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Standardization of Laparoscopic Total Mesorectal Excision for Rectal Cancer: A Structured International Expert Consensus

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Abstract
Objective: To establish a structured international expert consensus on a detailed technical description of the laparoscopic total mesorectal excision (TME).

Background: Laparoscopic TME is a common surgical approach for the treatment of rectal cancer, but there is little agreement on technical details and standards.

Methods: Sixty leading surgical experts from 5 different world regions with a median overall experience of 250 laparoscopic TME participated in this study. Four stages of mixed quantitative and qualitative consensus-finding methods were applied. (1) Semistructured expert interviews were independently analyzed by 2 assessors. (2) Consensus on the interview data was reached using reiterating questionnaires (Delphi method). (3) This was further refined in an interactive workshop. (4) Based on this meeting, a comprehensive text was drafted and final approval was sought by all experts.
Findings: Three theme categories were identified in 9 detailed interviews (anatomical landmarks, description of tissue retraction, and operating strategies). Following 2 rounds of a 54-item questionnaire, 29 items achieved very high agreement ($A^* \geq 90\%$), 14 with good agreement ($\geq 80\%$), 13 with moderate agreement ($\geq 50\%$), and 18 with little or no agreement ($< 50\%$). In the workshop, areas of agreement were consolidated and conclusions were sought for those with less agreement. The final document was approved after 2 further rounds of surveys by all respondents.

Conclusions: This detailed and agreed technical description of laparoscopic TME may have implications on training, assessment, quality control, and future research.

Total mesorectal excision (TME) is a descriptive term for a surgical technique to remove the rectum and the mesorectal envelope as part of an anterior resection for rectal cancer.1,2 There is evidence that this technique is associated with low local recurrence rates and hence considered to be the gold standard surgical treatment of rectal cancer.3 It has been shown that rigorous surgical precision tissue dissection along defined embryological fusion planes is paramount to achieve complete resection and to avoid collateral nerve damage causing permanent bladder and sexual dysfunction.4–6 Over the past 2 decades, there has been a wide uptake of laparoscopic techniques in the treatment of colorectal cancer due to their proven short-term benefits in terms of reduced postoperative complication rates and recovery time and is proven to be an oncologically sound technique.7–10 However, a laparoscopic approach is technically demanding, and the average learning curve to competency is at least 30 to 40 cases per surgeon when supervised by an experienced teacher 11 and up to 3 times longer when self-taught.12 It has been shown that among the various tasks during laparoscopic anterior resections, the TME is the most difficult to learn.11 Despite descriptions of institutionally standardized techniques and an international survey about the practice of various surgeons, there is no international consensus on standard technical requirements of the laparoscopic TME procedure.13–15 An agreed approach on laparoscopic TME is essential in training, assessment, and quality control for both clinical and research purposes.

The aim of this study was to establish a structured international expert consensus on a detailed description of a technique for laparoscopic TME that is reproducible, instructive, and compatible with favorable clinical and oncological outcomes.

METHODS

A modified Delphi technique was used in this study to obtain a wide expert opinion from
various sources using combined qualitative and quantitative methods. The consensus process was conducted in 4 sequential steps: (1) initial interviews to develop the themes for the Delphi questionnaires; (2) 2 rounds of Delphi questionnaires to obtain initial views/opinions; (3) an interactive workshop, and (4) a final consensus statement survey.

**Study Steering Group**
Representatives of 5 different world regions were invited to form a study steering group, which was responsible for the identification and invitation of further experts in their respective regions, to encourage them to participate in the Delphi study, and facilitate the final steps of the consensus (workshop and final consensus statement). The steering group included representatives from North and South America, Europe (including Eastern Europe/Russia), and Australasia. The members of the steering group were selected through peer recommendation on the basis of their long-standing clinical experience, track record in research, and/or evidence of networking skills such as leading positions in national and international specialist societies in their corresponding world regions.

**Expert Group**
A total of 60 experts representing 20 countries were identified by the steering group [21 from the Americas (9 South, 12 North), 24 from Europe, and 15 from Australasia]. The only fixed criterion was a minimum experience of performing 50 laparoscopic TME cases. A recognized track record of teaching activity and published research in this field was favorable but not mandatory. For the workshop, 2 additional internationally recognized experts in rectal cancer surgery without any specific laparoscopic experience were invited to mediate the process.

**Consensus Finding Process**
**Step 1: Semistructured Interviews**
Between October 2012 and January 2013, 2 researchers with previous experience in interview techniques (D. M. and J. F.) performed 20 to 30 minutes of semistructured expert interviews, focusing on technical aspects of laparoscopic TME surgery. The interviewees were specifically asked to describe the technique they would recommend for training for laparoscopic TME. Although certain core themes (such as task order, use of traction and assistants, and identification of landmarks and dissection planes) were revisited in each interview, other questions were added during the interviews for clarification or to explore further areas.16 After critical review of 9 interviews, the themes and answers had evidently achieved saturation and further interviewing was omitted. All interviews were audio-
recorded and transcribed verbatim. Transcripts were independently analyzed by the 2 investigators and response items were extracted and categorized according to the task area and themes of the operation.

Step 2: Reiterating Questionnaire Study (Delphi)

Based on the categorized item list from the interview study, a questionnaire was created covering all themes and possible replies from the interviews (see Supplement Digital Content 1, available at http://links.lww.com/SLA/A583).

Fifty-four questions covered perioperative issues, port access, colonic mobilization, the mesorectal dissection, resection, and anastomosis. Twenty-one questions aimed specifically at technical details of the TME. The question types included multiple-choice (with single or multiple answers), Likert-type, and free-text answer questions. Whenever possible, free comment sections were added in case information was missing within the given answer options. The questionnaire was sent to the experts using a commercial electronic survey platform (www.surveymonkey.com). After a first round, the results were analyzed and a similar questionnaire, but this time with the results from the first round attached, was sent to the same group. This reiterating procedure aimed to achieve increasing consensus. To maintain transparency of the process, the levels of agreement from the step 2 questionnaire were categorized to facilitate understanding according to the following scale: A* >=95% agreement, A >=90%, B >=50%, and C <50%. Decisions that have been made in the workshop meeting were highlighted with the letter “W.” In addition, the percentages are given. See Appendix 1 for details.

Step 3: Interactive Workshop

The results of both rounds of the questionnaire study were discussed at an expert group meeting, which was held in Portsmouth (United Kingdom) and was attended by 21 experts on May 9, 2013. The aim of the meeting was to explore areas of dispute from the first 2 Delphi rounds, to clarify terminology, and to decide how to word the final draft of the consensus. The agenda for the workshop was based on the analysis of the responses obtained by the initial postal questionnaire, supported by a comprehensive review of the literature on the subject matter. A series of statements/questions were presented using projection slides delivered to the participating group by D.M., who did not participate in voting but defined the terminology used and encouraged group discussion before the experts voted on each issue. Where appropriate, additional questions were added and discussed by the experts at the focus group for further voting.
Step 4: Approval of Consensus Document

Based on the workshop meeting, a comprehensive text was drafted and sent to the whole expert group for final agreement. In a first round, the experts voted for each paragraph and could add further comments. In the second round, the text as a whole was sent for approval.

RESULTS

Sixty surgeons from 20 countries participated in the survey. Four respondents reported an overall experience of less than 50 laparoscopic TME cases and their responses were excluded from further analysis. The median experience of the included surgeons was 250 cases per surgeon, with a median annual workload of 30 cases per surgeon. The median experience in performing laparoscopic TME was 10 years per surgeon. The majority of respondents were male (57:3).

Step 1: Interview Study

Based on the interview transcripts, responses were identified as referring to different tasks of laparoscopic TME, and these items were categorized into (1) anatomical landmarks, (2) description of tissue retraction, and (3) operating strategies. For the questionnaire design, interview data were summarized where possible. One expert said, for example (with regard to the posterior plane dissection): “(I go down) as far as possible posteriorly, but sometimes if you don't mobilise laterally it is difficult to proceed further down so I would then go to the right side.” Another expert on the same subject:

If I find it hard to find the plane I will go laterally. I think it is easier to find the plane laterally (...) (Normally) I would recommend careful, try medial dissection, but if it is difficult you shouldn't risk to damage the nerves and you should go laterally. I would go down on the right side because I have already defined the plane.

More similar statements would be summarized in the questionnaire as a single answer option for a question on posterior plane dissection: “I go down posteriorly as much as I can, before opening the right lateral peritoneum to gain further access then proceed” (question 37, option a).

Step 2: Reiterating Questionnaires (Delphi)

The questionnaire contained 54 questions (see Supplement Digital Content 1, available at http://links.lww.com/SLA/A583). There is evidence for increasing consensus during the reiteration process. Figure 1 demonstrates that for questions with single or multiple answers, the answer options with the highest proportion of responses increased consistently between the 2 rounds, indicating rising consensus. The results following the
second round of questionnaires included a total of 29 items with very high agreement (A* >=90%), 14 with good agreement (>=80%), 13 with moderate agreement (>=50%), and 18 with little or no agreement (<50%). The detailed results can be found within the final consensus text (Appendix 1).

Step 3: Interactive Workshop
The results from step 2 were discussed, analyzed, and presented to the expert group at the workshop. The expert group consolidated all areas of high agreement. In certain cases, the group considered that questionnaire results lay outside the remit of the project and advised rejection or amendment of the statements. For example, a recommendation regarding thromboembolic prophylaxis (question 10) was rejected by the expert group, as it was deemed to be beyond the scope of this consensus and was replaced by a general statement ("Adherence to local guidelines regarding venous thromboembolism prophylaxis is recommended," Appendix 1). For other areas, the group complemented certain statements such as the landmarks for completion of TME by adding the posterior raphe indicating the point where the anococcygeal ligament fuses with the rectal tube and signifies the lower border of the posterior dissection. All additional decisions made by the group are highlighted in the text with the letter “W” and can be found within the consensus text (Appendix 1).

Step 4: Approval of Consensus Document
A descriptive text as agreed in the workshop was drafted and sent around to the wider expert group. They were asked to either agree or disagree and comment on each paragraph of the consensus document. Forty-nine experts responded and high levels of agreement were achieved; details on comments can be found in Table 1. After considering all comments and some minor amendments, the final text was sent to the same group and 42 surgeons responded. All of them (100%) agreed with the final version of the text (Appendix 1).

DISCUSSION
This is the first report of an international expert consensus on a surgical technique for laparoscopic TME surgery for rectal cancer using a structured, scientific process. Expert consensus was found in all task areas, including the identification of important landmarks and description for strategies of optimal exposure and task execution.

In a previous study, the responses of 368 surgeons from around the world on their current practice in TME surgery were analyzed and several areas of disagreement were
The aim of the current study was to overcome differences and achieve a worldwide expert consensus. This process involved a structured, modified Delphi technique involving both quantitative and qualitative methods, with the aim to reach high levels of agreement among a group of dedicated experts. Similar techniques have been used previously to establish consensus among surgical specialists. The purpose of the consensus statement was to provide a comprehensive and detailed technical description of the surgical procedure with potential applications in training, assessment, quality control and research. (1) Training: Although several techniques may lead to the same clinical result, a defined and reproducible technique will support both trainer and trainee by clarifying the aims and solutions for each operative task not only during hands-on teaching sessions but also as part of learning agreement and feedback meetings. (2) Assessment: Competency assessment within training programs will be simplified by defining a technical standard to compare to. (3) Quality control: A standardization will enable a process rather than a purely result-orientated quality control, and negative clinical outcomes can be prevented before they accumulate. (4) Clinical research: By standardizing the technique, surgeon's bias in randomized controlled trials involving TME surgery can be reduced.

There are limitations to this study. First, representatives of the different world regions selected the experts on the basis of personal relationships. Nevertheless, it has to be assumed that a significant number of world-leading experts were not included. However, the method of using regional leaders to identify experts on the basis of their personal networks was highly practical, and other ways of expert identification were deemed to be flawed or unworkable. In addition, there was some control to exclude surgeons with only moderate experience by selecting a lower threshold of a self-reported experience of 50 cases. Second, evidence from the literature was not routinely used to evaluate expert recommendations. Nevertheless, wherever possible, the literature was reviewed if there was an evident conflict between expert opinion and evidence. A typical example was the issue on bowel preparation before surgery. Although a majority of surgeons recommended mechanical bowel preparation, some pointed out that there is an evidence base against this statement. However, the specific evidence on low anterior resections is more controversial, and the results of a more recent multicenter study support bowel preparation for TME surgery. Hence, after considering the controversial evidence within the literature, the recommendation of the expert group was preserved in this case. Third, it is
evident that not only one single surgical technique would lead to a favorable outcome. It was made clear during the whole process that the consensus will describe only a single technique that is likely to result in an oncologically complete resection with minimal risk for collateral damage. Therefore, the consensus statement is not a prescriptive or even legal document exclusive for other techniques and has to remain subject to future amendments.

CONCLUSIONS

In the future, similar consensus statements can be developed for other areas in surgery. In the current climate of outcome-orientated quality control, an agreed standardization of a surgical technique provides a platform to move toward a more process-based assessment. This may include the evaluation of the efficacy of innovative technologies and ergonomics, future training programs, and appraisal of surgical units or individuals. The consensus statement should be revisited and adjusted on a regular basis to include anticipated technological and clinical advancements.

REFERENCES


