Incidence of myocarditis caused by drugs for ulcerative colitis examined using VigiBase, a spontaneous adverse drug reaction reporting database

Yumi Kawai[1], Yasuko Kurata[2], Hirofumi Hamano[2], Takahiro Niimura[3], Mitsuhiro Goda[4], Yoshito Zamami[2], Keisuke Ishizawa[3], and Hideki Nawa[1]

[1]Shujitsu University
[2]Okayama University Hospital
[3]Tokushima University Graduate School of Biomedical Sciences
[4]Tokushima University Hospital

March 30, 2024

Abstract

Aim: To investigate the association between ulcerative colitis drugs and myocarditis as an adverse event based on the detection of adverse event signals using a spontaneous reporting database. Methods: We searched for five drugs, namely mesalazine, sulfasalazine, azathioprine, mercaptopurine, and budesonide, listed in the treatment guidelines for ulcerative colitis, using VigiBase. The information component was calculated. A signal was considered present when the lower limit of the 95% confidence interval of the information component exceeded zero. Results: The total number of VigiBase reports and of myocarditis as a target adverse event was 32 520 983 and 61 567, respectively. No trend was identified based on age or sex. Analysis of the five ulcerative colitis drugs for severity in VigiBase showed that most patients recovered, and deaths were few. However, the time to onset of adverse drug reactions varied among drugs. Conclusion: Mesalazine signals were detected regardless of age or sex. This suggests that myocarditis, an adverse event, may be a potential complication regardless of patient characteristics. These results warrant multifaceted investigations, including basic and clinical studies, on the characteristics of each drug with regard to the development of myocarditis as an adverse event caused by ulcerative colitis drugs.

Hosted file

`Manuscript.docx` available at https://authorea.com/users/761138/articles/737248-incidence-of-myocarditis-caused-by-drugs-for-ulcerative-colitis-examined-using-vigibase-a-spontaneous-adverse-drug-reaction-reporting-database

Mesalazine
(a = 700)
        *
2.37

Sulfasalazine
(a = 139)
0.28

Azathioprine
(a = 159)
0.24

Mercaptopurine
(a = 19)
-0.96

Budesonide
(a = 185)
-0.81

∗ Signal detection

-2.00   -1.00   0.00   1.00   2.00   3.00   IC