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Systematic Evaluation And Meta-Analysis Of The Effectiveness Of Novel Coronavirus Pneumonia Vaccine Against Omicron Mutant

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Abstract

Objective: To systematically evaluate the effectiveness of the novel coronavirus pneumonia vaccine in preventing the infection of variant strains of the Omicron virus.

Methods: The databases of Web of Science, PubMed, Embase, The Cochrane Library, CNKI, WanFang Data, and CBM were searched by computer, and the case-control studies were collected to evaluate the effectiveness of the novel coronavirus pneumonia vaccine in preventing the infection of Omikron and its variants. The search time was from establishing the database to March 8, 2023. After two researchers independently screened the literature, extracted data, and evaluated the risk of bias included in the study, a meta-analysis was conducted using RevMan 5.3 software.

Results: A total of 9 studies were included, including 2865389 subjects. The meta-analysis results showed that the infection rate (OR=0.56, 95% CI (0.48, 0.65), P<0.001), hospitalization rate (OR=0.44, 95% CI (0.39, 0.51), P<0.001), and severe illness rate (OR=0.53, 95% CI (0.35, 0.81), P<0.001) of the vaccination group were significantly lower than those of the non-vaccination group.

Conclusion: Vaccination can effectively prevent the infection of the novel coronavirus Omikron strain and reduce the incidence of hospitalization and critical illness caused by the virus. This provides an essential reference for the formulation and implementation of epidemic prevention policies such as vaccine promotion.

Keywords: novel coronavirus pneumonia vaccine; Omicron variants Effectiveness; Meta-analysis; Case Control Study.

Introduction

Novel coronavirus pneumonia is an acute respiratory infectious disease caused by severe acute respiratory syndrome coronavirus 2. Since the first report of unknown coronavirus pneumonia in China in 2019, the pandemic has caused great harm at home and abroad, seriously affecting public health, economic development, and people's health in China and the world **[10-11]**.

Epidemiological data shows that 20% of the confirmed patients with COVID-19 infection need to be hospitalized, of which the demand ratio of ICU is 1∶16000, the case fatality rate of patients under 65 years old is 0.6% ～ 2.8%, and that of patients over 70 years old is 5.4% ～ 16.6% [**12-14]**. Because of the Lack of effective antiviral drugs and the fact that the epidemic has never been fundamentally controlled, vaccines are considered one of the most effective means to prevent COVID-19 infection **[15]**.

Since the first case of the Omicron variant was reported in South Africa in November 2021, the Omicron variant has developed into a dominant strain following the Alpha variant, Beta variant, Gamma variant, and Delta variant. However, most vaccines currently in the clinical evaluation stage are designed for the wild type of COVID-19 virus, and its effectiveness in preventing the infection of the Omicron variant remains to be discussed **[16-17]**.

This study systematically evaluated the effectiveness of the COVID-19 vaccine in preventing the infection of the Omicron variant to provide medical evidence for optimizing the prevention and treatment strategy of COVID-19 and formulating the grading diagnosis and treatment system of COVID-19.

1. Materials and Methods

1.1 Inclusion and Exclusion Criteria

1.1.1 Study Type Case-Control Trials.

1.1.2 Subjects Patients with suspected symptoms of COVID-19 (cough, fever, shortness of breath, vomiting, diarrhoea) **[18]** who went to medical institutions for treatment.

1.1.3 Intervention test group: intramuscular injection of COVID-19 vaccine and primary immunization or reinforcer injection after basic immunization; Control group: did not receive any SARS-CoV-2 vaccine.

1.1.4 Outcome indicators: SARS-CoV-2 infection rate, hospitalization rate, critical illness rate, and mortality rate.

1.1.5 Exclusion criteria: ① Non-Chinese and English literature; ② Publish multiple articles on the same vaccinated population and select the most recent or informative one; ③ Non-Phase I/II, Phase II, and Phase II/III clinical trials: ④ Full text cannot be obtained; ⑤ Lack of outcome indicators or inability to extract raw data.

1.2 Literature Retrieval Strategy

Computer searches Web of Science, PubMed, Embase, The Cochrane Library, CNKI, WanFang Data, and CBM databases to collect RCTs of different types of COVID-19 vaccines applied in the population. The search time limit is from establishing the database **to March 8, 2023**. The retrieval is carried out by combining theme words and free words. The keywords include COVID-19, novel coronavirus, novel coronavirus Pneumonia, New Coronavirus Variant, Omicron, novel coronavirus Pneumonia Vaccine, novel coronavirus Pneumonia Intensive Needle, effectiveness, vaccine efficacy, negative detection case-control study, etc. Taking PubMed as an example, the specific search strategy is shown in Box 1.

#1 COVID-19 vaccines
#2 COVID-19 virus vaccines
#3 2019-nCoV vaccines
#4 2019 Novel coronavirus vaccines
#5 SARS-CoV-2 vaccines
#6 SARS coronavirus 2 vaccines
#7 SARS2 vaccines
#8 SARS-CoV-2 variant vaccines
#9 Omicron vaccines
#10 # 1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9
#11 vaccine efficacy
#12 VE
#13 # 11 OR #12
#14 #10 AND #13

Box 1 PubMed Retrieval Strategy

1.3 Literature Screening and Data Extraction

Two researchers independently screened the literature, extracted data, and cross-checked it. If there are differences, they can be resolved through discussion or consultation with third parties. When selecting literature, first read the title, and after excluding significantly unrelated literature, further read the abstract and full text to determine whether to include it. If necessary, contact the original research author via email or phone to obtain information that still needs to be confirmed but is crucial to this study. The content of data extraction includes ① basic information contained in the study: research topic, first author, publication country, publication time, etc.; ② Baseline characteristics of the study subjects; ③ Specific details of exposure factors; ④ Key elements of bias risk assessment; ⑤ Outcome indicators and outcome measurement data of concern.

1.4 Risk assessment of bias included in the study

Two researchers independently evaluated the bias risk of inclusion in the cohort study using the Newcastle Ottawa Scale and cross-checked the results. Each item is assessed as' yes,' 'no,' or 'unclear'.

1.5 Statistical Analysis

Meta-analysis was conducted using RevMan 5.3 software. The binary variable uses relative risk ratio (RR) as the effect indicator, and their point estimates and 95% CI are given. Heterogeneity adoption among included studies χ 2 tests for analysis (inspection level: α= 0.1) while Combining I2 to determine the magnitude of heterogeneity quantitatively. If there is no statistical heterogeneity among the research results, a fixed effects model is used for meta-analysis. If there

is statistical heterogeneity between the outcomes of each study, subgroup analysis and sensitivity analysis are used to explore the sources of heterogeneity further. After excluding the impact of significant clinical heterogeneity, a random effects model is used for meta-analysis. The testing level for meta-analysis is set to bilateral $\alpha = 0.05$.

2. Results

2.1 Literature screening process and results

180 relevant literatures were initially identified, and after layer-by-layer screening, they were ultimately included in 9 cohort studies, with a total of 2865389 people. The literature screening process and results are shown in **Figure 1**.

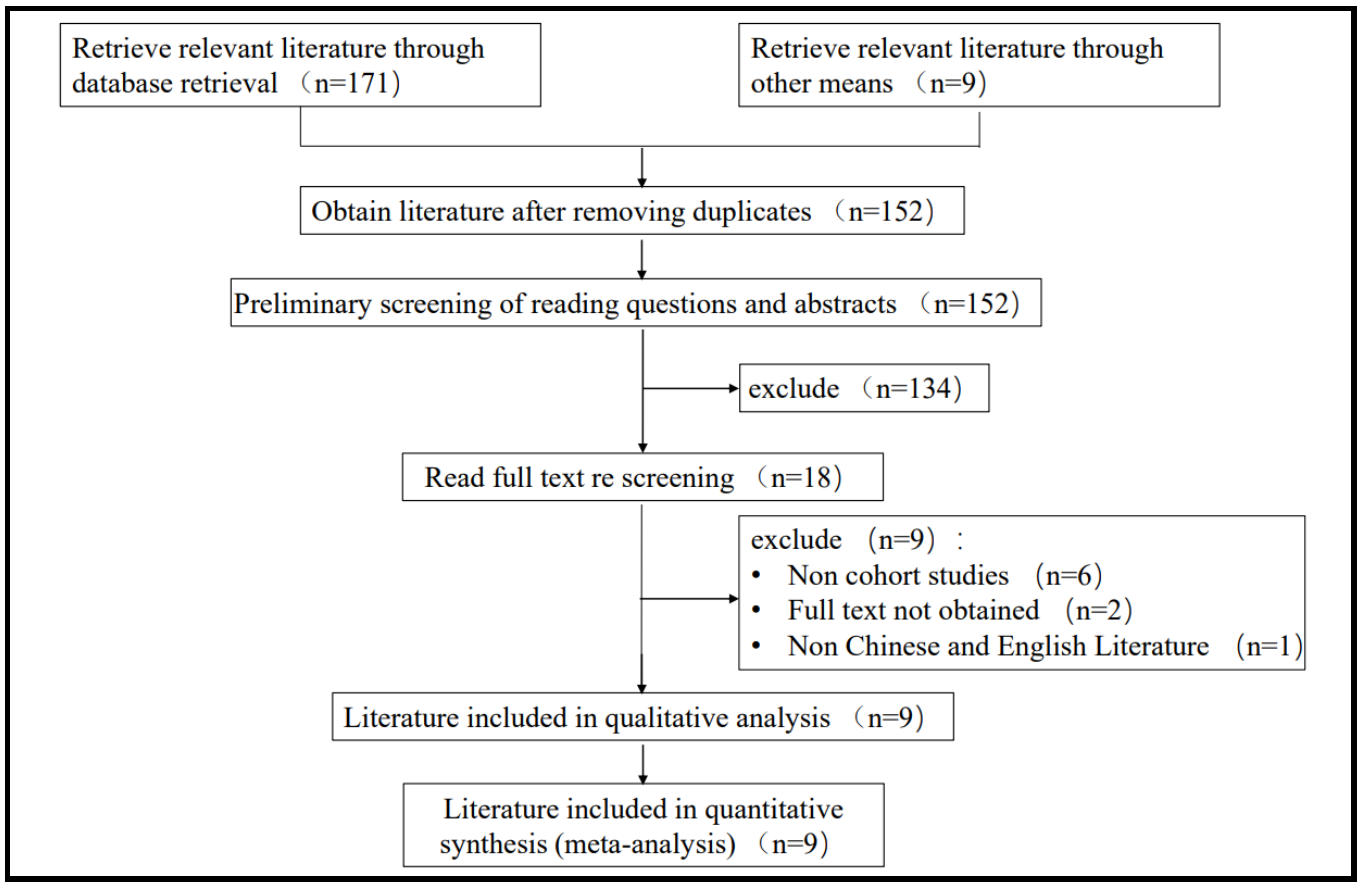

Figure 1: Literature screening process and results

2.2 Basic characteristics and bias risk assessment results included in the study.

The basic characteristics included in the study are shown in Table 1, and the results of bias risk assessment are shown in Table 2.

Table 1: Basic characteristics of inclusion in the study

Include studies	country	age	Study type	Basic information of vaccines			case group (Omicron+)		control group (Omicron-)		Outcome indicators
				Vaccine name	Vaccine type	vaccine program	Vaccine group	Unvaccina-ted group	vaccine group	Unvaccina-ted group	
Mark2022[1]	America	⩾18	a retrospective study	BNT162b2 mRNA-1273	nucleic acid vaccine	booster jab	3148	3398	7883	3598	infection rate
Andrews2022 [2]	Britain	⩾18	Negative Case Control Study	ChAdOx1 nCoV-19 BNT162b2 mRNA-1273	Virus vector vaccine nucleic acid vaccine	Basic immunity+s trengthening needle	785665	101109	1465383	107238	infection rate
Adam2022[3]	America	⩾18	prospective study	BNT162b2 mRNA-1273	nucleic acid vaccine	booster jab	291	268	3908	2054	Infection rate、hospitalization rate、Severity rate、mortality rate
Price2022[4]	America	5-18	Negative Case Control Study	BNT162b2	nucleic acid vaccine	Basic immunity	284	2086	1184	2070	Infection rate、hospitalization rate severity rate
Hung2022[5]	America	⩾18	Negative Case Control Study	mRNA-1273	nucleic acid vaccine	booster jab	13769	25790	33725	45393	infection rate
Nemet2021[6]	South Africa	not mentioned	Negative Case Control Study	BNT162b2	nucleic acid vaccine	Basic immunity	11181	7889	40661	18442	Infection rate hospitalization rate
Nicola2022[7]	America	5-17	a retrospective study	BNT162b2	nucleic acid vaccine	booster jab	1050	4434	1527	5203	infection rate
Jill2022[8]	America	⩾18	a retrospective study	BNT162b2 mRNA-1273	nucleic acid vaccine	booster jab	10289	13991	20464	10808	infection rate
Sheikh2022[9]	Scotland	⩾16	Negative Case Control Study	ChAdOx1 nCoV-19 BNT162b2 mRNA-1273	Virus vector vaccine nucleic acid vaccine	Basic immunity+s trengthening needle	9936	1003	90968	9299	infection rate

Table 2: Bias Risk Assessment Results for Inclusion in the Study

Include studies	Selection of research subjects				Intergroup comparability	outcome measure		
	Representative exposure group	Selection of non-exposed groups	Determination of exposure	Outcome events before the start of the study	comparability	Outcome event evaluation	Is the follow-up sufficient	Integrity of follow-up
Mark2022[1]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Andrews2022[2]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Adam2022[3]	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Price2022[4]	Yes	Yes	Yes	Yes	unclear	Yes	Yes	Yes
Hung2022[5]	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Nemet2021[6]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Nicola2022[7]	Yes	Yes	Yes	Yes	Yes	unclear	Yes	Yes
Jill2022[8]	Yes	Yes	unclear	Yes	Yes	Yes	Yes	Yes
Sheikh2022[9]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

2.3 Meta analysis results

2.3.1 Meta analysis of novel coronavirus vaccine for prevention of infection of Omicron mutant

A total of 9 cohort studies were included **[1-9]**, and the random effects model meta-analysis results showed that the infection rate of the Omicron virus strain in the vaccinated group was significantly lower than that in the non-vaccinated group [OR=0.56, 95% CI (0.48, 0.65), P<0.001] **(Figure 2)**.

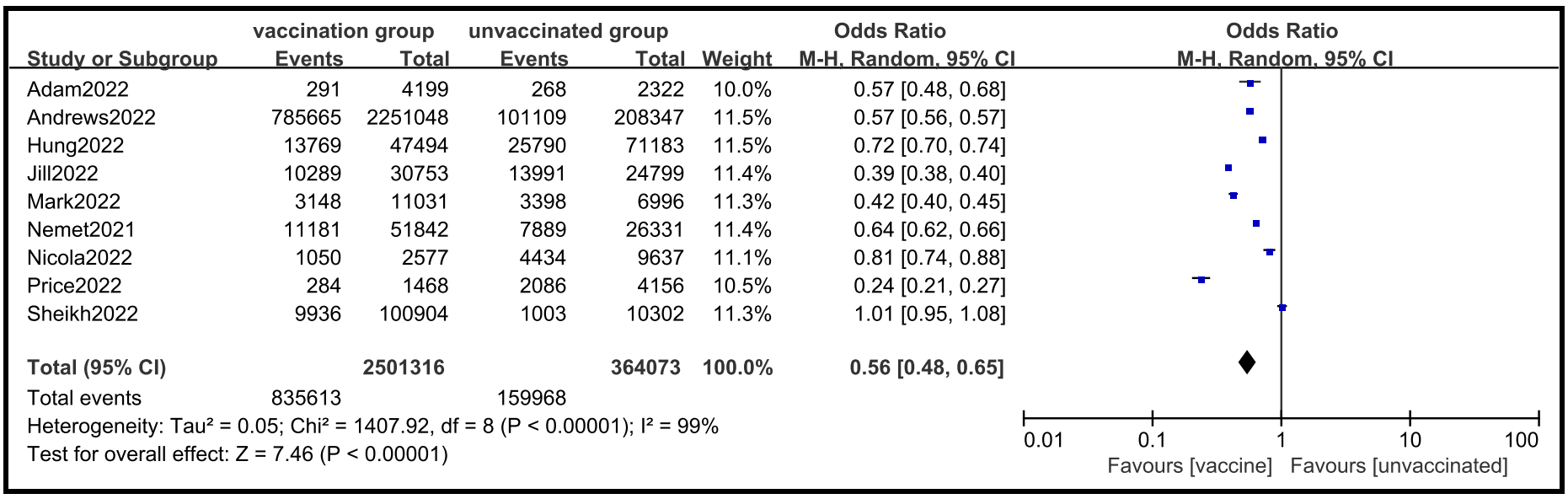

Figure 2: Meta analysis of the comparison of infection rates of Omicron virus strains between vaccinated and non-vaccinated groups

2.3.2 novel coronavirus vaccine prevents hospitalization caused by Omicron.

Three cohort studies were included **[3,4,6]**, and the fixed effects model meta-analysis results showed that the hospitalization rate caused by COVID-19 in the vaccinated group was lower than that in the non-vaccinated group [OR=0.44, 95% CI (0.39, 0.51), P<0.001] **(Figure 3)**.

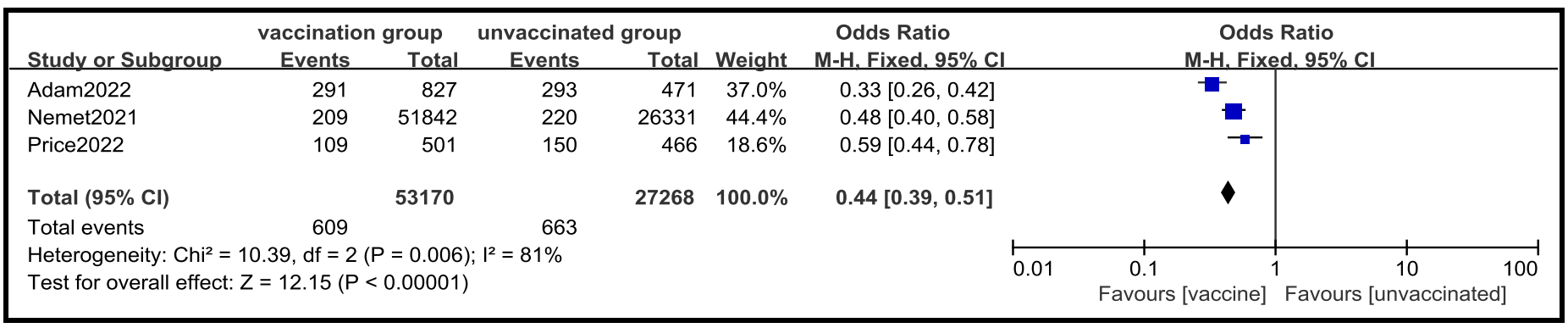

Figure 3: Meta analysis of comparison of COVID-19 admission rates between vaccinated and non-vaccinated groups

2.3.3 Novel coronavirus Vaccine Prevents Critical Illness Caused by Omicron

Two cohort studies were included **[3,4]**, and the fixed effects model meta-analysis results showed that the rate of progression to critical illness in the vaccinated group was lower than that in the non-vaccinated group [OR=0.53, 95% CI (0.35, 0.81), P<0.001] **(Figure 4)**.

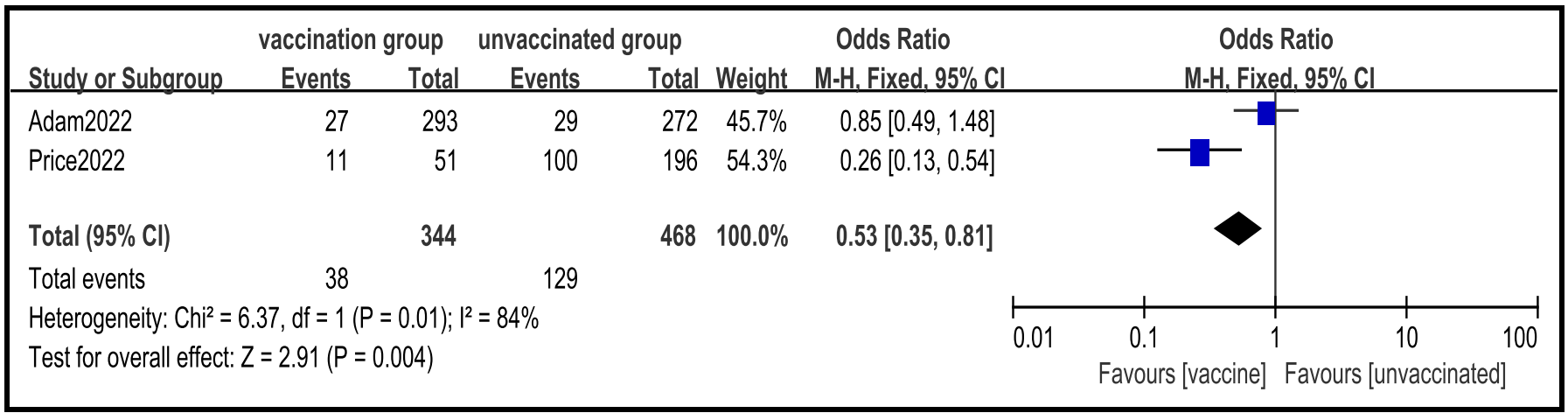

Figure 4: Meta analysis of the rate of progression to critical illness between vaccinated and non-vaccinated groups

2.3.4 Sensitivity analysis

Sensitivity analysis was conducted using the method of removing each study one by one, and the merged results showed no significant changes, indicating that the results were relatively stable.

2.4 Publication bias

Using a funnel plot to test publication bias on outcome indicators, it can be seen that the distribution of each study is symmetrical, indicating a low possibility of publication bias (due to space limitations, the funnel plot can be obtained by contacting the corresponding author).

3. Discussion

Since the first report of a novel coronavirus in November 2019, the virus sequence has undergone multiple mutations. At present, the dominant strains at home and abroad are mainly the Omicron mutant strains, while the new coronavirus vaccines in use are specifically designed based on the wild-type virus sequence **[19]**. This study showed that the infection rate [OR=0.56, 95% CI (0.48, 0.65), P<0.001] of the group vaccinated with the novel coronavirus vaccine was significantly lower than that of the group not vaccinated. This may be because the design targets of existing vaccines mainly focus on relatively conserved spike protein domains, which requires more extensive epidemiological investigations to verify **[20]**.

The pathogenesis of novel coronavirus is still unclear. Chen et al. **[21]** showed that the vaccine designed based on the SARA-CoV-2 RBD sequence can produce specific antibodies in mice, alleviate eosinophil infiltration, and prevent hospitalization and severe cases caused by inflammatory storms. This is consistent with the significantly lower hospitalization rate (OR=0.44, 95% CI (0.39, 0.51), P<0.001) and severe illness rate (OR=0.53, 95% CI (0.35, 0.81), P<0.001) in the vaccination group shown in this study compared to the non-vaccination group. This may be related to the mixed Th1/Th2 responses of helper T cell 1 and helper T cell 2 **[22]**.

Pollet et al. **[23]** found in their study of humoral and cellular immunity induced by COVID-19 vaccine that the total IgG and neutralizing antibody content in the experimental group were higher than those in the control group after 35, 43, and 57 days of vaccination. Flow cytometry results showed that CD4 (+) T cells were highly expressed in IL-4 and IFN-γ、Downregulation of IL-2 suggests an increase in the number of functional T cell follicular helper cells, which promote the production of follicular plasma cells and long-term memory B cells. These studies support the conclusion that the infection rate [OR=0.56, 95% CI (0.48, 0.65), P<0.001], hospitalization rate [OR=0.44, 95% CI (0.39, 0.51), P<0.001], and severity rate [OR=0.53, 95% CI (0.35, 0.81), P<0.001] of the vaccination group are significantly lower than those of the non-vaccination group from the perspective of immune protection.

Limitations of the study: 1. Due to the lack of basic research on vaccine efficacy in China, all 9 articles included were from non-Asian countries. Due to different vaccination policies in other countries, the age distribution of the population included in this study is ≥ 5 years old. Children under 5 years old and infants and young children do not apply to the conclusions of this study. 3. COVID-19 vaccines abroad are primarily nucleic acid vaccines or viral vector vaccines, such as BNT162b2 (Pfizer Biotechnology, USA) and mRNA-1273 (Modner, USA), which are commonly used in the United States and ChAdOx1 nCoV-19 (AstraZeneca, UK), which are commonly used in the United Kingdom; In China, inactivated vaccines are mainly used, such as Sinovac V (Kexing, China).

In summary, this study is the first to explore the effectiveness of existing vaccines against SARS-CoV-2 Omicron and its variants in

terms of infection rate, hospitalization rate, and risk/severity rate after COVID-19 vaccination, providing an essential reference for the formulation of epidemic prevention policies, especially for vaccine promotion.

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