Original Article

The Improvements of Outcomes in Stage II-III, Middle and Lower Third Rectal Cancer Patients in Recently Ten Years: The Improvements are Associated with Neo-adjuvant Concurrent Chemo-radiotherapy

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Key Words
Rectal cancer;
Total meso-rectal excision;
Selective neoadjuvant concurrent chemo-radiotherapy

Purpose. We investigated survival and local recurrence in stage II-III, middle and lower third rectal cancer patients who underwent total mesorectal excision (TME) in recently ten years.
Methods. Medical records from January 1999 to December 2011 were reviewed and 103 patients with stage II-III, middle and lower third rectal cancer (lower margin of tumor within 0-11 cm from anal verge) who received potentially curative resection, were identified. We divided the patients into two groups: Group1 patients from January 1999 to December 2006, and Group 2 patients from January 2007 to December 2011. We analyzed the clinical and oncological data from those patients.
Results. The 5-year overall survival (OS), and local recurrence (LR) rates were 59%, and 16%, respectively in Group 1. The 5-year OS and LR rates were 76% and 6%, respectively in Group 2. The patients in Group 2 had better 5-year overall survival rate than Group 1 statistically significant (p = 0.023). The patients in Group 2 had lower local recurrence rate than Group 1, but not statistically significant (p = 0.0547). The sphincter preservation rate increased from 65% to 94% between two groups. The patients in Group 2 had better sphincter preservation rate (p = 0.002). The patients in Group 2 had undergone neo-adjuvant concurrent chemo-radiotherapy (CCRT) more frequently than Group 1 (p = 0.0001). So, the improvements are associated with neo-adjuvant CCRT.
Conclusions. In this study, the patients in Group 2 had better outcomes than Group 1 including 5-year OS, 5-year LR and sphincter preservation rate. The improvements of outcomes were found in patients with stage II-III, middle and lower third rectal cancers who underwent TME in recently ten years. The improvements are associated with neo-adjuvant CCRT.
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The treatment of rectal cancer is still a challenging problem including how to reduce local recurrence rates, avoid permanent stomas and increase survivals. Before the introduction of total mesorectal excision (TME),[1] the local recurrence rate after curative resection of rectal cancer had been reported to be as high as 28%-38%, and 5-year overall survival (OS) rates were around 45%-62%.[2,3] However, the improvements in surgical techniques accompanying TME have improved the local recurrence to only 4%-10%.[4,5] The removal of the entire mesorectum by sharp dissection under direct visualization along the visceral fascia of the mesorectum is currently accepted as the standard approach in rectal cancer surgery.

Several large randomized controlled trials have assessed the use of radiotherapy before or after major surgery for rectal cancer.[6-11] A reduction in local recurrence with the treatment has been well-documented and at least one study has shown a survival advantage.[7] The results of a meta-analysis conducted in 2000 showed that preoperative radiotherapy improves overall and cancer-specific survival compared with surgery alone in patients with resectable rectal cancer.[12]

A 2004 German rectal cancer study demonstrated that TME combined with preoperative concurrent chemo-radiotherapy (CCRT) can improve local control and is associated with reduced toxicity, compared with TME plus postoperative CCRT.[13] Since then neoadjuvant CCRT combined with TME has been adopted as the standard treatment worldwide for patients with preoperatively staged as II or III rectal cancer.

However, side effects of radiotherapy include fecal incontinence, sexual dysfunction, bowel dysfunction, and secondary malignancy, all of which can impair quality of life and may shorten life expectancy[14,15] although neo-adjuvant CCRT plus TME can reduce toxicity rate from 40% to 28%, compared with postoperative chemo-radiotherapy and TME.[13]

In 2003, highly selective use of pre-operative CCRT in patients with lower rectal cancer or fixed tumors was recommended in order to limit the need for radiotherapy with its potentially severe side effects.[16] But they had no definite inclusion criteria. In the Dutch TME trial,[17] radiotherapy has not shown significant benefit of 10-year local recurrence in upper rectal cancer patients (10-15 cm from anal verge). So, we suggested that neo-adjuvant concurrent chemo-radiotherapy (CCRT) will be recommended in middle and lower third rectal cancer patients. In our hospital, Neo-adjuvant CCRT had been applied since 2006. So, we compared the outcomes before and after the introduction of neo-adjuvant CCRT in stage II-III, middle and lower third rectal cancer patients underwent TME.

The purpose of this study was to investigate the local recurrence and overall survival in patients with stage II-III, middle and lower third rectal cancer in recently ten years.

Methods

Study participants

From January 1999 to December 2011, we enrolled 103 consecutive patients with histologically proven rectal adenocarcinomas that had been defined pre-operatively to have the lower tumor margin within 11 cm from the anal verge as measured by rigid sigmoidoscopy at the Taipei Medical University-Wan Fang Medical Center. Our inclusion criteria were stage II-III and middle to lower third rectal cancer patient who underwent TME. The patients who had synchronous colorectal cancer or another malignancy were excluded. The study protocol was approved by the Taipei Medical University – Joint Institutional Review Board.

Protocol of pre-operative CCRT

Pre-operative CCRT had begun to apply to rectal cancer patients in our hospital since May, 2006. We constructed a combined committee which included colorectal surgeon, gastroenterologist, radiologist, pathologist, medical oncologist, and radiation oncologist to discuss whether the rectal patients underwent pre-operative CCRT or not. Abdomen and pelvic Computed Tomography (CT) was used to evaluate the patients preoperatively. The inclusion criteria of pre-operative CCRT are stage II/III lower third rectal cancer and large (> 5 cm in diameter or > 1/2 of circumference) stage II/III middle third rectal cancer in our hospital.

Three-dimensional conformal radiotherapy or intensity modulated radiotherapy was planned on the PINNACLE treatment planning system (Philips, Amsterdam, Netherlands) using 10- or 6-MV X rays to advanced rectal cancer patients. Clinical target volumes (CTVs) included the primary rectal tumor lesions and the two end portions of the rectum; the perirectal tissues; the anterior sacral lymph, iliac lymph, obturator lymph and true pelvis internal iliac lymph drainage areas. For patients with stage T4 lesions or tumors invading the bladder, the CTV also included the external iliac lymph drainage area. Planned target volume (PTV) is defined as CTV or gross tumor volume (GTV) +8 mm. The median total dose was 45 Gy delivered to the CTV in 25 fractions of 1.8 Gy without a boost dose. A 5.4-Gy boost comprising 3 fractions of 1.8 Gy to the GTV increased the total dose to 50.4 Gy. During the first and fifth weeks of radiotherapy, fluorouracil was given as a 120-hour continuous infusion at a dose of 1000 mg per square meter per day. In patients who were assigned to preoperative treatment, surgery was scheduled to take place four to six weeks after the completion of chemo-radiotherapy. Four cycles of bolus fluorouracil (500 mg per square meter per day, five times weekly, every four weeks) were started four weeks after surgery (in the preoperative-treatment group).

Surgery and follow-up

We defined cancers as lower-third (0-7 cm from the anus), middle- third (7.1-11 cm from the anus) and upper-third (11.1-15 cm from the anus).[18] The surgical technique (TME) included high ligation of the inferior mesenteric artery and vein; mobilization of the sigmoid colon, descending colon, or splenic flexure; and mobilization of the rectum by sharp dissection with diathermy or scissors under direct visualization in the avascular plane between the visceral fascia of the mesorectum and the parietal fascia of the pelvis, as had been originally described by Heald et al.[1] Pathological staging of the disease was performed according to the American Joint Cancer Committee (AJCC) on cancer staging manual, 7th edition. The pre-operative clinical stage, evaluated by abdomen and pelvic CT, was used as their stage in the patients who underwent neoadjuvant CCRT.

Adjuvant chemotherapy, 6 cycles of fluorouracil (500 mg per square meter per day, five times weekly, every four weeks) was suggested in patients with high risk (obstruction, T4 lesions, perforation, lymph-vascular permeation or peri-neural invasion) or lymph node positive rectal cancer who did not receive neoadjuvant concurrent chemo-radiotherapy, four weeks after operation. The indications of adjuvant radiotherapy were the same as adjuvant chemotherapy. The total dosage of adjuvant radiotherapy was 50.4 Gy in 28 fractions. Following surgery, all patients were entered into a surveillance program designed to detect recurrent local and distant disease. Clinic visits were scheduled every three months for the first two years, then at six-month intervals for three years. At each visit, rectal digital examination was performed and serum levels of carcino-embryonic antigen (CEA) were measured. Patients underwent abdominal ultrasound or computed tomography (CT) screening every six months, and colonoscopy after one and three years. If any patients did not maintain their follow-up appointments at the outpatient clinic, we contacted those patients by telephone or mail. Any symptom potentially related to local tumor recurrence was investigated with digital rectal examination, colonoscopy and CT, or magnetic resonance imaging. Recurrence was confirmed by biopsy if possible, but any pelvic mass with progressively increasing size on imaging studies was classified as recurrence unless this was clearly disproved.

Statistical analysis

End points for the study included documentations of recurrent local disease, distant spread without local recurrence, death due to cancer recurrence and death without recurrence. Data on patients who were lost to follow-up were censored at the time of the last follow-up. Frequency tables are used for patients' presentations and treatment characteristics. We used the two-tailed chi-square test for differences in proportions and the Student's t-test for continuous numerical variables. We estimated the cumulative proportions of 5-year local recurrence rates and the 5-year survival

rates with the Kaplan-Meier method. Kaplan-Meier survival curves were compared using the Log-rank test. Statistical significance was defined as a value of $p < 0.05$. We compared all study data with Statistical Package for the Social Sciences (SPSS) version 13.0 for Windows (SPSS Inc., Chicago, IL, USA).

Results

The demographic characteristics of the 104 patients, as well as the characteristics of their tumors, were displayed in Table 1. The average lymph nodes harvested were 19 ± 10. Between group 1 and group 2, there were no association in age, gender, tumor stage, laparoscopic surgery or not, adjuvant chemotherapy and adjuvant radiotherapy. The patients in Group 2 had smaller tumor size than Group 1 ($p = 0.043$). The patients in Group 2 had undergone neo-adjuvant CCRT and sphincter-saving procedure more frequently than Group 1 ($p = 0.0001$ and 0.002).

During the periods of follow up with average of 78 ± 46 months (1-201 months), 12 local recurrences and 51 deaths were identified (9 local recurrences and 35 deaths in Group1; 3 local recurrences and 16 deaths in Group 2). The 5-year overall survival (OS) rate and local recurrence (LR) rate in rectal cancer patients in Group 1 were 59% and 16% by the Kaplan-Meier method. The 5-year OS and LR rate were 76% and 6% in Group 2 patients (Figs. 1 and 2). The Group 2 patients had higher OS rate and lower LR rate than the Group 1 patients, as shown in Table 2. Otherwise, the Group 2 patients also had higher sphincter preservation rate than Group 1 patients (94% versus 65%, $p = 0.002$). Analyzing overall survival rate, local recurrences, and sphincter sparing rate, the results in Group 2 were superior to Group 1.

There were 20 patients had stage II rectal cancers

Table 1. Characteristics of patients and their tumor in two groups

	Group 1 N = 52	Group 2 N = 51	*p*
Male	29	34	0.314
Female	23	17	
Age ≤ 65	17	25	0.110
Age > 65	35	26	
Stage II	20	20	1.0
Stage III	32	31	
Open surgery	52	50	0.495
Laparoscopic surgery	0	1	
Pathological tumor size (cm)	5.3 ± 1.9	4.4 ± 2.2	0.043
Adjuvant CT (-)	24	17	0.154
Adjuvant CT (+)	25	34	
CCRT (-)	51	37	0.0001
CCRT (+)	1	14	
Adjuvant RT (-)	39	30	0.096
Adjuvant RT (+)	13	21	
APR (-)	34	48	0.002
APR (+)	18	3	
Middle rectum	27	33	0.232
Lower rectum	25	18	

APR, abdominal perineal resection; RT, radiotherapy; CT, chemotherapy; CCRT, concurrent chemoradiotherapy.

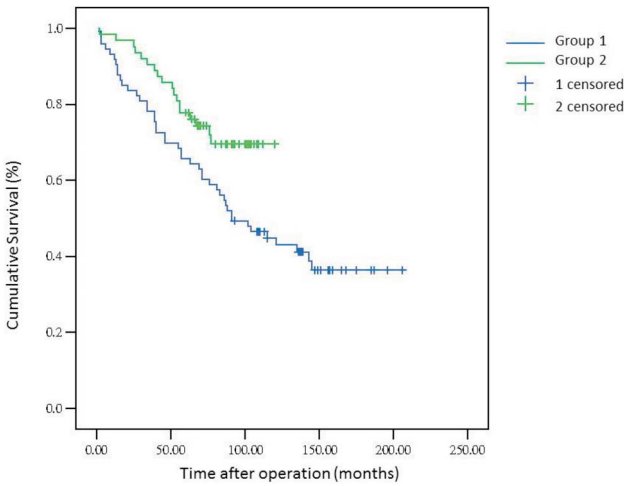

Fig. 1. Overall survival rate in two groups.

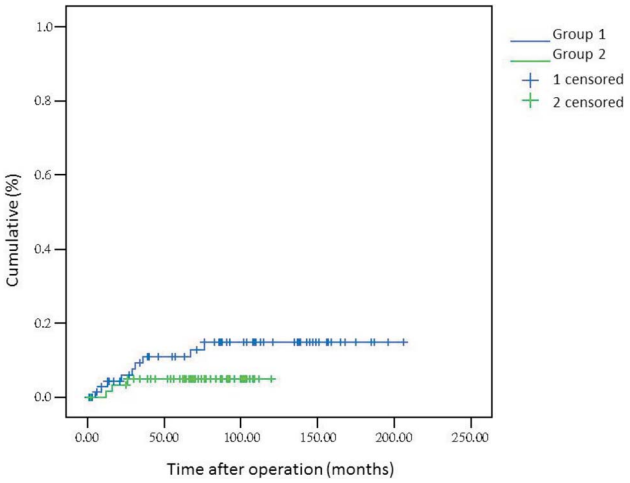

Fig. 2. Local recurrence rate in two groups.

Table 2. Overall survival rate and local recurrence rate in different groups

	Group 1	Group 2	*p*
5-year overall survival rate	59%	76%	0.023
5-year local recurrence rate	16%	6%	0.0547

and 32 patients had stage III rectal cancers in Group1. Otherwise, there were 20 patients with stage II rectal cancers and 31 patients with stage III rectal cancers in Group 2. We compared the patients with stage II rectal cancer in two groups and concluded that the patients with stage II rectal cancers in Group 2 also had better results than Group 1, but not significant statistically (5-year OS rate: 90% versus 65%: $p = 0.155$ and 5-year LR rate: 5% versus 13 %; $p = 0.141$). The patients with stage III rectal cancers in Group 2 also had superior oncologic results to Group 1, but not significant statistically. (5-year OS rate: 67% versus 56%; $p = 0.093$ and 5-year LR rate: 7% versus 16%; $p = 0.200$).

Discussion

The definitions of lower rectal cancer differ among various studies. In the 1982 St. Mark's Hospital series, the investigators defined mid-rectal cancer as a tumor with the lower border within 8-12 cm from the anal verge.[19] In the 1984 Memorial Sloan-Kettering Cancer Center series, lower rectal cancer was defined as a tumor within 0-5 cm from the anal verge, middle rectal cancer as one within 6-11 cm, and upper rectal cancer as one within 12-18 cm.[20] In contrast, in the 2001 series, the investigators defined lower rectal cancer as a tumor at a distance of 0-7 cm from the anal verge and middle and upper rectal cancer as tumors located at distances of 7.1-11 cm, and 11.1-15 cm, respectively, from the anal verge.[18,21] In large multiple hospitals randomized controlled trials involving multiple hospitals, such as the Stockholm II trial and the Dutch TME trial, lower rectal cancer was defined to be located within 0-5 cm from the anal verge and middle and upper rectal cancer were defined as located within 6-10 and 11-15 cm from the anal verge.[7,17] In our study, we adopt lower third rectal cancer as 0-7 cm from anal verge, and middle third rectal cancer as 7.1 to 11 cm from anal verge because anal canal was estimated as 3-4 cm in length.[18] Low third rectal cancer was defined as 0-7 cm from anal verge including two parts: one part was rectal cancer invading anal canal (about 3 cm in length), the other part was located within 3-7 cm from anal verge (4-cm length rectum). The middle third rectal cancer and upper third rectal cancer also had 4-cm length rectum.

The major change of treatment of rectal adenocarcinoma was the introduction of pre-operative concurrent chemo-radiotherapy (CCRT) in recently ten years. In the 2004 Germany trial, TME combined with preoperative CCRT improve local control (LR rate from 13% to 6%), compared with TME plus postoperative CCRT.[13] However, TME with neoadjuvant CCRT did not improve overall survival. At the same time, the long-term complications of radiotherapy could not be avoided and which can impair quality of life and may shorten life expectancy. So, selective use of pre-operative CCRT in patients with lower rectal cancer or fixed tumors was recommended to minimalize their potentially severe side effects in the 2003 study.[16] In this study, we adopt selective application of pre-operative CCRT in selective patients. The inclusion criteria of neoadjuvant CCRT were lower third locally advanced rectal cancer and large middle third stage II/III cancer (tumor size > 5 cm or > 1/2 of circumference) in our study. Selective use of pre-operative CCRT was suggested to avoid the unnecessary radiotherapy and its potential severe side effects. We hope that those policies can improve the patient's life quality and overall survival. The outcomes of Group 2 patients had lower 5-year LR rate and better 5-year overall survival (OS) rate than Group 1 patients (LR rate from 16% to 6% and OS rate from 59% to 76%). (Table 2) The results indicated that selective use of neoadjuvant CCRT may be a good choice for patients with locally advanced rectal cancers.

The 5-year LR rate was 6% in Group 2 (selective application of pre-operative CCRT in locally advanced rectal cancer patients), and that was a similar result compared with the previous study.[16] The percentage of neoadjuvant CCRT application was 27.4% (14/51) in the present study, and the result was also similar to the 2003 study (23.3%).[16] Different part between the two studies was just that we excluded upper third rec-

tal cancer patients.

The average pathological tumor size was smaller in Group 2 patients than in Group 1 ($p = 0.043$) (Table 1). The possible explanation might be that pre-operative CCRT could shrinkage the tumor size, and the patients in Group 2 underwent pre-operative CCRT more frequently than in Group 1 ($p = 0.0001$).

In our study, Group 2 patients had better sphincter-preservation rate than Group 1 ($p = 0.002$). The result agrees with the 2004 Germany trial which indicated that preoperative CCRT plus TME may increase sphincter reservation rate.[13]

The patients in Group 2 had undergone neo-adjuvant CCRT more frequently than Group 1 (14/51 versus 1/52, $p = 0.0001$). So, the improvements from patients in Group 1 to Group 2 are associated with application of neo-adjuvant CCRT.

Meanwhile, the Group 2 had more middle rectal tumors and adjuvant chemotherapy and radiotherapy applied than Group 1, but the degree of difference were not significant statistically ($p = 0.232$, 0.154 and 0.096). In a 2005 report,[22] they pointed that lower rectal cancer (0-6 cm from the anal verge) was associated with a poorer prognosis than upper rectal cancer (> 6 cm from the anal verge) with 5-year OS rates of 59% and 78%, respectively. Wibe et al. also obtained similar results in their lower rectal cancer study.[23] So, the Group 2 had more middle rectal tumors than Group 1 that may be a possible factor to influence the survival and local recurrence. The Group 2 also had more adjuvant chemotherapy and chemo radiotherapy applied than Group 1 that may be another two possible factors to improve the survival and local recurrence.

Study limitation

The primary limitations of our study are that our data came from a single hospital and were obtained without randomization of the patients. Therefore, patient selection bias cannot be excluded.

Summary

The improvements of outcomes were found in patients with stage II-III, middle and lower third rectal cancers who underwent TME in recently ten years. The improvements are associated with selective neo-adjuvant concurrent chemo-radiotherapy.

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原　著

近十年來第二、三期中低位直腸癌患者治療的結果有進步 – 此進步與術前化放療相關

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目的　我們探查近十年來第二、三期直腸癌患者接受全直腸繫膜切除 (Total mesorectal excision) 後之局部復發率及存活率。

方法　我們回顧西元 1999 年 1 月至 2011 年 12 月期間的病歷記錄，共有 103 位病患符合下列標準：腫瘤下緣位於距肛門口 11 公分內，接受根治性切除手術者及第二、三期的直腸癌病患。

我們將其分為兩群：第一群為西元 1999 年 1 月至 2006 年 12 月。第二群為西元 2007 年 01 月至 2011 年 12 月。我們分析他們的臨床資料，包括局部復發及存活率等。

結果　第一群病患 5 年存活率 (Overall survival rate) 及 5 年局部復發率為 59% 及 16%。第二群為 76% 及 6%。明顯的發現第二群病患有較佳之 5 年存活率達統計學差異 (p 值為 0.023)，第二群病患也有較低之 5 年局部復發率，但未達統計學差異 (p 值為 0.0547)。第二群病患同時有較佳的肛門保存率 (從 65% 至 94%) (p 值為 0.002)。第二群病患有較高比率接受術前化放療 (p 值為 0.0001)。因此，上述治療結果的進步與術前化放療相關。

結論　第二群病患有較佳的 5 年存活率、肛門保存率及較低之 5 年局部復發率，近十年來第二、三期中低位直腸癌患者之治療有改善。上述之改善與術前化放療相關。

關鍵詞　直腸癌、全直腸繫膜切除、選擇性術前同步化學放射治療。