Clinical and oncological outcomes of transanal total mesorectal excision considering the embryology along the fascia in rectal cancer patients: a propensity score-matched analysis

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Abstract

Purpose

Transanal total mesorectal excision (TaTME) remains a challenging technique for rectal dissection. This study aims to evaluate the clinical and oncological outcomes of TaTME, compared to those of the laparoscopic total mesorectal excision (LaTME) in rectal cancer.

Methods

Using propensity score-matched analyses, we analyzed retrospective data from 134 consecutive patients with rectal cancer who underwent TaTME or LaTME from January 2011 to June 2020 in our hospital. Clinical and oncological outcomes were evaluated. The primary endpoint was the 2-year local recurrence rate.

Results

Before data analysis, significant group-dependent differences were observed only in the tumor height ($p < 0.01$). After analysis, preoperative patients' demographics were similar between the TaTME and LaTME-defined groups. The operative time was significantly shorter in the TaTME group ($p = 0.02$), and the rates of hand-sewn anastomosis and protective loop ileostomy were significantly higher($p < 0.01$). TaTME showed a 29% overall morbidity rate and LaTME 44%. Furthermore, the rate of Clavien–Dindo grade III tended to be lower in the TaTME group ($p = 0.07$). There were no statistically significant differences in terms of pathological findings, and the 2-year local recurrence rate was similar between the two groups (both 5.9%)

Conclusions

TaTME based on embryology along the fascia is feasible and seems a safe alternative to LaTME in selected patients with rectal cancer when considering the conversion rate and the operative time.

Introduction

Total mesorectal excision (TME) for rectal cancer is a dissection technique associated with a low local recurrence rate and good long-term survival, consequently becoming a standard surgical treatment accepted worldwide [1–7]. When performed by skilled surgeons, laparoscopic TME (LaTME) results in better short-term and similar long-term outcomes compared with open surgery in selected rectal cancer patients [4, 5]. Although laparoscopy provides improved pelvic visualization leading to more effective TME, LaTME technical difficulties are still encountered: poor visualization of the deep prostate or vaginal

plane and difficult instrument insertion due to lack of space, especially in patients with obesity, narrow pelvis, low rectal cancer, or bulky tumors [4–7].

Surgical treatment for rectal cancer has dramatically evolved during the last decade. Recently, transanal TME (TaTME) was successfully applied in rectal cancer surgery following laboratory-based experience in cadavers [8–15]. This new technique potentially leads to the acquisition of intact specimens, low rates of circumferential resection margin (CRM) involvement, and a higher rate of sphincter-saving rectal resection [16–20]. However, some reports show that TaTME is related to multifocal local recurrence (LR) rate [21, 22]. Noteworthy, van Oostendorp et al. reported that the multifocal local recurrence rate associated with TaTME might be related to sub-optimal execution rather than the technique itself [22]. Conversely, Roodbeen et al. confirmed reasonable loco-regional control after TaTME in selected cases from tertiary referral centers, indicating no oncological risk in the surgical technique [24]. Roodbeen et al. supported the oncologic safety of the TaTME approach with data from an international registry cohort of rectal cancer patients, reporting an acceptable 2-year LR rate and a predominantly unifocal LR pattern [24]. TaTME remains a challenging technique, and its oncological validity in rectal cancer is still controversial.

We evaluated the clinical and oncological outcomes of TaTME based on embryology along the fascia, comparing those of LaTME for rectal cancers. Using this technique, the dissection plane between tissues of different embryological origins can be recognized through enhanced transanal visualization of the surgical plane.

Patients And Methods

Patients

Data from 134 patients with rectal cancer who underwent TaTME or LaTME from January 2011 to June 2020 in Kagoshima University Hospital was retrospectively analyzed using propensity score-matched (PSM) analysis. The inclusion criteria consisted of TaTME or LaTME with anastomosis; age of 20 to 89 years; histologically proven adenocarcinoma; tumors located in the rectum; cT1–3, or cT4a lesions; node stages cN0–3; and tumor size of $\leq$ 8 cm. Patients were excluded if they had cT4b tumors, a tumor height of > 12 cm, bowel obstruction or perforation caused by the primary tumor, or an American Society of Anesthesiologists physical status classification of $\geq$ IV. The primary endpoint was the 2-year LR rate after PSM. The secondary endpoint was clinical outcomes after PSM. The following topics were assessed: operative time, blood loss, rate of lateral pelvic lymph nodes dissection (LPLND), type of anastomosis, rate of conversion, intraoperative complications, protective loop ileostomy, postoperative complications, rate of anastomotic leak, rate of re-operation within 30 days, length of hospital stay, readmission rate, mortality, and pathological findings. Postoperative complications were classified according to the Clavien-Dindo classification [25]. The radial margin (RM) (i.e., CRM) was graded as RM0 (no tumor identified at the RM), RM1 (tumor identified at the RM), or RMX (inability to assess tumor involvement of the RM) according to the Japanese Classification of Colorectal Carcinoma [26]. All mesenteric lymph

nodes were retrieved and fixed in formalin, and two pathologists assessed each specimen. Oncological outcomes during the study term were also evaluated.

This study was reviewed and approved by the Ethics Committee of Kagoshima University Hospital.

Surgical Technique For Tatme

All patients were placed in the modified lithotomy position and subjected to general anesthesia. We conducted a two-team approach for TaTME as described by Arroyave et al. [27]. Three 10-mm trocars and one 15-mm trocar (AirSeal Access Port; CONMED, Utica, NY, USA) were inserted through the access device (GelPOINT path; Applied Medical, Rancho Santa Margarita, CA, USA) in the form of a quadrant. After setting the self-retaining anal retractor (Lone Star Retractor; CooperSurgical, Trumbull, CT, USA), the access device was introduced through the anus to the rectum. After temporarily clamping the rectosigmoid using an atraumatic endo bulldog clip (Aesculap AG, Tuttlingen, Germany), the pneumorectum was maintained at 15 mmHg with carbon dioxide via an AirSeal platform (AirSeal System; CONMED, Utica, NY, USA). A double purse-string suture was applied in a clockwise manner using 0–0 polypropylene with a 26-mm rounded needle to tightly occlude the rectum with a 3-cm margin distal to the tumor. After irrigation with saline, the dissection line was marked by tattooing the rectal mucosa distal to the mucosal folds (Fig. 1a). The mucosal dissection of the rectum was initiated (Fig. 1b), and full-thickness rectal transection was then performed circumferentially (Fig. 1c). After rectal transection, a sharp circumferential dissection within the embryological plane was performed. Dissection proceeded to the outer surface of the mesorectum with recognition of mobility between the visceral and parietal fascia on the anterior side. The dissection was performed toward the presacral plane between the parietal pelvic fascia and mesorectal fascia in the loose areolar tissue, which was facilitated by anterior traction of the rectum using gauze on the posterior side (Fig. 1d). The dissection proceeded toward the peritoneal reflection between Denonvilliers' fascia (rectovaginal septum) and the mesorectal fascia on the anterior side. The dissection then proceeded behind the neurovascular bundle (NVB), keeping the layer of Denonvilliers' fascia (rectovaginal septum) intact on both lateral sides and identifying the pelvic nerve using the NVB and parietal pelvic fascia as a landmark. Finally, the rectosacral fascia on the posterior side and the peritoneal reflection on the anterior side were dissected to connect to the abdominal field with the cooperation of the abdominal surgical team (supplemental video). The specimen was extracted transabdominally. A single-stapling technique with end-to-end anastomosis was implemented with a circular stapler (29-mm CDH; Ethicon Endo-Surgery, Cincinnati, OH, USA) using the anastomotic method described by Penna et al. [28]. The hand-sewn anastomosis was performed in patients who underwent partial intersphincteric resection (ISR). A diverting ileostomy was then created if necessary. A suction drain was placed in the deep pelvis through the left lower quadrant in all patients. Another suction drain was placed transanally in the patients.

Propensity Score-matched Analysis

The propensity score-matched (PSM) analysis was carried out to minimize the possibility of selection bias and to adjust for a significant difference in the baseline characteristics of patients. The propensity score was calculated using a logistic regression model with the surgical approach (TaTME or LaTME). Independent variables included in the models were age, sex, body mass index (BMI), American Society of Anesthesiologists (ASA) score, tumor height, and clinical TNM stage. The TaTME and LaTME groups were matched according to the propensity scores using the nearest neighbor matching in a 1:1 ratio without replacement, using a caliper set at 0.2. After propensity score-matching (PSM), 34 patients, each in the TaTME and LaTME groups, were included in the final analysis. Then, baseline characteristics were compared between the two groups using bivariate analyses.

Statistical analysis

Data was presented as a median and interquartile range for continuous variables and as frequency and percentage for categorical variables. When appropriate, categorical variables were compared with Chi-square test or Fisher's exact test. Non-parametric variables were presented as median values and ranges. Wilcoxon's t-test was used to determine the significance of differences between continuous variables. A P-value < 0.05 was considered statistically significant. Kaplan–Meier estimates of local recurrence (LR) were calculated, and the log-rank test was used to compare LR curves. All statistical analyses were performed using JMP version 16.0 software (SAS Institute, Cary, NC, USA).

Results

The patients' demographics are shown in Table 1. Before the PSM analysis, significant group-dependent differences were observed in the tumor height ($p < 0.01$). After matching, preoperative patients' demographics were similar between the two groups, and 34 patients were finally included in each group.

The perioperative outcomes are shown in Table 2. After PSM, the TaTME group showed significantly shorter operative time ($p = 0.01$) and null conversion to open surgery than the LaTME group (5.9%). Hand-sewn anastomosis and protective loop ileostomy procedures presented significantly higher in the same group ($p < 0.01$). Regarding postoperative complications, the TaTME group showed 24% of Clavien–Dindo grade II and 6% of grade III, while the LaTME group showed 21% for both grades II and III. Interestingly, grade III tend to be lower in the TaTME group ($p = 0.07$). Moreover, the anastomotic leak was lower in the TaTME group (6% vs. 12% in the LaTME group). Finally, the overall morbidity rate was lower in the TaTME group (29% vs. 44% in the LaTME group), and the length of hospital stay was similar between the two groups.

The pathological findings are shown in Table 3. There were no statistically significant differences in terms of pathological findings. The median number of retrieved lymph nodes was 18 in the TaTME group and 16 in the LaTME group. Also, the median of the distal margin was 2.5 cm in the TaTME group and 2.0 cm in the LaTME group. Before PSM, a positive radial margin was observed in only one patient (1%) in the TaTME group and one (2%) in the LaTME group.

The 2-year LR rate was similar between the two groups (Table 4 and Fig. 2). The median follow-up period was 54 (range, 14–82 months) months in the TaTME group and 65 (range, 9–111 months) in the LaTME group. It is worth mentioning that two patients in the TaTME group developed lateral pelvic lymph node metastasis and two more developed posterior pelvic recurrences. All patients were diagnosed with systemic disease progression, including lung or liver metastasis treated with radiotherapy and subsequent chemotherapy. Regarding survival, one of these patients presented final Stage IIIc (pT4b, pN2, M0: after neoadjuvant chemotherapy) with pathology of signet-ring cell carcinoma, mucinous adenocarcinoma, poorly differentiated adenocarcinoma, and tubular adenocarcinoma who developed posterior local recurrence and died due to the development of lung metastasis 35 months after surgery. The second case was a Stage I (pT1b, pN0) patient who developed lateral lymph node metastasis with accompanying lung metastasis and died due to the development of lung metastasis 28 months after surgery. The third patient exhibited a final Stage IV (pT3, pN0, M1: after neoadjuvant chemotherapy) tumor, developed multifocal recurrences, and died due to the development of liver and lung metastasis 29 months after surgery. The last patient presented a final Stage I (pT2, pN0, M0: after neoadjuvant chemotherapy) tumor who developed lateral lymph node metastasis with accompanying lung metastasis, continued adjuvant chemotherapy, and is alive 84 months after surgery.

Contrarily, three patients in the LaTME group developed lateral pelvic lymph node recurrences before PSM. One of these patients presented a final Stage IV (pT3, pN0, M1: after neoadjuvant chemotherapy) tumor, developed lateral pelvic lymph node metastasis, and died due to the development of lung metastasis 32 months after surgery. Another patient who underwent lateral pelvic lymph nodes dissection with a final Stage IIIb (pT3, pN2a, M0: after neoadjuvant chemotherapy) tumor developed lateral pelvic lymph node recurrence with accompanying lung metastasis and died due to the development of lung metastasis 108 months after surgery. Lastly, one patient who underwent lateral pelvic lymph nodes dissection with a final Stage IIIc (pT3, pN3, M0: after neoadjuvant chemotherapy) tumor developed lateral pelvic lymph node recurrence and underwent salvage surgery. The patient died 65 months after primary surgery due to the development of lung metastasis.

Discussion

In this observational cohort study, we compared clinical and oncological outcomes between TaTME and LaTME. Using PSM analysis, these techniques' median follow-up period was 54 months and 65 months, respectively. Before PSM, the 2-year LR rate for TaTME and LaTME was 4.5% and 6.5% in each group, while after the analysis, it was 5.9% for both groups. These results tie in well with previous studies. A few examples, the 2-year LR rates for LaTME of the ALaCaRT and ACOSOG trials were 5.4% and 4.6%, respectively. Furthermore, the 3-year LR rate for LaTME in the COLOR III trial was 5.0% [4, 6, 7], and the 2-year LR rate for TaTME was 4.5%, comparable with established conventional techniques. However, one patient in the TaTME group developed multifocal recurrence in early phase after neoadjuvant chemotherapy. The patient had a threatened mesorectal fascia in the baseline MRI after chemotherapy with an anterior lesion located 4 cm from the anal verge. Additional chemoradiotherapy and an abdominoperineal resection should be considered in this case. Roodbeen et al. informed a 2-year LR rate

of 4.8% with a unifocal LR pattern in 99 of 103 patients (96%). The independent risk factors for LR were male sex, threatened resection margin on baseline MRI, pathologic stage III cancer, and a positive circumferential resection margin on final histopathology from the data of an international registry (a total of 2,803 patients) [24]. Therefore, a more intensive strategy like total neoadjuvant therapy should be considered for patients of male sex with threatened resection margin on baseline MRI (29, 30).

Operative outcomes differ in terms of the operative time, the rate of stapled anastomosis, the rate of conversion to open surgery, and the rate of protective loop ileostomy. The operative time was significantly shorter, and conversion to open surgery was null, as in previous reports for the TaTME group [31–33]. The conversion rate in large clinical trials, including ALaCaRT, ACOSOG, and COLOR II trials, ranged from 9 to 16% [4, 6, 7]. There are surgical difficulties during laparoscopic rectal cancer surgery for patients with obesity, narrow pelvis, male sex, and bulky tumors. TaTME via two-teams approach reduces these surgical difficulties, resulting in a shorter operative time and a minimum conversion rate. The rate of protective loop ileostomy was significantly higher in the TaTME group and seemed to be caused by the increase in hand-sewn anastomosis to preserve the sphincter resection and the difficulty of the single stapling technique for low anterior resection. The postoperative complications (Table 2), including anastomotic leak, were comparable between the two groups. Moreover, these results are acceptable when compared to the International TaTME Registry: the informed rate of postoperative complications and anastomotic-related morbidities are 35.4% and 19.8%, respectively [20]. We attribute these complications to the fact that TaTME was performed along the fascia in the loose areolar tissue facilitated by proper traction of the rectum through enhanced transanal visualization of the surgical plane.

TME for rectal cancer is the gold standard technique accepted worldwide [1–3]. Anterior retraction of the rectum creates loose areolar tissue between the mesorectal fascia and the endopelvic fascia dorsolaterally [2]. The basic principle of TME is sharp dissection within the holy plane [2]. TaTME potentially provides improved visualization of the deep prostate or vaginal plane with the acquisition of intact specimens and a low rate of CRM involvement [15–18]. In the present study, RM was 1.1% and 2.2% in the TaTME and LaTME groups, respectively, before PSM. We focused on the surgical technique of TaTME considering the embryology along the fascia to perform an adequate TME. This technique can recognize the holy plane through enhanced transanal visualization. The pelvic nerves are preserved by pursuing an intact layer via fascial separation. However, because pneumodissection can occur deep to the nerve plexus with TaTME, the surgeon must be alert to the possibility of going too laterally, which could lead to dissection in a plane deep to the parietal pelvic fascia and resultant inadvertent pelvic nerve injury [34].

Taking into consideration our results, safely TaTME application is crucial. A formal structured training pathway should be completed to implement the technique in clinical practice [35], including self-learning, cadaver workshops, mentorship of initial 5–10 TaTME cases, and independent practice [36]. A detailed framework for a structured TaTME training curriculum that promotes competent performance is also essential to ensure that the introduction of a new technique occurs in a safe and controlled manner to protect both the patient and the surgeon [35–37]. Discussion of case selection with a mentor or

supervisor, optimization of the technique, and inclusion of TaTME data into the international registry, are also recommended to achieve quality control of the method [35–37].

Our study has some limitations. Despite using PSM to decrease the selection bias, this cannot be entirely excluded because the study is retrospective and with a small number of patients. Larger-scale randomized controlled trials are necessary to optimize this challenging approach's benefits and potential indications. Also, it should be noted that the mean duration of the postoperative hospital stay in our institution was 14 days, and we attribute postoperative complications to this extended time. In contrast, we consider acceptable the postoperative morbidity rate and the 30-day readmission rate. Lastly, the resultant mean duration of surgery was long due to careful dissection during TaTME to avoid visceral or parietal injury with minimal blood loss. Practitioners still need to gain further experience and polish the necessary technical skills. The final limitation of this study is that the CRM was assessed as the RM according to the Japanese Classification of Colorectal Carcinoma [26]. Possibly, the results do not adequately reflect the CRM since all mesenteric lymph nodes were retrieved after surgery and fixed in formalin.

Conclusion

TaTME based on embryology along the fascia is feasible and seems to be a safe alternative to LaTME for selective patients with rectal cancer when considering the conversion rate and the operative time.

Declarations

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Author contribution

Protocol/project development: Kohei Yoshimitsu and Shinichiro Mori. Data acquisition and interpretation: Yuki Hamada, Ryutaro Yasudome, Daisuke Matsushita, Masaki Shimonosono, and Kentaro Hokonohara. Statistical analysis: Shinichiro Mori and Chihaya Koriyama. Manuscript drafting: Kohei Yoshimitsu and Shinichiro Mori, Kan Tanabe, Masumi Wada, Takaaki Arigami, Ken Sasaki, Hiroshi Kurahara, Akihiro Nakajo. Pathology: Michiyo Higashi. Manuscript revision and accountability for all aspects of the work: Takao Ohtsuka. All authors approved the final version of the manuscript.

Declarations

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

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nothing

Consent

We applied opt-out method to obtain consent on this study.

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Organisation), EAES (European Association of Endoscopic Surgeons), ESSO (European Society of Surgical Oncology), CSCRS (Canadian Society of Colorectal Surgery), CNSCRS (Chinese Society of Colorectal Surgery), CSLES (Chinese Society of Laparo-Endoscopic Surgery), CSSANZ (Colorectal Surgical Society of Australia and New Zealand), JSES (Japanese Society of Endoscopic Surgery), SACP (Argentinian Society of Coloproctology), SAGES (Society of American Gastrointestinal and Endoscopic Surgeons), SBCP (Brazilian Society of Coloproctology), Swiss-MIS (Swiss Association for Minimally Invasive Surgery). (2020). International expert consensus guidance on indications, implementation and quality measures for transanal total mesorectal excision. Colorectal Dis. 22(7):749–755.

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Tables

Tables 1 to 4 are available in the Supplementary Files section.

Figures

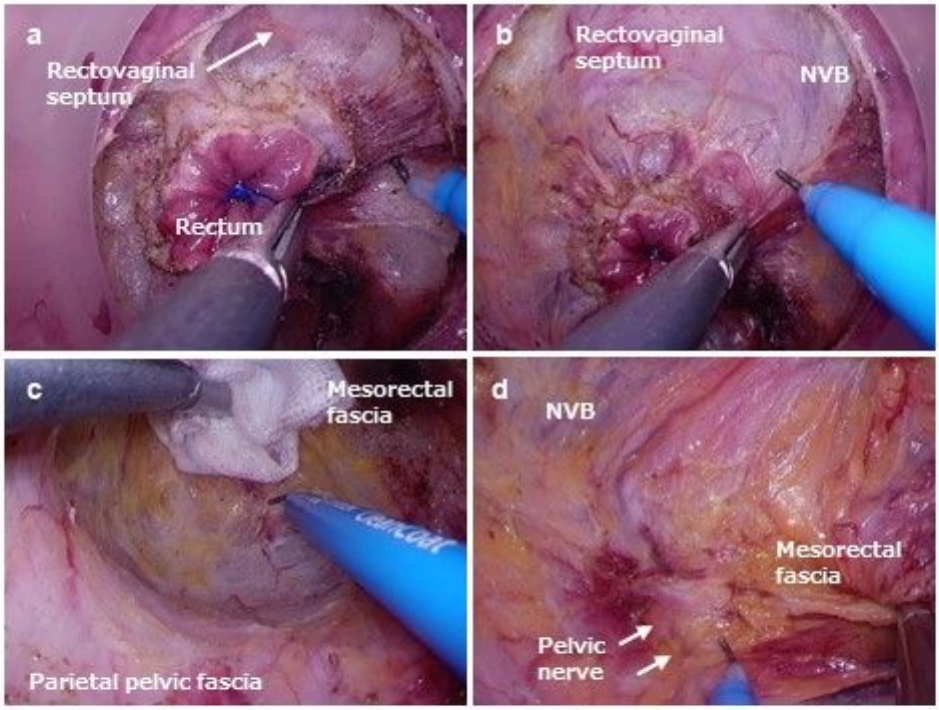

Fig. 1

Figure 1

Dissection within the embryological plane along the fascia

(a) Dissection line mark via tattoo in the rectal mucosa distal to the mucosal folds. (b) Mucosal dissection of the rectum. (c) Circumferential full-thickness rectal transection. (d) Dissection between the endopelvic fascia and mesorectal fascia on the posterior side.

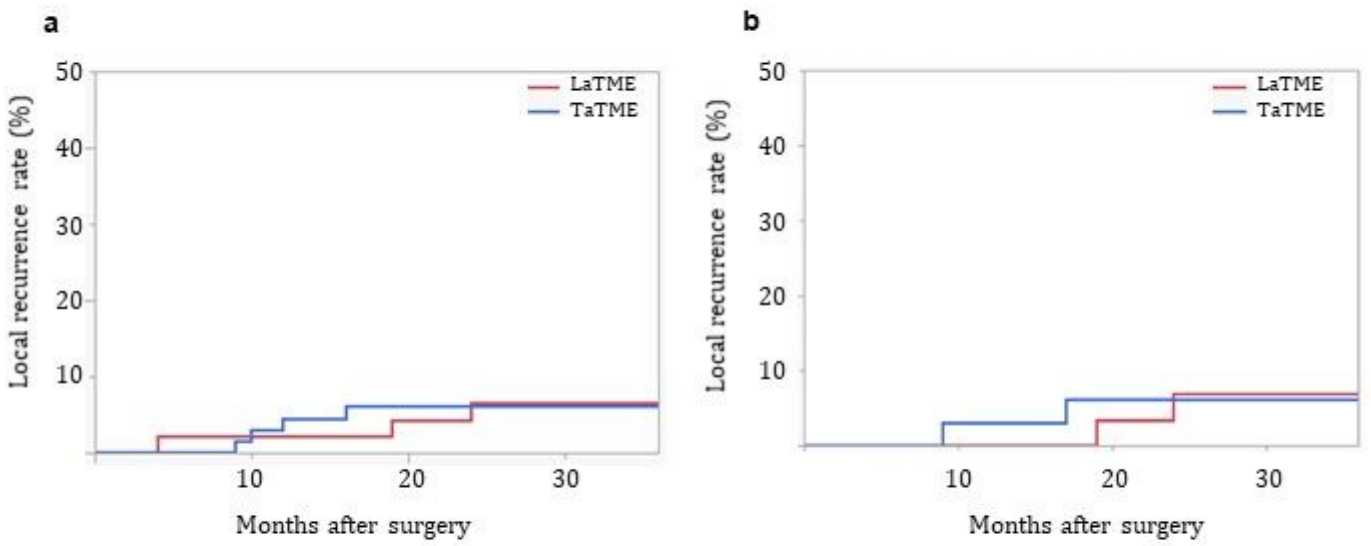

Fig. 2

Figure 2

Two-year local recurrence rate

The 2-year LR rate (a) before PSM: 4.5 % in TaTME group and 6.5 % in LaTME group; (b) after PSM: 5.9 % in TaTME group and 5.9% in LaTME group.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Table.docx
- Supplementaryvideo.wmv