

Transanal Endoscopic Microsurgery Is Feasible for Adenomas Throughout the Entire Rectum: A Prospective Study

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INTRODUCTION: Transanal endoscopic microsurgery for rectal adenomas is safe and has low recurrence rates. However, the feasibility of the procedure for all rectal adenomas is unclear. This issue was investigated prospectively.

METHODS: From 1996 to 2007, 353 consecutive rectal adenomas were evaluated according to a standard protocol. Transanal endoscopic microsurgery was intended in all rectal adenomas.

RESULTS: The median diameter was 3 cm and median distance was 8 cm. The peritoneum was opened peroperatively without any adverse effects in 8.7 percent. The conversion rate was 9.6 percent, with an alternative local procedure performed in 4.2 percent and a transabdominal procedure performed in 5.4 percent. Conversion rate correlated with the distance of the tumor ($P = 0.007$) and the operating surgeon's level of experience ($P = 0.004$). The median operation time was 45 minutes. Operation time correlated with specimen area, experience, and operating surgeon (all $P < 0.001$). All rectal adenomas were excised in one piece. Complete margins were observed in 85 percent. Rectal adenomas with incomplete margins were larger ($P < 0.001$) and were located more proximally ($P < 0.001$). Morbidity was 7.8 percent and mortality 0.6 percent. The median hospital stay was four days. The median follow-up was 27 months. The recurrence rate at three years was 9.1 percent. The median time from operation to recurrence was 12 (range, 4–54) months. Resection

margin status was a predictor of recurrence, with 6.1 percent recurrence in cases of complete margins and 25.2 percent in cases of incomplete margins ($P < 0.001$).

CONCLUSIONS: For nearly all rectal adenomas, transanal endoscopic microsurgery is safe, feasible, and has excellent results.

KEY WORDS: Transanal endoscopic microsurgery; Transanal excision; TEM; Adenoma; Rectum; Feasibility.

For a fairly long time, transanal excision (TE) has been the most frequently used technique for local excision of rectal adenomas (RA). Although relatively safe, its use seems limited to smaller RA in the distal and mid-rectum. The recurrence rates can be as high as 60 percent, with invasive cancer recurring in up to 4 percent. Fragmentation and positive resection margins are considered major causes of recurrence.^{1–6}

In 1983, Gerhard Buess introduced transanal endoscopic microsurgery (TEM), an endoscopic operation for local excision of RA.^{7–9} The operation, also performed in larger RA as well as RA in the proximal rectum and distal sigmoid colon, is associated with minimal morbidity, mortality, and recurrence. These excellent results are attributed to the technical features of TEM that create a clear and stable view and also excision in one piece with complete margins.^{5,9–18}

As an additional and major advantage, TEM could be a single surgical technique for the removal of all RA. However, feasibility of TEM for all RA has not been investigated. We therefore conducted a prospective study of the feasibility of TEM for RA throughout the entire rectum.

PATIENTS AND METHODS

All patients referred for surgical treatment of RA between January 1996 and February 2007 were offered TEM. All

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Dis Colon Rectum 2009; 52: 1107–1113
DOI: 10.1007/DCR.0b013e3181a0d06d
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patients were evaluated according to a standard protocol that included history, physical examination with digital rectal examination, colonoscopy with biopsy, rigid rectoscopy, and endorectal ultrasound (ERUS). For each patient, both the distance and the location of the tumor were assessed as well as the rate of captured circumference of the rectal wall by the tumor. Distance was defined as the distance from the dentate line to the lower margin of the tumor. The location of the tumor was assessed because the patient should be positioned with the tumor downward during surgery.

Patients underwent full preoperative mechanical bowel preparation and were given antibiotic prophylaxis. The patients were given general anesthesia and placed, according to the location of the RA, in supine, prone jack-knife, or left or right lateral positions. All RA were excised full-thickness except for RA within the anal canal. Patients were allowed to resume a full diet postoperatively on the day of the operation and were dismissed the first or second postoperative day after uneventful recovery.

TEM (Wolf GmbH, Knittlingen, Germany) is a minimally invasive operation. The technique is described extensively elsewhere.⁹ Various excisional devices were used during the study period, the results of which have already been published.¹⁹ All TEM operations were performed by two surgeons (EDG and GT) who were trained in intensive TEM courses. Neither of the surgeons had any clinical experience with TEM before the start of this study.

The parameters studied were operation time, perioperative problems, conversions, blood loss, morbidity, mortality, length of hospital stay, resection margin status, and recurrence rate. Operation time was defined as the time from introduction of the rectoscope to completion of the last suture. Intraoperative problems were defined as any events during the procedure that were unexpected and unwanted. Any time needed to correct the problem was recorded. If conversion was necessary, its cause was recorded. The type of conversion was based on the operating surgeon's preference.

All specimens were pinned on cork with fine pins at short distance through the margin of macroscopically normal mucosa. The longitudinal and transversal diameters of both the specimen and the base of the tumor were measured at that time. Subsequently, the whole was fixed in 4 percent formalin solution, buffered in saline, and sent to the pathology department. Resection margin status was investigated by serial transversal sectioning every 0.5 cm. All sections were evaluated by a pathologist. Margin status was scored as complete (> 1 mm) or incomplete (≤ 1 mm). If an invasive carcinoma was found, the patient was excluded from the study.

Follow-up included surveillance endoscopy at one and four years after TEM and every five years thereafter. Additional rectoscopy was performed 6, 18, 24, and 36 months

after TEM and in cases of suspected local recurrence. The last follow-up date was determined by the last endoscopy. Local recurrence was defined as recurrent tumorous tissue within the proximity of the scar tissue from the earlier operation. Histologic confirmation was mandatory.

All data were collected in a database and analyzed with SPSS^[reg] statistical software (version 11.5 for Windows, SPSS Inc., Chicago, IL). Percentages and continuous data were compared using the chi-squared test, Fisher's exact test, and the Mann-Whitney *U* test. Multiple regression was used to evaluate various factors' effects on operation time, with the latter variable transformed logarithmically in order to approximate a normal distribution. Spearman's correlation coefficients are given. The cumulative percentage of patients with recurrence over time was calculated using the Kaplan–Meier method, and comparisons between groups were made using the log-rank test. The limit of significance was *P* = 0.05 (two-sided).

RESULTS

A total of 353 RA were excised in 342 patients. Patient and tumor characteristics are presented in Table 1.

Peroperative problems occurred during 42 procedures (11.9 percent). The median time to correct the problems was five minutes (range, 0–65). In 28 of the RA, the peritoneum was opened during excision (8.7 percent). In 18 of the RA, this did not interfere with the progress of the

TABLE 1. Patient and tumor characteristics

Patients	
women: men	175: 167
age (yrs)	69 (29–91)
ASA 1: 2: 3: 4	170: 103: 68: 1
Adenomas	
recurrent	111
longitudinal diameter (cm)	3 (0–20)
transverse diameter (cm)	3 (0–16.5)
area (cm ²)	9 (0–330)
captured circumference (%)	40 (5–100)
distance (cm)	8 (0–24)
0–5 cm	84
5–10 cm	151
10–15 cm	99
> 15 cm	16
most proximal (cm)	25.8
location	
anterior	75
posterior	100
left lateral	90
right lateral	77
circular	11
Specimens	
longitudinal diameter (cm)	4 (0.5–21.5)
transverse diameter (cm)	4 (0.5–16.5)
area (cm ²)	16 (0.25–346.5)

ASA = American Association of Anesthesiologists; data given are numbers or medians with ranges in parentheses.

TABLE 2. Cause vs. type of conversion in 353 adenomas, based on 342 patients who underwent transanal endoscopic microsurgery

	<i>Prolapsing</i>	<i>No pneumorectum</i>	<i>Not within reach</i>	<i>Too bulky</i>	<i>n</i>
Local procedures					
transanal excision	5	6			11
Altemeier's procedure	2				2
"open" TEM			2		2
Abdominal procedures					
lap. ass. snare polypectomy			2		2
TME		1	4	5	10
sigmoid colectomy			6	1	7
<i>n</i>	7	7	14	6	34

"Open" TEM = removing the working insert, inverting the tumor into the rectoscope tube, and excising the tumor; TME = total mesorectal excision; data given are numbers.

operation and the defect was closed within the running suture when closing the rectal wall. In ten of the RA, the operation was interrupted for 5 to 15 minutes in order to close the opening. This process mainly involved more proximal and larger tumors ($P < 0.001$ and $P = 0.009$, respectively), however, and never lead to conversion or increased morbidity. In nine of the RA (2.5 percent), the multifunctional instrument²⁰ was not functioning properly for various reasons and resulted in substantial bleeding in three patients (range, 300–1000 ml). In six of the RA (1.7 percent), technical problems related to the TEM device occurred; malfunctioning of the needle used for rinsing occurred in four RA and malfunction of gas flow measurement occurred in two RA. In one case, a patient with a history that included radical excision for an adenoma, repeated TE for recurrences, and also a suture line recurrence, approximation of the margins of the defect was not possible and the defect was left open (0.3 percent). The patient recovered uneventfully. Repositioning for completion of excision was never necessary.

Conversion was performed in 34 out of 353 RA (9.6 percent; Table 2, Figs. 1 and 2). The type of conversion depended on distance from the dentate line ($P = 0.007$). Another type of local excision was performed in 15 (4.2 percent), and a transabdominal procedure was performed in 19 (5.4 percent). Conversion to another type of local excision was mainly in RA located in the distal rectum ($P < 0.01$), whereas conversion to transabdominal procedures was mainly in RA located in the proximal rectum and distal sigmoid ($P < 0.001$). In addition, circumferentially located RA had a higher risk of conversion ($P = 0.001$). During the course of the study, the conversion rate decreased for the surgeon who had performed TEM operations since the study's inception in 1996 (EDG; $P = 0.004$) and RA, actually treated with TEM, increased during the course of the study with regard to all specimen and tumor characteristics (P ranging from 0.04 to 0.003). Distance did not change. Conversion rate did not differ between the two surgeons participating in this study.

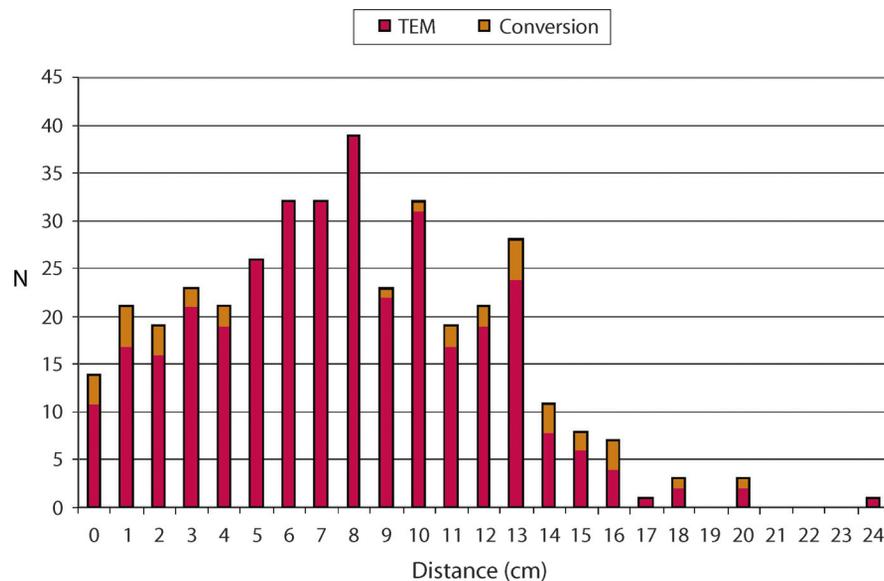


FIGURE 1. Relation between distance and conversions in 353 adenomas that underwent TEM.

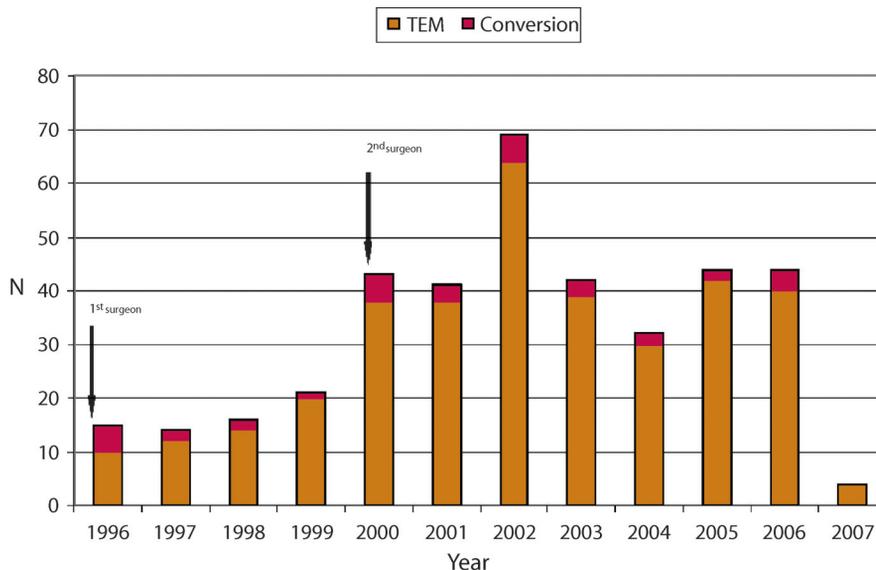


FIGURE 2. Conversions in 353 adenomas that underwent TEM from 1996 to 2007. One surgeon (EDG) started in 1996 another surgeon (GT) started in 2000.

Operation characteristics of the two operating surgeons (EDG and GT) are shown in Table 3 and Figure 3. Operation time correlated with the area of the specimen, was dependent on the operating surgeon (both $P < 0.001$; Fig. 3), and decreased with increase in experience ($P <$

0.001). Operation time was not related to distance. Mild morbidity, treated conservatively, was observed in 19 patients (6.4 percent). Wound abscesses spontaneously drained perianally, after digital rectal examination or with the use of a rectoscope. Anastomotic stenosis was corrected with Hegar dilatation. Severe morbidity that required surgical reintervention was observed in four patients (1.3 percent). Suture line dehiscence and rebleeding after TEM for RA proximal to the peritoneal fold were corrected *via* laparotomy with covering ileostomy. A rectovaginal fistula was closed with TEM after laparoscopically creating a covering ileostomy. In the study's 66th patient, partial sphincter excision with fecal incontinence

TABLE 3. Operation characteristics of 319 adenomas, based on 309 patients who underwent transanal endoscopic microsurgery

Operation time (min)	45 (2–260)
Blood loss (cc)	25 (0–1000)
Cooperations	15 (4.9)
right-sided colectomy	7
lap. Right-sided colectomy	1
transverse colectomy	2
left-sided colectomy	1
sigmoid colectomy	1
TME	1
lap. cholecystectomy	1
ankle fracture	1
Morbidity (%)	23 (7.8)
mild	19 (6.4)
urinary retention	5
urinary tract infection	2
rebleeding	3
anastomotic stricture	1
wound abscesses	7
pneumonia	1
severe	4 (1.3)
wound dehiscence	1
rebleeding	1
rectovaginal fistula	1
partial sphincter excision	1
Mortality (%)	2 (0.6)
Hospital stay (days)	4 (2–28)

Mortality = in 294 patients that were only treated with TEM; mild morbidity = could be treated conservatively; severe morbidity = needed reintervention; data given are medians with ranges in parentheses or numbers with percentage in parentheses.

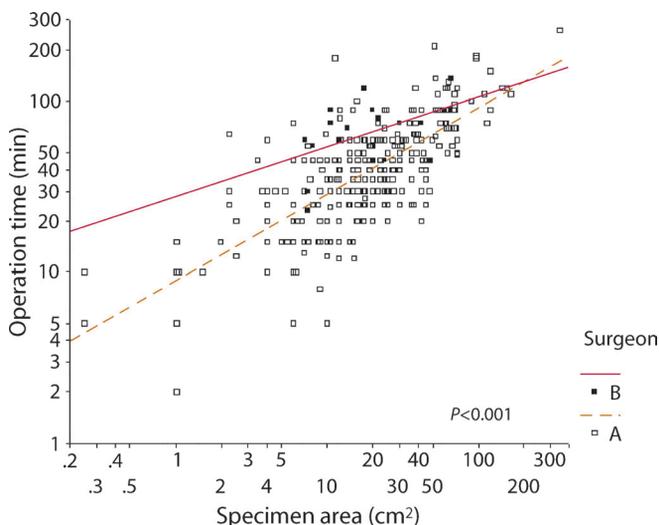


FIGURE 3. Operation time of TEM in adenomas depends on the area of the specimen as well as the surgeon (EDG and GT). Note the logarithmic scaling of both axes.

occurred in the first segmental excision from 0 to 11 cm. A covering ileostomy and sphincterplasty was performed. The covering ileostomy was removed in all patients. Two elderly patients died suddenly (0.6 percent).

Follow-up data were available for 315 RA. The median follow-up was 27 months (range, 0–123). Local recurrence occurred in 21 RA (6.6 percent). The cumulative recurrence rate was 9.1 percent at three years after TEM (95 percent confidence interval [CI] 5 to 13; Fig. 4). The median time from operation to recurrence was 12 months (range, 4–54). All but one recurrence occurred within 34 months (94.1 percent). An invasive carcinoma was never observed as a recurrence.

Complete margins were observed in 85 percent and incomplete margins in 15 percent. In comparison with RA with complete margins, RA with incomplete margins had a larger longitudinal diameter ($P < 0.001$), a larger transverse diameter ($P < 0.001$), a larger tumor area ($P < 0.001$), a larger rate of captured circumference of the rectal wall ($P < 0.004$), and were more proximally located ($P < 0.001$). Resection margin status was not dependent on the surgeon ($P = 0.006$). Resection margin status was a predictor for recurrence (complete margins: 6.1 percent (95 percent CI 3 to 9) vs. incomplete margins 25.2 percent (95 percent CI 11–40; $P = 0.0004$); Fig. 5). Metachronous rectal tumors were found in eight patients (2.5 percent).

Fifty-nine patients were lost for follow-up (17.2 percent). In one patient with multiple adenomas throughout the colon, TEM was performed as a first step for two presumed RA. Histology of the specimen showed one RA

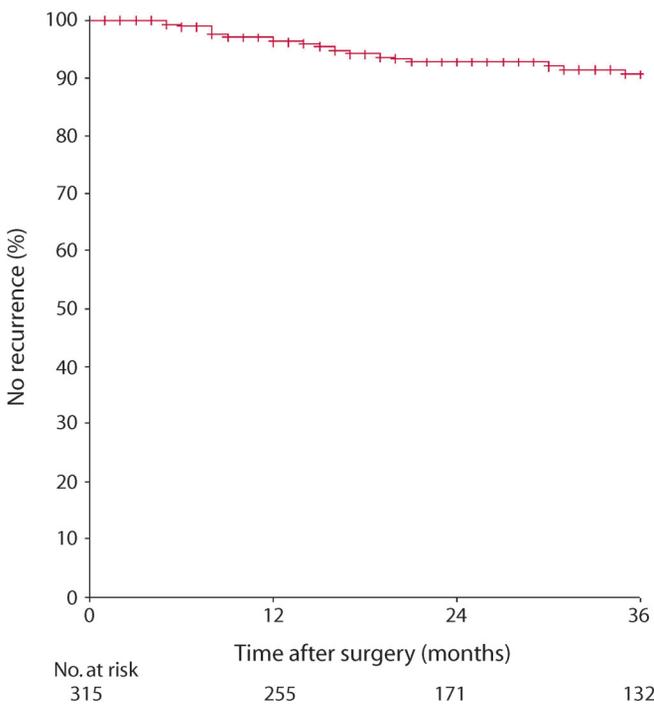


FIGURE 4. Recurrence rate in 315 adenomas that underwent TEM.

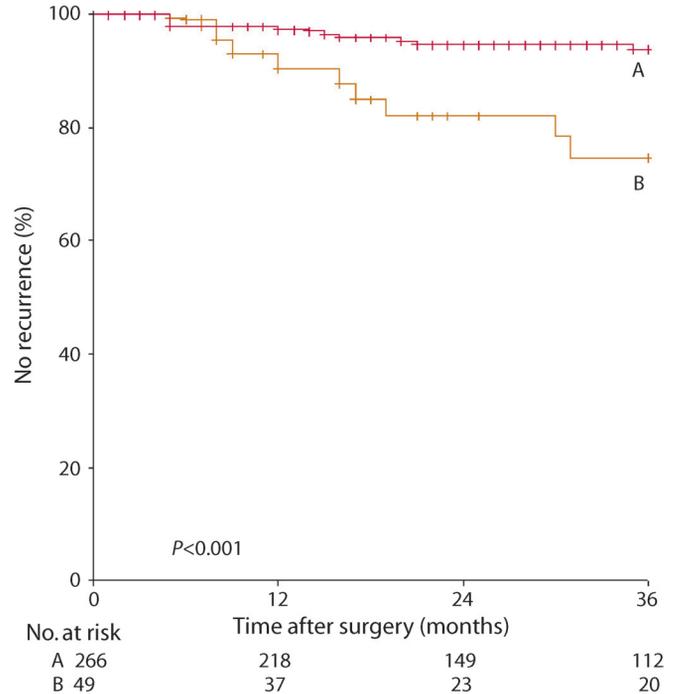


FIGURE 5. Recurrence rate in 315 adenomas that underwent TEM, subdivided by complete (A) and incomplete (B) margins.

and one T1 rectal carcinoma. Consequently, proctocolectomy with ileoanal pouch anastomosis was performed. Four patients refused follow-up, eight patients did not show up and could not be traced, and seven patients died of unrelated causes. Follow-up was discontinued for thirty-nine patients because of age and/or severe comorbidity.

Recurrences were treated with snare polypectomy ($n = 9$), TE ($n = 2$), re-TEM ($n = 9$), and abdominoperineal excision ($n = 1$). In the last patient, local recurrence at the dentate line caused progressive stenosing with functional complaints not responding to Hegar dilatation.

DISCUSSION

This study presents the world’s largest single-institute prospective series on TEM for RA. TEM has gradually surpassed all other local surgical techniques for excision of RA, as is evident in the number of studies, the number of patients treated, the aspects studied, the level of evidence, and the results. Total morbidity ranges from 3 to 17 percent, severe morbidity ranges from 1.2 to 2.5 percent, and mortality ranges from 0 to 1.1 percent. These ranges are not different from TE, and are significantly less than after radical excision.^{5,14,16–19,21–27} Comorbidity rate was not a criterion in this study, and ASA 3 patients were largely present. Total morbidity was 8 percent, severe morbidity 1.3 percent, and mortality 0.6 percent, highlighting again the safety of TEM for RA.

Despite all of this, implementation of TEM in the surgical armamentarium has been relatively slow. This is

remarkable because both the median diameter and the distance of RA, excised with TEM, were often larger.^{5,14,27} Furthermore, subjective assessments stated that radical excision would have been necessary in 50 to 100 percent of the patients who underwent TEM, because TE would not have been feasible for excision of the tumor.^{12,18} Thus, compared with TE, TEM also appears to more frequently prevent laparotomy. Unfortunately, in all series mentioned, a selection bias may have been introduced, and therefore the question as to whether TEM can be applied to all RA still remains unanswered.

Another aspect of feasibility in endoscopic surgery is conversion rate. Salm *et al.*¹⁰ described retrospectively a conversion rate to laparotomy of 11.6 percent, decreasing to 1.2 percent with experience. In his systematic review, Middleton *et al.*¹⁶ determined a median conversion rate of 5.7 percent. Said and Stipple¹¹ retrospectively described a consecutive series of 260 RA excised with TEM. Eligibility according to type of RA was well-defined, but it was unclear if all referred RA were included. Additionally, Said and Stipple's rationale for alternative techniques in 18 RA (7 percent) was not disclosed.¹¹ The current study appears to be the first to assess prospectively the feasibility of TEM for all RA. All referred RA were included, without exception, and TEM was intended in all. The conversion rate in this study was 9.6 percent, meaning RA were excised with TEM in more than 90 percent (Table 2).

Another type of local excision was performed in 4.2 percent. These RA were located in the distal rectum. In our explorative study, all tumors in the distal rectum were converted. We shared the opinion that TEM did not seem feasible in this part of the rectum.^{8,28} This was partly because we were unable to create a stable pneumorectum by gas leakage along the rectoscope. Gradually, we realized that detailed positioning of the patient, necessary for other types of perineal surgery, could be a cause. Refraining from detailed positioning led to enclosing of the rectoscope by the buttocks, reduction of gas leakage, and a decrease in the conversion rate. If we still encountered gas leakage, in larger RA in the distal rectum, we started submucosal dissection distally with help of the Lone Star retractor and continued with TEM proximally. We did not consider this a conversion. Conversion was limited to 14 of 84 RA in the distal rectum (16.6 percent; Fig. 2). Conversion rate decreased with increasing experience, and if converted, the alternative procedures could be performed safely. Our opinion is that TEM is feasible in the distal rectum.

In the mid-rectum, feasibility is obvious with only one conversion to radical excision, because of a bulky tumor at a distance of 9 cm (Fig. 2). We had to convert to a transabdominal procedure in only 5.4 percent, and in each case the RA were located in the proximal rectum and distal sigmoid colon. As the study progressed, the conversion rate further decreased and resulted in an increase

in all tumor characteristics of RA treated with TEM, except for distance. The latter is logical since TEM was intended in all RA throughout the rectum. Often, to our surprise, larger and circumferentially located RA could be excised with TEM. If not for this study, we question whether we would have considered TEM for these RA. Operation time was substantial in these patients, but there was no impact on morbidity. We should note that Salm *et al.*¹⁰ observed a similar reduction in conversion rate to laparotomy in relation to an increase in experience with TEM. It must be concluded that nearly all RA can be safely removed with TEM throughout the entire rectum.

Opening of the peritoneum, occurring in 8.7 percent, was the most frequent and striking perioperative problem that we encountered. Nonetheless, it did not lead to conversion, nor did it seriously delay the operation. Further, it had no impact on either morbidity or mortality. Proximity of both distal and proximal margins and a larger rate of captured circumference of the RA were obvious risk factors. Both Bretagnol *et al.*¹⁸ and Gavagan *et al.*²¹ also explored the consequences of opening the peritoneum. They also found no impact on morbidity. Thus, opening of the peritoneum should not be considered *a priori* as a reason for conversion. This would deny many patients the advantages of TEM.

During this study, operation time decreased as experience increased, and was correlated with the area of the specimen as well as the operating surgeon (all $P < 0.001$). Operation time was not related to distance (Fig. 3). Because all operating surgeons began with the same level of (in)experience, this is most likely the effect of a learning curve. As we have reported elsewhere, however, use of the ultracision harmonic scalpel, compared with both the monopolar knife and the multifunctional instrument, caused a significant reduction of operation time and blood loss. We used the ultracision harmonic scalpel progressively during this study, and it may have played a role in the decrease of operation time.^{5,19,20}

CONCLUSIONS

This study demonstrates that TEM is safe and feasible for rectal adenomas throughout the entire rectum. Opening of the peritoneum can occur, but this does not have any impact on morbidity and does not lead to conversion. The conversion rate is minimal, even in the distal rectum, particularly as experience increases. Recurrence rate is minimal, especially after complete excision.

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