Surgical Quality Assurance in COLOR III Trial

epitaler erke	Please make sure to find up VIDEO UPLOAD FORM		tane sheet in				
rent 1	Haghel Prysian Data of Pagasation	And the second s	ALC N				
n Sud Annue anorre (1) annu (1)	Denie of patient New of BMS Peaks toloots whether you are obtaining a stellar from a caserwards Table of Tensorer Table proceeder	Net Description					
	forms patient 2CL-004	Video accoring for		rom sous : New York Lock Kata : LOR III - Pre Trial [Velidation]	J. One!		
	Surgery Web Lipited form						
	form (2)	Select surgery plase.	lelect phase TV/MI: Addential Plase TV/MI: Pave Streetter	2 Joolinal Phase or Pel	vic Dissection		
			1. Sec. 1. Van Peel		-	4 Rept. 8 Anatomotic	
	R stotlour stor		npetency Assessment Tool (CAT				
	B pheriCourrent	xposure apersecopic platform or 4. ideal port insertion	ngetency Assessment Tool (CAT Abdominal Phase elup and pattert position: and platform setue. Pattert security) for Transanal TME: A - 1. Platform Set Up 2. Execution Insertion of por	bdominal Phas ts and manipulating insertion and bow	ie ng small bowelt	
	(finition atom)	Con xposure apersecopic platform or	npetency Assessment Tool (CAT Abdominal Phase while and patient paction: and platium setup. Petient security a) for Transanal TME, A - 1. Platform Set Up 2. Execution Insertion of port movement () () () () () () () () () () () () () (bdominal Phas ts and manipulation y insertion and lows to, safe lissue hand	ie ng small bowelt	
	atodoser. gites	Eposture Japanescojić platform s 1. Slovel port insettion adequate and secu- 2. Inefficience port posting adequate and secu- 2. Inefficience port posting postion readequare 1. Poor port posting incomenty placed at	Abdominal Phase Abdominal Phase and plattern position: and plattern setup. Petert securely servy shere (microson pr to biotic) for Transanal TME, A - 1. Platform Set Up 2. Execution Insertion of port movement () () () () () () () () () () () () () (bdominal Phas to and manipulation (insertion and been to add block band to be block band to block	ia ing shall boest el naripulator. Purpost ing	
	I and the set of the s	Epoteure Agenreicogie gladtem sa 4, libel por leatron 3, deut por leatron 3, deut por leatron 3, deut por leatron 2, liveffactive por p portion radious 2, liveffactive por p portion radious 2, liveffactive por portion radious 2, liveffactive portion 2, liveffactive port	Abdominal Phase Abdominal Phase and plattern position: and plattern setup. Petert securely servy shere (microson pr to biotic) for Transand TME: A - 1. Platform Set Up 2. Execution Intertion of per - 4. Non-Neuron - 4. Non-Neuron - 2. Non-Neuro	bdominal Phas to and manipulation (insertion and been to add block band to be block band to block	ing and based an rangoation. Purposed Brig Status storegy Status Superv Frys Yotas (part bor Street Superv Frys Frys (part bor Street Superv Frys (part Frys (part bor Street Frys (part Frys (part Frys (part bor Street Frys (part Frys (pa	

Competency Assessment Tool



Imperial College London

Surgical Quality Assurance (SQA)

1.WHAT IS SURGICAL QUALITY ASSURANCE (SQA)?

Variations of the surgical technique and surgeon's competency are the most criticised components in a surgical RCT. It is crucial to control for the heterogeneity amongst the surgical practices.

SQA is a protocol that addresses the issue of heterogeneity by:

- (i) Standardisation of the operation
- (ii) Evaluate the surgeon's performance against the agreed standard.

2. HOW DOES SQA WORK IN COLOR III?

Extensive work has been done alongside the main COLOR III trial design.

- (i) **Standardisation** of TaTME with experts' consensus; operation manual is written.
- (ii) **Competency Assessment Tool (CAT)** development for TaTME for objective and reliable video analysis
- (iii) **Before entering** the trial, each centre is invited to submit operative videos, which are assessed using CAT.
- (iv) **During the trial,** video analysis is used to investigate incidences and adverse events.



Competency Assessment Tool (CAT)

1. WHAT IS A COMPETENCY ASSESSMENT TOOL (CAT)?

CAT is a marking sheet for the evaluation of surgical skills for an operation. It is designed to ensure standardised technical performance through robust methodology.

2. HOW is CAT USED IN SQA of COLOR III TRIAL?

Imperial College

London

CAT is used in video analysis, measuring and monitoring the compliance to the agreed operative standard in COLOR III.

Each centre who wishes to participate are asked to submit 2 TaTME and 1 Lap TME unedited, full length videos. The videos are assessed by 2 independent assessors trained to use CAT to decide whether the surgical performance is compliant.

Feedback is given to either start enrolling patients or explore the areas where standards are not met.

	4. Transanal Set Up & Purse String			5. Rectotomy	6. Posterior Mesorectal Dissection		
	Transanal platfo	rm setup, constant pressure insufflation system	Retraction and e	sposure throughout task:	Retraction and ex	posare throughout task:	
Exposure	4. Ideal	ergonomic platform setup. Optimal pneumorectum; clear operative field for task.	4. Clearly	demonstrate the level of dissection with optimal traction and tissue tension	4. Clearly	demonstrates fascial planes with versatile traction and tissue tension.	
	3. Good platform setup. Efficient and safe insertion. Good pneumorectum and operative field for task.		 Demonstratemost of dissection plane with appropriate traction and tension on tissue. 		 Demonstrates most of the fascial planes with appropriate traction and tension on tissue. 		
	2. Inadequate	platform setup. Laborious insertion. Suboptimal pneumorectum and view for task.	2. Ineffective	exposure of plane. Tractions often in wrong directions. Utile tension.	2. Ineffective	exposure of planes. Tractions are often in wrong directions. Utile tension	
	1. Poor	platform set up. Hazardous and unsafe insertion. Poor pneumorectum; unclear view.	1. Fails	to demonstrate dissection plane. Lack of traction and no tissue tension.	1. Fails	to demonstrate fascial planes. Poor views. Lack of traction and no tissue tension.	
	Unable to comment		Unable to comm	ent	Unable to comment		
Execution	Purse string placement with regular intramuscular bites:		Circumferential full thickness dissection:		Dissection in posterior TME plane close to mesorectal fascia, demonstrating angel's hair.		
	4. Masterly	suturing with even and intramuscular bites of 8- 10. Safe, protective tissue handling.	4. Masterly	full thickness dissection, smoothly followed circumferentially. Safe and purposeful movement.	4. Masterly	dissection close to mesorectal fascia following established planes. Safe & purposeful movements	
	3. Efficient	with good bites. Occasional uneven spacing or bites, quickly corrected. Rarely unsafe handling.	3. Efficient	occasional less than full thickness or too deep, quickly corrected. Rarely unsafe tissue handling.	3. Efficient	desection, occasional loss of plane, quickly corrected. Rarely unsafe tissue handling	
	2. Laborious	Unevery/big bites. Frequent loss of level causing some spiralling of suture, unsafe tissue handling.	2. Laborious	dissection. Repeated less than full thickness or too deep, corrected. Frequent unsafe tissue handling.	2. Laborious	dissection, repeated loss of plane. Inefficient and frequent unsafe tissue handling.	
	1. Hazardous	Poor bites/spacing, Loss of level, significant spiralling, uncorrected. Unsafe handling.	1. Hazardous	dissection. Mostly less than full thickness or too deep. Uncoordinated and unsafe tissue handling.	1. Hazardous	dissection, mostly in the wrong plane. Uncoordinated and unsafe tissue handling.	
	Unable to comment		Unable to comment		Unable to comment		
adverse Events	This task was performed with:		This task was performed with:		This task was performed with:		
	4.No	bleeding. Adjacent structure protected. No collateral injury/mucosal trauma	4.No	bleeding. Adjacent structure protected. No collateral injury/perforation.	4. No	bleeding/avultion. Adjacent structure protected. No collateral injury/perforation.	
	3. Minimal	bleeding, quickly controlled. No collateral injury/mucosal trauma.	3. Minimal	bleeding, quickly controlled. No collateral injury/perforation.	3. Minimal	bleeding/avulsion, quickly controlled. No collateral injury/perforation.	
	2. Moderate	bleeding, controlled; small rectal wall haematoma. Mild injury/mucosal trauma.	2. Moderate	bleeding/avulsion, controlled. Potential collateral injury or rectal perforation.	2. Moderate	bleeding/avulsion, controlled. Potential collateral injury e.g. pelvic nerves/perforation.	
		bleeding, uncontrolled; large rectal wall haematoma. Significant injury/mucosal trauma.		bleeding/avulsion, uncontrolled. Rectal perforation/collaterial injury.Purse-string breaking	1. Significant	bleeding/avulsion, uncontrolled. Definite Collateral injury e.g. pelvic nerves/perforation.	
	Unable to comment		Unable to comment		Unable to comment		
End- product Quality	Quality of pneumorectum and purse string with even radial folds.		Quality of Rectotomy before TME dissection begins:		Quality of mesorectum and pelvis		
	4. Optimal	pneumorectum. Tight purse string closure, even radial folds. Ideal position.	4. Complete	circumferential full thickness rectotomy before beginning TME dissection.	4. Smooth	intact mesorectum. No obvious destruction or visible defects. No mesorectal tissue left in situ.	
		pneumorectum. Closed purse string, slightly uneven. Good position.		full thickness dissection rectotomy; minor incomplete areas, able to proceed to TME.	3. Occasional	minor mesorectal injury to fascia only. No obvious destruction or defects. Minimal tissue left in situ.	
		pneumorectum. Loose purse string, uneven. Slight spiralling. Small leak of bowel content.		rectotomy with some incomplete areas, too shallow or too deep with injury to rectal wall	2. Sub-optimal	with obvious injury into fat. Some mesorectal tissue remaining in pelvis	
	1 Poor	pneumorectum. Purse string undone. Significantly spiralling position. Large leak.	1. Poor	rectotomy largely incomplete, significantly too shallow or too deep. Rectal wall perforation.	1. Incomplete	posterior mesorectum with deep injuries into fat. Significant destruction. Tissue left in pelvis.	
	Unable to comment		Unable to comm	ent	Unable to comment		
Comments							

3

How do I take Part in SQA?

First of all, thank you for joining us in COLOR III!!

Please see the videos requirements for entering the trial:

1.THREE VIDEOS

2 x TATME – at least one of which needs to be of a <u>Male</u> patient. And 1 x Lap TME of a **Male** patient.

2. FULL-LENGTH UNEDITED

Ensuring both abdominal and transanal operative fields are recorded. This may require more attention where two separate systems are used – remember to press the recording button for both cameras.

3. EXTERNAL VIDEO RECORDINGS

Certain steps are crucial but difficult to be captured.

Please ensure the following steps are demonstrated by asking your assistant to hold the camera externally:

- Transanal platform setup +/- purse string
- Specimen retrieval
- Anastomosis, especially in second purse-string and hand-sewn coloanal anastomosis.

For further information, please contact:

Miss Alice Tsai

Imperial College

London

a.tsai@imperial.ac.uk Imperial College London Supervised by Professor George Hanna

Mr Stefan van Oostendorp

s.vanoostendorp@vumc.nl

COLOR III / VUMC Supervised by Professor Jaap Bonjer and Dr. Jurriaan Tuynman

