Ear, Nose & Throat Journal
2021, Vol. 0(0) 1–3

DOI: 10.1177/01455613211048975
journals.sagepub.com/home/ear
SAGE

Incidence of Audiological Adverse Effects Induced by COVID-19 Vaccines: A Preliminary Study

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Keywords
Audiology, COVID-19 vaccines, adverse effects

Dear Editor

Since the COVID-19 pandemic outbreak in the latter months of 2019, physicians and researchers have rushed to develop effective and safe vaccinal procedures as quickly as possible. Without any doubt, vaccination is the most effective strategy against the spread of the COVID-19 infection. With an unprecedented acceleration in industrial production times, the combination of global scientific and medical efforts yielded numerous vaccination strategies. However, a number of adverse events have been reported for the Pfizer, Moderna, and AstraZeneca vaccines, which are considered the major players in the global vaccination protocols.

The objective of this paper is an initial assessment on the reported post-vaccination adverse effects, involving the auditory and vestibular system. Published on-line data were consulted from two databases: (i) The Italian Drug Agency (Agenzia Italiana del Farmaco—AIFA)[1] and (ii) the Medicines and Healthcare Products Regulatory Agency (MHRA) of the United Kingdom.[2] AIFA strongly recommends that the adverse effects cited in the database should be considered as reports of "suspected" adverse reactions in relation to the COVID-19 vaccination. In this context, the AIFA and the MHRA data represent only a warning of a possible correlation between the vaccination and the reported symptoms. The available information does not constitute clear evidence for a cause-and-effect relationship, between a vaccine and the reported adverse effects.

The Italian AIFA database was updated on June 26, 2021; for a total of 49 512 799 doses administrated, a total of 76 208 adverse reactions have been reported with 246 391 different symptoms. The MHRA database was updated on July 14, 2021: For 79 564 768 doses administrated, 323 967 adverse reactions were reported with 1 080 156 different symptoms. The incidence of adverse reactions reported is .15% for the AIFA and .41% for the MHRA data. The information is summarized in Table 1.

Among the symptoms reported, only selected audio-vestibular disorders were considered (including hearing loss, tinnitus, dizziness, middle ear diseases, external ear diseases, and other) both from Italian and UK's reports. The category "other" included Eustachian tube disorders, hyperacusia, and inner ear inflammation. The reported symptoms were categorized into these six sub-groups, named Dizziness, Tinnitus, Hearing Loss, Middle Ear Diseases, External Ear Diseases, and Other, for each of the three different vaccines (Pfizer, Moderna, and AstraZeneca) in Italy and in the UK.

The following observations can be made on the available data: overall, different patterns emerged from the two databases. For the Italian data, most complaints were (in terms of decreasing significance) in the areas of Vertigo and Dizziness (.96%), Tinnitus (.11%), and Other (.07%). For the UK data, most complaints were in the areas of Tinnitus (.47%), Vertigo and Dizziness (.30%), and External Ear Disorders (.29%). For the areas of Tinnitus and Vertigo, the complaints per vaccine and per country are not consistent. For example, the Italian

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database indicates that for the Vertigo complaints, most of the subjects were inoculated with the Pfizer vaccine. The corresponding data from the UK indicate that the majority of complaints originated from subjects inoculated with the AstraZeneca vaccine. Interestingly, the number of reports from AstraZeneca vaccinated subjects in Italy is much less that the Pfizer ones (18 827 vs 52 604). These numbers suggest that the data available are directly influenced by the unequal number of doses of the delivered vaccines to the target populations and that additional considerations per type of vaccine are not possible at this stage. Unfortunately, since the data refer to adverse post-vaccination symptoms and not to a single disease (ie, Meniere's disease or sudden sensorineural hearing loss), it is not possible to compare this sort of data with the established incidence of audiological and vestibular disorders in the Italian and UK populations. Furthermore, since the reported adverse symptoms refer only to a part of the population (due to various national vaccination policies), it is not possible in this moment of time, to confront the reported adverse effects with the statistical indices established in the literature. Additionally, with the available data, it is not possible to identify the precise locus (and the systems involved) of the side effects reported, since Vertigo, Dizziness, and Tinnitus could have contributing causes outside the Auditory/Vestibular system. There is current research indicating the spectrum of possible factors accounting for the differences in the reported adverse effects (besides the vaccination type), such as age or blood type, but these are still under investigation.[3] The analytical data per database and audiological subgroup are presented in Table 2.

A closing note on the topic, despite the importance of the vaccination adverse effects on the various human systems, the available literature in the area of hearing and balance is rather poor. The available studies refer to preliminary pilot observation

Table 1. Incidence of Adverse Reactions Reported by MHRA and AIFA.

Italy—AIFA												
	Vertigo		Tinnitus		Hearing Loss		Middle Ear Disorders		External Ear Disorders		Other	
Comirnaty (Pfizer)	1406	.84%	153	.09%	71	.04%	2	.00%	147	.09%	160	.10%
Spikevax (Moderna)	90	.80%	12	.10%	10	.09%	0	.00%	0	.00%	1	.00%
Vaxzevria (AstraZeneca)	885	1.33%	113	.17%	25	.04%	0	.00%	12	.02%	11	.02%
United Kingdom—MHRA												
	Vertigo		Tinnitus		Hearing loss		Middle ear disorders		External ear disorders		Other	
Comirnaty (Pfizer)	985	.38%	1257	.49%	355	.14%	6	.00%	777	.30%	118	.04%
Spikevax (Moderna)	78	.26%	110	.37%	24	.08%	0	.00%	69	.23%	11	.04%
Vaxzevria (AstraZeneca)	2175	.27%	3727	.47%	724	.09%	6	.00%	2265	.28%	294	.04%

Abbreviations: MHRA, Medicines and Healthcare Products Regulatory Agency; AIFA, Agenzia Italiana del Farmaco.

Table 2. Audio-Vestibular Reported Symptoms Have Been Categorized into These Six Groups (Dizziness, Tinnitus, Hearing Loss, Middle Ear Diseases, External Ear Diseases, and Other).

	United Kingdom—Medicines and Healthcare Products Regulatory Agency			
Vaccine	Number of Reports	%	Total Symptoms Reported	%
Pfizer/BioNTech	91 567	28.3	256 005	23.7
Spikevax (Moderna)	10 109	3.1	29 606	2.7
Oxford University/AstraZeneca	222 291	68.6	794 545	73.6
Total doses administrated = 79 564 768	Total reports = 323 967		Total symptoms reported = 1 080 156	
Italy—AIFA				
Vaccine	Number of reports	%	Total symptoms reported	%
Comirnaty (Pfizer)	52 604	69	166 294	67.6
Spikevax (Moderna)	3947	5.2	11 163	4.5
Vaxzevria (AstraZeneca)	18 827	24.7	66 526	27
COVID-19 Vaccine Janssen	816	1.1	2408	0.9
Total doses administrated = 49 512 799	Total reports = 76 208		Total symptoms reported = 246 391	

attempts on small datasets of subjects. For example, in a recent retrospective study, Wichova et al[4] presented a cohort of 30 patients affected by otologic symptoms shortly after COVID-19 vaccination but without any evidence of a real correlation. Formeister et al, in a cross-sectional study[5] evaluating the data by the American CDC Vaccine Adverse Events Reporting System, attempted to establish a relationship between the incidence of sudden sensorineural hearing loss (SSHL) in those vaccinated against the COVID-19 and those non-vaccinated; they reported a similar incidence of SSHL in both sub-groups.

In conclusion, we would like to remark that according to the AIFA recommendation, the available data should be considered as "reported adverse effects" and they do not offer evidence for a real clinical correlation between the symptoms reported and the COVID-19 vaccine mechanisms. Nevertheless, the fact that numerous adverse effects have been reported should be an initiative to investigate in more detail future cases reporting various adverse symptoms. Even a randomized protocol (ie, not including all reported cases, a limit imposed by the available economic resources) would benefit the knowledge which can be acquired on the true performance of these vaccines, in the populations under COVID-19 health surveillance.

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