

Establishment of a quality control circle to reduce biofilm formation in flexible endoscopes by improvement of qualified cleaning rate

Yingxia Luo¹, Qixuan Yang¹, Bingkun Li¹  and Yao Yao²

Abstract

Objective: In recent years, the Emergency Care Research Institute has advised that endoscope cleaning is of considerable importance. In the present study, a quality control circle (QCC) was used to reduce the formation of biofilms in flexible endoscopes within one hospital in Guangdong Province, China.

Methods: During reprocessing of 235 flexible endoscopes in the urology surgical suite, adenosine triphosphate (ATP) detection was used to monitor the efficacy of biofilm removal. The internal and external parts of flexible endoscopes were used as sampling sites by means of the flushing and smudge methods, respectively. When the two results reached the standard of less than 500 relative light units/piece at the same time, endoscopic biofilm clearance was considered to be qualified. A QCC was established to implement a 10-step plan-do-check-act model.

Results: The baseline qualified rate (i.e., ATP monitoring pass rate) during reprocessing of 235 flexible endoscopes was 50%. During the study, the qualified rate increased to 85.29% after establishment of the QCC. During reprocessing of 150 flexible endoscopes in the following 6 months, the qualified rate remained at 90%.

Conclusion: Establishment of the QCC improved the removal of biofilm from flexible endoscopes in the urology surgical suite.

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Keywords

Quality control circle, flexible endoscope, biofilm, qualified rate, cleaning, China, urology

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Introduction

Many types of endoscopes are used in clinical diagnosis and treatment. However, the decontamination of these endoscopes is challenging. From 2011 to 2019, the Emergency Care Research Institute has advised that endoscope cleaning is of considerable importance. Reprocessing lapses are regarded as a widespread and ongoing problem, despite the existence of guidelines.^{1,2} Cystoscopies and ureteroscopies have been linked to outbreaks of infections.^{3,4} Unfortunately, some healthcare workers do not fully follow the guidelines and protocols necessary to ensure the microbiological safety of endoscopes. There is increasing evidence that infections are transmitted by flexible endoscopes.⁵ A bacterial biofilm is defined as a community of microorganisms encased within an extracellular polysaccharide matrix, which adheres to a surface.⁶ Bacterial biofilms are associated with a wide range of infections. Notably, more than 60% of endoscopic infections have been caused by bacterial biofilms.⁷ A large number of studies have shown that biofilms persist in sterilized endoscopes.⁸ Specific cleaning methods are needed to remove residual bacteria and reduce the probability of biofilm formation. A recent study of flexible endoscopes (including ureteroscopes) revealed that more than 70% were not sufficiently clean to prevent infection.⁹ In the USA, a survey of 67 centers in three states demonstrated that more than 28% of the centers did not strictly follow the recommended guidelines for endoscopic reuse.¹⁰

Quality control circles (QCCs) based on the Deming cycle (also known as the plan-do-check-act [PDCA] model) include 10 steps for ensuring adherence to specific procedures.¹¹ This study was performed to assess the efficacy of the QCC approach with respect to reducing the formation of biofilms in flexible endoscopes in the urology surgical suite.

Methods

Ethical considerations

All analyses were based on guidelines to improve the cleaning quality of flexible endoscopy, which is a routine procedure. Therefore, the requirement for ethical approval or patient consent was waived by the hospital's ethics committee.

QCC team

The QCC team comprised two doctors, nine nurses (two head nurses, six urological specialist nurses, and one sensor nurse), one quality control manager, and one engineer. Senior titles, junior titles, and master's degree or above were held by 23%, 21%, and 30% of the team, respectively. Table 1 shows the demographics of the team.

Plan

Issue selection. The 13 members of the QCC team voted to select one issue from among five issues generated by circle members, scored according to the following characteristics: urgency, importance, hospital policy,

Table 1. Demographics of the quality control circle team.

Number	Gender	Experience (years)	Area of specialty	Position in the circle	Responsibilities
1	Female	15	Quality control senior diagnostician	Instructor	Project executive
2	Female	7	Nursing management	Group Leader	Planning, organization, training, supervision
3	Female	8	Urology specialist nurse	Member	Training and statistics
4	Female	29	Nursing management	Member	Guidance, supervision, and evaluation
5	Female	25	Nursing management	Member	Guidance, supervision, and evaluation
6	Male	5	Urology physician	Member	Laboratory analysis
7	Male	5	Urology physician	Member	Research regarding instruments and reagents
8	Female	15	Infection management specialist nurse	Member	Guidance, supervision, evaluation, and specimen collection
9	Female	3	Urology endoscopy nurse	Member	Implementation
10	Female	3	Urology endoscopy nurse	Member	Implementation
11	Female	3	Urology endoscopy nurse	Member	Implementation
12	Female	3	Urology endoscopy nurse	Member	Implementation
13	Male	15	Equipment engineer	Member	Market research

and lap capacity based on the “5-3-1” rule.¹² The most important issue was to reduce biofilm formation in flexible endoscopes by improvement of the qualified cleaning rate, based on the weighted rating method.

Plan and goal establishment. The study was designed based on implementation of the PDCA model in Zhujiang Hospital, Southern Medical University from March 2018 to May 2019. Cleaning processes were examined for three types of flexible endoscopes: flexible video-uretero-renoscopes (Karl Storz 11278VS; Karl Storz, Tuttlingen, Germany), uretero-fiberscopes (Karl Storz 11278A1; Karl Storz), and flexible cystoscopes (HAWK DPG-II; Hangzhou Hawk Optical Electronic Instruments Co., Ltd., Hangzhou, China). Adenosine triphosphate (ATP) detection was used to monitor the efficacy of biofilm removal from flexible

endoscopes after the completion of cleaning during the period from 1 March 2018 to 31 June 2018. The internal and external parts of flexible endoscopes were used as sampling sites by means of the flushing and smudge methods, respectively.

In total, 235 operations were examined in the planning period, including 45 involving a flexible video-uretero-renoscope, 93 involving a uretero-fiberscope, and 97 involving a flexible cystoscope. The results showed that the ATP monitoring pass rate was 50%, based on a criterion of concurrent external and internal ATP monitoring results less than 500 relative light units. Based on the results of a questionnaire checklist for cleaning flexible endoscopes before establishment of the QCC, the cumulative frequency of four dominant factors (monitoring, pre-treatment, cleaning, and leak detection; all determined using Pareto's principle¹²) was 81.18%. These four factors were regarded as the focus of

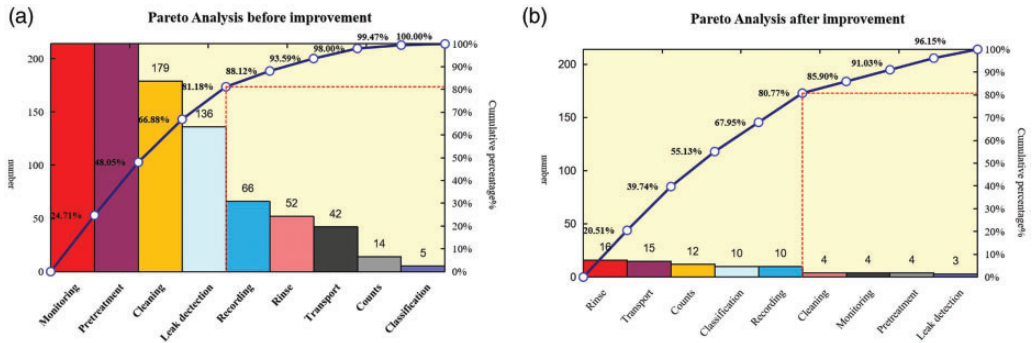


Figure 1. Pareto analysis before and after improvement. a: before improvement; b: after improvement.

efforts to prevent the formation of biofilms in flexible endoscopes in the urology surgical suite, prior to sterilization. The results of Pareto analysis before improvement are shown in Figure 1a. This study set the following goals for removal of biofilm from flexible endoscopes:

1. Goal value = value before improvement + $(1 - \text{value before improvement}) \times \text{lap capacity} \times \text{improvement focus} \times 100\%$
2. Growth rate = $(\text{goal value} - \text{value before improvement}) / \text{value before improvement} \times 100\%$

The ATP monitoring pass rate before improvement was 50%, the lap capacity (i.e., according the “5-3-1” rule, grading registration was divided into three levels:¹² 5 = solve problems by themselves, 3 = one department must cooperate; and 1 = many departments must cooperate; lap capacity = $\text{average score} / 5 \times 100\%$) was calculated to be 82.23%, and the improvement focus (i.e., cumulative frequency based on the goal of solving the first 80% of major problems¹²) was 81.18%. Therefore, the team planned to increase the pass rate from 50% to 83.38% by January 2019, which constituted a 38.41% growth rate.

Cause analysis. During “brainstorming” sessions, fishbone diagrams were generated by

the team members (Figure 2). For monitoring of four factors including monitoring unqualified, pretreatment unqualified, cleaning unqualified, and side leakage unqualified, 32 terminal causes were proposed (Table 2) from the following five aspects: people, machines, materials, methods, and environment. Team members scored the terminal causes. In accordance with Pareto’s principle, terminal causes with scores >52 were extracted. Finally, seven causes that might affect endoscope reprocessing were identified: lack of consistent cleaning personnel, lack of professional training, lack of a traceability system, lack of pre-treatment wipes, lack of specified leak detection process, lack of detailed cleaning, and lack of biofilm removal monitoring process. To identify the “root causes,” the team generated new follow-up checklists. For example, to affirm the lack of pretreatment wipe application, the team developed an audit standard to assess whether enzyme-containing gauze towels were used for pre-treatment. The audit tool was a custom clinical checklist of pre-treatment tasks to be performed after the use of a flexible endoscope; the audit method comprised case-by-case traceability. Audits revealed that all seven of the above suggested causes constituted root causes. Table 3 depicts the root cause analysis.

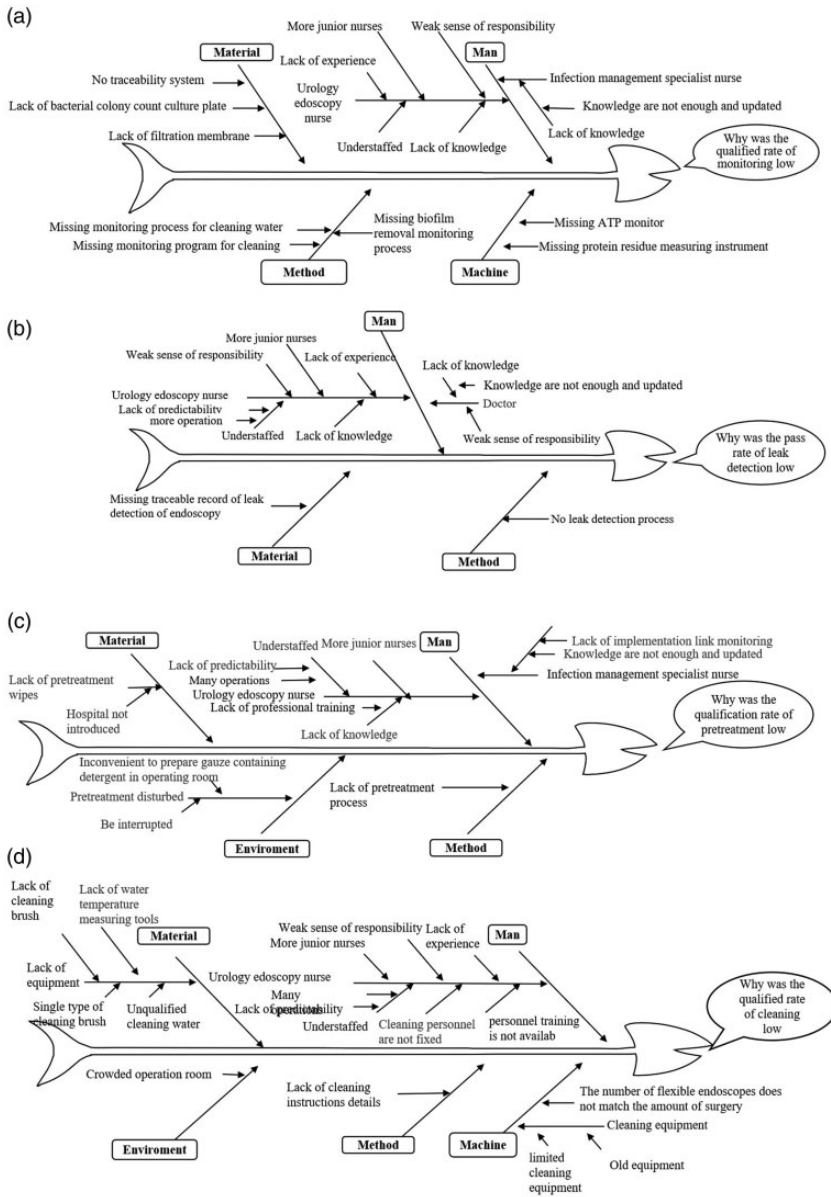


Figure 2. Fishbone diagram. a: Why was the qualified rate of monitoring low?; b: Why was the pass rate of leak detection low?; c: Why was the qualification rate of pretreatment low?; d: Why was the qualified rate of cleaning low?

ATP, adenosine triphosphate.

Table 2. Terminal cause analysis.

Five aspects	Terminal factor	Score
People	Lack of predictability	33
	Insufficient and outdated knowledge	39
	Weak sense of responsibility	29
	Lack of experience	25
	Lack of professional training	63
	Lack of knowledge	47
	Inconsistent cleaning personnel	53
	Understaffing	35
	High number of junior nurses	41
Materials	Lack of bacterial colony count culture plates	49
	Lack of filtration membranes	36
	Inadequate water filtration	34
	Lack of traceability system	57
	Missing traceable record of endoscope leak detection	49
	Lack of pretreatment wipes in the hospital	63
	Lack of cleaning brushes	34
	Lack of tools for measurement of water temperature	43
	Limited types of cleaning brushes available	36
Methods	Lack of biofilm removal monitoring process	56
	Lack of monitoring process for water filtration	35
	Lack of monitoring program for cleaning	33
	Lack of leak detection process	53
	Lack of pretreatment process	37
Environment	Lack of detailed cleaning instructions	53
	Inconvenience regarding preparation of detergent-containing gauze in operation room	35
	Crowded operation room	31
Machines	Presence of interruptions	33
	Lack of ATP monitoring	35
	Lack of instrument for measurement of protein residue	21
	Old equipment	31
	Limited access to cleaning equipment	34
	Insufficient supply of flexible endoscopes	31

Solution formulation. In accordance with the principles of “5W1H” (i.e., Why, What, Where, When, Who, and How), the team developed countermeasures. These countermeasures consisted of four categories: creation of an evidence-based process for removal of biofilm from flexible endoscopes, optimization of endoscopic traceability management, introduction of effective pretreatment wipes, and development of a standardized training program.

Do

Creation of an evidence-based process for removal of biofilm from flexible endoscopes. Prior to establishment of the QCC, there were three relevant root causes for this removal process: lack of a specified leak detection process, lack of a detailed cleaning process, and lack of a biofilm removal-related monitoring process. From 30 November 2018 to 30 December 2018, the team established a

Table 3. Root cause analysis.

Causes	Inspection method	Inspection tools	Inspection standard	Number of samples	Number of defects	Defect rate	Judgment results
Inconsistent cleaning personnel	Case-by-case traceability	Custom "Flexible endoscope cleaning personnel checklist"	Cleaning is completed independently	36	29	80.56%	Root cause
Lack of professional training	Questionnaire investigation	"Questionnaire regarding flexible endoscope cleaning knowledge" based on published guidelines	Questionnaire score >80	26	23	11.54%	Root cause
Lack of traceability system	Case-by-case traceability	Custom "Endoscope leak detection traceability checklist"; "Endoscope cleaning and disinfection/sterilization registration"	Cleaning personnel, cleaning time, leakage detection personnel, and leakage detection results can be traced	50	49	98.00%	Root cause
Lack of filtration membrane	Case-by-case traceability	Custom clinical checklist for implementation of pretreatment to remove biofilm from flexible endoscopes	Use of enzyme-containing gauze for pretreatment	36	30	83.33%	Root cause
Lack of leak detection process	Case-by-case traceability	Custom "Biofilm clearance from flexible endoscopes leak detection checklist"	Flexible endoscope leakage detection process consistent with published guidelines	36	32	88.89%	Root cause
Lack of detailed cleaning instructions	Case-by-case traceability	Custom "Flexible endoscope cleaning implementation process checklist"	Flexible endoscope cleaning process consistent with published guidelines	36	32	88.89%	Root cause
Lack of biofilm removal monitoring process	Case-by-case traceability	Custom "Flexible endoscope cleaning monitoring process checklist"	Implementation of biofilm removal monitoring	36	33	91.67%	Root cause

process for removal of biofilm from flexible endoscopes, using the following three steps. First, the team reviewed and summarized guidelines^{13,14} regarding the use of flexible endoscopes, then conducted an evaluation of guidelines for implementation in our hospital. This evaluation comprised quantitative assessment of feasibility, suitability, significance, and effectiveness by three doctors and two nurses from our hospital. Grading registration was divided into four levels: 4 = strongly agree, 3 = agree, 2 = disagree, and 1 = strongly disagree. In accordance with the usability survey results, all evaluated guidelines were implemented. Second, based on the principles of evidence, professional judgment, and situational analysis, the reviewed guidelines were converted into a process for monitoring the removal of biofilm from flexible endoscopes and an accompanying evaluation index that could be used by the surgical endoscopy center in our hospital. The timing and staff in charge of the monitoring process were discussed. Third, combined with the above guidelines and experience in clinical practice, the monitoring index, monitoring method, and timing of flexible endoscopic biofilm removal were determined.

Optimization of endoscopic traceability management. With respect to the lack of consistent cleaning personnel, the team discussed determination of clear job responsibilities to ensure identification of consistent cleaning personnel. The team defined the contents of traceability management and enabled traceability through modifications of the warehouse management software system.

Introduction of effective pre-treatment wipes. Through literature review and market research, team members identified suitable multi-enzyme pre-treatment wet wipes. All literature reviews were performed using the PubMed, ScienceDirect, and

CNKI databases during the period from 1 January 2009 to 31 December 2019. The key words used in literature review were “pretreatment,” “endoscopy,” and “detergent.” Pretreatment was confirmed to improve the effects of cleaning and reduce the formation of biofilm on the surface and within the conduit of flexible endoscopes.¹³ The market research involved brief introductions of potential products into the hospital. Because some Gram-negative bacteria undergo cell division every 20 to 30 minutes, all reprocessing steps must be completed rapidly prior to the onset of bacterial growth and contamination on the endoscope surface.¹⁵ The team determined that one-time use wipes should be used immediately after operation under the supervision of the circulating nurse in the operating room.

Development of a standardized training program for removal of biofilm from flexible endoscopes.

The research team sent a nurse to the National Endoscopy Conference to receive detailed training. On the basis of theoretical training and interpretation of the guide, one-on-one training was carried out for removal of biofilms from flexible endoscopes. Before and after training, all nurses completed assessments of their knowledge regarding biofilm removal.

Check

The flexible endoscope cleaning pass rate was investigated in the urology surgery suite during the period from 1 January 2019 to 12 May 2019. ATP values were compared before and after establishment of the QCC.

Act

The flowchart was standardized for improvement and renewed at 1-year intervals.

Effect confirmation

The evaluation indices for tangible outcomes included achievement and improvement indexes with the following equations:

1. Achievement Index = $(\text{value after improvement} - \text{value before improvement}) / (\text{goal value} - \text{value before improvement}) \times 100\%$
2. Improvement Index = $(\text{value after improvement} - \text{value before improvement}) / \text{value before improvement} \times 100\%$

New Pareto analyses were repeated to determine whether factors had changed, with respect to unqualified cleaning of flexible endoscopes, after initial improvement.

For intangible outcomes, evaluations were made regarding problem-solving ability, sense of responsibility, communication and coordination, team cohesiveness, self-confidence, and approach to quality control. The activity growth value was used to assess intangible outcomes, such that positive values indicated improvement and negative values indicated deterioration. Each aspect was assessed by QCC members through self-evaluation; the highest possible score was 5 points and the lowest possible score was 1 point, as previously described.¹⁶ Scores were recorded using the following equation:

$$\begin{aligned} \text{Activity Growth Value} \\ &= \text{mean score after activity} \\ &\quad - \text{mean score before activity} \end{aligned}$$

Results

Tangible outcomes

From 1 January 2019 to 12 May 2019, 235 operations were analyzed, including 48 involving a flexible video-ureterorenoscope, 95 involving a ureterofiberscope, and 92 involving a flexible

cystoscope. The ATP monitoring pass rate (i.e., qualified rate) increased from 50% to 85.29% after establishment of the QCC. According to the calculation formula, the achievement index was 105.72%, while the improvement index was 70.58%. Table 4 shows that the cumulative frequency of the following new dominant factors was 80.77%, based on repeated Pareto analysis: rinse, transport, counts, classification, recording. The results of Pareto analysis after improvement are shown in Figure 1b. Continuous quality improvement showed that the ATP monitoring pass rate among 150 additional operations (April 2019 to October 2019) increased from 85.29% to 90%.

Process for removal of biofilm from flexible endoscopes

The flowchart depicting flexible endoscope reprocessing in the urology surgical suite prior to establishment of the QCC is shown in Figure 3a; reprocessing after establishment of the QCC is shown in Figure 3b. Careful manual cleaning was a prerequisite for further cleaning and disinfection in automated endoscope washer-disinfectors. Artificial cleaning, especially the basis for washing procedures for mechanical cleaning, was considered an irreplaceable step for mechanical cleaning. The process of manual cleaning is shown in Figure 4. Leak detection was an important step. This study established three-leak detection, as shown in Figure 5. In addition, the QCC team established diagrams to help nurses understand the standardized process. A diagram of the manual cleaning process for flexible cystoscopy is shown in Figure 6.

Intangible outcomes

After establishment of the QCC, considerable improvements were noted in problem-solving ability, sense of responsibility,

Table 4. Factors associated with biofilm removal: relationships with qualified rates of flexible endoscopes before and after establishment of the quality control circle.

Assessed factors	Before establishment of QCC			After establishment of QCC		
	Unqualified frequency	Percentage	Cumulative percentage	Unqualified frequency	Percentage	Cumulative percentage
Monitoring	235	100.00%	24.71%	4	1.70%	91.03%
Pretreatment	222	94.47%	48.05%	4	1.70%	96.15%
Cleaning	179	76.17%	66.88%	4	1.70%	85.90%
Leak detection	136	57.87%	81.18%	3	1.28%	100%
Recording	66	28.09%	88.12%	10	4.26%	80.77%
Rinse	52	22.13%	93.59%	16	6.81%	20.51%
Transport	42	17.87%	98.00%	15	6.38%	39.74%
Counts	14	5.96%	99.47%	12	5.11%	55.13%
Classification	5	2.13%	100.00%	10	4.26%	67.95%

QCC, quality control circle.

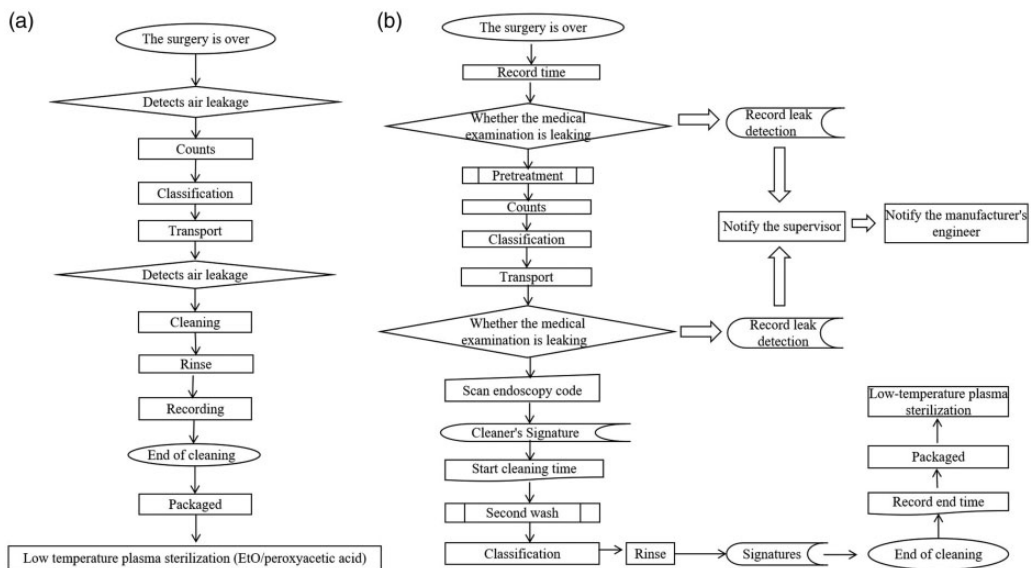


Figure 3. Reprocessing flowcharts of urology flexible endoscopy before and after establishment of the QCC. a: Cleaning comprised six steps before establishment of the QCC; b: Cleaning comprised 14 steps after establishment of the QCC.

QCC, quality control circle; EtO, ethanol.

coordination, communication and self-confidence, team unity, enthusiasm, and quality control practices and harmony. Specifically, the activity growth values

were 1.5 for ability to solve problems, 1.3 for sense of responsibility, 1.3 for communication and coordination, 1.5 for confidence, 1.3 for cohesion, 1.5 for initiative,

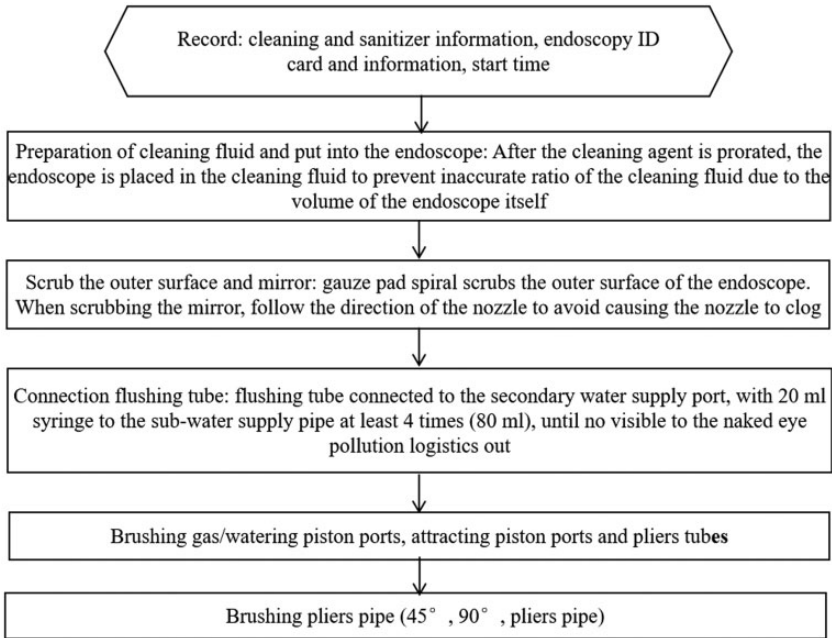


Figure 4. Flexible endoscope manual cleaning process. ID, identification.

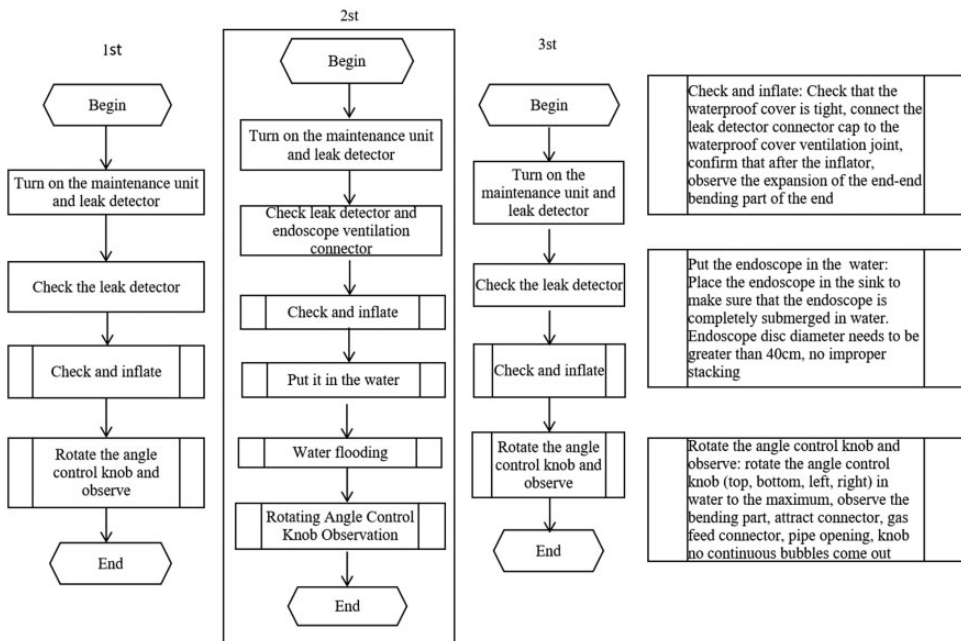
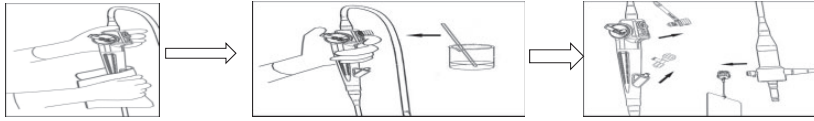


Figure 5. Leak detection implementation process.

Pretreatment

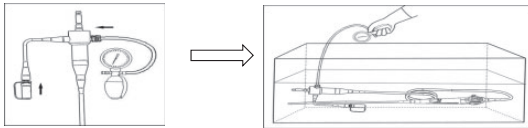


Soft cloth soaked in detergent wipes surface from top to bottom

By attracting the pipe to inhale the detergent and then inhale the air

Remove all removable parts and cleaning utensils

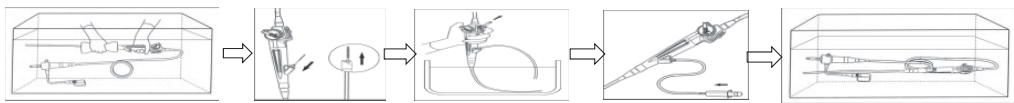
Leak test



Before soaking, lock the plug to disinfect the cover and attach it

- Use the leak detector to fill the air, and then soak the entire endoscope in clean water
- Adjust the angle of the front end during leak detection
- First rotate the deflating nut, remove the leak after the pointer returns to zero and the bent rubber returns to normal

Manual cleaning



Soak the endoscope in freshly prepared washing liquid. Cleaning all outer surfaces

Brush the insertion part of the pipe that attracts it, brushing repeatedly until the debris is completely removed

Inhale detergent into the suction pipe

Rinse with washing fluid into the clamppipe

Soak the endoscope in the washing liquid at the time recommended by the detergent manufacturer

Figure 6. Diagram of manual cleaning process for flexible endoscopes in the urology surgical suite.

2.0 for approach of QC, 1.5 for harmonious degree, 1.4 for language skills, 1.2 for sense of honor, and 1.4 for personal qualification.

Discussion

Endoscopic reprocessing is a multi-stage process. Ten steps (i.e., pretreatment, transfer, leak detection, hand cleaning and self-cleaning, rinsing, monitoring, disinfection/sterilization, final rinsing, drying, and storage) are included in the most recent domestic and international endoscopic reprocessing guidelines.^{13,14} The European Society of Gastrointestinal Endoscopy,

European Society of Gastroenterology and Endoscopy Nurses and Associates, and American Society for Gastrointestinal Endoscopy have emphasized that cleaning is the most important step in the reprocessing process, but that disinfection or sterilization alone is insufficient.^{17,18} Considering that biofilms are irreversible after they have formed, this study aimed to reduce the biofilm formation in flexible endoscopes by improving the quality of cleaning protocols prior to disinfection/sterilization of flexible endoscopes. The results showed that the pass rate of biofilm removal from flexible endoscopes increased from 50% to

85.29%, indicating that establishment of the QCC was effective for improving the flexible endoscope cleaning process.

The evidence-based countermeasures implemented in this study were developed to enhance cleaning of flexible endoscopes in the urology surgical suite. The “Technical regulations for cleaning and veal of the flexible endoscopes”¹⁵ was the main basis for the development of cleaning and monitoring processes in this study; this set of technical regulations adheres to China’s existing standards and norms, as well as international requirements for cleaning and detoxification of flexible endoscopes. In present study, we developed standard processes for general use of flexible endoscopes, including manual cleaning, leak detection, and monitoring.

Previous studies have suggested that improving the awareness of cleaning personnel through regular education and competency assessments is an important strategy for prevention of reprocessing errors.¹⁶ In the present study, all endoscopy nurses were required to pass a regular assessment regarding reprocessing of flexible endoscopes. The results showed an increased quality of reprocessing staff, as well as a reduction of >30% regarding the risk of infection.¹⁷ However, a limited number of specialist endoscopy nurses were responsible for cleaning all endoscopes in our hospital. This approach was implemented to improve the quality of the cleaning process, which ensured consistency.

In conclusion, we established a QCC that implemented a new cleaning process and relevant monitoring. Establishment of this QCC led to improvement of the flexible endoscopy cleaning pass rate. The literature suggests that a conventional assessment and multidisciplinary team microbial monitoring method should be carried out for flexible endoscope reprocessing.¹⁸ Notably, only one method of ATP monitoring was used in this study. During the quality

improvement process follow-up analysis, the QCC team will enhance their assessments of the methods used for flexible endoscope reprocessing.

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Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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