



Technical assessment in minimally invasive complete mesocolic excision: Is the complete mesocolic excision competency assessment tool valid and reliable?

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Abstract

Aim: The complete mesocolic excision competency assessment tool (CMECAT) is a novel tool designed to assess technical skills in minimally invasive complete mesocolic excision (CME) surgery. The aim of this study was to assess construct validity and reliability of CMECAT in a clinical context.

Method: Colorectal surgeons were asked to submit video recorded laparoscopic CME resections for independent assessment of their technical abilities. The videos were grouped by surgeons' training level, and four established CME experts were recruited as CMECAT assessors. Extended reliability analysis (G-theory) was applied to describe assessor agreement.

Results: A total of 19 videos and 72 assessments were included in the analysis. Overall, technical skills assessed by CMECAT improved with increased training level: the experts scored significantly better than the untrained surgeons (3.3 vs. 2.5 points; p < 0.01). On right-sided resections, significantly higher scores were reported with increased training level for all categories and sections, while for left-sided resections, the variance across groups was smaller and significantly higher scores were only reported for oncological safety describing items. Overall, assessor agreement was high (G-coefficient: 0.81).

Conclusion: This study confirms that CMECAT can be applied to video recorded CME cases for technical skill assessment. Further, it can reliably assess technical performance in right sided CME surgery, where construct validity has now been established. More videos are required to evaluate its validity on left colonic CME. In the future, we hope CMECAT can improve feedback during CME training, serve as a tool in certification processes and contribute to distinguishing CME from conventional surgery in future research.

KEYWORDS

assessment tool, colorectal surgery, complete mesocolic excision, reliability, technical skills, validitv

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INTRODUCTION

Minimally invasive complete mesocolic excision (CME) has been associated with increased cancer-specific survival [1-4] but the technical complexity of the procedure has raised safety concerns, especially the risk of central vascular injury [5]. As technical skills may vary considerably between surgeons, assessment of operative performance when implementing minimally invasive CME is thus necessary to predict the likelihood of adverse patient outcome [6].

With the growing adoption of robotic and laparoscopic CME, outcomes of this technique compared to those of 'conventional' colon cancer surgery have been discussed in the literature [4, 7-9]. Included in the CME definition is dissection performed in the mesocolic plane; bowel resection margins at a sufficient distance from the tumour; and central vascular ligation to ensure lymphadenectomy and mesocolic excision close to its origin [2, 3]. For left-sided CMEs, this entails ligating the inferior mesenteric artery at its origin and the inferior mesenteric vein below the pancreas [2]. In the case of right sided CMEs, the ileocolic and right colic vessels are divided at their origin; however, for tumours located in the caecum and ascending colon, only the right branch of the middle colic artery is centrally divided. In the case of tumours located at the flexure, central ligation of the middle colic artery and vein becomes necessary [2]. However, ambiguous, or incomplete definitions of CME in published studies highlight the lack of standardisation and confuse whether CME procedures have been properly performed [1, 3, 5, 10]. Hence, a valid and reliable assessment tool, proficient in standardising the necessary steps, may benefit the surgeons in CME training and the surgical research environment.

The complete mesocolic excision competence assessment tool (CMECAT), specifically designed for CME surgery, has recently been developed and its content validity has previously been presented [11]. While existing tools tend to focus on instrument and tissue handling [12], the CMECAT includes an assessment of the oncological resection quality and the operative steps crucial for maintaining the CME principles. Thus, the purpose of CMECAT is to comprehensively, reliably, and objectively assess the surgeon's technical abilities to perform a safe and efficient CME.

As part of the clinical implementation process, the aim of this study was to evaluate construct validity (to which degree the scores reflect surgical performance) and reliability (evaluation of assessor agreement on surgical performance) of the CMECAT in a clinical context on video recorded CME cases.

METHOD

This validation study and clinical test of the CMECAT was conducted from April 2020 to December 2021 in the UK and Denmark.

What does this paper add to the literature?

This paper reports validity and reliability evidence of a new procedure-specific tool for skill assessment during minimally invasive CME when first tested on video recorded CME cases as part of a clinical implementation process.

Level of training

Video recorded laparoscopic CME resections (LCME) were obtained from national certified general surgeons with a specific interest in colorectal surgery and certified where possible in their respective countries. A training programme was developed in the UK and three levels of competency were defined: before training (untrained group), after training (trained group) and trainers (expert group). The untrained group were surgeons attending the training programme; the trained surgeons had completed the training programme, and the experts were members of the training faculty. The training programme consisted of a theoretical explanation of the CME concept with a laparoscopic approach, followed by six laparoscopic CME sessions with individual supervision by the trainers.

Videos

Fourteen minimally invasive CME surgeons were asked to video record and submit full-length laparoscopic colon cancer resections, representing their technical abilities for independent assessment of their LCME performance. All videos were by surgeons' choice, performed unsupervised, and no restriction was imposed on the resection side (right or left LCME). Videos were muted and anonymised before they were forwarded to the assessors.

Assessors

Four minimally invasive CME experts from high-volume units (>100 CME cases each year excluding rectopexies, ileocaecal resections, and other rectum resections) in the UK, Norway, Spain, and Germany were included in the assessor panel. All assessors were colorectal surgeons with an average experience of 430 minimal invasive CMEs (average left:220, right: 210), who had previously contributed to the development of CMECAT. They were not systematically trained but were given an instruction manual prior to video rating. The assessors knew the resection side but were blinded to the performing surgeon, hospital, and any patient identifiers.

Assessment tool

In the present study, assessors used the CMECAT to rate the submitted video recordings. The development of CMECAT has previously been described [11]. In short, the tool was designed as an assessment tool for minimally invasive CME surgery. The tool content was developed through semi-structured expert interviews and the Delphi method. Further relation to other clinical outcomes has not yet been described, as this is the first time it has been tested in a clinical setting. The CMECAT is divided into side-specific versions and procedural sections (Right section: exposure, ileocolic vessels [IMV], middle colic vessels [MCV], gastrocolic trunk [GCT], mobilisation and anastomosis. Left section: exposure, inferior mesenteric vein [IMV], inferior mesenteric artery [IMA], mobilisation and anastomosis). Within each section, four categories are evaluated (instrument handling, tissue handling, clinical safety, and oncological safety). All items in CMECAT are scored on a numeric scale ranging from 1 to 4, where 4 represents 'excellent performance'. The CMECAT score is calculated as an overall mean: for each section, the total score is summed up and divided by the number of applicable items (section score). To ensure all sections carry equal weight, the final score is calculated as the average of section scores. The final score ranges from 1.0 (poor performance) to 4.0 (excellent performance), where a predefined score of 3.0 represented competent performance. The scores given by the assessors were reported directly in an online survey tool, RedCap (Vanderbilt University, 2004) [13, 14].

stratified by right versus left side, sections, and categories. As some cases were performed by the same surgeon and to relax the assumption of independent observations, we applied a random intercept on assessors crossed with a random intercept on videos in the construct validity analysis.

The inter-rater reliability (IRR), (the level of agreement across assessors), was described by extended reliability analysis (generalisability theory [15, 16]). In short, IRR was assessed both on the absolute scale (assessor agreement regarding the specific score given the individual surgeon's performance) and on the relative scale (assessor agreement regarding the performance in relation to other surgeons' performances). The IRR range from 0 (poor agreement) to 1.0 (excellent agreement), with a G-coefficient>0.80 considered reliable. A decision study (D-study) was further applied to the G-study results, investigating how many assessors required to obtain a reliable score in a training situation. Items scored as 'not applicable' were treated as missing in all analyses. How each assessor averagely assessed the surgical performance was analysed using a mixed-effect model with a random intercept on video. The G- and D-study was performed in R (R Core Team, 2020). All other analyses were performed using STATA (StataCorp. 2019: Stata Statistical Software: release 17).

RESULTS

Video selection

Statistical analysis

To examine differences in CMECAT scores between training levels (construct validity), we used a linear regression mixed-effect model,

A total of 29 videos were available for assessment (Figure 1A). Of these, 10 were considered inappropriate for analyses either due to technical challenges (3 videos); sensitive information was available on the video (5 videos); or the video was not full-length

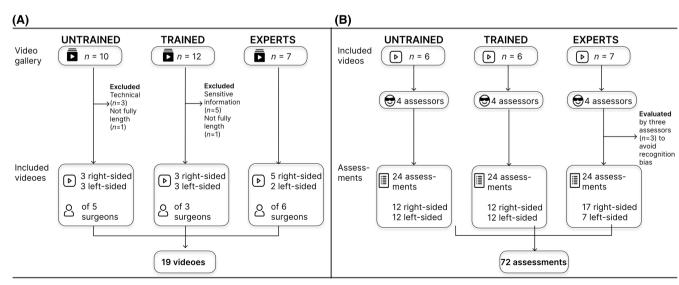


FIGURE 1 Video selection (A) and assessments (B): A total of 29 videos were available for assessment (Figure 1A). Of these, 10 were considered inappropriate for analyses either due to technical challenges (3 videos); sensitive information was available on the video (5 videos); or the video was not full-length (2 videos). A total of 19 videos were submitted to the assessors (Figure 1B). All four assessors evaluated all videos (blinded), except for three videos, which were evaluated by only three of the assessors to avoid recognition bias from the fourth. A total of 72 assessments (31 left-sided and 41 right-sided) were included in the analysis.

(2 videos). The remaining 19 videos were submitted to the assessors (Figure 1B). All four assessors evaluated all videos, except for three videos, which were evaluated by only three of the assessors to avoid recognition bias from the fourth. Finally, 72 assessments (31 left-sided and 41 right-sided) were included in the analysis.

Construct validity: Relation to training level

Overall, the CMECAT scores differed significantly between experts (3.3 points [95% CI: 2.9:3.7]) and untrained surgeons (2.5 points [95% CI: 2.1:3.0]) (Table 1). The CMECAT score improved 0.4 points (95% CI: 0.1:0.7) with each increase in training level.

The largest difference in CMECAT scores was reported for right-sided assessments: the CMECAT scores improved 0.6 points (95% CI: 0.3:1.0, p = < 0.01) with an increased level of training (Figure 2). A significant difference in CMECAT score was reported for all right-sided categories (instrumental handling, tissue handling, clinical and oncological safety) and sections (exposure, ICV, MCV, GCT, and mobilisation and anastomosis) (Figure 3 and Tables S1A and S1B).

In contrast, no significant difference across training level was observed for left-sided assessments (0.1 points [95% CI: -0.3:0.4, p = 0.73]) (Figure 2). However, stratified by subcategories, a statistical trend was observed across groups for inferior mesenteric vein items (0.3 points [95% CI: 0.0:0.7], p = 0.06) and a significant difference was found between groups for oncological safety items (0.4 points [95% CI: 0.0:0.7], p = 0.04) (Figure 3 and Tables S1A and S1B).

 TABLE 1
 Complete mesocolic excision competency assessment

 tool (CMECAT) scores across training level.

Groups	Videos (n)	Mean (95% CI)	Trend in training level (95% Cl)	p-value
Both sides				
Untrained	6	2.5 (2.1:3.0)	0.4 (0.1:0.7)	<0.01
Trained	6	2.9 (2.3:3.4)		
Expert	7	3.3 (2.9:3.7)		
Right side				
Untrained	3	2.1 (1.5:2.6)	0.6 (0.3:1.0)	<0.01
Trained	3	2.9 (2.4:3.4)		
Expert	5	3.4 (2.9:3.8)		
Left side				
Untrained	3	2.9 (2.5:3.3)	0.1 (-0.3:0.4)	0.73
Trained	3	2.6 (2.1:3.1)		
Expert	2	3.1 (2.6:3.6)		

Note: Mean: mean CMECAT score, trend in training level: differences in CMECAT scores with an increasing level of training level *p*-value: the probability of obtaining the observed results, assuming there is no difference between groups.

Reliability: Agreement between assessors

The overall assessor agreement was high (relative G-coefficient: 0.81 [95% Cl: 0.65:0.90], absolute: G-coefficient: 0.75 [95% Cl: 0.56:0.88]).

On the relative scale, describing to which extent the assessor agreed on the performance in relation to other surgeons' performances, suboptimal agreement was observed on the left (G coefficient 0.55 [95% CI: 0.20:0.82]) and good assessor agreement on the right (G-coefficient 0.89 [95% CI: 0.74:0.96]). In general, when observed individually, one assessor (assessor 3) graded significantly more liberally and another (assessor 4) significantly more conservatively than the remaining two (Table S3). On the absolute scale, similar findings were reported for IRR (describing to which extent the assessors agreed on the specific score given each performance): suboptimal IRR on the left (G-coefficient 0.49 [95% CI: 0.17:0.78]) and good agreement on the right (G-coefficient 0.86 [95% CI: 0.65:0.94]). Estimates of the contributed variance from the assessors, items, and videos in the calculated G-coefficients can be found in Table S2.

For reliable and reproducible assessments, based on relative G-coefficients >0.80, a minimum of one assessor was needed for evaluation of right-sided procedures, whereas a minimum of four assessors were needed for left-sided procedures (Figure S1).

DISCUSSION

This is the first study to test CMECAT, a procedure-specific tool for technical skill assessment on video-recorded CME cases, and it presents data on reliability and construct validity.

Overall, CMECAT scores were able to significantly discriminate between untrained, trained, and expert CME surgeons. When stratified by resection side, CMECAT's discriminative ability was significantly better on right-sided resections, whereas no statistically significant discriminative ability was found on the left. This could imply that the CMECAT construct validity is limited to right LCMEs. However, the lack of discriminative ability could also be explained by the different technical requirements of the two procedures: for laparoscopic rightsided resections, the complex vascular anatomy necessitates a higher psychomotor skill level learned from numerous repeated procedures to avoid surgical errors [5]; greater experience and improved technical ability after LCME training will therefore expectantly impact performance and subsequently CMECAT scores across training levels. In contrast, left-sided LCME resection principles are more like 'conventional' left hemicolectomies. Thus, for certified colorectal surgeons who already perform left-sided resections, CME training may result in only minor performance improvements, which is difficult to measure in a small cohort. However, the training improvements would mostly concern technical skills and procedural steps for maintaining the oncological safety, which are exactly the two subcategories (IMV items and 'oncological safety' items) where the left CMECAT version showed discriminative abilities across training levels.

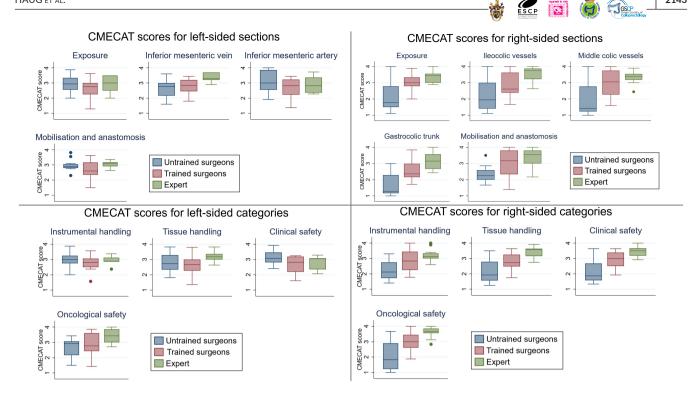


FIGURE 2 Complete mesocolic excision competency assessment tool (CMECAT) scores across groups for left- and right-sided sections and categories. Significant difference: Inferior mesenteric vein, left oncological safety end all right-sided categories end right-sided sections.

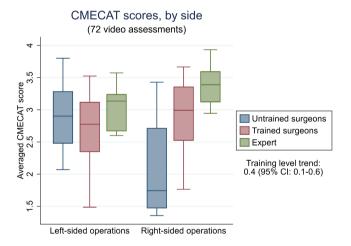


FIGURE 3 Box plot illustrating the complete mesocolic excision competency assessment tool (CMECAT) score between different groups for the left and right side. The bold line marks the median of the score.

Further, results from the construct validity analysis showed that the CMECAT score variance decreased with increased training level. Similar findings have been reported in validation processes of other colonic surgery assessment tools [17, 18]. This may illustrate that the technical performance of the experts is more consistent and in line with the previously defined assessment criteria for CME surgery [2, 11]. As seen in Figure 2, the between-training-level variance was substantially smaller for all left-sided resections compared to right-sided resections: again, this may

reflect more familiarity with the left CME technique given its closer similarity to 'conventional' left hemicolectomy. As less variance has been observed across training groups on the left, a larger number of videos are needed to evaluate the construct validity of the left CMECAT version.

Differences between the right and left discriminative ability of CMECAT also became apparent in the reliability results. When stratified by the resection side, the left IRR was substantially smaller compared to the IRR describing right-sided resections. The computation of IRR should, however, be carefully considered when interpreting the results: as the IRR is depended on the betweenvideo variance in relation to the total variance, the general high performance on the left causes less variance between training groups, which contributes to the low IRR. In contrast, the right IRR were remarkable high even without systematic rater training. Hence, results indicate that assessor agreement can be reached without rater training on the right, at least when the assessors are experienced minimally invasive CME surgeons. Further research is needed to determine how CMECAT rater training impacts assessor agreement and evaluate to which degree non-CME surgeons can be recruited as CMECAT assessors, without compromising the assessment quality. This may ease the implementation of CMECAT in the clinical and/or research setting.

An interesting finding from our reliability results was the level of assessor agreement on both the relative and absolute scale: the assessors agreed both on the specific CMECAT score (absolute) and on how the surgeons performed in relation to each other (relative). Assessor agreement on the absolute scale is often not reported, but is pivotal for determining a specific, reproducible

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CMECAT score [19]. Agreement regarding the specific CMECAT score and how surgeons perform in relation to each other suggest that there is a common understanding of a 'proper' CME. Finally, assessor agreement on both the absolute and relative scale are essential when evaluating the utility of CMECAT in competency assessments or pass-fail evaluations.

This study had some limitations. First, a small number of videos were included, specifically on the left side, which may have caused inconclusive results (type II error); a larger number of left sided videos may allow CMECAT to successively distinguish between training groups. The small number of videos further oppose generalisation of the results to a clinical setting and can only be used as an early indicator of future CMECAT scores. Second, all cases were self-selected, which is a potential cause of bias, as it is plausible that surgeons select their best performance for assessment. Although this bias occurred in all training groups, this may be more prominent for low level surgeons. Third, most surgeons in our study contributed with only one video each. The degree to which the general competence level can be represented by one video is guestionable. However, more data are needed to perform a test-retest analysis. Fourth, CMECAT may be valid and reliable in other minimally invasive techniques, but our results are restricted to laparoscopic cases. Although the laparoscopic and robotic CME procedures are similar, CMECAT needs revalidation before it can be applied to a new setting. Likewise, a revalidation is needed before it can be used live in the operating theatre. Finally, the CME-CAT only evaluates technical skills: nontechnical skills are equally essential for patient outcome but were beyond the scope of our study. The strength of our study is that the assessors were blinded to the patient, tumour characteristics, and surgeon identifiers. and that they represented different manners of practising LCME surgery. The number of performing surgeons participating in our study is another advantage, representing the diversity of operative performance.

For CMECAT to be applied to a clinical setting, further research is required to establish evidence of other validity dimensions. Aimed at technical performance in cancer surgery, particular attention should be directed to the relationship between the 'oncological safety' items and pathological reports, as the plane of surgery has been associated with improved patient outcome [20]. To increase the ease of use in a clinical setting, it is necessary to evaluate the association between CMECAT scores and patient outcomes (complications, readmissions, or cancer recurrence) in a large set-up with a higher number of video-recorded cases to secure enough statistical power in the data analysis. Likewise, it will be interesting to compare CMECAT to existing tools examining technical skills in laparoscopic colon surgery, for example, the competency assessment tool or the American Society of Colon and Rectal Surgeons Assessment Tool [6, 21-23], both of which have reported improved patient outcome with increased performance scores. Average assessment time and results from survey describing the accessibility in a clinical setting should as

well be considered in future studies, to ease the CMECAT implementation process. Finally, the consequences of test scores need to be further addressed. Preferably a pass-fail score in a large clinical cohort should be established; this pass-fail score should help distinguish surgeons that 'need further training' from those where 'competent surgery has been demonstrated'. In this manner, CMECAT can support the training programme directors in certification and recertification processes of CME surgeons. The establishment of a pass-fail score and further validity evidence could as well enable researchers to use the tool as a quality marker of CME.

CONCLUSION

In conclusion, the CMECAT can be applied to video-recorded CME cases for technical skill assessment. Further, it can reliably assess technical skills in right sided CME surgery, where the CMECAT scores differ significantly between untrained, trained, and expert surgeons. For left LCMEs, a larger number of video-recorded cases are required to establish conclusive construct validity and reliability measures. Therefore, this study is a solid foundation for future studies to examine the validity of CMECAT in left CMEs, to evaluate the correlation between CMECAT and clinical/pathological outcomes, and as we move towards a clinical implementation, to establish a pass-fail CMECAT score that can be used as a quality control measure in certification programs of CME surgeons and confirm proper CME surgery in research activities.

AUTHOR CONTRIBUTIONS

Tora Rydtun Haug: Writing – original draft; funding acquisition; conceptualization; formal analysis; project administration; methodology; investigation; visualization; data curation; validation; resources. Mai-Britt Worm Ørntoft: Writing – original draft; supervision; visualization. Danilo Miskovic: Conceptualization; methodology; writing – review and editing; supervision; resources. Lene Hjerrild Iversen: Writing – review and editing. Søren Paaske Johnsen: Writing – review and editing. Jan Brink Valentin: Software; formal analysis; supervision; writing – review and editing; data curation. Stefan Benz: Methodology; writing – review and editing. Kristian Eeg Storli: Methodology; writing – review and editing. Adam T. Stearns: Methodology; writing – review and editing. Anders Husted Madsen: Funding acquisition; conceptualization; resources; supervision.

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CONFLICT OF INTEREST STATEMENT

None.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ETHICS STATEMENT

None.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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