Original Article

Technological advances in single-use or disposable bronchoscopy: an evaluation of the Innovative Ambu® aScope™ 5 in a quaternary referral bronchoscopy unit

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Background: Single-use flexible bronchoscopes (SUFBs) offer various advantages over reusable bronchoscopes (RBs) including portability and cost-effectiveness, and potentially reduced infection transmission. Our study aimed to review the performance of the Ambu® aScope™ 5 Broncho suite in Cork University Hospital.

Methods: Following ethical approval, data was collected prospectively on procedures performed with the Ambu® aScope™ 5 in Cork University Hospital. Data included patient demographics, procedure details (location, indication, SUFB size, procedures, complications), and user satisfaction and demographics.

Results: There were 98 procedures performed with the Ambu® aScope™ 5, all in the endoscopy suite. There were 42 female patients (42.9%) and 56 male (57.1%). Various sized models were used—2.7/1.2 (n=3), 4.2/2.2 (n=4), 5/2.2 (n=60), 5.6/2.8 (n=31). Infection was the most common indication while others included malignancy, haemoptysis, sarcoidosis, and asthma. The most commonly performed procedure was airway inspection (n=98), while bronchoalveolar lavage (BAL) (n=84), brushings (n=3), endobronchial biopsies (n=5), transbronchial needle aspiration (TBNA) (n=1), and argon plasma coagulation (APC) (n=1) were among others. The average user satisfaction rating (from one to five in ascending order of satisfaction) was 4.8 [5 (n=85), 4 (n=9), 3 (n=1), 2 (n=3), 1 (n=0)]. The most common reason for user dissatisfaction was related to suction (n=3). Conversion from single-use to RB was not required in any case. There were no bronchoscope-related patient complications.

Conclusions: Within this cohort of patients, the Ambu® aScope™ 5 was both safe and versatile with a high level of user satisfaction.

Keywords: Single-use flexible bronchoscope (SUFB); bronchoscopy; interventional pulmonology

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Introduction

The number of companies producing single-use flexible bronchoscopes (SUFBs) is increasing with a recent publication identifying 15 commercially available devices (1). The coronavirus disease 2019 (COVID-19) pandemic, in parallel to a growing realisation that reusable bronchoscopes (RBs) are associated with pulmonary infection, is the main driver of development (2-4).

Since Ambu® brought the first SUFB to market in 2009, they have been the global leader in production and development (5-10). The initial markets were the operating room (OR) and intensive care units (ICUs), however both the COVID-19 pandemic and acceptance of the risk of infection with RB naturally piqued the interest in usage by bronchoscopists outside the ICU and OR (3,5,6,11-14). It is important to recognize that prior Ambu® SUFB iterations (used for intubation and basic ICU proximal airway management) did not compare well to other newer devices which was confirmed in a recent bench-top and pre-clinical comparison (15). The main reason for this is that the subsequent approved scopes were similar to RBs principally as regards the design of the scope handle (15) (*Figure 1*). Thus, the Ambu® aScope™ became commercially available recently. Ambu® aScope™ 5 Broncho is a family of single-use sterile bronchoscopes that works with Ambu® aBox™ 2 Advance displaying and processing unit (*Figure 1*). Other than a more ergonomic and recognizable handle design, advantages of this scope over other single-use scopes is that the device is rotatable (120° to left and right), has favourable tip angulation, and is the only current SUFB compatible with electrocautery devices. Although not compared to other processors, technological developments included in the Ambu® aBox™ 2 [including full HD resolution (1,920×1,080) and advanced imaging processing] would suggest superiority over the majority of other scope screen displays.

To test the performance of the Ambu® aScope™, we prospectively collected data on sequential patients presenting to a quaternary referral centre undergoing basic and advanced bronchoscopic procedures using the Ambu® aScope™ 5 Broncho in family with the Ambu® aBox™ 2 displaying and processing unit. We present this article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-24-1538/rc).

Highlight box

Key findings

- The innovative Ambu® aScope™ 5 Broncho is a rotatable scope compatible with electrocautery. It was deemed safe and adequate in a study of 98 patients in a quaternary referral centre with an interventional pulmonology program. All procedures were completed without complication, technical difficulties, or reason to switch to a reusable scope.

What is known and what is new?

- Single-use flexible bronchoscopes have compared favourably with reusable bronchoscopes in functioning, cost, clinical outcome, and environmental impact while potentially reducing infection transmission.
- Our research is the only evaluation to date that confirmed that the Ambu® aScope™ family of scopes performed well in a quaternary referral centre bronchoscopy unit with an interventional pulmonology program.

What is the implication, and what should change now?

- Single-use flexible scopes are becoming more prevalent in bronchoscopy units. This study adds to the current portfolio of data regarding safe and satisfactory usage of single-use scopes. Further invasive studies may be warranted to further elucidate risk of infection transmission.

Methods

Following ethical approval data was collected prospectively from 2022 to 2024 in a tertiary care centre with an interventional pulmonology service regarding the use of the Ambu® aScope™ 5 Broncho (national medical standards certification achieved for medical devices prior to use). The option to use the Ambu® aScope™ was at the discretion of the bronchoscopist for each case with a reusable scope available immediately if required. Specimen sampling products were not adjusted from our standard practice (thus the dedicated Ambu® BronchoSampler was not used) (8). All patients were adults and had provided informed consent for the procedure.

Data collected included patient demographics and COVID-19 status, procedure details (location, indication, SUFB size, procedure performed, complications), and user satisfaction and demographics (see appendix available at https://cdn.amegroups.cn/static/public/JTD-24-1538-1.docx for sample questionnaire). User satisfaction was visualized using a Likert scale of one to five in ascending order of satisfaction. Satisfaction ratings were also recorded with regards to workflow, ease of instrument passage, and image quality. Incidence of technical limitations relating to scope handle, suction connector, suction quality, image failure, or

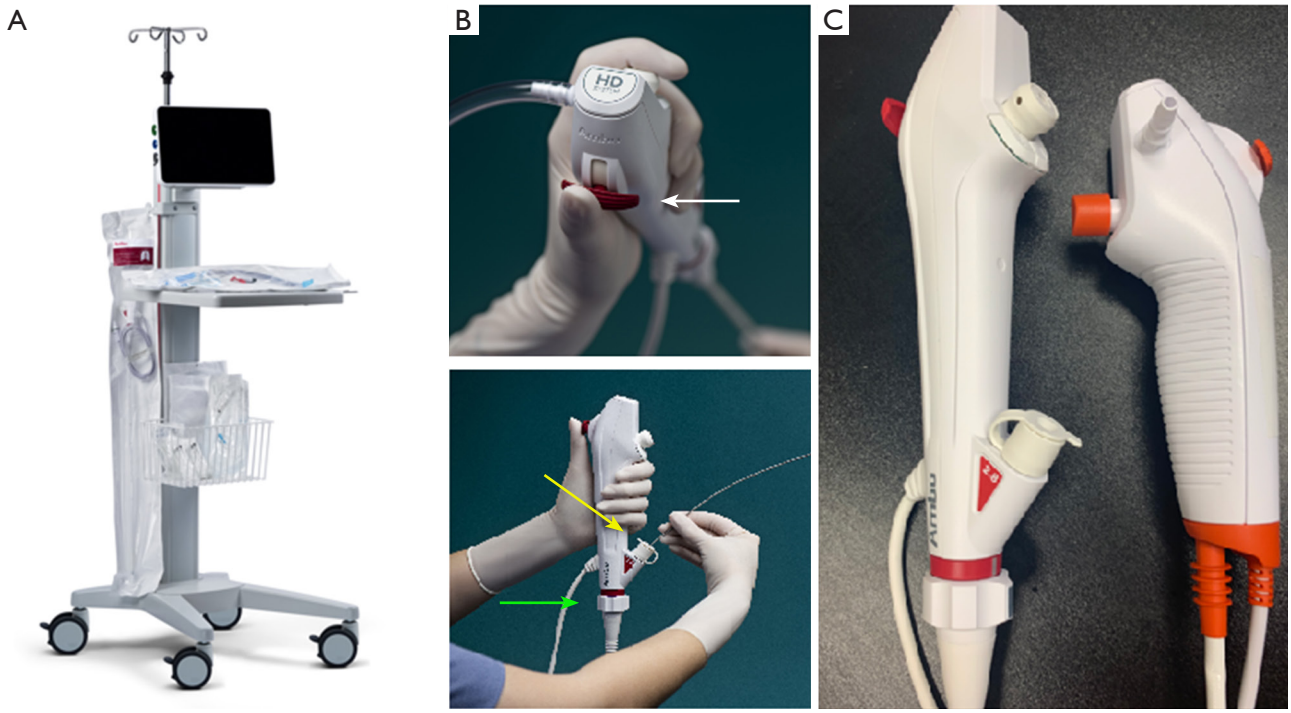

Figure 1 Ambu® aScope assessment: (A) Ambu® aScope™ 5 and Ambu® aBox™ 2 processing unit (Courtesy of Ambu® Endoscopy); (B) Ambu® aScope™ 5 control lever (white arrow), device *in situ* (yellow arrow), and rotation ring (green arrow) (Courtesy of Ambu® Endoscopy); (C) Ambu® aScope™ 5 compared with Ambu® aScope™ 4 (right).

inability to sample lobes were also recorded. Incidence of patient-related complications was also recorded.

Recorded data from procedures performed over a 2-year period were compiled and simple statistics were applied.

Statistical analysis

Simple statistics were applied for calculating mean values.

Ethical statement

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the Clinical Research Ethics Committee at University College Cork [No. ECM4(d), 1/6/2021]. All patients had provided informed consent for the procedure.

Results

From 2022 to 2024, all 98 procedures performed with the Ambu® aScope™ 5 were included.

Eight endoscopists were included in the study with experience levels ranging from 1 to 24 years. Of these, six were right-handed (*Table 1*).

The patient cohort included 42 female patients (42.9%) and 56 male (57.1%). All patients were COVID-19 negative. All procedures were performed in the endoscopy unit under conscious sedation with midazolam and/or fentanyl.

Various sized models were used—2.7/1.2 (n=3), 4.2/2.2 (n=4), 5/2.2 (n=60), 5.6/2.8 (n=31). Infection (n=43) was the most common indication while others included malignancy (n=5), asthma (n=6), interstitial lung disease (ILD) (n=6), lung nodules (n=5), and haemoptysis (n=3) (*Figure 2*). The most commonly performed procedure was airway inspection (n=98) while bronchoalveolar lavage (BAL) (n=84), washing (n=15), brushings (n=3), endobronchial biopsies (n=5), transbronchial needle aspiration (TBNA) (n=1), and argon plasma coagulation (APC) (n=1) (*Figure 3*) were among others (*Figure 4*).

The average user satisfaction rating (rated from 1 to 5 in ascending order of satisfaction) was 4.8 [5 (n=85), 4 (n=9), 3 (n=1), 2 (n=3), 1 (n=0)] (*Figure 5*). Technical limitations

Table 1 User demographics

Endoscopist	Gender	Grade	Hand	Experience (years)	Number of bronchoscopies performed in past year
1	Male	Consultant	Right	20	400
2	Female	Specialist registrar	Right	1.5	30
3	Male	Consultant	Right	11	>50
4	Male	Consultant	Right	7	>50
5	Male	Consultant	Right	24	60
6	Female	Consultant	Left	7	250
7	Male	Consultant	Right	8	>100
8	Female	Registrar	Left	1	10

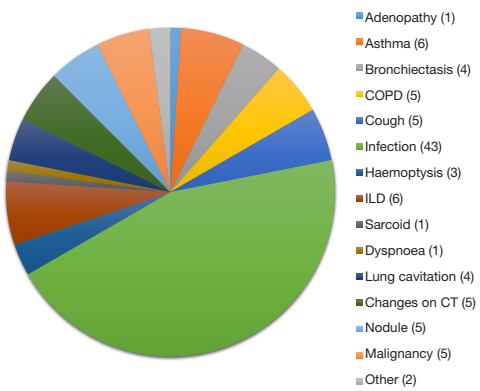

Figure 2 Ambu® aScope assessment: indications for procedure (n). COPD, chronic obstructive pulmonary disease; ILD, interstitial lung disease; CT, computed tomography.

included stiff scope handle (n=1), suction failure (n=2), and image failure (n=1). There were no issues with the suction connector or inability to sample lobes. The most common reason for user dissatisfaction was related to suction (n=3). The average user satisfaction [0–5] for workflow, instrument passage and image quality were 4.88, 4.85, and 4.86 respectively (*Figure 5*). In two instances, the bronchoscopist was unable to photograph the desired abnormality and thus could not attach a photo to the procedure report. It was commented in one instance that the scope handling was stiff. Of note, there was positive feedback regarding the rotation ring located at the handle allowing easier access to apical segments.

Conversion from single-use to RB was not required in any case, however one case required conversion to a smaller SUFB in order to access more distal airways. There were no bronchoscope-related patient complications.

Discussion

Our research is the only evaluation to date of the Ambu® aScope™ family of scopes and our findings support their use in a quaternary referral centre bronchoscopy unit with an interventional pulmonology program.

There were no technical complications and more importantly no patient-related complications. No cases required conversion to a reusable scope and scope satisfaction was favourable. The Ambu® aBox™ 2 was easy to connect to our standard scope monitors allowing images on both the left side and right side of the patient. Our endoscopy nurses frequently commented on their ease of use and our bronchoscopists and endoscopy staff were very satisfied with the fact that there were no delays in parallel busy bronchoscopy lists due to waiting on scope availability. Our bronchoscopists were satisfied with their use and the option to use SUFB is now permanently available in all our bronchoscopy units.

Preclinical and cost-effective analyses suggest that SUFB compare favourably with RB in suction (8,10,15,16), scope handling and ergonomics (15-17), cost (9,18-28), and even environmental impact (1,27,28). Cost comparison depends on a number of factors including the number of annual procedures, cost and incidence of scope-related infection, and the cost of SUFBs.

Although data are gathering as regards the adequacy

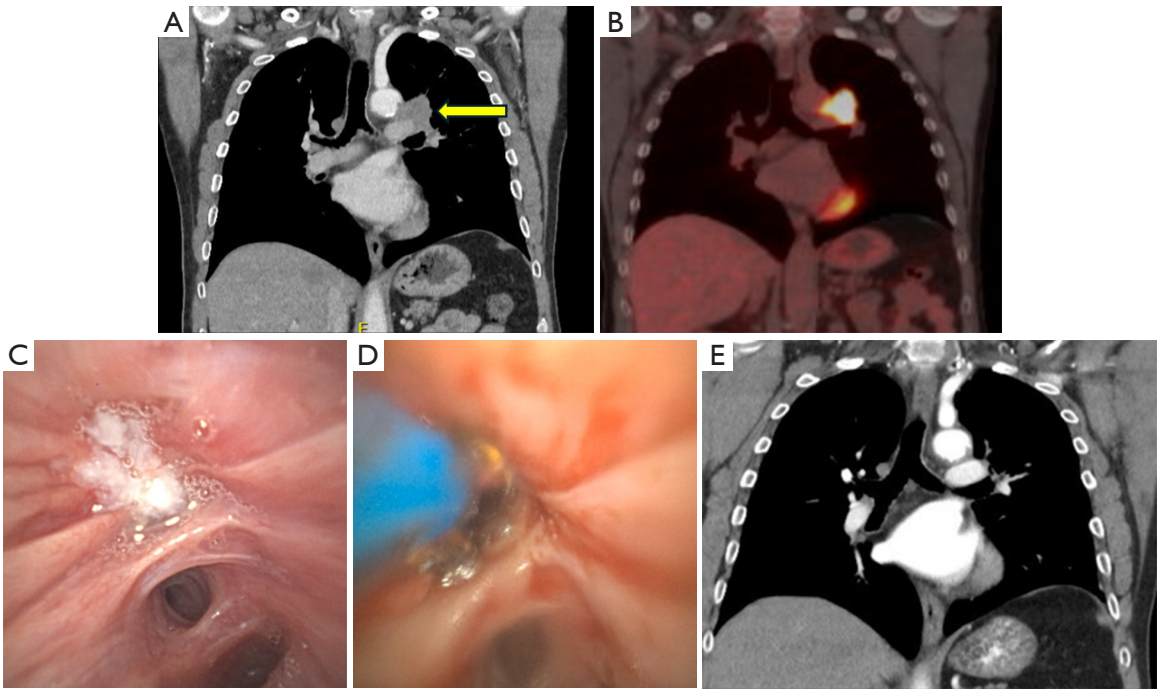

Figure 3 A 57-year-old male with non-small cell lung cancer. (A) Sagittal CT thorax with contrast image with left upper lobe T4N0M0 indicated by yellow arrow. (B) Sagittal fused PET-CT indicating PET avid left upper lobe mass. (C) Endobronchial image using the Ambu® aScope™ 5 2.8 single use bronchoscope identifying malignant airway obstruction in the anterior segment of the left upper lobe. (D) APC of the left upper lobe tumour using the Ambu® aScope™ 5 2.8 single use bronchoscope. (E) Sagittal CT thorax with contrast image showing response of the tumour to neoadjuvant chemotherapy and immunotherapy. The patient declined subsequent surgery. CT, computed tomography; PET, positron emission tomography; APC, argon plasma coagulation.

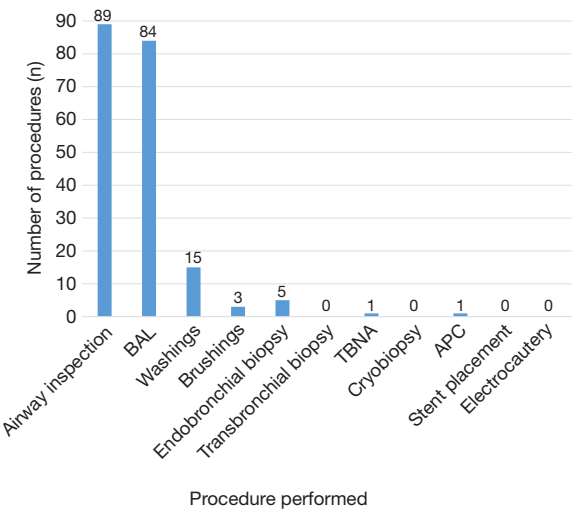

Figure 4 Ambu® aScope Assessment: procedures performed (n). BAL, bronchoalveolar lavage; TBNA, transbronchial needle aspiration; APC, argon plasma coagulation.

of SUFB in the bronchoscopy suite (10,13,14,29), there are a number of questions that remain unanswered. The first question is how do they compare to reusable scopes in practice. The fact that our study did not include any cases where conversion to a reusable scope was required is reassuring. However, the fact that the selection of an SUFB was at the discretion of the bronchoscopist would lead to a bias towards lower risk procedures. The inclusion of five patients with endobronchial tumours (which can be associated with bleeding) is reassuring. In the evaluation of a novel device prior to a randomized trial, ethical approval usually requires this option of using standard equipment by the proceduralist. Another limitation of our study is that it is a single centre, however five consultant pulmonologists were included.

To date, we can identify only one study which directly compares SUFB with RB in the bronchoscopy suite (29). This study compared 30 RB procedures with 15 SUFB

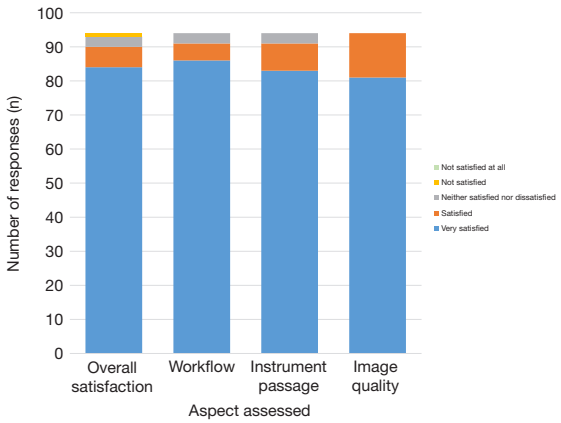

Figure 5 Ambu® aScope assessment: user satisfaction.

procedures using the Vathin® H-steriScope™ single-use bronchoscope. There were no significant differences between procedure time, BAL recovery volume and positive biopsy rate. Operator reporting of performance of the scope (from 1 to 5) was satisfactory (>4) other than image clarity, brightness and eye comfort [3–4]. There was no comparison between RB and SUFB monitor performance. No one has assessed the hypothesis that SUFBs are advantageous because of their ease of access, ready availability, and reduced time in setting up the device. It could be argued that this study is not required and indeed in the only published expert consensus of the application of SUFB this advantage was identified (30). Of course, ease of access and ready availability is more of an advantage in emergency bronchoscopy in the ICU or OR (3). Most procedures in the bronchoscopy unit are elective and thus typically reusable scopes are readily available. Our current study reinforced our opinion of the advantages of SUFB however in situations where their ready availability has been very important to complete a procedure list such as requiring a bronchoscope during endobronchial ultrasound (EBUS) procedures, unexpected RB scope damage, lack of availability of scope cleaning staff, and breakdown in high-level disinfection processors (2-4,13,14).

The other frequently published reason for considering SUFB is a reduction in scope-related infection (12,25). Common sense would suggest that this is the case due to the vast literature on infection related to reusable scopes (12,31-35). A prospective study evaluating this question would need to be large and invasive as regards monitoring the patient for any signs or symptoms of infection along with radiology and lab investigations in the days after bronchoscopy. Biomarkers may be helpful, however given the fact that scopes are commercially available and there is a global drive towards switching to single-use devices (36) whether or not an adequate study to evaluate this question will be published is questionable.

If you decide to invest in a SUFB system, which should you invest in? Although bench top and pre-clinical data highlight some advantages and disadvantages in specific systems (15,16), there are no head to head comparisons. Compatibility with a hospital's current technology and local availability and scope company service are as important as the cost of individual scopes. Without the availability of comparison data, meta-analyses or systematic reviews evaluating SUFB in practice is not possible. A comprehensive list of other potential advantages has been identified (3). During the COVID-19 pandemic, societies recognised advantages of SUFB (2,37,38). However, SUFB has not been endorsed to date in standard bronchoscopy society guidelines. The only available expert consensus addressed nine key issues concerning SUFBs: definition, construction, benefits, application scenarios, pre-operative preparation, sedation, anaesthesia requirements, disinfection processes, and training requirement and management (30). Twelve recommendations were developed and all were favourable with the requirement of standardised and systematic training.

Conclusions

In conclusion, the Ambu® aScope™ family of scopes were deemed safe and adequate in a study of 98 patients in a quaternary referral centre with an interventional pulmonology program. All procedures were completed without complication, technical difficulties, or reason to switch to a reusable scope. This adds to the large portfolio of data available for Ambu® scopes (5-9) (although most of which is related to the ICU) and SUFB scopes in general in the bronchoscopy unit (10,13,14,29). Although SUFB scopes produced by many companies are approved and commercially available, most bronchoscopists would rather comparative studies with RB before completely switching their practice to SUFB.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-24-1538/rc

Data Sharing Statement: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-24-1538/dss

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-24-1538/coif). M.P.K. reports that Ambu® Endoscopy provided all the scopes free of charge to Cork University Hospital. M.P.K. received consulting fees and speaker fees from the Surgical Company and Boston Scientific, and has been on the advisory board of both companies. He has served as a key opinion leader for the Surgical Company, which has also previously granted Cork University Hospital single-use bronchoscopes and monitors as training material. He is the president of the Irish Thoracic Society and the Irish Regent of the World Association of Bronchoscopy and Interventional Pulmonology. The other authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the Clinical Research Ethics Committee at University College Cork [No. ECM4(d), 1/6/2021]. All patients had provided informed consent for the procedure.

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