underwent cardiac surgery (myocardial revascularization or valve replacement) and median sternotomy. Patients were operated under general anesthesia, receiving mechanical ventilation with volume guaranteed by ventilator between 6 and 8 ml/kg body weight, ventilated with final positive expiratory pressure (PEEP) between 6 and 8 $cmH_2O$. All the patients were weaned from mechanical ventilation after surgery in a period not superior to eight hours, been placed under regular oxygen therapy, though a nasal catheter, when necessary, aiming an oxygen saturation (SpO2) ≥ 92%.

The sample was obtained by adopting the following inclusion criteria: individuals with cognitive preservation to understand simple orders submitted to coronary artery bypass grafting or valve replacement, and in the VAD group presence of an access with use of VADs. We excluded patients who did not understand the techniques that would be performed, those who refused to participate, those who presented hemodynamic instability during the pre-test evaluations. Also those who presented some physical limitation to the proposed tests and who were unable to respond to information about their functional status before surgery. Patients with decompensated heart failure and presence of comorbidities, such as: unstable angina; moderate to severe respiratory disease; active infectious disease or febrile condition; disabling peripheral vascular disease; unstable ventricular arrhythmia and use of cardiac pacing. There was no discrimination of sex, race, color of skin, socioeconomic level, schooling, origin, marital status or religion.

All volunteers were submitted to a standard questionnaire for data collection such as age and sex. They underwent a physical-clinical evaluation that included collection of the physiological variables (DX 2022 Dixtal vital signs multi-parameter monitor©, AM, Brazil): heart rate (HR), SpO2, mean arterial blood pressure (MAP) and BORG scale for upper limbs and dyspnea during rest, exercise and recovery phase. For the analysis of the results referring to the cardiorespiratory variables, the difference between the values obtained in the fifth minute of exercise minus the values observed at rest (example: ΔHR = HR5th minute - HR at rest) was used. The number of events related to the loss of the radial artery catheter was also observed by visual inspection. In the process of visual inspection two of the researchers, with at least one of them being an assistant physician, observed the area of the arterial access, looking for signs of active bleeding or redness or hematoma. Visual inspection was performed immediately after the cycle ergometer and after 30 and 60 minutes at the end of the exercise. Considering the analysis of possible ruptures of steel wire in the sternum resulting from the ergometer cycle for upper limbs, a radiograph before the beginning of the exercise and another radiograph after the exercise was performed. Both radiographs were evaluated by visual inspection using a negatoscope, by the attending physician and by the physiotherapist who accompanied the patient, in search of signs of rupture of the steel wires in the sternum.

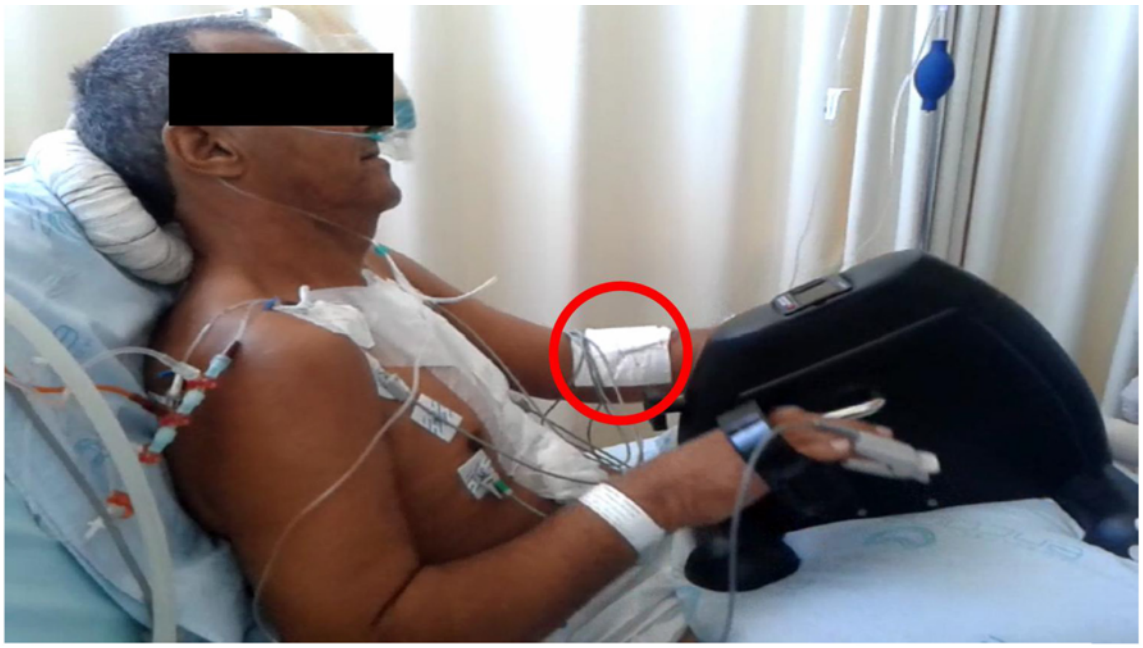
All the individuals were in the ICU when the protocol was carried out. On the first postoperative day, all the patients in the sample had a pleural drain and a mediastinal drain, both in the subxiphoid region. The cycle ergometer protocol would not be performed if the patient in the pre-intervention phase presented any of the following vital signs: SpO2 < 90%; Respiratory rate > 30 ipm; New onset of cardiac arrhythmias; HR > 120 bpm; MAP < 60 mmHg or > 140 mmHg; Increased dose or adoption of a new VAD.

**Cycle ergometer procedures**

In the 1st post-operative day the patients were in the bed in position of sitting in flexion of trunk. It was requested that the patient remain in sedestation in the bed, with bedside at 90º and later was explained the necessity and the form of realization of the cycle ergometer for upper limbs (Liveup©, PR, Brazil)). After 3 minutes of rest, the cycle ergometer training for upper limbs was started actively for 5 consecutive minutes. Exercise would be discontinued in any of the following situations: presence of hemodynamic instability, loss of arterial catheter or under any patient request manifesting his desire to interrupt activity. Were acquired signs from the physiological variables at rest (3 minutes), exercise (5 minutes) and recovery (2 minutes). Some variables, such as fatigue of upper limbs ad dyspnea were acquired specifically at the 3rd minute of rest, at the 1st and 5th minutes of exercise, and, in the second minute of recovery. All the physiological variables were acquired by manual annotation against the parameters evidenced in the multiparametric monitor used during the exercise phase of the protocol and also during the recovery. Three researchers independently performed the notes for future conference and adjustment of values. If there was a divergence between the values recorded by two researchers, the value that was repeated between the three vital signs control cards was chosen for analysis. Patients were instructed to maintain 50-60 rotations per minute on the cycle ergometer. The resistance imposed by the cycle ergometer to the pedaling was adjusted by the assistant physiotherapist seeking to maintain a subjective sensation of fatigue (Modified Borg scale with values from 0 to 10) between 04 and 05. The parameters evaluated during the exercise were HR,

SpO2, dyspnea (Borg), fatigue of upper limbs (Borg) and MAP. All the individuals studied were medically fit for the protocol. (figure 01).

**Figure 1.** Patient being submitted to upper limb cycle ergometer on the first postoperative day of cardiac surgery. The highlight (red circle) shows the insertion point of the invasive blood pressure catheter in the radial artery



### Statistical Analysis

The results obtained in the study were expressed as mean and standard deviation of the means. The software used for statistical analysis was Statistica 5.0 (StatSoft, TIBCO Statistica™, Palo Alto, CA, USA). Data normality was assessed based on the Shapiro-Wilk test. Comparing the groups regarding quantitative variables of the study, it was used the test for analysis of variance (ANOVA) of two ways, with post hoc of Scheffé for p values <0.05. In the comparison of anthropometric characteristics, it was used the test for analysis of variance of one way, and post hoc of Newman-Keuls test for p values<0.05. Hypotheses were created to assess whether there were significant differences in vital signs (HR, SpO2, MAP, Borg for Dyspnea and fatigue of upper limbs) and in the radial catheter losses or of steel wire fractures in the sternum during or after exercise.

## Results

Regarding the anthropometric and baseline characteristics of the sample, the data are presented in table 01. Both groups presented similar behavior in the studied physiological variables despite the use of VADs. The behavior of the physiological variables studied during the performance of the upper limb cycle ergometer is presented in table 02. HR behavior during rest, cycle ergometer exercise for upper limbs and recovery are presented in figure 02. It is important to note that the HR of both groups increased physiologically during the exercise, from the second minute of cycle ergometry onwards, until the end of the exercise phase, in relation to the values observed at rest.

**Table 1.** Anthropometric and baseline characteristics of the sample

| | CO (n = 13) | DVA (n = 13) | *p |
|---|---|---|---|
| Dispneia (Borg) | 1.1±1.0 | 0.8±0.6 | 0.80 |
| Fadida de MMSS (Borg) | 0.7±0.6 | 1.9±1.3 | 0.44 |
| PAM (mmHg) | 86.7±14.3 | 87.3±13.0 | 0.68 |
| SpO2 (%) | 95.7±1.3 | 94.3±2.9 | 0.42 |
| Idade (anos) | 57.2 ± 12.4 | 61.9 ± 10.6 | 0.18 |
| Sexo (masculino/feminino) | 9/4 | 7/6 | 0.38 |
| IMC | 26.38 ± 5.20 | 28.10 ± 7.13 | 0.42 |

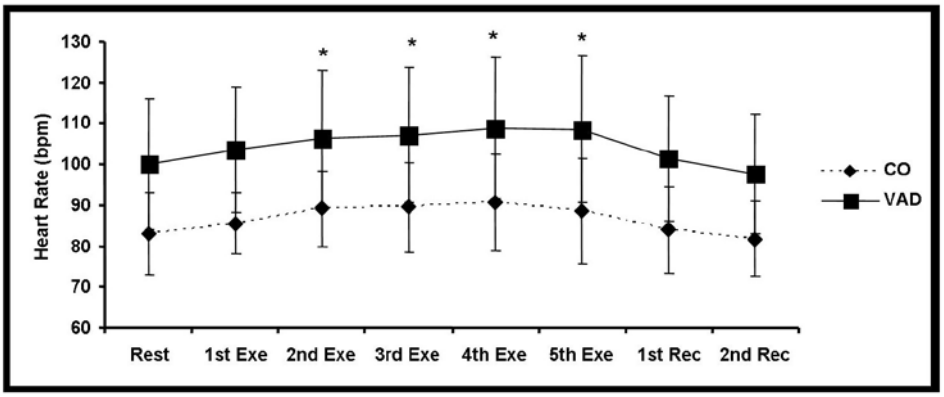
Abreviaturas: CO: Grupo controle; DVA: drogas vasoativas; PAM: pressão arterial média; SpO2: saturação arterial de oxigênio; IMC: índice de massa corporal; MMSS: membros superiores. * "p" assumindo como significativos valores menores ou iguais a 5%. Análise de variância de um caminho (ANOVA), com post hoc de Newman-Keuls, quando necessário.

**Table 2.** Behavior (absolute deltaΔ) of the variables studied, comparing the 5th minute of exercise on cycle ergometer with rest

| Itens avaliados no protocolo | CO (n = 13) | DVA (n = 13) | *p |
|---|---|---|---|
| Dispneia (Borg) | 3.8±0.9 | 4.0±1.7 | 0.78 |
| Fadiga de MMSS (Borg) | 0.6±1,7 | 0.6±1.4 | 0.04 |
| PAM (mmHg) | 1.4±4.9 | -1.3±10.5 | 0.25 |
| SpO2 (%) | -1.7±2.4 | -0.6±3.0 | 0.49 |

Abreviaturas: CO: Grupo controle; DVA: drogas vasoativas; PAM: pressão arterial média; SpO2: saturação arterial de oxigênio; MMSS: membros superiores. Valor de "p" baseado em ANOVA de dois caminhos, com Post Hoc de Scheffé (5%) versus repouso.

**Figure 2.** Behavior of heart rate during the cycle ergometer performance, showing an increase in both groups during exercise (*p:0.00), with no differences among groups (p:0.97). VADs: Vasoactive drugs; CO: Control group




Regarding the radial artery catheter and the steel wire fractures in the sternum, no event was observed throughout the study.

None of the subjects had to interrupt the exercise, which was well tolerated by all, even in those receiving VADs. There were no follow-up losses considering the cycle ergometer activity in the 1st postoperative day since all the patients enrolled for the study were able to perform the proposed activity.

## Discussion

The aims of an exercise-based cardiac rehabilitation programme in the early postoperative period after cardiac surgery are to restore the physical functional capacity of the patient and establish appropriate levels of physical activity after hospital discharge[6]. The American College of Sports Medicine has published guidelines for exercise prescription in the early postoperative period after cardiac surgery[6]. These guidelines make recommendations on the intensity,

duration, frequency and mode of exercise. Upper limbs stationary cycling is neither recommended in the guidelines, nor customarily selected as a mode of exercise in the early postoperative period[6].

We observed that early cycling exercise with upper limbs is feasible and can be performed safely for patients who undergone cardiac surgery, while in the ICU. The proposed exercise did not promote significant changes in the evaluated parameters, even in individuals receiving VADs. Although we observed a significant difference in HR and upper limbs dyspnea, these differences were observed when comparing the rest within the fifth minute of exercise, and therefore, were expected, based in the exercise physiology, since the patient's metabolic work was increased by muscle recruitment during effort. Both alterations were clinically irrelevant.

In agreement with our study, Pires-Neto et al revealed that a single 5 minutes active exercise intervention of cycle ergometer can promote an increase in the HR, respiratory rate and Borg perception in a study carried out in the Respiratory ICU of the Clinics Hospital of the Medical School of the University of São Paulo, with patients who were hemodynamically stable. At the end, the authors concluded that the adoption of active cycle ergometer implied in small cardiorespiratory changes, besides being a viable activity to be performed in collaborative ICU patients. This intervention was associated with a high degree of acceptance by the patients. It also observed that 85% of the patients liked to perform this type of activity[3].

Concerning the risk involved in early mobilization in the ICU, another study that focused on early mobilization during the first 24 hours of ICU admission, involving 171 patients admitted for a two-month period, reported a 0.8% incidence of hemodynamic events that resulted in the interruption of the physiotherapy session, primarily by hypotension or changes in heart rhythm due to exercise[7]. It is important to highlight the fact that in our study there was no need of interruption of the exercise sessions.

Burtin et al.[8] described that using the upper limb cycle ergometer in addition to a regular physical therapy program resulted in less respiratory discomfort compared to a control group, in critically ill patients. Specifically, on heart surgery, as already mentioned, a Swiss study aiming to promote early mobilization in this population, within 12 to 24 hours postoperatively, was able to demonstrate that all patients successfully completed the mobilization protocol without experiencing myocardial ischemia or other major complications. In numbers, eighteen patients had a significant decrease in mean blood pressure, but only nine required treatment, with seven receiving additional intravenous fluids (approximately 500 ml) and two receiving vasopressors (low dose norepinephrine infusion). Seven patients complained of self-limiting nausea with one of them reporting transient dizziness. Three patients had self-limited arrhythmias (two sinus tachycardias and one paroxysmal supraventricular arrhythmia). In their conclusion, the authors also suggest that because of compromised cardiovascular system after cardiac surgery, mobilization must be performed under strict clinical and hemodynamic monitoring in an intensive environment, with special attention to blood lactate and central venous saturation[2].

When considering the risk associated with early mobilization, specifically on cardiovascular parameters, there is no consensus among specialists on the dose of VADs (and the combination of these drugs) that would allow safe mobilization in ICU. Specialists assume that the administration of VADs alone is not an absolute contraindication to mobilization, and it should be considered that there is a direct influence of the absolute dose or of the change in the dose of VADs on the level of early mobilization adopted[5]. In our opinion, the use of VADs should not be associated with a barrier to the early mobilization procedures, once the assisting team shall decide together for its realization, evaluating carefully the details of each case.

Hirschhorn et al.[9] reports that after three days post cardiac surgery, walking or cycle ergometer exercises can already be used. The article recommends two sessions of moderate-intensity exercise, of 10-min duration, from postoperative day 3 until discharge from hospital. The author concludes that a well-designed physical conditioning program of stationary cycling provides a well-tolerated and clinically effective alternative to walking in the early postoperative period after coronary artery bypass graft surgery, possibly enabling better outcomes, mainly in respiratory discomfort and in the return to ADLs. It is important to note that in the aforementioned study, the exercise session would not be initiated if the patient was receiving DVAs.

As in the study by Hirschhorn et al., it is common to find in the literature exercises to be performed after about three days of the surgical act. As far as we know, this is the first study that focused on the safety of performing a cycle ergometer for upper limbs after cardiac surgery, evaluating the risk of loss of radial artery catheter, and not finding any event related to catheter loss reinforces our hypothesis of that early mobilization is safe and should be undertaken in this population as early as possible.

Cordeiro and colleagues submitted patients after cardiac surgery to a 20 minute cycle ergometer for upper limbs and demonstrated that the this type of exercise implied in a small and not statistically significant increase in HR, blood pressure and SpO2, also been well tolerated and safe for this population[4], agreeing with our study, were we could not identify changes in SpO2, MAP or dyspnea in the population studied. The slight increase in the sensation of tiredness in the upper limbs is expected, in front of the type of intervention performed. Another relevant point rests on the fact that both groups (CO and VAD) presented increases in heart rate during exercise, which demonstrates that the metabolic stress of physical activity occurred without any significant intercurrences. In fact, we believe that when we check for such increases in HR (expected during exercise), we can provide the assisting team, specifically the physician, with a reflection on whether there is still a need to maintain VADs undergoing infusion. Although we did not have this as the goal of the study, in several situations, after exercise, the infused doses were decreased, without hemodynamic repercussions. This fact may be useful in order to optimize the weaning of vasoactive drugs in the ICU, using cardiovascular responses to exercise as a parameter.

Nydahl et al.[10] in 2017 published an elegant systematic review with meta-analysis where they investigated several aspects concerning the safety of early mobilization in critically ill patients. In the cardiovascular / hemodynamic aspect they found 27 publications, which together totaled 6,082 patients studied. They found incidence of adverse events of 3.8 episodes for every 1,000 mobilization sessions. Among the cardiovascular events described, increases in heart rate (considering values greater than 125-140 bpm) were present at an incidence of 1.9 episodes for every 1,000 mobilization sessions. Mean arterial pressure drops (values lower than 55-70 mmHg) presented an incidence of 4.3 episodes for every 1,000 mobilization sessions. Decreases in systolic blood pressure (values lower than 80-90 mmHg) were reported at an incidence of 1.8 episodes for every 1,000 mobilization sessions. Still considering blood pressure, increases of the same were also studied. At mean arterial pressure, considering values greater than 100-140 mmHg as increased, incidence of 3.9 episodes was reported for every 1,000 mobilization sessions. Systolic blood pressure increased with an incidence of 0.3 episodes for every 1000 mobilization sessions, considering as increased values higher than 180-200 mmHg.

We also highlight a fact that may generate apprehension in teams not accustomed to cardiac rehabilitation still inside the ICU. All the individuals studied performed the cycle ergometer for upper limbs for five minutes without interruption. One could hypothesize that such a conduct could generate stress on the sternum bone, increasing the risk of steel wire fracture or other complications. It is important to describe that all the patients had a chest x-ray before discharge to the ward and no steel wire fracture was verified in the studied population (a physician and a physiotherapist jointly evaluated the radiographs), which reinforces the safety of the cycle ergometer for upper limbs after heart surgery.

Our study has limitations that must be considered. We were unable to evaluate the presence or intensity of pain in the studied population, which can create a bias in the motor behavior of upper limbs. It is important to emphasize that no individual complained of pain during the cycling. Other point concerns the number of subjects studied. We included 26 individuals, based in the numbers of surgeries performed in our center and the results achieved may not represent the same power/safety if larger populations were addressed. A third point is related with the VADs doses. We did not have explicit values of the doses administered at the time of the intervention, therefore the concept of low doses was established by the attending physicians. This can contribute to another bias in the present study. Other limitation concerns temporal questions. No results were followed in the medium and long terms, regarding the loss of the infusion line beyond the day itself or in eventual incidence of steel wire fractures in the sternum which, although unlikely, could occur in the medium or long term, due to stress on the sternum wall resulting from the cycle ergometer for upper limbs.

## Conclusion

The adoption of the cycle ergometer for upper limbs was safe in the 1st post-operative day, not promoting unfavorable alterations in the cardiorespiratory parameters studied, even in the individuals using VADs. There was no relationship between the use of the upper limbs cycloergometer and the risk of loss of radial arterial catheter or steel wire fractures in the sternum, in the studied population. It has been demonstrated that the early completion of cycle ergometer for upper limbs after cardiac surgeries is safe and should therefore be encouraged, minimizing negative repercussions of bed rest.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### Author contributions

Gardenghi G was responsible for the study design, statistical analysis, data collection and writing of the manuscript. Kushida CL, Dias AF, Cruz JB and de Lima KR were responsible for data collection and revision of the manuscript. de Souza AH was responsible for the study design, data collection and writing of the manuscript.

### Competing interests

No financial, legal or political competing interests with third parties (government, commercial, private foundation, etc.) were disclosed for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.).

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