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EUROPEAN COLON OBSTRUCTION SURVEY(EUCOBS)

ESTUDIO EUROPEO SOBRE OBSTRUCCION COLON

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STUDY PROMOTOR

GRUPO ESPAÑOL REHABILITACION MULTIMODAL

HEAD OF THE PROJECT :

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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.

Comentado [A1]:

Comentado [A2R1]:

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.

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

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 1year after surgery

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).

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 (χ^2, 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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INCLUSION CRITERIA

YES

No

EXCLUSION CRITERIA

- ASA IV

- Stent before surgery

- UCI stay more than 48 houres

-Peritonitis

-Out of protocol ; total parenteral in postoperative or Clavien-Dindo more or equal than II

-Other.

*In case of stent before Surgery:

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

Hospital stay in days

Time to the elective surgery in days

INCLUSION CRITERIA YES

VARIABLES.

Preoperative variables table 1

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 less than 1 year
No smoker o ex smoker more than 1 year

Diabetes
Yes
- Type I
- Type II

No

Atheroesclerotic disease
Yes
No

Pulmonary disorder
- Asthma
- COPD(Crhonic Obstruction Pulmonary Disorder)
- Emphysema
- Other…

Charlson comorbidity index(appendix 1)
0

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1
≥2
Possum score(appendix 2)
Physiologic score
Operative severity score

Modified frailty score(appendix 3):

ASA

I
II
III

Table 2 laboratory parameters

Hemoglobin g/dl

Hematocrit %

Iron ugr/dl

Transferrin microgr/dl

Glucose mg/dl

Urea mg/dl

Creatinine mg/dl

Na(sodium) meq/l

K(potassium) meq/l

C Reactive Protein mg/l

Platels 10^3/ul

White cells 10^3/ul

Protrombin g/dl

International normalized ratio**(INR)**

Protein g/dl

Albumin g/d

Table 3. colon cancer obstruction management

Emergency surgery
Yes
No
Type of surgery:
Primary anastomosis
Primary anastomosis + protective ostomy
In case of protective ostomy: ileostomy
Colostomy
Hartmann
Only temporary ostomy

Postoperative complications:
Surgical site infections
Anastomosis leakage
Ileus and small bowell obstruction
Respiratory failure
Pulmonary embolism
Acute coronary syndrome
Heart failure
Stroke
Acute renal failure
Urinary tract infection
Sepsis
Reoperation
Death

Clavien-Dindo (appendix 4)

Hospital stay in days

TABLE 4. ERAS in emergency surgery

Preoperative

Frailty scale
yes
No
Beer criteria

Body temperature control
intraoperative only
Perioperative period
No use

Urinary catheter
Yes
No
Glycemia control under 180

Yes
No

Antibiotics profilaxis(before 60 minutes of surgery)
Yes
No
Electric shavered
Yes
No
Nasogastric tube
Yes
No
Informed consentment
Yes
No
C reactive protein before surgery
Yes
No

Intraoperative

Who surgical checklist
Yes
No
Routine intraoperative monitoring
Invasive
Non invasive
No monitoring
Surgical approach
Minimal invasive
Minimal invasive converted to open

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Open

In case of minimal invasive:

Pressure before 12 mmHg

Yes

No

Rapid secuence induction

Yes

No

Peroperative oxygenation (>50%)

Yes

No

Fluid therapy

Guided by goal

Conventional

Urinary catheter

Yes

No

Nasogastric tube

Yes

No

Normothermia maintenance

Active warm system

Passive system

No maintenance

Perioperative glycemia control(each hour below 180, mainly in obese, diabetes and elderly)

Yes

No

Pain drugs

NAIDS

Lidocaine

Ketamine

Morphine

Other

Pain control

Epidural catheter

Neuromuscular block

Interfascial catheter

Other

Nothing

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Profilaxis

Nauseas and vomiting

Ulcus

Thromboembolic

In case of thromboembolic profilaxis

Drugs

Mechanic system

Abdominal drain

Yes

no

Inmediate postoperative

Active temperature maintance

Yes

No

Oxigen theraphy (>50% during the following 2 hours)

Yes

No

Pain scale(from 1-10)

Opiod drugs

Yes

No

In case of opiod drugs

Dosifying pump

No dosiying pump

Perioperative glycemia control(180 , mainly in obese. Elderly and diabetes)

Yes

No

Early mobilization

Yes

No

Urinary catheter

Removal

No removal

Nasogastric tube

Removal

No removal

Early intake

Yes

No

Profilaxis

Nausea and vomiting
Ulcus
Thromboembolic
In case of thromboembolic profilaxis
Drugs
Mechanic system

Respiratory physiotherapy
Yes
No

Postoperative day 1

Perioperative glycemia control(180 mainly in obese, elderly and diabetes)
Yes
No
Early mobilization
Yes
No
Respiratory physiotherapy
Yes
No
Antibiotic therapy
Yes
No
C reactive protein
Yes
No
In case of C reactive protein value …. mg/l
Pain scale(from 1 to 10)
Opiod drugs
Yes
No
In case of opiod drugs
Dosifying pump
No dosifying pump
Nasogastric tube
Removal
No removal

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Urinary catheter

Removal

No removal

Epidural catheter

Yes

No

Antibiotic therapy

Yes

No

Profilaxis

Nausea and vomiting

Ulcus

Thromboembolic

In case of thromboembolic profilaxis

Drugs

Mechanic system

Postoperative day 2

Perioperative glycemia control(180 , mainly in obese, elderly and diabetes)

Yes

No

Fully ambulated

Yes

No

Respiratory physiotherapy

Yes

No

Intravenous liquid

Removal

No removal

Oral analgesia

Yes

No

Intravenous venous access

Removal

No removal

Profilaxis

Nausea and vomiting

Ulcus

Thromboembolic

In case of thromboembolic profilaxis

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Drugs
Mechanic system

C reactive protein
Yes
No
In case of C reactive protein value…. mg/l
Discharge
Yes
No
Postoperative day 3
Perioperative glycemia control(180 , mainly in obese, elderly and diabetes)
Yes
No
Fully ambulated
Yes
No
Respiratory physiotherapy
Yes
No
Intravenous liquid
Removal
No removal
Oral analgesia
Yes
No
Intravenous venous access
Removal
No removal
Profilaxis
Nausea and vomiting
Ulcus
Thromboembolic
In case of thromboembolic profilaxis
Drugs
Mechanic system

C reactive protein
Yes
No

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In case of C reactive protein value,,, mg/l

Discharge

Yes

No

Postoperative day 4

Perioperative glycemia control(180 , mainly in obese, elderly and diabetes)

Yes

No

Fully ambulated

Yes

No

Respiratory physiotherapy

Yes

No

Intravenous liquid

Removal

No removal

Oral analgesia

Yes

No

Intravenous venous access

Removal

No removal

Profilaxis

Nausea and vomiting

Ulcus

Thromboembolic

In case of thromboembolic profilaxis

Drugs

Mechanic system

C reactive protein

Yes

No

In case of C reactive protein value… mg/l

Discharge

Yes

no

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Postoperative day 5

Perioperative glycemia control(180 , mainly in obese, elderly and diabetes)

Yes

No

Fully ambulated

Yes

No

Respiratory physiotherapy

Yes

No

Intravenous liquid

Removal

No removal

Oral analgesia

Yes

No

Intravenous venous access

Removal

No removal

Profilaxis

Nausea and vomiting

Ulcus

Thromboembolic

In case of thromboembolic profilaxis

Drugs

Mechanic system

C reactive protein

Yes

No

In case of C reactive protein value… mg/l

Discharge

Yes

no

in case of no discharge.

Cause

Postoperative discharge day

Postdischarge control

Follow up control up to 24 hours

Yes

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No

Thromboembolic profilaxis

Yes

No

In case of thromboembolic profilaxis. Days of treatment

Last value of C reactive protein before discharge…. mg/l

Antibiotic treatment

Yes

No

In case of antibiotic treatment days of treatment

Table 5. hystopathological findings after surgery

Tumor caracteristics

Well Differentiated
Moderated differentiated
Undifferentiated

Sample caracteristics

Microperforation
Macroperforation
Lymphovascular invasion
Perineural invasion
Margins free
Number of nodes
K-RAS positive

Tumor staging

T

T1
T2
T3
T4

N(number of nodules)

N1
N2

N3
M
M0
M1
Stadio: T(1-4), N(x/total), M(0 o 1)

Table 6. Chemotherapy

Postoperative treatment
YES
No

Bevacizumab treatment

Table 7 Recurrence data

Time after surgery in months

Locoregional recurrence
Yes
No

Systemic recurrence
Hepatic
Yes
No
Pulmonary
Yes
No

APPENDIX.

Appendix 1. https://www.mdcalc.com/calc/3917/charlson-comorbidity-index-cci

Appendix 2. https://www.mdcalc.com/calc/3927/possum-operative-morbidity-mortality-risk

MODIFIED FRAILTY INDEX	
Patient functional status before surgery partially or totally dependent	Yes No reset
Diabetes mellitus treated with insulin or oral medications	Yes No reset
Hypertension requiring treatment	Yes No reset
Congestive heart failure (CHF)	Yes No reset
Myocardial infarction (MI)	Yes No reset
Prior cardiac surgery or percutaneous coronary angioplasty, or history of angina	Yes No reset

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chronic obstructive pulmonary disease (COPD) or pneumonia	Yes No reset
Rest pain or gangrene secondary to peripheral vascular disease (PVD) or PVD treated with angioplasty, revascularization, amputation	Yes No reset
Impaired sensorium within 48 h prior to the surgical procedure not in the context of concomitant neurologic disease such as dementia	Yes No reset
History of transient ischemic attack (TIA) or cerebrovascular accident (CVA) without neurologic deficits	Yes No reset
CVA with neurologic deficits	Yes No

Appendix4.https://www.google.com/search?rlz=1C1GCEA_enES964ES964&sxsrf=ALiCzsYm7W2pyy5_t0-JNH5DtCoZMggmVw%3A1665591128477&lei=WOdGY7fM

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