

**The Effects of temporary ileostomy on outcome in
patients with rectal cancer, A prospective
Comparative Cohort Study protocol**

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Background

Colorectal cancer(CRC) represents the most common type of gastrointestinal cancer [1]. It is the third most commonly diagnosed cancer in males and the second in females according to the World Health Organization (WHO), with various rates of incidence around the world [2]. CRC is a multifactorial disease process that includes genetic factors, environmental exposures, and inflammatory diseases [3]. There is an improvement in outcome and death rates have declined progressively which can be attributed to early detection and removal of CRCs in earlier stages and effective adjuvant therapy [4]. Surgery is considered currently the definitive treatment modality for rectal cancer, and surgical intervention is performed either by local or radical excision depending on the clinical stage, size, and location of the primary tumor [5].

There are many techniques to be used including local excision, low anterior resection(LAR), abdominoperineal resection, and multi-visceral resection [6]. LAR represents a sphincter-sparing resection and is performed in patients who meet all the following criteria: invasive rectal cancer, the ability to perform negative distal margin, and an adequate anorectal sphincter function before surgery [7]. Numerous postoperative complications can significantly lead to morbidities, prolonged hospitalization, and even mortality, and management of these complications can be beneficial for survival rate and improvement of quality of life [7]

Anastomotic leakage(AL) represents a frequent complication after LAR in patients with rectal cancer and is responsible for significant morbidity and mortality. The incidence of AL varies from 3 to 21% with a high rate of mortality despite improvements in

surgical techniques [8]. In addition, AL is associated with worsened functional outcomes, reduced quality of life, and increased financial burden. Risk factors for AL include more distal anastomoses, neoadjuvant pelvic radiation therapy, male gender, prolonged operative time, advanced stage of tumor, and multiple firings of linear stapler across rectal stump [9]. The role of a protective stoma has been debated. Therefore, the aims of our study were: 1- to evaluate the effect of temporary ileostomy on the occurrence of AL, 2-to compare complications between patients according to the presence of protective ileostomy.

Methodology

Patients

This is a prospective comparative study of a group of patients with a diagnosis of colorectal cancer of both sexes and all ages that required low anterior resection(LAR) attending the Department of General Surgery at Tishreen University Hospital in Lattakia-Syria during the two years (May 2021- May 2023). The exclusion criteria are patients who undergo abdominoperineal resection with permanent ileostomy. The following workup included: a history and physical examination.

Preparation of the bowel is performed before surgery with the administration of intravenous perioperative antibiotic prophylaxis. The surgical procedure is performed by laparotomy, with resection of the rectum and mesorectum (TME) up to the level of the pelvic diaphragm, sparing the autonomic nerves. End-to-end anastomosis is performed either with a stapler or by hand-sewn. Patients are assigned to group I (19 patients) who will undergo temporary ileostomy, and group II (28 patients) who will not undergo ileostomy. Patients are followed up at regular intervals and outcomes were compared between two groups.

Data collection

the following data will be collected through clinical examinations, patient interviews, and medical records including : Demographic data including : Age as Continuous variable measured in years, Sex as Categorical variable (Male/Female), Tumor Stage as Categorical variable representing the clinical stage of colorectal cancer, Radiotherapy as Binary variable indicating whether the patient received radiotherapy before surgery. The Surgical Characteristics are : the Type of Anastomoses as

Categorical variable (Hand-sewn/Stapled), and Protective Ileostomy as Binary variable indicating the presence or absence of a temporary ileostomy. The Outcomes which will be measured are : the Duration of Surgery as Continuous variable measured in hours, the Anastomosis Leakage as Binary variable indicating the presence or absence of leakage, the Surgical Site Infection as Binary variable indicating the presence or absence of infection, and the Local Recurrence as Binary variable indicating the presence or absence of local recurrence.

Patients will be followed for 30 days after surgery to assess short-term outcomes. Assessments will be conducted at regular intervals to monitor the occurrence of outcomes.

Ethical Considerations

Written informed consent will be obtained from the patient for publication and any accompanying images. A copy of the written consent is available for review on request. Ethical approval for this study (Ethical Committee 2021-GS-104) was provided by the Ethical Committee of Tishreen University Hospitals, Latakia, Syria on 10 October 2021. In addition, the investigators ensure that the study conforms to the principles of the Declaration of Helsinki (last revised in 2013) and is conducted in accordance with the ICH Guideline for Good Clinical Practice.

Statistical Analysis Plan

Statistical analysis was performed by using the IBM SPSS version. Basic Descriptive statistics included means, standard deviations(SD), median, Frequency, and percentages. To examine the relationships and comparisons between the two groups, the chi-square test was used. Independent t student tests were used to compare 2 independent groups. All the tests were considered significant at a 5% type I error rate($p<0.05$), $\beta:20\%$, and power of the study:80%.

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