Letter

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Safety of COVID-19 Vaccines among Patients with Type 2 Diabetes Mellitus: Real-World Data Analysis (*Diabetes Metab J* 2023;47:356-65)

Jung Hun Ohn

Department of Internal Medicine, Seoul National University Bundang Hospital, Seoul National University College of Medicine, Seongnam, Korea

Patients with diabetes face increased risk for the development of severe coronavirus disease 2019 (COVID-19) disease [1] as well as elevated COVID-19-related mortality [2] compared with healthy patients. This study systematically analyzed 25 severe adverse events (AEs) following the administration of COVID-19 vaccines reported in the Vaccine Adverse Event Reporting System (VAERS) to assess the safety of COVID-19 vaccines among patients with diabetes.

In this article, a natural language processing algorithm was applied to identify people with and without diabetes among 625,628 reports in VAERS. By comparing 6,829 patients with type 2 diabetes mellitus (T2DM) and 20,487 healthy controls after 1:3 matching, they report that patients with diabetes were more likely to experience eight severe AEs: cerebral venous sinus thrombosis, encephalitis myelitis encephalomyelitis, Bell's palsy, lymphadenopathy, ischemic stroke, deep vein thrombosis (DVT), thrombocytopenia (TP), and pulmonary embolism (PE) [3]. Additionally, they compared the risk of severe AEs with respect to the type of COVID-19 vaccines.

However, there are some questions that need to be explored. Firstly, diabetes is an independent risk factor for thrombotic complications such as DVT, PE, and ischemic stroke [4,5]. The elevated incidence of thrombotic AE reports among patients with diabetes might simply have resulted from the thrombogenic predisposition caused by diabetes. VAERS research is inherently limited by the inability to assess the contribution of vaccination to thrombotic AEs among patients with diabetes. The general public could misinterpret the results as suggesting that diabetes patients are at higher risk of experiencing thrombotic events due to COVID-19 vaccination, which the study did not address.

Secondly, the study performed 1:3 matching between patients with diabetes and control subjects. It might be necessary to check whether the findings are robust after the matching ratio was changed to 1:4 or 1:5 because the severe AE cases are rare and selection bias from matching could exist.

Lastly, it is described in the abstract that "Patients with T2DM vaccinated with BNT162b2 and mRNA-1273 were more vulnerable to DVT and TP than those vaccinated with JNJ-78436735." However, TP events were less common among patients with T2DM vaccinated with mRNA-1273 compared to those vaccinated with JNJ-78436735 (Table 4) and this statement in the abstract should be corrected. In the discussion section, "TP was more common in patients vaccinated with mRNA-1273 than in those vaccinated with JNJ78436735" also needs correction to "TP was less common in patients vaccinated with mRNA-1273 than in those vaccinated with JNJ78436735."

In conclusion, this is a sentinel study that investigated severe AEs associated with T2DM after COVID-19 vaccination with different types of vaccines using a huge dataset from the vaccine side effect reporting system. To accurately assess the safety of COVID-19 vaccines, data about the incidence of severe clinical events such as thrombotic events, TPs, and encephalitis among diabetic subjects that did not undergo COVID-19 vac-

Corresponding author: Jung Hun Ohn https://orcid.org/0000-0001-5415-4505
Department of Internal Medicine, Seoul National University Bundang Hospital, Seoul National University College of Medicine, 82 Gumi-ro 173beon-gil, Bundang-gu, Seongnam 13620, Korea
E-mail: jhohn2@gmail.com

cination are necessary in future studies.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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