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Review Of The Covid-19 Vaccine Variants' Efficacy, Safety, And Tolerance For People Of Various Ages.

Abdelsalam Abuzreda[1], Amenh B. Yousif [2]*, Hanan Alsgheer [3]

[1]Department of Health Safety and Environment (HSE), Arabian Gulf Oil Company (AGOCO) and University of Benghazi, Benghazi, Libya.

[2]Department of Family and Community Medicine, Faculty of Medicine, University of Benghazi, Benghazi, Libya.

[3]Department of Ophthalmology, Faculty of Medicine, University of Benghazi, Benghazi, Libya.

[2]*E-mail: dr.aminabarsi@yahoo.com, Tel:00218925326636, https://orcid.org/0000-0001-6001-2917.

Abstract – The COVID-19 pandemic has caused significant morbidity and mortality throughout the world, as well as major social, educational and economic disruptions. There is an urgent global need to make COVID-19 vaccines available at scale and equitably across all countries. The coronavirus disease (COVID-19) appears to be spreading faster, leading to an urgent need for COVID-19 vaccines. People aged 60 years old or older and those with existing respiratory or cardiovascular diseases are at high risk of serious disease and death if they are infected with COVID-19. According to different targets and technologies, vaccines can be divided into the following categories: inactivated vaccines, recombined spike protein vaccines, viral vector vaccines, RNA vaccines, live attenuated vaccines, and virus-like particle vaccines. Several thousand people have already succumbed to the disease worldwide with higher mortality rates in the elderly. Current medical management is largely supportive with no targeted therapy available.

Keywords –

I. INTRODUCTION

The COVID-19 pandemic has caused significant morbidity and mortality throughout the world, as well as major social, educational and economic disruptions. There is an urgent global need to make COVID-19 vaccines available at scale and equitably across all countries [(1)]. The whole world currently faces an emergency health crisis, as a result of the spread of the new Corona virus [(2)].

The novel coronavirus is synonymous with severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) due to its equitability (~80%) to SARS-CoV, resulting in acute respiratory distress syndrome (ARDS) associated mortality during 2002-2003. Several thousand people have already succumbed to the disease worldwide with higher mortality rates in the elderly. Current medical management is largely supportive with no targeted therapy available [(3)].

The coronavirus disease (COVID-19) appears to be spreading faster, leading to an urgent need for COVID-19 vaccines. People aged 60 years old or older and those with existing respiratory or cardiovascular diseases are at high risk of serious disease and death if they are infected with SARS cov-2, so the elderly need to be vaccinated. According to different targets and technologies, vaccines can be divided into the following categories: inactivated vaccines, recombined spike protein vaccines, viral vector vaccines, RNA vaccines, live attenuated vaccines, and virus-like particle vaccines [(4)].

II. VACCINE PHYSIOLOGY:

The efficacious vaccine that elicits a lasting protective immune response against SARS-CoV-2. This will be an essential armament for the prevention and mitigation of the downstream morbidity and mortality caused by SARS-CoV-2 infection. As of July 20, 2021, there are approximately 108 vaccines in clinical development and 184 vaccines in pre-clinical development with several vaccines being distributed globally. The technologies employed in the vaccine synthesis and development aim to trigger the adaptive immune system and elicit memory cells that will protect the body from subsequent infections. These technologies may be mRNA-based vaccines such as the Moderna and Pfizer/BioNTech, inactivated virus vector vaccines, DNA vaccines, and numerous other technologies. Due to the urgent implementation of vaccine development, the most obvious target will be the robust proteins expressed on the surface of the virus. Therefore, these technologies target molecular expression of the trimeric SARS-CoV-2 spike (S) glycoprotein. These targets could include its mRNA, DNA, full S1 subunit, or fusion subunits. The S protein is a major component of the virus envelope, it is vital for viral fusion, receptor binding, and virus-entry through recognition of host-cellular receptor. The S protein comprises of two main functional units, the S1 subunit, which contains the receptor-binding domain (RBD) and the S2 subunit which is responsible for virus fusion with the host-cell membrane. The choice to proceed with S protein as the target was reinforced when a study by Dan et al. confirmed that in 169 patients infected with SARS-CoV-2, spike specific immunoglobulin G (IgG) remained stable for over 6 months. In addition, both spike-specific CD4+ T-cells (CD137+ and OX40+) and spike-specific CD8+ T-cells (CD69+ and CD137+) were present at the 6-month post-convalescence period, but their subpopulations exhibited a steady decline with a half-life of 139 days and 225 days, respectively [(5)].

III. TYPES OF VACCINE:

3.1. BIONTECH/PFIZER:

The BNT162b2 COVID-19 vaccine developed by BioNTech and Pfizer is a lipid nano particle formulated, nucleoside-modified RNA vaccine that encodes a prefusion membrane-anchored SARS-CoV-2 full-length spike protein. It was the first vaccine approved by the US Food and Drug Association (FDA) and now it has been approved in many other countries. The BNT162b2 COVID-19 vaccine may be stored at standard refrigerator temperatures prior to use, but it requires very cold temperatures for long term storage and shipping (−70°C) to maintain the stability of the lipid nanoparticle [(5)].

the randomized trial of the vaccine, a two-dose regimen of BNT162b2 given 21 days apart conferred 91% protection (95% CI 89−93%) 7 days post dose 2 against symptomatic SARS-CoV2- infection with the ancestral strain in persons aged 16 years and above, based on a median follow-up of two months Similar vaccine efficacy (generally 90 to 100%) was observed across subgroups, defined by age, sex, race, body mass index and comorbidities. Immunogenicity, in terms of neutralizing antibodies, is increased with a longer inter-dose interval to 12 weeks highlighting that extended inter-dose intervals will result in a good immune response, including in older adults. Multiple studies have shown that post-introduction effectiveness of two doses is consistent with findings from the Phase 3 trials in the general population with very high protection against hospitalization and death and moderate vaccine impact against transmission. However, with the emergence of Variants of Concern (VoC) since the ancestral strain, lower vaccine effectiveness has been observed, in particular with regards to mild breakthrough infections and impact on transmission. Protection against severe disease and hospitalizations remains high for the Delta variant although some waning (30%) against mild infections six months after completion of the primary series. For the Omicron variant, which is antigenically the most distant from the ancestral strain, vaccine effectiveness against severe and mild disease after two doses is lower compared to Delta virus [(6)].

Children and adolescents: A trial in adolescents aged 12-15 years showed a vaccine efficacy against symptomatic SARS-CoV-2 infection of 100% (95% CI 75−100%) from 7 days after dose 2. Multisystem inflammatory syndrome in children (MIS-C) is a severe postinfectious hyperinflammatory condition, which generally occurs 2–6 weeks after a typically mild or asymptomatic infection with SARS-CoV-2. A post-introduction study in the U.S. using a test-negative case-control design amongst hospitalized patients aged 12–18 years showed a vaccine efficacy of 91% (95% CI = 78%–97%) against MIS-C. A Phase 3 trial was completed in children aged 5-11 years and showed similar immunogenicity and reactogenicity as in young adults. Efficacy against symptomatic disease was 90.7% (CI 67.7; 98.3). No cases of myocarditis were reported among 3,082 trial participants aged 5–11 years with ≥7 days of follow-up after receipt of dose 2, although the study was not powered to assess the risk for myocarditis.

Early post-introduction safety data from the U.S. show that the risk of myocarditis is lower in this age group compared to adolescents. No post-introduction vaccine effectiveness studies for the age group 5-11 years are currently available [(6)].

Contraindications A history of anaphylaxis to any component of the vaccine is a contraindication to vaccination. If anaphylaxis occurs after the first dose, a second dose of the vaccine should not be administered[(6)].

3.2. MODERNA:

The mRNA-1273 vaccine, developed by Moderna, relies on mRNA technology to encode prefusion stabilized SARS-CoV-2 spike protein. It is the second COVID-19 vaccine to receive emergency use approval by the US FDA, and it is given as two 100-µg doses intramuscularly into the deltoid muscle, 28 days apart.13 Storage of the vaccine is done at temperatures between −25°C to −15°C for long-term storage, 2°C to 8°C for 30 days, or 8°C to 25°C for up to 12 hours [(5)].

The initial results of the phase 3 trial in persons aged ≥18 years, conducted in 2020, showed an efficacy in preventing COVID-19 of any severity of COVID-19 of 94%. After a median follow-up of 5.3 months at the end of the blinded phase of the trial, vaccine efficacy in preventing COVID-19 was 93% (95% confidence interval [CI]: 91–95%); in preventing severe disease, efficacy was 98% (95% CI: 93–100%); and in preventing asymptomatic infection, 63% (95% CI: 57–69%). Antibody levels declined but remained high throughout this period. The geometric mean titre was lower in those aged ≥56 years than in trial participants aged 18–55 years. Several studies have shown that the mRNA-1273 vaccine is effective in preventing symptomatic laboratory confirmed COVID-19 (pooled effectiveness = 89.2% [95% CI: 82.0–98.6%]); hospitalizations (pooled effectiveness = 94.8% [95% CI: 93.1–96.1%]); and deaths (pooled effectiveness = 93.8% [95% CI: 91.5–95.4%] [(7).]

Children and adolescents below the age of 18 years Children aged 12–17 years with comorbidities that put them at higher risk of serious COVID-19 disease should be offered vaccination. For healthy children and adolescents, COVID-19 is rarely severe. Some children develop multisystem inflammatory syndrome, even after mild or asymptomatic infection. In accordance with the WHO Prioritization Roadmap, WHO recommends that countries could consider using mRNA-1273 in children aged 12–17 years, only when high vaccine coverage (primary series and booster doses) has been achieved in the higher priority-use groups. A phase 2 trial for children aged 6–12 years was recently completed and is currently under review by regulatory authorities. Until this age indication has received emergency use authorization or listing, children aged [(7)].

Older persons the risk of severe COVID-19 and death increases steeply with age. Data from the phase 3 trial indicate that the efficacy and safety of the vaccine are comparable across all age groups. Post-introduction vaccine effectiveness studies have shown high effectiveness and good safety profiles in older persons. Vaccination is recommended for older persons without an upper age limit [(7)].

3.3. ASTRAZENECA:

The Oxford and AstraZeneca ChAdOx1 COVID19 vaccine uses a chimpanzee adenovirus vector to deliver the genetic sequence of a full-length spike protein of SARS-CoV-2 into host cells. The storage for the ChAdOx1 vaccine is favorable, as it may be refrigerated at 2°C–8°C for 6 months [(5)].

The global phase 3 trial (conducted in Chile, Peru and the United States of America) enrolled 32 451 participants, with approximately 20% of the trial population aged 65 years or older. The vaccine efficacy against symptomatic SARS-CoV-2 infection was 74% (95% confidence interval [CI]: 65.3–80.5%). No severe or critically ill cases occurred in the vaccinated group; Vaccine efficacy in trial participants aged 65 years or older was 83.5% (95% CI: 54.2–94.1%) . More detailed data on the efficacy and safety of this vaccine may be found in the 1 March 2021 Background document on the AZD1222 vaccine. Based on the phase 3 trials, the ChAdOx1-S [recombinant] vaccine against COVID-19 has an efficacy of 72% (95% CI: 63–79%) against symptomatic SARS-CoV-2 infection, as shown by the primary analysis of data irrespective of interdose interval (data cutoff, 14 January 2021) from trial participants who received 2 standard doses with an interval varying from about 4 to 12 weeks. Vaccine efficacy tended to be higher when the interval between doses was longer. This, together with the finding of higher antibody levels with increasing interdose interval, supports the conclusion that longer dose intervals within the 4–12-week range are associated with greater vaccine efficacy against COVID-19 [(8)].

Persons aged 65 years and over the risk of severe COVID-19 and death increases steeply with age. Phase 3 clinical trials demonstrated an efficacy against symptomatic COVID-19 of 83.5% (95% CI: 54.2–94.1%) in individuals aged 65 years and

older. The trial data also indicate that the vaccine is safe for this age group. Post-introduction vaccine effectiveness studies from the United Kingdom show high rates of protection against hospitalizations, severe COVID-19 and death in older persons, including those over the age of 80 years . WHO recommends the vaccine for use in persons aged 65 years and older. In accordance with the WHO a booster dose is recommended for the highest and high priority-use groups such as older adults, administered 4–6 months after completion of the primary series [(8)].

Children and adolescents below 18 years of age There are limited data on efficacy or safety for persons below the age of 18 years for the ChAdOx1-S [recombinant] vaccine. Until more data are available, vaccination of individuals in this age range with this vaccine is not routinely recommended [(8)].

3.4. JANSSEN COVID-19 VACCINE:

The Janssen (Johnson & Johnson) COVID-19 vaccine, developed by Janssen Pharmaceutical in Netherlands. It is a single-dose intramuscular (IM) vaccine that contains a recombinant, replication incompetent human adenovirus (Ad26) vector encoding the spike protein of SARS-CoV-2 in the stabilized conformation. It can be stored between 2°C and 8°C for up to 6 hours or at room temperature for a duration of 2 hours [(5)].

The Phase 3 efficacy trial (ENSEMBLE 1; one dose) showed that a single dose of Ad26.COV2. S protected against moderate to severe-critical Covid-19 with onset at least 14 days after administration (116 cases in the vaccine group vs. 348 in the placebo group; efficacy, 67%; adjusted 95% confidence interval [CI], 59–73) and at least 28 days after administration (66 vs. 193 cases; efficacy, 66%; adjusted 95% CI: 55–75). Vaccine efficacy against severe-critical Covid-19 was 77% [adjusted 95% CI: 55–89] for onset at ≥14 days and 85% [adjusted 95% CI: 54–97] for onset at ≥28 days). Vaccine efficacies were similar in different gender, age and ethnic groups declined to about 50% two or more months after vaccination, whereas the efficacy against severe critical Covid-19 was maintained. Older people the risk of severe COVID-19 and death increases steeply with age. Data from the phase 3 trial indicate that the efficacy and safety of the vaccine are comparable across all age groups (above the age of 18). Vaccination is recommended for older persons [(9)].

Children and adolescents below the age of 18 years for most children and adolescents the disease profile is less severe. There are currently no efficacy or safety data for children or adolescents below the age of 18 years. Until such data are available, vaccination of individuals below 18 years of age is not routinely recommended [(9)].

3.5. SINOPHARM:

Develop by China National Pharmaceutical Group Co., Ltd. b Is inactivated vaccine, it is two intramuscular doses of inactivated vero cell, it can be stored 2°C–8°C. The COVID-19 vaccine, is an aluminums-hydroxide-adjuvanted, inactivated whole virus vaccine. A large multi-country phase 3 trial has shown that 2 doses, administered at an interval of 21 days, have an efficacy of 79% (95% confidence interval (CI): 66–87%) against symptomatic SARS-CoV-2 infection, 14 or more days after the second dose. Vaccine efficacy against hospitalization was 79% (95% CI: 26–94%). Women were underrepresented in the trial. The median duration of follow-up available at the time of evidence review was 112 days [(10)].

Children and adolescents: Studies were conducted among children aged 3–17 years to assess immunogenicity, including after a booster dose, and safety of COVID-19 vaccine. The vaccine was well tolerated in this age group; most adverse events were mild, with a rate of severe reactions of 0.088/100 000 doses administered. A booster dose given at a longer interval (4 months versus 2 months) after completing the primary series, resulted in higher levels of neutralizing antibodies in children, as in all age groups. Antibody levels were higher using a 3-dose versus a 2-dose schedule, though, consistent with adults, immunogenicity declined after around 6 months [(10)].

Older persons: A relatively small number of participants in the phase 3 clinical trial were aged 60 years and older and data for this age group remain limited. Vaccine efficacy in individuals aged 60 years and older against symptomatic disease after a median follow-up time of 213 days was 80% (95% CI: 5–98%). There was no significant difference in post-immunization safety between populations aged 60 years and populations aged 18–59 years [(10)].

IV. CONCLUSION:

COVID-19 vaccines for everyone ages 5 years and older, if eligible.

People who are moderately or severely immunocompromised have specific recommendations for COVID-19 vaccines, including boosters.

RECOMMENDATION:

- A health education program is a necessary first step in accepting appropriate vaccination in order to reduce morbidity, mortality, and the economic burden of COVID-19.
- Future research should evaluate the long-term effects of vaccines, compare different vaccines and vaccine schedules, assess vaccine efficacy and safety in specific populations, and include outcomes such as preventing long-term COVID-19. Ongoing evaluation of vaccine efficacy and effectiveness against emerging variants of concern is also vital.

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