

2019 Annual Congress of Taiwan Society of Pulmonary and Critical Care Medicine  
And Taiwan Society of Thoracic Surgeons, Taiwan Society for Respiratory Therapy,  
Taiwan Society of Sleep Medicine Joint Conference

# Endobronchial Localization of Small Lung Nodules : MacKay Memorial Hospital Epx

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MacKay Memorial Hospital, Taiwan



# The NEW ENGLAND JOURNAL of MEDICINE

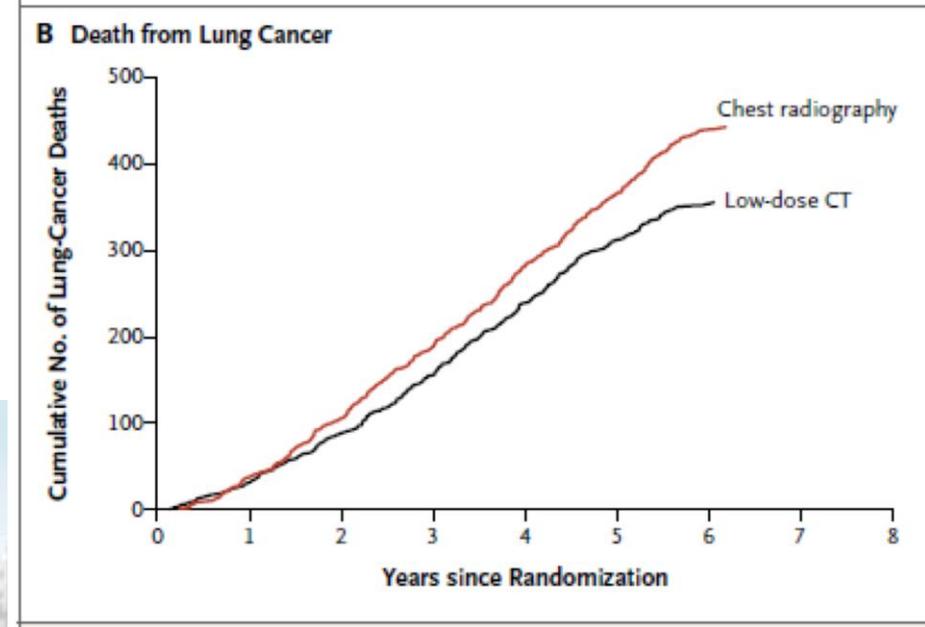
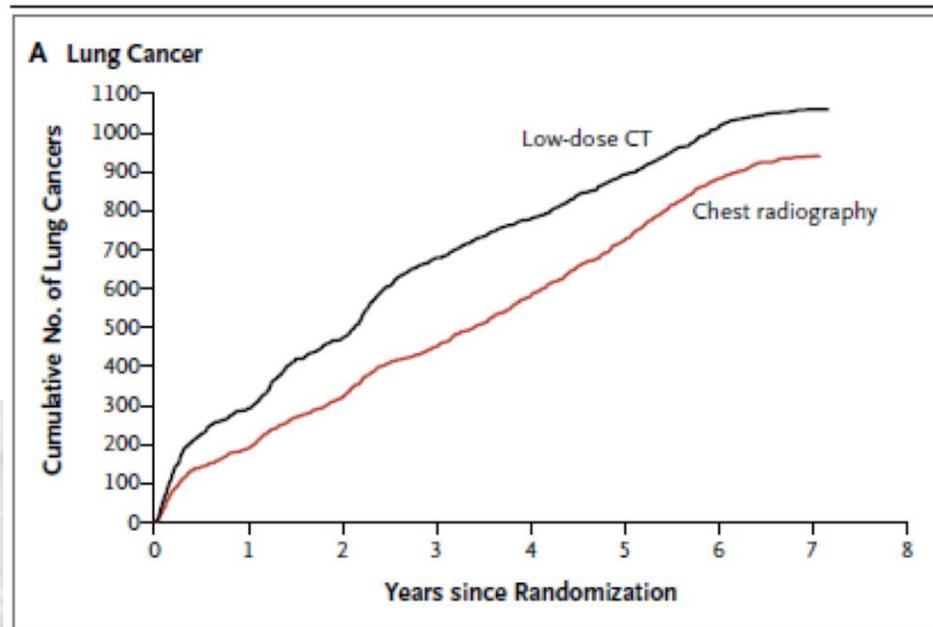
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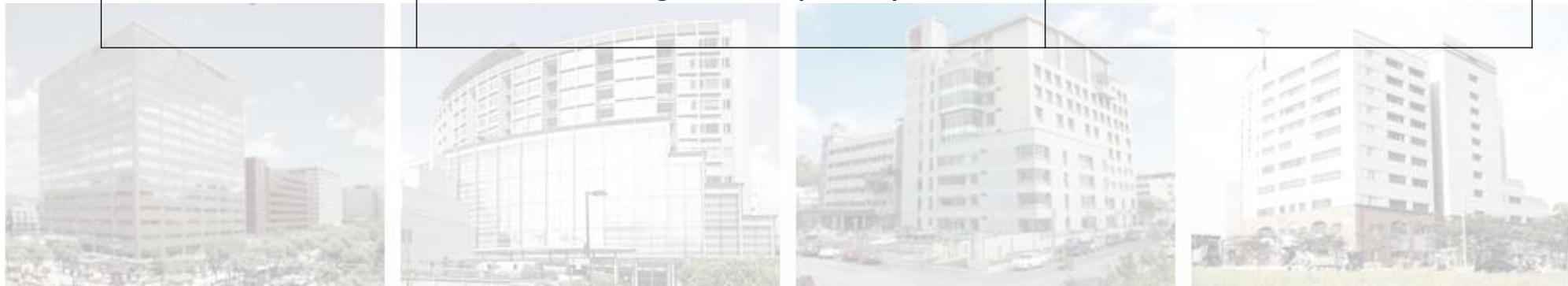
## Reduced Lung-Cancer Mortality with Low-Dose Computed

The National Lung Screening Trial Research Team\*

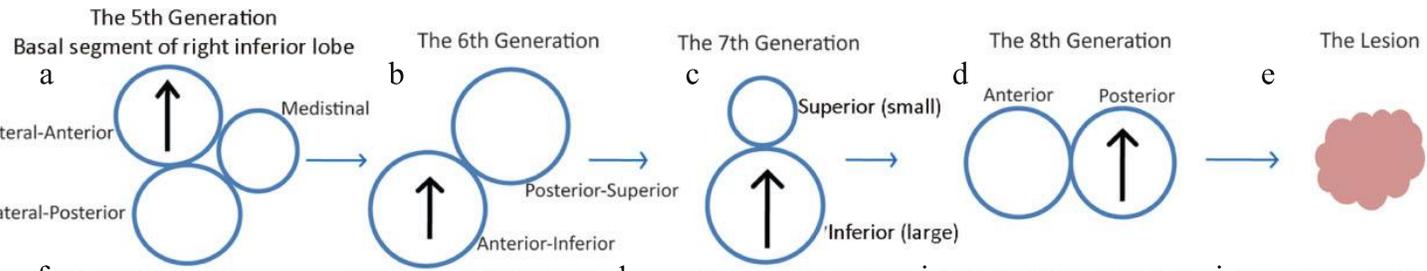


# Current Management of Small Lung Tumor

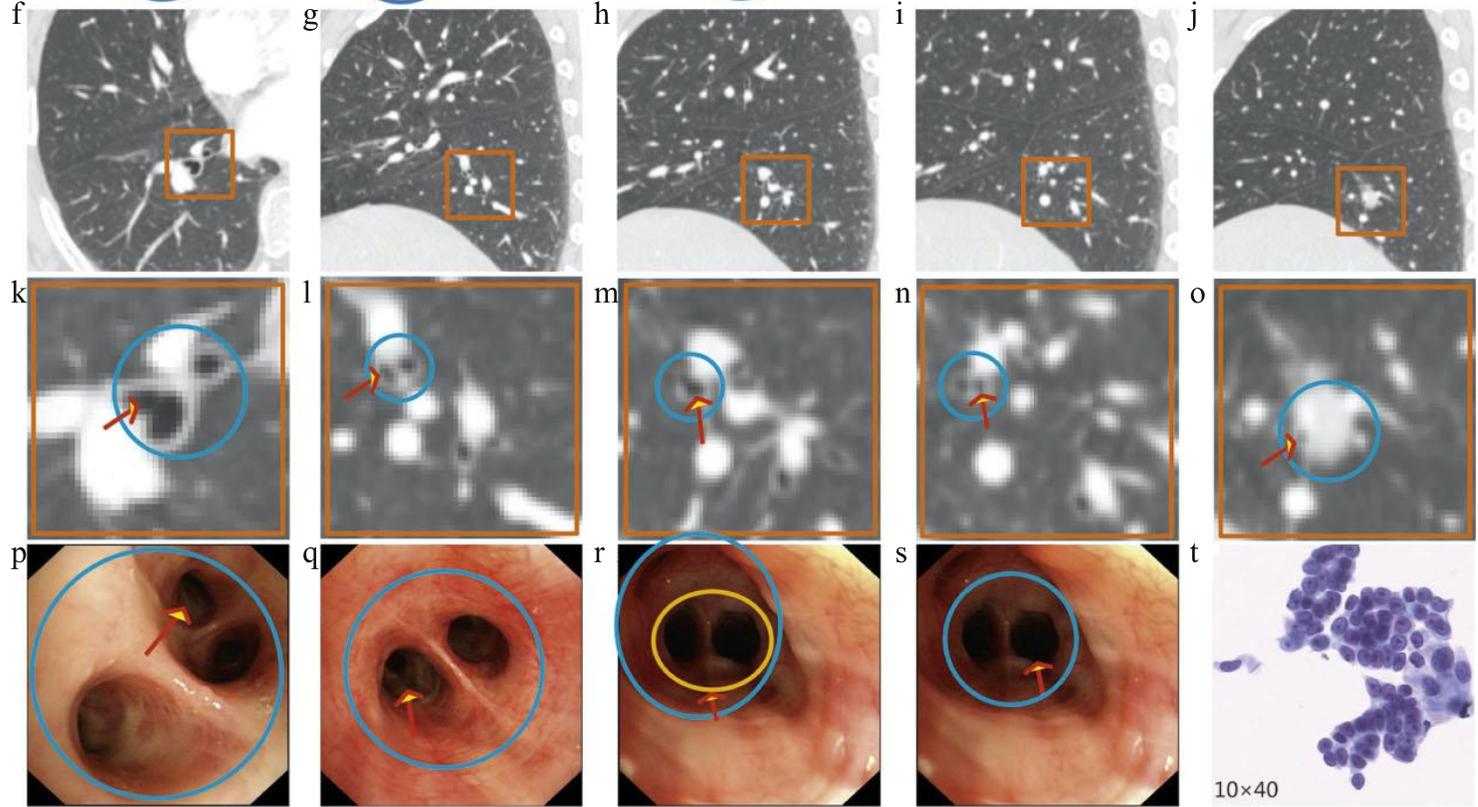
Image Oriented	Navigation Tool	Treatment
CT	Electromagnetic Navigational Bronchoscope (ENB)	Drugs SBRT Surgery
	Virtual Bronsoscopic Navigation (VBN)	



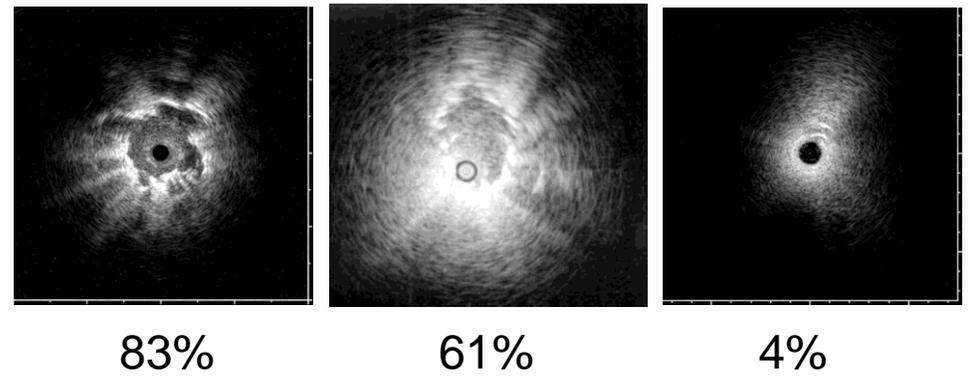
# Manual Mapping Method



**Factors Related to Diagnostic Yield of Transbronchial Biopsy Using Endobronchial Ultrasonography With a Guide Sheath in Small Peripheral Pulmonary Lesions\***



Diagnosis Yield



*Chest.* 2007 Aug;132(2):603-8

*Thorac Cancer.* 2016 Jan;7(1):72-9.

# Virtual bronchoscopic navigation combined with endobronchial ultrasound to diagnose small peripheral pulmonary lesions: a randomised trial

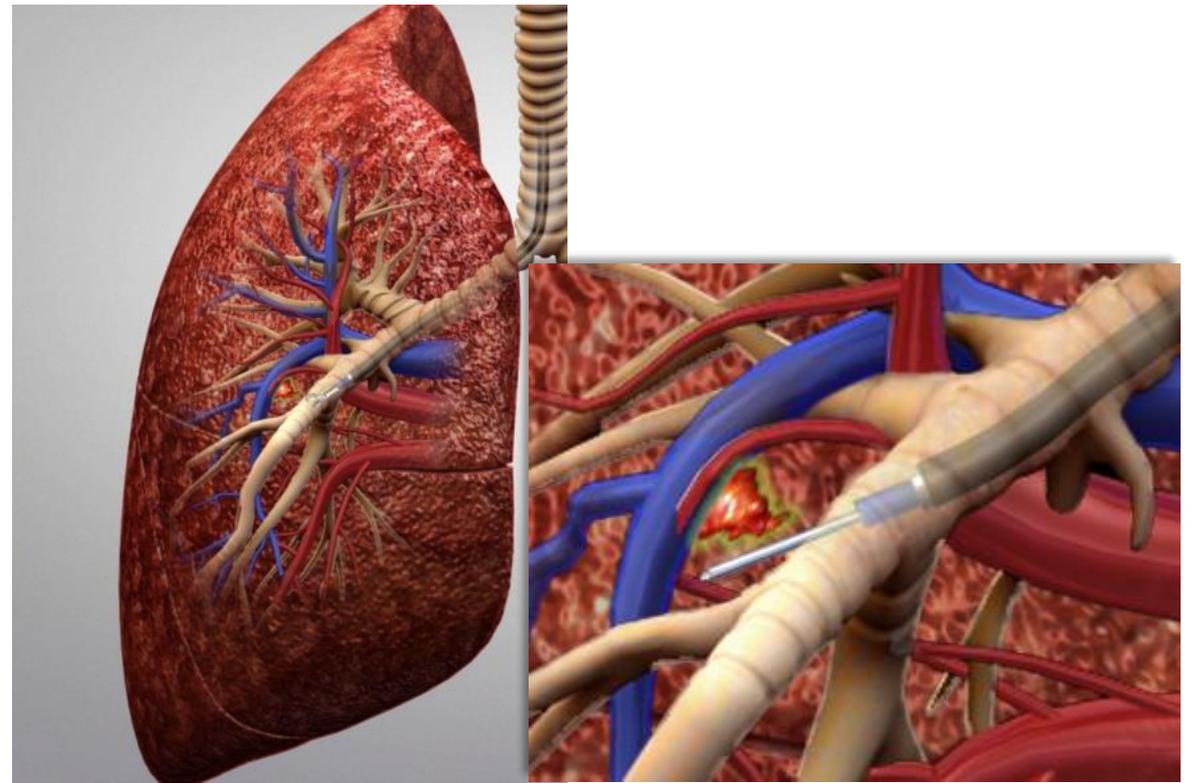
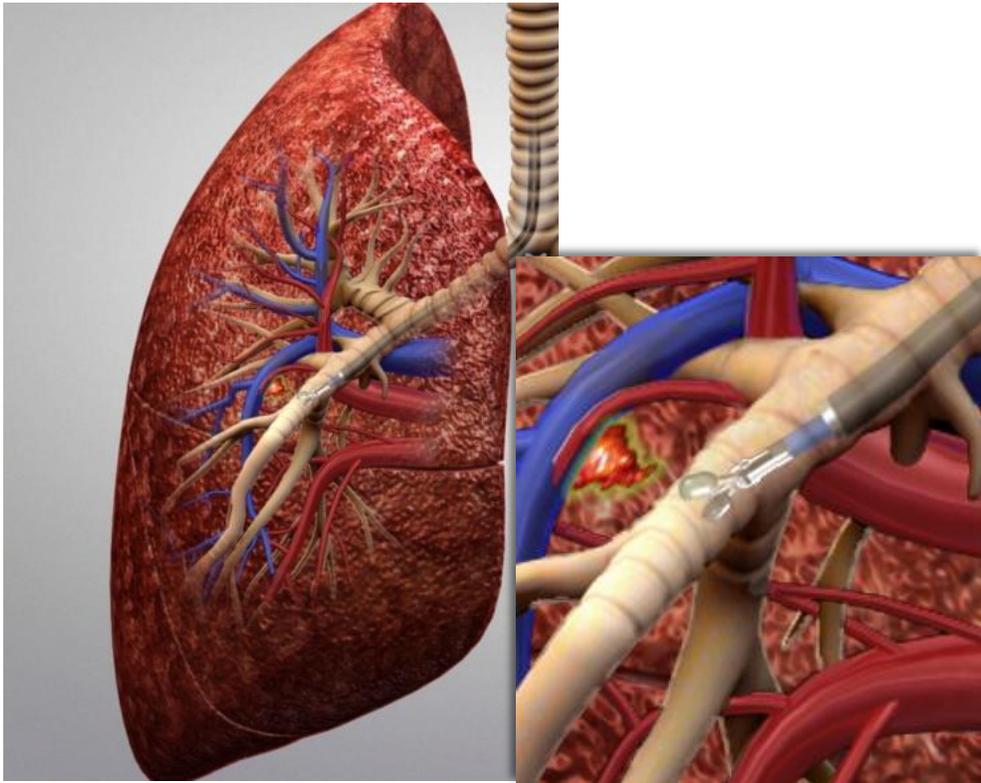
## Multimodality Bronchoscopic Diagnosis of Peripheral Lung Lesions

A Randomized Controlled Trial

	Bronchoscopic diagnosis		p Value
	VBNA	NVBNA	
Full intent-to-treat	82/102 (80.4)	65/97 (67.0)	0.032
Per-protocol	80/99 (80.8)	64/95 (67.4)	0.032
Data are shown as numbers of lesions/total lesions (%). NVBNA, non-virtual bronchoscopic navigation-assisted; VBNA, virtual bronchoscopic navigation-assisted.			
	VBNA	NVBNA	p Value
Endoscopically inserted bronchial generation (n, median) (range)	4 (2–8)	4 (2–7)	<0.001
EBUS-visualised peripheral lesion, n (%)	92 (92.9)	77 (81.1)	0.014
Sampling by biopsy, (n, median) (range)	5 (0–12)	4 (0–12)	0.113
Sampling by brushing/washing (n, median) (range)	3 (0–6)	3 (0–5)	0.42
Duration			
Total examination (min, median) (range)	24.0 (8.7–47.0)	26.2 (11.6–58.6)	0.016
Initial sampling (min, median) (range)	8.1 (2.8–39.2)	9.8 (2.3–42.3)	0.045
x-ray fluoroscopy exposure (min, median) (range)	9.7 (1.5–22.7)	11.0 (1.3–31.0)	0.058

	EBUS, n (%)		ENB, n (%)
Overall diagnostic yield	27/39 (69)		23/39 (59)
Yield by lesion size			
≤ 20 mm	7/9 (78)	p = 0.80	3/4 (75)
20–30 mm	16/23 (70)		11/22 (50)
> 30 mm	4/7 (57)		9/13 (69)
Yield by lobar location			
Bilateral upper lobes	16/27 (59)	p = 0.18	17/22 (77)
Right middle lobe	3/3 (100)		2/3 (67)
Bilateral lower lobes	8/9 (89)		4/11 (29)
Yield for malignant disease			
Sensitivity	23/32 (72)		16/29 (55)
Specificity	7/7 (100)		10/10 (100)
Positive predictive value	23/23 (100)		16/16 (100)
Negative predictive value	7/16 (44)		10/23 (44)
Yield for benign disease			
Sensitivity	4/7 (57)		7/10 (70)
Specificity	32/32 (100)		29/29 (100)
Positive predictive value	4/4 (100)		7/7 (100)
Negative predictive value	32/35 (91)		29/32 (91)
Pneumothorax rate	2/39 (5)		2/39 (5)

# Current Limitations of Bronchoscopic Navigation

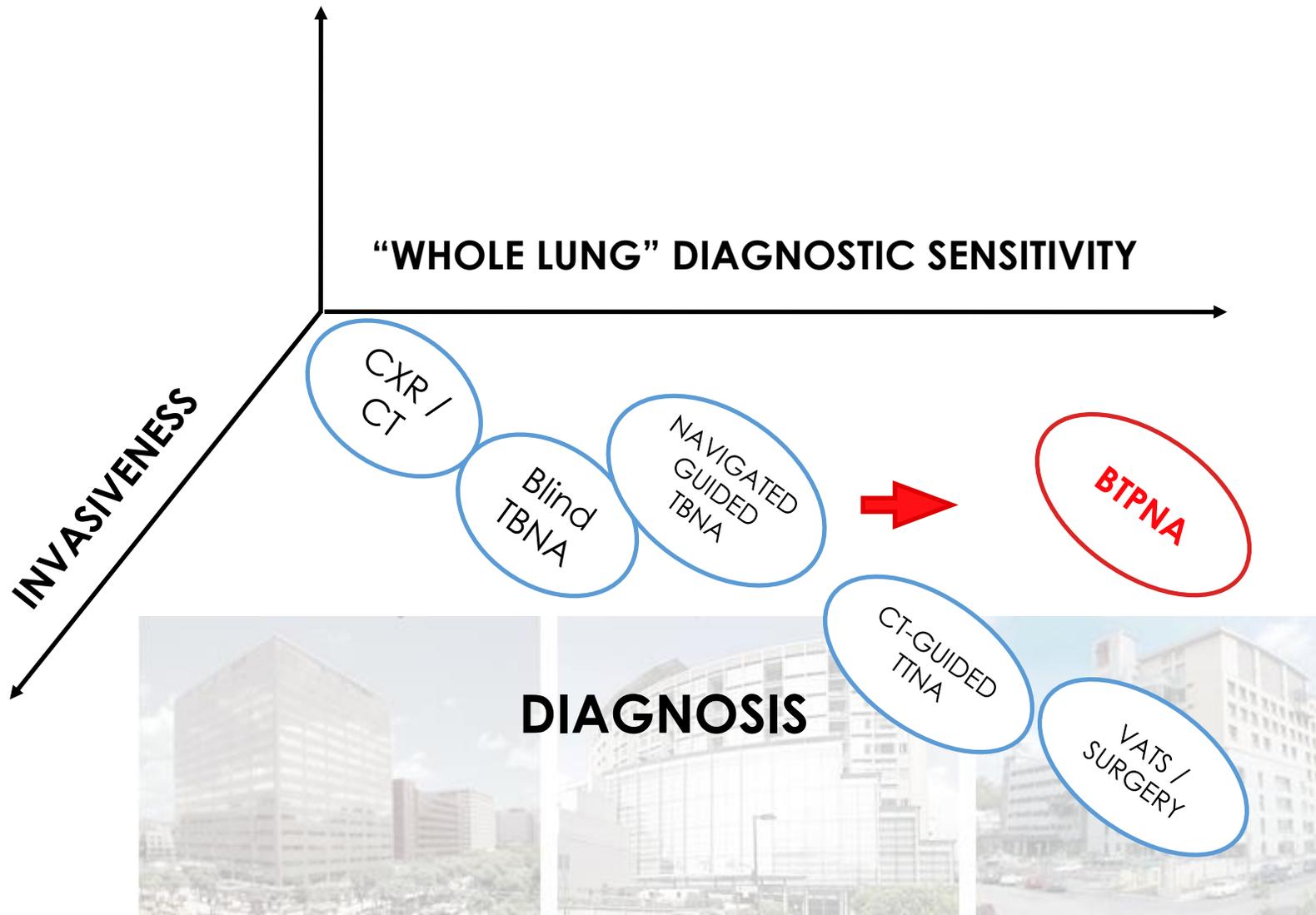


- Limited tool access to nodules outside the small, peripheral airways

- Inability to confirm location of tools in real time so target can be missed even when very close

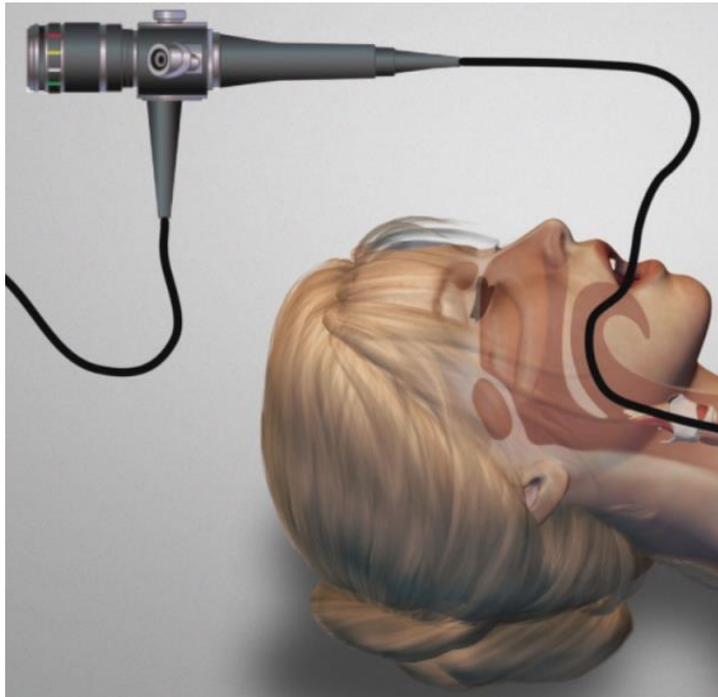


# Bronchoscopic Trans-Parenchymal Nodule Access

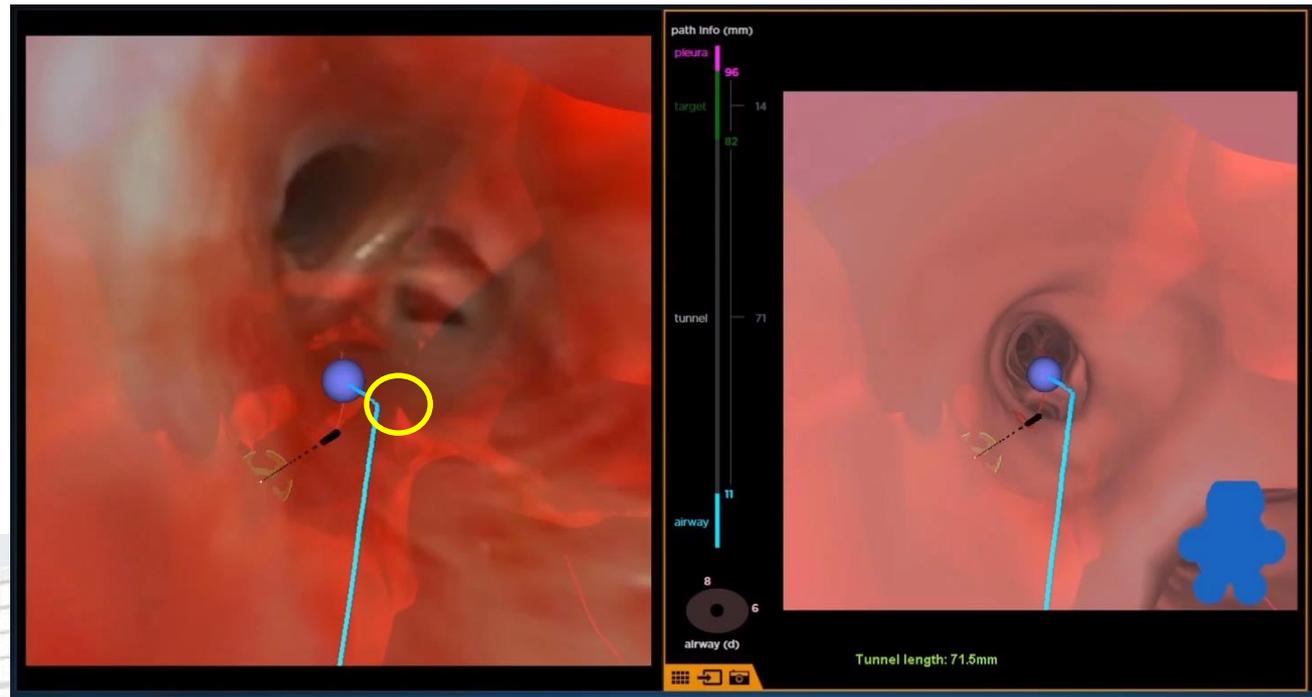


# TPNA Procedure with Virtual Bronchoscopic Navigation (VBN)

Access the central airways with a standard treatment bronchoscope

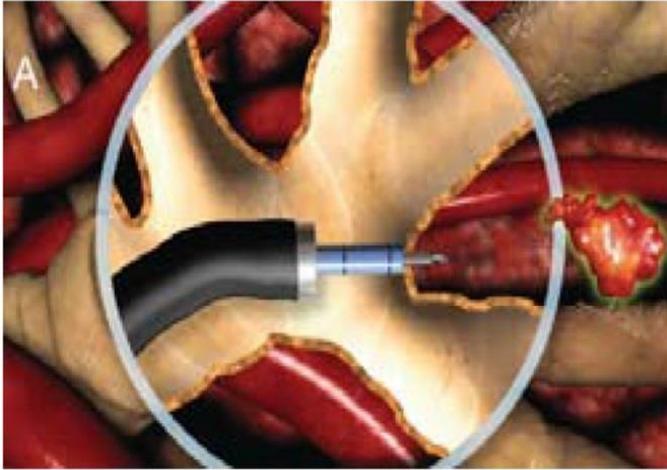


System provides navigation to point of entry in selected airway



# TPNA Procedure with Virtual Bronchoscopic Navigation (VBN)

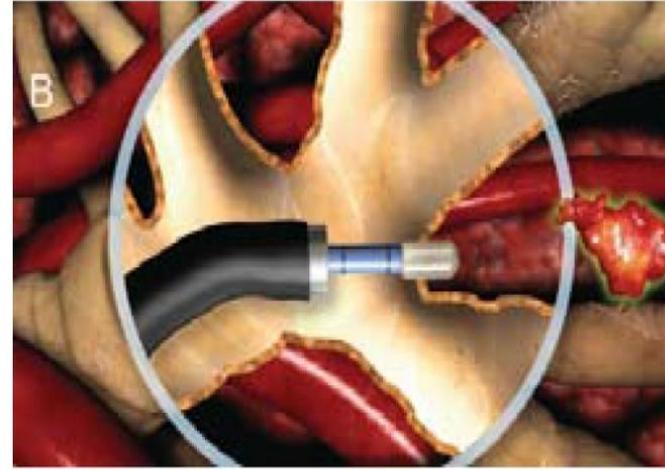
Create hole with Archimedes FlexNeedle



Fused fluoro guidance of Archimedes Sheath and blunt stylet to nodule



Dilate hole with Archimedes



Dx/Tx with standard bronchoscopic 2.0mm tools





# No any adverse events attributable to the BTPNA procedure

**Table 1** Safety and procedural aspects of Bronchoscopic Transparenchymal Nodule Access (BTPNA) procedure

	Site	Size (mm)	Visible at fluoroscopy	Procedure planning time (min)	Nodule access time (min)	Fluoroscopy time (min)	Intra-procedural adverse events	Tunnel length (mm)	Pathology	Inspection of resection specimen	TNM	Correlation with resection specimens	Postprocedure adverse events
1	LUL	40	Yes	10	40	11.6	None	10	Large cell carcinoma	*	T2aN0M0	Yes	Raised troponin level
2	Lingula	20	Yes	15	Data not recorded	7.09	None	50	Small cell cancer	*	T1aN0M0	Yes	None reported
3	LLL	25	No	30	30	5.18	None	60	Large cell carcinoma	*	T1bN0M0		None reported
4	LUL	31	Yes	18	No sample taken	5	Sheath could not be directed along optimal path	—	N/A	*	T2aN0M0		None reported
5	RML	22	No	15	26	6.7	None	50	NSCLC	*	T1bN0M0		None reported
6	LLL	22	No	12	13	3	None	30	NSCLC	*	T1bN0M0		None reported
7	RLL	30	No	25	30	1.8	None	30	NSCLC	*	T2aN0M0		None reported
8	RLL	18	Yes	15	17	3.6	None	60	Adenocarcinoma	*	T1aN0M0		None reported
9	RLL	20	No	30	12	4.2	None	90	NSCLC	*	T1aN0M0		None reported
10	RML	28	Yes	15	13	9.8	None	<u>70</u>	Adenocarcinoma	*	T1bN0M0		None reported
11	LUL	17	No	14	No sample taken	N/A	Sheath could not be directed along optimal path	—	N/A	*	T1a N0M0	N/A	None reported
12	LUL	31	No	10	15	2.1	None	20	NSCLC	*	T2aN0M0	Yes	None reported

Where size is the long axis diameter.

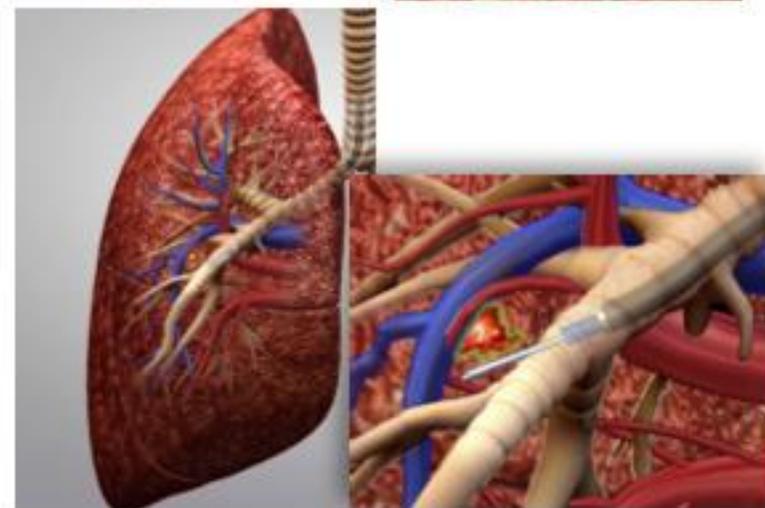
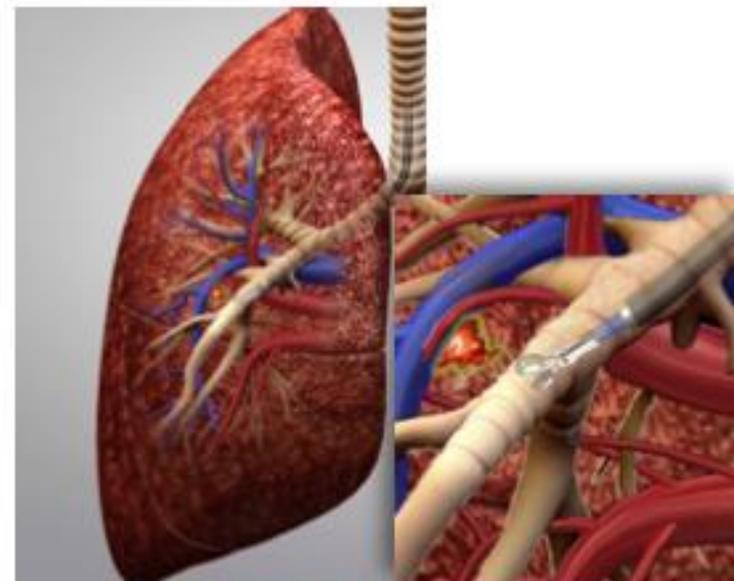
\*All areas involved in TPNA resected and no concerns identified.

LLL, left lower lobe; LUL, left upper lobe; NSCLC, non-small cell lung cancer; RLL, right lower lobe; RML, right middle lobe.

**90 mm long tunneled** pathway was safely created and a biopsy successfully performed.

# Bronchoscopic Diagnosis with VBN (Mackay Experience)

Number of patients		21
Mean Age		66.6 ± 8.5
Male Gender		12/21
Average diameter of nodule		3.1 ± 1.6 cm
Solid / GGO		18/1
Position	RUL	5
	RML	3
	RLL	7
	LUL	2
	LLL	2
Endobronchial lesion (+ : -)		7 : 14
Endobronchial lesion (+) Diagnosis Yield		100% (7/7)
Diagnosis	Inflammation	3
	Small cell Lung Cancer	1
	Adenocarcinoma	9
	Carcinoma	1
	Breast Cancer Lung Meta	1
	no Dx	6
Diagnosis Yield		71% (15/21)



# Precise sublobar lung resection for small pulmonary nodules: localization and beyond

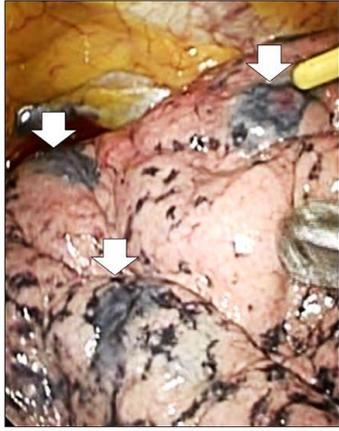
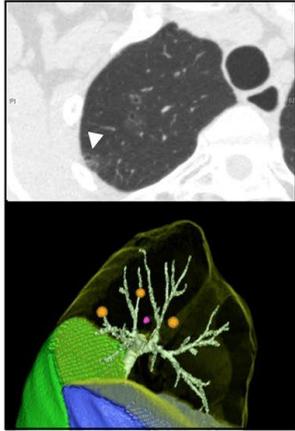
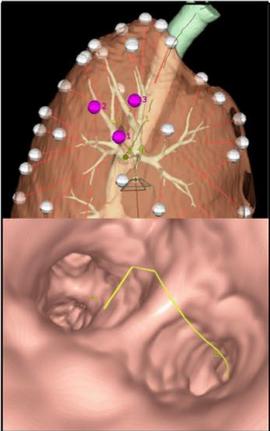
Masaaki Sato<sup>1</sup>

VAL-MAP design/plan  
(virtual bronchoscopy)

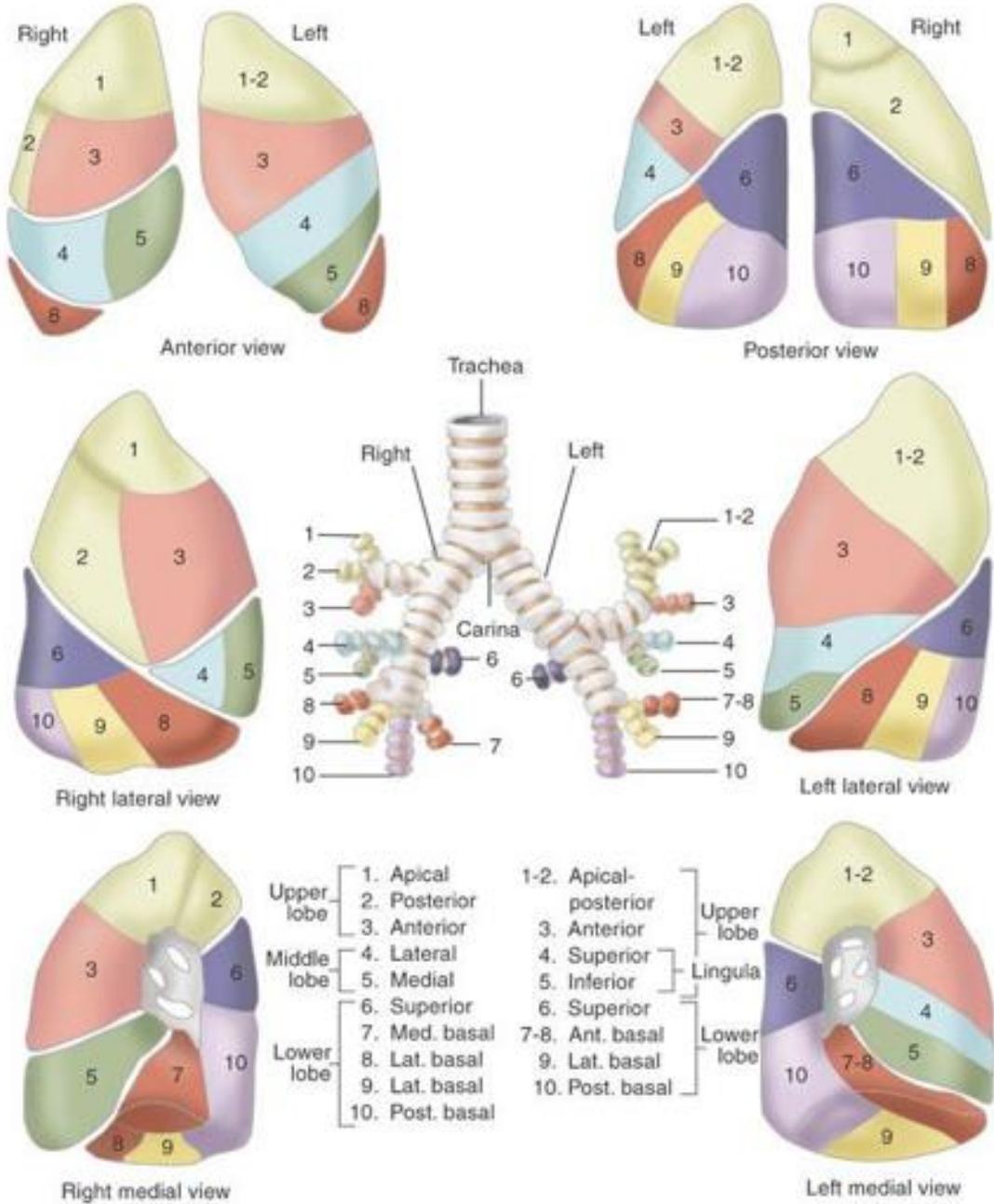
Bronchoscopic  
dye injection

Post-mapping CT/  
3D reconstruction

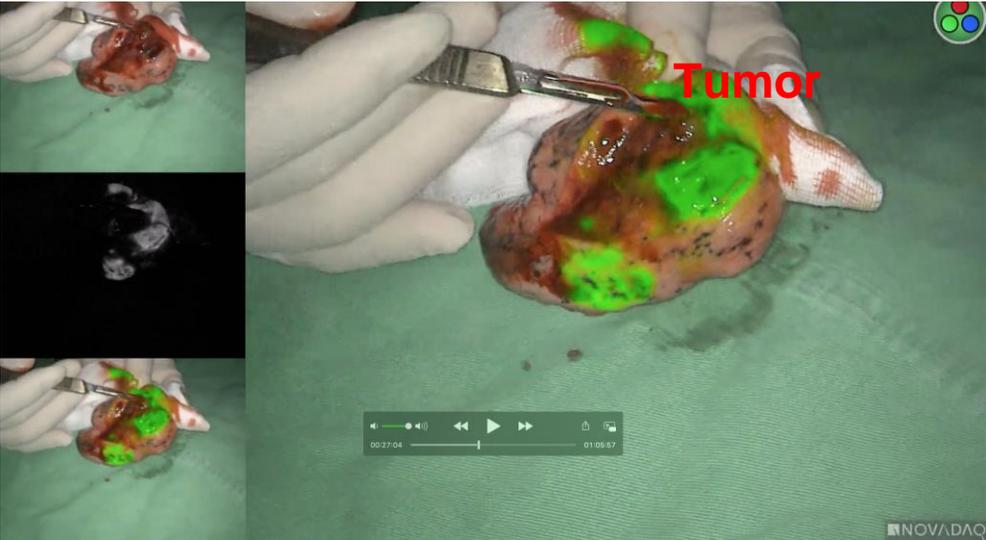
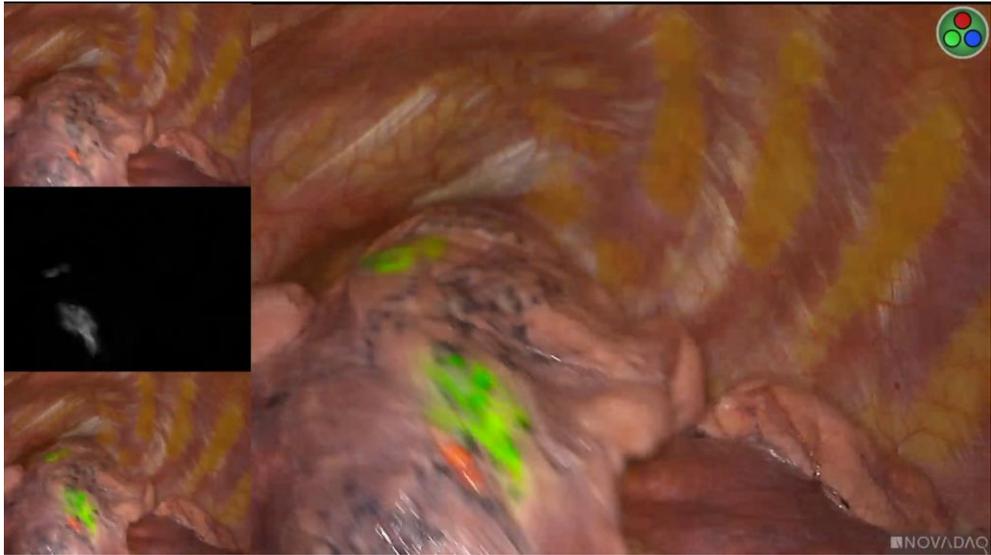
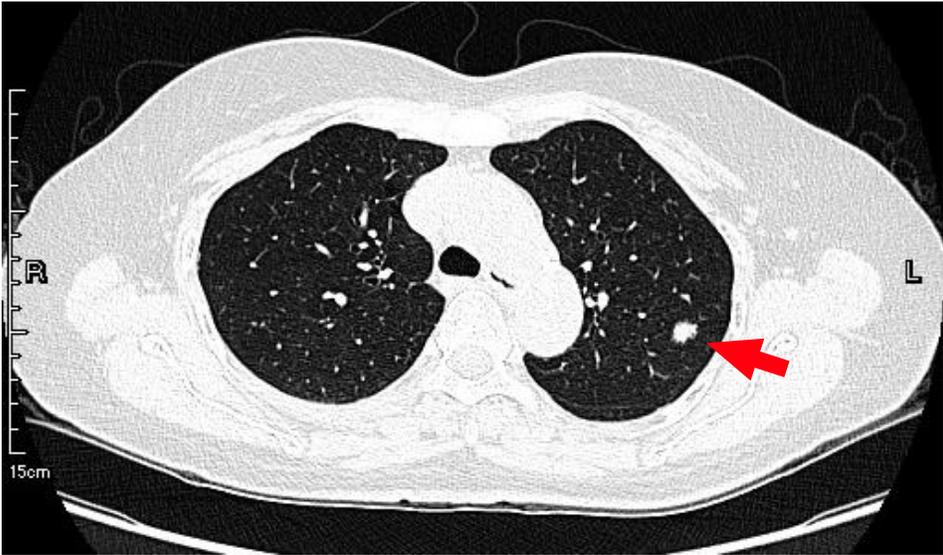
Operation



Sato. 25 October 2019



# Pulmonary Nodule Fluorescence Localization



**Airway Navigation**  
ICG injection

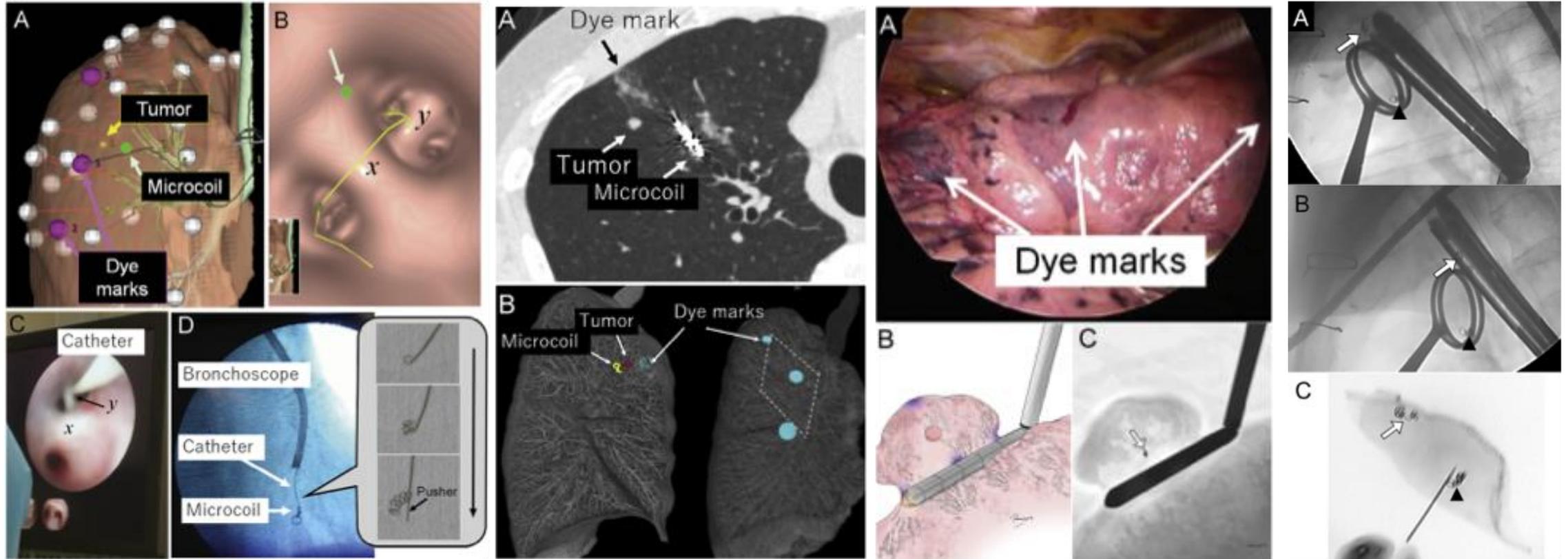
**Surgery**

**Mucinous Adenocarcinoma In Situ**

# Virtual-Assisted Lung Mapping 2.0: Preoperative Bronchoscopic Three- Dimensional Lung Mapping

Masaaki Sato, MD, PhD, Kazuhiro Nagayama, MD, PhD, Masashi Kobayashi, MD, PhD,  
and Jun Nakajima, MD, PhD

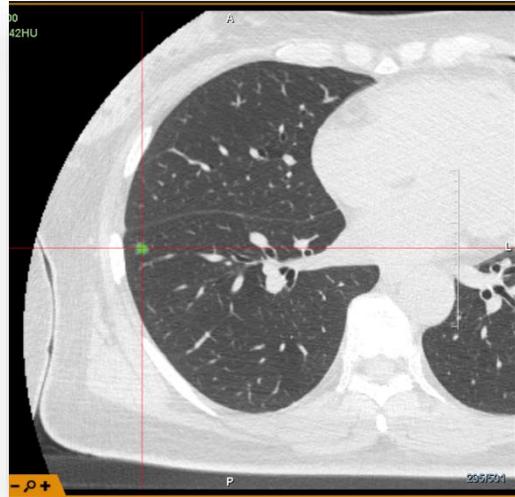
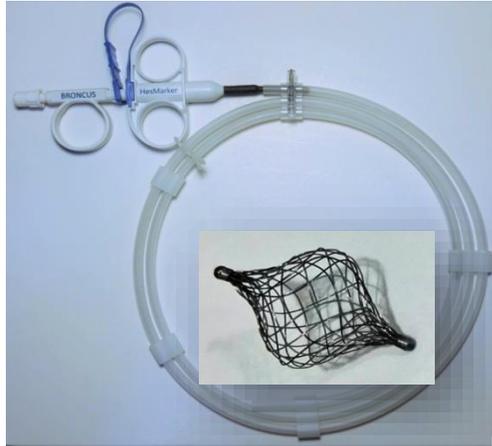
Department of Thoracic Surgery, The University of Tokyo Hospital, Tokyo; and Department of Thoracic Surgery, Tokyo Medical and Dental University, Tokyo, Japan



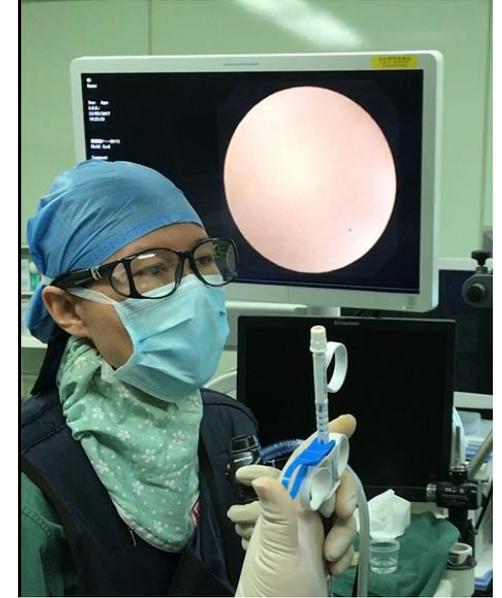
VAL-MAP 2.0, which combines bronchoscopic multispot dye marks and microcoil placement, assists surgeons in obtaining sufficient resection margins, even when removing deeply located lesions by pulmonary sublobar resection.

# Fiducial marker placement Implant

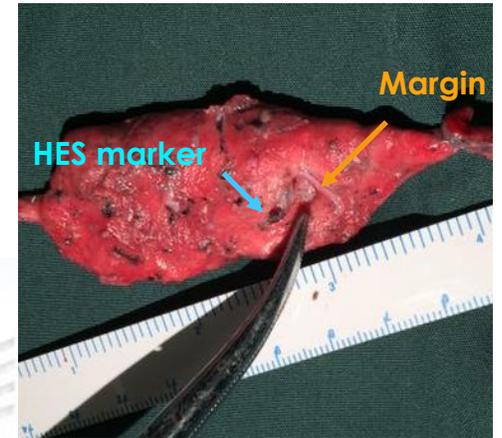
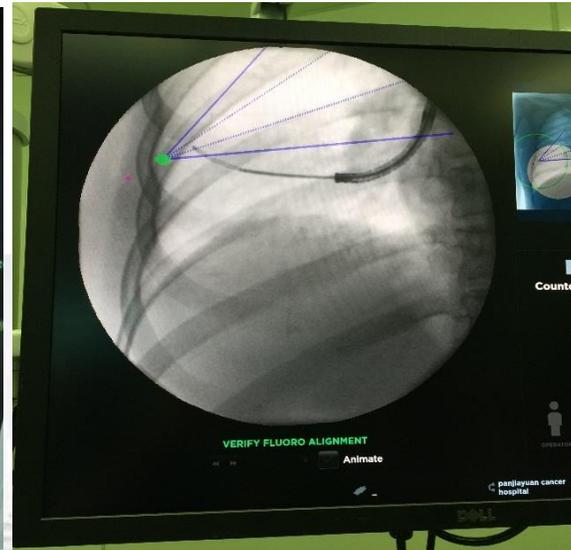
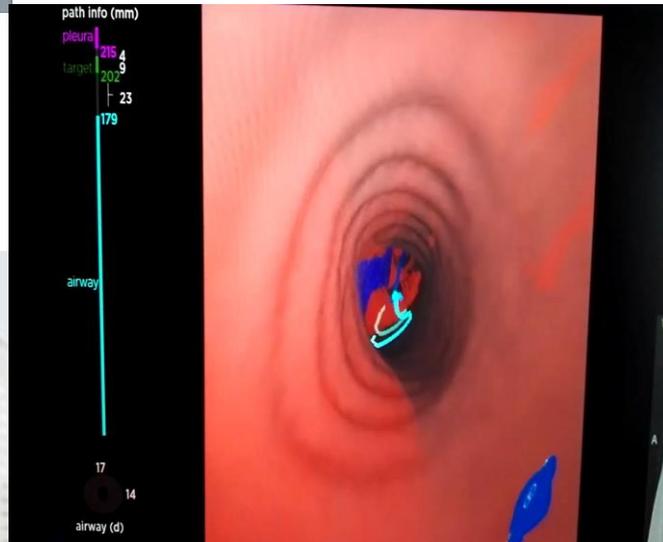
HES marker, Broncus®



Female ,54 years old,5\*6 Nodule in RLL



Visually highlights small nodules (< 1.5cm) including Ground Glass Opacity



Pathology : Adenocarcinoma  
Marker to Margin : 5 mm

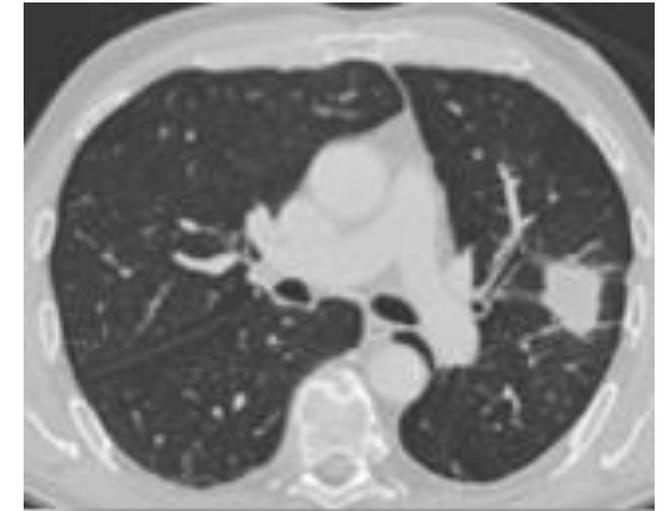
# Bronchus Sign on CT Scan

*Seijo, L. M., et al. (2010). "Diagnostic yield of electromagnetic navigation bronchoscopy is highly dependent on the presence of a Bronchus sign on CT imaging: results from a prospective study."*

- ✓ Diagnostic Yield 67% (34/51)
- ✓ **Diagnostic Yield if bronchus sign present: 79% (30/38)**
- ✓ **Diagnostic Yield with no bronchus sign present 31% (4/13)**
- ✓ No procedure related complications

## Conclusions:

- ✓ ENB diagnostic yield is highly dependent on the presence of a bronchus sign on CT
- ✓ Multiple publications site between 45%-76% of nodules with no discernible bronchus sign



*Chest. 2010 Dec;138(6):1316-21.*

# EAST 2 – Abstract at ERS 2018

## Methods

A series of 16 SPNs lack an airway path for biopsy was sampled by BTPNA using Archimedes system from October 2016 until January 2018 at 5 clinical sites. Trained bronchoscopist marked suspected SPN and selected suitable guided-bronchoscopy path to point of entry (POE) on airway wall. Hole creation and dilation at POE were performed prior to guide sheath insertion via the hole toward SPN under fused CT/Fluoroscopy guidance to get biopsy samples.

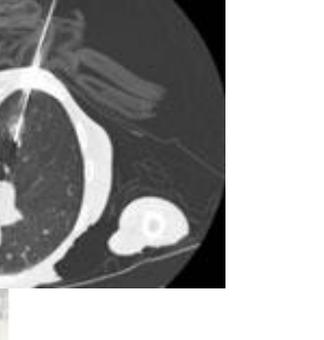
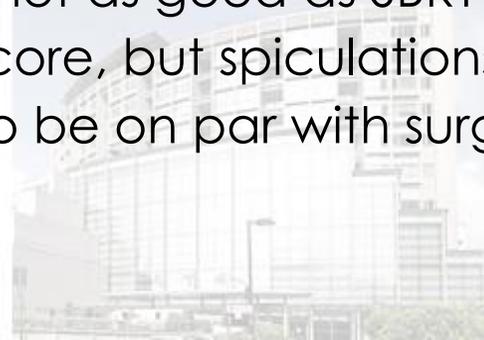
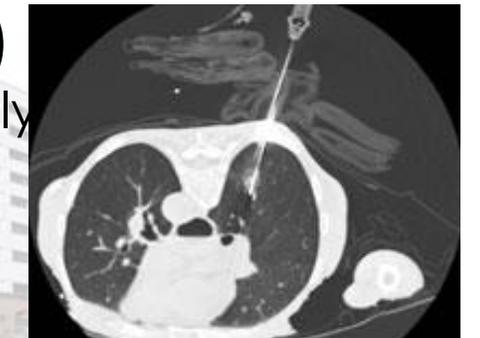
## Results

Lesion Size	Diagnostic Yield	SPN Major Axis Mean (mm)	Closest Distance to Pleura Based on Biopsy Angle Mean (mm)
<20.0mm (N=9)	77.8%	12.3 ± 4.2	21.3 ± 13.2
≥20.0mm (N=9)	77.8%	23.8 ± 2.5	19.0 ± 18.7

Overall diagnostic yield was 77.8% on SPNs with a mean major axis of 18.9±10.0 mm without major complications or pneumothorax.

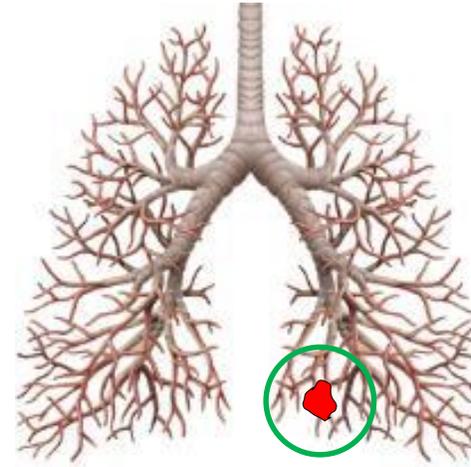
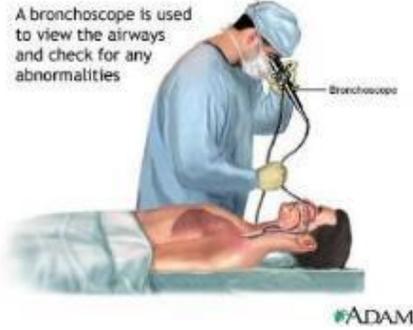
# Treatments for Localized Lung Cancer

- **Surgery is gold std.** for ability to completely remove tumor
  - Primary goal is complete tumor removal (100% local control)
  - Surgery has ~20% major complications rate, and is costly
  - 70% of patients are eligible for surgery
- **Stereotactic Radiotherapy (SBRT)** for 30% of non-surgical patients
  - Efficacy for SBRT is nearly as good as surgery (90% local control)
  - **Capital cost of SBRT and 3 procedures is often cost prohibitive**
- **RFA** for 30% of non-surgical patients with no SBRT option
  - Efficacy for RFA alone not as good as SBRT or surgery (60-80% local control)
  - Good at ablating the core, but spiculations and GGOs difficult to kill entirely
  - Need to **take margin** to be on par with surgery



# BTPNA Combined VATS

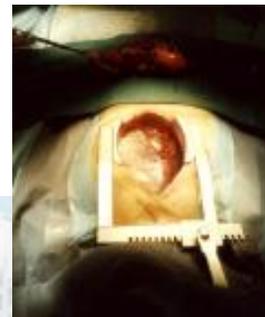
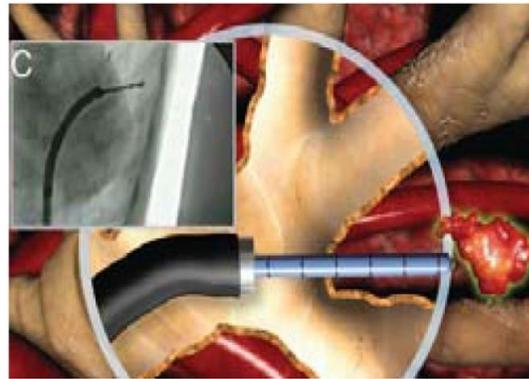
Patient sedated for bronchoscopy



Navigation Planning to tumor by Archimedes



BTPNA Sampling

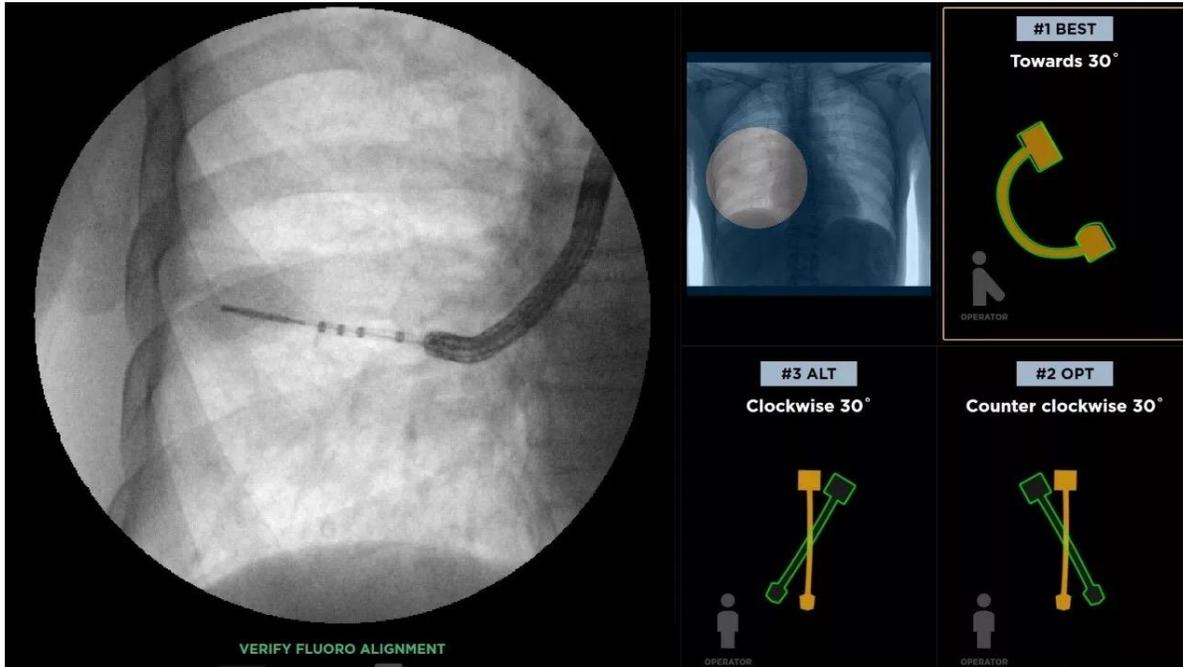


Immediate resection

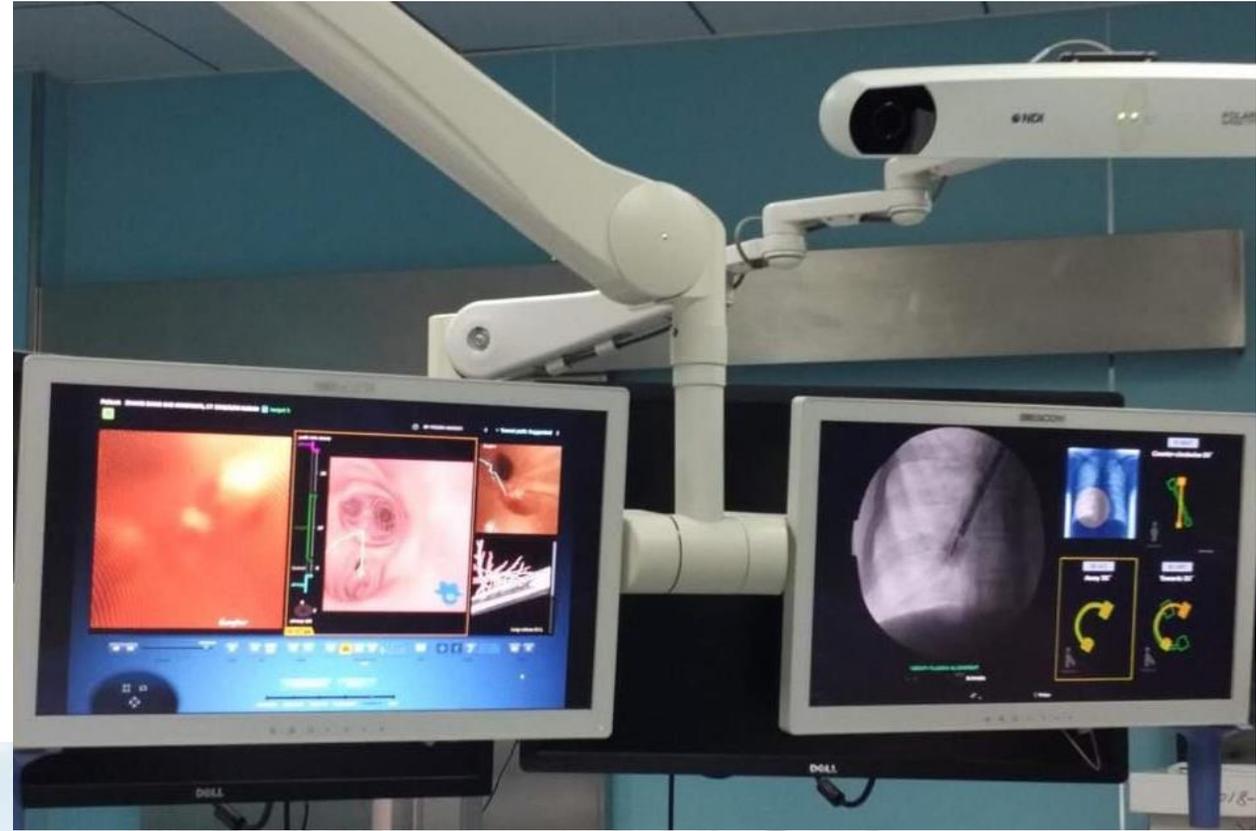
ROSE



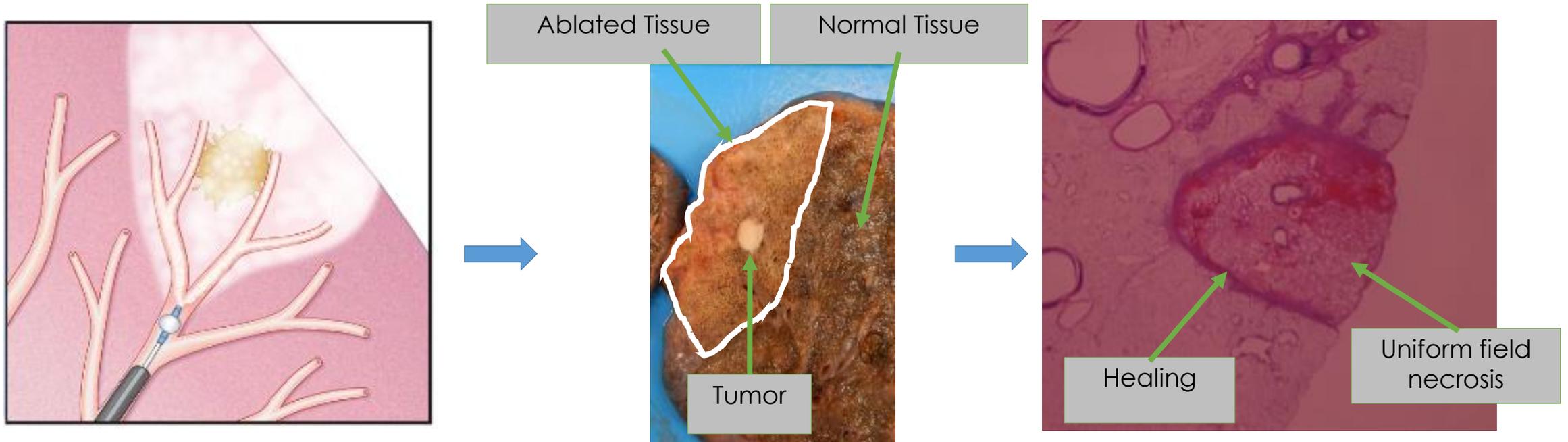
# RFA using Archimedes (clinical trial)



# MWA using Archimedes (clinical trial)



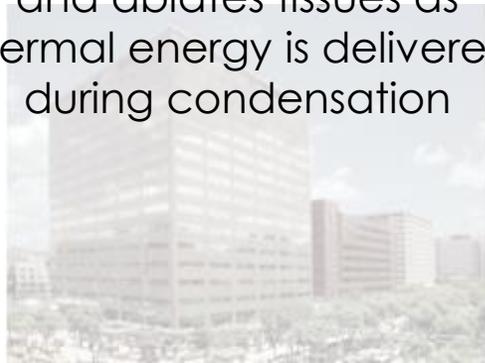
# Vapor Ablation for tumor margin and GGO



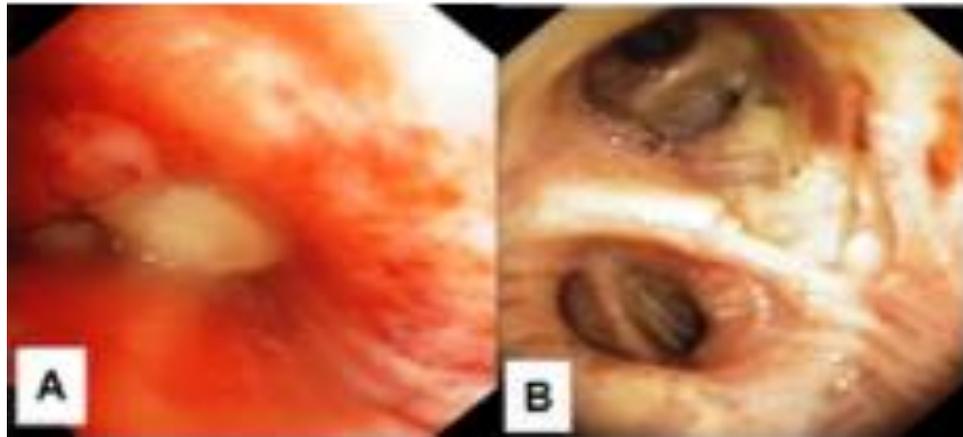
Vapor flows through airways and parenchyma and ablates tissues as thermal energy is delivered during condensation

Ablation occurs through mini-segment, destroying margin, micro-nodules and spiculations

Healing occurs from the outside of necrosis field



# Intratumoral chemotherapy for lung cancer: re-challenge current targeted therapies



Notes: (A) Bronchoscopy image upon diagnosis. (B) Bronchoscopy image after local intratumoral treatment.

Abbreviations: ITC, intratumoral chemotherapy.

Author	Methodology	Subjects	Cancer cells/ tissue	Response	Nanoparticles	Carriers
Jia et al	Intratumoral plus doxorubicin magnetic field	In vitro/in vivo	Lewis lung cancer	√	Magnetic Fe <sub>3</sub> O <sub>4</sub>	PLGA
Akeda et al	OK-432	In vivo	Squamous lung carcinoma	√	–	–
Li et al	Multifunctional theranostic liposome drug delivery system plus doxorubicin	In vitro/in vivo	Squamous cell carcinoma-4 tumor cells	√	Magnetic	Liposomes
Goldberg et al	Review	Review	Review	Review	Review	Review
Brincker et al	Review	Review	Review	Review	Review	Review
Cellikoglu et al	5-fluorouracil, mitomycin, methotrexate, bleomycin, mitoxantrone, cisplatin	Patients	Lung cancer	√	–	–
Fujievara et al	Intratumoral-P53	Patients	Lung cancer	√	–	–

Abbreviations: OK, lyophilized incubation mixture of group A *Streptococcus pyogenes* of human origin; PLGA, poly(lactic-co-glycolic acid).

Delivery by BTPNA ??

# Conclusions

- Minimally Invasive Surgery is the Future of Thoracic Surgery.
- Prospective studies should be analyzed the difference between Surgery and Transbronchoscopic Ablation for early Small lung lesion.



**THANK YOU  
FOR YOUR  
ATTENTION**

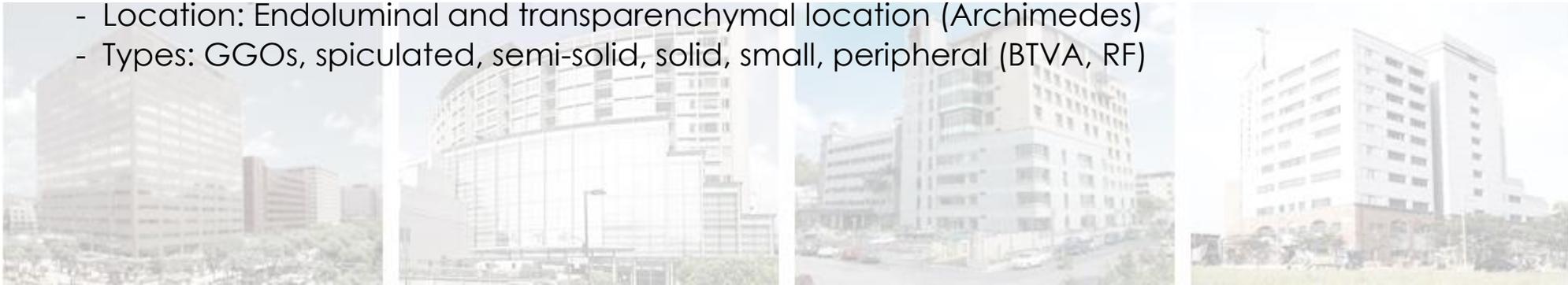




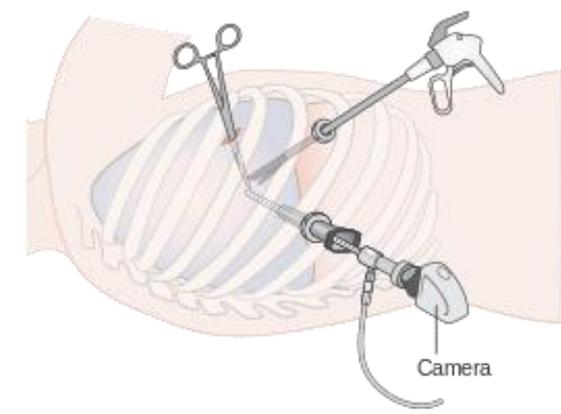
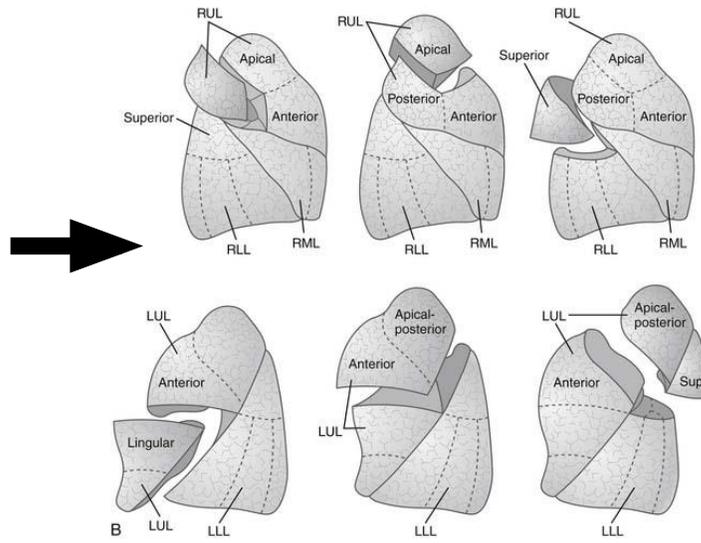
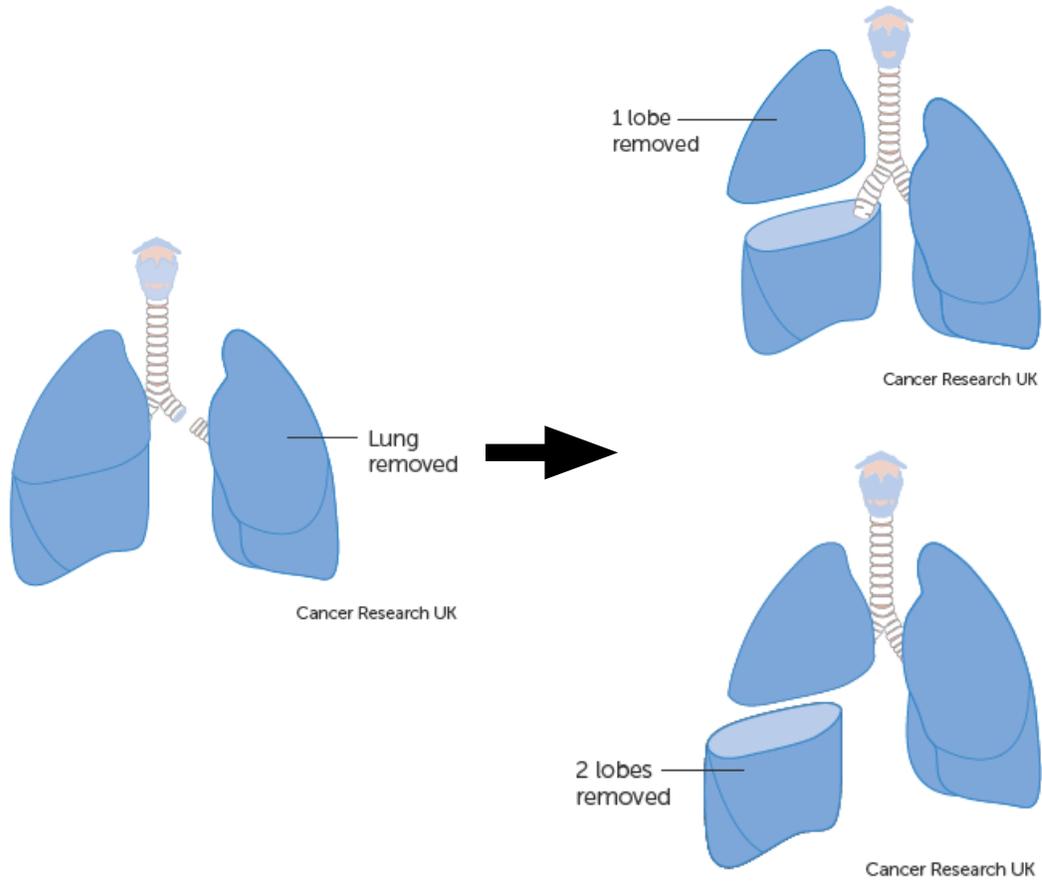


# Lung Cancer Therapy Selection in U.S.

- Most hospitals have tumor board or pathway: **Team of physicians** determine best therapy for each patient based on clinical data
- Lung Cancer tumor board often consists of **thoracic surgeon, oncologist, radiation oncologists, pathologist, radiologists, pulmonologist**
- Given high mortality associated with advanced lung cancer, complete removal or control of tumor is primary consideration for options
- Ablation of tumors with focused energy will be clinical success when:
  - Consistent, complete local control of lung cancer tumor is achieved**
  - Location: Endoluminal and transparenchymal location (Archimedes)
  - Types: GGOs, spiculated, semi-solid, solid, small, peripheral (BTVA, RF)



# Lung Cancer Surgical Treatment



**Pneumonectomy**

**Lobectomy**

**Segmentectomy**

**VATS & RATS**

# Lung Cancer Surgical Treatment

- Pneumonectomy 1933
- Lobectomy 1955
- Segmentectomy 1972
- VATS lobectomy 1992
- VATS Segmentectomy 1994
- Robotic Lobectomy 2004
- EBUS, Energy, sealants, pain treatment
- Alternative Treatment – SBRT, RFA, **BTPNA ablation**



# Different VATS Approaches

- Trans-cervical
- Trans-umbilicus
- Trans-diaphragm
- Subcostal
- NOTES
- Subxiphoid



European Journal of Cardio-thoracic Surgery 32 (2007) 766–769

EUROPEAN JOURNAL OF  
CARDIO-THORACIC  
SURGERY

www.elsevier.com/locate/ejcts

## The right upper lobe pulmonary resection performed through the transcervical approach<sup>☆</sup>

Marcin Zieliński<sup>a,\*</sup>, Juliusz Pankowski<sup>b</sup>, Łukasz Hauer<sup>a</sup>, Jarostaw Kuźdzał<sup>a</sup>, Tomasz Nabiatek<sup>c</sup>

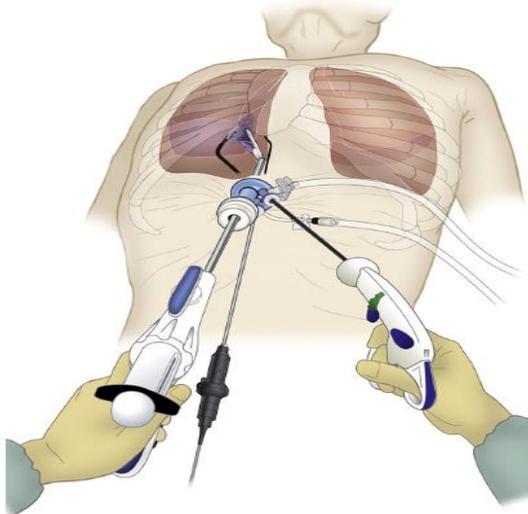
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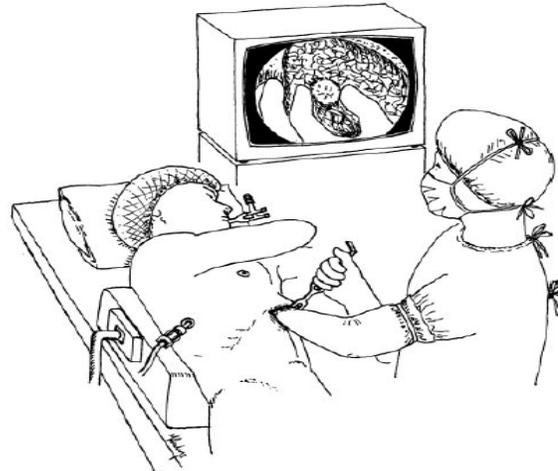
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HOW TO DO IT SUDA ET AL 719  
SINGLE-INCISION SUBXIPHOID APPROACH



Ann Thorac Surg  
1999;67:1808–10



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TRANSXIPHOID APPROACH IN VATS METASTASECTOMY

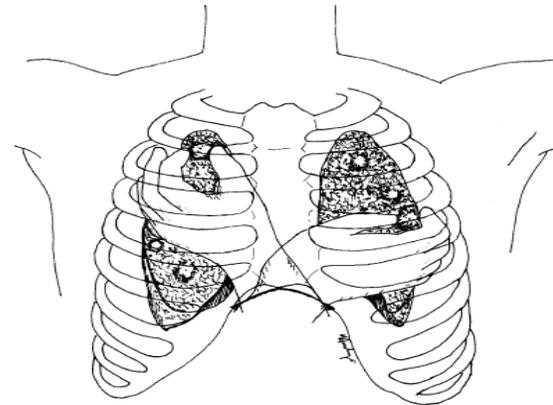
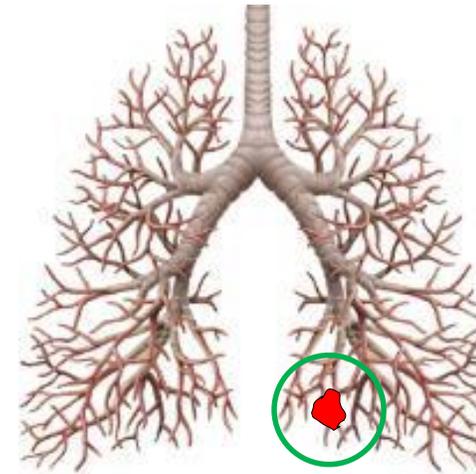
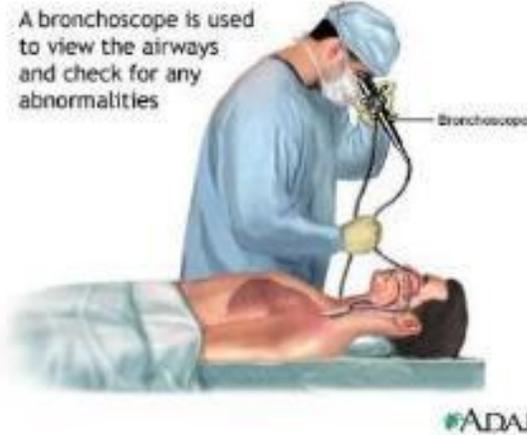


Fig 2. Bilateral palpation of both lungs through transxiphoid approach.



# Vapor Ablation: First in man study “Treat and immediate resect” protocol

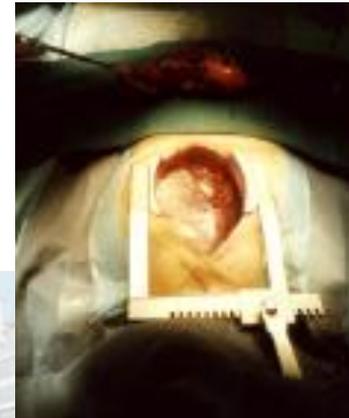
Patient sedated for bronchoscopy



Navigation to airway of tumor using navigation



Deliver vapor to airways.  
Vapor ablates everything it touches and constrained by anatomy.  
Vapor time 10 sec, total procedure time 10 min.

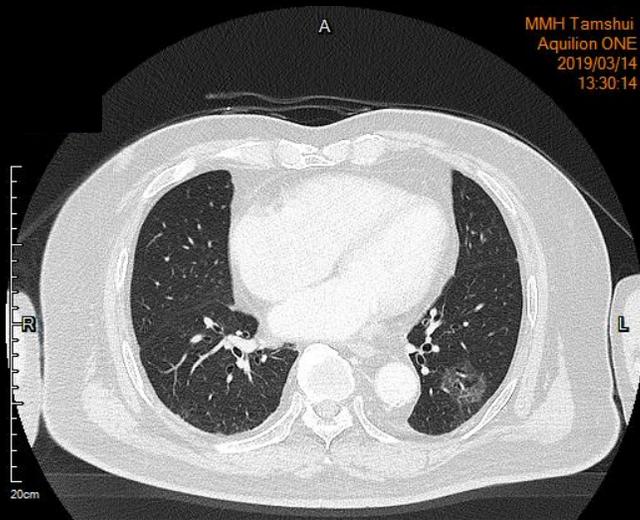


Immediate resection following ablation

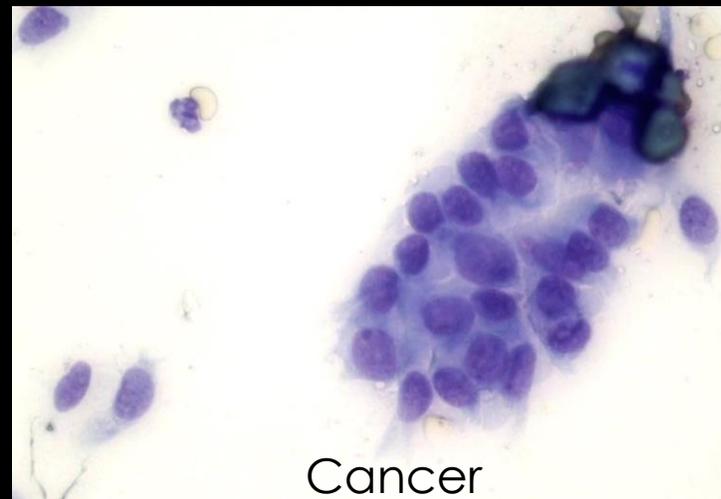
Vapor Ablation in Lung cancers in clinical trial



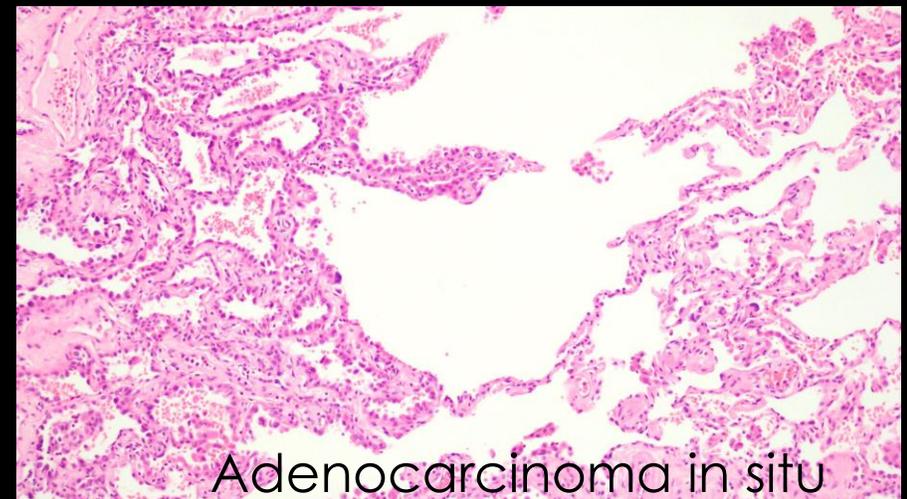
MMH Tamshui  
Aquilion ONE  
2019/03/14  
13:30:14



2.8x2.3 cm GGO lesion with air-cyst formation



Cancer



Adenocarcinoma in situ

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