Laparoscopic peritoneal lavage or sigmoidectomy for perforated diverticulitis with purulent peritonitis: a multicentre, parallel-group, randomised, open-label trial

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Summary

Background Case series suggest that laparoscopic peritoneal lavage might be a promising alternative to sigmoidectomy in patients with perforated diverticulitis. We aimed to assess the superiority of laparoscopic lavage compared with sigmoidectomy in patients with purulent perforated diverticulitis, with respect to overall long-term morbidity and mortality.

Methods We did a multicentre, parallel-group, randomised, open-label trial in 34 teaching hospitals and eight academic hospitals in Belgium, Italy, and the Netherlands (the Ladies trial). The Ladies trial is split into two groups: the LOLA group comparing laparoscopic lavage with sigmoidectomy and the DIVA group comparing Hartmann's procedure with sigmoidectomy plus primary anastomosis. The DIVA section of this trial is still underway but here we report the results of the LOLA section. Patients with purulent perforated diverticulitis were enrolled for LOLA, excluding patients with faecal peritonitis, aged older than 85 years, with high-dose steroid use (≥20 mg daily), and haemodynamic instability. Patients were randomly assigned (2:1:1; stratified by age [<60 years *vs* ≥60 years]) using secure online computer randomisation to laparoscopic lavage, Hartmann's procedure, or primary anastomosis in a parallel design after diagnostic laparoscopy. Patients were analysed according to a modified intention-to-treat principle and were followed up after the index operation at least once in the outpatient setting and after sigmoidoscopy and stoma reversal, according to local protocols. The primary endpoint was a composite endpoint of major morbidity and mortality within 12 months. This trial is registered with ClinicalTrials.gov, number NCT01317485.

Findings Between July 1, 2010, and Feb 22, 2013, 90 patients were randomly assigned in the LOLA section of the Ladies trial when the study was terminated by the data and safety monitoring board because of an increased event rate in the lavage group. Two patients were excluded for protocol violations. The primary endpoint occurred in 30 (67%) of 45 patients in the lavage group and 25 (60%) of 42 patients in the sigmoidectomy group (odds ratio 1·28, 95% CI 0·54–3·03, p=0·58). By 12 months, four patients had died after lavage and six patients had died after sigmoidectomy (p=0·43).

Interpretation Laparoscopic lavage is not superior to sigmoidectomy for the treatment of purulent perforated diverticulitis.

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Introduction

Diverticular disease is the fourth most costly gastrointestinal disorder in developed countries with an estimated annual hospital admission rate of 209 per 100 000 adults in Europe.[1,2] The prevalence of this disorder increases with age and is estimated at 5% of people in their forties and can be as high as 80% in those aged older than 80 years.[2,3] Of patients with acute diverticulitis, 8–35% presented with perforated disease with abscesses or peritonitis.[2,4] Perforated diverticulitis is graded according to the Hinchey classification,[5] with abscess formation scored as Hinchey I or II, purulent peritonitis as Hinchey III, and faecal peritonitis as Hinchey IV.

Laparoscopic peritoneal lavage has emerged as a promising alternative to sigmoidectomy in patients with purulent peritonitis owing to perforated diverticulitis. This non-resectional strategy was first described in 1996.[6,7] In 2008, Myers and colleagues[8] reported a 95% success rate of laparoscopic peritoneal lavage in 92 patients. 2 years later a systematic review[9] of case series showed a mortality rate of less than 5% and a colostomy was avoided in most patients. Since these publications, laparoscopic lavage for purulent perforated diverticulitis has gained popularity because of its great potential to improve outcomes and reduce costs. Despite the absence of robust evidence from randomised trials, laparoscopic lavage has been embraced by many surgeons. Even some national and international guidelines state that it is a safe approach in purulent perforated diverticulitis.[10,11]

The laparoscopic lavage (LOLA) group of the Ladies trial[12] postulated that laparoscopic lavage compared with