

Introduction: Response rates to immunotherapy in metastatic non-small cell lung cancer (NSCLC) are low and survival varies significantly. It has been suggested that factors like age, sex, race, and histology may modulate immunotherapy response. Existing analyses are limited to clinical trials, with limited generalizability, and meta-analyses where data cannot be adjusted for potential confounders. Here, we present a patient-level analysis to explore how personal and clinical characteristics moderate the effectiveness of chemo-immunotherapy in metastatic NSCLC. **Methods:** Stage IV NSCLC patients diagnosed in 2015 were drawn from Surveillance Epidemiology, and End Results (SEER)-Medicare linked data. Overall survival was studied in those treated with chemo-immunotherapy vs. chemotherapy alone. Multivariable Cox-proportional hazards regression models and propensity-score matching were performed to evaluate the effectiveness of chemo-immunotherapy versus chemotherapy. **Results:** 349 patients were treated with chemo-immunotherapy and 1122 (76%) received chemotherapy alone. Survival was significantly better among those treated with chemo-immunotherapy compared to those who received chemotherapy alone (HR_{adj} : 0.72, 95% CI: 0.63-0.83), after adjustment for age, sex, race, marital status, Charlson comorbidity status, and histology. Males treated with chemo-immunotherapy reported significantly better OS than those treated with chemotherapy alone (HR_{adj} : 0.62, 95% CI: 0.51-0.75), but females did not (HR_{adj} : 0.81, 95% CI: 0.65-1.01) ($p[interaction] = 0.0557$). After propensity-score matching, the effect of chemo-immunotherapy was statistically significantly different by sex ($p[interaction]=0.0414$), but not by age or histology (Figure 1). **Conclusions:** Chemo-immunotherapy is associated with better overall survival compared to chemotherapy alone. Male patients may benefit more from chemo-immunotherapy, but there is limited evidence suggesting age, histology, race, and comorbidities contribute to differences in immunotherapy effectiveness. **Keywords:** Immunotherapy, Non-small cell lung cancer, Survival disparities

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Spanish Immunotherapy Registry of Cardiovascular Toxicity (SIR-CVT): Preliminary Analysis of the Lung Cancer Cohort



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Introduction: Immunotherapy has transformed the landscape of lung cancer treatment. Owing to the growing use of ICIs in the treatment of lung cancer, we will increasingly be confronted with common but also rare immune-related adverse events (irAEs). Acute cardiovascular irAEs occur in less than 5% of patients treated with ICIs; however they involve a potentially fulminant toxicity. On the other hand, ICIs also have a potential role in the development and exacerbation of long-term cardiovascular complications. In addition, the diagnosis and treatment of cardiovascular irAEs may be delayed due to poor specificity of symptoms and the absence of monitoring protocols. **Methods:** We present the Spanish Immunotherapy Registry of Cardiovascular Toxicity (SIR-CVT). The aim of this registry is to identify cardiovascular

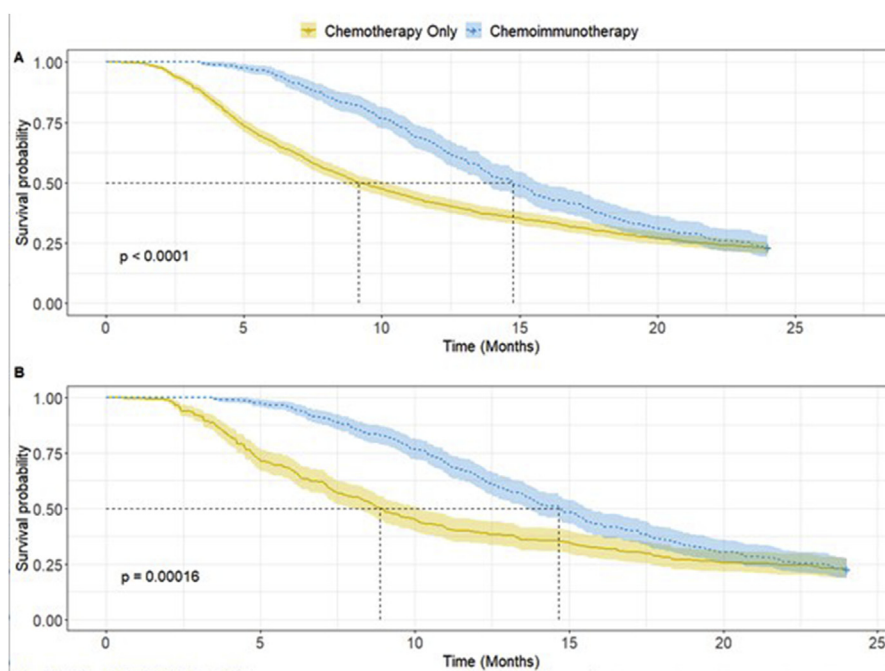


Figure 1. Overall survival according to treatment in the (a) overall cohort (n=1471); (b) the propensity matched cohort (n=662)

toxicity events in the short and medium term in patients with solid tumors, including lung cancer, who will be treated with immunotherapy for the first time, conducting a systematic baseline study based on blood test including cardiac biomarkers, electrocardiograms, advanced imaging test such as echocardiogram and cardiac magnetic resonance (CMR) and joint clinical follow-up. Other objectives are to validate the usefulness of a new biomarker of myocarditis, the micro RNA721, which could help in the early diagnosis of patients who develop myocarditis; and to define the inflammation profile of these patients. This registry includes the participation of 19 Spanish centers and is already recruiting patients in some of them. It is expected to include 500 patients. At present, 29 patients with lung cancer have been included in the registry from July 2021 to February 2022. **Results:** The majority (n=25, 86.2%) are males with a median age of 65 years old. 23 patients (79.3%) have smoking history. Regarding cardiovascular risk factors, 11 patients (37.9%) have hypertension, 8 patients (27.6%) have diabetes mellitus and 13 patients (44.8%) have dyslipidemia. Concerning previous cardiovascular disease, 7 patients (24.1%) have previous myocardial infarction, 3 patients (10.3%) have previous heart failure and 2 patients (6.9%) have previous non-ischemic cardiomyopathy. The median left ventricular ejection fraction by echocardiogram and CMR at baseline visit was 57.2% and 55.7%, respectively; and the median left ventricular global longitudinal strain was -17.3%. The median cardiac troponin was 10.5ng/L and the median NT-pro-BNP was 1039.5pg/ml. Regarding the type of cancer, 19 patients (65.5%) have lung adenocarcinoma and 10 patients (34.5%) have lung squamous cell carcinoma. Most patients (n=22, 75.9%) have stage IV, 5 patients (17.2%) stage III and 2 patient (6.9%) stage II. Two third of the patients (n=21, 72.4%) receive pembrolizumab, 4 patients (13.8%) durvalumab, 3 patients (10.3%) atezolizumab and 1 patient (3.5%) nivolumab. **Conclusions:** The results of this real-world registry will allow us to know the incidence, symptoms and improve the management of cardiovascular irAEs. All of that will lead to the development of monitoring protocols, the discovery of specific biomarkers in this high cardiovascular risk population and the prevention of potentially fulminant adverse events. It would be advisable to perform a baseline cardiovascular study prior to starting immunotherapy to find out if patients have any unknown cardiovascular disease. **Keywords:** Lung cancer, Immunotherapy, Immune- related adverse events

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Unscheduled Hospitalizations in Patients With Thoracic Tumors in the Era of Immunotherapy

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Introduction: Patients with advanced lung cancer and other thoracic tumors (TT) generally have higher hospitalization rates than other tumors due to their high mortality and associated comorbidity. Immune checkpoint inhibitors have changed the treatment paradigm of these tumors and are generally well tolerated but they can be associated with rare and life-threatening immune related adverse events (irAEs). The aim of this study was to assess the characteristics of patients that require hospital admission over a period of 6 months, focusing on patients with TT. **Methods:** We retrospectively reviewed the 454 unscheduled hospitalizations that occurred between June 2021 to November 2021 in the Medical Oncology Service of La Paz University Hospital, Madrid (Spain). In this study we specifically analyzed the cohort of patients with TT. The patients were followed up until February 2022. **Results:** 348 patients were admitted. Most patients (n = 90, 26%) had TT. In the TT cohort, the majority were males (n=54, 60%) with a median age of 66 years old (range 27-89). The most frequent histology was non-small-cell lung cancer (n=69, 77%), composed of adenocarcinoma (n=43, 48%), squamous cell (n=18, 20%), undifferentiated (n=7, 8%) and giant-cell (n=1, 1%), followed

by small-cell lung cancer (n=17, 19%) and other less common TT such as carcinoid (n=1, 1%), salivary gland (n=1, 1%), mesothelioma (n=1, 1%) and thymoma (n=1, 1%). Only a few patients (n=7, 8%) underwent previous surgery. The majority (n=78, 87%) had stage IV disease. Regarding the last treatment received prior to admission, most patients (n=82, 91%) were receiving systemic treatment, of whom 54 patients (60%) were receiving immunotherapy. The main cause of admission recorded was tumor-related (n=44, 49%), followed by infection (n=24, 27%), irAEs (n=9, 10%), venous thromboembolic disease (n=6, 7%), non-infectious chemotherapy-related toxicity (n=5, 6%) and heart failure (n=2, 2%). 50 patients (56%) died during admission or during the follow-up. The median overall survival since diagnosis was 25.2 months (95%CI: 15.5 - 35.0) and since admission 3.7 months (95%CI: 0.7 - 6.8). IrAEs were observed in 20 of the 54 patients (37%) treated with immunotherapy. The most frequent irAE was pneumonitis (n=10), followed by cutaneous irAEs (n=3), hepatitis (n=3), thyroid irAEs (n=2), musculoskeletal irAEs (n=3), colitis (n=2), myocarditis (n=1), myasthenia gravis (n=1), nephritis (n=1) and hypophysitis (n=1). More than one irAE occurred in seven patients. The average number of cycles until the onset of irAE was 7 (range 1-53). Discontinuation of immunotherapy was required in 10 patients (19%). Of the 9 patients who required hospitalization due to irAEs, 4 patients died during hospitalization (3 patients due to pneumonitis and 1 patient due to myocarditis), and 1 patient died during follow-up due to other causes. **Conclusions:** TT (especially non-small-cell lung cancer) were the most frequent malignancies among patients admitted in our department. Within this subgroup, the main cause of admission was tumor-related. IrAEs were the third cause of admission. However, they had a high rate of mortality. Therefore, we must keep in mind that irAEs that require hospitalization can be a life-threatening medical condition. **Keywords:** Thoracic tumor, Immunotherapy, Hospitalization

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Survival Outcome of Metastatic Pulmonary Sarcomatoid Carcinoma Treated with Immunotherapy: An Analysis of National Cancer Database (NCDB)

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Introduction: Pulmonary sarcomatoid carcinoma (PSC) is a rare subtype of non-small cell lung cancer (NSCLC), associated with aggressive disease course, refractoriness to chemotherapy, and poor survival. Excellent response of PSC to immune checkpoint inhibitors were reported in small case reports/series, but it remains unclear whether PSC is still associated with poor prognosis compared to other NSCLC when treated with immunotherapy. **Methods:** NCDB, a US national database capturing more than 70% of newly diagnosed lung cancer was queried for stage IV PSC diagnosed from 2016 to 2017, as pembrolizumab was approved in the US for NSCLC in 2016. Patients who were treated with chemotherapy doublets only or immunotherapy only in the first course of treatment are included. Because bevacizumab is part of first line treatment for nonsquamous NSCLC in the US and bevacizumab is recorded as immunotherapy in NCDB, only squamous NSCLC diagnosed during the same period is used as comparison. Log-rank was used for survival analysis and adjusted by cox regression for age, gender, race, academic center, insurance, and comorbidity. **Results:** A total of 80 PSC patients were identified, of whom 59% were male. The median age was 67 years old. 29 patients (36%) received immunotherapy alone, while 51 (64%) received chemotherapy alone. Receipt of immunotherapy alone was associated with numerically longer survival than chemotherapy alone (median overall survival: 8.9 vs. 3.8 months, log-rank p = 0.054). After adjustment by multivariate analysis, this association became significant (HR 0.44, 95% CI 0.24-0.83). When comparing PSC to squamous cell NSCLC, there is significant interaction between histology and immunotherapy treatment for survival (p = 0.049). Among