

Original Article

Should Rectosigmoid Junction Cancer be Classified as Colon or Rectal Cancer in pT1-3N+M0 Cases? Clinical Results of Different Adjuvant Therapeutic Modalities

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Key Words

pT1-3N+M0 rectosigmoid colon cancer;

Concurrent chemoradiotherapy;

Adjuvant chemotherapy (FOLFOX);

Prognosis

Purpose. The optimal treatment approach for adenocarcinoma of the rectosigmoid junction remains unclear. This study aimed to compare the outcomes of different treatment modalities in treating pT1-3N+M0 rectosigmoid junction cancer.

Methods. This retrospective study enrolled 104 patients who had undergone radical surgery of the primary tumor with a pathologic diagnosis of adenocarcinoma of the rectosigmoid junction (T1-3N+M0) in Chi-Mei Hospital between January 2007 and December 2015. Twenty-four patients received adjuvant concurrent chemoradiotherapy (CCRT) after radical surgery and 80 patients received adjuvant chemotherapy (FOLFOX). The clinicopathologic features, recurrence patterns, and prognosis of the two groups were analyzed and compared.

Results. Significant differences were found in clinical and pathologic N status between the two groups (41.67% vs. 16.25%, $p = 0.0306$; 58.33% vs. 33.75%, $p = 0.0354$, respectively). No significant differences were found in the other observed parameters. Distant metastases were the most common recurrence pattern in both groups (90.91% vs. 73.91%, $p = 0.3844$). No significant differences were shown in duration of follow-up, recurrence rate and type; and overall, cancer-free, and cancer-specific survival between the two groups.

Conclusion. No differences in overall, cancer-free, and cancer-specific survival are observed between patients receiving CCRT and FOLFOX adjuvant therapeutic modalities for treating pT1-3N+M0 rectosigmoid colon cancer.

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In Taiwan, colorectal cancer (CRC) is the most common cancer and the third most frequent cause of cancer-related deaths. Over the last few decades mortality related to colorectal cancer has decreased. This decrease has been attributed to advances in multimodal screening as well as the increased availability

of effective treatment regimens. Despite these advances, colorectal cancer is projected to account for an estimated 5722 deaths in Taiwan in 2016.¹ About 35% of patients diagnosed with colorectal cancer present with locally advanced tumors classified as Stages II and III using American Joint Committee on Cancer

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(AJCC) criteria, and have an estimated 5-year survival rate of 71.1%.² Although colon and rectal adenocarcinoma are often grouped as a common entity, notable differences exist in the natural history and treatment strategies between the two cancers. For locally advanced colon cancer, current evidence supports the use of resection with curative intent with adjuvant chemotherapy,^{3,4} while neoadjuvant chemoradiation with definitive surgery is the standard of care for locally advanced rectal cancer.^{5,6} The American Society of Colorectal Surgeons recommends either pre- or postoperative adjuvant therapy for upper-third rectal cancers.^{8,9} However, the optimal treatment approach for adenocarcinoma of the rectosigmoid junction (the transition zone between the distal sigmoid colon and the upper rectum) remains unclear. Few studies have directly compared different treatment outcomes for pT1-3N+M0 rectosigmoid junction colon cancer. Therefore, the purpose of this study was to analyze the different long-term outcomes of patients with cancers of the rectosigmoid junction who had been treated with two separate treatment modalities in Chi-Mei Hospital from 2007-2015 and to clarify potential differences in prognosis between the different adjuvant therapeutic modalities.

Patients and Methods

Patients

This retrospective study recruited eligible patients from a total of 491 patients who were diagnosed with rectosigmoid junction cancer in Chi-Mei Hospital between January 2015 and December 2019. Of these, 463 had undergone definitive treatment. Each patient had a colonoscopy and biopsy to locate the tumor and to confirm the histologic diagnosis. The clinical stage of the tumor was determined before treatment via computed tomography (CT) scan or magnetic resonance imaging (MRI) of the abdomen and pelvis. If necessary, chest CT and liver ultrasonography (US) were performed to exclude the presence of distant metastases. Fifty-two patients received neoadjuvant CCRT first, and the other 411 patients underwent radical surgery first. Among the 411 patients, 177 were diagnosed with stage III

rectosigmoid junction colon cancer. Finally, 104 patients with rectosigmoid cancers, defined as tumors that were located 15~18 cm from the anal verge with a pathologic diagnosis of adenocarcinoma (stage T1-3N+M0), were enrolled in this study (Fig. 1).

Methods

All data in this study were obtained from the Cancer Registry Database, the Cancer Center of Chi-Mei Hospital, and patient charts, and were analyzed retrospectively. All included patients who were diagnosed with pT1-3N+M0 rectosigmoid junction cancer were discussed by our multidisciplinary team regarding the next treatment protocol. Patients with rectosigmoid colon cancer classified as rectal cancer would receive adjuvant CCRT (long-course radiotherapy) and then 8 courses of FOLFOX-4. Patients with rectosigmoid colon cancer classified as colon cancer would receive adjuvant chemotherapy (12 courses of FOLFOX-4). We then analyzed the clinicopathologic characteristics and demographic features, such as age, gender, peri- and post-operative complications, primary tumor size, pathologic T/N status, the number of harvested lymph nodes, recurrence rate, recurrence pattern, and prognosis. All patients were followed for at least 3 years from the date of diagnosis. The end of follow-up was 31 December 2019.

Surgical technique

All of the patients had pre-operative bowel preparation. Conventional or laparoscopic low anterior resections were performed as follows: first, the inferior mesentery artery was ligated and divided at its origin; second, the rectum was sharply mobilized along the anatomic plane to maintain the integrity of the mesorectum. There was no patient received complete total mesorectal excision in both groups, but partial mesorectal excision had been performed to achieve an adequate distal margin ≥ 5 cm.

Adjuvant chemotherapy group

Patients with rectosigmoid junction cancer classified

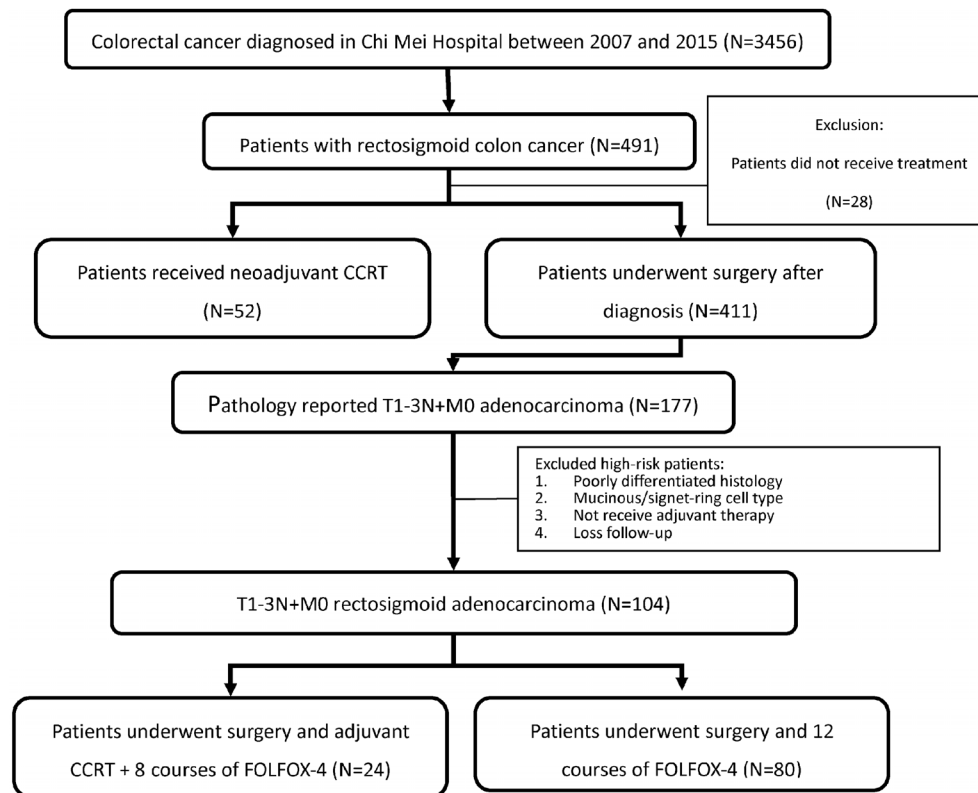


Fig. 1. Diagram of study flow.

as colon cancer received 12 courses of FOLFOX-4. Standard FOLFOX-4 consists of 2-hour intravenous infusion of oxaliplatin (85 mg/m²) on day 1, and 2-hour intravenous drip infusion of calcium folinate (200 mg/m²) on days 1-2, followed by intravenous injection of 5-FU (400 mg/m²) and continuous infusion of 5-FU (600 mg/m²) lasting 22 hours on days 1-2, every 2 weeks.

Adjuvant chemoradiotherapy group

Patients with rectosigmoid junction cancer classified as rectal cancer underwent post-operative radiotherapy with a total dose of 5040 cGy in 25 fractions given over a period of 5 weeks with a concurrent 24-hour continuous infusion of 5-fluorouracil (5-FU). After complete of CCRT, the patient received another 8 courses of FOLFOX-4.

Statistical analysis

Continuous data are represented as means and standard deviations, and comparisons between the

groups were made using a two-sample t-test. Categorical data are presented by count and percentage and compared using a chi-square or Fisher's exact test, as indicated. The survival curves are presented using the Kaplan-Meier method with the log-rank test for comparing differences between the two groups. All data were analyzed using SAS 9.4 (SAS Institute Inc., Cary, NC, USA). The Kaplan-Meier curves were plotted using STATA (version 12; Stata Corp., College Station, TX, USA). Statistical significance was established as $p < 0.05$.

Results

Patients and clinical data

A total of 104 patients were enrolled in this study. Twenty-four patients with rectosigmoid junction cancers were classified as rectal cancer and received adjuvant CCRT + 8 courses of FOLFOX-4 after surgery. The other 80 patients with rectosigmoid junction can-

cers were classified as colon cancer and received 12 courses of FOLFOX-4 after surgery. Significant differences were found in distribution of clinical and pathologic N status between the two groups (41.67% vs. 16.25%, $p = 0.0306$; 58.33% vs. 33.75%, $p = 0.0354$, respectively). Additional clinical data are shown in Table 1. No significant differences were found in the other observed parameters between the two groups.

Recurrence and survival

The mean follow-up for all patients was 57.17 ± 27.75 months, including 55.43 ± 24.58 months in the

surgery with adjuvant CCRT group, and 57.69 ± 28.57 months in the surgery with adjuvant chemotherapy group ($p = 0.7055$; Table 2). Eleven patients (11/24 [45.83%]) in the surgery with adjuvant CCRT group and 23 patients (23/80 [28.75%]) in the surgery with adjuvant chemotherapy group developed local or distant recurrences ($p = 0.1400$). In the surgery with adjuvant CCRT group, one patient had local recurrence and ten patients had distant metastasis. In the surgery with adjuvant chemotherapy group, six patients developed local recurrences and seventeen patients developed distant metastases. The surgery with adjuvant CCRT group had 1-, 3-year, and 5-year overall sur-

Table 1. Demographic and clinical profiles of patients with pT1-3N+M0 rectosigmoid junction cancer

Variable	Surgery with CCRT (N = 24), N (%)	Surgery with C/T (N = 80), N (%)	<i>p</i> value
Gender			> 0.9999
Male	15 (62.50)	49 (61.25)	
Female	9 (37.50)	31 (38.75)	
Age			0.1797
≤ 50 years	3 (12.50)	7 (8.75)	
51-69 years	17 (70.83)	44 (55.00)	
≥ 70 years	4 (16.67)	29 (36.25)	
Means ± SD	61.13 ± 11.88	65.30 ± 11.51	0.1368
Clinical T stage			0.8935
1	2 (8.33)	6 (7.50)	
2	7 (29.17)	22 (27.50)	
3	15 (62.50)	48 (60.00)	
4	0 (0.00)	4 (5.00)	
Clinical N stage			0.0306
0	8 (33.33)	45 (56.25)	
1	6 (25.00)	22 (27.50)	
2	10 (41.67)	13 (16.25)	
Pathology T stage			0.1802
2	1 (4.17)	13 (16.25)	
3	23 (95.83)	67 (83.75)	
Pathology N stage			0.0354
1	10 (41.67)	53 (66.25)	
2	14 (58.33)	27 (33.75)	
Number of LN harvest			0.1347
Means ± SD	22.17 ± 7.03	19.66 ± 7.07	0.1347
Tumor size			0.6045
≤ 5 cm	16 (66.67)	59 (73.75)	
> 5 cm	8 (33.33)	21 (26.25)	
Distal margin			0.3458
Means ± SD	3.32 ± 1.72	3.40 ± 1.32	0.3458
Peri- and post-operative complications			0.3820
Yes	3 (12.50)	5 (6.25)	
No	21 (87.350)	75 (93.75)	

Table 2. Recurrence and survival

	Surgery with CCRT (N = 24), N (%)	Surgery with C/T (N = 80), N (%)	<i>p</i> value
Mean follow-up (months)	55.43 ± 24.58	57.69 ± 28.75	0.7055
Recurrence			0.1400
Yes	11 (45.83%)	23 (28.75%)	
Recurrence type			0.3844
Local recurrence	1 (9.09%)	6 (26.09%)	
Distant recurrence	10 (90.91%)	17 (73.91%)	
Overall survival rate	75.87%	68.37%	
1 year	100%	97.50%	-
3 year	91.67%	83.19%	0.2300
5 year	75.87%	68.37%	0.8943
5-year cancer-free survival rate	50.70%	63.63%	0.2970
1 year	79.17%	92.50%	0.1297
3 year	62.22%	73.31%	0.8599
5 year	50.70%	63.63%	0.2970
5-year cancer-specific survival rate	75.87%	78.23%	0.9716
1 year	100%	98.73%	-
3 year	91.67%	88.96%	0.9727
5 year	75.87%	78.23%	0.9716

vival rates of 100%, 91.67%, and 75.87%, respectively; the corresponding rates were 97.50%, 83.19%, and 68.37%, respectively, in the surgery with adjuvant chemotherapy group (Fig. 2). No significant differences were found in 5-year overall survival between the two groups ($p = 0.8943$). As shown in Figs. 3 and 4, the 5-year cancer-free and cancer-specific survival in the surgery with adjuvant CCRT group (50.70% and 75.87%, respectively) were not significantly higher ($p = 0.2970$ and $p = 0.9716$, respectively) than corresponding rates in the surgery with adjuvant chemo-

therapy group (63.63% and 78.23%, respectively).

Discussion

Recto-sigmoid junction (RSJ), a segment of bowel between sigmoid colon and rectum, has its own special characteristics. On physiological and functional aspects, it had been proved as a physiological and anatomical sphincter, coordinating stool passage with sigmoid colon and rectum.¹⁰ Under histological exam,

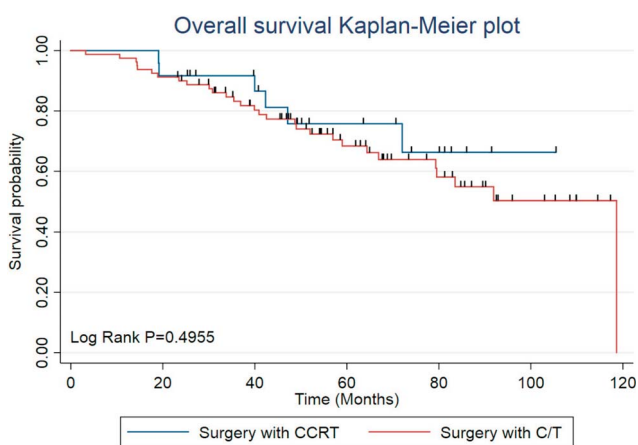


Fig. 2. Kaplan-Meier estimates of overall survival for patients with pT1-3N+M0 rectosigmoid junction cancer.

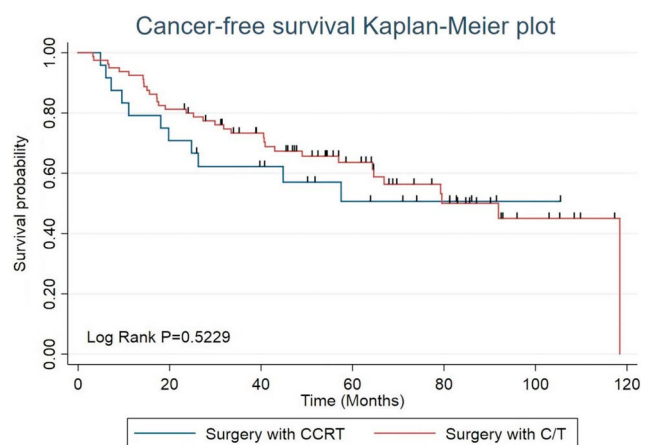


Fig. 3. Kaplan-Meier estimates of cancer-free survival for patients with pT1-3N0+M0 rectosigmoid junction cancer.

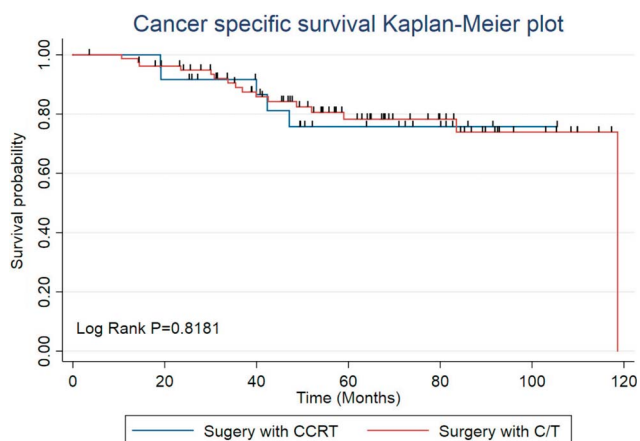


Fig. 4. Kaplan-Meier estimates of cancer-specific survival for patients with pT1-3N+M0 rectosigmoid junction cancer.

it shows more muscularis mucosa, vasculature, lymphocyte aggregation and higher nervous innervation.¹¹ Neither sigmoid nor rectum has these unique microscopic patterns. On embryology, RSJ originates from endoderm, as same as sigmoid colon, and is different from rectum, which develops from ectoderm.¹² About arterial supply, inferior mesenteric artery provides left side colon from distal transverse colon to upper rectum. On the other hand, lower rectum is supplied by internal iliac artery.¹³ In cancerous disease, cancer grown from colon to upper rectum, including sigmoid colon, tend to metastasize to liver. However, in lower rectal cancer, lung metastasis is more than liver metastasis.¹⁴⁻¹⁷ Considering all above evidences, we think RSJ should be considered as an independent part, not belong to sigmoid colon or rectum. But when it comes to malignant diseases, grouping RSJ and sigmoid colon together may be more suitable, because of the similar disease process.

The question of whether carcinomas located in the rectosigmoid junction should be treated as colon cancers or as rectal cancers remains unanswered because there are currently no consensus guidelines for the management of rectosigmoid cancers. Both national guidelines and randomized trials suggest that neoadjuvant chemoradiation followed by total mesorectal excision in 6-8 weeks is the standard of care for locally advanced rectal cancer.^{5,6} Despite this guideline, a clear gap exists between the guidelines and clinical practice. The reality is that very few rectosigmoid

junction cancer patients will receive neoadjuvant CCRT. In our series, only 11.23% of patients (52/463) received neoadjuvant CCRT. Rectosigmoid colon tumors are located above the peritoneal reflection. The surgical technique to removal of the intraperitoneal lesion is not difficult for well-trained surgeons. Otherwise, we typically performed a diverting ostomy in neoadjuvant CCRT patients, since a temporary stool diversion could avoid immediate complications such as anastomosis leakage or intraperitoneal abscess. Patients generally needed to receive another operation to restore the continuity of bowel several months later. Most patients resist stoma creation; thereafter, the true situation was that most patients with clinical stage II or III rectosigmoid colon cancer underwent surgery directly after undergoing a complete staging survey. This fairly standard process may explain why a lower percentage of patients with rectosigmoid junction cancer received neoadjuvant CCRT (11.23%) in our hospital.

In Taiwan, many surgeons claim that patients with rectosigmoid junction cancers should be treated identically to colon cancer patients. In other words, pT1-3N+M0 rectosigmoid junction cancer should receive adjuvant chemotherapy with FOLFOX regimen. However, some medical oncologists and radiation oncologists insist that the rectosigmoid junction cancer should be treated identically to rectal cancer. According to the NCCN guidelines, patients with pathologic T1-3N+M0 rectal cancer should receive adjuvant CCRT.¹⁸ The aim of this study was to clarify potential differences in prognosis between different adjuvant therapeutic modalities for patients with pT1-3N+M0 rectosigmoid junction colon cancer. After a mean follow-up of 57.17 ± 27.75 months, the overall recurrence rate was 32.69% (34/104) in our series. We found no significant differences in the percentage of recurrence between the two groups (45.83% vs. 28.75%, $p = 0.7209$) and no significant statistical differences in overall, cancer-free, and cancer-specific survival between the two groups. In our series, 25.96% of patients (27/104) developed distant metastases (10 in the surgery with CCRT + FOLFOX group [41.67%] and 17 in the surgery with FOLFOX group [21.25%]). Distant metastasis was the major recurrent pattern in

the surgery only group, and we know that CCRT has no effect on distant recurrences. Therefore, to reduce distant metastases and improve prognosis, we should consider adjuvant chemotherapy instead of adjuvant CCRT. Even if we applied adjuvant CCRT after radical surgery, although local recurrence may be improved, there was no way to reduce distant metastases. In addition, pre-operative chemoradiotherapy, as compared with post-operative chemoradiotherapy, improved local control and was associated with reduced toxicity.⁵

Considering oncologic control and long-term toxicity of radiation, postoperative chemoradiotherapy was not favored. When it comes to long-term toxicity, we must mention the most important sequelae of oxaliplatin — neurotoxicity. Results of the Multicenter International Study of Oxaliplatin/5-Fluorouracil/Leucovorin in the Adjuvant Treatment of Colon Cancer (MOSAIC) trial,¹⁹ along with the initial report of National Surgical Adjuvant Breast and Bowel Project (NSABP) C-07,²⁰ showed that oxaliplatin added to fluorouracil and leucovorin significantly improved cancer-free survival and established oxaliplatin as part of the standard of care for the adjuvant treatment of colon cancer. Since 2004, oxaliplatin with combination regimens of infusional 5-fluorouracil/leucovorin (FOLFOX) has been standard adjuvant chemotherapy in patients with stage III colon cancer. Oxaliplatin is a cytotoxic agent that blocks DNA synthesis and replication. The toxicity of oxaliplatin is the result of inhibiting DNA synthesis such as replication and transcription. These mechanisms also influence normal cells, causing neurotoxicity, neutropenia, and thrombocytopenia. Oxaliplatin is associated with cumulative dose-dependent neurotoxicity, which can be debilitating for a significant number of patients in both the short and long term. The rate of neurotoxicity was recorded in more than 90% of patients who received oxaliplatin, and this neurotoxicity will persist even 2-3 years after cessation of oxaliplatin.^{21,22} In the final result of the MOSAIC study,²³ we noted that even four years after completion of therapy, 15.5% of patients had residual peripheral sensory neuropathy, but less than 1% of patients had symptoms that were graded as severe. Clinically, dose reductions and early discontinuations of oxaliplatin-based therapy are common.

Thus, another question is “can a shorter course of adjuvant FOLFOX treatment benefit patients with stage III colon cancer without a loss of efficacy and with less neuropathy”? In the present series, no significant differences were found in recurrence rate and type, overall, cancer-free, and cancer-specific survival between the two groups (adjuvant CCRT + 8 courses of FOLFOX vs. 12 courses of FOLFOX). However, because we did not perform short- and long-term neurologic assessments on patients in both groups, we couldn't evaluate the neuropathy in this retrospective study.

Our study had some limitations. First, the present study was retrospective and not a randomized control trial. Selection bias existed. For example, there was significant difference in distribution of clinical and pathologic N status, which might influence the prognosis. Second, the sample size was relatively small. Third, not all patients accepted neurologic assessments to evaluate the neuropathic effects under different courses of FOLFOX treatment.

Conclusion

Comparison of short- and long-term outcomes of different adjuvant therapeutic modalities in the management of patients with locally advanced adenocarcinoma of the rectosigmoid junction revealed that survival was similar regardless of the treatment approach adopted.

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原 著

在病理期別 T1-3N+M0 的直腸乙狀結腸連接處 惡性腫瘤應視為大腸癌還是直腸癌治療： 不同輔助性治療的臨床結果

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目的 臨床上，乙狀結腸與直腸交界處的腫瘤，因其位置應該歸類為直腸或者大腸腫瘤，目前仍有爭議。本回顧性研究目的，是要分析比較病理上診斷為 T1-3N+M0 乙狀直腸交接處腫瘤，術後接受同步化放療與接受化療的預後。

方法 從 2007 年 1 月至 2015 年 12 月，在奇美醫學中心有 177 位被診斷為乙狀直腸交界處 T1-3N+M0 腫瘤，經排除篩選後，最後有 104 名患者列入本研究。24 名病人手術後接受後續化放療治療；80 名病人手術治療接受後續化放療。我們分析比較各組的臨床病理特徵及其治療結果。

結果 手術後併輔助性同步放射及化學治療組 (CCRT + FOLFOX) 與手術後併輔助性化學治療組 (FOLFOX) 相比，患者有較高比例的臨床影像、病理診斷淋巴結轉移 (41.67% vs. 16.25%, $p = 0.0306$; 58.33% vs. 33.75%, $p = 0.0354$)。兩組在性別、年齡、臨床影像/病理診斷腫瘤侵犯範圍、採集淋巴結數量、原發腫瘤大小、切除腫瘤遠端邊緣距離，和術中/術後併發症並無顯著性差異。遠處轉移是兩組中最常見的復發模式 (90.91% vs. 73.91%, $p = 0.3844$)。兩組在追蹤時間、復發率/復發型態、總體生存率，無病生存率和癌症特異性生存率上，兩組並無明顯統計學上差異。

結論 在診斷為 T1-3N+M0 的乙狀直腸連接處之腫瘤，這兩種不同的輔助治療方式，沒有觀察到生存差異。

關鍵詞 病理期別 T1-3N+M0 的直腸乙狀結腸連接處惡性腫瘤、同步放射及化學治療、化學治療 (FOLFOX)、預後。