

Analysis Of Survival, Response And Safety Of Immunotherapy In Elderly Patients With Advanced Non-small-cell Lung Cancer

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OBJECTIVES

The number of elderly patients receiving immunotherapy based on **immune checkpoint inhibitors (ICI)** is increasing nowadays and there are no clear results about its efficacy and safety for this population group.

👉 The aim of the study was to analyze the **efficacy and toxicity** of ICI in **elderly patients** with metastatic non-small-cell lung cancer (NSCLC).

KEY WORDS

Carcinoma, Non-Small-Cell Lung; Immunotherapy; Aged.

MATERIAL AND METHODS

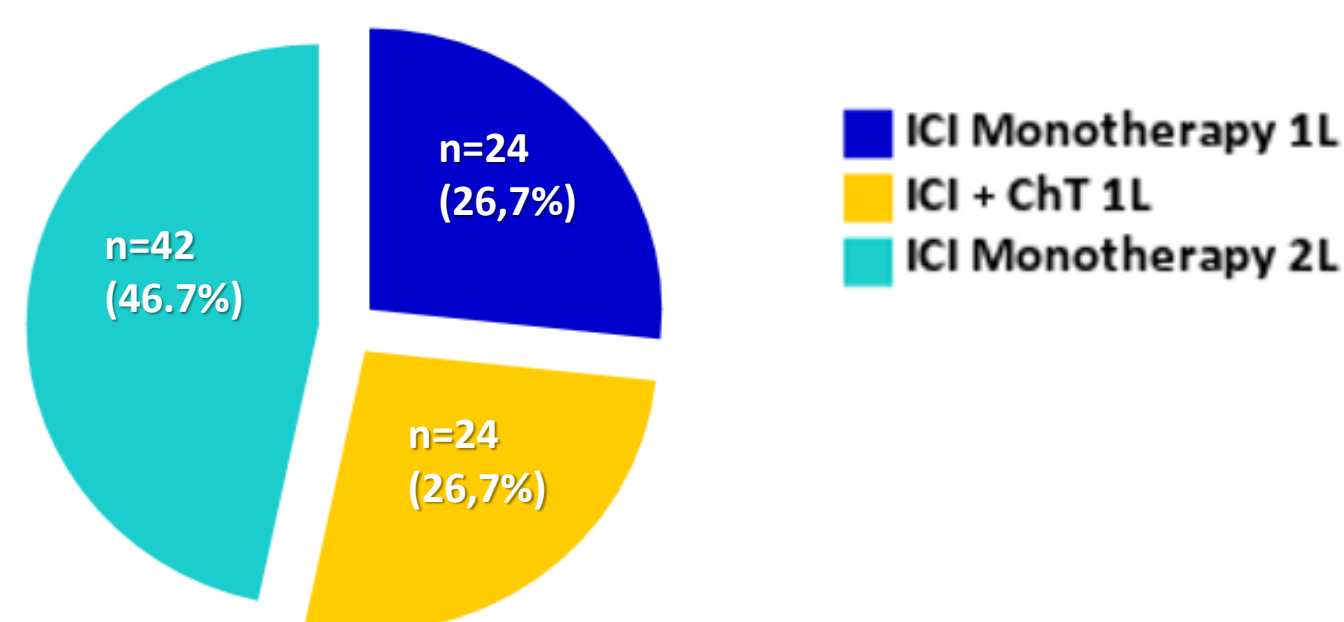
A single-center ambispective observational study of **90 elderly patients** (≥70 years, ASCO-defined criteria) diagnosed with **metastatic NSCLC** who received ICI between **2015 and 2022** was carried out.

- ✓ **Epidemiological** and **clinical** variables, as well as response to immunotherapy treatments (overall survival "OS", progression-free survival "PFS" and objective response rate "ORR" measured by RECIST1.1 criteria) were included.
- ✓ **Toxicity** was recorded according to CTCAEv5.0 criteria. Survival analysis was performed using *Kaplan-Meier* (Log-Rank) and *Cox Regression* methods.

RESULTS

BASIC CHARACTERISTICS, SURVEILLANCE AND TOXICITY ANALYSIS

The median age was **74 years** [70-86], with **88.9% of males**. The most frequent histology was **adenocarcinoma** (61.6%). Most patients had ECOG 0-1 at baseline (83.3%). **PD-L1 ≥1%** in 76.7% of tumours (69 patients) and **PD-L1 ≥50%** in 30.1% (27 patients).



For **Pembrolizumab** monotherapy in first-line OS was **13 months**, PFS 10 months and ORR 50%. In case of **Pembrolizumab + ChT**, the OS reached **24 months**, PFS 12 months and ORR 41.7%. **Second-line Nivolumab** achieved **11 months** of OS, 6 months PFS and ORR 45.2%.

Immune-related adverse events (AE) were reported in 28.9% of cases (n=26); thyroid affection was the most frequent (n=6; 6.7%), followed by nephritis (n=4; 4.4%), hepatitis (n=4; 4.4%), colitis (n=3; 3.3%) and two cases of pembrolizumab-associated pneumonitis (n=2; 2.2%).



The presence of these **toxic events** was correlated to statistically significant **higher ORR** in patients treated with first-line ICI monotherapy (ORR: 100% vs 33.3%; $p=0.005$) and higher OS, although not statistical significance (14 months vs 6 months; $p=0.195$).

Table 1. Baseline characteristics and surveillance study of elderly patients with metastatic NSCLC, treated with ICI.

TOTAL PATIENTS (n=90)		1 ST L: PD-L1 ≥ 50% (ICI) (n=24; 26.7%)	1 ST L: PD-L1 < 50% (ICI + ChT) (n=24; 26.7%)	2 ND L ICI (Nivolumab) (n=42; 46.7%)
Age - yr (median, range)	74 (70 - 86)			
Male sex - no. (%)	80 (88,9)			
ECOG - no. (%)				
0-1	75 (83,3)			
Immune-related AE - n. (%)	26 (28,9)			
Thyroides afecion	6 (6,7)			
Skin reaction	2 (2,2)			
Hepatitis	4 (4,4)			
Colitis	3 (3,3)			
Nephritis	4 (4,4)			
Arthralgia	2 (2,2)			
Pneumonitis	2 (2,2)			
Asthenia	1 (1,1)			
Hyperthermia	1 (1,1)			
Myositis	1 (1,1)			
Toxicity grade - no. (%)				
Grade I	6 (6,7)			
Grade II	13 (14,5)			
Grade III	5 (5,5)			
Grade IV	2 (2,2)			
OS (months) - IC95%		13 (3,72 - 22,28)	24 (8,09 - 39,91)	11 (8,09 - 13,91)
PFS (months) - IC95%		10 (5,69 - 14,31)	12 (7,25 - 16,76)	6 (3,59 - 8,41)
ORR - no. (%)		12 (50)	10 (41,7)	19 (45,2)

In total, 9 patients were **older than 80 years** (10%)

- 6 received pembrolizumab monotherapy, with **22 months OS**, **13 months PFS** and **ORR 50%**. Another 3 were treated with nivolumab: **12 months OS**, **9 months PFS**, **ORR 66.7%**. Developing in total 3 immune-related AE (33.3%).

CONCLUSIONS

👉 Immunotherapy administration in elderly patients with NSCLC was **effective** and **safe**, similar to general population, although slightly **less effective** in ICI monotherapy for PD-L1 ≥50%

👉 It is essential to **identify and record data** corresponding to **this subgroup** of population in future research, which has usually been **under-represented**

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