Implementation of IDEAL framework of UK training programme for TaTME

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Background: As international concern grows regarding the reported early oncological outcomes and technical challenges of transanal total mesorectal excision (TaTME), there is a need for a structured and robust quality assurance process to ensure safe introduction and monitoring of a novel surgical technique. The IDEAL framework has been advocated to guide such a process. The aim of this study was the report the application of IDEAL framework in the development and implementation of TaTME training in the UK.

Methods: A five-stage outline (idea, development, exploration, assessment, and long-term study) was applied to describe the development, delivery and assessment of the TaTME training initiative in the UK. Surveys that incorporated the experience of both learners and more experienced surgeons of TaTME, together with experts in education, initiated the process with concepts and development of the training initiative explored at a centrally co-ordinated pilot training programme. Key components included a cadaver training workshop and a formal proctorship process. Data were recorded on demographics, tumour location, intraoperative, post-operative and histological outcomes. Educational assessment of technical progress was performed using custom-made Global Assessment Scoring (GAS) forms which were completed by both learners and proctors. Long-term outcomes were captured at 24 months.

Results: Five selected pilot sites were used by 10 colorectal surgeons during the training initiative and 24 cases were proctored in this period in the exploration phase. Median operative time reduced from initial 331±90 [195–610] to 283±62 [195–340] minutes in the final case. No visceral injuries were reported however there was one conversion to open (4.2%). Histological assessment reported as intact mesorectal TME specimens with clear distal margin and no bowel or tumour perforation in all cases. One case had positive circumferential margin (4%). Assessment of educational outcomes showed GAS score 5 (independent performance) was achieved by case 5 in most operative steps. Long-term follow up showed no evidence of local or regional recurrence but three liver and one lung metastasis at 24 months.

Conclusions: Dissemination of a new surgical technique within the confines of IDEAL framework demonstrates the feasibility and safety of surgical training programme for TaTME at a national level.

Keywords: IDEAL; transanal total mesorectal excision (TaTME); transanal; surgical training

Introduction

Rectal cancer remains one of the most common cancers in the Western world with over 700,000 new cases diagnosed annually and a mortality rate greater than 300,000 (1). Minimal invasive technique has been increasingly used in the management of rectal cancer in last two decades. However, the role of laparoscopy in rectal cancer has been recently questioned as two major randomised controlled trials (RCTs) failed to demonstrate non-inferiority of the laparoscopic approach compared to open (2,3). Conflicting meta-analysis reports have resulted in a lack of consensus of the optimal approach for rectal cancer surgery, resulting in variation throughout daily practice (4,5).

Total mesorectal excision (TME) is considered as gold standard in the treatment of rectal cancer. However, this procedure can be technically difficult especially when tumour is located in the lower third of rectum, in male patient with high body mass index (BMI) and narrow pelvis. Thus, a transanal technique for TME has been developed to conquer the challenges of distal rectal dissections as this offers broader view and possibility of permitting better dissection (6). While initial results were promising, the potential advantages of this approach are yet to be appraised in multicentre RCTs. Despite this, dissemination of transanal total mesorectal excision (TaTME) has speedily unfold across several institutions since the first reported case performed in 2009 (6). The first data analysis from the international TaTME registry has been published, suggesting it an oncologically safe and effective technique with acceptable short-term patient outcomes (7,8).

More recent reports on TaTME specific complications, such as urethral injuries and CO_2 embolism, have raised concerns regarding the safety of the procedure (9-12). Lately, early oncological fears have conjointly been raised regarding this technique in Norway and the Netherlands, with high local recurrence rates in a multifocal pattern (13), resulting in the moratorium of this technique in Norway.

It remains unclear whether these issues are related to poor performance of the TaTME technique because of meagrely procedural training or an actual risk factor of the technique itself given the rectotomy created that leaves rectal mucosa exposed to the pelvis and use of high flow insufflators. Until this is fully and scientifically resolved, robust training with a quality assurance mechanism must be in place to ensure patient safety.

A five-stage framework was introduced for scientific evaluation of such innovations: the IDEAL recommendations (14). These recommendations describe five stages of development that occur when new interventional procedures are evaluated and introduced into clinical practice: idea, development, exploration, assessment, and long-term study (14) (http://www.ideal-collaboration.net). In the UK, a national training initiative has been developed as a pilot training programme to aid safe dissemination of this technique (15). The aim of this study was to report on the evolution of the national training initiative for TaTME in the UK, in terms of development, exploration and assessment, using the IDEAL framework.

We present the following article in accordance with the MDAR reporting checklist (available at http://dx.doi.org/10.21037/ales-20-69).

Methods

The study was approved by London Bromley Research Ethics Committee on September 2017 REC reference 15/LO/0499 IRAS project ID 156930.

The evolution of a national pilot training initiative for TaTME is described under the five stages of IDEAL framework (idea, development, exploration, assessment, and long-term study).

Idea of a training programme

The concept of a national training initiative was in response to a member survey of the Association of Coloproctologists of Great Britain and Ireland (ACPGBI) in July 2015 (16). A total of 390 responses were obtained and reported on gaps in education and learning needs for knowledge, technical and non-technical skills and how to meet these challenges in the future (16). This was part of a larger project to develop an educational agenda for the coloproctology society in the UK.

Ninety percent of respondents believed mentorship programmes for TaTME to be very important and 44% estimated 5–10 cases to achieve competency. Analysis of the international TaTME registry also demonstrated a rapid uptake of this novel technique globally and across the UK (17), with many surgeons performing cases without mentorship. Both observations highlighted the need for the concept to develop a structured training programme for this technique in the UK.
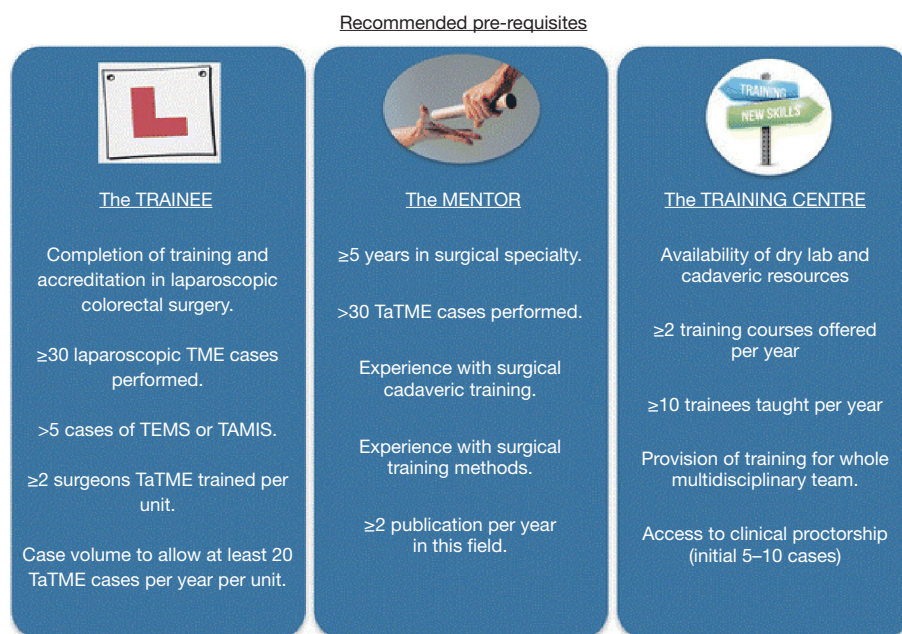
Figure 1 Essential pre-requisites to learning TaTME, being a TaTME mentor and running a TaTME training centre. (Reproduced with permission from Springer Nature). TaTME, transanal total mesorectal excision.

Development

Development of consensus on structured training pathway

An international workshop on TaTME was organised in Bristol, UK, on 12 October 2015 (18). The aim of this workshop was to review the results of the above learners' survey and outline the consensus statements describing the essential elements for structured training programme on TaTME. A bespoke Global Assessment Scale forms were also built during the workshop to be tested on a cadaver model as a formative assessment tool (18). The expert group at the workshop drafted a number of statements for structured training pathway. These were voted on by 78 international experts in the field of TaTME who were nominated by peer recommendations as the pioneers and early implementers of the TaTME technique. A formal Delphi process was carried out to reach a consensus on the various elements of the training pathway (19).

The consensus outcomes and the recommendations summarising the training pathway are outlined in *Figures 1,2*.

Development of project management and secure funding

A steering group was formed in May 2017 to lead the project, consisting of educational and research leads, representative from ACPGBI, Chair of OCCTOPUS (Oxford Colon Cancer Trust), expert TaTME surgeons from UK, project manager, sponsor and other key stakeholders. The main task of this group was to manage the development and delivery of the training initiative, select the trainers for the programme and monitor the outcomes along with financial performance.

In order to secure funding to support this training initiative, a series of individual discussions and a joint meeting with representatives from an array of healthcare companies was organised in November 2017. The plan for the project was presented and a consortium was formed including four healthcare companies (Medtronic, Applied Medical, Conmed/Lawmed and Stryker) to support this programme. OCCTOPUS, which is a cancer charity and an independent party, was also invited to facilitate and have oversight of this project. The partnership with business industry entailed supporting and facilitating the training that was provided by the expert trainers and while not influencing the educational contents, the training method itself or the outcome data collection and analysis. In order to coordinate the training centrally, an agreement was drawn between the South West Surgical Training Network and OCCTOPUS. The project plan was also presented to
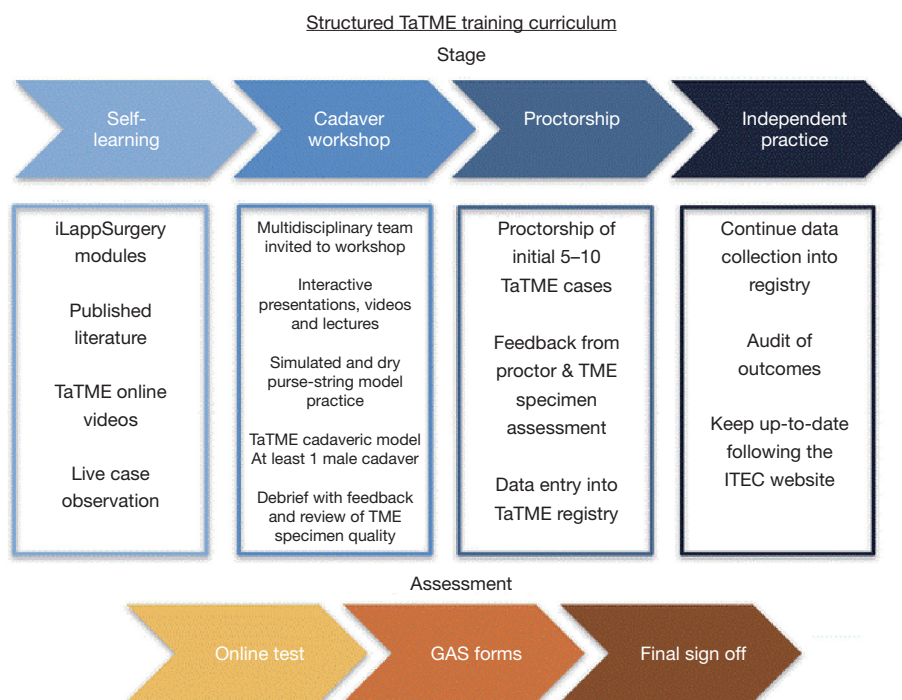
Structured TaTME training curriculum

Stage

Self-learning	Cadaver workshop	Proctorship	Independent practice
iLappSurgery modules Published literature TaTME online videos Live case observation	Multidisciplinary team invited to workshop Interactive presentations, videos and lectures Simulated and dry purse-string model practice TaTME cadaveric model At least 1 male cadaver Debrief with feedback and review of TME specimen quality	Proctorship of initial 5–10 TaTME cases Feedback from proctor & TME specimen assessment Data entry into TaTME registry	Continue data collection into registry Audit of outcomes Keep up-to-date following the ITEC website

Assessment

Online test	GAS forms	Final sign off

Figure 2 Structured TaTME training curriculum. (Reproduced with permission from Springer Nature). TaTME, transanal total mesorectal excision; GAS, Global Assessment Scores.

the council and the executive board of the ACPGBI, who agreed to endorse the pilot training initiative to ensure quality assurance before wide scale training could be offered.

Selection of the pilot centres

Following the ACPGBI announcement in May 2017, the pilot sites were selected by open and fair method if the centre fulfilled the essential criteria. In order for the sites to be considered, they were required to send an expression of interest with a full application form. The project office received initial interest from over 30 sites. The complete application method required providing details of:

❖ Colorectal units with two consultant surgeons and associated theatre team;
❖ Annual caseload for rectal cancer surgery;
❖ Supporting letter from medical or clinical director affirming the support of the trust during the training period of their staff;
❖ A business plan or a statement confirming provision of appropriate kit and facility at the trust;
❖ To ensure the selected surgeons possess the required laparoscopic skills, each consultant surgeon had to

submit the unedited version of recent laparoscopic TME for assessment.

The video was assessed objectively by two independent experts using bespoke laparoscopic TME performance tool (L-TMEpt, Figure S1). It was specifically designed for lap TME and its consistency and validity have been approved (20). This form was developed as an extension of LAPCO L-CAT assessment form, previously been utilised as an evidence of competency during the national training for laparoscopic colorectal surgery (21). With the help of the above selection criteria, top five centres that scored highest L-TMEpt score and annual case volume were selected to participate in the national TaTME training initiative.

Selection of proctors

A small group of surgeons with appropriate expertise in TaTME, and a keen interest in teaching, were invited to join the faculty as proctors for this project. They were selected based on their earlier teaching and training credential in previous national laparoscopic colorectal training programme. They were experts who all worked in centre which had high case volume for rectal cancer (over 30), had existing training experience in clinical proctorship

and contributed to TaTME registry. They received clear guidance on their role and responsibility within this training initiative and were also invited to join the steering group.

Exploration: clinical training phase

The five selected pilot centres were offered the proctorship programme which was centrally coordinated, funded by educational grants which were made to the healthcare companies. The training programme was multi-modal, including online educational application (App), cadaveric workshop and clinical preceptorship.

Online app

Each consultant was provided free access to the app containing educational modules and videos (http://ilappsurgery.com/app-modules.html) (22). This platform provided them with the knowledge such as case selection, video on steps of operation plus experts' presentations on tip and tricks and how to avoid pitfalls.

Cadaver workshop

A 2-day cadaveric workshop was organised at the Cushieri Skills Centre (Ninewells Hospital, Dundee). The pilot team (two consultants and their theatre staff who would be working with them) from five selected sites were given the overview of the training initiative by the project lead. Patient selection, theatre setup, operative steps and pitfalls was discussed with the help of series of presentation and debate by the expert faculty. The learners were then able to practice rectal purse string suture on a customized simulator before embarking on a full TaTME on a Thiel preserved human cadaver under the guidance of expert proctors. The bespoke formative Global Assessment tool was also tested in the cadaveric workshop to acquaint both the trainees and trainers with its format and to identify the learning targets during the clinical preceptorship phase.

Clinical preceptorship

Clinical preceptorship was coordinated centrally with the allocation of trainers to the trainees. A team training approach method was implemented whereby the pilot site's lead surgeon, co surgeon and theatre team received training and guidance on the theatre setup, operative technique and aftercare of the patient. Honorary contract was drawn for each faculty member for a selected pilot site and the process of arranging a preceptored case was then followed. Informed consent was obtained from patients, confirming

their participation in the training programme as well as in the study.

Data collection and analysis including assessment tools

On completion of each case, detailed data was entered on the TaTME international registry. This included patient demography, preoperative staging, abdominal and transanal phase of the operation. The primary clinical end point was to obtain high quality TME specimens as defined by Quirke and colleagues for the planes of mesorectal dissection (23). The quality of TME specimen was assessed by means of photographic evidence (anteroposterior and lateral view) and histological examination of the specimen which included distal and circumferential margin status, lymph node yield and lymphovascular invasion. All the above information was entered on the registry including 30 days post-operative complications using the Clavien-Dindo classification.

It was also mandatory to complete the Global Assessment Score (GAS) form designed specifically for TaTME. This was filled independently both by the "trainee" consultant surgeon and "tutor" after each case using a scale of 1 (unable to perform operative step) to 6 (proficient performance) (18).

Assessment

A total of 24 TaTME cases were performed by the trainee consultant surgeon of five pilot sites under mentorship as a part of the national training initiative between November 2017 to October 2018. The patients demographic and tumour characteristic are as detailed in *Tables 1,2*. Majority of the patients were male (17/24; 70.8%) with a mean age [standard deviation (SD)] 65.6 (12.3) years and BMI of 27.9 (4.6) kg/m^2 respectively. On preoperative staging by magnetic resonance imaging (MRI) median tumour distance was 5.5 [1–9] cm and almost fifty percent of tumour was located anteriorly. Neoadjuvant chemotherapy was given in 37.5% of cases (*Table 2*).

Clinical outcomes
Intra-operative results

All 24 cases were performed for rectal cancer of which 20 (83.3%) had low anterior resection and 4 (16.6%) underwent intersphincteric abdomino-perineal excisions (APEs). In view of position of the tumour or patient's preference given the presence of pre-operative faecal incontinence, three of the above APE were planned procedure. One case was at the start planned as a low

Table 1 Patient characteristics

Factor	TaTME data (total: 24 cases)
Gender, n (%)	
Male	17 (70.8)
Female	7 (29.2)
Age in years, mean ± SD [range]	65.6±12.3 [41–87]
ASA score, n (%)	
I	9 (37.5)
II	11 (45.8)
III	4 (16.7)
BMI in kg/m^2, mean ± SD (range)	27.9±4.6 (19.6–33.7)
Smoker, n (%)	3 (12.5)
Diabetic, n (%)	3 (12.5)
Previous non-cancer abdominal surgery—appendicectomy, n (%)	2 (8.3)
Previous cancer related surgery—colostomy, n (%)	2 (8.3)

TaTME, transanal total mesorectal excision; SD, standard deviation; ASA, American Society of Anesthesiologists; BMI, body mass index. (Reproduced with permission from Wiley and Sons).

Table 2 Cancer cases: pre-operative staging and neoadjuvant therapy

Factor	TaTME data (total: 24 cases)
Pre-operative staging	
Clinical tumor height from anal verge on rigid sigmoidoscopy in cm, median [range]	8.5 [1–12]
Tumor height from anorectal junction on MRI in cm, median [range]	5.5 [1–9]
Predominant tumor location, n (%)	
Anterior	11 (45.8)
Posterior	10 (41.7)
Lateral	3 (12.5)
Pre-operative MRI staging, n (%)	
≥T3	11 (45.8)
N+	13 (54.2)
Metastatic disease	0 (0.0)
Pre-operative CRM involvement on MRI, n (%)	6 (25.0)
EMVI positive on MRI, n (%)	5 (20.8)
Neoadjuvant therapy	
Received neoadjuvant therapy, n (%)	9 (37.5)
Short course radiotherapy	4 (16.7)
Long course chemoradiotherapy	4 (16.7)
Long course radiotherapy alone	1 (4.2)
Additional chemotherapy	2 (8.3)
Contact radiotherapy	0 (0.0)
TRG response post neoadjuvant therapy, n (%)	
mTRG 1 & 2 (no or small residual tumour)	6 (60.0)
mTRG 3 (mixed fibrosis and tumour)	4 (30.0)
mTRG 4 & 5 (mainly or only tumour)	0 (0.0)

TaTME, transanal total mesorectal excision; MRI, magnetic resonance imaging; CRM, circumferential resection margin; N+, positive nodal status (N1 or N2); EMVI, extra-mural venous invasion; TRG, tumour regression grading on MRI. (Reproduced with permission from Wiley and Sons).

anterior resection, however, because of poor blood supply of the left colon, recognised intra-operatively, the procedure was modified to APE. *Table 3* outlines additional operative details. All cases were performed using GelPoint Path Transanal Access Platform (Applied Medical, Rancho Santa Margarita, CA, USA) and AirSeal™ insufflation system (CONMED, Utica, NY, USA).

There was a reduction in median operative time from 331±90 minutes [195–610] in the first case, to 283±62 [195–340] in the final case, however this was not significant.

Reassuringly no visceral injuries occurred intra-operatively throughout any of the 24 cases. Transanal dissection was terminated early in one case because of a gas embolus triggering transient haemodynamic instability. The planned low anterior resection was then completed laparoscopically and the patient was discharged on seventh post-operative day with no additional complications.

There were four purse-string failures which was identified soon after tying the purse-string in place. They were re-inserted under the direction of the mentors without causing any spillage of bowel contents into the operating field.

Post-operative outcomes

Post-operative complications were reported according to Clavien-Dindo classification (I–V). Out of 15 (62.5%) patient who suffered post-operative complications, majority

Table 3 Operative details

Factor	TaTME data (total: 24 cases)
Indication: cancer, n (%)	24 (100.0)
Operations performed, n (%)	
Low anterior resection	20 (83.3)
Intersphincteric APE	4 (16.7)
Simultaneous abdominoperineal operating, n (%)	6 (25.0)
Surgical approach—abdominal phase, n (%)	
Laparoscopic	20 (100.0)
Splenic mobilization	21 (87.5)
Pelvic drain insertion	14 (58.3)
Defunctioning stoma—ileostomy, n (%)	20 (100.0)
Specimen extraction site, n (%)	
Pfannenstiel	6 (25.0)
Umbilical	6 (25.0)
Left iliac fossa	5 (20.8)
Transanal	4 (16.7)
Colostomy site	1 (4.2)
Lower midline	2 (8.3)
Anastomotic technique, n (%)	
Manual	0 (0.0)
Stapled	19 (100.0)
Anastomotic configuration, n (%)	
End-to-end	15 (75.0)
Side-to-end	4 (20.0)
Missing	1 (5.0)
Stapler diameter, mm, n (%)	
28	4 (20.0)
29	13 (65.0)
33	2 (10.0)
Missing	1 (5.0)
Height of anastomosis from anal verge in cm, median [range]	4.0 [2–9]

Table 3 (*continued*)

Table 3 (*continued*)

Factor	TaTME data (total: 24 cases)
Operative time, hours: mins, mean ± SD (range)	
Total operative time	5:31±1:30 (3:15–10:10)
Total operative time per case (P=0.11)	
Case 1	5:58±1:07 (5:00–7:55)
Case 2	6:10±2:48 (3:38–10:10)
Case 3	5:06±0:43 (4:04–5:44)
Case 4	5:34±1.39 (3:45–7:45)
Case 5	4:43±1:02 (3:15–5:40)
Intra-operative adverse events, n (%)	
Conversion (stopped transanally-air embolus case 3)	1 (4.2)
Pursestring failure (cases 1,1,2,4)	4 (16.7)
Set-up problem*	2 (8.3)
Incorrect dissection plane	3 (12.6)
Pelvic bleeding	1 (4.2)
1500 mL blood loss from IMV	1 (4.2)
Poor blood supply to left colon resulting in permanent stoma	1 (4.2)
Visceral injury	0 (0.0)
Distal donut incomplete at 6 o'clock	1 (4.2)

*, Set-up problem includes poor platform seal, unstable pneumopelvis or inefficient smoke evacuation. TaTME, transanal total mesorectal excision; APE, abdomino-perineal excision; SD, standard deviation; IMV, inferior mesenteric vein. (Reproduced with permission from Wiley and Sons).

(73.3%) of them were classified as I or II (*Table 4*). Three (12.5%) patients required emergency surgery within 30 days of the index procedure. The surgical interventions were evacuation and washout of pelvic haematoma, examination under anaesthesia with further stitch placement for anastomosis dehiscence and bilateral leg fasciotomies for compartment syndrome.

There was zero 30 days reported mortality.

Late morbidity (diagnosed more than 30 days post-operatively) has been recorded in five cases. They comprise

Table 4 Post-operative short-term clinical outcomes

Factor	TaTME data (total: 24 cases)
Length of hospital stay in days, median [range]	8·00 [4–19]
Post-operative morbidity at 30 days, n (%)	15 (62.5)
I or II	11 (73.3)
III	4 (16.7)
IV	0 (0.0)
V	0 (0.0)
Post-operative complications at 30 days, n (%)	
Early anastomotic leak (case 1,4,4)	3 (12.5)
Delayed anastomotic leak (case 3)	1 (4.2)
Compartment syndrome bilateral legs (case 1)	1 (4.2)
Mucocutaneous separation of ischaemic colostomy	1 (4.2)
Pelvic haematoma requiring drainage and washout	1 (4.2)
Prolonged ileus	4 (16.7)
Urinary tract infection	1 (4.2)
Urinary retention	1 (4.2)
Wound infection	2 (8.4)
Pneumonia	3 (12.5)
Presacral collection treated with antibiotics	1 (4.2)
Pelvic collection drained by CT imaging	1 (4.2)
Surgical re-interventions*, n (%)	3 (12.5)
Compartment syndrome bilateral legs (case 1)	
Examination under anaesthesia, washout and additional stitches for dehisced anastomosis (case 4)	
Pelvic haematoma requiring drainage and washout (case 5)	
Unplanned hospital readmissions, n (%)	7 (30.0)

Table 4 (*continued*)

Table 4 (*continued*)

Factor	TaTME data (total: 24 cases)
Reasons for readmissions, n (%)	
Acute kidney injury from high output stoma	1 (5.0)
Wound infection and low stoma output	1 (5.0)
Wound infection requiring antibiotics	2 (10.0)
Pelvic haematoma requiring drainage and washout	1 (5.0)
Bleeding per rectum	1 (5.0)

*, Surgical re-intervention at any time point following index operation. TaTME, transanal total mesorectal excision; CT, computerised tomography. (Reproduced with permission from Wiley and Sons).

pelvic haematoma following APE which was drained through the perineum, delayed anastomotic leak treated conservatively, parastomal hernia awaiting repair and two cases of chronic sinus (one case following a diagnosed early anastomotic leak).

Histological outcomes
TME specimen was intact in 24 (100%) cases with negative distal resection margin (DRM) in all. However, 1 (4%) had positive circumferential margin (R0 resections 96%). *Table 5* describes histological outcomes

Educational outcomes
GAS of training
The overall GAS recorded by learners (consultant trainees) and tutors (expert trainers) are shown in Figure S2. Good correlation between trainer and trainee scores was found with an intra-class correlation coefficient of 0.878. All trainees attained competency in overall performance (score 5 or 6) by the time of their final mentored case (Figure S2). A score of at least 4 (performed with minor verbal support) for each operative step was reached by the final mentored case (Figure S3). The posterior and lateral TaTME dissections were found to be most challenging as were given the lowest score on the GAS form stating trainees requiring additional input from the trainers on these areas (Figure S3).

Long-term outcomes
At a median follow-up period of 1 year, (range, 4.2–

Table 5 Histopathological data

Factor	TaTME data (total: 24 cases)
Pathological T stage, n (%)	
T0	0 (0.0)
T1	1 (4.2)
T2	11 (46.8)
T3	11 (46.8)
T4	1 (4.2)
Pathological N stage, n (%)	
N0	17 (70.8)
N1	2 (8.3)
N2	5 (20.8)
Quality of TME specimen, n (%)	
Intact	24 (100.0)
Minor defects	0 (0.0)
Major defects	0 (0.0)
Rectal perforation	0 (0.0)
Number of lymph nodes harvested	
Mean ± SD	25.2±12.0
Median [range]	24.5 [7–58]
Maximum tumor size in mm	
Mean ± SD	36.8±18.3
Median [range]	30 [8–80]
Distal margin in mm	
Mean ± SD	29.8 ± 30.7
Median [range]	20 [9–140]
Positive DRM, n (%)	0 (0.0)
CRM in mm	
Mean ± SD	9.7±6.8
Median [range]	10 [0–24]
Positive CRM, n (%)	1 (4.2)
R1 resection, n (%)	1 (4.2)
Recurrences	
Local	0 (0.0)
Systemic (liver mets)	1 (4.2)

TaTME, transanal total mesorectal excision; SD, standard deviation; DRM, distal resection margin; CRM, circumferential resection margin. (Reproduced with permission from Wiley and Sons).

20.8 months), all patients were alive with no local recurrences but only one case of systemic recurrence with liver metastasis.

Computerised tomography (CT) of the chest, abdomen and pelvis were obtained from only available from 12 patients at 24 months follow up. Three patients developed liver metastases and one developed lung metastasis. There is no evidence of any local or regional recurrences.

Discussion

The IDEAL framework (14) appears to be valuable for the evaluation and reporting of novel techniques, and to aid in the safe disseminating of effective surgical procedures that can be widely adopted. TaTME is an example of a complex novel surgical intervention that has gained a rapid popularity over a very short period of time and not supported by evidence from RCTs or long-term data. It was appropriate to appraise the evolution of the UK training initiative for TaTME using the IDEAL framework (24), given the early reports of technical challenges with visceral injuries and the latest oncological concern about this technique (*Table 6*).

In this study, IDEAL stage 1 (idea of the training programme) was driven by the rapid change of practice, as surgeons were seeking a better approach/access for low rectal cancer particularly in obese male patients. This overwhelming need coupled with the unsupported rapid uptake of the technique and lack of structured training programme underpinned the concept of the development of training programme.

IDEAL stage 2 (development of the training pathway) followed a formal Delphi process to gain consensus on the essential elements of the training curriculum, including defining the learners, the mentor, the training centre and agreeing on the assessment tools (19). These were implemented in the exploration phase (IDEAL stage 3) of the project to develop and successfully launch a multimodal training programme with online training, cadaveric workshop and clinical preceptorship.

IDEAL stage 4 (assessment) was an integral part of this programme, which demonstrated its clinical and oncological safety. Educational outcomes were also measured objectively with the help of customised validated and reproducible tool.

Long-term outcome (IDEAL stage 5) was captured by radiological imaging and reported no evidence of local or regional recurrence in the available data at 24 months.

IDEAL framework has been reported to monitor safe

Table 6 Stages of evolution of surgical innovation of TaTME-UK training programme

Stage	Purpose	Study method	Outcomes assessed	No. (type) patients	No. (type) surgeons
Stage 1					
Idea	Proof of concept	Structured case reports	Did the intervention achieve the physical or physiological goal?	Single to few (highly selected)	Very few (innovators)
Outcome	Learning need	Learners survey	Learning needs and educational gaps were identified	N/A	390
Stage 2a					
Development	Safety, procedural efficacy	Prospective development studies	What is the optimal technique?	10s (selected)	Few (innovators and early adopters)
Outcome	Develop training pathway	Delphi process	Consensus achieved on all elements of training curriculum	N/A	72 international experts
Stage 2b					
Exploration	Safety, short-term clinical efficacy	Prospective efficacy, feasibility RCT and diagnostic trials	How successful is adoption of the given intervention at various centres?	100s (may expand to mixed)	Many (innovators, early adopters, early majority)
Outcome	Pilot a training programme for TaTME in the UK	Structured proctorship programme	Clinical, oncological and educational outcomes	24	10 experts and 10 pilot site surgeons
Stage 3					
Assessment	Clinical outcomes, comparative effectiveness (including resource utilization)	RCTs with or without modifications	How does the new intervention compare with the established standard of care?	100s+ (well-defined expanded indications)	Many (early majority)
Outcome	Ensure quality assurance in place	Prospective data collection of the national programme	Complete data collection on all domains demonstrating acceptable outcomes	24	10 experts
Stage 4					
Long-term study	Long-term outcomes, quality assurance	Registry/database	What are the long-term outcomes?	100s–1,000s (all eligible)	All eligible
Outcome	Ensure long-term safety	CT of chest and abdomen at 24 months	No evidence of local or regional recurrence at 24 months	12	N/A

TaTME, transanal total mesorectal excision; N/A, not applicable; CT, computerised tomography. (Adapted from Tradewell *et al.*, *BJU Int*).

implementation of innovative surgical techniques (25-27) but there is very little evidence on its application on previous national surgical training programme. There are other training initiatives specifically designed for TaTME in the USA, Australia and Netherlands (9,28,29) which adopted some aspects of quality assurance measures. The UK training model however adopted IDEAL framework as a robust quality assurance across all the stages of the programme from the selection process and up to the follow up surveillance scans.

In a review by Peter McCulloch's group on the application of the IDEAL framework, the authors found that despite the growing interest and enthusiasm for using IDEAL, the current level of familiarity and usage of the recommendations is low (30). This seems to be mainly due to lack of interpretation of the details of the IDEAL recommendations or how to apply them or omitting important key elements of the framework. In our study, the quality assurance process was developed and prospectively implemented as an integral part of the educational agenda to develop, implement and prospectively evaluate the training programme.

This programme developed and utilised bespoke objective assessment tools which were specifically designed for rectal cancer surgery. This project was the first to report on the application of objective assessment method of technical skills to select the learners. We used a validated tool to ensure competency in laparoscopic TME prior to their selection in TaTME training. The assessment tool (L-TME performance tool) has proven its consistency and validity through a wide evaluation process which involved two RCTs (20). With the aid of application of these robust selection criteria, the project team were able to select five pilot sites that were in the best position to benefit from the training initiative.

Additionally, we developed and utilised GAS forms as formative assessment of surgical skills during the clinical preceptorship phase (18). Such assessments have objectively demonstrated the learning curve of each team and identified the areas that require further training prior to the subsequent case. Implementing these assessment tools is likely to focus and enhance the efficiency of learning which is suggested by the rapid reduction of operative time from case one to five. The GAS forms also objectively demonstrated progression of learner to an independent level with the increasing number of cases.

Furthermore, the programme followed robust prospective clinical assessment criteria with complete

data set across a number of domains including clinical, histological, oncological and educational outcomes. These assessment methods reported on a number of technical operative challenges such one gas embolism and one compartment syndrome. Because of the prospective nature of assessment, a full appraisal was carried out for both events and a number of actions were instated to avoid their occurrence which was the case for the rest of the programme. For instance, the insufflation pressure was reduced to as low as feasible enough to maintain adequate rectal wall tension and steep head-down was minimised following the reported incidence of gas embolism. The bilateral compartment syndrome observed in one case (first case) was due to prolonged surgery and mal-positioning of the patient which was corrected on the following cases with no further incidence. This modification was applied across the five pilot sites.

Reassuringly, this programme yielded high quality specimens with no incidence of bowel or tumour perforation and clear distal margins in all specimens and acceptable clear circumferential margins of 96%. One recent article from Norway reported on showing alarming oncological results in terms of high local and multifocal recurrence, resulting in moratorium of this technique in Norway (13), hence it was essential to examine the long-term data. At 1 year (full data) and with the limited data at 2 years (only 50% of cases), there has been no reports of early local or regional recurrence.

This work has a number of limitations. First, despite the comprehensive approach of implementing and reporting on all elements of IDEAL framework, the exploration part targeted to five pilot sites and with only 24 cases. Therefore, one must be careful while drawing any firm conclusions about the outcomes of this phase. The exploration stage however was set up as a pilot initiative to ensure that it was feasible to deliver this multi-modal training to a small number of centres and to carry out robust quality assurance process to demonstrate its safety and feasibleness before wider adoption. Additionally, given the limited available expert trainers for this relatively novel procedure and the financial constraints, it was only possible to provide training to a limited number of centres. Long-term data at 24 months was not complete and we continue to monitor the remaining patients.

The clinical proctorship phase of the programme faced a number of operative challenges, including purse string failure which was noticed in the early stage. This was identified and immediately corrected by the mentor which

again demonstrates the importance of preceptorship in the early phase of training. Failure of purse string suture leads to leakage of faecal materials and or cancel cells during the perineal dissection which can potentially increase the local recurrence. This may be a likely mechanism and explanation for the high rates of local recurrences following TaTME reported in Norway leading to the procedure being stopped nationally (13), but further research is required to identify the exact mechanism of this observation, so that a corrective action can be implemented.

Conclusions

A competency based multi-modal training programme for TaTME can be feasible and safe to implement at a national level. Dissemination of a new surgical technique within the confines of a structured surgical innovation IDEAL framework may allow for evidence-based assessment of the technique and may minimize the risk of harm to the patient.

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Footnote

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