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RESEARCH PAPER

Safety survey by clinical pharmacists on COVID-19 vaccination from a single center in China

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ABSTRACT

This study explored the safety of COVID-19 vaccine (Aikewei) and the role of clinical pharmacists in the implementation of COVID-19 vaccination. A total of 2305 hospital employees in Children's Hospital of Fudan University in Shanghai, China received the COVID-19 vaccine. The whole process of vaccination was monitored by clinical pharmacists, and the occurrence, types, severity of adverse reactions were recorded in detail. Through the investigation and analysis on the safety of COVID-19 vaccination of the 2305 people, the important role and value of clinical pharmacists in the vaccination process was elaborated. Common adverse reactions included local pain, dizziness and fatigue, with the incidence rates of 2.09%, 0.67% and 0.49%, respectively. Others such as headache, nausea, skin itching, cough, palpitation, dry mouth, hand anesthesia, local induration, muscle soreness, local rash, and chill had incidence rates of less than 0.30%. Three cases of serious adverse events that occurred in this vaccination returned to normal after treatment, with no subsequent discomfort. Clinical pharmacists played an important role in the safety monitoring of COVID-19 vaccination. The safety of the inactivated COVID-19 vaccine is good. Most of the common adverse reactions were mild and tolerable, with generally low incidence. The work of clinical pharmacists is important and can be expanded in the future to ensure the safety of vaccination and to provide better health care service.

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Introduction

Coronavirus disease 2019 (COVID-19) is caused by the virus named SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2), which is highly contagious and pathogenic. According to the World Health Organization (WHO), the number of confirmed cases in the world has exceeded 100 million, and the death toll has exceeded 2.5 million.[1] It is predicted that SARS-CoV -2 may coexist with human beings for a long time. Although this cannot be confirmed now, the epidemic has indeed lasted for more than one year and new cases are still appearing every day, so there is an urgent need for COVID-19 vaccine with both satisfactory safety and effectiveness.[2]

On December 31st, 2020, China's National Medical Products Administration (NMPA) approved the marketing application of SARS-CoV-2 Inactivated Vaccine (Aikewei), which was developed by Sinopharm Beijing Institute of Biological Products Co., LTD.[3] The vaccine is prepared by inoculating SARS-CoV-2 strain into Vero cells, culturing, inactivating, purifying, adsorbing with adjuvant, and packaging. It is suitable for people 18 years old and above, especially medical staff and vulnerable population who are at a high risk of contracting the virus.[4] According to the data from the Phase III clinical trial of Sinopharm China Biology, the safety after vaccination is good. After two doses of injection, all the subjects in the vaccine group produced high titer antibodies, and the positive conversion rate of neutralizing antibodies is 99.52%. The protection effectiveness of the vaccine against disease caused by SARS-CoV-2 infection (COVID-19) was 79.34%.[4] These rates meet the Guiding Principles for Clinical Evaluation of Preventive Vaccines in SARS-CoV-2 (Trial) issued by NMPA.[5] However, because the post-marketing data for the vaccine has not been obtained yet, the effectiveness and safety need to be further confirmed in larger population. In this study, the adverse events following COVID-19 immunization (AEFI) of employees in Children's Hospital of Fudan University from December 22nd, 2020 to February 23rd, 2021 were collected, the safety of vaccination was evaluated, and the role that clinical pharmacists could play in the vaccination process was discussed.

Materials and methods

Employees in Children's Hospital of Fudan University in Shanghai, China received the COVID-19 vaccine (Aikewei) in this study. The specification of the vaccine was 0.5 mL per unit, and two doses with an interval of 21–28 days were required for basic immunity in total, and each dose was 0.5 mL (containing 4 μg

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of inactivated SARS-CoV-2 protein).[4] The vaccine was injected into the deltoid muscle of the upper arm by intramuscular injection, and a 30-minute observation was required strictly after vaccination. The contraindication of this vaccine included: 1) having a history of severe allergy to any vaccines; 2) currently having acute diseases or severe chronic diseases, undergoing acute phases of chronic diseases, or having a fever; 3) pregnant or breast-feeding women, or women with plans for pregnancy within next 3 months; 4) having a history or family history of convulsion, epilepsy, encephalopathy or psychiatric disorders, or having Guillain-Barré syndrome or other neuropathy; 5) having been diagnosed with congenital or acquired immunodeficiency, human immunodeficiency virus infection, lymphoma, leukemia or other autoimmune diseases; 6) having known or suspected severe respiratory diseases, severe cardiovascular diseases, hepatic or renal diseases, or malignancies; 7) currently using anti-tumor or other immunomodulatory drugs; 8) having a history of SARS-CoV-2 infection; 9) having other conditions that are considered unsuitable for the vaccination by the clinicians or vaccinators.

AEFIs that occurred after the first dose and second dose of vaccination were recorded by clinical pharmacists from December 22nd, 2020 to February 23rd, 2021, in Children's Hospital of Fudan University. Specifically, local pain that occurred after vaccination was evaluated with the pain evaluation scale with 12 questions shown in Table 1.

Results

Safety monitoring results of the vaccine

From December 22nd to December 26th, 2020, only first dose of vaccine was administered. Starting from January 9th, 2021, the second dose of vaccine was administered to people who had received first-dose. Within the 14 vaccination days, 4458 doses of COVID-19 vaccine were administered to the hospital employees, with 2305 receiving the first dose and 2153 receiving the second dose. Recorded AEFIs included 93 cases of local pain, 30 cases of dizziness, 22 cases of fatigue, 10 cases of nausea, 8 cases of headache, 7 cases of muscle soreness, 6 cases of skin itching, 4 cases of palpitation, 4 cases of dry mouth, 3 cases of cough, 2 cases of hand anesthesia on the vaccination side, 2 cases of local induration, 2 cases of local rash, 2 cases of chill and 3 cases of serious adverse events (SAEs). The numbers of AEFIs that happened in each day were presented in Table 2.

A 24-year-old woman presented with SAE, whose onset time was 8 minutes after vaccination, and her main clinical manifestations were palpitation, chest distress, shortness of breath, general anesthesia, limb weakness, limb shaking, and transient vague consciousness for several seconds. She recovered after symptomatic treatment, and her physical condition returned to normal after about 4 hours, with no discomfort at follow-up.

A second case of SAE is a 41-year-old woman who had symptoms of nausea, limb weakness and limb anesthesia 7 minutes after vaccination. Physical examination revealed a heart rate of 104 beats per minutes, a respiratory rate of 21 breaths per minutes, pulse oxygen saturation (S_pO_2) of 100%, blood pressure of 140/94 mmHg, normal body temperature and blood sugar of 6.0 mmol/L. No other abnormality was found in further physical and laboratory examination. Treatment including fluid infusion and cimetidine was administered 100 minutes after the vaccination. The symptoms gradually relieved with blood pressure and heart rate back to normal.

Another case of SAE is a 59-year-old man who experienced dizziness, nausea, fatigue, and skin flush about one hour after the vaccination. At the time of emergency room admission, physical examination reported a heart rate of 95 beats per minute, a respiratory rate of 18 breaths per minute, S_pO_2 of 100%, and

Table 1. Post-vaccination local pain evaluation scale.

No.	Questions	Answers/multiple–choices
1	Your sex	A. Male B. Female
2	Your birthday	/
3	The highest education you've received	A. High school or below B. College C. Bachelor degree D. Master degree or above
4	Years you have worked here	/
5	Your occupation	/
6	The body part with the most severe pain	A. Shoulder B. Upper arm C. Forearm D. Other
7	The quality of the pain	A. Piercing B. Sore C. Burning D. Other
8	Complications	Nausea, vomiting, constipation, diarrhea, skin itching, dry mouth, dizziness, anesthesia, depression, anxiety, fever, other, no symptoms
9	The level of the pain	0-10 (larger the number, more severe the pain)
10	The pain relief goal you hoped to achieve	A. 10%-30% B. 30%-50% C. 50%-80% D. 100%
11	The pain relieved during the past half an hour	10%–100%
12	The influence of the pain on you	For daily life: 0–10 For mood: 0–10 For routine work: 0-10

Table 2. Main adverse reaction manifestations after vaccination.

	Dec.22	Dec.23	Dec.24	Dec.25	Dec.26	Jan.9	Jan.10	Jan.19	Jan.20	Jan. 21	Jan.22	Feb.7	Feb.8	Feb.23	Total	Rate (%)
Numbers of receivers	236	335	383	414	141	157	95	690	500	570	110	310	357	160	4458	
First-dose	236	335	383	414	141	154	94	186	31	164	71	0	0	96	2305	
Second-dose	0	0	0	0	0	3	1	504	469	406	39	310	357	64	2153	
AEFI types																
Local pain	22	9	16	10		9	1	3	10	2	3	3	5		93	2.09
Dizziness	2	1	4	6				7	6		1		3		30	0.67
Headache		1				2				2	2	1			8	0.18
Nausea		1	1			2	1		1	1	3				10	0.22
Fatigue				2			1	3	4	4	4		4		22	0.49
Skin itching	2				1	1		1			1				6	0.13
Cough		1						1		1					3	0.067
Palpitation			1			2				1					4	0.090
Dry mouth				1					1	1			1		4	0.090
Hand anesthesia				1					1						2	0.045
Local induration										2					2	0.045
Muscle soreness										3	4				7	0.16
Local rash									1	1					2	0.045
Low-grade fever							1								1	0.022
Chill											2				2	0.045
SAE			1			2									3	0.067

AEFI: adverse event following immunization. SAE: serious adverse event.

normal body temperature. Except for an abnormal value of CRP at 11 mg/L, other laboratory test indices were within normal range. Dexamethasone, loratadine, cimetidine, and fluid supplement were administered, after which his physical conditions were back to normal.

Common AEFIs after the COVID-19 vaccination included local pain, dizziness, and fatigue with the incidence rates of 2.09%, 0.67%, and 0.49%, respectively. Other adverse reactions such as headache, nausea, skin itching, cough, palpitation, dry mouth, hand anesthesia, local induration, muscle soreness, local rash, and chill had incidence rates of less than 0.30%. The types of these adverse reactions are basically consistent with the initial results obtained in clinical trials of the vaccine.[4] Three cases of SAEs that occurred shortly after the first dose of vaccination returned to normal with treatment, and no subsequent discomfort was reported.

Post-vaccination pain evaluation

In total, 93 people (19 male, 74 female) reported local pain after vaccination were further evaluated. The characteristics of these 93 people (57 from December 22nd to December 26th; 36 from January 9th to February 23rd) and their feelings of pain were presented in Table 3. The most common type of pain occurred in the upper arm with sore quality. The median percentage of pain relief after 30 minutes of vaccination was 30%. The local pain caused by the vaccination had little impact on the daily life for most of the vaccine recipients.

Discussion

This study investigated the safety profile of the inactivated COVID-19 vaccine developed by a Chinese company through self-report and professional observation. The results show that this vaccine is quite safe for wide application beyond clinical trial. The rate of each type of adverse event observed in this study is actually lower than that in Phase III study of this vaccine,[4] which is probably due to the comparatively small sample size, the lack of long-term observation, the potential omission in recording and reporting, and the selective vaccine receiver population that mainly consisted of hospital employees.

The common adverse events recorded during this investigation were consistent with those reported for the two mRNA COVID–19 vaccines developed by the Pfizer and the Moderna, including local pain and fatigue.[6–9] The SAE incidence rate in this study is 0.067%, and all of the three cases of SAE occurred after the first dose of vaccination. However, for the Pfizer and the Moderna mRNA vaccines, severe reactions of third grade or higher were more common after the second dose,[7,8] and the SAE incidence rate of the Pfizer vaccine was 0.60%,[7] higher than the rate observed in our study. Due to the limitation of our study methods, we were not able to distinguish the mild adverse events occurred after the second dose from those of the first dose. Despite of this inadequacy, the safety profiles and the local pain quality were similar for both doses based on the available data collected in this study. Moreover, it was reported that for the Pfizer vaccine, adverse reactions of grade three or higher were less prevalent in older vaccine receivers than younger receivers.[7] In our study, the age of the vaccine receivers was not available, but the three SAE cases (aged at 24, 41 and 59 years) indicated uniform distribution in term of age.

In order to ensure the safety of COVID–19 vaccination, the adverse reaction monitoring and data recording, including the occurrence, types, and severity of adverse reactions, of this vaccination were completed by clinical pharmacists in the Children's Hospital of Fudan University in China. Obviously, clinical pharmacists have played an important role in improving the safety of vaccination in this medical site. In China, doctors, assistant doctors and nurses who have received professional training and passed the relevant examination are responsible for vaccination, but pharmacists have yet been legally appointed to inoculate the people.[10]

In fact, since 1990s, some developed countries have gradually developed the service of administering vaccines by pharmacists whose role also includes safety monitoring during vaccination.[11–14] After nearly 30 years of development, this

Table 3. Characteristics of people who reported local pain after vaccination.

Variables	First-dose vaccination	First- and second-dose vaccination
Date of vaccination	Dec. 22 to Dec. 26	Jan. 9 to Jan. 10, Jan. 19 to Jan. 22, Feb. 7 to Feb. 8, Feb 23
Number of receivers	1509	2949
First-dose receivers	1509	796
Second–dose receivers	0	2153
Number of people with pain	57	36
Sex (male/female)	13/44	6/30
Education		
High school or below	5 (8.77%)	2 (5.56%)
College	6 (10.53%)	4 (11.11%)
Bachelor degree	30 (52.63%)	21 (58.33%)
Mater degree or above	16 (28.07%)	9 (25.00%)
Work Years	5 (0–25)	4.5 (0–20)
Occupation		
Nurse	18 (31.58%)	12 (33.33%)
Doctor	16 (28.07%)	5 (13.89%)
Administrator	6 (10.53%)	1 (2.78%)
Technician	6 (10.53%)	10 (27.78%)
Cleaner	3 (5.26%)	1 (2.78%)
Other	8 (14.04%)	7 (19.44%)
Body Part with the most severe pain		
Shoulder	3 (5.26%)	2 (5.56%)
Upper arm	50 (87.72%)	34 (94.44%)
Forearm	1 (1.75%)	0 (0%)
Other	3 (5.26%)	0 (0%)
Pain Quality		
Piercing	5 (8.77%)	1 (2.78%)
Sore	48 (84.21%)	24 (66.67%)
Burning	3 (5.26%)	2 (5.56%)
Other	1 (1.75%)	9 (25.00%)
Complication		
Nausea	1 (1.75%)	0 (0%)
Dry mouth	1 (1.75%)	4 (11.11%)
Dizziness	3 (5.26%)	2 (5.56%)
Anesthesia	2 (3.51%)	0 (0%)
Itching	0 (0%)	1 (2.78%)
Other	1 (1.75%)	2 (5.56%)
No symptoms	49 (85.96%)	26 (72.22%)
Pain level	4 (2–8)	3 (2-6)
Pain relief goal		
10%-30%	14 (24.56%)	4 (11.11%)
30%-50%	4 (7.02%)	11 (30.56%)
50%–80%	7 (12.28%)	8 (22.22%)
100%	32 (56.14%)	13 (36.11%)
Pain relieved (%)	30 (10–100)	30 (10–80)
Influence of the pain		
Influence on daily life	1 (1–6)	1 (1–5)
Influence on mood	1 (1–8)	1 (1-4)
Influence on routine work	1 (1–9)	1 (1-6)

Data were presented as number (percentage) or median (range) depending on the variables.

work mode has gradually matured and accepted by the medical system and the public in those countries. In December 2013, The Pharmacy Board of Australia (PBA) officially announced that "vaccination belongs to the practice scope of pharmacists".[15] By 2016, 50 States and the District of Columbia in the United States have allowed licensed pharmacists to obtain authorization to manage vaccines to varying degrees, and about 280,000 pharmacists have received vaccination training.[16] The scope of pharmacists' vaccination authority is expanding.[17] Up to now, many regions in Australia have legislated to give pharmacists the right to manage vaccines.[18] In addition, Canada, Britain and many other countries have also given pharmacists their corresponding legal rights.[19]

In China, vaccine safety has always been a major challenge in drug safety regulation. Now in the face of the COVID-19 pandemic era, vaccine safety surveillance is of great concern.[20] As part of the medical professional service talents, the team of clinical pharmacists is growing. Due to various restrictions, they cannot directly participate in vaccine management, but the work content in safety monitoring can be continuously expanded to make clinical pharmacists play a greater role. For example, pharmacists can record the information and physical condition of the subjects after vaccination, report the SAEs to the local authority or the pharmaceutical company and lead the research projects in post-marketing clinical studies.

There are several limitations of this study. First, the sample size of this single-center study is relatively small with only 2,305 people vaccinated included in this study, which may not represent the safety data of large-scale vaccination of COVID-19 vaccine in China. Second, as the observation time of the vaccinated population was only 30 minutes after administration, some mild and moderate adverse reactions that occurred at a later time may have been ignored, though the vaccinated people could actively report their adverse reactions. Third, data gathered from the same subjects over the vaccination process were not specifically analyzed.

Conclusion

The inactivated COVID-19 vaccine was safe, and most of the common adverse reactions were mild and tolerable and the incidence was generally low. There were three cases of serious adverse events, but they completely recovered after treatment. Clinical pharmacists have played an important role in the safety monitoring of COVID-19 vaccination, but there is still more room to realize their own value, and their work can be expanded in the future to ensure the safety of vaccination and to provide better health care service.

Disclosure of potential conflicts of interest

The authors declared no conflict of interest.

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