Research on the Establishment and Effectiveness Evaluation of a Quality Monitoring System for Soft Endoscope Cleaning and Disinfection

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Abstract: In order to improve the stability of cleaning and disinfection quality of soft endoscopes, a full process quality control system was established starting from important operational links such as pre-treatment, manual brushing, disinfection, and final drying, and the implementation effect was evaluated. The results indicate that the cleaning qualification rate, disinfection compliance rate, operation specification execution rate, and record completeness rate have all been improved after the operation of the system, with minimal process fluctuations. Research shows that a quality monitoring system centered on controlling key operational behaviors can improve the quality management level of cleaning and disinfection of soft endoscopes.

***Keywords*:** flexible endoscope; cleaning and disinfection; quality control

1. Introduction

Soft endoscopes have complex structures and are often reused, and the quality of cleaning and disinfection directly affects medical safety. The effect of cleaning and disinfection is not only affected by the final test results, but more importantly, whether the pre-treatment is timely, whether the brushing is sufficient, and whether the drying is thorough. Establishing a quality control system that focuses on controlling key operational behaviors can have practical significance for stabilizing the processing process and reducing the risk of infection.

2. Basic manifestations of cleaning and disinfection quality of soft endoscopes

2.1 Operation status of pre-treatment stage before cleaning

After the diagnosis and treatment of soft endoscopes, the quality of pre-treatment is crucial for the subsequent cleaning and disinfection results. In practical work, used endoscopes are usually first treated in the diagnosis and treatment unit before entering the endoscope cleaning area. Bedside pretreatment, surface pollutant wiping, preliminary flushing of the lumen, and sealed transportation have all become routine operations. Overall, the process framework is relatively complete, but there are still differences in the degree of execution. Some positions can complete the removal of pollutants in a timely manner after the operation is completed, with good control of washing time and low load of mirror contamination. During peak hours, due to an increase in the number of consultations or delayed job connections, the start time of pre-treatment is relatively late, and the secretion stays on the body surface for a longer time, making it difficult to clean. This indicates that there is still some fluctuation in the execution of the pre-treatment stage.

2.2 Implementation of Cleaning and Disinfection Process

After entering the cleaning stage, soft endoscopes are generally subjected to leak detection, enzyme washing soaking, manual brushing, lumen perfusion, rinsing, disinfection, final rinsing, drying, and stored in designated locations. Most medical institutions already have relatively fixed processing paths, with increasingly complete configurations of equipment such as cleaning tanks, perfusion devices, and drying equipment, and a solid foundation in the process. In practical operation, the accuracy of the operation is reduced due to various factors such as human-machine cooperation, equipment turnover pressure, and complex endoscopic structure. It is difficult to clean some slender lumens or curved parts, and there may be differences in the depth of brushing and disinfection time control. Although record management can cover most aspects, there are still some issues with untimely filling and incomplete information at certain nodes.

2.3 Main manifestations of quality fluctuation links

The quality inspection results indicate that most of the fluctuations in the cleaning and disinfection of soft endoscopes occur in several important stages. Short pre-treatment time at the bedside can lead to an increase in organic residues. Due to differences in experience, the degree of thorough cleaning in the manual brushing process cannot be guaranteed to be consistent. Inadequate drying management after disinfection can lead to new risks of residual moisture in the lumen during

storage. Record management emphasizes results over processes, lacks process information, and makes problem tracing difficult. Overall, there are periodic fluctuations in the quality of cleaning and disinfection within the basic standard range, mainly due to the lack of monitoring of key nodes.

3. Construction of a Quality Monitoring System for Cleaning and Disinfection of Soft Endoscopes

3.1 Setting of Quality Monitoring Objectives

The establishment of a quality monitoring system for cleaning and disinfection of soft endoscopes is not about adding traceability links, but about controlling key operational behaviors that affect cleaning quality. The monitoring objectives mainly focus on four aspects: timeliness of pre-processing, adequacy of manual brushing, standardization of disinfection effects, and integrity of final drying, while also considering record management, abnormal feedback, and problem analysis. Quality control shifts from final result inspection to process control, allowing problems to be identified and corrected before entering the next processing step. The determination of such goals is more in line with the characteristics of concealed lumen, fine structure, and high dependence on manual operation of soft endoscopes.

3.2 Setting of Quality Monitoring Indicators

The setting of indicators should follow the principle that the quality of key operations can be measured, verified, and compared. The main observation indicators of the system include the washing interval after use, enzyme washing soaking time, completion rate of tube brushing, implementation of brushing in key areas, effective concentration of disinfectant, disinfection time, final rinsing execution, drying time, ATP residue results, colony monitoring results, and record completeness rate. The three stages of pre-treatment, brushing, and drying are considered as key control objects because they directly affect the degree of removal of mirror contamination load and are also the areas where the fluctuation of cleaning qualification rate is most likely to occur. Specific numerical standards have been set for each indicator, which is beneficial for frontline employees to operate according to the standards and for quality control personnel to continuously compare and analyze each indicator.

Table 1. Setting of core indicators for monitoring the cleaning and disinfection quality of flexible endoscopes

Indicator	Monitoring standard value	Monitoring frequency
Washing interval after use (in minutes)	≤15.0	1.0 times per lens
Enzyme washing and soaking time (in minutes)	2.0–5.0	1.0 times per lens
Lumen brushing completion rate %	100.0	1.0 times per lens
Effective concentration of disinfectant (%)	≥2.0	2.0 times per shift
Disinfection duration (in minutes)	≥5.0	1.0 times per lens
Drying time (min)	≥10.0	1.0 times per lens
ATP residual value RLU	≤200.0	3.0 times daily
Colony monitoring pass rate %	100.0	1.0 times per week
Record completeness rate %	≥98.0	Once daily

3.3 Abnormal situation feedback handling mechanism

The abnormal feedback mechanism operates in an instant reporting, on-site verification, time limited rectification, and closed-loop review mode. Delayed washing, incomplete brushing, excessive concentration of disinfectant, insufficient drying, and abnormal test results are all considered as key feedback contents. Once the abnormality is confirmed, the endoscope is immediately discontinued and can only be put back into use after reprocessing and re examination. Classify and summarize abnormal events on a monthly basis, mainly analyzing high-frequency problems such as untimely pre-processing, inadequate brushing of key areas, and insufficient final drying, and then improving them through job training and process correction. This mechanism enables quality control to be truly implemented in specific operational behaviors, and also returns record management to the functional positioning of auxiliary analysis and continuous improvement.

Table 2. Settings for the handling time limit of abnormal feedback related to the cleaning and disinfection of flexible endoscopes

Exception Type	Reporting deadline min	Time limit for disposal completion (in minutes)	Responsible Position
Exceeding the laundry deadline	10.0	30.0	Job position
Leak test anomaly	5.0	20.0	Cleaning position
Abnormal disinfectant concentration	5.0	15.0	Cleaning position
Insufficient drying	10.0	25.0	Cleaning position
ATP detection exceeds the standard	10.0	40.0	Quality Control Position
Abnormal colony monitoring	30.0	120.0	Quality Control Position

The key to this system lies not in the form of recording itself, but in implementing important operational processes such as pre-treatment, brushing, and drying to specific positions, and relying on monitoring to detect and correct deviations in a timely manner. Record management in the system mainly plays a role in process tracking and problem analysis. This construction method transforms the experience based cleaning and disinfection of soft endoscopes into a controlled state of key behaviors, laying the foundation for subsequent effectiveness evaluation.

4. Quality improvement after the implementation of the quality monitoring system

4.1 Changes in Cleaning Quality

After the operation of the quality monitoring system, there is a more stable improvement trend in the cleaning quality of soft endoscopes. The cleaning effect before implementation is affected by whether the pre-treatment is timely, whether the manual brushing is sufficient, and whether the lumen perfusion is in place. Fluctuations often occur at different time periods. After the implementation of the system, pre-treatment time became the main control object, and the brushing requirements for key areas became more specific. The depth of manual brushing and the treatment of the lumen were strengthened. The frequency of abnormal values in ATP detection has significantly decreased, and the rate of repeated backwashing has also decreased synchronously, indicating that the improvement in cleaning quality is mainly due to the standardization of key operating behaviors, rather than relying solely on final inspections.

4.2 Changes in disinfection standards

After the implementation of the system, the disinfection compliance rate has greatly improved. In the past, the quality of disinfection mainly relied on final spot checks, and deviations in disinfectant concentration, action time, and final rinsing were prone to occur during peak work periods. After the monitoring system is put into operation, the concentration of disinfectant, action time, and program matching are all included in real-time verification, and operational review allows deviations to be detected during the shift. The colony detection results indicate that the disinfection qualification rate has remained at a high level, and the periodic fluctuation range has also decreased. The improvement of disinfection standards relies on the stable improvement of cleaning quality, and it is also the result of process control having a direct impact on the final outcome.

4.3 Record management of complete changes

After the system is put into operation, the integrity of record management is greatly improved. Before monitoring, there was more focus on result registration, with little process information, making it difficult to accurately identify the link where the deviation occurred during problem analysis. After the implementation of the system, the recorded content is closer to important operational links, including washing time, brushing nodes, disinfection parameters, drying conditions, and abnormal handling, all of which are made into continuous traces. After improving the completeness of records, quality analysis can be directly judged based on the original operational information. It should be pointed out that record management is not the main intervention method in this study. It plays a more auxiliary role in discovering and supporting quality analysis, and is also the basis for future job improvement.

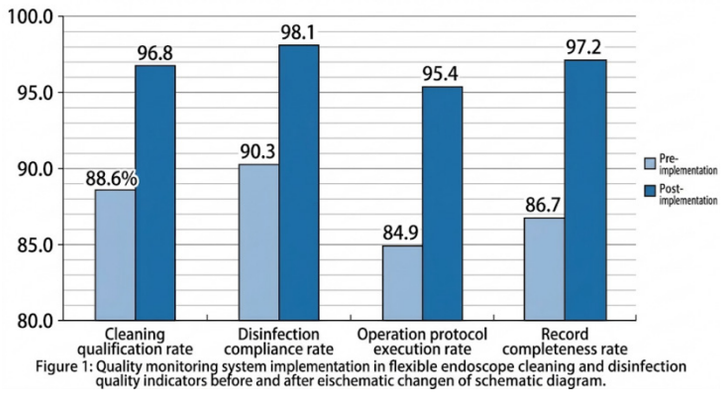

Figure 1. Schematic diagram of changes in soft endoscope cleaning and disinfection quality indicators before and after the implementation of the quality monitoring system

Figure 1 illustrates that after the establishment of the quality control system, there have been significant improvements in various indicators. The cleaning qualification rate has increased from 88.6% to 96.8%, the disinfection compliance rate has increased from 90.3% to 98.1%, and the execution rate of operating standards and the completeness rate of records have also increased synchronously. The results indicate that full process monitoring with a focus on previous processing, brushing, drying, and other main steps can reduce process fluctuations and improve the stability of cleaning and disinfection quality of soft endoscopes.

5. Conclusion

The research results indicate that implementing key control measures throughout the cleaning and disinfection process of flexible endoscopes, using critical operational behaviors as a means, can effectively improve various indicators of the quality of cleaning and disinfection of flexible endoscopes, and enhance the stability of the cleaning and disinfection process. The timeliness of pre-treatment, adequacy of manual brushing, and completeness of final drying are the main factors determining the cleaning qualification rate and disinfection compliance rate. Strengthening monitoring of important nodes and immediately rectifying quality issues can reduce quality fluctuations. Record management here mainly plays a role in assisting analysis and problem localization. This model provides a feasible management approach for medical institutions to improve the safety level of endoscopic processing.

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