

Nivolumab in Non Small Cell Lung Cancer (NSLCC): French evaluation of use, current practices and medico economic approach

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Observatory of Cancer BPL (OMEDIT)

- Created in 2003 by Regional Representatives of French ministry of health
- Collects data from both private and public hospitals
- Provides a reflexion on drug management to optimize health care

Introduction

In 2016, **Nivolumab/Opdivo**® could be prescribed according to French registration in **stage IIIB/IV NSCLC** after disease progression after prior platinum-based chemotherapy and TKI therapy for patients with EGFR mutation. Patients had to be in good general state (ECOG PS 0-1)
 OMEDIT has evaluated its use, current practices and medico economic approach in Bretagne and Pays de la Loire areas.

Methods

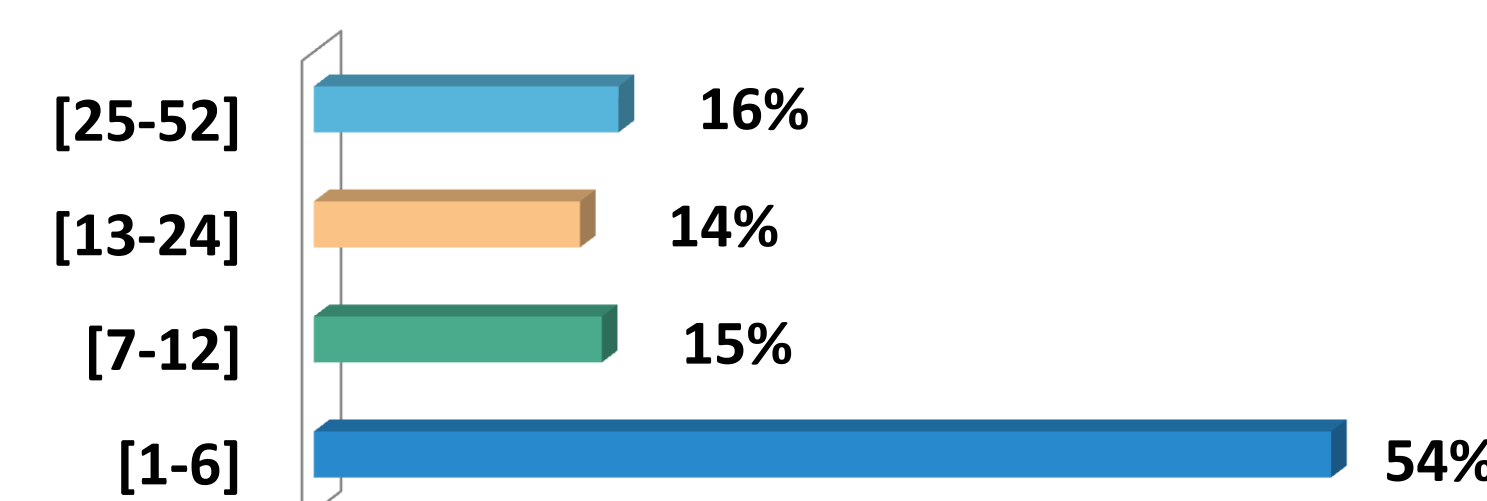
Adult patients with stage **IIIB/IV NSCLC** initiated nivolumab (3 mg/kg every 2 weeks) in 2016 according or not to French Registration (ECOG PS).
 → Minimum follow-up was 12 months (point date : December 31, 2017)

Collected data : Sex, age, mutation profile, toxicities, **Clinic Benefit (CB** : pts with complete/partial response/stable disease as the best response), **Progression Free Survival (PFS)** and **Overall Survival (OS)**

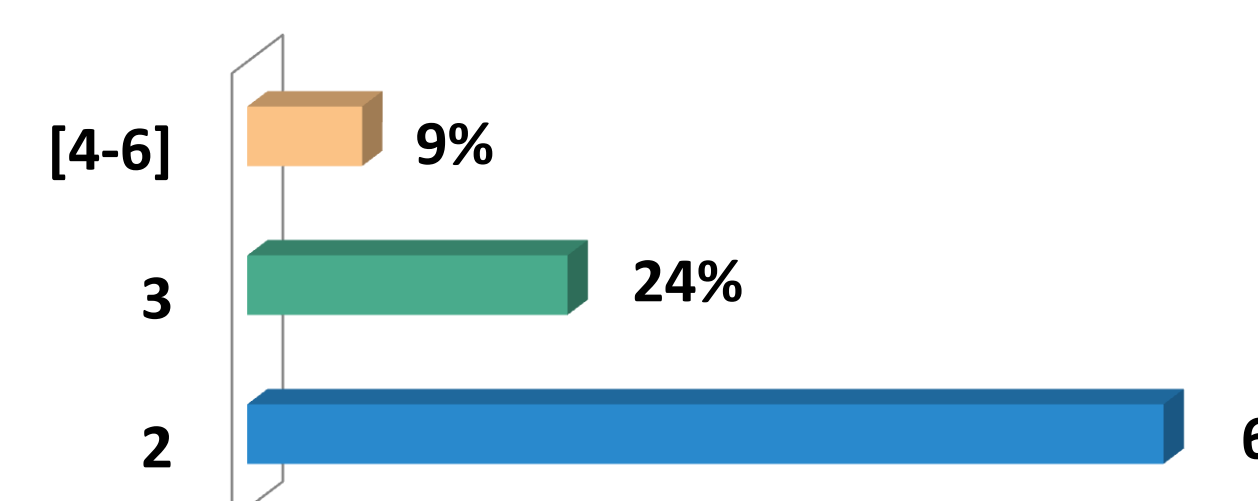
Population description

- 781 patients (pts)** included in **28 centers**
- Sex ratio** : 70.2% Men / 29.8% Women
- Mean age** : 64 years for Men / 62 years for Women (**11.5% ≥ 75 years old**)
- NSLCC**: 28.4 % squamous, 54.7% non-squamous and 16.9% undifferentiated
- 20.6 % PS ≥ 2** ⇒ not according to French Registration

distribution of the number of cures received by patient

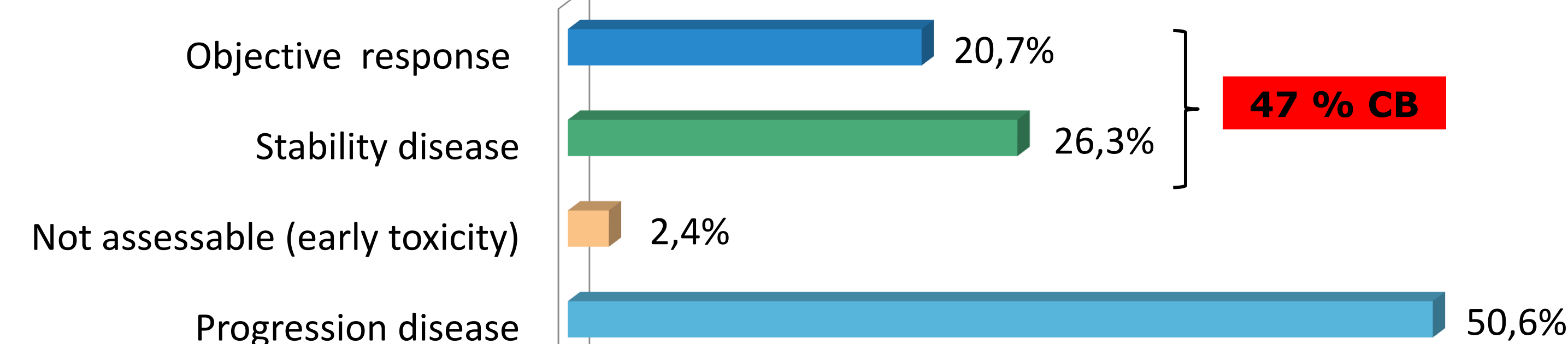


distribution of the treatment line number



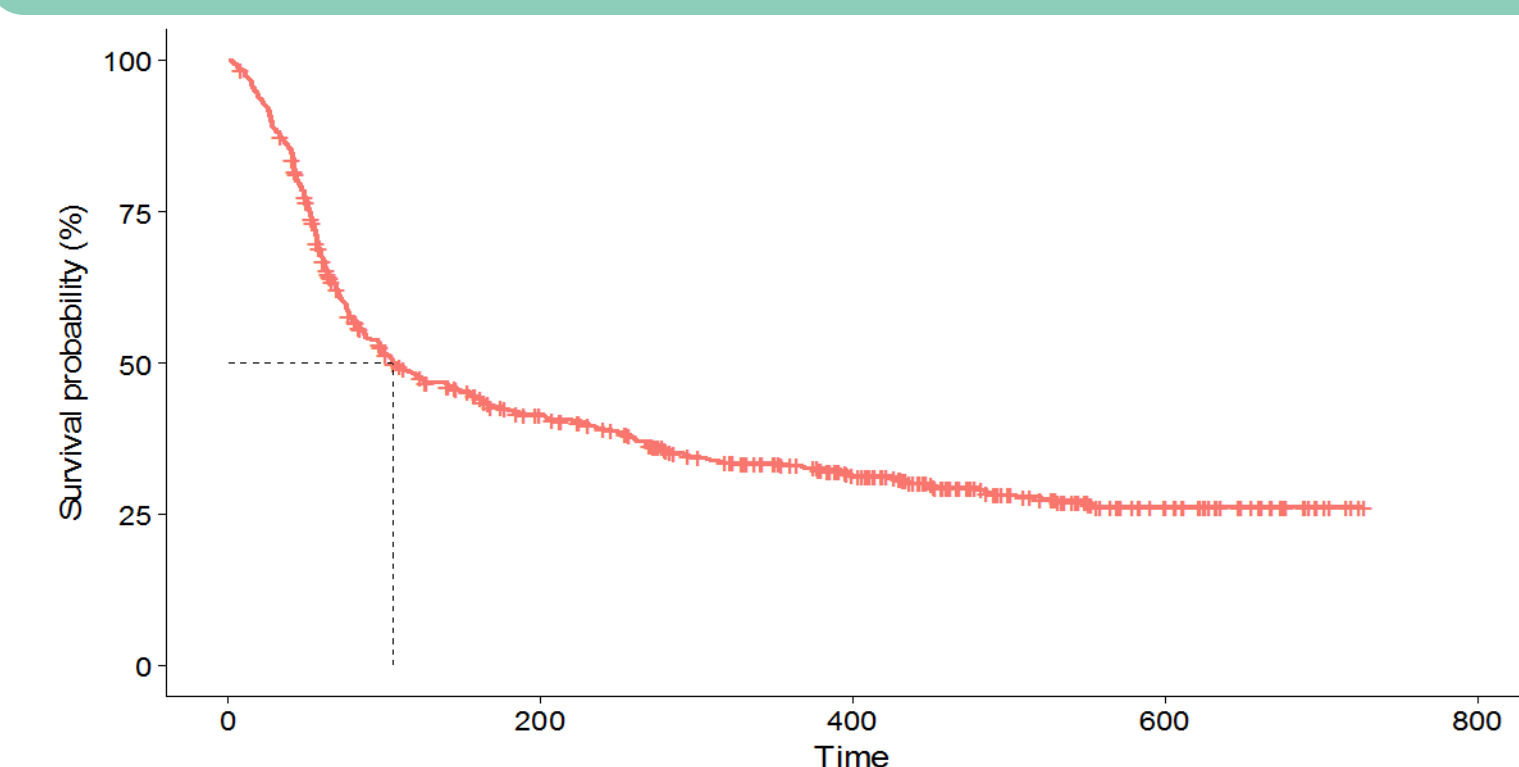
Treatment efficacy

Response of treatment (%)

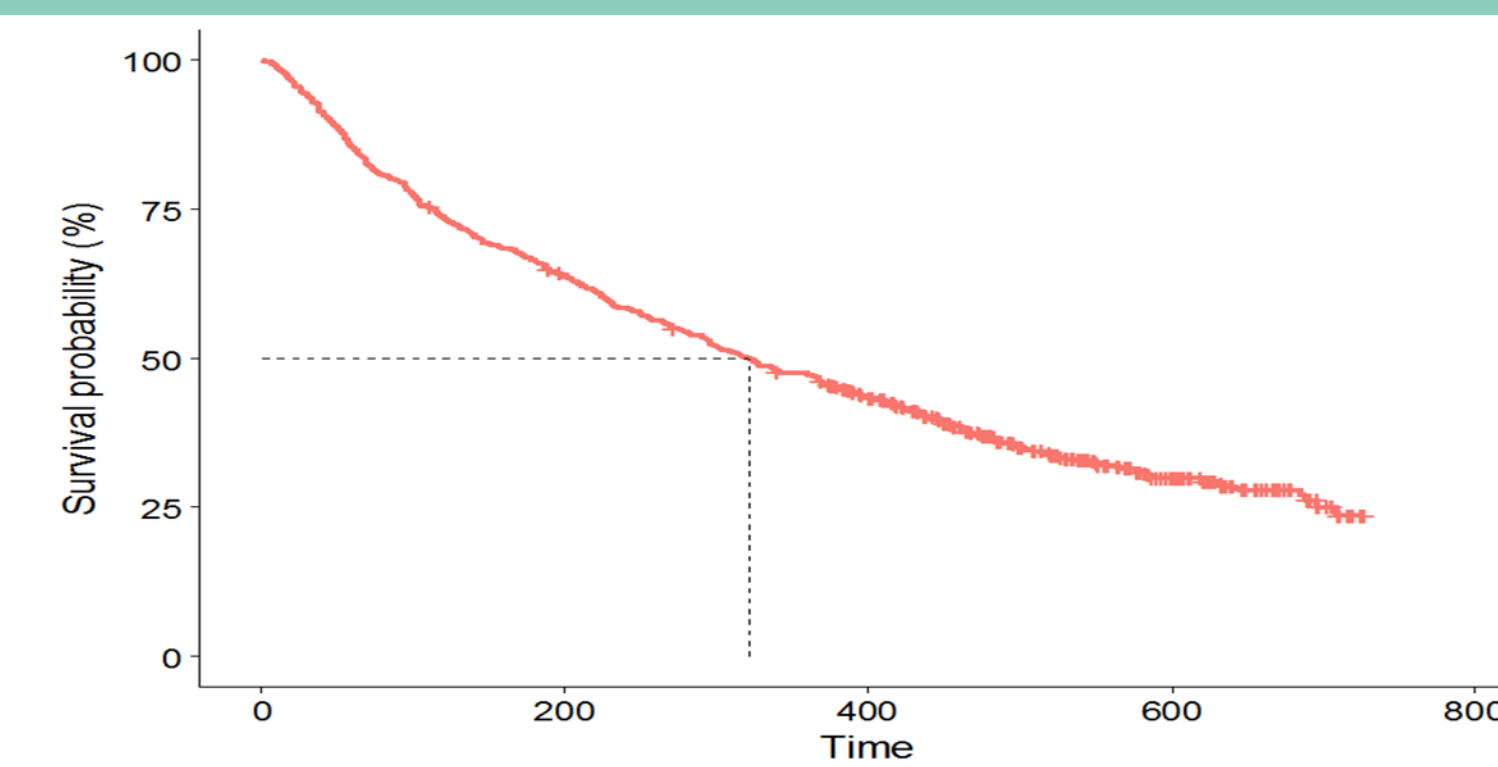


Best Response	Number of administration			
	[1-6]	[7-12]	[13-24]	[25-52]
CB	14.7%	73.3%	98.2%	100%
Progression Disease	85.3%	26.7%	1.8%	0%

Global PFS and OS



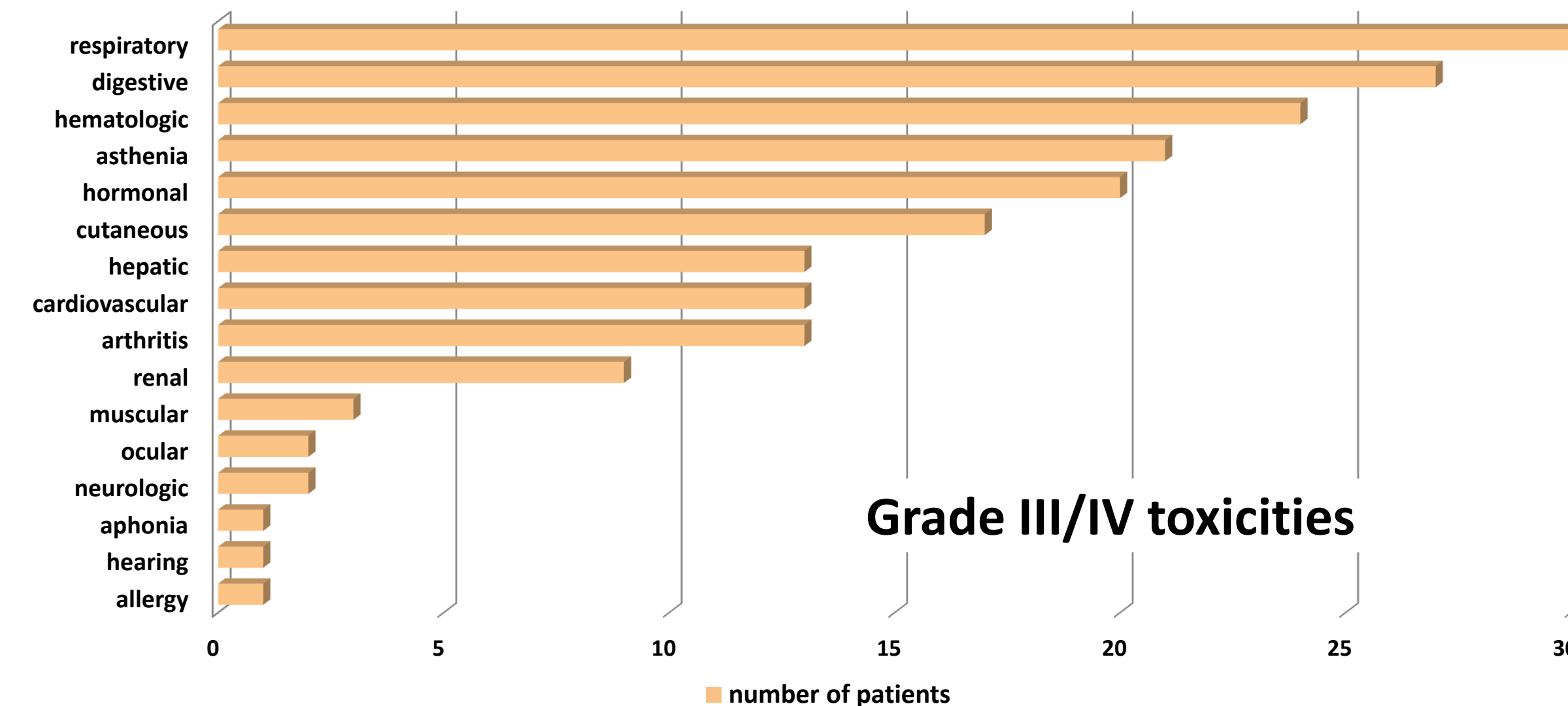
Median PFS = 3.5 months



Median OS = 10.6 months

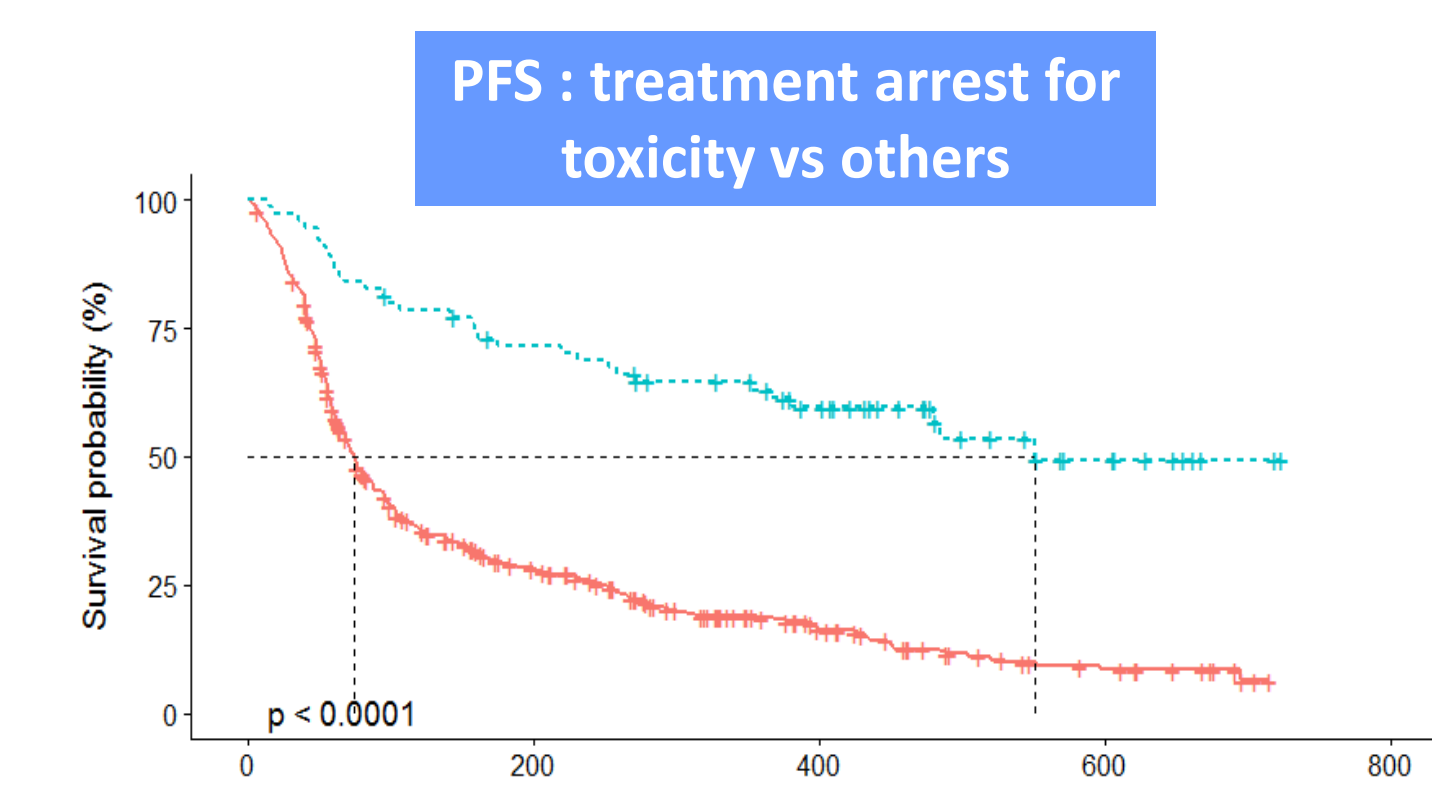
⇒ no statistical influence (at the risk level of 5 %) on survival according to tumor histology (squamous, non-squamous, undifferentiated), to treatment line number (2 vs 3 vs [4-6]), to previous treatment (ttt) (data not shown).

Safety

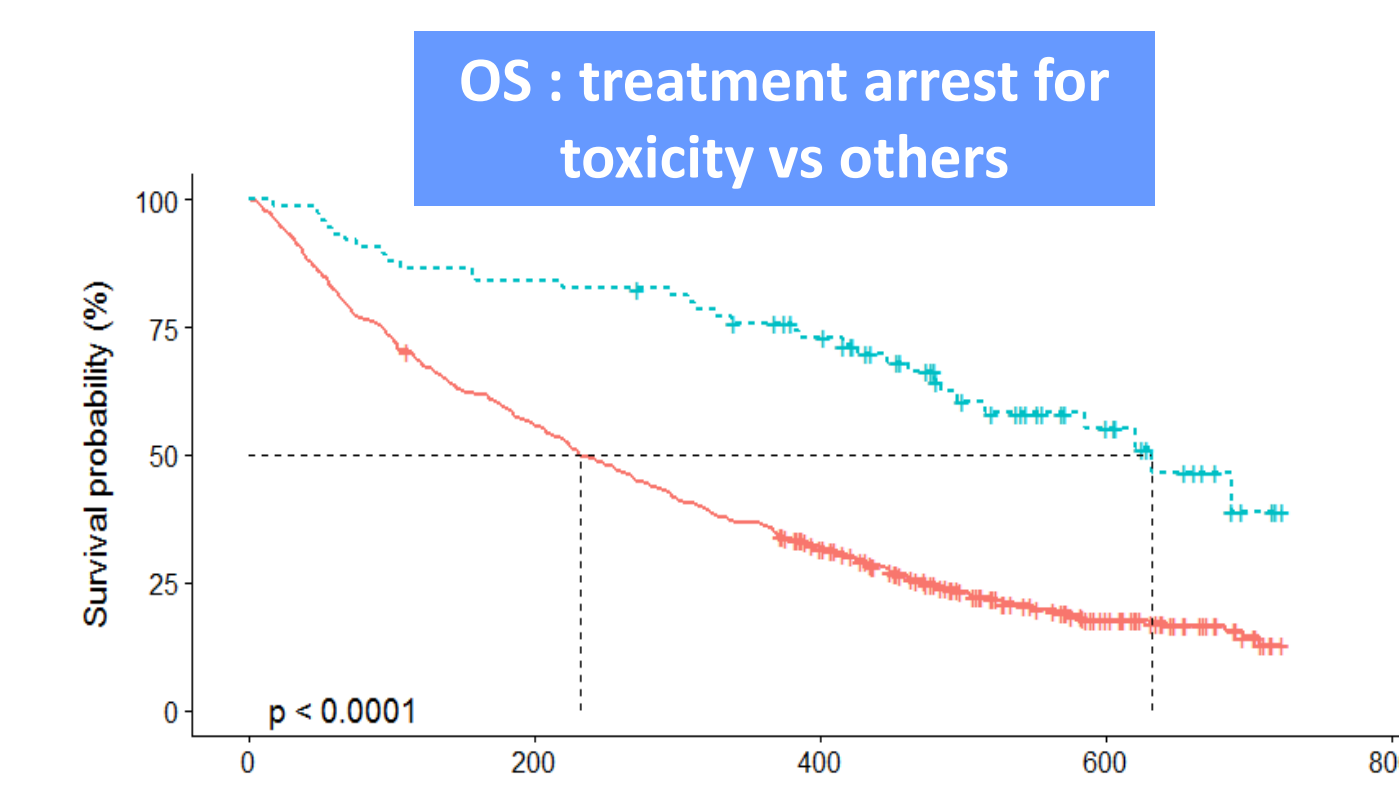


	Number of administration				Total
	[1-6]	[7-12]	[13-24]	[25-52]	
Pts with toxicity	67	31	29	25	152
Ttt arrest for toxicity	31	17	18	9	75

19.7% of patients had at least one grade III/IV toxicity (immediate or late toxicities)



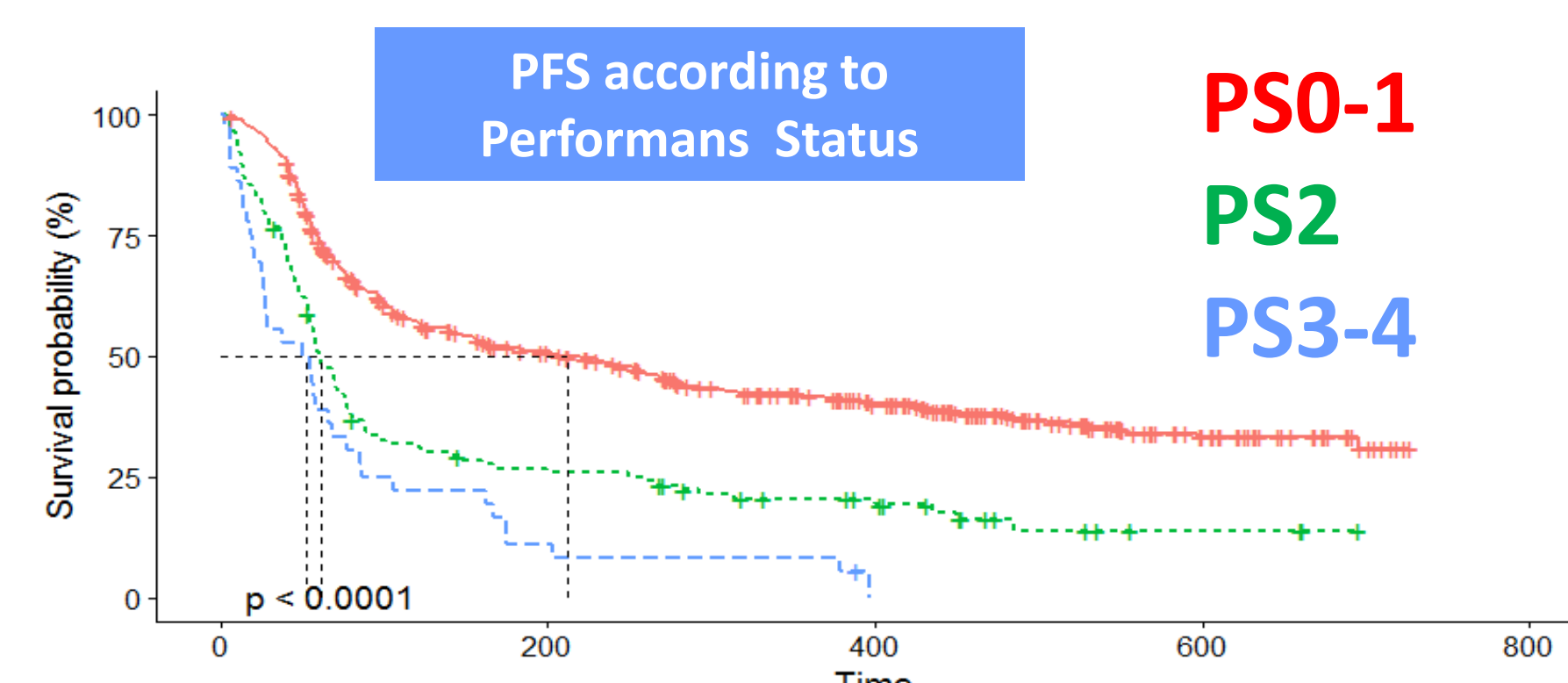
mPFS = 18.1 m vs 2.5m



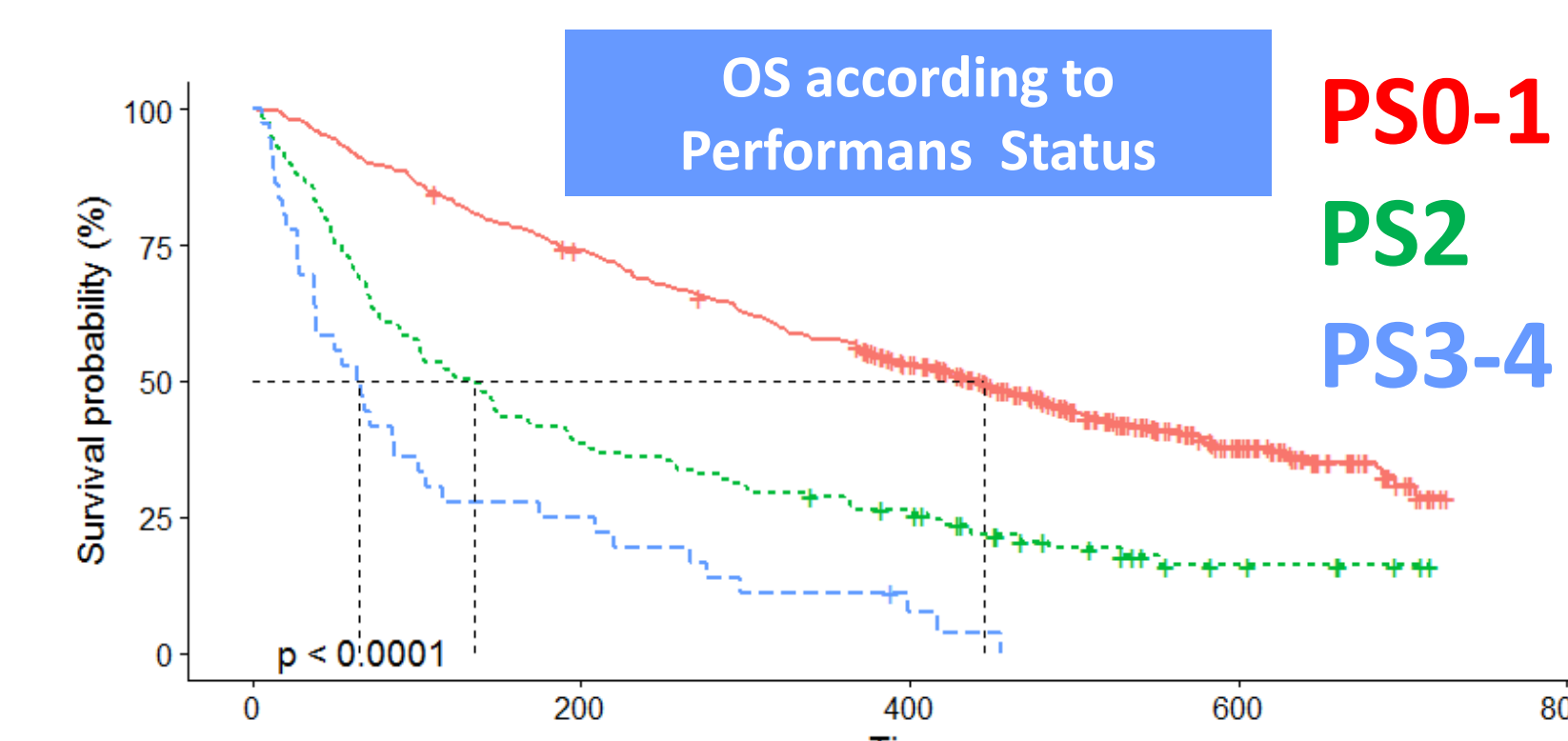
mOS = 20.8 m vs 7.6 m

⇒ better PFS and OS when nivo treatment has been stopped for grade III/IV toxicity
 ⇒ better PFS and OS when patients have presented grade III/IV toxicity (respectively p<0.0001 and p=0.0028, data not shown)

Performans Status (ECOG)



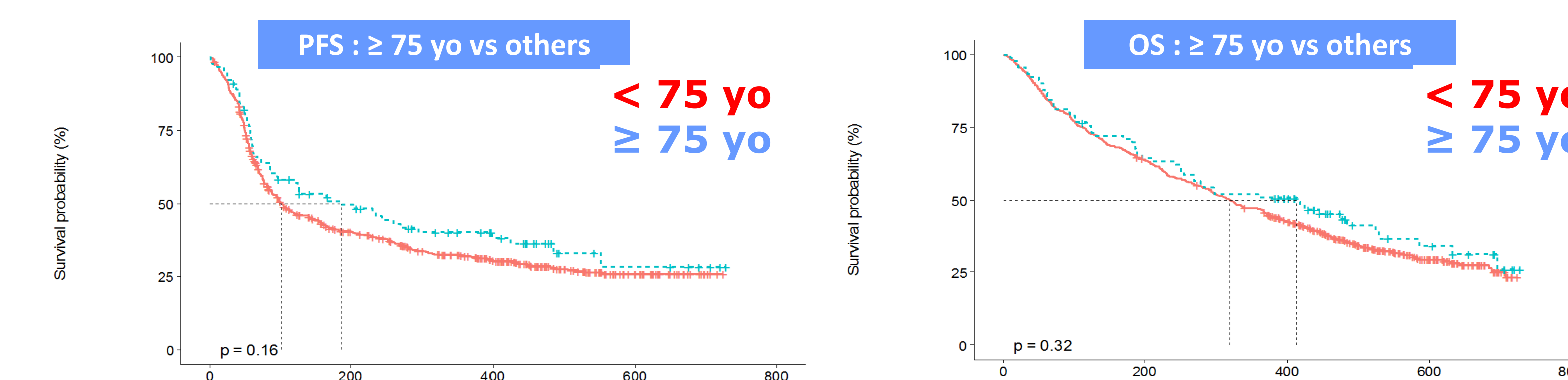
mPFS PS0-1 = 7.0 m
mPFS PS2 = 2.0 m
mPFS PS3-4 = 1.7 m



mOS PS0-1 = 14.6m
mOS PS2 = 4.4 m
mOS PS3-4 = 2.1 m

⇒ Important loss of OS and PFS for PS ≥ 2 patients

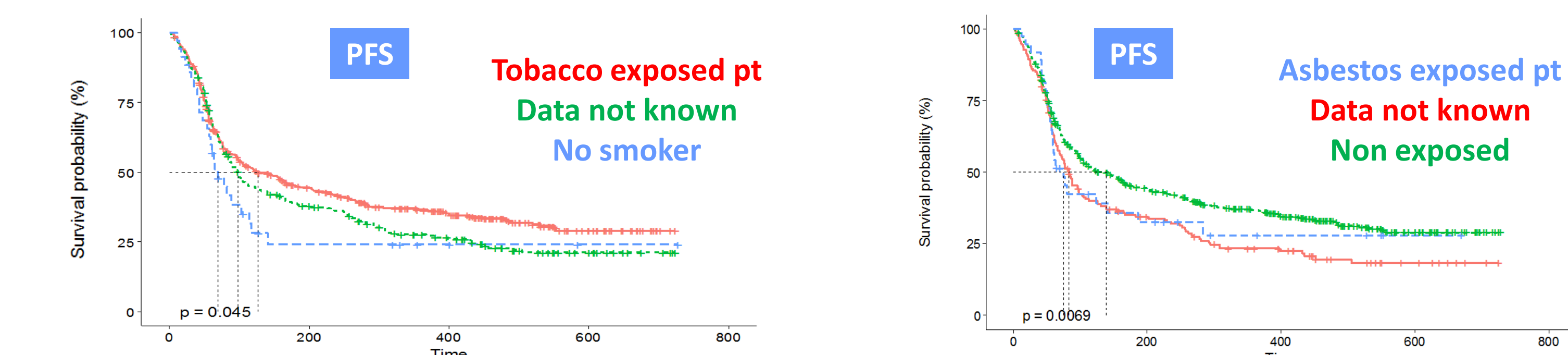
Elderly patients (≥ 75 years old)



	mean number of cures	p-value	grade III/IV toxicity	p-value
<75 yo	11.4	0.84	19.7%	1
≥75 yo	11.7		20.0%	

⇒ No statistical differences between “young” or elderly patients for PFS, OS, treatment duration and toxicity.

Tobacco / Asbestos



Similar data for OS (data not shown).
 Survival seems a bit better for tobacco exposed pts (current and former smokers, passive tobacco) and for non exposed to asbestos pts.

Medico economic

- Mean hospitalization cost = 389 € (public center= 403 € / private = 309 €) and mean sanitary transport cost= 31 €
 ⇒ **Mean hospital and transport cost = 417 €**
- Cost of nivolumab cure (3mg/kg) = 3 000 €**
- 781 patients received 8 932 cures of treatment (in 2016 and 2017). Among them, 7 408 cures for patients who presented clinical benefit (CB)
- Total cost = 30.5 millions € (3417*8932)**
- CB cost = 25.3 millions € (3417*7408)**

⇒ **83%** of costs were dedicated to patients who experienced CB

Conclusion

Differences in patient survival have been found according to the care centers which could be explained by difference in practices (PS≥2 proportion, ...).
 It is important to remember the **recommendations NCCN** for the medical care of NSCLC (2017) : supportive care only for PS 3/4 patient. Moreover, strong decrease of survival has been shown here for PS2 patients too. Feedback will be done by care center.