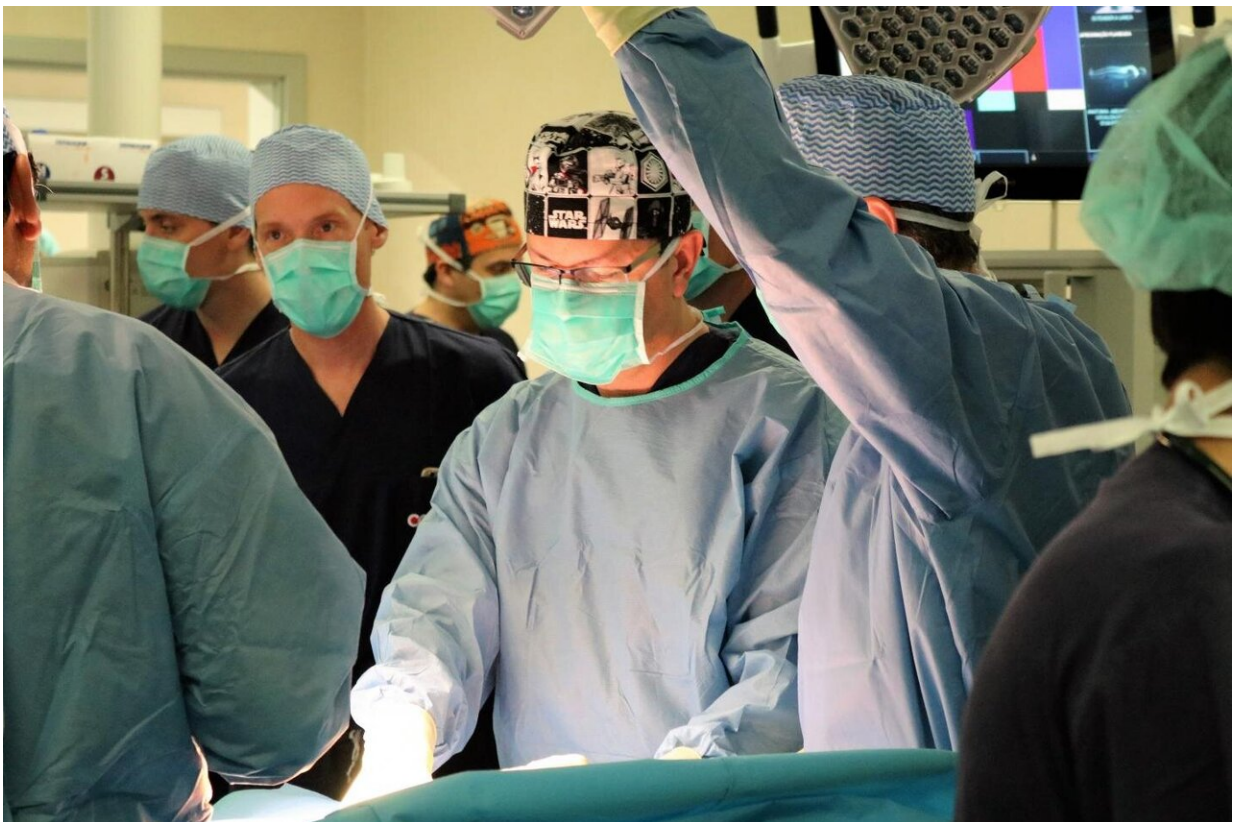


'Watch-and-wait' strategy could safely replace surgery in more than 20% of rectal cancers

February 6 2020



Robotic surgery for rectal cancer at the Champalimaud Clinical Centre. Credit: Rafael Falcão/CCU

A team of doctors and scientists from the Champalimaud Clinical Centre

in Lisbon, Portugal, and the Netherlands Cancer Institute in Amsterdam, has shown that patients with "low" rectal cancer (that is, very close to the anus) who show no sign of tumors after a course of radio- and chemotherapy can safely choose to postpone invasive and complication-prone surgical procedures. These results have been published in the journal *Annals of Surgery*.

Agreeing instead to submit to a very close and strict surveillance of their condition during a period of at least two years in a "watch-and-wait" strategy, they might even evade [surgery](#) without any negative impact on their health outcome, since (around two-thirds of these [patients](#) do not show any regrowth of the tumour after the first two years.

According to the scientists, it is notable that of the remaining patients (around one-third), who do experience tumour regrowth within those first two years and who undergo exactly the same surgical procedure as was initially planned for them, 97% show the same outcome as if the surgery had been performed immediately after radio-chemotherapy. In other words, no precious time will have been wasted by waiting and watching the patient.

Surgery still is, today, the frontline classical treatment protocol for [rectal cancer](#) cases, which represent about 30% of all colorectal cancers, or about 6 million new cases per year worldwide, according to [2018 estimates](#). But the fact is that, for complicated locations of the tumor in the rectum, a previous course of radio-chemotherapy before surgery is required, because in these cases, it is necessary to reduce the size of the tumor that might already be invading the pelvic wall structures or even other organs.

This pre-operative treatment comes with its own side effects, increasing the probability of urinary and sexual dysfunction, worse bowel function or even a deficient healing process. These could, in turn, have

devastating post-operative consequences, such as suture defects leading to peritonitis.

"For rectal tumors located less than 7 centimeters from the anus, the patient is often submitted to radiochemotherapy during five weeks, having a subsequent recovery period of another eight to 10 weeks before the surgical intervention," explains Nuno Figueiredo, head of the Champalimaud Surgical Centre and a colorectal surgeon at the Digestive Cancer Unit of the Champalimaud Clinical Centre, and one of the co-authors of the new study, together with his colleagues Marit Van der Sande and Geerard Beets, from the Netherlands Cancer Institute.

Moreover, in more than half of these low rectal [cancer](#) cases—which represent 30% to 40% of all rectal cancers, that is, around 2 million new cases per year worldwide, the surgery may require removal of the rectum and surrounding tissue (abdominoperineal amputation), a condition that implies permanently redirecting the colon toward an incision made in the abdomen (colostomy). In these cases, the patient is fitted for life with a "bag" to collect stools directly through that artificial orifice.

For all the above reasons, surgery is potentially a very invasive procedure in low rectal cancer. But what if there was a non-invasive option to surgery that did not put eligible patients' lives at risk? The new study shows that this may actually be the case.

Unnecessary surgery?

The watch-and-wait strategy for rectal cancer was pioneered by surgeon Angelita Habr-Gama at the University of São Paulo, Brazil, some 20 years ago. Habr-Gama observed that when patients with low rectal cancer were irradiated to prepare them for surgery due to the proximity of the tumor to the anus, histology results (biopsy) of the tissue harvested during the surgery often showed no trace of cancer cells. And

she wondered whether the surgery, with its cohort of potential complications and lifelong impact on patients' quality of life, had actually been necessary in those cases.

In the mid-2000s, surgeons in the Netherlands proposed the alternative protocol to eligible patients. And in 2013, the Champalimaud Clinical Center and the University of Manchester in the U.K. were some of the first institutions in the world to follow suit. "Today, 53 centers around the world are using the same watch-and-wait protocol," says Figueiredo. "And in 2013, we created the International watch-and-wait Database to collect all the data generated by these centers."



Robotic surgery for rectal cancer at the Champalimaud Clinical Centre. Credit: Rafael Falcão/CCU

The protocol consists of performing a series of diagnostic tests eight to 10 weeks after the chemoradiotherapy course before deciding if surgery is warranted. "We use clinical and radiological observations to decide whether surgery is needed or not," says Figueiredo. "We perform three exams: digital rectal examination, endoscopy and magnetic resonance imaging." And if the patient's clinical response is "complete"—that is, if the tumor does not show up in any of these exams—the patient then enters the watch-and-wait (W&W) protocol. "One-hundred percent of our patients at the Champalimaud Center choose this option," Figueiredo points out.

Before they make their decision, the patients are told that if, at any time during the following 24 months, any sign of tumor reappearance (or "regrowth") were to emerge, that would mean undergoing immediate surgery to remove the tumor in the exact way as initially programmed.

But if the cancer does not regrow during those first 24 months, the patient will then go on to be examined at least every six months for three additional years. After that, if it still doesn't reappear, the exams will continue at a rate of once a year.

Is it wise to wait?

Criticism of this protocol has focused, in particular, on the possibility of wasting precious time, during which the tumor could become, if not metastatic, possibly uncontrollable and impossible to remove surgically. It is this deferment of the surgery that the team has now shown to be safe in 97% of cases of tumor regrowth.

The new study involved 385 patients from both centers (83 from the Champalimaud) that were diagnosed between 2005 and 2018 and found to have a complete clinical response following chemoradiotherapy. Of those 385 patients, 89 (23 from Champalimaud) - or around 25% - had

tumor regrowth during the first 24 months. And of the patients who experienced regrowth, "97% were rescued, which means operated on as initially programmed," says Figueiredo.

In other words, the W&W period did not compromise the outcome for those patients. The final result was the same they would have obtained if the surgery had been performed immediately.

There were also some patients included in W&W (3%) who were either too frail or too old to sustain a major abdominal operation—or who, experiencing a regrowth after the W&W period, refused to have surgery. These patients were then given the best possible palliative care.

Another line of criticism has to do with the possibility that waiting to see what happens could increase the risk of developing distant metastases, that is, of the initial tumor spreading to other parts of the body, in particular to the liver and lungs. Figueiredo points out that this study was not designed to answer this question.

However, what these researchers have effectively observed is that, compared to historical rectal series in the literature, for which 25% of the patients with rectal cancer go on to develop metastases, this only happened to 8.2% of the patients submitted to the W&W protocol. According to Figueiredo, this could simply reflect the fact that eligible patients for the alternative protocol have a much better prognosis than the general population of rectal cancer patients—and start out with a reduced risk of metastases.

Two next steps, he adds, are already ongoing, namely at the Champalimaud. One is to intensify radiation oncology protocols in order to increase the number of rectal cancer patients who reach a clinical complete response and become eligible for W&W—that is, to contemplate radio and chemotherapy as a standard standalone treatment

for these tumours and not just a precursory step for surgery. The other is to improve the diagnostic accuracy of MRI and endoscopy exams in order to reduce the number of "false negatives"—that is, the number of apparently complete responses in which the [tumor](#) is actually still there after chemoradiotherapy but fails to be detected.

Provided by Champalimaud Centre for the Unknown

Citation: 'Watch-and-wait' strategy could safely replace surgery in more than 20% of rectal cancers (2020, February 6) retrieved 26 April 2024 from <https://medicalxpress.com/news/2020-02-watch-and-wait-strategy-safely-surgery-rectal.html>

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