NAVIGATING THE LUNG

A QUICK INTRODUCTION TO ELECTROMAGNETIC NAVIGATION BRONCHOSCOPY
Joanne L McKell, MD
Disclosures

- I have no personal financial interests in commercial entities that are relevant to my presentation.

- My knowledge of Electromagnetic Navigational Bronchoscopy (ENB) is derived from the Superdimension System.
Objectives

- Participants will be able to describe the indications for navigational bronchoscopy along with its risks, benefits and limitations.
- The participant will be able generally describe the mechanism and technology used during navigational bronchoscopy.
- The learner will be able to summarize how navigational bronchoscopy differs from other bronchoscopic technologies such as standard video bronchoscopy and endobronchial ultrasound.
- The audience member will be able to identify the specific requirements for navigational bronchoscopy set up, the role of the endoscopy nurse in procedural support, documentation and sample processing.
C diff Barbie
She blinded me with science:
ENB principles.

- Creating a magnetic field around the patient
- A sensor device to detect location within the magnetic field space
- An interface to allow for displaying position within the space and input desired target location(s)
- Data from a CT scan for 3-D reconstruction to overlap the magnetic field
**PROCEDURE**

**Steerable Guide Catheters**
Allow bronchoscopy access via mouth or nose, provide 360° steerability to hard-to-reach lesions and lymph nodes, and lock in place at lesion for the insertion of diagnostic and therapeutic tools.

Are available in a variety of options to best suit the patient and procedure.

**Automatic Registration**
Matches patient's anatomy to virtual roadmap.

**Real-Time Location**
Enables LG tip position to be synchronized in real time.

**Compact, User-Friendly Console**
Moves easily for use in multiple rooms.

**Patient Sensor Triplets (Tracking Sensors)**
Compensate for changes in patient position and orientation during the procedure.

**Location Board**
Creates an electromagnetic field.
Novel bronchoscopic strategies for the diagnosis of peripheral lung lesions: Present techniques and future directions

A: SpinDrive

B: Superdimension
Applications of ENB technology

MINIMALLY INVASIVE, MULTIPLE APPLICATIONS

The superDimension™ system may be used to:

- Navigate to Peripheral Lung Lesions for Biopsy and Sample Tumor Biomarkers to Inform Targeted Therapy
- Stage Lymph Nodes for Diagnosis and Pre-Operative Planning
- Place Radiosurgical Markers for Follow-up Radiation Treatment
- Localize Nodules for More Precise Thoracic Procedures
CT scan 3-D reconstruction is superimposed on the real anatomy of the patient based on the magnetic field and sensor.

Analogy: ENB is like Global Positioning System technology
A generated magnetic field is the satellite system.

The locatable guide is your car.
Indications and Contraindications

Indications for Use
- 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.

Contraindications
- Absolute contraindications include but are not limited to:
  - Absence of consent from the patient or his/her representative unless a medical emergency exists and patient is not competent to give permission
  - Absence of an experienced bronchoscopist to perform or closely and directly supervise the procedure
  - Lack of adequate facilities and personnel to care for such emergencies as cardiopulmonary arrest, pneumothorax, or bleeding
  - Inability to adequately oxygenate the patient during the procedure
  - Pediatric patients
Contraindications

- The same as any fiberoptic bronchoscopy procedure
  - Coagulopathies
  - Severe obstructive airways disease
  - Refractory hypoxemia
  - Unstable hemodynamic status
Relative Contraindications

- Lack of patient cooperation
- Recent myocardial infarction or unstable angina
- Partial tracheal obstruction
- Respiratory failure
- Uremia
- Pulmonary hypertension
- Lung abscess
- Superior vena cava syndrome
- Debility, advanced age and/or malnutrition
- Known or suspected pregnancy
- Disorders requiring laser therapy, multiple transbronchial biopsies or biopsies of lesions obstructing large airways
Increase from 67.17 – 86.9%

**72.47%** N=67
(range 71.4-76.9%)
2 studies 1,2

**71.4%** N=105
(range 67-75.5%)
2 studies 11,12

**82.41%** N=271
(range 74.5-85%)
3 studies 14-16

**67.17%** N=609
(range 57-74%)
Diagnostic yield for lymph nodes: 94-100%
8 studies 3-10

**77%** N=48
1 study 13

**86.9%** N=287
(range 75-94%)
3 studies 17-19

Clinical publication sources on Appendix A
Supporting Literature Trends

- First studies in humans surfaced around 2003
  - Initial diagnostic yield was 69% when patient samples were carefully included
  - Decreased to 59% with more realistic samples around 2007
- Rapid on-site evaluation (ROSE) increased sensitivity to 95% (2007) in peripheral lesions.
  - Sensitivity decreased to 85% and 76.9% in subsequent studies (2009)
- Combination with endobronchial ultrasound (EBUS) increased sensitivity to 93%
  - Without EBUS, yield was only 48%
Procedure performed under general anesthesia in initial studies while later studies used moderate sedation without impacting diagnostic yield.

Lesion size did not impact diagnostic yield.

Pneumothorax rate is consistently low compared to fluoroscopy or blind trans-bronchial biopsies (around 2-5%).

Ahmed et al. published a report demonstrating safety when using ENB in patients with defibrillators or pacemakers (2013).
How ENB measures up

- Traditional transbronchial biopsy (TBNA) yields a diagnosis 36-86% of the time.
- EBUS has diagnostic yields more than 54-92%.
- ENB yields a diagnosis 48-95% of the time.
  - Better in peripheral lesions
  - Better with ROSE

## Table 5. Diagnostic Yields by Size, Location, and Disease Type, and Pneumothorax Rate

<table>
<thead>
<tr>
<th></th>
<th>EBUS, n (%)</th>
<th>ENB, n (%)</th>
<th>EBUS and ENB, n (%)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall diagnostic yield</td>
<td>27/39 (69)</td>
<td>23/39 (59)</td>
<td>35/40 (88)</td>
<td>0.02*</td>
</tr>
<tr>
<td>Yield by lesion size</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 20 mm</td>
<td>7/9 (78)</td>
<td>3/4 (75)</td>
<td>9/10 (90)</td>
<td>0.02*</td>
</tr>
<tr>
<td>20–30 mm</td>
<td>16/23 (70)</td>
<td>11/22 (50)</td>
<td>21/24 (88)</td>
<td>p = 0.99</td>
</tr>
<tr>
<td>&gt; 30 mm</td>
<td>4/7 (57)</td>
<td>9/13 (69)</td>
<td>5/6 (83)</td>
<td></td>
</tr>
<tr>
<td>Yield by lobar location</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bilateral upper lobes</td>
<td>16/27 (59)</td>
<td>17/22 (77)</td>
<td>17/20 (85)</td>
<td>0.01*</td>
</tr>
<tr>
<td>Right middle lobe</td>
<td>3/3 (100)</td>
<td>2/3 (67)</td>
<td>2/2 (100)</td>
<td>p = 0.99</td>
</tr>
<tr>
<td>Bilateral lower lobes</td>
<td>8/9 (89)</td>
<td>4/11 (29)</td>
<td>16/18 (89)</td>
<td></td>
</tr>
<tr>
<td>Yield for malignant disease</td>
<td></td>
<td></td>
<td></td>
<td>0.009*</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>23/32 (72)</td>
<td>16/29 (55)</td>
<td>28/31 (90)</td>
<td></td>
</tr>
<tr>
<td>Specificity</td>
<td>7/7 (100)</td>
<td>10/10 (100)</td>
<td>9/9 (100)</td>
<td>—</td>
</tr>
<tr>
<td>Positive predictive value</td>
<td>23/23 (100)</td>
<td>16/16 (100)</td>
<td>28/28 (100)</td>
<td>—</td>
</tr>
<tr>
<td>Negative predictive value</td>
<td>7/16 (44)</td>
<td>10/23 (44)</td>
<td>9/12 (75)</td>
<td>0.16</td>
</tr>
<tr>
<td>Yield for benign disease</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sensitivity</td>
<td>4/7 (57)</td>
<td>7/10 (70)</td>
<td>7/9 (78)</td>
<td>0.79</td>
</tr>
<tr>
<td>Specificity</td>
<td>32/32 (100)</td>
<td>29/29 (100)</td>
<td>31/31 (100)</td>
<td>—</td>
</tr>
<tr>
<td>Positive predictive value</td>
<td>4/4 (100)</td>
<td>7/7 (100)</td>
<td>7/7 (100)</td>
<td>—</td>
</tr>
<tr>
<td>Negative predictive value</td>
<td>32/35 (91)</td>
<td>29/32 (91)</td>
<td>31/33 (94)</td>
<td>0.90</td>
</tr>
<tr>
<td>Pneumothorax rate</td>
<td>2/39 (5)</td>
<td>2/39 (5)</td>
<td>3/40 (8)</td>
<td>0.99</td>
</tr>
</tbody>
</table>

For definition of abbreviations, see Table 3. 
* p < 0.05.
The Real World

Table 1. Bronchoscopic Procedures Using Electromagnetic Navigational Bronchoscopy

<table>
<thead>
<tr>
<th>Case</th>
<th>Age (year)</th>
<th>Sex</th>
<th>Location</th>
<th>Histology</th>
<th>By ENB</th>
<th>By Confirmatory Procedure</th>
<th>ENB Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>61</td>
<td>M</td>
<td>Subcarinal lymph node</td>
<td>Benign lymphoid tissue</td>
<td>Benign lymphoid tissue</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>2</td>
<td>67</td>
<td>M</td>
<td>4R and subcarinal lymph node</td>
<td>Metastatic adenocarcinoma</td>
<td>Not necessary</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>3</td>
<td>53</td>
<td>F</td>
<td>Subcarinal lymph node</td>
<td>Nondiagnostic</td>
<td>Epithelial granuloma (sarcoid)</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>4</td>
<td>61</td>
<td>M</td>
<td>Left hilar lymph node</td>
<td>Metastatic carcinoma</td>
<td>Not necessary</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>5</td>
<td>85</td>
<td>F</td>
<td>Right hilar lymph node</td>
<td>Metastatic carcinoma (fiducial placed)</td>
<td>Not necessary</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>6</td>
<td>66</td>
<td>F</td>
<td>Right upper lobe</td>
<td>Reactive bronchial cells</td>
<td>Bronchogenic adenocarcinoma</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>7</td>
<td>69</td>
<td>F</td>
<td>Right upper lobe</td>
<td>Reactive bronchial cells</td>
<td>Bronchogenic adenocarcinoma</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>8</td>
<td>56</td>
<td>F</td>
<td>Left lower lobe</td>
<td>Inflammatory infiltrate</td>
<td>Inflammatory reaction around synthetic material</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>9</td>
<td>48</td>
<td>F</td>
<td>Right lower lobe</td>
<td>Metastatic carcinoma (fiducial placed)</td>
<td>Not necessary</td>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>

ENB = electromagnetic navigational bronchoscopy.
NEW YORK – Citing slow load times, confusing menu structure, and overall frustration with the user interface, St. Barnaby’s Hospital has announced that the old electronic health record (EHR) will be replaced with a new state of the art binder-based system, in which a so-called “paper chart” is kept for each patient.

The new system, brainchild of prominent New York internist Dr. Brent Shelby, was developed to improve efficiency of workflow on the wards and to cut down on the burden of useless autopopulated information that currently makes up approximately 95% of every clinical note in the EHR.
ENB

- A generated magnetic field is the satellite system
- The locatable guide is your car.
Location Board and Sensing Volume

- Location board creates a low frequency magnetic field above and below the patient called the sensing volume

- Locatable guide position in the sensing volume is determined by measuring low level magnetic fields generated by the location board
Navigation Catheter

• Locatable guide sensors transmit location from 6 degrees of freedom: X, Y, Z, Roll, Pitch and Yaw

• Continuous data acquisition
Edge™ Navigation Catheter Components

<table>
<thead>
<tr>
<th>Edge™ extended working channel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edge™ locatable guide</td>
</tr>
<tr>
<td>Edge™ bronchoscope adapter</td>
</tr>
</tbody>
</table>

Edge™ Navigation Catheter
Procedure Workflow

1. Setup
2. Registration
3. Navigation
4. Insert Endoscopic Tools
Chest, Lung or Pulmonary Embolism Protocol CT scan
Virtual bronchoscopy

(A) Left mainstem bronchus, (B) carina, (C) bronchus intermedius and segmental orifices, and (D) right upper lobe bronchus. An external shaded surface display (CT bronchography) and a sagittal multiplanar reconstruction are provided to the right of the virtual bronchoscopy image.
Planning
Setting up for ENB

A. System Preparation
1. Power system
2. Enter password
3. Select procedure from main screen
4. Verify room configuration
5. Position location board on bed
6. Attach cables to system (location board, video input, PST, LG and foot switch)

B. Bronchoscope & Tool Preparation
1. Confirm therapeutic bronchoscope
2. Attach bronchoscope adapter and clip
3. Mark endoscopic tool length

C. Procedure start
1. Select source and load appropriate patient
2. Enter patient data & procedure details

D. Patient Preparation
1. Position patient’s chest in sensing volume using reference arrows
2. Attach patient sensor triplets with sensor patches in proper location utilizing sensing volume display
Navigation System Setup

- Software guides user through setup
- Procedure must be performed on a qualified bed and in a qualified room
- Verify there is no metal within 2 feet of the bed
Navigation Technology

Location Board

Patient Sensors

Navigation Catheter

Localization
Generated Magnetic Field
Patient Sensors

- Account for nominal patient movement
Patient Preparation

- Patient should be centered and aligned on the location board so that the patient's shoulder is aligned with the arrow nearest the head of the bed
1. Prepare
2. Position
3. Survey
4. Verify
CT scan 3-D reconstruction is superimposed on the real anatomy of the patient based on the magnetic field and sensor.

- The main carina and four other landmarks are identified in the software.
- Subsequently they are identified in the lung by the locatable guide (LG).

- The virtual reconstruction of the Lungs and the LG's location in the actual lungs are now aligned.
- GPS analogy: the satellite system now knows where the car is in the terrain.
Registration

Identifying the Main Carina
Registration

Identifying the Main Carina
Registration

Place the tip of the Locatable Guide at the actual body location of the selected Registration Point, as marked in the Virtual Bronchoscopy image and press the "Acquire" button.

Eberhardt, R et al. AJRCCM. 2007;176(1):36-41
Hospital Administrators Rename RNs to “Refreshments and Narcotics”

11.3k
SHARES

TAMPA, FL – In order to comply with new government healthcare regulations involving patient satisfaction, hospital administrators at Tampa Memorial Cross Hospital have decided to rename registered nurses (RNs) to a more appropriate title, “Refreshments and Narcotics”.

“Change had to occur,” said Hospital CEO Karen Wildrens. “Government mandated health care changes have forced us to adopt new hospital practices. We need to update our current workers and recruit for what we actually need at the hospital.”

In order to allow nurses to still hold and maintain a title of RN, a simple replacement of the words starting with the same letters easily allowed the hospital to maintain the abbreviation.

Wildrens continued: “I think our nurses will appreciate a more accurate job title. Who wants to be called one...”
Navigation: the long and winding road
Navigation
Navigation
Video
Fluoroscopic Confirmation

- Extended working channel displacement
- Proper operation of endoscopic tools
Procedures

- Confirm location.
- Remove the locatable guide.
- Slide in the brush, forceps, needle, needle-brush as indicated.
- The bronchoalveolar lavage is last.
Complete Procedure

Acquire Tissue

Place Fiducial Markers

Navigate

Stage

Dye Localization
Other considerations

- Sample preparation is the same as with traditional bronchoscopy.
- Be aware, that your bronchoscopist may want ROSE:
  - Make room for the cytotechnologist.
- If there are technical problems during navigation, the procedure can go long.
- Anesthesia is often involved in these procedures which can add complexity to your work environment.
CPT codes were approved in 2010.
Your coders/IT folks may not be familiar with this code.
In addition to the codes for regular bronchoscopy, transbronchial biopsy, needle aspiration, etc, include

Bronchoscopy, including fluoroscopy, with computer-assisted, image-guided navigation +31627
Navigational bronchoscopy is useful but it’s only one type of technology
  - Should be used in tandem with other sampling techniques, particularly EBUS

The learning curve is painful for hospitals and staff

Communication with pathology, respiratory techs and your bronchoscopist is key.

In skilled hands, it lives up to the hype.
Thank You

- Questions? Concerns?
- Contact me at jmckell@uic.edu
- Or ask Debbie.*

* I call her “D.”
Appendix A: Clinical publication sources for Diagnostic Yield by Year


Problem: Patients aren’t identical

- GPS functions with the same satellite system and the relatively stable earth geography.
  - Hills, roads and built structures don’t change
- We switch out patients all the time
- How do we get our system to relearn the “geography” with each new patient?