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Immune checkpoint inhibitors and potential risk of thromboembolic events: Analysis of the WHO global database of individual case safety reports

Introduction: Thromboembolic events with the use of immune checkpoint inhibitors (ICIs) in patients with cancer have been reported in few studies. However, the detailed profile of these cases remains mostly uncertain.

Method: A descriptive analysis of Thromboembolic events associated with ICIs retrieved from the VigiBase, between 1967 to November 2020. We extracted the data using the terms of 'pulmonary embolism' OR 'deep vein thrombosis' OR 'acute coronary syndrome' OR 'myocardial infarction' OR 'ischemic stroke' (preferred term (PT) (MedDRA).

Results: We included 161 cases from 26 countries in our descriptive analysis. Patients' ages were reported in 141 (87.6%) cases, with a median of 68 years (interquartile range 61–74), and 63.4% of the patients were male. Indications for ICIs were reported in 151 (93.8%) cases, as follows: lung cancer (n = 85, 52.8%), renal cell carcinoma (n = 24, 14.9%), melanoma (n = 20, 12.4%), urethral carcinoma (n = 12, 7.45%), breast cancer (n = 4, 2.48%), adenocarcinoma of the gastroesophageal junction (n = 3, 1.9%), gastric cancer (n = 2, 1.24%), and skin cancer (n = 1, 0.62%). Nivolumab was reported as a suspected drug in 76 cases (47%), pembrolizumab in 46 cases (28.5%), atezolizumab in 21 cases (13%), durvalumab in 14 cases (8.6%), and avelumab in four cases (2.4%).
The time to onset of thromboembolic events was reported in 127 (78.8%) cases. Most of these patients (n = 109, 85.8%) reported thromboembolic events within the first six months. The causality assessment of included cases showed that 50.3% of reported thromboembolic events were possibly related to the suspected reported medication, 13.7% were probably related, 13% were unlikely to be related, and 23% were not assessable due to insufficient information.

Conclusion: This study demonstrates a possible association between the use of ICIs and thromboembolic events. Further epidemiological studies are needed to assess this association and to elucidate the underlying mechanism.

Biography:

Alghamdi has completed her Masters of Pharmacy (MPharm) with Honors in 2013 from Griffith university, Australia, she is an MBA/International Health Management candidate in 2024 from Frankfurt Bussiness School. Currentltly she is Senior Drug Safety Expert at Saudi Food & Drug Authority in the Pharmacovigilance Executive Directorate. She plays a critical role in ensuring the safety of medicies used by the saudi population, she is repsosible for overseein the implementation of pharmacovigilance system and procedures, as well as monitoring and analysing data related to adverse drug reaction.

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