Monthly endoscopy surveillance culture facilitates detection of breaches in the scope reprocessing procedure: 5 year-experience in an endoscopy center

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Research article

Keywords: endoscopy surveillance culture, scope reprocessing procedure, endoscope contamination

Posted Date: December 20th, 2019

DOI: https://doi.org/10.21203/rs.2.19420/v1

Abstract

AIM To review the clinical impact of monthly microbiology surveillance culture for monitoring endoscope contamination after high-level disinfection.

METHODS Monthly surveillance culture of the endoscopes was conducted from January 2014 to December 2018 at our endoscopy center. A total of 1931 cultures were collected, including 765 cultures from 16 gastroscopes, 730 cultures from 18 colonoscopes, 379 cultures from 8 duodenalscopes, 46 cultures from 1 echoscopes, and 11 cultures from 1 enterscope. Cultures were obtained from ready-to-use endoscopes after a full reprocessing cycle and storage. Samples were cultured to test for aerobic and anaerobic bacteria.

RESULTS The positive culture rates for the endoscope were 2% (15/765) for gastroscopes, 1.9% (14/730) for colonoscopes, 0.8% (3/379) for duodenscopes, 4.3% (2/46) for echoscopes, and 9.1% (1/11) for enterscopes. These findings were predominantly attributed to human factors (71.4%, 25/35) followed by storage cabinet failure (14.3%, 5/35), automatic endoscope reprocessing failure (11.4%, 4/35), and endoscope channel damage (2.8%, 1/35). Multivariate analysis showed that the years 2015 [odds ratio (OR) 0.19, 0.04 to 0.91], 2016 (OR 0.21, 0.05 to 0.80), and 2017 (OR 0.22, 0.06 to 0.83) were associated with decreased risk of endoscope contamination. The age, type, and number of times the scope was used were not related to contamination.

CONCLUSIONS A low risk of endoscope contamination was found over a 5-year period in our endoscopy center. The most common cause of contamination was human factor. Duodenalscopes showed the lowest scope contamination rate. We suggested the implantation of a systematic endoscope culture regardless of the type of scope to facilitate early detection of breaches in the scope reprocessing procedure in clinical practice.

Introduction

Modern endoscopes have delicate designs with long channels, valves, or elevators that are difficult to clean and are prone to damage. Endoscope reprocessing is a complex process that decontaminates endoscopes for subsequent reuse [1–3]. Failure of reprocessing can result in the transmission of pathogens. Endoscopy-associated infection has become an important issue since the outbreak of carbapenem-resistant Enterobacteriaceae (CRE) infection after endoscopic retrograde cholangiopancreatography in the USA between 2012 and 2015 [4]. These outbreaks resulted in efforts to investigate the quality and efficacy of endoscope reprocessing, as well as factors that influence transmission between endoscopes and patients [2, 5, 6].

Microbiological surveillance is a method used to evaluate the outcome of endoscopy reprocessing and is used for regular quality control in endoscopy units [1, 7]. Rigorous culturing of all duodenoscopes after reprocessing of every instrument was reported to terminate an ongoing outbreak of transmission related to duodenoscopes [8]. In the so-called culture and quarantine approach, all instruments are sampled after

reprocessing then stored for 48 h, pending the return of culture results verifying the absence of pathogenic organisms, before reuse [8]. Although this approach is ideal, it is not practical in busy daily practice and is expensive. The frequency of obtaining microbiology cultures varies from different international guidelines. The European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology and Endoscopy Nurses and Associates guidelines recommend routine testing at intervals of no longer than 3 months [7]. The Australia guideline recommends that duodenoscopes and endoscopic ultrasound instruments are monitored every month, and other endoscopes are monitored every 3 months [9]. In the USA, microbiology testing of endoscopes after reprocessing, during storage, or before use is not advised [2]. The Digestive Endoscopy Society of Taiwan (DEST) recommends randomly testing at routine intervals [10].Surveillance culturing as a quality assurance measure is advised in these reprocessing guidelines but the optimal interval of surveillance remains controversial. In 2014, our institution began a monthly microbiology surveillance program for all endoscopy in use as a quality indicator due to lack of a reliable real-time indicator after endoscopy reprocessing. The present study reviewed the results of intensive microbiology surveillance, identifying risk factors related to scope contamination and its clinical impact on daily practice.

Materials And Methods

Endoscope reprocessing cycles and storage

The ESGE and DEST guidelines recommend that endoscope reprocessing cycle consists of bedside precleaning, manual leak testing, manual cleaning in the cleaning facility, and high-level disinfection in the automatic endoscope reprocessing (AER) [1, 10, 11]. Endoscopes were cleaned manually by qualified endoscopy technicians by brushing and rinsing with tap water and an enzymatic detergent. Manual cleaning was followed by decontamination by the technician using an AER (DSD EDGE Dual Basin AER, Medivators Inc., Minnesota, USA). The liquid disinfectant used was 0.55% ortho-phthalaldehyde solution, which was stored at 15 °C to 30 °C and tested using a test strip prior to each use to ensure the concentration was above the minimum effective concentration. Following AER reprocessing and drying, the scope was transported or stored in a temperature-controlled cabinet for clinical use. The endoscopy unit have a standard protocol for reprocessing and education for the staff. The study didn’t involve human material and the study was approved by the Institutional Research Board of the Changhua Christian Hospital (No. Y-108-0188).

Endoscope sampling and culture methods

In 2014, we began monthly sampling of the endoscope after high-level disinfection performed by two senior endoscopy technicians. Rinse samples were obtained by flushing the biopsy channels with 100 mL of sterile distilled water under highly aseptic conditions, distributing 50 mL into the working channel and 50 mL into the air/water channel. The distilled water was contained in an aseptic vial (20 mL/vial) manufactured for medical use. The total sample (100 mL) was recovered at the distal end of the endoscope and incubated at 30 °C on plate count agar after filtration of 100 mL through a 0.45 μm filter

(Biosart100 Monitors 16401-47-06—ACK, Sartorius, Germany). The filter membrane obtained was aseptically removed, transferred to the total count broth (Biosart100 Nutrient Media 16400-02—TC-K, Sartorius, Germany), and incubated at 35 °C ± 1 °C for 48 ± 3 h. After incubation, results were expressed as the number of colony-forming units per 100 mL. After culturing was complete, the endoscope was reprocessed and returned for reuse, pending negative culture results. Each endoscope was tested by culture once monthly, and the schedule for culturing was based on a scheduled volume and was preferentially performed at a weekend as the endoscope would be out of circulation for approximately 48 h.

Microbiology review process of the endoscopy units

Positive cultures from the endoscope were followed up by a discussion with the infection control unit, followed by investigation into the source of contamination by the endoscopy center. The infection control unit identified and followed patients who underwent procedures using the contaminated device, reviewed the reprocessing process with staff, repeated the reprocessing of the endoscope, and only returned the endoscope to clinical use only after a repeat culture was found to be negative. In cases of persistent contamination, the scope was sent for ethylene oxide gas sterilization followed by a repeated reviewing process. The scope was sent to the manufacturer if permanent contamination occurred [2, 12] .

Statistical Analysis

The extracted data were presented in Microsoft Excel software and analyzed using MedCalc Statistical Software version 18.11 (MedCalc Software bvba, Ostend, Belgium; https://www.medcalc.org; 2018). Chi-square test or Fisher's exact test was used for categorical variables. Statistical significance was considered for values of $P < 0.05$.

Results

Microbiology surveillance results

From January 2014 to December 2018, a total of 1931cultures, including 765 cultures from 16 gastroscopes, 730 cultures from 18 colonoscopes, 379 cultures from 8 duodenalscopes, 46 cultures from 1 echoscopes, and 11 cultures from 1 enterscope (Fig 1). The type, age, and monthly use of the scopes are summarized in Table 1. The overall positive culture rate was 1.8% (35/1931), with three positive culture results considered to be insignificant (<10 colonies of skin flora). The positive culture rates of the endoscopes were 2% (15/765) for gastroscopes, 1.9% (14/730) for colonoscopes, 0.8% (3/379) for duodenscopes, 4.3% (2/46) for echoscopes, and 9.1% (1/11) for enterscopes. The most frequently cultured pathogenic organism was *Klebsiella pneumoniae* (n = 13) followed by *Pseudomonas aeruginosa* (n = 11), *Enterococcus* spp. (n = 1), *Candida* spp. (n = 5), *Alcaligenes faecalis* (n = 1), and *Acinetobacter baumannii* (n = 1).

Analysis of the year of microbiology sampling revealed a higher rate (3.9%) of scope contamination in 2018 (Table 2). There was no association between the age and type of scope and scope contamination

rate (Tables 3 and 4). Multivariate analysis showed that the years 2015 [odds ratio (OR) 0.19, 0.04 to 0.91), 2016 (OR 0.21, 0.05 to 0.80), and 2017 (OR 0.22, 0.06 to 0.83) were associated with a decreased risk of endoscope contamination. The age, type, and monthly use of the scopes were not related to endoscope contamination.

Risk factors for scope contamination

A monthly meeting was held between the infection control center and endoscopy center for root cause analysis to investigate the cause of scope contamination (Table 5). The most common causes were found to be human factors (71.4%; 25/35), followed by storage cabinet damage (14.3%; 5/35), AER failure (11.4%; 4/35), and endoscope channel damage (2.8%; 1/35). In 2018, there were five incidents of *Candida* spp. contamination in the same month. An investigation found that all the contaminated scopes were placed in the same endoscope storage cabinet and the cabinet drying function was found to be damaged. There were four incidents of scope contamination, and a review of the reprocessing procedure identified damage to the AER endoscope connector. There was one incident of persistent scope contamination, despite repeated culturing and ethylene oxide gas sterilization. The scope was finally sent to the manufacturer, and damage to the internal channel was found. The contamination was resolved by changing the channel of the scope.

Discussion

The present study reviewed a 5-year monthly microbiology endoscopy surveillance and found a low risk of endoscope contamination in our endoscopy unit. Consistent with previous reports, the most common cause of scope contamination was found to be human factors [1, 5, 13, 14]. Despite the complex design of the duodenal scope and recent concerns about duodenal scope contamination [3, 5, 15, 16], duodenal scopes showed a lower scope contamination rate in our study compared with those in previous reports [7, 17, 18] and the frequency of microbiology surveillance should be the same regardless the type of endoscope. A monthly culture of all endoscopes in our unit helped to detect scope contamination and pinpoint the step in the endoscope reprocessing procedure in which contamination occurred.

There are two main methods used to evaluate endoscope contamination after high-level disinfection: non-culture and culture-based methods. The former includes the use of ATP and bioburden testing for point-of-care testing for contamination to measure the performance of manual cleaning [4, 19, 20]. However, this method shows a poor correlation with cultures of fully reprocessed devices [4] and requires extra work, particularly in a high-volume unit. The microbiological culture of endoscopes is critical to understanding the efficacy of reprocessing and transmission of microorganisms during outbreak investigations [8, 17, 18, 21-23]. However, the existing guidelines are inconsistent in terms of the recommended frequency and method of microbiological monitoring [7, 9, 24] (Table 6). In Europe [7] and Australia [9, 10], endoscopy microbiology surveillance is regarded as a critical indicator of endoscope reprocessing quality. DEST recommend that microbiology surveillance is performed at a regular

frequency [10]. In contrast, the US guidelines recommend against the use of endoscopy microbiology and require more data before a surveillance program should be implemented by healthcare facilities [2]. In the present study, a low risk of scope contamination from various etiologies was identified in the monthly endoscopy surveillance program. Although scope contamination may not be correlated with patient infection, we found this strategy helped early identification of the breach of the reprocessing process before the occurrence of outbreak of scope-related infection.

Many studies have reported a higher rate of duodenal scope contamination [7, 17, 18, 25], and the ESGE recommends a close surveillance interval for duodenal scope compared with that for other types of scopes [1, 7]. Because of increased awareness of the high risk of duodenal scope reprocessing failure and the report of duodenal scope transmitted infection in 2014, our endoscopy staff were trained and audited for duodenal scope reprocessing [20]. The rate of inadequate manual cleaning decreased from 70.4% to 18.8% after auditing the reprocessing process [20]. The present study found a low rate of duodenal scope contamination compared with that of other types of scopes. This may be due to an increased awareness of reprocessing of this specific type of scope within the unit. As prompt identification of contaminated endoscopes is vital to prevent an outbreak of scope transmission, we suggest that monthly microbiology surveillance program should be performed, regardless of the type of endoscope, especially in this era of overemphasizing duodenal scope contamination.

The present study found that human error was the most common cause of scope contamination [26, 27]. Despite established processing guidelines, high rates of non-compliance to the reprocessing process remain [13, 28]. A lack of regular evaluation of reprocessing staff competence (60%) and regular microbiological inspection (56%) [29, 30] in the endoscopy unit was previously shown to result in guideline non-compliance. Education of endoscopy staff was shown to decrease the rate of endoscope contamination after high-level disinfection [19, 27]. In our unit, we performed an annual competence evaluation of endoscopy staff and still failed to eliminate non-adherence to the reprocessing guidelines. In 2018, our unit introduced the Olympus 290 system, which has a different design than the previously used Olympus 260 system. Thus, in 2018, a lack of familiarity with the new system and a mixture of different endoscope modes (Olympus 260 model and Olympus 2290 model) were attributed to the increased incidence of human error in our endoscopy unit. This obvious challenge in the current endoscopy reprocessing procedures [30-32] was not addressed in the recent endoscopy reprocessing guidelines [1, 2]. A wide variety of devices continually require reprocessing in the endoscopy unit, and technicians need to identify each type, brand, and model of endoscope and apply appropriate reprocessing procedure. Furthermore, complete reprocessing of each endoscope takes up to 40 min [33], and the technician may speed up the process due to high-volume loads, which may lead to an increased reprocessing error [26, 34]. Memory violation due to too many reprocessing steps, a lack of real-time feedback, and visibility violation were the most causes of human errors during endoscopy reprocessing [32, 35, 36]. Therefore, future studies into endoscopy reprocessing are required to identify the optimal workload for endoscopy technicians, improve the design of endoscopes to simplify and unify the reprocessing procedures, and improve the reprocessing environment to make a safer, more efficient, and more compatible workspace [32].

The present study has some limitations. Quality control is fundamental to the delivery of safe and efficient endoscopic procedures, and surveillance cultures are an important method; however, the optimal method for sampling and culture incubation periods vary among different countries [37]. We adopted the flush method for microbiology surveillance, as recommended by the DEST guidelines, and the culture recovery rate may be lower than using the flush–brush–flush methods [22, 37]. Furthermore, we did not perform cultures for slow-growing agents such as *Mycobacterium*. Low scope contamination was found in our study compared with that in previous reports of 12.9% to 71.4% [17, 18, 23, 25], although this may be an underestimation due to the culturing methods used and an incubation period of only 48 h. Since there were no outbreaks of endoscope-related transmission such as CRE infection at our institution, we are not able to evaluate the impact of monthly culturing to prevent scope-related transmission. As culture-negative endoscopes may have clinically significant biological residues, monthly culture monitoring should not replace other infection control methods in the unit. Culturing methods can help to detect flaws in the reprocessing procedure that could increase the risk of transmission of infectious agents in the unit.

Conclusions

A low risk of endoscope contamination was found over a 5 year period in our endoscopy center. Human factors were found to be the leading cause of scope contamination. We suggest the implementation of a systematic endoscope culture regardless of the type of scope for the early detection and etiology of scope contamination in daily practice.

Declarations

Acknowledgments

The authors would like to thank Enago (www.enago.tw) for their English language review.

Disclosure of interest

The authors report no conflicts of interest.

Ethic Statement

The study didn't involve human material and the study was approved by the Institutional Review Board of the Changhua Christian Hospital (No. Y-108-0188).

Author contributions

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Tables

Table 1. Type of scope and scope contamination rate.

Type of scope	Number of scopes	Age of scope (years; mean ± SD)	Mean monthly usage (number of times; mean ± SD)	Number of sampling	Number of positive cultures	Scope contamination rate (%)
EGD	16	4.5 ± 2.11	45.54 ± 22.69	765	15	2
Colon	18	5.1 3.03	27.96 ± 17.02	730	14	1.9
ERCP	8	5.6 ± 2.58	15.12 ± 7.92	379	3	0.8
EUS	1	2.5 ± 1.13	9.39 ± 3.97	46	2	4.3
Balloon endoscope	1	1 ± 0	3.18 ± 2.09	11	1	9.1

EGD, esophagogastroduodenoscopy; ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasound

Table 2. Scope culture and scope contamination rate by sampling year.

Year	Number of sampling cultures	Number of positive cultures	Scope contamination rate (%)
2014	316	9	2.8
2015	318	2	0.6
2016	416	3	0.7
2017	415	3	0.7
2018	466	18	3.9*

* $P = 0.0003$ compared with year 2014

Table 3. Scope contamination rate by scope age.

Age of endoscope	Number of sampling cultures	Number of positive cultures	Scope contamination rate (%)
0	3	0	0
1	233	4	1.7
2	216	2	0.9
3	230	8	3.5
4	212	6	2.8
5	246	1	0.4
6	207	4	1.9
7	215	4	1.9
8	193	1	0.5
9	97	3	3.1
10	54	1	1.9
11	25	1	4.0

Table 4. Type of scope and microbiology culture results.

Type of scope	EGD	Colon	ERCP	EUS	Balloon	Total
Bacillus spp.		1	1			2
Corynebacterium spp.				1		1
Acinetobacter baumannii		1				1
Alcaligenes faecalis		1				1
Candida spp.	4	1				5
Enterococcus spp.	1					1
Klebsiella pneumoniae	5	4	2	1	1	13
Pseudomonas aeruginosa	5	6				11

EGD, esophagogastroduodenoscopy; ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasound

Table 5. Scope contamination from 2014 to 2018.

Type of scope	Year	CFU/mL	Bacteria	Monthly scope usage (times)	Cause of scope contamination	Need for Subsequent EO
EGD	2014	12	*Klebsiella pneumoniae*	70	Human error	No
Colon	2014	10	*Pseudomonas aeruginosa*	29	Human error	No
EGD	2014	80	*Pseudomonas aeruginosa*	10	Human error	No
Colon	2014	40	*Pseudomonas aeruginosa*	22	Human error	No
Colon	2014	40	*Pseudomonas aeruginosa*	65	Human error	No
Colon	2014	10	*Alcaligenes faecalis*	15	Human error	No
Colon	2014	20	*Pseudomonas aeruginosa*	37	Human error	Pass after EO
Colon	2014	10	*Pseudomonas aeruginosa*	61	Scope breakdown	Failed after EO, change scope channel
Colon	2015	20	*Klebsiella pneumoniae*	52	Human error	No
EGD	2015	6	*Klebsiella pneumoniae*	62	Human error	No
EGD	2017	20	*Klebsiella pneumoniae*	9	Human error	No
Colon	2017	100	*Klebsiella pneumoniae*	4	Break of AER	No
EGD	2016	2	*Pseudomonas aeruginosa*	43	Human error	No
Colon	2016	200	*Klebsiella pneumoniae*	41	Human error	No
Colon	2016	10	*Acinetobacter baumannii*	2	Human error	No
EGD	2018	50	*Pseudomonas aeruginosa*	17	Break of AER connector	No
EGD	2018	200	*Klebsiella pneumoniae*	23	Break of AER connector	No
EGD	2018	80	*Enterococcus* spp.	19	Break of AER connector	No
EGD	2018	10	*Klebsiella pneumoniae*	19	Human error	No
DBE	2018	15	*Klebsiella pneumoniae*	3	Human error	No
EUS	2018	50	*Klebsiella pneumoniae*	11	Human error	No
			Klebsiella			

ERCP	2018	80	*pneumoniae*	9	Human error	Pass after ethylene oxide disinfection
Colon	2018	5	*Klebsiella pneumoniae*	7	Human error	No
EGD	2018	1	*Candida* spp.	59	Storage cabinet damage	No
EGD	2018	5	*Candida* spp.	61	Storage cabinet damage	No
EGD	2018	120	*Candida* spp.	58	Storage cabinet damage	No
EGD	2018	25	*Candida* spp.	52	Storage cabinet damage	No
Colon	2018	5	*Candida* spp.	14	Storage cabinet damage	No
EGD	2018	10	*Pseudomonas aeruginosa*	57	Human error	No
ERCP	2018	2	*Klebsiella pneumoniae*	2	Human error	No
Colon	2018	5	*Pseudomonas aeruginosa*	8	Human error	No
EGD	2018	15	*Pseudomonas aeruginosa*	47	Human error	No

CFU, colony-forming units; DBE, double balloon enteroscopy; EGD, esophagogastroduodenoscopy; ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasound

Table 6. Summary of current guideline recommendation about the frequency of microbiology surveillance of endoscope unit.

Year of Publication	Society Guidelines	Frequency of Microbiology Surveillance
2007	ESGE–ESGENA[7]	The frequency of microbiological surveillance and recommended test procedures differs across Europe. Monthly interval (Denmark, Monaco), 3-monthly interval (Croatia, Germany, Spain, Sweden, Switzerland), yearly-interval (Austria, France), and UK (no tests of endoscopes).
2016	Multisociety guideline on reprocessing flexible GI endoscopes (USA) [2]	Microbiologic testing of endoscopes after reprocessing, during storage, or before use, has not been advised in current U.S. standard
2017	Gastroenterological Society of Australia [38]	Surveillance frequency depends on types of endoscopes. Monthly interval (ERCP and EUS scope), and 3- monthly (other gastrointestinal scopes)
2017	World Endoscopy Organization [10]	Endoscopes should be randomly tested at routine intervals. Regular interval (Taiwan), quarterly (China), every 6 months (Indonesia), or institution specific (India)

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Figures

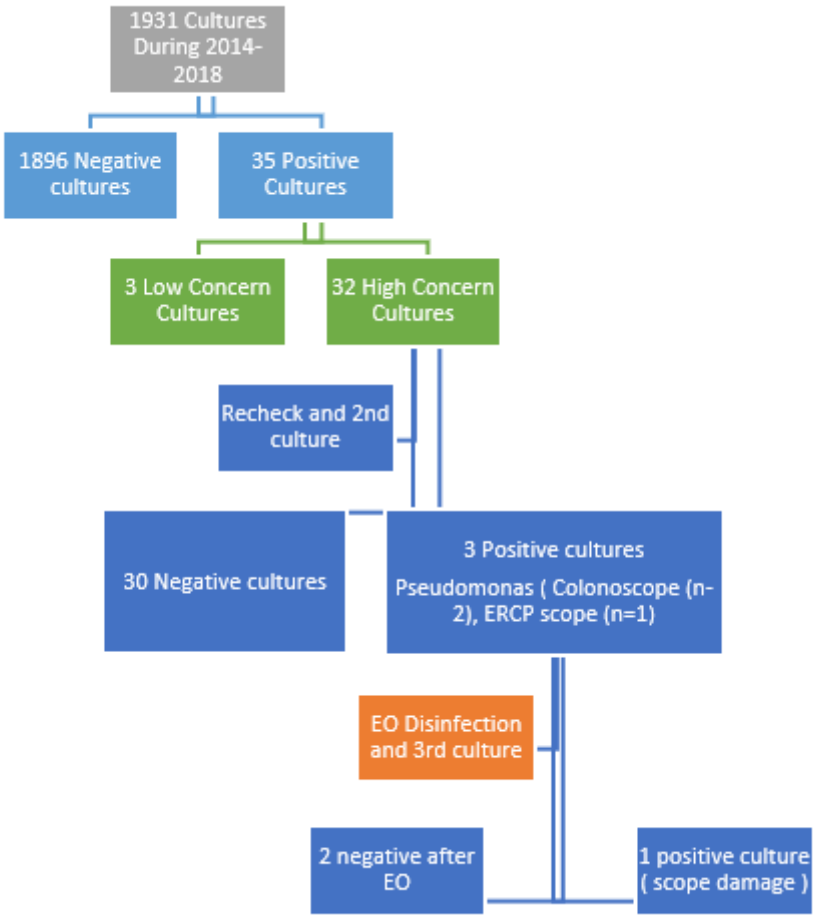

Figure 1

Endoscopy unit culture results from 2014 to 2018.