Management of Hilar Node-Positive (N1) Non-Small Cell Lung Cancer

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UNMC

Disclosures

None

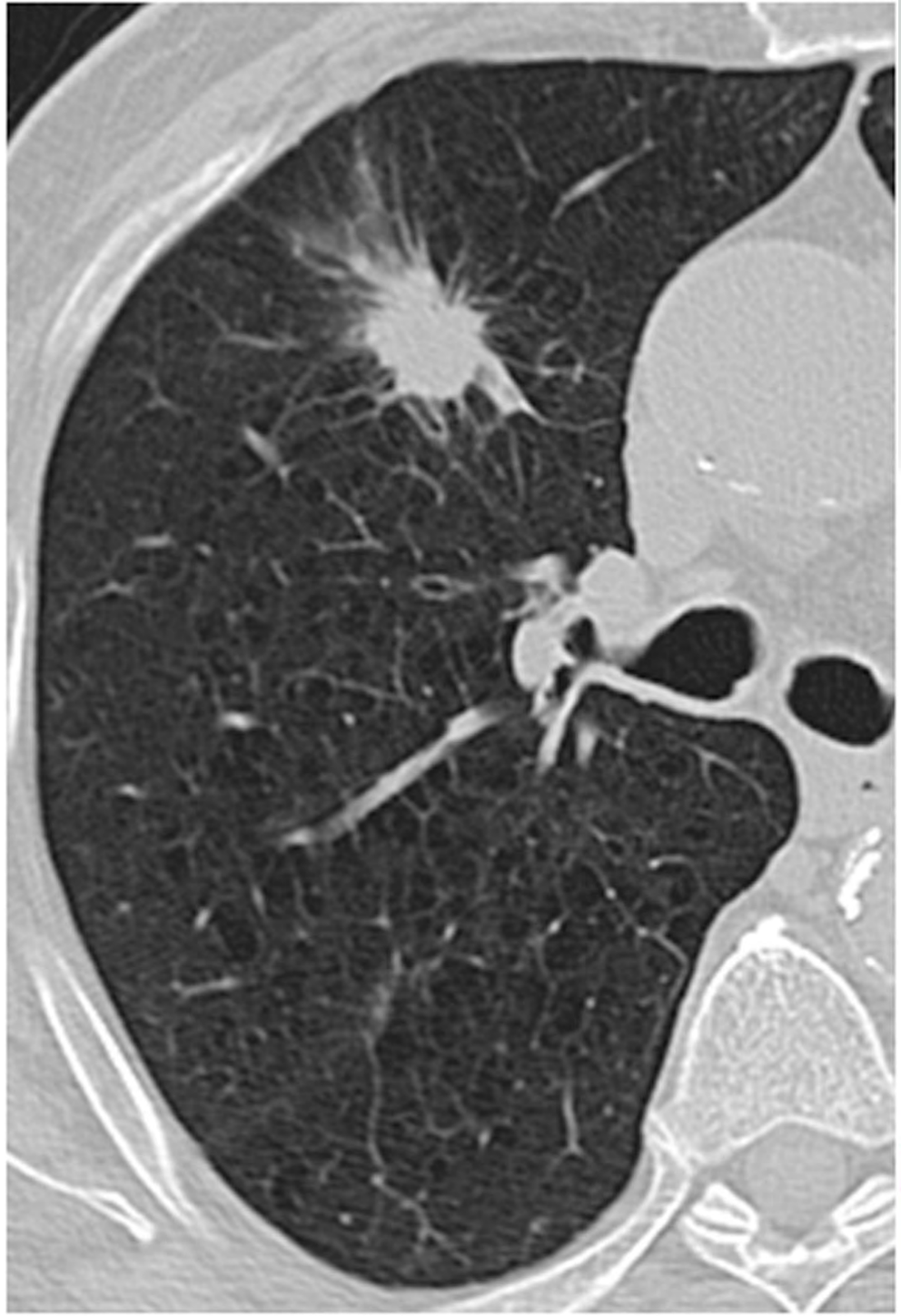
Objectives

- Review Staging of NSCLC
- Define Nodal Disease in NSCLC
- Discuss Workup of Nodal Disease in NSCLC
- Review Current Treatment for NSCLC with N1 disease
- Discuss Clinical Trials for NSCLC with N1 disease

Lung Cancer

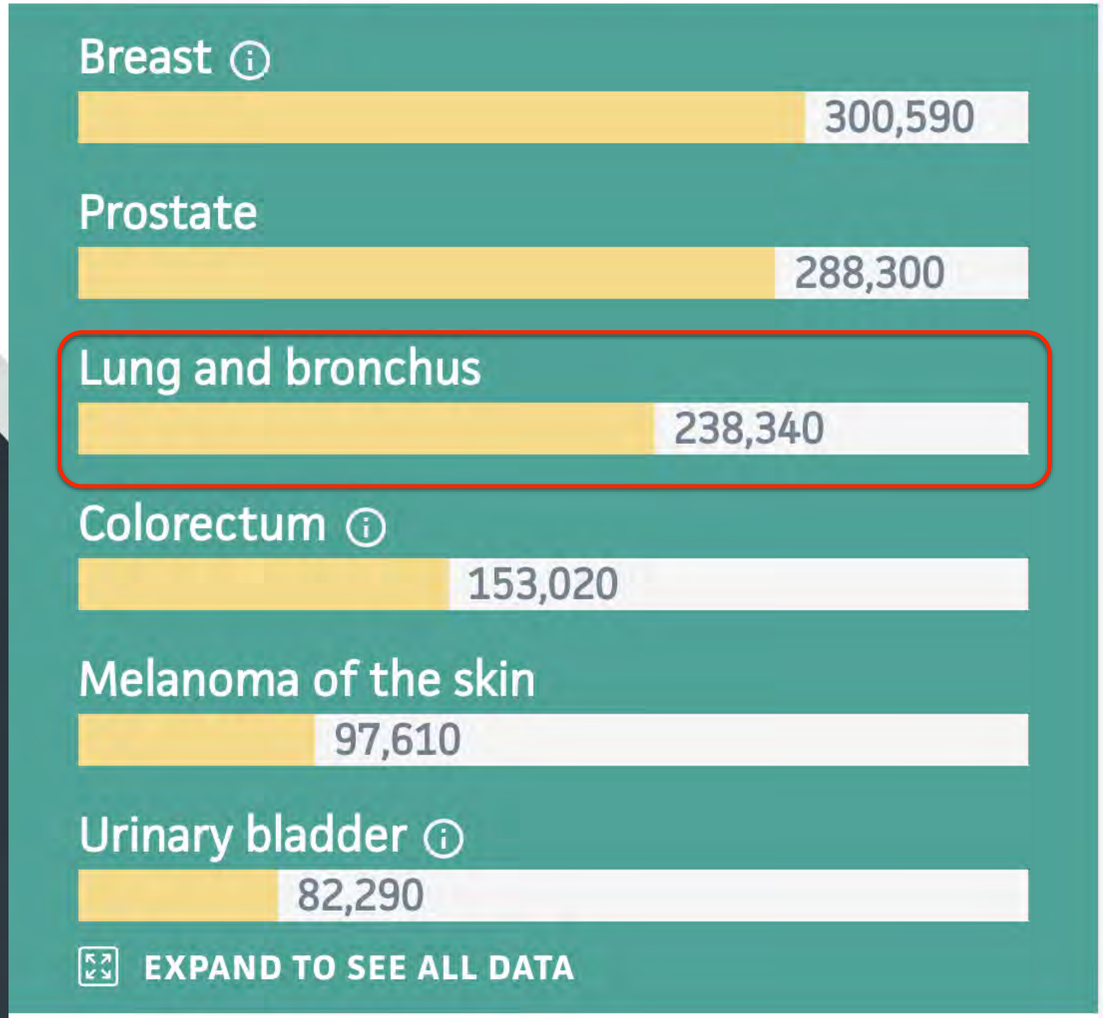
- Non-Small Cell vs Small Cell
- Non-Small Cell
  - Adenocarcinoma and Squamous Cell Carcinoma
- Estimated new cases 2023
  - US: 238,340
  - NE: 1340
- Estimated deaths 2023
  - US: 127,070
  - NE: 630

https://cancerstatisticscenter.cancer.org



Estimated new cases, 2023

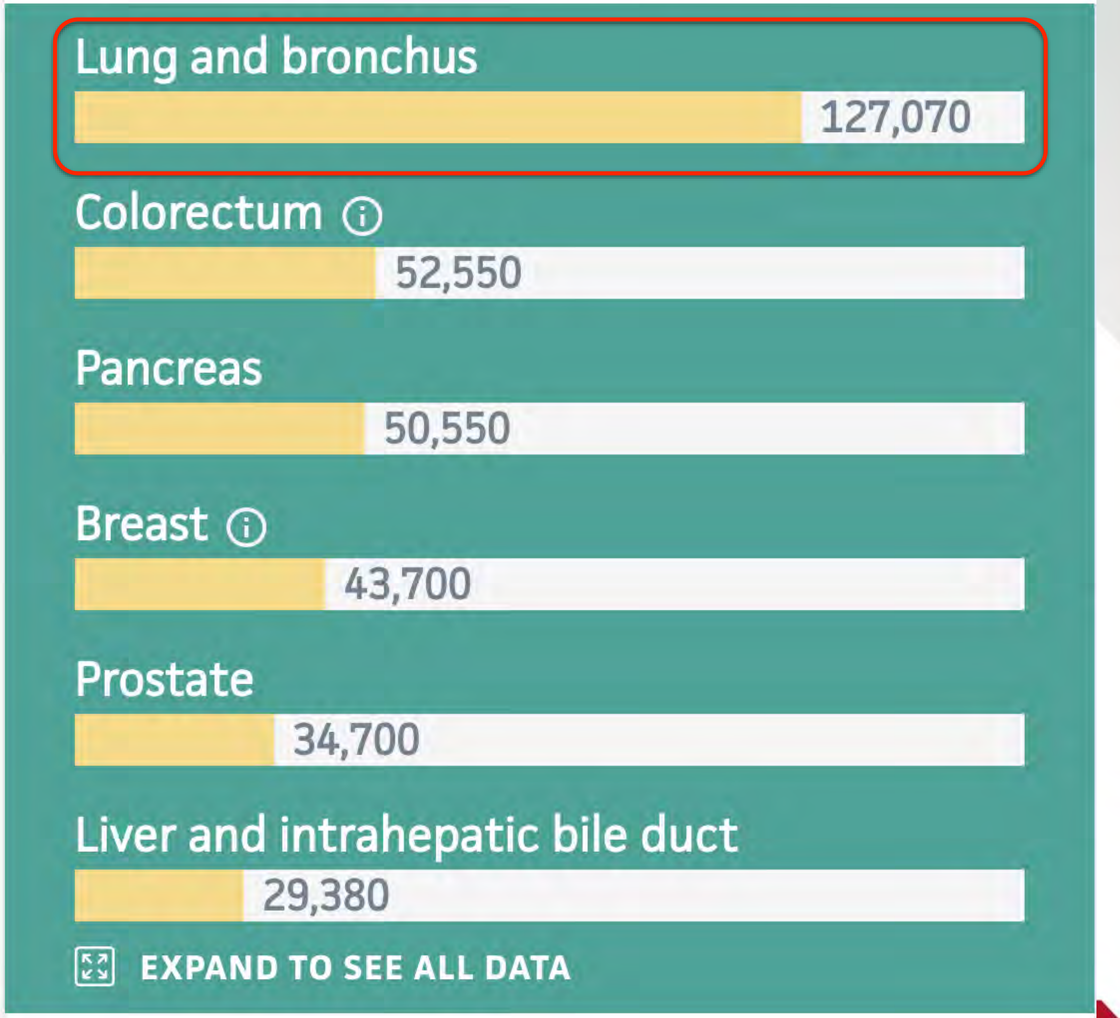
By cancer type, both sexes combined



American Cancer Society, 2023

Estimated deaths, 2023

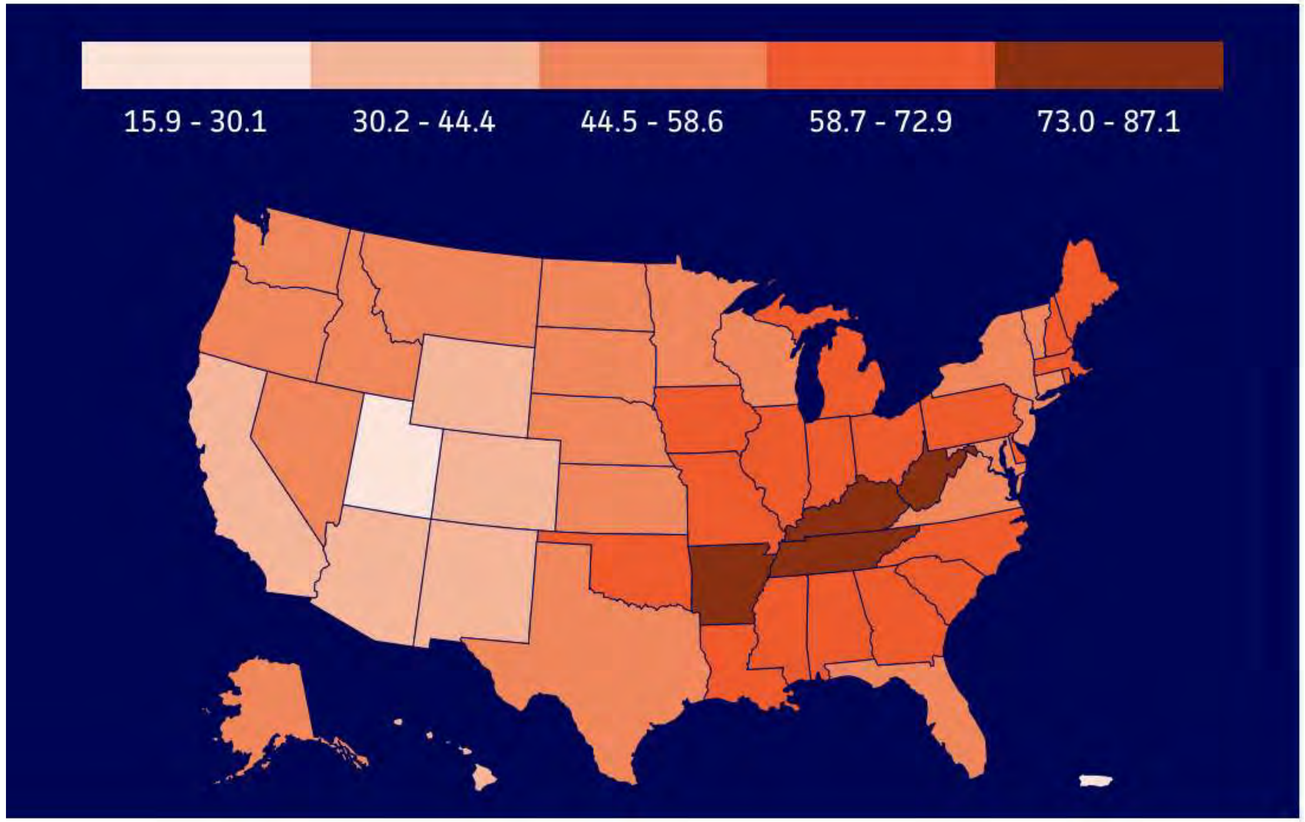
By cancer type, both sexes combined



American Cancer Society, 2023

Incidence rates, 2015-2019

Lung and bronchus, by state



Average annual rate per 100,000, age adjusted to the 2000 US standard population.

Data sources: North American Association of Central Cancer Registries (NAACCR), 2022

https://cancerstatisticscenter.cancer.org

Table 1. **Definitions for T, N, M (continued)**

N	Regional Lymph Nodes
NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Metastasis in ipsilateral peribronchial and/or ipsilateral hilar lymph nodes and intrapulmonary nodes, including involvement by direct extension
N2	Metastasis in ipsilateral mediastinal and/or subcarinal lymph node(s)
N3	Metastasis in contralateral mediastinal, contralateral hilar, ipsilateral or contralateral scalene, or supraclavicular lymph node(s)

M	Distant Metastasis
M0	No distant metastasis
M1	Distant metastasis
M1a	Separate tumor nodule(s) in a contralateral lobe; tumor with pleural or pericardial nodules or malignant pleural or pericardial effusion[a]
M1b	Single extrathoracic metastasis in a single organ (including involvement of a single nonregional node)
M1c	Multiple extrathoracic metastases in a single organ or in multiple organs

Table 2. **AJCC Prognostic Groups**

	T	N	M
Occult Carcinoma	TX	N0	M0
Stage 0	Tis	N0	M0
Stage IA1	T1mi	N0	M0
	T1a	N0	M0
Stage IA2	T1b	N0	M0
Stage IA3	T1c	N0	M0
Stage IB	T2a	N0	M0
Stage IIA	T2b	N0	M0
Stage IIB	T1a	N1	M0
	T1b	N1	M0
	T1c	N1	M0
	T2a	N1	M0
	T2b	N1	M0
	T3	N0	M0
Stage IIIA	T1a	N2	M0
	T1b	N2	M0
	T1c	N2	M0
	T2a	N2	M0
	T2b	N2	M0
	T3	N1	M0
	T4	N0	M0
	T4	N1	M0
Stage IIIB	T1a	N3	M0
	T1b	N3	M0
	T1c	N3	M0
	T2a	N3	M0
	T2b	N3	M0
	T3	N2	M0
	T4	N2	M0
Stage IIIC	T3	N3	M0
	T4	N3	M0
Stage IVA	Any T	Any N	M1a
	Any T	Any N	M1b
Stage IVB	Any T	Any N	M1c

[a] Most pleural (pericardial) effusions with lung cancer are a result of the tumor. In a few patients, however, multiple microscopic examinations of pleural (pericardial) fluid are negative for tumor, and the fluid is nonbloody and not an exudate. If these elements and clinical judgment dictate that the effusion is not related to the tumor, the effusion should be excluded as a staging descriptor.

Used with permission of the American College of Surgeons, Chicago, Illinois. The original source for this information is the AJCC Cancer Staging Manual, Eighth Edition (2017) published by Springer International Publishing.

TNM Staging

Developed in France in the 1940s by Pierre Denoix at the Institute Gustav-Roussy

First International TNM recommendations were published in the International Union Against Cancer in 1958

American Joint Committee on Cancer (AJCC) and the Union for International Cancer Control (UICC) maintain the TNM staging system

Currently on the 8th edition released in 2017

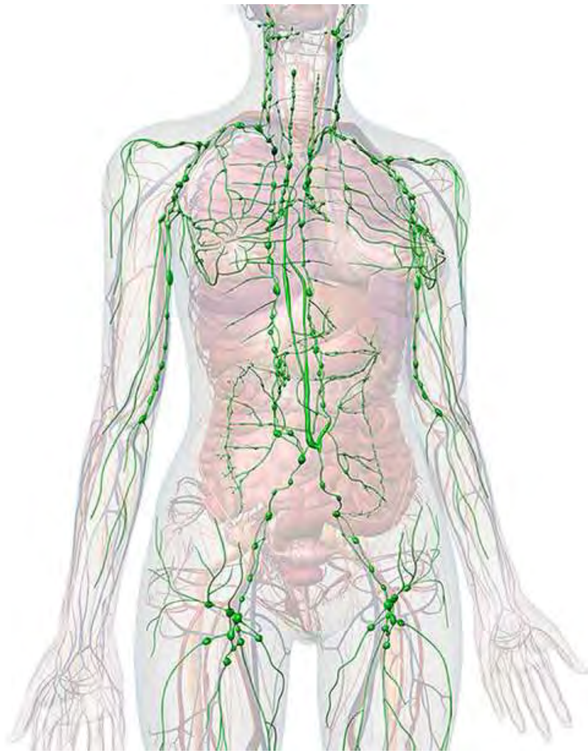
In the 5th edition (1997) N1 disease was Stage III

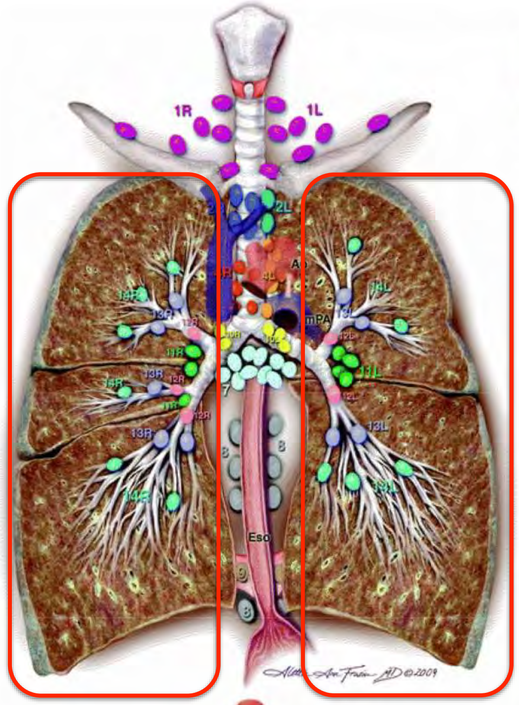
Lymphatics

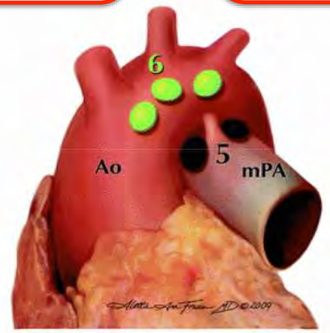
Third vessel in the body

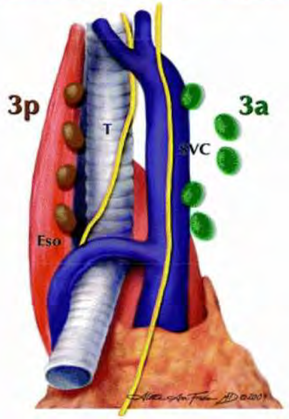
Help prevent infection and helps manage fluid levels in the organs and soft tissues

Nodes are aggregates of primarily B and T cells









Supraclavicular zone

1 Low cervical, supraclavicular, and sternal notch nodes

SUPERIOR MEDIASTINAL NODES

Upper zone

- 2R Upper Paratracheal (right)
- 2L Upper Paratracheal (left)
- 3a Prevascular
- 3p Retrotracheal
- 4R Lower Paratracheal (right)
- 4L Lower Paratracheal (left)

AORTIC NODES

AP zone

- 5 Subaortic
- 6 Para-aortic (ascending aorta or phrenic)

INFERIOR MEDIASTINAL NODES

Subcarinal zone

- 7 Subcarinal

Lower zone

- 8 Paraesophageal (below carina)
- 9 Pulmonary ligament

N1 NODES

Hilar/Interlobar zone

- 10 Hilar
- 11 Interlobar

Peripheral zone

- 12 Lobar
- 13 Segmental
- 14 Subsegmental

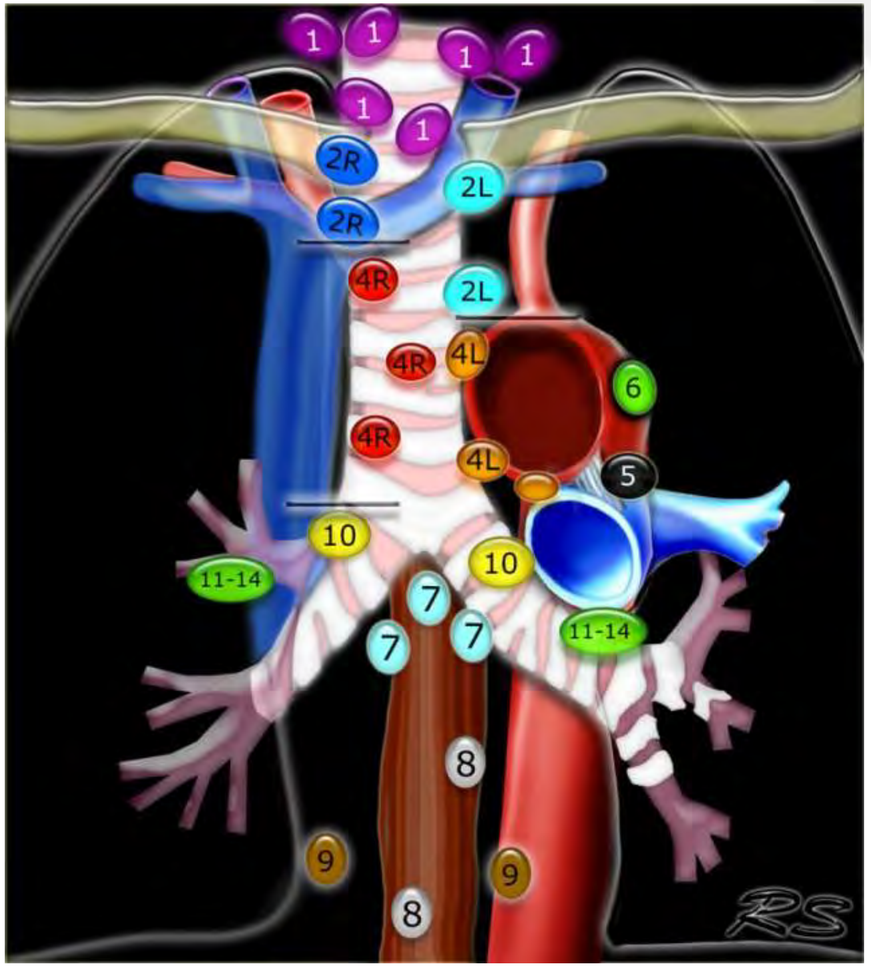
Tumor Spread through Lymphatics

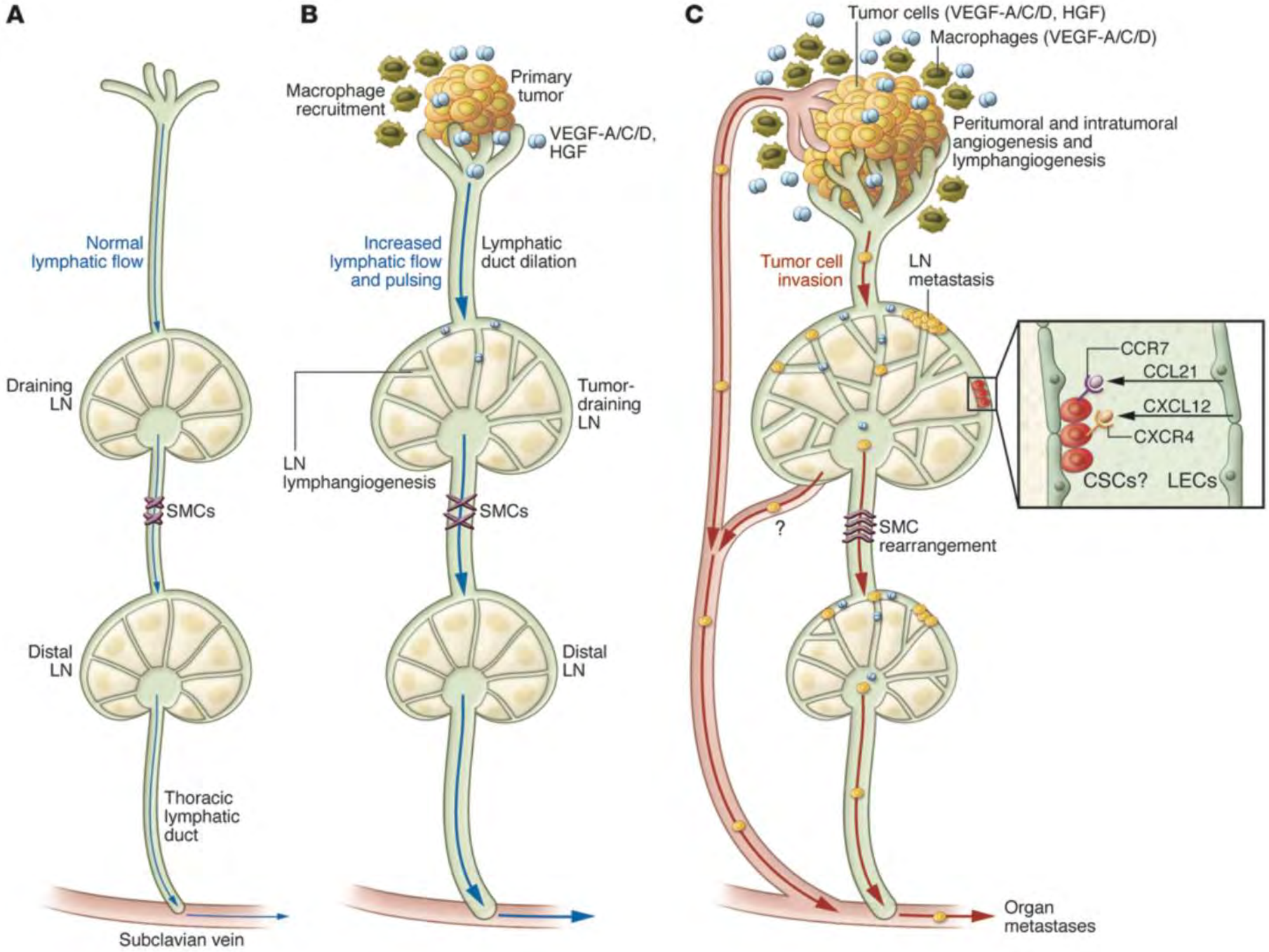
Used to be thought as a more passive process

- Lymphatics were just a channel for spread

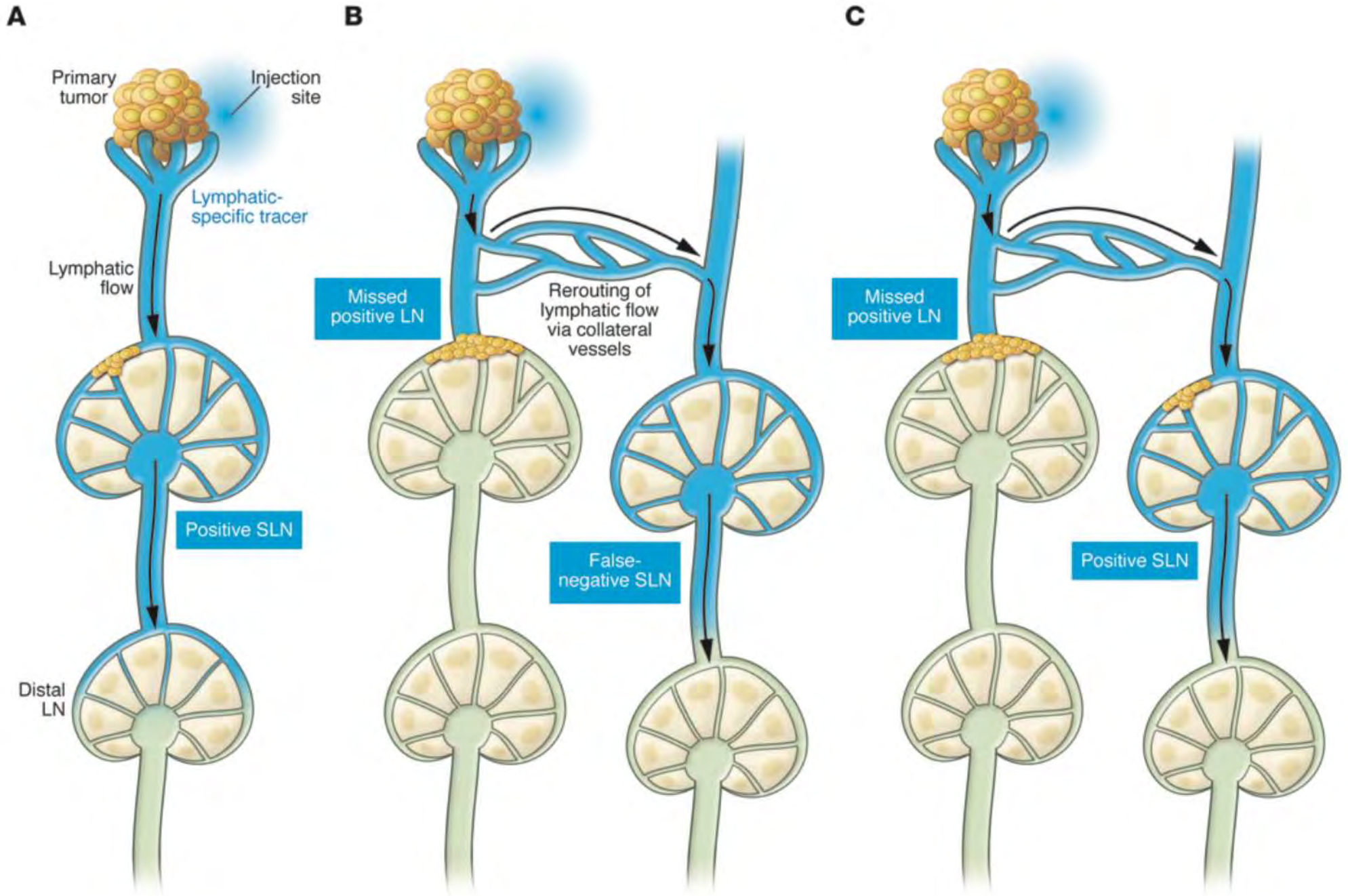
Now, known to be a more active process

- Vascular endothelial growth factor (VEGF)
- Lymphangiogenesis





J Clin Invest. 2014;124(3):922-928. https://doi.org/10.1172/JCI71606.



J Clin Invest. 2014;124(3):922-928. https://doi.org/10.1172/JCI71606.

5-year relative survival rates for non-small cell lung cancer

These numbers are based on people diagnosed with NSCLC between 2012 and 2018.

SEER stage	5-year relative survival rate
Localized	65%
Regional	37%
Distant	9%
All SEER stages combined	28%

https://www.cancer.org/cancer/types/lung-cancer/detection-diagnosis-staging/survival-rates.html

www.impactjournals.com/oncotarget/ Oncotarget, 2017, Vol. 8, (No. 28), pp: 45777-45783

Research Paper

Prognostic significance of subclassification of stage IIB lung cancer: a retrospective study of 226 patients

Nanchang Yin[1], Minwen Ha[2], Yu Liu[3], Huizi Gu[4], Zetian Zhang[5] and Wei Liu[2]

Liaoning Cancer Hospital and Institute China

2001 - 2010

Completely resected, pathologically examined N1 disease, patient did not have adjuvant therapy

pT1b, pT1c, pT2a, pT2b 5 year survival rate

- 67%, 33%, 21%, and 27%

Eur Respir J 2013; 41: 649–655
DOI: 10.1183/09031936.00058512

Prognostic factors in resected pathological N1-stage II nonsmall cell lung cancer

Chao-Yu Liu*,#,+, Jung-Jyh Hung*,#,+, Bing-Yen Wang¶, Wen-Hu Hsu*,# and Yu-Chung Wu*,#

Retrospective Review from Taiwan

210 patients from 1992 to 2010

Pathologic N1 Stage II resected at Taipei Veterans General Hospital

Interesting because the AJCC 7th edition had two subgroups of stage II (N0 and N1)

Overall 5 year survival 43%

Significant predictors of worse overall survival:

- Hilar/interlobar node involvement
- Poorly differentiated

Prognostic Significance of Surgical-Pathologic N1 Disease in Non-Small Cell Carcinoma of the Lung

Marc Riquet, MD, Dominique Manac'h, MD, Françoise Le Pimpec-Barthes, MD, Antoine Dujon, MD, and Antoine Chehab, MD

Service de Chirurgie Thoracique, Hôpital Laennec, Paris, and Centre Chirurgical du Cèdre, Boisguillaume, France

256 patients from 1984 - 1993 retrospective review

Resected N1 disease

Overall 5 year survival 47.5%

Survival not related to:

- Site, pT, histologic type, type of resection, number of N1 stations involved, nor type of N1 involvement (met, direct)

Survival was significantly better:

- When N1 disease was intralobar (stations 12 and 13) vs extralobar (stations 10 and 11)
- 53.6% vs 38.5%

Ann Thorac Surg
1999;67:1572–6

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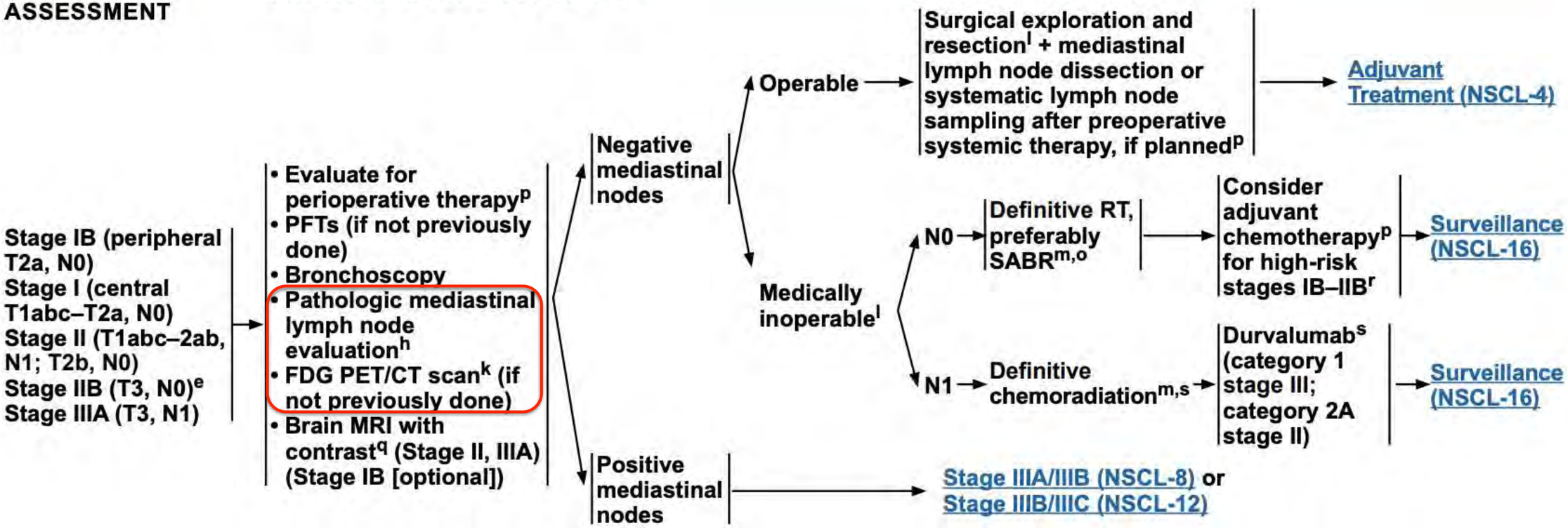


PET Scan and Pathologic Mediastinal Lymph Node Evaluation

Positron Emission Tomography

Nuclear medicine scan

Often used with FDG or fluorodeoxyglucose

- Other radiotracers
  - Oxygen, carbon, nitrogen, gallium

Not just a structural scan but a functional scan

The brighter the image, the more metabolism of the radio tracer within the tissue being studied

Results of the American College of Surgeons Oncology Group Z0050 Trial: The utility of positron emission tomography in staging potentially operable non–small cell lung cancer

Carolyn E. Reed, MD,[a] David H. Harpole, MD,[b] Katherine E. Posther, MD,[c] Sandra L. Woolson, MPh,[d] Robert J. Downey, MD,[e] Bryan F. Meyers, MD,[f] Robert T. Heelan, MD,[g] Homer A. MacApinlac, MD,[h] Sin-Ho Jung, PhD,[i] Gerard A. Silvestri, MD,[j] Barry A. Siegel, MD,[k] and Valerie W. Rusch, MD[l]

From 2000 - 2002 in 22 institutions

303 patients with NSCLC underwent PET after being deemed resectable

- Resectability was determined by CT chest and abdomen, bone scan and brain imaging.

PET was significantly better than CT for the detection of N1 and N2/3 disease (42% vs 13%, p = 0.0177 and 58% vs 32%, p = 0.0041)

The Journal of Thoracic and Cardiovascular Surgery • Volume 126, Number 6

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Staging of Non–Small-Cell Lung Cancer with Integrated Positron-Emission Tomography and Computed Tomography

Didier Lardinois, M.D., Walter Weder, M.D., Thomas F. Hany, M.D., Ehab M. Kamel, M.D., Stephan Korom, M.D., Burkhardt Seifert, Ph.D., Gustav K. von Schulthess, M.D., Ph.D., and Hans C. Steinert, M.D.

50 patients, prospective, single institution

NSCLC

Three groups:

- CT alone, PET alone, Integrated PET/CT

Compared to the pathologic stage

- Found Integrated to be superior to CT or PET alone, and it was superior to having both scans independently

Limitations of PET/CT in the Detection of Occult N1 Metastasis in Clinical Stage I(T1-2aN0) Non-Small Cell Lung Cancer for Staging Prior to Stereotactic Body Radiotherapy

Adil S. Akthar, MD[1], Mark K. Ferguson, MD[2,3], Matthew Koshy, MD[1], Wickii T. Vigneswaran, MD[4], and Renuka Malik, MD[1]

Retrospective review of stage I NSCLC by PET from 2003 - 2011

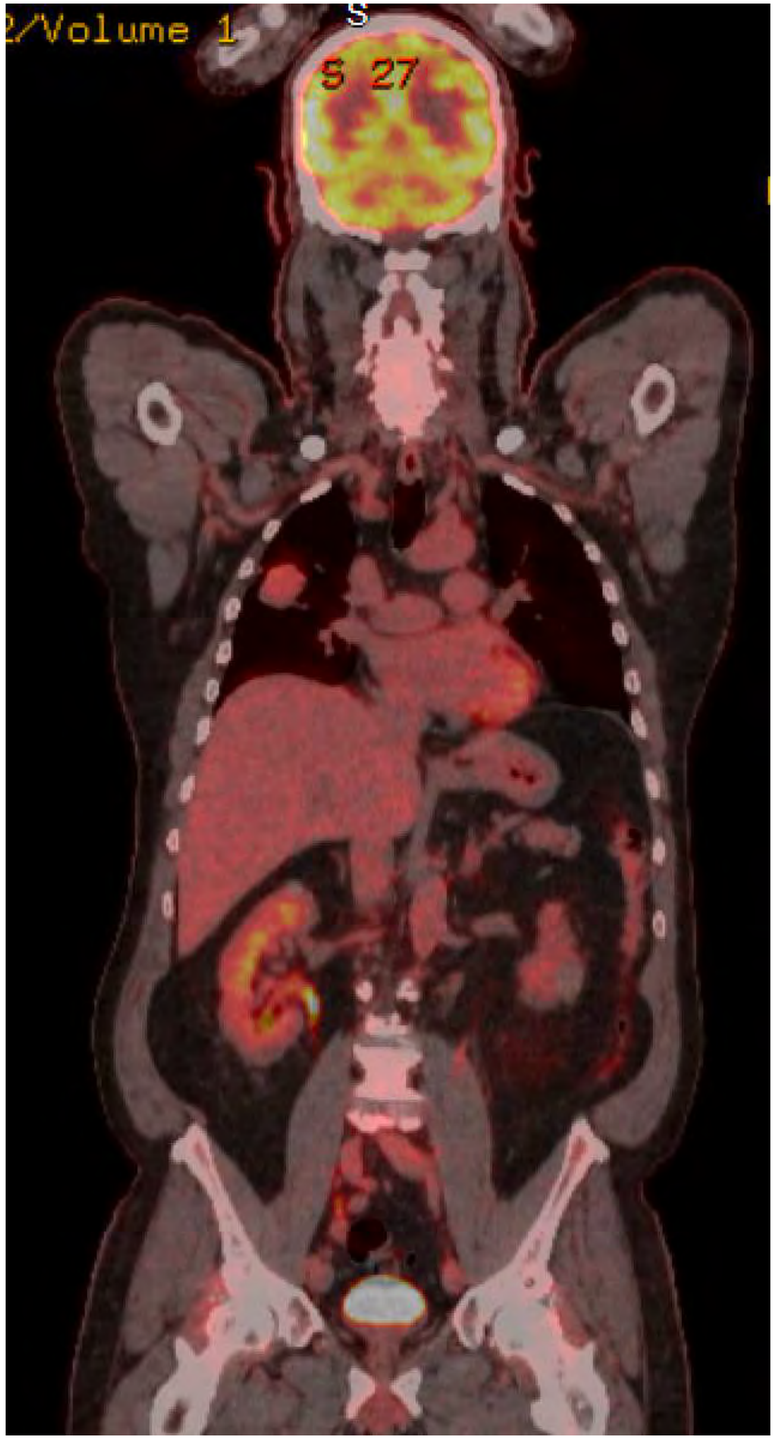
105 patients

Looked at negative predictive value and predictors of occult spread

Negative predictive value:

- All N1 disease of 92.4%
- All T1 vs T2 (96% vs 83%)
- All peripheral vs central tumors (98% vs 74%)
- Peripheral T1 and T2 (98% and100%)
- Central T1 and T2 (85% and 64%)

Technology in Cancer Research & Treatment
2017, Vol. 16(1) 15–21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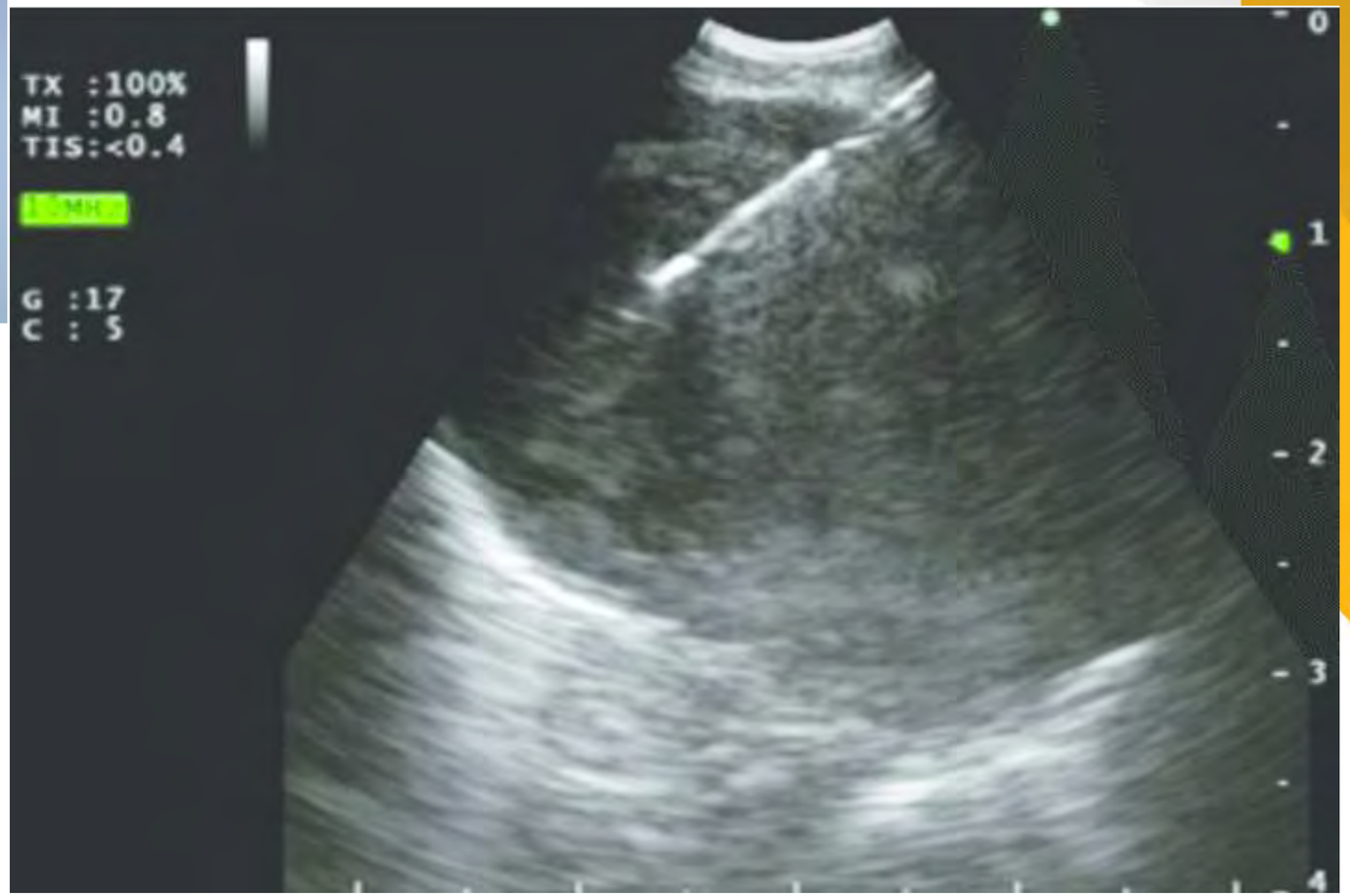
S 27


TX :100%
MI :0.8
TIS:<0.4
G :17
C : 5
0
1
2
3
4

Endobronchial ultrasound-guided transbronchial needle aspiration of lymph nodes in the radiologically normal mediastinum

F.J.F. Herth*, A. Ernst*,#, R. Eberhardt*, P. Vilmann¶, H. Dienemann+ and M. Krasnik§

Prospective

2003 - 2005 Multi-center, Heidelberg German

100 patients

NSCLC with no enlarged mediastinal or hilar nodes

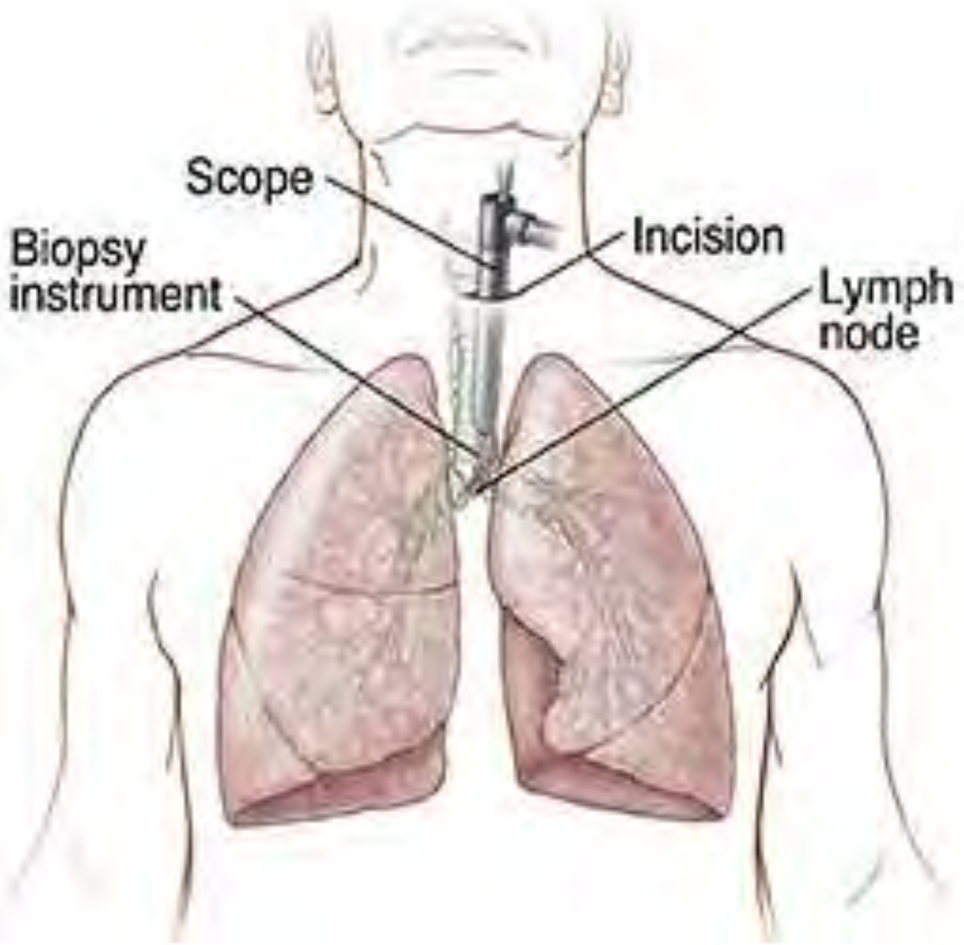
All had EBUS then resection

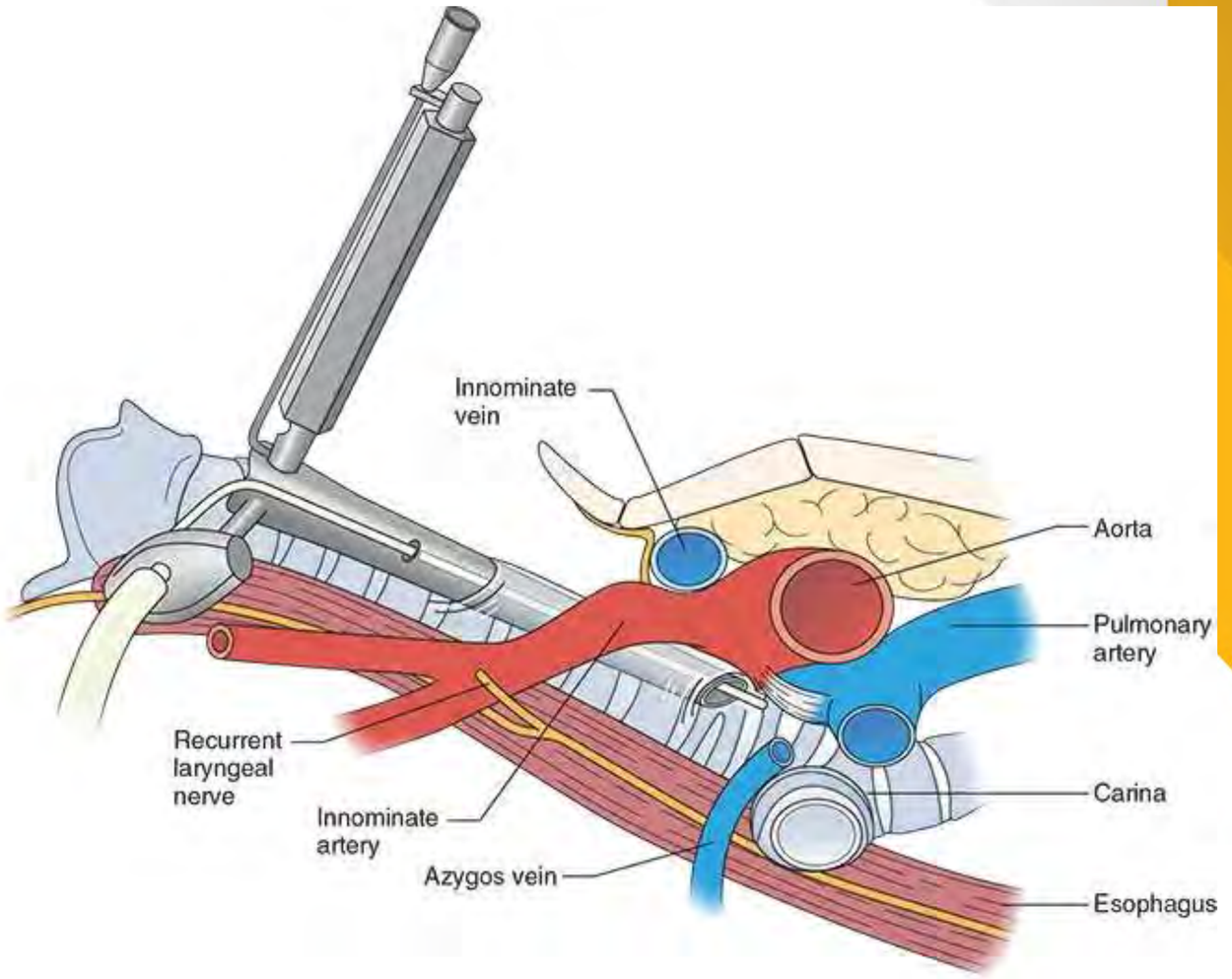
TABLE 1 Results of endobronchial ultrasound-guided transbronchial needle aspiration in 100 patients with nonsmall cell lung cancer

Location	Biopsied nodes	Nodes positive for cancer	Surgically confirmed diagnoses
2r	13	5 (38)	6 (46)
2l	16	2 (13)	2 (13)
4r	17	2 (12)	2 (12)
4l	17	3 (18)	3 (18)
7	13	1 (8)	1 (8)
10r	12	3 (25)	3 (25)
10l	10	1 (10)	1 (10)
11r	10	1 (10)	2 (20)
11l	11	4 (36)	4 (36)
Total	119	22 (19)	24 (20)

Data are presented as n or n (%).

Eur Respir J 2006; 28: 910–914
DOI: 10.1183/09031936.06.00124905


Scope
Biopsy instrument
Incision
Lymph node


Innominate vein
Aorta
Pulmonary artery
Recurrent laryngeal nerve
Innominate artery
Carina
Azygos vein
Esophagus

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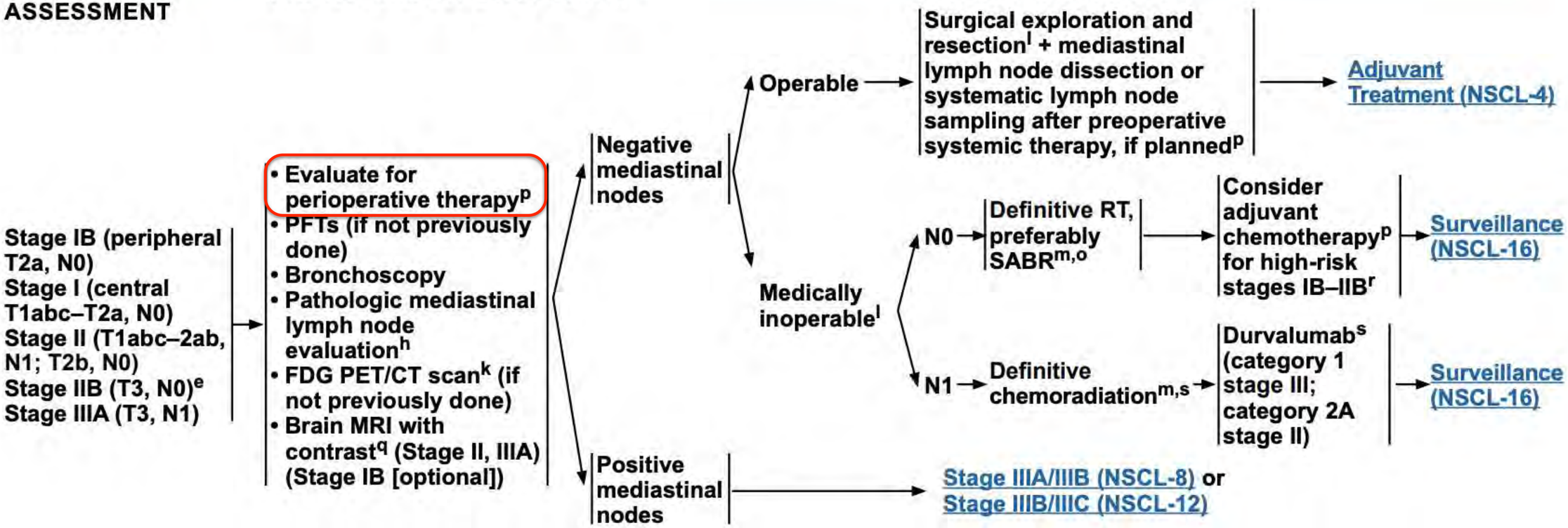


PERIOPERATIVE SYSTEMIC THERAPY

Neoadjuvant Systemic Therapy

- All patients should be evaluated for preoperative therapy, with strong consideration for nivolumab + chemotherapy for those patients with tumors ≥4 cm or node positive and no contraindications to immune checkpoint inhibitors.* Otherwise refer to the Neoadjuvant Systemic Therapy for Patients Not Candidates for Immune Checkpoint Inhibitors.
- Test for PD-L1 status, *EGFR* mutations, and *ALK* rearrangements (stages IB–IIIA, IIIB [T3,N2]).
  Principles of Molecular and Biomarker Analysis (NSCL-H)
- After surgical evaluation, patients likely to receive adjuvant chemotherapy may be treated with induction systemic therapy as an alternative.

Neoadjuvant Systemic Therapy in Patients Candidates for Immune Checkpoint Inhibitors

- Nivolumab 360 mg and platinum-doublet chemotherapy every 3 weeks for 3 cycles[1]
  - Platinum-doublet chemotherapy options include:
    - ◊ Carboplatin AUC 5 or AUC 6 day 1, paclitaxel 175 mg/m² or 200 mg/m² day 1 (any histology)
    - ◊ Cisplatin 75 mg/m² day 1, pemetrexed 500 mg/m² day 1 (nonsquamous histology)
    - ◊ Cisplatin 75 mg/m² day 1, gemcitabine 1000 mg/m² or 1250 mg/m² days 1 and 8 (squamous histology)
    - ◊ Cisplatin 75 mg/m² day 1, paclitaxel 175 mg/m² or 200 mg/m² day 1 (any histology)
  - Chemotherapy Regimens for Patients Not Candidates for Cisplatin-Based Therapy
    - ◊ Carboplatin AUC 5 or AUC 6 day 1, pemetrexed 500 mg/m² day 1 (nonsquamous histology)
    - ◊ Carboplatin AUC 5 or AUC 6 day 1, gemcitabine 1000 mg/m² or 1250 mg/m² days 1 and 8 (squamous histology)

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 MAY 26, 2022 VOL. 386 NO. 21

Neoadjuvant Nivolumab plus Chemotherapy in Resectable Lung Cancer

P.M. Forde, J. Spicer, S. Lu, M. Provencio, T. Mitsudomi, M.M. Awad, E. Felip, S.R. Broderick, J.R. Brahmer, S.J. Swanson, K. Kerr, C. Wang, T.-E. Ciuleanu, G.B. Saylors, F. Tanaka, H. Ito, K.-N. Chen, M. Liberman, E.E. Vokes, J.M. Taube, C. Dorange, J. Cai, J. Fiore, A. Jarkowski, D. Balli, M. Sausen, D. Pandya, C.Y. Calvet, and N. Girard, for the CheckMate 816 Investigators*

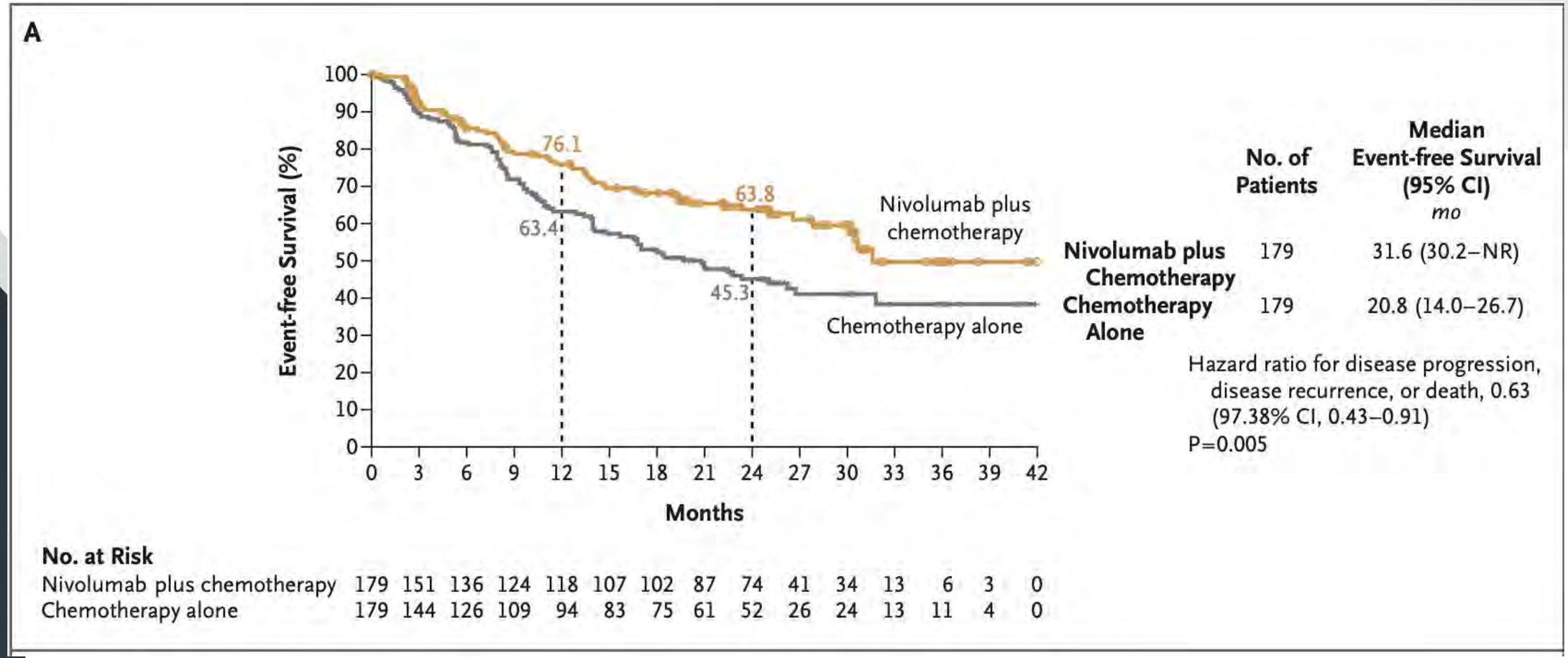
Phase III trial Stage Ib - IIIa resectable NSCLC

Nivolumab + platinum based chemo vs platinum based chemo alone followed by resection

- 176 patients in each group

March 2017 - November 2019

Primary End-Point



	No. of Patients	Median Event-free Survival (95% CI) *mo*
Nivolumab plus Chemotherapy	179	31.6 (30.2–NR)
Chemotherapy Alone	179	20.8 (14.0–26.7)

Hazard ratio for disease progression, disease recurrence, or death, 0.63 (97.38% CI, 0.43–0.91)
P=0.005

Secondary End-Point

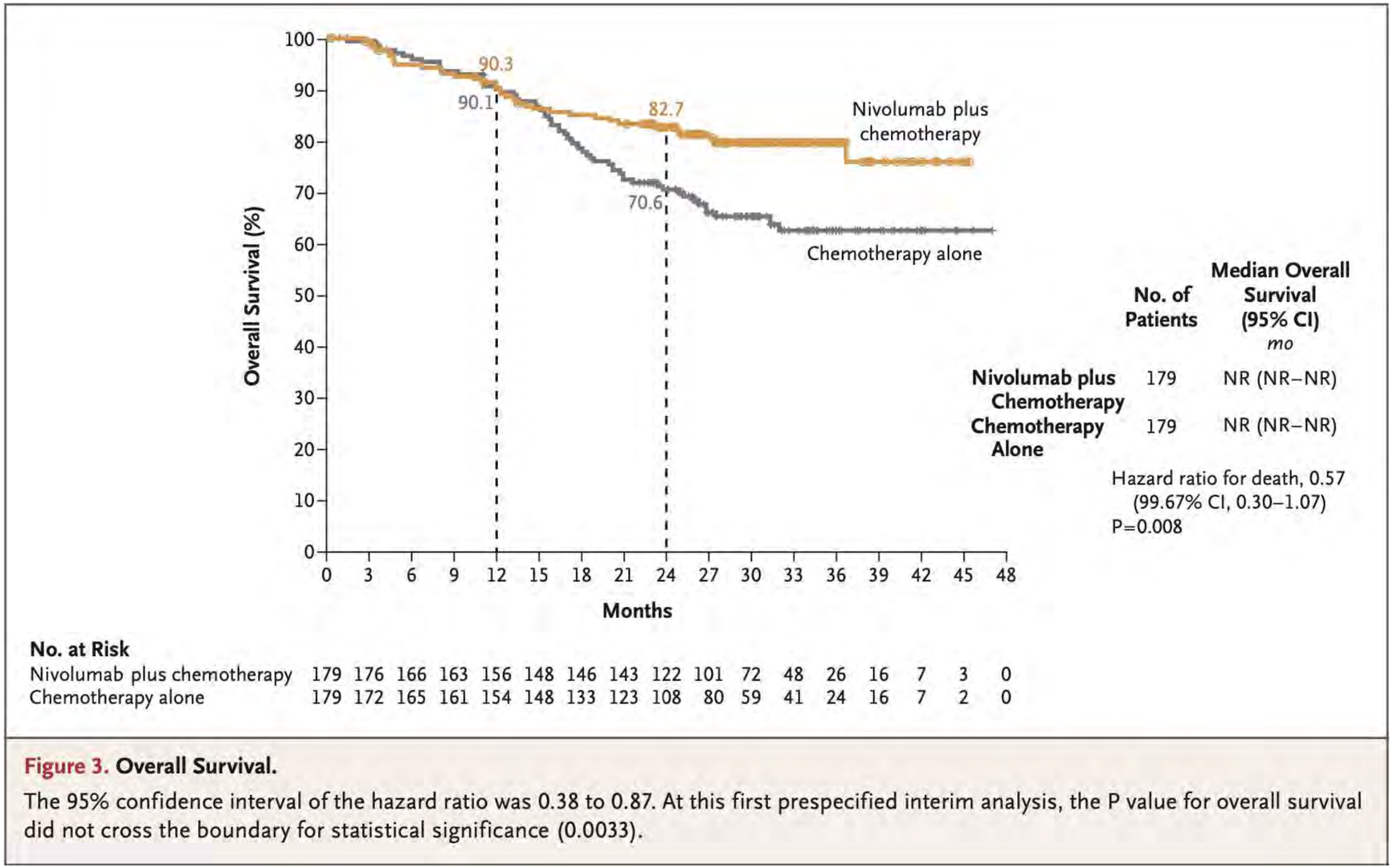


Figure 3. Overall Survival.

The 95% confidence interval of the hazard ratio was 0.38 to 0.87. At this first prespecified interim analysis, the P value for overall survival did not cross the boundary for statistical significance (0.0033).

Neoadjuvant Systemic Therapy for Patients Not Candidates for Immune Checkpoint Inhibitors

Preferred (nonsquamous)

- **Cisplatin 75 mg/m^2 day 1, pemetrexed 500 mg/m^2 day 1 every 21 days for 4 cycles[2]**

Preferred (squamous)

- **Cisplatin 75 mg/m^2 day 1, gemcitabine 1250 mg/m^2 days 1 and 8, every 21 days for 4 cycles[3]**
- **Cisplatin 75 mg/m^2 day 1, docetaxel 75 mg/m^2 day 1 every 21 days for 4 cycles[4]**

Other Recommended

- **Cisplatin 50 mg/m^2 days 1 and 8; vinorelbine 25 mg/m^2 days 1, 8, 15, and 22, every 28 days for 4 cycles[5]**
- **Cisplatin 100 mg/m^2 day 1, vinorelbine 30 mg/m^2 days 1, 8, 15, and 22, every 28 days for 4 cycles[6,7]**
- **Cisplatin 75–80 mg/m^2 day 1, vinorelbine 25–30 mg/m^2 days 1 and 8, every 21 days for 4 cycles**
- **Cisplatin 100 mg/m^2 day 1, etoposide 100 mg/m^2 days 1–3, every 28 days for 4 cycles[6]**

Useful in Certain Circumstances

- **Chemotherapy Regimens for Patients Not Candidates for Cisplatin-Based Therapy**
  - **Carboplatin AUC 6 day 1, paclitaxel 200 mg/m^2 day 1, every 21 days for 4 cycles[8]**
  - **Carboplatin AUC 5 day 1, gemcitabine 1000 mg/m^2 days 1 and 8, every 21 days for 4 cycles[9] (squamous histology)**
  - **Carboplatin AUC 5 day 1, pemetrexed 500 mg/m^2 day 1 every 21 days for 4 cycles[10] (nonsquamous histology)**

All chemotherapy regimens listed above can be used for sequential chemotherapy/RT.

Adjuvant Systemic Therapy

* Contraindications for treatment with PD-1/PD-L1 inhibitors may include active or previously documented autoimmune disease and/or current use of immunosuppressive agents; some oncogenic drivers (ie, *EGFR* exon 19 deletion or exon 21 L858R, *ALK* rearrangements) have been shown to be associated with less benefit from PD-1/PD-L1 inhibitors.

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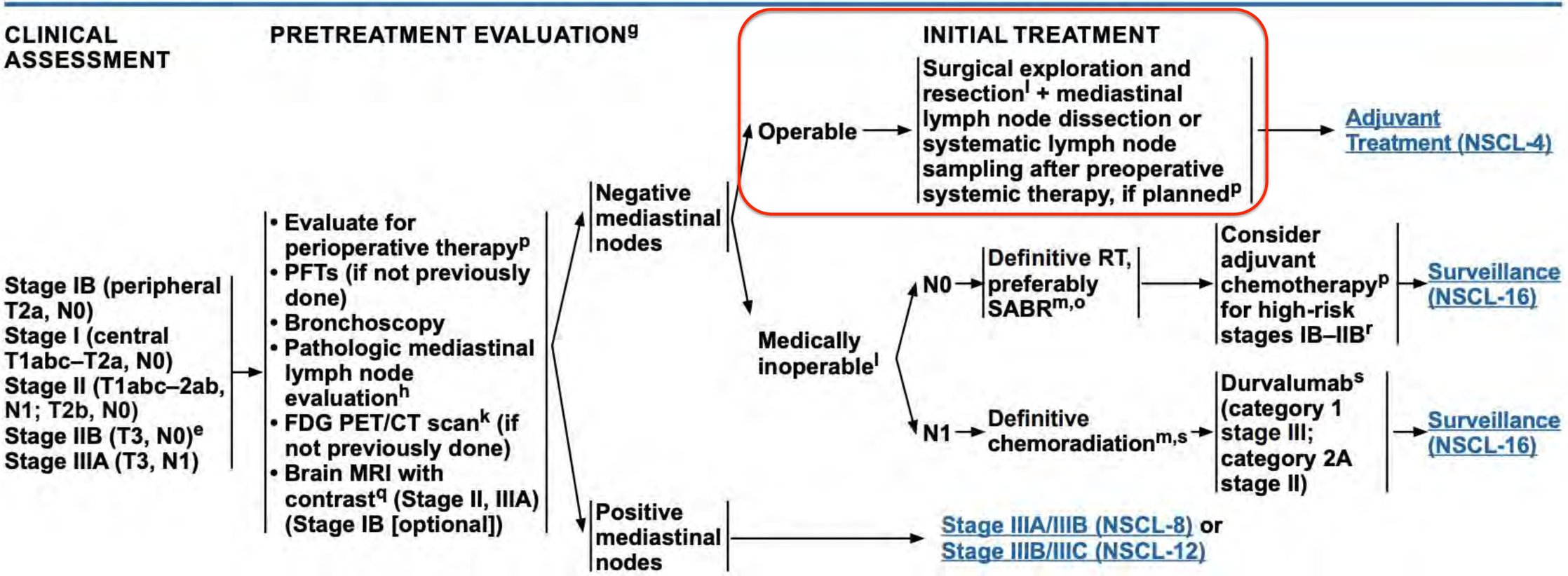

Pathologic N1 non–small cell lung cancer: Correlation between pattern of lymphatic spread and prognosis

Alessandro Marra, MD, PhD
Ludger Hillejan, MD
George Zaboura, MD
Toshio Fujimoto, MD
Dieter Greschuchna, MD
Georgios Stamatis, MD

Published 2003

Retrospective

1990 - 1995

541 patients with N1 disease

5 year survival 40%

Poorer prognosis for hilar, interlobar, or both compared to intralobar.

The Journal of Thoracic and Cardiovascular Surgery • Volume 125, Number 3

TABLE 3. Univariate analysis of clinical-pathologic prognostic factors

	5-y survival (%)	*P* value
pT classification		
T1	65	.0000
T2	45	
T3	29	
T4	8	
Adjuvant therapy		
None	47	.0000
Radiotherapy	23	
Chemoradiotherapy	0	
R status		
R0	44	.0001
R1	30	
R2	19	
Involved node stations		
Single station	44	.0002
Multilevel	27	
No. of involved nodes		
1	49	.0145
2-5	40	
>5	30	
pN classification		
N1d	45	.0184
N1p	41	
N1i	39	
N1h	30	
Karnofsky Index		
100%	45	.0181
90-80%	41	
≤70%	27	

National Comprehensive Cancer Network®

NCCN Guidelines Version 3.2023
Non-Small Cell Lung Cancer

NCCN Guidelines Index
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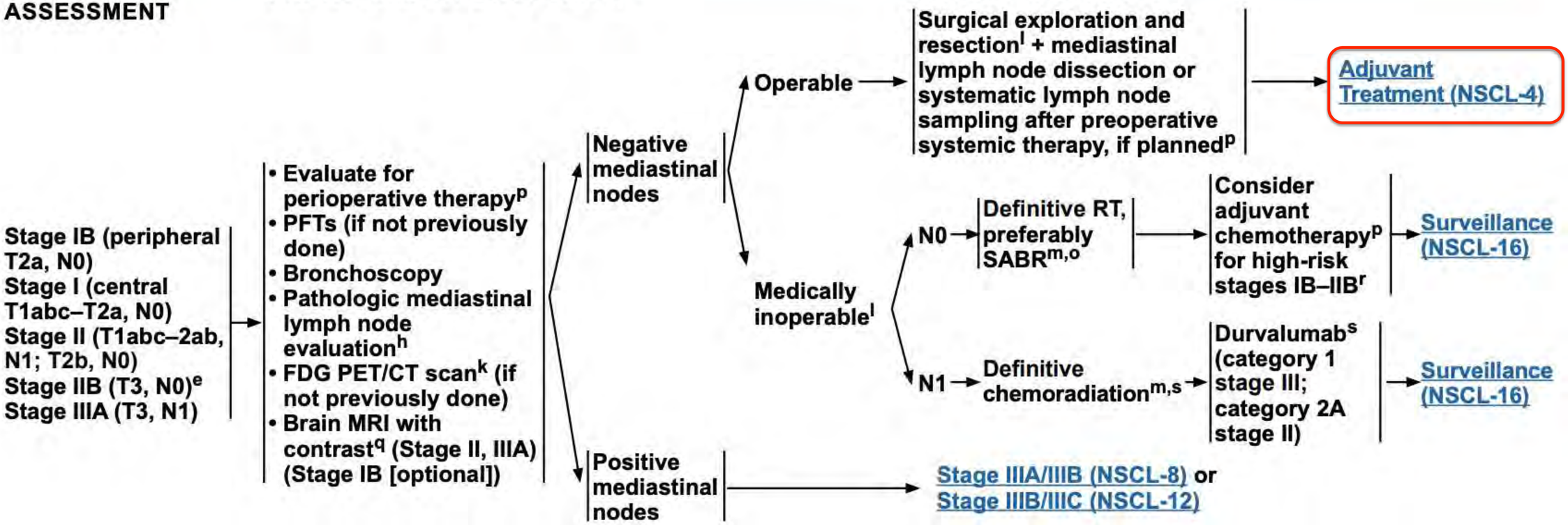
Discussion



PERIOPERATIVE SYSTEMIC THERAPY

Adjuvant Systemic Therapy

- Test for PD-L1 status, *EGFR* mutations, and *ALK* rearrangements (stages IB–IIIA, IIIB [T3,N2]). Principles of Molecular and Biomarker Analysis (NSCL-H).

Preferred (nonsquamous)

- Cisplatin 75 mg/m^2 day 1, pemetrexed 500 mg/m^2 day 1 every 21 days for 4 cycles[2]

Preferred (squamous)

- Cisplatin 75 mg/m^2 day 1, gemcitabine 1250 mg/m^2 days 1 and 8, every 21 days for 4 cycles[3]
- Cisplatin 75 mg/m^2 day 1, docetaxel 75 mg/m^2 day 1 every 21 days for 4 cycles[4]

Other Recommended

- Cisplatin 50 mg/m^2 days 1 and 8; vinorelbine 25 mg/m^2 days 1, 8, 15, and 22, every 28 days for 4 cycles[5]
- Cisplatin 100 mg/m^2 day 1, vinorelbine 30 mg/m^2 days 1, 8, 15, and 22, every 28 days for 4 cycles[6,7]
- Cisplatin 75–80 mg/m^2 day 1, vinorelbine 25–30 mg/m^2 days 1 and 8, every 21 days for 4 cycles
- Cisplatin 100 mg/m^2 day 1, etoposide 100 mg/m^2 days 1–3, every 28 days for 4 cycles[6]

Useful in Certain Circumstances

- Chemotherapy Regimens for Patients Not Candidates for Cisplatin-Based Therapy
  - Carboplatin AUC 6 day 1, paclitaxel 200 mg/m^2 day 1, every 21 days for 4 cycles[8]
  - Carboplatin AUC 5 day 1, gemcitabine 1000 mg/m^2 days 1 and 8, every 21 days for 4 cycles[9]
  - Carboplatin AUC 5 day 1, pemetrexed 500 mg/m^2 day 1 every 21 days for 4 cycles[10] (nonsquamous histology)

All chemotherapy regimens listed above can be used for sequential chemotherapy/RT.

Neoadjuvant vs Adjuvant

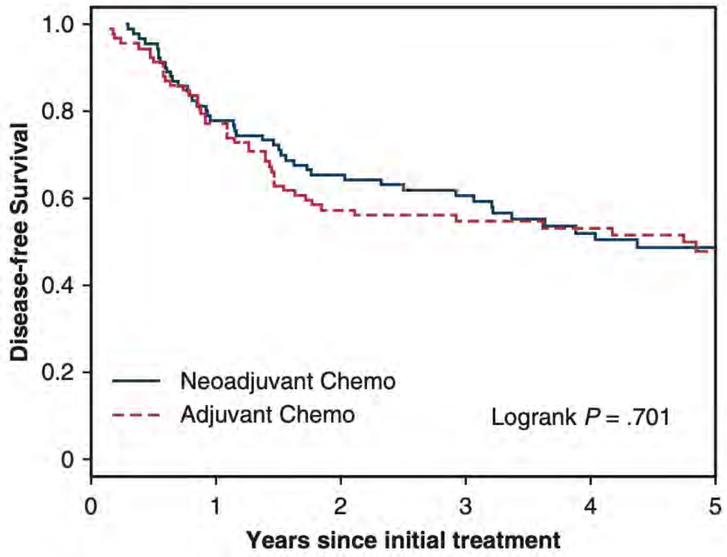
Outcomes after neoadjuvant or adjuvant chemotherapy for cT2-4N0-1 non–small cell lung cancer: A propensity-matched analysis

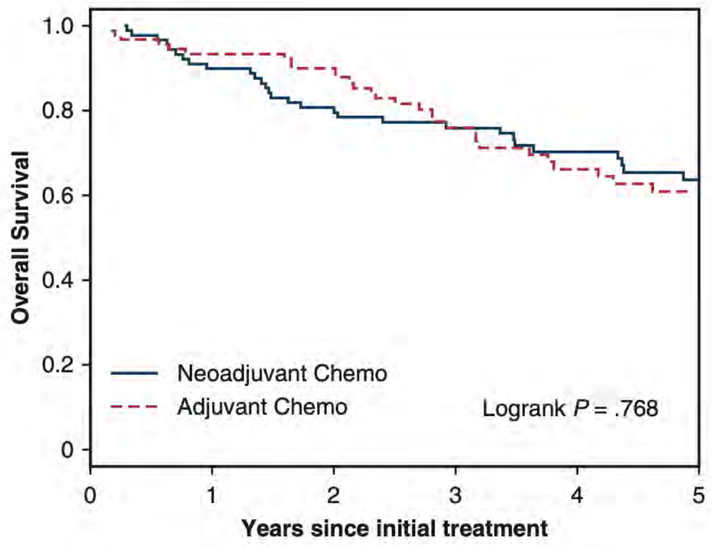
Whitney S. Brandt, MD,[a] Wanpu Yan, MD,[a] Jian Zhou, MD,[a] Kay See Tan, PhD,[b] Joseph Montecalvo, MD,[c] Bernard J. Park, MD,[a] Prasad S. Adusumilli, MD,[a] James Huang, MD,[a] Matthew J. Bott, MD,[a] Valerie W. Rusch, MD,[a] Daniela Molena, MD,[a] William D. Travis, MD,[c] Mark G. Kris, MD,[d] Jamie E. Chaft, MD,[d] and David R. Jones, MD[a]

2018 propensity matched retrospective review

cT2-4N0-1 NSCLC

92 patients per propensity matched group neoadjuvant vs adjuvant





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Future Studies

Future Studies

NEJM will soon publish the KEYNOTE 671 data

- Randomized, Double Blind Phase III Trial
- Resectable stage II and III NSCLC patients
- Neoadjuvant Pembrolizumab vs Placebo
- Event free survival, major pathologic response, and complete pathologic response will show significant difference favoring neoadjuvant Pembrolizumab

ALCHEMIST chemo-IO Trial (ACCIO)

- Resectable Stage Ib - IIIa
- Adjuvant Pembrolizumab

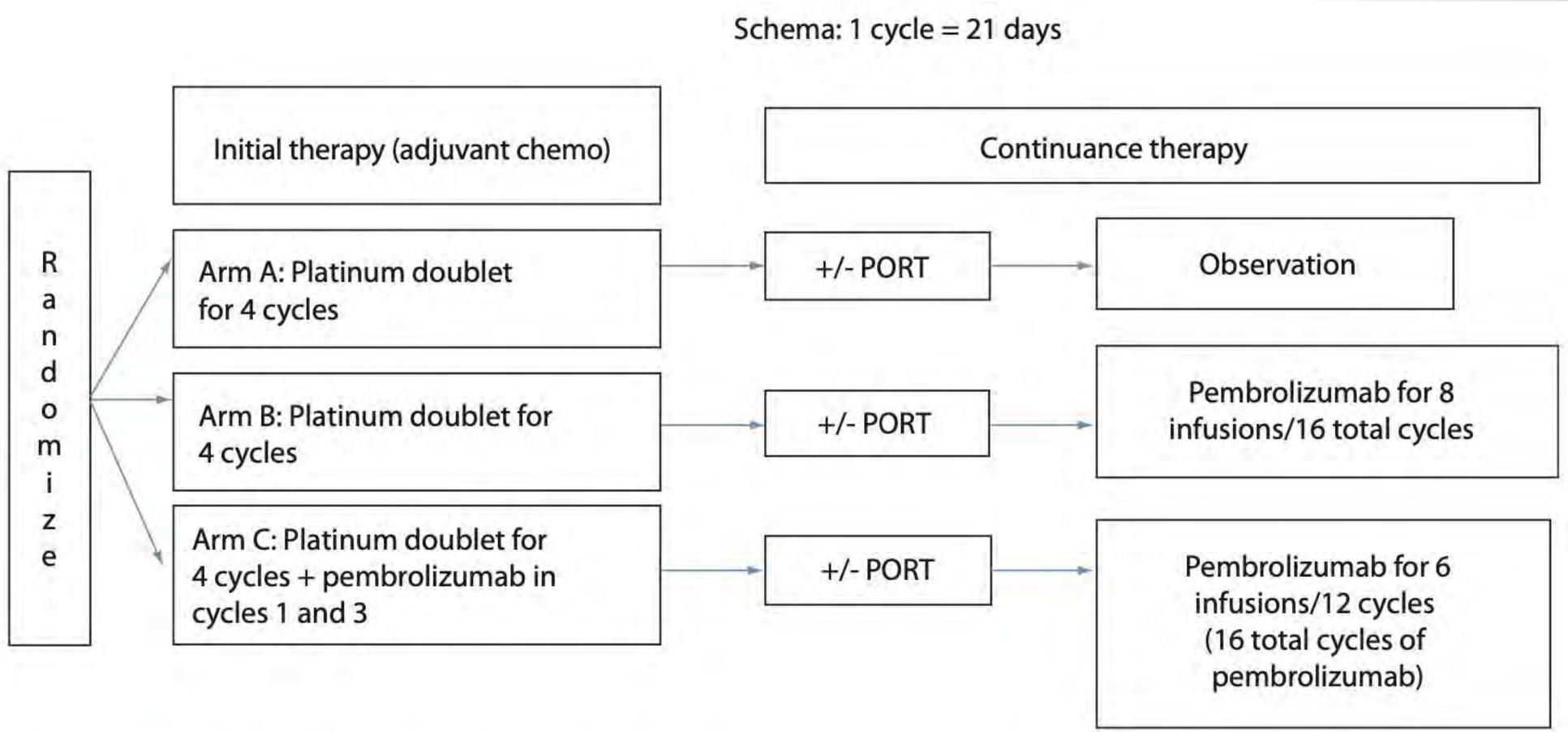

Figure 1. Schema of the ACCIO trial including three arms. Pembrolizumab dosing is every 6 weeks. Sequential and concurrent arms each include about 1 year of pembrolizumab.
PORT: Postoperative radiation therapy.

Summary

Many advances in diagnosing N1 disease in NSCLC though there is a wide range of survival data in the literature presently (~25 - 55% 5 year survival)

Likely due to the grouping together of a more diverse process

Some data suggesting level of node and how many stations involved may correlate to survival

We currently treat N1 disease with adjuvant therapy (though there is freedom in the guidelines for neoadjuvant)

Future studies seem to be directed toward neoadjuvant and adjuvant immunotherapies for earlier stages of NSCLC

Questions?