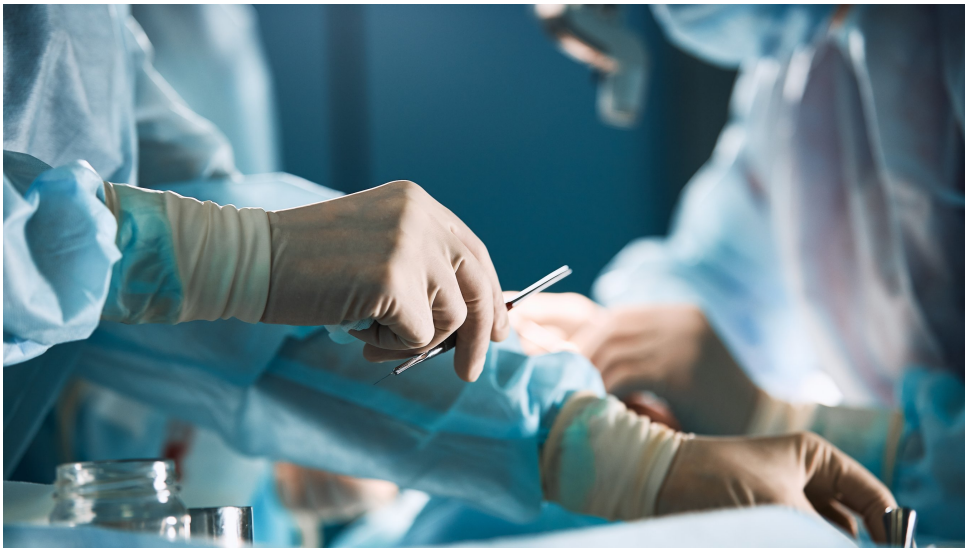
Summary



Ukom



MAINTAINING PATIENT SAFETY WITH NEW SURGICAL AND INVASIVE METHODS

Summary

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Our investigation concerns the transanal total mesorectal excision (taTME) method, which was implemented at seven Norwegian hospitals in the period from 2014 to 2018. It was used as the primary surgical tecnique for rectal cancer at these hospitals.

The taTME operations were eventually halted when it emerged that the 157 patients operated on using the new method had elevated complication and recurrence rates compared to patients who underwent surgery by the established method, i.e. total mesorectal excision (TME).

Development of new treatment methods is important for the continuous quality improvement of the health and social care services. The goal is to provide increasingly more accurate treatment. New treatment methods must have an improved effect on the disease being treated and limit the risks of the actual treatment. Before a decision is made to introduce a type of treatment as a new method, the method undergoes a research and trial phase. Legislation, national guidelines and established decision-making processes must ensure that new treatment methods are introduced safely and are consistent with national priorities.

Our investigation shows that the introduction of new surgical and invasive methods has traditionally been far less systematic than in the case of e.g. new drug treatments. Trial of a new treatment requires careful monitoring of the individual patient within a standardised framework. This is particularly important in the cancer area, so as not to inflict an increased risk of recurrence and death on patients.

Our report is based on review of documents, as well as interviews with a number of informants in the specialist health service, administration and professional and interest organisations. In this investigation we have not had any opportunity to present an individual patient story. None of the hospitals involved reported recurrences or complications in taTME-operated patients as serious

adverse events related to patient treatment. The patient perspective of the investigation is safeguarded through dialogue with patient and user organisations.

The story of taTME in Norway is an important reminder that there should be a low threshold for new surgical techniques, the use of new technical equipment or new organisation of a procedure to be deemed to constitute trial of a new method. As a general rule, trial of a new method should adhere to clinical research principles.

Our investigation should be of interest to all professional disciplines in the specialist health service that develop and adopt new treatment techniques, even though the starting point and the event investigated are from the gastrointestinal surgical field. The report should be studied in particular by responsible professional managers at our hospitals, as the report presents some key learning points that can help ensure wider safeguarding of quality and patient safety when new surgical and invasive methods are adopted.

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