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Comparative Efficacy of Decontamination Methods for Laparoscopic Equipment: A Systematic Review and Meta-Analysis

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 30 September 2025 and was last updated on 30 September 2025.

INTRODUCTION

Review question / Objective To compare the effectiveness of manual cleaning, alkaline multi-enzyme immersion with ultrasonic cleaning, and automatic reprocessing machines in decontaminating laparoscopes through a systematic review and meta-analysis of randomised controlled trials.

Condition being studied The cleaning and disinfection of medical equipment, particularly endoscopes and laparoscopes, remain critical components of infection prevention in healthcare settings. Inadequate decontamination of these instruments can lead to biofilm formation, cross-contamination and healthcare-associated infections (HAIs). With the increasing use of minimally invasive procedures, laparoscopes and other endoscopic instruments have become essential in modern surgical practice, requiring effective cleaning and disinfection protocols to ensure patient safety.

The traditional manual cleaning method, although widely used, has limitations, including operator-dependent variability, the potential for human error and difficulties in cleaning complex instrument designs with small lumens and intricate components. To overcome these challenges, alternative methods have been developed, such as alkaline multi-enzyme immersion cleaning combined with ultrasonic cleaning and automated reprocessing and disinfection systems.

Proper decontamination underpins the entire reprocessing procedure for reusable medical devices. Even high-level disinfection or sterilisation

may be compromised if instruments are not adequately sanitised beforehand, as organic residues can shield microorganisms from sterilants and disinfectants. According to established guidelines, thorough cleaning can reduce bioburden by 2–6 $\log_{10}$, substantially improving the effectiveness of subsequent disinfection or sterilisation processes.

The complex design of laparoscopes presents particular challenges for reprocessing. These instruments often contain small lumens, intricate joints and delicate optical components that can harbour biological debris if not properly processed. Studies have shown that protein residues as low as 6.4 μg/cm² can interfere with sterilisation efficacy, underlining the critical importance of thorough cleaning before disinfection or sterilisation.

Various detection methods have been employed to assess cleaning efficacy, including visual inspection, magnification with a light source, protein residue testing, occult blood testing, adenosine triphosphate (ATP) bioluminescence and specialised cleaning verification tools. Each method has distinct advantages and limitations in terms of sensitivity, specificity, ease of use and cost-effectiveness. Professional organisations recommend using multiple verification methods to ensure cleaning adequacy, as no single test can detect all potential contaminants.

Despite international guidelines emphasising validated cleaning methods and quality control measures, significant gaps remain in our understanding of comparative cleaning efficacy. Current evidence is limited by heterogeneity in cleaning protocols between studies, lack of standardised outcome definitions, absence of long-term clinical outcome data linking cleaning adequacy to infection rates, and limited data from diverse geographic regions and healthcare settings. Furthermore, existing systematic reviews have not quantitatively synthesised the available randomised controlled trial evidence, leaving clinicians without clear guidance on optimal cleaning strategies.

To provide high-quality evidence to inform clinical practice, we conducted a systematic review and meta-analysis of randomised controlled trials to quantitatively compare the efficacy of different decontamination methods for laparoscopes. The primary objective was to determine whether enhanced cleaning methods (alkaline multi-enzyme with ultrasonic cleaning or automated reprocessing) provide superior decontamination compared with manual cleaning alone. Secondary objectives included evaluating the reliability of various detection methods for assessing cleaning adequacy and identifying optimal protocols for clinical implementation.

METHODS

Participant or population Studies were selected based on predefined inclusion and exclusion criteria. To be eligible, studies had to be randomised controlled trials focusing on laparoscopes, comparing different cleaning and disinfection methods and reporting the qualified rate of cleaning as assessed by at least one detection method.

The inclusion criteria were as follows: (1) randomised controlled trial design; (2) study participants specifically focusing on laparoscopes; (3) interventions clearly comparing different cleaning and disinfection methods; (4) outcome measures reporting the qualified cleaning rate evaluated by at least one detection method; (5) full-text availability for complete evaluation.

Studies were excluded under the following conditions: (1) non-randomised controlled trial design; (2) duplicate publications or studies with overlapping data; (3) incomplete data or unclear methodology; (4) reviews, case reports or conference abstracts without primary data.

The "qualified rate" was defined as the proportion of instruments meeting predetermined cleanliness thresholds for each detection method: visual inspection (no visible soil), protein residue (<6.4 μg/cm²), ATP bioluminescence (<200 relative light units), occult blood test (negative result), magnifying glass inspection (no visible residue at 5× magnification), and 3M cleaning test rod (pass according to manufacturer specifications).

Intervention Studies were selected based on predefined inclusion and exclusion criteria. To be eligible, studies had to be randomised controlled trials focusing on laparoscopes, comparing different cleaning and disinfection methods and reporting the qualified rate of cleaning as assessed by at least one detection method.The "qualified rate" was defined as the proportion of instruments meeting predetermined cleanliness thresholds for each detection method: visual inspection (no visible soil), protein residue (<6.4 μg/cm²), ATP bioluminescence (<200 relative light units), occult blood test (negative result), magnifying glass inspection (no visible residue at 5× magnification), and 3M cleaning test rod (pass according to manufacturer specifications).

Comparator Studies were selected based on predefined inclusion and exclusion criteria. To be eligible, studies had to be randomised controlled trials focusing on laparoscopes, comparing

different cleaning and disinfection methods and reporting the qualified rate of cleaning as assessed by at least one detection method.The "qualified rate" was defined as the proportion of instruments meeting predetermined cleanliness thresholds for each detection method: visual inspection (no visible soil), protein residue (<6.4 μg/cm²), ATP bioluminescence (<200 relative light units), occult blood test (negative result), magnifying glass inspection (no visible residue at 5× magnification), and 3M cleaning test rod (pass according to manufacturer specifications).

Study designs to be included A systematic literature search was conducted from database inception to February 2025. Multiple electronic databases were searched, including PubMed (n = 12), Embase (n = 3), Cochrane Library (n = 6), Web of Science (n = 4), Sinomed (n = 2), CNKI (n = 378) and Wanfang (n = 165). The search used combinations of the following keywords: 'cleaning and disinfection', 'cleaning and disinfection method', 'randomised controlled trial', 'medical equipment', 'medical device' and 'endoscope'. Boolean operators (AND, OR) were applied to combine search terms as appropriate.The final PubMed search syntax.

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The final PubMed search syntax was as follows: '(medical device[Title/Abstract] OR endoscope*[Title/Abstract] OR laparoscope*[Title/Abstract]) AND (clean* OR decontaminat* OR disinfec*) AND (randomised controlled trial[Publication Type])'.
Similar Boolean logic with appropriate field tags and truncation symbols was applied across all databases. No language restrictions were applied. Reference lists of relevant reviews and included studies were manually screened. Grey literature and trial registries were not systematically searched, representing a potential source of publication bias.

Main outcome(s) Eleven randomised controlled trials involving 4,661 cases (2,339 experimental, 2,322 control) were included. All studies focused on laparoscopes, with sample sizes ranging from 140 to 800 cases. Publication years ranged from 2016 to 2025. All studies were conducted in China, limiting geographic generalisability.
The interventions compared were: (1) manual cleaning (control); (2) alkaline multi-enzyme immersion cleaning + ultrasonic cleaning; (3) automatic cleaning and disinfection machine. Detection methods varied across studies, with visual inspection being most common (11 studies), followed by ATP bioluminescence (4 studies) and occult blood testing (4 studies).

Quality assessment / Risk of bias analysis Risk of bias assessment revealed moderate overall quality (Figures 2-3). Adequate random sequence generation and allocation concealment were reported in 72.7% of studies. Blinding of participants/personnel was achieved in 54.5% of studies, outcome assessment blinding in 72.7%. Complete outcome data were available in 81.8% of studies. Selective reporting bias was low in 36.4% of studies, unclear in 63.6%. Other bias remained unclear in 81.8% of studies, potentially affecting result interpretation.

Strategy of data synthesis Meta-analysis was conducted using Review Manager 5.4 software. Risk ratios (RR) with 95% confidence intervals were calculated for dichotomous outcomes. Heterogeneity was evaluated using the chi-square test and I^2 statistic (25%, 50%, and 75% indicating low, moderate, and high heterogeneity, respectively). Fixed-effects models (Mantel–Haenszel) were used when $I^2 < 50\%$; random-effects models (DerSimonian and Laird) when $I^2 \geq 50\%$.
Subgroup analyses were performed by detection method and intervention comparison. Sensitivity analyses were conducted by excluding studies with high risk of bias in key domains. Publication bias was assessed visually using funnel plots and statistically using Egger's test when ≥10 studies were available per outcome. Statistical significance was set at $P < 0.05$.

Subgroup analysis Funnel plot analysis for visual inspection outcomes (11 studies) showed slight asymmetry suggesting potential publication bias favouring positive results. Egger's test approached significance ($P = 0.08$), indicating possible small-study effects. Sensitivity analysis excluding smaller studies ($n < 200$) did not substantially alter the main findings (RR = 1.06, 95% CI: 1.01–1.11).

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Country(ies) involved China.

Keywords healthcare-associated infections; decontamination methods; medical equipment.

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