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Transient sensory symptoms among first-dose recipients of the BNT162b2 mRNA COVID-19 vaccine: A case-control study

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ABSTRACT

Vaccines are the single most effective mechanism to control the ongoing COVID-19 global crisis. However, in part due to their relatively recent incorporation into the preventive armamentarium, hesitancy towards mRNA-based COVID-19 vaccines is high despite evidence of efficiency. Hesitancy is partly due to a misperception of their potential adverse events. Non-specific sensory symptoms (NSSS) following immunization are thought to be mediated by stress-related responses. In this case-control study, we evaluated NSSS from a cohort of 7,812,845 BNT162b2 first-dose recipients, of whom 10,929 reported an adverse event following immunization (AEFI). We found an overall frequency of 3.4% (377 cases) or 4.8 cases per 100,000 doses administered. Anatomically, the arms (61%) and face/neck region (36.2%) were the most commonly affected sites. The control group had significantly higher rates of reactogenicity-associated symptoms, suggesting that NSSS are reactogenicity-independent; in multivariable analysis, healthcare workers reported sensory symptoms less frequently (aOR 0.54; 95% CI 0.40–0.72; p p<0.001). This is the first study describing the topography and associated factors for developing NSSS among BNT162b2 recipients. The benign nature of these symptoms may help dissipate hesitation towards this vaccine.

	Cases (n = 354)	Control (n = 708)	Total (n = 1,062)	*p*-value
Age, mean (± SD), years	40 (12.5)	39.8 (12.3)	39.9 (12.3)	0.844
Age > 40 years	156 (44.1)	306 (43.2)	462 (43.5)	0.793
Sex, n (%)				0.952
Female	299 (84.5)	599 (84.6)	898 (84.6)	
Male	55 (15.5)	109 (15.4)	164 (15.4)	
Healthcare workers, n (%)	232 (65.5)	552 (78)	784 (73.8)	< 0.001
Medical history, n (%)				
Allergies (any)	233 (65.8)	511 (72.2)	744 (70.1)	0.033
Non-SARS-CoV-2 infection ≤ 15 days	6 (1.7)	11 (1.6)	17 (1.6)	0.863
History of confirmed SARS-CoV-2 infection	105 (29.7)	209 (29.5)	314 (29.6)	0.962
Time to AEFI report, median (IQR), minutes	20 (10–180)	60 (15–720)	30 (10–600)	< 0.001
Reported symptoms, n (%)				
Fever, ≥ 38°C	35 (9.9)	140 (19.8)	175 (16.5)	< 0.001
Headache	140 (39.5)	416 (58.8)	556 (52.4)	< 0.001
Injection site pain	145 (41)	332 (46.9)	477 (44.9)	0.067
Fatigue	76 (21.5)	262 (37)	338 (31.8)	< 0.001
Malaise	55 (15.5)	172 (24.3)	227 (21.4)	0.001
Dizziness	99 (28)	213 (30.1)	312 (29.4)	0.475
Chills	42 (11.9)	201 (28.4)	243 (22.9)	< 0.001
Joint pain	48 (13.6)	207 (29.2)	255 (24)	< 0.001
Muscle pain	68 (19.2)	236 (33.3)	304 (28.6)	< 0.001
Tachycardia	55 (15.5)	101 (14.3)	156 (14.7)	0.581
Nausea	69 (19.5)	191 (27)	260 (24.5)	0.007
Vomiting	18 (5.1)	45 (6.4)	63 (5.9)	0.408
Diarrhea	25 (7.1)	39 (5.5)	64 (6)	0.316

Baseline characteristics and reported adverse event following immunization.
Abbreviations: SD, standard deviation; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

BIOGRAPHY

Valdes-Ferrer's lab is broadly interested in the interactions between nervous and immune systems in health and disease. We are actively exploring the role of cholinergic agonists in HIV-induced immune dysfunction. For the past year we are interested in finding new therapeutic agents to treat severe COVID-19. We also have a vested interest in understanding vaccine safety beyond the controlled setting of randomized clinical trials. The lab is funded by the National Council of Science and Technology of Mexico. Dr. Valdes-Ferrer has no conflicts of interest to declare.

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