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Transanal Endoscopic Microsurgery with or without Completion Total Mesorectal Excision for T2 and T3 Rectal Carcinoma

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Keywords
T2 rectal cancer · T3 rectal cancer · Transanal endoscopic microsurgery · Total mesorectal excision · Outcome

Abstract
Aim: Transanal endoscopic microsurgery (TEM) is used for the resection of large rectal adenomas and well or moderately differentiated T1 carcinomas. Due to difficulty in preoperative staging, final pathology may reveal a carcinoma not suitable for TEM. Although completion total mesorectal excision is considered standard of care in T2 or more invasive carcinomas, this completion surgery is not always performed. The purpose of this article is to evaluate the outcome of patients after TEM-only, when completion surgery would be indicated. ***Methods:*** In this retrospective multicenter, observational cohort study, outcome after TEM-only ($n = 41$) and completion surgery ($n = 40$) following TEM for a pT2–3 rectal adenocarcinoma was compared. ***Results:*** Median follow-up was 29 months for the TEM-only group and

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31 months for the completion surgery group. Local recurrence rate was 35 and 11% for the TEM-only and completion surgery groups respectively. Distant metastasis occurred in 16% of the patients in both groups. The 3-year overall survival was 63% in the TEM-only group and 91% in the completion surgery group respectively. Three-year disease-specific survival was 91 versus 93% respectively. ***Conclusions:*** Although local recurrence after TEM-only for pT2–3 rectal cancer is worse compared to the recurrence that occurs after completion surgery, disease-specific survival is comparable between both groups. The lower unadjusted overall survival in the TEM-only group indicates that TEM-only may be a valid alternative in older and frail patients, especially when high morbidity of completion surgery is taken into consideration. Nevertheless, completion surgery should always be advised when curation is intended.

Introduction

Transanal endoscopic microsurgery (TEM) was introduced by Buess et al. [1, 2]. Currently, TEM is the preferred treatment of large rectal adenomas and selected early rectal carcinomas [3–5]. TEM proved to be an oncological safe procedure for curing low-risk pT1 carcinomas with low morbidity rates and good postoperative anorectal function [6–9]. Despite optimized preoperative imaging techniques, unexpected T2-T3 rectal cancers after TEM are discovered. For high-risk pT1 and pT2–3 stages, total mesorectal excision (TME) has shown to be superior compared to TEM in oncologic outcome but at the cost of high morbidity and poor functional outcomes [10–13]. Although advised in current national guidelines, unpublished data suggest that many patients are refrained from completion TME. This may be on doctor's or patient preferences, although this remains unclear. In those cases, where completion TME is not performed, TEM-only is regarded as a palliative treatment option. In contrast to patients treated with curative intent, where literature is extensive [14–19], to our knowledge no literature exists on the course of disease following TEM for pT2 or more invasive rectal carcinomas without (neo-)adjuvant (chemo)radiotherapy in comparison to completion TME. This study presents the oncologic outcomes and short-term morbidity of patients with pT2 or more invasive rectal carcinomas, treated with TEM-only, and outcomes were compared in patients who did undergo completion TME.

Materials and Methods

A retrospective study was performed with patient data that were collected at the surgical departments of 6 hospitals in the Netherlands (see list in Appendix). Between 1994 and 2010, all patients with a pT2 or pT3 rectal carcinoma in whom TEM was performed, with or without completion TME, were included. In these patients, initial TEM was performed as treatment when a benign lesion or a T1 rectal cancer was clinically assumed or as diagnostic procedure when T2–3 rectal cancer was suspected on endorectal ultrasound, but multiple biopsies could not prove malignancy or the lesion was found to be obviously malignant at colonoscopy. No patient received a TEM with palliative intent. Patients with radical resection of the carcinoma after TEM were compared to patients with radical resection after completion TME. Neoadjuvant therapy prior to TEM, adjuvant therapy in the TEM-only group, and after completion TME were exclusion criteria; however, patients who received (chemo)radiotherapy according to the Dutch guideline on rectal cancer prior to the completion TME were included in the analysis. Patients with adenomatous polyposis, Lynch syndrome, more than 1 colorectal carcinoma, a converted TEM procedure to technique other than as described by Buess et al. [2], or recurrent disease were excluded from the study.

The preoperative work-up included clinical evaluation, colonoscopy, biopsy, and endorectal ultrasound (ERUS) when a benign lesion was expected. When patients had a biopsy-proven carcinoma, they received CT, MRI, or contrast-enhanced MRI prior to the TEM. The TEM procedure was performed in full thickness following the standard technique as described by Buess et al. [2]. In general, completion TME was performed 8 weeks after the local excision was carried out.

Local recurrence was defined as a recurrence endoscopically diagnosed and confirmed by histology or pelvic lymph node detected on MRI. A distant metastasis was defined as any tumor recurrence outside the pelvis. Morbidity was defined as any unexpected event in the postoperative course requiring a medicinal, surgical, radiological, or endoscopic intervention until 30 days from surgery. Radical resection (R0) was defined as a minimal margin of 1 mm from the resection plane to the microscopically visible carcinoma.

Primary endpoint was oncological outcome in terms of local and distant recurrence, overall survival, and disease-specific survival. Disease-specific survival was defined as death from recurrent rectal carcinoma or postoperative death after salvage surgery. Secondary endpoint was treatment-related morbidity of the TEM and completion TME procedures. This study was approved by the medical ethical review board in Maastricht, the Netherlands.

Statistical Analyses

Baseline characteristics were collected and compared between the rectal preserving group and the completion TME group. Differences in baseline characteristics were evaluated using Mann-Whitney U tests for comparison of median values. A chi-square test was used for the comparison of proportions. Kaplan-Meier survival functions were used to estimate the cumulative proportions of 3-year local recurrence and distant metastasis rate, overall, and disease-specific survival. Difference between cumulative proportions was calculated and pre-

Table 1. Baseline characteristics

	TEM (n = 41)	TEM + TME (n = 40)
Age, years, median (range)	81 (56–96)	65 (36–82)
Gender, male, %	44	65
ASA I–II, *n* (%)	16 (47)	29 (83)
ASA III–IV, *n* (%)[1]	18 (53)	6 (17)
Distance from anal verge in centimeters, mean (SD)	7.1 (3.6)	7.4 (3.3)
Follow-up in months, median (max)	29 (155)	31 (168)
Neoadjuvant radiotherapy, *n*/*n* (%)	0/41	23/40 (55)
Tumor characteristics, *n*		
Anterior location	13	10
Circumferential tumor	3	2
Preoperative T-stage, *n* (%)		
Benign	21 (52)	27 (68)
uT1	10 (24)	7 (18)
uT2–3^	10 (24)	6 (14)
Pathologic T-stage, *n* (%)		
pT2	35 (85)	32 (80)
pT3	6 (15)	8 (20)
Differentiation, *n* (%)*		
Well differentiated	6 (15)	6 (15)
Moderately differentiated	27 (66)	21 (53)
Poorly differentiated	3 (8)	6 (15)
Unknown	5 (13)	8 (20)
Lymphatic invasion	1/17	0/14
Unknown lymphatic invasion	24/41	26/40
Vascular invasion	2/19	3/22
Unknown vascular invasion	22/41	18/40

[1] American Society of Anesthesiology (ASA) Classification was unknown in 6 patients in TEM only group and in 5 patients in TEM + TME group.

^ Diagnostic TEM as tumor could be T2–3 based on ERUS; however, no positive biopsies or malignant aspect at colonoscopy.

* Grading according to the American Joint Commission on Cancer.

sented with 95% CI. Cox regression function was used to adjust overall survival between both groups for American Society of Anesthesiology (ASA) classification and age. A p value of <0.05 was considered statistically significant. Statistical analyses were performed using IBM SPSS software version 20.

Results

Patient Characteristics

Between January 1994 and December 2010, 81 patients (37 female and 44 male patients) with a pathological T2–3 rectal carcinoma were included. The TEM-only group consisted of 41 patients and the completion TME group of 40 patients. The median age was 81.0 (SD 8.7) and 65.5 (SD 9.8) years in the TEM-only and completion TME groups respectively (p < 0.001). A pT2 rectal carcinoma was reported in 67/81 (83%) patients, 35/41 (85%) patients in the TEM-only group, and 32/40 (80%) patients in the completion TME group. In the TEM-only group, 6/41 (15%) were a pT3 carcinoma versus 8/40 (20%) in the completion group. Other baseline characteristics are presented in Table 1. In 69% of the patients in the TEM-only group, a reason for not continuing with additional treatment was given. Thirteen patients refused further treatment and in 14 patients, the choice for not continuing treatment was based on high age (median 86.0 years, interquartile range 83.5–88.3). In the records of the other 14 patients, no conclusive reason could be retrieved. In the completion TME group, 16 (21%) patients received an end colostomy, including 4 Hartmann procedures and 12 abdominoperineale resections (APR). Median follow-up in the TEM-only group was 29 (range 0–155) months and 31 (range 3–168) months in the completion TME group.

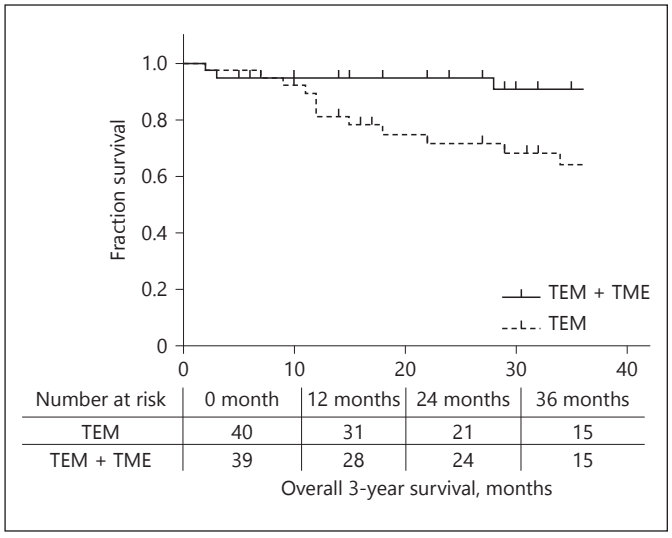

Fig. 1. Kaplan-Meier showing the difference in overall survival between the TEM group (dots) and the completion TME group (line). Follow-up period has been truncated at 36 months. TEM, transanal endoscopic microsurgery; TME, total mesorectal excision.

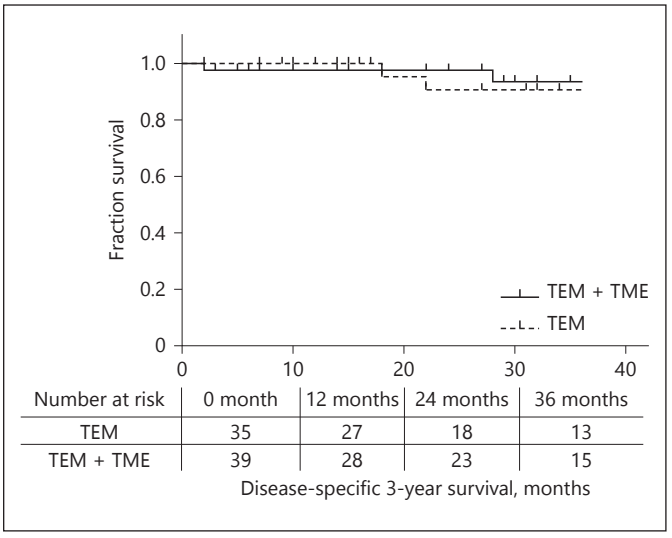

Fig. 2. Kaplan-Meier showing the difference in disease-specific survival between the TEM group (dots) and the completion TME group (line). Follow-up period has been truncated at 36 months. TEM, transanal endoscopic microsurgery; TME, total mesorectal excision.

Local Recurrence

At 3 years, local recurrence rate was 35.4% (n = 11) in the TEM-only group compared to 10.5% (n = 3) in the completion TME group (difference 24.9%; 95% CI 4.8 to 45.8%, p = 0.020). Median time to local recurrence was 9 months (range 3–36) and 11 months (range 11–18), respectively, with p = 0.555. One patient in the TEM-only group and 1 patient in the completion TME group had a local recurrence with signs of a distant recurrence. In the TEM-only group, local recurrence was managed by TEM in 1 patient, low anterior resection in 2 patients, APR in 3 patients, Hartmann procedure in 1 patient, and non-operative therapy in 3 patients. One patient with concurrent liver metastasis died of the disease. In the completion group, local recurrence was managed by APR in 1 patient, and non-operative therapy in 1 patient. One patient with concurrent liver metastasis was not treated for the local recurrence and so died of the disease.

Distant Recurrence

At 3 years, distant recurrence rate was reported in 16.0 and 16.0%, respectively (difference 0.0%; 95% CI –21.2 to 21.2%). Median time to distant recurrence was 18 months (range 10–21) and 17 months (range 9–36), p = 0.886. Three out of 4 patients in the TEM-only group and 3 out of 4 in the completion TME group had distant recurrence without signs of local recurrence.

Survival

The overall 3-year survival was 62.6% in the TEM-only group and 90.8% in the completion TME group (difference 28.2%; 95% CI 8.8 to 47.6%, Fig. 1); adjusted for age and ASA classification no significant difference between both groups was found (p = 0.128). The disease-specific 3-year survival was 90.5 versus 93.3%, respectively (difference 2.8%; –12.9 to 18.5%, Fig. 2). The disease-specific survival showed no significant difference between both groups.

Morbidity

Combining both groups, complications after TEM occurred in 12 patients (15%). In the TEM-only group 8 patients (20%) had 1 or more postoperative complications, including an intraabdominal abscess (5%), rebleeding (8%), urinary tract infection (5%), and bladder retention (3%). In 4 patients, complications outside the abdomen occurred (Table 2). One patient died because of a bilateral pneumonia within 30 days after the TEM procedure. One patient was reoperated and a stoma was created after bleeding happened at the local excision site. In the completion TME group, 4 patients (10%) were affected by a complication after TEM, as specified in Table 2.

Postoperative morbidity following completion TME was reported in 18 patients (45%) including an anastomotic leakage in 7 patients (18%). Of these 7 patients, 1 patient died postoperatively and another patient needed a reoperation with formation of a stoma.

Discussion

TEM-only for pT2-T3 without (neo-)adjuvant treatment results in a substantially higher local recurrence rate than TEM followed by completion TME, and therefore should only be considered a palliative treatment. These results are in line with current national guide-

Table 2. Cumulative morbidity and mortality

Variable	TEM (n = 41)	TEM prior to TME (n = 40)	TME (n = 40), n (%)
Postoperative complications (number of patients)	8/41	4/40	18/40 (45)
Prolonged fever (events)	0	1	0
Rebleeding (events)	3	1	0
Urinary tract infection (events)	2	1	2
Bladder retention (events)	1	0	1
Presacral abscess/anastomotic leakage (events)	2	0	7/40 (18)
Stoma formation (events)	1	1	2
Other	4	0	9
Mortality <30 days	1	0	1

lines and patients who have a pT2-pT3 carcinoma should undergo completion TME [12, 20]. In this retrospective cohort with mainly older and ASA III patients in whom only TEM was performed, worse 3-year overall survival was observed compared to patients in whom completion TME was performed. When looking at the disease-specific survival of the comorbid and almost octogenarian group treated with TEM as a standalone procedure, similar results were found for the group treated with the completion TME group, indicating that mortality was mainly caused by factors other than rectal cancer.

With a patient population increasing in life expectancy, and a shift toward a higher incidence of early rectal cancers due to the national screening programs, treatment-related morbidity, mortality, and quality of life play a pivotal part in the decision-making process of the optimal treatment strategy of rectal cancer. TME following TEM is associated with a higher complication rate, than TME alone, especially shown in the high rate of anastomotic leaks within 30 days. Even though the literature on completion TME is scarce, the 18% anastomotic leakage after completion TME found in our study doubles the rate found in the study from Hompes et al. [21]. They did report that in half of the cases, the dissection was considered difficult due to the disruption of the normal tissue planes at the TEM site. Levic et al. [22] reported that a perforation at the TEM site happened in 20% of the patients during completion TME. Additionally, scarring of the mesorectal plane and a weakened rectal wall could be attributing to the increased risk on perforation, and subsequently contribute to an increase of the local recurrence rate [23]. Our study was limited by its retrospective nature, and unfortunately, we are unable to report on perforation during completion TME, since it was not clearly reported in the patient records. However, the high recurrence rate at 3 years (10.5%) in our completion TME cohort support this hypothesis.

No significant difference was found between groups for distant recurrences. De Graaf et al. [7] reported a similar distant recurrence rate in patients treated with TEM or TME alone with comparable overall survival and disease-specific survival.

Without a doubt, this study has its limitations. The TEM procedure without additional treatment is as expected an oncologic inferior procedure in pT2 and pT3 rectal tumors but is often chosen as a palliative option for unexpected pT2-T3 rectal carcinomas. The size of the cohort was too small to conduct an univariable or multivariable analysis to identify independent predictors for recurrence or impaired survival. Due to the sample size, it was also not possible to identify which patient, at what age, and with what ASA classification should be considered for this option. As the median follow-up is around 30 months mainly due to death or some lost to follow-up, especially in the TEM-only group, we had decided to limit the analysis to 3-years follow-up in order to increase the level of evidence of our results.

Nevertheless, nowadays, early rectal cancers will increasingly be diagnosed due to the implementation of screening programs, and elderly patients more often request for rectal preserving therapy. This study may lend support for a more conservative way of treating "accidentally" found T2–3 rectal cancer after local excision

in the comorbid elderly patient, since completion radical treatment will decrease the risk for local recurrence, but not distant recurrence nor disease-specific survival, and is associated with increased risk on postoperative complications. If an unexpected T2–3 rectal carcinoma after local excision is discovered, rectal saving therapy might be suggested with postoperative (chemo)radiotherapy, as it could decrease the local recurrence [24]. This is, however, not common practice at the moment in the Netherlands, as clear evidence is lacking and data of the randomized clinical trial TESAR comparing adjuvant chemoradiotherapy after local excision versus completion TME are yet to be collected [25].Therefore, we believe that this study, despite these limitations, provides evidence that for a specific group of patients, TEM for pT2 and pT3 might be a valid alternative for completion TME when all options are to be discussed with the patient.

In conclusion, palliative TEM for old and frail patients with a T2-T3 rectal cancer could be considered because it results in a lower morbidity rate with similar disease-specific survival at 3-year follow-up compared to completion surgery.

Disclosure Statement

All authors have no conflicts of interest or financial ties to disclose.

Appendix

List of all participating centers located in the Netherlands: Radboud UMC, Nijmegen; Laurentius Hospital, Roermond; IJsselland hospital, Capelle aan den Ijssel; Reinier de Graaf Gasthuis, Delft; MC Slotervaart, Amsterdam; and Canisius Wilhelmina Hospital, Nijmegen.

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