Original Article

Should Rectosigmoid Junction Cancer be Classified as Colon or Rectal Cancer in pT3N0M0 Cases? Clinical Results under Different Adjuvant Therapeutic Modalities

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Key Words
pT3N0M0 rectosigmoid colon cancer; Concurrent chemoradiotherapy

Abbreviations
CCRT, Concurrent chemoradiotherapy; CRC, colorectal cancer

Purpose. Whether or not rectosigmoid junction cancer should be classified as colon or rectum cancer in the classification of diseases has been a controversial issue due to tumor location. The aim of this study was to compare the different treatment modality results in pT3N0M0 rectosigmoid junction cancer.

Method. Between January 2007 and December 2015, a total of 67 patients who underwent radical surgery of the primary tumor with a pathologic diagnosis of adenocarcinoma of the rectosigmoid junction (T3N0M0) were retrospectively enrolled in this study. Fifteen patients received adjuvant concurrent chemoradiotherapy after radical surgery and the other 52 patients were observed clinically without further adjuvant therapy. The clinicopathologic features, recurrence pattern, and prognosis of the two groups were analyzed.

Result. Elder predominance was noted in the surgery only group compared with the surgery with adjuvant concurrent chemoradiotherapy group (70.42 ± 10.14 years vs. 61.07 ± 10.30 years, $p = 0.0050$). There was no significant difference in gender, co-morbidity, primary tumor size, number of lymph nodes harvested, distal margin of the resected tumor, post-operative complications, and recurrence rate between the two groups. Distant metastases were the most common recurrence pattern in both groups (50% vs. 80 %, p = 0.4545). There was no significant difference in overall, disease-free, and cancer-specific survival between the two groups.

Conclusion. Post-operative concurrent chemoradiotherapy group did not provide significant survival benefit for pT3N0M0 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, accounting for an estimated 5722 deaths in 2016.[1] Currently, after complete pre-operative staging, the main treatment for localized CRC (stages I-III) is radical resection.[2] Radical resection includes complete removal of the tumor and associated major lymphovascular pedicles of the affected colonic segment. This operative procedure provides specimens for pathologic, histochemical, and genetic testing, which

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help determine the prognosis of CRC in patients.[3] Treatment decisions and estimates of patient prognosis are largely based on assessments of tumor stage according to the tumor-node-metastasis (TNM) system. Overall, between 30% and 40% of CRC cases are classified as stage II.[4]

Whether or not carcinomas located in the rectosigmoid colon junction should be treated as colon or rectal cancers remains unanswered. The purpose of adjuvant chemotherapy is to eradicate micrometastatic disease present at the time of surgery, preventing the development of distant metastatic disease and thereby curing such patients of cancer. National and international guidelines for the adjuvant treatment of stage II colon cancer recommend observation for patients without high-risk features (poorly differentiated histology, presence of lymphovascular invasion, presence of perineural invasion, report of < 12 lymph nodes, bowel obstruction, localized perforation, or positive margins). For rectal cancer, both national guidelines and randomized trials suggest that all rectal cancers should be treated via the use of neoadjuvant concurrent chemoradiotherapy (CCRT) and radical intervention.[5] The American Society of Colorectal Surgeons recommends either pre- or post-operative adjuvant therapy for upper third rectal cancers.[6,7] Few studies exist that directly compare different treatment outcomes for lower risk pT3N0M0 rectosigmoid junction colon cancer. Therefore, we retrospectively analyzed the different long-term outcomes for patients with cancers of the rectosigmoid junction who had been treated from 2007-2015 in Chi-Mei Hospital with two separate treatment modalities.

Method

Patients

Between January 2007 and December 2015, a total of 491 patients were diagnosed with rectosigmoid junction cancer in the Chi-Mei Hospital. Patients with rectosigmoid cancers, defined as tumors that were located 15~18 cm from the anal verge with a pathologic diagnosis of adenocarcinoma (stage T3N0M0), were enrolled in this study. Of the patients, 463 underwent definitive treatment in our hospital. 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 scan or magnetic resonance imaging of the abdomen and pelvis. If necessary, a chest computed tomography scan and liver ultrasonography 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, 86 were diagnosed with stage II rectosigmoid junction colon cancer. Patients with high-risk features, such as poorly differentiated histology, presence of lymphovascular invasion, presence of perineural invasion, report of < 12 lymph nodes, bowel obstruction, localized perforation, or positive margins, were excluded. Finally, 67 patients with a lower risk of rectosigmoid junction cancer were retrospectively enrolled in this study (Fig. 1). All of these lower risk rectosigmoid junction cancer patients were discussed by our multidisciplinary team for the next treatment protocol. We then analyzed the clinicopathologic characteristics and demographic features, such as age, gender, tumor size, the number of harvested lymph nodes, distal margin of the resected tumor, peri- and post-operative complications, 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 March 2018. All data in this study were obtained from the Cancer Registry Database, the Cancer Center of Chi-Mei Hospital, and patient charts.

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-h continuous infusion of 5-fluorouracil (5-FU).

Surgical technique

All of the patients had pre-operative bowel prepa-

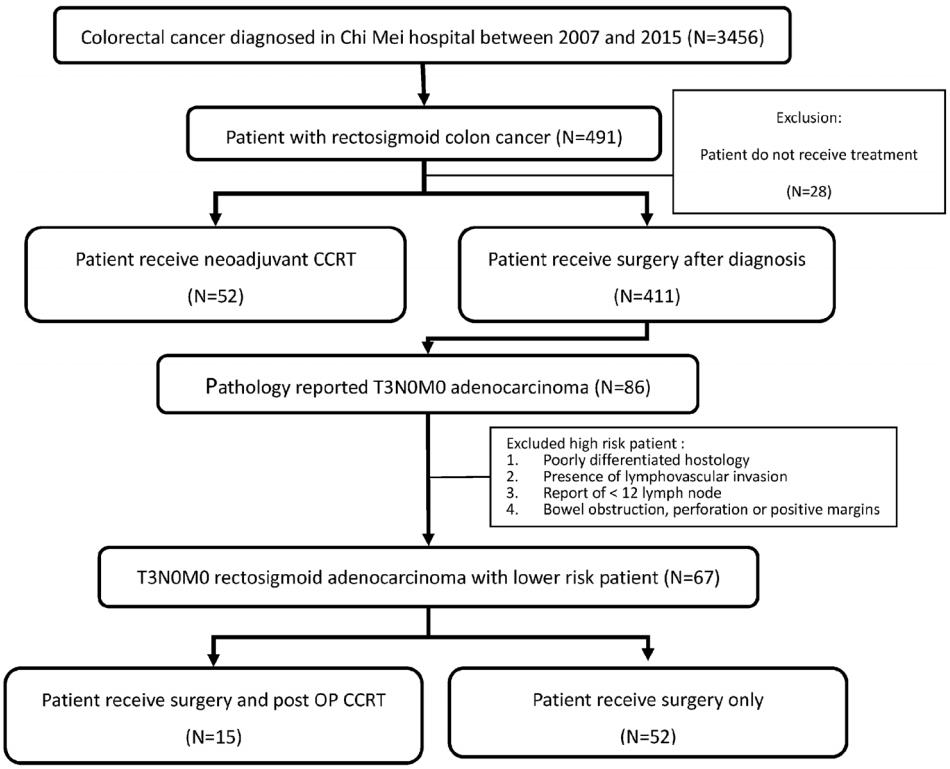

Fig. 1. Diaphragm of study flow.

rations. 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.

Statistical analysis

Continuous data are represented as the mean and standard deviation, and comparisons between the groups were made using a two-sample t-test. Categorical data were presented by count and percentage and compared using a chi-square or Fisher's exact test, as indicated. The survival curves were presented using the Kaplan-Meier method with the log-rank test for comparing the difference 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 set at a $p < 0.05$.

Results

Patients and clinical data

A total of 67 patients were enrolled in this study. Fifteen patients with rectosigmoid junction cancers were classified as rectal cancer and received adjuvant CCRT after surgery. The other 52 patients with rectosigmoid junction cancers were classified as colon and received no further adjuvant therapy after surgery. The patients had regular observation and follow-up in our outpatient department. The mean age was 68.33 ± 10.75 years and elder predominance existed in the surgery only group (61.07 ± 10.30 years vs. 70.42 ± 10.14 years, $p = 0.0050$). Additional clinical data are shown in Table 1. The clinical T stage was more advanced in the surgery only group ($p = 0.0407$). The other observed parameters showed no significant differences between the two groups.

Recurrence and survival

The mean follow-up in all patients was 62.66 ±

Table 1. Demographic profiles of patients with pT3N0M0 rectosigmoid junction cancer

	Surgery with CCRT (N = 15), N (%)	Surgery only (N = 52), N (%)	*p* value*
Gender			0.3563
Male	12 (80.00)	34 (65.38)	
Female	3 (20.00)	18 (34.62)	
Age			0.0050
Means ± SD	61.07 ± 10.30	70.42 ± 10.14	
Clinical T stage			0.0407
1	2 (13.33)	0 (0.00)	
2	6 (40.00)	14 (26.92)	
3	6 (40.00)	34 (65.38)	
4	1 (6.67)	4 (7.69)	
Clinical N stage			> 0.9999
0	9 (60.00)	33 (63.46)	
1	5 (33.33)	16 (30.77)	
2	1 (6.67)	3 (5.77)	
Tumor size			> 0.9999
≤ 5 cm	7 (46.67)	25 (48.08)	
> 5 cm	8 (53.33)	27 (51.92)	
Distal margin (cm)			0.4370
Means ± SD	3.52 ± 1.62	3.15 ± 1.44	
Number of LN harvest			0.1987
Means ± SD	21 ± 7.51	18.06 ± 7.86	
Complication			> 0.9999
Yes	1 (6.67)	3 (5.77)	
No	14 (93.33)	49 (94.23)	

27.98 months, 64.52 ± 27.68 months in the surgery with adjuvant CCRT group, and 62.12 ± 28.57 months in the surgery only group (p = 0.7711; Table 2). Two patients (2/15 [13.33%]) in the surgery with adjuvant CCRT group and 10 patients (10/52 [19.23%]) in the surgery only group developed local or distant recurrences (p = 0.7209). In the surgery with adjuvant CCRT group, there was one patient with local recurrence and one patient with distant metastasis. In the surgery only group, two patients developed local recurrences and 8 patients developed distant metastases. The surgery with adjuvant CCRT group had a 1-, 3-, and 5-year overall survival rate of 100%, 100%, and 91.67%, respectively; the corresponding rates were were 98.08%, 94.15%, and 75.72% in the surgery only group (Fig. 2). There was no significant difference in the 5-year overall survival between the two groups (p = 0.1208). As shown in Figs. 3 and 4, the 5-year disease-free and cancer-specific survival in the surgery with adjuvant CCRT group (86.67% and 92.31%, respectively) was not significantly higher (p = 0.1520 and p = 0.3376, respectively) than the surgery only group (70.74% and 83.26%, respectively).

Discussion

Whether rectosigmoid junction cancer should be

Table 2. Recurrence and survival

	Surgery with CCRT (n = 15)	Surgery only (n = 52)	*p* value
Mean follow-up (months)	64.52 ± 27.69	62.12 ± 28.58	0.7711
Recurrence			0.7209
Yes	2 (13.33%)	10 (19.23%)	
Recurrence type			0.4545
Local recurrence	1 (50.00%)	2 (20.00%)	
Distant metastasis	1 (50.00%)	8 (80.00%)	
Overall survival rate			
1 year	100%	98.08%	-
3 year	100%	94.15%	-
5 year	91.67%	75.72%	0.1208
Disease-free survival rate			
1 year	93.33%	92.31%	0.8908
3 year	86.67%	80.39%	0.5459
5 year	86.67%	70.74%	0.1520
Cancer-specific survival rate			
1 year	100%	100%	-
3 year	100%	91.50%	-
5 year	92.31%	83.26%	0.3376

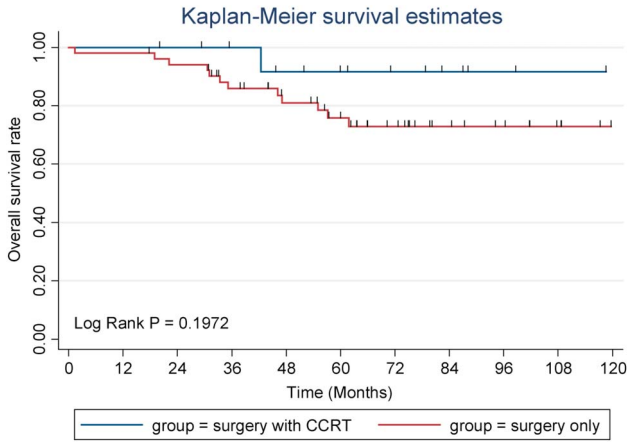

Fig. 2. Kaplan-Meier estimates of overall survival for patients with pT3N0M0 rectosigmoid junction cancer.

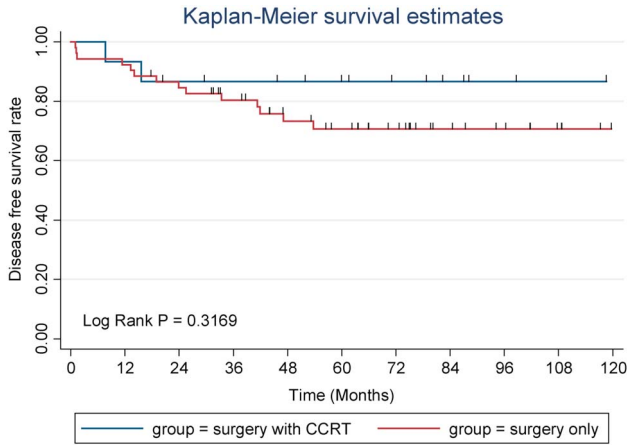

Fig. 3. Kaplan-Meier estimates of disease-free survival for patients with pT3N0M0 rectosigmoid junction cancer.

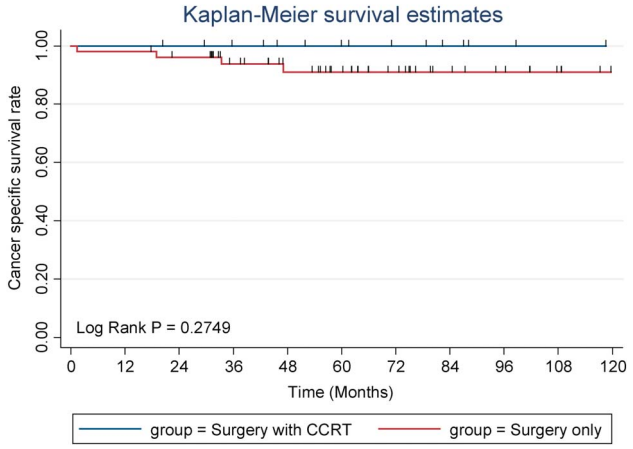

Fig. 4. Kaplan-Meier estimates of cancer-specific survival for pT3N0M0 rectosigmoid junction cancer.

classified as colon or rectum cancer in the classification of diseases has been a controversial issue due to tumor site. Specifically, whether or not carcinomas located in the rectosigmoid junction should be treated as colon or rectal cancers remains unanswered. In daily practice, with multi-disciplinary meetings on CRC, there is often discussion about the exact localization. The macroscopic landmarks of the rectosigmoid junction (loss of the taeniae coli and appendices epiploicae with a wide variation between individuals) cannot be assessed before surgery. Therefore, the rectosigmoid junction in rectal cancer has been defined by the distance from the anal verge during rigid sigmoidoscopy as below 16 cm (UICC TNM classification[8]), below 15 cm (most European studies[9]), and below 12 cm (USA[9]). Radiologic localization is usually preferred and endoscopic localization of the tumor is not considered to be decisive. Loffeld et al. reported sensitivity and specificity for endoscopy in sigmoidal cancer to be 100% and 77%, respectively, and 77% and 100% for rectal cancer, respectively. The sensitivity of radiology for sigmoid and rectum cancers are 80% and 98%, respectively. The specificity for both cancers is 98% and 80%, respectively. Both the endoscopist and the radiologist should not be too overconfident in cases of high rectal or low sigmoidal cancer. Radiologic examinations should be studied carefully, and loops of the sigmoid below the line of the promontorium should be taken into account.[10] According to cancer screening and the diagnosis/treatment measurements index promulgated by the Health Promotion Administration of the Ministry of Health and Welfare, rectosigmoid junction cancer is classified as rectal cancer and the treatment protocol should follow the principle of rectal cancer treatment guidelines.[11] Rectosigmoid junction cancer with clinical stage II~III pre-operatively should receive neoadjuvant CCRT and then undergo radical surgery. This is a significant conflict in 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. We know that the loco-regional recurrence rate of resectable stage II~III rectal

cancer patients is 15%-65%. Even with total mesorectal excision, the local regional recurrence rate of stage III patients is 20%~30%. To improve the local control and long-term survival rates, it is necessary for resectable stage II~III patients to receive neoadjuvant therapy before surgery. Pre-operative CCRT have become the standard treatment for resectable stage II~III patients.[12] The disadvantage of pre-operative CCRT is mainly anastomotic leakage. The incidence of clinically significant leakage after rectal anastomosis varies from 3%-21%, and anastomotic leakage is associated with 6%-30% mortality.[13-15] The effect on oncologic outcomes is less clear, but early reports have suggested that anastomotic leakage results in an increase in local recurrence and a decrease in cancer-specific survival.[13-15] Neoadjuvant therapy may also have an adverse impact on anastomotic healing and may be associated with anastomotic leakage following anterior resection, although the literature on this issue is controversial. Some research has suggested that pre-operative pelvic irradiation not only results in pelvic fibrosis, abscess formation, and bowel obstruction, but sepsis and a local inflammatory response.[19-21] These findings support the idea that pre-operative pelvic irradiation degrades a colorectal or coloanal anastomosis and may be associated with the increased incidence of anastomotic leakage. A randomized controlled trial and a meta-analysis[22,23] demonstrated that a non-functioning stoma reduces anastomotic leakage after low anterior resection for rectal cancer. This implies that a non-functioning stoma may partially or completely offset the effect of neoadjuvant radiotherapy on anastomotic leakage. Most patients resist stoma creation; thereafter, if the patients receive neoadjuvant CCRT following radical surgery, they will have temporary protective stoma. This may explain why a lower percentage of patients with rectosigmoid junction cancer received neoadjuvant CCRT (11.23%) in our hospital. In Taiwan, many surgeons believe that patients with locally advanced (T3/4 or N+) rectosigmoid junction cancers should be treated identically to colon cancer patients. Lower risk pT3N0M0 rectosigmoid junction cancer has no need to receive adjuvant therapy; however, some medical oncologists insist on the rectosigmoid junction cancer treated identically to rectal cancer. According to the NCCN guidelines, patients with pathologic T3N0M0 rectal cancer should receive adjuvant CCRT.[24] The aim of this study was to clarify the difference in prognosis between different therapeutic modalities for patients with pT3N0M0 rectosigmoid junction colon cancer. For our series, patients with pathologic T3N0M0 rectosigmoid junction cancers without high risk factors were retrospectively enrolled. One group was classified as rectal cancer and received adjuvant CCRT, while the other group was classified as colon cancer and only received regular follow-up in the outpatient department. After a mean follow-up of 62.66 ± 27.98 months, there was no significant difference in the percentage of recurrence between the two groups (13.33% vs. 19.23%, $p = 0.7209$). We observed that there was no significant statistical difference in overall, disease-free, and cancer-specific survival between the two groups. In our series, 13.43% of patients (9/67) developed distant metastases (1 in the surgery with CCRT group [6.67%] and 8 in the surgery only group [15.38%]). To reduce distant metastases and improve prognosis, we should consider adjuvant chemotherapy instead of adjuvant CCRT. Distant metastasis was the major recurrent pattern in the surgery only group, and we know that CCRT has no effect on distant recurrences. Even if we applied adjuvant CCRT in the surgery only group, local recurrence may be improved, but 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.[25] Considering oncologic control and long-term toxicity of radiation, post-operative chemoradiotherapy was not favored.

Our study had some limitations. First, the current study was retrospective and not a randomized control trial. Selection bias existed. Second, the sample size was relatively small. Third, not all patients accepted mismatch repair gene expression testing.

Conclusion

The oncologic results (recurrence rate, overall survival, disease-free survival, and cancer-specific

survival) in our series indicated that there are no significant differences between the two treatment modalities. Primary radical surgery for patients with lower risk pT3N0M0 rectosigmoid tumors without adjuvant CCRT is a viable treatment choice, which would not compromise long-term oncologic results.

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原　著

在病理期別 T3N0M0 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，是要分析病理上診斷為 T3N0M0 乙狀直腸交接處腫瘤，術後有無化放療治療的預後。

方法　從 2007 年 1 月至 2015 年 12 月，在奇美醫學中心有 86 位被診斷為乙狀直腸交界處 T3N0M0 腫瘤，排除高風險族群後，最後有 67 名患者列入本研究。15 名病人手術後接受後續化放療治療；52 名病人接受手術治療而無後續化放療。我們分析比較各組的臨床病理特徵及其治療結果。

結果　單純手術組與手術後併輔助性同步放射及化學治療組相比，患者有較老的診斷年齡 (70.42 ± 10.14 比 61.07 ± 10.30, $p = 0.0050$)。 兩組在性別、合併症、原發腫瘤大小、採集淋巴結數量，切除腫瘤遠端邊緣距離，術後併發症，復發率並無顯著性差異。遠處轉移是兩組中最常見的復發模式 (50% vs. 80%, $p = 0.4545$)。兩組在總體生存率，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 T3M0N0 的乙狀直腸連接處之腫瘤，術後輔助性同步電化療並沒有提供顯著的生存益處。

關鍵詞　病理期別 T3N0M0 的直腸乙狀結腸連接處惡性腫瘤、同步放射及化學治療。