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Assessment of Immediate Adverse Reactions After the Initial Administration of COVID-19 Vaccines in Residents of Australia

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ABSTRACT

Objective: This study aimed to explore the extent and severity of reported injurious effects, focusing on variations linked to the type of vaccine administered.

Methods: A survey involving 1435 COVID-19 vaccine adult recipients was conducted via online social media websites and emails from April to November 2022. Potential associations between reported side effects and factors such as gender, age, comorbidities, and prior or recurrent COVID-19 infection were examined and stratified by vaccine type.

Results: Primary side effects reported by study participants included pain at the injection site (47.2%), drowsiness and fatigue (22.8%), headache (18%), and muscle / joint pain (11.5%). Notably, recipients of the mRNA Pfizer-BioNTech vaccine (P) vaccine exhibited a much higher prevalence of adverse effects compared to those receiving the inactivated Sinopharm vaccine (S) vaccine (odds ratio of 1.28 (95% CI 1.23–1.57). The number of side effects reported per person for P and S vaccines was 2.48 ± 2.27 and 1.72 ± 1.79 respectively, demonstrating a statistically significant difference between the two ($p < 0.001$). Instances of severe side effects post-COVID-19 vaccination were infrequent, with 93% of reported symptoms categorized as mild and requiring none or home-based care.

Conclusion: This research identified certain demographic and vaccine-related factors associated with a higher likelihood of adverse effects post-COVID-19 vaccination. Specifically, individuals aged below 55, females, those with one or more comorbid diseases, recipients of the P vaccine, and those with a history of COVID-19 infection were found to have elevated odds of developing adverse effects compared to their counterparts.

Keywords: Community; Data; Health; Patient; Public; Vaccines

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Introduction

Amid the global battle against the pandemic of COVID-19, various vaccines were produced as a critical solution, with numerous candidates entering clinical trials at the beginning of 2020. Several of these vaccines secured emergency sanctions, leading to vaccination campaigns worldwide. [1]

The Australian government successfully concluded the clinical trial for the infamous Sinopharm or BBIBP-CorV (Beijing Bio-Institute of Biological Products) vaccine, approving it for public use in December 2020. [2] Subsequently, an intensive vaccination drive was launched, propelling Australia to the forefront globally with a distribution rate surpassing 90% of the vaccinated population. In addition to Sinopharm, the Australian government also approved vaccines such as adenovirus-based AstraZeneca, mRNA Pfizer-BioNTech, and Sputnik V, making them accessible to the entire population. [3]

While global COVID-19 vaccination coverage remains relatively low, as of November 24, 2021, only 42% of the world population

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received mandatory two doses of COVID-19. Data from vaccine trials indicate that common adverse effects include mild symptoms such as fatigue, fever, joint pain, muscle pain, and headache, with serious symptoms being rare. [4] Notably, the two most common vaccines were inactivated Sinopharm and the Pfizer-BioNTech mRNA. Both showed mild to moderate side effects in the general population including light headache, low-grade fever, and general body fatigue. [5,6] Similarly, trials for AstraZeneca and Sputnik vaccines reported primarily mild to moderate adverse effects. [7]

Drug safety research conducted globally on vaccine reactogenicity revealed mainly local injection site symptoms in mRNA COVID-19 vaccine recipients rather than systemic reactions, with severe symptoms being rare. [8] Younger individuals and females are reportedly more prone to the adverse effects of vaccines than other demographics. [9] Despite the vaccine safety data being published, concerns and hesitancy regarding vaccination persist globally. Studies indicate that there is mixed intention of the masses to get vaccinated as the positive reaction is linked with beliefs, while the highlighted concerns about potential adverse effects are linked with apprehension to get vaccinated. [10] Even healthcare workers hold sub-optimal acceptance towards COVID vaccine due to doubts about quality control, safety, and potential side effects resulting from the rapid emergence of vaccines.

There are several studies conducted on the nature of COVID-19 vaccines, their mechanism of action, perceptions of the general public and healthcare workers, and the acceptance level. [11] Now that the mass majority has been vaccinated, a new surge of data is required to investigate the side effects of these vaccines in the mass population. Hence, the objective of this survey is to offer comprehensive insights into the side effects encountered by Australians who have been administered COVID-19 vaccines, thereby enhancing comprehension of the varied nature of these effects across different vaccine types. Such insights can contribute to building confidence in individuals considering COVID-19 vaccination.

Materials and Methods

A cross-sectional investigation utilizing an online survey and telephone interviews transpired from April 20, 2022, to November 15, 2022, involving residents in Australia. The study was conducted in accordance with the declaration of Helsinki and approved by the institutional board (ECU/ERC/22/174). The survey aimed to uncover reported side effects following COVID-19 vaccination, ensuring the exclusion of personal identification details. Online consent was procured during the electronic questionnaire, and only individuals who explicitly consented proceeded to participate. Similarly, participants in telephone interviews provided oral consent before engaging in the survey.

The survey instrument was crafted to determine the reactogenicity associated with COVID-19 vaccination, including factors linked to the emergence of vaccine-related adverse effects. A pre-validated survey was adapted for this study. [12] The survey consisted of a list of adverse effects, with a provision for participants to add any additional side effects. The questionnaire inquired demographic information of the participants including gender, age, monthly income, educational status, history of COVID infection, any comorbid conditions, type of vaccine taken, and the number of doses administered.

To ensure the questionnaire's construct validity, five experts with backgrounds in public health, epidemiology, vaccine trials, and family medicine reviewed and refined the survey. A pilot test involving five participants gauged the feasibility and facilitated further refinement based on participant feedback. The next part of the survey comprised questions regarding vaccination status. The survey did not include people who were not vaccinated at least once. second part of the questionnaire included questions on vaccination status, excluding people who had not received at least one dose of the COVID-19 vaccine. The subsequent sections covered comorbid diseases, demographic variables, history of immunocompromised health status or allergies, past COVID-19 infection and its severity, vaccination details, and adverse effects experienced.

For participants reporting adverse effects, additional questions delved into the nature, doses of vaccination associated with the effects, and severity. A Likert scale (1–10) was employed for participants to rate the severity of side effects, with 1 indicating "none to mild symptoms" and 10 denoting "very severe symptoms." The severity of the symptoms was further assessed by inquiring whether the side effects necessitated treatment,

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specifying whether it was hospital-based, consultant's advice, or home-based treatment.

Participants were stratified into three age groups less than 35 years of age, 36–54 years, and 55 years and above, aligning with established literature and systematic review methodologies on COVID-19 vaccine safety. Vaccine side effects were categorized into local (injection site reactions) and systemic (headache, fever, flu-like symptoms, joint pain, muscle pain) for analysis.

The study focused solely on residents of Australia, with an approximate population of 25.8 million. The percentages (%) of adverse effects observed after vaccination were calculated and a chi-square test was employed to assess the differences between other variables and demographics (such as previous COVID-19 infection history and comorbid conditions) about the harmful effects based on the doses and type of vaccine's adverse effects. Additionally, the chi-square test was utilized to compare adverse effects based on the type of vaccine and doses, with the calculation of odds ratios. A p-value < 0.05 was considered statistically significant. All statistical analyses were conducted using SPSS software version 28.0.

Results

A total of 1435 people participated in the study. Out of these 646 individuals (45%) fell within the 35–54-year age bracket, 832 (57.9%) were females, and 603 (42%) were males. Among the participants, 459 (31.9%) people suffered from associated comorbid diseases, and 200 (13.9%) people previously had COVID-19 infection.

Regarding the type of vaccine received, 720 individuals (50%) received the inactivated Sinopharm vaccine (S), 531 (37%) received the mRNA Pfizer-BioNTech vaccine (P), and the remaining 184 (12.8%) people were given the Adenovirus vector AstraZeneca vaccine. Among the study participants, 1291 individuals (89.9%) were recipients of at least two doses of COVID-19 vaccine had received two or more doses of the COVID-19 vaccination, while 144 (10%) had received only one dose.

A total of 947 participants (65.9%) in the study reported experiencing one or more adverse effects after receiving the COVID-19 vaccine. Primary adverse effects reported by study participants included pain at the injection site (47.2%), drowsiness and fatigue (22.8%), headache (18%), and muscle / joint pain (11.5%). Notably, recipients of the mRNA Pfizer-BioNTech vaccine exhibited a higher prevalence of adverse effects in comparison to those receiving the inactivated Sinopharm vaccine (odds ratio of 1.28 (95% CI 1.23–1.57). Since the majority of participants received either the S or P vaccine, with only a negligible percentage having received other vaccines, further analyses were conducted exclusively on these two vaccine groups. The adverse effects following Sinopharm and Pfizer-BioNTech are presented in Table 1.

Among individuals who received the inactivated Sinopharm vaccine (S), 155 (21.5%) started having side effects after the first dose, 166 (23%) had observed side effects after the second dose, and 109 (15.1%) complained about side effects doses. Additionally, 66 (12.4%) individuals complained of side effects after receiving the first dose of mRNA Pfizer-BioNTech vaccine (P), 160 (30.1%) observed side effects after the second dose only, and 133 (25%) complained about side effects after both doses. The chances of first-dose side effects in individuals who received the Sinopharm vaccine are 1.8 times higher than in those who received the Pfizer-BioNTech vaccine (p < 0.005). However, the scenario reverses after the second dose where individuals who received the Pfizer-BioNTech vaccine are 1.6 times higher than those who received the Sinopharm vaccine (p < 0.001). Sinopharm vaccine recipients reported 288 (40%) local symptoms and 310 (43%) systemic symptoms. Whereas, in Pfizer vaccine recipients, 292 (54.9%) people reported regional symptoms and 244 (45.9%) complained about systemic symptoms after vaccination.

As far as local side effects are concerned, there was no statistically significant difference between the first and the second doses of both vaccines. Whereas the occurrence of systemic adverse effects after the Sinopharm vaccine (75.8%) was slightly greater than the first dose of the Pfizer vaccine (61.4%) (odds ratio 2.03, p-value 0.005). Nevertheless, following the administration of the second Pfizer vaccine dose, individuals noted a higher incidence of systemic adverse effects (85.5%). There was a statistically significant difference in the systemic side effects reported after the second dose of the Sinopharm vaccine (71.2%) (odds ratio 1.32, p-value <0.001).

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Table 1: Association of factors with the adverse effects after receiving the inactive Sinopharm vaccine and mRNA Pfizer-BioNTech vaccine

Factors		Total (n)		Side Effects		Odds Ratio		*p*-value	
		S	P	S	P	S	P	S	P
Gender	Male	310	229	54.3%	61.2%	0.528	1.87	0.04	0.001
	Female	410	302	71.4%	47.5%				
Age Group	<35	294	217	68.8%	51.3%				
	35-54	324	240	67.1%	66.5%	1.061	1.82	0.001	0.001
	> 55	102	74	63.3%	69.8%				
Income Status	Low	375	277	71.1%	64.8%	1.077	1.34	0.001	0.001
	High	345	254	64.5%	51.9%				
Educational Status	Diploma/ Undergraduate	521	385	71.8%	50.2%	1.172	1.28	0.122	0.08
	Postgraduate	199	146	62.7%	51.5%				
Previous COVID infection	Yes	242	178	66.2%	64.1%	1.457	0.74	0.06	0.02
	No	478	353	59.8%	63.2%				
Comorbidities	With comorbidities	152	112	70.5%	61.4%	1.510	1.04	0.017	0.03
	Without comorbidities	568	419	70.2%	62.5%				

Note: 'S' = Sinopharm 'P' = Pfizer-BioNTech

Discussion

Vaccine reactogenicity encompasses various local and systemic manifestations resulting from the inflammatory response to vaccination. The extent of reactogenicity is influenced by factors such as host characteristics (age, gender, etc.), vaccine type, composition, route of administration, and others. [13] Consequently, it is expected that a significant proportion of individuals would manifest a reaction following COVID-19 vaccination. Our questionnaire revealed that approximately 65.9% of people complained of one or more adverse effects after COVID-19 vaccination. Notably, no participant experienced severe allergic reactions to the COVID-19 vaccines.

The most reported side effects of both inactivated and mRNA vaccines were pain at the site of vaccination. Previously conducted studies in India and the UAE have also reported similar side effects. [12, 14] Additional common adverse effects of Pfizer included fever, headache, and fatigue, while inactivated Sinopharm vaccine caused fatigue and headache. A study conducted in Japan revealed that the Pfizer vaccine caused headache, erythema, skin pain, and itching which was more prevalent in females and younger age groups. [15] A study conducted in UAE describes the most common side effects observed in Sinopharm receivers to be fatigue, pain, and headache. [16] The results of these studies are quite aligned with the results of our study. Some uncommon side effects of the COVID-19 vaccine reported in Middle Eastern countries include depression, constipation, vomiting, swollen lymph nodes, anaphylactic shock, cough, metallic taste, lip corner infection, and bleeding gums. [17, 18]. These side effects were not noted during our study.

The Centers for Disease Control and Prevention detailed in their report that the severity of the side effects greatly depends on the underlying comorbid conditions of a patient. People with underlying conditions like anemia, respiratory disease, diabetes, chronic kidney disease, chronic heart disease, neurological disease, and other immunosuppressive diseases are more likely to be hospitalized due to COVID. [18] In a similar study, it was noted that the COVID-19 vaccines were immunogenic in patients with autoimmune inflammatory rheumatic disorder. [19]

When initially developed, the mRNA vaccine was perceived as safer than inactivated vaccines due to its noninfectious nature, eliminating the potential risk of infection. [20] Contrary to this expectation, our study found that the mRNA Pfizer-BioNTech vaccine was responsible for a significantly greater percentage of side effects in comparison to the inactivated Sinopharm vaccine. Similar results were documented in other studies that compared the local and systemic adverse effects of the Sinopharm and Pfizer vaccines. [21, 22] Additionally, the pattern of

side effects showed that local reactions were more prevalent after the first dose, while systemic effects were more prominent after the second dose, aligning with findings from a study documented in the United Kingdom. [23] Studies have shown that the documentation of side effects has a negative impact on patient willingness to get vaccinated, increasing fear and apprehension towards medical treatments. Since our data was not collected through any online data portal, rather it was the patient's self-reported symptoms, the results may be subjective.

The significance of this study lies in its exploration of vaccine reactogenicity, encompassing a spectrum of local and systemic manifestations triggered by the body's inflammatory response to vaccination. Understanding the factors influencing reactogenicity, such as host characteristics and vaccine composition, is crucial for assessing the safety and efficacy of COVID-19 vaccines.

The study has a few limitations. To begin with, it was a cross-sectional study and not a qualitative study which could gather more detailed information about symptoms, side effects, and feelings of vaccine recipients. The subjective nature of reported adverse effects underscores the need for a standardized evaluation method in subsequent studies. Additionally, the absence of a robust governmental system for tracking serious adverse events, coupled with insufficient funding for physical follow-ups, hindered the assessment of ICU-hospitalized patients and those experiencing severe outcomes, including permanent injuries or death. Consequently, we advocate for the establishment of a governmental follow-up system to overcome such limitations in future research. Furthermore, future investigations should thoroughly examine post-vaccination antibody titers, vaccine efficacy, and potential long-term side effects.

Conclusion

In essence, the reported adverse effects are predominantly mild. Public awareness regarding the nature of these side effects and the associated factors contributing to a higher likelihood of experiencing them can foster confidence, address vaccine hesitancy, and contribute to increased vaccine coverage, addressing the current imperative.

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Author Contribution

FS conceived the idea, collected data, and wrote the initial manuscript. RK collected data, analyzed the data, validated the results, and proofread the finalized manuscript.

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Conflict of Interest

None

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