

Evaluation of time to onset and outcome of cardiac adverse events related to pembrolizumab using post-marketing surveillance

Yuko kanbayashi¹, Eren Tsuchiya¹, Hitomi Akiba¹, Tadashi Shimizu¹, and Mayako Uchida¹

¹Affiliation not available

January 30, 2023

Abstract

Aim: The present study aimed to evaluate time to onset, incidence rates, and outcomes for pembrolizumab-induced cardiac adverse events (AEs) in patients with cancer using the Japanese Adverse Drug Event Report database. **Methods:** We analysed data for the period from April 2004 to March 2022. Data on cardiac AEs were extracted and relative risks of AEs were estimated using the reporting odds ratio. **Results:** We analysed 2,021,907 reports and identified 15,306 reports of AEs caused by pembrolizumab. Of these, 399 cardiac AEs were associated with pembrolizumab. Signals were detected for six cardiac AEs: myocarditis, immune-mediated myocarditis, pericardial effusion, cardiac tamponade, pericarditis, and pericarditis malignant. A histogram of median times to onset showed occurrence from 33 to 138 days, but some cases occurred even more than 1 year after the start of administration. Among these, myocarditis was the most frequently reported (27.1%), with fatal cases also reported. **Conclusion:** This study focused on cardiac AEs caused by pembrolizumab as post-marketing AEs. Some cases could potentially involve serious outcomes, so patients should be monitored for signs of onset of these AEs not only at the start of administration, but also over an extended period, especially for myocarditis.

Hosted file

BJCP_paper_20230129_FIX.docx available at <https://authorea.com/users/580868/articles/621759-evaluation-of-time-to-onset-and-outcome-of-cardiac-adverse-events-related-to-pembrolizumab-using-post-marketing-surveillance>