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Brief Report

Bacterial bioburden of duodenoscope elevator mechanism in different reprocessing stages

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Over the past decade, infections linked to duodenoscopes have become a significant concern, primarily due to the intricate design of the elevator mechanism. Currently, there is limited evidence regarding the bacterial contamination level of the elevator mechanism after clinical use and throughout its various reprocessing stages. This study utilized the swab culture technique to examine the bacterial contamination on the duodenoscope elevator mechanism after clinical use and after 3 reprocessing stages at a Center of tertiary hospital. Our findings revealed severe bacterial contamination after clinical usage, emphasizing that the effectiveness of manual cleaning greatly influences the subsequent high-level disinfection quality.

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Duodenoscopes feature specialized designs that allow medical professionals to carry out endoscopic retrograde cholangiopancreatography (ERCP) procedures. This device, in comparison to other endoscopes, boasts more intricate structures, posing substantial challenges during the reprocessing and high-level disinfection or sterilization processes. Recent reports about endoscopy-related infections have spotlighted the elevator mechanism at the distal end of the duodenoscope as a critical reservoir for pathogenic microorganisms.[1,2]

Although many studies affirm that even with strict compliance to technical guidelines and manufacturer-recommended reprocessing procedures, the sophisticated design of duodenoscopes might still harbor harmful pathogens, including drug-resistant bacteria. Such contamination can result in cross-transmission between patients.[3,4] Contributing factors to this problem encompass delayed or insufficient postuse cleaning,[5,6] minuscule crevices on the elevator's surface,[7] and incorrect positioning of the elevator mechanism during automated reprocessing.[8] However, a concrete understanding of the bacterial contamination levels on the duodenoscope's elevator mechanism postuse and throughout its reprocessing phases is still elusive. Hence, our study utilized a swabbing technique to collect microbiological samples from this mechanism after clinical usage, bedside precleaning, manual cleaning, and high-level disinfection. Our primary goal was to gauge the overall viable bioburden without identifying the specific bacterial species.

METHODS

Setting

This research took place at the Digestive Endoscopy Center of a tertiary hospital in Jiangxi Province, China, a facility known for conducting approximately 2,400 ERCP operations annually. The study incorporated 6 duodenoscopes: 5 TJF-260V models and 1 JF-260V model (Olympus Corporation), which had been in clinical use for periods spanning from half a year to 3.5 years. These instruments represent the entirety of those used clinically during the period of our study, with each duodenoscope undergoing microbial sampling at least twice. An individual with over 8 years of expertise in duodenoscope reprocessing managed the cleaning process, and microbiological sample collection was undertaken by 2 well-trained personnel.

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Reprocessing

After clinical procedures, the reprocessing of the duodenoscope adhered to the hospital's standard protocols. This included an initial bedside precleaning using a 1:200 concentration of a high-efficiency multienzyme cleaning solution (3M Company). The process involved wiping the external surface with gauze with a premoistened enzyme cleaning solution and flushing the channels with 250 mL of the same solution. The duodenoscope was then fully submerged in a 1:200 the same enzyme solution, and its exterior, elevator mechanism, and channels were manually scrubbed. To ensure a thorough cleaning of the elevator mechanism, a specialized duodenoscope cleaning brush (MAJ-1534, Olympus Corporation) was used until no visible residues remained. Subsequently, high-level disinfection was carried out using a 0.1% peracetic acid solution (Schulke Gigaset PAA) for a duration of 5 minutes.

Sampling and culturing

For sampling and culturing, sterile swabs (CLASSIQSwab, Copan) were used to repeatedly swab the upper and lower sides of the elevator for 3 times, as well as the elevator recess. This was performed across 4 stages: after treatment, bedside precleaning, manual cleaning, and after the high-level disinfection. Each swab's tip was then placed in a sterile test tube filled with 10 mL of broth (BD-difco Letheen Broth), and promptly dispatched to the microbiology lab. Following thorough agitation using a vortex mixer, a 1 mL aliquot of each sample was seeded onto 2 nutrient agar plates. Bacterial colony counts (CFU) were then documented after incubation at 37 °C for both 48 and 72-hour intervals.

Data analysis

All data were tabulated into Excel 2019 and scrutinized using SPSS 25.0 software. Metrics related to contamination, denoted in colony forming unit, were described through medians, interquartile ranges, and the full range (minimal to maximum) of average contamination for each phase. The nonparametric Kruskal-Wallis H test facilitated the comparison of colony counts, deeming any *P*-value under .05 as statistically significant.

RESULTS

From the 6 duodenoscopes, a total of 112 microbial samples were collected, with each instrument being sampled at least on 2 times. Of the 14 patients who underwent ERCP treatment, 9 (64.3%) had common bile duct stones. The remaining 35.7% of patients exhibited various conditions including acute pancreatitis, biliary bleeding, duodenal papillary bile duct fistula, narrowing of the lower segment of the common bile duct, or pancreatic pseudocysts.

Following clinical usage, bacterial contamination of the elevator ranged between a minimum of 1.59×10^3 cfu/piece and a peak of 5.95×10^8 cfu/piece, with a median value of 5.23×10^5 cfu/piece.

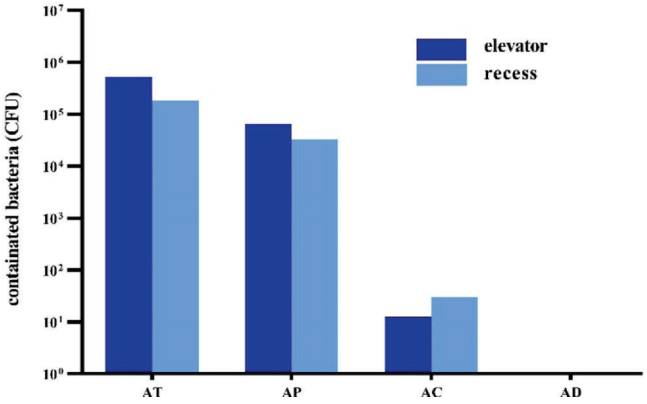


Fig. 1. The median (P_{50}) of the bacterial bioburden at different reprocessing stages (48 hours culture data). AT, after treatment; AP, after precleaning; AC, after cleaning; AD, after high-level disinfection.

Conversely, the recess samples varied from 9.10×10^2 cfu/piece to 9.15×10^8 cfu/piece, with a median standing at 1.81×10^5 cfu/piece over 48 hours (refer to Table 1, Fig 1).

Post precleaning, bacterial loads on the elevator spanned from a low of 5.45×10^2 cfu/piece to a high of 1.46×10^7 cfu/piece, with a median count of 6.50×10^4 cfu/piece. The recess samples exhibited a range of 1.65×10^2 cfu/piece to 5.05×10^6 cfu/piece, and a median of 3.28×10^4 cfu/piece over a duration of 48 hours. Impressively, effective precleaning resulted in a substantial decline of up to 2.59 $\log_{10}$ in bacterial count on the elevator mechanism. The positive impact of precleaning in bacterial elimination was statistically profound ($P < .001$) (refer to Table 1, Fig1).

Manual cleaning showcased significant bacterial eradication, achieving a commendable 6.70 $\log_{10}$ reduction in contamination ($P < .001$). However, traces of bacteria persisted on the elevator mechanism. After this stage, the elevator's bacterial counts ranged from a nondetectable level to 1.59×10^3 cfu/piece, while the recess samples varied from nondetectable levels to 5.60×10^3 cfu/piece (see Table 1, Fig 1). The high-level disinfection phase yielded a maximal bacterial reduction of 3.70 $\log_{10}$. Yet, one sample from both the elevator and recess showed bacterial growth (2/28, 7.14%), with each revealing a colony count of 5 cfu. Notably, no meaningful disparities in bacterial colony counts found between the 48-hour and 72-hour culture durations for the elevator mechanism across all stages (refer to Table 1).

DISCUSSION

Duodenoscopes, by virtue of their intricate design featuring unique elements like elevators and recesses, pose specific challenges during the reprocessing phase, distinguishing them from general gastrointestinal endoscopes.[9] Our investigation stands as a pioneer in quantifying bacterial contamination on the duodenoscope's elevator mechanism postprocedure. After clinical utilization of duodenoscope, the peak bacterial contamination observed for the elevator

Table 1
The bacterial bioburden of the duodenoscope elevator mechanism at different reprocessing stages

Cultivation time	Sampling	Bacterial (CFU) contamination level in reprocessing steps *M* (P_{25}, P_{75})				*P*
		After treatment	After precleaning	After cleaning	After disinfection	
48 h	Elevator	5.23×10^5 (7.03×10^4,1.04×10^8)	6.50×10^4 (9.65×10^3,5.76×10^5)	1.25×10^1 (0.00,2.71×10^2)	0.00 (0.00, 0.00)	< .001
	Recess	1.81×10^5 (6.61×10^4,9.79×10^6)	3.28×10^4 (4.25×10^3,8.39×10^5)	3.00×10^1 (0.00,2.04×10^2)	0.00 (0.00, 0.00)	< .001
72 h	Elevator	5.33×10^5 (8.23×10^4,1.06×10^8)	6.95×10^4 (1.10×10^4,6.45×10^5)	2.50×10^1 (0.00,3.13×10^2	0.00 (0.00, 0.00)	< .001
	Recess	1.91×10^5 (7.2×10^4,1.10×10^7)	3.58×10^4 (4.64×10^3,8.61×10^5)	4.50×10^1 (0.00,2.11×10^2)	0.00 (0.00, 0.00)	< .001
P(48 h vs 72 h)	Elevator	0.713	0.730	0.745	1.000	-
	Recess	0.679	0.783	0.691	1.000	-

and recess were 5.95×10^8 cfu/piece and 9.15×10^8 cfu/piece respectively. Rigorous reprocessing, encompassing precleaning, manual cleaning, and high-level disinfection, managed to diminish the bacterial presence on the elevator and recess by 2.59 $\log_{10}$, 6.36 $\log_{10}$, 3.20 $\log_{10}$ and 2.26 $\log_{10}$, 6.70 $\log_{10}$, 3.75 $\log_{10}$, respectively. Manual cleaning emerged as the pivotal step for bacterial eradication, echoing the effectiveness insights for gastrointestinal endoscopes postuse as documented by Neves et al.[10] Emphasis, hence, needs to be heavily placed on meticulous execution during the manual cleaning phase.

From our observations, 7.14% (2/28) of bacterial cultures remained positive after the high-level disinfection of the elevator mechanism, all of which had a higher level of bacterial residue ($\geq 10^2$ cfu/piece) postmanual cleaning. This infers that even adept individuals, with 8 years of cleaning expertise, might fall short of achieving impeccable cleaning. The heightened bacterial load postclinical use mandates rigorous precleaning and manual cleaning to substantially cut down biological counts. New staff members should undergo rigorous professional training, and the daily cleaning quality needs constant surveillance. The implementation of a real-time monitoring system, coupled with an immediate feedback mechanism, will help improve the quality of reprocessing. In addition, initiatives should focus on the development of specialized cleaning tools specifically for the elevator mechanism or even the advent of fully automatic cleaning and disinfection devices to reduce human involvement.

While reprocessing duodenoscopes, thorough cleaning stands out as the cornerstone for ensuring effective disinfection or sterilization.[11] It has been evidenced that meticulous manual cleaning paves the way for superior high-level disinfection, eliminating up to 99.9% of the microbes and organic contaminants.[12] Our analysis pinpointed that postclinical procedure and bedside precleaning, the elevator had heightened bacterial contamination compared to the recess. However, postmanual cleaning, the recess's bacterial load exceeded the elevators. Thus, introducing detachable distal caps could bolster the cleaning of the elevator mechanism, especially the underside, enhancing the safety quotient of these devices. Any recalibration in duodenoscope design or reprocessing strategies must prioritize the impeccable cleaning of the elevator assembly.

This study employed swab techniques for separate culturing and monitoring of both the duodenoscope elevator and the groove sites, provides a meticulous sampling method to identify contaminated elevator mechanisms and offers evidence of microbial contamination across four reprocessing stages, revealing bacterial contaminations that can reach as high as 9.15×10^8 cfu/piece. Moreover, we discovered that the groove sites presented more significant contamination postmanual cleaning. This information is instrumental in refining reprocessing steps to address the infection transmission issues associated with the duodenoscope's elevator mechanism.

However, our study isn't devoid of limitations. Its single-center nature might constrict the universal applicability of our findings. The limited sample size can potentially undercut the statistical robustness and the consequent conclusions drawn. The cleaning technician's 8 years of experience, combined with the watchful eyes of 2 microbial samplers, could have inadvertently triggered a behavioral shift in the technician, introducing the potential "Hawthorne effect" Bias. Achieving a blind design for tracking microbial sampling across the duodenoscope's reprocessing stages postclinical usage proved challenging.

CONCLUSIONS

To encapsulate, our research underscored the pronounced bacterial contamination on the duodenoscope's elevator mechanism following clinical treatment. Yet, it is pivotal to recognize the study's inherent limitations. Even with these constraints, our findings emphasize that severe bacterial contamination, impacting the quality of ensuing high-level disinfection or sterilization procedures.

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