

Gastrointestinal Outcomes Following Segmental Colorectal Resection for Treating Deep Infiltrating Endometriosis: A Retrospective Study

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Abstract

Introduction: Often, symptoms of bowel endometriosis are mistaken, with incorrect diagnoses such as irritable bowel syndrome being made, with endometriosis going untreated for many years. Surgical treatment involves the resection of endometriosis lesions. A low anterior resection can leave patients with a broad spectrum of symptoms, leading to erratic bowel habits that reduce their quality of life. This protocol aims to assess whether colorectal segmental resection for deep infiltrating bowel endometriosis improves gastrointestinal functional outcomes for women undergoing surgery for pelvic endometriosis.

Methods and Analysis: A multicentre retrospective study from 2011 to 2021 will be conducted. It will include women who underwent pelvic surgery for endometriosis requiring colonic or rectal resection. Operative and post-operative patient data will be obtained. The Clavien Dindo grading of surgical complications between all patients will be assessed. The low anterior resection syndrome score data will be summarised using their median, range, and percentage of total and compared using the Mann-Whitney U-test.

Ethics and dissemination: The study will be conducted in compliance with the conditions of ethics committee approval. Results are intended to be published in peer-reviewed scientific journals and, where appropriate, presented at national and international surgical meetings.

Registration details: Ethics approval reference number: 2022/ETH00809 (PID00910)

Keywords: Colorectal resection; Endometriosis; Gastrointestinal outcome

Strengths and Limitations

- A multicentre retrospective cohort study of previously collected data from 2011-2021 of patients undergoing laparoscopic or open surgery for deep infiltrating endometriosis and having a subsequent segmental colorectal resection is quicker, cheaper, and more accessible than prospective cohort studies.
- The sample size is limited to the number of participants that meet the inclusion criteria.
- Due to this study's retrospective and multicentre nature, it will be prone to recall or misclassification bias.

Background

Endometriosis is a heterogeneous disease that has extensive variation in anatomical and clinical presentations, and it affects up to 15% of women in their reproductive years. Deep endometriosis can affect surrounding pelvic structures, including the bowel and rectosigmoid [1]. Rates of bowel endometriosis vary, with reports ranging from 3 to 37%. Of the bowel involved, the rectum, or rectosigmoid junction, will be affected in up to 90% of cases [2]. The main reason for operative management of endometriosis is pain (ref); often, symptoms of bowel endometriosis are mistaken, with incorrect diagnoses such as IBS being made, with endometriosis going untreated for many years. These symptoms include pelvic pain, constipation, diarrhea, tenesmus, cramping, and bloating. Endoscopic evaluation is typically standard. Colorectal involvement occurs at the time of laparoscopic surgery. However, there are no widely accepted guidelines to direct the workup or intra-operative colonic management (shaving, disc resection, segmental resection with anastomosis), and it is often surgeon-dependent with a gross assessment of nodules on laparoscope and assisted by pre-operative ultrasound scans with varying accuracy [3]. Young and otherwise fit females are sometimes subject to the morbidity of colonic resections, which, when undertaken, increase the likelihood of complications, prolong the operation, and may not lead to better functional outcomes. Leaks occur in up to 8% of patients who undergo an anterior resection, depending on the study and cohort [4,5]. Conflicting data exists regarding leak rates of resections undertaken for endometriosis, although there is a relative lack of data surrounding this, possibly because of the difficulty in standardizing surgical techniques for this disease [6,7]. Although studies have investigated the functional outcomes of disc resection [8,9], A low anterior resection can leave patients with a broad spectrum of symptoms leading to erratic bowel habits that reduce their quality of life [10,11]. These symptoms may not be any better than the symptoms of bowel endometriosis. These symptoms

are likely less prevalent with more conservative measures, such as shaving of endometrial deposits or a disc resection [8]. Unfortunately, complete excision of pelvic disease may not be possible. In a systematic review of women who underwent bowel resection for colorectal endometriosis, six studies reported up to 20% of specimens had margins positive for endometriosis [7]. The rates of recurrence of endometriosis should, therefore, also be considered in the decision-making process, as this leads to a recurrence in their pre-operative symptoms. Current literature suggests this is up to 50% in 5 years for some patients [12,13].

Data on patients' gastrointestinal functional outcomes following segmental resection is limited and conflicts with low-volume quality studies. This study will assess whether colorectal segmental resection for deep infiltrating bowel endometriosis improved gastrointestinal functional outcomes for women undergoing surgery for pelvic endometriosis. It will identify overall rates of complications among patients undergoing colonic or rectal resection.

Methods and Analysis

Study Objectives

Primary Outcome Measures: The primary outcome of this study is to assess whether segmental colorectal resection leads to improvement in gastrointestinal function. This will be measured by the patient's gastrointestinal symptoms, using the low anterior resection syndrome questionnaire, which was recorded by the physician at follow-up.

Secondary Outcome Measures: The secondary outcome is to identify overall complication rates, compare the literature for colorectal resections, and review if resection led to improvements in pelvic pain. Rates of complications will be measured by including morbidity as determined by the Clavien Dindo grading system, length of hospital stay, unplanned readmission rates, unplanned return to the intensive care unit, and non-surgical complications (such as a urinary tract infection). In addition, the same data will be used to compare the different types of colorectal resections and see if superiority between the resections exists. Lastly, patient notes will be hand-searched to identify pre and post-surgical pain scores.

Study Design

A multicentre retrospective cohort study of previously collected data from 2011-2021 of patients undergoing laparoscopic or open surgery for deep infiltrating endometriosis and having a subsequent segmental colorectal resection in co-located hospitals within urban New South Wales, Australia. All study sites perform the same procedure and with the same surgeons. Patients with deep infiltrating bowel endometriosis who have undergone segmental

colorectal resection will be retrospectively identified from a database. Patients not undergoing resection will be excluded from the study.

Inclusion Criteria

Women who underwent pelvic surgery for endometriosis requiring colonic or rectal resection in the 10-year study period. Both laparoscopic and open resections will be included.

Exclusion Criteria

Those patients who either had no bowel involvement, diseased shave from their colon or rectum, or were undergoing disc resection will be excluded from the study.

Statistical Methods

Categorical variables will be presented as counts and percentages and analyzed using Fisher's exact or Chi-square tests. Continuous variables will be expressed as the mean and standard deviation for normally distributed data and analyzed using T-tests. The Low Anterior Resection Syndrome (LARS) score data will be summarised using their median, range, and percentage of total and compared using the Mann-Whitney U-test.

Data Management

Data Collection

Over the past 10 years, data has been collected through surgeon consultation notes, pre-and post-operative follow-up appointments, and in-hospital assessments. This information has been transcribed into an electronic database.

Existing data in the database will be collected from various sources, such as electronic medical records via Powerchart, corresponding letters, and pathology systems. The database contains the following information;

- 1) Patient characteristics include age, sex, smoking status, the American Society of Anesthesiologist grade of the patient, comorbidities, operative details, use of adjuvant therapy, and type and stage of disease.
- 2) Post-operative data includes length of stay, unplanned return to theatre, unplanned intensive care unit admission, unplanned re-intubation, and unplanned readmission to the hospital.
- 3) Specific surgical complications recorded include anastomotic leak, haemorrhage, intra-abdominal abscess, and wound infection.
- 4) Non-surgical complications include respiratory, cardiac, and thromboembolic.

Data Storage

Data is routinely collected on all patients who undergo endometriosis surgery by the surgeons at our institution. Patients sign consent to allow this information to be stored and used for clinical research in a de-identified way. The data in the database is controlled by a single researcher and is stored securely in a password-protected manner. Identifiable data is only stored using a code; therefore, patient data is anonymous. The data resides on a password-protected computer within a locked room within the surgical department offices, which require key card swipe access. Privacy will be maintained by ensuring only the principal investigators can access this. All data sheets and databases will be retained for at least five years post-study completion and then appropriately destroyed.

Ethics and Dissemination

The study will comply with all protocol stipulations, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007), and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95). Ethics approval has been granted by the Research Ethics Governance Information System (REGIS), REGIS reference number 2022/ETH00809 (PID00910). Results are intended to be published in peer-reviewed scientific journals and, where appropriate, presented at national and international surgical meetings.

Discussion and Limitations

This study can guide future studies by generating hypotheses to be studied further by more extensive, more expensive prospective studies. The results from this study will be presented to the scientific and clinical communities. We would expect results from the study to be presented at national and international levels and to be published in a scientific journal with open access. We intend that results will be used to inform consensus guidelines on optimum treatment pathways following Gastrointestinal outcomes following segmental colorectal resection for treating deep infiltrating endometriosis. We acknowledge that there is a risk of selection bias.

Patients and Public Involvement

Since all data will be retrieved from medical records and anaesthesia charts without any impact on future treatment for the involved patients, we did not involve patients or the public in designing this study or writing the protocol.

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