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Efficacy and safety of abdominal paracentesis drainage on patients with acute pancreatitis: a systematic review and meta-analysis

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To cite: Lu Z, Zhu X, Hua T, *et al*. Efficacy and safety of abdominal paracentesis drainage on patients with acute pancreatitis: a systematic review and meta-analysis. *BMJ Open* 2021;**11**:e045031. doi:10.1136/bmjopen-2020-045031

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2020-045031).

Received 20 September 2020
Accepted 26 July 2021

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ABSTRACT

Objectives To conduct a systematic review and meta-analysis of the efficacy and safety of abdominal paracentesis drainage (APD) in patients with acute pancreatitis (AP) when compared with conventional 'step-up' strategy based on percutaneous catheter drainage (PCD).

Design Systematic review and meta-analysis.

Methods PubMed, EMBASE, Cochrane Library, MEDLINE (OVID), China National Knowledge Infrastructure and Wanfang Database were electronically searched to collect cohort studies and randomised controlled trials (RCTs) from inception to 25 July 2020. Studies related to comparing APD with conventional 'step-up' strategy based on PCD were included.

Outcomes The primary outcome was all-cause mortality. The secondary outcomes were the rate of organ dysfunction, infectious complications, hospitalisation expenses and length of hospital stay.

Results Five cohort studies and three RCTs were included in the analysis. Compared with the conventional 'step-up' method, pooled results suggested APD significantly decreased all-cause mortality during hospitalisation (cohort studies: OR 0.48, 95% CI 0.26 to 0.89 and p=0.02), length of hospital stay (cohort studies: standard mean difference (SMD) −0.31, 95% CI −0.53 to −0.10 and p=0.005; RCTs: SMD −0.45, 95% CI −0.64 to −0.26 and p<0.001) and hospitalisation expenses (cohort studies: SMD −2.49, 95% CI −4.46 to −0.51 and p<0.001; RCTs: SMD −0.67, 95% CI −0.89 to −0.44 and p<0.001). There was no evidence to prove that APD was associated with a higher incidence of infectious complications. However, the incidence of organ dysfunction between cohort studies and RCTs subgroup slightly differed (cohort studies: OR 0.66, 95% CI 0.34 to 1.28 and p=0.22; RCTs: OR 0.58, 95% CI 0.35 to 0.98 and p=0.04).

Conclusions The findings suggest that early application of APD in patients with AP is associated with reduced all-cause mortality, expenses during hospitalisation and the length of stay compared with the 'step-up' strategy without significantly increasing the risk of infectious complications. These results must be interpreted with caution because of the limited number of included studies as well as a larger dependence on observational trials.

PROSPERO registration number CRD42020168537.

Strengths and limitations of this study

- ► This trial was the first systematic review and meta-analysis comparing abdominal paracentesis drainage (APD) with conventional percutaneous catheter drainage method in treating patients with acute pancreatitis.
- ► Thorough searching of six major electronic databases, including two major non-English-language databases.
- ► The study protocol has been registered in PROSPERO and reported according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.
- ► This study relied greatly on cohort studies due to the limited number of published randomised controlled trials, which means that final pooled results must be interpreted very cautiously.
- ► The meta-analysis results might be affected by the length of follow-up, canal diameter of APD and aetiology given the limited numbers of studies. Confirmation of findings by further clinical trials is warranted.

INTRODUCTION

Acute pancreatitis (AP), a rapidly progressing disease characterised by severe complications and high mortality, leads to many admissions to intensive care units.[1] According to the updated 2012 Atlanta Classification, AP is classified into mild AP (MAP), moderate–severe AP (MSAP) and severe AP (SAP). MAP particularly causes upper abdominal pain; moreover, MSAP and SAP are associated with local or systemic complications, including peripancreatic fluid collection, which causes persistent organ dysfunction eventually.[2]

Early conservative treatments of AP involve active rehydration, retropyloric feeding and pancreatin inhibitors. Once abdominal compartment syndrome and/or intestinal ischaemia occurs, surgery is usually required to remove the necrotic tissue.[3] However, it

had been reported that open surgery is connected to high mortality, infectious complications and prolonged hospitalisation.[4] Freeny *et al* (1998), for the first time, reported a novel treatment, commonly known as the 'step-up' method based on percutaneous catheter drainage (PCD), whose purpose was to progressively manage infections rather than immediately eliminates necrosis.[5] The efficacy and safety of the 'step-up' method had been confirmed through further clinical trials.[6 7] Although most acute peripancreatic fluid collection and acute necrotic collection were detected from week 2 to week 3 after AP onset, PCD was suggested to be performed at least 4 weeks later until the necrosis formed a wrap.[8 9] It indicated that PCD seemed not to be optimum as an early invasive intervention and management. Recently, a retrospective cohort study to this problem had reported a new insert catheters technique, which is called as the abdominal paracentesis drainage (APD). It was performed via the right paracolic sulci or left paracolic sulci if abdominal collection volume was greater than 50 mL.[10] The results demonstrated that early APD treatment could effectively lessen the release of inflammatory factors and improve the clinical prognosis. However, it is uncertain that the use of APD is associated with an increased risk of exogenous infection in patients with AP.

Considering the current controversies, the purpose of this systematic review was to compare the efficacy and safety of APD with the 'step-up' strategy in published clinical trials of patients with AP.

MATERIAL AND METHODS

The present systematic review and meta-analysis were reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[11]

Data sources and searches

PubMed, EMBASE, Cochrane Library, MEDLINE (OVID), China National Knowledge Infrastructure and Wanfang Database were electronically searched to collect cohort studies and randomised controlled trials (RCTs) about the APD for the treatment of AP from inception to 15 February 2020, by using keywords combined with Medical Subject Headings terms, regardless of language and region. We retrieved it again on 25 July 2020, to include the latest published paper. In addition, the reference lists of related literature were manually searched for possible trials. The search strategy for PubMed was shown in online supplemental table 1.

Study selection

ZL and XZ searched independently, according to predefined inclusion and exclusion criteria. Duplicate literature deletion and title and abstract screening for relevance had been done using EndNote software. Then, the full text was acquired to determine inclusion eligibility eventually. Any disagreement was resolved through discussion, a third review author (MY) participated where necessary.

Published RCTs and cohort studies meeting the following criteria were included: (1) Population: adult patients with AP regardless of pathogenesis; however, detailed diagnostic criteria for AP must be required, and each participant must conform to the requirement of APD: (1) enough volume of coeliac fluid collections (>50 mL) and (2) a feasible pathway existed. No limitation on race and nationality. (2) Intervention: APD was administered within 4 weeks of onset. (3) Comparison: traditional 'step-up strategy' in which APD was not performed. (4) The sample size of each group exceeds 20.

Outcomes and data extraction

Two authors (ZL and DJ) independently extracted data using a prepiloted form designed by Excel 2019 software (Microsoft Corporation), and the results were confirmed by another author (TH). The collected data include the first author, publish year, sample size, mean age and sex ratio of each group, study period, following time, cause of AP, acute physiology and chronic health evaluation (APACHE) II scores at admission, catheter diameter and outcomes data. If any information above was inadequate, we contacted the original author via email to consult related data. We resolved discrepancies through discussion. The predefined primary outcome was all-cause mortality during hospitalisation. The secondary outcomes were the rate of organ dysfunction; the rate of related infectious complications such as microbial infection, sepsis and bacteraemia after treatment; expenses during hospitalisation; and the length of hospital stay.

Quality assessment

The quality of filtered articles has been assessed by two authors (WX and JZ), respectively. The risk of bias tool performed was specific to the study type. For RCTs, the revised Cochrane tool to assess risk of bias (ROB-2) was used for each of the following five domains: randomisation process, deviations from intended interventions, missing outcomes data, measurement of the outcome and selection of the reported results.[12] We reviewed each RCT and classified them as low, probably low, probably high or high risk of bias. However, blinding of patients and clinicians was often unrealistic in invasive treatment, which has limited influence on primary outcomes. So, trials were seen as low risk in the domain of deviations from intended interventions and measurement of the outcome even without double blinding.

Meanwhile, cohort studies were assessed using the Risk Of Bias In Non-randomised Studies—of Interventions tool, in which seven key domains were contained: (1) confounding, (2) selection of participants, (3) classification of interventions, (4) deviations from intended interventions, (5) missing data, (6) measurement of outcomes and (7) selection of the reported results. It was widely used in the non-RCT evaluation and recommended by the Cochrane Collaboration.[13]

Quality of evidence

Two authors assessed the quality of each evidence respectively by using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system for risk of bias, inconsistency, indirectness, imprecision, publication bias, large effect, confounder and dose–response gradient.[14] The quality was divided into very low, low, moderate or high. The results were generated by using the GRADE profiler.

Statistical analysis

RevMan V.5.3 (Nordic Cochrane Centre) was applied for statistical analysis of the included studies. The OR and the 95% CIs were calculated for dichotomous data with the Mantel-Haenszel method. For continuous data, we calculated the standard mean difference (SMD) and 95% CIs, because of the differences in measurement methods and units. P values less than 0.05 denoted statistical significance. Meta-analysis was performed if there were predefined outcomes from two or more studies. Statistical heterogeneity across trials was examined using the I^2 statistical tests and p values. Values with p<0.1 and I^2 greater than 50% denoted significant heterogeneity. The statistical test for heterogeneity may not be sensitive due to the limited number of component studies and patients. We employed the random-effect model to merge each result because the fix-effect model could amplify the weight of large sample studies. Subsequently, subgroup analysis according to the RCTs or cohort studies was performed when sufficient data were available to avoid the influence of inappropriate pooled results on the validity of evidence. Sensitivity analysis was carried out by the leave-one-out method to evaluate the sources of heterogeneity and the feasibility of results. The funnel plot and Egger's test were performed to detect potential publication bias.

RESULTS

Literature research

The flow diagram showed the process of literature screening, selection and reasons for exclusion (figure 1). Our initial search yielded 299 records. After removing duplication and reviewing the titles/abstracts, 23 articles were considered to be potentially eligible for inclusion. After reading the full text, 15 studies were excluded for the following reasons: no available data (n=5), animal experimental (n=2), case report (n=2), intervention measures inconsistent (n=5) and the possibility of data duplication (n=1). As a result, eight studies[10 15–21] were eventually included in this meta-analysis.

Trials characteristics

The characteristics of the eligible trials had been summarised in table 1. There were five cohort studies and three RCTs published between 2014 and 2020, which compared the clinical prognosis of patients with AP who were cured by APD or conventional 'step-up' approach. Population sizes ranged from 82 to 255, with a total of 1086 patients. Except for the catheter diameter and the catheter numbers, there was no statistical difference of baseline between APD and control groups in each trial, according to the report.

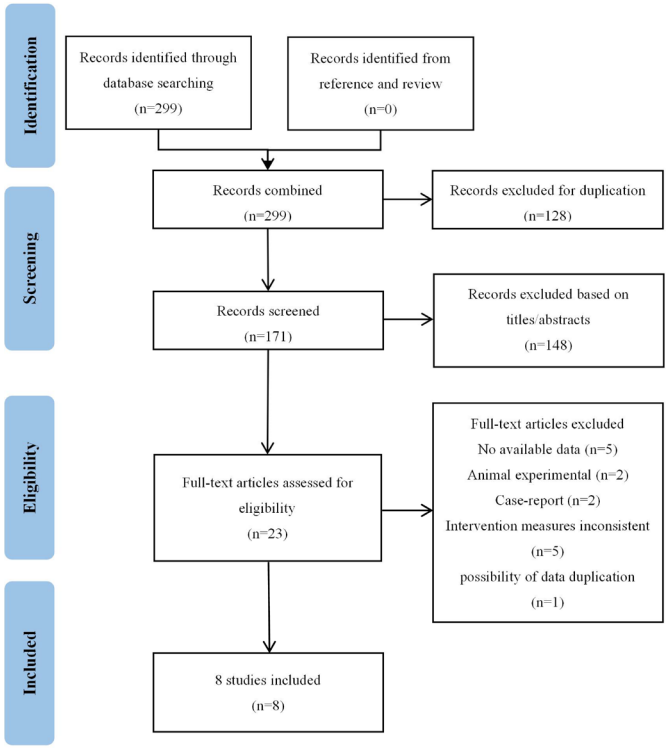

Figure 1 Flow diagram of study selection.

Risk of bias assessment and grade profile evidence

The details about the risk of bias were respectively shown in figure 2 and table 2. For included cohort studies, three studies were classified as low risk of bias,[10 15 17] Li *et al* were categorised as a severe risk of bias due to the lack of necessary baseline comparison and we could not determine whether the outcome indicators were measured at the same time of each group in this trial.[19] Meanwhile, Ma *et al* did not report an appropriate method to balance the treatment start time, so we categorise it as moderate risk through discussion.[20] For RCTs included, one was categorised as low risk of bias in each domain[16]; others were considered as some concerns because they did not report the way of allocation concealment.[18 21]

GRADE evidence profiles are showed in online supplemental table 2. Due to either unclear risk of bias or imprecision resulted from small sample size influence and relative wide CI, the quality of evidence of outcomes in the RCTs subgroup was low or very low, according to the GRADE framework. In addition, we also determined the GRADE evidence of cohort studies subgroup as low or very low eventually, considering the natural risk of observational trials and small effect size except for all-cause mortality.

Table 1 The characteristics of included trials comparing abdominal paracentesis drainage with conventional 'step-up' approach

First author (publish year)	Study period	Study type	Sample size		Mean age (years)		Aetiology of AP	APACHE II at admission		Catheter diameter	Following time	Outcomes*
			APD group	Non-APD group	APD group	Non-APD group		APD group	Non-APD group			
Liu[10] (2015)	06/2009–06/2011	RCS	53	49	59±13.5	57±12.7	Gallstone, alcohol abuse, hyperlipaemia	15.5±3.55	14.7±3.25	8–22 Fr	About 20 d from the onset of AP	1, 2, 3, 4, 5, 6, 7
Li[19] (2018)	01/2012–12/2017	RCS	46	42	47.0±14.6	48.8±13.5	NR	NR	NR	8–16 Fr	In-hospital	1, 2, 5, 6, 7
Liu[15] (2015)	08/2013–10/2014	PCS	126	129	57±13	55±11	Biliary, alcohol abuse	13.5±3.1	14.2±2.8	8–22 Fr	In-hospital	1, 3, 4
Ma[20] (2017)	11/2009–11/2015	RCS	43	39	55.89±4.59	56.28±3.60	Biliary, alcohol abuse	23.69±2.46	22.95±3.26	NR	In-hospital	1, 3, 4, 5, 6, 7
Huang[17] (2016)	05.2010–05/2015	RCS	68	64	50 .33±11.17	48.79±9.54	Non-HTG induced	15.21±3.48	15.47±3.10	NR	In-hospital	1, 6
Luo[18] (2019)	07/2016–11/2018	RCT	49	49	45.69±11.87	44.37±11.21	NR	17.51±4.47	17.86±4.64	12 Fr	7 days	2, 6
Liang[16] (2016)	01/2015–04/2016	RCT	83	78	55.6±14.6	53.7±12.8	Gallstone, alcohol abuse, hyperlipaemia	13.4±4.1	13.9±4.9	8–16 Fr	In-hospital	1, 2, 5, 6
Zhang[21] (2020)	03/2014–11/2018	RCT	84	84	63.22±12.43	63.43±12.37	Biliary, alcohol abuse	NR	NR	NR	NR	2, 6, 7

Data are mean±SD deviation unless otherwise indicated.
*Outcomes: 1=all-cause mortality, 2=the rate of organ dysfunction, 3=the rate of sepsis, 4=the rate of bacteraemia, 5=hospitalisation expenses, 6=length of hospital stay and 7=the rate of microbial infection.
AP, acute pancreatitis; APACHE, Acute Physiology and Chronic Health Evaluation; APD, abdominal paracentesis drainage; HTG, hypertriglyceridemia; NR, not report; PCS, prospective cohort study; RCS, retrospective cohort study; RCT, randomised control trial.

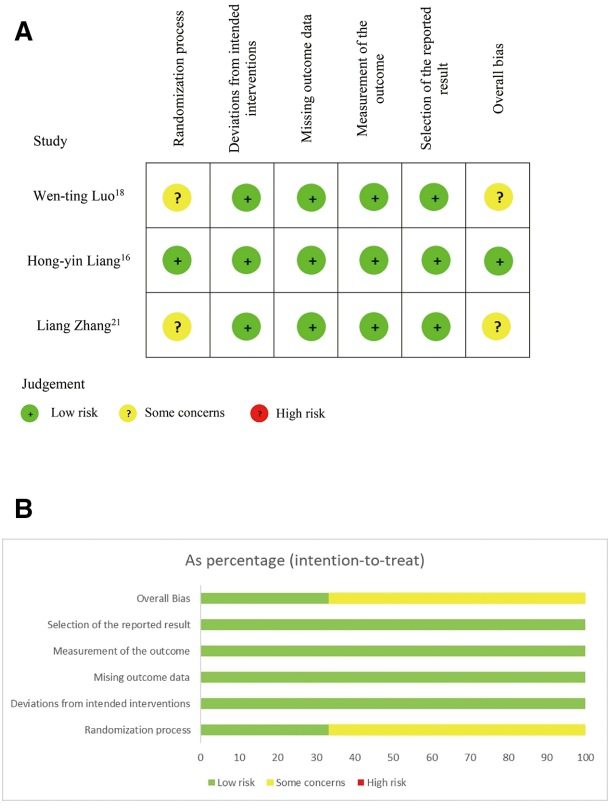

Figure 2 The risk of bias about included randomised control trials (RCTs) by using the revised Cochrane tool to assess risk of bias (ROB) -2 tool. (A) Traffic light plot of RCT bias assessment; (B) weighted summary plot of the overall type of bias encountered in RCTs.

Primary outcome

All-cause mortality during hospitalisation was reported in six trials, which included 820 patients.[10 15–17 19 20] Compared with the conventional 'step-up' approach, five cohort studies[10 15 17 19 20] of APD intervention reported a significantly reduced risk of all-cause mortality in patients with AP (OR 0.48, 95% CI 0.26 to 0.89 and p=0.02) with low heterogeneity (I^2=0.0%) (figure 3). In RCTs subgroup, there were no statistical differences in all-cause mortality (n=161, OR 0.55, 99% CI 0.13 to 2.37 and p=0.42).[16]

Secondary outcomes

The rate of organ dysfunction

Five studies provided data on the rate of organ dysfunction with a total of 617 patients.[10 16 18 19 21] Compared with the conventional 'step-up' approach, the results of cohort studies subgroup[10 19] showed that there were no significant differences in the incidence of organ dysfunction (n=190, OR 0.66, 95% CI 0.34 to 1.28 and p=0.22). However, the results of RCTs subgroup[16 18 21] supported APD (n=427, OR 0.58, 95% CI 0.38 to 0.98 and p=0.04) (online supplemental figure 1). We considered that the inconsistencies of results between the two subgroups resulted from the difference in sample size because preferred APD trends have appeared in cohort studies subgroup. The heterogeneity in cohort studies and RCTs subgroup was I^2=0% and I^2=29%, respectively.

Infectious complications

Five studies reported the number of infectious complications, which included microbial infection,[10 19–21] sepsis[10 15 20] and bacteraemia,[10 15 20] with a total of 695 patients. We pooled data from three cohort studies,[10 19 20] which showed no significant differences in the incidence of microbial infection (OR 1.05, 95% CI 0.52 to 2.12 and p=0.89) with I^2=0%, and this concurred with another RCT's result (OR 1.56, 95% CI 0.53 to 4.60 and p=0.42).[21] For the incidence of sepsis and bacteraemia, the pooled results from three cohort studies showed that APD could not significantly increase the related risk versus the conventional 'step-up' approach (sepsis: OR 0.69, 95% CI 0.41 to 1.16 and p=0.16; bacteraemia: OR 0.93, 95% CI 0.58 to 1.48 and p=0.75). The heterogeneity in both of them was I^2=0%. (online supplemental figure 2)

Length of hospital stay

Four cohort studies (including 404 patients)[10 17 19 20] and three RCTs (including 427 patients)[16 18 21] were included in this analysis. The results of the cohort studies subgroup revealed that APD significantly decreased the length of hospital stay when compared with the conventional 'step-up' approach (SMD −0.31, 95% CI −0.53 to −0.10 and p=0.005). This result was also consistent with that for the

Table 2 The risk of bias assessment of included cohort studies by using the ROBINS-I tool

Study/ domain	Confounding	Selection of participants into the study	Classification of interventions	Deviations from intended interventions	Missing data	Measurement of outcomes	Bias in selection of the reported result	Overall risk
Liu[10]	LOW	LOW	LOW	LOW	LOW	LOW	LOW	LOW
Li[19]	SEVERE	LOW	MODERATE	LOW	LOW	MODERATE	LOW	SEVERE
Liu[15]	LOW	LOW	LOW	LOW	LOW	LOW	LOW	LOW
Ma[20]	MODERATE	LOW	LOW	LOW	LOW	LOW	LOW	MODERATE
Huang[17]	LOW	LOW	LOW	LOW	LOW	LOW	LOW	LOW

ROBINS-I, Risk Of Bias In Non-randomised Studies—of Interventions.

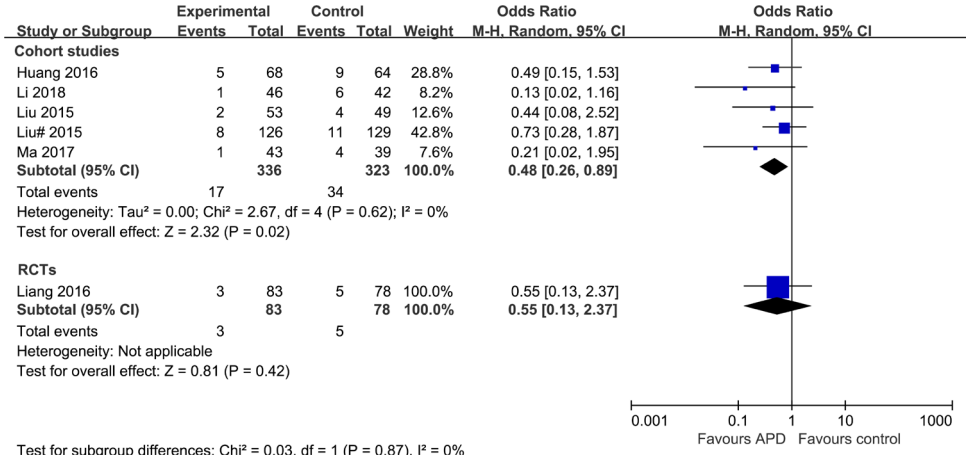

Figure 3 Forest plot for all-cause mortality.

RCTs subgroup (SMD −0.45, 95% CI −0.64 to −0.26 and p<0.001). And the heterogeneity in each subgroup was I^2=18% and I^2=0% (online supplemental figure 3).

Hospitalisation expenses

We extracted the data about spending during hospitalisation from three cohort studies and two RCTs, with a total of 601 patients.[10 16 19–21] The pooled results of cohort studies subgroup[10 19 20] demonstrated that APD could significantly reduce the spending versus conventional 'step-up' approach (SMD −2.49, 95% CI −4.46 to −0.51 and p<0.001), which was consistent with the result of RCTs subgroup[16 21] (SMD −0.67, 95% CI −0.89 to −0.44 and p<0.001), and heterogeneity was I^2=97% and I^2=0% in cohort studies and RCTs subgroup, respectively (online supplemental figure 4).

Publication bias and sensitivity analysis

We just included cohort studies to explore the potential publication bias for primary outcomes, due to the limited number of RCT. The funnel plot demonstrated an unsymmetrical shape (figure 4). In addition, the subsequent Egger's test showed p<0.05 (p=0.025), which suggested a possible publication bias exists. Sensitivity analysis was conducted by the leave-one-out method. For the spending, we found that the I^2 value decreased to 0% after excluding the trial conducted by Li *et al* (2018), in which the retroperitoneal catheter drainage was performed[19]; however, the pooled result was stable by using sensitivity analysis. Finally, we excluded studies with a severe risk of bias and finally proved that the pooled results were still stable. Thus, the high heterogeneity may result from the difference in sample size, the quality of trial and PCD pathways.

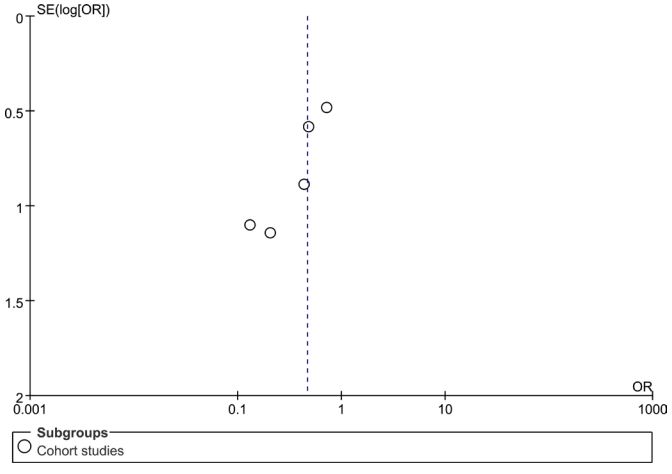

Figure 4 Funnel plot for all-cause mortality.

DISCUSSION

The present systematic review and meta-analysis of three RCTs and five cohort studies demonstrated that APD is an effective and safe intervention for the treatment of AP. In line with evidence based on cohort studies, we found that APD had significant decreased trends towards all-cause mortality, length of stay and expenses as compared with the conventional 'step-up' treatment that is consistent with the findings of high-quality evidence from the RCTs but no conspicuous difference in the risk of extra infection and the rate of organ dysfunction.

Pancreatic ascites was enriched in proteases, along with lipases and cytokines, which would be a natural medium for specific intestinal bacteria.[22] Several factors could account for its formation: (a) Pancreatic local inflammation activated host cytokine in the first to the second week.[2] Excessive inflammatory cascades aggravated pancreatic vasospasm and capillary permeability, causing massive plasma extravasation and extensive cell necrosis. (b) A large amount of intravenous fluid infusion and capillary leak syndrome (CLS) could exacerbate the accumulation of peritoneal fluid. Thus, it is important to inhibit the activation and release of those inflammatory cytokines. Peritoneal lavage, within 48 hours after SAP, could decrease serum levels of tumor necrosis factor (TNF)-α and nterleukin-6 (IL-6) and increase IL-10 levels[23] but remained controversial in short-term mortality and complications.[24–26] Instead, the protective effects of PCD on the outcomes of patients with AP had been demonstrated, but it is not suitable for early

intervention.[27] Compared with the above-mentioned two methods, APD could not only significantly decrease serum IL-6, TNF-α, C reaction protein levels and the incidence of subsequent minimally invasive necrosectomy but also improve survival rates.[10 16 20] Furthermore, it was suggested to operate as soon as possible if abdominal or pelvic cavity fluid accumulated more than 50 mL.

Furthermore, possibly owing to the relief of intra-abdominal pressure (IAP), APD is more effective than the conventional 'step-up' strategy. Intra-abdominal hypertension (IAH) has been established as relevant for the inflammatory response, CLS-induced abdominal effusion and visceral oedema.[28] IAH damaged the intestinal mucosal perfusion, so as the intestinal barrier, which consequently increases the possibility of bacterial translocation. It also had some adverse effects on the host circulatory system, which was mirrored by the reduction of venous return and cardiac output.

As an invasive intervention, the operator routinely focuses on the additional risks of infectious complications because the impact of exogenous infection has a fatal impact on critical patients and can offset the endeavour by previous treatment. This systematic review concluded that APD did not increase the risk of microbial infection, sepsis and bacteraemia as compared with PCD. Similar results were reported in trials with a low risk of bias.

Some limitations should be acknowledged. First, this review relied greatly on cohort studies because published RCTs are limited, and it is generally known that observational studies have the risk of selection bias. Second, although sensitivity analysis proved the stability of results of the expenses, the heterogeneity was very large; as such, we needed to be cautious about this result. Thirdly, the effect of APD could be influenced by the difference in catheter position, catheter lumen, catheter time and diameter. Fourth, the morbidity of organ dysfunction and related infectious complications are likely to be influenced by the length of follow-up time. Nonetheless, there were insufficient subgroups to identify this. Lastly, the sample size in the included studies was small, and in the meta-analysis, the small study effect in small trials could magnify the positive effects of the intervention compared with large trials.[29] The difference in the results of the cohort studies and the RCTs subgroups could also be explained partly by the fact that component studies were less and with a small sample size. Although the search strategy has been ameliorated and strictly followed the PRISMA statement, we should be careful when interpreting the final pooled results.

Because the role of APD in improving the prognosis of patients with AP remains unclear, there are currently no guidelines or consensus for APD. In the future, researchers and clinicians should focus on the following questions: First, which subgroup of AP can benefit from APD? Second, when is the optimal timing to initiate APD? Finally, is the combination of APD and dynamic monitoring of IAP more beneficial for improving the prognosis of patients with AP?

CONCLUSIONS

The findings suggest that early application of APD compared with 'step-up' strategy is significantly associated with reduced all-cause mortality, expenses during hospitalisation and the length of stay in patients with AP, without increased infectious complications. These results must be interpreted with caution because of the limited number of included studies as well as a larger dependence on observational trials.

Contributors ZL and XZ contributed equally to this work, who designed the study, collected and analysed the data, drafted and revised the article and finally approved the version to be published; MY and TH contributed to the interpretation of data, revising of the article and final approval of the version to be published; WX, JZ and DJ contributed to acquisition of data, analysis of data and drafting of the article.

Funding This work is supported by the following funding: (1) National Outstanding Youth Science Fund Project of National Natural Science Foundation of China (CN) (grant 81601661) and (2) Natural Science Foundation of Anhui Province (CN) (grant 1608085MH195).

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available in a public, open-access repository. Data are available upon reasonable request. All data relevant to the study are included in the article or uploaded as supplementary information. The data set used and analysed for this review will be available from the corresponding author upon a reasonable request.

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