

**Local Excision in Early Stage Rectal Cancer  
EVIDENCE TABLE**

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Strength of Evidence
1. Jessup JM, Stewart AK, Menck HR. The National Cancer Data Base report on patterns of care for adenocarcinoma of the rectum, 1985-95. <i>Cancer</i> 1998; 83(11):2408-2418.	3b	N/A	An observational study using National Cancer Data Base (NCDB) data to describe patterns of care.	Rectal adenocarcinoma is being diagnosed at a later stage, especially among the young and African Americans. Increased use of multimodal therapy for the treatment of stage II and III disease continues.	3
2. Heald RJ, Moran BJ, Ryall RD, Sexton R, MacFarlane JK. Rectal cancer: the Basingstoke experience of total mesorectal excision, 1978-1997. <i>Arch Surg</i> 1998; 133(8):894-899.	3a	519	A prospective consecutive case series to examine local recurrence and cancer-specific survival after total mesorectal excision (TME).	Rectal cancer can be cured by surgical therapy alone in 2/3 patients undergoing surgical excision in all stages and in 4/5 patients having curative resections.	2
3. Martling AL, Holm T, Rutqvist LE, Moran BJ, Heald RJ, Cedemark B. Effect of a surgical training programme on outcome of rectal cancer in the County of Stockholm. Stockholm Colorectal Cancer Study Group, Basingstoke Bowel Cancer Research Project. <i>Lancet</i> 2000; 356(9224):93-96.	3a	447	A prospective study of surgical management of colorectal cancer compared outcomes before and after a surgical training program was conducted in TME at a single hospital in Sweden.	The proportion of abdominoperineal procedures and the local recurrence rate decreased by more than 50% and there is already evidence of a decline in rectal-cancer mortality.	3
4. Wibe A, Rendedal PR, Svensson E, et al. Prognostic significance of the circumferential resection margin following total mesorectal excision for rectal cancer. <i>Br J Surg</i> 2002; 89(3):327-334.	3a	3,319	A study using registry data to determine the significance of the status of the margins in predicting patient outcomes.	The circumferential margin has a significant and major prognostic impact on the rates of local recurrence, distant metastasis and survival.	2
5. Chakravarti A, Compton CC, Shellito PC, et al. Long-term follow-up of patients with rectal cancer managed by local excision with and without adjuvant irradiation. <i>Ann Surg</i> 1999; 230(1):49-54.	3a	99	A retrospective study to compare long-term outcomes for patients treated with either: A. Local excision alone; or B. Local excision + adjuvant pelvic irradiation.	<u>5-years</u> Local control <u>A</u> <u>B</u> RFS                72%        90% 66%        74%	2
6. Endreseth BH, Myrvold HE, Romundstad P, Hestvik UE, Bjerkeset T, Wibe A. Transanal excision vs. major surgery for T1 rectal cancer. <i>Dis Colon Rectum</i> 2005; 48(7):1380-1388.	3a	291	An observational study to compare long-term results of T1 rectal cancer patients treated with either transanal excision or major surgery.	Transanal excision had inferior results both in terms of OS and RFS, but patient groups were not comparable.	3
7. Madbouly KM, Remzi FH, Erkek BA, et al. Recurrence after transanal excision of T1 rectal cancer: should we be concerned? <i>Dis Colon Rectum</i> 2005; 48(4):711-719; discussion 719-721.	3a	52	A retrospective review of all T1 low risk rectal cancer patients treated with local excision alone considering local recurrence, distant metastasis, disease-free interval, results of salvage surgery, DFS and OS.	5-year recurrence: 29.38%. Transanal excision has a high rate of recurrence. Although overall cancer survival rates might be regarded as satisfactory, high recurrence and low salvage rates suggest that transanal excision might require adjuvant therapy or an increased role for resective surgery.	3

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8. Paty PB, Nash GM, Baron P, et al. Long-term results of local excision for rectal cancer. <i>Ann Surg</i> 2002; 236(4):522-529; discussion 529-530.	3a	125 74-T1 51-T2	A retrospective review of patients treated at a single hospital treated by local excision as definitive surgery. 31 patients received adjuvant RT, and 15 of those received adjuvant CT as well.	Ten-year LR and OS were 17% and 74% for T1 rectal cancers and 26% and 72% for T2 cancers. 2/3 of patients with tumor recurrence have local failure, implicating inadequate resection in treatment failure. In this study, neither adjuvant radiotherapy nor salvage surgery was reliable in preventing or controlling local recurrence. The postoperative interval to cancer death is as long as 10 years, raising concern that cancer mortality may be higher than is generally appreciated.	3
9. Wentworth S, Russell GB, Tuner, II, et al. Long-term results of local excision with and without chemoradiation for adenocarcinoma of the rectum. <i>Clin Colorectal Cancer</i> 2005; 4(5):332-335.	3a	285	Review of patients undergoing curative resection for rectal cancer, either local excision, APR or LAR. 12 patients received postoperative RT and 4 received adjuvant CT.	<u>LE</u> 5-year OS: 76% 10- year OS: 42% 5- year DFS: 69% 10- year DFS: 58% Adjuvant therapy did not affect survival or recurrence rates in patients undergoing LE compared with other surgeries. The rate of local failure (16%) is comparable to that observed in the Cancer and Leukemia Group B (CALGB) 8984 prospective study and suggests that highly selected patients undergoing local excision can expect good local control of rectal cancer.	2
10. Steele GD, Jr., Herndon JE, Bleday R, et al. Sphincter-sparing treatment for distal rectal adenocarcinoma. <i>Ann Surg Oncol</i> 1999; 6(5):433-441.	4	177	Prospective study to test the hypothesis that the anal sphincter can be preserved in some patients with distal rectal adenocarcinoma (DRA).	At 48 months median follow-up, 6-year survival and failure-free survival rates of the eligible patients are 85% and 78% respectively. Sphincter preservation can be achieved with excellent cancer control without initial sacrifice of anal function in most patients.	2
11. Russell AH, Harris J, Rosenberg PJ, et al. Anal sphincter conservation for patients with adenocarcinoma of the distal rectum: long-term results of radiation therapy oncology group protocol 89-02. <i>Int J Radiat Oncol Biol Phys</i> 2000; 46(2):313-322.	2	65	Phase II study to assess the outcome of a multi-institutional, national cooperative group study attempting functional preservation of the anorectum for patients with limited, distal rectal cancer.	With median follow-up of 6.1 years, 11 patients have failed. 5-year survival was 88%. Based on these results, the authors conclude that conservative, sphincter-sparing therapy is a feasible alternative treatment for selected patients with limited cancer involving the middle and lower rectum. Risk of both local and distant failure appears to escalate with increasing depth of tumor invasion.	2

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12. Kim HJ, Wong WD. Role of endorectal ultrasound in the conservative management of rectal cancers. <i>Semin Surg Oncol</i> 2000; 19(4):358-366.	6	N/A	Expert opinion on role that US can play in management of rectal CA.	Endorectal ultrasonography (ERUS) extends the ability of the clinician to define the clinical features assessed on routine physical examination, and remains the best modality for accurately staging depth of penetration and presumptive nodal status in rectal cancers.	4
13. Schaffzin DM, Wong WD. Endorectal ultrasound in the preoperative evaluation of rectal cancer. <i>Clin Colorectal Cancer</i> 2004; 4(2):124-132.	7	N/A	Review of different diagnostic imaging devices.	Multiple modalities are available to stage rectal cancer, including digital rectal examination, CT, MRI, and ERUS. Overstaging and understaging occurs in all.	4
14. Rothenberger DA, Ricciardi R. Procedures for Rectal Cancer. In: Souba WW, Fink MP, Furkovich GJ, et al., eds. <i>ACS Surgery: Principles &amp; Practice</i> . Vol 4; WebMD; 2004:A.D.:1-16.	15 (Book Chapter)	N/A	Book chapter.	N/A	N/A
15. Willett CG, Compton CC, Shellito PC, Efid JT. Selection factors for local excision or abdominoperineal resection of early stage rectal cancer. <i>Cancer</i> 1994; 73(11):2716-2720.	3a	125	Retrospective study to determine outcomes for patients undergoing local excision or abdominoperineal resection.	For patients with favorable histologic features, both local excision and abdominoperineal resection gives good outcomes. However, patients who have tumors with poorly differentiated histologic features and/or venous/lymph vessel involvement, have poorer rates of survival and of local control with either of these surgical approaches alone.	3
16. Willett CG, Tepper JE, Donnelly S, et al. Patterns of failure following local excision and local excision and postoperative radiation therapy for invasive rectal adenocarcinoma. <i>J Clin Oncol</i> 1989; 7(8):1003-1008.	3a	66	Retrospective review to determine failure patterns among patients undergoing conservative surgery alone or in combination with RT.	5-year OS, DFS and local control rates were 70%, 77%, and 63%, respectively for both groups combined. Prognostic factors for each group are defined.	3
17. Chen H, George BD, Kaufman HS, Malaki MB, Mortensen NJ, Kettlewell MG. Endoscopic transanal resection provides palliation equivalent to transabdominal resection in patients with metastatic rectal cancer. <i>J Gastrointest Surg</i> 2001; 5(3):282-286.	3a	49	A comparative study to determine whether ETAR provides palliation equivalent to LAR or APR.	There was a trend toward more stomas in the LAR/APR group (28% vs 17%), with a significantly higher morbidity rate (24% vs 4%; P=0.049). ETAR provides equivalent palliation to LAR.	3

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18. Garcia-Aguilar J, Mellgren A, Sirivongs P, Buie D, Madoff RD, Rothenberger DA. Local excision of rectal cancer without adjuvant therapy: a word of caution. <i>Ann Surg</i> 2000; 231(3):345-351.	3a	82	A review evaluating the results of local excision alone for the treatment of T1 and T2 rectal cancer, applying strict selection criteria.	54-months Recurrence: <u>T1</u> 18% <u>T2</u> 37% Survival rate of salvage surgery: 98% 89% Local excision of early rectal cancer, even in the ideal candidate, is followed by a much higher recurrence rate than previously reported.	2

## Evidence Table Key

### Study Type Key

*Numbers 1-7 are for studies of therapies while numbers 8-15 are used to describe studies of diagnostics.*

1. Randomized Controlled Trial — Treatment
2. Controlled Trial
3. Observation Study
  - a. Cohort
  - b. Cross-sectional
  - c. Case-control
4. Clinical Series
5. Case reviews
6. Anecdotes
7. Reviews
  
8. Randomized Controlled Trial — Diagnostic
9. Comparative Assessment
10. Clinical Assessment
11. Quantitative Review
12. Qualitative Review
13. Descriptive Study
14. Case Report
15. Other (Described in text)

### Strength of Evidence Key

- Category 1 - The conclusions of the study are valid and strongly supported by study design, analysis and results.
- Category 2 - The conclusions of the study are likely valid, but study design does not permit certainty.
- Category 3 - The conclusions of the study may be valid but the evidence supporting the conclusions is inconclusive or equivocal.
- Category 4 - The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.