

Clinical Trial Report: Protocol for Accelerated Recovery in Patients Undergoing Thoracic Surgical Procedures (PROSM). Study Randomized Comparative between the Adoption of the Proposed Guidelines and the Traditional Method Currently Used in the Institution (PROSM)

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Abstract

Aiming at reducing costs and optimizing the use of these financial resources, several postoperative recovery protocols have emerged that aim to reduce the length of hospital stay by accelerating surgical recovery. The investigators developed a protocol (PROSM) that aims to meet this need using resources already available and offered in Brazilian public health system. A clinical trial was created to evaluate the impact of PROSM on: the length of hospitalization in days and postoperative pain (visual analog pain scale - VAS) in patients submitted to surgical procedures performed by the thoracic surgery team of the Hospital Santa Marcelina de Itaquera, and to evaluate the impacts of PROSM in reducing the costs (US dollars) of surgical treatment and hospitalization of these patients. The object of the present paper is to describe the clinical trials in details. This study will give us information about the real impact of PROSM adoption on thoracic surgical patients care. If the positive value of PROSM is confirmed this will allow a new perioperative care possibility to these patients.

Keywords: Thoracic Surgical Procedures; PROSM; Traditional Method; Fast Track; Europrogram

Introduction

Aiming at reducing costs and optimizing the use of these financial resources, several postoperative recovery protocols have emerged that aim to reduce the length of hospital stay by accelerating surgical recovery [1,2]. In view of the current Brazilian political and economic scenario allied to the existing scientific knowledge on the subject, the investigators developed a protocol that aims to meet this need using resources already available and offered in Brazilian public health system. The investigators called this protocol as Protocol of Operative Recovery Santa Marcelina (PROSM) that had as inspiration the protocols of accelerated postoperative recovery already used in several European health services.

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Goals of the Study

1. To evaluate the impact of PROSM on the length of hospitalization in days and postoperative pain (visual analog pain scale - VAS) in patients submitted to surgical procedures performed by the thoracic surgery team of the Hospital Santa Marcelina de Itaquera.
2. Evaluate the impacts of PROSM in reducing the costs (US dollars) of surgical treatment and hospitalization of these patients.

Materials and Methods

The present trial is registered at ClinicalTrials.gov under the identifier number: NCT03271749.

A group of 200 patients with elective pulmonary resections (segmentectomies, lobectomies or pneumonectomies) to treat neoplastic lung diseases will be selected by the investigators.

The participants will be randomized into two groups (rate of randomization 1/1).

The first group will be submitted to the standard surgical treatment that is currently used in Santa Marcelina - Itaquera hospital (conventional anesthesia, Patient Controlled Analgesia in epidural catheter, regular physiotherapy distributed in 3 daily sessions. The second group will be submitted to treatment with the adoption of the PROSM guidelines, which will be detailed later.

Investigators will evaluate in the two groups: surgical time in minutes, intraoperative complications: intraoperative bleeding in milliliters, need for transfusion of blood products, intraoperative clinical complications. Investigators will also evaluate the need for postoperative recovery in Intensive Care Unit (ICU), medications used to maintain the anesthetic plane during the procedure (amount of drugs in milligrams), medications used for postoperative analgesia, length of hospital stay in days, postoperative clinical complications, need for surgical re-boarding, immediate postoperative pain (VAS), postoperative pain at the time of discharge and the first outpatient return (VAS), the need for opioid analgesics at home after discharge.

After the data collection, the investigators will analyze them and make a comparative study of the costs of surgical treatment and hospitalization between the two groups. This data will be obtained from the billing department of the Hospital Santa Marcelina de Itaquera.

Arms and interventions

No intervention: Conventional.

The participants of this arm will receive the conventional pre-operative, anesthesia and postoperative care for lung resections for treatment of lung neoplasms.

Experimental: PROSM interventional.

The participants of this arm will receive the PROSM protocol pre-operative, anesthesia and postoperative care for lung resections for treatment of lung neoplasms.

Eligibility criteria

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Inclusion criteria

- Patients with elective pulmonary resections (segmentectomies, lobectomies or pneumonectomies) to treat neoplastic lung diseases.

Exclusion criteria

- Unable to read, understand and sign informed consent
- Patients with compromised performance status (ECOG greater than 2)
- Body mass below 60 kg or greater than 120 kg
- Allergy to latex
- Patients with a history of allergy to any of the drugs used in anesthesia for PROSM
- Patients with renal dysfunction
- Liver dysfunction
- Severe cardiac dysfunction (cardiac failure).

PROSM guidelines (intervention)

Preoperative preparation: patients from ambulatory that are candidates who agree to participate in the study will be approached by the medical team who will inform all stages of the protocol, the potential benefits of the approach and the risks of surgical treatment. Patients with sedentary habits will be invited to start physical activities with daily walks lasting 15 minutes. Preoperative exams and assessments will be checked and treatment of comorbidities that may not be properly treated by candidates will begin.

Upon admission, the participants will be prescribed preemptive analgesia with 500 mg of dipyron orally for non-allergic candidates. Participants allergic to dipyron will receive 750 mg of paracetamol with equal administration interval.

The eight-hour preoperative fast will be shortened by administering a clear liquid solution containing maltodextrin two hours before the surgical procedure. Before going to surgical room the patients receive auricular acupoint stimulation using mustard seeds in order to reduce anxiety and perioperative distress and minimize the need of postoperative analgesic drugs [3]. Positive patient communication using neuro linguistic programming technique is performed by investigators prior to anesthesia.

Intraoperative care

Anesthesia: Anesthesia is performed through the administration of intravenous drugs with rapid metabolism adjusted according to the patient’s body mass and according to the analysis of the bispectral index (BIS). To induce hypnosis investigators use propofol and to maintain intraoperative analgesia remifentanyl is the drug of choice. In addition to intravenous anesthesia, the surgical team performs an intercostal paravertebral local anesthesia following the spinal erector muscle topography on the operated side using a multi-drug

analgesic solution called PTAS solution, consisting in: 1 mcg/kg of clonidine, 5 mg of ketamine, 7.5 mg of ropivacaine, 10 mg of lidocaine, 10 mg of dexamethasone, 500 mg of hydrocortisone, 20 µl of 8.4% sodium bicarbonate solution and 1000 mg of magnesium sulfate. All drugs are diluted in 500 ml of 0.9% saline solution. We did not use an epidural catheter with patient controlled analgesia (PCA) [4,5].

Awakening from anesthesia

Upon awakening from anesthesia, the participants are seated on the operating table with the help of the medical team and light exercises for raising and lowering the upper limbs and lower limb flexion are initiated in order to increase venous return, accelerate the metabolism of residual anesthetic drugs and give confidence to the patients so that they feel safe in moving [6].

Electrostimulation at acupuncture points

To prevent pain and reduce the need for systemic analgesics and their potential harmful adverse effects, we stimulate acupuncture points by applying an electric field on the skin over the topography corresponding to them. The acupuncture points involved were Huatuojiagi from T2 to T9, Dingchuan and Neiguan at the same side of surgical incision.

For the application of the electric field, we used a transcutaneous electric nerve stimulation (TENS) machine (Ibramed®) in AcuTENS mode in two daily sessions of 30 minutes duration, the first being immediately after the surgical procedure.

The intention of using acupuncture is to obtain immediate pain relief so that the patient collaborates with physiotherapy exercises until the specific pain medication has the desired effect, in addition to helping control of nausea and vomiting [7].

Postoperative prescription

The postoperative prescription contains general voluntary diet, previous home used medications, prophylactic antibiotics in the first 24 hours of the postoperative period, non-opioid analgesics, antiemetics, laxative, gabapentin and opioid analgesic only in case of severe pain (> 6 according to VAS). The medications are preferably administered by mouth.

Daily chest radiographic exams are performed while the participants have chest tubes. Laboratory tests are requested if patient shows any type of abnormality on physical examination or in case of high cardiovascular perioperative risk [8].

Physiotherapy exercises

Upon arrival at the Post-Anesthetic Recovery Unit or inpatient unit, conscious, active and responding to commands, the post-operative exercise program starts [8].

The patient receives physiotherapeutic care as follows: Sitting in a wheelchair, maintaining monitoring of vital signs. Deep breathing exercises and breathing exercises associated with the upper limbs.

The physiotherapist put the patient in orthostatic position training for 4 minutes in order to assess postural hypotension and the participant's ability to sustain his body weight. Interruption criteria are:

- Systolic blood pressure < 90 mmHg or > 200 mmHg;
- Mean arterial pressure < 65 or > 120 mmHg;
- Heart rate > 120 bpm or 30 bpm increase from baseline;
- Angina, syncope or leg cramps;

- Disabling pain in the surgical incision;
- Tachypnea and sensation of dyspnea.

As soon as the medical team evaluates that patients are ready to walk, walking exercises start in the sector forty minutes after surgery. Oxygen saturation is assessed during the test with a portable finger oximeter by investigators. Rest breaks are performed in an armchair as required by the patient. The administration of oxygen in a nasal catheter is marked according to the blood oxygen saturation observed in pulse oximetry.

Arm flexion-extension exercises (patient in orthostatic position with upper limbs supported on the wall) and squat exercises (knee flexion-extension in orthostatic position and upper limbs supported on the wall) are performed as soon as the candidate performs the first walk. Two sets of ten repetitions are performed in each physiotherapy session with rest according to the participant's needs. There are three physiotherapy sessions lasting 45 minutes each session and an interval of 15 minutes from the end to the beginning of the next session.

A family companion is allowed to stay with the patient to receive guidance and assistance if necessary. On the next day after surgery, the patient enters on the institution's conventional physiotherapy program [6,9].

Hospital discharge

During hospital discharge, the participant is instructed to return to the thoracic surgery clinic in 7 days to continue the postoperative follow-up. The participant receives prescription of painkillers for home use and guidance on possible postoperative complications. They also receive guidance on warning signs of potential serious complications so that they can return to the emergency room (fever, dyspnoea, bleeding or chest pain refractory of medication use).

Deadlines

- From 5th September 2017 to 5th September 2023: Recruitment.
- From 6th September 2023 to 3th January 2024: Data analysis.
- From 4th January 2024 to 1st May 2024: Publication of results.

Conclusion

This study will give us information about the real impact of PROSM adoption on thoracic surgical practices. If the positive value of PROSM is confirmed this will allow a new perioperative care possibility to these patients, and some perioperative paradigms will be dissolved.

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