



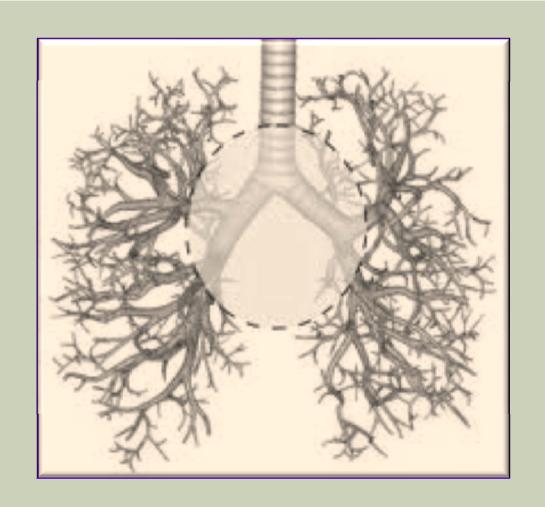
NAVIGATION ÉLECTROMAGNÉTIQUE: POSSIBILITÉS ET LIMITES

CC, DR. PAOLA GASCHE»





LUNG TERRITORY REACHABLE BY CONVENTIONAL BRONCHOSCOPY





THE PROBLEM OF THE PERIPHERAL NODULE

Peripheral nodule less than 2cm of diameter can be reached by conventional bronchoscopy only in **30%** of cases (14% if in the outer ½ portion of lung parenchyma) Chest 2003;123:115S-128S.







CONVENTIONAL APPROACH

Ultra thin bronchoscope (2mm) and fluoroscopic guidance; 64.7% of sensitivity (Rooney CP, Respiration 2002;69:63-68)





BIOPSY & RADIOLOGICAL GUIDANCE

Guidance & fluoroscopy (*Chest 2006;129:147-150*)

- Irradiation
- Visibility ? 40% (54/138) of < 2.2cm lesions are **not** visible

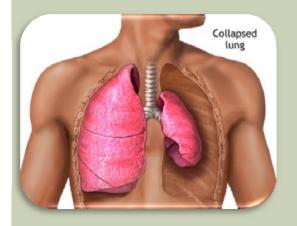
CT-scan trans-thoracic bx

- From 65 to 90% of sensitivity depending on the type of lesion
- Requires immobility of the patient during procedure
- Risk of hemorrhage (10-20%)
- Risk of pneumothorax(>30%)



PNEUMOTHORAX RISK OF TTNA

- **↑** with number of passes 37% one pass; 57% five passes
- ↑with distance from pleura 15% 0 cm (pleura based); 50% 0-5 cm
- with lesion size 0-2 cm = 50%; 2-4 cm = 35%; >4 cm = 15%
- ↑with presence of emphysema
 With emphysema = 50% (chest tube 27%)
 Without emphysema = 35% (chest tube 9%)



Sources: Cox et al. Radiology July 1999;212:165-168

NODULE = REAL PROBLEM?

Procedure	Approx. #/year	Hospital Days	Reimburse- ment	Performed by
Diagnostic Bronchoscopy	3,500,000	1	\$1,700	Interventional Pulmonologist
Therapeutic Bronchoscopy	200,000	1-4	Up to \$5,000	Interventional Pulmonologist
CT-Guided Needle Biopsy	700,000	1	Up to \$4,500	Interventional Radiologist
Open Surgery	1,000,000	6	Up to \$70,000	Surgeon

Interventional Pulmonary procedures (Europe / N. America / Asia ~30% each)

ELECTROMAGNETIC NAVIGATION SYSTEM

Based on regular GPS system







1. Magnetic field; the board



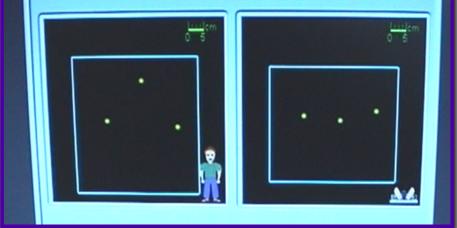






2. Magnetic field: electrodes







3. Sensor





- Receptor of EM wave
- Position detected in 3 axes by software (X, Y, Z-axes, roll, pitch & yaw)
- Position shown on a monitor at a rate of 161 images/sec.



3. The guide



- 4 wires
- Rotating handle
- •8 positions



Pre-specified thoracic Ct-scan data ($Dicom\ CD$) \Rightarrow Upload of the images in the navigation system



⇒ Route planning

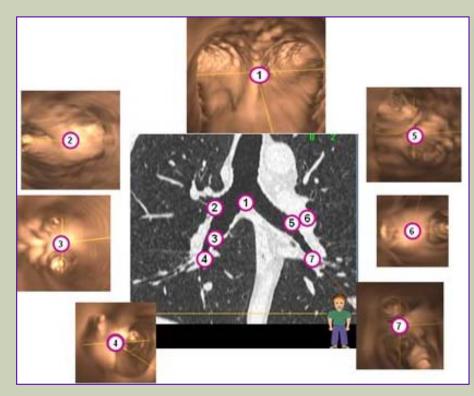
3-D reconstruction & virtual bronchoscopy

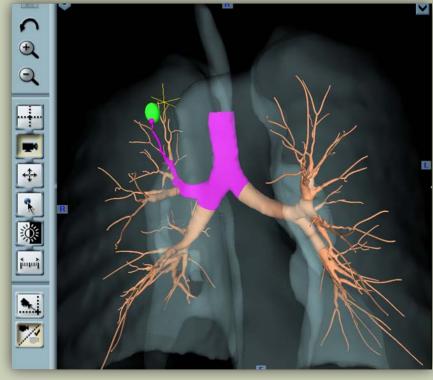


Choice of the target (1 or more)



Choice of the pathway to the target

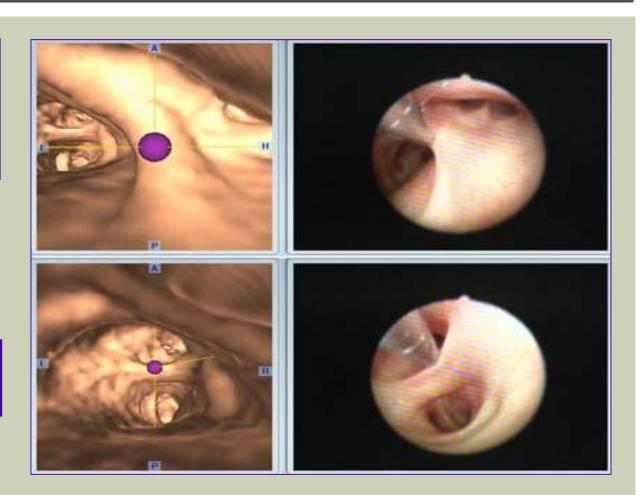




Synchronisation of the virtual with the real bronchoscopy Images (FB 2.8mmm)

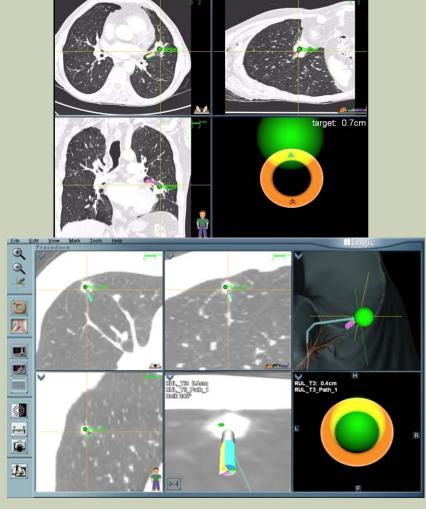


Navigation toward target



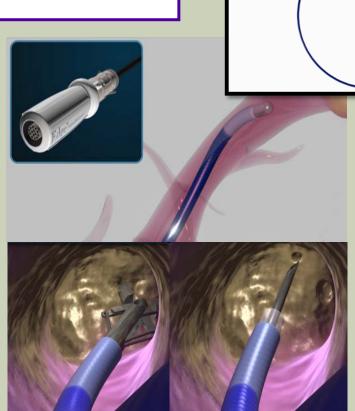
Navigation toward target(s) with steerable catheter inserted in a working channel

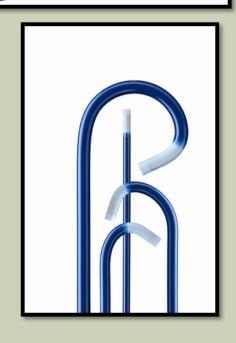




Navigation toward target(s) with steerable catheter inserted in a working channel



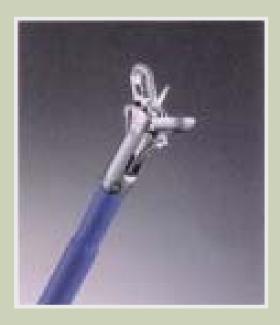




PROCEDURE: TISSUE SAMPLING

Once the target is reached:

- Lock working channel
- Remove steerable navigation catheter
- Use instruments to remove tissue samples











ENB (ELECTROMAGNETIC NAVIGATION BRONCHOSCOPY)

ROSE: Rapid On Site Evaluation



MODIFICATION OF ENB PERFORMANCE

Table 5. Study-level characteristics associated with significant modification of ENB's performance.

		Nb of studies	Pooled outcome [95% CI]	p-values
			Diagnostic yield	
General anesthesia	Yes	9	69.2% [60.6 – 76.7]	0.02
	No	7	57.5% [53.2 – 61.8]	
			Sensitivity for malignancy	
ROSE	Yes	4	80.2% [72.1 – 86.4]	0.006
	No	10	66.3% [60.3 – 71.8]	
			Diagnostic yield	
Fluoroscopy	Yes	6	56.3% [51.5 – 60.9]	0.006
	No	10	68.8% [61.3 – 75.4]	-

ENB(inReachTM): RESULTS

Electromagnetic Navigation Bronchoscopy Performed by Thoracic Surgeons: One Center's Early Success

Daryl Phillip Pearlstein, MD, Curtis C. Quinn, MD, Charles C. Burtis, BS, Kwang Woo Ahn, PhD, and Aaron J. Katch, MS

Divisions of Cardiothoracic Surgery, and Biostatistics, Medical College of Wisconsin, Milwaukee; Division of Cardiothoracic Surgery, Waukesha Memorial Hospital, Waukesha; and Aurora Advanced Healthcare, Milwaukee, Wisconsin

Table 1. Negative Predictive Value and Sensitivity Based on Lesion Size N=104

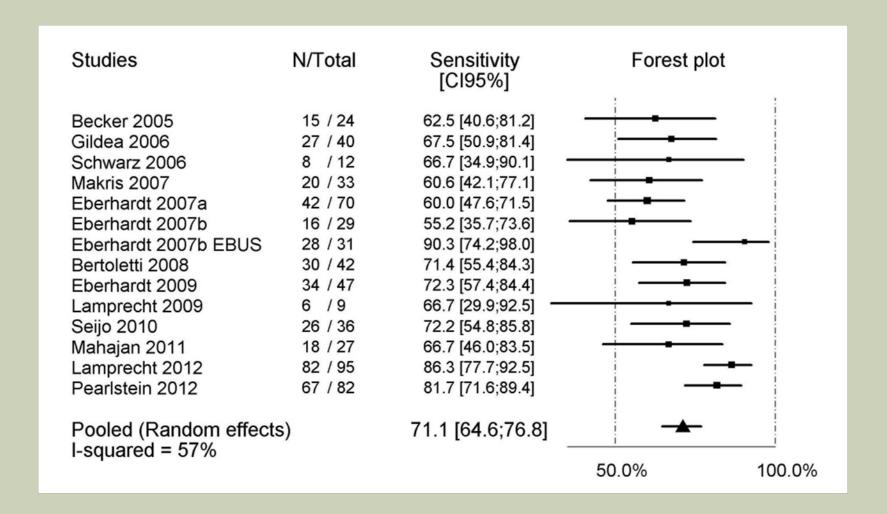
Lesion Size (cm)	<1.5	1.5-2	>2	Overall
Negative predictive	78%	20%	55%	56%
value Sensitivity	78%	69%	85%	82%

Fisher exact test p value for negative predictive value: 0.141; Fisher exact test p value for sensitivity: 0.333.

(Ann Thorac Surg 2012;93:944-50) © 2012 by The Society of Thoracic Surgeons

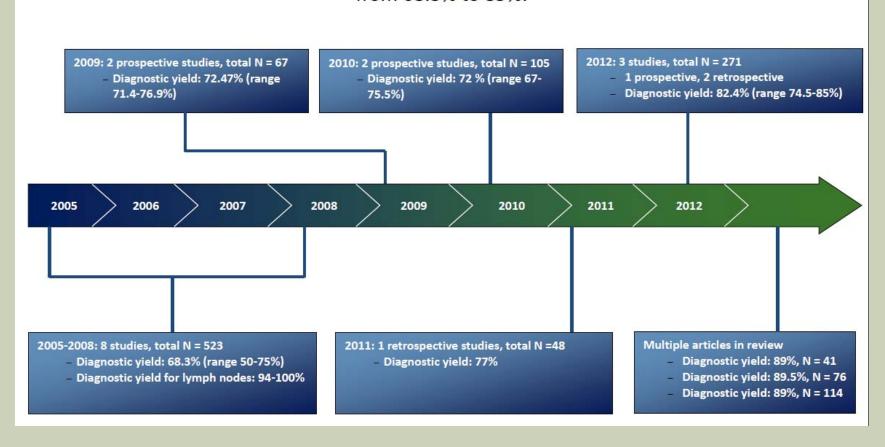


SENSITIVITY FOR MALIGNANCY

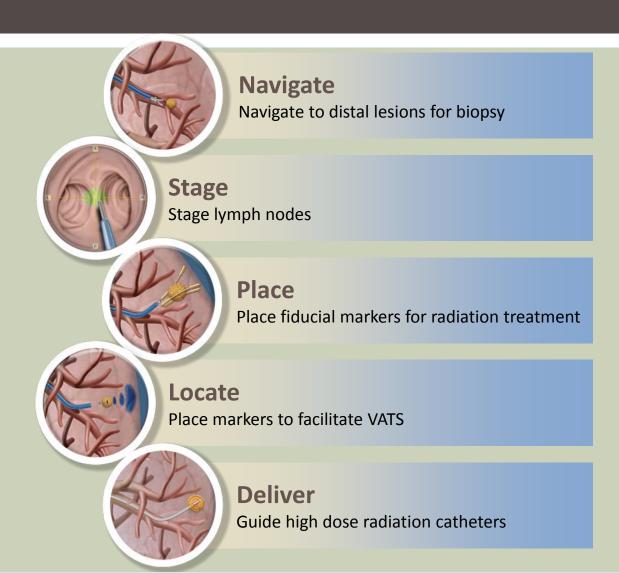


Electromagnetic Navigation Bronchoscopy: Diagnostic Yield by Year

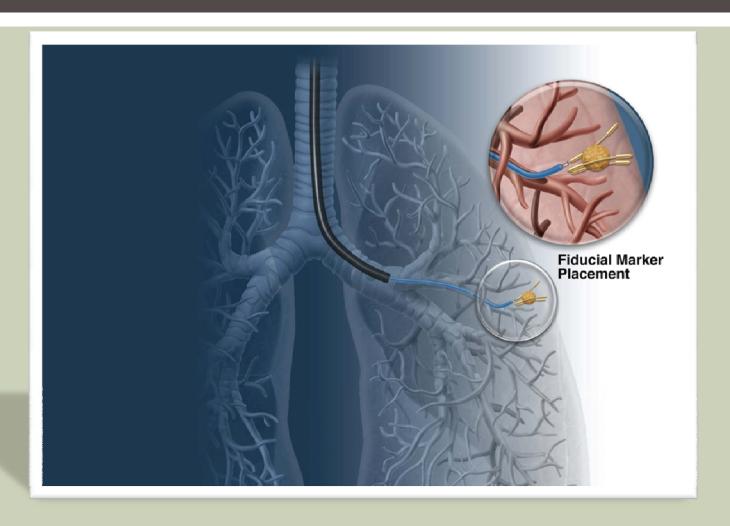
ENB diagnostic yield has increased significantly from 68.3% to 85%.



ELECTROMAGNETIC NAVIGATION BRONCHOSCOPY (ENB) ALLOWS YOU TO:



TRANSBRONCHIAL PLACEMENT OF FIDUCIAL MARKERS USING ENB



TRANSBRONCHIAL PLACEMENT OF FIDUCIAL MARKERS USING ENB

superDimension® superLock® Bands

(13-23mm: 3mm gold)







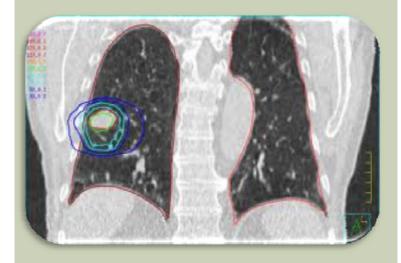
superDimension® **superLock® Coils** (5-10-20mm, 0.9, gold)

superDimension® superLock Cobra® Fiducial Marker

(7mm : Nitinol & gold seed 3.5x0.8)

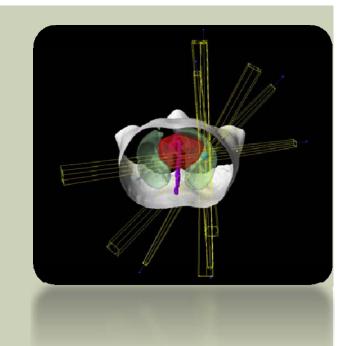
Stereotactic Body Radiotherapy (SBRT/SRT)

- Uses a combination of precise patient positioning/immobilization to administer radiation with extreme accuracy
- Increasingly being used to treat patients
 with early-stage NSCLC who are not
 candidates for surgical resection or refuse
 surgery



SBRT IN EARLY STAGE LUNG CANCER

- Studies show a 5-year survival rate of 50% for early stage lung cancer patients that are inoperable or refuse surgery ¹⁻⁴
- Early data shows comparable results to surgery with acceptable toxicity and comparable local control and survival rates
 5-8



SOURCES:

- 1) Sibley GS. (1998) Radiotherapy for patients with medically inoperable Stage I non-small cell lung carcinoma. Smaller volumes and higher doses: a review. Cancer 82:433, Åì 438.
- 2) Armstrong IG, et al. (1989) Radiation therapy for medically inoperable stage I and II non-small cell lung cancer. Cancer Treat Rev. 16(4):247-255.
- 3) Dosoretz DE, et al. (1996) Medically inoperable lung carcinoma: the role of radiation therapy. Semin Radiat Oncol. 6(2):98-104.
- 4) Kaskowitz L, et al. (1993) Radiation therapy alone for stage I nonsmall cell lung cancer. Int J Radiat Oncol Biol Phys. 27(3):517-523.
- 5) Timmerman R; et al. (2010) Stereotactic Body Radiation Therapy for Inoperable Early Stage Lung Cancer JAMA 303(11):1070-1076.
- 6) Nagata Y, et al. (2005) Clinical outcomes of a phase I/II study of 48 Gy of stereotactic body radiotherapy in 4 fractions for primary lung cancer using a stereotactic body frame. Int J Radiat Oncol Biol Phys. 63(5):1427-1431.
- 7) Timmerman R, et al. (2006) Excessive toxicity when treating central tumors in a phase II study of stereotactic body radiation therapy for medically inoperable early-stage lung cancer. J Clin Oncol. 24(30):4833-4839.
- 8) Lagerwaard Fl,et al. (2008) Outcomes of risk-adapted fractionated stereotactic radiotherapy for stage I non-small-cell lung cancer. Int J Radiat Oncol Biol Phys. 70(3): 685-692.

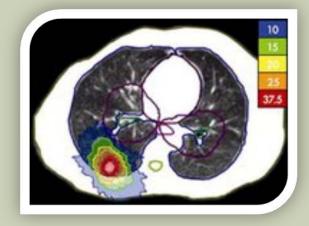
COMMON SBRT/SRT SYSTEMS

- Novalis Tx®
- TomoTherapy HiArt®
- Varian Trilogy[®]
- Varian TrueBeam®
- Elekta Synergy[®]
- Elekta Axesse®
- Siemens Primatom®
- Accuray CyberKnife[®]



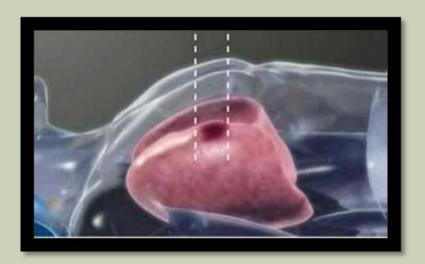
SBRT/SRT USES

- Primary Treatment Modality Curative
 - Inoperable patients (COPD, ILD)
 - Patients who refuse surgery
- (Neo) Adjuvant Treatment
 - Pre-operative treatment for subsequent surgical curative intent (Stage IIIA disease)
- Palliative Treatment



Motion Management is Critical to SBRT

- Lung targets are dynamic
- Failure to manage motion may result in inaccurate dose delivery
- Preserves normal lung tissue



Problems of Respiratory Motion

- Causes artifact during imaging acquisitions
- Target shape and volume uncertainty due to CT artifact
- Dose uncertainty if motion is not accounted for

Motion varies markedly between patients, indicating that an individual approach to respiratory management is required in SBRT



RESPIRATORY GATING

Defined as a specific window in the breathing cycle, much like a baseball strike zone, when it is optimal to turn on the radiation beam. Ideally, this "strike zone" is a period of time in the breathing cycle when the tumor moves the least.



RESPIRATORY TRACKING

Defined as delivering tightly contoured beams that move precisely with tumor motion throughout the respiratory cycle.



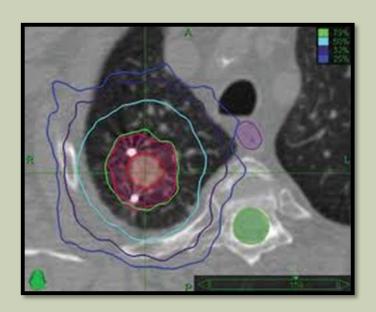
ABDOMINAL COMPRESSION

Defined as using a compression board to help minimize tumor motion during breathing cycles.



FIDUCIAL MARKERS FOR LUNG SBRT/SRT

Localization with fiducial markers directly into and/or around a lung tumor is considered an accurate way to aid respiratory motion management when delivering SBRT/SRT.



IMPORTANCE OF FIDUCIAL MARKERS FOR AIDING MOTION MANAGEMENT

- Allows synchronization of patient's anatomy from imaging to radiation delivery, accounting for respiratory motion
- Allows smaller/conformal radiation fields; less radiation to adjacent critical structures, higher doses to primary tumors and potentially better control
- Internal fiducial markers are a better surrogate of tumor motion compared to an external marker

FIDUCIAL PLACEMENT USING ENB

Planning Phase

Target selected with planning software

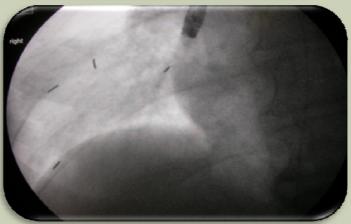
Navigation

Using navigation catheter under electromagnetic guidance

Marker Placement - Several Methods

Stereotactic Radiotherapy Procedure Proceeds





THE ENB SOLUTION - CLINICAL DATA

Six (6) articles published on transbronchial placement of fiducial markers using ENB ¹⁻⁶

- Fiducial markers successfully placed in over 80 patients
- 2-5 markers placed per tumor
- Lesion size varied from 0.8 cm to 6.5 cm in diameter
- Minimal migration and pneumothoracies reported

SOURCES:

- 1) Harley, D, et al. Fiducial Marker Placement Using Endobronchial Ultrasound and Navigational Bronchoscopy for Stereotactic Radiosurgery: An Alternative Strategy. Ann Thorac Surg 2010; 89:368-374.
- 2) Schroeder, C, et al. Coil Spring Fiducial Markers Placed Safely Using Navigation Bronchoscopy in Inoperable Patients Allows Accurate Delivery of CyberKnife Stereotactic Radiosurgery J Thorac Cardiovasc Surg; 140:1137-1142.
- 3) Andrade, R. Seminars in Thoracic and Cardiovascular Surgery 2010; Vol 22, No 3.
- 4) Anatham, D, et al. Electromagnetic Navigation Bronchoscopy Guided Fiducial Placement for Robotic Stereotactic Radiosurgery of Lung Tumors A Feasibility Study. Chest 2007; 132:930-935.
- 5) McGuire, F, et al. Radiotherapy Monitoring Device Implantation into Peripheral Lung Cancers: A Therapeutic Utility of Electromagnetic Navigational Bronchoscopy. Jrl of Bronch 2007; 14(3): 173-176.
- 6) Kupelian, P, et al. Implantation and Stability of Metallic Fiducials within Pulmonary Lesions. J Radiation Oncology Biol Phys 2007; 69(3): 777-785.

CONCLUSIONS

1. Effective diagnostic technique

- Successful diagnosis of peripheral lesions in 69-82% of cases
- No association with size of nodule
- Probable even higher success rates for lymph nodes

2. Safe diagnostic technique

- Pneumothorax rate of 0-2.3%
- No need for irradiation
- Short learning curve

3. New option for SBRT/SBT





