

# Specimen acquisition training with a new biosimulator in endobronchial ultrasound-guided transbronchial needle aspiration

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## Abstract

Training for endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) has focused on the procedure itself; however, the techniques for obtaining adequate sample are also important for achieving a pathological diagnosis as well as for molecular testing. The aim of this study was to evaluate the feasibility and efficacy of a biosimulator for training subjects in adequate sample acquisition during EBUS-TBNA.

A total of 19 bronchoscopists voluntarily participated in this study. A biosimulator (ArtiCHEST, HARADA Corporation, Tokyo, Japan) was used for the training. After a 10-minute briefing, the first pass was performed by pairs of trainees. The trainees then received a 30-minute lecture that focused on the acquisition of samples using EBUS-TBNA. The trainees next performed their second pass under the supervision of the trainers. Each participant obtained a cytological smear that was coded and evaluated for quantity as well as quality by an independent cytotechnologist.

The trainees had an average of 5.9 years of bronchoscopy experience. With regard to the quantity evaluation, 9 (47.4%) subjects sampled a greater number of lymphocytes on the second pass than on the first, whereas 2 were better on the first pass, and the others sampled roughly the same amount both times. With regard to the quality assessment, 9 (47.4%) subjects obtained better quality samples on the second pass, whereas the quality of the first and second pass was deemed to be roughly the same for the remaining subjects.

A biosimulator can be used to train doctors in specimen acquisition and evaluate their skills with sampling using EBUS-TBNA.

**Abbreviations:** EBUS-TBNA = endobronchial ultrasound-guided transbronchial needle aspiration, JSRN = The Japan Society for Respiratory Endoscopy.

**Keywords:** biosimulator, EBUS-TBNA training, learning curve, specimen acquisition

## 1. Introduction

Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) is a minimally invasive modality for nodal staging in lung cancer patients as well as for diagnosing lesions adjacent to the airway.<sup>[1]</sup> In recent guidelines, EBUS-TBNA has been deemed the best first test for suspicious lymph nodes

identified by radiology before surgical staging, particularly for nodal staging in patients with lung cancer.<sup>[2,3]</sup>

However, these guidelines also describe the experience necessary for the procedure, as sufficient knowledge and skills are required to achieve a high diagnostic yield with EBUS-TBNA. Recently, guidelines and expert panel reports on the technical aspect of EBUS-TBNA have been published.<sup>[4]</sup> These guidelines

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suggest that low- or high-fidelity simulation be incorporated into training and that validated EBUS skills assessment tests be used to objectively assess the skill level of those performing the procedure.<sup>[4]</sup> Present training courses and simulators focus on the EBUS-TBNA procedure itself<sup>[5,6]</sup> and are unsuitable for evaluating the sample acquisition skills that are important in present lung cancer clinics.

A biosimulator (chest phantom) of porcine cardiothoracic structures connected to an artificial intubation training model (ArtiCHEST; HARADA Corporation, Tokyo, Japan) was introduced.<sup>[7]</sup> In this study, the feasibility and capability of this training model, focusing on an evaluation of the EBUS-TBNA sample acquisition skill, were examined.

## 2. Materials and methods

### 2.1. Participants

A total of 19 bronchoscopists voluntarily participated in this study. Before the start of the course, a questionnaire assessing the subjects' experience with bronchoscopy, certification in bronchoscopy by The Japan Society for Respiratory Endoscopy (JSRN), and experience with EBUS-TBNA was distributed. We also obtained permission to perform this study evaluating the efficacy of this training course using a biosimulator without providing detailed information regarding the analysis. Ethical approval was not required because this study was for the training program evaluations and did not include any patients' subjects or experimental animals.

### 2.2. Biosimulator (chest phantom)

A biosimulator of porcine cardiothoracic structures connected to an artificial intubation training model (ArtiCHEST; HARADA Corporation) was used for the training (Fig. 1, Supplementary Video 1, <http://links.lww.com/MD/B628> [Supplemental Video 1. EBUS-TBNA using the ArtiCHEST biosimulator. Subjects can train to perform EBUS-TBNA under conditions similar to an actual clinical setting using the biosimulator. The trainee can see the needle passes within the lymph node.]) The thoracic cavity of this model is an air-tight structure, and an inflated lung condition can be maintained by applying continuous suction to the thoracic cavity. The porcine cardiothoracic structures were removed from specific-pathogen-free pigs that had been raised to be sold for their meat. The lung parenchyma was delicately treated when the organ was removed in order to avoid insufficient inflation of the lung. The mediastinum and hilar structures were maintained with as little dissection as possible in order to avoid the detachment of the lymph nodes during TBNA.

### 2.3. EBUS-TBNA training course

After a 10-minute briefing before the start of the training course, the first pass was performed by pairs of trainees. During the initial EBUS-TBNA by trainees, the trainers only observed the trainees' procedure, offering neither technical assistance nor advice. The trainees then received a 30-minute lecture that focused on the acquisition of adequate samples using EBUS-TBNA, with particular focus on manipulating the needle during the procedure that was based on expert experience. After the lecture, the trainees performed their second pass under the supervision of the trainers (TN and TF). During the second pass, the trainers were more actively involved in the procedure, offering technical assistance and advice to help the trainees obtain enough tissue.



**Figure 1.** The biosimulator (lung phantom), ArtiCHEST. The porcine cardiothoracic structures were removed from specific-pathogen-free pigs farmed for their meat and connected to an artificial pharynx of ArtiCHEST. The mediastinum and hilar structures were maintained with as little dissection as possible in order to avoid the detachment of the lymph nodes during TBNA. By applying negative pressure to the ArtiCHEST thoracic cavity, the lung can be maintained in an inflated condition. TBNA = transbronchial needle aspiration.

Each sample obtained by the first and second passes was sprayed onto glass slides, dry-smear, and stained with the DiffQuik staining solution. The trainees then engaged in discussion about the acquired samples with trainers, focusing on how the trainees might improve the quantity as well as quality of the aspirates. All of the subjects used the same dedicated 22-gauge needle (NA-201SX-4022; Olympus, Tokyo, Japan) for EBUS-TBNA.

### 2.4. Evaluation of EBUS-TBNA sampled material

The glass slides were randomly coded by number, and the quantity (amount of lymphocytes) and quality (amount of blood contamination) of the samples were evaluated by an independent cytotechnologist (FS) with reference to the samples obtained by the trainers. In addition, an objective evaluation of adequacy was also performed based on the previously published definition, with an adequate sample defined as a mean lymphocyte density  $>40$  cells/10 fields at  $40\times$ .<sup>[8,9]</sup>

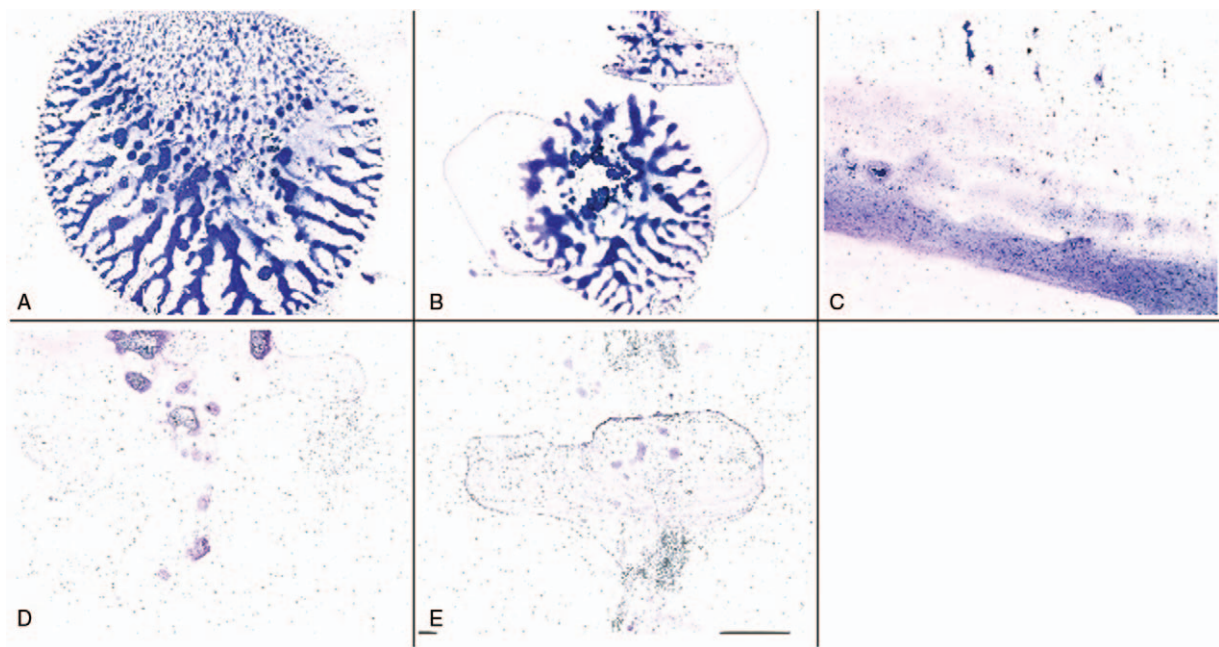
The quantity of the samples was graded as follows: 3+, samples with as many as or more lymphocytes than the trainers; 2+, samples with a sufficient number of lymphocytes to meet the adequacy criteria but less than the trainers; +, samples with a number of lymphocytes only barely meeting the adequacy criteria; -, samples with a number of lymphocytes not meeting the adequacy criteria (Fig. 2).

The quality of the samples was graded as follows: good, very little blood contamination and lymphocytes dominating the material; fair, some contamination with nonlymphocyte material but more lymphocytes than contaminants; and poor, substantial nonlymphocytic contamination within the sample, comprising more than the lymphocytes (Fig. 2). The data were evaluated by the standard definition using the Microsoft Excel software program (Microsoft Corporation, Redmond, WA).

## 3. Results

### 3.1. Experience of bronchoscopists

The trainees had an average of 5.9 years of bronchoscopy experience (range:  $<1$ –15 years), and there were 2 JSRN board-



**Figure 2.** Representative images of quantity and quality assessments. (A) 3+ quantity with good quality, (B) 2+ quantity with good quality, (C) + quantity with fair quality, (D) + quantity with poor quality, and (E) - quantity with poor quality.

certified bronchoscopists. The experience with EBUS-TBNA was as follows: 2 had no experience, 8 had experienced 1 to 10 cases, and 9 had experienced 11 to 50 cases. The experience of EBUS-TBNA was not concordant with the experience of bronchoscopy. Both of the trainers (TN and TF) were also JSRN board-certified bronchoscopists and had substantial experience with EBUS-TBNA in a clinical setting as well as experience as trainers in an EBUS-TBNA training course offered by the JSRN.

**3.2. Training results**

On the first pass, 4 subjects were unable to obtain enough material for a diagnosis, and the poor quality of the samples was reflected in the small amount obtained. On the second pass, all subjects were able to obtain enough material for a diagnosis, and 18 of the 19 subjects obtained good-quality samples.

The results of the quantity evaluation are shown in Table 1. Nine subjects sampled more lymphocytes on the second pass than

**Table 1**

**The results of the quantity and quality evaluations of the first and second passes.**

No.	Years of bronchoscopy experience	Board certification	EBUS-TBNA experience (cases)	Quantity evaluation in the 1st pass	Quantity evaluation in the 2nd pass	Quantity between the 1st and 2nd pass	Quality evaluation in the 1st pass	Quality evaluation in the 2nd pass	Quality between the 1st and 2nd pass	Technical improvement?
1	4	No	8	3+	3+	Equal	Good	Good	Equal	No
2	4	No	10–50	3+	2+	Better in the 1st pass	Good	Good	Equal	No
3	4	No	None	3+	3+	Equal	Good	Good	Equal	No
4	4	No	1–10	2+	2+	Equal	Good	Good	Equal	No
5	15	Yes	1–10	3+	2+	Better in the 1st pass	Good	Good	Equal	No
6	4	No	10–50	2+	3+	Better in the 2nd pass	Good	Good	Equal	No
7	10	No	1–10	3+	3+	Equal	Good	Good	Equal	No
8	2	No	10–50	3+	3+	Equal	Good	Good	Equal	No
9	8	Yes	1–10	2+	2+	Equal	Good	Good	Equal	No
10	10	No	10–50	+	+	Equal	Good	Good	Equal	No
11	4	No	1–10	+	3+	Better in the 2nd pass	Poor	Good	Better in the 2nd pass	Yes
12	1	No	1–10	+	3+	Better in the 2nd pass	Poor	Good	Better in the 2nd pass	Yes
13	<1	No	None	–	3+	Better in the 2nd pass	Poor	Good	Better in the 2nd pass	Yes
14	<1	No	1–10	2+	3+	Better in the 2nd pass	Good	Good	Equal	No
15	14	No	10–50	–	+	Better in the 2nd pass	Poor	Fair	Better in the 2nd pass	Yes
16	15	No	10–50	–	3+	Better in the 2nd pass	Poor	Good	Better in the 2nd pass	Yes
17	4	No	1–10	–	2+	Better in the 2nd pass	Poor	Good	Better in the 2nd pass	Yes
18	5	No	10–50	+	3+	Better in the 2nd pass	Fair	Good	Better in the 2nd pass	Yes
19	3	No	10–50	3+	3+	Equal	Good	Good	Equal	No

EBUS-TBNA = endobronchial ultrasound-guided transbronchial needle aspiration.

on the first, 8 sampled the same amount, and 2 sampled more on the first pass. The results of the quality assessment are also shown in Table 1. Nine doctors obtained better quality samples on the second pass than on the first, whereas the quality between the first and second pass was deemed to be roughly the same for the remaining subjects. Given these findings, 7 doctors (years of experience: range <1 to 15; EBUS-TBNA experience: 0–50 cases) showed improvement in the quantity as well as the quality of the cytological material obtained by EBUS-TBNA.

#### 4. Discussion

Adequate training is important for performing EBUS-TBNA safely and achieving a high diagnostic yield. However, there is a learning curve with EBUS-TBNA, and sufficient clinical experience must be obtained in order to reach the optimum diagnostic yield being.<sup>[10]</sup> There have been several reports on training programs for EBUS-TBNA. Basic training is needed in order to be able to perform this technique, and several training models and simulators have been developed.<sup>[11]</sup> The recent data suggest that the early use of a virtual reality simulator improves the skills and confidence of trainees.<sup>[12]</sup> However, these training programs have focused on the EBUS-TBNA procedure itself, with the main purpose of the training ensuring that the trainees could puncture the target adequately without any complications.

Once trainees learn to properly puncture the target, the next step is to obtain a sufficient amount of sample to make a diagnosis. At present, the amount of cytological material that can normally be obtained is insufficient to adequately reveal the existence of malignant cells, and therefore, this method is not helpful in the clinical decision-making process. As a result, additional information, such as subtyping of histology, including molecular testing findings, is often required to determine the optimum treatment plan. A sufficient quantity and quality of aspirates by EBUS-TBNA are needed. As such, additional training focusing on the acquisition and preparation of TBNA samples is warranted. Thus far, sample acquisition training has largely been performed either in a wet lab using experimental animals or through clinical experience on actual patients. Reducing the use of experimental animals and avoiding performing such a procedure on patients without having sufficient experience will require the development of an advanced EBUS-TBNA training program and training model.

A biosimulator of porcine cardiothoracic structures connected to an artificial intubation training model (ArtiCHEST; HARADA Corporation) can be used for several kinds of interventional pulmonology training. This model uses the discarded cardiothoracic structures from specific-pathogen-free pigs farmed for their meat, which may reduce the use of experimental animals for training purposes. The simulator did not require any special facility, which resulted in easier access to high-fidelity models for trainees. In addition, the trainees can not only practice obtaining lymphocytes but also have the quantity and quality of the aspirates reviewed. A recent survey showed that fellows and practitioners preferred a traditional course structure with a high-fidelity training course to a flipped classroom model and low-fidelity simulators.<sup>[13]</sup> The 30-minute lecture followed by a hands-on session might contribute to a better understanding of the procedure. In the hands-on session with a biosimulator, subjects can review their skills immediately. The combination of a lecture and hands-on approach using a biosimulator might improve the efficiency of such a learning program.

Evaluating EBUS skills is important, and the EBUS technical guidelines suggest that validated EBUS skills assessment tests be

used to objectively assess the skill level.<sup>[4]</sup> In the USA, the large registry database “AQUIRE registry” for diagnostic and interventional bronchoscopy was developed by the members of American College of Chest Physicians. This database has been used to evaluate the quality of bronchoscopic procedures, including EBUS-TBNA, and has provided a benchmark for EBUS-TBNA procedures, which may help ensure quality control.<sup>[14–15]</sup> Given the increasing number of EBUS-TBNA procedures being performed, the approaches to education and training for this procedure should be reconsidered,<sup>[16]</sup> and a more efficient standardized training program is warranted.<sup>[17]</sup> We recently introduced a preliminary training program that consists of 5-step lessons in a tandem trainee and trainer setting.<sup>[18]</sup> This program was designed as an “ongoing quality and process improvement system after initial skill acquisition introduced.”<sup>[17]</sup> Twelve successful needle punctures is the minimum for achieving a satisfactory diagnostic yield for a trainee.<sup>[18]</sup> Using the present biosimulator, the quantity as well as quality of cytological material obtained by EBUS-TBNA can be assessed without using experimental animals or a cadaveric training model. When we used a rapid on-site evaluation during the training course, the trainees received feedback immediately during the training course, which helped improve their competency in EBUS-TBNA.

This study is primarily limited by the small number of participants in the training course and the existence of a learning curve for the biosimulator itself. The experience of EBUS-TBNA was not concordant with the experience with bronchoscopy. As such, some doctors with more experience in bronchoscopy showed worse results than less-experienced doctors. However, the results of this study may help clarify whether or not a biosimulator can be used to train subjects in specimen acquisition for EBUS-TBNA. We were able to assess the quantity as well as the quality of the obtained cytological material using this biosimulator, which facilitated discussions about how to improve the quantity and quality of aspirates. Unfortunately, there was no control group in this study because sampling cannot be done using a conventional dry training model. Therefore, the efficacy of “improvement of sampling” was unevaluable. However, performing actual sampling of lymph nodes and evaluating their own sampled material would be a meaningful experience for trainees in EBUS-TBNA. By evaluating their own samples, trainees can obtain feedback and tips for sampling to use the next time they perform the procedure. We also surveyed the participants regarding their thoughts on the training course with this biosimulator; 17 of the 19 doctors strongly felt that this training had helped improve their EBUS-TBNA skills, and all 19 responded that they would recommend this training course to their colleagues.

#### 5. Conclusion

A biosimulator can be used to train subjects in proper specimen acquisition and evaluate their sampling skills using EBUS-TBNA. This model is appropriate for trainees with different levels of experience and can be used in accordance with a trainee’s skill level. Evaluating the efficacy of using this biosimulator in an EBUS-TBNA training course will require a randomized prospective trial.

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## References

- [1] Nakajima T, Yasufuku K, Fujiwara T, et al. Recent advances in endobronchial ultrasound-guided transbronchial needle aspiration. *Respir Investig* 2016;54:230–6.
- [2] Silvestri GA, Gonzalez AV, Jantz MA, et al. Methods for staging non-small cell lung cancer: diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines. *Chest* 2013;143:e211S–250S.
- [3] Vilmann P, Clementsen PF, Colella S, et al. Combined endobronchial and esophageal endosonography for the diagnosis and staging of lung cancer: European Society of Gastrointestinal Endoscopy (ESGE) Guideline, in cooperation with the European Respiratory Society (ERS) and the European Society of Thoracic Surgeons (ESTS). *Endoscopy* 2015;47:545–59.
- [4] Wahidi MM, Herth F, Yasufuku K, et al. Technical aspects of endobronchial ultrasound-guided transbronchial needle aspiration: CHEST guideline and expert panel report. *Chest* 2016;149:816–35.
- [5] Stather DR, MacEachern P, Chee A, et al. Evaluation of clinical endobronchial ultrasound skills following clinical versus simulation training. *Respirology* 2012;17:291–9.
- [6] Davoudi M, Colt HG, Osann KE, et al. Endobronchial ultrasound skills and tasks assessment tool: assessing the validity evidence for a test of endobronchial ultrasound-guided transbronchial needle aspiration operator skill. *Am J Respir Crit Care Med* 2012;186:773–9.
- [7] Fabel M, Biederer J, Jochens A, et al. Semi-automated volumetric analysis of artificial lymph nodes in a phantom study. *Eur J Radiol* 2011;80:e451–7.
- [8] Jeffus SK, Joiner AK, Siegel ER, et al. Rapid on-site evaluation of EBUS-TBNA specimens of lymph nodes: comparative analysis and recommendations for standardization. *Cancer Cytopathol* 2015;123:362–72.
- [9] Choi SM, Lee AR, Choe JY, et al. Adequacy criteria of rapid on-site evaluation for endobronchial ultrasound-guided transbronchial needle aspiration: a simple algorithm to assess the adequacy of ROSE. *Ann Thorac Surg* 2016;101:444–50.
- [10] Groth SS, Whitson BA, D’Cunha J, et al. Endobronchial ultrasound-guided fine-needle aspiration of mediastinal lymph nodes: a single institution’s early learning curve. *Ann Thorac Surg* 2008;86:1104–9.
- [11] Wahidi MM, Hulett C, Pastis N, et al. Learning experience of linear endobronchial ultrasound among pulmonary trainees. *Chest* 2014;145:574–8.
- [12] Wahidi MM, Silvestri GA, Coakley RD, et al. A prospective multicenter study of competency metrics and educational interventions in the learning of bronchoscopy among new pulmonary fellows. *Chest* 2010;137:1040–9.
- [13] Lee HJ1, Coleman B, Lerner AD, et al. Procedural Learning Perspectives of Pulmonary Fellows and Practitioners. *J Bronchology Interv Pulmonol*. 2017 doi: 10.1097/LBR.0000000000000362. [Epub ahead of print].
- [14] Ost DE, Ernst A, Lei X, et al. Diagnostic yield of endobronchial ultrasound-guided transbronchial needle aspiration: results of the AQUIRE Bronchoscopy Registry. *Chest* 2011;140:1557–66.
- [15] Eapen GA, Shah AM, Lei X, et al. Complications, consequences, and practice patterns of endobronchial ultrasound-guided transbronchial needle aspiration: results of the AQUIRE registry. *Chest* 2013;143:1044–53.
- [16] Kennedy MP, O’Callaghan MP, McCarthy J, et al. The impact of the introduction of an endobronchial ultrasound-guided transbronchial needle aspiration program on teaching of conventional bronchoscopic sampling techniques in an academic institution. *Am J Respir Crit Care Med* 2013;188:255.
- [17] Ernst A, Wahidi MM, Read CA, et al. Adult bronchoscopy training: current state and suggestions for the future: CHEST Expert Panel Report. *Chest* 2015;148:321–32.
- [18] Sakairi Y, Saegusa F, Yoshida S, et al. Evaluation of a learning system for endobronchial ultrasound-guided transbronchial needle aspiration. *Respir Investig* 2012;50:46–53.