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Lancet Gastroenterol Hepatol. **2019** Aug;4(8):599-610. doi: 10.1016/S2468-1253(19)30174-8. Epub **2019** Jun 6.

Hartmann's procedure versus sigmoidectomy with primary anastomosis for perforated diverticulitis with purulent or faecal peritonitis (LADIES): a multicentre, parallel-group, randomised, open-label, superiority trial.

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Abstract

BACKGROUND: Previous studies have suggested that sigmoidectomy with primary anastomosis is superior to **Hartmann's** procedure. The likelihood of stoma reversal after primary anastomosis has been reported to be higher and reversal seems to be associated with lower morbidity and mortality. Although promising, results from these previous studies remain uncertain because of potential selection bias. Therefore, this study aimed to assess outcomes after **Hartmann's** procedure versus sigmoidectomy with primary anastomosis, with or without defunctioning ileostomy, for perforated diverticulitis with purulent or faecal peritonitis (Hinchey III or IV disease) in a randomised trial.

METHODS: A multicentre, randomised, open-label, superiority trial was done in eight academic hospitals and 34 teaching hospitals in Belgium, Italy, and the Netherlands. Patients aged between 18 and 85 years who presented with clinical signs of general peritonitis and suspected perforated diverticulitis were eligible for inclusion if plain abdominal radiography or CT scan showed diffuse free air or fluid. Patients with Hinchey I or II diverticulitis were not eligible for inclusion. Patients were allocated (1:1) to **Hartmann's** procedure or sigmoidectomy with primary anastomosis, with or without defunctioning ileostomy. Patients were enrolled by the surgeon or surgical resident involved, and secure online randomisation software was used in the operating room or by the trial coordinator on the phone. Random and concealed block sizes of two, four, or six were used, and randomisation was stratified by age (<60 and ≥60 years). The primary endpoint was 12-month stoma-free survival. Patients were analysed according to a modified intention-to-treat principle. The trial is registered with the Netherlands Trial Register, number NTR2037, and ClinicalTrials.gov, number NCT01317485.

FINDINGS: Between July 1, 2010, and Feb 22, 2013, and June 9, 2013, and trial termination on June 3, 2016, 133 patients (93 with Hinchey III disease and 40 with Hinchey IV disease) were randomly assigned to **Hartmann's** procedure (68 patients) or primary anastomosis (65 patients). Two patients in the **Hartmann's** group were excluded, as was one in the primary anastomosis group; the modified intention-to-treat population therefore consisted of 66 patients in the **Hartmann's** procedure group (46 with Hinchey III disease, 20 with Hinchey IV disease) and 64 in the primary anastomosis group (46 with Hinchey III disease, 18 with Hinchey IV disease). In 17 (27%) of 64 patients assigned to primary anastomosis, no stoma was constructed. 12-month stoma-

free survival was significantly better for patients undergoing primary anastomosis compared with **Hartmann's** procedure (94·6% [95% CI 88·7-100] vs 71·7% [95% CI 60·1-83·3], hazard ratio 2·79 [95% CI 1·86-4·18]; log-rank p<0·0001). There were no significant differences in short-term morbidity and mortality after the index procedure for **Hartmann's** procedure compared with primary anastomosis (morbidity: 29 [44%] of 66 patients vs 25 [39%] of 64, p=0·60; mortality: two [3%] vs four [6%], p=0·44).

INTERPRETATION: In haemodynamically stable, immunocompetent patients younger than 85 years, primary anastomosis is preferable to **Hartmann's** procedure as a treatment for perforated diverticulitis (Hinchey III or Hinchey IV disease).

FUNDING: Netherlands Organisation for Health Research and Development.

PMID: 31178342 DOI: 10.1016/S2468-1253(19)30174-8

Secondary source ID

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