Original Article

Incidence of Local Recurrence in pT1 Rectal Cancer after Local Excision and Additional Radical Resection

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Key Words
Rectal cancer;
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Purpose. Pathological T1 lesions can be managed by alternative treatment of local excision and adjuvant chemoradiotherapy, fewer surgical morbidities and permanent stoma are the key benefits of these local excisions. Since local recurrence of rectal cancer was higher than colon cancer, the radical resection was suggested for better oncological outcome. This paper aims to evaluate the incidence of local recurrence of high risk pT1 rectal cancer among patients who underwent either local excision or additional radical resection.

Methods. We retrospectively enrolled data of 285 patients with high risk pT1 rectal adenocarcinoma, 134 patients were selected. Forty-four patients underwent local excision, and 90 patients underwent additional radical resection.

Results. In our evaluation, seven patients (15.9%) had local recurrence with distant metastasis from the local excision group while five patients (5.6%) had distant metastasis without local recurrence from the additional radical resection group. Five-year recurrence-free survival was 81.8% for local excision and 94.4% for additional radical resection ($p = 0.029$), and 5-year overall survival was 71.3% for local excision and 92.8% for additional radical resection ($p = 0.014$). In the additional radical resection group, 9 patients (10.0%) experienced surgical morbidities, however, no surgical mortality was observed.

Conclusion. Current study showed that local excision in high risk pT1 rectal adenocarcinoma patients was associated with higher local recurrence rates when compared to additional radical resection, and the latter treatment measure resulted in better 5-year recurrence-free survival and 5-year overall survival. The two treatment groups did not significantly differ with regard to distant metastasis incidence rates.

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Colorectal cancer (CRC) typically exhibits high incidence rates and relatively low mortality rates in Taiwan[1] due to effective treatment measures including curative-intent radical resection (RR) and adjuvant treatments such as chemotherapy and radiotherapy. Current practices are based on the JSCCR,[2] ESMO,[3] and NCCN[4] guidelines for oncology, and the CRC lesions can be classified into stages I to IV using the TNM (tumor, lymph node, and distant metastasis) method. While low risk pT1 can be managed using local

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excision (LE), high risk pT1s require curative-intent RR or LE followed by adjuvant chemoradiotherapy (CRT). High-risk tumors typically exhibit poorly differentiated pathology; submucosal, lymphovascular, or perineural invasion; and resection margin involvement.

Preoperative images and pathological factors have an important role for cancer stage. The advancements in medical technology have made computed tomography (CT), magnetic resonance imaging (MRI), and endorectal ultrasonography (ERUS) more easily accessible. However, in comparison to MRI, ERUS exhibits slightly lower accuracy with regard to detection of tumor invasion depth.[5,6] Hence, conventional minimally invasive tests such as CT and MRI are becoming increasingly popular for the diagnosis of rectal cancer.

Recent evidence suggests that surgery of LE for en bloc resection of early rectal tumors has a similar survival compared to RR.[7,8] Furthermore, Melnitchouk et al. reported observing similar oncological outcomes in T1 distal rectal cancer patients who underwent LE with adjuvant CRT when compared to those who underwent RR.[9]

This study aims to compare the local recurrence (LR) and distant metastasis (DM) rates as well as the long-term oncological and surgical outcomes by treatment type (LE and LE then additional RR) in rectal adenocarcinoma pT1 patients.

Materials and Methods

Patient selection

In this study, we recorded the following data: sex, age, ASA (American Society of Anesthesiology) score, carcinoembryonic antigen (CEA), and tumor location (distance away from the anal verge recorded in centimeters).

We retrospectively enrolled data from patients admitted to Veterans General Hospital – Kaohsiung and Taipei (VGHKS and VGHTPE) between January 2008 and December 2018. We recorded the pathology of adenocarcinoma of rectum, and pathologic stage of high risk T1 patients. The tumor locations should be within the rectum, 0 to 15 centimeters away from the anal verge, measured by either colonoscopy or digital rectal examination.

The exclusion criteria included patients that have had neoadjuvant treatments before the surgical treatment, pathologic reports ypT1 or neuroendocrine component, familial adenomatosis polyposis (FAP) or inflammatory bowel disease (IBD) or were diagnosed with synchronous or metachronous CRCs previously or at the time of admission and who underwent RR without primary LE.

Design

All patients underwent complete colonoscopy, pelvic MRIs, and/or abdominal/pelvic CT examination, and the colonoscopic excision (CE) was performed first. The risk of surgical morbidity and tumor recurrence was established using tumor location, pathological risk factors, tumor invasion depth, and lymph nodal enlargement (determined through imaging). The study sample was divided into two groups based on treatment type [LE and aRR (LE + RR)].

The LE group included those that underwent CE first (e.g., polypectomy; endoscopic mucosal resection; endoscopic submucosal dissection) or were treated using direct surgical approaches via the trans-anal platform [e.g., trans-anal excision (TAE) and trans-anal endoscopic microsurgery (TEM)]. Adjuvant CRT was provided based on the surgeon's recommendation. The aRR group included those that received CE followed by additional radical resection via the abdomen using laparoscopic or laparotomy approaches. Where necessary, a temporary stoma was recommended taking patient characteristics into consideration,[10-12] while adjuvant chemotherapy was prescribed in the presence of lymph node metastasis.

Follow-up and outcomes

Complete follow-up examinations was carried out in all patients and included digital rectal examination, complete blood count, liver function test, serum CEA level measurement, colonoscopy, chest radiography,

and CT of the abdomen. Serum CEA levels were measured using a recommended upper normal limit of 5 ng/ml.

Follow-up was carried out until September 30, 2021, or the date of patient's death, whichever came earlier. The primary outcome measures were 5-year LR (pathological tumor relapse seen at the site of LE) and DM (defined as the period between surgical intervention and recurrence), while the secondary outcome measures were long-term oncological (e.g., 5-year RFS and 5-year OS) and surgical results.

Surgical complications

Surgical complications included those that occurred within 30 days of the operation, and only patients with a Clavien–Dindo classification score > 3 and requiring surgery were considered.[13] Surgical mortality was defined as death within 30 days of the operation.

Statistical analyses

Differences in the categorical and continuous variables were analyzed using the chi-square and t-tests, respectively. The Kaplan-Meier (log rank) test was used to create survival curves, and statistical significance was fixed at p-value < 0.05. All analyses were performed using SPSS (SPSS, version 26 for Windows, Chicago, IL, USA).

Results

A total of 285 pT1 rectal adenocarcinoma patients were eligible for inclusion, of which 152 were excluded (neoadjuvant/ypT1 n = 8; neuroendocrine component n = 3; FAP n = 1; IBD n = 1; synchronous or metachronous CRC n = 8; underwent RR without primary LE n = 131). The final sample included 134 patients, of which 44 (32.8%) were in the LE group and 90 (67.2%) were in the aRR group (Fig. 1). All 134 patients received complete colonoscopy examination before surgical intervention. Out of 44 patients in the LE group, 26 patients underwent CT imaging, ten patients underwent pelvic MRI, and eight patients had missing imaging reports. Of the 90 patients in the aRR group, 83 patients underwent pelvic CT and seven underwent pelvic MRI imaging.

In the LE group, 13 patients underwent CE, 2 underwent TEM, and 29 underwent TAE, while 27 (27.8%) patients in the aRR group underwent laparotomy surgery, 65 (72.2%) underwent laparoscopic surgery, one underwent APR, 83 underwent LAR, and six underwent LAR with trans-anal total mesorectal excision.

With regard to patient characteristics (Table 1), sex, ASA score, and CEA levels exhibited no significant differences between the two groups. The mean

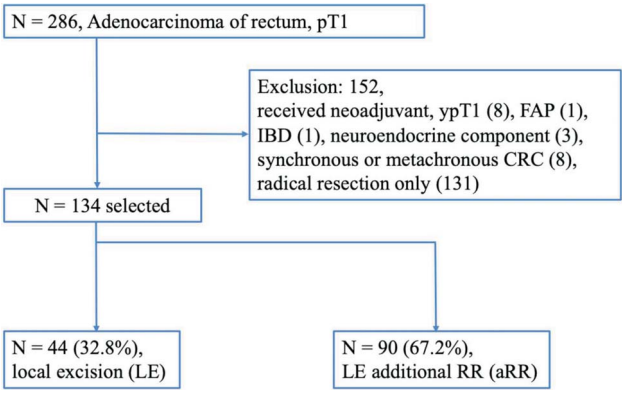

Fig. 1. Flowchart of patient's selection in pT1 rectal adenocarcinoma.

Table 1. Characteristics of 134 patients with pT1 rectal cancer

	LE (n = 44)	aRR (n = 90)	p-value
Sex			0.142
M	19 (43.2%)	51 (56.7%)	
F	25 (56.8%)	39 (43.3%)	
Age	66.66 (±12.2)	60.77 (±11.3)	0.006
ASA score			0.600
1	11 (25.0%)	28 (31.1%)	
2	28 (63.6%)	49 (54.4%)	
3	5 (11.4%)	11 (14.4%)	
CEA (ng/ml)	2.39 (±1.7)	2.18 (±1.0)	0.386
Tumor location[a]			< 0.001
Upper	2 (4.5%)	35 (38.9%)	
Middle	19 (43.2%)	46 (51.1%)	
Lower	23 (52.3%)	9 (10.0%)	

[a] Tumor location: 11-15 cm as upper rectum, 6-10 cm as middle rectum, 0-5 cm as lower rectum.
ASA, American Society of Anesthesiology; CEA, carcinoembryonic antigen.

age of the patients in the aRR group was significantly lower than that of the LE group (LE vs. aRR: 66.66 ± 12.2 vs. 60.77 ± 11.3; $p = 0.006$). The LE and aRR groups had significantly fewer patients with upper (LE vs. aRR: 4.5% vs. 38.9%; $p < 0.001$) and lower (LE vs. aRR: 52.3% vs. 10.0%; $p < 0.001$) tumor locations, respectively.

In the LE group, 10 patients received additional TAE after CE due to insufficient margin (< 2 mm), 5 cases exhibited no residual malignant tumors in the resected specimens, and seven underwent adjuvant long-course radiotherapy with or without chemotherapy [CT/MRI examination showed lymphadenopathy in mesorectum n = 1; lymphovascular invasion n = 1; positive resection margin (< 1 mm) seen during postoperative pathological examination n = 5]. None of the LE patients exhibited surgery-related morbidity (e.g., stenosis, perforation, infection, or bleeding).

In the aRR group, 11 (12.2%) patients received elective temporary diverting stomas and 1 (1.1%) received a permanent stoma (APR) without any associated surgical morbidity. All surviving LAR patients with temporary diverting stomas underwent reversal enterostomy (reversal rate of diverting stoma: 100%). Nine (10.0%) aRR patients experienced surgical morbidity and received unexpected temporary diverting stomas after surgical intervention. Of these, five experienced anastomotic leakage, three exhibited rectovaginal fistula, and one presented with bleeding at the anastomosis site. No surgical mortality within 30 days of surgery was observed. The median specimen length and distal margins in the aRR group were 14 cm (range 7-29 cm) and 3 cm (range 0.5-7 cm), respectively. Additionally, 85 patients exhibited no residual malignant tumors in the resected specimens, while 7 (7.8%) presented with pathological lymph node metastasis (median number of harvested lymph nodes 13, range 3-35) and received adjuvant systemic chemotherapy using 5-fluorouracil based regimen of FOLFOX, FOLFIRI, or tegafur.

In the current study, 7 (15.9%) patients in the LE group and 0 (0%) in the aRR group exhibited LR, and this difference was statistically significant ($p < 0.001$; Table 2). Moreover, 7 (15.9%) patients in the LE group and 5 (5.6%) in the aRR group had DM ($p = 0.059$; Table 3). Statistically significant better of aRR patients had 5-year RFS, LE vs. aRR, 81.8% vs. 94.4%, $p = 0.029$ (Fig. 2). The same goes to the 5-year OS, LE vs. aRR, 71.3% vs. 92.8%, $p = 0.014$ (Fig. 3).

Discussion

Complete CRC staging should typically include

Table 2. Patterns in local recurrence and distant metastasis in LE and aRR groups

Case	Sex	Age	OP	Margin	LR	DM	Time to recurrence[a]	AAV[b]	Stage
1	F	84	TAE	Not mentioned	Excision site	-	3	5	-
2	F	80	TAE	-	Excision site	Lung	40	4	cN0M0
3	F	65	TAE	-	Excision site	Lung + bone	30	3	cN0M0
4	F	46	TAE	-	Excision site	Lung	24	7	cN0M0
5	M	81	CE	< 1 mm	Excision site	Lung	41	3	cN0M0
6	M	81	CE	< 1 mm	Excision site	Lung	52	10	cN0M0
7	M	49	CE	< 1 mm	Excision site	Liver	37	8	cN0M0
8	F	80	TAE	-	-	Lung	13	4	cN0M0
9	M	57	LAR	-	-	Lung	9	6	pT1N0
10	F	72	LAR	-	-	Lung	9	4	pT1N0
11	M	57	LAR	-	-	Liver	32	8	pT1N0
12	M	48	LAR	-	-	Liver	36	12	pT1N0
13	M	67	LAR	-	-	Lung	11	15	pT1N1

[a] Time to recurrence: from the time of treatment to time of recurrence occur, in months (M).
[b] AAV is in centimeters (cm).
OP, operation; LR, local recurrence; DM, distant metastasis; AAV, above anal verge; TAE, transanal excision; CE, colonoscopic excision; LAR, low anterior resection.

Table 3. Long-term oncological outcome of pT1 rectal cancer

	LE (n = 44)	aRR (n = 90)	*p*-value
Recurrence			
Local	7 (15.9%)	0	< 0.001
Distant	7 (15.9%)	5 (5.6%)	0.059
Recurrence-free survival (M[a])	127.4 (±8.1)	147.2 (±3.4)	
5-year	81.8%	94.4%	0.029
Overall survival (M[a])	114.2 (±9.1)	137.0 (±5.0)	
5-year	71.3%	92.8%	0.014

[a] Recurrence-free survival and overall survival is in months (M).

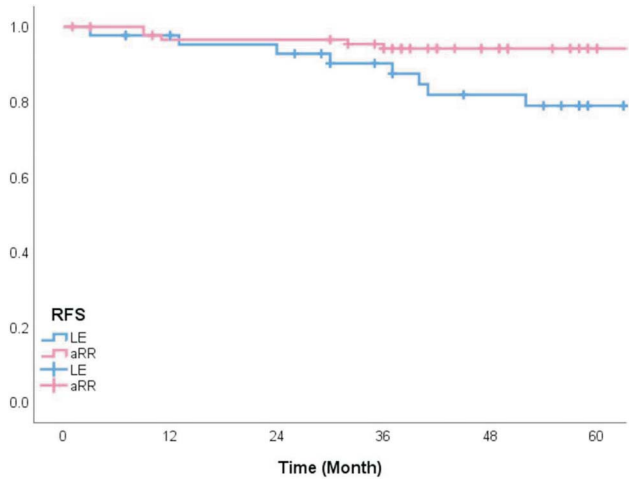

Fig. 2. Kaplan-Meier survival curve for 5-year recurrence-free survival in LE and aRR groups.

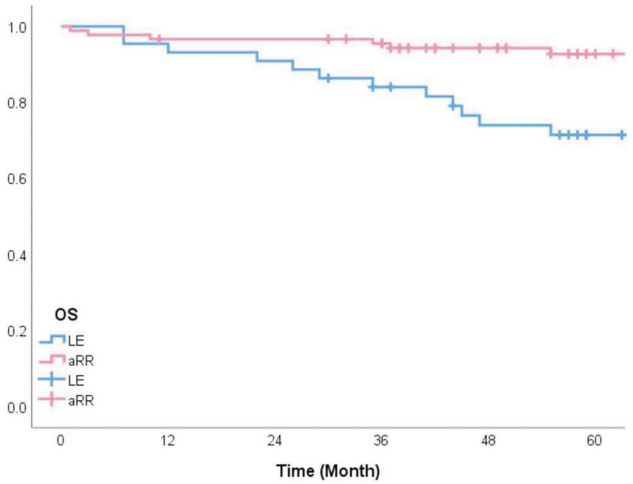

Fig. 3. Kaplan-Meier survival curve for 5-year overall survival in LE and aRR groups.

comprehensive evaluation of tumor invasion depth, lymph node metastasis, and distant organ metastasis. The most effective treatment measures for CRC include curative-intent RR and adjuvant treatments such as chemotherapy and radiotherapy. LE is currently used as an alternative treatment measure in pT1 rectal cancer patients as it provides advantages such as lower surgical morbidity (e.g., low risk of anterior resection syndrome and urinary and sexual dysfunction) and improved quality of life in patients with lower tumors requiring anal sphincter preservation (i.e., APR).[14,15] Recent evidence suggests that endoscopic surgeries can be carried out via the trans-anal platform for en bloc resection of early rectal tumors as it is associated with a lower risk of LR compared to other traditional techniques.[16-18] Furthermore, Melnitchouk et al. reported observing similar oncological outcomes in T1 distal rectal cancer patients who underwent LE with adjuvant CRT when compared to those who underwent RR (HR 0.89; 95% CI 0.65-1.22; $p = 0.49$).[9]

In the current study, seven out of 44 LE patients received adjuvant long-course radiotherapy with or without chemotherapy and five exhibited positive resection margins (< 1 mm), while ten patients received additional TAE caused by insufficient margin (≤ 2 mm) from CE. In the aRR group, 85 out of 90 patients exhibited no residual malignant tumors and the median length of the distal margin was 3 cm (range 0.5-7 cm). As per the NCCN guidelines, the safety resection margin is 2 mm for CE, > 3 mm for TAE, and 1-2 cm for mesorectal excisions.[4] Advances in surgery and later in CRT have improved outcomes such as LR considerably, although DM remains a significant problem. Lai et al. found that the 5-year LR rates in stage I rectal cancer patients ranged between 4 to 20% in the LE group and 0 to 10% in the RR group. The higher LR rates in the LE group could be attributed to insufficiently resection margins.[18] In the current study, sig-

nificantly higher LR rates were observed in the LE group compared to the aRR group (15.9% vs. 0%, $p < 0.001$). Moreover, DM was seen to be associated with LR in the LE group, although no such relationship was seen in the aRR group. This result aligned with that of Junginger et al., who found that lower LR rates did not improve the incidence rates of DM.[19]

The findings of this study showed that younger patients were more willing to undergo major operations (LE vs. aRR: 66.66 ± 12.2 vs. 60.77 ± 11.3 years; $p = 0.006$) due to lower risk of surgical comorbidities and rates of stoma creation when compared to elderly patients.[20] Nascimbeni et al. compared 70 LE and 74 RR patients and reported a lower mean age in the latter group (LE vs. RR: 69 ± 11.2 vs. 63 ± 10.2 years; $p = 0.001$).[8] Singh et al. reported significantly higher rates of comorbidities (cardiovascular and pulmonary disease *p*-values of 0.002 and 0.006, respectively) in older (≥ 80 aged) compared to younger (< 80 aged) patients, and no significant differences in surgical and medical complication rates were observed among older patients ($p = 0.58$ and 0.69, respectively).[21]

Moreover, the tumor location was an important factor to effectively perform a patient's additional RR (upper location, LE vs. aRR: 4.5% vs. 38.9%; lower location, LE vs. aRR: 52.3% vs. 10.0%; $p < 0.001$). The tumor located distally from anal verge had lower rate of elective temporary diverting stoma, and lower surgical morbidities.[10-12] However, if the tumor was located proximally from the anal verge, it had a higher risk of anastomotic leakage and lower rate of anal sphincter preservation, which is why only one patient received APR in the aRR group. Of these aRR patients, 9 (10.0%) patients experienced surgical morbidity and received unexpected temporary diverting stomas after surgical intervention. Lin et al. examined anastomotic leakage in 999 patients receiving primary resection and anastomosis with or without diverting stomas, and found that operative method was an independent risk factor for anastomotic leakage (LAR vs. ultra-LAR, HR 2.14; 95% CI 1.22-3.77; $p = 0.002$) while diverting stomas did not exert any protective effect.[22]

Recent studies examining pT1 CRCs found that the 5-year RFS and OS ranged from 83.0 to 97.5% and 75.3 to 92.8%, respectively, in the LE group, while the corresponding values in the RR group were 84 to 97.2% and 89 to 95.2%, respectively.[18,20,23,24] In the current study, the 5-year RFS was 81.8% and 94.4% in the LE and aRR groups, respectively ($p = 0.029$), while the corresponding 5-year OS was 71.3% and 92.8%, respectively ($p = 0.014$), these results show similarities to recently published articles.

Limitations

This study had several limitations, including a retrospective study design and a multicenter database. The differences in the pathological reporting format for each center and the lack of depth in analysis of submucosal invasion serve as limitations to this study. Although the treatment of choice was based on shared decision making, the multidisciplinary surgical team would differ between the centers. Moreover, functional outcomes such as LAR syndrome, fecal incontinence, stenosis, and quality of life were not compared between the cohorts, and further research in this field is necessary.

Conclusion

Current study showed that LE in high risk pT1 rectal adenocarcinoma patients was associated with higher LR rates when compared to aRR, and the latter treatment measure resulted in better 5-year RFS and 5-year OS. The two treatment groups did not significantly differ in DM incidence rates.

Conflict of Interest

There are no conflicts of interest in this manuscript.

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原　著

病理分期 T1 的直腸癌在行局部切除與額外根除性切除術後的局部復發發生

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目的　對於病理分期 T1 的直腸癌，替代治療可以是局部切除及輔助性放射治療，局部切除的優勢在於較低的手術併發症及永久性腸造口。由於直腸癌比大腸癌容易造成局部復發，根除性切除術仍然是建議的治療法。所以本篇想要探討高風險病理分期 T1 的直腸癌以局部切除及根除性切除術後的局部復發發生率。

方法　我們回溯性的收集 285 個病理 T1 的直腸腺癌病人，共 134 個被納入。44 個進行局部切除，90 個病人進行額外根除性切除術。

結果　在我們的研究中，在局部切除族群中有 7 位 (15.9%) 病人有局部復發合併遠端轉移，在額外根除性切除術族群中有 5 位 (5.6%) 病人有遠端轉移但並沒有合併局部復發。無 5 年復發生存率在局部切除族群為 81.8%，在額外根除性切除術族群為 94.4% (p = 0.029)。5 年總生存率在局部切除族群為 71.3%，在額外根除性切除術族群為 92.8% (p = 0.014).。9 位 (10.0%) 病人遇到手術相關的併發症，但並沒有手術相關的死亡。

結論　在本篇研究中，高風險 pT1 的直腸癌在局部切除的族群相較於額外根除性切除術族群有高的局部復發率，所以後者有較好的無復發生存率及總生存率，然而兩個族群中遠端轉移並沒有統計學上的差異。

關鍵詞　直腸癌、病理分期 T1、局部復發、局部切除、額外根除性切除術。