Single-use duodenoscopes: where are we and where are we going?

Shajan Peter[a], *Ji Young Bang*[b], *and Shyam Varadarajulu*[b]

Purpose of review
Given the growing concerns about infection transmission from use of contaminated reusable duodenoscopes, technological advancements have been made that vary from modifications of existing designs to development of single-use devices.

Recent findings
To circumvent mechanical limitations that preclude access to critical areas of a duodenoscope to perform thorough cleaning and disinfection, single-use disposable duodenoscopes have been developed. A thorough assessment of this technology is limited by the minimal published data that is currently available. This opinion assesses the current technical functionality of these devices, potential for further improvements, implications for healthcare economics and the future of gastrointestinal endoscopy.

Summary
Currently available data suggest that majority of endoscopic retrograde cholangiopancreatography procedures can be safely performed using single-use duodenoscopes. The ability to improve technical functionality, incorporate futuristic technology and secure financial reimbursement from insurance carriers will largely define the future prospects of this recent innovation.

Keywords
ERCP, infection control, single-use duodenoscope

INTRODUCTION

Infection control and prevention seem to be buzzwords at the dawn of 2021 as the world slowly adapts to the reality of a global COVID-19 pandemic. The Hippocratic principle for hygiene, *every disease has its own nature and arises from external causes*, holds value even for the discipline of endoscopy where despite best practices in reprocessing techniques there persists substantial risks for infection transmission, particularly for duodenoscopes.

Outbreaks of duodenoscope-related infection (DRI) have been reported with pathogenic organisms that include *Klebsiella pneumoniae*, *Pseudomonas aeruginosa* and more recently carbapenem-resistant *Enterobacteriaceae* (CRE) [1,2]. These adverse events involving multidrug resistant organisms have raised serious concerns regarding current standards-of-care. While professional societies have revised existing guidelines for duodenoscope reprocessing techniques, significant limitations persist [3,4]. The Food and Drug Administration (FDA) has published numerous safety communications on this topic and recently mandated that endoscope manufacturers transition away from fixed endcap duodenoscopes to those with features that significantly improve cleaning and disinfection or eliminate the need for reprocessing altogether [5]. Consequently, with objective of eliminating infection transmission associated with use of contaminated reusable duodenoscopes, endoscope manufacturers have moved to develop single-use platforms. This opinion will review the current status and future prospects of this new technology.

WHERE ARE WE TODAY?

Contamination rates

Over the last few years, protocols of high-level disinfection have been implemented in endoscopy

[a]Division of Gastroenterology and Hepatology, University of Alabama at Birmingham, Birmingham, Alabama and [b]Digestive Health Institute, Orlando Health, Orlando, Florida, USA

Correspondence to Shyam Varadarajulu, MD, Medical Director, Digestive Health Institute, Orlando Health, 1335 Sligh Blvd, Orlando, FL 32806, USA. Tel: +1 321 841 9022; e-mail: svaradarajulu@yahoo.com

Curr Opin Gastroenterol 2021, 37:416–420

DOI:10.1097/MOG.0000000000000755

KEY POINTS

- To overcome risks of infection transmission associated with use of contaminated reusable duodenoscopes, single-use platforms have been developed.
- Preliminary observations from a randomized trial suggest that a majority of ERCP procedures can be safely and effectively performed using single-use duodenoscopes.
- Further technical improvements, technological enhancements and measures to minimize economic barriers to procedural reimbursement are likely to increase utilization of this technology.

units as standard practice. With these protocols in place, transmission of infection was presumed to be very low. However, a large CRE outbreak linked to duodenoscope exposure was reported in a healthcare facility in the United States [6]. Since then, several outbreaks have been reported worldwide. In a Dutch survey, one-fifth of sampled duodenoscopes were contaminated with any microorganism, and the presence of gastrointestinal or oral microorganisms were detected in 15% of ready-to-use duodenoscopes [7]. In another study that evaluated 4032 surveillance culture specimens from 106 duodenoscopes or linear echoendoscopes, the microbial contamination rate was 5% with 0.6% being pathogenic organisms [8]. The FDA postmarket surveillance communication reported duodenoscope culture results representing contamination rates of up to 3.6% for low and moderate-concern organisms, and up to 5.4% for high-concern organisms in reprocessed reusable duodenoscopes [9].

Contributing factors

While the lumen of the gastrointestinal tract acts as reservoir for microorganisms that are capable of translocation during endoscopic procedures, patient-specific characteristics such as underlying comorbidity (diabetes, posttransplant immunosuppression etc.) and disease process (biliary obstruction) accentuates this risk. Also, external factors that include poor adherence to infection prevention protocols during manual cleansing and automated disinfection sequences can contribute to infection transmission. More specifically, unlike standard endoscopes, the duodenoscope is a complex instrument whose structural design includes a recessed space containing an elevator, elevator cable and channel. Because the elevator is recessed and has a complex surface pattern, it is difficult to clean and has been incriminated as a major source of infection in outbreaks. Also, persistent bacterial growth has been attributed to the presence of a biofilm, which protects the organisms from gas or liquid disinfection. The biofilms allow bacteria to survive on contaminated duodenoscopes for several weeks in most environment and remains a potential source for infection transmission [10].

Clinical dilemma

While detachable caps may enable better visualization and cleaning of the elevator mechanism, the most radical and bold proposition has been the development of single-use duodenoscopes. However, the feasibility and practicality of widespread adoption of this novel concept is dependent on two key factors. First, as endoscopic retrograde cholangio pancreatography (ERCP) is a high-risk and technically challenging procedure, the functionality of single-use duodenoscope should match the current standard-of-care (reusable duodenoscopes). Second, no matter how appealing, the concept must be financially viable and not burden the financial status of healthcare systems.

Single-use duodenoscopes

There are two types of single-use platforms that are commercially available.

EXALT – EXALT Model D (Boston Scientific Corporation, Marlborough, Massachusetts, USA) is lightweight, made of recyclable plastic, and has a four-way bending distal tip with guidewire locking capability for the elevator. An image capture button on the scope handle records pictures that can be integrated within endoscopy reports. The working length of the duodenoscope is 1240 mm, with insertion tube outer diameter of 11.3 mm, working channel inner diameter of 4.2 mm, up–down angulation of 120–90° and right–left range of 110–90°. The duodenoscope is delivered in a complete sterile package that is opened only prior to use. As with reusable duodenoscopes, the water bottle and suction are connected to dedicated ports. The duodenoscope is plugged into a dedicated EXALT processor (Boston Scientific Corporation) which provides operational power (Fig. 1).

AMBU aSCOPE – Ambu aScope Duodeno (Ambu Inc, Columbia, Maryland, USA) is built with side viewing optics, deflectable tip and an elevator to control the position of compatible endoscopic accessories (Fig. 2). The distal end outer diameter is 13.7 mm, insertion, tube outer diameter 11.3 mm, working length 1240 mm, illumination is via dual light-emitting diode and weighs 700 g. The angulation ranges are up 120°/down 90°, left 90°/right 110° and is plugged into a dedicated processor.

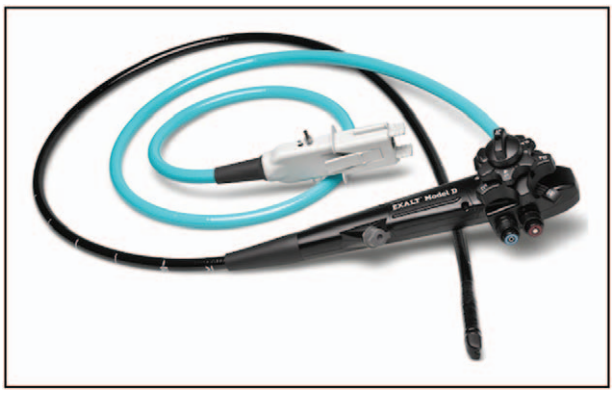

FIGURE 1. EXALT Model D single-use duodenoscope.

Technical performance

Currently there is no published clinical data on technical performance of the Ambu duodenoscope. A pilot, multicenter case series, reported outcomes of 73 patients who underwent ERCP examinations using the EXALT-D duodenoscope [11]. Fifty-eight procedures (96.7%) were completed successfully and two required crossover to examination using a reusable duodenoscope. These cases were performed across all ASGE procedural complexity grades 1–4. No major adverse events were observed. In a recently concluded randomized trial by these authors, 98 patients underwent ERCP using the single-use EXALT-D or reusable duodenoscope [12▪▪]. While the median number of attempts to achieve successful cannulation was significantly less for the single-use duodenoscope cohort (2 versus 5, $P = 0.013$), the scores for technical aspects, such as, image quality/stability and air water channel functionality, were suboptimal. There was no significant difference in rates of cannulation, adverse events, cross-over to alternate arm, or need for advanced cannulation techniques to achieve ductal access, between cohorts. It was observed that the inherent stiffness of single-use duodenoscope facilitates a straight but stable scope position when enface to the major duodenal papilla. Consequently, the papilla is engaged from a superior or horizontal angle rather than from below upward, as with reusable duodenoscopes, and thereby likely facilitates easier ductal access (Fig. 3). Another potential advantage is the shaft stiffness that provides firm anchorage for pulling retrieval balloons in line with the bile duct axis thereby making stone extraction easier. Furthermore, the passage of accessories such as biopsy forceps and laser fibers during single-operator cholangioscopy procedures is also technically easier with single-use duodenoscopes. The inherent stiffness of single-use duodenoscope shaft straightens the rubber tubing of the cholangioscope and facilitates easier passage of accessories through its working channel. A limitation of the randomized trial was that majority of enrolled patients required only low complexity ERCPs.

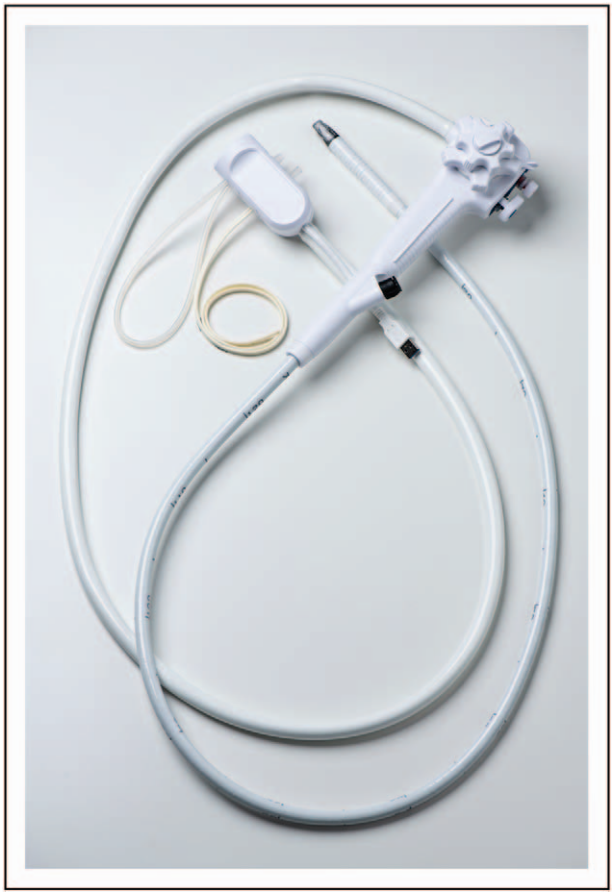

FIGURE 2. AMBU aSCOPE single-use duodenoscope.

Financial considerations

When considering the economics related to single-use duodenoscopes, it's important to look at the cost of the device, reimbursement and the associated cost offset by not having to reprocess. As for the current costs of reprocessing, these are often underappreciated. Depending on the type of reprocessing method at an institution, it can represent significant costs to a healthcare system and should be included in an economic analysis. This savings may help offset some of the cost of the single-use duodenoscope.

A recent study utilized an activity-based costing and financial model to assess the per procedure cost of performing an ERCP procedure using the single-use duodenoscope [13]. It was found that the cost varied from $797 to 1547 for centers performing at the 75th percentile of ERCP procedure volume and from $1318 to 2068 for centers performing at the

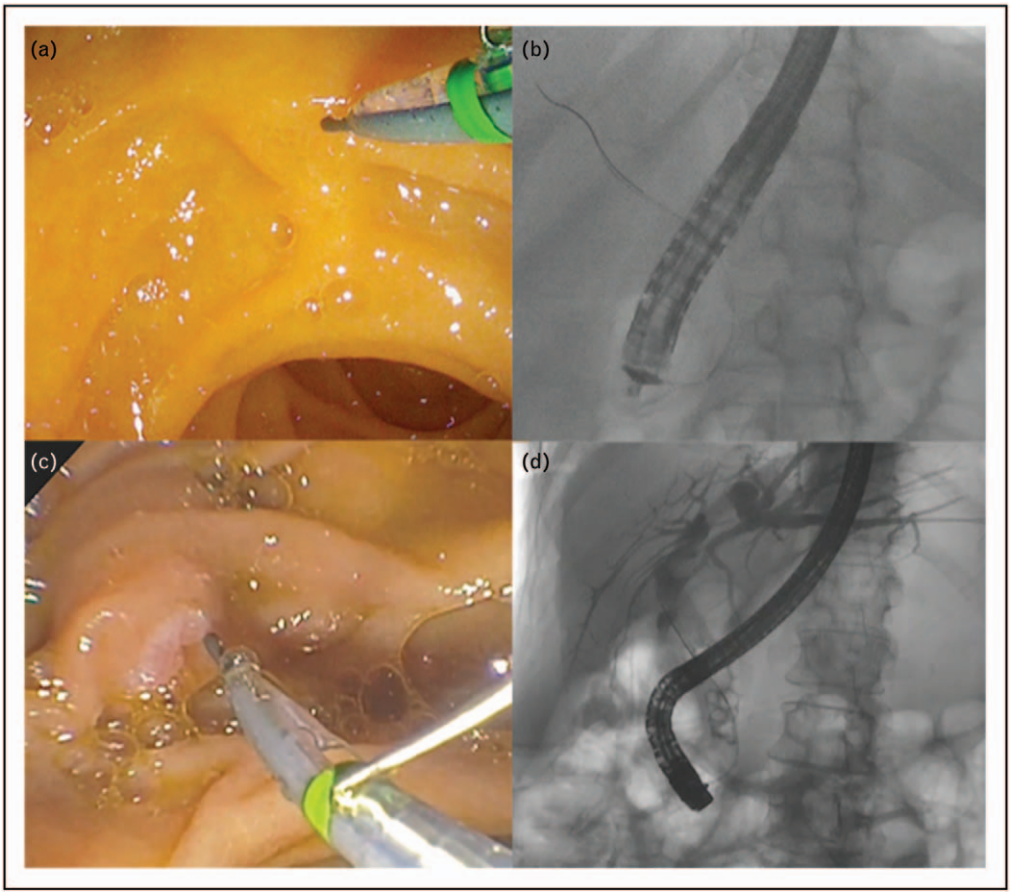

FIGURE 3. Fluoroscopic (a) and endoscopic (b) imaging reveals a fairly straight scope position with enface access to the major duodenal papilla with single use-duodenoscopes versus a traditional position (c) where the papilla is accessed from below upward (d) as with reusable duodenoscopes.

25th percentile of procedure volume, based on infection rates of 0.4–1%, respectively. Adopting the microcosting approach, another study determined the cost to range between $1110.29 and 2685.76 depending on annual procedure volume, infection risk and number of duodenoscopes used [14].

In terms of reimbursement, the Centers for Medicare and Medicaid Services (CMS) recently approved a transitional pass-through payment for outpatient ERCP procedures performed using single-use duodenoscopes. This is a device-specific payment in addition to the ERCP procedural payment. Boston Scientific has also submitted an application to CMS for a New Technology Add-on Payment for device payment for inpatient ERCP procedures performed using the EXALT Model D single-use duodenoscope. If approved, this device payment will become available in October 2021. CMS is also reviewing a request for the creation of a unique International Classification of Diseases-10-procedure code to support hospitals in reporting the use of single-use duodenoscopes for ERCPs when performed in the inpatient setting.

WHERE ARE WE GOING?

Clinical perspective

The risk of transmitting high-risk infections by a contaminated device can be eliminated by performing ERCPs with single-use duodenoscopes and this most certainly will improve patient care. One could speculate that a single-use duodenoscope should be preferably utilized to perform ERCPs in high-risk cases such as, immunocompromised patients, or in known carriers of multidrug-resistant organisms. Also, procedures that may have to be performed on an emergent basis outside of the endoscopy unit (operating/emergency room or ICU) are likely to benefit given the ease of mobility and elimination of the need to reprocess the duodenoscope, which is often delayed while setting-up for offsite procedures. They may also be useful in the event that reusable duodenoscopes are unavailable due to repairs or quarantined awaiting culture results.

Financial perspective

Given that CMS has approved a transitional pass-through payment for outpatient ERCPs performed

on Medicare patients, it is likely that a device-specific payment for inpatient procedures may also be approved in the near future. This may pave the way for private insurance carriers to follow suit. The use of single-use duodenoscopes may also be particularly relevant for small volume institutions that do not want to invest in major capital equipment but have the requisite technical expertise to perform ERCPs.

Innovation perspective

Reusable duodenoscope is currently designed with a one-size-fits-all concept. Studies have shown that endoscopists can suffer from occupational injuries related to ergonomics, partially due to endoscope design. The current single-use duodenoscope is lighter and more importantly, given the nature of manufacturing process, there is greater flexibility for refinements in design. Therefore, we speculate that it may be possible to manufacture an ergonomically custom-designed duodenoscope tailored to specific hand sizes to meet individual needs. There is also room for design and performance improvement by providing enhanced mechanics and optics such as, variable scope stiffness, and superior image quality and stability, to meet optimal standards. With current concepts on incorporation of artificial intelligence in endoscopy, these advances can be more easily pilot tested and if successful integrated within the single-use platform.

Research perspective

A major limitation is the lack of data on 'clinically relevant' infection transmission from use of contaminated reusable duodenoscopes. Although challenging, it is important to conduct studies to identify the burden of this problem and examine the real impact of single-use duodenoscope technology on patient outcomes, particularly infection transmission. Also, given the paucity of data, more studies are required to assess the technical performance of the single-use duodenoscope in high complexity ERCPs.

CONCLUSION

Significant advancements have been made in a relatively short period to mitigate DRI transmission, particularly with the development of the single-use duodenoscope technology. Further technical improvements, technological enhancements and measures to minimize economic barriers are likely to increase the utilization of this technology and its adaptation to other areas of flexible endoscopy. Finally, it is imperative to foster research to gain a better understanding of the impact of this innovation on patient outcomes.

Acknowledgements

None.

Financial support and sponsorship

None.

Conflicts of interest

S.V. is a Consultant for Boston Scientific Corporation, Olympus America, Creo Medical, Medtronic. J.Y.B. is a Consultant for Boston Scientific Corporation and Olympus America.

REFERENCES AND RECOMMENDED READING

Papers of particular interest, published within the annual period of review, have been highlighted as:
- ■ of special interest
- ■■ of outstanding interest

1. Rauwers AW, Voor In 't Holt AF, Buijs JG, *et al.* Nationwide risk analysis of duodenoscope and linear echoendoscope contamination. Gastrointest Endosc 2020; 92:681–691.e1.
2. Kim S, Russell D, Mohamadnejad M, *et al.* Risk factors associated with the transmission of carbapenem-resistant *Enterobacteriaceae* via contaminated duodenoscopes. Gastrointest Endosc 2016; 83:1121–1129.
3. Calderwood AH, Day LW, Muthusamy VR, *et al.*, ASGE Quality Assurance in Endoscopy Committee. ASGE guideline for infection control during GI endoscopy. Gastrointest Endosc 2018; 87:1167–1179.
4. Beilenhoff U, Biering H, Blum R, *et al.* Reprocessing of flexible endoscopes and endoscopic accessories used in gastrointestinal endoscopy: position statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA) – update 2018. Endoscopy 2018; 50:1205–1234.
5. The FDA is recommending transition to duodenoscopes with innovative designs to enhance safety: FDA Safety Communication. https://www.fda.gov/news-events/press-announcements/fda-recommends-health-care-facilities-and-manufacturers-begin-transitioning-duodenoscopes-disposable. [Accessed 29 August 2019].
6. Epstein L, Hunter JC, Arwady MA, *et al.* New Delhi metallo-beta-lactamase-producing carbapenem-resistant *Escherichia coli* associated with exposure to duodenoscopes. JAMA 2014; 312:1447–1455.
7. Rauwers AW, Voor In 't Holt AF, Buijs JG, *et al.* High prevalence rate of digestive tract bacteria in duodenoscopes: a nationwide study. Gut 2018; 67:1637–1645.
8. Brandabur JJ, Leggett JE, Wang L, *et al.* Surveillance of guideline practices for duodenoscope and linear echoendoscope reprocessing in a large healthcare system. Gastrointest Endosc 2016; 84:392–399.
9. The FDA continues to remind facilities of the importance of following duodenoscope reprocessing instructions: FDA Safety Communication. In: Safety UFaDAFMD, ed, 2019. https://www.fda.gov/medical-devices/safety-communications/fda-recommending-transition-duodenoscopes-innovative-designs-enhance-safety-fda-safety-communication. [Accessed 12 April 2019].
10. Chhaya R, Bhatwadekar K. Microbial bio-film an unpredictable trouble on medical devices. Int J Basic Appl Med Sci 2015; 5:83–93.
11. Muthusamy VR, Bruno MJ, Kozarek RA, *et al.* Clinical evaluation of a single-use duodenoscope for endoscopic retrograde cholangiopancreatography. Clin Gastroenterol Hepatol 2020; 18:2108–2117.e3.
12. ■■ Bang JY, Hawes R, Varadarajulu S. Equivalent performance of single-use and reusable duodenoscopes in a randomised trial. Gut 2020; 70:838–844.
Reference is of outstanding interest as it is the first randomized trial comparing technical performance of single-use and reusable duodenoscopes.
13. Bang JY, Sutton B, Hawes R, *et al.* Concept of disposable duodenoscope: at what cost? Gut 2019; 68:1915–1917.
14. Travis HS, Ehlers LH, Thornton J. The total cost of reusable duodenoscopes – are singleuse duodenoscopes the future of ERCP? Pharmacoeconomics 2020; 5:1–3.