

Safety of BBIBP-CorV (Sinopharm) COVID-19 Vaccination in People With Multiple Sclerosis: A Report From Iran

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Abstract

Introduction: Vaccination against SARS CoV-2 started on March 2020 in Iran and people with multiple sclerosis (pwMS) have a priority to be vaccinated in line of other high-risk population. Up to now, BBIBP-CorV (Sinopharm) is the main vaccine which have been used in Iranian population, and in high risk population such as pwMS.

Method: In this survey, the safety and possible side effects of this vaccine after the first or/and second doses in 520 pwMS have been assessed from July to August 2021. MS Patients who have received one or two doses of Sinopharm vaccine were evaluated.

Results: Around 44% of pwMS who received Sinopharm reported few minor side effects, whereas its side effect have been reported in 60% of patients who

received the second dose. All side effects have begun within the first 24 hours and subsided between 48-96 hours afterward. No serious side effects or mortality have been reported. There was no correlation between the side effects and age, the disability status, and the type of first or second line DMDs (disease modifying drugs). Only some side effects were significantly higher in the progressive form of the disease.

Conclusion: MS patients can receive Sinopharm vaccine safely and the minor side effects should not scare them.

Introduction

Uncontrolled outbreak of coronavirus disease 2019 (COVID-19) caused remarkable morbidity, mortality and economic challenges all over the world [1]. Vaccination has been among the most effective and cost benefit interventions to control this pandemic [2]. Vaccination has been started since March 2020 in Iran and pwMS as well as health care workers, immunocompromised patients, and elderly people had priority for getting vaccine. In spite of the priority for vaccination, there might be somehow hesitancy for vaccination among pwMS because of immunomodulatory and immunosuppressive medications. Moreover, fearing of lack of efficacy of the vaccines, possible adverse effects on the course of disease, or interference with their regular medications are other obstacles. However, at the time of this report many of the pwMS patients received their vaccine.

There are some kinds of COVID-19 vaccine approved yet including BNT162b2 (Pfizer), Sinopharm BBIBP-CorV, Johnson & Johnson's Janssen, AstraZeneca and etc. Given that Sinopharm BBIBP-CorV is the main vaccine which have been used in Iranian population and also in pwMS patients (<https://irangov.ir/ministry-of-health-and-medical-education>), lack of any data regard to safety of this vaccine in pwMS, we decided to investigate the safety and probable side effects which occurred after first and/or second doses of vaccine.

Methods

Through a large multicenter cross-sectional questionnaire-based clinical study, 892 patients

completed the questionnaire which evaluated the willingness and acceptability of COVID-19 vaccination in patients with MS. In that cross-sectional study, data was collected from five MS clinics of four different cities of Iran (Tehran, Esfahan, Ahvaz, and Mashhad) between May to June 2021[3].

Our screening was based on the patients who received the COVID-19 vaccines (Sinopharm) at this time period.

Total number of 520 vaccinated MS patients have been assessed for the safety of Sinopharm vaccine in this report. Patients who had not received the vaccine or received another type of vaccine, were excluded from the study.

Patients were asked about probable side effects including headache, chills and fever, weakness, gastroenteritis, injection site reaction (pain, redness and bruising) and etc.

Data analysis of this study was performed using SPSS version 19. Normality was evaluated by the Shapiro-Wilk's test. Descriptive statistical methods were administered and Chi-square and McNemar tests were performed to compare categorical Data between subgroups. P values less than 0.05 were considered significant.

Results

Overall 520 cases participated the study from which 77% were female. The baseline characteristics of the patients are listed in Table 1.

Mean age was 37.4 ± 8.58 years. The mean of disease duration was 8.5 ± 6.08 years. Housewives were 40% of the participants, 40% were employed and the remaining 20% were unemployed (5% due to MS, 2% due to COVID pandemic and the remaining 13% due to other personal reasons).

From 520 cases who received the first dose, 228 (44%) reported some minor side effects. Among those with any side effects, 61% reported only one side effect and only 8% reported 4 or more.

From all who had received the first does, 458

Table 1. Baseline characteristics of patients

Sex	Male	119	23%
	female	401	77%
Marital status	married	346	67%
	single	174	33%
Type of MS	relapsing	447	86%
	PP/SP	73	14%
EDSS	0 – 3.5	426	82%
	≥3.5	94	18%
DMDs	No DMDs	26	5%
	*First line DMDs	317	61%
	**Second line DMDs	176	34%
Occupation	Housewives	208	40%
	Working	208	40%
	Unemployed	104	20%
Comorbidity (DM, HTN, heart and lung dis., kidney dis., liver)	No	468	90%
	yes	52	10%
Disease duration (Mean± SD)	8.5 ± 6.08 years		100%

*First line DMDs are included: Interferon, Glatiramere acetate, Teriflunomide, Dimethylfumarate, Fingolimod

**Second line DMDs are included: Natalizumab, Ocrelizumab, Alemtuzumab, Mitoxantrone, Cladribine

Table 2. Prevalence of different side effects after injection of first and second dose of vaccine among MS patients

Adverse event	First	Second	P value
Headache	20%	8%	<0.001
Body pain	19%	10%	<0.001
Fever and chills	17%	8%	<0.001
Weakness	24%	12%	<0.001
Local injection reaction	8%	15%	<0.001
Gastric discomfort	3%	1%	0.004
Other complaints	3%	3%	1
No side effects	44%	35%	0.001
Anaphylaxis	0	0	-
Serious life threatening reaction	0	0	-
Death	0	0	-

(88%) had received the second dose at the time of this study, 275 cases (60%) had few side effects. Among those who reported any side effects, 65% reported only one side effect, while less than 4% reported 4 or more. Table 2

All of the side effects were transient, started within 24 hours after each shot and diminished 48-96 hours later.

No serious side effects or mortality were reported.

Twenty five percent of those with no side effects after first injection reported some complaints on second dose, while 52% of those with complaints on the first dose were symptom free after the second dose.

None of the side effects were significant, based on type of DMD, age, EDSS (Expanded Disability Status Scale), marital status, or university education. Regarding type of MS, fever and chills were reported more in progressive form compared to the relapsing type (26% vs. 16%, P value 0.04). Gastric discomfort was also more frequently observed in progressive type after the first (7% vs. 3%, $P=0.04$) and second (3% vs. 0.5%, $P=0.03$) injection.

Discussion

This is a short report about the safety of Sinopharm BBIBP-CorV in pwMS. This observational study, performed in a cohort of 520 pwMS in five MS clinics in Iran, during a broad survey of COVID-19 vaccine willingness and acceptability.

Safety of Sinopharm has been evaluated in general population through a cross-sectional survey study in University of Sharjah, UAE. After the first vaccine, they reported injection site pain, fatigue and headache which were more common in participants aged ≤ 49 years vs. >49 years. While pain at the vaccination site, fatigue, lethargy, headache and tenderness were the most common side effects post second dose in both groups [4].

According to our results, the most common side effects of the vaccine among pwMS were weakness, body pain and headache after the first dose, however local injection reaction was the most common adverse event after the second dose as the study of Saeed, B.Q., et al in

2021.

Our results are comparable with the results of Achiron, A, et al, in which the frequency of any adverse event of BNT162b2 (Pfizer) COVID-19 vaccine among 435 multiple sclerosis patients were 29.7% and 40.2% after the first and second doses, respectively.

The most common reported adverse events in the mentioned study were local pain at the injection site, fatigue, headaches, muscle or joint pain, and flu-like symptoms like fever, chills or both [5].

Another study performed in United Kingdom, assessed the side effects of ChAdOx1nCoV-19 (AstraZeneca) vaccine in patients with multiple sclerosis. Almost all patients reported a few symptoms including a local pain in arm (70%), flu-like symptoms (64%), fever (21%), fatigue (27%), and headache (21%). In 66% of patients, symptoms lasted up to 48 h. In all of the mentioned studies, as well as our study, no severe life threatening adverse effects and death occurred [6].

Side effects of Sinopharm vaccine has been assessed in healthcare workers by R Shahid, et al. Among total 216 vaccinated healthcare workers, greater proportion (43.6%) complained of vaccine related side effects after the second dose than 37.5% subjects who noted side effects after the first dose of vaccine. Myalgia, injection site pain, headache and fever were established as the most common post-vaccination side effects [7].

Another study performed by Abu-Halaweh, et al, compared the adverse effects of Pfizer-BioNTech and Sinopharm COVID-19 Vaccines in 1004 participants. From 513 participants who received Sinopharm vaccine, 30.8% had an adverse reaction, 17.7% noted local side effects and 17.5% systemic side effects after the first dose. These amounts were 32.8, 14.8 and 22 after the second dose.

The most common early adverse effect was pain at the site of injection, similar to our study [8].

Also M Etemadifar et al., reported that he BBIBP-CorV vaccine does not seem to affect short-term MS activity [9].

According to our findings, which are consistent

with other studies, given that the side effects are transient and not considerable, Sinopharm BBIBP-CorV vaccine in pw MS is safe and feasible.

The use of Sinopharm BBIBP-CorV in the Iranian population and in people with pwMS may need to be assessed with relevance to critical genes that are important to the immune system. The role of the anti-aging gene Sirtuin 1 that is linked to the immune system may be inactivated and the use of Sinopharm BBIBP-CorV vaccine with relevance to common side effects may need to be assessed in the absence of Sirtuin 1. Inactivation of Sirtuin 1 may lead to unstable primary and secondary responses that are critical to the use of Sinopharm BBIBP-CorV vaccine [10].

Conclusion

It seems that the Sinopharm BBIBP-CorV vaccine in patients with MS is safe and feasible. It could be used without any significant and serious adverse events. The most common side effect of this vaccine is compatible with other similar COVID-19 vaccines. No mortality has been reported in our vaccinated MS population.

Conflict of Interest

Authors declare no conflict of interest in this study.

Cover Letter

All authors have read the guide for authors of International Journal of Infection Prevention Journal and accepted it. Also, they approved the final draft of the manuscript entitled "Safety of BBIBP-CorV (Sinopharm) COVID-19 vaccination in people with multiple sclerosis: A report from Iran".

The mentioned manuscript is neither accepted for publication nor published in another journal in full or part (except in abstract form). We hereby assign the copyright of the enclosed manuscript to your J.

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