Local Management of Rectal Neoplasia

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ABSTRACT

The treatment of rectal neoplasia, whether benign or malignant, challenges the surgeon. The challenge in treating rectal cancer is selecting the proper approach for the appropriate patient. In a small number of rectal cancer patients local excision may be the best approach. In an attempt to achieve two goals—cure of disease with a low rate of local failure and maintenance of function and quality of life—multiple approaches can be utilized. The key to obtaining a good outcome for any one patient is balancing the competing factors that impact on these goals. Any effective treatment aimed at controlling rectal cancer in the pelvis must take into account the disease in the bowel wall itself and the disease, or potential disease, in the mesorectum. The major downside of local excision techniques is the potential of leaving untreated disease in the mesorectum. Local management techniques avoid the potential morbidity, mortality, and functional consequences of a major abdominal radical resection and are thus quite effective in achieving the maintenance of function and quality of life goal. The issue for the transanal techniques is how they fare in achieving the first goal—cure of the cancer while keeping local recurrence rates to an absolute minimum. Without removing both the rectum and the mesorectum there is no completely accurate way to determine whether a rectal cancer has moved outside the bowel wall, so any decision on local management of a rectal neoplasm is a calculated risk. For benign neoplasia, the challenge is removing the lesion without having to resort to a major abdominal procedure.

KEYWORDS: Cancer, rectum, neoplasms, transanal, villous adenoma

Objectives: On completion of this article, the reader should: (1) understand the patient and tumor characteristics that might support the decision to treat an early rectal cancer with local excision; (2) understand the results reported on treatment of rectal cancer using local excision techniques; and (3) be able to summarize the local treatment options and outcomes for benign rectal neoplasms.

LOCAL EXCISION OF MALIGNANT RECTAL NEOPLASIA

The evaluation of any patient with a newly diagnosed rectal neoplasm begins with a thorough history and physical examination. The important points to keep in mind are the premorbid bowel function of the patient, comorbid medical conditions, and worrisome local

symptoms like constant pain that may indicate local invasion. The physical examination should start with a good digital examination to assess the status of the anus, including tone and squeeze, and the tumor characteristics. This includes location of the tumor in relation to the anorectal ring; the exact location of the tumor in terms of anterior, posterior, or right or left lateral; and

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whether the lesion is exophytic, endophytic, ulcerated, mobile, tethered, or fixed. A proctoscopic and/or anoscopic examination will follow to confirm digital examination findings and to determine the size of the lesion, how much of the rectal circumference is taken up by the lesion, and the exact distance of the lesion above the anal margin and the dentate line.

ISSUES TO CONSIDER IN CHOOSING AN APPROACH

In selecting a treatment approach for a patient with rectal cancer, assuming that colonoscopy shows an otherwise normal colon, there are three issues to consider. The first is the patient, the second is the location of the tumor, and the third is the stage of the tumor.

The patient issue involves young versus old and sick versus healthy. The questions to be answered include whether the patient can tolerate aggressive treatment for the tumor or, based on comorbidities or age, should less aggressive therapy be considered. Is the patient fit for a major resection? Major resections for rectal cancer involve morbidity rates of 20 to 30% and mortality rates of 2 to 3%.^{1,2} There will be a certain number of patients who are simply too sick to undergo an abdominal operation for treatment of their rectal cancer. Some patients will have physical limitations that dictate a local approach. For example, there will be patients who might be candidates for a low anterior resection based on the location of their tumor, but due to mobility concerns (arthritis, severe joint disease, need for wheelchair, etc.) they may not tolerate this approach with the disordered postoperative bowel function that ensues. What is the status of the anal sphincter and the pelvic floor? Although from a technical standpoint, a low anterior resection with a colo-anal anastomosis may be possible, poor anal sphincter or pelvic floor function may result in unacceptable defecatory dysfunction. For some patients, continence issues will push patient and surgeon toward local excision. There will be patients who might, from an oncologic standpoint, be best served with an abdominal perineal resection, but their ability to manage a stoma may be so poor that placing one may result in a major change in their ability to live independently. And in some rare patients, in the setting of metastatic disease, when simple local control of the primary tumor is a concern, local treatment may be indicated. And finally, there will always be patients who, for one reason or another, will refuse a radical resection, leaving some sort of local treatment as the only option. Another consideration is potential years of life put at risk should a primary treatment approach fail. Local failure after local excision in a perfectly healthy 50-year-old has implications that are much different from the same situation in an 85-year-old with significant medical issues and a relatively short life expectancy.

In terms of the second issue, the location of the tumor, as a general rule, the vast majority of tumors

considered for local excision will be in the mid- or low rectum. These tumors are located in the extraperitoneal rectum. From a practical standpoint, a very useful landmark for the surgeon is the middle rectal valve. In the average patient, the middle rectal valve is located ~9 to 10 cm above the anal margin. This will vary considerably based on body habitus. In the very large male with a long anal canal, it may be much higher. In a very small woman, it may be much lower. But generally, the middle rectal valve marks the area of the anterior peritoneal reflection. Local excision of a rectal cancer well beneath this point will keep the surgeon out of the abdominal cavity. Local management of rectal cancers near the middle rectal valve, especially in a small, multiparous woman who may have a deep anterior cul de sac, may mean that at the proximal extent of a full thickness excision, the surgeon may find himself or herself in the abdominal cavity. Obviously, there is more extraperitoneal rectum posteriorly and laterally than there is anteriorly.

The third issue for consideration, the stage of the tumor, is critical. From an oncologic standpoint, obtaining a good result with local management of rectal cancer will come down to proper tumor selection. Local staging involves rectal ultrasound or magnetic resonance imaging (MRI); evaluation for distant metastatic disease involves a computed tomography (CT) scan of the chest, abdomen, and pelvis. In the absence of distant metastatic disease, any effective treatment of rectal cancer must take into account the disease in the rectal wall and the disease, or potential disease, in the mesorectum.

Because short of removing both the rectum and the mesorectum there is no completely accurate way to determine whether a rectal cancer has moved outside the bowel wall, any decision on local management of a rectal neoplasm is a calculated risk. The following is a guide to this calculation.

The ideal tumor for local excision is the tumor with a predictably low potential for lymph node involvement. Multiple factors help the surgeon predict the rate of lymph node positivity, including T-stage, or depth of tumor invasion, the size of the tumor, and tumor histology. Ultimately, it is our ability, or inability, to determine whether there has been spread of tumor outside the bowel wall, that will determine the success or failure of a local treatment approach.

The risk of lymph node involvement is directly related to the depth of tumor penetration into or through the bowel wall. The rate of metastatic mesorectal nodal disease for T1, T2, T3, and T4 tumors is 5 to 11%, 20 to 30%, 50 to 65%, and 75 to 80%, respectively.^{1,3-6}

Accurate determination of the depth of tumor penetration is critical when considering a local approach for a rectal cancer. Rectal ultrasound is the most commonly utilized tool in making a T-stage determination. Accuracy rates vary, but are generally reported to be in

the 60 to 90% range, with an overall T-stage accuracy of ~85%. The accuracy varies by T-stage, with T3 lesions most accurately identified and T1 and T2 lesions accurately identified in 59% of cases.⁷⁻¹⁰

Rectal ultrasound is also used to directly evaluate mesorectal lymph node status. The accuracy is reported to be ~75%, with a range of 44 to 87%.^{11,12} The accuracy rates are higher for larger nodes (> 5 mm). For nodes < 5 mm in size, the accuracy decreases to 30%.^{13,14} This is a problem, given that up to 20% of involved lymph nodes are < 3 mm in size.¹³

The absolute size of the tumor must be taken into consideration. The tumor should be < 3 cm in size and involve no more than 30 to 40% of the circumference of the rectal wall. From a technical standpoint, full-thickness local excision of lesions larger than this will be very difficult to manage through the anus. In addition, there is data to suggest that increasing tumor size correlates with increasing lymph node positivity rate and higher rates of local recurrence.^{15,16} However, more recent data suggest that tumor size is not an independent predictor of lymph node positivity in multivariate analysis.^{17,18}

Tumor histology has significance in deciding on local management.¹⁸ Poorly differentiated tumors have a high rate of lymph node positivity¹⁹ and generally this finding should push one to consider a more radical approach than simple local excision alone. Mucinous tumors also behave aggressively; in several studies, this type of pathology has been shown to be an independent negative prognostic feature for local excision.^{19,20} Ulceration has been shown in some studies to be a predictor of lymph node involvement.^{21,22} However, some do not consider ulceration to be a contraindication to local excision.^{19,23} Lymphatic invasion, vascular invasion, and perineural invasion are other histologic features that predict aggressive tumor biology^{24,25}; these pathologic findings should push the surgeon to recommend something more than local excision alone.

Another histologic feature that may be important is the absolute depth of tumor penetration into the submucosa. Based on a classification system suggested by Kikuchi et al,²⁶ T1 tumors are classified as either SM1, SM2, or SM3, based on whether they penetrate into the superficial one third of the submucosa, the middle third of the submucosa, or the deepest third of the submucosa. Using the classic Haggitt's classification system for malignant polyps, Haggitt's level 1, 2, or 3 invasion would be SM1. Haggitt's level 4 invasion, whether in a pedunculated or a sessile polyp could be SM1, SM2, or SM3. The authors found that when evaluating 182 Haggitt's level 4 polyps, none of 64 SM1 patients developed local recurrence or lymph node metastasis, despite a 30% rate of lymphovascular invasion and a 12.5% rate of poor differentiation. The Mayo Clinic¹⁷ used this classification system to reclassify

344 T1 sessile colorectal lesions that had been removed by radical resection. Multivariate analysis revealed that SM3 invasion, lymphovascular invasion, and origin of lesion in the distal third of the rectum to be independent risk factors predictive of lymph node metastasis. Whether this new classification system ultimately is valuable in making clinical decisions is not clear.

The ideal tumor for local excision, then, is a nonulcerated tumor that is < 3 cm in size and located well beneath the middle rectal valve. Its histology shows good or moderate differentiation with no lymphovascular or perineural invasion and no mucinous features. Its rectal ultrasound reveals uT1N0 disease. In this scenario, the risk of having tumor deposits outside of the bowel wall should be predictably low, which should bode well for a good outcome after local excision. When all factors are taken into consideration, one finds that only a small number of rectal cancer patients, perhaps 5 to 10%, are good candidates for local management. Based on the use of neoadjuvant chemotherapy and radiation therapy in addition to local surgical techniques, this number may increase in the future.

TRANSANAL EXCISION TECHNIQUES

Preoperative Preparation With any transanal approach, a full mechanical and antibiotic bowel preparation is administered on the day before surgery. An intravenous, prophylactic antibiotic is administered before the operation starts. The majority of these local excisions will be performed in the ambulatory setting as an outpatient. However, when the overriding reason for choosing a local approach is the poor overall medical condition of the patient, inpatient observation may be warranted. The type of anesthetic chosen will depend on the medical condition of the patient, the position of the patient (regional anesthesia in prone jackknife in a feeble patient with airway concerns can be problematic), and the exact type of procedure planned. A long operation for a lesion in the midrectum that will challenge the surgeon technically may best be conducted with the patient under a general anesthetic. A low lesion that is easily visualized might call for a regional anesthetic. In very poor risk patients an anal block combined with sedation may be the best option.

The position of the patient will be determined primarily by the location of the tumor. For posterior lesions that are in the midrectum, the lithotomy position will likely be best. However, for distal lesions located posteriorly, prone jackknife might be a better position as gravity will help bring the lesion into view. This is especially the case in men with a long anal canal and a very sharp anorectal angle. Posterior lesions in these cases can be hard to visualize with the patient in the lithotomy position as they can hide behind the anorectal angle. For anterior lesions, prone jackknife position is

best. When conducting a standard transanal local excision for a lateral tumor, prone jackknife position is almost always chosen.

When performing transanal endoscopic microsurgery, positioning is especially important. Anterior lesions are treated with the patient in prone jackknife, posterior lesions, whether in the mid- or distal rectum are treated with the patient in lithotomy, and lateral lesions are treated in the right or left lateral decubitus position so that the lesion is located on the "downside" of the rectum.

With the anesthetic administered and the patient positioned, the rectum is evacuated with a proctoscope and it is prepped (flooded and evacuated) with a Beta-dine[®] (Purdue Pharma, Stamford, CT) solution.

Conventional Transanal Excision

For distal lesions, the anus is usually effaced with four to six heavy sutures or with a Lone Star retractor[®] (Lone Star Medical Products, Inc., Stafford, TX). Using either, the concept is to pull the mucocutaneous junction outwards and therefore shorten the length of the anal canal. This technique may not help much for lesions located well above the dentate line. For exposure, we usually use a fiberoptically equipped Sawyer retractor[®] (Electro-Surgical Instrument Co. [ESI], Rochester, NY). The broad and deep blade is quite useful for exposure and having the light directly in the operative field is a tremendous help. This retractor is placed opposite the lesion while a narrow, lighted Deaver retractor[®] (ESI, Rochester, NY) is placed in the anal canal on the side of the lesion. If lighted retractors are not available, a good headlight may suffice. With the lesion exposed, the electrocautery unit is used to mark out around the lesion with a 1-cm margin of normal tissue. Burn marks are made every few millimeters. These are used to guide the excision in a "follow the dotted line" manner. Frequently, 3-0 stay sutures are placed to help with exposure and traction. These sutures are placed just inside the margin of normal mucosa, so that they come out with the specimen. Usually one will be placed distally, and one will be placed laterally, both right and left. The excision generally starts distally and is performed almost completely with the electrocautery. Bleeding points in the mesorectum may require a 3-0 absorbable suture for control. Full thickness excision is confirmed by visualization of perirectal fat for lesions up in the rectum. For very distal lesions, the deep aspect of the excision will be the external sphincter after the excision comes through fibers of the internal sphincter. Of course, fat will eventually be encountered at the proximal aspect of the dissection during local excision of a very distal tumor. Some authors advocate taking the dissection into the mesorectum down to the fascia propria of the mesorectum. If the surgeon is of the opinion that for a given patient local treatment is absolutely the definitive treat-

ment, then this type of dissection is reasonable. However, if there is any thought that a radical resection might follow the local excision, one must consider that taking the local excision to the outer aspect of the mesorectum may well later disturb a proper or clean dissection in this critical plane..

Local Excision through the Operating Proctoscope

Although the above technique usually is sufficient for distal lesions, more proximal lesions may not be well visualized and a different approach may be required. In these situations, one useful technique is performing the local excision through an operating proctoscope. We use a Salvati operating proctoscope[®] in either a 12- or 19-cm length (ESI, Rochester, NY). This is a 4-cm diameter scope that has a fiberoptic light tube that runs out to near the tip of the scope; it has a suction tube built in to keep the field clear of smoke generated by the electrocautery unit. The concept is that the patient is positioned such that the lesion in question can be pinned down in the lumen of the scope, then using either a long electrocautery pencil and a long forceps through the shorter of the two scopes, or a laparoscopic electrocautery tip and a laparoscopic grasper through the longer scope, one simply marks out around the lesion as described above and then performs a full-thickness local excision. The defect left in the rectal wall can be repaired using either a long needle driver through the shorter scope or a laparoscopic needle driver (or Endo-Stitch[®] device; Covidien, Norwalk, CT) and a knot pusher through the longer scope. Again, the advantage here over standard transanal excision is that using these scopes, one can get higher in the rectum to manage more proximal lesions.

Transanal Endoscopic Microsurgery

Local management of rectal neoplasia was advanced with the introduction of transanal endoscopic microsurgery (TEM). Professor Gerhard Buess, along with Richard Wolf Medical Instruments (Vernon Hills, IL), pioneered this technology in an effort to obtain better visualization, improve surgical dissection, and increase the ability of surgeons to reach more-proximal rectal tumors. TEM entails using a 40-mm diameter scope with two different length options (12 and 20 cm). The scope is lighted, utilizes carbon dioxide insufflation, and has three operative ports. The scope is held in position on the table with a special clamp. The surgeon can operate through a binocular eyepiece or a camera system can be secured to the scope so that the image is projected on a screen, similar to laparoscopic surgery. This technology is ideal for large rectal villous tumors and for early rectal cancers. The advantages conferred by this technique are multiple. It allows for superior visualization

when compared with conventional transanal excision. The dissection, whether submucosal or full-thickness, can be much more precise. There is improved lymph node harvest for full-thickness resection (of unknown significance). It can make resection of larger tumors easier. Finally, TEM can facilitate exposure to the more proximal rectum²⁷⁻²⁹. Although TEM makes local excision of proximal rectal lesions possible, the advisability of approaching upper rectal cancers with this technique is debatable. For the purpose of this discussion, these resections should still be limited to the extraperitoneal rectum. This usually means that maximum distance from the anal verge is ~11 cm anteriorly, 14 cm on the sidewalls, and 20 cm posteriorly. The major drawbacks of TEM are the cost of the equipment and the steep learning curve. In addition to the learning curve, the tumors that are best served by this technology are not common, which means that gaining proficiency in this procedure can be difficult.

When using TEM it is especially important to note the exact tumor location in the rectum so that the patient can be properly positioned. Due to the configuration of the TEM equipment, the tumor must be positioned exactly opposite the beveled end of the scope. So for anterior tumors, the patient should be in the prone position and for posterior tumors, lithotomy position. Variations of left and right lateral decubitus can be used to position tumors that are located on the lateral wall of the rectum.

Once the scope is secured to the table and the rectum insufflated, the dissection is first mapped out with diathermy. Then the tumor is excised with diathermy. The defect in the rectal wall is closed with a running suture. Knot tying is difficult with TEM and the suture is routinely secured at each end with special clips. Postoperative complications are similar to those with conventional transanal excision (TAE). Hemorrhage and perforation occur ~6% of the time. Perforation may be more of a concern because TEM allows one to work more proximally in the rectum closer to or even in the intraperitoneal rectum. Anal stenosis can be a late complication in ~3% of patients, especially with the larger tumors that require a wider resection margin.

By any of the techniques described, after the specimen has been excised, it is pinned onto a piece of cork or foam and marked for the pathologist as to right, left, proximal, and distal to help with margin status evaluation. The rectum is then irrigated with saline and a tumoricidal solution like sterile water or Beta-dine[®], and the defect in the rectal wall is closed. The method of wound closure with TEM is described above. With conventional transanal excision or excision through the operating proctoscope, the closure will generally be transverse using interrupted sutures. Corner sutures are placed, a suture is placed near the center of the wound and subsequent sutures are placed to contin-

ually "half" the wound until it is closed. Some advocate leaving these wounds in the extraperitoneal rectum open with little apparent consequence. This has been the author's (KAL) experience as well.

Other techniques have been used for local excision of rectal lesions. A posterior, trans-sacral, Kraske approach has been advocated for reaching lesions that in the past could not be reached via a transanal approach. This approach is associated with a significant rate of wound breakdown and subsequent fistulization posteriorly.³⁰ This is not an easy problem to manage. Although there may still be a rare patient and lesion that are suited to this approach, the techniques described above have rendered this approach almost obsolete. A trans-sphincteric, York-Mason approach has also been described.³¹ Here the surgeon divides the sphincter complex posteriorly in the midline from the anus back to near the coccyx. This provides good exposure to the anterior wall of the rectum, at the risk of incontinence issues that accompany division of the entire sphincter complex.³² It is performed rarely for local excision of rectal lesions.

OUTCOMES FOR TRANSANAL EXCISION OF EARLY RECTAL CANCER

Local excision of early rectal cancers is not a new concept. However, the widespread use of rectal ultrasound for staging or rectal lesions is fairly new and the use of TEM is fairly new. Have these newer technologies produced any improvement in outcome? Given the data from the most recent reports, one might conclude that globally, there is room for improvement. In the series of 108 patients treated by the group at the University of Minnesota (Minneapolis-St. Paul, MN),³³ recurrence rates for T1 and T2 tumors were 18% and 47%, with a corresponding 5-year survival rate of 72 and 65%, respectively. This 18% rate of local recurrence is disturbing. It is about twice what one would expect to see if local recurrence was simply a matter of having left involved nodes (5 to 11% rate of lymph node positivity for T1 tumors) untreated in the mesorectum. This same group presented an update on their series of local excisions in 2005. With 151 patients, the local failure rate after transanal excision of T1 tumors was 21%.³⁴ In 2002, the group at Memorial Sloan Kettering (New York, NY), published a review of their experience examining 125 patients with T1 or T2 tumors treated locally.³⁵ The local failure rate for T1 tumors was 17% with an overall 10-year survival rate of 74%. Local resection of T1 rectal cancers conferred a 3- to 5-fold higher risk of tumor recurrence when compared with radical resection, but overall survival rates were similar for the two groups. And finally, in 2005, the Cleveland Clinic, Cleveland, Ohio, published a review of their experience in 52 patients treated locally for T1 rectal cancer.³⁶ The

local recurrence rate was an alarming 29% for T1 tumors with a corresponding 75% overall survival rate, but an 89% cancer specific survival.

The Norwegian Rectal Cancer Group performed a national, prospective study to evaluate the long-term results with treatment of T1 rectal cancers, whether by radical surgery or by TAE.¹ None of the radical resection group patients had a margin positive resection, compared with 17% for those patients undergoing TAE. The radical resection group compared with the TAE group had a statistically lower rate of local recurrence (0% versus 12%), a better overall survival (80% versus 70%) and a better disease free survival (77% versus 64%). None of the patients in either group was treated with preoperative radiation therapy. This allowed for a rather pure look at the lymph node positivity rate for those in the radical resection group. It was 11%. This nodal rate in T1 disease reconfirms the need for selecting patients carefully for TAE so that as many patients as possible with lymph node positive tumors are excluded from a treatment approach that will leave tumor behind in the mesorectum.

In a break from the standard individual surgeon or single institution report, You et al³⁷ analyzed a large number of cases from the National Cancer Database. The authors were able to make some very interesting observations regarding how local excision (LE) was being used for stage I rectal cancer in the United States and how this treatment compared with standard resection (SR) in terms of local recurrence, overall survival and disease specific survival. Over a 14-year period from 1989 to 2003, use of LE increased significantly for both T1 lesions (26.6 to 43.7%) and T2 lesions (5.8 to 16.8%). As one would expect, LE had a lower 30-day morbidity rate than SR, but after adjusting for patient and tumor characteristics, the 5-year local recurrence rate for LE was significantly higher than SR for both T1 (12.5 to 6.9%) and T2 (22.1 to 15.1%) tumors. However, the 5-year overall survival rate after LE versus SR for T1 disease (77.4 to 81.7%) was not significantly different. This held at the 8-year mark as well. In addition, the 5-year disease specific survival was actually significantly lower for LE versus SR (93.2 to 97.2%). For T2 tumors, overall survival was lower after LE versus SR (67.6 to 76.5%), whereas disease specific survival was not different (90.2 to 91.7%) at 5 years. The authors conclude that despite data showing overall worse tumor control after LE (a nearly 3-fold increase in local recurrence rates), these techniques are being utilized more frequently, probably as the result of decisions being based on overall survival figures, the perioperative benefits of LE, and the functional and quality of life gains associated with LE. Clearly, the choice for local excision is complex and is made on an individual, patient-centered basis taking into account the factors discussed earlier.

The data regarding TEM is rather more encouraging than what has been reported for standard transanal

excision alone. In a systematic review of the literature on TEM, Middleton et al looked at three comparative studies, including one randomized trial, and 55 case series published from 1980 to 2002. They concluded that there was no survival advantage when comparing TEM to low anterior resection in the trials that examined this issue, and local failure rates after TEM was 6% compared with 22% for standard TAE. TEM also produced a lower complication rate than standard TAE.³⁸

As TEM is being used more frequently, its role in the treatment of rectal cancers still needs to be further elucidated. It is an accepted technique for the resection of T1 lesions. Steele et al concluded that if the intent of surgery is curative, then only those with early and small tumors are candidates.³⁹ In a randomized control study evaluating TEM versus APR for T1 lesions, Winde et al⁴⁰ showed that there is no difference between the two treatment modalities in long-term outcomes. The local recurrence rate after TEM for these early tumors was 4%, with a 96% 5-year survival rate. Floyd and Saclarides,⁴¹ Lezache et al,⁴² and Lee et al,⁴³ have all reported local recurrence rates similar to those found in the Winde study. Local recurrence rates after TEM for T2 tumors are significantly higher, as one would anticipate based on the rate of lymph node involvement for these more advanced tumors. Lee and colleagues⁴³ showed a recurrence rate of 19.5% for T2 tumors; Steele et al³⁹ reported a 15.4% recurrence rate at only 6 months of follow-up.

SALVAGE THERAPY

For rectal cancer patients considering local excision with curative intent, a critical component of the decision involves a discussion of what ensues should local recurrence occur. One concept that should be understood is that for low lesions that may be treated by low anterior resection with colo-anal anastomosis, proceeding with local excision may make a sphincter saving resection, in the face of local recurrence, very difficult, if not impossible. In addition, the likelihood of cure in the face of local recurrence after local excision is reduced over what might have been the case had a radical resection been undertaken at the start. In a report by Baron, et al, most patients who had local recurrence after local excision were salvaged with an abdominal perineal resection, not a low anterior resection.⁴⁴ In addition, the overall survival for these salvage patients was 50% compared with an overall survival of 94% for those patients who had resection for early tumors with negative pathologic features. In a report from Memorial⁴⁵ that examined 50 patients undergoing salvage surgery for local recurrence after local excision, 31 patients were treated with an abdominal perineal resection, 11 underwent low anterior resection, 4 had a pelvic exenteration, and

3 had repeat local excision. Twenty seven (55%) required extended pelvic dissection with en bloc resection. The overall 5-year disease-free survival was 53%. It can fairly be said that salvage treatments for patients who recur locally after TAE require extensive surgery that results in a high stoma rate and a survival rate that is in the 50% range. In trying to calculate whether local excision is the best treatment for a patient with an early rectal cancer, this is the type of information that should be considered by the surgeon and the patient.

ADJUVANT THERAPY AND LOCAL RESECTION OF RECTAL CANCER

Although surgical treatment is still primary in curative treatment plans for rectal cancer, radiation and chemotherapy certainly are critical modalities in optimizing outcomes in several settings. With respect to local treatment, these modalities have been studied in the adjuvant setting to improve results of local excision.

The Radiation Therapy Oncology Group (RTOG) protocol 89-02 assessed the ability to conserve the anal sphincters in patients with small, distal rectal cancers.⁴⁶ All patients underwent local excision. Patients were then assigned, based on histology and other tumor characteristics, to three treatment arms: observation or bolus 5-fluorouracil (5-FU) with two different dose levels of radiation. Local control was successful in 96% of T1 tumors, 83% of T2 tumors, and 77% of T3 tumors. This study suggests that reasonable local control can be achieved with a combination of local excision and postoperative chemoradiation in select tumors. Bleday et al⁴⁷ also showed a benefit to postoperative chemoradiation for locally excised T2 and T3 tumors. Several additional studies have evaluated local excision followed by postoperative radiation and chemotherapy.

Given the rather high rate of local recurrences that have been reported for local excision alone, and given the rather high rate of margin positivity with local excision, the use of neoadjuvant chemotherapy and radiation therapy followed by local excision has been proposed and is currently being evaluated by the American College of Surgeons Oncology Group in the ACO-SOG Z6041 trial. This is a phase II trial, with patients receiving preoperative chemoradiation, followed by local excision for ultrasound T2N0 tumors.⁴⁸ This treatment approach was first described years ago by Marks and Mohiuddin.⁴⁹

LOCAL EXCISION OF BENIGN RECTAL NEOPLASIA

RECTAL VILLOUS TUMORS

Making a decision about how to approach a benign lesion in the rectum is more straightforward than decid-

ing on the approach to a known cancer. The vast majority of benign lesions should be approached through the anus. The majority of rectal polyps can be removed endoscopically without much difficulty. However, rectal villous adenomas can be quite large and often require some sort of operative intervention. They are classically sessile lesions with a soft, velvety, glistening appearance. The borders of these lesions can be difficult to discern on examination because the color and texture of these lesions can be very much like that of the normal mucosa. These lesions can produce a large amount of mucous (up to 3 L a day) and this can produce electrolyte abnormalities (hyponatremia, hypokalemia, and metabolic acidosis) and local symptoms such as diarrhea and mucous discharge. Other symptoms include bleeding, prolapse, and a feeling of rectal fullness. The lesions are generally soft on digital rectal examination. Rectal villous tumors can attain a quite large size, sometimes carpeting almost the entire rectum, without degenerating into a malignancy. Random biopsy of a large villous tumor of the rectum is inaccurate in determining a malignancy with high false-negative rates of from 25 to 40%.⁵⁰ Greater than 90% accuracy has been reported in excluding a cancer based on visual conformation of no ulceration and absence of induration on physical examination.^{50,51} Rectal ultrasound may help in determining the nature of a rectal villous tumor. If the ultrasound shows evidence of invasion, directed biopsies should be taken before definitive therapy is undertaken. If ultrasound gives a good image throughout the extent of the lesion, accuracy has been reported to be 94%.⁵² If the bulk of the lesion hinders the examination or if a lesion cannot be imaged well due to location in either the proximal rectum or very distal rectum, ultrasound accuracy falls significantly. If cancer is identified in a rectal villous tumor, decisions regarding definitive treatment proceed based on the considerations and factors outlined above. If a villous lesion is thought to be benign, multiple approaches can be utilized to eradicate the lesion. How to proceed will be based on the size of the lesion and its location within the rectum. Conventional transanal excision, TEM, and proctoscopic techniques have all been used to treat these lesions. Although various techniques for fulguration and ablation have been described, the best approach remains a total excision of the lesion using the least morbid approach possible.

Transanal Excision Techniques

Preoperative preparation for any of the techniques described below is as described previously for malignant lesions. For small lesions located in the upper or mid-rectum, proctoscopy and use of the rigid snare excision is effective. For anterior lesions, one should consider raising the lesion up off of the wall of the rectum by injecting a dilute epinephrine solution into the submucosa. Using

a rigid snare, the lesion can be excised in total or for larger lesions, in a piecemeal fashion. Bleeding at the excision site can be managed with a ball-tipped suction cautery, which can also be used to fulgurate any questionable margins.

For small distal lesions, a standard transanal excision technique can be utilized, as described above. The major difference for treatment of the benign lesion is that the excision will be conducted in the submucosal plane: there is no need for a full thickness excision for a benign lesion. This plane can be expanded by injecting beneath the lesion with a dilute epinephrine solution. The point of raising the lesion on a bleb is to make staying in the correct dissection plane easier. This having been said, staying in the submucosal plane can be challenging and during excision of large flat villous tumors, it is not at all unusual to find oneself going outside the rectal wall periodically. As long as the defect in the rectal wall is in the extraperitoneal portion of the rectum, there should be little consequence. Full-thickness defects in the rectal wall above the peritoneal reflection are closed and the patient is observed carefully. If the defect cannot be closed adequately, an abdominal approach to the problem will be needed.

The operating proctoscope (as described above) can be utilized for excision of large rectal villous lesions located in the middle or upper rectum. One can either excise in the submucosal plane using standard instrumentation or the rigid snare device can be utilized for a piecemeal excision. TEM can also be utilized successfully for excision: its principle advantage being the ability to remove the lesion as a single specimen with precise dissection, even in the very proximal rectum. Despite the technique used for excision, depending on the size of the defect and on what percentage of the rectum is involved circumferentially, different closure techniques may be required. Mucosal defects can be left open or the edges of the defect can be marsupialized, but if closure is possible, it is preferred. Simple closure with interrupted or running suture as described in the previous section is done when the defect allows.

Most challenging is the management of a large circumferential "carpet" type villous tumor of the rectum. These lesions can start in the dentate line and extend into the middle or upper rectum. These tumors are generally approached with the patient in the prone jackknife position. The anus is effaced with sutures or a Lone Star retractor[®] and a dilute epinephrine solution is injected into the submucosa. Dissection in the submucosal plane starts distally and proceeds proximally. A lighted Sawyer retractor and a lighted Deaver retractor are utilized. As the dissection proceeds proximally into the mid-rectum, there is often a point at which it seems that the dissection will go no further. The dissection becomes tedious, and then, as one comes out of the hollow of the pelvis, rather suddenly, length is gained

and the dissection can actually proceed to a point above the middle rectal valve. When the upper extent of the lesion is reached, the mucosal sleeve is excised and the proximal mucosa is brought to the distal edge of the excision. To gain length, the muscular wall of the rectum can be imbricated just as one would do during a Delorme procedure.

Following transanal excision of rectal villous adenomas, recurrence rates range from 8% to 40%,^{50,53} with most studies reflecting a recurrence rate around 20%. Because of the ability to perform more precise dissections, TEM appears to confer a lower recurrence rate than that seen for conventional TAE. Recurrence rates appear to be lower than 10%.^{27,29} Most recurrences can be managed via a transanal approach. The etiology of these recurrences is not clear. It may simply be that these large lesions are difficult to remove and small areas of adenomatous mucosa are left behind. The possibility of a mucosal field defect has also been raised.⁵⁴ New dye spray techniques or optical advances in endoscopy may be useful in reducing the recurrence rates.

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