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[原著]

The incidence rate of adverse reactions following COVID-19 vaccination among university students

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Summary

This study aimed to determine the incidence rate of adverse reactions following COVID-19 vaccination, as well as examine the influence of sex, number of doses received, days elapsed since vaccination, and past medical history. The survey involved students who participated in any of the three vaccination program sessions that took place at these universities. The participants noted their health statuses for eight days, including on the vaccination day itself, and provided demographic information and reports of any adverse reactions. An analysis of the surveys revealed incidence rates of pain at the injection site, swelling, fatigue, myalgia, and fever that all exceeded 50%. A generalized linear model analysis indicated a higher incidence in women than men, and a higher incidence following the second dose compared to the first. The incidence peaked the day after vaccination and gradually decreased over the following days. Those with medical histories of bronchial asthma and pollinosis were found to be associated with a higher incidence of adverse reactions. The findings of this study will hopefully contribute to public health data, particularly regarding university students—who have been under-represented in previous studies on this topic.

Keywords: COVID-19, Vaccination, Adverse drug reactions

Introduction

Since the emergence of the novel coronavirus infection (COVID-19) in 2020 (1), Japan has initiated a vaccination program. Research has demonstrated that mRNA-based vaccines, which were the ones predominantly used in mass vaccination campaigns, effectively prevent COVID-19 infection—although they may also cause mild adverse reactions such as pain at the injection site, fatigue, and headache (2)(3). The Ministry of Health, Labour and Welfare of Japan has conducted surveys on post-vaccination health and informed potential vaccine recipients about the risks and benefits of vaccination (4). Although a number of reports have been conducted on the topic of COVID-19 vaccinations among various

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age groups, information is lacking regarding the younger demographics —particularly university students. Although healthcare professionals and medical institutions are mandated to report the occurrence of severe adverse reactions such as anaphylaxis and thrombosis, mild reactions, which have been abundant among the general vaccinated population, have yet to be sufficiently documented. Furthermore, it has been indicated that younger Japanese individuals, particularly females, exhibit higher vaccine hesitancy than other age groups (5). Disseminating accurate information and enhancing the willingness to vaccinate among younger populations is therefore critical.

Two Universities, located in Saitama prefecture, held mass COVID-19 vaccination programs between 2021 and 2022, mainly for their students. The program provided the Takeda/Moderna COVID-19 vaccine. We investigated the frequency of mild adverse reactions following vaccinations through these vaccination programs.

According to previous studies, > 50% of COVID-19 vaccine recipients experienced specific reactions, such as fatigue, fever, and myalgia, following each vaccine dose (6)(7). However, estimating accurate incidence rates and examining the factors that influence them through statistical analysis has yet to be conducted.

Purpose of the study

We aimed to estimate the frequency of adverse reactions following COVID-19 vaccination among young recipients. We also explored the impact of factors such as sex, number of doses received, and number of days elapsed since vaccination. This study re-analyzed data from surveys conducted in previous studies of ours (6)(7).

Materials and Methods

Study population

The study population focused on university students who have been underrepresented in previous studies on this topic. Surveys were administered to university students, including undergraduate and postgraduate students.

Questionnaire

The surveys were conducted during the COVID-19 vaccination program at Josai University and Nihon Institute of Medical Science. All participants received the Takeda/Moderna COVID-19 vaccine (Spikevax Intramuscular Injection). The first round of vaccination was conducted in July and August of 2021, the second in September and October of the same year, and the third from March to May of 2022. The responses were collected anonymously through a web-based form after consent to participate in the study was obtained from each participant.

Survey items

The participants were asked to provide their demographic data and medical history, as well as report any suspected reactions they experienced, starting from the date each vaccination was administered until the eighth day afterward. The reactions were classified into one of two categories, based on previous research (8): local reactions (such as pain, redness, swelling, and itching), and systemic reactions (including fatigue, headache, myalgia, fever ≥ 37.5°C, chills, joint pain, nausea, diarrhea, and abdominal pain).

Statistical analysis

The incidence rates for each reaction up to eight days post-vaccination and their 95% confidence intervals (CIs) were

estimated. The CIs were derived using a normal approximation of the population proportion. Fisher's exact test was conducted to investigate significant differences in the incidence of each symptom between the first, second, and third vaccination doses. The false discovery rate (FDR) was used as a *p*-value adjustment method. Additionally, a generalized linear logistic regression model was then used to estimate the odds ratios for the occurrence of local and systemic reactions associated with sex, number of doses received, days elapsed since vaccination, and medical history. Medical history data for bronchial asthma, atopic dermatitis, and pollinosis —with a frequency of ≥ 10—were used as explanatory variables. The regression coefficients were determined using the maximum likelihood method (iteratively reweighted least-squares). The odds on day 1 for the first dose administered to the male participants were used as the reference. All statistical analyses were conducted using R (version 4.1.2, Austria).

Ethical considerations

All participants consented to voluntary participation after reading an online informational sheet that specified the survey's purposes and procedures. This study was approved by the Josai University Ethics Review Committee for Medical and Life Science Research on Human Subjects (approval no.: 2021-10) and the Nihon Institute of Medical Science Research Ethics Committee (approval no.: 2021008).

Results

Demographics and medical history

A total of 2,626 responses from university students were analyzed. The response rates for the first, second, and third surveys were 53.3%, 23.8%, and 26.3%, respectively. The participants' demographics and medical histories are presented in Table 1. Of the respondents, 50.9% were male and 49.1% were female. The majority of participants were in the 20–30-year age group (61.7%), followed by the 18–20-year age group (38.1%), with a small number in the 30–40-year age group (0.2%). Regarding medical history, 55.0% of the participants reported no pre-existing conditions. The most common medical conditions were hay fever (38.1%), atopic dermatitis (9.4%), and bronchial asthma (5.2%). Other conditions, such as cancer, hypertension, dyslipidemia, and diabetes mellitus, were reported at lower rates. Detailed breakdowns of the demographics and medical histories by vaccination dose are provided in Table 1.

Incidence rates of reactions

The incidence rates of local reactions were as follows: pain at the injection site was reported by 89.4% of the participants, redness by 35.5%, swelling by 58.1%, and itching by 31.5%. In terms of systemic reactions, fatigue was reported by 65.7%, headache by 48.8%, myalgia by 75.8%, fever by 51.1%, chills by 35.9%, joint pain by 31.8%, nausea by 11.8%, diarrhea by 9.3%, and abdominal pain by 8.1%.

Figure 1 illustrates the incidence rates and 95% confidence intervals (CIs) for adverse reactions up to seven days post-vaccination for the first, second, and third vaccine doses. The incidence of the majority of symptoms was significantly higher following the second vaccination compared to that after the first and third doses. In particular, some systemic symptoms (fatigue, headache, fever, and chills) differed considerably between the first and second vaccinations. In addition, digestive system-related symptoms (nausea, diarrhea, and

Table 1. Demographics and medical histories of the participants

Demographics	Dose 1 (N = 1623)	Dose 2 (N = 644)	Dose 3 (N = 359)	Total (N = 2626)
Sex				
Male	866 (53.4)	290 (45.0)	181 (50.4)	1337 (50.9)
Female	757 (46.6)	354 (55.0)	178 (49.6)	1289 (49.1)
Age category				
18 to < 20	597 (36.8)	274 (42.5)	129 (35.9)	1000 (38.1)
20 to < 30	1022 (63.0)	368 (57.1)	230 (64.1)	1620 (61.7)
30 to < 40	4 (0.2)	2 (0.3)	0 (0.0)	6 (0.2)
Medical history				
None	890 (54.8)	368 (57.1)	187 (52.1)	1445 (55.0)
Bronchial asthma	89 (5.5)	29 (4.5)	19 (5.3)	137 (5.2)
Cancer	4 (0.2)	1 (0.2)	0 (0.0)	5 (0.2)
Hypertension	3 (0.2)	2 (0.3)	1 (0.3)	6 (0.2)
Dyslipidemia	4 (0.2)	1 (0.2)	0 (0.0)	5 (0.2)
Diabetes	2 (0.1)	1 (0.2)	0 (0.0)	3 (0.1)
Atopic dermatitis	159 (9.8)	52 (8.1)	37 (10.3)	248 (9.4)
Pollinosis	623 (38.4)	234 (36.3)	144 (40.1)	1001 (38.1)

The numbers in brackets represented the percentage (%) of participants for each dose.

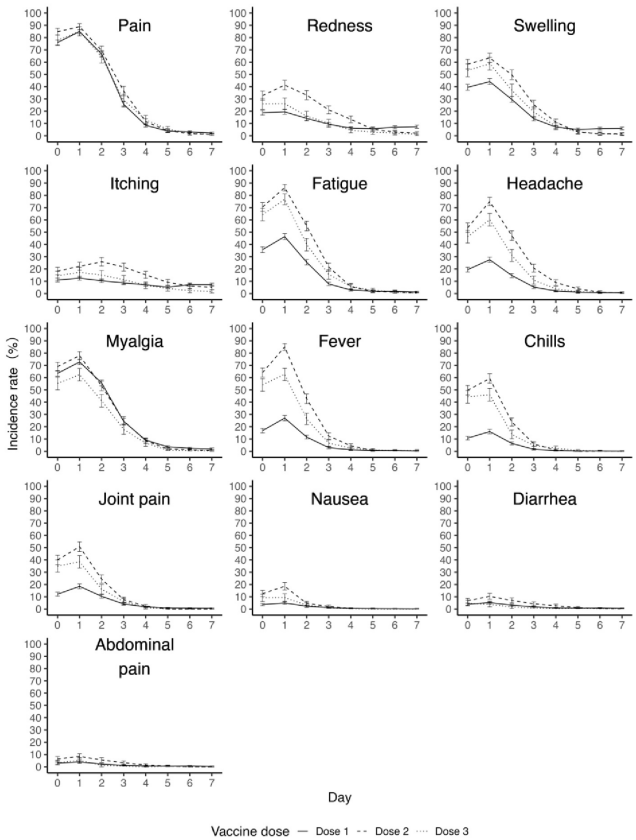

Figure 1. Incidence rates for each symptom according to days elapsed since vaccine administration.

Error bars indicate 95% confidence intervals. Local reactions: pain, redness, swelling, and itching; systemic reactions: fatigue, headache, myalgia, chills, fever, joint pain, nausea, diarrhea, and abdominal pain.

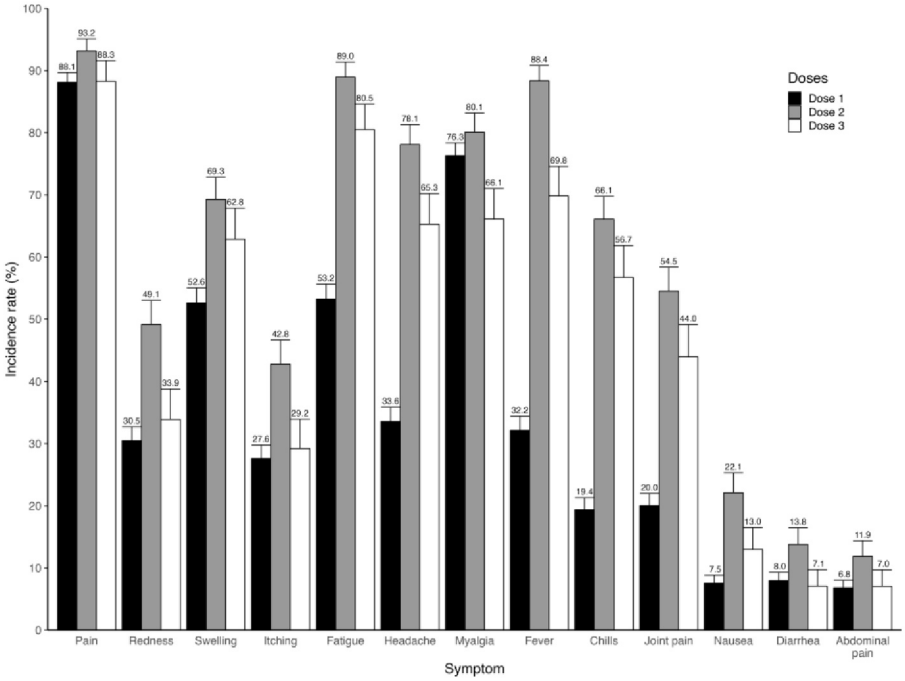

Figure 2. Incidence rates for each symptom according to vaccination doses.

Error bars indicate 95% confidence intervals. Data labels above the bars indicate the incidence rates.

abdominal pain) had a lower peak incidence. Overall, the results indicate that vaccine-related adverse reactions were most prominent on the day after vaccination, particularly after the second dose, and generally decreased to < 10% within a week.

The other symptoms reported through the respondents' free-text responses were as follows: other symptoms experienced by at least two respondents included drowsiness (five), chest pain (five), menstrual irregularities (four), lymph node swelling (two), dizziness (two), and bruising at the injection site (two). However, the association between these symptoms and vaccinations remains unclear.

Difference in incidences between vaccine doses

The incidence of each symptom is shown in Figure 2. The results of the pairwise comparisons using Fisher's exact test for the incidences after the first, second, and third rounds of vaccination were as follows: the incidence of pain following the second dose was higher than that after the first and third doses ($p < .001$, $p < .001$), with no significant difference between the first and third doses. The incidence of redness after the second dose was higher than that after the first and third doses ($p < .001$, $p < .001$), with no significant difference between the first and third doses. The incidence of swelling after the second dose was higher than that after the first and third doses ($p < .001$, $p < .001$), and after the third dose, it was higher than that after the first dose ($p < .05$). The incidence of itching after the second dose was higher than that after the first and third doses ($p < .001$, $p < .001$), with no significant differences between the first and third doses. The incidence of fatigue after the second dose was higher than that after the first and third doses ($p < .001$, $p < .001$), and after the third dose, it was higher than that after the first dose ($p < .001$). The

incidence of headache after the second dose was higher than that after the first and third doses ($p < .001$, $p < .001$), and after the third dose, it was higher than that after the first dose ($p < .001$). The incidence of myalgia after the first and second doses was higher than that after the third dose ($p < .001$, $p < .001$), with no significant differences between the first and second doses. The incidence of fever after the second dose was higher than that after the first and third doses ($p < .001$, $p < .001$), and after the third dose, it was higher than that after the first dose ($p < .001$). The incidence of chills after the second dose was higher than after the first and third doses ($p < .001$, $p < .001$), and after the third dose, it was higher than that after the first dose ($p < .001$). The incidence of joint pain after the second dose was higher than that after the first and third doses ($p < .001$, $p < .001$), and after the third dose it was higher than that after the first dose ($p < .01$). The incidence of nausea after the second dose was higher than that after the first and third doses ($p < .001$, $p < .001$), and after the third dose, it was higher than that after the first dose ($p < .01$). The incidence of diarrhea after the second dose was higher than that after the first and third doses ($p < .001$, $p < .01$), with no significant difference between the first and third doses. The incidence of abdominal pain after the second dose was higher than that after the first and third doses ($p < .001$, $p < .05$), with no significant difference between the first and third doses. In summary, for all symptoms except myalgia, the highest incidence was observed after the second vaccination dose.

Odds ratios of local and systemic reactions

Table 2 presents the odds ratios for local and systemic reactions. For local reactions, females exhibited a higher incidence compared to males. The incidence was higher after the second dose than after the first and third doses, and higher after the first dose compared to the third. The incidence was higher on the following day than on the vaccination day but decreased from the third to eighth day post-vaccination. Medical histories of bronchial asthma and pollinosis were associated with this incidence. Regarding systemic reactions, the results were broadly similar to those for local reactions; however, no significant difference in the incidence was observed after the first and third vaccinations.

Discussion

This study estimated the incidence of adverse reactions following COVID-19 vaccination. The associations between the incidence rates and influencing factors such as sex, number of vaccine doses received, days elapsed since vaccination, and past medical history, were then examined. The study population was focused on university students, who have been under-represented in previous studies on this topic.

The average incidence rates estimated after the three doses showed that reactions such as pain at the injection site, swelling, fatigue, myalgia, and fever had estimated incidence rates of > 50%, indicating that these are common reactions to COVID-19 vaccines. The results of these symptoms being the most frequent vaccine adverse reactions were consistent with those of previous studies from other countries (9)(10)(11), suggesting that these are typical reactions that are not significantly influenced by ethnic differences.

Table 2. Odds ratios of local and systemic reactions

	Local reactions	Systematic reactions
Sex		
Male	1.00	1.00
Female	1.97 (1.82, 2.12)***	1.62 (1.49, 1.75)***
Dose		
Dose 1	1.00	1.00
Dose 2	1.37 (1.25, 1.50)***	1.79 (1.62, 1.97)***
Dose 3	0.88 (0.79, 0.98)*	1.03 (0.91, 1.16)
Day		
Day 1	1.00	1.00
Day 2	1.76 (1.50, 2.07)***	2.05 (1.75, 2.39)***
Day 3	0.55 (0.48, 0.63)***	0.55 (0.48, 0.63)***
Day 4	0.12 (0.11, 0.14)***	0.12 (0.11, 0.14)***
Day 5	0.05 (0.04, 0.05)***	0.04 (0.03, 0.05)***
Day 6	0.02 (0.02, 0.03)***	0.02 (0.01, 0.02)***
Day 7	0.02 (0.02, 0.02)***	0.01 (0.01, 0.02)***
Day 8	0.02 (0.02, 0.02)***	0.01 (0.01, 0.01)***
Medical history		
Bronchial asthma	1.23 (1.03, 1.45)*	1.41 (1.18, 1.70)***
Atopic dermatitis	1.06 (0.93, 1.21)	0.95 (0.83, 1.09)
Pollinosis	1.41 (1.30, 1.53)***	1.27 (1.17, 1.38)***

The incidence rates demonstrated in the present study were generally higher than those reported by the Ministry of Health, Labour, and Welfare of Japan (4). For instance, fever following vaccination with the Takeda/Moderna vaccine was <10% after the first dose and approximately 80% after the second dose in the previous report (4). In the present study, among university students, the incidence of fever was 32.2% after the first dose and 88.4% after the second dose, indicating a higher incidence than previously reported. This discrepancy may be attributed to a more robust immune response in younger individuals, characterized by the production of higher levels of cytokines and inflammatory mediators, leading to a more pronounced febrile reaction (12). Previous studies also found a significantly lower incidence of adverse reactions in the ≥ 65-year age group compared to that in other age groups (13).

The lower incidence of adverse reactions after the third vaccination than after the second vaccination is consistent with the results of previous studies (14). The first and second vaccinations were administered approximately two months apart, whereas the third vaccination was administered approximately six months after the second vaccination. The lower incidence rate after the third dose may depend on the interval between vaccinations, as not all vaccine-induced plasmablasts are maintained as long-lived memory plasma cells (15).

Additionally, most reactions tended to peak the day after vaccination (Figure 1). This is consistent with the results of a previous study, which indicated that adverse reactions typically last 1–3 days (10). The Ministry of Health, Labour, and Welfare of Japan also reported that the peak incidence of most adverse reactions was observed the day after vaccination (4). This indicates that the mRNA vaccine promotes cytokine release (16). The initial inflammatory response and

cytokine release usually peak within 24-48 hours after vaccination (16). Adverse reactions are most pronounced during this period as the body recognizes the mRNA as foreign and activates the immune system (16).

The estimated odds ratios (Table 2) suggested a higher incidence among women than men, which is also corroborated by previous results (17). It has been suggested that women appear to have higher antibody production because of the immunomodulatory properties of estrogen and the X chromosome (12). An increased odds ratio was also observed following the receipt of a second vaccine dose compared to the first. It has been reported that the second dose of the COVID-19 vaccine elicits a more robust immune response, owing to the immunity acquired from the first dose. This, in turn, leads to more frequent adverse reactions such as fever and fatigue (18). Therefore, it may be considered that more adverse reactions following the second dose may be related to the vaccine's effectiveness. Finally, an increased incidence was suggested among those with a medical history of bronchial asthma, which is also consistent with the results of a previous report (19). Recent reports have indicated that vaccine recipients with a history of immunity develop systemic adverse reactions more frequently than those who are not immunized (20). For example, studies have indicated that individuals allergic to polyethylene glycol (PEG), a component of the lipid nanoparticle shells of mRNA vaccines, may have an elevated risk of anaphylaxis following vaccination (21). However, to the best of our knowledge, the association between adverse reactions and pollinosis has not been previously reported. Therefore, further epidemiological studies covering all age groups may be needed to clarify this association.

This study was subject to four limitations worth noting. First, the data used were completely anonymized by the vaccination program itself, preventing individual tracking for a longitudinal study. Second, the severity of each symptom was not assessed in this survey. Third, the response rates for the second and third surveys were lower than the first, which may have potentially affected the accuracy of the incidence rates for these doses. Fourth, the impact of medicines on the incidence of adverse reactions is unknown, as the present study did not investigate the medications that the participants had taken after vaccination. Future research should address these issues.

Conclusion

University students who receive the COVID-19 vaccine may experience adverse reactions such as pain and swelling at the injection site, fatigue, muscle pain, and fever. These reactions are more common in women and those receiving their second vaccine dose. Most of the reactions occur on the day following vaccination and subside within a week. These findings are essential for increasing public awareness of health and hygiene, particularly among university students.

Acknowledgments

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Conflicts of interest

The authors declare no conflicts of interest related to this study.

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大学生における COVID-19 ワクチン接種後の副反応発症率

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要旨

本研究の目的は、大学生における COVID-19 ワクチン接種後の副反応の発症率を調べ、さらに、性別・接種回数・接種後の経過日数・既往歴が発症率に及ぼす影響 (オッズ比) を検討することである。調査対象は、ある大学で実施された 3 回のワクチン職域接種に参加した者である。参加者は、ワクチン接種日を含む 8 日間の健康状態を観察し、人口統計学的情報と副反応症状の報告を行った。分析の結果、参加者の 50 %以上が注射部位の痛み、腫れ、疲労、筋肉痛、発熱を経験していた。発症率は接種翌日にピークに達し、その後数日間かけて徐々に減少した。一般化線形モデルによるオッズ比の推定結果から、女性は男性に較べて発症率が高く、2 回目の接種は 1 回目に較べて発症率が高いことが示された。くわえて、気管支喘息と花粉症の既往歴は発症率と正の関連を示唆した。本研究が大学生における保健衛生の一助となれば幸いである。

キーワード：COVID-19、ワクチン接種、副反応