National Institute for Health and Care Excellence IP1184/2 Transanal total mesorectal excision for rectal cancer

IPAC date: 14 October 2021

Com.	Consultee name	Sec.	Comments	Response
no.	and organisation	no.		Please respond to all comments
1	The Association of Coloproctology of Great Britain & Com Ireland We we the second lead In lin ACP ACP prov both that	General	IP1184 - Transanal total mesorectal excision for rectal cancer – NICE Consultation	Thank you for your comment.
			Comment from the Association of Coloproctology of Great Britain & Ireland. (on behalf of the Executive of the ACPGBI)	A reference to the cited publication (8) has been added to the committee comments in the draft guidance.
			We write in response to the request from NICE for comment on the safety and efficacy of IP1184 Transanal total mesorectal excision for rectal cancer (TATME). The ACPGBI has provided	References 2, 4 and 7 are included in the key evidence table in the overview.
			leadership in the Training and Utilisation of TATME in the UK. In line with the previous NICE IPG514 Guidance on TATME, the ACPGBI issued guidance to its members (1). Subsequently, the	References 3, 5 and 6 are included in the appendix of the overview.
		ACPGBI set up a Pilot Training Initiative for TATME which provided a training programme based on defined criteria for both involved institutions and surgeons. It has been mandated that all cases have been recorded in the UK Transanal TME Registry.	Reference 8 is cited in the overview under 'Issues for consideration by IPAC' and the full text was included in the IPAC papers when the procedure was discussed.	
			The short term outcome of this UK cohort has demonstrated safe initial outcomes with an R1 resection rate of 4% and a significant complication rate of 13% (2) which are comparable to outcomes from other reported series of TATME(3) and with resection of low rectal cancer by alternative modalities. Long term outcome data from the UK cohort is currently awaited. Initial published international series have	

demonstrated good oncological outcomes with local recurrence	
rates and survival rates comparable with other modalities	
(4,5,6). However, and importantly, data from the Norwegian	
series have demonstrated different and concerning short term	
outcomes with a significantly increased local recurrence rate	
(7.6%) compared with 2.4% for other modalities (7). Concern	
has been compounded by the extensive or multifocal pattern of	
recurrence seen in two thirds of these patients.	
recurrence seen in two tillios of these patients.	
Careful review of the Norwegian Data in the context of other	
published series has been undertaken by the ACPGBI and the	
following published recommendations (8) have been made:	
1. Temporary closure of the proctoring programme to new sites.	
2. Extending the number of proctored cases from the current	
recommendation of 5-10 where sites are still completing the	
proctoring process	
3. Individual institutions to reconsider whether to continue	
Transanal TME after review of local data and subject to formal	
notification to local clinical governance authorities and the	
written permission of the medical director.	
4. Transanal TME should only be carried out in institutions that	
undertake more than 40 rectal cancer resections (with rigorous	
exclusion of rectosigmoid cancer resections) each year to allow	
sufficient ongoing experience to maintain surgical competence	
in the procedure.	
· · · · · · · · · · · · · · · · · · ·	
5. Transanal TME should only be carried out in institutions that undertake more than 25 transanal rectal resections each year	
•	
for rectal cancer and benign disease , to allow sufficient ongoing experience to main surgical competency in the technique,	
6. Concentration of institutional experience in Transanal TME by	
limiting performance of the procedure to two or three colorectal	
surgeons. Isolated practitioners are discouraged in order to	
ensure adequate local service delivery	
7. Use of procedure-specific enhanced patient consent.	
8. Mandatory entry of data about patient demographics, patient	
selection, operative details and outcomes on the International	
Transanal TME Registry	

 9. Updating the international registry with long-term oncological outcomes in patients who have undergo resection for rectal cancer 10. Independent review of the data held by the International Transanal TME Registry 11. Assessment of the level of English and Welsh case ascertainment and data completeness in the International Transanal TME Registry through cross-referencing with NHS Digital data 12. Collection of Transanal TME as a data item in the National Bowel Cancer Audit for England and Wales and by the Scottish Colorectal Cancer networks. It is the view of the ACPGBI that these recommendations should continue to be adopted within the UK until there is formal evaluation of the long term outcome of TaTME cases in the UK which is currently awaited and further mature long term outcome data including from the COLOR III trial (8). It is also our view that the recommendations (excluding those related to Oncological Outcomes) are applied to use of TaTME for benign disease. The ACPGBI supports the updating of NICE Guidance regarding the use of TaTME for Rectal Cancer Resection and would request consideration that these guidelines (8) are adopted by NICE for inclusion within the updated Interventional Parent Parent	
would request consideration that these guidelines (8) are	
References: (1) https://www.acpbi.org.uk/new/acpbi-position-stattement-on- transanl-total-meorectal-exciions-tatme/	
(2) Roodbeen SX., Penna M., Arnold S et al. A nationwide study on the adoption and short-term outcomes of transanal total meorectal excision in the UK. Minerva Chir 2019;74:279-88.	

	1
(3) Roodbeen SC, de Lacy FB, van Dieren S et al. Predictive factors and risk model for positive circumferential resection margin rate after transanal total mesorectal excision in 2653 patient with rectal cancer. Ann Surg 219;270:884-91.	
(4) Denost Q., Loughlin P., Chevalier R., Celerier B., Didailler R., Rullier E. Trananal versus abdominal low rectal dissection for rectal cancer: long term results or the Bordeaux' randomised trial. Surg Endosc 20189;32: 1486-94.	
(5) Hol JC., van Oostendorp SE, Tuynman JB., Sietses C. Long-term oncological results after transanal total mesorectal excision for rectal carcinoma. Tec Coloproctol 2019; 23: 903- 11.	
(6) D'Andrea AP, McLemore EC, Bonaccorso A, Cuevas JM et al. Transanal total mesorectal excision for rectal cancer: beyond the learning curve. Surgical Endoscopy 2020; 34(9):4101-9.	
(7) Wasmuth HH., Faerden AE., Mykelbust TA et al. Transanal total mesorectal excision for rectal cancer had been suspended in Norway. Br J Surg 2020;107 121-130.	
(8) Fearnhead NS., Acheson AG., Brown AR., Hancock., L et al. The ACPGBI recommends pause for reflection on tranasanal total mesorectal excision. Colorectal Dis. 2020;22: 745-748.	

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."