

**American College of Radiology
ACR Appropriateness Criteria®**

Clinical Condition:**Local Excision in Early-Stage Rectal Cancer****Variant 1:**

57-year-old male with preoperative stage uT1N0, freely mobile, moderately differentiated adenocarcinoma. Tumor is 2 cm in diameter, involves <25% circumference, and located 6 cm from anal verge. There is no lymphovascular space invasion.

| Treatment | Rating | Comments |
|---|--------|----------|
| Local Excision, pT1N0 and Negative Margins | | |
| Observation | 9 | |
| RT alone | 2 | |
| RT + chemotherapy | 1 | |
| Local Excision, pT1N0 and Positive Margins | | |
| LAR or APR | 9 | |
| RT alone | 2 | |
| RT + chemotherapy | 2 | |
| Observation | 1 | |
| <u>Rating Scale:</u> 1=Least appropriate, 9=Most appropriate | | |

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Clinical Condition:**Local Excision in Early-Stage Rectal Cancer****Variant 2:**

65-year-old otherwise healthy female with preoperative stage uT2N0 moderately differentiated adenocarcinoma. Tumor is 3 cm in diameter, freely mobile, and located 4 cm from anal verge. No lymphovascular space invasion is noted.

| Treatment | Rating | Comments |
|--|--------|---|
| Surgery | | |
| LAR or APR | 9 | |
| Local excision | 2 | |
| If Local Excision, then | | |
| RT + chemotherapy | 8 | |
| RT alone | 2 | |
| Observation | 1 | |
| If RT + Chemo: RT Dose to Primary | | |
| 45 Gy/1.8 Gy | 2 | |
| 50.4 Gy/1.8 Gy | 8 | |
| 54 Gy/1.8 Gy | 8 | If small bowel can be excluded. |
| 59.4 Gy/1.8 Gy | 2 | |
| Simulation | | |
| Patient prone | 9 | |
| Small-bowel contrast at simulation | 9 | |
| Patient immobilized | 9 | |
| Use belly board | 9 | If patient is prone. |
| Anal marker | 9 | |
| Bladder full at simulation | 8 | |
| Patient supine | 5 | |
| If RT + Chemo: RT Volume | | |
| L5/S1 pelvis to include perineum | 9 | In some cases where the lesion is 4 cm above the anal verge, perineum may be spared as long as 3 cm of inferior margin can be maintained. |
| RT Technique | | |
| 3 field with photons | 8 | |
| 4 field with photons | 8 | |
| AP/PA | 2 | |
| Rating Scale: 1=Least appropriate, 9=Most appropriate | | |

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Clinical Condition:

Local Excision in Early-Stage Rectal Cancer

Variant 3:

60-year-old female with uT3Nx adenocarcinoma, located 4 cm from anal verge.

| Treatment | Rating | Comments |
|-------------------------------|--------|--|
| Neoadjuvant RT + chemotherapy | 9 | Refer to the ACR Appropriateness Criteria® topic on Resectable Rectal Cancer . |
| LAR or APR | 9 | |
| Local excision | 1 | |

Rating Scale: 1=Least appropriate, 9=Most appropriate

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LOCAL EXCISION IN EARLY STAGE RECTAL CANCER

Expert Panel on Radiation Oncology–Rectal/Anal Cancer: A. William Blackstock, MD¹; Stacy Wentworth, MD²; Andre A. Konski, MD³; W. Warren Suh, MD⁴; Joseph Herman, MD, MSc⁵; Mohammed Mohiuddin, MD⁶; Matthew M. Poggi, MD⁷; William F. Regine, MD⁸; William Small Jr, MD⁹; Bard C. Cosman, MD¹⁰; Leonard Saltz, MD.¹¹

Summary of Literature Review

Background

Thirty-four percent of patients diagnosed with rectal cancer present with American Joint Commission on Cancer (AJCC) stage I disease [1]. Historically these patients have been treated with low anterior resection (LAR) or abdominoperineal resection (APR) with excellent local control (LC) and survival rates [2-4]. Postulating that early-stage lesions may not warrant such aggressive treatment as well as acknowledging the mortality and morbidity of these procedures, investigators have examined less morbid sphincter-sparing approaches such as local excision (LE). In addition, LE has been presented as an option to patients whose other comorbid conditions would not allow them to tolerate more extensive surgery. Most of the data supporting the use of local excision are from single-institution, retrospective reviews [5-9]. Few prospective multi-institutional trials have investigated the efficacy of LE with or without radiation therapy (RT) in these patients [10,11].

Workup

All patients should receive a full colonoscopy with biopsy, pathology review, proctoscopy, carcinoembryonic antigen (CEA), and computerized topography of the chest, abdomen, and pelvis. In addition, patients being considered for local excision should have an endorectal ultrasound (EUS) to evaluate depth of penetration. EUS is 62%-92% accurate for T staging and 64%-88% accurate for N staging but is highly operator dependent [12,13].

Surgical Techniques

There are three operative approaches for LE of a distal rectal lesion; transanal, posterior trans-sphincteric (York-Mason procedure), or posterior proctotomy (Kraske procedure). Transanal excision (TAE) is the most

commonly used approach. Under direct visualization, the lesion is excised with a 1 cm margin including the perirectal fat. The mural defect is then closed. The posterior trans-sphincteric and posterior proctotomy approaches are used less commonly and involve posterior approaches with dissection above or below the levator ani to the rectum [14]. It is important to note that none of these procedures includes lymph node evaluation.

Patient Selection

In general, the best candidates for LE include small (<4 cm), low-lying tumors confined to the muscularis propria. Patients with adverse pathologic features (signet ring histology, poor differentiation, lymphovascular space invasion) or whose tumors occupy more than 40% of the rectum are at high risk for local recurrence, and local excision is not recommended [15,16]. Patients with positive margins after local excision or piecemeal resections are at very high risk of local recurrence and should be offered immediate APR or LAR. Patients with tumors invading through the muscularis propria (T3) are at very high risk (>30%) for local recurrence following local excision and should not be treated with local excision. Palliative local excision may be performed in advanced-stage patients [17].

Local Excision with or without Radiation Therapy

Single-institution reviews have reported failure rates of 7%-40% and 25%-62% for local excision alone in T1 and T2 tumors, respectively [5-9,18]. Postoperative RT may lower these rates to 10%-20%. An initial phase II study by the Radiation Oncology Therapy Group[®] (RTOG[®]) assigned patients observation (low-grade T1 tumors with negative margins) or chemoradiation (54-65 Gy with 5-fluorouracil (5-FU) 1,000 mg/m² IV d1-3, d29-31) based on postexcision pathology [11]. Local recurrence rates were 7%, 8%, and 23% for T1, T2, and T3 tumors, respectively. Cancer and Leukemia Group B study (CALGB 8984) evaluated the role of LE with or without chemotherapy and RT in 177 patients with T1 and T2 adenocarcinomas of the rectum [10]. T1 patients underwent local excision followed by observation. T2 patients underwent local excision followed by RT (54 Gy/30 fractions) and chemotherapy (5-FU 500 mg/m² IV d1-3, d29-31). At 48 months of median follow-up, the 6-year overall survival rate was 85% and the disease-free survival rate was 78% for all patients. Three of the 59 eligible T1 patients had experienced local failure and seven of the 51 eligible T2 patients. It is important to note, however, that these were highly selected patients and one-third of patients were excluded after surgery due to large tumor size and/or questionable margin status.

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Future Directions

A phase II trial by the American College of Surgeons Oncology Group (ACSOG Z6041) is investigating neoadjuvant chemoradiation and local excision in T2 patients and is currently accruing patients.

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