

SYNOPSIS

Review of “Effectiveness of an Inactivated SARS-CoV-2 Vaccine in Chile”

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One-minute summary

- The authors report analyses of the effectiveness of the inactivated COVID-19 vaccine (CoronaVac/Sinovac) in preventing laboratory-confirmed Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and related hospitalization, admission to the intensive care unit (ICU), and death in the Chilean population.
- This was a prospective observational cohort study conducted in Chile, including 10,187,720 participants 16 years of age or older who were affiliated with Fondo Nacional de Salud (FONASA), the national public health insurance program which covers approximately 80% of the Chilean population. **Eligibility criteria included individuals ages 16 years or more, who were affiliated with FONASA, and had received at least one dose of the CoronaVac/Sinovac vaccine between February 2 and May 1, 2021, or no receipt of any COVID-19 vaccination.** Individuals with a probable or confirmed SARS-CoV-2 infection, on or before February 2, 2021, and those who had received at least one dose of the BNT162b2 (Pfizer/BioNTech) vaccine were excluded.
- The vaccine was administered in a **two dose schedule, with doses separated by 28 days.** Participants for this study were categorized into three groups: unvaccinated, partially vaccinated (≥ 14 days after first dose and before receipt of second dose), and fully vaccinated (≥ 14 days after receipt of second dose).
- In the **fully vaccinated** group, the adjusted vaccine effectiveness was:
 - 65.9% (95% CI, 65.2 to 66.6) for prevention of laboratory-confirmed COVID-19
 - 87.5% (95% CI, 86.7 to 88.2) for prevention of hospitalization
 - 90.3% (95% CI, 89.1 to 91.4) for prevention of ICU admission
 - 86.3% (95% CI, 84.5 to 87.9) for prevention of COVID-19-related mortality
- The adjusted vaccine effectiveness among **partially vaccinated** individuals was:
 - 15.5% (95% CI, 14.2 to 16.8) for prevention of laboratory-confirmed COVID-19

- 37.4% (95% CI, 34.9 to 39.9) for prevention of hospitalization
- 44.7% (95% CI, 40.8 to 48.3) for prevention of ICU admission
- 45.7% (95% CI, 40.9 to 50.2) for prevention of COVID-19-related mortality

Additional information

- Sinovac-CoronaVac vaccine was listed by the World Health Organization (WHO) as a vaccine on the emergency use list (EUL) as of June 1, 2021.¹
- Twenty two (22) low and middle income countries have approved CoronaVac/Sinovac vaccine for emergency use. Phase 1-2 trials have been conducted in China, and findings suggested the vaccine resulted in an adequate immune response and was safe in most patients 14 days after receipt of the second dose.
- In this cohort study, the authors used the Cox proportional-hazards model which allowed for a time-varying vaccination status of the persons in the study, to estimate the hazard ratio associated with partial immunization and full immunization. The study controlled for confounding variables that could impact vaccination and outcomes, including age, sex, region of residency, income, nationality, and underlying health conditions that have been associated with severe COVID-19 (e.g., diabetes, chronic kidney disease, autoimmune disease, HIV). The vaccine-effectiveness estimates in the stratified model were consistent with these study results.
- To evaluate whether the vaccine effectiveness results were affected by potentially different access to health care between vaccinated persons and unvaccinated persons, subgroup analyses involving the subgroup of persons with access to RT-PCR or antigen testing for SARS-CoV-2 was done.
 - The adjusted vaccine effectiveness among fully vaccinated individuals in this subgroup was:
 - **72.9%** (95% CI, 72.3 to 73.4) for prevention of **laboratory-confirmed COVID-19**
 - **89.2%** (95% CI, 88.5 to 89.8) for prevention of **hospitalization**
 - **91.6%** (95% CI, 90.5 to 92.5) for prevention of **ICU admission**
 - **87.8%** (95% CI, 86.2 to 89.2) for prevention of **COVID-19-related mortality**
- The vaccine effectiveness results were maintained in both age-subgroup analyses (16-59, ≥ 60).
- Efficacy results for CoronaVac/Sinovac phase 3 trials taking place in Brazil, Chile, Indonesia and Turkey have not yet been published. However, efficacy estimates for phase 3 clinical trials for mild COVID-19 vary among the four countries: 50.7% (95% CI, 35.6 to 62.2) in Brazil, 65.3% in Indonesia, and 83.5% (95% CI, 65.4 to 92.1) in Turkey. To date, there have been no estimates of real-world effectiveness of CoronaVac in preventing COVID-19 in the general population, or those who have been fully vaccinated that have been made publicly available.

PHO reviewer's comments

- The CoronaVac/Sinovac vaccine is currently not approved in Canada, but it may have implications for those working, travelling or moving to Canada from other countries in which the vaccine is authorized for use.
- 93.2% of the study cohort was of Chilean nationality, this may reduce generalizability to other populations including Ontarians. There may be differences in access to healthcare, overall health status, genetics, across and between these jurisdictions.
- Given the observational nature of the data, selection bias is a potential concern. There may be differences in overall health-seeking behaviour and access to healthcare between those receiving the vaccine and those who were unvaccinated which may confound study outcomes. Although the authors included a range of variables for adjustment (e.g., age, sex, region of residency, income, nationality, co-morbid health conditions), there still may remain underlying unaccounted differences across these strata.
- The prospective observational study was conducted from February 2 to May 1, 2021. Due to the short follow-up period, the study did not assess the long-term effectiveness or side effects of the CoronaVac/Sinovac vaccine.
- The study looked at the following outcomes: prevention of laboratory-confirmed COVID-19; prevention of hospitalization; prevention of ICU admission; and prevention of COVID-19-related death. However, it did not look at the rate of transmission or provide any data on the effectiveness of CoronaVac/Sinovac against asymptomatic infection.
- The national genomic surveillance system in Chile has reported circulation of two variants of concern (P.1 (Gamma) and B.1.1.7 (Alpha)); however, this observational study was not able to estimate the relative vaccine effectiveness of CoronaVac/Sinovac against these variants. As of July 2021, 76.0% of the COVID-19 cases in Ontario are of the Delta (B.1.617.2) variant.² As such, variants currently present in Chile are not representative of those in Ontario. This may result in potentially different vaccine effectiveness of CoronaVac/Sinovac in the Canadian population.
- All the vaccines authorized in Canada demonstrate effectiveness against preventing COVID-19, COVID-19 related hospitalization and death. Vaccine effectiveness ranges from 70-90% for Pfizer-BioNTech (BNT162b2), Moderna (mRNA-1273), and AstraZeneca (AZD1222/ChAdOx1-S) in preventing severe disease and COVID-19-related hospitalization.³ This study provides data demonstrating CoronaVac/Sinovac has similar outcomes to the vaccines currently authorized in Canada.

Additional References

1. World Health Organization. WHO validates Sinovac COVID-19 vaccine for emergency use and issues interim policy recommendations [Internet]. Geneva: World Health Organization; 2021 [cited 2021 Sep 15]. Available from: <https://www.who.int/news/item/01-06-2021-who-validates-sinovac-covid-19-vaccine-for-emergency-use-and-issues-interim-policy-recommendations>

2. Ontario Agency for Health Protection and Promotion (Public Health Ontario). COVID-19 Delta variant: risk assessment and implications for practice [Internet]. Toronto, ON: Queen's Printer for Ontario; 2021

[cited 2021 Sep 15]. Available from: https://www.publichealthontario.ca/-/media/documents/ncov/voc/2021/08/covid-19-delta-variant-risk-assessment-implications.pdf?sc_lang=en

3. Ontario Agency for Health Protection and Promotion (Public Health Ontario). COVID-19 real-world vaccine effectiveness – what we know so far [Internet]. Toronto, ON: Queen’s Printer for Ontario; 2021 [cited 2021 Sep 15]. Available from: https://www.publichealthontario.ca/-/media/documents/ncov/covid-wwksf/2021/04/wwksf-vaccine-effectiveness.pdf?sc_lang=en

Citation

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