

Background to our investigation





MAINTAINING PATIENT SAFETY WITH NEW SURGICAL AND INVASIVE METHODS

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A new surgical method for rectal cancer, called transanal total mesorectal excision (taTME), was adopted at seven Norwegian hospitals in the 2014-2018 period.

The professional surgical communities in Norway suspended use of the method in autumn 2018 as a consequence of concerns related to complications and recurrences. A national review was then conducted under the auspices of the Norwegian Gastrointestinal Cancer Group (NGICG-CR). The review showed that the use of taTME in Norwegian hospitals has an elevated complication and recurrence rate compared to the standard surgical method of total mesorectal excision (TME).

NGICG and NGICG-CR

The method was subsequently also assessed in the Norwegian National System for Managed Introduction of New Health Technologies (New Methods) by the interregional medical directors meeting, which in April 2020 decided that the method would not be introduced, due to inadequate documentation.

Ukom (Statens undersøkelseskommisjon for helse- og omsorgstjenesten), hereinafter referred to in English as NHIB (the Norwegian Healthcare Investigation Board) initiated an investigation into the introduction of this surgical method as a serious patient safety issue. The aim is to identify risk areas associated with the introduction of new surgical methods on the basis of the process for using taTME. The report will also point to key learning points that could help improve patient safety related to the introduction of new surgical methods.

Due to the scope of the report, we will not further consider the technical surgical details or professional discussions concerning the taTME method itself. For the same reason, we do not make any assessment of various drivers for the introduction of new surgical methods.

This report has become even more relevant due to the recent media reports on the Norwait study, which also concerns the treatment of rectal cancer. The Norwait study is not discussed in our investigation.

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