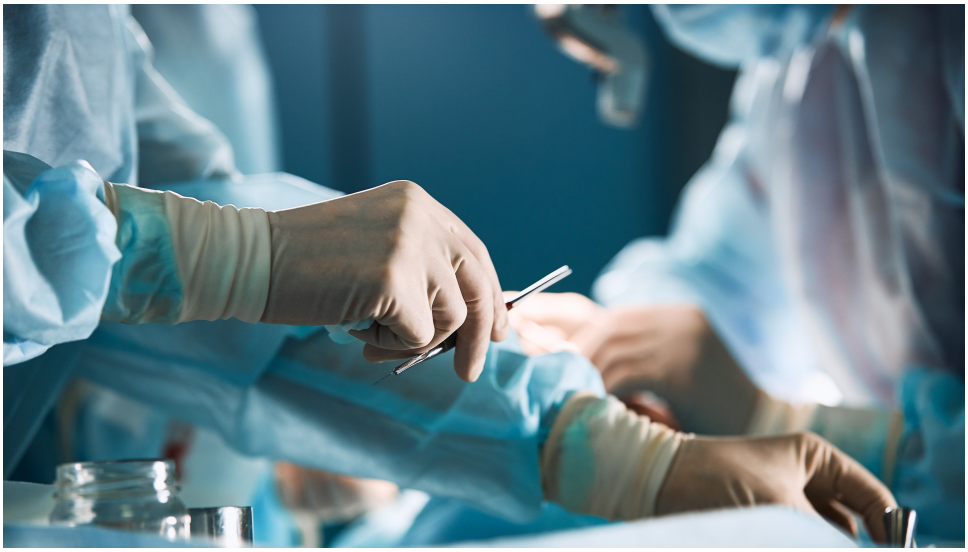
Follow-up after the taTME method was suspended



Ukom



MAINTAINING PATIENT SAFETY WITH NEW SURGICAL AND INVASIVE METHODS

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Subsequent information to patients

The hospitals we investigated 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 of rectal cancer. In view of concerns from parts of the gastrointestinal surgical professional community about complications and oncological outcomes in connection with taTME surgery, NGICG-CR sent a letter dated 14 January 2019 to the medical directors of the regional health authorities discouraging the use of taTME surgery in the treatment of rectal cancer in Norway (Appendix 3). NGICG-CR requested that the letter be forwarded to relevant hospitals and departments.

An article in Dagens medisin in June 2019 shows that Health Minister Bent Høie was not satisfied with the information the hospitals gave to the 157 patients who underwent taTME surgery, and he therefore required the regional health authorities to send out better information to patients (27). The situation concerning taTME had to be fully disclosed, and opportunities for appeal and to seek compensation from the Norwegian System of Patient Injury Compensation (NPE) had to be made clear. All the hospitals stated that they sent letters to the patients affected to inform them. At this time, the hospitals performing taTME surgery had already been contacted by the regional medical directors on behalf of NGICG-CR (January 2019) with the recommendation to stop using the taTME method, as well as a recommendation for how the patients who had undergone this surgery should be followed up with control.

Quality improvement and learning

In the Western Norway Regional Health Authority and the South-Eastern Norway Regional Health Authority, after the taTME-method was suspended, an internal review about the introduction of the method was conducted. All of the hospitals in question were involved.

Besides this, the hospitals' responses showed that after
the taTME method was stopped, quality improvement and learning were followed up in different ways. Some hospitals stated that internal meetings and discussions were held at the individual hospital and in the professional community after the incident with the taTME method. No minutes were taken of these meetings. One hospital stated that the experience with the taTME method had led to significantly greater awareness concerning the introduction of new methods in general, but did not describe in further detail what this entailed in practice. Another hospital stated that they had involved the expert director concerning questions about future introduction of new methods and equipment, but this was not concluded. Two hospitals stated that they had created research committees at department-level to assess and approve new methods prior to introduction and to initiate performance monitoring.

Notification to the supervisory authorities

None of the hospitals that had patients with severe local recurrences or complications responded that they notified this to the Norwegian Board of Health Supervision or the county governor (now the state administrator). One hospital stated that they requested a patient who suffered a recurrence to report this to the Norwegian System of Patient Injury Compensation (NPE).

Complaints to the Norwegian System of Patient Injury Compensation (NPE).

In the last five years, the Norwegian System of Patient Injury Compensation (NPE) has paid out over NOK 60 million in compensation to patients with colon cancer. NPE has stated that delayed diagnostics and use of an incorrect treatment technique or method are among the most common reasons stated concerning failed treatment.

NPE has informed NHIB that so far they have received 12 cases concerning use of the taTME method. The first three cases were reported in March and April 2019, respectively. Ten cases have so far been dismissed, while two cases have been partly upheld. NPE states that there are various reasons for dismissal of cases. Some dismissals are, for example, explained by the fact that at the time of surgery it was not known that the taTME surgical method presented an increased risk of recurrence. Other dismissals are explained by the fact that the cases concerning the spread of the cancer disease and local recurrence were not related to the method of surgery.

Norwegian System of Patient Injury Compensation (NPE)

NPE is a government agency under the Norwegian Ministry of Health and Care Services. They consider compensation claims from patients who believe they have suffered an injury following treatment failure in the health service. Cases are considered free of charge (60).
NPE has three regulatory tasks:

1. Determine whether compensation applicants are entitled to compensation and determine the size of the compensation.
2. Contribute with statistical data for quality improvement and injury prevention in the health service.
3. Provide information about the patient injury compensation scheme to patients, the health service and the general public.



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