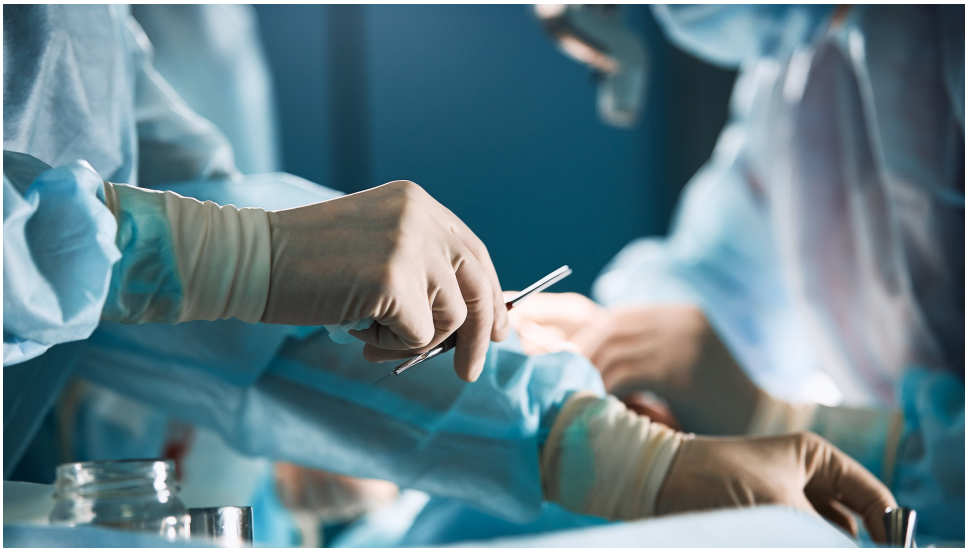
Treatment of rectal cancer in Norway



Ukom



MAINTAINING PATIENT SAFETY WITH NEW SURGICAL AND INVASIVE METHODS

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Around 1,100 cases of rectal cancer are diagnosed annually in Norway (2). The diagnosis is made on the basis of tissue samples via scopy examination of the intestine. Once the diagnosis has been made, it is assessed how far the cancer has spread and whether surgery to attempt to remove the cancer is relevant. In principle, all patients with newly diagnosed rectal cancer must be assessed for surgery, either for curative or life-prolonging purposes, unless the patient will not be able to cope with this or the disease is very far advanced (3). The survival rate for rectal cancer has improved over the last 50 years. The five-year relative survival rate has increased from approximately 15 per cent to 70 per cent (4).

In Norway, we have a national cancer treatment strategy (2006-2009) whereby various expert medical groups have contributed to professional recommendations for the diagnosis and treatment of various different types of cancer. These recommendations have been continued and formalised through national action programmes for which the Norwegian Directorate of Health is responsible. The first Action Programme with Guidelines for Diagnostics, Treatment and Follow-up of Colorectal Cancer was published in 2010. So far, a total of eight editions have been published, the most recent in December 2020. The national guidelines are “not directly legally binding, but to a great extent govern the choices made” in the health service, including to ensure professional soundness (3). The cancer treatment action programmes must contribute to public-sector cancer care of good quality, with equal access across Norway.

The Norwegian Directorate of Health sets up its own working groups for each action programme, based on input from the four regional health authorities (RHA). The Norwegian Directorate of Health leads the work and is the responsible publisher. NGICG and NGICG-CR have contributed to the work of revising the content of the action programme relating to colorectal cancer (3).

The TME method

The total mesorectal excision (TME) method was first described in professional communities internationally in 1979 (5). The method was adopted internationally as the standard treatment in the 1990s (6). In Norway, TME became the standard treatment for rectal cancer as from 1993 (6). The technique has contributed to reducing local rectal cancer recurrence rates from well over 20 per cent to around 4 per cent today (7.8).

For some patients with low tumours down towards the anus, TME is not a complete solution, however. In these cases, a rectum amputation is still necessary – which means removing the entire area with the rectum and pelvic floor, with a good margin to the tumour. However, this operation entails permanently opening the bowel.

TME (total mesorectal excision)

TME stands for total mesorectal excision. This entails removal of all tissue around the rectum (“mesorectal tissue”) together with the tumour and rectum (3). The mesorectum contains fat, nerves, blood vessels, lymph pathways and lymph nodes in an anatomically defined organ around the rectum (9). The mesorectum, as the fatty tissue envelop of the rectum, isolates the tumour and ensures that the tumour is packed in as well as possible, and that the cancer cells do not reach surfaces with a risk of recurrence (local relapse) (10). Removing this completely reduces the risk of cancer remaining after surgery, and consequently the chances of local recurrence (10, 11).

The taTME method

When keyhole surgery (laparoscopy) was introduced, ordinary TME became more difficult to perform for some patients, due to cramped pelvic conditions and difficult access at the bottom of the pelvis. This applies especially to men, in particular if they are overweight. As a consequence, a new method with access through the anus, called transanal total mesorectal excision (taTME) was presented by Sylla and Lacy in 2010 (12). Treatment using the taTME method could, give patients a very low splicing of the rectum, giving better opportunities to avoid a permanent colostomy bag (stoma) (3, 6).

TaTME (transanal total mesorectal excision)

TaTME stands for transanal total mesorectal excision. The method is performed using a keyhole technique through the anus. Just inside the rectum, the surgeon passes through the intestinal wall to the anatomical plane outside the mesorectum (6,12, 13). This means that the surgeon gets the whole (“total”) mesorectum. At the same time, ordinary laparascopic TME takes place from above. The tissue to be removed (“mesorectal excision”) is released completely when the surgery from below meets the surgery from above (“rendezvous”). The rest of the colon can then be spliced down onto the rectum. This is all performed as keyhole surgery (6, 13). TaTME breaks with the principle for TME by creating a common cavity between the inside (lumen) of the intestine where the cancerous tumour is located, and the plane of dissection from above through the pelvis, with the risk of spreading cancer cells (6).

However, the method is debated in the international gastrointestinal surgical community. Some have considered the method to be promising, based on results from early trials (14-16). Others expected that the method might lead to fewer postoperative complications, and believed that the method provided a safer splicing (6,17). From the professional community there were also early objections to the method for violating safe TME surgery and for being used for tumours that did not need a low splicing (6,18). TaTME was implemented in e.g. the UK, the Netherlands, Denmark, the USA and China, while other countries waited. At the time of writing, the National Institute for Health and Care Excellence (NICE) in the UK has put the method on hold (19), while the Netherlands has limited taTME surgery to a single centre (20).

The detailed course of the introduction of taTME in Norway is described in the timeline in the next chapter. In brief, the method was adopted at seven hospitals in Norway from 2014 to 2018. The first hospital already started up taTME in October 2014, while the last hospital adopted the method in January 2018. All use of taTME was suspended by the gastrointestinal surgical professional community in Norway in autumn 2018, due to elevated complication and recurrence rates. The method was subsequently also assessed by the National System for Managed Introduction of New Health Technologies (New Methods), where the interregional medical directors' meeting in April 2020 made the decision that the method could not be approved due to insufficient documentation. This shows that the documentation was no better when the method was adopted in Norway in 2014.

Statens undersøkelseskommisjon
for helse-og omsorgstjenesten

Postboks 225 Skøyen
0213 Oslo
E-post: post@ukom.no
Org nr: 921018924