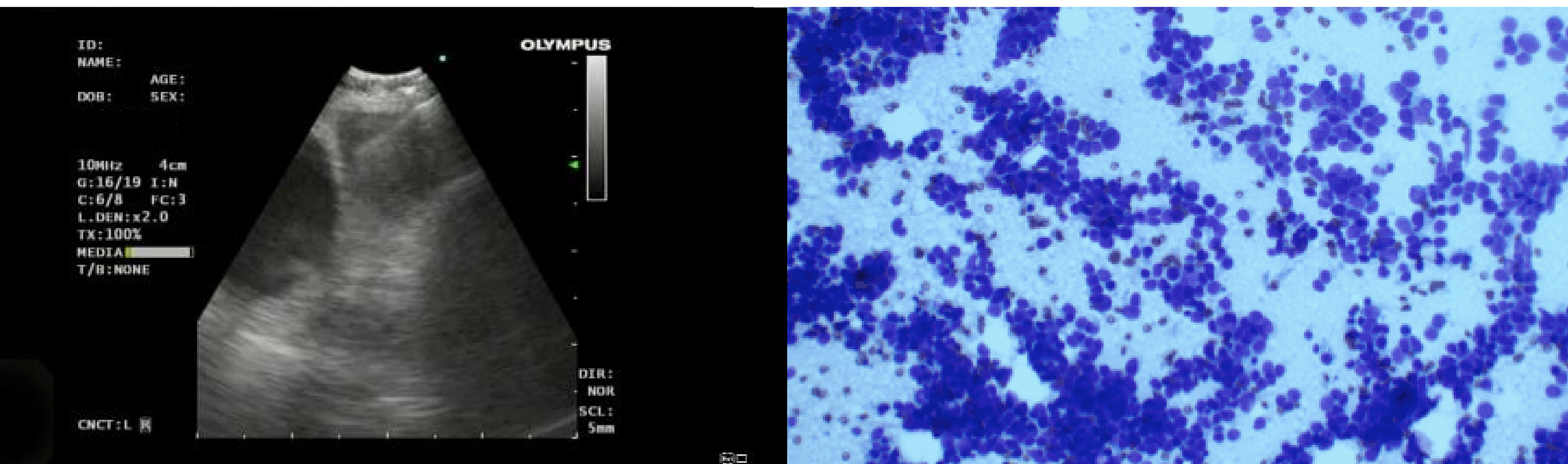


Clinical Perspective

REVIEW OF THE 25ga EXPECT™ PULMONARY EBUS-TBNA NEEDLE

A Physician Technique and Procedural Overview



Presented by:
Septimiu Murgu, MD, FCCP
The University of Chicago Medicine

Scope and History



Purpose

The purpose of this clinical perspective is to describe the Physician's best practices for using the 25ga Boston Scientific Expect Pulmonary EBUS Needle and to summarize its advantages.

Scope

The information contained herein is relevant for all chest physicians using EBUS–TBNA for diagnosing intra–thoracic adenopathy and masses.

Background History

EBUS–TBNA is recommended as the best first test for diagnosis and staging of mediastinum in the setting of lung cancer¹. It has also been found useful for the diagnosis of sarcoidosis and lymphoma^{2,3}. For lung cancer, in patients with an abnormal result on FDG–PET scans, further evaluation of the mediastinum with sampling of the abnormal lymph node should be performed. Traditionally, this has been done via mediastinoscopy or VATS, but now guidelines recommend EBUS–TBNA as the first test because of its high sensitivity of 89% and safety profile¹. Even when PET and chest CT are normal in mediastinal lymph nodes, further staging is needed prior to surgery or definitive chemoradiotherapy in the following circumstances: centrally located tumors, clinical N1 disease, or tumors larger than 3 cm⁴. Most patients with lung cancer are still diagnosed in advanced stages, when molecular testing and biomarker–driven therapy become relevant⁵. The quality and quantity of EBUS–TBNA specimens is increasingly relevant for diagnosis, staging, and individualized treatment. Manufacturers increasingly develop a variety of EBUS needles, which may vary significantly in regards to sampling technique as well as the quantity, type (histology or cytology) and quality of the sampled specimen⁶. Commonly used EBUS–TBNA needle systems vary in handle, needle design (e.g. core trap, standard), size (i.e. needle gauge), locking mechanism (e.g. adapter valves, luer–lock) and material (e.g. stainless steel)⁶.

The Opportunity

Issues that demand resolution in EBUS–TBNA include:

- 1 Potential difficulty in sampling certain **left lower paratracheal lymph nodes** (station 4L) when using the standard 22 or 21ga EBUS needles available on the market



Sampling of station 4L

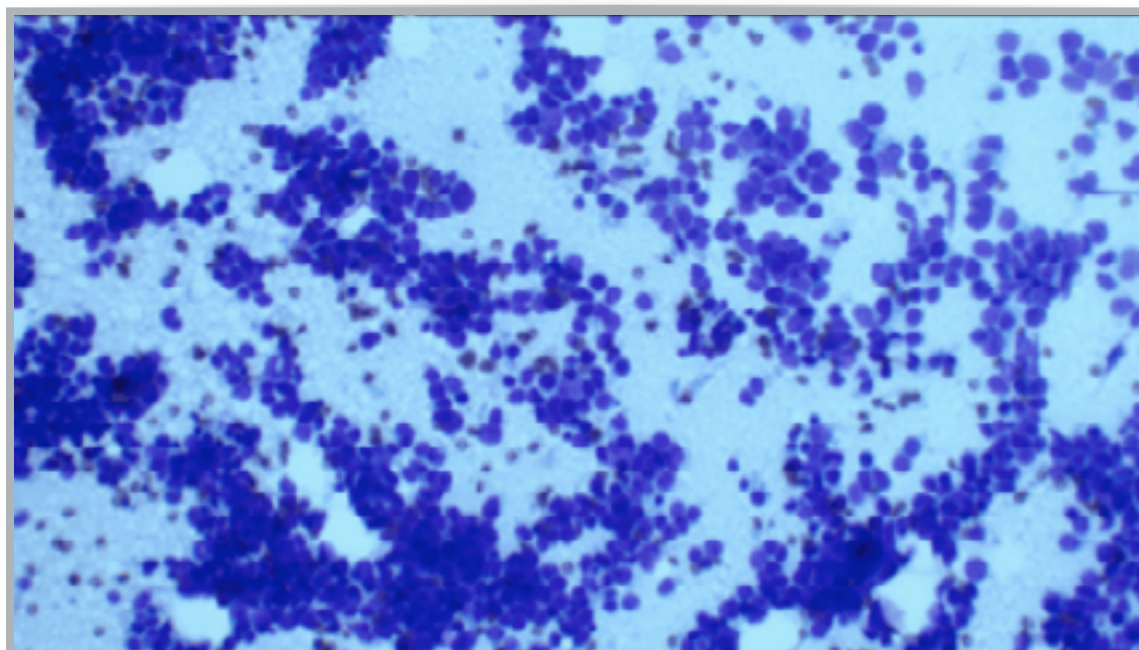
From our point of view, this could be due to the needle stiffness, lack of flexibility, suboptimal sharpness and potentially anatomy. Mediastinal staging must involve mediastinal EBUS exploration of all mediastinal lymph node stations that affect staging. These include the IASLC stations 2R, 2L, 4R, 4L and 7. Due to the relatively more acute angle between the left main bronchus and the trachea, station 4L is sometimes difficult to sample once the needle sheath is advanced and locked. In fact, one of the reasons for the false negative rate of EBUS–TBNA is the inability to sample station 4L. Studies show that the benefit of adding EUS to EBUS as part of the endosonographic staging of the mediastinum occurs when EBUS specimens from stations 4L and 7 are non–diagnostic or when these stations were unable to be sampled via EBUS^{7,8,9}. **“In this regard, we found the 25ga Expect Pulmonary EBUS Needle is flexible and sharp and to date, we have had no difficulty sampling station 4L nodes” (see video).**

Video courtesy of Dr. Septimiu Murgu

The Opportunity

Issues that demand resolution in EBUS–TBNA include:

- 2** **Bloody specimens** may compromise adequacy for genetic profiling



Less blood in specimens from 25ga needle

Image courtesy of Dr. Septimiu Murgu

In our experience, some vascular lymph nodes may result in bloody EBUS specimens when sampled with the 21ga and 22ga needles. In fact, the published literature suggest that while the specimen adequacy for diagnosis is not necessarily affected by the needle size, the 22ga needles result in less bloody samples when compared with the 21ga needles¹⁰. Data from thyroid lesions sampling also suggest that the smaller the needle gauge, the less bloody the specimens. This may explain why FNAs from thyroid are often performed by using 25ga needles¹¹.

- There is an increasing body of literature showing that next generation sequencing (NGS) for genetic profiling of tumors is feasible and offers relevant information from cytology specimens and using platforms that need ~10 ng of DNA^{12,13}.
Studies now demonstrate that molecular testing on cytology cellblocks is as sensitive and specific as that on histology¹⁴.
- There is emerging experience with NGS on cytology smears in tertiary cancer hospitals.
- For both smears and cell block, however, tumor purity is important and most molecular laboratories require that tumors are evaluated by a pathologist to confirm that a minimum of 20% of nucleated cells that were forwarded for DNA extraction are malignant¹⁵.

In this regard, consistent with data from other organ sampling, **“based on practical experience, we found that the 25ga Expect Pulmonary EBUS Needle results in less bloody specimens” (see image)**. Of note, we only use suction in the rare circumstance when the first two passes retrieve no material (i.e. dry aspirates). Please note, Boston Scientific’s Expect Pulmonary EBUS-TBNA Needle’s directions for use advises using suction during a standard procedure.

The Opportunity

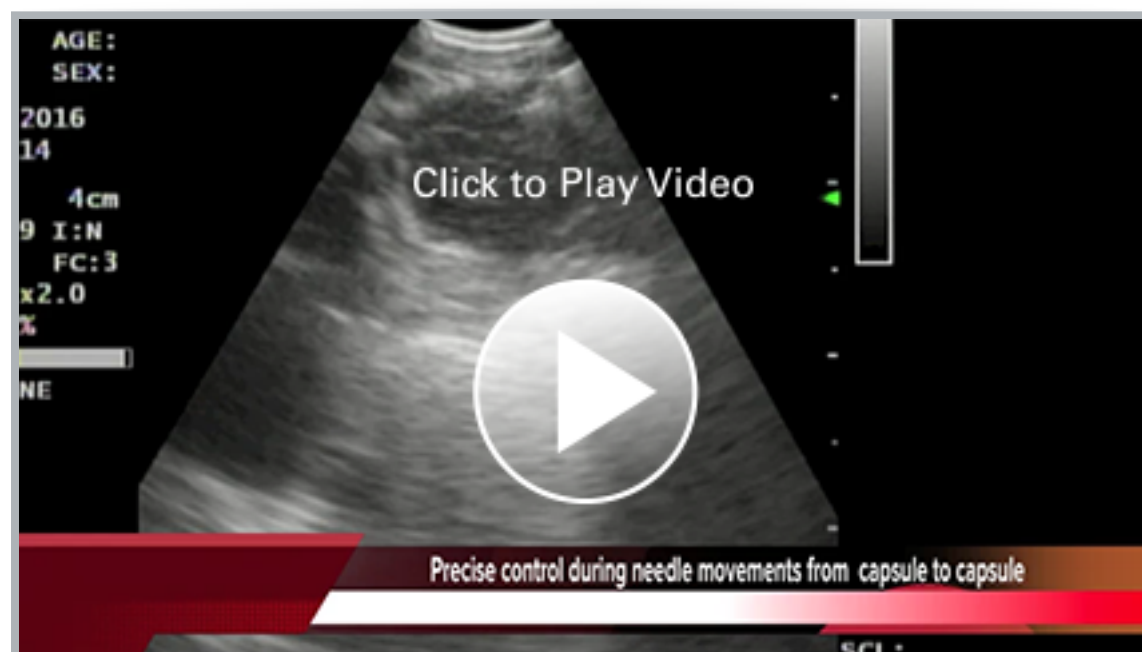


Issues that demand resolution in EBUS–TBNA include:

- 3** **Improvement in the sensitivity** for metastatic lymph node involvement

Based on practical experience, EBUS–TBNA already has a high diagnostic rate but this can potentially be further improved by optimizing the specimen acquisition technique.

- **“The sharpness of the 25ga Expect Pulmonary Needle allows for better needle control during the lymph node penetration and during the back and forth movement of the needle inside the node” (see video).** This is relevant for clinicians, as the needle must be moved from capsule to capsule, covering the entire diameter of the node. Studies show that in adenocarcinoma, about 20% of patients have only subcapsular lymph node metastatic involvement¹⁶; moving the needle only in the center of the node will potentially miss the involved area and result in a false negative EBUS–TBNA sampling.



Demonstration of needle control

Video courtesy of Dr. Septimiu Murgu

The Opportunity

Issues that demand resolution in EBUS–TBNA include:

4 Difficulty in sampling **fibrotic lymph nodes**

This is not uncommon with the 21ga or 22ga needles when attempts are made to re-stage the mediastinum after neoadjuvant chemo- or radiotherapy¹⁷.

- Neither mediastinoscopy, nor EBUS are ideal for restaging the mediastinum. Two studies show that EBUS has a sensitivity of only 64% and 76%, respectively for restaging^{17, 18}. This is likely related to the fibrotic tissues inside or around the node. Paradoxically, a smaller gauge sharp needle may be preferred in this situation. Data from breast FNA supports this hypothesis¹¹. **"We have used the 25ga Expect Pulmonary EBUS needle to penetrate lymph nodes after neoadjuvant chemo and radiation therapy, in circumstances when the 22ga could not be advanced in the node."** In fact, data from breast and thyroid FNA suggest that for fibrotic nodes, the 25ga may perform better^{6, 11}.

The Opportunity

Issues that demand resolution in EBUS–TBNA include:

- 5** Reported hesitancy in sampling **small size lymph nodes (5–7 mm)**

It is not uncommon for less seasoned practitioners to feel nervous about sampling these small size lymph nodes, especially when major vascular structures are adjacent to the nodes (i.e. 4L, anterior 4R, low 7).

The 25ga Expect Pulmonary EBUS Needle is sharp and allows for a smooth back and forth movement and easy airway wall penetration.

Because of the increased control on needle operation, the proceduralist may feel more comfortable sampling smaller size lymph nodes close to major vascular structures (see video). In addition, we believe that the 22ga or 21ga needles often traumatize the small nodes and result in suboptimal specimens.¹⁰ The 25ga needle may counteract these issues.



Sampling of lymph node close to major vascular structures

Video courtesy of Dr. Septimiu Murgu

The Opportunity

Issues that demand resolution in EBUS–TBNA include:

6 Echogenicity on ultrasound image



Echogenicity of 25ga needle on ultrasound

Due to its smaller gauge, the 25ga needle is less echogenic than the 22ga or 21ga needles. Some operators find it difficult to visualize the needle on the EBUS display monitor, especially when the brightness of the image is not adjusted and when the lymph node is hyperechoic. **We believe that this problem occurs not just due to an inadequate use of the “gain” processor function, but also due to the fact that given its small diameter**, the needle can easily “get out” of the EBUS scanning plane when the wrist is inadvertently moved even 1 mm in the axial plane.

Photo courtesy of Dr. Septimiu Murgu

The Opportunity



Issues that demand resolution in EBUS–TBNA include:

7 Locking mechanism



Demonstration of needle adjustments

As seen in practical experience, on occasion, when the EBUS scope is in the mainstem or lobar bronchi, even with the thumb off the lever (i.e. neutral position), sometimes it is difficult to advance the needle all the way in and lock the housing. We learned to trouble shoot this problem by applying one of the following two maneuvers:

- 1 Pull the EBUS scope in the lower trachea, then advance the needle all the way in and lock the housing; then the entire system can be advanced to the desired location; OR
- 2 While the scope is in the desired location, the thumb pushes up on the lever, gently retroflexing the scope. This allows for relative straightening of the tip of the scope while still in the mainstem / lobar airway and the needle system can be advanced and locked without difficulty (**see video**).

Video courtesy of Dr. Septimiu Murgu

Expert Proposed Solutions

The recently proposed FASTER technique is feasible using the 25ga Boston Scientific Expect Pulmonary EBUS-TBNA Needle. Herein, a summary of each criteria used in the FASTER technique is provided to illustrate how the 25ga EBUS-TBNA needle can be used for this purpose.

Physician Proposed FASTER Technique

- 1 Frequency:** we suggest one or two downstroke movements of the needle per second as specimens are often acquired by the cutting action of the needle; this is done in a more controlled fashion with a sharp 25ga needle than with larger needles; in fact, nodal tissue and cells are conducted into the needle by capillary action; in this regard, based on the physics principles of capillarity, the smaller gauge needle could result in a higher column of tissue medium inside the node¹⁹.
- 2 Amplitude:** the movement of the needle from one edge to the other (capsule to capsule) assures sampling of all intranodal regions (**see video**); this is relevant as in a significant proportion of patients with lung cancer, subcapsular region of the node may be the only site of malignant involvement¹⁶.



Precise control during needle movements from capsule to capsule

Video courtesy of Dr. Septimiu Murgu

Expert Proposed Solutions

- 3 Suction:** physicians may not use suction routinely, and particularly some may not use it for the first two passes. Please note, Boston Scientific's Expect Pulmonary EBUS-TBNA Needle's directions for use advises using suction during a standard procedure. Studies show that suction applied during EBUS-TBNA for lung cancer diagnosis and staging may not increase the yield and in fact, may result in bloodier specimens; a non-bloody specimen is preferred for molecular testing. When non-suction technique fails to retrieve an adequate sample, then suction should be used⁶.



Needle actuation with no suction

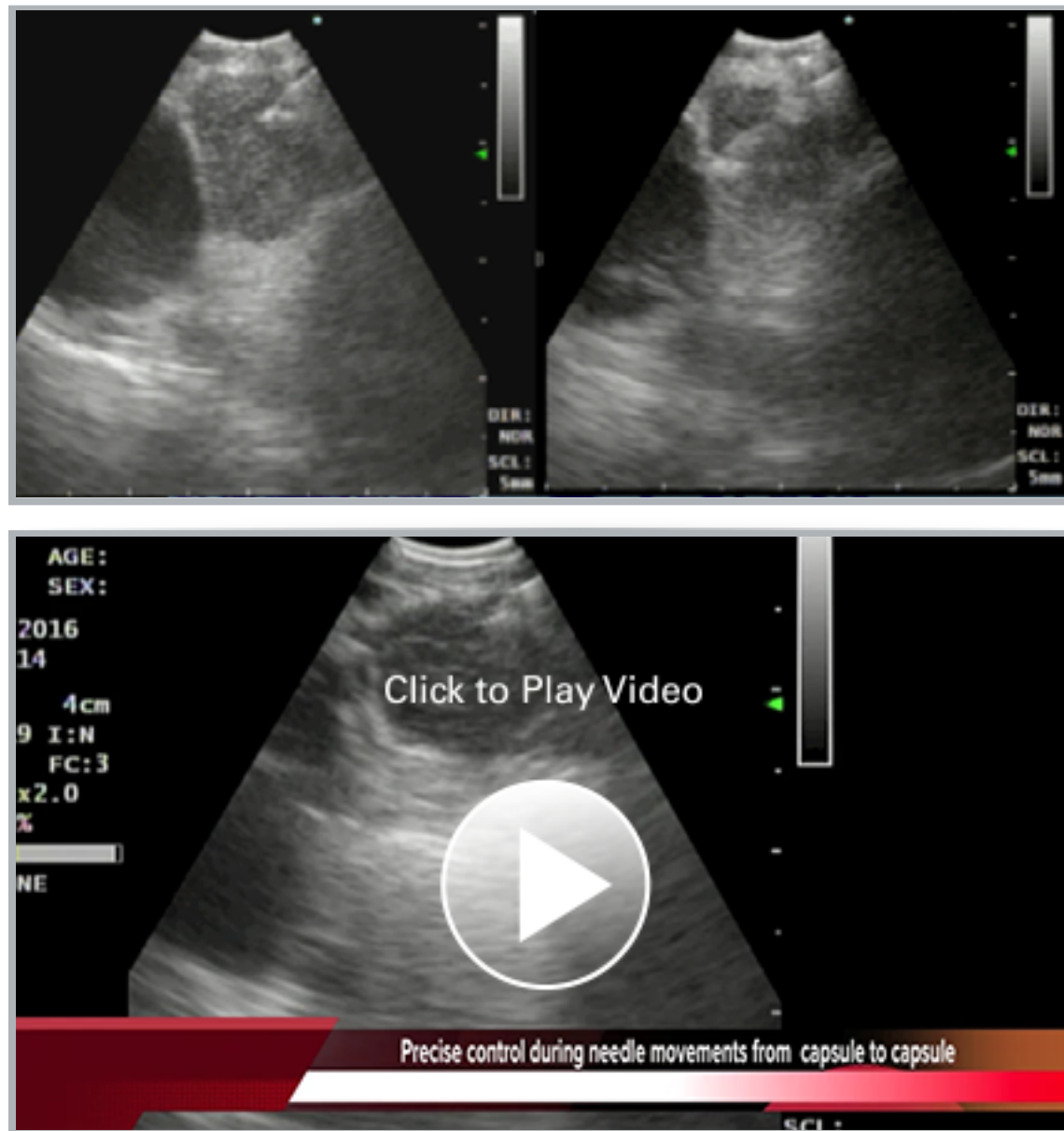
- 4 Time:** it is suggested that the time spent in the node should be less than 6–10 seconds (**see video**); the longer the time spent during sampling, the higher the chance for capillary trauma and bloodier samples. In fact, data from breast and thyroid FNAs shows that the less time spent in the node, the better the specimen purity. That is probably why the 25ga may perform better in hypervascular nodes¹¹.



Time spent in the node should be less than 6-10 seconds

Video/image courtesy of Dr. Septimiu Murgu

Expert Proposed Solutions



Demonstration of fanning technique

Video/image courtesy of Dr. Septimiu Murgu

5 Edge: the operators must pay close attention to the needle tip as the needle is moved back and forth inside the node. A through and through aspiration of the node (penetrating the distal capsule on EBUS image), could result in puncturing of the lung parenchyma or blood vessel. In addition, pulling the needle back too much (out of the node) and then advancing it again inside the node, could result in a compromised adequacy due to pick up of bronchial cells, mucus and blood from the puncture site (**see image**).

6 Route: the change in the direction of the needle inside the node by flexing or extending the lever of the bronchoscope handle allow for the so-called "fanning technique" (**see video**).

Traditionally, it was not possible or advisable to do this for EBUS-TBNA sampling. This is commonly done in GI EUS sampling of pancreatic lesions, where it was shown to improve the diagnostic yield when compared with the standard techniques²⁰.

Cutting through previously non-traumatized lymph node tissues can potentially increase the quantity and quality of the sampled material.

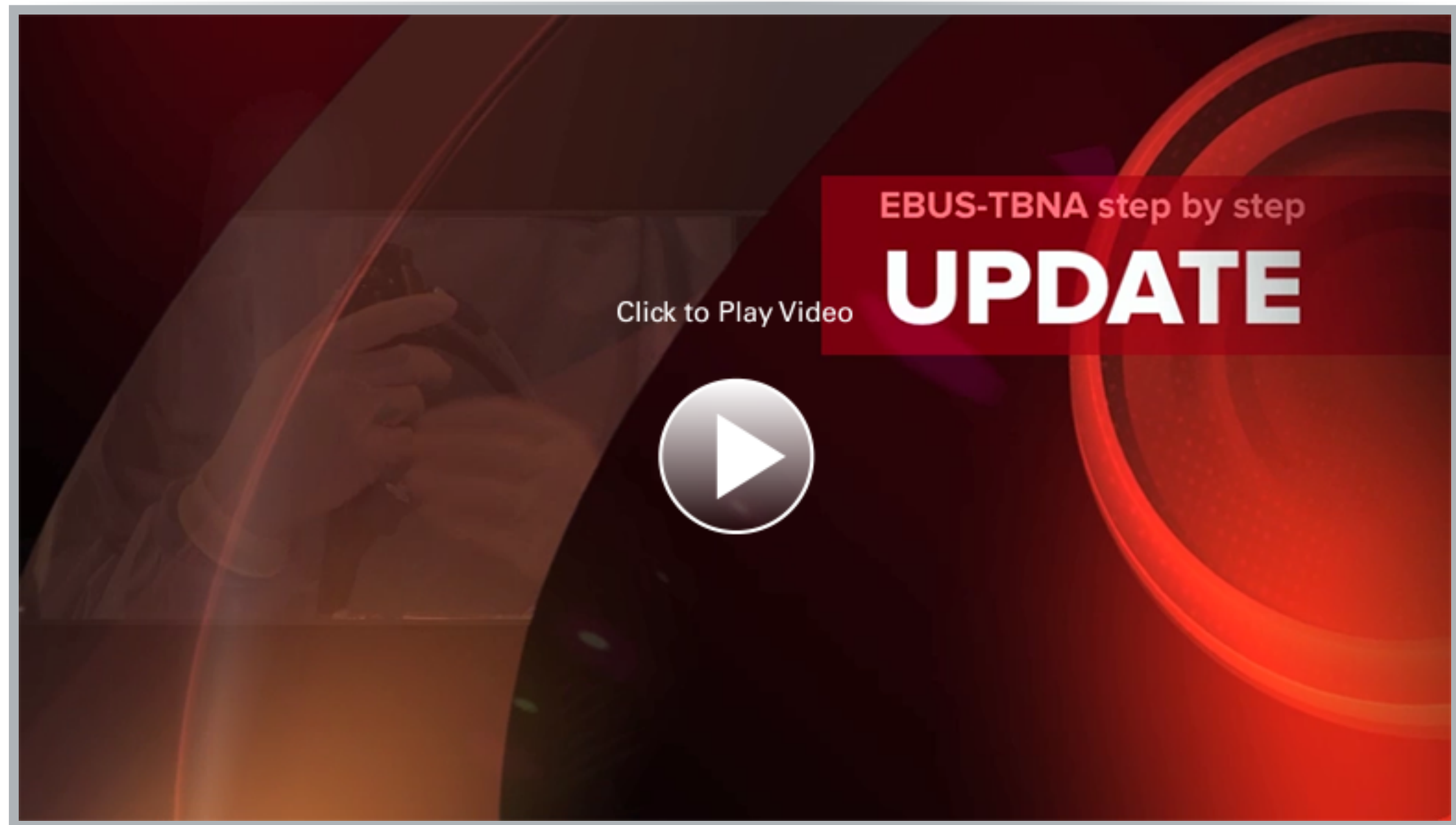
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Expert Proposed Solutions

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In our experience, this may be much easier to perform with the Expect Pulmonary 25ga needle than with the Olympus 21ga or 22ga needles, likely because of increased flexibility. The 25ga needle penetrates the node at a more shallow (more acute angle) than the standard 21ga or 22ga needle on the market. If the operators consider this an issue as they cannot sample certain areas of the node, and if the problem cannot be overshoot by flexion/extension of the lever, then it is suggested that the entire scope–needle assembly is gently pushed forward a few millimeters while the tip of the needle is inside the node, but in a more superficial location; this will result in a change in the direction of the needle during subsequent needle back and forth movements.

Step-by-Step Overview



Video courtesy of Dr. Septimiu Murgu

Scope & History

Opportunity

Solutions

Technique Video

Recommendation

Expert Recommendation



Adopting the recommendations from this clinical perspective will allow practitioners to safely obtain a less bloody and potentially more adequate specimen during EBUS–TBNA; this is particularly true for smaller lymph nodes, difficult locations or even for more fibrotic nodes such as those post chemo–and radiotherapy.

It is recommended that EBUS-TBNA practitioners implement the use of 25ga Boston Scientific Expect Pulmonary EBUS Needle in their practice and apply the above listed FASTER technique.



References

Scope & History

Opportunity

Solutions

Technique Video

Recommendation

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300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

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