Original Article

Clinical Outcomes of Transanal Endoscopic Microsurgery after Neoadjuvant Concurrent Chemoradiotherapy among Patients with T3N0M0 Rectal Cancer

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Key Words
Neoadjuvant concurrent chemoradiotherapy;
Rectal cancer;
Transanal endoscopic microsurgery

Purpose. Total mesorectal excision is a standard surgical treatment for rectal cancer. Transanal endoscopic microsurgery is an alternative treatment that typically involves fewer complications but has a higher recurrence rate. This study examined whether transanal endoscopic microsurgery after neoadjuvant concurrent chemoradiotherapy is suitable as an alternative treatment for patients with cT3N0M0 rectal cancer.
Methods. We retrospectively enrolled patients with cT3N0M0 rectal cancer who underwent neoadjuvant concurrent chemoradiotherapy between January 2016 and December 2021 at Taipei Medical University Hospital. Patients were divided into two groups according to whether they underwent total mesorectal excision or transanal endoscopic microsurgery. The clinical outcomes in each group were compared.
Results. Of the 29 included patients, 17 underwent total mesorectal excision and 12 underwent transanal endoscopic microsurgery. The transanal endoscopic microsurgical approach resulted in less blood loss and shorter operating and hospitalization times than total mesorectal excision ($p < 0.05$). The median follow-up period was 51.0 (27.0-64.0) months. Among patients who underwent transanal endoscopic microsurgery, one had local recurrence, and none had distant metastases. The 3-year disease-free survival rates of the groups were similar. No significant differences in local recurrence and distant metastasis were observed.
Conclusions. Transanal endoscopic microsurgery after neoadjuvant concurrent chemoradiotherapy among select patients with cT3N0M0 rectal cancer is a safe and feasible procedure that preserves the rectum. The degree of complete remission may be a key factor in determining whether a patient can receive transanal endoscopic microsurgery.
[*J Soc Colon Rectal Surgeon* (*Taiwan*) *2023;34:155-163*]

Colorectal cancer is the third most common cancer and the second most common cause of cancer death globally.[1] The number of new cases of colorectal cancer in 2021 was estimated at 149,500, and colorectal cancer-related mortality in the same year was 52,980.[1] Treatment of locally advanced rectal

Received: February 22, 2023. Accepted: May 16, 2023.
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cancer after chemoradiation therapy generally involves total mesorectal excision (TME),[2] which is a procedure that removes most of the bowel segments around the target tumor.

Anastomotic leakage and stenosis are two of the most common complications after TME,[3,4] which can lead to permanent stoma and negatively effects of quality of life.[5,6] Consequently, alternative treatment strategies for locally advanced rectal cancer after chemoradiation therapy are being investigated.

Transanal endoscopic microsurgery (TEM) is a treatment alternative for patients with rectal cancer with a clinical complete response after concurrent chemoradiotherapy (CCRT).[7-9] Unlike TME, TEM removes only a specific area around the tumor to preserve the majority of the bowel.[7] By preserving the bowel and thereby avoiding permanent stoma, quality of life can be improved. In addition, TEM has received positive feedback from patients, such as low complication rates, good postoperative bowel function and short hospital stay.[10,11] However, due to no removal of lymph node and high local recurrence rate of T2, T3 lesion, TEM is only suitable for patients with T1 staging according to the TNM classification system.[12]

This retrospective study evaluated the suitability of TEM after CCRT for the treatment of cT3N0M0 cancer by comparing the surgical and pathological features and the 3-year disease-free survival rates of TME and TEM.

Methods

Patients who received a diagnosis of cT3N0M0 rectal cancer at Taipei Medical University Hospital between January 2016 and December 2021 were enrolled in this retrospective study. All patients had biopsy-proven malignancy of the rectum, and all lesions had a distal border within 12 cm from the anal verge, as determined by endoscopy. All patients underwent digital rectal examination, chest to pelvic computed tomography (CT), and magnetic resonance imaging (MRI) of the pelvis before treatment. All patients accepted neoadjuvant CCRT which was administered by 5-FU 400 mg/m^2 IV bolus + 2400 mg/m^2 IV run 48 hours + leucovorin 20 mg/m^2 IV bolus for 4 days during week 1 and 5 of radiotherapy, or capecitabine 825 mg/m^2 PO twice daily 5 days/week + radiotherapy 5 weeks. Radiotherapy involved a total dose of 50.4 Gy given in 28 fractions of 1.8 Gy. Surgery was performed 8-12 weeks after the completion of neoadjuvant CCRT. Patients were divided into two groups (TME and TEM groups) according to their choice of surgical approach; for each patient, the choice was made on the basis of remission status after neoadjuvant CCRT and in shared decision-making between physician and patient. Complete remission of rectal cancer means disappearance of all signs of cancer in digital examination, colonoscopy, and image exam (pelvis CT and MRI) according to physician experience and judgement. Partial remission of rectal cancer means the size of tumor has gotten smaller in response to treatment. The study process is illustrated in a flow chart in Fig. 1. This study was approved by the Joint Institutional Review Board of Taipei Medical University (TMU-JIRB No.: N2022 06073).

Patients in the TME group were placed in the lithotomy position. TME was performed in a standardized manner with a robotic four-arm approach using the da Vinci Si Surgical System (Intuitive Surgical Inc., Sunnyvale, CA, USA). Under robotic vision, medial to lateral dissection was performed to free the sigmoid and descending colon. Dissection downward was done through the peritoneum reflection to dissect

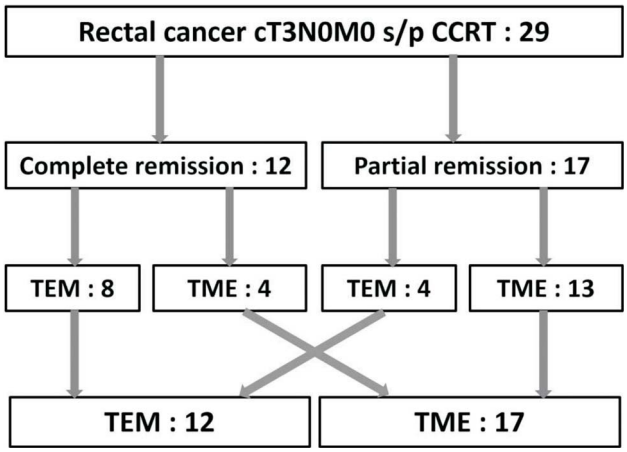

Fig. 1. Study flowchart. CCRT, concurrent chemoradiotherapy; TEM, transanal endoscopic microsurgery; TME, total mesorectal excision.

the mesorectum toward the pelvic floor. After satisfactory mobilization of the rectosigmoid, the inferior mesenteric artery and vein were reached and ligated with hemolocks or endoclips. The rectum was subsequently transected with an Endo GIA 45 stapler (green) or an Endo GIA 60 stapler (gold). Anastomosis of the lower rectum and descending colon was performed with a circular stapler (CDH29).

Patients in the TEM group were placed in the prone jackknife or lithotomy position depending on tumor location. The robotic transanal approach was performed on most patients in this group. The GelPOINT Path Transanal Access Platform was placed into the anal canal and anchored to the surrounding skin with a suture. The rectum was insufflated with CO2 at 10-15 mmHg, and then the robotic system was docked. A 30° camera and two 8-mm articulated robotic instruments were used. An additional trocar was placed at the GelPOINT. After full-thickness resection, a 15-cm 3-0 V-LocTM 90 was used to close the rectal defect. Patients in the TEM group adopted a similar approach to those undergoing robotic approach. Patients in the TEM group were placed either in the jackknife or lithotomy position depending on tumor location. The Ferguson retractor was inserted, and the anal canal was inspected. Then, rectum lesion was excised in full thickness with a safety margin of 1 cm. Then, rectal defect was then closed by vicryl 3-0.

Demographic characteristics and clinical parameters, namely age, gender, body mass index (BMI), smoking status, American Society of Anesthesiologists (ASA) physical status score, lesion distance from the anal verge, and hemoglobin (Hb), albumin, and carcinoembryonic antigen (CEA) levels, were collected before surgery. Operative and pathological parameters, namely operative time, blood loss, length of hospital stay, surgical method, lesion size, margin status, histological grading, lymphovascular invasion, perineural invasion, tumor deposit, and final ypT stage, were collected. The primary outcomes were the rates of local recurrence, distant metastasis, and 3-year disease-free survival.

Patient follow-up was performed at visits of 3-month intervals for the first year and at yearly visits thereafter. Follow-up studies included digital rectal examination, CEA assays, abdominal ultrasonography or CT, and colonoscopy. Additional tests, such as positron emission tomography–CT (PET–CT), were performed on an as-needed basis.

Continuous variables are presented as mean ± standard deviation (SD) and median (interquartile range [IQR]), and categorical variables are presented as numbers and percentages. The Mann-Whitney U test was used to compare between-group quantitative characteristics. Categorical variables were analyzed using the chi-square and Fisher's exact tests. Kaplan-Meier and log-rank tests were used to evaluate the effect of TME and TEM treatment on patient survival. All tests were 2-tailed, and $p < 0.05$ was considered statistically significant. Statistical analyses were performed in SAS version 9.4 and STATA version 14.0

Result

Among the patients enrolled in this study, 17 underwent TME and 12 underwent TEM (Fig. 1). No significant differences in age ($p = 0.1904$), gender ($p = 0.9789$), BMI ($p = 0.6739$), smoking status ($p = 0.5534$), ASA physical status score ($p = 0.1399$), distance to anal verge ($p = 0.3700$), and Hb ($p = 0.2400$) and CEA levels ($p = 0.5208$) between the two groups were observed (Table 1). Only albumin levels significantly differed between the two groups ($p < 0.05$).

In the TEM group, the mean operation time was shorter (92.9 ± 52.3 vs. 297.9 ± 131.6 min, $p < 0.0001$), less blood was lost (10.0 ± 0 vs. 36.5 ± 45.8 ml, $p < 0.05$), and the mean hospital stay was shorter (2.8 ± 1.9 vs. 10.5 ± 3.3 days, $p < 0.0001$) than in the TME group (Table 2). Among the 12 patients who underwent TEM, 4 (33.3%) received transanal TEM and 8 (66.7%) received robotic TEM. All TME procedures were performed through robot-assisted methods. No significant differences in pathological features, namely lesion size ($p = 0.4491$), margins ($p = 0.1626$), histological gradings ($p = 0.4902$), lymphovascular invasion ($p = 1.0000$), perineural invasion ($p = 0.6221$), and pT stage ($p = 0.0908$), between the TEM and TME groups were observed. Among the 12 patients who underwent TEM, 8 (66.7%) achieved a pCR after

Table 1. Patient characteristics

	TEM group (n = 12)	TME group (n = 17)	*p* value*
Age (years)			0.1904
Mean (SD)	62.8 (10.8)	57.2 (13.1)	
Median (IQR)	67.0 (54.5-70.5)	54.0 (51.0-66.0)	
Gender (n)			0.9789
Male (%)	7 (58.3%)	10 (58.8%)	
Female (%)	5 (41.7%)	7 (41.2%)	
BMI (kg/m^2)			0.6739
Mean (SD)	24.6 (2.7)	24.0 (4.0)	
Median (IQR)	25.3 (22.3-26.9)	24.7 (20.0-26.5)	
Smoking status (n)			0.5534
Smoking (%)	2 (16.7%)	1 (5.9%)	
Nonsmoking (%)	10 (83.3%)	16 (94.1%)	
ASA physical status score (n)			0.1399
I (%)	0 (0.0%)	4 (23.5%)	
II (%)	11 (91.7%)	12 (70.6%)	
III (%)	1 (8.3%)	1 (5.9%)	
Distance to anal verge (cm)			0.3700
Mean (SD)	4.3 (2.2)	5.5 (3.3)	
Median (IQR)	4.5 (2.5-5.0)	5.0 (2.5-9.0)	
Hb (g/dL)			0.2400
Mean (SD)	13.5 (1.3)	12.7 (1.3)	
Median (IQR)	13.2 (12.4-14.4)	13.2 (11.7-13.7)	
Albumin (mg/dL)			**0.0182**
Mean (SD)	4.4 (0.3)	3.9 (0.5)	
Median (IQR)	4.2 (4.1-4.7)	4.0 (3.7-4.3)	
CEA (ng/mL)			0.5208
Mean (SD)	2.5 (1.1)	3.8 (6.0)	
Median (IQR)	2.3 (1.8-2.8)	2.0 (1.2-3.8)	

* Mann-Whitney U test, chi-square test, or Fisher's exact test.

CCRT. Among the 17 patients who underwent TME, 4 (23.5%) had complete remission after CCRT (p = 0.0202; Table 2). There were two patients with margin involvement in the final pathological report, so salvage surgery was then performed. One accepted LAR surgery with final stage ypT3N1a, while another one accepted APR surgery with final staging ypT3N0. However, no further adjuvant chemotherapy was performed later due to ECOG:3. No local recurrence and distal metastasis was found during follow up period.

The median follow-up period was 51.0 (27.0-64.0) months. One patient in the TEM group and no patients in the TME group experienced local recurrence. No patients in the TEM group but three patients in the TME group experienced distant metastases. The 3-year disease-free survival rate in each group was similar (91.7% and 82.4% in the TEM and TME groups, respectively; Fig. 2). No significant between-group differences in local recurrence and distant metastases were observed (Table 3).

Discussion

TME has long been considered the mainstay post-CCRT treatment alternative for patients with rectal cancer. TME removes most of the bowel segments and is associated with a lower local recurrence rate.[2] However, a variety of anastomotic complications may occur after TME, such as anastomotic fistula, stenosis, and leakage; chronic sinus; and pelvic abscess.[3] Anastomotic leakage is a major complication, increasing postoperative morbidity and mortality. The incidence rate of anastomotic leakage after colorectal surgery is

Table 2. Surgical and pathological features

	TEM group (n = 12)	TME group (n = 17)	*p* value*
Operation time (min)			**< 0.0001**
Mean (SD)	92.9 (52.3)	297.9 (131.6)	
Median (IQR)	76.5 (59.5-103)	269.0 (240-330)	
Blood loss (mL)			**0.0470**
Mean (SD)	10.0 (0.0)	36.5 (45.8)	
Median (IQR)	10.0 (10-10)	10.0 (10-50)	
Length of hospital stay (day)			**< 0.0001**
Mean (SD)	2.8 (1.9)	10.5 (3.3)	
Median (IQR)	2.5 (2-3)	10.0 (8-12)	
Surgical methods (n)			**0.0208**
Transanal (%)	4 (33.3%)	0 (0.0%)	
Robotic (%)	8 (66.7%)	17 (100.0%)	
Lesion size (mm)			0.4491
Mean (SD)	14.0 (13.9)	16.7 (11.0)	
Median (IQR)	7.0 (5-30)	13.5 (11-20)	
Margin (n)			
Free (%)	10.0 (83.3%)	17.0 (100.0%)	0.1626
Involved (%)	2.0 (16.7%)	0.0 (0.0%)	
Histological grading (n)			0.4902
I (%)	1 (8.3%)	0 (0.0%)	
II (%)	2 (16.7%)	6 (35.3%)	
III (%)	2 (16.7%)	7 (41.2%)	
Missing	7 (58.3%)	4 (23.5%)	
Lymphovascular invasion (n)			1.0000
Yes (%)	1 (8.3%)	1 (5.9%)	
No (%)	11 (91.7%)	16 (94.1%)	
Perineural invasion (n)			0.6221
Yes (%)	1 (8.3%)	3 (17.6%)	
No (%)	11 (91.7%)	14 (82.4%)	
Tumor deposit (n)			
Yes (%)	0 (0.0%)	0 (0.0%)	
No (%)	12 (100.0%)	17 (100.0%)	
pT stage (n)			
ypT0 (%)	8 (66.7%)	4 (23.5%)	0.0908
ypT1 (%)	1 (8.3%)	1 (5.9%)	
ypT2 (%)	2 (16.7%)	7 (41.2%)	
ypT3 (%)	1 (8.3%)	5 (29.4%)	
Remission (n)			**0.0202**
Partial (%)	4 (33.3%)	13 (76.5%)	
Complete (%)	8 (66.7%)	4 (23.5%)	

* Mann-Whitney U test, chi-square test, or Fisher's exact test.

2%-27%.[13,14] In a study involving 1442 patients from 11 hospitals who underwent anterior resection for rectal cancer, 144 (10%) experienced anastomotic leakage and 90 in 144 (62.5%) had permanent stoma at long-term follow-up.[14] In addition, fecal incontinence and urinary and sexual dysfunction were noted in some patients after colorectal surgery.[15] These complications are usually unexpected, dramatically affect quality of life, decrease patient satisfaction, and affect the doctor-patient relationship.

The TEM technique was primarily developed by Gerhard Buess in the 1980s.[16] TEM is a form of laparoscopic surgery that involves using a natural opening of the body and the use of long-shafted instrumen-

tation.[17] Without the need to create an artificial opening, TEM reduces surgical injury to the body. In contrast to TME, TEM results in less blood loss, a shorter operating time, a shorter hospitalization time, and lower reoperation and stoma formation rates.[18] TEM better preserves the rectum and consequently is gaining popularity. Consistent with the aforementioned findings, this study found that relative to TME, TEM results in less blood loss and shorter operating and hospitalization times. However, the oncological safety of TEM is still unclear. The surgical area is smaller in TEM than in TME, and the perirectal lymph node is not retrieved.[19] Current guidelines recommend TEM only be used to treat early (i.e., stage T1) rectal cancer with favorable histopathology.[20] According to a meta-analysis by Dekkers et al., the overall pooled cumulative incidence of recurrence was 9.1% for T1 lesions with TEM treatment.[21] A higher risk of recurrence was observed after TEM for later cancer stages. For example, Tsai et al. noted that the recurrence rate of T2 and T3 cancer after TEM was 23.5% and 100%, respectively.[22] Currently, a consensus has been reached in which TEM treatment is accepted for T1 lesions but not for T2 and T3 lesions.

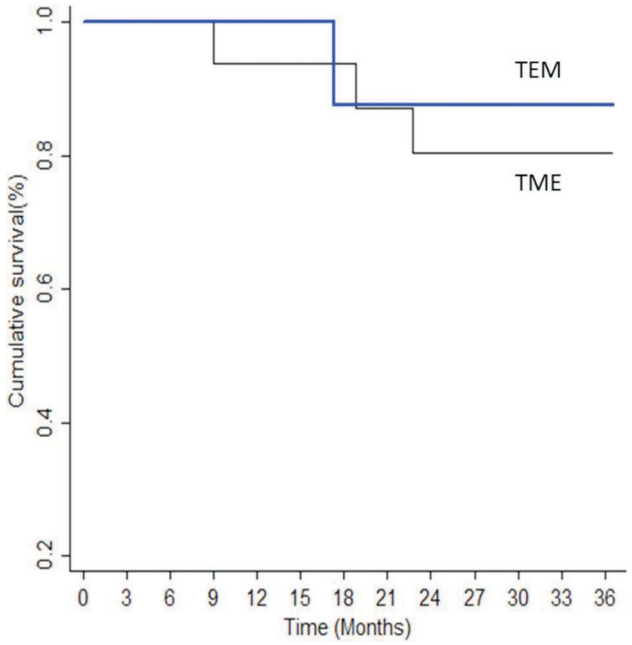

Fig. 2. Kaplan-Meier survival curve for 3-year disease-free survival in the two groups (log-rank test, p = 0.6362).

Studies have suggested that local excision after neoadjuvant CCRT is suitable for the treatment of T2N0M0 and T3N0M0 lesions among carefully selected patients.[23,24] The widespread use of neoadjuvant therapy for locally advanced rectal cancer in recent decades has had a dramatic downstaging effect. Manatakis et al. reported that mean T downstaging (ypStage 0-1) was 49.6%, mean N downstaging was 69.6%, and mean pCR was 10.7%.[25] Studies have demonstrated that 8%-25% of patients who receive neoadjuvant CCRT achieve pCR.[24-26] These favorable

Table 3. Postoperative follow-up

	TEM group (n = 12)	TME group (n = 17)	*p* value
Follow-up (months)			0.0727
Median (IQR)	35.1 (23.2)	52.6 (22.9)	
Range (min-max)	30 (12-60.5)	60 (37-71)	
Local recurrences (n)			0.4138
Yes (%)	1 (8.3%)	0 (0.0%)	
No (%)	11 (91.7%)	17 (100.0%)	
Distant metastases (n)			0.2463
Yes (%)	0 (0.0%)	3 (17.6%)	
No (%)	12 (100.0%)	14 (82.4%)	
Adjuvant chemotherapy (n)			
Yes (%)	7 (58.3%)	15 (88.2%)	0.0920
No (%)	5 (41.7%)	2 (11.8%)	
Survival rate (%)			
Yes (%)	12 (100.0%)	14 (82.4%)	0.2463
No (%)	0 (0.0%)	3 (17.6%)	

* Mann-Whitney U test, chi-square test, or Fisher's exact test.

findings suggest that local excision is a suitable treatment option among select patients with T2-T3-N0 rectal cancer. Preservation of the rectum can be achieved in 73%-95% of patients with acceptable local control.[27] However, for patients without a pCR, salvage radical surgery should be suggested. Hallam et al. reported that among patients without a pCR after local excision who did not undergo radical surgery, the local recurrence rate was 21.9% and median disease-free survival rates was 68.0%.[24] In our study, two-thirds of the TEM-treated patients achieved complete remission after CCRT, and 76.5% of TME-treated patients had partial remission after CCRT, with ypT2 (7/17, 41.2%) and ypT3 (5/17, 29.4%). In the TEM group, four patients had partial remission after CCRT, two of whom eventually received salvage radical surgery because of margin involvement. No patient with partial remission was found to have recurrence of rectal cancer in the TEM group, but one patient with complete remission developed local recurrence. Distant metastases did not occur in TEM-treated patients.

Distant metastases occurred in 17.6% (3/17) of TME-treated patients. The 3-year disease-free survival rate of TEM-treated patients was not significantly different from that of TME-treated patients. Our experience indicates that TEM combined with neoadjuvant CCRT is a safe and feasible method of preserving the rectum in selected patients with rectal cancer without evidence of nodal involvement.

The decision-making process for selecting TME or TEM depends on remission status after CCRT. However, determination of partial versus complete remission is challenging. Currently, the response to CCRT is assessed by using digital rectal examinations, biomarkers, random biopsies under colonoscopy,[28] or imaging systems, such as diffusion-weighted magnetic resonance imaging and F-FDG PET-CT.[18,29] Except for radical resection, no precise tool exists for examining and confirming the presence of residual tumors,[28] and physicians and surgeons must assess the response to CCRT according to their own judgment. Artificial intelligence could be used to precisely determine the response to CCRT.[30] Jia et al. developed a deep learning model based on magnetic resonance images of 1,873 patients that could predict pCR (pooled area under the curve: 0.91; sensitivity: 0.82; pooled specificity: 0.86).[30] Although many methods have been proposed to assess the response to CCRT, additional research, with prospective, large-scale, multicenter studies, is required to strengthen the diagnostic power of pCR.

This study has several limitations. First, this was a retrospective non-randonmized study, and some of the patient records were incomplete. Second, this was a single-center study with a small sample size. Multicenter, large-scale research is required to further evaluate TEM. Thirdly, there is a selection bias to the ratio of complete remission rate in both groups. The complete remission rate in TEM group is higher than TME group.

In conclusion, TEM combined with neoadjuvant CCRT is a feasible approach for preserving the rectum among select patients with cT3N0M0 rectal cancer. The remission status may be a key factor in determining whether a patient can undergo TEM.

Conflicts of Interest

The authors have no conflicts of interest to declare.

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原　著

T3N0M0 直腸癌患者新輔助同步放化療後經肛門顯微內鏡手術的臨床結果？

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目的　全直腸系膜切除術是直腸癌的標準治療方法，但可能會出現多種手術併發症。與全直腸系膜切除術不同，經肛門內視鏡顯微手術的副作用較低，但對局部晚期直腸癌的複發率較高。本研究的目的是驗證經肛門內視鏡顯微手術是否可以作為臨床分期 cT3N0M0 的直腸癌患者在新輔助同步放化療後的替代治療。

方法　我們回顧性分析了 2016 年 1 月至 2021 年 12 月在台北醫學大學附設醫院臨床分期為 cT3N0M0 的直腸癌患者，所有患者接受新輔助同步放化療後，分為全直腸系膜切除術組和經肛門內視鏡顯微手術組兩組，對臨床療效進行隨訪和比較。

結果　在納入的 29 例患者中，17 例接受了全直腸系膜切除術，12 例接受了經肛門內視鏡顯微手術。與全直腸系膜切除術相比，經肛門內視鏡顯微手術在統計學上顯著減少了失血量、手術時間和住院時間。在平均隨訪 51.0 (27.0-64.0) 個月後，經肛門內視鏡顯微手術組有 1 例患者局部復發，無遠處轉移。兩組患者的三年無病存活率相似，局部復發和遠處轉移的概率無顯著差異。

結論　我們的經驗表明對於臨床分期為 cT3N0M0 的直腸癌患者，經肛門內視鏡顯微手術加上新輔助同步放化療是一種安全有效的方法，病理性緩解程度可能是這類患者可以是否接受肛門內視鏡顯微手術的關鍵因素。

關鍵詞　新輔助同步放化療、直腸癌、經肛門內視鏡顯微手術。