Replacing Transanal Excision with Transanal Endoscopic Microsurgery and/or Transanal Minimally Invasive Surgery for Early Rectal Cancer

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Abstract

Keywords

- local excision of rectal cancer
- transanal endoscopic microsurgery
- transanal excision
- transanal minimally invasive surgery

The use of local resection of rectal polyps and early rectal cancer has progressed to become the standard of care in most institutions with a colorectal surgery specialist. The use of transanal excision (TAE) with anorectal retractors and standard instrumentation has been supplanted by the application of endoscopic techniques which allow direct video augmented visualization. The transanal endoscopic microsurgery method provides a 3D view and works under a constant flow of air to keep the rectal vault open. Instruments capable of accomplishing a surgical excision and suture closure work through a long 4 cm tube set at the anal canal. The newest version of TAE is transanal minimally invasive surgery which is similar to a single-site laparoscopic technique using a hand access port at the anal canal to maintain a seal for insufflation of the rectum, regular 2D video camera for visualization, and laparoscopic instrumentation through the port in the anus. Each of these techniques is described in detail and the outcomes compared, which show the progress being made in this area of colorectal surgery.

Rectal cancer affects more than 40,000 individuals each year in the United States with a mortality rate near 40%.¹ Surgery is the principle single curative therapy for patients with resectable rectal cancer but is combined with radiation or chemotherapy in most circumstances. The choice of surgery depends on location, aggressiveness, invasiveness, stage, and size of the lesion. Most patients present with aggressive and deeply invasive cancers that require radical resection with sphincter-sparing resection or abdominoperineal resection (APR). Only 25% of patients with rectal cancer are found to have stage I disease (i.e., T1/2 and N0).² Patients with early superficial (T0/T1) and small (<3 cm) cancers may be effectively managed with limited surgery. Local excision is an acceptable option in patients with favorable clinical and histological features. For patients with more advanced disease who are medically unfit to undergo radical surgery, this

approach can be their definitive treatment, mainly as palliative and symptom control.³

Morbidity Associated with Radical Resection as Treatment of Low Rectal Cancer

Based on the depth of invasion, tumors require a sphincter-sparing procedure (low anterior resection) or permanent stoma construction after APR. Local excision has been an attractive alternative to a more extensive surgery because it eliminated the need for a stoma, and complications such as anastomotic leaks, sepsis, and impotence can be avoided.

In the Dutch rectal cancer trial, mortality was 3.3%, anastomotic leakage was 16% (in the absence of protective stoma), and 30% of patients had a permanent stoma. Twenty-five to 34% had genitourinary sequelae; nearly 60% had anal

incontinence, and 30 to 40% had urgency and fragmentation of stools.⁴

Locally advanced tumors that are adherent or fixed to adjacent structures such as sacrum, pelvic sidewalls, prostate, or bladder require a more extensive resection. Additionally, radiation therapy is associated with local morbidity as well.

Initial Reports of Local Excision

Several retrospective studies since 1970s demonstrated that local excision of superficial tumors with negative margins may provide similar survival and local control but without the morbidity of the APR.⁵ Since that time, there have been many studies assessing the role of local excision of rectal cancer that have yielded conflicting results, some reporting up to 17% local recurrence rate.⁶ Despite the poor outcomes in these studies, the use of local excision has increased to 17.1% for T1 lesions and 11% for T2 lesions from 1989 to 2003.⁷

Oncological Results

In 1999, the only prospective multi-institutional study on local excision by transanal excision (TAE) technique of distal rectal adenocarcinoma was reported through the Cancer and Leukemia Group B (CALGB) 8984.⁸ The rate of local recurrence after 10 year following local excision varied from 7 to 21% for T1 lesions and from 26 to 47% for T2 lesions.⁹

The main disadvantage of all local excision approaches is the inability to excise and stage mesorectal lymph nodes. Even T1 lesions have a 6 to 11% risk of having metastatic nodes, and the risk depends on several histological features such as differentiation and lymphovascular invasion.¹⁰ Local excision for T1 lesions can offer durable local control and acceptable overall survival in certain patient subgroups. Data from sentinel lymph node trials suggest that a 4 cm disk of mesorectal tissue should contain 90% of all positive lymph nodes around a rectal tumor.¹¹ This may be a means of staging more accurately if mesorectal tissue is removed with the specimen.

A retrospective review of 175 patients with rectal cancer, treated initially by a local excision, found that patients with completely resected low-risk T1 cancers had a local recurrence rate of 6%, with the median time to local recurrence of 20 months. The 10-year disease-free survival and overall survival were 92 and 98%, respectively.¹² Additionally, this study showed that patients undergoing immediate reoperation to treat unfavorable histological findings such as inadequate margins or $\geq$ T2 cancers had a lower (8 vs 37%) local recurrence rate compared with waiting for recurrence and performing salvage surgery.

Patient Selection and Algorithm for Selection of Lesions for Local Excision and Choosing Technique

As mentioned previously, local excision is suitable for Tis or T1 tumors with favorable histology. Criteria for local treatment include T0 or Tis lesions, well-to-moderately differentiated T1

cancer, the absence of lymphovascular or perineural invasion, and tumors less than 3 cm in diameter occupying less than one-third of the circumference of the rectal lumen. With the exception of poor operative candidates, patients with T2 lesions should undergo total mesorectal excision. Local excision following neoadjuvant therapy for rectal cancer may be considered in the setting of a clinical trial.¹³

These principles apply to all local excision techniques. Additionally, patients should have routine preoperative cardiopulmonary assessment, full endoscopic evaluation of the colon, and, in case of malignancy, complete staging workup with rectal protocol MRI and liver CT scan.

Techniques for Local Excision

- Transcoccygeal (Kraske)
- Transsphincteric excision (York-Mason)
- Transanal excision (TAE)
- Transanal Endoscopic Microsurgery (TEM)
- Transanal minimally invasive surgery (TAMIS)

The transcoccygeal approach, formerly known as Kraske approach, requires a skin incision, mobilization of posterior pelvic floor muscles away from the coccyx to expose the rectum, and a posterior proctectomy, which may lead to wound infections and the development of fistulas. The transsphincteric (York-Mason) approach involves complete division of the anal sphincter, which may result in fecal incontinence if the muscles fail to heal. Most of the rectal cancers that are candidates for local excision can be excised through the anus. With the development of new technologies for endoluminal operation, the transsphincteric and transcoccygeal approaches are rarely used today.

Transanal Excision

Indication

See above, especially very distal lesion in anal canal.

Benefits

TAE is a simple method that can be easily performed if the tumor is located in the anal canal and easily accessible. There is no need for additional equipment, and it can be done as outpatient. An additional benefit to this approach is minimal, if any, compromise of anorectal, bladder, and sexual function. These factors make TAE the most common method of local excision.¹⁴

Description of Technique

After induction of local, regional, or general anesthesia, patient is placed in position. Most local excisions are performed with the patient in the prone jackknife position; however, some posteriorly located lesions may be better approached using the modified lithotomy position. Digital exam and proctoscopy is performed to confirm the location of the lesion. Some authors propose addition of pudendal block for sphincter relaxation. The perianal area is exposed by taping the buttocks apart, and the Lone Star retractor (Lone

Star Inc., Dallas, Texas) is used to efface the anus and facilitate exposure of the distal rectum. The lesion is examined with direct vision using a Hill Ferguson, Park, or a Barr retractor. Using electrocautery, a 1-cm margin is marked around the lesions. Proximal lesions are brought closer to outside of the anus by placing a suture at the apex. Care must be taken not to manipulate the lesion or handle it with an instrument. Full thickness excision of the lesion is performed. If the lesion is placed posterior and above the puborectalis muscle, the defect is closed with absorbable sutures. In anteriorly located lesions, care should be taken to avoid injury of adjacent structures, such as the vagina, prostate, or urethra. At the end of the procedure, a proctoscopic examination is essential to ensure that the rectal lumen was not inadvertently closed or narrowed.

Limitations, Complications, and Rate of Recurrence

Urinary retention, urinary tract infections, infections in the perirectal or ischiorectal spaces, fecal impaction, and delayed hemorrhage are commonly occurring postop complications. Even so, the incidence of these complications is low and mortality is zero. This approach is technically difficult with higher lesions due to poor visualization. Another disadvantage of TAE alone is the high recurrence rate, up to 31%.⁶ In a prospective study of 291 patients with T1M0 rectal cancer within 15 cm from the anal verge, patients treated with a TAE without neoadjuvant therapy were more likely to have macroscopic tumor remnants compared with patients undergoing a major resection (6/35 vs. 0/226 patients). Patients treated with a TAE had a significantly higher five-year local recurrence rate (12 vs. 6%) and lower five-year survival rate (70 vs. 80%) and five-year disease-free rate (64 vs. 77%).¹⁵

Transanal Endoscopic Microsurgery

This technique was first described by Gerhard Buess of Tubingen, Germany, in 1980.¹⁶

Indication

As above, up to 15 cm above the anal verge.

Benefits

TEM is a minimally invasive technique that is useful for treating lesions in the mid or upper rectum. It facilitates local excision of very early rectal cancers or large polyps between 4 and 18 cm from the anal verge that are too high for the traditional transanal approach. The use of CO₂ insufflation and 3D optics leads to better visualization and precision of the excision.¹⁷

Description of Technique

The patient is positioned using a beanbag and secured to the table with tape, which allows the patient to be rotated laterally during the procedure. The lesion needs to be situated in the 180 degree angle of the scope view. For a posterior lesion, the patient is placed in a modified lithotomy position. For an anterior lesion, the patient is placed in the prone jackknife position. For lateral lesions, the patient can be

placed on right or left lateral so the lesion is in the lower visual field. Pudendal/perianal nerve block with 15 to 20 mL of a local anesthetic is performed in addition to general anesthesia to improve relaxation of anal sphincter muscles. A 4-cm diameter operating rectoscope, obturator, and fixation supporting arm is secured to the table, followed by insertion of the working scope through the anus and the obturator removed. The cap of the rectoscope is attached and contains working and CO₂ gas ports, and through which a stereotactic telescope is inserted with connection to a 3D video system. The lesion is then centered in the scope view. Using scissors, hook cautery, and graspers, a dotted line is burned around the target lesion with a 1 cm margin.

The mucosa is then incised, at the lower edge, with full-thickness incision through muscle and into perirectal fat. Circumferential dissection and mobilization of the lesion allows complete excision and maintenance of specimen orientation. Care must be taken to avoid traumatizing and fragmentation of the specimen. Homeostasis is obtained and the defect is closed with absorbable full-thickness suture in a transverse line.

The wound can be left open to heal secondarily if the defect is posterior and surrounded by mesorectal fat. An anterior defect must be closed; closure is facilitated by placing a central stay suture and sewing from each corner to avoid tension on the suture line.

Limitations and Rate of Recurrence

Morbidity associated with TEM is similar to other local resections; however, TEM is associated with short-term reduction in anorectal function.^{18,19} Since the surgeon is working on a high lesion, inadvertent entry into the peritoneal cavity during the procedure may require conversion to an open procedure.²⁰ Therefore, full-thickness tumor excision using TEM must be limited to lesions below the peritoneal reflection and all openings into the peritoneal cavity must be closed securely.

The limitations of the procedure include equipment expense and technical expertise. Very distal lesions near the sphincter are difficult to excise with the TEM due to the configuration of the equipment and inability to maintain insufflations of CO₂ to distend the rectum. This is the reason that traditional TAE is easier for low-lying lesions.

A retrospective review of 74 patients with rectal cancer treated by TEM alone found a lower five-year local recurrence rate for patients with T1 tumors ($n = 52$) compared with T2 tumors (4.1 vs. 19.5%). In comparison, the local recurrence rates for patients with T1 ($n = 17$) and T2 rectal cancers ($n = 83$) following a major intra-abdominal resection were 0 and 9.4%, respectively.²¹ This difference in recurrence needs to be considered in any case where a less than curative approach is contemplated.

In the United States, TEM is mainly performed in a small number of high-volume centers.²² Due to complex and expensive instrumentation, as well as a steep learning curve and the requirement for specialized training to master this technique, TEM has not gained widespread adoption in the United States.²³ The technique of TEM is best learned on

moderate-sized villous adenomas of the mid rectum, not a very common lesion. Thus, it has required a high-volume center with a single focused surgeon to develop an adequate experience.

Transanal minimally invasive surgery

TAMIS is a technique first developed in 2009 for local excision of well-selected rectal tumors.²⁴

Indication

Same as other local excisions: Tis, T1, and villous adenomas.

Benefits

The main benefits of TAMIS are the relative ease of use and low cost, since it uses regular laparoscopic instruments. It is ideal for lesions at 8 to 12 cm from the anal verge. Distal lesions are covered by the transanal port, and excision of very proximal lesions can cause entry into the peritoneal cavity.

When compared with TEM, TAMIS has several advantages. Devices that are used for TAMIS are more pliable than the 40-mm rigid scope used for TEM and possibly lead to less impairment of sphincter function; setup time is significantly lower for TAMIS; use of regular straight laparoscopic instruments, as opposed to the fixed eyepiece of the TEM rectoscope, makes it possible to advance the scope into the proximal rectum and look beyond the tumor; TAMIS is easily learned by surgeons because of its simplicity and similarity with conventional laparoscopic surgery; and it is a cost-effective alternative to TEM.²⁴

Description of Technique

Once patients are carefully selected according to the above-mentioned algorithm, mechanical bowel prep or enema is administered preoperatively. After induction of general endotracheal anesthesia with pharmacological paralysis, patient is placed in the high dorsal lithotomy position, or, at the discretion of the operating surgeon, patients with an anterior lesion can be placed in the prone position. Preoperative antibiotics are administered. A transanal port, either GelPOINT Path (Applied Medical, Rancho Santa Margarita, CA) or the SILS Port (Covidien, Mansfield, MA) is inserted and secured in place. Pneumorectum is established by using CO₂ insufflation with an initial pressure set at 15 mm Hg and flow set at 40 mm Hg per minute. High-definition 30° or 45° 5-mm laparoscopic cameras are used for visualization. Standard laparoscopic instruments are used to perform excision. Full-thickness excision is performed on all malignant lesions with the objective of obtaining a 1-cm minimum negative margin. All defects are closed completely with absorbable suture material. The GelPOINT port allows for larger instruments such as the Endo360 suturing device (EndoEvolution, Boston, MA) to facilitate closure.

Limitations and Rate of Recurrence

Since its initial description, small series and case reports have shown TAMIS to be a feasible, low-cost alternative to TEM.^{25,26} Albert et al reported efficacy and outcome in their

first 50 patients. In their series, all specimens were removed with grossly negative margins, although three (6%) were found to have microscopically positive margins on final pathology. There were two recurrences (4%) at 6- and 18-month follow-up. Early complications occurred in three patients (6%). No long-term complications were observed at a median follow-up of 20 months.²⁷ Early complications were bleeding, intraperitoneal entry, scrotal emphysema, and chronic obstructive pulmonary disease exacerbation.

Pathological Evaluation of Locally Excised Rectal Lesions

The pathological examination of the specimen, pinned on a cork-board for orientation, is the essential next step. Histological analysis of the specimen allows identification of the prognostic criteria that correlate with lymph node involvement, a principal decision point for this therapeutic strategy. It is key to have the orientation in the report in case margins are found to be involved.

Histology for Predictive Factors

In T1 colorectal cancer, a high risk for lymph node metastasis is associated with lymphovascular invasion, tumors in the lower third of the rectum, and tumors that invade deep into the submucosa.²⁸ According to Kikuchi's classification, the risk of lymph node involvement is related to the degree of tumor penetration into the submucosa, and is divided into three sublevels²⁹: sm1 = slight submucosal invasion from the muscularis mucosa to the depth of 200 to 300 µm; sm2 = intermediate invasion; and sm3 = carcinoma invasion near the inner surface of the muscularis propria. The risk is zero when the tumor does not penetrate the muscularis mucosae (Tis), less than 5% when the tumor is T1sm1, 15% when the tumor is T1sm2, and nearly 25% when the tumor is T1sm3, which is equivalent to a T2 tumor.

Positive Margins

Patients with positive margins should be treated based on other histopathological factors. One can consider re-excision for a T1 lesion with no lymphovascular invasion. If there are high risk factors for the presence of lymph node metastases or local recurrence, proctectomy is the next step.

Importance of Specimen Orientation

After local excision, the specimens are measured, stretched, and pinned on cardboard by the surgeon before submitting to pathology. The margins should be clearly marked and indicated. Further treatment is based on the presence and location of positive margin. It is difficult to evaluate deep margins on a folded specimen. Therefore, pinning on a solid base is an important adjunct to histological evaluation.

Summary

Local excision has been an accepted therapy for carefully selected early cancers, with recurrence and survival rates considered to be similar to radical surgery such as

abdominoperineal resection and low anterior resection. Choice of technique depends on the location of the tumor and experience of the surgeon. Thorough pathological examination of the specimen and close follow-up is necessary.

References

- 1 Stamos MJ, Murrell Z. Management of early rectal T1 and T2 cancers. *Clin Cancer Res* 2007;13(22 Pt 2):6885s-6889s
- 2 Blumberg D, Paty PB, Picon AI, et al. Stage I rectal cancer: identification of high-risk patients. *J Am Coll Surg* 1998;186(5):574-579, discussion 579-580
- 3 NCCN Clinical Practice Guidelines in Oncology Rectal Cancer 3 2014 Available at: http://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf
- 4 Marijnen CAM, Kapiteijn E, van de Velde CJ, et al; Cooperative Investigators of the Dutch Colorectal Cancer Group. Acute side effects and complications after short-term preoperative radiotherapy combined with total mesorectal excision in primary rectal cancer: report of a multicenter randomized trial. *J Clin Oncol* 2002;20(3):817-825
- 5 Morson BC, Bussey HJ, Samoorian S. Policy of local excision for early cancer of the colorectum. *Gut* 1977;18(12):1045-1050
- 6 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
- 7 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
- 8 Steele GD Jr, Herndon JE, Bleday R, et al. Sphincter-sparing treatment for distal rectal adenocarcinoma. *Ann Surg Oncol* 1999;6(5):433-441
- 9 Greenberg JA, Shibata D, Herndon JE II, 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 1191-1194
- 10 Garcia-Aguilar J, Pollack J, Lee SH, et al. Accuracy of endorectal ultrasonography in preoperative staging of rectal tumors. *Dis Colon Rectum* 2002;45(1):10-15
- 11 Finan KR, Lewis JS Jr, Winslow E, Mutch MG, Birnbaum EH, Fleshman JW. Ex vivo sentinel lymph node mapping in patients undergoing proctectomy for rectal cancer. *Dis Colon Rectum* 2010;53(3):243-250
- 12 Borschitz T, Gockel I, Kiesslich R, Junginger T. Oncological outcome after local excision of rectal carcinomas. *Ann Surg Oncol* 2008;15(11):3101-3108
- 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
- 14 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
- 15 Endreseth BH, Myrvold HE, Romundstad P, Hestvik UE, Bjerkset T, Wibe A. Norwegian Rectal Cancer Group. Transanal excision vs. major surgery for T1 rectal cancer. *Dis Colon Rectum* 2005;48(7):1380-1388
- 16 Buess G, Theiss R, Hutterer F, et al. Transanal endoscopic surgery of the rectum - testing a new method in animal experiments [in German]. *Leber Magen Darm* 1983;13(2):73-77
- 17 Neary P, Makin GB, White TJ, et al. Transanal endoscopic microsurgery: a viable operative alternative in selected patients with rectal lesions. *Ann Surg Oncol* 2003;10(9):1106-1111
- 18 Herman RM, Richter P, Walega P, Popiela T. Anorectal sphincter function and rectal barostat study in patients following transanal endoscopic microsurgery. *Int J Colorectal Dis* 2001;16(6):370-376
- 19 Kennedy ML, Lubowski DZ, King DW. Transanal endoscopic microsurgery excision: is anorectal function compromised? *Dis Colon Rectum* 2002;45(5):601-604
- 20 Gavagan JA, Whiteford MH, Swanstrom LL. Full-thickness intraperitoneal excision by transanal endoscopic microsurgery does not increase short-term complications. *Am J Surg* 2004;187(5):630-634
- 21 Lee W, Lee D, Choi S, Chun H. Transanal endoscopic microsurgery and radical surgery for T1 and T2 rectal cancer. *Surg Endosc* 2003;17(8):1283-1287
- 22 Cataldo PA. Transanal endoscopic microsurgery. *Surg Clin North Am* 2006;86(4):915-925
- 23 Koebrugge B, Bosscha K, Ernst MF. Transanal endoscopic microsurgery for local excision of rectal lesions: is there a learning curve? *Dig Surg* 2009;26(5):372-377
- 24 Atallah S, Albert M, Larach S. Transanal minimally invasive surgery: a giant leap forward. *Surg Endosc* 2010;24(9):2200-2205
- 25 Lim SB, Seo SI, Lee JL, et al. Feasibility of transanal minimally invasive surgery for mid-rectal lesions. *Surg Endosc* 2012;26(11):3127-3132
- 26 Barendse RM, Doornebosch PG, Bemelman WA, Fockens P, Dekker E, de Graaf EJ. Transanal employment of single access ports is feasible for rectal surgery. *Ann Surg* 2012;256(6):1030-1033
- 27 Albert MR, Atallah SB, deBeche-Adams TC, Izfar S, Larach SW. Transanal minimally invasive surgery (TAMIS) for local excision of benign neoplasms and early-stage rectal cancer: efficacy and outcomes in the first 50 patients. *Dis Colon Rectum* 2013;56(3):301-307
- 28 Nascimbeni R, Burgart LJ, Nivatvongs S, Larson DR. Risk of lymph node metastasis in T1 carcinoma of the colon and rectum. *Dis Colon Rectum* 2002;45(2):200-206
- 29 Kikuchi R, Takano M, Takagi K, et al. Management of early invasive colorectal cancer. Risk of recurrence and clinical guidelines. *Dis Colon Rectum* 1995;38(12):1286-1295