

Single-Use Duodenoscopes for ERCP: Rationale, Feasibility, Cost, and Environmental Impact

Timothy Lee, MD,¹ Sarah Enslin, PA-C,² and Vivek Kaul, MD²

¹Division of Internal Medicine, Department of Medicine, University of Rochester Medical Center, Rochester, New York

²Division of Gastroenterology and Hepatology, Department of Medicine, University of Rochester Medical Center, Rochester, New York

Corresponding author:

Dr Vivek Kaul

Segal-Watson Professor of Medicine

Division of Gastroenterology and

Hepatology

University of Rochester Medical Center

601 Elmwood Ave, Box 646

Rochester, NY 14642

Tel: (585) 275-4711

Fax: (585) 276-0101

E-mail: vivek_kaul@urmc.rochester.edu

Abstract: Recent outbreaks of duodenoscope-associated multidrug-resistant organism infections have increased awareness and concern about the pitfalls in high-level disinfection protocols and duodenoscope design. A call for innovative approaches to reduce the risk of transmission of multidrug-resistant organisms through duodenoscopes has led to the development of single-use duodenoscopes. As a new technology, questions have been raised regarding the performance, safety, cost, feasibility of implementation, and environmental impact of these novel duodenoscopes. This article discusses several of these aspects and presents a brief review of the literature.

Since its inception nearly 50 years ago, endoscopic retrograde cholangiopancreatography (ERCP) has transformed the care of patients with pancreatic-biliary disease. Approximately 500,000 ERCP procedures are being performed annually in the United States for a variety of indications (mostly therapeutic).¹ During the past decade, there has been increased recognition of duodenoscope-associated infection outbreaks related to multidrug-resistant organisms (MDROs) such as *Pseudomonas aeruginosa* and carbapenem-resistant Enterobacteriaceae, including *Klebsiella pneumoniae* and *Escherichia coli*.²⁻⁶

Numerous factors are thought to contribute to the transmission of MDROs via duodenoscopes, including the design of the duodenoscope elevator mechanism, biofilm formation, deficiencies in high-level disinfection (HLD) processes, duodenoscope wear, and patient factors such as immunosuppression and comorbid conditions.⁷⁻⁹ In response to these outbreaks, the US Food and Drug Administration (FDA) ordered US duodenoscope manufacturers to conduct postmarket surveillance. The FDA also released voluntary standardized protocols for duodenoscope surveillance and endoscope cultures and encouraged new, innovative duodenoscope designs to improve or eliminate reprocessing.^{1,10} As a result, 2 single-use, fully disposable duodenoscopes have been developed and are now commercially available. Although published data have grown

Keywords

Duodenoscope, single-use, disposable, infections, multidrug-resistant organisms

since the FDA approval of the first single-use duodenoscope in 2019, data remain relatively limited and largely sourced from expert centers and endoscopists. This article reviews the single-use duodenoscopes currently available and highlights key concepts involving their performance, safety, efficacy, cost, and environmental impact, as well as the overall challenges of their implementation in an ERCP practice.

Infection Transmission During ERCP and the Rise of the Single-Use Duodenoscope Paradigm

The transmission of drug-resistant organisms to patients from duodenoscopes has been reported since at least the 1980s.¹¹ Over time, reported cases of MDROs have increased and have been accentuated by multiple large outbreaks associated with duodenoscopes. From January to April 2012, samples of VIM-2–producing *P aeruginosa* were detected in 30 patients at a tertiary care center in the Netherlands and were linked to a contaminated duodenoscope.² Another instance was reported between November 2012 and August 2013 when 32 patients in a Seattle hospital were found to be infected with multidrug-resistant *E coli*, which was traced to multiple contaminated duodenoscopes.⁴ Both outbreaks occurred despite adherence to strict recommended HLD protocols. In subsequent years, outbreaks of MDROs were reported with increasing frequency, as highlighted by Kovaleva's 2016 review of infectious complications in gastrointestinal endoscopy.¹² Increasing concerns for transmission of infections via duodenoscopes led to FDA-ordered postmarket surveillance studies of 3 manufacturers of duodenoscopes in the United States. In 2019, preliminary results revealed duodenoscope contamination rates of 3.6% and 5.4% for low to moderate and high concern organisms, respectively, despite adherence to recommended reprocessing guidelines.¹³ Although the inadequacy of HLD to completely eliminate pathogens has been shown in numerous studies, it is not the only reason that is thought to contribute to transmission of MDROs.^{14,15} Duodenoscopes are highly specialized endoscopy instruments that contain numerous small, recessed components arranged in a complex design. In particular, the duodenoscope elevator, water, and air channels are especially difficult to clean and decontaminate completely.^{16,17} Additionally, biofilm accumulation can impede effective HLD and has been suggested as a contributory factor to HLD failure, even under the best circumstances.^{18,19} Other factors that contribute to the transmission of, and clinical infection with, MDROs include patient immunosuppression, recent antibiotic use, clinical setting, comorbid conditions, and reprocessing errors.^{7-9,20-22}



Figure 1. EXALT Model D single-use duodenoscope. **A:** Handle of scope. **B:** Head of scope (dial view). **C:** Distal end. **D:** EXALT controller with EXALT Model D single-use duodenoscope. All images provided courtesy of Boston Scientific.

In an effort to reduce duodenoscope-associated infection rates, manufacturers have developed innovative single-use duodenoscopes. Currently, 2 single-use duodenoscopes are available: the EXALT Model D single-use duodenoscope (Boston Scientific), which was approved by the FDA in December 2019 (Figure 1), and the aScope Duodeno (Ambu), which was approved by the FDA in July 2020 (Figure 2). The following sections summarize some of the pertinent literature related to the use of these

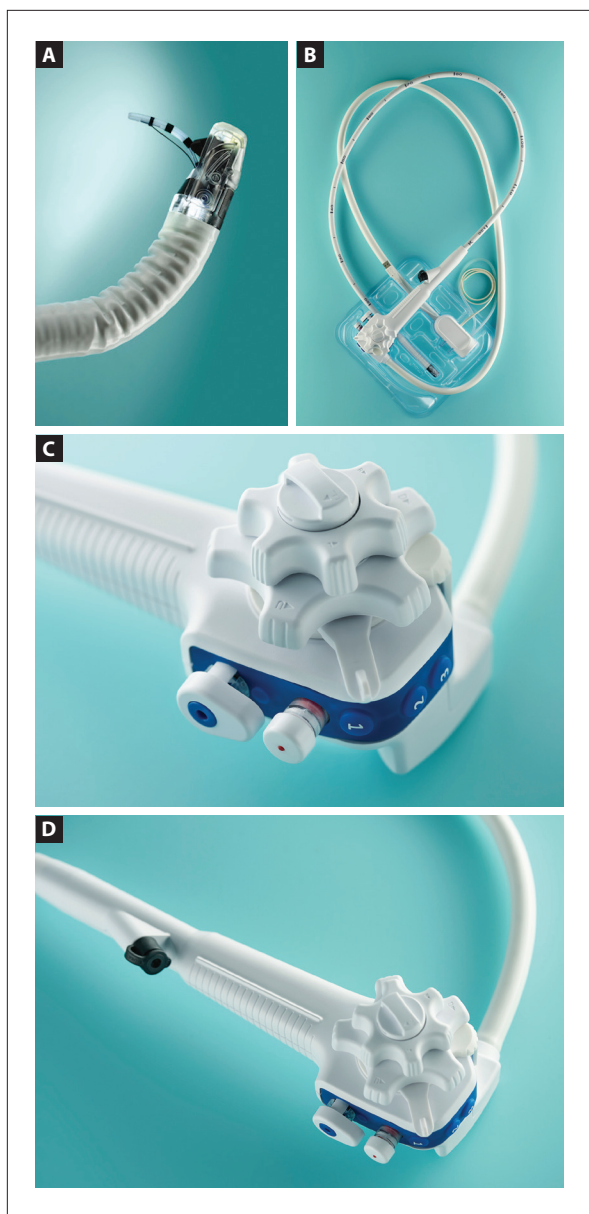


Figure 2. Ambu aScope Duodeno. **A:** Distal tip with elevator. **B:** Ambu aScope Duodeno (view of entire device). **C:** Duodenoscope head (dial view). **D:** Duodenoscope head with view of accessory channel. All images provided courtesy of Ambu.

devices for ERCP, as well as review several aspects relevant to current clinical practice.

Single-Use Duodenoscope Performance and Safety

A major area of concern regarding single-use duodenoscopes is their ability to perform as safely and as effectively as traditional reusable duodenoscopes, particularly

in regard to therapeutic interventions. Since their release to the market, several published studies have evaluated single-use duodenoscope safety and performance in both simulated and real-world settings.

Ross and colleagues used a bench simulation model to compare the performance and efficiency of completing 4 ERCP tasks between the EXALT Model D single-use duodenoscope and 3 different reusable duodenoscopes available on the market.²³ Six expert endoscopists completed the 4 simulated ERCP tasks, which included guidewire locking, plastic stent placement and removal, metal stent placement and removal, and basket sweeping of the bile duct. There was no significant difference in the time to complete the studied tasks between any of the duodenoscopes studied. Participants were asked to rate various performance metrics for each duodenoscope on a scale from 1 to 10. The median overall performance ratings ranged from 8.0 to 10.0 for all 4 duodenoscopes studied. Although the EXALT Model D single-use duodenoscope did rate significantly lower than 2 of the 3 reusable duodenoscopes in the category of navigation/pushability (median 8.0 for EXALT Model D single-use duodenoscope vs median 9.0-10.0 for the reusable duodenoscopes; $P < .01$), it rated similarly to the reusable duodenoscopes in the categories of tip control, image quality, and guidewire-locking ability.²³

Several other prospective clinical studies have been performed since that initial evaluation. Muthusamy and colleagues reported a recent prospective case series measuring single-use duodenoscope feasibility, safety, and performance in 73 consecutive patients.²⁴ Seven expert endoscopists were asked to perform a variety of tasks using the EXALT Model D single-use duodenoscope across all 4 American Society for Gastrointestinal Endoscopy (ASGE) ERCP complexity grades. Outcomes for this study included completion of ERCP for the intended clinical indication, crossover (switch from a single-use duodenoscope to a reusable duodenoscope), endoscopist performance ratings of the device, and serious adverse events.

The second prospective trial was a clinical series by Slivka and colleagues of 200 ERCPs in adult patients without altered pancreaticobiliary anatomy from January 2020 to February 2021.²⁵ The series examined procedural success and device performance ratings using the EXALT Model D single-use duodenoscope in a group of 14 expert endoscopists (defined as those who have performed more than 2000 ERCPs) and 5 less-expert endoscopists (defined as those who have performed fewer than 2000 ERCPs). Procedures varied across all 4 ASGE grades of complexity, with 41% of procedures classified as high-complexity cases (ASGE grade 3 or 4). This series evaluated procedural success, device crossover rate, procedure completion

Table 1. Comparison of 3 Prospective Trials Using Single-Use Duodenoscopes for Endoscopic Retrograde Cholangiopancreatography^{24,26}

	Muthusamy et al ²⁴	Slivka et al ²⁵	Napoléon et al ²⁶
Overall completion rate without need for crossover ^a	96.7% (58/60)	88.5% (177/200)	95% (57/60)
Crossover rate	3.3% (2/60)	9.5% (19/200)	5% (3/60)
Crossover success rate	50% (1/2)	84.2% (16/19)	0% (0/3)
Overall success rate	98.3% (59/60)	96.5% (193/200)	95% (57/60)

^aCrossover is defined as a switch from a single-use duodenoscope to a reusable duodenoscope in the same procedure for clinical or technical reasons.

time, completion of specific maneuvers, device performance characteristics, median overall satisfaction, and serious adverse events.

The third prospective trial was a recent single-arm multicenter study from France by Napoléon and colleagues.²⁶ In this study, ERCP was performed in 60 patients using the EXALT Model D single-use duodenoscope. Outcomes for this study included successful completion of ERCP without the need for crossover, technical performance of the single-use duodenoscope, and adverse events.

Although similar aspects were evaluated by the various investigators, each study had slightly different aims and designs. Muthusamy and colleagues measured the ability of the endoscopist to perform a roll-in maneuver (ability to navigate to and visualize the duodenal papilla) with 100% success (13/13 procedures).²⁴ Performance of the single-use duodenoscope compared with the endoscopist's usual duodenoscope was rated as preferred, neutral, or not preferred across 14 ERCP maneuvers. Overall, 92.3% of the ratings were recorded as either preferred or neutral. Overall satisfaction was rated a median of 9 (scale, 1-10).²⁴ In the clinical series by Slivka and colleagues, expert and less-expert endoscopists were found to have a similar procedure completion rate, crossover rate to reusable duodenoscope, mean number of cannulation attempts, and proportion of cases with high complexity.²⁵ These authors also compared outcomes based on ASGE grade and found that, for cases graded 1 or 2 and cases graded 3 or 4, there were similar results for mean number of cannulation attempts, ERCP completion rate, crossover rate, and median rating of overall satisfaction.²⁵ Napoléon and colleagues recorded a 100% success rate in all biliary maneuvers tracked.²⁶ All endoscopists rated the duodenoscope as clinically satisfactory in 21 of 22 performance metrics recorded, with 96.7% of endoscopists rating the

remaining performance metric (evaluating the papilla) as clinically satisfactory. The single-use duodenoscope was rated as comparable to a reusable duodenoscope for 97.9% of all performance metrics measured.²⁶

Each of the 3 prospective studies previously discussed evaluated usability, crossover rates, and overall technical success rates (Table 1). Muthusamy and colleagues reported an overall ERCP completion success rate of 96.7% (58/60) without the need for crossover.²⁴ Of the 2 cases requiring crossover, 1 patient had a high-grade stricture of a left-sided intrahepatic bile duct that was unable to be cannulated with the EXALT Model D single-use duodenoscope. This was successfully performed with a reusable duodenoscope. In the second event, the pancreatic duct was unable to be cannulated. Switching to a reusable duodenoscope was similarly unsuccessful, and advanced techniques were required to complete the procedure.²⁴ Napoléon and colleagues reported a similar procedure success rate of 95%.²⁶ Need for duodenoscope crossover occurred during 3 cases in this study, none of which were able to be completed despite switching to a reusable duodenoscope.²⁶ Slivka and colleagues reported the lowest success rate without the need for crossover at 88.5%; however, all 3 studies reported overall success rates of at least 95% when including crossover events.²⁵

In the studies by Muthusamy and colleagues and Slivka and colleagues, a Likert scale was used to measure endoscopist preference of the EXALT Model D single-use duodenoscope compared with the endoscopist's usual reusable duodenoscope across 23 identical performance characteristics.^{24,25} A score of 1 indicated that the EXALT Model D single-use duodenoscope was not preferred to the endoscopist's usual reusable duodenoscope and a score of 5 indicated that the EXALT Model D single-use duodenoscope was comparable to the endoscopist's usual reusable duodenoscope. Muthusamy and colleagues reported

performance characteristic ratings of at least 3 for 98.1%, and in both studies, the median performance rating for all of the characteristics studied was at least 4.^{24,25}

Serious adverse events in the 3 prospective studies were similar to adverse events of traditional ERCP.²⁷ Although none of these studies directly linked any serious adverse events to the single-use duodenoscope, esophageal perforation has occurred using the EXALT Model D single-use duodenoscope as described in a recent case report.²⁸

A randomized trial comparing single-use duodenoscopes and reusable duodenoscopes was conducted recently by Bang and colleagues.²⁹ In this study, 98 ERCP procedures were randomized to use either the EXALT Model D single-use duodenoscope or a reusable duodenoscope. The most common indications for ERCP in this study included biliary stricture and bile duct stones. Similar numbers of patients were used for each indication for the single-use and the reusable duodenoscope groups. The primary outcome was comparing the number of attempts to achieve successful cannulation of the desired duct, and secondary outcomes included various technical performance outcomes. The authors found no significant difference in the rate of successful cannulation of the intended duct; however, the median number of attempts required to cannulate was significantly lower in the single-use duodenoscope cohort. Overall, 46 of 48 cases starting with the single-use duodenoscope were successfully completed without the need for crossover; the 2 cases requiring crossover were not able to be completed with a reusable duodenoscope. No significant differences were noted in the total procedure duration, rate of crossover to alternative treatment, or rate of advanced cannulation techniques needed. This study found that the single-use duodenoscope was rated significantly worse in various performance metrics, including the ease with which the duodenoscope was passed into the stomach, image quality, image stability, and air-water button functionality. No significant difference was found in the overall rate of adverse events between the duodenoscopes.²⁹

There are few publications using the aScope Duodeno. A recent single-center, prospective case series of ERCP was performed using the aScope Duodeno and presented at the American College of Gastroenterology's annual meeting in October 2021.³⁰ In this study, a total of 25 patients were enrolled, and cases ranged in ASGE complexity grades (grade 1: 10 cases [40%]; grade 2: 12 cases [48%]; and grade 3: 3 cases [12%]). The authors reported an 84% successful completion rate, with 4 cases requiring crossover to a reusable duodenoscope owing to inability to position the duodenoscope optimally to complete the clinical objective. Median overall satisfaction was rated 3.9 of 5.³⁰ A press release from Ambu in November

2021 cited interim results from a multisite clinical trial of 60 ERCP cases using the aScope Duodeno across all levels of complexity.³¹ The release claims a procedural success of 98.3% (59/60). One case that was unable to be performed by the single-use duodenoscope was also unable to be performed with the reusable duodenoscope. Further results, including data from 150 patients, are expected later in 2022.³¹ A prospective, nonrandomized, single-arm, postmarket observational study is currently underway using the aScope Duodeno and is expected to be completed in May 2022.³²

Future studies are needed to compare the performance of the 2 duodenoscopes currently on the market, study the generalizability of these findings to endoscopists with different levels of experience and expertise, and further evaluate single-use duodenoscope safety and cost.

Cost

As with any new technology with the potential to significantly impact current practice, the product must not only be physically capable of performing the desired task, but also must factor in fiscal responsibility and the economic impact of change. According to 1 study, retail prices of single-use duodenoscopes range from \$1995 for the aScope Duodeno to up to \$4400 for the EXALT Model D single-use duodenoscope, but prices likely vary per facility based on individual contract negotiations, tier status, and discounts.³³

To better understand the cost of transitioning to single-use duodenoscopes, Bang and colleagues estimated the per-procedure cost of ERCP using a single-use duodenoscope.³⁴ The authors created an activity-based costing and financial model and considered facility-specific estimates of the costs of a duodenoscope, duodenoscope reprocessing, repair, maintenance, cleaning supplies, filters, and labor, as well as the potential cost related to medical treatment of duodenoscope-associated infections based on an estimated 0.4% to 1.0% rate of infection.

For a facility performing at the 25th percentile of US ERCP procedural volume (≤ 50 ERCPs per year), the per-procedure cost of reusable duodenoscopes was estimated to vary from \$1318 to \$2068. These estimates dropped to \$797 and \$1547, respectively, for a facility with a procedural volume at the 75th percentile (125-150 ERCPs per year). These figures highlight a breakeven point for transitioning to single-use duodenoscopes.³⁴ Using a micro-costing approach, Travis and colleagues also estimated the per-procedure cost of ERCP.³⁵ With estimated infection rates of 1% and 1.2%, the authors calculated the per-procedure cost of reusable duodenoscopes to range from \$1110 to \$2685 for a variety of annual ERCP volumes. This study also suggests that there

are increasing per-procedure costs as annual procedures performed decrease.³⁵

To evaluate the cost-effectiveness of single-use duodenoscopes, Das and colleagues developed a model to compare HLD of reusable duodenoscopes, culture-and-quarantine (CQ), ethylene oxide sterilization, and the EXALT Model D single-use duodenoscope in a simulated cohort of patients undergoing ERCP for choledocholithiasis.³⁶ Cost estimates included procedural costs, infectious outbreaks and associated treatments, and hospital costs. The EXALT Model D single-use duodenoscope yielded the most quality-adjusted life years (QALYs) but was also the costliest at \$3000 (vs the least costly option, HLD at \$962). The incremental cost-effectiveness ratio (ICER) was calculated and determined that CQ was more costly and no more effective than HLD. The ICER for the EXALT Model D single-use duodenoscope was \$62,185 over HLD. The authors then performed a subanalysis using Medicare outpatient transitional pass-through payment (TPT) and new technology add-on payment (NTAP) and concluded that the EXALT Model D single-use duodenoscope is the most cost-effective (zero cost using TPT) and generates an increase in QALYs (0.15%) compared with HLD.³⁶

Environmental Impact

The World Gastroenterology Organization (WGO) has raised concerns regarding the environmental impact of endoscopy through its established Climate Change Working Group (CCWG). Leddin and colleagues compiled a review that highlighted waste within gastroenterology and endoscopy.³⁷ This review highlighted the waste generated within endoscopy and presented measures that can be taken by the stakeholders (eg, individual gastroenterologists, gastroenterology societies) with the aim of reducing the level of greenhouse gas emissions, reducing nonrecyclable waste, and working toward developing environmentally friendly single-use substitutes. Concern for environmental impact led the WGO-CCWG to state their intention to further assess topics such as reusable endoscopy equipment.³⁷

The lack of studies on the environmental impact of single-use duodenoscopes has been noticed by the gastroenterology community.^{38,39} One of the few studies on this topic involves preliminary results from a life cycle assessment comparing cradle-to-grave environmental effects of reusable and single-use duodenoscopes.⁴⁰ The authors compared a reusable duodenoscope, a duodenoscope with single-use end caps, and the EXALT Model D single-use duodenoscope. Infection rates of 0.02% and intensive care unit stays associated with duodenoscope contamination were considered in the analysis with the

intent of estimating the carbon dioxide emissions produced by each duodenoscope. Use of the EXALT Model D single-use duodenoscope released an estimated 29.3 kg of carbon dioxide, which is approximately 20 times more than the carbon dioxide emissions with the use of a reusable duodenoscope (1.55 kg of carbon dioxide) and a duodenoscope with reusable end caps (1.37 kg of carbon dioxide). The authors noted that 96% of energy consumption from the single-use duodenoscope is related to its production.⁴⁰

Single-use duodenoscope manufacturers are taking steps to reduce landfill waste, lower greenhouse gas emissions, and destroy contaminants through novel medical recycling and waste management solutions.⁴¹ Reducing the need for reprocessing not only decreases the chemical waste from HLD but also decreases the amount of personnel exposure to chemicals and decreases use of personal protective equipment. Additionally, some materials are able to undergo a waste conversion process to generate electricity, such as the plastics from Ambu's single-use duodenoscopes.⁴² As the climate change discussion gains traction in health care, it will be important to continue to innovate and manage the carbon footprint of reusable devices as well as that of traditional processes and operations.

Advantages and Disadvantages of Single-Use Duodenoscopes

Although few would disagree that changes are necessary to reduce or eliminate the transmission of MDROs through duodenoscopes, the strategies used and the extent to which this transition needs to occur remain topics of great debate. The obvious advantages of single-use duodenoscopes involve the elimination of manual labor, reprocessing costs, and duodenoscope-related infection transmission with its associated clinical and financial implications. Transition to single-use duodenoscopes could also lead to financial advantages such as the elimination or reduction in the need for reusable duodenoscope repairs, decreased need for reprocessing equipment and trained staff, and a lower capital equipment cost. Single-use duodenoscopes may also be attractive to smaller, low ERCP volume facilities without sophisticated reprocessing equipment and/or expertise. This may be particularly relevant in the current health care landscape, in which large health systems are continuously expanding their affiliations and scope of service to smaller facilities in their regions for a variety of reasons, but mainly related to population management.

Bang and colleagues have suggested other possible technical advantages related to the single-use duodenoscope.²⁹ The authors proposed that the stiffness of the

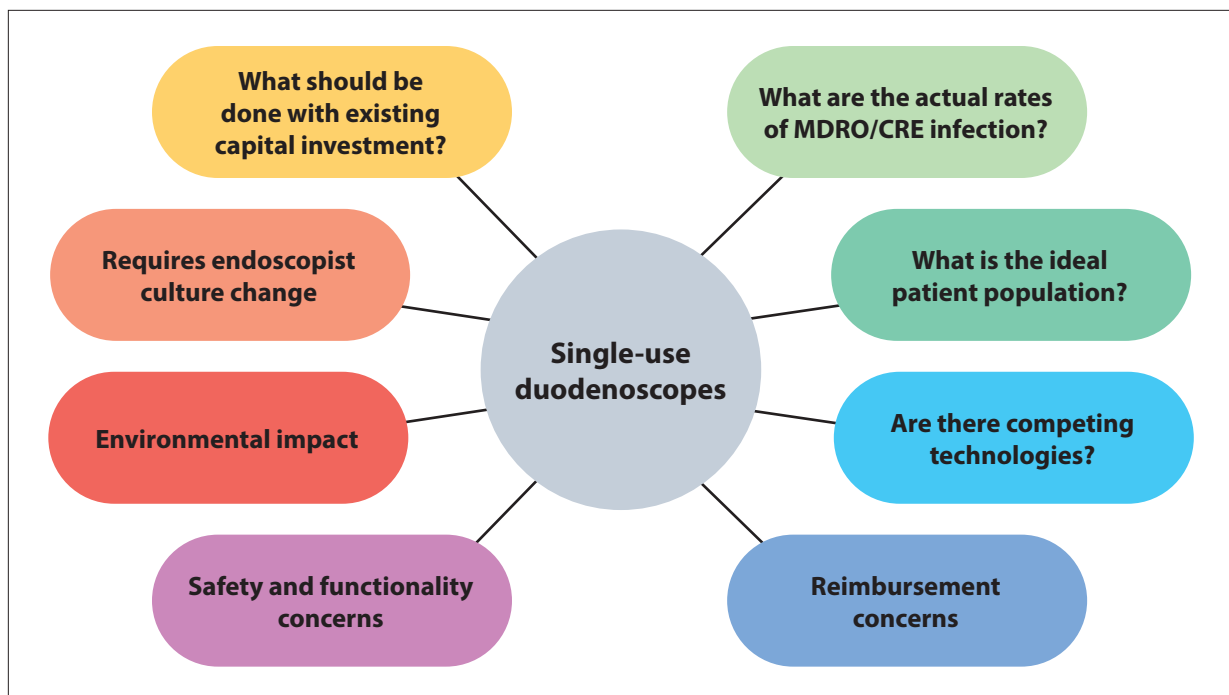


Figure 3. Typical concerns and factors impacting decision-making related to the single-use duodenoscope paradigm. CRE, carbapenem-resistant Enterobacteriaceae; MDRO, multidrug-resistant organism.

single-use duodenoscope allows for engagement of the papilla at an alternative angle and acts as an anchor to facilitate stone extraction. Overall, the data from prospective and randomized studies support that single-use duodenoscopes perform similarly to reusable duodenoscopes, can be used successfully by endoscopists of varying experience, are successful for procedures of variable complexity, and are safe.

On the other hand, there are concerns related to single-use duodenoscopes, including safety, cost, and environmental impact. A limited number of cases that were completed successfully after crossover from a single-use duodenoscope to a reusable duodenoscope raises questions about single-use duodenoscope performance and generalizability of study results to all patients and providers, particularly for difficult cases. Specifically, studies have raised concerns about navigation/pushability, image quality, image stability, and air-water button functionality.^{23,29} Shifting to single-use duodenoscopes could be an expensive endeavor, especially for smaller facilities with limited budgets or facilities with significant equipment investments already in place.^{34,35} Furthermore, results generated from a small number of patients in studies with procedures performed by expert endoscopists may not be generalizable to endoscopists with varying levels of experience in a community or real-life setting. The performance of these duodenoscopes in altered anatomy

settings and for difficult cases also remains largely unexplored. Another practical issue to address is whether facilities would maintain a dual platform (ie, both single-use and reusable duodenoscopes in their inventory) to allow safe and complete performance of a particular procedure where crossover to a reusable duodenoscope is needed, given the unpredictable nature of technical challenges during the ERCP procedure.

Also, the environmental impact of single-use duodenoscopes must not go overlooked. Although data in this area are particularly sparse, the preliminary results of a study by Hernandez and colleagues show that single-use duodenoscopes produce more than 20 times the carbon dioxide emissions than both reusable duodenoscopes and duodenoscopes with single-use end caps.⁴⁰ Additional considerations include identifying which patients and practices are most likely to benefit from transitioning to single-use duodenoscopes. Some guidance in terms of risk stratification of patient populations that would benefit the most from single-use duodenoscopes would be helpful to practices and centers considering this technology.

Limitations and Future Considerations

Although the literature regarding single-use duodenoscope safety and performance is growing rapidly, there is a relative paucity of high-quality data generated from large

Table 2. Questions for a Practice/Center to Consider When Contemplating Single-Use Duodenoscopes

1. What is the annual ERCP volume?
2. How many providers perform ERCP at this center?
3. Is there provider consensus on a reusable vs single-use approach?
4. What level (ASGE grade) of ERCP is typically performed at this center?
5. What are hospital/local/regional rates of CRE and MDRO infections?
6. What are the annual costs related to duodenoscope reprocessing?
7. What are the annual costs related to duodenoscope repair?
8. What is the annual cost of the duodenoscope service contract?
9. Has there been a duodenoscope-related infection or near miss at this center?
10. What is the frequency of after-hours ERCP at this center?

ASGE, American Society for Gastrointestinal Endoscopy; CRE, carbapenem-resistant Enterobacteriaceae; ERCP, endoscopic retrograde cholangiopancreatography; MDRO, multidrug-resistant organism.

prospective trials across a variety of practice settings. At the time of publication, most studies have looked at the EXALT Model D single-use duodenoscope, highlighting that more studies are needed to evaluate the aScope Duodeno. The breakeven points of approximately \$1300 and approximately \$800 for the 25th and 75th percentiles of annual procedure volume, respectively, estimated by Bang and colleagues provide a starting point for practices to discuss the viability of implementing single-use duodenoscopes in their own entities, but individual discretion is needed and each calculation will be unique financially.³⁴ Although a host of different variables were considered in this cost analysis, other factors (eg, clinical, fiscal, personnel-based) may impact decision-making for individual practices when contemplating reusable duodenoscopes for their patients (Figure 3 and Table 2). In July 2020, Medicare released a device-specific pass-through code that would enable hospitals to seek reimbursement for this technology in the outpatient setting, and this should be factored into the calculation. In October 2021, Medicare authorized additional reimbursement through the NTAP when using single-use duodenoscopes in the inpatient setting.⁴³

Further research should characterize the precise clinical role and the patient populations in which single-use duodenoscopes are most appropriate (Figure 4). Although the exact patient population that will benefit most from the use of single-use duodenoscopes is largely unknown, patients with significant comorbidities, patients at risk for MDROs (or who currently have MDROs), or patients who have a history of MDROs would be appropriate candidates.⁹ Current data do not support the use or avoidance of single-use duodenoscopes depending on established ERCP complexity grading, but this could be another area of future investigation. Single-use duodenoscopes have a hypothetical advantage in emergent cases outside the endoscopy unit (especially after-hours) where staff and reprocessing availability or mobility of equipment renders the use of reusable duodenoscopes inconvenient or unfeasible.⁹

Additional studies are needed to further evaluate and refine duodenoscope reprocessing, from technological advances to improved training of reprocessing staff. Addressing the major flaws and shortcomings in reprocessing efforts may further reduce risk for patients undergoing procedures with reusable duodenoscopes. The development of newer-generation reusable duodenoscopes with improved elevator and end-cap designs, the emergence of single-use end caps, and new technology for cleaning the elevator mechanism⁴⁴ are all variables that individual practices and institutions will need to consider when deciding the best pathway for a particular entity.

Individual practices must take all of these factors into consideration, including procedure volume, clinical setting, amount of existing capital equipment, local rates of infection, and patient populations served, to determine whether the transition to single-use duodenoscope would be advantageous (Table 2). With regard to the environmental impact of single-use duodenoscopes, more studies are certainly needed and will likely be involved in the overall climate change and endoscopy discussion.

Conclusion

Single-use duodenoscopes are an innovative solution and one of several strategies developed to eliminate the transmission of duodenoscope-associated MDROs. Several studies have reported a similar safety profile and acceptable technical performance when compared with traditional reusable duodenoscopes. However, provider expertise and preference, patient factors, and downstream effects of implementing single-use duodenoscopes such as cost and environmental impact must be considered when evaluating this new paradigm for a given clinical practice. Future prospective, randomized controlled trials on single-use duodenoscopes across different practice settings,

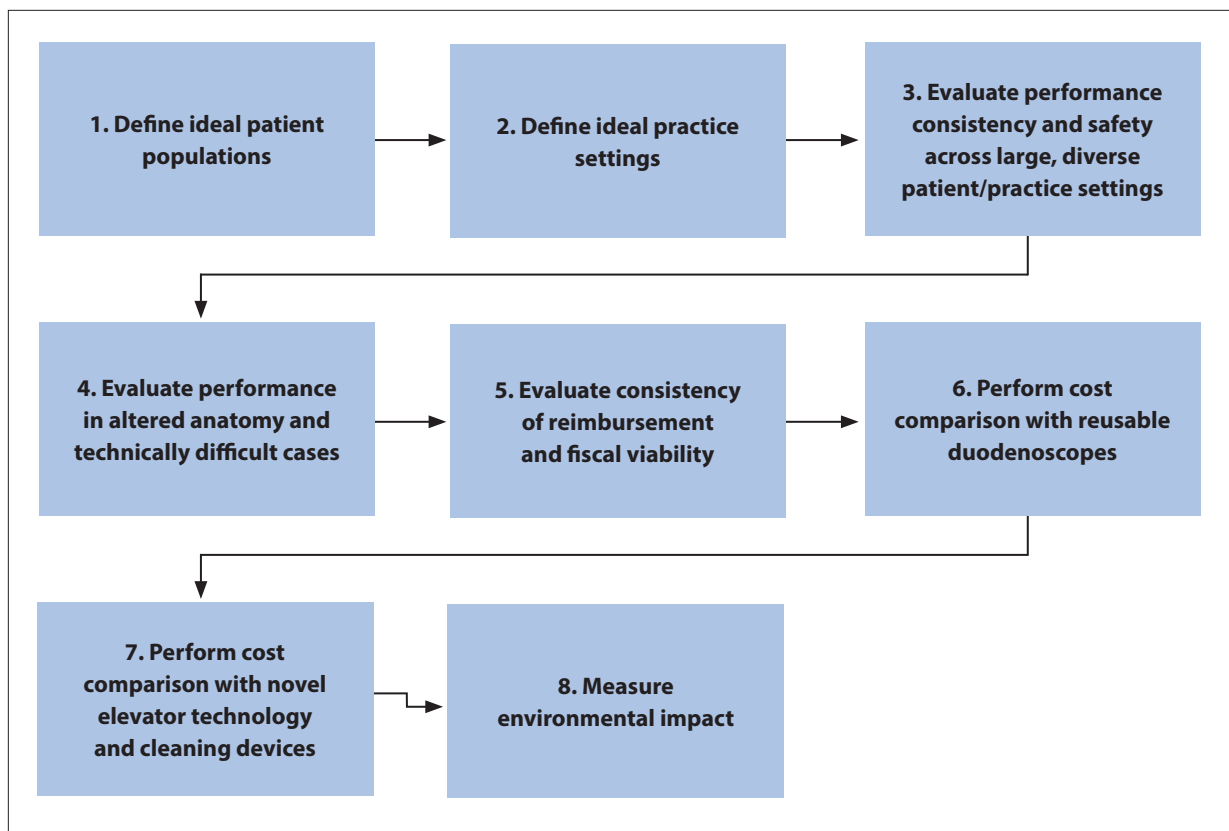


Figure 4. Areas for future research involving single-use duodenoscopes.

varying levels of endoscopist experience, and in patients with a broad range of biliary and pancreatic therapeutic indications will further evaluate the impact and usability of these novel duodenoscopes and position them optimally in clinical practice.

Disclosures

Dr Kaul has served as a consultant for Ambu. The other authors have no relevant conflicts of interest to disclose.

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