



Bell's palsy following vaccination with mRNA (BNT162b2) and inactivated (CoronaVac) SARS-CoV-2 vaccines: a case series and nested case-control study

Eric Yuk Fai Wan*, Celine Sze Ling Chui*, Francisco Tsz Tsun Lai, Esther Wai Yin Chan, Xue Li, Vincent Ka Chun Yan, Le Gao, Qiuyan Yu, Ivan Chun Hang Lam, Raccoon Ka Cheong Chun, Benjamin John Cowling, Wing Chi Fong, Alexander Yuk Lun Lau, Vincent Chung Tong Mok, Frank Ling Fung Chan, Cheuk Kwong Lee, Lot Sze Tao Chan, Dawin Lo, Kui Kai Lau, Ivan Fan Ngai Hung, Gabriel Matthew Leung, Ian Chi Kei Wong

Summary

Lancet Infect Dis 2022;
22: 64–72

Published Online
August 16, 2021

[https://doi.org/10.1016/S1473-3099\(21\)00451-5](https://doi.org/10.1016/S1473-3099(21)00451-5)

See [Comment](#) page 5

For the Chinese translation of the abstract see Online for appendix 1

*Co-first authors. EYFW and CSLC contributed equally to this Article

Centre for Safe Medication Practice and Research, Department of Pharmacology and Pharmacy (EYFWan PhD, FTT Lai PhD, EWY Chan PhD, X Li PhD, V K C Yan BPharm, L Gao MSc, Q Yu MPH, I C H Lam MPharm, Prof I C K Wong PhD), Department of Family Medicine and Primary Care (EYFWan), School of Nursing (CSL Chui PhD), School of Public Health (CSL Chui, Prof B J Cowling PhD, Prof G M Leung MD), Department of Medicine (X Li, K K Lau PhD, Prof I F N Hung MD) Li Ka Shing Faculty of Medicine, The University of Hong Kong, Hong Kong Special Administrative Region, China; Laboratory of Data Discovery for Health (D24H), Hong Kong Science and Technology Park, Sha Tin, Hong Kong Special Administrative Region, China (EYFWan, CSL Chui, FTT Lai, EWY Chan, X Li, Prof B J Cowling, Prof G M Leung, Prof I C K Wong); Department of Health, The Government of the Hong Kong Special Administrative Region, Hong Kong Special Administrative Region, China (R K C Chung MCLinPharm, F L F Chan BScPharm, L S T Chan MPH, D Lo MBChB); Department of Medicine, Queen Elizabeth Hospital, Hospital Authority, Hong Kong

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 within 42 days following vaccination with BNT162b2 (Fosun–BioNTech [equivalent to Pfizer–BioNTech]) or CoronaVac (from Sinovac Biotech, Hong Kong) using data from voluntary surveillance reporting with the Hospital Authority, the COVID-19 Vaccine Adverse Event Online Reporting system for all health-care professionals, and the Hospital Authority's territory-wide electronic health records from the Clinical Data Analysis and Reporting System. We described reported cases of Bell's palsy among vaccine recipients (aged 18–110 years for CoronaVac and aged 16–110 years for BNT162b2). 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.

Findings 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.

Interpretation 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.

Funding The Food and Health Bureau of the Government of the Hong Kong Special Administrative Region, China.

Copyright © 2021 Elsevier Ltd. All rights reserved.

Introduction

Bell's palsy, also known as acute peripheral facial nerve palsy of unknown cause, commonly manifests with sudden onset of unilateral facial paralysis. Bell's palsy is usually transient, with 70% of patients recovering within 6 months without treatment.¹ Timely corticosteroid treatment can increase the chance of recovery to more than 90% by 9 months.² However, patients with incomplete recovery of facial function might have incomplete eye closure, brow ptosis, and nasal valve collapse,³ which can potentially affect daily life.

The BNT162b2 (international non-proprietary name tozinameran; Pfizer–BioNTech) and mRNA-1273 (international non-proprietary name elasomeran; Moderna) COVID-19 vaccines use mRNA technology, and are currently widely used in different parts of the world. Two clinical trials of these vaccines reported seven cases of Bell's palsy in the vaccinated group of 35 000 patients.^{4,5} The US Food and Drug Administration (FDA) did not consider there to be a clear basis on which to conclude a causal relationship. Therefore, the FDA recommended further surveillance of these vaccines as they have been