SPECIAL REPORT

Improving Infection Prevention in Endoscopy and the Role of Single-Use Technologies

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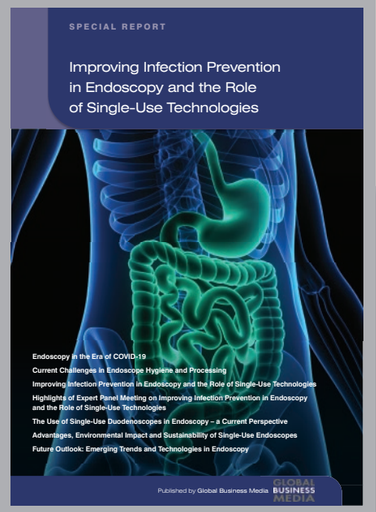

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Foreword

The utility of endoscopy and clinical outcomes related to endoscopic procedures continues to evolve with new circumstances and new technologies. Improved imaging, artificial intelligence and safety innovations have taken endoscopy into new interventional realms and improved diagnostic yield. Safety in regard to healthcare-acquired infection has recently been an area of concern, particularly that involving multidrug-resistant organism transmission during endoscopy.

Safety of endoscopic procedures for both patients and healthcare workers has come to the forefront in recent years because of the COVID-19 pandemic, accompanied by increased cost, stress on staff and requirements for sanitation and scope reprocessing. New technologies, including sterilizable duodenoscopes, disposable components and single-use endoscopes have been introduced as solutions to these problems. In this Report, we discuss (i) the implications of endoscopy in the COVID-19 era, including workflow, wait times and reprocessing requirements; (ii) emerging issues, insufficiencies and challenges in successful reprocessing and high-level disinfection of reusable endoscopes in the context of recent outbreaks of multidrug-resistant organisms; (iii) the utility of single-use endoscopes to mitigate the risk of infection from endoscopic procedures, such as endoscopic retrograde cholangiopancreatography (ERCP) and endoscopy of the pancreatobilliary tree; (iv) performance, acceptance and patient selection for single-use endoscopy; (v) economic sustainability and environmental impact of single-use scopes, and (vi) emerging trends and advancements in endoscopic procedures, imaging, computer-aided diagnosis and prevention of infection. Continued innovation and technology is broadening the utility of endoscopic procedures. These innovations are bringing new challenges in assessment, implementation and training related to new technologies and procedures but are also improving our ability to ensure positive outcomes and safety for patients.

Michael James
Editor

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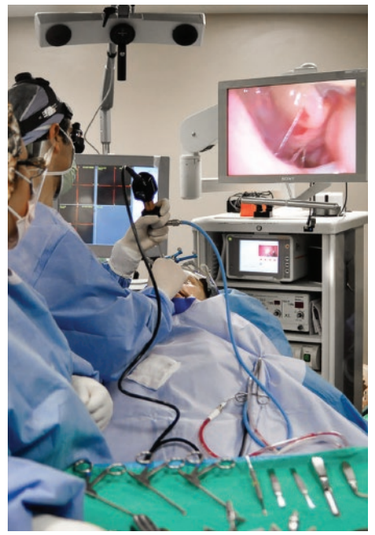
IMPROVING INFECTION PREVENTION IN ENDOSCOPY AND THE ROLE OF SINGLE-USE TECHNOLOGIES

Endoscopy in the Era of COVID-19

Michael A James, PhD

THE COVID-19 pandemic has had significant impact on the safety and efficiency of endoscopy procedures. The causal virus, SARS-Cov-2, is known to be transmitted through respiratory droplets, surfaces and aerosols[1]. In addition to consideration of potential exposure to body fluids and contamination of surfaces during endoscopy, it is appropriate to consider endoscopy an aerosol-generating procedure. With over 50% of COVID-19 patients exhibiting gastrointestinal (GI) symptoms[2] and detection of virus in feces (although not correlative to GI symptoms[3]), oral-fecal transmission should also be considered.

SARS-CoV-2 has been found to be stable for 3 hours as an aerosol and 72 hours on certain surfaces, including plastic and stainless steel[4]. An early study of SARS-CoV-2 infection in Wuhan showed that healthcare workers comprised 29% of patients[5],[6]. Accordingly, the World Health Organization offered interim guidance on the use of personal protective equipment (PPE) during endoscopy[7], including the use of hairnets, face shields, goggles, N-95 or FFP-2/3 masks, full sleeve gowns, gloves and shoe covers. In high-risk cases of fever, COVID-19 symptoms, positive contact or travel to endemic areas, endoscopy was recommended to be limited to designated rooms or isolation rooms if available. Decontamination procedures included surface disinfection of procedure rooms and standard high-level disinfection of endoscopy equipment. Despite fecal detection of virus, lower endoscopy is viewed as lower risk by US and UK guiding organizations, leading to less strict PPE guidelines for these procedure[8]. GI endoscopy in general is considered to be relatively safe when appropriate PPE and decontamination are observed[9]. However, compliance with PPE use, decontamination procedure and safety precautions cannot be assumed. While PPE use and decontamination are important for the prevention of SARS-CoV-2 transmission to health care workers, documented cases of transmission to patients through endoscopy are rare. However, with increasing transmissibility of modern variants, this may be changing. There is also special risk conferred by asymptomatic infection, which is on the rise[10].



Endoscopy room and PPE. "File:Mani Zadeh MD Endoscopic Sinus Surgery.jpg" by BestInPlastics is licensed under CC BY-SA 3.0.

Precautions for the Prevention of SARS-CoV-2 Causing Longer Wait Times

Perhaps a more significant impact has been on efficiency of endoscopic work flow and wait times. Endoscopy procedures are taking longer because of precautions for the prevention of SARS-CoV-2 transmission, causing concern among physicians that cancer patients and those with other GI illnesses are not getting diagnoses and treatment in a timely manner. GI endoscopy wait times may have already been a problem before the pandemic as illustrated by a Canadian study in 2008 showing that 78.6% of patients were not meeting standards for wait times[11]. In a simulation model, workflow changes brought on by the COVID-19 pandemic significantly and negatively affected operation and productivity measures for endoscopy, thereby

In addition to consideration of potential exposure to body fluids and contamination of surfaces during endoscopy, it is appropriate to consider endoscopy an aerosol-generating procedure. With over 50% of COVID-19 patients exhibiting gastrointestinal (GI) symptoms and detection of virus in feces (although not correlative to GI symptoms), oral-fecal transmission should also be considered

A factor that has significantly affected turnover time for endoscopy procedures has been enhanced decontamination procedures that have been implemented to combat COVID-19 infection

affecting financial metrics[12]. The British Society of Gastroenterology published guidance in 2020 recommending that non-essential endoscopic procedures be reduced and that FIT screening and Bowel Scope be paused, limiting procedures to emergency and essential procedures[13]. Emergency and essential procedures were limited to acute bleeding, foreign bodies, obstructions, hepato-pancreatobiliary, nutrition, vacuum therapy and ongoing GI bleeds. Globally, similar guidance has left surveillance and cancer staging procedures with extended wait times and decreased availability. In a global survey of GI endoscopy units, 85% reported decreasing procedure volumes by over 50% because of the pandemic with 2.45% completely halting procedures[14].

Components of COVID-19-related measures that have affected workflow and wait times for endoscopy have included the need for dedicated or isolated rooms (depending on COVID-19-status), COVID-19 screening and assessment before procedures, staffing issues and enhanced sanitation procedures[12]. Site structure of endoscopy units has significantly changed as a result of COVID-19. These changes have included modification of unit layouts, incorporating risk based dedication of spaces in waiting, recovery and procedure rooms, implementation of new checkpoint and PPE donning areas and the creation of separate pathways and processes according to risk assignments[15]. Staffing issues have included training of staff in COVID-19 precautions, reassignment of at-risk staff, illness with COVID-19 among staff, increasing staff furloughs and greater staff needs for screening and assessment[16].

Enhanced Decontamination Features

A factor that has significantly affected turnover time for endoscopy procedures has been enhanced decontamination procedures that have been implemented to combat COVID-19 infection[17]. Surface disinfection of rooms and surfaces is a large part of enhanced procedures that contributes to increased turnover time. Another is disinfection of endoscopy equipment. Endoscope disinfection procedures are to include high-level disinfection (HLD), which is typically performed on an automatic endoscope reprocessor. Such reprocessors employ cycles of exposure to a chemical disinfectant solution at specific temperatures and for a recommended duration[18]. Although guidelines have not advised significant changes to endoscope disinfection protocols, strict adherence to existing recommendations is emphasized[19]. Proper disinfection of endoscopy equipment is highly dependent on operator training. Standard procedures for endoscope reprocessing include pre-cleaning at the bedside, testing for leaks, manual cleaning and HLD, which have been shown to be effective at eliminating SARS-CoV-2 contamination[19]. Novel approaches to endoscope sterilization have included techniques such as low-temperature plasma-activated gas, which produces ultraviolet light and free radicals to kill a broad range of microorganisms[19]. Additional advances have been made in the use of infection barriers and the disposable endoscopes or endoscope components.

The Need for New Technologies for Efficient and Safe Endoscopy

Effects of the COVID-19 pandemic on endoscopy in terms of both safety and efficient work flow are having a significant impact on patients, health care workers and endoscopy units. To best ensure safe procedures and provide effective and timely services to patients, new perspectives on operations in these units and new technologies for efficient and safe endoscopy will need to be implemented.

In a simulation model, workflow changes brought on by the COVID-19 pandemic significantly and negatively affected operation and productivity measures for endoscopy, thereby affecting financial metrics

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Perhaps a more significant impact has been on efficiency of endoscopic work flow and wait times. Endoscopy procedures are taking longer because of precautions for the prevention of SARS-CoV-2 transmission, causing concern among physicians that cancer patients and those with other GI illnesses are not getting diagnoses and treatment in a timely manner

Current Challenges in Endoscope Hygiene and Processing

Michael A James, PhD

Effective reprocessing of endoscopy equipment is challenging and may not be regularly accomplished, thus increasing the risk for cross-contamination and infection

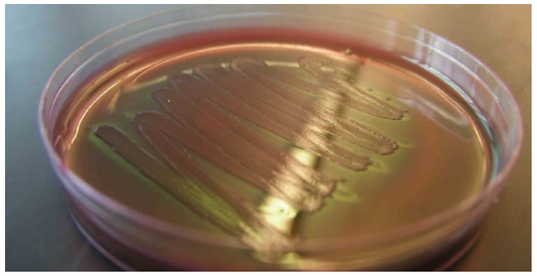

Figure 1. E. coli on EMB agar. Credit: Adonofrio (Biology101.org). Licensed under CC BY 2.0.

Risk of Infection During Endoscopy

Infection related to endoscopic procedures is a long-standing issue, with nosocomial infections being a common complication following endoscopic retrograde cholangiopancreatography (ERCP)[1]. Infection in endoscopy patients has two sources, endogenous infections which come from the patient's own microflora[2] and exogenous, which originate from environmental sources, typically a contaminated endoscope[2]. The most commonly isolated pathogens from contaminated duodenoscopes are *Escherichia coli, Staphylococcus aureus, Klebsiella pneumoniae, Enterococcus faecalis and Pseudomonas aeruginosa*[2],[3]. The 2020 British Society of Gastroenterology guidelines for endoscope decontamination have identified four microorganisms of concern during the past 20 years[4]. These include mycobacteria, which can be spread during bronchoscopy, particularly to immunocompromised or HIV-positive patients; bacterial spores from *Bacillus* or *Clostridium* species, which have been isolated from endoscopes but not linked to infections; multidrug-resistant gram-negative bacilli; and prions, which are highly resistant to decontamination procedures. Additionally, recent outbreaks of multidrug-resistant organism infections have been associated with duodenoscopy[2], including those occurring after ERCP[5]. Many of these events occurred despite proper reprocessing of endoscopy equipment[6]. A 2019 review of duodenoscope contamination rates published between 1998 and 2018 showed that contamination rates range between 0.69% and 60%[6]. Because of concerns with duodenoscope contamination data and ongoing challenges with endoscope reprocessing efficacy the FDA has recommended a transition from re-usable duodenoscopes with fixed endcaps to fully disposable duodenoscopes or reusable duodenoscopes with disposable components[7].

Insufficiency of Decontamination of Endoscopes

Effective reprocessing of endoscopy equipment is challenging and may not be regularly accomplished, thus increasing the risk for cross-contamination and infection. A major factor leading to ineffective reprocessing and increased risk of infection is non-adherence to reprocessing guidelines coupled with the complex design of endoscopes[7],[8]. In a prospective study of endoscope reprocessing effectiveness, 1.4% of manual cleaning procedures and 75.4% of automatic HLD procedures were found to adhere to documented guidelines[9]. There is frequent residual microbial presence on reusable endoscopes following HLD, and disinfectants commonly fail tests of minimum effective concentration (MEC) prior to the expiration of their maximum use periods[10]. The US Food and Drug Administration (FDA) monitored adherence to endoscope reprocessing protocols for multiple major manufacturers of duodenoscopes and found that protocols were not followed correctly 27–94% of the time[11],[12]. In addition, unacceptably high contamination rates of endoscopic equipment even after reprocessing following guidelines were reported in this study.

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Complex instructions for the use and testing of HLD and human failures to properly conduct these procedures were suggested to contribute to these issues. Non-adherence to guidelines, use of insoluble products (e.g. simethicone), contaminated water, inadequate drying and damaged endoscopes were cited as specific factors influencing the effectiveness of HLD.

Endoscope decontamination procedures recommended by 2020 British Society of Gastroenterology guidelines start with bedside pre-cleaning to remove visible organic material[4]. This step prevents blockage of the channels due to dried soil and is followed by a leak test to rule out damage that might allow internal endoscope exposure to fluids. Manual cleaning is next, which includes brushing and flushing of the channels with a compatible detergent to remove organic material and clear blockages. Recommendations for the use of enzymatic detergents during this step have been reduced because of related hypersensitivities[13]. Finally, the endoscope is rinsed and dried before automatic high-level disinfection in an endoscope washer/disinfector (EWD). A recent systematic review of the literature published from 2008 to 2020 sought to identify failures in endoscope processing that have led to insufficient decontamination[14]. The most common failure was the absence of or inadequacies in drying. The next most common failure was manual cleaning without brushing all appropriate channels. Other gaps included failure to test for leaks, improper storage, improper use of disinfectant solution, insufficient time of immersion, insufficient monitoring of MEC, failure to pre-clean and improper transportation to processing facilities.

Aside from issues of adherence to reprocessing guidelines, contamination rates have been estimated as high as 60% on duodenoscopes even after proper decontamination[6],[15]. Outbreaks of multidrug-resistant organisms have been attributable to ERCP in cases where endoscope reprocessing has adhered to manufacturer's guidelines[5]. This residual risk despite strict reprocessing guideline adherence highlights the need for technologies that minimize the risk of infection.

Reprocessing Delays

Delays in endoscope reprocessing occur for a wide variety of reasons and may result in a disruption of patient care. In a survey of healthcare workers, the majority of respondents reported pressure to work faster during duodenoscope cleaning procedures[16]. Greater than 75% of these healthcare workers experienced discomfort or fatigue when conducting cleaning procedures. When asked to identify practices to best improve reprocessing comfort and efficiency, respondents identified mentoring and retention of experienced staff as most important. Delays in endoscopy procedures were recently found to negatively impact quality-of-care and increase the length of hospital stays for inpatients by a median of 2 days[17]. This study also identified inpatient endoscopy delays as an independent risk factor for readmission within 30 days. Workflow limitations are a significant factor in these delays as endoscopy unit availability was one of the most common causes of delays in inpatient endoscopy in the study. Positive cultures or use on high-risk of COVID-19-positive patients requires quarantine of endoscopes, which contributes to downtime and equipment availability. Enhanced surveillance and reprocessing techniques have been developed as a result of recent outbreaks, which further increase scope downtime, requiring 3.4 times the number of scopes to maintain the same volume of procedures[18]. These recommended procedures include microbial culture, liquid chemical sterilization, repeat HLD or ethylene oxide sterilization in addition to manufacturer-recommended reprocessing. The available clinical data indicate that these supplemental measures to enhance duodenoscope reprocessing do not effectively eliminate duodenoscope contamination[19].

It has been proposed that a shift to sterilization or the use of sterile, disposable endoscopes is required to ensure the safety of patients[20]. Disposable, single-use endoscopy equipment represents a technology that may minimize downtime and improve safety for endoscopic procedures. Single-use endoscopes eliminate the need for reprocessing and related costs, staff requirements and training. In an early study comparing a disposable sheath for fiber optic sigmoidoscopy to reprocessing of endoscopes found that overall downtime was reduced from 32.8 minutes to 8.1 minutes[21]. This advantage is in addition to potentially improved staff and patient safety. Disposable technology may also minimize cost and downtime associated with scope repair. It was determined that colonoscopies require repair over 3 times each year[22].

Conclusions

It is clear that there are ongoing challenges in effective disinfection of endoscopy equipment and the efficiency of endoscopic procedures in terms of workflow, staffing, training, downtime and cost. As such, improved endoscopy unit design, protocols and technologies are required to ensure quality patient care and the safety and efficient employment of healthcare workers. Implementation of these measures will require analysis of benefits to safety and efficiency, financial considerations and education of physicians and healthcare workers.

Improved endoscopy unit design, protocols and technologies are required to ensure quality patient care and the safety and efficient employment of healthcare workers

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Delays in endoscope reprocessing occur for a wide variety of reasons and may result in a disruption of patient care

IMPROVING INFECTION PREVENTION IN ENDOSCOPY AND THE ROLE OF SINGLE-USE TECHNOLOGIES

Improving Infection Prevention in Endoscopy and the Role of Single Use Technologies

This paper describes the potential risk of infection after endoscopy of the pancreatobiliary tree and discusses about alternatives to solve this problem. This review focusses more in the new single-use duodenoscopes as a promising alternative.

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Conflict of Interest Disclosure

EVS: Has received money from lectures and/or consultancy by Ella-Biomed, Boston Scientific, Olympus and Ambu.

Key Words (3-5 MeSH)

Single use duodenoscope; disposable; cost; infectious disease; safety.

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Although a minimally invasive procedure, any endoscopy performance associates a non-neglectable risk of infection

To perform an upper or lower gastrointestinal endoscopy, an endoscope has to be introduced through a natural orifice (mouth or anus). Although a minimally invasive procedure, any endoscopy performance associates a non-neglectable risk of infection. This risk is significantly higher when a side-viewing endoscope, either a duodenoscope or an echoendoscope, more complex in design and therefore difficult to clean, is used[1]. These types of endoscopes, with the camera and working channel exit located at the side of the distal end of the endoscope and an elevator nail for needle or catheter redirection at the same level, may certainly be more difficult to clean. A suboptimal disinfection of these side-viewing endoscopes will result in a higher risk for bacterial infection. The magnitude of this problem increases in patients with a higher risk for infection, such as oncologic patients and those receiving chemotherapy or immune suppressive drugs, i.e. transplanted patients. If the transmitted bacteria is a so-called ¨superbug¨ or multidrug-resistant (MDR) organism (e.g. carbapenem-resistant Enterobacteriaceae), the risk for a lethal outbreak of infection related to endoscopic retrograde cholangiopancreatography (ERCP) will certainly increase, as has been shown in recent years[2,3].

Potential Solutions to Reduce the Risk of Duodenoscope Transmission of Infections

Adequate disinfection of endoscopes has become a major problem in recent years, especially for side-viewing endoscopes, and a number of potential solutions have been proposed to solve or at least minimize this problem:

Adequate disinfection of endoscopes has become a major problem in recent years, especially for side-viewing endoscopes

1.) Sterilization: Sterilization of side-viewing duodenoscopes has been proposed by experts in the field as an effective alternative. However, this approach requires a longer time to reprocess the duodenoscope, and the elevated temperatures needed for sterilization may damage the endoscope and reduce the lifecycle of the expensive duodenoscopes[4]. These shortcomings of sterilization would result in a need to buy a larger number of duodenoscopes to do the same number of ERCPs, and endoscopes would need to be replaced for damage more frequently. For these reasons, sterilization does not seem to be an adequate option and is only reserved for selected cases, such as contaminated duodenoscopes despite repeated high-level disinfection[4].

2.) Modifications of design of reusable duodenoscopes: Manufacturers of reusable duodenoscopes have also been very active at trying to solve the problem of infections related to the use of their products and difficulties encountered in the cleaning of their non-disposable duodenoscopes. Some companies have modified the protocols and material used (e.g. specifically designed cleaning brushes) for manual cleaning of the distal end of the duodenoscope. Furthermore, all manufacturers of duodenoscopes (Fujifilm Corporation, Olympus Medical Systems and Pentax Medical) have redesigned the distal part of the endoscope by adding disposable/single-use components such as disposable end-caps or single-use elevator nails in an attempt to minimize the risk for infection[5-7]. These initiatives directed to the most critical parts of the duodenoscope disinfection process are very valuable but cannot completely prevent an infection.

3.) Fully disposable (single-use) duodenoscopes: A final alternative to avoid iatrogenic infections related to the use of a duodenoscope, and probably the more ambitious and safer one, would be the use of single-use duodenoscopes. This futuristic approach has become a reality in the very recent years and is the fruit of intensive research at leading companies in the field of endoscopy. The Boston Scientific Corporation EXALT Model D (Figure1) is the first single-use duodenoscope that reached the market and has been fully available for commercial use since that moment, while the Ambu Innovation GmbH (aScope) has also introduced a disposable duodenoscope in more recent dates. Endoscopists should be aware that single-use duodenoscopes, despite differences between manufacturers, are essentially similar in design to reusable ones (working channel length: 1240 mm; insertion tube outer diameter: 11.3 mm; angulation range: up: 120º; down: 90º; right: 110º; left: 90º; working channel inner diameter: 4.2 mm; field of view: 108-130º). The concept of single-use duodenoscopes would eliminate the transmission of microorganisms from one patient to another due to ineffective processing[7,8] and appears to be the more reasonable approach to pursue in coming years if we want to definitively avoid risks for crossover infection related to ERCP performance.

Questions Regarding Single-Use Duodenoscopes

Although we believe that the single-use duodenoscope approach is the way to go in the future, there are still some questions that need to be further clarified:

1.) Performance characteristics of single-use vs reusable duodenoscopes: Before we decide to switch to single-use duodenoscopes, we need to be sure that they are equally effective, both technically and clinically, when compared with current state of the art ¨reusable duodenoscopes¨. At present time we can only find published data reporting the efficacy of single-use duodenoscopes manufactured by the Boston Scientific Corporation (EXALT Model D) (Figures 1, 2 and 3).[7,8]. These initial reports have been very promising, demonstrating that ERCP performance with these new endoscopes is feasible and provides reasonable clinical results[7,8]. This was elegantly shown in a recent multicenter study conducted at 6 academic medical centers[8]. The authors demonstrated that 96.7% of 60 patients evaluated could be successfully treated with a disposable duodenoscope, and only 2 of the 60 patients (3.3%) required a rescue ERCP

Figure 1. Single-use duodenoscope EXALT Model D with image processor (white box).

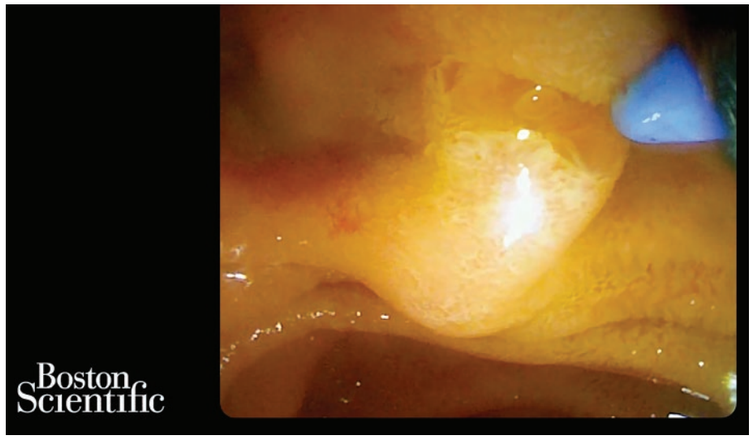

Figure 2. Endoscopy image of the major papilla.

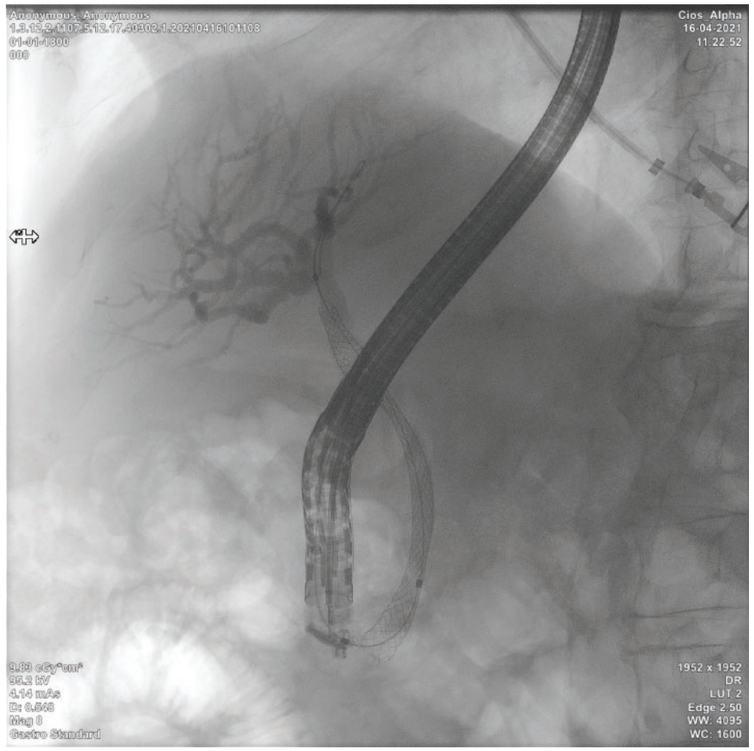

Figure 3. A self-expandable metal stent is placed in the bile duct.

with a conventional duodenoscope[8]. These results, along with other subsequent studies, support a similar efficacy of non-reusable duodenoscopes[9-10].

2.) Single-use duodenoscopes are equally effective in low and in high-grade complexity procedures?: From a clinical perspective, this is an important point. One may question whether these good results of single-use duodenoscopes will remain when difficult cases are performed. Although results in this area are still limited, we have strong evidence in the literature demonstrating in a prospective randomized controlled trial that single-use duodenoscopes have no significant differences in technical performance and safety compared with conventional reusable duodenoscopes in cases of low complexity ERCP (Grade 1–2 of the American Society for Gastrointestinal Endoscopy (ASGE) Complexity Scale)(9–10). Other non-comparative studies showed that 3.3% of cases

There are 4 specific groups of potential indications that would be wise to bear in mind when a decision between single-use or reusable duodenoscopes has to be taken

It appears clear that any modification in our clinical practice, such as transitioning into single-use endoscopes, may affect our environmental impact, as suggested by recent publications

required a switch from single-use duodenoscope to a reusable duodenoscope because of ERCP failure in patients with a grade of complexity of 2 or 3 (8-9). Although some high complexity ERCP cases (Grade 4) have been reported with remarkable success, the performance characteristics of single-use duodenoscopes in such cases is yet to be proven.

3.) Clinical indications for single-use duodenoscopes: Although still in the process of being fully defined, there are 4 specific groups of potential indications that would be wise to bear in mind when a decision between single-use or reusable duodenoscopes has to be taken:

3.a.) Patients with an elevated risk of having a MDR bacteria:[11]

- ✓ Previous colonization of the patient by a MDR.
- ✓ Patient admitted or with a recent admission to the Intensive Care Unit (ICU).
- ✓ Patient receiving or having received recently mechanical ventilation.
- ✓ Patients with exposure to broad-spectrum antimicrobial within 30 days (e.g. fluroquinolones, 3rd generation cefalosporin and/or carbapenem).
- ✓ Recent placement of intravascular devices or urinary probes.
- ✓ Patient who has recently developed nosocomial infections.
- ✓ Patient who has undergone recent surgery or another invasive procedure.
- ✓ Patient with neutropenia (< 500 PMN/mm^3).
- ✓ Presence of a local outbreak of MDR.

3.b.) Patients with a higher risk of morbidity-mortality if infected by MDR or other bacteria:

- ✓ Aged-patients.
- ✓ Patients with a long-hospitalization.
- ✓ Oncologic patients.
- ✓ Immune suppressed patients.
- ✓ Transplanted patients.
- ✓ Patients affected by an autoimmune disease.

3.c.) Patients with a higher risk of developing an infection after ERCP performance:

- ✓ ERCP placement of a biliary stent.
- ✓ Patients with a diagnosis of cholangiocarcinoma.
- ✓ Incomplete drainage of the bile duct.
- ✓ Hospitalized patients.

3.d.) Logistic indications: (Potential indications)

- ✓ ERCP has to be performed outside the Endoscopy Unit (Operation Room, Emergency Department, ICU,…).
- ✓ ERCP performed in non-laboring hours (cleaning of endoscopes not available).
- ✓ Reusable duodenoscope under repair or in quarantine.
- ✓ Low-volume ERCP centers (avoids large investment associated with buying a reusable duodenoscope).

4.) Alternative strategies of use for disposable duodenoscopes: Three potential alternative strategies for informed use of duodenoscopes are presented:

4.a.) Replacement of all reusable duodenoscopes by single-use endoscopes: This approach could be the best from a patient´s perspective. Initial cost analysis studies (including durability of the duodenoscope, cost of the duodenoscope, washer and cleaning supplies, labor costs and cost of treatment of infections) suggest an extra cost of $612 per procedure in high-volume institutions (a little more in low volume centers) if all reusable endoscopes are replaced by single-use duodenoscopes[12]. The affordability of this strategy by the healthcare system appears to be difficult at present time.

4.b.) Selective use of disposable duodenoscopes: It seems a wise decision to pursue this more economically affordable strategy, reserving the economic resources available for those patients at an increased risk of being infected and for those with a major probability of being carriers of MDR bacteria. A marginal increase in healthcare cost (e.g. 5–10% of ERCP patients) may be better assumed by sanitary authorities.

4.c.) Use of duodenoscopes with a disposable cup: Improvements in duodenoscope design are likely to reduce the risk of infection, and partially disposable duodenoscopes should replace current non-disposable ones. However, this alternative appears to be insufficient as supported by the 37% rate of persistent organic residue contamination after reprocessing these partially disposable duodenoscopes[13].

5.) Environmental impact of disposable duodenoscopes: Although not the subject of this review, it appears clear that any modification in our clinical practice, such as transitioning into single-use endoscopes, may affect our environmental impact, as suggested by recent publications[14]. A reasonable balance between potential patient benefits, cost and environmental impact appears to be mandatory.

In summary, single-use duodenoscopes are certainly a key stone to avoid infections related to ERCP. Preliminary reports support high efficacy and safety, but efforts are still needed to better define indications and reduce the cost associated with incorporation into routine clinical practice.

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In summary, single-use duodenoscopes are certainly a key stone to avoid infections related to ERCP. Preliminary reports support high efficacy and safety, but efforts are still needed to better define indications and reduce t he cost associated with incorporation into routine clinical practice

Improving Infection Prevention in Endoscopy and the Role of Single-Use Technologies – Expert Panel Meeting

Evidence, Experience and Expert Opinion

Highlights of the Expert Panel Meeting for the Middle East and North Africa, 15 September 2021*

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Ahmed Abd El-Azeem El-Mikkawy, Consultant of Hepato-gastroenterology and Liver Transplantation; Associate Professor Gastroenterology & Hepatology Department[12]

Khalid Osman Elamin Elsayed, Consultant Gastroenterology and Director of Endoscopy[13]

Ayman Yosry Abdel-Rahim Hamad, Emeritus Professor of Gastroenterology and Hepatology; Chairman Faculty of Medicine[14]

Ibrahim Mostafa, Founder and CEO; Lecturer of Gastroenterology & Hepatology[15]

Data from global registries and reports have shown that patients with IBD do not present a higher risk of infection or a worse course of COVID-19 compared to the general population

IMPROVING INFECTION PREVENTION IN ENDOSCOPY AND THE ROLE OF SINGLE-USE TECHNOLOGIES

*Virtual meeting sponsored by Boston Scientific

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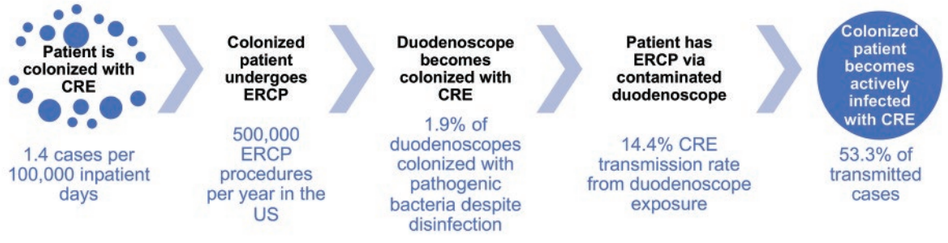
Requisite events for infection transmission via duodenoscope and associated probabilities/rates



CRE, carbapenem-resistant *Enterobacteriaceae*; ERCP, endoscopic retrograde cholangiopancreatography
Figure adapted from 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(6):1121–9

"Figures vary and this is an issue that requires meticulous examination to prove the problem, but I do believe that ERCP-associated infection happens more than we would like to think."

Raman Muthusamy
UCLA Health System, Los Angeles, USA

Introduction

The burden of healthcare-acquired infections (HAIs) or nosocomial infections (NIs) is largely unrecognized and under-reported. HAIs are the sixth leading cause of death, surpassing the combined deaths from HIV/AIDS, cancer and traffic accidents[1,2].

Data from the USA show that more than 100,000 hospitalized patients die every year due to NIs, with the direct economic burden of HAIs estimated at $28–$45 billion[1]. A report by the Organization for Economic Cooperation and Development (OECD) mentions that a single resistant infection has cost of about €8,500 to €34,000 more than a non-resistant infection[3].

While reporting from Western countries is more consistent, there are studies indicating that bacterial profiles in the Middle East are similar[4,5], which suggests a comparable situation. In one study at King Abdulaziz Specialist hospital in Saudi Arabia, *Klebsiella pneumoniae* was identified in 30 patients[6]. *K. pneumoniae* is an opportunistic pathogen responsible for a significant proportion of nosocomial and community-acquired infections, and its genotypic variation is a major barrier to controlling public health risks associated with pathogens[6].

Infection outbreaks have a significant impact on patients and institutions. Those involving multidrug-resistant organisms (MDRO) have the greatest clinical consequence and are also the most easily tracked. Such outbreaks are currently rare, but the era of MDRO is only beginning and is likely to worsen in future. For an affected unit, any outbreak can create poor morale, temporarily reduce interventional capacity and surgical volume, increase the costs for additional equipment, cleaning and legal fees; and damage the reputation of the institution[7].

Patient and Device Factors Related to Duodenoscope-Transmitted Infections

Up to 8% of patients undergoing endoscopic retrograde cholangiopancreatography (ERCP) may develop an infection due to a contaminated duodenoscope[7].

The main patient-related risk factors for duodenoscope-transmitted infections were inpatient status and biliary stent placement in a study comparing 15 patients with active infection or colonization against 89 who had been exposed but had no infection. Additionally, biliary stent placement and male sex were associated with active infection compared to colonization[7]. In an earlier study of 39 patients, of whom 35 had duodenoscope exposure, risk factors for transmission included stent placement and brushings[8].

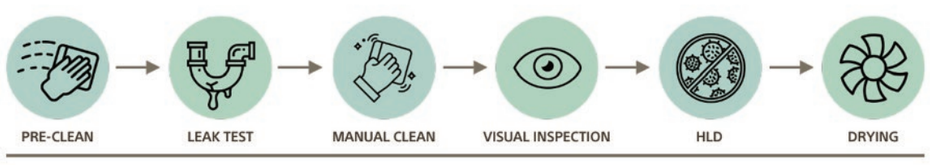
Infection outbreaks are also associated with a combination of device-related factors[9,10]. Firstly, the duodenoscope has a complex design, with the distal tip and elevator making it difficult to achieve complete clearance of debris and contaminated fluids[2,11,12].

Secondly, devices used during ERCP create higher levels of mechanical stress than gastroscopes or colonoscopes, with subsequent permanent damage that favors bacterial contamination and creates the conditions for biofilm formation[10]. Foreign debris such as tissue, fibres, and metal clips are frequently retrieved from the working channel of the scope – in 48% of inspected duodenoscopes (N=50) and 59% of all flexible endoscopes (N=126) in one survey[13].

Following large outbreaks in three major Dutch medical facilities, Rauwers et al[14] identified a range of device abnormalities, including: brown staining on the distal tips; cracking at the distal end on the inside of the biopsy channel; inadequate connection of the replaced protective cap, leaving space between the cap and the tip frame; and white and brown oxidation stains on the elevator[14].

Single-use technologies have become available and may provide a solution to the complex problem of device-associated infection outbreaks[15,16]. The world's first single-use model, EXALT D (Boston Scientific Corporation, Marlborough Mass, USA) reaches equivalent performance to reusable duodenoscopes while eliminating the risk of bacterial colonization due to ineffective processing, and the need for reprocessing and repairs[16].

Cleaning duodenoscopes is a complex process, with no single point to confirm that infection risk is truly controlled[12]



HLD, high-level disinfection

The impact of single-use devices on the environment is also a consideration, but must be balanced against the waste produced by reusable devices and the disinfection process, as well as the overall risk reduction in specific patients. Importantly, in a study comparing single-use and reusable ureteroscopes, Davis et al (2018) showed that the environmental impact of a single-use flexible endoscope is comparable to that of the reusable flexible endoscope[17].

Considerations for Patient Selection: Center Experience with Single-Use Duodenoscopes

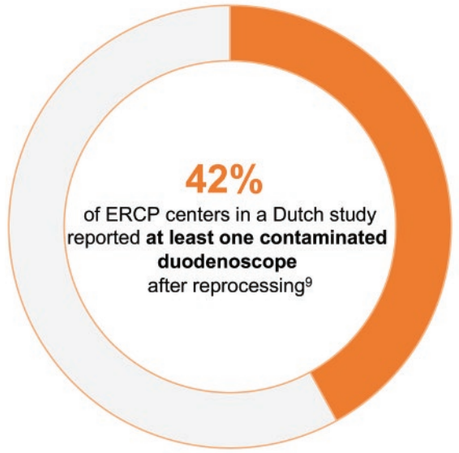
There are now over 400 published cases for the Exalt D single-use duodenoscope showing levels of satisfaction and adverse event rates comparable to reusable duodenoscopes. The device is under constant review and a new iteration is now available, with a particular focus on ergonomics and hand experience. However, a key question remains around patient selection for single-use technologies.

The Humanitas University Hospital, Milan, Italy

According to the protocols at Humanitas University Hospital, Exalt D is routinely used in three select indications:

- sick and frail patients with advanced cancer, or cancer suitable for surgery, who are jaundiced and require simple, complication-free decompression
- post-transplant patients, including those who have had a stem cell transplant
- patient cases involving the use of SpyGlass™ DS System.

For every case where a single-use duodenoscope might be indicated, the team discusses the advantages and disadvantages of the procedure, as well as its potential impact on the patient and budget in the context of risk for post-ERCP infection complications.



UCLA Health System, Los Angeles, USA

At UCLA Health System, the team uses four criteria for deciding on single-use technologies with the hospital analysis committee on price:

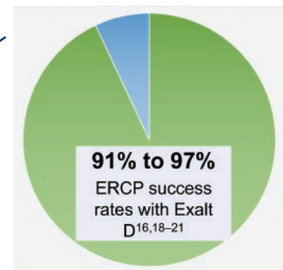
- to facilitate logistics/operations, e.g. weekend/night cases; operating room cases; backup fleet on busy days; low-volume/off-site centers
- to protect the fleet, e.g. in patients with known MDROs[22] to avoid the risk of transmission, which has been estimated around 14%[7]
- in critically ill patients who would not be able to withstand a duodenoscope-acquired infection; these include hospitalized patients, in particular those receiving transplantation and intensive care unit patients with pressor support
- in procedures at high risk for bacteremia/infection transmission, such as cholangioscopy, biliary radiofrequency ablation, and stent placement

The experience to date at UCLA Health System suggests that patient preference may also come to play a role in the choice of single-use duodenoscope. Emerging data on cost considerations related to an enhanced

An expert panel was convened to share experiences with the Exalt D, review important factors impacting its use, and identify those patients who will benefit the most from a single-use versus reusable duodenoscope

Exalt D Single-Use Duodenoscope: Published Data on Efficacy, Comparability and Safety

Publication	Number of patients	Key outcomes
Muthusamy et al. 2020 (18)	60	97% success with SUD; AE rate 6.6%; median overall satisfaction 9/10
Bang et al. 2021 (19)	48 (all native papilla)	96% success; no difference in cannulation success, procedure time or AE rates (4% for SUD) compared to reusable devices
Slivka et al. 2021 (20)	200 (n=19 endoscopists)	40.5% ASGE Grade 3-4); crossover rate 11.3% vs. 2.5% (N=19); success 97%; AE rate 6.5%; similar time and satisfaction between experts and "less-experts"
Napoléon et al. 2021 (21)	60	95% success; median satisfaction 9/10; AE rate 5% (not SUD related)
Ehrlich et al. 2021 (16)	36	91.7% success rate; AE rate 3.2%



Data from global registries and reports have shown that patients with IBD do not present a higher risk of infection or a worse course of COVID-19 compared to the general population

duodenoscope reprocessing protocol suggest a cost efficacy for single-use duodenoscopes that may even lead to savings in certain settings[23-25].

Patient Selection: Perspectives from Middle Eastern Centers

Defining the Issue of Duodenoscope-Associated Infection

The group agreed that the risk of duodenoscope-associated infection is increasingly apparent globally. However, many centers do not track the issue, while others are unable to do so because the patients return to other medical facilities after undergoing ERCP in the center.

Demonstrating the true extent of the problem will be challenging until active screening is implemented. In the Middle East, there is a general acceptance that MDROs are a growing issue, but the link has not yet been made to ERCP or duodenoscopes.

Experts suggested there should be more active screening of duodenoscopes and greater follow-up of ERCP patients, especially oncology patients. The group expressed enthusiasm for a multi-center prospective study to routinely culture duodenoscopes and understand the contamination rates. Protocols could be drawn up and a central laboratory used to ensure consistency and enable the collection of meaningful region-specific data.

Experience

There was some experience within the group with the Exalt D single-use duodenoscope, which was reportedly comparable with the current gold standard.

Some participants raised concerns that Exalt D might handle differently, but it was noted that Pentax™ and Olympus™ do not handle in the same way either, and the more experienced in the group advised that after 5–10 cases with the Exalt D single-use duodenoscope, they were no longer conscious of the difference.

It was observed that different centers may have different processing protocols and disinfection standards, and legal challenges were also discussed. Single-use technology may head off any legal challenges arising around reprocessing.

The group agreed that infection risk with duodenoscopes must be addressed in clinical practice. Since contamination was shown to occur in the duodenoscope channel as well as in the tip[26], single-use tips may not provide a full solution. A 'clean' device is also challenging to prove. All these factors point to a strong argument for eliminating infection risk by investing in single-use duodenoscopes.

Indications for the Exalt D Single-Use Duodenoscope

All centers face budget limitations, which may affect how often single-use duodenoscopes are deployed. However, the group felt there is a clear indication for their use in post-transplant patients, those with compromised immunity and/or known MDRO colonization.

In some private centers in the Middle East, patients have requested a duodenoscope solely for their use, and patient preference may become a strong driver for single-use devices.

There is a need for a convincing argument for reimbursing single-use devices. Currently under a procedure tariff system, the levels of funding are insufficient. In all cases, until appropriate guidelines are developed, there needs to be an individualized discussion with payers to argue the case for single-use devices by highlighting patients with comorbidities, cancer or undergoing multiple medical therapies.

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Expert Consensus

The experts agreed fully that the single-use device should be used after organ transplantation, in patients at high risk of transmission due to known MDRO colonization, and in those with the highest risk of infection, e.g. immunocompromised patients. Consensus was also strong that the evidence and experience from the Middle East region should be collated, and considered together with the identified indications for single-use duodenoscope deployment, to strengthen the case for reimbursement.

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Authors' Contributions

All authors contributed to the interpretation of findings and writing and reviewing of this manuscript. All authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility for the integrity of the work as a whole, and have given their approval for this version to be published.

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It is hard to argue against a single-use duodenoscope in the context of infection, which can be a human as well as a financial disaster

It was observed that different centers may have different processing protocols and disinfection standards, and legal challenges were also discussed. Single-use technology may head off any legal challenges arising around reprocessing

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IMPROVING INFECTION PREVENTION IN ENDOSCOPY AND THE ROLE OF SINGLE-USE TECHNOLOGIES

The Use of Single-Use Duodenoscopes in Endoscopy – a Current Perspective

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Key words

Single-use duodenoscopes, infection prevention, ERCP

There is currently no credible estimate of infection rate associated with endoscopic procedures

Introduction

Clinically relevant infections caused by the use of contaminated, flexible endoscopes have become the focus of clinical and scientific interest in the literature. In this regard, endoscopy-associated infections can be differentiated as (i) endogenous and (ii) exogenous infections. Endogenous infections are caused by the spread of the patient's own local flora and mainly involve *Escherichia coli, Klebsiella, Enterobacter* and *Enterococci* species. These infections can cause issues, such as pneumonia due to aspiration of secretions in sedated patients and the spread of microorganisms from the oral cavity during endoscopic procedures. Furthermore, cholangitis and bacteremia have been reported in patients with biliary obstruction after endoscopic retrograde cholangiopancreaticography (ERCP[1-3]. Although endogenous infections that are directly related to an endoscopic procedure can occur, they cannot be prevented by strictly controlled disinfection, sterilization or the use of disposable materials. In contrast, exogenous infections from consumables or endoscopes that are contaminated with microorganisms originating from other patients can be significantly reduced or even prevented by the highest hygienic standards as well as the use of single use endoscopes and consumables.

There is currently no credible estimate of infection rate associated with endoscopic procedures. Despite the very high number of flexible endoscopies worldwide, the published number of iatrogenic, endoscopy-associated infections is rather low. However, the actual transmission rate is vastly underestimated because of inadequate surveillance strategies and lack of clinical symptoms[4]. In the early 1990s, Gorse and Messner estimated an infection rate of 6% after gastrointestinal endoscopies[5]. Furthermore, in the period between 1974 and 2004, 30 infection outbreaks from flexible endoscopies involving a total of 251 patients were identified[6]. A recent meta-analysis by Kovaleva et al. showed that flexible bronchoscopy and ERCP confer the highest risk of exogenous infection[4]. The decisive factor that is emerging is the complex geometry of the aforementioned endoscopes with small working channels, particularly that of the distal end, resulting in a residual biofilm that favors further microbial growth even after proper high-level disinfection (HLD).

Hard costs comprise the cost of the SUD itself and the dedicated processor. Furthermore, costs for reprocessing equipment, cleaning solutions and repair have to be taken into account

A recent meta-analysis including 15 studies showed a contamination rate of duodenoscopes of 15.2% after adequate reprocessing. A subgroup analysis including only studies with HLD or sterilization demonstrated a residual contamination rate of 9.2%. However, the proportion of clinically relevant infections in these studies remained unclear[7]. In a prospective study in 73 ERCP centers, 155 duodenoscopes were tested for residual microorganisms after HLD. Contamination was defined as the detection of >20 colony forming units (CFU)/20ml of sample solution for all microorganisms or >1 CFU/20ml of sample solution for microorganisms originating from the oral cavity or the gastrointestinal tract. Despite adequate HLD, the authors found a contamination rate of reprocessed duodenoscopes of 15%[10]. Based on the published outbreaks of infection from Europe and the USA over the last five years, an infection rate of about 1.22% can be extrapolated, although the number of unreported cases is presumed to be high[7-11]. Based on these worrisome data and published case series, the FDA (Federal Drug Administration of the US) recommended in a recent safety warning (24.07.2020; https://fda.gov/medical-devices/safety-communications/fda-recommending-transition-duodenoscopes-innovative-designs-enhance-safety-fda-safety-communication) that "Hospitals and endoscopy facilities should transition to innovative duodenoscope designs that include disposable components such as disposable endcaps, or to fully disposable duodenoscopes when they become available.". Consequently, the world`s first single-use duodenoscope (SUD), Exalt Model D from Boston Scientific (Boston Scientific, Marlborough,, MA, USA) was licensed in December 2019 in the US and January 2020 in Europe. Irrespective of potential hygienic advantages of SUD, three topics need to be discussed to implement SUDs in clinical routine: clinical functionality, cost effectiveness and patient selection for an SUD.

Clinical Functionality of Single-Use Duodenoscopes

When using the SUD for the first time, the endoscope feels much lighter with ergonomics of the handle being similar to the standard reusable Olympus duodenoscopes that are widely available. Of note, the distal end of the scope does not straighten by itself after releasing the locks of the wheels. Therefore, the endoscopist has to actively straighten the scope before withdrawing it from the duodenum (personal experience).

In a first clinical multicenter trial with seven ERCP experts performing 60 ERCPs using the Exalt Model D, the ERCP was successfully completed in 96.7% of patients. The satisfaction score was rated 9/10 on average without additional adverse events being observed[12]. A prospective, randomized study evaluated the use of an SUD (EXALT Model D) in comparison to standard reusable duodenoscopes. In 98 cases (48 SUD), no significant differences in the advancement time to the Papilla vateri or in the successful cannulation of the target area were observed. However, the mean number of cannulation attempts was significantly lower with 6.7 attempts using a SUD compared to 12.7 with reprocessable duodenoscopes, which resulted in a significantly shorter time to successful cannulation. The authors characterized disposable duodenoscopes as offering a more favorable anatomical position in front of the papilla vateri with the EXALT Model D[13]. However, a final evaluation cannot yet be made because of the small number of cases. Clinical functionality was confirmed in a multicenter European study in 60 patients undergoing ERCP with an SUD. A technical success rate of 95% with a median operators' satisfaction rating of 9 (range 7–9) was observed[14].

Cost Assessment of Single-Use Endoscopes

To assess total costs of SUDs, two groups of cost have to be evaluated: (i) hard costs and (ii) soft costs. Hard costs comprise the cost of the SUD itself and the dedicated processor. Furthermore, costs for reprocessing equipment, cleaning solutions and repair have to be taken into account. Soft costs primarily occur during the use of reusable duodenoscopes, including personnel for reprocessing, costs of endoscopy associated infections (prolonged hospital or ICU stay) and costs for surveillance programs (culturing, scope quarantine, sterilization).

In a theoretical cost calculation model by Bang et al., cost effectiveness of SUD was assessed. They showed that the overall cost per ERCP directly depended on the annual volume of ERCPs per center and the respective infection rates[15]. Given an infection rate of 1%–1.2%, total costs of an ERCP in a high volume center (>350 ERCP/year) ranged from $1,110–$1,338, whereas in low volume centers (<350 ERCP/year), ERCP costs were $1,220–$2,68516. In cases where SUD is not additionally reimbursed, the cut-off for cost-effectiveness is not currently met.

Due to the differences in international health care systems, reimbursement strategies for ERCP and SUD cannot be directly compared and need to be evaluated in further detail from a national perspective. In the US, 100% of the SUD costs are reimbursed in an outpatient setting by a transitional pass-through payment (TPT). In Germany, the situation is completely different and is based on the DRG system (diagnosis related groups), where hospitals receive a fixed reimbursement depending on the level of clinical complexity of the procedure independently of the costs of the deployed consumables. So far, only an additional procedure code for SUD has been established, which currently does not result in an additional reimbursement.

Patient Selection for Single-Use Duodenoscopes

Based on the authors' experience and recently supported by a publication by Gromski et al., three tiers for patient selection for SUD can be defined[17]: recommend the use of SUD, consider the use of SUD and do not recommend the use of SUD.

1. Recommend the use of SUD:
In this group, patients colonized with multi-drug resistant organisms (MDRO) or at risk of MDRO including those with (i) prior carbapenum-resistant Enterobacteriaceae (CRE) infection anywhere; (ii) prior multi-drug resistant infection with bile e.g. CRE, vancomycin-resistant Enterobacteriaceae (VRE), extended spectrum beta-lactamase-producing bacteria or (iii) high risk of recurrent cholangitis, e.g. primary sclerosing cholangitis (PSE), hilar malignancies with recurrent cholangitis or incomplete drainage of high grade strictures.
2. Consider the use of SUD
The second group consists of proven or potentially immunocompromised patients including (i) patients on immunosuppressive medication, e.g. those with liver transplant, PSC with ulcerative colitis or on biological therapy in general; (ii) patients with malignancies undergoing chemotherapy or (iii) patients with special circumstances of immune suppression, e.g. those with HIV infection, neutropenia or bone marrow transplantation.
3. Do not recommend the use of SUD
In all patients that do not belong to group 1 or 2, the use of SUD is not recommended. Furthermore, the use of SUD in weekend procedures and in low-volume centers should be discussed on an individual basis[19].

Conclusion

SUDs are, by definition, always sterile, which eliminates the risk of contamination due to ineffective reprocessing, minimizes the risk of infection with exogenous pathogens and thus contributes to improving patient safety in flexible endoscopy. Assuming that supply chains from manufacturers to the end users reliably function, disposable endoscopes are always available. Thus, depending on the structure of the endoscopy unit, the use of disposable endoscopes frees up considerable staff resources because of elimination of reprocessing. These staff members are available for the core activity of direct patient care and assistance, which contributes to optimizing process quality.

The additional costs of consumables for disposable endoscopes are seen as a significant disadvantage, especially with the currently varying reimbursement systems. Moreover, the use of additional consumables produces a significant amount of additional contaminated hospital waste. Optimization of the recycling of this waste must be established to ensure sustainability. Focusing on the economic burden of SUD, the total costs of SUD is "optimized" by including the costs of clinically relevant infections. However, the threshold for cost neutrality has not yet been reached for the majority of hospitals. When it comes to the question of "paying it off", economic factors alone do not make up the total bill. Rather, the maximum safety and well-being of our patients should be at the center of our medical and ethical interest.

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Hospitals and endoscopy facilities should transition to innovative duodenoscope designs that include disposable components such as disposable endcaps, or to fully disposable duodenoscopes when they become available

Advantages, Environmental Impact and Sustainability of Single-Use Endoscopes

Michael A James, PhD

Interest in the use of disposable, single-use endoscopes has grown because of evident risk of nosocomial infection from reusable endoscopes. While reusable endoscopes are most commonly used, single-use products have been gaining traction since the 1970s. Single-use duodenoscopes (Figure 1) were FDA-cleared for clinical use in 2019. In addition to reduction in risk of infection, elimination of downtime due to reprocessing of reusable endoscopes, decreased requirements for staffing, training and consumables for reprocessing, immediate availability and quality of function are attractive aspects of single-use endoscopes. Even given these attractors to the use of disposable endoscopes, significant thought is required regarding their environmental and economic sustainability.

Figure 1. Example of a single-use, disposable duodenoscope. Source: Boston Scientific

Advantages

Risk of infection from endoscopic devices continues to be prevalent, particularly from duodenoscopes during endoscopic retrograde cholangiopancreatography (ERCP). This is evidenced by a large number of published studies highlighting outbreaks of multidrug-resistant *Klebsiella pneumoniae, Escherichia coli* and *Pseudomonas aeruginosa* infections from duodenoscopy since 2014[1]. A recent study of ERCP in the Netherlands involving 73 endoscopy centers showed that 22% of patient-ready duodenoscopes were contaminated with bacteria, 15% with microorganisms of gastrointestinal origin[2]. It is estimated that there are 670,000 infections with drug-resistant bacteria resulting in 33,000 deaths annually in Europe[3]. Since disposable, single-use duodenoscopes are sterile, it can be assumed that risk of infection due to contamination is eliminated with their use instead of reusable endoscopes. In addition to mitigating risk of nosocomial spread of multidrug-resistant organisms, single-use endoscopes may reduce risk of disease transmission and complication in high-risk patients, such as the immunocompromised and COVID-19-positive patients.

Since turnover time, efficiency, availability and waiting periods for endoscopy procedures are a significant problem for patients, and enhanced sterilization technique recommendations post-COVID-19 have increased reprocessing burden, eliminating reprocessing downtime is a clear advantage of single-use endoscopes. A systematic review of 22 studies across gastrointestinal (GI), urologic and respiratory procedures determined that disposable sheath endoscopes resulted in faster turnover times than reusable components since high-level disinfection (HLD) or sterilization was not required[4].

Performance Comparison

Both disposable distal endcaps and disposable duodenoscopes have comparable or superior specifications to reusable endoscopes including field-of-view, diameter, bending angles and working length[5]. Complementary metal oxide semiconductor (CMOS) imaging has become

Multiple studies have demonstrated ≥ 95% success rates with single-use duodenoscopy for ERCP, and one reported equivalent time requirements and satisfaction ratings regardless of level of expertise of the operator

relatively inexpensive and improved greatly in terms of resolution in recent decades. Combined with LED lighting, these sensors, employed in single-use endoscopes, provide clear imaging at high resolution.

A single-use duodenoscope for ERCP was found to achieve comparable completion times and comparable performance ratings for overall performance, tip control and image quality versus reusable duodenoscopes[6]. Navigation/pushability was rated slightly lower for the single-use endoscope. Another clinical study found similar overall safety and technical performance and decreased attempts required for successful cannulation with single-use duodenoscopes compared to reusable endoscopes[7]. However, ease of passage into the stomach, image stability and quality and air-water button functionality were inferior. Multiple studies have demonstrated ≥ 95% success rates with single-use duodenoscopy for ERCP[7-10], and one reported equivalent time requirements and satisfaction ratings regardless of level of expertise of the operator[9]. Continued innovation in imaging and functionality has and will continue to improve visualization using single-use endoscopes. This is true for bronchoscopy as well, which requires clear imaging of lungs and small airways. Several late-generation bronchoscopes feature improved degree of angulation and image quality to overcome these limitations[11].

The impact of endoscopy on the environment and climate change is significant. The environmental impact of single-use endoscopes is equivocal in some cases, but depends on the balance of increased manufacturing impact versus decreased impact of reprocessing procedures

Environmental Impact

Reducing or eliminating healthcare-acquired infections (HAIs) is a major benefit of single-use endoscopy; however, potential differences in the impact of these procedure on the environment compared to reusable endoscopy should be considered. The World Gastroenterology Organization's Climate Change Working Group has expressed trepidations about the impact of endoscopy on the environment and set a goal of further assessing the impact of reusable endoscopes[12]. While disposable endoscopes themselves create consumable waste, this burden is partially mitigated by a decrease in waste from disinfecting consumables needed for the reprocessing of reusable endoscopes. Some studies suggest that full transition to single-use endoscopes would increase net waste[13], while others indicate that it would result in a lower carbon footprint[14]. The overall carbon footprint of current endoscopy practice in the US has been estimated to be 86,000 tons of CO_2 equivalents[15]. A study comparing total lifetime carbon emissions reported 4.43 kg of CO_2 equivalent per case with single-use ureteroscopy and 4.47 kg per case with reusable uteroscopy[14]. However, another study indicated a significantly higher carbon footprint of a single-use duodenoscope compared to reusable duodenoscopes, mostly attributable to manufacturing[16]. Manufacturers are taking steps to improve that impact though transition to renewable energy recycling solutions and goals for carbon neutral manufacturing and net-zero emissions[17].

Economic Sustainability

Enhanced reprocessing and surveillance practices for duodenoscopes significantly increases reprocessing costs. Doubling HLD procedures increased costs by 47% as reported by a recent US study in 2 high-volume institutions[18]. In this study, ethylene oxide sterilization increased cost by 270%, and the surveillance practice of culture and quarantine increased cost by 160%. These increases translated into an additional annual cost of $406,000 for high-volume centers a necessitated a 3.4-fold increase in the number of endoscopes.

There is also the economic impact of HAIs to consider. US data estimates the HAI-related death of 90,000 hospitalized patients yearly with an estimated cost of HAIs of $28–$45 billion[19]. An analysis of ERCP cases in US institutions estimated a cost per procedure of $612–$1362 with reusable duodenoscopes including the cost of procedure-related infection at a rate of 0.4–1.0%[20]. While the upfront cost of disposable endoscopes was higher, depending on the volume of procedure performed at the institution, the price per single-use procedure was reduced to $112 without the cost of procedure-related HAIs.

Since high-volume endoscopy centers can distribute the cost of investment in equipment, maintenance and treatment of infection, they have a lower break-even price per procedure as opposed to small-volume centers, whose capital investment per case is higher[20]. For this reason, the use of disposable, single-use endoscopes may be most economically viable in centers with smaller procedure volumes. The insurer Medicare has created new ICD-10-PCS procedure codes and approved applications for New Technology Add-on Payments and Transitional Pass-through Payments for single-use duodenoscopes making 40% of ECRPs in the US eligible for device reimbursement[21].

Conclusion

The major advantages of single-use endoscopes are reduction or elimination of endoscopy-related infections and elimination of downtime and resources required for reprocessing reusable endoscopes. The impact of endoscopy on the environment and climate change is significant. The environmental impact of single-use endoscopes is equivocal in some cases, but depends on the balance of increased manufacturing impact versus decreased impact of reprocessing procedures. Improvements in manufacturing impact are ongoing. Accessing the economic sustainability of single-use endoscopes is complex; however, considering the cost of HAIs, single-use endoscopes may present an economically viable technology, particularly for low-volume or high-risk-case use.

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Future Outlook: Emerging Trends and Technologies in Endoscopy

Michael A James, PhD

New Procedures and Training

Continuingly evolving endoscopy technologies are improving procedural safety and broadening the diagnostic and interventional repertoire of the field, but also bringing increasing complexity and training demands. While training programs previously focused on endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic ultrasound (EUS), education and training now needs to include stenting, ablation procedures, third space endoscopy and endoscopic bariatric therapy (EBT). Regulation of training through accredited programs and assessment of competence are yet to catch up to increased training complexity and demand. This increased complexity and demand have led to a focus on competency-based assessment rather than that which is based on the number of training procedures accomplished[1,2].

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Several advanced procedures that have recently been more broadly implemented contribute to increasing complexity and training demands in endoscopy. Submucosal endoscopy, or third-space endoscopy, involves access to deeper gastrointestinal tract layers in the submucosal space. These include endoscopic submucosal dissection (ESD) and peroral endoscopic myotomy (POEM). ESD has the advantage over mucosal dissection in that en block lesion resection is possible, making large lesions resectable and decreasing the risk of recurrence locally[3]. With extensive training required and risk of serious complications, ESD expertise and training have not been sufficient in Western countries as opposed to Japan, which has enjoyed specialized training and success in terms of safety and efficacy[2]. The European Society of Gastrointestinal Endoscopy (ESGE) has accordingly introduced recommendations for training in ESD requiring expert supervision and structured fellowships[4]. Training requires a priori proficiency in endoscopic classification and lesion characterization and skill in hemostasis, adverse event management, resection and injection. POEM is a technique that provides a minimally invasive procedure for managing motility disorders of the esophagus with superior outcomes and safety compared to surgery[5]. These disorders include esophageal achalasia and esophageal motility disorders. A paucity of clinical data and small sample sizes have limited the establishment of recommendations for these procedures[6]. POEM is another complex procedure requiring considerable skill. Finally, EBT is emerging as an adjunctive therapy for obesity, such as sleeve gastrectomy, and bariatric surgery-related adverse events. With a variety of EBT procedures, complexity and training requirements also vary. Those with greater complexity will require supervision and training programs that are structured for rigor.

Advancements in Wireless Capsules

Wireless capsules have been used for small bowel endoscopy since 2001 and since expanded to colon and esophagus endoscopy. Capsules have been instrumental in managing gastrointestinal bleeding, Crohn's disease, polyposis and celiac disease[7]. Limitations of these newer applications in the esophagus, stomach and large bowel stem from the increased surface area and volume of these spaces[8]. Capsule endoscopy (CE) has limited utility for identifying gastric lesions for similar reasons. However, advancements have been made in attempt to overcome these limitations in the form of locomotion systems, air insufflation techniques, improved imaging technologies and AI-assisted image interpretation. Reduced cost and improved technological advancements present the potential for broader application of CE to the gastrointestinal tract.

Despite recent improvements in imaging resolution and field-of-view, identification of disease using CE remains challenging. Imaging algorithms, adoptive frame rate and suspected blood indicators have somewhat improved interpretation; however, these improvements have been incremental with modest or insignificant improvement in diagnostic interpretation and misidentification[7]. Recently, the use of artificial intelligence for the interpretation of CE imaging has been a subject of interest and technologic development to overcome limitations in human detection and diagnosis. Terms used for AI in CE have included computer-aided detection (CADe) and computer-aided diagnosis (CADx). AI has been investigated for use in polyp identification, optical biopsy and inspection of the colonic mucosa[9]. Since colon polyps can be difficult to identify, CADe has been applied to their detection. Initial studies of this application demonstrated a detection rate of 97.7% of polyps, although false positives were common (36 per colonoscopy)[10]. Optical biopsy allows the diagnosis of adenomas among polyps without pathologic review, which is useful given that small polyps are unlikely to exhibit invasive or advanced histology[9]. Dependence on the expertise of operators has led to the application of CADx to optical biopsy, employing magnifying and non-magnifying narrow band imaging, laser-induced fluorescence spectroscopy and endocytoscopy[9] (Figure 1). The accuracy of specific computer-aided magnifying narrow band imaging, endocytoscopy and laser-induced fluorescence spectroscopy technologies have been quantified at 93%, 90% and 85%, respectively[11-13]. These AI technologies are burgeoning and promise to improve the diagnostic yield of CE.

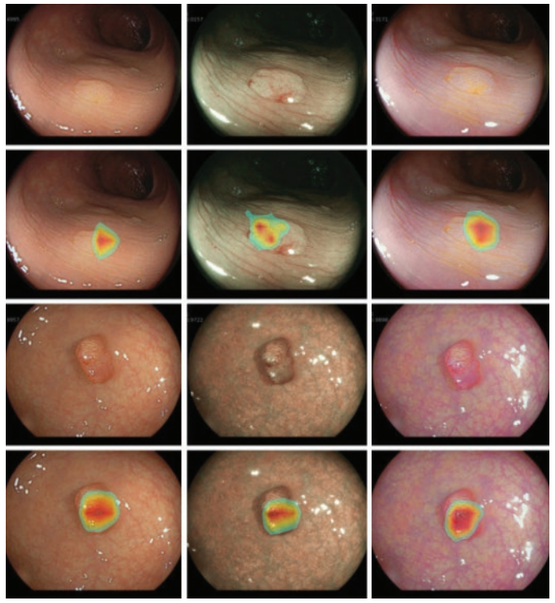

Figure 1. Output from CADx identification of pre-malignant components of colorectal polyps. Benign-green, pre-malignant-red. Fonollà, R.; E. W. van der Zander, Q.; Schreuder, R.M.; Masclee, A.A.M.; Schoon, E.J.; van der Sommen, F.; de With, P.H.N. A CNN CADx System for Multimodal Classification of Colorectal Polyps Combining WL, BLI, and LCI Modalities. Appl. Sci. 2020, 10, 5040. https://doi.org/10.3390/app10155040 https://creativecommons.org/licenses/by/4.0/

Imaging Technologies

In addition to AI technologies, which can be applied to both CE and traditional endoscopy, several advancements in imaging have been made to improve detection and diagnosis. Hypoxia imaging using oxygen-sensitive fluorescent stains have been applied to the detection of neoplasias in the pharynx, esophagus and colon and of inflammatory bowel disease[14]. In cases of the above malignancies, hypoxia imaging was able to detect significant changes in oxygen saturation mapping of neoplastic versus non neoplastic tissues[15]. In inflammatory bowel disease, hypoxia of the intestinal epithelium is increased, making its detection using hypoxia imaging plausible[14]. This application requires further research. Three-dimensional imaging, which combines optical axes to create depth is an older technology that has expanded in application to endoscopy. A study of detection of non-polypoid lesion indicated a 25% increase in trainee detection in simulations over detection using two-dimensional images[16].

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The most prominent technological imaging advancement in recent years has been AI-assisted visual sensing, as described in the context of CE above. This technology also applies to other endoscopic techniques, including duodenoscopy for gallbladder stones[17]. In a recent clinical study, AI-assisted duodenoscopic imaging of gallbladder stones using a convolutional neural network resulted in 95% precision and less procedural, recovery and hospital time[17]. Further, bleeding and residual stones were greatly decreased.

ERCP/Duodenoscopy Advancements

The long established role for ERCP in diagnostic procedures has expanded to interventions over time. A common example is biliary obstruction management. ERCP can be used to place stents for strictures and radiofrequency ablation for hilar structures. Improvements in duodenoscopy,

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in addition to the applicable imaging and AI integrations, as discussed above, have included robotic manipulation. For example, a flexible mechanical robotic system for coaxial catheter intervention using cholangiopancreatography was recently described with demonstrated feasibility in models[18]. Given better outcomes in modern duodenoscopy, there has also been a trend in outpatient ERCP, previously predominantly done in an inpatient setting[19].

The main focus of advancements in duodenoscopy and ERCP in recent years has been in infection prevention. The insurgence of multidrug-resistant organism infections related to duodenoscopy has largely driven this focus. While such infections are not considered common, they are of considerable public health concern, and rates contamination with MDROs on endoscopes are surprisingly high[20]. Solutions to this problem that have been put forth include more rigorous reprocessing training and assessment, further research into ERCP-associated infection risk and epidemiology, mandatory inspection and servicing of duodenoscopes and novel technologies, including sterilizable duodenoscopes, disposable scope components and single-use disposable duodenoscopes[20]. Single-use scopes have been demonstrated to be tantamount to reusable scopes without the risk of transmission of infectious disease between patients[21].

Conclusion

The clinical utility of endoscopy has greatly broadened in recent years while simultaneously becoming safer. Better technology, techniques, imaging and computer-assisted interpretation have resulted in shorter, safer procedures that can more commonly be done in outpatient setting. These advancements have also improved both disease-specific and adverse-event related outcomes. With the use of algorithms to more reliable identify disease and robotics for more precise manipulation, there is promise for continued improvement in outcomes. With increasing procedure complexity, the risk of infection may increase, making the prevention of infection particularly timely with the development of advanced techniques. With safety as a priority, duodenoscope technologies are also now addressing the significant concern of healthcare acquired infection. Such technological advancements are certain to result in more well-equipped clinicians and increased wellness for patients.

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IMPROVING INFECTION PREVENTION IN ENDOSCOPY AND THE ROLE OF SINGLE-USE TECHNOLOGIES

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