

# Long-term Outcome of Surgery Versus Conservative Management for Recurrent and Ongoing Complaints After an Episode of Diverticulitis

## 5-year Follow-up Results of a Multicenter Randomized Controlled Trial (DIRECT-Trial)

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**Objective:** The aim of this study was to establish whether surgical or conservative treatment leads to a higher quality of life (QoL) in patients with recurring diverticulitis and/or ongoing complaints.

**Summary of Background Data:** The 6 months' results of the DIRECT trial, a randomized trial comparing elective sigmoidectomy with conservative management in patients with recurring diverticulitis (>2 episodes within 2 years) and/or ongoing complaints (>3 months) after an episode of diverticulitis, demonstrated a significantly higher QoL after elective sigmoidectomy. The aim of the present study was to evaluate QoL at 5-year follow-up.

**Methods:** From January 2010 to June 2014, 109 patients were randomized to either elective sigmoidectomy (N = 53) or conservative management (N = 56). In the present study, the primary outcome was QoL measured by the Gastrointestinal Quality of Life Index (GIQLI) at 5-year follow-up. Secondary outcome measures were SF-36 score, Visual Analogue Score (VAS) pain score, EuroQol-5D-3L (EQ-5D-3L) score, morbidity, mortality, perioperative complications, and long-term operative outcome.

**Results:** At 5-year follow-up, mean GIQLI score was significantly higher in the operative group [118.2 (SD 21.0)] than the conservative group [108.5 (SD 20.0)] with a mean difference of 9.7 (95% confidence interval 1.7–17.7). All

secondary QoL outcome measures showed significantly better results in the operative group, with a higher SF-36 physical ( $P = 0.030$ ) and mental score ( $P = 0.010$ ), higher EQ5D score ( $P = 0.016$ ), and a lower VAS pain score ( $P = 0.011$ ). Twenty-six (46%) patients in the conservative group ultimately required surgery due to severe ongoing complaints. Of the operatively treated patients, 8 (11%) patients had anastomotic leakage and reinterventions were required in 11 (15%) patients.

**Conclusion:** Consistent with the short-term results of the DIRECT trial, elective sigmoidectomy resulted in a significantly increased QoL at 5-year follow-up compared with conservative management in patients with recurring diverticulitis and/or ongoing complaints. Surgeons should counsel these patients for elective sigmoidectomy weighing superior QoL, less pain, and lower risk of new recurrences against the complication risk of surgery.

**Keywords:** elective sigmoidectomy, ongoing complaints, quality of life, recurring diverticulitis

(*Ann Surg* 2019;269:612–620)

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HE Bolkenstein was involved in data acquisition, data analysis, interpretation of the data, and writing of the report. ECJ Consten, BJM van de Wall, IAMJ Broeders, WA Bemelman, JF Lange, MA Boermeester, and WA Draaisma were involved in the study design, data acquisition, interpretation of the data, and writing of the report. J van der Palen was involved in data analysis, interpretation of the data, and writing of the report. All authors gave final approval of the version to be published and agree to be accountable for all aspects of the work.

The DIRECT trial was funded by the Netherlands Organization for Health Research and Development (ZonMW: 171002201).

The authors declare no conflict of interest.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site ([www.annalsurgery.com](http://www.annalsurgery.com)).

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ISSN: 0003-4932/18/26904-0612

DOI: 10.1097/SLA.0000000000003033

Diverticulitis is currently ranked as the third most common gastrointestinal discharge diagnosis in the United States.<sup>1</sup> Approximately 20% of diverticulitis patients develop recurrences after a conservatively treated episode of diverticulitis and up to 33% can experience ongoing complaints.<sup>2–4</sup> There has been major controversy on the use of elective sigmoidectomy to treat patients with recurrences and/or persistent symptoms. One of the concerns regarding this topic is the difficulty in distinguishing persistent symptoms after an episode of diverticulitis from irritable bowel syndrome (IBS). As IBS is a functional disorder, operative treatment is obviously not the treatment of choice, as it is unlikely to improve and might even fuel the symptoms. Moreover, operative intervention is associated with inherent complication risks, such as anastomotic leakage or abscess.<sup>4–7</sup> As (uncomplicated) diverticulitis is generally considered a mild and self-limiting disease, performing a potentially harmful procedure in these patients does not seem justified. Guidelines published by the American Society of Colon and Rectal Surgeons (ASCRS) in 2014 and the World Society of Emergency Surgery (WSES) in 2016 recommend a tailored approach for each individual patient where the impact of multiple recurrences and ongoing complaints on quality of life (QoL) should form the most decisive factor.<sup>8,9</sup> It is therefore pertinent that the effect of elective sigmoidectomy on QoL in this patient group is better understood.