International Platform of Registered Systematic Review and Meta-analysis Protocols

INPLASY

Safety, Immunogenicity and Effectiveness of China-Made COVID-19 Vaccines in the Real World: A Systematic Review

INPLASY202470021
doi: 10.37766/inplasy2024.7.0021
Received: 06 July 2024
Published: 07 July 2024

Qi, YY.

Corresponding author:
Yang-Yang Qi

yyqi22@m.fudan.edu.cn

Author Affiliation:
Fcudan.

ADMINISTRATIVE INFORMATION

Support - The Chinese Centre for Disease Control and Prevention under the COVID-19 Vaccines Evaluation Program (COVEP).

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202470021

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 July 2024 and was last updated on 07 July 2024.

INTRODUCTION

Review question / Objective 1. occurrence of rare adverse events; 2. protection against different variants; 3. protection in elderly; 4.dynamics of humoral immunity and effectiveness.

Condition being studied To date, 8 COVID-19 vaccines have been approved for emergency use in China, including 5 inactivated whole virion vaccines, two subunit protein vaccines, and one adenovirus type 5 vector vaccine. Of these, three China-made COVID-19 vaccines have been added to the WHO Emergency Use Listing (EUL), including two inactivated vaccines (BIBP-CorV and CoronaVac), and an adenovirus type 5 vector vaccine (Ad5-nCoV-S). As of November 3, 2022, 3.44 billion doses of vaccines were rolled out over China, resulted in a coverages of primary series and booster jabs of 90% and 70% respectively, in target age groups. Of these, inactivated vaccines, especially BIBB-CorV and CoronaVac vaccines accounted for 95% of doses. Moreover, both vaccines contributed almost half of the COVID-19 vaccine doses delivered globally, and have been enormously important in fighting the pandemic.
Though studies conducted worldwide have demonstrated good safety profiles and promising efficacy of BIBP-CorV and CoronaVac vaccines against the ancestral Wuhan strain in the short term. However, after the efficacy demonstration of BIBP-CorV and CoronaVac vaccines, the world experienced several epidemic waves caused by the emergence of new global dominant variants, namely Alpha, Delta and Omicron strains. Thus, knowledge syntheses based on studies that focused on the performance of inactivated vaccines in the real world are extremely important to inform vaccine policy in a timely manner.

METHODS

Participant or population children/adolescents (< 16 or 18 years), adults (< 60 years), and elderly (≥60 or 65 years).

Intervention People who received Chinese-made COVID-19 vaccine or not.

Comparator NA.

Study designs to be included Case report, case serials, cross-sectional study, case-control study, cohort study, clinical trials.

Eligibility criteria Exclusion criteria included: studies not related to COVID-19 vaccines; COVID-19 vaccine-related non-clinical studies, COVID-19 vaccine-related clinical studies but not including Chinese vaccines; COVID-19 vaccine-related clinical studies that did not provide numerator and denominator; sample size < 100 participants per arm or < 50 participants per arm for effectiveness studies and immunogenicity studies respectively; or immunogenicity studies that did not test neutralizing antibody, either live virus or pseudovirus; effectiveness studies with only a clinical syndromic case definition. In addition, since this review focused on real-world data, the prelicensure clinical trials were excluded.

Information sources Medline, Embase (contained preprints in medRxiv, and bioRxiv), and WanFang Data (A Chinese Literature Service platform).

Main outcome(s) safety: the incidence of solicited and unsolicited adverse events, rare adverse events immunity: live SARS-CoV-2 and pseudovirus) for the neutralizing test, seropositive rate, and geometric mean titer of neutralizing antibodies effectiveness: protection by the inactivated COVID-19 vaccines against severe disease and death.

Quality assessment / Risk of bias analysis the Joanna Briggs Institute (JBI) Critical Appraisal Checklist for case report, case serials and cross-sectional study was employed accordingly. The risk of bias tools developed by the Cochrane Bias Methods Group and the Cochrane Non-Randomised Studies Methods Group were applied for the quality assessment of case-control and cohort studies (ROBINS-I, risk of bias in non-randomised studies of interventions), and clinical trials (RoB 2, a revised tool for assessing risk of bias in randomised trials). The overall risk of bias for each domain was rated as low, moderate, and high with regard to the algorithms of each assessment tools.

Strategy of data synthesis If an I2 ≥50%, high heterogenicity was indicated, and thus random-effects models were used to calculate the point estimate and 95% confidence interval for the summary measures; otherwise a fixed-effects model was employed. Pooled proportions were computed with the inverse variance method using the variance-stabilizing Freeman-Tukey double arcsine transformation. Confidence intervals (CIs) for individual studies were calculated using the Wilson score CI method with continuity correction. For pooling of means of continuous variables (ORs and GMTs) and their 95%CIs, a logarithmic transformation was applied.

Subgroup analysis NA.

Sensitivity analysis NA.

Country(ies) involved China.

Keywords effectiveness; safety; inactivated vaccines; COVID-19; meta-analysis.

Contributions of each author

Author 1 - Yang-Yang Qi.
Email: yyqi22@m.fudan.edu.cn