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Research Article

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Sars-Cov-2 Breakthrough Infection and Death in Covid-19 Vaccines Recipients in North of Iran in 2021

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Abstract

Aim: *This study aimed to assess the cases of SARS-CoV-2 breakthrough infection and death among, Sinopharm, Sputink V, Soberana, and COVAXIN vaccines receivers in Mazandaran.*

Methods: *This retrospective cohort study was involving 320260 cases who received fully vaccinated (two doses) with five types of COVID-19 vaccine (ChAdOx1 nCoV-19, Sinopharm, Sputink V, Soberana, and COVAXIN) between February 2021 to August 2021 in the Mazandaran province. The outcomes of interest were SARS-CoV-2 breakthrough infection and death due to COVID-19 after vaccination. Data were analyzed using R software.*

Results: *Among 320260 COVID-19 vaccine recipients, 712 (0.22%) cases of SARS-CoV-2 breakthrough infections were identified and 94 (0.029%) hospitalized patients died from COVID-19. The cases of SARS-CoV-2 breakthrough infections were in Sinopharm (0.26%), ChAdOx1 nCoV-19 (0.09%), Sputnik (0.21%) Soberana (0.01%) and Covaxin (0.38%), respectively. The cases of death in vaccine recipients in Sinopharm, AZD1222, Sputnik, Soberana, and Covaxin were 81, 11, 1, 1, and 0 cases, respectively. A significant difference was observed between COVID-19 vaccines in terms of death ($P<0.05$).*

Conclusion: *Based on the findings, the most cases of SARS-CoV-2 breakthrough infection and death were observed in Sinopharm vaccine receivers.*

Keywords: COVID-19, SARS-CoV-2 Breakthrough Infection, Mortality Rate, Covid-19 Vaccines

Introduction

During the recent outbreak of pneumonia in January 2020, the seventh human coronavirus, coronavirus 2 (SARS-CoV-2), was detected in Wuhan, Hubei Province, China [1-3]. SARS-CoV-2 is highly contagious, spread worldwide in a short period, and was declared a pandemic by the World Health Organization (WHO) on March 11, 2020 [4]. Since then, the virus has spread worldwide, infecting 458,479,635 people and killing 6,047,653 as of March 12, 2022. In addition, as of March 12, 2022, 10,704,043,684 vaccinations had been administered [5]. Comorbidities such as older age, male gender, elevated inflammatory markers, hypertension, and cardiovascular disease are currently considered to be significant risks of COVID19-related hospitalization [6-16]. The increase in COVID19-related mortality with age is similar to the aging rate of the population. On average, people over the age of 65 have a surprisingly higher COVID19 mortality rate than younger people, and men have a higher risk of COVID19 death than women. People with cardiomyopathy with signs of acute inflammation and intrinsic organ damage are at increased risk of dying from COVID19 infection and require intensive care [17, 18].

Countries worldwide are beginning to take action to reduce infectious diseases and mortality. These measures can be divided into four categories: social distance, home isolation, school closure, and incident isolation. Antiviral agents such as lopinavir/ritonavir, remdesivir, and novel molecules (11a and 11b) help control the clinical progression and complications of COVID19. In addition to previous experience with SARS patients, anti-inflammatory drugs (including monoclonal antibodies) have been used in rheumatology to suppress the immune response. Although precautions are still needed, approved vaccines provide a high level of protection against actual SARSCoV2.

Several vaccines to protect against COVID19 infections are available in different countries. These vaccines are available on a variety of platforms. One group of these vaccines contains modified nucleoside messenger RNA (modRNA). Of these, BNT162b2 was developed by Pfizer / Biontech, a formulation of lipid nanoparticles, and the messenger RNA is nucleoside-modified (mRNA) and includes the entire column length. On the surface, it encodes a variant of the reperfusion construct SARSCoV2, and the mRNA 1273 developed by Moderna is also a lipid nanoparticle, encoding a pre-perfusion stable spike glycoprotein. When deployed in a high proportion of the adult population, currently approved vaccines effectively prevent COVID19, especially severe illness. Vaccination can reduce disease severity or reduce mortality. For example, the vaccine's effectiveness against infection in a large cohort of 49,220 US health care workers with a median age of 41 years exceeded two doses of BNT162b2 or mRNA1273 of 96 years. More openly available data are urgently required on the efficacy and effectiveness of these vaccines. This study aimed to assess the cases of SARS-CoV-2 breakthrough infection and death among ChAdOx1 nCoV-19, Sinopharm, Sputink V, Soberana, and COVAXIN vaccines receivers.

Methods

The retrospective cohort study was performed in the Mazandaran province, Iran between February 2021 to August 2021. A total of 320260 cases were included in the study. Data were collected from electronic medical records of 21 cities. The inclusion criteria included: 1) COVID-19 vaccine recipients (two doses of ChAdOx1 nCoV-19, Sinopharm, Sputink V, Soberana, and COVAXIN vaccines), 2) SARS-CoV-2 breakthrough infection after vaccination (after 000 days after the second vaccination), 3) Positive reverse transcription-polymerase chain reaction (RT-PCR) diagnostic test (of pharyngeal specimens), 4) death, 5) Complete and available outcome information. All patients' data remained confidential.

The variables of this study focused on age, sex, type of COVID-19 vaccines, SARS-CoV-2 breakthrough infection, and death. This study was approved by the ethics committee of Mazandaran University of Medical Sciences, Mazandaran, Iran with the ethical code number of IR.MAZUMS.REC.1400.11485.

Descriptive analysis of the collected data was performed as mean (±SD: standard deviation). To compare the age between survivors and victims and between men and women, the independent t-test was used. For categorized variables, Chi-square and Fisher's exact test were used. Logistic regression was used to evaluate the risk factors with a significant effect on patient mortality. All analyzes were performed at a significance level of 5% using Statistical Package for Social Sciences (SPSS Inc., Chicago, Illinois, USA) version 24.0.

Results

A total of 320260 COVID-19 vaccine recipients, including ChAdOx1 nCoV-19, Sinopharm, Sputink V, Soberana, and COVAXIN were included in the study. The Demographic characteristic of COVID-19 vaccine recipients is shown in Table 1. The overall flow chart of COVID-19 vaccines recipients, SARS-CoV-2 breakthrough infection, and death of people is shown in Figure 1. A total of 320260 COVID-19 vaccine recipients, the cases of SARS-CoV-2 breakthrough infection and death were 712 and 94, respectively.

Table 1: Demographic characteristic of COVID-19 vaccine recipients

Characteristic	Sinopharm	AZD1222	Sputnik	Soberana	Covaxin
Sex (n=320260)					
Male (%)	115371 (49.63%)	32959 (50.30%)	7243 (48.69%)	2644 (52.27%)	902 (38.25%)
Female (%)	117077 (50.37%)	32561 (49.70%)	7633 (51.31%)	2414 (47.73%)	1456 (61.75%)
Total	232448 (72.58%)	65520 (20.46%)	14876 (4.64%)	5058 (1.58%)	2358 (0.74%)
Age (n=318345) *					
Mean (Min-Max)	66.15 (16-106)	66.24 (17-103)	45.87 (18-101)	57.50 (19-100)	40.01 (22-82)
<30					
30-40	5407 (2.33%)	4473 (6.83%)	2844 (19.33%)	16 (0.46%)	421 (19.03%)
40-50	7461 (3.21%)	4338 (6.62%)	3741 (25.42%)	41 (1.19%)	705 (31.87%)
50-60	8264 (3.56%)	3265 (4.98%)	3437 (23.36%)	146 (4.23%)	774 (34.99%)
60-70	33708 (14.50%)	2881 (4.40%)	2495 (16.96%)	2355 (68.24%)	298 (13.47 %)
70-80	97527 (41.95%)	14832 (22.64%)	531 (3.61%)	819 (23.73%)	13 (0.59%)
≥80	52625 (22.64%)	24468 (37.34%)	325 (2.21%)	70 (2.03%)	0 (0.00%)
	27456 (11.81%)	11263 (17.19%)	1341 (9.11%)	4 (0.12%)	1 (0.05%)
Total	232448(73.02%)	65520(20.58%)	14714(4.62%)	3451(1.08%)	2212(0.69%)

* Age was not mentioned for 1915 participants

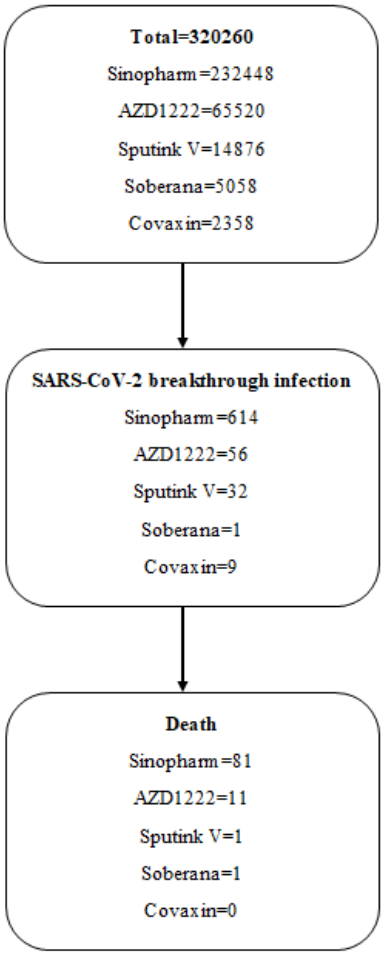

Figure 1: The overall flow chart of COVID-19 vaccines recipients, SARS-CoV-2 breakthrough infection and death

The overall SARS-CoV-2 breakthrough infection and death were 0.22% and 13.2%, respectively. The mean age of SARS-CoV-2 breakthrough infection for ChAdOx1 nCoV-19, Sinopharm, Sputink V, and COVAXIN were 75.38, 72.51, 48.22, and 45.67 years, respectively (Table 2).

Table 2: Number of SARS-CoV-2 breakthrough infection among COVID-19 vaccine recipients

Characteristic	Sinopharm (n=614)	AZD1222 (n=56)	Sputnik (n=32)	Soberana (n=1)	Covaxin (n=9)
Sex (n=712)					
Male (%)	319 (51.95%)	33 (58.93%)	16 (50.00%)	0 (0.00%)	3 (33.33%)
Female (%)	295 (48.05%)	23 (41.07%)	16 (50.00%)	1 (100.00%)	6 (66.67%)
Age (n=712)					
Mean (Min-Max)	72.51 (24-98)	75.38 (36-91)	48.22 (25-88)	-	45.67 (32-76)
<30					
30-40	8 (1.30%)	0 (0.00%)	5 (15.63%)	0 (0.00%)	1 (11.11%)
40-50	18 (2.93%)	1 (1.79%)	10 (31.25%)	0 (0.00%)	2 (22.22%)
50-60	20 (3.26%)	0 (0.00%)	8 (25.00%)	0 (0.00%)	6 (66.67%)
60-70	45 (7.33%)	3 (5.36%)	2 (6.25%)	1 (100.00%)	0 (0.00%)
70-80	120 (19.54%)	9 (16.07%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
≥80	232 (37.79%)	20 (35.71%)	1 (3.13%)	0 (0.00%)	0 (0.00%)
	171 (27.85%)	23 (41.07%)	6 (18.75%)	0 (0.00%)	0 (0.00%)
Total	614 (86.24%)	56 (7.87%)	32 (4.49%)	1 (0.14%)	9 (1.26%)

The mean age of overall SARS-CoV-2 breakthrough infection and death were 70.8 and 77.96 years, respectively. The majority of cases of SARS-CoV-2 breakthrough infection and death for all vaccines were in the age group over 70 years (Table 3).

Table 3: Number of Deaths among COVID-19 Vaccine Recipients

Characteristic	Sinopharm (n=81)	AZD1222 (n=11)	Sputnik (n=1)	Soberana (n=1)	Covaxin (n=0)
Sex (n=94)					
Male (%)	45 (55.56%)	9 (81.82%)	1 (100.00%)	0 (0.00%)	0 (0.00%)
Female (%)	36 (44.44%)	2 (18.18%)	0 (0.00%)	1 (100.00%)	0 (0.00%)
Age (n=94)					
<30					
30-40					
40-50	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
50-60	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
60-70	2 (2.47%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
70-80	6 (7.41%)	0 (0.00%)	0 (0.00%)	1 (100.00%)	0 (0.00%)
≥80	6 (7.41%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
	30 (37.04%)	5 (45.45%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
	37 (45.68%)	6 (54.55%)	1 (100.00%)	0 (0.00%)	0 (0.00%)
Total	81 (56.17%)	11 (11.7%)	1 (1.06%)	1 (1.06%)	0 (0.00%)

The highest and lowest cases of SARS-CoV-2 breakthrough infection were observed in Sinopharm (n=614, 86%) and Soberana (n=1, 0.001%), respectively. The highest SARS-CoV-2 breakthrough infection of ChAdOx1 nCoV-19, Sinopharm, Sputink V, Soberana, and COVAXIN vaccines was in the age groups of ≥80, 70-80, 30-40, 50-60 and 40-50 years, respectively. The lowest SARS-CoV-2 breakthrough infection of ChAdOx1 nCoV-19, Sinopharm, and Sputink V, vaccines was in the age groups of <30, <30, 60-70, and years, respectively. The rate of SARS-CoV-2 breakthrough infection for ChAdOx1 nCoV-19, Sinopharm, Sputink V, Soberana, and COVAXIN were 56 (7.86%), 614 (86%), 48.22, 32 (4.5%), 1 (0.14%), and 9 (1.26%), respectively. The overall estimation of SARS-CoV-2 breakthrough infections and death were in males greater than female. The assessment of clinical records showed that most of the deaths occurred in older people. The highest death belonged to patients who received Sinopharm vaccine. Proportion of mortality among COVID-19 vaccine recipients showed in Table 4.

Table 4: Proportion of Mortality among Covid-19 Vaccine Recipients

Characteristic	Sinopharm	AZD1222	Sputnik	Soberana	Covaxin	
Sex						
Male (%)	0.141	0.273	0.063	0	0	
Female (%)	0.122	0.087	0	1	0	
P-value	0.56	0.17	---	---	---	
Age						
<30	0	0	0	0	0	
30-40	0	0	0	0	0	
40-50	0.1	0	0	0	0	
50-60	0.133	0	0	1	0	
60-70	0.05	0	0	0	0	
70-80	0.129	0.25	0	0	0	
≥80	0.216	0.261	0.167	0	0	
P-value	0.001	---	---	---	---	P-value
Total	0.132	0.196	0.031	1	0	0.012

Results

Discussion

The purpose of this study was to assess the rate of SARS-CoV-2 breakthrough infection and death, as well as risk factors associated with ChAdOx1 nCoV-19, Sinopharm, Sputnik V, Soberana, and COVAXIN in in Mazandaran Province, Iran.

The results of study indicated that rate of SARS-CoV-2 breakthrough infection in ChAdOx1 nCoV-19, Sinopharm, Sputnik V, Soberana, and COVAXIN was 0.09%, 0.26%, 0.21%, 0.01%, and 0.38%, respectively. Arora et al. (30) showed that breakthrough infections were 7.91% in people who have been received least one dose of either Covaxin or Covishield. These differences can be explained due to risk factors including age groups, male gender, co-morbidities, prior SARS-CoV-2 infection, Beta or Delta variants, presence of symptoms and contact with a confirmed case, higher peri-infection neutralizing antibody titers, persons with immune dysfunction, occupation status that can impact on rate of breakthrough infections [17-23].

Showed that breakthrough cases among fully vaccinated health care workers were 2.6%. It must be pointed out that these people received two doses of the BNT162b2 vaccine. Reported that mortality rate was 22% [18,19].

However, these people had received the Pfizer/BioNTech's BNT162b2 vaccine. This high mortality rate is due to the fact that 96% of the participants in this study had underlying diseases including hypertension, diabetes, congestive heart failure, chronic kidney and lung diseases, dementia and cancer. A possible explanation for this might be that patients with COVID-19 disease who have comorbidities, have greater progression of the disease and mortality rate [24,25]. The finding of a study showed that Patients with cancer who develop breakthrough COVID-19 following full vaccination remain susceptible to severe outcomes (48). Result of study in Turkey showed that reinfection was higher in two doses of Sinovac compare two doses of Pfizer/BioNTech, however in this study finding showed that hospitalization or mortality was observed in fully vaccinated patients [26]. IgG among and efficiency type of vaccine can impact on SARS-CoV-2 breakthrough infection, the Pfizer-BioNTech vaccine recipients had more positive IgG than Sinopharm recipients [27]. Taib et al. (2022) showed that mortality rate of COVID-19 is associated with vaccination status, age, and comorbidities. Among vaccinated individuals, the mortality rate of those who received inactivated vaccines was higher than the recipients of the BNT162b2 and ChAdOx1 vaccines.

This study supports evidence that age and type of vaccine can impact on mortality rate after vaccination [28]. The overall hospitalization risk and mortality risk for patients with hematologic malignancies were 37.8% and 5.7%, respectively that significantly higher than those who had no breakthrough infections [29].

The results of current study indicated that SARS-CoV-2 breakthrough infection was higher in males than females who have received Sinopharm and ChAdOx1 nCoV-19 vaccines. This finding is consistent with other studies [30,31]. However, it was higher in females than males who have received Soberana and COVAXIN vaccines. This finding is consistent with the results of study indicated that the cases of SARS-CoV-2 breakthrough infection in Sputink vaccine was equal in both males and females [19,23]. Therefore, the male gender can be considered as a risk factor for SARS-CoV-2 breakthrough infection. The results of current study indicated that the majority cases of death occurred in males and older people (over 70 years). It seems that there is a relationship between gender, age and death after COVID-19 vaccination. Gup-

ta et al observed that fatality was 0.4% cases [31]. The results of study showed that the majority of SARS-CoV-2 breakthrough infection in Sinopharm and ChAdOx1 nCoV-19 vaccines were in people over 70 years of age, while in Sputink V, Soberana, and COVAXIN vaccines it was more in people under 60 years of age. This finding is consistent with that the median of age of breakthrough cases was under 53.

The results of study showed that number of cases of deaths was in people over 70 years. Majority of rate of SARS-CoV-2 reinfection was in the older people. This result is contrary to that of Bergwerk et al. (19) who found the average age of the 39 infected participates was 42 years. This result may be explained by the fact that healthcare workers with higher exposure to COVID-19 patients were at higher risk of breakthrough infection [17].

The results of study indicated that the most and least cases of SARS-CoV-2 breakthrough infection and death observed in Sinopharm and COVAXIN. Sinopharm provides partial protection against SARS COV 2 infection. That might be due to lack of its potential to detect recent variations in the protein structure of spike (S) protein of virus [32].

Conclusion

Our study showed that SARS-CoV-2 breakthrough infection and death was higher in males and older people. Older age, and male gender are significant risk factors in COVID-19 vaccines recipients.

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None

Conflict of Interest

The authors have no conflicts of interest to declare.

Data Availability Statement Information

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