CASE REPORT

Case Report: Anorexia as a new type of adverse reaction caused by the COVID-19 vaccination: a case report applying detailed personal care records [version 1; peer review: awaiting peer review]

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Abstract

Background: In Japan, more than 1,000 participants died shortly after receiving the coronavirus disease 2019 (COVID-19) vaccine, but the causal relation between the injection and death remains uncertain.

Methods: Applying long-term personal vital care data for 28 months for an elderly patient, I investigated and evidenced adverse reactions after the first dose of the COVID-19 Pfizer vaccination. **Results:** The precise, detailed, and continuous data statistically clarified the long-term fevers associated with no meals or drinks. Interrupted time series analysis showed significant and fluctuating increases of body temperatures, pressures, and pulses, although solely long-term plots showed an abrupt and timely increase in these vital data after the vaccine. **Conclusions:** Anorexia was fatal, and newly reported in the present care records since the patient received the first dose of the COVID-19 vaccine.

Keywords

case report, COVID-19 vaccine, adverse reactions, before-after study, statistic interrupted time analyses, fever, anorexia

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Competing interests: The author had an existing relationship with the patient prior to the study.

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Introduction

According to the descriptions by the [World Health Organization \(2021\)](#):

“Like any vaccine, coronavirus disease 2019 (COVID-19) vaccines can cause mild to moderate, short-term side effects, such as a low-grade fever or pain or redness at the injection site, fatigue, headache, chills, diarrhea, and allergic reaction. Most reactions to vaccines are mild and go away within a few days on their own. More serious or long-lasting side effects to vaccines are possible but extremely rare. Vaccines are continually monitored for as long as they are in use to detect rare adverse events and implement approaches to limit their occurrence.”

To date, except for anaphylactoid reactions, blood clots, myocarditis ([Nassar *et al.*, 2021](#)) or pericarditis ([Ashaari *et al.*, 2021](#)), and Guillain-Barré syndrome ([McKean and Chircop, 2021](#); [Kanabar and Wilkinson, 2021](#)), adverse reactions to the COVID-19 vaccines are mild or moderate, occur shortly after vaccination and are not associated with more serious or lasting illness ([Medicines & Healthcare products Regulatory Agency UK, 2021](#)). Similarly, the reactions peaked within one day, although in rare cases lasted a week ([Menni *et al.*, 2021](#)). The likelihood of accepting the vaccine were lower when the probability of serious adverse reactions such as paralysis was 1/100,000 in contrast to 1/million or 1/100 million ([Kaplan and Milstein, 2021](#)).

The present research, including a kind of “implementation research” (“an integrated concept that links research and practice to accelerate the development and delivery of public health approaches”; [Theobald *et al.*, 2018](#)), is associated with evidence-based intervention but not a clinical study in sensu stricto associated with a clinical double-blind study, and so is presented as a case report. I applied the statistical concept of interrupted time series analysis for an elderly participant who received the first dose of the COVID-19 Pfizer vaccine on 2 June 2021. This analysis is usually applied to populations, but the concept is the same even for a single participant. In Japan, more than 1,000 participants died shortly after the injections of the COVID-19 vaccine until September 2021, but the causal relation between the injection and death remains uncertain ([Ministry of Health, Labour and Welfare, Japan](#)). I herein report previously unreported serious side effects, including unexpected adverse reactions, based on thoroughly monitored reliable long-term care records.

Case report

Patient information

The participant was diagnosed with dementia in 2015 and a femoral neck fracture on 1 March 2019, and when the fracture was almost repaired in a hospital, the participant moved to the Geriatric Health Services Facility, on 2 April 2019. This facility is staffed by with physicians, nurses, physical therapists, occupational therapists, nutritionists, and care workers.

The Japanese Government (Ministry of Health, Labour and Welfare) decided that healthcare workers and people over 65 years were the first to be vaccinated, and elderly participants were initially included as targeted persons. The participant was 90 years old and died on 25 August 2021, 28 weeks after the first vaccination. The second injection was planned on 25 June was cancelled due to the severe side effects that presented immediately after the first injection. The original nursing care level was 2 (partial assistant) but changed to level 5 (bedridden) on 20 July 2021.

The personal vital data and other related data were continuously monitored from April 2019 to August 2021 and included the day of the vaccine, 2 June 2021. The night shift care worker checked the digital data every hour for example, and the “Care Records” were precise and detailed. The records include timetable records of three meals (a meal, e.g., expressed as main dish 6/10, side dish 9/10, where 10/10 = complete meal, 0/10 = no meal), drinks (ml), body temperature, blood pressure, pulse, saturation of percutaneous oxygen (SpO₂), urination, defecation, and physical and medical examinations. The data summary can be checked on a computer screen in the facility. Note that when fevered, the temperature is measured several times a day, and the last monitored temperature, not the maximum, appears on the PC screen as the default setting.

Contrasting the questionnaire survey among participants ([Suehiro *et al.*, 2021](#)) and contrasting the multinational network cohort with electronic health records and health claims data ([Li *et al.*, 2021](#)), the concept of the analysis is also applicable to a single participant. Because data from the million participants with mild to moderate and short-lasting side effects were privately measured and lacked long-term records, the present high-quality data, even for a single participant, are valid for scientific analyses.

Methods

This research used a method of statistical analysis that involves tracking a long-term period before and after a point of intervention, in order to assess the intervention’s effects. According to [Ferron and Rendina-Gobioff \(2005\)](#) and others, “the time series refers to the data over the period, while the interruption is the intervention, which is a controlled external influence or set of influences. The effects of the intervention are evaluated by changes in the level and slope of the

Figure 1. Continuously monitored body temperature ($^{\circ}\text{C}$), maximum and minimum pressures (mmHg), pulse (beat per minute), meals (a meal expressed as main dish such as 6/10 and side dish 9/10; e.g., 10/10 = complete meal, 0/10 = no meal), drinks (ml), and weight (kg) since admission in April 2019 to the patient's death in August 2021. The COVID-19 vaccine was injected on 2 June 2021 (intervention), but the second injection planned on 25 June was cancelled. 5 pre-injection disorders are also shown.

time series and the statistical significance of the intervention parameters". For this case report, the intervention is the COVID-19 Pfizer (Comirnaty) vaccination, given on 2 June 2021.

I made a figure of vital data tracking a long-term period (28 months) produced by the Care Records for the patient (1,500 page hard copies in Japanese; **Figure 1**; made by Excel 2008 for Mac). I also made a figure of vital data tracking a short-term period (6 months) from the summary records (28 page hard copy in Japanese) produced by the care records for the

Figure 2. Interrupted time-series analysis for monitored body temperature (°C), maximum and minimum pressures (mmHg), pulse (beat per minute), meals (maximum/day: 60 = 20 x 3 meals), and drinks (ml) for 180 days (6 months) interrupted by 92nd day when the patient received the COVID-19 vaccine. The last one-week plots were omitted by body temperature disturbance. The regression line with the equation, coefficient of determination (R^2), and level change by the interruption are shown.

Table 1. Statistical data for monitored body temperature (°C), maximum and minimum pressures (mmHg), pulse (beat per minute), meals (maximum/day: 60 = 20 x 3 meals), and drinks (ml) for 180 days (6 months) interrupted by 92nd day of COVID-19 vaccine injection. The last one week of data were omitted by body temperature disturbance.

	Temperature		Systolic pressure		Diastolic pressure		Pulse		Meals		Drinks	
	Pre injection	Post injection	Pre injection	Post injection	Pre injection	Post injection	Pre injection	Post injection	Pre injection	Post injection	Pre injection	Post injection
Approximate line	$Y = 0.0198X + 363.82$	$Y = -0.01184X + 386.05$	$Y = 0.0631X + 126.48$	$Y = -0.461X + 202.14$	$Y = 0.0067X + 70.176$	$Y = -0.1926X + 105.84$	$Y = 0.0234X + 70.028$	$Y = -0.0924X + 93.87$	$Y = -0.0568X + 43.378$	$Y = -0.00613X + 9.1024$	$Y = -1.106X + 711.49$	$Y = -2.9479X + 499.76$
R ²	0.05456	0.3092	0.0229	0.13881	0.00076	0.08187	0.01625	0.07037	0.04908	0.015306	0.00059	0.47893
R	0.2336	0.5561	0.1513	0.3726	0.02757	0.2861	0.2336	0.5561	0.2215	0.1237	0.02429	0.692
Intersept	365.6416	375.15	132.276	159.728	70.7924	88.1208	365.6416	375.15	38.1524	3.3064	701.3148	228.452
Level change	9.5084		27.452		17.3284		9.5084		34.846		472.8628	
Mean	364.7391304	370.3506494	129.3870968	141.5128205	70.48387097	80.51282051	71.11956522	81.78205128	40.80434783	0.571428571	707.0108696	110.3246753
Variance	5.293836598	22.3885851	126.7398317	786.1232101	43.29593268	232.6946387	24.58994267	60.7960373	48.31294792	2.537593985	15269.26362	9186.406357
Degree of freedom	106		98		101		126	126	102		166	
T	-9.508283138		-3.584842235		-5.400334604		-10.4218197		53.85510717		35.32764719	
PT (≤ t) one cided	3.58883E-16		0.000263903		2.21535E-07		5.0612E-19		4.90704E-77		1.98408E-79	
T-statistic value one cided	1.659356034		1.660551217		1.66008063		1.657036982		1.659529976		1.654084713	
PT (≤ t) two cided	7.17767E-16		0.000527805		4.43071E-07		1.01224E-18		9.81407E-77		3.96815E-79	
T-statistic value two cided	1.982597262		1.984467455		1.983731003		1.978970602		1.983495259		1.974357764	
Standard error	0.23741822	0.540398724	1.167387635	3.174665761	0.682310533	1.727212957	0.51710209	0.872923671	0.71799775	0.360827835	12.75840106	10.92938891
Median	365	369	128	145.5	70	81	71	82	42	0	715	100
mode	366	370	118	134	69	79	69	85	41	0	750	0
Standard deviation	2.289578397	4.80316892	11.25787865	28.03788883	6.579964489	15.2543318	4.986751967	7.758715299	6.924119548	3.186745151	123.0375641	96.52574931
Kurtosis	-0.158797152	4.18250794	-0.496755519	-0.502688586	1.435971906	-0.274371303	0.558465175	-0.142253583	2.078199143	43.9182879	1.797232424	2.607666508
Skewness	-0.244577106	1.782714479	0.270761688	-0.479761826	-0.070640615	-0.430961688	0.637685506	0.097637692	-1.251988422	6.172032188	-0.34146775	1.184237268
Confidence interval (95%)	0.471533078	1.075851215	2.318532607	6.32156715	1.355127613	3.439320392	1.027009386	1.737857532	1.426005507	0.718500012	25.33928576	21.76319372

Table 2. Representative patient's care records from June 2 – June 14, after Osozawa (2021).

Date	Time	Temperature, °C	Notes	SpO ₂
2 nd June	07:50	36.0	Received vaccine at 09:30	
2 nd June	13:40	37.7		
2 nd June	13:48	37.6		
2 nd June	15:14	38.0		
2 nd June	19:41	37.1		
3 rd June	06:19	37.1		
3 rd June	11:18	37.2		
3 rd June	14:40	38.0		95
3 rd June	19:42	37.8		
4 th June	07:00	37.4	Visual hallucination of 15 dancing girls	
4 th June	15:00	38.6	Noted decreased mental status	95
4 th June	16:40	38.8		
4 th June	19:13	37.0		
5 th June	05:56	36.8		95
5 th June	08:42	36.9		95
5 th June	14:50	37.1		95
5 th June	19:08	37.0		95
6 th June	08:32	36.9	Temperature continued around 37.0	94
14 th June	12:36	38.8	Maximum temperature before death	

patient (Figure 2; made by Excel 2021) for applying the interrupted time series analyses. Table 1 is a summary of the statistical analyses.

For body temperature for example, an interrupted time-series analysis approach was utilized. A linear regression model was fitted to describe the magnitude of change in temperatures in transitioning from one phase to another and the trend of temperatures at any specific time segment. Parameters of interest included: baseline error trend; immediate change in daily temperatures from the last observation in the pre-implementation phase to the first observation in the implementation phase; change in the slope of temperature trend from pre-implementation to implementation; immediate change in daily temperatures from the last observation in the implementation phase to the first observation in the post-implementation phase; temperature trend in the post-implementation phase; and estimated reduction in daily temperatures into the implementation phase (Elsaid *et al.*, 2013).

Timeline

Vital records covering 28 months (Figure 1) showed that body temperature, maximum and minimum pressures, and pulse drastically increased and violently fluctuated, and that both intake of meals and drinks and weight significantly decreased (ultimately no meal and drink; patient lost 1/4 body weight) after the COVID-19 vaccination, contrasting to the pre-injection “steady state” which had continued for more than two years with sporadic, short-termed disorders (detailed in Figure 1).

Vital records restricted to the last 6 months (180 days; Figure 2) show the pre-injection horizontal regression line, large + level change for temperature, pressures, and pulse, and – level change for meals and drinks, post-injection – regression line. The R² value and other statistical parameters (Table 1) suggested that the injection strongly influenced and affected the vital system and induced a critical phase.

Table 2 presents detailed care records for the period of June 2nd – June 14th, taken from the full care records (Osozawa, 2021). During this time, the patient's temperature increased and remained increased until death. The patient also experienced hallucinations and decreased mental status, as well as decreased SpO₂ levels. Another visual hallucination was observed on 17 June. The tongue coat was observed on 18 June. The final dinner (including breakfast and lunch) was on 2 June, the day of vaccination, after which the patient developed anorexia and did not eat, contrasting with the pre-vaccination time where the patient usually had full meals and drinks.

Discussion

Factor of disorder: adverse reaction of the COVID-19 vaccination

Pre-injection disorders are shown on [Figure 1](#), and they were short-term, recovered from, and of course unrelated to the vaccination.

Abrupt and serious disorders that appeared just after the COVID-19 vaccination were clearly causally related to the vaccination ([Figures 1 and 2](#); [Table 1](#)). Death was probably caused by these adverse reactions, especially by no meal or drink for nearly three months.

The fevers just after the injection in early June were likely a consequence of an adverse reaction to the vaccine ([Table 2](#)). The consequent fevers in mid-June and early August were potentially causally related ([Figures 1 and 2](#); [Table 1](#)).

CRP (C-reactive protein) increased from 0.11 mg/dl on 18 February 2021 (pre-injection) to 1.25 on 22 June and 1.12 on 9 July 2021 (post-vaccination; associated fever), and the leukocyte count decreased below the reference values. Thrombocytopenia frequently associated with critical thrombosis ([Ministry of Health, Labour and Welfare](#); [Fueyo-Rodriguez *et al.*, 2021](#); [Waraich and Williams, 2021](#); [Sessa *et al.*, 2021](#)) was not found in the patient, but neutropenia reported by [Charan *et al.* \(2021\)](#) was probable. Increased CRP over 0.3 (< 0.3: normal level) suggested moderate class inflammation and might have been related to the following reported symptoms: fever flash on 2 June; leg pain on 3 June; nausea on 4 June; visual hallucinations (15 dancing girls are visible; deceased husband is visible) on 4 and 17 June; tongue coat on 18 June; and tongue swelling on 21 June. Fevers over 38°C tended to be associated with SpO₂ 95 (note that SpO₂ was minimal at 94 on 6 June) and implied lung dysfunction and pneumonia. Polymyalgia rheumatica in early 2020 (see [Osozawa, 2021](#)) had a much higher CRP of 7.4 (c.f., [Parperis and Constantinou, 2021](#)), which later descended within the reference values and was unrelated to the present case. These disorders were possibly associated with cytokine release (or storm).

Significant increases in blood pressure and pulse to higher levels can be considered adverse reactions of injection ([Figures 1 and 2](#); [Table 1](#)), presumably caused by inflammation. Inflammation was possibly associated with belching and nausea (and partial chills and fatigue; diarrhea was uncertain due to the dosage of magnesium oxide), which might have affected the appetite, reduced it, and led to anorexia. Note that the participant retained chewing and swallowing abilities as the dentists and physical therapists regularly checked and trained. Thus the anorexia nervosa triggered by the vaccination reduced the patient's weight to 3/4 of the pre-vaccination weight.

Recommendations

Another concern was the dosage of the vaccine (0.3 ml/participant in a present case of the COVID-19 Pfizer (Comirnaty) vaccine). The amount is the same between men and women and Japanese and American individuals. The mean weight of an American woman was 77 kg in 2015-2016 ([CNN](#)), but the patient's weight was only just over half of 77 kg at 40.5 kg (so the vaccine dosage should have been 0.15 ml). Therefore, I am concerned about the overdosage risk and its increased adverse reactions acting on the Japanese population. Centers for Disease Control and Prevention recently (November 2021) decided that the dose should be 0.1 ml/US children less than 11 years old.

Conclusion

The long-term vital records of this patient offered excellent data for adverse reactions to the COVID-19 Pfizer vaccine, including abnormally long-lasting fevers, high blood pressure, high pulse, and severe anorexia, ultimately leading to the patient's death.

Informed consent

Written informed consent for publication of the patient's clinical details was obtained from the patient's family member. The personal care data are protected by the Personal Information Protection Law, Japan.

Data availability

Underlying data

Zenodo: Table S2: In Anorexia as a new type of adverse reaction caused by the COVID-19 vaccination: a case study applying detailed personal care records. <https://doi.org/10.5281/zenodo.5778025> ([Osozawa, 2021](#))

Data are available under the terms of the [Creative Commons Attribution 4.0 International license](#) (CC-BY 4.0).

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