








Evaluation of the effectiveness and adverse effects of COVID-19 vaccines administered at Kashan University of Medical Sciences

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Abstract

Objectives: The development of protective immunity through COVID-19 vaccines is influenced by both host factors and the composition of the vaccine. Therefore, it is essential to assess the efficacy and side effects of different vaccines among individuals with diverse socioeconomic and genetic backgrounds.

Methods: In this cross-sectional descriptive study, we examined 192 vaccinated individuals (126 recipients of Sinopharm and 66 recipients of AstraZeneca) for neutralizing antibodies two to four weeks after receiving their second vaccine dose. Additionally, we monitored these individuals for the presence or absence of COVID-19 symptoms and adverse effects over a one-month period following vaccination.

Results: There was no significant difference in mean antibody titers between the Sinopharm and AstraZeneca vaccine groups ($p=0.452$). The percentage of positive antibody results in the Sinopharm and AstraZeneca groups was 69.8% and 84.8%, respectively, with no statistically significant variance ($p=0.437$). The most common side effect reported in the Sinopharm group was malaise (87.3%), while in the AstraZeneca group, malaise was also prevalent (95.5%). Compared to Sinopharm, the AstraZeneca group experienced a higher incidence of side effects ($p<0.05$). However, the Sinopharm group had a higher percentage of injection site pain as a complication ($p<0.001$).

Conclusion: Our study revealed that there is no significant difference in efficacy between Sinopharm and AstraZeneca vaccines in individuals without a history of COVID-19. Common side effects following COVID-19 vaccination were observed in both Sinopharm and AstraZeneca recipients, with higher frequencies noted in the AstraZeneca group in most cases. This information may aid individuals who are concerned about potential vaccine side effects in making informed decisions.

Keywords: COVID-19, Coronavirus vaccine, Efficacy, Adverse effects.

Introduction

At the end of December 2019 in China, the city of Wuhan in the province of Hubei witnessed a cluster of acute respiratory syndromes, now identified as novel coronavirus-infected pneumonia (NCIP).^[1,2] In severe COVID-19 cases, the progression to pneumonia with acute respiratory distress syndrome (ARDS) and hypoxic respiratory failure has been observed. Additionally, extrapulmonary organ involvement, such as cardiac,

neurologic, endocrine, gastrointestinal, hepatic, renal, ocular, and dermatologic complications, along with the loss of smell or taste pose significant health risks.^[3,4] Initial reports from Wuhan indicated that 26 to 33 percent of patients required specialized care, with reported death rates ranging from 4 to 15 percent in different regions.^[5,6] Subsequent waves of the disease revealed increased hospital admissions and higher mortality rates; however, improved awareness and treatment center availability were noted.^[7]

Immunosuppressive therapy emerged as a fundamental treatment strategy early on to address hyperinflammation and cytokine storm syndrome (CSS) in COVID-19 patients.^[8] Studies have demonstrated that immunosuppressive therapies like systemic corticosteroids, janus kinase (JAKs) inhibitors, and inflammatory cytokine blockers targeting IL-6, IL-1, TNF α , and granulocyte-macrophage colony-stimulating factor (GM-CSF) are associated with reduced mortality rates.^[9,10] Despite these benefits, reports have highlighted several opportunistic infections in COVID-19 patients, including *Aspergillus* spp., *Candida* spp., *Cryptococcus neoformans*, *Pneumocystis jirovecii* (carinii), mucormycosis, cytomegalovirus (CMV), herpes simplex virus (HSV), Stroncorgiloside, *Mycobacterium tuberculosis*, and *Toxoplasma gondii*.^[11]

Vaccination plays a crucial role in preventing these infections and reducing hospitalization costs and duration.^[12] Antibody responses following vaccination or natural infection are pivotal in establishing immunity and preventing reinfection. Post-infection, the immune system produces natural neutralizing antibodies that block virus re-entry into the body.^[13-15] Prominent vaccine names include RNA vaccines (Pfizer-BioNTech and Moderna), conventional inactivated vaccines (BBIBP-CorV, Covaxin, and CoronaVac), viral vector vaccines (Sputnik V, Oxford-AstraZeneca, Convidicea, Johnson & Johnson), and the EpiVacCorona peptide vaccine.^[12,16] Notably, Sputnik and AstraZeneca vaccines have been utilized in Iran, while the Chinese Sinopharm (BBIBP-CorV) vaccine has also been administered. Real-world studies have demonstrated high and durable two- and three-dose inactivated vaccine effectiveness against severe/critical illness and death associated with Omicron across all age groups. However, these vaccines exhibit lower efficacy against Omicron infection itself, underscoring the importance of completing the full vaccination series and timely booster doses for eligible individuals.^[17] Furthermore, individuals who received the AZD1222 booster dose reported fewer symptoms compared to those who received three doses of Sinopharm.^[18]

Despite utilizing a safe and traditional vaccine manufacturing method similar to Sinopharm's, doubts persist among the general population regarding the effectiveness of Sinopharm's vaccine. Similarly, concerns surround the AstraZeneca vaccine due to reported side effects.^[19]

Considering the ongoing mutations of the COVID-19 virus in various regions and populations, the absence of specific treatments for the virus, and the diverse

environmental and genetic characteristics among individuals, it is imperative to investigate the efficacy and side effects of COVID-19 vaccines in different regions.

Objectives

This study aims to evaluate the effectiveness and side effects of different COVID-19 vaccines in the actual population of Kashan to address the question: Are Sinopharm and AstraZeneca vaccines effective in preventing COVID-19? Additionally, we seek to identify any complications these vaccines may have caused in individuals.

Methods

The study included individuals aged 18 and above with no prior history of COVID-19 or other infectious diseases within 14 days prior to the study, excluding those with vaccine contraindications. Participants were monitored for neutralizing antibody IgG levels two to four weeks after receiving the second dose of either Astrazenka or Sinopharm vaccine. Over the course of one month, individuals were assessed for COVID-19 symptoms (fever, shortness of breath, cough, muscle pain, etc.) and post-vaccination complications (fever, myalgia, rash, hypotension, dizziness, itching, nausea-vomiting, joint pain, pericarditis, cough), with all observations recorded in a checklist. Antibody levels were determined using ELISA methods, specifically anti-SARS-CoV-2 neutralizing antibodies by Pishtazteb kits. Interpretation of ELISA results were based on the Cut-off Index (COI) values as follows: COI <0.9 (negative), COI 0.9–1.1 (borderline), COI >1.1 (positive).

The protocol for measurements was approved by the Department of Health at Kashan University of Medical Sciences.

A comprehensive checklist was created, covering demographic characteristics and vaccine-related complications. Demographic data included age, sex, blood group, BMI, smoking history, systemic diseases, and their types. Common complications associated with COVID-19 vaccines and other vaccines from previous studies were categorized into 12 groups following expert consultation across various medical disciplines: Constitutional, Skin, Local, Upper Respiratory Tract (URT), Pulmonary, Gastrointestinal, Musculoskeletal, Hematologic, Neurologic, Autoimmune, Renal, and Cardiovascular. Data collection was completed through researcher-conducted telephone or face-to-face interviews.

The continuous variables were expressed as the mean \pm

SD, and the categorical variables were presented as a percentage and frequency. Because the data showed a non-normal distribution, data analysis was performed with Chi-squared test, Fisher's exact test, independent t-test, ANCOVA, and logistic regression. All statistical analyses were performed with SPSS (version 26.0, SPSS Inc, Chicago, IL, USA). A "P-value" less than 0.05 was considered significant.

The study was conducted in accordance with the Declaration of Helsinki. This study received approval from the Ethical Committee of Kashan University of Medical Sciences (Code: IR.KAUMS.REC.1400.047). The present study did not interfere with the process of diagnosis and treatment of patients and all participants signed an informed consent form.

Results

Between April and May 2021, a total of 200 individuals who had received either the Sinopharm or AstraZeneca vaccines were randomly selected for the study. Due to the

voluntary nature of vaccine administration, the number of individuals vaccinated with Sinopharm was twice that of those vaccinated with AstraZeneca. Consequently, the Sinopharm group consisted of 126 individuals, while the AstraZeneca group comprised 66 individuals. During the study, 6 individuals declined to have their neutralizing antibody levels measured, and 2 individuals did not cooperate in reporting side effects after one month, resulting in a final sample size of 192 participants.

Demographic characteristics were analyzed and are presented in Table 1, which includes age, gender, blood group, BMI, smoking status, presence of underlying diseases, and their types. The mean age of individuals in the Sinopharm group was significantly higher than that of the AstraZeneca group ($p < 0.001$). Furthermore, 65.1% of individuals in the Sinopharm group had at least one underlying disease, compared to 43.9% in the AstraZeneca group ($p = 0.005$). Notably, rheumatoid arthritis was more prevalent in the Sinopharm group at 29.4% compared to only 1.5% in the AstraZeneca group ($p < 0.001$).

Table 1. Demographic characteristics of individuals in Sinopharm and AstraZeneca groups

Variable		AstraZeneca (n=66)	Sinopharm (n=126)	P value
Sex	Male	23 (8.34)	41 (5.32)	0.747*
	Female	43 (2.65)	85 (5.67)	
Age (year)		42.11±61.43	55.11±27.58	0.000**
Blood group	A+	17 (8.25)	33 (2.26)	0.983***
	A-	2 (3)	4 (2.3)	
	B+	13 (7.19)	28 (2.22)	
	B-	1 (5.1)	2 (6.1)	
	AB+	3 (5.4)	7 (5.6)	
	O+	24 (4.36)	45 (7.35)	
	O-	6 (1.9)	7 (6.5)	
Obesity ($30 \geq \text{BMI}$)		12 (2.18)	36 (6.28)	0.114*
Smoking/drug use		6 (1.9)	25 (8.19)	0.055*
The presence of at least one underlying disease		29 (9.43)	82 (1.65)	0.005*
Type of underlying disease	Diabetes	11 (7.16)	28 (2.22)	0.363*
	Hypertension	7 (6.10)	15 (9.11)	0.788*
	Cardiovascular	10 (2.15)	28 (2.22)	0.243*
	Pulmonary	8 (1.12)	11 (7.8)	0.455*
	Renal	0	4 (2.3)	0.301***
	Rheumatoid Arthritis	1 (5.1)	37 (4.29)	0.000***
	Malignancy	1 (5.1)	2 (6.1)	1***
	Organ transplant	0	1 (8.0)	1***

The data in the table are reported as (percentage) frequency or average± standard deviation.

* Chi-squared test/ ** Independent t-test/ *** Fisher's exact test

Analysis of antibody titers in Table 2 revealed no significant difference between the Sinopharm and AstraZeneca groups ($p=0.452$). The proportion of individuals with positive antibody results was 69.8% in the Sinopharm group and 84.8% in the AstraZeneca group, with no significant difference observed ($p=0.437$).

Table 3 presents the most common side effects reported by individuals in each vaccine group. In the Sinopharm group, malaise (87.3%), injection site pain (87.3%), fever (64.3%), and myalgia (56.3%) were the predominant side

effects. Conversely, individuals in the AstraZeneca group reported malaise (95.5%), myalgia (80.3%), fever (72.7%), and injection site pain (56.1%) as the most common side effects. Notably, the AstraZeneca group exhibited a higher prevalence of side effects such as chills, anorexia, weakness, fatigue, loss of smell, cough, dyspnea, nausea & vomiting, and myalgia compared to the Sinopharm group ($p<0.05$). The only exception was injection site pain, where the prevalence was higher in the Sinopharm group ($p<0.001$).

Table 2. Antibody titers in Sinopharm and AstraZeneca groups

Variable	AstraZeneca (n=66)	Sinopharm (n=126)	P value (Crude)	P value (Adjusted [§])
Antibody titer	118.75±71.78	101.98±81.02	0.118*	0.452***
Antibody Range[#]	Negative (<0.9)	(13.6) 9	0.037**	0.437****
	Borderline (0.9 to 1.1)	(1.5) 1		
	Positive (>1.1)	(84.8) 56		

The data in the table are reported as (percentage) frequency or average± standard deviation.

Results are based on COI and in the calculation of statistical tests, the borderline range was not considered.

&the variables of age, BMI, smoking/drug use, presence of at least one underlying disease and rheumatoid arthritis (p -value<0.25) were considered as covariates. * Independent t-test/ ** Chi-squared test/ *** ANCOVA/ **** Logistic regression

Table 3. The most common side effects in Sinopharm and AstraZeneca groups

Complications	AstraZeneca (n=66)	Sinopharm (n=126)	P value *	
Constitutional	Fever	(72.7) 48	(64.3) 81	0.237
	Malaise	(95.5) 63	(87.3) 110	0.072
	Chills	(48.5) 32	(11.9) 15	0.000
	Diaphoresis	0	0	-
	Anorexia	(36.4) 24	(3.2) 4	0.000
	Weakness	(45.5) 30	(5.6) 7	0.000
	Fatigue	(50) 33	(19) 24	0.000
Skin	Rash	(4.5) 3	(7.9) 10	0.548
	Pruritus	(3) 2	(3.2) 4	1
	Urticaria	0	(3.2) 4	0.301
	Diffuse Erythema	0	(0.8) 1	1
	Hair loss	(1.5) 1	(7.1) 9	0.169
	Nail involvement	0	(1.6) 2	0.456
Local	Cellulitis	(3) 2	(8.7) 11	0.225
	Abscess	0	(0.8) 1	1
	Injection site pain	(56.1) 37	(87.3) 110	0.000
Upper respiratory tract	Sore throat	(10.6) 7	(11.1) 14	0.915
	Rhinorrhea	(16.7) 11	(7.9) 10	0.066
	Anosmia	(10.6) 7	(1.6) 2	0.009
	Taste loss	(3) 2	0	0.117
	Otitis	0	(3.2) 4	0.301
	Hearing loss	0	(1.6) 2	0.546
	Sinusitis	0	0	-
Pulmonary	Cough	(22.7) 15	(7.9) 10	0.004
	Dyspnea	(15.2) 10	(3.2) 4	0.006
	pneumonia	0	(2.4) 3	0.552

Gastrointestinal	Diarrhea	(3) 2	(4) 5	1
	Nausea & Vomiting	(24.2) 16	(7.9) 10	0.002
	Abdominal pain	(24.2) 16	(5.6) 7	0.054
	Hepatitis	0	0	-
Musculoskeletal	Myalgia	(80.3) 53	(56.3) 71	0.001
	Arthralgia	(19.7) 13	(10.3) 13	0.071
	Arthritis	(4.5) 3	(5.6) 7	1
	Reactive Arthritis	(3) 2	(3.2) 4	1
Hematologic	Anemia	(1.5) 1	(2.4) 3	1
	Leukopenia	(1.5) 1	(1.6) 2	1
	Thrombocytopenia	(1.5) 1	(3.2) 4	0.662
	Thrombosis	(4.5) 3	(3.2) 4	0.693
	Immune thrombocytopenia	0	0	-
Neurologic	Headache	(39.4) 26	(34) 34	0.078
	Vertigo	(10.6) 7	(11.1) 14	0.915
	cerebrovascular accident	0	(0.8) 1	1
	Seizure	0	(0.8) 1	1
	Bell's palsy	0	0	-
	Guillain-Barre	0	0	-
Renal	Hematuria	(1.5) 1	0	1
	Proteinuria	(1.5) 1	(5.6) 7	0.267
	Glomerulonephritis	0	0	-
	Hyponatremia	(1.5) 1	(4.8) 6	0.425
	Hypokalemia	(3) 2	(0.8) 1	0.272
Cardiovascular	Chest pain	(6.1) 4	(4.8) 6	0.739
	Myocardial infarction	0	(1.6) 2	0.546
	Pericarditis	0	0	-
	Myocarditis	0	0	-
	Hypertension	0	(2.4) 3	0.552

The data in the table are reported as (percentage) frequency. * Chi-squared test/Fisher's exact test

Discussion

Following the emergence of COVID-19, numerous vaccines with varying formulations were developed by different companies worldwide. The efficacy of vaccines in inducing protective immunity is influenced by both host factors and the vaccine's components and structure, necessitating the assessment of vaccine effectiveness across diverse social, economic, and genetic backgrounds.

In our study, the rates of positive antibody results in the Sinopharm and AstraZeneca groups were 69.8% and 84.8%, respectively, with no significant difference observed ($p=0.437$). Several studies have explored vaccine safety and side effects. For instance, Feng Y. conducted a Randomized Controlled Trial^[20] focusing on young individuals vaccinated with inactivated vaccines, reporting a 100% serum conversion rate with mild adverse reactions. Similarly, the Omran et al., study^[21] documented a neutralizing antibody positive rate of 67.4%, particularly

among older individuals, aligning closely with our findings.

In a study by Chau et al.,^[22] investigating neutralizing antibodies following different doses of the AstraZeneca vaccine, 98.1% of vaccinated individuals exhibited positive serum levels after two doses, mirroring our results. Contrary to the study by Pourakbari et al.,^[23] which reported higher neutralizing antibodies induced by AstraZeneca compared to Sinopharm, our study found a higher level of neutralizing antibodies in the AstraZeneca group without a significant difference between the two.

This disparity may be attributed to two main factors: firstly, previous research has shown that neutralizing antibody titers decline with age,^[24] and notably, the mean age of individuals in the Sinopharm group was significantly higher than that of the AstraZeneca group ($p<0.001$). Secondly, Pourakbari et al.,'s study included individuals with a history of COVID-19, unlike our

exclusion criteria.

In this study, the average age of the Sinopharm vaccine group was significantly higher than that of the AstraZeneca group ($p < 0.001$). Pourakbari's study reported a mean age of 40 ± 9 , slightly lower than the age range observed in our study. Additionally, their study did not exclude individuals with a history of COVID-19.

In a study similar to ours, Anvari et al.,^[24] found that individuals around 35 years old showed AstraZeneca to have a stronger effect in increasing neutralizing antibodies compared to the Sinopharm vaccine. However, an important point to note is the exclusion criteria used in their study, which included individuals with a history of alcohol usage, smoking, infections with hepatitis viruses and HIV, autoimmune disorders, malignancies, allergies, anaphylaxis, immunocompromised status, corticosteroid use, and immunosuppressant drug intake. In contrast, our research included these individuals as part of the normal population.

Our study revealed higher neutralizing antibody results in the AstraZeneca group; however, these results did not show statistical significance. Noteworthy differences from previous studies include our study's age range of 18 to 65 years, exclusion of patients with a history of COVID-19 infection, a smaller population vaccinated with AstraZeneca compared to Sinopharm, and the timing of data collection at the onset of the COVID-19 pandemic before the emergence of new mutations.

In Iran, similar to many other countries,^[25] the acceptance rate of potential COVID-19 vaccines was poor. During face-to-face interviews, one of the primary concerns expressed by individuals was related to the potential side effects associated with vaccines. Just like any other medication or vaccine that offers treatment and prevention, there is a possibility of adverse effects.

In our study, the group receiving the Sinopharm vaccine exhibited common side effects such as malaise (87.3%), injection site pain (87.3%), fever (64.3%), and myalgia (56.3%). On the other hand, in the AstraZeneca group, common side effects included malaise (95.5%), myalgia (80.3%), fever (72.7%), and injection site pain (56.1%). Meo et al.'s study^[26] highlighted common side effects of the Sinopharm vaccine, including injection site pain, general malaise, myalgia, body aches, low-grade fever, and headache. In Babae et al.'s study,^[27] the most reported Sinopharm side effects after 72 hours from the second dose were general fatigue, local reactions, chills, fever, dizziness, and headache. However, unlike other studies,^[26, 28-30] a significant portion of individuals experienced no adverse effects (82.2%).

Ganesan et al.'s study^[28] also identified common Sinopharm adverse effects as injection site pain, drowsiness and fatigue, muscle and joint pain, headache, and fever, aligning with our findings. Similarly, for AstraZeneca adverse effects, Babae et al.'s study^[27] reported general fatigue, skeletal pain, chills, fever, dizziness, and fever in the AstraZeneca group. However, similar to the Sinopharm group, it appears to have been underestimated. Yesuf et al.'s study^[31] highlighted headache, fatigue, fever, and joint and muscle pain as the most common adverse effects. Desalegn's study also noted injection site pain as the most reported symptom, followed by headache, fatigue, tenderness at the site, fever, and joint pain.^[31]

Comparing the adverse effects of the two vaccine groups revealed that the AstraZeneca group had a higher percentage of side effects such as chills, anorexia, weakness, fatigue, loss of smell, cough, dyspnea, nausea and vomiting, and myalgia, which was statistically significant. Only in terms of injection site pain, the Sinopharm group had a higher percentage. This trend is consistent with other studies on Sinopharm and AstraZeneca vaccines.^[33,34] Omeish et al.'s study^[33] indicated an overall dominance of AstraZeneca adverse effects. However, in contrast to our study, injection site pain was higher in the AstraZeneca group. Hatmal et al.'s study^[34] showed significantly higher severity of side effects with AstraZeneca compared to other groups. Al-Muftay et al.'s study^[35] also reported more side effects in the AstraZeneca group overall.

One limitation of our research was the lack of assessment of the vaccine's effectiveness against mutated strains of the coronavirus.

Conclusions

The study revealed that the efficacy of Sinopharm and AstraZeneca vaccines in individuals without a history of COVID-19 did not show a significant difference between them. Both vaccines were found to induce a suitable level of neutralizing antibodies in the host's body within 2 weeks after the administration of the second dose. Therefore, both vaccines can be considered effective in providing protection against COVID-19 in the general population. Additionally, while side effects following vaccination with Sinopharm and AstraZeneca vaccines were common, they were generally mild, predictable, non-serious, and non-life-threatening. It is worth noting that complications were more frequent in the AstraZeneca group, which should be considered by individuals concerned about vaccine side effects.

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Competing interests

The authors declare that they have no competing interests.

Abbreviations

Coronavirus disease 2019: COVID-19;
 Novel coronavirus-infected pneumonia: NCIP;
 Acute respiratory distress syndrome: ARDS;
 Cytokine storm syndrome: CSS; Janus kinase: JAKs;
 Granulocyte-macrophage colony-stimulating factor: GM-CSF;
 Cytomegalovirus: CMV; Herpes simplex virus: HSV;
 Cut-off Index: COI; Upper Respiratory Tract: URT.

Authors' contributions

Conceptualization: ZS and KE; Methodology: MJA; Formal Analysis: MJA; Writing- Original Draft Preparation: MMSK and RE; Review and Editing: MMSK and RE. All authors read and approved the final manuscript. All authors take responsibility for the integrity of the data and the accuracy of the data analysis.

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Availability of data and materials

The data used in this study are available from the corresponding author on request.

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki. This study received approval from the Ethical Committee of Kashan University of Medical Sciences (Code: IR.KAUMS.REC.1400.047). The present study did not interfere with the process of diagnosis and treatment of patients and all participants signed an informed consent form.

Consent for publication

By submitting this document, the authors declare their consent for the final accepted version of the manuscript to be considered for publication.

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