EVIDENCE DOSSIER

Ambu® aScope™ 4 Broncho

Ambu

February 2023, 2nd edition

This document includes published peer-reviewed studies on clinical performance, infection control, contamination, cost-effectiveness and organizational impact related to the Ambu® aScope™ 4 Broncho.

CONTENTS

ABBREVIATIONS

AABIP: The American Association for Bronchology and Interventional Pulmonology

AAMI: The Association for the Advancement of Medical Instrumentation®

BAL: Bronchoalveolar lavage

CDC: Centers for Disease Control and Prevention

ECRI: Emergency Care Research Institute

FDA: U.S. Food & Drug Administration

FOB: Flexible fibre-optic bronchoscope

HICPAC: Healthcare Infection Control Practices Advisory Committee

HLD: High-level disinfection

ICU: Intensive care unit

MDR: Medical device report

MTG: Medical technology guidance

OI: Organizational Impact

SEPAR: Spanish Society of Pneumology and Thoracic Surgery

SPLF: French Language Society of Pneumology

SUFB: Single-use flexible bronchoscope

PREFACE

This dossier will help you get an overview of the clinical landscape related to Ambu® aScope™ 4 Broncho, a single-use bronchoscope. The introduction summarizes the Safety Communications the Food & Drug Administration (FDA) has issued regarding the risks of patient cross-contamination inherent to reusable bronchoscopes and Manufacturer and User Facility Device Experience (MAUDE) reports. The main section is comprised of studies published from January 2010 to January 2021 related to contamination, infectious outbreaks, clinical performance and health economics aspects of reusable bronchoscopes and single-use bronchoscopes. The last section offers an introduction to the benefits of aScope 4 Broncho.

Each study summary is true to the original publication, and a link to the original manuscript can be found in the references. 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 Russell (raru@ambu.com) or Global Health Economist Helena Travis (hetr@ambu.com).

The studies presented have been selected to provide an overview of the most impactful publications regarding aScope 4 Broncho.

The study titles are taken from the publications as they appear in their original form, allowing the reader to make an accurate internet search if they wish to find out more.

We hope this evidence dossier provides you with an understanding of the overall evidence landscape concerning aScope 4 Broncho 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

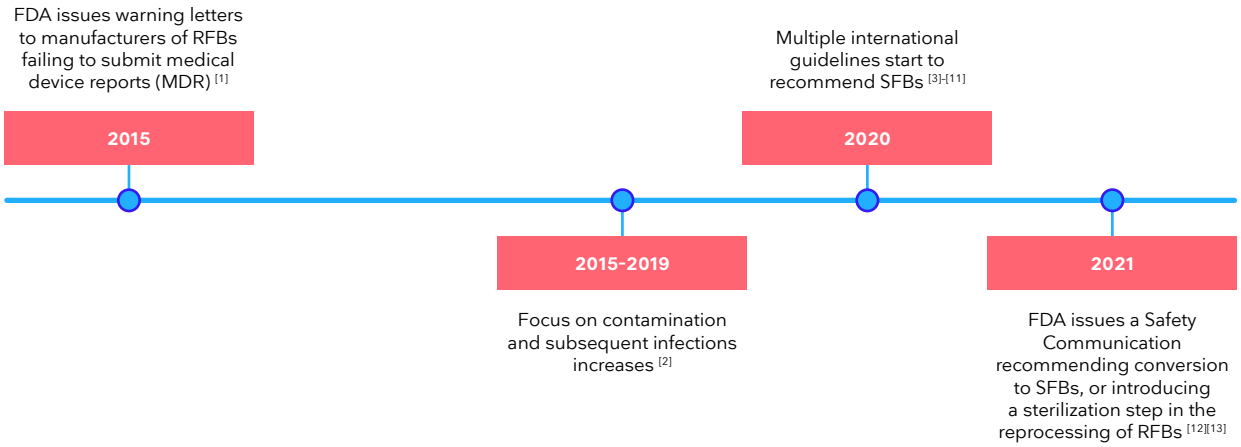
Ambu has been bringing the solutions of the future to life since 1937. Today, millions of patients and healthcare professionals worldwide depend on the efficiency, safety and performance of our single-use endoscopy, anaesthesia, and patient-monitoring diagnostics solutions. The manifestations of our 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 delivering innovative quality products, like aScope 4 Broncho, which have a positive impact on your work. As the world's leading supplier of single-use endoscopes, with more than 1 million scopes sold in 2020 alone, Ambu leads by example, offering a service to help you dispose of our bronchoscopes in the most cost-effective, risk-free and eco-friendly way possible.

Headquartered near Copenhagen, Denmark, Ambu employs approximately 4,200 people in Europe, North America and the Asia-Pacific region.

For more information, please visit ambu.com

FDA SAFETY COMMUNICATIONS

In recent years, the FDA has continually posted Safety Communications and Warning Letters related to reusable flexible endoscopes that potentially compromised patient safety.



UPDATED SAFETY COMMUNICATION, 25 JUNE 2021

On June 25, 2021, the FDA published a safety communication substantiating bronchoscope-associated cross-infection. To alleviate the cross-infection risk, FDA recommends introducing a sterilization step during the reprocessing of RFBs, and further that SFBs should be considered when there is an increased risk of spreading infection. The FDA gives five scenarios where there is an increased risk of spreading infection, and where SFBs should be considered [12]:

1. Multidrug resistant organisms (MDROs)
2. Immunocompromised patients
3. Patients with prion diseases
4. When there is limited support for reprocessing
5. When treating patients with the severe acute respiratory syndrome coronavirus 2 (COVID-19)

Read the full communication here

> **Consider using a single-use bronchoscope in situations where there is increased risk of spreading infection or when there is no support for immediate reprocessing of the bronchoscope**
>
> *U.S. Food and Drug Administration*

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 studies 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?

Two major scientific online databases, PubMed (MEDLINE) and Embase, were searched for all relevant articles up to 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 economic relevance were excluded. This document only includes studies published after 2013, in order to provide the reader with the most up-to-date studies.

This clinical evidence dossier includes summaries of 14 published peer-reviewed studies related to bronchoscopes and bronchoscopy procedures.

CLINICAL PERFORMANCE

★★☆ Clinical Performance | Not open access

TAKE AWAY

This study proves that there is high acceptance of Ambu® aScope™ 4 Broncho. Further, physicians prefer aScope 4 Broncho to their conventional reusable bronchoscope, both for intubation and bronchoscopy.

KEY FINDINGS

Overall, physicians had the following preference after conducting 175 intubations and bronchoscopy procedures: 103 (59%) preferred aScope 4 Broncho; 35 (20%) had no preference; and 37 (21%) preferred their conventional reusable bronchoscope.

After conducting 149 bronchoscopy procedures, physicians had the following preference: 86 (58%) of doctors preferred aScope 4 Broncho; 29 (19%) had no preference; and 34 (23%) preferred their conventional reusable bronchoscope.

After conducting 26 bronchoscope-assisted intubations, physicians had the following preference: 17 (65%) preferred aScope 4 Broncho; 6 (23%) had no preference; and 3 (12%) preferred their conventional reusable bronchoscope.

Evaluation of intubation and intensive care use of the new Ambu® aScope™ 4 Broncho and Ambu® aView™ compared to a customary flexible endoscope a multicentre prospective, non-interventional study[14]

Kriege et al. 2020

STUDY AIM

This study aims to compare the utility between the novel aScope 4 Broncho and the standard bronchoscope in a non-interventional study.

METHODS

- The study is an international, multicenter non-interventional study, investigating the user perspective on aScope 4 Broncho.
- During normal clinical procedures within the OR, ICU and ER, where a bronchoscopy was requested, the physician decided which bronchoscope they would use for the procedure.
- After the procedure, the physician filled out the case report form to evaluate the bronchoscope.

★★☆ Clinical Performance | Cost | Not open access

TAKE AWAY

Ambu® aScope™ 3 Broncho enabled an equivalent microbiological yield after bronchoalveolar lavage, while significantly reducing the delay from indication to procedure at a similar or lower direct cost of use.

KEY FINDINGS

The median interval between identification of the need-to-start of the procedure was shorter with single-use bronchoscopes (10 min) versus conventional bronchoscopes (66 min).

The direct cost of performing single-use bronchoscopy was similar to that of conventional bronchoscopy; however, if we include the cost of repair, cost of disinfection, and cost of remuneration for support staff such as technicians, involved in cases done on weekends and after office hours, single-use bronchoscopy is conceivably more economical. In addition, conventional bronchoscopy took longer, and also took a greater number of staff to organize in the ICU.

In terms of the use of single-use bronchoscopes for obtaining microbiological samples in the ICU, microbiological cultures were positive in 70% of cases. These rates were identical to samples obtained with conventional bronchoscopes.

Experience With the Use of Single-Use Disposable Bronchoscope in the ICU in a Tertiary Referral Center of Singapore[15]

Marshall et al. 2017

STUDY AIM

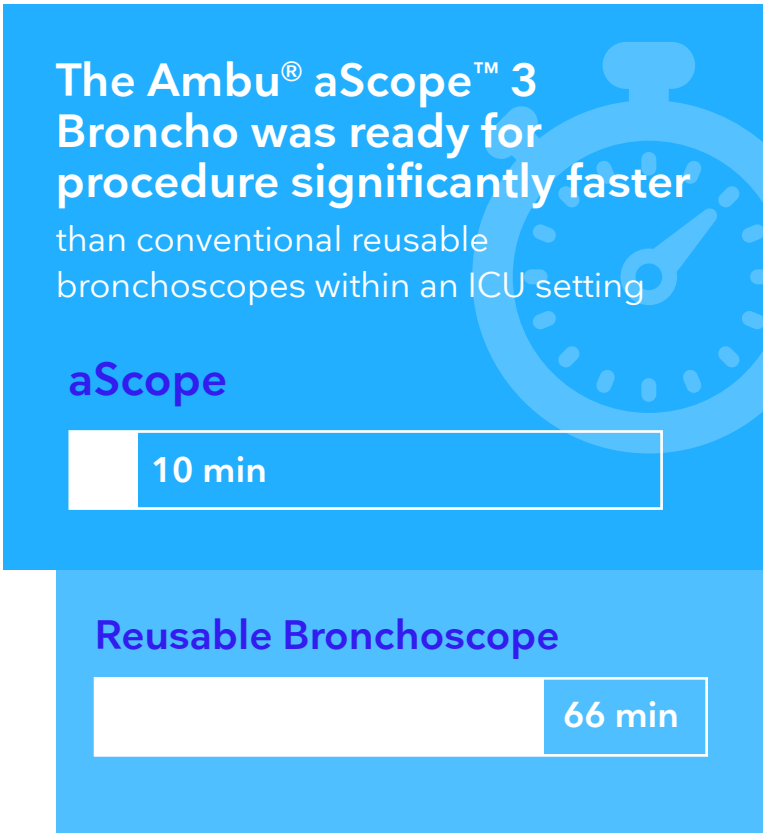
This study aimed to compare the utility of single-use bronchoscopes with conventional bronchoscopes in an ICU.

METHODS

- Medical records from the medical, surgical, cardiac and neuro-ICU wards in a hospital in Singapore were studied retrospectively. Data involved demographics, indications for procedure, and procedure outcomes.
- Devices included aScope 3 Broncho Regular 5.0/2.2 and Olympus BF-P190.
- For statistical analysis they used the SPSS, version 17 (SPSS, Chicago, IL) software The results were compared using either Wilcoxon 2-sample test or Fisher exact test. P-values were 2-sided and considered indicative of a significant difference if <0.05.

The Ambu® aScope™ 3 Broncho was ready for procedure significantly faster

than conventional reusable bronchoscopes within an ICU setting



★★★ Clinical Performance Open access

TAKE AWAY

Single-use bronchoscopes achieved a larger BAL volume yield than conventional bronchoscopes, with comparable cell yield and viability. Better volume yields can potentially reduce post-procedure side effects such as pleuritic chest pain and cough.

KEY FINDINGS

The median BAL volume yield from the single-use bronchoscopes was 152 mL (IQR 141- 166 mL) as compared to 124 mL (110- 135 mL), p < 0.01, from the conventional bronchoscopes. The greater BAL volume return achieved with single-use bronchoscopes could lead to reduced risk of post-procedure side effects such as cough, pleuritic chest pain and fever, which may improve tolerability and patient comfort.

The median total cell yield from single-use bronchoscopes was 7.33 × 10^6 (5.13 × 10^6- 9.80 × 10^6) compared with 7.0 × 10^6 (4.53 × 10^6- 1.64 × 10^7) for conventional procedures, p = 0.61.

Single use and conventional bronchoscopes for Broncho alveolar lavage (BAL) in research: a comparative study (NCT 02515591)[16]

Zaidi et al. 2017

STUDY AIM

This study aimed to compare the BAL volume yield, total cell yield and viability between samples obtained using single-use and conventional bronchoscopes.

METHODS

- At a hospital in Liverpool, UK, 10 healthy patients underwent bronchoscopy with aScope™ 4 Broncho Regular 5.0/2.2, and 50 healthy patients underwent bronchoscopy with a conventional bronchoscope.
- Warmed 0.9% saline was instilled to the right middle lobe in sequential aliquots (60, 50 and 40 mL), with aspiration into a sterile syringe using gentle manual suction. BAL yields were recorded, and the fluid was transported immediately to the laboratory on melting ice.
- BAL fluid was filtered through double-layered gauze to remove mucus plugs. Cells were pelleted by centrifugation (1500 rpm for 10 min at 4 °C) and washed with 50 mL cold RPMI medium (Gibco™ RPMI 1640 Medium) containing antibiotics.
- Primary outcome measures were compared with values from the preceding 50 conventional procedures using the Mann-Whitney U Test.

★★☆ Clinical Performance Open access

TAKE AWAY

The Ambu® aScope™ 4 scored well for ease of use, imaging and aspiration. They found a learning curve with excellent scores from the 9th procedure. Bronchoscopists highlighted its portability, immediacy of use, and the possibility of taking and storing images.

KEY FINDINGS

In more than 90% of the cases, all the pulmonary segments could be reached, and all the planned techniques could be performed, for a general level of satisfaction with the device of 86% and a recommendation for its use in similar cases.

300 procedures were performed in total. 282 bronchoscopies were satisfactorily performed with the single-use bronchoscope. In 6% of the procedures the specialists had to change the aScope for their usual bronchoscope.

The specialists rated the ease of intubation and maneuvering in the tracheobronchial tree as "very easy" (average score 8/10) and the image and aspiration quality as "optimal" (average score 8/10).

The learning curve showed excellent results from the 9th procedure.

Bronchoscopist's perception of the quality of the single-use bronchoscope (Ambu® aScope™ 4) in selected bronchoscopies: a multicenter study in 21 Spanish pulmonology services[17]

Flandes et al. 2020

STUDY AIM

The purpose of the study is to assess the quality of aScope 4 based on 300 bronchoscopies in 21 Spanish hospitals.

METHODS

- They evaluated the quality of the single-use aScope 4 bronchoscope by setting up a prospective, observational, multicenter, cross-sectional study in 21 Spanish pulmonology services.
- They used a standardized questionnaire completed by the bronchoscopists at the end of each bronchoscopy.
- The variables were described with absolute and relative frequencies, measures of central tendency and dispersion, depending on their nature.
- The existence of learning curves was evaluated by using the cumulative checksum analysis.
- All statistical methods were assessed via Microsoft Excel 2016 (Microsoft Corporation, Redmond, WA, USA) and STATA version 14.0 (StataCorp, Texas, USA).

GUARANTEED STERILITY

★★☆ Infection Not open access

TAKE AWAY

Bronchoscopes may pose an underrecognized potential for transmission of CRE and related MDROs.

KEY FINDINGS

This study identified cases that suggest the cleaning and HLD of bronchoscopes performed in accordance with published guidelines/standards and manufacturer instructions may not always be sufficiently effective to eliminate the risk of transmission of CRE and related MDROs, such as in an outbreak setting or if the bronchoscope is persistently contaminated with an inaccessible biofilm of carbapenem-resistant bacteria. Other identified factors that can adversely affect a bronchoscope's reprocessing include use of a damaged or improperly maintained and serviced bronchoscope.

Bronchoscope-Related "Superbug" Infections[18]

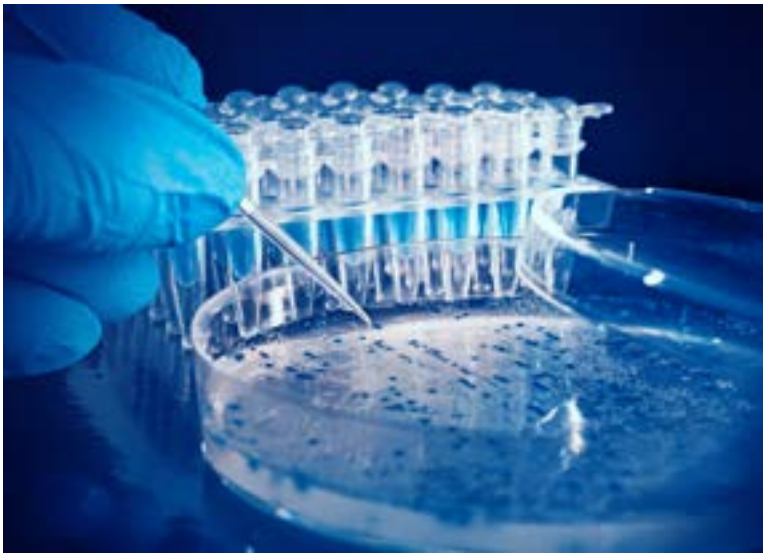
Mehta and Muscarella 2019

STUDY AIM

The primary aims of this review were to investigate the risk of bronchoscopes transmitting infections of CRE and related MDROs, and to assess whether supplemental measures might be advisable to enhance the safety and effectiveness of bronchoscope reprocessing.

METHODS

- They reviewed the available medical literature by searching the MEDLINE/PubMed database beginning in 2012, when endoscopy first emerged as a recognized risk factor for transmission of CRE.
- The FDA's Manufacturer and User Facility Device Experience database (MAUDE) was similarly searched to identify these same types of infections by using the product codes "EOQ" and "PSV", which the FDA uses to refer to bronchoscopes. The FDA's device recall database was also searched to determine whether any bronchoscope models associated with an infection of CRE or a related MDRO had been recently recalled due to a potential reprocessing or infection concern.
- The review focuses on "true" infections associated with flexible bronchoscopy and excludes cases involving a rigid bronchoscope or other types of microorganisms (e.g., mycobacteria and fungi).



★★☆ Contamination Not open access

TAKE AWAY

Researchers examined 24 clinically used bronchoscopes. After manual cleaning, 100% of bronchoscopes had residual contamination. Microbial growth was found in 14 fully reprocessed bronchoscopes (58%), including mold, Stenotrophomonas maltophilia,and Escherichia coli/Shigella species.

KEY FINDINGS

Researchers examined 24 clinically used bronchoscopes (nine therapeutic, nine pediatric, and six EBUS) and two newly acquired therapeutic bronchoscopes that had not been used or reprocessed. Protein was detected in samples from 100% of bronchoscopes after manual cleaning. Microbial growth was found in 14 fully reprocessed bronchoscopes.

Species identified post-HLD included environmental bacteria and normal flora (e.g., Bacillus spp., Staphylococcus epidermidis), as well as recognized pathogens (e.g., Stenotrophomonas maltophilia, Escherichia coli/Shigella spp.) and mold (Lecanicillium lecanii/Verticillium dahliae).

Researchers observed irregularities on all clinically used bronchoscopes. Internal examinations identified fluid, discoloration, scratches, filamentous debris, and dented channels. There did not appear to be an association between bronchoscope age, study site, and irregularities.

Effectiveness of Reprocessing for Flexible Bronchoscopes and Endobronchial Ultrasound Bronchoscopes[19]

Ofstead et al. 2018

STUDY AIM

To evaluate the effectiveness of real-world bronchoscope reprocessing methods, using a systematic approach.

METHODS

- This prospective study was conducted in three large, tertiary-care hospitals in the United States in 2017.
- Site personnel performed reprocessing in accordance with their institutional practices. Researchers maintained strict aseptic technique while obtaining samples after manual cleaning and post-HLD. Tests performed before and after HLD allowed evaluation of changes in organic residue levels after disinfection.
- Microbial culture samples were harvested from ports and distal ends, using sterile swabs moistened with sterile, deionized water that were placed into transport medium (480/482C ESwabs; COPAN Diagnostics). Channel effluent was obtained using the flush-brush- flush technique and channel swabs and effluent were placed into Dey-Engley neutralizing broth (Hardy Diagnostics). Samples were processed at FDA-registered, International Organization for Standardization–certified microbiology laboratories and incubated at 28° C to 32° C for 5 to 7 days. Species identification was performed for moulds and gram-negative bacteria.
- To confirm the validity of sampling and testing methods, clinically used gastroscopes were sampled for use as positive control subjects. Sterile materials were used as negative control subjects.

★★☆ Contamination Open access

TAKE AWAY

A total of 620 samples were obtained. 564 samples (91%) tested negative, and 56 samples (9%) tested positive for at least one specimen, of which 3% were pathogenic or potentially pathogenic microorganisms.

KEY FINDINGS

620 control samples for microbiology-culture tests were obtained from 18 different bronchoscopes: 13 from the Pneumology Department, 2 from the Intensive Care Department and 3 from the Anesthesia Department. 564 (91%) were negative for bacteria, mycobacteria and fungi, and 56 (9%) were positive for at least one specimen, of which 37 (6%) corresponded to alert level 1, 10 (1.6%) corresponded to alert level 2 and 9 (1.4%) corresponded to alert level 3.

Globally, the flushing of channels with 70% ethyl alcohol at the end of the disinfection process showed a significant reduction of level-2 and 3 alerts.

The mean annual cost of the surveillance program was estimated at 23,035 euros for sampling processing, which represented a mean cost of 111.5 euros per analyzed bronchoscope.

Microbiological monitoring of flexible bronchoscopes after high-level disinfection and flushing channels with alcohol: Results and costs[20]

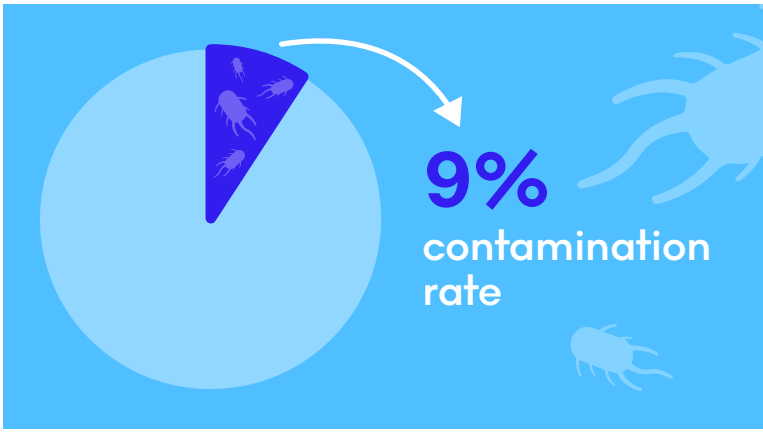
Gavaldà et al. 2015

STUDY AIM

The study aims to assess whether bronchoscope-reprocessing methods achieved an appropriate decontamination level and whether manual flushing of 70% ethyl alcohol at the end of the cycle reduces the risk of microbiological contamination.

METHODS

- During the study period all bronchoscopes were cultured on a monthly basis, provided that they were available. Main reasons for non-availability were bronchoscope in use or out of order. The cultures were obtained according to the recommendations of the Spanish Society of Pneumology and Thoracic Surgery (SEPAR).
- All the samples were handled by an infection control nurse and a technician under an aseptic process. The samples were obtained by a retrograde method, flushing 20 mL of sterile physiological saline through the working channel and waiting for 5 min before collecting the flow-through in three sterile containers to examine growing of bacteria, fungi and Mycobacterium species, respectively.
- When bronchoscope contamination with a relevant microorganism was reported by the Microbiology Department, the bronchoscope was taken out of use in patients, and a second sample was obtained. Bronchoscopes shown to be contaminated with the same microorganism in two consecutive cultures were kept out of clinical use and underwent exhaustive revision and sterilization by the manufacturer.



★★☆ Infection Open access

TAKE AWAY

In this study, 569 patients are contaminated by a bronchoscope, of whom 115 (20.21%) are showing symptoms of infection. Most of the infections are linked directly to a bronchoscope, which in most cases causes pneumonia.

KEY FINDINGS

Flexible endoscopes for therapeutic procedures (bronchoscopy) and reusable accessories, such as biopsy forceps, are used in sterile body cavities and should be classified as critical devices. They should be sterilized after each procedure.

Inadequate cleaning of flexible endoscopes has been frequently associated with microbial transmission during endoscopic procedures.

The true rate of transmission during endoscopy may go unrecognized because of technically inadequate surveillance, no surveillance at all, low frequency, or the absence of clinical symptoms.

Transmission of Infection by Flexible Gastrointestinal Endoscopy and Bronchoscopy[21]

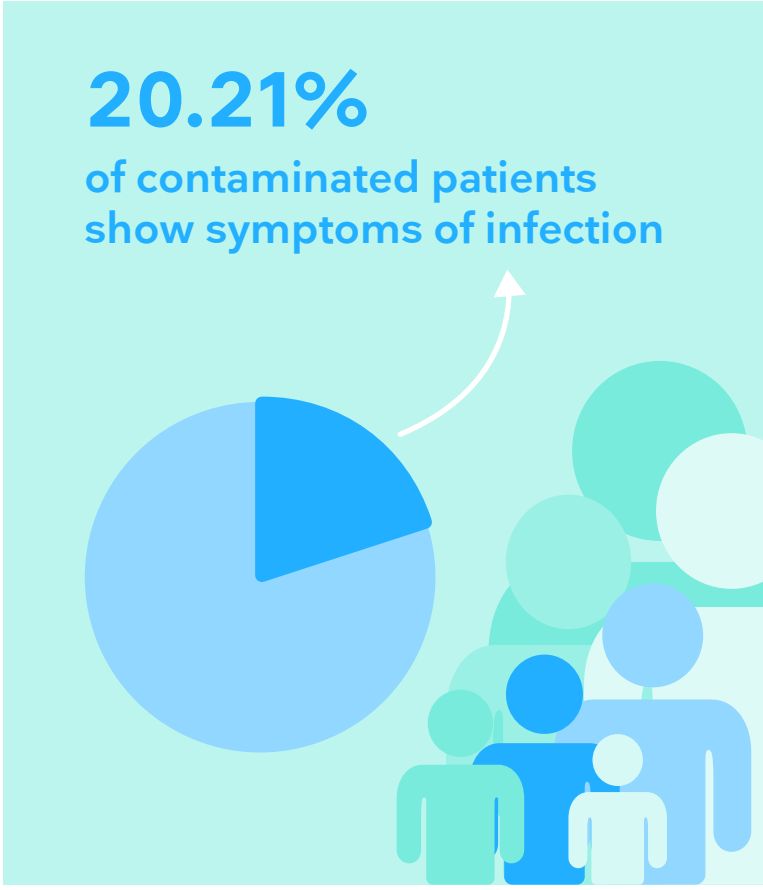
Kovaleva et al. 2013

STUDY AIM

The aim is to present an overview of the infections and cross-contaminations related to flexible bronchoscopy, and to illustrate the impact of biofilm on endoscope reprocessing and post-endoscopic infection.

METHODS

This review was conducted to create an overview of what has been published over time, in order to inform about contamination, infection, microorganisms, reprocessing methods, and reprocessing guidelines.



READY WHEN YOU ARE

★☆☆ Conta-mination | Infection | Costs | Open access

TAKE AWAY

Single-use bronchoscopes hold several advantages compared to reusable bronchoscopes, including decreased delay, cost, risk of nosocomial infection spread, and portability.

KEY FINDINGS

Single-use bronchoscopy allows for parallel as opposed to linear use in the respiratory suite, which can decrease delays between procedures and increase the number of bronchoscopies that can be performed.

Bronchoscopy is an aerosol-generating procedure associated with a high risk of viral transmission during the COVID-19 pandemic.

Single-use flexible bronchoscopes (SUFBs) can reduce the number of healthcare personnel exposed to SARS-CoV-2.

SUFBs have many advantages over their reusable counterparts.

Most of the studies on SUFB efficacy and cost-effectiveness have been in an anaesthetic setting.

We outline the benefits of SUFBs during the COVID-19 pandemic and provide a rationale for their more frequent use in the pulmonology suite.

Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy?[22]

Barron and Kennedy 2020

STUDY AIM

This study aims to outline the potential uses of the single-use bronchoscope in a respiratory setting, both during and after the current pandemic.

METHODS

This review was conducted in order to inform about the situation around a pandemic, and how pulmonologists could translate their new workflow into their everyday work setting.

COST-EFFECTIVENESS

★★☆ Cost-effectiveness Open access

TAKE AWAY

The findings from this study suggest benefits of single-use flexible bronchoscopes in terms of cost-effectiveness, cross-contamination and resource utilization.

KEY FINDINGS

Base-case results indicate a net saving of £291.00 to hospitals and an avoided risk of infection of patients undergoing bronchoscopy of 2.8% with single-use flexible bronchoscopes, compared with reusable flexible bronchoscopes.

The results from the micro-costing analysis revealed a mean (SE) capital cost per use of a reusable flexible bronchoscope at £116.40 (29.10), whereas the repair and reprocessing costs per use of a reusable flexible bronchoscope were estimated at £92.90 (23.20) and £39.90 (10.00), respectively. This equates to a total cost per use of a reusable flexible bronchoscope at £249.20.

In the cost-effectiveness analysis, they found reusable flexible bronchoscopes to have a mean (SE) cost per patient of £511.00 sterling (59.60), with an associated risk of infection of 2.8%.

A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes[23]

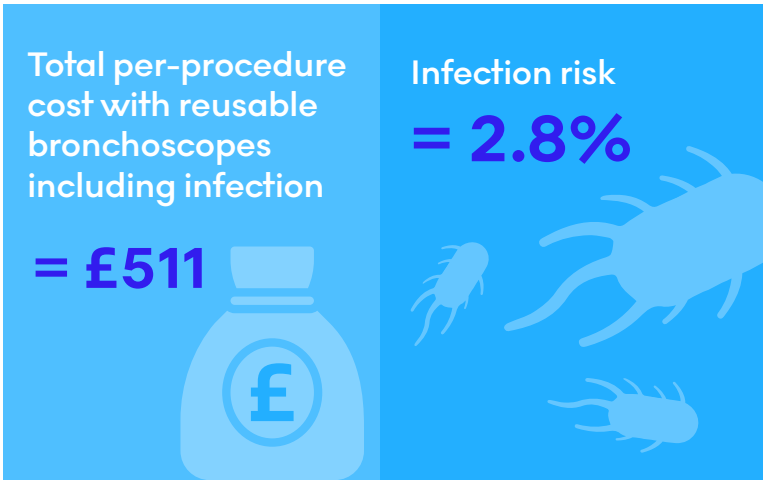
Mouritsen et al. 2019

STUDY AIM

This study aimed to determine the cost per use and cross-contamination risk of reusable flexible bronchoscopes, and to ascertain the cost-effectiveness of single-use flexible bronchoscopes compared with reusable flexible bronchoscopes in various clinical settings.

METHODS

- The preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidance was adhered to in the conduct of the systematic review. Given an evident risk of patient cross-contamination and infection with reusable flexible bronchoscopes.
- In the event of incomplete data on the number of bronchoscopic procedures and number of patients included, a simple regression method was applied to predict missing data.
- The effect measure was the risk of infection. The time horizon of the cost-effectiveness analysis was within 1 year. The micro-costing analysis was conducted at Guy's and St Thomas' NHS Foundation Trust Department of Anaesthesia.
- The modelling approach was based on principles of good practice for decision-analytic modelling in healthcare analyses and constructed using TreeAge (2016 version, TreeAge Software, MA, USA).
- Sensitivity analyses were undertaken to capture uncertainty within parameters and to provide sufficient insight for decision-makers.



★★☆ Cost-effectiveness Open access

TAKE AWAY

This study suggests that implementation of the single-use technology in the intensive care unit is cost-effective in most scenarios.

KEY FINDINGS

Estimates from the Delphi method found approximately a 3% risk of cross-contamination and approximately a 21% risk of subsequent infection related to reusable bronchoscopes. Pneumonia was estimated as the most likely manifestation of infection. The CEA showed a saving of $US118 per procedure and an elimination of 0.7% of the risk of infection with the single-use technology. Relevant sensitivity analyses generally validated this result.

Early Assessment of the Likely Cost Effectiveness of Single-Use Flexible Video Bronchoscopes[24]

Terjesen et al. 2017

STUDY AIM

This study aims to indicate whether implementation of a single-use flexible video bronchoscope (Ambu® aScope™ 3) is cost-effective when solely looking at cross-contamination and possible subsequent infections with bronchoscopes in a typical ICU setting, compared with current best practice involving reusable flexible video bronchoscopes.

METHODS

- They conducted a literature search using a mix of methods, primarily a PICO (population, intervention, comparator, outcome) search of PubMed, the Cochrane Library and Embase to find relevant data concerning cross-contamination and subsequent infection due to bronchoscopy. The literature findings support or validate the estimation of the risk of cross-contamination and infection for the estimates provided from a panel of experts using the Delphi method.
- The cost per procedure using a reusable flexible video bronchoscope was estimated based on literature findings.
- They constructed a decision-analytic model based on the best available evidence to estimate the short-term costs and benefits of single-use flexible video bronchoscopes compared with reusable flexible video bronchoscopes. The setting was a US hospital ICU. The time horizon was short (within 1 year). Costs were estimated in $US, year 2015 values. The model was drawn up in TreeAgePro 2014 with the Healthcare Module addition.
- They conducted several analyses to test the robustness of the base-case results with various sensitivity analyses.

★★☆ Cost Open access

TAKE AWAY

The study indicates that significant savings can be made by using single-use bronchoscopes to guide percutaneous dilatational tracheostomy (PDT) in preference to reusable bronchoscopes.

KEY FINDINGS

The mean cost per use of a reusable bronchoscope was estimated based on 11 studies, describing 4,476 procedures. The studies were from the US, the UK, France and Denmark and were published between 2011 and 2017. The mean acquisition cost for a reusable bronchoscope was calculated to be $US135 per use, with a mean reprocessing cost of $US123.

Ninety-nine completed responses were received from 366 questionnaires. A repair ratio of 1:27 (corresponding to 3.7%) was associated with a mean repair cost of $US3,530, giving a mean repair cost per PDT use of $US133.

The total cost per use of a reusable bronchoscope for PDT was calculated to be $US406, by combining acquisition, reprocessing and weighted mean repair costs.

The two-way sensitivity analyses indicated potential cost savings in different scenarios for the reusable bronchoscopes for PDT. The one-way sensitivity analysis using the range of identified purchase costs for single-use bronchoscopes demonstrated that single-use devices remained cheaper than reusable devices.

Cost Comparison of Single-Use Versus Reusable Bronchoscopes Used for Percutaneous Dilatational Tracheostomy[25]

Sohrt et al. 2019

STUDY AIM

This study aimed to calculate the cost of using single-use or reusable bronchoscopes per PDT procedure.

METHODS

- A systematic literature search, using a PICO approach, was conducted to identify articles assessing the cost of single-use and reusable bronchoscopes.
- Acquisition cost and reprocessing cost per bronchoscope use were extracted for all included papers. All costs were estimated in 2016 prices, and the calculated costs were presented as means (standard deviations) in United States Dollars ($US).
- Only costs that could be directly attributed to the use of bronchoscopes and costs that differed between single-use and reusable bronchoscopes were included. It was assumed that staffing and consumable costs related to conducting the procedure did not differ between devices.
- To gather PDT-specific data, a questionnaire regarding repair rates and the costs of reusable bronchoscopes used for PDT was conducted to supplement the estimation from the literature.
- Two-way sensitivity analyses were conducted to test the relationship between the cost of reusable and single-use bronchoscopes in two different scenarios.

★★☆ Cost-effectiveness Open access

TAKE AWAY

This CUA demonstrates that Ambu® aScope™ 4 Broncho is cost-effective in comparison to RFBs, and is associated with a cost saving of £211.12 and a small gain in QALYs (0.0105).

KEY FINDINGS

In the base-case analysis, the total cost and QALYs gained (discounted) regarding the aScope 4 Broncho and RFBs were estimated to be £220.00 and 1.59 QALYs, and £431.13 and 1.58 QALYs, respectively. This resulted in an incremental cost of -£211.12 (i.e., a saving) and an incremental QALY gain of 0.105 QALYs for the aScope 4 Broncho, indicating that the aScope 4 Broncho was dominant in the base case analysis.

The PSA scatterplot demonstrates that the aScope 4 Broncho was dominant in all iterations. The incremental costs ranged from -£22 up to -£424 per bronchoscopy procedure (i.e., the aScope 4 Broncho procedure was less costly than the RFB procedure).

Cost-Utility Analysis of the Ambu® aScope™ 4 Broncho Single-Use Flexible Video Bronchoscope Compared to Reusable Flexible Video Bronchoscopes[26]

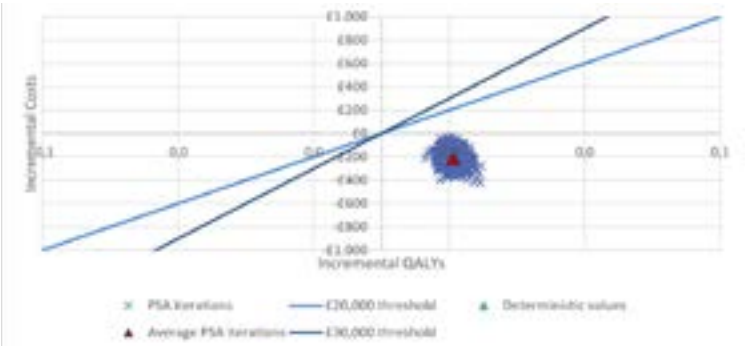
Mærkedahl et al. 2020

STUDY AIM

This study aims to evaluate the cost-utility of the aScope 4 Broncho compared to reusable flexible bronchoscopes (RFBs) from a UK National Health Service (NHS) perspective.

METHODS

- They developed a simple decision tree model to estimate the cost-utility of aScope 4 Broncho vs. RFB for bronchoscopy procedures in intensive care units (ICUs) for elective care patients.
- The model included costs from a UK third-party payer perspective within a 24-month time horizon.
- The model provided estimates of costs (e.g., acquisition, repair, reprocessing, and infections) and quality-adjusted life years (QALYs). All costs and QALYs beyond the first year were discounted at 3.5% in line with the NICE reference case.
- The model evaluated aScope 4 Broncho vs. RFB in two separate arms. Each arm had four possible and mutually exclusive outcomes: (1) no infection, (2) sepsis, (3) pneumonia, and (4) tuberculosis (TB). The probability of no infection was set to 1 minus the total probability of the three infection outcomes.
- As the aScope 4 Broncho has demonstrated equal performance to RFBs for bronchoscopy procedures, they assumed that both cohort pathways were identical, with the only differences being the costs associated with the use of each device, costs of infections, risks of infections, and the associated utility scores, based on health-related quality of life (HRQoL) scores.



ORGANISATIONAL IMPACT

★★★ Organizational impact Open access

TAKE AWAY

Organizational impact should be considered when assessing MDs. They show in this study that, from an organizational viewpoint, there are many advantages to using single-use bronchoscopes.

KEY FINDINGS

Process maps highlighted the complexity of the reusable device process when compared with the single-use device process.

Among the 12 types of OI, the single-use FB process scored better than the reusable FB process in 75% of cases.

With the "fleet" of 15 reusable FBs available in the institution, using single-use FBs would represent an extra cost of €154 per procedure.

Single-use and reusable devices would have the same cost (€232 per procedure) with a theoretical annual activity of 328 bronchoscopies, which is much lower than our current activity (1,644 procedures per year).

Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution[27]

Châteauvieux et al. 2018

STUDY AIM

The aim of this study was to assess, at a hospital level, the organizational and economic impacts of the introduction of a new medical device, specifically the single-use flexible bronchoscope (FB).

METHODS

- Both the organizational and economic impacts of the single-use FB were evaluated in comparison with the reusable FB.
- Based on the 12 types of OI defined by Roussel et al., interviews were conducted with all stakeholders, and the positive and negative aspects of the reusable and single-use processes were analysed.
- Micro-costing analysis was conducted to determine the most economical balance in the use of the two technologies.

ENVIRONMENTAL IMPACT

★★☆ Environmental impact Open access

TAKE AWAY

Using one set of PPE per reprocessing, along with the materials for cleaning and disinfection, determines that RFBs have comparable or higher material and energy consumption, as well as higher emissions of CO_2 equivalents.

KEY FINDINGS

- **The materials used for the cleaning operations of the RFBs are a key factor affecting the assessed aspects: energy consumption and emission of CO_2 equivalent.**
- **Using one set of PPE per reprocessing, and the materials for cleaning and disinfection, determines that reusable scopes have comparable or higher material and energy consumption, as well as higher emissions of CO_2 equivalents.**
- **The three assessed parameters are highly dependent on the cleaning procedure and the use of PPE.**

Comparative Study on Environmental Impacts of Reusable and Single-Use Bronchoscopes[28]

Sørensen et al., 2018

STUDY AIM

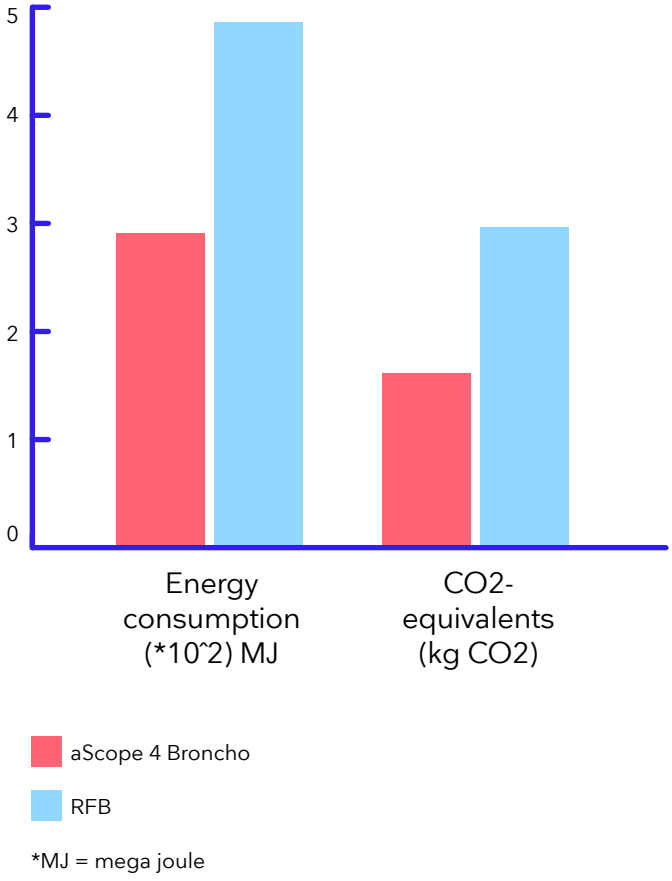
This study aims to compare CO_2 equivalent emissions and energy consumption from a SFB (Ambu® aScope™ 4 Broncho) with an RFB.

METHODS

- The comparison is made using a simplified life-cycle-assessment methodology.
- The assessment compares:

  The use and disposal of one aScope 4 Broncho with the cleaning and sterilisation of one conventional RFB, including PPE.

Resource consumption



*MJ = mega joule

ENVIRONMENTAL INITIATIVES

TAKING A STAND ON THE ENVIRONMENT

As the world's largest supplier of single-use endoscopes, Ambu want to act responsibly. Current regulations prevent Ambu and the end user from recycling the materials used in endoscopes due to the possibility of cross-contamination. The hazardous waste must be burned or sterilized before being disposed of in a landfill. That is why we work towards materials that enable the recycling of our products, and thus contribute to a circular economy. These actions include targets, like recyclable secondary packaging, goals we've already achieved, like phthalate-free products, and other sustainability projects like our partnership with Plastic Bank®.

100% **recyclable, reusable or compostable** packaging by 2025*

*if solutions and/or technology exist

Mapping our existing packaging material down to the specific type and following our circular design principles enables us to develop the best possible packaging solution.

Our products are **100% phthalate-free**

This achievement is the result of many years of dedicated work, collaboration and the prioritisation of safety for patients and healthcare professionals.

Ambu and Plastic Bank®

Our partnership with Plastic Bank, is one example of how we contribute to the circular economy. Plastic Bank is an organisation that builds ethical recycling ecosystems and reprocesses the materials for reintroduction into the global manufacturing supply chain.

A plastic-neutral partnership

Our partnership with Plastic Bank ensures that Ambu® aScope™ endoscopes are plastic neutral in EMEA and Latin America.

- Collectors gather plastic waste that otherwise would have ended up in the ocean in exchange for a premium.
- The plastic is reprocessed for reintroduction into the global manufacturing supply chain.
- The quantity of plastic collected corresponds to the amount of plastic used in all of the Ambu single-use aScope products in EMEA and Latin America throughout the year.

Read about all our Environmental Initiatives here:
www.ambu.com/sustainability

Ambu® aScope™ 4 Broncho

Choosing Ambu® aScope™ 4 Broncho is about improving patient safety and workflow. It is about ensuring immediate access to a flexible bronchoscope and eliminating the risk of cross-contamination. It is about delivering clear, sharp imaging and easy navigation during your bronchoscopy procedures. aScope 4 Broncho comes in three sizes in one system at no additional cost:

Ambu® aScope™ 4 Broncho Slim

Ambu® aScope™ 4 Broncho Regular

Ambu® aScope™ 4 Broncho Large

The risk of cross-contamination is completely avoided by ensuring that optimal steps to safeguard the patient are taken. The single-use scope is easy to set up and requires zero handling or reprocessing after use. As a result, the risk of sample loss and contamination is reduced.

Ready when you are
Reduces the risks and frustrations associated with waiting for an available endoscope. aScope 4 Broncho can be stored directly in the units.
The aScope 4 Broncho single-use bronchoscopy solution is portable, easy to set up and intuitive to use, thus saving valuable time.

Sterile straight from the pack
There is growing concern that even with the most stringent high-level disinfection procedures, sterility cannot be assured. This potentially puts the patients at risk.
With the aScope 4 Broncho solution, there is a brand-new, sterile bronchoscope straight from the pack every time.

Hassle-free bronchoscopy solution
An integrated solution that helps deliver the very best in-patient care.

KEY FEATURES:

Hassle-free solution: Fully integrated, easy-to-set-up, closed-loop system with three models at no additional cost
Guaranteed sterility: No risk of cross-contamination
Brand new every time you use it: A single-use solution improves patient safety
Ready when you are: Portable, intuitive, lightweight and ergonomic
Cost-effective: No handling, zero reprocessing, nothing to repair
High-quality bronchoscopy: Clear, crisp images and smooth and easy navigation

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