



Review: Disposable Duodenoscopes in the Era of Climate Change—A Global Perspective

Harish Darak^{1,*} Suprabhat Giri^{2,*} Sridhar Sundaram³

¹Department of Gastroenterology, Seth GS Medical College and King Edward Memorial Hospital, Mumbai, Maharashtra, India

²Department of Gastroenterology, Nizam's Institute of Medical Sciences, Hyderabad, Telangana, India

³Department of Digestive Diseases and Clinical Nutrition, Tata Memorial Hospital, Mumbai, Maharashtra, India

Address for correspondence Sridhar Sundaram, MD, DM, Department of Digestive Diseases and Clinical Nutrition, Homi Bhabha National Institute, Tata Memorial Hospital, Dr. E Borges Road, Parel, Mumbai 400012, Maharashtra, India (e-mail: drsridharsundaram@gmail.com).

J Gastrointest Infect 2022;12:11–17.

Abstract

Endoscopic retrograde cholangiopancreatography remains a major interventional procedure in gastroenterology clinical practice. There have been concerns of hospital related infections secondary to the reusable duodenoscopes despite optimal strategies for high-level disinfection. While there are have been potential changes in duodenoscope design with availability of disposable caps, the increased risk of infection has led to the advent of single-use duodenoscopes in clinical practice. This innovation may help reduce infections due to duodenoscope reprocessing, while ensuring optimal performance similar to reusable duodenoscopes. However, their impact on the environment and overall carbon footprint has not been discussed. Moreover, disposable duodenoscopes are costly equipments. In developing countries with low income and poor insurance coverage, the clinical utility of this equipment is yet to be ascertained. With major push for Go-Green initiatives by various governments, there has to be clarity on not just use but also disposal and recycling of disposable duodenoscopes. In this narrative review, we discuss the role of disposable duodenoscopes in clinical practice in this era of climate change from the Indian perspective.

Keywords

- climate change
- environment
- equipment reuse
- New Delhi metallo-beta-lactamase
- sustainability

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is a routinely performed procedure in gastroenterology practice. The primary indication of ERCP is the establishment of biliary drainage in case of biliary obstruction due to both benign and malignant causes. In the United States, approximately 5,00,000 to 6,60,000 ERCPs are performed yearly.^{1,2} No such data are available on number of ERCPs performed in

India annually. The procedures performed with reusable endoscopes are considered safe if they are performed in strict accordance with manufacturer reprocessing instructions for use and multisociety reprocessing guidelines. Usually, post-ERCP procedure infections are caused by the patients' own gut flora due to ascending cholangitis.³ Another mode of transmission of infection is contaminated endoscopes that can also transmit infection. Duodenoscopes are considered semicritical devices as per the Spaulding classification (► **Table 1**).⁴ Cleaning and high-level disinfection are

* Co-first authors.

received

January 17, 2022

first decision

February 1, 2022

accepted after revision

February 21, 2022

DOI <https://doi.org/10.1055/s-0042-1757186>.

ISSN 2277-5862.

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Table 1 Spaulding classification for disinfection of medical devices

Device classification	Contact surface	Minimum inactivation level	Examples
Noncritical	Intact skin	Cleaning and low/intermediate level disinfection	Stethoscopes
Semicritical	Mucous membranes or nonintact skin	High-level disinfection	Endoscopes
Critical	Sterile areas of the body including contact with blood	Sterilization	Surgical instruments

considered the standard practice for reusable duodenoscopes across the globe.⁴

The need for single-use duodenoscopes arose due to the outbreak of duodenoscope related infections. In a report by Epstein et al, there was outbreak of New-Delhi metallo-β-lactamase producing carbapenem-resistant *Enterobacteriaceae* (CRE) among 39 patients at a hospital in Northeast Illinois, United States.⁵ Infections with highly pathogenic organisms like *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and CRE,^{6,7} which are resistant to multiple antibiotics have been reported. Centers for Disease Control and Prevention has classified CRE as “Urgent” and *Pseudomonas* as “Serious” among antibiotic-resistant threats to public health.⁸ In a study from China, which included 1743 ERCP procedures, the post-ERCP infection rate varied from 3.58 to 13.51%.⁹ A multicentric, prospective, nationwide study was done by Rauwers et al who cultured 150 duodenoscopes (from multiple site) at 73 centers in the Netherlands after high-level disinfection.¹⁰ This study showed that 39% centers in the Netherlands had at least one contaminated duodenoscope with colony count of more than 20 colony-forming unit, with 15% having micro-organisms of gastrointestinal or oral origin indicating residual organic material of previous patients. The U.S. Food and Drug Administration (FDA) post-market 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.¹¹ As a large number of procedures are being done worldwide, this mode of transmission accounts for a huge number of potential post-ERCP infection and hence this issue needs to be addressed.

Why Does Only the Duodenoscope Need to Be Changed?

Duodenoscope are semicritical devices (touches mucous membrane) as per Spaulding classification. It requires high level of disinfection (→Table 1). Duodenoscope is a complex mechanical instrument that has a different structure at the tip compared with other scopes. It has an elevator and recess behind the elevator that can act as a potential corpus for infection (→Fig. 1). Also, this part of the scope is difficult to clean and requires appropriate manual cleaning. Another possible mechanism is the formation of biofilm, which allows bacteria to survive for several weeks in a difficult environment and can act as a persistent nidus for infection. Inadequate adherence to reprocessing guidelines further adds to the process. The Human Factors Study conducted

by the FDA showed that the reprocessing instructions in various user manuals provided by manufacturers are difficult to follow for the reprocessing staff. Also, descriptions of some of the steps for reprocessing were incomplete. A study assessing duodenoscope reprocessing showed that 45 of 73 manual cleaning tasks were performed incorrectly by 27% of participants.¹² To deal with these issues, U.S. FDA approved the use of single-use duodenoscopes.

Journey and Real-World Data of Single-Use Duodenoscope

Currently, there are two FDA-approved single-use duodenoscopes- EXALT Model D (Boston Scientific, Marlborough, Massachusetts, United States) (→Fig. 2) and Ambu aScope Duodeno (Ambu Inc, Columbia, Maryland, United States)



Fig. 1 Sideview duodenoscope with elevator channel in open (A) and closed position (B), with recess under the elevator channel (arrow).

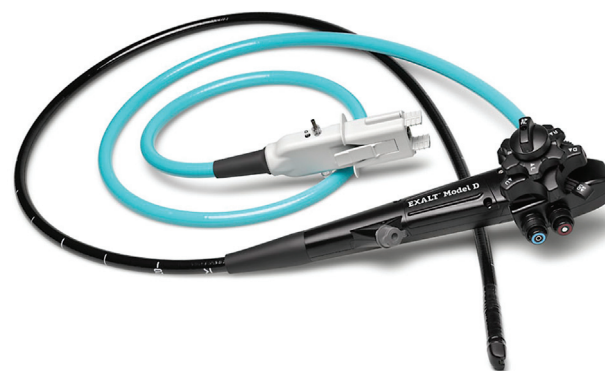


Fig. 2 EXALT D single-use duodenoscope.



Fig. 3 Ambu aScope Duodeno single-use duodenoscope.

(► **Fig. 3**).¹³ The preclinical testing of single-use duodenoscope started in 2017. Most of the available data on single-use duodenoscope is available with the EXALT D model. Ross et al then published their findings of comparison of single-use duodenoscope to three reusable duodenoscopes in an anatomic bench model.¹⁴ Four tasks were performed using these duodenoscopes: guidewire locking, plastic stent placement and removal, metal stent placement and removal, and balloon sweeps. The single-use scope was rated similar on all these tasks to reusable scopes by six expert endoscopists. The first study of clinical use of single-use endoscopes was published in 2019¹⁵ that included 73 patients and was performed at six medical centers by seven expert endoscopists. While in 13 patients, the duodenoscope was primarily used to assess passage into stomach, in 60 patients ERCPs were performed. The indications included ERCPs of all American Society for Gastrointestinal Endoscopy (ASGE) complexities (1–4) (86.6% were ASGE grade 2 and 3 severity). Fifty-eight ERCPs (96.7%) were completed using the single-use duodenoscope only and two ERCPs (3.3%) were completed after crossover to a reusable duodenoscope from a single use one. The median overall satisfaction rate among endoscopists was 9 out of 10. A major limitation of the study was the lack of randomization and the absence of a control group. Another limitation was that the study was sponsored and hence satisfaction score may have been affected. Further

studies have been published clearing the various aspects and applicability of single-use duodenoscope. In May 2021, the first study to compare reusable duodenoscope and single-use duodenoscope was published by Bang et al.¹⁶ Of the 98 patients, ERCP was performed with single-use duodenoscope in 48 patients and with reusable duodenoscopes in 50 patients and low complexity procedures being the predominant type (> 80%). The single-use cohort had less ease of passage into stomach, quality and stability of image with poor function of air-water button. On the other hand, the number of attempts at cannulation was much lower in single-use cohort. There was no significant difference in the rate of cannulation, adverse events, need to crossover, or need for advanced cannulation techniques to achieve ductal access. The authors suggested that single-use duodenoscopes represent a viable alternative in low-risk ERCPs.

Slivka et al studied the use of single-use duodenoscope from a real-world perspective, using it in all ASGE complexity procedures (grade 1–4), and comparing their use between expert endoscopists (> 2000 lifetime ERCP procedures) and less expert (< 2000 lifetime ERCP procedures) endoscopists.¹⁷ The study was conducted across 7 academic centers with 14 experts and 5 nonexpert endoscopists. The ERCP procedures were included all four severity grades of ASGE encompassing grade 1–10.3%, 2–48.2%, 3–30.3%, 4–11.3%. Nineteen (9.5%) cases required crossover to reusable duodenoscope. No difference was seen in rates of completion of procedure (~97% in both arms), time taken for procedure (25 vs 28.5 minutes), crossover, and also high-complexity cases (43.6% and 33.4%) between expert and nonexpert endoscopists, showing that the single-use duodenoscope was easy and safe to use in most hands with similar satisfaction between both groups. ► **Table 2** summarizes the studies performed using reusable duodenoscope.

The Environmental Aspect of Reusable Duodenoscope

Approximately 4.4% of worldwide net emissions are attributed to the global healthcare industry.¹⁸ In the healthcare sector, the environmental footprint is dominated by procedure-oriented specialties like surgery and endoscopy. Namburath et al looked at the environmental impact of using single-use accessories and devices for endoscopy through a 5-day audit. They calculated the volume of nonrecycled waste (landfill) per endoscopy, per annum for each center, and extrapolated it to the annual procedure volume in the United States. They estimated that each endoscopy generated 2.1 kg of biomedical waste (BMW). Of the waste generated, only 9% was recycled with over 64% going into the landfill. Over 38,000 metric tons were estimated to be generated by endoscopic procedures alone per year from the United States. These could cover 117 soccer fields up to 1 m depth. If all the procedures used only single-use scopes and accessories, an additional 40% was added to this volume of waste generated. There was quadruple amount of waste generated only from reprocessing and endoscope disposal with exclusive single-use endoscopes.¹⁹ Sorensen and Gruttner²⁰ compared the

Table 2 Summary of major studies on disposable duodenoscopes in recent literature

Name of study	No of patients included	Inclusion criteria	Exclusion criteria	Result	Limitation	Comments
Clinical evaluation of a single-use duodenoscope for endoscopic retrograde cholangiopancreatography (Muthusamy et al. Clin Gastroenterol Hepatol. 2020) ¹⁵	73	All eligible patients with > 18 years of age	-Patients with altered pancreaticobiliary anatomy -Pregnant women -Patients for whom endoscopic techniques are contraindicated -Patients excluded at investigator discretion	-Technical success rate 96.7% (58/60) -Median satisfaction rate 9/10 -Serious adverse event 5/73 (6.8%)	-Lack of randomization -Absence of control group -Sponsored study that may affect satisfaction score	-First human study on use of single-use duodenoscope
Equivalent performance of single-use and reusable duodenoscopes in a randomized trial (JY Bang et al. Gut. 2021) ¹⁶	98	-Age ≥ 18 years -Biliary or pancreatic duct disorder, based on clinical symptoms and radiological findings at CT or magnetic resonance cholangiopancreatography -Native papilla	-Age < 18 years -Pregnancy -Altered upper GI surgical anatomy -Patients with percutaneous transhepatic biliary drainage catheters -Prior history of ERCP -Inability to provide informed consent	-No significant difference in the rate of cannulation, adverse events, need for crossover or need for advanced cannulation techniques to achieve ductal access	-Minor papilla interventions were not performed using single-use duodenoscope -Majority of patients were low grade complexity	-First study to directly compare between single-use duodenoscope vs. reusable duodenoscope
Single-use duodenoscope for ERCP performed by endoscopists with a range of experience in procedures of variable complexity (Slivka et al. Gastrointest Endosc. 2021) ¹⁷	200	-All eligible patients with > 18 years of age	-Patients with altered pancreaticobiliary anatomy -Pregnant women; -Patients for whom endoscopic techniques are contraindicated; -Patients excluded at investigator discretion	-No significant difference in procedural completion (96.3% vs 97.5%), procedure time (25 minutes vs 28.5 minutes), crossover rate (1.3% vs 2.5%), and proportion of high-complexity cases (43.6% vs 33.4%) between single-use duodenoscope to reusable duodenoscope	-Lack of randomization and absence of a control group in the clinical study	-First study to compare experience of use of single-use duodenoscope among endoscopists with varied levels of expertise
Cost utility analysis of strategies for minimizing risk of duodenoscope-related infections. (Barakat et al. Gastrointest Endosc. 2022) ²⁸	Monte Carlo analysis model for cost-utility (No subjects involved)	-Comparative cost-utility model between single HLD, double HLD, ethylene oxide sterilization, culture and hold, FD duodenoscopes, PD duodenoscopes with disposable endcap	NA	For infection rates < 1%, PD was the most effective modality from a cost-utility standpoint with low infection transmission rate and low-cost disposable accessory	-Cost and infection rates cannot be generalized to low volume community centers -Based on duodenoscope associated MDRO infections, and non-MDRO infections	-First study to report cost-utility standpoint of disposable duodenoscopes

Table 2 (Continued)

Name of study	No of patients included	Inclusion criteria	Exclusion criteria	Result	Limitation	Comments
					were not considered as part of the model -Cost analysis based on available duodenoscopes at the time of development of model -Crossover from FD to reusable duodenoscope in equipment failure not considered in model	

Abbreviations: CT, computed tomography; ERCP, endoscopic retrograde cholangiopancreatography; FD, fully disposable; HLD, high-level disinfection; MDRO, multidrug-resistant organism; PD, partially disposable.

carbon dioxide (CO₂)-equivalent emissions and resources utilized for the use and disposal of one single-use bronchoscope with the sterilization of a reusable bronchoscope (along with consumables needed for personal protection). The CO₂-equivalent emission and energy use of equipment were higher for reusable compared with single-use bronchoscope. This calculation was made using the assumption that one set of personal protective equipment (PPE) was utilized per cleaning operation. However, when cleaning two or more reusable scopes per set of PPEs was considered, the environmental impacts were comparable. But, the most important factor contributing to the CO₂ emission, which was not considered in this analysis, was the production of the scope.

For this purpose, a life cycle assessment (LCA) is used, which identifies the environmental impact of a product during the production, use, and disposal stages. In contrast to the other stages of the life cycle, the production step may have a much greater effect on the environment. Hernandez et al²¹ conducted an LCA study, comparing “cradle-to-grave” environmental effects of reusable duodenoscope, reusable duodenoscope with disposable cap, and single-use duodenoscopes. The analyzed parameters included the environmental effects of production, transportation, disposal, and high-level disinfection. Of the three scopes, the single-use duodenoscope had the highest CO₂ production which was approximately 20-times the CO₂ emission by the other two scopes. On further analysis of the effects on human health, ecosystems, and resource consumption, the single-use duodenoscope still performs 18 to 65 times worse than the other two duodenoscopes. Around 96% of the single-use duodenoscopes energy consumption and greenhouse gas emissions are attributed to its production.

Another issue that needs to be addressed is the disposal of these endoscopes. Ambu and Boston Scientific have been taking the support of Sharps Compliance, Inc. (Houston, Texas, United States), a company that helps in disposal and recycling of medical waste, particularly for reprocessing and recycling single-use duodenoscopes. Despite being promoted as “recyclable,” there is only a small metal portion of a duodenoscope that is recycled.²² Incineration is the mode of disposal for most plastic parts that generates significant amount of CO₂, nitric oxide, sulfur dioxide, and other pollutants. Again, transportation of these scope to the recycling centers generates CO₂ footprint. Furthermore, it is unclear if hospitals will engage in single-use endoscope recycling programs in addition to questions regarding endoscope recycling programs. Single-use bronchoscopes are being discarded as regular trash and not recycled.

In India, the scenario of biomedical waste management is completely different. India has a BMW rule, which was initially framed in 1998, and modified over the years until the present BMW rule of 2016.²³ However, the implementation of this rule remains a far-fetched dream. Even with strict rules and liabilities, the country reports a high degree of nonadherence to these rules. During the 2018 to 2019 fiscal year, 23,942 healthcare facilities (HCF) violated the BMW rules 2016, and 18,210 HCFs received warnings for the violations.²⁴ There is a lack of training among the healthcare workers concerning proper segregation and disposal. Hence,



Fig. 4 Pros and cons of single-use duodenoscope.

these single-use scopes are unlikely to be recycled or disposed of properly, leading to an increased environmental hazard. Hence, single-use duodenoscopes may have a higher negative impact on the environment compared with reusable scopes. Better quantification of the environmental impact of endoscopic procedures and waste is needed, as it will ultimately affect human health. In light of the significant environmental impacts of medical waste, it is essential to shift the discussion away from accepting medical waste as an inevitable by-product of high-quality healthcare to advocate for a more environmental-friendly approach.

Cost-Effectiveness and Relevance for Third-World Countries

In India, both the public and private sectors cater to the healthcare demands of the country. In the public sector, healthcare costs are borne by the government, while in the private sector, they are borne by the patients, their employers, or health insurance providers. However, the majority of the patients in India do not have any health insurance, and the treatment costs are met entirely by the patient's family. Hence, the analysis of cost-effectiveness, as done in the previous studies, does not apply to countries like India. The cost of an ERCP procedure with a reusable scope varies from Rs. 1500 (approx. \$20) in a government setup to a maximum of Rs. 60000 (\$800) in a private hospital. For a patient developing cholangitis/sepsis due to associated multidrug-resistant organism infection, the cost of intensive care unit (ICU) stay also needs to be considered. In a government setup, the daily expenditure in a surgical ICU is Rs. 11,241 (\$ 150), while patients are charged anywhere from Rs. 35 (<\$0.5) for general ward to Rs. 1,000 (\$14) for a private ward.²⁵ A similar study from an ICU in a private hospital reported average overall ICU charges per day of Rs. 15,556 (\$208).²⁶ The cost of a single-use duodenoscope in India is around Rs. 260,000 (\$3475) that along with accessories will lead to a

procedural cost of around Rs. 290,000 (\$3875). When reusable scopes are used, the maximum total cost incurred for a 7 days ICU stay for cholangitis (at \$2200) is lower than the cost incurred for one procedure with a single-use scope.

On the contrary, post-ERCP infections related to reusable duodenoscopes are usually caused by multidrug-resistant bacteria and are potentially life threatening. More importantly, there may be an outbreak before the source of infection is recognized. Cost concerns take a back seat while encountering a potentially life-threatening infection outbreak. Hence, alternative approaches to minimize the transmission of infection at a lower cost need to be considered. A partially disposable duodenoscope with a detachable and disposable cap with elevator mechanism was approved by the FDA for the same.²⁷ The disposable distal cap includes the difficult to clean elevator element of the duodenoscope. This potentially not only reduces risk of colonization by bacteria in this inaccessible site but also reduces infection risk from duodenoscopes. In a recent comparative study by Barakat et al,²⁸ partially disposable duodenoscope with disposable cap had a very low infection rate and also small disposable component which was low cost. This made it the most cost-effective option for reducing risk of infection. Hence, there is a need for comparative analysis of the clinical efficacy and cost-effectiveness of single-use duodenoscope and partially disposable duodenoscope with disposable cap in Indian setup.

In conclusion, single-use duodenoscopes are an innovation to prevent cross-infection attributed to the use of reusable devices. However, certain questions need to be addressed. A single-use duodenoscope only prevents cross-contamination (►Fig. 4). It will not prevent the endogenous spread of infection due to manipulation of the pancreaticobiliary system. Whether a single-use endoscope is needed in all patients or is it useful only for a certain profile of patients like patients on immunosuppressants, or patients with cholangitis and sepsis? Further studies are required to answer these questions especially in developing countries like India

where insurance coverage for the population is very low and patients have to bear most of the cost. With most governments looking at Go-Green initiatives, it is important to balance the carbon footprint of an innovation with its potential utility in clinical practice. Until a model is developed wherein all single-use duodenoscopes are recycled with significantly reduced carbon footprint, its routine use in clinical practice remains to be justified.

Ethical Statement

Not applicable.

Author Contributions

H.D. and S.G. performed the literature review and drafted the manuscript. S.S. provided critical inputs and edited the final draft of the manuscript.

Data Availability Statement

There is no data associated with this work.

Funding

None.

Conflict of Interest

None declared.

Acknowledgments

None.

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