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Research Article

Comparison of the efficacy of one, two, and third doses of BNT162b2 in patients suffering from cardiovascular diseases, respiratory diseases, and diabetes against COVID-19

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Abstract

The COVID-19 pandemic has had a major impact on human health around the world. Given the speed of the spread of the disease and its impact on people's lives, different countries including Jordan issued approval for the emergency use of the mRNA vaccine BNT162b2 for COVID-19. This respiratory disease has led to an increased risk of complications and significant mortality in patients with pre-existing medical conditions such as respiratory disease, cardiovascular disease, and diabetes. Vaccination against COVID-19 is recommended for people with chronic diseases to reduce the risk of infection, hospitalization, and death. The BNT162b2 vaccine has shown high efficacy in healthy adults. The results of our study suggest a high efficacy of the BNT162b2 vaccine in patients with diabetes and cardiovascular after the second and third doses compared to the first dose of the vaccine. Vaccine efficacy for the third dose was similar to that for the third dose while the effectiveness did not change between the first, second, and third doses in respiratory diseases.

In conclusion, receiving second and third doses of the COVID-19 vaccine was associated with a decreased risk of mortality and hospitalization compared with the first dose. Unfortunately, the efficacy of the first, second, and third doses was similar in respiratory patients.

Keywords

Covid-19, Vaccines, Diseaes, third dose, death, hospitalization

Introduction

For emergency use of mRNA vaccine BNT162b2 for COVID-19 was issued by the US Food and Drug Administration (FDA) on December 11, 2020. The efficacy of a vaccine against death, hospitalization, and infection has been demonstrated in observational studies and randomized controlled trials (Ioannou et al. 2022; Saadh and Jaber 2022). The pandemic of the coronavirus disease 2019 (COVID-19), which was caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), had a great impact on human health. COVID-19 has led to significant mortality and an increased risk of developing COVID-19 complications in patients with pre-existing health conditions such as cardiovascular disease diabetes, metabolic syndrome, and hypertension (Naruse et al. 2021; Saadh

and Jaber 2022). Vaccination for COVID-19 is recommended in patients with cardiovascular disease. The COVID-19 mRNA BNT162b2 vaccine has shown promising safety and efficacy in humans without pre-existing obvious comorbidities (Naruse et al. 2021).

The Pfizer – BioNTech BNT162b2 vaccine is based on an mRNA consisting of nucleoside-modified mRNA encoding a mutated form of the full-length SARS-COV-2 spike (S) protein that is stabilized in perfusion conformation as an immunogenic molecule or lipase-antigen-encapsulated antigen aids. The vaccine is given three weeks apart, intramuscularly, as two injections. BNT162b2 provides protection by triggering an immune system response to SARS-CoV-2 infection with spike (S) protein (Granados-Riveron and Aquino-Jarquin 2021). Because this vaccine only delivers mRNA encoding SARS-CoV-2 spike (S) protein, the immune response elicited is the production of immunoglobulin (Ig) M, IgA isotopes, and anti-S-RBD IgG, with the potential to neutralize inhibition of binding of RBD to cognate ACE2 receptors (Granados-Riveron and Aquino-Jarquin 2021). Vaccination for COVID-19 should be prioritized in diabetics, and patients with cardiovascular disease (Pal et al. 2021; Naruse et al. 2021). A cohort study showed that the efficacy of the BNT162b2 vaccine against infection and hospitalization after three doses was greater than the efficacy one month after the second dose (Tartof et al. 2022). This study aims to compare the efficacy of the first, second, and third doses of the BNT162b2 COVID-19 vaccine in patients with cardiovascular diseases, respiratory diseases, and diabetes.

Materials and methods

The study was conducted in the period from July 2021 to February 2022 in hospitals in Jordan. A total of 1917 patients who received one (n = 320; group 1), two (n = 1006; group 2), or three doses (n = 591; group 3) of (BNT162b2) COVID-19 vaccine participated in this study. Patients who participated in the study had one of the following chronic conditions: cardiovascular disease, respiratory disease, and diabetes. The mean age of the patients was 53 ± 17 years, 38% (728) were women, 62% (1189) were men, and 33% (633) of the participants were smokers. We calculated individually the percentage of groups of patients with cardiovascular disease, respiratory disease, and diabetes for death, infection without hospitalization, and infection with hospitalization to compare results and determine the efficacy of the (BNT162b2) COVID-19 vaccine.

Results

The number of deaths in all patients decreased with the additional dose of vaccine, except in patients with respiratory diseases where fewer patients died after the second dose compared to the number of deaths after the first dose (total percentage of deaths for the three diseases after first and second dose 34.74 and 13.12%, respectively), but there were similar percentages of deaths after the third dose (total percentage of deaths for the three diseases after second and third dose 13.12 and 13.03%, respectively). In patients with cardiovascular disease, the number of infected hospitalized patients decreased following the second and third doses of the vaccine, whereas the number of infected non-hospitalized patients increased following the second dose (Tables 1, 2, Fig. 1).

In patients with respiratory diseases, there was similar in the number of hospitalized and infected non-hospitalized patients after the second dose of the vaccine and a decrease in the number after the third dose of the vaccine. In patients with diabetes, there was a reduction in the number of deaths, infected hospitalized and non-hospitalized patients with each dose of the vaccine (Tables 1, 2, Figs 1–3).

Discussion

Immunity to SARS-CoV-2 induced by two doses of the BNT162b2 vaccine has been observed in various settings after a period of time which was confirmed by our study (Andrews et al. 2021; Chemaitelly et al. 2021; Goldberg et al. 2021; Rosenberg et al. 2021; Self et al. 2021; Skowronski et al. 2021; Tartof et al. 2021, 2022). However, after the third dose of BNT162b2, the level of protection against SARS-CoV-2 was similar in all patients who participated in our study. Our results are consistent with the results of other studies (Lasagna et al. 2022; Romero-Ibarguengoitia et al. 2022; Spitzer et al. 2022). In patients with cardiovas-

Table 1. Comparative Effectiveness of 1, 2, and 3-dose vaccination regimens.

Diseases	Complication	Pfizer 1st dose (N=320)		Pfizer 2nd dose (N=1006)		Pfizer 3rd dose (N=591)		X^2 for disease	X^2 for complication
		N	%	N	%	N	%		
Cardiovascular diseases	Death	44	13.75	28	2.78	13	2.20	0.57	0.61
	Infected without hospitalization	34	10.36	252	25.05	146	24.70		
	Infected with hospitalization	59	18.44	80	7.95	57	9.64		
Respiratory diseases	Death	65	20.31	102	10.14	64	10.83	0.49	0.57
	Infected without hospitalization	2	0.63	56	5.57	31	5.25		
	Infected with hospitalization	81	25.31	425	42.25	247	41.79		
Diabetes	Death	2	0.68	2	0.2	0	0.00	0.62	0.61
	Infected without hospitalization	26	8.13	60	5.96	33	5.58		
	Infected with hospitalization	7	2.19	1	0.10	0	0.00		

Table 2. Comparative Effectiveness of 2, and 3-dose vaccination regimens.

Diseases	Complication	Pfizer 2nd dose (N=1006)		Pfizer 3rd dose (N=591		X^2 for disease	X^2 for complication
		N	%	N	%		
Cardiovascular diseases	Death	28	2.78	13	2.20	0.018	0.021
	Infected without hospitalization	252	25.05	146	24.70		
	Infected with hospitalization	80	7.95	57	9.64		
Respiratory diseases	Death	102	10.14	64	10.83	0.023	0.019
	Infected without hospitalization	56	5.57	31	5.25		
	Infected with hospitalization	425	42.25	247	41.79		
Diabetes	Death	2	0.2	0	0.00	0.22	0.13
	Infected without hospitalization	60	5.96	33	5.58		
	Infected with hospitalization	1	0.10	0	0.00		

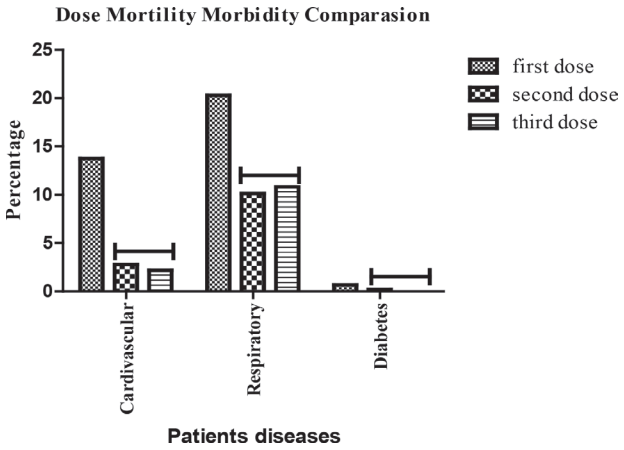

Figure 1. Comparison between 1st, 2nd+, and 3rd vaccine dose regarding mortality rate.

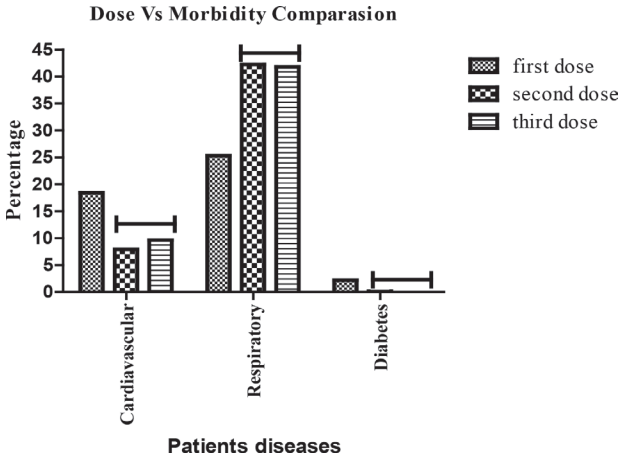

Figure 2. Comparison between 1st, 2nd+, and 3rd vaccine dose regarding morbidity rate.

cular disease, the number of infected patients increased after the second dose of the vaccine, while the number of infected patients was similar after the third dose. Antonelli et al. (2022) observed that a decrease in immunity occurs in patients with heart disease who received the first but not the second dose of the vaccine, while Hall et al. (2021) showed that there is an increase in immunogenicity in transplant patients. Nurse et al. (2021) showed that a higher number of infected patients occurs in patients with heart disease after the first dose of the vaccine compared

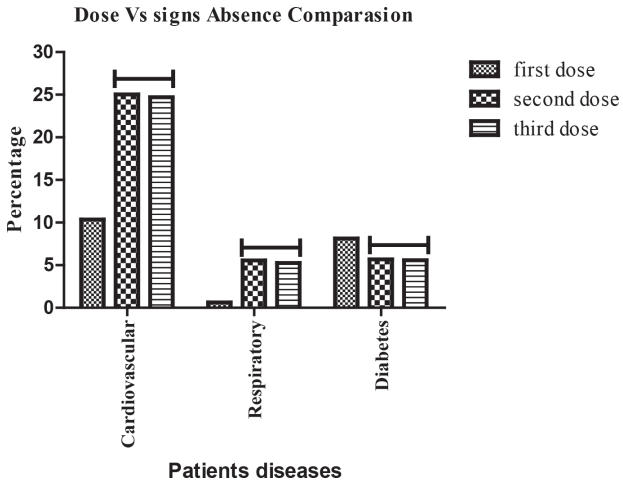

Figure 3. Comparison between 1st, 2nd+, and 3rd vaccine dose regarding signs and symptoms absence.

to healthy patients (Hall et al. 2021; Naruse et al. 2021; Antonelli et al. 2022). According to Moreira et al. (2022), the efficacy of the third dose of the BNT162b2 vaccine is 95% regardless of age, race, sex, ethnicity, and pre-existing disease (Moreira et al. 2022).

In our study, the vaccine was most effective in patients with diabetes, where there were two deaths after the first dose, two after the second dose, and no deaths after the third dose. The number of infected diabetics who were not hospitalized also decreased with the increase in the number of vaccine doses. However, among diabetics who received the second dose, there were fewer hospitalizations than after the first dose, and a similar in the percentages of hospitalized patients occurred after the third dose. Papadokostaki et al. (2022) an observational study that showed that at least two doses of vaccine are necessary for people with diabetes to ensure an immune response (Papadokostaki et al. 2022). Hirotsu et al. (2022) showed that there is an increase in the percentage of antibodies in patients with diabetes one week after the second dose of the vaccine, while Evans et al. (2022) and Barin et al. (2022) showed that antibody depletion occurs two months after the introduction of the second dose of vaccine (Hirotsu et al. 2021; Barin et al. 2022; Evans et al. 2022). Saciuk et al. (2022) an observational study that showed a high degree of efficacy

of the (BNT162b2) vaccine for the general population (91%, 93%, and 93% for death, hospitalization, and infection, respectively), and a slightly lower degree of efficacy in the elderly, diabetics, person with hypertension and obese (Saciuk et al. 2022). The (BNT162b2) vaccine did not eliminate the risk of death, or hospitalization, but did reduce the risk which is consistent with our results (Saadh and Jaber 2022; Saciuk et al. 2022).

According to Colaneri et al. (2021), a case study showed an exacerbation of asthma symptoms when the second dose of the BNT162b2 vaccine was introduced (Colaneri et al. 2021). Worsening of idiopathic pulmonary fibrosis is potentially associated with the BNT162b vaccine in a case study (Ghincea et al. 2022). Park et al. (2021) a case study also suggests that there is a potential link between worsening respiratory disease and the first dose of the BNT162b vaccine. Further studies involving more patients are needed to determine the effect of the BNT162b2 vaccine in patients with respiratory disease (Park et al. 2022; Saadh and Jaber 2022).

Conclusion

Receiving the second and third doses of the COVID-19 vaccine was associated with a lower risk of mortality and hospitalization than receiving the first dose. Unfortunately, the effectiveness of the first, second, and third doses in respiratory patients was comparable.

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