The history of taTME in Norway

MAINTAINING PATIENT SAFETY WITH NEW SURGICAL AND INVASIVE METHODS

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Publisert 28. juni 2022

ISBN 978-82-8465-022-7

Rectal cancer is a serious disease for which treatment methods have developed considerably over the past 50 years. Survival rates have improved significantly. Rectal cancer is treated with surgery, but some patients also receive additional radiation therapy, with or without chemotherapy. The total mesorectal excision (TME) surgical method, which is the standard treatment, was introduced in Norway in 1993. Following the introduction of keyhole surgery (laparoscopy), TME became a more difficult procedure for some patients, due to anatomical conditions. A new method was therefore developed internationally around 2010, called transanal total mesorectal excision (taTME). The method was considered to be promising and, based on early trials, drew interest in many countries. The aim of taTME was to improve the treatment of the cancer disease, and to avoid a permanent colostomy bag for the patient. In Norway, a total of 157 patients were subject to the taTME procedure, before the method was suspended in autumn 2018.

TaTME is considered to be a complex procedure that requires structured training and sound quality assurance. A total of seven Norwegian hospitals (five university hospitals and two local hospitals) implemented or trialled this technique from 2014. In the National Action Programme with Guidelines for Diagnostics, Treatment and Follow-up of Colorectal Cancer from 2017 (5th

edition), it was stated that the method was in a development phase and that it should therefore be used within the framework of prospective clinical trials, to provide more knowledge of results. Participating patients were also to receive thorough information about their treatment. This recommendation was only followed to a small extent during trial of the method. Only one of the hospitals stated in their response to NHIB that they began the introduction of the method as part of a clinical trial. Two hospitals stated that they viewed the introduction as a quality project. Therefore, they registered the taTME data in their respective local quality registries.

In 2018, preliminary findings were available from Norway, with worrying results in the form of elevated complication and recurrence rates related to the taTME method. The topic was first addressed at the oncosurgical spring meeting under the auspices of the Norwegian Gastro Intestinal Cancer Group (NGICG) in April 2018. Here, the negative results after taTME surgery were presented. At the surgical autumn meeting in October 2018, the concern about taTME was addressed further in a symposium. Here, the professional community agreed that use of the technique had to be suspended. There was also agreement on the need for a national review of all patients who were subject to the taTME surgical method and that the findings needed to be shared internationally. The National Quality Registry for Colorectal Cancer had no separate checkbox to register which patients had received taTME surgery. In the review, data therefore had to be obtained from each individual hospital where the method had been implemented.

The concerns about taTME were further addressed at the Norwegian Gastrointestinal Cancer Group-Colorectal's (NGICG-CR) meetings in September and December 2018. At the December meeting, NGICG-CR formally decided to notify the regional medical directors. In the letter that was sent, they discouraged use of the method until requirements for systematic training of surgeons and a clinical trial that included all taTME patients were in place. It was also decided to conduct a national scientific review (audit) under the auspices of NGICG.

The regional medical directors notified the taTME method to the Norwegian National System for Managed Introduction of New Health Technologies (New Methods) at the Bestillerforum (Ordering Forum) in June 2019. The Ordering Forum asked the Norwegian Institute of Public Health (FHI) to conduct a literature search to identify available documentation. Prior to this, NGICG-CR was requested by the regional medical directors to notify the method themselves, but they refused this.

NGICG-CR justified their refusal, because the method had already been suspended, the knowledge base was deficient, and that the national scientific audit was still ongoing.

In December 2019, results from the national audit were published in the British Journal of Surgery. The audit showed higher complication and recurrence rates among patients who had undergone taTME surgery compared to those treated by the standard TME method.

Most of the 157 patients who underwent taTME surgery only received oral information that taTME was a method that was subject to development. The hospitals stated that all patients who underwent taTME surgery were contacted subsequent to the operation, after it was discovered that the method presented an increased risk of complications and recurrence.
The Norwegian Health Minister at that time, Bent Høie, was not satisfied with the information provided by the hospitals and required the regional health authorities to issue more comprehensive patient information that included clear information about patients' rights. This took place in January 2020.

On 23 April 2020, the interregional medical directors meeting decided that the taTME method should not be introduced, as the documentation was deficient. In the decision, it was also indicated that if a new assessment of the method was required, this had to take place via a new request to the National System for Managed Introduction of New Health Technologies (New

Methods). The decision was based on a memo from FHI which concluded that data was mainly available from non-randomised trials with limited long-term survival and recurrence data. The decision of the interregional medical directors meeting is recorded in the minutes of the Decision Forum for new methods on 25 May 2020.

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