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COVID-19 vaccines: comparison of biological, pharmacological characteristics and adverse effects of Pfizer/BioNTech and Moderna Vaccines

S.A. MEO[1], I.A. BUKHARI[2], J. AKRAM[3], A.S. MEO[4], D.C. KLONOFF[5]

[1]Department of Physiology, [2]Pharmacology, College of Medicine, King Saud University, Riyadh, Saudi Arabia
[3]Department of Medicine, University of Health Sciences, Lahore, Pakistan
[4]Army Medical College, National University of Medical Sciences, Rawalpindi, Pakistan
[5]Diabetes Research Institute, Mills-Peninsula Medical Center, San Mateo, CA, USA

Abstract. – OBJECTIVE: The "Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)" disease has caused a worldwide challenging and threatening pandemic (COVID-19), with huge health and economic losses. The US Food and Drug Administration, (FDA) has granted emergency use authorization for treatment with the Pfizer/BioNTech and Moderna COVID-19 vaccines. Many people have a history of a significant allergic reaction to a specific food, medicine, or vaccine; hence, people all over the world have great concerns about these two authorized vaccines. This article compares the pharmacology, indications, contraindications, and adverse effects of the Pfizer/BioNTech and Moderna vaccines.

MATERIALS AND METHODS: The required documents and information were collected from the relevant databases, including Web of Science (Clarivate Analytics), PubMed, EMBASE, World Health Organization (WHO), Food and Drug Authorities (FDA) USA, Local Ministries, Health Institutes, and Google Scholar. The key terms used were: Coronavirus, SARS-COV-2, COVID-19 pandemic, vaccines, Pfizer/BioNTech vaccine, Moderna vaccine, pharmacology, benefits, allergic responses, indications, contraindications, and adverse effects. The descriptive information was recorded, and we eventually included 12 documents including research articles, clinical trials, and websites to record the required information.

RESULTS: Based on the currently available literature, both vaccines are beneficial to provide immunity against SARS-CoV-2 infection. Pfizer/BioNTech Vaccine has been recommended to people 16 years of age and older, with a dose of 30 µg (0.3 m) at a cost of $19.50. It provides immunogenicity for at least 119 days after the first vaccination and is 95% effective in preventing the SARS-COV-2 infection. However, Moderna Vaccine has been recommended to people 18 years of age and older, with a dose of 50 µg (0.5 mL) at a cost of $32-37. It provides immunogenicity for at least 119 days after the first vaccination and is 94.5% effective in preventing the SARS-CoV-2 infection. However, some associated allergic symptoms have been reported for both vaccines. The COVID-19 vaccines can cause mild adverse effects after the first or second doses, including pain, redness or swelling at the site of vaccine shot, fever, fatigue, headache, muscle pain, nausea, vomiting, itching, chills, and joint pain, and can also rarely cause anaphylactic shock. The occurrence of adverse effects is reported to be lower in the Pfizer/BioNTech vaccine compared to the Moderna vaccine; however, the Moderna vaccine compared to the Pfizer vaccine is easier to transport and store because it is less temperature sensitive.

CONCLUSIONS: The FDA has granted emergency use authorization for the Pfizer/BioNTech and Moderna COVID-19 vaccines. These vaccines can protect recipients from a SARS-CoV- 2 infection by formation of antibodies and provide immunity against a SARS-CoV-2 infection. Both vaccines can cause various adverse effects, but these reactions are reported to be less frequent in the Pfizer/BioNTech vaccine compared to the Moderna COVID-19 vaccine; however, the Moderna vaccine compared to the Pfizer vaccine is easier to transport and store because it is less temperature sensitive.

Key Words:
SARS-CoV-2 vaccine, Pfizer/BioNTech, Moderna vaccine, Pharmacology, Adverse effects.

Introduction

The "Severe Acute Respiratory Syndrome Corona virus 2 (SARS-CoV-2)" disease has caused

Corresponding Author: Sultan Ayoub Meo MD, Ph.D; e-mail: sultanmeo@hotmail.com
smeo@ksu.edu.sa

a challenging and threatening pandemic globally (COVID-19). This virus is highly contagious and has caused disruption of the world's health and economy[1]. The prevalence and mortality rates of SARSCOV-2 are changing on a daily basis[2]. According to World Health Organization (WHO) as of December 25, 2020, the COVID-19 pandemic involved 216 countries, and had affected 80.161.578,00 people with a fatality rate of 1.756.379,00 (2.19%)[3].

During the COVID-19 pandemic, globally people are facing major health care challenges, lockdowns, anxiety and stress[4], as there is no specific treatment and vaccination for this pandemic. Given the lack of specific therapy for and the rapid spread of this virus, vaccination would be a significant tool in the fight against the SARS-CoV-2 pandemic. More recently, on December 11, 2020 and December 18, 2020, respectively, the US Food and Drug Administration (FDA), granted emergency authorization to the Pfizer/BioNTech[5,6] and Moderna COVID-19 vaccines[7]. These two COVID-19 vaccines were developed quickly to benefit humanity and arrest the rise in the number of SARS-CoV-2 cases. From the time when the SARS-CoV-2 genome was released in early 2020[8] until these two vaccines received EUA status, less than one year passed. The fastest any vaccine had previously been developed, from viral sampling to approval, was four years, for mumps in the 1960s[9]. There have been some concerns about potential adverse effects of these vaccines. The present study aims to highlight evidence about the pharmacological characteristics, indications, contraindications and adverse effects of Pfizer/BioNTech and Moderna vaccines.

Materials and Methods

The required informations were collected from relevant databases, regarding the pharmacology, indications, contraindications, and adverse effects of Pfizer/BioNTech and Moderna vaccines. We reviewed the literature from various databases including "Web of Science Clarivate Analytics[10], PubMed[11], "Medline, EMBASE, World Health Organization (WHO), US Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), regional ministries, health institutes, and Google Scholar. The literature was searched by using the key terms: Coronavirus, SARS-CoV-2, COVID-19 pandemic, vaccines, Pfizer/BioNTech vaccine, Moderna vaccine, pharmacological characteristics, benefits, allergic responses, indications, contraindications, and adverse effects. The descriptive information was recorded and 42 articles, documents were identified. The studies, international organizations, and weblinks in which SARS-COV-2 and COVID-19 pandemic Vaccine were discussed were eligible for inclusion. No limitations on publication status, study design, or language of publication were imposed. The descriptive information was retrieved from the selected literature. Two co-authors reviewed the literature, and their findings were entered into tabular form. After that, a third co-author rechecked the literature and their findings. From the 24 identified documents, finally we included 12 documents including publications and few organizations such as "World Health Organization (WHO), US Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC).

Data extraction and Ethics statement

The findings were documented by using a standardized form including a full description of the study characteristics. In this study we recorded the publicly available database literature on coronavirus, SARS-CoV-2, COVID-19 vaccine, Pfizer/BioNTech and Moderna vaccines; hence, Ethical approval was not required.

Results

Table I presents a comparison between the pharmacology, indications, and adverse effects of Pfizer/BioNTech and Moderna vaccines. The US Food and Drug Authorities (FDA) have granted emergency authorization for use of the Pfizer/BioNTech and Moderna vaccines. Pfizer/BioNTech Vaccine has been recommended to people 16 years of age and older, with a dose of 30 μg (0.3 ml) at a cost of $19.50. It provides immunogenicity for at least about 119 days after the first vaccination and is 95% effective in preventing the SARS-COV-2 infection. However, Moderna Vaccine has been recommended to people 18 years of age and older, with a dose of 50 μg (0.5 mL) at a cost of $32-37. It provides immunogenicity for at least 119 days after the first vaccination and is 94.5% effective in preventing the SARS-CoV-2 infection (Table I). Based on the currently available literature, both vaccines are beneficial to provide immunity against a SARS-CoV-2 infection. However, some allergic responses have been reported.

Table I. Comparison between pharmacology, indications, and adverse effects of Pfizer/BioNTech and Moderna Vaccines.

Characteristics	Pfizer/BioNTech Vaccine	Moderna Vaccine
General name	Pfizer/BioNTech Vaccine[12].	Moderna Vaccine[13].
Generic name	Tozinameran, brand name Comirnaty[12].	Moderna COVID-19 Vaccine[13].
Manufacturer	Pfizer, Inc and BioNTech[12].	ModernaTX, Inc[13].
Type of vaccine	mRNA (BNT162b2)[12] .	mRNA (mRNA-1273)[13].
FDA Approval	Emergency authorization Dec 11, 2020[12].	Emergency authorization Dec 18, 2020[13].
Dose	Each dose contains 30 μg (0.3 mL)[14,15].	Each dose contains 50 μg (0.5 mL)[16,17].
Number of injections	2 shots, given 21 days apart[14].	2 shots, given 28 days apart[16].
Route of administration	Intramuscular-deltoid muscle[12].	Intramuscular-deltoid muscle[13].
Booster shots	Further research is needed to determine, whether shots will be required over the year to maintain immunity, or to be given annually like the flu shot.	Further research is needed to determine whether booster shots will be required over the year to maintain immunity, or to be given annually like the flu shot.
Age group for vaccination	16 years of age and older[14].	18 years of age and older[17].
Effectiveness	95% in preventing the SARS-COV-2 infection[14].	94.5% in preventing the SARS-COV-2 infection[16].
Approximate cost per dose	Freely available in many developed nations. However, $19.50 per dose excluding taxes, distribution, storage and health care services cost[18].	Free available in many developed nations. However, $32-37 per dose excluding taxes, distribution, storage and health care services cost[18].
Storage	Multiple dose vials are stored between -80ºC and -60ºC (-112ºF to -76ºF). Thaw and store undiluted vials in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] for up to 5 days (120 hours). For immediate use thaw undiluted vials at room temperature [up to 25ºC (77ºF)] for 30 minutes. Undiluted vials may be stored at room temperature for no more than 2 hours[19].	Multiple-dose vials are stored between -25º and -15ºC (-13º to 5ºF). Vials can be stored refrigerated between 2°C and 8°C (36° to 46°F) for up to 30 days prior to first use. After the first dose has been withdrawn, vial should be held between 2° and 25°C (36° to 77°F), discard the vial after 6 hours[20].
Transportation / Distribution	Complicated, difficult distribution particularly in low-income and hot climate countries.	Complicated, difficult distribution particularly in low-income and hot climate countries.
Mechanism of action	The vaccine is formulated in lipid particles, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. It elicits an immune response to the S antigen, which protects against COVID-19[21,22].	The nucleoside-modified mRNA vaccine is formulated in lipid particles. It enables delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19. The antibodies are specific to the SARS-CoV-2 virus, to protect against a future infection[21,22].

COVID-19 vaccine can cause mild adverse effects after the first or second dose, including pain, redness or swelling at the site of vaccine inject, fever, fatigue, headache, muscle pain, nausea, vomiting, itching, chills, muscle pain, and joint pain, and can also rarely cause anaphylactic shock. A comparison between pharmacology, indications, and adverse effects of Pfizer/BioNTech and Moderna Vaccines is presented in Table I. A comparison between the immunogenicity, adverse effects, risks, and contraindications between Pfizer/BioNTech and Moderna Vaccines reported by each of the two manufacturers is presented in Table II. The percentage of these adverse effects is reported to be lower with the Pfizer/BioNTech vaccine than with the Moderna vaccine (Figure 1), however the Moderna vaccine compared to the Pfizer vaccine is easier to transport and store because it

Table II. Comparison between immunogenicity, adverse effects, risks, and contraindications between Pfizer/BioNTech and Moderna Vaccines.

Immunogenicity	Immunogenicity persisted over a median of 2 months[14].	Immunogenicity persisted for at least 3 months. 119 days after first vaccination 90 days after the second vaccination[16].
Adverse events	Pain, swelling, redness, fever, fatigue, headache, chills, vomiting, diarrhea, muscle pain, joint pain, lymphadenopathy, shoulder injury, right axillary lymphadenopathy, paroxysmal ventricular arrhythmia, syncope, and right leg paresthesia[14].	Pain, swelling, redness at the site of vaccine, fever, fatigue, headache, chills, vomiting, arthralgia, myalgia, urticaria. These clinical symptoms were mild to moderate after the first dose of vaccine. However, after the second dose of vaccine the clinical symptoms were moderate to severe[17]. Moreover, facial swelling and Bell's palsy has also been reported[20].
Anaphylaxis Reaction	CDC has identified 6 case of anaphylaxis reaction following Pfizer-BioNTech vaccine[23].	No such reports in the peer reviewed medical literature, and so for in the trial[24].
Risks in pregnancy, infant and children	Not Known: the prevention of COVID-19 is not addressed in younger adolescents, children and pregnant women[14].	Not Known.
Contraindication	Individuals with a known history of severe allergic reactions, including anaphylaxis, immunocompromised persons, and individuals receiving immunosuppressive therapy[19].	Individuals with a known history of severe allergic reactions including anaphylaxis, immunocompromised persons, and individuals receiving immunosuppressive therapy[20].

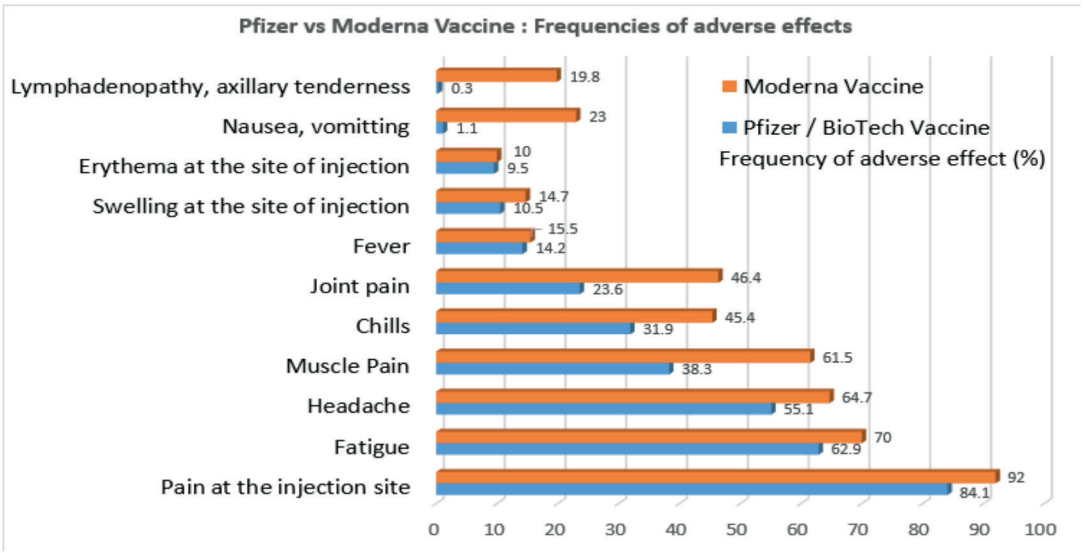

Figure 1. Comparison between frequencies of adverse effects of Pfizer/BioNTech and Moderna Vaccines[12,13,20].

is less temperature sensitive. It must be noted that because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

Discussion

The novel coronavirus, SARS-CoV-2 infection is an emerging global health concern and has infected a significant portion of the world's population[2]. During the COVID-19 pandemic, people worldwide are facing major health care challeng-

es, anxiety and stress[4], because there has been no specific treatment, and until December 2020 no vaccination for this pandemic. In mid-December 2020, the US Food and Drug Authority, (FDA), granted emergency authorization for the use of the Pfizer/BioNTech[5,6] and Moderna COVID-19 vaccines[7]. There is reasonable evidence that both Pfizer-BioNTech COVID19 Vaccine and Moderna COVID-19 Vaccine may be effective to combat the COVID-19 pandemic. In this study we compared the pharmacology, indications, contraindications, and adverse effects of Pfizer/BioNTech and Moderna vaccines.

It has been more than one year since the Coronavirus outbreak began and the pandemic became a global catastrophe. With a global lockdown amidst a fear of increasing morbidity and mortality, countries have witnessed their economies collapse and health systems devolve in crisis while hoping for a miraculous cure in the form of a vaccine for this new ailment. After a year, the authorization of the Pfizer vaccine on Dec 11, 2020[5] and Moderna vaccine on Dec 18, 2020[6] have brought forth a global ray of optimism for ending the fight against COVID-19.

Both authorized vaccines use modified RNA to encode the SARS-CoV-2 spike protein along with mutations in the mRNA added to lock the spike proteins into a three-dimensional shape that it naturally assumes just before it binds to the human ACE-2 receptors on cells with which elicited virus-neutralizing antibodies must interact[25]. Both also use lipid nanoparticle (LNP) delivery system[26]. These represent a new class of vaccine, which offer potential advantages, compared to traditional replicating or non-replicating viral vector vaccines, in that RNA vaccines are very potent and can be manufactured rapidly and at a relatively low cost. They have a good safety profile, compared to viral vaccines, since they are not made with an actual pathogen and do not integrate into host DNA. Both are administered in two doses into the deltoid muscle. A disadvantage of this class of vaccines is that because RNA is unstable, they require extreme refrigeration for stability during distribution.

The two approved vaccines, made available after thorough testing at almost the same time, have certain differences in their properties and actions on the body. The Pfizer vaccine is given in two slightly smaller dosages of 30 μg[14,15], whereas the Moderna vaccine is given in two 50 μg dosages[16,17]. The Pfizer vaccine is approved for ages 16 years up, whereas the Moderna vaccine is approved for ages 18 years and up. The efficacy reported for the Pfizer vaccine, at 95%[14] is very slightly more than that reported for the Moderna vaccine at 94.5%[16].

However, differences between the two arise when their factors of cost, storage requirements, and beneficial or adverse effects are considered. The Pfizer vaccine is significantly less costly than the Moderna vaccine, and their costs are $19.50 USD and $32-37 USD, respectively[18]. While certain developed nations are vaccinating their citizens free of charge, others are charging the public and must consider whether the vaccine is affordable by all the citizens, because the health and lives of all individuals of a society are equally important and universal vaccination is an excellent way to reach herd immunity. Special consideration must be taken by low-income countries where the average person can simply afford the vaccine or not, and if so, then cost would be a consideration. However, despite its lower cost, the Pfizer vaccine's major issue lies with its storage temperature between -80ºC and -60ºC (-112ºF to -76ºF)[19], whereas the Moderna vaccine is stored at a relatively much higher temperature between -25º and -15ºC[20] that is easier to maintain. This temperature requirement can pose a challenge to low-income countries, many of which also face an energy crisis, as to how they will manage such low storage temperature conditions to ensure the promising results of both the vaccines, especially the Pfizer vaccine, with although cheaper, requires much lower and more difficult to maintain storage temperatures. Published data has shown that both vaccines elicit a similar humoral response, and the published literature reports no difference in cellular immunity. There is, however, preliminary unpublished evidence that Pfizer's COVID-19 vaccine may trigger stronger CD8 T-cell responses than Moderna's vaccine[27]. This cellular response might provide added protection against an infection.

Regarding their adverse effects, both vaccines have in some cases produced serious adverse effects, and in rare cases, have produced severe allergic reactions, including anaphylaxis. Despite these issues that concern the vaccines, to date, Pfizer and Moderna vaccine are the only widely available vaccinations in the fight against corona. Countries, despite cost, are trying their best to vaccinate their citizens as early as possible, but further research is required to ensure that potential adverse effects are not triggered by any COVID-19 vaccines[28] and that planned phase 4 post marketing trials are also

complete for the vaccines to ensure their safety. So far, both COVID-19 vaccines have their own pros and cons and appear to be effective. The incidence of adverse effects is reported to be lower with the Pfizer/BioNTech vaccine than with the Moderna vaccine; however, the Moderna vaccine compared to the Pfizer vaccine is easier to transport and store because it is less temperature sensitive. With further research, the science community will hopefully bring forth new radical measures to fight this disease and finally bring an end to this pandemic.

Study Strengths and Limitations

This is the first study in the literature, to our knowledge, to highlight a comparison between the biology, pharmacology, indications, contraindications and adverse effects of the Pfizer/BioNTech and Moderna vaccines for a better understanding of these two vaccines.

Conclusions

The FDA has authorized, on an emergency basis, the Pfizer/BioNTech and Moderna vaccines. These two vaccines can provide protection from SARS-COV- 2 infection by formation of antibodies, to provide immunity against a SARS-COV-2 infection, with humoral as well as possibly cellular immunity, which has led to great hope for ending the COVID-19 pandemic. The available evidence supports the conclusion that both vaccines are beneficial, but may cause some adverse effects including pain, redness or swelling at the site of vaccine shot, nausea, vomiting, fever, fatigue, headache, muscle pain, itching, chills, and joint pain, as well as in rare cases they may cause an anaphylactic reaction. The occurrence of these adverse effects is reported to be lower with the Pfizer/BioNTech vaccine than with the Moderna vaccine. However, the Moderna vaccine compared to the Pfizer vaccine is easier to transport and store because it is less temperature sensitive. It must be noted that because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

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Conflict of Interest

The Authors declare that they have no conflict of interests.

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