

Management of Complete Response After Chemoradiation in Rectal Cancer

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KEYWORDS

- Rectal cancer • Complete clinical response • Non-operative management
- Neoadjuvant therapy

KEY POINTS

- Among rectal cancer patients treated with neoadjuvant chemoradiation, 15% to 30% achieve a pathologic complete response (pCR).
- Smaller and less advanced tumors are more likely to have a pCR than larger and more advanced tumors.
- A complete clinical response is denoted by involution of the tumor to a flat and pale scar, and can take 10 to 12 weeks to be achieved.
- Studies to date indicate that local recurrence after nonoperative management occur within 12 to 18 months of treatment and can be salvaged with surgery.
- Studies need to be completed to determine ideal patient selection, treatment sequencing, optimal assessment of response, and long-term surveillance strategies.

INTRODUCTION

When a pathology report returns stating that there is “no residual tumor” in a patient treated with neoadjuvant therapy and rectal resection, a clinician is confronted with two conflicting emotions. The dominant feeling is one of delight, because a complete response to chemoradiation is associated with excellent clinical prognosis: a reported 5-year survival rate of 85% to 90%.¹ There is also a troubling sense of frustration, however, and even regret. Did the major resection add anything valuable other than providing histologic proof of a complete response? Was the risk of complication—including alterations in bowel function and detriment in quality of life associated

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with surgery—justified? The question has largely been hypothetical, because it has been nearly impossible to detect a complete response by any means other than resection. There is growing evidence, however, that a more selective approach to surgery after chemoradiation may be rational. Although once limited to those patients too infirm to tolerate operation, several studies have now described organ-sparing treatment, or rectal preservation, in patients with significant tumor response to chemoradiation. These include reports of completely nonoperative approaches and minimal surgical approaches, such as local excision of the primary tumor site. This review investigates the concept of the nonoperative approach, also known as organ preservation, deferred surgery, or watch and wait, to rectal cancer patients treated for cure who have had a significant response to neoadjuvant therapy.

DEFINING COMPLETE RESPONSE

A pCR is defined as absence of viable tumor on histologic examination of a total mesorectal excision (TME) resection specimen, and is denoted as ypT0N0. A clinical complete response (cCR) is less clearly defined and usually describes absence of tumor, as based on a combination of digital rectal examination and endoscopy.² Thus, there is significant subjectivity and even potential bias in determining a cCR.

To further complicate matters, pCR is influenced by the interval between chemoradiation and surgery. If surgery is performed close to the time of radiation, tumor cells may be identified on histology but may not be viable. Furthermore, with current technology, it is impossible to histologically evaluate more than a small fraction of tissue after resection. Arguably, the best definition of a true complete response is retrospective: a sustained long-term absence of local tumor regrowth after nonoperative treatment.

INTERPRETING THE LITERATURE

In an attempt to understand the growing literature on organ-conserving treatment of rectal cancer, reports on patients treated with chemotherapy and radiation without surgery can be categorized into three clinical scenarios. Each category has limitations, but adds insight into the organ-preserving approach and is worth evaluating:

1. Patients who are unable or unwilling to have rectal resection. This group includes patients who are unfit for major operation, refuse surgery, or have disease such that they are treated in a palliative setting.
2. Patients with early rectal cancer who would likely be cured with radical TME surgery but elect chemoradiation in an attempt to avoid surgery. In these patients, cure with organ preservation is the aim of treatment.
3. Patients with locally advanced rectal cancer for whom neoadjuvant treatment and TME are the accepted standard. Although organ preservation is not the aim, it has been offered as an alternative treatment to those patients who obtain an excellent response.

Scenario 1: Patients Unfit for/Unwilling to Undergo Major Surgery

This group includes patients who decline surgery or are not candidates for operation. Most of these patients are not surgical candidates due to high operative risk related to frailty and excess comorbidity or advanced primary or metastatic disease, precluding curative resection. The primary aim in these cases is most often local control rather than long-term survival. The aim of treatment is palliation. To facilitate these goals, many centers prefer to give a higher radiotherapy dose than is delivered in the

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