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Establishing the learning curve of transanal minimally invasive surgery for local excision of rectal neoplasms

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Abstract

Introduction Transanal minimally invasive surgery (TAMIS) is an endoscopic operating platform for local excision of rectal neoplasms. However, it may be technically demanding, and its learning curve has yet to be adequately defined. The objective of this study was to determine the number of TAMIS procedures for the local excision of rectal neoplasm required to reach proficiency.

Methods and procedures All TAMIS cases performed from 07/2009 to 12/2016 at a single high-volume tertiary care institution for local excision of benign and malignant rectal neoplasia were identified from a prospective database. A cumulative summation (CUSUM) analysis was performed to determine the number of cases required to reach proficiency. The main proficiency outcome was rate of margin positivity (R1 resection). The acceptable and unacceptable R1 rates were defined as the R1 rate of transanal endoscopic microsurgery (TEM—10%) and traditional transanal excision (TAE—26%), which was obtained from previously published meta-analyses. Comparisons of patient, tumor, and operative characteristics before and after TAMIS proficiency were performed.

Results A total of 254 TAMIS procedures were included in this study. The overall R1 resection rate was 7%. The indication for TAMIS was malignancy in 57%. CUSUM analysis reported that TAMIS reached an acceptable R1 rate between 14 and 24 cases. Moving average plots also showed that the mean operative times stabilized by proficiency gain. The mean lesion size was larger after proficiency gain (3.0 cm (SD 1.5) vs. 2.3 cm (SD 1.3), $p = 0.008$). All other patient, tumor, and operative characteristics were similar before and after proficiency gain.

Conclusions TAMIS for local excision of rectal neoplasms is a complex procedure that requires a minimum of 14–24 cases to reach an acceptable R1 resection rate and lower operative duration.

Keywords Transanal minimally invasive surgery · Local excision · Learning curve

The management of early rectal cancer has undergone an important paradigm shift from radical surgery with total mesorectal excision to local excision of these tumors [1]. With this change, recent literature has questioned if the traditional oncologic end points of rectal cancer surgery have been superseded by patient-driven end points, such as quality of life, offered by local excision [2]. Local excision is accepted for benign and well-to-moderately differentiated tumors T1 cancers, being less than 3 cm in size, which occupy less than a third of the bowel wall circumference, are mobile, and lack high-risk features such as lymphovascular invasion, perineural invasion, or mucinous components. With increasing data to support this less-invasive approach [3–5], rates of local excision have been increasing steadily [6].

Local excision offers significantly lower morbidity and mortality than radical resection, but traditional transanal excision is associated with technical limitations and

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inferior surgical outcomes than radical resection, including suboptimal visualization and precision, higher rates of positive margins, tumor fragmentation, local recurrence, and inferior overall and disease-free survival rates [2, 7, 8]. To address these limitations, advanced endoscopic platforms were developed, including Transanal Endoscopic Microsurgery (TEM) in 1985 [9] and Transanal Minimally Invasive Surgery (TAMIS) in 2009 [10]. Compared with traditional transanal excision, TEM has proven superior oncologic outcomes, including higher negative resection margin rates, lower rates of tumor fragmentation, and lower regional, as well as overall recurrence rates [11]. Widespread utilization of the TEM platform has been limited from several factors, including the complex learning curve that has been found to impact conversion rate, procedure time, and complication rate [12–14]. TAMIS, a hybrid between TEM and single-port laparoscopy, has been increasingly used as an alternative to traditional transanal excision and TEM. Although a new technology, results to date support its safety, feasibility, and oncologic adequacy [15–17]. Our case series of the first 200 patients have been previously published reporting 7% margin involvement and 5% fragmentation, which are included in the results of the present study [18]. However, no prior study has evaluated the learning curve needed to attain proficiency in TAMIS. Therefore, the objective of this study was to determine the number of TAMIS procedures for the local excision of rectal neoplasm required to reach proficiency.

Materials and methods

All TAMIS cases performed from 07/2009 to 12/2016 at a single high-volume tertiary care institution for local excision of benign and malignant rectal neoplasia were identified from a prospective database. Ethics approval was granted from the local institution review board. All procedures were performed by a single group of colorectal surgeons at a tertiary referral center. The indication for TAMIS included benign and endoscopically unresectable (i.e., larger or equivocally malignant) rectal polyps, neuroendocrine tumors less than 2 cm in diameter, and early rectal cancer with favorable histology (clinical T1, less than 3 cm in diameter, well-differentiated, and absence of lymphovascular invasion). TAMIS local excision was also performed for patients that were unwilling or unfit to undergo radical surgery for more advanced (clinical T2+) or histologically unfavorable lesions, as well as patients with complete clinical response (cT0) after chemoradiation to confirm pathological complete response (ypT0). Patients with a preoperative diagnosis of malignancy underwent full local staging with endorectal ultrasound and 3-Tesla pelvic MRI to determine depth of invasion and assess for clinically suspicious lymph nodes in the mesorectum. A computed tomography scan of the chest, abdomen, and pelvis completed the staging evaluation. Location and position of the lesion was assessed by digital rectal exam and rigid proctoscopy.

The technical steps of the procedure were standardized, and have been previously described [10, 15]. All cases were performed under general anesthesia with patients in lithotomy. For access, a single-incision laparoscopic surgery port (GelPOINT® Path Transanal Access Platform, Applied Medical, Rancho Santa Margarita, CA or SILS Port, Covidien, Mansfield, MA) is introduced into the anal canal by applying steady manual pressure. Once seated in position, endoscopic access to the rectal vault is gained, and pneumorectum to 12-15 mm is established. With this access, ordinary laparoscopic instruments, including graspers, thermal energy devices, and needle drives, are used to perform the transanal excisions. Our practice is to perform full-thickness excision and defect closure whenever possible; however, in select patients, a partial thickness excision is performed (for example, a high anterior lesion that is clinically benign) or the defect cannot be closed (usually due to size or after a partial-thickness excision).

The main proficiency outcome in this study was the positive margin status (R1 resection). We defined the acceptable outcome rate to be the R1 resection rate of local excision of rectal neoplasia using the TEM platform (as this technique has been widely used since first described by Gerhard Buess in 1985 [9] and is considered the current 'gold standard' for transanal local excision). The unacceptable outcome rate was defined as the R1 resection rate of traditional TAE given both TEM and TAMIS were designed to replace this technique. The weighted aggregate probabilities of R1 resection for TEM and TAE were calculated using a random-effects model based on data obtained from studies directly comparing TEM and TAE for local excision of rectal neoplasia that were identified in the previously published meta-analysis [11].

A cumulative summation (CUSUM) analysis was performed to determine the number of cases required to reach proficiency [19]. The CUSUM method can continuously monitor performance and detect improvement toward a predefined level of achievement. This method has been previously validated and applied to describe skill acquisition in colorectal surgery [20–23]. To perform a CUSUM analysis, the acceptable and unacceptable proficiency outcome rate must be defined. The probabilities of type I and II errors (α and β) were set at 0.05 and 0.20, respectively. Based on these data, a constant s and two decision limits $h0$ and $h1$ are calculated. On a CUSUM graph, each case is plotted consecutively along the x-axis, and s is subtracted from the cumulative score (y-axis) for each successful outcome and $1—s$ is added for each failure. A negative trend therefore indicates improving outcomes. Proficiency is reached when the cumulative score crosses and stays below the lower decision limit (*h0*). Moving average plots for operating time were also created to examine the effect of learning curve on operative time.

All patients were divided into three groups (A, B, and C) based on their operating surgeon. A single surgeon performed all procedures in group A. Group B included patients of two surgeons that performed all procedures together. Group C included patients of two other surgeons, both of whom were fellowship trained at the study institution in TAMIS, who also performed procedures together. Group-specific CUSUM curves and moving average plots were generated to determine each surgeons' learning curve. Once each group's learning curve was determined, patients were divided into pre- and post-proficiency groups. Comparisons of patient, tumor, and operative characteristics before and after TAMIS proficiency were performed using Student's *t*, Chi-squared, and Fisher's exact tests, as appropriate. Multiple regression and multilevel modelings were used to determine independent predictors of margin positivity and operating time, using surgeon group as the higher-level variable. Statistical significance was defined as a *p* value <0.05. All statistical analyses were performed using STATA 12.1 (StataCorp, College Station, TX).

Results

A total of 254 patients were included for overall analysis (142 in group A, 72 in group B, and 40 in group C). Patient, tumor, operative, and pathologic characteristics of the entire study sample are shown in Table 1. When these characteristics were compared between groups A, B, and C,

Table 1 Patient, tumor, operative, and pathology characteristics of the overall cohort, and comparison between groups A, B, and C

	Overall ($n = 254$)	Group A ($n = 142$)	Group B ($n = 72$)	Group C ($n = 40$)	p value†
Mean age, years (SD)	64.3 (13.4)	65.3 (12.9)	63.7 (14.8)	62.1 (12.5)	0.863
Male gender	140 (55%)	83 (58%)	38 (53%)	19 (48%)	0.420
Mean body mass index, kg/m^2 (SD)	27.7 (6.1)	27.7 (6.1)	27.2 (5.7)	28.8 (7.2)	0.428
ASA score					0.795
I	33 (13%)	20 (14%)	7 (10%)	6 (15%)	
II	142 (56%)	81 (57%)	40 (56%)	21 (53%)	
III+	78 (31%)	40 (28%)	25 (35%)	13 (32%)	
Neoadjuvant chemoradiation	13 (5%)	6 (4%)	4 (6%)	3 (8%)	0.695
Pre-TAMIS endoscopic excision	59 (23.2%)	34 (24%)	15 (21%)	10 (25%)	0.602
Mean lesion size, cm (SD)	2.8 (1.5)	3.0 (1.6)	2.7 (1.3)	2.6 (1.4)	0.153
Mean distance from anal verge‡, cm (SD)	7.0 (3.2)	7.4 (3.6)	6.3 (2.5)	6.4 (2.8)	0.034
Final pathology					0.171
Adenoma	110 (43%)	69 (49%)	27 (38%)	14 (35%)	
Adenocarcinoma	108 (43%)	58 (48%)	33 (54%)	17 (50%)	
Tis	30 (12%)	12 (8%)	13 (18%)	5 (13%)	
T1	53 (21%)	33 (23%)	13 (18%)	7 (17%)	
T2+	25 (10%)	13 (9%)	7 (10%)	5 (13%)	
No residual tumor	19 (7%)	10 (7%)	6 (8%)	3 (7%)	
Carcinoid	17 (7%)	5 (3%)	6 (8%)	6 (15%)	
Full-thickness excision	228 (90%)	126 (89%)	67 (93%)	35 (88%)	0.539
Hybrid dissection	12 (5%)	4 (3%)	4 (6%)	4 (10%)	0.155
Defect closure	234 (92%)	139 (98%)	61 (86%)	34 (85%)	<0.001
Positive margin	17 (7%)	10 (7%)	6 (8%)	1 (3%)	0.481
Tumor fragmentation	12 (5%)	4 (3%)	7 (9%)	1 (3%)	0.061
Mean duration of surgery, min (SD)	67 (36)	62 (31)	82 (45)	61 (29)	<0.001
Mean blood loss, mL (SD)	22 (27)	22 (29)	28 (25)	13 (15)	0.015
Peritoneal violation	8 (3%)	5 (4%)	3 (4%)	0 (0%)	0.447
Postoperative complications	20 (8%)	16 (11%)	6 (8%)	0 (4%)	0.081
Mean length of stay, days (SD)	0.4 (1.2)	0.3 (0.8)	1.0 (1.9)	0.1 (0.3)	<0.001

† *p* value comparing groups A, B, and C

‡ Measured from the distal margin of the lesion

there were differences in the mean height from the anal verge, operative time, estimated blood loss, and length of stay, as well as the proportion of patients in which the rectal defect was closed (Table 1). There were no differences in margin positivity or lesion fragmentation between the three groups. A total of 17 patients (7% of the overall cohort) underwent robotic TAMIS, all of which were performed by group B. The first robotic case was performed on the 37th cumulative case in group B. Exclusion of robotic TAMIS cases reduced the mean operative time for group B to 72 min (SD 38), and comparison with groups A and C did not demonstrate a significant difference ($p = 0.089$). Differences in the other variables between the three group remained after exclusion of the robotic cases.

Five studies were included for pooled analysis to determine the proficiency limits (Table 2) [8, 24–27]. The incidence of margin positivity across these five studies was 9–53% for TAE and 3–24% for TEM. The pooled incidence of margin positivity was 26% (95% CI 22–31) for TAE and 10% (95% CI 3–16) for TEM (Fig. 1A, B). Using the incidence of margin positivity for TAE as the unacceptable proficiency outcome and TEM as acceptable proficiency outcome limits, CUSUM curves were generated for each of the three groups (Fig. 2A–C). None of the groups exceeded the unacceptable proficiency limit. Proficiency was obtained at the 24th case for group A, the 20th case for group B, and the 14th case for group C. Moving average operative time plots for each of the three groups are shown in Fig. 3A–C. Stabilization of mean operative time occurred before proficiency was obtained. A comparison of the 58 patients before proficiency was obtained (from all three groups) and the 196 patients after proficiency was obtained is shown in Table 3. The distribution of ASA grade and mean lesion size was different in pre- and post-proficiency groups, but all other characteristics, including margin positivity, tumor fragmentation, and the incidence of inadvertent peritoneal entry, were similar. Surgeon group (OR 1.06, 95% CI 0.33–3.37 for group B vs. A and OR 0.29, 95% CI 0.03–2.57 for group C vs. A) and post-proficiency group (OR 0.34, 95% CI 0.10–1.13) were

Table 2 Characteristics of the studies comparing transanal excision (TAE) and transanal endoscopic microsurgery (TEM) that were pooled to determine the upper and lower proficiency limits

Study	Design	Sample size TAE/TEM	Distance from anal verge (cm) TAE/TEM	Lesion size (cm) TAE/TEM	Proportion of malignant lesions TAE/TEM
Langer [23]	Retrospective	76/89	5.7(2.2)/6.2 (2.6)	2.3 (1.5)/3.0 (1.4)	26%/22%
Christofiordis [26]	Retrospective	129/42	5 [0–12]/8 [4–14]	3 [1–12]/2.6 [1–9]	100%/100%
Lebedyev [25]	Retrospective	22/20	7.3/6.7	2.5/3.4	100%/100%
Moore [8]	Retrospective	89/82	NR/NR	10 cm^2 (16)/12 (16)	56%/50%
de Graaf [24]	Prospective	43/216	4 [0–15]/8 [0–15]	2.5 [0.5–5]/3 [0.5–5]	0%/0%

Data are presented as mean (SD) or median [range]

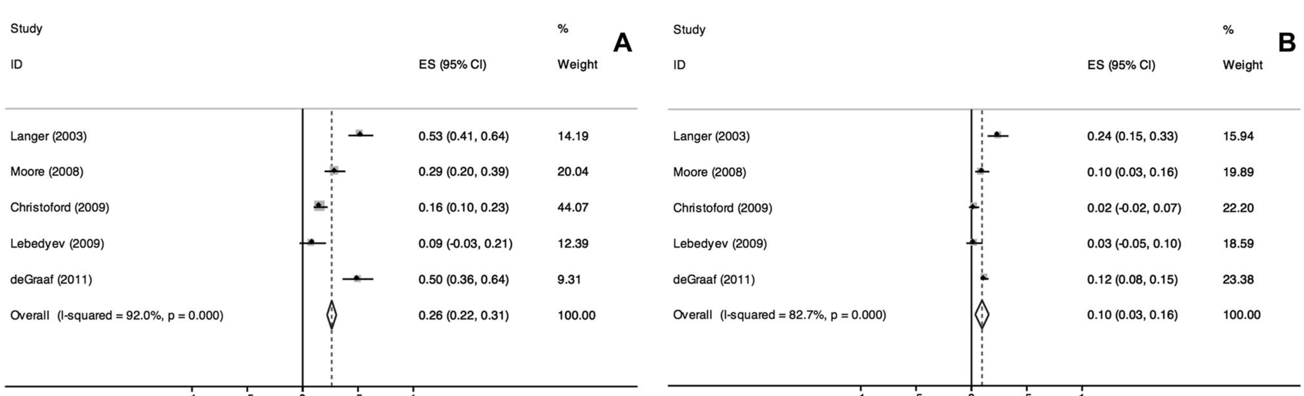

Fig. 1 Combined data on incidence of margin positivity (R1 resection) after **A** transanal excision (TAE), and **B** transanal endoscopic microsurgery (TEM). Studies were identified from a previously published meta-analysis comparing TAE and TEM for local excision of rectal neoplasia [11]

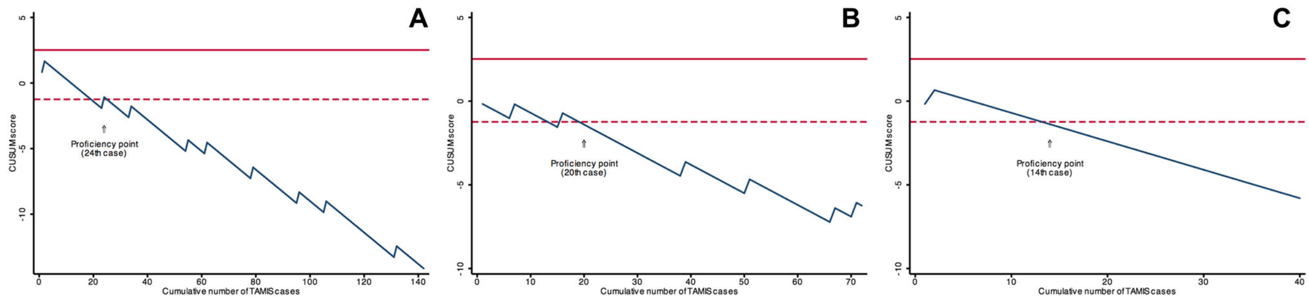

Fig. 2 Cumulative summation (CUSUM) plots for surgeons (**A**), (**B**), and (**C**). The *solid horizontal line* represents the unacceptable rate of positive margin, and the *dotted horizontal line* represents the acceptable rate of positive margin (defined as the pooled positive margin rate of transanal excision and transanal endoscopic microsurgery, respectively)

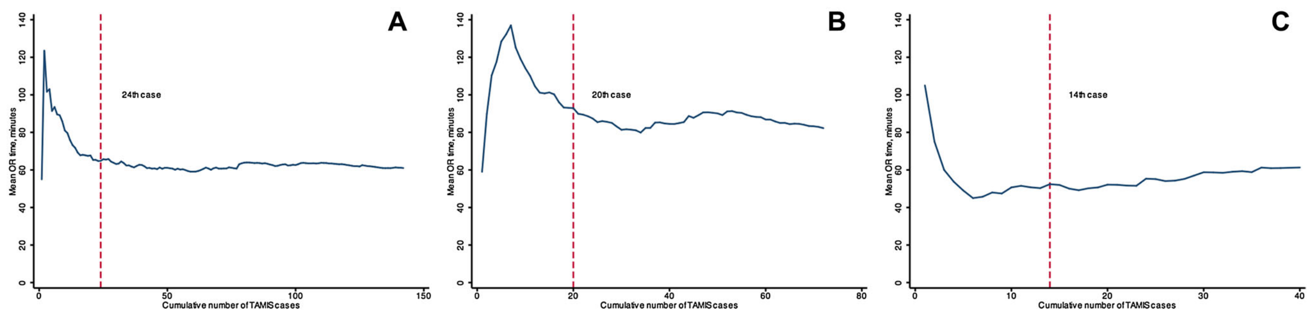

Fig. 3 Moving average plots of operative duration for TAMIS local excision of rectal neoplasm for surgeons (**A**), (**B**), and (**C**). The *dashed vertical line* indicates the point of individual TAMIS proficiency as estimated by CUSUM analysis

not independent predictors of margin positivity on multiple logistic regression (adjusting for age, gender, lesion size and height, fragmentation, and malignancy). The interaction between surgeon group and proficiency gain was not statistically significant ($p = 0.537$). In the alternate analysis using multilevel modeling, sequential case number was not statistically significant (OR 0.99, 95% CI 0.98–1.01) and the variability between surgeon groups was minimal. In terms of operative time, multilevel modeling reported lesion size (β 11.1, 95% CI 8.39, 13.93), height from anal verge (β 1.31, 95% CI 0.08, 2.53), and sequential case number (β −0.06, 95% CI −0.11, −0.01) as independent predictors. The between-group variability between surgeons was significant (variance 10.33, 95% CI 4.26, 25.03).

Discussion

The introduction of a new surgical technique requires careful evaluation of its outcomes, as well as its learning curve. TAMIS was developed as an alternative to TEM for local excision of rectal neoplasms. Major differences between TAMIS and TEM include the access platform and use of standard laparoscopic equipment. It was hypothesized that the use of familiar equipment and skillsets of TAMIS would facilitate adoption of this platform for transanal endoscopic surgery, and indeed use of TAMIS has increased significantly since its inception [28]. Heretofore, the learning curve for TAMIS local excision of rectal neoplasms had not been ascertained. The results of the present study suggest that proficiency is reached after 14–24 TAMIS cases.

Individual proficiency gain curves were generated for the three surgeon groups, which demonstrated similar case numbers to achieve competency. This number ranged from 14 to 24 cases. The two early adopters, groups A and B, had near-equivalent number to reach proficiency: 24 and 20 cases, respectively. These three surgeons were all experienced in laparoscopic colorectal surgery, but did not received any formal training in transanal endoscopic surgery, and indeed none had any prior experience with TEM. Group C required 14 cases, but both surgeons from this group underwent fellowship training with the surgeons from groups A and B, which may account for the shorter learning curve. There were minimal differences in patient and operative characteristics between the three groups, suggesting similar case mix. The longer operative time for group B may be accounted for the fact that 16 of 72 (23%) cases were performed robotically. When robotic cases were excluded, there were no differences in operating time. Surgical resection quality did not differ between the three

Table 3 Comparison of patient, tumor, and operative characteristics pre- and post-learning curvess

	Pre-proficiency ($n = 58$)	Post-proficiency ($n = 196$)	p value
Mean age, years (SD)	64.4 (13.4)	64.0 (13.5)	0.863
Male gender	36 (62%)	104 (53%)	0.226
Mean body mass index, kg/m^2 (SD)	27.1 (7.2)	27.9 (5.8)	0.402
ASA score			0.012
I	12 (20%)	21 (11%)	
II	23 (40%)	119 (61%)	
III+	23 (40%)	55 (28%)	
Neoadjuvant chemoradiation	4 (7%)	9 (5%)	0.484
Pre-TAMIS endoscopic excision	12 (21%)	47 (24%)	0.602
Mean lesion size, cm (SD)	2.3 (1.3)	3.0 (1.5)	0.008
Mean distance from anal verge‡, cm (SD)	7.4 (2.8)	6.8 (3.3)	0.196
Final pathology			0.361
Adenoma	21 (33%)	89 (47%)	
Adenocarcinoma	25 (43%)	83 (42%)	
Tis	7 (12%)	23 (12%)	
T1	21 (36%)	42 (26%)	
T2+	7 (12%)	18 (9%)	
No residual tumor	6 (9%)	13 (7%)	
Carcinoid	6 (9%)	11 (6%)	
Full-thickness excision	67 (93%)	35 (88%)	0.539
Hybrid dissection	2 (3%)	10 (5%)	0.602
Defect closure	53 (93%)	181 (92%)	0.873
Positive margin	6 (10%)	11 (6%)	0.205
Tumor fragmentation	2 (3%)	10 (5%)	0.602
Mean duration of surgery, min (SD)	71 (38)	66 (35)	0.317
Mean blood loss, mL (SD)	25 (29)	21 (26)	0.060
Peritoneal violation	1 (2%)	7 (4%)	0.687
Postoperative complications	2 (3%)	18 (9%)	0.129
Mean length of stay, days (SD)	0.6 (1.3)	0.4 (1.2)	0.180

groups. There was not a statistically significant decrease in margin involvement due to the learning curve effect on univariate or multivariate analysis, suggesting that resection outcomes may not be compromised during the initial phase of the learning curve—provided that the operator is experienced in laparoscopic surgery, as were the surgeons in this study. Comparison of patients pre- and post-learning curve did not demonstrate any significant differences other than larger lesion size in the latter group, suggesting that more difficult lesions were attempted as experience increased. Furthermore, the incidence of inadvertent peritoneal entry was similar pre- and post-proficiency, and was overall in line with other reported large TAMIS [17, 29] and TEM series [30–32]. Proficiency gain as defined by rate of margin involvement also correlated with stabilization of operative time for each of the three groups.

Robotic TAMIS was performed in 7% of all patients in the present study. Robotic TAMIS did not alter the CUSUM analysis for learning curve as the first case was performed well after proficiency gain at the 37th case in group B. There are few data on the use of robotic TAMIS [28, 33]. While these studies have shown that it is feasible, the benefit of the robotic platform over TEM and non-robotic TAMIS is unclear, and it is associated with higher cost. The utility of the robotic platform for local excision may lie in the transfer of technical skill to other more advanced endoluminal applications, such as transanal total mesorectal excision [34].

Several other studies have defined the learning curve for local excision using the TEM platform. Helewa et al. [35]. and Maya et al. [14]. both used average rate of excision, a measure of operative efficiency, to define proficiency gain.

Stabilization of operative efficiency occurred after 16 and 4 cases in these studies, respectively. These data suggest a shorter learning curve for TEM, but their analyses were based on operative time, which have important limitations. Operative speed is one of the objective measures of technical skills, but does not always directly correlate with how well the operation is performed [36]. Indeed, Chen et al. have shown that increasing experience, as measured by decreasing operative time and lower conversion rates for laparoscopic colorectal surgery, did not translate into better patient outcomes, but rather the faster of two high-volume surgeons had increased morbidity after adjustment for patient risk factors [37]. Furthermore, operative time or any of its corollaries (such as average rate of lesion excision) is limited by that fact that more complex cases are often incorporated with more experience, such that studies have shown that operative times actually rise as procedural volume increases [38, 39]. Barendse et al. found that a learning curve effect affected operating time, complication and conversion rates, but not recurrence rates [13]. A specific case volume to acquire proficiency was not defined. Importantly, none of these studies arbitrarily divided case volume and used a before-and-after study design, which has been widely used but has significant biases [40, 41].

The ideal outcomes for learning curve assessment are patient outcomes, such as recurrence or complications in the case of transanal endoscopic surgery. However, these outcomes are often rare and therefore require a considerable amount of time before enough data are acquired for analysis, but consequently harmful procedures and practices or incompetent physicians may not be identified during this time [42]. Margin involvement was chosen as the main outcome measure to evaluate proficiency. This outcome is especially important in the setting of transanal endoscopic surgery for early rectal cancer, as an R1 resection requires additional intervention. The decision limits for acceptable and unacceptable R1 resection rate were based on pooled incidences of margin involvement from comparative studies comparing TAE and TEM, identified form a previously published systematic review [11]. TAE is now considered inferior to local excision via transanal endoscopic platforms, mainly due to the higher resection quality offered by the endoscopic platforms such as TEM and TAMIS [2]. Furthermore, Kidane et al. demonstrated that local excision by TAE resulted in worse overall survival compared to radical surgery, whereas local excision by TEM did not [43]. It was proposed that using margin involvement rates from TEM data as the acceptable proficiency limit was appropriate given the equivalency of TAMIS and TEM [44, 45]. A separate pooled analysis of margin involvement rates from TEM data from Arezzo et al. [46] demonstrate similar results using different studies (0.89, 95% CI 0.84–0.93) as the pooled analysis from the present study (0.90, 95% CI 0.84–0.97) suggesting that the rate used for the decision limit was generalizable.

This study should be interpreted in view of several other limitations. This was a single-center study from a high-volume referral institution with surgeons skilled in minimally invasive techniques. Therefore the learning curve as defined from these data may not be applicable to surgeons with limited experience with laparoscopic colorectal surgery. Transanal total mesorectal excision (TA-TME) at our institution was also introduced during the study period, which requires a similar skillset as TAMIS. It is possible that the learning curve of the two surgeons in group C would have been affected by simultaneous exposure to TAMIS and TA-TME during fellowship training. However, the early learning curve cases of the three senior surgeons (group A and B) occurred prior to the first TA-TME case, and therefore would not have contaminated their TAMIS proficiency gain. High fidelity simulators [47] or proctored training may be useful to accelerate the learning curve. The main outcome measure to determine proficiency was the incidence of margin involvement, which is a measure of surgical quality but ultimately not a patient outcome [42]. We could not use recurrence due to the low incidence in our series. However, long-term recurrence is likely related to tumor biology and characteristics, rather than surgical skill as long as the lesion is completely excised [48].

In conclusion, proficiency in TAMIS local excision of rectal neoplasms was reached after 14–24 cases. After an appropriate number of cases, the quality of surgical resection and operative time stabilizes to acceptable levels. Defining the learning curve can facilitate safe adoption of the TAMIS platform, as novice surgeons have a benchmark for the number of cases necessary to develop competency with TAMIS. Training, informed consent, and credentialing policies should consider these findings to optimize patient care.

Compliance with ethical standards

Disclosures deBeche-Adams reports consultant's fees from Applied Medical. Atallah reports consultant's fees from Applied Medical, THD American, Medicaroid, and Conmed. Albert reports consultant's fees from Applied Medical, Stryker, and Conmed, and stock options from Applied Medical. Mancuso reports consultant's fees from Applied Medical and Mallinckrodt. Lee, Kelly, Keller, Nassif, and Monson have no conflicts of interest or financial ties to disclose.

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