Background

Anti-TNFα agents are widely used in a variety of autoimmune and inflammatory diseases. Pleuropericarditis associated with anti-TNFα agents was identified as a signal in a screening of VigiBase, the WHO global database of individual case safety reports.

Objectives

The aim of this study was to evaluate pleuropericarditis associated with anti-TNFα agents in VigiBase with a focus on its types and risk factors.

Methods

All variables contained in the pleuropericarditis reports were reviewed. Well-documented reports (vigiGrade completeness score ≥ 0.80 or with informative narrative) were analyzed for clinical features. Bradford-Hill criteria was used in the assessment.

Results

Up to 18 Dec 2019, there were 94 unique cases from 18 countries reporting pleuropericarditis with anti-TNFα agents. Among the 94 reports, 42 were identified as well-documented and further assessed. 39 were serious, including three fatal and seven life-threatening. In 35 cases, anti-TNFα agent was the only suspected drug. Positive de- / re-challenge were reported in 95% and 17%, respectively. The times to onset showed a large variability, ranging from one to 75 months (mean=24). The most commonly involved anti-TNFα agents are adalimumab, infliximab and etanercept; and the mostly reported pleuropericarditis types are autoimmune-related with (n=17) or without (n=15) co-reported drug-induced lupus (DIL), or infection-related (n=8). While adalimumab was mostly reported in the infection-related cases (7/8), infliximab was the mostly reported in the autoimmune-related cases, in particular co-reported with DIL (9/17). There have been four cases where the reaction occurred actually one to two months after the anti-TNFα agents were stopped. Based on the Bradford-Hill criteria the anti-TNFα agents associated pleuropericarditis are considered as a class effect.

Conclusions

To manage the serious cardiopulmonary complications, the health care professionals need to pay attention to the clinical features of pleuropericarditis cases, since they may cause diagnostic and therapeutic difficulties. Considering the long elimination time, clinicians need to be reminded to remain vigilant for the adverse reactions even after discontinuing anti-TNFα therapy.

Disclaimer

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