Tercera Reunión Anual del grupo:

Grupo de Farmacia Oncológica de la SEFH

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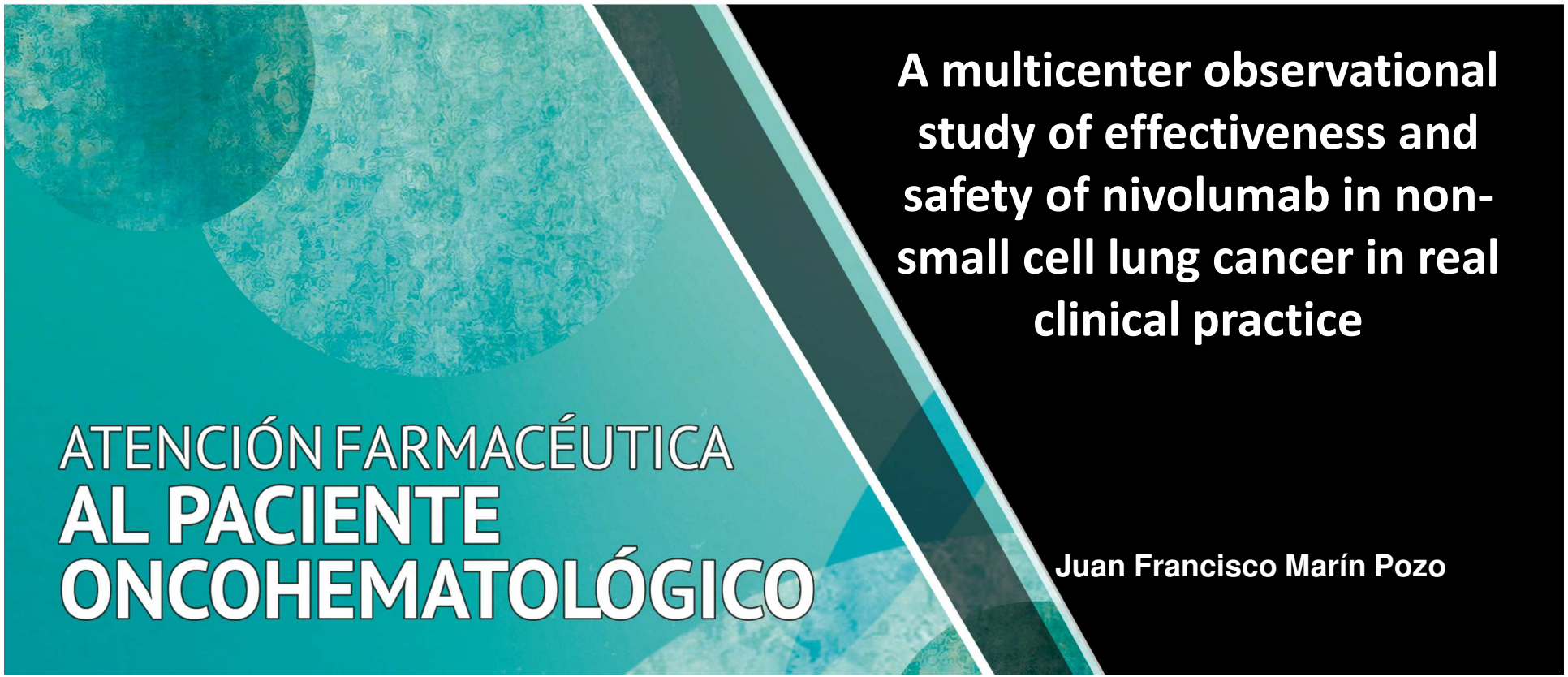

A multicenter observational study of effectiveness and safety of nivolumab in non-small cell lung cancer in real clinical practice

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DELIVERING DISCOVERIES: EXPANDING THE REACH OF PRECISION MEDICINE

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ATENCIÓN FARMACÉUTICA
AL PACIENTE ONCOHEMATOLÓGICO

Ficha del Estudio

Objetivo: Efectividad y Seguridad

Tipo Estudio:

Observacional, Retrospectivo, Multicéntrico, 15 Hospitales de Andalucía

Población Estudio:

Pacientes de Cáncer de Pulmón no Microcitico metastásico o avanzado

Tratamiento: Nivolumab en 2ª ó posterior línea de tratamiento según práctica clínica habitual en el centro

Periodo Reclutamiento: Enero 2016 – Julio 2017

Variables: -Supervivencia Global (OS)
-Supervivencia Libre de Progresión (PFS)
-Tasa Eventos Adversos Relacionados con el Tratamiento
-Variables descriptivas de la población

Patients characteristics

		Nº patients (%) (n=221)	
Age (years)	**Mean (sd)**	**64.5 (9.2)**	
	<70 years	162 (73.3%)	
	>70 years	59 (26.7%)	
Sex	**Male**	**185 (83.7%)**	
	Female	36 (16.3%)	
Smoking status (n=212)	Never/Former-smoker	60 (27.1%)	
	Current-smoker	**152 (68.8%)**	
Histology (n=216)	**Squamous**	**132 (59.7%)**	
	Non-squamous	84 (38%)	
ECOG (n=217)	0	62 (28.1%)	187 (84.7%)
	1	125 (56.6%)	
	2	30 (13.6%)	
Stage	**IV**	**119 (53.8%)**	
	III	**83 (37.6%)**	
	I-II	19 (8.6%)	

Patients characteristics

		Nº patients (%) (n=221)
Number of metastatic locations (n=209)	1	100 (45.2%)
	2	64 (29.0%)
	3	32 (14.5%)
	>3	13 (5.9%)
Type of metastatic locations (n=209)	Lung	115 (52.0%)
	Lymph nodes	72 (32.6%)
	Bone	69 (31.2%)
	Liver	41 (18.6%)
	Brain	22 (10.0%)
	Others	45 (20.4%)
Time since platinum therapy (months)	**Mean (sd)**	**15.6 (15.9)**
	< 6 months	47 (21.3%)
	>6 months	**174 (78.7%)**

Treatment Duration

1. Mean dose per cycle (3 mg/kg/14 days) and patient: 216 mg (sd=211).

2. Mean number of cycles administered was 9.7 (ds=9.1 - range [1-48]).

3. Median of treatment duration was 4.1 months (95%CI: 3.2-5) with a Mean 7.0 months (95%CI: 5.8-8.1).

Effectiveness

		PFS			OS		
		Median (m) [CI95%]	p	HR [CI95%]	Median (m) [CI95%]	p	HR [CI95%]
Population		5.3 [3.2-7.3]	-	-	9.7 [7.6-11.8]	-	-
Sex	Male	4.7 [3.2-6.2]	0.191	0.72 [0.44-1.18]	9.5 [4.9-14.2]	0.326	0.76 [0.44-1.32]
	Female	9.6 [5.2-14.1]			11.8 [6.5-17.0]		
Age	<70 years	5.2 [3.2-7.2]	0.662	0.92 [0.62-1.36]	9.7 [6.9-12.5]	0.821	0.95 [0.61-1.49]
	>70 years	5.1 [0.4-9.7]			12.8 [3.4-22.3]		
Smoking status	Never/Former	8.0 [3.6-12.3]	0.377	1.20 [0.80-1.81]	9.7 [5.7-13.7]	0.676	1.10 [0.70-1.74]
	Smoker	5.2 [3.1-7.3]			9.8 [6.0-13.7]		
Histology	Squamous	4.7 [2.7-6.8]	0.212	0.79 [0.55-1.14]	6.9 [3.6-10.2]	0.015	0.59 [0.38-0.91]
	Non-squamous	6.1 [2.9-9.3]			12.8 [7.8-17-9]		
Nº of metastatics locations	1	6.3 [3.1-9.6]	0.399	1.17 [0.81-1.69]	6.9 [3.7-10.1]	0.263	0.79 [0.52-1.19]
	>1	4.2 [2.9-5.6]			9.5 [7.7-11.7]		
ECOG	0-1	7.6 [5.2-9.9]	<0.0001	3.94 [2.53-6.11]	12.8 [9.5-16.1]	<0.0001	3.85 [2.40-6.18]
	2	1.9 [0.5-3.3]			2.9 [0.2-5.6]		
TiPT	<6 months	3.0 [0.7-5.3]	0.003	0.53 [0.34-0.80]	3.7 [1.5-5.9]	<0.0001	0.39 [0.26-0.60]
	>6 months	6.1 [3.9-8.3]			11.8 [8.2-15.3]		

PFS (univariate analysis)

		PFS		
		Median (m) [CI95%]	p	HR [CI95%]
Population		**5.3 [3.2-7.3]**	-	-
Histology	Squamous	4.7 [2.7-6.8]	0.212	0.79 [0.55-1.14]
	Non-squamous	6.1 [2.9-9.3]		
ECOG	0-1	**7.6** [5.2-9.9]	<0.0001	3.94 [2.53-6.11]
	2	**1.9** [0.5-3.3]		
TiTP	<6 months	**3.0** [0.7-5.3]	0.003	0.53 [0.34-0.80]
	>6 months	**6.1** [3.9-8.3]		

OS (univariate analysis)

		OS		
		Median (m) [CI95%]	p	HR [CI95%]
Population		**9.7 [7.6-11.8]**	-	-
Histology	Squamous	**6.9** [3.6-10.2]	0.015	0.59 [0.38-0.91]
	Non-squamous	**12.8** [7.8-17.9]		
ECOG	0-1	**12.8** [9.5-16.1]	<0.0001	3.85 [2.40-6.18]
	2	**2.9** [0.2-5.6]		
TiTP	<6 months	**3.7** [1.5-5.9]	<0.0001	0.39 [0.26-0.60]
	>6 months	**11.8** [8.2-15.3]		

OS Multivariate analysis

	HR	CI95%	p
Time from therapy with platinum (months)	0.97	0.95-0.99	0.002
Histology (squamous vs non-squamous)	0.56	0.37-0.92	0.019
ECOG (2 vs 0-1)	0.29	0.18-0.47	<0.0001

Treatment-Related Adverse Events

Side Effect	Any grade		Delay or discontinuation	
	n	%	n	%
Total	**157**	**71,0%**	**41**	**18,6%**
Asthenia	85	38,5%	7	3,2%
Dysnea	33	14,9%	6	2,7%
Diarrhea	26	11,8%	4	1,8%
Cough	21	9,5%	4	1,8%
Pneumonitis	17	7,7%	12	5,4%
Rash	16	7,2%	3	1,4%
Pain	15	6,8%	1	0,5%
Pruritus	15	6,8%	1	0,5%
Arthralgia	15	6,8%		
Nausea	14	6,3%		
Hypothyroidism	12	5,4%	2	0,9%
Fatigue	11	5,0%	2	0,9%

CONCLUSIONS

1. Effectiveness results of nivolumab in our study population are comparable to those obtained in the authorized clinical trials.

2. Nevertheless, the effectiveness results are not homogeneous in all the patient subgroups (ECOG=0-1 and TiTP>6 months).

3. OS is clearly lower in patients with squamous histology versus non-squamous histology.

4. Nivolumab treatment in patients with ECOG=2 is questionable, especially when this patient subgroup was not included in the authorized clinical trials.

5. In terms of its safety, the incidence of adverse events was similar to that obtained in the authorized clinical trials.

Este estudio se ha realizado sin recibir financiación ni patrocinio de ningún tipo por parte de entidad alguna pública o privada

GRACIAS