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Titolo (massimo 15 parole)

Immune-checkpoint inhibitor toxicity in elderly patients: analysis of WHO pharmacovigilance database

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Testo (massimo 250 parole, preferibilmente in italiano (accettato anche in inglese), suddiviso in Introduzione, ***Metodi***, ***Risultati***, ***Conclusioni*** e ***Finanziamento***

Introduction
Based on existing data, immune-checkpoint inhibitor (ICI) toxicity in elderly patients appears similar to that in younger individuals. However, because of the aging cancer patient population, further characterization of ICI toxicity in elderly patients is required.
Methods
We queried VigiBase, the WHO global database of suspected adverse drug reactions (ADRs), on Sept 01st 2017, and retrieved safety reports of patients aged≥65years, associated with ipilimumab, nivolumab, pembrolizumab, atezolizumab, avelumab or durvalumab, gathered in VigiBase from the FDA approval date of each substance. We aimed to determine the spectrum and severity of ICI-related ADRs, and to compare adverse event reporting in patients≥65years with that in patients<65years.
Results
We identified 3339 reports of suspected ICI-related ADRs in patients≥65years. The spectrum differed between regimens: gastrointestinal and endocrine disorders were more frequently reported with ipilimumab (OR4.4, 95%CI 3.7-5.6, P<0.0001, OR1.4, 95%CI 1.1-1.8, P=0.004, respectively); respiratory disorders with anti-PD1/PD-L1 (OR6.8, 95%CI 5.0-9.4, P<0.0001); and skin toxicity with ipilimumab plus nivolumab combination (OR3.0, 95%CI 1.4-6.4, P=0.01). In 415(12%) cases, ICI toxicity led to death. Of these, 113(27%) concerned respiratory disorders, including 43(10%) interstitial lung disease (ILD) events. Compared with adverse event reporting in patients<65years, reporting in patients≥65years was associated with higher frequency of ILD (logOR 0.7 99%CI 0.5-0.9, P<0.01).
Conclusions
By evaluating the largest cohort of elderly patients experiencing ICI toxicity, we observed that ILD was more frequently reported compared to younger patients, and was the single most common cause of death. Clinicians should be aware of this ICI toxicity in elderly patient care.

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Visto superiore* (prego indicare **Nome e Cognome** del superiore) ***campo obbligatorio**

Alessandro Ceschi

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Invio Abstract