Revista Española de Enfermedades Digestivas
The Spanish Journal of Gastroenterology

**Title:**
**Rectal cancer: organ preservation versus unnecessary radical surgery. A radiograph of a new paradigm**

Authors:
José Luis Domínguez-Tristancho

DOI: 10.17235/reed.2026.11468/2025
Link: PubMed (Epub ahead of print)

Please cite this article as:
Domínguez-Tristancho José Luis. Rectal cancer: organ preservation versus unnecessary radical surgery. A radiograph of a new paradigm. Rev Esp Enferm Dig 2026. doi: 10.17235/reed.2026.11468/2025.

Revista Española de Enfermedades Digestivas
The Spanish Journal of Gastroenterology

**Rectal cancer: organ preservation versus unnecessary radical surgery. A radiograph of a new paradigm**

José Luis Dominguez-Tristancho

Colorectal Surgery Department. Hospital Universitario Fundación Jiménez Díaz. Madrid, Spain

*Conflict of interest: The authors declare no conflict of interest.*

*Artificial intelligence: The authors declare that they did not use artificial intelligence (AI) or any AI-assisted technologies in the elaboration of the article.*



**The controversy surrounding near-complete clinical response**

There seems to be consensus on the approach to take with complete clinical responses (CCR) and incomplete clinical responses (ICR) after completing neoadjuvant therapy, but this is not the case with what is defined as a near-complete clinical response (NCCR), which can be a matter of debate as it is open to various interpretations.

In the case of an NCCR, we find ourselves in a “gray area” where therapeutic decisions are not so straightforward. On the one hand, some authors believe that a high percentage of these patients will achieve a complete clinical response later on if the re-evaluation period is extended, which would increase the chances of organ preservation (1). Other authors do not consider this option of waiting and advocate radical surgery with total mesorectal excision (TME). The former are based on the observation that clinical response “takes time”; the latter on the fact that NCCR means tumor persistence and delaying surgery increases the possibility of metastatic spread and, on the other hand, that regrowth is associated with a higher rate of systemic relapse (2). Many of these reflections are based on published studies involving standard chemotherapy and radiotherapy, but we now need to consider this aspect in the context of the new era of total neoadjuvant therapy (TNT). In randomized clinical trials (RCTs) published in 2020 (3,4) the rate of complete pathological responses (CPR) doubled with total neoadjuvant therapy (TNT), but without a statistically significant difference in group survival, which calls into question CPR as a surrogate for survival, a real enigma. As a reflection, perhaps about 30 % could have avoided radical surgery. The OPRA trial (5) explores TNT and organ preservation (OP). Patients are randomized to consolidation or induction and enter W&W, including NCCR. More than half of the patients retained their organ, especially if they had received TNT in the consolidation regimen, but overall survival was not modified when comparing both TNT regimens and these with a historical series of patients who had undergone TME after standard neoadjuvant therapy. Perhaps the real benefit of TNT is OP in patients who achieve a very good clinical response.

**The shadow of regrowth**

Between 20-30 % of patients who enter the W&W protocol will experience regrowth during follow-up (6,7). Those with NCCR will be the ones most likely to develop regrowth, which is why some authors advocate for "initial" TME. The International W&W Registry Consortium noted that regrowth was the only factor associated with the risk of metastatic disease (8). The same group presented oncological results at ASCO 2024: systemic disease-free survival at 3 years was 75 % in patients who underwent W&W compared to 87 % in patients in the Spanish "Vikingo" Registry who underwent radical surgery and whose surgical specimen showed a greater than 90 % reduction in the original tumor, which they interpreted as NCCR (9). However, we should ask ourselves whether this improvement of approximately 12 % would justify all the morbidity associated with radical surgery.

In the 2019 *JAMA Oncology* publication, García-Aguilar's group in the US had already reported the association between regrowth and metastatic spread (10). However, they pointed out that this was more likely due to the biology of the tumor than to the radical nature of the surgery. The Dutch series analyzes 385 patients who, after standard neoadjuvant therapy and having achieved CCR, entered the W&W protocol. There were 89 regrowths (23 %), practically all (94 %) of which could be rescued, and up to 31 % of these were rescued with local resection. The systemic disease-free period and overall survival rates at 2 years were 91.8 % and 98.4 %, respectively (11). In our personal series (pending publication), all regrowths ($n$ = 8) could be rescued, and

Revista Española de Enfermedades Digestivas
The Spanish Journal of Gastroenterology

5 of them were rescued with local resection. After regrowth, there were 2 systemic relapses, both of which were also successfully treated. All of our patients who underwent W&W are alive with a minimum follow-up of 3 years.

There is also concern that patients who undergo TME "late" due to regrowth have a worse oncological outcome than those who underwent TME "early." Other authors do not share this opinion; in the long-term results of the OPRA study, they found no significant differences in disease-free survival in patients who underwent TME at the outset or after the appearance of regrowth (12).

**Local resection**

Important studies have explored local resection after neoadjuvant therapy vs. TME in early stages (cT1-3, N0) (13-17), a clinical scenario in which we often find ourselves in re-evaluation after TNT, with a high rate of patients with response ("downstaging"). All these studies could be summarized by saying that standard neoadjuvant therapy, especially with long-cycle RT followed by local resection, is not inferior to TME and allows a high rate of organ preservation without oncological compromise. In the Spanish TAUTEM study, local resection was even superior to TME in many aspects, including R0 resection, questioning the "radicality" of TME (18).

In the French GRECCAR study, only 15 % of patients who underwent local resection and were indicated for complementary TME (cTME) due to histopathological findings of poor prognosis (> pT1-2, affected margin, etc.) were found to have disease in the surgical specimen. In other words, 85 % of these radical surgeries were unnecessary (16).

However, local resection also has its critics. It appears that suture dehiscence is the norm in patients who have received radiotherapy, and this leads to significant morbidity in the form of pain and defecation dysfunction that can last for months, as has been noted in important studies (14,17). On the other hand, secondary healing causes irregularities in the mucosa that could simulate regrowth, which in subsequent reviews could make interpretation difficult. Some authors criticize local resection, arguing that if complementary TME is needed, there would be greater morbidity, a higher rate of APR, etc. The Dutch group evaluated this aspect and concluded that cTME was not associated with greater morbidity or a worse oncological outcome compared to patients who underwent TME first (19). The Danish study also concluded that there were no significant differences in terms of perforation, APR rate, conversion rates, or incomplete mesorectums (20).

The recent standardization of TNT presents us with a new scenario in the therapeutic management of rectal cancer. The quality of care is better and more predictable, and due to its neoadjuvant nature, adherence to oncological treatments is higher. This implies greater efficacy with a higher clinical response rate, which should translate into a greater number of patients who can preserve the organ.

The fundamental issue that motivates us to avoid radical surgery is the deterioration in quality of life due to the high morbidity associated with it, without achieving a significant increase in survival. However, a more conservative treatment (local resection or W&W) may also be associated with morbidity secondary to oncological treatments. Local resection, especially in distal lesions, is associated with morbidity in the form of pain and defecation dysfunction, which can take months to recover from. Quality of life has also been explored in patients who underwent W&W. The Dutch Watch-and-Wait Consortium publishes long-term results in terms of quality of life. Twenty-five percent of patients who underwent W&W reported severely impaired defecation dysfunction and sexual dysfunction. Symptoms decreased during follow-up, but patients who underwent radical surgery obtained significantly worse scores on several quality of life subscales (21).

**Epilogue**

I would like to conclude with what I have come to call “Heald's legacy.” This author left us a fantastic technique, total mesorectal excision, which minimized the serious problem of local recurrence. In one of his recent papers, he pointed out that in recent years the use of neoadjuvant chemoradiotherapy has become widespread and, in his opinion, this would only be indicated if the circumferential margin were threatened by the tumor, by adenopathy, or by the presence of extramural venous invasion (EMVI). However, he also concludes that neoadjuvant therapy is capable of curing, with virtually no comorbidity, around half of all cases (including some of the most advanced

Revista Española de Enfermedades Digestivas
The Spanish Journal of Gastroenterology

ones) without the need for surgery, and that the world is taking too long to take advantage of this extraordinary advance for the benefit of patients (22).

We must move away from the belief that the scalpel cures everything, let go of our pride, be aware of the morbidity of surgery that we may be able to avoid, and embrace new therapeutic trends. In reality, this is not about preserving the organ "at all costs," but rather about avoiding surgeries that do not benefit the patient.

**REFERENCES**

1. Zivanov CN, Kau NS, Nalluri-Butz H, et al. Nonoperative Management of Rectal Cancer: Is "Near-Complete" Response Safe to Surveil? Ann Surg Oncol 2025;32(7):4922-30. DOI: 10.1245/s10434-025-17033-1

2. São Julião GP, Fernández LM, Vailati BB, et al. Local Regrowth and the Risk of Distant Metastases Among Patients Undergoing Watch-and-Wait for Rectal Cancer: What Is the Best Control Group? Multicenter Retrospective Study. Dis Colon Rectum 2024;67(1):73-81. DOI: 10.1097/DCR.0000000000002930

3. Conroy T, Bosset JF, Etienne PL, et al.; Unicancer Gastrointestinal Group and Partenariat de Recherche en Oncologie Digestive (PRODIGE) Group. Neoadjuvant chemotherapy with FOLFIRINOX and preoperative chemoradiotherapy for patients with locally advanced rectal cancer (UNICANCER-PRODIGE 23): a multicentre, randomised, open-label, phase 3 trial. Lancet Oncol 2021;22(5):702-15. DOI: 10.1016/S1470-2045(21)00079-6

4. Bahadoer RR, Dijkstra EA, van Etten B, et al.; RAPIDO collaborative investigators. Short-course radiotherapy followed by chemotherapy before total mesorectal excision (TME) versus preoperative chemoradiotherapy, TME, and optional adjuvant chemotherapy in locally advanced rectal cancer (RAPIDO): a randomised, open-label, phase 3 trial. Lancet Oncol 2021;22(1):29-42. DOI: 10.1016/S1470-2045(20)30555-6. Erratum in: Lancet Oncol 2021;22(2):e42. DOI: 10.1016/S1470-2045(20)30781-6

5. Garcia-Aguilar J, Patil S, Gollub MJ, et al. Organ Preservation in Patients With Rectal Adenocarcinoma Treated With Total Neoadjuvant Therapy. J Clin Oncol. 2022 Aug

10;40(23):2546-56. DOI: 10.1200/JCO.22.00032

6. Dossa F, Chesney TR, Acuna SA, et al. A watch-and-wait approach for locally advanced rectal cancer after a clinical complete response following neoadjuvant chemoradiation: a systematic review and meta-analysis. Lancet Gastroenterol Hepatol 2017;2(7):501-13. DOI: 10.1016/S2468-1253(17)30074-2

7. Renehan AG, Malcomson L, Emsley R. Watch-and-wait approach for rectal cancer: concepts of a subject-specific method. Lancet Gastroenterol Hepatol 2017;2(9):627. DOI: 10.1016/S2468-1253(17)30218-2

8. São Julião GP, Fernández LM, Vailati BB, et al. Local Regrowth and the Risk of Distant Metastases Among Patients Undergoing Watch-and-Wait for Rectal Cancer: What Is the Best Control Group? Multicenter Retrospective Study. Dis Colon Rectum 2024;67(1):73-81. DOI: 10.1097/DCR.0000000000002930

9. Fernandez LM, et al. Regrowth Predicts Metastasis in Rectal Cancer Watch- and-Wait. ASCO Gastrointestinal Cancer Simposyum (GICS). San Francisco, January 2024.

10. Smith JJ, Strombom P, Chow OS, et al. Assessment of a Watch-and-Wait Strategy for Rectal Cancer in Patients With a Complete Response After Neoadjuvant Therapy. JAMA Oncol 2019;5(4):e185896. DOI: 10.1001/jamaoncol.2018.5896.

11. van der Sande ME, Figueiredo N, Beets GL. Management and Outcome of Local Regrowths in a Watch-and-wait Prospective Cohort for Complete Responses in Rectal Cancer. Ann Surg 2021;274(6):e1056-e1062. DOI: 10.1097/SLA.0000000000003738

12. Verheij FS, Omer DM, Williams H, et al. Long-Term Results of Organ Preservation in Patients With Rectal Adenocarcinoma Treated With Total Neoadjuvant Therapy: The Randomized Phase II OPRA Trial. J Clin Oncol 2024;42(5):500-6. DOI: 10.1200/JCO.23.01208

13. Lezoche E, Baldarelli M, Lezoche Get al. Randomized clinical trial of endoluminal locoregional resection versus laparoscopic total mesorectal excision for T2 rectal cancer after neoadjuvant therapy. Br J Surg 2012;99(9):1211-8. DOI: 10.1002/bjs.8821

14. Stijns RCH, de Graaf EJR, Punt CJA, et al.; CARTS Study Group. Long-term Oncological and Functional Outcomes of Chemoradiotherapy Followed by Organ-Sparing Transanal Endoscopic Microsurgery for Distal Rectal Cancer: The CARTS Study. JAMA Surg 2019;154(1):47-54. DOI: 10.1001/jamasurg.2018.3752

15. Bach SP, Gilbert A, Brock K, et al.; TREC collaborators. Radical surgery versus organ preservation via short-course radiotherapy followed by transanal endoscopic microsurgery for early-stage rectal cancer (TREC): a randomised, open-label feasibility study. Lancet Gastroenterol Hepatol 2021;6(2):92-105. DOI: 10.1016/S2468-1253(20)30333-2

16. Rullier E, Vendrely V, Asselineau J, et al. Organ preservation with chemoradiotherapy plus local excision for rectal cancer: 5-year results of the GRECCAR 2 randomised trial. Lancet Gastroenterol Hepatol 2020;5(5):465-74. DOI: 10.1016/S2468-1253(19)30410-8

17. Garcia-Aguilar J, Renfro LA, Chow OS, et al. Organ preservation for clinical T2N0 distal rectal cancer using neoadjuvant chemoradiotherapy and local excision (ACOSOG Z6041): results of an open-label, single-arm, multi-institutional, phase 2 trial. Lancet Oncol 2015;16(15):1537-46. DOI: 10.1016/S1470-2045(15)00215-6

18. Serra-Aracil X, Pericay C, Badia-Closa J, et al. Short-term outcomes of chemoradiotherapy and local excision versus total mesorectal excision in T2-T3ab,N0,M0 rectal cancer: a multicentre randomised, controlled, phase III trial (the TAU-TEM study). Ann Oncol 2023;34(1):78-90. DOI: 10.1016/j.annonc.2022.09.160

19. Clermonts SHEM, Köeter T, Pottel H, et al. Outcomes of completion total mesorectal excision are not compromised by prior transanal minimally invasive surgery. Colorectal Dis. 2020 Jul;22(7):790-8. DOI: 10.1111/codi.14962

20. Levic Souzani K, Bulut O, Kuhlmann TP, et al. Completion total mesorectal excision following transanal endoscopic microsurgery does not compromise outcomes in patients with rectal cancer. Surg Endosc 2022;36(2):1181-90. DOI: 10.1007/s00464-021-08385-2

21. Custers PA, van der Sande ME, Grotenhuis BA, et al.; Dutch Watch-and-Wait Consortium. Long-term Quality of Life and Functional Outcome of Patients With Rectal Cancer Following a Watch-and-Wait Approach. JAMA Surg 2023;158(5):e230146. DOI: 10.1001/jamasurg.2023.0146

22. Heald RJ, Santiago I, Pares O, et al. The Perfect Total Mesorectal Excision Obviates the Need for Anything Else in the Management of Most Rectal Cancers. Clin Colon Rectal Surg 2017;30(5):324-32. DOI: 10.1055/s-0037-1606109

Revista Española de Enfermedades Digestivas
The Spanish Journal of Gastroenterology