Conservative Management of Rectal Cancer With Local Excision and Adjuvant Therapy

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The standard surgical treatment for cancer of the rectum is primarily abdominoperineal resection or low anterior resection. If the tumor is transmural or lymph node positive, adjuvant therapy with fluorouracil (5-FU)-based chemotherapy and radiation is indicated.[1,2] Standard management of lesions closer to the dentate line often mandates use of abdominoperineal resection, due to the need for an adequate distal margin. Depending on the exact location, abdominosacral resection, stapled low anterior resection, or proctectomy with coloanal anastomosis may be feasible in selected patients.[3,4] These radical approaches can be associated with complications and functional consequences.

Postoperative Complications and Recurrence Patterns

In some series, postoperative complication rates range from 30% to 46%, and postoperative mortality from 2% to 6%.[5,6] Neurogenic bladder with inability to void is common after extensive pelvic dissection.[6] Sexual dysfunction is also common, particularly in men. Retrograde ejaculation, related to sympathetic nerve dysfunction, is seen in 15% to 100% of men. Erectile impotence resulting from damage to the pelvic parasympathetic plexus is seen in 3% to 39% of men.[7-9] Even after a low anterior resection, up to 50% of patients report decreased rectal sphincter function, and up to 30% report urinary retention or sexual dysfunction.[9,10] Finally, the psychological and social consequences of colostomy in patients who require it cannot be underestimated.

With standard surgery for early-stage rectal cancer (T1/2, N0), local recurrence rates range from 0% to 10%, and 5-year survival rates from 78% to 100%.[11-14] Sticca et al evaluated 71 patients (T1: 20, T2: 51) with stage I rectal adenocarcinoma who were treated with an abdominoperineal resection. At a median follow-up of 81 months, the local control rate was 100% for T1 tumors, and 90% for T2 tumors. Of the 7 recurrences, 2 were local, 4 were distant, and 1 was local and distant. For patients with T2 disease, the 5-year disease-free survival rate was 88%.[13]

Willett et al reported the recurrence patterns of stage I rectal cancer treated by abdominoperineal resection. The local control and disease-free survival rates at 6 years were both 100% for 12 patients with T1 disease. For the 52 patients with T2 disease, the local control and actuarial disease-free survival rates were 84% and 80%, respectively.[14] These numbers represent the standard to which any proposed conservative treatment must be compared. However, functional outcome with conservative treatment approaches must be evaluated, because a poorly functioning sphincter may have a more detrimental effect on quality of life than a well-functioning colostomy.

Surgical Techniques

Local options for surgical management include transanal local excision, transsacral excision (Kraske approach), transspincteric resection (Bevan or York-Mason approach), transanal endoscopic microsurgery, and electrocoagulation. Transanal local excision should be performed as a full-thickness excision where the perirectal fat serves as the deep plane of dissection.
The Kraske excision is used for lesions too large or proximal for transanal local excision, and allows for removal of some perirectal lymph nodes. A perineal incision is made just above the anus, the coccyx is removed, and the fascia is divided. The rectum is mobilized through this incision, and a wide local excision or sleeve resection can be performed.

The transsphincteric procedure is identical to the Kraske procedure, except that the anal sphincter is divided posteriorly in the midline. The anus is reconstructed at completion of the operation, with little risk of functional impairment.[15]

In transanal endoscopic microsurgery, an operating rectoscope is used to perform a full-thickness disc excision of the rectum, with primary closure. Fulguration is completed in multiple steps with the patient under general or regional anesthesia, and involves charring of the tumor, then scraping with a curette. There is a 10% to 20% risk of delayed hemorrhage due to sloughing of the scar at 7 to 10 days.[16-21]

Full-thickness local excision is preferred over destructive approaches because the complete specimen is available for assessment of depth of invasion, margins, and pathologic features known to be prognostic for lymph node involvement.

**Selection Criteria**

Local treatment has historically been applied to patients with medical contraindications to radical surgery—for example, severe cardiopulmonary disease or patient blindness (which makes colostomy care difficult). More recently, the use of local treatment has been explored as an alternative to abdominoperineal resection. Studies suggest that small (< 3 cm), exophytic, well-differentiated tumors limited to the submucosa warrant this approach.

Local treatment approaches have also been used for selected tumors invading the muscularis propria. Tumors that would be suitable for a local approach should be chosen carefully, based on clinical, pathologic, and radiologic factors.

**Clinical Criteria**

An evaluation of clinical criteria in the series examining local excision is difficult due to variations in patient selection, the definition of clinical and pathologic features, and length of follow-up. Moreover, the series examining local excision alone were limited by the use of univariate analysis, rather than multivariate analysis. It is, therefore, difficult to make recommendations based solely on clinical criteria. However, tumors that are small, mobile, and involve less than 40% of the circumference of the rectal wall could most likely be excised with negative margins by a full-thickness, nonfragmented excision.

**Pathologic Criteria**

The impact of various pathologic factors on local recurrence and the overall outcome of rectal cancer has been studied extensively. Regional lymph node metastases that are unrecognized at the time of local excision are thought to account for the majority of local failures after conservative treatment. Factors that are known to have an impact on the incidence of lymph node involvement include the presence of high-grade features, lymphatic or blood vessel invasion, colloid histology, or penetration of tumor through the bowel wall.

Tumors without any of these features comprise only 3% to 5% of all rectal cancers. These select cancers have a low enough incidence of local failure (5% to 10%) and positive nodes (< 10%) so as not to require adjuvant therapy.[20] However, once adverse pathologic features manifest or the tumor invades the muscularis propria, the local failure rate approaches 20% and the incidence of positive pelvic or mesorectal lymph nodes is 10% to 15%.[22]

**Tumor Grade/Differentiation:** Minsky et al retrospectively studied various clinical and pathologic features in 168 patients who underwent a potentially curative surgery for rectosigmoid or rectal
cancer at the New England Deaconess Hospital. They found that the incidence of positive lymph nodes increased with the grade of adenocarcinoma. None of the well-differentiated tumors had lymph node involvement, while 30% of moderately differentiated, and 50% of poorly differentiated tumors had lymph node involvement ($P = .07$).[23]

Brodsky et al also found that grade significantly affected the incidence of lymph node metastases in 154 patients with pT1 or pT2 rectal cancer treated by radical resection. The risk of lymph node metastases was 0% for well-differentiated tumors, but rose to 24% for moderately and poorly differentiated tumors ($P = .04$).[24]

**Lymphatic/Blood Vessel Invasion:** It is established that the incidence of lymph node metastasis increases significantly with lymphatic or blood vessel invasion. Investigators from Memorial Sloan-Kettering Cancer Center analyzed 154 patients with pT1 or pT2 tumors and found that 17% of T1/T2 tumors without lymphatic or blood vessel invasion had lymph node metastasis, while 31% of T1/T2 tumors with lymphatic or blood vessel invasion had lymph node metastases ($P = .04$). Furthermore, within the group of patients with T1 tumors, 0 of 15 without vascular invasion had lymph node metastases, while 3 of 9 patients with vascular invasion had lymph node metastases ($P < .05$).[24]

**Margins:** Adam et al evaluated 141 specimens from resections thought by the surgeon to be curative. The closest point of the tumor to the circumferential margins was measured microscopically, and any specimen with tumor $\leq$ 1 mm from the circumferential margin of excision (25% of specimens) was recorded as having positive margins. At a median follow-up of 5 years, the authors found that local recurrence occurred in 78% of patients with involvement of the circumferential margin, compared with 10% of those without such involvement ($P < .001$).[25]

**T Stage:** Increasing T stage also significantly increases the risk of lymph node metastasis. A study from Basingstoke District Hospital evaluated 454 rectal excision specimens. Of 109 patients, 22 (20%) with tumor confined locally to the bowel wall had metastases in local lymph nodes. Among 27 patients (11%) with tumors that did not penetrate the submucosa, 3 (11%) had lymph node metastases ($P = .28$).[26] Minsky et al also found that increasing T stage was associated with increasing risk of lymph node metastases. In their series, lymph node involvement was seen after radical surgery in 0% of T1 tumors, 28% of T2 tumors, 36% of T3 tumors, and 53% of T4 tumors ($P = .04$).[23]

Use of these pathologic criteria in selecting "early" carcinomas of the rectum has been criticized. Nelson et al retrospectively reviewed 76 cases of adenocarcinoma of the lower rectum treated by abdominoperineal resection. They found that 50% of patients with tumors $\leq$ 4.0 cm had lymphatic invasion. Overall, 53% of patients who had well- or moderately differentiated tumors had lymphatic metastases, and 25% of those with only partial invasion of the muscular layer had lymphatic metastases. The authors concluded that the commonly used criteria of size and histologic grade are inadequate and do not allow confident selection of patients with lesions suitable for local treatment.[27]

Recent data from Memorial Sloan-Kettering Cancer Center suggest that the overall risk of lymph node metastasis in patients selected on the basis of small ($\leq$ 4.0 cm) tumor size and early T stage (T1/T2) is 15% (T1:10%, T2:17%). On subset analysis, while T stage, degree of differentiation, and lymphatic vessel invasion influenced the risk of lymph node metastasis, only blood vessel invasion reached statistical significance as a single predictive factor of lymph node metastases (blood vessel invasion-negative = 13%; blood vessel invasion-positive = 33%; $P = .04$). Even in patients in the most favorable group (T1 cancers with no adverse pathologic features), 7% had lymph node metastases.[28]

Other studies have confirmed that T1 and T2 tumors with unfavorable histologic features have decreased rates of survival and local control, whether treated by local excision or abdominoperineal resection. Willett et al found that tumor size greater than 3 cm, high-grade histology, invasion of the muscularis propria, vascular invasion, and positive margins were associated with a local failure rate of at least 20%, as well as an increase in distant metastases.[29,30] In summary, once adverse pathologic factors are present (high grade, lymphatic or blood vessel invasion, colloid histology,
signet ring cell or tumoral invasion of the muscularis propria), local therapy alone is inadequate.

**Radiographic Criteria**

An alternative approach for predicting the incidence of positive pararectal lymph nodes is the use of radiographic criteria. Investigators at the Cleveland Clinic used transrectal ultrasound (TRUS) to guide pararectal lymph node biopsies in 26 rectal cancer patients. They reported a sensitivity of 71% and a specificity of 89% with this approach.[31] Further studies have compared TRUS with magnetic resonance imaging (MRI) and computed tomography (CT), and have found equivalent accuracy between TRUS and MRI with endorectal coil. Both of these studies were superior to CT in staging.

For staging lymph node metastasis, the overall accuracy rate was 63.5% for TRUS, 63% for MRI, and 56.5% for CT.[32] A review of 78 reports, including 4,897 patients, evaluating CT, TRUS, MRI, and MRI with endorectal coil found that MRI with endorectal coil predicted the pathologic stage of rectal cancer most accurately. The sensitivity and specificity of MRI with endorectal coil was found to be 89% and 79% for T stage, and 82% and 83% for N stage. In contrast, the sensitivity and specificity of the next best imaging tool, TRUS, were 93% and 78% for T stage, and 71% and 76% for N stage.[33]

Because local excision does not allow pathologic examination of the lymph nodes at the time of surgery, one cannot compare the results of local excision with radical surgery, although there are data to help predict the incidence of positive pelvic nodes based on the clinicopathologic and radiographic features of the tumor. An accurate comparison of these techniques requires a randomized trial.

**Results With Local Excision Alone**

In most series using local excision without adjuvant therapy, local failure rates are < 10% (range: 0% to 33%) for T1 disease, but increase to 20% (range: 0% to 43%) for T2, and 31% (range: 0% to 75%) for T3.[34-37] Graham et al reviewed the results of 10 published series in which local excision alone was the definitive treatment for patients with invasive rectal carcinoma of the distal one-third of the rectum.[34] In total, of 404 patients evaluated, 94% had T1 or T2 lesions. The local recurrence rate was 19%, and the cancer- specific survival rate was 94%.

By univariate analysis, positive margins, poorly differentiated histology, and increasing T stage were associated with an increase in local recurrence and mortality.[34] More recent series suggest that even favorable T1 and T2 tumors treated with transanal excision (negative excision margins, well- or moderately differentiated tumors, without blood or lymphatic vessel invasion, and without a mucinous component) still have a high local recurrence rate.

Investigators at the University of Minnesota Cancer Center reviewed their experience with 82 patients with T1 or T2 rectal cancer treated by transanal local excision alone over a 10-year period. All tumors had negative excision margins, without lymphatic or blood vessel invasion, and were well or moderately differentiated. In this series, 10 (18%) of 55 T1 tumors and 10 (37%) of 27 T2 tumors had recurred at 54 months of follow-up. Of the 20 patients with local recurrence, 17 were able to undergo salvage surgery. The survival rate was 98% for patients with T1 tumors and 89% for patients with T2 tumors.[35]

**Local Excision vs Radical Surgery**

Mellgren et al evaluated all stage I patients treated with curative intent without adjuvant combined-modality therapy (chemotherapy and radiation) at the University of Minnesota Cancer Center between 1987 and 1996.[36] Of 1,367 rectal cancer patients receiving treatment, 108 patients with T1 or T2 tumors underwent local excision with negative margins. These patients were compared to 153 patients treated with radical surgery. The estimated 5-year local recurrence rate was 28% (18% for T1 and 47% for T2) after local excision, compared with 4% (0% for T1 and 6% for T2) after radical surgery ($P < .001$). Of the 27 patients whose disease recurred after local excision, 24 underwent salvage surgery. The estimated 5-year overall survival rate was 69% after local excision, compared with 82% after radical surgery ($P = .06$).[36]
The long-term outcomes of 52 patients with T1 or T2 rectal cancers undergoing local excision without adjuvant therapy at Massachusetts General Hospital and Emory University Hospital were evaluated recently.[37] The 5-year actuarial local control and recurrence-free survival rates were 72% and 66%, respectively. When this group was divided into low- and high-risk subgroups, based on the presence of a poorly differentiated histology or lymphatic or blood vessel invasion, the 5-year actuarial local control rates were 97% and 37%, respectively ($P = .0001$).

**Local Excision Plus Radiation**

In a comparable group of patients treated with local excision plus adjuvant radiation, the 5-year actuarial local control and recurrence-free survival rates were 90% and 74%, respectively. In patients selected for local excision and postoperative radiation therapy, the 5-year local control rate for patients with high-risk features was 85%. The authors noted that this improvement in outcome was evident despite the presence of a higher-risk patient population in the adjuvant irradiation group. They concluded that adjuvant combined modality therapy is recommended for all patients undergoing local excision for T2 tumors, and for T1 tumors with high-risk pathologic features.[37]

**Standard Surgery vs Local Excision**

Although no randomized trials are available to compare the outcome of standard surgery with local excision, two prospective cooperative group trials evaluating local excision have been reported recently. The Cancer and Leukemia Group B (CALGB) initiated a phase II trial to prospectively evaluate the outcome of patients with distal rectal cancer treated with local excision.[38] Eligible patients had biopsy-proven adenocarcinoma of the rectum or villous adenomas ≤ 10 cm proximal to the dentate line, ≤ 4 cm in diameter, and involving ≤ 40% of the bowel wall. At the time of entry, patients had no clinically or radiographically determined lymph node involvement or distant metastases. A total of 161 patients underwent full-thickness local primary tumor excision. Excluded from analysis were 51 patients with positive or unclear margins.

The study enrolled 59 patients with T1 adenocarcinoma; these patients received no further therapy. Patients with T2 adenocarcinomas received postoperative combined-modality therapy, and will be discussed in the next section. At a median follow-up of 48 months, 2 of 59 patients with T1 tumors developed isolated local recurrences. Both underwent salvage abdominoperineal resection; one remained disease-free at the time of last follow-up. The 6-year overall and failure-free survival rates for these patients were 87% and 83%, respectively.

Russel et al recently published the results of a second prospective cooperative group trial attempting functional preservation of the anorectum for patients with limited distal rectal cancer.[39] In this phase II Radiation Therapy Oncology Group (RTOG) trial 89-02, 65 patients were registered, who had been judged by their attending surgeon to be unsuitable for anal sphincter conservation by low anterior resection. Tumors were ≤ 4 cm and occupied ≤ 40% of the rectal circumference.

Protocol surgery was to include en bloc, transmural excision of an ellipse of rectal wall by transanal, transsacral, or transcoccygeal techniques with conservation of the anal sphincter. Patients were randomized postoperatively to three different treatment approaches, based on tumor size, T stage, grade, and adequacy of surgical margins. These regimens included observation alone, 5-FU with 5,000 to 5,600 cGy of external-beam irradiation, or 5-FU with 5,940 to 6,500 cGy of external-beam irradiation. Minimum follow-up was 5 years, and median follow-up was 6.1 years.

The 14 patients treated with observation alone had T1 tumors with margins at least 3 mm in all dimensions, absence of lymphatic or vascular space invasion, and a normal carcinoembryonic antigen (CEA) level. Local failure alone occurred in one patient, as did distant failure alone. Patterns of local failure for patients with T2 and T3 disease who received treatment with combined modality therapy will be discussed in the next section.

In summary, for T1 tumors without adverse pathologic factors, the local control and survival rates after local excision alone appear comparable to those seen with radical surgery. However, patients with adverse features or with invasion of the muscularis propria achieve less favorable results, and
should receive adjuvant therapy.

**Local Excision Plus Radiotherapy, With or Without Chemotherapy**

For T1 tumors with adverse pathologic factors, extensive T2 lesions, or transmural (T3) disease, local excision alone is not adequate treatment. If, after standard surgery, pathology confirms that tumor penetrates through the bowel wall or involves the mesorectal or pelvic lymph nodes, adjuvant therapy consisting of 6 cycles of 5-FU-based chemotherapy with concurrent pelvic radiation therapy is recommended.[1,2] Selected phase I/II reports of local excision with postoperative therapy are shown in Table 1.[37-48]

When the series are combined, the average crude local failure rate increases with increasing T stage (T1: 5%, T2: 14%, T3: 22%). Also, the greater the number of T3 cancers, the lower the local control rates. In the series from Massachusetts General Hospital, which included only T1/2 cancers, the local control rate was 90%. In the series from the University of Florida in which 2% of patients had T3 cancers, it was 86%.[40] and in the Memorial Sloan-Kettering series in which 21% of patients had T3 cancers, it was 73%. The 5-year actuarial survival was approximately 80% (range: 70% to 94%).[37,40-47]

In most series, patients had T1-3 tumors and underwent a local excision followed by 45 to 50 Gy of radiation to the pelvis 4 to 6 weeks later. Some series included patients who underwent a boost to the primary site by external-beam or brachytherapy techniques. Also, some series included patients who received 5-FU. Although these patients were not randomized, the data appear comparable—stage for stage—with the results of radical surgery alone for T1/2, N0 disease.

**Patterns of Failure**

In some series, higher local failure rates were seen with positive margins or piecemeal excisions. In the Memorial Sloan-Kettering series, the 5-year actuarial local failure rate was higher for patients with positive margins than for those with negative margins (35% vs 23%).[41] A similar increase was seen in the crude local failure rates in the Vancouver series (40% vs 6%).[42] In contrast, neither the series from Fox Chase Cancer Center[43] nor the one from Massachusetts General Hospital[37] found a significant difference in the local failure rate for positive vs negative margins.

In the Massachusetts General Hospital series, this result may have been related to higher radiation doses delivered to the subset of patients with positive margins. Among six such patients who remained locally controlled, five received doses greater than 60 Gy. Higher local failure rates are also seen with piecemeal excisions. Therefore, it is recommended that patients undergo a full-thickness local excision with negative margins, if technically feasible. If not technically feasible, higher doses of radiation (> 50.4 Gy) are indicated, provided the small bowel can be excluded from the field.

**Common Site of Local Failure:** In contrast to the patterns of failure seen with radical surgery, most local failures occur at the anastomotic site and not in the pelvic lymph nodes. In an analysis of the local failure rate reported in the Massachusetts General Hospital series, 1 of 18 local failures involved the pelvic lymph nodes. In the series from the University of Florida and Catholic University-Rome, none of the failures occurred in the pelvic lymph nodes. Moreover, salvage surgery of anastomotic failures is possible. As seen in Table 1, most series report that approximately half of all patients can undergo successful salvage with an abdominoperineal resection. Only the University of Florida and RTOG series report that only one of five local failures could be salvaged with abdominoperineal resection.

The results of the CALGB series further confirm that local excision and postoperative radiation therapy are associated with survival outcomes that are comparable to radical surgery. In the CALGB trial, 51 eligible patients had T2 adenocarcinomas. They received external-beam irradiation (5,400 cGy in 30 fractions) and 5-FU (500 mg/m² IV on days 1 to 3 and days 29 to 31) after local excision. Of these patients, seven suffered isolated local recurrences. All seven underwent salvage abdominoperineal resection and remained disease-free at the time of last follow-up.
In RTOG 89-02, 25 patients with T2 cancers, and 13 patients with T3 cancers were treated with 5-FU and external-beam irradiation (50 to 56 Gy if margins were at least 3 mm in all directions, 59.4 to 65 Gy if margins were < 3 mm in any dimension) after local excision. Locoregional failure occurred in 4 (16%) of 25 T2 patients and 3 (23%) of 13 T3 patients, and was found to increase with expanded involvement of the rectal wall circumference. In total, eight patients developed a local recurrence and five were salvaged. However, four of five patients ultimately developed metastatic disease.

These two cooperative group trials demonstrated results comparable to those seen in single-institution series, and suggest that this approach is feasible in a multi-institutional cooperative group setting.[38,39]

**Timing of Local Recurrence:** A second difference in patterns of failure after local excision vs radical surgery is associated with the timing of local recurrence. In patients who undergo radical surgery, approximately 80% of recurrences occur within the first 2 years. In contrast, after local excision and postoperative radiation therapy, local failures have been reported as late as 4 to 7.5 years after treatment. For example, in the series from Memorial Sloan-Kettering,[41] local failures were reported at 48 months. Similarly, in the Massachusetts General Hospital series, the median time to local recurrence was 55 months for patients treated with local excision and postoperative therapy, compared with 14 months for patients with more favorable features who underwent local excision alone. For this reason, patients treated with local excision and postoperative adjuvant therapy require close follow-up beyond 5 years.[48]

**Preoperative Radiation Therapy and Local Excision**

Several series have evaluated the use of preoperative therapy followed by local excision. Bannon and associates explored this approach in 109 patients with tumors arising 0.5 to 3 cm above the dentate line.[49] Patients were treated with 45 to 70 Gy of external-beam irradiation, followed by a sphincter-preserving radical approach (65 patients) or local excision (44 patients). With a mean follow-up of 40 months, the local recurrence rate in the group undergoing local excision was 14% and in the group undergoing radical surgery, 9%. Actuarial survival at 5 years was 90% and 85%, respectively.[49]

Rosenthal et al reported the results of a phase I/II trial of transanal local excision with combined preoperative and postoperative radiation therapy for biopsy-proven adenocarcinoma extending to within 6 cm of the anal verge. Patients received 500 cGy in one fraction to the pelvis within 24 hours before surgery and underwent transanal excision followed by postoperative radiation therapy (median dose: 5,040 cGy). With a median follow-up of 33 months, the 3-year actuarial overall survival was 94%. Two isolated local recurrences were successfully salvaged. The 3-year colostomy-free survival was 77%.[46]

Mohiuddin and colleagues evaluated 48 patients with invasive distal rectal cancer treated with 45 to 55 Gy of preoperative radiation, followed 6 to 8 weeks later by full-thickness local excision. Patients were divided into 3 groups. Group 1 comprised 15 patients with T3 tumors or tumors > 3 cm in size who were unable to undergo radical surgery due to cardiac or pulmonary disease. Group 2 comprised 18 patients with tumors staged < T2 and < 3 cm in size who were suitable for local excision by standard criteria. The 15 patients in group 3 initially had T3 tumors or tumors > 3 cm, but these tumors were downstaged by radiation to < T2 and < 3 cm.

The overall 5-year actuarial survival was 83.5%, and the local recurrence rate was 10%. Local recurrence by treatment group was 20% for group 1, 11% for group 2, and 0% for group 3. Five patients developed local recurrences, and three were salvaged. Sphincter function was scored as good to excellent in 88%.[50]

Despretz et al reviewed their experience with 25 patients who were medically inoperable or refused abdominoperineal resection and were treated with preoperative irradiation (35 Gy in 2.33-Gy fractions) followed 6 to 8 weeks later by local excision. The patients then received perioperative brachytherapy (20 or 25 Gy). With a mean follow-up of 40.5 months, five patients developed a local...
recurrence, three of whom underwent salvage surgery. Sphincter function in all 20 patients who remain locally controlled is "normal."[51]

Based on these results, standard-dose preoperative radiation therapy followed by full-thickness local excision may be an alternative option for the management of selected patients with distal, invasive rectal cancers. However, this strategy remains investigational. Moreover, a potentially significant drawback to the use of preoperative radiation therapy is the possible loss of important histologic information, including the depth of tumor penetration and the presence of lymphatic or vascular invasion.

**Functional Outcome**

There are only five series that have prospectively assessed the functional results of treatment with local excision and postoperative adjuvant therapy. It is difficult to gauge the impact of these results because they used different scales. However, the outcomes appear favorable. In the series from Memorial Sloan-Kettering and Catholic University-Rome, which used the previously published Memorial Sloan-Kettering Sphincter Function Scale,[41] good-to-excellent sphincter function was reported in 94% to 100% of patients. Investigators from Fox Chase Cancer Center[43] reported 82% good-to-excellent function using a different scale. The series from the University of Pennsylvania[46] reported satisfactory function in 92%, and the M. D. Anderson series reported "good continence" in more than 90% of patients.[48]

Local excision alone (without adjuvant therapy) can affect sphincter function. A prospective study of clinical, manometric, and proctographic outcome was undertaken in 36 patients who had undergone transanal endoscopic microsurgery at the University Hospital in Tubingen, Germany. Anorectal manometry showed no difference in maximal squeeze pressure before and 12 months after the surgery, although resting pressures were lower after surgery. Also, the rectoanal inhibitory reflex was lost in a significant group of patients. Despite these objective findings of impairment, clinical function was thought to be adequate.[51]

**Chemotherapy**

The role of chemotherapy in the setting of local excision for rectal cancer is unclear. In most of the previously mentioned series, 5-FU was used as a radiosensitizing agent but was not used in the adjuvant setting. The numbers are limited and the data are not stratified by T stage; therefore, the impact of chemotherapy is unclear. However, given the positive results reported in randomized trials addressing postoperative adjuvant therapy for rectal cancer,[1,2] all patients should receive 5-FU-based chemotherapy concurrently with radiation therapy. If the patient has T2/3 disease, or adverse pathologic features that suggest increased risk of pelvic node involvement, an additional four cycles of adjuvant chemotherapy are recommended.

**Conclusions**

Local excision and postoperative combined-modality therapy appears to be a reasonable alternative to radical surgery in selected patients. Local excision alone is an acceptable treatment alternative only for T1 tumors without adverse pathologic features. Local excision plus combined-modality therapy is acceptable for T1 tumors with adverse pathologic features, and for some T2 tumors. Functional results are generally good-to-excellent with this approach. Although some series suggest that preoperative therapy with local excision may be a reasonable treatment option for selected T3 tumors, the high local failure rate seen in series with local excision and postoperative therapy suggests that these tumors may be treated more effectively by radical surgery with pre- or postoperative therapy. Randomized trials are needed to determine whether this approach is associated with local control and survival rates comparable to those achieved with radical surgery.

**References:**


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