Timeline for use of taTME

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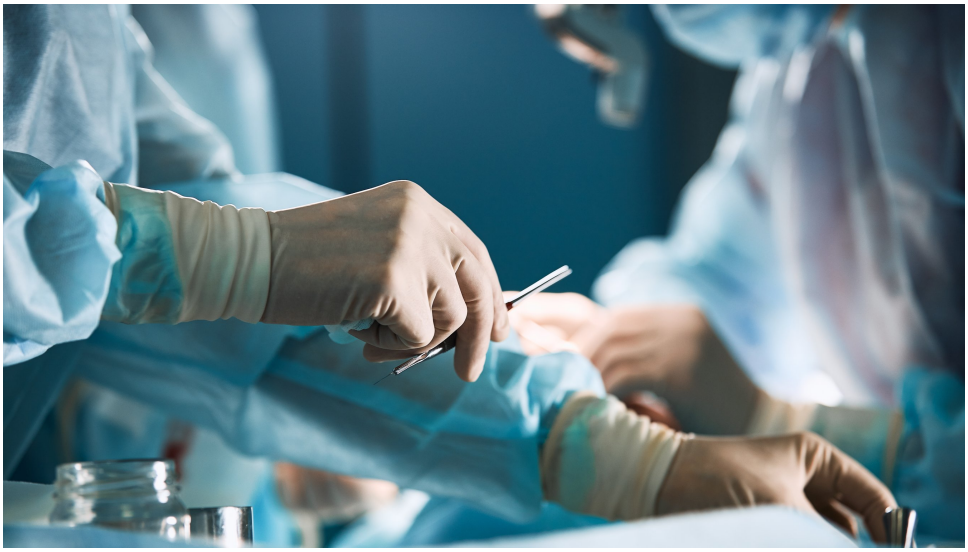

MAINTAINING PATIENT SAFETY WITH NEW SURGICAL AND INVASIVE METHODS

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Time	What happened
1979	The TME method is described for the first time (5).
1980s	The TME method becomes known internationally (21)
1993	TME is introduced in Norway as the standard treatment for rectal cancer (22)
2010	TaTME is implemented internationally (12)
October 2014	TaTME is used for the first time in Norway, at a local hospital
2015	A further three Norwegian hospitals adopt taTME (two university hospitals and one local hospital)
2015/2016	NGICG-CR discusses and revises text on the taTME method for the National Action Programme for Diagnostics, Treatment and Follow-up of Colorectal Cancer, 5th edition.

February 2017	TaTME is mentioned for the first time in the National Action Programme with Guidelines for Diagnostics, Treatment and Follow-up of Colorectal Cancer (5th edition), which is published by the Norwegian Directorate of Health, with the following wording in chapter 9.1.5 Laparoscopic transanal access: “The technique is in the development phase and although there are good results from individual centres, a systematic review in 2015 concludes that the oncological safety has not yet been adequately documented. The method should therefore be used within the framework of prospective clinical trials, with sound information for participating patients, to provide greater knowledge of outcomes.” (23)
May 2017	One university hospital implements taTME, but stops after one operation due to complications.
January 2018	One more university hospital uses the taTME method on two patients, but the planned operation on patient number three is stopped due to concerns from the Radium Hospital relating to early local recurrences. This hospital thus suspends taTME surgery before the national “stop order” is issued.
February 2018	Another university hospital implements TaTME, but stops after three operations.
March 2018	The Section for Oncological Pelvic Surgery of the Radium Hospital, which has a regional function for the treatment of recurrence of cancer in the South-Eastern Norway Regional Health Authority, identifies three patients with complicated (multifocal) local recurrences. Closer scrutiny identifies that these patients were operated on using the taTME method at hospitals in the regional health authority. This is notified to the clinic manager of the Division of Surgery, Inflammatory Medicine and Transplantation at Oslo University Hospital HF (OUS) and to the head of NGICG and NGICG-Colorectal.
April 2018	Oncosurgical spring meeting under the auspices of the Norwegian Gastro Intestinal Cancer Group (NGICG) – taTME results from two hospitals and notices of concern from the professional community at the Radium Hospital are presented.
May 2018	Concerns about taTME are addressed at an NGICG meeting.
June 2018	A member of NGICG writes a letter to the others within NGICG and to operating surgeons at the taTME hospitals about concerns relating to taTME,
September 2018	New discussion in NGICG. The Section for Oncological Pelvic Surgery of the Radium Hospital presents figures for five known recurrences after taTME.

October 2018	Autumn surgical meeting under the auspices of the Norwegian Association for Gastroenterological Surgery (NFGK) – preliminary results that included just over 100 patients were presented. Contributions from gastrointestinal surgeons at two hospitals were presented concerning recurrences after taTME for five and two patients, respectively. The method is discussed. The professional community decides to suspend the use of taTME in Norway, and NGICG is thereafter notified. There is agreement at the meeting to conduct a scientific audit of all taTME procedures that have been carried out in Norway. The agreement to suspend use of the method in Norway must be communicated internationally as quickly as possible.
December 2018	NGICG decides to recommend health authorities to put the taTME method on hold. They also decide to send letters about this to the medical directors of the four regional health authorities (RHA).
January 2019	**14.01.19**: Letters from NGICG-CR are sent to the medical directors of the regional health authorities to notify them about concerns regarding elevated complication and recurrence rates after taTME (Appendix 3). As a consequence, NGICG-CR discourages the use of taTME in the surgical treatment of rectal cancer in Norway until the following measures are established: "a national programme for systematic instruction and training of surgeons in this technique. A national prospective study that includes all of the patients to be treated using this technique." **24.01.-25.01.19**: The 9th Ahus Colorectal Symposium is held. For the first time, results are posted publicly, including to the international community. The symposium has participants from the USA and Europe. The preliminary results of the autumn surgical meeting are presented once again, but with updated data: nine patients with recurrences are known at this point. In addition, the special types of local recurrences observed are noted. The Norwegian results are commented on in a “Letter to The Editor” by Americans Gachabayov et al. in the international journal Updates in Surgery. (24).
March 2019	The first media reports about taTME in Norway and the recurrence rate appear. Minister of Health Bent Høie expects a thorough review of what has happened and the consequences it has had for the patients in question (25).

April 2019	NGICG-CR is encouraged by the medical directors of the regional health authorities to notify the method to the National System for Managed Introduction of New Health Technologies (New Methods). National Action Programme with Guidelines for Diagnostics, Treatment and Follow-up of Colorectal Cancer, 6th edition, is published with a minor text change from the 5th edition (the change is marked by NHIB in bold). In Chapter 9.1.5 Combined laparoscopic and transanal access, the following is stated: “The technique is in the development phase and although there are good results **from an international registry, the introduction of the technique requires structured training and randomised trials.** The method should therefore be used within the framework of prospective clinical trials, with sound information for participating patients, in order to gain greater knowledge of outcomes.” (26) It should be noted that the chapter on laparoscopic rectal surgery, Chapter 9.1.4, is expanded with a concern: “It gives grounds for concern, however, that recent studies show uncertainty regarding the oncological quality of the surgical preparation by laparoscopic access. Even though the laparoscopic technique for rectal cancer is increasingly gaining acceptance, it is important to impose requirements for training and quality assurance of the procedure. The individual hospital performing this type of intervention therefore has a special responsibility for itself documenting competence, safety and results.” However, when the 6th edition of the National Action Programme with Guidelines for Diagnostics, Treatment and Follow-up of Colorectal Cancer is published, the taTME method has already been suspended in Norway.
May 2019	NGICG-CR declines to register the taTME method with the National System for Managed Introduction of New Health Technologies (New Methods) on the grounds that the knowledge base concerning the method is insuffisient and that further results are needed to assess whether the method can be recommended in Norway, due to, inter alia, uncertainty concerning the local recurrences (relapses) detected in several Norwegian patients.
June 2019	TaTME is notified by the regional medical directors themselves to the Ordering Forum, as they consider the method to be technically demanding with a considerable training need on any introduction. The Norwegian Institute of Public Health (FHI) is commissioned to conduct a literature search to identify available documentation of the method. Media reports that Norwegian Health Minister Bent Høie is not satisfied with the information the hospitals have provided to the 157 patients who underwent taTME surgery. The Minister requires the regional health authorities to issue more detailed patient information (27).
July 2019	Editorial by Norwegian gastrointestinal surgeons on behalf of NGICG-CR concerning preliminary observations in Norway after the introduction of taTME is published in the British Journal of Surgery based on pending results from the national audit (Larsen et al.) (28).

September 2019	The scientific results from Norway are presented internationally for the first time at the annual “European Society of Coloproctology” (ESCP) meeting, 25.09-27.09.19, in Vienna (29). National Action Programme with Guidelines for Diagnostics, Treatment and Follow-up of Colorectal Cancer, 7th edition is published with the following update in Chapter 9.1.5 Combined laparoscopic and transanal access: “The procedure is considered to be highly complex and requires structured training and sound quality assurance before it can be implemented in standard patient care. In an earlier edition of the National Action Programme on Colorectal Cancer (6th edition), it was recommended that the method should not be used as part of standard patient treatment, but solely be used within the framework of prospective clinical trials. Preliminary reports on the use of this technique in some Norwegian hospitals give cause for concern in terms of complications and oncological outcome. Against this background, the use of taTME in the surgical treatment of rectal cancer is not recommended in Norway until there is more knowledge about this procedure.” (30).
December 2019	NGICG publishes results of the national audit in the British Journal of Surgery for all patients (n=157) operated on using taTME in Norway (Wasmuth et al.) (6).
January 2020	The Health Minister, in collaboration with the regional medical directors, has created a common template for a new letter to the patients, which is sent from the hospitals that have used the taMTME method (Appendix 1).
April 2020	The interregional medical directors meeting makes the following decision based on FHI’s documentation assessment of taTME: “Transanal total mesorectal excision (taTME) may not be introduced. The documentation is deficient. If the method is required to be assessed once again, a new order must be submitted to the National System for Managed Introduction of New Health Technologies (New Methods).” (31).
May 2020	Decision by the interregional medical directors meeting in April 2020 is registered in the minutes of the new methods Decision Forum (31).
December 2020	National Action Programme with Guidelines for Diagnostics, Treatment and Follow-up of Colorectal Cancer, 8th edition is published with the following update in Chapter 10.1.5 Combined laparoscopic and transanal access: “Preliminary reports on the use of this technique in some Norwegian hospitals give cause for concern in terms of complications and oncological outcome. The method may not be used in Norway following the decision of the RHA medical directors on the basis of letters from NGICG-CR in January 2019. The decision is valid until there is more knowledge about the procedure and the reasons for the poor results in Norway.” (3).

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