

# Chapter 17

## Rectal Cancer: Management of T1 Rectal Cancer

Woon Kyung Jeong and Jose G. Guillem

### Introduction

The widespread implementation of screening colonoscopy has led to a parallel increase in the detection of early staged rectal cancer including T1N0M0 lesions. Rectal cancers at this stage have invaded into the submucosal layer of the rectal wall without metastasis to lymph nodes and other organs and have been traditionally managed with a transabdominal radical resection (RR). However, since a RR is associated with significant postoperative morbidity, local excisional approaches (LE) such as transanal excision (TAE), transanal endoscopic microsurgery (TEM), and transanal minimally invasive surgery (TAMIS), have been adopted. Whether the oncological results of a less morbid LE approach is comparable to a more morbid RR approach for T1N0M0 rectal cancer is the essential question of this chapter.

When confronted with a patient with a presumed T1N0M0 rectal cancer based on preoperative physical exam and imaging studies, both LE and RR options have to be considered and the pros and cons of each approach and their associated long-term and short-term oncological outcomes and functional consequences and implications for the specific patient at hand carefully discussed.

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W.K. Jeong • J.G. Guillem (✉)  
Colorectal Service, Department of Surgery, Memorial Sloan-Kettering Cancer Center,  
New York, NY, USA  
e-mail: [guillemj@MSKCC.ORG](mailto:guillemj@MSKCC.ORG)

## Search Strategy

P (patients)	I (intervention)	C (comparator)	O (outcomes)
Patients with T1 rectal cancer	Local excision	Radical resection	Oncologic outcomes, quality of life

A literature search in Pubmed, Embase, and Scopus databases was performed. The terms used for the search included: “T1 rectal cancer”; “early staged rectal cancer”; “local excision”; “radical resection”; “recurrence”; “sexual function”; “anorectal function” and “quality of life”. Only articles written in English and published between 2010 and 2015 and reporting original data or meta-analysis on T1 rectal cancer were selected. Important and evidence-based studies published before 2010 were also included.

## Results

We found two meta-analyses which met our search criteria and included most of the significant data on the topic (Table 17.1) [1, 2]. Of these two studies, one was larger (2896 patients from 13 studies [1] versus 860 patients from seven studies [2]) and reported detailed preoperative diagnostic workup and oncologic data including lymphovascular invasion and surgical margin status as well as the use of neoadjuvant and/or adjuvant therapy [1]. However, these two meta-analyses included studies that were retrospective and non-randomized [3–15], and some of the retrospective studies included small numbers of patients. The one prospective randomized study on this topic which was included in both meta-analyses only enrolled 50 patients [16].

### *Oncologic Outcomes*

#### **Local Recurrence**

In our review of these two meta-analyses, rates of local recurrence were higher in patients undergoing a LE when compared to patients undergoing a RR (4–33 % versus 0–6 %, respectively) [1, 2].

#### **Distant Metastasis**

Of these two meta-analyses, only one compared distant metastasis rates between LE and RR and showed no significant differences (0–8 % versus 0–4 %, respectively) [2]. However, it is important to point out that this study included only patients undergoing TEM and did not include TAE or TAMIS.

**Table 17.1** Comparison of meta-analysis studies on T1 rectal cancer

Study	Year	Study design	Patients (LE/RR)	Local recurrence	Distant metastasis	DFS	OS	Morbidity	Mortality	Quality of evidence
Kidane et al. [1] (TAE, TEM, TAMIS vs. RR)	2015	Meta-analysis	2896 (1315/1581)	LE > RR (relative risk, 2.36; 95% CI, 1.64–3.39)	n/a	5-years DFS, LE < RR (relative risk, 1.54; 95% CI, 1.15–2.05)	5-years OS, LE < RR (relative risk, 1.46; 95% CI, 1.19–1.77)	LE < RR (relative risk, 0.20; 95% CI, 0.10–0.41)	LE < RR (relative risk, 0.31; 95% CI, 0.14–0.71)	moderate
Lu et al. [2] (TEM vs. RR)	2015	Meta-analysis	860 (303/557)	LE > RR (OR, 4.62; 95% CI, 2.03–10.53)	no difference (OR, 0.74; 95% CI, 0.32–1.72)	no difference (OR, 1.12; 95% CI, 0.31–4.12)	no difference (OR, 0.87; 95% CI, 0.55–1.38)	n/a	n/a	moderate

LE local excision, RR radical resection, DFS disease-free survival, OS, overall survival, TAE, transanal excision, TEM, transanal endoscopic microsurgery, TAMIS, transanal minimally invasive surgery, CI, confidence interval, OR, overall risk, SEER, surveillance, epidemiology, and end results, HR hazard risk

## Overall Outcome

In one meta-analysis, disease-free survival rate was higher in patients undergoing a RR [1]. However, in the other meta-analysis, no significant difference was noted in disease-free survival between the two surgical treatment options [2]. This may be due to the fact that in the latter met-analysis, only 2 studies reporting disease-free survival were included.

With regard to overall survival, one meta-analysis showed better results for RR over LE [1]. The other meta-analysis did not, even though it did demonstrate a significantly higher local recurrence rate in patients undergoing a LE (odds ratio, 4.62; 95% confidence interval, 2.03–10.53) [2]. The authors do not provide an explanation for this. However, it is possible that salvage radical surgery and adjuvant chemotherapy and/or radiation therapy may have eradicated some of the locally recurrent rectal cancer and impacted survival in a positive manner. However, other studies suggest that failure following a local excision may not be salvageable in a significant number of cases [17].

## Quality of Life

Of the two meta-analyses, only one reported on morbidity and noted a higher morbidity rate for RR over LE [1]. LE was associated with a much lower need for permanent stoma [1]. However, a number of the studies included were from over 20 years ago when sphincter sparing TME was not as established as it is today.

There is a paucity of literature comparing sexual or anorectal functions following RR and LE and none are prospective randomized studies. Therefore, the two meta-analyses [1, 2] did not discuss this topic. One study not included in the two meta-analysis, however, did compare the quality of life after TEM and TME in sex- and age-matched patients and reported no significant differences in quality of life between TEM and TME; but more frequent defecation disorders were observed after TME [18]. A trend toward better sexual function after TEM was also reported. However, a greater portion of patients in the TME group were T3 and received preoperative radiotherapy (18% versus 0%) which probably had a negative impact on sexual function.

## Other Studies

There are several recently published papers comparing local excision to radical resection that were not included in our analyses for specific reasons. One study included T1 and T2 rectal cancers and did not provide a subset analysis on T1 cancers [19] and the other included endoscopic polypectomy in the LE group [20]. One single institution study comparing LE to RR was not included in either of the meta-analyses [21]. It was a small sample (n = 124), retrospective study which demonstrated

a local recurrence rate of 11 % in the LE group versus 1.6 % in the RR group, but no difference in the disease-free and overall survival between the two groups. Our institutional experience at Memorial Sloan-Kettering Cancer Center (MSKCC) on a larger cohort (n=282) with a similar length of follow-up demonstrated an inferior disease-specific survival for patients with a T1 rectal cancer undergoing a LE relative to those undergoing a RR (87 % versus 96 %) [12].

In summary, the best available data suggest that a RR offers an oncologic advantage over a LE approach for early staged (T1N0M0) rectal cancer. This is probably related to the increased likelihood of a local recurrence noted after a LE approach, which is not always salvageable.

## Evidence Based Recommendations

A review of the published oncological results demonstrates that a RR provides the best oncologic outcome for a T1 rectal cancer. LE is an option for patients with T1 rectal cancer without high risk features who either are not suitable for a RR or are willing to accept the oncological risks in the interest of avoiding the functional consequences of a RR. There should not be enlarged mesorectal lymph nodes suspicious for metastasis on preoperative images nor evidence of poor differentiation (PD), lymphovascular invasion (LVI), perineural invasion (PNI), or submucosal (Sm) invasion >1 mm on pathological analysis. If one of these high risk features is noted, a RR is recommended [22, 23]. If such a patient were to insist on having a LE rather than the recommended RR, they have to understand that local recurrence rates after LE of a T1 rectal cancer range between 12 and 29 % with long-term follow-up, despite applying careful selection criteria for LE [5, 10, 15, 24, 25]. If a local recurrence develops and a salvage surgery is pursued, it would likely be extensive as one study reported the need for multivisceral pelvic resection in 33 % and total pelvic exenteration in 5 % of patients undergoing a RR after a recurrence following a LE of T1 rectal cancer [17].

1. Patients with a T1N0M0 rectal cancer that are otherwise fit should be offered a radical resection incorporating mesorectal excision.
2. Patients with a T1N0M0 rectal cancer not able to undergo a radical resection may be offered a local excision understanding the increased risk for failure with possible limited salvage options.

Grade of data: moderate quality

## A Personal View/Approach

If a patient is found to have a biopsy proven rectal adenocarcinoma that clinically looks and feels like it is not deeply invasive (mobile, non tethered, exophytic rather

than ulcerated) and possibly amenable to a LE, a careful review of the pathology as well as local [endorectal ultrasonography (ERUS) or rectal magnetic resonance imaging (MRI)] and distant [computed tomography (CT) of chest, abdomen and pelvis] staging has to occur in order to further determine if indeed a LE approach is appropriate. The presence of any adverse pathological features (PD, LVI, PNI, or Sm invasion >1 mm) would be associated with an increased likelihood of mesorectal lymph node involvement and in an otherwise healthy individual with good anorectal sphincter function (good baseline tonicity, squeeze, no paradoxical motion of puborectalis sling, etc.), a RR would be offered. In an elderly individual with significant co-morbidities and/or poor anorectal function, a LE approach would be a safer initial approach (lower morbidity, mortality, and probable better function) than a RR but would be associated with a possible increased risk of local and distant failure. A more challenging scenario is the otherwise healthy individual with a very distal (1 cm above upper part of anorectal sphincter) invasive (T1N0M0 on imaging) rectal adenocarcinoma with good pathological features who is interested in a restorative curative resection. In this situation, the patient has to be informed that if LE is pursued initially and pathology identifies a T2 lesion and he/she were to pursue a subsequent salvage RR, this may or may not be feasible since the prior suture line fibrosis of LE would compromise creation of coloanal anastomosis and function.

Numerous other clinical scenarios exist based upon the local and distant staging of the rectal cancer, the presence or absence of poor pathological features, the distal-most location of the lesion relative to the upper most portion of the anorectal sphincters, the function of the anorectal sphincters, the presence or absence of co-morbidities, etc. Optimal matching of the treatment plan to the individual patient requires that all the above variables be taken into consideration and that the patient and family be informed and engaged in a discussion where short and long term wishes, risks, gains and losses are clearly discussed and agreed upon.

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