Ambu
Ideas that work for life

Clinical & Health Economics Evidence Compendium

December 2020, 1st Edition

Ambu® aScope™ 4 Broncho

IndustryInsights
IPS Infection Prevention Society
Technology Programme
ENDORSED

Experts in Single-Use Bronchoscopy

Contents

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Author name:
Embedded link to original publication

Abbreviations:

RCT	Randomised Clinical Trial	**BAL**	Bronchoalveolar Lavage
SAD	Supraglottic Airway Device	**BW**	Bronchial Wash
RFB	Reusable Flexible Bronchoscope	**HE**	Health Economics
RB	Reusable Bronchoscope	**ICU**	Intensive Care Unit
SADFB	SAD Guided Flexible Bronchoscopic Intubation	**OR**	Operating Theatre
DLT	Double Lumen Tube	**PDT**	Percutaneous Dilatational Tracheostomy
BB	Bronchial Blocker	**VL**	Videolaryngoscope

Preface

Welcome to the first edition of the Ambu® aScope™ 4 Broncho Clinical & Health Economics Evidence Compendium. This compendium is a collation of all the clinical & health economics studies, including clinical trials, simulation studies, case series, reports, conference abstracts and correspondence, relating to this innovative single-use bronchoscope, up to December 2020.

Since the launch in 2009, Ambu® aScope™ Broncho has been the subject of numerous peer-reviewed publications. The objective of this Evidence Compendium is to provide a brief summary of all known published data on aScope™ Broncho, in an efficient and easy-to-understand manner. While each study summary is true to the original publication, the original copies can be made available upon request for a comprehensive overview. Alternatively, click on the embedded link in each study to access the original publication. Should you wish to discuss any publication in this compendium in more detail, do not hesitate to drop an inquiry to: UKCA-Marketing@ambu.com.

In an effort to include all known data irrespective of the outcome, a systematic literature search on aScope™ Broncho (from 1st to 4th generation) has been conducted to generate the Evidence Compendium, giving the reader every opportunity to obtain a balanced overview of the clinical data that exists for aScope™ Broncho. For briefness, aScope™ Broncho is sometimes referred to as aScope in the study summaries. 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 sincerely hope that this evidence compendium provides you with an understanding of the overall clinical landscape regarding aScope™ Broncho and facilitates your day-to-day evidence-based practice.

While every effort has been made to provide accurate information, we apologise in advance for any errors or omissions and will be pleased to make any corrections brought to our notice in any following editions.

"Ideas that work for life"

More than a tagline,
"Ideas that work for life" is everything we do

Ambu® aScope™ 4 Broncho

Single-use bronchoscopes with market-leading performance

aScope™ 4 Broncho

aScope 4 Broncho Slim
aScope 4 Broncho Regular
aScope 4 Broncho Large

- Always sterile with no risk of cross-contamination
- Always available and ready to use
- Eliminates repair costs and limitations of complex reprocessing
- Proven track record from millions of successful procedures and almost 200 supporting studies

aScope™ BronchoSampler

Closed-Loop System for Easy & Effective Bronchoscopic Fluid Sampling

- Sterile, closed-loop system reduces risk of sample loss and guarantees sample quality
- Single operator functionality from system assembly to sample procurement
- Vacuum bypass eliminates the need for suction tube switch

aView™ 2 Advance Full-HD Monitor with EHR Connectivity

- Portable 12.8" touchscreen displaying unit
- True 1920 x 1080p full-HD resolution offers excellent imaging
- Adaptive processing and user adjustments facilitate image optimisation
- Connectivity with PACS allows images and videos to be transferred to patient records
- Digital video-out displays live images in high quality on external screens and provides connectivity to content management systems
- Flexible design and intuitive user interface with 180-degrees rotation options
- Live image within seconds and over 3 hours battery time
- Upgradeable and repairable

Guidelines & Consensus Documents

Recommendations for the use of single-use bronchoscopes and safe bronchoscopic sampling

UK Guidelines & Consensus Documents

Guidelines: Infection prevention and control 2020[1]

"Single-use flexible fiberoptic bronchoscopes (FOBs) could potentially eliminate the risk of cross infection. The cable attached to the FOB is also single-use. The monitor can be disinfected and reused."

"The use of single-use FOBs may be cost effective as expenses related to processing, maintenance, repairs and any potential litigation are avoided."

Consensus guidelines for managing the airways in patients with COVID-19[2]

"Where practical, single-use equipment should be used."

Multidisciplinary guidance for safe tracheostomy care during the COVID-19 pandemic: the NHS National Patient Safety Improvement Programme (NatPatSIP)[3]

"The choice of using bronchoscopy during percutaneous tracheostomy in a patient with COVID-19 should reside with the operative team. If used, single-use bronchoscopes with a sealed ventilator circuit are recommended."

Multidisciplinary COVID-19 tracheostomy guidance[4]

"If used, single-use endoscopes with a sealed ventilator circuit are recommended."

Guidelines Relevant to Safe Bronchoscopic Sample Collection

Performing Bronchoscopy in Times of the COVID-19 Pandemic: Practice Statement from an International Expert Panel[5]

"Bronchoscopy in intubated COVID+ patients: Connect the bronchosampler to the scope; connect the scope to aView monitor."

American Association for Bronchology & Interventional Pulmonology (AABIP) Statement on the Use of Bronchoscopy and Respiratory Specimen Collection in Patients with Suspected or Confirmed COVID-19 Infection[6]

"If bronchoscopy is being performed for COVID-19 sample collection, a minimum of 2-3ml of specimen into a sterile, leak proof container for specimen collection is recommended in Suspected COVID-19 patients."

European Guidelines & Consensus Documents

Bronchoscopy during SARS CoV-2 pandemic. Recommendation of the Swiss Society for Pneumology[7]

"If possible, if the SARS infection is proven or suspected, the use of disposable bronchoscopes (e.g. from AMBU) should be considered. This means avoiding operations with SARS contaminated instruments with CoV-2, although proper preparation would kill the virus."

Irish Thoracic Society Statement on Bronchoscopy and SARS COVID-19[8]

"Single use bronchoscopes have a number of clear advantages: 1) Staff shortages: Where staff are absent there is no requirement to clean scopes; 2) Out of hours bronchoscopy: No requirement to prepare or clean scope; 3) Portablity: Small portable screen and scope - reduced requirement for staff; 4) Cross Contamination: No risk of Cross Contamination; 5) Cost: Single use bronchoscopes are not expensive ..."

The Italian coronavirus disease 2019 outbreak: recommendations from clinical practice[9]

"Single-use flexible bronchoscopes should be used as they are associated with a reduced risk of cross-contamination, and a separate screen is strongly advised."

Special precautions for performing a bronchial endoscopy during the COVID-19 epidemic phase. Recommendations of the French-speaking Pneumology Society (SPLF)[10]

"The use of a disposable endoscope must be considered and proposed to reduce the risk of aerial and manual exposure when cleaning the solied endoscope."

Spanish Society of Pulmonology and Thoracic Surgery (SEPAR) and the Spanish Society of Respiratory Endoscopy (AEER) consensus recommendatins on the Use of Bronchoscopy and Airway Sampling in Patients with Suspected or Confirmed COVID-19 Infection[11]

"Equipment: Of choice: disposable bronchoscopes for single-use with electronic screen for visualisation of the bronchoscopy. The bronchoscope is discarded in the container arranged for it and the screen is cleaned like the rest of the surfaces in the room."

Supporting Evidence-Based Practice with Best Available Evidence

In recent years, the body of evidence supporting aScope Broncho has grown extensively. There is now a significant bank of clinical and health economics studies reporting on its benefit to hospitals and patients, including preventing cross-contamination and infection, cost reduction, and workflow improvement.

As part of our on-going efforts to support evidence-based practice, here we included a brief methodology and approach for generating this evidence compendium.

How were the studies selected and organised?

A systematic, device-specific literature search is conducted. Online academic databases and search engines including EMBASE, MEDLINE, Wiley Online Library, Cochrane Library, Science Direct & Google Scholar are searched for all relevant articles up to 11th December 2020. All Articles published in the English language of the subject device (aScope Broncho) are included. 737 relevant articles were identified and screened. After excluding irrelevant articles, duplicates, off-label uses, 188 articles pertaining to all generations of aScope Broncho are included in this compendium.

Due to the sheer amount of publications, a pragmatic approach is taken in presenting the evidence. Key clinical and health economic studies are presented as a full page or half page literature summaries, in an easy to understand manner. This is to save the audience time from reading long articles; however, the link to the original article is also embedded on each page, allowing the reader to make an entirely accurate internet search should they wish to find out more. The compendium is organised by study type (e.g. Health Economics, Environmental & Clinical Studies), and the studies are organised by the clinical setting (e.g. ICU, OR) and indication for easy navigation under each section. Additional Evidence lists are provided with the embedded links for the articles that are not summarised, after each indication/clinical use of aScope Broncho.

Since launching the world's first disposable flexible endoscope in 2009, Ambu has been the global leader in single-use bronchoscopy. As the largest and longest-standing supplier, you can take confidence in the fact that our technology is present in over 150 NHS Trusts in the UK; and worldwide it has been successfully used in millions of airway procedures and validated by the studies in this compendium.

737 relevant articles identified & screened

188 relevant articles included after detailed screening

Over **10 years** as leaders in single-use bronchoscopy

HE study | ICU | aScope Broncho vs RFB

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

Mærkedahl A, et al., (2020). Journal Of Basic and Clinical Pharmacy.

Key Points

- **aScope: £220** vs. Reusable scope £431.13 — Total cost per procedure
- **aScope: £221.12 with willing-ness to pay threshold of £0** — Net monetary benefit
- **aScope superior to Reusable scope** — Quality-adjusted life years

Study Overview

The main objective of the study was to evaluate aScope Broncho vs reusable flexible bronchoscopes (RFB) by conducting a:

- **Cost-utility analysis, which enables comparisons to be made across disease areas**

Methods

A simple decision tree model was developed to estimate the cost-utility of aScope Broncho vs RFB for bronchoscopy procedures in intensive care units (ICUs) for elective care patients.

Clinical (i.e. infection) & utility inputs were derived from the literature.

Cost inputs: capital, repair, and reprocessing costs were estimated from the perspective of the UK NHS.

Cost of infection: estimated using the NHS reference costs from 2019/2020. For pneumonia, sepsis, and TB, a mean based on all the relevant Healthcare Resource Group (HRG) codes was used, amounting to £4,494.65, £5,466.89, and £2,938.25, respectively

Scenario and probabilistic sensitivity analyses (PSA) were performed to test the impact of changes in the time horizon, utility score assumptions, and cost inputs on the results.

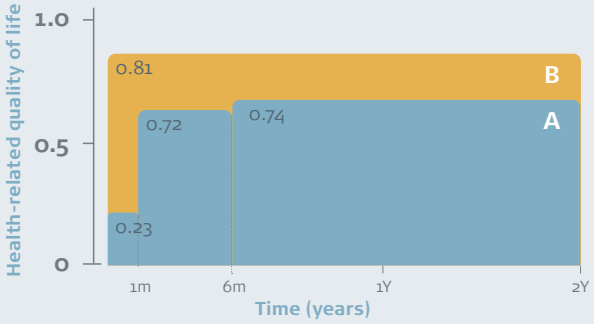
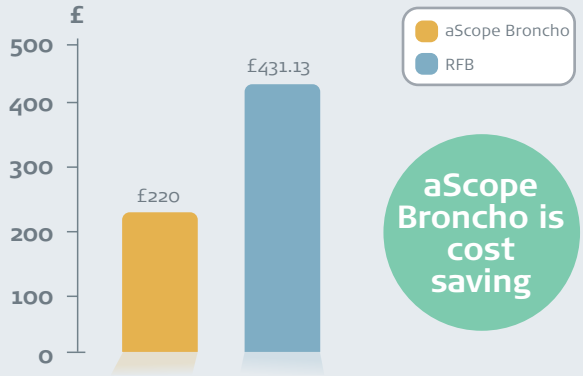


Fig. 1. QALYs based on a 24-month time horizon.
Individual A (examined with an RFB) has fewer QALYs than individual B (examined with aScope). The letters A and B designate the boundary lines, with the QALY for A being only the blue area, the QALY for B being the blue area plus the additional tan area



aScope Broncho is cost saving

Fig. 2. Total cost of aScope Broncho & RFB per procedure, based on a 24-month time horizon

Key Findings

1. Over a 24-month time horizon, the total cost and quality-adjusted life-years [QALYs] for the aScope Broncho & RFBs were estimated to be £220.00 and 1.59 QALYs, and £431.13 and 1.58 QALYs, respectively (Fig.1).
2. The total cost of RFB included costs per procedure obtained from the literature (£309.67), and the cost of various infections (£121.45) (Fig.2).
3. PSA indicated that the net monetary benefit (NMB) was £211.12 for aScope Broncho, using a willingness-to-pay (WTP) threshold of £0. Changing the WTP threshold to £10,000 per extra QALY gained resulted in an NMB of £315.68.

Conclusions

This cost-utility analysis demonstrates that aScope 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) over a 24-month time horizon. The sensitivity analyses demonstrated that aScope Broncho had a 100% probability of being cost-effective at a WTP threshold of £10,000/QALY by an NMB of £315.68.

Reference: Mærkedah A, Lindvig A, Pagh A, Russel R. Cost-Utility Analysis of the Ambu® aScope™ 4 Broncho Single Use Flexible Video Bronchoscope Compared to Reusable Flexible Video Bronchoscopes. Journal of Basic and Clinical Pharmacy. 2020;11:1-6.

HE study | ICU | aScope Broncho vs RFB

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

Terjesen CL, et al., (2017). PharmacoEconomics.

Key Points

- aScope: 0% Reusable scope: 21% — Risks of subsequent infection
- aScope is cost-saving by $118/ procedure — Cost per procedure
- Hospital savings + patient infections avoided — aScope benefits

Study Overview

An early cost-effectiveness analysis (CEA) of aScope Broncho compared with reusable bronchoscopes (RB) in the intensive care setting:

- **Literature search on the risk of cross-contamination & infection**
- **CEA per procedure & elimination of risk of infection**
- **Sensitivity analysis to validate the results**

Methods

A CEA was conducted to determine an incremental cost-effectiveness ratio, and a decision analytic model was constructed based on the best available evidence from a literature search and a Delphi panel.

Several one-way and two-way sensitivity analyses and a probabilistic sensitivity analysis were conducted to illuminate the uncertainty associated with the estimates.

The time horizon was short term (within one year). Costs were estimated in $US, the year 2015–2016 values.

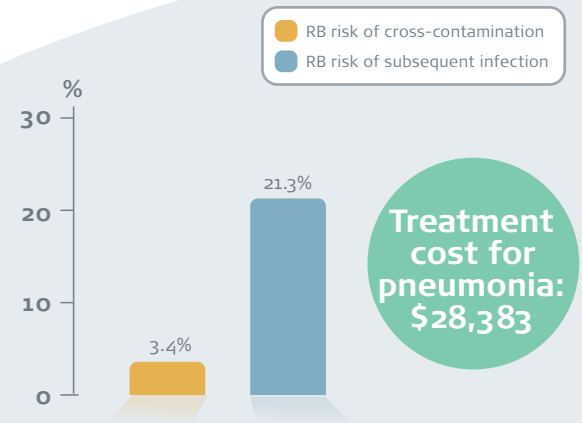


Fig. 1. Expert consensus using the Delphi method on the risk of cross-contamination & infection

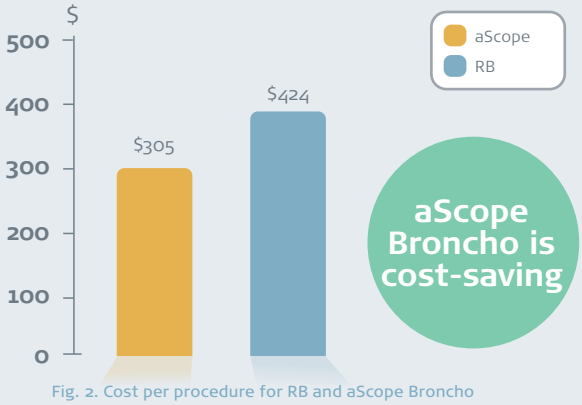


Fig. 2. Cost per procedure for RB and aScope Broncho

Key Findings

1. Estimates from the Delphi method found approximately a 3% risk of cross-contamination and approximately a 21% risk of subsequent infection. Pneumonia was estimated as the most likely manifestation of infection and cost per case for treatment was $US28,383 (Fig.1).
2. Using the reusable bronchoscope (RB) is estimated to have an average cost of $US424 and to hold a 0.7% risk of infection (Fig.2).
3. aScope Broncho has an average cost per use of $US305 and a 0% risk of infection (Fig.2).
4. Results show a possible saving of $US118.56 per procedure and the elimination of a 0.7% risk of infection if the single-use option is adopted instead of the reusable bronchoscope.

Conclusions

aScope Broncho reduced the cost per procedure by $118.56 and reduced the risk of infection to 0%. Based on limited evidence, the model suggests that implementation of the aScope Broncho in the ICU is cost-saving and associated with increased patient safety. The choice of strategy might differ in case settings other than ICUs.

Reference: Terjesen CL, Kovaleva J, Ehlers L. Early assessment of the likely cost effectiveness of single-use flexible video bronchoscopes. PharmacoEconomics-open. 2017;1(2):133-41.

HE study | ICU | aScope Broncho vs RFB

A Cost analysis of single-use (Ambu® aScope™) and reusable bronchoscopes in the ICU

Perbet S, et al., (2017). Ann. Intensive Care.

Study Overview

The main objective of this study was to compare:

- **The cost of bronchoalveolar lavage (BAL) & percutaneous tracheostomy (PT) with reusable flexible bronchoscope (RFB) & aScope Broncho**
- **The satisfaction of healthcare professionals with RFB & aScope Broncho**

Methods

The study was performed between 2009-2014 in a 16-bed ICU.

Sensitivity analysis was performed by applying discount rates (0, 3, and 5%) and by simulation of six situations based on different assumptions.

Healthcare professional satisfaction was determined based on eight factors.

Reusable scopes: Olympus® LF-TP, Pentax® FI-16BS

Key Findings

1. At a discount rate of 3%, the costs per BAL for the two reusable scopes were €188.86 (scope 1) and €185.94 (scope 2).
2. The costs per PT for the reusable scope 1 and scope 2 and aScope Broncho were €1613.84, €410.24 and €204.49, respectively.
3. Healthcare professionals were more satisfied with the third-generation aScope Broncho; notably, the quality of the image, implementation, anatomic landmarks, device insertion, and tracheal positioning.
4. The cost per procedure for the aScope Broncho is comparable to that for reusable scopes. When an ICU is considering the use of reusable scopes or single-use scopes, it should consider the annual number of procedures and the number of scopes that are needed.

HE study | ICU/OR | aScope Broncho vs RFB

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

Châteauvieux C, et al., (2018). Journal of Evaluation in Clinical Practice.

Study Overview

The main objective of this study was to compare:

- **The organisational and economic impact of aScope Broncho & reusable flexible bronchoscopes (RFB)**

Methods

The study took place between May-October 2016.

The process maps were created according to the 12 types of organisational impact (OI).

OI: Work process; Patient pathways/flow; patient involvement; training requirements; modes of communications and cooperation; vigilance & monitoring; working safety; accessibility; budget; infrastructure; logistics.

Micro costing analysis for determining cost impact.

Reusable scopes: 15 reusable Pentax® scopes were available at the university hospital

Key Findings

1. aScope Broncho scored better than the RFB in 75% of cases.
2. The use of RFB involves biomedical engineers and staff responsible for repairs and maintenance, staff responsible for disinfection, pharmacists and hospital technicians responsible for order validation and delivery of the consumables used to clean the RFBs, and microbiology staff to screen the RFBs and the endoscope washer disinfector.
3. With 15 RFBs available, using aScope Broncho would represent an extra cost of €154 per procedure. aScope Broncho and RFB have the same cost (€232 per procedure) with a theoretical annual activity of 328 bronchoscopies, which is much lower than our current activity (1644 procedures per year).
4. aScope Broncho provides a positive organisational impact, and the economical decision should be made based on procedure volumes and RFB availability.

References:
Perbet S, Blanquet M, Mourgues C, Delmas J, Bertran S, Longère B, *et al.* Cost analysis of single-use (Ambu® aScope™) and reusable bronchoscopes in the ICU. Annals of Intensive Care. 2017;7(1).

Châteauvieux C, Farah L, Guérot E, Wermert D, Pineau J, Prognon P, *et al.* Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. Journal of Evaluation in Clinical Practice. 2018;24(3):528-35.

HE study | ICU/OR | aScope Broncho vs RFB

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

Sohrt A, et al., (2019). PharmacoEconomics.

Key Points

- Reusable bronchoscopes = USD $406 (GBP £314) — Average cost per procedure:
- aScope Broncho = USD $249 (GBP £192) — Average cost per procedure:
- aScope Broncho = USD $157 (GBP £121) — Per procedure cost-savings

Study Overview

A cost comparison study to evaluate aScope Broncho vs reusable flexible bronchoscopes (RFB) for percutaneous dilatational tracheostomy (PDT) by conducting a:

- **Literature review for cost of RFB and aScope Broncho for PDT**
- **Cost comparison for cost per procedure**

Methods

A systematic literature search was conducted to identify studies comparing the costs of reusable and single-use bronchoscopes for PDT. 11 studies from the US, UK, France and Denmark published between 2011 and 2017 were included. Costs were estimated in 2016 prices.

A questionnaire regarding repair rates and costs for reusable bronchoscopes was sent to 366 hospitals in the US, UK and Germany to supplement the identified literature. 99 completed responses were received, of which 31 hospitals used reusable equipment for PDT.

Key Findings

1. Average per PDT cost of RFB was USD $406 (GBP £314), incl. acquisition cost of $135, repair cost of $148 and reprocessing cost of $125 with a repair ratio of 1:27 (corresponding to 3.7%) (Fig.1).
2. Average per PDT cost of aScope Broncho was USD $249 (GBP £192). Reprocessing and repair costs were USD $0 (Fig.1).
3. Estimated cost-savings associated with the use of aScope Broncho was USD $157 (GBP £121) per PDT procedure, equating to 39% saving per PDT procedure.
4. The higher cost per repair and repair rate for reusable bronchoscopes made the single-use technology more advantageous.

Single-use scope = 39% saving per PDT procedure

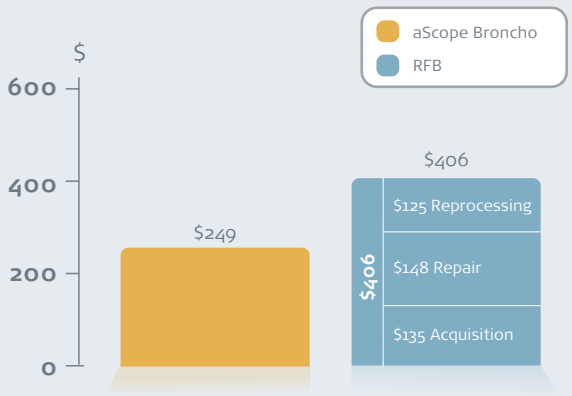


Fig.1. Per PDT procedure cost of RFB and aScope Broncho

Conclusions

The present study concluded that significant savings ($157/PDT procedure) can be made by using aScope Broncho to guide PDT in preference to RFB. Results depend on the hospital setting, the reprocessing procedures, annual bronchoscope procedures, individual repair cost, and repair rates. These findings have implications for the procurement of bronchoscopes by hospitals and units that perform PDT.

Reference: Sohrt A, Ehlers L, Udsen FW, Mærkedahl A, McGrath BA. Cost Comparison of Single-Use Versus Reusable Bronchoscopes Used for Percutaneous Dilatational Tracheostomy. PharmacoEconomics - Open. 2019;3(2):189-95.

HE study | OR | aScope Broncho vs RFB

Introducing a budget impact analysis comparing reusable to single-use bronchoscopes within a large UK university hospital

Russell R, Ockert LK. (2019). Value in Health.

Key Points

- **Saving of £115** per procedure with aScope — Cost of use (at 500 procedure)
- **Saving of £358** when including the cost for infection — Cost of use (at 500 procedure)
- aScope remained cost-saving when <3175 procedure/year with a MR of cross-infection — Annual cost-savings

Study Overview

A budget impact analysis comparing aScope Broncho vs reusable bronchoscopes (RB) for:

- **Cost of use: savings per bronchoscopy at 500 procedures per annum**
- **BIA sensitivity dependent on infection risk and volume of procedures per annum**

Methods

The efficacy of the two technologies was assumed to be equal based on published literature.

Costs of use per annum were sampled from King's College Hospital & the cost of infection was estimated from the published literature.

Cost of cross-infection was calculated using the formula: risk of cross-contamination (low, medium and high risk of cross-contamination) x risk of infection x the cost of ventilator associated pneumonia (VAP) (£15,000).

Robustness of the base-case results were tested via sensitivity analysis.

Isopleths were identified based on varying procedures p.a. and infection rates.

Key Findings

1. The risk of cross-contamination reported in the literature ranges from 3%-58%, resulting in subsequent infection risk of 20.21%. The cost of infection per bronchoscopy with a Medium Risk (MR, 8% x 20.21% x £15,000) of cross-infection was £243 (Fig.1).
2. At 500 procedures p.a., the aScope Broncho minimises costs by £115 per procedure on the direct cost of use and £358 when including the cost associated with a medium risk of cross-infection (Fig.2).
3. The cost per procedure for RB and aScope Broncho was comparable when there were 903 procedures per year without infection.
4. aScope Broncho was cost-saving when there were less than 903 procedures per year with or without infection.
5. aScope Broncho remained cost-saving when there were less than 3175 procedures per year with a medium risk of cross-infection.
6. The cost of RB varied significantly depending on the risk of infection, volume of procedures and capital cost infection.

Medium risk of cross-infection (8%)

0.08 X 0.2021 X 15,000

Risk of cross-infection	Risk of subsequent infection	The cost of VAP £15,000

= £243

Fig. 1. Estimated cost of infection from the published literature

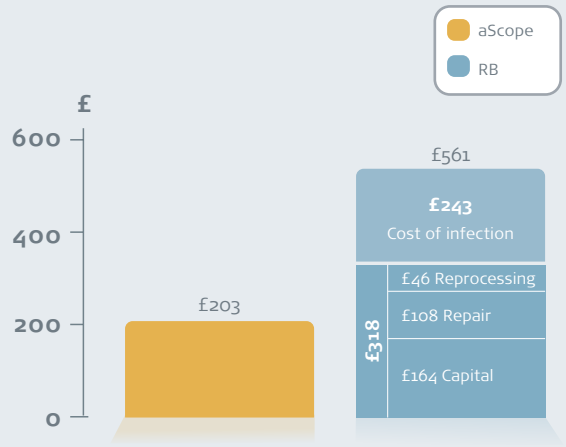


Fig. 2. Cost of use at 500 procedures per annum, assuming a medium risk of cross-infection (8%)

Conclusions

At 500 procedures per annum, aScope Broncho minimizes costs by £115 per procedure on the direct cost of use and £358 when including the cost associated with a medium risk of cross-infection. aScope Broncho remained cost-saving when there was less than 903 procedure per year with or without infection and less than 3,175 procedures per year with a medium risk of cross-infection.

Reference: Russell R, Ockert LK. PMD9 Introducing budget impact analysis comparing reusable to single-use bronchoscopes within a large UK university hospital. Value in Health. 2019;22:S670.

HE study | OR | aScope Broncho vs RFB

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

Mouritsen JM, et al., (2020). Anaesthesia.

Key Points

- **aScope: 0%** vs. Reusable scope 2.8% — Risk of patient infection
- **aScope: £0** vs. Reusable scope £262 — Cost of infection
- **aScope: £220** vs. Reusable scope £511 — Cost per procedure with risk of infection

Study Overview

A systematic review & cost comparison study to evaluate aScope Broncho vs reusable flexible bronchoscopes by conducting a:

- **Literature review on cross-contamination or infection risk with reusable flexible bronchoscopes (RFB)**
- **Micro-costing analysis to estimate cost per use**
- **Cost-effectiveness analysis**

Methods

A systematic review was conducted to identify cross-contamination or infection risk with RFB.

The micro-costing analysis was conducted at Guy's and St. Thomas' NHS Foundation Trust Department of Anaesthesia.

A cost-effectiveness analysis was computed by using the results from the literature review & the micro-costing analysis.

Key Findings

1. 16 studies were selected from the systematic literature review for the risk of cross-contamination or infection. The risk for patient contamination (15%) and infection (18%) resulted in a 2.8% risk of patient infection post bronchoscopy with RFB. The weighted average for the treatment-related costs per patient infected was also calculated from the literature as £9,454 (Fig.1).
2. The results of the micro-costing analysis found that when direct costs of use alone are considered, the cost per procedure with RFB is £249, compared to £220 with an aScope Broncho (Fig.2).
3. In the cost-effectiveness analysis, the RFB showed a mean cost per patient of £511 with an associated risk of infection of 2.8% vs £220 for aScope Broncho with 0% risk of infection. Thus, aScope broncho generates a net saving of £291 per procedure and an avoided risk of infection of the patient at 2.8%.

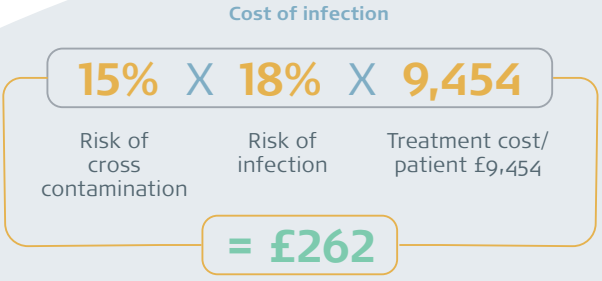


Fig. 1. Estimated cost of infection from the published literature

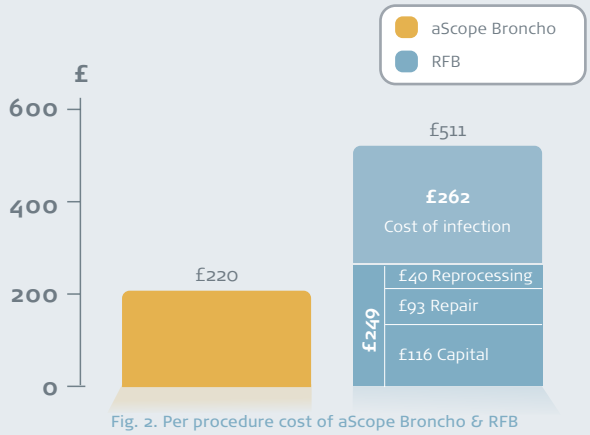


Fig. 2. Per procedure cost of aScope Broncho & RFB

Conclusions

Risk of patient infection following bronchoscopy with RFB is significant. When considering the risk of infection in the cost analysis, RFB has a mean cost per patient of £511 and the associated risk of 2.8% infection. In contrast, aScope Broncho has a mean cost per patient of £220 with an associated risk of 0% infection. The findings from this study suggest the benefits of aScope Broncho in terms of cost-effectiveness, prevention of cross-contamination and resource utilisation.

Reference: Mouritsen JM, Ehlers L, Kovaleva J, Ahmad I, El-Boghdadly K. A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes. Anaesthesia. 2020;75(4):529-40.

HE study | OR | aScope Broncho vs RFB

Cost comparison of re-usable and single-use fibrescopes in a large English teaching hospital

McCahon RA, et al., (2015). Anaesthesia.

Key Points

RFB: average ratio of number of procedures to number of repairs 18:1 — Repair incidents

aScope Broncho: £204 vs RFB £354 — Cost per procedure

aScope Broncho is cost-saving by £150 /procedure — Saved costs

Study Overview

The main objective of the study was to evaluate aScope Broncho vs reusable flexible bronchoscopes (RFB) by conducting a:

- **Cost assessment within operating theatres and emergency departments at Queen's Medical Centre (QMC), Nottingham, England**

Methods

QMC has 27 operating theatres with 141 annual fiberoptic intubations. The data was collected between 1 January 2009 and 31 March 2014.

Cost data included the cost of purchasing the capital equipment, repair cost as well as sterilisation and storage cost.

Reusable scopes: from various manufacturers including Olympus, Acutronic and Karl Storz with the eyepiece

Known health economic methods were used.

Key Findings

1. During the 5.3 years of study period, 14 RFBs were purchased with a total cost of £135,040.
2. Total annual cost of fibreoptic intubation with RFB was £46,385, which includes the capital cost of £19,292, storage cost of £3480, maintenance & repair cost of £19,927 and sterilisation cost of £3687 (Fig.1).
3. Based on 141 fibreoptic intubations per year, this equated to £329 per use, an average dominated by repair/maintenance costs (43%) and capital depreciation costs (42%). If video-visualisation were required, it would cost an additional £25 per intubation (Fig.2).
4. For 141 intubations, the cost of using aScope Broncho averaged at £204 per procedure when taking the cost of the new iteration into account (Fig.2).
5. It appears cheaper to use aScope Broncho at up to 200 fibreoptic intubations per year even when the repair rate for re-usable fibrescopes are low.

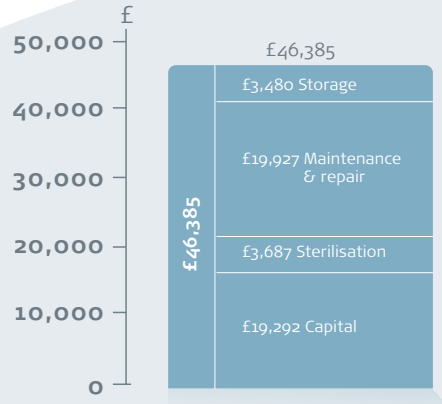


Fig. 1. Estimated cost associated with all 14 RFB scopes per year

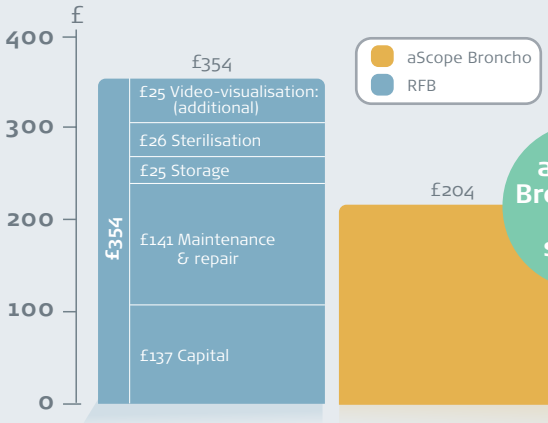


Fig. 2. Per procedure cost of aScope Broncho & RFB, based on 141 intubations per year

Conclusions

aScope Broncho was cost-saving at 141 procedures by £150. The annual cost of RFB intubations were £46,385, mainly dominated by the capital and repair costs, resulting in a high per-procedure cost of £354 vs the cost per procedure of £204 with aScope Broncho. aScope Broncho remained cost-saving up to 200 intubations per year, even when the repair rates were low. Any centre, knowing its fiberscope use and repair rate, can plot its data similarly to help ascertain which scope presents better value.

Reference: McCahon RA, Whynes DK. Cost comparison of re-usable and single-use fibrescopes in a large English teaching hospital. Anaesthesia. 2015;70(6):699-706.

HE study | OR | aScope Broncho vs RFB

Cost-effectiveness analysis of flexible optical scopes for tracheal intubation: A descriptive comparative study of reusable and single-use scopes

Gupta D, Wang H. (2010). Journal of Anaesthesia.

Key Points

RFB= 1:55, with $2,959.44 per instance of repair

Repair-to-intubation ratio

RFB= $119.75, based on 2009 data

Per intubation cost

Cost determined between $120-$132 per intubation to match RFB cost

Cost of aScope Broncho

Study Overview

The main objective of the study was to evaluate reusable flexible bronchoscopes (RFB) for:

- **Cost per intubation to determine a practical and justifiable cost for single-use intubation scopes**

Methods

The one-year intubation records of intubations performed with reusable intubation scopes, the one-year maintenance costs of these scopes, and their three-year repair cost records were analyzed. A total of 166 intubations were performed with reusable fiberoptic scopes in 2009 at Detroit Medical Center, USA.

Calculations to assess the costs per intubation based on the documented records were made. The total cost of intubation, the repair-to-intubation ratio, and the repair cost per intubation were determined.

Key Findings

1. In 2009, a total of 6 reusable intubation scopes were available. In 2004, 6 Olympus LF-GP Scopes were purchased at $8,365.35 each (total amount for 6 scopes was $50,192.00). Thus, the annual cost of purchasing 6 scopes was $3,346.14 with 15-year lifetime (Fig.1).
2. In 2009, a total of 166 intubations were performed with Olympus LF-GP scopes. The total cost of per intubation in 2009 using RFB was $119.75, which included $20.15 (capital), $53.48 (repair), $33.16 (maintenance) and $12.96 (labour) (Fig.2).
3. The repair-to-intubation ratio was 1:55. Repair costs were $2,959.44 per instance of repair.
4. A single-use intubation scope, the price range should be within 10% of above intubation cost (120.00 to 132.00 USD per intubation) to be cost-effective (Fig.2).

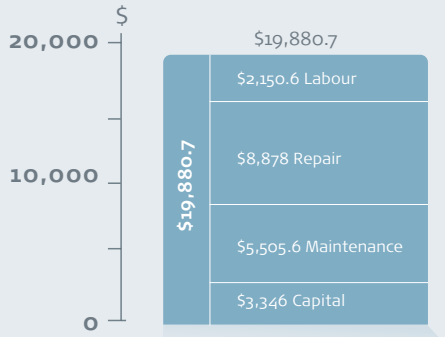


Fig. 1. Estimated cost associated with all 6 RFB scopes per year

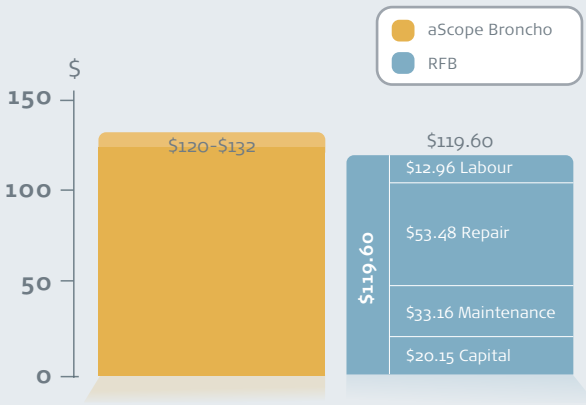


Fig. 2. Per procedure costs of RFB and aScope Broncho based on 166 intubation per year

Conclusions

Cost of intubation using reusable scopes were $119.70 based on 2009 data and 166 intubation per year. It was not clear whether the RFB scopes were with eyepiece or video capabilities, as the latter will be more expensive. Based on this data, the cost of aScope Broncho should be between $120-$132 per intubation to be comparable to the RFB option and be cost-effective.

Reference: Gupta D, Wang H. Cost-effectiveness analysis of flexible optical scopes for tracheal intubation: A descriptive comparative study of reusable and single-use scopes. Journal of Clinical Anesthesia. 2011;23(8):632-5.

HE study | OR | aScope Broncho vs RFB

Cost analysis comparing single-use (Ambu® aScope™) and conventional reusable fiberoptic flexible scopes for difficult tracheal

Aïssou M, et al., (2013). Annales Francaises d'Anesthesie et de Reanimation.

Study Overview

A medico-economic study to assess:

- **The cost of using a reusable flexible bronchoscope as compared to the aScope Broncho**

Methods

Minimization-cost analysis conducted between 2006 and 2012. The amortization cost per utilization for two reusable fiberscopes considered the acquisition and maintenance costs, as well as the costs related to disinfection. The cost of the single use fiberscope was calculated according to its acquisition cost.

Reusable fiberscope: Pentax® FB 15P

Key Findings

1. The total cost of the reusable material was €55,874 over 6 years, corresponding to a unitary cost of €206 per fiberscope. During this period, 780 sterilizations were carried out for a total cost of €32,611.
2. Acquisition and maintenance costs for reusable scopes were €18,382 and €4880, respectively. The cost of the single-use bronchoscope is €200 per scope.
3. This medico-economic evaluation shows that the utilization cost of single-use and reusable fiberscopes are very close. This should be analyzed at the light of some benefits of using single-use devices for the difficult tracheal intubation.

HE study | OR | aScope Broncho vs RFB

A cost analysis of reusable and disposable flexible optical scopes for intubation

Tvede MF, et al., (2012). Acta Anaesthesiologica Scandinavia.

Study Overview

The main objective of the study was to compare:

- **Cost of aScope Broncho & reusable flexible optical scopes (FOS) for intubation at a large anaesthesia department**

Methods

Data collection took place at Copenhagen University Hospital during 1 July–31 August 2009.

The department had 12 FOSs available, of which 8 were traditional scopes with eye-piece & 4 were videoscopes.

Reusable videoscopes: BF1T240, BF3C160, BFXP160F, Storz MEDI PACK

Recognised health-economic methodology was applied.

Key Findings

1. During a 1-year period, 360 FOS intubations were performed. It was estimated that 1/3 of the intubations were performed with videoscopes & 2/3 were performed using eye-piece scopes.
2. In this setting, the overall cost of using a reusable FOS for tracheal intubation was €177.7 per intubation vs the aScope Broncho, which was €204.4 per intubation.
3. The break-even point, i.e. the number of intubations per month where the cost of using disposable and non-disposable equipment is identical, was 22.5/month.
4. A subgroup analysis looking solely at intubations performed with videoscopes revealed that the cost per intubation was equal for disposable and reusable videoscopes (€204.4 vs €204.5).

References:
Aïssou M, Coroir M, Debes C, Camus T, Hadri N, Gutton C, *et al.* Cost analysis comparing single-use (Ambu® aScope™) and conventional reusable fiberoptic flexible scopes for difficult tracheal intubation. Annales Francaises d'Anesthesie et de Reanimation. 2013;32(5):291-5.

Tvede MF, Kristensen MS, Nyhus-Andreasen M. A cost analysis of reusable and disposable flexible optical scopes for intubation. Acta Anaesthesiologica Scandinavica. 2012;56(5):577-84.

HE study | OR | aScope Broncho vs RFB

Costs associated with a fibrescope inventory: what role for the disposable scope?

Norris A, et al., (2010). Difficult Airway Society Annual Meeting.

Study Overview

The main objective of the study was to evaluate:

- **Cost of aScope Broncho & reusable flexible bronchoscopes (RFB) for intubation and governance concerns associated with maintaining, repairing and replacing our existing devices**

Methods

Data was collected on all fibreoptic intubations for a 12 months period in Nottingham University Hospital in 2009.

The department had 11 RFBs available, of which 4 were paediatric.

Reusable scopes: variety of manufacturers including Karl-Storz.

Cost data was obtained from the manufacturers' repair records for costs and nature of damage to the fibrescopes, together with records where these could be obtained, from the Medical Equipment Service Unit and the theatres finance team.

Key Findings

1. It proved very difficult to obtain details of costs, and records were incomplete. Repair contracts for some of the devices totalled more than £4,000.
2. For RFB repairs, most problems related to the angulating tip, with leaks, tears and damaged vertebrae. There were also examples of severe damage to the shaft and eyepiece/camera.
3. In five out of seven episodes the damage was considered too extensive to repair and scopes were replaced under the customer arrangement, but not before costs of ~£12,000 were incurred. Four new scopes were ordered in that year at the cost of £32,000.
4. Two new scopes were ordered every four years on average to replace stock and increase supply as demand has grown. Our estimate, therefore, was around £32,000 in 2008-9 and we recorded performance of 141 fibreoptic intubations.
5. If all of these had been performed using disposable instruments at £200 each the cost would have been £28,000.

References:
Norris A, Wakeling P, Wiles M, McCahon R, Bennett M, editors. Costs associated with a fibrescope inventory: what role for the disposable scope? Difficult Airway Society Annual Meeting; 2010; Cheltenham.

Ambu
Ideas that work for life

Environmental Impact Study | **aScope Broncho vs RFB**

Comparative study on environmental impacts of reusable and single-use bronchoscopes

Sørensen BL, Grüttner H., (2018). American Journal of Environmental Protection.

Key Points

- Higher for one RB cleaning operation vs one aScope — Emissions of CO_2 equivalents
- Higher for one RB cleaning operation vs one aScope — Material & Energy used
- Higher for one RB cleaning operation vs one aScope — Scarce resource value

Study Overview

A comparative study to evaluate aScope Broncho & reusable bronchoscopes for:

- **Carbon dioxide (CO_2) - equivalent emissions**
- **Resource consumption**

Methods

The comparison is made using a simplified life-cycle-assessment methodology prepared for the Danish Ministry of Environment.

The assessment compares the use and disposal of one aScope Broncho with the cleaning and sterilisation of one conventional reusable bronchoscope (RB), including the miscellaneous consumables needed for personal protection.

RB: Attire and PPE are assumed changed between each reprocessing cycle and when moving from the decontaminated area to the clean area, thus implying one change of attire and PPE per RB complies with current practice at Rigshospitalet University Hospital, Denmark.

Key Findings

1. RB gives 8% crediting of energy when incinerated but adds an extra 26% emission of CO_2-equivalents. Because the incineration substitutes other fossil fuels, it also gives a credit of 6% scarce resources.
2. aScope Broncho gives a credit of 6% energy when incinerated but adds an extra 21% emission of CO_2-equivalents. Because the incineration substitutes other fossil fuels, it also gives a credit of 3% scarce resources.
3. The consequence for regions where incineration with energy recovery is not available is that the energy consumption will be 8% & 6% higher, the CO_2-equivalent emissions will be 26% & 21% lower, and the consumption of scarce resources will be 6% & 3% higher for the RB & aScope Broncho, respectively.
4. The use of cleaning materials and PPE determines that RBs have comparable or higher material and energy consumption as well as emissions of CO_2 equivalents and value of resource consumption to aScope Broncho (Fig. 1 & 2).

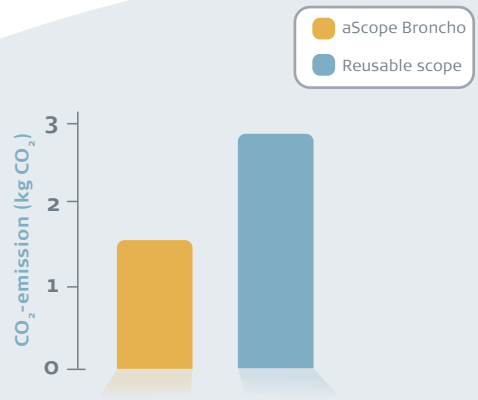


Fig. 1. CO_2 emissions of one aScope Broncho & one cleaning operation for RB

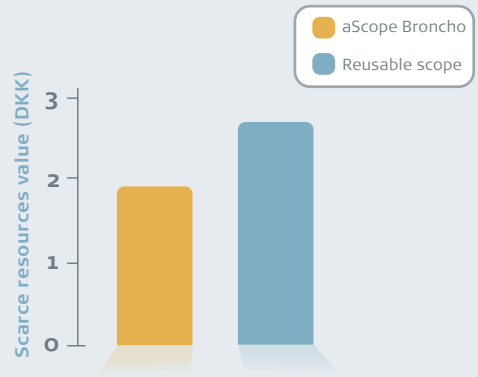


Fig. 2. Value of scarce resources in one aScope Broncho & one cleaning operation of RB

Conclusions

Parameters assessed for RB are highly dependent on cleaning procedures and the use of protective equipment. Cleaning two or more reusable scopes per set of PPE makes the impacts fairly comparable. However, in this study where one set of PPE is used/ cleaning operation for RB, one aScope Broncho had lower CO_2 emissions, less consumption of scarce resources and less energy consumption compared to the one cleaning operation of RB.

Reference: Sørensen BL, Grüttner H. Comparative study on environmental impacts of reusable and single-use bronchoscopes. Am J Environ Protec. 2018;7(4):55-62.

Observational Study | ICU | BAL, Aspiration, Biopsy | aScope Broncho

Bronchoscopist's perception of the quality of the single-use fiberoptic bronchoscope (Ambu® aScope™ 4) in conventional bronchoscopies. A multicenter study in 21 Spanish pulmonology services

Javier FA, et al., (2020). Respiratory Research.

Key Points

- **Taking & storing images/ videos: 99.3%** — Image/video capability
- **Portability & immediacy to start the procedure: 99.3%** — Portability
- **Ability to perform all the planned procedures: 95%** — All procedure performance

Study Overview

A prospective, observational study to evaluate bronchoscopist's perception of aScope broncho for:

- **Ease of use, image/video capability & quality, portability**
- **Sterile and disposable concept**
- **Suction quality & ability to reach all lung segments**
- **Ability to perform all planned procedures**
- **Overall satisfaction with the bronchoscope**
- **Recommendation for its use in similar cases**
- **Learning curve for bronchoscopists**

Methods

The study comprised of: 300 bronchoscopic evaluations.

Indications: diagnostic bronchial aspiration & lavage (69.3%), BAL (41.7%), therapeutic aspirations (10%) & bronchial biopsy (5.7%).

Highly recommended by broncho-scopists

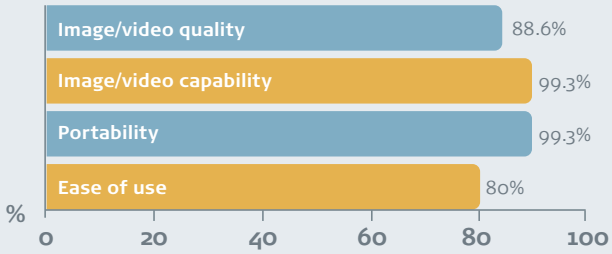


Fig. 1. Bronchoscopist's perception of the characteristics of aScope Broncho

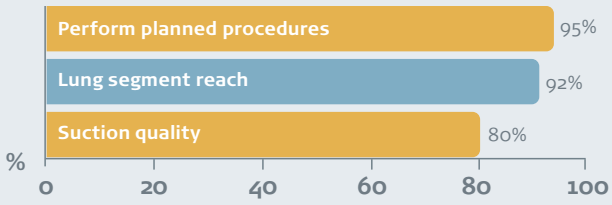


Fig. 2. Bronchoscopist's perception of the performance of aScope Broncho

Key Findings

1. The most outstanding characteristics of the bronchoscope were its ease of use (80%), portability and immediacy to start the procedure (99.3%), the capability of taking and storing images/videos (99.3%) and its quality (88.6%) (Fig. 1).
2. The sterile & disposable concept were rated useful by 96.3% and 93% bronchoscopists, respectively.
3. Overall suction quality, the ability to reach all lung segments and the ability to perform all the planned procedures were rated as 80%, 92% and 95%, respectively (Fig. 2).
4. The overall satisfaction rate with the bronchoscope was 86.4% and 86.4% the bronchoscopists recommended aScope 4 Broncho for similar procedures.
5. There was a learning curve in the use of aScope Broncho: a good performance from the 1st procedure, and excellent performance for ease of intubation from the 3rd procedure, ease of manoeuvring from the 4th procedure and good image quality during the bronchoscopy from the 9th procedure.

Conclusions

The aScope 4 Broncho scored well for ease of use, image/video capability, portability and overall performance. Bronchoscopists found it useful that it is sterile and disposable. The overall satisfaction was high, and the majority of the bronchoscopists recommended aScope Broncho for similar procedures. A good performance was achieved from the first procedure, and there was a learning curve for achieving excellence.

Reference: Javier FA, Luis G, Javier A, Iker F-N, Carlos A, Carmen ML, *et al.* Bronchoscopist's Perception of the Quality of the Single-use Fiberoptic Bronchoscope (Ambu aScope 4™) in Conventional Bronchoscopies. A Multicenter Study in 21 Spanish Pulmonology Services. Respiratory Research. 2020.

Retrospective study | ICU | BAL, Secretion/plug clearance, Tracheostomy | aScope Broncho

Safety and Efficacy of Bronchoscopy in Critically Ill Patients with Coronavirus Disease 2019

Chang SH, et al., (2020). Chest.

Study Overview

A retrospective analysis of the safety of bronchoscopy with intermittent apnoea for both patients and healthcare providers. The outcomes included:

- **Patient & healthcare provider**
- **Infection with bacterial or fungal pneumonia**

Methods

107 patients with COVID-19 and respiratory failure underwent bronchoscopy, and 241 bronchoscopies were performed on these patients between March 13 to April 24, 2020 in the ICU.

Bronchoscopy occurred in a routine manner to clear all secretions, clots, or mucus plugs. BAL samples were collected at the request of the treating ICU team or in the presence of purulent secretions.

aScope Broncho with aView monitor was the bronchoscope used.

Key Findings

1. No periprocedural complication of severe hypoxia that required bag-valve ventilation, pneumothorax, or intraprocedural arrhythmias occurred.
2. Fifty-four patients (50.5%) received BAL, and 35 patients (65%) had a positive culture.
3. Of 23 patients with a negative tracheal culture, eight patients had a positive BAL, which indicated a 35% diagnostic yield for patients with negative tracheal aspirates.
4. The bronchoscopy team included 10 bronchoscopists. None tested positive for COVID-19 post bronchoscopy procedure with at least one negative test performed 2 weeks after last bronchoscopy.
5. This study demonstrates the safety and feasibility of performing bronchoscopy with intermittent apnoea for patients with severe COVID-19.

Observational study | ICU | BAL | aScope Broncho

Bronchoscopy on Intubated COVID-19 Patients is Associated with Low Infectious Risk to Operators at a High-Volume Center Using an Aerosol-minimizing Protocol

Gao CA, et al., (2020). medRxiv.

Study Overview

A survey study to investigate the safety of a modified protocol to perform BALs on intubated COVID-19 patients. The reported outcomes included:

- **Bronchoscopist infection with COVID-19**
- **Difficulty of performing BAL on intubated patients**

Methods

52 pulmonary and critical care faculty and fellows were surveyed at North-western Memorial Hospital in Chicago.

Bronchoscopies were performed in the ICU on intubated patients with respiratory failure to establish a diagnosis or in others to exclude bacterial coinfection.

Bronchoscopy was performed with aScope Broncho.

Key Findings

1. Over 450 BALs on intubated COVID-19 patients were performed with the new protocol since March 2020. 47 completed the survey.
2. Many respondents (19/45, 42%) spent >5 weeks on an ICU service with COVID-19 patients.
3. 16 of the 35 providers (46%) who performed COVID-19 BALs underwent at least one nasopharyngeal swab to test for SARS-CoV-2, but none were positive. 27 of the 35 providers (77%) who performed COVID-19 BALs underwent SARS-CoV-2 serology testing, and only one (3.7%) was positive.
4. Respondents indicated occasionally not being able to follow aerosol-minimizing steps but overall felt BALs in COVID-19 patients were only slightly more difficult than routine ICU BAL. While the optimal role for COVID-19 BAL remains to be determined, these data suggest that BAL can be safely performed in intubated COVID-19 patients.

References:

Chang SH, Jiang J, Kon ZN, Williams DM, Geraci T, Smith DE, *et al.* Safety and Efficacy of Bronchoscopy in Critically Ill Patients with Coronavirus Disease 2019. Chest. 2020.

Gao CA, Bailey JI, Walter JM, Coleman JM, Malsin ES, Argento AC, *et al.* Bronchoscopy on Intubated COVID-19 Patients is Associated with Low Infectious Risk to Operators at a High-Volume Center Using an Aerosol-minimizing Protocol. medRxiv. 2020.

Observational study | ICU/OR | BAL, BW, Intubation | aScope Broncho vs RFB

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

Kriege M, et al., (2020). Trends in Anaesthesia and Critical Care.

Key Points

- **58% preferred aScope Broncho** — Bronchoscopy procedures
- **65% preferred aScope Broncho** — Intubation
- **Highly rated & has potential for replacing RFB** — Overall Characteristics

Study Overview

A prospective, observational study to compare user perspective on aScope Broncho & reusable flexible bronchoscopes (RFB) for:

- **Physician preference**
- **Navigation & advancement**
- **Manoeuvrability**
- **Image quality**
- **Suction capability**

Methods

aScope-aided interventions were evaluated in the OR, ICU or ER from 8 hospitals across 4 different countries.

All outcome measures were qualitative assessments based on the actual use of aScope Broncho, and they were compared to the physician's prior experience with the RFB.

Physicians: Anaesthesiology, Pulmonology, Chest surgeons, ICU specialists

Bronchoscopy procedures (n=150): Bronchial inspection (n=74), Suctioning of bronchial secretion (n=52), BW (n=30), BAL (n=67), Bronchial brush (n=9) & other (n=5). Intubation (n=26)

RFB: different models from Olympus, Pentax and Storz

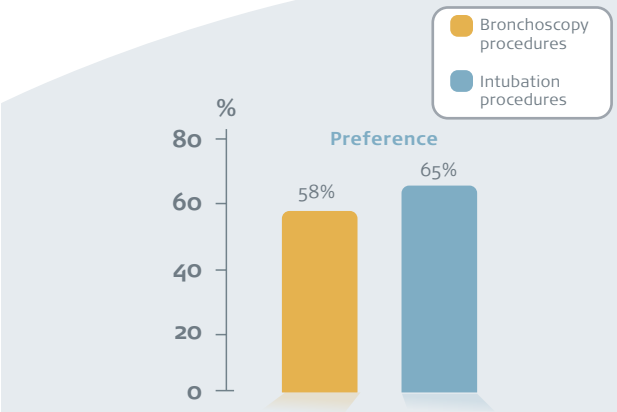


Fig. 1. Bronchoscopist's perception on aScope 4 Broncho for various procedures

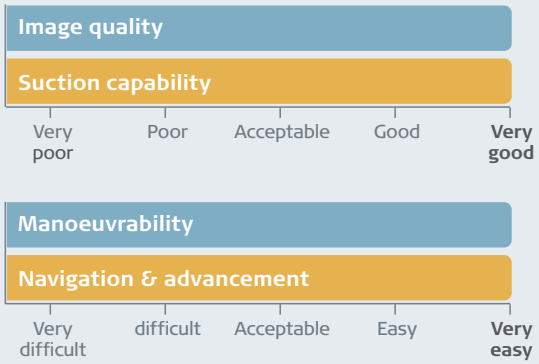


Fig. 2. Bronchoscopist's perception on the characteristics of aScope 4 Broncho

Key Findings

1. aScope 4 Broncho was preferred over customary endoscopes in 58% of cases for bronchoscopy and 65% of cases for intubation. aScope 4 was preferred over the aScope 3 Broncho in 59% of cases (Fig.1).
2. aScope Broncho demonstrated similar or more effective image quality, suction capability, manoeuvrability, navigation and advancement compared to RFB.
3. The physicians were asked if the aScope 4 Broncho could replace their existing reusable or single-use bronchoscope and the proportion of physicians answering "Yes" was significantly higher than the proportion answering "No" for all bronchoscopic procedures.

Conclusions

aScope 4 Broncho was preferred over RFB and the predecessor, aScope 3 Broncho, for bronchoscopy and intubation procedures. This was attributed to the better navigation, advancement, manoeuvrability, ergonomics and suction capabilities of aScope 4 Broncho. Based on this data, the aScope 4 Broncho may increase the quality of the diagnostic and therapeutic bronchoscopy in critically ill patients.

Reference: Kriege M, Dalberg J, McGrath BA, Shimabukuro-Vornhagen A, Billgren B, Lund TK, *et al.* 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. Trends in Anaesthesia and Critical Care. 2020;31:35-41.

Observational study | ICU | BAL | aScope Broncho

Multicentric satisfaction survey of aScope™ Bronchosampler™, a new sampling accessory for aScope™ 4 Broncho

Novy E, et al., (2020). Annals of Intensive Care.

Study Overview

A prospective multicentre satisfaction survey to assess the functionality of aScope BronchoSampler compared to the current practice by evaluating:

- **Bronchial sampling in ICU units/pulmonology departments**

Methods

BronchoSampler was evaluated in 4 hospitals in France, for 4 months. 48 evaluation forms have been collected and consolidated involving 23 operators already using aScope 4 Broncho in their practice.

BronchoSampler was evaluated in comparison to the standard sampling method used by the operators.

Key Findings

1. BronchoSampler was mainly used for the following procedures: Bronchial Wash—8 (17%) Bronchial Alveolar Lavage—36 (75%).
2. Usually, those procedures were done as follows: wall suction/specimen trap: 40 (84%), manual pull/syringe: 2 (4%), material preparation traditionally requires two dedicated persons 32 (67%) versus one operator only for BronchoSampler usage 27 (56%). It frees assistant time and enables the clinician to perform the sampling alone more often.
3. Evaluators consider that BronchoSampler rationalises the cumbersome sampling process and that the closed system design reduces the risk of losing sample or sample contamination.
4. The set-up, the suction capacity, the sampling quality and quantity have all been evaluated better or far better than that usually observed with usual sampling techniques and devices.
5. Finally, 36 (75%) users prefer BronchoSampler to their commonly used method & 39 (81%) consider that BronchoSampler should replace their current practice.

Observational study | ICU | BAL, Bronchial Inspection | aScope Broncho

Bronchoscopy in Patients with COVID-19 with Invasive Mechanical Ventilation: A Single-Center Experience

Torrego A, et al., (2020). Am. J. Respir. Crit. Care Med.

Study Overview

A Spanish hospital experience in performing flexible bronchoscopy in intubated patients with COVID-19. The report included:

- **Bronchoscopy indications**
- **Procedure duration**
- **BAL results**

Methods

Between March 16-April 4, 2020, a total of 101 bronchoscopies were performed in 93 patients with COVID-19. Eight patients required two bronchoscopies.

In 63 cases, a mini-BAL with 60-ml saline aliquots at room temperature was performed after airway inspection for microbiological sampling.

aScope Broncho was used for all cases.

Key Findings

1. Indications for bronchoscopy were as follows: radiological and/or clinical deterioration suggesting possible superinfection (63/101) as well as airway secretion management with/without atelectasis (38/101).
2. Bronchoscopic examination included an orotracheal tube positioning check, direct inspection of the tracheal and bronchial mucosa, suctioning of secretions, and mucoactive agent instillation if necessary (hypertonic saline combined with hyaluronic acid), and in 63 cases, a mini-BAL. The duration of the procedures was never more than 10 minutes.
3. Bronchoscopy results showed normal or mildly hyperaemic bronchial mucosa. The presence of white and gelatinous secretions, difficult to suction, was observed in 95% (88/93) of patients. In 12 cases, mucohematic plugs occupying the main or lobar bronchi were observed and removed after instillation of saline and a mucolytic agent.
4. 18/63 (28.6%) had positive cultures from BAL. In critically ill, mechanically ventilated patients with COVID-19, thick hypersecretion in the airway is the most common complication observed, and these patients can benefit from specific bronchoscopy management.

References:
Novy E, Meistelman C, Fournier C, Dhonneur G, Pottecher J. Multicentric satisfaction survey of aScope Bronchosampler™, a new sampling accessory for aScope™ 4 Broncho. The French Intensive Care Society International Congress; 5 - 7 February; Paris, France: Annals of Intensive Care; 2020. p. 116.

Torrego A, Pajares V, Fernández-Arias C, Vera P, Mancebo J. Bronchoscopy in Patients with COVID-19 with Invasive Mechanical Ventilation: A Single-Center Experience. American Journal of Respiratory and Critical Care Medicine. 2020;202(2):284.

Observational study | ICU | BAL | aScope Broncho

Alveolitis in severe SARS-CoV-2 pneumonia is driven by self-sustaining circuits between infected alveolar macrophages and T cells

Grant RA, et al., (2020). bioRxiv.

Study Overview

An observational study to compare the pathogenesis of COVID-19-induced acute respiratory distress syndrome (ARDS) vs other types of pneumonia, by:

- **Comparing BAL samples from patients with respiratory failure secondary to COVID-19 pneumonia and pneumonia induced by other pathogens**

Methods

BAL samples from 86 patients with SARS-CoV-2-induced respiratory failure were collected.

BAL samples were collected within 48 hours of intubation and sequentially over the course of illness.

Bronchoscopic BAL was performed using aScope Broncho.

Key Findings

1. It was found that despite a diagnosis of severe ARDS requiring mechanical ventilation, only 34.4% of patients with severe COVID-19 exhibited neutrophilia in BAL fluid within 48 hours of intubation. Instead, the alveolar space was significantly enriched for both CD4+ and CD8+ T cells and monocytes.
2. In the absence of a detected bacterial superinfection, BAL fluid remained non-neutrophilic in 62% of samples from patients admitted with SARS-CoV-2 pneumonia. BAL neutrophilia developed in 50% of patients with COVID-19 who developed bacterial superinfection.
3. The results suggest SARS-CoV-2 causes a slowly unfolding, spatially-limited alveolitis in which alveolar macrophages are harbouring SARS-CoV-2 transcripts and T cells form a positive feedback loop that drives progressive alveolar inflammation.

Case series | ICU | BAL | aScope Broncho

Acute eosinophilic pneumonia associated with elevated NKT cell response in COVID-19 patients

Kim D-M, et al., (2020). Research Square.

Study Overview

An observational case series to investigate the underlying mechanism of the fatal viral pneumonia caused by COVID-19 by analysing:

- **Immunological features of BAL samples**

Methods

Respiratory and blood specimens were collected from three confirmed patients with various degrees of clinical symptoms; one with mild symptoms without pneumonia and two with severe pneumonia.

BAL, sputa, and tracheal aspirates were analysed to characterise immunological responses upon viral infection.

aScope Broncho was used for all cases.

Key Findings

1. Patient 1 & 2 had acute and severe pneumonia requiring mechanical ventilation. Patient 2 suffered from a more prolonged and severe type of pneumonia than Patient 1, as evidenced by radiological chest imaging. Patient 3 had only mild symptoms without pneumonia.
2. BAL analysis of two COVID-19 patients with severe pneumonia revealed that lymphocytes accounted for 20% and eosinophils accounted for more than 35% of inflammatory cells, indicating acute eosinophilic pneumonia.
3. The current study demonstrates that acute eosinophilic pneumonia with elevated NKT cells is associated with COVID-19.

References:

Grant RA, Morales-Nebreda L, Markov NS, Swaminathan S, Guzman ER, Abbott DA, *et al.* Alveolitis in severe SARS-CoV-2 pneumonia is driven by self-sustaining circuits between infected alveolar macrophages and T cells. bioRxiv. 2020;n/a(n/a):n/a.

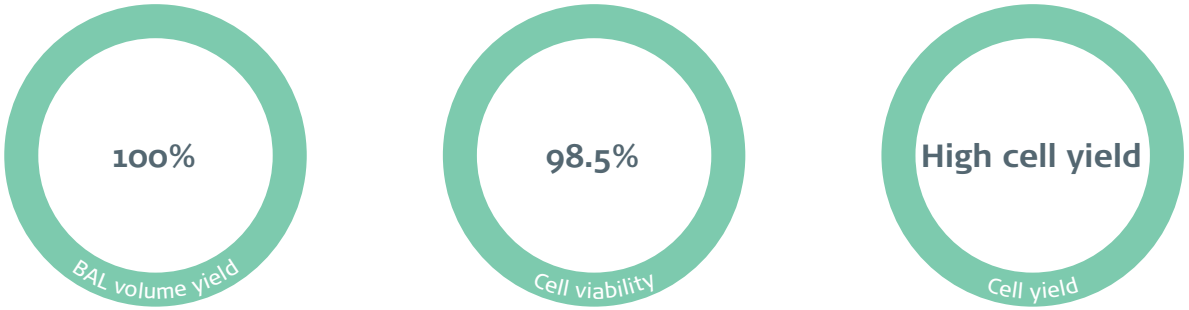
Kim D-M, Seo J-W, Kim Y, Park U, Ha N-Y, Park H, *et al.* Acute eosinophilic pneumonia associated with elevated NKT cell response in COVID-19 patients. Research Square. 2020;n/a.

Comparative study | Research ward/OR | BAL | aScope Broncho vs RFB

Single use and conventional bronchoscopes for Broncho alveolar lavage (BAL) in research: A comparative study (NCT 02515591)

Zaidi SR, et al., (2017). BMC Pulmonary Medicine.

Key Points



Study Overview

A comparative study to evaluate aScope Broncho Regular & conventional bronchoscopes for:

- **BAL volume yield (Median [IQR])**
- **Total cell yield**
- **Proportion of viable cells**

Methods

The study comprised of: 60 healthy volunteers

aScope Broncho: 10 volunteers

Conventional bronchoscope: 50 volunteers

BAL procedure: 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.

Conventional bronchoscopy was performed in the surgical theatres, whereas flexible bronchoscopy was performed in the research ward.

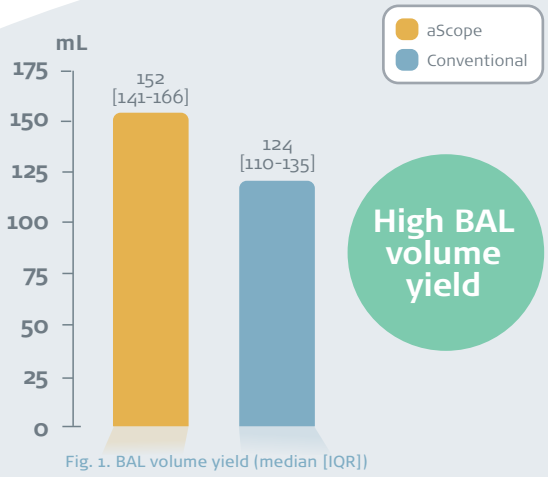


Fig. 1. BAL volume yield (median [IQR])

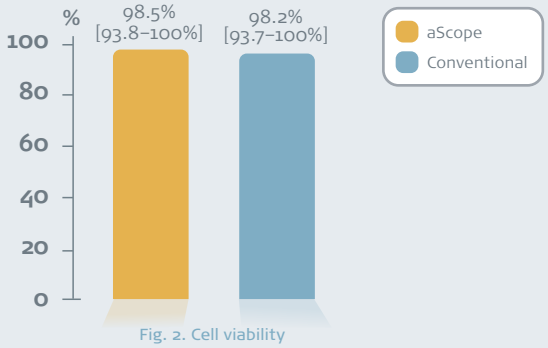


Fig. 2. Cell viability

Key Findings

1. The median BAL volume yield from the aScope Broncho was 152 mL (IQR 141– 166 mL) as compared to 124 mL (110– 135 mL) from the conventional bronchoscope (Fig.1).
2. The median total cell yield from aScope Broncho 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.
3. The median cell viability for samples from aScope Broncho was 98.5% (93.8–100) as compared to 98.2% (93.7–100%) from the conventional bronchoscope (Fig.2).
4. BAL volume yields were similar in male and female participants.

Conclusions

BAL with aScope Broncho achieved greater BAL volume yields than with conventional bronchoscopes. There was no significant difference between the cell yield and viability between the methods. aScope Broncho can be used to obtain BAL for research purposes to study immune responses and in early phase drug development studies.

Reference: Zaidi SR, Collins AM, Mitsi E, Reiné J, Davies K, Wright AD, *et al.* Single use and conventional bronchoscopes for broncho alveolar lavage (BAL) in research: A comparative study (NCT 02515591). BMC Pulmonary Medicine. 2017;17(1).

Retrospective study | ICU | BAL, BW, Airway Inspection | aScope Broncho vs RFB

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

Marshall DC, et al., (2017). J Bronchol Intervent Pulmonol.

Key Points

- **aScope: 3** Reusable scope: 5 — Personnel requirements
- **aScope: 0 mins** Reusable scope: 120 mins — Scope turn-around time
- **aScope is cost saving when all costs considered** — Overall cost

Study Overview

A retrospective review to compare aScope Broncho vs reusable flexible bronchoscope (RFB) by evaluating:

- **Microbiological yield**
- **Time requirement between identification of the need for bronchoscopy, to start the procedure & scope turn around time**
- **Staff/equipment requirements & cost differences**
- **Procedure time**

Methods

Medical records of 93 patients undergoing flexible bronchoscopy were studied between Jan-December 2015 in the ICU.

aScope Broncho: 83 bronchoscopic procedures on 71 patients, median age 62. Used in medical, surgical, coronary care unit & the neuro-ICU.

RFB (BF-P190; Olympus): 24 procedures on 22 patients, median age 67. Only used in medical ICU.

aScope Broncho indications: percutaneous tracheostomy (44.6%), BAL&BW (24.1%), airway inspection (9.6%), haemorrhage (6%), intubation (3.6%) & other (2.4%).

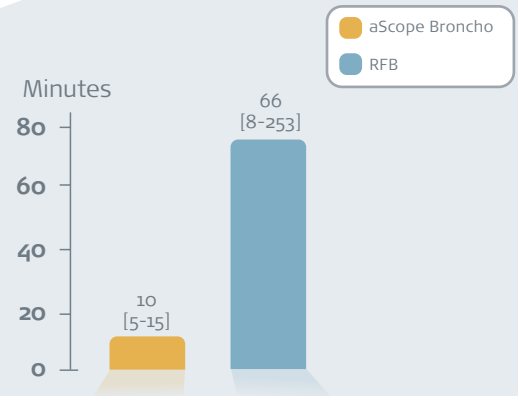


Fig 1. Time between identification of the need for bronchoscopy, to the start of the procedure (minutes, median [IQR])

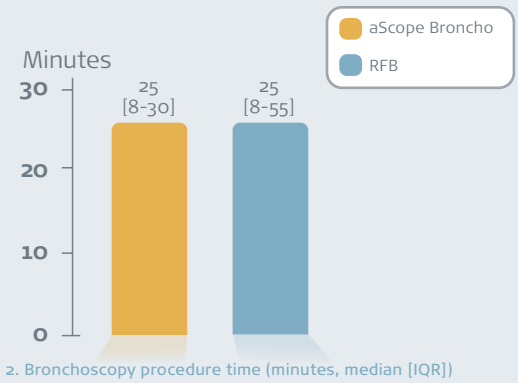


Fig. 2. Bronchoscopy procedure time (minutes, median [IQR])

Key Findings

1. Microbiological yield was comparable between aScope 70% (14/20) vs. RFB 70% (7/10). aScope was extremely beneficial in a patient with broncho-esophageal fistula who required regular bronchial toileting.
2. The median time required between the identification of the need for bronchoscopy to start of the procedure was significantly shorter with aScope (10 min [5-15]) versus (66 min [8-253]). This was due to longer turn around time with RFB (120 minutes) (Fig.1).
3. 3 personnel were needed with aScope vs 5 with RFB. aScope only required the scope & swivel connector, whereas the RFB additionally required video system, bronchoscope carrying trolly & disinfection equipment. Scope transportation to ICU also required additional personal for RFB.
4. Per procedure costs were similar between aScope (SGD450) vs RFB (SGD472). However, this price excludes the cost of repair, disinfection, weekend cases and after hours for reusable scope.

Conclusions

aScope Broncho performed as well as RFB, especially for microbiological sampling. PDT procedures were exclusively performed with aScope Broncho. aScope Broncho also required less resources and had superior scope turn-around time, which may increase efficiency. Overall, aScope Broncho may offer clinical, economic and logistical advantages over conventional bronchoscopes.

Reference: Marshall DC, Dagaonkar RS, Yeow C, Peters AT, Tan SK, Tai DY, *et al*. Experience with the use of single-use disposable bronchoscope in the ICU in a tertiary referral center of Singapore. Journal of Bronchology & Interventional Pulmonology. 2017;24(2):136-43

Observational study | ICU | BAL | aScope Broncho

Evaluating the Ambu® aScope™ 3 system for broncho-alveolar lavage and bronchial wash in invasively ventilated patients

McGrath BA, et al., (2013). Intensive Care Medicine.

Study Overview

An observational study to evaluate the functionality of aScope Broncho for BAL & BW procedures in invasively ventilated patients. The reported outcomes included:

- **Functionality**
- **Ease of use**

Methods

20 procedures (7 BW only, 4 BAL only, 9 both BW and BAL) were completed between 26/2/2013 and 9/4/2013 at acute intensive care unit of the University Hospital of South Manchester, UK.

Two experienced bronchoscopists carried out all procedures using aScope.

A 5-point Likert scale was used (1 fully disagree, 3 neutral, 5 fully agree) to evaluate functionality and ease of use of the system.

Key Findings

1. All six major segments of the bronchial tree were visualised for all endoscopies. Overall functionality and performance was rated as satisfactory in all procedures and the system was felt to be able to replace the existing non-disposable system in 19 procedures.
2. The following functionalities were rated between 4-5: easy to advance, easy to inject via working channel, ease of performing suction & adequate suction capability, adequate image quality for the procedure and ease of lens clearing.
3. The following functionalities were rated between 3-4: the functionality of the working channel & lightweight handle was a benefit.
4. The suction capabilities were comparable to our non-disposable bronchoscope & the system was assessed as easy to use and performs satisfactorily for BAL and BW in invasively ventilated critically ill patients.

Additional Evidence

Preparation of an intensive care unit in France for the reception of a confirmed case of Ebola virus infection.
Dubost C, Pasquier P, Kearns K, Ficko C, Rapp C, Wolff M, et al. Anaesth. Crit. Care Pain Med. 2015;34(6):349-55.

Early Identification of Acute Lung Injury in a Porcine Model of Hemorrhagic Shock.
Morris MC, Kim Y, Blakeman TC, Stevens-Topie S, Jung AD, Cox DB, et al. J Surg Res. 2020;247:453-60.

Evaluating the effect of operator experience and bronchoscope type in performance of simulated bronchoalveolar lavage.
Simons A, MaGrath B. BJA. 2017; p. e1-e20.

Evaluation of reusable and disposable bronchoscopes by user preference when performing simulated bronco-alveolar lavage on a manikin.
Whetton E, Simons A, Grath BMC. Journal of the Intensive Care Society. 2019; p. 150-1.

Regeneration of severely damaged lungs using an interventional cross-circulation platform.
Guenthart BA, O'Neill JD, Kim J, Queen D, Chicotka S, Fung K, et al. Nature communications. 2019;10(1):1-16.

Evaluating the effect of operator experience and bronchoscope type in performance of simulated bronchial wash.
Whetton E, McGrath B.BJA. 2015; p. e950-e62.

Broncho-alveolar inflammation in COVID-19 patients: a correlation with clinical outcome.
Pandolfi L, Fossali T, Frangipane V, Bozzini S, Morosini M, D'Amato M, *et al.* BMC pulmonary medicine. 2020;20(1):1-10.

COVID-19: the key role of pulmonary capillary leakage. An observational cohort study.
Wu MA, Fossali T, Pandolfi L, Carsana L, Ottolina D, Frangipane V, *et al.* medRxiv. 2020.

Reference:
McGrath BA, Bentley AM, editors. Evaluating the Ambu® aScope™ 3 system for broncho-alveolar lavage and bronchial wash in invasively ventilated patients. ESICM; 2013: Intensive Care Medicine.

Retrospective study | Field ICU | Bedside PDT | aScope Broncho

Percutaneous dilatational tracheostomy for saturating influx of COVID-19 patients: Experience of military ENT physicians deployed in Mulhouse, France

Morvan JB, *et al.*, (2020). European Annals of Otorhinolaryngology.

Key Points

- **7 minutes, with <12 minutes in 88.9%** — Mean procedure time
- **Easy: 72.2%, Moderately easy: 27.8%** — Difficulty of procedure
- **83.3% technically compliant** — Procedure compliance

Study Overview

A retrospective study to evaluate aScope Broncho for:

- **Survival rate after percutaneous dilatational tracheostomy (PDT)**
- **Admission to tracheostomy time**
- **Mean procedure time for PDT**
- **Procedure compliance (without difficulty)**
- **ENT self-assessment difficulty score**

Methods

The study comprised of: 47 adult COVID-19 patients.

PDT was performed on 18 patients (median age 64 years) by senior ENT physicians at the bedside in a military tent.

15 patients had a short neck and 88.9% had obesity with predominantly unfavourable anatomic conditions.

aScope 4 Broncho Regular was used with portable aView Monitor.

Indications: PDT, confirm positioning and aspirate blood and tracheobronchial secretions.

88.9% required <12 minutes

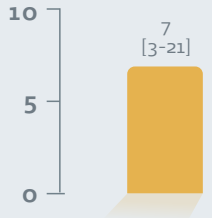


Fig. 1. Mean procedure time (minutes)

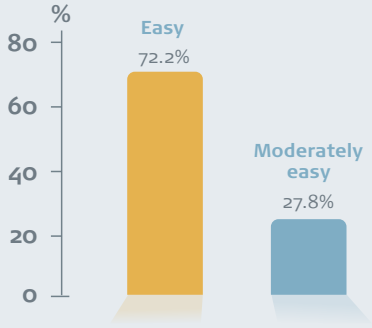


Fig. 2. ENT self-assessed difficulty of the procedure

Key Findings

1. All procedures were successful, with zero mortality. Median time to tracheostomy was 13 days (range 7-25 days) after admission and 11 days (range, 6-25 days) after orotracheal intubation.
2. Mean procedure time was 7 minutes (range, 3-21 min), and < 12 minutes in 88.9% of cases, counting from each surgeon's first procedure (Fig.1).
3. The procedure was technically compliant in 83.3% of cases, with slight technical difficulties in three cases.
4. Self-assessed difficulty was "easy" in 72.2% of cases, "moderately easy" in 27.8% and "difficult" in none (Fig.2).
5. There were four post-procedural complications, with no patient harm. None of the complications was related to aScope Broncho.
6. There were no probable, suspect or possible Covid-19 cases in staff involved in PDT.

Conclusions

The present study, conducted in the context of the Covid-19 pandemic, confirmed the feasibility and safety of percutaneous tracheostomy for patient and staff. aScope Broncho facilitated the success of all PDT procedures with no serious complications and with zero mortality. The procedure was easy with 83.3% of the cases being technically compliant. There were no infections in staff involved in PDT with COVID-19.

Reference: Morvan JB, Rivière D, Danguy des Déserts M, Bonfort G, Mathais Q, Pasquier P. Percutaneous dilatational tracheostomy for saturating influx of COVID-19 patients: Experience of military ENT physicians deployed in Mulhouse, France. European Annals of Otorhinolaryngology, Head and Neck Diseases. 2020.

Case series | ICU | Bedside PDT | aScope Broncho

Percutaneous Dilatational Tracheostomy in Coronavirus Disease 2019 Extracorporeal Membrane Oxygenation Patients: A Case Series

Valchanov K, et al., (2020). Journal of Cardiothoracic and Vascular Anesthesia.

Study Overview

A prospective tracheostomy database review to evaluate safe PDT procedures during March 27-May 15, 2020 at Royal Papworth Hospital, UK. The main outcome was:

- **Complications & safety**

Methods

38 PDT procedures were performed on mechanically ventilated patients on extracorporeal membrane oxygenation during 8 weeks of the COVID-19 pandemic.

The decision to perform tracheostomy was made by the duty day intensivist. The average time of tracheal intubation before tracheostomy was 11.66 days.

aScope Broncho was used in all patients.

Key Findings

1. The mean age of the patients was 45.5 ± 9.6 years, with various comorbidities such as asthma, diabetes & obesity.
2. All procedures were performed at the bedside in an ICU with isolation rooms and all were successful.
3. Ventilation was discontinued during withdrawal of the endotracheal tube, dilator exchange, and tracheostomy tube insertion. Ventilation then was resumed, and the position was confirmed bronchoscopically and via capnography.
4. Complications were minimal. No immediate complications, such as pneumothorax or tracheostomy malposition, were observed. No transfusion of blood products was required for tracheostomy bleeding.
5. Medical staff did not report any sickness or sick leave relating to the tracheostomies.

Case series | ICU | Bedside PDT | aScope Broncho

A single-centre case series assessing the Ambu® aScope™ 2 for percutaneous tracheostomies: A viable alternative to fibreoptic bronchoscope

Reynolds S, et al., (2015). Can J Respir Ther.

Study Overview

A quality improvement evaluation of aScope Broncho as an alternative to fibreoptic bronchoscopes for bedside PDT procedure by evaluating:

- **Subjective assessments of visualization**
- **Ease of use**
- **Adequacy of the device**
- **The incidence of cross-over to a fibreoptic video bronchoscope**

Methods

The aScope Broncho was used in 22 percutaneous bedside tracheostomies between 09/2012-01/2013 in the ICU.

The patients selected were medically stable, with minimal to moderate secretions.

Physician experience: experienced operators with >50 PDT with reusable fibreoptic bronchoscopes.

Key Findings

1. 16 questionnaires were completed for the study.
2. One conversion to a regular fibreoptic bronchoscope occurred during the 22 procedures due to the need for ongoing suction.
3. Mean 'ease of use' score was 8.19/10 (range 6/10 to 10/10). Mean 'visualization' score was rated 6.1/10 and the adequacy for the procedure was 20/22 (91%).
4. Our series demonstrated that, in a general ICU population, the aScope Broncho performed adequately for PDT in a population selected for ease of use. It is likely that next-generation disposable bronchoscopes will integrate a suction port. There may be a role for an inexpensive bronchoscope that provides adequate visualization and does not require the gentle care needed for glass-fibre (ie., fibreoptic)-based bronchoscopes in a busy ICU environment.

References:

Valchanov K, Salaunkey K, Parmar J. Percutaneous Dilatational Tracheostomy in Coronavirus Disease 2019 Extracorporeal Membrane Oxygenation Patients: A Case Series. Journal of Cardiothoracic and Vascular Anesthesia. 2020.

Reynolds S, Zurba J, Duggan L. A single-centre case series assessing the Ambu® aScope™ 2 for percutaneous tracheostomies: A viable alternative to fibreoptic bronchoscopes. Canadian Journal of Respiratory Therapy. 2015;51(2):43-5.

Case series | ICU | PDT | aScope Broncho

Evaluating the Ambu® aScope™ 3 system for performing percutaneous dilatational tracheostomy in critical care patients

McGrath BA, Bentley AM., (2013). Intensive Care Medicine.

Study Overview

A case series of performing PDT procedures in critical care patients with aScope Broncho. The main outcome was:

- **Functionality**
- **Ease of use**

Methods

5 PDT procedures were performed on critical care patients in the acute intensive care unit of the University Hospital of South Manchester, UK.

Standard practice: reusable Olympus® BF-260 to guide PDT insertion.

A 5-point Likert scale was used (1 fully disagree, 3 neutral, 5 fully agree) to evaluate functionality and ease of use of the system.

aScope Broncho was used in all patients.

Key Findings

1. All 5 procedures were completed uneventfully between 11/3/2013 and 8/4/2013. Clear images of the needle and guide-wire entering the trachea were recorded in all 5 procedures.
2. The following functionalities were rated 5 out of 5: easy to connect & setup, easy & intuitive to use, image quality clear & adequate, suction capability and the ability to clean blood & secretions.
3. The following functionalities were rated 4 out of 5: the functionality of working channel & the ergonomics of the device.
4. The lightweight design and ease of navigation & capability of recording images were rated 3 out of 5.
5. The authors agreed in all 5 PDTs that the aScope Broncho system was satisfactory and that the system could have replaced their existing non-disposable system for guiding the PDT.

Manikin study | Tracheostomy assessment | aScope Broncho vs RFB

A comparison of three endoscopes in assessment of tracheostomy position in simulation manikins

Templeton R, et al., (2013). Intensive Care Medicine.

Study Overview

A manikin study to evaluate aScope Broncho, Olympus LF-GP & Olympus MAF for assessment of tracheostomy tube placement by evaluating:

- **Time taken to achieve adequate views**
- **Operator's ease of endoscopy score**

Methods

25 anaesthetic trainees at University Hospital of South Manchester (UK) assessed tracheostomy tube placement using the aScope Broncho, Olympus LF-GP and Olympus MAF.

Observations were made using three training manikin variants: METIman (using both 'standard' and 'difficult' airway settings) and SimMan.

Tube position was assessed via the tube lumen and within the trachea by both the oral and nasal routes.

The trainee allocated an 'ease of endoscopy score'- with a score of '1' indicating great difficulty and a score of '10' indicating great ease.

Key Findings

1. 225 observations were made with each endoscope. Satisfactory visualisation was achieved in 120 seconds or less in over 99% of observations and in 60 seconds or less in 92%.
2. There was a small, but statistically significant, difference between the endoscopes in the meantime to achieve satisfactory visualisation, with the Olympus MAF taking slightly longer.
3. Generally, trainees perceived the overall procedure as 'easy', allocating a median 'endoscopy score' of 8 for all three endoscopes. No statistically significant differences in 'endoscopy scores' between the endoscopes were demonstrable.
4. Assessment of position is achievable in a clinically relevant timeframe with all scopes.

References:
McGrath BA, Bentley AM. Evaluating the Ambu® aScope™ 3 system for performing percutaneous dilatational tracheostomy in critical care patients. European Society of Intensive Care Medicine, 26th Annual Congress; 5-9 October; Paris, France: Intensive Care Medicine; 2013. p. S253-S4.

Templeton R, McGrath B, Webster K, Simpson W. A comparison of three endoscopes in assessment of tracheostomy position in simulation manikins. 26th ESICM ANNUAL CONGRESS. 2013;39:1-4.

Comparative study | ICU | PDT, BAL, Bronchial Cleaning | aScope Broncho vs RFB

Prospective and multicenter comparative study of the performance of Ambu® aScope™ 3 in intensive care: an interim analysis

Dhonneur G., (2015). Anesthésie & Réanimation.

Study Overview

A comparative study to evaluate aScope Broncho & reusable fiberscope in intensive care for the following outcomes

- **Performance**
- **Overall satisfaction of the practitioner**
- **Time taken from decision making to perform endoscopy**

Methods

5 anaesthesia and intensive care units were involved.

All patients requiring therapeutic procedures with endoscopy to perform alveolar lavage, bronchial cleansing, or percutaneous tracheostomy were included.

Scope choice was made in a pragmatic manner, according to the service procedures.

Key Findings

1. Over a period of 2 months, 98 bronchoscopy therapeutic procedure scorecards were analysed including 36 with a reusable fiberscope and 62 with aScope Broncho.
2. The mean time between the decision to perform the procedure and the start of the endoscopic treatment is 5 times shorter with aScope Broncho than with reusable fiberscope (17 versus 57 min).
3. This time was < 3 min in 52% of cases of aScope Broncho use versus 11% with a reusable fiberscope.
4. The possibility of carrying out the teaching, endoscopic image quality and the speed of implementation were greater with aScope Broncho vs reusable fiberscope (89 [17] versus 47 [26]; 82 [14] versus 69 [22]; 94 [7] versus 73 [21], respectively). (Rated from 0=absence to 100=maximum). Clinician satisfaction was comparable between scopes.

Case series | ICU | Bedside PDT | aScope Broncho

Experience of percutaneous tracheostomy in critically ill COVID-19 patients

Kim EJ., (2020). Acute and Critical Care.

Study Overview

A case series to evaluate the safety of PDT procedures on COVID-19 positive patients. The outcomes included:

- **COVID-19 infection status of healthcare personnel**

Methods

7 patients underwent PDT procedures in an ICU between February 24 and April 30, 2020. The average age of the patients: 71 years.

Percutaneous tracheostomy was performed at the bedside by an experienced physician who has worked in the ICU for 4 years and has performed more than 100 such procedures.

Ambu aScope with aView monitor was used.

Key Findings

1. One operator and one respiratory specialist examining the bronchoscopy were in close proximity to the patient. One nurse assisted with the procedure. The resident doctor also helped in some cases. All tracheostomy procedures were performed in the negative pressure unit.
2. The median duration from the application of the ventilator to percutaneous tracheostomy was 14 days (IQR, 9–16 days). The PDT procedure time was 10 (IQR, 7-12) minutes. Of seven patients who underwent a tracheostomy, the 30-day mortality rate was 0.
3. All medical staff, including the tracheostomy team, were tested for SARS-CoV-2 by real-time RT-PCR. All staff tested negative.
4. PDT was performed with conventional methods in the negative pressure cohort area. It was safe to perform percutaneous tracheostomy in an environment of COVID-19 infection.

Reference:
Dhonneur G, Bazin J-E, Haouache H, Diemunsch P, Koffel C, Meistelman C. Prospective and multicenter comparative study of the performance of Ambu® aScope™ 3 in intensive care: an interim analysis. 1S1 congrès SFAR 2015; September; France: Anesthésie & Réanimation; 2015. p. A268-A9.

Kim EJ, Yoo E-H, Jung CY, Kim KC. Experience of percutaneous tracheostomy in critically ill COVID-19 patients. Acute and Critical Care. 2020.

Additional Evidence:
Percutaneous Dilatational Tracheostomy with aScope Broncho

Management of tracheostomy-related tracheomegaly in a patient with COVID-19 pneumonitis.
Harper S, Robinson M, Manning G, Jones A, Hobson J, Shelton CL. Anaesthesia Reports. 2020;8(2):e12076.

Disposable bronchoscope-safe and cost effective tool in difficult airways, percutaneous tracheostomies and diagnostic/therapeutic bronchoscopy.
Paily Ck, Gillespie C, Phan C, Afifi S, Wunderink R, Touchton R. Respiratory Care; 2016. p. OF35.

Difficult Intubation: How to Avoid a Tracheostomy.
Lima R, Salomão LV, Rotava P. Tracheostomy: Springer; 2018. p. 335-62.

Percutaneous Tracheostomy with Apnea During Coronavirus Disease 2019 Era: A Protocol and Brief Report of Cases.
Niroula A, Van Nostrand KM, Khullar OV, Force S, Jaber WS, Sardi AH, *et al.* Crit Care Explor. 2020;2(5):e0134.

Percutaneous tracheostomy in patients with COVID-19: sealing the bronchoscope with an in-line suction sheath.
Al Yaghchi C, Ferguson C, Sandhu G. BJA. 2020;125(1):e185-e6.

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A novel approach to managing acute tracheostomy obstruction in a patient with anaplastic thyroid cancer.
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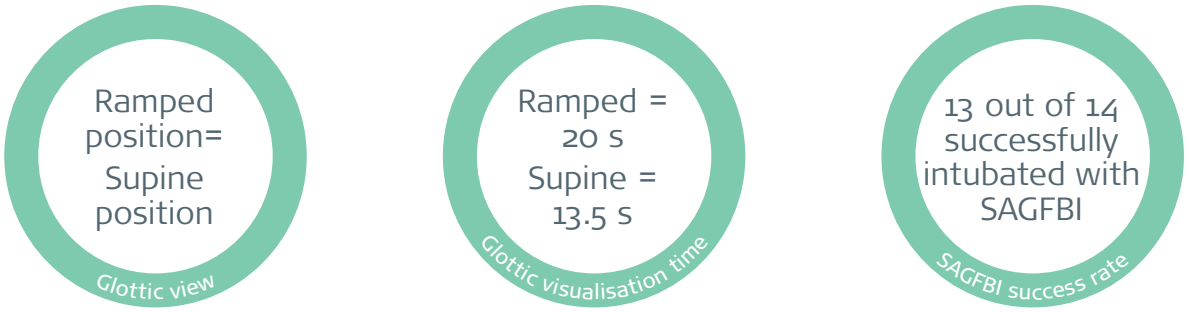
Pilot study | SADFB Intubation | Ramped vs Supine Position | aScope Broncho

Comparison of glottic visualisation through supraglottic airway device (SAD) using bronchoscope in the ramped versus supine 'sniffing air' position: A pilot feasibility study

Lim WY, et al., (2020). Indian J Anaesth.

Key Points



Study Overview

A pilot study to evaluate aScope Broncho for:

- **Bronchoscopic glottic views in ramped and supine "sniffing air" positions**
- **Time taken for supraglottic airway guided flexible bronchoscopic intubation (SAGFBI)**
- **Success rate of SAGFBI**
- **Airway manoeuvres undertaken**
- **Adverse events**

Methods

The study comprised of: 14 obese patients (median age 47), with a median BMI of 35.4 & patient distribution in Mallampati scores were 1/2/3/4=4/7/3/0

ET tube sizes: size 6 & 7

Laryngeal mask: AuraGain size 3 & 4

Glottic view: Cormack-Lehane grade*

Key Findings

1. The glottic views in the ramped vs supine position were comparable. 78.6% of the glottic views were Cormack–Lehane Grade 1 or 2 in both positions.
2. The median (IQR) times taken for bronchoscopic glottic visualisation in the ramped and supine positions were 20 (12.25, 28.25) and 13.5 (10.5, 19.75) s, respectively (Fig.1).
3. The median SAGFBI (supine position) and total study times were 91.5 and 225 s, respectively. In 92.9% of cases, minimal to moderate manipulation of the bronchoscope was required (Fig.2).
4. SAGFBI was successful in 13 out of 14 patients (92.9%). 12 of the 13 intubations (92.3%) were successful on the first attempt, in the remaining patients, intubation was successful on the second attempt.
5. Airway manoeuvres were required in three patients (21.4%). 35.7% of patients experienced tachycardia and 42.9% experienced hypertension, however, none were related to aScope.

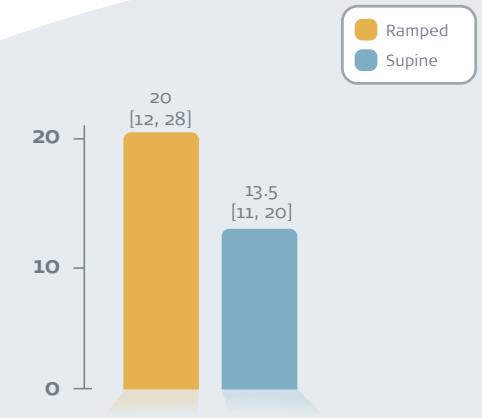


Fig. 1. Median glottic visualisation time in ramped or supine positions (seconds, IQR)

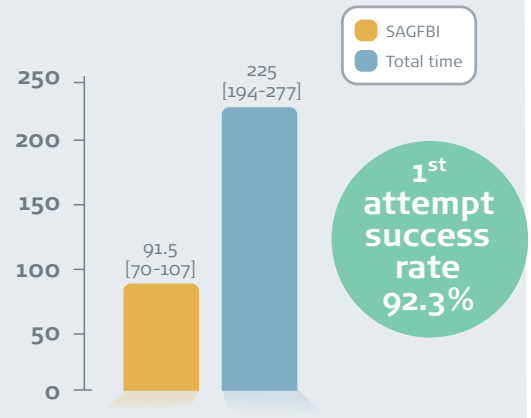


Fig. 2. Median SAGFBI time in supine position & total procedure time (seconds, IQR)

Conclusions

Protocol feasibility was established. SAGFBI was successfully and safely performed in obese patients. This pilot study provided preliminary data supporting future, larger-scale studies to evaluate glottic views in the ramped versus supine positions.

Reference: Lim WY, Fook-Chong S, Wong P. Comparison of glottic visualisation through supraglottic airway device (SAD) using bronchoscope in the ramped versus supine 'sniffing air' position: A pilot feasibility study. Indian Journal of Anaesthesia. 2020;64(8):681.

*Cormack-Lehane Grade: 1 - vocal cords fully visualised, 2a - vocal cords partially visualised, 2b - only arytenoids are visible, 3 - epiglottis visible, 4 - epiglottis not visible

RCT | SADFB Intubation | aScope Broncho

Flexible optical intubation via the Ambu® Aura-i vs blind intubation via the single-use LMA Fastrach: a prospective randomized clinical trial

Artime CA, et al., (2016). Journal of Clinical Anaesthesia.

Study Overview

An RCT to compare intubation with aScope Broncho + Aura-i vs Intubating LMA, by assessing:

- **Time to intubation**
- **Success rate**
- **Airway morbidity**

Methods

65 patients with normal airways scheduled for elective surgery requiring general anaesthesia were recruited.

aScope Broncho + Aura-i: 32 patients. Mean BMI was 25.8 ± 3.4 kg/m². Mean age: 39.8 ± 13.7

Intubating LMA: 33 patients, blind intubation. Mean BMI was 25.2 ± 4.1 kg/m². Mean age: 44.4 ± 13.7.

Key Findings

1. There was no difference in either the first-attempt intubation success rate (Aura-i = 26/33, 78.8%; ILMA = 27/33, 81.8%) or the overall intubation success rate (Aura-i = 29/33, 87.9%; ILMA = 31/33, 93.9%) between the 2 groups.
2. There was no oesophageal intubation in aScope + Aura-i group, whereas 2 patients in the ILMA group had a failed intubation due to oesophageal intubation.
3. Time for the overall intubation procedure was faster in the ILMA group (median = 52.1 seconds; IQR, 46.4-69.8 seconds) than in the Aura-i group (median = 89.6 seconds; IQR, 67.8-117.5 seconds).
4. OLPs were similar in the 2 groups. There were no statistically significant differences in post-operative complications between the Aura-i and ILMA groups.

RCT | SADFB Intubation | aScope Broncho vs RFB

Comparison of the single-use Ambu® aScope™ 2 versus the conventional fiberscope for Standard Tracheal Intubation through a Ambu® Aura-i™ laryngeal mask

Hengen M, et al., (2017). American Society of Anaesthesiologists.

Study Overview

An RCT to compare intubation with aScope Broncho + Aura-i vs conventional reusable FOB (Storz™ or Olympus™ FOB), by assessing:

- **Total intubation time**

Methods

Over 36 (31 in France and 5 in Denmark) patients with predicted difficult airways were recruited. Patients were included if they had 2 predictive criteria for difficult intubation.

Total intubation time: from introducing the tip of the B into the SAD to the appearance of a capnographic trace.

Reusable FOB: 21 patients

aScope Broncho: 15 patients

Key Findings

1. When subjects that required suctioning during the procedure were excluded, there was no statistical difference between the aScope Broncho and reusable FOBs with regards to total intubation time.
2. Four patients needed suction in the aScope Broncho group, who had longer total intubation time (290.3 +/- 151.9 sec) than those who did not need suction (112.7 +/- 31.1 sec).
3. Three patients needed suction in the FOB group and the intubation time was 137.7 +/-91.5 sec.
4. Total intubation time was significantly longer with aScope Broncho (167.3 +/-117.0 sec) than with conventional FOB (105.6 +/- 71.6 sec). This difference was observed only where suction through the device was needed.

References:

Artime CA, Altamirano A, Normand KC, Ferrario L, Aijazi H, Cattano D, *et al*. Flexible optical intubation via the Ambu® Aura-i™ vs blind intubation via the single-use LMA Fastrach: a prospective randomized clinical trial. Journal of Clinical Anesthesia. 2016;33:41-6.

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Additional Evidence:

SADFB Intubation & Bronchoscopic Assessment of the Glottic View with aScope Broncho

Supraglottic Airway Guided Flexible Bronchoscopic Intubation

Supraglottic Airway–Guided Intubation During the COVID-19 Pandemic: A Closed Technique.
Wong P, Lim WY, Mok M. Anesthesia and Analgesia. 2020;131(2):e120-e1.

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Chua H, Lim WY, Mok M, Wong P. Anesthesia and Analgesia. 2020.

Comparison of i-Gel as a Conduit for Intubation between under Fiberoptic Guidance and Blind Endotracheal Intubation during Cardiopulmonary Resuscitation: A Randomized Simulation Study.
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Paediatric ventilating bougie a rescue device in an unanticipated difficult mask ventilation in a patient with an impacted foreign body.
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A potential technique for flexible scope-assisted intubation using an Ambu® aScope™ 2 inserted via a supraglottic airway device.
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Bronchoscopic Assessment of the Glottic View

Pediatric airway management in undiagnosed congenital subglottic stenosis patients.
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A randomized comparison of the Ambu® AuraGain™ versus the LMA supreme in patients undergoing gynaecologic laparoscopic surgery.
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The Ambu® Aura-i™ Laryngeal Mask and LMA Supreme™: A Randomized Trial of Clinical Performance and Fibreoptic Positioning in Unparalysed, Anaesthetised Patients by Novices.
Yahaya Z, Teoh WH, Dintan NA, Agrawal R. Anesthesiology Research and Practice. 2016.

Cross-over assessment of the Ambu® AuraGain™, LMA Supreme New Cuff and Intersurgical I-Gel in fresh cadavers.
Lopez AM, Sala-Blanch X, Valero R, Prats A. Open Journal of Anesthesiology. 2014;4(12):332.

Emergency airway access in children – transtracheal cannulas and tracheotomy assessed in a porcine model.
Holm-Knudsen RJ, Rasmussen LS, Charabi B, Bøttger M, Kristensen MS. Pediatric Anesthesia. 2012;22(12):1159-65.

RCT | Orotracheal intubation | aScope Broncho vs RFB

Randomised controlled trial comparing the Ambu® aScope™ 2 with a conventional fibreoptic bronchoscope in orotracheal intubation of anaesthetised adult patients

Chan JK, et al., (2015). Anaesth Intensive Care.

Key Points

- **aScope: 3 (2-3)** vs. fiberscope: 2 (2-3) — Global Rating Score
- **aScope: 1 (1-2)** vs. fiberscope: 2 (2-3) — Ease of overall use
- **aScope: 2 (1-2)** vs. fiberscope: 2 (1-3) — Ease of manoeuvrability

Study Overview

An RCT to compare the aScope Broncho with Karl Storz fiberscope in:

- **Global Rating Scale score (GRSs): overall scope control, progression, orientation, view & collisions, accuracy**
- **Intubation success rate**
- **Number of intubation attempts**
- **Intubation time**
- **Ease of overall use, setup, manoeuvrability, railroading and image quality scores***

Methods

The study comprised of: 60 anaesthetised adult patients undergoing orotracheal intubation with ASA score of II-III

aScope: 30 patients, (mean age 52.1 years)

Reusable fiberscope: 30 patients, (mean age 50.6 years)

GRS: measured 1-5, 1=very poor unsafe, 5=superior expert

Key Findings

1. The median (IQR) GRSs between aScope Broncho [3(2-3)] & reusable fiberscope [2(2-3)] were comparable.
2. The intubation success rate was 97% for aScope and 93% for reusable fiberscope, and the average number of intubation attempts was lower in aScope Broncho group (Fig.1).
3. The mean (SD) intubation time was comparable between aScope Broncho 75.4 (28.7) & reusable fiberscope 71.2 (34.8) seconds (Fig.2).
4. The median (IQR) ease of overall use score was in favour of aScope Broncho [1(1-2)] compared to the reusable fiberscope [2(2-3)].
5. Ease of setup, manoeuvrability, railroading and image quality did not differ between groups.

*measured 1-5: 1 = best, 5 = worst

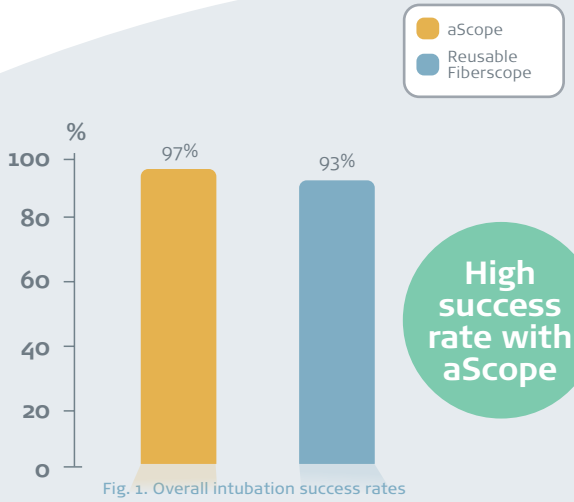

Fig. 1. Overall intubation success rates

High success rate with aScope

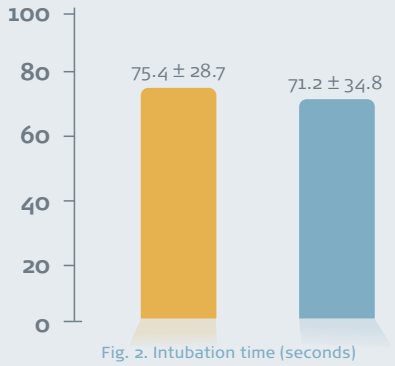

Fig. 2. Intubation time (seconds)

Conclusions

The aScope Broncho showed no significant difference in clinical performance when compared to a reusable fiberscope, in well-prepared anaesthetised patients undergoing elective fibreoptic intubation. It is relatively easy to use the device. It's practicality and disposability potentially make it an acceptable alternative to the reusable fiberscope.

Reference: Chan JK, Ng I, Ang JP, Koh SM, Lee K, Mezzavia P, *et al.* Randomised controlled trial comparing the Ambu® aScope™ 2 with a conventional fibreoptic bronchoscope in orotracheal intubation of anaesthetised adult patients. Anaesthesia and Intensive Care. 2015;43(4):479-84.

RCT | Tracheal intubation | aScope Broncho +VL vs Stylet +VL

Effect of Dynamic Versus Stylet-Guided Intubation on First-Attempt Success in Difficult Airways Undergoing Glidescope Laryngoscopy: A Randomized Controlled Trial

Mazzinari G, et al., (2019). Anesth Analg.

Key Points

- **aScope + VL: 91%** vs VL + Stylet: 70% — 1st attempt success rate
- **aScope + VL: 4%** vs VL + Stylet: 24% — Rescue technique needed
- **aScope + VL: 1%** vs VL + Stylet: 11% — Airway injury rate

Study Overview

An RCT to evaluate the combined use of aScope Broncho & videolaryngoscope (VL) vs VL & stylet, by evaluating:

- **First-attempt intubation success**
- **Time to successful intubation**
- **Airway injury rate**
- **Use of rescue techniques**
- **Ease of intubation**

Methods

The study comprised of: 158 adult patients (mean age 53.5) with predicted difficult airway & mean BMI of 37

The ASA physical status I/II/III/IV=9/95/53/1

aScope Broncho + VL group: 79 patients

VL+ stylet group: 79 patients

Key Findings

1. First attempt intubation success was higher in the aScope + VL (91%) vs VL+ Stylet group (70%). All patients were intubated in the first two attempts in aScope + VL group, whereas 11% in VL+ Stylet group required the third attempt (Fig.1).
2. Median time to successful tracheal intubation was shorter in the aScope + VL group (50 seconds [45-58]) vs. VL + Stylet group (64 s [54-87]) (Fig.2).
3. Airway injury rate was lower in the aScope + VL group than in the VL+ Stylet group (1% vs 11%).
4. Alternative rescue technique requirements to achieve tracheal intubation was higher in the VL+ Stylet group vs. aScope + VL group (24% vs 4%).
5. Intubation difficulty was measured by a scale of:
   Easy = aScope + VL 43% vs VL+Stylet 33%
   Slightly difficult = aScope + VL 53% vs VL+Stylet 56%
   Moderte/major difficulty = aScope + VL 4% vs VL+Stylet 11%

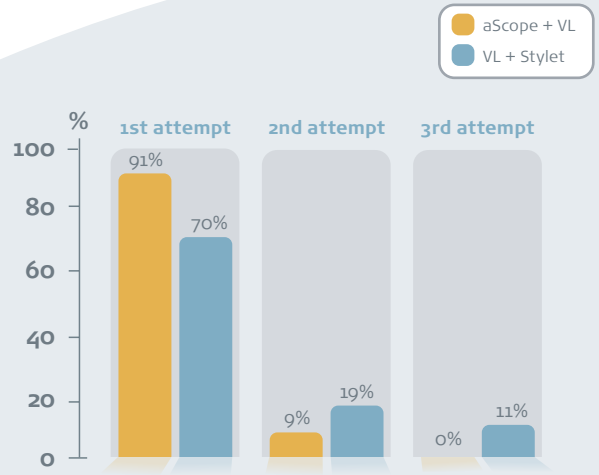

Fig. 1. Intubation success rate

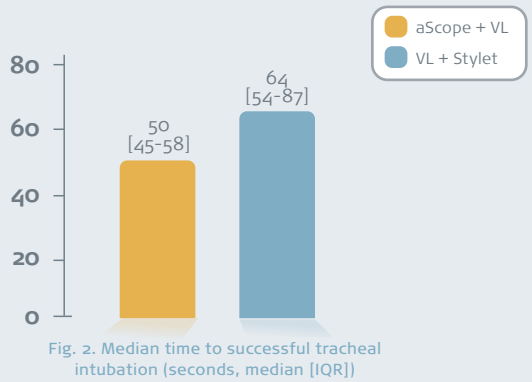

Fig. 2. Median time to successful tracheal intubation (seconds, median [IQR])

Conclusions

The combined use of aScope Broncho with video laryngoscopy in patients with a predicted difficult airway compared to a standard intubation technique improved first-attempt intubation success, decreased the incidence of airway injury and time to successful intubation, as well as the need for an alternative technique to succeed.

Reference: Mazzinari G, Rovira L, Henao L, Ortega J, Casasempere A, Fernandez Y, *et al.* Effect of Dynamic Versus Stylet-Guided Intubation on First-Attempt Success in Difficult Airways Undergoing Glidescope Laryngoscopy: A Randomized Controlled Trial. Anesthesia and Analgesia. 2019;128(6):1264-71.

RCT | Tracheal intubation | aScope Broncho+VL vs Stylet +VL

Is Video Laryngoscope-Assisted Flexible Tracheoscope Intubation Feasible for Patients with Predicted Difficult Airway? A Prospective, Randomized Clinical Trial

Lenhardt R, et al., (2014). Anesth Analg.

Key Points

- aScope +VL: 100% vs Stylet+VL: 80% — Success rate for CSP
- aScope +VL: 98% vs Stylet+VL: 92% — 1st & 2nd attempt success rate
- aScope +VL: 47 s vs Stylet+VL: 46 s — Time to vocal cord visualisation

Study Overview

An RCT to evaluate aScope Broncho with VL vs Stylet combined with video laryngoscopy (VL) by assessing:

- **Number of intubation attempts**
- **Time to successful intubation**
- **Intubation failure**
- **Ease of intubation and neck movements**

Methods

The study comprised of: 140 adult patients (mean age 45-46.5) with anticipated difficult airways

aScope Broncho+VL: 70 patients, ASA physical status I/II/III/IV=2/38/28/2

Stylet+VL group: 70 patients, ASA physical status I/II/III/IV=2/32/35/1

ET tube size: size 7=women, size 8=men

Key Findings

1. 98% achieved intubation in the first 2 attempts in the aScope group vs 91% in the stylet group. 6% in the Stylet group required change of technique (Fig.1).
2. The median time to intubation was comparable between aScope group (71 [52–100]) vs Stylet group (66 [47–89]).
3. The median time from the visualisation of vocal cords to intubation was also comparable between aScope group (47 [37–74]) vs Stylet group (46 [37–68]).
4. When the cervical spine pathology patients were compared separately, intubation performance for the intervention group was 100% (20/20), while for the control group, it was 80% (16/20) (Fig.2).
5. The operators rated ease of intubation as similar in the two groups. No complications were encountered. Events of arterial, as measured by pulse oximetry of <90%, were encountered in 6 patients in the stylet group and in 4 patients in the aScope group.
6. Neck movement as observed by an independent observer was not significantly different between the groups.

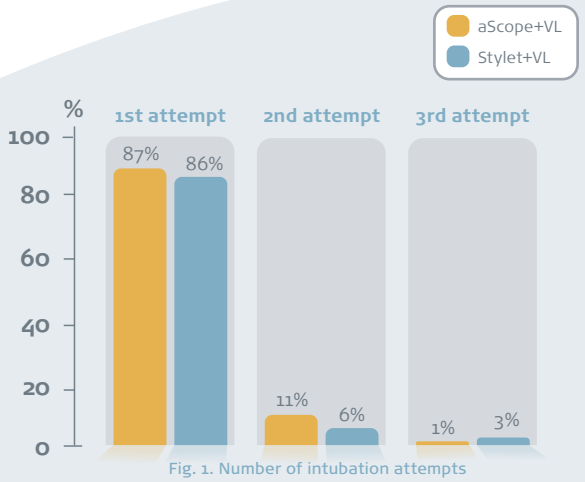

Fig. 1. Number of intubation attempts

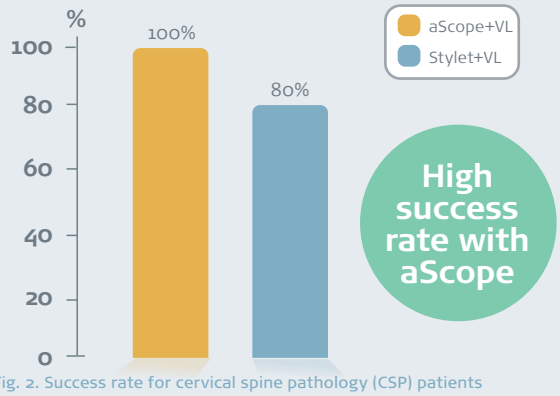

Fig. 2. Success rate for cervical spine pathology (CSP) patients

Conclusions

Time to intubation was comparable between groups; however the majority of cases achieved successful intubation in the first 2 attempts in the aScope group. aScope assisted video laryngoscopic intubation is a feasible alternative to video laryngoscope only intubation in patients with predicted difficult airways. It may increase the success rate of intubation in selected patients with a proven difficult airway, particularly when in-line stabilization is required.

Reference: Lenhardt R, Burkhart MT, Brock GN, Kanchi-Kandadai S, Sharma R, Akça O. Is video laryngoscope-assisted flexible tracheoscope intubation feasible for patients with predicted difficult airway? A prospective, randomized clinical trial. Anesthesia & Analgesia. 2014;118(6):1259-65.

Retrospective study | OR/ICU | Tracheal Intubation | aScope Broncho

Severe odontogenic deep neck space infections: risk factors for difficult airways and ICU admissions

Riekert M, et al., (2019). Oral and Maxillofacial Surgery.

Study Overview

A retrospective study to evaluate the patient's characteristics and perioperative risks concerning:

- **Difficult airway management**
- **Primary tracheostomy & need for ICU admission**

Methods

491 patients (mean age: 45.36 ± 17.95) with severe odontogenic infections were included between 2010-2017 in Department of Oral Maxillofacial Plastic Surgery & Intensive Care Medicine at University Hospital of Cologne.

All patients underwent extraoral incision and drainage under general anaesthesia with oral-tracheal or nasal-tracheal intubation.

aScope Broncho was used in the airway management of 88 patients of which 77 were under general anaesthesia, representing 15.4% of the cases & 11 were in the ICU, representing 35.5% of the ICU cases, respectively.

Key Findings

1. Airway securing in patients with restricted mouth opening led to significant use of the aScope Broncho.
2. Subgroup analysis showed that patients with acute dyspnoea were significantly more frequently intubated using aScope Broncho than direct laryngoscopy.
3. In patients with dysphagia, the necessity for aScope Broncho was significantly increased compared to the other airway management options.
4. Using advanced airway management such as video laryngoscopy or fibreoptic bronchoscopy led to the increased likelihood of ICU admission.
5. Factors such as limited mouth opening and dyspnoea were important predictors of difficult airway & ICU admission. The use of aScope Broncho for airway management in these cases was more often than other methods.

Prospective study | Tracheal Intubation | aScope Broncho +VL

Prospective validation of a new airway management algorithm and predictive features of intubation difficulty

Cook F, et al., (2019). BJA.

Study Overview

A prospective study to evaluate the efficacy & safety of a new enhanced airway management algorithm for difficult airway management. The reported outcomes included:

- **Intubation success**
- **Intubation time**
- **Predictors for enhanced airway management**

Methods

This study prospectively evaluated 16,695 patients and selected 1501 (9%) for enhanced airway management.

Enhanced airway management included:

Step 1: channelled videolaryngoscope (2 min)

Step 2: channelled videolaryngoscope + stylet (2 min)

Step 3: channelled videolaryngoscope + aScope (2 min)

Key Findings

1. Patients with difficult airways with previous difficult laryngoscopy, mouth opening, or cervical problems, would previously be considered for awake intubation.
2. The combination of the qualities of the videolaryngoscopy, the stylet, and the bronchoscope if needed, plus thorough training of the clinical staff, should allow more patients to be safely allocated to a plan for intubation under general anaesthesia.
3. Tracheal intubation was successful in all cases. Of these, 73% were intubated in less than 30 s, and only 4.5% required more than 4 min for intubation.
4. Progression to the second and third steps of enhanced management was predicted by restriction of mouth opening and reduced cervical spine mobility.

References:

Riekert M, Kreppel M, Zöller JE, Zirk M, Annecke T, Schick VC. Severe odontogenic deep neck space infections: risk factors for difficult airways and ICU admissions. Oral and maxillofacial surgery. 2019;23(3):331-6.

Cook F, Lobo D, Martin M, Imbert N, Grati H, Daami N, et al. Prospective validation of a new airway management algorithm and predictive features of intubation difficulty. British Journal of Anaesthesia. 2019;122(2):245-54.

Additional Evidence:
Bronchoscopy Guided Tracheal Intubation with aScope Broncho

Quest for an ideal route of intubation for oral and maxillofacial surgical manoeuvres.
Vadepally AK, Sinha BR, Subramanya A, Agarwal A. J. Oral Maxillofac. Surg. 2016;15(2):207-16.

Comparison of the single-use Ambu® aScope™ 2 vs the conventional fibrescope for tracheal intubation in patients with cervical spine immobilisation by a semirigid collar.
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Use of the Cook® Staged extubation set for reintubation following complications of major head and neck surgery.
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Evaluation of the novel, single-use, flexible aScope® for tracheal intubation in the simulated difficult airway and first clinical experiences.
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Bronchoscopy Guided Tracheal Intubation with aScope Broncho

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RCT | Awake Tracheal intubation | aScope Broncho vs RFB

The disposable Ambu® aScope™ vs a conventional flexible videoscope for awake intubation – a randomised study

Kristensen MS, Fredensborg BB., (2013). Acta Anaesthesiol Scand.

Key Points

- **aScope: 100%** vs Olympus 100% — Intubation success rate
- **aScope: 278 s** vs Olympus 234 s — Median total intubation time
- **aScope: 1 (1-4)** vs Olympus 2 (1-3) — Resistance with injection

Study Overview

An RCT to compare the performance of aScope Broncho with Olympus BF video-bronchoscope for awake intubation by evaluating:

- **Time to complete the awake intubation**
- **Success rate of tracheal intubation**
- **Image quality**
- **Insertion cord function**
- **An evaluation of the injection channel**

Methods

The study was carried out in the University Hospital of Copenhagen, Denmark in 2010. The first pilot part of the study included 20 patients with normal airways and all underwent oral tracheal intubation with aScope Broncho.

The subsequent RCT study comprised of 40 patients with ASA physical status of I-III & predicted difficult tracheal intubation.

aScope Broncho: 20 patients (mean age 60.1 years).

Olympus scope: 20 patients (mean age 60.9 years).

Investigators: experienced in using Olympus scope and had used aScope Broncho for at least 20 intubations.

Key Findings

1. The first pilot study revealed that oral tracheal intubation was successful with aScope in the first attempt in all 20 patients. The total duration of intubation was 73 seconds (53–147 s). The overall image quality was considered 'good' in 90% of cases and 'acceptable' in 10%.
2. In the RCT, all patients were successfully intubated. The median time needed for visualising epiglottis, injection of lidocaine, visualisation of the carina & ET tube advancement till first CO_2 curve was seen were comparable between aScope and Olympus scope (Fig.1). Although the total time was longer for aScope than Olympus scope by 56 seconds.
3. The success rate of both groups were 100%. The overall image quality was comparable between aScope (1.95) vs. Olympus scope (1.75). Image quality affected intubation only in one case in aScope group.
4. The aScope was superior regarding the resistance to injection via the injection channel and regarding the fixation of the tube on the insertion cord (Fig.2).
5. The lens of the aScope had to be cleaned more frequently than the lens of the Olympus scope, which contributed to the longer procedure time.

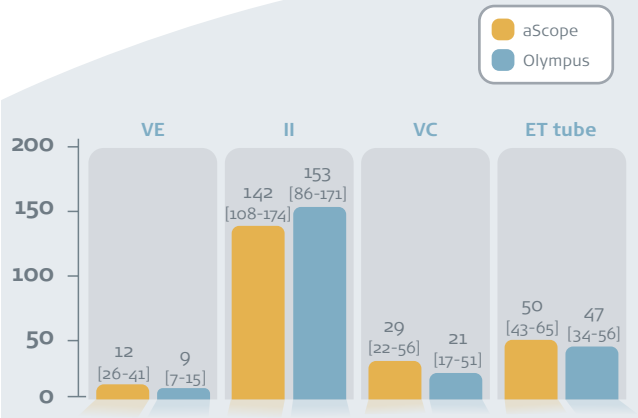

Fig. 1. Median time to visualise epiglottis (VE), injection of lidocaine (II), visualise carina (VC) and ET tube advancement (Seconds, median [IQ-range])

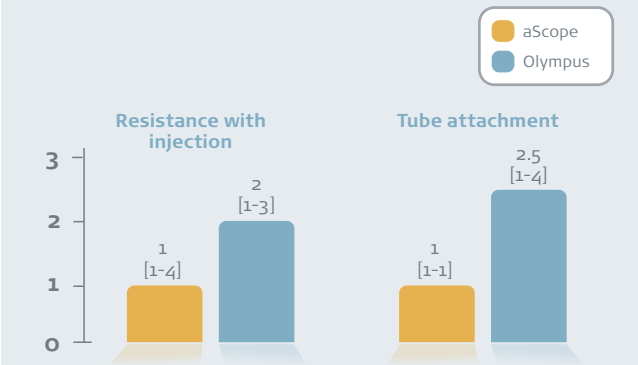

Fig. 2. Evaluation of the conical part of the scope handle, of the injection channel, and the injection cord

Conclusions

Both the pilot and RCT study showed that aScope achieved 100% success rate for awake intubation in both healthy and difficult airway patients. The time needed for each phase in intubation was comparable between aScope and Olympus scope. The overall image quality was comparable, however, aScope needed more regular lens cleaning. aScope presented superior injection channel and cord function.

Functional evaluation of insertion cord & scope handle: (1=very good, 5=very bad)

Reference: Kristensen MS, Fredensborg BB. The disposable Ambu aScope vs. a conventional flexible videoscope for awake intubation - A randomised study. Acta Anaesthesiologica Scandinavica. 2013;57(7):888-95.

RCT | Awake Nasotracheal intubation | Conventional vs Facilitated Technique

Evaluation of Ambu® aScope™ 2 in awake nasotracheal intubation in anticipated difficult airway using conventional or facilitated technique: A randomized controlled trial

Khalifa OSM (2015). Egyptian Journal of Anaesthesia.

Key Points

- **Facilitated group: 92%** vs Conventional group 84% — Overall success rate of intubation
- **Facilitated group: 198.6 ± 0.8** vs Conventional group 244.8 ± 1.2 — Total intubation time
- **Facilitated group: 84%** vs Conventional group 48% — First attempt success rate

Study Overview

An RCT to evaluate aScope Broncho in a conventional & facilitated technique for intubation by assessing:

- **Time needed to visualize vocal cords (Tvc) & to complete endotracheal intubation (Tti)**
- **Total time of nasotracheal intubation**
- **Success rate & number of attempts**
- **Need for facilitating manoeuvres, the incidence of oesophageal intubation and complications**

Methods

The study comprised of: 50 adult patients (18-45 years), undergoing elective maxillofacial surgery with anticipated difficult intubation. ASA physical status of I-III

Conventional videoscopic nasotracheal intubation group (CG): 25 patients

Facilitated technique group (FG) (tube-first approach): 25 patients

Key Findings

1. Tvc was significantly longer in the conventional group (201.6 ± 1.15) vs the facilitated group (156 ± 0.81).
2. Tti after the visualisation of vocal cords was comparable between conventional group (43.2 ± 0.1) vs the facilitated group (42.6 ± 0.12).
3. Total time needed for nasotracheal intubation was significantly longer in the conventional group (244.8 ± 1.15) vs the facilitated group (198.6 ± 0.82) (Fig.1).
4. The overall success rate of aScope Broncho guided intubation was 84% and 92% in the conventional and the facilitated groups, respectively (Fig.2).
5. The need for jaw thrust and neck flexion was significantly more often in the conventional group.
6. The incidence of oesophageal or any complication in terms of bleeding or desaturation was insignificant between the two groups.

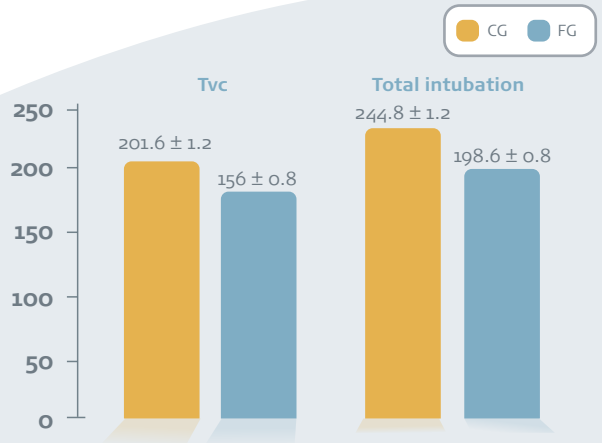

Fig. 1. Time to visualize vocal cord & total time of nasotracheal intubation (Seconds, mean ± SD)

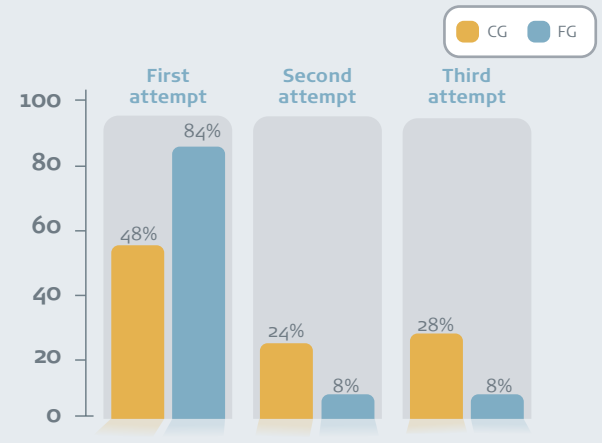

Fig. 2. Number of attempts

Conclusions

The aScope Broncho provided a high success rate in awake nasotracheal intubation in patients with anticipated difficult airway when using a tube-first approach. The time needed to visualise vocal cords and total intubation time was significantly reduced with this technique compared to the conventional technique, with less need of facilitating manoeuvres and higher first attempt success.

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Case series | Awake Tracheal Intubation | aScope Broncho

Awake fiberoptic intubation in fast track ambulatory surgery: a case report

Hannig KE, et al., (2018). A&A Practice.

Study Overview

A case series to present the feasibility of awake fibreoptic intubation in a Scandinavian fast track setting. Outcomes included:

- **Feasibility**
- **Time to intubation**

Methods

Three patients were intubated by a team consisting of anaesthesiologist, specially trained anaesthesia nurse, and postanaesthetic care unit nurse.

Awake fibreoptic intubation was carried out using aScope Broncho.

Patients were: 74, 71 & 58 years old with comorbidities and difficult airways.

Key Findings

1. Patient 1 had a Simplified Airway Risk Index (SARI²) score of 7 presented for colonoscopic polypectomy. Awake FOI was uneventful with an endotracheal tube with an internal diameter of 7.0 mm using the aScope Broncho Regular 9 minutes after entering the OR. The surgery & extubation were uneventful.
2. Patient 2 (SARI² 6) was scheduled for laparoscopic cholecystectomy. Awake FOI succeeded 10 minutes after the patient entered the OR. Surgery and extubation were uneventful.
3. Patient 3 (SARI² 7) presented for a laparoscopic inguinal hernia procedure. Intubation was performed 9 minutes after entering the OR. Extubation and PACU stay were uncomplicated.
4. These 3 cases illustrate that awake FOI can be performed safely in the fast track ambulatory surgical setting.

Case report | Awake Nasotracheal Intubation | aScope Broncho

Awake tracheal intubation in a suspected COVID-19 patient with critical airway obstruction

Ahmad I, et al., (2020). Anesthesia Reports.

Study Overview

The first reported case of awake tracheal intubation in a patient with suspected COVID-19 with impending airway obstruction requiring urgent surgical tracheostomy. Main points covered:

- **Modifications to reduce the aerosol generation**

Methods

This study describes a 54-year-old patient with a large squamous cell carcinoma at the base of his tongue presented with a worsening cough and respiratory deterioration.

He deteriorated with hypoxia, worsening stridor, an increased respiratory rate and a reduced level of consciousness. The decision was made to perform a surgical tracheostomy under general anaesthesia following awake tracheal intubation with aScope Broncho.

Key Findings

1. Various modifications were put in place during the awake tracheal intubation and surgical tracheostomy procedures to minimise aerosol generation from the patient, such as avoiding high-flow nasal oxygen, establishing conscious sedation with remifentanil before commencing airway topicalisation and avoiding transtracheal local anaesthetic infiltration.
2. A nasal route via the right nostril was selected and flexible bronchoscopy commenced using the aScope Broncho with a pre-cut 6.5-mm nasal tracheal tube. Once the flexible bronchoscope navigated past the tumour and with the tracheal carina visualised, the tracheal tube was railroaded into the trachea. The breathing circuit was immediately attached, the tracheal tube cuff gently inflated and the two-point check completed to confirm correct tracheal tube placement. The airway was secured 10 min after commencing airway topicalisation, with no coughing or positive pressure ventilation occurring throughout.
3. This report addresses the key procedural modifications required.

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Additional Evidence:
Awake Fibreoptic Intubation with aScope Broncho

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Additional Evidence:
Control of DLT/BB in Thoracic Surgery with aScope Broncho

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Tube Check/Airway Inspection with aScope Broncho

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