CLINICAL EVIDENCE DOSSIER

Ambu® aScope™ 4 RhinoLaryngo

Ambu

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This document includes published studies on rhinolaryngoscope performance, sterility, cost-effectiveness, and COVID-19 implications. The studies support claims related to Ambu aScope 4 RhinoLaryngo single-use endoscopes.

CONTENTS

PREFACE

Ambu aScope RhinoLaryngo is a sterile single-use rhinolaryngoscope that eliminates patient cross-contamination. aScope RhinoLaryngo eliminates the need for complex reprocessing and ongoing repairs.

The design of aScope RhinoLaryngo is based on the latest conventional rhinolaryngoscopes, and the familiar form and function delivers consistent performance.

This dossier provides an overview of the evidence related to aScope RhinoLaryngo. A systematic literature search was conducted to obtain a balanced and impartial overview of the data. It is comprised of studies published from 2010 to 2020 related to performance, sterility, cost-effectiveness, organizational impact, and COVID-19 implications.

A HISTORY OF BREAKTHROUGH IDEAS

Ambu has been bringing breakthrough healthcare solutions to life since 1937. Today, millions of patients and healthcare professionals worldwide depend on the efficiency, safety and performance of our single-use endoscopy, anesthesia, and patient monitoring diagnostics solutions. Our efforts have evolved from early innovations like the Ambu Bag™ resuscitator and the Ambu BlueSensor™ electrodes to our newest landmark solutions like aScope Broncho – the world's first single-use bronchoscope. Moreover, we continuously look to the future with a commitment to deliver innovative, high-quality products. Ambu leads by example by offering eco-friendly product disposal, all while remaining cost-effective to the consumer.

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

For more information, please visit www.SingleUseEndoscopy.com. or www.AmbuUSA.com.

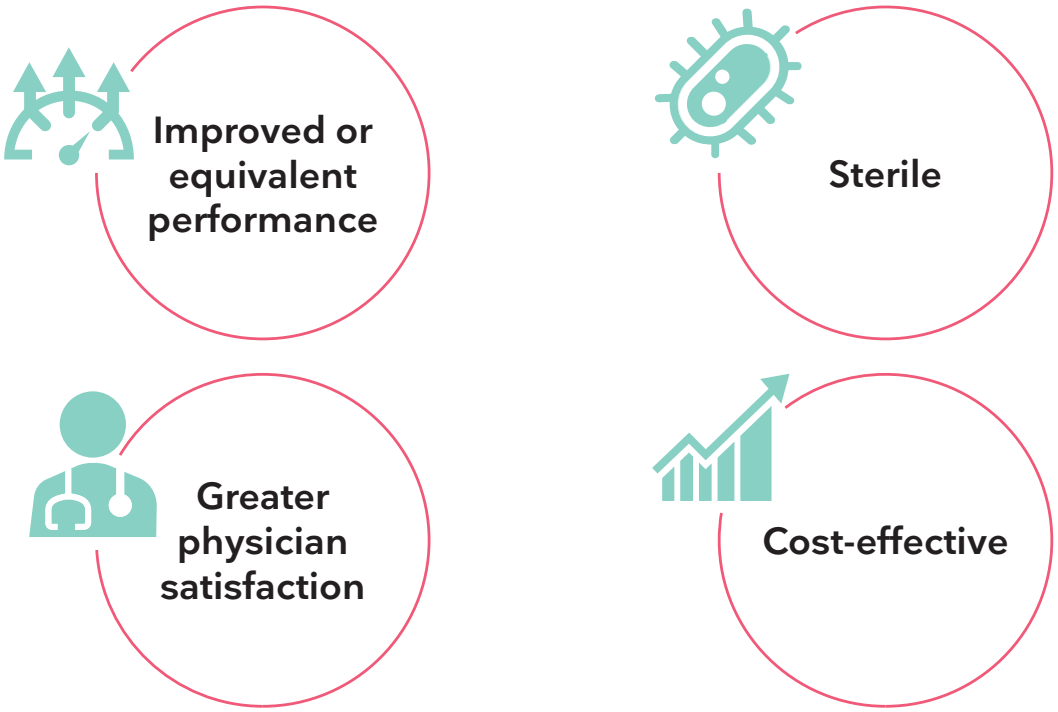
SUMMARY OF EVIDENCE

Ambu entered the field of ENT (Ear, Nose, Throat) in 2019 with the launch of the aScope 4 RhinoLaryngo. Since then, Ambu has increased its market share in the United States as the market continues to transition to single-use rhinolaryngoscopy to avoid costly and unnecessary expenses associated with mitigating cross-contamination.

The purpose of this dossier is to provide a comprehensive resource to describe the value of aScope RhinoLaryngo. The dossier provides a summary of performance, sterility, cost-effectiveness, and COVID-19 implications.

The studies included in this dossier demonstrate:

- The aScope RhinoLaryngo can successfully replace reusable rhinolaryngoscopes for flexible ENT procedures.[8]
- aScope RhinoLaryngo received high ratings from physicians in image quality, maneuverability, ergonomics, and overall impression.[2]
- Over one third of reusable nasopharyngoscope device failures involved contamination.[7]
- Even properly reprocessed reusable rhinolaryngoscopes cannot guarantee sterility and can lead to infection.[3]
- Single-use rhinolaryngoscopes have the potential to reduce the risk of COVID-19 transmission by eliminating reprocessing, an aerosol-generating procedure.[6]
- aScope RhinoLaryngo is often the cost-effective option for facilities when compared to reusable rhinolaryngoscopes.[8,9]



SYSTEMATIC LITERATURE REVIEW

SUPPORTING EVIDENCE-BASED PRACTICE WITH THE BEST AVAILABLE EVIDENCE

Quality of the studies

LOW QUALITY OF EVIDENCE

- 5-10 years old
- Commentary
- Weak external validity to the United States
- Small sample size

MEDIUM QUALITY OF EVIDENCE

- 1-5 years old
- Case control and cohort studies
- Moderate external validity to the United States
- Medium sample size

HIGH QUALITY OF EVIDENCE

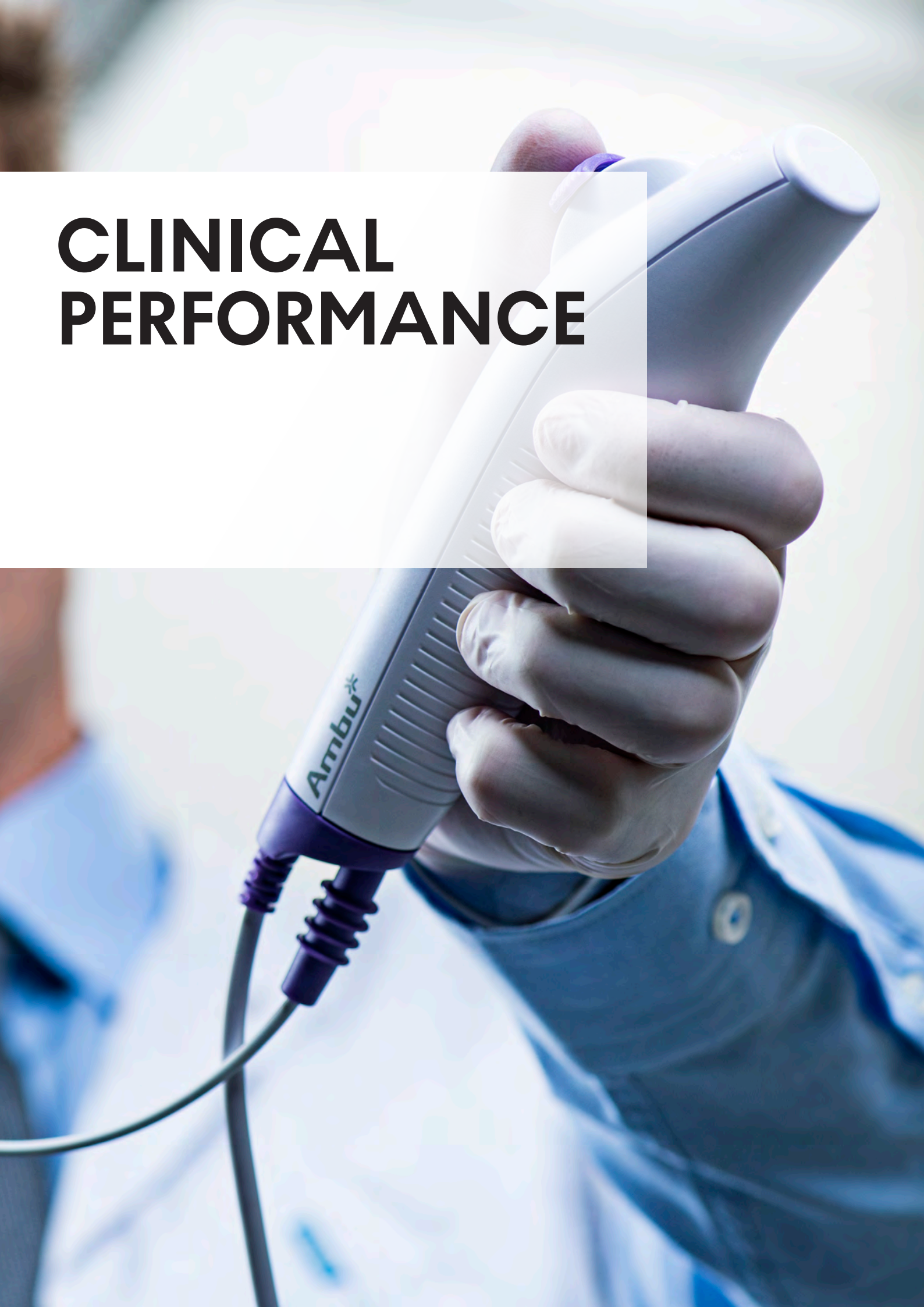
- Published in the last year
- Prospective or randomized studies/models and meta analyses
- Strong external validity to the United States
- Large sample size

HOW WERE THE STUDIES IN THIS DOSSIER SELECTED?

Two major scientific online databases, PubMed (MEDLINE) and Embase, were searched for all relevant articles from 2010 to 2020. Articles published in the English language within the areas of infection control, performance and health economics were included.

This evidence dossier includes summaries of 9 published studies related to rhinolaryngoscopes.

CLINICAL PERFORMANCE



Clinical performance | Not open access

First experiences with a new flexible single-use rhino-laryngoscope with working channel - a preliminary study

Becker et al., 2019

TAKEAWAY

aScope 4 RhinoLaryngo can be a good alternative to conventional laryngoscopy systems.

KEY FINDINGS

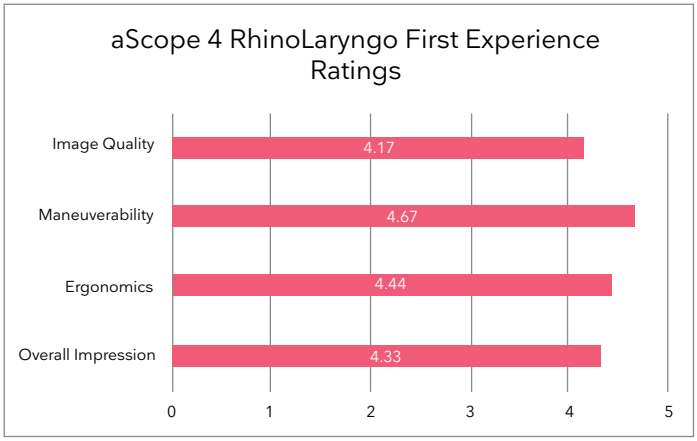
- **The following scores were reported (1-very poor, 2-poor, 3-acceptable, 4-good, 5-very good):**
  - **Image quality: 4.17 ± 0.38**
  - **Maneuverability: 4.67 ± 0.49**
  - **Ergonomics of the handle: 4.44 ± 0.51**
  - **Overall impression: 4.33 ± 0.49**
- **Two thirds of examiners mentioned the ease of storing pictures and videos on the monitor.**

STUDY AIM

To assess first impressions of flexible single-use rhinolaryngoscopes.

METHODS

- Ten patients with an indication for a rhinolaryngoscopy were examined with the aScope 4 RhinoLaryngo Intervention by 6 different examiners in 18 procedures.
- After the procedure, examiners had to fill out a questionnaire concerning image quality, maneuverability, ergonomics of the handle, and overall impression of the system on a 5-point scale (1-very poor, 2-poor, 3-acceptable, 4-good, 5-very good).
- Examiners were given the opportunity to comment on the system.



CONTAMINATION AND INFECTION

Contamination and infection | Not open access

Microbiological Sampling of Common Otolaryngological Office Equipment: What Lessons Can We Learn?

Bhatt et al. 2013

TAKEAWAY

Stricter protocols for cleaning the laryngoscope eyepiece, handle, and light cords are needed to minimize harmful organism growth after reprocessing.

KEY FINDINGS

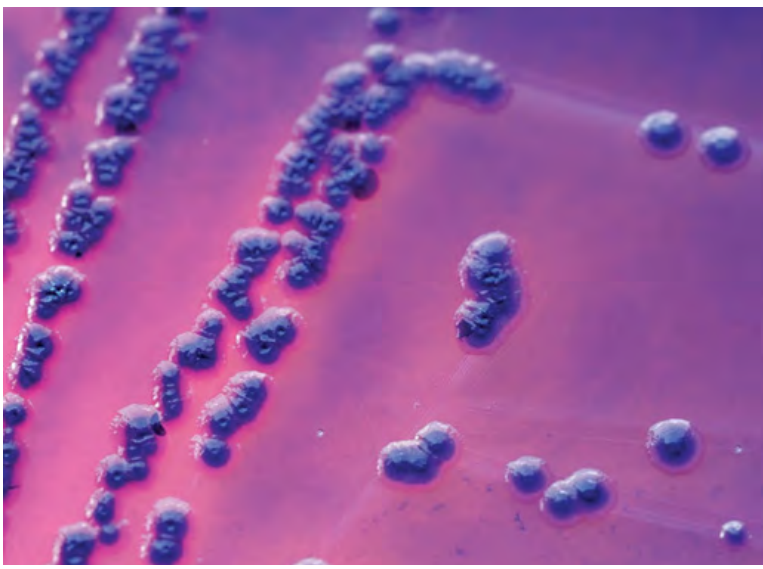
- **Bacterial growth was identified on 7 of 17 (41%) collected samples.**
- **60% of light cables, 17% of driver handles, and 50% of eyepieces were identified with positive bacterial cultures.**
- **Common bacterial isolates identified were:**
  - ***Corynebacterium***
  - **Bacillus species**
  - **Gram-negative rod**
  - ***Staphylococcus***

STUDY AIM

To analyze whether standard decontamination protocols are effective in cleaning integral components of common otolaryngological office equipment, including flexible fiberoptic laryngoscopes, detachable light cables, and otoscope handles.

METHODS

- A random microbiological sampling of 6 flexible fiberoptic laryngoscopes including the eye piece and the driver handle, 3 light cables, and 5 otoscope handles was performed.
- All scopes underwent the clinic's cleaning protocol: debridement with an enzymatic sponge of the shaft and body, tap water rinse, and immersion of the shaft in Cidex (2.5% glutaraldehyde), followed by air drying.
- Samples were delivered within 1 hour of collection to the UC Irvine Medical Microbiology Laboratory, for culturing and incubation.



Contamination and infection | Not open access

A comparison of two methods for preventing cross-contamination when using flexible fiberoptic endoscopes in an otolaryngology clinic: disposable sterile sheaths versus immersion in germicidal liquid

Elackattu et al. 2010

TAKEAWAY

Individually packaged disposable sterile sheaths on fiberoptic nasopharyngolaryngoscopes help prevent microbes from adhering to the shaft of the scope, mitigating infection risks.

KEY FINDINGS

- The post-disinfection microbial count for scope handles was 1/50 for the disposable sheath group and 4/50 for the immersion group.
- The post-disinfection microbial count for scope shaft was 1/50 for the disposable sheath group and 0/50 for the immersion group.
- Time spent using the sheath method averaged 89 seconds, whereas the immersion method took 14 minutes.

STUDY AIM

To assess the efficacy of using a sterile sheath to prevent cross-contamination when using a fiberoptic nasopharyngolaryngoscope in an otolaryngology clinic.

METHODS

- Prospective controlled trial.
- 100 nasopharyngolaryngoscopes were disinfected according to recommended guidelines and split into either a sheath alone group (experimental) or germicidal immersion reprocessing group (control).
- Swabs were taken before and after use in a patient from multiple sites to detect the presence of bacteria, viruses, or both.

Contamination and infection | Not open access

A Manufacturer and User Facility Device Experience Analysis of Upper Aerodigestive

Jiang et al. 2020

TAKEAWAY

Although the rates of contamination were comparable across all endoscope categories, nasopharyngoscope contamination was less commonly associated with patient harm or death than bronchoscopes or duodenoscopes.

KEY FINDINGS

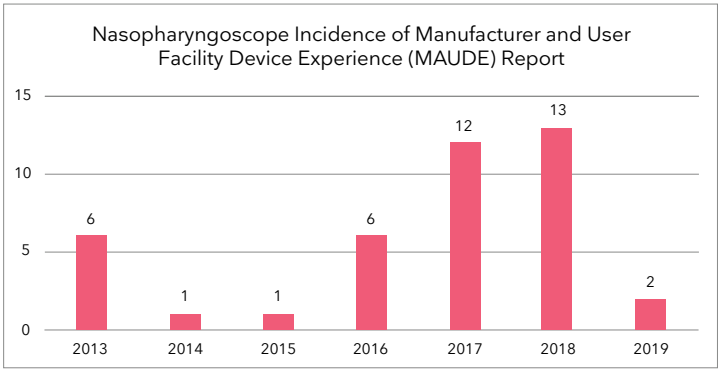
- **Nasopharyngoscope device failures were reported at an incidence of 0.64 cases per month. Bronchoscope, duodenoscope, and gastroscope failure were reported at incidences of 14.23, 28.08, and 4.34 cases per month, respectively.**
- **34% of device failures involved contamination, which is comparable to the frequency observed for bronchoscopes (23.4%, p = 0.118), duodenoscopes (29.2%, p = 0.493), and gastroscopes (45.3%, p = 0.178).**
- **Nasopharyngoscopes were significantly less associated with patient harm or death than bronchoscope (OR = 10.2) and duodenoscope (OR = 4.81) cases.**

STUDY AIM

To quantify nasopharyngoscope microbial contamination relative to that of other endoscope categories and characterize the manufacturers, outcomes, and microbial profiles associated with these cases.

METHODS

- Retrospective, cross-sectional study.
- 3,865 adverse events were collected from 2013 to 2019 using the US Food and Drug Administration Manufacturer and User Facility Device Experience database
- 3,027 reports were compiled after filtering.
- The fraction of total device failures associated with contamination was quantified for nasopharyngoscopes, bronchoscopes, duodenoscopes, and gastroscopes.
- Odds ratios of nasopharyngoscope contamination compared to that of bronchoscopes, duodenoscopes, or gastroscopes were calculated.



COVID-19

Covid-19 Open access

Moving Forward with Dysphagia Care: Implementing Strategies during the COVID19 Pandemic and Beyond

Fritz 2020

TAKEAWAY

Flexible endoscopic evaluation of swallowing and flexible laryngoscopy are problematic due to possible aerosol and droplet generation due to cough, gag or sneeze.

KEY FINDINGS

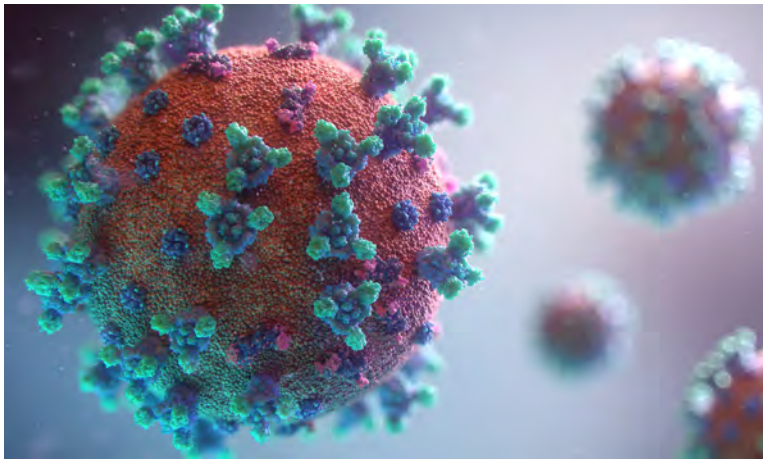
- **Disposable laryngoscopes should be considered to help reduce COVID-19 infection.**
- **In areas with high prevalence of SARS-CoV-2, infection should be suspected in asymptomatic patients, and flexible laryngoscopy should only be performed when findings would have an immediate impact on patient management.**
- **Physicians should utilize telemedicine when possible.**
- **To reduce risk to patients and clinicians, clinicians performing flexible endoscopic evaluation of swallowing are advised to don full PPE, including N95 masks, face shields, gowns, and gloves, even in facilities without any positive cases, as there is still a risk for community spread.**

STUDY AIM

To create a clinical algorithm and reference for dysphagia clinicians across clinical settings to minimize spread of COVID-19 cases while providing optimal care to patients suffering from swallowing disorders.

METHODS

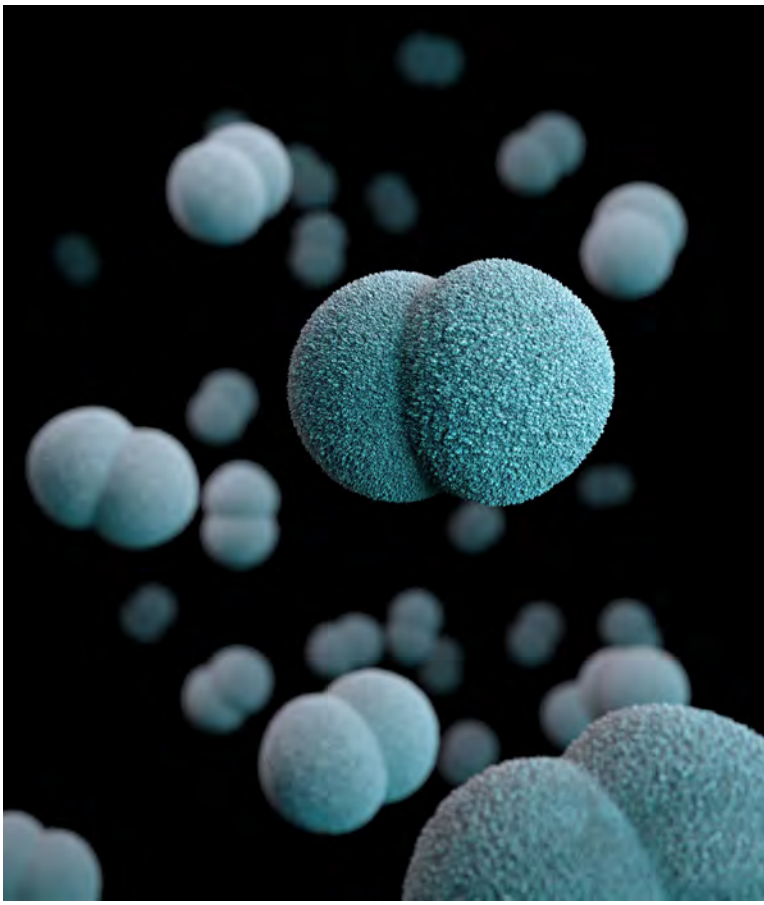
- A systematic review of literature and information at the time of publication.



Covid-19 Open access

COVID-19 Pandemic: Effects and Evidence-Based Recommendations for Otolaryngology and Head and Neck Surgery Practice

Kowalski et al. 2020



TAKEAWAY

All interventions that have the potential to aerosolize aerodigestive secretions should be avoided or used only when mandatory.

KEY FINDINGS

- **Health workers who are: pregnant, over 55 to 65 years of age, with a history of chronic diseases should avoid the clinical attention of a potentially infected patient.**
- **Health care facilities should prioritize urgent and emergency visits and procedures until the present condition stabilizes.**
- **Truly elective care should cease and be discussed on a case-by-case basis for patients.**
- **Rigorous adherence to infection control measures and attention to rapidly changing policies and procedures is essential to mitigate the spread of this disease.**
- **All airway management tools must be disposable and available including a video laryngoscope with disposable blades, and devices for needle or scalpel cricothyroidotomy.**

STUDY AIM

To present evidence-based COVID-19 recommendations for otolaryngology and head and neck surgery practices.

METHODS

- A review of literature, reports, and recommendations from around the world.

Covid-19 Open access

COVID-19 Pandemic: Effects and Evidence-Based Recommendations for Otolaryngology and Head and Neck Surgery Practice

Krajewska et al. 2020

TAKEAWAY

Ear, neck, and throat specialists are at a very high risk of COVID-19 infection while performing examinations and surgeries. Strict and proper guidelines must be put in place to help reduce possible exposure and infection of the virus.

KEY FINDINGS

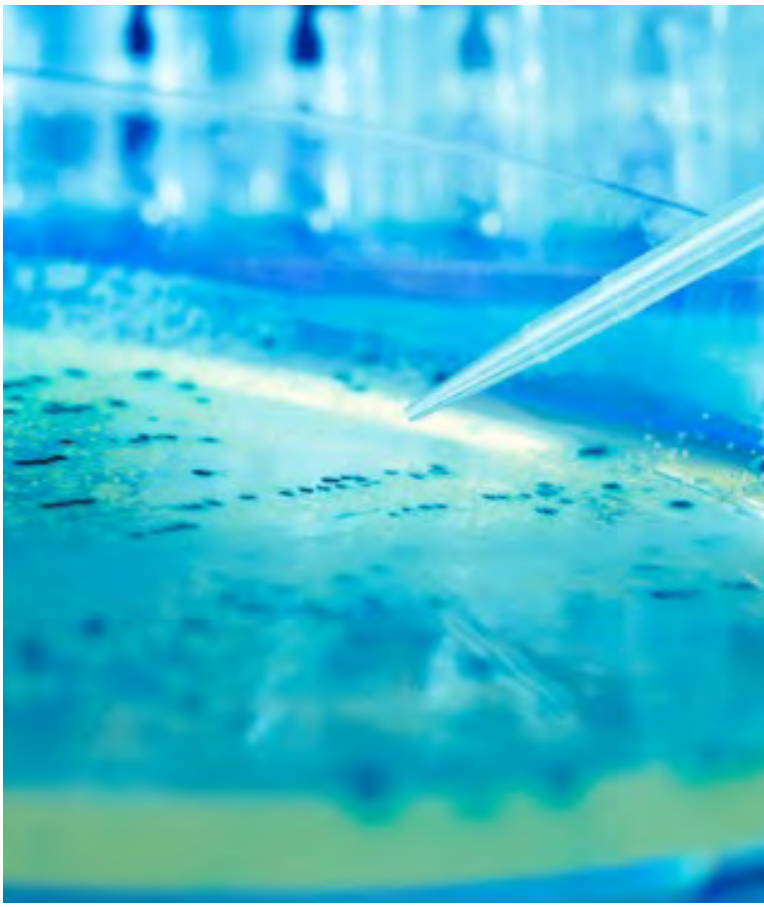
- **Patients in stable condition should be consulted using telemedicine options.**
- **Only emergency consultations and procedures should be performed during the COVID-19 pandemic.**
- **Procedures should be performed in a negative pressure operating room with high-efficiency particulate air filtration.**
- **Less urgent cases should have two negative COVID-19 tests within 48hrs of procedure.**

STUDY AIM

To synthesize and present evidence concerning otolaryngology during the COVID-19 pandemic

METHODS

- Comprehensive database search of current guidelines and recommendations concerning otolaryngological procedures and surgeries during the COVID-19 pandemic.



COST-EFFECTIVENESS

Cost-Effectiveness Open access

The single-use rhinolaryngoscope: an evaluation and cost comparison

Mistry et al. 2020

TAKEAWAY

aScope 4 RhinoLaryngo provides a clinically comparable, and potentially cost-minimizing, alternative to the reusable rhinolaryngoscopes.

KEY FINDINGS

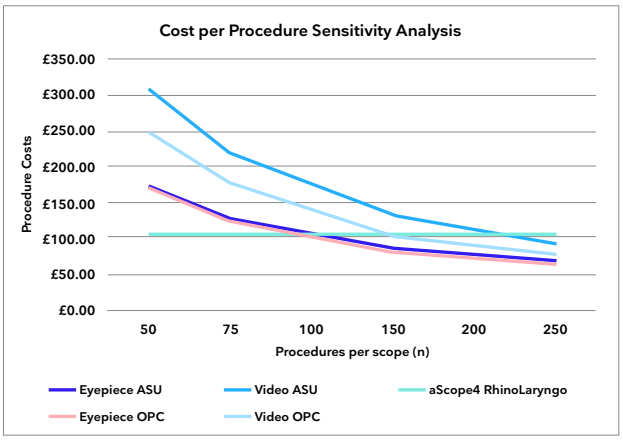
- **3% of the investigators reported that they had to change to the reusable rhinolaryngoscope because of patient intolerance.**
- **85% of investigators believed that the aScope 4 RhinoLaryngo could successfully replace the reusable rhinolaryngoscope.**
- **The cost of a procedure performed using the aScope 4 RhinoLaryngo was £105 ($148.61) in both the outpatient and acute surgical assessment unit settings.**
- **The aScope 4 RhinoLaryngo was £4 ($5.66) and £73 ($103.32) cheaper per procedure than eyepiece rhinolaryngoscopes and video rhinolaryngoscopes, respectively.**

STUDY AIM

To determine whether the aScope 4 RhinoLaryngo is clinically and economically comparable to conventional reusable rhinolaryngoscopes within a tertiary otolaryngology centre in the UK.

METHODS

- Single-arm, non-blinded, prospective trial and cost-comparison at a tertiary otolaryngology centre in the UK
- Investigators without previous single-use rhinolaryngoscope technology were trained prior to use.
- A Likert scale was used to quantify a range of parameters and provide an evaluation of the equipment, including image quality, advancing, navigation, overall perception, and ergonomics.
- Rhinolaryngoscopes were tracked and followed from the finalized procedure, through reprocessing, and until the start of a new procedure.



Cost-Effectiveness Open access

Reusable vs disposable nasopharyngolaryngoscopes: cost analysis and resident survey

Walczak et al. 2020

TAKEAWAY

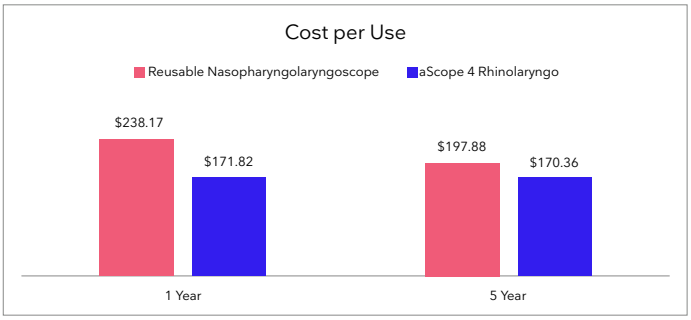
aScope 4 RhinoLaryngo may offer a cost-effective and highly favorable alternative to traditional reusable nasopharyngolaryngoscopes.

KEY FINDINGS

- **The aScope 4 RhinoLaryngo reported better ratings than reusable nasopharyngolaryngoscopes in ergonomics (4.4 vs 4.3), setup (4.4 vs 3.5), convenience (4.6 vs 2.9), and overall score (4.4 vs 4.0).**
- **The reusable nasopharyngolaryngoscopes reported better ratings than aScope 4 RhinoLaryngo in imaging (3.8 vs 4.5) and maneuverability 4.3 vs 4.5).**
- **The aScope 4 RhinoLaryngo was found to cost $171.82 and $170.36 per use and the reusable nasopharyngolaryngoscope was found to cost $238.17 and $197.88 per use for a lifespan of 1 and 5 years, respectively.**

STUDY AIM

To assess the quality of aScope 4 RhinoLaryngo through resident feedback at multiple academic institutions and provide a cost analysis of reusable and disposable nasopharyngolaryngoscopes at a single academic center.



METHODS

- An online survey was distributed to residents at institutions throughout the United States that have implemented use of aScope 4 RhinoLaryngo.
- The survey collected demographic information and asked residents to rate aScope 4 RhinoLaryngo and other reusable nasopharyngolaryngoscopes using a 5-point Likert scale.
- A cost analysis was performed comparing reusable nasopharyngolaryngoscopes and aScope 4 RhinoLaryngo using information obtained at a single academic center.

TECHNICAL SPECIFICATIONS

Ambu aScope RhinoLaryngo

aScope RhinoLaryngo is a sterile single-use rhinolaryngoscope that eliminates patient cross-contamination. aScope RhinoLaryngo eliminates the need for complex reprocessing and ongoing repair.

The design of aScope RhinoLaryngo is based on the latest reusable rhinolaryngoscope, and the familiar form and function delivers consistent performance.

Whether you need high-quality imaging and easy connectivity options for the outpatient clinic or a portable grab-and-go solution for when you're called to a consult, Ambu aScope 4 RhinoLaryngo benefits you. It helps you perform procedures confidently, document them easily and streamline your workflow.

Ambu aScope 4 RhinoLaryngo Intervention

Ambu aScope 4 RhinoLaryngo Slim

Innovative

aScope RhinoLaryngo is about enhancing patient safety and workflow. It is always available and sterile straight from the pack. It helps you save time and work smarter by eliminating time- consuming steps required to use, maintain, and handle a reusable scope. It is the ideal solution for a wide range of rhinolaryngoscopic procedures.

Simple set-up

The aScope RhinoLaryngo solution consists of a single-use rhinolaryngoscope and aView™ 2 Advance Full-HD monitor unit. Remove aScope RhinoLaryngo from its packaging, connect it to aView 2 Advance, 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

The aScope 4 RhinoLaryngo Slim has control wheels designed to ensure precise angulation and locking of the endoscope bending section (Up: 130°, Down: 130°). It provides high-definition imaging with the 85°-degree field of view and 6-50 mm depth of field ensure optimal visibility. The small outer diameter (3.0 mm, precise tip motion, and high-bending angles help minimize patient discomfort during procedures allow you to easily maneuver the endoscope in the upper airway).

KEY FEATURES

- **Always ready and sterilely packed eliminating the risk of cross-contamination**
- **Improves workflow with no hassle of cleaning or repairs and reduces associated costs**
- **Performs consistently with compatible endoscopic accessories**
- **Offers cost transparency – one rhinolaryngoscope, one price. No long-term service contracts or leasing agreements**
- **Offers a cost-effective single-use solution**
- **Ergonomic design that ensures all-day comfort**

The Ambu aScope RhinoLaryngo Family

Ambu aScope 4 RhinoLaryngo Slim

- Insertion cord diameter: 3.0 mm
- Distal end diameter: 3.5 mm
- Working length: 300 mm
- Bending capabilities: 130° up, 130° down

Ambu aScope 4 RhinoLaryngo Intervention

- Insertion cord diameter: 5.0 mm
- Distal end diameter: 5.4 mm
- Channel average inner diameter: 2.2 mm
- Working Length: 350 mm
- Bending Capabilities: 130° up, 130° down

Ambu aView 2 Advanced

- 12.8” Full-HD touchscreen display
- 3 Hours of battery life
- Transfer patient imaging data to EMR with WIFI, USB or LAN
- HDMI or 3G-SDI (1080p @ 60Hz) digital video outputs

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Ambu

Ambu Inc.
6230 Old Dobbin Lane
Columbia, MD 21045
Tel. 800 262-8462
Fax 800 262-8673
ambuUSA.com

US Rx only