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Long-Term Results After Laparoscopic Lavage for Perforated Diverticulitis Purulent Peritonitis in Sweden

A Population-Based Observational Study

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Objective: To compare long-term outcomes after laparoscopic lavage with resection surgery for perforated diverticulitis, Hinchey grade III as practiced in Sweden for 3 years.

Background: Laparoscopic lavage has been studied in 3 randomized controlled trials. Long-term results indicate that additional surgery and a remaining stoma are less common after lavage compared with resection, but data from routine care and larger cohorts are needed to get a more complete picture.

Methods: LapLav is a national cohort study with nearly complete coverage of all patients operated in Sweden between 2016 and 2018. The cohort was retrieved from the national patient register by a definition based on the Classification of Diseases and Related Health Problems-10 code plus the surgical procedural code. All medical records have been reviewed and data retrieved in addition to registry data. Propensity score with inverse probability weighting was used to balance the 2 groups, that is, laparoscopic lavage *vs* resection surgery.

Results: Before the propensity score was applied, the cohort consisted of 499 patients. Additional surgery was more common in the resection group [odds ratio, 0.714; 95% confidence interval (CI) = 0.529–0.962; $P = 0.0271$]. Mortality did not differ between the groups (hazard ratio, 1.20; 95% CI = 0.69–2.07; $P = 0.516$). In the lavage group, 27% of patients went on to have resection surgery.

Conclusions: In Swedish routine care, laparoscopic lavage was feasible and safe for the surgical treatment of perforated diverticulitis, Hinchey grade III. Our results indicate that laparoscopic lavage can be used as a first-choice treatment.

Keywords: acute surgery, diverticulitis, laparoscopic lavage

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Informed consent was obtained from all individual participants included in the study. This study was approved by the regional ethical review board in Gothenburg (Dnr 545-17).

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INTRODUCTION

Diverticulosis is a prevalent, often asymptomatic condition in about half of individuals aged >65 years in Western countries. Inflammation of 1 or more diverticula is called diverticulitis, and most commonly does not require any specific treatment. However, diverticulitis can be complicated by a perforation of the bowel, which can be life-threatening. The severity varies, and several classification systems have been developed to evaluate patients. The commonly used Hinchey classification, grades I–IV, is based on findings at surgery[1] and takes into account the reaction within the abdominal cavity. Hinchey grade III corresponds to purulent peritonitis, and Hinchey grade IV to fecal peritonitis. Both grades of diverticulitis may require emergency surgery.

Traditionally, perforated diverticulitis with peritonitis, regardless of Hinchey classification, was treated by resection of the inflamed part of the colon with an end-colostomy and a closure of the distal end of the bowel, a so-called Hartmann's procedure.[2] Another treatment option was introduced about 15 years ago, a laparoscopic procedure where the abdomen is rinsed with saline without bowel resection, a so-called laparoscopic lavage.[3] Since its introduction, laparoscopic lavage has been investigated for the treatment of perforated diverticulitis with purulent peritonitis (Hinchey grade III) in 3 randomized controlled trials (RCTs),[4–6] including a total of 308 patients. The proportion of patients requiring additional surgery after the emergency operation was similar across the 3 RCTs, while fewer patients had stoma in the lavage group compared with the resection group.[7–9] The prevalence of mortality and complications did not differ. Meta-analyses have reached somewhat diverse results due to differing definitions of outcomes.[10–14] Long-term results across the 3 RCTs[7–9] showed recurrent diverticulitis in around 20% of

the lavage cases together with sigmoid resections in 20–45%. Moreover, cohort studies have found a higher complication burden, as measured by the Comprehensive Complication Index, after resection[15] and similar quality of life results.[16]

To validate treatment for complicated diverticulitis in routine healthcare, the LapLav study was started as a large national cohort study. Short-term and patient-reported outcomes have already been published.[15,16] This article aims to compare long-term follow-up outcomes in terms of additional surgery, readmissions, and mortality 2 years after emergency laparoscopic lavage and colonic resection for Hinchey grade III perforated diverticulitis.

METHODS

Study Design

LapLav is a retrospective, national registry-based study of patients in Sweden who had an emergency operation for perforated diverticulitis between 2016 and 2018. The cohort was identified using the Swedish National In-Patient Registry and by a combination of International Statistical Classification of Diseases and Related Health Problems (ICD)-10 codes for diverticulitis and Nordic Medico-Statistical Committee Classification of Surgical Procedures (NOMESCO) codes for surgery due to the same. Through the registry, 1300 patients were identified and hospital records for 99.7% were retrieved and reviewed.

The patients were divided into 2 groups, laparoscopic lavage and resection surgery according to the index surgery done. Resection surgery was defined as any surgery where the perforated colon segment was removed, regardless of primary anastomosis or stoma formation.

Classification according to Hinchey, was performed by reading the operative charts. Description of diverticulitis with free pus or cloudy peritoneal fluid was defined as Hinchey grade III, whereas feces in the abdominal cavity anywhere else than in the bowel was deemed as Hinchey grade IV. If the classification was uncertain, the records were reviewed by a senior surgeon blinded to the previous classification. Consensus was reached in all these cases by discussion. Through this process, 669 patients with perforated diverticulitis with purulent or fecal peritonitis were identified and included. A questionnaire was sent out 2–3 years after surgery, but results regarding patient-reported outcomes are presented elsewhere.[16]

A renewed retrieval from the Swedish National In-Patient Registry of readmissions and operations for the 699 patients was made 2 years after the index surgery using a combination of ICD-10 and NOMESCO codes (surgical procedures) related to diverticulitis. Hospital records were retrieved, and data were collected about readmissions and operations using a prespecified clinical record form. A detailed description has been published previously.[15] Data were also collected from the Swedish Cancer Register and the Cause of Death Register.

The report adheres to the STROBE statement.

Endpoints

The primary endpoint was the need for additional surgery related to the initial treatment of the diverticulitis, such as later resection surgery or stoma reversal, within 2 years after index surgery.

Secondary endpoints were (1) mortality within 2 years, (2) stoma at 2 years, (3) readmissions, (4) length of hospital stay, (5) type of additional surgery, (6) resections in the lavage group, and (7) colorectal cancer diagnosis.

Additional surgery was defined as a surgical procedure performed in an operating theater under general anesthesia or a comparable method. During the first year after the index surgery, all additional surgeries were registered whereas only surgery related to the index operation was considered during the second year.

Within the estimand framework,[17] death was considered an intercurrent event for additional surgery and readmissions. The primary analysis handled a death event using a composite endpoint strategy, where death is defined as the worst possible outcome. The outcomes were analyzed as an ordinal scale. This scale was modeled by an ordered proportional odds logistic regression where results were presented as odds ratios (lavage *vs* resection) and with 95% compatibility intervals.[18] A supporting analysis, the "while-on-treatment" strategy, was also conducted including data up to the time of death.

Statistics

The power calculation used results from the 3 RCTs[4–6] assuming a 1:4 distribution of patients between laparoscopic lavage and resection. To gain 80% power, 1000 evaluable patients were required to detect a true reduction in the proportion of patients with additional surgery from 70% to 60% using a 2-sided test at a 5% significance level. In the DILALA trial,[9] the prevalence of 0, 1, 2, 3, and ≥4 additional surgeries in the resection group was 32%, 44%, 20%, and 5%, respectively. The number of patients was 140 and 265 in the lavage and resection group, respectively, after adjusting for confounders using inverse probability weighting. From a post hoc perspective, assuming the same prevalence values, there was 75% and 95% power (using a 2-sided test with a 5% significance level) to detect a reduction of 40% and 50%, respectively, in the proportional odds of additional surgery by laparoscopic lavage.

We used the same casual model as previous analyses of the LapLav study, with 5 variables as confounders: age, comorbidity (cardiovascular disease/diabetes), chronic obstructive pulmonary disease (COPD), sepsis, and immunosuppressive therapy.[15,16] To enable a comparison of the 2 groups and balance baseline characteristics, we used propensity scores with inverse probability weighting.[19,20] Propensity scores were obtained by generalized boosted regression with a minimal average standardized effect size as the optimal criteria. We estimated the average treatment effect (ATE) using the same weights as in Samuelsson et al.[15] The derived weights were used in weighted regression models with the surgical procedure as a fixed effect and the 5 variables added as adjustment variables, that is, "doubly robust estimation."[21] Age was standardized and adjusted for via a restricted cubic spline.[22] The properties of the synthetic groups are presented in the Supplemental Material, http://links.lww.com/AOSO/A346.

The number of additional surgeries and readmissions were modeled with negative binomial regression and the length of hospital stays with a linear regression of log (days). Results were presented as ratios of geometric means (lavage *vs* resection). Mortality was summarized by the Kaplan–Meier estimator and the effect of the type of surgery was estimated using Cox regression. R software[23] was used for the analysis. Estimation of propensity scores and weighting was performed using the twang package. In subsequent analyses, packages ordinal, glm2, splines, survey, survival, and survminer were used.

RESULTS

Out of the 1300 patients identified via the Swedish National In-Patient Registry, 669 patients with Hinchey grades III and IV were included in the study. A total of 499 had an operation due to perforated diverticulitis, Hinchey grade III, and were included in the current analysis (Fig. 1). Resection was more common, with 291 patients, than laparoscopic lavage, with 173 patients. We also identified patients (n = 35) who had an operation that was neither resection nor lavage, but they were excluded from the analysis. Patient demographics are shown in Table 1.

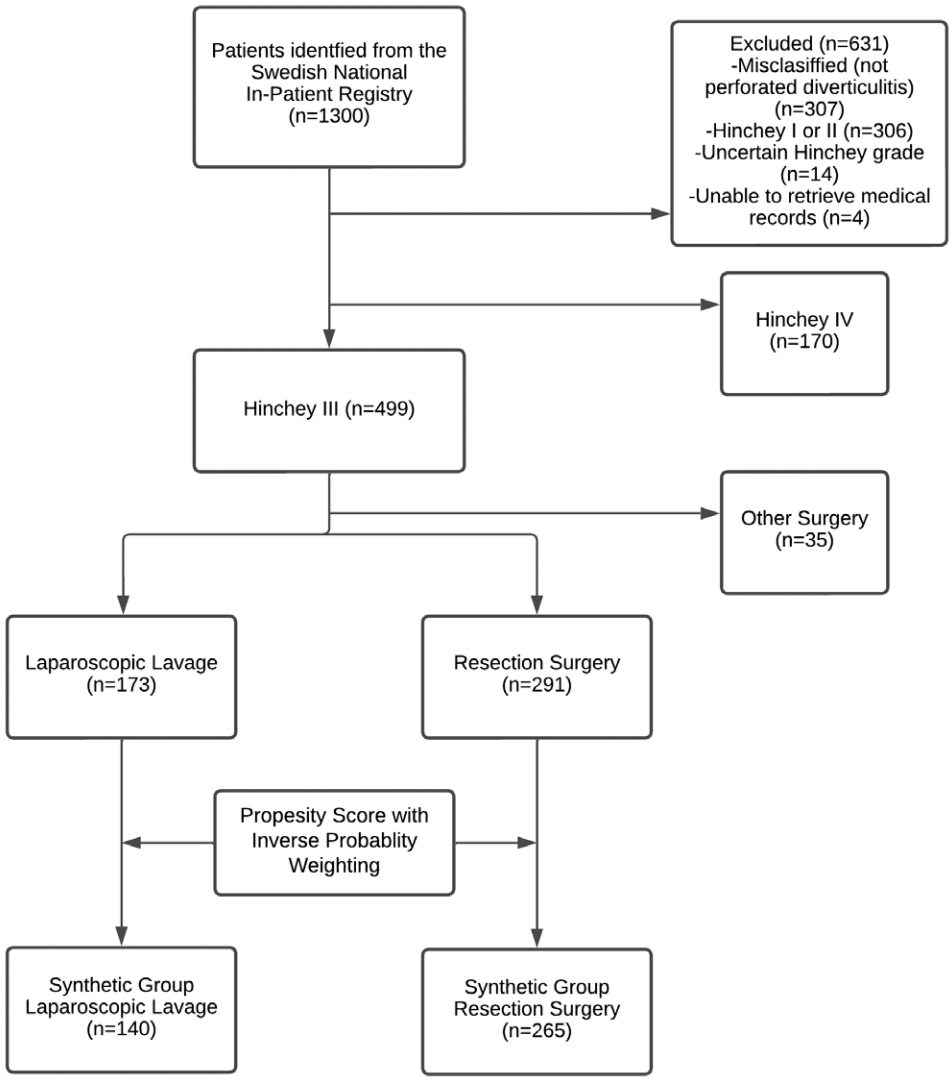

FIGURE 1. Flowchart.

The primary endpoint of additional surgery is described in Table 2 together with the type of surgery. The percentage of patients who had undergone additional surgery within 2 years after the index operation was significantly lower in the lavage group compared to the resection group [odds ratio (OR), 0.714; 95% confidence interval (CI) = 0.529–0.962; $P = 0.0271$], with a 5% increased probability that it will be more common after resection. Analysis of year 1 also showed a significant difference. The supporting analysis, which included only patients alive at follow-up, reinforced these findings.

In the unadjusted analysis, mortality within 2 years after the index operation was higher in the resection group, 74/291 (25%), *versus* the lavage group, 22/173(13%). After adjusting for confounders, no significant differences remained (hazard ratio, 1.20; 95% CI = 0.69–2.07; $P = 0.516$) (Fig. 2).

There was no statistically significant difference in the number of readmissions between the 2 groups (OR, 0.835; 95% CI = 0.653–1.07; $P = 0.151$). Laparoscopic lavage reduced the total length of hospital stays within 2 years by 47% (geometric mean ratio: 0.531; 95% CI = 0.417–0.676; $P < 0.001$) with a mean length of 26.8 days in the resection group *versus* 17.2 in the lavage group. In the resection group, 65% (190/291) of patients had a stoma 2 years after the index surgery, compared with 13% (23/173) in the lavage group. At 2 years, 27% (47/173) of patients in the lavage group had undergone resection. In either group, there were few cases of colorectal cancer, 6 in the resection group *versus* 7 in the lavage group.

Secondary outcomes on readmissions, cause of death, and stoma at 2 years are summarized in Supplemental Table 1, http://links.lww.com/AOSO/A347.

DISCUSSION

In our long-term analysis of the retrospective, national cohort study LapLav, we found that patients treated with laparoscopic lavage had a lower risk for additional surgery at 2 years compared with resection. In the lavage group, patients also had reduced length of hospital stays and a lower prevalence of stoma at the 2-year follow-up. These results indicate an advantage for laparoscopic lavage for patients operated on for purulent peritonitis, Hinchey grade III.

The definition of additional surgery, including bowel resections, stoma reversal, and hernia repair was in accordance with what has been used earlier.[7–9] Our national cohort reflects the clinical situation not uncommon in Europe, where Hartmann's procedure remains the dominating surgery performed for perforated diverticulitis together with laparoscopic lavage.

Based on the while-on-treatment estimand, the need for additional surgery was reduced by almost 50% (mean ratio 0.538) in the lavage group. This result may seem impressive,

TABLE 1.

Demography

	Laparoscopic Lavage (N = 173)	Resection Surgery (N = 291)	Other Surgery* (N = 35)	Overall (N = 499)
Age				
Mean (SD)	62 (±15)	69 (±13)	65 (±16)	66 (±14)
Sex				
Female	82 (47%)	161 (55%)	15 (43%)	258 (52%)
Male	91 (53%)	130 (45%)	20 (57%)	241 (48%)
Cardiovascular disease				
No	105 (61%)	108 (37%)	20 (57%)	233 (47%)
Yes	68 (39%)	178 (61%)	15 (43%)	261 (52%)
Missing	0 (0%)	5 (2%)	0 (0%)	5 (1%)
Chronic obstructive pulmonary disease				
No	164 (95%)	254 (87%)	35 (100%)	453 (91%)
Yes	8 (5%)	32 (11%)	0 (0%)	40 (8%)
Missing	1 (1%)	5 (2%)	0 (0%)	6 (1%)
Diabetes				
No	163 (94%)	256 (88%)	29 (83%)	448 (90%)
Yes	10 (6%)	31 (11%)	6 (17%)	47 (9%)
Missing	0 (0%)	4 (1%)	0 (0%)	4 (1%)
Immunosuppression				
No	151 (87%)	177 (61%)	28 (80%)	356 (71%)
Yes	22 (13%)	110 (38%)	7 (20%)	139 (28%)
Missing	0 (0%)	4 (1%)	0 (0%)	4 (1%)
Sepsis at surgery				
No	149 (86%)	200 (69%)	27 (77%)	376 (75%)
Yes	16 (9%)	67 (23%)	6 (17%)	89 (18%)
Missing	8 (5%)	24 (8%)	2 (6%)	34 (7%)

*Open lavage, laparoscopic lavage with stoma formation, colorafi without resection

Table 2.

Additional surgery

	Resection (n = 291)	Lavage (n = 173)	Estimand	Estimated Effect Laparoscopic Lavage *vs.* Resection Surgery (95% CI)
Number of further surgery within 2 years				
0	96/291 (33%)	101/173 (58%)	Composite*	0.714 (0.529;0.962)*, $P = 0.0271$
1	82/291 (28%)	21/173 (12%)	While-on-treatment†	0.538 (0.378;0.759)†, $P < 0.0001$
2	23/291 (7.9%)	21/173 (12%)		
3	8/291 (2.7%)	8/173 (4.6%)		
≥4	8/291 (2.7%)	0/173 (0%)		
Died within 2 years	74/291 (25%)	22/173 (13%)		
Number of further surgery within 1 year				
0	106/291 (36%)	101/173 (58%)	Composite*	0.681 (0.527;0.878)*, $P = 0.0031$
1	83/291 (29%)	21/173 (12%)	While-on-treatment†	0.626 (0.502;0.779)†, $P < 0.0001$
2	24/291 (8.2%)	22/173 (13%)		
3	8/291 (2.7%)	9/173 (5.2%)		
≥4	8/291 (2.7%)	0/173 (0%)		
Died within 2 years	62/291 (21%)	20/173 (12%)		
Type of further surgery				
Adhesiolysis	12	4		
Ventral hernia	21	5		
Sigmoid resection	2	47		
Hartmanns reversal	14	1		
Complication related to index surgery	80	19		
Other surgery related to index surgery‡	43	26		
Unrelated surgery	18	6		

*Composite endpoint analysis with death as worst possible outcome. Treatment contrast is odds ratio from ordinal logistic regression.

†While on treatment analysis with data up to death. Treatment contrast is geometric mean ratio from negative binomial regression.

‡Such as, other bowel resection, stoma formation or revision, failed Hartmann's reversal and explorative laparotomy.

but it is mediated by the higher mortality in the resection group. The composite estimand also accounts for deaths and is thus more relevant from a patient perspective. With this approach, the calculated OR for additional surgery or death was 0.714 in favor of laparoscopic lavage. While the effect size may seem small, given the current routine care design, we would in general expect the large effects seen in RCTs to become attenuated. Since laparoscopic lavage has been demonstrated to be more cost-effective than resection,[24,25] it would be sufficient to demonstrate the noninferiority of laparoscopic lavage *versus* resection.

It could be argued that resection via Hartmann's procedure reduces the risk for recurrence as the diseased segment is resected. Recurrent diverticulitis has been reported at a risk of up to 20 after laparoscopic lavage,[8] and during follow-up, resection rates

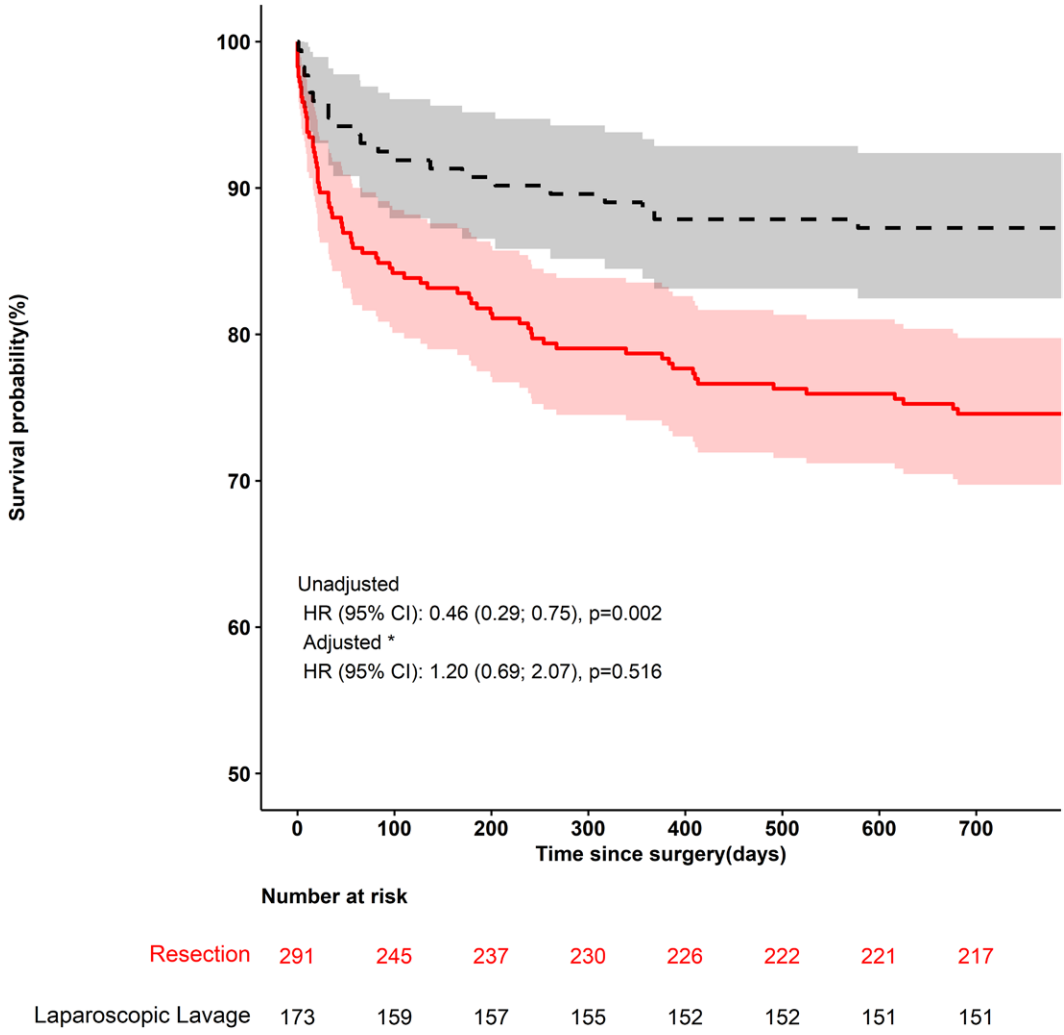

FIGURE 2. Kaplan–Meier graph of 2-year mortality.

vary between 20% and 45%.[7–9] Laparoscopic lavage has even been suggested as a "bridge to elective resection" surgery.[26] In our study, 27% of patients in the lavage group underwent resection within 2 years in routine care. This percentage could be expected to rise somewhat with an even longer follow-up time. However, as the majority have not been resected, it would be logical to see laparoscopic lavage as a definitive treatment, with resection performed in selected cases during planned follow-up. Our findings regarding the shorter length of hospital stays and the lower proportion of patients with a remaining stoma at 2 years are consistent with the results of 2 of 3 RCTs and a previous national registry study that showed laparoscopic lavage is cost-effective from a societal and a healthcare perspective.[24,25,27]

In this cohort, the difference in mortality between the 2 groups is likely due to residual confounding factors, possibly with the trauma of the peritonitis and surgery as an accelerating factor. However, mortality was not the primary outcome, and the sample size was not calculated for this endpoint. Finally, colorectal cancers were more uncommon than expected,[28] 2% in the resection group and 4% in the lavage group. Whether it is preferable to remove potential tumors directly in the acute setting or wait until follow-up and planned oncological surgery is still under debate. Data from acute malignant bowel obstruction suggest improved oncologic results if the emergency situation is deferred to an elective surgical procedure.[29] The important message is to include a colonoscopy in the work-up of all patients, and in particular after laparoscopic lavage treatment of Hinchey grade III.

Altogether, our findings contribute valuable real-world evidence from routine care, without the effects of participation in a trial. Resection via Hartmann's procedure remains the most common treatment for purulent peritonitis Hinchey grade III, and perhaps more surprising, the method of choice in more co-morbid and older patients. One could argue that resection may not be the preferred method, as our and previous data indicate a higher risk of postoperative complications and additional surgery.[14] Resection also renders patients with a higher risk of stoma. Less traumatic surgery with a reduced risk of additional surgical intervention should be beneficial for frail and elderly patients.

A strength of our study is the access to a large national, population-based cohort without selection bias identified through the use of The Swedish Patient Register. The registry has a high validity,[30] and we were able to retrieve the original patient documentation for >99% of the study population. This affords the study high external validity and the results possible to generalize. A limitation is the retrospective and nonrandomized design of the study. This reduces the ability to draw causal conclusions although this is mitigated in part by using propensity score weighting. Based on our power calculation, we needed 1000 patients to reach 80% power to detect a reduction of additional surgeries. This number was not reached as the condition was less common than anticipated. However, the 2 group sizes were more even due to a smaller patient distribution ratio between laparoscopic lavage and resection, therefore, this is somewhat balanced.

CONCLUSIONS

Laparoscopic lavage is feasible, safe, and effective in Swedish routine care in the treatment of diverticulitis Hinchey grade III. Resection surgery after lavage should be considered in selected cases only based on individual evaluation during follow-up.

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