Subject: Transanal Endoscopic Microsurgery (TEM)

Overview: Transanal endoscopic microsurgery (TEM) is a minimally invasive surgical technique developed for the local excision of rectal lesions in patients. The goal is to provide complete removal of the tumor without the morbidity associated with conventional surgical excision.

Policy and Coverage Criteria:

NOTE: Prior Authorization is NOT required

Harvard Pilgrim Health Care covers transanal endoscopic microsurgery for:

- Removal of rectal adenomas and other benign lesions of the rectum
- Removal of low risk, T1 rectal carcinomas moderately to well differentiated cell type, and without lymphovascular extension
- Removal or rectal carcinoids

Exclusions: Harvard Pilgrim Health Care does not cover Transanal Endoscopic Microsurgery (TEM) for lesions that do not meet the criteria above.

Supporting Information:

1. Technology Assessment: Transanal endoscopic microsurgery (TEM) is a minimally invasive surgical technique that was developed to avoid the morbidity of radical surgery for adenomas and early-stage rectal cancer, while still allowing for complete removal of the lesion. TEM requires specialized instrumentation. TEM uses a natural opening (the anus) to reach the target organ, and is a valuable surgical technique with a low complication rate for patients with appropriate rectal lesions. The main advantages of TEM are preservation of the rectum, anus and fecal continence, low complication rates, short operation times, lower blood loss, shorter hospital stays, and shorter recover times. Other advantages include better exposure, magnified stereoscopic view, and greater reach into the middle and upper rectum.

2. Literature Review: There is a substantial amount of clinical literature evaluating the use of TEM for treatment of rectal lesions. De Graaf et al. (2010) found TEM to be superior to transanal excision for rectal adenomas. The researchers compared results of 43 rectal adenomas treated with transanal excision to 216 rectal adenomas treated with TEM. TEM had significantly lower morbidity, and negative resection margins. A 2014 review by Heidary et al. found TEM to be safe for treating early T1 rectal cancer, for resection of endoscopically unresectable adenomas, and for the resection of rectal carcinoids. Tsai et al. (2010) also found TEM to be safe and effective in select patients with rectal lesions. Their results yielded the conclusion TEM can be offered for curative resection of benign tumors, carcinoid tumors, and select T1 adenocarcinomas, histopathologic staging in
indeterminate cases, and palliative resection in patients medically unfit or unwilling to undergo radical resection.

A 2009 prospective review of 487 patients treated with TEM for rectal cancer found TEM can produce long-term outcomes similar to those published for radical total mesorectal excision if applied to a select group of biologically favorable tumors (Bach et al.). Allaix et al. (2009) also found TEM to be safe and effective for adenoma and pT1 carcinoma because their results showed it carries a lower morbidity than conventional surgery and a recurrence rate comparable to that of conventional surgery.

Baatrup et al. (2008) presented long-term results on total survival, cancer-specific survival and recurrence in 143 patients treated with TEM for adenocarcinoma of the rectum. 50 percent of patients had T1 tumors, 33 percent had T2, 14 percent had T3, and 3 percent had an unknown stage. The procedure was performed with curative intent in 43 percent of patients, compromise in 52 percent, and palliation in 5 percent. Five year total survival was 66 percent and 5 year cancer-specific survival was 87 percent. For those with T1 tumors, cancer specific survival was 94 percent. Significant predictors for total survival were age and tumor size. Predictors for cancer specific survival were T stage, radical resection, tumor size and recurrence. 18 percent had recurrence and 15 percent had immediate reoperation. These positive results led Baatrup et al. to conclude TEM provides good long-term results for T1 tumors. Also, TEM may provide acceptable long-term results in older patients with no comorbidities with T2 cancers. Lastly, the authors stated TEM should not be used with intent to cure for tumors larger than 3 cm.

Guerrieri et al. (2008) reported on a study of 196 patients with distal rectal cancer without evidence of nodal or distant metastasis who underwent TEM. Of the 196 patients, 51 were T1, 84 T2 and 61 T3. All patients staged preoperatively as T2 and T23 underwent preoperative high-dose radiation. Since 1997, patients younger than 70 in good health also underwent preoperative chemo. The rectal cancer-specific survival rate at the end of the follow-up period was 100 percent for T1, 90 percent for T2, and 77 percent for T3. The researchers concluded the results of TEM appear not to be substantially different in terms of local recurrence and survival rate from those described for conventional surgery. Patients with T1 cancer and favorable histologic features may undergo local excision alone, whereas those with T2 and T3 require preoperative radiochemotherapy.

Bretagnol et al. (2007) reported on another prospective review of patients who underwent TEM for both benign and cancerous rectal lesions. 148 patients had adenomas and 52 had carcinomas. The median tumor distance from the anal verge was 8 cm (range 1-16 cm). At median follow-up of 33 months, local recurrence had developed in 11 patients with adenoma. At median follow up of 34 months, eight patients with carcinoma had developed local recurrence. Histological examination of the excised cancerous tumors revealed the following stages: T1 n=31, T2 n=17, and T3 n=4. Patients with carcinoma had an overall survival rate of 76 percent and a disease-free survival rate of 65 percent. The authors concluded TEM is an appropriate treatment option for benign rectal tumors. For carcinomas, it was deemed safe with strict patient selection and clear resection margins.

Floyd and Saclarides (2005) found TEM of T1 rectal cancers to yield low recurrence rates. Their study retrospectively reviewed records of 53 patients with T1 tumors treated with TEM. Radiation and chemotherapy were not administered. The mean follow-up was 2.84 years. Out of the 53, there were 4 recurrences occurring at 9 months, 15 months, 16 months, and 11
years respectively. Floyd and Saclarides concluded TEM of T1 rectal cancer yields low recurrence rates. There should be close follow-up for curative salvage for those with recurrence. A 2005 report by Maslekar et al. looked at the cost analysis for TEM for rectal tumors. The authors prospectively reviewed patient records that had undergone TEM between July 1997 and December 2003. A cost analysis was performed comparing procedural and related costs of TEM compared to the costs of the relevant open procedures. 124 patient cases were reviewed. Results showed a cost savings with the TEM procedure. The authors concluded TEM is a safe and cost-effective approach for selected rectal tumors and adenomas. Additional studies also support the use of TEM for certain benign and cancerous rectal lesions (Middleton et al., 2005; Lezoche et al., 2005; Moore et al., 2008; Doornebosch et al.; 2009). A 2012 study by Stipa et al. reported on the long-term outcomes of patients who underwent TEM at their facility between 1990 and 2011. The authors conducted a retrospective medical record review on 144 patients treated for rectal adenocarcinoma. In all cases, complete full-thickness excision was attempted. Overall 5-year survival was higher in patients who had the radical salvage procedure than in those who had transanal re-excision. The authors noted the study was limited by its retrospective nature, lack of technology at the beginning of the study and the mixed nature of the study group. They concluded outcomes depend on close surveillance for early detection of recurrence. Overall long-term survival after local excision with TEM followed by radical salvage surgery in cases of local recurrence is comparable to overall survival after initial radical surgery. Doornebosch et al. (2012) reported on the aim to better identify predictive histopathologic factors in patients with T1 rectal cancers treated with TEM only. The group evaluated specimens from 62 patients for whom the primary tumor containing invasive T1 carcinoma could be reevaluated. Tumors were scored according to predefined criteria and analysis of predictive factors for locoregional failure was performed. Results showed local recurrence rates at 3 years for tumors 3cm in size or smaller were significantly lower than for tumors larger than 3cm. The authors noted combining smaller tumors with submucosal invasion depth and budding led to identifying tumors that likely will not recur. Leonard et al. (2012) presented their 16-year experience with TEM. From November 1991 to August 2008, 123 patients (72 men and 51 women; median age, 68 years; range, 21-91 years) underwent TEM for excision of 105 adenomas with low- or high-grade dysplasia, 9 invasive adenocarcinomas (5 curative and 4 palliative resections), 2 neuroendocrine tumors, and 2 extramucosal lesions. Five additional patients had excisional biopsies, allowing staging after previous endoscopic resection. Most resections were full-thickness rectal resections. In addition, nontumoral indications included pelvic abscess (7 patients) and rectal strictures, which were either anastomotic or chemical. The authors results found TEM to be a safe and effective procedure for local excision of rectal lesions with a low recurrence rate and minimal consequences in terms of anorectal function. In addition, TEM proved to be feasible and effective for pelvic abscess drainage and rectal stenosis treatment. Steinhagen et al.’s (2011) experience found TEM is appropriate for benign lesions such as carcinoid tumors and adenomas and can also be curative in carefully selected patients with early-stage invasive rectal cancer. In cases of invasive adenocarcinoma, they felt it should be reserved for low-risk cancers in patients who accept the possible increased risk of recurrence. Sideris et al (2016) conducted a case control study comparing 10 early rectal cancers that had recurred against 19 cases with no recurrence. All participants in the study underwent TEMS for radiological Stage I rectal cancer. Data was prospectively collected on tumor histology,
morphological features, and follow-up parameters. Molecular analysis was performed to determine BRAF, KRAS, p16 O(6)-methylguanine-DNA methyltransferase (MGMT) and β-catenin. Out of the 29 specimens, 19 were KRAS wild type and 10 mutant. There was a significant association between KRAS mutant status and local recurrence. P16 expression greater than 5% was linked with earlier recurrence within 11.7 months. Membranous β-catenin expression was also related with KRAS mutant status but not with survival. BRAF gene was found to be mutant type in all cases tested. The authors concluded that KRAS/p16/β-catenin could be used as a combined biomarker for prediction of local recurrence and stratification of the risk for further surgery.

Allaix et al (2016) conducted an evidence-based review of current indications, controversies and future perspectives of TEM in the management of rectal cancer. The authors found that TEM allows to perform more accurate en bloc full-thickness local exision of rectal tumors compared to transanal excision. TEM alone seems to provide similar oncologic results in selected T1sm1 NO rectal cancers to those achieved by rectal resection and total mesorectal excision, without impairing anorectal function. The authors concluded that selected T1 rectal cancers with favorable features may be effectively treated with TEM without jeopardizing long-term oncologic outcomes. The lack of adequate lymphadenectomy represents the main concern of TEM for the treatment of rectal cancer.

Al-Najami et al (2016) analyzed the outcome after TEM procedures for ednomas and cancers with focus on local recurrence and complications. A total of 280 patients who had a TEM procedure were enrolled in this prospective study. Of the 280 tumors treated, 176 were benign and 104 were malignant. Complication rates were significantly higher in the malignant group compared to the benign group (24% and 10.8%, respectively), specifically in perforation/penetration to the peritoneal cavity. There was no difference in recurrence rate or mortality rates between groups. The authors concluded that TEM seems to be a safe and viable procedure for removing both benign and malignant lesions from the rectum. TEM offers low mortality, recurrence and complication rates after resection of malignant tumors.

4. Professional/Governmental Organizations:

American Society of Colon and Rectal Surgeons: The American Society of Colon and Rectal Surgeons' practice parameters for the management of rectal cancer states that local excision of rectal cancer is an appropriate alternative therapy for selected cases of rectal cancer with a low likelihood of nodal metastases. This probability is dependent on the depth of tumor invasion (T stage), tumor differentiation, and lympho-vascular invasion. Comparative trials to APR supported transanal local excision with curative intent for T1, well-differentiated cancers that are less than 3 cm in diameter and occupy less than 40 % of the circumference of the rectal wall. Furthermore, the tumor must be excised intact by full-thickness excision with clear margins. It should be orientated and pinned out for complete pathological examination. If unfavorable features are observed on pathological examination, a radical resection is warranted.

FDA: The Transanal Endoscopic Microsurgery (TEM) Combination System and Instrument Set (Richard Wolf Medical Instruments Corp) received 510(k) marketing clearance from the U.S. Food and Drug Administration in 2001.

Codes:

CPT:
46999 – Unlisted procedure, anus

References:


Summary of Changes

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<td>11/16</td>
<td>Updated references and literature</td>
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Approved by Medical Review Committee: 11/21/2016
Reviewed/Revised: 1/11; 11/12; 11/14; 11/16
Initiated: 1/11