

Modern Interventional Pulmonology in Lung Cancer Care: Precision Diagnosis and Targeted Ablation

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Eisenhower Health

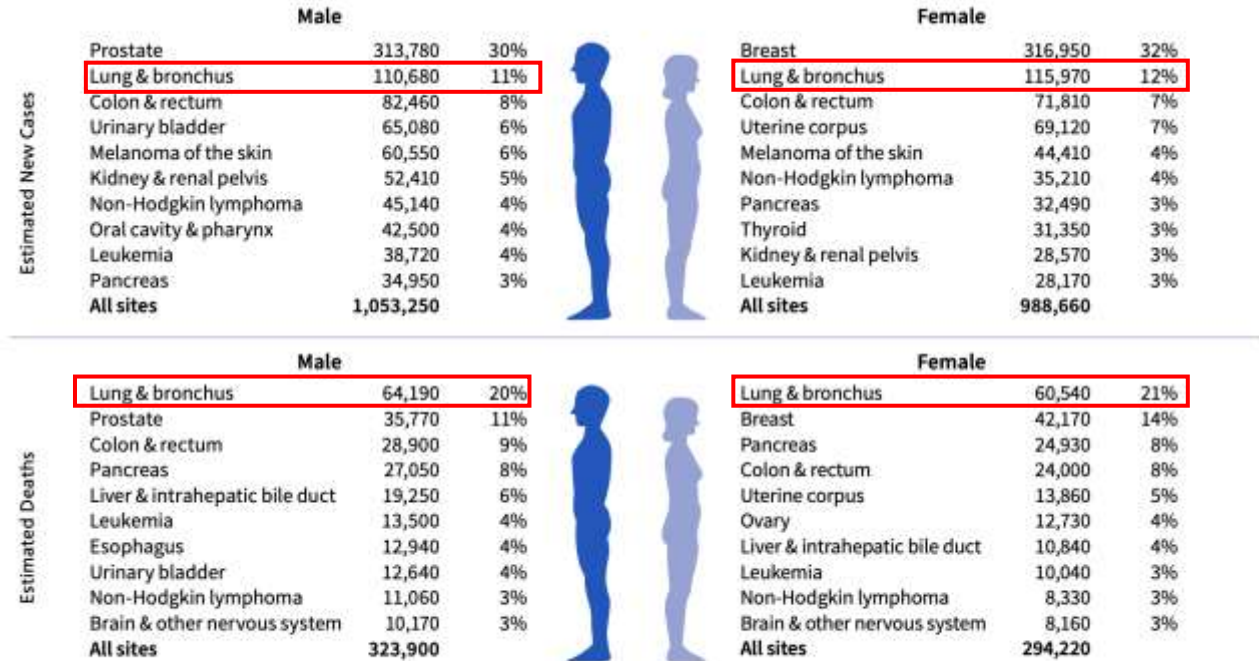
Medical Director of Pulmonary, Critical Care and Sleep Clinic

Director of Bronchoscopy and Interventional Pulmonology

Director of Lung Cancer Screening Clinic and Lung Nodule Clinic

The Problem of Lung Cancer Today

- Lung cancer is the most commonly diagnosed cancer and the leading cause of cancer death worldwide, accounting for almost 2.5 million cases and 1.8 million deaths (1 in 5) in 2022.¹
- Lung Cancer causes more or as much deaths than breast, colorectal, and prostate cancers combined.
 - Breast, colon and prostate cancers have had a long history of screening programs.
 - Breast, colon and prostate cancers receive an average of 3x more research funding than lung cancer.²
- Cancer care cost the U.S. an overall \$208.9 billion in 2020, \$18.8 billion of which is due to lung cancer.³
- 350 Americans will die from lung cancer today. →



Estimates exclude US territories and are rounded to the nearest 10; cases exclude basal cell and squamous cell skin cancers and in situ carcinoma except urinary bladder. Ranking is based on modeled projections and may differ from observed data.

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- CA Cancer J Clin. 2024;74(3): 229-263
- American Cancer Society. *Cancer Facts and Figures 2025*. Atlanta; American Cancer Society: 2025
- Cancer Epidemiol Biomarkers Prev. 2020;29(7):1304-12

Lung Cancer Screening Trials

National Lung Screening Trial (NLST)¹

- Ages 55-74, current or former smokers (quit within 15 yrs), 30 Pack years, randomized to low dose CT or CXR annually
- **Reduction in lung cancer mortality by 20%**, all cause mortality by nearly 7% with annual low dose CT

Multicentric Italian Lung Detection (MILD) Trial²:

- Ages 49-75, current or former smokers, ≥20 pack-years, randomized to screening (LDCT) or no screening for a median period of 6.2 years
- Significant **39% reduction in lung cancer mortality** (HR 0.61; 95% CI 0.39–0.95; P = 0.017)

NELSON Trial³:

- Ages 50 to 74 years, >15 cigarettes/d for >25 y or >10 cigarettes/d for >30 y; ≤10 y, Randomized to LDCT at Baseline, year 1, year 3 and year 5.5
- **Significant 24% lung cancer mortality decrease**

A recent meta-analysis of randomized LDCT screening trials has confirmed an overall LC **mortality reduction of 20%**⁴

Although still only 18% of eligible patients are screened in the US (1-14% in California)

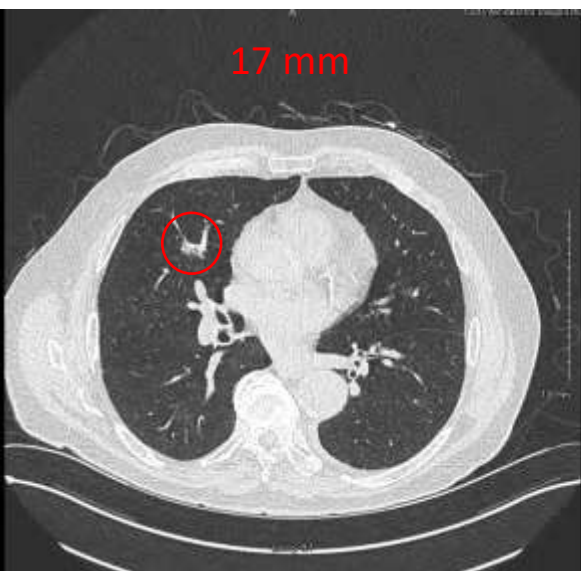
1. N Engl J Med 2011; 365:395-409
2. Ann Oncol. 2019 Jul 1; 30(7):1162-1169

3. N Engl J Med. 2020;382(6):503-513
4. Ann Oncol. 2019 Jul; 30(7): P1040-1043

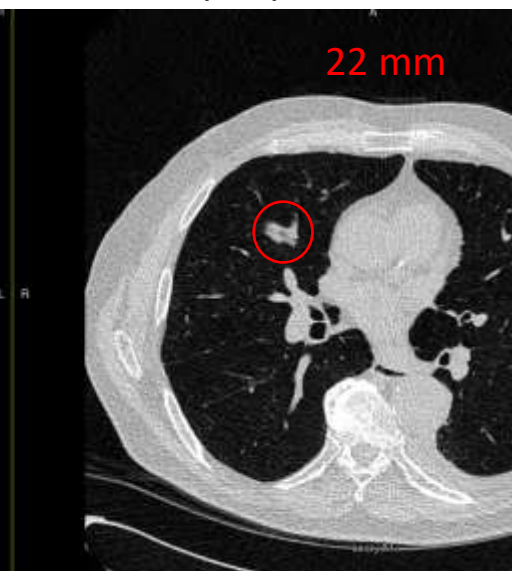
Case Example with Lung Cancer Screening and Why to Refer to Lung Cancer Screening Clinic

Date	Event
4/26/24	Low dose CT chest for lung cancer screening by PCP
9/18/24	Repeat CT chest 9/18/24 by PCP
9/26/24	Pulmonary referral made, I am contacted by my referral coordinator same day (Thursday afternoon)
10/2/24	Pt seen in Pulm Clinic Wednesday
10/17/24	Bronchoscopy and thoracentesis two weeks later
10/21/24	Cytology and Path Results—High grade neuroendocrine (large cell) left upper lobe and adenocarcinoma of right middle lobe

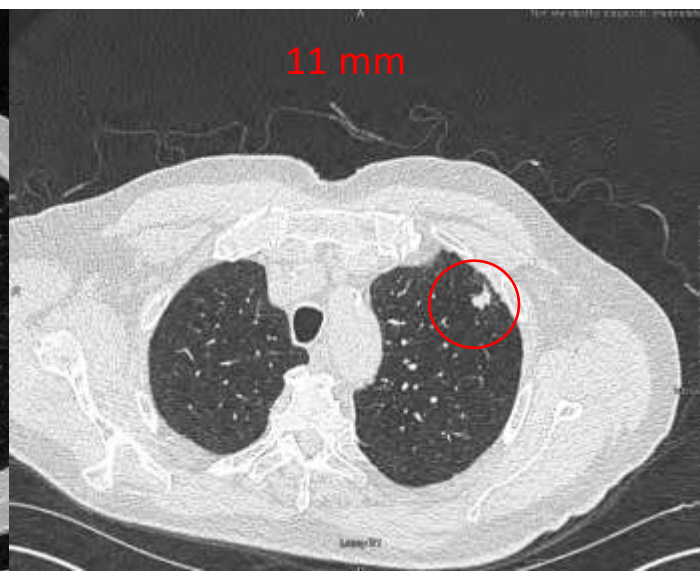
4/26/24



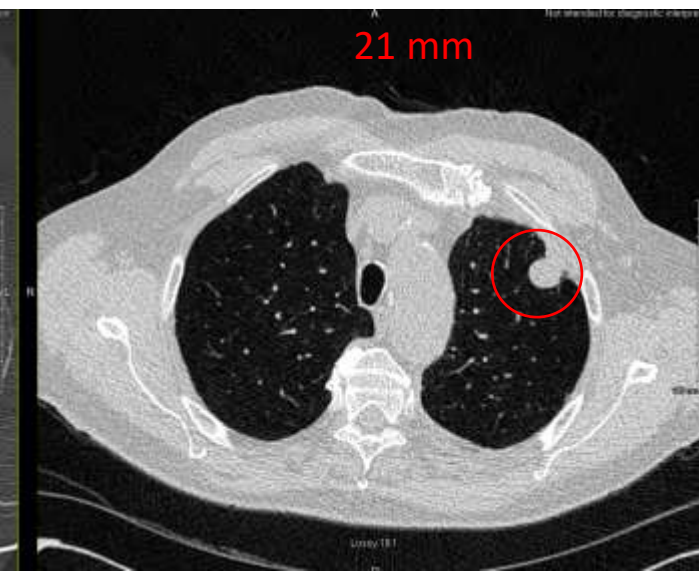
9/18/24



4/26/24



9/18/24

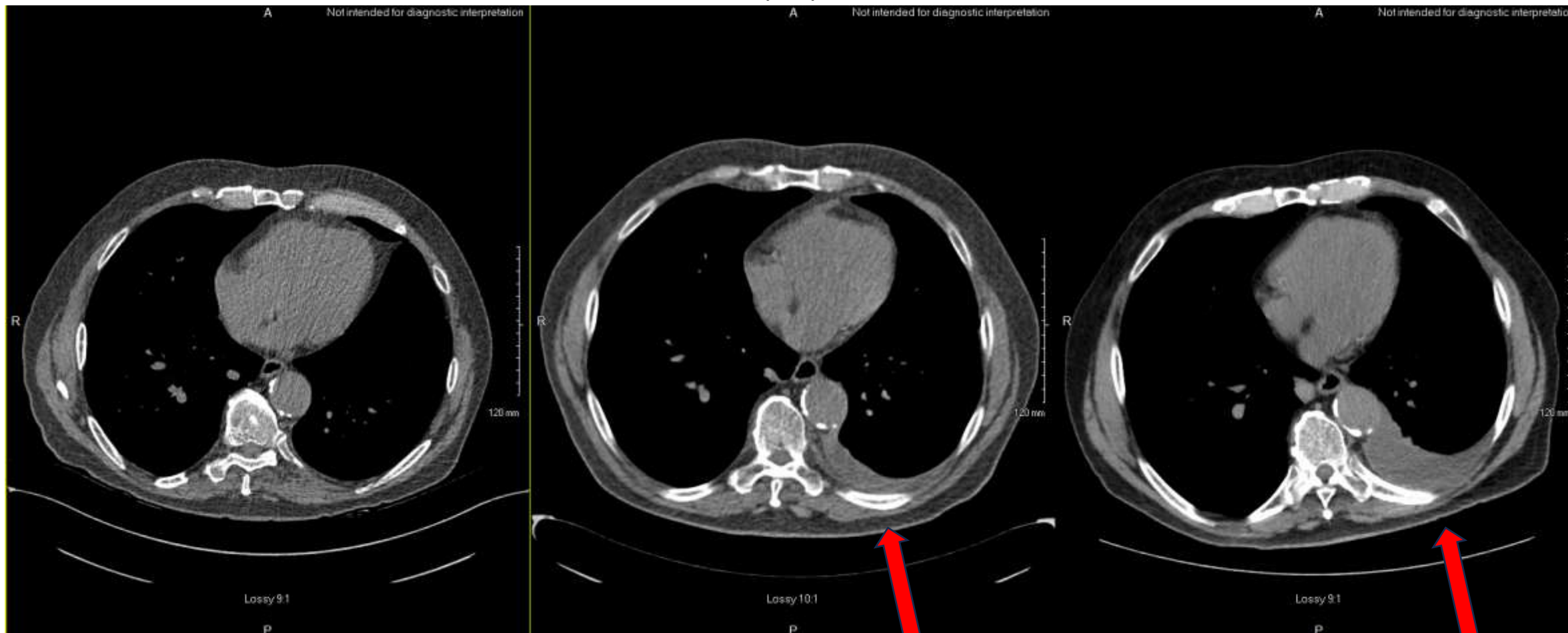


Here's the kicker!

4/26/24

9/18/24

10/17/24



Pleural fluid cytology reveals metastatic malignant pleural effusion
(Neuroendocrine Large Cell)

Time is Life

- Stage 1 NSCLC¹
 - Delay in diagnosis and treatment can affect outcome
 - 1 week delay:
 - 21.7% patients upstaged (2896/13325)
 - 8 week delay:
 - 31.5% patients upstaged (961/3046)
 - 12 week delay:
 - 32.6% patients upstaged (366/1027)
- Large VA Study: Patients with surgical treatment within 12 weeks of diagnosis had significantly **better overall survival than those with procedures delayed more than 12 weeks** (HR, 1.132; 95% CI, 1.064-1.204; P < .001).²
 - For each week of surgical delay beyond 12 weeks, the **hazard for recurrence** increased by 0.4% (HR, 1.004; 95% CI, 1.001-1.006; P = .002).

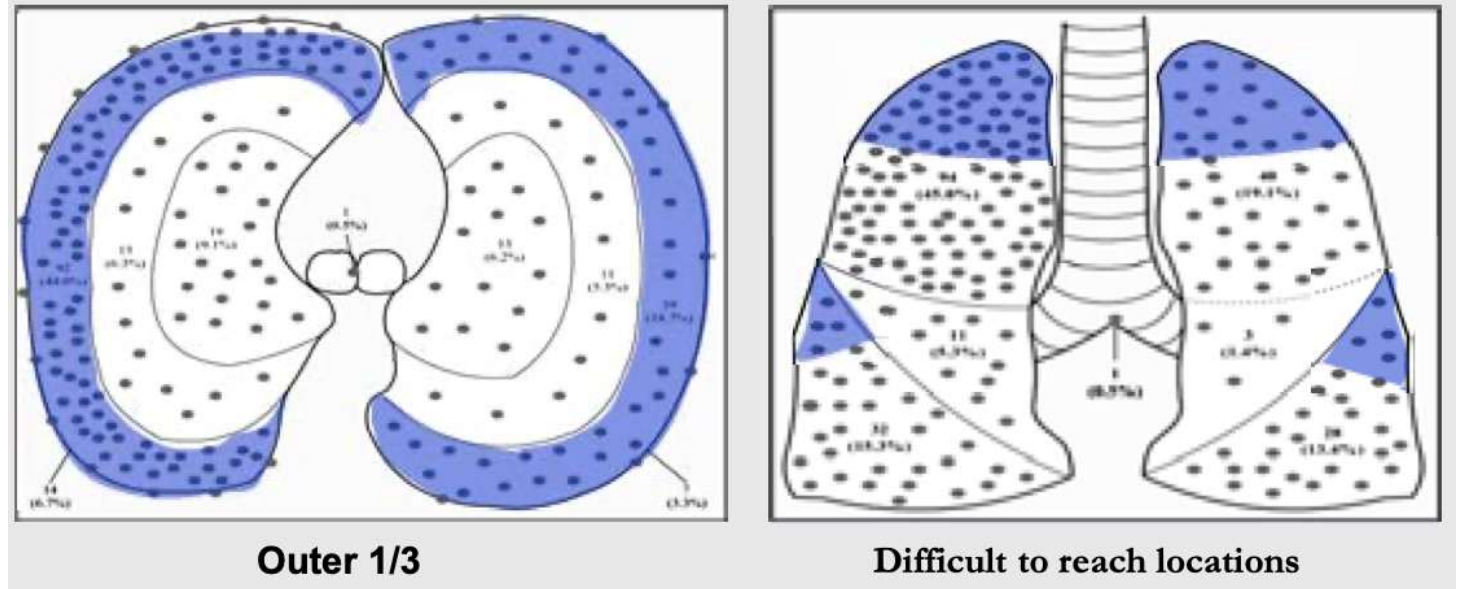


1. The National Cancer Comprehensive Network (NCCN) guidelines

2. *JAMA network open* 2021 May 27;4(5). e2111613.

Early Stage
Lung
Cancers are
Small and
Peripheral

Distribution of lung cancers as seen in the NELSON Trial



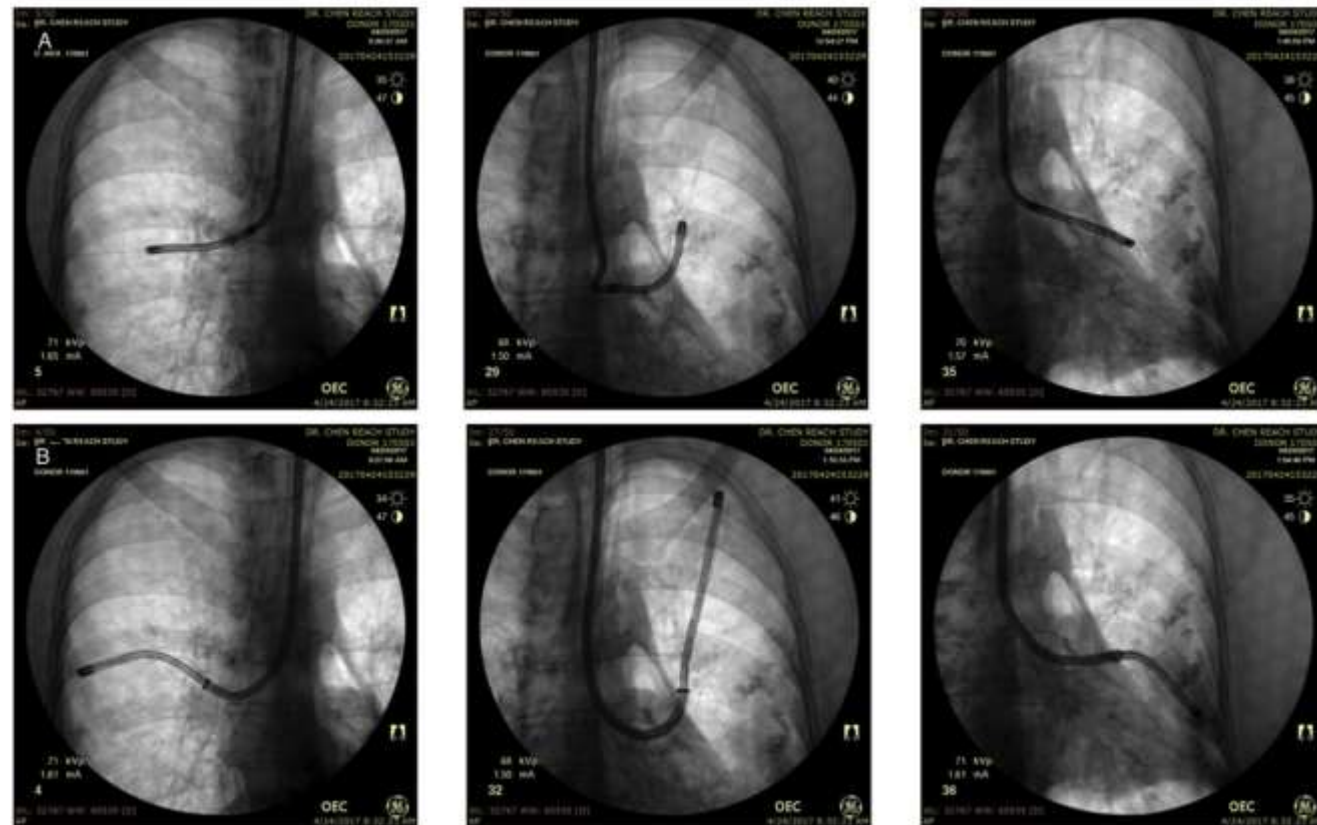
UICC 8th Edition (Proposal), J Thorac Oncol. 2016 Jan;11(1):39-51
Horeweg, N., et al. (2013). Am J Respir Crit Care Med 187(8): 848-854

Conventional Bronchoscopy vs. Robotic Bronchoscopy

Table 1. Generation Count

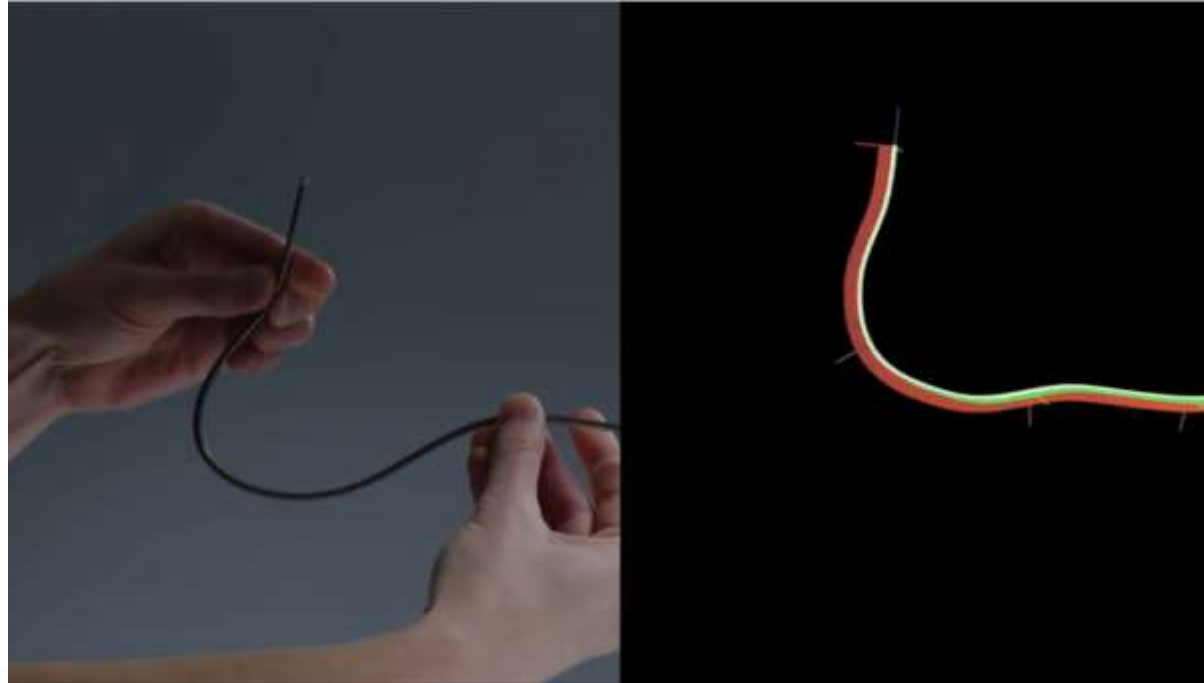
Segment	CTB Mean	RES Mean	Difference
Right upper lobe			
RB1	3.5	8	4.5
RB2	7.0	9.5	2.5
RB3	6.5	9.5	3.0
Right middle lobe			
RB4	7.0	9.5	2.5
RB5	5.5	8.5	
Right lower lobe			
RB6	4.5	6.0	1.5
RB7	3.0	8.0	5.0
RB8	5.0	8.0	3.0
RB9	7.0	10.0	3.0
RB10	6.5	9.0	2.5
Left upper lobe			
LB1+2	4.5	8.0	3.5
LB3	5.0	7.0	
Lingula			
LB4	5.0	11.0	6.0
LB5	7.0	9.5	2.5
Left lower lobe			
LB6	4.5	7.5	3.0
LB7+8	5.0	8.5	3.5
LB9	8.0	11.0	3.0
LB10	7.0	8.0	1.0

CTB = conventional thin bronchoscope; RES = robotic endoscopic system.



- Reach of robotic bronchoscopy is superior to conventional bronchoscopy due to size of catheter and proximal stability of the robotic bronchoscope

Ion Robotic Bronchoscopy—Shape Sensing Technology

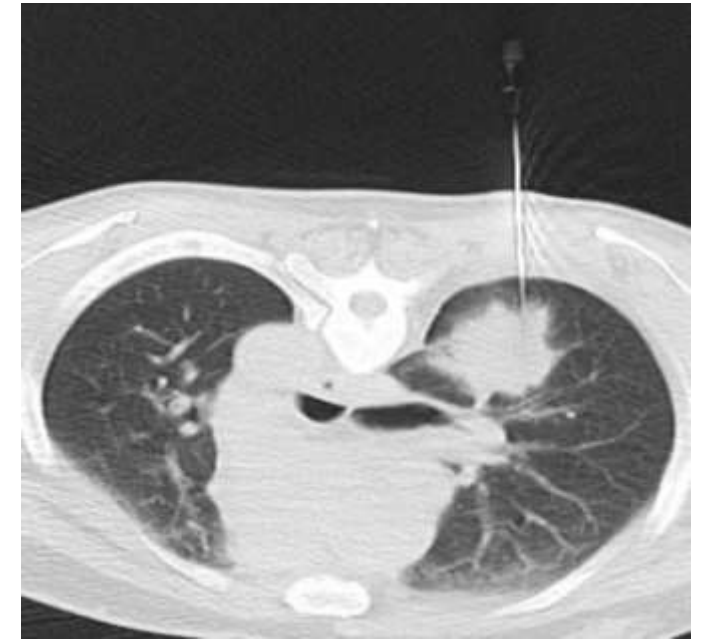


Single-center retrospective study, data collected from 11/23/21-3/10/23 with Monarch and 3/21/23 to 12/15/23 with Ion (365 patients with primary outcome diagnostic Yield)

- DY: 84.2% for Ion, 71% for Monarch ($p = 0.003$)
- Shorter Robot procedure time: (median IQR 37 min vs 70 min), $p < 0.001$
- Shorter radiation time: 4.6 min (3.00, 7.10) vs. 8.0 min (5.8,10.95), $p < 0.001$
- Pneumothorax 1.0% vs. 4.3% ($p = 0.089$)

TTNA/B vs. Navigational Bronch / Robotic Bronchoscopy

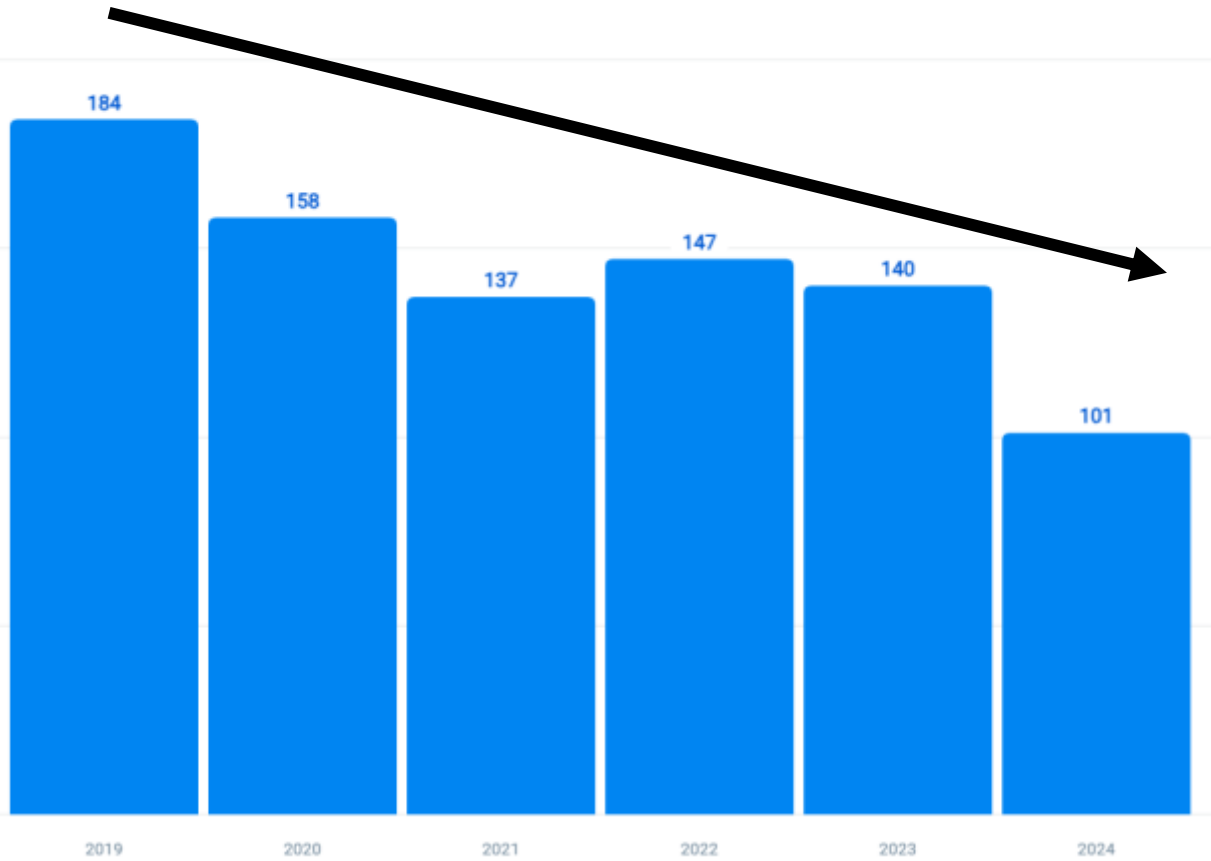
- VERITAS Trial: 2025 comparative study of navigational bronchoscopy (Illumisite) vs. TTNB found pneumothorax in 3.3% v.s. 28.3%, and chest tube/admission in 0.8% vs. 11.5%, respectively¹
 - Multicentric randomized parallel group non-inferiority trial-- 223 patient's with peripheral pulmonary nodules measuring 10-30 mm
 - primary outcome was diagnostic accuracy (strict criteria), secondary outcome was complications
 - 79% yield a navigational bronch group versus 73.6% in TTNB group (p=0.003 for noninferiority)
- ssRAB and mCBCT for peripheral pulmonary nodules (median size 14 mm, 8 mm from pleura)—155 consecutive patients, multicenter
 - Diagnostic yield (strict) 89%, sensitivity for malignancy 91.5%
 - No pneumothorax, and two grade 3 bleeding events



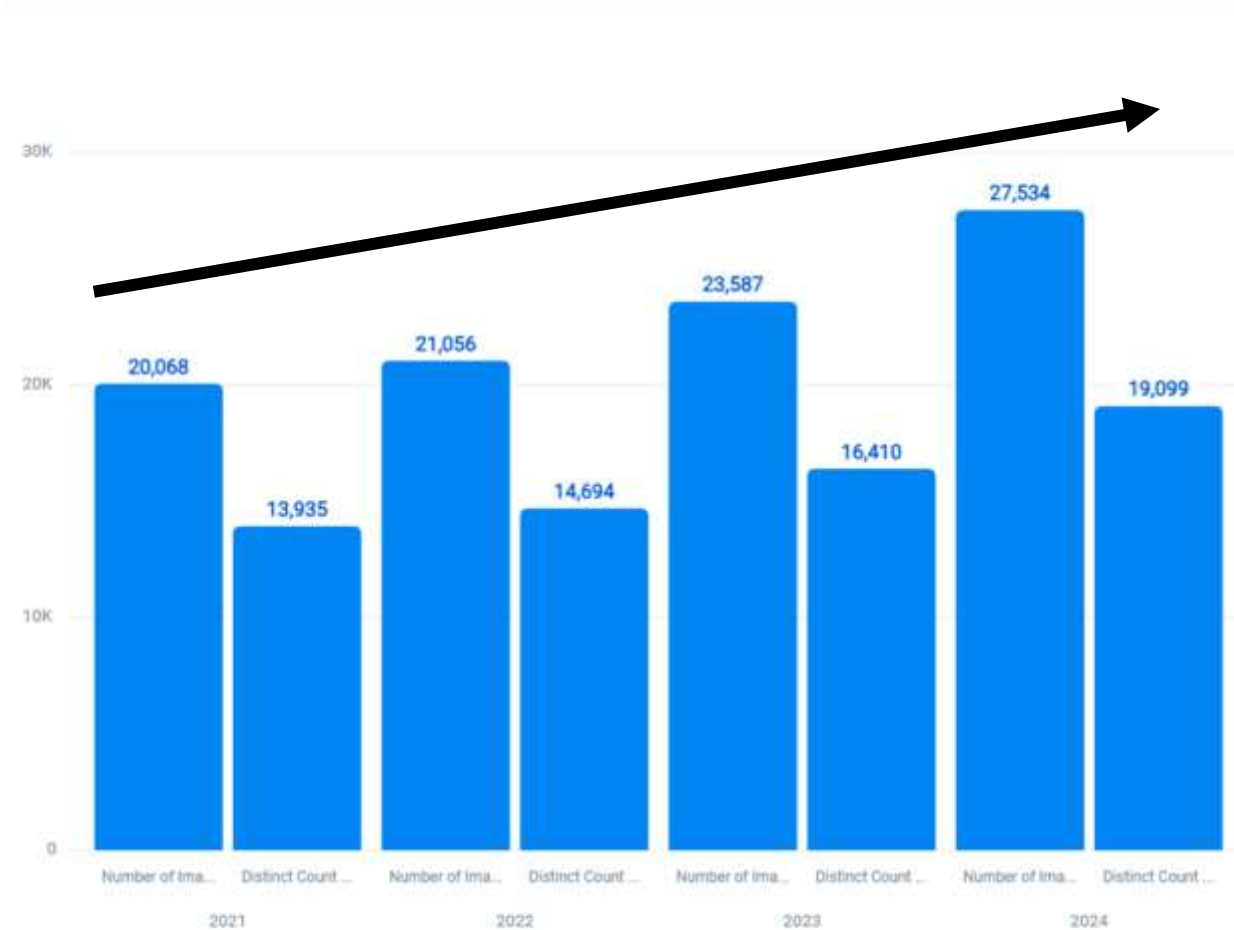
1. Lentz RJ, et al. N Engl J Med. 2025 Jun 5;392(21):2100-2112
2. Husta BC, et al. J Thoracic and Cardiovasc Surg. 2025; 170(4): 945-954

TTNAs done at Eisenhower

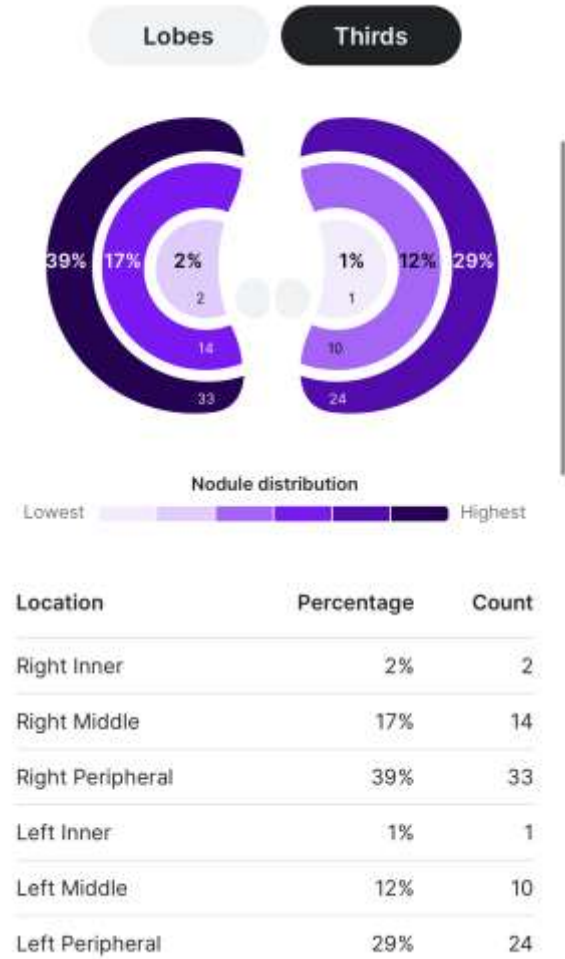
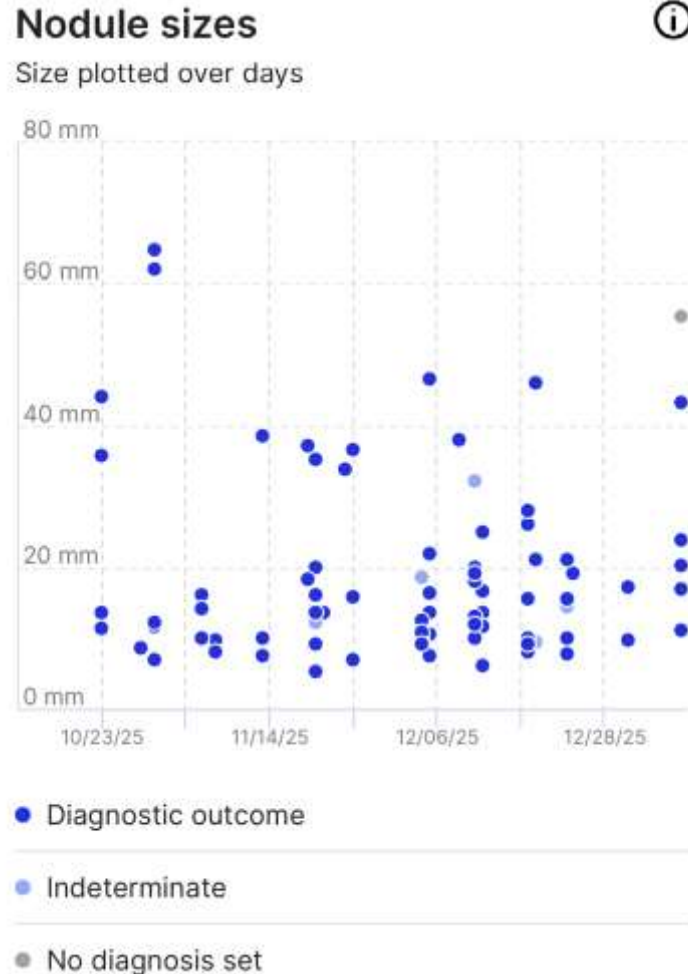
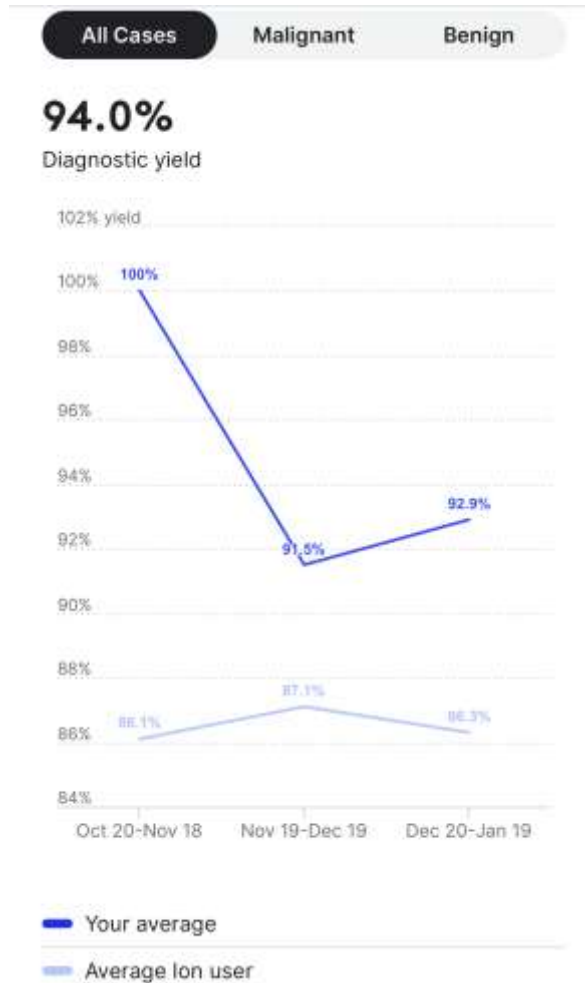
TTNA



CT Scans involving Chest at EMC



My Ion Robotic Bronchoscopy Data (Last 3 Months)



Thomas: 585 Cases since 2/15/24; De Silva: 150 Cases since September 2024

Incidence of Pulmonary Nodules

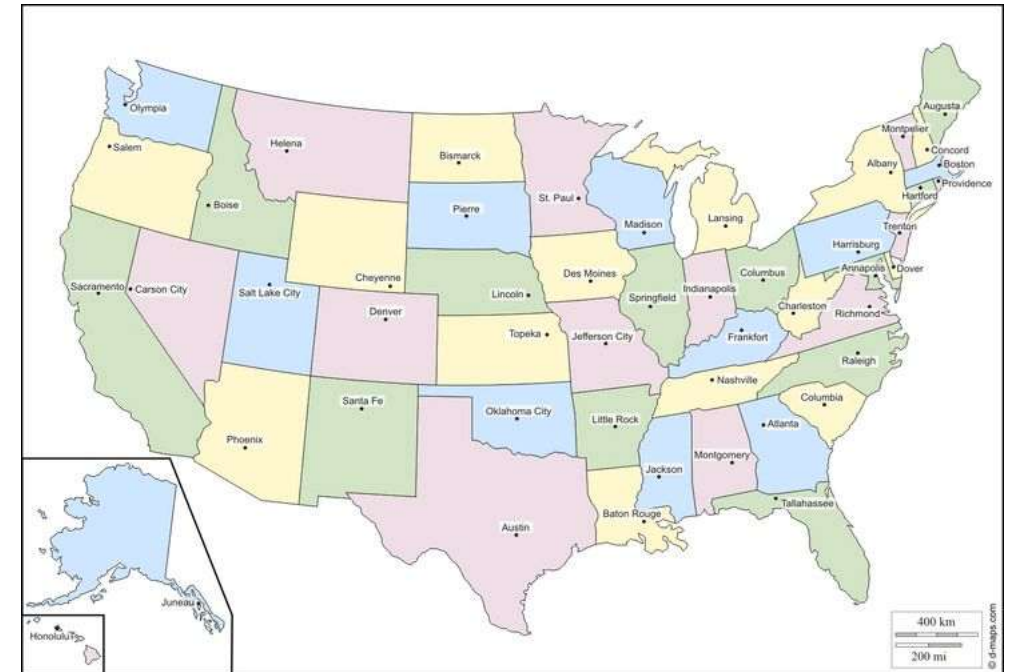
1. Dr. Michael Gould investigated the nodule incidence in 4.6M adults in Kaiser Permanente Southern California

5% of Adults Received a Chest CT

32% of members who had CT had a pulmonary nodule

2. According to the American Thoracic Society (ATS), 50% of adults who undergo CT scans will have one or more pulmonary nodules

1.6M incidental lung nodules



Estimated Annual US Incidence

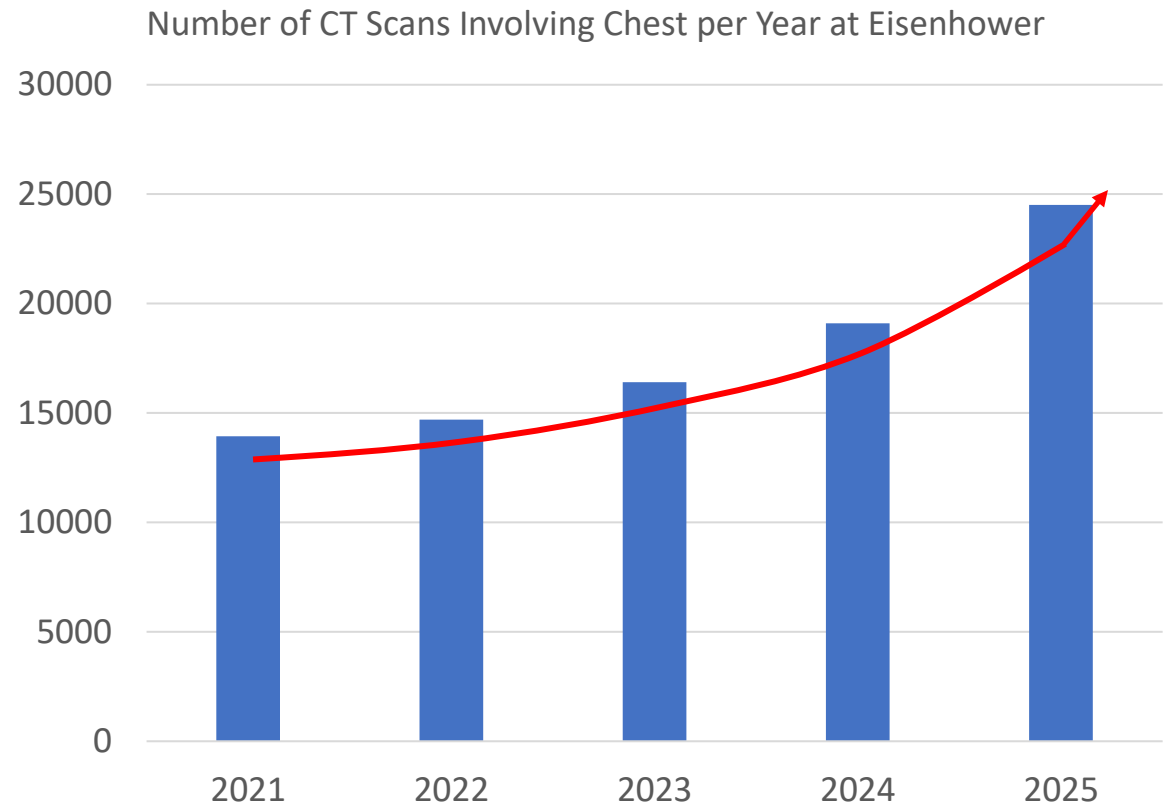
2024 Eisenhower Chest CT Volume

- Based on 2024, with 19,098 CT Scans involving the chest in unique patients:
 - **32-50%** will reveal pulmonary nodules^{1,2}:
6,111-9,549
(7,830 pts)
- **90%** will need follow up scans:
7,047 pts

10-20% will need biopsy:
1,174 pts

8-10% will be cancer:
704 pts

How are we going to handle this volume?



Based on first 2 quarters numbers)

1. Am J Respir Crit Care Med. 2015 Nov 15;192(10):1208-14

2. Eur Radiol. 2023 Jun 20;33(11):8279-88

2025 Eisenhower Chest CT Volume

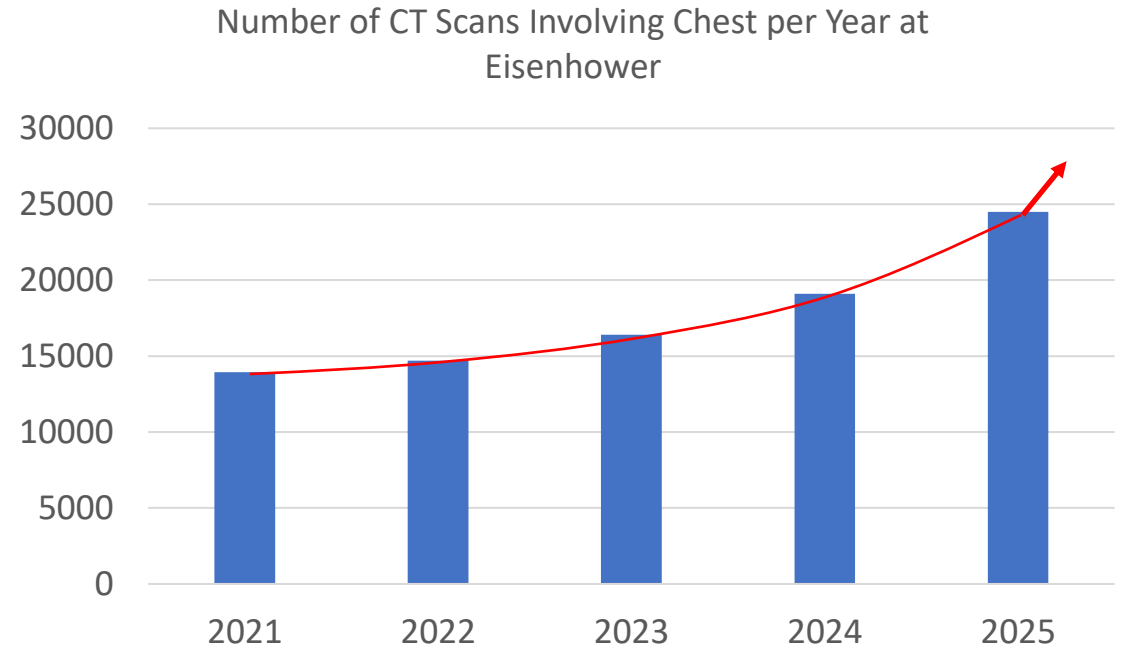
- Anticipate 25,000 CT Scans involving the chest in unique patients:
32-50% will reveal pulmonary nodules^{1,2}:
8,000-12,500 (10,250 pts)
- 90% will need follow up scans:
9,225 pts

10-20% will need biopsy:

1,538 pts

8-10% will be cancer:

923 pts



Based on first 2 quarters numbers)

How was I going to handle this volume?

1. Am J Respir Crit Care Med. 2015 Nov 15;192(10):1208-14

2. Eur Radiol. 2023 Jun 20;33(11):8279-88

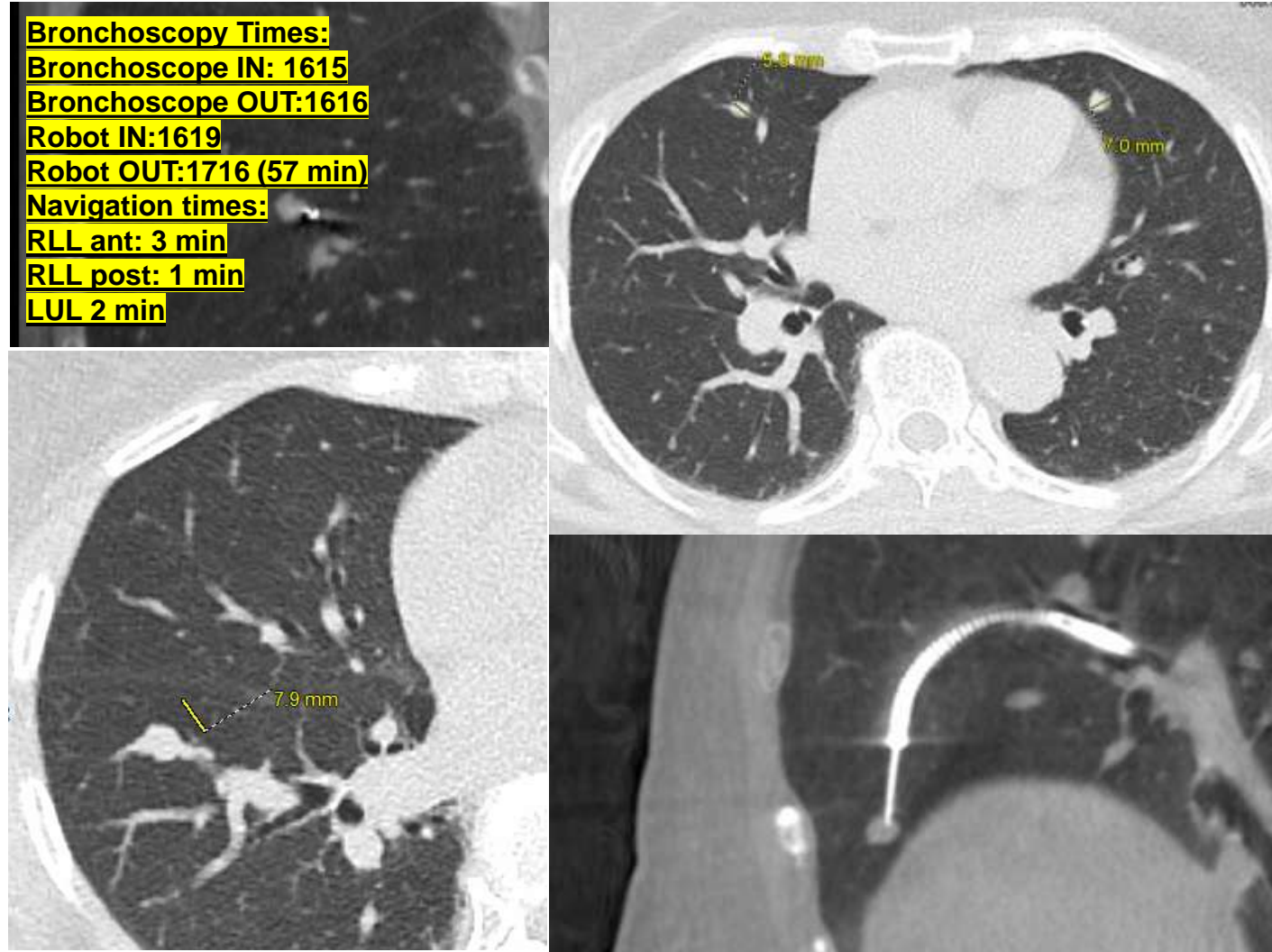
Eisenhower Health was the First to Implement Flip Rooms for Robotic Bronchoscopy in the Country

- Interventional Pulmonary and Critical Care physicians are busy, and have limited time in a week to do procedures
- Flip rooms have decreased wait time for patients and optimized physician time to be able to do 7-8 robotic bronchoscopies in a single day (previously 4-5 in a day).

	Current State	Flip Room without Additional Anesthesia	Flip Room with Additional Anesthesia
Daily	5	7	9
Weekly	10	14	19
Monthly	40	56	72
Quarterly	130	182	234
% Increase	-	40%	80%

Impact of flip rooms

- Ion has given me confidence to go after more nodules.
- I won't turn anything down. Volume is exponentially growing
- Instilled confidence on how quick I get patients in and accuracy in yields
- Getting patients in quickly improves outcomes
- Doing more in the same amount of time has helped significantly with my productivity so I can still get to other responsibilities without giving them up
- Backlog of patients: cut down the time to get in for a biopsy down by 50%



My Ion Robotic Bronchoscopy Experience

1st Year Numbers

Type of Encounter	Number of Cases
Total Ion Cases	321
Primary Lung Cancer	127
Stage I	103 (81.1%)
Surgeries Performed	66 (6 SABRE)
Radiation Therapy	53 (total)/46 (lung)

← Up from 40% with Monarch

← 19% of total cases
48% of lung cancer cases



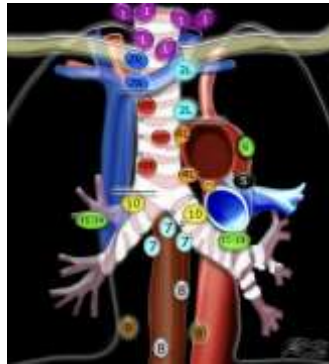
Why is Referral to a Dedicated Interventional Pulmonary Service Important?

- Referral to a dedicated Interventional Pulmonologist decreases wait time before treatment initiation for new lung cancer diagnoses¹
 - 87 pts with new dx lung cancer or metastatic cancer to chest
 - Median of 27 days passed from diagnostic biopsy to treatment initiation.
 - Median of 53 total days passed from abnormal imaging to definitive treatment.
 - EBUS commonly used (59%), NSCLC (64%)
 - For surgical patients, all biopsy-negative lymph nodes were cancer-free at surgical excision

Why refer to an Interventional Pulmonologist?



Can biopsy multiple nodules at the same time



Can stage the mediastinum at the same time

Baseline rate of occult lymph node mets at time of surgery is 3-19%

- Tumors ≤ 1 cm have nodal positivity of 4-7%
- Tumors 2-3 cm approach 13-19%



Lower risk procedure (1-3% risk of PTX/complication vs 15-45% with TTNA)¹



We have a team of providers (pulmonologists, trainees, mid-levels, RTs) who can expedite workup, schedule appropriate tests including procedures, and follow up after procedures to arrange appropriate referrals to thoracic surgery, oncology, radiation oncology, etc.



Most Interventional Pulmonologists direct tumor boards



Connected and have long-standing collegial relationships with thoracic surgery, radiology, radiation oncology, medical oncology

1. Nam BD, et al. Korean J Radiol. 2021 Dec;22(12):2082-2093.

Lung Tumor Ablation Framework

- **Goal:** local tumor control for patients who are **not surgical candidates** or who need a **parenchymal-sparing** option
- Common clinical lanes
 - **Early-stage peripheral NSCLC** in medically inoperable patients
 - **Oligometastatic / oligoprogressive lung metastases** (local control to maintain/extend systemic therapy benefit)
 - **Recurrence after SBRT / surgery**, selected cases
- Conceptual “menu” (multidisciplinary): **Surgery ↔ SBRT ↔ Image-guided ablation** (choice driven by tumor size/location + comorbidity + prior therapy)

Transthoracic Image-Guided Thermal Ablation: Big Picture

- Approach: CT (most common) or CT-fluoro guidance; percutaneous probe placement; planned ablation zone with margin
- Modalities
 - **RFA:** resistive heating; more “heat-sink” sensitivity
 - **MWA:** faster heating, larger zones, less heat-sink effect
 - **Cryoablation (CA):** Freeze-thaw injury; visible “ice ball”, often less intraprocedural pain
- Practical Selection Drivers
 - **Size:** ideal ≤ 3 cm (local control decreases as size increases)
 - **Location:** pleura, fissures, central structures, vessels/airways, proximity to diaphragm
 - **Patient factors:** lung reserve, anticoagulation/bleeding risk, ability to tolerate pneumothorax/atelectasis, pacemaker/defibrillator (RFA less well tolerated of the three)

Transthoracic Radiofrequency Ablation (RFA)

- Mechanism: alternating current → ionic agitation → **coagulative necrosis**
- Strengths
 - Long track record; widely available; cost familiar
- Limitations
 - **Heat-sink effect** near larger vessels (reduced margin)
 - Slower heating; ablation zones can be smaller vs MWA for same time
 - Performance decreases with **>3 cm** lesions (often needs overlapping ablations)
- Outcomes
 - Guideline-supported option in selected **inoperable peripheral early-stage NSCLC** and lung metastases cohorts
- Complications (common)
 - **Pneumothorax** (most common—11-52%), pleural effusion, hemoptysis; rare bronchopleural fistula

RFA Trials

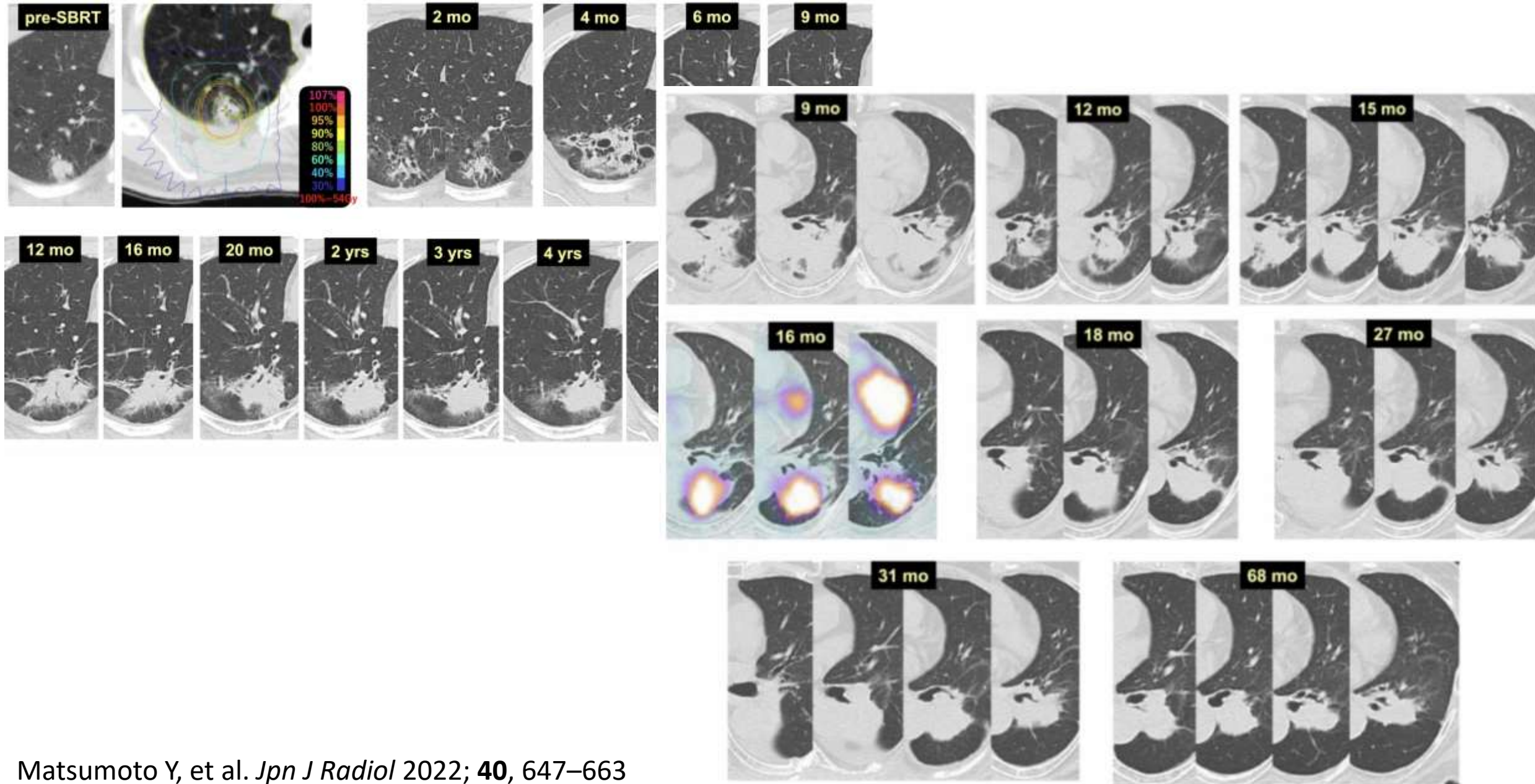
- More recently, the results from two prospective multicenter studies were reported.
 - 2015 Dupuy et al.: American College of Surgeons Oncology Group (ACOSOG) Z4033 Trial prospectively evaluated RFA for stage IA NSCLC in medically inoperable patients¹
 - OS rates at 1 and 2 years were 86.3% and 69.8%, respectively
 - Local recurrence-free survival rate at 1 and 2 years of 68.9% and 59.8%, respectively
 - 2018 Paulussière et al: prospective multicenter trial on RFA for stage IA NSCLC in 32 patients²
 - 1- and 3-year OS rates were 91.67% and 58.33%, respectively
 - 1- and 3-year progression-free survival rates were 71.76% and 25%, respectively
 - Metanalysis for SBRT vs. RFA³
 - For SBRT, the LC rates (with 95% confidence intervals) at 1, 2, 3, and 5 years were 98% (97–98%), 95% (95–96%), 92% (91–93%), and 92% (91–93%),
 - RFA [75% (69–82%), 31% (22–39%), 67% (58–76%), and 41% (30–52%), respectively (P<0.01).
 - Complications: \geq Grade 2 in 9.1% of patients treated with SBRT, while pneumothorax was the most common complication of RFA, making up 27.2%

1. Dupuy DE, et al. Cancer. 2015 Oct 1;121(19):3491-8. doi: 10.1002/cncr.29507.

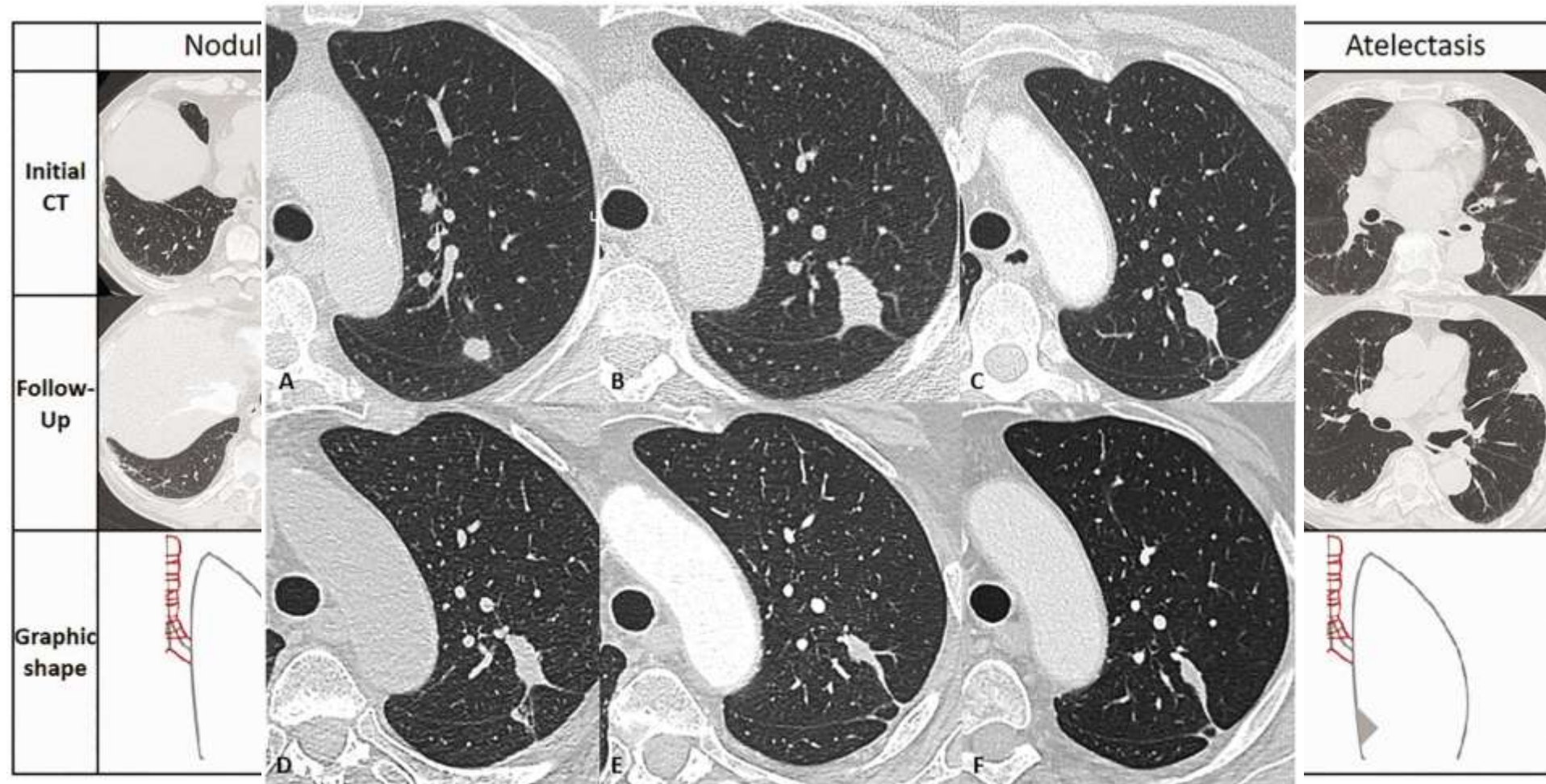
2. Palussière J, et al. J Cardiothorac Surg. 2018 Aug 24;13(1):91. doi: 10.1186/s13019-018-0773-y.

3. Zhang R, et al. Ann Transl Med. 2022 Jan;10(2):104. doi: 10.21037/atm-21-6256

What about changes after SBRT vs. PEF?



What about evolution of Radiographic change for RFA?



Pulsed Electric Field Ablation: A Non-Thermal Ablation Technique

Aliya PEF Ablation Delivered Percutaneously or Endoscopically



**INUMI Flex Endoscopic Needle
with electrode**



21 Ga



Aliya PEF Generator



**Aliya Percutaneous Needle
with electrode**

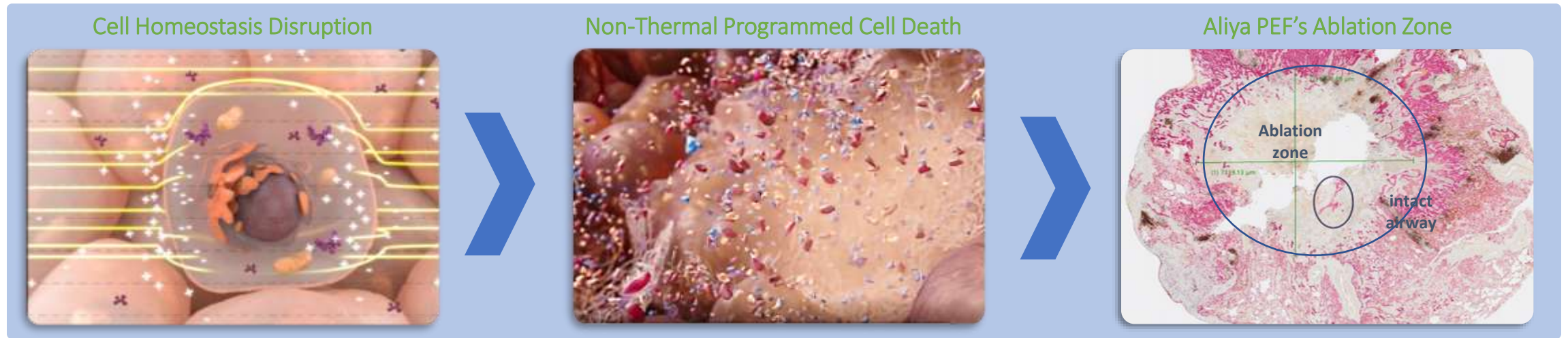


19 Ga

Delivered endoscopically, percutaneously, or with an open surgical procedure
Via same electrode and generator

* TR-00261 - Approximate ablation dimensions for one energy delivery based on in vivo porcine liver data. Zones involve additional tolerances.

Aliya Pulsed Electric Field (PEF) Ablation Induces Cell Death Through Non-Thermal Mechanisms



Aliya PEF consistently delivers high voltage, short duration electrical energy to alter the transmembrane potential of cells in target soft-tissue lesions, disrupting homeostasis and inducing non-thermal cell death while preserving the extracellular matrix and sensitive tissues.

INCITE-ES Study – Safety, Technical Success and Response



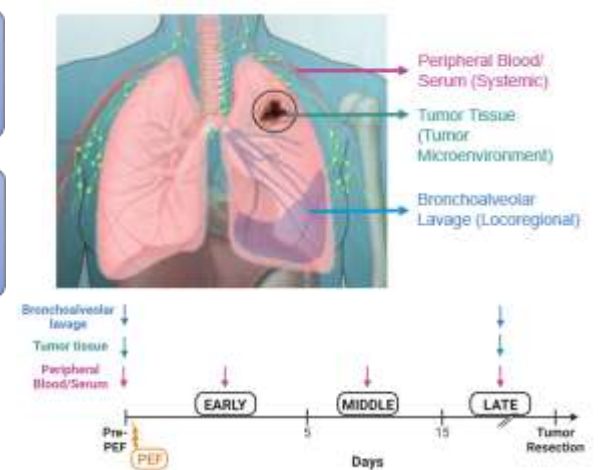
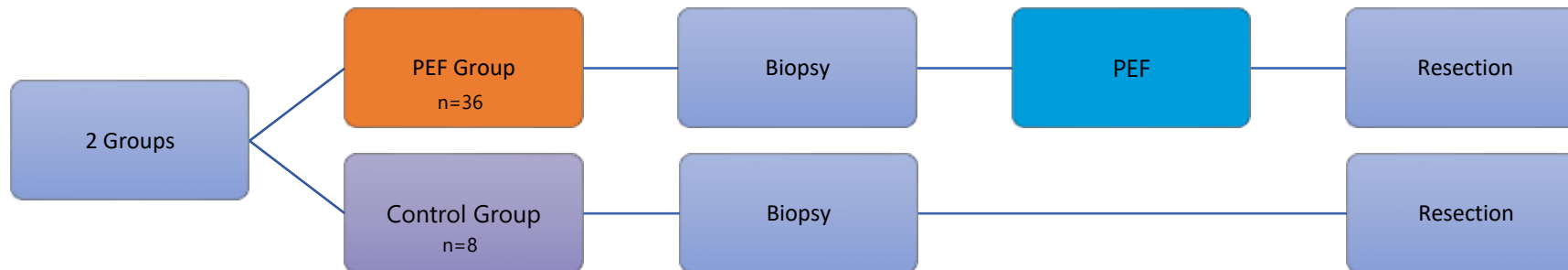
Study Criteria

- Stage IA2-IB 1° NSCLC; treatment naïve
- Planned resection
- Endoscopic or percutaneous treatment

Clinical Outcomes

- Primary Outcome: Safety
- Clinical Utility Endpoint: Technical success
- Other Outcomes: Induced immune response relative to control (blood, tissue, TME)

Intent was partial treatment independent of tumor morphology or tumor size to assess safety, dose stability, and the potential for immune engagement

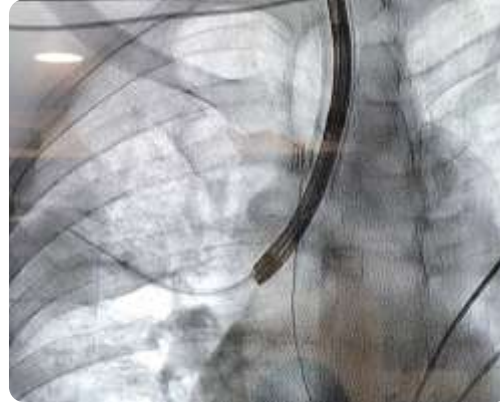


100% Technical Success Endoscopically (n=26) and Percutaneously (n=10)

Baseline



Intra-procedure



Post-procedure



Key outcomes:

100% technical success

No changes to planned surgical resection approach, nor impact to surgical field

No device related adverse events

Before Resection



Resection Day 18



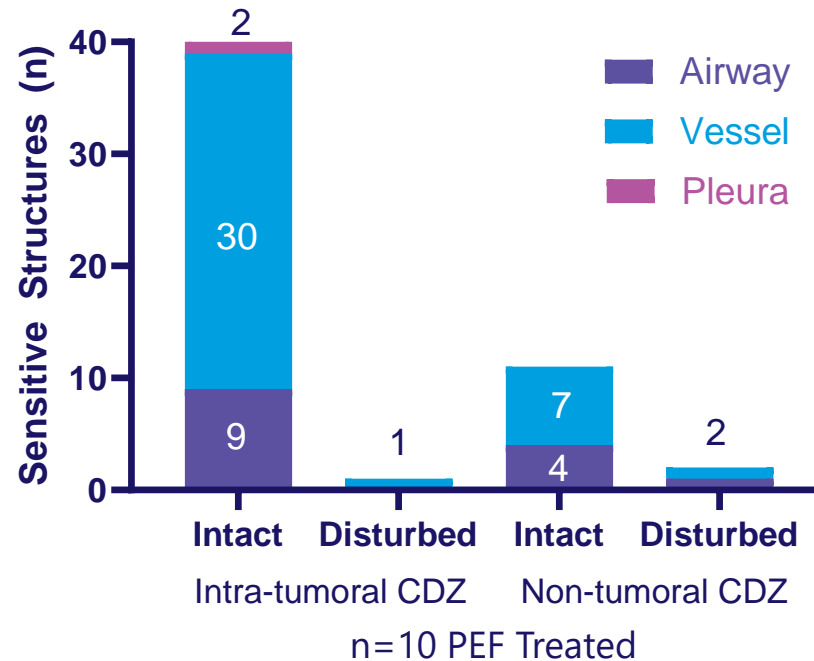
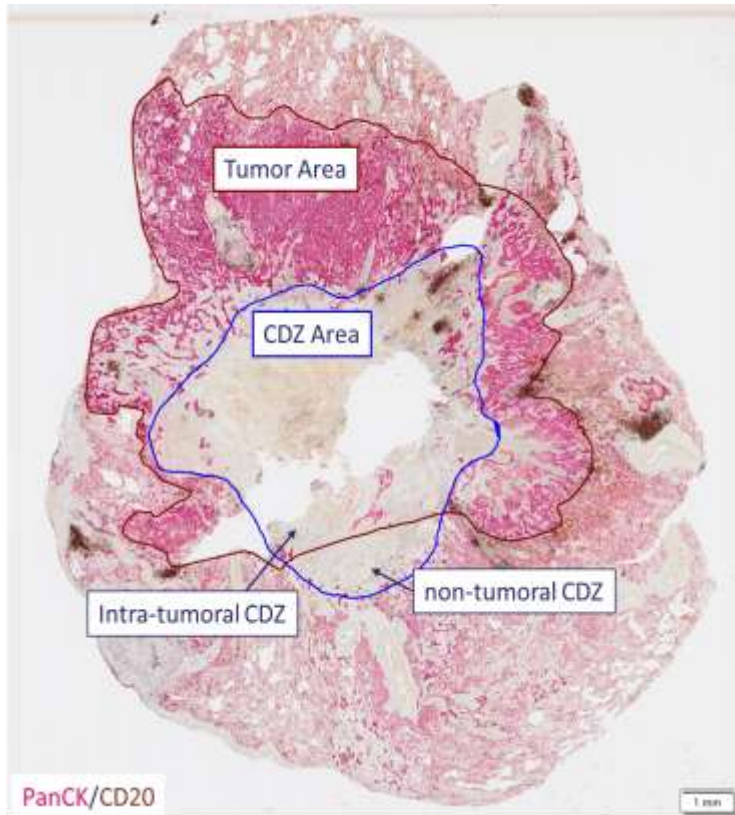
INCITE ES Demonstrated No Aliya PEF Related SAEs

- There were no serious adverse events related to Aliya PEF
- There were 5 non-serious adverse events with causal relationship or possibly related

All Non-Serious Adverse Events with Causal/Possibly Related by CTCAE Grade				
PEF Treatment	Mild	Moderate	Severe	Grand Total
CAUSAL RELATIONSHIP	1			1
Pneumothorax*	1			1
POSSIBLY RELATED	3	1		4
Post procedural discomfort		1		1
Hemoptysis	1			1
Oropharyngeal pain	1			1
Pneumothorax*	1			1
Grand Total	4	1	0	5

Note: None of the events were related to device.

Predictable Decellurization and Sensitive Structures Integrity Demonstrated Post Aliya PEF Ablation

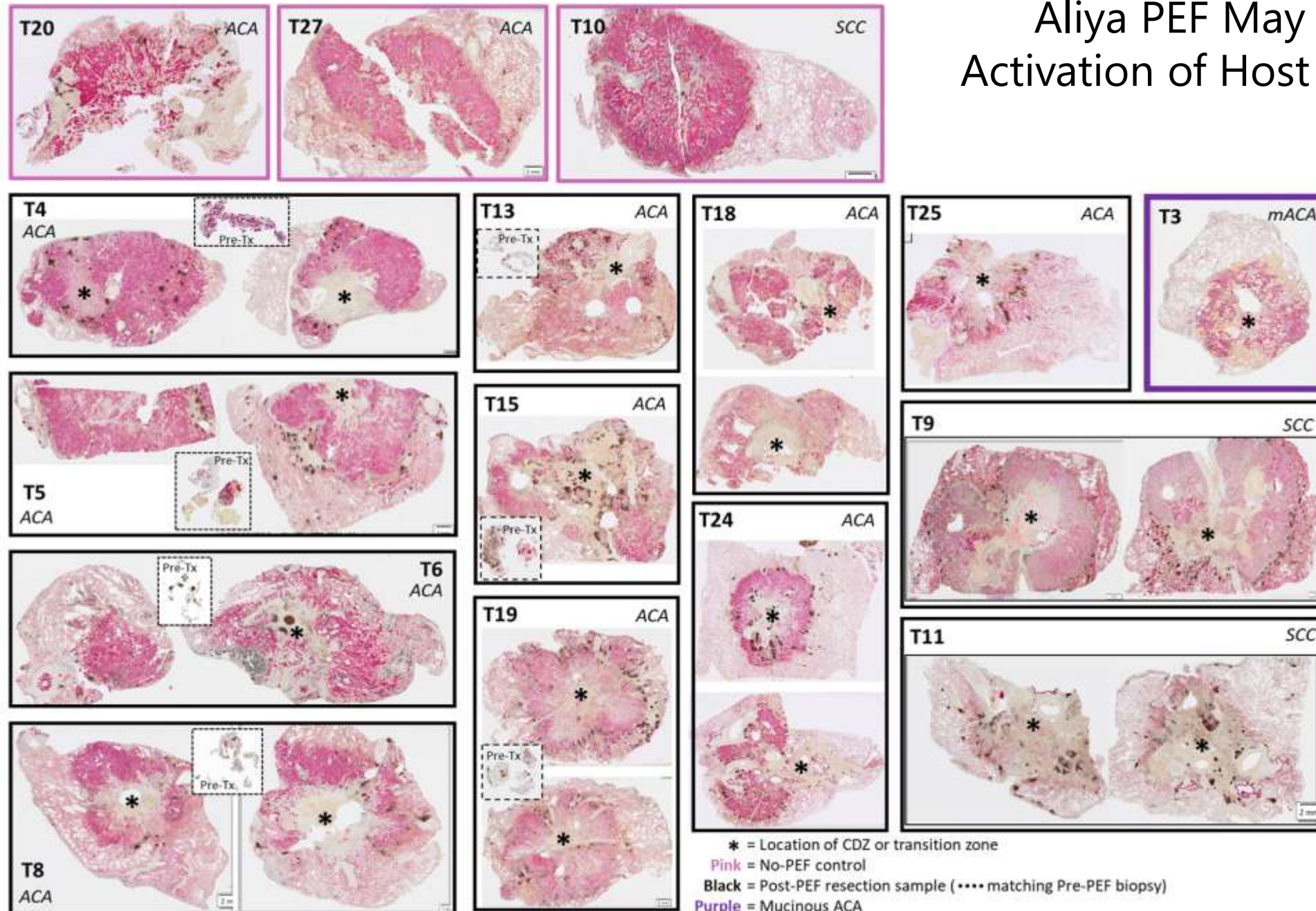


Significant decrease or absence of tumor cellularity and a variable degree of inflammation

Over 95% of all structures were viable and unaffected by PEF. The alterations that were present were arguably tumor induced

Only 3 out of 55 (6%) of the structures assessed showed some distortion and all three were in the transition zone

Aliya PEF May Induce a Stepwise Activation of Host Anti-Tumor Immunity



PEF induces the formation of TLS within the tumor, including within the PEF delivery zone in early-stage patients with NSCLC




TLS density and maturity observed may suggest ongoing immune activity

As such, PEF has the potential to induce or enhance an immune response irrespective of tumor morphology



Research Paper

Early experience with PEF in the setting of recalcitrant stage IV lung cancer

William H. Moore ^{a,*} , Mikhail Silk ^a, Priya Bhattacharji ^a, Bradley B. Pua ^b ,
Joseph Mammarrappallil ^c, Daniel H. Serman ^d , Abraham Chachoua ^d

- Retrospective review of patients treated with PEF at three academic institutions from January 2023-July 2024
- 41 patients with stage IV non-small cell lung cancer
- Propensity matched cohort of 50 patients with advanced NSCLC undergoing systemic therapy
- PEF-treated cohort had 1-year PFS of 63.2% and OS of 74.3% with matched cohort 1 year PFS of 11.8% and OS of 33%. PFS HR 3.66 and OS was 3.5

Table 1

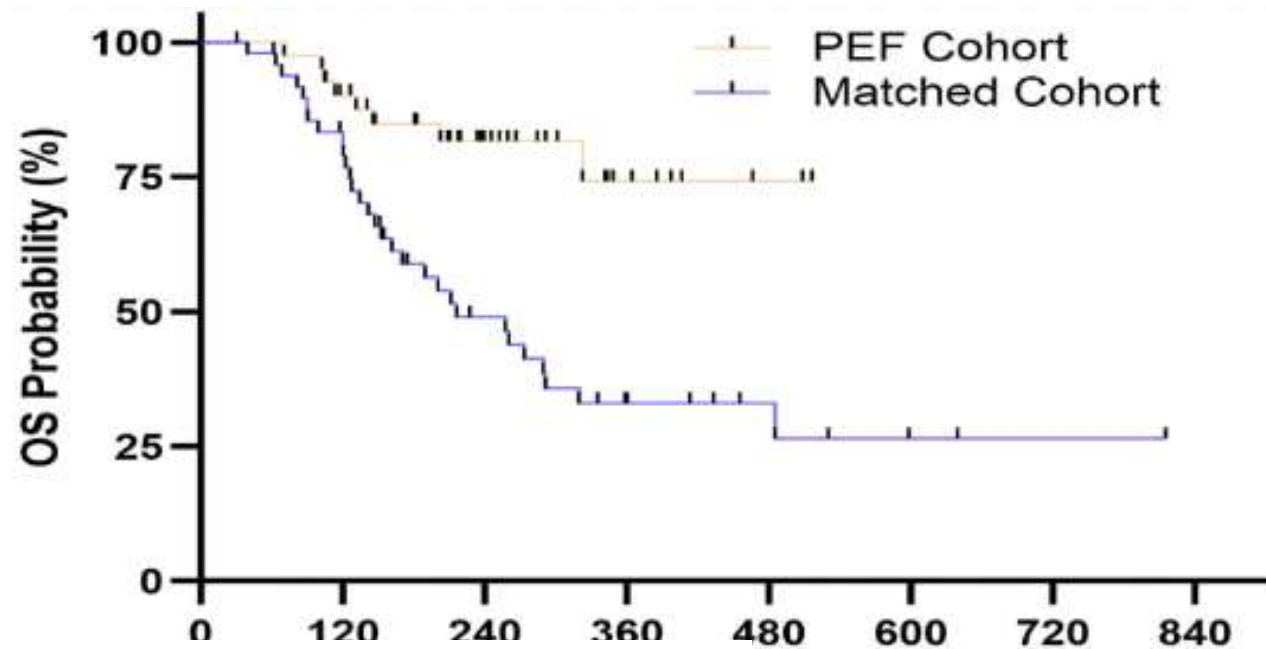
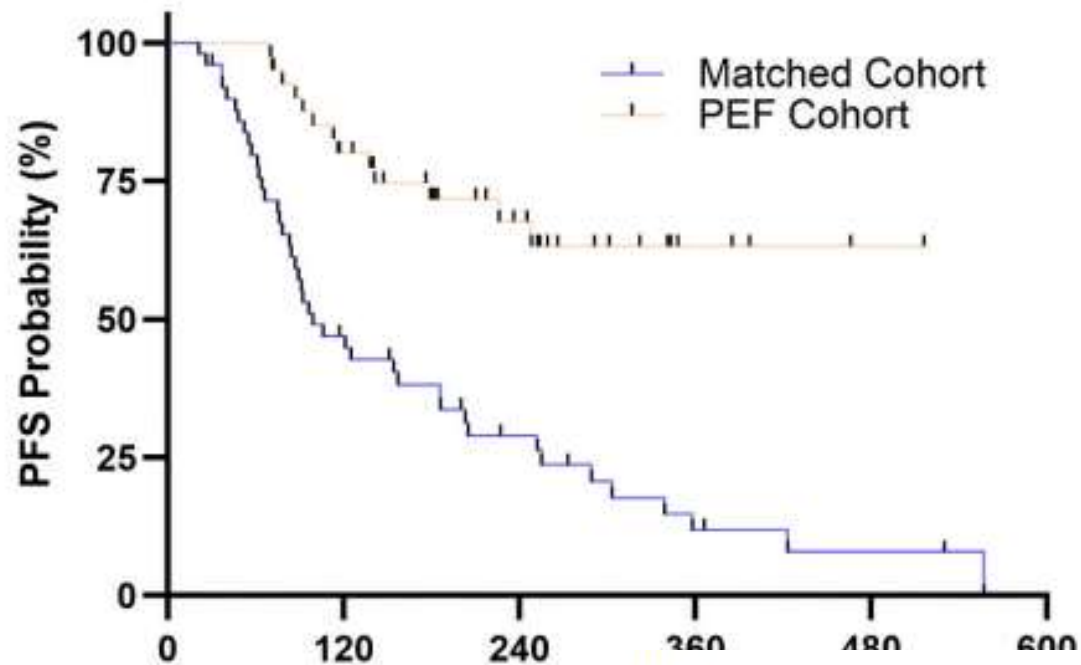
Demographics.

	PEF cohort	Match cohort	p Vaues
Age (SD)	71.2 (10.1)	64.4 (10.6)	0.15
Number of patients	41	50	
Male female ratio	18:23	24:26	0.85
ECOG (SD)	1.1 (0.6)	0.9 (0.7)	0.27
Number of prior treatments (SD)	1.9 (0.6)	1.66 (0.7)	0.18
Squamous Cell (%)	5 (12.2 %)	9 (18 %)	0.32
Adenosquamous (%)	1 (2.4)	1 (2 %)	0.99
Adenocarcinoma (%)	35 (87.8 %)	40 (80 %)	0.32
PDL High (%) *	8 (17.1 %)	18 (34.6 %)	0.15
PDL intermediate (%)	3 (7.3 %)	4 (7.6 %)	0.15
PDL low (%)	31 (75.6 %)	30 (57.7 %)	
EML-4 ALK	1	2	0.41
EGFR L858R	6	8	0.49
EGFR Exon 19 Deletion	4	8	0.54
EGFR Exon 20	0	5	0.04
Ros-1	1	1	0.99
K-Ras	6	9	0.36

Table 2

Percentage of Tumor Volume Ablation and Outcome.

	Less than 60 % ablation (SD), n = 16	Greater than 61 % ablation (SD) n = 25	P Value
Mean Target Tumor Volume (cm ³)	78.3 (73.2)	2.2 (2.4)	P = 0.005
Mean Ablation Volume (cm ³)	4.6 (2.8)	2.6 (2.0)	P = 0.007
Mean Number of Activations	6.8 (4.2)	3.8 (3)	P = 0.007
Mean Days of Survival	179.5 (71.5)	284.2 (117.5)	
OS (%)	60.9 (19.8–82.1)	83.7 (54.3–94.9)	P = 0.03
RECIST Response	PR: 0 SD:12 PD: 4	PR: 3 SD: 16 PD: 6	



D Table 3
Survival comparing PEF and Matched Cohort.

	Number at Risk		
PEF	41	32	17
Matched	50	23	12
	0	120	240

	Percent Survival at 1 year (95 % CI)	Median Survival (days)	Hazard Ratio (95 % CI)	p value
PEF Cohort PFS	63.2 % (44.1–77.3)	N/A	3.7 (2.2–6.2)	<0.0001
Matched Cohort PFS	11.8 % (5.7–24.4)	99		
PEF Cohort OS	74.3 % (51.4–87.6)	N/A	3.5 (1.7–5.8)	0.0007
Matched Cohort OS	33.0 % (19.2–47.4)	216		

/S			
3	0	0	0
5	3	1	1
480	600	720	840

Survival as a Function of Percent Ablated

	Less than 60% ablation (SD) n=16	Greater than 61% ablation (SD) n=25	P Value
Mean Target Tumor Volume (cm ³)	78.3 (73.2)	2.2 (2.4)	P=0.005
Mean Ablation Volume (cm ³)	4.6 (2.8)	2.6 (2.0)	P=0.007
Mean Number of Activations	6.8 (4.2)	3.8 (3)	P=0.007
Mean Days of Survival	179.5 (71.5)	284.2 (117.5)	HR = 4.2 (95% CI: 0.9-19.7)
1-yr OS (%)	60.9 (19.8-82.1)	83.7 (54.3-94.9)	P=0.03
RECIST Response	PR: 0 SD: 12 PD: 4	PR: 3 SD: 16 PD: 6	










AFFINITY Trial 6 Month Data

- Prospective, non-randomized, open-label, single-arm study evaluating the safety, immunological impact, and preliminary efficacy of Aliya PEF ablation in patients with solid tumors
- 31 patients enrolled, 30 received ablation (100% coverage of lesions) prior to continuation on SOC treatment, 28 received radiological assessment of ablated lesions at approximately 1, 3 and 6 months post-ablation
- At 6 months, two cohorts emerged: 12 received ablation only and 16 received ablation plus systemic and/or focal therapies (XRT or second ablation)



Article

Six-Month Local Control Rates and Immune Responses After Pulsed Electric Field Ablation in Metastatic Cancer

Alicia Moreno-Gonzalez ¹, Ebtesam H. O. Nafie ¹, Chiara Pastori ¹, Joseph Mammarrappallil ², Partha Seshaiiah ¹, Maria B. Plentl ¹, Beryl A. Hatton ¹, Robert E. Neal II ¹, Michael A. Pritchett ³, Janani S. Reisenauer ⁴, Sebastian Fernandez-Bussy ⁵, David DiBardino ⁶, Bradley B. Pua ⁷ and William S. Krimsky ^{1,*}

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⁶ Division of Pulmonary, Allergy and Critical Care, Department of Medicine, University of Pennsylvania, Philadelphia, PA 19104, USA

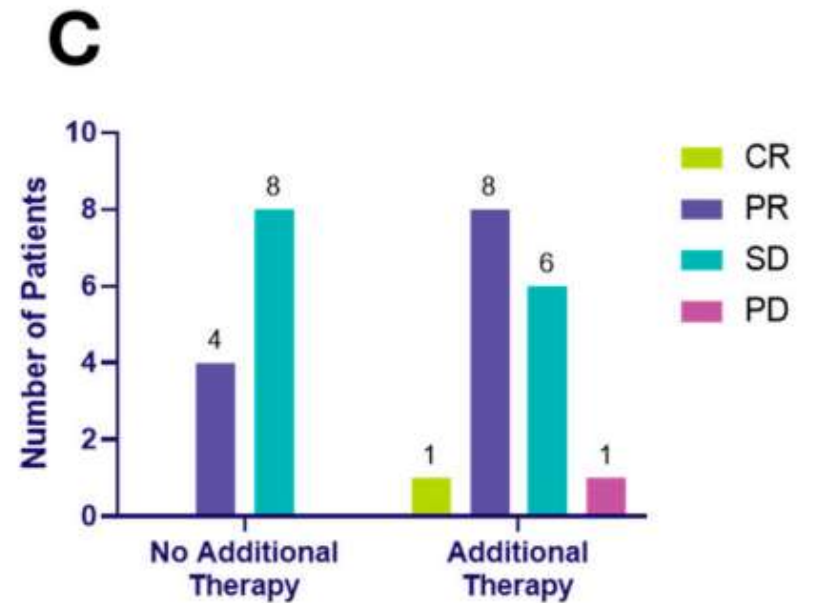
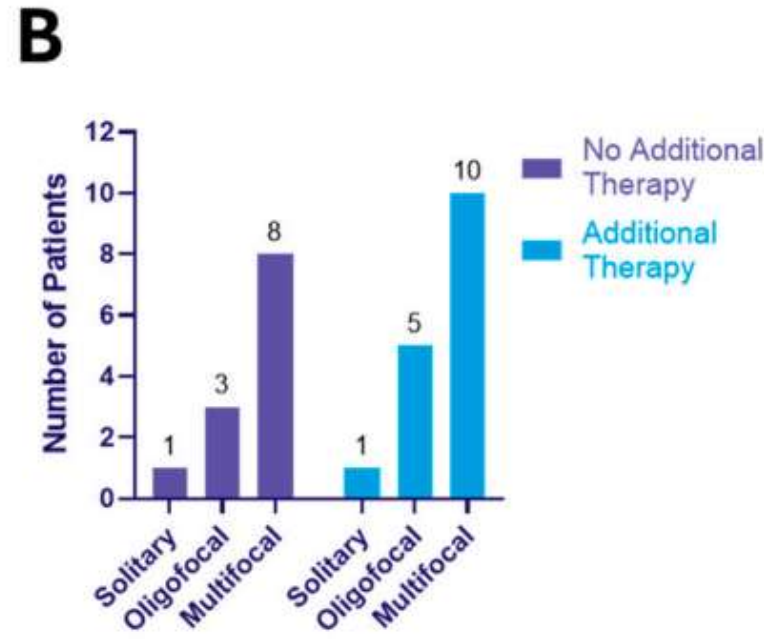
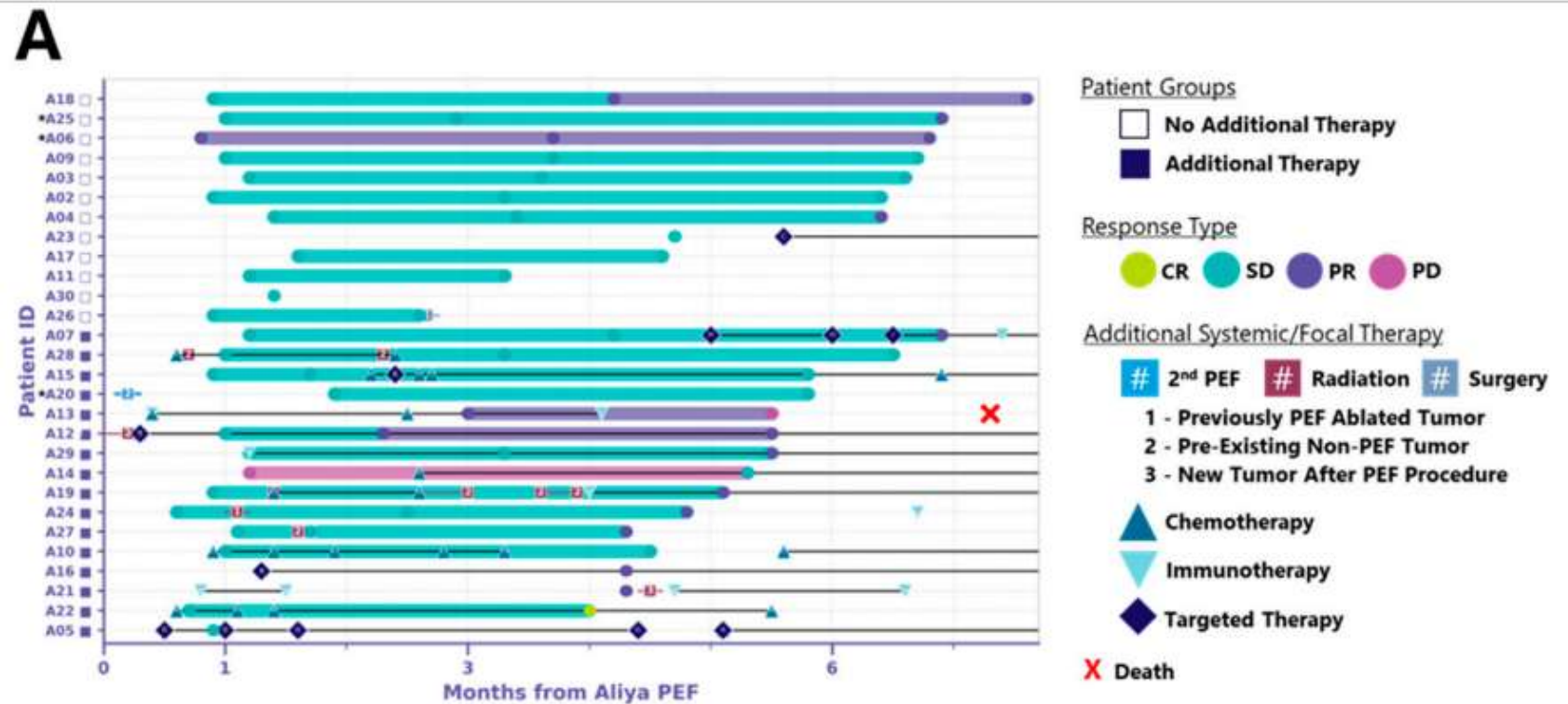
⁷ New York Presbyterian Hospital, Weill Cornell Medicine, New York, NY 10065, USA

* Correspondence: bkrimsky@galvanizetx.com; Tel.: +1-(410)-428-5953

Moreno-Gonzalez A, et al. *Cancers*. 2025; 17(21):3495.
<https://doi.org/10.3390/cancers17213495>

AFFINITY Results (6 months)

- Tumor response was measured by some of longest diameters using recist 1.1 and I had recist where target lesions included only the ablated tumors and included those with longest diameter less than 10 mm
- This did not involve measurement of non ablated lesions as this focused approach was chosen to isolate the local affects of this form of the ablation
- Broader disease response and covering all measurable and non target lesions will be evaluated in the planned 12 month analysis



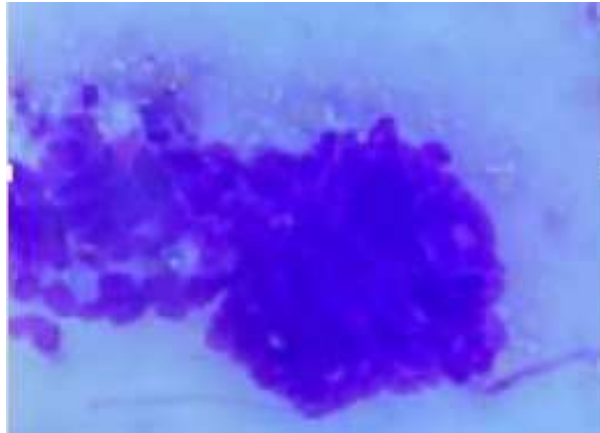
Summary of AFFINITY 6 Month Data

- Obtained local control in ablated tumors in the setting of stage IV disease
- May additionally induce a tumor-specific immune response, as evidenced by perturbation of biopsy-specific antibody production and favorable adaptive immune cell dynamics.
- Does not cause coagulation of structural and cellular proteins
- Activates humoral immunity, leading to increased production of biopsy-specific antibodies, as well as modulation of general TAA-IgG in some patients.
- May have significant implications for integrating focal ablation with immunotherapy strategies, such as checkpoint inhibition.
- Further research is warranted to validate these findings and explore the integration of this form of ablation with emerging immunotherapeutic strategies

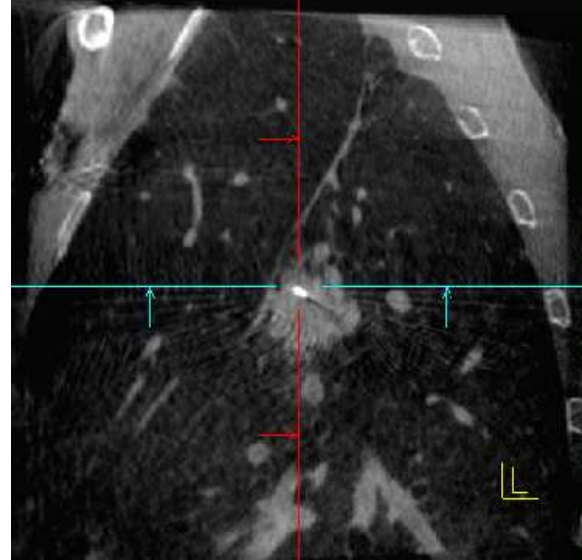
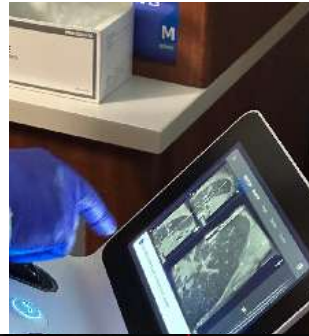
Bronchoscopic Aliya PEF Procedure Overview



Robotic navigation bronchoscopy with biopsy



ROSE confirmation of malignancy



Confirmation of needle not only in target but at distal edge of target



PEF delivery to ensure target coverage

Case 1: 85 y/o patient with metastatic adenocarcinoma of lung and B-Cell lymphoma of the scalp

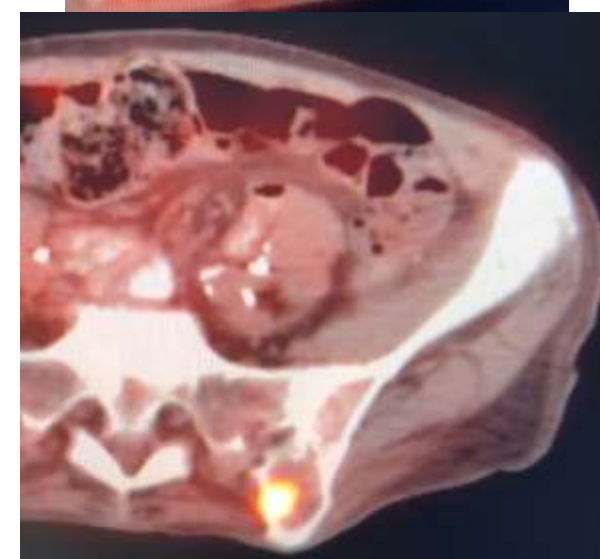
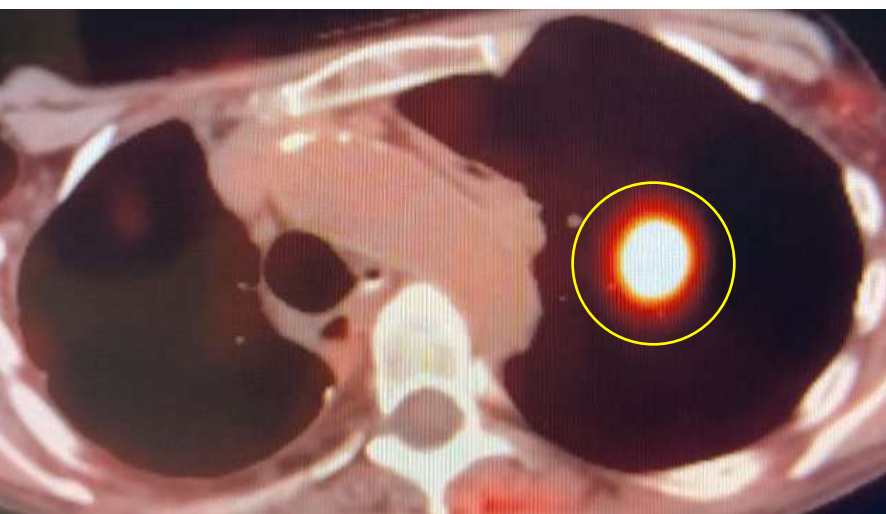
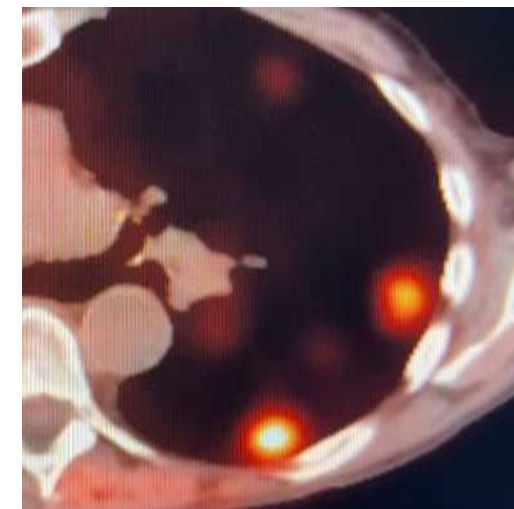
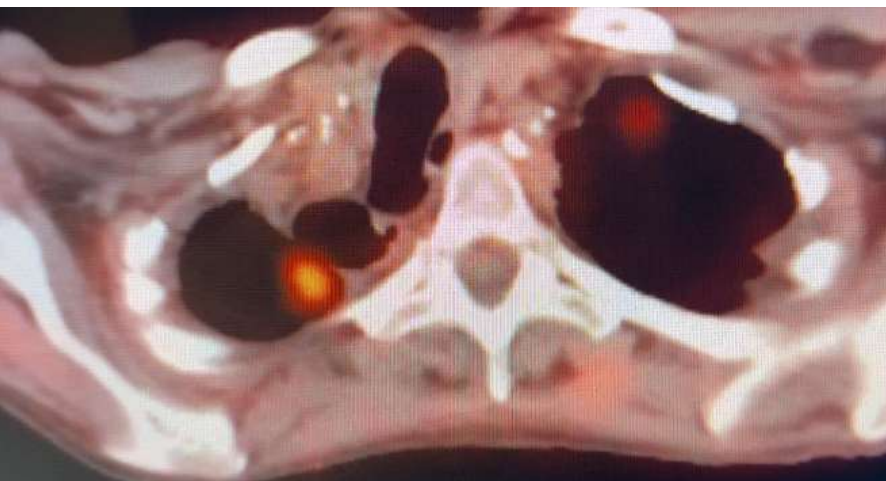
- History of left upper lobe stereotactic body radiation therapy (SBRT) July 2019
- Recurrent right middle lobe adenocarcinoma June 2021 s/p SBRT
- PET CT December 2023 for right hilar mass, underwent EBUS bronchoscopy and recurrent adenocarcinoma
- Progressive disease despite treatment pembrolizumab that started February 2024
- Treated with PEF on 6/18/24
 - Targeted two nodules of left lower lobe only (three treatments on one and two treatments on the other)
 - Both biopsies revealed diffuse large B-Cell lymphoma, germinal center immune type
- Treatment included Keytruda for minimum 6 months prior to PEF treatment
- Started chemotherapy about 1 month prior to post-PEF 3 month follow up scan

Patient with metastatic adenocarcinoma of lung and B-Cell lymphoma involving lung



Only symptom is patient having severe left buttock pain from metastatic lesion to posterior left ilium

Pre-PEF Treatment



(Treated lesion with yellow circle)
Left upper lobe superior 18 x 18
3 treatment zones

(Treated lesion with yellow circle)
Right lower lobe posterior 14 x 10
2 ablations

99 days Post-Treatment, 30 days after starting chemotherapy



Complete Response with pembrolizumab induced pneumonitis

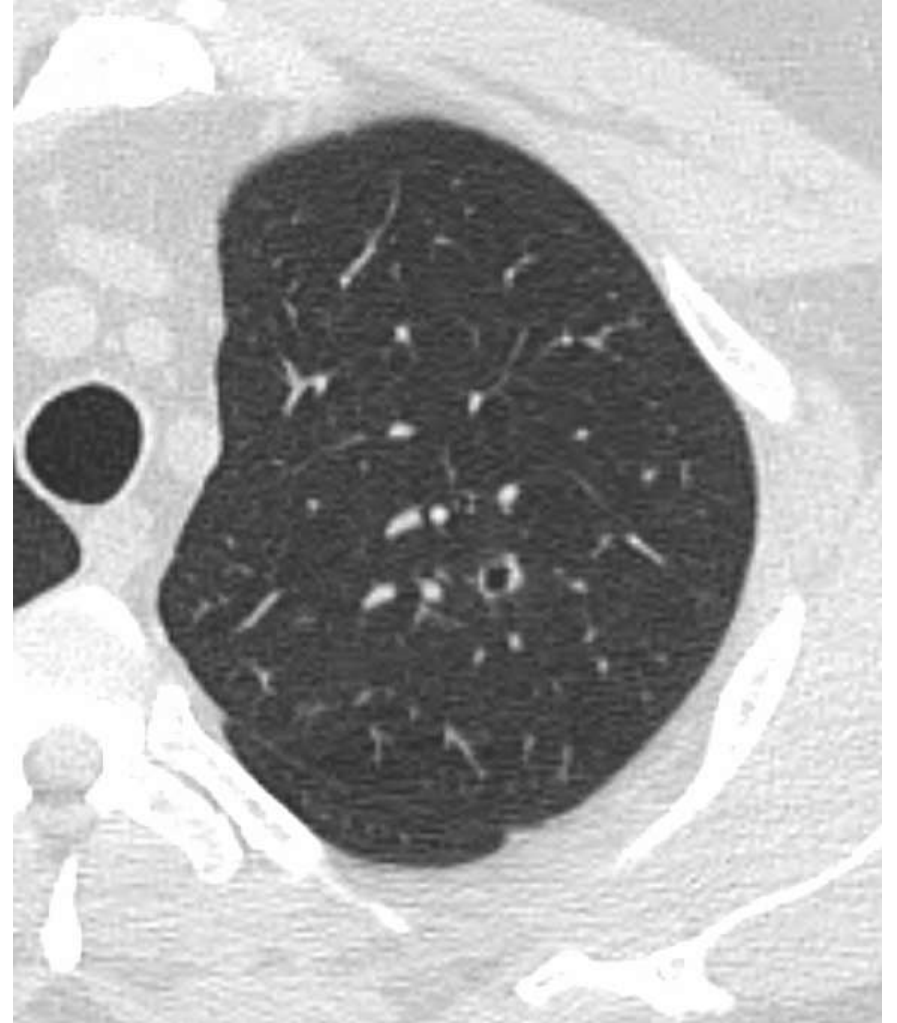
Case 2: 45 year old male with history of Colon Cancer

Diagnosed with rectal adenocarcinoma in 2019 s/p resection after neoadjuvant radiation and treatment with FOLFOX

New nodule in the left upper lobe in April 2024 with subsequent growth on July 2024 scan

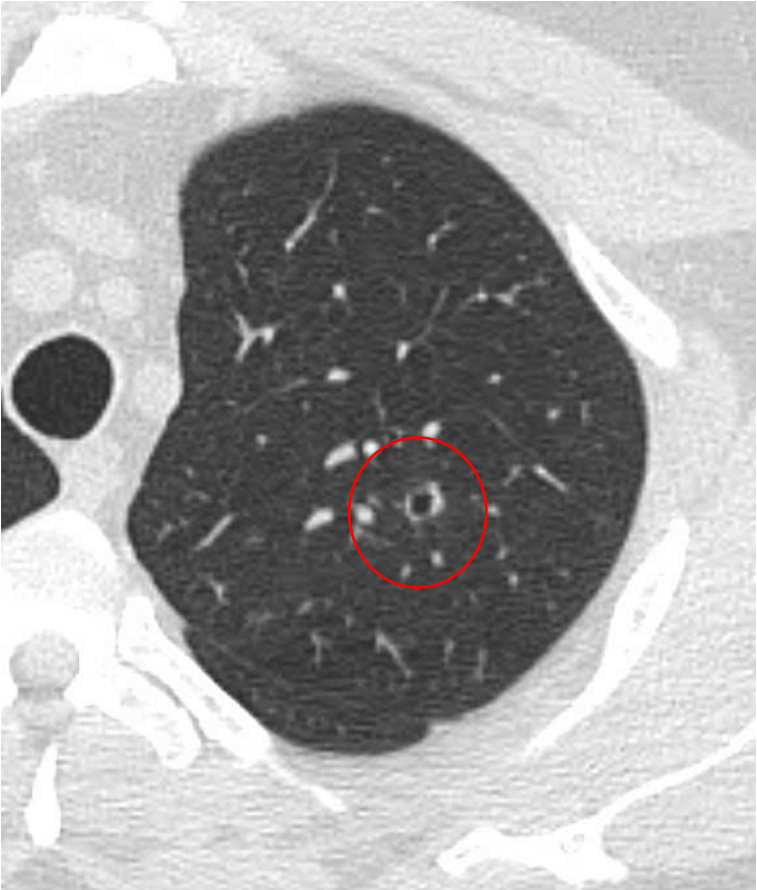
Underwent robotic bronchoscopy on 8/8/24 that revealed adenocarcinoma consistent with colorectal primary

PET CT negative



45 y/o male with metastatic colorectal cancer to lung

9/9/24



PEF
9/12/24

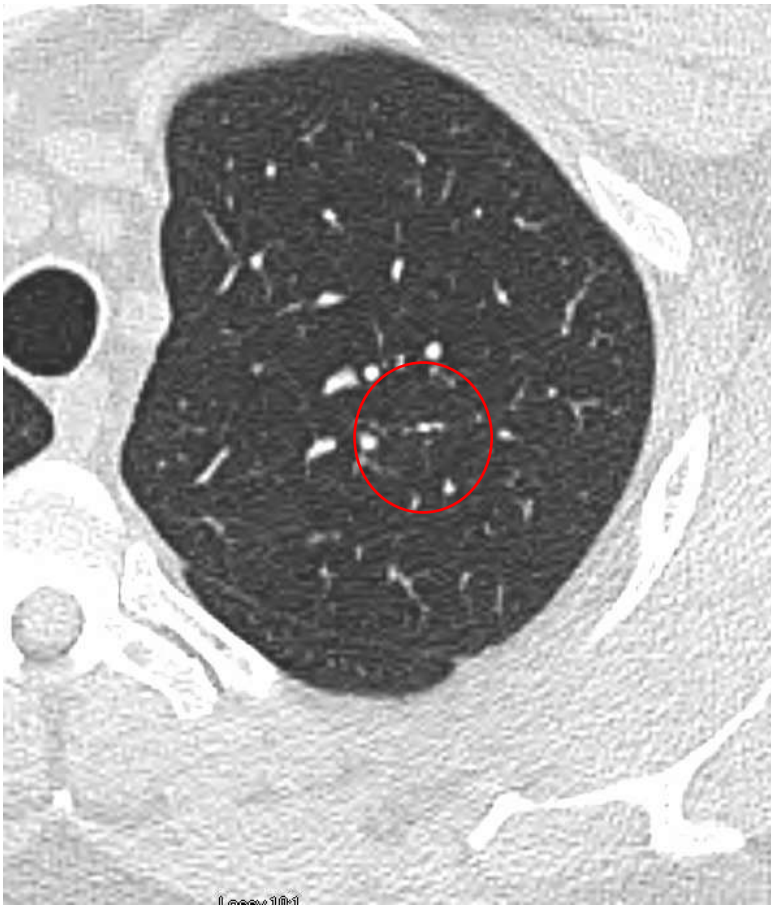
Pembrolizumab
9/19/24



Two overlapping fields of
treatment

45 minute procedure time

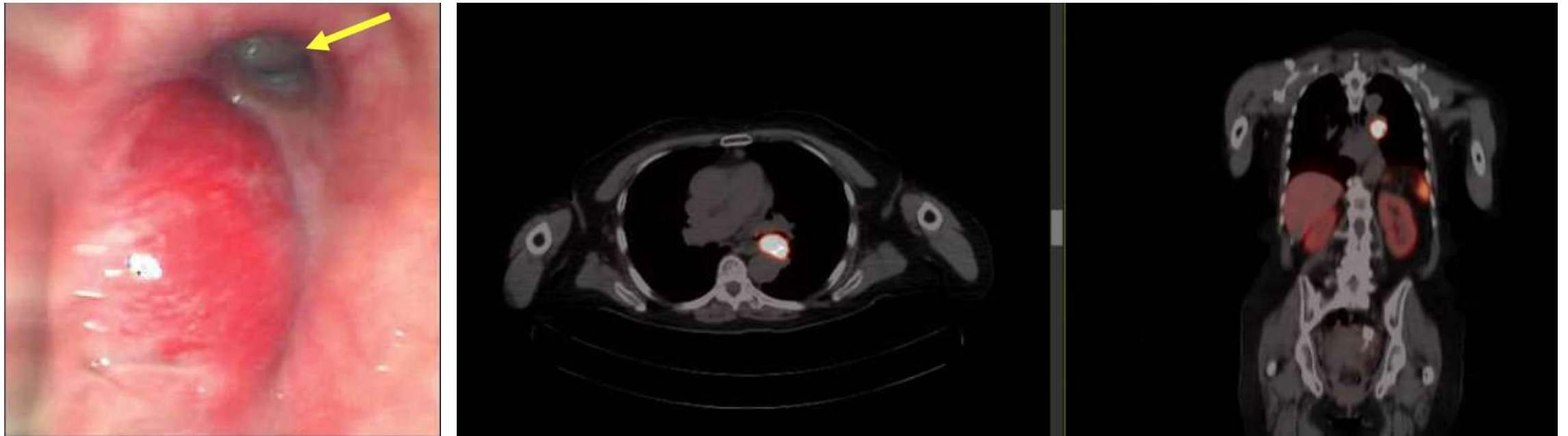
12/16/24



Stable findings 6 months out on 3/22/25 CT!!

Case 3: 79 Year-Old Female with Carcinoid Tumor

- Recurrent left lower lobe pneumonias over the prior year, presents to pulmonologist who discovers left hilar mass
- Underwent bronchoscopy on 2/7/25 with diagnosis of carcinoid tumor:



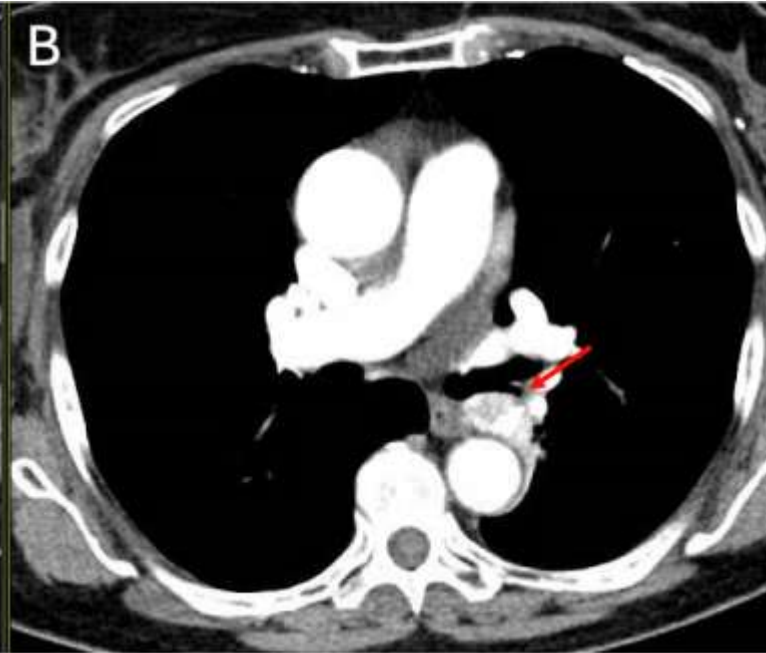
- Simultaneously diagnosed with right sided breast cancer requiring right lumpectomy and lymph node dissection followed by radiation then Docetaxel and Cyclophosphamide x 4 cycles early August 2025

Left Hilar Mass Regression after PEF

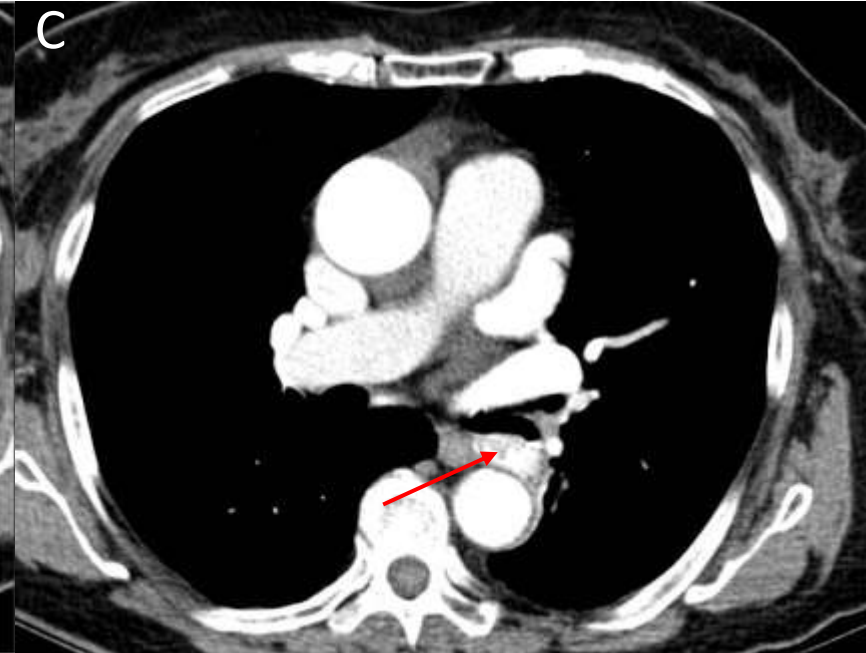
PRE-PEF



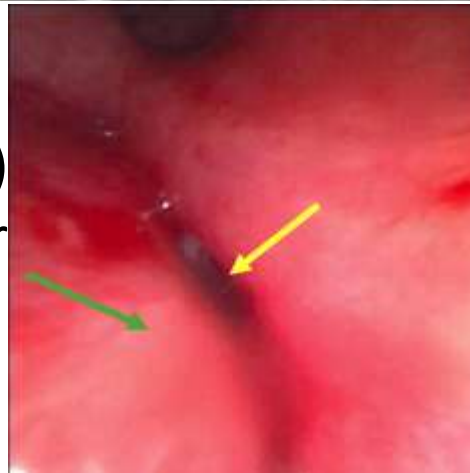
3 months after PEF (6/17/25)



3 months after 2nd PEF (10/30/25)



- PEF delivered to left hilar mass 3/18/25 (12 ablations, 4 vectors)
- 3 week after PEF, patient felt her lungs “open up”, could breath easier

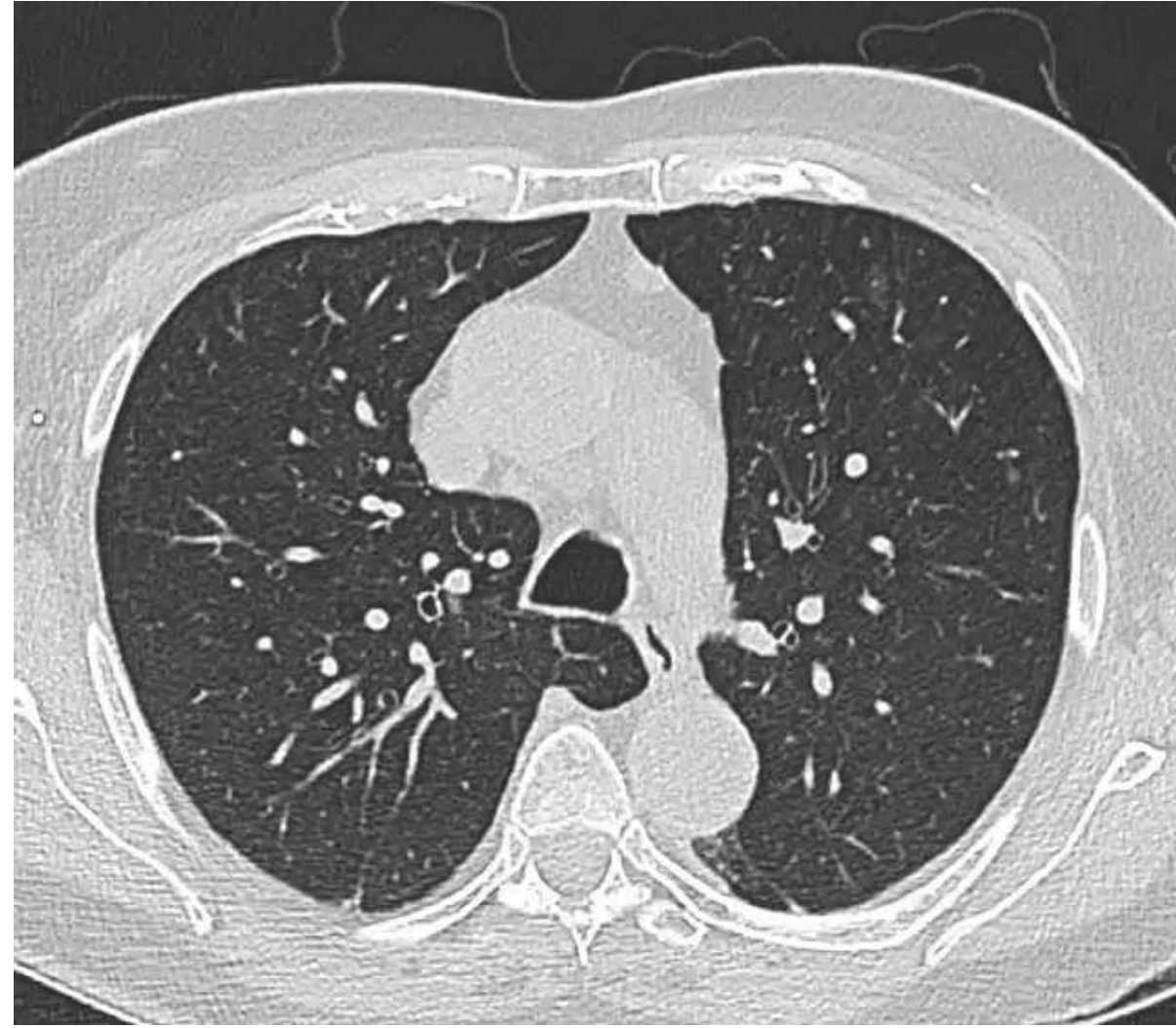
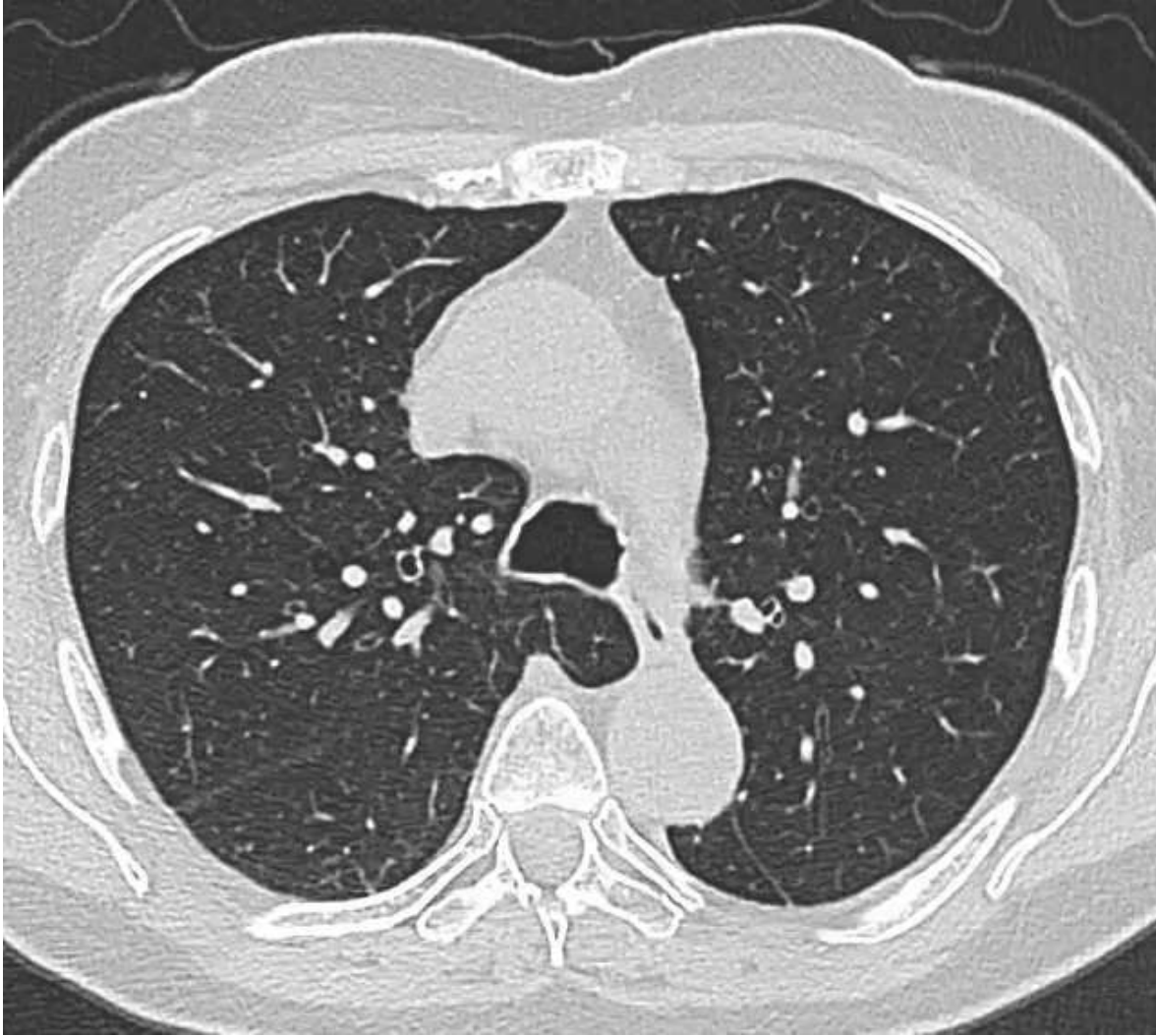


Repeat PEF
7/24/25
8 Ablations,
5 vectors



96.5% reduction in tumor size by volume, 70.5% by SOD

Carcinoid Tumor of Left Hilum Pre and 6-7 Months Post PEF



Airway, 100% open and no Pneumonia since PEF Ablation!

Eisenhower Preliminary Data, First 30 Patients

Demographics	Number (%)
Mean Age	74.9
# Men	18 (60)
# Women	12 (40)

Cancer Stage	Number (%)
Stage I	2 (6.7)
Stage II	1 (3.3)
Stage III	3 (10)
Stage IV	24 (80)

Cancer Type	Number (%)
Lung Adenocarcinoma	8 (26.7)
Renal	6 (20)
Squamous Cell Head and Neck	3 (10)
Colorectal	3 (10)
Lung Squamous Cell	2 (6.7)
Carcinoid	2 (6.7)
Large Cell Neuroendocrine	1 (3.3)
Vaginal Squamous Cell	1 (3.3)
Leiomyosarcoma	1 (3.3)
Urothelial	1 (3.3)
B-Cell Lymphoma	1 (3.3)
Melanoma	1 (3.3)

Eisenhower Preliminary Data, First 30 Patients

RECIST 1.1	3 mo	6 mo
PD	6 (20%)	7 (29.2%)
SD	10 (33%)	5 (20.8%)
PR	12 (40%)	10 (41.7%)
CR	2 (6.7%)	2 (8.3%)

3 month follow up (SD)	6 mo follow up (SD)
84.3 days (+/-26.64)	184.83 days (+/-43.93)

PEF Summary

FDA Cleared for Soft tissue ablation

Safe therapy--non-thermal

Adjunct to systemic therapy

Not a replacement to guideline-based therapy or standard of care

Over 2800 patients treated in the US.

Over 150 programs in the country and 15 in California.

Eisenhower was the first endoluminal program

Summary

- Lung cancer is the leading cause of cancer death in the U.S., surpassing breast, colon and prostate cancer combined
- Lung cancer screening saves lives and has been shown to be cost effective. Consider referral to lung cancer screening clinic.
- Robotic bronchoscopy is safer and as good if not better yield than TTNA and has the added advantage of sampling multiple nodules and staging the mediastinum/hilum in the same anesthesia setting
- Referral to an Interventional Pulmonary team for suspicious pulmonary nodules decreases complications and expedites workup for patients
- Thermal and non-thermal ablation of lung tumors is feasible and multiple applications for patients who may not be surgical or radiation candidates, with each modality having advantages and disadvantages. Multidisciplinary discussions are recommended for these modalities as they are not considered standard of care, but slowly being introduced into guidelines.

Medical Thoracoscopy and Pleural Service

Sewwandi De Silva, MD

Interventional Pulmonary and Critical Care

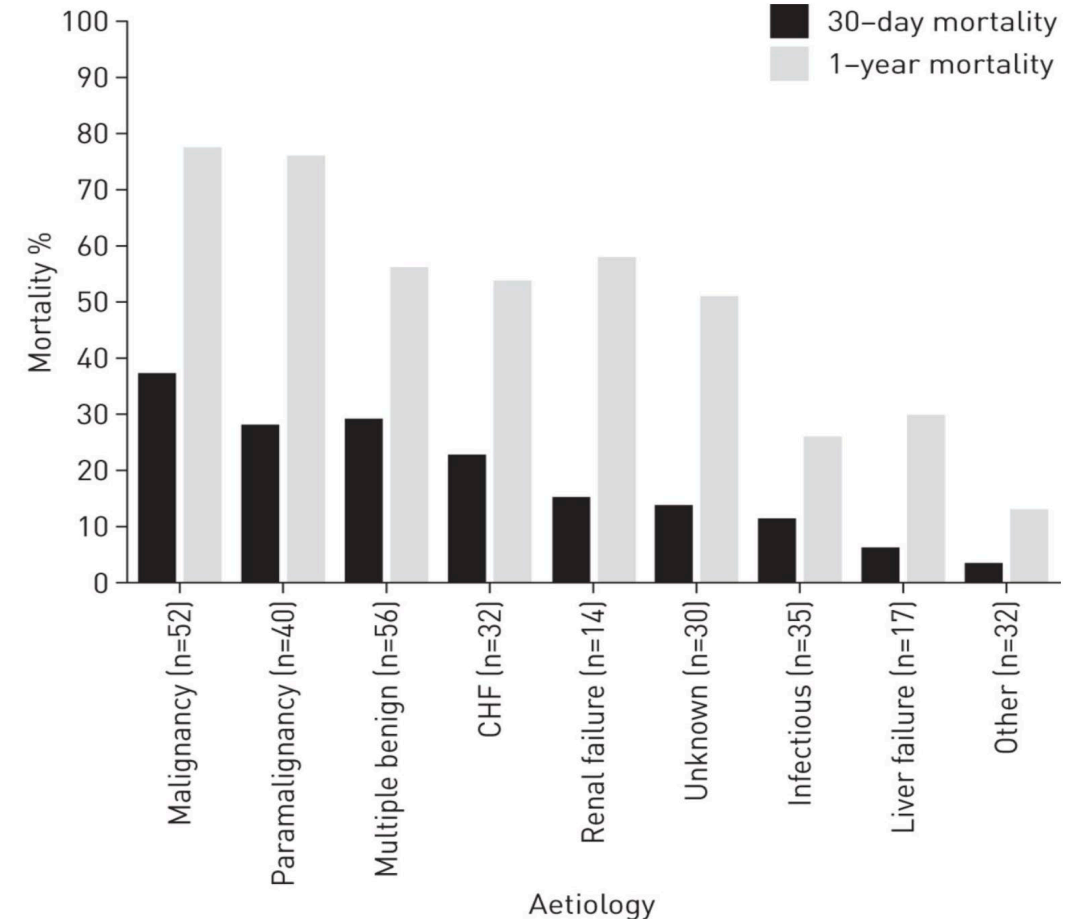
Eisenhower Health

Pleural Effusions

- Excessive fluid accumulation in the pleural space between the two pleural layers.
- Imbalance between pleural fluid formation and removal.
- Accumulation of pleural fluid is not a specific disease, but rather a reflection of underlying pathology.
- **Over 50 different systemic conditions are known to affect the pleura, and a number of these may co-exist in any one patient – increasing the need for specialty services.**

Epidemiology

- 1.5 million new cases in the U.S annually
 - 70%–80% of all effusions are non-malignant
 - 500,000 CHF
 - 300,000 Pneumonia
 - 200,000 Malignancy
- In 2016, a total of 361,270 hospitalizations occurred, resulting in national costs of \$10.1 billion.
- Up to 57% of patients admitted with pneumonia will develop a pleural effusion with many requiring pleural intervention
- Empyema
 - 20% mortality in 1st year
 - 20% Requires surgery
 - Hospital LOS ~ 10 days

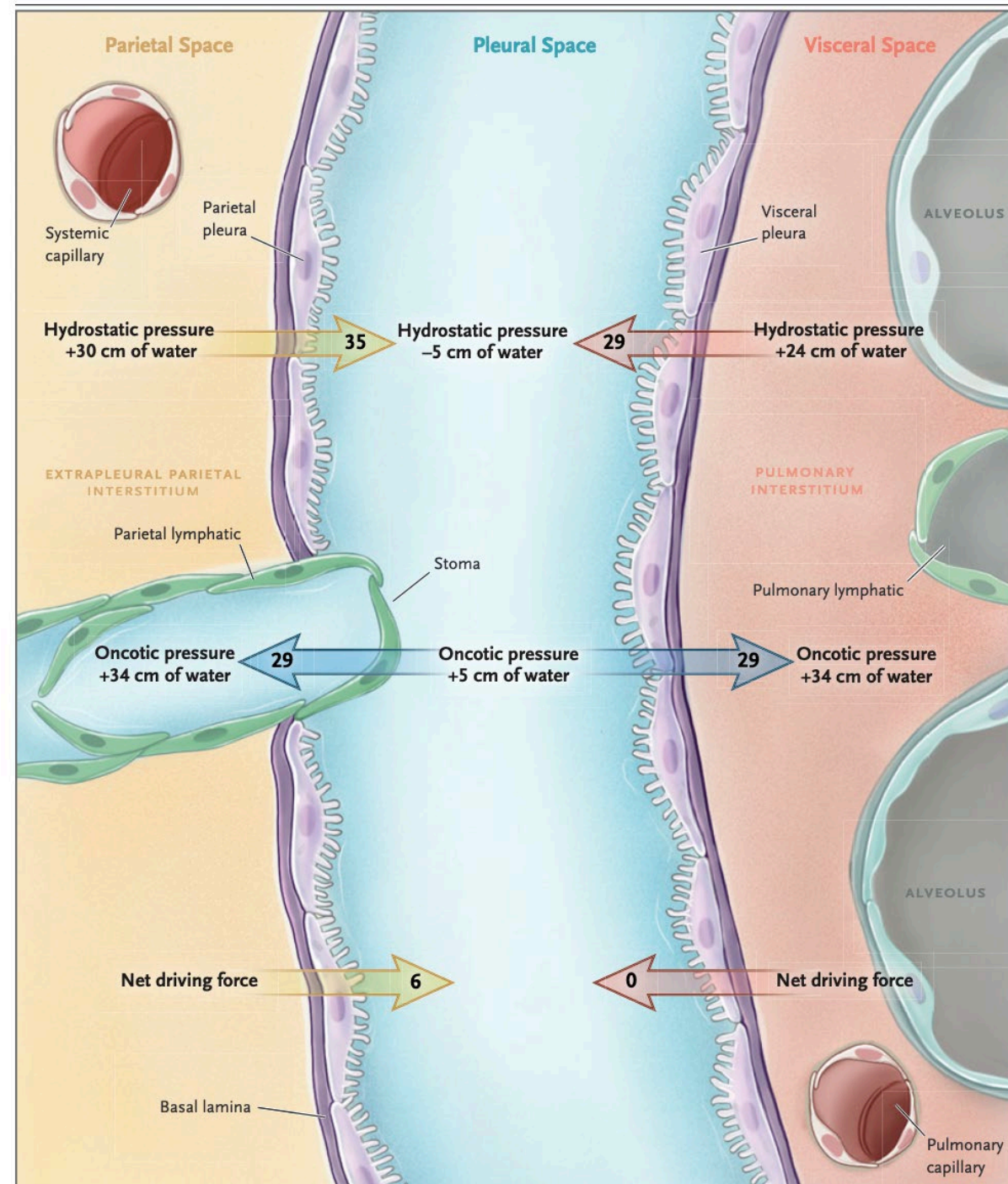


Pleural Physiology

- Absorption of pleural fluid occurs through the parietal pleura.
- Produce and remove $\sim 0.5\text{mL/hr}$ or 12mL/day of fluid each day for an adult.
- Can increase reabsorption up to 0.28mL/kg/hr (28 fold increase).
- Pleural fluid pH ~ 7.60

Pleural Physiology

- Increased pleural fluid almost always due to **BOTH** increase production and decrease reabsorption.
- Increase production
 - Increase hydrostatic pressure or lower oncotic pressure in veins supplying the pleura
 - Increase oncotic pressure in the pleural space
 - Increase vascular permeability
- Decrease reabsorption
 - Poor lymphatic flow
 - Blockage of lymphatic stomata

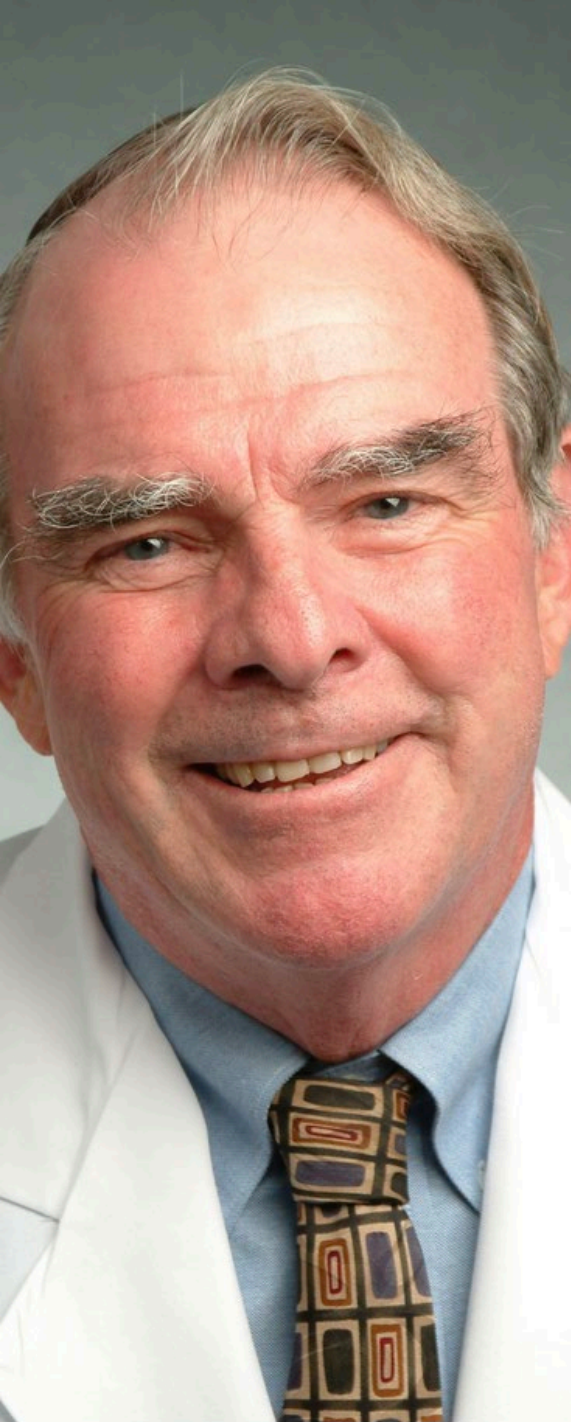


Classification of Pleural Effusion

Imaging (CXR, CT, US)	Simple (free flowing, not loculated), anechoic	Complex (loculations, pleural thickening $\geq 3\text{mm}$), echogenic
Mechanism (Light's Criteria)	Transudative	Exudative
Biochemical Analysis (pH, gluc, ADA etc)	Uncomplicated	Complicated
Fluid characteristic (Viscosity, color)	Straw color, clear	Pus, serosanguinous



Etiology	Para-pneumonic, CHF, hepatic hydrothorax, renal failure, Malignancy, Chylothorax, hemothorax, Urinothorax, etc
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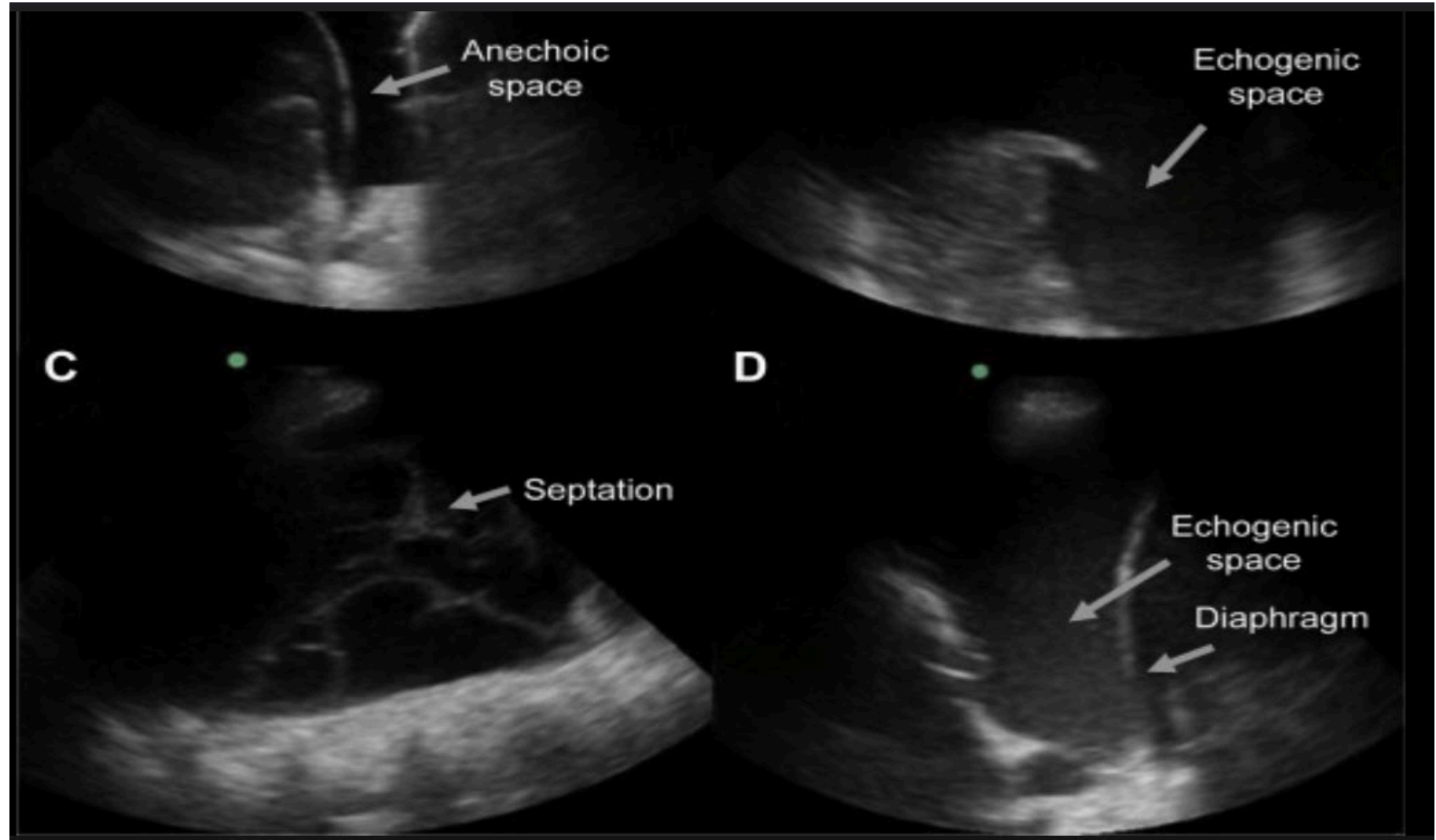
Pleural Effusion – Light's Criteria

- Created by Dr. Richard Light to **not misidentify exudates** as transudate → exudates requires a vastly different treatment approach.
- Intern at Johns Hopkins Hospital (1968 – 1969), studied around 150 pleural effusions.
 - First abstract in 1971 to ATS: Rejected
 - CHEST also rejected him the same year
 - ACP accepted his abstract in 1972 → Published in Annals of Internal Medicine.
- Sensitivity 98%, Specificity 74% .

How much fluid do you need on imaging?

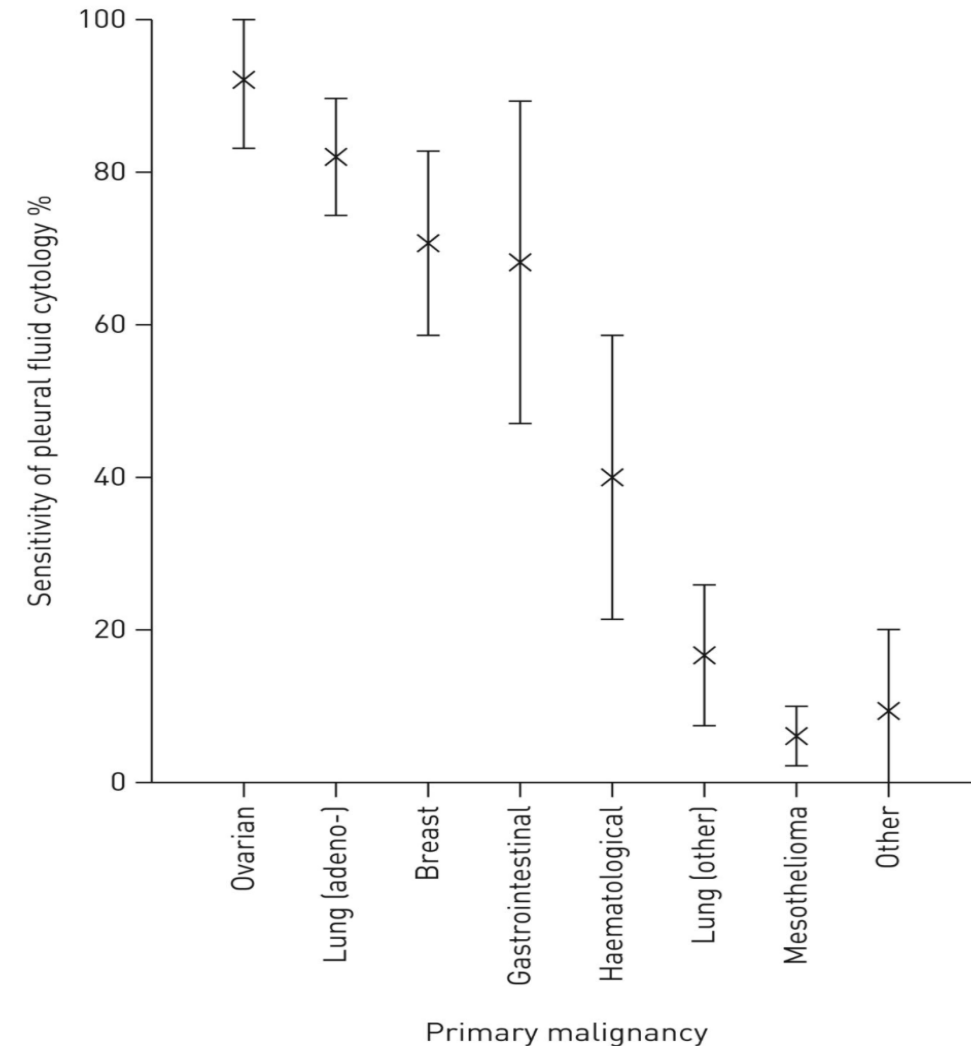
Imaging		Amount need to visualize
CXR	PA or Supine	200mL
	Lateral	50mL
	Decubitus	5mL
Ultrasound		5mL
CT		5-10mL

Pleural Effusion - US

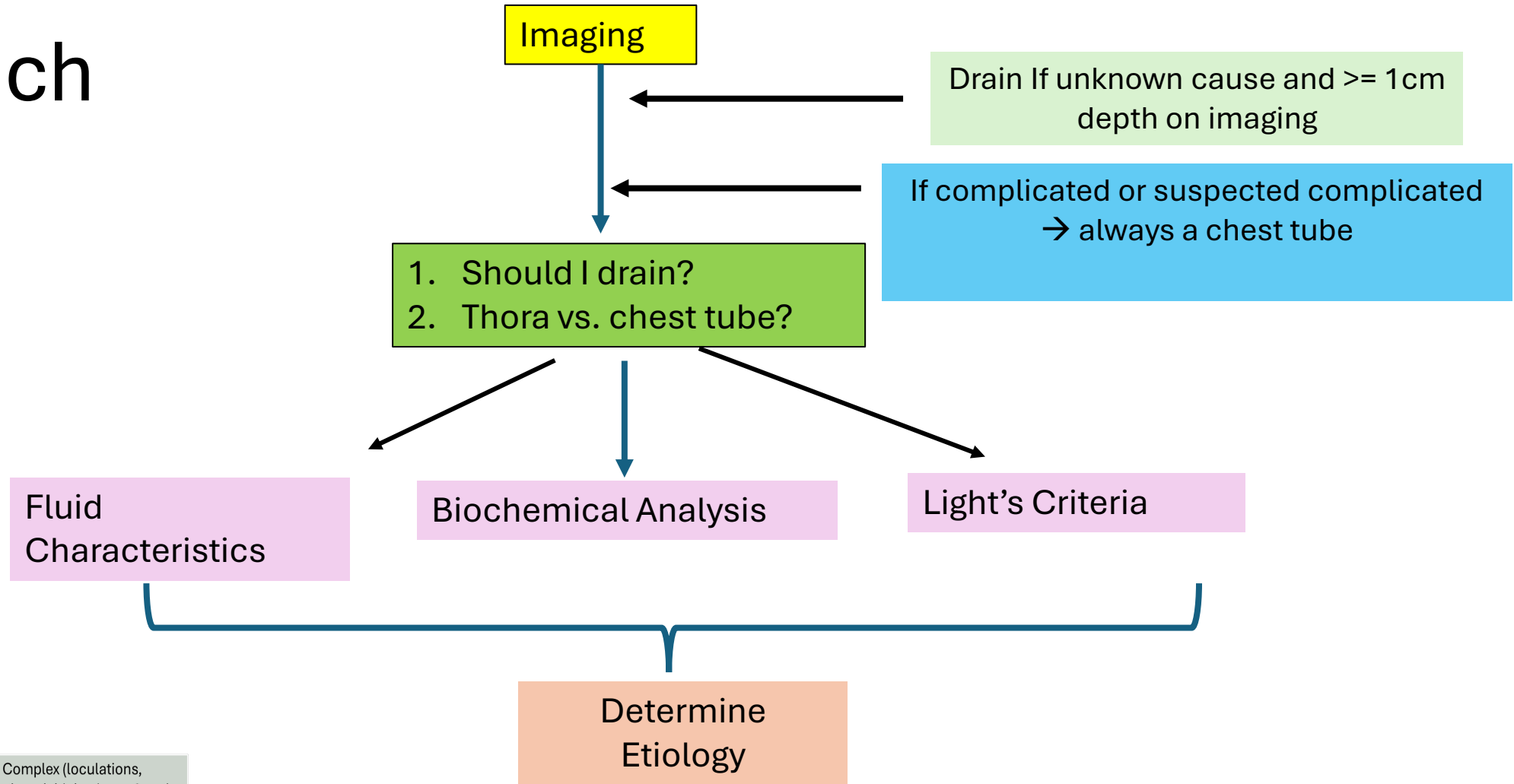


Pleural Fluid Cytology

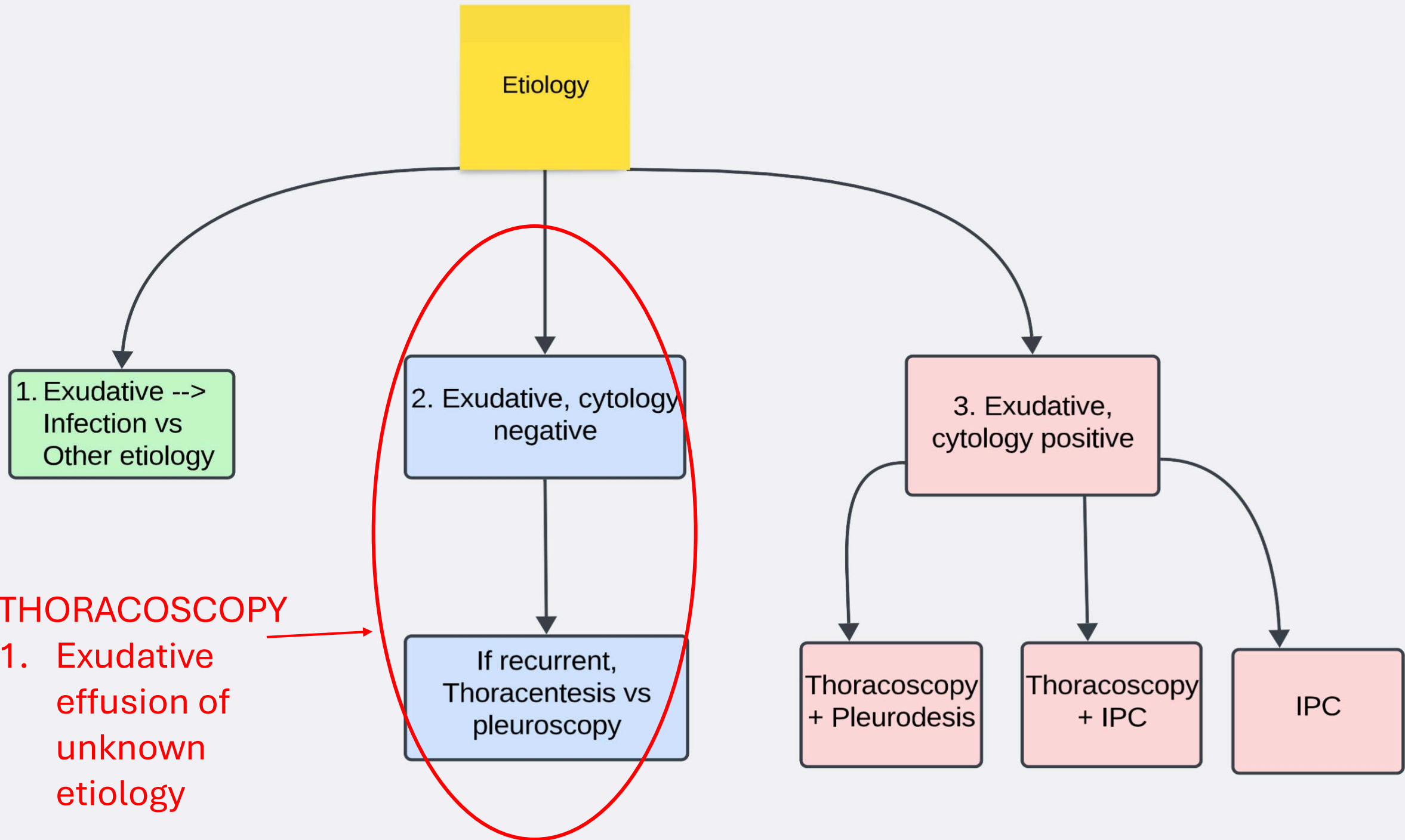
- 1st sample → Pleural cytology **60% sensitive**
- 2nd sample → Cytology sensitivity increases by **10-15%**
- Cytology has a higher sensitivity for detecting adenocarcinomas compared to other cancer types.
- Within adenocarcinoma, there is a significant difference depending on the primary cancer.
- Cytologic sensitivity for mesothelioma low.



Approach



Imaging (CXR, CT, US)	Simple (free flowing, not loculated), anechoic	Complex (loculations, pleural thickening >=3mm), echogenic
Mechanism (Light's Criteria)	Transudative	Exudative
Biochemical Analysis (pH, gluc, ADA etc)	Uncomplicated	Complicated
Fluid characteristic (Viscosity, color)		



Etiology

1. Exudative -->
Infection vs
Other etiology

2. Exudative, cytology
negative

3. Exudative,
cytology positive

If recurrent,
Thoracentesis vs
pleuroscopy

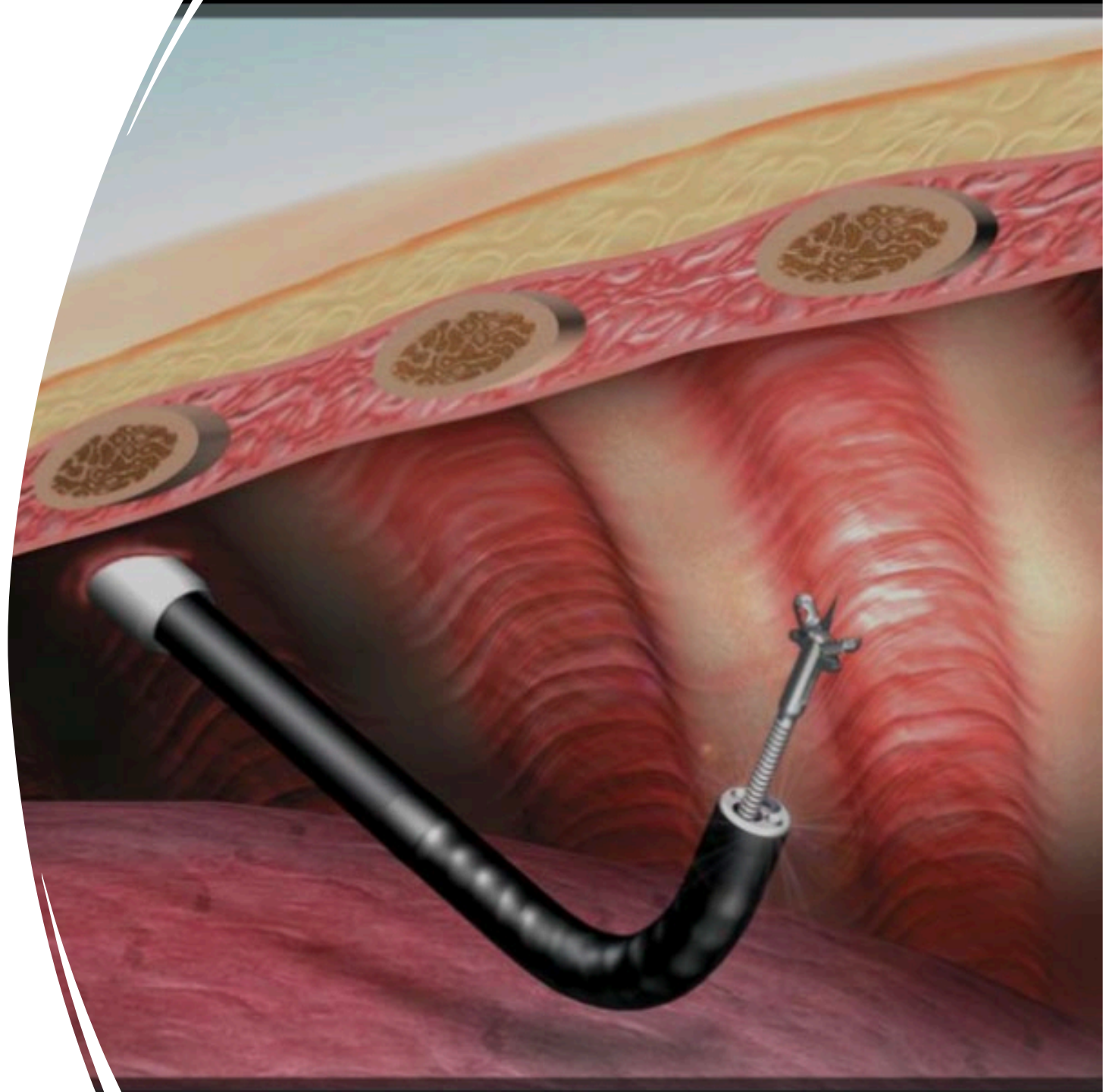
Thoracoscopy
+ Pleurodesis

Thoracoscopy
+ IPC

IPC

Medical Thoracoscopy

- Medical thoracoscopy (MT)/
Pleuroscopy: conducted by a
pulmonologists under local
anesthesia or moderate sedation.
- **Direct Visualization:** Allows direct
inspection of the parietal pleura,
enabling targeted biopsies.
- **Diagnostic and Therapeutic**
- Also commonly used for fluid
drainage, and pleurodesis.



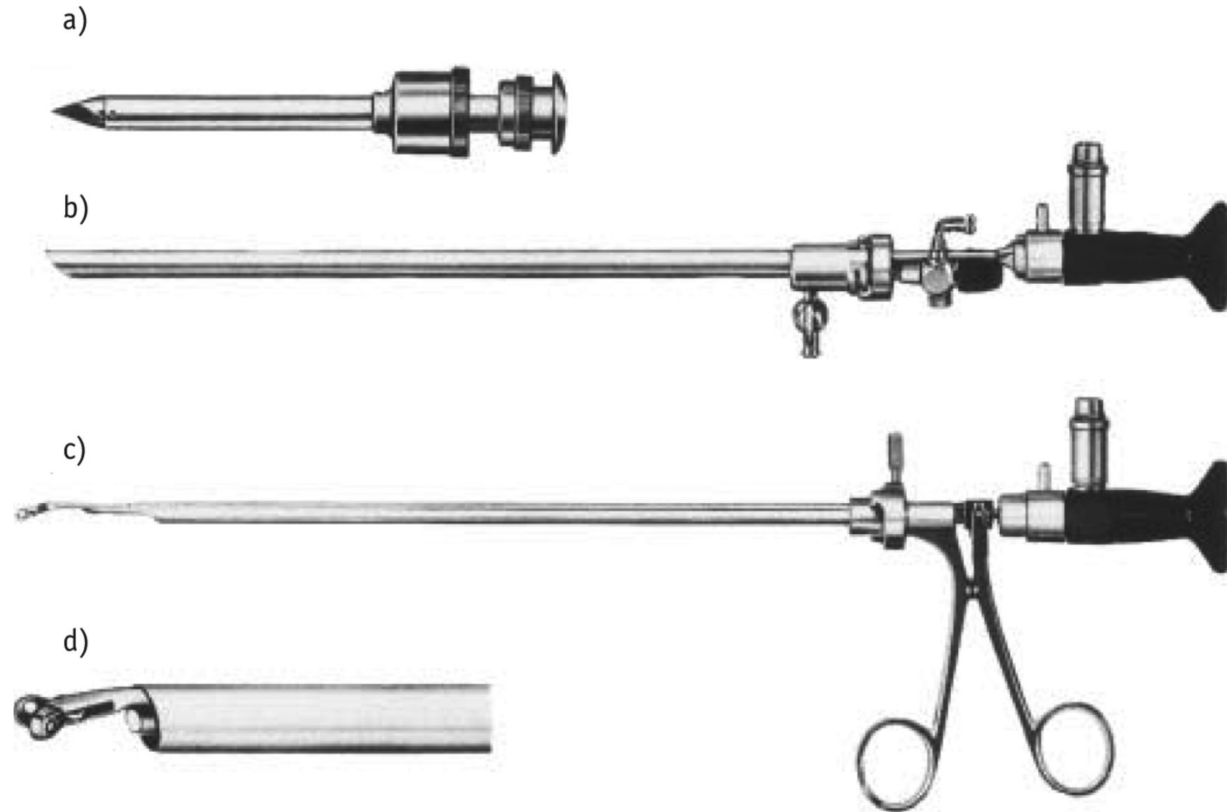
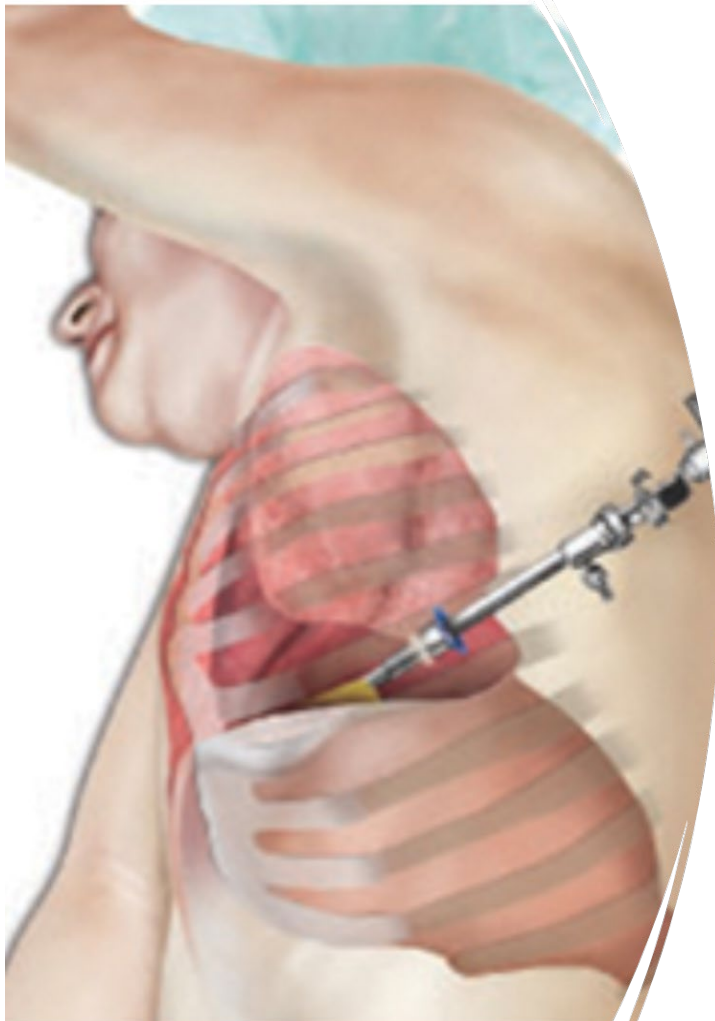
Background



Jacobaeus demonstrating the thoracoscopic approach (c. 1920).

- The first thoracoscopy → Sir Francis Cruise in conjunction with Dr. Samuel Gordon in 1865 in Dublin.
- In 1910, Hans Christian Jacobaeus, a Sweden internist, described examination of the thoracic cavity with a rigid cystoscope attached to an electric lamp.
- Jacobaeus was the first to use the term *thoracoscopy*, described as "replacing fluid with air" in order to examine the pleural surfaces for tuberculous pleurisy.
- During the 1950s and 1960s, thoracoscopy gained popularity with pulmonologists because of the tuberculosis endemic in the United States

Rigid Instruments



- Historically, rigid instruments such as trocars and telescopes were central to the technique.
- Rigid thoracoscopy requires a cold Xenon light source, an endoscopic camera, a video monitor and a recorder.
- A trocar (usually 7mm), 0 degree viewing 6 mm or 10 mm telescope, and 5 mm optical forceps will often allow for effective pleural biopsy without the need for second port.

Indications

- Thoracoscopy should be pursued if:

- 1. Undiagnosed exudative pleural effusion with at least one pleural fluid aspiration*
- 2. Pleural fluid cytology have been negative at least once.*

Pleural biopsies : diagnostic yield is higher than 90% in malignant pleural effusions.

Diagnostic

- Pleural effusions of indeterminate origin
- Staging of lung cancer with pleural effusion and of diffuse malignant mesothelioma
- Hormone receptor determination in breast cancer and culture in tuberculous pleurisy
- Staging of pneumothorax
- Diffuse lung diseases
- Localised chest wall (and lung) lesions

Therapeutic

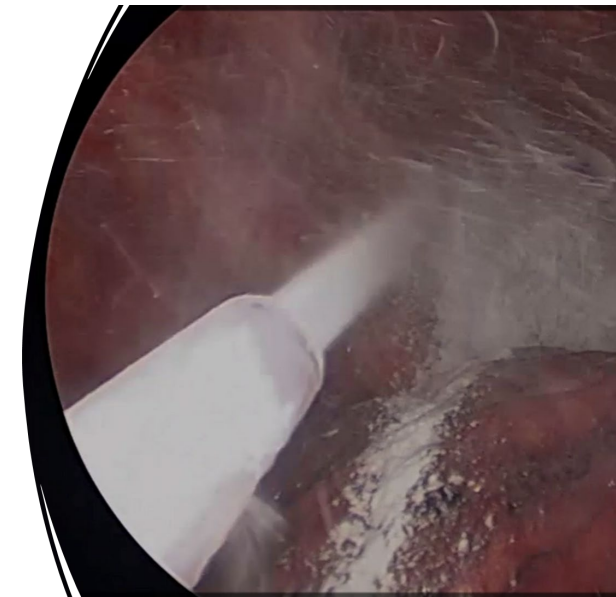
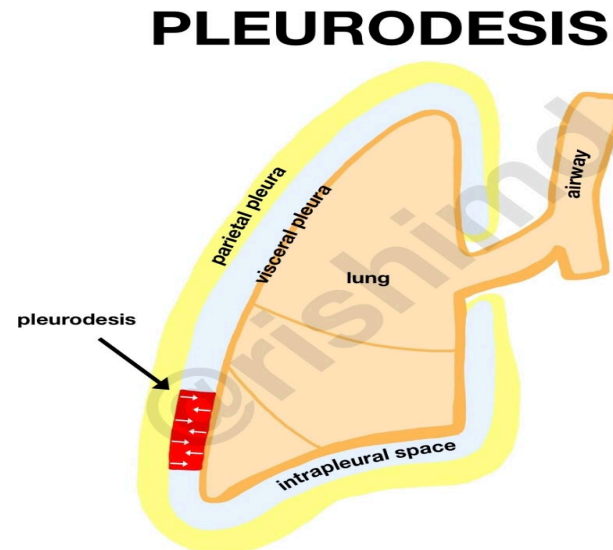
- Talc poudrage in malignant and chronic, recurrent non-malignant pleural effusions
- Talc poudrage in pneumothorax
- Parapneumonic effusions and empyema (opening of loculations)

Indications for medical thoracoscopy/pleuroscopy

Medical Thoracoscopy

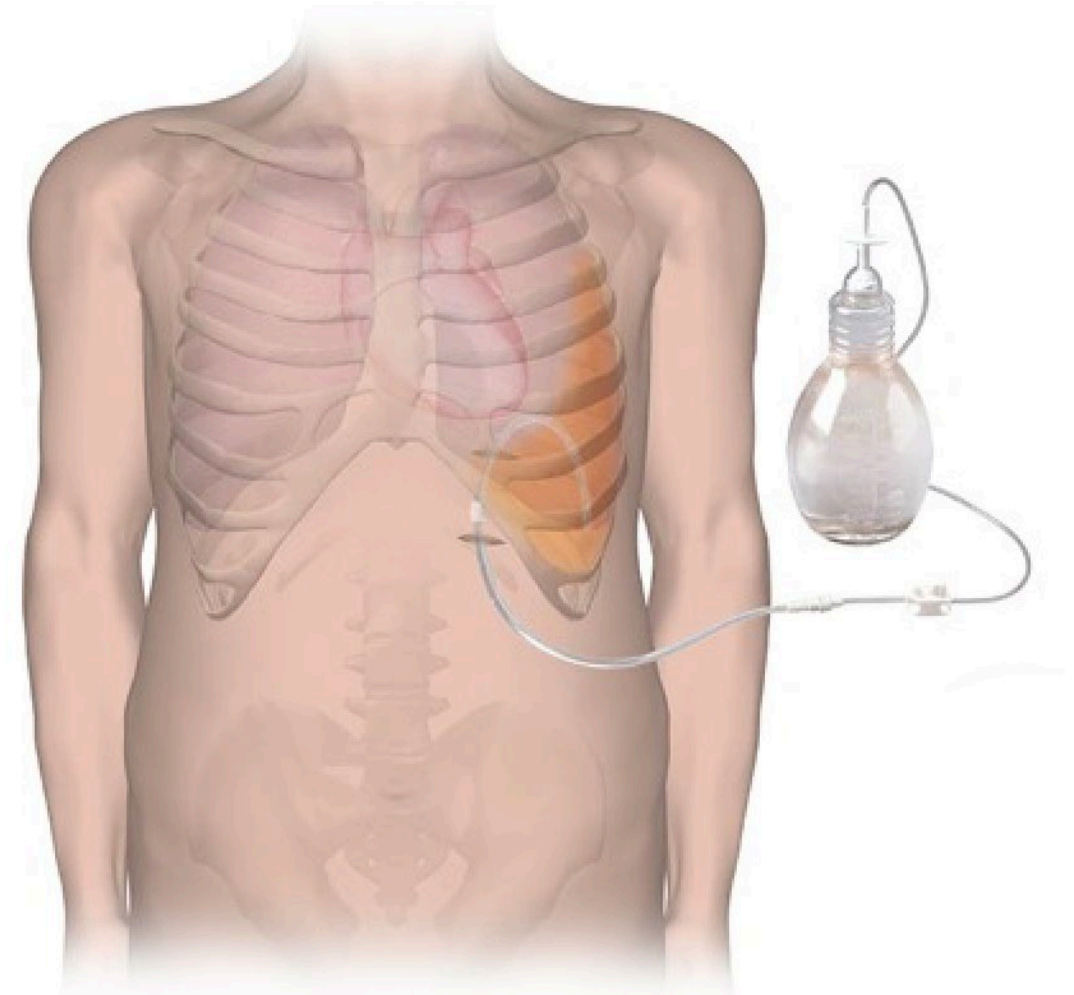
- Diagnostic
 - **Excellent Diagnostic Sensitivity:** High success rates (often >90%) for diagnosing malignant pleural effusions (MPEs) and tuberculosis (TB)
 - **"Actionable Histology":** Provides tissue for detailed cancer profiling (oncogenic mutations)
- Therapeutic
 - Drainage of effusion
 - Chemical Pleurodesis
 - Indwelling pleural catheter placement (PleurX)

Chemical Pleurodesis refers to obliteration of the pleural space by the induction of pleural inflammation and fibrosis using a chemical sclerosant



Indwelling Pleural Catheters for MPE

- Alternative to chemical pleurodesis or repeat thoracentesis.
- IPCs are widely used to manage MPE.
- Often a definitive management for recurrent malignant pleural effusions.
- The decision depends on many factors including:
 - The rate of fluid accumulation.
 - Presence of non expandable lung
 - Patient's life expectancy
 - Ability to tolerate a surgical procedure.
 - Social factors



Medical thoracoscopy, results and complications in 146 patients: a retrospective study

M. HANSEN, P. FAURSCHOU AND P. CLEMENTSEN

- 147 patients with undiagnosed pleural effusions.
- Overall diagnostic sensitivity 90.4%.
- 62% with malignancy of the pleura
- 38% revealed benign pleural diseases → 2% with TB.
- The sensitivity 88% and specificity 96% for malignancy.
- Both sensitivity and specificity was 100% for TB.
- Mortality was 0%.
- Morbidity was low - 0.6% (empyema, pleuro-cutaneous fistula, transcutaneous growth of tumor)

TABLE 1. Diagnostic outcome of thoracoscopy in 147 patients

MT offers a high safety profile, low complication rates, with a very high (>90%) diagnostic yield for undiagnosed pleural effusions

Eosinophilic granulomas 2 (1% of total)

Clinical Trial > Cancer. 1993 Jul 15;72(2):389-93.

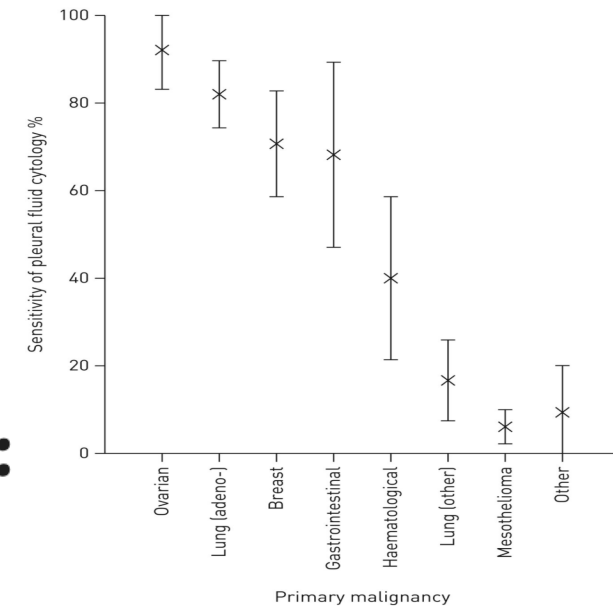
doi: 10.1002/1097-0142(19930715)72:2<389::aid-cnrcr2820720213>3.0.co;2-v.

Thoracoscopy in pleural malignant mesothelioma: a prospective study of 188 consecutive patients. Part 1: Diagnosis

C Boutin¹, F Rey

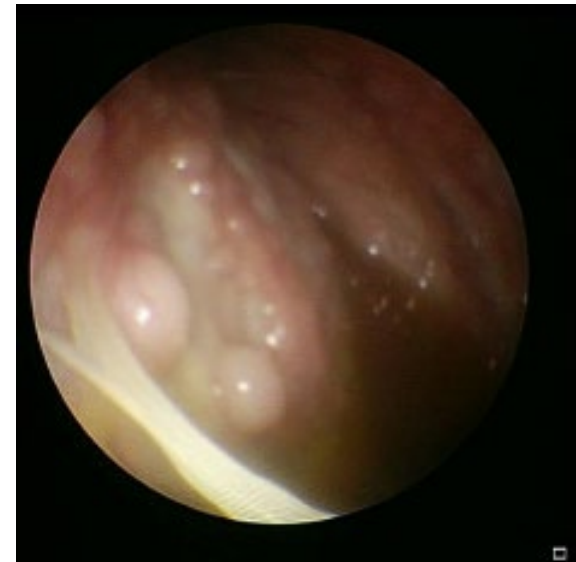
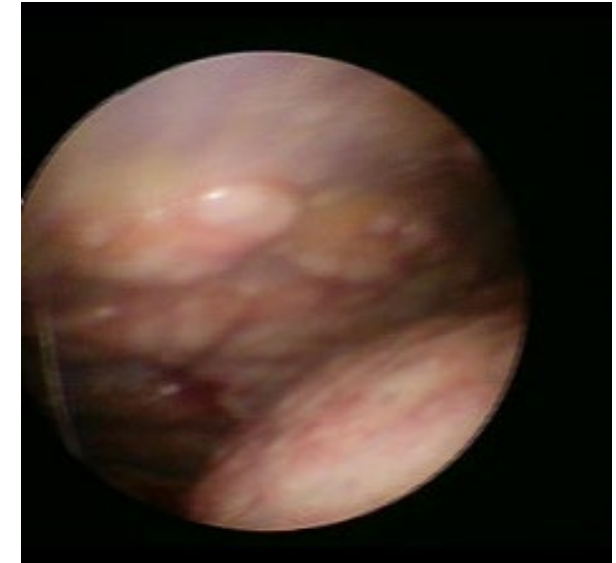
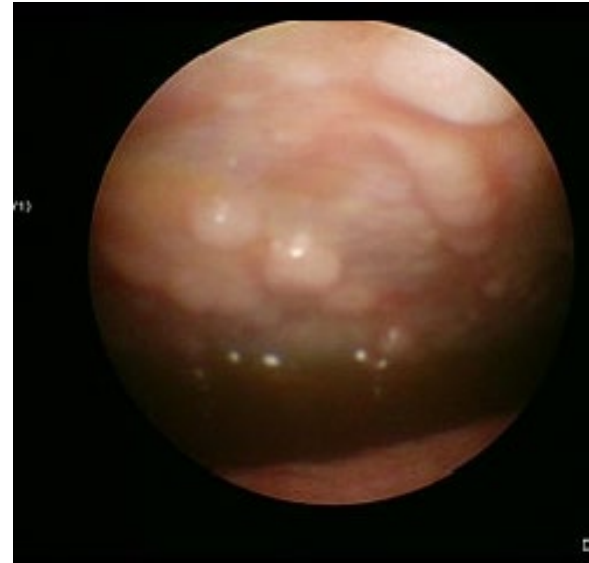
Mesothelioma

- 188 patients with malignant mesothelioma.
- 98% of whom were diagnosed on thoracoscopy.
- Invaluable diagnostic tool for mesothelioma.



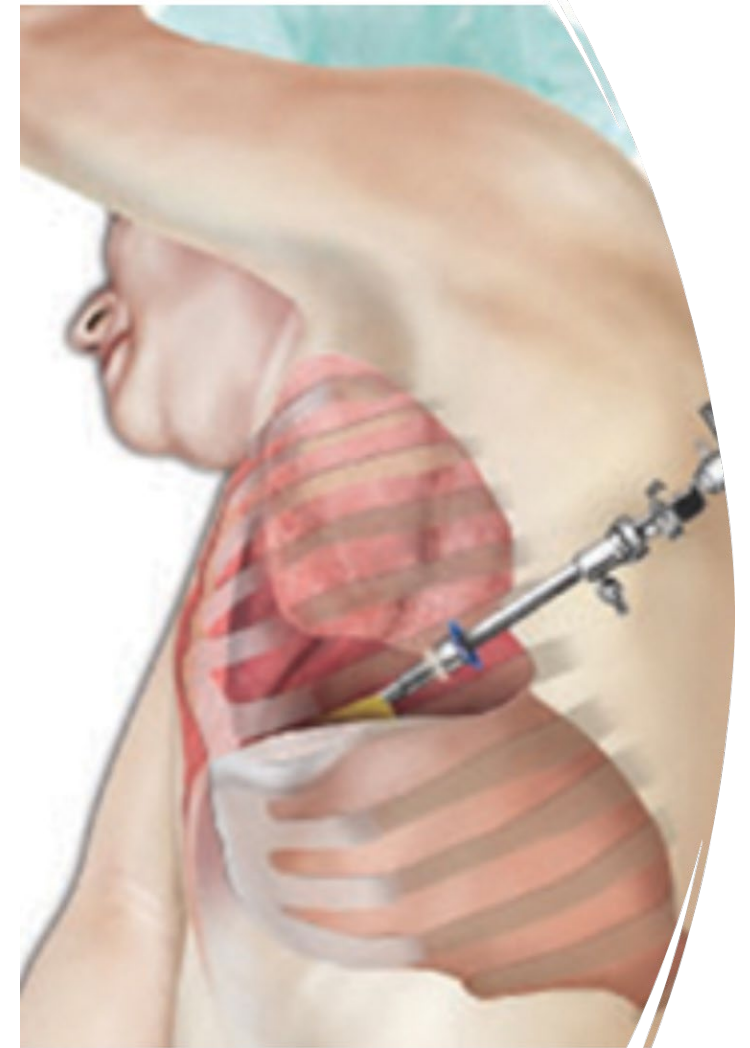
79 year old male with exudative effusion of unknown etiology

- 1st Thoracentesis (04/04/2025): Cytology showing atypical cells with abundant lymphocytes
- 2nd Thoracentesis (04/14/2025): cytology showing atypical cells with abundant lymphocytes – pulmonary consulted
- Patient underwent pleuroscopy with pleural biopsies the following week – Positive for malignant mesothelioma, epithelioid type



Contraindications

- Medical Thoracoscopy has an estimated mortality of 0.19 - 0.54%.
- Absolute contraindication
 - Inability to tolerate complete or partial lung collapse.
 - **Fused pleural space with dense adhesions.**
 - Shock or cardiac arrest
 - Unstable patients.
- Other patient factors:
 - Obesity or increase thickness of the chest wall.
 - Narrow rib spaces
 - Underlying conditions that increase risk of bleeding.



Local anaesthetic thoracoscopy: British Thoracic Society Pleural Disease Guideline 2010

Najib M Rahman¹, Nabeel J Ali, Gail Brown, Stephen J Chapman, Robert J O Davies, Nicola J Downer, Fergus V Gleeson, Timothy Q Howes, Tom Treasure, Shivani Singh, Gerrard D Phillips; British Thoracic Society Pleural Disease Guideline Group

- Complications in MT under local anesthesia with moderate sedation.
- 22 studies.
- Diagnostic yield of 92.6% for malignant pleural diseases.
- 2% major complications: 86/4736 cases (1.8%, 95% CI 1.4% to 2.2%).
- 7% minor complications: 177/2411 procedures (7.3%, 95% CI 6.3% to 8.4%).
- **Local anaesthetic thoracoscopy is a safe procedure.**

Major Complications

Empyema,
Hemorrhage
Port site tumor growth
Bronchopleural
fistula
Postoperative
pneumothorax
Air leak
Pneumonia

Minor

Complications

Subcutaneous
emphysema
Minor hemorrhage
Operative skin site
infection
Hypotension during
procedure
Raised temperature
atrial fibrillation

	Medical thoracoscopy	VATS
Location	Endoscopy or operating room	Operating room
Ports	Single	Single or multiple
Anesthesia	Moderate sedation	General anesthesia
Indications	Pleural fluid drainage, pleural biopsy, and pleurodesis	Diagnostic and therapeutic for pleura and lung

VATS vs Thoracoscopy

- VATS has multiple indications for other diseases of the thorax.
- VATS allows for a more efficient drainage of loculated effusions trapped in dense fibrous bands.
- VATS can be converted to open thoracotomy if necessary.
- **The major advantages of thoracoscopy is that it can be a cost-effective procedure in patients with poor tolerance for general anesthesia, in an outpatient setting (same day procedure)**

Why is it important to have a Pleural Service?

- Over the past decade, there have been significant advances in the investigation and treatment options for pleural disease, making the management of pleural disease far more complex and nuanced.
- Thus, management of pleural disease has become progressively more reliant on specialist input.
- Studies have suggested that patients with NMPE have a one-year mortality ranging from 25% to 55%.
- MPE signifies advanced disease and reduced life expectancy
→ median survival 3 to 12 months



Transforming Pleural Care: Efficiency, Safety, and Outcomes

- **Rapid Access to Expertise**
 - **Same-day or next-day evaluations**
 - **Streamlined triage for pleural needs**
 - Improved **diagnostic accuracy** and faster diagnosis
 - Multidisciplinary, guideline-based care

- **Improved Patient Outcomes**
 - ↓ LOS by up to 2 days
 - Reduces need for constant hospital admissions
 - **Shortens hospital days** when admission is unavoidable
 - **Reduces readmission rates**, particularly for MPE

Pleural Service: Increase Cost Effectiveness

- Fewer admissions & imaging → estimated \$2,000–\$3,000 savings per patient
- Proper treatment:
 - PleurX catheter or pleurodesis in MPE is more cost-effective than repeated thoracentesis in patients with expected survival > 1 month
 - Coordinated outpatient and inpatient follow-up

Reduces procedure-related complications

- Compelling data for the use of ultrasound guidance in ↓ complication rate by 50% (pneumothorax/bleeding).
- Many of our guidelines (BTS, ATS) strongly recommends ultrasound guidance for pleural disease.
- Procedures such as Thoracoscopy can be performed as an outpatient procedure using conscious sedation in endoscopy suite.
 - Avoids need for OR and GA as would be needed for VATS

Institutional Impact of a Pleural Service

- **Enhanced Multidisciplinary Collaboration**
 - Integrates oncology, cardiology, thoracic surgery, radiology
- **Supports Advanced Programs**
 - Complements lung cancer screening
 - Enables pleuroscopy & tunneled catheters
- **Education & Training Hub**
 - Hands-on training for residents, fellows, and nursing staff
- **Market Differentiation**
 - Positions hospital as referral center
 - Boosts regional reputation

Pleural Service – Multidisciplinary approach

- A pleural team has the potential to:
 - Streamline patient pathways
 - Improve patient care
 - Ensure the most appropriate use of resources (imaging studies, procedures).
 - Provide opportunities for practical skills training to trainees



1. The core services provided by a pleural team and the hospital staff who might form part of it.

Thank you!

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