

Findings do not support routine use of minimally invasive surgery for rectal cancer

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Compared to open resection (surgical removal) for rectal cancer, minimally invasive laparoscopic-assisted resection did not provide better cancer outcomes, according to two studies in the October 6 issue of *JAMA*.

Treatment of curable, locally advanced (stage II or III) rectal cancer relies on [surgical resection](#) as the core feature of a treatment process. Evidence about the efficacy of laparoscopic resection of rectal cancer is incomplete, particularly for patients with more advanced-stage disease. There are concerns that not all the cancer can be removed with minimally invasive techniques. James Fleshman, M.D., of Baylor University Medical Center, Dallas, and colleagues conducted a trial in which 486 patients with clinical stage II or III rectal cancer were randomly assigned to laparoscopic or open resection to examine whether laparoscopic resection is noninferior (not worse than) to open resection, as determined by several measures of the adequacy of cancer removal. A 6 percent noninferiority margin was chosen as being a clinically important difference. . The trial was conducted at 35 institutions in the United States and Canada and sponsored by the American College of Surgeons and the National Cancer Institute.

Two hundred forty patients with laparoscopic resection and 222 with open resection were evaluable for analysis. They underwent surgery by surgeons with experience and proven expertise in the operations they were performing. Pre-determined measures of overall surgical success occurred in 82 percent of laparoscopic resection cases and 87 percent of

open resection cases. "Laparoscopic resection failed to meet the criterion for noninferiority for pathologic outcomes compared with open resection and was thus potentially inferior," the authors write. In terms of cancer control, the laparoscopic procedure was not shown to be as good as the traditional, open operation.

Operative time was significantly longer for laparoscopic resection. Hospital length of stay, readmission within 30 days, and severe complications were not significantly different.

The researchers write that one explanation for their findings is that proctectomy (resection of the rectum) is challenging, and it can be even more difficult to work in the deep pelvis with in-line rigid instruments used in laparoscopic surgery. Access to this very difficult area of the body might be better with the open procedure. .

"Pending clinical oncologic outcomes [such as survival or cancer recurrence rates], the findings do not support the use of laparoscopic resection in these patients."

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In another study using the same design as the Fleshman study, Andrew R. L. Stevenson, M.B.B.S., F.R.A.C.S., of the University of Queensland, Brisbane, Australia, and colleagues conducted a phase 3 trial that included 475 patients with T1-T3 rectal cancer who were randomized to open laparotomy and rectal resection (n = 237) or laparoscopic rectal resection (n = 238) at 24 sites in Australia and New Zealand.

Proponents of the laparoscopic technique suggest that a similar tumor resection with better short-term outcomes can be achieved with minimal access surgery. Because of anatomical constraints, laparoscopic rectal resection may not be better because of limitations in performing an adequate cancer resection, according to background information in the article.

For this trial, the primary outcome of a successful resection (a composite of oncological factors, with a noninferiority margin of 8 percent) was achieved in 194 patients (82 percent) in the laparoscopic surgery group and in 208 patients (89 percent) in the open surgery group and was the same as that of the Fleshman study. Non inferiority was not shown for the laparoscopic resection, meaning that it was not shown to be as good as the open operation for rectal cancer. In fact, a post hoc test for superiority suggested that open surgery was better. Additional analysis with adjustment for baseline prognostic factors, including pathological grade, did not significantly change the overall treatment effect.

There were no differences between the two groups in hospital length of stay, intensive care unit stay or analgesic requirement.

"We were unable to establish noninferiority of laparoscopic rectal cancer surgery in this large randomized trial," the authors write. "Even though our trial was not designed to demonstrate whether one method of rectal dissection was superior to the other, the inability to establish noninferiority suggests that surgeons should be cautious when considering the suitability of a laparoscopic approach for a patient with rectal cancer."

The large, randomized, multicenter trials reported in this issue of *JAMA* substantiate recent findings from similar randomized trials that a laparoscopic resection may not be oncologically justified in many patients requiring proctectomy for rectal cancer, write Scott A. Strong,

M.D., and Nathaniel J. Soper, M.D., of the Northwestern University Feinberg School of Medicine, Chicago.

"The studies do not signal a moratorium on these approaches, but surgeons must proceed in a judicious manner to ensure that patients are informed about the benefits and risks associated with minimally invasive and open operations."

"Although the surgical management of patients with [rectal cancer](#) and diverticulitis has greatly improved, many questions persist and new ones continually arise that can be answered only with well-designed, rigorously conducted clinical trials. The utility of less intrusive strategies and minimally invasive approaches will undoubtedly expand as technologies evolve, but they must be responsibly incorporated into surgical practice based on evidence rather than subjective reasons."

More information: [DOI: 10.1001/jama.2015.12009](https://doi.org/10.1001/jama.2015.12009)
[DOI: 10.1001/jama.2015.11454](https://doi.org/10.1001/jama.2015.11454)

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