Original Article



# Important outcomes for transanal total mesorectal excision in a Canadian population after using transanal minimally invasive surgery (flexible) or transanal endoscopic microsurgery (rigid) platforms

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**Background:** There are no clinical studies comparing the short-term oncologic outcomes of transanal total mesorectal excision (TaTME) after using the flexible transanal minimally invasive surgery (TAMIS) *vs.* rigid transanal endoscopic microsurgery (TEM) platforms. The purpose of the study was to compare outcomes of TaTME surgery in a Canadian population when using a flexible *vs.* a rigid platform for patients with rectal neoplasia.

**Methods:** This is a retrospective, observational study utilizing prospectively collected data from two institutions. Inverse probability of treatment weights (IPTW) analysis was used to facilitate accurate estimation of treatment effects on outcome measures. The study was conducted at two high volume rectal cancer surgery centers in Canada. Only patients with rectal neoplasia who received TaTME were included, using either the flexible (TAMIS) or rigid (TEMS) platform.

**Results:** The total cohort consisted of 223 patients (116 with the rigid and 107 with the flexible platform). Two sets of patients 109 *vs.* 99 were eligible for inclusion. The incidence of complete/near complete specimens was 98.9% for TAMIS *vs.* 91.5% for TEMS. Oncological outcomes are comparable for both platforms when considering specimen completeness and negative margins (98.9% *vs.* 95.6%). A subgroup analysis demonstrated no difference between the two devices beyond proficiency (40 cases). Limitations include a relatively small number of cases and difficult generalizability since only 2 specialized centers participated in this project. Differences in patient selection and surgeon technique cannot be excluded.

**Conclusions:** Both flexible (TAMIS) and rigid (TEMS) platforms are safe and suitable options for TaTME. Surgical and oncological outcomes are equivalent once proficiency level is reached.

**Keywords:** Transanal total mesorectal excision (TaTME); flexible platform; rigid platform; complete; near complete; incomplete; circumferential margin; distal margin

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## Introduction

Access to the pelvis for radical excision of the rectum continues to pose a technical challenge for surgeons. The description of the mesorectal plane by Professor Heald represents the most important advancement impacting technical standards and oncologic outcomes for patients undergoing surgery for rectal cancer (1). Transanal total mesorectal excision (TaTME) was first described by Sylla *et al.* using the transanal endoscopic microsurgery (TEMS) rigid platform designed by professor Buess *et al.*; this new technique may facilitate a minimally invasive approach in patients where laparoscopy would not otherwise be possible (2,3). A contemporary alternative to the TEMS platform is the flexible transanal minimally invasive surgery (TAMIS) port developed and introduced by Atallah *et al.* (4). Both devices have been extensively used for local excision of early neoplastic lesions in the rectum (5,6).

Nearly 10 years after its initial description, registry and case series data suggest TaTME has similar short term oncologic outcomes and potential to overcome some of the technical challenges of conventional approaches (7-11). Regardless of the platform, TaTME is technically demanding with a prolonged learning curve (9,12-14). In contrast to its perceived benefits , it has become apparent that TaTME carries a significant potential for devastating injuries that were not previously common in rectal cancer surgery (12-14).

While both TEMS and TAMIS devices are used to perform TaTME surgery, there are no comparative studies to elucidate whether one platform leads to better results over the other. The objective of the current study was to compare the perioperative outcomes of patients undergoing TaTME surgery when using the flexible (TAMIS) versus the rigid (TEMS) platforms at two high volume specialized rectal cancer surgery centers in Canada.

## Methods

### *Patients*

Demographic, operative, pathologic and follow up data for all patients treated by TaTME technique at St. Paul's Hospital and Health Sciences North were independently and prospectively collected and maintained in separate databases at each institution since the time of inception (April 2014 and Jun 2015 respectively). After a data alignment strategy was developed, both databases were merged and queried for this study. Both hospitals had accumulated significant experience on transanal endoscopic surgery (TES) with their respective platforms, prior to introducing the TaTME procedure (15,16). Approval of the study protocol from the local ethics review board (ERB) was obtained at both institutions.

For inclusion criteria, only patients older than 18 years of age with a diagnosis of neoplasia of the rectum confirmed by histopathology were considered. Patients included required radical resection of the rectum and were offered TaTME at one of the two participating centers during the study period (2014 to 2018). Excluded from this study were patients treated by TaTME for diagnoses other than rectal neoplasia (e.g., ulcerative colitis, Crohn's disease) or patients with incomplete data regarding the surgical intervention, the primary outcome or relevant covariate data despite secondary chart review (*Figure 1*).

Preoperative evaluation included complete colonoscopy with focused endoscopic assessment and biopsy of the lesion, CT scan of the chest, abdomen and pelvis, regional pelvic MRI, and carcinoembryonic antigen (CEA) level. All cases were presented at multidisciplinary cancer conference (MCC) and those requiring neoadjuvant therapy were referred to the local cancer center. Restaging with repeat MRI was performed at the discretion of the managing team. Timing of surgery was determined according to accepted standards (17,18), and the multidisciplinary conference (MCC) recommendation. Those who did not require pre-operative chemo-radiation went straight for surgery. All operations were performed by subspecialty trained colorectal surgeons using a single-team (sequential) approach (19). Patients underwent full bowel preparation and were enrolled in multimodality perioperative ERAS interventions according to institutional protocols.

### *Outcomes measures*

The primary outcome measure of this cohort study was the presence of good quality mesorectal specimens (complete/near complete). Completeness of the mesorectum was scored by specialized pathologists as per the standardized mesorectal grading system (20). In the recent ACOSOG Z6051 trial acceptable rates for good quality mesorectal specimens were determined to be 81.7% and 86.9% for open and laparoscopic surgery, respectively (21). Secondary outcomes of interest were rates of uninvolved circumferential radial margin (CRM), defined by a minimum of 1 mm clearance from any identified tumour from the mesorectal margin, and distal resection margin

 

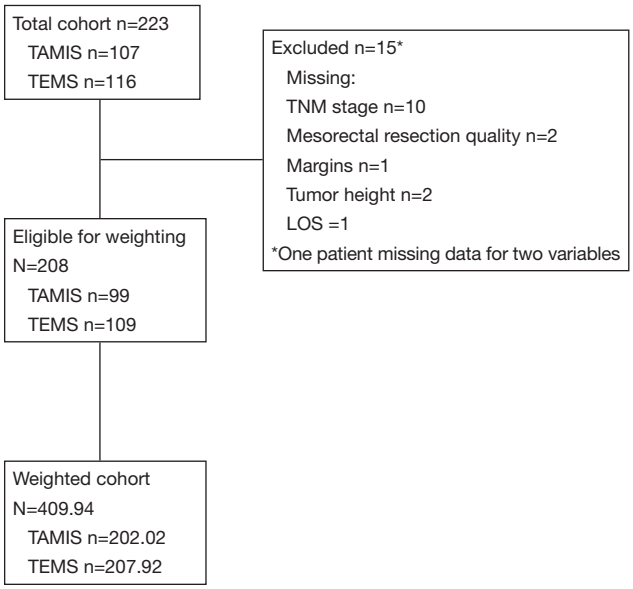


**Figure 1** Total patients on each cohort. Patients included required radical resection of the rectum and were offered TaTME at one of the two participating centers during the study period (2014 to 2018). Excluded from this study were patients treated by TaTME for diagnoses other than rectal neoplasia or patients with incomplete data. Cohort after weighting analysis. *, one patient missing data for two variables.

(DRM), defined by the absence of cancer cells at the distal margin of the specimen.

Other outcomes evaluated include perioperative morbidity (within 30 days of surgery), conversion rate, operative time, length of stay (LOS) and hospital readmission. Anastomotic leak was defined as clinical evidence of dehiscence, given by pelvic pain and/or signs of sepsis, with radiologic or endoscopic confirmation of anastomotic disruption required.

### *Statistical analysis*

Propensity scores (i.e., the probability of TAMIS compared to TEMS given a set of baseline patient characteristics) were calculated using logistic regression analysis with age, tumor height, body mass index (BMI), neoadjuvant chemotherapy, neoadjuvant radiotherapy, and TNM stage as covariates, and treatment group (TAMIS or TEMS) as the outcome. Scores were then transformed to inverse probability of treatment weights (IPTW) (22) and subsequent IPTW were truncated based on values of their 1% and 99% quantiles. This allows estimation of the average treatment effect (ATE) after eliminating potential confounding of the included covariates. However, this method does not account for unmeasured confounders.

Most baseline characteristics were unbalanced ($d \geq 10\%$) between TAMIS and TEMS groups in the original study cohort. Covariate balance between treatment groups was assessed before and after weighting using standardized differences ($d$); because hypothesis testing is dependent on sample size, standardized differences are preferred for assessing covariate balance (23) where $d \geq 10\%$ indicates a clinically relevant difference that requires further balancing (23,24). Adequate balance ($d < 10\%$) was achieved for all covariates after weighting using the IPTW approach. Patient and tumor characteristics are shown on *Table 1*. Analysis of the association between surgical procedures (TAMIS or TEMS) with binary outcome variables was conducted using weighted chi-square tests. For continuous outcomes, we used weighted quantile regression to accommodate weighted median testing. Results were considered statistically significant where $P<0.05$. For binary outcomes, we also calculated relative risks (RR) and their 95% confidence intervals (CI). All analyses were performed using SAS v9.4 software (SAS Institute, Carry NC).

A sensitivity analysis on the outcomes for the operators (two) with the largest number of cases on each platform was conducted on data beyond the learning curve (40 cases) as previously calculated by Koedam *et al.* (25) Available data resulted on an experience of n=61 *vs.* n=27 cases respectively per TAMIS *vs.* TEMS surgeon. For this analysis we used a weighted chi-square test where samples were big enough and Fisher's exact test for small samples. For the sensitivity analysis unweighted sample (no adjustment for cohort differences) were used, due to the size of the samples.

## Results

Between March 2014 and October 2018, 223 patients treated by TaTME were identified at the two participating centers (*Figure 1*). After exclusion criteria were applied, a total study cohort of 208 patients were included for analysis and two cohorts established: TAMIS (n=99) and TEMS (n=109).

After weighting the sample using IPTW, estimation of effects for surgical procedure on outcomes indicated a significant difference (P=0.019) for intraoperative complications where the TAMIS group was at lower risk of experiencing complications during the procedure compared to those undergoing TEMS (RR 0.353, 95% CI:

 

**Table 1** Baseline characteristics for TAMIS and TEMS groups before and after weighting

| Characteristic | Pre-weight | | | Post-weight | | |
|---|---|---|---|---|---|---|
| | TAMIS (n=99) | TEMS (n=109) | *d*, % | TAMIS (n=202.02) | TEMS (n=207.92) | *d*, % |
| Age (years), mean ± SD | 64.31±10.12 | 61.26±12.07 | 27.38 | 62.93±15.10 | 62.66±15.93 | 1.74 |
| Tumor height (cm), mean ± SD | 6.18±2.45 | 6.13±2.62 | 1.97 | 6.16±3.49 | 6.17±3.62 | 0.28 |
| BMI, mean ± SD | 27.68±6.93 | 27.58±5.61 | 1.59 | 27.32±9.89 | 27.58±7.28 | 2.99 |
| Male, n (%) | 72 (72.73) | 71 (65.14) | 16.46 | 132.93 (65.80) | 140.88 (67.76) | 4.16 |
| TNM stage I, n (%) | 15 (15.15) | 35 (32.11) | 40.74 | 51.54 (25.51) | 50.12 (24.11) | 3.24 |
| TNM stage II, n (%) | 27 (27.27) | 25 (22.94) | 10.0 | 51.15 (25.32) | 52.10 (25.06) | 0.60 |
| TNM stage III, n (%) | 49 (49.49) | 46 (42.20) | 14.67 | 88.37 (43.74) | 95.04 (45.71) | 3.96 |
| TNM stage IV, n (%) | 8 (8.08) | 3 (2.75) | 23.72 | 10.97 (5.43) | 10.66 (5.13) | 1.39 |
| Neoadjuvant chemotherapy, n (%) | 66 (66.67) | 50 (45.87) | 42.88 | 114.59 (56.72) | 116.22 (55.90) | 1.67 |
| Neoadjuvant radiotherapy, n (%) | 70 (70.71) | 67 (61.47) | 19.61 | 126.14 (62.44) | 129.66 (62.36) | 0.17 |

*d*, standardized difference (in percent %). SD, standard deviation; BMI, body mass index; TAMIS, transanal minimally invasive surgery; TEMS, transanal endoscopic microsurgery.

0.142–0.880). In the TAMIS group, 82.4% had a complete specimen *vs.* 87.1% in the TEMS, the near complete specimens were 16.5% and 6.3% respectively. When measured together the rate of complete/near complete was 98.9% for TAMIS and 91.5% for TEMS. No significant effects were observed for positive margins, postoperative complications, anastomotic leak, or readmission. There were no patients in the TAMIS group who experienced conversion, so hypothesis testing could not be accommodated in the weighted sample. Despite this caveat, the risk of conversion was lower in the TAMIS group compared to the TEMS group with regard to the overall proportions (*Table 2*). A higher proportion of patients in the TAMIS group underwent primary abdominoperineal resection (APR) 17% *vs.* 6% for the TEMS. For those that underwent restoration of bowel continuity, a stapled anastomosis was slightly more prevalent in the TAMIS group and transabdominal extraction more frequent in the TEMS group (*Table 3*).

When analyzing continuous outcomes for median differences, the TAMIS group showed longer OR time (median difference 43.0, 95% CI: 14.498–71.502). The incidence of intraoperative complications was lower for TAMIS, the difference was not significant between groups. Most complications were related to bleeding from the presacral space or the side walls. One case of hypercarbia was identified in the TEMS group requiring a break to reduce the levels of $CO_2$.

Postoperative morbidity was similar in both groups 37.5% *vs.* 42.6% (P=0.286) and no significant difference was identified (RR 0.808, 95% CI: 0.547–1.195). Other than leaks, urinary retention, ileus and high output from the ileostomy were prevalent. Anastomotic leak was identified on 7.90% *vs.* 13.91% (P=0.051) for TAMIS *vs.* TEMS (RR 0.568, 95% CI: 0.318–1.014). Patients in the TAMIS group experienced a shorter LOS (median difference –3.0, 95% CI: –4.134 to –1.866). There was no significant difference in hospital readmission between groups 15.72% *vs.* 20.60% (P=0.201) (*Table 2*).

### *Subgroup sensitivity analysis*

Data from the two surgeons beyond 40 cases was used to perform a subgroup analysis of the results. This demonstrated no significant difference for most outcomes, including intraoperative complications [n=0 for TAMIS *vs.* n=2 (7.4%) for TEMS, P=0.092] Incomplete specimens [n=1 for TAMIS (1.6%) *vs.* n=1 for TEMS (3.7%), P=0.522] and positive CRM [n=2 TAMIS (3.3%) *vs.* n=2 TEMS (7.4%), P=0.583]. The significant differences corresponded to anastomotic leaks [n=1 TAMIS (1.6%) *vs.* n=4 TEMS (14.8%), P=0.029] and conversions TAMIS [n=0 conversion (0%) and TEMS n=2 (7.4%), P=0.092].

Postoperative complications were weighted (IPTW)

 

**Table 2** Outcome analysis results; statistically significant results (P<0.05) are bold and effect estimates are for TAMIS with TEMS as the reference

| Outcome | TAMIS, % | TEMS, % | P | RR (95% CI) | β (95% CI) |
|---|---|---|---|---|---|
| Mesorectal resection | | | 0.001 | | |
| Incomplete | 1.12 | 8.54 | | 0.131 (0.033–0.516) | – |
| Complete/near complete | 98.88 | 91.46 | | | |
| Margins | | | 0.656 | | |
| CRM positive | 2.34 | 3.05 | | 0.766 (0.237–2.480) | – |
| CRM negative | 97.66 | 96.95 | | | |
| Intraoperative complications | | | 0.019 | | |
| Yes | 2.94 | 8.31 | | 0.353 (0.142–0.880) | – |
| No | 97.06 | 91.69 | | | |
| Postoperative complications | | | 0.296 | | |
| Yes | 37.76 | 42.82 | | 0.882 (0.696–1.117) | – |
| No | 62.24 | 57.18 | | | |
| Anastomotic leak | | | 0.051 | | |
| Yes | 7.90 | 13.91 | | 0.568 (0.318–1.014) | – |
| No | 92.10 | 86.09 | | | |
| Readmission | | | 0.201 | | |
| Yes | 15.72 | 20.60 | | 0.763 (0.503–1.157) | – |
| No | 84.28 | 79.40 | | | |
| Conversion* | | | – | | |
| Yes | 0.0 | 11.80 | | – | – |
| No | 100.0 | 88.20 | | | |
| OR time (minutes), median [IQR] | 312 [92] | 269 [94] | 0.003 | – | 43.0 (14.498 to 71.502) |
| Length of stay (days), median [IQR] | 3 [2] | 6 [6] | <0.001 | | –3.0 (–4.134 to –1.866) |

*, conversion outcomes were all negative for TAMIS group; weighted hypothesis testing could not be accommodated. OR, operating room; IQR, interquartile range; P, probability; RR, relative risk; CI, confidence interval; β, estimate (median difference); TAMIS, transanal minimally invasive surgery; TEMS, transanal endoscopic microsurgery.

TAMIS 32.14% and TEMS had 38.66%, weighted chi-square test P=0.370. Readmission was weighted (IPTW) TAMIS 11.82% and TEMS 31.49%, weighted chi-square test P=0.002.

## Discussion

Minimally invasive rectal cancer surgery is a technical challenge for surgeons, mainly due to the difficult access to the pelvis and the number of close critical structures necessary to preserve in this narrow space (26). The introduction of TEMS in the early 80's provided a great alternative for local excision of early lesions (2). The development of the flexible TAMIS platform has made transanal surgery more accessible to surgeons and has likely facilitated the rapid development of the TaTME technique (4). TaTME has been adopted by many surgeons worldwide using both flexible and rigid platforms (7,11,27-30).

There are clinical studies comparing the use of TAMIS *vs.* TEMS on patients undergoing local excision, results showed no difference in performance (5,31). TaTME is a more technically challenging procedure than local

 

**Table 3** Surgical characteristics of samples before and after weighting

| Surgical characteristics | Pre-weight | | Post-weight | |
|---|---|---|---|---|
| | TAMIS | TEMS | TAMIS | TEMS |
| Anastomosis, n (%) | | | | |
| Abdominoperineal reconstruction | 17 (17.17) | 6 (5.50) | 29.83 (14.77) | 11.0 (5.29) |
| Stapled | 71 (71.72) | 69 (63.30) | 146.32 (72.43) | 131.42 (63.21) |
| Hand sewn | 11 (11.11) | 34 (31.19) | 25.86 (12.80) | 65.49 (31.50) |
| Extraction site, n (%) | | | | |
| Transanal | 51 (51.52) | 17 (15.60) | 114.02 (56.44) | 30.56 (14.70) |
| Transabdominal | 47 (47.47) | 85 (77.98) | 86.83 (42.98) | 165.02 (79.37) |
| Other | 1 (1.01) | 1 (0.92) | 1.17 (0.58) | 1.49 (0.71) |
| Not documented | 0 (0.00) | 6 (5.50) | 0 (0.00) | 10.86 (5.22) |

TAMIS, transanal minimally invasive surgery; TEMS, transanal endoscopic microsurgery.

excision. To our knowledge, there are no comparative studies of TAMIS *vs.* TEMS ports for this procedure. In 2015, Kim *et al.* compared the performance of TaTME with flexible *vs.* rigid platforms using cadaveric models (32). The authors concluded that both devices are feasible for the procedure. According to their publication, some of the attributes of the flexible platform include a short set-up time, relatively atraumatic insertion and easy application. However, a narrow operative field is considered the main limiting factor. Conversely, the rigid platform offers a larger and more stable operative field, the rigidity of the channel, long time set-up and the narrow view were listed as limiting factors. In this study the authors concluded that both pieces of equipment are equivalent

Our study focused on the quality of surgical specimens and margin positivity (*Table 2*). These outcomes are well established surrogates for local recurrence and survival in rectal cancer (20,33-35). We identified a higher likelihood of achieving a complete specimen when using the TEMS platform. However, complete and near complete pathologic TME specimens share a similar low risk of local recurrence (34-36). When considered together, our TAMIS cohort demonstrated a statistically significant advantage when used for TaTME.

While we have used propensity scores to account for the numerous clinically measurable differences between the groups, we are cautious in overinterpreting these results. The unmeasured differences between the centers [e.g., referral pattern, patient selection, surgeon(s), pathologists, etc.] likely account for much of the variance observed. While the subgroup analysis of the post-learning curve data is a better comparison, it is underpowered to categorically confirm our finding that the two platforms are equivalent. We are reassured by the similar "good TME" rates observed in both cohorts when compared to established benchmarks from the previously published RCTs comparing laparoscopic and open TME (21,37,38).

In TaTME, intraoperative injuries rarely observed in conventional TME surgery have been described: urethral injury (13) and neurovascular bundle of Walsh damage (12). In this study, there were no major intraoperative injuries. The incidence of other complications were similar to the established benchmarks for TME surgery and not significantly different between groups (39).

Other variables analysed included operative time, conversion rate, type of reconstruction, extraction site and length of stay. Those may depend on different factors other than the type of platform utilized in surgery. Conversion rate is also variable depending on the judgement of the operating surgeon as well as site of extraction and perhaps type of reconstruction. LOS might be affected by cultural and social reasons or surgeon's preference, despite implementation of ERAS protocols.

This study has limitations that we recognize. There were numerous differences in the baseline characteristics of the groups. We used IPTW techniques to apply sample weights to each patient this is a well stablished methodology resulting in "an artificial population in which baseline covariates are independent of treatment status" (22) in order to account for some of these measurable differences.

 

However, there are likely many immeasurable differences in surgical practice and patient selection between the two groups. Also we acknowledge that having 1 surgeon in the TAMIS group, limits generalizability, however these results are similar to those from authors who have reported excellent outcomes with the flexible platform (25,27). The procedures were performed at two high volume centers by specialized colorectal surgeons which can also limit the ability to generalize the results.

We conclude that short term outcomes of TaTME appear to be safe and adequate regardless of the platform chosen by the surgeon/institution. While we did demonstrate a difference in the short-term oncologic outcomes between the platforms, we feel that these differences should be evaluated in a larger, multicenter study. Most importantly, we demonstrate that surgeons using both platforms can achieve similar short-term oncologic results to those considered the current benchmark for rectal cancer surgery with acceptable complication rates.

Currently, there are other devices, such as robotic platforms that are continuously evolving in an attempt to improve access to the pelvis, however limitations still exist regarding superiority of any technology (21,37,40).

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## Footnote

*Conflicts of Interest:* All authors have completed the ICMJE uniform disclosure form (available at http://dx.doi.org/10.21037/ales.2020.01.01). The authors have no conflicts of interest to declare.

*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Approval of the study protocol from the local ethics review board (ERB) was obtained at both institutions. Written informed consent was obtained from all patients.



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