



TAMIS is a valuable alternative to TEM for resection of intraluminal rectal tumors

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Abstract

Background The aim of this study was to compare the short-term outcome after Transanal Endoscopic Microsurgery (TEM) and Transanal Minimally Invasive Surgery (TAMIS) for intraluminal rectal lesions.

Methods Retrospective analysis of a prospectively maintained database of all TEM and TAMIS procedures performed at a single institution by one surgeon between March 2009 and September 2017 was conducted. Primary outcome was operating time. Secondary outcomes were blood loss, pathological outcome, length of hospital stay, 30-day readmission and mortality.

Results Fifty-three patients underwent TEM procedure and 68 patients underwent TAMIS. Operating time was significantly shorter for TAMIS compared with TEM (median 45 vs 65 min, $p < 0.0001$). Blood loss was negligible for both TEM and TAMIS. Resection margins, lesion grade and invasion depth were comparable for both approaches. A significantly higher postoperative readmission rate was observed in the TEM group (17% vs 4.4%, $p = 0.031$). Mortality was zero in both groups.

Conclusions TAMIS is a valuable alternative to TEM, leading to decreased operating times, because all resections can be done in lithotomy position.

Keywords Transanal Endoscopic Microsurgery · Rectal Neoplasms · Transanal Minimally Invasive Surgery

Introduction

Since its introduction in 1983 by professor Gerhard Buess, Transanal Endoscopic Microsurgery (TEM) has become the treatment of choice for resection of benign lesions and early cancers throughout the rectum [1, 2]. TEM has been shown to have superior oncologic outcomes in terms of margin positivity, lesion fragmentation, and recurrence compared to conventional transanal excision (TAE) [3]. For this procedure, a rigid proctoscope, a camera and specialized instruments have to be used. The TEM platform limits visualization and manipulation to a single quadrant because of the

rigid, side-viewing proctoscope. This approach requires the patient to be in a lesion-dependent position, which in turn makes setup time longer.

In 2010, a new technique called Transanal Minimally Invasive Surgery (TAMIS) was introduced as an alternative by Atallah, Albert and Larach [4]. It combined the use of rigid conventional laparoscopic instruments with more flexible transanal platforms, and—as such—could be seen as a hybrid TEM technique. Proponents of TAMIS argue that the learning curve is shorter, and purchase of expensive equipment can be avoided. Proposed advantages of TAMIS over TEM are transferability of familiar skills and equipment and the ability to use the lithotomy position regardless of lesion location. This significantly facilitates patient installation, as it avoids prone positioning for anterior lesions and also allows for readily obtainable abdominal access for instances in which the peritoneal cavity is entered unintentionally and defect closure cannot be managed using TAMIS techniques [5, 6]. Moreover, TAMIS provides a circumferential view of the rectum, allowing instrumentation in all quadrants without repositioning equipment. The aim of the present study was to compare short-term outcomes after TEM and TAMIS procedures.

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Materials and methods

Study population

This study consisted of an institutional review board (IRB)-approved retrospective database analysis from prospectively collected data of all patients who underwent TEM (Original Richard Wolf platform) or TAMIS (GelPOINT Path Transanal Access Platform, Applied Medical) between March 2009 and September 2017 performed by a single surgeon (AW). From March 2009 till September 2012, all patients had TEM, and from October 2012 till September 2017, all patients had TAMIS. There was no overlap between procedures. Inclusion criteria were adenomas and early tumors at a distance of 0–15 cm from the anal verge. Exclusion criteria were other benign conditions, such as high rectal fistulas and revision of anastomotic complications. The study was approved by the medical ethics committee.

Baseline patient demographics, operative variables, pathology data and short-term outcomes were assessed. The primary outcome variable was operating time. Operating time was calculated including patient positioning, so from the start of patient installation until the procedure was ended, meaning removal of the TEM/TAMIS platform. Secondary outcome variables were blood loss, pathological outcome, length of hospital stay, 30-day readmission and mortality.

Surgical procedure

All patients received a sodium phosphate enema on the evening before and morning of surgery and were administered a single-dose intravenous antibiotic (first generation cephalosporin and metronidazole) as prophylaxis. All procedures were carried out under general anesthesia. Patients undergoing TEM were positioned based on the location of the lesion: the lesion should be in the 6 o'clock position meaning ventral decubitus (prone) for anterior lesions, lithotomy for posterior lesions, and lateral decubitus for lateral lesions. Since the introduction of the use of semi-flexible platforms for the use of transanal surgery in October 2012, the authors made an institutional change and abandoned the use of the cumbersome TEM platform. All patients undergoing TAMIS were installed in lithotomy position, regardless of lesion location. For both groups, dissection was performed using standard electrocoagulation. A full-thickness excision comprising all layers of the rectal wall was performed with both TEM and TAMIS. All mucosal defects were closed using a resorbable suture in the same transverse manner. Perioperative management did not change over time. All patients received oral antibiotics during 5 postoperative days (500 mg levofloxacin once daily, and 500 mg ornidazol twice daily).

Statistical analysis

Quantitative data were reported as the median and range, and qualitative data were reported as the number of patients (percentage of patients). Independent *t* tests, Mann–Whitney *U* tests and Fisher exact tests were used to compare variables between both groups of patients. An analysis of covariance (ANCOVA) was used to compare the operative time between groups after correction for the lesion surface area. To meet the linearity assumption, lesions surface area was log²-transformed. Furthermore, it was verified if the difference between both groups depended on the lesion surface area (by including the interaction term). Since there were two outlying values for operative time, a sensitivity analysis was performed after exclusion of these two outliers. All reported *p* values are two-sided. *p* values < 0.05 were considered significant. Analyses were performed using SAS software (version 9.4 of the SAS System for windows).

Results

Patient characteristics

Overall, 121 patients (53 TEM and 68 TAMIS) were included in this study (Table 1). Both groups were comparable for body mass index (BMI). In the TAMIS group, there were more male patients and the patients were older. Median distance from the anal verge was 8.0 cm (range 5–10 cm) in the TEM group versus 6.0 cm (range 5–10 cm) in the TAMIS group (*p* = 0.105). Lesion location was comparable in both groups. All patients were placed in lithotomy position for TAMIS, whereas patient positioning was dependent on location of the tumor in TEM procedures (*p* < 0.001).

Surgical results

Median operating time was significantly shorter for TAMIS than for TEM: 45 (IQR 30–60) min vs 65 (IQR 45–90) min, respectively (*p* < 0.001) (Table 2). Lesion surface area appeared to be larger in the TEM group (median of 20.5 vs 13.5 cm², *p* < 0.001), with a difference in mean of 20 min (95% CI 10.5–29.5, *p* < 0.001). When corrected for lesion surface area, the operating time remained significantly shorter in the TAMIS group: the mean difference equaled 13.5 min (95% CI 3.7–23.3, *p* = 0.007). Analysis was repeated after removal of two patients with a > 2.5-h operative time, but similar findings were observed (Table 3). However, evaluation of the interaction term (*p* = 0.001) indicated that difference between both groups depended on lesion surface area (Fig. 1). Blood loss was negligible for both groups. No significant difference was seen in overall

Table 1 Patient characteristics

	TEM (<i>n</i> = 53)	TAMIS (<i>n</i> = 68)	<i>p</i> value
Gender (male)	12 (23%)	23 (34%)	0.0226
Age (years)	63 (57–71)	69 (61–78)	0.014
BMI (kg/m ²)	26 (24–29)	26 (24–29)	0.798
ASA grade			0.014
I	16 (30%)	6 (9%)	
II	27 (51%)	44 (65%)	
III–IV	10 (19%)	18 (26%)	
Symptoms			0.039
Bleeding	17 (32%)	11 (16%)	
Bowel habit change	9 (17%)	8 (12%)	
Other	27 (51%)	49 (72%)	
Location			0.283
Anterior	13 (25%)	11 (16%)	
Posterior	12 (23%)	13 (19%)	
Lateral	28 (53%)	36 (53%)	
Circular	0	1 (2%)	
Missing	0	7 (10%)	
Maximum lesion diameter (cm)	5 (4.2–7.5)	4.5 (2.8–5.5)	0.002
Distance from the anal verge (cm)	8 (5–10)	6 (5–10)	0.105
Patient installation			<0.001
Lithotomy	23 (43%)	68 (100%)	
Prone	12 (23%)	0	
Lateral decubitus	18 (34%)	0	

Variables are reported as median and interquartile range (IQR)

TEM transanal endoscopic microsurgery, TAMIS transanal minimally invasive surgery, BMI body mass index, ASA American Society of Anesthesiologists

morbidity. Bleeding was the most common complication in both groups, requiring reintervention in six TEM patients and five TAMIS patients, respectively ($p = 0.226$). There was no significant difference in final pathological results in both groups. Both TEM and TAMIS were most frequently performed for benign tumors (64% vs 65%, $p = 0.286$). Although slightly higher in the TAMIS group, rates of R1 resection were not significantly different (6% vs 12%, $p = 0.344$). Median length of hospital stay was 2 days in both groups, but there was a significantly higher postoperative 30-day readmission rate in the TEM group (17% vs 4%, $p = 0.031$). Mortality was zero in both groups.

Discussion

The present study showed a significantly shorter operating time for TAMIS compared with TEM, persisting after correction for lesion surface area. The main advantage of TAMIS over TEM is the fact that all procedures could be done in lithotomy position. This contributes to the general assumption that TEM can be cumbersome, with a steep learning curve, and may be limited by patient positioning

[4]. TAMIS was developed to avoid the need for specialized and expensive instruments and several case series have shown its safety and feasibility [4, 7–12]. The use of conventional laparoscopic instruments during TAMIS can reduce the costs of the operation and delivers perspective to broaden the use of TAMIS for other pathologies [4, 13–16]. With shorter operating time, TAMIS rendered comparable results with regard to perioperative outcome in this study. This has led to the use of this semi-flexible platform for all transanal procedures in our institution. As mentioned in the introduction, TAMIS allows for fully circumferential visualization of the rectum. This again underscores the versatility of the platform, because better visualization and easier set up could definitively account for the shorter operating time found in the present study. TAMIS has the potential to be used for larger resections and hybrid procedures such as transanal total mesorectal excision but could also be used for more complex surgery for other benign indications [17–20]. Only one experimental comparative study showed equivalent safety and effectiveness of TAMIS compared to TEM, but it was associated with an increased level of difficulty [16]. Several other comparative clinical studies reported outcome

Table 2 Operative characteristics and outcome for TEM and TAMIS

	TEM (n=53)	TAMIS (n=68)	p value
Operative time (min)	65 (45–90)	45 (30–60)	<0.001
Lesion surface area (cm ²)	21 (16–44)	14 (6–27)	<0.001
Blood loss (< 50 ml)	53 (100%)	68 (100.0%)	
Defect closure	53 (100%)	68 (100%)	
Resection margins			0.344
Negative	50 (94%)	60 (88%)	
Positive	3 (6%)	8 (12%)	
Fragmentation	3 (5.7%)	2 (2.9%)	0.456
Final pathology			0.286
Benign adenoma	34 (64%)	44 (65%)	
Adenocarcinoma	19 (36%)	24 (35%)	
T0	2	6	
T1	9	12	
T2	8	6	
Length of stay (days)	2 (2–3)	2 (1–3)	0.203
Mortality	0	0	
Readmission < 30 days			0.031
No	44 (83%)	65 (96%)	
Yes	9 (17%)	3 (4%)	
Morbidity			0.242
No	32 (60%)	49 (72%)	
Yes	21 (40%)	19 (28%)	0.242
≥ grade 3 complications	6 (11%)	5 (7%)	0.514
Bleeding			0.266
No	44 (83%)	62 (91%)	
Yes	9 (17%)	6 (9%)	

Variables are reported as median and interquartile range (IQR). T0 data include Tis and no residual disease

TEM transanal endoscopic microsurgery, TAMIS transanal minimally invasive surgery

of TAMIS and TEM [14, 15, 21]. This direct comparison between TEM and TAMIS, comprising a limited number of patients, resulted in shorter operating time and length of hospital stay for TAMIS, as well as minimal blood loss

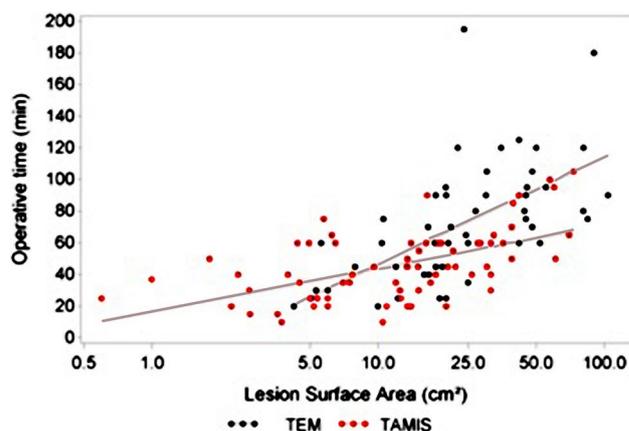


Fig. 1 Difference in operating time between TEM and TAMIS as a function of lesion surface area

compared with TEM (Table 4). Both Lee et al. and Mège et al. observed a significantly shorter length of stay after TAMIS, but the present study showed a median hospital stay of 2 days in both groups. However, this does not prove that TEM and TAMIS yield comparable outcomes. We do believe however, that the TAMIS platform offers a faster operation with similar outcomes, so TAMIS can be used instead of TEM. The findings of our study corroborate results of previous clinical studies. The strength of our data is its prospective nature and the fact that all procedures were performed by a single surgeon. There were no ‘conversions’ necessary from TAMIS to TEM. Limitations of our study include the inherent risk of bias when evaluating data in a retrospective manner. Another limitation is that surgeon’s learning curve was not taken into account when outcome was analyzed. Although, the present study showed results from a single surgeon, well trained in transanal surgery before embarking on both TEM and TAMIS techniques, results were not corrected for the number of procedures. This might have been important, because it has been shown that learning

Table 3 Difference with comparison after correction for lesion surface area

	Difference (95% CI)	Pr > t
General analysis		
Difference in mean time (t test)	– 19.97 (– 29.45; – 10.50)	<0.0001
Difference in mean time after correction for lesion surface area (ANCOVA)	– 13.49 (– 23.26; – 3.729)	0.0072
Analysis after removal of two outliers		
Difference in mean time (t test)	– 19.97 (– 29.45; – 10.50)	<0.0001
Difference in mean time after correction for lesion surface area (ANCOVA)	– 10.19 (– 18.42; – 1.955)	0.0157
Subgroup analysis for lithotomy installation		
Difference in mean time (t test)	– 21.04 (– 32.66; – 9.432)	0.0005
Difference in mean time after correction for lesion surface area (ANCOVA)	– 11.24 (– 21.54; – 0.932)	0.0329

Table 4 Studies comparing TEM and TAMIS

Author, year	No. of patients	Operative time (min)	<i>p</i> value	Morbidity (%)	<i>p</i> value	Resection margin (positive) (%)	<i>p</i> value	Length of Stay (days)	<i>p</i> value
Lee, 2017									
TEM	247	108 ± 56	0.0001	11	0.48	6	0.65	1 (1–3)	< 0.0001
TAMIS	181	70 ± 35		9		7		0 (0–0)	
Melin, 2016									
TEM	40	150.9 ± 66	0.2	12.5	0.55	2.5	0.19	NA	
TAMIS	29	120.5 ± 57		10.3		10.3		NA	
Mège, 2017									
TEM	41	53 (15–165)	0.6	12	0.53	21	0.2	5 (2–38)	< 0.008
TAMIS	33	53 (15–155)		19.5		10		4 (1–60)	
Present study									
TEM	53	65 (45–90)		11	0.514	6	0.344	2 (2–3)	0.203
TAMIS	68	45 (30–60)	< 0.0001	7		12		2 (1–3)	

Data are presented mean ± sd, or median (range)

NA not available, TEM transanal endoscopic microsurgery, TAMIS transanal minimally invasive surgery

curve plays a role in TEM and TAMIS. Barendse et al. analyzed the learning curve for TEM in four colorectal surgeons [22]. Conversion rate (4.3%), procedure time (median 55 min), and complication rate were significantly affected by a learning curve effect. Helewa et al. observed improvement of operative efficiency after 16 TEM cases [23]. Moreover, the average rate of lesion excision was lower when there was experience of fewer than five cases. These authors analyzed results from two TEM surgeons and found an average operative time of 82 min. Together with these rather short learning curves for TEM, there are also two studies investigating learning curve for TAMIS. Lee et al. showed that a minimum of 14–24 TAMIS cases are required to reach acceptable R1 resection rates and lower operative duration [24]. They analyzed results from five different surgeons and divided patients into three groups. Overall, 254 patients were included, and mean duration of surgery was 67 min, R1 resection rate was 7%, and tumor fragmentation was 5%. On the other hand, a group of TAMIS enthusiasts from The Netherlands suggested 18–31 TAMIS cases to be required to reach satisfactory results [25]. A total of 129 TAMIS cases were analyzed, unequally divided between two surgeons (103 vs 26). Overall, they observed a mean operative duration of 66 min, R1 resection rate of 8.5%, and 1.5% fragmentation. Moreover, they were able to show that when cases were proctored, the learning curve was shorter (six to ten cases) to reach proficiency. Therefore, for both TEM and TAMIS there is undoubtedly some learning curve effect, but this could also depend on surgeon's expertise with

other transanal procedures, and experience with advanced laparoscopic and single-port surgery.

Conclusions

The present study showed that TAMIS is a valuable alternative to TEM, with lower 30-day readmission rates and shorter operating times.

Compliance with ethical standards

Conflict of interest The authors declare no conflict of interest.

Ethical approval This study was approved by the medical ethical committee.

Informed consent For this type of study, formal consent is not required.

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