

## Physiotherapeutic protocol applied in the immediate postoperative period for accelerated recovery of patients submitted to thoracic surgery at the Hospital Santa Marcelina (Brazil): randomized clinical trial

### Protocolo fisioterapêutico aplicado no pós-operatório imediato para recuperação acelerada de pacientes submetidos à procedimentos cirúrgicos torácicos no Hospital Santa Marcelina – Itaquera (PROSM): estudo clínico randomizado

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**RESUMO | INTRODUÇÃO:** A cirurgia torácica pode causar uma série de complicações pulmonares após o processo cirúrgico. O momento e a circunstância ideais para sedestação fora do leito e suas implicações clínicas, após cirurgias no tórax, ainda necessitam de padronização. Assim, faz-se necessário um tratamento de mobilização precoce adequado visando minimizar as complicações no período pós-operatório. Objetivamos avaliar o efeito do atendimento fisioterapêutico no pós-operatório imediato de pacientes submetidos à cirurgia torácica. **MATERIAL E MÉTODOS:** Este será um ensaio clínico randomizado, no qual um grupo de pacientes submetidos às cirurgias de ressecções pulmonares eletivas (segmentectomias, lobectomias ou pneumonectomias) com idade superior a dezoito anos receberão atendimento fisioterapêutico através do PROSM. Serão excluídos os pacientes incapazes de assinar o termo de consentimento livre esclarecido, com performance status comprometido (ECOG superior à 2), com peso corporal inferior à 60 Kg ou superior à 120 Kg, com alergia a qualquer uma das drogas utilizadas na anestesia, portadores de disfunção renal, disfunção hepática (Child B e C) e Insuficiência Cardíaca (classe Funcional III e IV). O instrumento de classificação do grau da dor por meio da Escala Visual Analógica (EVA) e instrumento de classificação da independência funcional por meio da Escala MIF (medida de independência funcional) serão aplicados antes do início e após o término de cada sessão de fisioterapia. Também será analisado o número de sessões de cada paciente e o tempo de internação. Para análise estatística será utilizado o programa SPSS Statistics e o teste de Shapiro-Wilk será usado para identificar a normalidade dos dados coletados. Espera-se um menor tempo de internação e melhor independência funcional na alta hospitalar nos pacientes submetidos ao PROSM.

**PALAVRAS-CHAVE:** Fisioterapia. Pós-operatório. Recuperação acelerada.

**ABSTRACT | INTRODUCTION:** Thoracic surgery can cause a series of pulmonary complications after the surgical procedure. The ideal timing and circumstance for out-of-bed sedation and its clinical implications, after chest surgeries, still require standardization. Thus, an appropriate early mobilization treatment is necessary in order to minimize complications in the postoperative period. We aimed to evaluate the effect of physical therapy care in the immediate postoperative period of patients undergoing thoracic surgery. **MATERIAL AND METHODS:** This will be a randomized clinical trial in which a group of patients undergoing elective pulmonary resections (segmentectomies, lobectomies or pneumonectomies) aged over eighteen years will receive physiotherapeutic care through PROSM. Patients under the age of eighteen years, unable to sign the informed consent form, with compromised performance status (ECOG greater than 2), with a body weight below 60 kg or greater than 120 kg, with a history of allergy to any of the drugs used in anesthesia, patients with renal dysfunction, liver dysfunction (Child B and C) and Heart Failure (Functional class III and IV). The instrument of classification of pain grade by means of the Visual Analogue Scale (EVA) and instrument of classification of functional independence by means of the MIF Scale (functional independence measure) will be applied before the beginning and after the end of each physiotherapy session. We will also analyze the number of sessions of each patient and the length of hospital stay. For statistical analysis, the SPSS Statistics program will be used and the Shapiro-Wilk test will be used to identify the normality of the data collected. It is expected a shorter hospitalization time and better functional independence at hospital discharge in patients submitted to PROSM.

**KEYWORDS:** Physiotherapy. Postoperative. Accelerated recovery.

## Introduction

Large surgical procedures such as chest surgeries constantly promote considerable systemic alterations, directly affecting the lives of individuals who undergo them<sup>1</sup>. Surgical treatment can lead to postoperative pulmonary complications (CPPO), which occur after 25% to 50% of major surgical procedures<sup>1,2</sup>. These complications contribute to morbidity, mortality, and increase in hospital days. CPPO is understood as a second disease that occurs up to thirty days after surgery, altering the patient's clinical condition and necessitating a new therapeutic intervention<sup>2</sup>. CPPO are considered: pneumonia, tracheobronchial infection, clinically relevant atelectasis, bronchospasm, acute respiratory failure and prolonged mechanical ventilation (for more than 48 hours)<sup>2</sup>. Many still consider the presence of fever without a specific cause, pulmonary embolism, pleural effusion and broncho pleural fistulas as members of this group<sup>1,2</sup>.

Physical therapy is essential during hospital stay, both preoperatively and postoperatively, to prevent the effects of immobility in the bed and to optimize the patient's functional independence<sup>3</sup>. The progression of the stages of early mobilization has been safely performed in intensive care patients, although these may lead to hemodynamic and ventilatory variations<sup>4</sup>. Morris and colleagues<sup>5</sup> used an early mobilization protocol described as safe and effective, and no intercurrent was observed during their execution. Although safety and viability in critically ill patients are well established, this issue in postoperative patients still needs to be consolidated<sup>3,4,5</sup>.

In the postoperative period, the patient's early mobilization and the adoption of the seated posture contribute to the restoration of normal pulmonary function<sup>6,7</sup>. In addition to the existing scientific knowledge on the subject, our team of the services of Thoracic Surgery, Anesthesiology, Intensive Care and Physiotherapy of Santa Marcelina Hospital has developed a protocol entitled PROSM (Protocol of Operative Recovery Santa Marcelina) in which a randomized clinical trial which will be conducted to meet the need for rehabilitation using the resources already available and offered by the single health

system as well as by the supplementary health systems.

Our data may lead to the use of protocolized early-intervention intervention, including a dedicated patient mobility facilitator in surgery, which improves functional independence at hospital discharge and leads to better discharge provision. Our results are directly applicable to millions of surgical and critical patients. Precociously, the mobilization will probably be used in thoracic surgery patients. Potential barriers to this goal could be addressed in turn by closed-loop interprofessional communication within the institution.

## Goals

1. To evaluate the effectiveness of the PROSM aimed at an accelerated recovery compared to the institution's standard treatment in the primary outcome of mean daily mobilization of patients on the impact on length of stay.
2. Generate data for hypotheses and cost calculations during hospital stay.

## Hypothesis

Patients receiving early mobilization treatment with PROSM-directed goals compared with standard institution treatment will have shorter hospital stay and better functional independence at hospital discharge.

## Methods

PROSM (Santa Marcelina Operative Recovery Protocol) is an accelerated surgical recovery protocol that advocates intensive physiotherapeutic care in the first 6 postoperative hours of patients undergoing thoracic surgery at Santa Marcelina Hospital, upon arriving at Post Anesthesia Recovery or at Inpatient Unit.

This is a randomized controlled trial developed at the Department of Thoracic Surgery of the Santa Marcelina Hospital (Itaquera) in São Paulo. For the accomplishment of this study all the procedures were

submitted and approved by the Committee of Ethics of the Santa Marcelina Hospital (Itaquera) under the research protocol CAAE 70142917.0.0000.0066 e ruling number 2.187.393.

Patients with elective pulmonary resections (segmentectomies, lobectomies or pneumonectomies) for the treatment of pulmonary diseases over the age of eighteen will be included.

Patients under the age of eighteen years, unable to read, understand and sign informed consent, patients with compromised performance status (ECOG greater than 2),<sup>4,8</sup>, patients with a body weight below 60 kg or greater than 120 kg, patients with latex allergy, patients with a history of allergy to any of the drugs used in anesthesia for PROSM, patients with renal dysfunction, hepatic dysfunction (Child B and C) and Heart Failure (functional class III and IV). Patients not awake, unable to maintain sufficient level of consciousness to understand and respond to verbal commands within 50 min from extubation or if during awakening the same evolves with postural hypotension will be aborted the protocol and resume recovery by conventional measures and patients presenting respiratory and cardiovascular complications will be counted as failures to perform the method.

Early sedestation in the first hours will occur according to the phases established by the PROSM protocol elaborated by the researchers. In Phase 1, postural fitness will be performed in the armchair and exercises; in Phase 2, the patient will be placed in orthostatism, progressing with walking. The change from one phase to another will happen through rigorous monitoring and medical follow-up of the thoracic surgery team. After completing the PROSM protocol, the patient will enter the standard physiotherapy program of our institution.

Physiotherapeutic interventions, such as breathing exercises, progressive walking exercises and active exercises free of upper and lower limbs, will be performed in all patients. Patients will receive care from the immediate postoperative period until discharge, according to the routine already established by the Service.

Patients will be informed of all study procedures prior to their completion and will sign the Free and Informed Consent Form, as determined by Resolution 46612 of the National Health Council (CNS).

### **Physiotherapeutic evaluation**

For the data collection, an evaluation form will be used, where the following information will be collected: age, weight, height, vital signs, presence of cough, dor scale<sup>7</sup> and MIF<sup>1</sup> scale, number of physiotherapy sessions, withdrawal time thoracic drainage, hospitalization time and rehospitalization within 30 days postoperatively (if any).

The evaluation phase will begin after completion of the informed consent form, before the beginning of the protocol. In this phase, the classification of pain grade by means of Visual Analogue Scale (EVA) and functional independence by means of the MIF Scale will be performed before the beginning of each physical therapy session and after the end of each physical therapy session. All evaluations and appointments will be performed by the same physiotherapist.

### **Visual Analog Scale (EVA)**

It consists of a horizontal line of 10 centimeters numbered with a starting point 0 and final 10, in which 0 represents the absence of pain and disabling pain.

In order to classify the degree of pain, the individuals will be presented to the scale and oriented to classify the degree of the general pain that they are feeling in the region of the surgical incision of 0 - 10. The patient should mark in the line the place referring to the intensity of the pain, later the evaluator will use a ruler to number the mark registered by the individual, obtaining a numerical response to the pain, which is then graded. This scale is commonly used to grade the pain<sup>7</sup>.

### **MIF Scale (Functional Independence Measure)**

The Functional Independence Measure (MIF) is an evaluation tool designed to accompany people under rehabilitation through the capacity to carry out their daily activities. The MIF verifies the

performance of the patient to perform a set of 18 tasks, referring to self-care subscales, sphincter control, transfers, locomotion, communication and social cognition. The patient will describe how he / she performs each task and the physiotherapist scores according to the protocol for applying the instrument. The evaluation will be done by adding the score obtained in the 18 items, with a possible range of 18 to 126 points. Higher scores indicate greater functional independence.

### **Operative Recovery Protocol Santa Marcelina (PROSM)**

Patients selected and agreeing to participate in the study and whose randomization assign them to the intervention group will be subject to the following guidelines:

**Preoperative preparation:** In addition to the conventional preoperative preparation that includes smoking cessation and optimization of medications for continuous use for comorbidities, guidelines for preoperative fasting, verification of preoperative exams and cardiovascular and pre-anesthetic evaluations, the patient will receive guidelines for home exercises to perform daily walks with thirty minutes duration until the day of surgery.

**Anesthesia:** Anesthetic induction will be performed using short duration opioid (remifentanyl), hypnotic (propofol) and neuromuscular blocker with dose adjusted according to the body mass of the patient. Intraoperative analgesia will be obtained through

paravertebral and incisional intercostal block through the infiltration of a drug solution containing 500ml of saline, 1 vial of 5mg / 20ml bupivacaine, 20ml of lidocaine 2% without vasoconstrictor, 10mg of dexamethasone, 500mg of hydrocortisone, 1mg/kg of clonidine, 5mg of ketamine and 40ml of 8.4% sodium bicarbonate). Only the volume of solution sufficient to generate the intercostal blocks of the spaces pertaining to the incision and the orifice of the pleural drain and completely infiltrating the surgical wound will be used. The excess drug solution will be discarded. Patients will not undergo epidural anesthesia, only to the block in question. Intercostal block and infiltration of the surgical wound will be performed by the surgical team while the other anesthetic procedures will be performed and accompanied by the anesthesiologist.

**Protocol in the operating room:** Immediately after extubation, the patient will be positioned in a high position at 45 degrees from the surgical table maintaining constant observation of blood pressure, heart rate and pulse oximetry. And you will be kept in a high position until the patient is wide awake. If the patient does not wake up, is unable to maintain sufficient level of consciousness to understand and respond to verbal commands within 50 min from extubation or if during awakening the same evolves with postural hypotension the protocol will be aborted and recovery will resume by measures conventional. These cases will be counted as failures to execute the method and listed in detail the causes of the exclusion.

When the patient is conscious, active and respond to verbal commands, the postoperative exercise program will be started. Initially, breathing exercises will be performed with sustained inspirations and forced expirations associated with the upper limbs. While the patient is in the operating room, two sets of ten repetitions each with a 1 minute interval between sets will be performed. After the anesthesiologist's authorization, the patient will be referred for anesthetic recovery or hospitalization unit.

### **Physiotherapeutic Protocol in the first six postoperative hours**

Phase I (first two hours): Upon arriving at the Post-Anesthesia Recovery or at the Inpatient Unit, the patient will receive physiotherapeutic care as follows:

Patient will be positioned in the armchair seating, maintaining vital signs monitoring and will be performed diaphragmatic breathing exercises associated with upper limbs, active exercises free of elevation and abduction of upper limbs and active exercises free of flexion and extension of lower limbs in two series of ten repetitions each with rest according to the need of the patient. Three physiotherapy sessions lasting 45 minutes each session will be held in this first phase. A family escort will be allowed to remain with the patient to assist in doing the exercises if necessary and receive guidance.

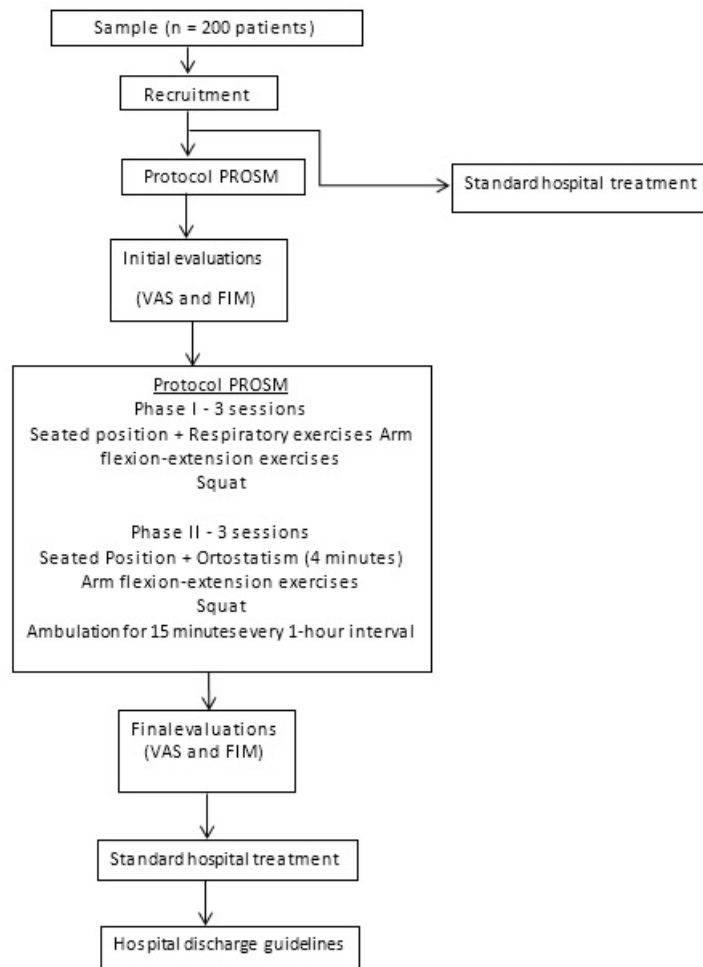
Phase II (after two hours): the physiotherapist will place the patient in orthostatism training for 4 minutes in order to evaluate possible postural hypotension and evaluate the patient's ability to sustain his body weight through rigorous monitoring and conditioned to the non-occurrence of criteria for interruption:

- Systolic blood pressure  $<90$  mmHg or  $> 200$  mmHg;
- Mean blood pressure  $<65$  or  $> 120$  mmHg;
- Heart rate  $> 120$  bpm or 30 bpm increase in baseline;
- Angina, syncope or cramps in the legs.
- Disabling pain in the surgical incision;
- Tachypnea and feeling of dyspnea;

If the patient does not tolerate orthostatism, he will be repositioned again in the armchair and continue with previous exercises. Otherwise, the protocol follows with closed-arm flexion-extension exercises (standing patient with upper limbs supported on the wall) and squatting (closed-loop knee flexion-extension with the patient standing and upper limbs supported on the wall) in two sets of ten repetitions each. The physiotherapist will then walk with the patient across the area for a period of 15 minutes every 1 hour, with rest breaks according to the patient's need until the sixth postoperative hour. During the intervals, the patient will sit in the armchair and after completing the 6 hours, the patient will enter the standard physiotherapy program of the institution and the water seal will be changed.

The flow chart below (figure 1) presents in detail all the procedures that will be adopted in the execution of the present study.

Figure 1. Flowchart



**Postoperative Prescription:** The postoperative prescription should contain a general voluntary diet, medications for continuous use of the patient, prophylactic antibiotics in the first 24 hours of the postoperative period, time analgesics, schedule antiemetics, laxative once daily, anxiolytics if necessary. Anticoagulants or antiplatelet agents will not be prescribed until the seventh postoperative day. Daily radiological imaging tests will be performed while the patient is undergoing thoracic drainage. Laboratory tests will be requested only if the patient shows some type of abnormality on

physical examination or with indication based on preoperative cardiovascular and anesthetic evaluations.

**Hospital discharge:** When the patient is able to leave hospital, this will be done through the following guidelines: return to the outpatient thoracic surgery in 7 days to continue postoperative follow-up, prescription of painkillers for home use and guidelines for possible postoperative complications (fever, dyspnea, bleeding or chest pain that is refractory to the use of medication).



## Statistical analysis

The data collected and the risks of the study will be described in mean values with the respective standard deviations. Data will be analyzed both in their absolute values and in relation to their percentage variation from the values obtained in the pre-exercise evaluations. The results obtained will be tested for their normality by the Kolmogorov-Smirnov test. If the data are parametric, the ANOVA test with Bonferroni post-hoc will be used. If the data is not parametric the Kruskal-Wallis test will be used. The level of statistical significance will be  $p < 0.05$ .

## Contributions of authors

Gomes AO participated in the elaboration, writing and revision of the manuscript and execution of the protocol. Ramos WR participated in the elaboration and supervision of the protocol. Dalfior CAP and Cavalcante MG participated in the manuscript revision. Abreu IRLB participated in the elaboration of the protocol, writing and revision of the manuscript. Abrão FC participated in the elaboration of the protocol, writing and revision 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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## References

1. Cordeiro ALL, Brito AAOR, Santana NMA, Silva INMS, Nogueira SCO, Guimarães ARF et al. Análise do grau de independência funcional pré e na alta da UTI em pacientes submetidos à cirurgia cardíaca. *Rev Pesq Fisio.* 2015;5(1):21-27. doi: [10.17267/2238-2704rpf.v5i1.574](https://doi.org/10.17267/2238-2704rpf.v5i1.574)
2. Saad IAB, Barusso MS, Gonçalves CPCRR, Melo B. Avaliação da distância percorrida no teste de caminhada de seis minutos e atendimentos em fisioterapia nos pacientes submetidos a cirurgia torácica por neoplasia pulmonar. *J Health Sci.* 2013;15(2):105-9. doi: [10.17921/2447-8938.2013v15n2p%25p](https://doi.org/10.17921/2447-8938.2013v15n2p%25p)

3. Zafropoulos B, Alison JA, McCarren B. Physiological responses to the early mobilization of the intubated, ventilated abdominal surgery patient. *Aust J Physiotherapy.* 2004;50(2):95-100.
4. Morris PE, Goad A, Thompson C, Taylor K, Harry B, Passmore L et al. Early intensive care unit mobility therapy in the treatment of acute respiratory failure. *Crit Care Med.* 2008;36(8):2238-43. doi: [10.1097/CCM.0b013e318180b90e](https://doi.org/10.1097/CCM.0b013e318180b90e)
5. Silva LN, Marques MJS, Lima RS, Fortes JVS, Silva MGB, Baldez TEP et al. Retirada precoce do leito no pós-operatório de cirurgia cardíaca: repercussões cardiopulmonares e efeitos na força muscular respiratória e periférica, na capacidade funcional e função pulmonar. *ASSOBRAFIR Ciência,* 8(2), 25-39.
6. Santos FTIS, Biazotto KSB, Santos VM, Nasralla MLS. Avaliação da força muscular respiratória de pacientes submetidos à cirurgia abdominal alta e cirurgia torácica. *Revista Coorte.* 2010;1(1):19-29.
7. Sabino GS, Souza MVS, Resende MA. Estimulação elétrica nervosa transcutânea no pós-operatório de cirurgia torácica ou abdominal. *Fisioterapia em Movimento.* 2006;19(1):59-71.
8. Dong Q, Zhang K, Cao S, Cui J. Fast-track surgery versus conventional perioperative management of lung cancer-associated pneumonectomy: a randomized controlled clinical trial. *World J Surg Oncol.* 2017;15:20. doi: [10.1186/s12957-016-1072-5](https://doi.org/10.1186/s12957-016-1072-5)
9. Wolk S, Meißner T, Linke S, Müsle B, Wierick A, Bogner A et al. Use of activity tracking in major visceral surgery - the Enhanced Perioperative Mobilization (EPM) trial: study protocol for a randomized controlled trial. *Trials.* 2017;18:77. doi: [10.1186/s13063-017-1782-1](https://doi.org/10.1186/s13063-017-1782-1)
10. Jones NL, Edmonds L, Ghosh S, Klein AA. A review of enhanced recovery for thoracic anaesthesia and surgery. *Anaesthesia.* 2013;68(2):179-189. doi: [10.1111/anae.12067](https://doi.org/10.1111/anae.12067)
11. Komatsu T, Kino A, Inoue M, Sowa T, Takahashi K, Fujinaga T. Paravertebral block for video-assisted thoracoscopic surgery: Analgesic effectiveness and role in fast-track surgery. *Int J Surg.* 12(9):936-939. doi: [10.1016/j.ijvsu.2014.07.272](https://doi.org/10.1016/j.ijvsu.2014.07.272)
12. Das-Neves-Pereira JC, Bagan P, Coimbra-Israel AP, Grimaillof-Junior A, Cesar-Lopez G, Milanez-de-Campos JR et al. Fast-track rehabilitation for lung cancer lobectomy: a five-year experience. *Eur J Cardio-thoracic Surg.* 2009;36(2):383-92. doi: [10.1016/j.ejcts.2009.02.020](https://doi.org/10.1016/j.ejcts.2009.02.020)

13. Chen L, Sun L, Lang Y, Wu J, Yao L, Ning J. Fast-track surgery improves postoperative clinical recovery, cellular, and humoral immunity after esophagectomy for esophageal cancer. *BMC Cancer*. 2016;16:449. doi: [10.1186/s12885-016-2506-8](https://doi.org/10.1186/s12885-016-2506-8)
14. Asteriou C, Lazopoulos A, Rallis T, Gogakos AS, Paliouras D, Barbetakis N. Fast-track rehabilitation following video-assisted pulmonary sublobar wedge resection: A prospective randomized study. *J Minim Access Surg*. 2016;12(3):209-213. doi: [10.4103/0972-9941.183483](https://doi.org/10.4103/0972-9941.183483)
15. Cangiani LM, Carmona MJC, Torres MLA, Bastos CO, Ferez D, Silva ED et al. *Tratado de Anestesiologia SAESP*. 8.ed. Rio de Janeiro: Atheneu; 2017.