Oncologic Outcomes

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Sharaf Karim Perdawood

Grading of TME Specimen

Total mesorectal excision (TME) is considered the gold standard surgical procedure for mid and low rectal cancer since Bill Heald described it and showed dramatic improvements in the long-term oncologic outcomes [1–3]. Thus, the goal of the surgery is to achieve a perfect quality TME, where the mesorectum is excised "totally" as the name implies. This goal is unfortunately not always achievable in every case, especially in challenging cases where there are anatomical factors that render the dissection difficult; prototypically this occurs when the dissection is performed on an obese male patient with a narrow pelvic inlet. With the introduction of TME in the era of open surgery, perfect specimens could be retrieved by well-trained colorectal surgeons in most cases, and data were reproducible in numerous studies. Even recently, data from open surgery show very high rates of satisfactory results [4, 5]. With the available evidence from open surgery, new minimal invasive techniques must be rigorously compared to these standards, as the oncological quality should never be jeopardized. Ever since the introduction of laparoscopic surgery, the question of whether it can reproduce the results from open surgery remains essentially unanswered for rectal cancer. With no doubt about the short-term benefits of laparoscopy, the oncologic results continue to be questioned [6–12]. In search for the optimal method to achieve a perfect TME, technological advances like robotic and transanal surgeries are to be regarded as ongoing efforts to achieve Heald's TME in a minimal invasive manner, especially where access to the low rectum is challenging by other modalities.

Regardless of the approach used, surgeons must assure that the quality of the TME is as close to perfect as possible. Fortunately, TME grading is well-standardized for the excised specimen. Efforts by pathologists alongside advances in the surgical technique and the surgeons who help modernize the approach to rectal cancer surgery have led to a standard and reproducible description of the excised specimens [13–15]. The plane of surgery during TME constituted an independent factor for local recurrence in a recent analysis of a randomized clinical trial ($P = 0.002$) [16]. While rates of "complete" specimens after open TME are acceptable in most publications from high-volume centers, laparoscopic surgery seems to lag behind. For this reason, taTME (a minimally invasive technique with improved access) could show immediate signs of improvement in the quality of the performed surgery through an improvement in the rates of "complete" mesorectal specimen as defined by Phil Quirke [15].

S. K. Perdawood (✉)
Slagelse Hospital, Department of Surgery, Slagelse, Denmark

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The initial reported cases of taTME demonstrated a remarkably high rate of "complete" mesorectal envelopes, and some even reported 100% intact TME specimens [17–24]. However, terms like "satisfactory" or "good" results should be interpreted with caution of whether the specimens were "complete" or "nearly complete."

With the increasing adoption of the procedure and liberal inclusion of difficult cases, a tendency is seen toward a fall in the rates of specimen "completeness" [25–28]. These studies have showed rates of "complete" specimens ranging from 47% to 84%. The largest published series with number of patients included ranging from 50 to 186 plus taTME registry data have shown promising results, with rates of specimen "completeness" that are comparable with those achieved through standard laparoscopic approach [28–37] .

In the taTME registry study by Penna et al. [29], the TME specimen was "complete or near complete" in 96% of cases (85% complete, 11% near complete, 4% incomplete). However, patients were registered from several centers, and there is probably a case selection bias, especially of the initial cases. The two reports from Barcelona with 140 and 186 patients are probably overlapping; nonetheless the series of 186 patients is the largest published to date [30, 31] . The authors reported rates of specimen "completeness" of 97.1% and 97.5%. These are without a doubt excellent results from experienced team that standardized the technique of taTME, which is still considered by most colorectal surgeons to be a challenging and complex approach. The second largest published series from one center to date is from Denmark [34] and shows a rate of 86% specimen "completeness." Other series have similarly acceptable rates of at least 84% [28, 32, 37] . A comparative study by Velthuis et al. (2014) demonstrated that the TME quality was improved with the taTME approach versus the laparoscopic approach (96% vs. 72%, $p < 0.05$) [37].

An apparent conclusion of the investigators has been that to improved surgical access with taTME, translated into improved TME quality. This has been shown to be the case with transanal dissection in similar fashion without using the transanal platforms, prior to the advent of the modern approach to taTME. Marks et al. [37] reported results of 370 rectal cancer surgeries where TME was initiated from below. In 96% of cases, the TME specimen was either "complete" or "nearly complete." In conclusion, taTME seems to overcome difficulties in the dissection of the lowest part of the rectum and may result in superior TME quality in select cases, although comparative, randomized trials are still lacking.

Circumferential Resection Margin

One of the most important goals of surgery for rectal cancer is to achieve a free resection margin, mainly through retrieval of a perfect specimen. The circumferential resection margin of the mesorectal specimen has a great prognostic impact on the local recurrence and distant metastasis [38, 39]. It is the circumferential resection that is more frequently involved and is one of the more challenging aspects of TME surgery. Numerous studies have shown alarmingly high rates of circumferential resection margin involvement, worse in tumors located in the lowest part of the rectum [40–42]. To date, published series of taTME have shown quite acceptable rates of involved circumferential resection margins. Even in advanced cases of rectal cancer selected for taTME, Rouanet et al. [19] reported a free margin in 87% of 30 patients with advanced rectal cancer. Overall, most studies report no involved circumferential resection margins; this can be partly attributed to selection of less challenging cases. The rates of circumferential margin involvement in the reported series range from zero to 11.8% [22, 25, 34, 36, 43–47] . Data from the international registry showed an involved circumferential margin rate of 2.4%; however as a cautionary note, 7.1% of this registry was "not reported" [29]. With the largest published number of consecutive cases from a single center, De Lacy et al. have reported a rate of involved margin of 8.1% (defined as CRM $\leq$ 1 mm, excluding T4 tumors) [31]. Perdawood et al. [48] have shown comparable rates of margin involvement among patients treated by open, standard laparoscopic and transanal procedures. In analyzing these rates with those of standard laparoscopic approach, clear

benefits of taTME could be demonstrated, showing at least comparative rates of involvement of circumferential resection margin [49–52]. Finally, in a randomized trial comparing the transanal approach to radical rectal resection versus laparoscopic surgery by Denost et al., the rate of circumferential resection margin was significantly lower with the transanal approach (4% vs. 18%, $p = 0.02$).

These data suggest that taTME has the potential to improve rectal cancer care, through lower rates of positive circumferential resection margins when compared to standard laparoscopic approaches, as realized by most published series to date. However, this must be interpreted with caution since they are mostly from centers with special interest and experience in taTME surgery. With appropriate training and experience, the rate of circumferential resection margin positivity may be lowered by utilizing this novel approach to radical rectal cancer resection.

Distal Resection Margin

In laparoscopic or open TME, transection of the rectum is done without direct view of the tumor itself and these techniques depending on tactile assessment of the tumor. Potentially, this can lead to lower anastomosis than necessary. Even worse, with such top-down approaches, there exists a real risk of transecting across the tumor and jeopardizing the oncologic outcome of the operation. This risk can be theoretically eliminated in taTME, due to direct visualization of the tumor allowing for a precise transection of the rectal lumen with a suitable safe margin.

While theoretically the risk of a positive distal resection margin should be zero, this is not what has been observed. While registry data suggests that the distal resection margin positive rate is quite low (0.3%) [29], other data contradict this finding. In fact, the rate of positive distal resection margin has been reported to be as high as 8.7% in the center with the most experience with this approach [53]. While positive distal resection margins are still inexplicably observed with taTME for rectal cancer, overall, a longer distal resection margin is appreciated [54]. In a 2015 study by Fernandez-Hevia et al., the distal resection margin was longer with the taTME approach when compared to the laparoscopic approach (2.8 vs. 1.7 cm, $p < 0.01$). This is not necessarily an advantage, and a very low anastomosis can be the end result, which compromises the functional outcomes.

Local Recurrence

The most crucial goal of surgery for rectal cancer is disease-free survival by providing local tumor clearance. Local cancer recurrence is therefore an important parameter of the quality of surgery. In standard laparoscopy, a local recurrence rate of 5% was observed in both laparoscopic and open TME groups in a randomized clinical trial comparing the two approaches for rectal cancer [55]. The study had locoregional recurrence at 3 years as the primary end-point.

While taTME is still a relatively new procedure and long-term results from the largest series are not yet available, several cases of local recurrences have already been reported. Rouanet et al. [19] reported local recurrence in 1 patient out of 30 with an observation period of 21 months. The circumferential resection margin was involved in this case. Veltcamp et al. reported two cases of local recurrence among 80 (2.5%) patients who underwent taTME [32]. The follow-up time was 30 months. A similar rate of local recurrence rate of 2.3% was reported among 140 patients by Lacy et al. where the mean follow-up time was 15 months [30]. One case of local recurrence among 32 (3.1%) operated patients was reported by de ´Angelis et al. [56], and here the follow-up time was 24 months. Burke et al. [35] reported local recurrence in 2 out of 50 patients (4%) after a median follow-up period of 15.1 months.

After nearly a decade since the introduction of taTME, more studies to be awaited with special focus on the long-term results, including local recurrence. The pattern of recurrence is also an interesting subject due to the inherent nature of the procedure that involves transluminal transection, insufflation of CO_2, fixation of the anal sphincter retractor with traumatic instruments, and transanal

specimen retrieval. All of these can potentially lead to tumor cell implantation and increase the risk of local recurrence. One published case of local recurrence raises the suspicion of implantation similar to port-site metastasis [57], which is seen in laparoscopic colorectal surgery.

Distant Metastasis

There is slowly emerging data on distant metastases after taTME for rectal cancer. However, the follow-up periods remain relatively short. Atallah et al. [25] reported 1 distant metastasis in 20 patients (5%) after a mean 6 months of follow-up. Lacy et al. [30] found 7.6% metastasis in 140 patients with a follow-up period of 15 months. Buchs et al. [36] found metastases in 6 out of 40 patients (15%). In this study, a case mix is seen, with a relatively high number of low tumors, and the complications rate is relatively high despite acceptable specimen grading quality. Burke et al. [35] reported 8 distant metastases in 50 patients (16%) after a follow-up of 15.1 months. Mege et al. [58] reported metastases of 15% in 34 patients with mean follow-up of 13 months.

It is not evident from the literature, whether these reported metastatic cases occurred in patients with more advanced cancers or in patients with a poor quality of the retrieved specimen. Further studies with longer follow-up and larger patient population can probably give a clearer picture of the rates and the metastatic pattern after taTME.

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