EVIDENCE DOSSIER

Ambu® aScope™ Duodeno

Ambu

April 2021, 2nd edition

This document includes published peer-reviewed studies on contaminated duodenoscopes infectious outbreaks, clinical performance and health economics.

All studies support claims related to the Ambu® aScope™ Duodeno single-use duodenoscope.

CONTENTS

ABBREVIATIONS

AER: automatic endoscope reprocessor

AK-Pae: amikacin-resistant P. aeruginosa isolates

AM20: any microorganism with >20 CFU/20 mL

ATP: adenosine triphosphate

CDC: Centers for Disease Control and Prevention

CFU: colony-forming units

CRE: Carbapenem-resistant Enterobacteriaceae

dHLD: double high-level disinfection

DLEs: duodenoscopes and linear echoendoscopes

E. coli: escherichia coli

ERCP: endoscopic retrograde cholangiopancreatography

EtO: ethylene oxide

FDA: Food & Drug Administration

HLD: high-level disinfection

K. pneumoniae: Klebsiella pneumoniae

LCS: liquid chemical sterilization

MDRO: multidrug-resistant organisms

MGO: microorganisms with gastrointestinal or oral origin, independent of CFU count

P. aeruginosa: Pseudomonas aeruginosa

RCT: randomized controlled trial

sHLD: single high-level disinfection

PREFACE

This dossier will help you get an overview of the evidence landscape related to Ambu® aScope™ Duodeno, a single-use duodenoscope. The introduction summarizes the Safety Communications FDA has issued regarding the risks of patient cross-contamination inherent to reusable duodenoscopes. The main section is comprised of all studies published from January 2010 to March 2021 related to contamination, infectious outbreaks, clinical performance, and health economics aspects of reusable duodenoscopes, duodenoscopes with disposable components and single-use duodenoscopes. The last section offers an introduction to the benefits of aScope Duodeno.

Should you wish to discuss any publication in this dossier in more detail, do not hesitate to drop an inquiry to Associate Health Economist, David Hoffman (dhof@ambu.com).

In an effort to include all known data irrespective of the outcome, a systematic literature search was conducted for this dossier, giving the reader every opportunity to obtain a balanced overview of the clinical data. The study titles are taken from the publications as they appear in their original form, allowing the reader to make a perfectly accurate internet search should they wish to find out more.

We hope this evidence dossier provides you with an understanding of the overall clinical landscape concerning aScope Duodeno and assists you in your day-to-day evidence-based practice.

While every effort has been made to provide accurate information, we will be pleased to correct any errors or omissions brought to our notice in following editions.

A HISTORY OF BREAKTHROUGH IDEAS

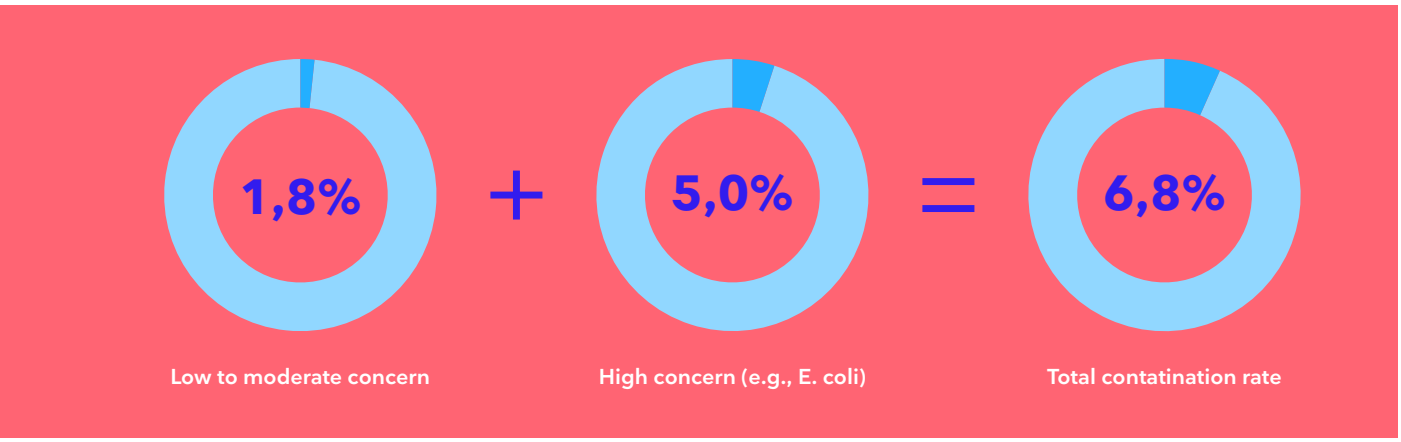
Ambu has been bringing the solutions of the future to life since 1937. Today, millions of patients and healthcare professionals worldwide depend on the efficiency, safety and performance of our single-use endoscopy, anesthesia, and patient monitoring & diagnostics solutions. The manifestations of our efforts have ranged from early innovations like the Ambu® Bag™ resuscitator and the Ambu® BlueSensor™ electrodes to our newest landmark solutions like Ambu® aScope™ – the world's first single-use flexible endoscope. Moreover, we continuously look to the future with a commitment to deliver innovative quality products, like Ambu® aScope™ Duodeno, which have a positive impact on your work. As the world's leading supplier of single-use endoscopes, Ambu leads by example offering a service to help you dispose of our duodenoscopes in the most cost-effective, risk-free and eco-friendly way possible.

Headquartered near Copenhagen, Denmark, Ambu employs approximately 4,000 people in Europe, North America and the Asia Pacific region.

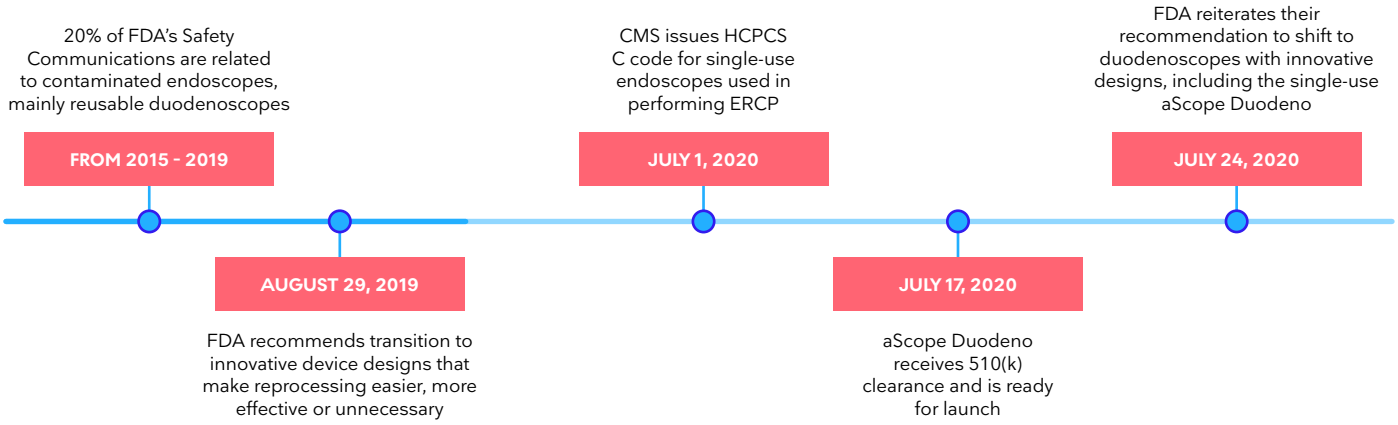
For more information, please visit ambu.com

FDA SAFETY COMMUNICATIONS

Multiple outbreaks have been reported across Europe, due to contaminated duodenoscopes leading to patient cross-infection. The majority of the reported outbreaks have been caused by multidrug-resistant organisms (MDROs). The number of infected patients is likely to be highly underestimated, since only reported outbreaks are captured. This reported incidence is therefore only the tip of the iceberg.



In recent years, FDA has continuously posted Safety Communications related to reusable endoscopes and potentially compromised patient safety.



UPDATED SAFETY COMMUNICATION, JULY 24, 2020

Important recommendations for hospitals and endoscopy facilities:

- Consider using duodenoscopes that have disposable components, if available at your facility; this design may lower but not eliminate risks of infection. When you do use them, carefully follow the manufacturer's instructions for the assembly of the caps and distal ends.
- Ensure staff are meticulously following reprocessing instructions.
- Institute a quality control program that includes sampling and microbiological culturing, and other monitoring methods.
- Consider including a sterilization step in reprocessing, in accordance with the manufacturer's instruction for use.
- Monitor your reprocessing procedures.
- Develop schedules for routine inspection and periodic maintenance in accordance with the duodenoscope manufacturer's instructions.

Read the full communication.

> **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.**
>
> *FDA*

SUPPORTING EVIDENCE-BASED PRACTICE WITH BEST AVAILABLE EVIDENCE

Evidence-based decision making is key when purchasing new devices. The core principle of evidence-based practice is the hierarchy of evidence, which identifies the best available evidence for a given clinical question. This document will not go into depth with the different levels of evidence, but instead provide an easy overview that indicates the quality of the respective study based on the system below.

Studies rated as "low quality of evidence" include conference abstracts, editorials, commentaries, and case reports. Studies rated as "medium quality of evidence" include descriptive studies, cohort studies, case-controls, and meta-analyses based on non-RCT studies. Lastly, studies rated as "high quality of evidence" include RCT-studies and meta-analyses based on RCT studies.

LOW QUALITY OF EVIDENCE

MEDIUM QUALITY OF EVIDENCE

HIGH QUALITY OF EVIDENCE

HOW WERE THE STUDIES IN THIS DOSSIER SELECTED?

Three major scientific online databases, Pubmed (MEDLINE), Embase, and Web of Science were searched for all relevant articles up to March 1, 2021. Articles published in the English language within the areas of infection control, performance, and health economics were included. Commentaries, letters to editor, book chapters, and publications with no clinical or economical relevance were excluded. This document only includes studies published after 2015 in order to provide the reader with the most up to date studies.

This Evidence Dossier includes summaries of 20 published peer-reviewed studies related to duodenoscopes and endoscopic retrograde cholangiopancreatography (ERCP) procedures.

PEER-REVIEWED STUDIES

Contaminated duodenoscopes

★★★ Infection Control Open access

Randomized Comparison of 3 High-Level Disinfection and Sterilization Procedures for Duodenoscopes, Gastroenterology[1]

Snyder et al., 2017

STUDY AIM

This single-center randomized study compared the frequency of duodenoscope contamination with multidrug-resistant organisms (MDRO) or any other bacteria after disinfection or sterilization by three different methods.

METHODS

- The study investigated duodenoscopes that were randomly reprocessed by single high-level disinfection (sHLD), double high-level disinfection (dHLD), or sHLD followed by ethylene oxide gas sterilization (sHLD/EtO).
- Samples were collected from the elevator mechanism and working channel of each duodenoscope and cultured before use.
- The primary outcome was the proportion of duodenoscopes with an elevator mechanism or working channel culture showing one or more MDRO.
- Secondary outcomes included the frequency of duodenoscope contamination with more than 0 and 10 or more colony-forming units (CFU) of aerobic bacterial growth on either sampling location.

TAKE AWAY

Enhanced disinfection methods (dHLD or HLD/EtO) did not provide additional protection against contamination. Bacterial growth of more than 0 CFU was noted in 16.1% duodenoscopes in the sHLD group, 16.0% in the dHLD group, and 22.5% in the HLD/EtO group

KEY FINDINGS

- **A total of 516 duodenoscope culture events were included in the final analysis.**
- **Bacterial growth of more than 0 CFU was noted in 16.1% duodenoscopes in the sHLD group, 16.0% in the dHLD group, and 22.5% in the HLD/EtO group (p = 0.21).**
- **Bacterial growth of 10 or more CFU was noted in 2.3% of duodenoscopes in the sHLD group, 4.1% in the dHLD group, and 4.2% in the HLD/EtO group (p = 0.36).**
- **Two endoscopes grew intestinal flora on several occasions despite multiple HLD. No multidrug-resistant organism was detected.**

Bacterial growth of more than 0 CFU was noted in:

16.1% of duodenoscopes in the sHLD group

16.0% in the dHLD group

22.5% in the sHLD/EtO group

★★★ Infection Control Not open access

TAKE AWAY

Double HLD and liquid chemical sterilization (LCS) both resulted in a low rate of positive cultures, for all organisms and for high-concern organisms. However, neither process completely eliminated positive cultures from duodenoscopes reprocessed with two different supplemental reprocessing strategies.

KEY FINDINGS

- **During the study period, there were 878 post-reprocessing surveillance cultures (453 in the dHLD group and 425 in the LCS group).**
- **1.9% were positive for any organism. Both groups (dHLD vs. LCS) had two cultures that grew high-concern organisms**
- **There was no significant difference of positive cultures when comparing the duodenoscopes undergoing dHLD (8 positive cultures, 1.8%) with duodenoscopes undergoing LCS (9 positive cultures, 2.1%; p=0.8).**
- **Both groups had two cultures that grew high-concern organisms.**
- **No multidrug-resistant organisms, including carbapenem-resistant Enterobacteriaceae, were detected.**

Double high-level disinfection versus liquid chemical sterilization for reprocessing of duodenoscopes used for ERCP: a prospective randomized study, GIE[2]

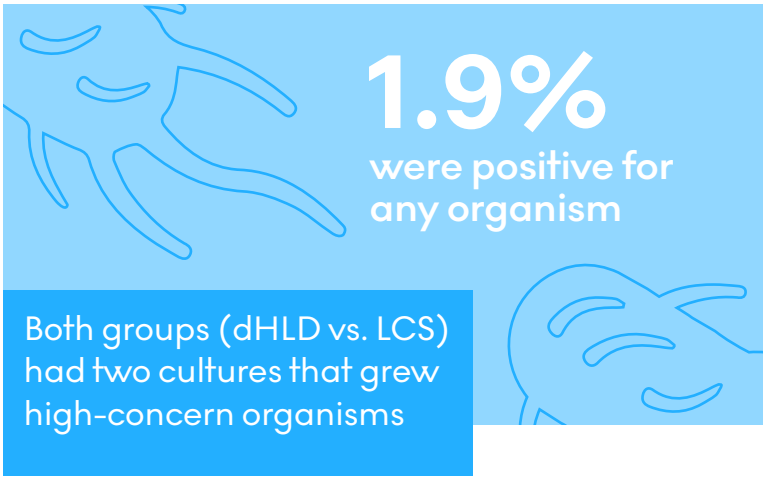
Gromski et al., 2020

STUDY AIM

The potential for transmission of pathogenic organisms is a problem inherent to the current reusable duodenoscope design. Recent outbreaks of multidrug-resistant pathogenic organisms transmitted via duodenoscopes has brought to light the urgency of this problem. Microbiologic culturing of duodenoscopes and reprocessing with repeat high-level disinfection (HLD) or liquid chemical sterilization (LCS) have been offered as supplemental measures to enhance duodenoscope reprocessing by the FDA. This study aimed to compare the efficacy of reprocessing duodenoscopes with double HLD (dHLD) versus LCS.

METHODS

- Two different modalities of duodenoscope reprocessing was prospectively evaluated from October 23, 2017 to September 24, 2018.
- Eligible duodenoscopes were randomly segregated to be reprocessed by either dHLD or LCS.
- Duodenoscopes were randomly cultured after reprocessing for surveillance based on an internal protocol.



★★☆ Infection Control Open access

TAKE AWAY

Duodenoscope and linear echoendoscope contamination was independent of age and usage. These results suggest that old and heavily used endoscopes, if maintained correctly, have a similar risk for contamination to new ones. The MGO contamination prevalence of ~15% was similarly high for duodenoscopes and linear echoendoscopes, rendering both patients undergoing ERCP as well as endoscopic ultrasound at risk for transmission of microorganisms.

KEY FINDINGS

- **Of all Dutch centers 97% participated in one of the studies, sampling 309 duodenoscopes and 64 linear echoendoscopes.**
- **In total, 54 (17%) duodenoscopes and 8 (13%) linear echoendoscopes were contaminated according to the AM20 definition.**
- **MGO were detected on 47 (15%) duodenoscopes and 9 (14%) linear echoendoscopes.**
- **Contamination was not age or usage-dependent, nor was it shown to differ between the reprocessing characteristics.**

Nationwide risk analysis of duodenoscope and linear echoendoscope contamination, GIE[3]

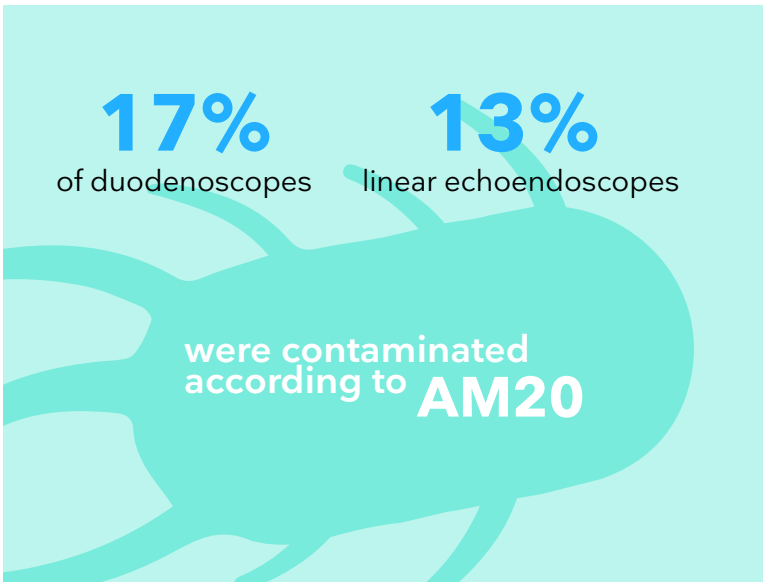
Rauwers et al., 2020

STUDY AIM

Contaminated duodenoscopes and linear echoendoscopes (DLEs) pose a risk for infectious outbreaks. To identify DLE and reprocessing risk factors, the nationwide study combined the data of the previously published nationwide cross-sectional study (PROCESS 1) with the follow-up study (PROCESS 2).

METHODS

- The investigators invited 74 Dutch DLE centers to sample >2 duodenoscopes during PROCESS 1, and all duodenoscopes as well as linear echoendoscopes during PROCESS 2. The studies took place one year after another.
- Local staff sampled each at DLE >6 sites according to uniform methods explained by online videos.
- **The study used two contamination definitions:**
  - AM20: any microorganism with >20 colony-forming units (CFU)/20 mL
  - MGO: presence of microorganisms with gastrointestinal or oral origin, independent of CFU count.



[1]Rauwers AW, Voor in 't holt AF, Buijs JG, et al., High prevalence rate of digestive tract bacteria in duodenoscopes: a nationwide study; Gut 2018;67:1637-1645.

★★☆ Infection Control Not open access

TAKE AWAY

dHLD did not eliminate pathogens from duodenoscope elevators. dHLD was associated with positive elevator cultures for any microorganism in 9.4% of cases. Investigators emphasize that additional improvements in HLD protocols and/or duodenoscope design are needed.

KEY FINDINGS

- **dHLD was associated with positive elevator cultures for any microorganism in 9.4 % of cases between May 2015 and February 2016.**
- **After February 2016, and in association with changing the precleaning fluid, as well as use of a new FDA-recommended cleaning brush, the rate of positive cultures for any microorganism after dHLD was 4.8 %.**
- **In a third phase, characterized by a change in personnel performing dHLD and retirement of a duodenoscope with a high rate of positive cultures, the rate of positive cultures for any microorganism was 4.9 %.**
- **To the best of the investigators' knowledge, no duodenoscope transmission of infection occurred during the study interval.**

A double-reprocessing high-level disinfection protocol does not eliminate positive cultures from the elevators of duodenoscopes, Endoscopy[4]

Rex et al., 2018

STUDY AIM

This randomized study aimed to observe the impact of performing HLD twice on the rate of positive cultures from duodenoscope elevators.

METHODS

Investigators performed double HLD (dHLD i.e., complete manual cleaning followed by automated reprocessing, with the entire process repeated) and then randomly cultured the elevators of the duodenoscopes on about 30 % of occasions.

★★☆ Infection Control Open access

TAKE AWAY

Withdrawal of duodenoscopes with a high rate of culture positivity and optimizing manual cleaning practices have contributed to an overall decline in the high-level disinfection defect rate. A stringent culture and quarantine protocol enabled identification of the culprit endoscopes.

KEY FINDINGS

- **A total of 4,307 duodenoscope cultures were obtained during the study period. High-concern organisms were isolated from 33 of these cultures, resulting in a 0.697% high-level disinfection defect rate.**
- **Statistically significant interventions included withdrawal of a high-frequency culture-positive duodenoscope from clinical service in addition to implementation of new manufacturer-recommended cleaning protocols.**
- **Withdrawal of a second high-frequency culture-positive duodenoscope and a mandatory device retrofit had no effect on the observed rate of positive duodenoscope cultures**

Optimizing duodenoscope reprocessing: rigorous assessment of a culture and quarantine protocol, Clinical Endoscopy[5]

Higa et al., 2018

STUDY AIM

This randomized study assessed the long-term results and impact of key interventions in the optimization of a rigorous "culture and quarantine" program for duodenoscope reprocessing.

METHODS

- Investigators reviewed a prospectively collected, quality assurance database of all duodenoscope cultures (n = 4,307) obtained for the initial 3-year duration of culture and quarantine from 2014 to 2017 in a single U.S.-based, high-volume endoscopy center.
- All duodenoscopes were subject to manual cleaning and automated reprocessing and drying, followed by sampling using a modified protocol developed by the Centers for Disease Control and Prevention (CDC).

4,307
duodenoscopes cultures were obtained during the study period

High-concern organisms were isolated from 33 of these cultures

0.69%
high-level disinfection defect rate

★★☆ Infection Control Not open access

TAKE AWAY

In 39% of all Dutch ERCP centers, at least one AM20-contaminated duodenoscope that was considered patient-ready was identified. A total of 15% of the duodenoscopes harbored MGO, indicating residual organic material of previous patients. These results suggest that the present reprocessing and process control procedures are not adequate and safe.

KEY FINDINGS

- **Sampling:**

67 out of 73 centers (92%) took 745samples from 155 duodenoscopes.

- **Duodenoscope types:**

10 different duodenoscope types from three distinct manufacturers were sampled, including 69 (46%) Olympus TJF-Q180V, 43 (29%) Olympus TJF-160VR, 11 (7%) Pentax ED34-i10T, 8 (5%) Pentax ED-3490TK and 5 (3%) Fujifilm ED-530XT8.

- **Contamination:**

33 (22%) duodenoscopes from 26 (39%) centres were contaminated (AM20).

- **Types of contamination:**

On 23 (15%) duodenoscopes, MGO were detected, including Enterobacter cloacae, Escherichia coli, Klebsiella pneumonia and yeasts.

- **Relation to duodenoscope types:**

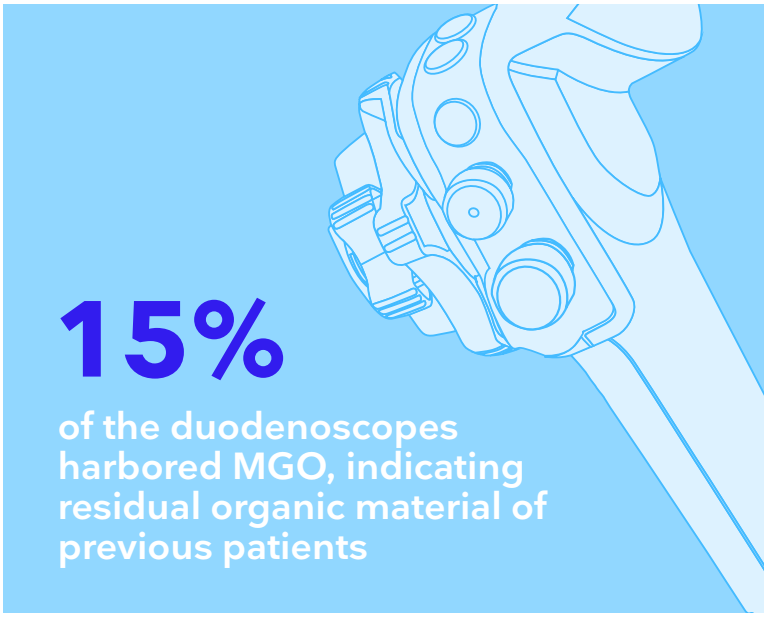
For both AM20 and MGO contamination was not duodenoscope-type dependent.

High prevalence rate of digestive tract bacteria in duodenoscopes: a nationwide study, Gut[6]

Rauwers et al., 2018

STUDY AIM

This nationwide cross-sectional study sought to determine the prevalence of bacterial contamination of reprocessed duodenoscopes in the Netherlands.



METHODS

- A total of 73 Dutch ERCP centers were invited to sample > 2 duodenoscopes using centrally distributed kits according to uniform sampling methods, explained by video instructions.
- Depending on the duodenoscope type, four to six sites were sampled and centrally cultured.
- **Contamination was defined as:**
  - AM20: any microorganism with >20 colony-forming units (CFU)/20 mL
  - MGO: presence of microorganisms with gastrointestinal or oral origin, independent of CFU count.

★★☆ Infection Control Open access

TAKE AWAY

18% of duodenoscopes had a positive culture after initial HLD. Repeated HLD was 86% and 75% effective at eliminating initial and repeat positive cultures respectively. Initial HLD per manufacturer recommendations is not always effective at eliminating bacterial contamination. Investigators state that additional steps are necessary to decrease risks of duodenoscope-transmitted infections.

KEY FINDINGS

- **There were 140 instances of duodenoscope cleaning with 280 specimens. A total of 18% of the cultured duodenoscopes were positive.**
- **Of the 36 (14%) second cultures, 5 were positive. Two of 8 (25%) third cultures were positive.**
- **Of the of organisms, 89% cultured were gram positive. There were 8 instances when both culture methods (brushing and flush) were positive; otherwise only one method was positive.**
- **There were 11 instances (8%) of duodenoscope removals from quarantine before final culture results.**
- **No patients had infections related to ERCP.**

Results of Duodenoscope Culture and Quarantine After Manufacturer-Recommended Cleaning Process, GIE[7]

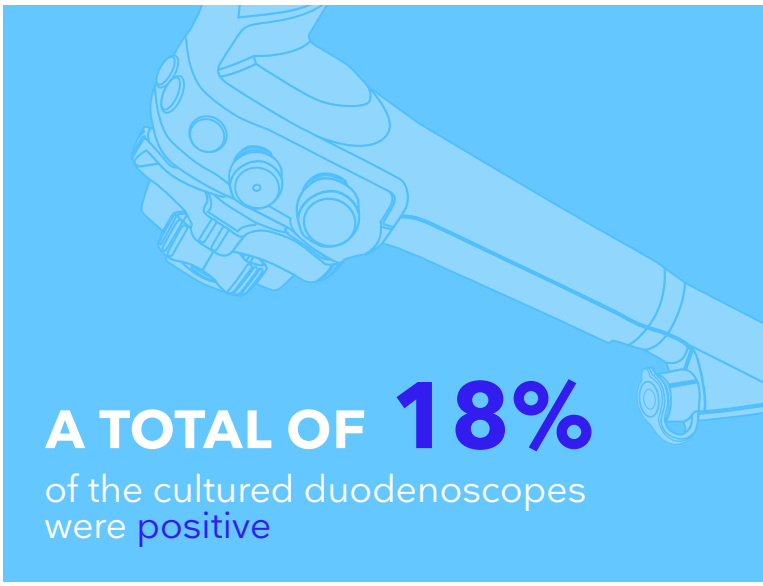
Mark et al., 2020

STUDY AIM

The study presents culture data after duodenoscope manufacturer-recommended high-level disinfection (HLD) and quarantine.

METHODS

- An institution adopted a combination of manufacturer-recommended cleaning with the CDC-recommended culture and quarantine in 2015.
- Duodenoscopes underwent HLD according to the manufacturer's reprocessing manual protocols after use.
- Two culture specimens were then obtained using a sterile brush from the distal tip, including elevator mechanism, and by flushing sterile water through the working channel. Duodenoscopes were quarantined until cultures resulted.
- Positive cultures were defined as >10 CFUs of low-concern organisms, or any CFUs of high-concern organisms according to CDC recommendations. If either culture specimen was positive, the process was repeated until cultures were negative.



★★☆ Infection Control Not open access

TAKE AWAY

In this multicenter surveillance study, microbial growth was recovered in 5.0% of cases, despite compliance with 2014 U.S. guidelines and manufacturers' recommendations for cleaning and HLD process. All endoscope models from three manufacturers in clinical use demonstrated microbial contamination at similar rates. The observed better performance of Custom Ultrasonics AER deserves further investigation.

KEY FINDINGS

- **Microbial growth was recovered from 201 of 4,032 (5%) duodenoscope cultures after HLD, including 0.9% that were positive for high-concern pathogen.**
- **Wide variations in culture-positivity rate were observed across facilities.**
- **No striking difference in culture-positivity rate was seen among endoscope models, manufacturers, age, or automatic flushing system use. However, there was suggestive evidence that Custom Ultrasonics AER had a lower culture-positivity rate than Medivators AER for high-concern pathogen growth.**
- **Two endoscopes grew intestinal flora on several occasions despite multiple HLD. No multidrug-resistant organism was detected.**

Surveillance of guideline practices for duodenoscope and linear echoendoscope reprocessing in a large healthcare system, GIE[8]

Brandabur et al., 2016

STUDY AIM

To assess the adequacy of currently recommended high-level disinfection (HLD) of duodenoscopes and linear echoendoscopes (DLEs).

Microbial growth was recovered from

201 of 4,032

duodenoscope cultures after HLD

0.9%

were positive for high-concern pathogen

METHODS

- The study was conducted within 21 facilities in which over 4500 ERCP procedures were performed each year, with individual facility volumes. Twenty-three linear echoendoscopes and 61 duodenoscopes were in service during the study period.
- All the facilities across five western states used minimum specifications consistent with American Society for Gastrointestinal Endoscopy guidelines and manufacturers' reprocessing recommendations for leak testing, cleaning, disinfection, drying, and storage.

★★★ Infection Control Not open access

TAKE AWAY

This randomized study, involving four separate endoscopy facilities showed that double HLD did not reduce culture positivity rates compared with single HLD in facilities with an already low positive culture rate. Alternative risk mitigation strategies must be assessed in an ongoing effort to reduce endoscope contamination.

KEY FINDINGS

- **Altogether, 5850 surveillance cultures were obtained from 45 duodenoscopes and linear echoendoscopes in clinical use.**
- **Double HLD demonstrated no benefit over single HLD because similar positivity rates were observed.**
- **The elevator mechanism was more frequently colonized than the biopsy channel (5.2% vs 2.9%, P<0.001).**
- **Among the cultures with positive growth, 62.5% recovered microbes from only the elevator mechanism, 32.6% recovered microbes from only the channels and 4.9% recovered microbes from both the elevator and the channels.**
- **Double HLD failed to improve contamination rates for either sample site at any of the four endoscopy facilities.**
- **Persistent growth was observed on two duodenoscopes. One grew Enterococcus spp on three occasions, and Escherichia coli was present on two of these occasions, one of which was a multidrug-resistant organism.**

A randomized trial of single versus double high-level disinfection of duodenoscopes and linear echoendoscopes using standard automated reprocessing, GIE[9]

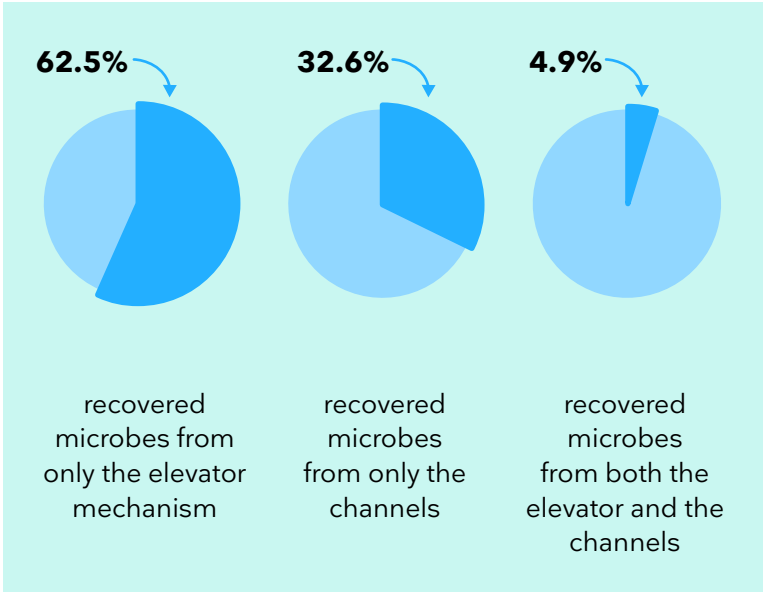
Bartles et al., 2018

STUDY AIM

This RCT study compared the effect of single high-level disinfection (HLD) versus double HLD to properly reprocess duodenoscopes and linear echoendoscopes at four different hospitals.

METHODS

- HLD of duodenoscopes and linear echoendoscopes was randomized, separately in each facility, to either single HLD or double HLD on weekdays, with standard double HLD on weekends or holidays.
- Daily qualitative surveillance cultures of dried reprocessed endoscopes were collected for six months (one swab sample from the elevator mechanism and one combined brush sample from the suction and working channels).
- Positivity rates of any microbial growth and growth of high-concern pathogens (potentially pathogenic enteric flora) were compared between the two study arms.



★★☆ meta-analysis Open access

Rate and impact of duodenoscope contamination: A systematic review and meta-analysis, EClinicalMedicine[10]

Larsen et al., 2020

TAKE AWAY

This is the first meta-analysis to estimate the contamination rate of patient-ready duodenoscopes used for ERCP. Based on the available literature, the analysis demonstrates that there is a 15.25% contamination rate of reprocessed patient-ready duodenoscopes. Additionally, the analysis indicates that dHLD and EtO reprocessing methods are superior to single HLD but still not efficient in regard to cleaning the duodenoscopes properly.

KEY FINDINGS

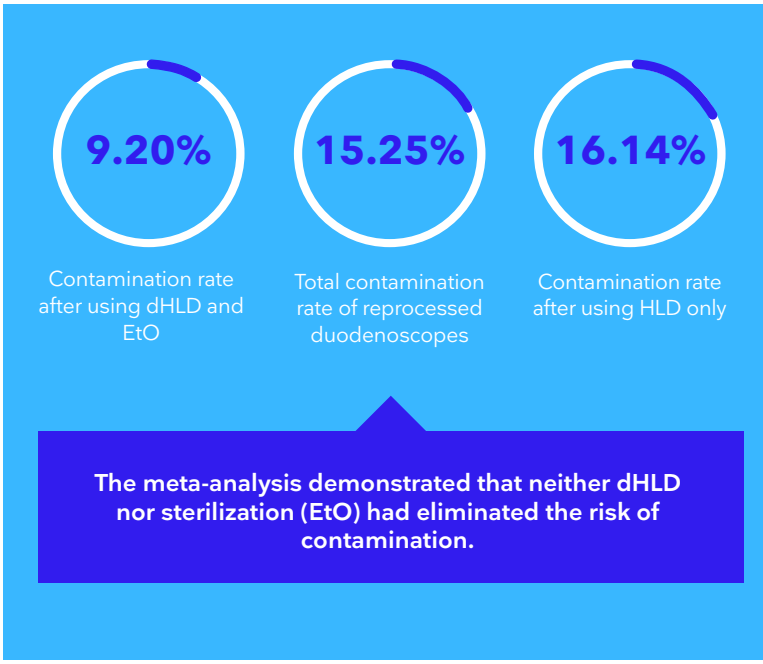
- **A total of 15 studies fulfilled the inclusion criteria, which included 925 contaminated duodenoscopes from 13,112 samples.**
- **The calculated total weighted contamination rate was 15.25% ± 0.018 (95% confidence interval [CI]: 11.74% - 18.75%).**
- **The contamination rate after only using HLD was 16.14% ± 0.019 (95% CI: 12.43% - 19.85%).**
- **After using either dHLD or EtO the contamination rate decreased to 9.20% ± 0.025 (95% CI: 4.30% - 14.10%).**

STUDY AIM

This meta-analysis aimed to estimate the contamination rate of reprocessed patient-ready duodenoscopes for ERCP based on currently available data.

METHODS

- PubMed and Embase databases were searched from January 1, 2010 until March 10, 2020, for citations investigating contamination rates of reprocessed patient-ready duodenoscopes.
- A random-effects model (REM) based on the proportion distribution was used to calculate the pooled total contamination rate of reprocessed patient-ready duodenoscopes.
- Subgroup analyses were carried out to assess contamination rates when using different reprocessing methods by comparing single high-level disinfection (HLD) with double HLD (dHLD) and ethylene oxide (EtO) gas sterilization.



Infectious outbreaks

★★☆ Infection Control Open access

TAKE AWAY

Multidrug-resistant E.coli were identified on four out of eight duodenoscopes after HLD, and 32 patients were infected following an ERCP with a contaminated duodenoscope. Seven patients died within 31 days of the organism being identified. It was difficult to directly attribute the deaths to the contaminated duodenoscope.

KEY FINDINGS

- **Between November 2012 and August 2013, 32 patients were found to be harboring one of two clonal strains of multidrug-resistant E. coli, all of whom had undergone ERCP.**
- **A total of 1,149 ERCPs were performed during the outbreak. Seven patients died within 31 days of the organism being identified in culture. The exact contribution of E. coli to death is unclear, because most patients had underlying late-stage malignancy or other severe medical comorbidities.**
- **No breach in high-level disinfection (HLD) protocol or infection control practices was identified.**
- **E. coli was identified on four out of eight duodenoscopes, three of which required critical repairs despite lack of obvious malfunction.**

A quarantine process for the resolution of duodenoscope-associated transmission of multidrug-resistant Escherichia coli, GIE[11]

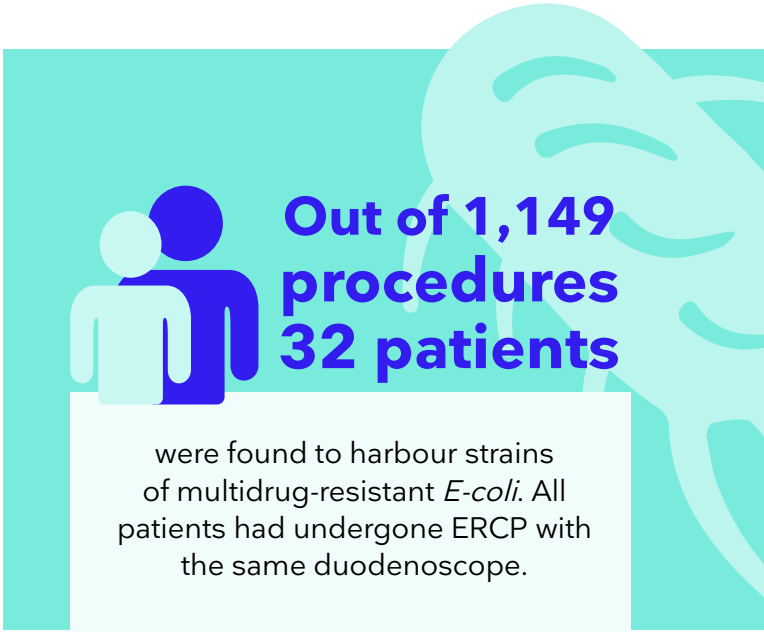
Ross et al., 2015

STUDY AIM

This study reports the results of an outbreak investigation at the Virginia Mason Medical Centre institution and the process improvements that were deployed in an effort to contain the outbreak.

METHODS

- A full investigation into the environment, infection control practices, and high-level disinfection process was undertaken in conjunction with the local county health authority and the Centers for Disease Control and Prevention.
- Duodenoscopes were cultured and quarantined for 48 hours until negative cultures were obtained.
- Changes were made to the endoscope reprocessing area; duodenoscopes were returned for routine maintenance; and surveillance cultures were obtained from all patients undergoing ERCP.



★★☆ Infection Control Not open access

TAKE AWAY

In patients undergoing ERCP with a contaminated duodenoscope, biliary stent placement, a diagnosis of cholangiocarcinoma, and active inpatient status are associated with an increased risk of CRE transmission. Out of 105 patients exposed to a contaminated duodenoscope, 15 patients acquired a CRE infection.

KEY FINDINGS

- **Between October 3, 2014, and January 28, 2015, a total of 125 procedures were performed on 115 patients by using either of the contaminated duodenoscopes.**
- **Culture data were available for 104 of the 115 exposed patients (90.4%).**
- **Among these patients, a total of 15 (14.4%) patients acquired a CRE infection.**
  - **Eight patients became actively infected (7.7%) with CRE**
  - **Seven patients became colonized (6.7%) with CRE.**
- **Recent antibiotic exposure (66.7% vs 37.1%; p = .046), active inpatient status (60.0% vs 28.1%; p = 0.034), and a history of cholangiocarcinoma (26.7% vs 3.4%; p = 0.008) were patient characteristics associated with an increased risk of CRE infection.**
- **Biliary stent placement (53.3% vs 22.5%; p = 0.024) during ERCP was a significant procedure-related risk factor.**

Risk factors associated with the transmission of carbapenem-resistant Enterobacteriaceae via contaminated duodenoscopes, GIE [12]

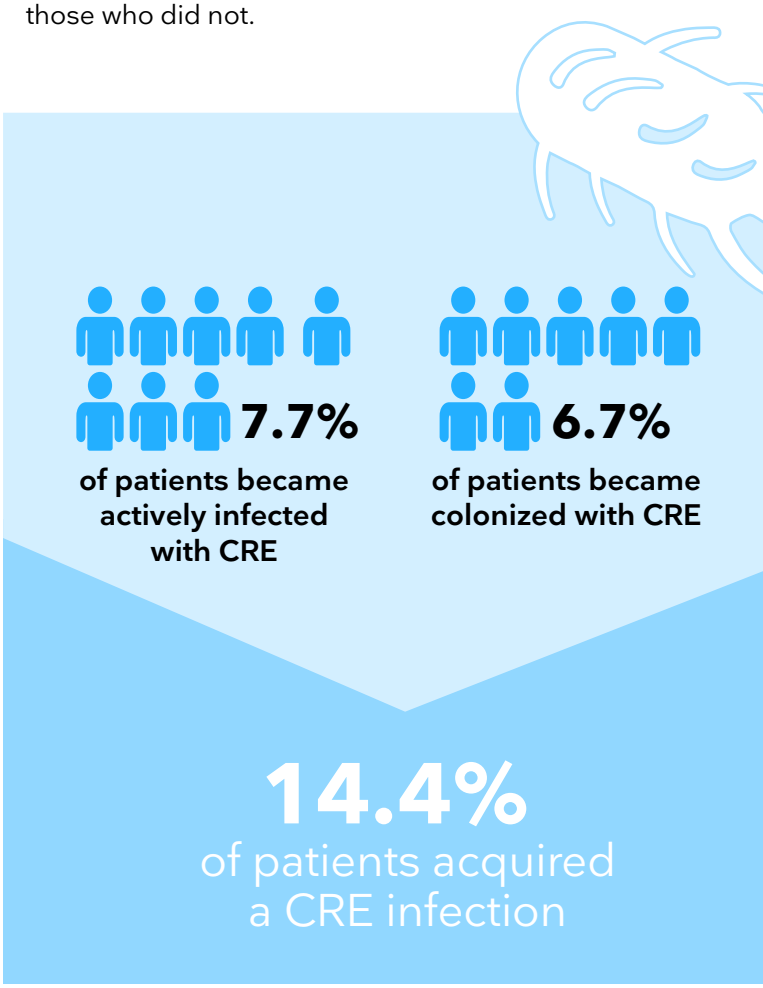
Kim et al., 2016

STUDY AIM

This retrospective, single-centre, case-control study sought to identify the risk factors associated with the transmission of carbapenem-resistant Enterobacteriaceae (CRE) via contaminated duodenoscopes.

METHODS

- All patients who underwent ERCP with either one of the two contaminated duodenoscopes were evaluated.
- The investigators compared the patients who acquired CRE (active infection or colonization) with those who did not.



★★☆ Infection Control Not open access

TAKE AWAY

Carbapenemase-producing Klebsiella pneumoniae were identified in five patients who underwent an endoscopy with the same duodenoscope. The duodenoscope was the only factor linking the patients. The duodenoscope had previously been used in an infected patient, which is thought to be the origin of the contamination.

KEY FINDINGS

- **A total of 5 cases of Carbapenemase-producing K. pneumoniae colonization were identified from patients who received an ERCP with the same duodenoscope over a short period in October 2015.**
- **The duodenoscope was the only epidemiological link between these cases.**
- **The investigators strongly suggest that this duodenoscope has become transiently contaminated following its use for known CPE carriers of a previous outbreak.**

Duodenoscopy: an amplifier of cross-transmission during a carbapenemase-producing Enterobacteriaceae outbreak in a gastroenterology pathway, The Journal of Hospital Infection[13]

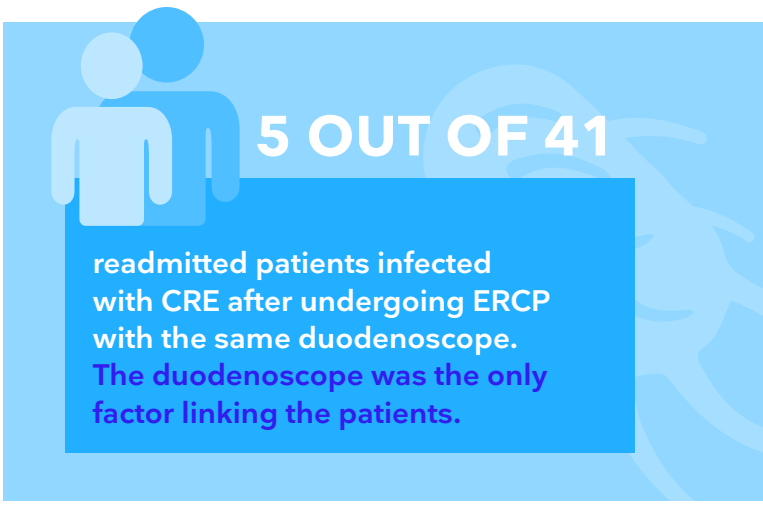
Bourigault et al., 2018

STUDY AIM

Carbapenemase-producing *K. pneumoniae* was identified in five patients who underwent ERCP with the same duodenoscope. The duodenoscope was the only epidemiological link between these cases. This study reports the epidemiological and microbiological investigations conducted to determine the origin of contamination of these patients.

METHODS

- Between December 2014 and October 2015, 61 patients underwent ERCP with the same duodenoscope. Forty-one patients were readmitted after exposure and screened.
- Five out of 41 readmitted patients had become infected with CRE after undergoing ERCP with the same duodenoscope
- The outbreak was identified at the Nantes University Hospital, France. Reprocessing of endoscopes has been centralized on one site that performs around 100 disinfections per day and is carried out in accordance with the French guidelines.
- A multidisciplinary team, comprising endoscopist physicians, bacteriologists, infection control specialists, biomedical engineers, and staff of the endoscope reprocessing unit, coordinated the epidemiological and microbiological investigations.



★★☆ Infection Control Not open access

TAKE AWAY

This outbreak demonstrated the previously underappreciated potential for duodenoscopes to transmit disease, even after undergoing high-level disinfection according to manufacturers' guidelines. A total of 9 patients become infected with CRE during the outbreak, and two patient deaths were attributed to the CRE infection.

KEY FINDINGS

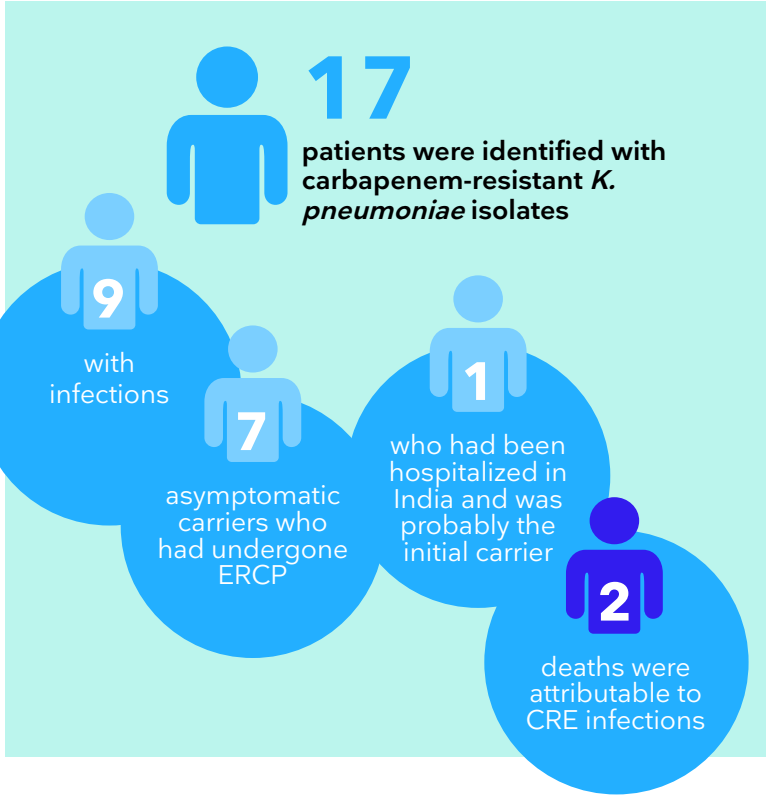
- **A total of 17 patients were identified with carbapenem-resistant K. pneumoniae isolates, including 9 with infections, 7 asymptomatic carriers who had undergone ERCP, and 1 additional patient who had been hospitalized in India and was probably the initial carrier.**
- **One year after the outbreak was identified and arrested, 6 of the 9 patients with CRE infections had died, although only 2 deaths were attributable to CRE infections.**
- **Two case-control studies established a point-source outbreak associated with 2 specific duodenoscopes.**
- **A field investigation of the use, reprocessing, and storage of duodenoscopes did not identify deviations from FDA or manufacturer recommendations for reprocessing.**

Duodenoscope-Related Outbreak of a Carbapenem-Resistant Klebsiella pneumoniae Identified Using Advanced Molecular Diagnostics, Clinical Infectious Diseases[14]

Humphries et al., 2017

STUDY AIM

This study describes an outbreak of carbapenem-resistant K. pneumoniae transmitted by contaminated duodenoscopes during ERCP procedures.



METHODS

- An outbreak investigation was performed when nine patients with carbapenem-resistant K. pneumoniae infections were identified at a tertiary care hospital.
- The investigation included two case-control studies, a review of duodenoscope reprocessing procedures and cultures of devices.
- On recognition of ERCP as a key risk factor for infection, targeted patient notification and Carbapenem-resistant Enterobacteriaceae (CRE) screening cultures were performed.

★★☆ Infection Control Not open access

TAKE AWAY

Duodenoscope design modifications may compromise microbiological safety as illustrated by this outbreak. Extensive pre-marketing validation of the reprocessability of any new endoscope design and stringent post-marketing surveillance are therefore mandatory. Twenty-two patients got infected during this outbreak.

KEY FINDINGS

- **From January to April 2012, 30 patients with a VIM-2-positive P. aeruginosa were identified, of whom 22 had undergone an ERCP using a specific duodenoscope, the TJF-Q180V.**
- **In total, 251 patients had undergone ERCP using the same duodenoscope, and 22 patients became infected with VIM-2-positive P. aeruginosa.**
- **This was a significant increase compared with the hospital-wide baseline level of two to three cases per month.**
- **Clonal relatedness of the VIM-2 P. aeruginosa was confirmed for all 22 cases and for the VIM-2 strain isolated from the recess under the forceps elevator of the duodenoscope.**
- **An investigational study of the new modified design, including the dismantling of the duodenoscope tip, revealed that the fixed distal cap hampered cleaning and disinfection, and that the O-ring might not seal the forceps elevator axis sufficiently.**
- **The high monthly number of cases decreased below the pre-existing baseline level following withdrawal of the TJF-Q180V device from clinical use.**

Withdrawal of a novel-design duodenoscope ends outbreak of a VIM-2-producing Pseudomonas aeruginosa, Endoscopy[15]

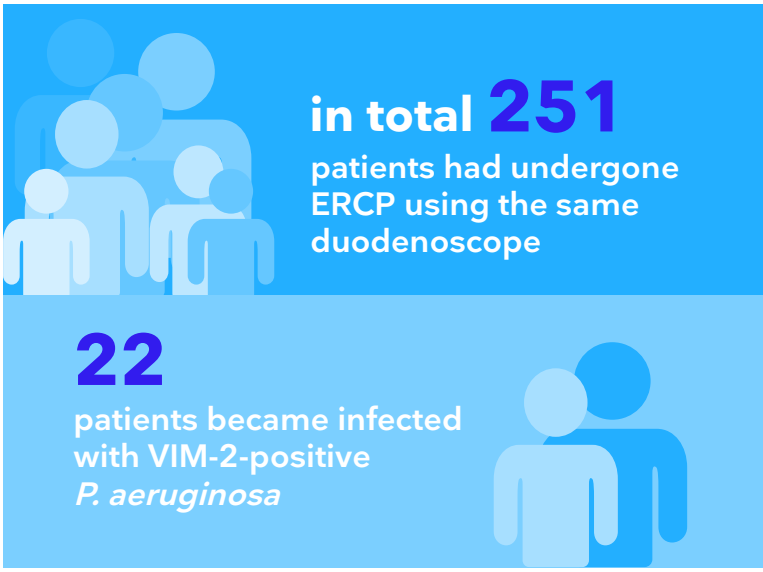
Verfaillie et al., 2015

STUDY AIM

This study reports a large outbreak of VIM-2-producing Pseudomonas aeruginosa that was linked to the use of a recently introduced duodenoscope with a specifically modified design (Olympus TJF-Q180V).

METHODS

- Epidemiological investigations and molecular typing were executed in order to identify the source of the outbreak.
- Audits on implementation of infection control measures were performed. Additional infection control strategies were implemented to prevent further transmission.
- The design and the ability to clean and disinfect the duodenoscope were evaluated, and the distal tip was dismantled.



Clinical performance

★★☆ Performance Open access

TAKE AWAY

A new single-use duodenoscope was used to simulate four ERCP tasks in an anatomic model. Performance ratings and completion times were comparable to three reusable duodenoscope models.

KEY FINDINGS

- **Four ERCP tasks including guidewire locking with elevator, plastic stent placement and removal, metal stent placement and removal, and basket sweeping were completed by six expert endoscopists. Tasks were completed with similar completion times for reusable and single-use duodenoscopes.**
- **Navigation/pushability ratings were lower for the single-use duodenoscope than for the three reusable duodenoscopes (median, 8.0, 10.0, 9.0, and 9.0, respectively; $p < 0.01$).**
- **Tip control ratings were similar among all the duodenoscopes (median, 9.0-10.0; $p = 0.77$).**
- **Image quality ratings were lower for one reusable duodenoscope compared with the single-use and the other two reusable duodenoscopes (median, 8.0, 9.0, 9.0, and 9.0, respectively; $p < 0.01$).**

Novel single-use duodenoscope compared with 3 models of reusable duodenoscopes for ERCP: a randomized bench-model comparison, GIE[6]

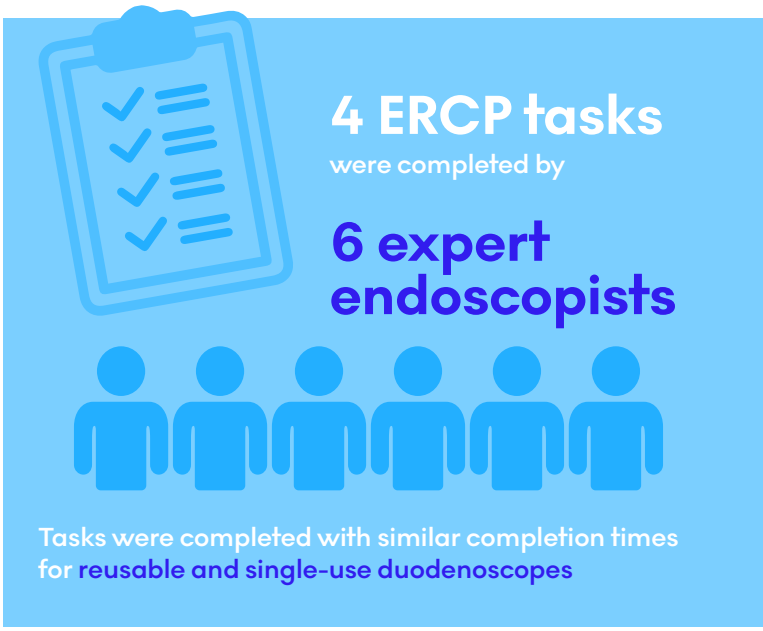
Ross et al., 2019

STUDY AIM

This study investigates the performance of a novel single-use duodenoscope (EXALT™ Model D, Boston Scientific).

METHODS

- A comparative bench simulation study of a new single-use duodenoscope and three models of reusable duodenoscopes was conducted on a synthetic anatomic bench model.
- Four ERCP tasks were performed: guidewire locking (single-use and one reusable duodenoscope only), plastic stent placement and removal, metal stent placement and removal, and basket sweeping.
- The study schedule included block randomization by four duodenoscopes, four tasks, and two anatomic model ERCP stations.
- Ability to complete tasks, task completion times, and subjective ratings of overall performance, navigation/pushability, tip control, and image quality on a scale of 1 (worst) to 10 (best) were compared among duodenoscopes.



★★☆ Performance Open access

TAKE AWAY

In a case-series study, investigators found that expert endoscopists can complete ERCPs of a wide range of complexity using a single-use duodenoscope for nearly all cases. This alternative might decrease ERCP-related risk of infection. Clinicaltrials.gov no: NCT03701958.

KEY FINDINGS

- **A total of 13 (100%) roll-in maneuver cases were completed using the single-use duodenoscope.**
- **ERCPs were of American Society for Gastrointestinal Endoscopy procedural complexity grade 1 (least complex; 7 patients [11.7%]), grade 2 (26 patients [43.3%]), grade 3 (26 patients [43.3%]), and grade 4 (most complex; 1 patient [1.7%]).**
- **A total of 58 ERCPs (96.7%) were completed using the single-use duodenoscope only and 2 ERCPs (3.3%) were completed using the single-use duodenoscope followed by crossover to a reusable duodenoscope.**
- **Median overall satisfaction was 9 out of 10.**
- **There were 3 patients who developed post-ERCP pancreatitis, 1 patient had post-sphincterotomy bleeding, and 1 patient had worsening of a pre-existing infection and required rehospitalization.**

Clinical Evaluation of a Single-Use Duodenoscope for Endoscopic Retrograde Cholangiopancreatography, Clinical Gastroenterology and Hepatology[7]

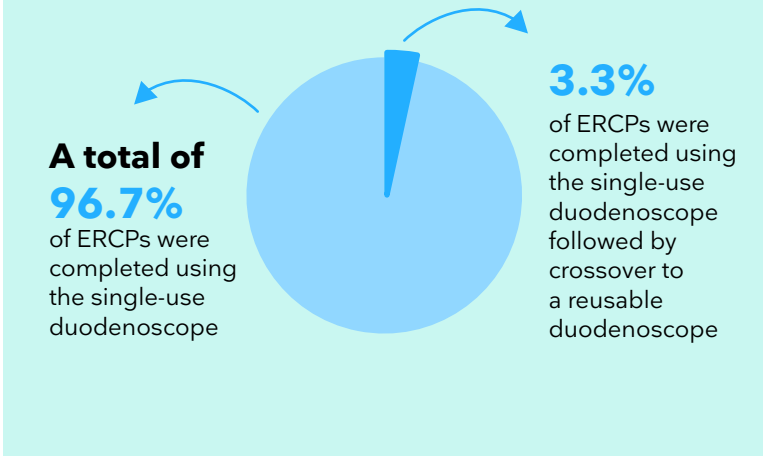
Muthusamy et al., 2020

STUDY AIM

This study tested the feasibility, preliminary safety, and performance of a new single-use duodenoscope (EXALT™ Model D, Boston Scientific) in patients undergoing ERCP.

METHODS

- A case-series study of the outcomes of ERCP with a single-use duodenoscope from April through May 2019 at six academic medical centers was conducted.
- Consecutive patients (18 years and older) without alterations in pancreaticobiliary anatomy were screened, and 73 patients were enrolled into the study.
- Seven expert endoscopists performed roll-in maneuvers (duodenoscope navigation and visualization of duodenal papilla only) in 13 patients and ERCPs in the 60 other patients.
- Outcomes analyzed included completion of ERCP for the intended clinical indication, crossover from a single-use duodenoscope to a reusable duodenoscope, endoscopist performance ratings of the device, and serious adverse events (assessed at 72 hours and 7 days).



★★★ Performance Open access

TAKE AWAY

Given the overall safety profile and similar technical performance, single-use duodenoscopes represent an alternative to reusable duodenoscopes for performing low-complexity ERCP procedures in experienced hands. Clinicaltrials.gov no: NCT04143698.

KEY FINDINGS

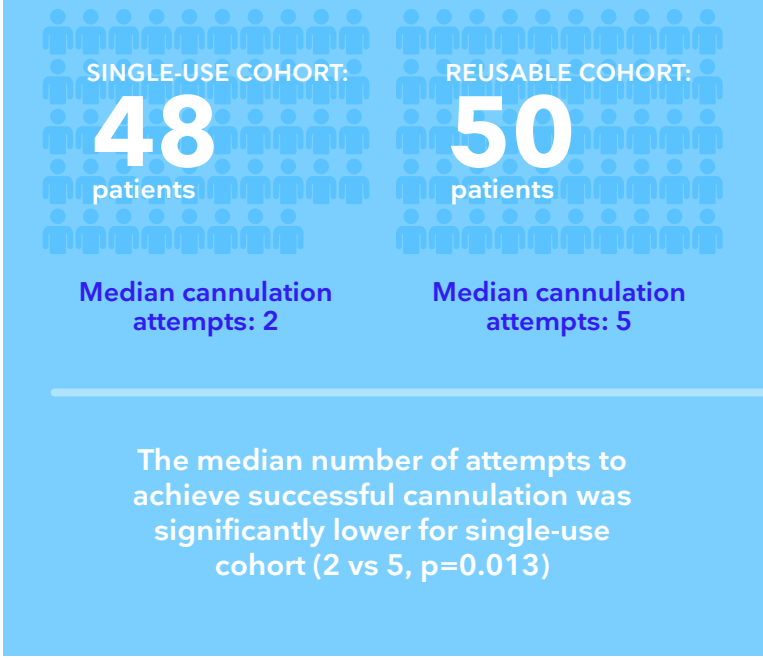
- **A total of 48 patients were treated using single-use, and 50 patients were treated using reusable duodenoscopes with >80% graded as low-complexity procedures.**
- **The median number of attempts to achieve successful cannulation was significantly lower for single-use cohort (2 vs 5, p=0.013)**
- **Ease of passage into stomach (p=0.047), image quality (p<0.001), image stability (p<0.001) and air-water button functionality (p<0.001) were significantly worse for single-use.**
- **There was no significant difference in rate of cannulation, adverse events including mortality (one patient in each group), need to cross-over or need for advanced cannulation techniques to achieve ductal access, between cohorts.**
- **On multivariate logistic regression analysis, only duodenoscope type (single-use) was associated with less than six attempts to achieve selective cannulation (p=0.012), when adjusted for patient demographics, procedural complexity and type of intervention.**

Equivalent performance of single-use and reusable duodenoscopes in a randomised trial, Gut[18]

Bang et al., 2020

STUDY AIM

This randomized controlled trial (RCT) compared performances of single-use and reusable duodenoscopes in patients undergoing ERCP.



METHODS

- Patients (n = 98) with native papilla requiring ERCP were randomized to single-use or reusable duodenoscopes.
- The primary outcome was comparing the number of attempts needed to achieve successful cannulation of desired duct with single-use duodenoscopes vs. reusable ones.
- Secondary outcomes were technical performance that measured duodenoscope maneuverability, mechanical-imaging characteristics and the ability to perform therapeutic interventions, the need for advanced cannulation techniques or a cross-over to an alternate duodenoscope group to achieve ductal access and adverse events.

★☆☆ Performance Open access

TAKE AWAY

A single-use duodenoscope can successfully accomplish fundamental steps of ERCP. This device can potentially eliminate the risk of patient-to-patient infections linked to contaminated instruments. Larger studies are required to assess device performance.

KEY FINDINGS

- **Videos of several key steps of ERCP obtained from four patients are shown to demonstrate that these steps can successfully be performed using the new single-use device.**
- **Clip 1 shows a patient with a large pancreatic duct stone, in which the image quality and maneuverability are demonstrated.**
- **Clip 2 shows a patient with choledocholithiasis, and demonstrates bile duct cannulation, cholangiography, and sphincterotomy**
- **Clip 3 shows a patient with acute cholecystitis and choledocholithiasis who underwent bile duct cannulation, sphincterotomy, and balloon sweeps.**
- **Clip 4 shows a patient with a history of liver transplant and refractory biliary anastomotic stricture who showed abnormal liver tests and fever, and underwent removal of a metal stent and placement of plastic stents.**
- **Watch the video clips here.**

Use of a novel single-use disposable duodenoscope for ERCP: selected clips from a real-world case series, VideoGIE[19]

Thaker et al., 2020

STUDY AIM

Single-use/disposable duodenoscopes represent one strategy to decrease the risk of patient infection related to ERCP. A preliminary case series was performed to demonstrate the feasibility and performance of a new single-use duodenoscope in a real-world clinical setting.

METHODS

A single expert endoscopist performed ERCP for standard indications using a single-use duodenoscope.

Health economics

★★☆ Health economics Open access

TAKE AWAY

The incremental cost per-procedure associated with reusable duodenoscopes is highly dependent on the annual ERCP volume, the amount of duodenoscopes and the given reprocessing setup. Per-procedure costs range from approx. $1,100 to $2,600. Single-use duodenoscopes might be cost-effective at most facilities due to the risk of infection and costs associated with reprocessing and maintaining reusable duodenoscopes.

KEY FINDINGS

- **Based on micro-costing data, the estimated incremental per-procedure cost of reusable duodenoscopes ranges from $1,110.29 to $2,685.76 based on infection rates of 1%-1.2%, respectively.**
- **For centers performing <350 ERCPs annually the incremental per-procedure cost ranges from $1,220.58 to $2,591.39 based on a 1% infection rate.**
- **For centers performing 500 or more ERCPs annually the incremental per-procedure cost ranges from $1,110.29 to $1,244.42 assuming 1% infection risk. With a 1.2% infection risk, the per-procedure cost would increase $94.36.**
- **The per-procedure cost is highly dependent on the annual procedure volume, duodenoscopes available and the reprocessing setup.**
- **Time spent on manual reprocessing was on average 26 minutes per duodenoscope.**

The Total Cost of Reusable Duodenoscopes – Are Single-Use Duodenoscopes the Future of ERCP?, Pharmacoeconomics[20]

Travis et al., 2020

STUDY AIM

This study sought to estimate the costs associated with reusable duodenoscopes to investigate whether single-use duodenoscopes may be a cost-effective alternative.

METHODS

- Micro-costing data were collected at seven different endoscopy units with different volumes at AdventHealth Orlando, FL, USA.
- Cost per-procedure was calculated for five different ERCP volume settings (50, 150, 350, 500, and 750) performed with two, four, five, six, and eight duodenoscopes.
- This study only investigated the incremental costs (i.e., costs that do not apply to single-use duodenoscopes)

Annual ERCP procedures →	**50**	**750**
Capital per-procedure cost	$1,713	$610
Repair/maintenance per-procedure cost	$304	$60
Reprocessing cost (including PPE, pre-cleaning, manual cleaning and storage)	$102	
Infection (1%)	$472	
Total per-procedure cost	**$2,591**	**$1,244**

Ambu® aScope™ Duodeno

Ambu® aScope™ Duodeno is a sterile single-use duodenoscope that helps you address serious concerns about patient cross-contamination. Due to its single-use modality, aScope Duodeno eliminates the need for complex reprocessing, ongoing repair and microbiological sampling and culturing. The design of aScope Duodeno is based on the latest conventional duodenoscopes, and the familiar form and function deliver consistent performance.

INNOVATING TO IMPROVE PATIENT SAFETY

Based on the difficulties of reprocessing conventional duodenoscopes, FDA is recommending that hospitals transition to duodenoscopes with innovative designs that improve patient safety. aScope Duodeno exceeds these recommendations.

SIMPLE SETUP

The aScope Duodeno solution consists of a single-use duodenoscope and aBox™ Duodeno unit. Remove aScope Duodeno from its packaging, connect it to aBox Duodeno and the system is ready. The system has an integrated rinsing function, and there is no need for an additional light source.

FAMILIAR CONTROL AND DESIGN

aScope Duodeno provides high-definition imaging and flexible bending angles (Up: 120°, Down: 90°, Right: 110°, Left: 90°), which enable detailed visualization of the mucosa and efficient navigation into the gastrointestinal tract. Additionally, the aScope Duodeno elevator performs reliably with compatible endoscopic accessories.

KEY FEATURES

- Sterile straight from the pack, eliminating the risk of patient cross-contamination
- There is no need for reprocessing or repair, which streamlines your daily workflow and reduces your hospital's costs
- Familiar design that ensures a seamless transition from conventional duodenoscopes
- Performs reliably with compatible endoscopic accessories
- Offers cost transparency - one duodenoscope, one price. No long-term service contracts or leasing agreements
- Offers a cost-effective single-use solution

CONTACT AMBU INC.

For more information, please visit www.ambuusa.com/single-use-duodenoscope or contact your local Ambu representative.

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