Original Article

Non-operative Management Following Concurrent Chemoradiotherapy for Rectal Cancer

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Key Words
Concurrent chemoradiotherapy;
Non-operative management;
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Clinical complete response;
Local recurrence

Purpose. Neoadjuvant chemoradiotherapy combined with total mesorectal excision has become the standard of care for most rectal cancers. A clinically complete response may develop following concurrent chemoradiotherapy. The potential clinical effectiveness of non-operative management is highlighted by pathologic response rates from neoadjuvant trials. This is of concern for elderly patients and for those with significant medical comorbidities. Another potential concern is the perceived reduction in quality of life with a permanent stoma. Therefore, we performed a retrospective study to evaluate the results of non-operative management after chemoradiotherapy, especially in clinically incomplete response patients with non-operative management.
Methods. Patients with stage II or III rectal cancer, treated between January 1, 2009 and December 31, 2017, were included in a retrospective study. Clinical data were acquired from computer databases and information concerning survival from the outpatient department follow-up and/or telephone questionnaire. Patients with nonmetastatic rectal cancer treated by neoadjuvant chemoradiation therapy, including 50.4 Gy and concomitant 5-fluorouracil and leucovorin or capecitabine, were assessed for tumor response six to eight weeks after chemoradiation therapy completion. Complete and incomplete clinical responses were defined based on clinical, image and endoscopic findings. After fully informed the patient and families about the risk of non-operative management, both groups of patients have adopted the policy of no surgery with a surveillance program.
Results. Ten of 20 patients experienced a clinically complete response at initial assessment after chemoradiotherapy (50%). Median follow-up time was 38.2 months. Two patients (20%) experienced local recurrence (median recurrence time, 20.0 months). Two patients (20%) experienced systemic recurrence. (median recurrence time, 8.0 months). By contrast, patients that experienced a clinically incomplete response had higher systemic recurrence (40%, median recurrence time, 11.0 months).
Conclusion. The local recurrence rate in clinically complete response patients is similar to previous study. The optimal tools and follow-up interval for assessing a clinically complete response remain to be determined. Although non-operative management is a promising, innovative approach in previous study, it should not be adopted into routine care until it has been proven to be an equivalent or superior treatment approach in multicenter prospective clinical trials.
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Surgical resection has always been the gold standard of curative treatment in nonmetastatic rectal adenocarcinoma. Starting around 2002, neoadjuvant chemoradiotherapy (CRT) in combination with total mesorectal excision (TME), either low anterior resection or abdominoperineal resection, became the standard of care for most rectal cancers.[1-3]

In addition, neoadjuvant CRT leads to variable degrees of tumor downstaging.[4] The potential clinical effectiveness of non-operative management (NOM) is highlighted by pathologic response rates from neoadjuvant trials, particularly those using long-course concurrent chemoradiotherapy (CCRT) for locally advanced cancers. Pathologic complete response (pCR) rates in these trials range from 8% to 20%.[4-9] For these patients, questions regarding the necessity of TME have been raised. Early studies with small samples from specialized centers report success with NOM or the watch-and-wait approach following neoadjuvant CRT for rectal adenocarcinoma.[10-14]

There was a doubling in the use of chemoradiation – only management for rectal cancer over the study period: 2.4% in 1998 to 5% in 2010.[15] This shift has been paralleled by improved preoperative imaging and staging, including endoscopic ultrasound (EUS) and magnetic resonance imaging (MRI). A NOM may avoid the complications associated with TME. This is of concern for elderly patients and for those with significant medical comorbidities. Another potential concern is the perceived reduction in quality of life with a permanent stoma.

Several large meta-analyses reporting significantly lower cumulative rates of local recurrence ranging from 0.7% to 0.8% as well as improved overall survival (OS) and disease-free survival (DFS) compared to partial responders or nonresponders.[16-19] Neoadjuvant CRT results in a clinical complete response (cCR) in up to 49% of patients.[19] Theoretically, if no viable tumors remain, then surgery may not add clinical benefit while potentially increasing morbidity. NOM precludes pathologic confirmation of the primary tumor and lymph node response. As a result, a cCR is used as a surrogate for pCR.[20]

Although studies are promising, there is still insufficient evidence to support general adoption of this treatment paradigm. Therefore, we performed a retrospective study to evaluate the results of NOM after CCRT, especially in clinically incomplete response patients with NOM.

Materials and Methods

In this retrospective cohort study, a total of 604 patients were registered at Taipei Medical University Hospital (TMUH) and had a diagnosis of stage II or III rectal adenocarcinoma. Data were obtained from a 9-year period spanning January 2009 to December 2017. We excluded patient cases for which treatment was indicated to be palliative, those with a prior cancer history, and those with surgical intervention. Patients with nonmetastatic rectal cancer treated by neoadjuvant chemoradiation therapy, including 50.4 Gy with 1.8 fractions and concomitant capecitabine (825 mg/m^2 twice per day orally, 5 days per week for 5 weeks) or 5-fluorouracil (continuous infusion 325 or 400 mg/m^2 per day, the first and the last 4 days) and leucovorin, were assessed for tumor response six to eight weeks after chemoradiation therapy completion. Clinical data were acquired from computer databases and information concerning survival from outpatient department follow-up and/or telephone questionnaire. We calculated OS in months from the date of diagnosis to the last contact or confirmed death. A complete clinical response was defined as "no residual tumor", based on digital rectal examination, direct visualization by colonoscopy with or without biopsy, and image studies including chest to abdomen computerized tomography (CT) scan, pelvis magnetic resonance imaging (MRI) scan. An incomplete response was defined as a residual ulcer/mass or positive biopsy. After fully informed the patient and families about the risk of non-operative management. The patients experienced both a clinically complete and incomplete response has adopted the policy of no surgery with a surveillance program. A surveillance program included complete physical and digital rectal examination every 1 to 2 months for the first year. After the first year, visits were recommended every 3 months and every 6 months for the 2nd and 3rd years. In addition, CEA

levels were determined every 2 to 3 months. Radiological assessment, including chest to abdomen CT scans and pelvic MRI, was performed at tumor response assessment after at least 8 weeks from CRT completion and every 6 months during this 12-month period. Additional radiological studies and colonoscopy with or without biopsy were ordered only in patients with any suspicion for disease recurrence.

Results

A total of 604 patients had received a diagnosis of rectal adenocarcinoma. 328 patients underwent CCRT and 302 of whom were excluded due to surgical intervention. Four patients did not finish CCRT and two patients had prior malignancy history (Fig. 1). Only 20 patients were finally included in the study. The characteristics of these patients are shown in Table 1. Mean age was 65.4 ± 10.24 years old. Three patients were pre-treatment clinical stage II and 17 patients were stage III. Four patients had local recurrence, six patients had distant metastasis. Twelve patients were death eventually. Median overall survival was 29.4 months. To focus on clinically incomplete response patients with non-operative management. Patients were divided into four subgroups (Fig. 2). Ten of 20 patients experienced cCR at initial assessment after CRT (50%). Median follow-up time was 38.2 months. Two patients (20%) experienced local recurrence (LR)

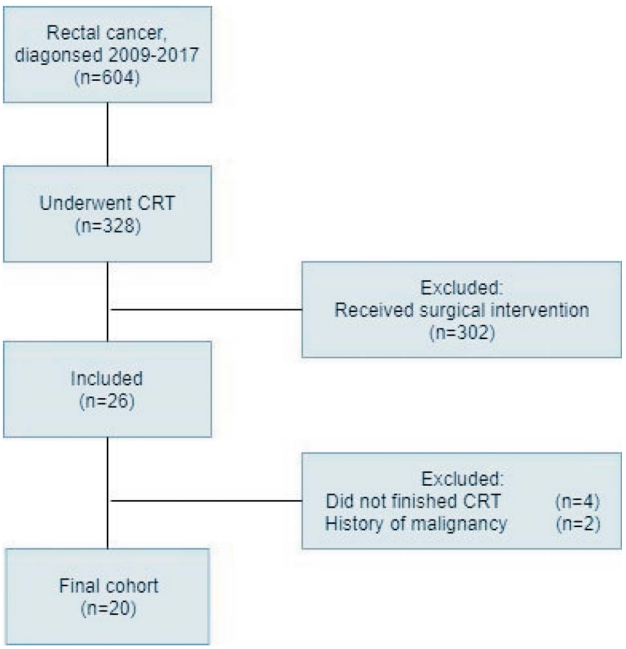

Fig. 1. Patient selection. CCRT: concurrent chemoradiation, CRT: chemoradiation.

Table 1. Patient characteristics

Characteristics	All patient, % (No.)	Clinical complete response, % (No.)	Clinical incomplete response, % (No.)
Overall	100.0 (20)	50.0 (10)	50.0 (10)
Sex			
Male	70.0 (14)	70.0 (7)	70.0 (7)
Female	30.0 (6)	30.0 (3)	30.0 (3)
Age, years			
< 50	10.0 (2)	0.0 (0)	20.0 (2)
50-59	25.0 (5)	10.0 (1)	40.0 (4)
60-69	35.0 (7)	60.0 (6)	10.0 (1)
70-79	25.0 (5)	20.0 (2)	30.0 (3)
> 80	5.0 (1)	10.0 (1)	0.0 (0)
Mean	65.4	69.06	61.71
Standard deviation	10.24	6.49	12.22
Initiall BMI[a], kg/m^2			
< 18.5	5.6 (1)	0.0 (0)	11.1 (1)
18.5-24	38.9 (7)	33.3 (3)	33.3 (3)
24-27	33.3 (6)	44.4 (4)	22.2 (2)
> 27	22.2 (4)	33.3 (3)	33.3 (3)
Mean	24.14	25.58	22.35
Standard deviation	3.51	2.61	3.81
Pre-Treatment stage			
II	15.0 (3)	20.0 (2)	10.0 (1)
III	85.0 (17)	80.0 (8)	90.0 (9)
N stage			
0	15.0 (3)	20.0 (2)	10.0 (1)
Ia	15.0 (3)	30.0 (3)	0.0 (0)
Ib	30.0 (6)	20.0 (2)	40.0 (4)
IIa	20.0 (4)	30.0 (3)	10.0 (1)
IIb	20.0 (4)	0.0 (0)	40.0 (4)
Local recurrence	20.0 (4)	20.0 (2)	20.0 (2)
Systemic recurrence	30.0 (6)	20.0 (2)	40.0 (4)
Mortality	60.0 (12)	50.0 (5)	70.0 (7)
Regimen			
Xeloda	30.0 (6)	10.0 (1)	50.0 (5)
5-FU + LV[b]	70.0 (14)	90.0 (9)	50.0 (5)
Initial CEA[c], ng/ml			
Mean	9.03	3.88	13.66
Overall survival, months			
Mean	29.4	37.2	21.6

[a] Body mass index; [b] 5-fluorouracil and leucovorin; [c] Carcinoembryonic antigen.

(median recurrence time, 20.0 months) and two patients (20%) experienced systemic recurrence (median recurrence time, 8.0 months). By contrast, patients experienced a clinically incomplete response had higher systemic recurrence (40%, median recurrence time, 11.0 months). And individual initial clinical stage, pre-CRT image study items, colonoscopy and image study to proved LR or DM, DFS and OS are shown in Table 2. LR or DM were proved mostly with CT, MRI and colonoscopy.

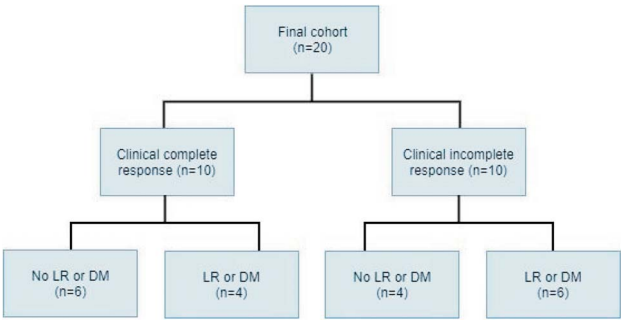

Fig. 2. 4 subgroups. LR: local recurrence, DM: distant metastasis.

Discussion

One prospective trial found delaying surgery for 11 weeks after CRT with integration of intensified chemotherapy (mFOLFOX6) during the rest period increased the pCR rate to 25% versus 18% with the usual 6-week period.[21] A recent update of this study reported two additional study groups with surgery delayed by 15 and 19 weeks (4 vs. 6 intervening cycles of mFOLFOX6); this resulted in pCR rates of 30% and 38%, respectively.[22] Prolonging the interval from preoperative RT to surgery by 2 versus 6 to 8 weeks, as in the Lyon 90-01 trial, improved the pCR rate from 7% to 14%.[23] However, delayed surgery did not appear to compromise clinical outcomes in several studies.[24,25]

In a series from Memorial Sloan Kettering Cancer Center evaluating patients treated with neoadjuvant CRT followed by a planned resection in six weeks, pCR was seen in only 25% of patients deemed as cCR by preoperative proctoscopy.[26] Determining a cCR is defined variably, but it is typically assessed with a

Table 2. Patient list

	Initial clinical stage	Image study items	Proof of LR[a] or DM[b]	Disease free survival, months	Overall survival, months
Patient 1	3C	CT+MRI	CT	2	7
Patient 2	3B	CT+MRI	MRI	4	26
Patient 3	3B	CT+MRI	CT	22	22
Patient 4	2A	CT+MRI	Excisional biopsy	5	8
Patient 5	3C	CT+MRI	Colonoscopy	2	10
Patient 6	3B	CT+MRI	CT	7	27
Patient 7	3B	CT+MRI	MRI	33	38
Patient 8	3A	CT+MRI	Colonoscopy+MRI	58	82
Patient 9	3B	CT	Colonoscopy	2	5
Patient 10	3B	CT+MRI	CT	1	1
Patient 11	2A	CT+MRI		24	24
Patient 12	3B	CT+MRI		21	21
Patient 13	3B	CT+MRI		19	19
Patient 14	3C	CT+MRI		4	4
Patient 15	3B	CT+MRI		48	48
Patient 16	3A	CT+MRI		24	24
Patient 17	3C	CT		34	34
Patient 18	3C	CT+MRI		34	34
Patient 19	2A	CT+MRI		127	127
Patient 20	3B	CT+MRI		27	27

[a] Local recurrence; [b] Distant metastasis.

combination of digital rectal examination (DRE), direct visualization by proctoscopy, and imaging studies with or without biopsy confirmation. Further study of radiographic and biologic predictors of cCR/pCR may ultimately facilitate improved selection of patients eligible for NOM instead of a waiting period for all patients. Radiographic techniques, particularly MRI, have already shown promise for defining favorable outcomes following neoadjuvant CRT.[27]

Additional improvements are necessary to improve the accuracy of cCR assessment. Biomarkers and gene expression profiles may also serve as predictive tools. Low pretreatment carcinoembryonic antigen (CEA) levels have been associated with an improved pathologic response. Low post-treatment CEA levels (< 5-6 ng/mL) may indicate significant pathologic downstaging when the pretreatment level was elevated.[28] Certain genetic expression profiles have also been correlated with tumor response, but reproducing these results in independent cohorts has been challenging.[29]

NOM is a promising, innovative approach for treating rectal cancer in a highly selective population of patients at specialized centers in previous study. However, NOM should not be adopted into routine care of rectal cancer until it has been proven to be an equivalent or superior treatment approach in multicenter prospective clinical trials.[10,20] Among a national sample of patients with clinical stage II/III rectal adenocarcinoma, patients treated with chemoradiotherapy only had inferior survival compared with conventional treatment. This finding is contrary to the results of previously published single-institution and clinical trial reports on NOM.[10-14] The highest use is observed among those who typically have less access to innovative care: black patients, uninsured or Medicaid insured patients, and individuals treated at low-volume centers.[15] These patients are less likely to receive a recommendation for guideline-concordant cancer care, including curative cancer surgery, even after accounting for patient risk factors and contraindications.[30]

Importantly, this publication describes the numbers of both initial and sustained responders, with 20% of the initial complete responders developing tumor regrowth within 12 months. When only those patients who retained a cCR after 12 months were selected, the endorectal recurrence rate was 6% (all were treated with salvage therapy, except for one patient with both local and systemic recurrence), and the 5-year OS and DFS rates were 93% and 85%, respectively.[19] According to the Habr-Gama and Memorial Sloan Kettering series, most recurrences for patients with an initial cCR occur within the first 12 months. Although local salvage therapy may be possible for most of these patients, 30% of those with early regrowth developed systemic recurrence.[11] An assessment eight weeks after CRT found 49% of the patients had a cCR. With a median follow-up of 60 months, 31% of the patients with an initial cCR developed a local recurrence. Of these recurrences, 60% occurred within the first 12 months. Salvage therapy was possible and effective for most local recurrences, with 7% of patients not amenable to salvage. Sphincter preservation was achieved in 86% of all patients with this strategy. Systemic recurrence was seen in 14% of patients, with 5-year cause-specific OS and DFS rates of 91% and 68%, respectively. Note, these authors offered full-thickness local excision (FTLE) for small residual lesions and used radical resection for adverse pathologic findings or a strict surveillance program for patients with ypT0 disease.[31]

These patients were compared with a group that achieved a pCR (approximately half of whom required a permanent colostomy and 35% of whom had major operative complications). The 2-year DFS (89% vs. 93%) and OS rates (100% vs. 91%) were similar for the cCR and pCR patients. The low cCR rate in this study versus Habr-Gama et al.'s study was likely a result of strict imaging criteria, classifying a cCR in only 5 of the 20 patients found to have a pCR in the operative group.[12]

Another important consideration is the toxicity and quality of life following definitive CRT for rectal cancer. Although the report from Maas et al.[12] suggests improved bowel function with NOM, there is little additional evidence documenting the toxicity and quality of life following definitive CRT. Moreover, despite a different treatment regimen being used, definitive CRT for anal canal carcinoma is associated with adverse effects on quality of life, including long-

term sexual and bowel dysfunction.[32]

NOM may improve sphincter-preservation rates, however, a non-functioning or poorly functioning sphincter will result in a significantly detrimental impact on quality of life. The intensity of follow-up and resources necessary to assess and monitor a cCR may also significantly affect quality of life and health care costs.

This study had some limitations. First, this was a retrospective study without randomization utilizing a small sample size in a single center. Second, the patient records were not perfectly complete, for example, there were two initial body mass index data were lost. Third, our follow-up period was short, so data concerning long-term outcomes were limited.

Conclusions

Initial reports of NOM for selected rectal cancer patients appear promising. The optimal tools for assessing cCR remain to be determined. The intensive follow-up and extensive surgical and radiologic experience necessary for an NOM program may limit its widespread use. In addition, robust prospective experiences and prospective quality-of-life and toxicity data are currently lacking. At present, combined-modality therapy including TME should remain the standard of care for locally advanced rectal cancer pending further prospective validation of a nonoperative approach.

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Nil.

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原　著

同步化放療後於直腸癌患者之非手術治療

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目的　術前化放療合併全直腸系膜切除術已成為大多數直腸癌的治療標準。同步放化療後可能會出現完全臨床反應。術前化放療後的病理反應率突顯了非手術治療的潛在臨床效果。因此我們進行了一項回顧性研究，以評估同步放化療後非手術治療的結果，尤其是針對不完全臨床反應的患者。

方法　本文為一項回顧性研究，包含 2009 年 1 月 1 日至 2017 年 12 月 31 日期間接受治療的 II 期或 III 期直腸癌患者。從醫院資料庫中獲取臨床數據，並從門診追蹤及電話調查中獲取生存率的訊息。

在術前化放療完成 8 週後，對接受術前化放療 (包括放射治療劑量 50.4 Gy 和伴隨的 5-fluorouracil 和 leucovorin 或 capecitabine) 治療的非轉移性直腸癌患者的腫瘤反應進行評估。根據臨床、影像和內視鏡檢查結果確定臨床反應。在充分告知病患惡性腫瘤 progress 的風險後，病患仍以門診理學檢查、大腸鏡及影像學密切追蹤。

結果　20 名患者中有 10 名在化放療後的初始評估中經歷了完全臨床反應 (50%)。追蹤時間的平均數為 38.2 個月。2 名患者 (20%) 經歷了局部復發 (平均復發時間為 20.0 個月)。2 名患者 (20%) 出現全身性復發 (平均復發時間為 8.0 個月)。相比之下，不完全臨床反應的患者有更高的全身復發率 (40%，平均複發時間為 11.0 個月)。

結論　完全臨床反應患者的局部復發率與以前的研究相似。評估完全臨床反應的最佳工具和回診時間間隔尚待確定。儘管在之前的研究中非手術治療是一種有前途的創新方法，但除非在多中心前瞻性臨床試驗中被證明是等效或優越的治療方法，否則不應將其用於常規治療。

關鍵詞　同步化放療後、非手術治療、直腸癌、完全臨床反應、局部復發。