EVIDENCE DOSSIER

Ambu® aScope™ Duodeno

Ambu

April 2021, 1st edition EMEA

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

CDC: Centers for Disease Control and Prevention

CFU: colony-forming units

CI: confidence interval

CPE: Carbapenemase-producing Enterobacteriaceae

CRE: Carbapenem-resistant Enterobacteriaceae

CRKP: Carbapenem-resistant K. pneumoniae

dHLD: double high-level disinfection

DLEs: duodenoscopes and linear echoendoscopes

E. coli: escherichia coli

ECRI: Emergency Care Research Institute

ERCP: endoscopic retrograde cholangiopancreatography

EtO: ethylene oxide

FDA: Food & Drug Administration

HLD: high-level disinfection

K. pneumoniae: Klebsiella pneumoniae

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

VIM-2: Verona integron-encoded metallo-ß-lactamase

PREFACE

This dossier will help you get an overview of the evidence landscape related to Ambu® aScope™ Duodeno, a single-use duodenoscope. The introduction provides an overview of European studies with reported patient infection from contaminated 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 send an inquiry to Global Health Economics Manager, Rasmus Vinther Russell (raru@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 subsequent editions.

A HISTORY OF BREAKTHROUGH IDEAS

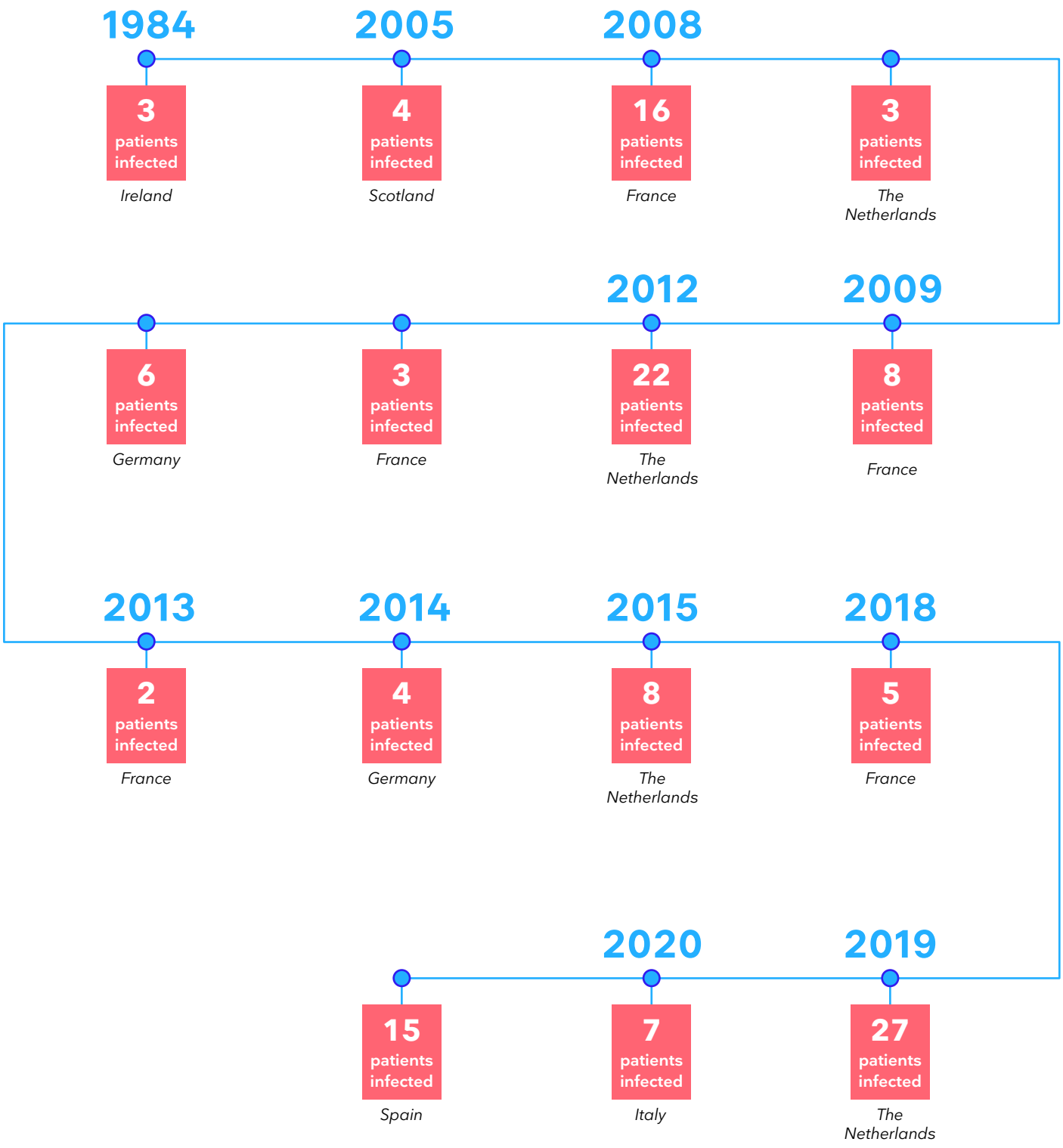
Ambu has been bringing the solutions of the future to life since 1937. Today, millions of patients and healthcare professionals worldwide depend on the efficiency, safety and performance of our singleuse endoscopy, anaesthesia, and patient monitoring & diagnostics solutions. The manifestations of our 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

EUROPEAN DUODENOSCOPE-RELATED OUTBREAKS

Multiple outbreaks have been reported across Europe, due to 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.



"TOP 10 HEALTH TECHNOLOGY HAZARDS" BY ECRI FROM 2010 TO 2020

For the past 10 years, endoscope reprocessing has reached ECRI's top 10 list. ECRI writes in its report that "Sterile processing failures can lead to surgical site infections, which have a 3% mortality rate and an associated annual cost of $3.3 billion".

Below is a table showing where endoscope reprocessing and cross-contamination have been listed on the ECRI top 10 list since 2010:

Years	Number on ECRI list	Headline of technology hazard
2020	5	"Device Cleaning, Disinfection, and Sterilization"
2019	5	"Mishandling Flexible Endoscopes after Disinfection Can Lead to Patient Infections"
2018	2	"Endoscope Reprocessing Failures Continue to Expose Patients to Infection Risk"
2017	2	"Inadequate Cleaning of Complex Reusable Instruments Can Lead to Infections"
2016	1	"Inadequate Cleaning of Flexible Endoscopes before Disinfection Can Spread Deadly Pathogens"
2015	4	"Inadequate Reprocessing of Endoscopes and Surgical Instruments"
2014	6	"Inadequate Reprocessing of Endoscopes and Surgical Instruments"
2013	8	"Inadequate Reprocessing of Endoscopic Devices and Surgical Instruments"
2012	4	"Cross-contamination from Flexible Endoscopes"
2011	3	"Cross-contamination from Flexible Endoscopes"
2010	1	"Cross-contamination from Flexible Endoscopes"

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 detail 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" typically cover 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 1 March 2021. Articles published in the English language within the areas of infection control, performance and health economics were included. Commentaries, letters to the editor, book chapters and publications with no clinical or economical relevance were excluded. This document only includes studies published after 2010, 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

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% of 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% of 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.**

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

Snyder et al., 2017

STUDY AIM

This single-centre 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 CFU of aerobic bacterial growth on either sampling location.

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

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TAKE AWAY

Duodenoscope contamination rates varied between 1.3% and 4.6% in this study. The authors state that "In the present study the contamination rate of endoscopes was low compared with results from other European countries, possibly due to the high quality of endoscope reprocessing, drying and storage."

KEY FINDINGS

- **The study found contamination rates of GI endoscopes varying between 1.3% and 4.6% despite adherence to the national guidelines. This suggests that 1.3–4.6 patients out of 100 could have had contact with hygiene-relevant microorganisms through an endoscopic intervention.**
- **The most commonly identified indicator organism was Pseudomonas spp., mainly Pseudomonas oleovorans.**
- **None of the tested viruses were detected in 40 samples.**

High-quality endoscope reprocessing decreases endoscope contamination, CMI[2]

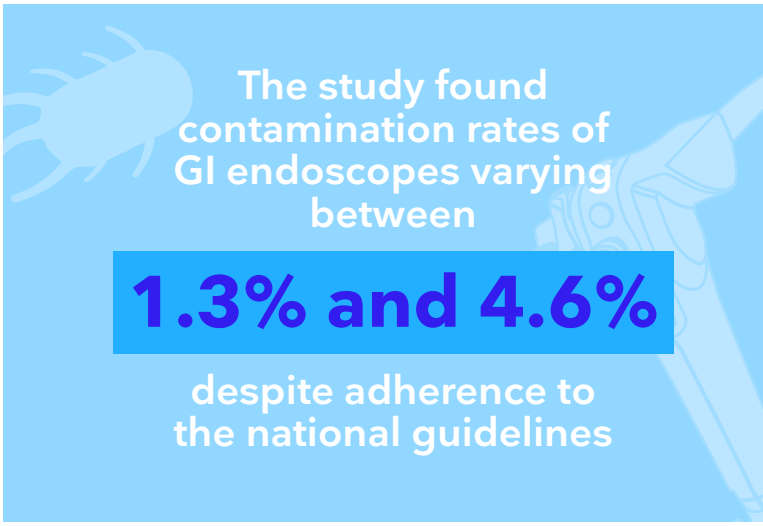
Decristoforo et al., 2018

STUDY AIM

Several outbreaks of severe infections due to contamination of gastrointestinal endoscopes, mainly duodenoscopes, were described. The aim of this multicentre prospective study was to evaluate the hygiene quality of endoscopes and AERs in Tyrol/Austria.

METHODS

- In 2015 and 2016, a total of 463 GI endoscopes and 105 AERs from 29 endoscopy centres were analysed by a routine sampling procedure, and a combined routine and advanced sampling procedure, and investigated for microbial contamination by culture-based and molecular-based analyses.
- All participating centres reprocessed the endoscopes adhering to the complete reprocessing chain (pre-cleaning, manual cleaning, AER, storing) recommended by the Austrian Society for Sterile Supply (ÖGSV) guidelines.
- Reprocessing of endoscopes was done directly after the GI procedure; enzymatic agents were used for pre-cleaning in 83% of study centres.
- All samples were obtained by two hygiene experts and processed under highly aseptic conditions. All specimens were stored on ice and immediately transferred for further analyses.



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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 of contamination to new ones. The MGO contamination prevalence of ~15% was similarly high for duodenoscopes and linear echoendoscopes, rendering patients undergoing both ERCP and endoscopic ultrasound at risk of transmission of microorganisms.

KEY FINDINGS

- **97% of all Dutch centres 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 (all p-values ≥0.27), nor was it shown to differ between the reprocessing characteristics (all p-values ≥0.01).**

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

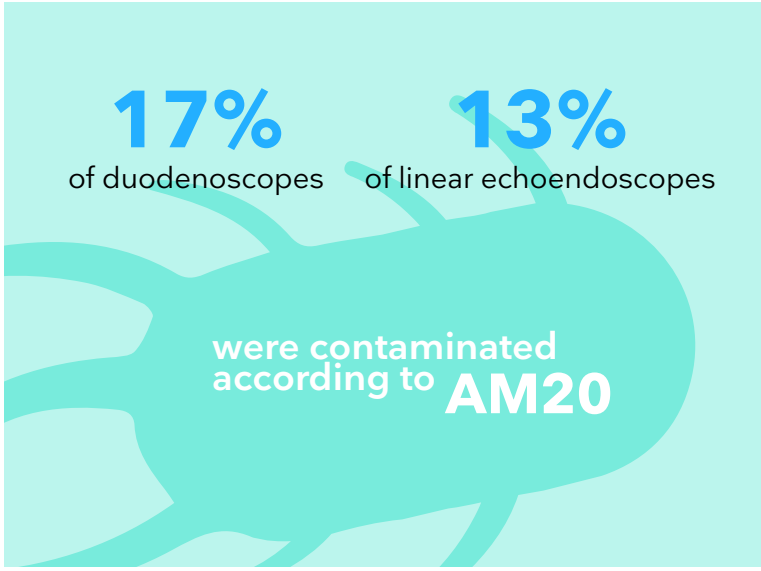
Rauwers et al., 2020

STUDY AIM

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

METHODS

- The investigators invited 74 Dutch DLE centres to sample >2 duodenoscopes during PROCESS 1, and all duodenoscopes and linear echoendoscopes during PROCESS 2. The studies took place in successive years.
- Local staff sampled >6 DLEs at each site 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

A total of 34.7% of the duodenoscope samples reached the action level (>100 CFU/endoscope). The findings of this study may support revision of guidance issued by governmental agencies and professional associations. These elements may be useful for redaction of guidelines to improve microbiological quality surveillance of gastrointestinal endoscopes and to prevent outbreaks linked to these devices.

KEY FINDINGS

- **A total of 118 microbiological tests were performed on duodenoscopes.**
- **6 out of 118 (5.1%) samples reached the alert level (25-100 CFU/endoscope).**
- **41 samples (34.7%) reached the action level (>100 CFU/endoscope).**
- **71 samples (60.2%) were within the target level defined as <25 CFU/endoscope.**
- **Gram-positive, gram-negative, fungi and yeast were isolated from endoscope samples.**
- **Microbial contamination was linked to the age of the endoscope. The more the endoscope is used, the higher the risk of damage.**
- **The use and disinfection of gastrointestinal endoscopes can lead to damage of the channels and to the formation of biofilms that are difficult to remove.**

Measures to improve microbial quality surveillance of gastrointestinal endoscopes, Endoscopy[4]

Saliou et al., 2016

STUDY AIM

Infectious outbreaks associated with the use of gastrointestinal endoscopes have increased in line with the spread of highly resistant bacteria. The aim of this study was to determine the measures required to improve microbial quality surveillance of gastrointestinal endoscopes.

118
microbiological tests were performed on duodenoscopes

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of samples reached the alert level (25-100 CFU/endoscope)

34.7%
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60.2%
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Gram-positive, gram-negative, fungi and yeast were isolated from endoscope samples

METHODS

- Results of all microbiological surveillance testing of gastrointestinal endoscopes performed at Brest Teaching Hospital from January 1, 2008 to June 1, 2015 were reviewed.
- When microbiological testing failed to comply with the target level, the endoscope was subjected to a double manual reprocessing before being retested.
- Target level was defined as total flora <25 CFU/endoscope and absence of indicator microorganisms.
- Alert level was defined as total flora 25-100 CFU/endoscope and absence of indicator microorganisms.
- Action level was defined as total flora ≥100 CFU/endoscope or presence of indicator microorganisms.

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TAKE AWAY

Three out of four duodenoscopes were contaminated with high-concern microorganisms, some of which were multidrug-resistant. Positive samples were cultured both from the distal end and from the instrument channel.

KEY FINDINGS

- **The initial phase of surveillance revealed that three duodenoscopes presented a high level of contamination with "high-concern" micro-organisms, some of which were multidrug-resistant.**
- **The 75% contamination rate applied to high-concern micro-organisms, both in the samples taken from the distal end and in those taken from the instrument channel.**
- **With regard to the distal end, the antibiogram revealed that 60% of the samples positive for P. aeruginosa contained strains resistant to multiple antibiotics (including carbapenems).**
- **Since the cultures were repeatedly positive on three successive occasions, the contaminated devices were sent to the manufacturer for evaluation.**
- **The authors state that "The risk of transmitting infections was formerly estimated to be 1 in 1.8 million endoscopic procedures. This figure now appears to be a significant underestimation for many reasons, including a lack of detailed surveillance for infections following endoscopy, under-reporting, and a lack of recognition of acknowledged transmissions".**

Is Post-Reprocessing Microbiological Surveillance of Duodenoscopes Effective in Reducing the Potential Risk in Transmitting Pathogens? IJERPH[5]

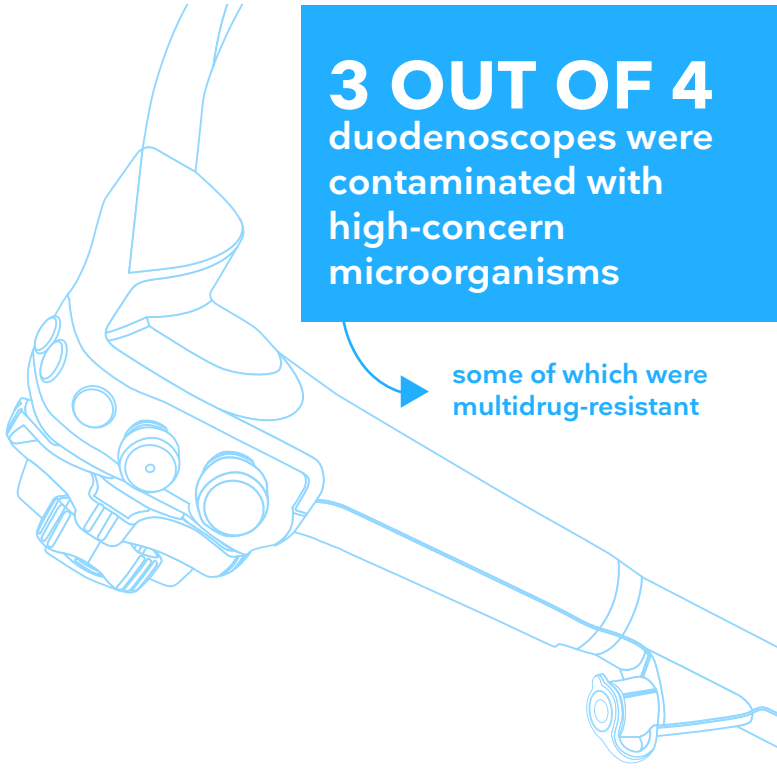
Cristina et al., 2020

STUDY AIM

In this study, post-reprocessing microbiological surveillance of duodenoscopes was carried out over a three-year period in the Digestive Endoscopy Unit of an Italian hospital.

METHODS

- From April 2017 to October 2019, 124 microbiological samples were taken from four duodenoscopes (62 from the distal end and 62 from the instrument channel) following post-reprocessing (after drying).
- The initial phase of surveillance involved the contemporary evaluation of the four duodenoscopes; afterwards, microbiological surveillance proceeded at monthly intervals.



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TAKE AWAY

A total of 11.2% of the samples tested positive for bacteria. The majority of the bacteria identified were skin bacteria. One endoscope tested positive for aerobe spore-forming bacilli. None of the samples from the elevator mechanism (n=88) tested positive.

KEY FINDINGS

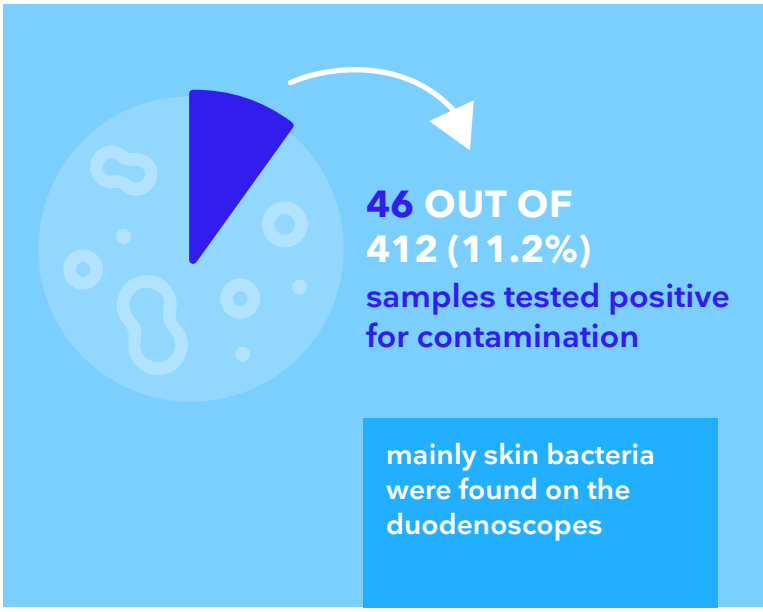
- **The evaluation yielded a total of 412 microbiological monitoring samples during the study period (November 2004 through March 2015), including 88 samples from the elevator mechanism.**
- **None of the samples taken from the elevator mechanism yielded any growth of microorganisms.**
- **Contamination with skin bacteria was found in 45 (11%) of the 412 samples.**
- **One endoscope tested positive for aerobe spore-forming bacilli. This endoscope was reprocessed and yielded no growth on resampling.**
- **Overall, 46 out of 412 (11.2%) samples tested positive for contamination; mainly skin bacteria were found on the duodenoscopes.**

Microbiologic surveillance of duodenoscope reprocessing at the Vienna University Hospital from November 2004 through March 2015, ICHE[6]

Paula et al., 2015

STUDY AIM

The aim of this study was to evaluate the efficacy of current reprocessing procedures of duodenoscopes in the Vienna University Hospital, Austria.



METHODS

- The Vienna University Hospital is a tertiary care university teaching hospital with 2,137 beds. The Division of Gastroenterology and Hepatology performs approximately 700 ERCPs per year using reusable duodenoscopes (eight duodenoscopes are in rotational use).
- All endoscopes are reprocessed using HLD according to manufacturer instructions.
- Microbiological sampling of all endoscopes and last rinse water of the AER is performed once a year.

★★☆ Infection Control Open access

TAKE AWAY

In 39% of all Dutch ERCP centres, at least one AM20-contaminated duodenoscope that was considered patient-ready was identified. A total of 15% of the duodenoscopes harboured MGO, indicating residual organic material from 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 centres (92%) took 745 samples 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[7]

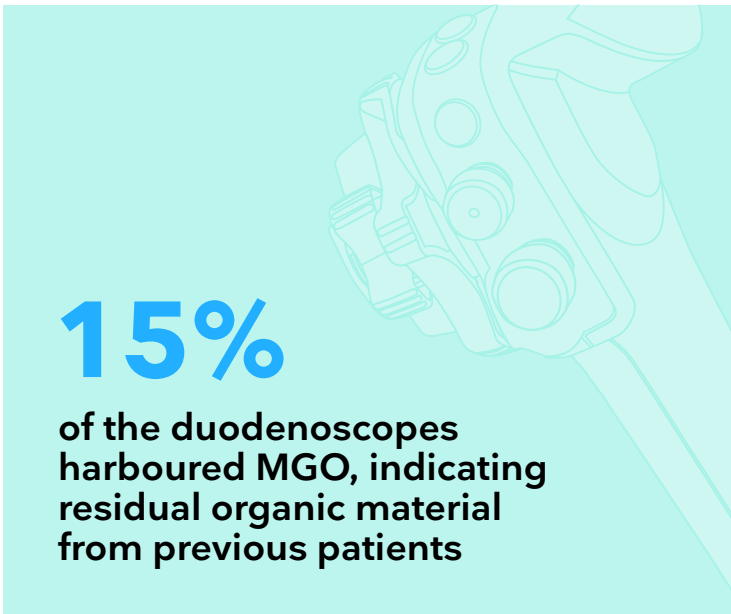
Rauwers et al., 2018

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 centres 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.



15%

of the duodenoscopes harboured MGO, indicating residual organic material from previous patients

★★☆ Infection Control Not 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 as 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

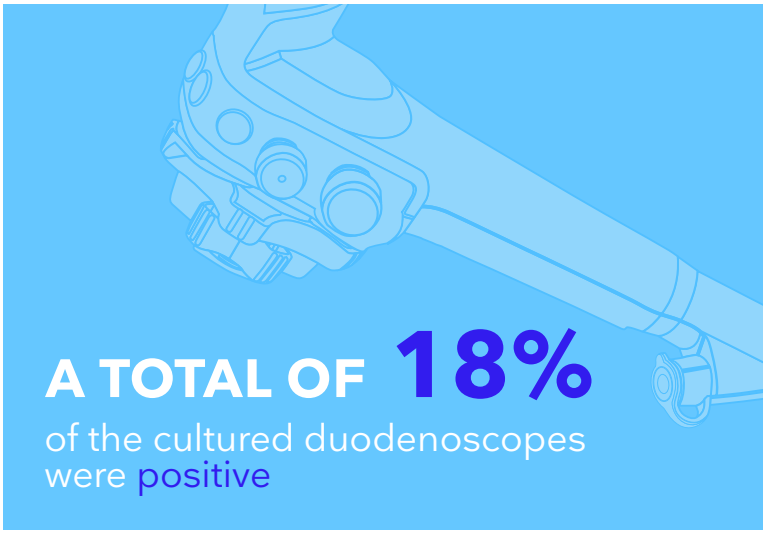
- **There were 140 instances of duodenoscope cleaning with 280 specimens. A total of 18% of the cultured duodenoscopes were positive.**
- **Of the 36 (14%) second cultures, 5 were positive. Two of 8 (25%) third cultures were positive.**
- **Of the organisms, 89% of the cultures were gram-positive. There 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[8]

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 CFU of low-concern organisms, or any CFU 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

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, 5,580 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]

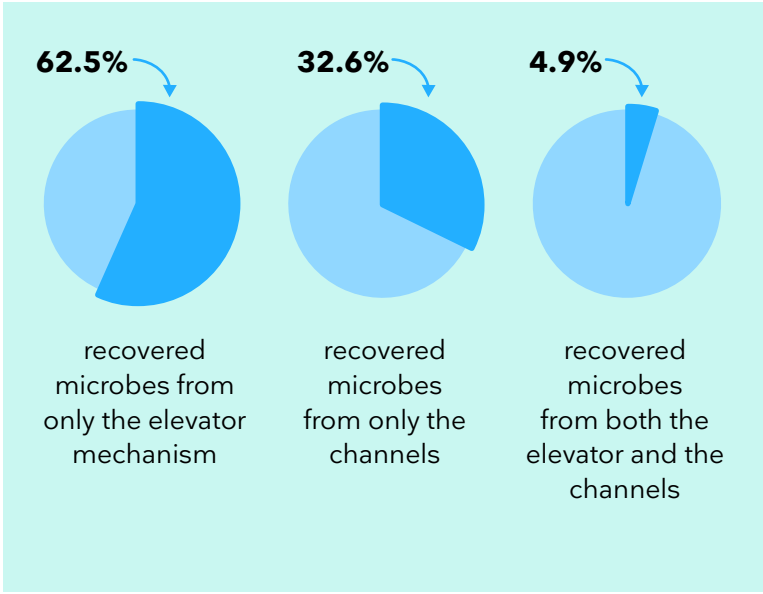
Bartles et al., 2018

STUDY AIM

This RCT study compared the effect of single 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

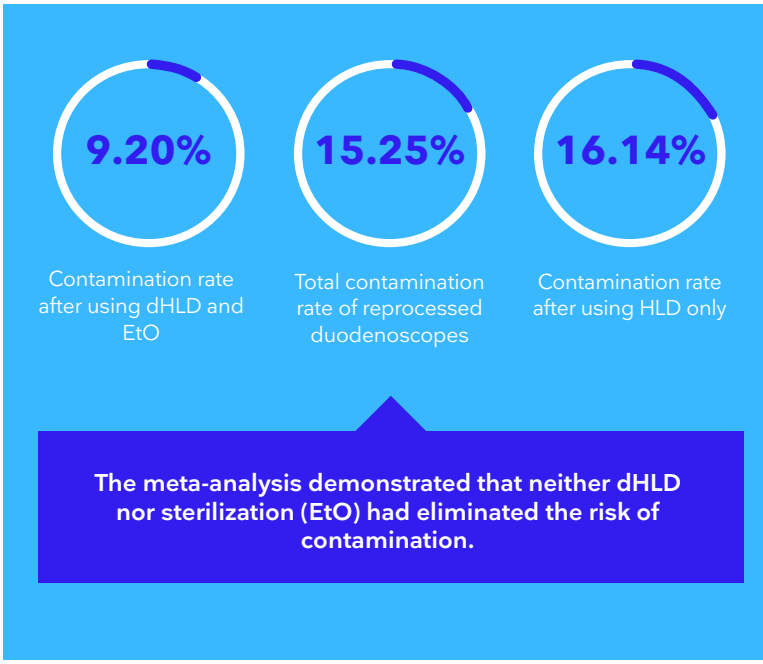
- **A total of 15 studies fulfilled the inclusion criteria, which included 925 contaminated duodenoscopes from 13,112 samples.**
- **The calculated total weighted contamination rate was 15.25% ± 0.018 (95% confidence interval [CI]: 11.74% - 18.75%).**
- **The contamination rate after only using HLD was 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 Not open access

TAKE AWAY

The endoscopes used for ERCP can act as a reservoir for the emerging K. Pneumoniae that produce extended-spectrum beta-lactamase. Regular audits to ensure rigorous application of cleaning, high-level disinfection and drying steps are crucial to avoid contamination.

KEY FINDINGS

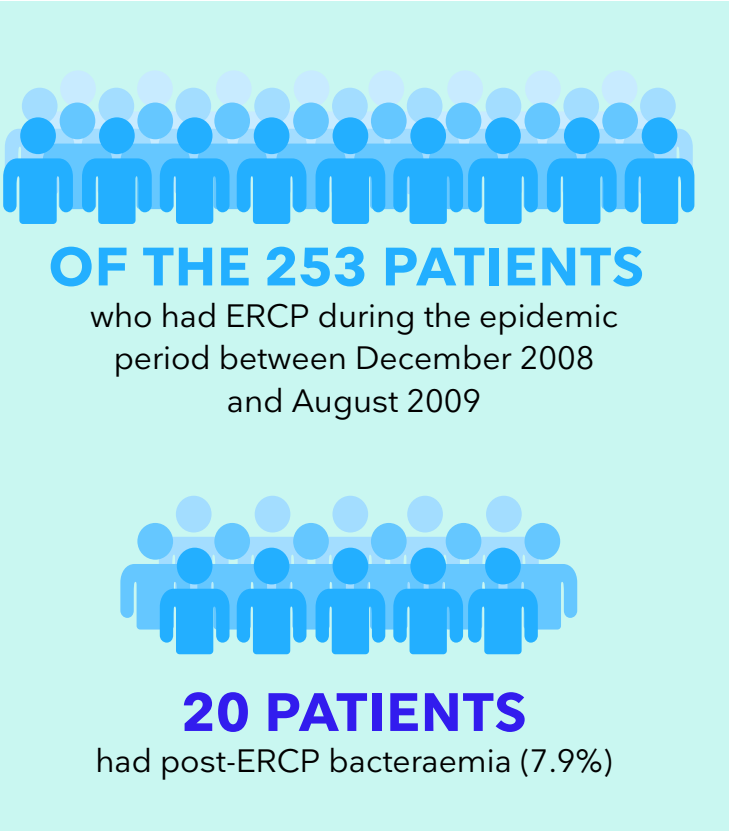
- **Between December 2008 and August 2009, 16 patients were identified post-ERCP with *K. Pneumoniae* that produced extended-spectrum beta-lactamase.**
- **Overall, of the 253 patients who had ERCP during the epidemic period between December 2008 and August 2009, 20 (7.9 %) had post-ERCP bacteraemia.**
- **There were eight bloodstream infections, four biliary tract infections and four cases of faecal carriage.**
- **The microorganism was isolated only from patients who had undergone ERCP.**
- **Environmental investigations found no contamination of the washer-disinfectors or the surfaces of the endoscopy rooms.**
- **Routine surveillance cultures of endoscopes were repeatedly negative during the outbreak, but the epidemic strain was finally isolated from one duodenoscope by flushing and brushing the channels.**
- **Molecular typing confirmed the identity of the clinical and environmental strains.**
- **Practice audits showed that manual cleaning and drying before storage were insufficient. Strict adherence to reprocessing procedures ended the outbreak.**

Multidrug-resistant Klebsiella pneumoniae outbreak after endoscopic retrograde cholangiopancreatography, Endoscopy[11]

Aumeran et al., 2010

STUDY AIM

Infection is a recognized complication of ERCP. This study describes epidemiologic and molecular investigations of outbreak of ERCP-related severe nosocomial infection due to *K. Pneumoniae* producing extended-spectrum beta-lactamase.



METHODS

- Epidemiologic and molecular investigations were conducted to identify the source of the outbreak in patients undergoing ERCP.
- Reviews of the medical and endoscopic charts and microbiological data, practice audits, surveillance cultures of duodenoscopes and environmental sites, and molecular typing of clinical and environmental isolates were carried out.

★★☆ Infection Control Open access

TAKE AWAY

Six patients acquired an infection following ERCP performed with the same duodenoscope. The outbreak ended after the endoscope was sent to the manufacturer for maintenance. The authors state "Accurate and stringent reprocessing of endoscopic instruments is extremely important, which is especially true for more complex instruments like the duodenoscope."

KEY FINDINGS

- **Between 6 December 2012 and 10 January 2013, carbapenem-resistant *K. pneumoniae* (CRKP) was cultured from 12 patients staying on four different wards.**
- **The amplification of Carbapenemase genes by multiplex PCR showed the presence of the blaOXA-48 gene.**
- **A total of six cases were all related to ERCP performed with the same duodenoscope. The outbreak ended after the endoscope was sent to the manufacturer for maintenance.**

An outbreak of carbapenem-resistant OXA-48 – producing Klebsiella pneumonia associated to duodenoscopy, ARIC[12]

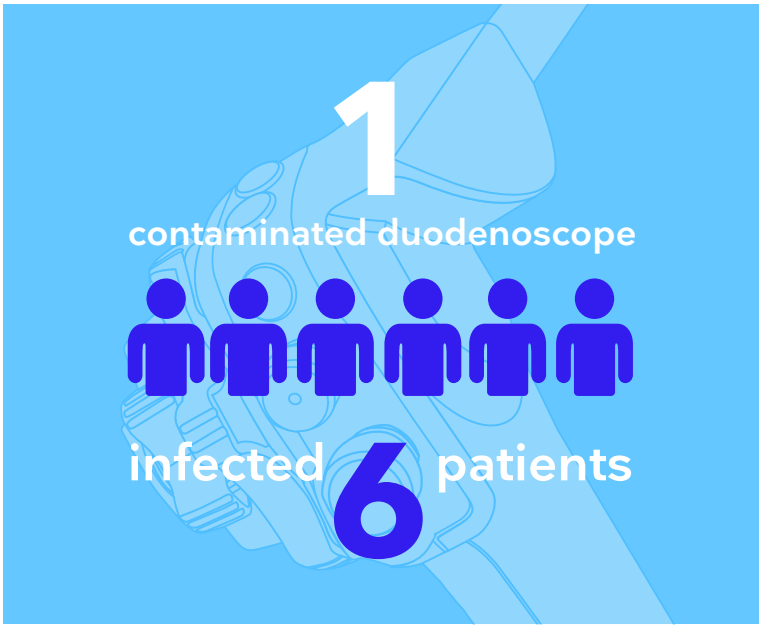
Kola et al., 2015

STUDY AIM

Carbapenemase-producing Enterobacteriaceae (CPE) have become a major problem for healthcare systems worldwide. While the first reports from European hospitals described the introduction of CPE from endemic countries, there is now a growing number of reports describing outbreaks of CPE in European hospitals. This study reports an outbreak of Carbapenem-resistant K. pneumoniae in a German University hospital, which was in part associated with duodenoscopy.

METHODS

- Medical records of patients with CRKP were reviewed. As the patients had also undergone ERCP, the endoscopy records were also inspected.
- Duodenoscopes were sampled by flushing each channel with sterile saline solution and swabbing the ends of the channels.



★★☆ Infection Control Not open access

TAKE AWAY

This outbreak was caused by a duodenoscope used for ERCP contaminated with an invasive, moderately virulent, biofilm-forming AK-Pae ST17 clone, suggesting the possible emergence of a new high-risk lineage of this clone. A total of five patients became infected and/or colonized.

KEY FINDINGS

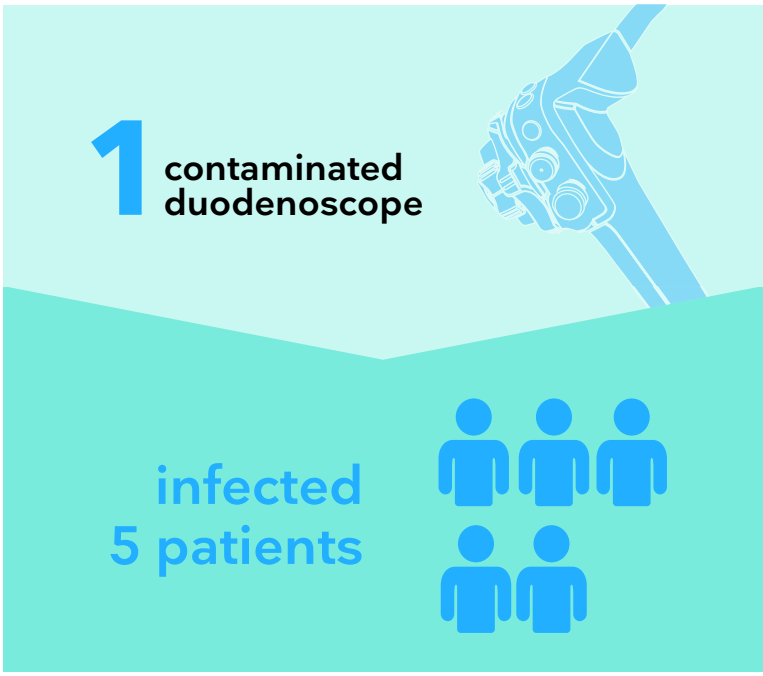
- **Two endoscopes were contaminated with AK-Pae.**
- **Isolates from one endoscope showed an identical pattern to 9 isolates (cluster I) and a different one (1-2 bands) to 5 isolates (cluster II).**
- **Isolates from these clusters belonged to the ST17 clone.**
- **This S17 clone was characterized by its low virulence in the C. elegans killing assay, and its biofilm-forming ability, slightly superior to that of high-risk clones of *P. aeruginosa* ST175 and ST235.**

Nosocomial Outbreak Linked to a Flexible Gastrointestinal Endoscope Contaminated With an Amikacin-Resistant ST17 Clone of Pseudomonas Aeruginosa, EJCMID[13]

Fernández-Cuenca et al., 2020

STUDY AIM

In August 2016, an unexpected increase in the incidence of amikacin-resistant *P. aeruginosa* isolates (AK-Pae) was observed at a tertiary care centre in the south of Spain. An epidemiological and microbiological investigation was performed to explain this finding.



METHODS

- Isolates from clinical and environmental samples (two endoscopes used for ERCP) were identified.
- Antimicrobial susceptibility testing was performed using the MicroScan system.
- Whole genome sequencing was performed to determine the resistome and virulome.
- Biofilm formation was performed using a colorimetric assay.
- Of the patients, four out of the five who were infected and/or colonized with AK-Pae in August 2016 had undergone ERCP <5 days before sample collection.

★★☆ 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 3 October 2014 and 28 January 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[14]

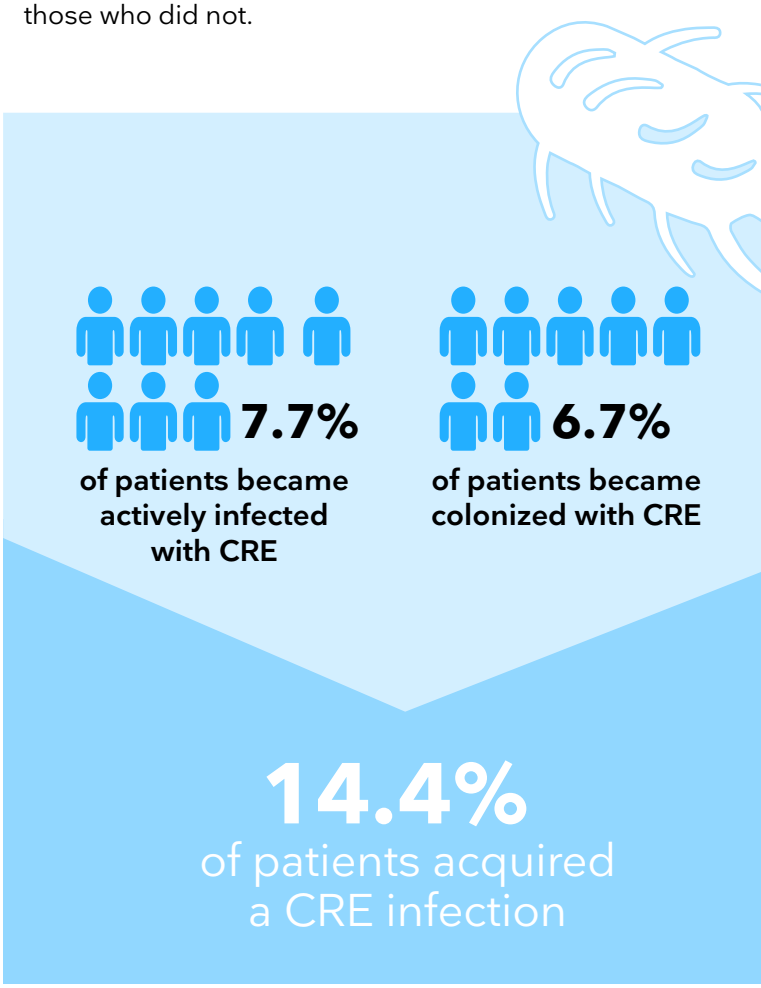
Kim et al., 2016

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 five 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 with 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[15]

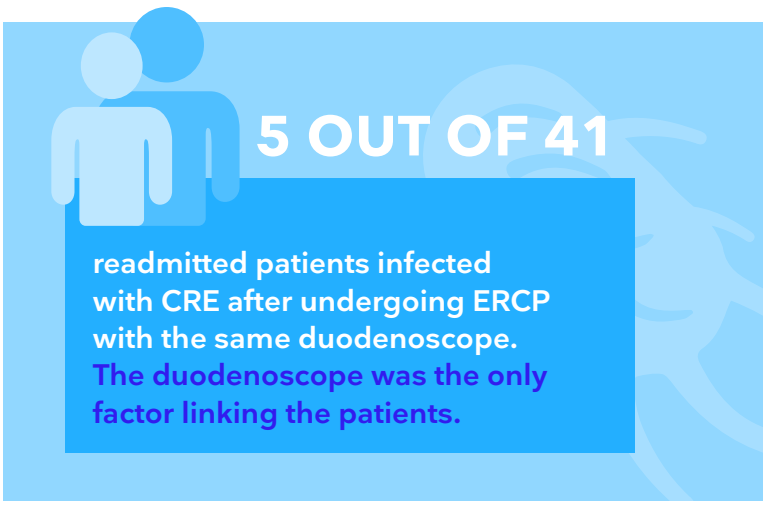
Bourigault et al., 2018

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 it 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.



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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 were infected with CRE during the outbreak, and two patient deaths were attributed to the CRE infection.

KEY FINDINGS

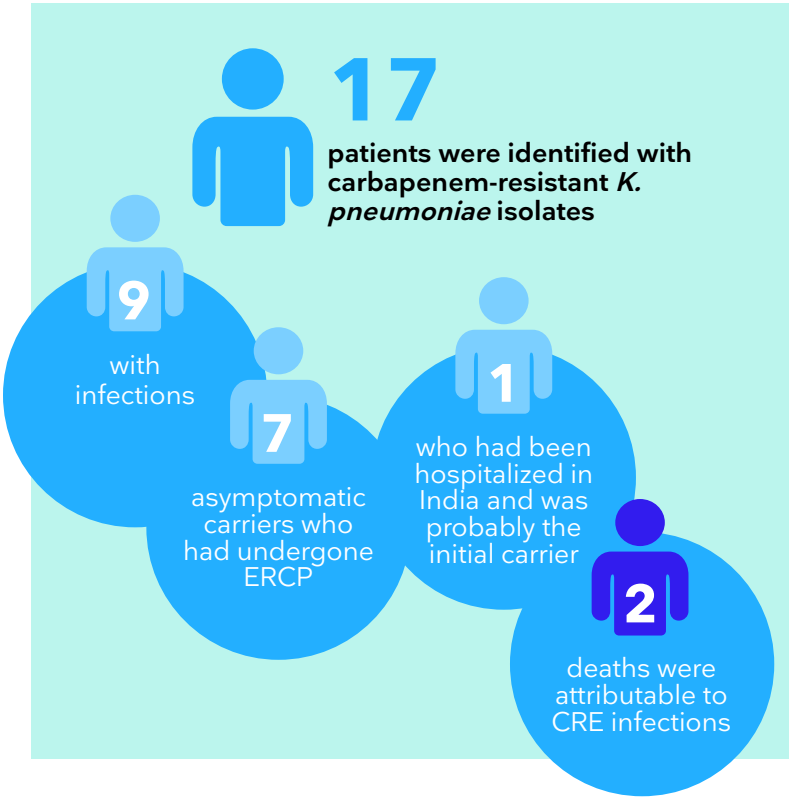
- **A total of 17 patients were identified with carbapenem-resistant *K. pneumoniae* isolates, including 9 with infections, 7 asymptomatic carriers who had undergone ERCP, and 1 additional patient who had been hospitalized in India and was probably the initial carrier.**
- **One year after the outbreak 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 from manufacturer recommendations for reprocessing.**

Duodenoscope-Related Outbreak of a Carbapenem-Resistant Klebsiella pneumoniae Identified Using Advanced Molecular Diagnostics, Clinical Infectious Diseases[16]

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 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[17]

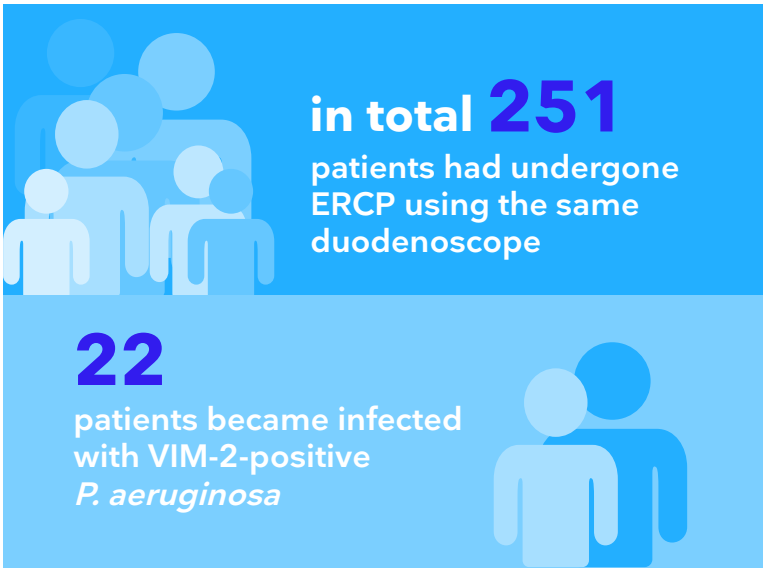
Verfaillie et al., 2015

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

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 manoeuvre 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[18]

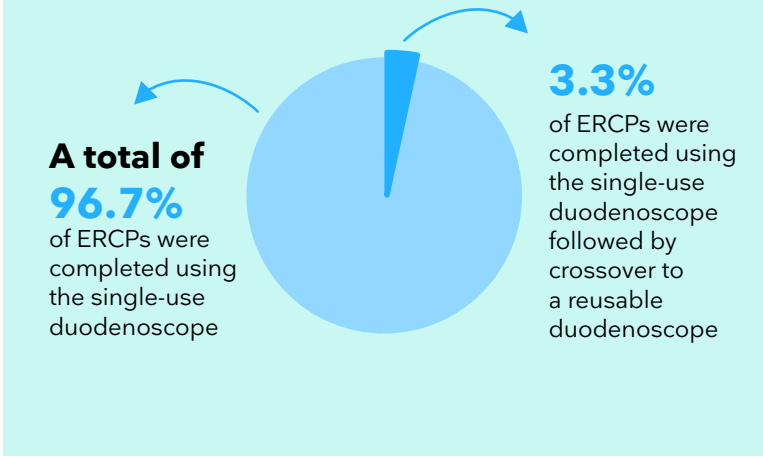
Muthusamy et al., 2020

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 centres 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 manoeuvres (duodenoscope navigation and visualization of duodenal papilla only) in 13 patients and ERCPs in the 60 other patients.
- Outcomes analysed 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

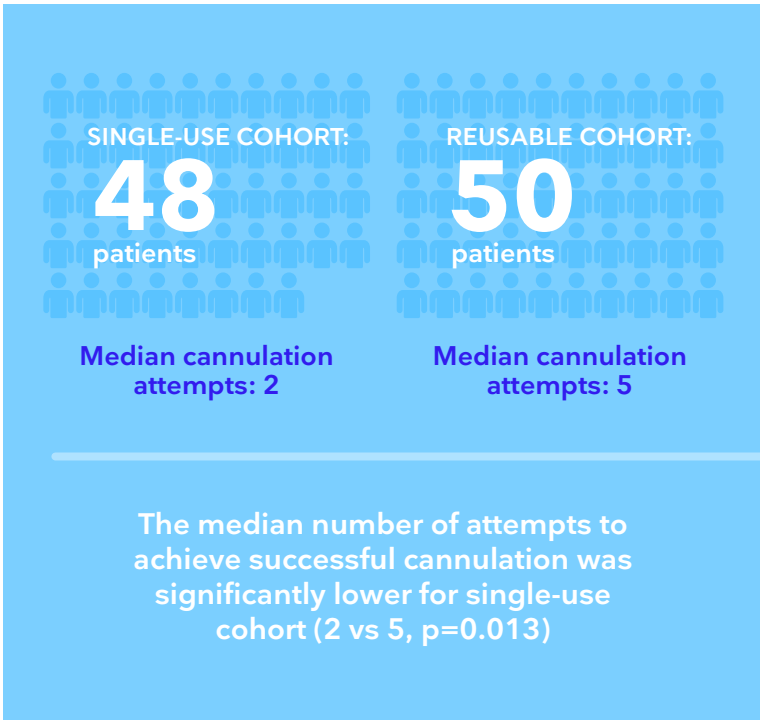
- **A total of 48 patients were treated using single-use duodenoscopes, and 50 patients were treated using reusable duodenoscopes, with >80% graded as low-complexity procedures.**
- **The median number of attempts to achieve successful cannulation was significantly lower for the single-use cohort (2 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 duodenoscopes.**
- **There was no significant difference between cohorts 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.**
- **On multivariate logistic regression analysis, only the single-use duodenoscope was associated with fewer 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[19]

Bang et al., 2020

STUDY AIM

This randomized controlled trial (RCT) compared the performance 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, which measured duodenoscope manoeuvrability, mechanical-imaging characteristics and the ability to perform therapeutic iinterventions, and the need for advanced cannulation techniques the need for to an alternate duodenoscope group to achieve ductal access and adverse events.

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 the 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 from 1% to 1.2%, respectively.**
- **For centres 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 centres performing 500 or more ERCPs annually, the incremental per-procedure cost ranges from $1,110.29 to $1,244.42 assuming a 1% infection risk. With a 1.2% infection risk, the per-procedure cost would increase by $94.36.**
- **The per-procedure cost is highly dependent on the annual procedure volume, the 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 recommends 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

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