

White paper from Ambu



The closed-loop, single operator solution for bronchoscopic fluid sampling

Clinical evaluation

Ambu® aScope™ 4 Broncho and BronchoSampler in the Intensive Care Unit (ICU)



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Introduction

Bronchoscopic Bronchoalveolar Lavage (BAL) and Bronchial Wash (BW) are valuable diagnostic tools for intensivists and pulmonologists working in the ICU. Despite the fast-paced innovations in bronchoscope and imaging technology, pulmonary and critical care clinicians have not seen major improvements in common techniques, such as BAL and BW, since their first introduction in the late 1970s¹. The workflow of BAL and BW remains somewhat cumbersome, with a potential risk of occupational exposure to pathogens for healthcare workers (HCW). The coronavirus global pandemic has focussed attention on bronchoscopy as an aerosol generating procedure (AGP), especially during the disconnection of suction tubing or splashes from specimen containers². The risk of HCW exposure to unexpected *Mycobacterium tuberculosis* during bronchoscopic BAL and BW has previously been reported³. The issue becomes even more relevant today, due to the novel coronavirus and concerns about the potential for cross infection affecting HCWs, although no reported cases have been ascribed to bronchoscopy.

A dedicated, compact sampling solution: Ambu® aScope™ BronchoSampler

Making the BAL/BW sampling procedure simpler, safer and more efficient is clearly desirable. The closed-loop Ambu aScope BronchoSampler, which connects directly to the single-use Ambu aScope 4 Broncho bronchoscope, has been developed with these benefits in mind.

First, the sampling system can be connected to the scope before the procedure starts and **stays connected until completion**.

Second, one can switch between wall suction and sampling during the procedure, thus **obviating the need to break the suction circuit** for sample trap exchange.

Third, **the sampling container can be disconnected and closed with one hand**, after which a new sterile container can be connected. This closed-loop system **reduces the risk of sample loss and contamination**, potentially improving the safety of HCWs, other patients, and improving sample yield.

"No break of the circuit and improves the workflow, safety and efficiency of the procedure"

Study aim

The aim of this evaluation was to assess the user perception of a new bronchoscopic sampling system in the ICU.

The outcome measures were predefined and assessed semi-quantitatively by an evaluation questionnaire.

They were:

1. Equipment assembly and sample collection time
2. Retrieved sample volume
3. Ease of setup
4. Ease of obtaining & protecting sample
5. Overall improvement in workflow

Study setup

This evaluation was carried out in Royal Brompton and Chelsea and Westminster Hospitals. The Ambu aScope 4 Broncho with Ambu aScope BronchoSampler system was used and evaluated in 20 procedures carried out in mechanically ventilated patients on the ICU, in whom either diagnostic or therapeutic mini bronchoalveolar lavage (mini-BAL) was clinically indicated. All procedures were carried out by Dr Singh, who has been a consultant in respiratory and intensive care medicine of nearly 20 years, with expertise and experience of over 5000 bronchoscopies. An evaluation questionnaire was filled out immediately after each procedure.

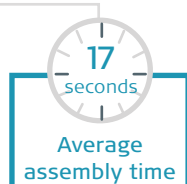


Results

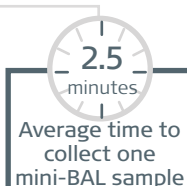
1. Equipment assembly and sample collection time

In this evaluation, the time taken from opening the package to connecting the Ambu aScope BronchoSampler to the Ambu aScope 4 Broncho was recorded in 13 procedures. In the remaining seven procedures, the Ambu aScope BronchoSampler was preconnected during the preparation for bronchoscopy. The time to obtain the mini-BAL sample, once saline was instilled, was also recorded for all 20 procedures.

The average time taken for connecting one Ambu aScope BronchoSampler to the Ambu aScope 4 Broncho during the procedure was 17 ± 6.4 seconds.

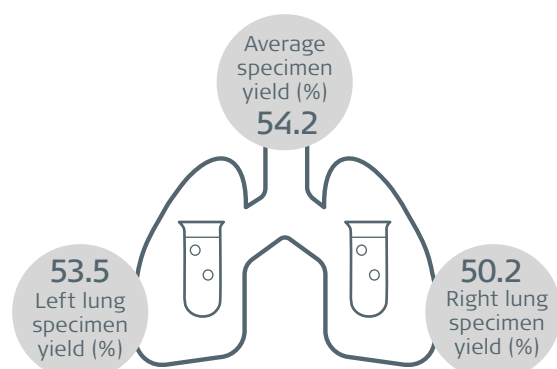


The average time taken for collecting one mini-BAL sample was 2.5 ± 0.8 minutes. This was similar to usual practice.



2. Retrieved specimen volume

The volume of the saline instilled and specimen recovered were also recorded. The instillation volume varied between 30-100ml depending on the condition of the patient, and the specimen recovered ranged from 15-60ml. The average 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 average specimen yield for the left lung and the right lung was $53.5 \pm 19.4\%$ and $50.2 \pm 16.9\%$, respectively.



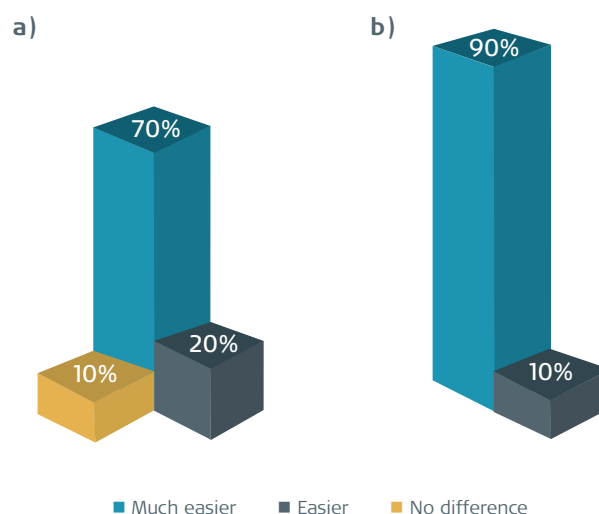
3. Ease of setup and use

The clinician's perception on:

a) the ease of the Ambu aScope BronchoSampler assembly and use and

b) the overall setup of bronchoscopic sampling with the device were compared to his usual sampling procedures.

The clinician rated:

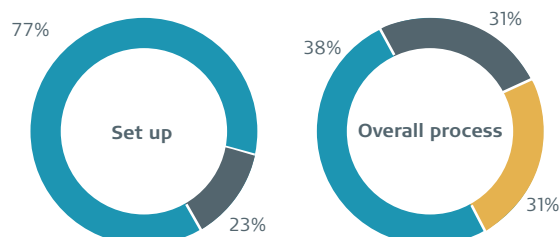


"The use of aScope 4 Broncho with BronchoSampler removed the need to ask for paraphernalia and simplified the sampling process with fewer connection steps"

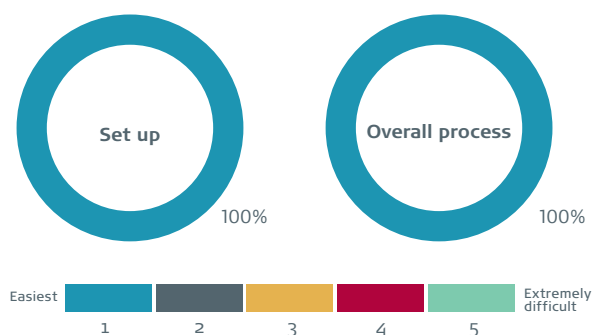
It is recommended to assemble Ambu aScope BronchoSampler with the Ambu aScope 4 Broncho before the procedure. There seems to be a difference in perception between assembling Ambu aScope BronchoSampler with Ambu aScope 4 Broncho pre-procedure and during the procedure, in terms of ease of setup and the overall process.

c) The physician was also asked to rank the **overall setup and sampling process for the 7 pre-procedure and 13 intra-procedure assemblies** of Ambu aScope BronchoSampler. The overall procedure was easiest when it was pre-connected.

During procedure setup and overall process



Pre-procedure setup and overall process



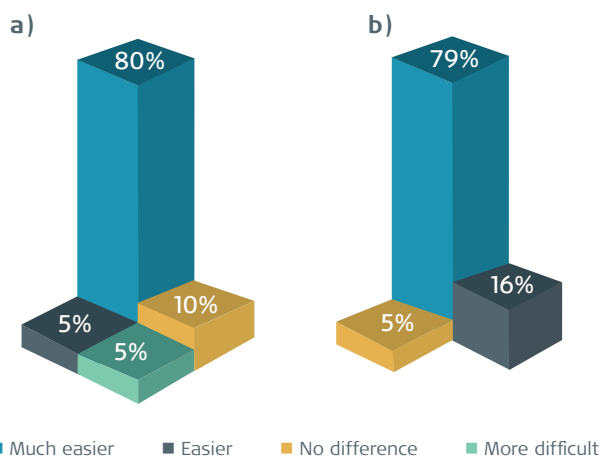
4. Ease of obtaining & protecting sample

The tubing needs to be switched after suction and between each sample with traditional bronchoscopic mini-BAL sampling, making it a cumbersome process.

The clinician's perception on **a) the ease of obtaining a sample without having to switch between suction and sampling** and **b) the ease of protecting a sample from start to finish** were compared to his usual sampling procedures.

In the cases that were rated either 'no difference' or 'more difficult', Ambu aScope 4 Broncho Regular was used, and it took longer to clear thick secretions; however, sampling was still successful.

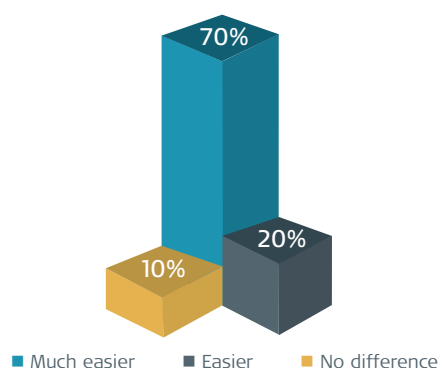
The clinician rated:



5. Improvement of overall workflow

Simplified workflow for BAL/BW procedures would benefit both doctors and patients.

- a) The **overall workflow** with the Ambu aScope BronchoSampler was compared to the current method, and it was rated 'no difference' in 2 (10%), 'Easier' in 4 (20%) and 'Much Easier' in 14 (70%) cases.



"Less steps from plan to procedure to completion"

- b) When the following statements about Ambu aScope BronchoSampler were provided with the options of 'agree' or 'disagree', it was agreed in 95% of the cases that Ambu aScope BronchoSampler was a simplified sampling solution and reduced the risk of sample loss or contamination. In 90% of the cases, Ambu aScope BronchoSampler improved overall workflow effectiveness. The study with a single operator experience prompted opinions on the following points:

	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 convenience of the 'click and go' technique for the BronchoSampler container and suction saves time, prevents detachment/reattachment of the suction tubing and potential loss of specimen"

Discussion

In this evaluation, Ambu aScope BronchoSampler increased the % sample yield compared to the historic standards of collection from BAL. The reported acceptable volume of retrieved fluid varies between 10-50%^{4,5,6} in the literature as this is influenced by many factors, including the variations in the protocols for BAL/BW, the experience of the bronchoscopist and the efficiency of the sample collection. In this evaluation, Ambu aScope 4 Broncho with Ambu aScope BronchoSampler recovered more than half of the instilled saline (50-54%).

In addition, the system was easy to setup and use with low risk of losing samples due to leakage or wall suction. It eliminated the need for having to switch between suction and sampling, which reduced the risk of sample contamination, improved overall workflow and, most importantly, reduced the potential chance of HCW exposure to pathogens.

Conclusion

Since its discovery, bronchoscopic sampling has emerged as an essential diagnostic and therapeutic tool. In the current standard of care, availability of a bronchoscope and all sampling accessories may be subject to time constraints, particularly for out-of-hours care. Standardising the procedure 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 sampling or HCW, and cumbersome workflow. In the current coronavirus pandemic, a better solution for secretion sampling needs to be found to secure the best treatment for the patient and to avoid the risk of inadvertent spread to HCW.

The single-use Ambu aScope 4 Broncho, together with Ambu aScope BronchoSampler and the portable aView 2 Advance monitor, significantly reduces the time needed for the preparation for bronchoscopy. The system may simplify bedside bronchoscopic sampling in the ICU setting.

References:

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2. Wahidi, M. M. et al. (2020) 'The Use of Bronchoscopy during the COVID-19 Pandemic: CHEST/AABIP Guideline and Expert Panel Report.', *Chest*. Elsevier Inc, (May), pp. 1-14. doi: 10.1016/j.chest.2020.04.036.
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5. Mohan, A. et al. (2019) 'Guidelines for diagnostic flexible bronchoscopy in adults: Joint Indian Chest Society/National College of Chest Physicians (I)/Indian Association for Bronchology Recommendations', *Lung India*, 36(2), pp. 37-89. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6681731/>.
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