# Implementation of an ERAS program in patients undergoing thoracic surgery at a third-level university hospital. An ambispective cohort study.

(Short title: ERAS implementation in thoracic surgery)

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NCT ID not yet assigned

## METHODS

*Study design and participants*

This study analyzes the implementation of an ERAS program in a thoracic service of a third level hospital *(Hospital Fundación Jiménez Díaz, Madrid, Spain).* To this end, we designed an ambispective cohort study, with a prospective arm of patients undergoing thoracic surgery within an ERAS program versus a retrospective arm of patients before the implementation of the protocol. Our centre's ethics committee approved our study before the start of patient recruitment, January 2018 Ref: EO071-18_FJD. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline for cohort studies[13].

After informed consent, we included patients consecutively since the implementation, except those who refused the inclusion in the study or were under 18 years old. We also asked for informed consent from the patients who were part of the retrospective cohort. For the calculation of the required sample size, we assumed that the ERAS program would result in a 25% reduction in the absolute risk of suffering a surgical complication. Since the surgical complication rate for our patients in 2016 was 40%, a type-I error of 5% and a power of 80% would require 47 patients per arm.

*Procedures*

We recruited 50 patients throughout 2018 and 2019 and compared them with data from the last 50 patients in 2016, the year in which we knew the surgical complication rate. We followed up each patient for 30 days after surgery through hospital and primary care medical records. Demographic and comorbidity data were collected from all patients, from which we calculated Charlson's comorbidity index[14] for all patients.

We designed our centre's ERAS program through different measures during the preoperative, intraoperative and postoperative period. During the preoperative period, the patients and their families received comprehensive multidisciplinary information about the protocol, as well as their daily goals and expected discharge date. Also, a team

specialized in therapy against lung diseases taught patients pulmonary expansion exercises to be carried out until surgery was performed. Smoking cessation and nutritional screening of the patient were also part of this stage.

The patients underwent video-assisted thoracoscopic surgery (VATS), whenever possible, leaving a chest tube at the end of the surgery. All subjects received antibiotic and antithrombotic prophylaxis. Intraoperative management of patients was performed under general anaesthesia combined with regional techniques for pain control, avoiding the use of benzodiazepines and opioids. Those patients in whom thoracic epidural catheter was implemented during surgery continued its use through a patient-controlled analgesia system. Besides, a hot air system warmed the patients during surgery to maintain normothermia. Extubation was performed as soon as possible after the end of the surgery, and we encouraged early removal of the urinary catheter.

From the time of extubation, the patients began oral tolerance and respiratory physiotherapy exercises. Also, the patients were allowed to walk around early. The patients were discharged when they were free of complications, without severe pain, urinary catheter or chest tube.

## Outcomes

The primary outcome was the number of patients with 30-day surgical complications. We defined air leakage, bleeding, infection, and reintervention as surgical complications. Secondary outcome included ERAS adherence, no-surgical complications, mortality, readmission, reintervention rates, pain (defined as any level of pain that prevents early ambulation) and hospital lenght of stay. To evaluate ERAS adherence, we defined seven items: VATS approach, regional analgesia, oral tolerance within 6 hours, urinary catheter removal within 24 hours, ambulation within 24 hours, respiratory physiotherapy within 24 hours and chest tube removal within 48 hours.