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https://doi.org/10.1016/j.jaad.2021.09.032

Comparison of constitutional and dermatologic side effects between COVID-19 and non–COVID-19 vaccines: Review of a publicly available database of vaccine side effects

To the Editor: In December 2020, the US Food and Drug Administration authorized the emergency use of 2 COVID-19 vaccines. The rapid development and authorization of these vaccines raised safety concerns among the general population.[1] In the Pfizer/BioNTech BNT162b2 messenger RNA (Pfizer/BioNTech) and Moderna messenger RNA-1273 SARS-CoV-2 (Moderna) COVID-19 vaccines phase 3 clinical trials, local and systemic reactions were reported.[2,3]

We sought to compare constitutional and dermatologic postimmunization side effects of the COVID-19 vaccines versus the hepatitis B virus (HBV) and seasonal influenza (Flu) vaccines on the Vaccine Adverse Event Reporting System (VAERS), a national, self-reported surveillance database.[4]

HBV and Flu (seasonal flu recombinant and inactivated) vaccines were selected because they are 2 established nonlive vaccines that have been administered to the general population for decades. For both COVID-19 vaccines, data were obtained from their rollout in December 2020 until February 26, 2021, whereas for the HBV and Flu vaccines, data were obtained from 1990 until February 26, 2021. Only constitutional and dermatologic side effects with reported rates ≥1% for all 4 vaccines were included. Data were analyzed using the χ^2 test in R-4.0.3. At the time the data from VAERS were obtained, Pfizer/BioNTech and Moderna vaccines were approved for adults aged ≥16 and 18 years, respectively. The HBV and Flu vaccines are approved for infants since birth and for ages of ≥6 months old, respectively.

In our research, reported constitutional side effects were higher for the Moderna and Pfizer/BioNTech when compared with the HBV and Flu vaccines. The dermatologic side effects reported for Moderna were greater than that of HBV but not Flu. However, Pfizer/BioNTech did not have a statistically significantly higher percentage of dermatologic side effects when compared with HBV or Flu. When comparing Moderna and Pfizer/BioNTech, the majority of constitutional and dermatologic side effects were higher for Moderna in terms of percent of cases reported (Table I).

Of note, Moderna had a significantly higher percentage of injection site reactions (ie, pain, erythema, swelling, and warmth) compared with Pfizer/BioNTech and HBV but not Flu. For the Pfizer/BioNTech vaccine, injection site reactions were lower than for the other vaccines.

In both Pfizer/BioNTech and Moderna trials, younger patients (16-55 and 18 to <65 years old, respectively) experienced more frequent and severe side effects, possibly due to their having a more robust immune system and consequently a higher degree of reactogenicity.[2,3] Overall, both COVID-19 vaccines have favorable safety profiles and proven efficacy.[2,3] It is vital for physicians to encourage appropriate vaccination of our patients. Our study may help address patients' concerns regarding the COVID-19 vaccines. Future studies should assess whether similar results are observed in children in whom the vaccine was approved recently. Limitations to our study are the incomplete capture and reporting from the VAERS database, which is self-reported and voluntary, although VAERS has previously successfully detected safety signals for other vaccines such as intussusception for the rotavirus vaccine.[5] Finally, the population receiving the COVID-19 vaccine may not match those getting the Flu and HBV vaccines.[4]

Stephanie R. Cohen, MD, David X. Gao, BA, Jared S. Kahn, MS, BS, and David Rosmarin, MD

From the Department of Dermatology, Tufts Medical Center, Boston, Massachusetts.

Funding sources: Supported by Tufts Medical Center Psoriasis Research Fellowship (grant ID: FS18343) from Janssen Scientific Affairs, LLC.

IRB approval status: Not applicable.

Correspondence to: David Rosmarin, MD, Department of Dermatology, Tufts Medical Center, 800 Washington Street, Box #114, Boston, MA 02116

E-mail: DRosmarin@tuftsmedicalcenter.org

Table I. Comparison among Pfizer/BioNTech BNT162b2 messenger RNA COVID-19 vaccine, Moderna messenger RNA-1273 SARS-CoV-2 vaccine, hepatitis B virus vaccine, and seasonal influenza vaccine

Vaccines	P vaccine	M vaccine	HBV vaccine	Flu vaccine	Vaccine comparison				
	14,649	10,403	58,063	152,627					
Total number of patients reporting SE	Number of reported SE (%)	Number of reported SE (%)	Number of reported SE (%)	Number of reported SE (%)	P-M	P-HBV	P-Flu	M-HBV	M-Flu
Constitutional SE									
Headache	2932 (20.02)	2242 (21.55)	3641 (6.27)	11,594 (7.60)	**.003**	**<.001**	**<.001**	**<.001**	**<.001**
Fatigue	2188 (14.94)	1537 (14.77)	1124 (1.94)	6305 (4.13)	.736	**<.001**	**<.001**	**<.001**	**<.001**
Pyrexia	2003 (13.67)	1853 (17.81)	9473 (16.32)	19,880 (13.03)	**<.001**	**<.001**	**.027**	**<.001**	**<.001**
Chills	1985 (13.55)	1763 (16.95)	1291 (2.22)	9890 (6.48)	**<.001**	**<.001**	**<.001**	**<.001**	**<.001**
Pain	1853 (12.65)	1622 (15.59)	3335 (5.74)	18,395 (12.05)	**<.001**	**<.001**	**.035**	**<.001**	**<.001**
Nausea	1794 (12.25)	1458 (14.02)	3602 (6.20)	9141 (5.99)	**<.001**	**<.001**	**<.001**	**<.001**	**<.001**
Myalgia	940 (6.42)	721 (6.93)	2669 (4.60)	7004 (4.59)	.113	**<.001**	**<.001**	**<.001**	**<.001**
Arthralgia	754 (5.15)	593 (5.70)	2363 (4.07)	4477 (2.93)	.059	**<.001**	**<.001**	**<.001**	**<.001**
Malaise	659 (4.50)	290 (2.79)	1683 (2.90)	5246 (3.44)	**<.001**	**<.001**	**<.001**	.554	**<.001**
Asthenia	621 (4.24)	433 (4.16)	2645 (4.56)	6407 (4.20)	.789	.103	.828	.079	.881
Dermatologic SE									
Pruritus	785 (5.36)	678 (6.52)	3651 (6.29)	9197 (6.03)	**<.001**	**<.001**	**.001**	.388	**.044**
Rash	779 (5.32)	528 (5.08)	4954 (8.53)	8305 (5.44)	.411	**<.001**	.540	**<.001**	.115
Urticaria	571 (3.90)	403 (3.87)	3715 (6.40)	8424 (5.52)	.949	**<.001**	**<.001**	**<.001**	**<.001**
Hyperhidrosis	474 (3.24)	314 (3.02)	1190 (2.05)	3225 (2.11)	.350	**<.001**	**<.001**	**<.001**	**<.001**
Erythema	416 (2.84)	498 (4.79)	1388 (2.39)	12,426 (8.14)	**<.001**	**.001**	**<.001**	**<.001**	**<.001**
Injection Site Pain	1192 (8.14)	1269 (12.20)	3102 (5.34)	18,140 (11.89)	**<.001**	**<.001**	**<.001**	**<.001**	.347
Injection site erythema	323 (2.20)	1104 (10.61)	2175 (3.75)	17,523 (11.48)	**<.001**	**<.001**	**<.001**	**<.001**	**.007**
Injection site swelling	291 (1.99)	839 (8.06)	1358 (2.34)	12,759 (8.36)	**<.001**	**.011**	**<.001**	**<.001**	.301
Injection site warmth	153 (1.04)	576 (5.54)	802 (1.38)	7831 (5.13)	**<.001**	**.001**	**<.001**	**<.001**	.073

Values in bold are values that are statistically significant (P value <.05). Cutoff value for statistical significance ≤.05.
Flu, Seasonal influenza vaccine; *HBV*, hepatitis B virus vaccine; *M*, Moderna messenger RNA-1273 SARS-CoV-2 vaccine; *P*, Pfizer/BioNTech BNT162b2 messenger RNA COVID-19 vaccine; *SE*, side effect.

Conflicts of interest

Dr Rosmarin has received honoraria as a consultant for AbbVie, Celgene, Dermavant, Dermira, Janssen, Lilly, Novartis, Pfizer, and Regeneron Pharmaceuticals Inc; has received research support from AbbVie, Bristol Meyers Squibb, Celgene, Dermira, Incyte, Janssen, Lilly, Merck, Novartis, Pfizer, and Regeneron Pharmaceuticals Inc; and has served as a paid speaker for AbbVie, Celgene, Janssen, Lilly, Novartis, Pfizer, Regeneron Pharmaceuticals Inc, and Sanofi. Dr Cohen and Authors Gao and Kahn have no conflicts of interest to declare.

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Biologic therapy is not associated with increased COVID-19 severity in patients with hidradenitis suppurativa: Initial findings from the Global Hidradenitis Suppurativa COVID-19 Registry

To the Editor: Hidradenitis suppurativa (HS) patients may be at increased risk of severe COVID-19 and poor outcomes due to comorbidities and biologic treatment.[1] COVID-19 cases in HS patients were reported in the Global Hidradenitis Suppurativa COVID-19 Registry (https://hscovid.ucsf.edu/) from April 5, 2020, to February 2, 2021.[1] Eligible cases had confirmed diagnosis of HS by a health care provider (HCP) or screening questions and COVID-19 diagnosis by an HCP. Comparisons were performed using the Fisher's exact or Pearson χ^2 test. Multivariable logistic regression was used to predict outcomes based on biologic use, adjusting for demographic features and comorbidities.