Research Article

Effectiveness of SARS-CoV-2 Vaccines used in Malaysia: A Systematic Review and Meta-Analysis

Anita Devi Krishnan Thantry[*], Palaniappan, Edwin Cheah Shenq, Dhanraaj

Department of Medicine, Manipal University College Malaysia (MUCM), Jalan Padang Jambu, Bukit Baru 75150, Malacca, Malaysia

ABSTRACT

Introduction: COVID-19 caused by SARS-CoV-2 was declared a pandemic by WHO in March 2020 following which many vaccines were synthesised which effectively reduced the case fatality ratio. Malaysia implemented community-wide COVID-19 vaccination using ChAdOx1 (AZD1222, Astra Zeneca), BNT162b2 mRNA (Pfizer BioNTech) and CoronaVac (Sinovac) vaccines in 2021. Efficacy was established by randomized control trials prior to its roll out, but the effectiveness of these vaccines in a real-world community setting can be assessed from hospital data and research articles published from 2021 onwards.

Aim: This study aimed to do a systematic analysis of the available articles from various countries which used the three vaccines introduced in Malaysia and compare with the outcome in Malaysia.

Methods: We performed a systematic analysis on various studies about the three vaccines from different parts of the world, based on Preferred Reporting Items for Systematic Reviews and Meta-Analyses Statement (PRISMA) recommendations with well-defined inclusion and exclusion criteria. The studies for each vaccine were analysed for the Relative Risk Reduction (RRR) and vaccine effectiveness. Further, a comparison between the three vaccines was attempted and compared with the effectiveness of the three vaccines in Malaysia.

Results: BNT162b2 had an RRR ≥ 90% against severe symptomatic SARS-CoV-2 with very high effectiveness upon completion of two doses. ChAdOx1 vaccine effectiveness showed a wide range from 67.5%-95.6%. Effectiveness for CoronaVac ranged from 54%-99.9%. Meta-analysis of the data was done using Microsoft Excel. A comparison between the three vaccines showed a higher effectiveness for BNT162b2(94.9%) followed by ChAdOx1(84.7%) and SinoVac(72.4%). The effectiveness of ChAdOx1 vaccine reported from our country is the highest among the studies.

Conclusion: Real-world evidence shows that COVID-19 vaccines are highly effective against severe disease, hospitalization, and death. Our study validates the importance of assessing effectiveness of COVID vaccines in preventing severe COVID.

Keywords: SARS-CoV-2 vaccines; COVID-19; Systematic review; Meta-analysis; Effectiveness; Safety; Side effects

INTRODUCTION

COVID-19 caused by the novel Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) was declared a global pandemic by the World Health Organization (WHO) on March 11, 2020, following the first case reported in Wuhan City, China, in December 2019 [1]. As of 20 September 2022, SARS-CoV-2 has affected more than 200 countries with 609,848,852 confirmed cases of COVID-19, including 6,507,002 deaths, reported to WHO [2].

Implementation of strict personal protective measures like wearing properly fitted masks, social distancing, staying at home, restricted travel, hand hygiene etc., played a major role in reducing transmission and protecting high-risk individuals and reducing the mortality and morbidity. Rapid development of COVID-19 vaccines has played a major role in drastically reducing COVID-19 Case Fatality Ratio (CFR). The mean cumulative Case Fatality Ratio (rCFR) of COVID-19 in the top-20 countries with vaccination rates was 1.18(95% CI: 0.73-1.62) on 5 Jan 2022 while the overall case fatality rate for Malaysia is 0.8% as of September 2022 [3,4].

Vaccines strategies included mRNA-based vaccines (Pfizer-BioNTech, Moderna), viral vector vaccines (Oxford-AstraZeneca,

Johnson & Johnson), whole pathogen inactivated/killed vaccines (Sinopharm, SinoVac, Bharat BioTech) and subunit vaccines (Novavax) [5].

The efficacy and safety of a vaccine is evaluated in randomized clinical trials prior to approval and roll out of vaccines. Further, its effectiveness and side effects are monitored by observational studies, mainly case control and cohort studies in vaccinated population *vs.* unvaccinated who have clinical and laboratory confirmed COVID-19. Effectiveness in the real world can differ from the efficacy measured in a trial, because we can't predict exactly how effective vaccination will be for a much bigger and more variable population getting vaccinated in more real life conditions [6].

Malaysia implemented community-wide COVID-19 vaccination using ChAdOx1 (AZD1222, Astra Zeneca), BNT162b2 mRNA (Pfizer BioNTech) and CoronaVac (Sinovac) vaccines in 2021 under the National COVID-19 Immunization Programme/ Program Imunisasi COVID-19 Kebangsaan. The efficacy and safety of these vaccines in a real-world community setting can be assessed from hospital data and research articles published from 2021 onwards. A systematic analysis of the available articles from various countries which used the three vaccines introduced in Malaysia was attempted. This helped to compare and analyse the effectiveness and safety of these vaccines in the real-world situation as well as get an idea of their effectiveness in our Malaysian population.

MATERIALS AND METHODS

Search strategy

This was done as per the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Statement (PRISMA) recommendations [8]. The electronic databases such Medline (*via* PubMed), EMBASE, Science Direct, SCOPUS and Google Scholar was systematically searched. Journal homepages and bibliographies were also searched to retrieve eligible studies. Manually, the articles were saved on a data extraction template created in Excel sheet and duplicated records were searched for reports [9].

Inclusion criteria

Study design: Observational studies (case-control and cohort studies) on effectiveness of the three vaccines in preventing hospitalisation or severe disease and side effects due to them.

Language: Articles published in the English language.

Publication date: From 2020 to 2022. Only full-text articles were included.

Setting: Worldwide.

Exclusion criteria

The exclusion criterion includes: Studies reporting exclusively on the immunogenicity of COVID-19 vaccine, Review articles, Abstracts, Ecological studies, Mathematical modelling analysis studies.

Study selection, extraction, and quality assessment

Full copies of articles identified by the search and meeting the inclusion criteria based on the title, abstract, and text contents are obtained for data synthesis. Three reviewers independently assessed studies for potential relevance, applied the eligibility criteria to the results. Duplicates were removed and any disagreements in the evaluation of studies were resolved through consensus among the authors.

Review synthesis

The systematic review approach was used to synthesize the evidence from the included studies. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guideline was followed to screen the studies (Figure 1).
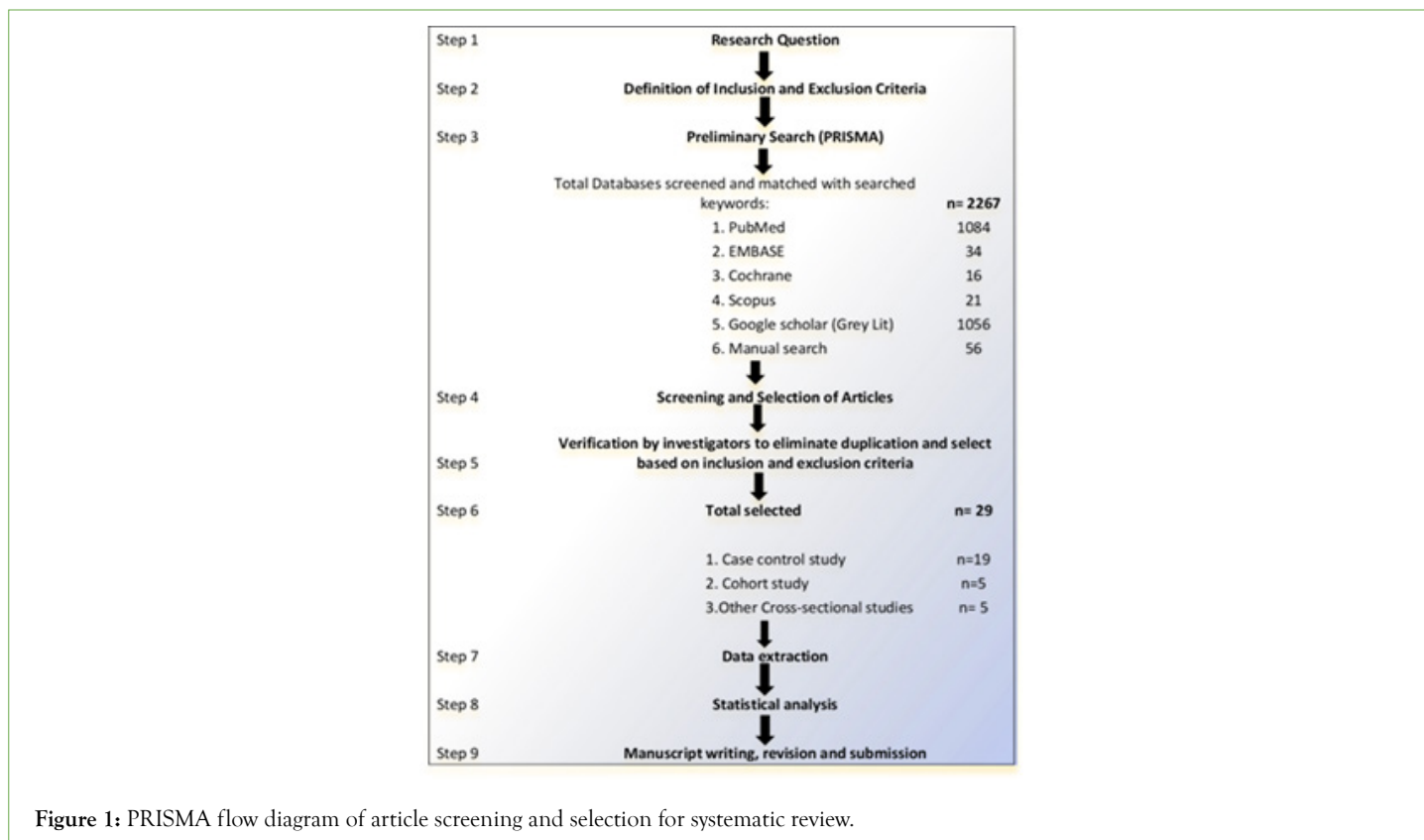

Figure 1: PRISMA flow diagram of article screening and selection for systematic review.

Studies where the patients had severe symptoms of COVID requiring hospital visits, hospitalisation or ICU admission and had already completed two doses of the vaccine were included. Cases were confirmed for COVID-19 infection by RT-PCR.

RESULTS

A total of 29 real world effectiveness studies of the three vaccines namely BNT162b2 mRNA (Pfizer BioNTech), ChAdOx1 (AZD1222, Astra Zeneca) and CoronaVac (Sinovac) vaccine studies done worldwide were selected. These included 10 case-control studies each of BNT162b2 mRNA and CoronaVac vaccines while 9 studies were identified for ChAdOx1 meta-analysis [10-34]. These were compared against Malaysian data provided from the Programme Imunisasi COVID-19 Kebangsaan-PICK (National COVID-19 Immunisation Programme) which began from 24 February 2021 [34]. The Relative Risk Reduction (RRR) of the vaccines in preventing severe COVID and hospitalisation as well as ICU admission and death was calculated.

BNT162b2 produced an RRR ≥ 90% against severe symptomatic SARS-CoV-2 infections requiring hospitalization and/ or ICU admission (Table 1). The studies selected for ChAdOx1 vaccine effectiveness showed a wide range from 67.5%-95.6% (Table 2). Similarly for CoronaVac, the effectiveness ranged from 54%-99.9% (Table 3). Meta-analysis of the data was further done using Microsoft Excel (Figures 2-5). p values were all significant and hence not displayed in the figures. A comparison on the effectiveness of the three vaccines was done to assess which vaccine elicited a better clinical outcome among the three (Table 4).

Table 1: Comparative meta-analysis of BNT162b2 vaccine effectiveness against severe disease presentation.

BNT162b2 (Pfizer BioNTech)			
Study	Effectiveness	Lower 95% CI	Upper 95% CI
Ref. Malaysia MOH	90.3	88.8	91.6
Samantha et al, US	94.1	90	96
Thiago Cerquerira et al, Brazil	89.7	54.3	97.7
Haas et al, Israel	97.5	95	98.2
Chung et al, Canada	95.6	90.2	96.7
Dagan et al, Israel	92.5	75.2	100
Flacco et al, Italy	99.6	97.1	100
Whitaker et al, UK	94.7	86.1	97
Stowe et al, UK	95.2	86.9	98.1
Abu Raddal et al, Qatar	100	75	100
Martinez-Bas et al, Spain	94.7	60.4	99.3

Table 2: Comparative meta-analysis of ChAdOx1 vaccine effectiveness against severe disease presentation.

ChAdOx1(AZD1222, Astra Zeneca)			
Study	Effectiveness	Lower 95% CI	Upper 95% CI
Ref. Malaysia MOH	95.6	88.3	98.1
Andrews et al, UK	82.8	74.5	88.4
Sheik et al, Scotland, UK	90	83	94
Thiago Cerqueira-Silva et al, Brazil	89.9	83.5	93.8
Thiruvengadam R et al, India	81.5	9.9	99
Sritipsukho P et al, Thailand	83	70	90
Hitchings et al Brazil	86.2	77.3	94
Stowe et al, UK	92.5	75.1	97
Whittaker et al, UK	77.9	70.3	84.7
Lopez Bernal2 et al, UK	67.5	61.7	72

Table 3: Comparative meta-analysis of CoronaVac vaccine effectiveness against severe disease presentation.

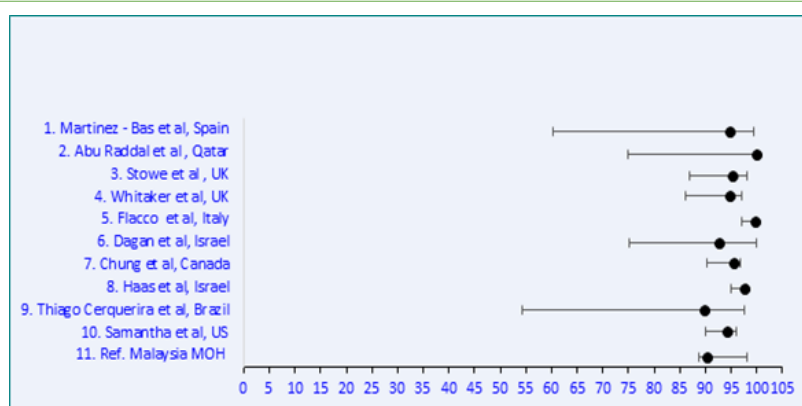| Study	Effectiveness	Lower 95% CI	Upper 95% CI
	CoronaVac (SinoVac)		
Ref. Malaysia MOH	72	66.9	73.9
Premikha M et al, Singapore	54	35	68
Cerqueira-Silva T et al, Brazil	81.3	75.3	85.8
Suryatma A et al, Indonesia	71.1	62.9	77.6
Sritipsukho P et al, Thailand	60	49	69
Serrano-Coll et al, Columbia*	99.9	87.8	100
Ranzani et al, Brazil	55	47.6	66.9
Jara et al, Chile	87.1	85	88.7
McMenamin ME et al, HK	91.7	88.7	94
Yan VKC et al, HK	58.9	50.3	66.1
Copur et al, Turkey	65	50	75

Figure 2: Vaccine effectiveness of BNT162b2 against severe COVID 19 requiring hospitalization or ICU care.
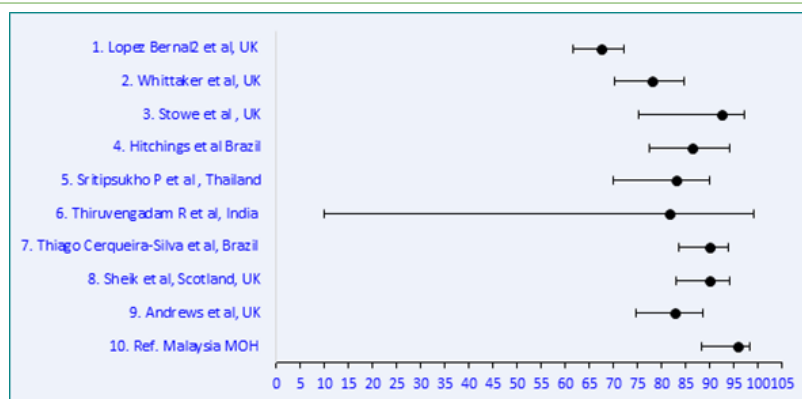

Figure 3: Vaccine effectiveness of ChAdOx1 against severe COVID 19 requiring hospitalization or ICU care.
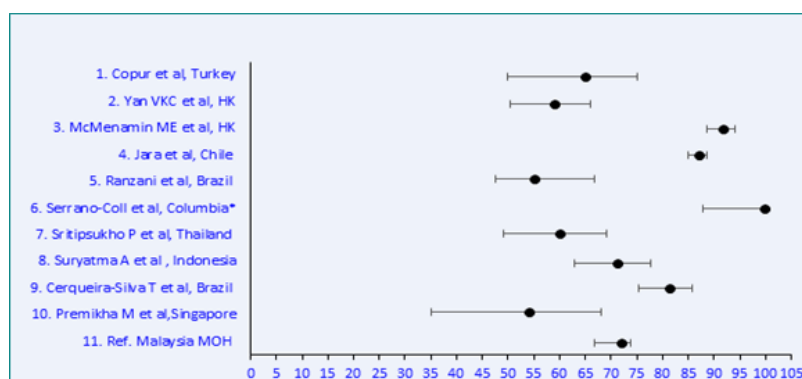

Figure 4: Vaccine effectiveness of CoronaVac against severe COVID 19 requiring hospitalization or ICU care.
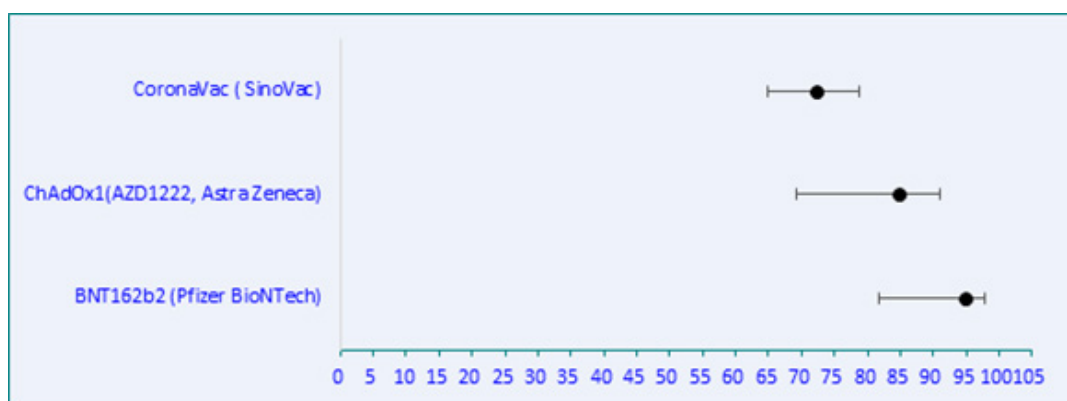
Figure 5: Comparison of effectiveness of the three vaccines.

Table 3: Comparative meta-analysis of CoronaVac vaccine effectiveness against severe disease presentation.

CoronaVac (SinoVac)			
Study	Effectiveness	Lower 95% CI	Upper 95% CI
Ref. Malaysia MOH	72	66.9	73.9
Premikha M et al, Singapore	54	35	68
Cerqueira-Silva T et al, Brazil	81.3	75.3	85.8
Suryatma A et al, Indonesia	71.1	62.9	77.6
Sritipsukho P et al, Thailand	60	49	69
Serrano-Coll et al, Columbia*	99.9	87.8	100
Ranzani et al, Brazil	55	47.6	66.9
Jara et al, Chile	87.1	85	88.7
McMenamin ME et al, HK	91.7	88.7	94
Yan VKC et al, HK	58.9	50.3	66.1
Copur et al, Turkey	65	50	75

Table 4: Comparison of effectiveness of the three vaccines.

	Mean	Lower 95% CI	Upper 95% CI
BNT162b2 (Pfizer BioNTech)	94.9	81.7	97.7
ChAdOx1 (AZD1222, Astra Zeneca)	84.7	69.4	91.1
CoronaVac (SinoVac)	72.4	64.9	78.6

DISCUSSION

BNT162b2, ChAdOx1 and CoronaVac vaccines are the three vaccines which were introduced in Malaysia following Emergency Use Approval (EUA) by WHO after clinical trials in various countries. Once the program was rolled out, various observational studies were conducted in different parts of the world to assess its effectiveness. Our study was focused on assessing the effectiveness of the vaccines against severe COVID-19 including hospitalisation and ICU admission. Hence a systematic analysis was performed to obtain peer-reviewed articles on the effectiveness of these vaccines from different countries. A total of 29 studies were finally approved for our meta-analysis which included 10 for BNT162b2,9 for ChAdOx1 and 10 articles for CoronaVac.

Among the 10 studies selected for BNT162b2, the effectiveness was very high (≥ 90%) upon completion of two doses. WHO had approved Pfizer BioNTech vaccine against COVID-19 as studies had shown very high efficacy against severe disease and moderate efficacy against symptomatic SARS-CoV-2 infection [35]. BNT162b2 vaccine was the most administered vaccine in Malaysia compared to the other two vaccines (61.2%) [36]. The effectiveness of BNT162b2 vaccine is 90.3% which is within the range observed from other countries and WHO data.

Nine articles selected for ChAdOx1 vaccine showed a wider range in its effectiveness (67.5%-97.6%). The effectiveness of the vaccine reported from our country is the highest among the studies. The cohort receiving ChAdOx1 vaccine in Malaysia was 7.9% of the total population [36].

29.8% of Malaysian population had received CoronaVac (SinoVac) vaccine. The vaccine effectiveness of CoronaVac varied from 54%-99.9% in the 10 studies selected for our meta-analysis. Malaysian data showed 72% effectiveness against severe disease. As per WHO, SinoVac-CoronaVac efficacy against hospitalization was 79% against severe COVID-19, and 100% against hospitalization starting 14 days after receiving the second dose [37]. A comparison between the three vaccines showed highest effectiveness for BNT162b2 (94.9%) followed by ChAdOx1 (84.7%) and SinoVac (72.4%).

Our study focused on the vaccine effectiveness in preventing severe disease, hospitalisation and ICU admissions. The effectiveness of these vaccines in preventing symptomatic disease or break-through infection cannot be assessed well and hence the overall effectiveness of these vaccines is not fully reflected as very few such studies are available.

Vaccine Efficacies (VE) ranging from 50% to 95% against symptomatic COVID-19 infections have been reported, using varying endpoint definitions. Real-world evidence from vaccine-rollout programs has shown that COVID-19 vaccines are highly effective against severe disease, hospitalization, and death, and reduce both asymptomatic infection and within household transmission [38]. According to Food and Drug Administration in order for an experimental COVID-19 vaccine to get the green light, it would need to be safe and "prevent disease or decrease its severity in at least 50% of people who are vaccinated" [39]. The 50% efficacy threshold set for COVID-19 vaccines is because COVID-19 was deemed such a severe disease, that if a vaccine is only 50% effective, it's still worth using. Fortunately, the emerging data on COVID-19 vaccines suggests that the vaccines are very safe with high efficacy, at least against some of the variants. AstraZeneca vaccine seems to have lower efficacy than the Pfizer vaccine at preventing mild to moderate disease, but has proven very useful in preventing severe disease, with nearly 100% efficacy against at least some variants of the virus that cause COVID-19. Given the very real risks from COVID-19 and the evidence that COVID-19 vaccines provide protection, especially against severe disease, hospitalization and death; makes it a good case to actively promote immunization with the currently available vaccines which have been shown to be very effective.

CONCLUSION

The wealth of real-world evidence confirms the remarkable efficacy of COVID-19 vaccines in thwarting severe disease, hospitalization, and mortality. Our study serves as a robust validation of the critical necessity to continually evaluate the effectiveness of these vaccines in safeguarding against severe COVID-19 cases. As we move forward, this knowledge remains pivotal in enhancing public health strategies and combating the pandemic effectively.

LIMITATIONS OF THE STUDY

• Multiple variants of COVID-19 have shown different severity in presentation, especially more with delta variant.

• Age related response is varied with severe symptoms and hospitalisation in aged population. Some studies have stratified the samples age wise to emphasize the skewing with people >60 years being more affected.

• Variation in country-wise data may reflect differences in the roll out of the vaccines with one or two of the three vaccines being used less, rolled out later, and phased out or regional factors.

• Asymptomatic COVID-19 accounts for a large percentage of the clinical presentation and hence the effectiveness of the vaccine on this group cannot be assessed as they don't subject them to testing or visit clinics and hence are not captured in many studies [40].

• Booster dose effect on immune response need to be studied further.

• The pandemic is still running its course with newer virus variants emerging and the effectiveness of vaccine and boosters need to be further assessed.

• Better understanding of the disease pathology, newer anti-viral drugs and immunotherapy has helped to improve the management of severe COVID-19 which also affects the final outcome of these studies, especially those done in late 2021 and 2022.

• Studies on the vaccine effectiveness on pregnant women, immunocompromised and those below 18 years of age are few.

SUGGESTIONS

• Subgroup analysis (based on age groups) will help to understand the age group most affected and whether it's affecting the overall data.

• Comparison between RCT and observational studies would give a more accurate picture of the difference between efficacy and real-world effectiveness.

DECLARATIONS

Ethics approval statement

The study was approved by the Institutional Ethics Board of the university.

Competing interests

There are no known competing financial interests or personal relationships that could have influenced our work.

Author contributions

Anita Devi Krishnan Thantry: Conceptualization, methodology and supervision of the project, Original draft preparation; Palaniappan A/L Palaniappan Lakshmanan, Edwin Cheah Shenq and Dhanraaj A/L Kunasakaran: Data collection and analysis, Design of figures and tables.

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Availability of data and materials

All data supporting the findings of this study are available within the paper and its supplementary information.

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