Original Article

Long-term Outcomes of Watch-and-wait versus Surgery in Rectal Cancer Patients with Clinical Complete Response Following Neoadjuvant Concurrent Chemoradiotherapy: A 5-year Single-center Analysis

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Key Words
Rectal adenocarcinoma;
Neoadjuvant concurrent chemoradiotherapy;
Watch-and-wait strategy;
Clinical complete response;
Non-operative management

Purpose. This study aims to evaluate the long-term outcomes of rectal cancer patients who achieved a clinical complete response after neoadjuvant concurrent chemoradiotherapy, by comparing surgical resection with a non-operative (watch-and-wait) approach.

Methods. Patients with rectal adenocarcinoma who achieved a clinical complete response after neoadjuvant concurrent chemoradiotherapy were enrolled in this study. They were stratified into two cohorts: one treated with radical surgical resection and the other managed non-operatively using a watch-and-wait strategy. Long-term oncologic outcomes were subsequently compared between the two groups.

Results. A total of 22 patients were ultimately enrolled in this study. 11 patients (50%) were managed using the watch-and-wait strategy, while the remaining 11 patients (50%) underwent radical surgical resection. The two groups were comparable in terms of demographic and tumor characteristics, with the exception that patients in the watch-and-wait group were significantly older. In the resection group, 6 patients (54.5%) received a temporary diverting ileostomy. The mean follow-up duration was 66.8 months in the watch-and-wait group and 64.5 months in the resection group. No systemic recurrences were observed in either group. Local regrowth occurred in two patients in the watch-and-wait group, whereas no local recurrences were reported in the resection group. No disease-related mortality was observed in either group.

The five-year overall survival, disease-free survival, and cancer-specific survival rates in the watch-and-wait group were 100%, 81.8%, and 100%, respectively; in the resection group, all three rates were 100%.

Conclusion. In patients with rectal cancer achieving a clinical complete response, the watch-and-wait approach yielded long-term outcomes comparable to those of radical surgical resection.

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A multimodal approach that includes radical surgery, radiotherapy, and chemotherapy remains the standard treatment for rectal cancer.[1-3] Many patients undergoing surgery benefit from concurrent chemoradiotherapy (CCRT), administered either preoperatively or postoperatively, resulting in improved survival and reduced recurrence rates.[3] CCRT followed by total mesorectal excision (TME) is the standard of care for patients with locally advanced rectal cancer.[3,4] Preoperative CCRT offers several advantages over postoperative treatment, including reduced acute toxicity, greater tumor response, and increased likelihood of sphincter-preserving procedures.[5] However, surgical resection based on TME principles carries a 2-5% risk of perioperative mortality.[6] A subset of patients who achieve a clinical complete response (cCR) after neoadjuvant therapy may be eligible for a non-operative management (NOM) approach, commonly referred to as the "watch-and-wait" strategy.[7,8] This approach seeks to preserve organ function and avoid the morbidity associated with radical surgery, such as bowel dysfunction, permanent stoma formation, and diminished quality of life.[9,10] Several studies have reported favorable outcomes with NOM in cCR patients, showing comparable survival and recurrence rates to those undergoing radical surgery.[8] Nevertheless, concerns remain regarding long-term oncologic safety, and the optimal selection criteria for this approach are still under investigation.[11] In this study, we retrospectively analyzed the clinical outcomes of rectal cancer patients with cCR who either underwent radical resection or were managed with observation following completion of CCRT. We aimed to compare oncologic outcomes, recurrence patterns, and survival between these two cohorts to evaluate the feasibility and safety of NOM in our clinical setting.

Materials and Methods

This was a single-center, retrospective cohort study conducted at Chi-Mei Medical Center, between January 2014 and December 2020, total of 1,407 patients were newly diagnosed with rectal adenocarcinoma. All patients underwent colonoscopy and biopsy to determine tumor location and confirm the histologic diagnosis. Clinical staging was performed prior to treatment using magnetic resonance imaging (MRI) of the abdomen and pelvis or endorectal ultrasound. When indicated, chest computed tomography (CT) and liver ultrasonography were used to exclude distant metastases. Tumor staging was based on the 7th edition of the American Joint Committee on Cancer (AJCC) Staging Manual.[12] Among the 1,407 patients, 315 were excluded due to an initial diagnosis of AJCC stage IV disease with distant metastases. Of the remaining patients, 497 received neoadjuvant CCRT. Radiotherapy consisted of 45-50.4 Gy delivered in 25 fractions (1.8 Gy per fraction) over five weeks, using 6 MV or 10 MV linear accelerators (GE Healthcare, Chicago, IL, USA). The radiation field extended from the L5 vertebral level superiorly, 1.5 cm lateral to the bony pelvis laterally to cover the pelvic lymph nodes, and inferiorly to include the entire rectum and tumor bed. Treatment planning was performed using three-dimensional conformal radiation therapy or intensity-modulated radiation therapy techniques. Chemotherapy was administered concurrently with radiotherapy using continuous infusion of fluorouracil at a dose of 1,000 mg/m^2/day for 120 hours during the first and fifth weeks of radiotherapy.

Following completion of neoadjuvant CCRT, tumor response was reassessed by an experienced radiologist and colorectal surgeon using the same imaging modalities as those used for initial staging. Clinical complete response (cCR) was evaluated based on digital rectal examination, colonoscopy, and imaging studies. The criteria for cCR included: (1) no palpable nodule on digital rectal examination (when the lesion was initially palpable); (2) no residual tumor or presence of a flat white scar with or without telangiectasias, and absence of ulceration or nodularity on endoscopy; (3) no residual tumor or suspicious lymph nodes on MRI; and (4) absence of distant metastasis. A total of 22 patients met the criteria for cCR and were enrolled in this study.

Among these, 11 patients with stage II/III rectal adenocarcinoma who achieved a cCR adopted a watch-and-wait strategy. Another 11 patients with cCR who underwent standard total mesorectal excision (TME)

during the same period were also identified for comparison. Patient data were collected through clinical chart reviews, physician records, patient correspondence, and telephone interviews. Treatment-related parameters primarily included clinical characteristics (e.g., age, gender, underlying comorbidities), tumor features at diagnosis, pre-treatment clinical staging, type of surgery, and surveillance outcomes. Follow-up assessments in the watch-and-wait group (WG) were conducted every 8-12 weeks during the first three years, and every six months thereafter. Surveillance for the resection group (RG) followed standard guidelines, with evaluations every three months during the first two years after treatment, and every six months during the subsequent three years. The final follow-up date was April 30, 2025.

Surgical procedures

Laparoscopy was the preferred surgical approach unless contraindicated or precluded by intraoperative technical difficulties. Distal rectal transection was performed based on tumor location, ensuring at least a 1 cm distal margin as described by Rullier et al.[13] Surgical procedures included high ligation of the inferior mesenteric artery, takedown of the splenic flexure colon, resection of adjacent organ when necessary, clearance of distal and radial margins, and total mesorectal excision. Surgical approaches included low anterior resection (LAR) with transanal TME (TaTME), or LAR with colorectal or coloanal anastomosis. A diverting loop ileostomy was created at the discretion of the operating surgeon.

Endpoints and definitions

The primary endpoint was cancer-specific survival (CSS), defined as the time from diagnosis to death specifically from rectal cancer. Secondary endpoints included disease-free survival (DFS) and overall survival (OS). Local recurrence was defined as recurrence within the pelvis, while distant metastasis referred to recurrence outside the pelvic region. In the watch-and-wait group, local recurrence was defined as local tumor regrowth after achieving a cCR. DFS was defined as survival without evidence of local recurrence or distant metastasis. OS was defined as the time from diagnosis to death from any cause. Time-to-event data were calculated from the date of radiotherapy completion until the occurrence of an event or were censored at the last follow-up. Deaths from causes unrelated to cancer were not considered events for DFS in this study.

Statistical analysis

Continuous variables are expressed as mean ± standard deviation and were compared using the two-sample t-test. Categorical variables are presented as counts and percentages, and comparisons were made using the chi-square test or Fisher's exact test, as appropriate. Survival curves were generated using the Kaplan-Meier method, and group differences were evaluated using the log-rank test. Statistical analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA), and Kaplan-Meier plots were created using STATA version 12 (StataCorp, College Station, TX, USA). A p-value < 0.05 was considered statistically significant.

Results

Among 22 patients who achieved a complete clinical response (cCR) following concurrent chemoradiotherapy (CCRT), 11 (50%) were managed with non-operative management and assigned to the WG, while 11 patients (50%) underwent radical surgery and were assigned to the RG (Table 1). The gender distribution was similar between groups ([WG]: 54.5% male; [RG]: 45.5% male). Patients in the WG were generally older, with a mean age of 70.73 ± 6.42 years (range: 63-82), compared to 62.0 ± 8.83 years (range: 49-73) in the RG. Tumors in the WG were located closer to the anal verge, with a mean distance of 6.17 ± 3.55 cm, compared to 8.45 ± 4.48 cm in the RG. The mean pre-treatment tumor sizes were 2.99 ± 1.74 cm in the WG and 3.33 ± 1.63 cm in the RG. Initial clinical T staging revealed a higher proportion of early-stage tumors in the WG, with 9.1% classified as T1,

compared to 0% in the RG; then in WW with 36.4% classified as T2, compared to 27.3% in the RG; with 36.4% classified as T3, compared to 45.5% in the RG; with 18.2% classified as T4, compared to 27.3% in the RG.

Regarding nodal status, the WG had a higher proportion of N0 disease (18.2% vs. 18.2%); the WG had a higher proportion of N1 disease (63.6% vs. 27.3%), while the RG had a higher proportion of N2 disease (54.5% vs. 18.2%). No significant differences were observed between the two groups in initial tumor size, gender distribution, tumor differentiation, or clinical staging, except for a higher mean age in WG (Table 1).

Surgical detail

Among the 11 patients in the resection group (RG), 2 patients (16.7%) underwent laparoscopic low anterior resection (LAR) with transanal total mesorectal excision (TaTME) and a diverting loop ileostomy, while the remaining 9 patients (83.3%) underwent standard laparoscopic LAR. Among those who underwent LAR, 4 patients (36.4%) received a colorectal anastomosis with a protective diverting loop ileostomy, whereas 5 patients (45.5%) did not receive a protective loop ileostomy during rectal cancer resection. There were no cases of surgical mortality or reoperation, and none of the patients experienced late postoperative complications. Histopathological examination in the resection group showed T1 adenocarcinoma in one patient, while the other patient had no residual tumor in the resected specimen (Table 2).

Table 2. Surgical details (resection group only)

	Number of patients (N = 11)
Operation methods	
LAR combined transanal TME (TaTME)	2 (18.2%)
LAR with colorectal anastomosis	9 (81.8%)
Stoma creation	
Yes	4 (36.4%)
No	5 (45.5%)
Pathology	
yPT0	10 (90.9%)
yPT1	1 (9.1%)
Stage 0	10 (90.9%)
Stage 1	1 (9.1%)

Table 1. Pretreatment clinical characteristic

Characteristic	Watch and wait group (n = 11) (50%)	Resection group (n = 11) (50%)	*p*-value
Gender (male/female)	6 (54.5%)/5 (45.5%)	5 (45.5%)/6 (54.5%)	1.0000
Mean age (years)	70.73 ± 6.42	62.0 ± 8.83	0.0161
BMI (kg/m^2)	23.51 ± 6.81	22.38 ± 2.80	0.6209
Diabetes mellitus	3 (27.3%)	2 (18.1%)	0.8164
Chronic kidney disease	0 (0%)	0 (0%)	1.0000
Hypertension	5 (45.5%)	2 (18.1%)	0.2256
Cerebrovascular accident	0 (0%)	0 (0%)	1.0000
Tumor size (cm)	2.99 ± 1.74	3.33 ± 1.63	0.6444
Distance from anal verge (cm)	6.17 ± 3.55	8.45 ± 4.48	0.2018
Pretreatment T/N status			
T1	1 (9.1%)	0 (0%)	0.4545
T2	4 (36.4%)	3 (27.3%)	0.6517
T3	4 (36.4%)	5 (45.5%)	0.4149
T4	2 (18.2%)	3 (27.3%)	1.0
N0	2 (18.2%)	2 (18.2%)	1.0
N1	7 (63.6%)	3 (27.3%)	0.0836
N2	2 (18.2%)	6 (54.5%)	0.0810
AJCC staging			
IIA	2 (18.2%)	2 (18.2%)	1.0
IIIA	4 (36.4%)	2 (18.2%)	0.3476
IIIB	2 (18.2%)	4 (36.4%)	0.6462
IIIC	3 (27.3%)	3 (27.3%)	0.6162

Recurrence and survival

The mean follow-up duration for all patients was 65.65 months (66.8 months in the WG and 64.5 months in the RG). No patients were lost to follow-up. In the WG, local endoluminal regrowth and distant metastasis occurred in two patients (18.2%), whereas no local or distant recurrences were observed in the RG. In the RG, no local recurrence or distant metastasis was observed. The five-year overall survival and cancer-specific survival rates were 100% in both groups. The five-year disease-free survival rate was 81% in the WG and 100% in the RG (Table 3). There were no statistically significant differences between the two groups in terms of five-year overall survival ($p = 1.0$), disease-free survival ($p = 0.2932$), or cancer-specific survival ($p = 1.0$) (Fig. 1).

Discussion

This study compared the long-term outcomes of rectal cancer patients who achieved a clinical complete response (cCR) after concurrent chemoradiotherapy (CCRT), managed either with observation (the "watch-and-wait" approach) or with radical surgery. Our findings suggest that, in carefully selected patients, non-operative management may yield oncologic outcomes comparable to those of surgical resection, while sparing patients from the morbidity associated with radical surgery, stoma creation, and loss of anal function. The five-year overall survival (OS), cancer-specific survival (CSS), and disease-free survival (DFS) rates in the WG were 100%, 100%, and 81.8%, respectively. These were not significantly different from the corresponding rates in the RG, which were 100%, 100%, and 100% ($p = 1.0$, $p = 1.0$, and $p = 0.2932$, respectively). These results are consistent with previous studies supporting the oncologic safety

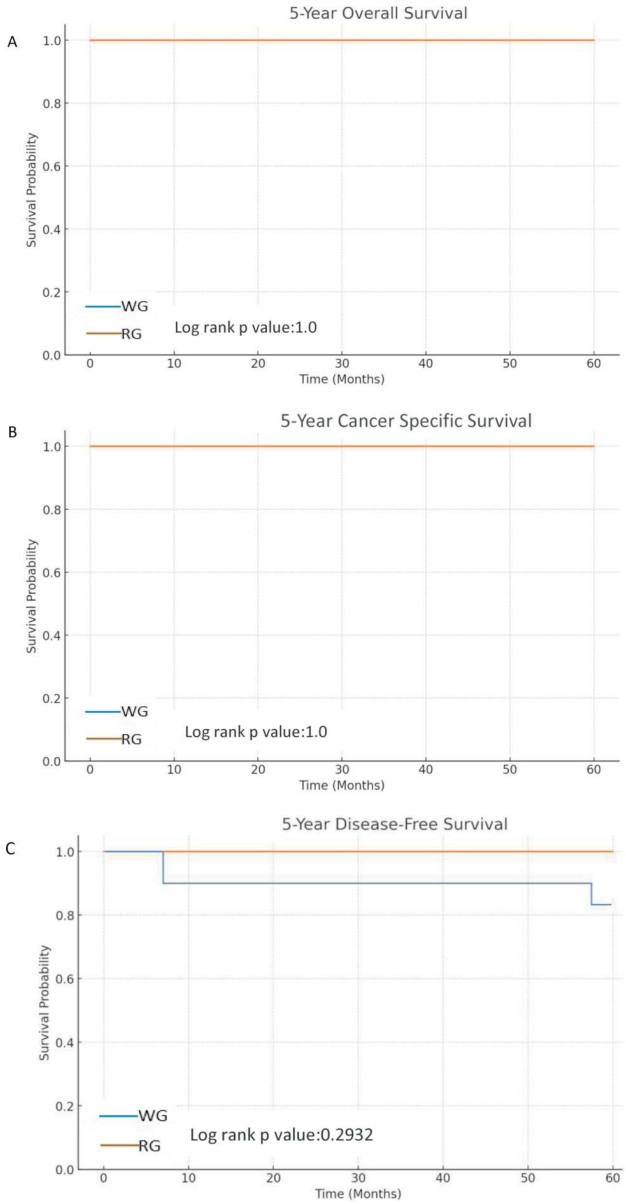

Fig. 1. (A) Overall survival. (B) Cancer specific survival. (C) Disease free survival.

Table 3. Surveillance outcome

	Watch and wait group (N = 11)	Resection group (N = 11)	*p*-value
Mean follow-up duration (months)	66.8	64.5	0.6210
Recurrence (local and/or distant)	2 (18.2%)	0 (0%)	0.471
Survival			
5-year overall survival	11 (100%)	11 (100%)	1.0
5-year disease free survival	9 (81.8%)	11 (100%)	0.2932
5-year cancer specific survival	11 (100%)	11 (100%)	1.0

of the watch-and-wait approach in patients achieving cCR.[13,14]

Local endoluminal regrowth occurred in two patients (18.2%) in the WG, both of whom have been managed within our institution. One patient developed local regrowth at 8 months after completion of CCRT and subsequently underwent radical surgical resection, with ongoing surveillance in our outpatient department. The other patient developed both local regrowth and distant metastasis at 57 months and is currently receiving palliative targeted therapy and chemotherapy through the hematology outpatient clinic. While the recurrence rate appeared higher in the WG (18.2%) compared to the RG (0%), the difference was not statistically significant.

Importantly, the combination of a watch-and-wait strategy with timely salvage therapy, when indicated, may allow for organ preservation in nearly 80% of patients.[15] This highlights the critical role of rigorous surveillance in non-operative management (NOM) protocols, as early detection of regrowth enables curative salvage interventions. Given that the risk of local regrowth is highest within the first three years after achieving a cCR — and acknowledging the potential for subsequent distant metastasis in this subgroup — current surveillance protocols are designed to mitigate these risks.[15,16] Surveillance is most intensive during the first three years, with assessments of the primary tumor typically performed every 8 to 12 weeks. Although the risk of regrowth decreases significantly after three disease-free years, continued long-term or even lifelong surveillance is recommended. Early detection remains essential to prevent delayed identification of regrowth, which could progress to more advanced stages (e.g., ypT3-4) by the time of eventual resection. Accordingly, patients are advised to undergo digital rectal examination (DRE), proctoscopy, carcinoembryonic antigen (CEA) testing, and pelvic magnetic resonance imaging (MRI) every 8 to 12 weeks during the initial three years of follow-up. After this period, follow-up intensity may be reduced to every six months, with ongoing monitoring of the primary tumor response.[17]

However, CCRT does not prevent distant metastasis. Some patients may develop systemic disease despite achieving a complete pathological response, likely due to undetected micro-metastases at the time of initial staging. In our cohort, there was one patient developed distant metastasis at 57 months after completion of CCRT, suggesting that effective systemic therapy is crucial even in the context of excellent local tumor response. This has led to increasing interest in total neoadjuvant therapy (TNT), which administers all systemic chemotherapy prior to surgery, aiming to reduce distant failures. In the RAPIDO trial, TNT significantly reduced the rate of distant metastasis (from 27% to 20%) and disease-related treatment failure in high-risk rectal cancer patients.[18] Similarly, the PRODIGE 23 trial demonstrated improved 3-year DFS (76% vs. 69%) and higher pathologic complete response (pCR) rates when TNT was implemented, supporting its role in systemic disease control.[19] In addition, the OPRA trial suggested that TNT not only increases cCR rates but may also facilitate organ preservation in responders without compromising long-term oncologic outcomes.[20] In our study, total neoadjuvant therapy (TNT) was not implemented, which represents a limitation. In future investigations, incorporating a TNT protocol in patients who achieve a cCR may further enhance local tumor response and potentially reduce the risk of distant metastases.

Overall, 54.5% of patients in the RG received temporary ileostomy. These data highlight the potential quality-of-life benefits of watch-and-wait in avoiding surgical morbidity and stoma-related issues.[9,21]

Current best practices recommend a multimodal assessment combining high-resolution MRI (especially with diffusion-weighted imaging), endoscopic evaluation, and digital rectal examination, with biopsy reserved for suspicious residual lesions.[15,22] However, recent findings indicate that clinical and pathological responses often poorly correlate, even when evaluations are performed by specialists. Hiotis et al. reported unexpectedly high rates of residual T2-T3 tumors and nodal metastasis in patients thought to be complete clinical responders.[23,24] Accurately identifying clinical complete response (cCR) is therefore critical for the safe implementation of a watch-and-wait strategy in rectal cancer management. In our study, three patients (13.6%) who were initially classified as

having achieved cCR based on comprehensive post-CCRT evaluations were later found to have tumor recurrence. Pathological examination revealed residual disease (pT1) in one patient from the RG, while two patients in the WG developed local tumor regrowth during the 5-year follow-up period. These findings underscore the inherent limitations and potential risks of relying solely on cCR status, even when stringent assessment protocols are followed. This study has several limitations that must be acknowledged. First, its retrospective design introduces inherent selection bias, particularly regarding the allocation of patients to the watch-and-wait or resection groups, which was based on clinical judgment rather than randomization. Second, the relatively small sample size in both groups limits the statistical power to detect subtle differences in oncologic outcomes, such as recurrence and survival. Additionally, inter-observer variability in interpreting MRI and colonoscopy findings across different physicians may introduce heterogeneity in response assessment, potentially affecting the reliability of treatment comparisons. Furthermore, this study did not include statistical analysis regarding whether patients received total neoadjuvant therapy (TNT). We acknowledge that recent evidence suggests TNT may improve outcomes in certain patient subsets, and this may have impacted our findings.

As such, meticulous and ongoing surveillance is essential in this management strategy. Moreover, comprehensive informed consent discussions with patients and their families are imperative to ensure a full understanding of the risks and responsibilities associated with a non-operative approach. Prospective studies with larger cohorts and standardized assessment protocols are needed to validate these findings and further establish the safety and efficacy of the watch-and-wait approach.

Conclusion

While non-operative management (NOM) provides excellent local control and improved quality of life for patients with sustained clinical complete response, disease recurrence remains a significant clinical challenge. Accurate identification of true complete responders is essential to ensure the safe and effective implementation of NOM. With appropriate patient selection and adherence to rigorous surveillance protocols, the watch-and-wait approach may serve as a safe and effective alternative to radical surgery.

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原　著

接受術前同步化學放射治療後達臨床完全緩解之直腸癌患者採行觀察等待與手術治療之長期結果：單一醫學中心五年分析

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目的　本研究旨在評估接受新輔助性同步化學放射治療後達到臨床完全緩解之直腸癌病患的長期治療結果，並比較其接受根除性手術與非手術 (觀察等待) 治療方式的差異。

方法　本研究納入那些在接受新輔助性同步化學放射治療後達到臨床完全緩解的直腸腺癌患者。這些患者被分為兩組：一組接受根除性手術切除治療，另一組則採取非手術的「觀察等待」策略。隨後比較兩組患者的長期腫瘤學治療結果。

結果　本研究最終共納入 22 位患者。其中 11 位患者 (50%) 採取「觀察等待」策略進行非手術治療，其餘 11 位患者 (50%) 接受根除性手術切除。除了「觀察等待」組患者年齡顯著較高外，兩組在人口學與腫瘤特徵方面皆具有可比性。在手術組中，有 6 位患者 (54.5%) 接受了暫時性迴腸造口手術。平均追蹤時間為「觀察等待」組 66.8 個月，手術組 64.5 個月。兩組皆未發現全身性復發情形。「觀察等待」組中有兩位患者出現局部復發，而手術組未見局部復發。兩組皆未出現與疾病相關的死亡事件。在「觀察等待」組中，五年整體存活率、無病存活率與癌症特異性存活率分別為 100%、81.8% 與 100%；而在手術組中，這三項指標皆為 100%。

結論　在達到臨床完全緩解的直腸癌患者中，「觀察等待」策略所達成的長期治療結果與根除性手術切除相當。

關鍵詞　直腸腺癌、術前同步化學放射治療、「觀察等待」策略、臨床完全緩解、非手術治療。