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REVIEW

Perforated sigmoid diverticulitis: Hartmann's procedure or resection with primary anastomosis—a systematic review and meta-analysis of randomised control trials

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Abstract

Introduction The surgical management of perforated sigmoid diverticulitis and generalised peritonitis is challenging. Surgical resection is the established standard of care. However, there is debate as to whether a primary anastomosis (PA) or a Hartmann's procedure (HP) should be performed. The aim of the present study was to perform a review of the literature comparing HP to PA for the treatment of perforated sigmoid diverticulitis with generalised peritonitis.

Methods A systematic literature search was performed for articles published up to March 2018. We considered only randomised control trials (RCTs) comparing the outcomes of sigmoidectomy with PA versus HP in adults with perforated sigmoid diverticulitis and generalised peritonitis (Hinchey III or IV). Primary outcomes were mortality and permanent stoma rate. Outcomes were pooled using a random-effects model to estimate the risk ratio and 95% confidence intervals.

Results Of the 1,204 potentially relevant articles, 3 RCTs were included in the meta-analysis with 254 patients in total (116 and 138 in the PA and HP groups, respectively). All three RCTs had significant limitations including small size, lack of blinding and possible selection bias. There was no statistically significant difference in mortality or overall morbidity. Although 2 out of the 3 trials reported a lower permanent stoma rate in the PA arm, the difference in permanent stoma rates was not statistically significant (RR = 0.40, 95% CI 0.14–1.16). The incidence of anastomotic leaks, including leaks after stoma reversal, was not statistically different between PA and HP (RR = 1.42, 95% CI 0.41–4.87, $p = 0.58$) while risk of a postoperative intra-abdominal abscess was lower after PA than after HP (RR = 0.34, 95% CI 0.12–0.96, $p = 0.04$).

Conclusions PA and HP appear to be equivalent in terms of most outcomes of interest, except for a lower intra-abdominal abscess risk after PA. The latter finding needs further investigation as it was not reported in any of the individual trials. However, given the limitations of the included RCTs, no firm conclusion can be drawn on which is the best surgical option in patients with generalised peritonitis due to diverticular perforation.

Keywords Diverticulitis, Colonic · Peritonitis · Colectomy · Anastomosis, Surgical · Surgical Stomas

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Introduction

The surgical management of perforated sigmoid diverticulitis with generalised peritonitis is a challenging and evolving issue [1]. Currently, resectional surgery is the treatment of choice, as recommended by most guidelines [2–5]. Hartmann's procedure (HP) has been the standard approach for decades. This was solidified in the surgical psyche after the seminal paper by Krukowski et al. in 1984 [6]. However, restoration of intestinal continuity after HP is associated with significant morbidity and mortality [7]. A large proportion (30–60%) of patients never undergo a reversal procedure [7–9]. This has led to the suggestion of resection with primary anastomosis (PA) as an alternative approach, with or without a covering ileostomy. A number of systematic review and meta-analyses have been published comparing these two approaches [10, 11]. However, there has been no consensus.

We performed a systematic review of the literature to compare HP to PA for the treatment of perforated sigmoid diverticulitis with generalised peritonitis.

Materials and methods

A systematic literature search was performed on MEDLINE, Embase, SCOPUS and Web of Science for publications up to March 2018. We considered only randomized controlled trials (RCTs) comparing the outcomes of sigmoidectomy with PA versus HP in adults with perforated sigmoid diverticulitis and generalised peritonitis (Hinchey III or IV). The Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines were followed [12] (Fig. 1).

The keywords used in the search were 'colon perforation' OR 'peritonitis' AND 'diverticulitis' and their combinations. We also manually searched the references of identified articles and relevant reviews. No language restrictions were applied.

Titles, abstracts and full texts of articles were evaluated independently by two authors (RC and RT). The same two authors independently performed the extraction of data from included articles. Any disagreements between the two authors were resolved by the senior author (GB).

The primary outcomes sought were the postoperative hospital mortality rate after the index intervention, the overall

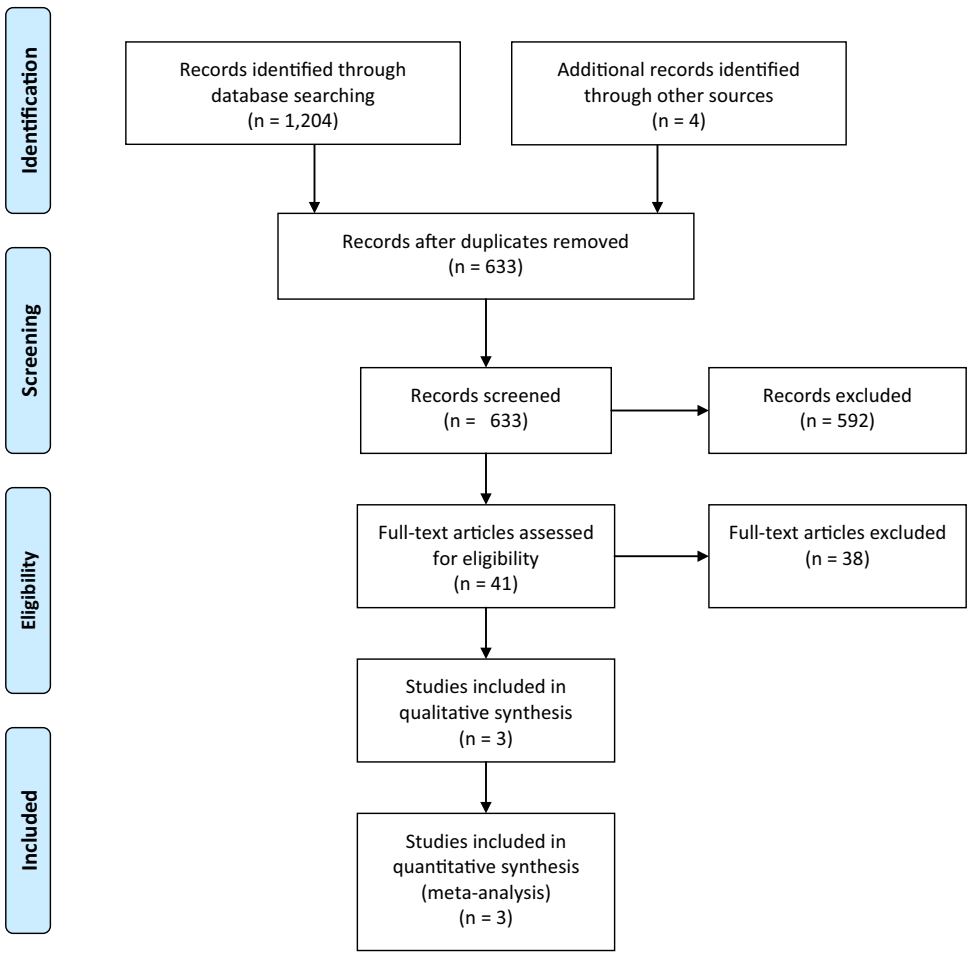


Fig. 1 PRISMA flow diagram

postoperative mortality rate after the index intervention and stoma reversal operation combined, as well as the permanent stoma rate.

The secondary outcomes sought were the postoperative morbidity rate after the index intervention, the overall postoperative morbidity rate after the index intervention and the stoma reversal operation combined, and the rate of postoperative intra-abdominal abscess after the index intervention, anastomotic leak rate, unplanned returns to theatre, length of hospital stay and cost-analysis.

The assessment of methodological quality was performed independently by two authors (RC and RT). Risk of bias was assessed using methods described in the Cochrane Handbook for Systematic Reviews of Interventions [13]. As there were only three included studies, we did not perform a funnel plot for analysis.

Statistical analysis

This meta-analysis was conducted using the Review Manager (RevMan Version 5.3) computer program (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014). The outcomes were pooled with a random-effects model with Mantel–Haenszel method to estimate risk ratios and their 95% confidence intervals. For continuous variables Weighted Mean Difference (WMD) and 95% confidence intervals were calculated. Heterogeneity was assessed using I^2 statistics. We considered an I^2 value exceeding 50% to be indicative of significant heterogeneity. A protocol for this meta-analysis was registered on PROSPERO (http://www.crd.york.ac.uk/prospero): CRD42017078566.

Results

The PRISMA flow diagram for the systematic review is presented in Fig. 1. The initial search yielded 1,204 potentially relevant articles. After removal of duplicates, screening titles/abstracts for relevance and assessment for eligibility, 41 studies were selected for analysis of full text. Of these, 38 were excluded because they were not RCTs. Three RCTs were included in this systematic review and meta-analysis (Table 1). The three included RCTs, encompassing 254 patients reported results comparing sigmoidectomy with PA versus HP in adults with perforated sigmoid diverticulitis and generalised peritonitis (Hinchey III or IV).

Characteristics of the studies

The three RCTs were multicentre studies conducted in Italy, France, Switzerland, Norway, Turkey, Poland, Slovenia, Israel and the USA, between 2001 and 2012. All the include studies were registered at ClinicalTrials.gov.

Table 1 Characteristics of the RCTs included

Study	Nation—participating centers	Registration on Clinical Trial. gov	Estimated sample size: number patients	Enrolling time in the study	Patients screened (*n*)	Patients randomised (*n*)	Randomisation		ITT (n) (%)	Patients lost during 1 year follow-up after emergency surgery (*n*) (%)
							PA (*n*)	HP (*n*)		
Bridoux et al. [16]	Multicenter: France	NCT 00692393	246	2008–2012	NR	102	50	52	Yes	0
Oberkofler et al. [14]	Multicenter: Switzerland	NCT 1239927	136	2006–2009	83	62	32	30	Yes	0
Binda et al. [15]	Multicenter: Italy, Norway, Turkey, USA, Poland, Slovenia, Israel	NCT 1239927	600	2001–2010	NR	90	34	56	Yes	4 (4.4%)

PA primary anastomosis, *HP* Hartmann procedure, *ITT* intention to treat, *n* number, *NR* not reported, *RCT* randomised controlled trial

All conducted power analyses, but none met the sample sizes suggested for those analyses. The inclusion criteria were perforated sigmoid diverticulitis with Hinchey III and IV generalised peritonitis. The exclusion criteria were Hinchey I and II, evidence of malignancy, clinical state which prevented patient's participation (septic shock or multi-visceral failure) and the lack of consent (Table 2).

The total number of screened patients was only reported by Oberkofler et al. [14]. They reported 83 patients who were screened with a suspected diagnosis of generalised peritonitis from complicated colonic diverticulitis. Of those, 62 were included for randomisation (74.7%). Overall, 1.6% of the randomised patients were lost to follow-up (4 out of 254 patients).

The characteristics of the patients [sex, age, body mass index (BMI), American Society of Anesthesiologists (ASA) class, Hinchey stage III/IV, Mannheim Peritonitis Index] were not significantly different between the two groups in any of the included studies, where reported (Tables 3, 4). Only two of the studies reported the level of expertise of the surgeons and the timing of the surgery (Table 4). Although none of the studies defined a 'permanent' stoma, all patients who did not have bowel continuity restored were followed up for at least 1 year. Therefore, stomas not reversed within 1 year of the index intervention are considered 'permanent' stomas for the purposes of this analysis.

The summary of the quality assessment of the included studies is shown in Fig. 2. The principal limitation of these trials was the small sample size. Lack of blinding was also a significant limitation. The risk for blinding of outcome assessment (detection bias) was unclear, since none of the studies described detail of any measures used to blind the outcome assessors from knowledge of which intervention a participant received. An intention-to-treat analysis was performed in all of the studies. The surgical procedures were not standardised and there was considerable heterogeneity in the use of a covering stoma in the PA group (all patients in the study by Binda et al. [15]; 46% in the study by Bridoux et al. [16]; and 30% in the study by Oberkofler et al. [14]).

Primary outcomes

There was no statistically significant difference in the rate of postoperative hospital mortality after the index intervention (RR = 0.63, 95% CI 0.23–1.70). Similarly, there was no statistically significant difference in the cumulative rate of postoperative hospital mortality after the index intervention and the stoma reversal operation (RR = 0.52, 95% CI 0.20–1.35). There was no statistically significant difference in the permanent stoma rate (RR = 0.40, 95% CI 0.14–1.16). (Fig. 3a–c).

Secondary outcomes

There was no statistically significant difference in the rate of postoperative morbidity after the index intervention (RR = 1.05, 95% CI 0.85–1.30). Similarly, there was no statistically significant difference in the cumulative rate of postoperative morbidity after the index intervention and the stoma reversal operation combined (RR = 0.96, 95% CI 0.71–1.30). Patients in the PA group had a 66% lower risk of a postoperative intra-abdominal abscess than the patients in the HP group (RR = 0.34, 95% CI 0.12–0.96). See Fig. 3d–f.

The pooled rate of cumulative anastomotic leak rate after index intervention including stoma reversal operation (Fig. 3g) was lower in HP group (5/138, 3.6%) than PA group (6/116, 5.2%), however, this difference was not statistically significant (RR = 1.42, 95% CI 0.41–4.87).

Binda et al. reported a single anastomotic leak in PA group after the index intervention ($n = 34$) who was converted to a HP [15]. Oberkofler et al. also reported a single anastomotic leak in the PA group after the index intervention ($n = 32$), but did not report how this was managed [14]. Bridoux et al. reported two patients with anastomotic leaks in the PA group after the index intervention ($n = 50$), one patient was converted to a HP and the other was treated with a colonic stent [16]. Bridoux et al. reported one patient with an anastomotic leak in the reversal of ileostomy after PA group ($n = 32$) without detail of their management and one patient who required drainage of abdominal abscess in the reversal of HP group ($n = 33$), although it is not clear whether

Table 2 Inclusion and exclusion criteria

Study	Inclusion criteria	Exclusion criteria
Bridoux et al. [16]	Left-sided perforated diverticulitis with Hinchey III and IV generalized peritonitis	Physical states which prevented patient's participation (septic shock or multi-visceral failure) failure to sign consent
Oberkofler et al. [14]	Left-sided perforated diverticulitis with Hinchey III and IV generalized peritonitis	Hinchey I and II evidence of metastasis failure to sign consent
Binda et al. [15]	Left-sided perforated diverticulitis with Hinchey III and IV generalized peritonitis	Failure to sign consent peritonitis secondary to perforated diverticulitis of right colon

Table 3 Patient characteristics

Study	Sex (M/F) n. pts		*P* value	Age, years (median, range)		*P* value	BMI, kg/m^2 (mean, range)		*P* value	ASA class *N* (%)		*P* value	Hinchey stage III/IV n. pts		*P* value
	PA	HP		PA	HR		PA	HR		PA	HR		PA	HR	
Bridoux et al. [16]	28/22	23/29	0.234	61 (25–93)	61.5 (29–92)	0.445	26.1 (20–43)	26.8 (19.3–44.6)	0.541	ASA > 1–45 (90%)	ASA > 1–43 (83%)	0.283	42/8	40/12	0.235
Oberkofler et al. [14]	12/20	9/21	0.598	72 (60–83)	74 (61–81)	0.652	24 (23–28)	24 (22–29)	0.987	ASA I–III—24 (75%) ASA IV—8 (25%)	ASA I–III—22 (73%) ASA IV—8 (27%)	1.000	24/8	23/7	1.000
Binda et al. [15]	22/12	27/29	0.190	63.5 ± 2.2[a]	65.7 ± 1.8[a]	0.481	NR	NR	NR	NR	NR	NR	30/4	45/11	0.394

PA primary anastomosis, *HP* Hartmann procedure, *n. pts* number of patients, *BMI* body mass index, *ASA* American Society of Anesthesiologists, *NR* not reported

[a]Mean ± SD

Table 4 Operative details

Author – year of publication	MPI score, median (range)		*P* value	First surgeon resident, n. pts (%)		*P* value	Night surgery, n. pts (%)		*P* value	C-reactive protein (mg/L), median (IQR)		*P* value
	PA	HP		PA	HR		PA	HR		PA	HR	
Bridoux et al. [16]	26 (16–39)	27 (20–43)	0.060	24 (48%)	23 (45.1%)	0.770	19 (38%)	22 (43%)	0.599	NR	NR	NR
Oberkofler et al. [14]	24 (19–28)	22 (16–28)	0.886	4 (12%)	6 (20%)	0.502	NR	NR	NR	194 (67–291)	236 (136–307)	0.105
Binda et al. [15]	11.4 ± 0.6[a]	12.7 ± 0.6[a]	0.145	NR	NR	NR	15 (44%)	36 (64%)	0.083	NR	NR	NR

PA primary anastomosis, *HP* Hartmann procedure, *MPI* = Mannheim peritonitis index, *n. pts* number of patients, *NR* not reported

[a]Mean ± SD

Fig. 2 Methodological quality assessment of the included studies

this resulted from an anastomotic leak [16]. Binda et al. only report the anastomotic leaks that needed re-operation: one in the in the reversal of ileostomy after PA group ($n=22$) and two in the reversal of HP group ($n=34$) [15]. Oberkofler et al. reported no anastomotic leaks in the reversal of ileostomy after PA group ($n=26$) and two anastomotic leaks in the reversal of HP group ($n=15$) without detail of their management [14].

Only two of the studies reported unplanned returns to theatre after the index procedure [15, 16]. Oberkofler et al. grouped this outcome with organ failure under Clavien-Dindo grades IIIb-V complications [14]. The pooled rate was lower in the PA group (3/84, 3.6%) compared with the HP group (5/108, 4,6%). However, this difference was not statistically significant (RR 0.71, 95% CI 0.17–2.91) (Fig. 3h).

Overall unplanned returns to theatre after the index intervention and stoma reversal operation combined was reported by two of the studies. The pooled rate was lower in PA group (5/84, 6%) than HP group (9/108, 8.3%), however, this difference was not statistically significant (Fig. 3i).

Length of hospital stay was similar in the HP and PA groups in the two of the included studies where it was reported (WMD −4.31 days, 95% CI −10.92–2.30)—See Fig. 3j [14, 16]. Cost-analysis was performed by one of the included studies [14], which reported similar costs for both groups after the index intervention, stoma reversal operation and with all procedures combined.

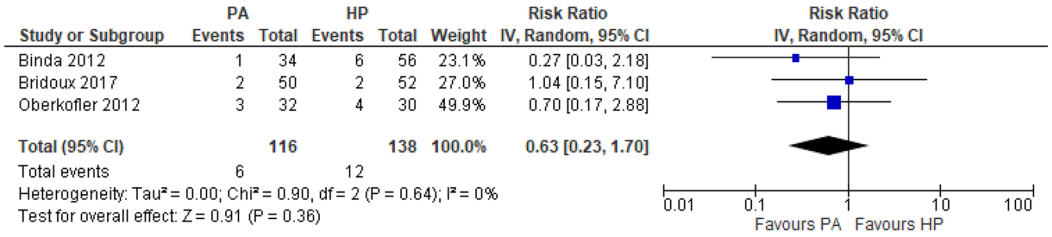
Discussion

In this meta-analysis of all currently available RCTs comparing HP to PA for the treatment of perforated sigmoid diverticulitis with generalised peritonitis, we found no significant difference between PA and HP in terms of postoperative morbidity and mortality after the index procedure or cumulatively after inclusion of the stoma reversal surgery. Despite two out of the three trials reporting a lower permanent stoma rate in the PA arm [14, 16], the difference in permanent stoma rates was not statistically significant in our meta-analysis. While none of the three studies found a significant difference in postoperative intra-abdominal abscess rates, a pooled analysis showed a reduced incidence in the PA arm. The reasons for this are unclear, but we speculate it may be related to rectal stump leakage in the HP group, which is not specifically reported in any of the included studies. The rectal stump leak rate after HP for perforated diverticulitis in the literature is reported to be around 2–3% [17, 18]. Other possible reasons are changes in the intraoperative conduct such as carrying out a more thorough intraoperative lavage. This finding warrants further investigation as the understanding of the reasons may lead to improvement of postoperative outcome after either PA or HP.

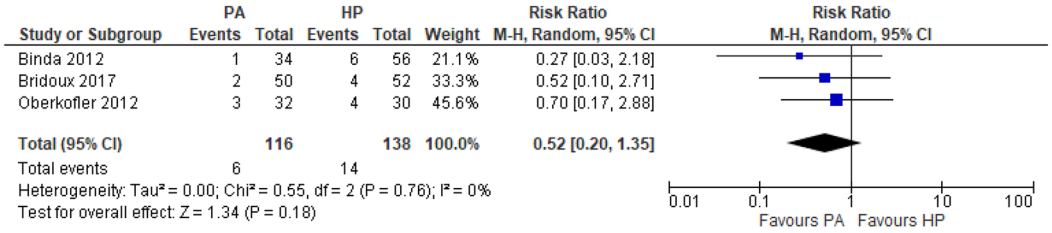
The management of complicated sigmoid diverticulitis is controversial. The literature is dominated by nonrandomised studies, the majority of which are retrospective [10, 18–20]. Selection bias in such studies impedes generalisability of the findings [20]. One prospective study identified predictors of patients undergoing HP instead of PA were BMI > 30 kg m^{-2}, Mannheim peritonitis index > 10, operative urgency (emergency/urgent compared to elective) and Hinchey grade III and IV [21]. This is the most likely explanation for the higher mortality and morbidity reported after HP compared to PA in observational studies [22, 23]. Therefore, although data from such nonrandomised studies show that PA is a feasible option in selected patients, RCTs are required to guide practice. To date, only the three RCTs included in this meta-analysis exist [14–16].

Fig. 3 Forest plots of pooled outcomes. **a** Postoperative hospital mortality rate after index intervention. **b** Overall postoperative mortality rate after index intervention and stoma reversal operation. **c** Permanent stoma rate (covering ileostomy or end colostomy). **d** Postoperative morbidity rate after index intervention. **e** Overall postoperative morbidity rate after index intervention and stoma reversal operation. **f** Postoperative intra-abdominal abscess after index intervention. **g** Overall anastomotic leak rate after index intervention and stoma reversal operation. **h** Unplanned returns to theatre after the index intervention. **i** Overall unplanned returns to theatre after the index intervention and stoma reversal operation. **j** Length of hospital stay after the index intervention

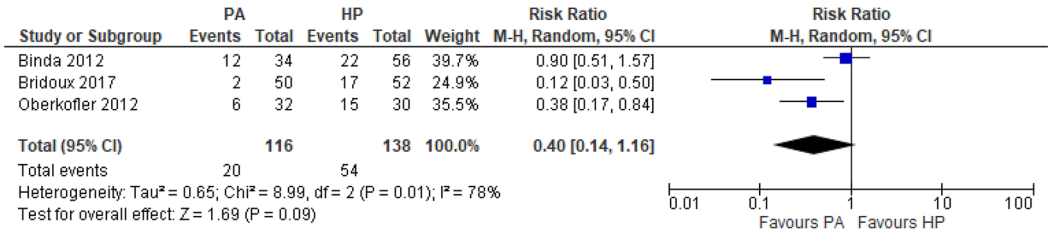
A Postoperative hospital mortality rate after index intervention



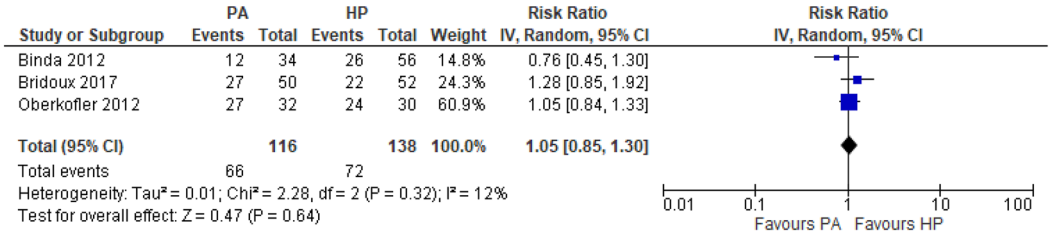
B Overall postoperative mortality rate after index intervention and stoma reversal operation



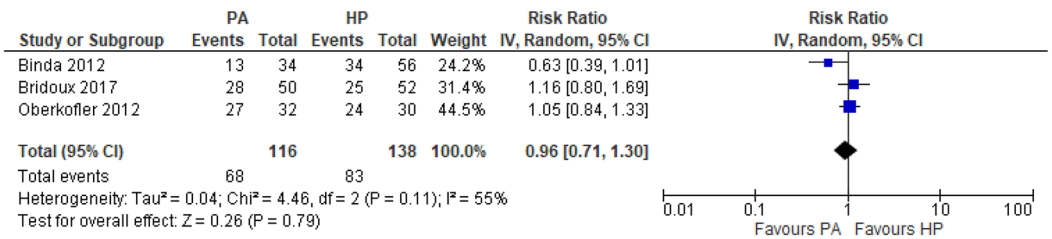
C Permanent stoma rate (covering ileostomy or end colostomy)



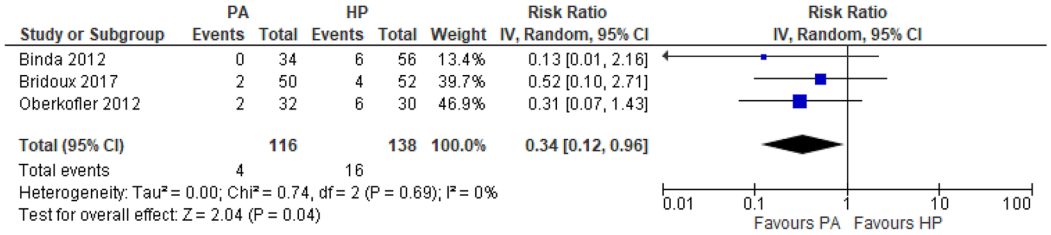
D Postoperative morbidity rate after index intervention



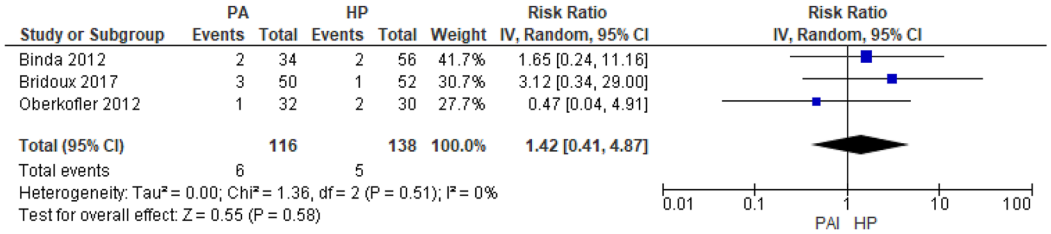
E Overall postoperative morbidity rate after index intervention and stoma reversal operation



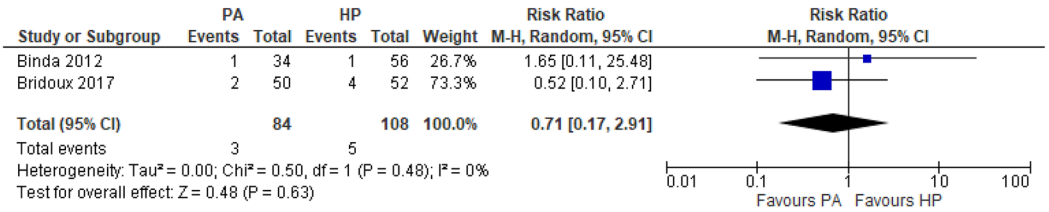
F Postoperative intra-abdominal abscess after index intervention



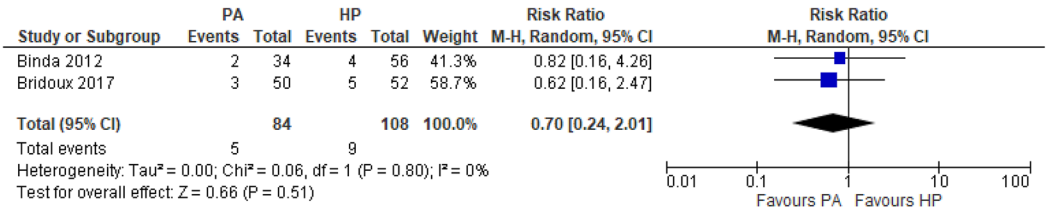
G Overall anastomotic leak rate after index intervention and stoma reversal operation



H Unplanned returns to theatre after the index intervention



I Overall unplanned returns to theatre after the index intervention and stoma reversal operation



J Length of hospital stay after the index intervention

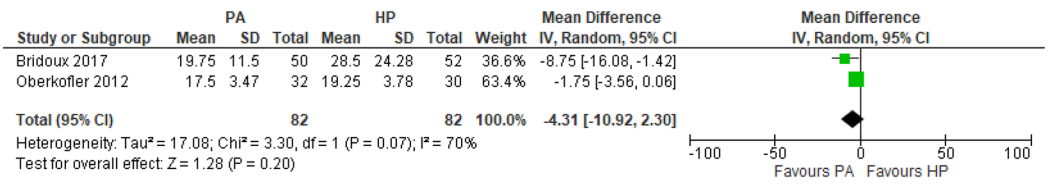


Fig. 3 (continued)

Most of the available guidelines recommend resection surgery in perforated diverticulitis; however, they do not give a clear preference for either PA or HP [2–5]. The World Society of Emergency Surgery (WSES) 2016 guidelines advise HP for managing generalised peritonitis in critically ill patients and in patients with multiple comorbidities [4]. However, they also advise that in clinically stable patients with no co-morbidities, PA with or without a diverting stoma may be performed [4]. The American Society of Colon and Rectal Surgeons (ASCRS) 2014 practice parameters recommend that "following resection, the decision to restore bowel continuity must incorporate patient factors, intraoperative factors and surgeon preference" [3]. The Association of Coloproctology of Great Britain and Ireland (ACPGBI) and Royal College of Surgeons (RCS) 2014 guidance on colonic diverticular disease states that both HP and PA with or without a covering stoma are potential options and the decision as to which to utilise should be made on an individual patient basis [5]. Reversal of HP is viewed by most surgeons as a more complex procedure with a higher risk of adverse events when compared to closure of a covering ileostomy [7, 24]. In our meta-analysis the cumulative morbidity and mortality were similar after PA and HP. It has to be borne in mind that in the included RCTs restoration of bowel continuity was largely dependent on surgeon and patients' choice. Therefore, selection bias may have been a factor. In previous nonrandomised studies, the reported rates of restoration of bowel continuity is usually higher after PA (80–90%) [8, 20], when compared to HP (40–70%) [7–9]. These figures are very similar to those reported in the RCTs included in this meta-analysis [14–16].

Interestingly, 67% of patients in the PA arms of the study by Bridoux et al. avoided a covering stoma [16]. This constituted deviation from the study protocol. All but one of the fifteen patients who did not have a covering stoma, had Hinchey III peritonitis and the morbidity was low in this select group. Previous studies have demonstrated that PA without a covering ileostomy is feasible; however, it can be associated with a significant rate of complications (24–84%) [9, 25, 26]. The covering ileostomy in the PA group was mandatory in the study by Binda et al. [15]. The aim was to create a more homogeneous group and to avoid confounding factors. In practice the decision to perform a covering ileostomy after a PA conducted in the emergency setting is based on a variety of factors including: the hydro-pneumatic leak test, perceived viability of the anastomosis and other intraoperative variables. Identifying patients undergoing PA who could safely avoid a covering stoma is an area for further research.

All RCTs included in this review had a small sample size. They were all terminated early and did not reach their target sample size because of difficulties in recruitment. Binda et al. achieved under a third of their calculated sample size over a lengthy 9-year recruitment period with an average of less than one patient recruited per participating centre per year [15]. Recruitment in the emergency surgical setting carries inherent logistical difficulties. Oberkofler et al. were also advised to stop the trial after an interim safety analysis that reported significantly more serious complications with stoma reversal after HP than after PA (20 vs 0%) [14]. Bridoux et al. achieved less than half their calculated sample size [16]. The authors' point to the uptake of laparoscopic peritoneal lavage to treat Hinchey III during their recruitment period, resulting in some surgeons not being willing to randomise patients to resection surgery, as a potential factor. Interest in laparoscopic peritoneal lavage rose after the publication of a large prospective series by Myers et al. in 2008 showing good outcomes [27]. More recently reports from three RCTs on laparoscopic peritoneal lavage have been published [28–30]. The interpretation of data from these RCTs has been the subject of some debate [31], resulting in a number meta-analysis, some with opposing conclusions [32–35].

All included trials were at high risk of bias. Despite the randomised design of the included studies, selection bias is still a potential concern. The higher number of patients recruited in the HP arm ($n = 56$) compared to PA ($n = 34$) in the study by Binda et al. suggests protocol violation and selection bias [15]. The higher proportion of patients with Hinchey IV in HP arm (20%) compared to PA arm (12%) in this study further points to this possibility. Oberkofler et al. report that around a half of all potentially eligible patients presenting to the recruiting units were not assessed for eligibility either because of the surgeons' disagreement about enrolment or the patient declining to participate [14]. Bridoux et al. did not record the number of patients excluded at the request of the Ethics Committee, but recognised the potential for selection bias as a limitation of their study [16]. This suggests a possible lack of equipoise, reversion to surgeons' preference and selection bias during the conduct of the RCTs included in this review. However, the extent of such biases is difficult to quantify. The tendency for critically ill patients with more severe pathology to have a HP is a recognised phenomenon [21, 22]. Moreover, PA and HP are rather different in terms of technical complexity and expertise required. HP is generally viewed as a faster and simpler index procedure [15]. The surgeon with less expertise may be more inclined to perform HP rather than PA.

None of the included RCTs were blinded, which also introduces risk of bias. Blinding of patients, surgeons or researchers is problematic in this setting. It is difficult to envisage a practical and effective solution to this problem.

None of the studies in our meta-analysis included quality of life (QOL) data. Both ileostomy and colostomy result in significant QOL impairment [36]. Ileostomies are generally better tolerated, although they can lead to complications,

including dehydration and renal impairment [36, 37]. Given that a proportion of patients with colostomy and ileostomy did not have bowel continuity restored, the impact on QOL is an important consideration when evaluating the merits of each surgical approach.

Statistical heterogeneity was low for all our outcomes of interest, except postoperative morbidity rate after index intervention including the stoma reversal operation and permanent stoma rate. The reasons for higher statistical heterogeneity in the latter two outcomes of interest are unknown, but are likely to be related to clinical differences between the studies due to patient factors, definitions of morbidity and surgeons' preferred practice for reversal of stomas.

The participants in the Oberkofler et al. study were on average around a decade older (mean age 73) than in the other two studies (mean age 61 and 65 in the studies by Bridoux et al. and Binda et al., respectively). The majority of patients had Hinchey III and the remainder had Hinchey IV disease, which was consistent across the included studies (mean range from 76–83%). The surgical interventions were not standardised and grades of operating surgeons varied significantly. All procedures were performed by a laparotomy in the study by Bridoux et al. [16]. In the study by Binda et al. 11.8% of PA and 5.4% HP procedures were performed laparoscopically [15]. Oberkofler et al. did not state if any of the procedures were laparoscopic.

Conclusions

PA and HP seem to be equivalent in terms of most outcomes of interest with a lower intra-abdominal abscess rate after the index procedure favouring PA. However, given the significant limitations of the included RCTs, these findings may not be applicable to all patients presenting with perforated sigmoid diverticulitis and generalised peritonitis. There is a need for well-designed and implemented RCTs with sufficient statistical power to address this question.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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