



Nivolumab treatment in advanced non-small cell lung cancer (aNSCLC): real-world 3-year outcomes within overall and special populations (the UNIVOC study)

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Introduction

Overview of the use of immune checkpoint inhibitors

- Immune checkpoint inhibitors have become the standard of care for treatment of advanced non-small cell lung cancer (aNSCLC) within five years^{1,2}, providing a significant increase in survival in pre-treated patients compared to standard chemotherapy.^{3,4}
- Nivolumab has demonstrated an increase in overall survival (OS) after chemotherapy in patients with locally advanced or metastatic NSCLC in large randomized studies in non-squamous (CheckMate057) and squamous (CheckMate017) aNSCLC, with an OS rate at four years of 14%⁵.

UNIVOC background

UNIVOC is a cohort of 10,452 patients, i.e. all patients with aNSCLC starting treatment with nivolumab within two years of the date of its availability in France, identified in the National Health Data System (SNDS)⁶ which provides detailed data on the use of health resources by all beneficiaries of the French health system insurance.

Study rationale

- The significant size of this cohort allowed for the evaluation of outcomes in subgroups of patients who have not been widely evaluated in smaller clinical trials or observational studies, either because they have been excluded or because they represent a small minority of patients treated.
- The median age of patients enrolled in clinical trials of nivolumab is 10 years younger than the median age of patients with aNSCLC observed in clinical practice.⁹
- Patients with renal failure represent a 4% of the aNSCLC¹⁰ population, this comorbidity appears to be associated with increased mortality^{11,12}
- Brain Metastases are seen in approximately 30-40% of patients¹³ with NSCLC and are associated with poor prognosis and high morbidity.¹⁴

Objective

The objective of this study was to describe long-term outcomes of patients treated with nivolumab for aNSCLC in everyday clinical practice in France, using the SNDS database, for the overall population and for three specific populations, those aged ≥80 years, those with renal impairment and those with brain metastases.

Method

Study design

This retrospective observational study used data from the hospital discharge database (PMSI; Programme de Médicalisation des Systèmes d'Information) of the SNDS.⁸ The study included all patients hospitalized with lung cancer in France who initiated treatment with nivolumab between January 1, 2015 and December 31, 2016.

Identification of patients

- Lung cancer was identified through C34* ICD-10 code on the hospitalization discharge summary.
- The date of the first treatment with nivolumab was taken as the index date.
- Cancer history and comorbidities were retrieved from information in hospital discharge summaries in the period preceding index date and information on the duration of nivolumab treatment and on survival was collected from the database throughout the period following the index date. This follow-up period could thus range from 24 to 48 months, depending on the index date (Figure 1).

Identification of subpopulations of interest

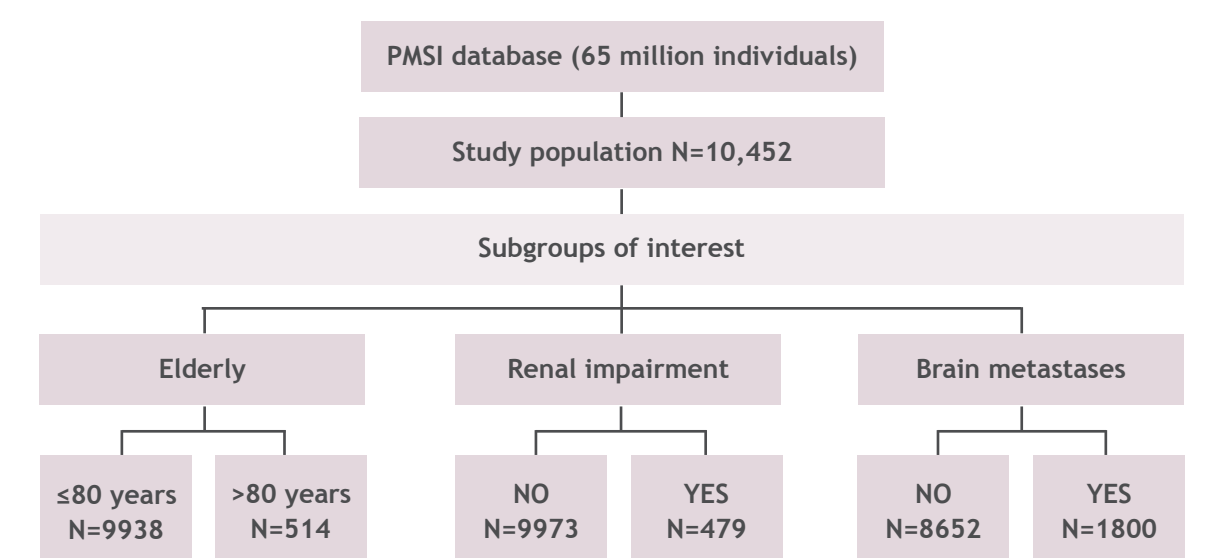
- Age (80 and over, or under 80) was determined on the index date.
- Renal impairment was identified from relevant ICD-10 codes (N17* or N18*) on hospital discharge summaries prior to the index date.
- Presence of brain metastases at or prior to the index date was documented from the ICD-10 code C793 on the hospital discharge summary.

Statistical analyses

- Patient characteristics were compared between subgroups of interest using the X² test for categorical variables or the Wilcoxon test for continuous variables.
- Time to treatment discontinuation (TTD) and OS rates were determined from Kaplan-Meier actuarial survival curves.
- Survival was compared between subgroups of interest using the log rank statistic.

Results

Selection process for sub-populations of interest



Conclusion

- This study assessed the effectiveness of nivolumab in these high-risk patient population within the 2L NSCLC population.
- OS is not compromised in the over 80 years old and possibly renal impairment populations
- Concerning patients with brain metastases, further studies using other types of design are merited to explore the benefits and safety of nivolumab in this patient subgroup.

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Disclosure

Funding

This study was supported by Bristol Myers Squibb (Princeton, NJ) and ONO Pharmaceutical Company Ltd. (Osaka, Japan).

Conflicting Interests

JBA was supported by grants from Fondation pour la Recherche Médicale (FRM).

CC reports consultancy fees from Astra Zeneca, Boehringer Ingelheim, MSD, Pierre Fabre Oncology, Lilly, Roche, Bristol-Myers Squibb and Novartis.

RC reports consultancy fees from Astra-Zeneca, Bristol-Myers Squibb, Roche and Takeda.

MGL reports consultancy fees/research funding from Bristol-Myers Squibb, Astra Zeneca, MSD, Roche and Novartis.

FEC, CYC, and AFG are employed by Bristol Myers Squibb.

BJ and RJ are employees of HEVA.

Acknowledgments

All the authors have contributed to and approved this poster. Assistance in the creation of the poster: A. Panes, PharmaD, PhD, and A. Loyer, HEVA.