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The VERITAS Study Comparing Navigational Bronchoscopy Versus CT-guided Biopsy

Implications for Pulmonologists, Physicians, and Hospitals

FROST & SULLIVAN WHITEPAPER

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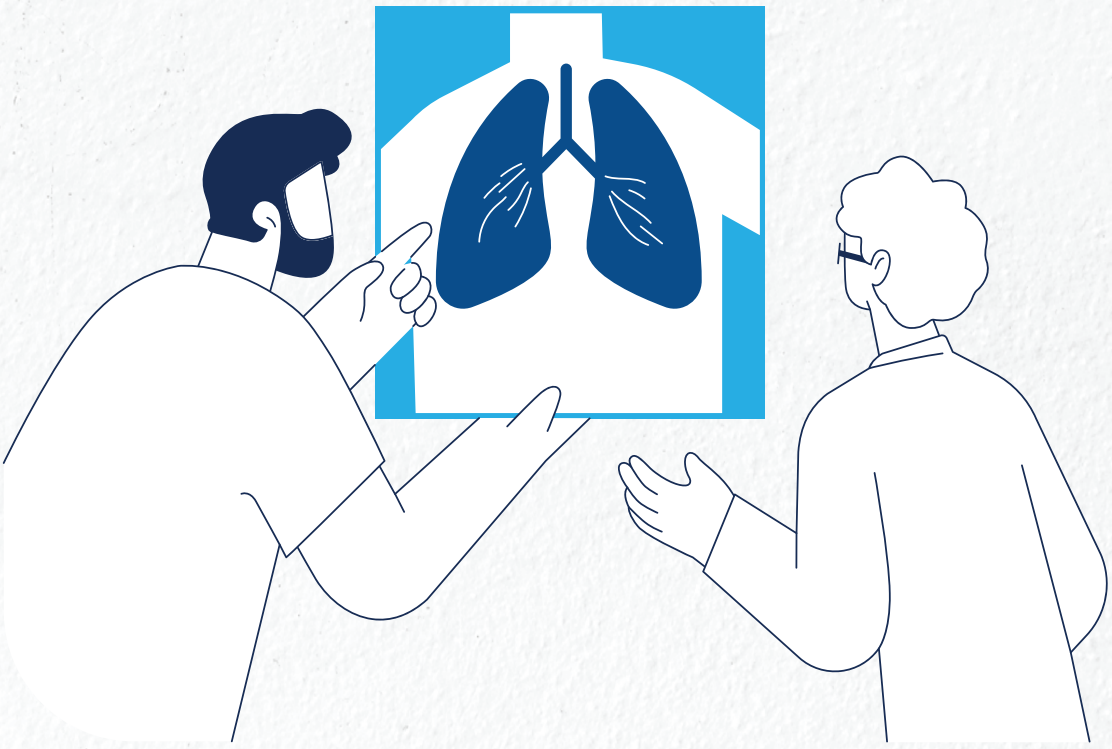

Introduction

The incidence of lung nodules has increased, in line with the frequency and sophistication of CT and other imaging techniques. Many of these nodules require biopsy to distinguish malignant from benign tissue and make a diagnosis that will support development of a treatment plan for the patient.

CT-guided transthoracic needle biopsy (CT-TTNB) has been the gold standard for minimally invasive biopsy. However, CT-TTNB has been associated with a 25% complication rate, including pneumothorax, hemorrhage, and air embolism.[1]

Navigational bronchoscopy has developed as an alternative biopsy method and is associated with improving diagnostic yield and lowering complication rates.†[2] Medtronic's ILLUMISITE™ fluoroscopic navigation platform provides critical advancements, primarily in the correction for CT-to-body divergence during the procedure.[3]

Until recently, comparison of the diagnostic yield of the two methods were largely based on non-comparative data, with significant risk for selection, referral, and publication biases. However, VERITAS, a randomized controlled trial, was conducted from 2021 to 2023 to compare the clinical utility of Electromagnetic Navigational Bronchoscopy (ENB) with the ILLUMISITE™ platform to CT-TTNB in a multicenter noninferiority study.

That study, published in 2024, found that ENB was noninferior to CT-TTNB for the diagnosis of lung nodules, with safer biopsy based on complication rate.†[2]

For decades, Frost & Sullivan has tracked the development and use of new technologies that advance healthcare. For this white paper, Frost & Sullivan interviewed three leading interventional pulmonologists to explore the implications of the VERITAS study for three key stakeholders:

Interventional pulmonologists

Referring physicians

Hospitals and health systems

Given the significance of the VERITAS study, Frost & Sullivan sought to understand how these learnings should be disseminated to impact care practices.

† Based on a non-inferiority RCT; safer biopsy based on complication rate.

Thought Leaders

Frost & Sullivan interviewed three leading interventional pulmonologists who have intimate knowledge of the VERITAS study and can explain the implications for these stakeholders:

- Jonathan S. Kurman, MD MBA, is an assistant professor of medicine and the director of interventional pulmonology at the Medical College of Wisconsin in Milwaukee, WI. He completed an interventional pulmonology fellowship at the University of Chicago and pulmonary and critical care training at the Medical College of Wisconsin. He is board certified in internal medicine, pulmonology, critical care, and interventional pulmonology. His interests are in diagnostic and therapeutic bronchoscopy, including airway stents, robotic bronchoscopy, endobronchial valves, next-generation navigational bronchoscopy, bronchothermoplasty, photodynamic therapy, and bronchoscopy education. He has published several articles on management of persistent air leaks, bronchothermoplasty, and bronchoscopy education. Dr. Kurman is also one of the principal investigators for the VERITAS study.
- Fabien Maldonado, MD, MSc, is a professor of medicine, thoracic surgery, and mechanical engineering at Vanderbilt University, which he joined in July 2015 after serving 9 years on the faculty at Mayo Clinic in the division of Pulmonary and Critical Care Medicine. Originally from France, he attended the School of Medicine in Dijon and then moved to the United States to eventually complete a fellowship in pulmonary and critical care medicine at Mayo Clinic, Rochester, MN. He then completed an Interventional Pulmonary fellowship in Marseille from 2009 to 2010. He helped start an Interventional Pulmonology fellowship program at Mayo Clinic as the co-program director, and serves as the program director for the interventional pulmonology fellowship at Vanderbilt University. He is a member of the Board of Directors of the American Association of Bronchology and Interventional Pulmonology and serves on several steering committees for the American College of Chest Physicians and the American Thoracic Society. He is pursuing a Master of Science in Philosophy, Science, and Religion at the University of Edinburgh, UK. His main research interests include clinical trials in interventional pulmonology, CT-based quantitative imaging for lung cancer and robotic bronchoscopy. Dr. Maldonado is also one of the principal investigators for the VERITAS study.
- Dr. Bryan S. Benn, MD, PhD, is an interventional pulmonologist practicing at the Cleveland Clinic in Cleveland, Ohio. He completed both his interventional pulmonology and pulmonary and critical care fellowships at the University of

California, San Francisco, internal medicine residency at Thomas Jefferson University Hospitals, and his combined MD/PhD at New Jersey Medical School. A board-certified physician in internal medicine, pulmonary diseases, critical care medicine, and interventional pulmonology, his clinic practice includes all aspects of advanced diagnostic and therapeutic bronchoscopy as well as pleural procedures. Dr. Benn's research interests focus on improving diagnostic accuracy of bronchoscopic biopsies of peripheral pulmonary lesions and increasing the safety and diagnostic accuracy of transbronchial lung cryobiopsies for interstitial lung disease.

Implications for Pulmonologists

VERITAS as a demonstration of confidence in the technology

This field has traditionally been supported by little rigorous clinical study, with almost no randomized controlled studies of many of the technologies and techniques in use today. As Dr. Kurman observed, "we don't have this quality of data for many things in our field, so the VERITAS study is really something special."

Here, these researchers—and Medtronic through its funding—significantly advanced the field by answering crucial questions regarding the diagnostic yield and safety profile of the two leading diagnostic methods. By funding that study, Medtronic made a significant investment based on its confidence in the technology. As Dr. Kurman explains,

> **I think our peers appreciate having this quality of data. I think that our peers recognize the risk Medtronic took in funding this study. This study could have shown that their product was inferior to CT-guided biopsy. But it didn't."**

Legitimizing advanced diagnostic bronchoscopy

ENB is a relatively recent innovation, with its first human trial in 2006.[4] Since then, its use has expanded rapidly with the ILLUMISITE™ fluoroscopic navigation platform.

However, lung nodule biopsy using ENB has trailed CT-guided biopsy, in large part because of questions regarding its diagnostic yield. The VERITAS study clearly answers those questions, finding that ENB was noninferior to CT-guided biopsy for the diagnosis of lung nodules, with a safer biopsy experience.[†2]

† Based on a non-inferiority RCT; safer biopsy based on complication rate.

These findings, as Dr. Maldonado concludes, "legitimizes the entire field of advanced diagnostic bronchoscopy." Combined with its other advantages, the VERITAS study clearly positions ENB over CT-guided biopsy.[†§2] As Dr. Maldonado continues,

> **A majority of these procedures are done by interventional radiologists as CT-guided transthoracic biopsies. I think that's going to change based on the results of VERITAS. With diagnostic bronchoscopy you can biopsy the nodule, but you can also biopsy lymph nodes. You can biopsy several nodules. You get less complications.[2] These are clear advantages of bronchoscopy over CT-guided biopsy."**

The VERITAS study demonstrated what interventional pulmonologists have long recognized: that ENB has significant advantages over CT-guided biopsy and should be considered the gold standard diagnostic modality. [†§2]

Opportunity for pulmonology to drive the conversation

Given the importance of carefully selecting a diagnostic path for lung patients and the value of ENB as a diagnostic tool, this may be the moment for pulmonologists to begin playing a more pivotal role in managing patient care on the suspicion of lung cancer. As Dr. Maldonado explained,

> **There is a vacuum at the center of the care pathway for lung cancer. Traditionally, surgeons coordinated care but now they come later in the process, after there's a diagnosis. But pulmonologists see patients in clinic, explaining and exploring their options. Increasingly, pulmonologists are becoming the quarterbacks of managing the care pathway for these patients."**

As Dr. Maldonado concludes, "pulmonologists—who are familiar with these procedures and the data—are involved at the beginning of the process, and they will drive a change in the current care pathways." Logically, given the available evidence, this will lead to more patients undergoing diagnostic bronchoscopy, resulting in superior diagnostic data with fewer patient complications.[†2]

† Based on a non-inferiority RCT; safer biopsy based on complication rate.

§ Given these findings plus additional advantages including the ability to simultaneously perform mediastinal staging, bronchoscopy should be preferred to CT-TTNB for the diagnosis of indeterminate pulmonary nodules.

Implications for Referring Physicians

Taking the right first step in the diagnostic process

Many patients enter the diagnostic process on referral from their primary care physician, who has recognized the risk of lung cancer and the need to refer the patient to a specialist for diagnosis. Prior to formal diagnosis, patients might also see pulmonologists, medical oncologists, or surgeons who will refer them to the next step in the diagnostic process.

Traditionally, that referral is for a CT-TTNB, which has long been the gold standard for lung biopsy. This is especially true for physicians who are primarily focused on treatment and are less conversant in the latest clinical evidence regarding treatment options. As Dr. Benn describes,

> **"You have physicians who refer their patients for surgery or medical oncology de novo, before diagnosis via any biopsy method. Other times, you will have a primary care physician, a pulmonologist, or a medical oncologist who recognizes the need for a diagnostic biopsy. Their focus is on the need for a diagnosis, and they may not be experts in how that biopsy is obtained."**

However, because this is such a critical juncture in the diagnostic process, the selection of the suitable diagnostic modality may have significant consequence for patients. As such, it is critical that these physicians become familiar with the key conclusions from the VERITAS study. Dr. Kurman explains,

> **"As the VERITAS data becomes more widely disseminated, navigational bronchoscopy using the ILLUMISITE™ platform will be the new gold standard in peripheral pulmonary nodule assessment, and providers will recommend that approach to patients. I think the VERITAS study is that compelling."**

Changing referral practices from CT-guided biopsy to navigational bronchoscopy will require these physicians to overcome the inertia that often impedes change that reflects the latest clinical evidence. As Dr. Maldonado explains,

> **I think inertia is a big problem in medicine. You publish high-quality data showing that doing things differently will improve patient outcomes. And 10 years down the road, you still have physicians doing the same thing over and over again. When—as here—you have this level of evidence, that needs to change the guidelines, and change where physicians refer their patients for biopsies."**

Building awareness of the VERITAS study among physicians referring patients for diagnosis will be critical to overcoming this inertia and helping them make the best recommendation for their patients. As Dr. Benn explains,

> **Physicians who have traditionally referred patients to CT-guided biopsy need to be the focus in sharing these findings, using this study as an opportunity to explain the value of diagnostic bronchoscopy approach compared to the CT-guided biopsy that they've traditionally relied upon. This is a way to say to say to them 'you need to really think about bronchoscopy based on this evidence—non-inferiority, and the enhanced safety profile.' I think the VERITAS study will help physicians consider the question with an open mind, and see that this technology and this approach is a reasonable thing to consider."**

These experts who are so intimately familiar with the evidence recognize that changing care practices will take time. However, they see the VERITAS study as significant enough to act as a tipping point. As Dr. Kurman explains,

> **Talking about these results will help disseminate the data, but it will take time for a cultural shift to occur. But I think that the VERITAS study will herald that shift, given the quality of the data and how profound the results are."**

Implications for Hospitals

Creating access to the most advanced diagnostic modality

Based on the findings of the VERITAS study, ENB has clear advantages in the evaluation of lung nodules over CT-guided biopsy.[†§2] However, access to this technique requires investment in technologies such as the ILLUMISITE™ platform.

Unfortunately, there is currently a lack of access to navigational bronchoscopy in large parts of the country. As Dr. Benn explains, for referring physicians who want to follow the evidence, "you may want to send your patient for a biopsy via navigational bronchoscopy, but you don't have anybody around who can do it."

Therefore, realizing the learnings of the VERITAS study should motivate hospitals and health systems to invest in these types of technologies. As Dr. Benn continues,

> **Where this conversation about VERITAS needs to happen is with hospital executives, and explaining why this is something they need to consider. It's win-win. It's freeing up your CT, and you're not losing that potential for revenue generation when you're tying up your CT with a guided biopsy. And you're helping your patients: you're getting them a safe and accurate procedure.[†2] It's a strong argument."**

Weighing investment in ENB versus robotics

Many hospitals will be in a position to weigh investment in navigational bronchoscopy solutions, such as the ILLUMISITE™ platform, against robotic platforms for the diagnosis of lung cancer.

ENB and robotic-assisted bronchoscopy have the same coding and same reimbursement landscape, but dissimilar direct and indirect costs.[‡5]

† Based on a non-inferiority RCT; safer biopsy based on complication rate.

§ Given these findings plus additional advantages including the ability to simultaneously perform mediastinal staging, bronchoscopy should be preferred to CT-TTNB for the diagnosis of indeterminate pulmonary nodules.

‡ Based on evidence from a single-center study.

Differences in acquisition, utilization, and reprocessing have been highlighted as important factors in evaluating platforms without sacrificing clinical outcomes.‡[5]

In Dr. Kurman's opinion, the evidence is clearly in favor of the ILLUMISITE™ platform:

> **"The alternative for hospitals is that they spend more money to get a robotic platform.‡◊[5,6] And some of those platforms are promoting their use with a separate cone-beam CT system in order to account for CT-to-body divergence. The ILLUMISITE™ platform doesn't need that additional imaging—just your standard C-arm.¶[3,7] What you get for what you pay for is amazing. This shouldn't be about money, but if it is, ILLUMISITE™ is a great solution."**

Conclusion

For interventional pulmonologists, the VERITAS study was the long-awaited answer to the question of whether navigational bronchoscopy was noninferior to CT-guided biopsy and validates their confidence in their specialty. However, Frost & Sullivan's interviews with these three thought leaders emphasized that VERITAS has implications far beyond their specialty.

In order to direct patients to the diagnostic modality supported by the most recent evidence, physicians who refer patients for biopsy need to be aware of how clearly this evidence supports ENB over CT-guided biopsy, both for its diagnostic yield and its better safety profile.†§[2]

And in order for patients to benefit from this safer path, hospitals and health systems need to wisely invest in economically viable technologies that make navigational bronchoscopy possible.‡[2,8,9]

Not for use in pediatric patients or those with unstable hemodynamic status. Specific risks include, but are not limited to, bleeding, pneumothorax, and respiratory failure. Refer to IFU for complete contraindication and risk information.

† Based on a non-inferiority RCT; safer biopsy based on complication rate.

§ Given these findings plus additional advantages including the ability to simultaneously perform mediastinal staging, bronchoscopy should be preferred to CT-TTNB for the diagnosis of indeterminate pulmonary nodules.

‡ Based on evidence from a single-center study.

◊ Based on evidence from a single-center retrospective study including a total of 133 consecutive robotic patients and 170 consecutive ENB patients.

¶ Based on evidence from a single-center prospective study including a total of 82 consecutive patients

Endnotes

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