

MEDTRONIC REVIEW: CLINICAL PAPER

Medtronic provides the following synopsis of the RELIANT study publication

TITLE Robotic Versus Electromagnetic Navigational Bronchoscopy for Pulmonary Lesion Assessment. Results From the RELIANT Randomized Trial

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INTRODUCTION Bronchoscopy is commonly used for the evaluation of peripheral pulmonary lesions, with advanced navigational systems helping to accurately reach small, difficult-to-access areas. Historically, Electromagnetic Navigational Bronchoscopy (ENB) has been the primary technique used. More recently, Robotic-Assisted Bronchoscopy (RAB) has emerged as an alternative. While both ENB and RAB are routinely employed in clinical settings, there is limited comparative data on their performance.

PURPOSE OF THE STUDY RELIANT was designed to evaluate the diagnostic yield of electromagnetic bronchoscopy and robotic assisted bronchoscopy. Randomized controlled trials are lacking in this area as conventional study designs may be poorly suited to assess new devices in a rapidly developing field.

METHODS The RELIANT trial is an investigator-initiated, unblinded, cluster randomized noninferiority trial conducted at Vanderbilt University Medical Center (VUMC) and embedded within routine clinical care. Each day, one of the two bronchoscopy platforms was randomly assigned to one of two operating rooms, with each OR day representing one cluster. Schedulers, patients and proceduralists were blinded to this allocation until randomization was revealed for each morning of the procedure. The primary outcome was diagnostic yield, defined as the proportion of procedures that resulted in acquisition of lesional tissue. This study followed the strict definition per consensus statement from the American Thoracic Society and the American College of Chest Physicians. The secondary outcome was procedural duration, measured in minutes from the start of airway registration to the removal of the bronchoscope. Safety outcomes assessed procedural complications within 7 days, including: pneumothorax, hemorrhage, respiratory failure and anesthesia complications.

RESULTS 411 total patients were included in the study with 208 randomized to ENB and 203 randomized to RAB. The groups were balanced with regard to patient and lesion characteristics.

- *Diagnostic yield:* ENB was diagnostic in 75.5% (n=157/208) and RAB was diagnostic in 77.8% (n=158/203) with a p-value for non-inferiority = 0.007.
- *Procedural duration:* ENB cases measured 32 minutes and RAB cases measured 37 minutes.
- *Procedural complications:* The most common complication was pneumothorax which was comparable between groups (n=6 for ENB and n=4 for RAB).

CONCLUSION Among patients undergoing bronchoscopy to biopsy a peripheral pulmonary lesion, the diagnostic yield of robotic assisted bronchoscopy was non-inferior to that of electromagnetic navigation bronchoscopy. As the first pragmatic, cluster randomized trial, RELIANT serves as a paradigm for future trials evaluating devices within a rapidly evolving technological landscape.

****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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