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Remote video auditing in the endoscopy unit for evaluation of duodenoscope reprocessing in a tertiary care center

Authors
Kara L. Raphael[1], Ellen McNoble[2], Jessica Goldbeck[3], Megan Stiles[3], Larry S. Miller[1], Arvind J. Trindade[1]

Institutions
1 Division of Gastroenterology, Zucker School of Medicine at Hofstra/Northwell, Long Island Jewish Medical Center, Northwell Health System, New Hyde Park, New York, United States
2 Perioperative Patient Care Services, Zucker School of Medicine at Hofstra/Northwell, Long Island Jewish Medical Center, Northwell Health System, New Hyde Park, New York, United States
3 Hospital Administration, Zucker School of Medicine at Hofstra/Northwell, Long Island Jewish Medical Center, Northwell Health System, New Hyde Park, New York, United States

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Corresponding author
Arvind J. Trindade, MD, Division of Gastroenterology, Long Island Jewish Medical Center, Zucker School of Medicine at Hofstra/Northwell, Northwell Health System, 270-05 76th Avenue, New Hyde Park, NY 11040, United States
Fax: +1-718-470-5509
arvind.trindade@gmail.com

ABSTRACT

Background A significant proportion of duodenoscope-transmitted infections have resulted from errors related to reprocessing. Remote video auditing (RVA) is a tool that can monitor reprocessing compliance but it has not been previously evaluated in a tertiary care setting. The aims of this study were to evaluate: 1) RVA feasibility in a tertiary care setting (defined as the ability to audit every step of duodenoscope reprocessing without delaying the next procedure due to unavailability of duodenoscopes); and 2) the use of RVA as a compliance monitoring tool.

Methods This was a prospective study at a tertiary care center. A video camera with offsite monitoring was installed in March 2018. Auditors delivered a compliance score after each procedure. The duodenoscope was not used until it passed the audit. Feasibility and compliance data were collected from April 2018 to August 2019 after a 1-month run-in phase. Both per-step compliance and overall 100 % compliance rates were measured.

Results Of 743 duodenoscope reprocessing procedures, 32 666 individual steps were audited and 99.9 % of the steps were fully viewable. The mean time per audit was 38.3 minutes, the mean duodenoscope turnover time was 76.1 minutes, and there were no delays to the next procedure due to unavailability of duodenoscopes. The per-step compliance rate was 99.5 % but the overall 100 % compliance rate was 90.3 %.

Conclusions The use of RVA in duodenoscope reprocessing was feasible and promoted sustained high-level compliance in a tertiary care center.

GRAPHICAL ABSTRACT

Introduction

In recent years, duodenoscopes have been implicated in the endoscopy literature for the transfer of multidrug-resistant bacterial infections. In 2013, the Centers for Disease Control and Prevention (CDC) alerted the Food and Drug Administration (FDA) to the finding that, in an Illinois hospital, there was a suspected relationship between an outbreak of carbapenem-resistant Enterobacteriaceae and contaminated duodenoscopes [1]. Several subsequent outbreaks around the world that were associated with contaminated duodenoscopes were also reported [2–7], many of which were deemed to be caused by human errors in reprocessing, and with that, scrutiny over the current duodenoscope reprocessing standards began to rise.

In 2010, an investigation by the CDC revealed that of 67 ambulatory surgical centers evaluated, over 28 % failed to adhere to the standard endoscope reprocessing recommendations

[8]. Dirlam Langlay et al. discovered that reported lapses in reprocessing endoscopes ultimately exposed over 33 000 patients to potentially contaminated endoscopes between 2005 and 2012 [9]. These lapses were reported in publicly available government and legal documents, but not in the medical literature. These lapses in infection prevention standards prompted the 2011 update to the Multisociety Guideline on Reprocessing Flexible Endoscopes [10], which were again updated in 2016 to specifically address the challenges of reprocessing duodenoscopes [11]. These guidelines echoed the FDA's recommendations [12] that duodenoscopes should be reprocessed with "strict adherence to the duodenoscope manufacturer's reprocessing instructions," and stated "each endoscopy unit must have a comprehensive quality control program for reprocessing endoscopes with a specific focus on duodenoscopes." The 2018 European Society of Gastrointestinal Endoscopy (ESGE) guidelines released similar strong recommendations [13].

Additionally, in 2015, the FDA ordered each of the duodenoscope manufacturers to conduct postmarket surveillance studies. The data were unsettling, as they demonstrated that despite the companies' published user materials and validated reprocessing guidelines, user compliance with the guidelines was very poor; for instance, Olympus' data revealed that 45/73 manual cleaning tasks were performed incorrectly by 27 % of the participants [14].

Although the governing agencies and manufacturers emphasize the urgent need for strict adherence to reprocessing protocols, there are few published data on effective methods to survey and assess compliance with the reprocessing procedure in real time. In our center, we have installed remote video auditing (RVA) cameras in the endoscope reprocessing room, which coincided with the opening of a new endoscopy unit. RVA has long been shown to improve safety and compliance in commercial industries such as meatpacking and fast food [15–19], and has recently been highly successful in improving compliance with surgical safety measures in the operating room [20, 21], procedure verification proceedings in the endoscopy unit [22], as well as in pilot evaluations of compliance with endoscope cleaning in a community setting within our hospital system [23] and in a center outside of our system [24]. However, it is not known whether RVA in a high-volume tertiary care center is feasible. RVA has not been previously evaluated in a tertiary care setting.

The aims of the current study were to evaluate: 1) RVA feasibility in a tertiary care setting (defined as the ability to audit every step of duodenoscope reprocessing without causing a delay to the start time of the next procedure due to unavailability of duodenoscopes); and 2) the use of RVA as a compliance monitoring tool. Both per-step compliance and 100 % compliance rate were measured.

Methods

Sample

This was a single-center, prospective feasibility study in an endoscopy unit at a tertiary care academic medical center (Long Island Jewish Medical Center, New Hyde Park, New York, USA) that performs over 3000 endoscopy procedures a year. Real-time auditing of the duodenoscope reprocessing procedure was performed in the endoscope cleaning room of the endoscopy unit on weekdays between the hours of 07:00 and 19:00. Duodenoscopes that were reprocessed outside of this time period were reprocessed in a cleaning room outside of the endoscopy unit, and thus these procedures were not included in the analysis. For the purposes of this study, the start date for data collection was April 2018, which was the month following a 1-month run-in phase during which the camera became operational in the new endoscopy unit, and the date of completion of data collection was the end of August 2019.

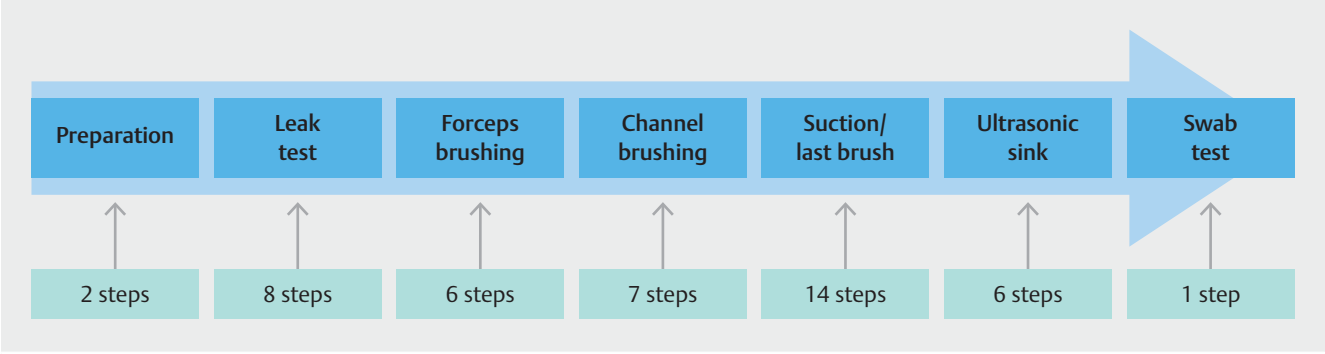
The study was approved as a quality improvement initiative and was exempt from institutional review board approval. Study subjects were the endoscopy technicians who cleaned the scopes. No patient information was collected during the study.

▶ **Fig. 1** The video camera with a wide-angle lens, installed to observe reprocessing of duodenoscopes.

Study design

A video camera with a wide-angle lens was installed in the new endoscope cleaning room and became operational in March 2018 (▶ **Fig. 1**). Muted video streams with low image resolution to prevent personnel identification were collected during the preset hours and stored on an onsite network video recorder. They were then transmitted via an encrypted virtual private network to offsite auditors (Arrowsight, Inc, Katonah, New York, USA) for a 24-hour period before being permanently deleted from the video recorder.

The offsite auditors were not provided with any information about the study protocol or about the personnel in the endoscope cleaning room. They were trained to recognize and score each of the steps of the duodenoscope reprocessing procedure. The duodenoscope reprocessing protocol was based on the standardized and validated Olympus TJF-Q180V Cleaning and Disinfecting Checklist, validated and updated in January 2016 [25], and adjusted for relevance to our endoscopy unit's equipment and institutional protocols. Each step of the protocol was audited independently and given a score by the auditors that included "pass," "fail," "process error," or "unviewable." A



▶ **Fig. 2** Summary of the 44 reprocessing steps summarized into seven distinct phases.

"pass" score was given if the step was performed correctly. A "fail" score was given if the step was not performed. A "process error" score was given if the step occurred but was performed incorrectly (i. e. out of order, incomplete, or did not last the minimum amount of time required for that step). An "unviewable" score was given if the step was performed out of view of the camera.

The endoscopy cleaning technicians held an orange tag under the camera prior to duodenoscope reprocessing in order to identify the duodenoscope and alert the auditors that a reprocessing procedure was about to occur. The auditors were tasked to complete the audit within 1 hour of completion of the duodenoscope reprocessing procedure and then provide feedback to the endoscopy technicians via an alert from an electronic messaging system. The only feedback given at this time was whether the scope reprocessing had passed the RVA audit, allowing the scope to be returned to the clinic for use. While the cleaned duodenoscope was being audited, it was held in the cleaning room. If the duodenoscope received a 100 % pass on every audited step, the duodenoscope was released for use. If the duodenoscope did not pass the audit, it was fully reprocessed again until it passed.

Outcome measures

The first outcome of interest was the feasibility of using RVA in a tertiary care center endoscopy unit. Feasibility was defined as the ability of the RVA system to audit each step of the duodenoscope reprocessing procedure (i. e. no "unviewable" steps) without causing any delay to the start time of the next procedure due to an unavailable duodenoscope. Potential delays caused by RVA were considered to be rate limiting for its clinical use and thus were chosen as an outcome measure. At our institution, based on the total number of duodenoscopes (n = 4), the number of procedures requiring duodenoscopes per day, and the average room turnover time, we estimated that a 2-hour duodenoscope turnover time (including time for completion of duodenoscope reprocessing and a 1-hour period to allow completion of the audit) would be acceptable to prevent delays in the start time of the next procedure.

The second outcome of interest was the feasibility of using RVA as a compliance monitoring tool. As mentioned previously, compliance with each step was audited individually (per-step compliance), and only scopes with 100 % pass rates (100 % compliance) on every step were considered "compliant." Both per-step compliance and 100 % compliance rates were measured.

The feasibility data (including per-step viewability scores, length of reprocessing time, length of auditing time, whether the audit was completed within 1 hour, and whether delays in the start time of the next procedure occurred), as well as the compliance data (per-step and overall compliance) were compiled by the RVA specialists during the entire study period from April 2018 to August 2019 in daily, weekly, and monthly reports. The preceding month (March 2018) was a run-in phase with 65 reprocessing procedures. Calibrations to the endoscope cleaning room and staff positioning, reprocessing protocol, and auditing process were made on a dynamic and reactive basis to daily audit reports during the run-in phase. Starting April 2018, the procedure, staff positioning, and auditing protocol remained unchanged.

RVA cost

A one-time setup fee for installation of the cameras was $ 7500. The yearly price for the auditing and system maintenance was $ 20 000. Pricing is subject to negotiations with Arrowsight, Inc. Pricing to our institution was based on our center being a pilot site and one of the first in the country to take this initiative.

Data analysis

Categorical variables were reported as numerical counts, percentages, and means (Microsoft Excel for Mac, version 16.34). Descriptive statistical analyses were performed. All data were stored in a Health Insurance Portability and Accountability Act-compliant database protected by the institution's firewall.

Results

Duodenoscope reprocessing

During the course of the study period from April 2018 to August 2019, four Olympus TJF-Q180V duodenoscopes with a total of 743 separate duodenoscope reprocessing procedures were audited. A total of 44 individual steps, grouped into seven distinct phases, were performed in our unit's endoscope cleaning room during each duodenoscope reprocessing procedure (▶ **Fig. 2**). A total of 32 666 steps were successfully audited.

Step	Step name	Mean compliance
S01	PPE	99.5 %
S02	Buttons removed from endoscope	100.0 %
S03	Sink fill	100.0 %
S04	Leakage test connected to MU1	99.9 %
S05	Leakage tester prep	99.9 %
S06	Connector cap attached to venting connector	99.9 %
S07	Leak test	98.5 %
S07b	Leak test forceps area	98.7 %
S08	Leakage tester detached I	99.6 %
S09	Leakage tester detached II	99.7 %
S10	Sink prep	100.0 %
S11	Scope and outer tubing wash	100.0 %
S12	Forceps elevator clean lowered	99.9 %
S13	Forceps elevator clean raised	99.9 %
S14	Elevator rinse and inspection	99.6 %
S15	Distal end cleaned	99.9 %
S16	Instrument channel cleaning 45 insert	100.0 %
S17	Instrument channel cleaning return	100.0 %
S18	Suction channel cleaning straight insert	100.0 %
S19	Suction channel cleaning straight return	100.0 %
S22	Suction cylinder opening clean	97.7 %
S23	Instrument channel opening brush clean	98.5 %

Step	Step name	Mean compliance
S24	Single use brush disposal	100.0 %
S25	Suction prep	98.8 %
S26	Suction	99.6 %
S27	Forceps elevator clean lowered	99.9 %
S28	Forceps elevator clean raised	99.9 %
S28a	Forceps elevator clean raised back	97.8 %
S29	Elevator rinse	99.9 %
S30	Recess flush raised	99.9 %
S31	Recess flush lowered	99.9 %
S31a	Forceps elevator clean raised back	98.0 %
S31b	Elevator rinse	99.6 %
S31c	Recess flush raised	99.5 %
S31d	Recess flush lowered	99.6 %
S32	Magnifying glass inspection	99.9 %
S33	Inspect brush and discard	99.9 %
S34	Ultrasonic sink prep	99.9 %
S35	Ultrasonic sink purge	99.9 %
S35a	Scope and outer tubing wipe	98.2 %
S36	Drain sink	100.0 %
S37	Ultrasonic sink rinse	99.6 %
S40	Dry scope	99.1 %
S44	Swab test color	100.0%
Overall		99.5 %

▶ **Fig. 3** Summary report card of the 44-step performance for the study period. Green represents 100 % compliance and red represents the lowest compliance, with color gradations for the compliance scores in between.

Feasibility

Of the 32 666 individual steps that were performed during the study period, 99.9 % were fully viewable and could be adequately audited by the RVA system. Less than 0.1 % of the steps (17/32 666) were unviewable.

The length of time it took to both reprocess the duodenoscopes and audit the reprocessing procedures was evaluated during the study period. The mean time it took to complete a duodenoscope reprocessing procedure with a 100 % pass rate was 37.8 minutes (range 22.0–97.1 minutes). The mean time for the audit to be completed and the score reported back by RVA staff was 38.3 minutes. Of the 743 duodenoscope reprocessing procedures, 699 (94.1 %) were successfully audited within the expected 1-hour time period before the duodenoscope was released. Overall, the mean duodenoscope turnover time from initiation of duodenoscope reprocessing to its release was 76.1 minutes. This process did not cause any delays within the unit for any procedures, including no delays to the start time for procedures that required a duodenoscope.

Compliance

Of the 743 duodenoscope reprocessing procedures audited during the entire study period, 90.3 % (671/743) received 100 % overall pass scores. A total of 599/671 duodenoscopes (89.3 %) did not require additional reprocessing after RVA audits. The remaining 72 duodenoscopes (10.7 %) required another round of reprocessing. No duodenoscopes required more than two rounds of reprocessing.

The per-step compliance rate of each of the 44 individual steps was also assessed (▶ **Fig. 3**). Overall, the mean per-step compliance rate was 99.5 % during the entire study period. The individual step with the lowest compliance rate was "Suction cylinder opening clean," with an overall compliance rate of 97.7 % over the entire study period. Additionally, "Forceps elevator clean raised back" also had a relatively low average compliance of 97.8 % over the study period. The range of per-step compliance over the study period was 97.7 %–100 %. When analyzing by month, the mean overall per-step compliance was 99.8 % (range 99.4 %–100 %). Of the 261 steps that did not pass, 92 steps received a process error score, 152 received a fail score, and 17 received an unviewable score. These contributed to the 72 reprocessing procedures that did not pass with 100 % compliance.

Discussion

Duodenoscope reprocessing is a highly complex procedure and, as such, poor compliance with reprocessing guidelines has been a source of universal concern as it contributes to the spread of multidrug-resistant bacterial infections. In this study, we have shown that detailed surveillance and stringent evaluation of the entire duodenoscope reprocessing procedure is feasible in a tertiary care center using an auditing tool such as RVA. Over our 17-month study period, 743 duodenoscope reprocessing procedures consisting of 32 666 individual steps were audited. Almost all (99.9 %) of the steps could be fully viewed and scored. The reprocessing procedure lasted a mean of 37.8 minutes, and the auditing and reporting time took 38.3 minutes, resulting in a duodenoscope turnover time of approximately 1 hour and 15 minutes. At our institution, this is a highly feasible turnover time for a duodenoscope when accounting for other interprocedural factors such as room turnover time, number of available duodenoscopes, and need for duodenoscopes.

In our study, we showed that the vast majority of our duodenoscopes (90.3 % overall) indeed met the 100 % compliance rate for the duodenoscope reprocessing procedure and were allowed to be released for use without the need for further reprocessing. These overall compliance data echo those of the pilot study performed at a community hospital within our institution [23], and not only establish the reproducibility of sustained high-level duodenoscope compliance with RVA use, but also emphasize that this can be successfully used on a larger scale and in a tertiary care center. Although we have shown that sustained high-level compliance is possible with RVA, we are not advocating this approach for all institutions given the added cost of both the system itself and the requisite additional cost of repeating the reprocessing procedure for duodenoscopes that are not 100 % compliant, which occurred in 10.7 % of reprocessing procedures in the current study. However, for institutions like ours that can absorb the cost, RVA can ensure proper reprocessing for every duodenoscope.

Perhaps the most valuable aspect of being able to individually assess the reprocessing steps, is to identify those steps that have the lowest compliance rates. In our study we identified two steps that had low pass rates – "Forceps elevator clean raised back" and "Suction cylinder opening clean." Theoretically, identification of difficult steps or steps with consistently poor compliance could also help to highlight areas where new reprocessing procedures, new equipment or endoscope accessories could be developed to improve reprocessing compliance and ease of use.

Compliance with duodenoscope reprocessing is critical, as it has been suggested that human error related to breaches in endoscope reprocessing is a major contributor to endoscope-associated bacterial contamination [26]. McCafferty et al. reported that in 18 endoscope-associated bacterial outbreaks between 2008 and 2018 (16 of which were caused by infected duodenoscopes), 9 were found to be attributable to issues with endoscope reprocessing [27]. Rahman et al. and Rubin et al. found that 6/16 and 5/13 outbreaks, respectively, were related to reprocessing errors [5, 6]. It is important to note, however, that 19 additional outbreaks studied in the Rubin et al. review did not mention whether compliance with duodenoscope reprocessing was evaluated [6]. This raises the question as to whether reprocessing adherence could have been an unidentified factor in these outbreaks, as it may be challenging to retrospectively determine whether duodenoscope reprocessing instructions were followed in the absence of a prior recording of the reprocessing process. Furthermore, Dirlam Langlay et al. reported that a review of public documents between 2005 and 2012 discovered lapses in all major reprocessing steps; however, only one report was found in the medical literature [9]. This suggests that there may be a bias in the medical community toward underestimating the prevalence and significance of poor compliance with duodenoscope reprocessing in bacterial transmission. Thus, we think that stringent surveillance of duodenoscope reprocessing compliance, with a method such as RVA, may reduce and prevent the spread of duodenoscope-related infections.

Although adherence to duodenoscope reprocessing may prevent infectious outbreaks, it may not prevent all. Some outbreaks persisted despite the lack of reprocessing errors. It has been shown that endoscope reprocessing has a failure rate of approximately 2 %, with biofilms that remain on the surfaces of difficult-to-clean areas of the scope being a possible source of contamination [28]. For duodenoscopes, these areas may include the distal tip, elevator, and elevator channel. Thus, methods to detect and reduce biofilms on duodenoscopes is another very important area for investigation and research. Surveillance microbial cultures are one way of detecting the presence of a biofilm and have been shown to be effective [29–31]. However, the optimal surveillance period has not yet been established, and obtaining surveillance cultures may not be practical in all settings due to the time and cost that the culturing process requires. The clinical relevance of bacterial cultures, however, has not been fully evaluated. For instance, it has been shown that some outbreaks have occurred despite negative surveillance cultures [32]. Conversely, it has been suggested that achieving a zero percent bacterial culture rate may not be feasible, and that a "near-zero" culture positive rate may be sufficient to mitigate patient risk of bacterial transmission [33]. Another method of bacterial detection includes adenosine triphosphate (ATP)

surveillance. This has been correlated to adequate duodenoscope reprocessing, but not necessarily to positive bacterial culture rates [34, 35].

Bartles et al. hypothesized that a second round of high-level disinfection may reduce culture positivity; ultimately, however, no difference was found between single and double high-level disinfection [36]. As a result, some studies have suggested switching to sterilization procedures in order to decrease rates of contamination [37]; however, limitations to this process exist as well [38].

Finally, disposable distal tips have been adapted to some duodenoscope models, and completely disposable duodenoscopes are under investigation [39–41]. In August 2019, the FDA issued a statement encouraging endoscopy facilities to transition away from fixed-cap duodenoscopes to those with newer design features that facilitate or eliminate the need for reprocessing [42]. Data regarding the bacterial transmission rates of scopes with disposable tips or elevators have yet to be published and are critically needed before determining the real-world feasibility and economic viability of these disposable options. Moreover, disposable accessories do not obviate the need for thorough reprocessing of the nondisposable components, as well as for the evaluation for compliance with reprocessing of these parts, and thus may still require protocols such as RVA to ensure adherence to reprocessing. Use of disposable duodenoscopes would eliminate the need for reprocessing and RVA; however, the medical economic impact of such an approach, together with evidence of how these function in the real world compared with current duodenoscopes are lacking.

There are limitations to our study that should be noted. In this study, bacterial detection through the use of cultures or ATP testing was not assessed after a scope failed to be cleared by RVA, as a second reprocessing procedure was required regardless of the ATP test result. Additionally, this was a single-center study, so further studies to evaluate RVA system-based duodenoscope reprocessing compliance at other tertiary care centers are indicated to corroborate our data. Furthermore, although the RVA system has been easily integrated for duodenoscope reprocessing as well as for quality improvement ventures within our institution, some centers will find contracting RVA systems to be cost-prohibitive. Another potential method of evaluating compliance is onsite audits of duodenoscope reprocessing; however, this method has its own limitations, as an auditing company should ideally be hired to ensure objectivity and an accurate evaluation of compliance rates, and this may be too costly for some units. In addition, not all reprocessed duodenoscopes are likely to be audited. Human behavior during an audit is important to note as well; compliance may increase when there is someone watching the reprocessing procedure, but fall when the auditor has gone and the pressure of being watched is eliminated. The RVA system audits every duodenoscope reprocessing procedure during daytime work hours through a camera; thus, correct reprocessing is ensured for every duodenoscope.

While innovative solutions to detect and reduce bacterial transmission from duodenoscopes are needed, methods to enhance surveillance and improve compliance with currently used duodenoscope reprocessing procedures are equally, if not more, critical at the current time. This opinion has recently been emphasized over and again in position statements made by multiple gastroenterology societies, including ESGE, American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy, and Society of American Gastrointestinal and Endoscopic Surgeons [43, 44]. In fact, video auditing with feedback for duodenoscope reprocessing has specifically been suggested as an area for future quality assurance [6]. In our study, we definitively showed that using RVA as a surveillance and evaluation system for duodenoscope reprocessing is feasible and promotes sustained high-level compliance in our institution.

Competing interests

Dr. Trindade is a consultant for Olympus America, Pentax America, and CSA Medical, and has received research support from Ninepoint Medical.

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