



# Transanal endoscopic microsurgery for rectal cancer

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## Abstract

If cure is intended for rectal cancer, total mesorectal excision with autonomic nerve preservation (TME) is the gold standard. Transanal resection is tempting because of low mortality and morbidity rates. However, inferior tumour control, provoked by the limitations of the technique, resulted in its cautious application and use mainly for palliation. Transanal endoscopic microsurgery (TEM) is a minimal invasive technique for the local resection of rectal tumours. It is a one-port system, introduced transanally. An optical system with a 3D-view, 6-fold magnification and resolution as the human eye, together with the creation of a stable pneumorectum, and specially designed instruments allow full-thickness excision under excellent view and a proper histological examination. The technique can also be applied for larger and more proximal tumours. Mortality, morbidity as well as incomplete excision rates are minimal. Local recurrence and survival rates seem comparable to TME in early rectal cancer. TEM is the method of choice when local resection of rectal cancer is indicated. Results justify a re-evaluation of the indications for the local excision of rectal cancer with a curative intent. © 2002 Elsevier Science Ltd. All rights reserved.

**Keywords:** Local excision; Rectal tumour; Rectal cancer; Local therapy; Minimally invasive surgery; Transanal endoscopic microsurgery (TEM)

## 1. Introduction

Total mesorectal excision with autonomic nerve preservation (TME) is the surgical technique of choice if cure is intended in rectal cancer. However, even in expert hands, mortality is 1–7% and morbidity, including genitourinary dysfunction, faecal incontinence and permanent colostomy, 13–46%. Moreover, disabling recurrent disease is observed in 4–10% and 5-year survival is reduced to 74–87% [1–5].

Because of limited mortality and morbidity, local resection is advocated. The method of choice is the transanal route. Mortality is 0–2% and morbidity 15–25%, usually mild. Only distal and smaller tumours can be excised with limited view. There are positive margins in 12–60% and local recurrence rate is 0–27% [6–10]. Because of these disadvantages, the sphincter-saving

Kraske technique, the sphincter-splitting York Mason technique and the transanal use of the transurethral resectoscope have been introduced. They are technically demanding, mortality is 1–5% and morbidity, often severe, ranges from 18 to 34%. As a result, these techniques are used sparingly and tumour control in rectal cancer is described only anecdotically [11,12]. The most natural conclusion is that resection transanally is the local technique of choice with less mortality and morbidity, but only possible in distal and smaller tumours with inferior tumour control compared with TME. Until now, these facts have led to the cautious application of local excision of rectal cancer and its use mostly only for palliation. In 1984, Buess introduced transanal endoscopic microsurgery (TEM) as an alternative technique for local resection of rectosigmoid tumours. Mortality was 0–0.3% and overall morbidity 4.8–8%. Complete margins were observed in 92%. In adenomas, the recurrence rate was 3.5% and in T1 tumours 3–4%. These excellent results were assessed, even though tumours up to 24 cm from the dentate line and circumferential tumours were

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excised. Either mucosectomy or full thickness excision was possible and in one piece, allowing a proper histological examination. These facts were thought to be due to the excellent view obtained due to the characteristics of the equipment [13–17].

Following these results, TEM was introduced in three Dutch hospitals, in the first instance for adenomas and for rectal cancer cases only for palliation. At a later stage, the technique was also used for T1 tumours with a curative intent. In this study, results after TEM for rectal cancer are presented.

## 2. Patients and method

From 1996 to 2001, TEM was performed in 76 patients with 76 carcinomas. The characteristics of the enrolled patients and tumours are shown in Table 1. All patients were analysed according to a standard protocol including history, physical examination with digital rectal examination, blood tests, colonoscopy with biopsy, rigid rectoscopy, anorectal endosonography, chest X-ray and liver ultrasound. Rigid rectoscopy was performed to measure the distance from the dentate line to the lower margin of the tumour and in particular to assess the exact location of the tumour because, at operation, the patient should be positioned with the tumour downward. The rate of captured circumference of the rectal wall and the

area of the tumour, being the multiplication of length and width of the base of the tumour, were measured at the time of operation. The longest distance refers to the most proximal margin reached.

TEM is a minimal invasive operation. The central component of the one-port system consists of a rectoscope, handle and a four-port working insert. It is introduced transanally and fixed to the operating table with a Martin arm allowing positioning in any conceivable position. A stereoscope with a documentation endoscope and a maximum of three instruments can be introduced in the working insert. An insufflator and specially developed TEM pump are connected via a tube system and take care of gas insufflation, pressure measurement, irrigation and suction. An elektro surgery unit is used for cutting and coagulation. The system is airtight, which is necessary for creating a pneumorectum. Use of a multi-functional instrument is advocated to reduce the number of instruments (Fig. 1) [13,18,19]. Marking dots are placed at a 0.5–1 cm margin around the tumour, followed by excision, possible in any desired plane—submucosal to full thickness. The different layers of the rectal wall and the perirectal fat can be clearly identified. After removal of the specimen, the defect is closed transversally with a running suture. Clips are used as

Table 1  
Patient and tumour characteristics

Sex	
Female	27
Male	49
Age	
Median (range)	74 (42–92 years)
Mean	71.6 years
ASA	
1	22
2	34
3	20
Diagnosis	
Tis	32
T1	21
T2	18
T3	5
Distance	
Median (range)	8 (0–17) cm
Mean	7.8 cm
Longest	22 cm
Circumference	
Median (range)	33 (5–90)%
Mean	36.5%
Area	
Median (range)	9 (0–77) cm <sup>2</sup>
Mean	14.7 cm <sup>2</sup>

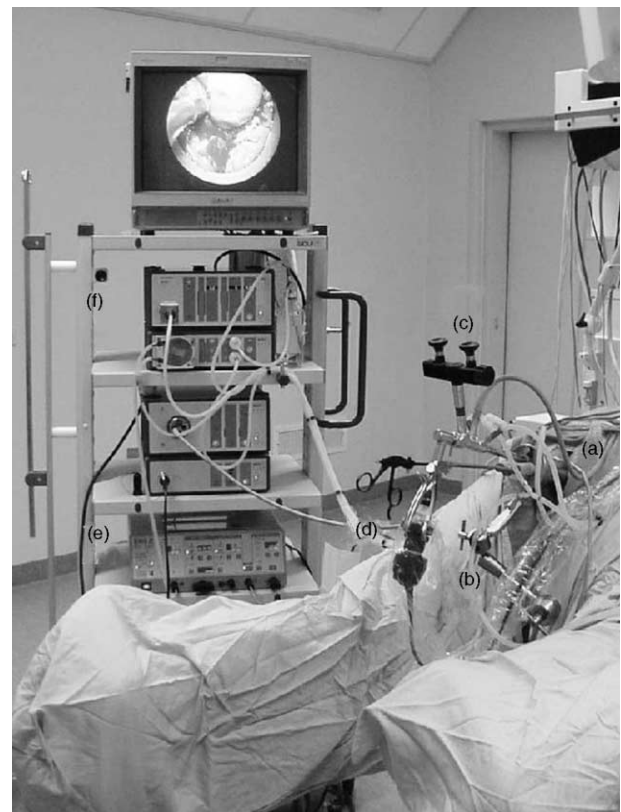


Fig. 1. Illustration of TEM equipment, consisting of a rectoscopy (a), fixed to the operating table by means of a Martin arm (b), the stereoscopic optic (c), inserted instruments (d), an elektro surgery unit (e) and specially developed TEM pump and insufflation system (f).

knots. The specimen is pinned on cork, fixed in formalin and sent to the pathologist. Circumferential margins were investigated (Fig. 2).

Patient data were stored in a central, digital database. For statistics, percentages and continuous data were compared using the Chi-square test and Mann–Whitney test, respectively. Multiple regression was used to evaluate factors simultaneously regarding their effect on operation time, the latter logarithmically transformed. Correlation coefficients given are Spearman's. Time to recurrence data were assessed using the Kaplan–Meier life-table method. *P* values given are two-tailed; *P* = 0.05 was considered the limit of significance.

### 3. Results

Median operation time was 75 min (mean 101; range 20–385 min) and mean blood loss a few cc (median few; range few–1000 cc). Operation time was independently influenced by area ( $r = 0.57$ ;  $P < 0.001$ ) and depth of infiltration ( $r = 0.49$ ;  $P < 0.001$ ) and not by distance ( $r = -0.15$ ;  $P = 0.15$ ) (Fig. 3). In 13 patients, we encountered perioperative problems (17%). Opening of the peritoneum, always at the side of the resection and never through the tumour, was observed in 7 patients. It was either sutured directly or at the end of the operation within the running suture. Six substantial technical problems were encountered. All could be corrected with the time lost varying between 0–40 min. In 1 patient, the defect could not be closed due to fibrosis caused by an earlier anterior resection. Recovery was uneventful. Median hospital stay, from the day of operation, was 4 days (mean 5.7; range 1–106 days). Mortality was 1.3% ( $n = 1$ ). It was a 87-year-old lady with a cardiac history and a T3 rectal carcinoma. TEM was performed because of severe blood loss, requiring blood transfusions. She died of a cardiac arrest on the fourth postoperative day. There were 15 patients with 16 postoperative complications. In 13 patients, complications were mild and treated conservatively (17%). In 2 patients, a severe complication occurred. These were an abscess and rebleeding needing reoperation with a protective stoma (3%) (Table 2).

Table 2  
Complications

Complication	<i>n</i>	R
Pelvic pain	1	Conservative
Urinary tract infection	3	Conservative
Urinary retention	2	Conservative
Cardiac	2	2 conservative
Faecal incontinence	1	Conservative
Rebleeding	4	3 conservative 1 reoperation and stoma
Abscess	3	2 conservative 1 reoperation and stoma

R, resection.

Indications for local treatment were adenoma ( $n = 43$ ), *in situ* carcinoma ( $n = 13$ ) and invasive carcinoma ( $n = 20$ ) at biopsy. Postoperative histology showed *in situ* carcinoma in 32 tumours, T1—carcinoma in 21 tumours, T2—carcinoma in 18 tumours, and T3—carcinoma in five tumours, meaning false-negative preoperative histology of rectal cancer in 43 tumours (Table 3).

Because 1 patient died and 8 patients underwent additional surgery, 67 patients were available for follow-up (Table 4). At follow-up, a digital rectal examination, rigid endoscopy and anorectal endosonography were performed every 3 months. 4 patients were lost during the follow-up because they refused ( $n = 1$ ) or died, not related to cancer ( $n = 3$ ). Median follow-up was 10 months (range 1–52; mean 13.9 months (Table 5)). The local recurrence rate for all patients at 3

Table 3  
Histological diagnosis pre- and postoperative

Preoperative	Postoperative			
	Tis	T1	T2	T3
Adenoma	20 (1)	12 (2)	10 (1)	1
Tis	9 (2)	4		
T1–3	3	5	8	4 (1)
	32	21	18	5
				76

Numbers between parentheses are numbers of complete excision.

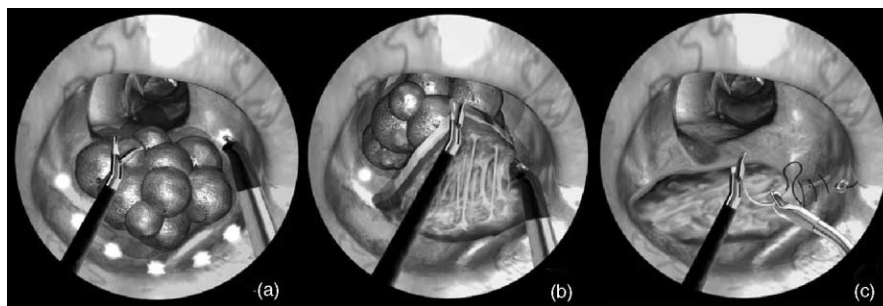


Fig. 2. Illustration of endoscopic view during TEM. The margin of excision is marked (a), after which the tumour is resected (b). The defect is closed transversally using a running suture (c).

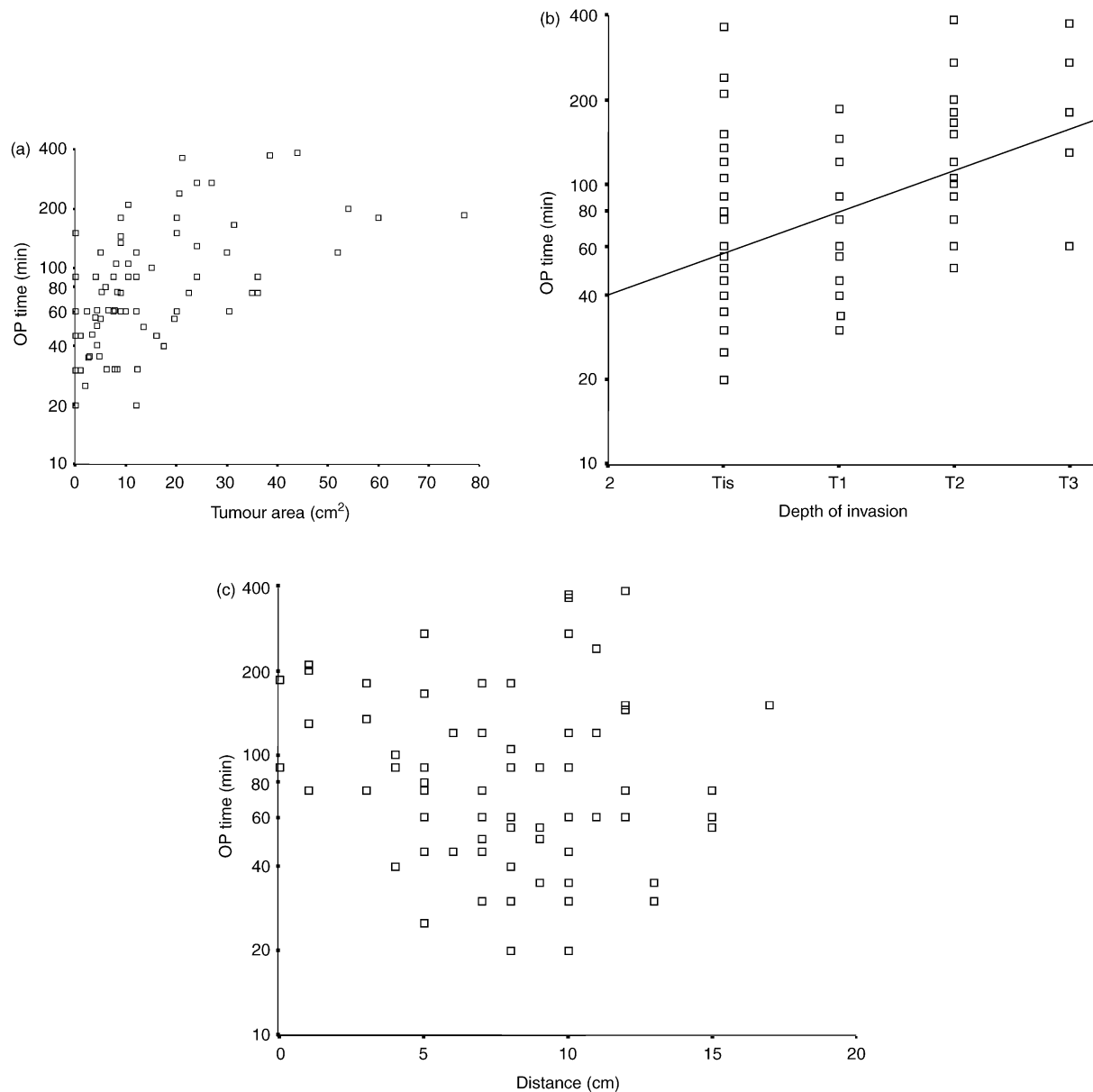


Fig. 3. Operation (OP) time was influenced by area and depth of infiltration and not by distance.

years was 18%. Numbers at risk per different stage of depth of infiltration are too little to determine representative recurrence rates. Only for *in situ* tumours were numbers of importance large enough and these cases had a recurrence rate of 0% at 1 year. So far, in *in situ* tumours 1, in T1 tumours 2, in T2 tumours 3 and in T3 tumours no local recurrences have been observed (Tables 4 and 5 and Fig. 4). No distant recurrences nor cancer-related deaths were observed.

Incomplete margins were observed in seven tumours (9%). Carcinomas with incomplete margins were significantly larger (9 versus 24 cm²;  $P=0.03$ ) (Fig. 5). No correlation could be demonstrated between the risk of recurrence and complete or incomplete margins of excision.

#### 4. Discussion

Transanal endoscopic surgery has been proven to be an excellent technique for the local resection of rectal adenomas. Its safety and low recurrence rate compared with other local techniques have been previously described. With TEM, tumours from the dentate line to the lower sigmoid, including circumferential tumours, can be excised. This avoids the need to master several, often technically demanding, local techniques which have the added limitations of increased mortality and morbidity. Without TEM, up to 50% of the tumours could not have been excised locally and laparotomy would have been inevitable [21–24]. In this study, mortality was 1.3% and severe morbidity 3% in an elderly group of

Table 4  
Selection of patients for follow-up

			Died postoperatively	TME	Follow-up		
					Indicated/ unfit	Unfit	Refused
Tis	32				32		
T1	21			2	19		
T2	18			6		8	4
T3	5	1				3	1
Total	76	1		8		67	

Table 5  
Length of follow-up

		Follow-up		
	<i>n</i>	Months		
		Median	Mean	Range
Tis	32	14	15.5	1–41
T1	19	7	12.5	1–47
T2	12	10.5	15.5	1–52
T3	4	2	5	1–15
Total	67	10	13.9	1–52

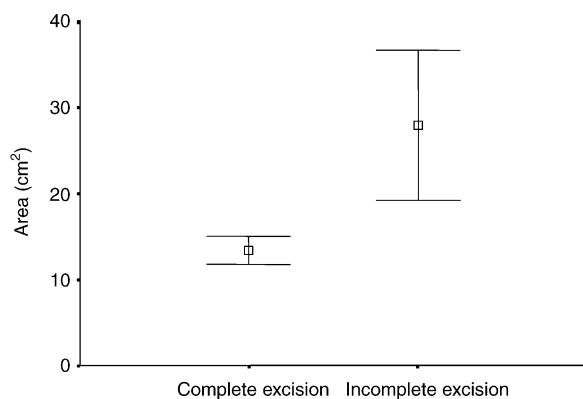
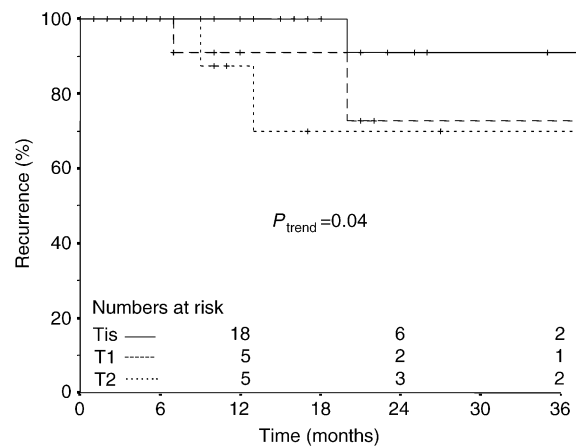


Fig. 5. Mean area ( $\pm$ S.E.M.) of complete versus incomplete margins.

patients with substantial comorbidity, with 20 patients (33%) considered unfit for TME preoperatively (Tables 2 and 4). This study confirms and underlines earlier findings that TEM is a superior technique that is feasible outside of specialised centres.

TEM is considered a difficult technique, demanding extensive training before starting. All participating surgeons in this study were trained extensively. Major technical and other interruptions were encountered at operation in 18%. All were solved without the need for laparotomy or diverting stoma. We strongly believe that, without such training, more problems would have resulted and would not have been solved without additional surgery [20,25,26].

Key elements in TEM are the excellent view and the pneumorectum. When the views via the documentation endoscope and the stereoscope are compared, the latter has a much larger range of vision, up to 180%. Moreover, the view from the stereoscope is of unmatched quality, since it can be viewed directly with the human eye, resulting in a three-dimensional view with the maximum depth of vision and resolution, and with a 6-fold magnification, this is unattainable even with the best cameras and monitor [17]. These advantages are essential for TEM use, because viewing and manipulation of the instruments has to be performed in a parallel plane. In a collapsed rectal cavity, a tumour is stowed away in the folds of the rectal wall. Inflation enlarges the view because it enables the exposure of the tumour on the unfolded and extended rectal wall. Therefore, creation of a pneumorectum is the second key element in the technique. Because the rectal cavity is relatively small, pressure measurement and gas insufflation are carried out separately, using two tubes and two connections. This enables both continuous gas insufflation and frequent pressure measurement. As a consequence, a very stable pneumorectum and operative field are guaranteed [20].

TEM has been developed for adenomas. However, because of its success, it is tempting to determine its role in the treatment of rectal cancer. Often rectal cancer is mistaken for adenoma preoperatively, due to negative findings at biopsy. This mistake correlates with the size of the tumour. Because in TEM there is apparently no limitation to the area of the tumour, very frequently the surgeon has to make decisions on tumour control after unintended local excision of rectal cancer, as was the case in this study in 43 tumours (Table 4).

*In situ* carcinomas do not have the potential for metastatic spread and local excision is justified in all cases [27]. The local recurrence rate of 0% and the absence of distant recurrences or cancer-related deaths in this study support this statement. There is growing support to redefine it as severe dysplasia, as already practised within the World Health Organization (WHO), advised by the same panel as the International Union Against Cancer (IUCC) [28,29].

In invasive rectal cancer, TME is the gold standard. At the start of this study, in all patients with invasive tumours and fit for major surgery, additional TME was performed. In 2 patients with T1 tumours, no residual cancer tissue nor lymph node metastasis were found in the TME specimen, as experienced in earlier reports [15,16,21,22,24]. In T1 tumours, lymph node metastases are found in 0–10% at the time of radical operation [30–32]. After TEM for T1 tumours, local recurrence rates of 0–4.2% and survival rates of 79–96%, no different from TME, have been reported [23,33,34]. Therefore, we decided not to reoperate for the T1 tumours.

After transanal resection, local recurrence is 0–27% for T1 tumours [6,9,10]. Tumour selection criteria, surgical technique in use and statistical pitfalls can be held responsible for differences in the local recurrence rates. Local recurrence can be expansion of lymph node metastases, left behind after surgery. Local excision should be confined to rectal cancers without any lymph node metastasis at the time of operation. Depth of infiltration is a major risk factor for the presence of metastasis, as discussed before. The use of histopathological criteria to predict nodal involvement is advocated. Well or moderate differentiation, no blood- or lymphatic-vessel invasion, and no mucinous component are defined as low risk criteria. Presence of lymph node metastasis in T1 low-risk rectal tumours is 7%, no different from T1 tumours as a group, possibly reflecting the vast majority of low-risk tumours within T1 tumours [6,9,32]. Anorectal endosonography is used to demonstrate local lymph node involvement in rectal cancer. A disadvantage of this technique is the moderate negative predictive value of 84% for all rectal cancers and its lack of value for T1-rectal cancers [35]. It is used for decision-making in T1 tumours, but the minimal amount of lymph node metastasis in this tumour stage probably camouflages the inadequacy of anorectal endosonography, enabling a low local recurrence rate [33].

Local recurrence can also be due to an expansion of residual tumour tissue because of incomplete excision. In 91% of the specimens, the circumferential margins were free of tumour. This finding is similar to other series and compares well with findings after TME [21,36]. After transanal resection, data on the completeness of excision are difficult to obtain, but incomplete excision has been reported in 12–60%. Both after TME and transanal excision, the frequency of local recurrence is significantly higher for patients with incomplete excisions [6,8,10,37–40]. It is advocated that adenomas can be resected submucosally and with smaller margins of macroscopically normal mucosa than rectal cancers. However, because rectal cancer is often mistaken for adenoma preoperatively, every tumour should be excised full thickness and with wide margins. In this study, mild dysplasia at the mucosal margin was the only histopathological finding when the excision was incomplete. Mild dysplasia per definition is

not visible macroscopically [29]. Because this was the only finding, it proves that all tumours were excised in macroscopically normal mucosa. In larger tumours, incomplete excision was observed more frequently. In larger tumours, one perhaps tends to excise with a smaller margin, because of fear for the size of the defect being created. It must be concluded that incomplete margins after TEM are of theoretical origin rather than of technical. It confirms the excellent view in TEM, all the more since tumours up to 22 cm from the dentate line and up to 77 cm<sup>2</sup> have been excised in one piece, unrivalled by any other local technique (Table 1).

For T1 tumours, survival rates after TME, transanal resection and TEM are similar, even in studies with high local recurrence rates [6,10]. Local recurrence after local excision can be salvaged by radical resection, with no extra mortality and morbidity compared with radical resection as the first option, in contrast with local recurrence after TME. Local recurrences after TME are usually associated with severe local symptoms, are difficult to palliate and lead to a miserable death. Survival after local recurrence after TME is very limited, whereas survival for patients who underwent a salvage operation after local recurrence following a local resection seems comparable to that for patients who did not [10,41]. Thus, local recurrence after local resection should be viewed differently. A prerequisite is an intensive follow-up with digital and endoscopic rectal examination, as well as an anorectal endosonography every 3–4 months to diagnose local recurrences at an early stage [10].

Proper statistical analysis is of crucial importance in evaluating the results. Calculated percentages have to be looked at with great care in less than 100 cases with a few incidents, since the actual percentages can vary considerably because of the large confidence intervals. We could find no studies on local resection of rectal cancer with numbers exceeding 50 per T stage. The same was true for local excision of higher stages of tumours. Moreover, often different regimes of adjuvant treatment are added, preventing a reliable analysis of the results [9].

In patients who are unfit for major surgery, TME is not a real option and local resection can be performed to relieve patients from distressing symptoms and improve local control with limited mortality and morbidity. This study shows that TEM is capable of doing this.

TEM is a safe technique, capable of excising rectal cancer, independent of the size and distance of the tumour. Incomplete excision is rarely observed. TEM should therefore be the method of choice when considering a local excision of rectal cancer. Local tumour control in T1 tumours seems comparable to TME with the same survival rates. In higher stages, the results are unclear. There is a lack of properly constructed, randomised trials with sufficient numbers of patients and length of follow-up to circumvent possible statistical pitfalls. However, the possibilities of TEM justify

proper evaluation of its role in local excision for rectal cancer.

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