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Completion proctectomy following transanal endoscopic microsurgery for early rectal cancer

Katarina Levic-Souzani[1], Orhan Bulut[1,2]

[1]Gastrounit-Surgical Division, Center for Surgical Research, Copenhagen University Hospital, Hvidovre 2650, Denmark.
[2]Institute of Clinical Medicine, University of Copenhagen, Copenhagen 1165, Denmark.

Correspondence to: Dr. Orhan Bulut, Gastrounit-Surgical Division, Center for Surgical Research, Copenhagen University Hospital, Hvidovre 2650, Denmark. E-mail: Orhan.Bulut@regionh.dk

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Abstract

Transanal endoscopic microsurgery (TEM) has proven to be a safe and effective procedure in removal of rectal lesions and may be used in treatment of early rectal cancer in selected patients. In cases when the TEM specimen shows non-radical resection, or histological high-risk factors, completion proctectomy (CP) is warranted. It is debated when it is the best time to perform CP following TEM. It is furthermore uncertain whether CP leads to an increased risk of abdominoperineal excision. Herein, we review the available literature regarding controversial issues with early completion proctectomy following TEM.

Keywords: Transanal endoscopic microsurgery, total mesorectal excision, completion proctectomy, early rectal cancer

INTRODUCTION

Transanal endoscopic microsurgery (TEM) was first introduced in 1984 by Buess *et al.*[1] as a minimally invasive surgical technique for the resection of large rectal adenomas. With TEM technique, a full-thickness *en bloc* excision is possible in the entire rectum, which may be technically difficult by other local procedures such as transanal excision (TAE). TEM has proven to be a safe and effective procedure in removal of rectal lesions[2-9]. TEM has furthermore considerably lower morbidity and mortality compared with conventional radical rectal resection for rectal tumors[10-15]. For patients with tumors in the lower part of the rectum, local excision by TEM may offer a chance for preserved bowel continuity and avoidance of rectal amputation with subsequent consequences.

The best management for early rectal cancer is still controversial. In terms of oncological results, local excision of early rectal cancer (pT1) by TEM has equivalent outcomes to radical resection[10,11,13,14]. Due to abovementioned advantageous attributes, the use of TEM for early rectal cancer is now considered a viable option in selected patients, and may be offered to patents with lesions pre-operatively staged as T1N0, with tumor diameter < 4 cm involving less than 30% of the rectal wall circumference, and no histological risk factors[16-20]. Preoperative staging with endoscopic rectal ultrasound (ERUS) and magnetic resonance imaging (MRI) of rectal lesions aid in decision making of selection for local treatment or radical resection. However, understaging is not uncommon[9,21-25]. Furthermore, unexpected malignancy is reported in 18%-43% of preoperatively assumed benign lesions in the rectum[9,26-28].

Early completion proctectomy (CP) is recommended in cases when the TEM specimen shows non-radical resection, low tumor differentiation or lymphovascular invasion, because of the increased risk of recurrence and lymph node metastasis in such cases. Some concerns have been raised regarding early CP. There may be increased morbidity due to two procedures being performed in the same area within a short period of time. The healing and scar formation and mesorectal fibrosis from the previous TEM procedure may disrupt the normal tissue planes and compromise the operative field. This may increase the difficulty during dissection in CP, and result in higher perforation rates, poor resection quality, prolonged operative time and higher conversion rates. The fibrotic scarring following TEM procedure may also contribute to tissue retraction and binding of the previous tumor site to the pelvic floor, which may lead to an increased abdominoperineal excision (APE) rate. We aim to review the available literature regarding controversial issues with early completion proctectomy following TEM.

OVERALL MORBIDITY AND APE RATE

Overall morbidity following rectal cancer surgery is about 40%, regardless of approach (open or laparoscopic)[29]. A concern with CP is that a previous operation in the rectum by TEM may influence surgical dissection plans, resulting in an increased risk for local complications. Regarding morbidity rates following CP, the results vary among studies, and interpretation is limited by small study samples and methodological issues. In a study reported by Piessen *et al.*[30], 14 consecutive patients who underwent full thickness TAE and subsequent radical resection, were matched and compared with 25 patients with primary radical resection. There was no significant difference in overall morbidity (64.3% *vs.* 32%, $P = 0.112$). However, a higher rate of surgical complications was shown in the TAE group (57.1% *vs.* 20%, $P = 0.048$). The frequency of specific surgical site complications, including anastomotic leakage and pelvic abscess, was also higher in the TAE group (42.8% *vs.* 8%, $P = 0.032$). The study cohort consisted of patients with preoperative chemo- or radiation therapy (5/14 patients in the TAE group), and the defect in the rectal wall was left unsutured in all patients, which may have contributed to the higher local compliactions. Although not fully investigated yet, the non-sutured defect at the TEM site may weaken the rectal wall and result in higher risk of perforation during CP.

In contrast, Morino *et al.*[31] didn't find any difference in the incidence of complications. They compared 17 patients with laparoscopic total mesorectal excision (LTME) after TEM with 34 patients undergoing primary TME and found that the results on rate of intraoperative complications and conversion to open surgery did not differ significantly (5.9% *vs.* 8.8%, $P = 0.854$, and 5.9% *vs.* 5.9%, $P = 0.528$, respectively). There was, however, a significantly longer operating time in the TEM group (206 min *vs.* 188 min, $P = 0.025$). Although there were only 25 patients in each group, the study by Levic *et al.*[32] is the largest comparative study on early CP up to date. Twenty-five patients with early CP were matched and compared with 25 patients with primary TME. There was no difference in intra- or postoperative complications, operating time or estimated blood loss between the two groups. Only a minority of the patients in both groups were oper-

ated with laparoscopy, hence it is therefore not possible to say whether previous TEM had an influence on conversion rates.

The fibrotic changes in the mesorectum and granulation tissue surrounding the previous TEM site is also a concern following CP, because of potentially higher APE rates. Although recognized among surgeons, there is still a lack of evidence on the subject in the literature. Hompes *et al.*[33] reported a 14% APE rate in a study consisting of 36 patients with CP. Piessen *et al.*[30] didn't find any difference in rate of sphincter saving procedures performed. One of the matching factors was, however, the procedure type. Likewise, there was no difference in the APE rate in the study by Levic *et al.*[32], although the control group was also matched based on procedure type. Morino *et al.*[31] performed matching based on gender, age, American Society of Anesthesiologist (ASA) score, body mass index (BMI), tumor size, and tumor distance from the anal verge. A significantly higher APE rate was observed in the CP group (41.2% *vs.* 11.7%, $P = 0.028$). Following multivariate analysis, previous TEM was the only independent predictor for APE (OR 4.13, 95%CI 1.09-15.55, $P = 0.046$)[31]. In a study by van Gijn *et al.*[34] where 59 patients with CP were compared with 881 patients from the TME-trial (with preoperative radiotherapy) the results showed a higher rate of colostomies in patients with previous TEM (OR 2.51, 95%CI 1.30-4.86, $P = 0.006$). The TEM group had, however, a higher rate of Hartmann procedures, but the same rate of APE.

PATHOLOGICAL FINDINGS

Another concern with CP after TEM may be pathologic findings and completeness of the mesorectal fascia (MRF). The risk of poorer quality of the mesorectum may be due to the scar formation and mesorectal fibrosis from the previous TEM, as previously mentioned. In Morino's study, where a higher rate of APE was reported, no difference was seen in the integrity of the mesorectum, with preserved integrity in all patients included in the study[31]. Likewise, although there were incomplete pathological data on all patients, Levic *et al.*[32] didn't find any difference in the number of patients with nearly complete or complete MRF (11 *vs.* 16 patients, $P = 0.31$). The perforation rate at or near the previous TEM site was, however, 20% in the CP group. Piessen *et al.*[30] reported major difference in completeness of the mesorectum. The MRF was complete in only 4/25 with previous full-thickness TAE *vs.* 24/25 in the group with primary TME ($P < 0.001$). Furthermore, tearing of the rectal wall down to the mucosa occurred was more frequent in the group with CP (35.7% *vs.* 0%, $P = 0.009$). Again, it is worth to mention that the defect after the full thickness excision was left unsutured in all patients, which may have had an influence on these figures. None of the studies comparing CP with primary TME showed difference in the circumferential margin involvement rate (Levic *et al.*[32]: 4% in both groups; Morino *et al.*[31]: 0% in both groups; Piessen *et al.*[30]: 14% *vs.* 4%).

ONCOLOGICAL RESULTS

The reported high perforation rates during CP lead to worries regarding survival in these patients, as iatrogenic rectal perforation is one of the most important risk factors for both local and distant recurrence and impaired survival[35-37]. Results regarding long-term oncological results in patients with CP are, however, very limited. Borschitz *et al.*[38]'s study on 21 patients with CP following TEM showed low rates of both local recurrence and distant metastases (6%). The 5-year disease-free survival (DFS) was 75% in patients with T1R0, and 93% in patients with T1/R1 or those with "high risk factors". Similarly, Hompes *et al.*[33] reported good survival rates with 1-year DFS of 91% and 5-year DFS of 83%. Local recurrence occurred in 3% (1/36) and distant metastases in 14% (5/36). However, only one study comparing CP with primary TME has reported oncological results[32]. There was no difference in rate of local recurrence between CP and primary TME (0% *vs.* 8%, $P = 0.49$), or rate of distant metastases (4% *vs.* 12%, $P = 0.26$). Cumulative survival rates were not reported. The median follow-up time was 25 and 19 months, respectively. The remaining two studies comparing CP with primary TME only reported short-term results, and oncological data is therefore unfortunately lacking from these studies[30,31].

WHEN TO PERFORM EARLY COMPLETION SURGERY

Whether the time between TEM and CP as an influence on outcomes is not known. The precise definition of "early" and the time frame in which CP should be performed is unclear. Most studies report outcomes after CP perform surgery within 6-8 weeks of TEM. Levic *et al.*[32] defined "early" as CP within 12 weeks of TEM. The median time to CP was 37 days with a range between 14 and 90 days. Similarly, Issa *et al.*[39] had a median time of 47 days to CP (range 32-70) and Piessen *et al.*[30] 37 days (range 7-120). van Gijn *et al.*[34] reported longer interval of 15 weeks to the completion of TME, due to logistic reasons, but the decision of CP was made immediately after the TEM results. In Morino's study only patients with laparoscopic TME within 8 weeks of TEM were included, with a median of 40 days[31]. Hahnloser *et al.*[40] had even shorter criteria, and performed CP following TAE within 30 days, with median time of 7 days. So far only a few studies have reported outcomes based on the time frame to CP. Hompes *et al.*[33] found that poor quality specimen was more frequent after an interval from TEM to CP of more than 7 weeks. The median time to CP was 2 months with range between 0.5 to 8.7 months. However, Morino *et al.*[31] didn't find any difference in outcomes among patients operated within 30 days of TEM or more than 30 days after TEM.

FUTURE ASPECTS

Minimal invasive surgery has gained an increasing interest, especially in the field of rectal surgery. The transanal approach of rectal dissection is gaining wider use and acceptance, and the first randomized trial comparing taTME with laparoscopic TME is currently ongoing[41]. The advantages of trans-anal TME (taTME) include better visualization and possibility of approaching the lesion from below. This may have benefits for patients in need for CP following TEM. Approaching the lesion from below may limit the traction on the scarred tissue and thereby possibly reducing the risk of perforation and other surgical site complications. So far, only one study has reported outcomes of patients with CP by taTME. Letarte *et al.*[42] reported results on 41 patients with CP following TEM, of which 11 were operated by taTME and 30 with conventional TME. The patients with taTME had significantly less intraoperative blood loss (205 mL *vs.* 365 mL, $P = 0.04$). More interestingly, there was lower rate of conversion to open surgery (9.1% *vs.* 57%, $P < 0.001$) and higher sphincter preserving rates (100% *vs.* 50%, $P = 0.01$) despite of the significantly lower distance of tumor from the anal verge in the taTME group.

CONCLUSION

Completion proctectomy following TEM appears safe. Nevertheless, there seems to be an increased risk for intraoperative rectal perforation, which the operating surgeon needs to be aware of. The possible higher incidence of APE following TEM needs to be investigated in larger studies. The drawback in the current literature is the small series reporting outcome of CP following TEM. The published studies on the subject have different methodological approaches, and limited number of patients, which increases the risk of type II error. In order to further investigate whether there is a higher risk of APE and morbidity (particularly rectal perforation, which may influence survival) it is necessary to conduct more studies with higher number of patients, especially those comparing CP with primary TME.

DECLARATIONS

Authors' contributions

Substantial contribution to conception and design, and acquisition of data, and analysis and interpretation of data: Levic-Souzani K, Bulut O

Drafting the article and revising it critically for important intellectual content: Levic-Souzani K, Bulut O

Giving the final approval of the version to be submitted and any revised version: Levic-Souzani K, Bulut O

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All authors declare that there are no conflicts of interest.

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