## **Clinical Investigations**

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# Safe and Efficient Practice of Bronchoscopic Sampling from Mechanically Ventilated Patients: A Structured Evaluation of the Ambu Bronchosampler-Ascope 4 Integrated System

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## Keywords

Bronchoscopy · Bronchoscopic sampling · Bronchoalveolar fluid · Aerosolisation · COVID-19 · Disposable bronchoscopy · Intensive care unit · Safety · Efficacy · Infection control

## **Abstract**

Background: Bronchoscopic sampling of bronchoalveolar fluid (BAL) should be safe and effective. Current sampling practice risks loss of sample to the attached negative flow, aerosolisation, or spillage, due to repeated circuit breaks, when replacing sample containers. Such concerns were highlighted during the recent coronavirus pandemic. Objectives: Evaluation of an alternative integrated sampling solution, with the Ambu Bronchosampler with aScope 4, by an experienced bronchoscopist in ICU. Methods: An observational study of 20 sequential bronchoscopic diagnostic sampling procedures was performed on mechanically ventilated patients with suspected ventilator-associated pneumonia. Mixed methods assessment was done. The predefined outcome measures were (1) ease of set up, (2) ease of specimen collection, (3) ease of protecting specimen from loss or spillage, and (4) overall workflow. The duration of the procedure and the % volume of sample retrieved were recorded. Results: The mean (±standard deviation [SD]) time for collecting 1 sample was 2.5  $\pm$  0.8 min. The mean ( $\pm$ SD) specimen yield for instilled miniBAL was 54.2 ± 17.9%. Compared with standard sampling, the set-up was much easier in 18 (90%), or easier in 2 (10%) of procedures, reducing the connection steps. It was much more intuitive to use in 14 (70%), more intuitive in 4 (20%), and no more intuitive to use in 2 (10%). The overall set-up and workflow was much easier in 69% of the 13 intraprocedural connections and easier or as easy in the remaining 31% procedures. All procedures where pre connection was established were much easier (7, 100%). The Ambu Bronchosampler remained upright in all procedures with no loss or spillage of sample. Obtaining a sample was much easier in 60%, easier in 10%, no different in 20%, and worse in 10%. The ability to protect a sample from start to finish compared to standard procedures was *much easier* in 80%, easier in 15%, and no different in 5% of procedures. Overall workflow was much easier in 14 (70%), easier in 4 (20%), and no different in 2 (10%) of procedures. Conclusions: The Ambu Bronchosampler unit was a reliable, effective, and possibly safer technique for diagnostic sampling in ICU. It may improve safety standards during the coronavirus pandemic. A randomized control trial against the standard sampling technique is warranted. © 2021 The Author(s)

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#### Introduction

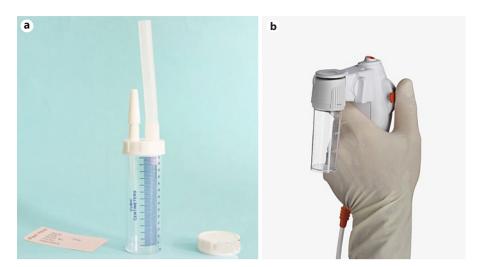
Bronchoscopy is designated an aerosol-generating procedure by the World Health Organization [1]. Hence, there are concerns of health care professional infection as reported in previous outbreaks [2]. As such, its use in mechanically ventilated patients with COVID-19 has been advised against or recommended only following a careful risk-benefit assessment [1, 3]. And yet, bronchoscopy in intensive care has important diagnostic and therapeutic roles [4]. These include diagnosis of SARS-CoV2 when nasopharyngeal aspirates prove to be falsely negative and suspected ventilator-associated pneumonia when directed sampling improves the accuracy of diagnosis and antibiotic stewardship [5]. In addition to diagnostic directed bronchial wash (BW), therapeutic mini-BAL is often required to resolve segmental lobar collapse due to inspissated airway secretions. This is a cause of worsening gas exchange, perhaps exacerbated by withholding standard warm humidification of ventilator circuits due to concerns about aerosol generation during their replacement. In the non-ICU setting, day case diagnostic bronchoscopy has been temporarily suspended for several weeks, except for urgent or life-threatening cases. In this context, expert recommendations for safe practice of bronchoscopy during the pandemic have been published [6]. Key elements include a benefit-risk assessment of the indication for bronchoscopy, the use of full personal protection equipment for all personnel involved, and if feasible use of negative pressure environments in which to undertake the procedure. Further, single-use-only bronchoscopes may have an important role. In the ICU, additional safe practice to minimize aerosolization involves preloading of the bronchoscope into the bronchoscopy adaptor of the endotracheal tube, pausing the ventilator and wall suction for the circuit change prior to commencing the procedure. Similarly on completion, the bronchoscope and adaptor are only withdrawn and replaced by the standard circuit again during a ventilatory pause manoeuvre. Whilst conventional reusable video bronchoscopes with their processor and video monitor units, and currently superior optics remain the mainstay of day case bronchoscopy practice, the emergence and improvement of single-use disposable bronchoscopes with portable video monitors, offer potential benefits in the intensive care and acute care settings. These are primarily related to accessibility, ease of set up, and a very small footprint. The single-use nature offers safety from cross infection, as previously reported, albeit rarely [7, 8].

Bronchoscopic sampling of bronchoalveolar fluid must then be performed safely and effectively. Current practice of sampling containers connected to and resting loosely between the bronchoscope and wall suction, risks loss of sample to the waste container due to lack of accurate control of the applied negative flow. Further, the need to detach fully and reattach replacement sampling containers during the procedure is subject to repeated breaks in the circuit, aerosolization, spillage of sample, or contamination of the collected sample, if not closed immediately. Moreover, connection of generic suction tubing to the product specific ports of bronchoscopes may result in an inadequate seal or increase the chance of leakage. These issues have been apparent and reported for years and yet accepted as part of standard practice in the ICU and day case bronchoscopy. Thus, fast-paced innovations in bronchoscope and imaging technology, have not been matched by similar improvements in common techniques, such as BAL and BW, since their first introduction in the late 1970s. Further, whilst the diagnostic accuracy and clinical value of directed versus non-directed bronchoscopic sampling with qualitative or semiquantitative microbiological reporting are still debated, the minimum return volume for infection and cellular analysis is different and subject to varying standards [9, 10].

By convention, during bronchoscopic fluid sampling the retrieved sample is collected into a specimen container or "trap" via wall suction or into the same syringe via hand suction. Several types of specimen traps are available, the Lukens trap being one of the most commonly used (Fig. 1a). The sampling procedure itself is not complicated. However, it is cumbersome, and there is a definite risk of sample loss, contamination, or indeed unexpected exposure of health care workers (HCWs) to pathogens.

The BAL/BW procedure requires a series of preparation steps. Generic sampling accessories might result in an insecure vacuum seal and thereby inefficient suction. During the procedure itself, the tubing or sample container or both need to be disconnected/reconnected between each sample.

Losing a sample during a BAL/BW procedure is not uncommon. The main reasons are fluid leakage from the specimen trap and loss of sample to negative pressure wall suction. As the specimen trap often hangs freely in space unless the operator or assistant holds it upright (or it is secured in a holder), manipulation of the bronchoscope can lead to an inversion of the specimen trap and subsequent loss of sample to the wall suction. A risk of sample



**Fig. 1.** A standard bronchoscopic sampling container ("trap") (**a**), Ambu Bronchosampler with adaptor attached to an aScope4 bronchoscope (**b**).

contamination may occur if sample traps are left open after collection. Thus, a number of factors contribute to the inefficiency of current bronchial sampling practice.

Returning to aspects of safe and efficient sampling a potential risk of occupational exposure to pathogens for HCWs is real. Many of the current sampling techniques pose a risk for healthcare professionals throughout the workflow: contamination through exposure to the aspirated (and most likely infected) fluid, particularly during the circuit breaks for switches between suction and sampling, and by open containers. Considering BAL/BW procedures are regularly performed in the ICU, these risks should be of great concern, not least with the concerns of HCW-associated infection of SARS-CoV2 through aerosol generation.

Making the BAL/BW sampling procedure simpler, safer, and more efficient is clearly desirable. We assessed the utility of a new bronchoscopic sampling system (Ambu Bronchosampler) in the ICU as compared to current standard sampling practice.

## **Methods**

A prospective observational study with the Ambu aScope 4 Broncho with Bronchosampler system was carried out in the Royal Brompton and Chelsea & Westminster Hospitals between March 15 and April 30, 2019. The system consists of a 30-mL container which is attached to a single-use aScope 4 bronchoscope through a bridge adaptor with an external dial that controls the flow of bronchial fluid into the container or to the wall suction by thumb movement. This allows maintenance of an upright container-bronchoscope unit throughout the procedure, thereby minimizing sample loss, and the ability to change containers intraprocedurally without disconnection of suction tubing or circuit breaks

(Fig. 1b). A learning curve of 2 pilot sampling procedures, with prior review of an Ambu bronchosampler training video and simulated set-up and procedure, was deemed suitable to proceed to the study.

We evaluated in 20 procedures carried out in mechanically ventilated patients on the intensive care unit, in whom either diagnostic sampling for suspected ventilator-associated pneumonia or therapeutic miniBAL for segmental collapse was clinically indicated. All procedures were carried out by a single bronchoscopist, a consultant in respiratory and intensive care medicine of nearly 20 years, with expertise and experience of over 5,000 bronchoscopies. An evaluation questionnaire was filled out immediately after each procedure.

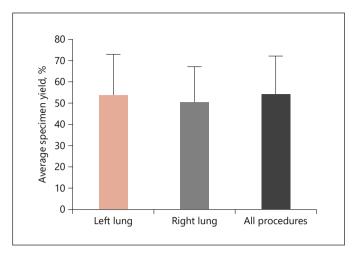
The quantitative assessments included the estimated airway sample collection time and sample volume. The qualitative assessments consisted of physician's perception on ease of set up and use, ease of obtaining samples, ease of sample protection, and overall workflow, with the option to choose between "much easier, easier, no difference, more difficult, and much more difficult."

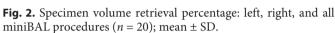
The Ambu Bronchosampler was commercially available, and all procedures were considered part of a service evaluation. Ethics approval was therefore not deemed necessary. Descriptive statistics were adopted.

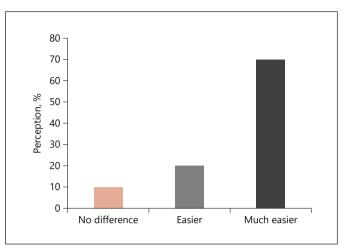
## Results

Equipment Assembly and Sample Collection Time

In this evaluation, the time taken from opening the package to connecting Ambu Bronchosampler to the Ambu aScope 4 Broncho was recorded in 13 procedures. The mean ( $\pm$ standard deviation [SD]) time taken for connecting 1 Bronchosampler to the aScope 4 Broncho during the procedure was  $17 \pm 6.4$  s. In the remaining 7 procedures, the Ambu Bronchosampler was pre-connected during the preparation for bronchoscopy. The mean







**Fig. 3.** How intuitive was the Bronchosampler to set up compared with usual sampling practice? (% perception); n = 20.

**Table 1.** Bronchoscopic sampling procedure and outcome metrics

	Overall (n)	Left lung	Right lung	
Time for assembly of Ambu Bronchosampler and aScope4 Broncho	17±6.4 s	_	_	_
Time for completion of miniBAL	2.5±0.8 min	_	_	-
The specimen yield for instilled miniBAL volumes (%) (mean $\pm$ SD)	54.2±17.9	53.4±19	50.2±19.9	-
	No difference, % ( <i>n</i> )	Easier, % (n)	Much easier, % (n)	Worse, % (n)
Ease of set up versus conventional sampling	0	10 (2)	90 (18)	0
Intuitive set up and workflow versus conventional sampling	10(2)	20 (4)	70 (14)	0
Overall set up and workflow – pre-procedure connection $(n = 7)$	0	0	100 (7)	0
Overall set up and workflow – intra-procedure connection $(n = 13)$	23 (3)	23 (3)	54 (7)	0
Ease of obtaining a sample without having to switch between suction and sampling	80 (16)	5(1)	10 (2)	5(1)
Ease of protecting a sample from start to finish	79 (15)	16 (4)	5(1)	0
Overall workflow versus conventional sampling	70 (14)	20 (4)	10(2)	0

( $\pm$ SD) time to obtain 1 miniBAL sample, once saline was instilled, was 2.5  $\pm$  0.8 min (Table 1).

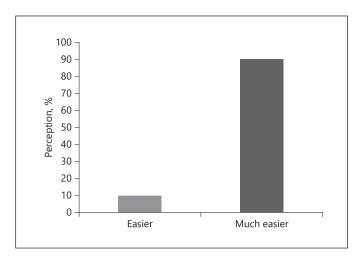
## Specimen Volume Retrieved

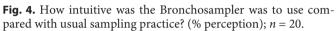
The instillation volumes varied between 30 and 250 mL depending on the condition of the patient, and the specimen recovered ranged from 15 to 150 mL. The mean ( $\pm$ SD) specimen yield for all the 20 procedures was 54.2  $\pm$  17.9%. In eleven procedures, both the right and left lungs were sampled. The mean ( $\pm$ SD) specimen yield for the left lung and the right lung was 53.5  $\pm$  19.4 and 50.2  $\pm$  16.9%, respectively (Fig. 2; Table 1).

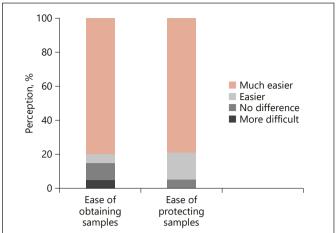
Ease of Set up and Use

The physician rated his perception of how easy and intuitive Bronchosampler was to set up (assemble) and use for each procedure, as compared to his usual sampling procedure. For set up, the physician rated it "no different" in 2 (10%), "easier" in 4 (20%), and "much easier" in 14 (70%) cases (Fig. 3; Table 1). It was considered easy once accustomed to the procedure and steps.

With regard to the ease of use of the Bronchosampler compared to current methods, the physician rated it "easier" in 2 (10%) and "much easier" in 18 (90%) cases (Fig. 4; Table 1). The use of the Bronchosampler removed the need to ask for paraphernalia and simplified the sampling process.







**Fig. 5.** Physician's perception on ease of obtaining and protecting miniBAL samples with Bronchosampler system (% perception); n = 20.

**Table 2.** Perception of overall workflow process of bronchoscopic sampling (n = 20)

	Agree, %	Disagree, %
Simplifies sampling process	95	5
Reduces risk of losing or contaminating the sample	95	5
Improves workflow effectiveness	90	10
Innovative and integrated system (with Ambu aScope 4 Broncho	100	0

The Ambu Bronchosampler is suggested to be connected to the aScope 4 Broncho before the procedure. There was a difference in perception between assembling the Bronchosampler during the procedure or pre-procedure, in terms of ease of set up and the overall sampling process. When asked to rank the ease of set up and sampling process using a Likert scale from 1 to 5 (1 = easiest, 5 = extremely difficult) for the 13 intra-procedure and 7 pre-procedure assemblies of the Bronchosampler, it was considered easiest when the Bronchosampler was preconnected (Table 1). The overall procedure was also easiest when the Bronchosampler was set up beforehand (Table 1).

## Ease of Obtaining & Protecting Sample

The physician's perception of the ease of obtaining a sample without having to switch between suction and sampling was assessed. He rated "more difficult" in 1 (5%), "no difference" in 2 (10%), "easier" in 1 (5%), and "much easier" in 16 (80%) cases (Fig. 5; Table 1). In the cases that were rated either "no difference" or "more dif-

ficult," aScope 4 Broncho regular was used, which has a smaller working channel (2.2 mm vs the aScope 4 Broncho large's 2.8 mm), and it took longer to clear thick secretions. However, sampling was still successful.

Losing a sample during a BAL/BW procedure is not uncommon. The physician's perception of the ease of protecting a sample from start to finish was assessed. The clinician rated "no difference" in 1 (5%), "easier" in 3 (15%), and "much easier" in 16 (80%) cases (Fig. 5; Table 1).

## Improvement of Overall Workflow

The overall workflow with the Bronchosampler compared with standard sampling was rated "no different" in 2 (10%), "easier" in 4 (20%) and "much easier" in 14 (70%) cases (Table 1). When the following statements about aScope Bronchosampler were provided with the options of "agree" or "disagree," the physician agreed in 95% of the cases that Bronchosampler simplified the sampling solution, reduced the risk of sample loss or contamination. In 90% of the cases, the Bronchosampler improved overall workflow effectiveness (Table 2).

#### Discussion

Standardizing the procedure of bronchoscopic sampling is important to achieving the full potential of mini-BAL. Usual standard techniques are subject to concerns such as sample loss, fear of contamination of either the sample or HCWs, and unwieldy workflow. In the current coronavirus pandemic and thereafter, a better solution for bronchial fluid sampling would be desirable, to improve sampling efficiency and reduce the risk to HCWs.

In this study, the Bronchosampler recovered more than half of the instilled saline (50–54%). In addition, the system was deemed to be much easier to set up and use with much lower risk of losing samples due to leakage or wall suction. It eliminated the need for repeated manual isolation of the sampling container from suction, during the aspiration, and avoided disconnecting the circuit intermittently. This reduced the perceived risk of sample contamination greatly, improved overall workflow, and by implication likely reduced the chance of HCW exposure to unexpected pathogens, although this was not specifically measured in this study.

By the current standard of care, availability of a bronchoscope and all sampling accessories on the ICU may be subject to time constraints, particularly outside usual working hours. The single-use Ambu aScope 4 Broncho, portable aView monitor and Bronchosampler, through its portability, can reduce the time needed for the preparation for bronchoscopy. In this evaluation, Bronchosampler provided an excellent % sample yield from the mini-BAL. The reported acceptable volume of retrieved fluid varies between 10 and 50% for diagnosis of infection or cellular analysis [9–11]. The actual yield is influenced by many factors, including the variations in the protocols for BAL/BW, the experience of the bronchoscopist, endobronchial aspects, and the efficiency of the sample collection.

This study has clear limitations. It is a single-operator case series, with historical controls, and therefore subject to selection and reporter biases. These are acknowledged. Nevertheless, the consistently high differences described for each predefined evaluation question when compared to standard sampling suggest an important signal of likely improvement on sampling technique by the Bronchosampler that warrants further study.

In summary, a single operator's experience of the Ambu bronchosampler with A4 scope found it to be much easier to set up once a learning curve of 2 trials was completed, able to obtain higher yield samples, and to minimize risk of sample contamination or spillage. The

system may simplify bedside bronchoscopic sampling in the ICU setting. A randomized controlled study of the Ambu bronchosampler versus usual standard sampling methods, both with the single-use Ambu A4 scope should be undertaken to confirm these preliminary findings.

## **Acknowledgements**

We are grateful to the staff of the intensive care units at both institutions for their assistance in this study.

## Statement of Ethics

This study was conducted as a service evaluation of a commercially available product. All procedures were clinically indicated and undertaken as part of routine practice on the intensive care unit. It was therefore not deemed necessary to obtain specific ethics approval.

## **Conflict of Interest Statement**

Dr. Suveer Singh has received speaker fees for advisory work for Ambu Ltd. and Fisher & Paykel. He is director of an educational Bronchoscopy in Intensive care (BrIC) course, which receives sponsorship from Ambu Ltd. and Olympus UK.

Prof. Pallav Shah receives sponsorship for educational Bronchoscopy courses from a number of companies including Olympus, Erbe, and others. He has received speaker and advisory board fees previously.

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The authors did not receive any funding.

#### **Author Contributions**

Dr. Singh conceived the study, did the bronchoscopic sampling and analysis, and wrote the first draft of the manuscript. Prof. Shah reviewed the data and coedited the manuscript.

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