

Transanal Endoscopic Microsurgery

A Single Surgeon's Experience

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Objective: To evaluate a single surgeon's experience with transanal endoscopic microsurgery (TEM) with regard to incidence of complications, recurrence rate of benign and malignant lesions, and impact on the treatment of rectal cancer.

Design: Prospective tumor registry.

Setting: Tertiary care university hospital.

Patients: Seventy-three patients undergoing TEM between January 1991 and November 1996.

Main Outcome Measures: Complications, recurrence rates, and use of this technique with respect to radical operations.

Results: The arrival of TEM was associated with an increase in the number of operations for rectal cancer; however, the use of TEM remained constant relative to radical resections. Use of TEM resection alone is appropriate for all adenomas and cancers staged Tis and T1. Use of TEM alone is not an appropriate treatment for T2 cancers. Four patients (5%) experienced fecal soilage, which was long lasting in only 1 (1%).

Conclusions: Transanal endoscopic microsurgery is a safe technique and provides improved access to lesions in the middle and upper rectum. Thus far, it has not had a significant impact in the overall treatment of rectal cancer.

Arch Surg. 1998;133:595-599

LOCAL EXCISION of rectal neoplasms is an accepted method of treating selected lesions and can be accomplished through either a transanal approach or a posterior proctotomy. The former is hindered by poor exposure and visibility of lesions in the middle and upper rectum. While the latter approach does give somewhat improved exposure of these more cephalad tumors, it may be complicated by fecal fistulae or sphincter impairment. Transanal endoscopic microsurgery (TEM) has emerged as a better technique for removing lesions in the middle and upper rectum, and it obviates the need for a posterior proctotomy.¹⁻⁴

Pioneered by Gerhard Büess, MD, in Tübingen, Germany, and manufactured by the Richard Wolf Company (Rosemont, Ill), the rectoscope has excellent optics and a long instrument casing, both of which greatly facilitate transanal surgery. Furthermore, the transanal rectoscope extends the boundaries of transanal surgery by providing access to lesions previously inaccessible with conven-

tional means. The net result is an operative approach to rectal lesions that is not hindered by the poor exposure and limited reach associated with conventional retractors.

Virtually any adenoma of any size or degree of circumferential involvement can be removed with TEM. Adenomas are removed with a 5-mm margin of normal mucosa, and dissection is undertaken in the submucosal plane. For large adenomas or those that have firm areas within them or previous histological evidence of atypia or dysplasia, the risk of harboring an occult cancer is increased⁵; for such lesions, it is generally recommended that a full-thickness excision be performed. Other benign indications for TEM include transrectal rectopexy for prolapse, for which there has been limited experience to date, and correction of anastomotic strictures by stricturoplasty.

Properly selected rectal cancers can also be removed with TEM; for such lesions, a 1-cm margin of normal tissue surrounding the lesion should be obtained. A full-thickness excision is mandatory to accurately stage the depth of penetration

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MATERIALS AND METHODS

The basic TEM instrumentation includes the combined endosurgical unit, which regulates carbon dioxide insufflation, saline irrigation, and suction. The rectoscope is 40 mm in diameter and is available in lengths of 12 and 20 cm. Once the rectoscope is inserted to the desired location within the rectum, it is secured to the operating room table with a double ball-and-socket supporting arm. During the dissection, the supporting arm is moved frequently to maintain direct visibility of the lesion. The end of the rectoscope is sealed with an airtight face piece that has 5 entry ports. These ports, in turn, are sealed by rubber caps and sleeves so that the various instruments necessary for the dissection can be inserted. The binocular stereoscopic eyepiece is inserted through one of the ports, and it has an accessory scope for video hookup. The various instruments needed are suction catheter, a needle-tipped high-frequency electrical knife, tissue graspers that are oriented to either the right or left, scissors, and a needle holder. The suction catheter, tissue graspers, and needle-tipped knife can all be connected to the cautery unit, which greatly facilitates control of hemorrhage and coagulation of bleeding vessels.

Training for the TEM technique was obtained during a 1-week course taught by Gerhard Büess in October 1990. The instrumentation was then purchased by Rush-Presbyterian-St Luke's Medical Center, Chicago, Ill, and procedures were started in January 1991. A prospective registry was then instituted; patient and tumor demographics were recorded.

Before the procedure, the entire colon was evaluated with either colonoscopy or barium enema. Most of the cancers were evaluated with transrectal ultrasonography to determine suitability for local excision. A formal bowel cleansing was performed initially with polyethylene glycol lavage solutions; however, recently cleansing with a phosphosoda solution (C.B. Fleet Co Inc, Lynchburg, Va) has been instituted. This report represents our initial 6-year experience from January 1991 to October 1996. A minimum of 1-year of follow-up is available for the patients operated on in 1996.

by the cancer. Strict patient selection cannot be overemphasized, and the necessary selection criteria have been well established in the literature. These selection criteria include a well-differentiated tumor, lack of vascular invasion of the tumor, minimal tumor penetration of the rectal wall, a tumor containing no mucinous component, a tumor smaller than 4 cm, and good exposure and visibility of the entire lesion. These favorable features are associated with a low propensity for lymph node metastases, thereby giving favorable cure rates when local excision is performed with curative intent.⁶

Care should be exercised when operating on anterior lesions, especially in women, where there may be inadvertent entry into the vagina or the peritoneal cavity through the cul-de-sac, which is quite low in some women

and unpredictable in its location. The position of the patient in the operating room is dependent on tumor location. Since the bevel of the rectoscope must face downward, patients with anterior lesions are placed in the prone position, whereas patients with posterior lesions are placed in the lithotomy position. Patients with lateral lesions are placed accordingly into the appropriate decubitus position.

The purpose of this study was to evaluate a single surgeon's experience with TEM at a tertiary care university hospital. Specifically, this study was to determine the incidence of complications, the recurrence rate of benign and malignant lesions following excision, and overall impact of TEM on the treatment of rectal cancer.

RESULTS

Table 1 shows the number of TEMs performed per year, as well as the overall indications for the procedure. Despite the cumulative experience gained, operative time and amount of blood loss did not change appreciably with time. This is probably because increasingly difficult lesions were addressed as more experience was gained with the technique.

Of the 28 adenomas removed by TEM, the average size was 3.2 cm (range, 1.0-8.0 cm) and average distance was 6.0 cm from the dentate line (range, 1.0-12.0 cm). Average blood loss was 48 mL, and average operative time was 94 minutes. Four (14%) of 28 lesions recurred: 3 were treated with proctoscopic fulguration and 1 with TEM.

Since the arrival of TEM at this institution, the total number of operations for rectal cancer has increased appreciably (**Table 2**). The most common operation performed has been low anterior resection; abdominoperineal resections were performed infrequently during the study period, reflecting the general trend noted during the past decade. Of the 43 cancers treated by TEM (including in situ carcinoma), average size was 3.6 cm (range, 1.0-8.0 cm); average distance from the dentate line, 5.7 cm (range, 1.0-12.0 cm); average blood loss, 61 mL; and average operative time, 111 minutes. Of the 13 lesions with in situ carcinoma, 2 recurred (15%). One was treated with a conventional transanal excision because of its close proximity to the anus, and the other recurred as a benign adenoma and was treated simply with proctoscopic fulguration.

Of the TEM procedures performed for 16 T1 carcinomas, 1 was converted immediately to low anterior resection because of poor operative exposure. The lesion extended up and around the rectosigmoid junction, and it was not possible to see the complete lesion. Two T1 cancers recurred as adenomas (13%), 1 was treated with proctoscopic fulguration and 1 was excised transanally. In 2 patients, T1 cancers recurred as cancer (13%). One of these patients had received radiotherapy after TEM because of a positive lateral margin; nevertheless, recurrence was noted 1 year later, and the patient subsequently underwent an abdominoperineal resection. The patient is alive and free of disease 3 years postoperatively. The remaining T1 cancer that recurred following TEM was treated with low anterior resection. This patient is alive and free of disease 4 years postoperatively.

Table 1. Transanal Endoscopic Microsurgery Cases by Year

| Year | Total Cases, No. | Adenoma, No. | Cancer, No.* | Carcinoid, No. | Procedure Time, min† | Blood Loss, mL‡ |
|--------------|------------------|--------------|--------------|----------------|----------------------|-----------------|
| 1991 | 13 | 5 | 8 | 0 | 111 | 56 |
| 1992 | 6 | 2 | 4 | 0 | 115 | 38 |
| 1993 | 14 | 3 | 11 | 0 | 128 | 75 |
| 1994 | 7 | 3 | 4 | 0 | 107 | 81 |
| 1995 | 17 | 8 | 9 | 0 | 74 | 56 |
| 1996 | 16 | 7 | 7 | 2 | 96 | 28 |
| Total | 73 | 28 | 43 | 2 | NA | NA |

*Of the 43 cases of cancer, 13 were stage Tis; 16 stage T1; 13, stage T2; and 1, stage T3.

†NA indicates data not applicable.

Table 2. Total Operations (N = 168) for Rectal Cancer by Year

| Year | Total Operations, No. | TEM,* No. (%) |
|--------------------------------|-----------------------|----------------|
| Before TEM Introduction | | |
| 1988 | 16 | NA |
| 1989 | 17 | NA |
| 1990 | 13 | NA |
| After TEM Introduction | | |
| 1991 | 30 | 8 (27) |
| 1992 | 17 | 4 (24) |
| 1993 | 35 | 11 (31) |
| 1994 | 27 | 4 (15) |
| 1995 | 28 | 9 (32) |
| 1996 | 31 | 7 (23) |
| Total† | 168‡ | 43 (26) |

*TEM indicates transanal endoscopic microsurgery; NA, data not applicable.

†Total is sum after 1990.

‡Other types of operations performed were low anterior resection (n = 91; 54%), abdominoperineal resection (n = 27; 16%), and conventional local excision (n = 7; 4%).

There have been no cancer-related deaths among the patients with T1 carcinomas.

The patients with T2 carcinomas represent a very heterogeneous group, having undergone different treatment plans after TEM excision. Healthy patients with T2 cancers are routinely advised to undergo either radical resection or adjuvant chemotherapy and radiation after local incision. Only the very elderly or medically unfit patients are simply observed. Of our 13 patients with T2 lesions, 3 refused all treatment after TEM excision and all experienced recurrent cancer. Two of these patients died of cancer and 1 is currently asymptomatic with recurrent cancer. Three patients received radiotherapy after TEM excision; 1 was cured, 1 died of a myocardial infarction during radiotherapy, and 1 experienced recurrent cancer. This latter patient subsequently underwent an abdominoperineal resection, but died of metastatic disease. Two patients underwent prompt radical excision of their T2 cancer following TEM resection, and both died of disseminated disease, 1 and 4 years postoperatively. Four patients were octogenarians and did not undergo any further therapy; 2 subsequently experienced recurrent cancer, 1 was cured, and 1 was unavailable for follow-up. The remaining patient with T2 lesions underwent radiotherapy and chemotherapy after

Table 3. Transanal Endoscopic Microsurgery Complications

| Complication | Cases, No. |
|---|------------|
| Fecal soilage* | 4 |
| Fever | 3 |
| Delayed bleeding | 2 |
| Diarrhea caused by <i>Clostridium difficile</i> | 2 |
| Immediate conversion† | 2 |
| Hemorrhoid thrombosis | 1 |
| Pneumonia | 1 |
| Urinary retention | 1 |
| Entry into peritoneum | 1 |
| Broken ribs‡ | 1 |
| Total | 18 |

*Fecal soilage was permanent in 1 case.

†This indicates transanal endoscopic microsurgery procedure converted to laparotomy.

‡This patient's ribs were broken during positioning.

TEM and was subsequently unavailable for follow-up. Therefore, of the 10 patients with T2 carcinomas with available follow-up after TEM excision, 8 patients had either local or distant recurrences. However, as noted above, this is a very diverse group of patients treated with a variety of different means.

The complications from TEM are shown in **Table 3**. Of note, 4 (5%) of the 73 patients experienced temporary fecal soilage, which resolved in all but 1 patient (1%). Two patients experienced delayed bleeding after TEM; however, only 1 required admission to the hospital and was treated conservatively without blood transfusion. There was a recognized entry into the abdominal cavity in 1 patient; the abdominal entry was repaired in layers, and the procedure completed as planned. Two patients underwent immediate conversion to laparotomy and resection because of large bulky lesions.

COMMENT

Transanal endoscopic microsurgery is a safe technique, as shown by the low number of complications; however, this procedure is not a license to disregard established criteria for local excision of cancers. The exceptions to this may be tumor size and location. With its superior optics, constant rectal distention, and longer instrument casing, TEM is not limited to small, distally located lesions. One may argue that cancers within the middle and upper rectum should all be treated with low

anterior resection; however, if we accept the criteria for local excision as being appropriate for lesions in the distal rectum, we must embrace them as well for lesions in the middle and upper rectum. Many of the lesions addressed in this report were located in the distal rectum. The explanation for this is 2-fold. First, to gain sufficient experience and familiarity with the technique, all lesions were addressed with TEM at the onset of this study. As experience was gained, the benefits of the superior optics and exposure produced by constant rectal distention with carbon dioxide became obvious, and, at this point, it is not possible to revert to the cumbersome conventional instruments.

A comparison between TEM and conventional transanal excision cannot be made based on the experience reported here. As stated, TEM has been adopted almost exclusively for local excision. However, there are disadvantages of TEM instrumentation when operating in the distal rectum. First, the lower lip of the beveled end of the rectoscope may slip externally, allowing carbon dioxide to escape. If this occurs, the operative field collapses and visibility is lost. Second, there may be bleeding from the hemorrhoidal veins encountered near the anal canal. Brisk hemorrhage is difficult, but not impossible, to control with TEM instrumentation. Overall, TEM has more obvious advantages than conventional instrumentation when addressing lesions in the middle and upper rectum and avoids cutaneous fistulae, which may complicate transsacral operations.

The results reported herein confirm that local excision alone (TEM in this case) is appropriate treatment for Tis and T1 cancers; recurrence rates of 15% and 13%, respectively, were noted. No cancer-related deaths occurred in these groups. The patients with T2 cancers form a heterogeneous group with treatment varying based on individual circumstances. In this group, the safest conclusion that can be reached is that local excision alone by TEM has an unacceptable recurrence rate. The same probably holds true for transsacral and conventional transanal techniques. This reflects the higher likelihood of nodal metastases with increasing depth of penetration and is not a condemnation of the technique or carbon dioxide insufflation.

Overall, the arrival of TEM at this institution was associated with an increase in the total number of operations for rectal cancer. However, the percentage of local excisions has remained relatively unchanged. Radical procedures remain the most common operation because most patients do not come in with small superficial lesions. The increase in the number of total operations is probably multifactorial. Some patients are referred for TEM resections, but do not meet the selection criteria for local excision and receive either a low anterior resection or abdominoperineal resection. Also, the increase in total number of operations may be attributed to my known interest in colorectal cancer or to the medical center's being increasingly proactive in securing health care contracts.

Currently, TEM has not had a significant impact on the treatment of rectal cancer. If, however, preoperative chemotherapy and radiation becomes the standard of care and has the effect of causing a downgrade of tumor stage,

shrinking tumors, or even inducing a complete remission, TEM may have an increased role. However, this remains to be seen and can only be answered with further studies.

Presented at the 105th Scientific Session of the Western Surgical Association, Colorado Springs, Colo, November 17, 1997.

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DISCUSSION

Susan Galandiuk, MD, Louisville, Ky: Dr Saclarides has presented an amazing series of more than 70 patients. One third of them were treated for polyps, and two thirds of them were treated for cancers. Were endorectal ultrasound scans performed in these patients? In my practice, that has been one of the most useful tools in terms of determining the degree of penetration of a lesion preoperatively, which enables choice of the proper technique intraoperatively. The TEM will have its most valuable use in the treatment of mid to upper rectal villous adenomas that can be removed by conventional techniques transanally, but are obviously much more easily removed using this technique. Dr Saclarides in his paper states that regardless of size, and regardless of degree of circumferential involvement, most polyps will be able to be treated by this technique; I disagree simply because in lesions larger than 4 cm in diameter, there is a much higher risk of invasive adenocarcinoma (about 30% in those lesions) and also a higher recurrence rate, although his 14% recurrence was quite acceptable.

In terms of treatment of cancers with this approach, I have the same opinion of TEM as I do of local excision in general. There are very few patients who are good candidates for this. Local excision was very popular about 15 years ago or so when there were not a lot of good sphincter-saving procedures. With the work of Professors Lazarus and Park, the ease of doing low anterior resection with staple techniques, the very good functional and oncologic results we see with colopouch-anal anastomosis, and the very good oncologic results in those patients, there is less and less of a role for TEM.

One patient I would like to tell you about is a patient who demonstrates that one has to be careful of saying a patient is too old or too infirm or should just be treated by a local excision. I had a 77-year-old patient who had a very large rectal villous adenoma. He had recurrent ventricular tachycardia and an implantable pacemaker. We did a transanal excision, and there was 1 area of submucosal invasion. I had counseled the

patient that he should have a coloanal anastomosis with rectal excision because of the chance of there being invasive disease. His doctors all argued that he was too ill for that procedure. Well, 3 years later, I wound up doing a colopouch-anal anastomosis, and he received postoperative radiation and chemotherapy; he now is dying of pulmonary metastasis. So, just because you have the technical ability to do something, I do not know if local excision is the wisest oncologic option. What part of the cost of attaining this equipment is in acquisition and operating fees?

Robert D. Madoff, MD, St Paul, Minn: My question for Dr Saclarides is that the great majority of the lesions in your series of patients were smaller than 10 cm and that is an area where most surgeons are happy to address lesions either transanally or transrectally. Is this really a technical advance for removal of low and mid rectal cancers? Is it easier to do TEM or a transanal excision on patients whose tumors are from 6 cm to 10 cm?

Dr Saclarides: Were ultrasound scans performed? Not routinely. We started using the TEM technique in 1991, but did not start doing ultrasound scans until 1992. I still do not use them routinely now, because if I have an elderly patient with a small, 1-cm tumor, I do not care what the ultrasound scan reveals, I am going to excise that lesion transanally. If I have a patient who is not fit medically for radical surgery and has a small lesion, I am not going to do an ultrasound scan. With regard to the degree of circumferential involvement being a contraindication, I disagree. I learned this technique from Ger-

hard Büess, who does sleeve resections and hand-sewn end-to-end anastomosis transanally. If your pathological result comes back with invasive cancer, you can certainly address that cancer at a later date. It is true that low anterior resections are easy to do with stapling devices; it is true that coloanal anastomoses are nice, but do not forget that we are subjecting patients to a long hospital stay and, despite what the published reports state, the functional result after a coloanal anastomosis is not perfect. It is nice to hear anecdotal reports about how sick people can tolerate radical surgery, but there is no scientific evidence to back that up. In my series of patients, there were 4 octogenarians, and there were several cardiac patients who were found to have early-stage lesions because of bleeding secondary to warfarin sodium (Coumadin) taken for severe cardiomyopathy. These patients cannot undergo a radical operation.

Dr Madoff, there is no question that this is an easier operation once you become familiar with the technique. There is a steep learning curve. This is the hardest thing I have had to learn. It is very much different than laparoscopy where if you need countertraction, you simply put in another port and pull in the opposite direction. With TEM, everything is operated and manipulated in parallel, sort of like playing that hockey game where you are twisting the men. It is difficult to learn, but having done so, I cannot go back and do it the old-fashioned way. The exposure is just too good with this technique.

The cost of the equipment in 1991 was \$44 000. That is why you have to have the volume to justify the expense.

IN OTHER AMA JOURNALS

JAMA

Characteristics of Women With and Without Breast Augmentation

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Objective.—To compare selected characteristics of women with and without augmentation mammoplasty to identify differences between these 2 groups of women.

Design and Study Participants.—White women identified as controls in previously conducted population-based, case-control studies formed the study population for the present cross-sectional analysis (N=3570).

Main Outcome Measure.—Interview information on selected characteristics was compared between women who had received augmentation mammoplasty (n=80) and other women (n=3490) using the prevalence odds ratio (pOR) as the measure of association.

Results.—Women with breast implants were more likely to drink a greater average number of alcoholic drinks per week (for ≥ 7 drinks vs 0 drinks: pOR=2.9, 95% confidence interval [CI]=1.5-5.5), be younger at first pregnancy (for age <20 years vs age 20-29 years: pOR=1.6, 95% CI=1.0-2.7), be younger at first birth (for age <20 years vs age 20-29 years: pOR=1.9, 95% CI=1.1-3.3), have a history of terminated pregnancies (for ≥ 1 termination vs 0 terminations: pOR=2.0, 95% CI=1.2-3.4), have ever used oral contraceptives (pOR=2.2, 95% CI=1.0-4.7), have ever used hair dyes (pOR=4.5, 95% CI=1.3-15.4), and have had a greater lifetime number of sexual partners (for ≥ 14 partners vs ≤ 4 partners: pOR=8.9, 95% CI=3.1-25.5) than other women. A history of smoking, lactation, high blood pressure, or thyroid disorders, as well as the number of pregnancies, full-term births, or miscarriages, differed little between women with and without implants. Women with breast augmentation were much less likely to be heavy than other women (for ≥ 74 kg vs <56 kg: pOR=0.1, 95% CI=0.03-0.3).

Conclusion.—The differences we found between women with and without breast implants suggest that consideration and evaluation of confounding factors in future studies will help to clarify some of the long-term health consequences of having breast implants. *JAMA.* 1997;277:1612-1617

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