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This is the author's manuscript		
Original Citation:		
Availability:		
This version is available http://hdl.handle.net/2318/1635398 since 2017-05-17T12:33:23Z		
Published version:		
DOI:10.1007/s00464-017-5562-5		
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This is the author's final version of the contribution published as:

Francis, Nader; Penna, Marta; Mackenzie, Hugh; Carter, Fiona; Hompes, Roel. Consensus on structured training curriculum for transanal total mesorectal excision (TaTME). SURGICAL ENDOSCOPY. 31 (7) pp: 2711-2719. DOI: 10.1007/s00464-017-5562-5

The publisher's version is available at: http://link.springer.com/10.1007/s00464-017-5562-5

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Consensus on structured training curriculum for transanal total mesorectal excision (TaTME).

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Abstract

Background

The interest and adoption of transanal total mesorectal excision (TaTME) is growing amongst the colorectal surgical community, but there is no clear guidance on the optimal training framework to ensure safe practice for this novel operation. The aim of this study was to establish a consensus on a detailed structured training curriculum for TaTME.

Methods

A consensus process to agree on the framework of the TaTME training curriculum was conducted, seeking views of 207 surgeons across 18 different countries, including 52 international experts in the field of TaTME. The process consisted of surveying potential learners of this technique, an international experts workshop and a final expert's consensus to draw an agreement on essential elements of the curriculum.

Results

Appropriate case selection was strongly recommended, and TaTME should be offered to patients with mid and low rectal cancers, but not proximal rectal cancers. Pre-requisites to learn TaTME should include completion of training and accreditation in laparoscopic colorectal surgery, with prior experience in transanal surgery. Ideally, two surgeons should undergo training together in centres with high volume for rectal cancer surgery. Mentorship and multidisciplinary training were the two most important aspects of the curriculum, which should also include online modules and simulated training for purse-string suturing. Mentors should have performed at least 20 TaTME cases and be experienced in laparoscopic training. Reviewing the specimens' quality, clinical outcome data and entering data into a registry were recommended. Assessment should be an integral part of the curriculum using Global Assessment Scales, as formative assessment to promote learning and competency assessment tool as summative assessment.

Conclusions

A detailed framework for a structured TaTME training curriculum has been proposed. It encompasses various training modalities and assessment, as well as having the potential to provide quality control and future research initiatives for this novel technique.

Keywords

Transanal TME Consensus Training Curriculum Assessment

Members of International TaTME Educational Collaborative Group are listed in Acknowledgements.

Transanal total mesorectal excision (TaTME) is the latest advanced surgical technique for rectal mobilization that has captured the focus and attention of the colorectal surgical community. The adoption of TaTME has been growing rapidly worldwide and, although initially pioneered for rectal cancer [1], the procedure has also been adapted for benign disease [2, 3]. The first data analysis from the international TaTME registry and largest cohort to date was recently published, suggesting an oncologically safe and effective technique with acceptable short-term patient outcomes [3]. Surgeons, however, did experience intra-operative equipment and technical difficulties in approximately 40% of cases, including incorrect plane dissection, pelvic bleeding, unstable pneumopelvis with excessive smoke and visceral injuries.

Technical challenges of the transanal approach have been acknowledged by expert surgeons and early adopters of this technique as partly due to the unfamiliar view and interpretation of the anatomy from below, with possible difficulty in identifying correct tissue planes. This is likely to have contributed to the early reports of visceral injuries which occurred during the perineal phase, of which five were urethral injuries reported in the registry data [3]; a complication rarely seen with traditional abdominal TME surgery.

These early reports have highlighted the importance of provision of optimal training prior to embarking on this technique, taking advantage of all the lessons learnt so far from the early adopters. Early adopters of the technique advocate proctorship early in the learning curve. Evidence from previous surgical training studies suggest that proctoring can shorten the learning curve, help to avoid long operative times, reduce conversions and most importantly, reduce major complications (i.e. urethral injury, rectal tube perforations, pelvic sidewall bleeding) [4, 5, 6, 7].

Despite the perceived advantages of the mentorship, the registry data suggest that less than onethird of initial cases are actually mentored, suggesting a lack of a formal training pathway.

In a recent survey of the Association of Coloproctology of Great Britain and Ireland (ACPGBI) consultant members, structured TaTME training was the top educational-need priority. However, there is no evidence of an established training pathway that can assist surgeons who wish to commence TaTME [8]. Training guidance is required to ensure safe adoption of this technique in patients who truly benefit from this approach. This should encompass not only the technical steps of the operation but case selection as there is a lack of clarity about the indications for this approach.

The aim of this study, therefore, was to establish a consensus on a detailed structure of the whole training curriculum for TaTME to support the safe introduction of a new surgical access technique to benefit selected patients with mid or distal rectal cancer.

Materials and methods

A consensus process to agree on the framework of a TaTME training curriculum was conducted, seeking the views of 207 surgeons across 18 different countries worldwide including 52 international experts in the field of TaTME.

The consensus process was conducted in three phases: (i) learners survey; (ii) expert workshop and (iii) final expert consensus.

1. (i)

TaTME potential learners

This phase aimed to seek the thoughts of colorectal surgeons as potential learners of this technique in order to identify the learning needs and potential gaps in training for this novel technique. It was also targeted to capture their views on the essential elements of the training curriculum. An initial survey was distributed by electronic mail [9] with a subsequent reminder to all colorectal consultant members (829) of the ACPGBI. The survey consisted of 21 questions which were formulated by the study steering group and reviewed by both medical and non-medical professionals to ensure clarity and avoid any biased or ambiguous phrases. The questionnaires included open-ended questions and a 3- or 5-point Likert scale was preferentially used when appropriate in order to allow the individual to express how much they agree or disagree with a particular statement. Respondents also had the opportunity to share further thoughts and comments by free text.

1. (ii)

TaTME training and assessment expert workshop

This first international consensus workshop on TaTME was conducted in Bristol (United Kingdom) on 12th October 2015 [10] and aimed to discuss the results of the learners' survey and draft the consensus statements for the final process. The workshop involved twelve expert surgeons from seven different countries with extensive experience in rectal and transanal surgery as well as education leads who attended the workshop and discussed the need for and structure of a TaTME

training curriculum. The workshop proposed the consensus statements of the training framework for final voting by a wider group of international experts as the final stage of the process. During the Workshop, the Global Assessment Scale forms were developed and tested as a formative assessment tool [10]. In addition, it proposed the formation of the international TaTME educational collaborative group to help develop the TaTME training curriculum.

1. (iii)

TaTME final expert consensus process

This final stage aimed to obtain consensus from a wider group of international experts on six main themes of the TaTME educational curriculum: (i) indications and case selection, (ii) development of TaTME service focusing on selection of units, the number of surgeons per unit and how many cases each unit should perform in order to maintain competency, (iii) learning and mentoring requirements, (iv) training centres requirements (v) key elements of training curriculum, (vi) assessment and data collection (registry).

An online survey was designed using 'Survey monkey' [11] and sent to 78 international experts in the field of TaTME who were selected by peer recommendations as the innovators and early adopters of the TaTME technique.

The international experts were presented with statements that were proposed at the consensus workshop and asked to indicate their level of agreement to a set of statements/questions based on a scale from 1 to 5 (1 = strongly disagree, 5 = strongly agree). The experts were also invited to make any additional suggestions on the proposed aims and objectives of the international TaTME educational collaborative drafted during the consensus workshop.

Data analysis and study steering group

The final results were tabulated and expressed as a percentage of the respondents, mean \pm standard deviation or median with range. The final consensus results were presented with the level of experts' agreement required to obtain consensus.

The project steering group consists of the national tutor for coloproctology in the UK (NF), the cofounder of the international TaTME registry (RH), educational experts (HM and FC) and a PhD research fellow (MP) on the subject of TaTME. NF and MP were in charge of designing the questionnaires; collating the results and drafting the manuscript with the help of HM, FC and RH. NF and RH oversaw the whole project.

Results

1. (i)

Learners' survey

148 colorectal surgeons (18% of the total consultant members) responded to the initial survey and were distributed across 16 different regions in Great Britain and Ireland. The median number of years' experience as independent practitioners in rectal surgery was 7 years (0.5–25) with 89% being independent in laparoscopic TME. Only 33% were independent in transanal surgery (TEMS or TAMIS) and 17 (11%) surgeons had some degree of TaTME experience.

Ninety-two surgeons (62%) felt that a TaTME service should not be offered in every unit and a minimum of 10–15 cases should be performed per year per unit in order to maintain competence. The majority of respondents (86%) believed that at least 20 cases of laparoscopic rectal resections should be performed independently prior to learning TaTME. Key components of a training curriculum were also explored. The learners group assigned clinical proctorship (90%) and MDT training (88%) as the two most important aspects that must be incorporated into a TaTME curriculum. Surprisingly, technical skills training on cadavers received the lowest level of importance proposed by the learners group. Comments were made regarding the limited availability of cadaver courses for TaTME at present, including the difficulties in organizing such a course and their associated high attendance fees.

1. (ii)

TaTME training and assessment expert workshop

All statements from the learners survey were presented at the TaTME expert workshop [10]. Key components of a training curriculum were also explored and the final questionnaires proposed by the experts for the final consensus phase. In addition, the GAS forms to assess the performance of the operative technique in a proctored case were adapted for TaTME, agreed on by the experts and piloted at the workshop [10]. Finally, an international TaTME educational collaborative group was developed and the experts proposed the aims, objectives and remits for final voting.

1. (iii)

Final consensus

Fifty-nine experts (76%) responded to the final consensus survey, representing 48 colorectal units in 18 different countries (Argentina, Australia, Austria, Belgium, Brazil, England, France, Germany, Italy, Korea, Netherlands, New Zealand, Norway, Russia, Scotland, Spain, Switzerland, USA), including 24 professors of surgery/heads of department and 35 consultant surgeons. Fifty-two of these respondents are amongst the group of international surgeons with the most experience in TaTME, whilst the remaining seven are colorectal surgeons with expertise in education and advanced rectal surgery. The median years of experience was 10 (1–30) as independent practitioners in rectal surgery. 90% of them were independent in laparoscopic TME and 93% in transanal surgery. The median number of TaTME performed by the experts was 25 cases (10–250).

1. (i)

Indication for TaTME

There was a clear positive majority verdict that TaTME should be offered to both male and female patients (86% agreement) with mid and low rectal cancers (78% agreement). There was no agreement that TaTME should be restricted to only cancer patients, or patients with a raised body mass index, (BMI); only low rectal cancers; or only offered to male patients.

Experts commented that TaTME should be viewed as a "tool" that can be used to assist the surgeon in obtaining better quality of surgery represented by the best specimen under the circumstances available. The experts proposed that attempting more difficult cases (bulky low tumours) should only be considered once a surgeon has become more experienced with the technique.

1. (ii)

TaTME service development

The majority of the experts (69%) agreed that TaTME should not be offered by every colorectal unit, but rather, the operation should be centralized to specialist centres with a high volume of rectal cancer cases of a minimum of 20 cases per year. Furthermore, 21 respondents (36%) stated that only well-trained, experienced surgeons with a dedicated team and infrastructure in place should take on this advanced surgical approach.

There was no real agreement on the number of cases per year which is required to maintain competency, but 52% of the experts quoted at least 20 cases per year (median 20 cases, range 5–60). The majority of surgeons (88%) agreed that ideally two surgeons per unit should be trained to perform TaTME.

1. (iii)

TaTME learning and mentoring

A positive majority verdict was reached that the top two pre-requisites to learning TaTME were completion of training and accreditation in laparoscopic colorectal surgery and a minimum number of laparoscopic rectal cases performed independently, 97 and 95%, respectively (Fig. <u>1</u>). The majority of the experts agreed (68%) that the number of laparoscopic rectal cases to be performed independently should be at least 30 cases (range 10–100). Comments from the experts suggested demonstration of surgical outcomes after laparoscopic rectal cancer surgery was preferred rather than solely counting cases performed, in particular with regards to the ultralow anterior resections. The vast majority of the expert group (92%), proposed a minimum of 5 TEMS and TAMIS cases prior to attempting TaTME.

Recommended Pre-requisites

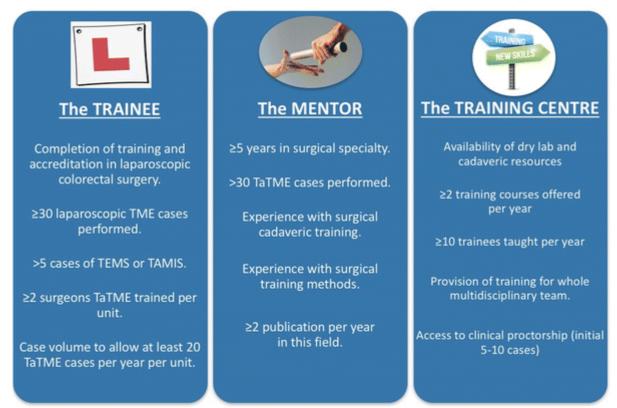


Fig. 1

Essential pre-requisites to learning transanal total mesorectal excision (TaTME), being a TaTME mentor and running a TaTME training centre

The experts gave majority verdict for the top three desirable pre-requisites of an educational mentor or trainer for TaTME: (i) at least 30 TaTME cases performed independently, (ii) provision of training courses for the operation, and (iii) at least 5 years in the surgical specialty (Fig. <u>1</u>). Most respondents (72%) recommended that each mentor should aim for at least 2 (0-10) papers per year in this field as academic output.

1. (iv)

TaTME Training Centre

Availability of dry lab equipment, especially for purse-string practice, and running at least two workshops per year were deemed essential criteria to define a training centre in TaTME (68 and 69%, respectively) (Fig. <u>1</u>). The majority of experts (76%) also felt that the most important and useful resource that a training centre should provide are cadaveric models.

1. (v)

Key elements of TaTME training curriculum

The expert group of respondents assigned with a positive majority verdict for clinical proctorship and multidisciplinary team (MDT) training as the most important components of a TaTME training curriculum (90 and 81%, respectively). The group also gave a majority positive verdict for training on indication and case selection (81%), technical skills training on cadavers and immersion courses (78%), and technical skills training on physical models (74%) as other important aspects of the training curriculum. The proposed structure of the TaTME training curriculum is outlined in Fig. 2.

Structured TaTME Training Curriculum

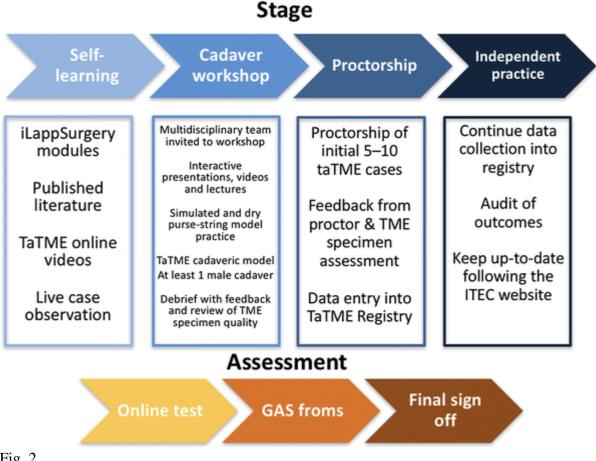
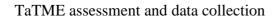


Fig. 2

Transanal total mesorectal excision (TaTME) structured training curriculum. TaTME transanal total mesorectal excision, ITEC International TaTME Educational Collaborative, GAS Global Assessment Score

1. (vi)



A majority positive verdict felt that the two most important methods to assess competency in TaTME include reviewing the pathological quality of the resected TME specimens, and analysis of clinical outcome data including complications, mortality and oncological results, 97 and 91%, respectively (Fig. 2). Approximately 70% selected review of registry data, although comments were made that a central registry may be prone to selective data submission and hence reporting bias. Observation of unedited operative videos, either live or retrospectively, was deemed important by 55% of surgeons, whilst individual e-logbook assessment was considered the least efficient method.

Formative assessment

GAS forms were recommended by the experts to be used to monitor trainees' progress and highlight areas that require more focused attention and practice during the initial cadaveric training and subsequent mentored live cases (Online Appendix 1).

Summative assessment and accreditation

Assessment of operative competency can be achieved using objective assessment tools. The majority of the experts (66%) felt that between 1 and 10 mentored cases should be sufficient to achieve safe independent TaTME practice.

Data entering and TaTME registry

Amongst expert surgeons who are performing TaTME, 80% are recording their cases on the TaTME registry [12]. The majority (80%) of surgeons recording cases on the TaTME registry commented that the database is useful, easy to use and takes no longer than 5 min once used to the system. A few responders (10%) find the registry too complex and time consuming, especially since "time to enter data is at a premium".

Formation of 'International TaTME Educational Collaborative'

The 'International TaTME Educational Collaborative' (ITEC) was selected by the experts as the name for the group of experienced surgeons forming the advisory committee (Online Appendix 2). There was a final consensus on the mission of the collaborative is "to promote the safe introduction of TaTME by driving the educational standard of the procedure through professional communications with relevant societies and collaborating with a wider international representation and stakeholders". Shared platforms of communication to build and maintain links amongst expert surgeons and educationalists in TaTME will also be created.

The agreed objectives and recommendations of the international collaborative group are outlined in the order of importance in Tables <u>1</u> and <u>2</u>, and Fig. <u>1</u>. Table 1

Objectives for the International TaTME Educational Collaborative

Aims and objectives

1) To develop consensus statements and recommendations aiming to enhance training and safe practice in TaTME

2) To propose a research agenda and establish evidence-based practice by conducting robust research in this field

3) To establish an international collaborative group led by surgeons with expertise in TaTME and education with local representation from each country

4) To establish a training curriculum for TaTME using validated teaching methods and developing assessment tools

5) To develop and maintain effective shared platforms of communication between the TaTME stakeholders with a web-based forum containing the training curriculum, published literature, educational materials, interactive forum and link to the registry

6) To promote networking with relevant industry in order to facilitate the accessibility of training

Aims and objectives

resources to surgeons undergoing training in TaTME Table 2

Recommendations on training and safe implementation of transanal total mesorectal excision (TaTME)

Recommendation	Level of agreement (%)
	59 surgeons
TaTME must be adopted in a safe and sustainable manner	98
All transanal cases should be registered on the TaTME registry	91
Previous experience in laparoscopic or robotic rectal surgery, with a minimum volume of 20 cases per unit per annum is essential prior to learning TaTME	86
Dual consultant/specialist operating is recommended during the initial learning curve of the operation	84
A competency-based modular training is recommended which entails:	`82
Online modules with web-based educational materials	
Dry lab workshop	
Cadaveric course	
Proctorship programme	
The minimum annual volume of TaTME cases per unit should be 10	74
TaTME can be considered for any patient requiring a full TME (total mesorectal excision)	68

Discussion

Transanal total mesorectal excision is a novel access technique which has attracted substantial interest amongst colorectal surgeons throughout the world due to the perceived benefits for both short- and long-term outcomes in patients with rectal cancer. The introduction and adoption of this procedure, however, should be carefully planned, and surgeons need to be trained and confident to optimize patient outcomes. The essential elements of the training curriculum for this novel technique, although important and needed, have not yet been defined. Since there is currently no evidence of an established training pathway that can assist surgeons who wish to commence TaTME, it was important to obtain a consensus from all relevant stakeholders including, early adaptors, innovative and the potential learners of this technique to guide training of this technique.

To our knowledge, this is the first project to provide a cohesive and agreed training curriculum that can guide learners on all aspects of TaTME training. The proposed curriculum encompasses clear guidance on case selection, different methods of teaching that include online modules, dry lab purse-string simulators, cadaveric training and clinical proctoring as well as assessment and data collection.

This project has achieved its aim in outlining the important and key items of the training curriculum and education in TaTME. Although the practical steps of TaTME have been generally standardized by surgeons around the world, there is a lack of clarity about the indications for this approach. A

consensus was achieved on the indications for TaTME, specifically for patients (both male and female) with mid and low rectal cancer. One could argue that female patients could be competently and safely treated using a conventional laparoscopic TME approach. However, the experts felt that the level of experience of the surgeon will also influence patient selection, as more 'straightforward' cases (female with higher tumour) are more likely to be selected at the start of the surgeon's learning curve. Interestingly BMI was felt to be less important than other parameters such as girth size, amount of visceral fat and waist-to-hip ratio.

Optimal prior training in laparoscopic and rectal surgery was proposed as a pre-requisite for TaTME training. This agrees with the UK National Institute for Health and Care Excellence guidelines, which recommend "TaTME should only be done by surgeons who are experienced in laparoscopic and transanal rectal resection and who have had specific training in this procedure" [13]. NICE guidelines also encourage clinicians to enter all patients undergoing TaTME onto the clinical registry, which was reported to be easy to use and provides the surgeon a complete record of patient cases and individual hospital outcomes.

Technical skills training was deemed to be essential to learn TaTME by the experts. In TaTME, there are several technical challenges such as the unfamiliar view and interpretation of the anatomy from below, with possible difficulty in identifying correct tissue plans. In addition, operating through a single port requires advanced level of technical skills and the availability of up-to-date imaging and insufflation equipment.

Due to the complex anatomy of the human pelvis, human cadavers are the best training models available to practice the full operation, since simulated reconstructions at present are unable to capture all the intricate detail required [14].

In a recent study evaluating TaTME in the UK and the USA [15], those authors reported that the key lessons learnt by running the TaTME cadaveric workshops were the importance of team training with two surgeons together with their scrub team, the preferential use of male cadavers and immediate expert feedback and assessment of TME quality. They also found that simulated pursestring practice prior to the cadaveric procedure resulted in a more secure rectal closure with fewer leakages. In addition, Aigner et al. have recently stressed the importance of simulated cadaveric training on the identification of proper dissection tissue planes, particularly with anterior dissection around the prostate to avoid urethra injury [16].

These findings are in line with our proposed multimodal training in the curriculum for TaTME, as each component has a unique purpose and enables different skills to be accomplished. Cadaveric training was proposed by the expert group in our study as an essential pre-requisite to clinical training. The importance of MDT training also along with post-course mentorship were considered the most important aspects of the training curriculum for TaTME.

The proposed elements of the training curriculum for TaTME in this study are mostly in agreement with McLemore's six key elements [17], who found expertize in TME surgery, laparoscopic and/or robotic surgery, transanal approaches and intersphincteric dissection to be essential components. They also recommend training on human cadaver models as well as data collection of clinical outcomes.

Our study, however, has gone one step further to quantify each factor, such as the number of previous laparoscopic TME cases, in order to provide even more detailed guidance. However, experts commented that the number of cases would depend on the previous surgical experience of the trainee and this needs to be evaluated on a case-by-case basis.

Furthermore, the importance of clinical proctorship was highlighted in our study as a key component of the training curriculum and is estimated to be required for at least the first five cases. Knowledge of key operative steps is not enough to avoid intra-operative complications. Identifying errors and knowing how to 'rescue' the situation before harm occurs is an essential role of the proctor. It is not uncommon to enter into the wrong dissection plane in TaTME, but an experienced surgeon would be able to recognize the error at an early stage and safely find the correct plane again, whereas inexperienced surgeon without proctorship is more likely to lead to complications. Aided by the GAS scores, the mentor and trainee will discuss when the time has come for the trainee (likely to vary between surgeons) to perform an independent TaTME case without the presence of the proctor, and retrospective review of the unedited video capture. New technology that allows remote mentoring is currently being developed and will be potentially a useful adjunct for both proctoring and general teaching [18].

We feel that a traditional Delphi approach to reach consensus was not appropriate for this project, given the novel nature of the technique and the complexity of developing the service within the current challenges in health care service. The consensus process in this project, therefore took a trainees' centred approach. This study commenced with "training need analysis" by surveying the learners and building from their views the consensus statements to develop themes that were then discussed by a group of experts at the workshop prior to the final consensus process by a wider group of international experts in TaTME. A limitation of this study was the response rate of 18% in the initial survey (the learners) which may limit the generalisability of learners' views. TaTME, however, is a novel technique, and it is anticipated that not all colorectal consultants would be interested in training for this novel technique, and hence responding to this survey. We feel that the 148 responders may represent the potential learners of this technique in the UK. The response of the experts nevertheless was much higher (76%), which shaped the final statements and training framework.

Certain aspects of the outcome of this project have already started to be put into action. A structured training programme based on the agreed framework of the training curriculum has been proposed and agreed on by the ACPGBI to run a pilot TaTME pilot training programme in the UK in the near future. In addition, an interactive online website for the International TaTME Educational Collaborative (<u>http://www.tatme.com</u>) was launched at the European Association for Endoscopic Surgery congress in June 2016 [19]. The site provides excellent educational material with animated videos as well as published literature and access to the TaTME registry [12]. The iLappSurgery Foundation has also designed a superb App to deliver extensive educational modules in a clear modern and user-friendly way [20]. Live congress talks and TaTME operations can be viewed via the Advances In Surgery (AIS) channel which also offers further educational material and courses [21]. These online platforms have created a shared platform for communication amongst colorectal surgeons worldwide and stimulated collaboration and support.

In conclusion, a detailed framework for a structured TaTME training curriculum that promotes a competent performance has been proposed to ensure that the introduction of a new technique occurs in a safe and controlled manner to protect both the patient and the surgeon. The framework encompasses various training modalities and assessment, as well as having the potential to provide quality control and future research initiatives for this novel technique.

Acknowledgements

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Funding

The TaTME educational workshop in Bristol was funded by an educational Grant from the Olympus Medical (OKMEXP00001988) but had no input on the contents of the workshop or the study.

Compliance with ethical standards

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