

Parallel Session 1: Combating COVID-19

T1e - COVID-19 Vaccines Adverse Events Response and Evaluation (CARE) Programme [Title of presentation: Bell's palsy following Vaccination with mRNA (BNT162b2) and Inactivated (CoronaVac) SARS-CoV-2 vaccines: a Case Series and Nested Case-control Study.]

Prof Ian WONG Chi-kei

*Lo Shiu Kwan Kan Po Ling Professor in Pharmacy, Head of Department of Pharmacology and Pharmacy,
The University of Hong Kong, Hong Kong SAR, China*

Background: Bell's palsy is a rare adverse event reported in clinical trials of COVID-19 vaccines. However, to our knowledge no population-based study has assessed the association between the inactivated SARS-CoV-2 vaccines and Bell's palsy. The aim of this study was to evaluate the risk of Bell's palsy after BNT162b2 and CoronaVac vaccination.

Methods: In this case series and nested case-control study done in Hong Kong, we assessed the risk of Bell's palsy following vaccination with BNT162b2 (Fosun-BioNTech [equivalent to Pfizer-BioNTech]) or CoronaVac (from Sinovac Biotech, Hong Kong) using data from the Department of Health and Hospital Authority's territory-wide electronic health records (the Clinical Data Analysis and Reporting System -CDARS). We described reported cases of Bell's palsy among vaccine recipients. We compared the estimated age-standardised incidence of clinically confirmed cases among individuals who had received the CoronaVac or BNT162b2 vaccination (up to 42 days before presentation) with the background incidence in the population. A nested case-control study was also done using conditional logistic regression to estimate the odds ratio (OR) for risk of Bell's palsy and vaccination. Cases and controls were matched (1:4) by age, sex, admission setting, and admission date.

Results: Between February 23 and May 4, 2021, 451 939 individuals received the first dose of CoronaVac and 537 205 individuals received the first dose of BNT162b2. 28 clinically confirmed cases of Bell's palsy were reported following CoronaVac and 16 cases were reported following BNT162b2. The age-standardised incidence of clinically confirmed Bell's palsy was 66.9 cases per 100 000 person-years (95% CI 37.2 to 96.6) following CoronaVac vaccination and 42.8 per 100 000 person-years (19.4 to 66.1) for BNT162b2 vaccination. The age-standardised difference for the incidence compared with the background population was 41.5 (95% CI 11.7 to 71.4) for CoronaVac and 17.0 (-6.6 to 40.6) for BNT162b2, equivalent to an additional 4.8 cases per 100 000 people vaccinated for CoronaVac and 2.0 cases per 100 000 people vaccinated for BNT162b2. In the nested case-control analysis, 298 cases were matched to 1181 controls, and the adjusted ORs were 2.385 (95% CI 1.415 to 4.022) for CoronaVac and 1.755 (0.886 to 3.477) for BNT162b2.

Conclusion: Our findings suggest an overall increased risk of Bell's palsy after CoronaVac vaccination. However, the beneficial and protective effects of the inactivated COVID-19 vaccine far outweigh the risk of this generally self-limiting adverse event. Additional studies are needed in other regions to confirm our findings. (Lancet Infect Dis. 2021 Aug 16;S1473-3099(21)00451-5.)

Project Number: COVID19F01