Local Excision in Rectal Cancer
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
1. American Cancer Society. Cancer Facts & Figures 2012: Atlanta: American Cancer Society; 2012.	Review/Other-Tx	N/A	Summarizes basic cancer facts and figures.	Third most common cancer in the U.S. are cancers of the colon and rectum, with a 5-year relative survival rate of 64%. SEER study found that most common second cancers among colon cancer survivors are new cancers of the colon and rectum. Among colon cancer survivors, the observed to expected ratio for rectal cancer is 1.36.	4
2. Heald RJ, Moran BJ, Ryall RD, Sexton R, MacFarlane JK. Rectal cancer: the Basingstoke experience of total mesorectal excision, 1978-1997. *Arch Surg.* 1998;133(8):894-899.	Observational-Tx	519 patients	A prospective consecutive case series to examine local recurrence and cancer-specific survival after TME.	Rectal cancer can be cured by surgical therapy alone in two-thirds of patients undergoing surgical excision in all stages and in four-fifths of 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. *Lancet.* 2000;356(9224):93-96.	Observational-Tx	447 patients	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.	2
4. Wibe A, Rendedal PR, Svensson E, et al. Prognostic significance of the circumferential resection margin following total mesorectal excision for rectal cancer. *Br J Surg.* 2002;89(3):327-334.	Observational-Tx	3,319 patients	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. *Ann Surg.* 1999;230(1):49-54.	Observational-Tx	99 patients	A retrospective study to compare long-term outcomes for patients treated with either: LE alone; or LE + adjuvant pelvic irradiation.	After 5-years: local control was 76% for LE alone, and 90% for LE + adjuvant pelvic irradiation. RFS was 66% for LE alone, and 74% for LE + adjuvant pelvic irradiation.	2
6. Endreseth BH, Myrvold HE, Romundstad P, Hestvik UE, Bjerkeset T, Wibe A. Transanal excision vs. major surgery for T1 rectal cancer. *Dis Colon Rectum.* 2005;48(7):1380-1388.	Observational-Tx	291 patients	An observational study to compare long-term results of T1 rectal cancer patients treated with either TAE or major surgery.	TAE had inferior results both in terms of OS and RFS, but patient groups were not comparable.	1
7. Madbouly KM, Remzi FH, Erkek BA, et al. Recurrence after transanal excision of T1 rectal cancer: should we be concerned? *Dis Colon Rectum.* 2005;48(4):711-719; discussion 719-721.	Observational-Tx	52 patients	A retrospective review of all T1 low risk rectal cancer patients treated with LE alone considering local recurrence, distant metastasis, disease-free interval, results of salvage surgery, DFS and OS.	5-year recurrence: 29.38%. TAE has a high rate of recurrence. Although OS rates might be regarded as satisfactory, high recurrence and low salvage rates suggest that TAE might require adjuvant therapy or an increased role for resective surgery.	2

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8. Paty PB, Nash GM, Baron P, et al. Long-term results of local excision for rectal cancer. *Ann Surg.* 2002;236(4):522-529; discussion 529-530.	Observational-Tx	125 patients	A retrospective review of patients treated at a single hospital by LE as definitive surgery. 31 patients received adjuvant RT, and 15 of those received adjuvant chemotherapy as well.	10-year local recurrence and OS were 17% and 74% for T1 rectal cancers and 26% and 72% for T2 cancers. Two-thirds of patients with tumor recurrence have local failure, implicating inadequate resection in treatment failure. In this study, neither adjuvant RT 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.	2
9. Wentworth S, Russell GB, Tuner, II, et al. Long-term results of local excision with and without chemoradiation for adenocarcinoma of the rectum. *Clin Colorectal Cancer.* 2005;4(5):332-335.	Observational-Tx	285 patients	Review of patients undergoing curative resection for rectal cancer, either LE, APR or LAR. 12 patients received postoperative RT and 4 received adjuvant chemotherapy.	LE 5-year OS: 76%, 10- year OS: 2%, 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 LE can expect good local control of rectal cancer.	2
10. 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. *Int J Radiat Oncol Biol Phys.* 2000;46(2):313-322.	Observational-Tx	65 patients	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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11. Greenberg JA, Shibata D, Herndon JE, 2nd, Steele GD, Jr., Mayer R, Bleday R. Local excision of distal rectal cancer: an update of cancer and leukemia group B 8984. *Dis Colon Rectum.* 2008;51(8):1185-1191; discussion 1191-1184.	Observational-Tx	59 patients with T1 lesions; 51 patients with T2 lesions	To examine the efficacy of LE in the treatment of early-stage distal rectal cancers.	10-year rates of OS were 84% for patients with T1 and 66% for T2 rectal cancer. DFS was 75% for T1 and 64 % for T2 disease. Local recurrence rates for patients with T1 and T2 lesions were 8% and 18%, respectively, and rates of distant metastases were 5% for T1 and 12% for T2 lesions. LE alone for T1 rectal adenocarcinomas is associated with low recurrence and good survival rates that remain durable with long-term follow-up. T2 lesions treated via LE and adjuvant therapy are associated with higher recurrence rates.	1
12. Belluco C, De Paoli A, Canzonieri V, et al. Long-term outcome of patients with complete pathologic response after neoadjuvant chemoradiation for cT3 rectal cancer: implications for local excision surgical strategies. *Ann Surg Oncol.* 2011;18(13):3686-3693.	Observational-Tx	139 patients	To analyze long-term outcome of cT3 rectal cancer treated by neoadjuvant chemoradiation therapy in relation to complete pathologic response and type of surgery.	Tumors of 42 patients (30.2%) were classified as complete pathologic response. After a median follow-up of 55.4 months, comparing patients with complete pathologic response to patients with no complete pathologic response, 5-year disease-specific survival was 95.8% vs 78.0% (P=0.004), and 5-year DFS was 90.1% vs 64.0% (P=0.004). In patients with complete pathologic response, no statistically significant outcome difference was observed between TME and LE. In patients treated by LE, comparing patients with complete pathologic response to patients with no complete pathologic response, 5-year DFS was 100% vs 65.5% (P=0.024), and 5-year local RFS was 92.9% vs 66.7% (P=0.047).	2

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13. Garcia-Aguilar J, Shi Q, Thomas CR, Jr., et al. A phase II trial of neoadjuvant chemoradiation and local excision for T2N0 rectal cancer: preliminary results of the ACOSOG Z6041 trial. *Ann Surg Oncol.* 2012;19(2):384-391.	Experimental-Tx	90 patients	A phase II trial to assess the efficacy and safety of neoadjuvant chemoradiation and LE for T2N0 rectal cancer.	90 patients were accrued; 6 received nonprotocol treatment. The remaining 84 were 65% male; median age 63 years; 83% Eastern Cooperative Oncology Group performance score 0; 92% white; mean tumor size 2.9 cm; and average distance from anal verge 5.1 cm. 5 patients were considered ineligible. Therapy was completed per protocol in 79 patients, but 2 patients did not undergo LE. Among 77 eligible patients who underwent LE, 34 patients achieved a pathologic complete response (44%) and 49 (64%) tumors were downstaged (ypT0-1), but 4 patients (5%) had ypT3 tumors. Five LE specimens contained lymph nodes; one T3 tumor had a positive node. All but 1 patient had negative margins. 33 (39%) of 84 patients developed chemoradiation therapy-related grade ≥3 complications. Rectal pain was the most common perioperative complications.	1
14. Han SL, Zeng QQ, Shen X, Zheng XF, Guo SC, Yan JY. The indication and surgical results of local excision following radiotherapy for low rectal cancer. *Colorectal Dis.* 2010;12(11):1094-1098.	Observational-Tx	83 patients	To evaluate the outcome of LE followed by adjuvant RT for rectal cancer for curative purposes.	The procedures of LE were trans-anal resection in 83 patients, trans-sacral resection in 16, trans-sphincteric local resection in 5, and trans-vaginal resection in 3. The overall DFS rate was 80.4% (86/107), including 90.0% (54/60) for T1 and 72.3% (34/47) for T2 tumors, respectively. 82/107 patients underwent adjuvant postoperative RT after LE, and 25 did not, and the DFS rates between radiation and nonradiation group were significantly different for T2 [81.6% (31/38) vs 33.3% (3/9), P<0.05], but not for T1 tumors (90.9%vs 87.5%, P>0.05). The rates of local recurrence and distant metastasis were 13.1% (14/107) and 4.7% (5/106), respectively, and the median time to relapse was 15 months (range: 10-53) for local recurrence and 30 months (21-65) for distant recurrence. The risk factors for local recurrence were large tumor (≥3 cm), poorly differentiated adenocarcinoma and T2 tumor.	2

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15. Kundel Y, Brenner R, Purim O, et al. Is local excision after complete pathological response to neoadjuvant chemoradiation for rectal cancer an acceptable treatment option? *Dis Colon Rectum.* 2010;53(12):1624-1631.	Observational-Tx	320 patients	To evaluate the correlation between pathological T and N stages following neoadjuvant chemoradiation for locally advanced rectal cancer and the outcome of patients with mural pathological complete response undergoing LE.	After chemoradiation, 93% patients had radical surgery, 6% had LE, and 3% did not have surgery. In the 291 patients undergoing radical surgery, the pathological T stage correlated with the N stage (P=.036). We compared the outcome of patients with mural complete pathological response (n = 37) who underwent radical surgery (group I) and those (n = 14) who had LE only (group II). With a median follow-up of 48 months, 4 patients in group I had a recurrence and none in group II had a recurrence; 1 patient died in group I and none died in group II. DFS, pelvic RFS, and OS rates were similar in both groups.	2
16. Perez RO, Habr-Gama A, Sao Juliao GP, Proscurshim I, Scanavini Neto A, Gama-Rodrigues J. Transanal endoscopic microsurgery for residual rectal cancer after neoadjuvant chemoradiation therapy is associated with significant immediate pain and hospital readmission rates. *Dis Colon Rectum.* 2011;54(5):545-551.	Observational-Tx	36 patients	To compare the clinical outcomes of patients undergoing TEM with and without neoadjuvant chemoradiation.	Overall, median hospital stay was 2 days. Immediate (30-d) complication rate was 44% for grade II/III complications. Patients undergoing neoadjuvant chemoradiation therapy were more likely to develop grade II/III immediate complications (56% vs 23%; P=.05). Overall, the 30-day readmission rate was 30%. Wound dehiscence was significantly more frequent among patients undergoing neoadjuvant chemoradiation therapy (70% vs 23%; P=.03). Patients undergoing neoadjuvant chemoradiation therapy were at significantly higher risk of requiring readmission (43% vs 7%; P=.02).	1

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17. Ding PR, An X, Cao Y, et al. Depth of tumor invasion independently predicts lymph node metastasis in T2 rectal cancer. *J Gastrointest Surg.* 2011;15(1):130-136.	Review/Other-Tx	346 consecutive pT2 rectal cancers	To identify risk factors of LNM for T2 rectal cancer.	Age, tumor location, pathological features, and depth of invasion were independent predictors for overall LNM. Tumor location, pathological features, and depth of invasion were independent predictors for intermediate/apical LNM. Tree analysis showed that the incidence of LNM was 7.7% for upper rectal cancer with favorable pathological features, and 3.4% for mid/lower rectal cancer without other identified risk factors. The incidence of intermediate/apical LNM was 5.7% for superficial T2 rectal cancer with favorable pathological features, and 3.1% for deep T2 rectal cancer locating in upper rectum with favorable pathological features.	4
18. Kim HJ, Wong WD. Role of endorectal ultrasound in the conservative management of rectal cancers. *Semin Surg Oncol.* 2000;19(4):358-366.	Review/Other-Dx	N/A	Expert opinion on role that US can play in management of rectal cancer.	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
19. Schaffzin DM, Wong WD. Endorectal ultrasound in the preoperative evaluation of rectal cancer. *Clin Colorectal Cancer.* 2004;4(2):124-132.	Review/Other-Dx	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
20. Zorcolo L, Fantola G, Cabras F, Marongiu L, D'Alia G, Casula G. Preoperative staging of patients with rectal tumors suitable for transanal endoscopic microsurgery (TEM): comparison of endorectal ultrasound and histopathologic findings. *Surg Endosc.* 2009;23(6):1384-1389.	Observational-Dx	81 patients	To assess the accuracy of ERUS.	81 patients (46 males, mean age 66 years) underwent TEM. Mean distance of the tumor from the anal verge was 6.6 cm (range 2-12 cm). ERUS staged 15/27 adenomas (55%) as uT1. Of 54 carcinomas, 5 were pT0 because TEM was performed to remove resection margins of a malign polyp already snared. 5/19 pTis (26%) were overstaged uT1, while 7/17 pT1 (41%) were understaged. Overall, ERUS enabled distinction between early and advanced rectal lesion with 96% sensitivity and 85% specificity, giving accuracy of 94% (65/67). 13 patients had advanced lesions (8 pT2 and 5 pT3). Only in 2 of them (15%) was depth of invasion underestimated by ERUS (one uT0, one uT1) and thus was subsequent salvage surgery necessary.	3

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21. Stepansky A, Halevy A, Ziv Y. Preoperative staging using transrectal ultrasound in high and low rectal cancer. *Isr Med Assoc J.* 2010;12(5):270-272.	Observational-Dx	95 patients	To determine the accuracy of transrectal ultrasound in the staging of rectal cancer.	60 patients underwent radical surgery. Of these, 34 received no preoperative chemo-irradiation owing to microT1, was suggested to patients with adenocarcinoma that proved to be microT3. The overall accuracy rate was 80% for T stage. Overstaging was found in 13.3% and understaging in 6.7%. The N-stage was correctly assessed in 70%. The overall accuracy rate for tumors was 73.9% in the lower part and 90.9% in the upper. A trend towards a lower accuracy rate for low-lying tumors compared to high-located rectal tumors was found (P=0.532), which did not reach statistical significance.	3
22. Santoro GA, Gizzi G, Pellegrini L, Battistella G, Di Falco G. The value of high-resolution three-dimensional endorectal ultrasonography in the management of submucosal invasive rectal tumors. *Dis Colon Rectum.* 2009;52(11):1837-1843.	Observational-Dx	126 patients	1) To evaluate the accuracy of high-resolution 3D ERUS in distinguishing slight from massive submucosal invasion of early rectal tumors, and 2) to determine the technology's role in treatment selection.	3D ERUS staged 77 lesions as uT0, 25 as uT1-slight, 20 as uT1-massive, and 4 as uT2. Histologically, adenomas were found in 75 patients and tumor invasion was found in 44 lesions (24 pT1-slight, 16 pT1-massive, 4 pT2). The overall kappa for the concordance between ultrasonographic and histopathologic staging was 0.81 (95% CI, 0.72-0.89). No invasive carcinomas remained undetected. The depth of invasion was correctly determined in 87.2% of both pT1-slight and pT1-massive lesions. Considering the complete series of 126 patients, the accuracy of this modality in selecting appropriate management was 95.2% (kappa, 0.84; 95% CI, 0.71-0.96). Adequate surgery was performed in 87.5% of pT1 tumors.	2
23. Bellows CF, Jaffe B, Bacigalupo L, Pucciarelli S, Gagliardi G. Clinical significance of magnetic resonance imaging findings in rectal cancer. *World J Radiol.* 2011;3(4):92-104.	Review/Other-Dx	N/A	To establish a correlation between MRI findings, prognosis, and available treatment options.	(MRI is currently 1 of the most accurate modalities on which to base treatment decisions for patients with rectal cancer. MRI can accurately detect the mesorectal fascia, assess the invasion of the mesorectum or surrounding organs and predict the circumferential resection margin. Although nodal disease remains a difficult radiological diagnosis, new lymphographic agents and diffusion weighted imaging may allow identification of metastatic nodes by criteria other than size.	4

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24. O'Neill BD, Salerno G, Thomas K, Tait DM, Brown G. MR vs CT imaging: low rectal cancer tumour delineation for three-dimensional conformal radiotherapy. *Br J Radiol.* 2009;82(978):509-513.	Observational-Dx	10 patients	To review imaging and planning data for patients with locally advanced low rectal cancer (defined as <6 cm from the anal verge on digital examination).	CT consistently overestimates rectal tumor volume and the width, length and height of low rectal cancers from the anal verge, relative to the same measurements defined on MR. MR-defined tumor volumes are smaller and further from the anal sphincter, and therefore likely to contribute to sparing of normal tissues, especially the anal sphincter. Smaller and more accurate MR-based gross tumor volume definition may facilitate the addition of phase II ‘‘boosts’’, based on the gross tumor volume alone, with acceptable sphincter morbidity.	3
25. Taylor FG, Quirke P, Heald RJ, et al. Preoperative magnetic resonance imaging assessment of circumferential resection margin predicts disease-free survival and local recurrence: 5-year follow-up results of the MERCURY study. *J Clin Oncol.* 2014;32(1):34-43.	Observational-Dx	374 patients	To report the relationship between preoperative MRI assessment of circumferential resection margin staging, American Joint Committee on Cancer (AJCC) TNM stage, and clinical variables with OS, DFS, and time to local recurrence.	Surviving patients were followed for a median of 62 months. The 5-year OS was 62.2% in patients with MRI-clear circumferential resection margin compared with 42.2% in patients with MRI-involved circumferential resection margin with a HR of 1.97 (95% CI, 1.27 to 3.04; P<.01). The 5-year DFS was 67.2% (95% CI, 61.4% to 73%) for MRI-clear circumferential resection margin compared with 47.3% (95% CI, 33.7% to 60.9%) for MRI-involved circumferential resection margin with an HR of 1.65 (95% CI, 1.01 to 2.69; P<.05). Local recurrence HR for MRI-involved circumferential resection margin was 3.50 (95% CI, 1.53 to 8.00; P<.05). MRI-involved circumferential resection margin was the only preoperative staging parameter that remained significant for OS, DFS, and LR on multivariate analysis.	2
26. Rothenberger DA, Ricciardi R. Procedures for Rectal Cancer. In: Souba WW, Fink MP, Jurkovich GJ, et al., eds. *ACS Surgery: Principles & Practice.* Vol 4: WebMD; 2004:A.D.:1-16.	Review/Other-Tx	N/A	Book chapter.	N/A	4

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27. Allaix ME, Arezzo A, Caldart M, Festa F, Morino M. Transanal endoscopic microsurgery for rectal neoplasms: experience of 300 consecutive cases. *Dis Colon Rectum.* 2009;52(11):1831-1836.	Observational-Tx	300 patients	A retrospective review of prospective series of TEM procedures to verify the advantages of local treatment in terms of disease recurrence and complication rates.	From January 1993 to January 2007, 300 patients underwent TEM at our institution. The mean operating time was 66 minutes. The peritoneum was inadvertently opened in 13 cases. The overall morbidity rate was 7.7%. The mean hospital stay was 5 days. Histology demonstrated cancer in 90 patients. At a mean follow-up of 60 months, the recurrence rate was zero in pT1, 24% in pT2, and 50% in pT3. The overall estimated 5-year survival rate was 87%, and the DFS rate was 82%.	2
28. Ramirez JM, Aguilella V, Valencia J, et al. Transanal endoscopic microsurgery for rectal cancer. Long-term oncologic results. *Int J Colorectal Dis.* 2011;26(4):437-443.	Observational-Tx	88 patients	To analyze survival and recurrence of patients with rectal cancer who were operated by TEM with curative intention.	After definitive histological findings, 54 patients were to group A, 28 to group B, and 6 had immediate radical surgery. 1 patient was lost for follow-up. At a mean follow-up of 71 months, 7 (4 from group A and 3 from group B) out of 81 patients recurred. 5-year OS was of 94% and cancer-specific survival of 96%.	1
29. Christoforidis D, Cho HM, Dixon MR, Mellgren AF, Madoff RD, Finne CO. Transanal endoscopic microsurgery versus conventional transanal excision for patients with early rectal cancer. *Ann Surg.* 2009;249(5):776-782.	Observational-Tx	42 TEM and 129 TAE patients	Retrospectively review information on all patients with stage pT1 and PT2 rectal adenocarcinoma to compare TEM with conventional TAE in terms of the quality of resection, local recurrence, and survival.	In the TAE group, 52 (40%) of tumors were <5 cm from the anal verge; in the TEM group, 1 (2%). Surgical margins were less often positive in the TEM group (2%) than in the TAE group (16%). For patients with tumors ≥5 cm from the anal verge, the estimated 5-year DFS rate was similar between the TEM group (84.1%) and the TAE group (76.1%) (P=0.651). But within the TAE group, the estimated 5-year DFS rate was better for patients with tumors ≥5 cm from the anal verge (76.1%) vs <5 cm from the anal verge (60.5%) (P=0.029). In multivariate analysis, the tumor distance from the anal verge, the resection margin status, the T stage, and the use of adjuvant therapy were independent predictors of local recurrence and DFS. Quality of resection is better with TEM than with TAE.	2

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30. Hon SS, Ng SS, Chiu PW, et al. Endoscopic submucosal dissection versus local excision for early rectal neoplasms: a comparative study. *Surg Endosc.* 2011;25(12):3923-3927.	Observational-Tx	14 patients	To compare the short-term clinical outcomes between endoscopic submucosal dissection and LE for early rectal neoplasms.	The mean lesion size was comparable between the endoscopic submucosal dissection and LE groups (2.9 vs 2.6 cm; P=0.423), but the mean distance of the lesions from the anal verge was greater in the endoscopic submucosal dissection group (8.6 vs 5.0 cm; P=0.001). En bloc resection was achieved for 12 patients (85.7%) in the endoscopic submucosal dissection group and for all the patients in the LE group. The endoscopic submucosal dissection group exhibited a trend toward a longer operative time (77.5 vs 50.0 min; P=0.081) but lower morbidity (7.1% vs 33.3%; P=0.076). The time to full ambulation was shorter in the endoscopic submucosal dissection group (0 vs 1 day; P=0.005), but the hospital stay was similar in the 2 groups (2.5 vs 4.0 days; P=0.129).	2
31. Bach SP, Hill J, Monson JR, et al. A predictive model for local recurrence after transanal endoscopic microsurgery for rectal cancer. *Br J Surg.* 2009;96(3):280-290.	Observational-Tx	487 patients	To examine a predictive model for local recurrence after TEM. A national database, collated prospectively from 21 regional centers, detailed TEM treatment in patients with rectal cancer.	Postoperative morbidity and mortality were 14.9% and 1.4% respectively. The Cox regression model predicted local recurrence with a concordance index of 0.76 using age, depth of tumor invasion, tumor diameter, presence of lymphovascular invasion, poor differentiation and conversion to radical surgery after histopathological examination of the TEM specimen.	1
32. Guerrieri M, Baldarelli M, Organetti L, et al. Transanal endoscopic microsurgery for the treatment of selected patients with distal rectal cancer: 15 years experience. *Surg Endosc.* 2008;22(9):2030-2035.	Observational-Tx	196 patients	Authors report their experience with TEM used to manage selected cases of distal rectal cancer without evidence of nodal or distant metastasis (N0M0).	Rectal cancer-specific survival rate at the end of the follow-up period was 100% for pT1, 90% for pT2, and 77% for pT3 patients. Patients with T1 cancer and favorable histologic features may undergo LE alone, whereas those with T2 and T3 rectal cancer require preoperative radiochemotherapy.	2

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33. Lezoche G, Baldarelli M, Guerrieri M, et al. A prospective randomized study with a 5-year minimum follow-up evaluation of transanal endoscopic microsurgery versus laparoscopic total mesorectal excision after neoadjuvant therapy. *Surg Endosc.* 2008;22(2):352-358.	Observational-Tx	70 patients	Prospective randomized study to compare the oncologic results for LE via TEM and those for laparoscopic resection via TME in the treatment of T2N0, G1-2 rectal cancer after neoadjuvant therapy with both treatments, using a 5-year minimum follow-up period.	Two local recurrences (5.7%) were observed after TEM and 1 (2.8%) after laparoscopic resection. Distant metastases (2.8%) occurred in 1 case each after TEM and laparoscopic resection. The probability of survival for rectal cancer was 94% for TEM and 94% for laparoscopic resection. Study shows similar results between the 2 treatments in terms of local recurrences, distant metastases, and probability of survival for rectal cancer.	1
34. Marks JH, Valsdottir EB, DeNittis A, et al. Transanal endoscopic microsurgery for the treatment of rectal cancer: comparison of wound complication rates with and without neoadjuvant radiation therapy. *Surg Endosc.* 2009;23(5):1081-1087.	Observational-Tx	62 patients	Compare morbidity rates and wound complication rates for patients undergoing TEM and LE with and without neoadjuvant radiation to determine whether this could be accomplished safely. Data for all patients undergoing TEM are prospectively entered into a database.	Overall morbidity rate was 33% for the neoadjuvant therapy with radiation group and 5.3% for the non-neoadjuvant therapy with radiation group. The wound complication rates were 25.6% for the neoadjuvant therapy with radiation group (11 patients) and 0% for the non-neoadjuvant therapy with radiation group (P=0.015). 9 patients in the neoadjuvant therapy with radiation group (82%) had minor wound separations, and 2 patients (18%) had major wound separation. 10 patients with wound separations were treated as outpatients and administered long-term oral antibiotics. 1 patient required additional surgery (diverting stoma).	1
35. Moore JS, Cataldo PA, Osler T, Hyman NH. Transanal endoscopic microsurgery is more effective than traditional transanal excision for resection of rectal masses. *Dis Colon Rectum.* 2008;51(7):1026-1030; discussion 1030-1021.	Observational-Tx	171 patients	Retrospective study to compare the effectiveness of TEM with traditional TAE.	TEM was more likely to yield clear margins (90% vs 71%, P=0.001) and a nonfragmented specimen (94% vs 65%, P<0.001) compared with TAE. Recurrence was less frequent after TEM than after traditional TAE (5% vs 27%, P=0.004). TEM is recommended for LE of rectal neoplasms.	2
36. Palma P, Horisberger K, Joos A, Rothenhoefer S, Willeke F, Post S. Local excision of early rectal cancer: is transanal endoscopic microsurgery an alternative to radical surgery? *Rev Esp Enferm Dig.* 2009;101(3):172-178.	Observational-Tx	51 patients	Retrospective analysis of prospectively collected data was performed to examine the results of TEM compared with radical surgery for T1 rectal cancer.	Operative time, blood loss, and duration of hospitalization were significantly lower in the TEM group compared with the radical surgery group. Local recurrence was 5.88% (n = 2) in the TEM group compared with none after radical surgery (P=0.547). OS and DFS showed no significant statistical differences between both groups (P=0.59; P=1.000, respectively).	2

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
37. Callender GG, Das P, Rodriguez-Bigas MA, et al. Local excision after preoperative chemoradiation results in an equivalent outcome to total mesorectal excision in selected patients with T3 rectal cancer. *Ann Surg Oncol.* 2010;17(2):441-447.	Observational-Tx	47 patients underwent LE; 473 patients underwent TME	To compare the outcomes of LE vs TME in patients with T3 rectal cancer who underwent preoperative chemoradiation with a larger cohort of patients and to evaluate the outcome of the original group of 26 patients with longer follow-up.	Median follow-up was 63 months for the LE group and 59 months for the TME group. 23 LE patients (49%) had a complete response to chemoradiation, 17 (36%) had microscopic residual disease, and 7 (15%) had gross residual disease, compared with 108 (23%), 89 (19%), and 276 (58%) TME patients, respectively. There was no significant difference between the 10-year actuarial local recurrence rate for the LE group vs the TME group (10.6% and 7.6%, respectively; P=.52), and no significant difference in DFS, disease-specific survival, or OS rates between groups.	2
38. Lezoche G, Guerrieri M, Baldarelli M, et al. Transanal endoscopic microsurgery for 135 patients with small nonadvanced low rectal cancer (iT1-iT2, iN0): short- and long-term results. *Surg Endosc.* 2011;25(4):1222-1229.	Observational-Tx	135 patients	To analyze the short- and long-term results for a series of 135 patients with small nonadvanced low rectal cancer who underwent LE by TEM.	Minor complications were observed in 12 patients (8.8%) and major complications in 2 patients (1.5%). During a median follow-up period of 97 months (range, 55-139 months), local recurrences occurred for 4 patients and distant metastases for 2 patients. The patients who experienced a recurrence had been preoperatively staged as iT2 and were low or nonresponders to neoadjuvant treatment (ypT2). At the end of the follow-up period, the DFS rates were 100% for the iT1 patients and 93% for the iT2 patients.	1
39. Willett CG, Compton CC, Shellito PC, Efird JT. Selection factors for local excision or abdominoperineal resection of early stage rectal cancer. *Cancer.* 1994;73(11):2716-2720.	Observational-Tx	125 patients	Retrospective study to determine outcomes for patients undergoing LE or APR.	For patients with favorable histologic features, both LE and APR 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.	2
40. 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. *J Clin Oncol.* 1989;7(8):1003-1008.	Observational-Tx	66 patients	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.	2

Local Excision in Rectal Cancer
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
41. Bokkerink GM, de Graaf EJ, Punt CJ, et al. The CARTS study: Chemoradiation therapy for rectal cancer in the distal rectum followed by organ-sparing transanal endoscopic microsurgery. *BMC Surg.* 2011;11:34.	Review/Other-Tx	55 patients	To investigate the role of rectum saving surgery for distal rectal cancer.	No results stated in abstract.	4
42. 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. *J Gastrointest Surg.* 2001;5(3):282-286.	Observational-Tx	49 patients	A comparative study to determine whether endoscopic transanal resection 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). Endoscopic transanal resection provides equivalent palliation to LAR.	2
43. Borschitz T, Gockel I, Kiesslich R, Junginger T. Oncological outcome after local excision of rectal carcinomas. *Ann Surg Oncol.* 2008;15(11):3101-3108.	Review/Other-Tx	Group A: 93 patients; Group B: 39 patients; Group C: 43 patients	To evaluate if, after LE, immediate reoperation is required or awaiting salvage surgery is sufficient. Three groups were created.	Groups A (n = 93) and B (n = 39) showed high tumor-free survival and tumor-related survival rates: group A, 92% and 98%; group B, 86% and 89%. In group C (n = 43), the tumor-free survival and tumor-related survival were significantly lower with 54% and 72%. Group A showed low recurrence rates and a wide range of International Union Against Cancer (UICC) stages. In group B, similarly low recurrence rates were found, but, in contrast, all recurrences were UICC IV. Group C had significantly higher recurrences rates and, in addition, two-thirds of these patients showed advanced UICC stages (III-IV).	4
44. Borschitz T, Heintz A, Junginger T. Transanal endoscopic microsurgical excision of pT2 rectal cancer: results and possible indications. *Dis Colon Rectum.* 2007;50(3):292-301.	Observational-Tx	44 patients	To determine the value of LE for T2 rectal carcinomas, prognostic factors, and the need for reoperation.	Local recurrence rates after local R0 resection alone of low-risk T2 carcinomas were 29%, whereas patients with unfavorable criteria developed recurrences in 50%. After immediate reoperation, the local recurrence risk in patients without lymph node filiae was reduced to 7%.	2
45. Bretagnol F, Merrie A, George B, Warren BF, Mortensen NJ. Local excision of rectal tumours by transanal endoscopic microsurgery. *Br J Surg.* 2007;94(5):627-633.	Observational-Tx	200 patients	To determine the morbidity and long-term results for rectal tumors excised by TEM.	The OS and DFS 5-year rates for patients with carcinomas were 76% and 65%, respectively. TEM is an appropriate surgical treatment option for benign rectal tumors.	2

Local Excision in Rectal Cancer
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
46. Folkesson J, Johansson R, Pahlman L, Gunnarsson U. Population-based study of local surgery for rectal cancer. *Br J Surg.* 2007;94(11):1421-1426.	Observational-Tx	10,181 patients; 643 had a LE	To determine long-term survival and recurrence rates after LE of rectal cancer from a prospectively registered population-based database.	5-year cancer-specific survival rate for 256 patients with stage I disease who had LE was 95.3%. The 5-year local recurrence rate was 7.2%. After adjustment for age, sex, tumor stage and preoperative RT, the relative risk of death from cancer was the same as that after major resection.	2
47. 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. *Ann Surg.* 2000;231(3):345-351.	Observational-Tx	82 patients	A review evaluating the results of LE alone for the treatment of T1 and T2 rectal cancer, applying strict selection criteria.	10/55 patients with T1 tumors (18%) and 10/27 patients with T2 tumors (37%) had recurrence at 54 months of follow-up. Average time to recurrence was 18 months in both groups. 17/20 patients with local recurrence underwent salvage surgery. The survival rate was 98% for patients with T1 tumors and 89% for patients with T2 tumors. Preoperative staging by ERUS did not influence local recurrence or tumor-specific survival.	2
48. Lezoche E, Baldarelli M, De Sanctis A, Lezoche G, Guerrieri M. Early rectal cancer: definition and management. *Dig Dis.* 2007;25(1):76-79.	Observational-Tx	135 patients	To analyze the results of patients with early stage low rectal cancer treated with LE by TEM.	Minor complications observed in 12 patients (8.8%) while major complications seen in 2 patients (1.5%). Local recurrences occurred in 4 patients and distal metastasis in 2 patients (all patients were staged preoperatively T2). DFS rates in T1 and T2 patients were 100% and 93%, respectively at the end of follow-up.	2
49. Min BS, Kim NK, Ko YT, et al. Long-term oncologic results of patients with distal rectal cancer treated by local excision with or without adjuvant treatment. *Int J Colorectal Dis.* 2007;22(11):1325-1330.	Observational-Tx	76 patients	Review long-term oncologic results of LE and examine the validity and feasibility of LE as a treatment option for distal rectal cancer.	5-year local RFS rate was 89.4% in the pT1 group and 75.0% in the pT2 group (P=0.012). Among the patients with pT1 cancer, those who received adjuvant RT showed a 5-year local RFS of 100%, compared to those who did not, 76.0% (P=0.038).	2
50. Nash GM, Weiser MR, Guillem JG, et al. Long-term survival after transanal excision of T1 rectal cancer. *Dis Colon Rectum.* 2009;52(4):577-582.	Observational-Tx	145 radical resections and 137 TAE	To compare oncologic outcomes of TAE with those of radical resection. Patients were identified from a prospective database.	Local recurrence was noted in a higher proportion of TAE patients (13.2% vs 2.7%, P=0.001). After TAE the HR for local recurrence was 11.3%, and disease-specific survival was inferior (8%7 vs 96% at 5 years, P=0.03, HR 2.8 [range, 1.04-7.3]). TAE has inferior oncologic results, including greater risk of cancer-related death.	1

Local Excision in Rectal Cancer
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
51. You YN, Baxter NN, Stewart A, Nelson H. Is the increasing rate of local excision for stage I rectal cancer in the United States justified?: a nationwide cohort study from the National Cancer Database. *Ann Surg.* 2007;245(5):726-733.	Observational-Tx	35,179 patients with stage I rectal cancer (1989-2003); Special study 2,124 patients (1994-1996)	To determine rates of LE over time, and test the hypothesis that LE carries increased oncologic risks but reduced perioperative morbidity when compared with standard resection.	From 1989 to 2003, the use of LE has increased (T1, 26.6%–43.7%; T2, 5.8%–16.8%; P<0.001 both). Special study showed lower 30-day morbidity after LE vs standard resection (5.6% vs 14.6%; P<0.001). 5-year local recurrence after LE vs standard resection was 12.5% vs 6.9% for T1 tumors, and 22.1% vs 15.1% for T2 tumors. The 5-year OS was influenced by age and comorbidities but not the type of surgery. Study provides the best evidence for both the increasing use and the associated risks of LE vs standard resection.	2
52. Peng J, Chen W, Venook AP, et al. Long-term outcome of early-stage rectal cancer undergoing standard resection and local excision. *Clin Colorectal Cancer.* 2011;10(1):37-41.	Observational-Tx	350 patients	To explore the long-term outcome and prognostic factors for early stage rectal cancer patients undergoing standard resection or LE.	The 5-year local recurrence rate was 14.1% in LE group vs 3.3% in standard resection group (P= .0004), and the 10-year OS rate was not significantly different between the 2 groups. Multivariate analysis suggested that LE was an independent risk factor for 5-year local recurrence rate and 10-year OS rate. Tumor grade was found related to 5-year local recurrence, and T stage was found related to 10-year OS. Tumor size of 2.5 cm is found as a possible cut-off for predicting 5-year local recurrence rate in LE group, with a sensitivity of 77.8% and a specificity of 75.9%. In patients with LE, the 5-year LR rate for tumors ≥2.5 cm was 40%, compared with 4.3% for tumors <2.5 cm (P=.001).	2
53. Perez RO, Habr-Gama A, Proscurshim I, et al. Local excision for ypT2 rectal cancer--much ado about something. *J Gastrointest Surg.* 2007;11(11):1431-1438; discussion 1438-1440.	Observational-Tx	289 patients	To examine role of LE for pT2 distal rectal cancer. Patients with final pathological stage ypT2 were analyzed to determine the risk of unfavorable pathological features that could represent unacceptable risk for local failure after LE.	LNM were present in 19% of patients with ypT2 and were significantly associated with poor OS and DFS rates. The risk LNM could not be predicted by radiological staging or tumor size. Radical surgery should be considered the standard treatment option for ypT2 rectal cancer after chemoradiation therapy.	2

Local Excision in Rectal Cancer
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
54. Rasheed S, Bowley DM, Aziz O, et al. Can depth of tumour invasion predict lymph node positivity in patients undergoing resection for early rectal cancer? A comparative study between T1 and T2 cancers. *Colorectal Dis.* 2008;10(3):231-238.	Observational-Tx	303 patients	Retrospective study to examine the risk of LNM according to the depth of tumor invasion in patients undergoing resection for rectal cancer.	The incidence of LNM in the T1 group was 12.7% (7/55), compared to 19% (47/247) in the T2 group. The node positive and negative groups were similar with regard to patient demographics, although the former contained a significantly higher number of poorly differentiated (P=0.001) and extramural vascular invasion tumors (P=0.002). No significant difference in the number of patients with sm1-3, or T2 tumor depths within the lymph node positive and negative groups. On multivariate analysis the presence of extramural vascular invasion (odds ratio = 10.0) and tumor grade (odds ratio for poorly vs well-differentiated = 11.7) were independent predictors of LNM.	2
55. Morino M, Allaix ME, Caldart M, Scozzari G, Arezzo A. Risk factors for recurrence after transanal endoscopic microsurgery for rectal malignant neoplasm. *Surg Endosc.* 2011;25(11):3683-3690.	Observational-Tx	355 patients	A prospective database was analyzed with the intent to identify risk factors for recurrence after TEM.	Among 355 patients subjected to TEM, 107 had an adenocarcinoma: 48 pT1, 43 pT2, and 16 pT3. Comparing pre- and postoperative data, histological discrepancy was 20% and staging discrepancy was 34%. Mortality was nil, morbidity was 9%. Mean follow-up was 54.2 months (range = 12-164), follow-up rate was 100%. The 5-year DFS rate was 85.9%, 78.4%, and 49.4% for pT1, pT2, and pT3, respectively (P=0.006). Recurrence rate was 0% (0/26) in pT1sm1 cancers and 22.7% (5/22) in sm2-3 (P<0.05). A submucosal infiltration represented a significant risk factor for recurrences: 0% sm1, 16.7% sm2, and 30% sm3. Recurrence in pT2 was 0% in patients who had neoadjuvant therapy and 26% in the others. At univariate analysis, diameter, sm stage, pT stage, tumor grading, margin infiltration, and lymphovascular invasion demonstrated statistical significance. Multivariate analysis indicated sm stage, pT stage, and tumor grading as independent predictors of recurrence.	2

Local Excision in Rectal Cancer
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
56. Peng J, Chen W, Sheng W, et al. Oncological outcome of T1 rectal cancer undergoing standard resection and local excision. *Colorectal Dis.* 2011;13(2):e14-19.	Observational-Tx	124 patients	To study the outcome and prognostic factors for T1 rectal cancer patients undergoing standard resection or TAE.	The 5-year local recurrence rate was 11.0% in the TAE group vs 1.6% in the standard resection group (P=0.031) but the 5-year DFS and OS rates were not significantly different between the 2 groups. Multivariate analysis suggested that a high tumor grade and perineural or lymphovascular invasion were independent risk factors for local recurrence and RFS. For high-risk patients (with at least 1 of the above risk factors), the 5-year local recurrence and 10-year RFS rates were 21.2% and 74.5%, vs 1.2% and 92.0% in low-risk patients (P=0.00003 and P=0.003). In patients undergoing TAE, none in the low-risk group had local recurrence during follow up, while 40% (6/15) of patients in the high-risk group developed local recurrence within 5 years after surgery. The 5-year local recurrence rate was 45.0%.	2
57. Kobayashi H, Mochizuki H, Kato T, et al. Is total mesorectal excision always necessary for T1-T2 lower rectal cancer? *Ann Surg Oncol.* 2010;17(4):973-980.	Observational-Tx	567 patients	To clarify the determinants of LE for patients with T1-T2 lower rectal cancer.	The independent risk factors for LNM were female gender, depth of tumor invasion, histology other than well-differentiated adenocarcinoma, and lymphatic invasion. According to the first 3 parameters that can be obtained preoperatively, only 0.99% of the patients without risk factors had LNM. On the other hand, even if the lower rectal cancer was at stage T1, women with histological types other than well-differentiated adenocarcinoma had an approximately 30% probability of having LNM. Lymphatic invasion was most useful to predict nodal involvement among patients with T2 lower rectal cancer. The rates of LNM in T2 patients with and without lymphatic invasion were 32.9% and 9.1%, respectively.	2
58. Engelen SM, Beets-Tan RG, Lahaye MJ, et al. MRI after chemoradiotherapy of rectal cancer: a useful tool to select patients for local excision. *Dis Colon Rectum.* 2010;53(7):979-986.	Observational-Dx	79 patients	To determine whether postchemoradiation MRI in rectal cancer can accurately identify ypT0 to 2/ypN0, because both features are essential for identification of good responders.	For prediction of whether a tumor penetrated the bowel wall, there was an negative predictive value of 0.90 and 0.76 for the expert and general radiologist, respectively. The negative predictive value for prediction of nodal status was 0.95 and 0.85 for expert and general radiologist, respectively.	2

Local Excision in Rectal Cancer
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
59. Kang JH, Kim YC, Kim H, et al. Tumor volume changes assessed by three-dimensional magnetic resonance volumetry in rectal cancer patients after preoperative chemoradiation: the impact of the volume reduction ratio on the prediction of pathologic complete response. *Int J Radiat Oncol Biol Phys.* 2010;76(4):1018-1025.	Observational-Dx	84 patients	To determine the correlation between tumor volume changes assessed by 3D MR volumetry and the histopathologic tumor response in rectal cancer patients undergoing preoperative chemoradiation therapy.	There were no significant differences in the post-treatment tumor volume and the volume reduction ratio shown by 3D MR volumetry with respect to T and N downstaging and the tumor regression grade. In a multivariate analysis, the tumor volume reduction ratio was not significantly associated with T and N downstaging. The volume reduction ratio (>75%, P=0.01) and the pretreatment carcinoembryonic antigen level (≤3 ng/ml, P=0.01), but not the post-treatment volume shown by 3D MR (≤5 ml), were, however, significantly associated with an increased pathologic complete response rate.	2
60. Park IJ, You YN, Agarwal A, et al. Neoadjuvant treatment response as an early response indicator for patients with rectal cancer. *J Clin Oncol.* 2012;30(15):1770-1776.	Observational-Tx	725 patients	To assess and compare oncologic outcomes associated with the degree of pathologic response after chemoradiotherapy.	In all, 725 patients were classified by tumor response: complete (131; 18.1%), intermediate (210; 29.0%), and poor (384; 53.0%). Age, sex, cN stage, and tumor location were not related to tumor response. Tumor response (complete vs intermediate vs poor) was associated with 5-year RFS (90.5% vs 78.7% vs 58.5%; P<.001), 5-year distant metastasis rates (7.0% vs 10.1% vs 26.5%; P<.001), and 5-year LR only rates (0% vs 1.4% vs 4.4%; P=.002).	2
61. Borschitz T, Wachtlin D, Mohler M, Schmidberger H, Junginger T. Neoadjuvant chemoradiation and local excision for T2-3 rectal cancer. *Ann Surg Oncol.* 2008;15(3):712-720.	Review/Other-Tx	237 patients, 7 studies	To examine neoadjuvant chemoradiation and LE for T2-3 rectal cancer. 7 studies about LE after neoadjuvant chemoradiotherapy of cT2-3 tumors were analyzed after a PubMed search.	Patients with ypT1 tumor consistently showed low local recurrence rates of 2% (range, 0%–6%), while ypT2 findings had local recurrence rates of 6%–20%. Strongest prognostic factors were a complete response (ypT0) or responses on submucosa level (ypT1). Results will have to be confirmed in a prospective trial with an appropriate sample size to ensure high statistical power.	4

Local Excision in Rectal Cancer
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
62. Kim TH, Chie EK, Kim DY, et al. Comparison of the belly board device method and the distended bladder method for reducing irradiated small bowel volumes in preoperative radiotherapy of rectal cancer patients. *Int J Radiat Oncol Biol Phys.* 2005;62(3):769-775.	Observational-Tx	20 patients	To determine the most effective method to reduce the irradiated small bowel volume when using a belly board device, a distended bladder, or both in patients with rectal cancer undergoing preoperative pelvic RT.	All patients underwent 4 sets of CT scan under the conditions of 4 different methods as follows: Group I = empty bladder without the use of belly board; Group II = empty bladder with the use of belly board; Group III = distended bladder without the use of belly board; Group IV = distended bladder with the use of belly board. We found that the volume of irradiated small bowel decreased in the order of Group I, Group II, Group III, and Group IV at all dose levels ($P<0.05$). Compared with Group I, the mean volume reduction rate (reduced volume) of irradiated small bowel in Group II varied between 14.5% and 65.4% (15.5-80.4 cm(3)), in Group III it varied between 48.1% and 82.0% (21.6-163.1 cm(3)), and in Group IV between 51.4% and 96.4% (28.6-167.1 cm(3)).	2
63. Drzymala M, Hawkins MA, Henrys AJ, Bedford J, Norman A, Tait DM. The effect of treatment position, prone or supine, on dose-volume histograms for pelvic radiotherapy in patients with rectal cancer. *Br J Radiol.* 2009;82(976):321-327.	Observational-Tx	19 patients	To evaluate the volume of bowel and dose received in the prone and supine positions in patients undergoing preoperative rectal cancer chemoradiation.	Using CT planning, 19 consecutive patients with rectal cancer with a full bladder underwent CT scanning first in the prone position and then immediately afterwards in the supine position. The planning target volume was outlined for the prone position and transcribed to the supine scan using pre-set criteria. The bladder and small bowel were outlined in both positions. RT was planned using 3D conformal planning, and treatment was delivered using 3 fields with multileaf collimators in 2 phases: phase I, pelvis 45 Gy/25 fractions; and phase II, tumor 9 Gy/5 fractions. For both positions, the volume of bowel receiving doses in 5 Gy increments from 5-45 Gy was calculated using dose-volume histograms. At 5 Gy and 10 Gy dose levels, a significantly higher volume of bowel was irradiated in the supine position ($P<0.001$). At 15 Gy, it was marginally significant ($P=0.018$). From 20-45 Gy, there was no significant difference in the volume of bowel irradiated with each 5 Gy increment.	2

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EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
64. Siddiqui F, Shi C, Papanikolaou N, Fuss M. Image-guidance protocol comparison: supine and prone set-up accuracy for pelvic radiation therapy. *Acta Oncol.* 2008;47(7):1344-1350.	Observational-Dx	30 patients	To investigate the impact of prone vs supine patient set-up and use of various image-guidance protocols on residual set-up error for RT of pelvic malignancies and to aim to identify an optimal frequency and protocol for image-guidance.	Of 5 Image-guidance RT protocols analyzed, the protocol with the highest imaging frequency, alternate day imaging with a running mean (50% imaging frequency), provided the best set-up error reduction. This protocol would have reduced the average length of 3D corrective vector shifts derived from daily image-guidance from 15.2 and 13.5 mm for prone and supine set-up, to 5 and 5.4 mm, respectively. A No Action Level protocol, averaging shifts of the first 3 fractions (No Action Level3), would have reduced the respective set-up variability to 6.3 (prone), and 7.5 mm (supine). An extended No Action Level protocol, averaging shifts of the first 3 fractions plus weekly imaging, would have reduced the daily positioning variability to 6 mm for both prone and supine set-ups. Daily image-guidance yielded set-up corrections >10 mm in 64.3% for prone and 70.3% for supine position. Use of the No Action Level3 protocol would have reduced the respective frequency to 14.4%, and 21.2% for prone, and supine positioning. In comparison, the alternate day running mean protocol would have reduced the frequency of shifts >10 mm to 5.5% (prone), and 8.3% (supine), respectively.	3
65. Radboud University. Transanal Endoscopic Microsurgery (TEM) After Radiochemotherapy for Rectal Cancer (CARTS). In: ClinicalTrials.gov. Bethesda (MD): National Library of Medicine (US). 2013 March 29. Available from: http://www.clinicaltrials.gov/ct2/show/NCT01273051?term=NCT01273051&rank=1. NLM Identifier: NCT01273051.	Review/Other-Tx	Ongoing	To evaluate whether neo-adjuvant chemo-radiotherapy in small non-advanced rectal cancers can be used to obtain a complete or near complete remission.	This trial is still recruiting study subjects and results are not available yet.	4

Local Excision in Rectal Cancer
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
66. Rullier E, Vendrely V. Can mesorectal lymph node excision be avoided in rectal cancer surgery? *Colorectal Dis.* 2011;13 Suppl 7:37-42.	Review/Other-Tx	N/A	To review rectal excision as the standard in rectal cancer treatment.	The morbidity of rectal excision, together with the low rate of positive lymph nodes in patients with a good response after radiochemotherapy, raises the challenging concept of organ preservation. Patients with a complete response can benefit from a nonoperative strategy based on a strict follow-up. Those with a complete or subcomplete response can be treated by LE. Limitations in accurately assessing a complete response by conventional and modern imaging modalities suggest that LE is more appropriate for the majority of patients when organ preservation is being considered. The encouraging results of retrospective series of LE in downstaged clinical T2/T3 low rectal cancer after radiochemotherapy, however, need to be confirmed by the ongoing multicenter phase II United States and phase III French trials before routinely proposing organ preservation in patients with a good response.	4
67. University Hospital, Bordeaux. Local Excision in Downstaged Rectal Cancer (GRECCAR 2). In: ClinicalTrials.gov. Bethesda (MD): National Library of Medicine (US). 2013 March 29. Available from: http://www.clinicaltrials.gov/ct2/show/NCT00427375?term=NCT00427375&rank=1. NLM Identifier: NCT00427375.	Review/Other-Tx	Ongoing	A prospective randomized multicenter study to compare local vs rectal excision in good responders after radiochemotherapy for low rectal cancer.	This trial is still recruiting study subjects and results are not available yet.	4
68. Polish Colorectal Cancer Study Group. Preoperative Radiotherapy and Local Excision in Rectal Cancer. In: ClinicalTrials.gov. Bethesda (MD): National Library of Medicine (US). 2013 March 29. Available from: http://www.clinicaltrials.gov/ct2/show/NCT00738790?term=NCT00738790&rank=1. NLM Identifier: NCT00738790.	Review/Other-Tx	Ongoing	To compare the short-course radiotherapy schedule with the chemoradiation in order to determine an optimal scheme. The study hypothesis is that the chemoradiation assures 25% more patients who do not require conversion to an open surgery. In addition, the aim is to assess safety and efficiency of preoperative radiotherapy and LE for radiosensitive rectal cancer.	This trial is still recruiting study subjects and results are not available yet.	4

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EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
69. Corporacion Parc Tauli. Preoperative Chemoradiotherapy and Transanal Endoscopic Microsurgery Versus Total Mesorectal Excision in T2-T3s N0, M0 Rectal Cancer. In: ClinicalTrials.gov. Bethesda (MD): National Library of Medicine (US). 2013 March 29. Available from: http://www.clinicaltrials.gov/ct2/show/NCT01308190?term=NCT01308190&rank=1. NLM Identifier: NCT01308190.	Review/Other-Tx	Ongoing	A multicenter clinical trial to compare the results of local recurrence at 2 years in patients treated with preoperative chemoradiotherapy and TEM and in patients treated with conventional radical surgery (TME). In addition, the secondary objective is to analyze the 3-year survival results in patients treated with chemotherapy/RT.	This trial is still recruiting study subjects and results are not available yet.	4

Evidence Table Key

Study Quality Category Definitions

- *Category 1* The study is well-designed and accounts for common biases.
- *Category 2* The study is moderately well-designed and accounts for most common biases.
- *Category 3* There are important study design limitations.
- *Category 4* The study is not useful as primary evidence. The article may not be a clinical study or the study design is invalid, or conclusions are based on expert consensus. For example:
  a) the study does not meet the criteria for or is not a hypothesis-based clinical study (e.g., a book chapter or case report or case series description);
  b) the study may synthesize and draw conclusions about several studies such as a literature review article or book chapter but is not primary evidence;
  c) the study is an expert opinion or consensus document.

Dx = Diagnostic

Tx = Treatment

Abbreviations Key

APR = Abdominoperineal resection

CI = Confidence interval

CT = Computed tomography

DFS = Disease-free survival

ERUS = Endorectal ultrasound

HR = Hazard ratio

LAR = Low anterior resection

LE = Local excision

LNM = Lymph node metastasis

MRI = Magnetic resonance imaging

OS = Overall survival

RFS = Recurrence-free survival

RT = Radiation therapy

TAE = Transanal excision

TEM = Transanal endoscopic microsurgery

TME = Total mesorectal excision