MAY 21, 2024

VERITAS study shows Medtronic fluoroscopic navigation platform offers a safer lung biopsy experience and the same diagnostic yield as CT-guided biopsy

Preliminary findings of the first and only head-to-head trial comparing standard-of-care CT-guided biopsy with electromagnetic navigation bronchoscopy (ENB) for the diagnosis of lung nodules demonstrate non-inferiority and fewer complications when using ENB

Medtronic announced today new preliminary data from the VERITAS clinical study using its ILLUMISITE™ fluoroscopic navigation platform for the ENB procedure to diagnose lung nodules (growth in the lung). Clinical researchers at Vanderbilt University Medical Center who conducted VERITAS as an investigator-initiated study with funding from Medtronic, presented the preliminary results at the American Thoracic Society conference in San Diego.

The data demonstrated that the ENB platform with digital tomosynthesis that was used in the study is the first and only system clinically proven to be non-inferior to CT-guided biopsy – the current standard of care in lung biopsy. The non-inferiority finding indicates that the rates of lung disease diagnosis based on biopsy findings were similar for ENB and CT-guided biopsy. The findings also show the platform significantly reduces the rate of procedure-related complications, which are a key limitation of CT-guided biopsy.

“These findings suggest that ENB should be the preferred option over CT-guided biopsy for diagnosing indeterminate pulmonary nodules when both approaches are options,” said Fabien Maldonado, MD, MSc, Overall Principal Investigator at Vanderbilt-Ingram Cancer Center. “ENB enables providers to biopsy and stage multiple lung nodules within a single procedure. This means one episode of care for patients versus a possible two episodes of care with CT-guided biopsy, potentially reducing delays in patient care and treatment.”

In CT-guided biopsy, a needle is directed through the chest wall under conscious sedation to obtain tissue from suspicious areas. ENB involves guiding a bronchoscope through the throat and into the lungs for tissue sampling while under general anesthesia. Until VERITAS demonstrated the platform’s non-inferiority, diagnostic yield has generally been estimated to be higher with CT-guided biopsy because its use of real-time CT imaging enables accurate navigation to the target nodule.

The ENB platform incorporates intra-procedure digital tomosynthesis (a type of fluoroscopic imaging) that allows the bronchoscopy path to the nodule to be adjusted in real time[1,†] and enables accurate navigation to the target site.[1,2,3, †,‡] It also offers potential advantages by circumventing complications associated with chest wall puncture, such as pneumothorax and pain.[4]

Due to the absence of head-to-head comparative data with bronchoscopy approaches, CT-guided biopsy has remained the standard of care despite its 25% complication rate.[5] VERITAS is the first multicenter, non-inferiority randomized controlled trial to provide a direct comparison of CT-guided biopsy and ENB for diagnosing indeterminate pulmonary nodules.

About the VERITAS study

In the study, patients with peripheral lung nodules 10-30 mm with pre-test probability of malignancy ≥10% were randomized 1:1 to ENB or CT-guided biopsy following central review by an independent panel confirming that both procedures were appropriate for the patient and the target nodules. The primary endpoint was navigation diagnostic accuracy through 12 months of follow-up (data for which are anticipated in summer 2024); secondary endpoints included diagnostic yield and safety. Diagnostic yield was strictly defined as the combination of the primary endpoint (diagnostic accuracy) and yield from endobronchial ultrasound-guided mediastinal and/or hilar lymph node biopsies. This definition was consistent with the 2024 consensus statement from the American Thoracic Society Assembly on Thoracic Oncology and the American College of Chest Physicians. All non-malignant biopsies were reviewed centrally with diagnostic adjudication by a panel of lung nodule experts blinded to biopsy technique.

Of the 258 patients randomized at seven U.S. sites, 234 underwent biopsy procedures. Key findings include:

- For the secondary endpoint of diagnostic yield, ENB was diagnostic in 92 of 121 patients (76%) while CT-guided biopsy was diagnostic in 86 of 113 (76%). The probability that ENB was noninferior to CT—guided biopsy is 97%, exceeding the noninferiority threshold.
- Complications occurred in significantly fewer ENB procedures (5.8%, n=7) compared with CT-guided biopsy procedures (31%, n=35) ($p<0.001$).
    - These included pneumothoraces requiring tube thoracostomy (0.8%, n=1 for ENB vs. 8.8%, n=10 for CT-guided), and pneumothoraces not requiring thoracostomy (2.5%, n=3 for ENB vs. 19.5%, n=22 for CT-guided), and hemorrhage (0% for ENB vs. 2.7%, n=3 for CT-guided).

These findings, plus additional advantages of the ENB platform including the ability to simultaneously perform mediastinal staging in the same procedure,[6,7] support ENB as preferred approach over CT-guided biopsy for the diagnosis of indeterminate pulmonary nodules when both approaches are reasonable options.

“Medtronic Surgical is committed to providing clinicians with robust clinical data that allow them to make informed treatment decisions,” said Matt Anderson, senior vice president and general manager, Advanced Surgical Technologies within the Surgical business, which is part of the Medical Surgical Portfolio at Medtronic. “The findings clearly demonstrate that higher complication rates of CT-guided biopsy should no longer be considered a necessary tradeoff for diagnostic yield. The reductions in episodes of care and complications with our platform may also reduce the costs of accurate and timely early-stage lung cancer diagnosis.”

About the platform

The ILLUMISITE™ platform is indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

About lung cancer and the importance of early detection and diagnosis

Lung cancer is the number-one cause of cancer-related death in the United States.[8] At the same time, patients have a 92% chance of survival when lung cancer is diagnosed at an early stage and resected immediately.[9]

Early detection and diagnosis can improve survival rates of patients with lung cancer before symptoms arise. Healthcare technology innovations help clinicians to effectively and safely sample lung nodule tissue to determine if it's cancerous and whether the cancer has spread to the lymph nodes. ENB procedures result in significantly fewer patient complications as compared to CT-guided biopsy without compromising cancer detection rates.[10]

About Medtronic

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Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the U.S. Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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

‡ Based on evidence from a single-center retrospective study including a total of 72 consecutive patients

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https://news.medtronic.com/VERITAS-study-shows-Medtronic-fluoroscopic-navigation-platform-offers-a-safer-lung-biopsy-experience-and-the-same-diagnostic-yield-as-CT-guided-biopsy