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A Meta-Analysis Comparing Two Disinfectants for Digestive Endoscope Disinfection

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ABSTRACT: Objective This meta-analysis aimed to systematically compare the disinfection efficacy of Peracetic Acid (PAA) and Phthalaldehyde (OPA) for digestive endoscopes. **Methods** Randomized controlled trials (RCTs) comparing PAA and OPA for digestive endoscope disinfection were independently identified by two investigators through systematic searches of databases, including Wanfang Data, China National Knowledge Infrastructure (CNKI), VIP Database, Chinese Biomedical Database (CBM), PubMed, Cochrane Library, Web of Science, and Embase. Study selection, data extraction, and quality assessment of included studies were also performed by them independently. A meta-analysis was conducted using RevMan 5.4 software on studies that met the predefined quality criteria. **Results** Seven RCTs involving a total of 1038 digestive endoscope procedures were included. The meta-analysis demonstrated a significantly higher disinfection qualification rate for PAA compared to OPA (OR=2.31, 95% CI: 1.04–5.12, P=0.04). No statistically significant differences were found between the two disinfectants regarding post-disinfection bacterial colony counts or associated disinfection costs (P>0.05 for both). **Conclusion** Immersion in PAA provides superior disinfection efficacy for digestive endoscopes compared to OPA.

KEY WORDS: Peracetic Acid (PAA); Phthalaldehyde (OPA); Endoscope; Disinfection; Meta-Analysis

Digestive endoscopy serves as a cornerstone diagnostic and therapeutic modality in clinical practice[1], offering substantial value in the management of diseases affecting the esophagus, stomach, and colorectum[2]. As reusable medical devices, digestive endoscopes present unique reprocessing challenges. Although the reported incidence of infection associated with gastrointestinal endoscopy is low (less than 1 in 1.8 million procedures)[3], endoscopes are frequently heavily contaminated with microorganisms before reprocessing. However, their intricate design, high-precision components, and specialized materials preclude the use of high-temperature or high-pressure sterilization, complicating effective cleaning and disinfection[4]. Significant microbial residue may persist even after rigorous cleaning and high-level disinfection, creating a tangible risk of infection. Such infections can increase healthcare costs, extend hospital stays, and undermine patient-clinician trust[5]. Consequently, ensuring effective disinfection and sterilization of endoscopes represents a critical yet challenging priority in hospital infection control.

Currently, high-level disinfectants recommended for digestive endoscopes primarily include peracetic acid (PAA)[6], ortho-phthalaldehyde (OPA)[7], chlorine-based compounds[8], and glutaraldehyde[9]. Among these, PAA and OPA are commonly utilized in clinical settings. Although several primary studies have compared the disinfection efficacy of PAA and OPA for digestive endoscopes, no systematic review or meta-analysis has yet synthesized this evidence. Therefore, it remains unclear which agent offers superior overall disinfection performance. To address this gap, this study systematically identified randomized controlled trials (RCTs) by comparing the disinfection qualification rates of endoscopes reprocessed

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with PAA versus OPA. Through a comprehensive meta-analysis, the study aimed to evaluate and compare the efficacy of these disinfectants, thereby providing an evidence-based foundation to inform clinical disinfectant selection.

1 Materials and Methods

1.1 Search strategy

A comprehensive literature search was performed independently by two investigators. For publications written in the Chinese language, the Wanfang, China National Knowledge Infrastructure (CNKI), Chinese Biomedical Database (CBM), and VIP Database were searched using the following terms and their variants: "过氧乙酸 (corresponding to PAA)", "新型过氧乙酸 (new PAA)", "邻苯二甲醛 (OPA)", "内镜 (endoscope)", and "消毒 (disinfection)". For publications in English, the PubMed, Cochrane Library, Web of Science, and Embase databases were searched using the strategy: (peracetic acid* OR PAA) AND (ortho-phthalaldehyde* OR o-phthalaldehyde* OR OPA) AND (endoscope*) AND (disinfection*). The search encompassed all records from the inception of each database up to July 2025. The reference lists of all included studies were also reviewed manually to identify additional relevant publications.

1.2 Literature inclusion and exclusion criteria

1.2.1 Inclusion criteria

Studies were included if they met the following criteria: (1) Study Design: randomized controlled trials (RCTs); (2) Language: published in Chinese or English; (3) Participants: flexible digestive endoscopes (e.g., gastroscopes, colonoscopes, duodenoscopes); (4) Intervention: disinfection with PAA; (5) Comparison: disinfection with OPA; (6) Outcomes: at least one of the following is reported: disinfection qualification rate, post-disinfection bacterial colony count, disinfection time, cost, or disinfectant stability.

1.2.2 Exclusion criteria

Studies were excluded for any of the following reasons: (1) use of hybrid disinfection protocols combining PAA or OPA with other agents/methods; (2) unavailability of the full-text, publication in a language other than Chinese or English, low methodological quality (e.g., unclear randomization), or article type being a review, editorial, or conference abstract only; (3) incomplete reporting of outcome data or evidently erroneous data.

1.3 Literature quality assessment and data extraction

Two reviewers independently screened titles, abstracts, and subsequently full texts against the inclusion criteria. Data were extracted using a standardized form, which captured the first author, publication year, sample size (number of endoscopes per group), detailed intervention and comparison protocols, outcome measures, and results. Any disagreements during screening or extraction were resolved by consensus or by consulting a third reviewer. The methodological quality of each included RCT was assessed independently by two reviewers using the Cochrane Risk of Bias Tool (Version 5.1.0)[10], which evaluates seven specific domains of potential bias.

1.4 Statistical analysis

Meta-analysis was conducted using Review Manager (RevMan) software, version 5.4[11]. Statistical heterogeneity across studies was quantified using the I^2 statistic and assessed with the Chi-square test. A fixed-effects model was applied if significant heterogeneity was absent ($I^2 \leqslant 50\%$ and $P>0.10$). In cases of substantial heterogeneity ($I^2>50\%$ or $P \leqslant 0.10$), a random-effects model was used. If considerable heterogeneity ($P<0.1$) was present but its source could not be identified, the results were synthesized and presented descriptively[12].

2 Results

2.1 Literature search results

The initial database search retrieved 1 071 records (421 in English, 650 in Chinese). After the removal of duplicates using EndNote X9 software, 835 unique articles remained. Among these, 427 were excluded as they were irrelevant to the topic or were review articles. After screening the titles and abstracts against the inclusion criteria and examining the outcome measures, a further 401 articles were excluded. Ultimately, seven studies qualified for in-

clusion in the meta-analysis. The detailed selection process is outlined in the literature screening flow chart (Figure 1).

2.2 Basic characteristics of included studies

All seven included studies were RCTs[13-19], collectively reporting on 1 038 endoscopes (519 disinfected with PAA and 519 with OPA). Each study provided a detailed description of the disinfection protocols and clearly defined outcome measurement indicators. The basic characteristics of the included studies are summarized in Table 1.

Table 1 Basic Characteristics of the 7 Studies

Included Study	Sample Size (Intervention/ Control)	Intervention Measures		Outcome Indicators*
		Intervention Group	Control Group	
ZHOU, 2022[13]	40/40	New PAA	OPA	(1), (2), (4)
DING, 2019[14]	150/150	New PAA	OPA	(3), (4)
WU, 2012[15]	10/10	New PAA	OPA	(3)
YANG, 2020[16]	180/180	New PAA	OPA	(1), (5)
LIANG, 2015[17]	35/35	New PAA	OPA	(1), (2)
LU, 2012[18]	64/64	New PAA	OPA	(2)
HAN, 2020[19]	40/40	New PAA	OPA	(1)

*Note: (1) Disinfection qualification rate; (2) Bacterial count after disinfection; (3) Disinfection time; (4) Cost; and (5) Stability.

The methodological quality of the included RCTs was assessed independently by two reviewers using the Cochrane Risk of Bias Tool (version 5.1.0)[10]. This tool evaluates seven domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other potential biases. Each domain was judged as having a "low", "high", or "unclear" risk of bias. Studies that fully met the criteria with a low risk of bias across domains were classified as Grade A; those partially meeting the criteria with a moderate risk were Grade B; and those failing to meet the criteria with a high risk were Grade C[11]. Any discrepancies in quality ratings were resolved through discussion or by consulting a third reviewer. The results of the quality assessment are presented in Table 2.

2.3 Meta-analysis results

2.3.1 Disinfection qualification rate

Four of the seven studies[13,16-17,19] reported the disinfection qualification rate, involving 295 endoscopes in each group (PAA vs. OPA). The meta-analysis revealed low heterogeneity among these studies (χ^2=3.43, P=0.33, I^2=13%), warranting the use of a fixed-effects model. The pooled analysis demonstrated a statistically significant advantage for PAA over OPA, with an odds ratio (OR) of 2.31 (95% CI: 1.04 to 5.12, P=0.04). The forest plot is presented in Figure 2.

To assess the robustness of this finding, a sensi-

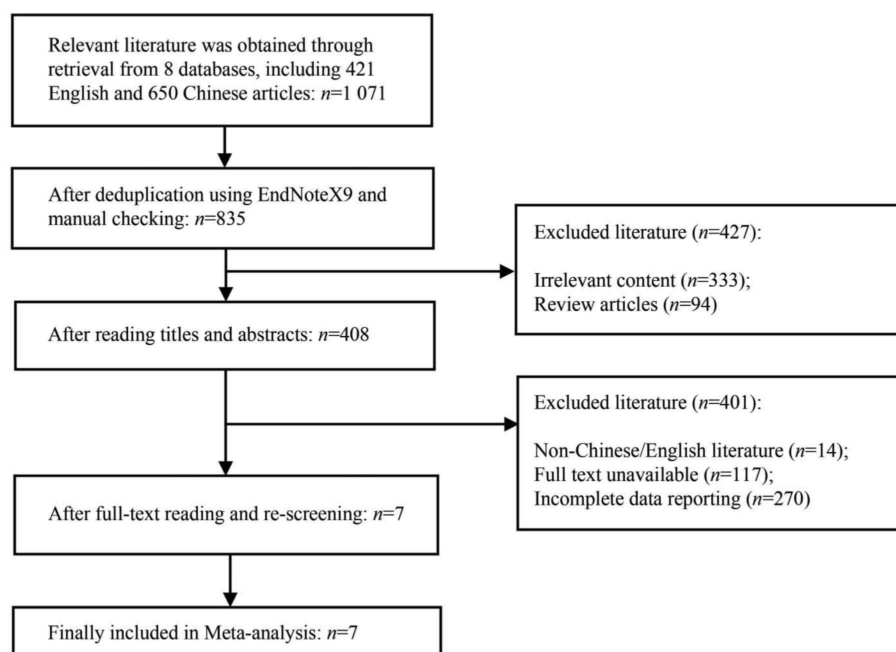


Figure 1 Literature Screening Flow Chart

Table 2 Quality Assessment Results of the Seven Studies

Included Study	Random Sequence Generation (Selection Bias)	Allocation Concealment (Selection Bias)	Performance Bias	Detection Bias	Attrition Bias	Reporting Bias	Others
ZHOU, 2022[13]	Low risk	Low risk	Unclear	Unclear	Unclear	Unclear	Unclear
DING, 2019[14]	Low risk	Low risk	Unclear	Low risk	Unclear	Unclear	Unclear
WU, 2012[15]	Low risk	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
YANG, 2020[16]	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
LIANG, 2015[17]	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
LU, 2012[18]	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
HAN, 2020[19]	Low risk	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear

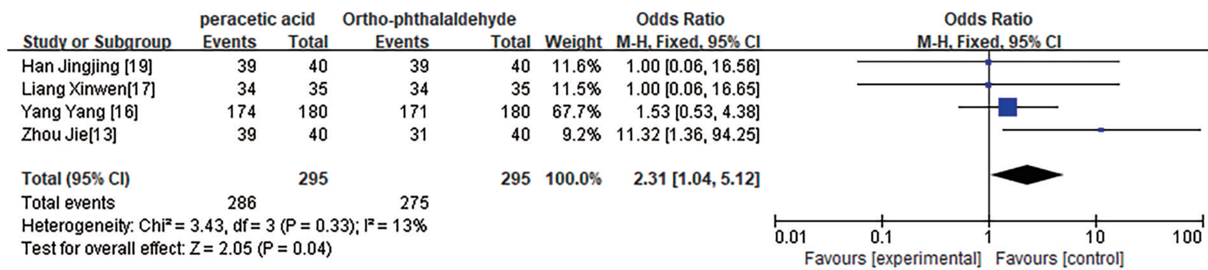


Figure 2 Forest Plot for Disinfection Qualification Rate

tivity analysis was conducted by excluding the study with the largest sample size[16]. The result remained consistent, indicating a higher disinfection qualification rate for PAA (OR=3.94, 95% CI: 1.09 to 14.25, P=0.04), as shown in Figure 3.

2.3.2 Bacterial colony count after disinfection

Three studies[13-14,18] evaluated the bacterial colony count on endoscopes post-disinfection, comprising 225 endoscopes per group. Significant heterogeneity was observed (χ^2=36.30, P<0.000 01, I^2=94%), which persisted in the sensitivity analysis by removing any single study. Consequently, a random-effects model was applied. The mean difference (MD) was −0.48 (95% CI: −6.47 to 5.51), with the confidence interval spanning the null value. The pooled effect was not statistically significant (P=0.88), which suggests no clear difference between PAA and OPA in reducing bacterial colony counts. The forest plot is shown in Figure 4.

2.3.3 Disinfection cost

Two studies[13-14] provided data on disinfection cost, involving 390 endoscopes in the PAA group and 365 in the OPA group. Considerable heterogeneity was present (χ^2=20.11, P<0.000 01, I^2=95%)

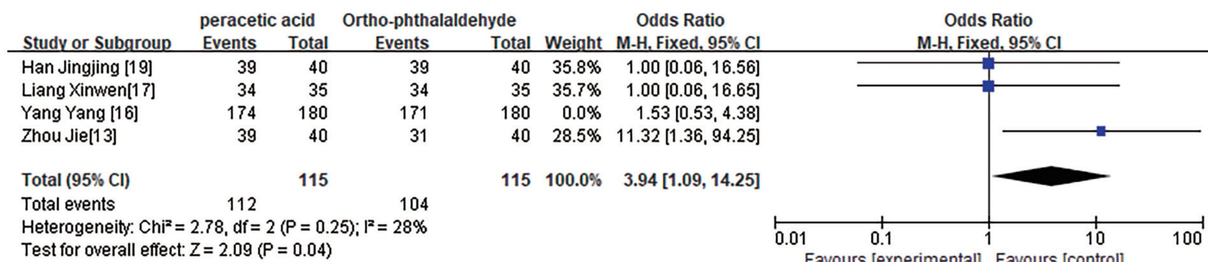


Figure 3 Sensitivity Analysis for Disinfection Qualification Rate

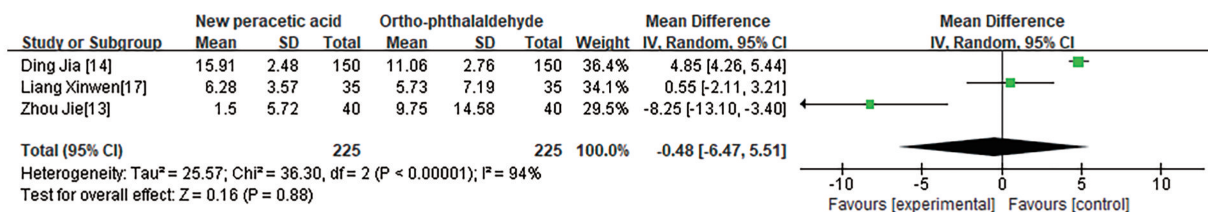


Figure 4 Forest Plot for Bacterial Count after Disinfection

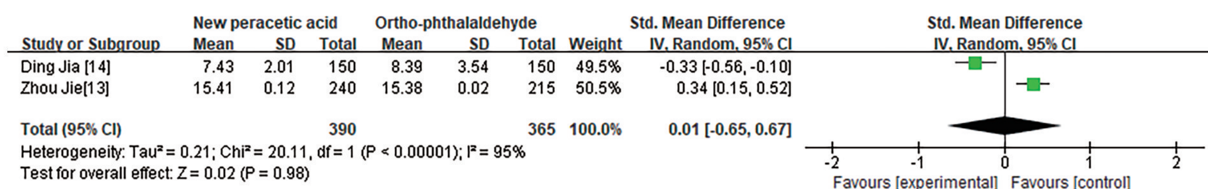
and remained unchanged in the sensitivity analysis by removing any single study. A random-effects model was therefore used. The analysis yielded an MD of 0.01 (95% CI: −0.65 to 0.67, P=0.98), indicating no statistically significant difference in cost between the two disinfectants. The corresponding forest plot is displayed in Figure 5.

3 Discussion

Endoscopy is a widely utilized and relatively reliable diagnostic modality in clinical practice, providing critical information for disease diagnosis. The efficacy of endoscope disinfection and sterilization is intrinsically linked to the risk of hospital-acquired infections. Both Chinese and international guidelines underscore disinfectant immersion as a pivotal stage in endoscope reprocessing[20-23]. Consequently, the selection of an appropriate disinfectant is paramount to ensuring the quality of endoscope disinfection and, ultimately, patient safety. This study conducted a comprehensive and systematic review of clinical studies comparing the disinfection efficacy of PAA and OPA. Through rigorous screening and meta-analysis of the seven identified studies, our findings indicate that PAA holds an advantage over OPA regarding the disinfection qualification rate, while no statistically significant differences were observed in post-disinfection bacterial colony counts or associated costs. These results align with the conclusions reported by other researchers around the world[24-25].

For the long-term disinfection of endoscopes, ideal disinfectant properties include potent bactericidal activity, short exposure time, operational safety, and ease of storage. As an aromatic dialdehyde, OPA is commonly used in clinical settings owing to its stable chemical profile, low irritancy, and generally mild action. However, it is documented that OPA can bind to proteins, leading to “gray staining” of equipment and triggering “pseudo-allergic” reactions, necessitating additional rinsing steps for residue removal[24]. This concern is corroborated by the findings of WU et al.[15] and YANG et al.[16] included in the present analysis. Therefore, when utilizing OPA, healthcare personnel must adopt appropriate protective measures, such as avoiding direct skin and mucosal contact and ensuring adequate ventilation, to mitigate potential risks to reprocessing staff.

The results of this meta-analysis suggest that the disinfection performance of PAA is superior to that of OPA. The advantages of PAA in endoscope disinfection stem from broad-spectrum, high-efficacy bactericidal action mediated by a dual mechanism, low adsorption resulting in minimal residue and reduced potential for material damage, and short required immersion time, which aligns well with fast-paced clinical workflows. PAA is characterized by high germicidal efficacy, ease of rinsing, and a favorable environmental profile[20]. A typical immersion time of five minutes is sufficient to achieve high-level disinfection and effective elimination of a wide range of microorganisms, including mycobacteria and bacterial spores. This enhances the efficiency of sequential endoscopic procedures and supports the need for rapid clinical turnover, contributing to its growing acceptance and use among healthcare professionals in recent years. Furthermore, PAA is recognized as a high-level disinfectant in major endoscope reprocessing guidelines and is noted to be particularly suitable for disinfecting endoscopes with complex luminal structures[20-21]. It is important to note, however, that the study by YANG et al.[16] highlighted certain limitations of PAA, including its potential for greater irritancy compared to some alternatives, the necessity for preparation immediately before use due to instability, susceptibility to decomposition under high temperature or light expo-



Study or Subgroup	New peracetic acid Mean	SD	Total	Ortho-phthalaldehyde Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Ding Jia [14]	7.43	2.01	150	8.39	3.54	150	49.5%	-0.33 [-0.56, -0.10]
Zhou Jie[13]	15.41	0.12	240	15.38	0.02	215	50.5%	0.34 [0.15, 0.52]
Total (95% CI)			390			365	100.0%	0.01 [-0.65, 0.67]

Heterogeneity: Tau² = 0.21; Chi² = 20.11, df = 1 (P < 0.00001); I² = 95%
Test for overall effect: Z = 0.02 (P = 0.98)

Figure 5 Forest Plot for Disinfection Cost

sure, and relatively high demands of storage conditions.

All studies included in this meta-analysis originated from Chinese literature. This may reflect a geographical focus in the available comparative studies of PAA versus OPA or indicate a potential selection bias in our search strategy. Additionally, none of the incorporated studies reported the use of blinding procedures. The methodological quality of all included trials was assessed as Grade B, suggesting the potential performance and selection biases. Therefore, the generalizability of our conclusions is currently limited and may be most applicable to clinical endoscope disinfection practices within similar contexts. To enable a more comprehensive, multi-dimensional comparison of the two disinfectants, future research should prioritize conducting large-sample, multicenter controlled studies. Applying rigorous methodologies, including adequate randomization, proper allocation concealment, and double-blinding, would significantly enhance the quality of evidence and strengthen the validity of subsequent findings.

4 Conclusion

This study demonstrated that PAA yields a significantly higher disinfection qualification rate compared to OPA. However, no statistically significant differences were observed between the two agents in terms of post-disinfection bacterial colony counts or associated economic costs. Given its established high efficacy and rapid antimicrobial action, PAA represents a more advantageous option for disinfecting endoscopes that require fast turnover or possess complex luminal structures.

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