Editorial

Transanal total mesorectal excision international registry results of the first 720 cases

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It is a great pleasure and honor to comment on the article entitled "Transanal Total Mesorectal Excision: International registry results of the first 720 cases" by Penna and her colleagues in the "*Annals of Surgery*" (1). In 2014, the registry went online via the Low Rectal Cancer Development (LOREC) website (http://www.lorec.nhs.uk) and the study population for this study comprised data gathered between July 2014 and December 2015. Data entry can be performed on a voluntary base and surgeons performing taTME worldwide were invited to join. This is a retrospective database analysis of an international registry on taTME. The first 720 consecutive cases entered in the database, coming from 66 centers in 23 countries, were analyzed. The primary endpoint was 'good-quality TME surgery' and secondary endpoints were short-term adverse events. In detail, 634 patients with rectal cancer and 86 with benign pathology were included. There were 489 male patients (68%) with mean age 62 years, and mean BMI 27 kg/m^2. Intact TME specimens were achieved in 85%, with minor defects in 11% and major defects in 4%. Unfortunately, in 42 patients (6.6%) data regarding quality of TME specimen was missing or was not reported at all. This reflects the retrospective nature of the present study and the voluntary aspect of data registration. Overall, 16 patients had a positive resection margin, leading to an R1 resection rate of 2.7%: 2 positive distal resection margins (0.3%), and 14 positive circumferential resection margins (CRM, 2.4%), respectively. On multivariate analysis, risk factors for poor specimen outcome (defined as suboptimal TME specimen, perforation, and/or R1 resection) were positive CRM on staging MRI, low rectal tumor <2 cm from anorectal junction, and laparoscopic posterior dissection to <4 cm from anal verge. Overall postoperative morbidity at 30 days was around 33%, with 40 recorded anastomotic leaks (6.7%) and surgical or radiological (re)interventions in 66 (10.1%) patients. The principles of TME were developed more than 25 years ago and it remains the gold standard to treat patients with rectal cancer (2). Based on embryological principles, the rectum and its mesorectum should be excised *en bloc* to optimize oncological outcome. With the introduction of laparoscopic surgery, especially laparoscopic colorectal surgery, now more than 20 years ago, it became clear that short-term outcome improved considerably (3). Over the last 2 decades, there is abundant evidence that a minimally invasive approach for colonic cancer has equivalent results regarding survival and recurrence when compared to open surgery, but with better short-term outcomes (4-7). For rectal cancer, discussion about 'which surgical approach is best' is still on going. In the best of both worlds, a patient should have all benefits of a minimally invasive approach, but also have optimal rectal cancer surgery with good functional and oncological outcome. In the absence of long-term data on oncological outcome, routine laparoscopic TME was not recommended (8) and was only advocated to be performed by skilled surgeons (9), although similar safety and better recovery could be achieved. Randomized controlled trials of laparoscopic versus open TME were initiated to investigate the role of a minimally invasive approach in rectal cancer surgery. Indeed, recent publications of trials comparing open versus laparoscopic approaches for rectal cancer have shed a different light on the long-believed

benefits of a minimally invasive approach. Apart from the fact that non-inferiority could not be shown in 2 trials (which is not the same as saying that laparoscopic TME is inferior to open TME), there was still a 9% conversion rate in the laparoscopic group, indicating that in about 1 in 10 cases, the patient cannot benefit from a minimally invasive approach, and has to endure all the downsides of open surgery. In my opinion, taTME can make a difference in these difficult cases, which would have been converted otherwise. Indeed, when the dissection by laparoscopic approach has become impossible to proceed any further, a transanal approach can be performed to dissect the most distal part under direct control and do a 'rendez-vous' with the dissection performed from above. Therefore, the rationale behind taTME has always been driven by the fact that the use of this technique has better ergonomics and superior visualization. What we can learn from many debates in literature is that the exact role of laparoscopy and robotic surgery in rectal cancer still is unclear and that data are accruing (10,11). It seems unlikely that surgeons who have overcome the learning curve for laparoscopic or robotic TME will go back to open surgery. Moreover, a recent meta-analysis comparing the oncologic outcomes of laparoscopy and open surgery for rectal cancer showed equivalent results. Positive CRM-rate was similar in both groups (10.3% versus 11.6%), and 5-year local recurrence rate was 3.5% versus 5.6% (P=0.413). Mesorectal intactness was around 85% (12). Bearing in mind the results of the present study by Penna and colleagues, oncologic results regarding R1 resection rate (i.e., 2.7%) and mesorectal intactness (85%), outcome of taTME is encouraging. When you look even further, poor pathological outcome (which was R1 + poor TME specimen) was only as high as 7.4%. Furthermore, the surgeon has more visual control of the distal resection margin, potentially resulting in a reduction of positive distal resection margins and ultimately local recurrences. A small study has already observed a longer distal resection margin and in addition to this, improvement in the quality of mesorectal dissection has also been shown (13,14). What we can also learn from this study is the rather low conversion rates. Abdominal conversion, defined as conversion from a laparoscopic or robotic to an open approach, was 6.3%. In the discussion, the authors also include conversion from laparoscopic to transanal approach in abdominal conversion rates. So in my opinion, it should be discussed whether a change from laparoscopic to transanal dissection should really be counted as a true conversion. When you can still perform the operation in a minimally invasive way, any approach, being either laparoscopically or transanally, can be used. With lack of procedural standardization, questions regarding where to start (laparoscopically or transanally) and when to stop the dissection are still open. In my experience, when you can reach the S3 level posteriorly (either laparoscopically *or* transanally) and you are able to open the pouch of Douglas anteriorly, you will be able to complete the dissection from above or from below. In this study, perineal conversion, defined as conversion from a perineal approach to any abdominal approach, was 2.8%. Anyhow, conversion rates of taTME remain low, especially when you look at reported conversion rates of laparoscopic and robotic TME to be around 8–10%.

The gold standard for the surgical treatment of rectal cancer is a total mesorectal excision. A well-performed TME requires meticulous and precise surgical technique along embryological ("Holy") planes. Although this procedure has extensively been studied regarding surgical anatomy, it remains a difficult operation whether performed open, laparoscopically, or robotically, especially in an obese male patient with a narrow pelvis and/or low bulky tumor. A minimally invasive approach to rectal cancer, particularly low tumors (<5 cm from the anal verge), has a steep learning curve and is a technique difficult to master, because of poor visualization deep down in the bony pelvis, and the use of non-adapted instruments (such as inadequate staplers). This is why surgical innovation plays an important role in the development of new instruments and techniques to dissect the most distal and most difficult part of a TME. Continuous innovation of surgical techniques and perioperative surgical care is necessary, but may complicate formal assessment by randomized controlled trials. Therefore, it can be useful to assess the process of innovation of a surgical intervention. Definition of an innovative surgical procedure has been stated as 'a new or modified surgical procedure that differs from currently accepted local practice, the outcomes of which have not been described, and which may entail risk to the patient' (15). A comprehensive model to describe and assess the development of surgical innovation is to divide it into different sequential stages (IDEAL paradigm) (16). In 2013, professor Heald predicted that 2013 would be the year of new endoscopic transanal approaches to distal rectal dissection (17). Combined experience in laparoscopic techniques, single port surgery, transanal approaches (such as TATA, TEM and TAMIS), and NOTES has led to the birth of what we now call 'Transanal Total Mesorectal

Excision' (taTME). I believe that taTME could be the next incremental step in the minimally invasive approach to TME. The problem with surgical innovation is adoption and implementation into practice and formal assessment. Adoption of a new technique is defined by the increase in the number of surgeons performing the procedure over time, either until accepted or discarded by them. A tipping point, describing the onset of a peak rate of diffusion of new technology is usually identified anywhere between 10–20% of surgeons having adopted the technique (18). However, innovation of a surgical procedure often continues after adoption into clinical practice, and it is therefore necessary to formally assess a novel surgical procedure. Indeed, for these novel surgical approaches, it can be difficult to decide when to shift from exploratory stages to more formal assessment. The learning curve might not be overcome and technique refinement might not be fully optimized. It is clear that with the results of the present study, published outcome still reflects surgeons in the developmental and exploratory stages of the taTME-technique. Indeed, on average 634/66=10 taTME cancer cases were included per center, with the following caseload distribution: 0–5 (50%), 6–10 (18%), 11–20 (12%), and >20 (20%). So, only one fifth of the collaborating centers contributed data of more than 20 taTMEs. It has already been shown that high-volume centers (>30 cases) have lower conversion rates with better quality TME specimens when compared to low-volume centers (<30 cases) (19). In future, when more and more surgeons will gain experience with this technique, which should be standardized at some point, even better short-term oncologic results light be expected. Therefore, I'm hopeful and enthusiastic about the further development of this technique to continuously optimize outcomes in the interest of the patient.

The authors conclude that taTME appears to be an oncologically safe and effective procedure for distal mesorectal dissection with acceptable short-term patient outcomes and good specimen quality. An important advantage of taTME is that the bottom-up dissection technique is equally appropriate to perform sleeve mucosal and/or partial intersphincteric resection, depending on the level of the tumor as classified by Rullier *et al.* (20). A distal purse string will close the rectal tube and depending on that level of closure, either a single stapled or a hand-sewn coloanal anastomosis can be performed. Whether this could result in a significantly decreased anastomotic leak rate is of major interest and results of studies investigating single-stapled coloanal anastomosis are eagerly awaited. Although expectations from taTME such as, shorter operating times (13), better short-term outcome with lower conversion rates, and better oncological outcome are clear, no randomized clinical trials have been performed yet. Although we might be at the tipping point, having 'the early majority' of surgeons performing taTME, some balance is needed. TaTME seems to gain fast in popularity, but we are still in the exploratory stage with inherent shortcomings and learning curve issues. A word of caution regarding required skills and complications unique to this operation might therefore be necessary. Different skill sets are required to safely implement taTME. Advanced laparoscopic skills and experience with laparoscopic colonic and rectal resections is required, as taTME is a hybrid laparoscopic procedure. Furthermore, the surgeon should be trained in colo-anal anastomosis and have experience with sleeve resections. Finally, basic skills for and experience with TAMIS are necessary to allow a safe transanal approach. Different skills labs, including cadaver courses, have been offered for surgeons to acquire confidence with TAMIS and should be part of formal surgical training to master this technique (21). There are pitfalls linked to taTME and they are inherent to a change in anatomic landmarks. Recently, two publications specifically highlighted the anatomical peculiarities of this approach (22,23). Too large an anterior dissection puts the bulbar urethra at risk. Indeed, in the pilot series of Rouanet *et al.*, two urethral lesions occurred in a series of 30 difficult male patients (24). A lateral dissection that is too broad easily directs the surgeon lateral to the pelvic nerve plexus and can lead not only to autonomic nerve damage (sacral nerve plexus) but also to major vascular (internal iliac vein) and ureteral injuries. Therefore, it is of paramount importance to distinguish the plane between the mesorectal fascia and the presacral fascia posteriorly, and Denonvilliers' fascia and the prostate capsula or dorsal vaginal wall, anteriorly. The lateral dissection margins are subtler and should respect the pelvic nerve plexus. From our own combined experience, a dissection beginning at the anorectal junction (just above the level of the puborectalis muscle) is more straightforward than an intersphincteric resection (25). In the future, taTME should be compared to laparoscopic TME in a randomized controlled trial regarding postoperative outcome (e.g., anastomotic leak rate of a single stapled anastomosis), functional and oncological results. In my humble opinion, taTME is definitely there to stay and will be an important tool in the armamentarium of colorectal surgeons involved in the treatment of ultra-low rectal cancer. As such, it's not a one-size fits all, or one

operation fits all rectal cancer patients. The way we look at rectal cancer has changed in every sense of the word and it goes without saying that Hompes and colleagues have heavily contributed to this outstanding achievement.

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Footnote

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