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COVID-19 Vaccine Associated Parkinson's Disease, A Prion Disease Signal in the UK Yellow Card Adverse Event Database

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ABSTRACT

Many have argued that SARS-CoV-2 spike protein and its mRNA sequence, found in all COVID-19 vaccines, are priongenic. The UK's Yellow Card database of COVID-19 vaccine adverse event reports was evaluated for signals consistent with a pending epidemic of COVID vaccine induced prion disease. Adverse event reaction rates from AstraZeneca's vaccine were compared to adverse event rates for Pfizer's COVID vaccines. The vaccines employ different technologies allowing for potential differences in adverse event rates but allowing each to serve as a control group for the other. The analysis showed a highly statistically significant and clinically relevant (2.6-fold) increase in Parkinson's disease, a prion disease, in the AstraZeneca adverse reaction reports compared to the Pfizer vaccine adverse reaction reports (p= 0.000024). These results are consistent with monkey toxicity studies showing infection with SARS-CoV-2 results in Lewy Body formation. The findings suggest that regulatory approval, even under an emergency use authorization, for COVID vaccines was premature and that widespread use should be halted until full long term safety studies evaluating prion toxicity has been complete. Alternative vaccines like the Measles Mumps Rubella (MMR) vaccine should be explored for those desiring immunization against COVID-19.

Keywords

COVID-19, Immunization, Vaccines, Parkinson's disease.

Introduction

Many have raised the alarm about the wisdom of wide spread immunization campaigns using COVID-19 vaccines without first performing long term human safety studies and well-planned animal toxicity studies. Concern has been raised regarding evidence that the SARS-CoV-2 virus, which causes COVID-19, is actually a lab derived bioweapon [1-4]. Several peer reviewed papers [3,5,6] have indicated that the spike protein of the SARS-CoV-2 virus and its nucleic acid sequence are actually prion forming toxins. A toxicity study in monkeys infected with SARS-CoV-2 showed the formation of Lewy Bodies [8] and supports these findings. All the COVID-19 vaccines on the market contain spike protein or its nucleic acid sequence creating a possible catastrophic epidemic of prion disease in the future.

The COVID vaccines from AstraZeneca and Pfizer are quite different in their composition. The AstraZeneca COVID vaccine utilizes live adenoviruses that are genetically engineered to make the spike protein. Pfizer's COVID vaccine utilizes mRNA encapsulated in lipids to cause formation of spike protein in the recipient. Both vaccines technologies have the potential to induce prion disease [4]. Because the technologies are unique it was hypothesized their rates of prion induction may be contrasting enough to be detected as a difference in a spontaneous adverse event reporting database. The UK's Yellow Card adverse event reporting system was chosen to evaluate whether a difference in prion related vaccine's reaction reports could be detected. As discussed below there were theoretical benefits for studying this effect in a database from a single small country as opposed to larger EU or US databases.

Method

Yellow Card adverse reporting data from the United Kingdom government website (***https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting***) was

downloaded. Data was in the form of 4 PDF documents, one each for vaccines from AstraZeneca, Pfizer, Moderna, and one for reports where the vaccine was not identified. Each document categorized adverse event reports into specific groups primarily sorted by organ system as summarized in Table 1. Adverse events in each major category are further classified more or less by specific disease or symptom. While the documents do not specifically say outright, the website indicates the reports may come from both lay persons and healthcare professionals and may include both spontaneous reports and reports derived from clinical trials.

Table 1.

General Categories	Pfizer	AstraZeneca	Risk
Blood Disorders	7164	6645	0.93
Cardiac Disorders	2776	7879	2.84
Congenital Disorders	32	65	2.03
Ear Disorders	2855	8250	2.89
Endocrine Disorders	85	263	3.09
Eye Disorders	3558	12181	3.42
Gastrointestinal	21225	73305	3.45
General Disorders	57080	233977	4.10
Hepatic Disorders	84	363	4.32
Immune System Disorders	1188	2594	2.18
Infections	5202	16093	3.09
Injuries	2343	7065	3.02
Investigations	2552	9499	3.72
Metabolic Disorders	1268	8090	6.38
Muscle and Tissue Disorders	27007	90733	3.36
Neoplasm	140	317	2.26
Nervous Disorders	**38876**	**160834**	**4.14**
Pregnancy	186	191	1.03
null	62	117	1.89
Psychiatric Disorders	**3900**	**15206**	**3.90**
Renal and Urinary Disorders	581	2234	3.85
Reproductive and Breast Disorders	3839	7839	2.04
Respiratory Disorders	9087	24655	2.71
Skin Disorders	15642	45995	2.94
Social Circumstances	85	266	3.13
Surgical and Medical Procedures	186	584	3.14
Vascular Disorders	3165	10725	3.39
Total Reactions	**210168**	**745965**	3.55
Total Reports	**73944**	**205221**	2.78
Fatal Reports	**425**	**904**	2.13
Reactions per Report	**2.84**	**3.63**	1.28
Fatalities per Report	**0.006**	**0.004**	0.77

The frequency of adverse event reports pertaining to possible prion induced neurological symptoms were compared between AstraZeneca and Pfizer vaccines. No analysis was made for other potential adverse events except that the rates of total psychological reactions ("Psychiatric Disorders") was also compared. The analysis was specifically intended for detecting prion disease in the "Nervous Disorders" reaction reports. An analysis was not performed on the "Psychiatric Disorders" reactions or any other category of diseases listed in Table 1. A Chi square analysis using a 2x2 table was used to calculate statistical p values for just 3 clearly specific signals. An online statistical chi square calculator (*https://www.socscistatistics.com/tests/chisquare*) was used. Chi square analysis was also performed, one each, for "Nervous Disorders" and "Psychiatric Disorders" in Table 1. In addition, a separate chi square analysis was performed for 3 specific neurological reactions that could relate to prion disease. A single "negative" control chi square analysis was performed to verify that the calculator software was functioning properly.

Results

Four documents were downloaded from the UK government database. The documents state the data lock date was June 16th, 2021 and the Report Run Date was June 17, 2021. The documents indicated that the following number of adverse event reactions were reported for each vaccine, Pfizer: 210,168; AstraZeneca: 745,965; Moderna: 14,781; brand unspecified: 2,521. Because of insufficient data only the Pfizer and AstraZeneca adverse event reports were analyzed. According to the documents the Pfizer adverse events were reported between December 9, 2020 and June 16, 2021 while the AstraZeneca adverse events were reported between January 4, 2021 and June 16, 2021. There were thus only a few days difference in the dates the adverse events were reported. Additional publicly available data from the UK indicates by June 16th, 72,891,861 vaccine doses had been administered ***https://coronavirus.data.gov.uk/details/vaccinations***). The proportion of these doses attributed to Pfizer or AstraZeneca vaccines was not readily available.

Adverse reactions to the Pfizer and AstraZeneca vaccines were categorized by Yellow Card into major categories based on organ system and are summarized in Table 1. Table 1 shows that in general there are 3.55 times more adverse reactions reported and 2.78 more reports filed for the AstraZeneca vaccine than for the Pfizer vaccine. In general, there were 3.63 adverse reaction disclosed for each report pertaining to the AstraZeneca vaccine compared 2.84 reactions for each report pertaining to the Pfizer vaccine.

Data in Table 1 was specifically analyzed looking for a signal of a potential difference in prion disease between the vaccine groups. There were 4.14 times ($p = 0.00001$) as many "Nervous Disorders" reactions and 3.9 times ($p = 0.00001$) as many "Psychiatric Disorders" reactions reported for the AstraZeneca Vaccine compared to the Pfizer vaccine. These differences were elevated compared to a 3.55 times difference for all adverse event reactions reported between the two groups respectively.

Analysis of the "Nervous Disorders" data, Table 2**,** showed a highly significant and specific increase in Parkinson's disease reactions in the AstraZeneca reports compared to the Pfizer vaccine reports. There were 185 reactions listing Parkinson's disease reactions in the AstraZeneca reports compared to only 20 in the Pfizer vaccine reports ($p=0.000024$). Table 3 shows how the Parkinson's disease patients were classified in the reactions. These Parkinson's disease cases were primarily identified using a highly specific, pathognomonic, symptom "Freezing Phenomenon". Table 3 shows that "tremor", a less specific but more sensitive

symptom found in Parkinson's disease patients was present in 9,288 reactions reported for the AstraZeneca vaccine but found in only 937 reactions reported for the Pfizer vaccine (p=0.00001).

Table 2: Nervous Disorders

	Pfizer	Ratio	AstraZeneca
Abnormal reflexes	11	4.73	52
Abnormal sleep-related events	11	2.09	23
Absence seizures	16	2.06	33
Acute polyneuropathies	39	8.44	329
Autonomic nervous system disorders	7	2.71	19
Central nervous system aneurysms and dissections	2	2.00	4
Central nervous system haemorrhages and cerebrovascular accidents	404	4.13	1668
Central nervous system inflammatory disorders NEC	1	17.00	17
Central nervous system vascular disorders NEC	5	5.40	27
Cerebrovascular venous and sinus thrombosis	36	7.17	258
Cervical spinal cord and nerve root disorders	3	3.00	9
Choreiform movements	2	2.50	5
Chronic polyneuropathies	1	14.00	14
Coma states	6	3.67	22
Coordination and balance disturbances	283	3.58	1013
Cortical dysfunction NEC	43	3.37	145
Cranial nerve disorders NEC	2	3.00	6
Dementia (excl Alzheimer's type)	11	2.55	28
Demyelinating disorders NEC	12	2.08	25
Disturbances in consciousness NEC	3236	2.96	9592
Disturbances in sleep phase rhythm	1	**10.00**	10
Dyskinesias and movement disorders NEC	143	3.08	440
Dystonias	14	1.86	26
Encephalitis NEC	3	2.00	6
Encephalopathies NEC	3	4.00	12
Encephalopathies toxic and metabolic	0		2
Eye movement disorders	14	1.21	17
Facial cranial nerve disorders	587	1.45	854
Generalised tonic-clonic seizures	22	3.55	78
Headaches NEC	16896	4.68	79069
Hydrocephalic conditions	1	11.00	11
Hypoglossal nerve disorders	1	5.00	5
Increased intracranial pressure disorders	6	9.00	54
Intellectual disabilities	1	9.00	9
Lumbar spinal cord and nerve root disorders	44	3.75	165
Memory loss (excl dementia)	163	3.38	551
Mental impairment (excl dementia and memory loss)	242	3.56	861
Migraine headaches	1689	4.29	7248
Mixed cranial nerve disorders	1	1.00	1
Mononeuropathies	35	2.91	102
Motor neurone diseases	0		1
Multiple sclerosis acute and progressive	40	2.58	103
Muscle tone abnormal	14	3.14	44
Myelitis (incl infective)	20	3.20	64
Narcolepsy and hypersomnia	57	3.46	197
Nervous system cysts and polyps	0		1
Nervous system disorders NEC	8	6.50	52
Neurologic visual problems NEC	13	1.92	25
Neurological signs and symptoms NEC	6599	3.63	23971
Neuromuscular disorders NEC	22	3.05	67
Neuromuscular junction dysfunction	8	1.75	14
Olfactory nerve disorders	274	2.33	639
Optic nerve disorders NEC	19	2.16	41
Paraesthesias and dysaesthesias	3987	3.58	14281
Paralysis and paresis (excl cranial nerve)	205	3.04	623
Parkinson's disease and parkinsonism	20	**9.25**	185
Partial complex seizures	8	3.88	31
Partial simple seizures NEC	0		8
Peripheral neuropathies NEC	73	3.00	219
Seizures and seizure disorders NEC	509	3.40	1732
Sensory abnormalities NEC	1765	3.02	5330
Sleep disturbances NEC	3	**16.00**	48
Speech and language abnormalities	140	3.37	472
Spinal cord and nerve root disorders NEC	11	2.82	31
Structural brain disorders NEC	4	8.75	35
Transient cerebrovascular events	99	3.91	387
Tremor (excl congenital)	937	**9.91**	9288
Trigeminal disorders	43	2.98	128
Vertigos NEC	1	2.00	2

Table 3: Parkinson's Disease

	Pfizer	Ratio	AstraZeneca
Parkinson's disease and parkinsonism	20	9.25	185
Freezing phenomenon	7		152
Parkinson's disease	3		15
Parkinsonian gait	1		0
Parkinsonism	4		10
Reduced facial expression	5		7
Vascular parkinsonism	0		1
Tremor (excl congenital)	937	9.91	9288
Action tremor	1		2
Asterixis	0		1
Essential tremor	3		5
Head titubation	5		15
Intention tremor	0		1
Postural tremor	0		1
Resting tremor	2		5
Tremor	926		9258

Another striking imbalance found in the analysis of "Nervous Disorders" of Table 2 was sleep disturbance. This is of interest because sleep disorders are a hallmark symptom of a genetically transmitted prion disease called Fatal Familial Insomnia. A detailed analysis of neurologically characterized sleep disturbance reactions is disclosed in Table 4. The data indicate there were 4 sleep disturbance or sleep phase rhythm reactions in the reports pertaining to the Pfizer vaccine versus 58 reactions in reports pertaining to the AstraZeneca vaccine (p=0.003).

Table 4: Sleep Disorders

	Pfizer	Ratio	AstraZeneca
Disturbances in sleep phase rhythm	1	10.00	10
Advanced sleep phase	0		1
Circadian rhythm sleep disorder	0		5
Delayed sleep phase	0		1
Irregular sleep phase	0		1
Irregular sleep wake rhythm disorder	1		1
Non-24-hour sleep-wake disorder	0		1
Sleep disturbances NEC	3	16.00	48
Microsleep	0		2
Periodic limb movement disorder	0		1
Sleep deficit	2		45
Sudden onset of sleep	1		0

Discussion

The current analysis was performed on COVID vaccine adverse reactions reported through the UK's Yellow Card system. While analysis is challenging a clear signal of a specific prion disease, Parkinson's disease, was found as discussed below. The findings are consistent with knowledge of the spike protein and its nucleic acid sequence [3-7], well accepted pathophysiology of prion disease, and animal toxicity data in monkeys [8]. The findings in this paper represent an urgent warning to halt mass immunization with COVID vaccines until proper safety studies are complete. Alternative vaccines like the Measles Mumps Rubella (MMR) vaccine should be explored for those desiring immunization against COVID-19 outside of clinical trials [4].

Analysis of spontaneous reporting data, as found in the Yellow Card system is limited for several reasons including the historical finding that spontaneous reporting under reports adverse events 95% of the time. Only 5% of drug adverse events are typically reported [9]. These figures on reporting of adverse events pertain to acute adverse events, essentially none of the adverse events occurring years or decades after administration of a pharmaceutical are ever reported. Analysis of the adverse events that are reported may be difficult to interpret, outside a controlled clinical trial, since it is often difficult to know the expected rate of a specific event in the recipient population.

The current study attempted to avoid previous problems associated with analysis of spontaneous adverse event reports by comparing reports between groups receiving different COVID vaccines. In this case those receiving the Pfizer COVID vaccine acted as the controls for those receiving the AstraZeneca COVID vaccine and visa versus. The fact that mass administration of both vaccines was started within days of each other worked in favor of the analysis as did the fact that there was an acute shortage of vaccines. People wanting a COVID vaccine would likely be forced to take what was available and not allowed much choice. These factors as well as government policies on what populations would be offered the vaccine first may have helped minimize demographics differences relating to which vaccine was received, at least in regards to age and sex. However, this is only theoretical since demographic data pertaining to use of specific vaccines was not readily available on the internet at the time this paper was written.

The data shows that that there are more adverse reactions reported for the AstraZeneca vaccine than for the Pfizer vaccine. On a whole there are 3.55 time more adverse reactions and 2.78 times more reports for the AstraZeneca vaccine than for the Pfizer vaccine. This may be explained in part by the number of vaccine doses administered but this information was not readily available. However, it is also possibly that there may be more acute reactions to the AstraZeneca vaccine. On average there were 3.63 adverse reactions per report for the AstraZeneca vaccine compared to 2.84 adverse reactions per report for the Pfizer vaccine. Demographics of the recipients and also the reporters (academic versus community clinicians) may also account for some of the differences.

The goal of this research was to determine if there was an early signal of prion disease. Because of the differences in vaccine composition [4] it was hoped that differences between vaccine groups may manifest early enough to create a signal. The analysis was specifically geared to look for evidence of a few prion diseases. No analysis was performed for non prion diseases such as autoimmune diseases or clotting diseases for example. The prion diseases of interest included: ALS, frontotemporal lobar degeneration, Alzheimer's disease, CJD, Parkinson's disease, and Fatal Familial Insomnia. Unfortunately, many of these prion diseases are characterized by non specific neurological and psychological symptoms [10]. There is overlap of symptoms between prion diseases making a definitive diagnosis slow at times.

Prion disease may take years or decades to manifest from onset however there were several reasons to hope that a signal may be detected within months of the immunization. First it was believed that there was a pool of people with either subclinical prion disease or mild prion disease that had not been correctly diagnosed. One theory is that COVID vaccines may accelerate disease progression causing these undiagnosed patients to have frank disease that is rapidly diagnosed after immunization.

A second reason to believe that a signal could be detected soon after immunization relates to knowledge of the spike protein. It is believed that the spike protein and its nucleic acid sequence may be a complex bioweapon capable of inducing prion disease by several different mechanisms. The mRNA nucleic acid may cause certain intrinsic proteins like TDP-43 and FUS to fold into prions which eventual leads to disease [3,4]. The spike protein also has a prion like region [5] which may catalyze a chain reaction and eventually lead to prion disease. However, a third group published data [6] that the spike protein may cause proteins including prions already in cells to aggregate, forming Lewy Bodies for example, and causing relatively rapid cell death. It is this third method that could allow fairly rapid detection of prion disease after immunization.

The current analysis showed a specific signal for an increased risk of Parkinson's disease. There were 20 Parkinson's disease reactions reported with the Pfizer vaccine and while 71 reactions (3.55 x 20) were expected in the AstraZeneca reports, there were 185 reactions actually reported (p=0.000024). The analysis was able to detect this signal because adverse event reports were filed

disclosing a very disease specific, pathognomonic, symptom "Freezing Phenomenon" which made up the bulk of the Parkinson's disease reports. It is not clear if the reports were primarily related to new onset Parkinson's disease or worsening of a previously diagnosed patient. The signal is supported by a proportionally similar imbalance in reports of a more sensitive, but less specific symptom of Parkinson's disease, tremor (Table 3). A total of 937 tremor reactions were reported for the Pfizer vaccine and while 3,326 reactions (9.37 x 3.55) were expected to be reported for the AstraZeneca vaccine, a total of 9,288 reactions were reported (p=0.00001). The net effect is that the clinical relevance could be logs in magnitudes higher than the reports of Parkinson's disease even after adjusting approximately 20-fold for under reporting [9].

Many but not all cases of Parkinson's disease are believed to be caused by prion disease [11]. It is believed that α-synuclein aggregates in the substantia nigra of the brain in Parkinson's disease patients causing the formation of Lewy Bodies. The relation of Lewy Bodies to Parkinson disease provides strong bio plausible support for a causal effect with this signal because infections of monkeys [8] with the SARS-CoV-2 virus lead to development of Lewy Bodies. The relative rapid onset of Parkinson's disease symptom after immunization may be explained by the vaccine derived spike protein's heparin binding site. One group [6] showed that the spike protein heparin binding site binds "to a number of aggregation-prone, heparin binding proteins including Aβ, α-synuclein, tau, prion, and TDP 43 RRM. These interactions suggests that the heparin-binding site on the S1 protein might assist the binding of amyloid proteins to the viral surface and thus could initiate aggregation of these proteins and finally leads to neurodegeneration in brain."

Another prion disease with some more unique features is Fatal Familial Insomnia. It is a rare genetic prion disorder characterized by an inability to sleep [12]. It was noted in the analysis of Nervous Disorder data of Table 2 and Table 4 that there was an imbalance of sleep reports between vaccine groups. There were 4 sleep reactions reported for Pfizer's vaccine and while 14 reactions (4 x 3.55) were expected in the AstraZeneca reports, a total of 58 reactions were reported (p=0.003). A rapid onset of difference between the two groups could be explained by the spike protein aggregating prion molecules already in the cells as discussed with Parkinson's disease symptoms above.

The Yellow Card database does not provide good insight on possible risk of developing many different prion diseases as can be expected. There is however an highly statistical increase in Nervous Disorders and Psychiatric Disorders reactions reported for the AstraZeneca vaccine compared to Pfizer vaccine, Table 1. This imbalance suggests that there may be underlying differences in prion disorders other than Parkinson's disease. Unfortunately most prion diseases have symptoms not specific to prion disorders and symptoms of different prion diseases overlap [10]. This fact delays diagnosis and, in some cases, the definitive diagnosis is delayed until post mortem autopsy.

The current analysis is not intended to indicate that one COVID vaccine is safer than another in regards to prion disease. One limitation of the analysis is that both vaccines may equally increase the rates of one or more prion diseases and no difference will be detected in the Yellow Card database. Imbalances in rates of reactions detected in this analysis can be explained by the striking differences in composition of the two vaccines allowing one vaccine to induce some prion diseases quicker. The AstraZeneca adenoviral virus based COVID vaccine may concentrate in the gastrointestinal system [4] to a greater extent leading to faster transport of the spike protein via the vagus nerve to the brain [13]. By contrast over the long run the Pfizer mRNA vaccine may induce more TDP-43 and FUS to form prions [3] and lead to more prion disease.

This analysis should serve as an urgent warning to those mindlessly following advice of politicians and public health officials regarding COVID immunization. Both groups have had a dismal record of protecting the health of the public. US public health officials ran the infamous Tuskegee syphilis study allowing people of color to die from syphilis because the public health officials refused to inform the patients, they had syphilis and that a treatment existed. There have been numerous less well-known experiments on prisoners and other vulnerable populations in North America. The infamous Nazi physician Josef Mengele was a public health doctor. Founding father politicians in the US championed civil liberties while owning slaves and running extermination campaigns against Native Americans. The current policy to immunize the masses with COVID vaccines before proper safety studies are complete is likely to follow in the steps of the previously mentioned historical acts.

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