American Journal of Infection Control 47 (2019) 1233–1239

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major Article

Enhanced manual cleaning efficacy of duodenoscope in endoscopy units: Results of a multicenter comprehensive quality control program

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Key Words:
Reprocessing
Adenosine triphosphate
Quality control

Background: Multiple outbreaks from contaminated duodenoscopes have been reported since 2008. This study assessed results of a multicenter comprehensive quality control (QC) program to enhance manual cleaning efficacy of duodenoscopes in endoscopy units.

Methods: Digestive Endoscopy Society of Taiwan implemented a QC program with adenosine triphosphate (ATP) testing of patient-used duodenoscopes in 2 rounds of on-site audit in endoscopy units. ATP samples were obtained from 5 different locations of the duodenoscope after manual cleaning. Duodenoscope exceeding ATP benchmark of 200 relative light units indicated inadequate manual cleaning.

Results: During the first round on-site audit, 12 hospitals and 27 patient-used duodenoscopes were analyzed. Distal end outer surface (29.6%), elevator mechanism (51.9%), distal attachment cap (59.3%), elevator wire channel (37.0%), and suction biopsy channel (37.0%) were inadequately cleaned. Overall, 19 (70.4%) duodenoscopes had inadequate manual cleaning, ranging widely from 0%-100% among endoscopy units. During the follow-up on-site audit, 32 patient-used duodenoscopes were analyzed, and 6 (18.8%) had inadequate manual cleaning.

Conclusions: ATP tests may provide real-time feedback on the cleaning efficacy of patient-used duodenoscopes. Implementing a comprehensive QC program could enhance the efficacy of manual cleaning in endoscopy units.

Duodenoscopes undergo multistep cleaning and a high-level disinfection procedure called reprocessing so that they can be reused among patients. The complex design of duodenoscopes may impede effective cleaning.[1] Multiple outbreaks of infection due to carbapenem-resistant Enterobacteriaceae (CRE) associated with contaminated duodenoscopes have been reported since 2008.[2] CRE often spread during gastrointestinal endoscopy in hospitals.[3,4]

Several outbreaks of multidrug-resistant bacteria associated with endoscopic retrograde cholangiopancreatography (ERCP) have been reported in the United States, France, Germany, and the Netherlands.[5-9] Taiwan had a significant increase in the number of oxacillinase-48-like carbapenemases among carbapenem-resistant *Klebsiella pneumoniae* between 2012 and 2015.[10] CRE outbreak after endoscopy was reported at a regional teaching hospital in Taiwan in 2013.[11] To reduce the risk of transmission of infection through duodenoscopes, the US Food and Drug Administration on February 19, 2015 recommended that institutions or societies should implement meticulous manual cleaning along with the comprehensive quality control (QC) program, which includes written guidelines and procedure protocol for monitoring, training, and adherence to reprocessing procedures.[12,13]

Manual cleaning is the most important step in removing the microbial burden from an endoscope.[12,13] Adenosine triphosphate (ATP) cleaning verification test can provide real-time feedback on the adequacy of the manual cleaning process for each duodenoscope and indicate the need for additional cleaning.[14,15] The World Endoscopy Organization found that reprocessing procedures are lagging behind, compared with those of Western countries, for cultural reasons, lack of financial resources, and variations in reprocessing methods.[16]

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Funding/support: This quality control program was funded by the Digestive Endoscopy Society of Taiwan. 3M Taiwan Company cohosted and participated in the audit team training.

Conflicts of interest: None to report.

https://doi.org/10.1016/j.ajic.2019.03.029
0196-6553/

After this awareness of the reprocessing challenge, Digestive Endoscopy Society of Taiwan (DEST) implemented a nationwide comprehensive QC program in endoscopy units. The aims of this study were to assess the results of the multicenter comprehensive QC program, using ATP as the clearing marker, to identify manual cleaning problems, verify compliance with duodenoscope cleaning, formulate plans for corrective action, and take additional actions for improvement in endoscopy units.

METHODS

Study design

This prospective study was conducted in 14 major tertiary care teaching hospitals in Taiwan. Each hospital approved the study protocol and volunteered to participate in the QC program. The present study was approved by the institutional review board of Tri-Service General Hospital, Taipei, Taiwan. The comprehensive QC program encompassed 4 main phases of the on-site audit: preparation phase, first round on-site audit, intervention and enrichment period, and follow-up audit.

Preparation phase of the QC program

Duodenoscope reprocessing guideline: DEST issued the duodenoscope reprocessing guideline in 2015.[17] Patient-used duodenoscope reprocessing procedures included bedside precleaning, which involves the wiping of external surfaces and flushing channels with enzymatic detergent immediately after ERCP procedures, followed by manual cleaning and high-level disinfection in the reprocessing room. Manual cleaning procedures include (1) the detachment of removable parts; (2) cleaning of the exterior surfaces of the endoscope with a soft, lint-free cloth or sponge saturated with the enzymatic detergent; (3) all internal channels are cleaned with a channel-cleaning brush at least 3 times or more until all residual debris is removed. The channel cleaning brush protrudes from the distal end of the endoscope, bristles are cleaned under running water; and (4) elevator mechanism, recess parts, endoscopic channel outlet, and distal attachment cap are cleaned thoroughly using the manufacturer-approved soft cleaning brush.

Hands-on ERCP workshop training: DEST organized hands-on ERCP workshop training twice a year. Workshop focused on reprocessing of duodenoscopes and providing care to patients undergoing ERCP procedures. This workshop was tailored toward endoscopy nurses who provide care for patients undergoing ERCP procedures at the endoscopy units, and was designed to help participants acquire knowledge, skill, and competence to promote good nursing practices in the endoscopy units.

ERCP endoscopy nurse certification: ERCP endoscopy nurse candidate is required to be a registered nurse, have prerequisite endoscopy nurse certification, and at least 2 years of full-time employment in the endoscopy unit. The candidate is required to participate in a minimum of 60 ERCP procedures, have an additional 2 years of working experience in the ERCP procedure room, and the completion of a hands-on training workshop for ERCP endoscopy nurses. A certificated ERCP endoscopy nurse must pass a 2-step examination: written examination and objective structured clinical examination. Step 1: written examination includes multiple choice and essay questions. Step 2: objective structured clinical examination that uses simulator models for ERCP procedure and reprocessing.

On-site audit team training: DEST and 3M Taiwan Company (3M Company, St. Paul, MN) cohosted the on-site audit training for the external observers, site coordinators, and site endoscopy nurses before conducting on-site audit. To standardize the observation process and ensure coverage of all important items, DEST reviewed and developed an observation record checklist. The site coordinator, who was a manager or supervisor of the visited endoscopy unit, managed the study activities within its institution. Two external observers including 1 endoscopist and 1 endoscopy nurse (who were not working in the same hospital), were assigned to each endoscopy unit for on-site audit. The external observers documented none of the activities occurring in patients' care areas prior to the duodenoscope being delivered to the reprocessing room. Audit team members were trained to independently perform the ATP testing before the on-site audit. During the on-site audit, ATP testing was performed by the audit team member.

First round on-site audit

The purpose of the first round audit was to identify the manual cleanliness status of patient-used duodenoscopes by conducting ATP tests in each endoscopy unit. ATP test for patient-used duodenoscope cleanliness was assessed immediately after the manual cleaning procedure without high-level disinfection. A dedicated room adjacent to the procedure room was used by the audit team member for ATP testing. Personnel wore gloves, gown, goggles, and surgical masks to perform the cleaning and ATP test.

ATP tests were conducted in accordance with the manufacturers' instructions.[18] ATP sampling involves the sampling of 5 locations on the patient-used duodenoscope: 10 cm along the distal end outer surface (L-1), elevator mechanism (L-2), distal attachment cap (L-3), elevator wire channel (L-4), and suction biopsy channel (L-5). ATP surface samples were obtained from locations L-1, L-2, and L-3 by ATP test (Clean-Trace ATP Surface, 3M, St. Paul, MN). ATP channel rinsate samples obtained from locations L-4 and L-5 were flushed with sterile water and then the channel rinsate was harvested for ATP test (Clean-Trace ATP Water, 3M). ATP levels are presented as the relative light units (RLUs). Based on the published benchmark, 200 RLUs were set as the pass/fail standard for endoscope cleaning.[14,15] ATP level exceeding the benchmark at 1 or more locations of the duodenoscope indicated that the manual cleaning of the endoscope was inadequate. An endoscopy nurse in each visited endoscopy unit provided data on duodenoscope age, ERCP procedure volume, and repair history.

Intervention and enrichment period

To standardize the QC program during the intervention and enrichment period, DEST proposed observation checklists of the main manual cleaning problems: (1) personnel and training problems, (2) reprocessing guideline and procedure problems, and (3) endoscope and accessory problems. The reasons for inadequate manual cleaning were voted on by the QC program team members (external observers and site coordinators) based on the actual reprocessing practice documents and observation. The finalized observation checklists were presented to the DEST after the follow-up audit. Information reported was confidential and submitted to individual endoscopy units.

During the 3-month intervention and enrichment period, site coordinator and endoscopy nurses of each endoscopy unit engaged together to identify the specific reasons for the inadequacy of manual cleaning related to the specific location, endoscope, procedure, and personnel. Each endoscopy unit formulated plans for corrective action and took additional steps to ensure guideline adherence and standardization of practice.[18]

Follow-up audit

The purpose of the follow-up on-site audit was to ensure manual cleaning efficacy and correct performance of manual cleaning after the 3-month intervention and enrichment period.

Statistical analysis

All data were entered into an Excel software (Microsoft, Redmond, WA) spreadsheet. Statistical analyses were carried out using SPSS version 22.0 (IBM, Armonk, NY). The Fisher exact test or the Pearson χ^2 test was used to compare ATP test results by different location, high- and low-volume endoscopy units, and workshop training. The paired t test was used to compare the ATP test results at the same location between 2 on-site audits. Range and mean of ATP test results between 2 on-site audits were analyzed by the Student t test. Statistical significance was defined as a *P* value <.05.

RESULTS

First round on-site audit

First round audit was conducted from October to December 2016. Fourteen hospitals participated in the QC program (Table 1). The 14 enrolled hospitals had different characteristics including the hospital level, number of hospital beds, volume of endoscopy procedures, volume of ERCP procedures, number of endoscopy nurses, number of certified ERCP endoscopy nurses, and the number of endoscopy staff nurses who attended the hands-on training workshop. Two hospitals were excluded because hospital M was noncompliant with the study protocol, whereas at hospital N, the endoscopy unit was undergoing a renovation project during the study period. Twelve hospitals and 27 patient-used duodenoscopes (models JF-260V, n = 20; TJF-260V, n = 7; Olympus Medical Systems, Tokyo, Japan) were included in the analysis.

A total of 135 ATP tests were conducted from 5 locations of the 27 patient-used duodenoscopes in the 12 hospitals during the first round of audit (Table 2). A total of 58 of 135 (43.0%) ATP tests exceeded the 200 RLU benchmark and were considered as ATP test fail. ATP test fail was detected from 8 (29.6%), 14 (51.9%), 16 (59.3%), 10 (37.0%), and 10 (37.0%) samples at L-1 to L-5 in the patient-used duodenoscopes, respectively. Nineteen of 27 (70.4%) patient-used duodenoscopes were recorded as inadequate manual cleaning. Inadequate manual cleaning in patient-used duodenoscopes showed a wide percentage range from 0-100% among the 12 hospitals.

Follow-up audit

Follow-up audits were conducted from April to August 2017. Twelve hospitals and 32 patient-used duodenoscopes (models JF-240, n = 2; JF-260V, n = 20; TJF-260V, n = 10; Olympus Medical Systems) were included in the analysis.

ATP test results during follow-up audit: A total of 160 ATP tests were conducted from 5 locations of 32 patient-used duodenoscopes during the follow-up audit. Fourteen of 160 (8.8%) ATP tests exceeded the 200 RLU benchmark and were considered as ATP test fail. ATP test fail was detected from 2 (6.3%), 3 (9.4%), 4 (12.5%), 5 (15.6%), and 0 (0%) at L-1 to L-5 of the duodenoscopes, respectively. Six of 32 (18.8%) patient-used duodenoscopes were recorded as having inadequate manual cleaning from hospital E, I, and L (Table 3).

ATP tests for each location on the duodenoscope: ATP test fail markedly decreased between the first round and the follow-up audit, respectively, at L-1 (29.6% vs 6.3%; *P* = .045), L-2 (51.9% vs 9.4%; *P* < .001), L-3 (59.3% vs 12.5%; *P* < .001), L-4 (37.0% vs 15.6%; *P* = .042), and L-5 (37.0 vs 0%; *P* < .001) (Fig 1).

Range and mean of ATP tests for each location on the duodenoscope: After the intervention and enrichment period, significant decrease occurred in the range and mean of ATP levels at L-1 to L-5 of the duodenoscopes. The maximum ATP levels for the L-1 (264 RLUs), L-2 (700 RLUs), L-3 (427 RLUs), and L-4 (560 RLUs) failed to achieve the ideal ATP benchmark of <200 RLUs during the follow-up audit (Table 4).

ERCP training workshop: During the first round of audit, ATP test failure rate of 65.2% was for the endoscopy nurses that attended the workshop training, whereas 100.0% was for the endoscopy nurses that did not attend the workshop training (*P* = .286). After the intervention and enrichment period, ATP test fail rate markedly decreased for the endoscopy nurses with previous workshop training (65.2%-21.7%; *P* = .003) and without workshop training (100.0%-11.1%; *P* = .007).

High- and low-volume endoscopy units: Volume of ERCP procedure of endoscopy units were arbitrarily divided into 2 endoscopy units: high-volume (>50 per month) and low-volume (<50 per month). The ATP test fail among high-volume (72.2%) and low-volume (66.7%) endoscopy units did not show significant difference (*P* = 1.000) during the first round audit. After the intervention and enrichment period, ATP test fail markedly decreased in the high-volume (72.2%-13.0%; *P* < .001) but did not reach significant difference in the low-volume (66.7%-33.3%; *P* = .347) endoscopy units.

Advanced reprocessing measures: The rates of repeat testing after rewashing that continued to be abnormal were 18.5% in the first round and 6.3% in the follow-up audit. Twelve hospitals employed various advanced reprocessing measures such as double cycles of high-level disinfection (9 hospitals); ethylene oxide sterilization (2 hospitals); and culture surveillance (performed by all enrolled hospitals, periodically) (Table 3).

Table 1
Hospital characteristics

Hospital	Hospital level	Hospital beds (n)	Endoscopy procedures (per month)	ERCP procedures (per month)	Endoscopy nurses (number of persons)	ERCP endoscopy nurses (number of persons)	Hands-on training workshop
A	Medical center	2,100	1,500	100	17	4	Yes
B	Medical center	2,200	2,000	70	13	1	Yes
C	Regional hospital	740	1,000	25	13	0	No
D	Regional hospital	980	800	20	5	3	Yes
E	Regional hospital	1,050	800	25	6	2	Yes
F	Medical center	1,190	1,500	90	12	0	No
G	Medical center	3,410	2,500	110	22	5	Yes
H	Medical center	1,740	1,200	62	7	2	Yes
I	Medical center	1,280	1,500	97	17	1	Yes
J	Regional hospital	1,040	500	15	8	0	No
K	Medical center	1,200	1,600	45	12	0	No
L	Medical center	1,310	1,000	25	10	0	No
M	Regional hospital	1,020	800	20	6	1	Yes
N	Medical center	1,030	700	20	9	2	Yes

ERCP, endoscopic retrograde cholangiopancreatography.

Table 2
ATP test of duodenoscope during first round on-site audit

Hospital	*ATP test fail at different locations of duodenoscope (n = 27)					Manual cleaning of duodenoscope (n = 27)		
	L-1	L-2	L-3	L-4	L-5	Inadequate	Total	Percentage
	(n)	(n)	(n)	(n)	(n)	(n)	(n)	(%)
A	0	1	1	1	0	1	3	33%
B	1	0	1	0	0	2	4	50%
C	1	1	1	1	1	1	2	50%
D	0	0	1	1	1	2	2	100%
E	0	0	0	0	0	0	1	0%
F	0	2	2	0	0	2	2	100%
G	4	6	5	5	5	6	6	100%
H	1	1	1	0	1	1	2	50%
I	0	1	1	1	0	1	1	100%
J	1	1	1	1	1	1	1	100%
K	0	0	0	0	0	0	1	0%
L	0	1	2	0	1	2	2	100%
Total	8 (29.6%)	14 (51.9%)	16 (59.3%)	10 (37.0%)	10 (37.0%)	19	27	70.4%

ATP, adenosine triphosphate; *L-1*, distal end outer surface; *L-2*, elevator mechanism; *L-3*, distal attachment cap; *L-4*, elevator wire channel; *L-5*, suction biopsy channel.
*ATP tests fail (%) at locations of duodenoscope were analyzed using the Fisher exact test ($P = .456$).

Table 3
ATP test for duodenoscopes during the follow-up audit (n = 32)

Hospital	*ATP test fail at different location					Manual cleaning of duodenoscope			Advanced reprocessing measures		
	L-1 (n)	L-2 (n)	L-3 (n)	L-4 (n)	L-5 (n)	Inadequate (n)	Total (n)	Percentage (%)	Double HLD	EO sterilization	Culture surveillance
A	0	0	0	0	0	0	3	0%	✓		✓
B	0	0	0	0	0	0	4	0%	✓		✓
C	0	0	0	0	0	0	1	0%			✓
D	0	0	0	0	0	0	2	0%	✓		✓
E	0	0	2	2	0	2	2	100%			✓
F	0	0	0	0	0	0	4	0%	✓	✓	✓
G	0	0	0	0	0	0	4	0%	✓		✓
H	0	0	0	0	0	0	4	0%	✓		✓
I	2	3	2	2	0	3	4	75%	✓	✓	✓
J	0	0	0	0	0	0	1	0%			✓
K	0	0	0	0	0	0	1	0%	✓		✓
L	0	0	0	1	0	1	2	50%	✓		✓
Total	2	3	4	5	0	6	32	18.8%	9	2	12

ATP, adenosine triphosphate; *EO*, ethylene oxide; *HLD*, high-level disinfection; *L-1*, distal end outer surface; *L-2*, elevator mechanism; *L-3*, distal attachment cap; *L-4*, elevator wire channel; *L-5*, suction biopsy channel.
*ATP tests fail (%) at locations of duodenoscope were analyzed using the Fisher exact test ($P = .001$).

Main problems with manual cleaning

The reasons for inadequate manual cleaning were voted on by the QC program team members. Observation checklists were presented to DEST after the follow-up audit.

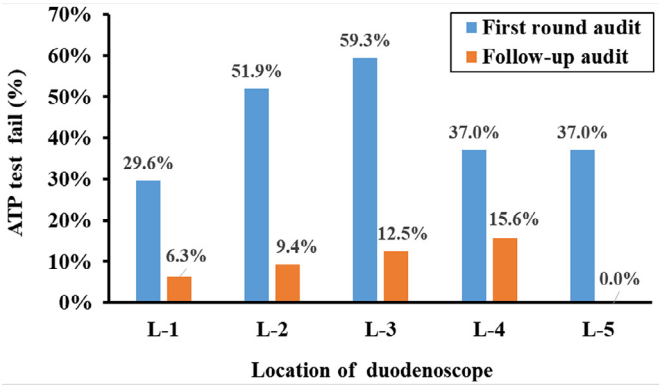

Fig 1. ATP test fail for each location on the duodenoscope. Distal end outer surface, L-1; elevator mechanism, L-2; distal attachment cap, L-3; elevator wire channel, L-4; suction biopsy channel, L-5. *ATP*, adenosine triphosphate.

Personnel and training problems: Nine of 30 (30.0%) respondents reported that the endoscopy cleaning staff did not attend the hands-on training workshop, 5 (16.7%) reported that manual cleaning was not performed by certified ERCP endoscopy nurses, and 1 (3.3%) respondent reported inadequate training of endoscopy staff personnel.

Reprocessing guideline and procedure problems: Twenty-four (80.0%) respondents reported that they did not use double cycles of high-level disinfection for reprocessing, 23 (76.7%) respondents reported that they did not use ethylene oxide sterilization for reprocessing, 21 (70.0%) respondents reported that they had no ATP monitoring protocol after manual cleaning, whereas 20 (67.7%) indicated not having had immersed duodenoscope in enzymatic detergent per manufacturer's instructions. Furthermore, 16 (53.3%) respondents reported not having had sufficient time for an effective manual cleaning, 11 (36.7%) reported not having used the enzymatic detergent with biofilm removal efficiency, whereas 4 (13.3%) reported a delay of >60 minutes prior to the manual cleaning of the patient-used duodenoscope.

Endoscope and accessory problems: Seven of 30 (23.3%) respondents did not discard the damaged cleaning brush, 6 (20.0%) respondents did not thoroughly clean or disinfect the cleaning brush between uses, and 3 (10.0%) respondents did not use the manufacturer-approved cleaning brush. Furthermore, 7 of 30 (23.3%)

Table 4
Range and mean of ATP tests for each location on the duodenoscopes

Location	ATP test (RLU) first round on-site audit (n = 27)		ATP test (RLU) follow-up audit (n = 32)		*P* Value
	Min – Max	Mean ± SD	Min – Max	Mean ± SD	
L-1	24 – 13,347	956 ± 2,740	9 – 264	93 ± 63	.040
L-2	38 – 20,032	1,749 ± 4,284	18 – 700	112 ± 153	.017
L-3	77 – 5,409	898 ± 1,348	27 – 427	101 ± 92	.001
L-4	16 – 2,899	399 ± 74	3 – 560	109 ± 119	.017
L-5	7 – 2,322	415 ± 656	3 – 182	58 ± 47	.002

ATP, adenosine triphosphate; *RLU*, relative light units; *L-1*, distal end outer surface; *L-2*, elevator mechanism; *L-3*, distal attachment cap; *L-4*, elevator wire channel; *L-5*, suction biopsy channel; *Min*, Minimum; *Max*, Maximum.

respondents reported damaged endoscope at the outer surface of the distal end, 6 (20.0%) at the elevator mechanism, 0 (0.0%) at the distal attachment cap, 6 (20.0%) at the elevator wire channel, and 6 (20.0%) at the suction biopsy channel.

DISCUSSION

This study demonstrated that the adequacy of the manual cleaning of duodenoscopes varied widely among endoscopy units across the country. Theoretically, endoscopy units received regular microbiological surveillance monitoring, documentation of training and competency verification, and hospital accreditation process by internal and external reviewers.[16] However, our real-world audits showed that there is a great variation in the ability of the reprocessing staff to achieve adequacy in manual cleaning. This raises concern that current reprocessing guideline or procedure cannot ensure patient-safe endoscopy.

ATP tests can provide documentation to verify the cleaning efficacy of each duodenoscope at each of its locations, on each personnel regarding adherence, and in each endoscopy unit.[19,20] Duodenoscopes are difficult to clean and disinfect and are easy to damage because of their complex design.[21] Consistent with previous studies, indeed, we found that elevator mechanism (L-2), elevator wire channel (L-4), and suction biopsy channel (L-5) were not adequately cleaned. It is most likely that there was no effective physical brushing of the elevators and channels during the manual cleaning process.

Surprisingly, we found a high percentage of the distal attachment caps (L-3) were not adequately cleaned (Table 2). Models (Olympus JF-240, JF-260V, and TJF-260V) used in many Asian countries with the characteristic “exposed” elevator wire channel requires reprocessing. The distal attachment cap requires cleaning using a medical cleaning brush.[1] Brushes may break, become damage, or have missing bristles. Our results suggest that reprocessing procedures were not sufficient to ensure the successful decontamination of the distal attachment caps and/or cleaning brush for patient-used duodenoscope after manual cleaning. What can we do to enhance the manual cleaning in the endoscopy units? Previously published QC programs were usually performed for high-level disinfection, but not commonly implemented to verify the efficacy of the manual cleaning in the endoscopy units.[22] DEST developed several strategies to check and improve the adequacy of manual cleaning considering the inherent complexity of duodenoscopes.

High-volume endoscopy units

Endoscopy units with high-volume ERCP procedures usually have sufficiently well-trained personnel performing manual cleaning, but do not always ensure an adequate manual cleaning time for effective cleaning.[22,23] It is necessary to have 100% manual cleaning compliance and a near zero infection rate in a busy endoscopy unit.[24]

There is the potential for biofilm formation with a >60 minute delay after precleaning.[25] The cleaning of a patient-used endoscope may take place beyond the 60 minute delay prior to manual cleaning, then, the endoscope should be soaked in cleaning solution after the delayed processing per the manufacturer-validated instruction.

Low-volume endoscopy units

Small endoscopy units usually have insufficient resources to perform the manual cleaning. These small endoscopy units require a thorough understanding of associated capital and costs, compared with quality improvements.[23]

Widely varying levels of compliance with the manual cleaning in the endoscopy units occurred. Nurses with special training in endoscopy units are key players in maintaining repossessing standards. Taiwan endoscopy nurses in the low-volume endoscopy units may not have adequate experience in the training regarding reprocessing of endoscopes, ERCP procedures, and patient care, overall. Accordingly, DEST provided the financial support to organize the hands-on training workshops and courses, as well as the ERCP endoscopy nurse’s certification, as part of the local cascade of options for QC improvement.

Endoscope and accessory damage

Duodenoscopes and accessories are easy to damage because of their complex design, with narrow lumens and multiple internal channels.[21] With continuous use of the damaged endoscope or accessories, organic debris may enter into different areas of the device, interfere with the reprocessing procedure, and may allow biofilm development.[13] Feasibility and appropriateness in the use of additional modalities suggested by the US Food and Drug Administration for duodenoscopes in the practice must be considered.[26,27]

Response for ATP testing repeated failures

If patient-used duodenoscope ATP testing fails, the duodenoscope should be cleaned manually and the ATP test should be performed again. The failure of repeated ATP testing at the same location or by the same personnel raises the concern that there may be minor or unseen duodenoscope damage, or that such personnel did not follow the reprocessing guideline. Advanced reprocessing measures such as double cycles of high-level disinfection, ethylene oxide sterilization, and culture surveillance could be considered.

Staff training, competency, and certification

Endoscopy nurses’ competencies on endoscope reprocessing were assessed at initiation of personnel duties and periodically including at ATP test fail, microbiologic culture failure, anytime a breach is identified, or when a new technique or equipment is introduced. Competency verification included direct observation in addition to other assessments per facility policy.[12] The

following were documented for each procedure: endoscope, automated endoscope reprocessor, date and type of the procedure, and name of the personnel performing the endoscopic reprocessing. The certification of the ERCP endoscopy nurse was encouraged to meet competency standards on ERCP procedure and endoscope reprocessing in clinical practice. Audit program for endoscope reprocessing was followed by training, and retesting is important and has proved useful locally in Taiwan.

Limitations

Limitations include the following: (1) surveillance cultures can be considered as the affirmation of the overall duodenoscope reprocessing. Culturing of endoscopes every month is recommended by Taiwan reprocessing guidelines. All enrolled hospitals performed duodenoscope culture surveillance periodically (Table 3). We did not perform additional cultures because the focus was on the manual cleaning of duodenoscopes, but not the entire process, in this study. (2) ATP tests were performed for patient-used duodenoscopes immediately after the manual cleaning on the day of the audit visit. It is inevitable to have variations in patient-used duodenoscopes and models between the 2 on-site visits. This study could not clearly define the flaw of each manual cleaning procedure in the endoscopy units. (3) Endoscopy unit may use nonstandardized protocol, developed off of the DEST guideline but with the exact instructions on use.[28] DEST developed the second version of the duodenoscope reprocessing guideline in 2019.[29] Endoscope reprocessing practices should be interpreted in specific clinical situations and according to resource availability, but may not be optimally conveyed in generalizable terms to different countries.

CONCLUSIONS

Our study demonstrated that adequacy in the manual cleaning of duodenoscopes varied widely among endoscopy units across the country. ATP cleanliness monitoring may provide real-time feedback on cleaning efficacy of the patient-used duodenoscopes. Endoscopy managers or supervisors need to set clear expectations in competency verification and ensure adequacy of the manual cleaning for patient-used duodenoscopes. Implementing a comprehensive QC program could improve the efficacy of cleaning in endoscopy units.

Acknowledgments

The authors thank 3M Taiwan Company and Tzu-Ling Liu who cohosted and participated in the audit team training. The authors thank all external observers, site coordinators, and site endoscopy nurses who participated in this study. The quality control program external observers included the following: Chao-Chen Shen, RN, Ming-Yao Su, MD, Chang Gung Memorial Hospital, Linko; Chih-Jen Chen, MD, Mackay Memorial Hospital, Taipei; Hsiao-Fen Lin, RN, His-Chang Lee, MD, Taipei City Hospital, Ren-Ai Branch; Yu-Wen Huang, RN, Tseng-Shing Chen, MD, Taipei Veterans General Hospital; Cheuk-Kay Sun, MD, Shin Kong Wu Ho-Su Memorial Hospital; Tao-Chieh Liu, RT, Wei-Kuo Chang, MD, Tri-Service General Hospital; Chen-Ling Peng, RN, Hsiu-Po Wang, MD, National Taiwan University Hospital; Jui-Hsiang Tang, MD, Taipei Medical University Hospital; Chin-Chuan Wu, RN, Buddhist Tzu Chi Medical Foundation Hualien Tzu Chi Hospital; Ying-Chyn Feng, RN, Jiann-Hwa Chen, MD, Buddhist Tzu Chi Medical Foundation Taipei Tzu Chi Hospital; Ming-Chu Wen, RN, China Medical University Hospital; Chien-Hua Chen, MD, Show Chwan Memorial Hospital, Changhua; E-Ming Wang, RN, Kaohsiung Veterans General Hospital; Wei-Na Chen, RN, Yen-Chun Peng, MD, Taichung Veterans General Hospital; Hui-Ching Chuang, RN, Kaohsiung Medical University Chung-Ho Memorial Hospital; Jeng-Shiann Shin, MD, Cheng Ching Hospital Chung Kang Branch.

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