Original Article

Long Term Outcome of Local Excision for T1-2 Rectal Cancer

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Purpose. Local excision is an alternative method of treatment for middle to low rectal cancer due to low morbidity and good functional result. We reviewed the experience with local excision of early rectal cancer to evaluate the long term result.

Patients & Methods. Between January 1982 and December 2004, patients with T1-2 adenocarcinoma of the middle to lower rectum (below 10 cm from anal verge) treated by local excision were reviewed. The pathology of specimen was reviewed. Seventy-six patients were assessed and 44 were T1 and 32 were T2 cancers. Eleven patients received adjuvant radiation therapy. Data analysis included clinical characteristics and pathological features. The tumor recurrence was identified as local, distant or both. 59 patients (77%) were followed until death or more than five years and 51 patients (67%) were followed until death or more than ten years. The outcomes were defined as five-year and ten-year cumulative data of tumor recurrence rate, cancer-specific and disease-free survival rates.

Results. The ten-year local and overall recurrence rate were 9.1% and 15.9% for T1 lesion and 12.5% and 21.9% for T2 lesion. The five-year and ten-year cancer-specific survival rates of T1 lesion were 97.2% and 92.1% and of T2 lesion were 83.9% and 76.3%. On multivariate analysis, the significant prognostic factors of cancer-specific survival rate were T stage (p = 0.038) and angio-vascular invasion (p < 0.001). The only significant factor of disease-free survival rate was angio-vascular invasion (p < 0.001). Of the eight patients who had isolated local recurrence, five patients received salvage surgery and the disease-free survival rate was 60% with mean follow up of 77 months.

Conclusion. Local excision for middle to lower T1 rectal cancer is acceptable with good long-term result but is not considered in T2 lesion due to unsatisfied cancer-specific survival rate. The pathological feature of angio-vascular invasion seems to be the prognostic factor of disease-free and cancer-specific survival.

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The traditional standard treatment of middle to low rectal cancer is radical surgery, either low anterior resection or abdominal perineal resection. However, significant morbidity and mortality were associated with these operations, such as anastomosis leaks, bowel obstruction, urinary or sexual dysfunction, or deep vein

thrombosis.[1-6] Moreover, a temporary or permanent colostomy may make patients inconvenient and result in functional or psychological disability. Local excision has been an alternative procedure for the rectal cancer with low morbidity and sphincter preservation. In theory, if the tumor is located at low to middle rectum and confined in the bowel wall without regional lymph node metastases, the tumor could be totally removed by local excision. Currently the selection criteria for local excision of rectal tumor includes that the tumor limited to the mucosa or submucosa, tumor size less than 3 cm, the proximal margin less than 8 cm from dentate line, less than 40% of circumference, mobile on digital rectal examination, well or moderately differentiation and absence of identifiable lymph nodes metastases.[7-9] Some retrospective series of early stage rectal cancer were reported. Sharma et al.[10] reviewed local excision treatment for rectal cancer. The local recurrence rate was ranged from 0 to 50% and the distant metastasis rate was ranged from 0 to18%. The five-year survival was ranged from 66 to 100%. These study results are variable and few long term outcome were reported. In this study, we assessed our experience in the local excision of clinical T1-2N0M0 rectal cancers and investigated the effectiveness of therapy in a long term follow up.

Material and Method

All patients who received local excision for rectal cancer at Veteran General Hospital, Taipei, between January 1982 to December 2004, were identified from the hospital computerized database. The inclusion criteria was pathological T1 or T2 adenocarcinoma of middle and low rectum without clinical lymph nodes metastasis or distant metastasis, less than 10 cm away from anal verge. The method of local excision included transanal excision and Kraske's operation with full-thickness excision. Thirteen cases were excluded and the exclusion reasons were: five carcinoma in situ, five T3 cancer, one immediate salvage surgery after local excision, one stage III and two stage IV rectal cancer. The analyzed data included the patients age, gender, operative procedure, tumor size and morphology, location, adjuvant therapy, recurrence and survival. The pre-operative studies included digital

rectal examination, colonoscopy and biopsy of the tumor, chest X ray, abdominal sonography, computed tomography (CT) scan or magnetic resonance imaging (MRI) of the pelvis. The gross tumor morphology was described as ulcerative or polypoid type according to the operative fiding. The pathology of specimen was reviewed. Tumor grade was distinguished as poor, moderate, and well differentiation. Vessel invasion was identified as cancer cell invaded the lumens of blood vessels or lymphatic vessels. Eleven patients received post-operative adjuvant radiation therapy with 5040cGy/28 fraction to the pelvis. The patients were followed every 3 months interval for the first two years, every 6 months interval from third to fifth years and then annually. The patients were followed until death or at least more than three years in this study group. The tumor recurrence was confirmed according to the pathological report, progressive radiological change, and the obvious clinical features in medical record. Local recurrence was defined as tumor recurrence at the previous excision site or in the pelvis. Distant recurrence was defined as tumor recurrence out of the pelvis. The recurrence rate was expressed as the percentage of patients who had recurrence. Salvage surgery was defined as surgery after recurrence. Time to recurrence or death was counted from the day of surgery to the day of first recurrence or death.

Statistics

The local recurrence rate and overall recurrence rate between different cancer stages were compared with chi-square test or Fisher's exact test. The cancer-specific and disease-free survival rate were calculated with Kaplan-Meier method and the difference between each group was compared with log-rank test or Wilcoxon test. On multivariate analyses, the potential prognostic factors were evaluated with Cox regression method.

Result

General data

Seventy-six patients were assessed and the clini-

cal characteristics of age, gender, tumor location, size, gross morphology, differentiation of the tumor, depth of tumor invasion, method of treatment, and period of follow up were described in Table 1. The median age was sixty-nine and there were 44 T1 patients and 32 T2 patients. Fifty-seven patients received transanal excision and nineteen patients received Kraske's procedure. The mean tumor size was 2.4 cm (range 0.5-6 cm). Tumor size less than 3 cm in size were noted in 53 cases (64.6%). The tumor location less than 6 cm from anal verge were found in 66 cases (80.5%). The tumor size and location were not related to the operative methods (Fisher's exact test; p = 0.102 and p = 1.0). No surgical mortality was noted. One patient received transanal excision and transmural resection was noted. The defect was closed and protective sigmoid loop colostomy was performed. The colostomy was closed six months later smoothly. There were eleven patiens received adjuvant radiation therapy, in which 5 were T1 and 6 were T2 tumor. In T1 stage radiation group, adverse pathological feature of lymphatic invasion were noted in two patients. In T2 stage radiation group, one lymphatic invasion, one mucinous adenocarcinoma, and one microscopically po-

sitive margin were noted. The other radiation cases were determined according to the surgeon's judgement. No recurrence was found in the patient whose margin was not free at the follow up for 33 months after the adjuvant radiation therapy.

Recurrence and survival

The overall five-year and ten-year survival rates were 74.6 and 64.8%. The pattern of recurrence was described in Table 2. Four T1 tumors developed local recurrence at the follow up of 2, 23, 26 and 71 months post-operatively. Two T1 tumors developed distant recurrence, one liver metastasis and one liver and lung metastases at the follow up of 24 and 50 months post-operatively. The median relapse time of local recurrence was 21 months (range 2-71 months) with only one case had local recurrence beyond five years. Two cases of T1 group died at 30 and 71 months after local exacision respectively. Six cases of T2 group died of rectal cancer with a median time of survival of 13.5 months (range 6-19 months). The tumor recurrence and cancer-specific survival rates relating to T stage were shown in Table 3. The ten-year local and

Table 1. Characteristics of the patients (n = 76)

Age	Mean (year) ± S.D	69 ± 10.6
	Range (year)	38-94
Gender	Male	44 (57.9%)
	Female	32 (42.1%)
Depth of invasion	T1	44 (57.9%)
	T2	32 (42.1%)
Tumor size	Mean (cm) ± S.D	2.8 ± 1.2
	Range (cm)	0.5-6
Tumor morphology	Polypoid type	62
	Ulcerative type	12
	Missing data	2
Differentiation	Well	16
	Moderate	58
	Poor	2
Tumor location from anal verge	Mean distance (cm) ± S.D	5 ± 2.7
	Range (cm)	0-10 cm
Operative procedure	Transanal excision	57 (75%)
	Kraske procedure	19 (25%)
Follow up	Mean (year) ± S.D	7.3 ± 5
	Range (months)	7-234

S.D: standard deviation.

Table 2. Patterns and rates of recurrence of rectal cancer treated after local excision

	Number and rate of recurrence		
Pattern of recurrence	T1 (n = 44)	T2 (n = 32)	Total (n = 76)
Local	4 (9.0)	4 (12.5)	8 (10.5)
Distant	2 (4.6)	3 (9.4)	5 (6.6)
Local + Distant	1 (2.3)	0 (0)	1 (1.3)
Total	7 (15.9)	7 (21.9)	14 (18.4)

data are numbers with percentage in parentheses.

Table 3. Recurrence and cancer-specific survival rate

	N	5 Year (%)			10 Year (%)		
		LR	OR	Survival	LR	OR	Survival
T1	44	6.8	13.6	97.2	9.1	15.9	92.1
T2	32	12.5	18.8	83.9	12.5	21.9	76.3
Overall	76	9.2	15.8	91.4	10.5	18.4	85.4

LR: local recurrence, OR: overall recurrence.

overall recurrence rates were 9.1% and 15.9% for T1 lesion and 12.5% and 21.9% for T2 lesion. There was no statistical difference between T1 and T2 groups in terms of both local and overall recurrence rates (Fisher's exact test; $p = 0.63$ and 0.51). The five-year and ten-year cancer-specific survival rates for T1 lesion were 97.2% and 92.1% and for T2 lesion were 83.9% and 76.3%. The ten-year cancer-specific survival rate was significantly different between T1 and T2 groups (Wilcoxon test; $p = 0.021$, Figure 1).

Prognostic factors

We analyzed the clinical characteristics and pathological features for potential prognostic factors that may influence recurrence and cancer mortality. The gross tumor morphology was not related to the overall and local recurrence (Fisher's exact test; $p = 0.68$ and $p = 1.0$). The different operative methods of Kraske's procedure and transanal excision were also analyzed and the overall and local recurrence rates between the two operative methods showed no significance statistically (Fisher's exact test; $p = 0.16$ and $p = 0.43$). The result of multi-variate analyses was described in Table 4. On multivariate analysis, the independent prognostic factors of cancer-specific survival were T stage ($p = 0.038$) and angio-vascular invasion ($p < 0.001$). The only significant factor of disease-free survival was angio-vascular invasion ($p < 0.001$).
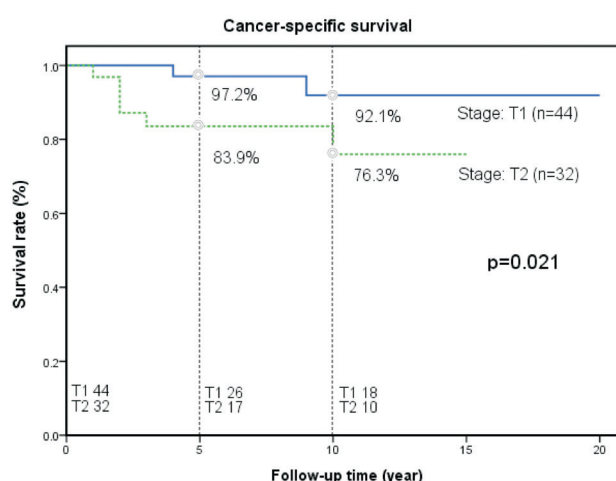

Fig. 1. Comparison of the cancer specific survival rates for T1 (solid line) and T2 (dash line) rectal cancers treated by local excision. The cancer-specific survival rate was significant difference between the T1 and T2 groups (Wilcoxon test, $p = 0.021$).

Salvage surgery

Local recurrence occurred in eight patients, 4 in T1 and 4 in T2 group respectively. Two patients refused for further surgical intervention and both of them died of advanced disease eventually. Two patients received local excision again and either of them took adjuvant radiation therapy and chemotherapy respectively. Both of them were alive at the last follow up. One local recurrent case received radiation the-

Table 4. Multivariate analysis of potential prognostic factors of disease-free and cancer-specific survival

		N	Disease-free survival P value Hazard ratio (95% C.I.)	Cancer-specific survival P value Hazard ratio (95% C.I.)
Depth of tumor invasion	T1 T2	44 32	NS	0.038 6.4 (1.1-37.3)
Radiation therapy	Yes No	11 65	NS	NS
Differentiation	Well Moderate Poor	16 58 2	NS	NS
Inflammatory reaction in tumor tissue	Yes No	6 70	NS	NS
Lymphovascular invasion	Yes No	9 67	NS	NS
Angio-vascular invasion	Yes No	3 73	0.005 9.0 (1.9-41.9)	< 0.001 43.0 (5.4-340.4)

Perineural invasion: 0, isolated cancer nodule: 0, NS: no significance.

rapy, but local recurrence again in the pelvis with liver metastasis was noted about 10 months later. Further abdomino-perineal resection with adjuvant systemic chemotherapy of 5-FU plus irinotecan regimen was given. Salvage radical surgery of abdomino-perineal resection was performed in three cases, with or not with adjuvant radiation therapy and chemotherapy.

Discussion

In 1826, Lisfranc first described transanal local excision of rectal tumor.[11,12] During transanal excision, the patient is in Jack-Knife position and the operative field is well exposed with retractor. The incision is made through full thickness of the rectal wall with 1 cm safe margin grossly. It is a convenient method for the low rectal tumor with minimal morbidity. In 1885, Paul Kraske reported the transsacral approach to rectal tumor.[11,12] The Kraske's procedure makes a posterior midline incision from coccyx to upper border of external sphincter. The levator ani muscle is dissected and the rectum is mobilized. The internal and external sphincters are preserved. The posterior lesion is excised directly and the anterior lesions is excised after posterior proctotomy. The advantage of Kraske's operation is good exposure and the sampling of some regional lymph nodes. There was one case whose lymph nodes were sampled after the Kraske's operation and one of four lymph nodes metastasis was noted. This case was excluded from our study because of stage III and the patient received radical surgery immediately. However, the Kraske approach is associated with some complication such as wound breakdown, fecal incontinence, or fecal fistula.[13,14]

Since the improvement of general anesthesia and surgical equipment, radical surgery has become a gold standard treatment of rectal cancer and the local excision has been recognized as a palliative choice for the poor risk patients. However, the mortality of radical surgery were reported around 1-12.5%.[15] The anastomosis leakage rate was 3-20% and the rates of bladder and sexual dysfunction were even up to 40%.[16-19] The local excision could avoid such morbidity and could preserve good anorectal functional results. In recent years, local excision has been used increasingly. Nancy et al.[20] collected a nationwide cohort study in America to compare the results between local excision and standard resection. From 1989 to 2003, the use of local excision has increased (T1, 26.6-43.7%; T2, 5.8-16.8%) and significantly lower 30-day morbidity after local excision versus standard resection (5.6% vs 14.6%; p < 0.001) was noted. They analyzed local recurrence and survival in 2124 patients diagnosed between 1994 and 1996. Totally 765 cases (T1, 601; T2, 164) were treated with local excision. The

5-year local recurrence after local excision was 12.5% for T1 tumors and 22.1% for T2 tumors. The 5-year disease-specific survival after local excision was 93% for T1 tumors and 90.2% for T2 tumors.

We reviewed several retrospective studies about the local excision for early rectal cancer and the different results among these studies were shown in Table 5. The local recurrence rate ranged 8~18% in T1 tumors and 17~62% in T2 tumors. The five-year cancer-specific survival was ranged 66~95%. The variation of these results may be contributed by the bias of patient selection, staging method, and whether adjuvant therapy was given. In our study, the result of local excision for T1 rectal cancer is acceptable but not for T2 lesion. Though the overall recurrence rate has no difference between the two groups but the cancer-specific survival rate of T2 group is not as good as T1 group. The possible reason for the result may be related to the lymph nodes staging. The current pre-operative staging modality included physical examination and image studies (Table 6). The accuracy rate for staging of the depth of tumor invasion and lymph node involvement by digital examination of rectum, performed by colorectal specialists, ranged 44-83% and 57-67% respectively, dependent on the experience of examiners.[16,20,21] The image modalities include endorectal ultrasound(ERUS), CT scanning or MRI. The accuracy of endorectal ultrasound assessment of tumor invasion depth and lymph nodes spread has been reported ranging 82-93% and 65-81%.[20,22-25] The CT scanning and MRI showed accuracy about 22-73% and 39-95% in predicting lymph node involvement and 52-74% and 65-86% in predicting the tumor invasion depth.[20,26] So nowadays the pre-operative staging modalities still have its limita-

tion to offer the status of lymph nodes metastases precisely. In our series, only eleven patients received CT scanning and eleven patients received MRI for pre-operative staging. The staging of ERUS were not recorded. Most patients were staged with digital rectal examination by experienced colorectal surgeons.

The most accurate way for prediction of metastatic lymphadenopathy may be the depth of tumor invasion. Studies reported that the rates of regional lymph nodes metastatses of rectal cancer were 0-12% in T1, 12-28% in T2, and 36-79% in T3 tumor.[27-30] So the T2 tumors are potentially less curative than T1 tumors if the lymph nodes are not removed for staging. It may explain that why our T2 group patients had a lower survival rate as compared with T1 group patients. Hence, we suggest that adjuvant therapy should be arranged for T2 lesion after local excision. On multi-variate analysis of our data, the adjuvant radiation didn't influence the recurrence rate and survival. This result may be restricted to the selection bias and the limited case number. Moreover, we used radiation only for adjuvant therapy rather than chemo-radiation because most radiated patients were aged between 65 and 88 years old and according to the patient's willing and general condition. Although the results of adjuvant therapy were variable in many studies because

Table 6. The accuracy of different diagnostic methods for rectal cancer staging

Diagnostic method	T-stage*	N-stage*
Digital rectal examination[16,20,21]	44-83	57-67
Endorectal ultrasound[20,22-25]	83-93	65-81
Computed tomography[20,26]	52-74	22-73
Magnetic resonance image[20,26]	65-86	39-95

*: % of accuracy

Table 5. Results of local excision in different series

		Stage			Local recurrence			
	Case number	T1 (n)	T2 (n)	Mean follow up (month)	T1 (%)	T2 (%)	Distant metastasis (%)	5-year cancer specific survival (%)
Hager[15]	59	39	20	36	8	17	3.4	90
Chkravarti[33]	52	44	8	52	11	62	NS	66
Garcia[11]	82	55	27	54	18	37	3.7	95
Mellgren[18]	108	69	39	53	17	46	3.7	69
Paty[32]	125	74	51	80	17	26	8.8	86
VGH TPE	76	44	32	90	9.0	12.5	7.9	91

NS: not specified.

of different patients selection and different regimens of treatment, generally the adjuvant therapy is beneficial to decrease the recurrence rate and improve the survival.[10,31] Currently the combination of chemoradiation is recommended as adjuvant therapy for T2 lesion or T1 lesion with poor pathological characteristics.

In addition, the pathological features of the rectal cancer were also analyzed. Angio-vascular invasion is the significant prognostic factor. Although only three of patients (4%) had positive angio-invasive tumor, two of the T2 angio-invasive tumors had recurrence and died of disease. The remainder one did not recur. The interpretation of our study may be restricted because of the limited case numbers. However, there were studies showed the similar reports. Paty et al.[32] studied 125 patients with T1-2 rectal cancer treated by local excision (74 were T1 & 51 were T2). They found that the only factor associated with local recurrence and cancer mortality was blood vascular invasion. It is compatible with our finding. More studies are needed to confirm this result.

Mellgren et al.[17] reported the salvage surgery for local recurrence after local excision of early rectal cancer. In 23 cases of isolated local recurrence, 5 patients received local excision again and 19 patients was treated by radical surgery. The mean follow up was 35 months and the disease-free survival was 52%. In our experience, local recurrence occurred in eight patients and five patients received salvage surgery. The mean follow up was 77 months and the disease-free survival was 60%. The chance of salvage resection for local recurrence was about 62.5% which was relative low than it should be. So close follow up and immediate salvage surgery is recommended in patients who received local excision.

Conclusion

Ideally, local excision in early stage rectal cancer could offer good results. However, local recurrence rate is high and the survival in T2 group is not ideal. We conclude that local excision for T1 rectal cancer is acceptable with good long-term result but is not considered for T2 lesion due to unsatisfied survival. Angio-vascular invasion seems to be a prognostic factor of disease-free and cancer-specific survival. Adjuvant therapy should be considered in patients with poor pathological factors and T2 lesion.

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原　　著

T1-2 直腸癌經局部切除手術後之長期結果

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目的　對於中低位之直腸癌，局部切除手術因具有較低的罹病症及較佳的功能結果，可視為另一選擇的手術方式。我們回顧本院早期直腸癌接受局部切除後長期之結果。

病患及研究方式　我們回顧從 1982 年 1 月到 2004 年 12 月，診斷為中低位 (距肛門口 10 公分以內) 之 T1-2 直腸癌，接受局部切除手術之病患資料及其病理切片。共有 76 位患者，其中 44 位為 T1 及 32 位為 T2。有 11 位患者接受術後放射線治療。資料分析包含臨床特性及病理特徵。腫瘤復發分為局部、遠端復發，或兩者皆有。59 位病患 (77%) 追蹤至病逝或五年以上；51 位病患 (67%) 追蹤至病逝或十年以上。資料結果包括五年及十年的腫瘤復發率、癌病存活率、及無復發存活率。

結果　對於十年之腫瘤局部復發率及全復發率，T1 分別為 9.1% 及 15.9%，T2 分別為 12.9% 及 21.9%。對於五年及十年之癌病存活率，T1 為 97.2% 及 92.1%，T2 為 83.9% 及 76.3%。多變異分析結果顯示，癌病存活率之預後因子為腫瘤侵犯深度及血管有無侵犯。無復發存活率之預後因子則為血管侵犯與否。在八位腫瘤局部復發的病患當中，有五位接受救癒性手術，其無復發存活率為 60%，平均追蹤時間為七十七個月。

結論　就長期追蹤而言，局部切除手術對於中低位之 T1 直腸癌有不錯的結果，但對於 T2 直腸癌則因存活率較差而不甚理想。病理上有無血管侵犯可視為癌病存活率及無復發存活率之預後因子。

關鍵詞　直腸癌、局部切除手術、T1 & T2 癌。