

WSES RESEARCH PROPOSAL

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TITLE

The management of complicated colon rectal cancer in older patients in a global perspective: the CO-OLDER study.



ClinicalTrials.gov Identifier: NCT05788224

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<https://forms.gle/8Xhq7VXTSDfMhTe66>

SPECIFIC AIMS

- Assess outcomes in terms of morbidity and mortality correlated to the surgical management of older (=> 75 years old) patients admitted to the emergency department with complicated colorectal cancer;
- Assess the management of frail older patients admitted to the emergency department with complicated colorectal cancer such as the first manifestation, before the COVID-19 outbreak (11th March 2020) and during the Covid pandemic;
- Improving cancer care in geriatric patients;
- Improving the management of frail, older patients in the emergency setting.

BACKGROUND

Colorectal cancer (CRC) is the second leading cause of cancer death.

The incidence of CRC is strongly related to age, with the highest incidence rates being in older people. Nearly 60 % of cases develop over the age of 65; 30% are 75 years or older.

The highest rates are in the 85 to 89 age group for both females and males.

CRC is becoming a disease of the elderly.

The median age at death is 72 years. 45% of the deaths occur in patients of 75 years old or more, and 21% in patients 85 years or more.

Ageing is the most significant risk factor for CRC.

Every country in the world is experiencing growth in both the size and the proportion of older persons in the population.

The number of persons aged 80 years or older is expected to triple between 2020 and 2050 to reach 426 million.

The significant age shift in the incidence of CRC is having an important impact on health care including cancer care, because cancer in patients aged over 75 years, could represent an ethical dilemma for families, general practitioners, surgeons and oncologists.

The screening for CRC is recommended for subjects of 50-year-old or more and is carried out mainly in patients between 60 and 70 years of age. The U.S. Multi-Society Task Force of Colorectal Cancer suggests continuing screening for up to 85 years only if no previous screening has been done and stopping it at 75 years if prior screening tests have been negative. In clinical practice the majority of older (having age over 75 years old) patients, if asymptomatic, are not screened for CRC.

The lack of high-quality data to guide our care for geriatric patients makes their management suboptimal.

In addition to this, delay in diagnosis has increased after the Covid-19 pandemic, due to the re-allocation of resources and disruption of screening programs since March 2020 and a slow resumption of medical and surgical elective activities after the beginning of the vaccination against SARS-Co-V-2 in December 2020.

Most elderly people experienced isolation to avoid Covid infection in healthcare facilities and the difficulty to access care due to long waiting lists.

Accordingly, the number of elderly people presenting with acute abdomen admitted to the emergency department is increasing. Most of them need to be managed surgically on the first presentation of advanced colorectal cancer which can be complicated by obstruction and perforation.

To the best of our knowledge, there are no available studies investigating:

-How this delay is impacting on older people at high risk of presenting CRC only for ageing;

-How to best address and monitor frailty preoperatively in the emergency setting;

-Modifiable risk factors for negative outcomes and mortality after emergency surgery for complicated CRC in older patients;

-Postoperative outcomes of emergency management of this group of patients in terms of morbidity and mortality from a global perspective.

RESEARCH METHOD

• STUDY DESIGN

The CO-OLDER study is an international multicenter observational cohort study, analysing data collected in 2 periods:

1. before the 11th March, 2020 that is before the COVID-19 Pandemic outbreak (retrospective data);

2. After the 11th March 2020, during the COVID-19 Pandemic till 30th September 2023 (retrospective and prospective data) ;

- **SETTING**

Management of complicated colorectal cancer in the emergency setting.

- **STUDY SUBJECTS**

All patients aged 75 years old and over who were admitted to the surgical department with obstruction due to complicated colorectal cancer.

Inclusion criteria

Patients aged 75 years old and over who were admitted to the emergency department presenting with obstruction due to advanced colorectal cancer.

Exclusion criteria

Patients having an age \leq 75 years and those \geq 75 years old presenting with an acute abdomen, not due to complicated colorectal cancer.

- **MAIN OUTCOMES**

Morbidity and mortality of emergency surgical procedures in older patients presenting with obstructed colorectal cancer.

- **SECONDARY OUTCOMES**

Define the risk factors associated with a negative surgical outcome in the emergency setting.

• **STATISTICAL ANALYSIS**

The patients will be divided into two groups: pre-Covid and post-Covid groups.

Qualitative data will be presented as number (%). Quantitative and ordinal data will be presented as median (25-75 interquartile range (IQR)). The qualitative data of the two groups will be done using Pearson Chi-Square. Fisher's exact will be used if the expected value of a cell was < 0.5 . Continuous and ordinal data will be analyzed using Mann Whitney U Test. All tests will be two-sided, and a p-value of 0.05 will be accepted as statistically significant.

To investigate the factors associated with death, a univariate comparison will be done between those who died and those who survived. A logistic regression model will be done including variables which had a loose $p < 0.1$ in the univariate analysis.

• **TIMELINE RESEARCH PROJECT**

The project will be conducted over a 12-months period where data from the period of 1st January 2018 to 30th August 2023 will be collected.

1/3/6 months follow-up will be observed for patients enrolled in the study.

The first statistical analysis will be carried out in October 2023 and data will be published in January 2024.

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