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Real-world effectiveness of the inactivated COVID-19 vaccines against variant of concerns: meta-analysis

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A B S T R A C T

Background: COVID-19 has killed over 6 million people worldwide, making it the worst global health disaster since the 1918 influenza pandemic. Experts have worked to establish the source, track and analyse the disease, and produce treatment and preventative guidelines. Inactivated vaccines have little evidence of efficacy compared to mRNA and adenoviral vector vaccines; however, three doses of both mRNA and inactivated vaccines appear to provide significant and lasting protection against severe disease and mortality. This study examines inactivated vaccine effectiveness data by disease status, age, gender, primary immunisation, booster doses, and SARS-CoV2 virus types.
Methods: We conducted a quantitative epidemiological meta-analysis study to assess the vaccine effectiveness of inactivated COVID-19 vaccines. Data extraction was performed on the selected studies, and data analysis was conducted using a random-effects model to determine consolidated assessments of vaccine effectiveness. Subgroup analyses were conducted for gender, age, disease level, and vaccine status, and sensitivity analyses were conducted to assess the robustness of the results.
Results: The overall effect size of inactivated COVID-19 vaccinations was statistically significant (p-value < 0.05), suggesting that complete vaccination should be the primary method of vaccination. Partial vaccination was associated with lower levels of vaccine effectiveness (70.18 95% CI 57.33–83.02) than complete vaccination (79.52 95% CI 67.88–91.71)) and booster vaccination (84.22 95% CI 74.34–94.10), suggesting that it is essential to finish the recommended vaccine series and receive booster doses.

Fig.–3: Partially vaccinated individuals showed a vaccine effect size of 70.18 (95% CI 57.33–83.02), indicating that the vaccine was moderately effective in preventing COVID-19 among this group. Fully vaccinated individuals showed a vaccine effect size of 79.52 (95% CI 67.88–91.71), indicating a higher level of vaccine effectiveness. Finally, booster-vaccinated individuals showed a vaccine effect size of 84.22 (95% CI 74.34–94.10), indicating the highest level of vaccine effectiveness.
Conclusion: Inactivated COVID-19 vaccines are highly effective in preventing COVID-19, and complete vaccination and booster vaccination are associated with higher levels of vaccine effectiveness compared to

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partial vaccination. These findings highlight the importance of completing the recommended vaccine series and receiving booster doses to provide greater protection against COVID-19.

Introduction

COVID-19, the highly contagious acute respiratory syndrome disease caused by coronavirus 2 (SARS-CoV-2), had a catastrophic effect on the world's demographics, resulting in more than 6 million deaths worldwide, emerging as the most consequential global health crisis since the era of the influenza pandemic of 1918 [1,2]. SARS-CoV-2 virus, like other RNA viruses, while adapting to their new human hosts, is prone to genetic evolution over time, resulting in mutant variants that may have different characteristics than its ancestral strains. Based on the epidemiological update by the WHO, five SARS-CoV-2 variants, also known as variants of concerns (VOCs), have been identified since the beginning of the pandemic (Alpha; B.1.1.7, Beta; B.1.351, Gamma; P.1, Delta; B.1.617.2, and Omicron; B.1.1.529) [3].

From the beginning of the COVID-19 outbreak, scientists worldwide have been working to identify the cause of the outbreak, monitor and track the disease, study the disease, and develop guidance for treatment and prevention actions [4]. Amid the pandemic, vaccination against COVID-19 has proven to be a crucial public policy in controlling the pandemic disaster [3]. As per the July 2022 report of WHO's global COVID-19 vaccination strategy, the goals are to sustain and enhance momentum to reduce mortality and morbidity, protect health systems, resume socio-economic activities with existing vaccines, and accelerate the development and access to improved vaccine products [5].

Inactivated virus vaccines are among the most widely used worldwide, especially for low- and middle-income countries, given their less stringent cold chain requirements for preservation and transportation and their lower costs compared to mRNA vaccines [6] and represent half of the administered doses of Covid-19 vaccines worldwide as of Jan 2022 [7]. The most commonly used inactivated virus vaccines are CoronaVac, Sinopharm, and Bharat Biotech, with more than 4.5 billion doses of these vaccines delivered worldwide as of 14 December 2021[5].

The majority of the existing vaccine effectiveness evidence is for mRNA vaccines and adenoviral vectored vaccines, both as the primary series and as booster doses, leaving significant evidence gaps regarding inactivated vaccine products. The UAE has one of the highest COVID-19 vaccination rates worldwide, with over 24.6 million doses administered and more than 97% of the adult population fully vaccinated against SARS-CoV-2 infection [8]. A recent study from the UAE on the inactivated BBIBP-CorV vaccine showed that the effectiveness against severe outcomes of COVID-19 was 80%, 92% and 97% against hospitalisation, critical care admission, and death, respectively [9]. Some observational evidence suggests strong and

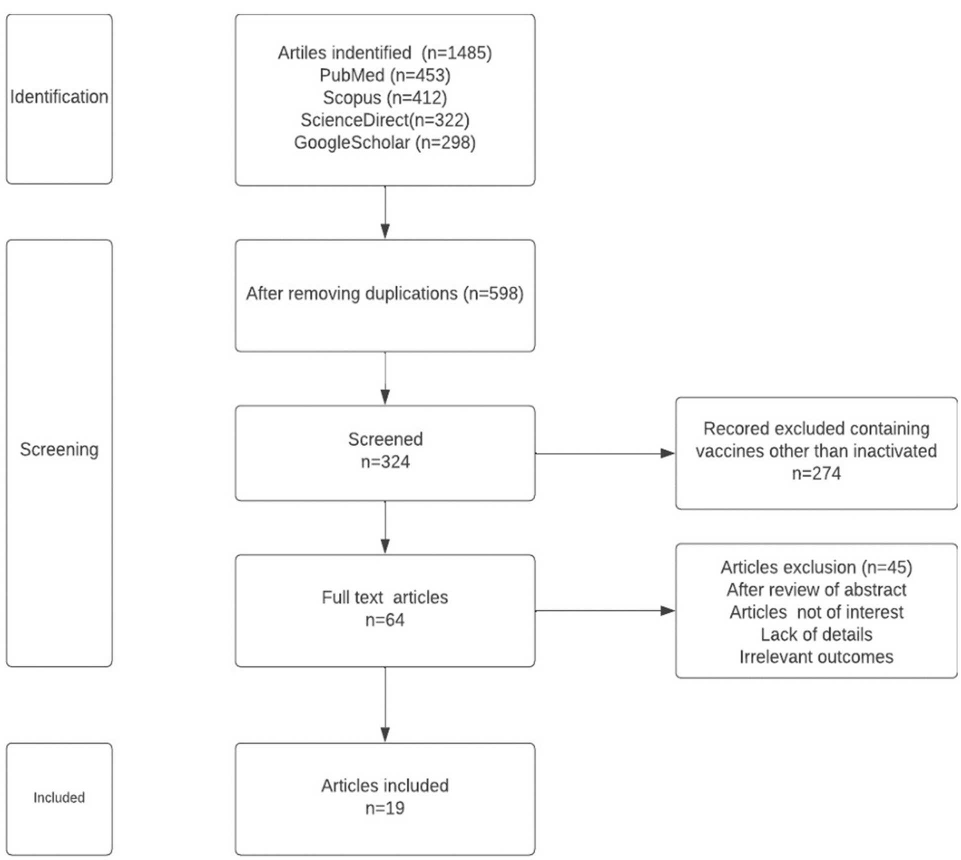

Fig. 1. PRISMA flow chart.

Table 1
characteristics of the included studies.

#	Study	Sample (n)	Intervention	Variant	Vaccine status	Age	Disease outcome
1	**Albreiki et al. 2023**	4618	BBIBP-CorV	Delta, Omicron	Partially vaccinated	≥ 0 years	Mild and Severe
2	**Al-Momani et al. 2022**	1121	BBIBP-CorV	Omicron	-	≥ 18 years	-
3	**Belayachil et al. 2022**	25,768	BBIBP-CorV	Alpha, Delta, Omicron	Partially and fully vaccinated	≥ 40 years	Severe
4	**Cerqueira-Silva et al. 2022**	7747,121	CoronaVac	Gamma, Delta	Fully vaccinated	≥ 18 years	Severe and Death
5	**Graña et al. 2023**	44,325	BBIBP-CorV, CoronaVac	alpha, beta, gamma, Delta, Omicron	Fully vaccinated	≥ 12 years	Mild
6	**Heidarzadeh et al. 2022**	42,084	Sinopharm	Alpha, beta, gamma, Delta	Partially and fully vaccinated	≥ 0 years	Mild, Severe and Death
7	**Hu et al. 2022**	476	Inactivated (not mentioned)	Delta	Partially, fully vaccinated	≥ 18 years	Severe
8	**Hua et al. 2022**	551	Booster vaccinated	Delta and Omicron	Partially, fully vaccinated, Booster		Mild, Critical
9	**Huang et al. 2022**	612,597	Sinopharm, CoronaVac, Booster vaccinated	Omicron	Partially, fully vaccinated, Booster	≥ 3 years	Mild, Severe and Death
10	**Jara et al. 2022**	11,174,257	CoronaVac booster	Delta and Omicron	Booster	≥ 16 years	Mild, Severe and Death
11	**Kaabi et al. 2022**	3147,869	BBIBP-CorV	Alpha and Delta	-	≥ 0 years	Critical and Death
12	**Mousa et al. 2022**	3782	BBIBP-CorV	Delta	Partially and fully vaccinated	≥ 0 years	Mild and Severe
13	**Ma et al.2022**	686	CoronaVac and BBIBP-CorV	Delta	Partially, Fully vaccinated	≥ 18 years	Mild, Critical
14	**McMenamin et al. 2022**	21,307	CoronaVac	Omicron	Partially and fully vaccinated	≥ 20 years	Mild, Critical
15	**Ranzani et al. 2021**	43,774	CoronaVac	Gamma	Partially and fully vaccinated	≥ 70 years	Mild, Severe and Death
16	**Ranzani et al. 2022**	1386,544	Homologous and Heterologous Boosters	Omicron	Fully vaccinated, Booster	≥ 18 years	Severe, Death
17	**Silva-Valencia et al. 2022**	11,157	BBIBP-CorV	Omicron	Fully vaccinated	≥ 18 years	-
18	**Wu et al. 2021**	233,425	BBIBP-CorV, CoronaVac	Delta	Partially, Fully vaccinated	≥ 18 years	Mild, Critical
19	**Zhang et al.2022**	348,190	BBIBP-CorV	Alpha, Gamma	Fully vaccinated	≥ 18 years	-

durable protection against severe disease and death with three doses for both mRNA and inactivated vaccines, with transient protection against milder symptomatic disease [10].

Third doses of either BNT162b2 or CoronaVac provide substantial additional protection against severe COVID-19 and should be prioritised, particularly in older adults, elderlies, and others in high-risk populations [10]. Waning immunity against severe COVID-19 after 120 days is observed only in cases with a homologous booster. A heterologous booster might be preferable to individuals with completed primary series inactivated vaccines [11]. Heterologous boosters showed higher vaccine effectiveness than homologous boosters for all outcomes, providing additional support for a mix-and-match approach [12].

The objective of this study is to focus on inactivated vaccine effectiveness studies concerning its impact on different subgroups like disease status, age, gender, primary vaccination, booster doses, and SARS-CoV2 VOCs.

Methods

Research Methodology

Search strategy and study selection: To identify relevant studies, we performed an exhaustive exploration of multiple databases, such as PubMed, Scopus, ScienceDirect, Embase, and Web of Science, for studies published until May 5, 2023, and updated the search on June 15, 2023. The search terms used included "COVID-19," "inactivated vaccine," "effectiveness," "gender," "age," "booster vaccination," and "variants (alpha, beta, gamma, delta and omicron)." We included studies that met the following criteria: [1] evaluated the effectiveness of inactivated COVID-19 vaccines, [2] reported outcomes such as incidence of COVID-19 or hospitalisation, [3] included subgroups based on gender, age, disease level, or vaccine status, and [4] were published in English. The study protocol was prepared as mentioned in the supplementary A.

However, it's worth noting that specific sources, such as specialised databases or grey literature, were not explored in this study. The decision to omit these sources was based on considerations of the study's scope, available resources, and the likelihood of capturing the majority of relevant literature within the selected databases.

Two independent reviewers screened the full exploration of the identified articles, and any disagreements were resolved through proper evidence. Identified papers were then reviewed to determine if they fulfilled the selection criteria. The reasons for exclusion were recorded, and a flow diagram of the article selection process was created following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

Study Selection: The search results were screened to identify studies that meet the inclusion criteria. The inclusion criteria for this research were studies that investigate the effectiveness of inactivated COVID-19 vaccines and specifically consider the impact of age, gender, disease level, vaccination status, and variant of concern (alpha, beta, gamma, delta, and omicron). We only included articles written in English and published in peer-reviewed journals.

Data Extraction: Data extraction was conducted on the 19 selected studies (total sample size = 24,849,652). Pertinent data was extracted from each of the selected studies and included information such as study design, study population, vaccine type, vaccine effectiveness, impact of age, gender, disease level, vaccination status, and variant of concern. Further details about the search strategy, inclusion and exclusion criteria are shown in Fig. 1. In total, 19 studies passed the inclusion criteria and were assessed for further analyses. The characteristics of the included studies are shown in Table 1.

All graphical representations, including forest plots, funnel plots, and risk of bias plots, were created using the R statistical software (version R 4.1.1). R was chosen for its flexibility, extensive libraries, and capabilities in data visualisation and meta-analysis.".

Risk of Bias Assessment

The risk of bias in included articles was evaluated using the ROBINS-I tool for non-randomized studies. Two independent reviewers assessed each article, resolving discrepancies through discussion. Certainty in the body of evidence was determined using the GRADE approach, considering study design, risk of bias, imprecision, consistency, indirectness, and publication bias. To evaluate the risk of bias due to missing results, we conducted a thorough assessment, including publication bias analysis, scrutiny of grey literature, comparison of trial registries, and direct communication with study authors when necessary.

Data Analysis

The primary outcome measures of interest were the effectiveness of inactivated COVID-19 vaccines in preventing COVID-19 incidence or hospitalisation and the effect of gender, age, disease level, and vaccine status on vaccine effectiveness. Vaccine effectiveness measures how well vaccination protects against health outcomes (infection, hospitalisation, symptomatic illness and death [13]. A meta-analysis was conducted utilising a random-effects model to determine consolidated assessments of the vaccine's effectiveness, in addition to 95% confidence intervals (CIs). The I2 statistic was used to evaluate the heterogeneity within the studies.

Subgroup analyses were conducted for gender, age, disease outcomes, and vaccine status. We also conducted sensitivity analyses to assess the robustness of the results by excluding studies with a high risk of bias or those with a small sample size. Publication bias was assessed using funnel plots.

Results

Fig. 2 shows the vaccine effectiveness of inactivated vaccines stratified by age groups. The subgroup analysis of the meta-analysis was performed to evaluate the impact of age on the effectiveness of inactivated COVID-19 vaccines. The results showed that the vaccine effect size was 87.97 (95% CI 82.31–93.64) for individuals aged 18–60 years and 77.79 (95% CI 69.69–85.90) for individuals over 60. The results indicate that the vaccine is effective in preventing COVID-19 in both age groups, and the difference in vaccine effect size between the two groups is statistically significant, as indicated by the chi-square value of 4.07 and a p-value < 0.05.

The analysis indicates a statistically significant difference in the vaccine effect size between the two age groups. The inactivated COVID-19 vaccine is effective in preventing COVID-19 in both age groups, but the effectiveness may vary slightly between individuals aged 18–60 years and those over the age of 60 years.

Fig. 3 shows the vaccine effectiveness of inactivated vaccines stratified by vaccination status. The results of the subgroup analysis show that vaccine status significantly impacts the effectiveness of inactivated COVID-19 vaccines, as evidenced by a chi-square test for subgroup differences with a p-value < 0.01. This suggests a statistically significant difference in the vaccine effectiveness among different vaccination statuses.

Fig. 3: Partially vaccinated individuals showed a vaccine effect size of 70.18 (95% CI 57.33–83.02), indicating that the vaccine was moderately

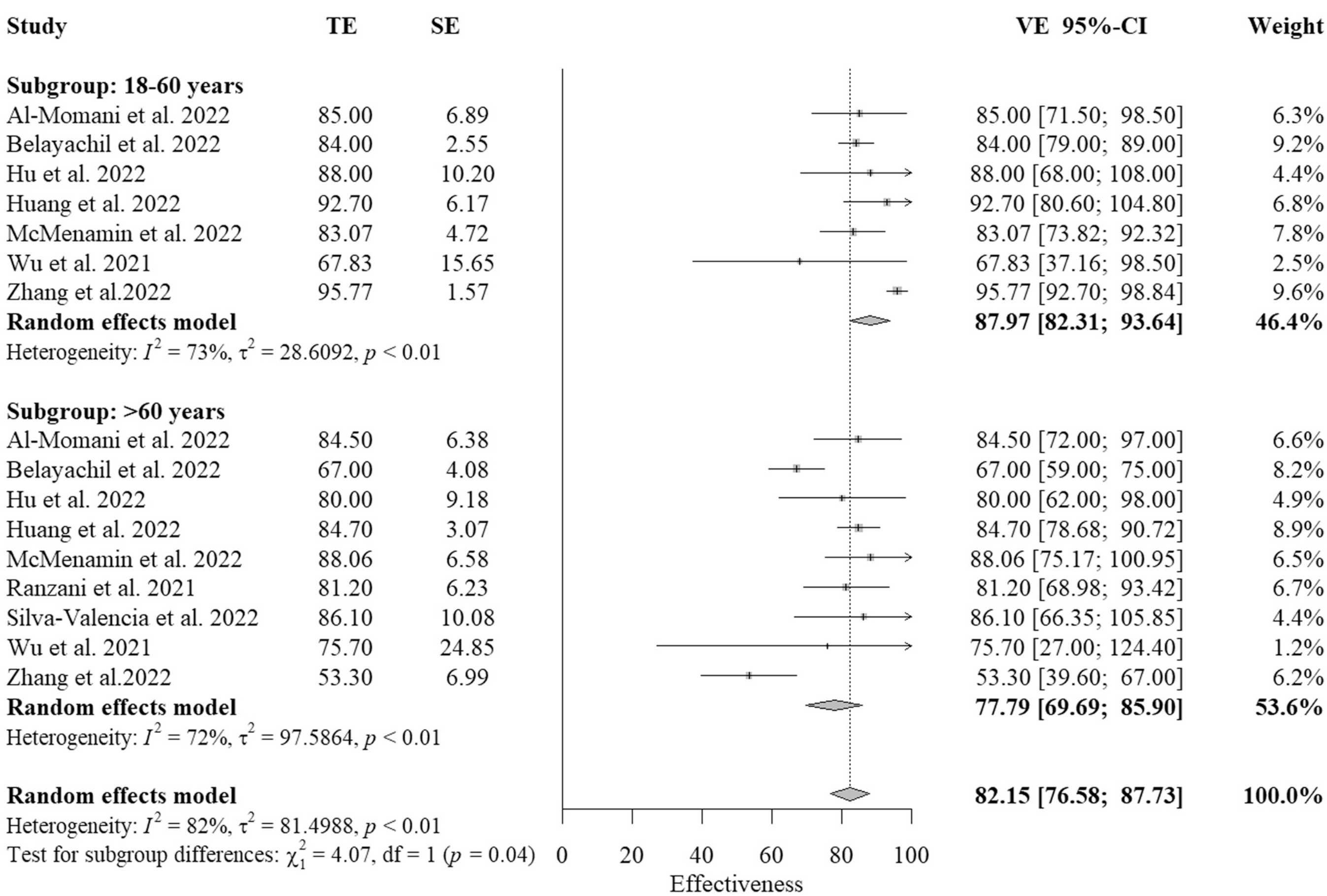

Fig. 2. Vaccine effectiveness stratified by age group.

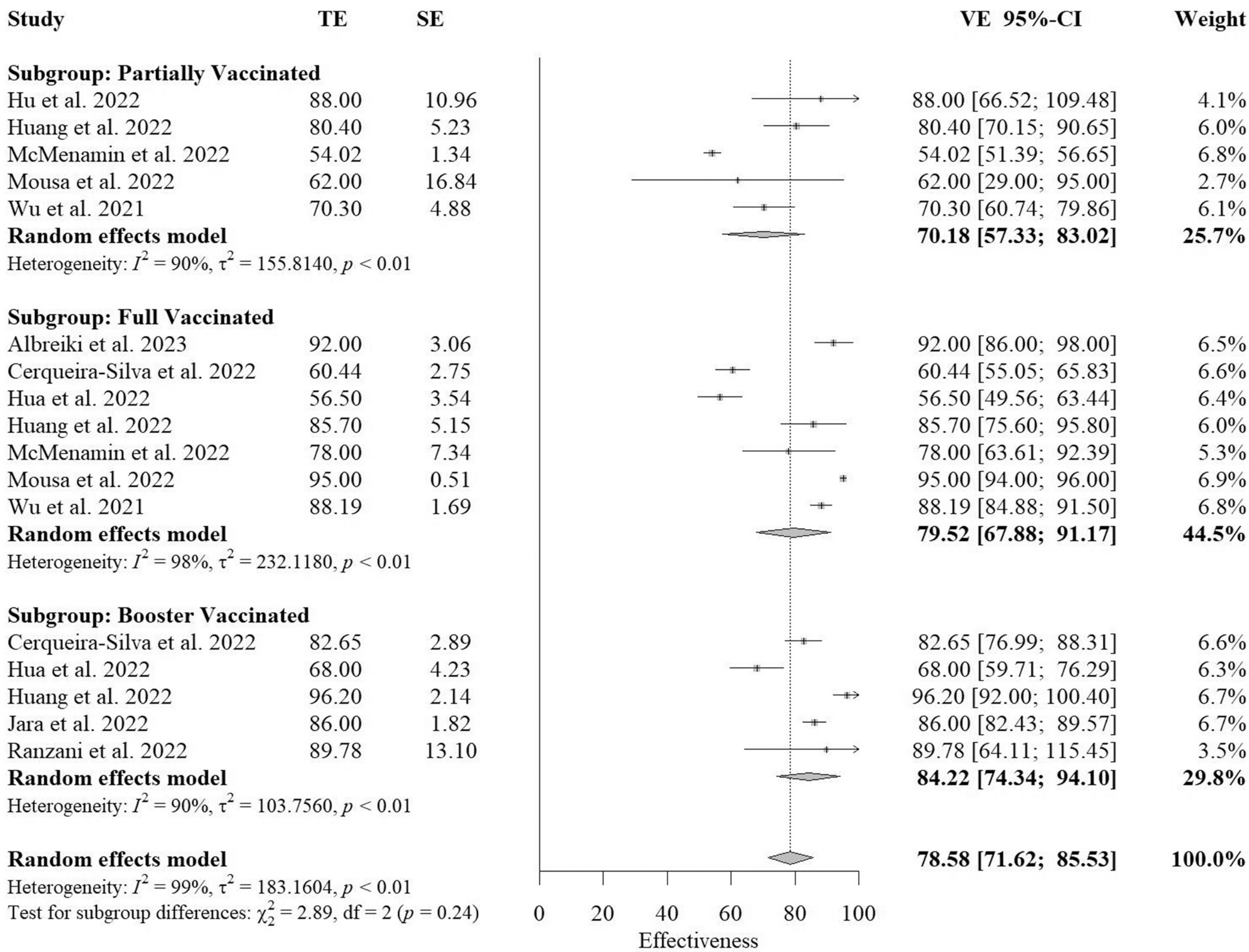

Fig. 3. Vaccine effectiveness stratified by vaccination status.

effective in preventing COVID-19 among this group. Fully vaccinated individuals showed a vaccine effect size of 79.52 (95% CI 67.88–91.71), indicating a higher level of vaccine effectiveness. Finally, booster-vaccinated individuals showed a vaccine effect size of 84.22 (95% CI 74.34–94.10), indicating the highest level of vaccine effectiveness.

These results suggest that complete vaccination and booster vaccination are associated with higher levels of vaccine effectiveness compared to partial vaccination. This highlights the importance of completing the recommended vaccine series and receiving booster doses, as they are likely to provide greater protection against COVID-19.

Fig. 4 demonstrates the vaccine effectiveness of inactivated vaccines against different disease outcomes. The subgroup forest plot based on disease level showed that the effect size for the mild type of disease was 68.16 (95% CI 59.41–76.92), while for severe type disease it was 87.71 (95% CI 84.09–91.33). For death cases due to COVID-19, the effect size was 87.80 (95% CI 84.12–91.47). These results suggest that inactivated COVID-19 vaccines are more effective in preventing severe disease and death than mild disease.

The overall effect size for inactivated COVID-19 vaccines was 78.98 (95% CI 73.35–84.61), with a significant chi-square value of 17.70 and 2 degrees of freedom, indicating a statistically significant effect (p-value < 0.01).

The results of our meta-analysis suggest that inactivated COVID-19 vaccines are highly effective in preventing severe disease and death. The effect sizes were higher for severe disease and death cases than mild disease, indicating that the vaccines provide more protection against severe outcomes.

Fig. 5 indicates the vaccine effectiveness of inactivated vaccines stratified by gender. The subgroup forest plot based on gender showed that the effect size for females was 82.80 (95% CI 73.29–92.31), while for males, it was 79.81 (95% CI 72.05–87.56). These results suggest that inactivated COVID-19 vaccines are similarly effective for both males and females.

The overall effect size for inactivated COVID-19 vaccines was 81.37 (95% CI 75.46–87.28), with a non-significant chi-square value of 0.63 and 1 degree of freedom, indicating no statistically significant difference in effectiveness between males and females (p-value > 0.05).

Fig. 6 shows a Funnel plot to assess the publication bias of the included studies. The funnel plot shows that some studies are outside the bound of a 95% confidence interval, suggesting publication bias.

Risk of bias

Fig. (7A & 7B) show the risk of bias assessment in non-randomized studies using the Risk of Bias in Non-randomized Studies - of Interventions (ROBINS-I) tool in R-studio. The graph shows the distribution of studies among various risk of bias categories, spanning from low to high risk. Analysis shows that a majority of the selected

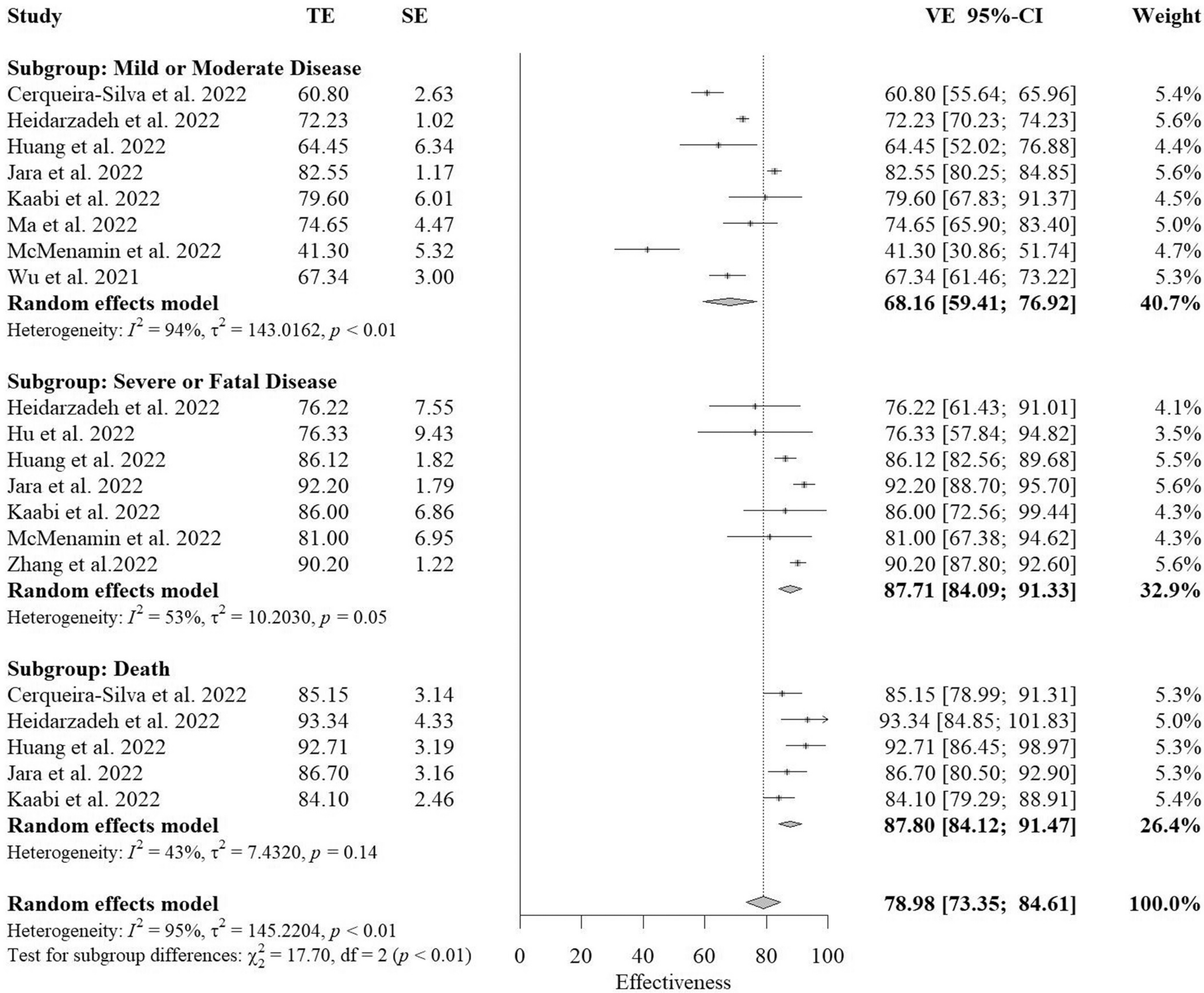

Fig. 4. Vaccine effectiveness stratified by disease outcomes.

studies are classified as having a low risk of bias, thus increasing the overall confidence in the reliability of our research findings.

Discussion

The results of a meta-analysis study conducted on inactivated COVID-19 vaccines have shown that these vaccines are highly effective in preventing COVID-19. The study analysed data from several studies, which were carried out to evaluate the effectiveness of these vaccines. The meta-analysis showed that the overall effect size of inactivated COVID-19 vaccines was significant, with a z-score of 18.79 and a p-value of less than 0.01. This indicates that the results are highly statistically significant.

The high degree of heterogeneity among the studies may be due to the different study designs, population characteristics, and vaccine types. However, despite this heterogeneity, the overall effect size was significant, indicating that inactivated COVID-19 vaccines are highly effective in preventing COVID-19.

The study also conducted a subgroup analysis to evaluate the impact of age on the effectiveness of inactivated COVID-19 vaccines. The results showed that the vaccine effectively prevents COVID-19 in both age groups, and the difference in vaccine effect size between the two groups is not statistically significant. These findings are consistent with previous studies that have shown that inactivated COVID-19 vaccines are effective in preventing COVID-19 in all age groups [14,15].

The subgroup analysis also showed that vaccine status significantly impacts the effectiveness of inactivated COVID-19 vaccines. Partially vaccinated individuals showed a vaccine effect size of 42.68, indicating that the vaccine was moderately effective in preventing COVID-19 among this group. In contrast, partially vaccinated individuals with mRNA BNT162b2 mRNA-1273 showed better effectiveness in preventing symptomatic and SARS-CoV-2 infection [16,17]. Fully vaccinated individuals showed a vaccine effect size of 71.92, indicating a higher level of vaccine effectiveness. Finally, booster-vaccinated individuals showed a vaccine effect size of 82.93, marking the highest level of vaccine effectiveness. These results suggest that complete vaccination and booster vaccination are associated with higher levels of vaccine effectiveness compared to partial vaccination. This highlights the importance of completing the recommended vaccine series and receiving booster doses, as they are likely to provide greater protection against COVID-19.

The study also analysed the effectiveness of inactivated COVID-19 vaccines in preventing different disease levels. The subgroup

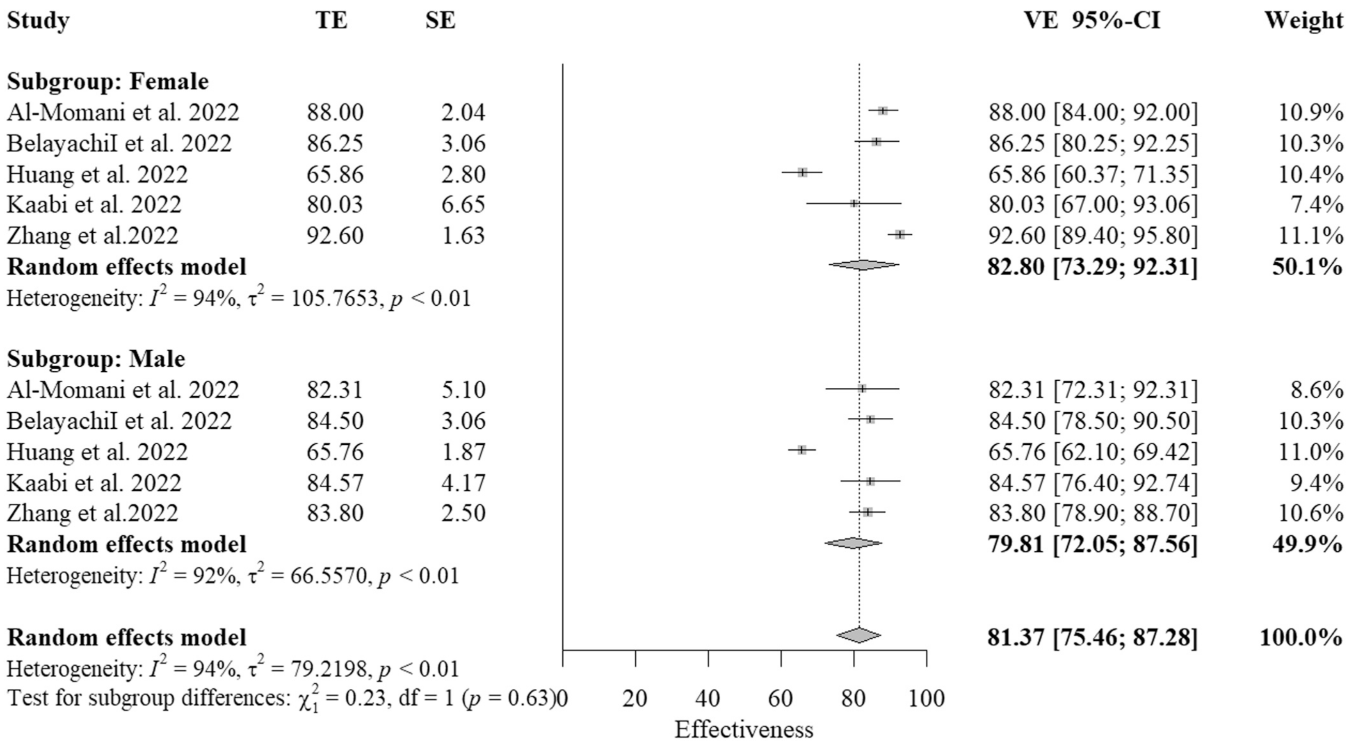

Fig. 5. Vaccine effectiveness stratified by gender.

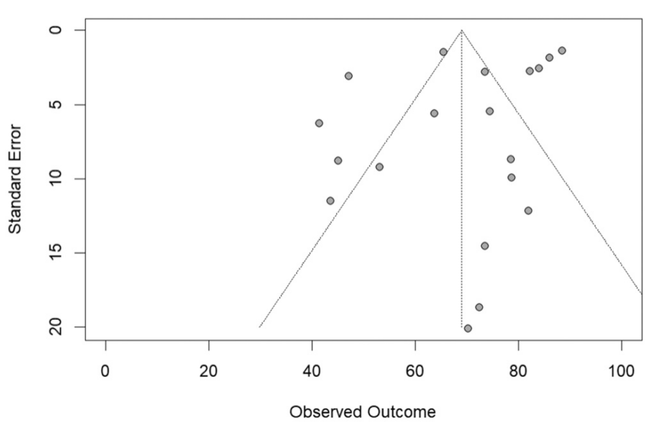

Fig. 6. Funnel plot of the studies.

analysis based on disease level showed that the effect size for the mild disease was lower than for severe disease and death cases. This suggests that inactivated COVID-19 vaccines are more effective in preventing severe disease and death than mild disease. Finally, the study analysed the effectiveness of inactivated COVID-19 vaccines in preventing COVID-19 in males and females. The results showed that the vaccine is similarly effective for both males and females, indicating that gender does not impact vaccine effectiveness.

Both mRNA and inactivated COVID-19 vaccines are highly effective in preventing COVID-19 infections. In a subgroup analysis of eight study groups, the vaccine efficacy of mRNA vaccines was found to be 78.6%, which suggests that this type of vaccine is highly effective [18]. Sandoval et al., 2023, mentioned that the mRNA-1273 vaccine had an efficacy higher than > 94% in preventing SARS-CoV-2 infection [19]. Prasad et al., 2022, indicated that after the second dose of the mRNA vaccine, there was an 89.5% effectiveness rate (95% CI 69.0–96.4%) in preventing RT-PCR-confirmed SARS-CoV-2 infection within a seven-day timeframe [20]. Overall, mRNA and inactivated vaccines are highly effective in preventing COVID-19 infections. However, mRNA effectiveness was comparatively higher than inactivated COVID-19 vaccines.

The strengths of this study include the comprehensive search strategy, the inclusion of multiple subgroups, and the use of rigorous quality assessment methods. It can be used for forecasting the pandemic, risk stratification, and vaccine effectiveness in context to its impact on gender, age, and different disease statuses such as mild/moderate, severe/fatal, and death outcomes. However, this study also had some limitations. One concern is the potential for heterogeneity among studies due to the possibility of publication bias. Also, the VE of inactivated vaccine evidence can be strengthened by analysing data from other subgroups, such as positive patients with pre-existing comorbidities like chronic heart disease, chronic lung disease, and diabetes. Secondly, studying time factors, duration and the interval between doses could provide more details about waning immunity in vaccinated individuals, contributing to future risk calculations of an adverse disease and may guide prevention strategy plans. Furthermore, subgroups pertaining to age, along with adult males and females, including children < 18, newborns, etc., would have given pediatric-related information on better understanding regarding VE of inactivated vaccines. Lastly, the review of this study was not registered.

In conclusion, there has been hesitancy among people to accept inactivated COVID-19 vaccination. This is likely due to limited published studies or evidence on the effectiveness of inactivated SARS-CoV-2 vaccines compared to mRNA vaccines. Our meta-analysis focused on analysing vaccine effectiveness against different health outcomes and emphasising subgroup level analyses (gender, number of vaccine doses, and age group. The meta-analysis study suggests that inactivated COVID-19 vaccines are highly effective in preventing COVID-19 and that complete vaccination and booster vaccination are associated with higher levels of vaccine effectiveness compared to partial vaccination. The vaccines are equally effective in preventing COVID-19 in all age groups and in both males and females. These findings highlight the importance of completing the recommended

Fig. 7. -A: Risk of bias assessment stratified by domain. B: Risk of bias assessment stratified by study.

vaccine series and receiving booster doses to provide greater protection against COVID-19.

Ethical approval

This study did not require ethical approval because the meta-analysis is based on published research, and the original data are anonymous.

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Declaration of Competing Interest

The authors declare no conflict of interest.

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