DOI: 10.11910/j.issn.2791-2043.2023.2.05

Status, causes and improvement of duodenoscope contamination

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ABSTRACT: The risk of infection associated with duodenoscopy is gradually attracting social attention. At present, the quality of cleaning and disinfection or sterilization cannot be guaranteed even if the reprocessing is carried out according to the manufacturer's instructions. It is necessary for the manufacturer and the user to work together to improve the structural design and the reprocessing specifications, and take measures to minimize the risk. The purpose of this review is to clarify the current situation of duodenoscopy contamination at home and abroad, find the causes of the problem, and put forward the current feasible scheme in the world, in order to improve the qualified rate of duodenoscopy reprocessing and reduce the risk of patient infection.

KEY WORDS: Duodenoscope; Reprocessing; Cleaning; Disinfection; Sterilization

Duodenoscope is a flexible endoscope applied for endoscopic retrograde cholangiopancreatography (ERCP) to diagnose and treat pancreatic and biliary duct issues. It is more complicated than a typical flexible endoscope due to a forceps elevator at the apex. If it is incompletely cleaned and disinfected when reprocessed, it may cause cross-infection between patients. An absolutely safe disinfection effect is difficult to achieve even with the manufacturer's recommended reprocessing method. Therefore, how to attain completely safe disinfection is still a challenge.

1 Research status

Multiple outbreaks of Carbapenem-resistant Enterobacteriaceae (CRE) have been associated with dudenoscope since 2008[1-3]. The cross-contamination of Pseudomonas aeruginosa (PA) between patients was confirmed by Multiple Locus Variable-number Tandem Repeat Analysis (MLVA) of strains isolated from patients' bile and endoscopes[4]. Ross *et al.* demonstrated that the processing cost after an infection outbreak is much higher compared with the cost of prevention and early detection of CRE (to intensify reprocessing, regularly monitor, and increase endoscopic inventory)[5].

Cleanliness is the most important prerequisite for effective disinfection in endoscope reprocessing. However, implementation varies by region worldwide. A survey from Brazil in 2022 showed that 72.3% of flexible endoscopes were not fully immersed in cleaning solution, 63.6% were non-standardly irrigated, 13.6% of biopsy channels were not scrubbed, 25% were detected positive of microbiological culture during the storage, and the contamination rate was as high as 32% after reprocessing[6].

This cannot be attributed to the reprocessing irregularities. Most studies have shown that even though the manufacturer's reprocessing instructions are followed exactly for cleaning and disinfection or sterilization, effective bacterial decontamination can not be guaranteed[5,7-9] and cases of infection still occur.

The U.S. Food and Drug Administration (FDA) was alerted by the Centers for Disease Control and Prevention (CDC) in 2013 about a potential connection between the duodenoscope and multidrug-resistant bacteria (MDROS), and the FDA was required to strengthen monitoring. In 2015, the FDA required post-market surveillance studies from the duodenoscope manufacturers including Olympus, Fujifilm, and Pentax to ascertain if medical institu-

tions could effectively clean and disinfect it. But as of 2018, none of the manufacturers had fulfilled the aforementioned requirement. Thus, the FDA issued warnings to these three manufacturers on this matter on March 9 of the same year[10], requesting the submission of comprehensive plans and the collection of pertinent data within a specific time frame. Following this, it was revealed in a 2019 safety announcement that, compared with the predicted rate of 0.4%, up to 5.4% of duodenoscopes suffered contamination of E. coli and PA of high concern[11]. In terms of greater contamination rates in the next-year study [12], the manufacturer modified the reprocessing procedure.

22% of duodenoscopes are still above normal levels after reprocessing with the standard of 20 CFU/20 mL, according to a Dutch study from the same period[13]. In a US investigation using the ATP method, 22% of flexible endoscopes (including duodenoscopes and colonoscopies) gave values that were higher than the upper limit of the reference value[14]. Considering the duodenoscope-associated infections, the infection rate in the Netherlands between 2008 and 2019 is 180 times higher than that in the report published by Kimmey *et al.* in 1993. The actual risk may be much higher due to under-reporting, under-identification, or false negatives of microbiological cultures related to infections caused by MDROS with sensitive bacteria[15-16]. Data from 15 Italian institutions revealed contamination rates for duodenoscopes after reprocessing, regulated storage, and unauthorized storage of 27,5%, 40%, and 100%, respectively[17]. Findings from 490 French hospitals using flexible endoscope microbiological cultures in 2021 showed that 8.1% reached alarm levels and 13.0% required suspension[18].

2 Contamination causes

2.1 Structure design

The duodenoscope, which has its apex orientated along the scope whereas the apex is perpendicular to the body, has the most complex structure that makes cleaning and disinfection challenging because the duodenum is too narrow to bend the apex to 90° so that the wall is unable to be observed during the ERCP. Thus, the duodenoscope's objective lens and light source are perpendicular to the scope. When the scope is moved downward to locate the duodenal papilla for operation, the intestinal wall can be observed clearly.

The apex of the flexible endoscope usually consists of an objective lens, a light source, and a nozzle for water and air delivery. Additionally, a sub delivery water outlet is added by the colonoscope to flush the digestive tract and improve visibility. Due to the duodenoscope's complex structure and the forceps elevator at the apex for flexible operation, the cleaning task is extremely demanding.

The forceps elevator's guide wire connects the control bar in the operating portion. The operator adjusts the angle of the forceps elevator by pulling the guidewire up and down with the operating bar while performing the inspection. But when it ascends and descends, the guidewire may contaminate the guidewire tube. Because of its motion, if the tube is not thoroughly cleansed and disinfected, the contamination could be transferred from the guide wire tube to the exposed wire segment during the surgery. Therefore, both the forceps elevator and the guidewire tube should be thoroughly cleaned and sanitized after reprocessing. Guidewire tube can only be reprocessed by irrigation because the forceps elevator is too narrow. Water is ejected from the biopsy, hydro gas, and sub-feed pipelines in flexible endoscopes during irrigation, while the guidewire tube of the forceps elevator can only ooze out just a little of water under the same pressure due to high resistance and low flow rate, greatly minimizing the cleaning effect. According to data from SINGH H *et al.*, the detection of 74.3% of guidewire tubes of non-confined forceps elevators and 73.5% of guidewire tubes of confined forceps elevators shows that fecal enterococci or total bacteria or both arrive at intervention levels[19], while other studies reveal that the pass rate of guidewire tubes is much lower than that of water-air pipelines, suction-biopsy pipelines and sub delivery pipelines[20-21].

2.2 Device damages

If diagnostic tools are operated incorrectly, such as when sharp metal tools are not clamped shut, they may produce scratches at the bend of the biopsy tube during the up and down motion of the biopsy tube. The ETO cap of the duodenoscope should be installed during cryogenic gas sterilization; otherwise, there may be an imbalance in the air pressure between the area around the electrical components and the outside during the evacuation, which could result in the endoscope bursting.

A visual inspection of duodenoscope lines using an endoluminal detector in Taiwan, China, revealed that 52.6% of the endoscopes had scratches on the inner surface and 73.7% had stains, and the duodenoscopes used for longer than 12 months made greatly more abnormal results than those used for less time[22]. Damage to the flexible endoscope's interior and exterior surfaces might result in ineffective cleaning and disinfection, and may even foster the formation of biofilm[23]. This ultrastructure is particularly advantageous for bacterial survival thanks to the 1000 times greater resistance to bacterial inhibition and capacity to periodically discharge germs to the outside as a reservoir[24]. According to a study conducted in Berlin, Germany, biofilms produced by Klebsiella pneumoniae (KPN) became resistant to the disinfection solution of peroxyacetic acid (PAA)[25]. If the detection of side leakage, the maintenance, service, and overhaul of the flexible endoscope are not performed periodically as recommended by the manufacturer[26], it may impede the timely repair of the endoscope in the event of hidden damage.

2.3 Reprocessing

The cleaning and disinfection personnel of the flexible endoscope should be professionally trained and it is important to strictly follow the manufacturer's instructions for reprocessing endoscopes. Currently, the error tolerance of the entire reprocessing is very low[27]. However, the human factor is also the most variable in the whole process. Considering the time and cost, there occurs non-brushing of biopsy lanes, improper handling of forceps elevator, reuse of enzyme cleaning solution, etc. Studies have shown that forceps elevator not being at the prescribed angle during reprocessing and being tight to the bottom or top can cause the failure of the reprocessing[28], even if the subsequent steps are handled using a machine.

Complete compliance with the manufacturer's recommendations may not give a favorable effect[27]. The suction-biopsy tube can be gently washed with a brush since it is rough. However, the water-injection-gas injection tube and the sub-delivery tube lack sufficient room for operation, so cleaning and disinfection, as well as machine cleaning, completely rely on full-tube irrigation. Additionally, guidewire tubes, as one of the tiniest forceps elevator of duodenoscope, have a very slow flow rate and make an unsatisfied cleaning effect, though applied to irrigation.

2.4 Defoamers and lubricants

Operators commonly adopt defoamers (such as dimethyl silicone oil) and insoluble lubricants during endoscopy. However, according to certain research, these solvents can not be effectively removed by traditional reprocessing and remain on the interior and external surfaces, which causes the reprocessing to fail[29-30]. Olympus Corporation issued a warning in 2018 that the medical institutions would be responsible for any risks associated with silicone-based items applied by doctors who disregarded the manufacturer's instructions. Tissue gels are another challenge that arises during reprocessing because of their accelerated adhesion to the endoscopic surface[29].

2.5 Inadequate monitoring

Endoscope surveillance sampling and culture are not suggested in the US recommendations on endoscope reprocessing and infection control, which has caused only specific medical institutions to implement routine or regular monitoring. In China, the only area that needs to be monitored is the biopsy channel, according to the technical standards for cleaning and disinfecting flexible endoscopes[31-32]. Both solids and liquids from the subject's digestive tract enter through this channel and are collected into the suction bottle. Thus, the monitoring of the

biopsy channel is the most crucial and fundamental since it is the tube that is most polluted. However, China's standards only include this channel but lack corresponding requirements and guidelines for the external surface of the endoscope (including the forceps elevator), the water and gas injection tubes, and the sub delivery guidewire tubes of the forceps elevator. As they deliver sterile and filtered water during endoscopy, the water and air injection tube as well as the sub-feeding tube are mildly polluted and the test pass rate is relatively high[20]. However, it can also raise the risk of infection if contamination occurs in the sterile water itself or during preparation because of operational mistakes, or if the cleaning or disinfecting solution is already contaminated. According to the data, the guidewire tubes of the forceps elevator, as the most challenging of them to clean, have lower pass rates than biopsy access[20]. The contamination in the guidewire tube of the forceps elevator is continuously displaced by the up and down movement of the guidewire during the operation, which eventually results in contamination of the exposed guidewire, even if the reprocessing of the forceps elevator and the exposed guidewire connected to it satisfies the requirements. Numerous domestic tests have also revealed that the guide wire tube of forceps elevator is at risk of contamination[21]. Thus, patients will suffer in unknown danger due to the contamination that the monitoring does not cover.

3 Improvement methods

Additional measures may help to further lower the risk of related infections based on strict adherence to the manufacturer's reprocessing recommendations of the duodenoscope.

3.1 Improved design

The construction of the mirror can be simplified for reprocessing since the forceps elevator of the duodenoscope is too complicated to clean the guidewire tubes, which, however, requires the collaboration of several experts (including gastroenterologists, microbiologists, government organizations, monitoring agencies, and manufacturers) [27]. The current solution is composed of disposable duodenoscopes, forceps elevators, and apex caps[33-34]. The challenge of cleaning can be significantly reduced and the safety of the component used on each patient is guaranteed by using disposable apex caps and forceps elevators. Nevertheless, the expense of disposable devices, which is determined by both the ERCP amount and the infection incidence, is the major issue. The price of the disposable duodenoscope must be low enough for institutions performing an enormous amount of operations (≥150 ERCP per year) to break even on costs[35-36]. According to an evaluation of the Monte Carlo model, disposable apex caps are preferred because of lower infection rates and low cost[37].

3.2 Early detection of damage

The penetrating damage on the interior and exterior surfaces of the duodenoscope can be promptly detected by performing side leakage following the instructions given. Small scratches on the outside surface can only be seen under magnification or with the naked eye, whereas the damage to the inner surface can only be identified using an endoscopic endoluminal detector. Since common medical institutions lack the required supplies, the endoscope must be sent back to the manufacturer for routine maintenance, repair, and overhaul. The manufacturer advises sending it at least once a year [27, 38].

3.3 Improving reprocessing levels

3.3.1 Quality control

A routine monitoring and assessment system is set up to guarantee that personnel carries out standardized procedures and complete cleaning and disinfection following the manufacturer's instructions[39]. Training and compliance with all systems monitoring should be regarded as a part of the department's quality control and be executed by higher authorities. Currently, nurses and staff members share this responsibility in medical institutions in China. As medical professionals, nurses achieve a high implementation rate of the specification, which can guarantee high-quality reprocessing but may cause human resource waste. Some medical institu-

tions implement a rotation system for position specificity and the potential of occupational damage, which causes a continuous drain of professional employees and the engagement of fresh talents. However, there is also a frequent turnover of employees due to poor salaries. Thus, it is important to improve the treatment, guarantee the stability of personnel and provide them with systematic training before they are qualified to start work. Furthermore, timely cleaning and pretreatment for the devices are important since the longer the interval between them, the higher the risk of bacteria colonizing and biofilms forming.

3.3.2 Repeating high-level disinfection

Repeated disinfection is equivalent to a longer disinfection duration, which theoretically leads to more adequate disinfection[34-40], but may cause some difficulties in the turnover of the flexible endoscope. However, it has also been found that repetitive disinfection brings minimal improvement [41-42]. Therefore, the effectiveness of repeated high-level disinfection still needs to be confirmed with more data.

3.3.3 Sterilization

Sterilization has been required for ERCP in recent years since it may damage the mucosa, thus impair its integrity, and even touch with sterile tissue (e. g., the bile ducts) [43]. According to Lawrence's findings, ethylene oxide (EO) sterilization is an effective method to improve the security of ERCP[44]. EO is a low-temperature sterilization method that avoids damage to endoscopes during sterilization. However, it has some limitations, such as the time-consuming reprocessing that the hazardous EO must be resolved harmlessly after sterilization, which can take up to 10 hours. Thus, it is recommended if the workload is not too heavy and the deliverability of duodenoscopes can meet daily consultation requirements.

PAA is another commonly utilized sterilization method, which can be programmed to achieve high-level disinfection or sterilization by setting different infusion times for the sterilization solution on the device. Unlike the EO-sterilized without paper-plastic packaging that can prevent contamination, this method can not provide complete sterilization because the terminal rinse water is not sterile and may be recontaminated during subsequent removal and transfer. It is prone to generate microorganisms when stored in a mirror cabinet since it has no paper-plastic packaging. Thus this PAA applies to ready-to-sterilize.

3.4 Drying and storage

Microbial infection is also associated with drying and storage. Up to 95% of endoscopes still retained fluid remnants when being stored overnight after alcohol rinsing and drying, according to a study by Ofstead *et al.*[23,45]. Defoamers like dimeticone may cause these residues[29]. Extending cleaning times and adopting enzyme cleansers that clean dimeticone well can also help to reduce remnants[46]. Extending the duration can improve the drying effect by achieving a balance between endoscopic transfer and effective drying. Microbial contamination may occur in the common storage cabinet after 12 hours. The newly developed storage cabinets for pipeline purification maintain clean air inside the cabinet and keep a pressure difference from outside air through high-efficiency air filtration. They are attached to the endoscope pipelines through a connecting tube that permits continuous airflow in the lumen to maintain sufficient drying with no bacteria.

3.5 Monitoring

3.5.1 Microbiological culture The methods for flexible endoscope sampling and culture have long been a topic of discussion overseas. According to a guideline on sample and culture for duodenoscope monitoring published in 2019 by the FDA[47], the sites that are routinely examined include the forceps elevator, forceps elevator guidewire tubes, and biopsy access. The guideline also provides specifics on sampling and culture methods. Water-air tubes and biopsy access can be inspected if necessary. Besides, it is crucial to note that the BAP (Blood Agar Plate) is utilized in the microbiological culture method, which is based on bacteria of high concern, and that the culture conditions must be adjusted when other microorganisms are suspected. As

shown in Table 1, the recommendations also provide various levels of reference values for certain microorganisms of concern.

China's current requirements only demand monitoring the biopsy access. Although it avoids the greatest risk, the efficacy of cleaning and disinfecting other tubes, particularly the guide wire tube of the forceps elevator, is troubling, as several findings demonstrate. Even if there are issues, they cannot be identified in time if not continuously monitoring these areas. According to current standards in China, the sampling solution must include an eluent containing an appropriate neutralizing agent. When selecting pre-made items or making their own, the infection management department must take into account the type of disinfectant solution used for high-level disinfection and the alcohol content used in drying. Higher yields of microbial cultures and a more accurate and objective representation of the endoscope contamination can both be achieved by adding the right amount of neutralizing agents[48]. Additionally, monitoring may not always accurately reflect the actual contamination[26] and must be carried out taking other considerations due to the duodenoscope's complex design. Multiple negative test results do not mean that there are no issues. with limitations of the sampling method, accurate data can only be acquired by taking apart the endoscope.

The quality of the terminal rinse water is a risk easy to ignore. Although obtaining the needed high-level disinfection, the entire reprocessing will fail if the terminal rinse water is polluted. Disinfection of purified water production and pipeline is necessary for ensuring the quality of the water[49], and the monitoring step can be divided to focus on these two processes to precisely identify the links of contamination.

The inner surface of the mirror cabinet also requires microbiological monitoring[49].

3.5.2 ATP fluorescence detection

ATP fluorescence detection can monitor biological residues quickly and thus its major advantage is real-time feedback of reprocessing, while traditional microbiological culture methods take longer than 48 hours. Scholars worldwide have conducted a great deal of research on the relationship between findings and cultural methodology. The majority of studies show that the ATP method correlates well with the culture method[39,50-56]. However, some studies take the opposite attitude[57-59], arguing that ATP cannot accurately represent microbiological culture results when the sample location is a forceps elevator. ATP is not a reliable indicator of bacterial contamination, though it can indicate biological remains other than non-aerobic bacteria. Nevertheless, a consistent ATP testing program may encour-

Table 1 Illustration of 72-hour culture results of BAP

BAP culture results				
	>100 CFU	11-100 CFU	1-10 CFU	0 CFU
Microorganisms of high concern	Interfere	Interfere	Interfere	Not interfere
Microorganisms of low/medium concern	Interfere	Warn	Not interfere	Not interfere
Liquid culture results				
	Detected with growth		Detected with no growth	
Microorganisms of high concern	Interfere		Not interfere	
Microorganisms of low/medium concern	Resample or adopt BAP		Not interfere	

Note: **Microorganisms of high concern:** Microorganisms associated with disease, including gram-negative bacilli (such as bacillus coli, PA, KPN, or other Enterobacteriaceae), gram-positive bacteria, including staphylococcus aureus, streptococcus hemolyticus, enterococci, and saccharomycetes.

Microorganisms of low/medium concern: Microorganisms that are less associated with disease and generate by environmental contamination during the sampling process. Microorganisms of low concern include many gram-positive bacteria, such as Micrococcaceae, coagulase-negative staphylococci (CNS) (excluding staphylococcal pneumonia), and bacilli and diphtheroid bacilli or other gram-negative bacilli, which generate possibly due to environmental contamination during sampling or culture. Microorganisms of medium concern include organisms commonly found in the oral cavity (e. g. , neisseriaceae, Streptococcus viridans, and Moraxella spp).

age personnel to carry out more thorough cleaning[50].

Additionally, ATP testing performed on a patient before surgery is ineffective and does not differentiate between microorganisms of high, low, or medium concern. Alfa *et al.* suggested applying ATP testing to verify if manual cleaning was effective in removing patient-derived organic waste and bioburden. The ATP approach offers a quick method for evaluating endoscope reprocessing at this stage to ensure that substandard endoscopes are reprocessed before high-level disinfection and before use on the next patient[20].

4 Conclusion

The risk of infection with the duodenoscope still needs to be advanced by domestic experts Manufacturers should continuously follow up on product developments in technology, produce single-use parts or entire endoscopes, and identify damage as early as possible using specialized tools. Medical facilities should strictly enforce leak detection and standardize the usage of the duodenoscope and other relevant diagnostic tools to promptly diagnose issues. In addition, manufacturers of cleaning solutions should continue to overcome technical challenges in the development of new products to improve the removal of stubborn residues (especially biofilm) on the internal and external surfaces of endoscopes. Quality control of the entire process from pretreatment to cleaning, disinfection or sterilization, and final drying, needs to be implemented. This includes staff access and regular evaluations, as well as maintenance of all cleaning and disinfection equipment. To enhance the effectiveness of sterilization or disinfection, medical facilities should select workable supplemental programs based on their specific circumstances. The current surveillance standard for endoscopy in China is 20 CFU/piece, and additional testing is only carried out when it is suspected that hospital-acquired infections are connected to endoscopic consultation procedures. This method may reduce pointless tests, but there is a safety concern that it can only be identified after the emergency appears but cannot be prevented beforehand. The duodenoscope, as one of the flexible endoscopes, should also be included in the scope of routine monitoring since it can not only monitor the forceps elevator and its guidewire tube, but also the exterior surface and other tubes (such as suction-biopsy tube and water-gas tube)[20].

In addition, therapeutic ultrasound endoscopes with similar complex structures (including forceps elevator and its lumen) have contamination rates comparable to those of duodenoscopes, thus attracting high attention[34].

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