

Original Article

Transanal Local Excision Versus Radical Surgery for T1N0 Lower Rectal Adenocarcinoma

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Key Words

Rectal adenocarcinoma;
Local excision;
Survival

Background. The aim of this study was to compare surgical outcomes including survival in T1N0 rectal adenocarcinoma patients undergoing transanal local excision or radical surgery.

Methods. We retrospectively reviewed 87 and 176 patients who underwent transanal local excision and radical surgery, respectively, for T1N0 rectal adenocarcinoma without neoadjuvant chemotherapy or radiotherapy between May 1995 and January 2013.

Results. The mean age, sex distribution, and carcinoembryonic antigen level were similar between the 2 groups. The mean duration of hospital stay was 4.66 days in the local resection group and 12.32 days in the radical surgery group ($p < 0.05$). The overall survival rate at 5 years was 91% in the local resection group and 83% in the radical surgery group ($p = 0.928$). The disease-free survival rate at 5 years was 87% in the local resection group and 93% in the radical surgery group ($p = 0.037$). The disease-free survival rate at 5 years in the local resection group was significantly poorer than in the radical surgery group.

Conclusion. Local excision is an alternative method of treatment for early lower rectal adenocarcinoma. With selection, the oncologic outcomes for local excision are similar to that of radical surgery. Advantages of local excision include early bowel function recovery, shorter hospital length of stay, lower morbidity, and avoidance of colostomy.

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Traditional surgical therapy for lower rectal adenocarcinoma is either low anterior resection or abdominoperineal resection. Radical Surgical treatment has been shown to confer lower local recurrence rates and better long-term outcomes.^{1,2} However, these surgical procedures are associated with significant morbidity rates and may need a temporary or permanent colostomy. Colostomies can result in functional and psychological disabilities and impair qual-

ity of life. Radical surgery may come *major complications*, including anastomotic leakage, bowel obstruction, difficulty in defecation and voiding, sexual dysfunction, and even perioperative death.³

Thus, for early rectal adenocarcinoma, transanal local excision offers a less radical approach and decreased postoperative morbidity and sphincter preservation with better functional outcomes and acceptable oncologic outcomes.^{4,5} However, the transanal local

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excision has the potential of incomplete tumor resection and no lymphadenectomy. The aim of this study was to compare surgical outcomes including survival among T1N0 rectal adenocarcinoma patients undergoing transanal local excision or radical surgery.

Materials and Methods

We retrospectively reviewed 87 and 176 patients who underwent transanal local excision and radical surgery, respectively, for T1N0 rectal adenocarcinoma without neoadjuvant chemotherapy or radiotherapy between May 1995 and January 2013. The definition of lower rectal tumor was a tumor located less than 8 cm from the anal verge and the clinical stage was T1N0M0 from the computed tomography scan of the abdomen and pelvis. The patient had a single, small (polypoid shape < 4 cm or ulcerative shape < 1 cm), mobile adenocarcinoma of the rectum with the ratio of the circumference of the rectum less than quarter receiving transanal local excision. All patients underwent rigorous preoperative medical, psychological, and anatomic evaluation. They were evaluated by digital rectal examination, full colonoscopy to exclude synchronous lesions. Chest x-ray and computed tomography scan of the abdomen and pelvis found no evidence of metastatic lesions nor local extrarectal invasion. The rectal tumor was first detected on a rectal examination (59.7%; 157 patients), colonoscopy (27%; 71 patients), sigmoidoscopy (12.9%; 34 patients), and barium enema/computed tomography scan (4%; 1 patient). All patients underwent full mechanical and antibiotic bowel preparation. They all received elective surgery without neoadjuvant treatment by 10 surgeons. At our institution, all surgical protocols were according to the guideline of the National Comprehensive Cancer Network and were approved by the Oncology Committee of Chang Gung Memorial Hospital. All cases were discussed at the combined conference of Colon and Rectal Surgeons every week.

Transanal local excision

All patients in this study underwent local excision

with the patient in left lateral position by a standard transanal approach. The anus was partially exposed by taping the buttocks apart. The tool used for anal exposure is Hill-Ferguson rectal retractors. The method of anesthesia is intravenous sedation with local anesthesia or spinal anesthesia. Full-thickness excision was performed with the aiming for a circumferential margin of at least 1.0 cm around the lesion. After hemostasis, primary closure was performed using a single layer of interrupted absorbable suture. Patients were discharged from the hospital if they had no fever and good recovery of gastrointestinal function.

The post-operative adjuvant treatment was according to the National Comprehensive Cancer Network guideline. Patients choose the adjuvant concurrent chemoradiotherapy or radiotherapy if the unfavorable histopathology (angiolymphatic invasion, close margin, positive resection margin, or lymph node metastasis) found.

Whether patients receiving local excision or radical surgery, follow-up examinations were arranged for all patients at 1 month after surgery then every 3 months in the first two years. The patients were back to the clinic for follow-up examinations every 6 months from the 3rd to the 5th years and then annually thereafter. The patients were followed until death or at least more than five years in this study group. Examinations included digital examination, proctoscopy, and serum carcinoembryonic antigen. Abdominal and chest CT was arranged 1 year after surgery or on clinical suspicion of recurrence.

We retrospectively reviewed patients from two treatment groups: a local excision group and a radical surgery group (low anterior resection group: 89.8%, 158 patients; abdominoperineal resection group: 10.2%, 18 patients). These patients had been followed-up according to the protocol. A local recurrence was defined as evidence of recurrent disease within the pelvis after surgical resection. The patients' data and tumor characteristics are shown in Table 1. In the local excision group, there were 22 patients who received postoperative adjuvant treatment owing to unfavorable histopathology (angiolymphatic invasion, close margin, or positive resection margin). Of these 22 patients, 20 received postoperative concurrent chemora-

Table 1. Patients' data and tumor Characteristics of patients and tumors

	Local excision (n = 87)	Radical surgery (n = 176)	<i>p</i>
Patient characteristics			
Gender: Male	46	91	0.86
Female	41	85	
Age (yr)	62.67 ± 12.76	62.74 ± 11.82	0.94
CEA (ng/mL)	2.49 ± 2.34	3.39 ± 10.32	0.43
Hb (g/dL)	13.07 ± 2.07	12.89 ± 1.94	0.49
Duration of hospital stay	4.66 ± 2.87	12.32 ± 7.79	0.00
Follow-up time (yr)	65.89 ± 38.73	70.19 ± 43.07	0.43
Tumor characteristics			
Tumor location from anal verge (cm)	5.00 ± 2.06	5.92 ± 1.72	0.00
Tumor size Width (cm)	3.66 ± 10.41	3.62 ± 10.37	0.98
Length (cm)	3.02 ± 10.46	3.41 ± 10.38	0.77
Resection margin (cm)	0.17 ± 0.99	1.65 ± 1.11	0.00
Histology type			
Adenocarcinoma (%)	96.6 (n = 84)	96.6 (n = 170)	0.52
Signet ring cell adenocarcinoma (%)	0	1.1 (n = 2)	
Mucinous adenocarcinoma (%)	3.4 (n = 3)	2.3 (n = 4)	
Histology differentiation			
Well differentiation (%)	49.4 (n = 43)	40.9 (n = 72)	0.13
Moderate differentiation (%)	44.8 (n = 39)	54.5 (n = 96)	
Poor differentiation (%)	2.3 (n = 2)	4.0 (n = 7)	
Data loss	3.4 (n = 3)	0.6 (n = 1)	

Figures are mean ± standard deviation unless otherwise specified.

CEA: carcinoembryonic antigen; Hb: hemoglobin.

Radical Surgery: Low anterior resection (89.8%; 158 patients) and Abdominoperineal resection (10.2%; 18 patients).

diotherapy (long course radiotherapy: 5040 cGy in 28 fractions), and the remaining 2 patients received long course radiotherapy only.

In the low anterior resection group, there were 39 patients who received adjuvant treatment due to lymph nodes metastasis (18 patients were treated with adjuvant chemotherapy; 21 people accepted radiotherapy or concurrent chemoradiotherapy). In the abdominoperineal resection group, there were one person receiving adjuvant chemotherapy, and another one person accepting concurrent chemoradiotherapy. Early morbidity is defined as complications during hospitalization and the definition of late morbidity is complication developing after patient discharge.

Unpaired *t*-tests were used to compare sex, age, follow-up time, duration of hospital stay, tumor location from the anal verge and postoperative complications between the 2 groups. Survival was estimated by Kaplan-Meier curves. A log-rank test was used to compare survival curves. *p* < 0.05 was considered sta-

tistically significant. Statistical analyses of all data were performed using statistical software (IBM SPSS Statistics Software v16.Chicago, IL).

Results

The mean age and sex distribution were similar between the 2 groups (62.67 years in the local resection group and 62.74 years in the radical surgery group). The mean carcinoembryonic antigen level was 2.49 ng/mL in the local resection group and 3.39 ng/mL in the radical surgery group (*p* = 0.43). The mean hemoglobin level was 13.07 g/dL in the local resection group and 12.89 g/dL in the radical surgery group (*p* = 0.49). The mean duration of hospital stay was 4.66 days in the local resection group and 12.32 days in the radical surgery group (*p* < 0.05). The mean follow-up time was 65.89 months in the local resection group and 70.19 months in the radical surgery

group ($p = 0.43$). The mean tumor location from the anal verge was 5.0 cm in the local resection group and 5.92 cm in the radical surgery group ($p < 0.05$). The mean tumor size was 3.66 cm in the local resection group and 3.62 cm in the radical surgery group ($p > 0.05$).

The characteristics of medical illness in the two groups are shown in Table 2. In the local resection group, there were 32 people who had no other underlying diseases (32/87, 36.8%), and in the radical surgery group of 82 people without other diseases (82/176, 46.6%). However, some patients have multiple underlying diseases. In the local resection group, there were 26 people who had one medical illness (26/87, 29.9%) and 29 patients who had more than 2 underlying diseases (29/87, 33.3%). In the radical surgery group, there were 56 people who had one medical illness (56/176, 31.8%) and 38 patients who had more than 2 underlying diseases (38/176, 21.6%).

The 5-year overall survival (OS) was 91% in the local resection group and 83% in the radical surgery group ($p = 0.928$, Fig. 1). The 5-year disease free survival (DFS) was 87% in the local resection group and 93% in the radical surgery group ($p = 0.037$, Fig. 2).

Table 2. Characteristics of medical illness of two groups

No.	Local excision (n = 87)	Radical surgery (n = 176)	<i>p</i>
Without underlying disease	32 (36.8%)	82 (46.6%)	0.131
1 medical illness	26 (29.9%)	56 (31.8%)	
More than 2 underlying diseases	29 (33.3%)	38 (21.6%)	
No. of medical illness			
Hypertension	32	54	
Cardiac disease	5	15	
Cerebral vascular accident	5	3	
Asthma	2	3	
Diabetes mellitus	18	19	
Peptic ulcer	10	15	
Hepatitis	4	4	
Liver cirrhosis	2	2	
Gallstone	5	5	
Thyroid problem	1	5	
Other medical illness	15	29	

* Some patients have multiple underlying diseases.

In the local excision group, 22 patients received postoperative long course adjuvant radiotherapy (5040 cGy in 28 fractions). The histologic grade of the 22 patients, 8 of whom were well differentiated carcinoma, and the remaining 14 people were moderate

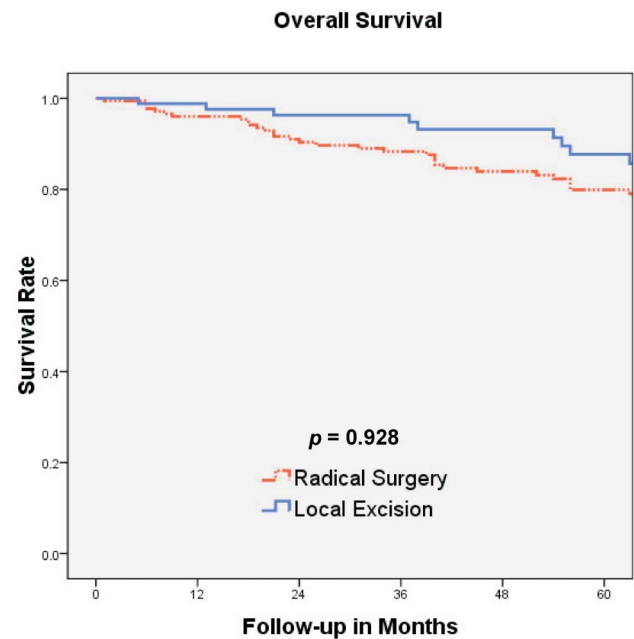


Fig. 1. Overall Survival between local excision group and radical surgery group.

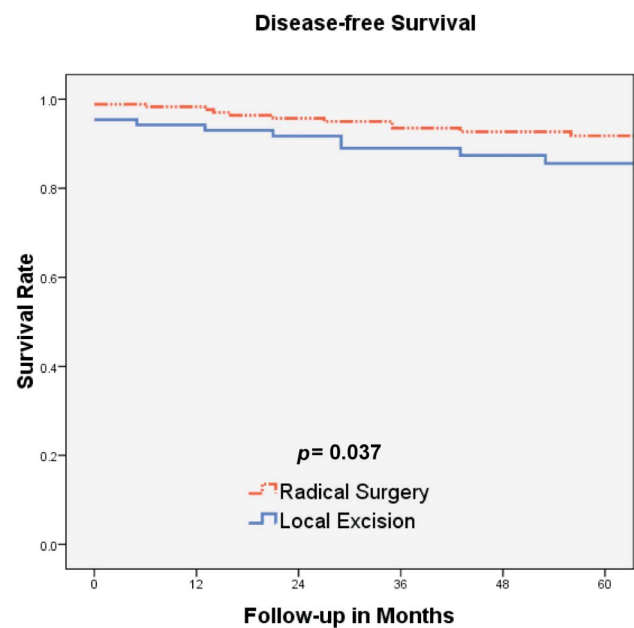


Fig. 2. Disease-free Survival between local excision group and radical surgery group.

differentiated carcinoma. There were 17 cases were found to have circumferential involvement. The resection margin was 0 cm in most patients and 1 cm in only 2 people. The 5-year OS and DFS were similar in patients with or without adjuvant radiotherapy. (OS: 95% vs. 89%, $p = 0.728$, Fig. 3; DFS: 82% vs. 89%, $p = 0.123$, Fig. 4).

In the local excision group, 9 (9/78, 11.5%) patients had recurrence during follow-up. Two patients with local recurrence underwent only transanal local excision plus postoperative adjuvant long course radiotherapy. Two patients with distant metastases received palliative chemotherapy only owing to multiple lungs metastasis. One patient with lung metastasis in the right lower lobe received lung wedge resection plus palliative chemotherapy. Four patients had both local recurrence and distant metastasis: 3 patients underwent curative resection for both local and distant recurrent sites, and 1 patient received palliative chemotherapy. The salvage surgery rate was 77.78%. The recurrence patterns and disease status in the local resection group are shown in Table 3.

In the radical surgery group, 20 patients had recurrence during follow-up. One patient had local recurrence and 19 patients had distant metastases (lung

metastases: 8 patients; liver metastases: 7 patients; bone metastases: 2 patients; brain metastases: 1 patient; retroperitoneal metastases: 1 patient).

The postoperative complications including early morbidity, late morbidity, and mortality are shown in Table 4. The early morbidity rate was 6.9% ($n = 6$) in the local resection group and 22.7% ($n = 40$) in the radical surgery group. The late morbidity rate (complications developing after discharge from hospital) was 1.1% ($n = 1$, wound infection) in the local resection group and 7.4% ($n = 13$) in the radical surgery group. There was no mortality in the local resection group. In the radical surgery group, 1 patient died because of myocardial infarction on postoperative day 10 ($p = 0.481$).

Discussion

From the previous to the present, all surgical protocols were according to the guideline of the National Comprehensive Cancer Network guideline in our hospital. The method of transanal local excision was similar to other local excision. And the surgical guideline was not different from other previous articles. Steele

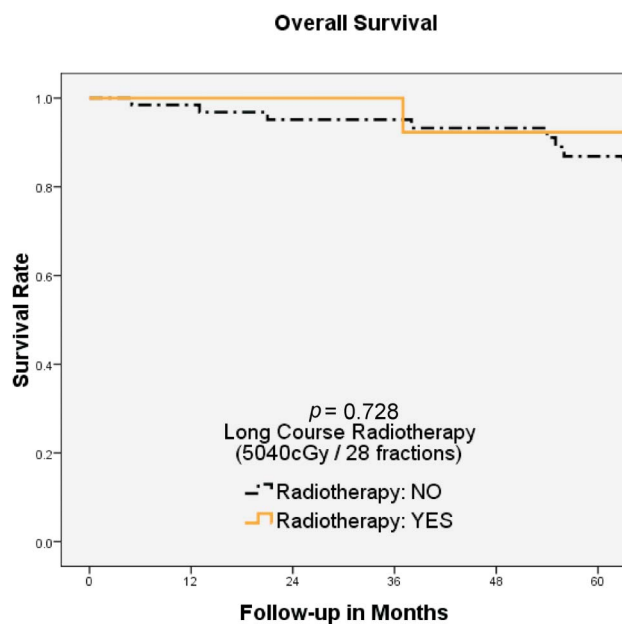


Fig. 3. Overall Survival in local excision group with or without radiotherapy.

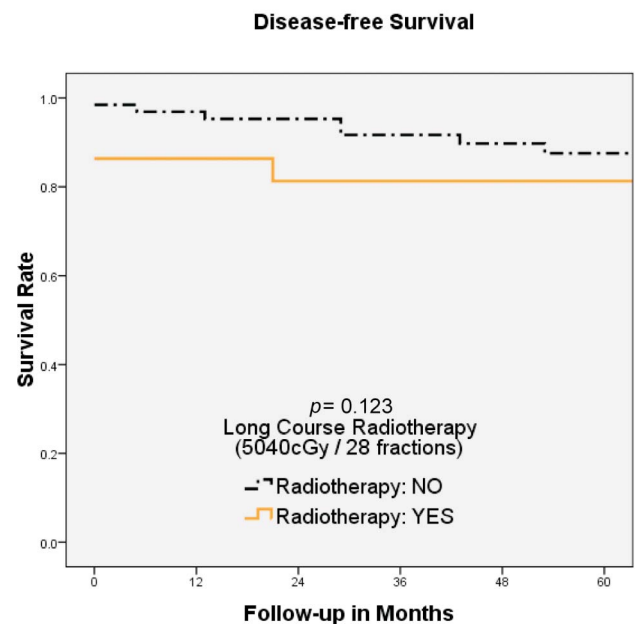


Fig. 4. Disease-free Survival in local excision group with or without radiotherapy.

Table 3. Recurrence patterns in the local resection group

Recurrence pattern	Age/Gender	Salvage surgery	Palliative treatment	Disease status	Cause of death	Time of death* (year)
Local	74/M	Local excision	CCRT	Dead	Sepsis	1.67
	50/F	Local excision	Long course radiotherapy	Alive		
Distant	31/M	Wedge resection of lung	FOLFIRI	Alive	Lung metastasis	8.25
	64/M		Uracil-Tegafur	Dead		
	60/F		CPT-11	Dead		
Local + Distant	26/F	APR	5-FU + Leucovorin	Dead	Sepsis and pancytopenia	7.5
	44/M	APR	FOLFOX	Dead	Obstruction due to carcinomatosis	8.33
	51/F	LAR	Uracil-Tegafur	Dead	Lung metastasis	4.5
	76/F	Local excision	No	Dead	Cholangiocarcinoma with lung metastasis	3.08

* Time of death: Time of death from the first local excision surgery.

APR = abdominoperineal resection, LAR = lower anterior resection, CCRT = concurrent chemoradiation therapy.

Table 4. Post-operative morbidity and mortality

No.	Local excision (n = 87)	Radical surgery (n = 176)	<i>p</i>
Early morbidity	n = 6	n = 39	0.002
Wound (infection, dehiscence,...)	3 (3.4%)	10 (5.7%)	
Bladder dysfunction	1 (1.1%)	12 (6.9%)	
GI (obstruction, bleeding)	1 (1.1%)	10 (5.7%)	
Abdomen (abscess, peritonitis,...)	0	4 (2.3%)	
Anastomosis (leakage, stenosis,...)	1 (1.1%)	3 (1.7%)	
Late morbidity	n = 1	n = 13	0.033
Wound infection	1 (1.1%)	3 (1.7%)	
Bladder dysfunction	0	3 (1.7%)	
GI (obstruction, bleeding)	0	4 (2.3%)	
Abdominal abscess	0	1 (0.6%)	
Anastomosis (leakage, stenosis,...)	0	2 (1.1%)	
Mortality	0	n = 1	0.481

GI = Gastrointestinal disease.

GD Jr1 et al.⁶ had stated that 110 patients who had T1/T2 adenocarcinoma \leq 4 cm in diameter, which encompassed \leq 40% of the bowel wall circumference, and were \leq 10 cm from the dentate line receiving transanal local excision. Anders Mellgren, M. D. et al.⁷ reported that 108 patients treated with curative intent for stage I (pT1 and pT2) adenocarcinoma without adjuvant chemoradiation via transanal excision. The rectal mass was defined as the distal 15 cm of the gastrointestinal tract measured from the anal verge. Yu-Chen Shiu et al.⁵ reviewed that 76 patients with T1-2 adenocarcinoma of the middle to lower rectum (below 10 cm from anal verge) treated by local

excision (transanal excision or Kraske's operation). Full-thickness excision was performed with the aiming for a circumferential margin of at least 1.0 cm around the lesion. The indication for receiving transanal local excision was a tumor located less than 8 cm from the anal verge and the clinical stage was T1N0M0 from the computed tomography scan of the abdomen and pelvis. Surgical indications in our hospital is no difference from the past study.

The Cancer and Leukemia Group B trial,⁶ which was a multiinstitutional, prospective trial, examined patients treated by either local excision alone for T1 tumors or with local excision followed by chemora-

diotherapy for T2 tumors. The results of this trial, published in 1999, demonstrated that this treatment strategy provided similar overall local control and survival rates when compared with historical controls for radical surgery. In our study, the outcome of local excision is similar to that achieved with radical surgery. The OS rate at 5 years in the local resection group (91%) was better than that of the radical surgery group (83%, $p > 0.05$). However, the differences between the 2 groups were not statistically significant. However, the disease-free survival between local excision group and the radical surgery group had statistically significant. This result may be associated with the patients in the local excision group did not receive lymphadenectomy. Matthew R. et al.⁸ stated that local excision when performed on appropriately selected patients and when using an advanced transanal platform (transanal endoscopic microsurgery) for early-stage (T1) rectal adenocarcinoma, results in excellent survival and low recurrence rates, with outcomes comparable to that observed with radical resection.^{4,9,10}

Previous studies have shown that postoperative chemoradiotherapy may reduce the incidence of local recurrence and increase OS rates after local excision for rectal adenocarcinoma; nonetheless, further follow-up is needed to determine the definitive long-term outcome.^{5-7,11} Borschitz et al.¹² reported that in local excision after preoperative chemoradiotherapy, the local recurrence rate ranged between 6% and 20% for ypT2 cases. Pucciarelli S et al.¹³ evaluated 63 patients with preoperative chemoradiotherapy, and found the estimated cumulative 3-year OS, DFS, and local DFS rates to be 91.5%, 91.0%, and 96.9%, respectively. Yulia Kundel et al.¹⁴ report a low rate of regional lymph node metastases after neoadjuvant concurrent chemoradiotherapy for locally advanced rectal adenocarcinoma in patients with mural pathological complete response (ypT0) but not with microscopic residual disease. However, Philip B. Paty¹⁵ reported that local excision for T1 and T2 rectal adenocarcinoma is associated with recurrence rates that are higher than those reported for radical surgery. Postoperative adjuvant therapy does not appear to be reliable in preventing local tumor recurrence, and sur-

gical salvage of recurrent adenocarcinoma has a low cure rate.¹⁵ In our local excision group, the 5-year OS in those who received adjuvant radiotherapy (OS 95%) was better than that those who did not receive adjuvant treatment (OS 89%, $p > 0.05$). However, the differences between the 2 groups did not reach statistical significance. The disease-free survival in those who received adjuvant radiotherapy (DFS 82%) was a little worse than that those who did not receive adjuvant treatment (DFS 89%, $p > 0.05$). This result may be associated with only the patients who had unfavorable histopathology would receive adjuvant radiotherapy. Therefore, it would seem that long-course adjuvant radiotherapy for early rectal adenocarcinoma with unfavorable histopathology is still questionable.

Local recurrence rate is strongly associated with depth of invasion and lymph node involvement. The risk for tumor spread to the lymph nodes is 0% to 12% for T1 tumors.^{7,16,17} Bentrem¹⁸ et al. reported that patients with early rectal adenocarcinoma treated with local excision could have a 3- to 5-fold higher risk of tumor recurrence compared with patients treated with radical surgery. The source of tumor recurrence is the remaining metastatic lymph nodes in the mesorectum, and thus, patients undergoing local excision need close follow-up. Sharma et al.¹⁶ reported that the distant metastasis rate ranged from 0% to 18% after local excision for rectal cancer. The 5-year survival rate ranged from 66% to 100%. However, these study results are variable and few long-term outcomes were reported.

The radical surgery-associated mortality for rectal adenocarcinoma were reported to be in the range of 1-12.5%.¹⁹ The anastomosis leakage rate was 3-20% and the rates of bladder and sexual dysfunction were up to 40%.^{7,20-22} In our study, the early and late morbidity rate were 6.9% and 1.1%, respectively, in the local resection group. In the radical surgery group, the early and late morbidity rate were 22.7% ($n = 40$) and 7.4% ($n = 13$), respectively. Mortality after radical surgery was 0.6% in our study. Compared to the radical surgery group, the local excision group had a shorter duration of surgery, lesser blood loss, shorter hospital stay, lower analgesic demand, and lower mor-

bidity and mortality. Earlier reports have shown that permanent urinary and sexual dysfunctions are common sequel after radical proctectomy.²³⁻²⁵ In our study, primary complications, including wound infection, urine retention, intestinal obstruction, gastrointestinal bleeding, postoperative hemorrhage, and pulmonary infection were cured by conservative treatment. No anal dysfunction or incontinence were seen in the transanal local excision group.

Conclusion

In the last few decades, local excision for early rectal adenocarcinoma has become common.^{5,17} In patients with unfavorable histopathology after transanal local excision, postoperative concurrent chemoradiotherapy still yields similar oncologic outcomes as compared with radical surgery. Consequently, transanal local excision offers the advantages of faster bowel function recovery, shorter length of hospital stay, lower morbidity, better survival, and avoidance of colostomy. Transanal local excision is an ideal and less invasive technique for early lower rectal adenocarcinoma, but requires careful selection of patients with favorable tumor characteristics (low-lying, small, low-grade, without evidence of invasion).^{7,17} Radical surgery may be arranged immediately after transanal local excision if patients have poor pathological factors. Moreover, close regular follow-up and salvage surgery should be performed in cases of resectable local recurrence or distant metastasis.

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原 著

T1N0 低位直腸腺癌之經肛門局部切除術 與根治手術之比較

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目的 本研究的目的是比較治療 T1N0 期直腸癌利用經肛門局部切除手術或根治性手術其二者效果和生存率是否有差異。

方法 我們回顧性分析在 1995 年 5 月至 2013 年 1 月間，患者全部都是 T1 期直腸腺癌（病理 pT1 期無手術前輔助化療或放射治療）。其中有 87 例患者接受經肛門局部切除術和 176 例患者接受根治性手術治療。

結果 平均年齡，性別分佈，癌胚抗原水平（CEA）的結果在這 2 組間是相似的。平均住院時間在局部切除術這組為 4.66 天，而在根治性手術組為 12.32 天 ($p < 0.05$)。5 年總生存率 (overall survival)，在局部切除術這組為 91%，而在根治性手術組為 83% ($p = 0.928$)。5 年無病生存期 (disease-free survival)，在局部切除術這組為 87%，而在根治性手術組為 93% ($p = 0.037$)。局部切除術這組的 5 年無病生存期 (disease-free survival) 顯著較差。

結論 局部切除是治療早期低位直腸癌腺癌的一種替代方法。經篩選後局部切除術其預後是與根治性手術相似。局部切除術的優點包括早期腸道功能恢復，縮短住院時間，降低併發症和避免人工造口形成。

關鍵詞 直腸惡性腫瘤、局部切除、存活率。