Original Article

Is Adjuvant Chemotherapy Necessary for Rectal Cancer Patients with Downstaging to ypT0-2N0 after Neoadjuvant Chemoradiotherapy and Radical Resection?

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Key Words
Downstaging;
Rectal cancer;
Adjuvant chemotherapy

Purpose. The potential benefits of adjuvant chemotherapy for patients who have undergone radical resection and achieved downstaging after neoadjuvant chemoradiotherapy remain unclear. This study analyzed data from our institution to determine whether adjuvant chemotherapy confers advantages in this patient population and to identify prognostic factors.
Methods. This single-center retrospective study included 37 patients with ypT0-2N0 rectal cancer who underwent neoadjuvant chemoradiotherapy followed by radical resection between January 2011 and October 2019. Oncological outcomes were compared between the adjuvant chemotherapy group and non-adjuvant chemotherapy group. Statistical analysis was performed using the Kaplan-Meier method, log-rank test, and Cox regression analysis.
Results. Of the 37 patients with rectal cancer, 20 received postoperative adjuvant chemotherapy (the adjuvant chemotherapy group), and 17 did not (the non-adjuvant chemotherapy group). No significant differences were observed in 5-year disease-free survival (HR = 0.800, $p = 0.562$) and 5-year overall survival (HR = 1.186, $p = 0.844$) between the 2 groups. However, patients with a higher initial T cancer stage were more likely to receive postoperative adjuvant chemotherapy ($p = 0.051$).
Conclusions. Our data suggest that individuals with rectal cancer who achieve ypT0-2N0 after neoadjuvant chemoradiotherapy followed by radical surgery do not derive clear survival benefits from adjuvant chemotherapy. These findings highlight that a more individualized, risk-adapted treatment approach should be implemented rather than a one-size-fits-all strategy. Further prospective investigations and larger cohort analyses are warranted to achieve more effective stratification of patients according to relevant risk factors and to guide treatment decision-making.

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Locally advanced rectal cancer (LARC) is commonly treated using a multimodal strategy involving neoadjuvant chemoradiotherapy (nCRT) followed by surgical resection. Many patients with LARC also receive adjuvant chemotherapy.[1,2] Despite advancements in surgical techniques and standardized

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use of total mesorectal excision (TME), local recurrence and distant metastasis remain significant challenges in the management of rectal cancer. Local recurrence is often associated with inadequate resection margins, suboptimal lymph node clearance, or microscopic cancer cells that are not eliminated by nCRT. Distant metastasis, particularly to the liver and lungs, may result from cancer cells detach from the primary tumor and travel through the bloodstream or lymphatic system.

To address these risks, the standard of care for LARC typically includes nCRT followed by TME and, in many cases, adjuvant chemotherapy.[1,2] The rationale behind adjuvant chemotherapy is to eradicate residual microscopic cancer cells and reduce the risk of systemic relapse. However, whether patients who achieve substantial downstaging (ypT0-2N0) after nCRT benefit from postoperative chemotherapy remains unclear.[3,4] Several retrospective and prospective trials have reported that this subset of good responders may not benefit from the survival advantage conferred by adjuvant chemotherapy.[5-7] In consideration of this, the current single-center retrospective study investigated whether adjuvant chemotherapy improves oncologic outcomes in patients with ypT0-2N0 rectal cancer and explored potential prognostic factors.

Materials and Methods

Patient selection

This single-center retrospective study included 37 patients with ypT0-2N0 rectal cancer who underwent nCRT followed by radical resection between January 2011 and October 2019. Among these patients, 20 received postoperative adjuvant chemotherapy (the adjuvant chemotherapy group), and 17 did not (the non-adjuvant chemotherapy group).

Staging

All of the patients underwent colonoscopy and pathological diagnosis was confirmed. Before treatment, computed tomography with intravenous contrast of abdomen and pelvis was performed for clinical staging. Clinicopathological classification and staging were based on the American Joint Committee on Cancer tumor-node-metastasis (TNM) staging system.

Outcomes

The oncological outcomes included overall survival (OS), disease-free survival (DFS), and recurrence patterns (local vs. distant). Clinicopathological variables such as age, sex, clinical stage, carcinoembryonic antigen (CEA) level, and number of retrieved lymph nodes were analyzed to identify prognostic factors.

Surgical methods and treatments

All patients underwent TME in accordance with standard oncological principles. Resection margins (both distal and circumferential) were confirmed to be negative (R0 resection). The nCRT regimens consisted of long-course chemoradiotherapy followed by an interval of 6-8 weeks before surgery. The nCRT is indicated for patients with LARC, including cT3-4, cN1-2, tumors located at mid to low rectum, or tumors involved mesorectal fascia on images. The decision of receiving adjuvant chemotherapy was based on discussion between patients and doctors. On the basis of the clinicians' judgment, some patients received the UFUR regimen, and others received intravenous chemotherapy with the XELOX or FOLFOX regimen for nCRT.

Follow up

Follow-up data was retrospectively obtained from the medical records. The follow-up ended on February 3, 2024. Each patient was followed-up every three months for the first two years, every six months for the next three years. The levels of CEA was determined at every follow-up visit. Computed tomography with intravenous contrast of the liver and pelvis was performed every 6 to 12 months after surgery. Colonoscopy was performed 1 year after surgery. Disease-free survival was defined as the time between the

surgery and tumor recurrence or distant metastasis. Overall survival was defined as the time between surgery and death or last follow-up.

Statistical analysis

All statistical analyses were performed using SPSS, version 23. Categorical variables were examined using the chi-square test. An independent sample *t* test was used to analyze differences in continuous variables between the groups. A p value of < 0.05 was considered significant.

Results

Baseline characteristics

A total of 37 patients with rectal cancer were enrolled in this study, that is, 29 men (78.3%) and 8 women (21.6%). The average age was 56.2 ± 15.4 years (range, 30-85 years). Regarding the clinical stage before neoadjuvant therapy, 5, 28, and 4 patients had cT2, cT3, and cT4 rectal cancer, respectively. In addition, 24 patients received nCRT alone, and 13 patients received additional consolidation chemotherapy (XELOX or FOLFOX) after nCRT. The median interval between completing radiotherapy and undergoing surgery was 6.7 weeks. All patients achieved R0 resection with negative distal and circumferential margins. Postoperative pathology revealed that 13, 5, and 19 patients had ypT0, ypT1, and ypT2 rectal cancer, respectively. The adjuvant chemotherapy group comprised 20 patients (54.1%), and the non-adjuvant chemotherapy group comprised 17 patients (45.9%). No significant intergroup differences were noted in sex, age, clinical stage, pretreatment CEA level, or number of retrieved lymph nodes (Table 1).

Table 1. Demographic and clinic-pathological characteristics of patients with ypT0-2N0

	Chemo (n = 20)	Non-chemo (n = 17)	*p* value
Age (mean ± SD)	54.2 ± 13.6	58.6 ± 17.4	0.390
Male gender (%)	15 (75)	14 (82.4)	0.588
Distance to anal verge, cm			0.054
≤ 5	8 (40)	2 (11.8)	
> 5	12 (60)	15 (88.2)	
cT			0.051
cT2-3	16 (80)	17 (100)	
cT4	4 (20)	0 (0)	
cN			0.715
cN0	19 (95)	16 (94.1)	
cN1-2	1 (5)	1 (5.9)	
CEA before treatment, ng/mL			0.297
≤ 5	16 (80)	11 (76.5)	
> 5	4 (20)	6 (23.5)	
Preoperative treatment			0.173
RT + UFUR	11 (55)	13 (76.5)	
RT + XELOX or FOLFOX	9 (45)	4 (23.5)	
Interval between radiotherapy and operation, week			0.152
≤ 8	17 (85)	11 (64.7)	
> 8	3 (15)	6 (35.3)	
Operation type			0.647
LAR	18 (90)	16 (94.1)	
APR	2 (10)	1 (5.9)	
No. of retrieved lymph nodes			0.502
< 12	6 (30)	6 (35.3)	
≥ 12	14 (70)	11 (64.7)	
ypT			0.627
ypT0	7 (35)	6 (35.3)	
ypT1-2	13 (65)	11 (64.7)	
Distal margin (cm)			0.436
< 1	3 (15)	4 (23.5)	
≥ 1	17 (85)	13 (76.5)	
Follow-up median, m (interquartile range)	77.2 (61.1-95.8)	85.6 (61.1-105.2)	0.286

cT, clinical T stage before treatment; cN, clinical N stage before treatment; CEA, carcinoembryonic antigen; RT, radiotherapy; LAR, low anterior resection; APR, abdominoperineal resection; DFS, disease-free survival; OS, overall survival.

Follow-up and survival outcomes

The median follow-up duration for all patients was 81.3 months (interquartile range (IQR), 61.3-105.5). The median follow-up was 77.2 months (IQR, 61.1-95.8) in the adjuvant chemotherapy group and 85.6 months (IQR, 61.1-105.2) in the non-adjuvant chemotherapy group; the difference was not significant ($p = 0.286$). During follow-up, 4 patients experienced relapse, with local recurrence in 2 patients and distant metastasis in 2 patients. Of these patients, 3 were from the adjuvant chemotherapy group (2 patients with distant metastasis and 1 patient with local recurrence), and 1 patient with local recurrence was from the non-adjuvant chemotherapy group. A total of 6 patients died (2 in the adjuvant chemotherapy group and 4 in the non-adjuvant chemotherapy group). The 5-year DFS and OS rates for the entire cohort were 81.0% and 83.0%, respectively. In the adjuvant chemotherapy and non-adjuvant chemotherapy groups, the 5-year DFS rates were 80.0% and 82.4% ($p = 0.562$), respectively, and the 5-year OS rates were 90.0% and 88.2% ($p = 0.844$), respectively (Table 2 & Fig. 1).

Cox univariate analysis was used to identify risk factors influencing DFS and OS, which included distance to the anal verge, cT, cN, interval between RT and surgery, operation type, number of retrieved lymph nodes, ypT stage, and adjuvant chemotherapy. None of these risk factors were significant (Table 3). In addition, Cox multivariate analysis revealed that cT4 and adjuvant chemotherapy were not independent risk factors for DFS and OS (Tables 4 and 5).

Discussion

LARC is typically treated using a multimodal approach; in many regions, the standard approach for such treatment has long included nCRT, surgery (most often TME), and adjuvant chemotherapy.[3,4] However, contemporary evidence indicates that adjuvant chemotherapy may not be required in all patient subgroups, including patients who experience considerable downstaging after nCRT.[6,7] Aldo Sainato et al. reported that adjuvant chemotherapy did not improve 5-year OS and DFS rates and that nCRT had no impact on the distant metastasis rate in patients with LARC.[8]

Table 2. Oncological outcomes of patients with ypT0-2N0

	Chemo (n = 20)	Non-chemo (n = 17)	*p* value
Local recurrence (%)	1 (5.0)	1 (5.9)	0.715
Distant metastasis (%)	2 (10.0)	1 (5.9)	0.647
5-year OS	90	88.2	0.844
5-year DFS	80	82.4	0.562
Mortality (%)	4 (20.0)	2 (11.8)	0.383

OS, overall survival; DFS, disease-free survival.

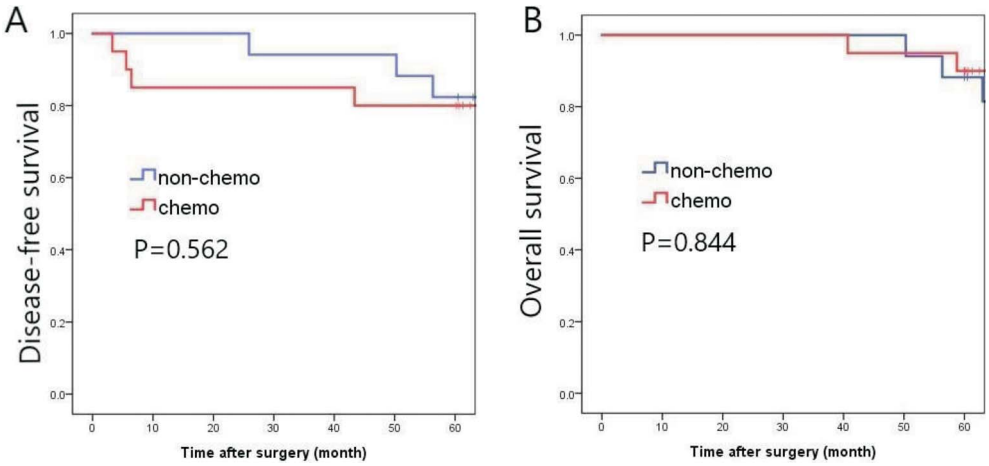

Fig. 1. Oncological outcomes of 37 patients with ypT0-2N0 rectal cancer. (A) The 5-year disease-free survival rate. (B) The 5-year overall survival rate.

Table 3. Univariate analysis of the 5-year DFS and OS rates in patients with a pathological diagnosis of ypT0-2N0

Variable	Total (n = 37)	DFS		OS	
		5-year rate	*p*	5-year rate	*p*
Distance to anal verge, cm (%)			0.935		0.450
≤ 5	10 (27.0)	80.0		90.0	
> 5	27 (73.0)	81.4		88.9	
cT			0.897		0.338
cT2-3	33 (89.2)	81.8		90.9	
cT4	4 (10.8)	75.0		75.0	
cN			0.685		0.995
cN0	2 (5.4)	50		100.0	
cN1-2	35 (94.6)	82.9		88.6	
Preoperative treatment			0.646		0.387
RT + UFUR	24 (64.9)	83.3		87.5	
RT + XELOX or FOLFOX	13 (35.1)	76.9		92.3	
Interval between radiotherapy and operation, week			0.757		0.969
≤ 8	28 (75.7)	82.1		89.3	
> 8	9 (24.3)	77.8		88.9	
Operation type			0.519		0.993
LAR	34 (91.9)	82.4		88.2	
APR	3 (8.1)	66.7		100.0	
No. of retrieved lymph nodes			0.699		0.832
< 12	12 (32.4)	83.3		91.7	
≥ 12	25 (67.6)	80.0		88.0	
ypT			0.431		0.708
ypT0	13 (35.1)	76.9		84.6	
ypT1-2	24 (64.9)	83.3		91.7	
Distal margin			0.734		0.536
< 1	7 (18.9)	85.7		85.7	
≥ 1	30 (81.1)	73.3		80.0	
Adjuvant chemotherapy			0.562		0.844
Yes	20 (54.1)	80.0		90.0	
No	17 (45.9)	82.4		88.2	

cT, clinical T stage before treatment; cN, clinical N stage before treatment; CEA, carcinoembryonic antigen; RT, radiotherapy; LAR, low anterior resection; APR, abdominoperineal resection; DFS, disease-free survival; OS, overall survival.

Table 4. Multivariate analysis of the DFS rate in patients with ypT0-2N0

Variable	Total	Hazard ratio	95% confidence interval	*p*
cT (%)			0.083-7.728	0.849
cT4	4 (10.8)	1		
cT2-3	33 (89.2)	0.803		
Adjuvant chemotherapy			0.170-4.174	0.833
Yes	20 (54.1)	1		
No	17 (45.9)	0.842		

cT, clinical T stage before treatment.

Table 5. Multivariate analysis of the OS rate in patients with ypT0-2N0

Variable	Total	Hazard ratio	95% confidence interval	*p*
cT (%)			0.016-4.196	0.344
cT4	4 (10.8)	1		
cT2-3	33 (89.2)	0.262		
Adjuvant chemotherapy			0.017-20.727	0.607
Yes	20 (54.1)	1		
No	17 (45.9)	1.879		

cT, clinical T stage before treatment.

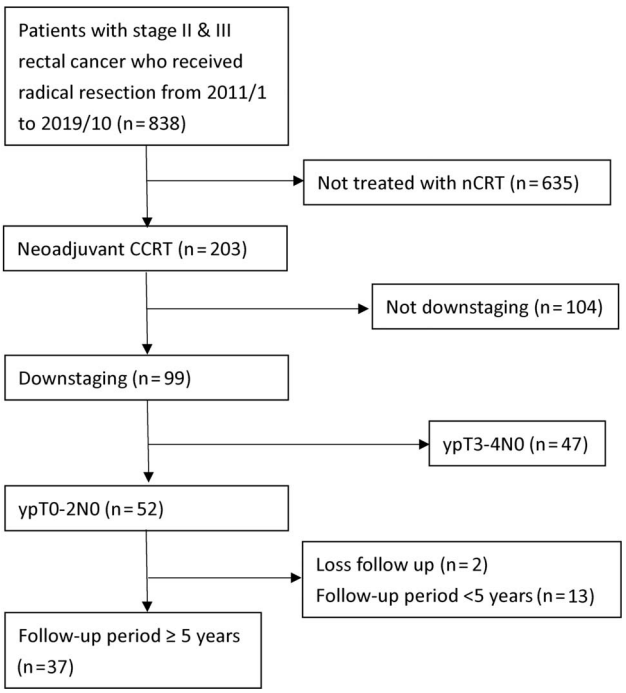

Fig. 2. The flowchart of recruited patients.

Furthermore, a study demonstrated that patients with ypT0-2N0 rectal cancer who underwent nCRT followed by radical surgery who exhibit favorable responses to nCRT and have a favorable oncological prognosis[9] may not derive survival benefits from adjuvant chemotherapy.[10]

The present study investigated the role of adjuvant chemotherapy in patients with ypT0-2N0 rectal cancer who underwent nCRT followed by radical resection. The findings revealed that adjuvant chemotherapy did not confer significant benefits in terms of OS or DFS in this subset of patients. These results align with a growing body of evidence indicating that adjuvant chemotherapy may not be beneficial in patients with considerable downstaging after nCRT.[11,12]

A crucial explanation for this lack of apparent benefits from adjuvant chemotherapy in patients with ypT0-2N0 rectal cancer is a significantly decreased tumor burden following nCRT. In patients who achieve downstaging, micrometastatic disease, which systemic chemotherapy is employed to eradicate, may already be minimal. Maas et al. reported that patients experiencing substantial tumor regression (and a complete response) achieved excellent long-term outcomes, regardless of whether they received adjuvant chemotherapy.[13]

Notably, a meta-analysis focusing on patients with ypT0-2N0 rectal cancer revealed that adjuvant chemotherapy did not significantly improve OS, DFS, local recurrence, or distant metastasis rates in this subgroup.[14] However, some investigators have argued that even after experiencing marked downstaging, patients originally presenting with factors (e.g., cT4 lesions, poorly differentiated tumors, and vascular invasion) contributing to a high risk of adverse oncological outcomes might benefit from postoperative chemotherapy. In their 2020 study, Zhang et al. reported that adjuvant chemotherapy might be selectively beneficial for patients with initial clinical T4 disease, even if they exhibit a favorable response to nCRT and are downstaged at final pathology. These findings indicate that a one-size-fits-all approach may not be ideal and that risk-adapted strategies should be applied to achieve more effective stratification of patients on the basis of initial risk factors.[15] However, in our study, we did not identify any specific risk factor (e.g., initial cT stage, age, gender, distance to the anal verge, or number of retrieved lymph nodes) that predicted a patient subgroup clearly benefitting from adjuvant chemotherapy. In our study, all patients classified as having cT4 cancer received adjuvant chemotherapy. Patients with a higher initial T stage had a higher tendency to receive adjuvant chemotherapy. The tendency may introduce bias, preventing us from identifying risk factors for predicting patients who may benefit from adjuvant chemotherapy.

For patients with pathologic complete response after nCRT, the benefit from adjuvant chemotherapy is also unclear. Patricio M. Polanco et al. reported that better 5-year OS was found in adjuvant chemotherapy group compared to postoperative observation group, especially in patients with cT3/4 and node-positive disease.[16] On the other hand, Fang He et al. reported that 1041 pCR individuals treated with or without adjuvant chemotherapy had similar 3-year OS and 3-year DFS.[17] In our study, adjuvant chemotherapy did not improve OS and DFS in patients with pCR.

In the context of ypT0-2N0 rectal cancer, the potential adverse effects and toxicities of adjuvant che-

motherapy become more relevant. Adjuvant treatment can impair quality of life by causing adverse events such as neuropathy, persistent fatigue, and gastrointestinal disturbances. In older or frail patients, these toxicities may exacerbate preexisting conditions (e.g., heart failure and renal insufficiency) or reduce functional independence.[18] Therefore, selectively sparing older patients from adjuvant chemotherapy when their risk of recurrence is low could improve their quality of life while preventing complications associated with overtreatment.

This study has several limitations that warrant discussion. The retrospective nature of the study introduces potential biases, including selection bias and confounding effects, that may affect the validity of the study results. Furthermore, the small sample size limits the statistical power of our study, and we may not have been able to detect smaller differences in survival outcomes.

Overall, our study results align with a growing body of literature suggesting that patients with ypT0-2N0 rectal cancer might not require routine adjuvant chemotherapy to achieve optimal oncological outcomes. Ongoing prospective trials and larger multi-institutional analyses should be conducted to clarify and refine the criteria for selecting patient subgroups who will benefit from additional systemic therapy after surgery.

Conclusions

Our data suggest that patients with rectal cancer who achieve ypT0-2N0 after nCRT and radical surgery do not derive clear survival benefits from adjuvant chemotherapy. The study findings highlight that an individualized, risk-adapted approach should be implemented rather than a one-size-fits-all strategy. Ongoing prospective investigations and larger cohort analyses are warranted to achieve more effective stratification of patients on the basis of relevant risk factors and to guide treatment decision-making.

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原　著

接受前導型放化療與根治性切除後達到降期的直腸癌患者會得益於輔助性化療嗎？

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目的　對於那些經歷了根治性切除並經過前導型放化療後實現降期的患者，輔助性化療的潛在益處仍不清楚。本研究分析了我們醫療機構的數據，以確定輔助性化療是否對這類患者群體帶來優勢，並識別預後因素。

方法　這是一項單中心的回顧性研究，納入了 37 名在 2011 年 1 月至 2019 年 10 月期間接受了前導型放化療後進行根治性切除的 ypT0-2N0 直腸癌患者。比較了輔助性化療組和非輔助性化療組之間的腫瘤學結果。統計分析使用了 Kaplan-Meier 方法、對數秩檢驗和 Cox 回歸分析。

結果　在 37 名直腸癌患者中，20 名接受了術後輔助性化療 (輔助性化療組)，17 名沒有接受 (非輔助性化療組)。兩組之間在 5 年無病生存率 (HR = 0.800, p = 0.562) 和 5 年總生存率 (HR = 1.186, p = 0.844) 方面未觀察到顯著差異。然而，初始 T 癌症分期較高的患者更傾向接受術後輔助性化療 (p = 0.051)。

結論　我們的數據顯示，在接受前導型放化療後再接受根治性手術且分期為 ypT0-2N0 的直腸癌患者中，沒有從輔助性化療中獲得明確的生存益處。這些發現強調應該實施更個性化和風險適應的治療方法，而不是通用的策略。目前仍需要進一步的前瞻性研究和更大樣本的分析，以便根據相關風險因素實現更有效的患者分類並指導治療決策。

關鍵詞　降期、直腸癌、輔助性化療。