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Research Article

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Safety Monitoring of Covid Vaccines and Perception of Post-Vaccination Side-Effects: Preliminary Findings from The First Month of Routine Monitoring in A Hospital Vaccination Setting of China

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Abstract

Objectives: *Safe and effective vaccines are urgently needed to control the pandemic. Two COVID-19 vaccines have been recently approved in China and the vaccination is initiated targeting people who are occupationally exposed to high-risk of the infection. This study aims to explore the occurrence of post-vaccination side-effects from the vaccines and its affecting factors in a hospital vaccination setting of China.*

Methods: *A total of 811 vaccinees aged 17 to 58 years, who finished the full package of two doses in February 2021, have been recruited at the second vaccination uptake via an overwhelmingly used social network application. An online survey has been conducted using a structured questionnaire created in the application, in which basic demographical information and self-reported post-vaccination side effects were collected. Data collection has been closed on March 16, 2021.*

Results: *Among all, there have been 66 participants who reported one or more mild side effects, while none of them developed severe cases. Those with history of immune deficiency were more likely to report side effect(s). Although with several concerns, most participants showed willingness to get vaccinated (98.8%) with relevant high proportions of perceived safety (99.5%) and effectiveness (97.3%).*

Conclusions: *The monitoring investigation has detected several self-reported mild side effects after the vaccination. It provides useful information on the uptake in particular at the recent moment that knowledge on the side-effects is still limited. Continuous monitoring of safety and effectiveness is warranted to promote vast acceptance and uptake of COVID-19 vaccines.*

Keywords: COVID-19 Vaccines, Vaccination Uptake, Safety, Pandemic, China

1. Introduction

The COVID-19 pandemic has swept throughout the world and posed multifaceted substantial challenges in public health, the economy and society. To mitigate the pandemic, safe and effective vaccines are urgently needed. Development of vaccines was initiated when the genetical sequence of the virus was available in January 2020, since then more than 200 candidates derived from multiple platforms, including inactivated vaccines, live virus vaccines, recombinant protein vaccines, vectored vaccines, and DNA or RNA vaccines, have jointed the race and strived to pass the clinical evaluation stages, gradually adding knowledge on the nature of protective immune responses to COVID-19 [1].

In China, two inactivated vaccines Sinopharm and Sinovac have been recently approved with conditional marketing authorization for emergency-use in December 2020 and February 2021, respectively [2,3]. Then, the vaccination has been at first initiated targeting people who are occupationally exposed to high-risk of the infection, including those engaging in cold-chain imports and quarantine at ports / airports, maritime pilot, air crew, those working at fresh markets, those engaging in public transportation, healthcare staffs and those planning to go abroad in a short

term, for border enforcement to prevent the imported cases. For the nationwide uptake, it is expected to expand the vaccination coverage in stages, and high-risk populations are prioritized. On the other hand, limited knowledge on safety and effectiveness have provoked vaccine hesitancy domestically and globally as well [4-6].

To this end, since rolling out the vaccination in the hospital setting, we have initiated routine monitoring the occurrence of post-vaccination side effects from the vaccines and its affecting factors, in order to inform the large-scale uptake. This short report summarized latest findings of the effort.

2. Methods

The study has investigated those with good health status who were vaccinated with the full package of two doses at the vaccination center of a tertiary hospital in Jinan, China, in February 2021. They were derived from the key target groups with occupational exposure to the high-risk infection. We invited them to a brief online survey after two weeks of getting vaccinated via Wechat, an overwhelmingly used social network application in China. A total of 811 vaccinees have been eventually recruited and completed the online questionnaire, which included basic demographical information, the occurrence, duration and severity of self-reported post-vaccination side effects as listed in Table 1. Data collection was closed on March 16, 2021. The study has been approved by the ethical committee of the 4th People's Hospital of Jinan, China.

		N	%
Age group	< 20 years	26	3.21
	20-29 years	332	40.94
	30-39 years	253	31.2
	40-49 years	131	16.15
	50-59 years	69	8.51
Sex	Male	407	50.18
	Female	404	49.82
Location	Shandong Province	800	98.64
	Other provinces	11	1.36
Education	Middle school or below	18	2.22
	High school	61	7.52
	University / College	599	73.86
	Graduate school or above	133	16.4
Occupation	Professionals	294	36.25
	Formal sector staff	273	33.66
	Student	182	22.44
	Others	62	7.64
Vaccines	1	294	36.25
	2	517	63.75

Table 1. Basic information of the participants

Data were analyzed by using Stata 15.0. At first, participants' attitude to the vaccination and the occurrence of self-reported post-vaccination side effects were summarized by using univariate analysis. Then, a multivariate regression analysis was performed to determine independent factors affecting the occurrence of the side effects.

3. Results

Table 2 reflected participants' perception aspects to the vaccination, including knowledge on the vaccines, the main reason to get vaccinated, willingness to get vaccinated, recommendation to others, concerns on the vaccines, perceived effectiveness, and perceived safety. Regarding knowledge on the vaccines, among 811 vaccinees, 69.8% perceived themselves knowing a little and 25.9% having good knowledge. For the main reason to get vaccinated, a majority of the vaccines answered either occupational exposure to the high-risk (39.5%) or planning to go aboard (51.9%). Most of them showed willingness to get vaccinated (98.8%) and to recommend to others (96.2%), with relevant high proportions of perceived safety (99.5%) and effectiveness (97.3%). The detailed concerns on the vaccines included getting infected after vaccination (69/811, 8.5%), ineffectiveness for the mutant strain (195/811, 24.0%), unknown risks due to the short time on the market (232/811, 28.6%), and unknown length of the protection period (191/811, 23.6%).

		N	%
Knowledge on the vaccines	No knowledge	35	4.32
	Knowing a little	566	69.79
	Knowing a lot	210	25.89
Reasons to get vaccinated	Occupational exposure	320	39.46
	Planning to go abroad	421	51.91
	No special reason or others	70	8.63
willingness to get vaccinated	Not willing	10	1.23
	Fairly willing	408	50.31
	Strongly willing	393	48.46
Recommendation to others	Not willing	31	3.82
	fairly willing	533	65.72
	Strongly willing	247	30.46
Perceived effectiveness	Limited effectiveness	22	2.71
	No idea	460	56.72
	Good effectiveness	329	40.57
Perceived safety	Limited safety	4	0.49
	No idea	323	39.83
	Good safety	484	59.68
Total		811	

Table 2. Knowledge, willingness and perceptions

Among 811 vaccinees, there have been 66 participants who reported one or more side effects (8.1%), which was fully listed in Table 3. All of these symptoms disappeared within 2 weeks. The most frequently reported side effects were including soreness in the injection site (46 vaccinees), somnolence (38 vaccinees), and tiredness (31 vaccinees). On the other hand, there was no severe cases that required clinical measures as the results of monitoring these participants. We input the age group by 10 years, educational background, occupation, history of allergy, history of immune deficiency and type of the vaccines in the multivariate regression analysis. The result suggested those with history of immune deficiency were more likely to report side effect(s) (OR=4.16, 95% CI: 1.03-16.85), while other factors did not have significant impact on the target outcome.

	N	%
Redness at the injection site	3	0.37
Swelling at the injection site	8	0.99
Hardening at the injection site	3	0.37
Burning sensation at the injection site	2	0.25
Soreness in the injection site	46	5.67
Bruising at the injection site	2	0.25
Itching at the injection site	1	0.12
Fever	4	0.49
Feeling cold	2	0.25
Shaking Chill	1	0.12
Oppression in chest	1	0.12
Headache	11	1.36
Arthralgia	2	0.25
Myalgia	13	1.60
Neuralgia	1	0.12
Dizziness	9	1.11
Somnolence	38	4.69
Nausea	2	0.25
Diarrhea	4	0.49
Anorexia	1	0.12
Tiredness	31	3.82
Eruption	1	0.12
Eczema	1	0.12
Elevated heart beat	1	0.12
Fatigue	2	0.25
Hypopsia	1	0.12
Weakness	5	0.62
Emotional instability	2	0.25
Others	2	0.25

Table 3. List of self-reported side effects

4. Discussion

To our knowledge, this is the first short report on side effects of the COVID vaccines in China. The latest monitoring results indicated an overall low-level occurrence of side effects, mostly manifesting mild temporary symptoms including inoculation site, somnolence and fatigue. To date, we confirmed that no severe case has been reported. The online survey also revealed overwhelm proportion of perceived safety (99.5%) and effectiveness (97.3%), though concerning issues remain in terms of getting infected after vaccination, ineffectiveness for the mutant strain, unknown risks due to the short time on the market, and unknown length of the protection period.

It is worthy to note potential limitations when interpreting these findings. First, our small-scale investigation derived from a relevantly short period of observation as a part of the ongoing routine monitoring in one hospital vaccination setting, and therefore have limited capacity to identify all adverse outcomes of the vaccination. Another fact limiting this capacity is that the investigation was in the initial phrase of the vaccination campaign in China, merely targeting those occupationally exposed to the high-risk infection, whereas the nationwide vaccination is gradually expanding to the general population. Moreover, these side effects as showed in the results were based on the self-report of the vaccinees, which is the first step of our routine monitoring to identify the occurrence, duration and severity of adverse reactions via the social networking platform, consequently followed by tracking the symptoms and necessary clinical procedures for severe / emergent or long-lasting cases (more than two weeks). To date, no serological test to identify the antibody level has been implemented in the study setting.

The latest findings on the ground nevertheless are informative to the upcoming expanded nationwide vaccination. The current low-level occurrence of mild and temporary side effects is in favor of the vaccine safety and supportive to the uptake of the universal

vaccination by improving the acceptance and dismantling the behavioral barriers, which remained as a spreading concern substantially due to limited information on the safety in China and the world. With expanding of the large-scale vaccination, more monitoring data from both research and real-world are expected to further fill the knowledge gap [7,8].

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