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Safety and Efficacy of Approved COVID-19 Vaccines- A Narrative Review

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Abstract

Background: SARS-CoV-2 causes many COVID-19 cases worldwide. Strategies like social isolation and hand washing are in place to control the pandemic, but a vaccine is needed for herd immunity.

Objective: To discuss the most recent WHO-approved COVID-19 vaccine subtypes, their status, safety, efficacy, and effectiveness of COVID-19 vaccines.

Result: Eleven vaccines against SARS-CoV-2 have received Emergency Use Authorization by the WHO that can protect the world's population during the COVID-19 pandemic last updated 3 May 2023. Here, we review the research on the efficacy, effectiveness, and safety of COVID-19 vaccines, focusing on specific populations and novel SARS-CoV-2 strains. Urgent efforts were made to develop and test COVID-19 vaccines to ensure efficacy and safety, but long-term post-marketing surveillance data is needed to guarantee safety.

Conclusion: It can be seen that the efficacies of three vaccines against mild and severe COVID-19 infection were higher (>90%) for Pfizer BioNTech (95%), Moderna (94%), and Sputnik V (92%) than for Oxford-AstraZeneca (70%) and Janssen (66%). The remaining vaccines have efficacy above 55% and below 90%, proving that these vaccines effectively reduce the incidence and severity of SARS-CoV-2 infection among the study populations. As of the last update on May 23, 2023, the number of countries where vaccines were approved is as follows: Pfizer and AstraZeneca in 149 countries, Janssen in 113, Vero Cell in 93, Sputnik V in 74, CoronaVac in 56, and Nuvaxovid (NVX-CoV2373) in 40. Additionally, Covaxin was approved in 13 countries, Convidecia in 10, and Covovax in 6.

Keywords: Covid-19 vaccine; Approved; Efficacy; Safety

Abbreviations: SARS CoV-2: Severe Acute Respiratory Syndrome Corona Virus-2; WHO: World Health Organization; EUL: Emergency Use List; EUA: Emergency Use Authorization

Introduction

Severe acute respiratory syndrome Corona virus-2 (SARS-CoV-2) is responsible for a large number of global COVID-19 cases. Different strategies such as social isolation, personal hygiene, and frequent hand washing have been implemented to reduce the transmission of Covid-19. However, a protective vaccine is required to achieve sufficient herd immunity to SARS-CoV-2 infection to ultimately control the COVID-19 pandemic [1]. The WHO Emergency Use Listing (EUL) process determines whether a product can be recommended for use based on all the available data on safety and efficacy and its suitability. Vaccines are assessed to ensure they meet acceptable standards of quality, safety, and efficacy using clinical trial data, manufacturing, and quality control processes [2]. The humoral and cellular immunity, safety profiles, and protection efficacy of COVID-19 vaccines with clinical data published by 21 May 2021 [3].

As of 3 May 2023 [4], the following vaccines have obtained EUL as per WHO:

- The Pfizer/BioNTech Comirnaty vaccine, 31 December 2020.
- The SII/COVISHIELD and AstraZeneca/AZD1222 vaccines, 16 February 2021.
- The Janssen/Ad26.COV 2.S vaccine developed by Johnson & Johnson, 12 March 2021.
- The Moderna COVID-19 vaccine (mRNA 1273), 30 April 2021.
- The Sinopharm COVID-19 vaccine, 7 May 2021.
- The Sinovac-CoronaVac vaccine, 1 June 2021.
- The Bharat Biotech BBV152 COVAXIN vaccine, 3 November 2021.
- The Covovax (NVX-CoV2373) vaccine, 17 December 2021.
- The Nuvaxovid (NVX-CoV2373) vaccine, 20 December 2021
- The convidecia, 19 May 2022

According to the McGill COVID-19 vaccine tracker system, the following vaccines have been approved in multiple countries [5].

- Nucleic acid vaccines (mRNA vaccines)
  BNT162b2 (Pfizer/BioNTech)
  m-RNA-1273 (Moderna)
- Adenoviral-based vaccines
  Oxford/AstraZeneca
  Janssen by Johnson and Johnson
  Sputnik V
- Protein subunit vaccines
  Novavax

- Inactivated virus vaccines
  CoronaVac (Spinovac)

The objective of the study is to discuss the most recent WHO-approved COVID-19 vaccine subtypes, their status, and several countries where the vaccine was approved, compare the side effects, safety, and toxicity of COVID-19 vaccines available, and discuss the impact of SAR CoV-2 variants on efficacy and effectiveness of COVID-19 vaccines.

Methods

The databases of PubMed, Cochrane Library Cochrane COVID-19 Study Register, WHO Coronavirus Disease, and Google Scholar were searched using the following search keywords COVID-19 OR SAR CoV-2 AND Vaccine approved AND Safety. Articles published in the English language were included. The articles were selected based on relevance to the COVID-19 vaccine, its approval safety, and efficacy. Articles published from January 2021 to March 2023 were included for analysis purposes. Adult volunteer and randomized controlled trial-type studies were included. Exclusion criteria were observational studies, case reports, and children.

Result

Covid-19 Vaccine Approved by WHO as an EUL

To date, 140 vaccines are in clinical development. Vector, RNA, subunit, inactivated vaccines, and DNA vaccines have been approved for human use6. A lipid nanoparticle-formulated, nucleoside-modified mRNA vaccine called BNT162b2 (Comirnaty®; BioNTech and Pfizer) is intended to prevent the novel coronavirus illness 2019 (COVID-19), which is brought on by infection with the SARS-CoV-27. The World Health Organization listed BNT162b2 for emergency use on December 31, 2020, and represents the first COVID-19 vaccine to receive emergency validation via this pathway with 95% efficacy8. Moderna/mRNA-1273 vaccine is a nanoparticle–encapsulated nucleoside-modified messenger RNA (mRNA)–based vaccine. It has an efficacy of 94.1%. The Moderna vaccine compared to the Pfizer vaccine is easier to transport and store because it is less temperature sensitive9. The Oxford/AstraZeneca/AZD122/ChAdOx1 n-CoV-19 vaccine is a viral vector vaccine. Covishield (AstraZeneca vaccine ChAdOx1/AZD1222), approved for EUA by the WHO, is a two-dose version of the Oxford/AstraZeneca vaccine manufactured by the Serum Institute of India with 70.4% efficacy2.

Janssen is a non-replicating, recombinant human adenovirus type 26 with an efficacy of 66.9%10. Covaxin (BBV152 vaccine) is an inactivated virus vaccine. Phase I (safety and immunogenicity) and phase II trial (immune response and safety) data of Covaxin are published. A phase 3 study confirmed the clinical efficacy of BBV152 against symptomatic COVID-19 disease and safety monitoring and assessment did not raise concerns about the vaccine11. The dual vector-based vaccination Sputnik V (Gam--COVID-Vac), which combines type 26 and rAd5 recombinant adenovirus (rAd), demonstrated 91.6% efficacy against COVID-1912. In a large, multi-country phase III trial, Sinopharm's BBIBP-CorV (Covilo) demonstrated 79% efficacy against symptomatic SARS-CoV-2 infection and hospitalization after administering two doses 21 days apart. However, efficacy could not be determined in individuals aged 60 and over and with comorbidities, and there was an underrepresentation of women13. The inactivated vaccine is CoronaVac. WHO recommends two doses spaced two to four weeks apart for those 18 and older. Effectiveness is 51% in preventing illness with symptoms and 100% in preventing hospitalization14. The SARS-CoV-2 spike protein and Matrix-M adjuvant are both components of the Novavax COVID-19 vaccine. It is provided under emergency use authorization (EUA) to protect people 12 years of age and older against COVID-19. Although it is made up of nanoparticles, which cannot spread disease, it still includes the spike protein of the coronavirus itself15. COVID-19 vaccine Convidecia (Ad5-nCoV-S [Recombinant]) According to results from clinical trials, the Ad5-nCoV vaccination was 92% effective against severe

illness and 58% effective against symptoms. COVID-1915. As per the last updated 3 May 2023, only eleven vaccines were granted as emergency use lists by the WHO were mentioned in Table 1

Safety and Efficacy of Vaccine

Urgent efforts were made to develop and test COVID-19 vaccines to ensure efficacy and safety, but long-term post-marketing surveillance data is needed to guarantee safety. According to the WHO and European Medicine Agency (EMA) guidelines, the Immunogenicity of vaccines must be assessed in clinical development programs to evaluate potential long-term efficacy[4,16]. In clinical studies, the efficacy of three vaccines against mild and severe COVID-19 infection was higher (>90%) for Pfizer BioNTech (95%), Moderna (94%), and Sputnik V (92%) than for Oxford-AstraZeneca (70%) and Janssen (54–72%). 10. Moderna, Sputnik V, Janssen, and Oxford-AstraZeneca vaccines reduced the likelihood of severe forms of COVID-19 infection and deaths, while the mRNA vaccines showed great efficacy against infection and a very high level of protection against severe disease, hospitalization, and death[2]. The efficacy and safety of the most important COVID-19 vaccine were demonstrated in Table 2.

Impact of SARS-CoV-2 Variants on Vaccine Efficacy and Effectiveness

There were four types of variants were seen in different countries which decreased the efficacy and effectiveness of the COVID-19 vaccine. The impact of SARS-CoV-2 variants on vaccine efficacy and effectiveness was mentioned in Table 3.

Discussion

The COVID-19 pandemic is one of the most significant global public health crises of this generation, with SARS-CoV-2 causing a vast number of infections worldwide. As of January 20, 2021, 143 vaccines were in preclinical development, and 64 had entered clinical trials1. There are now 334 COVID-19 vaccines available or in development worldwide, of which 140 are being tested in clinical trials and 194 are in preclinical development6.

The mRNA vaccine against COVID-19 was approved for emergency use by the WHO on December 31, 2020, making this Pfizer/BioNTech immunizer the first to do so since the outbreak's inception. Regulatory agencies in various regions of the world already gave nine vaccinations emergency permission in January 202117. There are different types of COVID-19 vaccines were used to prevent transmission and improve the immunity against SAR CoV-2 virus. Vaccines include peptides, DNA, inactivated virus (IV), non-replicating viral vector (VVnr), RNA, and single vaccines in clinical development. 33 vaccinations have been approved in at least one nation 6. But as per the last updated 3 May 2023, only eleven vaccines were granted as emergency use list by the WHO.

By May 16, 2021, the number of countries approving and distributing COVID-19 vaccines had significantly increased. The Pfizer vaccine was approved in 85 countries, Moderna (mRNA-1273) in 46 countries, Oxford/AstraZeneca (AZD122/ChAdOx1 n--CoV-19) in 139 countries, and Janssen in 41 countries10. Currently, there is increased rapidly the vaccines were approved and distributed. As per the last updated, there were eleven vaccines were approved in many countries were shown in Table 117. Common side effects of COVID-19 vaccines include injection site pain, fever, muscle pain, fatigue, and headache. Serious adverse events were noted in some trials, along with temporary laboratory abnormalities like elevated bilirubin and altered liver enzymes. These effects were self-limiting and not clinically significant. Long-term post-marketing surveillance, especially for high-risk populations such as the elderly, those with comorbidities, pregnant women, and children, is essential to ensure vaccine safety18. It can be seen that the efficacies of three vaccines against mild and severe COVID-19 infection were higher (>90%) for Pfizer BioNTech (95%), Moderna (94%), and Sputnik V (92%) than for Oxford-AstraZeneca (70%) and Janssen (66%)19. The full-dose regimen from Pfizer and BioNTech works best for B. 1 infections and 351 variations of 7B. The effective-

ness of the COVID-19 vaccine against novel variations needs to be tested further 5. After the second dosage, the Moderna vaccine was >80% effective against infection, severe infection, and infection necessitating hospitalization. Although the AstraZeneca vaccine's efficiency after the second dose was not mentioned in any of the studies that were included, it was 80. The J&J vaccination was >60% effective in protecting against illness, infections that required hospitalization, and severe infections. The Sputnik, Novavax, and Sinovac vaccines did not have efficacy values published after the second dose, but the latter two did, with efficacy values of 60. It is crucial to highlight that the dominance of specific viral variations inside specific vaccines may be to blame for the comparatively low efficacy values of particular vaccines that were achieved in some experiments20.

Conclusion

WHO approved eleven vaccines as emergency use list (EUL) in the last updated 3 May 2023. It can be seen that the efficacies of three vaccines against mild and severe COVID-19 infection were higher (>90%) for Pfizer BioNTech (95%), Moderna (94%), and Sputnik V (92%) than for Oxford-AstraZeneca (70%) and Janssen (66%). The remaining vaccines have efficacy above 55% and below 90%, proving that these vaccines are effective at reducing the incidence and severity of SARS-CoV-2 infection among the study populations. As of last updated 23 May 2023, the number of countries where the vaccines approved that Pfizer and AstraZeneca in 149, Janssen in 113, Vero Cells in 93, Sputnik V in 74, CoronaVac in 56, Nuvaxovid (NVX-CoV2373) in 40 and the other three were Covxin, , and Covovax was 13, and 6 respectively.

Declarations

Ethics approval and Consent to Participate

Not applicable - because this review typically synthesizes and discusses findings from previously published literature, without involving new human or animal subjects, data collection, or experiments.

Consent for publication

Not applicable

Availability of Data and Material

The corresponding author will provide the data supporting the research study after a request for a specific reason. This is a narrative review so we synthesized and discussed the result. We provide the appropriate credit to all tables. Continue to provide appropriate credit in your publication also.

Competing Interests

There are no conflicts of interest for all authors

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Authors' Contributions

Collection and review of articles were conducted by S.B., M.K.LD., and P.P. The final manuscript was prepared by SB and approved by all authors.

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Authors' Information

Not applicable

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