European Colon Obstruction Survey (EUCOBS)

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Abstract

The use of Enhancement Recovery After Surgery (ERAS) measures aren´t implemented so much in emergency surgery than in elective surgery. The aim of this paper is exposed an European study to know if ERAS measures in emergency cancer colon obstruction surgery would get better outcomes in these patients.

1. Introduction

Emergency laparotomy has been associated with high morbility rate, long hospital stay and high mortality rate. A Retrospective study performed in USA with 37553 patients including in it, showed a mortality rate of 14 percent after emergency laparotomy [1]. Other study in Danmark with 4920 patients in it, confirmed high mortality rate after emergency laparotomy, with a 19.5 percent [2]. A study designed in United Kingdom identified the importance of emergency laparotomy cares standardisation to reduce high morbimortality rate [3]. Implementation of Enhancement Recovery After Surgery(ERAS) measures have been widely studied in elective surgery since Ljunquist deployed them [4]. ERAS measures scope within elective surgery has dramatically reduced hospital stay by up to 30 percent without readmission increase. Medical postoperative complications have also declined with ERAS measures scope. But, nevertheless, these measures haven´t been used as much in emergency surgery due to mainly, impossiblity of preoperative measures application because their emergency condition and on the other hand, patients´ diversity, different comorbidities and different systemic impacts such as shock, sepsis and Systemic Inflammatory Response Syndrome (SIRS) [1, 5]. Use of ERAS measures in patients suffering from colon obstruction due to neoplasm was associated with a 20-percentage decrease of hospital stay. Postoperative complications decreased a 20 percentage in ERAS group compared with conventional measures in Clavien-Dindo scale type II, III and IV, although, there weren´t significant (p=0.12) [6]. ERAS measures aplication in colon cáncer obstruction has been studied in several studies. There are 3 cohort studies comparing ERAS vs conventional care in Emergency colon obstruction surgery [7. 8, 9]. In all of them, a reduction of hospital stay was demostrated in ERAS group (2 days, 3 days and 3 days, respectively). In the three studies, a postoperative complications decrease rate was shown. Dimitrov et cols [10] study confirmed decrease rate in hospital stay and postoperative complications in ERAS Group in cáncer colon obstruction.

2. Hypotesis

This study has been designed to support the working hypothesis that emergency surgery in a colon obstruction neoplasm is better than stent bridge due to better oncological outcomes.

The primary objective is to analyse the importance of ERAS program implementation in emergency colon obstruction surgery

The secondary objectives are to [1] the analysis of survival at 1-year, overall survival, disease-related survival and disease-free survival [2] evaluate the relationship between stent bridge and colon perforation and [3] evaluate the quality of life. The data

generated from this prospective, multicentre, observational cohort study will help to verify or better understand the suspected benefits of ERAS protocols regarding long-term survival in patients who have undergone colorectal surgery. The data will also help future research studies.

anteriormente sobre este tema.

3. Methods and Analysis

Design

A prospective, multicentre, observational cohort study in patients who meet the inclusion criteria.

Setting

This study will be conducted with different European hospitals promoved by Spanish multimodal rehabilitation group (GERM). All hospital selected received prior standarised the protocol of the study and they have to ask for local committee approbal.

Inclusion criteria

- All adult patients (aged >18 years) with a diagnosis of Malignant obstruction colorectal cancer. Informed consent will be obtained from all subjects who will participate in the study voluntarily.
- ASA I, II and III
- No more than 5 days from symptoms onset.
- Absence of proximal colon severe dilatation (no more than 8 centimeters), severe malnutrition.
- No Inmunocompromised patients
- Patients suffer from segmentary colectomy, with or without anastomosis with o witjhout lateral ileostomy
- Patients suffer from Hartmann procedure.

Exclusion criteria

- Patient refusal.
- Patients under 18 years of age.
- ASA IV
- Stent colocation
- ICU stay more than 2 days
- Peritonitis
- Out of protocol if patient would need total parenteral nutrition (NPT) during postoperative or Clavien-Dindo more or equal than II.

The research project will be monitored closely by a certified external auditor to ensure that study activities are carried out in accordance with the protocol, good clinical practice and applicable regulatory requirements. Local study documents can be selected for a local audit at participating hospitals. Data quality will also be audited.

4. Limitations of the study

The limitations are those inherent to a prospective, non-randomised study, including difficulty in recruiting patients due to potential structural or multidisciplinary team problems and inappropriate number of patients in any of the arms due to a very high or very low level of compliance.

Follow-up

The study is planned to start in March 2025, and for the survival study only patients with a minimum follow-up of 1 years will be considered. However, patients will still be recruited until the end of the 1-year period (March 2025) to allow study of the secondary objectives. The follow-up plan is as follows: tumour markers (used to monitor colorectal neoplasia)-carcinoembryonic antigen determined at [3, 6, 9, 12] and cancer antigen 19.9 determined at [3, 6,9,12,] CT performed at [6, 12] and complete colonoscopy performed at 1-year after surgery

5. Data Collection and Data Management

Data will be collected using an online data collection form via a secure, password-protected platform with predefined data fields at each centre. The variables to be collected are displayed in (Table 1). For the purpose of the study, we will record the following: complications at 60-day follow-up (surgical complications, infectious complications, cardiovascular complications), each rated as mild, moderate or severe and also according to the Clavien-Dindom classification; perioperative mortality (the number and percentage of deaths within 60 days of surgery); hospital stay, defined as the duration from the date of the end of surgery to the date of discharge from the hospital (in days); overall survival (the number and percentage of deaths that occur from the intervention to the end of follow-up); disease-free survival (the number of patients alive and with no cancer recurrence from the intervention period to the end of follow-up); and recurrence of the disease (detected by CT or FCC), from the day of the intervention until the end of follow-up. The data collection platform Castor EDC (https://www. castoredc. com) will be used. This platform complies with all applicable laws and regulations. All identifiable data collected, processed and stored for the purposes of the project will be kept confidential at all times and comply with Good Clinical Practice guidelines for Research and the General Data Protection Regulation (Regulation (EU) 2016/679).

Category	Parameter	Options / Details
Inclusion/Exclusion Criteria	Inclusion Criteria	Yes / No
	Exclusion Criteria	ASA IV; Stent before surgery; UCI stay >48 hours; Peritonitis; Out of protocol (total parenteral in postoperative or Clavien-Dindo ≥ II); Other
	Stent Before Surgery Details	Stent as bridge to elective surgery (BTS): Yes / No; Type of stent: Cover / No Cover
	Complications	Perforation; Stent migration; Stent obstruction; Hemorrhage; Pain; Colonic decompression failure; Reoperation; Death
	Clavien-Dindo (Complications)	[Record Grade]
	Hospital Stay	[Days]
	Time to Elective Surgery	[Days]
Preoperative Variables	Age	≤ 59; 60–79; 70–79; ≥ 80
	Sex	M; F
	BMI	<18.5; 18.5–24.9; 25.0–29.9; 30–40; ≥40
	Smoking	Current smoker; Ex-smoker (<1 year); Non-smoker or ex-smoker (>1 year)
	Diabetes	Yes (Type I, Type II); No
	Atherosclerotic Disease	Yes; No
	Pulmonary Disorder	Asthma; COPD (Chronic Obstructive Pulmonary Disorder); Emphysema; Other
	Charlson Comorbidity Index	0; 1; ≥2
	POSSUM Score	[Score Value]
	Physiologic Score	[Score Value]
	Operative Severity Score	[Score Value]
	Modified Frailty Score	[Score Value]
	ASA	I; II; III
	Hemoglobin	g/dL

Laboratory Parameters	Hematocrit	%
	Iron	µg/dL (as provided: Iron ugr/dl)
	Transferrin	µg/dL
	Glucose	mg/dL
	Urea	mg/dL
	Creatinine	mg/dL
	Sodium (Na)	mEq/L
	Potassium (K)	mEq/L
	C-Reactive Protein	mg/L
	Platelets	10^3/µL
	White Cells	10^3/µL
	Prothrombin	g/dL
	International Normalized Ratio (INR)	—
	Protein	g/dL
	Albumin	g/dL
Colon Cancer Obstruction Management	Emergency Surgery	Yes; No
	Type of Surgery	Primary anastomosis; Primary anastomosis + protective ostomy (if protective: ileostomy or colostomy); Hartmann; Only temporary ostomy
	Postoperative Complications	Surgical site infections; Anastomosis leakage; Ileus and small bowel obstruction; Respiratory failure; Pulmonary embolism; Acute coronary syndrome; Heart failure; Stroke; Acute renal failure; Urinary tract infection; Sepsis; Reoperation; Death
	Clavien-Dindo (Postoperative)	[Record Grade]
	Hospital Stay	[Days]

6. Statistical analysis

Given that the main objective (survival) may be subject to aspects inherent to each centre, irrespective of the intervention, it will be necessary to create comparable groups using the propensity score method (propensity score matching). A descriptive analysis of the data will be carried out. Qualitative variables will be represented by a frequency distribution of the percentages for each category, and quantitative variables will be explored using the Kolmogorov-Smirnov conformity test. The association between factors will be investigated using hypothesis contrast tests, with a comparison of proportions when both variables are qualitative (I2, Fisher's exact test), a comparison of mean when one of them is quantitative (Student's t-test, analysis of variance (ANOVA), and the Mann-Whitney U test or the Kruskall-Wallis test if they do not follow a normal distribution) and a bivariate correlation (Pearson correlation coefficient) when both are quantitative or the Spearman correlation if the conditions for application of the former are not met. For comparisons in related samples when one of them is quantitative, Student's t-test and/or ANOVA will be used (Wilcoxon or Friedman's test if they do not follow a normal distribution). The analysis will be completed using multivariate regression models. A survival analysis will be performed using the Kaplan-Meier method, and the log-rank test will be used for survival comparisons between groups. Effects will be considered to be significant with a p value of less than 0.05.

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