Ocular inflammatory events following COVID-19 vaccination: reporting of suspected adverse drug reactions to regulatory authorities in the United Kingdom

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Synopsis/Precis Ocular inflammatory events following COVID-19 vaccination have a very rare prevalence, with the most common phenotype being anterior uveitis.

Abstract

Background/Aims The UK Medicines & Healthcare products Regulatory Agency (MHRA) has published suspected adverse drug reactions to vaccines against COVID-19. Ocular inflammatory events following COVID-19 vaccination have been reported worldwide.

Methods We analysed MHRA data on spontaneous reports of suspected ocular inflammatory events following COVID-19 vaccination between January 2021 and September 2022.

Results The MHRA received 300 UK spontaneous suspected reports of ocular inflammatory events following COVID-19 vaccination, with a calculated prevalence of 6.6 events per 1,000,000 vaccinated individuals. Anterior uveitis was the most common phenotype (58.3%), followed by optic neuritis in 39.3%. Median number of days between vaccination and onset was 8 days. Resolution of the event was seen in 52.3%.

Conclusion Ocular inflammatory events following COVID-19 vaccination have a very rare prevalence in the UK. There is no increase in the reporting rate of uveitis, optic neuritis and scleritis following COVID-19 vaccination when compared with the range of incidence in the UK population. The Yellow Card System represents a vital instrument within the domain of pharmacovigilance, empowering patients and healthcare professionals to contribute to the ongoing monitoring of medication safety.

Key messages

- What is already known on this topic

Ocular inflammatory events have been reported following COVID-19 vaccination.

- What this study adds

Ocular inflammatory events following COVID-19 vaccination have a very rare prevalence in the UK, with anterior uveitis being the most common phenotype. There is no increase in the reporting rate of uveitis, optic neuritis and scleritis following COVID-19 vaccination when compared with the range of incidence in the UK population.

- How this study might affect research, practice or policy

No evidence supporting that people should avoid being vaccinated for fear of potential ocular inflammatory events can be derived from the study.

Keywords

COVID-19; ocular inflammation; uveitis; optic neuritis; scleritis; vaccination.

Introduction

In December 2020, the United States Food and Drug Administration (FDA) released the emergency use authorisation for the first vaccine for the prevention of COVID-19 disease. Among the authorized ones there were BNT162b2 (Pfizer Inc/ BioNTech SE) and mRNA-1273 (Moderna Therapeutics Inc). In January 2021, the European Medicines Agency (EMA) authorized the use of ChAdOx1 nCoV-19 (Oxford-AstraZeneca).

Cases of vaccine-associated uveitis have been reported with the use of universally administered vaccines, such as hepatitis A and B, influenza virus, human papillomavirus, measles- mumps-rubella, varicella virus, bacillus Calmette-Guerin, Neisseria meningitides and yellow fever (1-12). Ocular inflammatory events have also been reported following COVID-19 vaccination (13,14). The findings are based on a temporal association, and the hypothesised immunopathological mechanisms include molecular mimicry between uveal peptides and vaccine peptide fragments, antigen-specific cell and antibody-mediated hypersensitivity reactions, and inflammatory damage caused by the immune response to vaccine adjuvants (13,15-18). A recent study, using real word data and matched cohort and self-controlled case series approaches, reported an absence of an association of COVID-19 vaccination with new non-infectious uveitis events within a population of over 4.6 million individuals (19). However, there continue to be reports of other ocular inflammatory events, such as scleritis and optic neuritis, following COVID-19 vaccination (20-23).

The Medicines & Healthcare products Regulatory Agency (MHRA), serving as the governmental entity responsible for ensuring the safety of medicinal provisions and administration within the United Kingdom (UK), operates under the auspices of the Department of Health and Social Care. Functioning as the regulatory authority, the MHRA assumes oversight of medicinal substances, medical apparatus, and blood components within the UK. The reporting of adverse drug reactions falls under the purview of the MHRA through the Yellow Card System. This system, an integral component of pharmacovigilance, allows for the voluntary submission of information pertaining to observed adverse drug reactions by healthcare practitioners. A Yellow Card report cannot be considered as firm evidence of a causative association between a drug and the adverse event, with reports to the scheme known as suspected adverse drug reactions (ADRs).

In order to address the evidence gap around the association between the full spectrum of ocular inflammatory events with COVID-19 vaccination, we present the spontaneous reports of suspected ocular inflammatory ADRs following COVID-19 vaccination in the UK through the Yellow Card

System. We also report the demographics and medical characteristics of the patients diagnosed with such events after the administration of COVID-19 vaccination.

Methods

A freedom of information (FOI) request was made to the MHRA for data of new onset suspected adverse inflammatory ocular drug reactions (specifically, Uveitis, Panuveitis, Choroiditis, Chorioretinitis, Retinitis, Iritis, Retinal Vasculitis, Optic Neuritis, Scleritis, and Orbital Myositis) following COVID19 vaccinations. Adverse events reported between 1st January 2021 and 28th September 2022 were returned to the requesting research team. The returned data comprised: aggregated patient age, aggregated patient gender, suspect vaccine(s), adverse drug reaction(s), outcome of reaction (resolved, resolving or ongoing), reaction onset time from drug administration, patient medical history, and year of receipt of report. Ethical considerations apply to all identifiable data but not to aggregated anonymised Yellow Card data. Since individual patients or reporters cannot be identified, such data can be released without consent in accordance with FOI. This research involved re-use of robustly anonymised and aggregated data which were already in the public domain, and was not used for any purposes beyond those for which the data were originally gathered, thus ethical review is not deemed necessary by the National Health Service Health Research Authority.

Analysis Free text entries on symptoms were categorised. Systemic disorder categorised by system involved, and variable derived re immune mediated disorder (autoimmune, autoinflammatory or history of systemic steroid use). Continuous variables were reported as median, interquartile range and range. Categorical variables are presented as numbers (percentages) with 95% confidence intervals. Incidence of adverse events was calculated using as a denominator the number of individuals who had received their first dose of COVID vaccine between 1st January 2021 and 28th September 2022 (**Table 1**) (https://www.england.nhs.uk/statistics/statistical-work-areas/covid-19-vaccinations/covid-19-vaccinations-archive/).

Table 1 Number of individuals who received their first dose of COVID vaccine in the UK in Jan 2021- Sep 2022

– Age group	Number of vaccinations	Incidence (new cases) of ocular inflammatory events per million vaccinated
5 - 12	564,867	0, 95% CI 0 to 6.5
13-17	2,444,864	2 = 0.8 per million, 95% CI 0.1 to 2.9
18-35	10,187,216	72 = 7.1 per million, 5.5 to 8.9
36-65	20,654,527	153 = 7.4 per million, 6.3 to 8.7

66+	11,092,641	29 = 2.6, 1.8 to 3.8

Results

The MHRA has received 125 UK spontaneous suspected reports associated with COVID-19 Pfizer BioNtech vaccine, 154 reports associated with COVID-19 AstraZeneca, 21 reports associated with COVID-19 Moderna vaccine and none with COVID-19 Novavax vaccine (**Table 2**). During this period, 45,258,080 individuals received their first dose. The calculated prevalence of ocular inflammatory event following the COVID-19 vaccination was of 6.6 events per 1,000,000 vaccinated individuals (95% CI 5.9 – 7.4 per million).

Table 2 Number of reports associated with ocular inflammatory events following COVID-19 vaccination (by gender and age group)

	Number of reports					
(Case) Sex	Pfizer TOZINAMERAN		Moderna ELASOMERAN		Astrazeneca CHADOX1 NCOV-19	
Female	79	63%	15	71%	101	66%
Male	40	32%	5	24%	44	29%
Unknown	6	5%	1	5%	9	6%
Total	125	100%	21	100%	154	100%

	Number of reports					
Age group	Pfizer TOZINAMERAN		Moderna ELASOMERAN		Astrazeneca CHADOX1 NCOV-19	
5 - 12	0		0		0	
13-17	2	2%	0	0%	0	0%
18-35	42	34%	8	38%	22	14%
36-65	49	39%	10	48%	94	61%
66+	12	10%	1	5%	16	10%
Unknown	20	16%	2	10%	22	14%
Total	125	100%	21	100%	154	100%

Presenting symptoms included reduced vision in 59 (19.7%), floaters in 15 (5%), eye pain in 27 (9%), photophobia in 19 (6.3%), redness in 6 (2%). Accompanying febrile illness was present in 11 (3.7%),

headache 42 (14%) and arthralgia in 13 (4.3%). Other reported symptoms included in word cloud diagrams (other symptoms all n=1).

Median number of days between vaccination and onset was 8 days, IQR 2 – 29, range 1 – 369 (by vaccine: Pfizer, 8, IQR 2-33, range 1 – 229 days; Moderna median 2, IQR 1-4, range 1 – 85 days; Astrazeneca median 10, IQR 2 – 29, range 1 – 369).

Table 3 describes the reported ocular inflammatory events following COVID-19 vaccination, divided in uveitis, optic nerve involvement and others. Anterior uveitis was the most common phenotype, reported in 175 (58.3%) patients, followed by optic neuritis in 118 (39.3%). Scleritis was reported in 21 (7%). Resolution of the event was seen in 157 (52.3%). There are no data related to treatment. Prior diagnosis of an ocular inflammatory disorder (other than the post vaccination event) was reported in 82 (27.3%: Pfizer 30, 24%; Moderna 5, 23.8%; Astra Zeneca 47, 30.5%). Amongst the 218 individuals with no history of ocular inflammation, the most common disorders were: anterior uveitis in 139 (63.8%), followed by optic neuritis in 102 (46.8%). Resolution was seen in 111 (55.8%). There are no data related to treatment.

Table 3 Ocular inflammatory events following COVID-19 vaccination by phenotype

	Pfizer TOZINAMERAN n=125	Moderna ELASOMERAN n=21	Astrazeneca CHADOX1 NCOV-19 n=154	Total n=300
Uveitis				
Anterior uveitis	66 (52.8)	9 (42.9)	100 (64.9)	175 (58.3)
Retinal vasculitis	3 (2.4)	0	<3 (<1.4)	4 (1.3)
Retinitis	0	0	3 (2.0)	3 (1)
Chorioretinitis	0	1 (4.8)	0	1 (0.3)
Choroiditis	1 (0.8)	0	0	1 (0.3)
Uveitis (undifferentiated)	4 (3.2)	4 (19.0)	31 (20.1)	39 (13.0)
Optic nerve				
Optic neuritis	46 (36.8)	5 (23.8)	67 (43.5)	118 (39.3)
Papillitis	0	0	1 (0.7)	1 (0.3)
Other				
Scleritis	6 (4.8)	1 (4.8)	14 (9.1)	21 (7)
Orbital myositis	0	2 (9.5)	1 (0.7)	3 (1)
Resolution	63 (50.4)	11 (52.4)	83 (53.9)	157 (52.3)

Medical history of an immune mediated disorder was reported in 115 (38.3%: Pfizer 45, 36%; Moderna 8, 38.1%; Astra Zeneca 62, 40.3%) (**Table 4**), and prior known COVID-19 infection in 26 (8.7%: Pfizer 4, 3.2%; Moderna 2, 9.5%; Astra Zeneca 20, 13.0%). The infection was already resolved or resolving, at the time of reporting, in half of the cohort (52%). Diagnoses of systemic disorder associated with the ocular inflammatory disease was made in 11 patients: sarcoidosis and ankylosis spondylitis in 2 patients each (0.7%), and multiple sclerosis in 7 (2.3%). There are no data on systemic disease activity at the time of ocular inflammation.

Table 4 Medical history and prior conditions of patients who developed ocular inflammatory events following COVID-19 vaccination

	Pfizer TOZINAMERAN n=125	Moderna ELASOMERAN n=21	Astrazeneca CHADOX1 NCOV-19 n=154	Total n=300
Autoimmune disorder	14 (11.2)	2 (9.5)	23 (14.9)	39 (13.0)
Immunodeficiency	16 (12.8)	3 (14.3)	5 (3.3)	24 (8)
Neurological disorder	8 (6.4%0	1 (4.8%)	24 (15.6%)	33 (11.0)
Respiratory disorder	7 (5.6)	1 (4.8)	15 (9.7)	23 (7.7)
Musculoskeletal disorder	9 (7.2)	0	10 (6.5)	19 (6.3)
Gastrointestinal disorder	3 (2.4)	2 (9.5)	4 (2.6)	9 (3.0)
Skin disorder	5 (4.0)	0	3 (2.0)	8 (2.7)
Obstetric / gynaecological disorder	4 (3.2)	0	3 (2.0)	7 (2.3)
Psychiatric disorder	3 (2.4)	0	4 (2.6)	7 (2.3)
Cardiovascular disorder	3 (2.4)	0	3 (2.0)	6 (2.0)
Genitourinary disorder	1 (0.8)	0	3 (2.0)	4 (1.3)
Cancer	2 (1.6)	0	2 (1.3)	4 (1.3)

Discussion

The data from the Yellow Card UK Reporting System support the view that ocular inflammatory events following COVID-19 vaccination are very rare with a prevalence of 6.6 events per 1,000,000 vaccinated individuals. Recently, Kumar at al assessed the risk of non-infectious uveitis following COVID-19 vaccination in individuals without a prior history of uveitis (19). The incidence rate ratio

comparing uveitis incidence in exposed post-vaccine risk periods and unexposed control periods within an individual was 1.05 (95% CI: 0.89-1.23, p=0.57). The result therefore did not indicate a significant increased risk of uveitis following COVID-19 vaccination, and provided reassurance about the overall safety of the vaccine.

From the UK reporting system, it emerges that the most common ocular inflammatory event following COVID-19 vaccination was anterior uveitis, detected in 58.3% of the patients. Several case reports and case series have so far described ocular inflammatory events following COVID-19 vaccination (13,14,24,25). Testi et al reported 70 patients developing an ocular inflammatory event following COVID-19 vaccination, with the most common event being anterior in 58.6% (13). Similarly, in a retrospective study conducted using the data from the Centers for Disease Control and Prevention Vaccine Adverse Event Reporting System between December 2020 and May 2022, Singh et al found that, among the 1094 cases of vaccine-associated uveitis, the most common phenotype was anterior uveitis, reported in 44.8% (25).

In our analysis optic neuritis was reported in 39.3% of patients. Several individual case reports of optic neuritis following COVID-19 vaccination have been published in the literature, with optic neuritis being considered the most commonly reported neuro-ophthalmic event following COVID-19 vaccination (25-28). Jaffrey et al calculated the reporting rates of optic neuritis, collecting cases from the Vaccine Adverse Event Reporting System, and divided them into the pre-pandemic, COVID-19 pandemic, and COVID-19 vaccine periods (28). The authors showed no significant increase in the reporting rate of optic neuritis following COVID-19 vaccination when compared with the range of incidence in the general population (28). Similarly, our study did not detect an increase in the reporting rate of optic neuritis when compared with the cases expected from the UK incidence data. Optic neuritis in the UK has an incidence of 3.7 (95% CI, 3.6-3.9) per 100 000 person-years and the Yellow Card reporting rate was significantly lower than would have been expected if every incident case of optic neuritis which occurred in the month following vaccination for the 45 million individuals receiving vaccines had been reported (29). Likewise, we showed no increase in the reporting rate of scleritis following COVID-19 vaccination, given the incidence in the UK population being 2.79 (95% CI 2.19-3.39) per 100,000 person years (30).

From the Yellow Card System reporting system, it emerges that the median number of days between vaccination and onset of the event was 8 days with Pfizer and 2 days with Moderna. In the series of Testi et al, all 70 patients developed the episode within 14 days of vaccination, and in the reporting

by Singh et al the mean onset interval of the event was of 11.42 ± 23.16 days with Pfizer (13,25). However, a significantly longer duration of uveitis onset was found in patients who received Moderna (mean onset interval 21.22 ± 42.74 days) (25).

The fundamental purpose of the Yellow Card System is to enhance the post-marketing surveillance of medicinal products by capturing valuable data on the safety profile of medications. This system serves as a means to identify, evaluate, and monitor potential risks associated with pharmaceutical interventions, thereby facilitating proactive measures to mitigate harm and improve patient outcomes. The Yellow Card reporting process entails the completion of a structured form that encompasses pertinent details regarding the patient, the suspected drug or vaccine, and the nature of the adverse event. This information encompasses a range of variables, including patient demographics, medical history, concomitant medications, as well as a comprehensive description of the adverse reaction encountered. The Yellow Card form allows for flexibility in terms of submission methods, enabling individuals to report online, via a downloadable form, or through traditional mail. Upon receipt of these reports, the MHRA employs a rigorous evaluation process to assess the significance and causality of the reported adverse events. A team of expert assessors meticulously scrutinizes the information provided, employing specialized pharmacovigilance techniques to determine the likelihood of a causal relationship between the administered medication and the observed adverse reaction. This critical analysis aims to establish a comprehensive understanding of the safety profile of the implicated pharmaceutical agent. The Yellow Card System's strength lies in its ability to capture a wide range of adverse reactions, including rare or previously unreported events, enabling the identification of emerging safety concerns. This proactive approach to pharmacovigilance allows for the timely implementation of risk minimization strategies, such as regulatory action, labelling updates, or safety communications, to ensure the safeguarding of patient well-being. By encouraging active participation from both healthcare professionals and patients, the Yellow Card System fosters a collaborative approach towards drug safety surveillance. This inclusive framework amplifies the collective vigilance surrounding medication safety and reinforces the MHRA's commitment to fostering a culture of transparency and accountability within the realm of healthcare provision.

Conclusion

In conclusion, ocular inflammatory events following COVID-19 vaccination have a very rare prevalence in the UK, with anterior uveitis being the most common phenotype. There is no increase in the reporting rate of uveitis, optic neuritis and scleritis following COVID-19 vaccination when

compared with the range of incidence in the UK population. The Yellow Card System represents a vital instrument within the domain of pharmacovigilance, empowering patients and healthcare professionals to contribute to the ongoing monitoring of medication safety. Through the voluntary reporting of adverse drug reactions, this system serves as a cornerstone of the MHRA's regulatory efforts, enabling the detection of potential risks, the implementation of risk mitigation strategies, and ultimately, the optimization of patient care.

Declarations

Competing interests - The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

Funding - AL Solebo is supported by an NIHR Clinician Scientist award CS-2018- 18-ST2-005. This work was undertaken at UCL Institute of Child Health/ Great Ormond Street Hospital for children, and UCL Institute of Ophthalmology/Moorfields Eye Hospital, which receive a proportion of funding from the Department of Health's NIHR Biomedical Research Centers funding scheme.

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Carlos Pavesio - Review & Editing
Ameenat Lola Solebo - Conceptualization, Data analysis, Supervision, Writing - Review & Editing

Acknowledgements - None

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