Case Analysis

Postoperative Chemotherapy might be Indicated on Patients with Pathological Stage II Rectal Cancer after Preoperative Concurrent Chemoradiotherapy

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Key Words
Concurrent chemoradiotherapy;
Neoadjuvant chemoradiotherapy;
Postoperative chemotherapy;
Rectal cancer;
Survival

Purpose. Preoperative concurrent chemoradiotherapy for rectal cancer increases the incidence of down-staging and pathological complete response. This study examined the hypothesis that patients with pathological stage II rectal cancer would benefit from postoperative adjuvant chemotherapy after preoperative concurrent chemoradiotherapy.
Methods. Between July 2000 and December 2004, 99 patients with clinical stage II and III rectal cancer who received preoperative concurrent chemoradiotherapy followed by radical surgery were enrolled. Preoperative concurrent chemoradiotherapy involved a radiation dosage of 45 Gy in 20 fractions and oral tegafur-uracil and leucovorin. Regimens for adjuvant chemotherapy were infusional 5-fluorouracil (3000 mg/m^2) and leucovorin (150 mg/m^2) biweekly for 12 cycles or oral tegafur-uracil (300 mg/m^2/day) and leucovorin (60 mg/day) 3 weeks per month over a 6-month period. Adjuvant chemotherapy was arranged for patients with pathological stage III cancer. Basic characteristics were analyzed using the chi-square test. Survival was examined with Kaplan-Meier curves and comparisons were performed using the log-rank test.
Results. Five-year overall survival and disease-free survival percentages were 75.0 and 57.1 for patients with pathological stage II, and 86.4 and 67.5 for patients with pathological stage III, cancers, respectively. Patients with pathological stage II rectal cancer who did not receive adjuvant chemotherapy had relatively poorer overall and disease-free survivals compared to those with pathological stage III cancer who received adjuvant chemotherapy (p = 0.058 and 0.333, respectively).
Conclusion. A large prospective study is indicated to confirm the value of adjuvant chemotherapy for patients with pathological stage II rectal cancer after concurrent chemoradiotherapy and radical surgery.
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Surgical resection for rectal cancer is currently the foundation of curative treatment. Early rectal cancer is particularly susceptible to management with this approach.[1] For advanced disease treated with sur-

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gery alone, however, the reported rate of local recurrence approximates 10-30%.[2,3] When administered preoperatively, concurrent chemoradiotherapy (CCRT) or radiotherapy alone can decrease local recurrence.[4-6] Preoperative CCRT has been found effective with respect to tumor down-staging (DS) and pathological complete response (pCR).[7] In contrast, findings regarding the survival benefit of preoperative CCRT have been inconsistent.[8,9]

Adjuvant chemotherapy has been shown to increase the survival rate for patients with pathological stage III colon cancer and is therefore indicated for this form of cancer.[10] In contrast, the value of adjuvant chemotherapy in stage II colon cancer has not been established.[10,11] The value of adjuvant chemotherapy in stage II rectal cancer is similarly unclear, especially for those patients who have received preoperative CCRT. Because the final pathological staging of rectal cancer after CCRT is influenced by CCRT, such staging is not considered accurate. An evaluation of the extent to which prognosis is determined by pathological staging of rectal cancer after CCRT is therefore required. Some investigators have suggested that postoperative chemotherapy may not be necessary for patients with pathological stage 0 and I rectal cancer after CCRT and radical surgery.[12,13] However, the possibility that adjuvant chemotherapy is of value for patients with pathological stage II rectal cancer who received preoperative CCRT has not been adequately explored. The present study was performed to test that possibility.

Materials and Methods

Patients

Between July 2000 and December 2004, 99 patients diagnosed with clinical stage II or III rectal adenocarcinoma and who received preoperative CCRT and radical surgery were included in this study. Clinical data was collected prospectively, computerized, and retrieved for analysis. Patients who received local excision or who did not complete the required radiation course were excluded. Fig. 1 presents the consort diagram for the patient collection process. Patients who underwent clinical staging with pelvic MRI or CT scans also underwent chest CT and abdominal ultrasonography to exclude the possibilities of liver, intra-abdominal, or lung metastases.

Methods

All images of pelvic MRI or CT scans were interpreted by teams of gastrointestinal radiologists who recorded the depth of rectal wall invasion (T) and the extent of lymphadenopathy (N). Tumor-involved lymph nodes were classified by the criteria of size.[14,15]

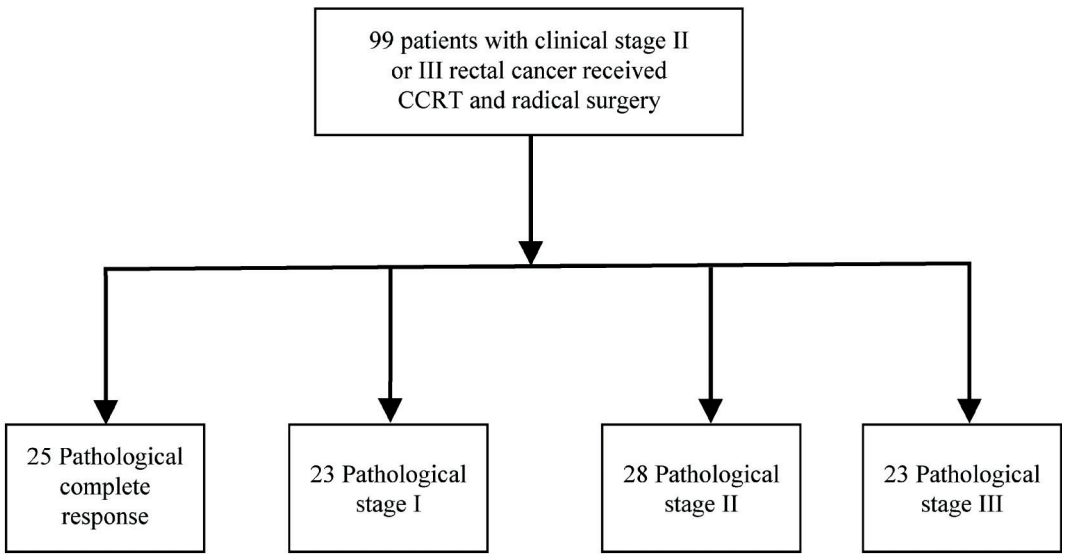


Fig. 1. Consort diagram of patients collection process.

Nodal sizes in excess of 5 mm in diameter were reported as nodal metastases.

Radiation therapy (RT) was administered with a linear accelerator producing 10 MV X-rays (Clinac 2100 C, 2100 CD, Varian, Palo Alto, CA). The entire pelvis was treated daily with AP-PA plus bilateral portals. To exclude the small bowel from the radiation volume, patients were routinely treated in the prone position with a belly board. A three-dimensional conformal technique was used. RT was delivered once per day, 5 days per week, with a 2.25-Gy fraction. The total dose over 4 weeks was 45 Gy. For T4 disease, a boost with 5.4 Gy/3 fractions was given.

Concurrent chemotherapy with oral tegafur-uracil (UFUR) at a 1:4 molar ratio (TTY Biopharm, Taipei, Taiwan) was administered throughout the entire course of RT (days 1-28). Initially, UFUR was administered at 200 mg/m^2/day in three divided doses. To potentiate the effects of UFUR, oral leucovorin (LV, Wyeth Lederle Laboratories, Taipei, Taiwan) was administered at 45 mg/day in three divided doses. Another 28-day cycle of oral chemotherapy was given on days 36-63 with UFUR administered at 250 mg/m^2/day and LV administered at 45 mg/day.

Surgical resection was scheduled at 6 to 8 weeks after completion of RT. The 2 cm distal margin rule was followed, and total mesorectal excision (TME) was performed for all patients. Pathological stages were determined and compared with the initial clinical stages. Patients were followed post-operatively every 3 months during the first 2 years and every 6 months thereafter.

Adjuvant chemotherapy was administered to patients with pathological stage III cancer at one month after radical surgery. Two adjuvant chemotherapy regimens were applied. The first involved administration of infusional 5-fluorouracil (5-FU, 3000 mg/m^2) and LV (150 mg/m^2) for 48 h biweekly for a total of 12 cycles. The second involved administration of oral UFUR (300 mg/m^2/day) and LV (60 mg/day) in three divided doses for 3 weeks per month for a period of 6 months.

The extent of DS after CCRT was obtained by comparing the pathological stage with the pre-radiation clinical stage, for both the T and N stages. pCR was defined as the absence of malignant cells in the resected specimen after CCRT and radical surgery. Pathological features were defined according to the College of American Pathologists consensus statement.[16] Local recurrence was identified by digital examination or an imaging study followed by punch or CT-guided needle biopsy. Distant metastases were defined as the appearance of new lesions in various parts of the body as located by imaging studies (CT, MRI, or positron emission tomography [PET] scan).

Statistical analyses

The Independent-Sample T test was used to analyze differences between the two groups of patients in the age of onset of rectal cancer and in the distance of the tumor proximal to the anal verge. The primary end point of this study, namely survival, was constructed using the Kaplan-Meier method, and differences were compared using the log-rank test. The distributions of each clinicopathological feature among patients with pathological stage II and III cancers were compared using the chi-square test. p values < 0.05 were defined as statistically significant (SPSS for Windows version 16.0).

Results

Between July 2000 and December 2004, 99 patients diagnosed with clinical stage II or III rectal adenocarcinoma received preoperative CCRT and radical surgery. The basic characteristics of these 99 patients are presented in Table 1. Twenty-eight patients were diagnosed with pathological stage II cancer and 23 patients with pathological stage III cancer. The percentages of DS and pCR were 67.7 and 25.3, respectively.

The general characteristics of patients with pathological stage II and III cancers are summarized in Table 2. Compared with pathological stage II cancer patients, those with pathological stage III cancer had a higher rate of clinical stage III disease ($p = 0.02$) and a higher percentage of receipt of adjuvant chemotherapy ($p < 0.01$).

Adjuvant chemotherapy

Twenty-three patients with pathological stage III disease were scheduled for postoperative adjuvant

Table 1. Basic characteristics in 99 patients with pre-op CCRT followed by radical surgery

Case number	99
Age, year, mean ± S.D.	62.6 ± 11.8
Tumor location, cm, mean ± S.D. (Distance from anal verge)	5.48 ± 1.73
Male gender	71 (71.7)
Clinical stage	
Stage II	26 (26.3)
Stage III	73 (73.7)
Type of resection	
Abdominoperineal resection	22 (22.2)
Low anterior resection[a]	77 (77.8)
Down staging	67/99 (67.7)
pCR	25/99 (25.3)
Pathological stage	
Stage 0	25 (25.3)
Stage I	23 (23.2)
Stage II	28 (28.3)
Stage III	23 (23.2)
T stage	
T0	25 (25.3)
T1	3 (3.0)
T2	23 (23.2)
T3	42 (42.4)
T4	6 (6.1)
N status	
Negative	76 (76.8)
Positive	23 (23.2)

S.D., standard deviation. a. Colorectal or coloanal anastomosis.

chemotherapy. However, only 78.3% (18/23) of these patients completed the course of postoperative adjuvant chemotherapy. Six patients received oral UFUR and LV and 12 patients received infusional 5-FU and LV. Five pathological stage III disease patients who did not receive adjuvant chemotherapy declined the treatment due to fear of toxicity from chemotherapy. Only one patient with pathological stage II cancer received adjuvant postoperative chemotherapy with oral UFUR and LV; the decision to administer the therapy to this patient was based on pathological findings indicating lymphovascular invasion of the cancer.

Local recurrence and distant metastases

The median follow-up time of patients with pathological stage II disease was 62.9 months (range, 3.1-102.7) and with pathological stage III disease was 68.6 months (range, 3.2-100.3). No significant differences were observed between these two groups in the total recurrence rate (including local recurrence or distant metastases, $p = 0.81$, Table 3) or in the time to relapse ($p = 0.29$, Table 3).

Table 2. Basic characteristics in patients with pathological stage II and III

Pathological stage	Stage II	Stage III	*p* value
Case number	28	23	
Age, year, mean ± S.D.	61.4 ± 10.6	58.1 ± 10.9	.62
Tumor location, cm, mean ± S.D. (Distance from anal verge)	5.29 ± 1.53	5.48 ± 1.65	.67
	Case number (%)	Case number (%)	
Male gender	23 (82.1)	14 (60.9)	.17
CEA (ng/ml)			.55
≥ 5	15 (53.6)[a]	9 (40.9)	
< 5	13 (46.4)[a]	13 (59.1)	
Clinical stage			.02
Stage II	8 (28.6)	1 (4.3)	
Stage III	20 (71.4)	22 (95.7)	
Type of resection			.17
Abdominoperineal resection	6 (21.4)	10 (43.5)	
Low anterior resection	22 (78.6)	13 (56.5)	
Pathological characteristics			
T stage			.273
T1	0 (0)	1 (4.3)	
T2	0 (0)	2 (8.7)	
T3	25 (89.3)	17 (73.9)	
T4	3 (10.7)	3 (13.0)	
Number of lymph node harvested, Median (range)	15 (4-38)	14 (6-32)	.78
R0 resection[b]	28 (100.0)	22 (95.7)	.27
Poor differentiation	1 (3.6)	2 (8.7)	.43
Mucinous component (> 50%)	1 (3.6)	4 (17.4)	.10
Percentage of adjuvant chemotherapy	1 (3.6)	18 (78.3)	< .01

a. CEA value before treatment. b. Lateral margin is more than 1 mm and bilateral cut ends are histologically free of tumor.

Table 3. Local recurrence or distant metastases in patients with pathological stage II and III

	Preoperative chemoradiotherapy		*p* value
	Stage II	Stage III	
Case number (%)	28	23	
Total recurrence[a]	13 (46.4)	9 (39.1)	.81
Local recurrence[b]	4 (14.3)	2 (8.7)	.54
Distant metastases[c]	12 (42.9)	9 (39.1)	1.00
Time to relapse, months, median (range)	22.4 (6.73-70.7)	28.1 (9.5-56.0)	29

a. Includes local recurrence or distant metastases. b. Tumor recurrence at anastomotic line, regional soft tissue or lymph nodes.
c. Tumor recurrence in liver, lung, peritoneum, bone, brain, ovary, inguinal or remote lymph nodes.

Overall survival, disease-free survival (DFS) and cancer-specific survival

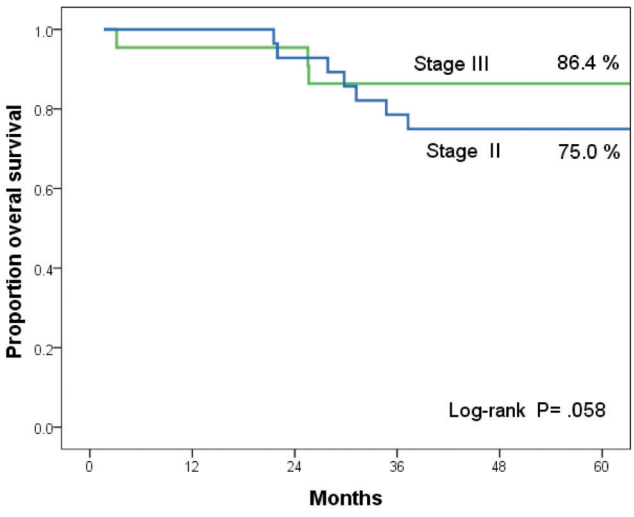
Sixty-six percent (34/51) of the participants were followed for at least 5 years. A total of 13 patients died during the follow-up period. No patient death was related to surgical mortality. One patient died at 84 months post-surgery because of another cancer.

The 5-year overall survival rate was 75.0% (21/28) for patients with pathological stage II and 86.4% (20/23) for those with pathological stage III disease (Fig. 2). Patients with pathological stage III disease had a relatively higher overall survival rate compared to those with pathological stage II disease ($p = 0.058$). Patients with pathological stage III cancer had a hazard ratio (HR) of 0.30 (95% confidence interval [CI], 0.08-1.12) for death compared with those with stage II cancer. Similar trends were also observed with respect to DFS ($p = 0.333$) and cancer-specific survival ($p = 0.097$) although statistical significance was not reached (Figs. 3 and 4).

Discussion

In our practice, postoperative chemotherapy was not routinely recommended for patients with pathological stage II rectal cancer following receipt of CCRT and radical surgery except when risk factors were identified. In particular, adjuvant chemotherapy was arranged for such patients only when pathological lymph node metastasis was present. A similar approach is traditionally taken for patients with stage II colon carcinoma.[12] Nonetheless, findings of the present study question this approach for patients with pathological stage II rectal cancer.

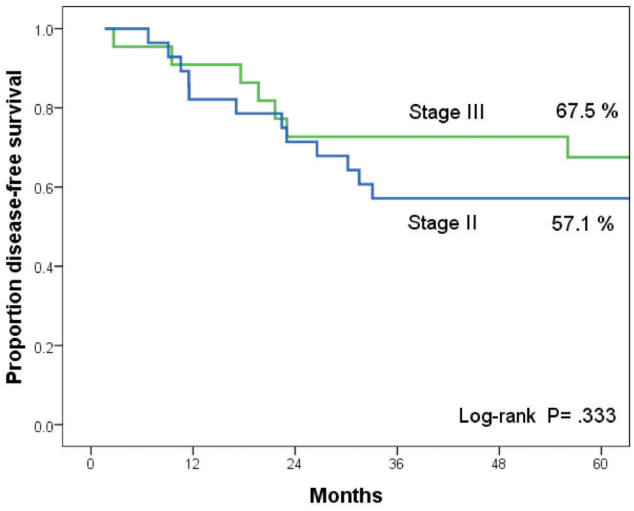
Although prospective randomized studies do not support the benefit of adjuvant chemotherapy in rectal cancer after CCRT, most experts favour this approach, especially for patients with pathological lymph node involvement. In one retrospective study,[17] patients with pathological stage II or III rectal cancer after CCRT who received postoperative adjuvant chemotherapy had significantly greater survival rates compared to those who did not receive adjuvant chemotherapy. In contrast, adjuvant chemotherapy was found to provide no significant survival benefit for patients with pathological stage 0 and I disease after CCRT. Another retrospective study[12] also failed to provide evidence that postoperative chemotherapy in-



No. at risk

Pathological stage III	23	20	20	18	17	16
Pathological stage II	28	28	25	21	19	16

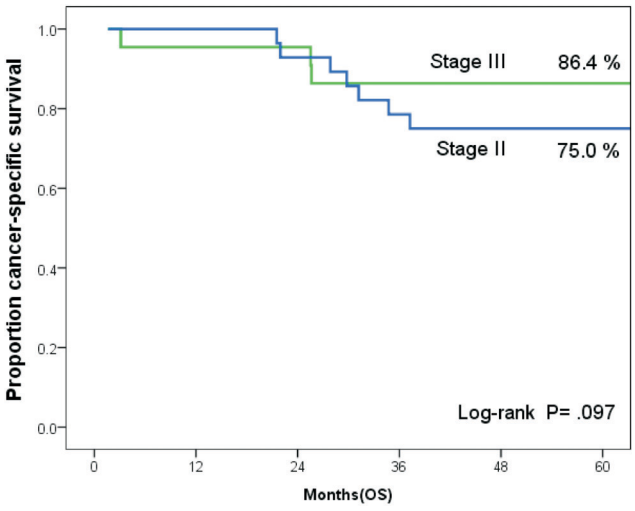
Fig. 2. Overall survival in patients with pathological stage II and III.



No. at risk

Pathological stage III	23	19	15	15	15	12
Pathological stage II	28	22	19	25	14	14

Fig. 3. Disease-free survival in patients with pathological stage II and III.



No. at risk

Pathological stage III	23	20	20	18	17	16
Pathological stage II	28	27	25	21	19	16

Fig. 4. Cancer-specific survival in patients with pathological stage II and III.

creases survival for patients with ypT0-2N0 rectal cancer after CCRT. According to the guidelines of the NCCN,[18] all rectal cancer patients who receive preoperative CCRT should receive 5-FU-based postoperative adjuvant chemotherapy. However, this recommendation requires validation by large prospective randomized trials.

In the present study, patients with pathological stage II rectal cancer tended to have poorer survival rates as compared to patients with stage III disease. This finding supports the proposal that the presence of pathological stage II after CCRT indicates a poor prognosis due to initially locally advanced disease and, probably, the presence of true stage III disease. More aggressive treatment for this group of patients should be seriously considered.

Several adjuvant chemotherapy regimens[19-21] have been employed for patients with rectal cancer who have received CCRT and radical surgery. However, the regimen(s) providing optimal benefit and the time period(s) over which this regimen should be administered remain to be established. These questions are further complicated by the variety of chemotherapy and radiation regimens that may be used during the preoperative as well as postoperative periods.

Certain limitations of this study should be addressed. First, this is not a prospective randomized study. Second, no control group was available for patients with pathological stage II rectal cancer, excepting the one patient receiving adjuvant chemotherapy because of evidence for lymphovascular invasion of the cancer. The control group was lacking because it was not our policy to recommend adjuvant chemotherapy for patients with pathological stage II rectal cancer in the absence of risks factors. Third, the number of subjects in each of the two study groups was relatively small. Finally, the adjuvant chemotherapy for this field was not uniform.

In conclusion, patients with pathological stage II rectal cancer after CCRT and radical surgery who did not receive adjuvant chemotherapy had a relatively poorer overall survival and DFS values compared to those with pathological stage III after CCRT who received adjuvant chemotherapy. The difference in overall survival between the two groups did not reach statistical significance. Whether adjuvant chemotherapy should be used for patients with pathological stage II rectal cancer after CCRT and radical surgery clearly requires further evaluation by a large prospective study.

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病例分析

術後化學藥物治療對於接受手術前合併電療及化療的第二期直腸癌病人之影響

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目的 對於直腸癌的病人，術前合併電療及化療可以增加腫瘤期數降底及腫瘤細胞完全消失的機會，這次的研究主要是要驗證這個假說，接受手術前合併電療及化療的第二期直腸癌病人，對於再接受手術後化學藥物治療是有好處的。

方法 從 2000 至 2004 年期間，共收集有 99 位臨床上為第二期及第三期的直腸癌病人，接受合併電療、化療及根除性手術。電療及化療包括放射線 45 Gray 共分 20 次，合併口服藥物 Tegafur-uracil 和 leucovorin，術後的輔助性化學藥物治療，包括注射 12 次的 5-FU 和 leucovorin，或是每個月口服化學藥物 Tegafur-uracil 和 leucovorin 三週，為期共六個月，術後病理為第三期的直腸癌病人，都會安排輔助性化學藥物，病人的基本特性及存活率分析是利用 chi-square 及 log-rank 的分析方法。

結果 病理為第二期的直腸癌病人，五年的總存活率及無疾病復發存活率分別為 75% 及 57.1%，而病理為第三期的直腸癌病人，五年的總存活率及無疾病復發存活率分別為 86.4% 及 65.7%，病理為第二期的直腸癌病人沒有接受化學藥物治療，比病理為第三期的直腸癌病人有接受化學藥物治療，五年的總存活率及無疾病復發存活率相對來說還要差一點 (p = 0.058 and 0.333)。

結論 是否病理為第二期的直腸癌病人需要接受化學藥物治療，還需要進一步大規模且前瞻性的研究來證實。

關鍵詞 合併電療及化療、術前電療合併化療、術後化學藥物治療、直腸癌、存活率。