STUDY PROTOCOL

Creation of a rectal cancer registry in Italy by the Advanced International Mini-Invasive Surgery (AIMS) academy clinical research network [version 1; peer review: 3 approved]

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Abstract

Background: The management of rectal cancer is multimodal and involves a multidisciplinary team of cancer specialists with expertise in medical oncology, surgical oncology, radiation oncology and radiology. It is crucial for highly specialized centers to collaborate via networks that aim to maintain uniformity in every aspect of treatment and rigorously gather patients' data, from the first clinical evaluation to the last follow-up visit. The Advanced International Mini-Invasive Surgery (AIMS) academy clinical research network aims to create a rectal cancer registry. This will prospectively collect the data of patients operated on for non-metastatic rectal cancer in high volume colorectal surgical units through a well design pre-fashioned database for non-metastatic rectal cancer, in order to take all multidisciplinary aspects into consideration.
Methods/Design: The protocol describes a multicenter prospective observational cohort study, investigating demographics, frailty, cancer-related features, surgical and radiological parameters, and oncological outcomes among patients with non-metastatic rectal cancer who are candidates for surgery with curative intent. Patients enrolled in the present registry will be followed up for 5 years after surgery.

Open Peer Review

Reviewer Status ✓ ✓ ✓

	Invited Reviewers		
	1	**2**	**3**
version 1 published 10 Oct 2019	✓ report	✓ report	✓ report

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Discussion: Standardization and centralization of data collection for neoplastic diseases is a virtuous process for patient care. The creation of a register will allow the control of the quality of treatments provided and permit prospective and retrospective studies to be carried out on complete and reliable high quality data. Establishing data collection in a prospective and systematic fashion is the only possibility to preserve the enormous resource that each patient represents.

Keywords
Rectal surgery, registry, network

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Any reports and responses or comments on the article can be found at the end of the article.

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Author roles: Mari GM: Conceptualization; **Achilli P**: Writing – Original Draft Preparation; **Maggioni D**: Investigation; **Crippa J**: Writing – Review & Editing; **Costanzi ATM**: Data Curation; **Scotti MA**: Investigation; **Giardini V**: Investigation; **Garancini M**: Investigation; **Cocozza E**: Methodology; **Borroni G**: Methodology; **Benzoni I**: Project Administration; **Martinotti M**: Supervision; **Totaro L**: Project Administration; **Origi M**: Investigation; **Mazzola M**: Investigation; **Ferrari G**: Supervision; **Ziccarelli A**: Investigation; **Petri R**: Investigation; **Bagnardi V**: Data Curation, Formal Analysis, Methodology; **Pugliese G**: Software; **Forgione A**: Methodology; **Pugliese R**: Supervision;

Competing interests: No competing interests were disclosed.

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Introduction

There are nearly 125,000 new cases of rectal cancer diagnosed every year in Europe, representing one of the leading causes of cancer-related morbidity and mortality world-wide[1]. Five decades ago, the prognosis of rectal cancer was poor, with locoregional cancer recurrence rates of up to 40% and 5-year survival rates of <50% for locally-advanced tumors[2]. These disappointing outcomes were improved by innovations in surgical technique, multimodality therapy and education[3].

Total mesorectal excision (TME) remains the cornerstone in the treatment of non-metastatic rectal cancer. To achieve high quality TME, which is the key-factor for proper oncological resection, surgeons must respect well-known embryological planes, which were made famous as the boundaries of Heald's Holy plane[4].

While the surgical principles for rectal cancer have changed little during the last decade, the novelties in the radiological study of the disease, as well as in the administration of neoadjuvant and adjuvant therapy, have largely modified the treatment of this neoplasm[5]. Nowadays, the management of rectal cancer is multimodal and involves a multidisciplinary team of cancer specialists with expertise in medical oncology, surgical oncology, radiation oncology and radiology. Therefore, it is becoming crucial for highly specialized centers to design prefashioned databases for non-metastatic rectal cancer in order to take all multidisciplinary aspects into consideration. Previous attempts to establish rectal cancer registries, such as The Norwegian Rectal Cancer Project[6] and The Spanish Rectal Cancer Project[7], were based on the need to first extend adequate oncological treatment, and second to increase the use of minimally invasive surgery.

The Advanced International Mini-Invasive Surgery (AIMS) academy clinical research network aims to create a rectal cancer registry that will prospectively collect data of patients operated on for non-metastatic rectal cancer in high volume colorectal surgical units, maintaining uniformity in every aspect of the treatment and rigorously gathering patients data, from the first clinical evaluation to the last follow-up visit.

Purpose

The aim of the AIMS academy clinical research network rectal cancer registry is to prospectively collect data from different minimally-invasive colorectal units in Northern Italy, with standardization of the pre-operative, intra-operative and post-operative management for patients operated on for non-metastatic rectal cancer with curative intent.

The primary outcome is to prospectively collect short and long term oncological outcomes. The second outcome is to collect information on the compliance of patients to oncological treatments, both in neoadjuvant and adjuvant settings and their quality of life.

Protocol

Study design

This protocol describes a multicenter prospective observational cohort study, investigating demographics, cancer-related features and oncological outcomes among patients who are non-metastatic rectal cancer candidates for surgery with curative intent. Patients enrolled in the present registry will be followed up for 5 years after surgery. All participating centres are public tertiary non-academic hospitals of northern Italy.

The study was approved by the Comitato Etico Scientifico Milano Area 3 (protocol number 295-052019). The study protocol has been registered as an observational study at ClinicalTrials.gov: NCT04045236 (first received, 3 August 2019). All participating centres received approval from local ethics committees.

Patients and eligibility criteria

Patients receiving the diagnosis of non-metastatic rectal cancer and the indication for a curative treatment will be enrolled in the registry. The target population will consist of all patients enrolled in the participating centers from the start of the rectal cancer registry on. Patients will be identified through their medical record numbers. One investigator in each center will obtain written informed consent from each patient and keep the patients updated on data collection.

Inclusion criteria: 1) histologically proved adenocarcinoma of the rectum; 2) patient aged > 18 years old; 3) indication for surgical resection with curative intent.

Exclusion criteria: need for emergency surgery, palliative operation or metastatic disease at presentation.

Data collection

Demographic information and anamnesis with a focus on oncologic history will be recorded at the first outpatient visit, together with a complete clinical examination. Data regarding the symptoms of presentation will be collected and categorized as haemorrhagic framework, alteration of bowel habits or pain. Every patient will undergo a pre-operative staging (see Extended data: CRF1) with chest-abdominal computerized tomography scan with intravenous contrast, complete colonoscopy, pelvic magnetic resonance (MR) imaging and endorectal ultra sound (EUS) examination. Blood sample with serum level of CEA, CA 19.9 and a full nutritional panel will be collected and analysed. Charlson Comorbidities Index adjusted for age[8] will be calculated for every patient, while those >70 years old will be assessed for frailty risk using the modified Frailty Index (mFI) described by Robinson *et al.*[9] (see Extended data: CRF1).

All data regarding radiation doses received, total amount of chemotherapy administered and number of cycles, toxicities or adverse reaction and possible reasons for not completed treatment

schedule will be collected for all the patients with locally advance rectal cancer, who received neo adjuvant chemo-radiotherapy. Radiological restaging after neoadjuvant treatment comprises MR imaging, EUS and colonoscopy. Radiological response to neoadjuvant treatment will be measured following a uniform score system among all centers involved[10]. Endoscopic assessment of tumour regression will be also recorded[11] (see *Extended data:* CRF2).

Intraoperative analysed parameters will be included in the registry (see Extended data: CRF3), with special attention to technical aspects of surgical procedures, such as level of inferior mesenteric artery ligation, type of energy device used, number and type of cartridge, and size of circular stapler and all other variables detailed in the Clinical Trials registration.

Histopathological examination will be performed according to WHO 2010 guidelines[12]. Macroscopic evaluation of the resected specimen will be classified according to the Quirke score[13], while pathologic regression grade will be estimated according to a five-point scoring system[14]. Mismatch repair status will be reported when analysed (see *Extended data:* CRF3).

Post-operative complications will be reported according to the Clavien-Dindo scale[15]. Length of stay and eventual post-discharge complications will be evaluated and recorded. Application of an ERAS protocol will be considered only for at least 80% of ERAS colorectal items satisfied (see *Extended data:* CRF4)[16].

Indication to adjuvant treatment will be defined within a multidisciplinary setting. Regarding adjuvant chemotherapy, all data of interest such as number of cycles, toxicities and possible early interruption of the treatment will be collected as previously shown in the neoadjuvant setting. Oncological follow-up will be performed according to National Comprehensive Cancer Network guidelines[17]. One investigator in each center will carry out the follow up. Functional follow up will be done yearly according to the Low Anterior Resection Syndrome Score (see *Extended data:* CRF5)[18].

Data management

Data will be collected daily using a pre-fashioned REDCAP database by one physician for each hospital and referred to a research fellow (GMM) who will monitor the included data for all institutions. Pre-fashioned CRFs are available as *Extended data*. There will be regular contact between the study coordinators and the participating centers through scheduled meetings every three months. A data manager (GP) will regularly control the quality of the data provided.

Dissemination of the registry

All researchers will be able to access the data uploaded. Data will be hosted by the AIMS Academy. All researchers will be able to use collected data to write scientific articles or to plan surgical audits.

Study status

The registry has been enrolling patients since January 2019.

Discussion

The primary aim of this registry is to prospectively collect data from different minimally invasive colorectal units in Northern Italy with a standardization of the pre-operative, intra-operative and post-operative management for patients operated on for non-metastatic rectal cancer with curative intent.

Standardization and centralization of data collection for neoplastic diseases is a virtuous process for patient care. The creation of a register allows the control of the quality of treatments provided and permits prospective and retrospective studies to be carried out on complete and reliable high quality data.

In the last few years, the need to raise the quality of care for rectal cancer patients has been reported in numerous studies[19], as well as the clear association between hospital volumes and outcomes after rectal surgery[20]. Speaking a common language in such a complex field is no longer a benefit but rather the only way to face new challenges waiting for us in the near future.

Due to the aging population, the number of frail patients affected by rectal cancer is expected to grow[21]. As a consequence, the identification of frail patients and the need to search for tailored management able to prevent adverse complications and to improve clinical outcomes of this population will play a fundamental role in oncological surgery in the years to come[22]. Thus, all methods available to screen a patient for frailty, such as the Mini Cog test, the Katz Index of Independence in Activities of Daily Living (ADL), and the Timed Up and Go (TUG) test must become an integrated part of daily clinical work[23,24].

The accuracy achieved by pre-operative MR imaging during the last decade[25] has lead to important results in both preoperative staging and radiologic response evaluation after neo-adjuvant therapy[26]. Indeed, radiologic restaging is increasingly involved in the therapeutic decision-making process[27]. Thus, structuring a synoptic and uniform MR report must become a prerogative in management of rectal cancer patients.

As mentioned in the study protocol section, intra-operative data concerning which type of devices or staplers used during surgery will be recorded in the registry, allowing us to look for possible correlations with clinical outcomes. A well-structured prospective analysis among high volume units will help to define the real complication rate after rectal cancer surgery, which has been usually derived retrospectively and therefore potentially underestimated[28].

Regarding surgical expertise among the centers involved, continuous monitoring of the integrity of the resected specimens should definitely increase the overall quality of surgery.

Detailed analysis of the compliance to adjuvant chemotherapy for locally advanced rectal cancer is extremely important considering recent data reported in the literature[29,30]. The unexpected low level of compliance reported in these previous case series has questioned the traditional administration of

adjuvant chemotherapy, searching for new strategies for locally advanced rectal tumours, such as total neoadjuvant chemotherapy[3].

Conclusions

The creation of a registry for patients operated on for non-metastatic rectal cancer is a necessary requirement. Establishing data collection in a prospective and systematic fashion is the only possibility to preserve the enormous resource that each patient represents.

Data availability

Underlying data

No underlying data is associated with this article.

Extended data

Zenodo: Rectal cancer AIMS Academy clinical research network registry, http://doi.org/10.5281/zenodo.3463627[31]

This project contains the following extended data:

- CRF1: Patient's information and cancer staging form.
- CRF2: Neo-adjuvant chemoradiotheraphy and cancer restaging form.
- CRF3: Surgery, surgical outcomes and pathological examination form.
- CRF4: Adjuvant chemotherapy form.
- CRF5: Oncological follow-up form.

Acknowledgements

AIMS Academy: www.aimsacademy.org

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http://www.doi.org/10.5281/zenodo.3463627

Open Peer Review

Current Peer Review Status: ✔ ✔ ✔

Version 1

Reviewer Report 14 November 2019

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✔ **Fabian Grass**
[1] Department of Colon and Rectal Surgery, Mayo Clinic, Rochester, MN, USA
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The Northern Italian research group presents a study protocol detailing specifics of a rectal cancer registry, which consists of a multicentric collaboration aiming to gather reliable, prospectively collected data for rectal cancer research. The authors need to be congratulated for their initiative. Multi-institutional collaborations are needed in the rapidly evolving field of multi-modal treatment of locally advanced rectal cancer. The authors emphasise new challenges of an ageing, frail population. Radiotherapy- or surgery-sparing strategies may represent interesting alternatives to conventional treatment schemes.

Overall the protocol is clear and concise. I would like to suggest expanding on the following points:

- Multi-institutional collaborations are challenging, since dealing with a heterogeous patient- and provider population, surgical and perioperative care. How do the authors account for that?
- Standardization: Do all centers use similar treatment protocols? How standardized is the surgical approach? Do all centers perform robotic proctoectomy? How experienced are participating surgeons? Are all participating centers teaching facilities?
- I think the authors may expand on complication assessment. Who is assessing complications, are these institution-specific abstractors or do centers dispose of surveillance tools, i.e. for surgical site infections?
- How do the authors ascertain data quality? National data registries ideally need (independent) audit and validation. Who is auditing data accuracy?

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Colorectal surgery, minimally-invasive surgery

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 05 November 2019

https://doi.org/10.5256/f1000research.22769.r55011

Abe Fingerhut
Section for Surgical Research, Department of Surgery, Medical University of Graz, Graz, Austria

This registry is unique and essential to reseach in Italy.
The Advanced International Mini-Invasive Surgery (AIMS) academy clinical research network has a major role in this multicenter prospective observational cohort study, I agree that standardization and centralization of data collection for neoplastic diseases is essential for patient care. The creation of a register will allow the control of the quality of treatments provided and permit prospective and retrospective studies to be carried out on complete and reliable high quality data.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Surgery and clinical research

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 17 October 2019

https://doi.org/10.5256/f1000research.22769.r55012

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This paper describes the creation of a national registry for non metastatic rectal cancer. The main issue is a high quality standardization of rectal cancer multimodal treatment, staging and follow up.
I think that the core of the project is well explained and clarified. Additional materials are clear and quite user friendly.
The methods are well described and expanded enough.
The need for well designed databases on rectal cancer is clearly expressed by the literature.
I believe that this registry represents a high quality attempt in the direction of a centralized and appropriate treatment for rectal cancer.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Colorectal surgery

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.