ORIGINAL ARTICLE

The implementation of a manual pretreatment phase increases the efficacy of automated reprocessing procedures in postprocedural bronchoscopes

La mise en œuvre d'une phase de prétraitement manuel augmente l'efficacité des procédures de retraitement automatisées dans les bronchoscopes post-procéduraux

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Abstract

Introduction: The reprocessing of flexible endoscopes has become a major research topic in recent decades. The risk of endoscopy-related bacterial, fungal or viral outbreaks is increasing, particularly those involving multi-resistant strains.

Aim: The aim of the present study was to assess the importance of implementing a manual pre-treatment phase in conjunction with HDL (High Level Disinfection) cleaning using a Steelco automated washer-disinfector. The aim of the study was to determine whether neglecting the manual pre-treatment phase, despite the use of a high-quality automated disinfector, leads to the spread of biofilms and of germs likely to cause healthcare-associated infections.

Methods: To achieve this objective, an extensive microbiological sampling process was carried out on bronchoscopes under normal cleaning and disinfection conditions prior to the introduction of the pre-treatment phase. Based on the results of these samplings, the Quality Control Circle (QCC) team proceeded to identify and analyze potential causes using the ISHIKAWA diagram during brainstorming sessions, following which microbiological sampling of the bronchoscopes after implementation of the results of the cause analysis was carried out.

Results: The results indicate complete elimination of bacterial strains after implementation of manual pretreatment followed by automated treatment, in line with international disinfection standards.

Conclusion: The implementation of a pre-treatment phase followed by a Steelco automated washer-disinfector significantly reduced microbial contamination in bronchoscopes.

Key words: Endoscope reprocessing, pretreatment phase, automated disinfection, microbial contamination, infection control.

Résumé

Introduction: Le retraitement des endoscopes flexibles est devenu un sujet de recherche majeur au cours des dernières décennies. Le risque d'épidémies bactériennes, fongiques ou virales liées à l'endoscopie augmente, en particulier celles qui impliquent des souches multirésistantes.

Objectif: La présente étude visait à évaluer l'importance de la mise en place d'une phase de prétraitement manuel en conjonction avec la désinfection de haut niveau à l'aide d'un laveur-désinfecteur automatisé de marque Steelco. L'objectif de l'étude était de déterminer si le fait de négliger la phase de prétraitement manuel, malgré l'utilisation d'un désinfecteur automatisé de haute qualité, entraîne la propagation de biofilms et de germe susceptible de causer des infections associées aux soins.

Méthodes: Pour atteindre cet objectif, un vaste processus d'échantillonnage microbiologique a été mené sur les bronchoscopes dans les conditions normales de nettoyage et de désinfection avant l'introduction de la phase de prétraitement. En se basant sur les résultats de ces prélèvements, l'équipe du cercle de contrôle qualité a procédé à l'identification et l'analyse des causes potentielles à l'aide du diagramme ISHIKAWA lors des séances de brainstorming, par suite un échantillonnage microbiologique des bronchoscopes après implantation des résultats de l'analyse des causes à été réalisé.

Résultats: Les résultats indiquent une élimination complète des souches bactériennes après la mise en œuvre d'un prétraitement manuel suivi d'un traitement automatisé, conformément aux normes internationales de désinfection.

Conclusion: La mise en œuvre d'une phase de prétraitement suivi d'un laveur-désinfecteur automatisé Steelco a permis de réduire de manière significative la contamination microbienne dans les bronchoscopes.

Mots-clés: Retraitement des endoscopes, phase de prétraitement, désinfection automatisée, contamination microbienne, contrôle des infections.

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Introduction

Reprocessing flexible endoscopes has emerged as a major research focus over the past few decades. As the frequency of endoscopic procedures increases each year, the risk of bacterial, fungal, or viral outbreaks linked to endoscopy also rises significantly. These outbreaks, especially those involving multiresistant strains, pose a significant challenge to healthcare systems worldwide. Every missed detail in the reprocessing protocol can have fatal consequences. Infection associated with endoscopy is now a common concern among physicians, healthcare specialists, and researchers. Numerous reviews and articles have addressed this issue, with many highlighting endoscope reprocessing as a critical factor in outbreaks (1).

In a recent review (2) analyzing 18 articles, 9 reported lapses in reprocessing, particularly during the drying, brushing, and timing phases. The outbreaks reviewed were mainly due to highly pathogenic strains such as *Pseudomonas aeruginosa, Salmonella enteritidis*, and *Klebsiella pneumoniae*. In respiratory endoscopic procedures, bronchoscopes are also highly susceptible to microbial contamination by strains such as *Escherichia coli, Mycobacterium tuberculosis, nontuberculous mycobacteria, Serratia marcescens, Stenotrophomonas maltophilia*, and *Legionella pneumophila*. (3) demonstrated that reprocessing lapses were common in these outbreaks. However, other factors, such as contaminated water, cleaning area contamination, and nonadherence to safety protocols, also contribute to these infections (1).

Reprocessing endoscopes is a critical step that requires meticulous attention to achieve optimal outcomes. Almost all guidelines breakdown the reprocessing process into multiple steps: manual pretreatment with a detergent liquid, brushing the internal and external structures of the endoscope, drying to prevent contamination between manual and automated reprocessing, and high-level disinfection through automated reprocessing. Despite the significant results achieved by today's automated reprocessors, guidelines emphasize the extreme importance of the pretreatment phase, as lapses in this step have been linked to many outbreaks (4).

Ensuring proper pretreatment and decontamination of endoscopes is not only essential but also pivotal. Healthcare associated infection (HCAI) tend to be fatal, and multiple reports indicate that inconsistencies in the drying phase, a crucial step in the reprocessing cycle, can lead to the transmission of these strains (5).

The importance of each phase in the reprocessing of endoscopes cannot be overstated. Manual pretreatment involves using a detergent liquid to remove biological debris, followed by brushing the internal and external surfaces of the endoscope. The drying phase ensures that no contamination occurs between manual and automated reprocessing. Automated reprocessing, which is designed to provide high-level disinfection, aims to sterilize the endoscope completely.

However, even with advanced automated reprocessing, manual pretreatment remains crucial. This is supported by numerous outbreak reports where lapses during pretreatment were identified as the cause (6).

The current study aimed to assess the significance of establishing a manuel pretreatment phase in conjunction with HLD cleaning using a Steelco automated washer disinfector. The objective of this study was to determine whether neglecting the pretreatment phase, despite the use of a high-quality automated disinfector, results in the spread of biofilms and HCAI in flexible endoscopes postprocedure and postreprocessing.

Methods

Study design

This is a prospective study comparing the results of automatic disinfection of bronchoscopes with and without a manual pre-treatment step. The study was divided into three stages:

- The bronchoscopes were sampled under normal cleaning conditions.
- Identification and analysis of potential causes using the ISHIKAWA diagram during brainstorming sessions.
- The results of Root-cause analysis and subsequent sampling were implemented; an extensive sampling process was carried out after the introduction of the pre-treatment phase.

Study parameters

Sample collection was carried out after respiratory endoscopy procedures and a complete high-disinfection cycle at the Moulay Youssef Hospital, part of the Ibn Sina Rabat Morocco University Hospital. This hospital specializes in pneumology and bronchoscopy, with a capacity of 84 beds, 2146 admissions, and 796 fibroscopic procedures in 2023.

The study period runs from July 2023 to February 2024 includes :

the collection of the first batch of samples prior to the implementation of manual pre-treatment was carried out in July, August, September 2023, a root cause analysis of the results carried out in October, November 2024.

and then the collection of a second batch of samples after the introduction of the pre-treatment phase during the period from December 2023 to February 2024.

Discontamination/decontamination procedure

Automated procedure

The automated cleaning of bronchoscopes was performed using a Steelco washer-disinfector (type EW1) following ISO15883 guidelines. The process includes external and internal disinfection and decontamination. First, external contaminants are removed, and then internal disinfection is performed using a specialized lavage disinfectant. The device operates at 45°C to ensure effective cleaning while protecting the thermosensitive endoscope (7).

After completion of the cycle, the endoscopes were placed in a 45°C drying cabinet. The cabinet uses UV light

to neutralize any remaining micro-organisms and prevent microbial growth. This drying step removes moisture and further disinfects the endoscopes, ensuring their cleanliness and sterility prior to the automated cleaning procedure

First batch of samples

The sampling procedure was carried out both externally and internally. For external sampling, swab sticks were used to collect the samples. For internal sampling, 05 internal samples were taken from 03 broncoscopes at different times. A sterile saline solution was injected into the internal tubes of the endoscopes, then the liquid was collected in sterile containers. The sampling procedure was carried out after a fully automated disinfection/ decontamination cycle.

Microbiological

The samples were taken to the microbiology unit of the hospital, where culture was performed, colonies were counted, and bacterial strains were identified using the standard microbial control procedure of the hospital.

Root-cause analysis

After analyzing the first set of results, the team proceeded to analyze each stage of the disinfection/decontamination process. The reflection started with a deep study of the scientific and reglementary articles found on the web. Each article and protocol were reviewed and analyzed, and the similarities and differences that were lacking in the process used in this study were determined. After a careful review of the documents, the quality control circle team (QCC) started the analysis of the process, and a fishbone model was used based on the 5 M method (machine, material, methods, measurement, man-power) [8]. Each step was carefully reviewed and analyzed during brainstorming sessions. The principal causes were then pinpointed, and potential solutions were then proposed and ranked using prioritization matrices by the QCC team. The selected solutions were then implemented in the process aim of the current study.

Second batch of samples

Based on the results of the brainstorming phase, the endoscopes were swabbed postimplementation and transported to the microbiology unit for further testing. At this level 06 samples were taken from 03 broncoscopes

Data analysis

Microbial analysis results are expressed in colony-forming units (CFU) per 100 milliliters of endoscope solution. Each set of results was compared with disinfection guidelines issued by French, Canadian and Swiss regulatory bodies French We sampled different parts of the bronchoscopes after they had been used at two different times:

1st time: After the automated disinfection procedure

2nd time: After the manual procedure and the automated disinfection procedure.

We then analyzed the microbiological data from samples taken from different parts of th bronchoscopes at these two times." (8).

Results

Before implementation testing

Quality control after a fully automated procedure. After a full round of automated decontamination, the samples were analyzed, and the results are shown in Table 1.

Table 1. Sample analysis after automated decontamination.

Sample number	endoscope number	Sample type	Conform ity	Germes	UFC /100 ml /Bronch oscope
1	Endoscope number 1	Interal liquid washing	None	*Pseudomnas aéroguénisa,*	10^5
2	Endoscope number 1	Interal liquid washing	None	*Acinetobacter baumanii*	10^6
3	Endoscope number 2	Interal liquid washing	None	*Pseudomonas putida*	10^6
4	Endoscope number 2	Interal liquid washing	None	*Staphylococcus cohni*	10^5
5	Endoscope number 3	Interal liquid washing	Non	*Eschirichia coli*	10^5
6	Endoscope number 1	Swab samples of the outer	Yes	No germ	0
7	Endoscope number 2	structure	Yes	No germ	0
8	Endoscope number 3		Yes	No germ	0
9	Storage cabinet	Swab of the cabinet inside (4 point)	Yes	No germ	0
10	Water analysis	Bacteriological research in the network water at the entrance to the device	Yes	No germ	0

Two bacterial strains responsible for HCAI, *Pseudomonas aeruginosa and Acinetobacter baumannii*, were isolated from the internal lavage fluid of the bronchoscopes. Bacterial enumeration revealed concentrations of 10^5 and 10^6 CFU/mL, respectively. According to infection control guidelines, the acceptable level for pathogens likely to cause HCAI such as *Pseudomonas aeruginosa* should be less than 1 CFU/100 mL. In our case, the *Pseudomonas* levels were significantly, greater at 10^5 CFU/mL, far exceeding the guideline limits. We also detected the presence of *Escherichia coli*, *Pseudomonas putida* and *Staphylococcus cohnii* at levels exceeding the guidelines needed.

Furthermore, guidelines stipulate that *Pseudomonas aeruginosa* should not be present at all in the samples and that other bacterial strains should not exceed 1 CFU/ mL.

Our findings revealed that the abundance of *Acinetobacter baumannii* at 10^6 CFU/mL, was significantly above the acceptable threshold. Interestingly, no bacterial strains were detected in the samples taken from the outer surfaces of the bronchoscopes or the storage cabinet. All the bacterial contamination was confined to the internal structure of the apparatus. This indicates that the internal channels are particularly susceptible to contamination and that the current cleaning protocols are insufficient for these critical areas.

Following the aforementioned results, the QCC team initiated a failure analysis, revisiting the guidelines utilized in the study. The mere presence of Pseudomonas aeruginosa indicated that the disinfection process was incomplete and inadequate. To identify the critical areas where the process failed, the team employed a fishbone diagram, as illustrated below. From this analysis, five potential critical points were detected. Their severity levels and corresponding solutions are outlined in Table 1.

Root-cause analysis

To identify the main causes of process inefficiency, the team worked during brainstorming session on a fishbone diagram, as illustrated below (Fig1).

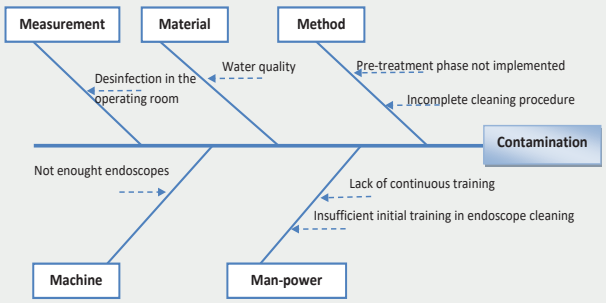

Figure 1. Chiffre 1. Ishikawa diagram of the study.

From this analysis, two main axes emerge (method and manpower), actions to be taken to treat the causes identified in each area were proposed and analyzed with prioritization matrice (Table 2).

Table 2. Action prioritization matrice

Essential	1. Raising staff awareness of endoscope treatment	2. Implementation of the pre-treatment phase	
Necessary		3. Planning of an ongoing training program for staff on controlling the risk of infection during endoscopy procedures	5. Acquisition of new endoscopes
Useful		4. Regular microbiological monitoring of water quality	6. Provide a special area for disinfection operations
	Easy	**Difficult**	**Very difficult**

This analysis highlighted two priority actions in order to remedy the potential causes of contamination, which are mainly linked to the neglect of the pre-treatment procedure prior to the complete automated disinfection cycle and the lack of training and awareness among staff of the procedures for disinfecting endoscopic equipment. The manual pre-treatment stage was identified as essential for reducing the microbial load prior to the automated cleaning process. After a thorough review of available protocols, the pre-treatment procedure was implemented.

This implementation was adapted from the guidelines and was performed following a specific set of steps that ensures decontamination of the apparatus throughout all the guidelines (9). The external structure of the endoscope must be preserved either via an automated washer-desinfector or by immersion in a chemically active detergent to facilitate cleaning, reduce contamination levels and protect the environment; this step should be performed directly after the end of the endoscopic act. After that, it is obligatory to use sterile swabs to complete the disinfection, followed by rinsing the endoscope with sterile water. The team added this phase accordingly, and another set of samples was collected (Table 3).

Postimplementation testing

After the implementation of the pretreatment phase, another round of sampling was performed, and the results are described in Table 3.

Table 3. Results after implementation of the pretreatment phase

Sample number	endoscope number	Sample type	Passed conformity?	Germe	CFU /100 ml /endoscope
1	**endoscope number 1**	Internal multicanal washing liquid	yes	none	0
2	**endoscope number 1**	Internal multicanal washing liquid	yes	none	0
3	**endoscope number 2**	Internal multicanal washing liquid	yes	none	0
4	**endoscope number 2**	Internal multicanal washing liquid	yes	none	0
5	**endoscope number 3**	Internal multicanal washing liquid	yes	none	0
6	**endoscope number 3**	Internal multicanal washing liquid	yes	none	0

After implementation the manual pretreatment phase, the bronchoscopes were completely decontaminated, as no bacterial strain was found in the outer or internal structure of the bronchoscopes. These results are in line with all the guidelines previously mentioned, and there was no qualitative or quantitative detection of bacteria in the samples, which confirmed that our process conformed to the normal conditions.

Discussion

Our findings suggest that implementing a pretreatment phase before starting automated disinfection/ decontamination procedures improves the microbiological control of materials. Prior to this implementation, we isolated five bacterial biofilms: Pseudomonas aeruginosa, Acinetobacter baumannii, *Escherichia coli, Staphylococcus cohnii*, and *Pseudomonas putida*.

The detection of these bacteria indicated that the initial decontamination process for flexible endoscopes did not meet international standards. The persistence of biofilms on endoscopes after automated cleaning can be attributed to various factors. Microbes are known to survive in diverse environments for extended periods. Traditional methods involving temperature and pressure for decontaminating non thermosensitive medical equipment are widely accepted as effective (10-13).

However, due to the heat sensitivity of endoscopes, alternative approaches such as chemical disinfection combined with pressure treatment are essential for accessing thermosensitive materials. Chemical agents such as detergents, while highly effective, have limitations due to the complex nature of biofilms, which include polysaccharides, eDNA, and other components that form an extracellular protective matrix around bacterial cells (12).

Currently, thorough disinfection relies on a comprehensive protocol that integrates both manuel pretreatment and automated treatment phases as the gold standard. Our analysis, utilizing a fishbone Ishikawa diagram, identified the absence of a manual pretreatment phase as a critical issue. To address this, our treatment protocol was revised to include pretreatment: immersing the endoscope in a disinfectant liquid, cleaning the outer structure with sterile brushes, and using sterile swab sticks and disinfectant liquid for internal structures. This pretreatment phase resulted in complete decontamination of bronchoscopes, eliminating residual bacteria, specifically *Pseudomonas* and *Staphylococcus strains*, which pose significant HCAI risks.

Root-cause analysis highlighted potential issues, particularly in personnel training. Effective reprocessing requires sterile conditions across all aspects, including personnel and work surfaces. Thus, comprehensive training of personnel is crucial, as emphasized by multiple studies and guidelines (13).

More parameters, such as water quality, surface microbial charge and personal equipment (gloves,brushes, etc…), are potential contaminants, indeed, a number of studies have highlighted the effect of contaminated water use on the microbial charge of endoscopes. In fact, many outbreaks have been shown to result from badly processed endoscopes, where water is one of the primary contaminants. The key to developing a stable, reproducible, robust and accurate treatment protocol relies heavily on constant checking and constant analysis. Routine testing should be applied constantly[14]. Microbiological testing can be costly on a routine basis, and a significant number of other tests that are less costly are available, such as the hemoglobin test or adenosine triphosphate (ATP) measurement tests.

Moreover, a full HLD process is of extreme importance in endoscope reprocessing, and missing a step has been shown to produce disastrous effects, which only adds to the importance of completing the HLD process. For instance, Bédard et al. (15) studied a significant number of endoscopes performed over eight months, focusing on parameters such as adenosine, hemoglobin, and bacterial count. Their findings underscore the importance of including a manual phase in the cleaning process. Similarly, Ofstead et al. (16) demonstrated that the use of the EVOTECH ECR streamlined time and costs compared to standard methods. In our study, outcomes from fully automated procedures were significantly improved with the inclusion of a manual pretreatment phase. This underscores the critical role of pretreatment in ensuring effective decontamination of flexible endoscopes, thereby enhancing patient safety and meeting microbiological standards.

A more recent approach involves low-temperature sterilization methods, such as vaporized gases, that hold promise for addressing potential prion contamination in endoscopes. Advances in Pulsed alternating current technologies (CAP) enable surface treatment at ambient pressure without significant heat generation, thereby identifying CAP as another viable option for endoscope decontamination. Gas plasma represents a transient state of matter containing various short-lived ionized gas species that exhibit effective antimicrobial properties against biofilm models within plastic channels and other clinically relevant surfaces. Moreover, the short lifespan of these reactive species eliminates the need for large volumes of rinsing water, thereby reducing the risks of exposure to patients, clinical staff, and the environment. These attributes position CAP as an appealing alternative to traditional chemical treatments (17, 18).

Study strength

Our study has led to an improvement in the safety of endoscopic procedures performed by our facility. However, this work has resulted in the introduction of a procedure for handling heat-sensitive endoscopes in line with good practice, thereby helping to control the risk of healthcare-associated infections.

Study limitations

Despite the crucial importance of our research into the quality of heat-sensitive endoscope processing, we were faced with certain limitations:

- The high cost of microbiological testing limited the number of samples to be analyzed.
- The microbiological study takes time (generally 48 to 72 hours for cultures), which can delay the availability of endoscopes for clinical use.
- It took several meetings to get all the staff involved in setting up a procedure for handling heat-sensitive endoscopes.

Conclusion

Our study emphasizes the indispensable role of the manual pretreatment phase in automatic endoscope reprocessing. The omission of this critical step results in incomplete decontamination of the apparatus, posing significant risks to patient safety. While contemporary automated disinfectors often include automated pretreatment capabilities, manual execution of this phase before placing endoscopes into the disinfectors remains essential to minimize contamination risks effectively.

Furthermore, advancements such as CAP represent promising strides toward enhancing endoscope safety. CAP offers potential benefits in efficiently removing biofilms and disinfecting endoscope surfaces without the drawbacks associated with traditional chemical methods. Therefore, exploration of novel chemical agents and innovative procedural approaches is warranted to further elevate the safety standards of endoscopic procedures.

Continuous research and development efforts are crucial for mitigating infection risks, ensuring thorough decontamination, and ultimately safeguarding patient health. By embracing new technologies and refining existing protocols, the medical community can enhance patient outcomes and reinforce confidence in endoscopy as a vital diagnostic and therapeutic tool.

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