Environmental and health outcomes of single-use versus reusable duodenoscopes

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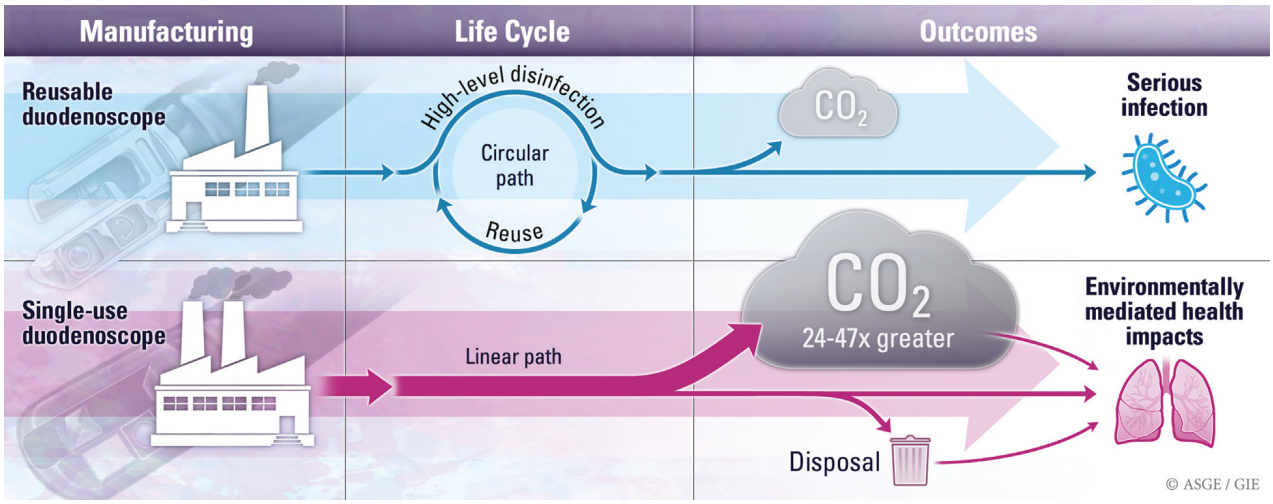
GRAPHICAL ABSTRACT



Background and Aims: The large-scale effects of duodenoscopes on the environment and public health have not been quantified. Our aim was to perform an exploratory life cycle assessment comparing environmental and human health effects of single-use duodenoscopes (SDs) and reusable duodenoscopes (RDs).

Methods: We evaluated 3 duodenoscopes: conventional RDs, RDs with disposable endcaps, and SDs. The primary outcomes were impacts on climate change and human health, complemented by multiple environmental impacts.

Results: Performing ERCP with SDs releases between 36.3 and 71.5 kg of CO_2 equivalent, which is 24 to 47 times greater than using an RD (1.53 kg CO_2) or an RD with disposable endcaps (1.54 kg CO_2). Most of the impact of SDs comes from its manufacturing, which accounts for 91% to 96% of its greenhouse gas emission. The human health impact of RDs becomes comparable with the SD lower bound if disposable endcaps or other design modifications can reduce serious infection rates below a target rate of 23 cases per year (.0046%).

Conclusions: Although SDs may provide incremental public health benefit compared with RDs, it comes at a substantially higher cost to the environment. As infection rates continue to decrease from more regimented cleaning protocols and enhanced designs such as disposable endcaps to facilitate cleaning, the negative impact to human health from contaminated RDs could be comparable with SDs. (Gastrointest Endosc 2022;96:1002-8.)

(footnotes appear on last page of article)

Single-use disposables have increasingly permeated the medical device industry for the past 20 years.[1] Advanced medical technologies have made it easier to manufacture single-use endoscopes containing complicated electronic components. There is a perception that recently introduced single-use duodenoscopes (SDs) are safer by almost

eliminating the risk of contamination. Indeed, the burden of serious infection from contaminated devices is not trivial. Over half a million ERCP procedures are performed yearly in the United States.[2] In 2013, multidrug-resistant organisms were detected in contaminated reusable duodenoscopes (RDs), prompting investigations associating outbreaks with a breach in cleaning protocols.[3] Fortunately, U.S. Food and Drug Administration (FDA)-mandated enhanced cleaning and reprocessing techniques, along with postmarket surveillance, have resulted in a steady decline in cases of 86%, from a peak of 250 reported infections in 2015 to 36 cases in 2018.[2] The FDA recommends hospitals to transition to duodenoscope designs that facilitate cleaning, such as RDs with disposable endcaps.

SDs can also be economically advantageous at a certain case volume threshold,[4] but the large-scale effects of their use on the environment and public health have not been analyzed to assist in policy decision-making. Studies show that toxic pollutants generated by the U.S. healthcare industry led to a loss of 614,000 disability-adjusted life years in 2013.[5] Greenhouse gas (GHG) emission was a major contributor to this health burden and came from 3 main sources: direct emissions from hospitals (eg, boilers, medical gases), indirect emissions from purchased electricity by hospitals, and supply chain emissions through the production of goods (eg, electricity for manufacturing, truck transportation, organic chemicals, waste management, etc). A recent audit showed that a typical endoscopic procedure generates 2.1 kg of waste, most of which goes to landfills.[6] However, electricity use by hospitals and supply chain remain the largest sources of U.S. healthcare carbon emissions, contributing 29% of total emissions in 2018.[5]

We hypothesize that using SDs leads to more environmental impacts than RDs while leading to comparable overall human health burden. Our aim was to perform an exploratory life cycle assessment (LCA) comparing "cradle-to-grave" environmental and human health burdens of SDs and RDs using the literature and empirical data.

METHODS

We evaluated 3 duodenoscopes: a conventional RD (TJF-Q180V; Olympus, Center Valley, Penn, USA), an RD with disposable endcaps (TJF-Q190V; Olympus), and an SD (Exalt Model D; Boston Scientific, Natick, Mass, USA). LCA is a method of quantifying the environmental and human health burdens of specific stages of procurement and use of various products including medical devices. Our exploratory LCA model included literature-based quantitative environmental and human health impacts of production, transportation, disposal, and electricity use of RDs and SDs as well as high-level disinfection of RDs. GHG emission is a verifiable metric for pollution in the healthcare industry. The primary outcome was carbon dioxide emissions (kg CO_2 equivalent), complemented by 22 other environmental indicators, and the secondary outcome was impact on human health. The functional unit of our LCA was 1 ERCP procedure, with detailed parameters shown in Supplementary Table 1 (available online at www.giejournal.org) for RDs and Supplementary Table 2 (available online at www.giejournal.org) for SDs.

The weights of the duodenoscopes were obtained from the manufacturers and were 1.49 kg for the RDs and .69 kg for the SD. The composition of the RDs was assumed to be 90% plastic, 4% steel, 4% electronics, and 2% rubber by weight. These values were based on available data for a similar medical device, the ureteroscope.[7] Because of the lack of data on the composition of SDs and similar disposable medical devices, we modeled a lower bound scenario and an upper bound scenario for the SD. The upper bound SD scenario would have the same mass of electronics as the RD, whereas the lower bound SD scenario would have the same percentage of electronics as the RD. This is a key parameter because the electronics account for over 95% of the impacts of duodenoscope manufacturing, and although the SD might have fewer complex electronics compared with the RD, the percentage of reduction in the weight of the electronics is likely lower than the percentage of reduction of the other components, leading to an effective composition within the above-described upper and lower bounds. We designed our model to provide a range to account for changes in future design from not just 1 but a variety of SD manufacturers. We believe our conclusions will not directionally change even if the duodenoscope's composition is slightly different because in general the largest percentage of carbon footprint comes from the manufacture of electronics, which make up a small fraction of the device.

The other components of the SD (plastic, steel, and rubber) were assumed to follow the same ratios as in the RDs. The intraprocedure electricity used for the RD was calculated based on the manufacturer's manual, assuming the same amount of energy was used across all scenarios. The 2 RDs were assumed to be reused 125 times per year for 5 years, thus a total number of 625 reuses, whereas the 5-g endcap was replaced after each use. We based this on the procedural volume of an average-sized community hospital. Although tertiary medical centers typically perform more ERCPs, our assumption underestimates the real-world lifespan of an RD, making our model optimistic toward the SD.

In addition, we assumed 500,000 ERCPs are performed in the United States annually, that conventional RDs were associated with a serious infection rate of .007% (36 cases out of 500,000 procedures) because of ineffective cleaning based on 2018 data,[2] and that the disposable endcap would be able to reduce this number by half. However, data are scant on the recently introduced RD with disposable

TABLE 1. Summary of model components and key assumptions covered in our model

Model component	Key assumptions
Composition of reusable duodenoscope (RD)	90% plastic, 4% steel, 4% electronics, and 2% rubber by weight. Total weight was 1.49 kg
Composition of the single-use duodenoscope	Total weight was .69 kg. Upper bound scenario: same mass of electronics as the RD (thus, SD would have higher percentage of electronics by weight than RD). The rest of the SD consists of plastic, steel, and rubber with the same weight ratios as the RD. Lower bound scenario: 90% plastic, 4% steel, 4% electronics, and 2% rubber by weight
Volume of ERCP performed in the United States	500,000 annually
Lifespan of an RD	The 2 RDs were assumed to be reused 125 times per year for 5 years, for a total number of 625 reuses
Infection rate	The conventional RD was associated with a serious infection rate of .007% (36 cases per 500,000 procedures) because of ineffective cleaning based on 2018 data[2] and that the disposable endcap would be able to reduce this number by half
Sensitivity analysis	Infection rate of RDs decreases to a theoretical level of .0046% (23 cases per 500,000 procedures)

RD, Reusable duodenoscope; *SD*, single-use duodenoscope.

endcaps. The 50% reduction is a goal we believe can be achieved based on what we believe are among the major reasons for the outbreaks first reported in 2013. Starting in 2010, several duodenoscope manufacturers changed the design from unsealed to a sealed elevator wire channel system. By transitioning to a disposable endcap design along with optimization of reprocessing, we believe the infection rate will continue to decrease. These infection rates were then used to calculate the impact of treating affected patients based on an average intensive care unit stay for sepsis.[8,9] Table 1 summarizes our key assumptions incorporated in our calculations.

Using a kilowatt meter, we prospectively recorded the average energy consumption of reprocessing 10 RDs used on 10 consecutive patients who underwent ERCP at All Saints Hospital (Racine, Wisc, USA) from February to March 2020. The endoscope reprocessor used was Advantage Plus (Medivators, Minneapolis, Minn, USA), and the detergents used in reprocessing the RDs (Intercept [Medivators], Rapicide high-level disinfectant [Medivators], and Prolystica 2X concentrate enzymatic presoak and cleaner [Steris, St Charles, Mo, USA) were also accounted for.

The SimaPro 9.1.1 software (Amersfoort, Netherlands) and the Ecoinvent 3.8 cutoff database (Zurich, Switzerland) (detailed process used shown in Supplementary Table 3, available online at www.giejournal.org) were used to estimate the midpoint impact on 23 different aspects of human and environmental health, such as particulate matter emission, carcinogen emission, effects on aquatic and terrestrial ecosystems, GHG emission, fossil resource consumption, water consumption, and land use. These midpoint impact results were then used to calculate the duodenoscopes' endpoint impact using the ReCiPe 2016 life cycle impact assessment method (Hierarchist ver sion).[10] This method considers 3 endpoint impact cate gories: human health, expressed as disability-adjusted life years; ecosystem quality, expressed as the number of potentially lost species integrated over time (species per year); and nonrenewable resource use, expressed as the extra cost for future mineral and fossil resource extraction (in U.S. dollars, reference year 2013). To facilitate the comparison of these impact categories, the results were normalized by dividing them by the total impact each person produces a year in each category globally. For example, a .01 normalized impact on ecosystems would equal 1% of an average person's impact on ecosystems annually from all his or her consumption and activities.

The fate of chemicals in the duodenoscope cleaning products after passing through the wastewater treatment plant was further modeled using the EPI Suite 4.11 and USEtox 2.12 packages. EPI Suite is a software developed by the Environmental Protection Agency and the Syracuse Research Corporation (Syracuse, NY, USA) and was used to estimate the fraction of the cleaning products' chemicals that reaches freshwater ecosystems after sewage water is processed at wastewater treatment plants.[11] USEtox is a scientific consensus model developed through a collaboration between the UN Environment Program and the Society for Environmental Toxicology and Chemistry and was used to evaluate the toxic impact of the cleaning products' chemicals on freshwater ecosystems.[12] Details of the calculations of ecotoxicologic impacts for the duodenoscope cleaning products are shown in Appendix 1 and Supplementary Table 4 (available online at www.giejournal.org).

In addition to the indirect human health effects of manufacturing, transporting, using, and disposing of the duodenoscopes, we also calculated the direct impact of infections associated with duodenoscope contamination in disability-adjusted life years. Data for the average age of patients undergoing ERCP and the mortality rate of severe sepsis were obtained from the literature.[9,13] To determine the years of life lost because of premature deaths from duodenoscope-associated infections, standard life expectancy data were obtained from the 2016 Global Burden of Disease Study Reference Life Table.[14] A sensitivity analysis was also performed with a range of infection rates. Further details of the calculations are available in

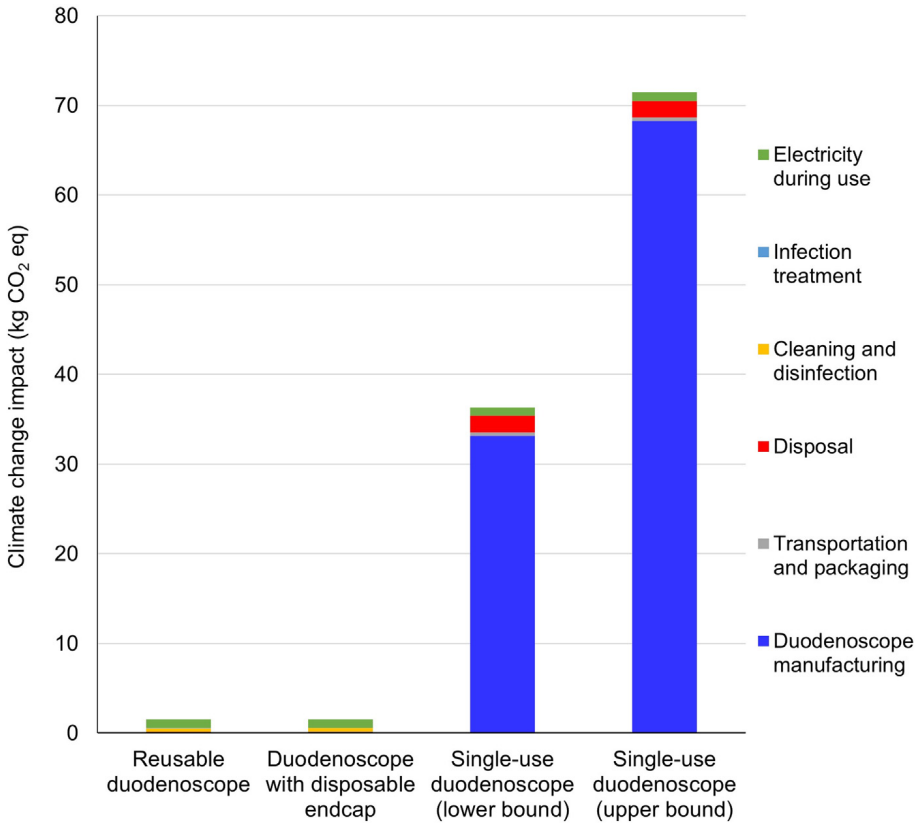


Figure 1. Comparison of the climate change impact (in terms of kg CO_2 equivalent emitted) of an ERCP procedure using 3 types of duodenoscopes, including the lower bound and upper bound for the single-use duodenoscope. The contributions of different life cycle stages are differentiated into duodenoscope manufacturing, transportation and packaging, disposal, cleaning, infection treatment, and electricity during use.

Appendix 2 and Supplementary Table 5 (available online at www.giejournal.org).

RESULTS

Performing an ERCP with an SD releases between 36.3 and 71.5 kg CO_2 equivalent, which is 24 to 47 times more than with an RD (1.53 kg CO_2 equivalent) or an RD with a disposable endcap (1.54 kg CO_2 equivalent). Figure 1 compares the CO_2 emission of the 3 types of duodenoscopes. Most climate change impact of SDs comes from their manufacturing, which accounts for 91% to 96% of the GHG emission. The second-highest contributor is the disposal of the SD, which generates 1.8 kg of CO_2 equivalent per procedure and accounts for 3% to 5% of the GHG emission. As for the RDs, the top contributor to GHG emission is electricity use during the procedure (62%), followed by RD cleaning and disinfection (26%). Regarding the overall human health and environmental impacts of the 3 duodenoscopes, the SD is 13 to 26 times worse than the 2 types of RDs in terms of environmentally mediated human health impacts (not counting direct impact from infections), 4 to 7.5 times worse in terms of ecosystem quality, and 26 to 50 times worse in terms of resource consumption (Fig. 2). On the other hand, RDs with disposable endcaps perform similarly to traditional RDs in all categories, with the advantage of potentially reducing infections. Supplementary Figure 1 (available online at www.giejournal.org) confirms these results for the 23 impact subcategories, except for water-related impacts, which were similar between all duodenoscopes.

However, both conventional RDs and RDs with disposable endcaps carry a small risk of contamination leading to serious infections. When the impact of these infections is included, the human health burden of the SD is close to the total human health impact of the RD, between a factor of .7 (SD lower bound, same relative weight fraction of electronics) and 1.4 (SD higher bound, same absolute weight of electronics) of the RD (Fig. 2). Furthermore, if our assumption that the disposable endcap can reduce the infection risk of RDs by 50% is realized, the human health burden of RDs with disposable endcaps would then be lower than that of the SDs (a factor of .75 of the SD lower bound).

Because the direct human health impact from infections dominates the overall impact of duodenoscopes, a sensitivity analysis was performed to determine the infection rate at which the human health impact of manufacturing SDs equals the burden of infections of RDs. If the infection rate of RDs decreases to a theoretical level of 23 per 500,000 or .0046%, the overall negative human health impact of an RD will fall

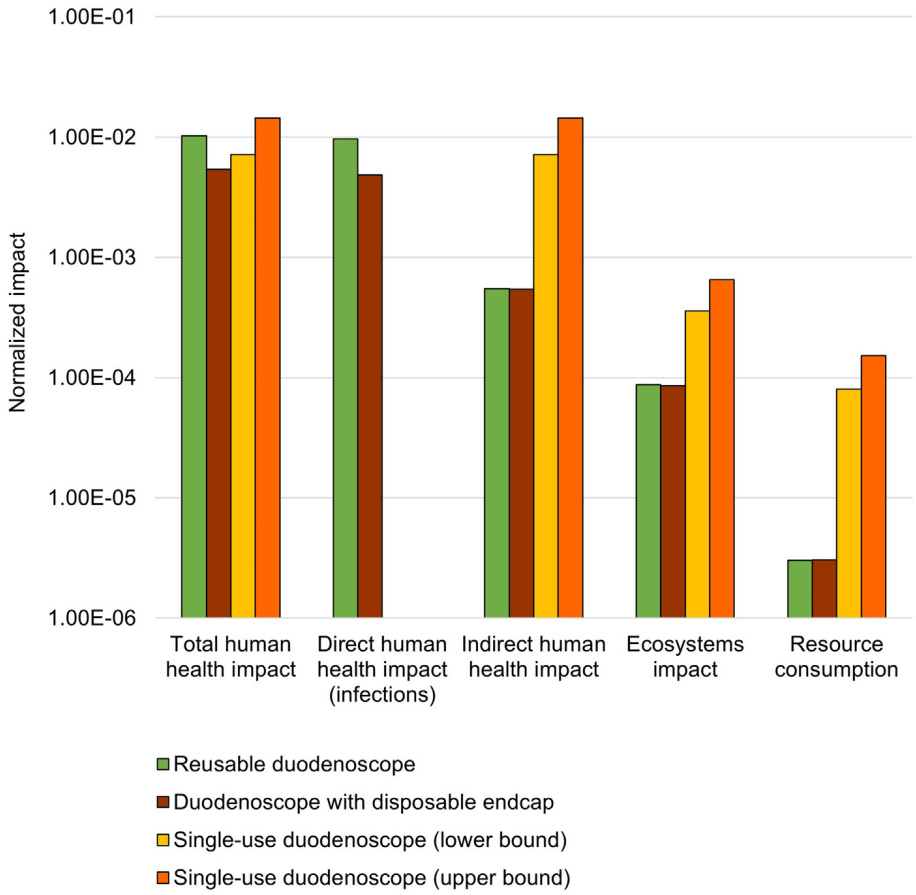


Figure 2. Cradle-to-grave normalized impacts of performing an ERCP procedure using 3 different types of duodenoscopes on human health (including direct impact from infections and indirect impact from life cycle emissions), ecosystem quality, and nonrenewable resource consumption according to the 2016 ReCiPe method and the USEtox model for disinfection impacts. Direct human health impact was calculated based on literature estimates of the infection rate of 36 cases per 500,000 ERCPs because of contaminated duodenoscopes, associated mortality rate, and the average age of ERCP patients. The total human health impact is the sum of the direct and indirect human health impact.

below the lower bound health impact of an SD. Detailed results of the sensitivity analysis are shown in Supplementary Table 9. (Supplementary Tables 6-8 show the overall model results without the sensitivity analysis) (Available online at www.giejournal.org).

DISCUSSION

We estimate that SDs emit 24 to 47 times more GHGs, have at least 4 times higher ecosystem impact, and consume at least 26 times more resources than RDs, even after accounting for postprocedure high-level disinfection of RDs. When serious infections from contaminated RDs are accounted for, the negative effects on human health of RDs and the lower bound of the SDs are comparable when we reach a threshold of 23 serious infections per 500,000 procedures for RDs. Using SDs for all ERCP procedures can have considerable environmental consequences. If all U.S. facilities adopted the use of SDs, over 18 million kg of CO_2 would be released into the atmosphere yearly, equivalent to the annual carbon emissions of 3945 passenger automobiles.[15]

The Medical Device Reporting system of the FDA is a critical countermeasure to monitor serious infections related to contaminated RDs.[2] It can be argued that information on contaminated RDs can be under-reported. However, distinguishing preventable from nonpreventable nosocomial infections remains challenging. Ascertainment bias is a potential limitation because of systematic differences in identification of cases. Reports starting from 2013 often lack standard case definition, making broad estimates of true case counts difficult. Several reports of contamination relied on cultures, but only a few used gene sequencing as the criterion standard. Serious outbreaks were not only because of breaches in cleaning protocol but also because of design flaws of earlier-generation duodenoscopes that impeded effective cleaning, which represented a substantial number of cases. Furthermore, the rate of serious infection from RDs is extremely low, and large sample sizes will be needed to prove the safety of SDs. For example, reducing nosocomial infections by 10% from a single intervention such as

use of an SD would require 500,000 patients in a controlled trial.[16] Fortunately, we are seeing a downward trend in infections from contaminated RDs, perhaps because of FDA-mandated enhanced reprocessing techniques and postmarket surveillance. Based on our findings, it is possible that a continued downward trend in serious infections from contaminated RDs could achieve parity with SDs in terms of impact to human health.

Single-use disposables are the hallmark of the *linear* economy that we have witnessed over the past 2 decades. This "take-make-waste" approach has contributed to 4.6% of global carbon emissions, of which one-fourth came from the U.S. health system.[17] Most pollutants originate in the supply chain (material procurement, manufacturing, transportation, and disposal). Hence, there is increasing interest in the *circular* economy that embodies reuse, reprocessing, and minimizing waste disposal to reduce GHG emissions.

Our exploratory study has limitations that require further refinement, integration with economic metrics, and real-world validation. It is important to note that our model was based on key assumptions (Table 1), and results may deviate from prospective evaluations. We could only approximate the material composition and manufacturing energy of the RDs and SDs using the ureteroscope as a surrogate device, because we have not been able to obtain empirical data on the duodenoscope's composition or the energy involved in assembling its components. To avoid favoring RDs, we took 5 steps to make our model tendentially biased against RDs and optimistic for SDs. First, duodenoscopes contain more complex electronics and elevator mechanism than ureteroscopes, and therefore using ureteroscopes' composition data likely underestimates the impact of manufacturing duodenoscopes. This bias favors the SD because manufacturing accounts for over 90% of the SD's impact but less than 10% of the RD's impact. Second, we modeled a lower bound and an upper bound for the amount of electronics contained in the SDs and then based our sensitivity analysis and conclusions on the SDs' lower bound. Third, we incorporated the risk of infection in our model, whereas most studies comparing LCA of disposable versus reusable devices (laryngoscopes,[18] bronchoscopes,[19] and ureteroscopes[7]) did not include risk of serious infection in their models. Fourth, we assumed a zero risk of serious infection for the SD despite the theoretical risk of introducing endogenous gut bacterial flora into the pancreaticobiliary tree during ERCP. Fifth, despite the recent accounts of perforations associated with SDs,[20] we did not include this in our calculations because of the preliminary nature of these reports. Therefore, our model favors SDs in 2 ways: RDs are compared with the best-case scenario of SDs and the risk of serious infection from RDs is included, whereas the risk of SDs is assumed to be zero.

We also did not account for the recycling of SDs. However, most of the energy consumption and carbon emission associated with duodenoscope manufacturing is not because of the materials (like steel or plastic) but primarily because of producing the electronic components. Therefore, unless the electronic components of SDs could be efficiently reused, recycling would have limited impact.

We observed that although disposable duodenoscopes provide an incremental public health benefit, it comes at a substantially higher cost to the environment compared with conventional duodenoscopes. As infection rates continue to decrease from more regimented cleaning protocols and the adoption of enhanced designs such as disposable endcaps to facilitate cleaning, the negative impact to human health from contaminated RDs could approach comparable levels with SDs. Intuitively, the mainstream adoption of disposables could eliminate the risk of infection and promises zero harm to individual patients. However, our findings offer a broader perspective by factoring environmental and public health costs to inform policy decision-making. An opportunity exists for device manufacturers to track GHG emissions across the product chain, accounting for pollutants from the production, electricity use, and transportation of its goods to downstream activity by end-users. The purposeful disclosure of these actionable milestones by manufacturers is a vital step towardenvironmental best practice. Ultimately, a Bayesian, risk-based approach for selecting between disposables and reusables will optimize treatment of individual patients in need of ERCP.

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Abbreviations: FDA, U.S. Food and Drug Administration; GHG, greenhouse gas; LCA, life cycle assessment; RD, reusable duodenoscope; SD, single-use duodenoscope.

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