WHITE PAPER aScope™ 4 Broncho Sampler Set

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THE CLOSED-LOOP, SINGLE OPERATOR SOLUTION FOR BRONCHOSCOPIC FLUID SAMPLING

Ambu[®] aScope[™] 4 Broncho Sampler Set in the Intensive Care Unit (ICU)

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 containers^{2, 3}. The risk of HCW exposure to unexpected Mycobacterium tuberculosis during bronchoscopic BAL and BW has previously been reported⁴. 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.

Ambu White Paper - Ambu $^{\text{\tiny{\$}}}$ aScope $^{\text{\tiny{\$}}}$ 4 Broncho Sampler Set

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BACKGROUND

A dedicated, compact sampling solution

Making the BAL/BW sampling procedure simpler, safer and more efficient is clearly desirable. The closed-loop Ambu® aScope™ BronchoSampler, specifically designed for use with the single-use Ambu® aScope™ 4 Broncho bronchoscope, is a fully integrated system developed with these benefits in mind.

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

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

Thirdly, the sampling container can be disconnected and closed with one hand, after which a new sterile container can be connected. Unlike other sampling solutions, the aScope $^{\text{TM}}$ 4 Broncho Sampler Set is a closed-loop system which reduces the risk of sample loss and contamination, potentially improving the safety of HCW patients.

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 semiquantitatively 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

METHODS

This evaluation was carried out in Royal Brompton and Chelsea and Westminster Hospitals. Ambu® aScope™ 4 Broncho Sampler Set 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

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 thirteen 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 17±6.4 seconds.

Average assembly time to connect one Ambu® aScope™ BronchoSampler to the Ambu® aScope™ 4 Broncho

17±6.4 seconds

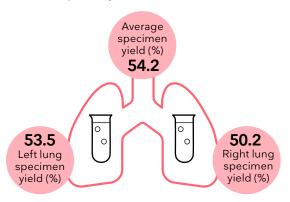
Average time to collect one mini-BAL sample

2.5±0.8 minutes

This was similar to usual practice.

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±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±19.4% and 50.2±16.9%, respectively.

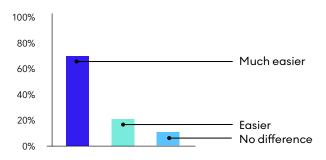


Ease of setup and use

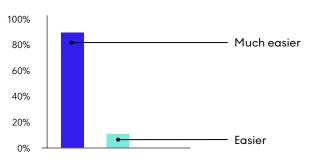
The clinician's perception on:

- 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 usual sampling procedures.

EASE OF ASSEMBLY AND USE



OVERALL SETUP



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

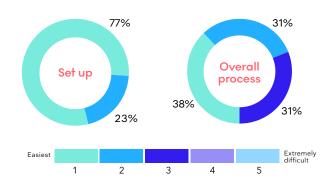
It is recommended to assemble Ambu® aScope™
BronchoSampler with the Ambu® aScope™ 4 Broncho before the procedure. There seems to be a difference in perception between assembling Ambu® aScope™ BronchoSampler with Ambu® aScope™ 4 Broncho pre-procedure and during the procedure, in terms of ease of setup 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 intraprocedure assemblies of Ambu® aScope™ BronchoSampler. The overall procedure was easiest when it was pre-connected.

PRE-PROCEDURE SETUP AND OVERALL PROCESS



DURING PROCEDURE SET UP AND OVERALL PROCEDURE

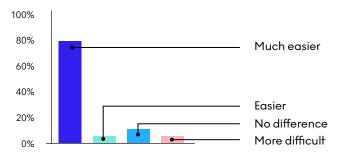


Ease of obtaining and protecting sample

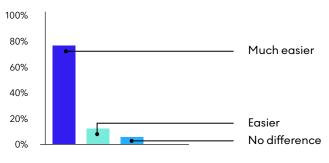
The tubing needs to be switched after suction and between each sample with traditional bronchoscopic mini-BAL sampling, making it a cumbersome process.

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 usual sampling procedures. In the cases that were rated either 'no difference' or 'more difficult', Ambu® aScope $^{\rm TM}$ 4 Broncho Regular was used, and it took longer to clear thick secretions; however, sampling was still successful.

EASE OF OBTAINING A SAMPLE



EASE OF PROTECTING A SAMPLE

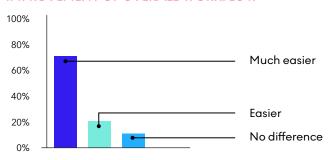


Improvement of overall workflow

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

a) The overall workflow with the Ambu® aScope™ Broncho Sampler Set 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.

IMPROVEMENT OF OVERALL WORKFLOW



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%

No break of the circuit and improves the workflow, safety and efficiency of the procedure...less steps from plan to procedure to completion

DISCUSSION

In this evaluation, Ambu® aScope™ 4 Broncho Sampler Set increased the % sample yield compared to the historic standards of collection from BAL. The reported acceptable volume of retrieved fluid varies between 10-50%^{5,6,7} 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 Sampler Set 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. Traditional sampling 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 Ambu® aScope™ BronchoSampler is specifically designed for use with the Ambu® aScope™ 4 Broncho. This single-use fully integrated system together with the portable aView™ 2 Advance monitor, significantly reduces the time needed for bronchosampling preparation and improves the procedure efficiency and safety. The Ambu® aScope™ BronchoSampler set is a single operator, closed loop sampling solution, reducing the risk of sample loss and contamination and the need for nurse support during the sampling procedure.

The Ambu® aScope™ 4 Broncho Sampler Set is a reliable, effective, and possibly safer technique for diagnostic sampling in ICU. The system may simplify bedside bronchoscopic sampling and may improve safety standards during the coronavirus pandemic in the ICU setting⁸.



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

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