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SURGICAL ENDOSCOPY
and Other Interventional Techniques

Transanal endoscopic microsurgery and radical surgery for T1 and T2 rectal cancer

Retrospective study

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Abstract
Background: Transanal endoscopic microsurgery (TEM) has gained increasing acceptance as a local treatment of early rectal cancer. The purpose of this study was to compare the results of TEM and radical surgery in patients with T1 and T2 rectal cancer.
Methods: From October 1994 to December 2000, 74 patients with T1 and T2 rectal adenocarcinoma treated with TEM were compared with 100 patients with T1N0M0 and T2N0M0 rectal adenocarcinoma treated with radical surgery. Retrospective analysis was performed regarding to recurrence and survival rate. Neither group received adjuvant chemoradiation. There was no significant difference in age, gender, tumor location, or follow-up period between the two groups. The only difference was in tumor size.
Results: Of the 74 patients in TEM group, 52 were T1 (70.3%) and 22 were T2 (29.7%). Of the 100 patients in radical surgery group, 17 were T1 (17%) and 83 patients were T2 (83%). The 5-year local recurrence rates were 4.1% for T1, 19.5% for T2 after TEM, 0% for T1, and 9.4% for T2 after radical surgery. There was no statistical difference between the TEM and radical surgery groups for T1 rectal cancer ($p = 0.95$), but for T2 rectal cancer, the 5-year local recurrence rate was higher after TEM than after radical surgery ($p = 0.04$). There were no significant statistical difference between the two groups in terms of the 5-year disease-free survival rate and the survival rate.
Conclusions: For T1 rectal cancer, there was no difference in recurrence or 5-year survival rate between the TEM and the radical surgery groups. For T2 rectal cancer, there was no statistical difference in the 5-year survival rate between the two groups, but TEM carried higher risk of local recurrence. Therefore, careful selection of the patients is required for TEM, and when proper muscle invasion is proven, the TEM procedure should be supplemented by further treatment, or radical surgery should be performed.

Key words: Transanal endoscopic microsurgery (TEM) — Radical surgery — T1, T2 Rectal cancer

Carcinoma of the rectum is conventionally treated by radical surgery such as abdominoperineal resection or low anterior resection [1]. However, radical surgery is associated with considerable complications and functional problems. Many patients refuse radical surgery because of the permanent colostomy, especially in distal rectal cancer. Local resections such as transanal excision and a transsphincteric approach have been performed selectively in the elderly, high-risk patients and those who refuse colostomy. Recently, with the advance of preoperative diagnosis and surgical technique, these procedures are being accepted as a desirable optional treatment of early rectal cancer [2, 6, 19].

For rectal cancer, a major problem of local resection is the possibility of lymph node metastasis. Fortunately, many studies report low lymph node metastasis rates of 0% to 12% for T1 rectal cancer, but for T2, the rate was 12% to 28%, and for T3, it was 36% to 79% [13, 14]. For T1 rectal cancer, local resections showed the same 5-year survival rate and recurrence rate as for radical surgery [8, 15, 20]. But for T2 cancer, with its relatively high lymph node metastasis rate, there are few reports about the therapeutic results of local resection [13].

Transanal endoscopic microsurgery (TEM), as described by Buess et al. [3], has been suggested as a novel local treatment for rectal tumors because it has many

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Table 1. Patient and tumor characteristics

	TEM (n = 74)	Radical surgery (n = 100)	p
Patient characteristics			
Mean age (years)	61.1 ± 11.2	57.7 ± 11.8	NS
M:F ratio	50:50	51:49	NS
Follow-up duration (months)	31.0 ± 17.2	34.6 ± 19.4	NS
Tumor characteristics			
Location[a] (cm)	6.7 ± 3.2	7.5 ± 4.0	NS
Size (mm)	23.5 ± 9.5	37.8 ± 15.3	<0.05
Stage T1 (n)	52	22	
Stage T2 (n)	17	83	

TEM, transanal endoscopic microsurgery; NS, not significant
[a] Distance from anal verge

advantages such as accurate full-thickness excision and closure under magnified view as well as more resection margin and accessibility to the upper rectum [4, 16]. In this study, to define the feasibility of TEM as a treatment for rectal cancer, we compared the results of TEM with those of radical surgery for T1 and T2 rectal cancer, retrospectively.

Materials and methods

From October 1994 to December 2000, 90 patients who had T1 or T2 rectal cancer (UICC classification, 1987) without clinical evidence of lymph node metastasis were treated by TEM in the Department of Surgery, Samsung Medical Center, Sungkyunkwan University. For the T1 lesion with favorable histology, TEM was considered preferentially, and radical surgeries were performed when patients chose this option. For the T2 lesion, radical surgeries were considered first, and TEM was performed only when patients refused radical surgery or were not suitable for it. Among these patients, 16 were excluded from the study group because of preoperative chemotherapy and radiotherapy (n = 5), conversion to radical therapy (n = 5), positive resection margin (n = 2), unfavorable histology (poorly differentiated or mucinous; n = 2), or follow-up loss (n = 2). Finally, 74 patients with rectal cancer were included in the TEM group: 52 patients with T1 cancer (70.3%) and 22 patients with T2 cancer (29.7%). During the same period, 114 patients with T1N0M0 or T2N0M0 rectal cancer were treated by radical surgery: 42 with abdominoperineal resection and 72 with low anterior resection. From the comparison group 14 patients were excluded because of follow-up loss (n = 7), preoperative chemotherapy and radiotherapy (n = 3), unfavorable histology (n = 3), or combined bile duct cancer (n = 1). Finally, 100 patients with rectal cancer were included in the radical surgery group: 17 patients with T1 cancer (17%) and 83 patients with T2 cancer (83%).

Well or moderately differentiated rectal adenocarcinomas within 15 cm from the anal verge were considered, and retrospective analysis was performed by review of medical records and standardized interview. Preoperative diagnostic workup included history, clinical examination, routine laboratory test, colonoscopy, barium enema, and computed tomography (CT). Endorectal ultrasonography was performed in 34 patients (45.9%) of the TEM group and 21 patients (21.0%) of the radical surgery group.

In the TEM group, general anesthesia was used, and the patients were placed in the lithotomy, prone, or lateral position depending on the location of the tumor. With the TEM apparatus (Richard Wolf, Knittlingen, Germany), full-thickness excision, including perirectal fat, was performed with a minimum of 1 cm resection margin. The defect was closed by a running suture of PDS 3.0 monofilament (Johnson & Johnson, Somerville, NJ, USA). A silver clip (Richard Wolf, Knittlingen, Germany) was applied to each end of the suture. In cases of peritoneal perforation during the resection, the same closure method was used instead of conversion to open surgery. The radical surgery technique included high ligation of the inferior mesenteric artery, a minimum distal resection margin of 2 cm, and total mesorectal excision as described by Heald [7].

The mean ages of the TEM and radical surgery groups were 61.1 years and 57.7 years, respectively. The gender ratio was 50:50 in the TEM group and 51:49 (M:F) in radical surgery group. The mean postoperative follow-up was 31 months for the TEM group and 34.6 months for the radical surgery group. There were no significant statistical differences between the two groups in terms of age, gender, or follow-up period (Table 1).

Student's t-test was used to evaluate the aforementioned parameters, and a p value exceeding 0.05 was considered significant. Kaplan–Meier calculation was used for the 5-year local recurrence rate, the 5-year disease-free survival rate, and the 5-year survival rate.

Results

Characteristics of tumor

The mean distance of the tumor from the anal verge was 6.7 ± 3.2 cm in the TEM group and 7.5 ± 4 cm in the radical surgery group. This difference was not statistically significant (p = 0.10). The mean tumor size was 23.5 ± 9.5 mm in the TEM group and 37.8 ± 15.3 mm in the radical surgery group, and the difference was significant (p = 0.009). Ultrasonography was performed for 34 patients in the TEM group and 21 patients in the radical surgery group. According to ultrasonography, 23 lesions were T1(uT1), 31 lesions were uT2, and 1 lesion was uT3. The pathologic findings showed that among the 23 uT1 lesions there were 20 pathologically proven T1(pT1) lesions and 3 pT2 lesions. There were 5 pT1 lesions and 26 pT2 lesions among the 31 uT2 lesions. One uT3 lesion was shown to be a pT2 lesion. The pathologically proven accuracy of endorectal ultrasonography was 83.6% in this study (Table 2).

Complications

Complications after TEM were considerably rare, as compared with those after radical surgery. In the TEM group, there were three cases of complications (bleeding, urinary difficulty, fecal incontinence), and the complication rate was 4.1%. All the complications occurred during the early postoperative period and improved with conservative management. In the radical surgery group, there were early and late complications. The early complications included temporary voiding difficulty (n = 17), anastomotic leak (n = 2), postoperative bleeding (n = 1), and rectovaginal fistula (n = 1).

Table 2. Pathologically proven results of endorectal ultrasonography

	uT1 (*n*)	uT2 (*n*)	uT3 (*n*)	Total (*n*)
pT1	20	5		25
pT2	3	26	1	30
pT3				
Total	23	31	1	55

u, ultrasonographic stage; p, pathologically proven stage

Bleeding, rectovaginal fistula, and two leaks were managed by surgery. The late complications included partial fecal soiling ($n = 8$), sexual problems ($n = 8$), anastomotic site stenosis ($n = 4$), intestinal obstruction ($n = 3$), and stoma problems ($n = 7$). All these were managed by conservative methods. The overall complication rate after radical surgery was 48%.

Recurrence and management

In the TEM group, there were six cases of recurrence. Three patients had local recurrence only, and the other three patients had distant metastasis during the follow-up period after local recurrence treatment. Two patients were treated by TEM, and the other four patients underwent abdominoperineal resection. One patient in the T2 stage died after abdominoperineal resection of distant metastasis.

In the radical surgery group, there were 11 cases of recurrence. Five patients had local recurrence only, and five patients had distant metastasis only. There was one case of combined local and distant metastasis. Surgical treatment was performed for the patients with local recurrence. Four patients underwent abdominoperineal resection, and one patient underwent a second resection and anastomosis. Two patients in the radical surgery group died during the follow-up period. One patient in the T1 stage died 14 months after abdominoperineal resection of liver metastasis, and one patient in the T2 stage died 50 months after abdominoperineal resection of lung metastasis.

5-Year local recurrence

For the patients in the T1 stage, the 5-year local recurrence rate was 4.1% in the TEM group and 0% in the radical surgery group. There was one delayed local recurrence after 64 months of TEM. For the patients in the T2 stage, the 5-year local recurrence rate was 19.5% in the TEM group and 9.4% in the radical surgery group. There was no significant statistical difference between the two groups for the T1 stage ($p = 0.94$). However, for the T2 stage, the TEM group showed a significantly higher recurrence rate than the radical surgery group ($p = 0.035$) (Fig. 1).

5-Year disease-free survival

For the T1 stage, 5-year disease-free survival rate was 95.9% in the TEM group and 94.1% in the radical surgery group. For the T2 stage, the 5-year disease-free survival rate was 80.5% in the TEM group and 83.3% in the radical surgery group. There were no significant statistical differences between the TEM and radical surgery groups for the T1 ($p = 0.35$) and T2 ($p = 0.12$) stages (Fig. 2).

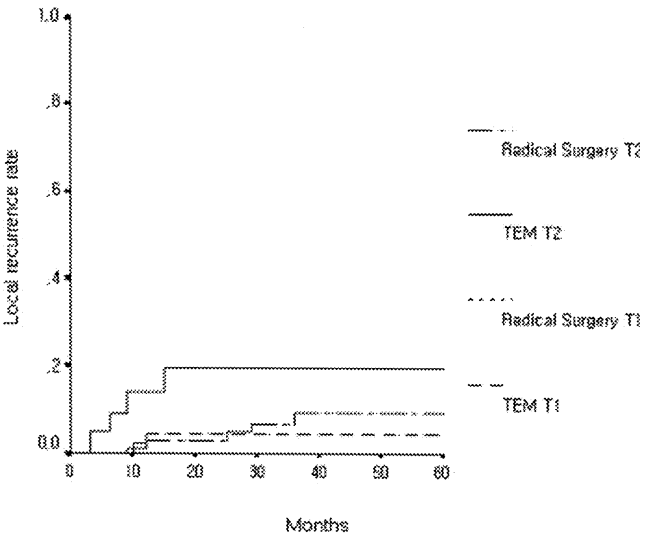

Fig. 1. Local recurrence rate after transanal endoscopic microsurgery and radical surgery for T1 and T2 rectal cancers.

5-Year survival

For the T1 stage, the 5-year survival rate was 100% in TEM group and 92.9% in the radical surgery group. For the T2 stage, the rate was 94.7% in the TEM group and 96.1% in the radical surgery group. There were no significant statistical differences between two groups in for the T1 ($p = 0.07$) and T2 ($p = 0.48$) stages (Fig. 3).

Discussion

Radical surgeries for rectal cancer such as low anterior resection and abdominoperineal resection have led to good results in terms of local recurrence and 5-year survival rates [7]. However, relatively high complication rates and the permanent stoma required after these methods have led patients and surgeons to choose local therapy for rectal cancer. The transanal and transsphincteric approaches have been used as local treatment. The transanal approach has benefits such as low morbidity and early recovery, but for technical reasons, this method is limited to low- and mid-rectal lesions, and it has a high local recurrence rate. The transsphincteric approach can reach higher lesions, but also has high complication rates [12]. Recently, Buess in Germany developed transanal endoscopic microsurgery (TEM) and resolved many problems of traditional local treatment. This method has advantages such as its magnified stereoscopic view, full-thickness excision with an appropriate margin, more precise closure, and accessibility

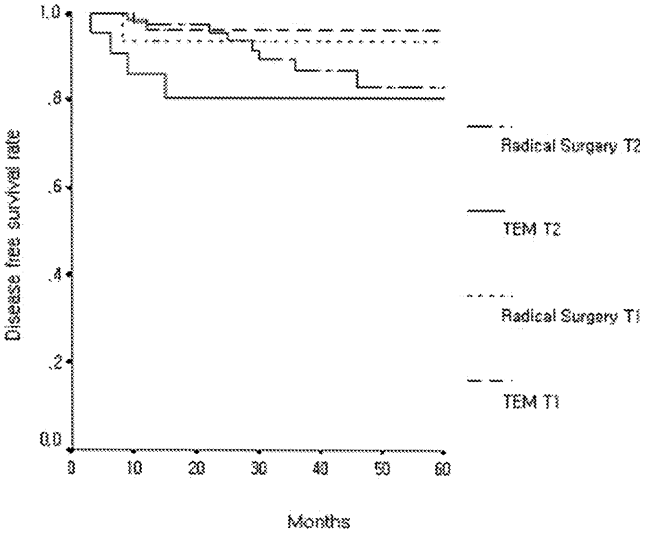

Fig. 2. Disease-free survival rate after transanal endoscopic microsurgery and radical surgery for T1 and T2 rectal cancers.

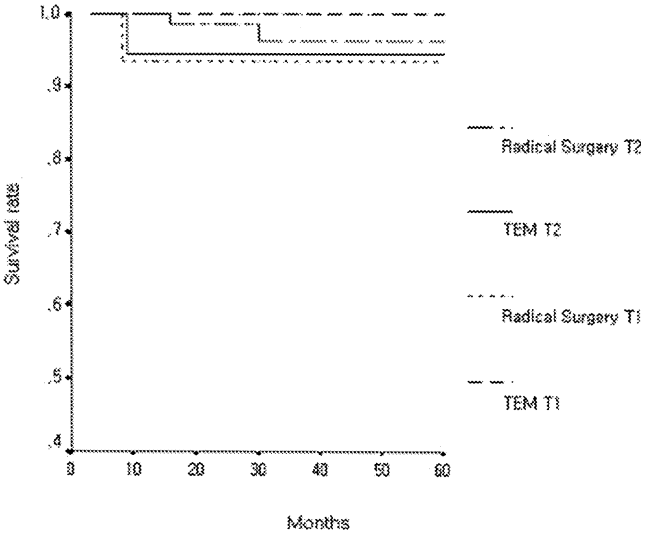

Fig. 3. Survival rate after transanal endoscopic microsurgery and radical surgery for T1 and T2 rectal cancers.

to the upper rectum or lower sigmoid. Because of these advantages and low morbidity, TEM has been accepted as a local therapy for benign rectal tumor and early rectal cancer [4, 16, 19]. Many reports have shown significantly low complication rates after TEM [4, 16]. We started performing TEM in 1994, applying this method to benign and malignant rectal lesions, and advantages such as those mentioned previously have been noted. As shown in many other reports, our data showed a clearly lower complication rate. In the TEM group, the complication rate was 4.1%, and the complications were improved by conservative methods. On the contrary, the complication rate for radical surgery in this study was relatively high (48%), and this included both major and minor complications. The major complication rate requiring reoperation was 4%, and other complications were treated successfully by the conservative method.

The main disadvantage of local therapy is that it cannot deal with lymph node metastasis. Fortunately, many studies have reported low lymph node metastasis rates of 0% to 12% for T1 rectal cancer, although it was 12% to 28% for T2 rectal cancer [13, 14]. The criteria for local excision are small size (less than 4 cm), good or moderate differentiation, no venous or lymphatic involvement, and minimum invasion of the rectal wall (confined to the mucosa or submucosa). These criteria are associated with the low incidence of lymph node metastasis [9]. With these criteria met, there are many reports that the results of TEM are comparable with those for radical surgery. Winde et al. [20] reported a 4.2% local recurrence rate and a 96% 5-year survival rate after TEM for T1 rectal cancer. But for T2 rectal cancer, any reports show that local resection had higher local recurrence rate of 8% to 47% [10]. Mellgren et al. [13] reported that local resection had a high 5-year local recurrence rate (47% vs 6%) and a low 5-year survival rate (65% vs 85%), as compared with those for radical surgery.

In our study, the 5-year local recurrence rate was 4.1% and the 5-year survival rate was 100% after TEM for T1 rectal cancer. This result was in accordance with that of previous studies [9, 19]. We believe this good outcome results from the strict criteria mentioned earlier. If the excised specimen proved to be T2 rectal cancer after TEM, we recommended radical therapy. If the patients refused radical surgery, another option was chemoradiation. The staging for 10 patients was changed from T1 to T2 after TEM in our study. Five patients underwent radical surgery, and the remaining five patients received chemoradiation. In this study, 22 patients with a preoperative diagnosis of T2 rectal cancer received TEM. Six were high-risk patients for anesthesia, and 16 patients refused radical surgery and chemoradiation. In this group, the 5-year local recurrence rate for TEM was significantly higher than for radical surgery, consistent with other reports [8, 10]. However, there were no significant differences between the two groups in terms of the 5-year disease-free survival rate and the 5-year survival rate. These results were different from those previously reported [13]. This different may have resulted from the discrepancy in the sample size and tumor size between the TEM and radical surgery groups. On the contrary, the radical surgery group in this study had pathologically proven T2N0M0, whereas the lymph node status of the TEM group was evaluated by computed tomography or endorectal ultrasonogrphy. The negative predictive value for lymph node metastasis of endorectal ultrasonography was reported to be 84% [17], and the accuracy of endorectal ultrasonography at our hospital is estimated to be approximately 80%. Therefore, the TEM group in this study may have included lymph node positive patients. For T2 rectal cancer, further study on the role of TEM as a local treatment is required. Chakravarti et al. [5] reported that preoperative chemoradiation for T2 and high-risk T1 rectal cancer reduced the local recurrence rate after local resection. There were many reports on the role of pre- or postoperative chemoradiation for local resection of rectal cancer [11, 18], but there still are no long-term results.

In conclusion, with accurate preoperative staging and strict selection criteria, TEM can be considered as a first-line therapy for T1 rectal cancer. If TEM is used for T2 rectal cancer, whether diagnosed preoperatively or postoperatively, further therapy to reduce the local recurrence rate should be considered.

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