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Transanal Endoscopic Microsurgery in Italy

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The Italian experience with Transanal Endoscopic Microsurgery (TEM) started in 1991. Until April, 1994, 122 patients were operated on by such a technique in six centres. The surgical protocol in the 66 patients with benign lesions was similar to that described by Buess. In contrast to the German experience, the indications of TEM for cancer have been extended to more advanced tumours and in 22 out of 56 patients with rectal carcinoma adjuvant radiation- or radiation-chemotherapy have been applied according to various protocols. In 88% of TEM for rectal tumours the operation has been carried out according to a full-thickness technique, with or without perirectal fat excision. Postoperative morbidity of TEM for adenoma was 15.8% and that of TEM for carcinoma 29.6%. There was no postoperative mortality. Local recurrence rate after TEM for adenoma was 10.5%, while that after TEM for cancer was 9.25%. No local recurrence has been reported among patients treated with a combination of TEM and adjuvant radiation treatments. The median follow-up in the 6 centres ranged between 7 and 16 months. A randomised prospective clinical trial has been planned in order to evaluate the role of transanal endoscopic microsurgery in the treatment of locally advanced rectal cancer.

Key words: Rectal Tumours, Endoluminal Microsurgery, Adjuvant Radiation Therapy

Introduction

In 1983 Buess developed a new technique for the endoscopic treatment of rectal tumours, called Transanal Endoscopic Microsurgery (TEM) (1–4). Such a technique required the development of dedicated technologies (1) and optimum surgical skills but allows a precise dissection and radical removal of all benign neoplasms and malignant tumours in selected cases. This new approach to local treatment of rectal tumours carries several advantages compared to other local procedures such as the Mason or the Parks operations: it allows the removal of very highly located tumours (up to 20 cm from the anal verge) and in the Buess series as shown led to fewer postoperative complications and a lower recurrence rate (2, 3).

The indications for TEM in cancer are very restricted in the German experience and mainly represented by T1 low-risk tumours (according to the Hermanek classification) (5–7).

Experience with TEM startet in Italy in 1991 (8) and the operation is today performed in 6 centres, in three of which, according to data collected from the international literature (9–13), the indications of TEM for cancer have been extended to more advanced neoplasms, in association with radio- or radio-chemotherapy. This paper is a review of the early results of the Italian experience in local treatment of rectal tumours by Transanal Endoscopic Microsurgery.

Material and Methods

Six centres have participated in the review of TEM data. The centre that first brought the TEM procedure into clinical practice in Italy started at the end of 1991, the last started in the first half of 1993. Until June, 1994 an overall number of 145 patients were operated on according to such a technique (see Table **1**), but the present report concerns only the first 122 cases.

Out of these 122 cases, 58 were adenomas, 54 adenocarcinomas, 2 epidermoidal carcinomas, 2 rectal ulcers and 6 other diseases. There were 71 males and 51 females with an age distribution as shown in Figure **1**.

The tumours were mainly located in the middle rectum or involved the first valve of Huston (60.7%) (Figure **2**).

Preoperative patient assessment consisted of digital exploration, rigid rectoscopy with multiple biopsies, endoluminal ultrasound (14, 15) and colonoscopy. In the cancer group the preoperative work-up was completed with CT scan and liver US. Two centres did not perform endoluminal US routinely or started in the last cases because of lack of such a diagnostic facility. Informed consent was obtained from all patients.

In all centres but one, polyethylene glycol was given preoperatively for bowel preparation. In one centre the preparation consisted of bowel lavage with 10 litres of isotonic solution via a nasogastric tube. Antibiotic association consisting of metronidazole and a 2nd generation cephalosporine was given preoperatively in all cases.

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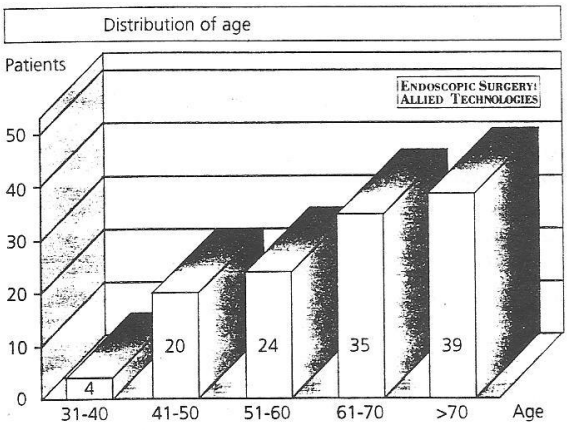

Figure 1: Age distribution.

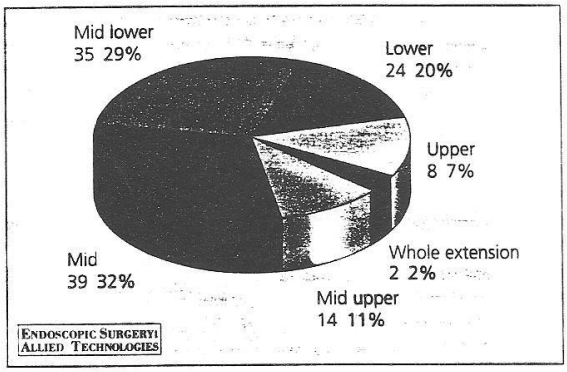

Figure 2: Tumour localisation.

In 91.8% of patients the operation was performed under general anaesthesia. In the remaining cases the intervention was carried out under loco-regional anaesthesia.

Out of 122 TEM procedures performed, 116 were resections of rectal tumours; the remaining cases were: 1 suture of parietal defect, 1 resection of rectal ulcer, 1 drainage of perirectal abscess, 1 rectal mucosectomy associated with open total colectomy and 2 immediate conversions to laparotomy. The operation was performed according to a full-thickness technique, with or without perirectal fat excision, in 88% of TEM for rectal tumours (Table **2**).

In 3 centres local treatment of T2 and T3 N-negative cancers were attempted in association with radiation therapy (Table **3**).

Results

Morbidity after TEM for adenoma was 15.8% (Table **4**), with no postoperative mortality. Patient follow-up ranged between 1 and 27 months, with a median follow-up ranging from 7 to 16 months depending on the centre.

The excision was performed in 44 cases (77.2%) with a full-thickness technique, in 2 cases (3.5%) with a partial thickness technique, and in 11 cases (19.3%) a mucosectomy was performed. In one case the operation was converted immediately.

There were 6 local recurrences (10.5%) treated in all cases but one by flexible endoscopy. In the remaining case the patient underwent a laparoscopic segmental resection of the rectum.

The postoperative T staging of adenocarcinomas after TEM is shown in Table **5**. Among these patients there were 13 cases of adenomas which the postoperative histological study showed to be malignant lesions or where a carcinoma was found in the adenoma. Of these 13 cases, 1 was a *carcinoma in situ*, 9 were pT1 cancers, 2 pT2 cancers, and 1 pT3 cancer.

In all cases a full-thickness excision with or without dissection of the perirectal fat was performed.

Postoperative morbidity of TEM for cancer was 29.6% (Table **6**). The postoperative follow-up observation (3 month period) ranged between 1 and 30 months, with a median follow-up in the 5 centres, where TEM for cancer have been performed respectively, of 7, 8, 12, 16, and 23 months.

Out of 52 completed TEM procedures for adenocarcinoma, local recurrences developed in 5 patients (9.8%); none of the local recurrences developed in patients with associated radiation therapy. Of these 5 patients, 4 were pT2 and 1 pT1 tumours (Table **7**). All the other patients were disease-free at the last follow-up observation.

Discussion

Local surgery for rectal adenomas has been described by several authors and is mainly carried out through the endoluminal or the trans-sphincteric approach (16). Because of the possibility of performing a full-thickness resection and reaching highly located tumours, the transanal endoscopic microsurgical approach has been shown highly effective with very large adenomas, which may have areas of degeneration in a high percentage of cases.

Despite the results of Buess, the recurrence rate in the Italian series is far too high. This seems to be related to technical problems (TEM is a challenging procedure!): the data presented were received from several centres with multiple learning curves. The analysis of data showed that there is a lower recurrence rate in the most experienced centres.

Results after TEM for cancer are not yet evaluable, since the follow-up is still too short (median follow-up in the centres where more than 1 operation for rectal carcinomas have been performed ranged from 7 to 16 months).

Well-differentiated T1 adenocarcinomas, well-differentiated T2 adenocarcinomas in elderly patients (> 75 years), and T2 and T3 adenocarcinomas in high-risk patients (palliative treatment) are the indications for TEM for rectal malignancy in the Italian centres where such a surgery is performed.

Table 1: Patient distribution.

	No. of cases
5th Dept. of General Surgery, University of Rome "La Sapienza"	51
Dept. of Surgery, University of Ancona	51
Dept. of General Surgery, University of Turin	25
4th Dept. of General Surgery, University of Rome "La Sapienza"	5
Dept. of General Surgery, S. Agostino Hospital, Modena	11
1st Dept. of Surgery, Martini Hospital, Turin	2
Overall	145

Table 2: Excision techniques during TEM for rectal tumours.

	Adenomas*	Malignant Tumours**
Full Thickness	44	56***
Partial Thickness	2	
Mucosectomy	11	
Overall	57*	56***

* 1 immediate conversion to open surgery not considered in this table
** enclosed 2 epidermoidal carcinomas
*** with or without perirectal fat excision

Table 3: Association of TEM and radio- or radio-chemotherapy.

	T2	T3	T2M1	T3M1
TEM + Postop. Radiotherapy	8	4		
TEM + Postop. Radio-chemotherapy			1	1
Preop. Radiotherapy + TEM + Postop. Radiotherapy	4	2		
Preop. Radiotherapy + TEM	1			
Preop. Radio-chemotherapy + TEM		1		

Table 4: Postoperative morbidity of TEM for adenoma (57 cases).

Bleeding	2
Dehiscence	3
Stenosis	2
Others	2
Overall	9 (15.8%)

In addition to the indications proposed by Buess and supported by other German authors, we have associated in locally advanced rectal cancers (T2–T3, N0) radio- and/or chemotherapy. The most important criterion for exclusion is the presence of positive lymph nodes (10).

Table 5: Postoperative T staging of patients operated on by TEM for carcinoma (52 patients).

Carcinoma *in situ*	1
T1	21
T2	21
T3	9

Table 6: Complications.

Dehiscence	8
Bleeding	3
Stenosis	2
Fistula	1
Incontinence	1
Pulmonary microembolism	1
Overall	16 (29.6%)

Table 7: Local recurrences after TEM for carcinoma.

	No.	Time interval	Treatment
pT1	1	5 months	APR
pT2	4	6 months	APR + Radiation Therapy (sandwich)
		8 months	TEM + Post-Radiation Therapy
		12 months	TEM + Radiation Therapy (sandwich)
		12 months	Radiation Therapy

The multicentric origin of the data makes it difficult to obtain homogeneous materials and consequently produces varying results. In our experience there are five subsets of patients (Table 3) treated with radio-therapy or radio-chemotherapy with 12 cases out of 22 who received only postoperative radiation therapy. Most of the other experiences reported in the international literature, indeed, show local excision to be associated with postoperative pelvic radiation therapy (10–13).

This may by related to the possibility of selecting patients suitable for such a treatment after the histological examination (10).

The present trend in the Italian centres where such a treatment is mostly performed is to combine high-dose preoperative radiation therapy and full-thickness TEM excision (12). Surgery is usually performed 3 to 4 weeks after completion of radiation therapy. In the early cases, when the healing response after high-dose radio-therapy was not yet known, patients were treated by postoperative radio-therapy or combined preoperative and postoperative radiation therapy.

To obtain homogeneous data in relation to a standardised treatment of locally advanced rectal cancer (T2, N0) we plan to start a prospective trial of preoperative radio-chemo-therapy and local excision with TEM.

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