NICE advice

Ambu aScope 4 Broncho for routine diagnostic and therapeutic bronchoscopy

Medtech innovation briefing
Published: 17 January 2023

www.nice.org.uk/guidance/mib314

Summary

- The **technology** described in this briefing is Ambu aScope 4 Broncho. It is intended for use in routine diagnostic and therapeutic bronchoscopy procedures. NICE has produced medical technologies guidance on Ambu aScope4 Broncho for use in unexpected difficult airways.
- The **innovative aspects** are that the single-use bronchoscope potentially reduces the risk of cross-infection and eliminates the need for complex reprocessing of reusable endoscopes.
- The intended **place in therapy** would be wherever a flexible fibre-optic endoscope is needed for routine diagnostic and therapeutic bronchoscopy procedures. This device can be used for adults in hospital settings, including in theatre, in the emergency department and in critical care.

- The **main points from the evidence** summarised in this briefing are from 4 studies (2 prospective observational studies, 1 retrospective observational study and 1 cross-sectional study) including a total of 551 patients. The studies suggest that some clinicians accept, are generally satisfied with, and sometimes prefer Ambu aScope 4 Broncho when used in routine diagnostic and therapeutic bronchoscopy. Low video image quality was reported but it is not clear if this quality is lower than with reusable bronchoscopes. Loss of functionality during the procedure, and failure to reach some lung segments in a few cases, have also been reported.
- The **key uncertainty** around the evidence or technology is that the studies mainly focus on user experience and satisfaction and there is limited published evidence reporting relevant clinical outcomes to support routine use of the technology for endoscopic procedures and airway examination. Also, most studies were done outside the UK and sample sizes were mostly too small to generalise the findings.
- **Experts advised** that the technology is not a major innovation, but can simplify access to bronchoscopes, especially in urgent cases.
- **Safety issues** identified are the same as those with reusable endoscopes. Some experts noted problems with the quality of the display images.
- The **cost** of Ambu aScope 4 Broncho plus the Ambu aScope 4 BronchoSampler (Broncho Sampler Set) is £185 per unit and £925 for a box of 5 (excluding VAT). The aView 2 Advance display monitor is an additional £4,000.

The technology

Ambu aScope 4 Broncho (Ambu Ltd) is a sterile, flexible and single-use endoscope that is connected to the portable aView 2 Advance monitor to display the images. Ambu aScope 4 Broncho is available in 3 sizes: slim, regular and large. The slim bronchoscope is used for difficult intubation, placement and control of double lumen tubes and bronchial blockers, and use with an Aintree Intubation Catheter. The regular and large bronchoscopes can both be used for tracheal intubation, percutaneous dilatational tracheostomy, bronchoalveolar lavage (BAL), bronchial wash (BW), protected specimen brush sampling and training in bronchoscopy skills. The Ambu aScope 4 Broncho can also be used for direct visualisation and airway examination, collection of bronchoscopic biopsies and removal of secretions and clots. The bronchoscopes need to be connected to the portable aView 2 Advance monitor to display the images. According to the company, the technology can be used for adults in hospital settings, including on the ward, in theatre, in

the emergency department and in critical care.

The Ambu aScope 4 BronchoSampler, an add-on technology to Ambu aScope 4 Broncho, is a sterile single-use device for use during BAL and BW. The Ambu aScope 4 Broncho Sampler Set is a combination of Ambu aScope 4 Broncho and aScope 4 BronchoSampler. It is attached to the Ambu aScope 4 Broncho to enable aspiration and collection of fluid samples from the bronchioles or alveoli.

Innovations

According to the company, the single-use bronchoscope reduces the risk of cross-infection and eliminates the need for complex and potentially costly reprocessing. The Ambu aScope 4 Broncho Sampler Set is a closed-loop system, which reduces the risk of contamination and sample loss during BAL and BW.

Current care pathway

Bronchoscopy procedures are used to help diagnose, and sometimes treat, conditions of the airways and lungs. Most bronchoscopy procedures in the NHS are done with reusable flexible bronchoscopes. Single-use flexible bronchoscopes have been reported to be used in some cases. Reusable flexible bronchoscopes have been reported to carry a 2.8% risk of cross-infection (Mærkedahl et al. 2020).

Population, setting and intended user

The technology is intended for people aged 18 and over having routine diagnostic and therapeutic bronchoscopy procedures of direct visualisation and airway examination, BAL, BW, collection of bronchoscopic biopsies and patient samples, tracheal intubation, percutaneous dilatational tracheostomy, and removal of secretions or blood and blood clots. This device can be used in hospital settings, including on the ward, in theatre, in the emergency department and in critical care. According to the company no formal staff training is needed, although product training is highly recommended.

Costs

Technology costs

The cost of Ambu aScope 4 Broncho plus the aScope 4 BronchoSampler (Broncho Sampler Set) is £185 per unit, and £925 for a box of 5 (excluding VAT). The cost for the aView 2 Advance monitor is £4,000. The cost per procedure of using Ambu aScope 4 Broncho has been reported as £220 (Mærkedahl et al. 2020).

Costs of standard care

The cost per procedure of using the reusable bronchoscope is £310, or £431 when including the cost of cross-infection (Mærkedahl et al. 2020). Additional costs incurred with reusable flexible bronchoscopes are reprocessing and repair costs.

Resource consequences

The technology is used in 229 NHS trusts. The NHS purchased 57,724 units of Ambu aScope 4 Broncho between June 2021 and June 2022. Evidence on Ambu aScope 4 Broncho from a published budget impact analysis by Russell and Ockert (2019) showed that at 500 procedures per year, the technology may be cost-minimising. The study claims potential cost savings of £115 per procedure in direct costs and £358 when including costs associated with a 1.6% risk of cross-infection. NICE's medical technologies guidance recommends Ambu aScope 4 Broncho for use in unexpected difficult airways.

Regulatory information

Ambu aScope 4 Broncho is a CE-marked class IIa medical device.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

There were no equality issues identified relating to the use of Ambu aScope 4 Broncho.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement for medtech innovation briefings. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

There are 4 studies summarised in this briefing. This includes 2 prospective observational studies, 1 retrospective observational study and 1 cross-sectional study. Studies reporting on Ambu aScope 4 RhinoLaryngo Intervention endoscope are excluded from this briefing.

Further published evidence is available but not summarised in this briefing because it:

- has been included in previous guidance
- is not specific to use of Ambu aScope 4 Broncho
- is lacking in detail (Russell and Ockert 2019, Mehta et al. 2020, and McCahon and Whynes 2015), or
- is focused on economics (Mærkedahl et al. 2020 and Mouritsen et al. 2019).

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

There are too few studies and those available are of low methodological quality and lack patient outcomes. Most studies were done outside the UK. Generalising these findings to the NHS is difficult as product performance and acceptability is very specific to local practice.

Evidence on the use of Ambu aScope 4 Broncho outside the current guidance recommendation in unexpected difficult airways is mainly focused on usability and acceptability of the technology. It would benefit from UK studies reporting clinical and

adverse event outcomes.

Singh and Shah (2021)

Study size, design and location

Prospective observational study evaluating the safety and efficiency of Ambu aScope 4 BronchoSampler in 20 bronchoscopic sampling procedures in mechanically ventilated patients.

Intervention and comparator

Ambu aScope 4 BronchoSampler with Ambu aScope 4 Broncho compared to standard sampling methods. Performance of the standard sampling methods was based on operator historical recall.

Key outcomes

The study concluded that the Ambu aScope 4 BronchoSampler was a reliable, effective and potentially safer technique for diagnostic sampling in intensive care. Ambu aScope 4 Broncho Sampler Set minimises aerosolisation which prevents potential risk of occupational exposure to pathogens for healthcare workers.

The setup was much easier in 18 (90%) and easier in 2 (10%) of the procedures because of reduced connection steps using the Broncho Sampler Set. The technology was reported to be intuitive by 18 (90%) of respondents. The mean duration of the procedure to collect 1 sample was 2.5 minutes with a percentage volume of sample retrieved of 54.2%. The overall set up and workflow were much easier in 69% of the 13 intraprocedural connections and easier or as easy as the comparator in the remaining 31% of procedures. Obtaining a sample was reported to be easier in 70%, no different in 20% and worse in 10% of procedures. The ability to protect a sample from start to finish was easier in 95%, and no different in 5% of procedures. Overall, workflow was easier in 18 (90%) and no different in 2 (10%) procedures.

Strengths and limitations

One of the strengths of the study is that it provides a basis for future randomised controlled studies. The major limitation of the study is that it was a single-operator case

series and used a small study sample size, which poses a challenge in generalising results. The observational study design is another limitation, as results are prone to selection bias. The comparator was not observed during the study but was only based on the bronchoscopist's perception of their historical experience. This was likely to introduce selection and reporter bias. This study did not report on any clinical outcomes.

Taton et al. (2020)

Study size, design and location

Retrospective observational multicentre study investigating the added value of Bronchoalveolar Lavage (BAL) using Ambu aScope 4 Broncho in 55 non-critically ill patients during the SARS-CoV-2 epidemic.

Intervention

Ambu aScope 4 Broncho; no comparator was used.

Key outcomes

This study measures the impact of BAL results on patient management and outcome. Therapeutic management in 33 patients (60%) was changed because of the BAL results. Using BAL fluid analysis, non-SARS-CoV-2 infection was diagnosed in 23 patients (42%). An alternative diagnosis was provided in 10 patients (18%) out of the 55 patients in the study.

Strengths and limitations

The major strength of this study is it provides evidence of using the Ambu aScope 4 Broncho outside of difficult airways. This was a non-comparative study which was focused more on the added value of BAL than the performance of the technology. The study had a relatively small sample size and was done outside the NHS, which limits generalisation of the findings to the NHS.

Kriege et al. (2020)

Study size, design and location

Prospective observational multicentre study evaluating the Ambu aScope 4 Broncho for different indications involving 176 endoscopic procedures.

Intervention and comparators

Ambu aScope 4 Broncho compared to customary endoscope (both single use and reusable).

Key outcomes

The study assumed equivalent therapeutic performance of the Ambu aScope 4 Broncho compared to customary endoscopes. This study found significant acceptability and preference for Ambu aScope 4 Broncho. The study claimed this could potentially be because of easy manoeuvrability of the scope and optimised visualisation.

A total of 176 Ambu aScope 4 Broncho-aided interventions were evaluated (150 bronchoscopy and 26 intubation). The primary finding of the study was that the Ambu aScope 4 Broncho was preferred over customary endoscopes for both diagnostic and therapeutic bronchoscopy in 58% (86 out of 149) of users and awake intubation with a flexible endoscope in 65% (17 out of 26) of users. Pooled data showed a 59% (103 out of 175) preference in users. In 3 cases (1 in bronchoscopy and 2 in intubation), the physician changed from Ambu aScope 4 Broncho to the customary endoscope to complete the procedure because of insufficient lighting and a defective Ambu aScope 4 video chip.

Secondary outcomes were ease of advancing and navigating the Ambu aScope 4. Up to 87% (130 out of 150) of the users rated the advancing of Ambu aScope 4 as easy or very easy and only 1% (2 out of 150) rated it as difficult. In navigating the Ambu aScope 4, 83% (124 out of 149) of users rated it as easy or very easy and 3% rated it as difficult. Manoeuvrability of the Ambu aScope 4 was rated as easy or very easy by 62% of users compared with 8% for the flexible reusable endoscope.

Strengths and limitations

One of the strengths of this study is that 2 out of 8 study centres, with a study population

of 45, were in the UK (Manchester and Edinburgh). But the sample size was small, meaning that generalising findings should be done with caution.

This study was sponsored by Ambu. Participating centres received 180 Ambu aScope 4 Broncho single-use bronchoscopes and 9 aView 2 Advance monitors for study purposes.

Flandes et al. (2020)

Study size, design and location

Cross-sectional study evaluating the quality of the Ambu aScope 4 Broncho disposable in 300 bronchoscopies.

Intervention

Ambu aScope 4 Broncho; no comparator.

Key outcomes

Up to 69.3% of the bronchoscopies were bronchial aspiration and 41.7% were BAL. The median duration of bronchoscopy was 9.1 minutes and the mean score for ease of use, image quality and aspiration quality was 80 out of 100. Bronchoscopists highlighted the portability, immediacy of the Ambu aScope 4 to start the procedure, and possibility of taking and storing images as some of the reasons for their satisfaction. The cumulative sum analysis showed an increase in the average score exceeding 80 out of 100 in more than 80% by the ninth procedure compared with about 70 out of 100 from the first procedure. Learning points noted were: ease of passing the fibre-optic bronchoscope to the trachea (intubation) in the third procedure, ease of manoeuvring during the bronchoscopy in the fourth procedure and image quality during the bronchoscopy in the ninth procedure. There was 46% general satisfaction with the Ambu aScope 4 Broncho.

It was necessary to change the Ambu aScope 4 in about 6% of procedures because of limitations in reaching goals of the procedure and damage to the bronchoscope. Loss of functionality or deterioration during the procedure was reported in 3% of cases. Up to 54.4% of users considered Ambu aScope 4 to have lower image quality than video endoscopes. About 13% of users reported that they would recommend the use of Ambu aScope 4 in only very selected cases, 40% in an acceptable number of cases, 35% in most cases, and 12% reported that they would always use it.

Strengths and limitations

One of the strengths of this study is that it provides evidence of acceptability of using Ambu aScope 4 outside of difficult airway intubation.

The study was not done within the NHS. This limits the generalisation of the results to the NHS. There is potential for selection bias in the recruitment of bronchoscopists. The study did not provide direct comparison with reusable flexible bronchoscopes. This has potential to introduce recall bias.

The study was sponsored by the company. But the sponsor did not participate in the analysis and interpretation of the results.

Sustainability

The company claims that their goal is to design products that enable full recycling. The company states that they contribute to responsible consumption and production by monitoring and reducing their energy and water use. The company has a strategy for reducing the environmental impact of their single-use endoscopes. They have initiated a recycling pilot program of their bronchoscopes in Germany and have plans for a similar programme in the UK. There is no published evidence to support these claims.

Recent and ongoing studies

A Randomised controlled trial to Assess the Safety and Efficiency of a self-Contained sampling device and disposable bronchoscope system versus usual sAmpLing procedure (RASECAL). Trail register identifier: 289572. Status: unknown. Indication: bronchoscopy in intensive care. Devices: Ambu aScope 4 Broncho Sampler Set. Date registered: 15 June 2021. Country: UK.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Three experts contributed to the development of this briefing. One expert has experience

using the technology and another in using the predecessor model for difficult intubation in theatre. The third expert used the technology in intensive care in a difficult airway setting, in percutaneous tracheostomies, ventilation unit, routine diagnostic and sampling settings. Two experts said that the technology is increasingly used for diagnostic and therapeutic purposes in critical care environments. One of the experts was not aware of its use in routine respiratory medicine for diagnostic bronchoscopy. An expert reported that Ambu aScope 4 Broncho is available as back up for high usage times and when there are down times of their own endoscope reprocessing facility in surgical theatre.

Level of innovation

Experts said that this is not a major innovation, but it has simplified access in the event of needing a bronchoscope urgently and provides quality improvement for patient care. The quality of the technology has improved over time, with the range of different scope sizes providing more flexibility of use. The scopes are light, easy to use and robust, enabling the user to move from a difficult airway setting to more routine use, particularly in the acute setting and critical care.

One expert saw the technology as an alternative to standard care in hospital settings such as in theatre, the emergency department and critical care. Another expert said that if current standard care is regarded as the use of expensive reusable devices which need careful and expensive reprocessing between patients, then this has the potential to replace current standard care.

All the experts highlighted the availability of other single-use endoscopes to the NHS.

Potential patient impact

An expert said that cross-infection reduction is a potential patient benefit of using the technology. Another expert mentioned that the technology would be beneficial for critically ill inpatients requiring urgent bronchoscopy for the management of an airway problem, in tracheostomy complications such as displacement, and in a percutaneous tracheostomy procedure. The expert added that the technology would benefit patients with lung collapse and mucus plugging in an acute setting such as critical care. The technology is also beneficial in routine sampling of airways.

Potential system impact

Two experts noted the key benefit that the equipment is readily available, which increases accessibility. Single-use devices provide an "off the shelf solution" with very little start-up costs. They also provide a solution for the inevitable downtime from using endoscope washers and drier or storage units and can buffer the unpredictable peak usage requirements so that smaller numbers of reusable devices are needed. The technology has the functionality and capability to be adopted for routine endoscopies.

Experts had mixed views on the potential of the technology to change the current pathway or clinical outcomes to benefit the healthcare system. An expert said the technology did not have potential. But another expert said that the accessibility and ease of use in acute settings has led to a change in care pathways in many trusts, having the single-use scopes on resuscitation trolleys in theatre and critical care and on ventilation units. The technology reduces risks from transferring the patient to an endoscopy unit and needing to move endoscopy unit equipment. In addition, the single-use bronchoscope technology improves and simplifies staff training on the equipment. The experts thought that the technology would cost less than standard care (reusable endoscopes). There would be minimal change in clinical facilities, apart from needing an area to store the aView 2 Advance monitor and scopes within easy reach. Two experts highlighted that staff already experienced in endoscopy would need minimal training on understanding some functions such as video recording, taking images and using the Ambu aScope 4 BronchoSampler.

General comments

One expert highlighted that the harms from single-use bronchoscopes are the same as those from reusable ones. The harms include risks from sedation leading to oxygen desaturation and respiratory failure, bleeding from airways and trauma. The experts added that a theoretical harm would be failure to undertake the procedure because of device failure or unsuitability for the procedure. Technical problems may include poor image quality or inability to access lower airway subdivisions. The other expert reported that the optical display of Ambu aScope 4 is not as good as that of the reusable scope.

The expert said that the key efficacy outcomes for the technology would be optical view, and suction and lavage performance. The other experts said that accessibility, time to set up for procedure, time to undertake procedure and ability to undertake procedure and interventions compared to reusable scopes were the key efficacy outcomes of the

technology.

Experts said there are no uncertainties or concerns about the efficacy and safety of the technology and mentioned that the technology would be suitable in most or all general hospitals. Another expert mentioned that the uncertainty lies in costs and the impact on the global environment because of increased reliance on single-use technologies within healthcare.

According to an expert, the additional benefit of the technology is the range of scope sizes for different uses. For example, the larger scope is useful for clearing secretions and mucus plugs. The slim scope is mostly used in the difficult airway setting, for percutaneous dilatational tracheostomies and is easier to pass through the nose (nasendoscopy). The regular scope is multi-purpose.

An expert said that there is a need for additional research modelling the costs of reprocessing reusable endoscopes, compared against the cost of pre-existing reprocessing facilities and the need for endoscope washers for other endoscopy services.

Expert commentators

The following clinicians contributed to this briefing:

- Prof Andrew Bentley, consultant respiratory physician, Wythenshawe Hospital, Manchester University NHS Foundation Trust. Did not declare any interests.
- Dr Ali Diba, consultant anaesthetist, Queen Victoria Hospital NHS Foundation Trust. Did not declare any interests.
- Dr Heather Gorton, consultant anaesthetist, Leeds Teaching Hospitals NHS Trust. Did not declare any interests.

Development of this briefing

This briefing was developed by NICE. The interim process and methods statement for medtech innovation briefings sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

ISBN: 978-1-4731-4697-6