ROLADI

RObotic vs **LA**paroscopic colectomy for **Di**verticulitis.

A multicenter observational prospective study

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Principal Investigator	**Giuliani Giuseppe** • Department of general and emergency surgery- Scuola di Chirurgia Robotica. Via Senese, 161 - 58100 Grosseto (GR) - Italy. Mob: +393407356132 Mail: giu.giuliani86@gmail.com
Coordinator Center	**Department of general and emergency surgery - Scuola di Chirurgia Robotica** • **Direttore: Coratti Andrea, MD** Ospedale Misericordia, Via Senese, 161 - 58100 Grosseto (GR).
Co-investigator	**Guerra Francesco, MD** • Department of general and emergency surgery- Scuola di Chirurgia Robotica. Via Senese, 161 - 58100 Grosseto (GR) - Italy. **Sofia Esposito, MD** • Department of General, Emergency Surgery and New Technologies, Baggiovara General Hospital, AOU Modena, Italy
Biostatician	• **Daniela Nuvolone** Agenzia regionale di sanità della Toscana Osservatorio di epidemiologia

Background

Over the past decade, there has been a growing interest in the use of robotic surgery for diverticular disease (DD). The evidence available in the literature is based on retrospective studies and two meta-analyses. To date, the robotic approach offers significant advantages over laparoscopic surgery in terms of conversion rate and shortened hospital stay for the treatment of diverticular disease.

We aimed to evaluate whether elective robotic colectomy may offer some advantages over the laparoscopic approach for surgical treatment of diverticular disease performing a prospective multicenter study.

Methods and Materials

This is a multicenter, prospective, nonprofit study that will include patients undergoing elective surgical treatment for left-sided colonic diverticular disease. The study will have a duration of one year and will start in May 2023.

Inclusion criteria are:

- Age > 18 years
- Elective or delayed urgency colorectal resection for left-sided DD
- Fully minimally invasive (robotic or laparoscopic) procedures.

Exclusion criteria are:

- Age < 18 years
- Urgent resection for DD
- Hybrid minimally invasive resection
- Conventional open resection.

The primary objective is to evaluate whether the robotic approach reduces the rate of conversion to open surgery compared to laparoscopic surgery. Secondary objectives are to assess the difference between the two approaches in terms of rate of intraoperative and postoperative complications (according to Clavien and Dindo classification), hospital stay and disease recurrence.

Data collection:

Data will be collected in a prospective database using an easy to fill out Google form, also available on mobile devices (https://docs.google.com/forms/d/1IVQj_A0LhZWLPPWhWP9CTJGOQ_w4K0FdPcxK-pRsqsI/edit).

Participating centers should report the number of patients treated conservatively for diverticular disease for the entire duration of the study. In addition, the experience in colorectal surgery of the surgeons participating in the study should be reported at the time of enrollment.

OUTCOMES

Pre-Operative

- Demographic Outcomes: Age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA), Charlson Comorbidity Index (CSI: https://www.mdcalc.com/calc/3917/charlson-comorbidity-index-cci)
- Indications for surgery:
    - Complicated DD: colonic stenosis, abscess, fistula, others;
    - Recurrent DD: multiple episodes of diverticulitis affecting quality of life;
- Planned vascular ligation (inferior mesenteric artery vs. sigmoid arteries)
- Preoperative bowel preparation
- Indication for minimally invasive approach pursued (Why Rob vs Lap)

Intraoperative

- Surgical approach (laparoscopic or robotic)
- Intraoperative findings (sigmoid stenosis, stricture, adhesion, fistula)
- Intraoperative complications (specify types)
- Conversion to open approach
- Effective vessel ligation
- Splenic flexure mobilization
- Type of colon resection (sigmoidectomy, left colectomy, anterior rectal resection, Hartmann procedure)
- Stoma (ileostomy vs. colostomy)
- Associated procedures
- Specimen extraction (midline, off midline, suprapubic or natural orifice)

Postoperative

- 30-day postoperative complications (Clavien-Dindo classification)
- 30-day reoperation
- 30-day readmission
- Length of stay LOS
- Time to return to work (days)
- 30 days - Mortality
- One-year follow-up

Sample size

The estimated sample sizes for the study using a p1=0.125 (Laparoscopic approach) e p2=0.074 (robotic approach) with a risk of conversion OR=0.56 (IC95% 0.45-0.70), is at least 1450 patients (725 for the group - alpha = 0.0500, power = 0.9000, delta = 0.5600). This number would allow the proposed statistical tests to have a power of of 99% and a significance level between 5% and 1%. MICE (Multivariate Imputation via Chained Equations) is the procedure used to impute missing data for explanatory variables. In this approach, instead of imputing all missing values with a single value (mean/median), the statistical information is derived from the median), it takes into account the statistical information derived from the distribution of the other variables. The missing values are considered as an outcome to be predicted. This allows to take into account the correct variability in the entire data set and to obtain estimates that are as unbiased as possible.

Statistical Analysis

The quantitative variables included in the study are expressed as mean ± standard deviation, median and deviation, median and range (distance between maximum and minimum values), both at the overall level and level and by surgical approach.

The qualitative (categorical) variables are presented as as percentages and absolute values, both at a general level and divided by surgical approach. It will be evaluated, if necessary, to perform a case matching procedure between the two approaches (Rob and Lap), using the nearest neighbor matching technique, if confounding variables may be significantly different in the two groups. The comparison between the quantitative variables of interest is performed by the two-tailed Student T-test (in case of heteroskedasticity of variances) or with nonparametric tests, such as the Mann-Whitney U test or the Kruskal-Wallis test. The comparison between qualitative variables of interest is carried out to evaluate the association or not between them, through an extension of the chi-square test suitable for multicenter studies (the Cochran - Mantel - Haenszel test). The respective odds ratios associated with the potential associations between variables are calculated along with the overall significance.

Ethics and dissemination

The trial will be conducted in accordance with the Declaration of Helsinki and in compliance with the Good Clinical Practice, Principle E6 (R2). The study will be approved by the Ethics Committee of the coordinating center (Comitato Etico di Area Vasta Sud Est Dipartimento Politiche del Farmaco e Attività Farmaceutiche Segreteria Amministrativa) and then will be registered at ClinicalTrial.gov. Subsequently, all participating centers will receive approval to participate from the local institutional review board. Authorship for written publications will be confirmed for all participating investigators (2

investigators per center). Anonymized participant-level data sets will be made available upon reasonable upon reasonable request by contacting the principal investigator. Study results will be presented at international or national meetings and published in surgical journals.

References

1. Giuliani G, Guerra F, Coletta D, Giuliani A, Salvischiani L, Tribuzi A, Caravaglios G, Genovese A, Coratti A. Robotic versus conventional laparoscopic technique for the treatment of left-sided colonic diverticular disease: a systematic review with meta-analysis. Int J Colorectal Dis. 2022 Jan;37(1):101-109. doi: 10.1007/s00384-021-04038-x. Epub 2021 Oct 1. Erratum in: Int J Colorectal Dis. 2021 Oct 23;: PMID: 34599362.
2. Larkins K, Mohan H, Apte SS, Chen V, Rajkomar A, Larach JT, Smart P, Heriot A, Warrier S. A systematic review and meta-analysis of robotic resections for diverticular disease. Colorectal Dis. 2022 Oct;24(10):1105-1116. doi: 10.1111/codi.16227. Epub 2022 Aug 9. PMID: 35723895.