

# MEDTRONIC REVIEW: CLINICAL PAPER

## **Medtronic provides the following synopsis of the VERITAS Study publication**

<b>TITLE</b>	Navigational Bronchoscopy or Transthoracic Needle Biopsy for Lung Nodules
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<b>JOURNAL</b>	<a href="#"><i>New England Journal of Medicine</i></a>

**INTRODUCTION** Navigational bronchoscopy (NB) has not been compared to computed tomography-guided transthoracic needle biopsy (CT-TTNB) in a randomized controlled trial. CT-TTNB remains the standard of care for tissue diagnosis of indeterminate pulmonary nodules which has been reported to cause pneumothorax in up to 25% of cases. The purpose of this study was to compare the clinical utility of NB to CT-TTNB in a noninferiority randomized controlled study.

**METHODS** Investigator-initiated, multi-center, open-label, randomized parallel-group, non-inferiority trial. Patients with single peripheral lung nodules 10-30 mm with pre-test probability of malignancy  $\geq 10\%$  determined to be technically accessible to both procedures by independent panels of bronchoscopists and interventional radiologists were randomized 1:1 to NB or CT-TTNB, with randomization stratified according to nodule location, pre-test probability of malignancy and trial site. The primary endpoint was diagnostic accuracy through 12 months of follow-up; secondary endpoints included diagnostic yield and procedural complications, procedure duration, procedural and radiologic features associated with yield, need for subsequent nodule biopsy or staging procedure, and radiation exposure.

**RESULTS** A total of 258 patients at seven US sites were randomized and 234 underwent biopsy procedures. Among the 234 patients included in the primary-outcome analysis (5 of whom were lost to follow-up), biopsy resulted in a specific diagnosis that was confirmed to be accurate through month 12 in 94 of 119 patients (79.0%) in the navigational bronchoscopy group and in 81 of 110 patients (73.6%) in the transthoracic needle biopsy group (absolute difference, 5.4 percentage points; 95% confidence interval, -6.5 to 17.2;  $P=0.003$  for noninferiority). Procedure complications occurred in 6 of 121 (5.0%) in the navigational bronchoscopy group and in 33 of 113 patients in the transthoracic needle biopsy group, with pneumothorax as the most common complication. Pneumothorax occurred in 4 of 121 patients (3.3%) in the NB group and in 32 of 113 patients (28.3%) in the CT-TTNB group. Additionally, chest tube placement, hospitalization or both occurring in 1 patient (0.8%) and 13 patients (11.5%) for NB and CT-TTNB respectively.

**CONCLUSION** NB was preferred to CT-TTNB for the diagnosis of lung nodules, with a much better safety profile.

**\*\*THIS CONCLUDES THE CLINICAL SYNOPSIS OF THIS PUBLICATION\*\***

The ILLUMISITE™ Platform is not for use in pediatric patients or those with unstable hemodynamic status. Specific risks include but not limited to: bleeding, pneumothorax, and respiratory failure.

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