Limitations and Concerns with Transanal Total Mesorectal Excision for Rectal Cancer

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Abstract

Transanal total mesorectal excision (TaTME) was developed to overcome the technical challenges of a minimally invasive (ultra-) low anterior resection. This new technique has recently come under careful scrutiny as technical pitfalls were reported, in specific relation to the transanal approach. Patients are at risk for urologic lesions. Moreover, carbon dioxide embolism is a rare but potentially life-threatening complication. The benefit of TaTME from an oncological point of view has neither been clarified. Hypothetically, better visualization of the lower rectum could lead to better dissection and total mesorectal excision (TME) specimens, resulting in better oncologic results. Up until now, retrospective multicenter reports seem to show that short-term oncologic results are not inferior after TaTME as compared with after laparoscopic TME. Alarming reports have however been published from Norway suggesting a high incidence and particular multifocal pattern of early local recurrence. In this article, a balanced overview is given of the most important technical pitfalls and oncological concerns arising with this new procedure.

Keywords

- rectal cancer
- transanal total mesorectal excision
- complications

The laparoscopic treatment of low rectal cancer still poses challenges even to the most experienced minimally invasive surgeons. Especially in obese male patients with a narrow pelvis, visualization of the lowest part of the often bulky mesorectum can be challenging. Traditional laparoscopic instruments and stapling devices are sometimes insufficient to reach the lower rectum. More specifically, with the conventional stapling devices, angulation to cross-staple the lower rectum is often not adequate, leading to multiple stapling lines and higher anastomotic leak rates. These technical challenges lead to a relatively high conversion rate (9–16%) as has been shown by several randomized controlled trials.[1–3]

In an attempt to address these limitations, transanal total mesorectal excision (TaTME) was developed, combining the abdominal approach with a completely new transanal approach. The technique was first described by Sylla et al in a pivotal article in *Surgical Endoscopy* in 2010 and has slightly been modified since then, as the flexible transanal minimally invasive surgery platform is now most commonly used for the transanal phase.[4] It was hypothesized that, thanks to better visualization of the lower rectum, conversion rates as well as stoma rates would decrease with an increase in sphincter-preserving procedures. A lower conversion rate has indeed been shown in a study by Roodbeen et al.[5] In addition to abovementioned technical advantages, improvement of oncological outcome was also anticipated. Indeed, marking the distal resection margin (DRM) under direct vision could lead to a decrease in positive DRM rates. Better visualization of the lower rectum could lead to a more complete total mesorectal excision (TME) and less circumferential resection margin (CRM) positive rates, all of these leading to better oncological results. Nevertheless, TaTME is a relatively new technique that confronts us with some technical pitfalls specific to the transanal approach. Long-term oncological advantages are yet to be proven. In this article, an overview will be given of the most important technical pitfalls and challenges, and oncological concerns.

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Technical Aspects

The transanal approach provides the surgeon with a new vantage point to approach the lowest part of the rectum. Details of platform setup and transanal insertion are beyond the scope of this article. However, tumor assessment in relation to the anal sphincter is necessary to decide which approach is indicated. Either sleeve mucosectomy with purse-string luminal closure and secondary port placement or primary port placement with distal purse string is options to start the most distal part of the dissection. Care must be taken to insert the working port transanally. During transanal dissection, some specific technical pitfalls have been reported, such as prostatic urethral lesions in male patients and carbon dioxide (CO_2) embolism. In a series of 1,594 TaTME cases taken from an international registry, Penna et al reported an incidence of 1.8% of visceral injuries during the transanal phase.[6] Development and implementation of a new technique inevitably come with a learning curve. However, some of the perioperative complications described later are uniquely attached to the transanal approach. As such, these pitfalls only become apparent during TaTME and should be avoided.

Urologic Lesions

In a small retrospective series of 30 selected male patients with unfavorable anatomical and/or tumor characteristics, Rouanet et al were the first to describe two urethral injuries during transanal endoscopic proctectomy.[7] Although the authors selected difficult patients to undergo this approach, and the procedure was not called TaTME at that time, it should have warned all enthusiasts starting with this new technique. Indeed, during worldwide implementation of this new approach with clear operational benefits, it soon became clear that many more intraoperative trauma to the urologic system had occurred. Urethral lesion has been reported to occur in 0.8% of TaTME patients but the incidence is likely underestimated.[6] Recently, the results of an inquiry published by Sylla et al showed 39 self-reported urologic injuries of which 34 were urethral injuries, 2 were ureteral injuries, and 3 were bladder injuries. Of note, half of urologic injuries occurred during the first eight TaTME cases of the respective teams. The rest of the injuries' incidence was scattered between the 12th and 101st TaTME cases.

Of the 32 urethral injuries identified intraoperatively, 31 were sutured primarily; 1 was managed leaving the transurethral catheter in place. Postoperatively, 26% of patients developed substantial morbidity after urethral repair, namely, urethral stricture, rectourethral fistula, urethral dehiscence, and urethral–perineal fistula. Three patients required permanent cystostomy.[8]

The mechanism and reason of urethral injury during TaTME should be analyzed. Obviously, trauma is caused by a too deep anterior dissection. Therefore, finding and recognizing the right surgical plane are of paramount importance, when dissecting from down to up.

The pars membranacea of the urethra is most at risk, so the lower the dissection starts, the higher the risk of iatrogenic damage to the urethra. When dissection is started in the anal canal before placing a distal purse string and before the port is placed, for example, during sleeve mucosectomy, urethral damage can occur because of the fusion of surgical planes at that level. Anterior tumors, a hypertrophied prostate, previous prostatectomy, and neoadjuvant radiation have been identified as risk factors.[9] It is important to recognize several landmarks, previously described by Atallah et al: first is the neurovascular bundle of Walsh that is characterized by paired arteries deriving from the inferior vesical artery.[10,11] Dissection should be done superficial to these bundles. Second, the symmetric shape and relatively white aspect of the inferior lobe of the prostate should be recognized. Finally, the cylindrical shape of the prostatic urethra should be recognized. Preventive strategies include preoperative stenting of the urethra with a lighted stent, and transurethral injection of indocyanine green, but many of these tools are still in development. Considerable research is ongoing on the role of stereotactic navigation in pelvic surgery, possibly improving functional as well as oncological outcomes. Atallah et al reported on three patients with anteriorly localized advanced rectal tumors operated on using stereotactic navigation with good clinical, functional, and oncological results at a mean of 30 months follow-up.[12]

Vaginal Lesion

The incidence of vaginal lesions is around 0.3%.[6] Vaginal lesions are less frequent than urethral lesions because the rectovaginal septum is usually easily recognized, sparing the more anteriorly located structures.[13] Of course, anterior tumors, previous pelvic surgery, and radiotherapy can complicate this otherwise straightforward dissection. Moreover, during very low dissection, starting in the anal canal, it is sometimes difficult to identify the right plane and to open the rectovaginal septum. Vaginal lesions can generally be prevented by frequent palpation of the posterior wall during anterior dissection. They should be repaired with interrupted sutures and sometimes omentoplasty can be of help when handsewn coloanal anastomosis is performed.

Bleeding from the Sacral Venous Plexus

A too deep posterior dissection reaching into the retrosacral endopelvic fascia can lead to devastating bleeding. The presacral venous plexus consists of large veins that drain into the internal and common iliac veins and intertwine with deeper veins in the sacrum itself. Careful preoperative magnetic resonance imaging (MRI) review can help the surgeon to anticipate the sacral curvature and timely move dissection in a more upward direction. Although this complication is not life threatening, it can be annoying, especially at the start of the procedure. Because of the limited space created at that stage, the presacral cavity fills up with blood, hampering view and slowing down further dissection.

Injury to Autonomic Nerves

A too lateral dissection will lead to injury of the pelvic side wall. If the side walls are accidentally entered, autonomic nerves may be injured, leading to internal sphincter and sexual dysfunction which has been reported in 4.2% of patients.[6] Kneist et al showed that better visualization of pelvic autonomic nerves using electrophysiological confirmation of the extrinsic innervation to the internal anal sphincter near the levator muscle can help improve functional results.[14]

CO_2 Embolism

The reported incidence of CO_2 embolism, a potentially fatal complication, is fortunately low and thus far, no associated deaths have been reported in the TaTME registry. Harnsberger et al reported a retrospective series in which 3 out of 80 TaTME patients developed CO_2 embolism.[15] Another small case series was described by Shiraishi et al in the same year.[16] During the transanal phase, dissection is done in a very confined space with high insufflation pressures (15 mm Hg) and with the patient placed in Trendelenburg position leading to low venous pressure.[16] Especially when venous bleeding in this phase occurs, one should be extra alert about the risk of CO_2 embolism. Early signs are a drop in end-tidal CO_2 and oxygen saturation which should alarm the surgeon and prompt him or her to release pneumorectum immediately, and place the patient in Trendelenburg position tilted to the left. Hemodynamic instability can occur. The surgeon is to ensure hemostasis and can irrigate the operative field with saline.[15] It has been hypothesized that the use of suction during insufflation causes more turbulent CO_2 flow and thus poses an extra risk for CO_2 emboli to develop. Some authors therefore advise the use of a gauze instead of suction in the event of bleeding.[17]

Patient Selection

As TaTME is still considered a new emerging technique, the ideal patient to undergo this procedure is still to be defined. Many early adopters have published predominantly retrospective studies analyzing results from a selected group of patients.[18–26] Eligibility to undergo a TaTME ranged from tumors <7, <10, between 3 and 12, <15 cm, to low or mid to low rectal cancers. It seems that this technique should be reserved for patients with low rectal tumors to overcome the difficulties during laparoscopic pelvic dissection. Moreover, tumor-specific characteristics were T1 to T3 tumors, without threatened margins. Most importantly, conversion rates were 0% in most studies, meaning that all selected patients could benefit from a minimally invasive approach. As such, the use of a transanal platform should be considered an adjunct to laparoscopic or robotic approaches, so that open TME could be avoided. Thus, although sometimes difficult, ideal candidates are obese male patients with bulky tumors and prostate hypertrophy. Another potential strategy is to "convert" to a transanal approach, when the surgeon fails to progress during laparoscopic or robotic dissection.[9]

Oncological Outcomes

Several randomized clinical trials have shown that laparoscopic TME provides no inferior oncological results as compared with open TME.[1–3,27] There are currently two ongoing clinical trials still in the recruitment phase aiming to compare the oncological results in laparoscopic TME versus TaTME.[19,28] The data that we have until now are thus retrieved from retrospective reports. However, assessment of oncological outcome of a relatively new procedure is of paramount importance because the goal of TME is to obtain a good specimen, to cure the patient, and to minimize the risk of local recurrence. Surrogate end points such as negative margins (both CRM and DRM), number of nodes, and TME specimen quality are helpful and should be analyzed when the data are scrutinized.

Short-Term Oncological Outcomes

Many retrospective studies have focused on the quality of the pathological specimen as a marker to score short-term oncological outcome. In the largest series so far, positive CRM rate was 3.9% with 0.6% positive DRM rate.[6]

Jiang et al performed a systematic review and meta-analysis of studies comparing laparoscopic TME with TaTME concerning pathological outcome. In a total of 762 patients, there was evidence of more favorable outcomes in TaTME: more specifically, the TaTME group had lower CRM positive rates, wider CRMs, and longer DRMs.[29] However, this study contained an important factor of heterogeneity by including abdominoperineal resection and Hartmann-type resections. In another more recent systematic review and meta-analysis by Rubinkiewicz et al, analyzing 778 patients undergoing laparoscopic TME versus pure TaTME, no significant difference was found concerning completeness of rectal excision, R0 resection rate, and number of harvested lymph nodes. Length of DRM was not significantly different, although there was substantial heterogeneity between the studies.[30] The only significant difference noted in this study was a lower rate of severe postoperative complications in the TaTME group. Aubert et al most recently reported a significantly reduced rate of CRM involvement in a meta-analysis. Of note, the TaTME and laparoscopic TME groups did differ significantly in mean distance of the tumor from the anal verge.[31] The lower rate of severe morbidity in TaTME was confirmed in this study.

In a retrospective series of a total of 74 patients undergoing laparoscopic TME versus TaTME, Fernández-Hevia et al found a similar number of lymph nodes harvested and similar CRM positive rates. The advantage of TaTME was shorter surgical time—working with two teams at a time—and lower early readmission rate.[18]

Although patient-related risk factors for positive CRM are mitigated by TaTME, certain tumor-related factors exist that are associated with an increased risk for positive CRM. Roodbeen et al identified five risk factors significantly associated with positive CRM being low tumors located within 1 cm of the anorectal junction (ARJ) (odds ratio [OR]: 2.09; $p = 0.001$), anteriorly located tumors (OR: 1.66; $p = 0.012$), cT4 tumors (OR: 1.92; $p = 0.028$), extramural venous invasion on MRI (OR: 1.94; $p = 0.001$), and involved or threatened CRM on baseline MRI (OR: 1.75; $p = 0.051$).[32]

Mid- to Long-Term Oncological Results

In a recent Spanish retrospective multicenter study of 173 patients undergoing TaTME over a 6-year period and a median follow-up of 23 months, local recurrence rate was 3%, and 8.1% of patients developed metastatic disease.[33]

In a series of 159 patients undergoing TaTME in the Netherlands, local recurrence rates after 3 and 5 years were 2 and 4%, respectively, with a median time to local recurrence of 19.2 months.[34] In contrast, in 2019, the Norwegian group of Larsen et al reported at least 9.5% local recurrence rate within a median of 11 months raising great concerns on the oncological safety of TaTME.[35] Moreover, the local recurrences seemed to show a particular multifocal pattern different from that after conventional TME. This observation urged the Norwegian surgical community to temporarily suspend the TaTME program and perform a thorough audit of which the results were recently published.[36] All 157 patients who underwent TaTME in Norway since 2014 were compared with a matched national cohort of patients undergoing conventional TME. The incidence of local recurrence was indeed significantly higher in the TaTME group (11.6 vs. 2.4% in the control group, $p < 0.001$). The tumors treated in the TaTME group were generally smaller and fewer patients had received preoperative neoadjuvant treatment. Also, anastomotic leakage and mortality were higher. All of this led to the definitive abandonment of TaTME in Norway.

These concerns were countered again by the results of the multicenter observational cohort study by Roodbeen et al analyzing oncological outcomes in 767 patients from six tertiary-referral centers.[37] Rationale for this study was to critically evaluate oncological outcome of the technique in expert centers, in view of the recent published Norwegian data. In this study, 3-year local recurrence rate was 4% after a median follow-up of 13.5 months. In the 24 patients who developed local recurrence, none of the recurrences was multifocal, suggesting a conventional rate and pattern of local recurrence similar to other TME approaches. Eleven of 24 patients did have metastatic disease. The Danish group of Perdawood et al reported 81% disease-free survival in 200 patients after a mean follow-up of 29 months.[38] The mean time to local recurrence was 24 months. A total of 12% of patients developed metastatic disease after a median time of 19 months.

The Learning Curve and the Role of Centralization

With the advent of a completely new approach to rectal resection and its associated specific morbidity, pioneers in this technique reach out to their colleagues to facilitate the dispersion of this technique yet keeping in mind to do so in a very standardized and controlled way. Structured teaching courses are available and have proven their value even though they do not completely diminish the risk of significant morbidity, for instance, urethral lesions in male patients.[39] It is clear that the learning curve for TaTME is a steep one and is still not clearly identified. Deijen et al showed that high-volume centers, defined as doing more than 30 cases yearly, have lower conversion rate, lower major complication rate, and better TME quality.[40] As suggested by Lee et al, a surgeon seems to reach acceptable results after approximately 45 to 51 cases when high-quality TME is considered.[41] When looking at major postoperative complications and leakage, a decrease in morbidity rate can be observed after a minimum of 40 cases.[42] The TaTME Guidance Group's consensus statement, published in 2020, states that didactic learning, observation of live procedures, hands-on cadaver workshops, and a formal proctorship program. All should form part of a structured training curriculum.[43]

Conflict of Interest
None declared.

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