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Press review

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Intérêt d'une sigmoïdectomie élective en cas de douleur chronique ou de crises rapprochées après une première poussée de diverticulite non compliquée : résultats d'un essai contrôlé hollandais multicentrique

van de Wall BJ, Stam MA, Draaisma WA, et al. Surgery versus conservative management for recurrent and ongoing left-sided diverticulitis (DIRECT trial): an open-label, multicentre, randomised controlled trial. Lancet Gastroenterol Hepatol 2017;2:13—22.
http://dx.doi.org/10.1016/S2468-1253(16)30109-1

Background

Patients with recurrent or persisting complaints after an episode of left-sided diverticulitis are managed with either conservative measures or elective sigmoidectomy. To date, there are no data from randomized trials. We aimed to establish which treatment leads to a better quality of life for patients with diverticulitis.

Methods

We did an open-label, multicenter, randomized controlled trial (DIRECT trial) in 24 teaching and two academic hospitals in the Netherlands. Patients aged 18—75 years presenting with either recurrent (three or more presentations with clinical signs of acute diverticulitis within 2 years) or persistent abdominal complaints (ongoing lower left abdominal pain or persistent change in bowel habits for ≥ 3 months) after an episode of left-sided diverticulitis, confirmed by CT, ultrasound, or endoscopy, were included. Patients were excluded if they had previous elective or emergency surgery for acute sigmoid diverticulitis, an absolute operation indication, suspicion of a colorectal malignancy, with a preoperative or postoperative risk greater than III (on the American Society of Anesthesiologists classification), or were unable to complete questionnaire or follow-up. Patients were randomly assigned (3:3) to receive conservative management or elective (laparoscopic) sigmoidectomy using a digital randomization system, stratified by type of disease and center, with a block size of six. Patients, physicians, and researchers were not masked to treatment allocation. Our primary endpoint was health-related quality of life, measured by the Gastrointestinal Quality of Life Index (GIQLI) at 6 months after inclusion or surgery, depending on randomization group. This trial is registered with trialregister.nl, number NTR1478, and is closed for inclusion.

Findings

Between July 1, 2010, and April 1, 2014, we randomly assigned 109 patients to receive surgical treatment (resection; $n = 53$) or conservative management ($n = 56$), after which the Data Safety and Monitoring Board prematurely terminated the trial because of increasing difficulties in recruitment. In total, 47 (89%) of 53 patients received surgical treatment and 43 (77%) of 56 patients received conservative management. The GIQLI score at 6 months' follow-up was significantly higher in patients randomly assigned to receive surgical treatment (mean 114.4 [SD 22.3]) than conservative management (100.4 [22.7]; mean difference 14.2, 95% CI: 7.2—21.1, $P < 0.0001$). In total, 43 (38%) of 109 patients had a severe adverse event in the first 6 months after treatment (18 [34%] of 53 patients in the surgical treatment group vs. 23 [40%] of 57 patients

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in the conservative treatment group). Seven (15%) patients who received surgical treatment developed anastomotic leakage. Of the 56 patients assigned to be treated conservatively, 13 (23%) ultimately underwent elective resection due to ongoing abdominal complaints, with no anastomotic leakage. We recorded no patient deaths.

Interpretation

Elective sigmoidectomy, despite its inherent risk of complications, results in better quality of life than conservative management in patients with recurrent and persisting abdominal complaints after an episode of diverticulitis.

Comments

1. This trial was terminated early because of insufficient accrual and included only 109 of the 214 initially planned patients. However, with clinically pertinent and statistical significance, this trial favors prophylactic surgery for diverticular disease in these indications.
2. If only by the existence of the trial, it is probable that the surgical group benefited from a placebo effect, all the more so since no real treatment was proposed in the control arm.
3. The six-month delay to evaluate the quality of life seems rather short; it would have been of interest to know if this difference persisted in the longer term.
4. The permanent stoma rate, often given as an argument against prophylactic surgery, was low, less than 2%. On the other hand, the temporary stoma rate was 19%, particularly high for left colectomy with intra-peritoneal anastomoses.
5. It would now be interesting to run a new randomized trial assessing the value of prophylactic surgery in patients having sustained a first flare of diverticulitis with abscess or micro-perforation treated medically with success.

Danielsen AK, Park J, Jansen JE, et al. Early closure of a temporary ileostomy in patients with rectal cancer: a multicenter randomized controlled trial. Ann Surg 2017;265:284—290.
http://dx.doi.org/10.1097/SLA.0000000000001829

Objective

The objective was to study morbidity and mortality associated with early closure (8—13 days) of a temporary stoma compared with standard procedure (closure after > 12 weeks) after rectal resection for cancer.

Background

A temporary ileostomy may reduce the risk of pelvic sepsis after anastomotic dehiscence. However, the temporary ileostomy is afflicted with complications and requires a second surgical procedure (closure) with its own complications. Early closure of the temporary ileostomy could reduce complications for rectal cancer patients.

Methods

Early closure (8—13 days after stoma creation) of a temporary ileostomy was compared with late closure (> 12 weeks) in a multicenter randomized controlled trial, EASY (www.clinicaltrials.gov, NCT01287637) including patients undergoing rectal resection for cancer. Patients with a temporary ileostomy without signs of postoperative complications were randomized to closure at 8 to 13 days or late closure (> 12 weeks after index surgery). Clinical data were collected up to 12 months. Complications were registered according to the Clavien-Dindo Classification of Surgical Complications, and Comprehensive Complication Index was calculated.

Results

The trial included 127 patients in eight Danish and Swedish surgical departments, and 112 patients were available for analysis. The mean number of complications after index surgery up to 12 months follow-up was significantly lower in the intervention group (1.2) compared with the control group (2.9), $P < 0.0001$.

Conclusions

It is safe to close a temporary ileostomy 8 to 13 days after rectal resection and anastomosis for rectal cancer in selected patients without clinical or radiological signs of anastomotic leakage.

Comments

1. The conclusions of this trial must be interpreted with caution because the methodology is, for the least, surprising. First of all, the calculation of the number of patients necessary was based on the hypothesis that early closure (vs. late closure) would decrease the complication rate by 62%, whereas the only available controlled trial in the literature, more powerful, found that early closure did not lead to less overall morbidity [1]. Moreover, the analysis was not performed with intention to treat as 15 patients, that is, 11% of the initial sample, were withdrawn from analysis after randomization for unclear reasons. Last, we can consider that the trial was artificially positive by protocol violation. Effectively, in the group undergoing late closure, ileostomy should have been closed within 12 weeks but in fact, the median delay for closure was 18.5 weeks. Maintaining an ileostomy longer than planned could have contributed to the increased stoma-related complication rate.
2. The population in this study was highly selected: only 30% of potentially eligible patients were included. The main reason seems to be medical, but no clear explanation was given. This suggests that most patients were in poor physical condition eight days after proctectomy, and were not inclined, even in the absence of fistula, to undergo a second intervention so quickly.
3. If a third trial on the topic were to surface, a main end point of quality of life might be much more pertinent.

Reference

[1] Br J Surg 2008;95:693—698.

Roulin D, Saadi A, Di Mare L, et al. Early versus delayed cholecystectomy for acute cholecystitis, are the 72 hours still the rule? A randomized trial. Ann Surg 2016;264:717—722.
http://dx.doi.org/10.1097/SLA.0000000000001886

Objective

The aim of this study was to compare clinical outcomes of early versus delayed laparoscopic cholecystectomy (LC) in acute cholecystitis with more than 72 hours of symptoms.

Background

LC is the treatment of acute cholecystitis, with consensus recommendation that patients should be operated within 72 hours of evolution. Data however remain weak with no prospective study focusing on patients beyond 72 hours of symptoms.

Methods

Patients with acute cholecystitis and more than 72 hours of symptoms were randomly assigned to early LC (ELC) or delayed LC (DLC). ELC was performed following hospital admission. DLC was planned at least 6 weeks after initial antibiotic treatment. Primary outcome was overall morbidity following initial diagnosis. Secondary outcomes were