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¹ Current management status of cleaning and disinfection for gastrointestinal endoscopy: a meta-analysis

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Objective This study aimed to evaluate the current status of cleaning and disinfection management for digestive endoscopy, provide data for standardization processing techniques, and improve the quality of cleaning and disinfection. Methods Two reviewers independently and comprehensively searched the PubMed, Cochrane Library, EMBASE, Web of Science, CNKI, Wanfang, and CBM databases on February 1, 2023. The inclusion and exclusion criteria were strictly followed during the literature survey and data extraction. All observational studies detailing the current cleaning and disinfection management status for digestive endoscopy in hospitals were included. Meta-analysis was performed using STATA 16.0 software. Results After removing different articles, the meta-analysis finally included 54 articles associated with multiple countries. The authors favor auditing staffers to confirm compliance with guidelines. The meta-analysis results indicated a configuration rate of 76% (95% CI: 68-83%) for separate rooms designated for reprocessing; 79% (95% CI: 72-84%) for reprocessing rooms with adequate ventilation; 30% (95% CI: 24–36%) for automated endoscope washer-disinfectors; 68% (95% CI: 55–81%) for complete protective equipment usage; 90% (95% CI: 83–95%) for the configuration rate of endoscope and accessory storage cabinets; 50% (95% CI: 38–61%) for changing enzymatic-type detergents after each use; 51% (95% CI: 30-71%) for the use of purified or sterilized water for final rinsing; 80% (95% CI: 70-88%) for monitoring disinfectant concentration; 87% (95% CI: 80-93%) for microbial monitoring; and 44% (95% CI: 26-62%) for the usage of protective equipment. Conclusion The configuration of the automated endoscope washer-disinfector, non-standard cleaning and disinfection procedures, and a lack of occupational protection awareness among personnel responsible for cleaning and disinfecting digestive endoscopy were all apparent issues. It was suggested that all departments enhance their levels of management and supervision, standardize reprocessing procedures and quality control details, upgrade hardware facilities and spatial layouts, reinforce personnel training, and increase staff awareness of nosocomial infection risks.

Keywords Digestive endoscopy, Cleaning and disinfection, Management, Meta-analysis

Abbreviations

ERCP	Endoscopic retrograde cholangiopancreatography
STROBE	Strengthening the reporting of observational studies in epidemiology
CI	Confidence interval

Digestive endoscopy is widely used in clinical practice to diagnose and treat various digestive system diseases. According to reports, more than 20 million gastroenterological examinations and over 660,000 ERCP procedures are performed annually in the United States¹, while surveys have shown that >90% of medical institutions in China conduct digestive endoscopy-related diagnosis and treatment projects².

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Digestive endoscopes are susceptible to cross-infection by many pathogens due to their intricate design, narrow and multiple lumens, and vulnerability to bacterial contamination and biofilm development on the inner lumen walls if cleaning and disinfection are poorly performed^{3–5}. To reduce the risk of endoscope infection caused by improper cleaning and disinfection, different countries have developed various regulations and guidelines to standardize the treatment of digestive endoscopes and maximize the safety of their applications^{6–9}. These guidelines underscore the need for rigorous compliance with the principles of reprocessing digestive endoscopes. Several outbreaks of iatrogenic infections resulting from deficiencies in endoscope cleaning and disinfection have been reported in many countries due to hospitals' noncompliance with established criteria for standardized cleaning and disinfection protocols or poor use of resources¹⁰.

However, many countries have provided information on endoscope cleaning and disinfection status to improve clinical practice¹¹⁻¹³. However, still, there is a lack of systematic data exploring the current situation. Therefore, this study adopted the meta-analysis method to comprehensively analyze and merge multiple studies on the resource configuration and infection control status of cleaning and disinfecting digestive endoscopes in hospitals. The main focus was to understand the current situation of cleaning, disinfecting, and managing digestive endoscopes in hospitals and provide a theoretical basis for improving the quality of endoscope reprocessing in medical institutions and reducing hospital-acquired infections.

Methods

Study registration

This study has been registered on Prospero(CRD42023422204) and followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses reporting guidelines.

Literature search strategy

To collect literature on the current status of cleaning and disinfection management of gastrointestinal endoscopes, the PubMed, Cochrane Library, EMBASE, Web of Science, CNKI, Wanfang Data, and CBM databases were searched on February 1, 2023. The search queries comprised keywords such as "digestive endoscopy," "gastrointestinal endoscopy," "cleaning," "disinfection," "status," "current situation," and "surveys and questionnaires." Appendix 1 provides a comprehensive analysis of the full-text search method. The reference lists of the shortlisted articles were manually investigated, but no further eligible articles were identified.

Inclusion and exclusion criteria

This systematic study and meta-analysis were based on the following inclusion criteria: (1) observational studies; (2) subjects were included from different regions; (3) studies focused on the configuration of resources for cleaning and disinfection of gastrointestinal endoscopes and infection control; (4) outcome indicators for the cleaning and disinfection of gastrointestinal endoscopes in the regulation for the cleaning and disinfection technique of flexible endoscopes are defined by the current status of resource configuration and infection control measures¹⁴. These included the sample size, the rate of configuration of separate rooms for reprocessing, the rate of reprocessing rooms with good ventilation, the rate of configuration of automated endoscope washerdisinfector, the rate of full provision of personal protective equipment, the configuration rate of an endoscope and accessory storage cabinet, the rate of changing enzymatic-type detergents each time after use, the rate of usage of purified water or sterilized water for final rinsing, the rate of disinfectant concentration monitoring, the rate of microbiological monitoring, and the rate of personal protective equipment usage. The definitions of the concepts were as follows. The configuration rate of independent endoscope cleaning and disinfection rooms referred to the proportion of hospitals with independent endoscope cleaning and disinfection rooms among all surveyed hospitals. Good ventilation in endoscope cleaning and disinfection rooms relates to the rooms having good air circulation and a good ventilation system, preferably using a "top supply and bottom exhaust" method, with ventilation frequency preferably > 10 times/h and a replacement volume of fresh air at least 2 times/h. The rate of fully automatic endoscope cleaning and disinfection machine configuration is defined as the proportion of hospitals equipped with fully automatic endoscope cleaning and disinfection machines among all surveyed hospitals. Purified water refers to tap water from which all impurities, particles, and suspended matter have been removed by specific methods to meet standard requirements. The conductivity of the purified water should be \leq 15 uS/cm (25 °C). Sterile water is defined as water that has been sterilized through physical and chemical processes to eliminate or kill bacteria, viruses, and other microorganisms.

As per the guidelines, the endoscope must be rinsed with purified or sterile water for the final time. The exclusion criteria were as follows: (1) literature types such as reviews, reports, or commentaries; (2) duplicate publications; (3) imperfect or incomplete data that failed to provide appropriate indicators; (4) non-Chinese or non-English literature; (5) unobtainable full texts.

Literature screening and data extraction

The literature was screened by two researchers using Endnote software. Before deciding whether to include the full text, they initially reviewed the title and abstracts and excluded any unrelated publication. All discrepancies were resolved *via* consultation or discussion with a third party. The researchers contacted the corresponding authors *via* email or phone to obtain the necessary information. The extracted data included the first author, year of publication, region, sample size, etc. Data was cross-checked after its extraction.

Literature quality evaluation

To assess the quality of the literature, the methodological section suggested by STROBE and the evaluation markers for observational studies proposed by Sanderson et al¹⁵. were combined. Each item was assigned a score

of 1 if it met the criteria and 0 if it did not, for a total score of 12. Studies with scores of \geq 7 were considered of high quality. Appendix 2 provides the specific contents of the evaluation indicators.

Statistical analysis

The effect size of the combined outcome indicators was calculated *via* the STATA16.0 software. Heterogeneity among the results of each study was tested using the Q-test, with a significance level of $\alpha = 0.100$, and heterogeneity size was evaluated using the I² statistic. If the results of the studies were homogeneous (p > 0.05, I² < 0.500), a fixed-effect model was used for meta-analysis. A random-effect model was adopted if the results of the studies were heterogeneity. A forest plot was drawn to obtain the pooled estimate and 95% CI. Funnel plots and Begg's and Egger's tests were used to evaluate publication bias.

Results

Literature screening process and results

A total of 2228 relevant articles were retrieved. Approximately 879 duplicate publications and 116 meta-analyses or systematic reviews were removed, as these are based on other publications. After reviewing the titles and abstracts, around 1143 articles were excluded. After reading the full text and conducting quality evaluations, 36 articles were further excluded. Finally, 54 articles were included in the meta-analysis. The authors favor auditing staffers to confirm compliance with guidelines. These involved several countries, specifically China, Spain, Romania, and countries in the Asia-Pacific region (Fig. 1). Among them, 51 studies were from China and 3 from other countries. Appendix 3 provides the basic information of the included studies. The quality of the included studies was assessed, with 10 articles receiving a score of 10, 25 scoring 9, and 19 scoring 8. Thus, the quality was high; the specific results are presented in Appendix 4.

Configuration of cleaning and disinfection resources for gastrointestinal endoscopes

The results showed heterogeneity among the included studies; therefore, a random-effects model was used for the analysis.



Fig. 1. Flowchart of the study selection for meta-analysis on the current status of cleaning and disinfection management of gastrointestinal endoscopes in hospitals.

Configuration rate of separate rooms for reprocessing. The heterogeneity was $I^2 = 93.78\%$, p < 0.001. The pooled configuration rate of separate rooms for reprocessing was 76% (95% CI: 68–83%), as shown in Fig. 2(a).

Rate of reprocessing rooms with good ventilation.

The heterogeneity was $I^2 = 77.92\%$, p < 0.001. The pooled rate of reprocessing rooms with good ventilation was 79% (95% CI: 72-84%), as shown in Fig. 2(b).

Configuration rate of automated endoscope washer-disinfector. The heterogeneity was $I^2 = 86.34\%$, p < 0.001. The pooled configuration rate of automated endoscope washerdisinfectors was 30% (95% CI: 24-36%), as shown in Fig. 2(c).

Rate of implementation of complete provision of protective equipment. The heterogeneity was $I^2 = 93.77\%$, p < 0.001. The pooled implementation rate of complete provision of protective equipment was 68% (95% CI: 55-81%), as shown in Fig. 2(d).

Configuration rate of endoscopes and accessory storage cabinets (units).

The heterogeneity was $I^2 = 86.97\%$, p < 0.001. The pooled configuration rate of endoscopes and accessory storage cabinets (units) was 90% (95%CI: 83–95%), as shown in Fig. 2(e).

Digestive endoscopy cleaning, disinfection, and infection control

The results showed heterogeneity among the included studies; therefore, a random-effects model was used for the analysis.



Fig. 2. Forest plots showing cleaning and disinfection resource configurations for gastrointestinal endoscopes. **a** Forest plot of the configuration rate of separate rooms for reprocessing.**b** Forest plot of the rate of reprocessing rooms with good ventilation.**c** Forest plot of the configuration rate of automated endoscope washer-disinfectors.**d** Forest plot of the rate of complete provision of protective equipment.**e** Forest plot of the configuration rate of endoscopes and accessory storage cabinets.

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Rate of changing enzymatic-type detergents every time after use.

The heterogeneity was $I^2 = 89.75\%$, p < 0.001. The combined implementation rate of changing enzymatic-type detergents every time after use was 50% (95% CI: 38–61%), as shown in Fig. 3(a).

Usage of purified or sterilized water for final rinsing.

The heterogeneity was $I^2 = 92.25\%$, p < 0.001. The combined implementation rate of purified or sterilized water for final rinsing was 51% (95% CI: 30–71%), as shown in Fig. 3(b).

Monitoring of disinfectant concentration.

The heterogeneity was $I^2 = 91.69\%$, p < 0.001. The combined implementation rate of disinfectant concentration monitoring was 80% (95% CI: 70–88%), as shown in Fig. 3(c).

Microbiological monitoring.

The heterogeneity was $I^2 = 86.54\%$, p < 0.001. The combined implementation rate of microbiological monitoring was 87% (95% CI: 80–93%), as depicted in Fig. 3(d).

Usage of protective equipment.

The heterogeneity was $I^2 = 92.25\%$, p < 0.001. The combined implementation rate of protective equipment usage was 44% (95% CI: 26–62%), as depicted in Fig. 3(e).

Sensitivity analysis

A sensitivity analysis was performed on the included studies, showing that none significantly interfered with the meta-analysis results, indicating that the survey was stable. Appendix 5 provides the specific results of the sensitivity analysis.

Publication bias

Funnel plots were used to analyze the publication bias associated with the implementation and configuration rates for each indicator. The results showed that the symmetry of the funnel plots was moderate, indicating the possibility of publication bias, as shown in Fig. 4. The results of Egger's and Begg's tests showed that there might be publication bias in the configuration rate of separate rooms for reprocessing and the rate of reprocessing





Fig. 3. Forest plots of digestive endoscope cleaning, disinfection, and infection control status. **a** Forest plot of the configuration rate of changing enzymatic-type detergents each time after use.**b** Forest plot of purified or sterilized water implementation rates for final rinsing.**c** Forest plot of the implementation rate of disinfectant concentration monitoring.**d** Forest plot of the implementation rate of microbiological monitoring.**e** Forest plot of the implementation rate of protective equipment usage.



Fig. 4. Funnel plots of hospital endoscopy resource configuration and infection control status. **a** Funnel plot of the configuration rate of separate rooms for reprocessing; **b** Funnel plot of the rate of reprocessing rooms with good ventilation. **c** Funnel plot of the configuration rate of automated endoscope washer-disinfectors; **d** Funnel plot of the implementation rate of complete protective equipment. **e** Funnel plot of the configuration rate of endoscopes and accessory storage cabinets/warehouses; **f** Funnel plot of the implementation of changing enzymatic-type detergents each time after use. **g** Funnel plot of the implementation rate of using purified or sterilized water for final rinsing; **h** Funnel plot of the implementation rate of using purified or sterilized water for final rinsing; **h** Funnel plot of the implementation rate of the usage rate of protective equipment.

rooms with good ventilation (p = 0.022, p = 0.041, respectively). No publication bias was found for other results (all p > 0.05), as shown in Table 1.

Discussion

The management of digestive endoscopy is a major consideration in infection prevention and control. Since 2010, the Emergency Medicine Research Institute in the USA has published an annual list of endoscopy-related infections as one of the top 10 patient safety concerns in medical institutions¹⁶. The literature review revealed that 281 cases of pathogenic infections resulting from digestive endoscopy were reported in 265 articles between 1965 and 1992¹⁷. Poor endoscope cleaning, defective endoscope design, imperfect high-level disinfection procedures, incomplete endoscopes are common causes of endoscopy-related infections¹⁷. Epstein L. et al. comprehensively evaluated studies published between 2005 and 2012, identifying deficiencies in endoscope reprocessing as a "common problem," with over 33,000 patients exposed to contaminated endoscopes¹⁸. Therefore, the quality of reprocessing of digestive endoscopes should be prioritized to reduce infections. The present study analyzed the recent cleaning, disinfection, and management of digestive endoscopes and found that the conditions need improvement. The main issues included poor configuration of automated endoscope washer-disinfector, non-standard cleaning and disinfection processes, and inadequate awareness of occupational protection among staff. Therefore, it is necessary to enhance standardized management practices to effectively prevent and control hospital infections while maintaining patient safety.

Configuring digestive endoscope cleaning and disinfection resources requires more investment

Serious shortage of automated endoscope washer-disinfectors.

The study showed that the configuration rate of fully automatic cleaning and disinfection machines in hospitals was only 30%. Fully automatic endoscope cleaning and disinfection machines provide many advantages, such as easy use, manpower saving, reduced occupational exposure of staff, and good disinfection¹⁹. Thus, multiple guidelines suggest the adoption of fully automatic cleaning and disinfection machines as the primary tool for high-level endoscope disinfection^{8–10}. National physical examination programs have progressively added digestive endoscopy examinations as the importance of individuals' health has increased. A higher percentage of patients will undergo digestive endoscopy examinations at medical institutions of all levels. To protect the safety of patients and staff, it is suggested that the government and medical institutions prioritize the standardization of facilities and equipment for reprocessing digestive endoscopes after use. Implementing fully automated cleaning and disinfection systems should be prioritized whenever possible, particularly for medical institutions performing many diagnoses and treatments.

Basic specifications for building layouts and hardware facilities.

According to many guidelines, hospitals should establish independent cleaning and disinfection rooms with good ventilation to prevent indoor air contamination with chemical disinfectants and pathogenic aerosols released during endoscope cleaning and disinfection. The main focus is to prevent the growth of microorganisms and reduce the risk of cross-infection and occupational hazards for staff¹⁹. Endoscope drying can be performed rapidly and cost-effectively by flushing the internal channels of the endoscope and cleaning its external surfaces with 70–90% ethyl or isopropyl alcohol, followed by the use of compressed or pressurized air²⁰. After drying, endoscopes should be stored in a specialized storage cabinet al.ong with their accessories¹⁴. This meta-analysis showed that 76% of hospitals equipped with digestive endoscopes had separate reprocessing rooms, and 79% had good ventilation. Furthermore, 90% of endoscopes were stored in dedicated storage cabinets after processing, indicating that most medical institutions comply with the standard by adopting reasonable building layouts and storage facilities. However, some medical institutions still face challenges due to insufficient funding and outdated building structures, resulting in the co-existence of diagnosis and treatment processes in the same room and poor ventilation in the cleaning and disinfection room. Therefore, it is advised that the relevant hospital management departments intensify their efforts to plan and prioritize the efficient use of space to sanitize and clean digestive endoscopes¹⁹.

Project		Egger's test
Configuration rate of separate rooms for reprocessing		0.127
Rate of reprocessing rooms with good ventilation		0.172
Configuration rate of automated endoscope washer-disinfector		0.784
Implementation rate of a complete supply of protective equipment		0.602
Configuration rate of the endoscope and accessory storage cabinet (or storage room)		0.398
Implementation rate of changing enzymatic-type detergents each time after use		0.892
Implementation rate of using purified water or sterilized water for the final rinse		0.638
Implementation rate of disinfectant concentration monitoring		0.489
Implementation rate of microbiological monitoring		0.803
Usage rate of protective equipment		0.268

Table 1. Results of Begg's test and Egger's tests.

Standardize and prioritize digestive endoscope cleaning and disinfection infection control

The standard endoscope handling procedure in domestic and international guidelines includes pre-processing, leakage testing, cleaning, high-level disinfection, rinsing, drying, and storage. Among them, the cleaning and high-level disinfection processes are particularly crucial, as their quality impacts the overall quality of endoscope handling.

Non-standard processes used for cleaning digestive endoscopes

In contrast to the findings of Fratila et al., this study revealed that only 50% of medical institutions replaced the cleaning solution promptly following each cleaning¹¹. Enzymatic cleaning solutions can effectively degrade contaminants in the lumen of the endoscope, improve cleaning quality, and confirm disinfection quality. Thus, they are strongly recommended by international guidelines^{1,7,8}due to their superiority in removing endoscope contaminants compared to other cleaning solutions. However, due to the relatively high price of enzymatic cleaning solutions, this study found that 50% of medical institutions did not strictly adhere to the "one endoscope, one change" requirement. Changing the cleaning solution for multiple endoscopes using a multi-enzyme cleaning solution causes a decrease in enzyme activity after 2–3 h of dilution, affecting the endoscope's cleaning quality. However, effective cleaning can remove organic residue from the surfaces of flexible endoscopes, preventing the formation of biofilms and ensuring the success of high-level disinfection. Poor disinfection increases the risk of infection, especially among immunocompromised patients, potentially leading to cross-contamination²¹. To reduce the occurrence of healthcare-associated infections, it is suggested that medical institutions strengthen the execution of the requirement of changing the cleaning solution for each endoscope during the cleaning of digestive endoscopes.

Another key factor contributing to disinfection failure is bacterial contamination of the water used for the final rinsing of endoscopes. Therefore, many guidelines mandate that endoscopes be rinsed with purified or sterile water^{1,7,8}. According to the findings of this study, only 51% of hospitals used filtered or sterilized water for the final rinse of digestive endoscopes, and the execution status was poor. The endoscope may be re-contaminated through the use of non-purified or non-sterile water in the final rinse procedure, which can result in a failed disinfection and an elevated risk of healthcare-associated infections. Furthermore, non-purified water contains high levels of inorganic ions and other impurities, which can corrode the endoscope and affect its service life²².

Lack of occupational protection awareness among digestive endoscopy staff

This study demonstrated that hospitals did not prioritize the use of protective equipment during digestive endoscopic procedures. The compliance rate for the complete implementation of protective equipment was 68%, and the usage rate was even lower at 44%. This result indicates insufficient awareness of occupational protection among gastrointestinal endoscopy personnel when handling endoscopes. Some management and departmental staff in medical institutions do not pay enough attention to occupational safety, resulting in insufficient protective equipment or low compliance in wearing them, particularly crucial areas such as the face and eyes. To prevent occupational exposure, many guidelines specify that strict occupational protection measures must be implemented during the cleaning and disinfection of digestive endoscopes²³. Endoscope disinfectants, such as glutaraldehyde and peracetic acid, irritate the eyes, skin, and mucous membranes. Inhalation can cause inflammation of the throat and bronchi, chemical pneumonia, pulmonary edema, allergic reactions, and other complications. Incomplete rinsing can also result in abdominal pain, enteritis, and diarrhea²⁴. The inadequate use of personal protective equipment (PPE) may be attributed to the substandard quality of the equipment, which can potentially lead to discomfort or impede operational efficiency when used by personnel. It is suggested that all medical institutions have an adequate supply of high-quality and different specifications of protective equipment, boost protection training and assessments, improve awareness of occupational safety among staff, and enhance compliance with wearing PPE²⁵.

Basic specifications for monitoring the cleaning and disinfection of digestive endoscopes

Based on the guidelines, the disinfectant concentration must be monitored daily and recorded regularly²⁶. To ensure their efficacy, disinfectants should not be used beyond the time limit specified in the product manual. Disinfectants to be reused should have their concentrations measured once after preparation and monitored before each use¹⁴. The disinfectant concentration can be monitored to determine its effectiveness and ensure disinfection. This study showed that 80% of medical institutions regularly monitored disinfectant concentrations. International guidelines also emphasize the importance of microbiological monitoring. Regular microbiological monitoring of disinfected endoscopes can evaluate the disinfection quality and ensure their effectiveness¹⁴. This study demonstrated that 87% of digestive endoscopy centers implement consistent microbiological monitoring. However, some hospitals still fail to conduct regular monitoring. To ensure patient safety, it is suggested that hospital departments or higher-level administrative departments conduct regular inspections and provide quality monitoring of endoscope cleaning and disinfection.

Limitations of the study

Most of the literature included in this study is Chinese studies, and fewer studies from other countries may cause some bias in the research results. This study expects to acquire more comprehensive research findings in the future.

Conclusions

Endoscope infection control is a common issue in digestive endoscopy diagnosis and treatment, and there are still some difficulties in cleaning and disinfecting digestive endoscopes. Thus, to reduce the incidence of

healthcare-associated infections related to digestive endoscopy and ensure patient safety, departments should conduct inspections and provide guidance in terms of multiple aspects and channels, increase the configuration of resources for the cleaning and disinfection of digestive endoscopes, improve equipment and rational spatial layout, pay close attention and strengthen personnel training, standardize operating procedures, and enhance awareness of infection control among staff members.

Data availability

The datasets used and/or analysed during the current study are available from the corresponding authors on reasonable request.

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Author contributions

JH and RH conceived the study and designed the protocol. YC, RH per-formed the literature search and study selection. YC and RH extracted the relevant information and validated the data, RH conducted the data analysis with support from LY. RH wrote the first draft of the paper. All authors critically revised successive drafts of the paper and approved the final version. Tianle Zou and Wei Pan revised the paper. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Additional information

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