

foro debate oncología

Zaragoza 26-29 septiembre 2023



¿Pueden o deben devolverse los pacientes con afectación mediastínica a la arena quirúrgica?

Josep Belda. Cirujano Torácico

H. de la Santa Creu i Sant Pau – H. del Mar, Barcelona.

UAB. UPF





No tengo conflictos de interés





ALGUNOS
ALGUNAS
TODOS
TODAS
NINGUNO
NINGUNA

SOY UNA
PERSONA
CON LAS
DUDAS MUY
CLARAS

foro debate oncología

Zaragoza, 19 de junio 2019

Formigal, 20 al 22 de junio 2019

EDICIÓN 2019



Cirugía tras tratamiento neoadyuvante

Josep Belda. Cirujano Torácico





Tanto como puedan...

1. formen un buen equipo (MDT)
2. eviten operar pacientes cyN2
3. eviten la neumonectomía
4. miren la mortalidad a 90 días



Factores de buen pronóstico tras inducción con QT±RT

ypN0-1

- 👉 Strauss, et al. J Clin Oncol 1992
- 👉 Kirn, et al. JTCVS 1993
- 👉 Albain, et al. J Clin Oncol 1995
- 👉 Sugarbaker, et al. JTCVS 1995
- 👉 Rice, et al. Ann Thorac Surg 1998
- 👉 Stamatis, et al. Ann Thorac Surg 1999
- 👉 Okada, et al. Chest 2000
- 👉 Bueno, et al. Ann Thorac Surg 2000
- 👉 Voltolini, et al. EJCTS 2001
- 👉 Cyjon, et al. ATS 2002
- 👉 Martin, et al. J Clin Oncol 2002

R0

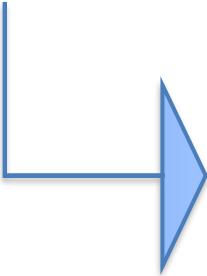
- 👉 Betticher, et al. J Clin Oncol 2003
- 👉 Rusch, et al. Lung Cancer 2005
- 👉 Van Meerbeeck, et al. Lung Cancer 2005
- 👉 Jaklitsch, et al. J Surg Oncol 2006
- 👉 Van Meerbeeck, et al. J Natl Cancer Inst 2007
- 👉 Garrido, et al. J Clin Oncol 2007
- 👉 Thomas, et al. Lancet Oncol 2008
- 👉 Carreta, et al. World J Surg 2008
- 👉 Albain, et al. Lancet 2009
- 👉 Li, et al. Clin Lung Cancer 2009
- 👉 Decaluwe, et al. EJCTS 2009

RPC

- 👉 Higgins, et al. IJROBPh 2009
- 👉 Krasna, et al. Ann Thorac Surg 2010
- 👉 Call, et al. EJCTS 2011
- 👉 Paul, et al. JTCVS 2011
- 👉 Pataer, et al. JTO 2012
- 👉 Steger, et al. ICVTS 2012
- 👉 Lococo, et al. EJCTS 2013
- 👉 Yang, et al. EJCTS 2016
- 👉 Couñago, et al. CTO 2019
- 👉 Cascone, et al. ATS 2019
- 👉 Joosten, et al. Acta Oncol 2020
- 👉 Sinn, et al. ESMO Open 2022

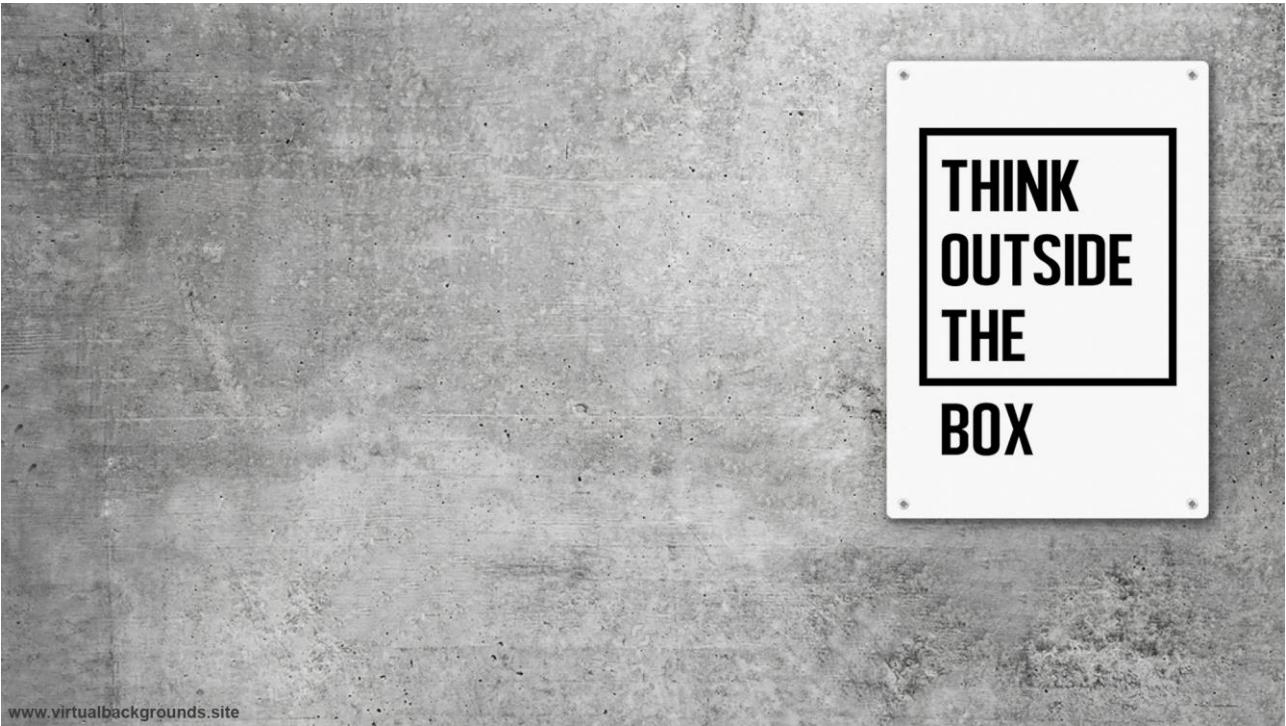


Probablemente... **SOLO**
deberían operarse ycN0-1



el “problema” de la **reestadificación** tras
la neoadyuvancia para certificar el
downstaging ganglionar mediastínico

ALGUNOS
ALGUNAS





N2 resecable tratado con inducción

Downstaging mediastínico

Factor de buen
pronóstico

No downstaging mediastínico

¿Factor que contraindica
siempre la cirugía?

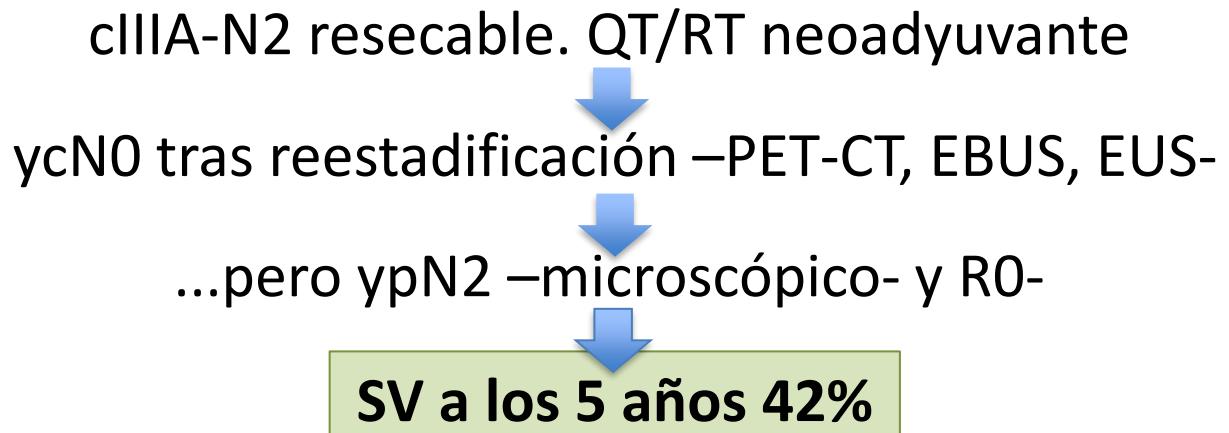


The Treatment of Patients with Stage IIIA Non-Small Cell Lung Cancer From N2 Disease: Who Returns to the Surgical Arena and Who Survives

Robert J. Cerfolio, MD, Lee Maniscalco, BS, and Ayesha S. Bryant, MSPH, MD

Division of Cardiothoracic Surgery, University of Alabama at Birmingham, Birmingham, Alabama

Ann Thorac Surg 2008;86:912–20





MA08.09

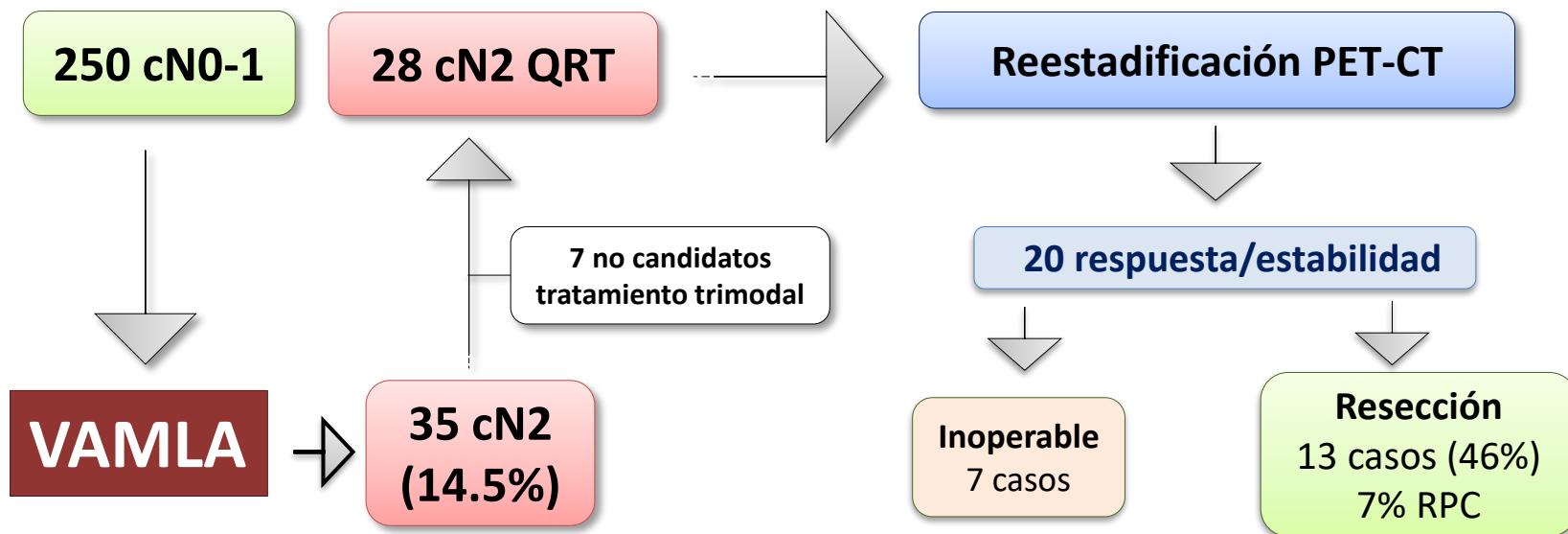
Results of Trimodality Therapy for Patients with cN2 Lung Cancer Diagnosed by Video-Assisted Mediastinoscopic Lymphadenectomy (VAMLA)

S. Call,¹ C. Obiols,¹ R. Rami-Porta,¹ S. Catot,² M. Nuñez,³ M. Campayo,⁴ F. Perez Ochoa,⁵ M. Serra-Mitjans,¹ J. Belda-Sanchis¹

MINI ORAL ABSTRACT SESSIONS | VOLUME 14, ISSUE 10, SUPPLEMENT, S279-S280, OCTOBER 2019



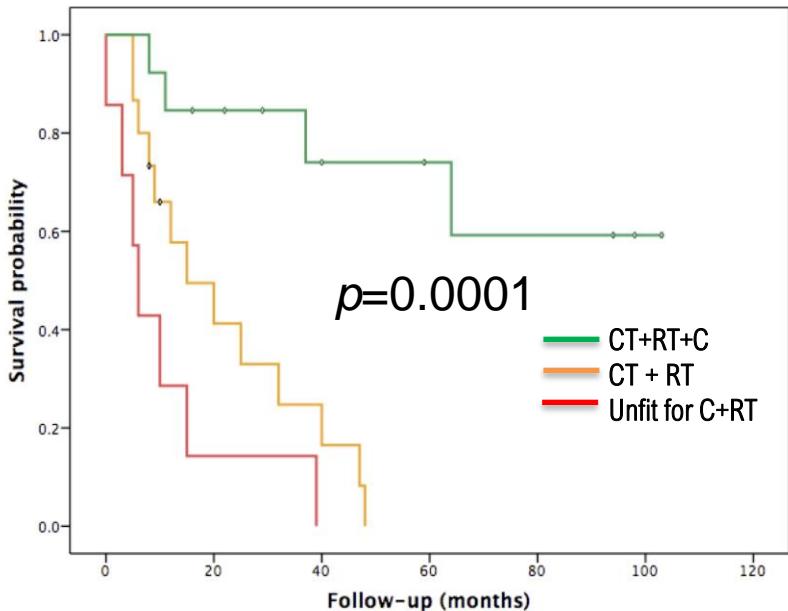
2019 World Conference
on Lung Cancer
September 7-10, 2019 | Barcelona, Spain



2010-17



Survival all N2 cases (n=35)

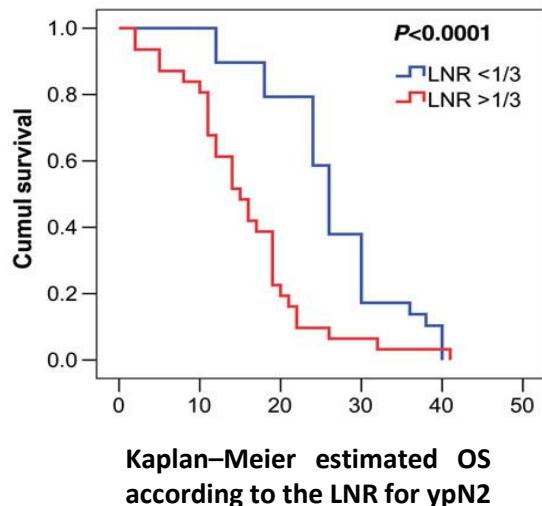


	3-y Sv	5-y Sv
CT + RT + C	85%	74%
C + RT	25%	0%
Unfit for C+RT	14.3%	0%



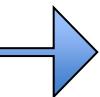
Mediastinal downstaging after induction is not a significant prognostic factor to select patients who would benefit from surgery: the clinical value of the lymph node ratio.

Renaud, et al. ICVTS 2015



Porque hay “pocos” ganglios ypN2 afectos

SV ypN2 con LNR bajo = ypN1 con LNR alto

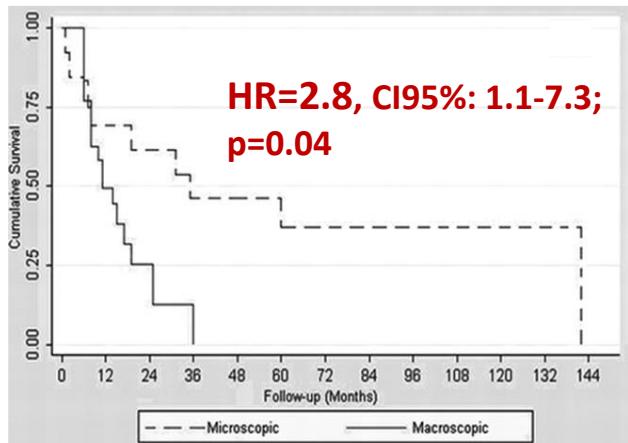


Downstaging mediastínico fue un factor pronóstico independiente pero **NO** suficiente para contraindicar siempre la cirugía tras la inducción



Surgery for patients with persistent pathological N2 IIIA NSCLC after induction RCT:
the microscopic seed of doubt. Meacci E. EJCTS 2011

“Poco ypN2” porque es “solo” microscópico



- 161 IIIA-N2
- Induction CRT
- 40 ypN2 (26%)



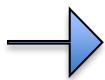
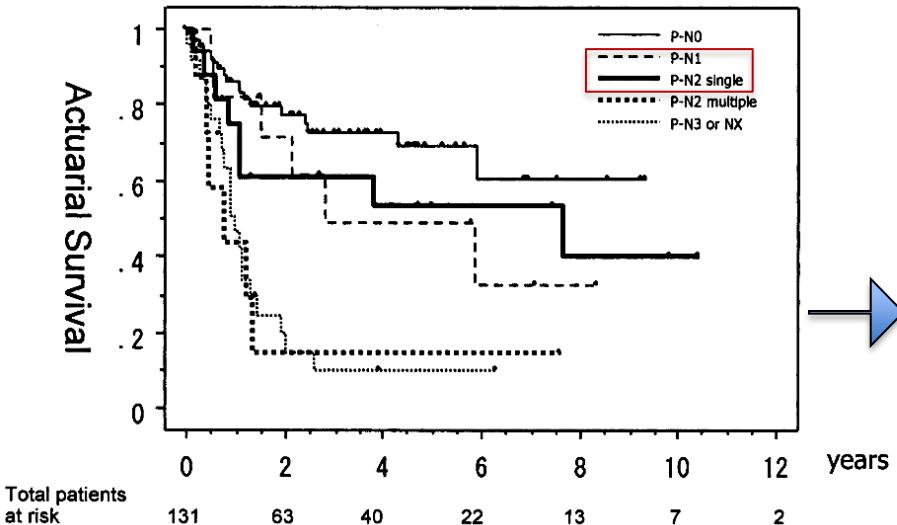
Minor residual ypN2 does not exclude favorable outcomes.



The impact of residual multi-level N2 disease after induction therapy for NSCLC.

Sawabata, et al. LC 2003

“Poco ypN2” porque hay un solo nivel afecto



Actuarial survival of patients with single N2 is similar to patients with N1 disease





Einstein con la Ronda Jotera. Zaragoza 1923

Assistant: Dr. Einstein, aren't these the same questions as last year [physics] final exam?

Dr. Einstein: Yes, but this year the answers are different



Estudio	Estadios	IT/TD neoadyuvante (adj)	Restaging
CheckMate 816	IB-II vs IIIA	Nivolumab	
KEYNOTE-671	II, IIIA, IIIB (N2)	Pembrolizumab	
AEGEAN	IIA-select (N2)IIIB	Durvalumab	
NADIM ✿	IIIA (74% N2)	Nivolumab	
SAKK 16/14	IIIA(N2) -T1-3N2M0	Durvalumab	
NEOSTAR	IA-IIIA (16% N2)	Nivolumab± Ipilimumab	
NEOS	IIA-IIIB (T3-4 N2)EGFRm+	Osimertinib	
TEAM-LungMate 004	IIIA,IIIB,IIIC EGFRm+	Afatinib	
NeoADAURA	II-IIIB N2 EGFRm+	Osimertinib	
INCREASE	IIIA-IIIB (cT3-4N0-2M0)	Nivolumab-Ipilimumab	
LCMC 3 trial	IB-select IIIB (resectable T4,N2)	Atezolizumab	

✿ Clinical responses according to RECIST v1.1 criteria did not predict survival outcomes!

CT

**Radiographic
downstaging**

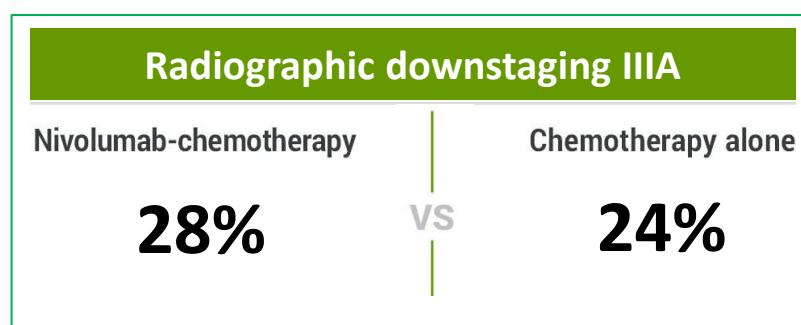
**TODOS
TODAS**

CheckMate 816 study

Supplement to: Forde PM, Spicer J, Lu S, et al. Neoadjuvant nivolumab plus chemotherapy in resectable lung cancer. N Engl J Med. DOI: 10.1056/NEJMoa2202170

Table S11. Radiographic Downstaging: Pre- and Post-treatment Stage of Disease.*

Stage	Nivolumab plus Chemotherapy (N = 179)		Chemotherapy (N = 179)	
	Disease Stage at Study Entry	Disease Stage after Neoadjuvant Treatment	Disease Stage at Study Entry	Disease Stage after Neoadjuvant Treatment
		<i>number of patients (percent)</i>		
0	0	2 (1.1)	0	2 (1.1)
IA	0	23 (12.8)	1 (0.6)	13 (7.3)
IB	10 (5.6)	14 (7.8)	8 (4.5)	23 (12.8)
IIA	30 (16.8)	29 (16.2)	32 (17.9)	20 (11.2)
IIB	25 (14.0)	15 (8.4)	22 (12.3)	12 (6.7)
IIIA	113 (63.1)	81 (45.3)	115 (64.2)	87 (48.6)
IIIB	0	3 (1.7)	0	6 (3.4)
IV	1 (0.6)	7 (3.9)	1 (0.6)	5 (2.8)
Not reported	0	5 (2.8)	0	11 (6.1)





CheckMate 816

KEYNOTE-671

NADIM

SAKK 16/14

NEOSTAR

NEOS

TEAM-LungMate 004

LCMC 3 trial

AEGEAN

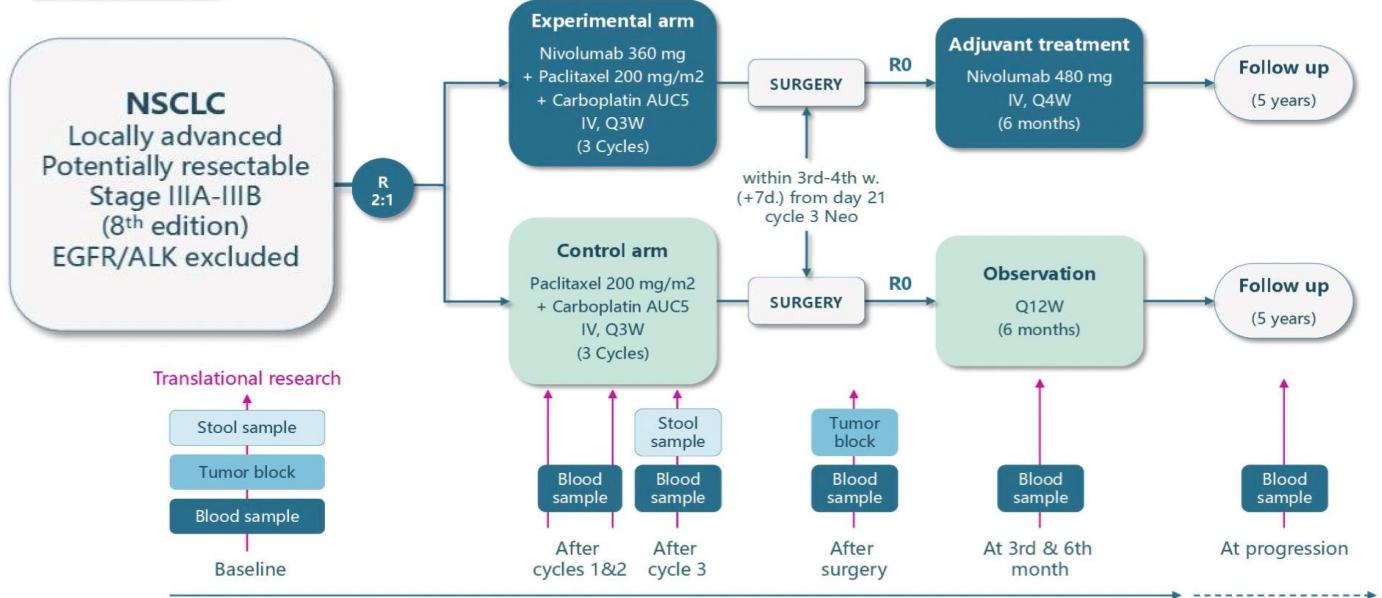


10 – 57% ypN2

- ¿Sigue siendo el ycN2 mediastínico un “surrogate” de enfermedad subclínica a distancia, riesgo de recidiva, factor pronóstico Sv, motivo para contraindicar la cirugía?
- ¿Tenemos tratamientos adyuvantes válidos o mejores que aumenten la supervivencia si ypN2 tras una R0?



NADIM II Study design



NADIM II (NCT03838159) is a randomized, phase 2, open-label, multicentre study evaluating nivolumab + chemotherapy vs chemotherapy as neoadjuvant treatment for potentially resectable NSCLC.



NADIM II Endpoints

5

Primary endpoint

- Pathological complete response in the intention-to-treat population (ITT)

Secondary endpoints

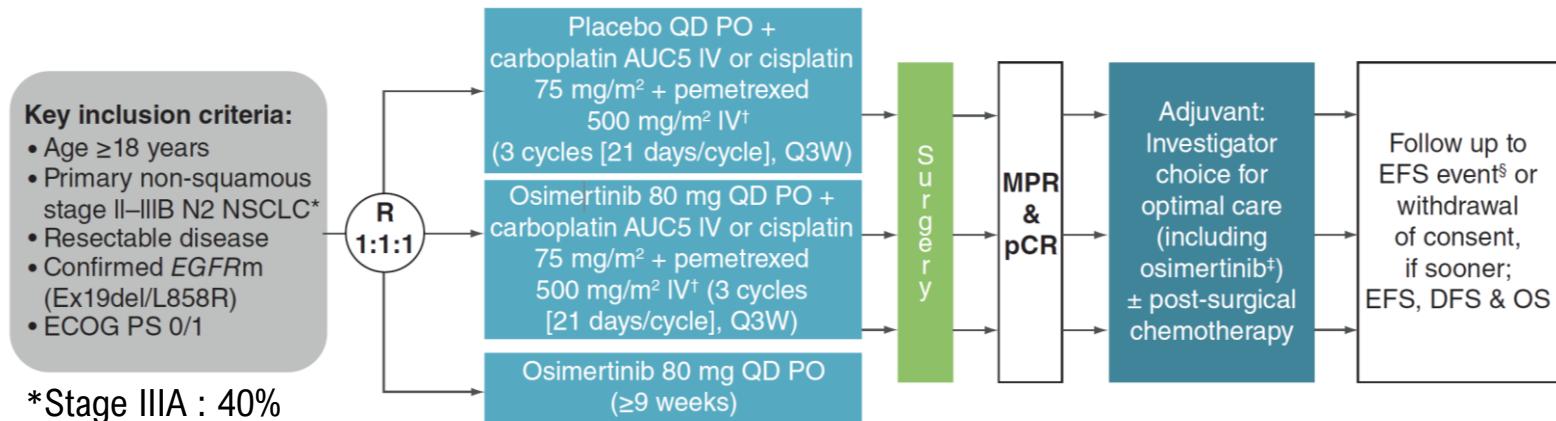
- Major pathological response (MPR)
- Portion of delayed/canceled surgeries, length of hospital stays, surgical approach, incidence of AE/SAE related to surgery
- Safety and tolerability: Adverse events graded according to CTCAE v5.0
- Potential predictive biomarkers (ctDNA, TCR)
- Other: (i) OS at 12, 18 and 24 months; (ii) PFS at 12, 18 and 24 months; (iii) Down-staging; (iv) Mortality at 90 days after surgery; (v) Association between clinical baseline characteristics and ORR, pathological response, AEs, PFS and OS; (vi) Association between pathological response and PFS or OS; (vii) Association between MPR and histology; (viii) Association between histology and PFS at 18 months



NeoADAURA study design

Clinical Trial Protocol Tsuboi, Weder, Escrivé et al.

Future Oncol. (2021) 17(31), 4045–4055



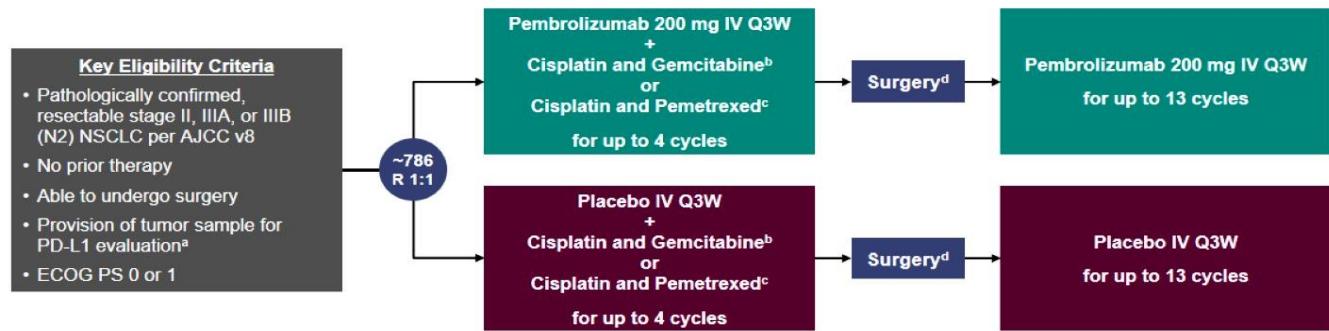
- Primary end point: MPR
- Secondary end point: pCR, EFS, OS, DFS, N2 to N0/N1 and N1 to N0 downstaging...



Wakelee KN671 ASCO 2023

KEYNOTE-671 Study Design

Randomized, Double-Blind, Phase 3 Trial

**Stratification Factors**

- Disease stage (II vs III)
- PD-L1 TPS^a (<50% vs ≥50%)
- Histology (squamous vs nonsquamous)
- Geographic region (east Asia vs not east Asia)

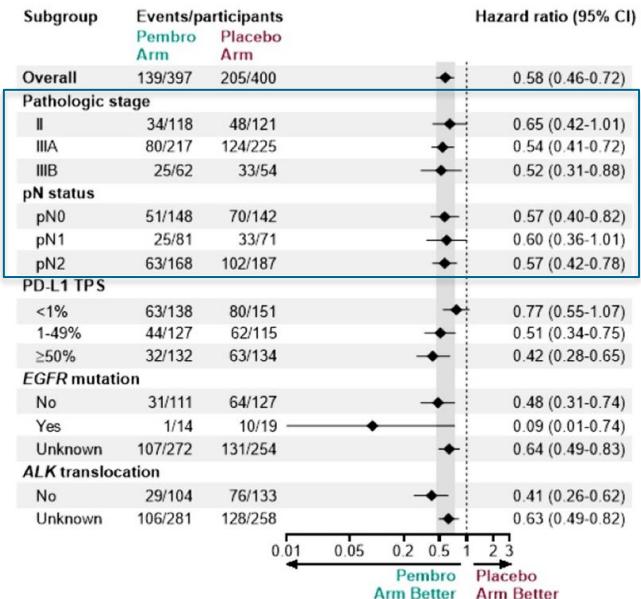
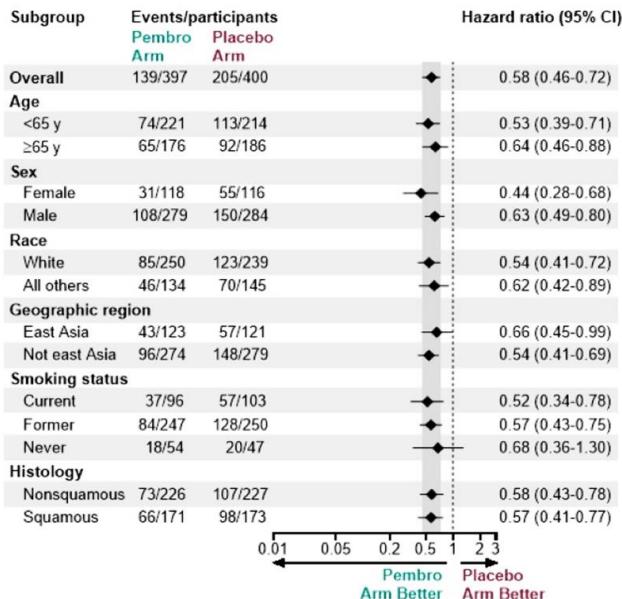
Dual primary end points: EFS per investigator review and OS**Key secondary end points:** mPR and pCR per blinded, independent pathology review, and safety

^a Assessed at a central laboratory using PD-L1 IHC 22C3 pharmDx. ^b Cisplatin 75 mg/m² IV Q3W + gemcitabine 1000 mg/m² IV on days 1 and 8 Q3W was permitted for squamous histology only. ^c Cisplatin 75 mg/m² IV Q3W + pemetrexed 500 mg/m² IV Q3W was permitted for nonsquamous histology only. ^d Radiotherapy was to be administered to participants with microscopic positive margins, gross residual disease, or extracapsular nodal extension following surgery and to participants who did not undergo planned surgery for any reason other than local progression or metastatic disease. ClinicalTrials.gov identifier: NCT03425643.



Wakelee KN671 ASCO 2023

Event-Free Survival in Subgroups



Downstaging mediastínico patológico
62,5% vs. 46%

Per the prespecified analysis plan, subgroups with <30 participants are excluded from the forest plot. Subgroups for stage IIIA and IIIB and pN status were post hoc; all other subgroups were prespecified.
Data cutoff date for IA1: July 29, 2022.

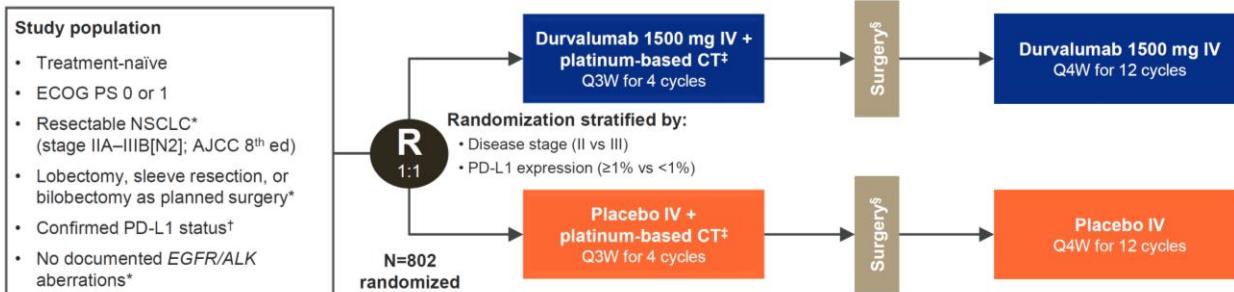


**2023 World Conference
on Lung Cancer**

SEPTEMBER 9-12, 2023 | SINGAPORE



AEGEAN study design



Primary endpoints: pCR by central lab (per IASLC 2020¹) and EFS using BICR (per RECIST v1.1)

Key secondary endpoints: MPR by central lab (per IASLC 2020¹), DFS using BICR (per RECIST v1.1)[¶] and OS[¶]

All efficacy analyses were performed on the mITT population (N=740), which included all randomized patients without documented EGFR/ALK aberrations

- Surgical outcomes were summarized using descriptive statistics

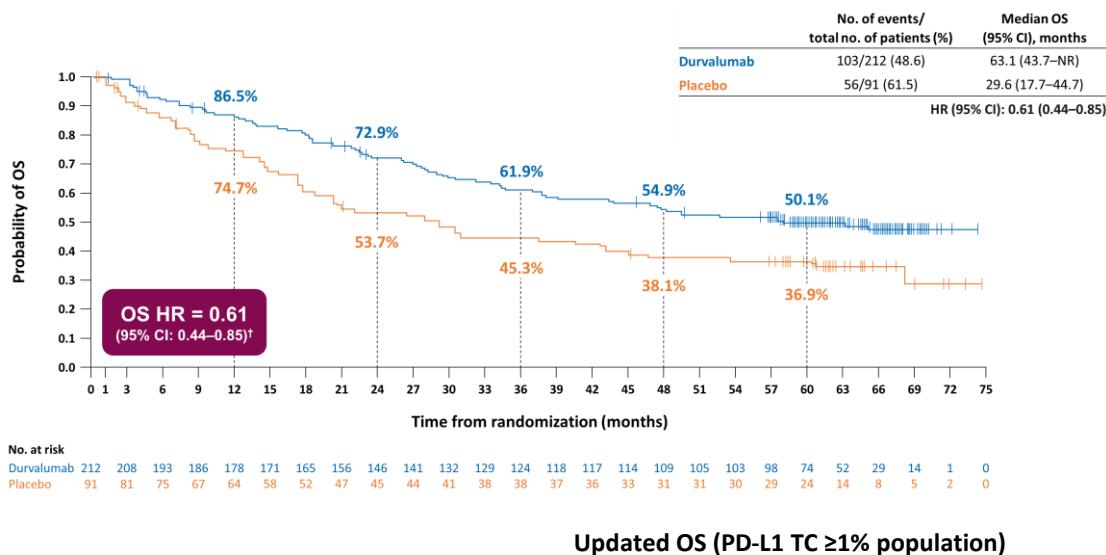
*The protocol was amended while enrollment was ongoing to exclude (1) patients with tumors classified as T4 for any reason other than size, (2) patients with planned pneumonectomies, and (3) patients with documented EGFR/ALK aberrations. Venetan P, et al. (S103) immunohistochemistry assay. †Choice of first regimen determined by histology and after an investigator's discretion. For non-smokers: cisplatin + pemetrexed; for smokers: carboplatin + paclitaxel; cisplatin + gemcitabine; carboplatin + pemetrexed. §For patients who had undergone definitive surgery were eligible to tolerate cisplatin per the investigator's judgment. ¶Post-operative radiotherapy (PORT) was permitted where indicated per local guidance. ¹AEGEAN continues for assessment of DFS and OS. AJCC, American Joint Committee on Cancer; BICR, blinded independent central review; DFS, disease-free survival; ECOG PS, Eastern Cooperative Oncology Group performance status; IASLC, International Association for the Study of Lung Cancer; IV, intravenous; mITT, modified intent-to-treat; MPR, major pathologic response; OS, overall survival; PD-L1, programmed cell death-ligand 1; QXW, every X weeks; RECIST v1.1, Response Evaluation Criteria in Solid Tumors, version 1.1.

¹Travis WD, et al. J Thorac Oncol 2020;15:709-40.



PACIFIC: Beneficio en OS & DFS demostrado a 5 años!

Diseño	Fase III, aleatorizado, doble ciego
N	713
Pacientes incluidos	<p>NSCLC en estadio III [IIIA, IIIB (7th ed TNM)]</p> <p>Irresecables</p> <p>CMD</p> <p>56% N2</p> <p>40% IIIA-N2</p>

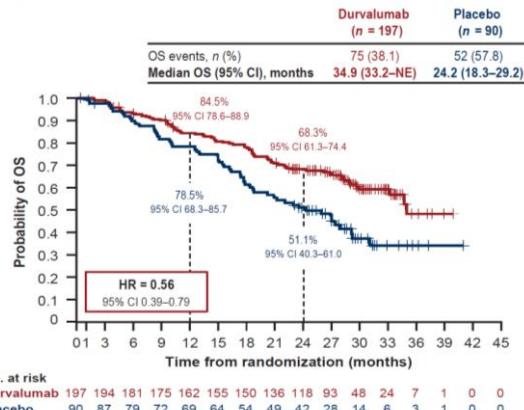
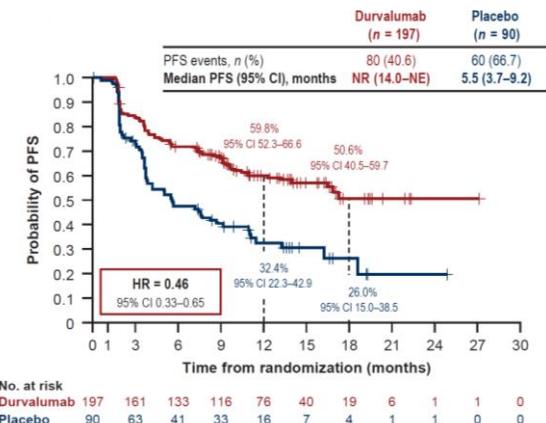




Outcomes with durvalumab after chemoradiotherapy in stage IIIA-N2 non-small-cell lung cancer: an exploratory analysis from the PACIFIC trial

S. Senan, et al. ESMO Open. 2022. doi: 10.1016/j.esmoop.2022.100410.

287/713 (40%) unresectable stage IIIA-N2





	IIIA-N2	IIIA-NO/N1 and IIIB
OS	HR = 0.56 (95% CI 0.39–0.79)	HR = 0.78 (95% CI 0.57–1.06)
PFS	HR = 0.46 (95% CI 0.33–0.65)	HR = 0.62 (95% CI 0.48–0.80)

Conclusions: Consistent with the intent-to-treat population, treatment benefits with durvalumab were confirmed in patients with stage IIIA-N2, unresectable NSCLC.

Prospective studies are needed to determine the optimal treatment approach for patients who are deemed operable.



EDITORIALS

Immunotherapy for Unresectable Stage III Non-Small-Cell Lung Cancer

Naiyer A. Rizvi, M.D., and Solange Peters, M.D., Ph.D.

N ENGL J MED 377;20 NEJM.ORG NOVEMBER 16, 2017

The data from the PACIFIC study may end the debate about the role of surgery in patients with stage III NSCLC, with durvalumab after chemoradiotherapy redefining best practice for all patients with stage III NSCLC. Of course, this notion will need to be tested prospectively.

Blood-based next-generation sequencing of tumor DNA may allow investigators to prospectively identify patients with resectable stage I to III NSCLC who are at the greatest risk for relapse.

“Resecabilidad biológica”

NINGUNO
NINGUNA



Resectable N2 NSCLC

Kenichi Suda

Division of Thoracic Surgery, Department of Surgery,
Kindai University Faculty of Medicine,
JAPAN

Can “oncologically unresectable” be resectable in the immunotherapy era?

My opinion:

Yes, possible...but we need biomarker for patient selection.
(neoadjuvant/adjuvant ICI + surgery vs. CRT → durvalumab)



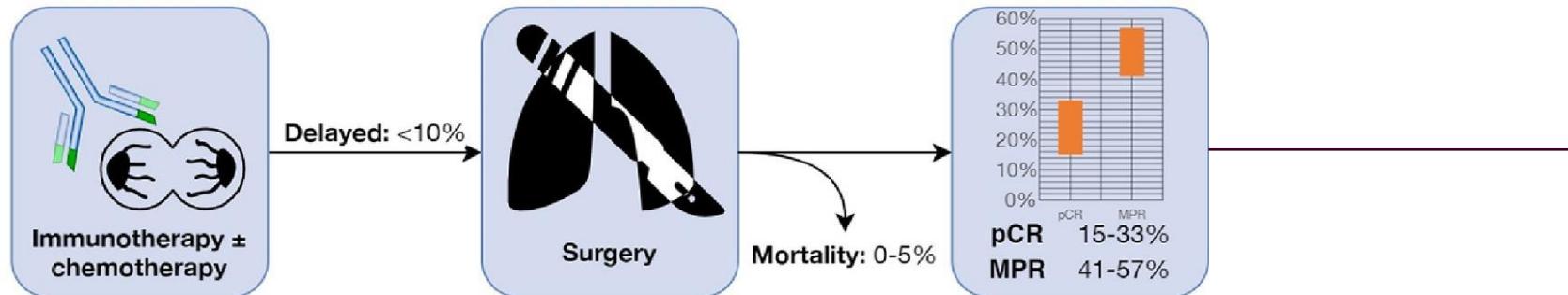
1.

TODOS
TODAS



Systematic Reviews Neoadjuvant IT (\pm CT) in (resectable) NSCLC

1. Cao, et al. Semin Thoracic Surg 2021
2. Ulas, et al. ESMO Open 2021
3. Zhang, et al. JTCVS 2021



Cao, et al. Semin Thoracic Surg 2021

La cirugía -R0- sigue siendo necesaria para el control local de la enfermedad y valorar la eficacia (al menos en términos de pCR/MPR) del tratamiento neoadjuvante.



Resultados de la cirugía tras neoadyuvancia con IT

	Estadio	Morbilidad (%)	Open/MIS (%)	Tasa conversión (%)	R0 (%)
Yang ChF, et al. ATS 2018. TOP1201	II-IIIA	PAL & urinary infection 15%, ACxFA & TEP 8%	8/92	27	100
Romero A, et al. EJCTS 2021. NADIM	IIIA	39%	49/51	19	100
Bott MJ, et al. JTCVS 2019	I-IIIA	50%	54/46	25 estadio I 71 estadios II y IIIA	-
Altorki N, et al. Lancet Oncology 2021	I-IIIA	Grade 3-4 events 17% Durva / 20% Durva + SBRT	Open 40/60 MIS 43/57	- -	77 83
Tong BC, et al. JTCVS 2022. TOP1505	IB-IIIA	48%	8/92	22	88
Gao Y, et al. FO 2022	IIIA-IIIB	11%	All RATS	4.5	100
Spicer J, et al. CheckMate 816. ASCO 2021	IB-IIIA	41% vs 47%	Open 59 vs 63 MIS 30 vs 22	11 vs 16	83 vs 78
Wakelee, et al. KEYNOTE-671. ASCO 2023	II-IIIB (N2)				92 vs 84
Mitsudomi, et al. AEGEAN. WCLC 2023	IIA-IIIB[N2]	59% vs. 60%	Open 49/49 MIS 47/50		95/91
Lv, et al. LC 2023. NEOS	IIA-IIIB (T3-4 N2)	75% any grade	50/50		94



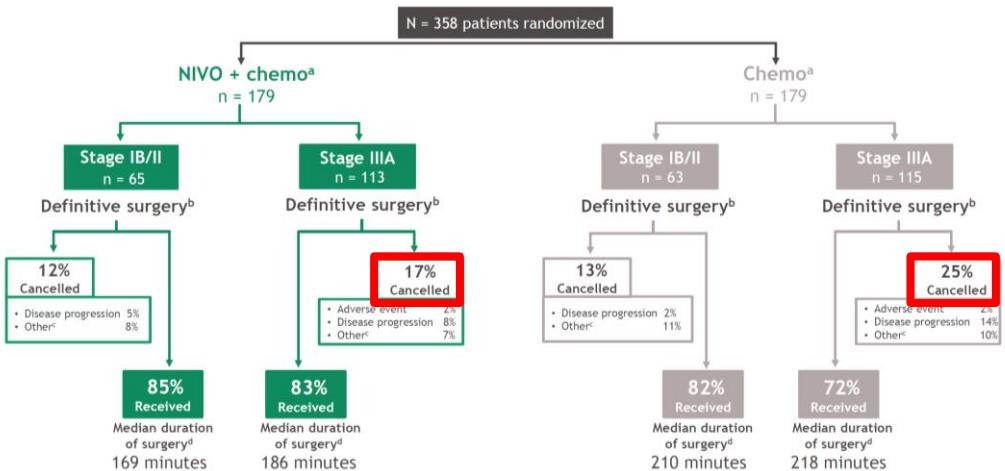
Cirugía tras tratamiento neoadyuvante (...IT).

- Es un poco más difícil. **A LITTLE BIT**
- **MIS...** es posible y segura. **BELEIVE ME**
- Cualquier magnitud de resección es posible. **PROBABLY**
- **Objetivo R0.** 
- La definición de pCR i MPR se basa en la ausencia o presencia de tumor viable **en la T y en la N.** 
- **Los pacientes se tienen que operar...a ser posible todos.** **I SAID ALL**

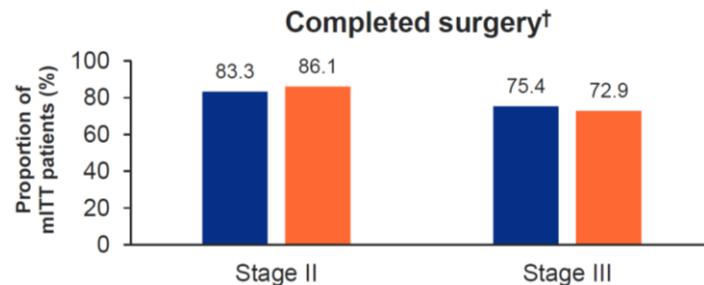
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CheckMate 816 study Treatment and surgery summary: all randomized patients
NSCLC en estadio **IB-IIIA** (7^a ed TNM), Resecables



AEGEAN study design



16 vs. 11% 21 vs. 23%

Spicer J, et al.

2021 ASCO[®]
ANNUAL MEETING

Tetsuya Mitsudomi, Division of Thoracic Surgery, Department of Surgery, Kindai University Faculty of Medicine, Osaka-Sayama, Japan



Spanish Lung Cancer Group **SCAT trial**: surgical audit to lymph node assessment based on IASLC recommendations. Jarabo JR, et al. Transl Lung Cancer Res 2021.

Table 2 Number of lymph node regions and lymph nodes resected and involved from hilar and mediastinal regions 1 to 14

Variables	LN region													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
	440	404	406	282	271	393	152	361	279	80	225	411	438	450

In 33.7%, 17.7% and 49.9% of cases, regions 7, 10 and 11 respectively were not assessed.

Conclusions: IASLC recommendations for surgical resections were not followed in a high proportion of surgical procedures.



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Consensual definition of stage III NSCLC Resectability: EORTC-Lung Cancer Group initiative with other scientific societies

A-M. Dingemans¹, J. Remon², L. Hendriks³, J. Edwards⁴, C. Faivre-Finn⁵, N. Reguart⁶, E. Smit⁷, A. Levy⁸, D. Sanchez⁹, J.C. Trujillo¹⁰, A. Filippi¹¹, K. Stathopoulos¹², T.G. Blum¹³, M. Guckenberger¹⁴, S. Popat¹⁵, I. Opitz¹⁴, A. Brunelli¹⁶, R. De Angelis¹², P. Hofman¹⁷, K. Hartemink¹⁸, RH. Petersen¹⁹, E. Ruffini²⁰, C. Dickhoff²¹, E. Prisciandaro²², J. Derk³, I. Bahce²¹, A. Mariolo²³, E. Xenophontos²⁴, N. Giaj Levra²⁵, I. Houda²¹, M. Brandão¹², T. Berghmans¹²

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2023 World Conference on Lung Cancer

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	N0	N1	N2 SINGLE (non-bulky, non-invasive)	N2 MULTI (non-bulky, non-invasive)	N2 BULKY [¶]	N2 INVASIVE	N3
T1-2	NOT STAGE III DISEASE	NOT STAGE III DISEASE	RESECTABLE	POTENTIALLY RESECTABLE*	UNCLEAR	UNRESECTABLE	UNRESECTABLE
T3 size / satellite / invasion	NOT STAGE III DISEASE	RESECTABLE	RESECTABLE	POTENTIALLY RESECTABLE*	UNRESECTABLE	UNRESECTABLE	UNRESECTABLE
T4 size / satellite	RESECTABLE	RESECTABLE	RESECTABLE	POTENTIALLY RESECTABLE*	UNRESECTABLE	UNRESECTABLE	UNRESECTABLE
T4 invasion	POTENTIALLY RESECTABLE [§]	POTENTIALLY RESECTABLE [§]	POTENTIALLY RESECTABLE [§]	POTENTIALLY RESECTABLE [§]	UNRESECTABLE	UNRESECTABLE	UNRESECTABLE

*Multiple station N2: case-by-case discussion; the exact number of nodes/stations cannot be defined

[¶]Bulky N2: lymph nodes with a short-axis diameter >2.5-3 cm; in specific situations of *highly selected patients*, including those patients in multidisciplinary trials with surgery as local therapy can be discussed

[§]Some T4 tumours by infiltration of major structures are potentially resectable – see Table 1



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Final Remarks

- This definition can be used for inclusion in clinical trials → for **specific/dedicated clinical trials**, inclusion criteria may be adapted to situations considered in most instances as unresectable (e.g. multi-station N2, bulky N2 or T4 by invasion)

METHODS

Systematic
Review

Abstract 2023-RA-2551-WCLC

International
Survey

Abstract 2023-RA-2409-WCLC

Clinical Cases
Discussion

Abstract 2023-RA-2574-WCLC

Delphi Process
Consensus reached
(F2F + online meetings)



Es una definición “anatómica” de resecabilidad...



¿Pueden o deben devolverse los pacientes con afectación mediastínica a la arena quirúrgica?

A día de
hoy,

en la práctica

clínica . . .

- Probablemente hay que empezar a reconsiderar / individualizar el valor de la ycN2 (ypN2).
- **Probablemente todos los pacientes** con un cN2 (potencialmente) resecable, tratados con inducción dirigida, sin progresión tras la reestadificación con un TC (...PET-TC) deben operarse con intención de realizar una R0 mediante MIS.

este mensaje
se autodestruirá
en 5 segundos...





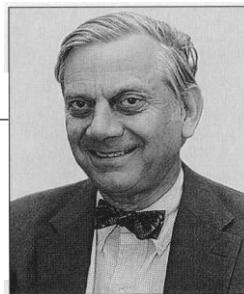
'Biology is King; selection of cases is Queen, and the technical details of surgical procedures are princes and princesses of the realm who frequently try to overthrow the powerful forces of the King and Queen, usually to no long-term avail, although with some temporary apparent victories'

PRESIDENTIAL ADDRESS

Basic Principles in Surgical Oncology

Blake Cady, MD

ARCH SURG/VOL 132, APR 1997



Died on July 15, 2023