## EFFECTIVENESS AND SAFETY OF PEMBROLIZUMAB MONOTHERAPY IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER

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## Abstract

ABSTRACT Introduction: Immunotherapy has become a standard treatment for lung cancer; the objective of this study was to evaluate the effectiveness, safety of pembrolizumab monotherapy in patients with advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) used in real-world clinical practice. Material and methods: Retrospective observational study of every patients treated with pembrolizumab in our centre from January 2017 to June 2019. Outcomes collected: sex, age, ECOG, PDL-1 levels, previous metastatic line therapies, adverse events (AE) and smoking status. Results: A total of 62 patients were reviewed. The median age was 62.34±10.62 years, 48 (77.41%) were men and 91.93% of patients had ECOG 0. The median doses administered was 170.5 mg (108-240 mg) and median follow-up was 3 months (range: 1-38). A median of 4 cycles of pembrolizumab (range 1 to 56) were administered as monotherapy. The reason for treatment discontinuation was mainly due to disease progression in 38.70% patients or death in 30.64%. As first-line pembrolizumab monotherapy, median progression free survival was 7.7 months (95% CI: 3.66-11.73) (N=33). With respect to patients who were treated in second-thirdline treatment, median PFS was 3.5 months (95% CI: 2.40-4.59) (N=29). As to overall survival, pembrolizumab-treated patients as first-line treatment reached 19 months median OG (95% CI: 13.36-24.63) (N=33) and those treated in second-third-line treatment got 11 months (95% CI: 3.4-18.5). 64.51% of patients presented some AE to pembrolizumab however, only, 9.38% of them were grade 3. Conclusion: Pembrolizumab represents an effective and feasible alternative in terms of SLP. It is a well-tolerated treatment option.

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Characteristics	Total	First line	Second line	Third line
	(n=62)	(n=33)	(n=26)	(n=3)
Age (years)				
<ul> <li>Median</li> </ul>	64	64	64	69
• Rank	39-86	40-75	39-86	55-78
Age (cate	gory) - n (%)			
< 65 years	33 (53.23%)	18 (54.55%)	12 (46.15%)	1 (33.33%)
≥ 65-75	22 (35.48%)	11 (33.33%)	10 (38.46%)	1 (33.33%)
≥ 75	7 (11.29%)	2 (6.06%)	4 (15.38%)	1 (33.33%)
Sex - n (%)	II.	<u> </u>		II.
Men	48 (77.42%)	26 (78.79%)	19 (73.08%)	3 (100%)
Women	14 (22.58%)	7 (21.21%)	7 (26.92%)	0
ECOG - n (%)	1		Ш	1
0	19 (30.65%)	10 (30.30%)	8 (30.77%)	1 (33.33%)
1	37 (59.68%)	19 (57.58%)	16 (61.54%)	2 (66.67%
≥2	4 (6.45%)	3 (9.09%)	1 (3.85%)	-
Not collected	2 (3.23%)	1 (3.03%)	1 (3.85%)	-
CNS†Metastase	16 (25.81%)	11 (33.33%)	4 (15.38%)	1 (33.33%
s - n (%)				
Previous treatme	nt - n (%)			
Carboplatin-	10 (16.13%)	-	9 (34.62%)	1 (33.33%)
gemcitabine				
Carboplatin-taxol	8 (12.90%)	-	7 (26.92%)	1 (33.33%
Carboplatin-	11 (17.74%)	-	10 (38.46%)	1 (33.33%)
pemetrexed				
Cisplatin-	2 (3.23%)	-		2 (66.67%)
vinorelbine				
Tumour Histolog		` ,		
Squamous	25 (40.32%)	13 (39.39%)	11	1 (33.33%
Non-squamous	35 (56.45%)	20 (60.61%)	13 (50%)	2 (66.67%
Unknown	2 (3.23%)	-	2 (7.69%)	-
Smoking status -				
Smokers	55 (88.71%)	29 (87.88%)	23 (88.46%)	3 (100%)
Non-smokers	7 (11.29%)	4 (12.12%)	3 (11.54%)	-
PD-L1 level (%)-	n (%)			
(≥50%)	52 (83.87%)	31 (9.94%)	19 (73.08%)	2 (66.67%)