

Diverticular disease: diagnosis and management

**[M] Evidence review for primary versus
secondary anastomosis (timing of anastomosis)
in complicated acute diverticulitis**

NICE guideline NG147

Intervention evidence review

November 2019

Final

*This evidence review was developed by
the National Guideline Centre*

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ISBN: 978-1-4731-3603-8

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1 Management of acute diverticulitis

1.1 Review question: What is the most appropriate time of anastomosis in people with complicated acute diverticulitis?

1.2 Introduction

Over the last decade, there have been marked changes in the surgical management of patients with complications of acute complicated diverticular disease. Resections are now frequently undertaken laparoscopically with the use of laparoscopic lavage in the emergency setting. The thresholds for elective resection after recurrent episodes of acute diverticulitis have changed with a greater focus on tailored decision making with the patient. There have been alterations to the threshold for primary anastomosis especially in the emergency setting. This review of the evidence aimed to provide information for both clinicians and patient on what were the clinically and cost effective surgical approaches to the management of acute complicated diverticular disease.

1.3 PICO table

For full details see the review protocol in appendix A.

Table 1: PICO characteristics of review question

| | |
|----------------------|---|
| Population | Adults 18 years and over with complicated acute diverticulitis |
| Interventions | Primary anastomosis Temporary stoma Permanent stoma |
| Comparisons | Compared to each other |
| Outcomes | <p>Critical outcomes:</p> <ul style="list-style-type: none"> • Quality of life • Mortality • Morbidity • Progression of disease • Complications: <ul style="list-style-type: none"> ○ infections ○ abscesses ○ perforation ○ fistula ○ stricture • Recurrence rates of acute diverticulitis • Hospitalisation • Need for further surgery • Anastomotic leak • Stoma complications <p>Important outcomes: Symptom control/recurrence, for example pain relief, bowel habit</p> |
| Study design | Randomised controlled trials (RCTs), systematic reviews of RCTs. |

If no RCT evidence is available, search for observational studies.

1.4 Clinical evidence

1.4.1 Included studies

Twenty-seven studies were included in the review;^{8-10, 12, 14, 17, 27, 29, 32, 34, 35, 42, 47, 49, 52, 53, 56, 59, 61, 64-71} these are summarised in Table 2 below. Evidence from these studies is summarised in the clinical evidence summaries below (Table 3 and 4).

Although three RCTs were identified and included in the review, observational studies were also included as the RCTs did not cover all of the critical outcomes listed in the protocol. The majority of the included studies compared primary anastomosis (with or without a protective stoma) with Hartmann's procedure, which involves the creation of a stoma at initial operation and subsequent secondary anastomosis at a stoma reversal operation where possible.

Outcomes from observational studies that had adjusted for potential confounders were presented separately to outcomes from those that had not adjusted for confounders.

See also the study selection flow chart in appendix C, study evidence tables in appendix D, forest plots in appendix E and GRADE tables in appendix F.

1.4.2 Excluded studies

See the excluded studies list in appendix I.

1.4.3 Summary of clinical studies included in the evidence review

Table 2: Summary of studies included in the evidence review

| Study | Intervention and comparison | Population | Outcomes | Concomitant treatment | Patient selection for intervention |
|---|--|---|---|--|------------------------------------|
| Binda 2012 ⁹ RCT N=90 | <p>Primary anastomosis: Left colon resection with primary anastomosis and loop ileostomy. Ileostomy reversal performed with trephine incision.</p> <p>Temporary stoma: Nonrestorative colon resection - left colon resection with end colostomy. Reversal of colostomy performed by laparotomy or laparoscopy.</p> | <p>Patients aged 18 years and over undergoing emergency operation for peritonitis secondary to perforated diverticulitis of the left colon.</p> <p>Diagnosis by clinical examination, plain X-ray and CT scan</p> | <p>Mortality</p> <p>Morbidity</p> <p>Complications (infections)</p> <p>Anastomotic leak</p> | <p>All patients received intravenous antibiotics and deep vein thrombosis prophylaxis prior to surgery. Intraoperative lavage of peritoneal cavity also performed.</p> | <p>Randomised</p> |
| DIVERTI trial: Bridoux 2017 ¹⁴ RCT N=102 | <p>Primary anastomosis: Primary anastomosis with or without protective stoma. Stoma reversal operations performed at least three months after first operation.</p> <p>Temporary stoma: Hartmann's procedure. Consisted of sigmoid resection, rectal closure and end colostomy.</p> | <p>Patients aged 18 years and over undergoing emergency operation for perforated diverticulitis of the left colon with faecal or purulent peritonitis (Hinchey stages III and IV).</p> <p>Diagnosis by clinical examination and CT scan</p> | <p>Mortality</p> <p>Morbidity</p> <p>Complications (abscesses)</p> <p>Complications (stricture)</p> <p>Need for further surgery</p> <p>Anastomotic leak</p> | <p>Primary anastomosis: Decisions to clean colon intraoperatively, to place a drain, and to perform ileostomy or colostomy were at discretion of surgeon. Not all patients had a protective stoma.</p> | <p>Randomised</p> |

| Study | Intervention and comparison | Population | Outcomes | Concomitant treatment | Patient selection for intervention |
|---|---|--|---|--|--|
| | Stoma reversal operation at least 6 months after Hartmann's procedure by laparotomy or laparoscopy. | | | | |
| Oberkofler 2012 ⁵³ RCT N=62 | <p>Primary anastomosis: Surgical resection of sigmoid colon with primary anastomosis and a diverting ileostomy. Stoma reversal operation set to take place up to 3 months after first operation.</p> <p>Temporary stoma: Hartmann's procedure. Surgical resection of the sigmoid colon with closure of the rectal stump and formation of an end colostomy. Stoma reversal operation planned at later stage.</p> | <p>Patients aged 18 years and over undergoing surgery for perforated diverticulitis with faecal or purulent peritonitis (Hinchey stages III and IV).</p> <p>Diagnosis by computed tomography and/or clinical and radiography evidence.</p> | <p>Mortality</p> <p>Morbidity</p> <p>Complications (infections): wound, intra-abdominal, urinary tract reported separately.</p> <p>Need for further surgery</p> <p>Anastomotic leak</p> <p>Stoma complications</p> <p>Extracted separately for initial and reversal operations.</p> | Decisions to take down splenic flexure or clean colon intraoperatively made individually by surgeons. | Randomised |
| Belmonte 1996 ⁸ Non-randomised retrospective N=227 | <p>Primary anastomosis: Primary anastomosis with or without diverting ileostomy.</p> <p>Intraoperative lavage used selectively in patients with no or poor bowel preparation to allow anastomosis and avoid colostomy.</p> | <p>Patients aged 18 years or over undergoing surgery for diverticular disease. Extracted data for those with pericolic or mesenteric abscess, pelvic abscess, or faecal or purulent peritonitis.</p> <p>Method of diagnosis</p> | Mortality | <p>All patients received perioperative intravenous broad spectrum antibiotics.</p> <p>Patients not undergoing emergency or urgent surgery underwent mechanical bowel preparation prior to surgery.</p> <p>Percutaneous drainage of</p> | <p>Surgeon selected type of operation based on condition of patient, status of abdomen, blood supply of bowel, completeness of bowel preparation and experience of operating team.</p> <p>No data to compare age or other prognostic factors</p> |

| Study | Intervention and comparison | Population | Outcomes | Concomitant treatment | Patient selection for intervention |
|--|---|--|---|----------------------------------|--|
| | Temporary stoma: Hartmann's procedure. | unclear – operative and pathological findings used to classify patients | | abscess performed in 2 patients. | between the two interventions. Majority of those with faecal/purulent peritonitis underwent HP. |
| Binda 1993 ¹⁰ Non-randomised retrospective N=92 | Primary anastomosis: Resection with immediate anastomosis with/without colostomy. Temporary stoma: Hartmann's procedure. | Patients aged 18 years or over undergoing emergency surgery for complicated colonic diverticulitis - surgery within 48 h of hospitalisation. Includes those with localised or diffuse peritonitis. Method of diagnosis not stated. | Mortality Morbidity Complications (infections) Complications (fistula) | Not reported. | Method of assignment not reported – likely to have been selected by surgeon based on severity of disease and condition of patients. No data to compare age between the two interventions. Higher proportion of diffuse peritonitis in HP group compared with PA group (81 vs. 28%). |
| Blair 2002 ¹² Non-randomised retrospective N=97 | Primary anastomosis: Primary anastomosis with/without proximal protective stoma. No patients had on-table colonic lavage. Temporary stoma: Hartmann's procedure. | Patients aged 18 years or over undergoing emergency surgery for complicated acute diverticulitis - surgery within 48 h of hospitalisation. Method of diagnosis not stated. | Mortality Complications (infections) Hospitalisation Anastomotic leak | Not reported. | Type of operation decided upon by surgeon. Median age: lower in PA group compared with HP group (54±14.8 vs. 64.6±15.7 years). Proportion over 70 years of age: higher in HP group compared with PA group (49% vs. 17%). Higher proportion of ASA III and IV score patients in HP group compared with PA group (65.6% vs. |

| Study | Intervention and comparison | Population | Outcomes | Concomitant treatment | Patient selection for intervention |
|---|--|--|---|-----------------------|---|
| | | | | | 30.3%). Higher proportion of Hinchey stages III and IV in HP group compared with PA group (50.8% vs. 27.3%) |
| Cauley 2018 ¹⁷ Non-randomised retrospective N=67,721 | Primary anastomosis: Colectomy with primary anastomosis and proximal diverting ileostomy. Temporary stoma: Colectomy with end colostomy. | Patients aged 18 years or over undergoing emergency or urgent surgery for acute diverticulitis - surgery on first or second day of admission. Method of diagnosis not stated. | Mortality Morbidity Complications (infections) | Not reported. | Method of assignment not reported – likely to have been selected by surgeon based on severity of disease and condition of patients. Higher proportion of those aged 80 years or over in the PA with DI group compared with end colostomy group (28.8% vs. 15.9%). Higher proportion of those with Charlson comorbidity score of 2+ in PA with DI group compared with end colostomy group (28.9% vs. 19.7%). |
| Gawlick 2012 ²⁷ Non-randomised retrospective N=2,018 | Primary anastomosis: Partial colectomy with primary anastomosis and proximal diversion with loop ileostomy. Temporary stoma: Hartmann's procedure - partial colectomy with colostomy. | Patients aged 18 years or over undergoing emergency surgery for perforated diverticulitis. Method of diagnosis not stated. | Mortality Complications (infections) Need for further surgery | Not reported. | Method of assignment not reported – likely to have been selected by surgeon based on severity of disease and condition of patients. Age, comorbidities and ASA scores similar between the two groups. |

| Study | Intervention and comparison | Population | Outcomes | Concomitant treatment | Patient selection for intervention |
|--|---|--|---|-----------------------|--|
| | | | | | Higher proportion of those with severe preoperative sepsis in HP group compared with PA group (5.6% vs. 2.4%). |
| Gooszen 2001 ²⁹ Non-randomised retrospective N=60 | Primary anastomosis: Acute sigmoid resection followed by primary anastomosis covered by a defunctioning stoma (7 loop ileostomy and 25 transverse colostomy). Temporary stoma: Hartmann's procedure. | Patients aged 18 years or over undergoing urgent surgery for acute complications of diverticular disease within 24 hours of admission (pericolic abscess, walled-off pelvic abscess, generalised purulent peritonitis or faecal peritonitis). Method of diagnosis not stated. | Mortality Complications (infections) Complications (abscesses) Need for further surgery Anastomotic leak Stoma complications | Not reported. | Surgeon decided which intervention patients received – surgeon preference and not based on intraoperative findings such as degree of faecal contamination or severity of peritonitis. Mean age similar between two interventions. Higher proportion of those with diffuse faecal contamination in HP group compared with PA group (21.4% vs. 6.25%). |
| Gregg 1987 ³² Non-randomised retrospective N=208 | Primary anastomosis: Combined one-stage and resection, primary anastomosis and temporary transverse colostomy groups reported in this study. Temporary stoma: Hartmann's procedure | Patients aged 18 years or over undergoing emergency surgery for complications of diverticular disease – at admission or after failure of medical therapy. Diagnosis by flat films, contrast radiography, | Mortality | Not reported. | Method of assignment not reported – likely to have been selected by surgeon based on severity of disease and condition of patients. No data to compare age or other prognostic factors between the two interventions. |

| Study | Intervention and comparison | Population | Outcomes | Concomitant treatment | Patient selection for intervention |
|---|--|---|---|---|---|
| | | ultrasonography and/or computerised axial tomography. | | | |
| Herzog 2011 ³⁴ Non-randomised retrospective N=40 | <p>Primary anastomosis: Midline laparotomy. Primary anastomosis with/without diverting ileostomy. Ileostomy performed in those with MP scores >21 (n=7).</p> <p>Temporary stoma: Hartmann's procedure. Performed in all cases of faecal peritonitis, severe comorbidity, need for high dose catecholamine or multiple organ failure. Surgeon free to choose between primary anastomosis and Hartmann's in other cases of peritonitis.</p> | <p>Patients aged 18 years or over undergoing emergency surgery due to complicated diverticulitis (perforation, abscess with sepsis, local or diffuse peritonitis, ileus secondary to recent diverticulitis episodes or haemorrhage).</p> <p>Triple contrast CT scan performed on admission.</p> | <p>Mortality</p> <p>Morbidity</p> <p>Complications (infections)</p> <p>Complications (abscesses)</p> <p>Need for further surgery</p> <p>Anastomotic leak</p> <p>Stoma complications</p> | <p>All patients received systemic antibiotics including metronidazole and a third generation cephalosporin before laparotomy.</p> <p>Depending on degree of peritonitis, patients received a combination of sulbactam and ceftazidime or a carbapenem unless change indicated by sensitivity of identified microorganisms.</p> <p>All patients had abdominal lavage with at least 5 litres of warm saline solution.</p> <p>Treatment of peritonitis included clearance of pus, faeces, exudates and as much debris and pseudomembranous material as possible.</p> | <p>Type of operation selected by surgeon depending on patient condition – Hartmann's performed in presence of faecal peritonitis, severe comorbidity, need for high dose catecholamine or multiple organ failure. In other cases surgeon free to choose.</p> <p>Mean age similar between groups.</p> <p>Proportion >65 years higher in HP group compared with PA group.</p> <p>Higher proportion of patients with comorbidity in HP group compared with PA group.</p> <p>Higher proportion of patients with MPI score >21 in HP group compared with PA group.</p> |
| Hold 1990 ³⁵ Non-randomised retrospective N=241 | <p>Primary anastomosis: Primary resection and anastomosis with/without protective proximal colostomy</p> <p>Temporary stoma:</p> | <p>Patients aged 18 years or over undergoing emergency surgery for perforated diverticulitis (walled-off perforation with peritonitis, localised peritonitis and diffuse peritonitis).</p> | <p>Mortality</p> <p>Morbidity</p> <p>Anastomotic leak</p> | Not reported. | <p>Method of assignment not reported – likely to have been selected by surgeon based on severity of disease and condition of patients.</p> <p>No data to compare age or</p> |

| Study | Intervention and comparison | Population | Outcomes | Concomitant treatment | Patient selection for intervention |
|--|--|---|--|--|--|
| | Hartmann's procedure - primary resection with end colostomy. | Diagnostic procedures included plain abdominal film, enema with water-soluble contrast media, colonoscopy and/or computed tomography. | | | other prognostic factors between the two interventions. |
| Kriwanek 1994 ⁴² Non-randomised retrospective N=112 | Primary anastomosis: When extracting, combined primary anastomosis and primary anastomosis with stoma groups reported in this study. Temporary stoma: Hartmann's procedure. | Patients aged 18 years or over undergoing surgery for perforated diverticulitis. Method of diagnosis not stated. | Mortality | Not reported. | Method of assignment not reported – likely to have been selected by surgeon based on severity of disease and condition of patients. No data to compare age or other prognostic factors between the two interventions. |
| Medina 1991 ⁴⁷ Non-randomised retrospective N=6 | Primary anastomosis: Primary resection and immediate anastomosis. Temporary stoma: Hartmann's procedure with terminal colostomy. | Patients aged 18 years or over undergoing emergency surgery for faecal peritonitis secondary to perforated diverticular disease (Hinchey stage IV). Diagnosis by clinical findings and symptoms. Radiology also mentioned. | Mortality Complications (abscesses) | Resuscitative measures established for all patients prior to surgery (administration of supplemental oxygen, insertion of large-bore intravenous catheters). Balanced salt solution (e.g. Ringer's Lactate) given intravenously and titrated according to vital signs and urine output. Patients underwent copious peritoneal lavage with warm saline at | Method of assignment not reported – likely to have been selected by surgeon based on severity of disease and condition of patients. Mean age higher in the HP group compared with the PA group (78.7 vs. 63.7 years). No data to compare other prognostic factors between the two interventions. |

| Study | Intervention and comparison | Population | Outcomes | Concomitant treatment | Patient selection for intervention |
|--|---|---|---|--|--|
| Mueller 2011 ⁴⁹ Non-randomised retrospective N=73 | <p>Primary anastomosis: Sigmoid colectomy and primary anastomosis with/without diverting loop ileostomy.</p> <p>Temporary stoma: Hartmann's procedure.</p> | <p>Patients aged 18 years or over undergoing emergency surgery for perforated diverticulitis (Hinchey stages I-IV). Perforation confirmed by X-ray or CT scan prior to surgery.</p> | <p>Mortality</p> <p>Morbidity</p> <p>Complications (infections)</p> <p>Complications (abscesses)</p> <p>Anastomotic leak</p> <p>Stoma complications</p> | <p>completion of procedure.</p> <p>Not reported.</p> | <p>Method of assignment not reported – likely to have been selected by surgeon based on severity of disease and condition of patients.</p> <p>Mean age similar between the two groups.</p> <p>Proportion of patients with ASA III and IV scores higher in HP group compare with PA group (76% vs. 31%).</p> <p>Proportion of Hinchey stage III and IV patients higher in HP group compared with PA group (46% vs. 4%).</p> <p>Comorbidity higher in HP group compared with PA group.</p> |
| Netri 2000 ⁵² Non-randomised retrospective N=239 | <p>Primary anastomosis: Resection with immediate anastomosis with or without a protective colostomy.</p> <p>Temporary stoma: Hartmann's procedure with stoma.</p> | <p>Patients aged 18 years or over undergoing emergency surgery for acute diverticulitis with signs of generalised or localised peritonitis</p> <p>Clinical evaluation, blood tests and ECG performed. Upright abdominal radiographs most utilised visual diagnostic test.</p> | <p>Mortality</p> | <p>All patients received antibiotic and infusion therapy prior to surgery.</p> | <p>Surgeon selected type of operation performed based on severity of disease and patient condition.</p> <p>No data to compare age or other prognostic factors between the two interventions.</p> |

| Study | Intervention and comparison | Population | Outcomes | Concomitant treatment | Patient selection for intervention |
|---|---|--|--|---|---|
| | | Abdominal ultrasound reserved for clarifying uncertain diagnoses. | | | |
| Pasternak 2010 ⁵⁶ Non-randomised retrospective N=111 | Primary anastomosis: Primary anastomosis with/without loop ileostomy. Surgeon decided whether a protective loop ileostomy was necessary in each patient depending on the quality of the anastomosis. Temporary stoma: Hartmann's procedure with stoma. | Patients aged 18 years or over undergoing emergency surgery within 6 h of decision to operate for perforated diverticulitis of left colon. Diagnosis by clinical evaluation and/or X-rays or triple contrast CT scan. | Mortality Morbidity Complications (abscesses) Need for further surgery Anastomotic leak Stoma complications | Primary anastomosis: Intraoperative colonic lavage only performed in cases where a protective loop ileostomy was considered. | Surgeon selected type of operation performed based on severity of peritonitis and grade of abdominal contamination, comorbidities, and general condition of the patient. Age similar between the two groups. Proportion of patients with immunosuppression higher in HP group compared with PA group (33.8% vs. 4.3%). Higher proportion of Hinchey stage III and IV patients in HP group compared with PA group (73.9% vs. 26.1%). Higher mean MPI in HP compared with PA group (21.2 vs. 13.9). |
| Richter 2006 ⁵⁹ Non-randomised retrospective N=41 | Primary anastomosis: One-stage sigmoid resection and primary anastomosis with/without protective ileostomy. Temporary stoma: Hartmann's procedure. | Patients aged 18 years or over undergoing emergency surgery for complicated sigmoid diverticulitis (Hinchey stages III and IV). All patients underwent triple contrast CT scan. | Mortality Anastomotic leak | Treatment of peritonitis comprised the use of 30 litres of warm Ringer's lactate for abdominal lavage to dilute the bacterial load of the abdominal cavity and postoperative antibiotic | Surgeon selected type of operation performed based on clinical condition of patient – Hartmann's performed in critically ill patients where anastomotic healing was considered doubtful. |

| Study | Intervention and comparison | Population | Outcomes | Concomitant treatment | Patient selection for intervention |
|--|--|--|---|---|---|
| | | | | therapy that was maintained for at least 5 days. | Higher mean MPI in HP compared with PA group (35 vs. 18.4). No data to compare age or other prognostic factors between the two interventions. |
| Schilling 2001 ⁶¹ Non-randomised retrospective N=55 | Primary anastomosis: One-stage sigmoid colon resection and primary anastomosis without protective colostomy. Temporary stoma: Primary sigmoid colon resection, Hartmann's procedure and descending colostomy. | Patients aged 18 years or over undergoing emergency surgery for perforated diverticulitis with peritonitis. Method of diagnosis not stated. | Mortality Morbidity Stoma complications | Extensive abdominal lavage with at least 20 litres of warm (37°C) ringers lactate solution performed in all patients. | Method of assignment not reported – likely to have been selected by surgeon based on severity of disease and condition of patients. Mean age similar between the two groups. ASA and MPI at admission similar between the two groups. Higher proportion of patients with diffuse peritonitis in HP group compared with PA group (61.9% vs. 46.1%). |
| Stumpf 2007 ⁶⁴ Non-randomised retrospective N=66 | Primary anastomosis: No further details given. Temporary stoma: Hartmann's procedure with stoma. | Patients aged 18 years or over undergoing emergency surgery within same hospital admission for complications of left-sided diverticulitis (perforation, peritoneal signs, abscess, | Mortality Morbidity Complications (infections) Complications (abscesses) Need for further surgery | Most surgeons performed mini colonic lavage with saline. Seven patients were able to be prepped the night before the operation as they were operated on due to failure of medical therapy | Method of assignment not reported – likely to have been selected by surgeon based on severity of disease and condition of patients. Proportion of patients >80 years of age similar between groups. |

| Study | Intervention and comparison | Population | Outcomes | Concomitant treatment | Patient selection for intervention |
|---|---|--|---|--|---|
| | | obstruction or failure of medical therapy). Method of diagnosis unclear – may have been confirmed in operation | Anastomotic leak | | Higher proportion of patients with comorbidity in HP group compared with PA group (83.3% vs. 58.3%). Higher proportion of patients with ASA score >3 in HP group compared with PA group (23.3% vs. 5.6%). Higher proportion of patients with ASA score >2 in HP group compared with PA group (50% vs. 16.6%). |
| Thaler 2000 ⁶⁵ Non-randomised retrospective N=82 | Primary anastomosis: One-stage primary sigmoid resection with primary anastomosis. No protective stomas were employed. Temporary stoma: Primary sigmoid resection with Hartmann's procedure. | Patients aged 18 years or over undergoing emergency surgery for perforated sigmoid diverticulitis with generalised peritonitis. Method of diagnosis not stated. | Mortality Morbidity | Broad spectrum antibiotics routinely administered in all patients starting preoperatively and given for at least 7 days after surgery. | Surgeons selected type of operation performed based on MPI and ASA classification of each patient. Mean age similar between the two groups. Higher proportion of ASA IV/V in HP group compared with PA group (71% vs. 35%). MPI score higher in HP group compared with PA group (23 vs. 18). |
| Trenti 2011 ⁶⁶ Non-randomised retrospective N=87 | Primary anastomosis: Resection of affected bowel segment with primary anastomosis, with or without protective | Patients aged 18 years or over undergoing emergency surgery for diverticular peritonitis (Hinchey stages III and | Mortality Morbidity Complications (infections) Complications | All patients were treated with an extensive intraabdominal lavage with warm saline solution and post-operative antibiotic | Method of assignment not reported – likely to have been selected by surgeon based on severity of disease and condition of |

| Study | Intervention and comparison | Population | Outcomes | Concomitant treatment | Patient selection for intervention |
|--|---|---|--|--|---|
| | <p>stoma (derivative ileostomy).</p> <p>Temporary stoma: Hartmann's procedure.</p> | <p>IV).</p> <p>Method of diagnosis not stated.</p> | <p>(abscesses)</p> <p>Need for further surgery</p> <p>Anastomotic leak</p> | <p>therapy for at least 14 days.</p> <p>All patients underwent the same postoperative care in the intensive care unit and in the ward with the same team of physicians.</p> <p>From 2007 onwards, only patients undergoing primary anastomosis with protective ileostomy received intraoperative colonic lavage.</p> | <p>patients.</p> <p>Mean age higher in HP group compared with PA group (69.7 vs. 58.1 years).</p> <p>Higher proportion of ASA score III and IV patients in HP group compared with PA group (80% vs. 18.5%).</p> <p>Higher proportion of Hinchey stage IV in HP group compared with PA group (23.3% vs. 3.7%).</p> |
| <p>Tucci 1996⁶⁷</p> <p>Non-randomised retrospective</p> <p>N=43</p> | <p>Primary anastomosis: Resection and primary anastomosis with/without stoma.</p> <p>Temporary stoma: Hartmann's procedure.</p> | <p>Patients aged 18 years or over undergoing urgent or emergency surgery for perforated diverticular disease (Hinchey stages I-IV).</p> <p>Acute condition or following failure of medical therapy.</p> <p>Method of diagnosis unclear – operative and pathological reports used to determine degree of peritoneal contamination.</p> | <p>Mortality</p> | <p>Not reported.</p> | <p>Method of assignment not reported – likely to have been selected by surgeon based on severity of disease and condition of patients.</p> <p>Higher proportion of Hinchey stages III and IV patients in HP group compared with PA group (87.5% vs. 4.2%).</p> <p>No data to compare age or other prognostic factors between the two interventions.</p> |
| <p>Tudor 1994⁶⁸</p> <p>Non-randomised</p> | <p>Primary anastomosis: Resection with primary anastomosis with or</p> | <p>Patients aged 18 years or over undergoing emergency surgery for</p> | <p>Mortality</p> | <p>Primary anastomosis: On-table colonic lavage performed in some of</p> | <p>Method of assignment not reported – likely to have been selected by surgeon</p> |

| Study | Intervention and comparison | Population | Outcomes | Concomitant treatment | Patient selection for intervention |
|---|--|---|---|--|--|
| prospective N=300 | without a stoma. Temporary stoma: Hartmann's procedure. | complications of diverticular disease (acute phlegmon, peircolic abscess, purulent peritonitis, faecal peritonitis, bowel obstruction and fistula). Method of diagnosis unclear – mentions use of clinical features, ultrasonography, confirmation at surgery and radiology for various complications. | | these patients. Preoperative percutaneous drainage in certain cases of abscess and purulent peritonitis was performed. | based on severity of disease and condition of patients. No data to compare age or other prognostic factors between the two interventions. |
| Vermeulen 2007 ⁶⁹ Non-randomised prospective N=200 | Primary anastomosis: Primary anastomosis with/without diverting ileostomy. Colon resections consisted of sigmoid resection, left hemicolectomy or anterior resection. Temporary stoma: Hartmann's procedure with stoma. | Patients aged 18 years or over undergoing surgery acute perforated sigmoid diverticulitis (Hinchey stages I-IV). Diagnosis based on clinical signs of diffuse peritonitis with acute abdominal pain, free gas on plain abdominal radiography or specific findings at ultrasonography or computerised tomography. | Mortality Need for further surgery Anastomotic leak | All patients received preoperative and postoperative broad-spectrum intravenous antibiotics. Preoperative bowel preparation was not used in any patients. | Surgeon selected which operation was performed in each patient. Higher mean age in HP group compared with PA group (69 vs. 62). Higher proportion of patients with Hinchey stages III and IV in HP group compared with PA group (68.3% vs. 42.6%). Higher proportion of patients with ASA scores III and IV in HP group compared with PA group (59.7% vs. 41%). Higher MPI in HP group compared with PA group (21 vs. 17). |

| Study | Intervention and comparison | Population | Outcomes | Concomitant treatment | Patient selection for intervention |
|--|--|---|---|-----------------------|--|
| Vermeulen 2010 and 2011 ^{70, 71} Non-randomised retrospective N=340 | <p>Primary anastomosis May include some with and some without loop ileostomy. Not all of those with loop ileostomy had it reversed.</p> <p>Temporary stoma: Hartmann's procedure with stoma. Not all stomas were reversed.</p> | <p>Patients aged 18 and over undergoing emergency surgery for perforated diverticulitis (Hinchey stages I-IV).</p> <p>Diagnosis based on clinical signs, radiography and/or CT scans.</p> | <p>Quality of life</p> <p>Mortality</p> <p>Need for further surgery</p> | Not reported. | <p>Surgeon selected which operation was performed in each patient.</p> <p>Median age similar between groups.</p> <p>Higher proportion of patients with ASA grades III or IV in HP group compared with PA group (47% vs. 25%).</p> <p>Higher proportion of patients with Hinchey III or IV scores in HP group compared with PA group (64% vs. 34%).</p> |

See appendix D for full evidence tables.

1.4.4 Quality assessment of clinical studies included in the evidence review

Table 3: Clinical evidence summary: Primary anastomosis vs. temporary stoma - RCTs

| Outcomes | No of Participants (studies) Follow up | Quality of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | |
|------------------------------------|--|---------------------------------|--------------------------|------------------------------|---|
| | | | | Risk with temporary stoma | Risk difference with Primary anastomosis (95% CI) |
| Anastomotic leak (first operation) | 254 (3 studies) | ⊕⊖⊖⊖ VERY LOW ^{b,c} | OR 4.24 (0.71 to | 7 per 1000 | 27 more per 1000 (from 8 fewer to 63 |

| Outcomes | No of Participants (studies) Follow up | Quality of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | |
|--|--|--|--------------------------|------------------------------|---|
| | | | | Risk with temporary stoma | Risk difference with Primary anastomosis (95% CI) |
| | | due to risk of bias, imprecision | 25.21) | | more) ^a |
| Anastomotic leak (second operation) | 162 (3 studies) | ⊕⊖⊖⊖ VERY LOW ^{b,c,d} due to risk of bias, inconsistency, imprecision | RR 0.6 (0.16 to 2.24) | 49 per 1000 | 24 fewer per 1000 (from 82 fewer to 34 more) ^a |
| Complications - deep incisional surgical site infections (first operation) | 90 (1 study) | ⊕⊖⊖⊖ VERY LOW ^{b,c} due to risk of bias, imprecision | RR 1.1 (0.43 to 2.81) | Moderate | |
| | | | | 161 per 1000 | 16 more per 1000 (from 92 fewer to 291 more) |
| Complications - deep incisional surgical site infections (second operation) | 56 (1 study) | ⊕⊖⊖⊖ VERY LOW ^{b,c} due to risk of bias, imprecision | OR 0.18 (0.02 to 1.92) | Moderate | |
| | | | | 88 per 1000 | 88 fewer per 1000 (from 204 fewer to 28 more) ^a |
| Complications - organ space site infections (first operation) | 90 (1 study) | ⊕⊖⊖⊖ VERY LOW ^{b,c} due to risk of bias, imprecision | OR 0.18 (0.03 to 1) | Moderate | |
| | | | | 107 per 1000 | 107 fewer per 1000 (from 199 fewer to 16 more) ^a |
| Complications - organ space site infections (second operation) | 56 (1 study) | ⊕⊖⊖⊖ VERY LOW ^{b,c} due to risk of bias, imprecision | OR 0.19 (0 to 10.66) | Moderate | |
| | | | | 29 per 1000 | 29 fewer per 1000 (from 119 fewer to 60 more) ^a |
| Complications - superficial incisional surgical site infections (first operation) | 90 (1 study) | ⊕⊖⊖⊖ VERY LOW ^{b,c} due to risk of bias, imprecision | RR 1.35 (0.62 to 2.91) | Moderate | |
| | | | | 196 per 1000 | 69 more per 1000 (from 74 fewer to 374 more) |
| Complications - superficial incisional surgical site infections (second operation) | 56 (1 study) | ⊕⊖⊖⊖ VERY LOW ^{b,c} | OR 0.17 (0.03 to | Moderate | |
| | | | | 147 per | 147 fewer per 1000 |

| Outcomes | No of Participants (studies) Follow up | Quality of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | |
|---|--|--|--------------------------|------------------------------|---|
| | | | | Risk with temporary stoma | Risk difference with Primary anastomosis (95% CI) |
| | | due to risk of bias, imprecision | 1.09) | 1000 | (from 282 fewer to 13 more) ^a |
| Complications - urinary tract infections (first operation) | 152 (2 studies) | ⊕⊖⊖⊖ VERY LOW ^{b,c,e} due to risk of bias, inconsistency, imprecision | RR 0.98 (0.09 to 11.24) | 47 per 1000 | 1 fewer per 1000 (from 68 fewer to 66 more) ^a |
| Complications - urinary tract infections (second operation) | 97 (2 studies) | ⊕⊖⊖⊖ VERY LOW ^{b,c} due to risk of bias, imprecision | RD 0 (-0.06 to 0.06) | Moderate 0 per 1000 | 0 fewer per 1000 (from 60 fewer to 60 more) ^f |
| Overall morbidity (first operation) | 254 (3 studies) | ⊕⊖⊖⊖ VERY LOW ^{b,c,g} due to risk of bias, inconsistency, imprecision | RR 1.24 (0.77 to 1.99) | Moderate 423 per 1000 | 102 more per 1000 (from 97 fewer to 419 more) |
| Overall morbidity (second operation) | 121 (2 studies) | ⊕⊖⊖⊖ VERY LOW ^{b,c} due to risk of bias, imprecision | RR 0.32 (0.12 to 0.85) | Moderate 283 per 1000 | 192 fewer per 1000 (from 42 fewer to 249 fewer) |
| Mortality (first operation) | 254 (3 studies) | ⊕⊖⊖⊖ VERY LOW ^{b,c} due to risk of bias, imprecision | RR 0.58 (0.22 to 1.55) | Moderate 107 per 1000 | 45 fewer per 1000 (from 83 fewer to 59 more) |
| Mortality (second operation) | 162 (3 studies) | ⊕⊖⊖⊖ VERY LOW ^{b,i} due to risk of bias, imprecision | RD -0.03 (-0.08 to 0.03) | 24 per 1000 | 30 fewer per 1000 (from 80 fewer to 30 more) ^h |
| Complications - intra-abdominal abscess (first operation) | 102 | ⊕⊖⊖⊖ | RR 0.52 | Moderate | |

| Outcomes | No of Participants (studies) Follow up | Quality of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | |
|--|--|--|--------------------------|------------------------------|--|
| | | | | Risk with temporary stoma | Risk difference with Primary anastomosis (95% CI) |
| | (1 study) | VERY LOW ^{b,c} due to risk of bias, imprecision | (0.1 to 2.71) | 77 per 1000 | 37 fewer per 1000 (from 69 fewer to 132 more) |
| Complications - intra-abdominal abscess (second operation) | 65 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,c} due to risk of bias, imprecision | OR 0.14 (0 to 7.03) | Moderate 30 per 1000 | 30 fewer per 1000 (from 111 fewer to 50 more) ^a |
| Complications - anastomotic stricture (first operation) | 102 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,c} due to risk of bias, imprecision | OR 7.69 (0.15 to 387.87) | Moderate 0 per 1000 | 20 more per 1000 (from 33 fewer to 73 more) ^a |
| Need for further surgery - reoperation (first operation) | 102 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,c} due to risk of bias, imprecision | RR 0.52 (0.1 to 2.71) | Moderate 77 per 1000 | 37 fewer per 1000 (from 69 fewer to 132 more) |
| Need for further surgery - reoperation (second operation) | 106 (2 studies) | ⊕⊕⊕⊕ VERY LOW ^{b,c,j} due to risk of bias, inconsistency, imprecision | RR 0.31 (0.03 to 3.71) | 83 per 1000 | 66 fewer per 1000 (from 151 fewer to 19 more) ^a |
| All complications - Clavien-Dindo I-V (first operation) | 62 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,c} due to risk of bias, imprecision | OR 1.35 (0.36 to 4.99) | Moderate 800 per 1000 | 44 more per 1000 (from 210 fewer to 152 more) |
| All complications - Clavien-Dindo I-V (second operation) | 41 (1 study) | ⊕⊕⊕⊕ LOW ^b due to risk of bias | OR 5 (1.26 to 19.84) | Moderate 400 per 1000 | 369 more per 1000 (from 57 more to 530 more) |
| Intra-abdominal infection (first operation) | 62 | ⊕⊕⊕⊕ | RR 0.31 | Moderate | |

| Outcomes | No of Participants (studies) Follow up | Quality of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | |
|--|--|---|--------------------------|------------------------------|---|
| | | | | Risk with temporary stoma | Risk difference with Primary anastomosis (95% CI) |
| | (1 study) | VERY LOW ^{b,c} due to risk of bias, imprecision | (0.07 to 1.43) | 200 per 1000 | 138 fewer per 1000 (from 186 fewer to 86 more) |
| Intra-abdominal infection (second operation) | 41 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,k} due to risk of bias, imprecision | RD 0 (-0.1 to 0.1) | Moderate 0 per 1000 | 0 fewer per 1000 (from 100 fewer to 100 more) ^h |
| Wound infection (first operation) | 62 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,c} due to risk of bias, imprecision | RR 0.79 (0.42 to 1.49) | Moderate 433 per 1000 | 91 fewer per 1000 (from 251 fewer to 212 more) |
| Wound infection (second operation) | 41 (1 study) | ⊕⊕⊕⊕ VERY LOW ^b due to risk of bias, imprecision | RR 0.58 (0.13 to 2.51) | Moderate 200 per 1000 | 84 fewer per 1000 (from 174 fewer to 302 more) |
| Stoma complications (first operation) | 62 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,c} due to risk of bias, imprecision | OR 0.12 (0.01 to 1.18) | Moderate 100 per 1000 | 100 fewer per 1000 (from 219 fewer to 19 more) ^a |

^aAbsolute risk difference calculated directly from risk difference as 0 events in some arms of some studies.

^bDowngraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

^cDowngraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

^dWide variation in point estimates between studies. All studies have wide confidence intervals which may mask heterogeneity in heterogeneity statistics.

^eI² = 45% and wide variation in point estimates of studies.

^fAbsolute risk difference calculated from risk difference as 0 events in both arms of all studies.

^gVariation in point estimates of studies. I² = 67%.

^hControl group risk calculated directly as 0 events in intervention group.

ⁱSerious imprecision due to sample size >70 and <350.

^jVariation in point estimates. I² = 36%.

| Outcomes | No of Participants (studies) Follow up | Quality of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | |
|---|--|---------------------------------|--------------------------|------------------------------|---|
| | | | | Risk with temporary stoma | Risk difference with Primary anastomosis (95% CI) |
| ^k Very serious imprecision due to sample size <70. | | | | | |

Table 4: Clinical evidence summary: Primary anastomosis vs. temporary stoma – observational studies

| Outcomes | No of Participants (studies) Follow up | Quality of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | |
|--|--|--|--------------------------|------------------------------|--|
| | | | | Risk with temporary stoma | Risk difference with Primary anastomosis (95% CI) |
| Anastomotic leak (first operation) | 664 (8 studies) | ⊕⊕⊕⊕ VERY LOW ^b due to risk of bias | OR 15.41 (4.53 to 52.47) | Moderate 0 per 1000 | 79 more per 1000 (from 47 more to 110 more) ^a |
| Anastomotic leak (second operation) | 118 (3 studies) | ⊕⊕⊕⊕ VERY LOW ^{b,d} due to risk of bias, imprecision | OR 0.1 (0.02 to 0.51) | 96 per 1000 | 80 fewer per 1000 (from 190 fewer to 30 more) ^c |
| Anastomotic leak/rectal stump leak (first operation) | 111 (1 study) | ⊕⊕⊕⊕ VERY LOW ^b due to risk of bias | RR 9.18 (2.18 to 38.77) | Moderate 31 per 1000 | 254 more per 1000 (from 37 more to 1000 more) |
| Abscess (first operation) | 370 (6 studies) | ⊕⊕⊕⊕ VERY LOW ^{b,e,f} due to risk of bias, inconsistency, imprecision | RR 0.69 (0.23 to 2.03) | 107 per 1000 | 41 fewer per 1000 (from 98 fewer to 16 more) ^c |
| Abscess (second operation) | 49 | ⊕⊕⊕⊕ | RD 0 (- | Moderate | |

| Outcomes | No of Participants (studies) Follow up | Quality of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | |
|---|--|---|--------------------------|------------------------------|---|
| | | | | Risk with temporary stoma | Risk difference with Primary anastomosis (95% CI) |
| | (1 study) | VERY LOW ^{b,g} due to risk of bias, imprecision | 0.08 to 0.08) | 0 per 1000 | 0 fewer per 1000 (from 80 fewer to 80 more) ^a |
| Abscess/peritonitis (first operation) | 73 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 1.66 (0.18 to 15.16) | Moderate 39 per 1000 | 26 more per 1000 (from 32 fewer to 552 more) |
| Fistula (first operation) | 39 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | OR 6.74 (0.4 to 112.7) | Moderate 0 per 1000 | 95 more per 1000 (from 56 fewer to 246 more) ^a |
| Septic shock (first operation) | 39 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 0.17 (0.02 to 1.34) | Moderate 278 per 1000 | 231 fewer per 1000 (from 272 fewer to 95 more) |
| Wound sepsis (first operation) | 39 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 1.71 (0.17 to 17.38) | Moderate 56 per 1000 | 40 more per 1000 (from 46 fewer to 917 more) |
| Intra-abdominal infection (first operation) | 94 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 0.62 (0.07 to 5.69) | Moderate 49 per 1000 | 19 fewer per 1000 (from 46 fewer to 230 more) |
| Wound infection (first operation) | 334 | ⊕⊕⊕⊕ | RR 0.64 | Moderate | |

| Outcomes | No of Participants (studies) Follow up | Quality of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | |
|---|--|---|---------------------------|------------------------------|---|
| | | | | Risk with temporary stoma | Risk difference with Primary anastomosis (95% CI) |
| | (5 studies) | VERY LOW ^{b,f} due to risk of bias, imprecision | (0.37 to 1.12) | 154 per 1000 | 81 fewer per 1000 (from 153 fewer to 9 fewer) ^c |
| Wound infection (second operation) | 49 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 1.22 (0.22 to 6.68) | Moderate | |
| | | | | 91 per 1000 | 20 more per 1000 (from 71 fewer to 517 more) |
| Postoperative complications - infection (first operation) | 67721 (1 study) | ⊕⊕⊕⊕ VERY LOW ^b due to risk of bias | RR 1.88 (1.67 to 2.11) | Moderate | |
| | | | | 53 per 1000 | 47 more per 1000 (from 36 more to 59 more) |
| Sepsis (first operation) | 220 (3 studies) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 0.49 (0.24 to 1.01) | Moderate | |
| | | | | 214 per 1000 | 109 fewer per 1000 (from 163 fewer to 2 more) |
| Sepsis (second operation) | 49 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | OR 0.1 (0.01 to 1.72) | Moderate | |
| | | | | 91 per 1000 | 91 fewer per 1000 (from 227 fewer to 45 more) ^h |
| Urinary infection (first operation) | 100 (2 studies) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 0.22 (0.05 to 0.99) | Moderate | |
| | | | | 143 per 1000 | 112 fewer per 1000 (from 1 fewer to 136 fewer) |

| Outcomes | No of Participants (studies) Follow up | Quality of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | |
|--|--|--|--------------------------|------------------------------|---|
| | | | | Risk with temporary stoma | Risk difference with Primary anastomosis (95% CI) |
| Urinary infection (second operation) | 49 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,g} due to risk of bias, imprecision | RD 0 (-0.08 to 0.08) | Moderate 0 per 1000 | 0 fewer per 1000 (from 80 fewer to 80 more) ^a |
| Emergency readmission (first operation) | 97 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 1.08 (0.39 to 2.96) | Moderate 141 per 1000 | 11 more per 1000 (from 86 fewer to 276 more) |
| Hospital readmission (first operation) | 97 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | OR 0.21 (0.03 to 1.36) | Moderate 78 per 1000 | 78 fewer per 1000 (from 157 fewer to 1 more) ^h |
| Overall surgical morbidity (first operation) | 150 (2 studies) | ⊕⊕⊕⊕ VERY LOW ^{b,f,i} due to risk of bias, inconsistency, imprecision | RR 1.07 (0.44 to 2.61) | Moderate 338 per 1000 | 24 more per 1000 (from 189 fewer to 544 more) |
| Overall morbidity (first operation) | 68155 (5 studies) | ⊕⊕⊕⊕ VERY LOW ^{b,f,i} due to risk of bias, inconsistency, imprecision | RR 1.07 (0.75 to 1.52) | Moderate 233 per 1000 | 16 more per 1000 (from 58 fewer to 121 more) |
| Intraoperative morbidity (first operation) | 111 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 1.61 (0.63 to 4.14) | Moderate 108 per 1000 | 66 more per 1000 (from 40 fewer to 339 more) |

| Outcomes | No of Participants (studies) Follow up | Quality of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | |
|--|--|---|--------------------------|------------------------------|---|
| | | | | Risk with temporary stoma | Risk difference with Primary anastomosis (95% CI) |
| Postoperative medical morbidity (first operation) | 177 (2 studies) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 0.45 (0.24 to 0.81) | Moderate 318 per 1000 | 175 fewer per 1000 (from 60 fewer to 242 fewer) |
| Postoperative major morbidity (first and second operations combined) | 55 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 0.65 (0.08 to 5.04) | Moderate 119 per 1000 | 42 fewer per 1000 (from 109 fewer to 481 more) |
| Postoperative minor morbidity (first and second operations combined) | 55 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 1.79 (0.73 to 4.41) | Moderate 214 per 1000 | 169 more per 1000 (from 58 fewer to 730 more) |
| Major general complications (first operation) | 40 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 0.11 (0.02 to 0.82) | Moderate 421 per 1000 | 375 fewer per 1000 (from 76 fewer to 413 fewer) |
| Minor general complications (first operation) | 40 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 0.45 (0.09 to 2.2) | Moderate 211 per 1000 | 116 fewer per 1000 (from 192 fewer to 253 more) |
| Major surgical complications (first operation) | 40 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 0.15 (0.02 to 1.14) | Moderate 316 per 1000 | 269 fewer per 1000 (from 310 fewer |

| Outcomes | No of Participants (studies) Follow up | Quality of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | |
|---|--|---|--------------------------|------------------------------|--|
| | | | | Risk with temporary stoma | Risk difference with Primary anastomosis (95% CI) |
| | | | | | to 44 more) |
| Major postoperative complications (first operation) | 73 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 0.65 (0.35 to 1.18) | Moderate 462 per 1000 | 162 fewer per 1000 (from 300 fewer to 83 more) |
| Perioperative mortality (first operation) | 111 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 0.61 (0.06 to 6.48) | Moderate 39 per 1000 | 15 fewer per 1000 (from 37 fewer to 214 more) |
| 30-day surgical mortality (first operation) | 39 (1 study) 30 days | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 0.14 (0.02 to 1.08) | Moderate 333 per 1000 | 286 fewer per 1000 (from 326 fewer to 27 more) |
| Mortality | 641 (9 studies) | ⊕⊕⊕⊕ VERY LOW ^b due to risk of bias | RR 0.39 (0.25 to 0.63) | Moderate 167 per 1000 | 143 fewer per 1000 (from 195 fewer to 91 fewer) ^c |
| Mortality | 331 (1 study) 59 months | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias | RR 0.55 (0.41 to 0.75) | Moderate 601 per 1000 | 270 fewer per 1000 (from 355 fewer to 150 fewer) |
| In-hospital mortality (first operation) | 68518 (8 studies) | ⊕⊕⊕⊕ VERY LOW ^{b,f,j} due to risk of bias, | RR 0.56 (0.23 to 1.41) | Moderate 242 per 1000 | 106 fewer per 1000 (from 186 |

| Outcomes | No of Participants (studies) Follow up | Quality of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | |
|--|--|--|--------------------------|------------------------------|--|
| | | | | Risk with temporary stoma | Risk difference with Primary anastomosis (95% CI) |
| | | inconsistency, imprecision | | | fewer to 99 more) |
| In-hospital mortality (second operation) | 49 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | OR 0.11 (0 to 5.55) | Moderate 46 per 1000 | 46 fewer per 1000 (from 158 fewer to 67 more) ^h |
| Postoperative mortality (first and second operations combined) | 55 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 0.81 (0.1 to 6.6) | Moderate 95 per 1000 | 18 fewer per 1000 (from 86 fewer to 532 more) |
| Reintervention (first operation) | 406 (5 studies) | ⊕⊕⊕⊕ VERY LOW ^{b,f,k} due to risk of bias, inconsistency, imprecision | RR 0.9 (0.58 to 1.38) | 197 per 1000 | 20 fewer per 1000 (from 100 fewer to 50 more) ³ |
| Reintervention (second operation) | 49 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 0.49 (0.13 to 1.82) | Moderate 227 per 1000 | 116 fewer per 1000 (from 197 fewer to 186 more) |
| Stoma dysfunction (first operation) | 60 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | RR 0.38 (0.11 to 1.31) | Moderate 250 per 1000 | 155 fewer per 1000 (from 222 fewer to 77 more) |
| Colostomy insufficiency/stump insufficiency (first operation) | 113 (2 studies) | ⊕⊕⊕⊕ VERY LOW ^b due to risk of bias | OR 0.11 (0.02 to 0.56) | Moderate 158 per 1000 | 111 fewer per 1000 (from 207 fewer |

| Outcomes | No of Participants (studies) Follow up | Quality of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | |
|--|--|---|--------------------------|------------------------------|--|
| | | | | Risk with temporary stoma | Risk difference with Primary anastomosis (95% CI) |
| | | | | | to 15 fewer) ^h |
| Stoma necrosis (first operation) | 73 (1 study) | ⊕⊕⊕⊕ VERY LOW ^b due to risk of bias | OR 0.05 (0.01 to 0.43) | Moderate 154 per 1000 | 154 fewer per 1000 (from 297 fewer to 10 fewer) ^h |
| Stoma morbidity (first operation) | 111 (1 study) | ⊕⊕⊕⊕ VERY LOW ^b due to risk of bias | OR 0.16 (0.04 to 0.69) | Moderate 123 per 1000 | 123 fewer per 1000 (from 209 fewer to 37 fewer) ^h |
| Stoma complications (first and second operations combined) | 55 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | OR 0.26 (0.02 to 3.87) | Moderate 71 per 1000 | 71 fewer per 1000 (from 20 fewer to 56 more) ^h |
| 30-day organ space infection (first operation) | 2018 (1 study) 30 days | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | OR 0.71 (0.35 to 1.42) | Moderate 55 per 1000 | 15 fewer per 1000 (from 35 fewer to 21 more) |
| 30-day postoperative sepsis (first operation) | 2018 (1 study) 30 days | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | OR 1.02 (0.67 to 1.55) | Moderate 142 per 1000 | 2 more per 1000 (from 42 fewer to 62 more) |
| Wound infection (first operation) | 2105 (2 studies) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | OR 0.88 (0.59 to 1.32) | Moderate 226 per 1000 | 22 fewer per 1000 (from 79 fewer to |

| Outcomes | No of Participants (studies) Follow up | Quality of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | |
|--|--|--|--------------------------|------------------------------|---|
| | | | | Risk with temporary stoma | Risk difference with Primary anastomosis (95% CI) |
| | | | | | 52 more) |
| Postoperative morbidity (first operation) | 87 (1 study) | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | OR 0.21 (0.05 to 0.84) | Moderate 867 per 1000 | 289 fewer per 1000 (from 21 fewer to 621 fewer) |
| Postoperative mortality (first operation) | 2305 (3 studies) | ⊕⊕⊕⊕ VERY LOW ^{b,f,l} due to risk of bias, inconsistency, imprecision | OR 0.83 (0.34 to 2.03) | Moderate 338 per 1000 | 40 fewer per 1000 (from 190 fewer to 171 more) |
| Reoperation (first operation) | 2305 (3 studies) | ⊕⊕⊕⊕ VERY LOW ^{b,f,m} due to risk of bias, inconsistency, imprecision | OR 0.78 (0.38 to 1.6) | Moderate 200 per 1000 | 37 fewer per 1000 (from 113 fewer to 86 more) |
| Long term mortality post-hospital discharge - HR | 243 (1 study) 59 months | ⊕⊕⊕⊕ VERY LOW ^{b,f} due to risk of bias, imprecision | HR 0.54 (0.3 to 0.97) | Moderate 417 per 1000 | 164 fewer per 1000 (from 10 fewer to 268 fewer) |

^aAbsolute risk difference calculated directly as 0 events in control group.

^bDowngraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

^cAbsolute risk difference calculated directly as 0 events in some studies in some arms.

^dSerious imprecision as sample size >70 and <350

^eI²=39% and wide variation in point estimates across studies.

^fDowngraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

^gVery serious imprecision as sample size <70.

| Outcomes | No of Participants (studies) Follow up | Quality of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | |
|--|--|---------------------------------|--------------------------|------------------------------|---|
| | | | | Risk with temporary stoma | Risk difference with Primary anastomosis (95% CI) |
| <p>^hAbsolute risk difference calculated directly as 0 events in intervention group.</p> <p>ⁱI²=67% and wide variation in point estimates between studies.</p> <p>^jI²=89% with point estimate of one study widely different to the other studies.</p> <p>^kI²=19% and wide variation in point estimates across studies.</p> <p>^lI²=56% and wide variation in point estimates across studies.</p> <p>^mI²=44% and wide variation in point estimates across studies.</p> | | | | | |

See appendix F for full GRADE tables.

Outcomes not suitable for meta-analysis (observational studies)

Quality of life

Vermeulen 2010 and 2011 ^{70,71} assessed the general quality of life of patients undergoing primary anastomosis or Hartmann's procedure (temporary stoma) for emergency surgery due to perforated diverticulitis (Hinchey grades I-IV) using EuroQol EQ-VAS and EQ-5D index measures. A higher score for both of these outcomes indicates a higher quality of life. Quality of life was demonstrated to be higher in the primary anastomosis group compared with those undergoing Hartmann's procedure for both the EQ-VAS (P<0.05) and EQ-5D index (P<0.05) measures, based on mean values and ranges:

- Mean EQ-VAS score: Primary anastomosis, 74 (range, 10-100, n=53); Hartmann's procedure, 65 (range, 20-100, n=76)
- Mean EQ-5D index score: Primary anastomosis, 77 (range, 67-93, n=53); Hartmann's procedure, 67 (range, -18-100, n=76)

1.5 Economic evidence

1.5.1 Included studies

One health economic study was identified with the relevant comparison and it has been included in this review.⁵³ This study is summarised in the health economic evidence profile below (Table 5) and the health economic evidence table in appendix H.

1.5.2 Excluded studies

No health economic studies that were relevant to this question were excluded due to assessment of limited applicability or methodological limitations.

See also the health economic study selection flow chart in appendix G.

1.5.3 Summary of studies included in the economic evidence review

Table 5: Health economic evidence profile: Primary anastomosis with diverting ileostomy versus Hartmann's Procedure

| Study | Applicability | Limitations | Other comments | Incremental cost | Incremental effects | Cost effectiveness | Uncertainty |
|---|-------------------------------------|--|--|---|--|--------------------|--------------|
| Oberkofler 2012 ⁵³ (Switzerland) | Partially applicable ^(a) | Potentially serious limitations ^(b) | Within-trial analysis of a multicentre randomised controlled trial. The study was discontinued after the interim analysis due to low accrual rates and significant differences in relevant secondary outcomes (total number of complications). | Primary anastomosis saves £1,919 per patient ^(c) | Mortality: -2% Overall complication rate: +4% Severe complications (including reoperations): -6% Stoma reversal: -32% | Indeterminate | Not reported |

Abbreviations: ICER: incremental cost-effectiveness ratio; n/a: not applicable; QALY: quality-adjusted life years; RCT: randomised controlled trial

(a) Switzerland hospital perspective

(b) Both strategies were designed to include stoma reversal (planned for before 3 months). Cost year not reported. No detailed breakdown of cost components incorporated. Costs other than those incurred to the institutions not considered. Unclear whether the costs of any other admissions between index operation and stoma reversal are included. Stoma reversal was done after 6 months in the Hartmann's group and after 3 months in the anastomosis group. No assessment of quality of life was made. A small number of patients were included in the trial. One patient randomised to intervention 1 received a primary anastomosis, while 3 patients randomised to intervention 2 received Hartmann's procedure, at the discretion of the surgeon. No conflicts of interest reported.

(c) Converted using 2012 purchasing power parities⁵⁴

1.5.4 Unit costs

The unit costs below were presented to the Committee, to aid consideration of cost effectiveness.

Table 6: NHS cost of non-elective sigmoid resection

| Procedure (OPCS4) | Healthcare Resource Group (HRG) code and description | Unit Cost | Average Length of Stay | Source |
|---|---|-----------|------------------------|-------------------------------|
| Sigmoid colectomy and anastomosis | FF33 Distal Colon Procedures, 19 years and over, inclusive of non-elective short stay and non-elective long stay with excess bed days, weighted for complications and co morbidities for HRG codes: FF33A and FF33B; as recorded for Non-Elective Inpatients | £7,091 | 9.0 days | NHS Reference Costs 2016-2017 |
| Sigmoid colectomy and ileostomy HFQ Or Sigmoid colectomy and exteriorisation of bowel NEC | FF31 Complex Large Intestine Procedures, 19 years and over, inclusive of non-elective short stay and non-elective long stay with excess bed days, weighted for complications and co morbidities for HRG codes: FF31A, FF31B, FF31C and FF31D; as recorded for Non-Elective Inpatients | £8,312 | 11.0 days | NHS Reference Costs 2016-2017 |

Table 7: NHS cost of elective sigmoid resection

| | Currency Description | Unit Cost | Average Length of Stay | Source |
|---|---|-----------|------------------------|-------------------------------|
| Sigmoid colectomy and anastomosis | FF33 Distal Colon Procedures, 19 years and over, inclusive of excess bed days, weighted for complications and co morbidities for HRG codes: FF33A and FF33B; as recorded for Elective Inpatients | £6,487 | 5.2 days | NHS Reference Costs 2016-2017 |
| Sigmoid colectomy and ileostomy HFQ Or Sigmoid colectomy and exteriorisation of bowel NEC | FF31 Complex Large Intestine Procedures, 19 years and over, inclusive of excess bed days, weighted for complications and co morbidities for HRG codes: FF31A, FF31B, FF31C and FF31D; as recorded for Elective Inpatients | £8,140 | 7.6 days | NHS Reference Costs 2016-2017 |
| Closure of ileostomy | FF22 Major Small Intestine Procedures, 19 years and over, inclusive of excess bed days, weighted for complications and co morbidities for HRG codes: FF22A, FF22B, FF22C and FF22C; as recorded for Elective Inpatients | £5,151 | 5.97 days | NHS Reference Costs 2016-2017 |

1.6 Evidence statements

1.6.1 Clinical evidence statements

RCT evidence:

- There was no clinical difference or too much uncertainty to distinguish between primary anastomosis and temporary stoma for all outcomes measured following the first operation; anastomotic leak (3 studies, n=254), complications – deep incisional surgical site infections (1 study, n=90), complications – organ space site infections (1 study, n=90), complications – superficial incisional surgical site infections (1 study, n=90), complications – urinary tract infections (2 studies, n=152), overall morbidity (2 studies, n=121), mortality (3 studies, n=254), complications – intra-abdominal abscess (1 study, n=102), complications – anastomotic stricture (1 study, n=102), need for further surgery (1 study, n=102), Clavien-Dindo I-V complications (1 study, n=62), intra-abdominal infection (1 study, n=62), wound infection (1 study, n=62) and stoma complications (1 study, n=62). The evidence for all of these outcomes was rated as very low quality.
- A similar situation was observed for the majority of outcomes in the RCT evidence following the second operation, with substantial uncertainty or no clinical difference being identified between the primary anastomosis and temporary stoma groups; anastomotic leak (3 studies, n=162, very low quality), complications – deep incisional surgical site infections (1 study, n=56, very low quality), complications – organ space site infections (1 study, n=56, very low quality), complications – superficial incisional surgical site infections (1 study, n=56, very low quality), complications – urinary tract infections (2 studies, n=97, very low quality), mortality (3 studies, n=162, very low quality), complications – intra-abdominal abscess (1 study, n=65, very low quality), need for further surgery (2 studies, n=106, very low quality), intra-abdominal infection (1 study, n=41, very low quality) and wound infection (1 study, n=41, very low quality). however, 2 studies (n=121, very low quality) demonstrated a clinical benefit of primary anastomosis over temporary stoma for overall morbidity at the second operation, while 1 study (n=41, low quality) indicated a clinical benefit of temporary stoma over primary anastomosis for Clavien-Dindo I-V complications at the second operation.

Observational evidence:

Evidence for all outcomes extracted from observational studies was rated as very low quality.

There was no clinical difference or too much uncertainty to determine whether either intervention was beneficial for the majority of the outcomes extracted from observational studies:

- Following the first operation, those outcomes with too much uncertainty or no clinical difference included abscess (6 studies, n=370), abscess/peritonitis (1 study, n=73), fistula (1 study, n=39), septic shock (1 study, n=39), wound sepsis (1 study, n=39), intra-abdominal infection (1 study, n=94), sepsis (3 studies, n=220), emergency readmission (1 study, n=97), hospital readmission (1 study, n=97), overall surgical morbidity (2 studies, n=150), overall morbidity (5 studies, n=68155), intraoperative morbidity (1 study, n=111), minor general complications (1 study, n=40), major surgical complications (1 study, n=40), major postoperative complications (1 study, n=73), perioperative mortality (1 study, n=111), 30-day surgical mortality (1 study, n=39), in-hospital mortality (8 studies, n=68518), reintervention (5 studies, n=406), stoma dysfunction (1 study, n=60), 30-day organ space infection (adjusted outcome, 1 study, n=2018), 30-day postoperative sepsis (adjusted outcome, 1 study, n=2018),

wound infection (adjusted outcome, 2 studies, n=2105), postoperative mortality (adjusted outcome, 3 studies, n=2305) and reoperation (adjusted outcome, 3 studies, n=2305).

- Outcomes with too much uncertainty or no clinical difference following the second operation included anastomotic leak (3 studies, n=118), abscess (1 study, n=49), wound infection (1 study, n=49), sepsis (1 study, n=49), urinary infection (1 study, n=49), in-hospital mortality (1 study, n=49) and reintervention (1 study, n=49).
- In addition, 1 study (n=55) reported results for outcomes of postoperative major morbidity, postoperative minor morbidity, postoperative mortality and stoma complications for the first and second operations combined, of which all were associated with too much uncertainty to distinguish between the two interventions or no clinical difference.

There was evidence from observational studies for a clinical benefit of primary anastomosis over temporary stoma for wound infection (5 studies, n=334), urinary infection (2 studies, n=100), postoperative medical morbidity (2 studies, n=177), major general complications (1 study, n=40), mortality (median 59 months) follow-up (1 study, n=331), colostomy insufficiency/stump insufficiency (2 studies, n=113), stoma necrosis (1 study, n=73), stoma morbidity (1 study, n=111) and postoperative morbidity (adjusted outcome, 1 study, n=87) following the first operation. In addition, 9 studies (n=641) provided evidence of a clinical benefit of primary anastomosis over temporary stoma for mortality, but whether this was related to the first or second operations, or combined, was unclear. One study also reported a hazard ratio indicating a clinical benefit of primary anastomosis compared with temporary stoma in terms of mortality following discharge from hospital after surgery (n=243), which was reported as a hazard ratio and adjusted for age, ASA classification and Hinchey staging. In addition, one study (n=129) assessed quality of life following operation and indicated a better quality of life following primary anastomosis compared with temporary stoma on both EQ-VAS and EQ-5D index measures; however, only mean values were provided and this data could not be analysed.

Observational studies also conversely provided evidence of a clinical benefit of temporary stoma over primary anastomosis for certain outcomes, including anastomotic leak (8 studies, n=664), anastomotic leak/rectal stump leak (1 study, n=111) and postoperative complications – infections (1 study, n=67721) following the first operation.

1.6.2 Health economic evidence statements

One cost-consequences analysis found that primary anastomosis was less costly than Hartmann's procedure (-£1900) and led to more patients achieving stoma reversal (90% vs 58%). This study was rated as being partially applicable with potentially serious limitations.

1.7 The committee's discussion of the evidence

1.7.1.1 The outcomes that matter most

The guideline committee agreed that for this review quality of life, mortality, morbidity, progression of disease, complications (infections, abscesses, perforation, fistula, stricture), recurrence rates of acute diverticulitis, re-hospitalisation, need for further surgery, anastomotic leak rate and stoma complications were considered critical outcomes. Symptom control/recurrence, for example pain relief and bowel habit, were considered to be important outcomes in this review.

In this review, no clinical evidence was identified for the following critical outcomes; progression of disease, complications (perforation) and recurrence rates of acute diverticulitis. In addition, no clinical evidence was identified for the important outcome of symptom control/recurrence.

1.7.1.2 The quality of the evidence

In this review, clinical evidence from both RCTs and observational studies was included. The identified RCTs only covered one of the complications associated with acute diverticulitis (Hinchey stage III or IV diverticular perforation with peritonitis). Not all of the critical outcomes were provided in the RCTs. Observational studies that consisted of patients with various complications of acute diverticulitis (such as abscess, perforation and fistula) were included in the review to increase the breadth of the evidence base as RCTs only covered those with diverticular perforation.

For evidence from both the RCTs and observational studies, the quality of the evidence was rated as very low for all but one outcome. For RCTs, this was predominantly due to risk of bias and imprecision, with the main reasons for downgrading due to risk of bias being the presence of selection bias, lack of blinding and incomplete outcome data. Concerning observational studies, risk of bias and imprecision were also the main factors contributing to a quality rating of very low, with all studies having major issues with selection bias due to the fact that higher age and comorbidity were observed in the temporary stoma (for example Hartmann's procedure) groups compared with the primary anastomosis groups. A lack of blinding and incomplete outcome data were also factors that contributed to a high risk of bias in the observational studies.

1.7.1.3 Benefits and harms

The review of the clinical evidence demonstrated that for the majority of outcomes there was either no clinical difference between primary anastomosis and temporary stoma for complicated acute diverticulitis or there was too much uncertainty in the effect estimate to determine whether either intervention should be favoured.

Outcomes were reported separately for the first and second operations of each intervention where the studies provided this information. The first operation refers to the initial resection with anastomosis or stoma and the second operation refers to the operation to reverse stomas created as a result of Hartmann's procedure or temporary/diverting stomas used alongside primary anastomosis as an additional protective measure.

The included RCTs, which covered the population of diverticular perforation with peritonitis, demonstrated a clinical benefit of primary anastomosis in terms of overall morbidity at the second operation, while a clinical benefit of temporary stoma was observed for the outcome of Clavien-Dindo complications I-IV at the second operation. However, for all other outcomes reported in RCTs, no difference could be identified between primary anastomosis and temporary stoma, and the committee therefore concluded that there was insufficient evidence to favour one over the other, based on the RCT evidence for perforated diverticulitis with peritonitis. The committee also noted that the demographics of patients included in the RCTs may not accurately reflect the demographics of those that usually undergo these procedures in the UK and the RCTs may therefore have selected fitter individuals for inclusion. In particular, the average age of patients in two of the RCTs may be lower than usually observed and the BMI was reported to be within a normal range in two studies, which may not be reflective of the UK population in terms of this condition.

The observational evidence covered a more broad range of complications associated with acute diverticulitis; the population of these studies included various complications, including diverticular abscess, perforation and fistula, with a mixture of different complications present in some studies. Observational studies demonstrated a clinical benefit of one intervention for

some outcomes, including wound infection, urinary infection, postoperative medical morbidity, mortality and stoma necrosis, morbidity and insufficiency at the first operation for primary anastomosis, and anastomotic leak and postoperative complications at the first operation for temporary stoma. However, the committee agreed that they could not recommend one intervention over the other due to the uncertainty in the effect for numerous other outcomes and because of the substantial selection bias across the observational studies. This bias meant that those patients with the worst overall health at baseline were more likely to be present in the temporary stoma group, which is a confounding factor that may cause outcomes for this group to appear worse than they would if the overall health of participants at baseline was similar between temporary stoma and primary anastomosis groups. Another limitation of the observational studies was the fact that the length of follow-up for outcomes was not specified for the majority of the studies.

Due to the uncertainty observed in the clinical evidence, the committee called upon the experience of the surgeons on the committee to make a recommendation based upon the level of comorbidity and age of patients. The committee agreed that in older patients and/or those with higher levels of comorbidity, Hartmann's procedure may be safer due to the increased risk of anastomotic leak with primary anastomosis and the fact that patients are less likely to survive anastomotic leaks if they have a higher level of comorbidity. This decision was also supported by the approach taken by the observational studies included in the review, with the majority of studies reporting substantially higher age and comorbidity in the Hartmann's procedure groups compared with the primary anastomosis groups.

Overall, the lack of certainty for many outcomes reported in the clinical evidence led the committee to conclude that there was no overwhelming evidence to support recommending primary anastomosis or temporary stoma, such as by Hartmann's procedure, over one another. The committee noted that the decision should be made according to patient and/or surgeon preference, with consideration given to the age and level of comorbidity of each patient as well as the experience of the surgeon, for example, the committee mentioned that general surgeons may be less inclined to perform primary anastomosis over Hartmann's procedure than colorectal surgeons.

The committee recognised that primary anastomosis represents a more technically difficult procedure and studies reporting its use often came from dedicated colorectal surgeons rather than general surgeons. The choice to perform this technique may therefore be made based on the surgeon's experience of undertaking this type of surgery in their day-to-day practice such that colorectal surgeons would be more likely to undertake this than non-specialist surgeons.

The committee highlighted that there may be a group of patients that due to their underlying medical conditions and physiological state can only be offered a defunctioning stoma above the area of complicated disease for example with a diverticular fistula or stricture rather than a formal resection.

1.7.2 Cost effectiveness and resource use

Primary anastomosis is typically harder to perform and more costly than Hartmann's procedure. It is believed to be less safe in patients with comorbidities. However, primary anastomosis is less likely than Hartmann's procedure to leave patients with a permanent stoma, which is more costly in the longer term and less desirable to patients. The committee noted that primary anastomosis with temporary diverting ileostomy can mitigate the risk of anastomotic leakage.

There was one cost effectiveness study included in the review, based on a small (n=62), randomised controlled trial. The study found that primary anastomosis with diverting ileostomy was less costly than Hartmann's procedure by about £1,900 per patient and stoma

was reversed for more patients. It was not clear what cost components were included. Other outcomes were similar between the arms.

Given the uncertainties in the evidence and high risk of bias, the committee decided not to recommend one procedure over the other.

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Appendices

Appendix A: Review protocols

Table 8: Review protocol: Primary vs. secondary anastomosis

| Field | Content |
|---|---|
| Review question | What is the most appropriate time of anastomosis in people with complicated acute diverticulitis? |
| Type of review question | intervention review A review of health economic evidence related to the same review question was conducted in parallel with this review. For details see the health economic review protocol for this NICE guideline. |
| Objective of the review | To determine the most appropriate timing for of anastomosis in people with complicated acute diverticulitis |
| Eligibility criteria – population / disease / condition / issue / domain | Adults aged 18 years and over with complicated acute diverticulitis |
| Eligibility criteria – intervention(s) / exposure(s) / prognostic factor(s) | <ul style="list-style-type: none"> • Primary anastomosis • Temporary stoma • Permanent stoma |
| Eligibility criteria – comparator(s) / control or reference (gold) standard | Compared to each other |
| Outcomes and prioritisation | <p>Critical outcomes:</p> <ul style="list-style-type: none"> • Quality of life • Mortality • Morbidity • Progression of disease • Complications: <ul style="list-style-type: none"> ○ infections ○ abscesses ○ perforation ○ fistula ○ stricture • Recurrence rates of acute diverticulitis • Hospitalisation • Need for further surgery • Anastomotic leak • Stoma complications <p>Important outcomes: Symptom control/recurrence, for example pain relief, bowel habit</p> |
| Eligibility criteria – study design | Randomised controlled trials (RCTs), systematic reviews of RCTs. If no RCT evidence is available, search for observational studies |
| Other inclusion exclusion criteria | <p>Exclusions:</p> <ul style="list-style-type: none"> • Children and young people aged 17 years and younger • Prevention |
| Proposed sensitivity / | Subgroups: |

| | |
|---|---|
| subgroup analysis, or meta-regression | <ul style="list-style-type: none"> • Age: >50 vs <50 years • people of Asian family origin as they are known to develop right-sided diverticula |
| Selection process – duplicate screening / selection / analysis | Studies are sifted by title and abstract. Potentially significant publications obtained in full text are then assessed against the inclusion criteria specified in this protocol. |
| Data management (software) | <ul style="list-style-type: none"> • Pairwise meta-analyses performed using Cochrane Review Manager (RevMan5). • GRADEpro used to assess the quality of evidence for each outcome • Bibliographies, citations and study sifting managed using EndNote • Data extractions performed using EviBase, a platform designed and maintained by the National Guideline Centre (NGC) |
| Information sources – databases and dates | Medline, Embase, The Cochrane Library |
| Identify if an update | Not applicable |
| Author contacts | https://www.nice.org.uk/guidance/conditions-and-diseases/digestive-tract-conditions/diverticular-disease |
| Highlight if amendment to previous protocol | For details please see section 4.5 of Developing NICE guidelines: the manual. |
| Search strategy – for one database | For details please see appendix B |
| Data collection process – forms / duplicate | A standardised evidence table format will be used, and published as appendix D of the evidence report. |
| Data items – define all variables to be collected | For details please see evidence tables in Appendix D (clinical evidence tables) or H (health economic evidence tables). |
| Methods for assessing bias at outcome / study level | <p>Standard study checklists were used to critically appraise individual studies. For details please see section 6.2 of Developing NICE guidelines: the manual</p> <p>The risk of bias across all available evidence was evaluated for each outcome using an adaptation of the ‘Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox’ developed by the international GRADE working group http://www.gradeworkinggroup.org/</p> |
| Criteria for quantitative synthesis | For details please see section 6.4 of Developing NICE guidelines: the manual. |
| Methods for quantitative analysis – combining studies and exploring (in)consistency | For details please see the separate Methods report (Chapter R) for this guideline. |
| Meta-bias assessment – publication bias, selective reporting bias | For details please see section 6.2 of Developing NICE guidelines: the manual. |
| Confidence in cumulative evidence | For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual. |
| Rationale / context – what is known | For details please see the introduction to the evidence review. |
| Describe contributions of authors and guarantor | <p>A multidisciplinary committee developed the evidence review. The committee was convened by the National Guideline Centre (NGC) and chaired by James Dalrymple in line with section 3 of Developing NICE guidelines: the manual.</p> <p>Staff from NGC undertook systematic literature searches, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate, and drafted the evidence review in</p> |

| | |
|------------------------------|--|
| | collaboration with the committee. For details please see Developing NICE guidelines: the manual. |
| Sources of funding / support | NGC is funded by NICE and hosted by the Royal College of Physicians. |
| Name of sponsor | NGC is funded by NICE and hosted by the Royal College of Physicians. |
| Roles of sponsor | NICE funds NGC to develop guidelines for those working in the NHS, public health and social care in England. |
| PROSPERO registration number | Not registered |

Table 9: Health economic review protocol

| Review question | All questions – health economic evidence |
|------------------------|--|
| Objectives | To identify health economic studies relevant to any of the review questions. |
| Search criteria | <ul style="list-style-type: none"> • Populations, interventions and comparators must be as specified in the clinical review protocol above. • Studies must be of a relevant health economic study design (cost–utility analysis, cost-effectiveness analysis, cost–benefit analysis, cost–consequences analysis, comparative cost analysis). • Studies must not be a letter, editorial or commentary, or a review of health economic evaluations. (Recent reviews will be ordered although not reviewed. The bibliographies will be checked for relevant studies, which will then be ordered.) • Unpublished reports will not be considered unless submitted as part of a call for evidence. • Studies must be in English. |
| Search strategy | A health economic study search will be undertaken using population-specific terms and a health economic study filter – see appendix B below. |
| Review strategy | <p>Studies not meeting any of the search criteria above will be excluded. Studies published before 2002, abstract-only studies and studies from non-OECD countries or the USA will also be excluded.</p> <p>Each remaining study will be assessed for applicability and methodological limitations using the NICE economic evaluation checklist which can be found in appendix H of Developing NICE guidelines: the manual (2014).⁵⁰</p> <p>Inclusion and exclusion criteria</p> <ul style="list-style-type: none"> • If a study is rated as both ‘Directly applicable’ and with ‘Minor limitations’ then it will be included in the guideline. A health economic evidence table will be completed and it will be included in the health economic evidence profile. • If a study is rated as either ‘Not applicable’ or with ‘Very serious limitations’ then it will usually be excluded from the guideline. If it is excluded then a health economic evidence table will not be completed and it will not be included in the health economic evidence profile. • If a study is rated as ‘Partially applicable’, with ‘Potentially serious limitations’ or both then there is discretion over whether it should be included. <p>Where there is discretion</p> <p>The health economist will make a decision based on the relative applicability and quality of the available evidence for that question, in discussion with the guideline committee if required. The ultimate aim is to include health economic studies that are helpful for decision-making in the context of the guideline and the current NHS setting. If several studies are considered of sufficiently high applicability and methodological quality that they could all be included, then the health economist, in discussion with the committee if required, may decide to include only the most</p> |

applicable studies and to selectively exclude the remaining studies. All studies excluded on the basis of applicability or methodological limitations will be listed with explanation in the excluded health economic studies appendix below.

The health economist will be guided by the following hierarchies.

Setting:

- UK NHS (most applicable).
- OECD countries with predominantly public health insurance systems (for example, France, Germany, Sweden).
- OECD countries with predominantly private health insurance systems (for example, Switzerland).
- Studies set in non-OECD countries or in the USA will be excluded before being assessed for applicability and methodological limitations.

Health economic study type:

- Cost–utility analysis (most applicable).
- Other type of full economic evaluation (cost–benefit analysis, cost-effectiveness analysis, cost–consequences analysis).
- Comparative cost analysis.
- Non-comparative cost analyses including cost-of-illness studies will be excluded before being assessed for applicability and methodological limitations.

Year of analysis:

- The more recent the study, the more applicable it will be.
- Studies published in 2002 or later but that depend on unit costs and resource data entirely or predominantly from before 2002 will be rated as ‘Not applicable’.
- Studies published before 2002 will be excluded before being assessed for applicability and methodological limitations.

Quality and relevance of effectiveness data used in the health economic analysis:

- The more closely the clinical effectiveness data used in the health economic analysis match with the outcomes of the studies included in the clinical review the more useful the analysis will be for decision-making in the guideline.

Appendix B: Literature search strategies

The literature searches for this review are detailed below and complied with the methodology outlined in Developing NICE guidelines: the manual 2014, updated 2017

For more detailed information, please see the Methodology Review.

B.1 Clinical search literature search strategy

Searches were constructed using a PICO framework where population (P) terms were combined with Intervention (I) and in some cases Comparison (C) terms. Outcomes (O) are rarely used in search strategies for interventions as these concepts may not be well described in title, abstract or indexes and therefore difficult to retrieve. Search filters were applied to the search where appropriate.

Table 10: Database date parameters and filters used

| Database | Dates searched | Search filter used |
|----------------|-------------------------|---|
| Medline (OVID) | 1946 – 13 November 2018 | Exclusions Randomised controlled trials Systematic review studies |

| Database | Dates searched | Search filter used |
|------------------------------|--|--|
| | | Observational studies |
| Embase (OVID) | 1974 – 13 November 2018 | Exclusions Randomised controlled trials Systematic review studies Observational studies |
| The Cochrane Library (Wiley) | Cochrane Reviews to 2018 Issue 11 of 12 CENTRAL to 2018 Issue 11 of 12 DARE, and NHSEED to 2015 Issue 2 of 4 HTA to 2016 Issue 2 of 4 | None |

Table 11: Medline (Ovid) search terms

| | |
|-----|--|
| 1. | diverticul*.mp. |
| 2. | limit 1 to English language |
| 3. | letter/ |
| 4. | editorial/ |
| 5. | news/ |
| 6. | exp historical article/ |
| 7. | Anecdotes as Topic/ |
| 8. | comment/ |
| 9. | case report/ |
| 10. | (letter or comment*).ti. |
| 11. | or/3-10 |
| 12. | randomized controlled trial/ or random*.ti,ab. |
| 13. | 11 not 12 |
| 14. | animals/ not humans/ |
| 15. | exp Animals, Laboratory/ |
| 16. | exp Animal Experimentation/ |
| 17. | exp Models, Animal/ |
| 18. | exp Rodentia/ |
| 19. | (rat or rats or mouse or mice).ti. |
| 20. | or/13-19 |
| 21. | 2 not 20 |
| 22. | randomized controlled trial.pt. |
| 23. | controlled clinical trial.pt. |
| 24. | randomi#ed.ti,ab. |
| 25. | placebo.ab. |
| 26. | randomly.ti,ab. |
| 27. | Clinical Trials as topic.sh. |
| 28. | trial.ti. |
| 29. | or/22-28 |
| 30. | Meta-Analysis/ |
| 31. | exp Meta-Analysis as Topic/ |
| 32. | (meta analy* or metanaly* or metaanaly* or meta regression).ti,ab. |

| | |
|-----|--|
| 33. | ((systematic* or evidence*) adj3 (review* or overview*)).ti,ab. |
| 34. | (reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab. |
| 35. | (search strategy or search criteria or systematic search or study selection or data extraction).ab. |
| 36. | (search* adj4 literature).ab. |
| 37. | (medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab. |
| 38. | cochrane.jw. |
| 39. | ((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab. |
| 40. | or/50-59 |
| 41. | Epidemiologic studies/ |
| 42. | Observational study/ |
| 43. | exp Cohort studies/ |
| 44. | (cohort adj (study or studies or analys* or data)).ti,ab. |
| 45. | ((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab. |
| 46. | ((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab. |
| 47. | Controlled Before-After Studies/ |
| 48. | Historically Controlled Study/ |
| 49. | Interrupted Time Series Analysis/ |
| 50. | (before adj2 after adj2 (study or studies or data)).ti,ab. |
| 51. | or/30-39 |
| 52. | exp case control study/ |
| 53. | case control*.ti,ab. |
| 54. | or/41-42 |
| 55. | 40 or 43 |
| 56. | Cross-sectional studies/ |
| 57. | (cross sectional and (study or studies or review or analys* or cohort* or data)).ti,ab. |
| 58. | or/45-46 |
| 59. | 40 or 47 |
| 60. | 40 or 43 or 47 |
| 61. | 21 and (29 or 40 or 60) |

Table 12: Embase (Ovid) search terms

| | |
|-----|--|
| 1. | diverticul*.mp. |
| 2. | limit 1 to English language |
| 3. | letter.pt. or letter/ |
| 4. | note.pt. |
| 5. | editorial.pt. |
| 6. | case report/ or case study/ |
| 7. | (letter or comment*).ti. |
| 8. | or/3-7 |
| 9. | randomized controlled trial/ or random*.ti,ab. |
| 10. | 8 not 9 |
| 11. | animal/ not human/ |
| 12. | nonhuman/ |

| | |
|-----|--|
| 13. | exp Animal Experiment/ |
| 14. | exp Experimental Animal/ |
| 15. | animal model/ |
| 16. | exp Rodent/ |
| 17. | (rat or rats or mouse or mice).ti. |
| 18. | or/10-17 |
| 19. | 2 not 18 |
| 20. | random*.ti,ab. |
| 21. | factorial*.ti,ab. |
| 22. | (crossover* or cross over*).ti,ab. |
| 23. | ((doubl* or singl*) adj blind*).ti,ab. |
| 24. | (assign* or allocat* or volunteer* or placebo*).ti,ab. |
| 25. | crossover procedure/ |
| 26. | single blind procedure/ |
| 27. | randomized controlled trial/ |
| 28. | double blind procedure/ |
| 29. | or/20-28 |
| 30. | systematic review/ |
| 31. | meta-analysis/ |
| 32. | (meta analy* or metanaly* or metaanaly* or meta regression).ti,ab. |
| 33. | ((systematic* or evidence*) adj3 (review* or overview*)).ti,ab. |
| 34. | (reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab. |
| 35. | (search strategy or search criteria or systematic search or study selection or data extraction).ab. |
| 36. | (search* adj4 literature).ab. |
| 37. | (medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab. |
| 38. | cochrane.jw. |
| 39. | ((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab. |
| 40. | or/30-39 |
| 41. | Clinical study/ |
| 42. | Observational study/ |
| 43. | family study/ |
| 44. | longitudinal study/ |
| 45. | retrospective study/ |
| 46. | prospective study/ |
| 47. | cohort analysis/ |
| 48. | follow-up/ |
| 49. | cohort*.ti,ab. |
| 50. | 48 and 49 |
| 51. | (cohort adj (study or studies or analys* or data)).ti,ab. |
| 52. | ((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab. |
| 53. | ((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab. |
| 54. | (before adj2 after adj2 (study or studies or data)).ti,ab. |

| | |
|-----|---|
| 55. | or/41-47,50-54 |
| 56. | exp case control study/ |
| 57. | case control*.ti,ab. |
| 58. | or/56-57 |
| 59. | 55 or 58 |
| 60. | cross-sectional study/ |
| 61. | (cross sectional and (study or studies or review or analys* or cohort* or data)).ti,ab. |
| 62. | or/60-61 |
| 63. | 55 or 62 |
| 64. | 55 or 58 or 62 |
| 65. | 19 and (29 or 40 or 64) |

Table 13: Cochrane Library (Wiley) search terms

| | |
|-----|-----------------|
| #1. | diverticul*.mp. |
|-----|-----------------|

B.2 Health Economics literature search strategy

Health economic evidence was identified by conducting a broad search relating to Diverticular Disease population in NHS Economic Evaluation Database (NHS EED – this ceased to be updated after March 2015) and the Health Technology Assessment database (HTA) with no date restrictions. NHS EED and HTA databases are hosted by the Centre for Research and Dissemination (CRD). Additional searches were run on Medline and Embase for health economics, economic modelling and quality of life studies.

Table 14: Database date parameters and filters used

| Database | Dates searched | Search filter used |
|---|--|---|
| Medline | 1946 – 13 November 2018 | Exclusions Health economics studies Health economics modelling studies Quality of life studies |
| Embase | 1974 – 13 November 2018 | Exclusions Health economics studies Health economics modelling studies Quality of life studies |
| Centre for Research and Dissemination (CRD) | HTA - Inception – 13 November 2018 NHSEED - Inception to March 2015 | None |

Table 15: Medline (Ovid) search terms

| | |
|----|-----------------------------|
| 1. | diverticul*.mp. |
| 2. | limit 1 to English language |
| 3. | letter/ |
| 4. | editorial/ |
| 5. | news/ |

| | |
|-----|---|
| 6. | exp historical article/ |
| 7. | Anecdotes as Topic/ |
| 8. | comment/ |
| 9. | case report/ |
| 10. | (letter or comment*).ti. |
| 11. | or/3-10 |
| 12. | randomized controlled trial/ or random*.ti,ab. |
| 13. | 11 not 12 |
| 14. | animals/ not humans/ |
| 15. | exp Animals, Laboratory/ |
| 16. | exp Animal Experimentation/ |
| 17. | exp Models, Animal/ |
| 18. | exp Rodentia/ |
| 19. | (rat or rats or mouse or mice).ti. |
| 20. | or/13-19 |
| 21. | 2 not 20 |
| 22. | Economics/ |
| 23. | Value of life/ |
| 24. | exp "Costs and Cost Analysis"/ |
| 25. | exp Economics, Hospital/ |
| 26. | exp Economics, Medical/ |
| 27. | Economics, Nursing/ |
| 28. | Economics, Pharmaceutical/ |
| 29. | exp "Fees and Charges"/ |
| 30. | exp Budgets/ |
| 31. | budget*.ti,ab. |
| 32. | cost*.ti. |
| 33. | (economic* or pharmaco?economic*).ti. |
| 34. | (price* or pricing*).ti,ab. |
| 35. | (cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab. |
| 36. | (financ* or fee or fees).ti,ab. |
| 37. | (value adj2 (money or monetary)).ti,ab. |
| 38. | or/22-37 |
| 39. | exp models, economic/ |
| 40. | *Models, Theoretical/ |
| 41. | markov chains/ |
| 42. | monte carlo method/ |
| 43. | exp Decision Theory/ |
| 44. | (markov* or monte carlo).ti,ab. |
| 45. | econom* model*.ti,ab. |
| 46. | (decision* adj2 (tree* or analy* or model*)).ti,ab. |
| 47. | Models, Organizational/ |
| 48. | *models, statistical/ |
| 49. | *logistic models/ |

| | |
|-----|---|
| 50. | models, nursing/ |
| 51. | ((organi?ation* or operation* or service* or concept*) adj3 (model* or map* or program* or simulation* or system* or analys*)).ti,ab. |
| 52. | (econom* adj2 (theor* or system* or map* or evaluat*)).ti,ab. |
| 53. | (SSM or SODA).ti,ab. |
| 54. | (strateg* adj3 (option* or choice*) adj3 (analys* or decision*)).ti,ab. |
| 55. | soft systems method*.ti,ab. |
| 56. | (Meta-heuristic* or Metaheuristic*).ti,ab. |
| 57. | (dynamic* adj2 (model* or system*)).ti,ab. |
| 58. | (simulation adj3 (model* or discrete event* or agent)).ti,ab. |
| 59. | (microsimulation* or "micro* simulation*").ti,ab. |
| 60. | ((flow or core) adj2 model*).ti,ab. |
| 61. | (data adj2 envelopment*).ti,ab. |
| 62. | system* model*.ti,ab. |
| 63. | or/41-64 |
| 64. | quality-adjusted life years/ |
| 65. | sickness impact profile/ |
| 66. | (quality adj2 (wellbeing or well being)).ti,ab. |
| 67. | sickness impact profile.ti,ab. |
| 68. | disability adjusted life.ti,ab. |
| 69. | (qal* or qtime* or qwb* or daly*).ti,ab. |
| 70. | (euroqol* or eq5d* or eq 5*).ti,ab. |
| 71. | (qol* or hql* or hqol* or h qol* or hrqol* or hr qol*).ti,ab. |
| 72. | (health utility* or utility score* or disutilit* or utility value*).ti,ab. |
| 73. | (hui or hui1 or hui2 or hui3).ti,ab. |
| 74. | (health* year* equivalent* or hye or hyes).ti,ab. |
| 75. | discrete choice*.ti,ab. |
| 76. | rosser.ti,ab. |
| 77. | (willingness to pay or time tradeoff or time trade off or tto or standard gamble*).ti,ab. |
| 78. | (sf36* or sf 36* or short form 36* or shortform 36* or shortform36*).ti,ab. |
| 79. | (sf20 or sf 20 or short form 20 or shortform 20 or shortform20).ti,ab. |
| 80. | (sf12* or sf 12* or short form 12* or shortform 12* or shortform12*).ti,ab. |
| 81. | (sf8* or sf 8* or short form 8* or shortform 8* or shortform8*).ti,ab. |
| 82. | (sf6* or sf 6* or short form 6* or shortform 6* or shortform6*).ti,ab. |
| 83. | or/22-40 |
| 84. | 21 and (38 or 63 or 83) |

Table 16: Embase (Ovid) search terms

| | |
|----|-----------------------------|
| 1. | diverticul*.mp. |
| 2. | limit 1 to English language |
| 3. | letter.pt. or letter/ |
| 4. | note.pt. |
| 5. | editorial.pt. |
| 6. | case report/ or case study/ |
| 7. | (letter or comment*).ti. |

| | |
|-----|---|
| 8. | or/3-7 |
| 9. | randomized controlled trial/ or random*.ti,ab. |
| 10. | 8 not 9 |
| 11. | animal/ not human/ |
| 12. | nonhuman/ |
| 13. | exp Animal Experiment/ |
| 14. | exp Experimental Animal/ |
| 15. | animal model/ |
| 16. | exp Rodent/ |
| 17. | (rat or rats or mouse or mice).ti. |
| 18. | or/10-17 |
| 19. | 2 not 18 |
| 20. | Economics/ |
| 21. | Value of life/ |
| 22. | exp "Costs and Cost Analysis"/ |
| 23. | exp Economics, Hospital/ |
| 24. | exp Economics, Medical/ |
| 25. | Economics, Nursing/ |
| 26. | Economics, Pharmaceutical/ |
| 27. | exp "Fees and Charges"/ |
| 28. | exp Budgets/ |
| 29. | budget*.ti,ab. |
| 30. | cost*.ti. |
| 31. | (economic* or pharmaco?economic*).ti. |
| 32. | (price* or pricing*).ti,ab. |
| 33. | (cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab. |
| 34. | (financ* or fee or fees).ti,ab. |
| 35. | (value adj2 (money or monetary)).ti,ab. |
| 36. | or/20-35 |
| 37. | statistical model/ |
| 38. | *theoretical model/ |
| 39. | nonbiological model/ |
| 40. | stochastic model/ |
| 41. | decision theory/ |
| 42. | decision tree/ |
| 43. | exp nursing theory/ |
| 44. | monte carlo method/ |
| 45. | (markov* or monte carlo).ti,ab. |
| 46. | econom* model*.ti,ab. |
| 47. | (decision* adj2 (tree* or analy* or model*)).ti,ab. |

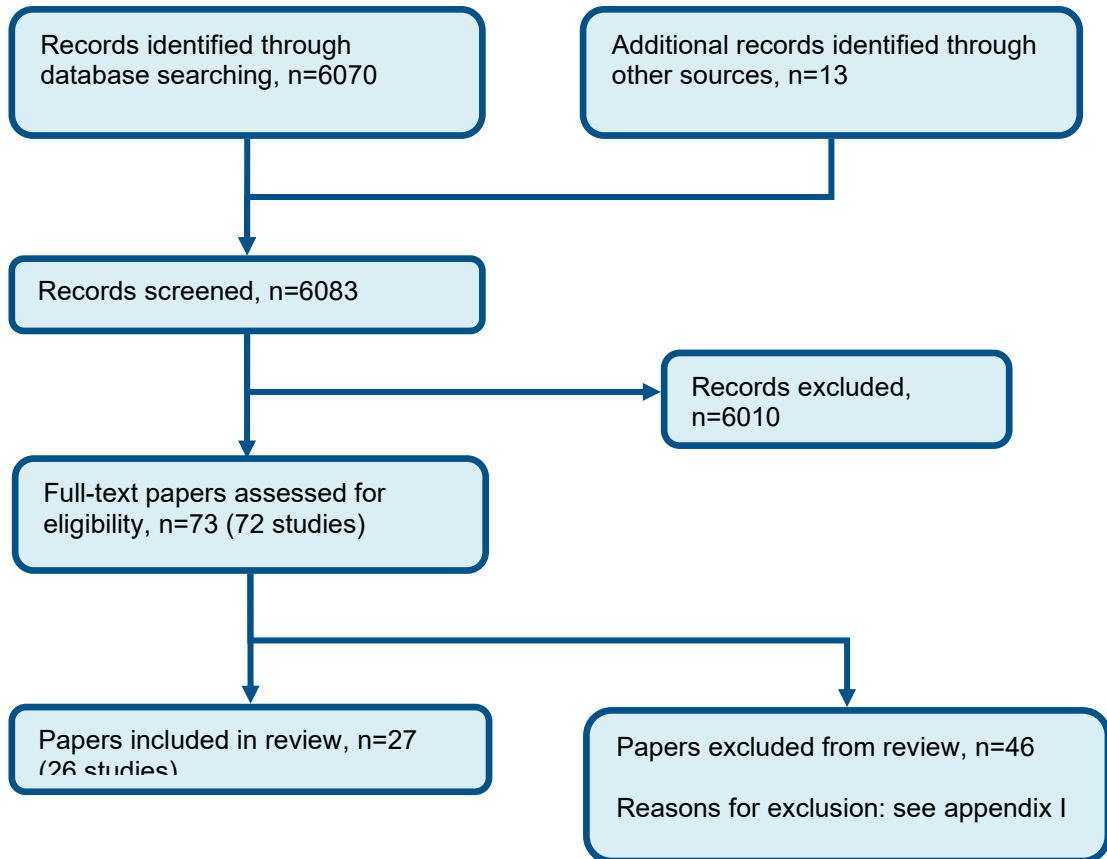
| | |
|-----|---|
| 48. | ((organi?ation* or operation* or service* or concept*) adj3 (model* or map* or program* or simulation* or system* or analys*)).ti,ab. |
| 49. | (econom* adj2 (theor* or system* or map* or evaluat*)).ti,ab. |
| 50. | (SSM or SODA).ti,ab. |
| 51. | (strateg* adj3 (option* or choice*) adj3 (analys* or decision*)).ti,ab. |
| 52. | soft systems method*.ti,ab. |
| 53. | (Meta-heuristic* or Metaheuristic*).ti,ab. |
| 54. | (dynamic* adj2 (model* or system*)).ti,ab. |
| 55. | (simulation adj3 (model* or discrete event* or agent)).ti,ab. |
| 56. | (microsimulation* or "micro* simulation*").ti,ab. |
| 57. | ((flow or core) adj2 model*).ti,ab. |
| 58. | (data adj2 envelopment*).ti,ab. |
| 59. | system* model*.ti,ab. |
| 60. | or/39-61 |
| 61. | quality adjusted life year/ |
| 62. | "quality of life index"/ |
| 63. | short form 12/ or short form 20/ or short form 36/ or short form 8/ |
| 64. | sickness impact profile/ |
| 65. | (quality adj2 (wellbeing or well being)).ti,ab. |
| 66. | sickness impact profile.ti,ab. |
| 67. | disability adjusted life.ti,ab. |
| 68. | (qal* or qtime* or qwb* or daly*).ti,ab. |
| 69. | (euroqol* or eq5d* or eq 5*).ti,ab. |
| 70. | (qol* or hql* or hqol* or h qol* or hrqol* or hr qol*).ti,ab. |
| 71. | (health utility* or utility score* or disutilit* or utility value*).ti,ab. |
| 72. | (hui or hui1 or hui2 or hui3).ti,ab. |
| 73. | (health* year* equivalent* or hye or hyes).ti,ab. |
| 74. | discrete choice*.ti,ab. |
| 75. | rosser.ti,ab. |
| 76. | (willingness to pay or time tradeoff or time trade off or tto or standard gamble*).ti,ab. |
| 77. | (sf36* or sf 36* or short form 36* or shortform 36* or shortform36*).ti,ab. |
| 78. | (sf20 or sf 20 or short form 20 or shortform 20 or shortform20).ti,ab. |
| 79. | (sf12* or sf 12* or short form 12* or shortform 12* or shortform12*).ti,ab. |
| 80. | (sf8* or sf 8* or short form 8* or shortform 8* or shortform8*).ti,ab. |
| 81. | (sf6* or sf 6* or short form 6* or shortform 6* or shortform6*).ti,ab. |
| 82. | or/20-40 |
| 83. | 19 and (36 or 60 or 82) |

Table 17: NHS EED and HTA (CRD) search terms

| | |
|-----|-------------|
| #1. | diverticul* |
|-----|-------------|

Appendix C: Clinical evidence selection

Figure 1: Flow chart of clinical study selection for the review of primary vs. secondary anastomosis



Appendix D: Clinical evidence tables

Table 18: Clinical evidence tables

| Study | Belmonte 1996 ⁸ |
|---|--|
| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=227) |
| Countries and setting | Conducted in USA; Setting: University of Minnesota-affiliated hospitals. |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Mean follow-up, 23 months (range, 1-132 months). |
| Method of assessment of guideline condition | Unclear method of assessment/diagnosis: Operative and pathological findings used to classify patients. |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Patients undergoing resection for diverticular disease. |
| Exclusion criteria | Not reported. |
| Recruitment/selection of patients | Consecutive patients treated for diverticular disease between 1988 and 1993 at hospitals affiliated with University of Minnesota. |
| Age, gender and ethnicity | Age - Mean (range): Whole cohort, 66 (25-98) years. Not available separately for complicated cases or to compare between intervention groups. Gender (M:F): Whole cohort, 84/143. Not available separately for complicated cases or to compare between intervention groups. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Mixture of emergent, urgent and elective surgery. Extracted for those with pericolonic or mesenteric abscess, pelvic abscess, or purulent or faecal peritonitis only (stages III-V as described in study). |
| Indirectness of population | No indirectness |
| Interventions | (n=85) Intervention 1: Primary anastomosis. Primary anastomosis with or without diverting ileostomy. . Duration Not reported. Concurrent medication/care: All patients received perioperative intravenous broad spectrum antibiotics. Patients not undergoing emergency or urgent surgery underwent mechanical bowel preparation prior to surgery. |

| | |
|--|--|
| | <p>Intraoperative lavage used selectively in patients with no or poor bowel preparation to allow anastomosis and avoid colostomy. Percutaneous drainage of abscess performed in 2 patients (unclear which intervention group these were in). Indirectness: No indirectness</p> <p>(n=26) Intervention 2: Temporary stoma. Hartmann's procedure. Duration Not reported. Concurrent medication/care: All patients received perioperative intravenous broad spectrum antibiotics. Patients not undergoing emergency or urgent surgery underwent mechanical bowel preparation prior to surgery. Percutaneous drainage of abscess performed in 2 patients (unclear which intervention group these were in). Indirectness: No indirectness Comments: Classed as temporary stoma as aim was to reverse stomas where possible.</p> |
| Funding | Funding not stated |
| <p>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH/WITHOUT DIVERTING ILEOSTOMY) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)</p> <p>Protocol outcome 1: Mortality at Define - Actual outcome: Perioperative mortality at Perioperative; Group 1: 2/85, Group 2: 1/26; Comments: All those that died has stage IV disease (pelvic abscess), as defined by the study. Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: No details given for separate interventions.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:</p> | |
| Protocol outcomes not reported by the study | <p>Quality of life at Define; Morbidity at Define; Progression of disease at Define; Complications (infections) at Define; Complications (abscesses) at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Need for further surgery at Define; Anastomotic leak at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define</p> |

| Study | Binda 1993 ¹⁰ |
|---|---|
| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=92) |
| Countries and setting | Conducted in Italy; Setting: Secondary care - two hospital surgery units |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Retrospective review of cases between 1980 and 1990 |
| Method of assessment of guideline condition | Method of assessment /diagnosis not stated |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Emergency surgery for complicated colonic diverticulitis. |
| Exclusion criteria | Those undergoing elective or deferred emergency surgery. |
| Recruitment/selection of patients | All eligible cases recorded between 1980 and 1990. |
| Age, gender and ethnicity | Age - Mean (range): Whole cohort, 66.7 (30-92) years. Not available separately for each intervention. Gender (M:F): Whole cohort, 44/48. Not available separately for each intervention. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Emergency surgery for complicated colonic diverticulitis - surgery within 48 h of hospitalisation (no adequate bowel preparation). Includes those with localised or diffuse peritonitis, or intestinal occlusion. Intestinal inclusion group was not extracted as the majority of this group had experienced recurrent episodes of diverticulitis which is not the correct review population. |
| Indirectness of population | No indirectness |
| Interventions | (n=21) Intervention 1: Primary anastomosis. Resection with immediate anastomosis with/without colostomy. Duration Not reported. Concurrent medication/care: Not reported. Indirectness: No indirectness (n=18) Intervention 2: Temporary stoma. Hartmann's procedure. Duration Not reported. Concurrent medication/care: Not reported. Indirectness: No indirectness |
| Funding | Funding not stated |

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH OR WITHOUT COLOSTOMY) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)

Protocol outcome 1: Mortality at Define

- Actual outcome: Surgical mortality at 30 days post-surgery; Group 1: 1/21, Group 2: 6/18

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Data not available to compare baseline factors between intervention groups. Distribution of age, gender and severity of disease may differ substantially between groups.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 2: Morbidity at Define

- Actual outcome: Overall surgical morbidity at Not reported; Group 1: 6/21, Group 2: 8/18

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Data not available to compare baseline factors between intervention groups. Distribution of age, gender and severity of disease may differ substantially between groups.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 3: Complications (infections) at Define

- Actual outcome: Wound sepsis at Not reported; Group 1: 2/21, Group 2: 1/18

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Data not available to compare baseline factors between intervention groups. Distribution of age, gender and severity of disease may differ substantially between groups.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome: Septic shock at Not reported; Group 1: 1/21, Group 2: 5/18

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Data not available to compare baseline factors between intervention groups. Distribution of age, gender and severity of disease may differ substantially between groups.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 4: Complications (fistula) at Define

- Actual outcome: Fistula at Not reported; Group 1: 2/21, Group 2: 0/18

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Data not available to compare baseline factors between intervention groups. Distribution of age, gender and severity of disease may differ substantially between groups.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

| | |
|---|--|
| Protocol outcomes not reported by the study | Quality of life at Define; Progression of disease at Define; Complications (abscesses) at Define; Complications (perforation) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Need for further surgery at Define; Anastomotic leak at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define |
|---|--|

| Study | Binda 2012 ⁹ |
|---|---|
| Study type | RCT (Patient randomised; Parallel) |
| Number of studies (number of participants) | 1 (n=90) |
| Countries and setting | Conducted in France, Israel, Italy, Norway, Poland, Slovenia, Spain, Turkey; Setting: 14 centres within eight different countries. |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Follow-up up to 30 days following ostomy reversal. |
| Method of assessment of guideline condition | Adequate method of assessment/diagnosis: Clinical examination, plain X-rays and CT scan. |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Aged 18 years and older with peritonitis secondary to perforated diverticulitis of the left colon. |
| Exclusion criteria | Failure to sign consent; peritonitis secondary to perforated diverticulitis of the right colon. |
| Recruitment/selection of patients | All patients who were hospitalised or came through the emergency room department of the participating centres. |
| Age, gender and ethnicity | Age - Mean (SD): Primary anastomosis, 63.5 (2.2); Nonrestorative colon resection, 65.7 (1.8). Gender (M:F): Primary anastomosis, 12/22; Nonrestorative colon resection, 29/27. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Patients undergoing emergency operation. |
| Indirectness of population | No indirectness |
| Interventions | (n=34) Intervention 1: Primary anastomosis. Left colon resection with primary anastomosis and loop ileostomy. Ileostomy reversal performed with trephine incision. Duration Not reported. Concurrent medication/care: All patients received intravenous antibiotics and deep vein thrombosis prophylaxis prior to surgery. Intraoperative lavage of peritoneal cavity also performed. Indirectness: No indirectness (n=56) Intervention 2: Temporary stoma. Nonrestorative colon resection - left colon resection with end colostomy. Reversal of colostomy performed by laparotomy or laparoscopy. Duration Not reported. Concurrent medication/care: All patients received intravenous antibiotics and deep vein thrombosis prophylaxis prior to surgery. Intraoperative lavage of peritoneal cavity also performed. Indirectness: No indirectness |
| Funding | Academic or government funding (Western Norwegian Health Authority) |

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH LOOP ILEOSTOMY) versus TEMPORARY STOMA (NONRESTORATIVE RESECTION)

Protocol outcome 1: Mortality at Define

- Actual outcome: Mortality (first operation) at First operation; Group 1: 1/34, Group 2: 6/56

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome: Mortality (second operation) at Second operation; Group 1: 0/22, Group 2: 0/34

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 12, Reason: One patient died after first operation. Others did not receive stoma ileostomy reversal for unknown reasons.; Group 2 Number missing: 22, Reason: Six patients died after the first operation. Others did not receive stoma reversal for unknown reasons.

Protocol outcome 2: Morbidity at Define

- Actual outcome: Overall morbidity (first operation) at First operation; Group 1: 12/34, Group 2: 26/56

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome: Overall morbidity (second operation) at Second operation; Group 1: 1/22, Group 2: 12/34

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 12, Reason: One patient died after first operation. Others did not receive stoma ileostomy reversal for unknown reasons.; Group 2 Number missing: 22, Reason: Six patients died after the first operation. Others did not receive stoma reversal for unknown reasons.

Protocol outcome 3: Complications (infections) at Define

- Actual outcome: Superficial incisional surgical site infections (first operation) at First operation; Group 1: 9/34, Group 2: 11/56

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome: Superficial incisional surgical site infections (second operation) at Second operation; Group 1: 0/22, Group 2: 5/34

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 12, Reason: One patient died after first operation. Others did not receive stoma ileostomy reversal for unknown reasons.; Group 2 Number missing: 22, Reason: Six patients died after the first operation. Others did not receive stoma reversal for unknown reasons.

- Actual outcome: Deep incisional surgical site infections (first operation) at First operation; Group 1: 6/34, Group 2: 9/56

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness : Group 1 Number missing: : Group 2 Number missing:

- Actual outcome: Deep incisional surgical site infections (second operation) at Second operation; Group 1: 0/22, Group 2: 3/34
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 12, Reason: One patient died after first operation. Others did not receive stoma ileostomy reversal for unknown reasons.; Group 2 Number missing: 22, Reason: Six patients died after the first operation. Others did not receive stoma reversal for unknown reasons.

- Actual outcome: Organ space surgical site infections (first operation) at First operation; Group 1: 0/34, Group 2: 6/56
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome: Organ space surgical site infections (second operation) at Second operation; Group 1: 0/22, Group 2: 1/34
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 12, Reason: One patient died after first operation. Others did not receive stoma ileostomy reversal for unknown reasons.; Group 2 Number missing: 22, Reason: Six patients died after the first operation. Others did not receive stoma reversal for unknown reasons.

- Actual outcome: Urinary tract infections (first operation) at First operation; Group 1: 0/34, Group 2: 3/56
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome: Urinary tract infections (second operation) at Second operation; Group 1: 0/22, Group 2: 0/34
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 12, Reason: One patient died after first operation. Others did not receive stoma ileostomy reversal for unknown reasons.; Group 2 Number missing: 22, Reason: Six patients died after the first operation. Others did not receive stoma reversal for unknown reasons.

Protocol outcome 4: Anastomotic leak at Define

- Actual outcome: Anastomotic leak (first operation) at First operation; Group 1: 1/34, Group 2: 1/56
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome: Anastomotic leak (second operation) at Second operation; Group 1: 1/22, Group 2: 2/34
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 12, Reason: One patient died after first operation. Others did not receive stoma ileostomy reversal for unknown reasons.; Group 2 Number missing: 22, Reason: Six patients died after the first operation. Others did not receive stoma reversal for unknown reasons.

| | |
|---|---|
| Protocol outcomes not reported by the study | Quality of life at Define; Progression of disease at Define; Complications (abscesses) at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Need for further surgery at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define |
|---|---|

| Study | Blair 2002 ¹² |
|---|--|
| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=97) |
| Countries and setting | Conducted in Canada; Setting: Secondary care - Royal Columbian Hospital, Vancouver, Canada. |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Retrospective chart review of patients undergoing surgery between 1989 and 2000. |
| Method of assessment of guideline condition | Unclear method of assessment/diagnosis: Not reported. |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Patients undergoing emergency surgery for acute diverticulitis within 48 hours of admission |
| Exclusion criteria | Uncomplicated diverticulitis cases; colovesical fistula and obstruction; any patient undergoing preoperative bowel preparation. |
| Recruitment/selection of patients | Consecutive patients undergoing emergency surgery for complicated acute diverticulitis between 1989 and 2000. |
| Age, gender and ethnicity | Age - Mean (SD): Primary anastomosis, 54 (14.8) years; Hartmann's procedure, 64.6 (15.7) years. Proportion >70 years: 17% vs. 49%. Gender (M:F): ~2/3 of patients in each group (primary anastomosis and Hartmann's procedure) reported to be male. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Emergency cases - operated on within 48 hours of admission. |
| Indirectness of population | No indirectness |
| Interventions | (n=33) Intervention 1: Primary anastomosis. Primary anastomosis with/without proximal protective stoma. Duration Not reported. Concurrent medication/care: No patients had on-table colonic lavage. Indirectness: No indirectness (n=64) Intervention 2: Temporary stoma. Hartmann's procedure. Duration Not reported. Concurrent medication/care: Not reported. Indirectness: No indirectness Comments: Classed as temporary stoma as aim is usually to reverse where possible. Study does not specify. |
| Funding | Funding not stated |

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH OR WITHOUT PROXIMAL PROTECTIVE STOMA) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)**Protocol outcome 1: Mortality at Define**

- Actual outcome: Mortality at Not reported; Group 1: 3/33, Group 2: 13/64

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Mean age differed: 54 vs. 64.6 years. Higher proportion >70 years in Hartmann group. ASA grade and Hinchey staging differed: Hartmann higher proportion of ASA 3 and 4; higher Hinchey stage 3 and 4 proportion in Hartmann; higher proportion Hinchey stage 1 in anastomosis group.; Key confounders: Age, gender; Group 1 Number missing: 0, Reason: Not applicable.; Group 2 Number missing: 0, Reason: Not applicable.

Protocol outcome 2: Complications (infections) at Define

- Actual outcome: Wound infection at Not reported; Group 1: 7/33, Group 2: 15/62

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Mean age differed: 54 vs. 64.6 years. Higher proportion >70 years in Hartmann group. ASA grade and Hinchey staging differed: Hartmann higher proportion of ASA 3 and 4; higher Hinchey stage 3 and 4 proportion in Hartmann; higher proportion Hinchey stage 1 in anastomosis group.; Key confounders: Age, gender; Group 1 Number missing: 0, Reason: Not applicable.; Group 2 Number missing: 2, Reason: Not reported.

- Actual outcome: Intra-abdominal infection at Not reported; Group 1: 1/33, Group 2: 3/61

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Mean age differed: 54 vs. 64.6 years. Higher proportion >70 years in Hartmann group. ASA grade and Hinchey staging differed: Hartmann higher proportion of ASA 3 and 4; higher Hinchey stage 3 and 4 proportion in Hartmann; higher proportion Hinchey stage 1 in anastomosis group.; Key confounders: Age, gender; Group 1 Number missing: 0, Reason: Not applicable.; Group 2 Number missing: 3, Reason: Not reported.

Protocol outcome 3: Hospitalisation at Define

- Actual outcome: Emergency readmission at Not reported; Group 1: 5/33, Group 2: 9/64

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Mean age differed: 54 vs. 64.6 years. Higher proportion >70 years in Hartmann group. ASA grade and Hinchey staging differed: Hartmann higher proportion of ASA 3 and 4; higher Hinchey stage 3 and 4 proportion in Hartmann; higher proportion Hinchey stage 1 in anastomosis group.; Key confounders: Age, gender; Group 1 Number missing: 0, Reason: Not applicable.; Group 2 Number missing: 0, Reason: Not applicable.

- Actual outcome: Hospital readmission at Not reported; Group 1: 0/33, Group 2: 5/64

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Mean age differed: 54 vs. 64.6 years. Higher proportion >70 years in Hartmann group. ASA grade and Hinchey staging differed: Hartmann higher proportion of ASA 3 and 4; higher Hinchey stage 3 and 4 proportion in Hartmann: higher

proportion Hinchey stage 1 in anastomosis group.; Key confounders: Age, gender; Group 1 Number missing: 0, Reason: Not applicable.; Group 2 Number missing: 0, Reason: Not applicable.

Protocol outcome 4: Anastomotic leak at Define

- Actual outcome: Anastomotic leak at Not reported; Group 1: 1/33, Group 2: 0/64; Comments: Note NA in HP group as anastomosis not attempted.

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Mean age differed: 54 vs. 64.6 years. Higher proportion >70 years in Hartmann group. ASA grade and Hinchey staging differed: Hartmann higher proportion of ASA 3 and 4; higher Hinchey stage 3 and 4 proportion in Hartmann; higher proportion Hinchey stage 1 in anastomosis group.; Key confounders: Age, gender; Group 1 Number missing: 0, Reason: Not applicable.; Group 2 Number missing: 0, Reason: Not applicable.

Protocol outcomes not reported by the study

Quality of life at Define; Morbidity at Define; Progression of disease at Define; Complications (abscesses) at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Need for further surgery at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define

| Study | Cauley 2018 ¹⁷ |
|---|--|
| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=67,721) |
| Countries and setting | Conducted in USA; Setting: Extracted data from Nationwide Inpatient Sample which includes hospital discharges across USA - secondary care. |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Retrospective review of patients between 1998 and 2011 |
| Method of assessment of guideline condition | Method of assessment /diagnosis not stated |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Patients with diagnosis of diverticulitis admitted emergently or urgently to hospital - resection performed on first or second day of admission. |
| Exclusion criteria | <18 years of age; concurrent pathology such as colorectal cancer, Crohn's disease or ulcerative colitis; patients undergoing colectomy with no designation for the type of diversion (e.g. colostomy or ileostomy); patients that did not undergo a diversion. |
| Recruitment/selection of patients | All patients matching criteria between 1998 and 2011. |
| Age, gender and ethnicity | Age - Other: Primary anastomosis: 18-39 years, 3.9%; 40-49 years, 8.00%; 50-59 years, 13.2%; 60-69 years, 21.3%; 70-79 years, 24.8%; ≥80 years, 28.8%. Resection with end colostomy: 18-39 years, 7%; 40-49 years, 15.3%; 50-59 years, 19.9%; 60-69 years, 21.0%; 70-79 years, 20.8%; ≥80 years, 15.9%. . Gender (M:F): Primary anastomosis, 1,267/1,370; resection with end colostomy, 32,447/32,637. Ethnicity: Primary anastomosis: White, 69.5%; Black, 21.6%; Hispanic, 3.4%; Asian, 0.5%; Native American, 0.5%; missing, 13.5%. Colectomy with end colostomy: White, 74.7%; Black, 4.9%; Hispanic, 4.9%; Asian, 0.5%; Native American, 0.3%; missing, 14.7%. |
| Further population details | |
| Extra comments | Those undergoing emergency or urgent resection for acute diverticulitis. |
| Indirectness of population | No indirectness |
| Interventions | (n=2637) Intervention 1: Primary anastomosis. Colectomy with primary anastomosis and proximal diverting ileostomy. Duration Not reported. Concurrent medication/care: Not reported. Indirectness: No indirectness |

| | |
|--|---|
| | (n=65084) Intervention 2: Temporary stoma. Colectomy with end colostomy. Duration Not reported. Concurrent medication/care: Not reported. Indirectness: No indirectness |
| Funding | Funding not stated |
| <p>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH DIVERTING ILEOSTOMY) versus TEMPORARY STOMA (COLECTOMY WITH END COLOSTOMY)</p> <p>Protocol outcome 1: Mortality at Define - Actual outcome: In-hospital mortality at In-hospital; Group 1: 422/2637, Group 2: 4164/65084 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Some differences with proportion of different age groups and Charlson score - higher proportion Charlson score 2+ and age >80 years in primary anastomosis group.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:</p> <p>Protocol outcome 2: Morbidity at Define - Actual outcome: Overall postoperative complications at Not reported; Group 1: 847/2637, Group 2: 15145/65084 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Some differences with proportion of different age groups and Charlson score - higher proportion Charlson score 2+ and age >80 years in primary anastomosis group.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:</p> <p>Protocol outcome 3: Complications (infections) at Define - Actual outcome: Postoperative complications - infection at Not reported; Group 1: 263/2637, Group 2: 3459/65084 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Some differences with proportion of different age groups and Charlson score - higher proportion Charlson score 2+ and age >80 years in primary anastomosis group.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:</p> | |
| Protocol outcomes not reported by the study | Quality of life at Define; Progression of disease at Define; Complications (abscesses) at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Need for further surgery at Define; Anastomotic leak at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define |

| Study | DIVERTI trial: Bridoux 2017 ¹⁴ |
|---|--|
| Study type | RCT (Patient randomised; Parallel) |
| Number of studies (number of participants) | 1 (n=102) |
| Countries and setting | Conducted in France; Setting: Four tertiary care referral hospitals in France. |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Follow-up up to 18 months after emergency operation |
| Method of assessment of guideline condition | Adequate method of assessment/diagnosis: Clinical assessment and CT scan. |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Aged 18 years or older. Perforated diverticulitis with fecal or purulent peritonitis (Hinchey stage III and IV). |
| Exclusion criteria | Failure to provide consent. Physical states preventing participation (e.g. septic shock or multivisceral failure). |
| Recruitment/selection of patients | Not reported. |
| Age, gender and ethnicity | Age - Median (range): Hartmann's procedure, 61.5 (29-92); Primary anastomosis, 61 (25-93). Gender (M:F): Hartmann's procedure, 23/29; Primary anastomosis, 28/22. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Patients undergoing emergency surgery. |
| Indirectness of population | No indirectness |
| Interventions | <p>(n=50) Intervention 1: Primary anastomosis. Performed through midline laparotomy according to standard technique. Anastomosis performed on well-vascularised segments according to preference of individual surgeons (mechanical or manual anastomosis; end to end or side to end). Stoma reversal operations performed at least three months after first operation and after performing barium enema to check for absence of fistula or stenosis at level of the anastomosis. Duration Median (range) operating time - primary anastomosis + stoma reversal, 197.5 (74-510) min. Concurrent medication/care: Decisions to clean colon intraoperatively, to place a drain, and to perform ileostomy or colostomy were at discretion of surgeon. Not all patients had a protective stoma. Indirectness: No indirectness</p> <p>(n=52) Intervention 2: Temporary stoma. Hartmann's procedure. Consisted of sigmoid resection, rectal closure and end colostomy, according to preferences of surgeon. Stoma reversal operation at least 6 months after Hartmann's procedure. Reversal performed by laparotomy or laparoscopy according to surgeon preference following rectal enema to assess length of rectal stump and confirm absence of fistula. Duration Median (range) operating time - Hartmann's</p> |

| | |
|---|---|
| | procedure + stoma reversal, 235 (45-650) min. Concurrent medication/care: Not reported. Indirectness: No indirectness |
| Funding | Academic or government funding (French Ministry of Health provided funding.) |
| <p>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH/WITHOUT DIVERTING STOMA) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)</p> <p>Protocol outcome 1: Mortality at Define - Actual outcome: Mortality (first operation) at First operation; Group 1: 2/50, Group 2: 2/52 Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: 5 did not receive allocated intervention - received Harmann's procedure instead. Analysed in original group.; Group 2 Number missing: 1, Reason: 1 did not receive allocated intervention - total colectomy instead. Analysed in original group. - Actual outcome: Mortality (second operation) at Second operation; Group 1: 0/32, Group 2: 2/33 Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 18, Reason: 2 patients died before second operation, 2 were unfit for surgery and 14 did not receive a stoma in the first operation (not applicable). Analysed in original group.; Group 2 Number missing: 19, Reason: 2 patients died before second operation, 8 patients chose not to have reversal and 9 were unfit for surgery. Analysed in original group.</p> <p>Protocol outcome 2: Morbidity at Define - Actual outcome: Overall morbidity (first operation) at First operation; Group 1: 27/50, Group 2: 22/52 Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: 5 did not receive allocated intervention - received Harmann's procedure instead. Analysed in original group.; Group 2 Number missing: 1, Reason: 1 did not receive allocated intervention - total colectomy instead. Analysed in original group. - Actual outcome: Overall morbidity (second operation) at Second operation; Group 1: 4/32, Group 2: 7/33 Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 18, Reason: 2 patients died before second operation, 2 were unfit for surgery and 14 did not receive a stoma in the first operation (not applicable). Analysed in original group.; Group 2 Number missing: 19, Reason: 2 patients died before second operation, 8 patients chose not to have reversal and 9 were unfit for surgery. Analysed in original group.</p> <p>Protocol outcome 3: Complications (abscesses) at Define - Actual outcome: Intra-abdominal abscess (first operation) at First operation; Group 1: 2/50, Group 2: 4/52 Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: 5 did not receive allocated intervention - received</p> | |

Harmann's procedure instead. Analysed in original group.; Group 2 Number missing: 1, Reason: 1 did not receive allocated intervention - total colectomy instead. Analysed in original group.

- Actual outcome: Intra-abdominal abscess (second operation) at Second operation; Group 1: 0/32, Group 2: 1/33

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 18, Reason: 2 patients died before second operation, 2 were unfit for surgery and 14 did not receive a stoma in the first operation (not applicable). Analysed in original group.; Group 2 Number missing: 19, Reason: 2 patients died before second operation, 8 patients chose not to have reversal and 9 were unfit for surgery. Analysed in original group.

Protocol outcome 4: Complications (stricture) at Define

- Actual outcome: Anastomotic stricture (first operation) at First operation; Group 1: 1/50, Group 2: 0/52

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: 5 did not receive allocated intervention - received Harmann's procedure instead. Analysed in original group.; Group 2 Number missing: 1, Reason: 1 did not receive allocated intervention - total colectomy instead. Analysed in original group.

Protocol outcome 5: Need for further surgery at Define

- Actual outcome: Reoperation (first operation) at First operation; Group 1: 2/50, Group 2: 4/52

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: 5 did not receive allocated intervention - received Harmann's procedure instead. Analysed in original group.; Group 2 Number missing: 1, Reason: 1 did not receive allocated intervention - total colectomy instead. Analysed in original group.

- Actual outcome: Reoperation (second operation) at Second operation; Group 1: 1/32, Group 2: 1/33

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 18, Reason: 2 patients died before second operation, 2 were unfit for surgery and 14 did not receive a stoma in the first operation (not applicable). Analysed in original group.; Group 2 Number missing: 19, Reason: 2 patients died before second operation, 8 patients chose not to have reversal and 9 were unfit for surgery. Analysed in original group.

Protocol outcome 6: Anastomotic leak at Define

- Actual outcome: Anastomotic leak (first operation) at First operation; Group 1: 2/50, Group 2: 0/52

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: 5 did not receive allocated intervention - received Hartmann's procedure instead. Analysed in original group.; Group 2 Number missing: 1, Reason: 1 did not receive allocated intervention - total colectomy instead. Analysed in original group.

- Actual outcome: Anastomotic leak (second operation) at Second operation; Group 1: 1/32, Group 2: 0/33

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low. Other 1 - Low; Indirectness of outcome: No indirectness : Group 1 Number missing: 18. Reason: 2 patients died before second operation. 2 were unfit

for surgery and 14 did not receive a stoma in the first operation (not applicable). Analysed in original group.; Group 2 Number missing: 19, Reason: 2 patients died before second operation, 8 patients chose not to have reversal and 9 were unfit for surgery. Analysed in original group.

| | |
|---|---|
| Protocol outcomes not reported by the study | Quality of life at Define; Progression of disease at Define; Complications (infections) at Define; Complications (perforation) at Define; Complications (fistula) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define |
|---|---|

| Study | Gawlick 2012 ²⁷ |
|---|---|
| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=2018) |
| Countries and setting | Conducted in USA; Setting: 211 hospitals - secondary care |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Retrospective review of cases between 2005 and 2009 |
| Method of assessment of guideline condition | Method of assessment /diagnosis not stated: Cases identified using CPT codes in database. Method of diagnosis not stated. |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Emergent operation for perforated diverticulitis; cases classified as dirty/infected; primary procedure was partial colectomy with primary anastomosis and proximal diversion with loop ileostomy (CPT code 44141) or partial colectomy with colostomy (Hartmann's procedure, CPT code 44143) |
| Exclusion criteria | Cases where contamination was the result of unintentional spillage during surgery (those with wound classification of clean/contaminated). |
| Recruitment/selection of patients | All cases of perforated diverticulitis requiring operative intervention between 2005 and 2009 matching inclusion criteria. |
| Age, gender and ethnicity | Age - Mean (SD): Primary anastomosis, 63.4 (15.8) years; Hartmann's procedure, 63.0 (15.0) years. Gender (M:F): Primary anastomosis, 164/176; Hartmann's procedure, 814/864. Ethnicity: Primary anastomosis: 85.3% white non-Hispanic, 0.6% Hispanic, 10.3% African American, 3.8% Asian, American Indian or Pacific Islander. Hartmann's procedure: 90.2% white non-Hispanic, 2.3% Hispanic, 6.0% African American, 1.5% Asian, American Indian or Pacific Islander. |
| Further population details | |
| Extra comments | Perforated diverticulitis requiring emergent operation. |
| Indirectness of population | No indirectness |
| Interventions | (n=340) Intervention 1: Primary anastomosis. Partial colectomy with primary anastomosis and proximal diversion with loop ileostomy. Duration Mean (SD) operative time: 136 (64.9) min. Concurrent medication/care: Not reported. Indirectness: No indirectness |

| | |
|---------|--|
| | (n=1678) Intervention 2: Temporary stoma. Hartmann's procedure - partial colectomy with colostomy. Duration Mean (SD) operative time: 131 (56.5) min. Concurrent medication/care: Not reported. Indirectness: No indirectness Comments: Classed as temporary stoma as aim is usually to reverse where possible. Study does not specify. |
| Funding | Funding not stated |

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH PROXIMAL LOOP ILEOSTOMY DIVERSION) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)

Protocol outcome 1: Mortality at Define

- Actual outcome: Mortality at 30 days post-operation; OR; 1.51 (95%CI 0.82 to 2.79, Comments: Controlled for potential confounders as identified in the study);
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Comparable for age, gender, race, comorbidities, ASA class, preoperative lab values and wound classification. Double amount with severe sepsis preoperatively in HP group vs. PA but this considered in confounding analysis.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 2: Complications (infections) at Define

- Actual outcome: Wound infection at 30 days post-operation; OR; 0.91 (95%CI 0.59 to 1.39, Comments: Controlled for potential confounders as identified in the study);
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Comparable for age, gender, race, comorbidities, ASA class, preoperative lab values and wound classification. Double amount with severe sepsis preoperatively in HP group vs. PA but this considered in confounding analysis.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome: Organ infection at 30 days post-operation; OR; 0.71 (95%CI 0.35 to 1.42, Comments: Controlled for potential confounders as identified in the study);
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Comparable for age, gender, race, comorbidities, ASA class, preoperative lab values and wound classification. Double amount with severe sepsis preoperatively in HP group vs. PA but this considered in confounding analysis.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome: Postoperative sepsis at 30 days post-operation; OR; 1.02 (95%CI 0.68 to 1.55, Comments: Controlled for potential confounders as identified in the study);

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Comparable for age, gender, race, comorbidities, ASA class, preoperative lab values and wound classification. Double amount with severe sepsis preoperatively in HP group vs. PA but this considered in confounding analysis.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 3: Need for further surgery at Define

- Actual outcome: Return to operating room at 30 days post-operation; OR; 0.99 (95%CI 0.58 to 1.69, Comments: Controlled for potential confounders as identified in the study);

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Comparable for age, gender, race, comorbidities, ASA class, preoperative lab values and wound classification. Double amount with severe sepsis preoperatively in HP group vs. PA but this considered in confounding analysis.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcomes not reported by the study

Quality of life at Define; Morbidity at Define; Progression of disease at Define; Complications (abscesses) at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Anastomotic leak at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define

| Study | Gooszen 2001 ²⁹ |
|---|--|
| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=60) |
| Countries and setting | Conducted in Netherlands; Setting: Secondary care - hospital |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Retrospective review of cases between 1979 and 1993 |
| Method of assessment of guideline condition | Method of assessment /diagnosis not stated |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Acute complications of diverticular disease (perforated diverticulitis with paracolic abscess, localised peritonitis or colonic obstruction as result of recurrent episodes with stenosis) requiring urgent operation within 24 hours of admission. |
| Exclusion criteria | Not reported. |
| Recruitment/selection of patients | Patients admitted between 1979 and 1993 with acute complicated diverticular disease requiring urgent operation. |
| Age, gender and ethnicity | Age - Mean (SD): Primary anastomosis, 63 (17) years; Hartmann's procedure, 68 (16) years. Gender (M:F): Whole cohort, 18/42. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Acute complications of diverticular disease requiring urgent operation within 24 hours of admission. |
| Indirectness of population | No indirectness |
| Interventions | <p>(n=32) Intervention 1: Primary anastomosis. Acute sigmoid resection followed by primary anastomosis covered by a defunctioning stoma (7 loop ileostomy and 25 transverse colostomy). Duration Mean (range) operation duration: initial operation - 172 min (75 - 300 min); second operation - 75 min (30 - 150 min). Concurrent medication/care: Not reported. Indirectness: No indirectness</p> <p>(n=28) Intervention 2: Temporary stoma. Hartmann's procedure. Duration Mean (range) operation duration: initial operation - 150 min (60 - 240 min); second operation - 172 min (90 - 195 min). Concurrent medication/care: Not reported. Indirectness: No indirectness</p> <p>Comments: Classed as temporary as study aimed to reverse stomas where possible.</p> |

| Funding | Funding not stated |
|---|--------------------|
| <p>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH DEFUNCTIONING STOMA) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)</p> | |
| <p>Protocol outcome 1: Mortality at Define</p> <p>- Actual outcome: In-hospital mortality (first operation) at In-hospital (first operation); Group 1: 5/32, Group 2: 6/28 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in grade of peritonitis and faecal contamination between groups. Some differences in % with cardiovascular disease - higher in PA group. Gender distribution not stated in different groups.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:</p> <p>- Actual outcome: In-hospital mortality (second operation) at In-hospital (second operation); Group 1: 0/27, Group 2: 1/22 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in grade of peritonitis and faecal contamination between groups. Some differences in % with cardiovascular disease - higher in PA group. Gender distribution not stated in different groups.; Key confounders: Age, gender; Group 1 Number missing: 5, Reason: Patients died prior to second operation.; Group 2 Number missing: 6, Reason: Patients died prior to second operation.</p> | |
| <p>Protocol outcome 2: Complications (infections) at Define</p> <p>- Actual outcome: Sepsis (first operation) at Not reported; Group 1: 3/32, Group 2: 6/28 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in grade of peritonitis and faecal contamination between groups. Some differences in % with cardiovascular disease - higher in PA group. Gender distribution not stated in different groups.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:</p> <p>- Actual outcome: Sepsis (second operation) at Not reported; Group 1: 0/27, Group 2: 2/22 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in grade of peritonitis and faecal contamination between groups. Some differences in % with cardiovascular disease - higher in PA group. Gender distribution not stated in different groups.; Key confounders: Age, gender; Group 1 Number missing: 5, Reason: Patients died prior to second operation.; Group 2 Number missing: 6, Reason: Patients died prior to second operation.</p> <p>- Actual outcome: Wound infection (first operation) at Not reported; Group 1: 1/32, Group 2: 4/28 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in grade of peritonitis and faecal contamination between groups. Some differences in % with cardiovascular disease - higher in PA group. Gender distribution not stated in different groups.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:</p> <p>- Actual outcome: Wound infection (second operation) at Not reported; Group 1: 3/27, Group 2: 2/22 Risk of bias: All domain - Very high. Selection - Very high. Blinding - High. Incomplete outcome data - High. Outcome reporting - Low. Measurement - Low. Crossover -</p> | |

Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in grade of peritonitis and faecal contamination between groups. Some differences in % with cardiovascular disease - higher in PA group. Gender distribution not stated in different groups.; Key confounders: Age, gender; Group 1 Number missing: 5, Reason: Patients died prior to second operation.; Group 2 Number missing: 6, Reason: Patients died prior to second operation.

- Actual outcome: Urinary infection (first operation) at Not reported; Group 1: 1/32, Group 2: 4/28

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in grade of peritonitis and faecal contamination between groups. Some differences in % with cardiovascular disease - higher in PA group. Gender distribution not stated in different groups.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome: Urinary infection (second operation) at Not reported; Group 1: 0/27, Group 2: 0/22

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in grade of peritonitis and faecal contamination between groups. Some differences in % with cardiovascular disease - higher in PA group. Gender distribution not stated in different groups.; Key confounders: Age, gender; Group 1 Number missing: 5, Reason: Patients died prior to second operation.; Group 2 Number missing: 6, Reason: Patients died prior to second operation.

Protocol outcome 3: Complications (abscesses) at Define

- Actual outcome: Intra-abdominal abscess (first operation) at Not reported; Group 1: 3/32, Group 2: 4/28

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in grade of peritonitis and faecal contamination between groups. Some differences in % with cardiovascular disease - higher in PA group. Gender distribution not stated in different groups.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome: Intra-abdominal abscess (second operation) at Not reported; Group 1: 0/27, Group 2: 0/22

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in grade of peritonitis and faecal contamination between groups. Some differences in % with cardiovascular disease - higher in PA group. Gender distribution not stated in different groups.; Key confounders: Age, gender; Group 1 Number missing: 5, Reason: Patients died prior to second operation.; Group 2 Number missing: 6, Reason: Patients died prior to second operation.

Protocol outcome 4: Need for further surgery at Define

- Actual outcome: Reintervention (first operation) at Not reported; Group 1: 5/32, Group 2: 6/28

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in grade of peritonitis and faecal contamination between groups. Some differences in % with cardiovascular disease - higher in PA group. Gender distribution not stated in different groups.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome: Reintervention (second operation) at Not reported; Group 1: 3/27, Group 2: 5/22

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in grade of peritonitis and faecal contamination between groups. Some differences in % with cardiovascular disease - higher in PA group. Gender distribution not stated in different groups.; Key confounders: Age, gender; Group

1 Number missing: 5, Reason: Patients died prior to second operation.; Group 2 Number missing: 6, Reason: Patients died prior to second operation.

Protocol outcome 5: Anastomotic leak at Define

- Actual outcome: Anastomotic leak (first operation) at Not reported; Group 1: 3/32, Group 2: 0/28; Comments: Note NA for HP group as anastomosis not attempted in first operation.

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in grade of peritonitis and faecal contamination between groups. Some differences in % with cardiovascular disease - higher in PA group. Gender distribution not stated in different groups.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome: Anastomotic leak (second operation) at Not reported; Group 1: 0/27, Group 2: 3/22

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in grade of peritonitis and faecal contamination between groups. Some differences in % with cardiovascular disease - higher in PA group. Gender distribution not stated in different groups.; Key confounders: Age, gender; Group 1 Number missing: 5, Reason: Patients died prior to second operation.; Group 2 Number missing: 6, Reason: Patients died prior to second operation.

Protocol outcome 6: Stoma complications at Define

- Actual outcome: Stoma dysfunction at Not reported; Group 1: 3/32, Group 2: 7/28

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in grade of peritonitis and faecal contamination between groups. Some differences in % with cardiovascular disease - higher in PA group. Gender distribution not stated in different groups.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcomes not reported by the study

Quality of life at Define; Morbidity at Define; Progression of disease at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define

| Study | Gregg 1987 ³² |
|---|---|
| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=208) |
| Countries and setting | Conducted in USA; Setting: Secondary care - those admitted for operation in four different time periods. |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Retrospective review of patients admitted between different time frames. |
| Method of assessment of guideline condition | Adequate method of assessment/diagnosis: Emergency operation indicated by free air/obstruction on flat films, abscesses diagnosed by contrast radiography, ultrasonography or computerised axial tomography, an extrinsic mass or leak shown by contrast study or failure to improve with medical treatment. |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Emergency operation defined as those performed at time of first admission for either acute condition or failure to respond to medical treatment. |
| Exclusion criteria | Not reported. |
| Recruitment/selection of patients | Patients admitting to various hospitals during four different time periods: one group was collected over a 30 year time period, one between 1974 and 1978, one between 1979 and 1983 and another during an 18 month period ending in July 1985. |
| Age, gender and ethnicity | Age - Other: Average age: primary anastomosis with/without temporary transverse colostomy, 60 years; Hartmann's procedure, 67 years. Gender (M:F): Not reported. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Extracted data only for emergency cases as the elective population consisted of unsuitable cases for this review question. One-stage and resection, anastomosis and temporary transverse colostomy groups were combined under 'primary anastomosis group' when extracting. Did not extract exteriorisation, descending colostomy or transverse colostomy groups as appear to be non-resective procedures. |
| Indirectness of population | No indirectness |
| Interventions | (n=55) Intervention 1: Primary anastomosis. Combined one-stage and resection, primary anastomosis and temporary transverse colostomy groups reported in this study. Duration Not reported. Concurrent medication/care: Not reported. Indirectness: No indirectness |

| | |
|--|--|
| | (n=23) Intervention 2: Temporary stoma. Hartmann's procedure. Duration Not reported. Concurrent medication/care: Not reported. Indirectness: No indirectness |
| Funding | Funding not stated |
| <p>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH OR WITHOUT TEMPORARY TRANSVERSE COLOSTOMY) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)</p> <p>Protocol outcome 1: Mortality at Define - Actual outcome: Mortality at Not reported; Group 1: 0/55, Group 2: 2/23 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Age substantially different between groups: 60 years vs. 67 years. Insufficient data to compare gender proportions.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:</p> | |
| Protocol outcomes not reported by the study | Quality of life at Define; Morbidity at Define; Progression of disease at Define; Complications (infections) at Define; Complications (abscesses) at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Need for further surgery at Define; Anastomotic leak at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define |

| Study | Herzog 2011 ³⁴ |
|---|--|
| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=40) |
| Countries and setting | Conducted in Germany; Setting: Secondary care - hospital |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Retrospective review of data from all patients admitted within a period of 18 months |
| Method of assessment of guideline condition | Adequate method of assessment/diagnosis: Triple contrast CT scan performed on admission |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Those undergoing emergency surgery due to complicated diverticulitis (perforated diverticulitis, abscess formation with sepsis, local or diffuse peritonitis, ileus secondary to recent episodes of diverticulitis or haemorrhage). |
| Exclusion criteria | Not reported. |
| Recruitment/selection of patients | Retrospective review of data from all cases matching inclusion criteria within 18 month period. |
| Age, gender and ethnicity | Age - Mean (SD): Primary anastomosis, 62 (16) years; Hartmann's procedure, 68 (13) years. Gender (M:F): Primary anastomosis, 13/8; Hartmann's procedure, 7/12. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Those undergoing emergency surgery due to complicated diverticulitis. |
| Indirectness of population | Serious indirectness: 3/40 patients with obstruction due to recurrent episodes of diverticulitis - unclear of distribution between two groups. Included as <10% of whole cohort. |
| Interventions | <p>(n=21) Intervention 1: Primary anastomosis. Midline laparotomy. Primary anastomosis with/without diverting ileostomy. Ileostomy performed in those with MP scores >21 (n=7). Duration Mean surgery duration, 223±19 min. Concurrent medication/care: All patients received systemic antibiotics including metronidazole and a third generation cephalosporin before laparotomy. Depending on degree of peritonitis, patients received a combination of sulbactam and ceftazidime or a carbapenem unless change indicated by sensitivity of identified microorganisms. All patients had abdominal lavage with at least 5 litres of warm saline solution. Treatment of peritonitis included clearance of pus, faeces, exudates and as much debris and pseudomembranous material as possible. Indirectness: No indirectness</p> <p>(n=19) Intervention 2: Temporary stoma. Hartmann's procedure. Performed in all cases of faecal peritonitis, severe comorbidity. need for high dose catecholamine or multiple organ failure. Surgeon free to choose between primary</p> |

| | |
|---|--|
| | <p>anastomosis and Hartmann's in other cases of peritonitis. Duration Mean surgery duration, 203±27 min. Concurrent medication/care: All patients received systemic antibiotics including metronidazole and a third generation cephalosporin before laparotomy. Depending on degree of peritonitis, patients received a combination of sulbactam and ceftazidime or a carbapenem unless change indicated by sensitivity of identified microorganisms. All patients had abdominal lavage with at least 5 litres of warm saline solution. Treatment of peritonitis included clearance of pus, faeces, exudates and as much debris and pseudomembranous material as possible. . Indirectness: No indirectness</p> |
| Funding | Funding not stated |
| <p>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH/WITHOUT DIVERTING ILEOSTOMY) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)</p> <p>Protocol outcome 1: Mortality at Define - Actual outcome: Postoperative mortality, in-hospital at In-hospital; Group 1: 1/21, Group 2: 6/19 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Substantial differences in gender and preoperative risk factors, including comorbidity and degree of peritonitis. Proportion >65 years was higher in the Hartmann group, with most severe cases also in this group.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:</p> <p>Protocol outcome 2: Morbidity at Define - Actual outcome: Major surgical complications at Not reported; Group 1: 1/21, Group 2: 6/19; Comments: Includes anastomotic leak, wound dehiscence, intraabdominal abscess and colostomy insufficiency Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Substantial differences in gender and preoperative risk factors, including comorbidity and degree of peritonitis. Proportion >65 years was higher in the Hartmann group, with most severe cases also in this group.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing: - Actual outcome: Major general complications at Not reported; Group 1: 1/21, Group 2: 8/19; Comments: Includes cardiac, septic organ failure, pneumonia, necrotising pancreatitis, stroke and pulmonary embolism. Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Substantial differences in gender and preoperative risk factors, including comorbidity and degree of peritonitis. Proportion >65 years was higher in the Hartmann group, with most severe cases also in this group.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing: - Actual outcome: Minor general complications at Not reported; Group 1: 2/21, Group 2: 4/19; Comments: Includes urinary tract infection and pleural effusion Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low. Subgroups - Low. Other 1 - Low; Indirectness of outcome: No indirectness : Baseline details: Substantial differences in gender and preoperative risk factors.</p> | |

including comorbidity and degree of peritonitis. Proportion >65 years was higher in the Hartmann group, with most severe cases also in this group.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 3: Complications (infections) at Define

- Actual outcome: Wound infection at Not reported; Group 1: 4/21, Group 2: 3/19

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Substantial differences in gender and preoperative risk factors, including comorbidity and degree of peritonitis. Proportion >65 years was higher in the Hartmann group, with most severe cases also in this group.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome: Urinary tract infection at Not reported; Group 1: 2/21, Group 2: 3/19

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Substantial differences in gender and preoperative risk factors, including comorbidity and degree of peritonitis. Proportion >65 years was higher in the Hartmann group, with most severe cases also in this group.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 4: Complications (abscesses) at Define

- Actual outcome: Intra-abdominal abscess at Not reported; Group 1: 0/21, Group 2: 1/19

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Substantial differences in gender and preoperative risk factors, including comorbidity and degree of peritonitis. Proportion >65 years was higher in the Hartmann group, with most severe cases also in this group.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 5: Need for further surgery at Define

- Actual outcome: Unplanned early reoperation at Not reported; Group 1: 1/21, Group 2: 5/19

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Substantial differences in gender and preoperative risk factors, including comorbidity and degree of peritonitis. Proportion >65 years was higher in the Hartmann group, with most severe cases also in this group.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 6: Anastomotic leak at Define

- Actual outcome: Anastomotic leak at Not reported; Group 1: 1/21, Group 2: 0/19; Comments: Note NA for HP as no anastomosis attempted

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Substantial differences in gender and preoperative risk factors, including comorbidity and degree of peritonitis. Proportion >65 years was higher in the Hartmann group, with most severe cases also in this group.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 7: Stoma complications at Define

- Actual outcome: Colostomy insufficiency at Not reported; Group 1: 0/21, Group 2: 3/19; Comments: Note NA for PA group as no colostomies attempted - only some with ileostomy.

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Substantial differences in gender and preoperative risk factors, including comorbidity and degree of peritonitis. Proportion >65 years was higher in the Hartmann group, with most severe cases also in this group.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcomes not reported by the study

Quality of life at Define; Progression of disease at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define

| Study | Hold 1990 ³⁵ |
|---|--|
| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=241) |
| Countries and setting | Conducted in Austria; Setting: Secondary care - 24 hospitals |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Retrospective review of cases between 1985 and 1987 |
| Method of assessment of guideline condition | Adequate method of assessment/diagnosis: Diagnostic procedures included plain abdominal film, enema with water-soluble contrast media, colonoscopy and/or computed tomography. |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Those undergoing surgery for perforated diverticulitis. |
| Exclusion criteria | Not reported. |
| Recruitment/selection of patients | Those undergoing surgery for perforated diverticulitis at 24 hospitals between 1985 and 1987. |
| Age, gender and ethnicity | Age - Median (range): Males, 62.13 (23-88) years; females, 68.73 (26-92) years. Gender (M:F): Whole cohort, 99/142. Not available separately for different interventions. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Those undergoing surgery for perforated diverticulitis. Note that when extracting primary anastomosis without protective colostomy and primary anastomosis with protective colostomy groups were combined. |
| Indirectness of population | No indirectness |
| Interventions | (n=99) Intervention 1: Primary anastomosis. Primary resection and anastomosis with/without protective proximal colostomy. Duration Not reported. Concurrent medication/care: Not reported. Indirectness: No indirectness (n=76) Intervention 2: Temporary stoma. Hartmann's procedure - primary resection with end colostomy. Duration Not reported. Concurrent medication/care: Not reported. Indirectness: No indirectness Comments: Classed as temporary stoma as aim is usually to reverse where possible. |
| Funding | Funding not stated |

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH OR WITHOUT PROTECTIVE PROXIMAL COLOSTOMY) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)

Protocol outcome 1: Mortality at Define

- Actual outcome: Mortality at Not reported; Group 1: 4/99, Group 2: 9/76; Comments: Note includes various complications such as peritonitis, ileus, colostomy infection, anastomotic leak and obstruction.

Risk of bias: All domain - --, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Cannot compare age and gender between the two groups. Difference in proportion of localised and diffuse peritonitis between the groups - higher proportion of diffuse peritonitis in Hartmann group, likely to be more severe cases.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 2: Morbidity at Define

- Actual outcome: Overall morbidity (first operation) at First operation; Group 1: 22/99, Group 2: 16/76

Risk of bias: All domain - --, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Cannot compare age and gender between the two groups. Difference in proportion of localised and diffuse peritonitis between the groups - higher proportion of diffuse peritonitis in Hartmann group, likely to be more severe cases.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 3: Anastomotic leak at Define

- Actual outcome: Anastomotic leak (second operation) at Second operation; Group 1: 1/15, Group 2: 4/42; Comments: Note number analysed are those that went on to have reversal operation in each group.

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Cannot compare age and gender between the two groups. Difference in proportion of localised and diffuse peritonitis between the groups - higher proportion of diffuse peritonitis in Hartmann group, likely to be more severe cases.; Key confounders: Age, gender; Group 1 Number missing: 84, Reason: Only 29/99 had protective colostomy and were therefore eligible for colostomy reversal - missing rate therefore 14/29 (48.28%) and more closely resembles that in the Hartmann's group. Reasons why 14/29 did not undergo reversal not clear. May have been due to deaths prior to second operation or considered unfit for reversal.; Group 2 Number missing: 34, Reason: Reasons reversal not performed unclear. May be due to deaths prior to second operation or considered unfit for reversal.

Protocol outcomes not reported by the study

Quality of life at Define; Progression of disease at Define; Complications (infections) at Define; Complications (abscesses) at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Need for further surgery at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define

| Study | Kriwanek 1994 ⁴² |
|---|--|
| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=112) |
| Countries and setting | Conducted in Austria; Setting: Secondary care - hospital. |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Retrospective review of patient records treated between 1979 and 1992 |
| Method of assessment of guideline condition | Method of assessment /diagnosis not stated |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Not reported. |
| Exclusion criteria | Not reported. |
| Recruitment/selection of patients | Records of patients treated for perforation of the colon between 1979 and 1992. |
| Age, gender and ethnicity | Age - Median (range): Whole cohort including all colon diseases, 68 (18-80) years. Not available separately for diverticulitis population. Gender (M:F): Whole cohort including all colon diseases, 51/61. Not available separately for diverticulitis population. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Extracted outcomes only for the diverticulitis population within this study, which gives outcomes for a larger cohort of colorectal diseases. |
| Indirectness of population | No indirectness |
| Interventions | (n=26) Intervention 1: Primary anastomosis. When extracting, combined primary anastomosis and primary anastomosis with stoma groups reported in this study. Duration Not reported. Concurrent medication/care: Not reported. Indirectness: No indirectness (n=33) Intervention 2: Temporary stoma. Hartmann's procedure. Duration Not reported. Concurrent medication/care: Not reported. Indirectness: No indirectness Comments: Classed as temporary as aim is usually to reverse stoma where possible. |
| Funding | Funding not stated |

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH OR WITHOUT STOMA) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)

Protocol outcome 1: Mortality at Define

- Actual outcome: Mortality at Not reported; Group 1: 4/26, Group 2: 5/33

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: No data available to compare baseline between groups for the diverticulitis population.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcomes not reported by the study

Quality of life at Define; Morbidity at Define; Progression of disease at Define; Complications (infections) at Define; Complications (abscesses) at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Need for further surgery at Define; Anastomotic leak at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define

| Study | Medina 1991 ⁴⁷ |
|---|--|
| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=6) |
| Countries and setting | Conducted in USA; Setting: Secondary care - emergency presentation. |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Review of records for those admitted between January 1983 and August 1988) |
| Method of assessment of guideline condition | Adequate method of assessment/diagnosis: Clinical findings and symptoms. Radiology. |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Hinchey stage IV diverticulitis - diverticulitis with faecal peritonitis. |
| Exclusion criteria | Not reported. |
| Recruitment/selection of patients | Consecutive patients presenting with diverticulitis with faecal peritonitis between January 1983 and August 1988. |
| Age, gender and ethnicity | Age - Mean (SD): Primary anastomosis, 63.7 years; Hartmann's procedure, 78.7 years. Gender (M:F): Primary anastomosis, 1/2; Hartmann's procedure, 1/2. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | All patients were Hinchey stage IV (perforated diverticular disease associated with faecal peritonitis). All were emergency cases. |
| Indirectness of population | No indirectness |
| Interventions | <p>(n=3) Intervention 1: Primary anastomosis. Primary resection and immediate anastomosis. Duration Not reported. Concurrent medication/care: Resuscitative measures established for all patients prior to surgery (administration of supplemental oxygen, insertion of large-bore intravenous catheters). Balanced salt solution (e.g. Ringer's Lactate) given intravenously and titrated according to vital signs and urine output. Patients underwent copious peritoneal lavage with warm saline at completion of procedure. Indirectness: No indirectness</p> <p>(n=3) Intervention 2: Temporary stoma. Hartmann's procedure with terminal colostomy. Duration Not reported. Concurrent medication/care: Resuscitative measures established for all patients prior to surgery (administration of supplemental oxygen, insertion of large-bore intravenous catheters). Balanced salt solution (e.g. Ringer's Lactate) given intravenously and titrated according to vital signs and urine output. Patients underwent copious peritoneal lavage with warm saline at completion of procedure. Indirectness: No indirectness</p> |

| | |
|---|---|
| Funding | Funding not stated |
| <p>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)</p> <p>Protocol outcome 1: Mortality at Define - Actual outcome: Mortality at Postoperative; Group 1: 0/3, Group 2: 1/3 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Mean age substantially different between the two groups: 63.7 vs. 78.7 years.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:</p> <p>Protocol outcome 2: Complications (abscesses) at Define - Actual outcome: Abscess at Postoperative; Group 1: 1/3, Group 2: 0/3 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Mean age substantially different between the two groups: 63.7 vs. 78.7 years.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:</p> | |
| Protocol outcomes not reported by the study | Quality of life at Define; Morbidity at Define; Progression of disease at Define; Complications (infections) at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Need for further surgery at Define; Anastomotic leak at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define |

| Study | Mueller 2011 ⁴⁹ |
|---|--|
| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=73) |
| Countries and setting | Conducted in Germany; Setting: Hospital - secondary care. |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Retrospective review of patients between 1996 and 2006 |
| Method of assessment of guideline condition | Adequate method of assessment/diagnosis: Perforation confirmed by X-ray or CT scan prior to surgery. |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Patients undergoing emergency surgery for perforated diverticulitis (Hinchey I-IV). |
| Exclusion criteria | Not reported. |
| Recruitment/selection of patients | All patients matching criteria between 1996 and 2006. |
| Age, gender and ethnicity | Age - Mean (SD): Primary anastomosis, 63 (12) years; Hartmann's procedure, 67 (13) years. Gender (M:F): Primary anastomosis, 26/21; Hartmann's procedure, 10/16. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Patients undergoing emergency surgery for perforated diverticulitis (Hinchey I-IV). |
| Indirectness of population | No indirectness |
| Interventions | (n=47) Intervention 1: Primary anastomosis. Sigmoid colectomy and primary anastomosis with/without diverting loop ileostomy. Duration Not reported. Concurrent medication/care: Not reported. Indirectness: No indirectness (n=26) Intervention 2: Temporary stoma. Hartmann's procedure. Duration Not reported. Concurrent medication/care: Not reported. Indirectness: No indirectness Comments: Classed as temporary stoma as aim is usually to reverse stoma where possible. |
| Funding | Funding not stated |

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH OR WITHOUT DIVERTING LOOP ILEOSTOMY) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)

Protocol outcome 1: Mortality at Define

- Actual outcome: Postoperative mortality at In-hospital; Group 1: 2/47, Group 2: 7/26

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference in gender distribution. Higher comorbidity proportion in HP group. Higher proportion of ASA III and IV patients in HP group. Higher proportion of Hinchey stages III and IV perforation in HP group. HP group more critically ill.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 2: Morbidity at Define

- Actual outcome: Major postoperative complications at Not reported; Group 1: 14/47, Group 2: 12/26

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference in gender distribution. Higher comorbidity proportion in HP group. Higher proportion of ASA III and IV patients in HP group. Higher proportion of Hinchey stages III and IV perforation in HP group. HP group more critically ill.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 3: Complications (infections) at Define

- Actual outcome: Postoperative wound infection at Not reported; Group 1: 3/47, Group 2: 4/26

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference in gender distribution. Higher comorbidity proportion in HP group. Higher proportion of ASA III and IV patients in HP group. Higher proportion of Hinchey stages III and IV perforation in HP group. HP group more critically ill.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome: Sepsis at Not reported; Group 1: 9/47, Group 2: 5/26

Risk of bias: All domain - ; Indirectness of outcome: No indirectness

Protocol outcome 4: Complications (abscesses) at Define

- Actual outcome: Abscess/peritonitis at Not reported; Group 1: 3/47, Group 2: 1/26

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference in gender distribution. Higher comorbidity proportion in HP group. Higher proportion of ASA III and IV patients in HP group. Higher proportion of Hinchey stages III and IV perforation in HP group. HP group more critically ill.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 5: Anastomotic leak at Define

- Actual outcome: Anastomotic leak at Not reported; Group 1: 10/47, Group 2: 0/26; Comments: Not NA in HP as anastomosis not attempted after first operation.

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference in gender distribution. Higher comorbidity proportion in HP group. Higher proportion of ASA III and IV patients in HP group. Higher proportion of Hinchey stages III and IV perforation in HP group. HP group more critically ill.: Key

confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 6: Stoma complications at Define

- Actual outcome: Stoma necrosis at Not reported; Group 1: 0/47, Group 2: 4/26; Comments: Note potentially NA for PA group?

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference in gender distribution. Higher comorbidity proportion in HP group. Higher proportion of ASA III and IV patients in HP group. Higher proportion of Hinchey stages III and IV perforation in HP group. HP group more critically ill.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome: Hartmann stump insufficiency at Not reported; Group 1: 0/47, Group 2: 2/26; Comments: Note NA for PA group.

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference in gender distribution. Higher comorbidity proportion in HP group. Higher proportion of ASA III and IV patients in HP group. Higher proportion of Hinchey stages III and IV perforation in HP group. HP group more critically ill.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcomes not reported by the study

Quality of life at Define; Progression of disease at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Need for further surgery at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define

| Study | Netri 2000 ⁵² |
|---|--|
| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=239) |
| Countries and setting | Conducted in Italy; Setting: General surgery department of Catholic University of the Sacred Heart. |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Retrospective review of patients between January 1977 and December 1997. |
| Method of assessment of guideline condition | Adequate method of assessment/diagnosis: Clinical evaluation, blood tests (Hct with formula, main hepatic and renal indexes) and ECG performed. Upright abdominal radiographs most utilised visual diagnostic test. Abdominal ultrasound reserved for clarifying uncertain diagnoses. |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Patients with acute diverticulitis. |
| Exclusion criteria | Not reported. |
| Recruitment/selection of patients | Patients admitted to General Surgery I Department of the Catholic University of the Sacred hearth between January 1977 and 1997 with acute diverticulitis. |
| Age, gender and ethnicity | Age - Other: Not reported. Gender (M:F): Not reported. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Extracted only for emergency cases as this was the only population matching protocol exactly. Consisted of emergency procedures (within 6 hours of admission), delayed emergency procedures (within 48 hours of admission) and delayed procedures (after 48 hours, but always within same admission). Emergency surgery performed in patients with instrumental and clinical signs of generalised or localised peritonitis. |
| Indirectness of population | No indirectness |
| Interventions | (n=31) Intervention 1: Primary anastomosis. Resection with immediate anastomosis with or without a protective colostomy. Duration Not reported. Concurrent medication/care: All patients received antibiotic and infusion therapy prior to surgery. Indirectness: No indirectness (n=6) Intervention 2: Temporary stoma. Hartmann's procedure with stoma. Does not specify if stomas reversed. Duration Not reported. Concurrent medication/care: All patients received antibiotic and infusion therapy prior to surgerv. Indirectness: No indirectness |

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| | Comments: Classed as temporary stoma as aim is usually to reverse stomas where possible, and study did not give details of this. |
| Funding | Funding not stated |
| <p>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH/WITHOUT PROTECTIVE COLOSTOMY) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)</p> <p>Protocol outcome 1: Mortality at Define - Actual outcome: Mortality at Not reported; Group 1: 1/31, Group 2: 1/6 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Unable to assess difference between primary anastomosis and Hartmann's procedure groups.; Key confounders: Age, gender; Group 1 Number missing: 0; Group 2 Number missing: 0</p> | |
| Protocol outcomes not reported by the study | Quality of life at Define; Morbidity at Define; Progression of disease at Define; Complications (infections) at Define; Complications (abscesses) at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Need for further surgery at Define; Anastomotic leak at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define |

| Study | Oberkofler 2012 ⁵³ |
|---|---|
| Study type | RCT (Patient randomised; Parallel) |
| Number of studies (number of participants) | 1 (n=62) |
| Countries and setting | Conducted in Switzerland; Setting: Two university hospitals. |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Median follow-up, 47 months. |
| Method of assessment of guideline condition | Adequate method of assessment/diagnosis: Computed tomography and/or clinical and radiography evidence. |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | German-language speaking. 18 years or older. Purulent or faecal peritonitis (Hinchey III and IV). |
| Exclusion criteria | Patients without generalised peritonitis (Hinchey I and II). Patients with evidence of metastasis. |
| Recruitment/selection of patients | Consecutive patients. |
| Age, gender and ethnicity | Age - Median (IQR): Hartmann's procedure, 74 (61-81); Primary anastomosis, 72 (60-83). Gender (M:F): Hartmann's procedure, 9/21; Primary anastomosis, 12/20. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Unclear whether all undergoing emergency surgery initially. |
| Indirectness of population | No indirectness |
| Interventions | <p>(n=32) Intervention 1: Primary anastomosis. Surgical resection of sigmoid colon with primary anastomosis and a diverting ileostomy. Stoma reversal operation followed at later stage. Stoma reversal set to take place up to 3 months after first operation. Duration Median (IQR) operation time - primary anastomosis + stoma reversal, 240 (205-330) min. Concurrent medication/care: Decisions to take down splenic flexure or clean colon intraoperatively made individually by surgeons. Indirectness: No indirectness</p> <p>(n=30) Intervention 2: Temporary stoma. Hartmann's procedure. Surgical resection of the sigmoid colon with closure of the rectal stump and formation of an end colostomy. Stoma reversal operation planned at later stage. Duration Median (IQR) operation time - Hartmann's procedure + stoma reversal, 383 (280-460) min. Concurrent medication/care: Decisions to take down splenic flexure or clean colon intraoperatively made individually by surgeon. Indirectness: No indirectness</p> |

| Funding | Funding not stated |
|--|--------------------|
| <p>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH DIVERTING ILEOSTOMY) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)</p> | |
| <p>Protocol outcome 1: Mortality at Define - Actual outcome: In hospital mortality (first operation) at In-hospital; Group 1: 3/32, Group 2: 4/30 Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: Three patients originally assigned to PA switched to HP at surgeon discretion. Analysed in original groups.; Group 2 Number missing: 1, Reason: One patient originally assigned to HP group switched to PA at surgeon discretion. Analysed in original groups.</p> | |
| <p>- Actual outcome: In hospital mortality (second operation) at In-hospital; Group 1: 0/26, Group 2: 0/15 Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 6, Reason: Six patients did not have ileostomy reversal in the PA group.; Group 2 Number missing: 15, Reason: Fifteen patients did not have colostomy reversal in the HP group.</p> | |
| <p>Protocol outcome 2: Morbidity at Define - Actual outcome: Morbidity (first operation) at First operation; Group 1: 24/32, Group 2: 12/30 Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - High, Outcome reporting - High, Measurement - High, Crossover - Low, Subgroups - Low, Other 1 - Low, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: Three patients originally assigned to PA switched to HP at surgeon discretion. Analysed in original groups.; Group 2 Number missing: 1, Reason: One patient originally assigned to HP group switched to PA at surgeon discretion. Analysed in original groups.</p> | |
| <p>Protocol outcome 3: Complications (infections) at Define - Actual outcome: Wound infections (first operation) at First operation; Group 1: 11/32, Group 2: 13/30 Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: Three patients originally assigned to PA switched to HP at surgeon discretion. Analysed in original groups.; Group 2 Number missing: 1, Reason: One patient originally assigned to HP group switched to PA at surgeon discretion. Analysed in original groups.</p> | |
| <p>- Actual outcome: Wound infections (second operation) at Second operation; Group 1: 3/26, Group 2: 3/15 Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 6, Reason: Six patients did not have ileostomy reversal in the PA group.; Group 2 Number missing: 15, Reason: Fifteen patients did not have colostomy reversal in the HP group. - Actual outcome: Intra-abdominal infection (first operation) at First operation; Group 1: 2/32, Group 2: 6/30 Risk of bias: All domain - Very high. Selection - Low. Blinding - Very high. Incomplete outcome data - High. Outcome reporting - Low. Measurement - Low. Crossover -</p> | |

Low, Subgroups - Low, Other 1 - Low, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: Three patients originally assigned to PA switched to HP at surgeon discretion. Analysed in original groups.; Group 2 Number missing: 1, Reason: One patient originally assigned to HP group switched to PA at surgeon discretion. Analysed in original groups.

- Actual outcome: Intra-abdominal infection (second operation) at Second operation; Group 1: 0/26, Group 2: 0/15

Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 6, Reason: Six patients did not have ileostomy reversal in the PA group.; Group 2 Number missing: 15, Reason: Fifteen patients did not have colostomy reversal in the HP group.

- Actual outcome: Urinary tract infection (first operation) at First operation; Group 1: 3/32, Group 2: 1/30

Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: Three patients originally assigned to PA switched to HP at surgeon discretion. Analysed in original groups.; Group 2 Number missing: 1, Reason: One patient originally assigned to HP group switched to PA at surgeon discretion. Analysed in original groups.

- Actual outcome: Urinary tract infections (second operation) at Second operation; Group 1: 0/26, Group 2: 0/15

Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 6, Reason: Six patients did not have ileostomy reversal in the PA group.; Group 2 Number missing: 15, Reason: Fifteen patients did not have colostomy reversal in the HP group.

- Actual outcome: All complications - Clavien-Dindo I-V (first operation) at First operation; Group 1: 27/32, Group 2: 24/30

Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: Three patients originally assigned to PA switched to HP at surgeon discretion. Analysed in original groups.; Group 2 Number missing: 1, Reason: One patient originally assigned to HP group switched to PA at surgeon discretion. Analysed in original groups.

- Actual outcome: All complications - Clavien-Dindo I-V (second operation) at Second operation; Group 1: 20/26, Group 2: 6/15

Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 6, Reason: Six patients did not have ileostomy reversal in the PA group.; Group 2 Number missing: 15, Reason: Fifteen patients did not have colostomy reversal in the HP group.

Protocol outcome 4: Need for further surgery at Define

- Actual outcome: Need for reoperation (second operation) at Second operation; Group 1: 0/26, Group 2: 3/15

Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 6, Reason: Six patients did not have ileostomy reversal in the PA group.; Group 2 Number missing: 15, Reason: Fifteen patients did not have colostomy reversal in the HP group.

Protocol outcome 5: Anastomotic leak at Define

- Actual outcome: Anastomotic leak (first operation) at First operation; Group 1: 1/32, Group 2: 0/30

Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: Three patients originally assigned to

PA switched to HP at surgeon discretion. Analysed in original groups.; Group 2 Number missing: 1, Reason: One patient originally assigned to HP group switched to PA at surgeon discretion. Analysed in original groups.

- Actual outcome: Anastomotic leak (second operation) at Second operation; Group 1: 0/26, Group 2: 2/15

Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 6, Reason: Six patients did not have ileostomy reversal in the PA group.; Group 2 Number missing: 15, Reason: Fifteen patients did not have colostomy reversal in the HP group.

Protocol outcome 6: Stoma complications at Define

- Actual outcome: Stoma complications (first operation) at First operation; Group 1: 0/32, Group 2: 3/30

Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: Three patients originally assigned to PA switched to HP at surgeon discretion. Analysed in original groups.; Group 2 Number missing: 1, Reason: One patient originally assigned to HP group switched to PA at surgeon discretion. Analysed in original groups.

Protocol outcomes not reported by the study

Quality of life at Define; Progression of disease at Define; Complications (abscesses) at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define

| Study | Pasternak 2010 ⁵⁶ |
|---|---|
| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=111) |
| Countries and setting | Conducted in Switzerland; Setting: Triemli Hospital - tertiary referral centre. |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Retrospective (2001-2004) and prospective (2005-2006) review of case notes, intensive care, anaesthetic protocols and surgery reports. |
| Method of assessment of guideline condition | Adequate method of assessment/diagnosis: Clinical diagnosis of generalised peritonitis, evidence of perforation indicated by free gas on plain X-rays, or localised peritonitis and contained/uncontained perforation on triple contrast CT scan. |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Emergency laparotomy for perforated diverticulitis of left colon between 2001 and 2006; clinical diagnosis of generalised peritonitis, evidence of perforation on plain X-rays or localised peritonitis and contained/uncontained perforation on triple contrast CT scan. |
| Exclusion criteria | Not reported. |
| Recruitment/selection of patients | Patients undergoing emergency laparotomy for perforated diverticulitis of left colon between 2001 and 2006. |
| Age, gender and ethnicity | Age - Median (range): Primary anastomosis, 71.5 (40-89); Hartmann's procedure, 78 (46-92). Gender (M:F): Primary anastomosis, 21/25; Hartmann's procedure, 25/40. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Emergency operation defined as procedure performed within 6 h of making decision to operate. |
| Indirectness of population | No indirectness |
| Interventions | (n=46) Intervention 1: Primary anastomosis. Surgeon decided whether a protective loop ileostomy was necessary in each patient depending on the quality of the anastomosis. Protective loop ileostomy performed in eleven patients. Duration Mean (standard deviation) duration of surgery, 160 (±56.9) minutes. Concurrent medication/care: Intra-operative colonic lavage only performed in cases where a protective loop ileostomy was considered. Indirectness: No indirectness (n=65) Intervention 2: Temporary stoma. Hartmann's procedure with stoma. . Duration Mean (standard deviation) |

| | |
|---|---|
| | duration of surgery, 165 (±48.7) minutes. Concurrent medication/care: Not reported. Indirectness: No indirectness Comments: Classed as temporary stoma as aim is usually to reverse stomas where possible, and study did not give details of this. |
| Funding | Funding not stated |
| <p>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH/WITHOUT PROTECTIVE ILEOSTOMY) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)</p> <p>Protocol outcome 1: Mortality at Define - Actual outcome: In-hospital mortality at In-hospital; Group 1: 8/46, Group 2: 19/65 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Age higher in HP group. Gender distribution similar. Immunosuppression higher in HP group.; Key confounders: Age, gender; Group 1 Number missing: 0; Group 2 Number missing: 0</p> <p>Protocol outcome 2: Morbidity at Define - Actual outcome: Intraoperative morbidity at Intraoperative; Group 1: 8/46, Group 2: 7/65 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Age higher in HP group. Gender distribution similar. Immunosuppression higher in HP group.; Key confounders: Age, gender; Group 1 Number missing: 0; Group 2 Number missing: 0</p> <p>- Actual outcome: Postoperative overall morbidity at Not reported; Group 1: 20/46, Group 2: 33/65 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Age higher in HP group. Gender distribution similar. Immunosuppression higher in HP group.; Key confounders: Age, gender; Group 1 Number missing: 0; Group 2 Number missing: 0</p> <p>- Actual outcome: Postoperative surgical morbidity at Not reported; Group 1: 17/46, Group 2: 15/65 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Age higher in HP group. Gender distribution similar. Immunosuppression higher in HP group.; Key confounders: Age, gender; Group 1 Number missing: 0; Group 2 Number missing: 0</p> <p>- Actual outcome: Postoperative medical morbidity at Not reported; Group 1: 7/46, Group 2: 24/65 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Age higher in HP group. Gender distribution similar. Immunosuppression higher in HP group.; Key confounders: Age, gender; Group 1 Number missing: 0; Group 2 Number missing: 0</p> <p>Protocol outcome 3: Complications (abscesses) at Define - Actual outcome: Post-operative intra-abdominal abscess at Not reported: Group 1: 7/46. Group 2: 5/65</p> | |

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Age higher in HP group. Gender distribution similar. Immunosuppression higher in HP group.; Key confounders: Age, gender; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 4: Need for further surgery at Define

- Actual outcome: Relaparotomy at Not reported; Group 1: 15/46, Group 2: 18/65

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Age higher in HP group. Gender distribution similar.

Immunosuppression higher in HP group.; Key confounders: Age, gender; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 5: Anastomotic leak at Define

- Actual outcome: Postoperative anastomotic/rectal stump leak at Not reported; Group 1: 13/46, Group 2: 2/65; Comments: Note anastomotic leaks apply to primary anastomosis group and rectal stump leaks apply to Hartmann's procedure.

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Age higher in HP group. Gender distribution similar.

Immunosuppression higher in HP group.; Key confounders: Age, gender; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 6: Stoma complications at Define

- Actual outcome: Stoma morbidity at Not reported; Group 1: 0/46, Group 2: 8/65; Comments: Note only eleven in PA group had protective ileostomy.

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Age higher in HP group. Gender distribution similar.

Immunosuppression higher in HP group.; Key confounders: Age, gender; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcomes not reported by the study

Quality of life at Define; Progression of disease at Define; Complications (infections) at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define

| Study | Richter 2006 ⁵⁹ |
|---|---|
| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=41) |
| Countries and setting | Conducted in Germany; Setting: Hospital - secondary care |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Retrospective review of patients between August 2001 and August 2003 |
| Method of assessment of guideline condition | Adequate method of assessment/diagnosis: All patients underwent triple-contrast CT scan. |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Patients undergoing emergency surgery for complicated sigmoid diverticulitis (Hinchey stages III and IV). |
| Exclusion criteria | Not reported. |
| Recruitment/selection of patients | All matching criteria between August 2001 and August 2003. |
| Age, gender and ethnicity | Age - Mean (SD): Whole cohort, 60 (2) years. Not available for the individual intervention groups. Gender (M:F): Whole cohort, 22/19. Not available for the individual intervention groups. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Patients undergoing emergency surgery for complicated sigmoid diverticulitis (Hinchey stages III and IV). |
| Indirectness of population | No indirectness |
| Interventions | <p>(n=36) Intervention 1: Primary anastomosis. One-stage sigmoid resection and primary anastomosis with/without protective ileostomy. Three had protective ileostomy. Duration Not reported. Concurrent medication/care: Treatment of peritonitis comprised the use of 30 liters of warm Ringer's lactate for abdominal lavage to dilute the bacterial load of the abdominal cavity and postoperative antibiotic therapy that was maintained for at least 5 day. Indirectness: No indirectness</p> <p>(n=5) Intervention 2: Temporary stoma. Hartmann's procedure. Duration Not reported. Concurrent medication/care: Treatment of peritonitis comprised the use of 30 liters of warm Ringer's lactate for abdominal lavage to dilute the bacterial load of the abdominal cavity and postoperative antibiotic therapy that was maintained for at least 5 days. Indirectness: No indirectness</p> <p>Comments: Classed as temporary stoma as aim is usually to reverse where possible.</p> |

| Funding | Funding not stated |
|--|---|
| <p>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH/WITHOUT PROTECTIVE ILEOSTOMY) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)</p> <p>Protocol outcome 1: Mortality at Define - Actual outcome: Mortality at Not reported; Group 1: 4/36, Group 2: 3/5 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Cannot compare age and gender between the groups. Those selected for HP group were those surgeons considered to be unsuitable for anastomosis and were more critically ill. More severe comorbidity in the HP group. MPI higher in HP vs. PA.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:</p> <p>Protocol outcome 2: Anastomotic leak at Define - Actual outcome: Anastomotic leak at Not reported; Group 1: 1/36, Group 2: 0/5; Comments: Note NA for the HP group as anastomosis not attempted in first operation. Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Cannot compare age and gender between the groups. Those selected for HP group were those surgeons considered to be unsuitable for anastomosis and were more critically ill. More severe comorbidity in the HP group. MPI higher in HP vs. PA.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:</p> | |
| <p>Protocol outcomes not reported by the study</p> | <p>Quality of life at Define; Morbidity at Define; Progression of disease at Define; Complications (infections) at Define; Complications (abscesses) at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Need for further surgery at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define</p> |

| Study | Schilling 2001 ⁶¹ |
|---|--|
| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=55) |
| Countries and setting | Conducted in Switzerland; Setting: Secondary care - hospital |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Retrospective review of cases between January 1994 and January 1998. |
| Method of assessment of guideline condition | Method of assessment /diagnosis not stated |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Patients undergoing emergency sigmoid colon resection for perforated diverticulitis and peritonitis. |
| Exclusion criteria | Not reported. |
| Recruitment/selection of patients | Patients undergoing emergency sigmoid colon resection for perforated diverticulitis and peritonitis between January 1994 and January 1998. |
| Age, gender and ethnicity | Age - Mean (SD): Primary anastomosis, 65 (12) years; Hartmann's procedure, 68 (10) years. Gender (M:F): Primary anastomosis, 6/7; Hartmann's procedure, 20/22. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Patients undergoing emergency sigmoid colon resection for perforated diverticulitis and peritonitis. |
| Indirectness of population | No indirectness |
| Interventions | (n=13) Intervention 1: Primary anastomosis. One-stage sigmoid colon resection and primary anastomosis without protective colostomy. Duration Not reported. Concurrent medication/care: Extensive abdominal lavage with at least 20 litres of warm (37•C) ringers lactate solution performed in all patients. Indirectness: No indirectness (n=42) Intervention 2: Temporary stoma. Primary sigmoid colon resection, Hartmann's procedure and descending colostomy. Duration Not reported. Concurrent medication/care: Extensive abdominal lavage with at least 20 litres of warm (37•C) ringers lactate solution performed in all patient. Indirectness: No indirectness Comments: Classed as temporary as aim was to reverse stomas where possible. |
| Funding | Funding not stated |

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITHOUT PROTECTIVE COLOSTOMY) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)

Protocol outcome 1: Mortality at Define

- Actual outcome: Postoperative mortality (first and second operations combined) at Not reported; Group 1: 1/13, Group 2: 4/42; Comments: Note for HP group events following first and second operations are given.

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Comparable for age, gender, ASA. Some differences between groups for proportion of local/diffuse peritonitis - higher diffuse peritonitis proportion in HP group.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 2: Morbidity at Define

- Actual outcome: Postoperative major morbidity (first and second operations combined) at Not reported; Group 1: 1/13, Group 2: 5/42; Comments: Major complications defined as those requiring change in therapy or prolonged therapy. Note for HP group events following first and second operations are given.

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Comparable for age, gender, ASA. Some differences between groups for proportion of local/diffuse peritonitis - higher diffuse peritonitis proportion in HP group.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome: Postoperative minor morbidity (first and second operations combined) at Not reported; Group 1: 5/13, Group 2: 9/42; Comments: Major complications defined as those requiring change in therapy or prolonged therapy.

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Comparable for age, gender, ASA. Some differences between groups for proportion of local/diffuse peritonitis - higher diffuse peritonitis proportion in HP group.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 3: Stoma complications at Define

- Actual outcome: Stoma complications (first and second operations combined) at Not reported; Group 1: 0/13, Group 2: 3/42; Comments: Note NA in PA group as no stoma.

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Comparable for age, gender, ASA. Some differences between groups for proportion of local/diffuse peritonitis - higher diffuse peritonitis proportion in HP group.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

| | |
|---|--|
| Protocol outcomes not reported by the study | Quality of life at Define; Progression of disease at Define; Complications (infections) at Define; Complications |
|---|--|

(abscesses) at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Need for further surgery at Define; Anastomotic leak at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define

| Study | Stumpf 2007 ⁶⁴ |
|---|--|
| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=66) |
| Countries and setting | Conducted in USA; Setting: Hospital Medical Centre |
| Line of therapy | 1st line |
| Duration of study | Follow up (post intervention): Retrospective review of records between 1998 and 2003. |
| Method of assessment of guideline condition | Unclear method of assessment/diagnosis: Diagnosis potentially confirmed in operation - brief mention but unclear. |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable: |
| Inclusion criteria | Patients treated surgically for complications of acute diverticulitis; emergency surgery within same hospital admission as presentation to emergency department with acute abdominal pain; operated on due to perforation, peritoneal signs, abscess, obstruction or failure of medical therapy. |
| Exclusion criteria | Right-sided diverticulitis; patients who underwent primary anastomosis and also received a proximal diverting loop ileostomy. |
| Recruitment/selection of patients | Retrospective review of those undergoing emergency surgery for complications of left-sided diverticulitis between 1998 and 2003. |
| Age, gender and ethnicity | Age - Other: Not reported. Proportion ≥80 years: Primary anastomosis, 6/36; Hartmann's procedure, 6/30. Gender (M:F): Primary anastomosis, 15/21; Hartmann's procedure, 17/13. Ethnicity: Not reported. |
| Further population details | |
| Indirectness of population | No indirectness |
| Interventions | <p>(n=36) Intervention 1: Primary anastomosis. No further details given. Duration Not reported. Concurrent medication/care: Most surgeons performed mini colonic lavage with saline. Seven patients were able to be prepped the night before the operation as they were operated on due to failure of medical therapy. Indirectness: No indirectness</p> <p>(n=30) Intervention 2: Temporary stoma. Hartmann's procedure with stoma. Does not specify whether stomas were reversed. Duration Not reported. Concurrent medication/care: Most surgeons performed mini colonic lavage with saline. Two patients were able to be prepped the night before the operation as they were operated on due to failure of medical therapy. Indirectness: No indirectness</p> <p>Comments: Classed as temporary stoma as intention is usually to reverse where possible but this study does not specifv.</p> |

| | |
|--|--------------------|
| | |
| Funding | Funding not stated |
| <p>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)</p> <p>Protocol outcome 1: Mortality at Define - Actual outcome: Mortality at Not reported; Group 1: 0/36, Group 2: 5/30; Comments: Note that all events occurred in patients that were considered to be high risk (≥ 80 years of age, ASA class >3, APACHE II score >4 and/or Hinchey score >2). Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Age not stated - similar proportion of patients >80 years each group. Difference in proportion without comorbidity in each group. Differences in ASA, APACHE II and Hinchey scores.; Key confounders: Age, gender; Group 1 Number missing: 0; Group 2 Number missing: 0</p> <p>Protocol outcome 2: Morbidity at Define - Actual outcome: Overall complications at Not reported; Group 1: 5/36, Group 2: 10/30; Comments: Note that all events occurred in patients that were considered to be high risk (≥ 80 years of age, ASA class >3, APACHE II score >4 and/or Hinchey score >2). Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Age not stated - similar proportion of patients >80 years each group. Difference in proportion without comorbidity in each group. Differences in ASA, APACHE II and Hinchey scores.; Key confounders: Age, gender; Group 1 Number missing: 0; Group 2 Number missing: 0 - Actual outcome: Other complications (medical) at Not reported; Group 1: 5/36, Group 2: 8/30; Comments: Note that all events occurred in patients that were considered to be high risk (≥ 80 years of age, ASA class >3, APACHE II score >4 and/or Hinchey score >2). Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Age not stated - similar proportion of patients >80 years each group. Difference in proportion without comorbidity in each group. Differences in ASA, APACHE II and Hinchey scores.; Key confounders: Age, gender; Group 1 Number missing: 0; Group 2 Number missing: 0</p> <p>Protocol outcome 3: Complications (infections) at Define - Actual outcome: Wound infection at Not reported; Group 1: 0/36, Group 2: 2/30; Comments: Note that all events occurred in patients that were considered to be high risk (≥ 80 years of age, ASA class >3, APACHE II score >4 and/or Hinchey score >2). Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Other 1 - Low; Indirectness of outcome: No indirectness; Baseline details: Age not stated - similar proportion of patients >80 years each group. Difference in proportion without comorbidity in each group. Differences in ASA, APACHE II and Hinchey scores.; Key confounders: Age, gender; Group 1 Number missing: 0; Group 2 Number missing: 0</p> | |

| | |
|--|---|
| <p>Protocol outcome 4: Complications (abscesses) at Define - Actual outcome: Abscess at Not reported; Group 1: 0/36, Group 2: 4/30; Comments: Note that all events occurred in patients that were considered to be high risk (≥ 80 years of age, ASA class >3, APACHE II score >4 and/or Hinchey score >2). Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Age not stated - similar proportion of patients >80 years each group. Difference in proportion without comorbidity in each group. Differences in ASA, APACHE II and Hinchey scores.; Key confounders: Age, gender; Group 1 Number missing: 0; Group 2 Number missing: 0</p> <p>Protocol outcome 5: Need for further surgery at Define - Actual outcome: Reoperation at Not reported; Group 1: 1/36, Group 2: 0/30; Comments: Note that all events occurred in patients that were considered to be high risk (≥ 80 years of age, ASA class >3, APACHE II score >4 and/or Hinchey score >2). Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Age not stated - similar proportion of patients >80 years each group. Difference in proportion without comorbidity in each group. Differences in ASA, APACHE II and Hinchey scores.; Key confounders: Age, gender; Group 1 Number missing: 0; Group 2 Number missing: 0</p> <p>Protocol outcome 6: Anastomotic leak at Define - Actual outcome: Anastomotic leak at Not reported; Group 1: 1/36, Group 2: 0/30; Comments: Note NA for Hartmann's group. Note that all events occurred in patients that were considered to be high risk (≥ 80 years of age, ASA class >3, APACHE II score >4 and/or Hinchey score >2). Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Age not stated - similar proportion of patients >80 years each group. Difference in proportion without comorbidity in each group. Differences in ASA, APACHE II and Hinchey scores.; Key confounders: Age, gender; Group 1 Number missing: 0; Group 2 Number missing: 0</p> | <p>Quality of life at Define; Progression of disease at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define</p> |
| <p>Protocol outcomes not reported by the study</p> | <p>Quality of life at Define; Progression of disease at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define</p> |

| Study | Thaler 2000 ⁶⁵ |
|---|---|
| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=82) |
| Countries and setting | Conducted in Austria; Setting: Secondary care - surgical department within hospital |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Retrospective review of patients between 1988 and 1998. |
| Method of assessment of guideline condition | Method of assessment /diagnosis not stated |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Those undergoing emergency surgery for perforated sigmoid diverticulitis. |
| Exclusion criteria | Not reported. |
| Recruitment/selection of patients | All eligible cases between 1988 and 1998 retrospectively reviewed |
| Age, gender and ethnicity | Age - Mean (SD): Primary anastomosis, 70 (13) years; Hartmann's procedure, 72 (15) years. Gender (M:F): Primary anastomosis,6/14; Hartmann's procedure, 25/37. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Emergency surgery for perforated sigmoid diverticulitis. |
| Indirectness of population | No indirectness |
| Interventions | (n=20) Intervention 1: Primary anastomosis. One-stage primary sigmoid resection with primary anastomosis. No protective stomas were employed. Duration Not reported. Concurrent medication/care: Broad spectrum antibiotics routinely administered in all patients starting preoperatively and given for at least 7 days after surgery. Indirectness: No indirectness (n=62) Intervention 2: Temporary stoma. Primary sigmoid resection with Hartmann's procedure. Duration Not reported. Concurrent medication/care: Broad spectrum antibiotics routinely administered in all patients starting preoperatively and given for at least 7 days after surgery. Indirectness: No indirectness |
| Funding | Funding not stated |

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITHOUT PROTECTIVE STOMA) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)

Protocol outcome 1: Mortality at Define

- Actual outcome: Mortality at Not reported; Group 1: 4/20, Group 2: 22/62

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Age comparable between groups. Difference in proportion of males in each group - higher in Hartmann's. Higher proportion of those with ASA IV/V scores in Hartmann's and also higher Mannheim Peritonitis Index score - more severe cases and most unwell patients in Hartmann's group.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 2: Morbidity at Define

- Actual outcome: Overall morbidity at Not reported; Group 1: 7/20, Group 2: 13/62

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Age comparable between groups. Difference in proportion of males in each group - higher in Hartmann's. Higher proportion of those with ASA IV/V scores in Hartmann's and also higher Mannheim Peritonitis Index score - more severe cases and most unwell patients in Hartmann's group.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome: Surgical morbidity at Not reported; Group 1: 6/20, Group 2: 7/62

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Age comparable between groups. Difference in proportion of males in each group - higher in Hartmann's. Higher proportion of those with ASA IV/V scores in Hartmann's and also higher Mannheim Peritonitis Index score - more severe cases and most unwell patients in Hartmann's group.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcomes not reported by the study

Quality of life at Define; Progression of disease at Define; Complications (infections) at Define; Complications (abscesses) at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Need for further surgery at Define; Anastomotic leak at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define

| Study | Trenti 2011 ⁶⁶ |
|---|---|
| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=87) |
| Countries and setting | Conducted in Spain; Setting: Secondary care - hospital |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Retrospective review of cases between January 1st 1995 and December 31st 2008. |
| Method of assessment of guideline condition | Method of assessment /diagnosis not stated |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Patients operated on for Hinchey stage III-IV diverticular peritonitis. |
| Exclusion criteria | Patients with colon cancer at definitive histopathology, Hinchey I-II peritonitis, fistula and bleeding complications. |
| Recruitment/selection of patients | All patients operated on for Hinchey stage III-IV diverticular peritonitis between 1st January 1995 and 31st December 2008. |
| Age, gender and ethnicity | Age - Mean (SD): Primary anastomosis, 58.1 (16.3) years; Hartmann's procedure, 69.7 (12.7) years. Gender (M:F): Primary anastomosis, 19/8; Hartmann's procedure, 34/26. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Patients operated on for Hinchey stage III-IV diverticular peritonitis. Emergency surgery. |
| Indirectness of population | No indirectness |
| Interventions | <p>(n=27) Intervention 1: Primary anastomosis. Resection of affected bowel segment with primary anastomosis, with or without protective stoma (derivative ileostomy). 5 patients had protective stoma. Duration Not reported. Concurrent medication/care: All patients were treated with an extensive intraabdominal lavage with warm saline solution and post-operative antibiotic therapy for at least 14 days. All patients underwent the same post-operative care in the intensive care unit and in the ward with the same team of physicians. From 2007 onwards, only patients undergoing primary anastomosis with protective ileostomy received intraoperative colonic lavage. Indirectness: No indirectness</p> <p>(n=60) Intervention 2: Temporary stoma. Hartmann's procedure. Duration Not reported. Concurrent medication/care: All patients were treated with an extensive intraabdominal lavage with warm saline solution and post-operative antibiotic therapy for at least 14 days. All patients underwent the same post-operative care in the intensive care unit and in the ward with the same team of physicians. From 2007 onwards, only patients undergoing primary anastomosis</p> |

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| | with protective ileostomy received intraoperative colonic lavage. Indirectness: No indirectness |
| Funding | Funding not stated |
| <p>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH OR WITHOUT PROTECTIVE ILEOSTOMY) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)</p> <p>Protocol outcome 1: Mortality at Define - Actual outcome: Postoperative mortality (first operation) at First operation; OR; 0.47 (95%CI 0.07 to 3.23) (P-value: 0.44) ; Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Lower proportion of females and lower mean age in the PA group compared with Hartmann's. Higher proportion of ASA scores III and IV in Hartmann's. Higher proportion of Hinchey stage IV in Hartmann's.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:</p> <p>Protocol outcome 2: Morbidity at Define - Actual outcome: Postoperative morbidity (first operation) at First operation; OR; 0.21 (95%CI 0.05 to 0.84) (P-value: 0.03) ; Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Lower proportion of females and lower mean age in the PA group compared with Hartmann's. Higher proportion of ASA scores III and IV in Hartmann's. Higher proportion of Hinchey stage IV in Hartmann's.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:</p> <p>Protocol outcome 3: Complications (infections) at Define - Actual outcome: Wound infection (first operation) at First operation; OR; 0.68 (95%CI 0.2 to 2.33) (P-value: 0.53) ; Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Lower proportion of females and lower mean age in the PA group compared with Hartmann's. Higher proportion of ASA scores III and IV in Hartmann's. Higher proportion of Hinchey stage IV in Hartmann's.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing: - Actual outcome: Ongoing sepsis (first operation) at First operation; Group 1: 1/27, Group 2: 14/60 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Lower proportion of females and lower mean age in the PA group compared with Hartmann's. Higher proportion of ASA scores III and IV in Hartmann's. Higher proportion of Hinchey stage IV in Hartmann's.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:</p> <p>Protocol outcome 4: Complications (abscesses) at Define - Actual outcome: Intraabdominal abscess (first operation) at First operation: Group 1: 0/27. Group 2: 8/60</p> | |

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Lower proportion of females and lower mean age in the PA group compared with Hartmann's. Higher proportion of ASA scores III and IV in Hartmann's. Higher proportion of Hinchey stage IV in Hartmann's.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 5: Need for further surgery at Define

- Actual outcome: Reoperation (first operation) at First operation; OR; 1.96 (95%CI 0.28 to 14.29) (P-value: 0.49) ;

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Lower proportion of females and lower mean age in the PA group compared with Hartmann's. Higher proportion of ASA scores III and IV in Hartmann's. Higher proportion of Hinchey stage IV in Hartmann's.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 6: Anastomotic leak at Define

- Actual outcome: Anastomotic leak (first operation) at First operation; Group 1: 3/27, Group 2: 0/60; Comments: Note NA for HP group as anastomosis not attempted in first operation.

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Lower proportion of females and lower mean age in the PA group compared with Hartmann's. Higher proportion of ASA scores III and IV in Hartmann's. Higher proportion of Hinchey stage IV in Hartmann's.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome: Anastomotic leak (second operation) at Second operation; Group 1: 0/3, Group 2: 0/9; Comments: Note only 5 patients originally had protective ileostomy in PA group and were therefore eligible for the reversal operation. Only 3 of these had this reversed within the follow-up. Only 9 in the HP group had had stoma reversal within the follow-up period.

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Lower proportion of females and lower mean age in the PA group compared with Hartmann's. Higher proportion of ASA scores III and IV in Hartmann's. Higher proportion of Hinchey stage IV in Hartmann's.; Key confounders: Age, gender; Group 1 Number missing: 24, Reason: Only 5 of PA group had protective ileostomy and were therefore eligible for this reversal operation - actual missing rate is 2/5 (40%). Of those with missing data, one died prior to the second operation and one still waiting at the end of follow-up due to kidney transplantation.; Group 2 Number missing: 51, Reason: Patients had died (nine), were considered unfit for reversal due to being a high surgical risk (four), or were still waiting for reversal (ten) at the end of the follow-up period. Follow-up not available in one patient.

Protocol outcomes not reported by the study

Quality of life at Define; Progression of disease at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define

| Study | Tucci 1996 ⁶⁷ |
|---|---|
| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=43) |
| Countries and setting | Conducted in Italy; Setting: Secondary care - hospital |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Retrospective review of cases between January 1975 and December 1994. |
| Method of assessment of guideline condition | Unclear method of assessment/diagnosis: Mention of operative and pathological reports being used to determine degree of peritoneal contamination. |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Those undergoing urgent or emergency surgery for perforated diverticular disease. |
| Exclusion criteria | Not reported. |
| Recruitment/selection of patients | Those undergoing urgent or emergency surgery for perforated diverticular disease between January 1975 and December 1994. |
| Age, gender and ethnicity | Age - Mean (range): Whole cohort, 62.7 (32-87) years. Not available for the different intervention groups. Gender (M:F): Whole cohort, 24/19. Not available for the different intervention groups. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Those undergoing urgent or emergency surgery for perforated diverticular disease. Acute condition or failure to respond to medical therapy. |
| Indirectness of population | No indirectness |
| Interventions | (n=24) Intervention 1: Primary anastomosis. Resection and primary anastomosis with/without stoma. Duration Not reported. Concurrent medication/care: Not reported. Indirectness: No indirectness (n=8) Intervention 2: Temporary stoma. Hartmann's procedure. Duration Not reported. Concurrent medication/care: Not reported. Indirectness: No indirectness |
| Funding | Funding not stated |

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH OR WITHOUT STOMA) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)

Protocol outcome 1: Mortality at Define

- Actual outcome: Hospital mortality at In-hospital; Group 1: 3/24, Group 2: 1/8

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Data not available to compare between the two interventions.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:

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| Protocol outcomes not reported by the study | Quality of life at Define; Morbidity at Define; Progression of disease at Define; Complications (infections) at Define; Complications (abscesses) at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Need for further surgery at Define; Anastomotic leak at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define |
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| Study | Tudor 1994-1 ⁶⁸ |
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| Study type | Prospective cohort study |
| Number of studies (number of participants) | 1 (n=300) |
| Countries and setting | Conducted in United Kingdom; Setting: Thirty UK hospitals - secondary care. |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: 3 year prospective audit, 1985-1988 |
| Method of assessment of guideline condition | Unclear method of assessment/diagnosis: Mentions use of clinical features as well as ultrasonography, confirmation at surgery or radiography for various complications but not clear if diagnosed by the same method in all cases. |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Complicated diverticular disease: defined as acute phlegmon, pericolic abscess, purulent or faecal peritonitis, bowel obstruction, fistula or acute gastrointestinal bleeding. |
| Exclusion criteria | Not reported. |
| Recruitment/selection of patients | Consecutive admissions of patients with complicated diverticular disease. |
| Age, gender and ethnicity | Age - Median (range): Whole cohort, 68 (31-94) years. Not available separately for different interventions for data extracted. Gender (M:F): Whole cohort, 115/185. Not available separately for different interventions for data extracted. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Emergency cases. Extracted and combined data for the following complications: acute phlegmon, peircolic abscess, purulent peritonitis, faecal peritonitis, bowel obstruction and fistula. . Did not extract for acute gastrointestinal bleeding complication as all were treated with primary anastomosis with/without stoma - none treated with Hartmann's/secondary anastomosis. |
| Indirectness of population | No indirectness |
| Interventions | (n=73) Intervention 1: Primary anastomosis. Resection with primary anastomosis with or without a stoma. Duration Not reported. Concurrent medication/care: On-table colonic lavage performed in some of these patients. Preoperative percutaneous drainage in certain cases of abscess and purulent peritonitis was performed. Indirectness: No indirectness (n=77) Intervention 2: Temporary stoma. Hartmann's procedure. Duration Not reported. Concurrent medication/care: |

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| | Not reported. Indirectness: No indirectness Comments: Classed as temporary stoma as aim of HP is usually to reverse where possible. Study does not indicate whether temporary or permanent. |
| Funding | Funding not stated |
| <p>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH OR WITHOUT STOMA) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)</p> <p>Protocol outcome 1: Mortality at Define - Actual outcome: Hospital mortality at Within 30 days of admission; Group 1: 7/73, Group 2: 16/77 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: No data available to compare between intervention groups.; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:</p> | |
| Protocol outcomes not reported by the study | Quality of life at Define; Morbidity at Define; Progression of disease at Define; Complications (infections) at Define; Complications (abscesses) at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Need for further surgery at Define; Anastomotic leak at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define |

| Study | Vermeulen 2007 ⁶⁹ |
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| Study type | Retrospective cohort study |
| Number of studies (number of participants) | 1 (n=200) |
| Countries and setting | Conducted in Netherlands; Setting: Four affiliated teaching hospitals in Rotterdam, The Netherlands. |
| Line of therapy | 1st line |
| Duration of study | Intervention + follow up: Retrospective review of patients between 1995 and 2005 |
| Method of assessment of guideline condition | Adequate method of assessment/diagnosis: Clinical signs of diffuse peritonitis on septic status with acute abdominal pain, free gas on plain abdominal radiography or specific findings at ultrasonography or computerised tomography. |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Patients undergoing primary anastomosis or Hartmann's procedure between 1995 and 2005 for acute perforated sigmoid diverticulitis. |
| Exclusion criteria | Not reported. |
| Recruitment/selection of patients | Consecutive patients undergoing primary anastomosis or Hartmann's procedure between 1995 and 2005 for acute perforated sigmoid diverticulitis. |
| Age, gender and ethnicity | Age - Mean (SD): Primary anastomosis, 62 (15) years; Hartmann's procedure, 69 (13) years. Gender (M:F): Primary anastomosis, 25/36; Hartmann's procedure, 64/75. . Ethnicity: Not reported. |
| Further population details | |
| Extra comments | Acute perforated sigmoid diverticulitis (Hinchey I-IV) |
| Indirectness of population | No indirectness |
| Interventions | <p>(n=61) Intervention 1: Primary anastomosis. Colon resections consisted of sigmoid resection, left hemicolectomy or anterior resection. Sixteen patients received a diverting ileostomy alongside primary anastomosis. Duration Not reported. Concurrent medication/care: All patients received preoperative and postoperative broad-spectrum intravenous antibiotics. Preoperative bowel preparation was not used in any patients. Indirectness: No indirectness</p> <p>(n=139) Intervention 2: Temporary stoma. Hartmann's procedure with stoma. Duration Not reported. Concurrent medication/care: All patients received preoperative and postoperative broad-spectrum intravenous antibiotics. Preoperative bowel preparation was not used in any patients. Indirectness: No indirectness</p> <p>Comments: Classed as temporary stoma as aim is usually to reverse stoma where possible. but study does not specify.</p> |

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| Funding | Funding not stated |
| <p>RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH OR WITHOUT DIVERTING ILEOSTOMY) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)</p> <p>Protocol outcome 1: Mortality at Define - Actual outcome: Postoperative mortality at 30 days; OR; 0.48 (95%CI 0.21 to 1.25) (P-value: 0.15) ; Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in age, ASA and Hinchey scores, and Mannheim peritonitis index between groups; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:</p> <p>Protocol outcome 2: Need for further surgery at Define - Actual outcome: Reinterventions (percutaneous drainage, open abdominal wound management or reoperations) at Not reported; OR; 0.42 (95%CI 0.18 to 0.83) (P-value: 0.05) ; Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in age, ASA and Hinchey scores, and Mannheim peritonitis index between groups; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:</p> <p>Protocol outcome 3: Anastomotic leak at Define - Actual outcome: Anastomotic leak at Not reported; Group 1: 3/61, Group 2: 0/139 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in age, ASA and Hinchey scores, and Mannheim peritonitis index between groups; Key confounders: Age, gender; Group 1 Number missing: ; Group 2 Number missing:</p> | |
| Protocol outcomes not reported by the study | Quality of life at Define; Morbidity at Define; Progression of disease at Define; Complications (infections) at Define; Complications (abscesses) at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define |
| Study (subsidiary papers) | Vermeulen 2010⁷⁰ (Vermeulen 2011⁷¹) |
| Study type | Retrospective cohort study |

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| Number of studies (number of participants) | 1 (n=340) |
| Countries and setting | Conducted in Netherlands; Setting: Patients following surgery - likely to be outpatients? |
| Line of therapy | Unclear |
| Duration of study | Follow up (post intervention): |
| Method of assessment of guideline condition | Adequate method of assessment/diagnosis: Surgery performed in all so would have been confirmed surgically. Radiography and CT scans used, as well as clinical signs. |
| Stratum | Overall |
| Subgroup analysis within study | Not applicable |
| Inclusion criteria | Patients undergoing emergency surgery for perforated diverticulitis between January 1990 and December 2005 at five surgical departments. |
| Exclusion criteria | Not reported. |
| Recruitment/selection of patients | Patients undergoing emergency surgery for perforated diverticulitis between January 1990 and December 2005 at five surgical departments. |
| Age, gender and ethnicity | Age - Other: Median only. Hartmann's procedure, 62; Primary anastomosis, 59. Gender (M:F): Hartmann's procedure, 40/36; Primary anastomosis, 21/32. Ethnicity: Not reported. |
| Further population details | |
| Extra comments | In population with diverticulitis complicated by perforation - includes Hinchey grades I, II, III and IV. None of the operations were laparoscopic. . ASA grades: Grade I, 25% in Hartmann's and 41% in primary anastomosis; Grade II, 28% in Hartmann's and 34% in primary anastomosis; Grade III, 33% in Hartmann's and 17% in primary anastomosis; Grade IV, 14% in Hartmann's and 8% in primary anastomosis. Hinchey staging: Hinchey I, 24% in Hartmann's and 23% in primary anastomosis; Hinchey II, 12% in Hartmann's and 43% |

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| | in primary anastomosis; Hinchey III, 52% in Hartmann's and 26% in primary anastomosis; Hinchey IV, 12% in Hartmann's and 8% in primary anastomosis. MPI <26/MPI = 26: Hartmann's procedure, 93/7 %; Primary anastomosis, 86/14 %. |
| Indirectness of population | No indirectness |
| Interventions | (n=93) Intervention 1: Primary anastomosis. Type of surgery left to discretion of surgeon on call. No further details given for primary anastomosis intervention. May have involved loop ileostomy in some or all of those that received primary anastomosis. Duration Not reported. Concurrent medication/care: Not reported. Indirectness: No indirectness (n=238) Intervention 2: Temporary stoma. Hartmann's procedure. Reversed in some but not all so termed temporary stoma. No further details provided concerning the procedure. Duration Not reported. Concurrent medication/care: Not reported. Indirectness: No indirectness |
| Funding | Funding not stated |

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PRIMARY ANASTOMOSIS (WITH/WITHOUT LOOP ILEOSTOMY) versus TEMPORARY STOMA (HARTMANN'S PROCEDURE)

Protocol outcome 1: Quality of life at Define

- Actual outcome: EQ-VAS at Questionnaire performed at median of 71 months post-operation (range, 23-205 months); Group 1: mean score 74 (range, 10-100, n=53), Group 2 : mean score 65 (range, 20-100, n=76)

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Very high, Outcome reporting - High, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in male/female ratio, Hinchey and ASA grading. Higher proportion in PA group received surgery from specialist colorectal surgeon compared to HP group.; Blinding details: Subjective assessed by those undergoing the operation.; Group 1 Number missing: 40, Reason: Lost to follow-up (moving abroad, home address not available), did not respond to questionnaire, died prior to questionnaire being sent.; Group 2 Number missing: 162, Reason: Lost to follow-up (moving abroad, home address not available), did not respond to questionnaire, died prior to questionnaire being sent.

- Actual outcome: EQ-5D index at Questionnaire performed at median of 71 months post-operation (range, 23-205 months); Group 1: mean score 77 (range, 67-93, n=53), Group 2: mean score 67 (range, -18-100, n=76)

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Very high, Outcome reporting - High, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in male/female ratio, Hinchey and ASA grading. Higher proportion in PA group received surgery from specialist colorectal surgeon compared to HP group.; Blinding details: Subjective measurement.; Group 1 Number missing: 40, Reason: Lost to follow-up (moving abroad, home address not available), did not respond to questionnaire, died prior to questionnaire being sent.; Group 2 Number

missing: 162, Reason: Lost to follow-up (moving abroad, home address not available), did not respond to questionnaire, died prior to questionnaire being sent.

Protocol outcome 2: Mortality at Define

- Actual outcome: Perioperative mortality (initial hospital stay) at in-hospital; Group 1: 13/93, Group 2: 75/238

Risk of bias: All domain - Very high, Selection - Very high, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in male/female ratio, Hinchey and ASA grading. Higher proportion in PA group received surgery from specialist colorectal surgeon compared to HP group. ; Group 1 Number missing: 0; Group 2 Number missing: 0

- Actual outcome: Post-operative mortality (follow-up) at Median follow-up 59 months (range, 1-210); Group 1: 31/93, Group 2: 143/238

Risk of bias: All domain - Very high, Selection - Very high, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in male/female ratio, Hinchey and ASA grading. Higher proportion in PA group received surgery from specialist colorectal surgeon compared to HP group. ; Group 1 Number missing: 0; Group 2 Number missing: 0

- Actual outcome: Long term survival after surviving initial emergency surgery for perforated diverticulitis at Median follow-up 59 months (range, 1-210 months); Group 1: n=80 ; Group 2: n=163; HR 0.54; Lower CI 0.3 to Upper CI 1.04; Test statistic: Test statistic from Cox, 0.07.; Advantage to research or control? Advantage to research; Follow up details: Median follow-up 59 months (range, 1-210 months); Comments: Adjusted HR from Cox multivariate analysis including age, ASA classification and Hinchey score.

Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in male/female ratio, Hinchey and ASA grading. Higher proportion in PA group received surgery from specialist colorectal surgeon compared to HP group. Adjusted for age, Hinchey and ASA grading for this outcome.; Group 1 Number missing: 13, Reason: Did not survive perioperative period - survival only analysed for those that survived this initial operation period.; Group 2 Number missing: 75, Reason: Did not survive perioperative period - survival only analysed for those that survived this initial operation period.

Protocol outcome 3: Need for further surgery at Define

- Actual outcome: Reintervention (percutaneous drainage, abdominal wound management or reoperation) at Median follow-up of 69-71 months post-operation.; Group 1: 7/53, Group 2: 14/76

Risk of bias: All domain - Very high, Selection - Very high, Blinding - Low, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences in male/female ratio, Hinchey and ASA grading. Higher proportion in PA group received surgery from specialist colorectal surgeon compared to HP group.; Group 1 Number missing: 40, Reason: Lost to follow-up (moving abroad, home address not available), did not respond to questionnaire, died prior to questionnaire being sent.; Group 2 Number missing: 162, Reason: Lost to follow-up (moving abroad, home address not available), did not respond to questionnaire, died prior to questionnaire being sent.

Protocol outcomes not reported by the study

Morbidity at Define; Progression of disease at Define; Complications (infections) at Define; Complications (abscesses) at Define; Complications (perforation) at Define; Complications (fistula) at Define; Complications (stricture) at Define; Recurrence rates of acute diverticulitis at Define; Hospitalisation at Define; Anastomotic leak at Define; Stoma complications at Define; Symptom control/recurrence (e.g. pain relief, bowel habit) at Define

Appendix E: Forest plots

E.1 RCTs: Primary anastomosis vs. temporary stoma

Figure 2: Anastomotic leak (first operation)

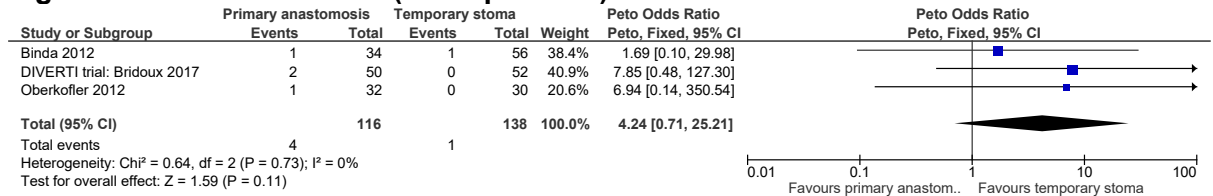


Figure 3: Anastomotic leak (second operation)

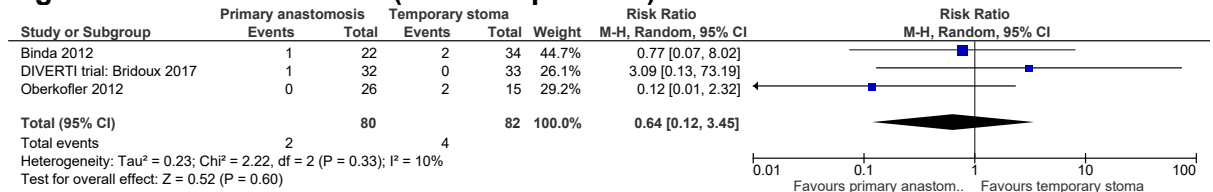


Figure 4: Complications - deep incisional surgical site infections (first operation)

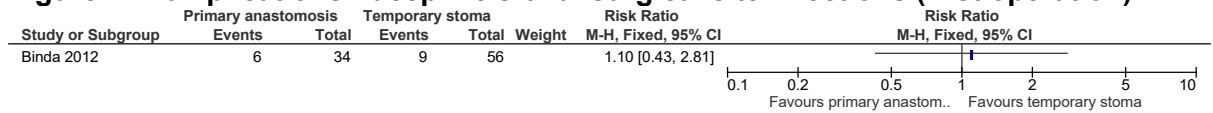


Figure 5: Complications - deep incisional surgical site infections (second operation)

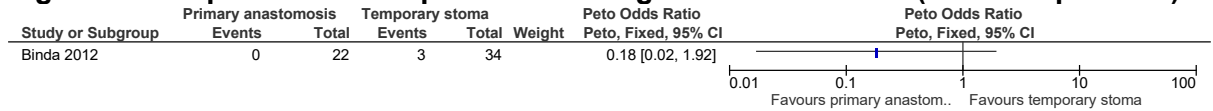


Figure 6: Complications – organ space site infections (first operation)

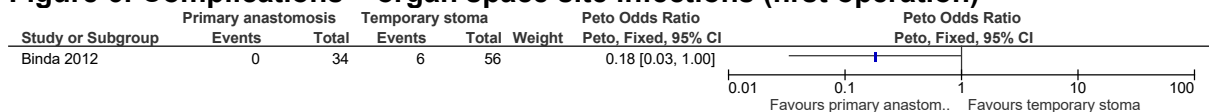


Figure 7: Complications – organ space site infections (second operation)

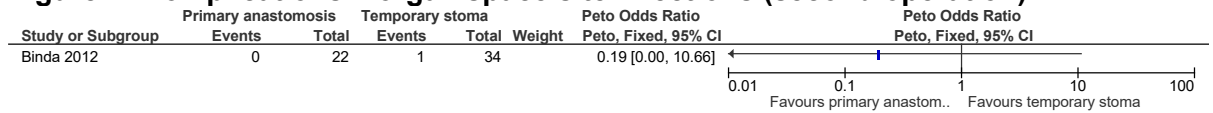


Figure 8: Complications – superficial incisional surgical site infections (first operation)

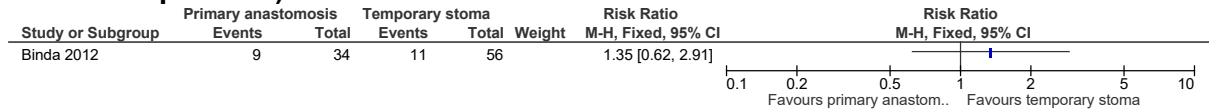


Figure 9: Complications – superficial incisional surgical site infections (second operation)

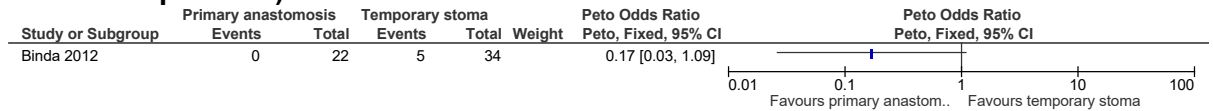


Figure 10: Complications - urinary tract infections (first operation)

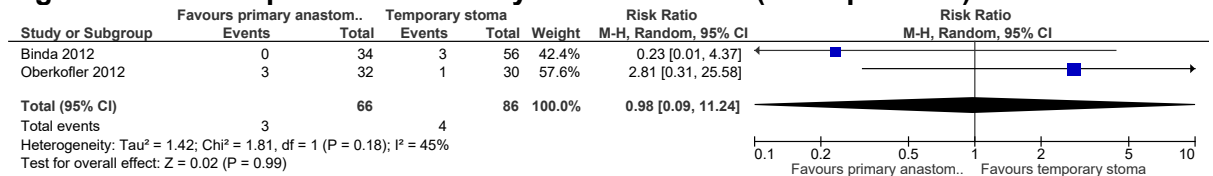


Figure 11: Complications - urinary tract infections (second operation)

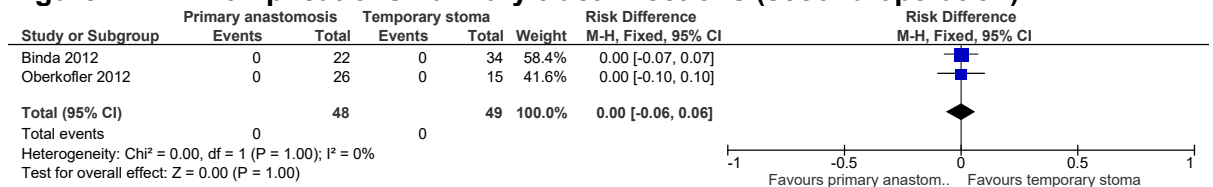


Figure 12: Overall morbidity (first operation)

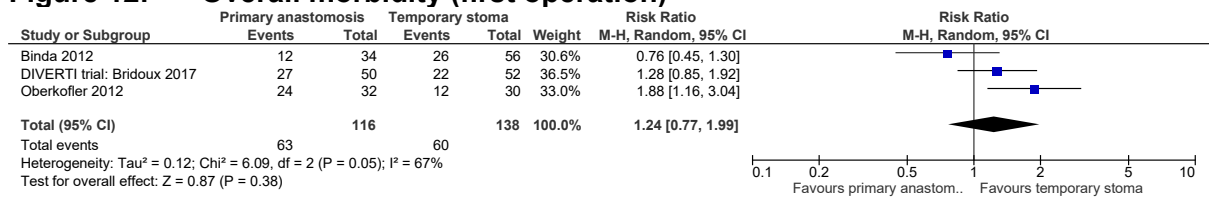


Figure 13: Overall morbidity (second operation)

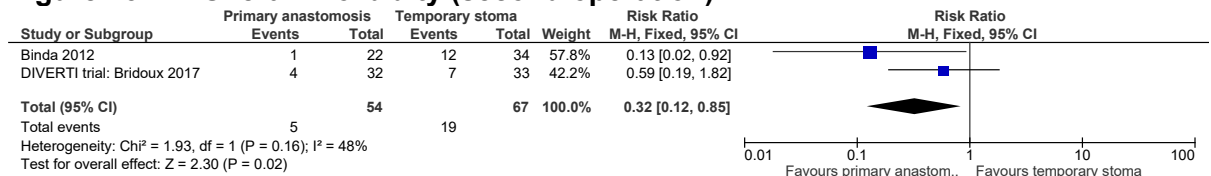


Figure 14: Mortality (first operation)

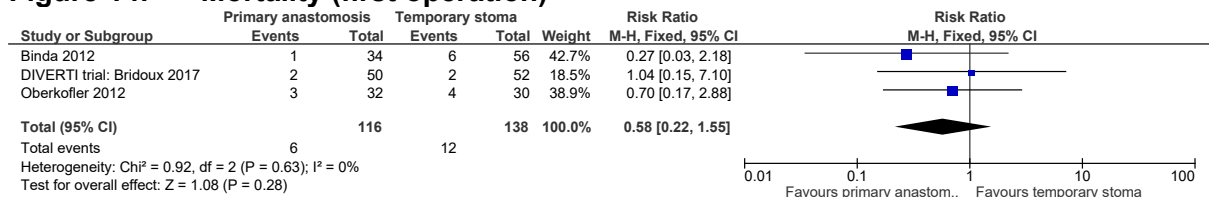


Figure 15: Mortality (second operation)

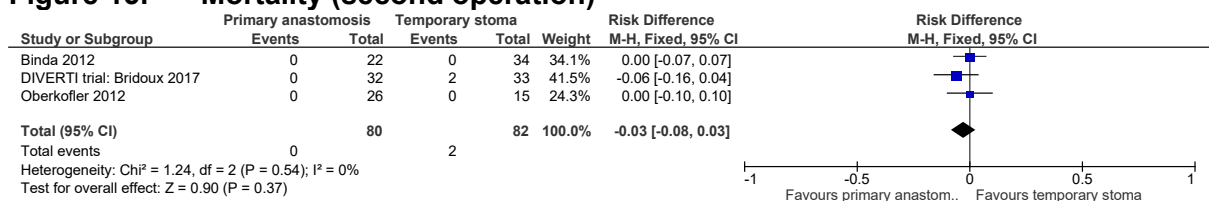


Figure 16: Complications – Intra-abdominal abscess (first operation)

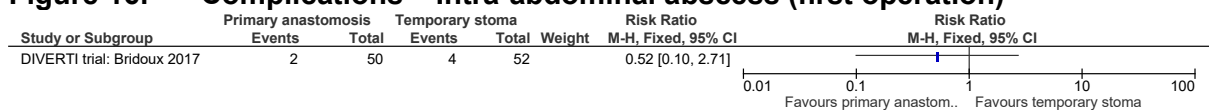


Figure 17: Complications – Intra-abdominal abscess (second operation)

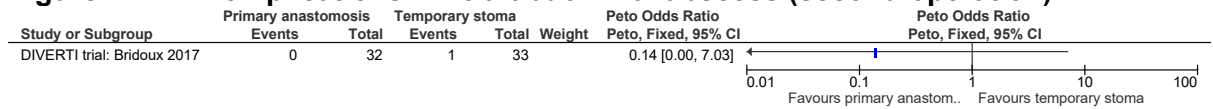


Figure 18: Complications – anastomotic stricture (first operation)

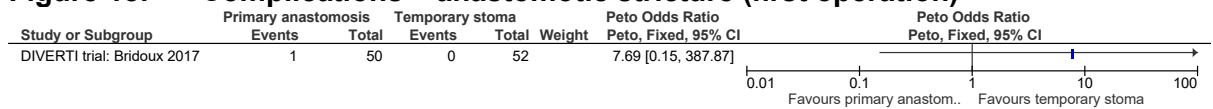


Figure 19: Need for further surgery – reoperation (first operation)

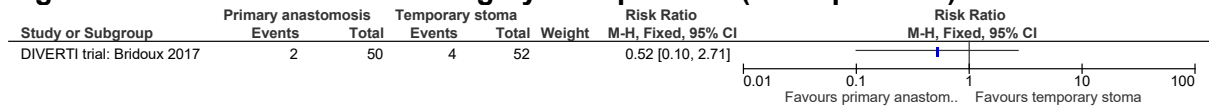


Figure 20: Need for further surgery – reoperation (first operation)

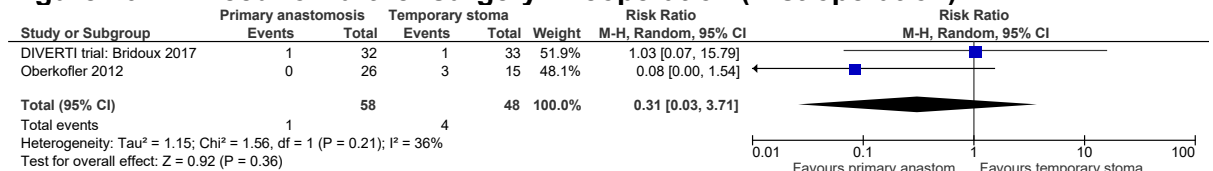


Figure 21: All complications – Clavien Dindo I-V (first operation)

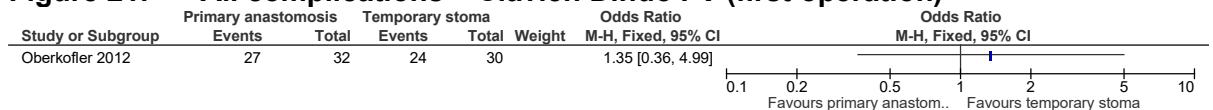


Figure 22: All complications – Clavien Dindo I-V (second operation)



Figure 23: Intra-abdominal infection (first operation)

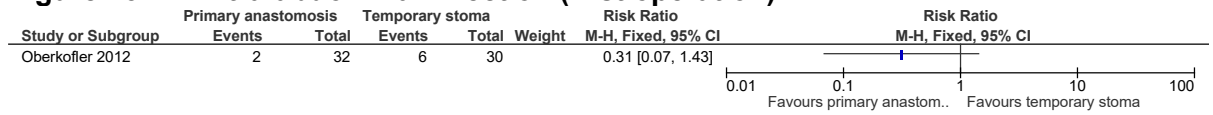


Figure 24: Intra-abdominal infection (second operation)

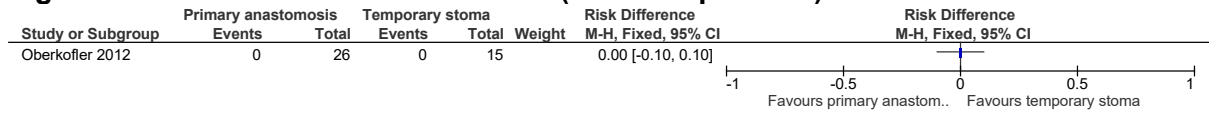


Figure 25: Wound infection (first operation)

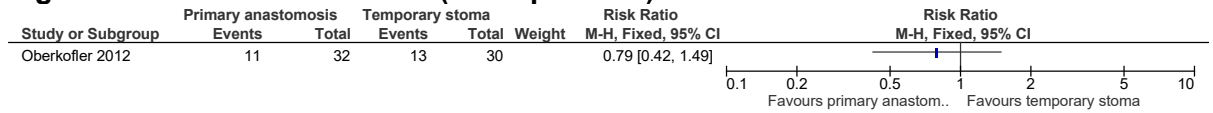


Figure 26: Wound infection (second operation)

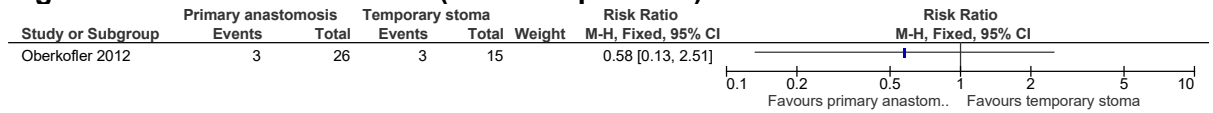
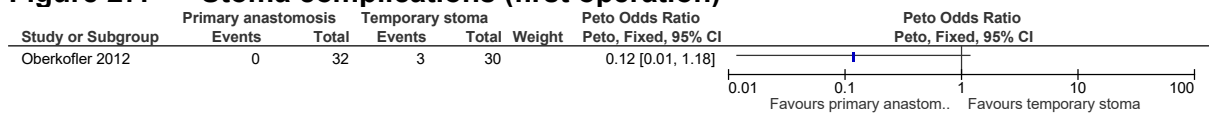


Figure 27: Stoma complications (first operation)



E.2 Observational studies: Primary anastomosis vs. temporary stoma

Figure 28: Anastomotic leak (first operation)

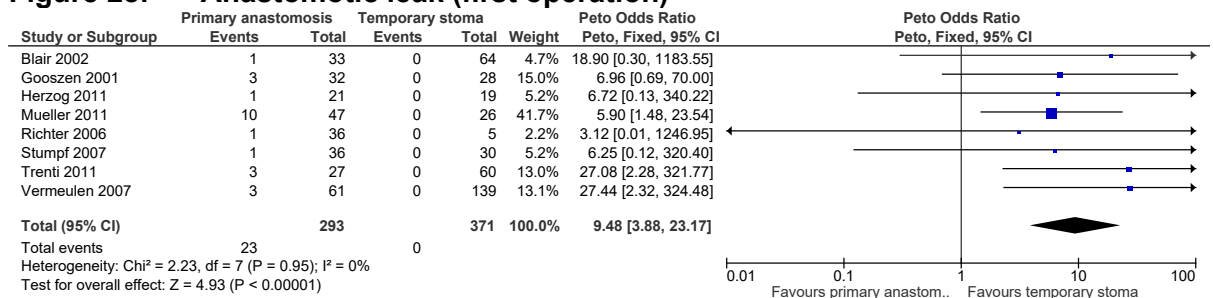


Figure 29: Anastomotic leak (second operation)

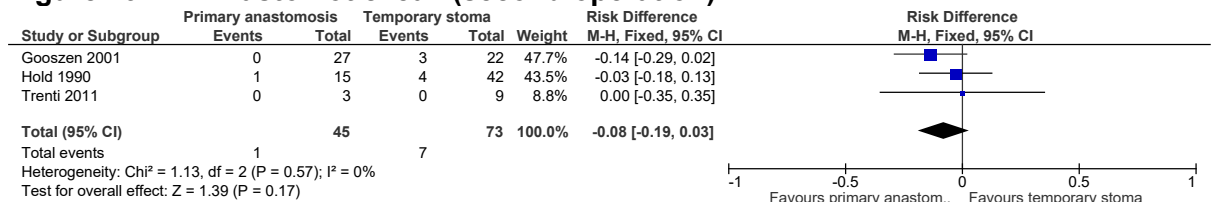


Figure 30: Anastomotic leak/rectal stump leak (first operation)

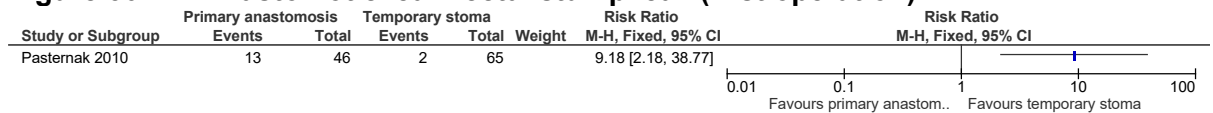


Figure 31: Abscess (first operation)

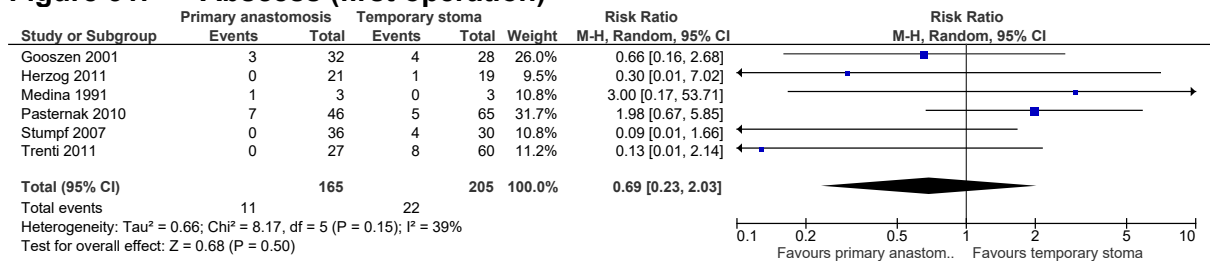


Figure 32: Abscess (second operation)

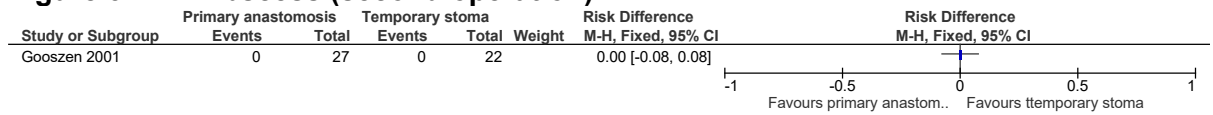


Figure 33: Abscess/peritonitis (first operation)

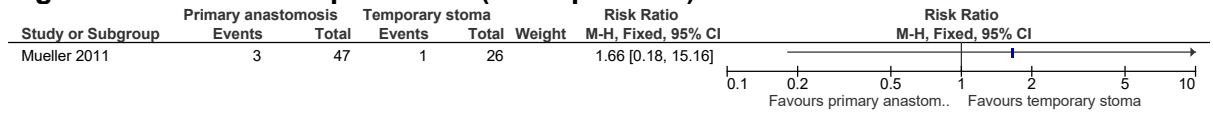


Figure 34: Fistula (first operation)

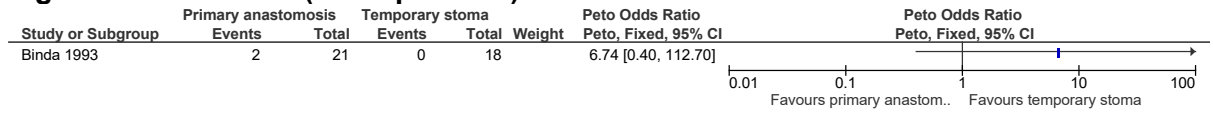


Figure 35: Septic shock (first operation)

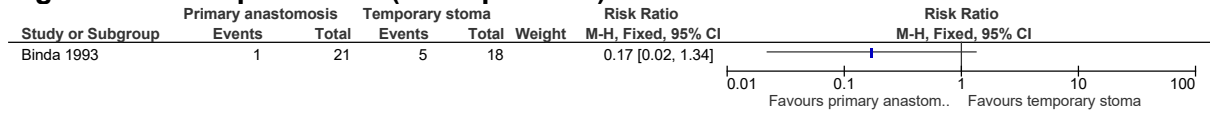


Figure 36: Wound sepsis (first operation)

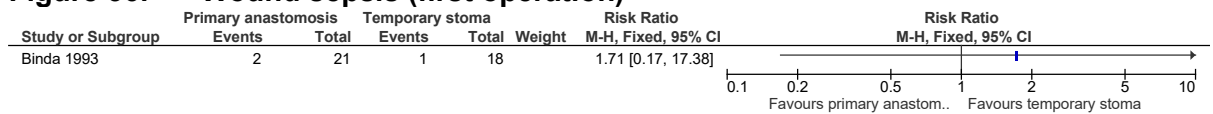


Figure 37: Intra-abdominal infection (first operation)

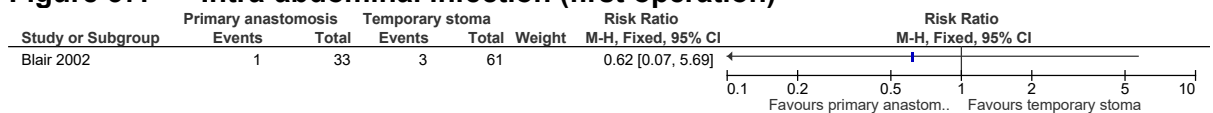


Figure 38: Wound infection (first operation)

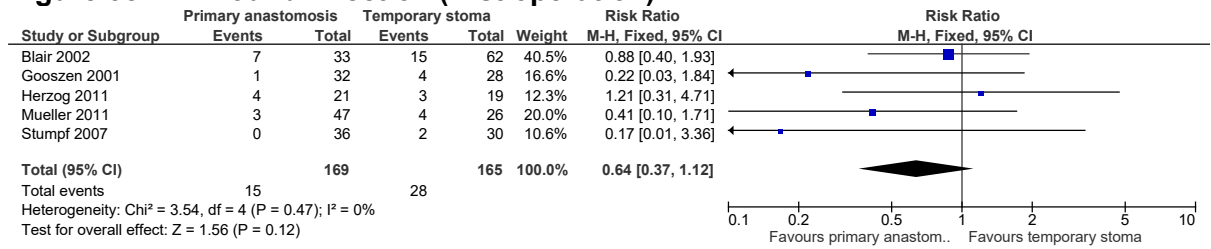


Figure 39: Wound infection (second operation)

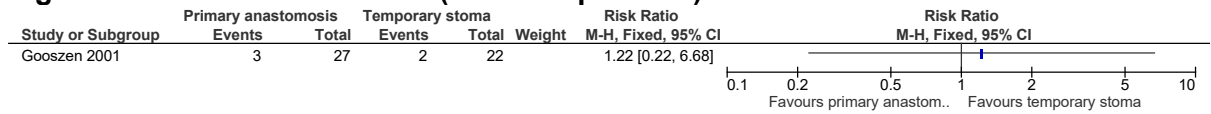


Figure 40: Postoperative complications – infection (first operation)

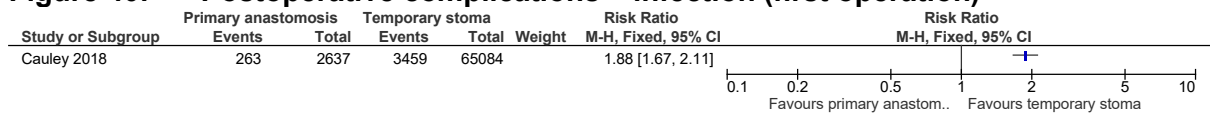


Figure 41: Sepsis (first operation)

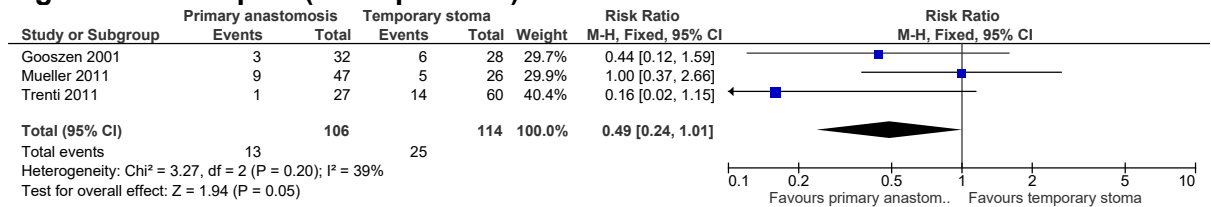


Figure 42: Sepsis (second operation)

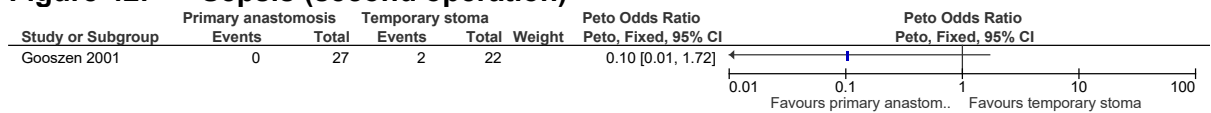


Figure 43: Urinary infection (first operation)

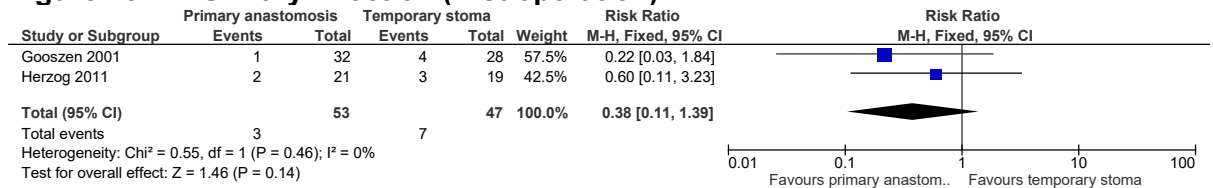


Figure 44: Urinary infection (second operation)

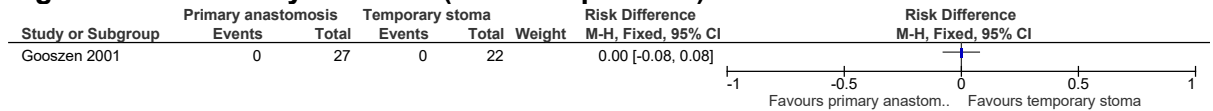


Figure 45: Emergency readmission (first operation)

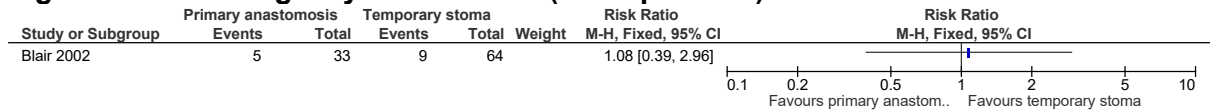


Figure 46: Hospital readmission (first operation)

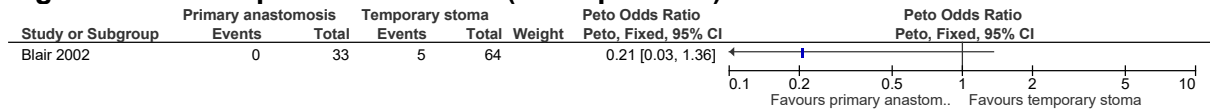


Figure 47: Overall surgical morbidity (first operation)

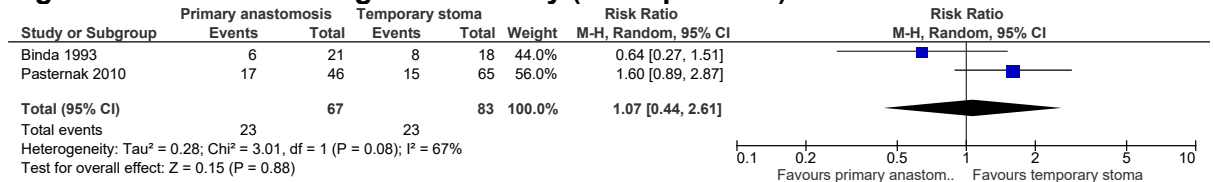


Figure 48: Overall morbidity (first operation)

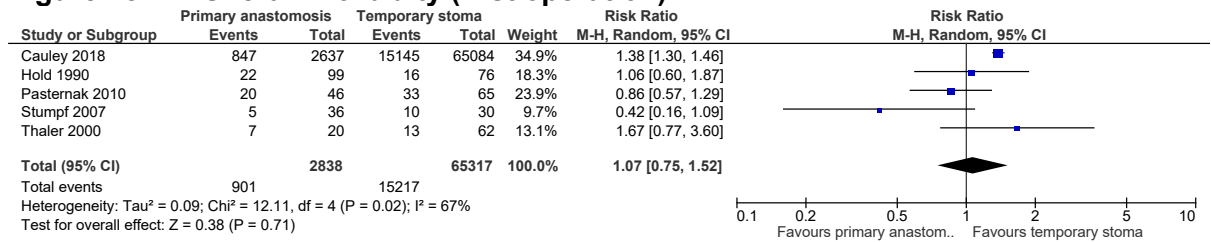


Figure 49: Intraoperative morbidity (first operation)

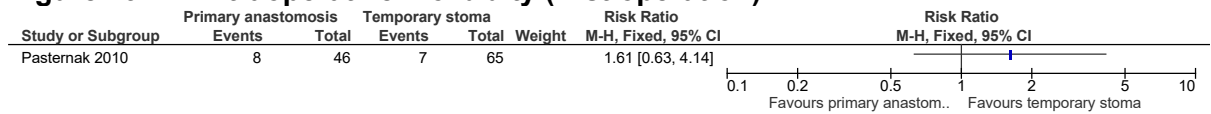


Figure 50: Postoperative medical morbidity (first operation)

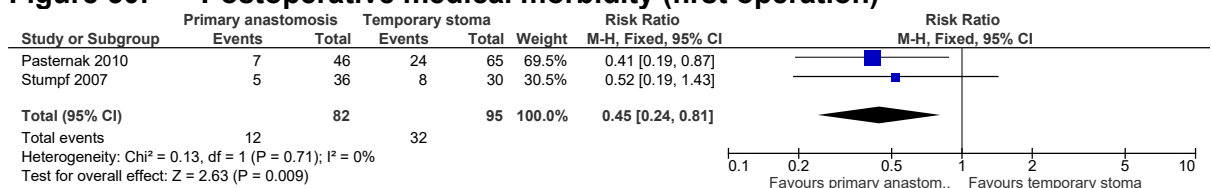


Figure 51: Postoperative major morbidity (first and second operations combined)

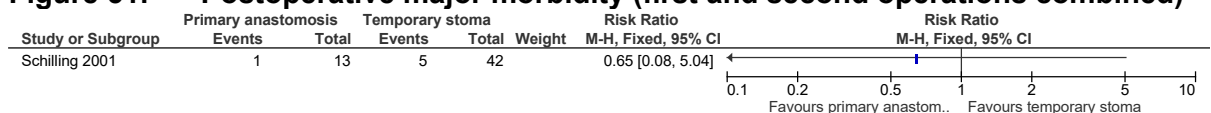


Figure 52: Postoperative minor morbidity (first and second operations combined)

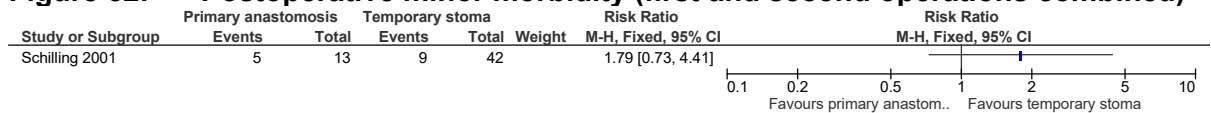


Figure 53: Major general complications (first operation)

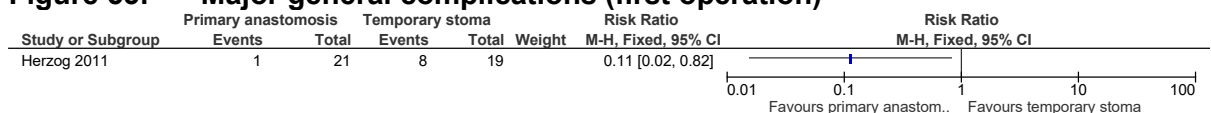


Figure 54: Minor general complications (first operation)

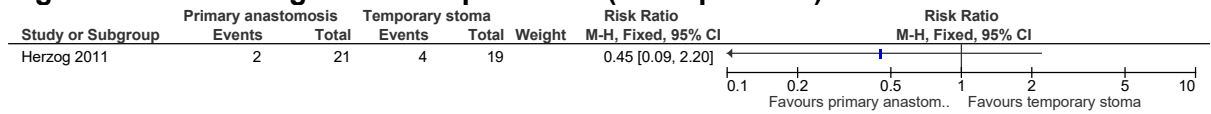


Figure 55: Major surgical complications (first operation)

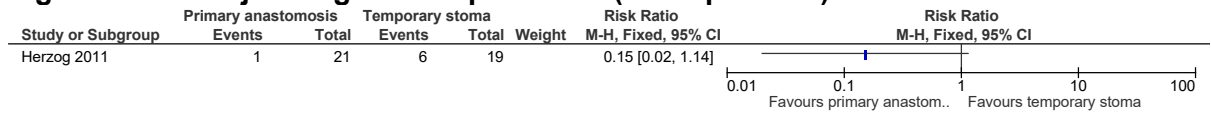


Figure 56: Major postoperative complications (first operation)

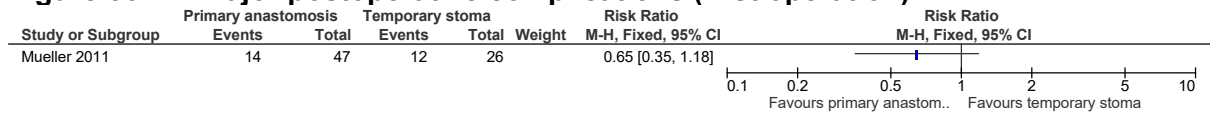


Figure 57: Perioperative mortality (first operation)

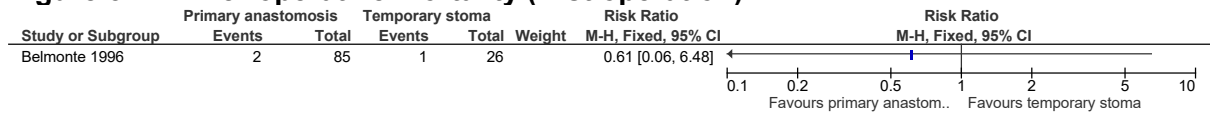


Figure 58: 30-day surgical mortality (first operation)

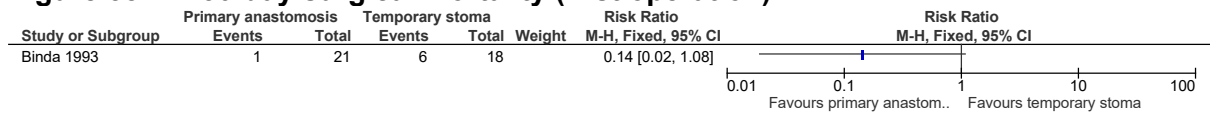


Figure 59: Mortality

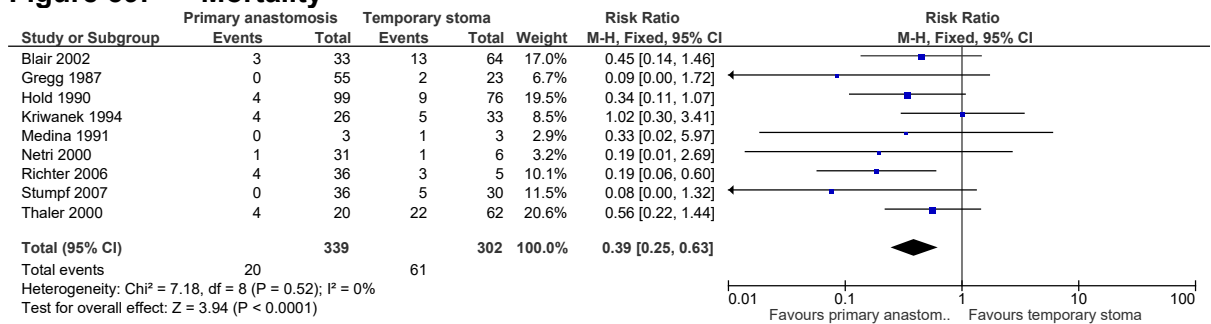


Figure 60: In-hospital mortality (first operation)

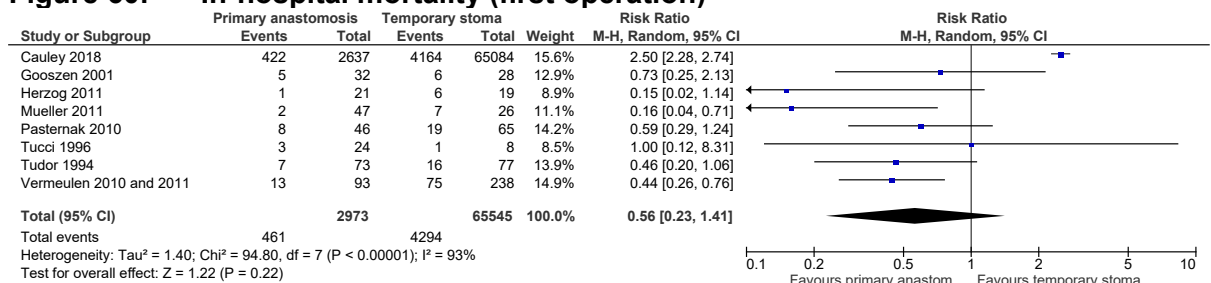


Figure 61: In-hospital mortality (second operation)

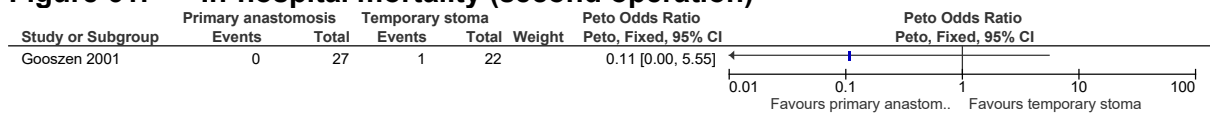


Figure 62: Mortality (median follow-up 59 months)

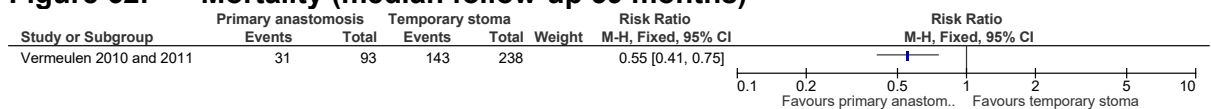


Figure 63: Postoperative mortality (first and second operations combined)



Figure 64: Reintervention (first operation)

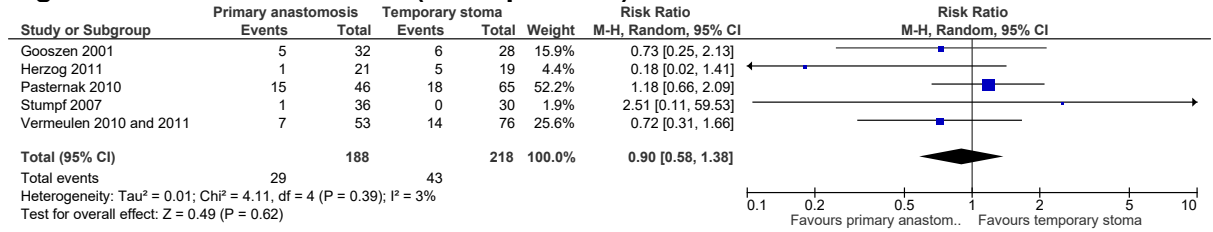


Figure 65: Reintervention (second operation)

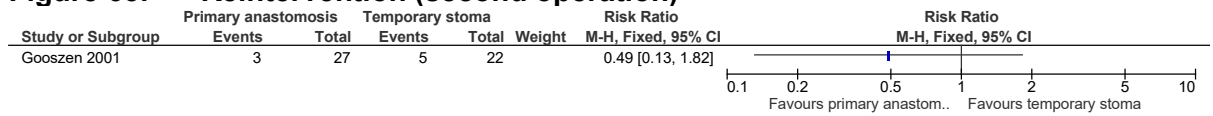


Figure 66: Stoma dysfunction (first operation)

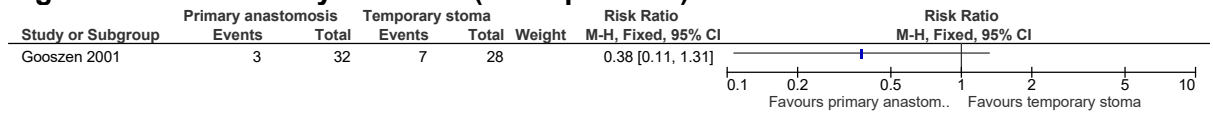


Figure 67: Colostomy/stump insufficiency (first operation)

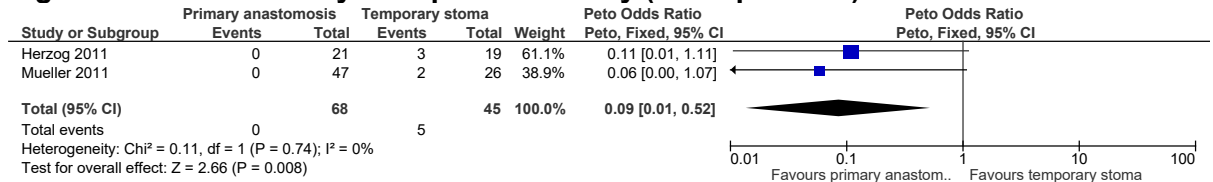


Figure 68: Stoma necrosis (first operation)

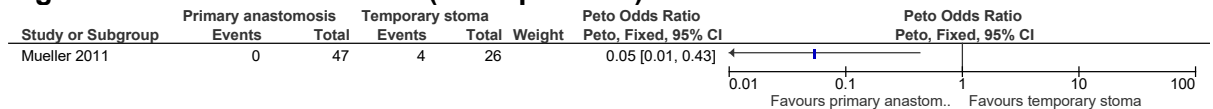


Figure 69: Stoma morbidity (first operation)

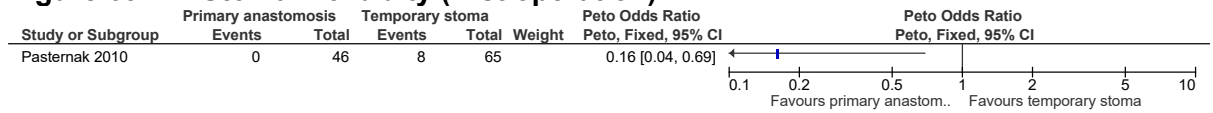


Figure 70: Stoma complications (first and second operations combined)

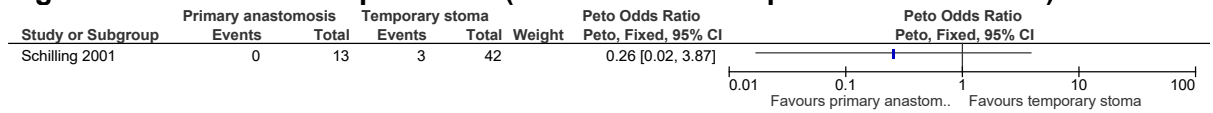


Figure 71: 30-day organ space infection (first operation)

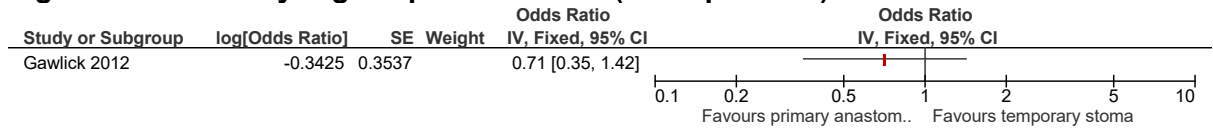


Figure 72: 30-day postoperative sepsis (first operation)

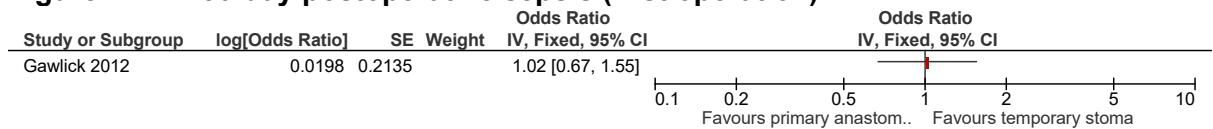


Figure 73: Wound infection (first operation)

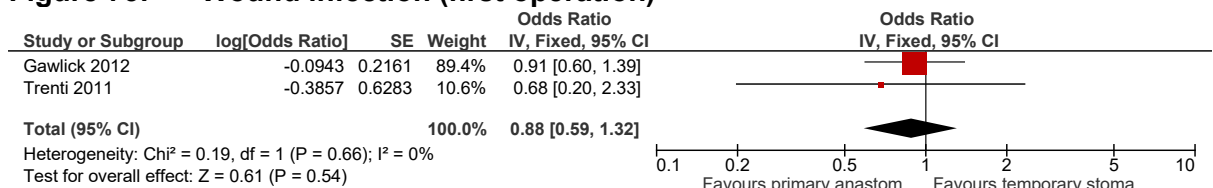


Figure 74: Postoperative morbidity (first operation)

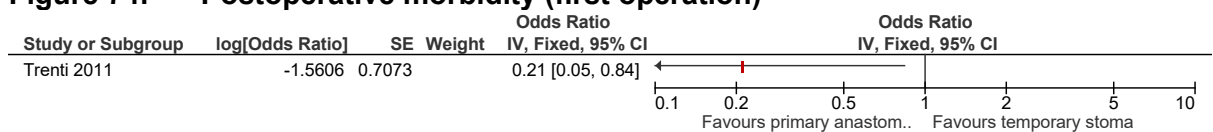


Figure 75: Postoperative mortality (first operation)

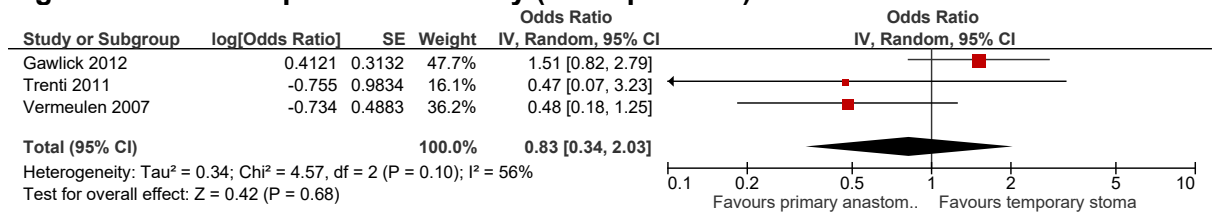


Figure 76: Reoperation (first operation)

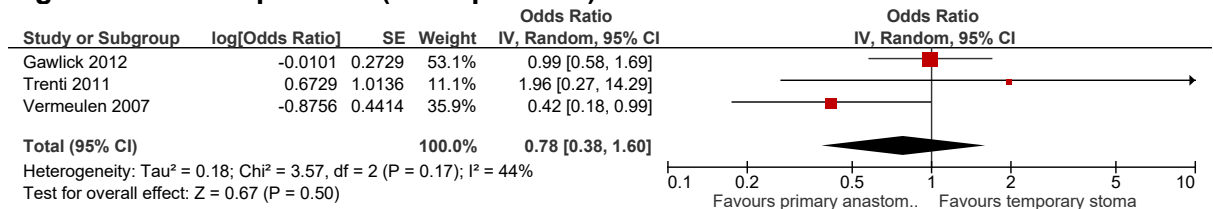
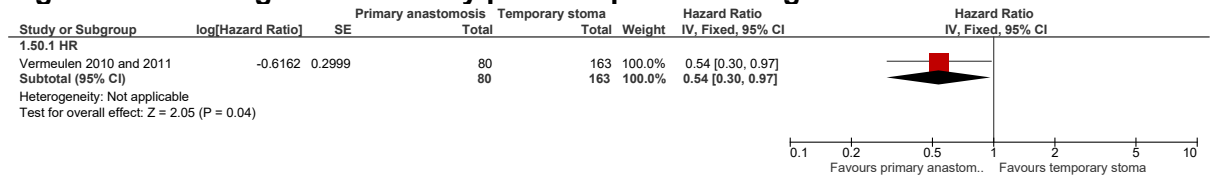


Figure 77: Long-term mortality post-hospital discharge



Appendix F: GRADE tables

Table 19: Clinical evidence profile: Primary anastomosis vs. temporary stoma - RCTs

| Quality assessment | | | | | | | No of patients | | Effect | | Quality | Importance |
|--|-------------------|---------------------------|--------------------------|-------------------------|---------------------------|----------------------|---------------------|-----------------|-------------------------|--|------------------|------------|
| No of studies | Design | Risk of bias | Inconsistency | Indirectness | Imprecision | Other considerations | Primary anastomosis | temporary stoma | Relative (95% CI) | Absolute | | |
| Anastomotic leak (first operation) | | | | | | | | | | | | |
| 3 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | serious ² | none | 4/116 (3.4%) | 1/138 (0.72%) | OR 4.24 (0.71 to 25.21) | 27 more per 1000 (from 8 fewer to 63 more) ³ | ⊕○○○ VERY LOW | CRITICAL |
| Anastomotic leak (second operation) | | | | | | | | | | | | |
| 3 | randomised trials | very serious ¹ | serious ⁴ | no serious indirectness | very serious ² | none | 2/80 (2.5%) | 4/82 (4.9%) | RR 0.6 (0.16 to 2.24) | 24 fewer per 1000 (from 82 fewer to 34 more) ³ | ⊕○○○ VERY LOW | CRITICAL |
| Complications - deep incisional surgical site infections (first operation) | | | | | | | | | | | | |
| 1 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ² | none | 6/34 (17.6%) | 16.1% | RR 1.1 (0.43 to 2.81) | 16 more per 1000 (from 92 fewer to 291 more) | ⊕○○○ VERY LOW | CRITICAL |
| Complications - deep incisional surgical site infections (second operation) | | | | | | | | | | | | |
| 1 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ² | none | 0/22 (0%) | 8.8% | OR 0.18 (0.02 to 1.92) | 88 fewer per 1000 (from 204 fewer to 28 more) ³ | ⊕○○○ VERY LOW | CRITICAL |
| Complications - organ space site infections (first operation) | | | | | | | | | | | | |

| | | | | | | | | | | | | |
|---|-------------------|---------------------------|---------------------------|-------------------------|---------------------------|------|----------------|-------------|-------------------------|---|------------------|----------|
| 1 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | serious ² | none | 0/34 (0%) | 10.7% | OR 0.18 (0.03 to 1) | 107 fewer per 1000 (from 199 more to 16 more) ³ | ⊕○○○ VERY LOW | CRITICAL |
| Complications - organ space site infections (second operation) | | | | | | | | | | | | |
| 1 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ² | none | 0/22 (0%) | 2.9% | OR 0.19 (0 to 10.66) | 29 fewer per 1000 (from 119 fewer to 60 more) ³ | ⊕○○○ VERY LOW | CRITICAL |
| Complications - superficial incisional surgical site infections (first operation) | | | | | | | | | | | | |
| 1 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ² | none | 9/34 (26.5%) | 19.6% | RR 1.35 (0.62 to 2.91) | 69 more per 1000 (from 74 fewer to 374 more) | ⊕○○○ VERY LOW | CRITICAL |
| Complications - superficial incisional surgical site infections (second operation) | | | | | | | | | | | | |
| 1 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | serious ² | none | 0/22 (0%) | 14.7% | OR 0.17 (0.03 to 1.09) | 147 fewer per 1000 (from 282 fewer to 13 more) ³ | ⊕○○○ VERY LOW | CRITICAL |
| Complications - urinary tract infections (first operation) | | | | | | | | | | | | |
| 2 | randomised trials | very serious ¹ | very serious ⁵ | no serious indirectness | very serious ² | none | 3/66 (4.5%) | 4/86 (4.7%) | RR 0.98 (0.09 to 11.24) | 1 fewer per 1000 (from 68 fewer to 66 more) ³ | ⊕○○○ VERY LOW | CRITICAL |
| Complications - urinary tract infections (second operation) | | | | | | | | | | | | |
| 2 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | serious ⁶ | none | 0/48 (0%) | 0% | RD 0 (-0.06 to 0.06) | 0 fewer per 1000 (from 60 fewer to 60 more) ⁷ | ⊕○○○ VERY LOW | CRITICAL |
| Overall morbidity (first operation) | | | | | | | | | | | | |
| 3 | randomised trials | very serious ¹ | serious ⁸ | no serious indirectness | serious ² | none | 63/116 (54.3%) | 42.3% | RR 1.24 (0.77 to 1.99) | 102 more per 1000 (from 97 fewer to 419 more) | ⊕○○○ VERY | CRITICAL |

| | | | | | | | | | | | | |
|---|-------------------|---------------------------|--------------------------|-------------------------|---------------------------|------|--------------|-------------|--------------------------|--|------------------|----------|
| | | | | | | | | | | more) | LOW | |
| Overall morbidity (second operation) | | | | | | | | | | | | |
| 2 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | serious ² | none | 5/54 (9.3%) | 28.3% | RR 0.32 (0.12 to 0.85) | 192 fewer per 1000 (from 42 fewer to 249 fewer) | ⊕○○○ VERY LOW | CRITICAL |
| Mortality (first operation) | | | | | | | | | | | | |
| 3 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ² | none | 6/116 (5.2%) | 10.7% | RR 0.58 (0.22 to 1.55) | 45 fewer per 1000 (from 83 fewer to 59 more) | ⊕○○○ VERY LOW | CRITICAL |
| Mortality (second operation) | | | | | | | | | | | | |
| 3 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | serious ⁶ | none | 0/80 (0%) | 2/82 (2.4%) | RD -0.03 (-0.08 to 0.03) | 30 fewer per 1000 (from 80 fewer to 30 more) ⁹ | ⊕○○○ VERY LOW | CRITICAL |
| Complications - intra-abdominal abscess (first operation) | | | | | | | | | | | | |
| 1 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ² | none | 2/50 (4%) | 7.7% | RR 0.52 (0.1 to 2.71) | 37 fewer per 1000 (from 69 fewer to 132 more) | ⊕○○○ VERY LOW | CRITICAL |
| Complications - intra-abdominal abscess (second operation) | | | | | | | | | | | | |
| 1 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ² | none | 0/32 (0%) | 3% | OR 0.14 (0 to 7.03) | 30 fewer per 1000 (from 111 fewer to 50 more) ³ | ⊕○○○ VERY LOW | CRITICAL |
| Complications - anastomotic stricture (first operation) | | | | | | | | | | | | |
| 1 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ² | none | 1/50 (2%) | 0% | OR 7.69 (0.15 to 387.87) | 20 more per 1000 (from 33 fewer to 73 more) ³ | ⊕○○○ VERY LOW | CRITICAL |

| Need for further surgery - reoperation (first operation) | | | | | | | | | | | | |
|--|-------------------|---------------------------|--------------------------|-------------------------|----------------------------|------|---------------|-------------|------------------------|--|------------------|----------|
| 1 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ² | none | 2/50 (4%) | 7.7% | RR 0.52 (0.1 to 2.71) | 37 fewer per 1000 (from 69 fewer to 132 more) | ⊕○○○ VERY LOW | CRITICAL |
| Need for further surgery - reoperation (second operation) | | | | | | | | | | | | |
| 2 | randomised trials | very serious ¹ | serious ¹⁰ | no serious indirectness | very serious ² | none | 1/58 (1.7%) | 4/48 (8.3%) | RR 0.31 (0.03 to 3.71) | 66 fewer per 1000 (from 151 fewer to 19 more) ³ | ⊕○○○ VERY LOW | CRITICAL |
| All complications - Clavien-Dindo I-V (first operation) | | | | | | | | | | | | |
| 1 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ² | none | 27/32 (84.4%) | 80% | OR 1.35 (0.36 to 4.99) | 44 more per 1000 (from 210 fewer to 152 more) | ⊕○○○ VERY LOW | CRITICAL |
| All complications - Clavien-Dindo I-V (second operation) | | | | | | | | | | | | |
| 1 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | no serious imprecision | none | 20/26 (76.9%) | 40% | OR 5 (1.26 to 19.84) | 369 more per 1000 (from 57 more to 530 more) | ⊕⊕○○ LOW | CRITICAL |
| Intra-abdominal infection (first operation) | | | | | | | | | | | | |
| 1 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ² | none | 2/32 (6.3%) | 20% | RR 0.31 (0.07 to 1.43) | 138 fewer per 1000 (from 186 fewer to 86 more) | ⊕○○○ VERY LOW | CRITICAL |
| Intra-abdominal infection (second operation) | | | | | | | | | | | | |
| 1 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ¹¹ | none | 0/26 (0%) | 0% | RD 0 (-0.10 to 0.10) | 0 fewer per 1000 (from 100 fewer to 100 more) ⁹ | ⊕○○○ VERY LOW | CRITICAL |
| Wound infection (first operation) | | | | | | | | | | | | |

| | | | | | | | | | | | | |
|--|-------------------|---------------------------|--------------------------|-------------------------|---------------------------|------|---------------|-------|------------------------|---|------------------|----------|
| 1 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ² | none | 11/32 (34.4%) | 43.3% | RR 0.79 (0.42 to 1.49) | 91 fewer per 1000 (from 251 fewer to 212 more) | ⊕○○○ VERY LOW | CRITICAL |
| Wound infection (second operation) | | | | | | | | | | | | |
| 1 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ¹ | none | 3/26 (11.5%) | 20% | RR 0.58 (0.13 to 2.51) | 84 fewer per 1000 (from 174 fewer to 302 more) | ⊕○○○ VERY LOW | CRITICAL |
| Stoma complications (first operation) | | | | | | | | | | | | |
| 1 | randomised trials | very serious ¹ | no serious inconsistency | no serious indirectness | serious ² | none | 0/32 (0%) | 10% | OR 0.12 (0.01 to 1.18) | 100 fewer per 1000 (from 219 fewer to 19 more) ³ | ⊕○○○ VERY LOW | CRITICAL |

Table 20: Clinical evidence profile: Primary anastomosis vs. temporary stoma – observational studies

| Quality assessment | | | | | | | No of patients | | Effect | | Quality | Importance |
|---|-----------------------|---------------------------|--------------------------|-------------------------|------------------------|----------------------|----------------|-----------------------|--------------------------|--|------------------|------------|
| No of studies | Design | Risk of bias | Inconsistency | Indirectness | Imprecision | Other considerations | Primary | secondary anastomosis | Relative (95% CI) | Absolute | | |
| Anastomotic leak (first operation) | | | | | | | | | | | | |
| 8 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | no serious imprecision | none | 23/293 (7.8%) | 0% | OR 15.41 (4.53 to 52.47) | 79 more per 1000 (from 47 more to 110 more) ² | ⊕○○○ VERY LOW | CRITICAL |
| Anastomotic leak (second operation) | | | | | | | | | | | | |
| 3 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | serious ³ | none | 1/45 (2.2%) | 7/73 (9.6%) | OR 0.1 (0.02 to 0.51) | 80 fewer per 1000 (from 190 fewer to 30 more) ⁴ | ⊕○○○ VERY LOW | CRITICAL |
| Anastomotic leak/rectal stump leak (first operation) | | | | | | | | | | | | |

| | | | | | | | | | | | | |
|--|-----------------------|---------------------------|--------------------------|-------------------------|---------------------------|------|---------------|----------------|-------------------------|---|------------------|----------|
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | no serious imprecision | none | 13/46 (28.3%) | 3.1% | RR 9.18 (2.18 to 38.77) | 254 more per 1000 (from 37 more to 1000 more) | ⊕○○○ VERY LOW | CRITICAL |
| Abscess (first operation) | | | | | | | | | | | | |
| 6 | observational studies | very serious ¹ | serious ⁵ | no serious indirectness | very serious ⁶ | none | 11/165 (6.7%) | 22/205 (10.7%) | RR 0.69 (0.23 to 2.03) | 41 fewer per 1000 (from 98 fewer to 16 more) ⁴ | ⊕○○○ VERY LOW | CRITICAL |
| Abscess (second operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁷ | none | 0/27 (0%) | 0% | RD 0 (-0.08 to 0.08) | 0 fewer per 1000 (from 80 fewer to 80 more) ² | ⊕○○○ VERY LOW | CRITICAL |
| Abscess/peritonitis (first operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | 3/47 (6.4%) | 3.9% | RR 1.66 (0.18 to 15.16) | 26 more per 1000 (from 32 fewer to 552 more) | ⊕○○○ VERY LOW | CRITICAL |
| Fistula (first operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | 2/21 (9.5%) | 0% | OR 6.74 (0.4 to 112.7) | 95 more per 1000 (from 56 fewer to 246 more) ² | ⊕○○○ VERY LOW | CRITICAL |
| Septic shock (first operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | 1/21 (4.8%) | 27.8% | RR 0.17 (0.02 to 1.34) | 231 fewer per 1000 (from 272 fewer to 95 more) | ⊕○○○ VERY LOW | CRITICAL |
| Wound sepsis (first operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | 2/21 (9.5%) | 5.6% | RR 1.71 (0.17 to | 40 more per 1000 (from 46 fewer to 917 | ⊕○○○ VERY | CRITICAL |

| | | | | | | | | | | | | |
|--|-----------------------|---------------------------|--------------------------|-------------------------|---------------------------|------|----------------|-------|------------------------|--|------------------|----------|
| | | | | | | | | | 17.38) | more) | LOW | |
| Intra-abdominal infection (first operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | 1/33 (3%) | 4.9% | RR 0.62 (0.07 to 5.69) | 19 fewer per 1000 (from 46 fewer to 230 more) | ⊕○○○ VERY LOW | CRITICAL |
| Wound infection (first operation) | | | | | | | | | | | | |
| 5 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | serious ⁶ | none | 15/169 (8.9%) | 15.4% | RR 0.64 (0.37 to 1.12) | 81 fewer per 1000 (from 153 fewer to 9 fewer) ⁴ | ⊕○○○ VERY LOW | CRITICAL |
| Wound infection (second operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | 3/27 (11.1%) | 9.1% | RR 1.22 (0.22 to 6.68) | 20 more per 1000 (from 71 fewer to 517 more) | ⊕○○○ VERY LOW | CRITICAL |
| Postoperative complications - infection (first operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | no serious imprecision | none | 263/2637 (10%) | 5.3% | RR 1.88 (1.67 to 2.11) | 47 more per 1000 (from 36 more to 59 more) | ⊕○○○ VERY LOW | CRITICAL |
| Sepsis (first operation) | | | | | | | | | | | | |
| 3 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | serious ⁶ | none | 13/106 (12.3%) | 21.4% | RR 0.49 (0.24 to 1.01) | 109 fewer per 1000 (from 163 fewer to 2 more) | ⊕○○○ VERY LOW | CRITICAL |
| Sepsis (second operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | 0/27 (0%) | 9.1% | OR 0.1 (0.01 to 1.72) | 91 fewer per 1000 (from 227 fewer to 45 more) ⁸ | ⊕○○○ VERY LOW | CRITICAL |

| Urinary infection (first operation) | | | | | | | | | | | | |
|--|-----------------------|---------------------------|--------------------------|-------------------------|---------------------------|------|------------------|-------|------------------------|---|------------------|----------|
| 2 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | 3/53 (5.7%) | 14.3% | RR 0.22 (0.05 to 0.99) | 112 fewer per 1000 (from 1 fewer to 136 fewer) | ⊕○○○ VERY LOW | CRITICAL |
| Urinary infection (second operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁷ | none | 0/27 (0%) | 0% | RD 0 (-0.08 to 0.08) | 0 fewer per 1000 (from 80 fewer to 80 more) ² | ⊕○○○ VERY LOW | CRITICAL |
| Emergency readmission (first operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | 5/33 (15.2%) | 14.1% | RR 1.08 (0.39 to 2.96) | 11 more per 1000 (from 86 fewer to 276 more) | ⊕○○○ VERY LOW | CRITICAL |
| Hospital readmission (first operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | 0/33 (0%) | 7.8% | OR 0.21 (0.03 to 1.36) | 78 fewer per 1000 (from 157 fewer to 1 more) ⁸ | ⊕○○○ VERY LOW | CRITICAL |
| Overall surgical morbidity (first operation) | | | | | | | | | | | | |
| 2 | observational studies | very serious ¹ | serious ⁹ | no serious indirectness | very serious ⁶ | none | 23/67 (34.3%) | 33.8% | RR 1.07 (0.44 to 2.61) | 24 more per 1000 (from 189 fewer to 544 more) | ⊕○○○ VERY LOW | CRITICAL |
| Overall morbidity (first operation) | | | | | | | | | | | | |
| 5 | observational studies | very serious ¹ | serious ⁹ | no serious indirectness | serious ⁶ | none | 901/2838 (31.7%) | 23.3% | RR 1.07 (0.75 to 1.52) | 16 more per 1000 (from 58 fewer to 121 more) | ⊕○○○ VERY LOW | CRITICAL |
| Intraoperative morbidity (first operation) | | | | | | | | | | | | |

| | | | | | | | | | | | | |
|---|-----------------------|---------------------------|--------------------------|-------------------------|---------------------------|------|------------------|-------|---------------------------|--|------------------|----------|
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | 8/46 (17.4%) | 10.8% | RR 1.61 (0.63 to 4.14) | 66 more per 1000 (from 40 fewer to 339 more) | ⊕○○○ VERY LOW | CRITICAL |
| Postoperative medical morbidity (first operation) | | | | | | | | | | | | |
| 2 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | serious ⁶ | none | 12/82 (14.6%) | 31.8% | RR 0.45 (0.24 to 0.81) | 175 fewer per 1000 (from 60 fewer to 242 fewer) | ⊕○○○ VERY LOW | CRITICAL |
| Postoperative major morbidity (first and second operations combined) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | 1/13 (7.7%) | 11.9% | RR 0.65 (0.08 to 5.04) | 42 fewer per 1000 (from 109 fewer to 481 more) | ⊕○○○ VERY LOW | CRITICAL |
| Postoperative minor morbidity (first and second operations combined) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | 5/13 (38.5%) | 21.4% | RR 1.79 (0.73 to 4.41) | 169 more per 1000 (from 58 fewer to 730 more) | ⊕○○○ VERY LOW | CRITICAL |
| Major general complications (first operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | serious ⁶ | none | 1/21 (4.8%) | 42.1% | RR 0.11 (0.02 to 0.82) | 375 fewer per 1000 (from 76 fewer to 413 fewer) | ⊕○○○ VERY LOW | CRITICAL |
| Minor general complications (first operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | 2/21 (9.5%) | 21.1% | RR 0.45 (0.09 to 2.2) | 116 fewer per 1000 (from 192 fewer to 253 more) | ⊕○○○ VERY LOW | CRITICAL |
| Major surgical complications (first operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | serious ⁶ | none | 1/21 (4.8%) | 31.6% | RR 0.15 (0.02 to 1.14) | 269 fewer per 1000 (from 310 fewer to 44 more) | ⊕○○○ VERY | CRITICAL |

| | | | | | | | | | | | | |
|---|-----------------------|---------------------------|----------------------------|--------------------------------------|-------------------------------------|------|------------------|-------|------------------------|--|------------------|----------|
| | | | | | | | | | | more) | LOW | |
| Major postoperative complications (first operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | serious ⁶ | none | 14/47 (29.8%) | 46.2% | RR 0.65 (0.35 to 1.18) | 162 fewer per 1000 (from 300 fewer to 83 more) | ⊕○○○ VERY LOW | CRITICAL |
| Perioperative mortality (first operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | 2/85 (2.4%) | 3.9% | RR 0.61 (0.06 to 6.48) | 15 fewer per 1000 (from 37 fewer to 214 more) | ⊕○○○ VERY LOW | CRITICAL |
| 30-day surgical mortality (first operation) (follow-up mean 30 days) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | serious ⁶ | none | 1/21 (4.8%) | 33.3% | RR 0.14 (0.02 to 1.08) | 286 fewer per 1000 (from 326 fewer to 27 more) | ⊕○○○ VERY LOW | CRITICAL |
| Mortality | | | | | | | | | | | | |
| 9 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | no serious imprecision | none | 20/339 (5.9%) | 16.7% | RR 0.39 (0.25 to 0.63) | 143 fewer per 1000 (from 195 fewer to 91 fewer) ⁴ | ⊕○○○ VERY LOW | CRITICAL |
| Mortality (follow-up median 59 months) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | no serious imprecision ⁶ | none | 31/93 (33.3%) | 60.1% | RR 0.55 (0.41 to 0.75) | 270 fewer per 1000 (from 150 fewer to 355 fewer) | ⊕○○○ VERY LOW | CRITICAL |
| In-hospital mortality (first operation) | | | | | | | | | | | | |
| 8 | observational studies | very serious ¹ | very serious ¹⁰ | no serious indirectness ⁶ | very serious ⁶ | none | 461/2973 (15.5%) | 24.2% | RR 0.56 (0.23 to 1.41) | 106 fewer per 1000 (from 186 fewer to 99 more) | ⊕○○○ VERY LOW | CRITICAL |

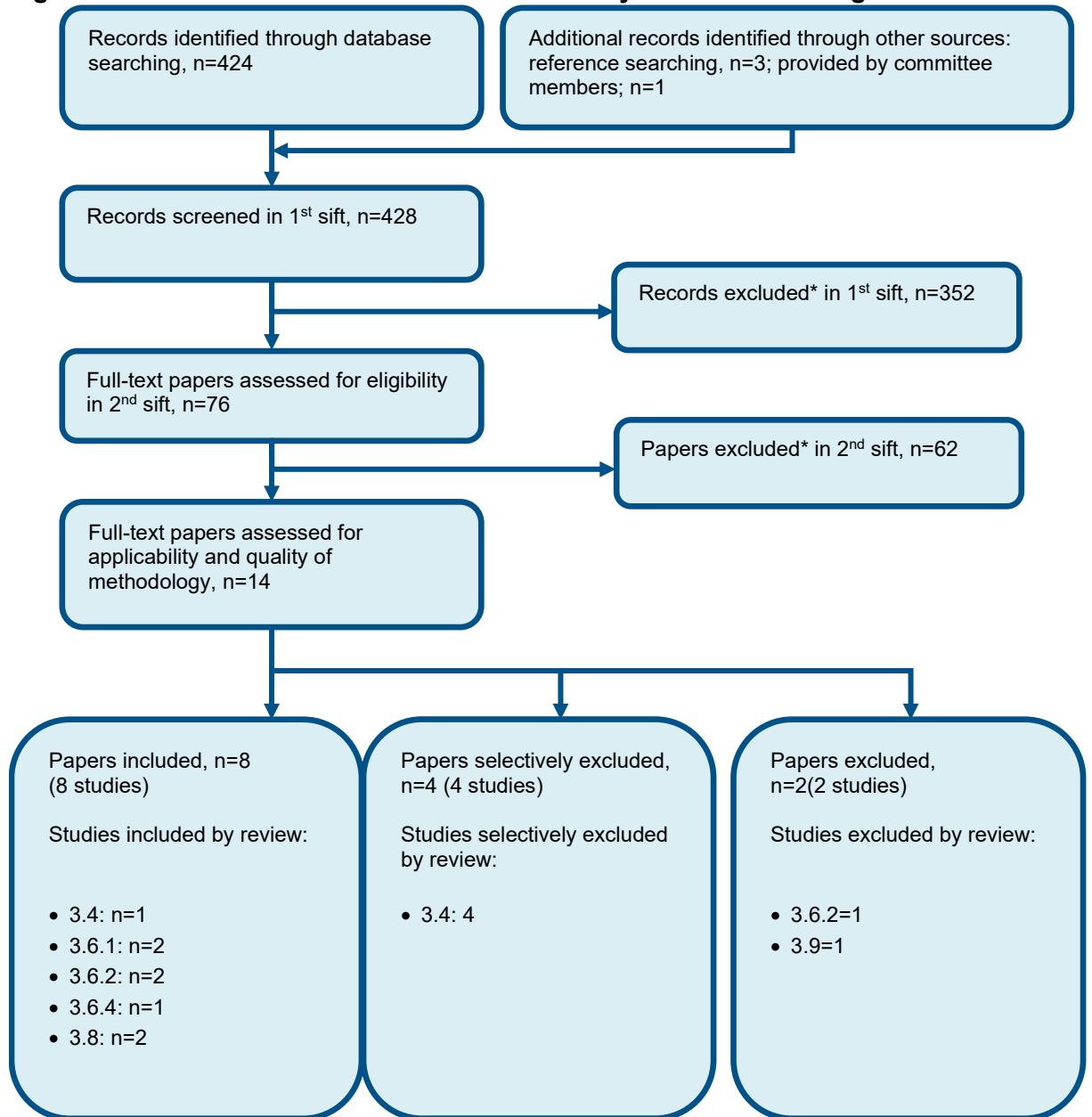
| In-hospital mortality (second operation) | | | | | | | | | | | | |
|---|-----------------------|---------------------------|--------------------------|-------------------------|---------------------------|------|----------------|----------------|------------------------|--|------------------|----------|
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | 0/27 (0%) | 4.6% | OR 0.11 (0 to 5.55) | 46 fewer per 1000 (from 158 fewer to 67 more) ⁸ | ⊕○○○ VERY LOW | CRITICAL |
| Postoperative mortality (first and second operations combined) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | 1/13 (7.7%) | 9.5% | RR 0.81 (0.1 to 6.6) | 18 fewer per 1000 (from 86 fewer to 532 more) | ⊕○○○ VERY LOW | CRITICAL |
| Reintervention (first operation) | | | | | | | | | | | | |
| 5 | observational studies | very serious ¹ | serious ¹¹ | no serious indirectness | very serious ⁶ | none | 29/188 (15.4%) | 43/218 (19.7%) | RR 0.9 (0.58 to 1.38) | 20 fewer per 1000 (from 100 fewer to 50 more) ⁴ | ⊕○○○ VERY LOW | CRITICAL |
| Reintervention (second operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | 3/27 (11.1%) | 22.7% | RR 0.49 (0.13 to 1.82) | 116 fewer per 1000 (from 197 fewer to 186 more) | ⊕○○○ VERY LOW | CRITICAL |
| Stoma dysfunction (first operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | 3/32 (9.4%) | 25% | RR 0.38 (0.11 to 1.31) | 155 fewer per 1000 (from 222 fewer to 77 more) | ⊕○○○ VERY LOW | CRITICAL |
| Colostomy insufficiency/stump insufficiency (first operation) | | | | | | | | | | | | |
| 2 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | no serious imprecision | none | 0/68 (0%) | 15.8% | OR 0.11 (0.02 to 0.56) | 111 fewer per 1000 (from 207 fewer to 15 fewer) ⁸ | ⊕○○○ VERY LOW | CRITICAL |
| Stoma necrosis (first operation) | | | | | | | | | | | | |

| | | | | | | | | | | | | |
|--|-----------------------|---------------------------|--------------------------|-------------------------|---------------------------|------|-----------|-------|------------------------|--|------------------|----------|
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | no serious imprecision | none | 0/47 (0%) | 15.4% | OR 0.05 (0.01 to 0.43) | 154 fewer per 1000 (from 297 fewer to 10 fewer) ⁸ | ⊕○○○ VERY LOW | CRITICAL |
| Stoma morbidity (first operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | no serious imprecision | none | 0/46 (0%) | 12.3% | OR 0.16 (0.04 to 0.69) | 123 fewer per 1000 (from 209 fewer to 37 fewer) ⁸ | ⊕○○○ VERY LOW | CRITICAL |
| Stoma complications (first and second operations combined) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | 0/13 (0%) | 7.1% | OR 0.26 (0.02 to 3.87) | 71 fewer per 1000 (from 20 fewer to 56 more) ⁸ | ⊕○○○ VERY LOW | CRITICAL |
| 30-day organ space infection (first operation) (follow-up mean 30 days) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | - | 5.5% | OR 0.71 (0.35 to 1.42) | 15 fewer per 1000 (from 35 fewer to 21 more) | ⊕○○○ VERY LOW | CRITICAL |
| 30-day postoperative sepsis (first operation) (follow-up mean 30 days) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | - | 14.2% | OR 1.02 (0.67 to 1.55) | 2 more per 1000 (from 42 fewer to 62 more) | ⊕○○○ VERY LOW | CRITICAL |
| Wound infection (first operation) | | | | | | | | | | | | |
| 2 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | very serious ⁶ | none | - | 22.6% | OR 0.88 (0.59 to 1.32) | 22 fewer per 1000 (from 79 fewer to 52 more) | ⊕○○○ VERY LOW | CRITICAL |
| Postoperative morbidity (first operation) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | serious ⁶ | none | - | 86.7% | OR 0.21 (0.05 to 0.84) | 289 fewer per 1000 (from 21 fewer to 621) | ⊕○○○ VERY | CRITICAL |

| | | | | | | | | | | | | |
|---|-----------------------|---------------------------|--------------------------|-------------------------|---------------------------|------|---------------|-------|------------------------|---|------------------|----------|
| | | | | | | | | | | fewer) | LOW | |
| Postoperative mortality (first operation) | | | | | | | | | | | | |
| 3 | observational studies | very serious ¹ | serious ¹² | no serious indirectness | very serious ⁶ | none | - | 33.8% | OR 0.83 (0.34 to 2.03) | 40 fewer per 1000 (from 190 fewer to 171 more) | ⊕○○○ VERY LOW | CRITICAL |
| Reoperation (first operation) | | | | | | | | | | | | |
| 3 | observational studies | very serious ¹ | serious ¹³ | no serious indirectness | very serious ⁶ | none | - | 20% | OR 0.78 (0.38 to 1.6) | 37 fewer per 1000 (from 113 fewer to 86 more) | ⊕○○○ VERY LOW | CRITICAL |
| Long term survival post-hospital discharge (mortality) - HR (follow-up median 59 months) | | | | | | | | | | | | |
| 1 | observational studies | very serious ¹ | no serious inconsistency | no serious indirectness | serious ⁶ | none | 18/80 (22.5%) | 41.7% | HR 0.54 (0.3 to 0.97) | 164 fewer per 1000 (from 10 fewer to 268 fewer) | ⊕○○○ VERY LOW | CRITICAL |

Appendix G: Health economic evidence selection

Figure 78: Flow chart of health economic study selection for the guideline



* Non-relevant population, intervention, comparison, design or setting; non-English language

3.4 Non-surgical treatment of acute diverticulitis (Evidence review H)

3.6.1 Timing of surgery (Evidence review J)

3.6.2 Laparoscopic versus open resection (Evidence review K)

3.6.4 Primary versus secondary anastomosis (Evidence review M)

3.8 Laparoscopic lavage versus resection for perforated diverticulitis (Evidence review O)

3.9 Management of recurrent diverticulitis (Evidence review P)

Appendix H: Health economic evidence tables

Table 21: Health economic evidence tables

| Study | Oberkofler 2012 ⁵³ | | | |
|---|--|--|---|---|
| Study details | Population & interventions | Costs | Health outcomes | Cost effectiveness |
| <p>Economic analysis: CCA (health outcomes: Mortality (5 years), complication rate, severe complications, stoma reversal)</p> <p>Study design: Within-trial analysis of a multicentre randomised controlled trial</p> <p>Approach to analysis: Data were analysed based on intention to treat principle. Study discontinued at interim analysis.</p> <p>Perspective: Switzerland, hospital</p> <p>Follow-up: Costs: None; Health outcomes: None, except mortality (5 years)</p> <p>Discounting: Costs: n/a; Outcomes: n/a</p> | <p>Population: German-speaking adults with perforated left-sided diverticulitis with purulent (Hinchey III) or fecal peritonitis (Hinchey IV).</p> <p>Patient characteristics: n: Intervention 1: 30; Intervention 2: 32 Median age: Intervention 1: 74; Intervention 2: 72 Male: Intervention 1: 30%; Intervention 2: 34%</p> <p>Intervention 1: Hartmann's procedure followed by later stoma reversal before 3 months</p> <p>Intervention 2: Primary anastomosis with diverting ileostomy followed by later stoma reversal before 3 months</p> | <p>Total costs (mean per patient): Intervention 1: £54,687 (SD £35,329) Intervention 2: £52,768 (SD £40,696) Incremental (2-1): Saves £1,919 (95% CI: NR; p=0.880)</p> <p>Currency & cost year: US dollars, cost year not reported (presented here as 2012 UK pounds^(b))</p> <p>Cost components incorporated: Both total costs (index and stoma reversal combined) and costs of index procedure and stoma reversal spell separately are presented. Fixed and variable costs for diagnostics, treatments and beds are included.</p> | <p>Mortality: Intervention 1: 4/30=13% Intervention 2: 3/32=9%</p> <p>Overall complication rate: Intervention 1: 24/30=80% Intervention 2: 27/32=84%</p> <p>Severe complications Intervention 1: 50% Intervention 2: 44%</p> <p>Stoma reversal: Intervention 1: 57% Intervention 2: 90%</p> | <p>ICER (Intervention 2 versus Intervention 1): n/a</p> <p>Analysis of uncertainty: n/a</p> |
| Data sources | | | | |
| <p>Health outcomes: Health outcomes obtained from Oberkofler RCT only. ⁵³ Quality-of-life weights: n/a Cost sources: Financial departments of University Hospital Zurich, University Hospital Lausanne, Chur and Winterthur Cantonal Hospitals. ⁵³</p> | | | | |

Comments

Source of funding: NR **Limitations:** Both strategies were designed to include stoma reversal (planned for before 3 months), which may limit the generalisability of the results, particularly in settings where reversal is not as common. Cost year not reported. No detailed breakdown of cost components incorporated. Costs other than those incurred to the institutions do not appear to be considered, such as GP appointments or the costs of people readmitted in other hospitals. Unclear whether the costs of any other admissions between index operation and stoma reversal are included. Stoma reversal was done after 6 months in the Hartmann's group and after 3 months in the anastomosis group. No assessment of quality of life was made. One patient randomised to intervention 1 received a primary anastomosis, while 3 patients randomised to intervention 2 received Hartmann's procedure, at the discretion of the surgeon. No conflicts of interest reported. **Other:** Stoma reversal was planned as part both interventions, but only 15 of 26 (58%) colostomies were reversed whereas 26/29 (90%) of ileostomies were reversed. The study was discontinued after the interim analysis due to low accrual rates and significant differences in relevant secondary outcomes (total number of complications).

Overall applicability: Partially applicable^(c) **Overall quality:** Potentially serious limitations^(d)

Abbreviations: CCA: cost–consequences analysis; 95% CI: 95% confidence interval; ICER: incremental cost-effectiveness ratio; n/a: not applicable; NR: not reported; RCT: randomised controlled trial; SD: standard deviation

(a) Converted using 2012 purchasing power parities⁵⁴

(b) Directly applicable / Partially applicable / Not applicable

(c) Minor limitations / Potentially serious limitations / Very serious limitations

Appendix I: Excluded studies

I.1 Excluded clinical studies

Table 22: Studies excluded from the clinical review

| Study | Exclusion reason |
|-----------------------------------|---|
| Ahad 2007 ¹ | Unsuitable study design |
| Alvarez 2009 ² | Not review population |
| Ambrosetti 1994 ³ | Not guideline condition |
| Aquina 2016 ⁴ | Inappropriate comparison |
| Auguste 1981 ⁵ | Incorrect interventions |
| Bacon 1967 ⁶ | Incorrect interventions |
| Bax 2007 ⁷ | Not review population |
| Biondo 2002 ¹¹ | Not review population |
| Bordeianou 2018 ¹³ | Not review population. Inappropriate comparison |
| Caricato 2007 ¹⁵ | Not review population. Incorrect interventions |
| Cartmell 2008 ¹⁶ | Not review population |
| Chua 1996 ¹⁸ | Not review population. Inappropriate comparison |
| Cirocchi 2018 ¹⁹ | Individual RCTs ordered and included |
| Constantinides 2006 ²⁰ | Not review population |
| Drumm 1984 ²¹ | Incorrect study design |
| Eisenstat 1983 ²² | Not review population. Inappropriate comparison |
| El-haddad 2018 ²³ | Not review population |
| El-sayed 2018 ²⁴ | Not review population. Incorrect interventions |
| Faltyn 1996 ²⁵ | Not review population |
| Gachabayov 2018 ²⁶ | Ordered individual studies within systematic review |
| Golda 2018 ²⁸ | Not review population |
| Gooszen 2001 ³⁰ | Inappropriate comparison |
| Gregersen 2018 ³¹ | Not review population. Incorrect interventions |
| Haas 2016 ³³ | Not review population |
| Howe 1979 ³⁶ | Incorrect outcomes |
| Kairaluoma 2002 ³⁷ | Not review population |
| Khan 1994 ³⁸ | Inappropriate comparison |
| Khoury 1987 ³⁹ | Not review population. Incorrect interventions |
| Kirson 1988 ⁴⁰ | Incorrect interventions |
| Kreis 2012 ⁴¹ | Unsuitable study design |
| Lacy 1997 ⁴³ | Not review population. Inappropriate comparison |
| Maggard 2001 ⁴⁴ | Not review population |
| Maitra 2013 ⁴⁵ | Not review population. Incorrect interventions |
| Makela 2005 ⁴⁶ | Not review population |
| Miccini 2011 ⁴⁸ | Inappropriate comparison |
| Nespoli 1993 ⁵¹ | Not review population |
| Parisi 2016 ⁵⁵ | Incorrect outcomes |

| Study | Exclusion reason |
|----------------------------------|---|
| Regenet 2003 ⁵⁷ | Incorrect interventions |
| Reyes-espejel 2015 ⁵⁸ | Full text not in English |
| Salem 2004 ⁶⁰ | Unsuitable study design |
| Schlegel 2001 ⁶² | Not review population. Inappropriate comparison |
| Schmidt 2018 ⁶³ | Individual RCTs ordered and included |
| Vermeulen 2010 ⁷² | Incorrect interventions |
| Wedell 1997 ⁷³ | Not review population |
| Zhang 2012 ⁷⁴ | Not review population. Incorrect interventions |
| Zorcolo 2003 ⁷⁵ | Not review population |