Safety Profile of Vascular Endothelial Growth Factor Receptor Tyrosine-kinase Inhibitors: A Pharmacovigilance Disproportionality Analysis

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Abstract

Background: Existing research focuses primarily on common adverse events (AEs) in adults using Vascular endothelial growth factor receptor tyrosine kinase inhibitors (VEGFR-TKI), systematic reports from real-world settings and safety research on off-label use in children are lacking. Therefore, we aimed to investigate the safety profiles of VEGFR-TKIs via the FAERS. Method: Data regarding VEGFR-TKIs were extracted from the FAERS between 2004Q1 to 2022Q2. Reporting odds ratio (ROR) was performed to identify risk signals associations of VEGFR-TKIs with AEs. A reported AE would be defined as a potential risk signal if it simultaneously met the report cases [?] 3, ROR [?] 2, the lower limit of 95% CI [?]1, and $\chi 2$ [?] 4. and categorized by the MedDRA terms. Results: A total of 51,841 reports containing 536 children were identified from May 18, 2005, to June 30, 2022. Despite some differences, 7 VEGFR-TKIs had similar safety profiles in the general population. The most significant ROR was PPES and the most frequent SOC was gastrointestinal disorders. In pediatrics, results varied in these agents, and the most frequent AE with significant ROR were PPES, followed by pneumothorax. Furthermore, blood and lymphatic system disorders and investigation abnormalities were both the most common SOCs. Conclusion: Disproportionality analysis based on the FAERS database is an effective path to recognize VEGFR-TKI-related AEs. Findings of the general population were largely consistent with real-world setting studies, and the widely recorded data in FAERS also made it possible to retrieve the safety of these agents in pediatrics.

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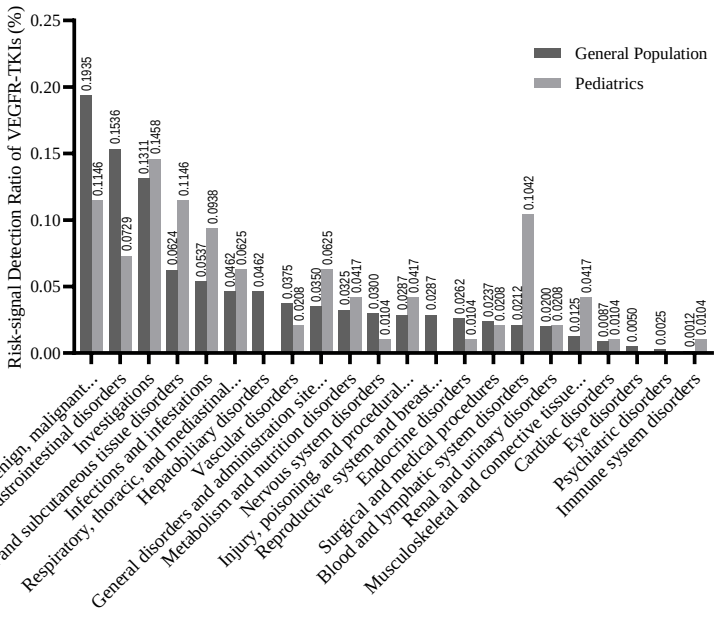

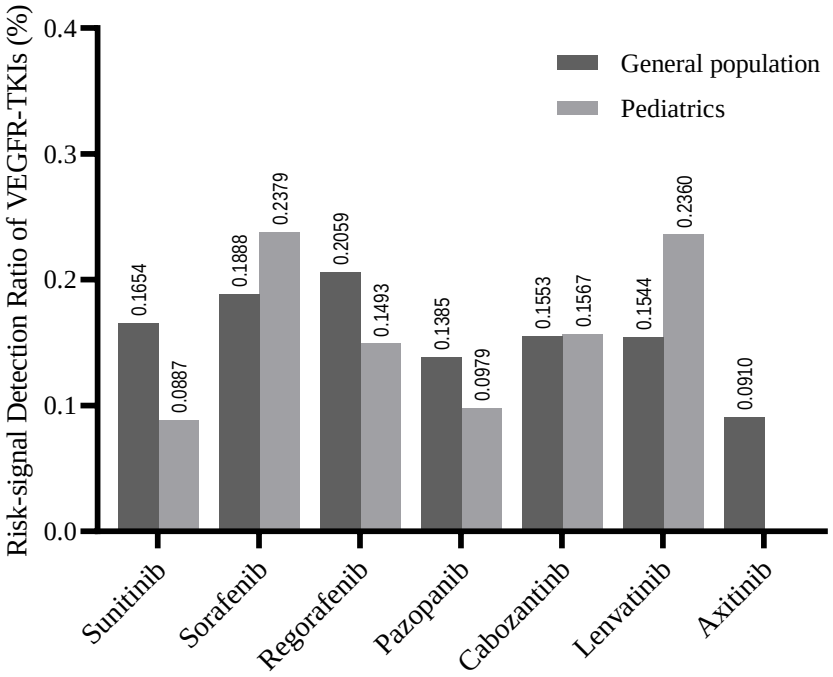

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