Lung Cancer UPDATES
IASLC HIGHLIGHTS
08-14 SEPTIEMBRE 2021

Iniciativa científica de:
GECP
lung cancer research

Cancer célula pequeña de pulmón y otros tumores torácicos

Dr. Joaquim Bosch-Barrera MD/PhD

ICO Girona, Hospital Universitari Dr. Josep Trueta

Cáncer microcítico de pulmón

Estudio ATLANTIS

Lurbinectedin/doxorubicin versus CAV or Topotecan in Relapsed SCLC Patients: Phase III Randomized ATLANTIS Trial

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ATLANTIS: Study design

- SCLC
- 1 prior chemotherapy line (additional biologic lines allowed)
- ECOG PS ≤ 2
- Measurable/ non-measurable per RECIST
- Pts with CTFI <30 d excluded

Randomization

DOX 40 mg/m² D1*
Lurbinectedin 2 mg/m² D1 q3w *

600 patients
1:1 Randomization

Stratified:
- ECOG (0 *vs* ≥1)
- CTFI (≥ 180, 179-90, <90)
- CNS involvement (Y/N)
- Prior PDL1/PD1 (Y/N)
- Investigator preference for control arm

Topotecan 1.5 mg/m² D1-5 q3w
OR, CAV combination D1, q3w

Primary endpoint OS

- Disease Progression
- Unacceptable Toxicity

Follow-up

Screening Up to 28D

Treatment period

Follow up period

Primary prophylaxis with **G-CSF was mandatory** in both arms

* Maximum 10 cycles, **lurbinectedin to be continued at 3.2 mg/m² D1 q3w**

Luis Paz-Ares
MD, PhD

Estudio ATLANTIS

- Grupos bien balanceados para los principales factores pronósticos

Lurbinectedin/doxorubicin versus CAV or Topotecan in Relapsed SCLC Patients: Phase III Randomized ATLANTIS Trial

Baseline Characteristics (II)

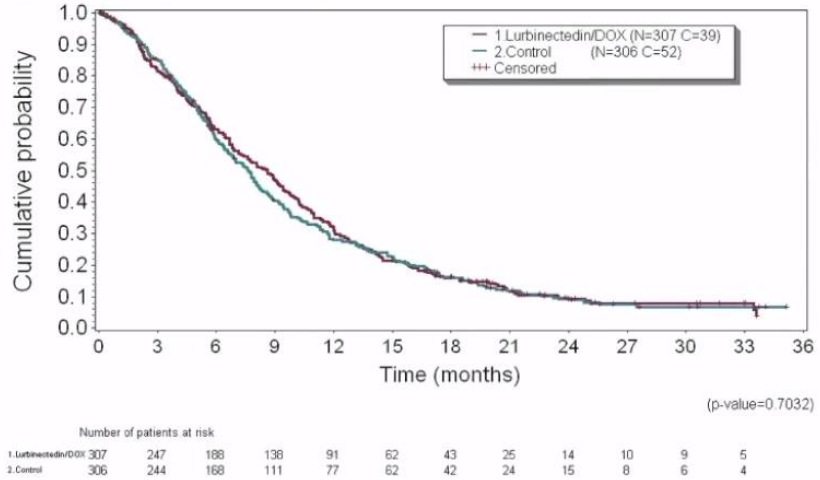
		Experimental Arm Lurbinectedin+DOX (n=307)	Control Arm Topotecan/CAV (n=306)
Bulky disease, %	one lesion ≥50mm	**46.9**	**41.5**
CNS Involvement , %		**15.0**	**16.0**
Prior lines of therapy (#), %	# median (range)	1.0 (1-2)	1.0 (1-2)
	1 line	97.1	98.7
	2 lines	2.9	1.3
Best response to prior chemotherapy, %	CR	**5.5**	**4.9**
	PR	**62.5**	**62.4**
	SD	23.1	20.6
	PD	5.5	6.9
	NE/UK/NA	3.3	5.2
Prior anti PD-1 or PD-L1, %		6.2	5.6
TTP to prior chemotherapy, months	median (range)	7.4 (0.8-40.2)	7.4 (1.6-33.7)
CTFI (days), %	median (range)	115.0 (0-1094)	120.5 (13-960)
	<90	**32.2**	**33.0**
	90-179	**37.5**	**37.9**
	≥180	**30.3**	**29.1**

Estudio ATLANTIS

- No beneficio en OS, endpoint principal del estudio.
- Dosis utilizada de 2 mg/m2 (en single agent es de 3,2 mg/m2).

Lurbinectedin/doxorubicin versus CAV or Topotecan in Relapsed SCLC Patients: Phase III Randomized ATLANTIS Trial

Overall Survival (ITT population)



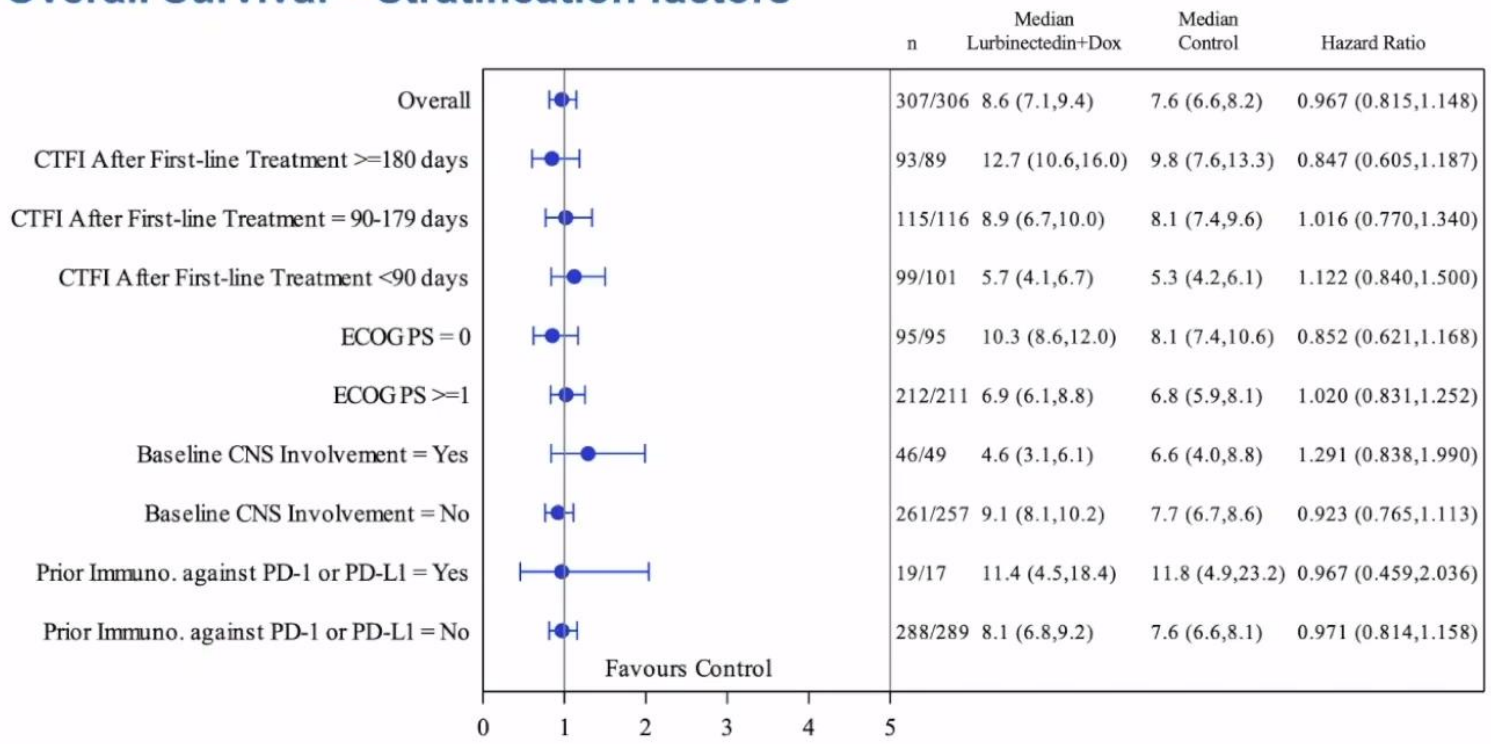
	Lurbinectedin+DOX (N=307)	Control (N=306)	Parameter	p-value
Events, n (%)	268 (87.3)	254 (83.0)		
Censored, n (%)	39 (12.7)	52 (17.0)		
Median OS (95% CI), months	8.6 (7.1, 9.4)	7.6 (6.6, 8.2)	HR : 0.967 (0.815, 1.148)	0.7032
Mean OS, months	10.6	9.9		

Estudio ATLANTIS

- No se identificaron subgrupos de mayor beneficio en el subanálisis para OS

Lurbinectedin/doxorubicin versus CAV or Topotecan in Relapsed SCLC Patients: Phase III Randomized ATLANTIS Trial

Overall Survival – Stratification factors



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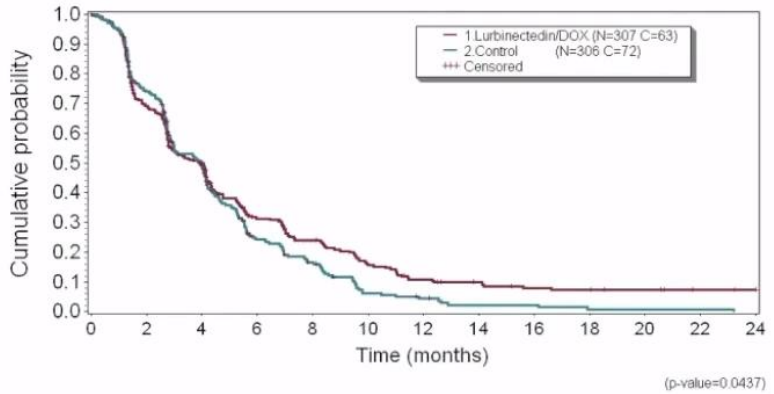
Estudio ATLANTIS

- Sí hubo beneficio en PFS a favor del brazo experimental (HR 0,831, p=0,0437)

Lurbinectedin/doxorubicin versus CAV or Topotecan in Relapsed SCLC Patients: Phase III Randomized ATLANTIS Trial

PFS by Independent Review Committee: Lurbinectedin/Doxo vs Control



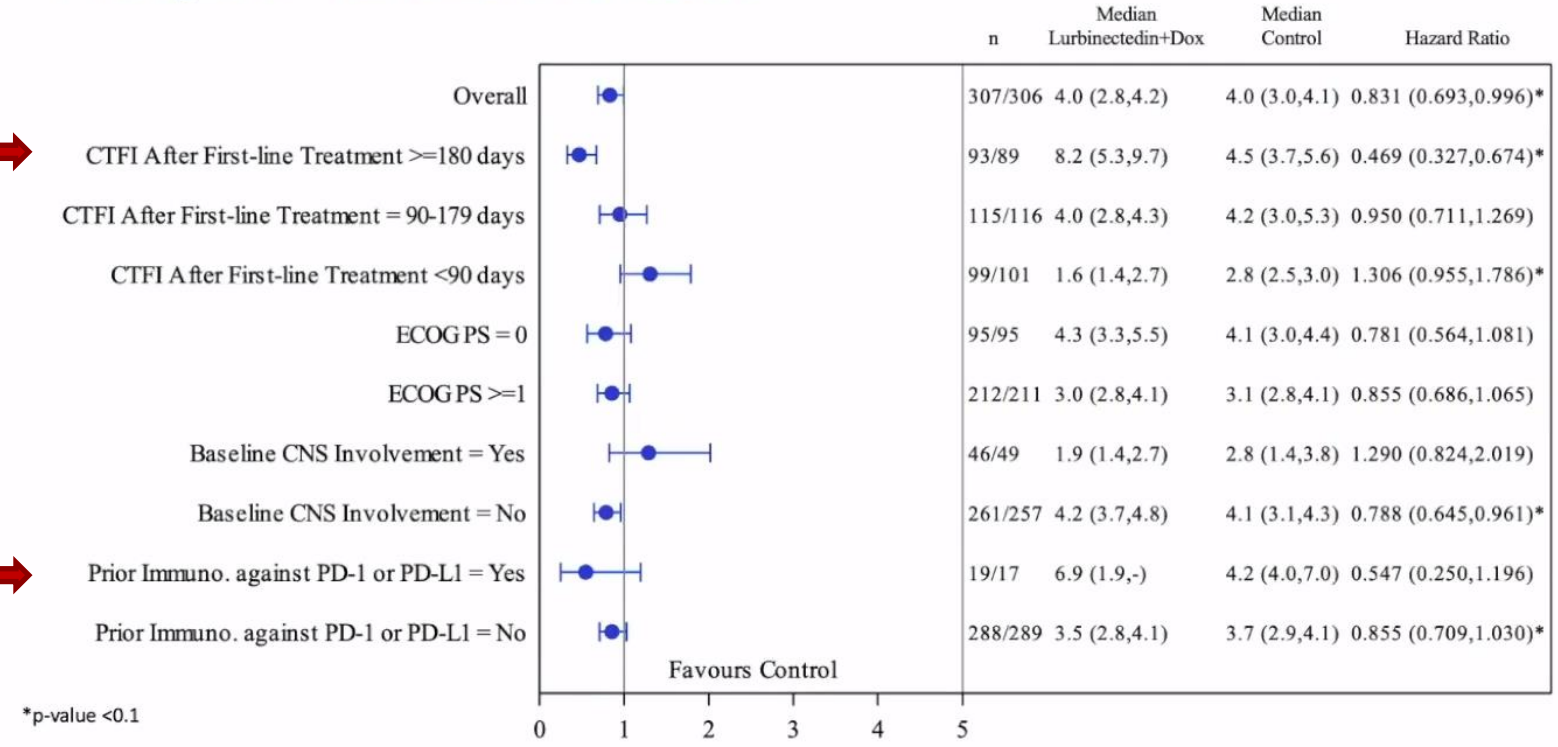
	Lurbinectedin+DOX (N=307)	Control (N=306)	Parameter	p-value
Events, n (%)	244 (79.5)	234 (76.5)		
Censored, n (%)	63 (20.5)	72 (23.5)		
Median PFS (95% CI), months	**4.0 (2.8, 4.2)**	**4.0 (3.0, 4.1)**	**HR: 0.831 (0.693, 0.996)**	**0.0437**
Mean PFS, months	5.9	4.6		
PFS (%) at 6 months (95% CI)	31.3 (25.8, 36.9)	24.4 (19.1, 30.1)		0.0851
PFS (%) at 12 months (95% CI)	10.8 (7.1, 15.3)	4.4 (2.1, 8.1)		0.0129

Estudio ATLANTIS

- En PFS, los pacientes con intervalo libre de quimioterapia >180 días (HR 0.469) y que habían recibido IO previamente (HR 0.547) fueron los que más se beneficiaron

Lurbinectedin/doxorubicin versus CAV or Topotecan in Relapsed SCLC Patients: Phase III Randomized ATLANTIS Trial

PFS by IRC – Stratification factors



*p-value <0.1

Estudio ATLANTIS

- Mayor toxicidad en brazo control que experimental, en especial hematológica.

Lurbinectedin/doxorubicin versus CAV or Topotecan in Relapsed SCLC Patients: Phase III Randomized ATLANTIS Trial

Safety Summary

Hematological	Lurbinectedin+DOX (n=303)	Control (n=289)	
	Grade ≥3	Grade ≥3	p-value
Anaemia	44 (14.5)	90 (31.1)	<0.0001
Neutropenia	112 (37.0)	200 (69.2)	<0.0001
Febrile neutropenia	12 (4.0)	24 (8.3)	0.0377
Thrombocytopenia	42 (13.9)	90 (31.1)	<0.0001

Non hematological	Lurbinectedin+DOX (n=303)	Control (n=289)	
	Grade ≥3	Grade ≥3	p-value
ALT increased	6 (2.0)	3 (1.0)	0.5057
AP increased	2 (0.7)	3 (1.0)	0.6783
AST increased	7 (2.3)	4 (1.4)	0.5463
Fatigue	26 (8.6)	31 (10.7)	0.4051
Nausea	6 (2.0)	4 (1.4)	0.7525
Vomiting	4 (1.3)	0	0.1242

	Lurbinectedin+DOX (n=303) n (%)	Control (n=289) n (%)
Any AE treatment-related	268 (88.4)	266 (92.0)
Any grade ≥3 AE	**143 (47.2)**	**218 (75.4)**
Any grade 4 AE	**49 (16.2)**	**158 (54.7)**
Any grade ≥3 SAE	38 (12.5)	83 (28.7)
Death associated with AEs	**1 (0.3)**	**10 (3.5)**
Treatment discontinuations associated with AEs	23 (7.6)	45 (15.6)
Delays associated with AEs	79 (26.1)	99 (34.3)
Reductions associated with AEs	66 (21.8)	138 (47.8)

Estudio ATLANTIS

Discussant

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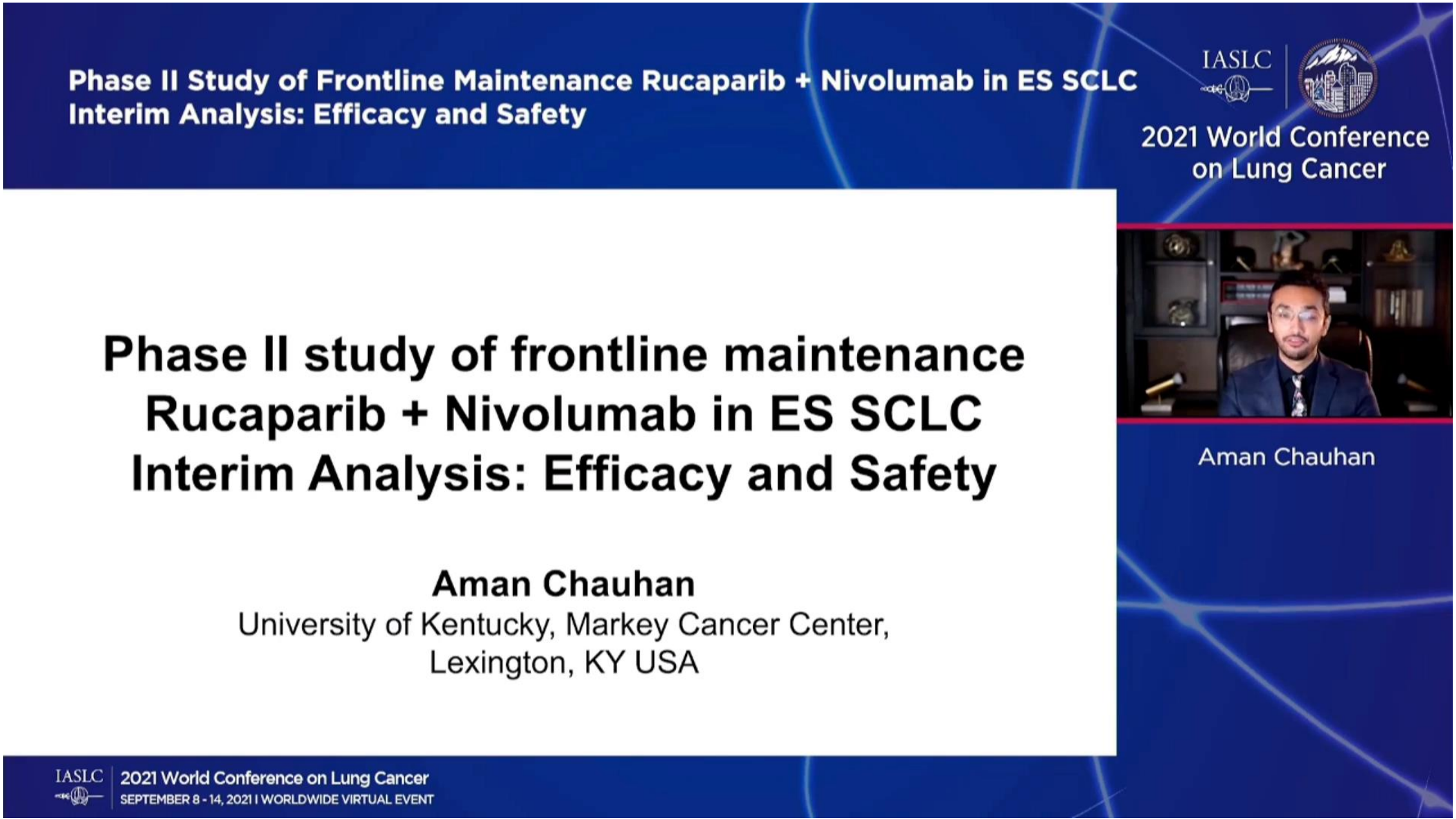
Conclusions –

and the inevitable coulda, shoulda, woulda –

- ATLANTIS joins the ranks of negative phase III studies in patients with recurrent small cell lung cancer.
- But in my view –
  - Offers support for the efficacy of lurbinectedin in patients with recurrent SCLC
    - your discussant opines: *stick to single agent*
  - Demonstrates similar outcome with superior safety profile over SOC
    - especially with regard to heme tox
- Lurbinectedin offers a new platform on which to build BETTER combo options for patients with recurrent small cell
  - The oncologist's glass is always half full

Charles Rudin
MD, PhD

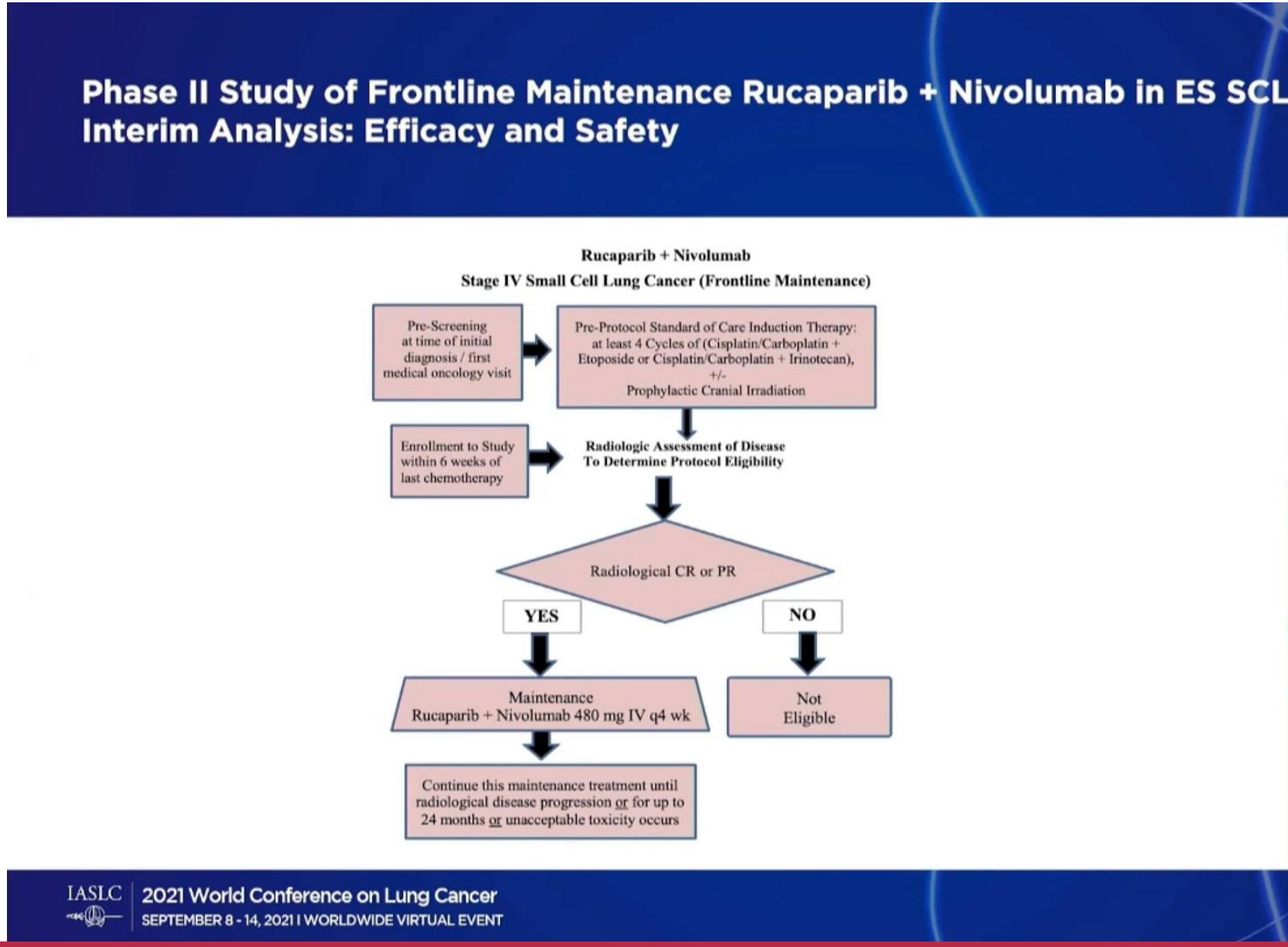
Estudio fase 2: rucaparib + nivolumab de mantenimiento



Quimio-immuno neo-adyuvante en mesotelioma

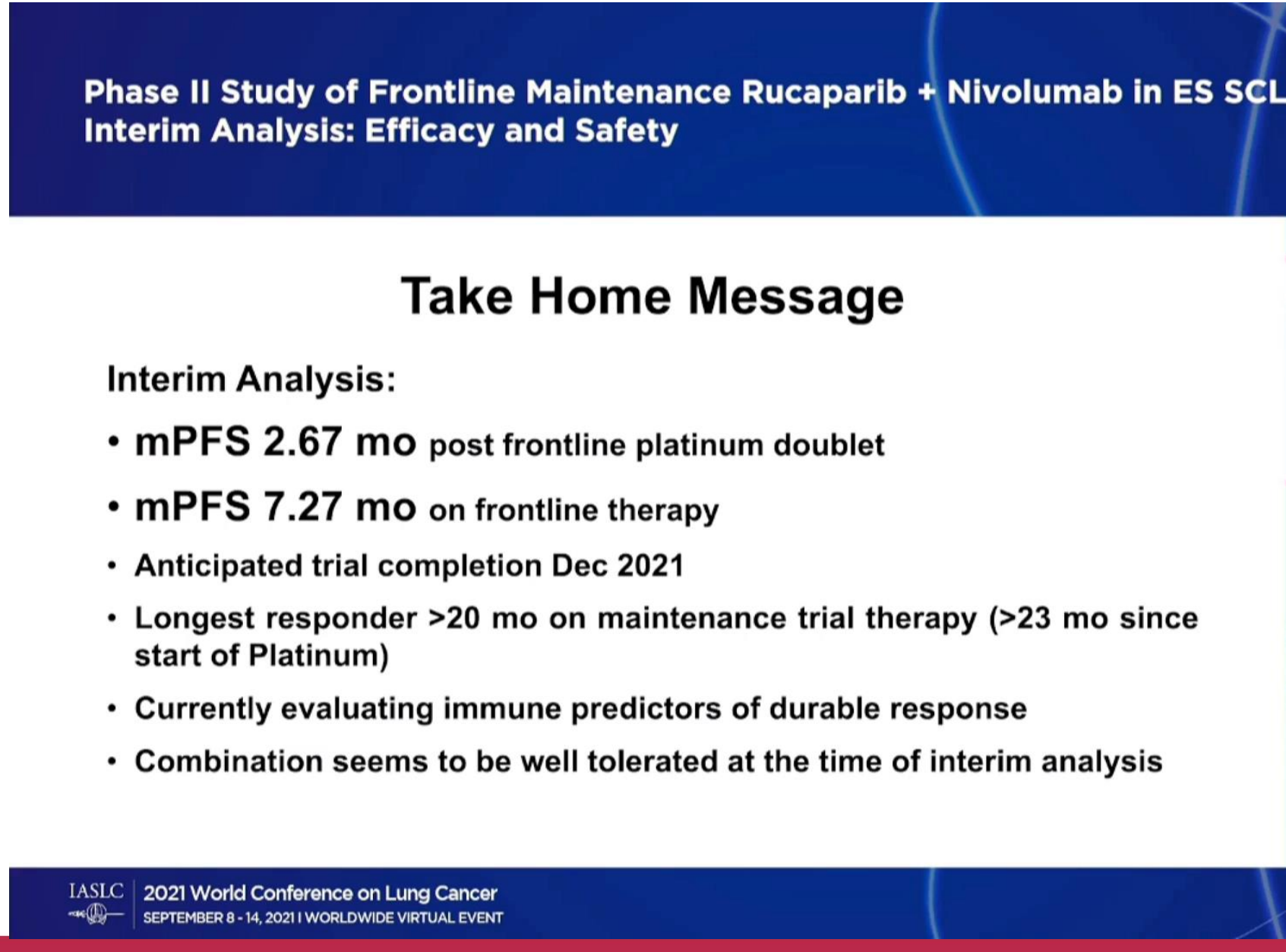
- Pacientes que completan al menos 4 ciclos de quimio +/- PCI con RP o RC

- Nivolumab mensual + rucaparib hasta toxicidad inaceptable, progresión o 2 años



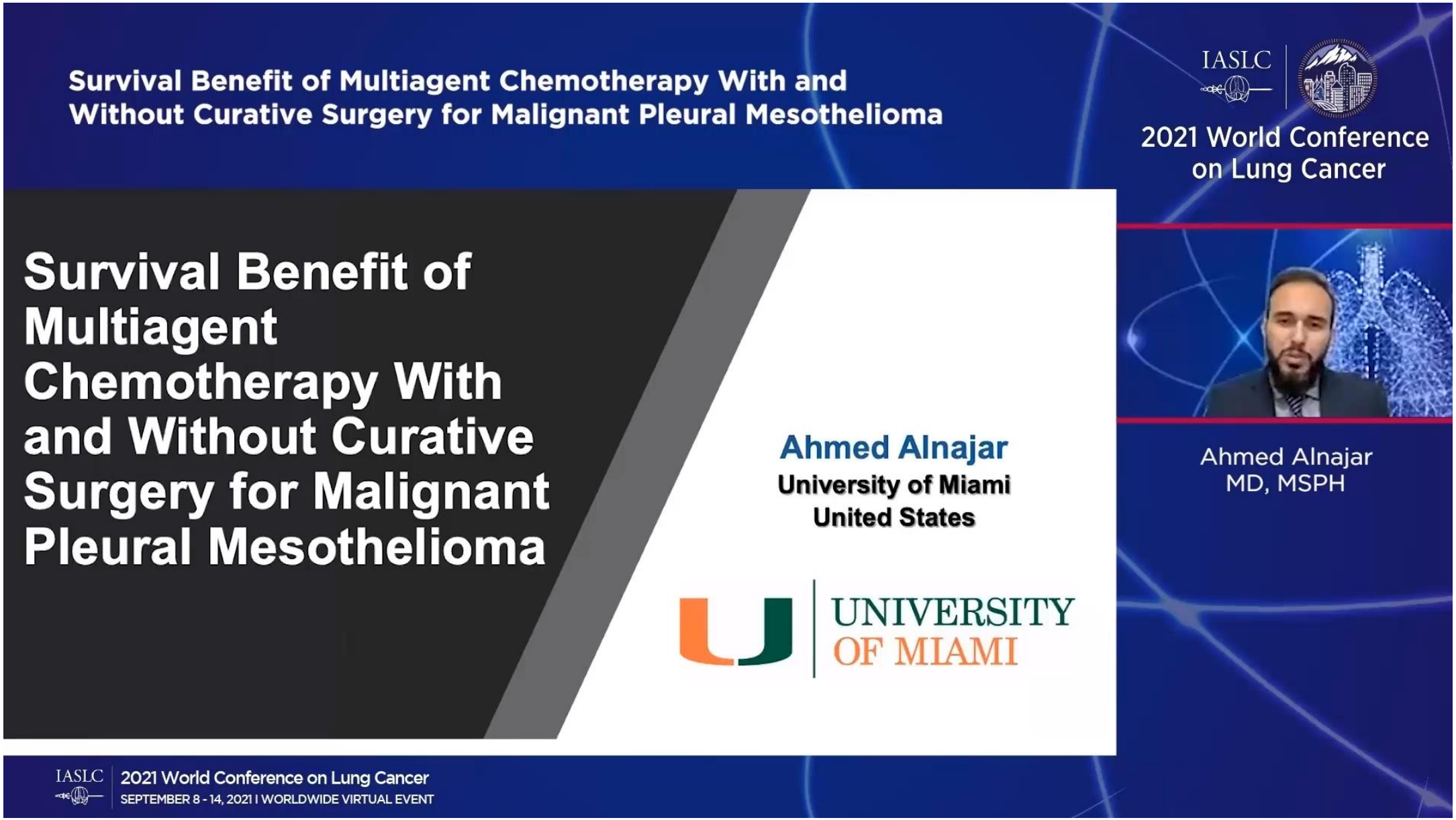
Quimio-immuno neo-adyuvante en mesotelioma

- Estudio en marcha.
- mPFS 2.67 meses desde inicio tratamiento.



Mesotelioma pleural maligno

Cirugia en mesotelioma estadios quirúrgicos



Cirugia en mesotelioma estadios quirúrgicos

- Análisis retrospectivo, estadios I-IIIA.

Survival Benefit of Multiagent Chemotherapy With and Without Curative Surgery for Malignant Pleural Mesothelioma

Methods

- **Inclusion and exclusion criteria:**
  - Using National Cancer Database from 2004 to 2017, we included patients with resectable stage I to IIIA MPM .
  - Surgeries included pleurectomy, decortication or extra pleural pneumonectomy.
  - No palliative surgery included in the surgical arm.
  - All patients underwent chemotherapy.
- There were **4036** patients eligible for curative-intent surgery.
- Propensity score matching employed to adjust for surgical treatment allocation confounders (such as patients and tumor characteristics, socio-economic status, and facility type).
- Kaplan Meir and Cox regression analyses were performed on **1402** matched pairs to estimate overall survival time and its predictors.

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Cirugia en mesotelioma estadios quirúrgicos

- Los pacientes que se operaron además de recibir quimioterapia presentaron mayor supervivencia a 5 y 10 años

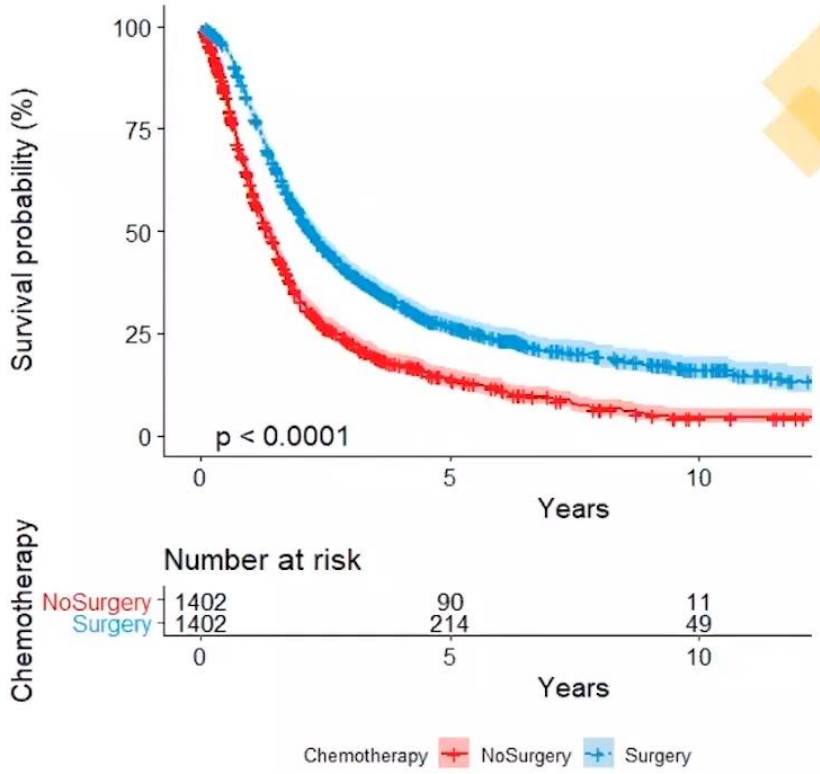
Survival Benefit of Multiagent Chemotherapy With and Without Curative Surgery for Malignant Pleural Mesothelioma

Results

Survival estimates for curative surgery with multiagent chemotherapy compared to multiagent chemotherapy alone:

- 5-Year survival estimates were **23.9%** vs. 11.2%.
- 10-Year survival estimates were **14.2%** vs. 3.6%.

Median survival time was **22** vs. 16 months.



Cirugia en mesotelioma estadios quirúrgicos

- Los factores de riesgo fueron ser hombre, atención en centros comunitarios (frente académicos) y edad.

Survival Benefit of Multiagent Chemotherapy With and Without Curative Surgery for Malignant Pleural Mesothelioma

Results

- Based on adjusted Cox analysis, we found surgical treatment with multiagent chemotherapy reduces mortality by **39.4%**.

Treatment Factors	MVA Cox	
	HR	p-value
Multiagent Chemotherapy alone	Ref	-
Chemo + radiotherapy	1.272	0.0604
Surgery with chemotherapy	**0.606**	<.0001
Surgery + chemo + radiotherapy	0.728	<.0001

- We found three primary independent risk factors associated with mortality.

Risk Factors	Cox HR	p-value
Male sex	1.575	<.0001
Community programs (vs. academic)	1.139	0.0243
Age	1.021	<.0001

Quimio-immuno neo-adyuvante en mesotelioma

S1619 A Trial of Neoadjuvant Cisplatin-Pemetrexed With Atezolizumab in Combination and Maintenance for Resectable Pleural Mesothelioma

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Anne Tsao
MD

S1619 A trial of neoadjuvant cisplatin-pemetrexed with atezolizumab in combination and maintenance for resectable pleural mesothelioma

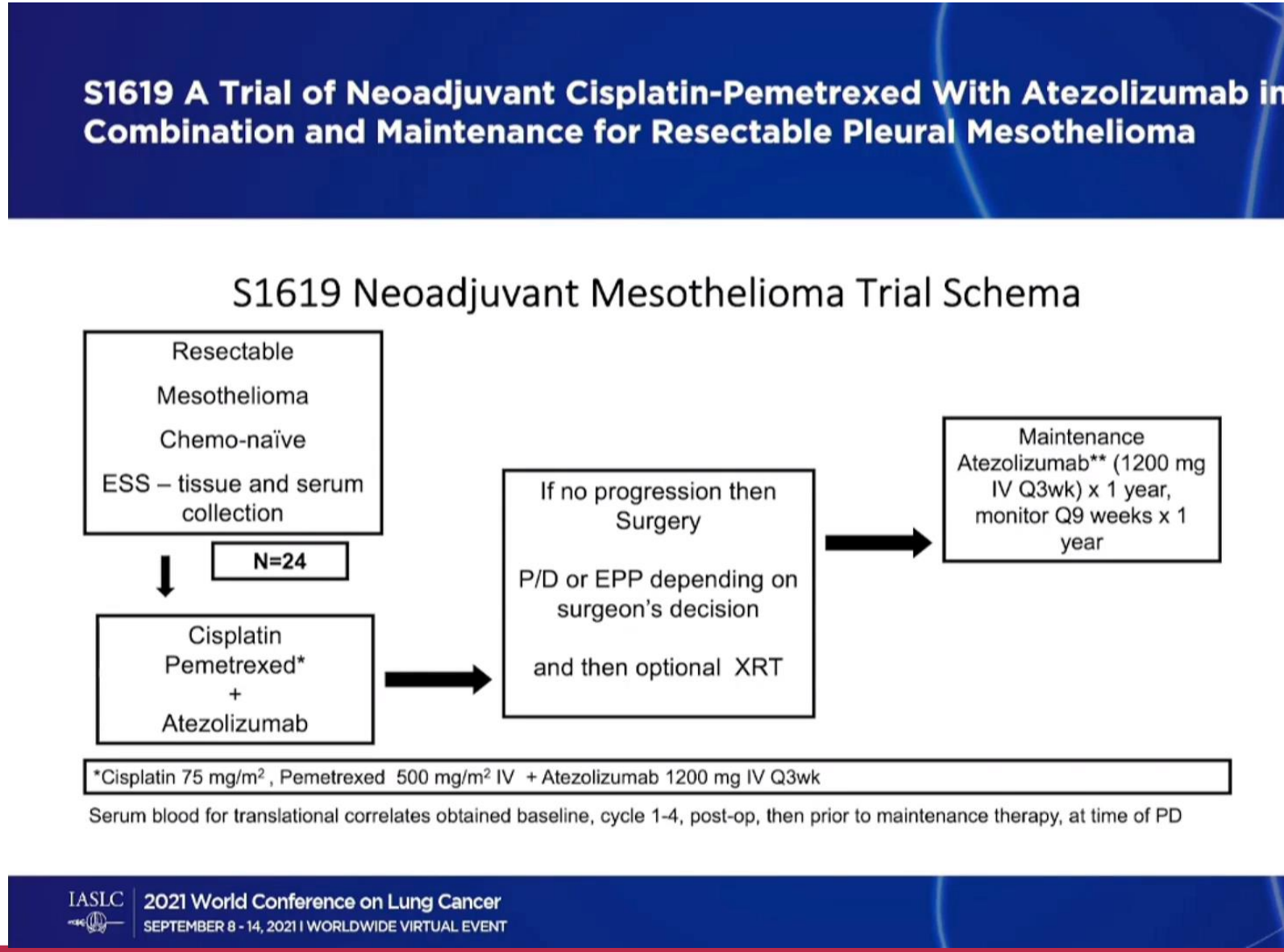
Anne Tsao, M.D.[1], Lu Qian, MS[2], Jeremy Cetnar, M.D. M.S.[3], Boris Sepesi, M.D.[1], Daniel R. Gomez, M.D.[1], John M. Wrangle, M.D.[4], George R. Simon, M.D.[5,6], Frank E. Mott, M.D.[1], Richard D. Hall, M.D.[7], Rafael Santana-Davila, MD[8], Marianna Koczywas, MD[9], Mary W. Redman, Ph.D.[2], Karen Kelly, MD10

[1]MD Anderson Cancer Center, Houston, TX; [2]SWOG Statistics and Data Management Center, Seattle, WA; [3]Oregon Health & Science University, Portland, OR; [4]Medical University of South Carolina/MUSC MU-NCORP, Charleston, SC; [5]MD Anderson Cancer Center, Houston, TX (during conduct of trial) and [6]Moffitt Cancer Center, Morsani School of Medicine, Celebration, FL (current); [7]University of Virginia Cancer Center, Charlottesville, VA/ECOG-ACRIN; [8]Fred Hutchinson Cancer Research Center, Seattle, WA; [9]City of Hope Comprehensive Cancer Center, Duarte, CA; [10]UC Davis Comprehensive Cancer Center, Sacramento, CA

Funding: NIH/NCI grant awards U10CA180888, U10CA180819 and U10CA180820

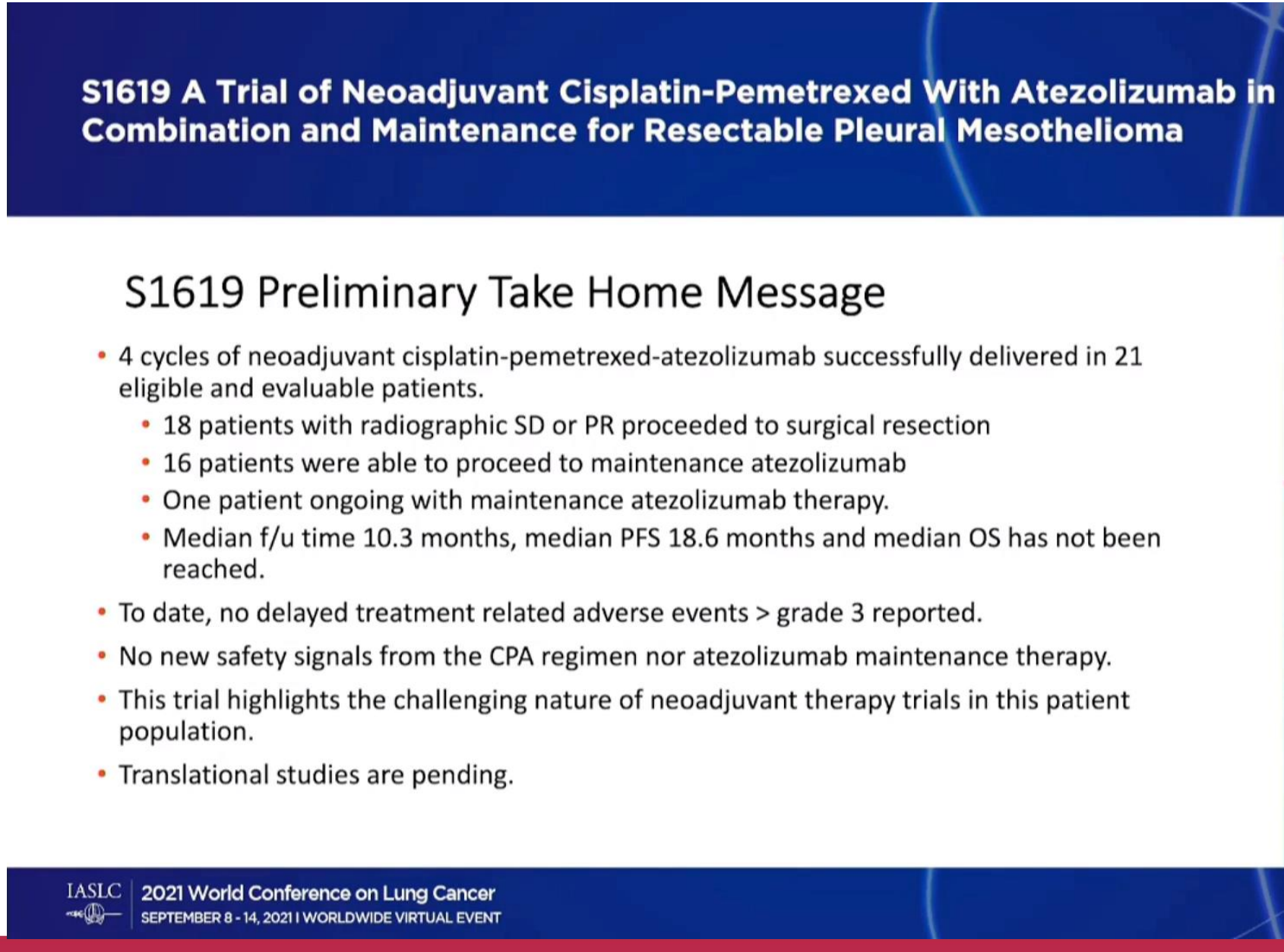
Quimio-immuno neo-adyuvante en mesotelioma

- Unico brazo experimental
- 24 pacientes resecables
- 4 ciclos inducción, operación (decorticación o EPP), y mantenimiento con atezolizumab por 1 año.



Quimio-immuno neo-adyuvante en mesotelioma

- 21 pacientes completaron inducción
- 18 se operaron
- 16 en mantenimiento



Mesotelioma y COVID19

Clinical Characteristics and Outcomes in Patients With Malignant Pleural Mesothelioma (MPM) with COVID-19 Infection

Conclusions

From our experience, 18% of MPM patients were diagnosed of COVID-19 infection during the 1st year of pandemic (previous to vaccines)

The majority of patients were hospitalized

Mortality rate was very high (57%)

Health care services need to pay particular attention to MPM p while managing the COVID-19 infection.

Tumores tímicos

Palbociclib para tumores tímicos pre-tratados

A Phase II Study of Palbociclib for Recurrent or Refractory Advanced Thymic Epithelial Tumor (KCSG LU17-21)

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A phase II study of palbociclib for recurrent or refractory advanced thymic epithelial tumor (KCSG LU17-21)

Hyun Ae Jung
MD, PhD

Presenter Hyun Ae Jung

Samsung Medical Center
Republic of Korea

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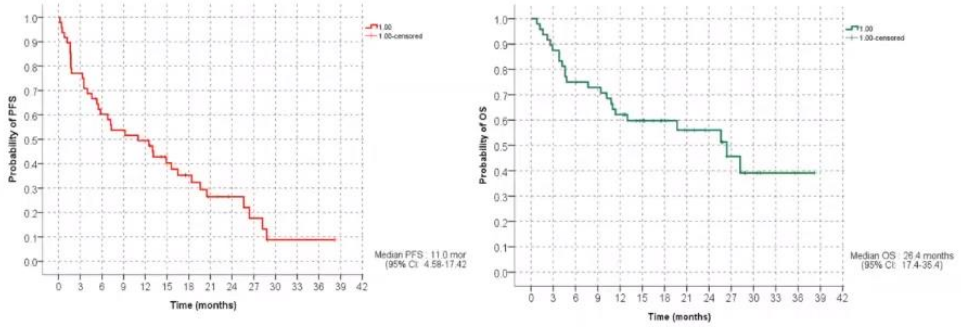
Palbociclib para tumores tímicos pre-tratados

- Los pacientes recibieron una mediana de 10 ciclos de palbociclib
- PFS de 11 meses y OS de 26,4 meses.

A Phase II Study of Palbociclib for Recurrent or Refractory Advanced Thymic Epithelial Tumor (KCSG LU17-21)

Results

Patient Characteristics	No of patients	%
Age (median: 54 years,32-92)		
<60 years	33	68.8%
≥60 years	15	31.2%
Sex		
Male	26	54.2%
Female	22	45.8%
ECOG PS		
0	2	4.2%
1	46	95.8%
Histology		
A	1	2.1%
B1	2	4.2%
B2	8	16.7%
B3	13	27.1%
C	23	47.9%
Unknown	1	2.1%
Masaoka stage		
IV-A	13	27.1%
IV-B	33	68.8%
Unknown	2	4.2%
History of thymectomy		
Yes	21	43.8%
No	27	56.2%
Line of previous chemotherapy		
1	31	64.6%
2	11	22.9%
3	5	10.4%
4	1	2.1%



With medial follow-up of 14.5 months (range 0.8-38.2), the median cycle of palbociclib was 10 (range : 1-40)

The median PFS was 11.0 months (95% CI: 4.6-17.4)

The median overall survival was 26.4 months (95% CI: 17.4-35.4)

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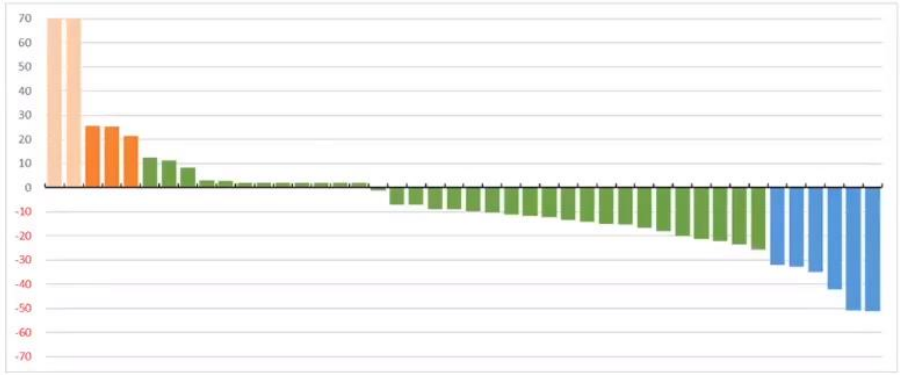
Palbociclib para tumores tímicos pre-tratados

- Se objetivó un 13,6% de tasa de respuestas.
- La toxicidad hematológica fue la más frecuente (neutropenia G3 en 41,7%)

A Phase II Study of Palbociclib for Recurrent or Refractory Advanced Thymic Epithelial Tumor (KCSG LU17-21)

Results

Responses to palbociclib



** Evaluable patient: 44

Objective response rate in evaluable patient : 6/44 (13.6%)

Summary of adverse events

Adverse Event	Any grade	Grade=>3
Neutropenia	30 (62.5%)	20 (41.7%)
Anemia	18 (37.5%)	7 (14.6%)
Thrombocytopenia	13(27.1%)	5 (10.4%)
Fever	9(18.8%)	0 (0%)
Fatigue	8 (16.7%)	0 (0%)
Anorexia	5 (10.4%)	0 (0%)
Diarrhea	5 (10.4%)	0 (0%)
Nausea	4 (8.4%)	0 (0%)
Constipation	4 (8.4%)	0 (0%)
Alopecia	4 (8.4%)	0 (0%)
Pneumonitis	4 (8.4%)	2 (4.2%)
Herpes zoster	3 (6.25%)	0 (0%)
Increased blood creatinine	2 (4.2%)	0 (0%)
Increased AST	1 (2.1%)	0 (0%)
Increased ALT	1(2.1%)	1(2.1%)
Increased bilirubin	1(2.1%)	0 (0%)

Tumores epiteliales tímicos estadio III: RYTHMIC

Multimodality Treatment and Outcome in Stage III Thymic Epithelial Tumors (TETs): A Retrospective Analysis From the French RYTHMIC Network

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rythmic.org Réseau tumeurs THYMiques et Cancer

INSTITUT NATIONAL DU CANCER — institutCurie — Necker — IFCT

Multimodality treatment and outcome in stage III thymic epithelial tumors (TETs): A retrospective analysis from the French RYTHMIC network

Benitez JC, Bluthgen MV, Boucher ME, Dansin E, Kerjouan M, Bigay-Game L, Pichon E, Thillays F, Falcoz PE, Lyubimova S, Oulkhouir Y, Calcagno F, Thiberville L, Clément-Duchêne C, Westeel V, Missy P, Thomas P, Maury JM, Molina T, Girard N, **Besse B**

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Jose Carlos Benítez
MD, MSc

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Tumores epiteliales tímicos estadio III: RYTHMIC

- Serie de 366 pacientes con tumores tímicos epiteliales estadio III

Multimodality Treatment and Outcome in Stage III Thymic Epithelial Tumors (TETs): A Retrospective Analysis From the French RYTHMIC Network

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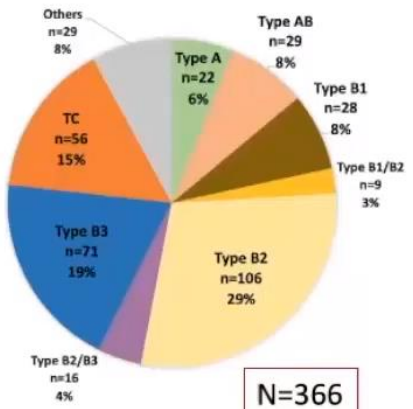
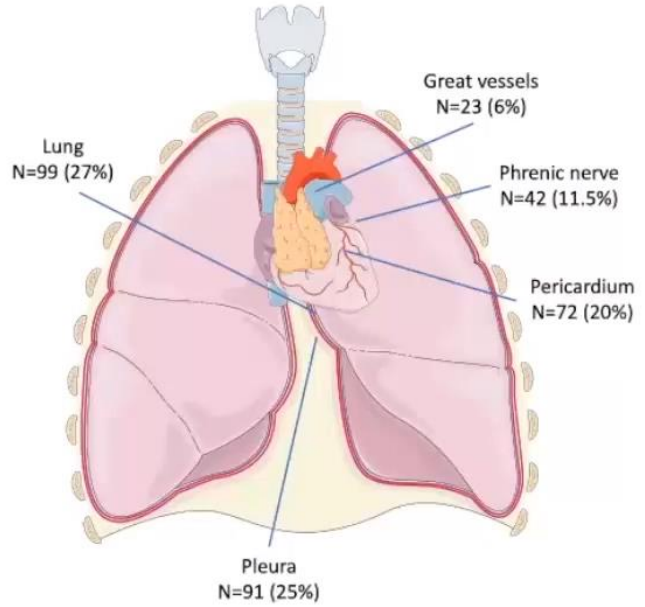
Clinico-pathological characteristics

rythmic.org

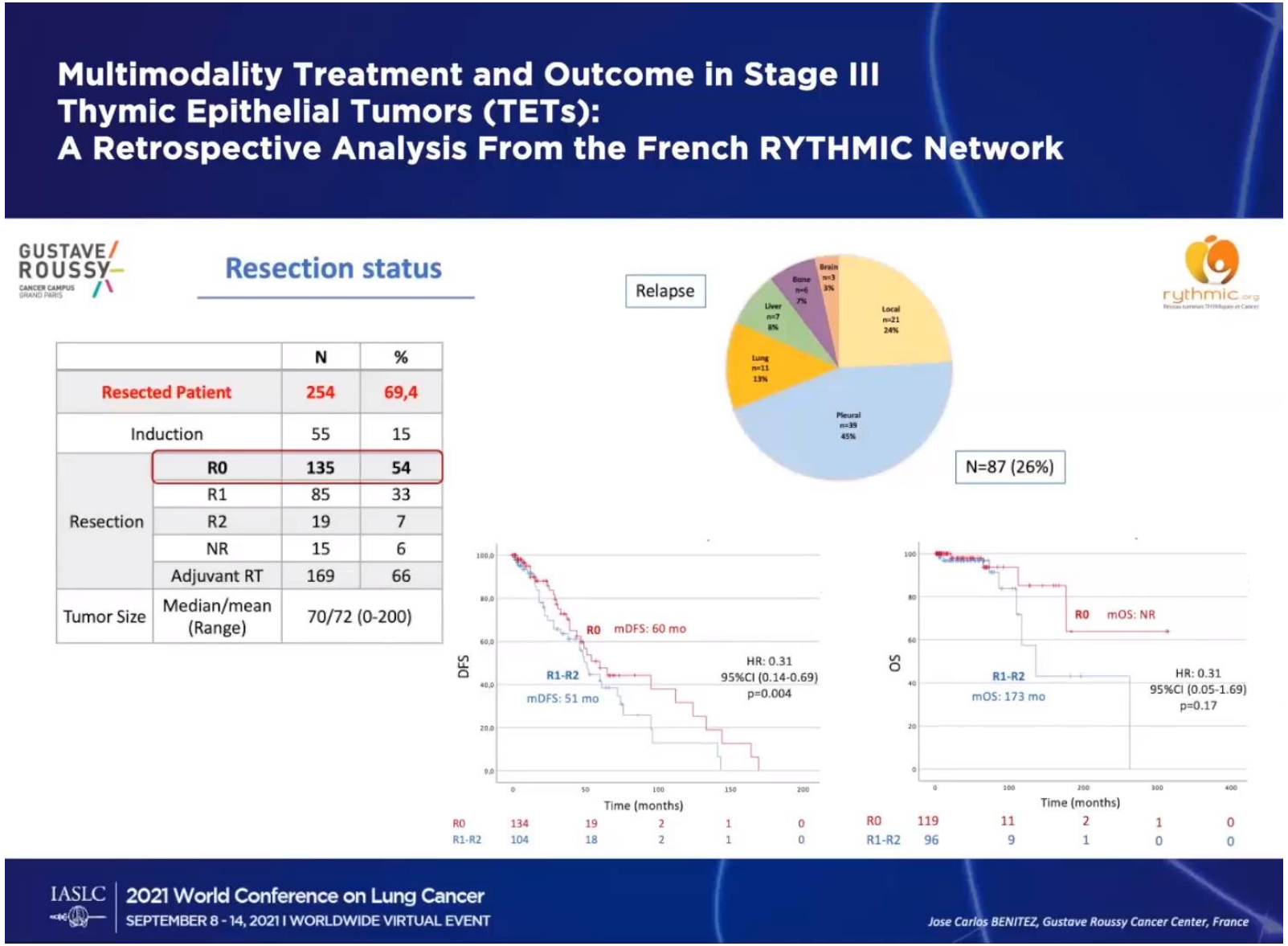
		N	%
Gender	Male	190	51,9
	Female	176	48,1
Age	Median/mean (Range)	61/59 (16-90)	
AID		99	27
	MG	82	83
	Good's Syndrome	4	4
	Red Cell aplasia	4	4
	Lupus	4	4
	Thyroiditis	2	2
	Arthritis	2	2
	Glomerulonephritis	1	1
	Neurophatty	2	2
	Dermatomyositis	1	1
	Other AID	4	4
AID onset	before	9	9
	at diagnose	80	81
	follow up	10	10





Tumores epiteliales tímicos estadio III: RYTHMIC

- La obtención de R0 es un factor pronóstico.



		N	%
Resected Patient		254	69,4
Induction		55	15
Resection	R0	135	54
	R1	85	33
	R2	19	7
	NR	15	6
	Adjuvant RT	169	66
Tumor Size	Median/mean (Range)	70/72 (0-200)	

Tumores epiteliales tímicos estadio III: RYTHMIC

- Un 70% pacientes recibieron cirugía.
- Recibir quimio inducción aportó un beneficio clínico.
- Radioterapia adyuvante no aportó estadísticamente beneficio, pero subgrupo R1-R2 podría tener más beneficio

Multimodality Treatment and Outcome in Stage III Thymic Epithelial Tumors (TETs): A Retrospective Analysis From the French RYTHMIC Network

GUSTAVE ROUSSY CANCER CAMPUS GRAND PARIS

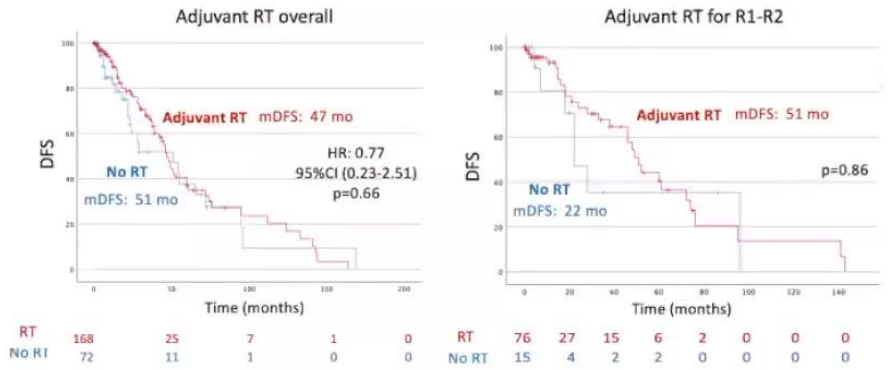
Peri-operative treatments

DFS	HR	95% C.I.	p-value
Sex (female)	4,95	2,09-11,70	<0,0001
Age	0,97	0,95-1,00	0,05
AIDs	0,79	0,29-2,12	0,64
T2	NA	NA	0,04
T3	1,46	0,51-4,14	0,47
T4	10,42	1,60-67,61	0,01
Type A	7,14	0,43-118,42	0,17
Type AB	NA	NA	0,98
Type B1	0,23	0,02-2,28	0,21
Type B2	2,33	0,60-8,99	0,21
Type B3	0,77	0,16-3,63	0,74
TC	43,18	7,60-245,21	<0,0001
R0	**0,31**	**0,14-0,69**	**0,004**
Induction CT	**0,37**	**0,14-0,96**	**0,04**
Adjuvant RT	**0,77**	**0,23-2,51**	**0,66**

Adjuvant RT subgroup

	R0 (n=83)		R1-R2 (n=78)	
	N	%	N	%
T2	26	31	11	14
T3	41	49	37	47
T4	2	2	5	6
Type A	1	1	3	4
Type AB	5	6	4	5
Type B1	2	2	5	6
Type B2	29	35	23	29
Type B3	16	19	11	14
TC	20	24	14	18
Induction CT	18	22	13	17

rythmic.org



IASLC | 2021 World Conference on Lung Cancer
SEPTEMBER 8 - 14, 2021 I WORLDWIDE VIRTUAL EVENT

Jose Carlos BENITEZ, Gustave Roussy Cancer Center, France

Principales conclusiones

- Estudio ATLANTIS: no diferencias en OS de doxo/lurbinectidina comparado con CAV/topotecan en 2ªL SCLC, aunque con mejor perfil de toxicidad.
- Rucaparib + nivolumab de mantenimiento en enfermedad SCLC extendida con actividad limitada mPFS de 2,67 meses en análisis interino.
- Importancia pronóstica de la cirugía en mesotelioma estadios I-IIIA, y datos preliminares favorables de cisplatino-pemetrexed-atezolizumab neoadyuvante.
- Tumores tímicos importancia del abordaje multimodal en estadios III, estudio exploratorio de palbociclib en tumores tímicos pre-tratados