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Efficacy and Safety of Nivolumab in Previously Treated Patients With Non-Small-cell Lung Cancer: Real World Experience in Argentina

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Abstract

Background: Nivolumab was the first anti-programmed cell death 1 drug approved in Argentina for non-small-cell lung cancer treatment in the second-line setting.

Materials and methods: The present study was a multicenter, observational, retrospective study of patients with progression to stage IV NSCLC during platinum-based chemotherapy who had received nivolumab monotherapy in a drug-expanded access program in Argentina.

Results: The data from 109 patients were assessed retrospectively for safety and clinical outcomes. The follow-up period was 8.83 months (interquartile range, 3.4-12.67); 57.8% were men, 29.4% were current smokers, and 78.0% had a diagnosis of nonsquamous cell cancer. The median number of chemotherapy lines before nivolumab was 2 (range, 1-4). Also, 59.6% had received radiotherapy and 89% had received platinum-based chemotherapy. The drug-related toxicity rate was 78.9%, the grade 2-3 toxicity rate was 28.4%, and 33.9% of patients had required corticosteroids. The treatment response was evaluated in 104 patients. The best response was a complete response in 2 (2%), partial response in 28 (27%), stable disease in 33 (32%), and progressive disease in 41 (39%). Univariate analysis revealed that the absence of corticosteroid use (P = .034), toxicity grade 1-3 (P = .0025), and performance status of ≤ 1 (P = .049) were associated with longer disease-free survival, performance status of ≤ 1 (P < .001), and toxicity grade 1-3 (P = .001) were associated with longer overall survival. On multivariate Cox regression analysis, toxicity grade 1-3 (hazard ratio [HR], 0.44; 95% confidence interval [CI], 0.24-0.81; P = .008) and age ≤ 50 years (HR, 0.28; 95% CI, 0.13-0.61; P = .001) were associated with longer progression-free survival and corticosteroid use was associated with shorter progression-free survival (HR, 2.06; 95% CI, 1.22-3.48; P = .007).

Conclusions: The use of nivolumab in the real world setting in patients with heavily pretreated NSCLC was well tolerated and showed promising clinical efficacy. The performance status, use of corticosteroids, and immune-mediated toxicity seem to be the conditions that can affect the clinical outcomes.

Keywords: Immunotherapy; NSCLC; PD-1; Prognostic factors; Toxicity.

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