Editorial

The learning curve in TaTME—considerations to guide safe implementation

Deborah S. Keller[1], Roel Hompes[2]

[1]Division of Colorectal Surgery, Department of Surgery, Columbia University Medical Center, New York, NY, USA; [2]Department of Surgery, Amsterdam University Medical Centers, University of Amsterdam, Amsterdam, The Netherlands

Correspondence to: Roel Hompes, MD. Department of Surgery, Amsterdam University Medical Centers, University of Amsterdam, Meibergdreef 9, 1105 AZ, Amsterdam, The Netherlands. Email: roelhompes@gmail.com.

Comment on: Lee L, Kelly J, Nassif GJ, *et al*. Defining the learning curve for transanal total mesorectal excision for rectal adenocarcinoma. Surg Endosc. 2018Defining the learning curve for transanal total mesorectal excision for rectal adenocarcinoma. Surg Endosc 2018. [Epub ahead of print].

Received: 28 December 2018; Accepted: 16 January 2019; Published: 17 January 2019.

doi: 10.21037/ales.2019.01.03

View this article at: http://dx.doi.org/10.21037/ales.2019.01.03

For a colorectal surgeon, the immediate goal in rectal cancer surgery is to extract a perfect total mesorectal excision (TME) specimen with clear oncologic margins. Since the introduction of the TME concept by Heald in 1982, data from both historic and modern randomized controlled trials (RCT) comparing surgical approaches for rectal cancer have demonstrated that this can be challenging (1-5). The subjective perception of a technically challenging and often unsatisfactory pelvic dissection, paired with the ongoing controversy regarding the optimal surgical approach, fuel the need for further innovation.

Transanal total mesorectal excision (TaTME) was introduced as an innovative procedure that may overcome the technical challenges of operating in the deep pelvis, where anatomic constraints and tumour specific characteristics have a major impact (6). While excellent short-term oncologic results have been reported, relatively high rates of complications and new procedure specific morbidity arose, most likely due to limited experience with the anatomic landmarks, critical procedural concepts, and pattern recognition with the "bottom up" view (7-15). The incidence and development of procedure specific complications reflects the unregulated nature of surgical innovation; analogous situations were seen with the introduction of laparoscopic cholecystectomy and minimal invasive colon cancer resections. A dilemma arises however, between prolonged waiting for sufficient safety and efficacy data or early adoption of new treatments that could potentially improve outcomes. A careful balance needs to be struck between the two as we keep in mind that "the new" is not always better, and too rapid widespread adoption of novel techniques may prove more harmful than beneficial for patients.

Adherence to the well-established IDEAL framework is recommended, which describes the five stages for evaluating and reporting surgical innovations: Idea, Development, Exploration, Assessment and Long-term (16). The concept of the learning curve is often overlooked but remains important in surgical innovation, and a key element in the "Exploration" phase within IDEAL. Lee *et al*. describe the institutional learning curve for TaTME in a single high-volume tertiary referral center with extensive experience in transanal minimally invasive surgery (TAMIS) and minimally invasive rectal cancer surgery (17). Their findings suggest 45–51 cases are needed to reach technical proficiency, with improvements in the pathologic outcomes resulting after 36 cases. The authors attempted to validate their reported patient numbers using an adjusted composite outcome measure of postoperative morbidity and operative times.

What constitutes an acceptable outcome measure as a proxy for clinical effectiveness with TaTME remains a contentious issue. Similar to the ALACART and ACOSOG Z6051 randomized controlled trials, a composite endpoint for high-quality TME was used by the authors to determine proficiency (3,4). In both trials, even though the laparoscopic arm did not meet the criteria for non-inferiority compared to the open arm, rates of 2-year

disease-free survival (DFS) and recurrence were not significantly different (18,19). Similarly, the significantly decreased rate of a positive circumferential resection margin following transanal low rectal dissection compared to a full laparoscopic approach reported by Denost *et al*. did not translate into a decreased incidence of local recurrence (20).

Other issues exist in the authors' chosen method to measure learning. Operating time is not an ideal outcome measure. Prior work has shown that operative times are a weak proxy for learning, and do not relate to proficiency (21-23). It may be assumed that with experience, operating times will drop. This assumption relies on all patients, tumors, and operative conditions being equal. In reality, surgeons will generally perform more complex cases with increased experience and comfort with a procedure; the more complex procedures have inherently longer operating times. Assessing for a second peak on the learning curve may add value if using operative times. There should also be consideration of the individual surgeon and center's case volumes, and experience with TAMIS. The work by Lee *et al.* represented a high-volume TaTME and TAMIS center, where their results may not be generalizable. Furthermore, cases from more than 1 surgeon at the center were bundled; a more accurate way to define the learning curve may be to evaluate consecutive cases from each individual surgeon to create individual CUSUM curves which can then be compared for validity and generalizability. Alternative suggestions for outcome measures that could serve as a proxy for clinical effectiveness in TaTME procedures are postoperative morbidities, particularly septic complications related to the anastomosis which can serve as an indirect indicator for quality, functional outcomes, and quality of life. In future studies, such outcomes can and should be used for the characterization of the learning curve following appropriate case mix.

Developing expertise in any procedure requires a steady case volume to optimize technical skills and improve clinical judgement. These attributes will improve performance along the learning curve. Therefore, centralization in high-volume centers with high-volume surgeons is an area for debate, particularly for complex procedures like TaTME, where the number to achieve proficiency is high and associated with morbidity along the learning curve. Aside from appropriate institutional case volume, parallel interventions are required to boost performance, shorten the learning curve, and reduce subsequent risk to patients. To ensure safe introduction amidst the enthusiasm, a structured training pathway that includes mentorship for the initial cases with participation in multicenter registries is recommended, and controlled trials are underway.

Acknowledgments

Funding: None.

Footnote

Provenance and Peer Review: This article was commissioned by the editorial office, *Annals of Laparoscopic and Endoscopic Surgery*. The article did not undergo external peer review.

Conflicts of Interest: Both authors have completed the ICMJE uniform disclosure form (available at http://dx.doi.org/10.21037/ales.2019.01.03). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

References

1. Jayne DG, Thorpe HC, Copeland J, et al. Five-year follow-up of the Medical Research Council CLASICC trial of laparoscopically assisted versus open surgery for colorectal cancer. Br J Surg 2010;97:1638-45.
2. Buunen M, Bonjer HJ, Hop WC, et al. COLOR II. A randomized clinical trial comparing laparoscopic and open surgery for rectal cancer. Dan Med Bull 2009;56:89-91.
3. Fleshman J, Branda M, Sargent DJ, et al. Effect of Laparoscopic-Assisted Resection vs Open Resection of Stage II or III Rectal Cancer on Pathologic Outcomes: The ACOSOG Z6051 Randomized Clinical Trial. JAMA 2015;314:1346-55.
4. Stevenson AR, Solomon MJ, Lumley JW, et al. Effect of

Laparoscopic-Assisted Resection vs Open Resection on Pathological Outcomes in Rectal Cancer: The ALaCaRT Randomized Clinical Trial. JAMA 2015;314:1356-63.
5. Laurent C, Leblanc F, Wutrich P, et al. Laparoscopic versus open surgery for rectal cancer: long-term oncologic results. Ann Surg 2009;250:54-61.
6. Battersby NJ, How P, Moran B, et al. Prospective Validation of a Low Rectal Cancer Magnetic Resonance Imaging Staging System and Development of a Local Recurrence Risk Stratification Model: The MERCURY II Study. Ann Surg 2016;263:751-60.
7. Ratcliffe F, Hogan AM, Hompes R. CO2 embolus: an important complication of TaTME surgery. Tech Coloproctol 2017;21:61-2.
8. Bernardi MP, Bloemendaal AL, Albert M, et al. Transanal total mesorectal excision: dissection tips using 'O's and 'triangles'. Tech Coloproctol 2016;20:775-8.
9. Veltcamp Helbach M, Deijen CL, et al. Transanal total mesorectal excision for rectal carcinoma: short-term outcomes and experience after 80 cases. Surg Endosc 2016;30:464-70.
10. Burke JP, Martin-Perez B, Khan A, et al. Transanal Total Mesorectal Excision for Rectal Cancer: early outcomes in 50 consecutive patients. Colorectal Dis 2016;18:570-7.
11. Atallah S, Albert M, Monson JR. Critical concepts and important anatomic landmarks encountered during transanal total mesorectal excision (taTME): toward the mastery of a new operation for rectal cancer surgery. Tech Coloproctol 2016 ;20:483-94.
12. Buchs NC, Wynn G, Austin R, et al. A two-centre experience of transanal total mesorectal excision. Colorectal Dis 2016;18:1154-61.
13. Penna M, Hompes R, Arnold S, et al. Transanal Total Mesorectal Excision: International Registry Results of the First 720 Cases. Ann Surg 2017;266:111-7.
14. de Lacy FB, van Laarhoven JJEM, Pena R, et al. Transanal total mesorectal excision: pathological results of 186 patients with mid and low rectal cancer. Surg Endosc 2018;32:2442-7.
15. Caycedo-Marulanda A, Jiang HY, Kohtakangas EL. Outcomes of a Single Surgeon-Based Transanal-Total Mesorectal Excision (TATME) for Rectal Cancer. J Gastrointest Cancer 2018;49:455-62.
16. McCulloch P, Cook JA, Altman DG, et al. IDEAL framework for surgical innovation 1: the idea and development stages. BMJ. 2013;346:f3012.
17. Lee L, Kelly J, Nassif GJ, et al. Defining the learning curve for transanal total mesorectal excision for rectal adenocarcinoma. Surg Endosc 2018. [Epub ahead of print].
18. Stevenson ARL, Solomon MJ, Brown CSB, et al. Disease-free Survival and Local Recurrence After Laparoscopic-assisted Resection or Open Resection for Rectal Cancer: The Australasian Laparoscopic Cancer of the Rectum Randomized Clinical Trial. Ann Surg 2018. [Epub ahead of print].
19. Fleshman J, Branda ME, Sargent DJ, et al. Disease-free Survival and Local Recurrence for Laparoscopic Resection Compared With Open Resection of Stage II to III Rectal Cancer: Follow-up Results of the ACOSOG Z6051 Randomized Controlled Trial. Ann Surg 2018. [Epub ahead of print].
20. Denost Q, Loughlin P, Chevalier R, et al. Transanal versus abdominal low rectal dissection for rectal cancer: long-term results of the Bordeaux' randomized trial. Surg Endosc 2018;32:1486-94.
21. Deijen CL, Tsai A, Koedam TW, et al. Clinical outcomes and case volume effect of transanal total mesorectal excision for rectal cancer: a systematic review. Tech Coloproctol 2016;20:811-24.
22. Francis N, Penna M, Mackenzie H, et al. Consensus on structured training curriculum for transanal total mesorectal excision (TaTME). Surg Endosc 2017;31:2711-9.
23. Tekkis PP, Fazio VW, Lavery IC, et al. Evaluation of the learning curve in ileal pouch-anal anastomosis surgery. Ann Surg 2005;241:262-8.

doi: 10.21037/ales.2019.01.03
Cite this article as: Keller DS, Hompes R. The learning curve in TaTME—considerations to guide safe implementation. Ann Laparosc Endosc Surg 2019;4:7.

