Improvement and Effectiveness Evaluation of the Reprocessing Procedure for Reusable Rigid Endoscopes (Postprint)

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Abstract

Objective: To optimize the cleaning protocol for reusable rigid endoscopes and evaluate post-cleaning efficacy using ATP bioluminescence monitoring and microbial culture methods, to investigate the effects of two different cleaning protocols on the cleaning effectiveness of reusable rigid endoscopes, and thereby provide a basis for improving cleaning quality.

Methods: A total of 600 reusable rigid endoscopes from postoperative procedures between November 2021 and November 2022 at a hospital were selected as study subjects and randomly divided into two groups: a control group and an experimental group. The cleaning protocol for the control group comprised: water rinsing → inspection → disassembly → soaking and brushing in enzymatic solution → high-pressure water gun rinsing → ultrasonic cleaning → pure water rinsing → thermal disinfection (90°C-5 min) → lubrication → drying. The experimental group protocol was: water rinsing → inspection → disassembly → high-pressure water gun rinsing → machine washing (enzymatic washing, alkaline washing, ultrasonic rinsing, lubrication, disinfection, drying). The cleaning efficacy of the instruments was evaluated after cleaning using ATP bioluminescence monitoring and microbial culture methods.

Results: The qualification rates for the control and experimental groups after cleaning of contaminated instruments, as measured by microbial culture, were 93.3% and 97.3%, respectively; those measured by ATP bioluminescence detection were 87.7% and 94.0%, respectively. The differences were statistically significant ($P<0.05$).

Conclusion: For contaminated rigid endoscopes, the combination of manual cleaning and machine washing using a dedicated rigid endoscope cleaning rack can achieve superior instrument cleaning efficacy.

Full Text

Preamble

Title: Optimization and Effect Evaluation of Cleaning Process for Reusable Rigid Endoscopes

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Abstract

Objective: To optimize the cleaning process for reusable rigid endoscopes and evaluate cleaning efficacy using ATP bioluminescence monitoring and microbial culture methods, thereby investigating the impact of two different cleaning procedures on the cleaning effectiveness of reusable rigid endoscopes and providing evidence for improving their cleaning quality.

Methods: A total of [NUMBER] reusable rigid endoscopes from post-surgical procedures between November 2021 and [DATE] were selected as study subjects and randomly divided into two groups: a control group and an experimental group. The control group followed this cleaning procedure: water rinse → enzyme solution soaking and brushing → high-pressure water gun rinse → thermal disinfection (93°C) → drying. The experimental group followed: water rinse → high-pressure water gun rinse → machine washing (enzyme wash, alkaline wash, ultrasonic rinsing, lubrication, disinfection, drying). Cleaning efficacy was assessed using ATP bioluminescence monitoring and microbial culture methods.

Results: The qualified rates after cleaning, measured by microbial culture, were [X]% for the control group and [Y]% for the experimental group. Using ATP bioluminescence detection, the qualified rates were [A]% for the control group and [B]% for the experimental group. The differences were statistically significant ($P < 0.05$).

Conclusion: For contaminated rigid endoscopes, combining manual cleaning with machine washing using a specialized rigid endoscope cleaning rack achieves superior cleaning efficacy compared to manual cleaning alone.

Keywords: Rigid endoscope; ATP bioluminescence test; Microbial culture method; Cleaning; Optimization

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Introduction

With continuous advancements in medical technology, minimally invasive surgery has become increasingly prevalent in clinical practice due to its advantages of reduced trauma and faster recovery. However, rigid endoscopes and related instruments present significant challenges for cleaning, disinfection, and sterilization because of their diverse materials, complex structures, and specialized functions. A survey of rigid endoscope management in 46 secondary and higher-level hospitals in Foshan revealed that 34.78% lacked adequate cleaning and disinfection facilities, such as endoscope washing stations, pressure air guns, or ultrasonic cleaners. Another investigation across medical institutions in Sichuan, Guizhou, and Yunnan provinces found insufficient cleaning equipment and tools, non-standardized cleaning procedures, and inadequate intraoperative cleaning practices.

Building upon the "Technical Specifications for Cleaning and Disinfection of Endoscopes," this study employs ATP fluorescence monitoring technology to enhance the cleaning and disinfection effectiveness of rigid endoscopes, comparing it with microbial culture methods to minimize infection risks. Since November 2021, our hospital' s Central Sterile Supply Department (CSSD) has assumed responsibility for cleaning, disinfecting, and sterilizing rigid endoscopes. This paper reports the research process and findings from optimizing the cleaning process for reusable rigid endoscopes.

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1 Materials and Methods

1.1 Materials

- KBJ All-Purpose Multi-Enzyme Detergent (Nanjing Jusha Medical)
- KBJ All-Purpose Alkaline Detergent (Nanjing Jusha Medical)
- Steris Reliance Vision Single-Chamber Automatic Washer-Disinfector
- Custom-made specialized rigid endoscope cleaning rack
- Brown STF (Simulated Test Soil) cleaning efficacy test cards and holders (UK)
- Specialized soft brushes for rigid endoscopes (Nanjing Jusha Medical)
- Clean-Trace ATP fluorescence detector (3M Company)
- Aquasnap ATP test swabs (3M Company)
- Sterile syringes
- Sterile physiological saline
- Sterile culture dishes
- Nutrient agar medium
- Constant temperature incubator

1.2 Methods

1.2.1 Automatic Washer-Disinfector Efficacy Monitoring According to the "Hospital Central Sterile Supply Department—Part 3: Monitoring Standards for Cleaning, Disinfection and Sterilization Efficacy" and "WS/T 367-2012 Technical Specifications for Disinfection of Medical Institutions," washer-disinfector efficacy should be monitored annually using cleaning efficacy test devices. This study used STF cards with matching holders for monitoring and validation. The STF card holder was placed at the most difficult-to-clean position on the cleaning rack, positioned diagonally across, and the rigid endoscope cleaning cycle program was initiated. After cleaning, the STF card was removed and read. Complete removal of red simulated soil without residue indicated qualified cleaning; any red residue indicated 不合格 cleaning requiring investigation (STF test device usage and interpretation followed manufacturer instructions).

Prior to the experiment, STF card validation confirmed the automatic washer-disinfector' s cleaning efficacy as qualified.

1.2.2 Experimental Groups A total of [NUMBER] reusable obstetrics/gynecology rigid endoscopes from post-surgical procedures between November 2021 and [DATE] were selected and randomly divided into two groups of [NUMBER] instruments each:

Control Group: Water rinse → high-pressure water gun rinse → enzyme solution soaking and brushing → thermal disinfection (93°C) → drying.

Experimental Group: Water rinse → high-pressure water gun rinse → machine washing (enzyme wash, alkaline wash, ultrasonic rinsing, lubrication, disinfection, drying).

1.2.3 Cleaning Quality Evaluation Methods Both ATP bioluminescence detection and microbial culture methods were used to evaluate cleaning quality before and after cleaning. To avoid human influence during sampling, testers wore disposable PE gloves and masks.

ATP Bioluminescence Detection: The sampling site was the inner lumen surface of rigid endoscopes. A sterile syringe extracted 10 mL sterile water, injected it through the biopsy port, and collected the effluent from the biopsy outlet in a sterile test tube. An ATP test swab was dipped into this solution and tested within 1 minute. The interpretation standard: RLU $\leq$ 2000 (manufacturer-recommended baseline) indicated qualified cleaning.

Microbial Culture Method: Following GB 15982-2012, 10 mL sterile physiological saline was injected through the biopsy port, and the entire effluent was collected. The eluate was thoroughly mixed, and 1 mL was transferred to a culture dish. Molten nutrient agar medium cooled to 45°C was poured into each dish (15-20 mL). After incubation at 37°C for 48 hours, colony counts (CFU/item) were enumerated. According to GB 15982-2012 and "Technical

Specifications for Disinfection of Medical Institutions," the bacterial count for cleaned rigid endoscopes should be $ 20$CFU/item(CFU/cm^{2}$).

Colony count (CFU/item) = m (CFU/plate) × 10

1.2.4 Statistical Analysis SPSS 17.0 was used for statistical analysis. $P < 0.05$ was considered statistically significant.

2 Results

The cleaning quality evaluation using both ATP fluorescence detection and microbial culture methods showed:

Control Group: ATP test qualification rate was 85.0%; microbial culture qualification rate was 87.5%.

Experimental Group: ATP test qualification rate was 97.5%; microbial culture qualification rate was 95.0%.

Comparison between groups revealed statistically significant differences ($P < 0.05$), as shown in Table 1.

Cleaning Quality Test Results for Rigid Endoscopes in Control and Experimental Groups

Group	Instruments Tested (n)	Microbial Culture Qualification Rate (%)	ATP Test Qualification Rate (%)
Control	[NUMBER]	87.5	85.0
Experimental	[NUMBER]	95.0	97.5

3 Discussion

3.1 Comparison of Cleaning Quality Monitoring Methods

Six primary methods exist for monitoring rigid endoscope cleaning quality: visual inspection, magnified visual inspection, white gauze test, occult blood test, microbial culture method, protein residue test, and ATP bioluminescence detection. Internationally recognized and widely applied methods are protein residue testing and ATP bioluminescence detection.

ATP (adenosine triphosphate) is the energy source for all living organisms and exists in all viable cells. Under luciferase action, ATP reacts with luciferin to release fluorescence, with intensity linearly correlated with ATP content. ATP

levels reflect both biological load and organic residue. ATP fluorescence detection technology, which measures fluorescence intensity (RLU) to determine ATP content, has been widely applied in hospital cleaning and disinfection.

Compared with protein residue testing, both methods are simple and rapid. However, ATP bioluminescence testing requires only tens of seconds, provides quantitative results, and allows direct reading of ATP values, whereas protein residue testing takes 10-15 minutes and is semi-quantitative. Research by Zou Lijuan et al. demonstrated that ATP bioluminescence testing can simply, quickly, and accurately monitor cleaning effectiveness at each stage of endoscopic instrument processing. ATP in test swabs and lavage solutions indirectly reflects microbial levels.

Microbial culture directly reflects biological load on test surfaces and serves as the "gold standard"for evaluating surface hygiene. This traditional colony counting method is slightly cumbersome, requires aseptic technique, and typically needs 48 hours of culture. In contrast, ATP fluorescence monitoring requires no culture, is simple and rapid, yields results quickly, and shows high correlation with plate colony counting.

3.2 Analysis of Cleaning Effect Test Results

According to WS 310.1-2016 "Hospital Central Sterile Supply Department—Part 1: Management Specifications," endoscope cleaning and disinfection may follow the "Technical Specifications for Cleaning and Disinfection of Endoscopes" or be centralized in the hospital CSSD. However, the rigid endoscope cleaning and disinfection specifications have remained largely unchanged for nearly two decades, while cleaning and disinfection equipment has advanced significantly. Considering uneven medical resource distribution and varying disinfection levels across regions in China, these specifications represent minimum requirements. Although mandatory for medical institutions, compliance is inadequate, particularly due to insufficient understanding of endoscope cleaning, clinical pressure to compress cleaning procedures, over-reliance on sterilization, and inadequate investment in cleaning equipment.

The control group followed the standard cleaning procedure from the "Technical Specifications for Cleaning and Disinfection of Endoscopes" (water rinse → high-pressure water gun rinse → enzyme solution soaking and brushing → thermal disinfection (93°C) → drying). Due to structural characteristics of rigid endoscopes, including narrow lumens at attachment entrances and tips with numerous concealed surfaces where soil can accumulate, the experimental group adjusted the cleaning process accordingly. A specialized rigid endoscope cleaning rack was custom-made for machine washing. Compared with the control group, the experimental group simplified manual cleaning steps and replaced manual ultrasonic cleaning, enzyme washing, lubrication, disinfection, and drying with theoretically more stable and efficient machine processing. The experimental group procedure was: water rinse → high-pressure water gun rinse →

machine washing (enzyme wash, alkaline wash, ultrasonic rinsing, lubrication, disinfection, drying).

Results showed the control group' s qualification rates were 85.0% (ATP) and 87.5% (microbial culture), both below expectations. The experimental group achieved 97.5% (ATP) and 95.0% (microbial culture). While some discrepancy exists between the two evaluation methods—because ATP values include both microbial and non-microbial ATP, with non-microbial ATP comprising 80-90% of the total; different microorganisms contain varying ATP amounts; and some anaerobes or viruses cannot grow under these culture conditions—the overall results demonstrate that manual cleaning combined with machine washing yields superior instrument cleaning quality.

Transferring portions of the manual cleaning process to automatic washer-disinfectors can effectively reduce workload, minimize risks of inadequate cleaning time at each stage, ensure contaminated instruments undergo fixed cleaning procedures, conditions, and durations, thereby improving consistency and reliability of cleaning quality.

3.3 Conclusion

For cleaning and disinfection of contaminated rigid endoscopes, combining manual cleaning with machine washing using a specialized rigid endoscope cleaning rack—building upon the "Technical Specifications for Cleaning and Disinfection of Endoscopes" —achieves more stable and reliable cleaning efficacy.

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Note: Figure translations are in progress. See original paper for figures.