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Association of SARS-CoV-2 Vaccination or Infection With Bell Palsy
A Systematic Review and Meta-analysis

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IMPORTANCE Bell palsy (BP) has been reported as an adverse event following the SARS-CoV-2 vaccination, but neither a causative relationship nor a higher prevalence than in the general population has been established.

OBJECTIVE To compare the incidence of BP in SARS-CoV-2 vaccine recipients vs unvaccinated individuals or placebo recipients.

DATA SOURCES A systematic search of MEDLINE (via PubMed), Web of Science, Scopus, Cochrane Library, and Google Scholar from the inception of the COVID-19 report (December 2019) to August 15, 2022.

STUDY SELECTION Articles reporting BP incidence with SARS-CoV-2 vaccination were included.

DATA EXTRACTION AND SYNTHESIS This study followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline and was conducted with the random- and fixed-effect models using the Mantel-Haenszel method. The quality of the studies was evaluated by the Newcastle-Ottawa Scale.

MAIN OUTCOMES AND MEASURES The outcomes of interest were to compare BP incidence among (1) SARS-CoV-2 vaccine recipients, (2) nonrecipients in the placebo or unvaccinated cohorts, (3) different types of SARS-CoV-2 vaccines, and (4) SARS-CoV-2–infected vs SARS-CoV-2–vaccinated individuals.

RESULTS Fifty studies were included, of which 17 entered the quantitative synthesis. Pooling 4 phase 3 randomized clinical trials showed significantly higher BP in recipients of SARS-CoV-2 vaccines (77 525 vaccine recipients vs 66 682 placebo recipients; odds ratio [OR], 3.00; 95% CI, 1.10-8.18; I^2 = 0%). There was, however, no significant increase in BP after administration of the messenger RNA SARS-CoV-2 vaccine in pooling 8 observational studies (13 518 026 doses vs 13 510 701 unvaccinated; OR, 0.70; 95% CI, 0.42-1.16; I^2 = 94%). No significant difference was found in BP among 22 978 880 first-dose recipients of the Pfizer/BioNTech vaccine compared with 22 978 880 first-dose recipients of the Oxford/AstraZeneca vaccine (OR, 0.97; 95% CI, 0.82-1.15; I^2 = 0%). Bell palsy was significantly more common after SARS-CoV-2 infection (n = 2 822 072) than after SARS-CoV-2 vaccinations (n = 37 912 410) (relative risk, 3.23; 95% CI, 1.57-6.62; I^2 = 95%).

CONCLUSIONS AND RELEVANCE This systematic review and meta-analysis suggests a higher incidence of BP among SARS-CoV-2–vaccinated vs placebo groups. The occurrence of BP did not differ significantly between recipients of the Pfizer/BioNTech vs Oxford/AstraZeneca vaccines. SARS-CoV-2 infection posed a significantly greater risk for BP than SARS-CoV-2 vaccination.

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Supplemental content

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Bell palsy (BP), also known as idiopathic facial nerve palsy, is the most prevalent cause of acute spontaneous peripheral facial paralysis, with a reported annual incidence rate of 15 to 30 cases per 100 000 population.[1,2] Although the exact cause of BP is unclear, viral infections (such as herpes simplex virus), ischemia, and inflammation are some of the suggested underlying mechanisms.[3] Notably, BP is also reported following SARS-CoV-2 infection.[4] COVID-19, caused by SARS-CoV-2, is a contagious respiratory syndrome with a wide range of manifestations, from asymptomatic and mild infection to hospitalization and death,[5] as well as a wide variety of neurologic manifestations.[6]

By August 19, 2022, a total of 591 683 619 patients with COVID-19 and 6 443 306 deaths had been reported worldwide.[5] As of August 16, 2022, a total of 12 409 086 286 doses of SARS-CoV-2 vaccines had been administered worldwide,[5] resulting in a marked decrease in COVID-19–associated hospitalizations and deaths.[7-9] The vaccines are safe and effective, as evidenced by several clinical trials and confirmed by the national and international public health agencies.[10-13] Nevertheless, apart from nonserious complications, such as local reactions,[14] other adverse events have also been reported, affecting the liver,[15] kidneys,[16] cardiovascular system,[17] and central nervous system.[18] Headaches,[19,20] Guillain-Barré syndrome (GBS),[21] cerebral venous sinus thrombosis,[22,23] and transverse myelitis[24,25] are the most frequently reported neurologic adverse events following SARS-CoV-2 vaccination. Bell palsy has also been reported following vaccination,[25] although neither a causative relationship nor a prevalence of the condition higher than the general population has been established.

Bell palsy is the sudden onset of facial paralysis or paresis due to facial nerve inflammation in the absence of central nervous system disease and after excluding the other causes of acute peripheral palsy.[2] The management includes early treatment with oral corticosteroids and eye care to prevent corneal injury.[26] The benefits of antiviral therapy have remained unproven.[26] Most cases of BP resolve after a few months. However, age and the severity of facial paralysis based on the House-Brackmann scale may predict poor outcomes.[27]

Because vaccination has been conducted globally, identifying the related short- and long-term adverse events is of great significance. A review of the literature reveals several studies reporting BP occurrence following SARS-CoV-2 vaccination.[28,29] The first documented case was in a 36-year-old woman with a previous history of BP who developed facial palsy 2 days after receiving the first dose of the Sinovac vaccine.[30] Currently, it is not known whether BP incidence is associated with SARS-CoV-2 vaccination, because studies differ in their time intervals, vaccine types, follow-up periods, and methods. To address this issue, we conducted a systematic review and meta-analysis of studies reporting BP following SARS-CoV-2 vaccination to examine whether SARS-CoV-2 vaccination is associated with a higher incidence of BP compared with unvaccinated or placebo-vaccinated individuals. We also asked whether BP occurrence is different among various types of SARS-CoV-2 vaccines, and whether it is different among SARS-CoV-2–infected vs SARS-CoV-2–vaccinated individuals.

Key Points

Question Is the incidence rate of Bell palsy (BP) following SARS-CoV-2 vaccination different from the incidence rate in those who have not received SARS-CoV-2 vaccines?

Findings This systematic review and meta-analysis of pooled randomized clinical trials found that the incidence of BP was significantly higher in vaccine vs placebo recipients. The occurrence of BP did not differ between recipients of the Pfizer/BioNTech and Oxford/AstraZeneca vaccines, and there was a greater risk of BP with SARS-CoV-2 infection compared with SARS-CoV-2 vaccination.

Meaning This study shows evidence for the association between SARS-CoV-2 and BP; however, this finding does not equate to causality, and further research is required to verify this association and investigate possible mechanisms.

Methods

Study Design and Search Strategy

We investigated BP incidence by measuring the pooled effect estimates in the following sets of comparisons: all phase 3 randomized clinical trial (RCT)–derived data on vaccine vs saline placebo recipients, messenger RNA (mRNA) SARS-CoV-2 vaccines vs unvaccinated participants in observational studies, Pfizer/BioNTech vs Oxford/AstraZeneca SARS-CoV-2 vaccines, and SARS-CoV-2 infections vs SARS-CoV-2 vaccines. This study followed the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).[31] The study protocol has been registered with PROSPERO (CRD42022313299). We performed a systematic search through MEDLINE (via PubMed), Web of Science, Scopus, Cochrane Library, and Google Scholar from the inception of the COVID-19 report (December 2019) to August 15, 2022. Our search also included review publications, editorials, letters to editors, and conference papers, as well as the references of all the studies included. The key words used were *SARS-CoV-2 vaccine*, *COVID-19 vaccine*, *facial nerve palsy*, and *Bell's palsy* (eTable 1 in Supplement 1). No restriction on the study design, age of the participants, literature language, or any other factors was imposed. The study was exempt from ethical approval by the local institutional ethics committee because we used previously published data.

Eligibility Criteria

The study participants were individuals who had undergone SARS-CoV-2 vaccination with all widely administered SARS-CoV-2 vaccine platforms, including mRNA, viral vector, inactivated, and protein subunit. The participants were compared with individuals receiving saline placebo or other vaccines (in case of RCTs) or unvaccinated individuals (in case of observational studies). The outcome of interest was BP occurring as an adverse event in the time frame after the vaccination or the respective time frame in the placebo recipients or unvaccinated matched participants. The BP diagnosis was determined based on the neurologist-confirmed clinical criteria and/or the

International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (*ICD-10*) codes, as mentioned by each study. We excluded any study that reported facial paralysis with known causes, including stroke, GBS, thromboembolic events, Lyme disease, bacterial otitis media, Ramsey Hunt syndrome, sarcoidosis, and multiple sclerosis.

Selection Process

For data selection, the records obtained from different search databases were first transferred to EndNote software, version X9 (Clarivate Plc). After removing duplicate records, 2 independent researchers (Y.P. and Melika Jameie) screened all articles from the systematic search through a stepwise process. First, all records were screened using the title and abstracts. Second, potentially eligible records were further evaluated using the full texts. The records that did not meet the preestablished eligibility criteria were excluded. Conflicts were resolved by joint discussions and the consensus of the authors.

Data Extraction

The data of interest were extracted as follows: (1) study-related variables (first author's name, publication year, sample size, study design, and the presence of control group and its general description); (2) vaccine-related variables, including vaccine type and number of doses received; (3) demographic and baseline variables, including age, sex, past medical history, prior SARS-CoV-2 infection, prior herpes zoster infection, history of BP, and drug history; and (4) clinical and BP-related variables, including number of patients with BP, BP laterality, concomitant signs and symptoms, initial physical examination, duration from vaccination to the event, paraclinical assessments, treatments, outcome, and recurrence if followed up. Two independent researchers (Mana Jameie and S.I.) extracted the data and completed the predesigned forms. Discrepancies were dealt with through the consensus of 2 authors (A.R. and Melika Jameie).

Quality Assessment

We assessed the quality of included studies and evaluated the risk of bias using the Newcastle-Ottawa Scale (NOS) for cross-sectional studies, self-controlled case series (SCCSs), case-control studies, and cohort studies (studies with an overall score of ≥7 points were considered high quality)[32,33] and the Cochrane assessment tool for RCTs (classifying studies as unclear, low risk, or high risk).[34] Two independent researchers (M.A. and D.S.) performed the risk of bias assessment, and conflicts were resolved via consensus.

Data Synthesis

The included studies for quantitative synthesis were pooled within 4 sections. In the first section, 4 studies[35-38] corresponding to the phase 3 RCTs of the major SARS-CoV-2 vaccines (ie, Pfizer/BioNTech, Moderna, Janssen, and Oxford/AstraZeneca) were evaluated. The BP occurrence was compared between vaccine and saline placebo recipients within subgroups of viral vector and mRNA vaccines. In the second section, all observational studies[39-46]comparing BP in mRNA vaccine recipients and the unvaccinated matched individuals were investigated. The third section compared the odds of BP in Pfizer/BioNTech vs Oxford/AstraZeneca recipients. The fourth section pooled the risk ratio (RR) of BP in SARS-CoV-2–infected patients vs SARS-CoV-2 vaccine recipients.

Statistical Analysis

All statistical analyses were performed using R software, version 4.2.1 (R Foundation for Statistical Computing), implementing the R package meta, version 5.2-0,[47] using the Mantel-Haenszel method.[48,49] For sections 1 and 2 of data analysis, the metabin function was used to pool the dichotomous data on the incidence of BP, and odds ratios (ORs), with corresponding 95% CIs, were used as the measure of effect. Subsequently, for sections 3 and 4, the metagen function was used to pool the measures of effect (OR and RR with the corresponding 95% CIs).

The between-study heterogeneity was assessed by the Cochran Q statistic, τ^2 using the restricted maximum-likelihood estimator, and I^2 index.[50,51] On the basis of the I^2 index, it was decided whether to choose between the fixed-effects or random-effects models. If $I^2 \geq 50\%$, representing substantial heterogeneity, the random-effects model was used; otherwise, the fixed-effects model was used. Publication bias was assessed visually with funnel plots, and asymmetry was statistically tested using the Egger test as well as the Peter test (a method of choice for binary outcomes).[52,53] A 2-tailed $P < .05$ was considered statistically significant.

Results

Study Selection

A summary of the inclusion process is represented in a PRISMA flow diagram in eFigure 1 in Supplement 1. An overall 643 records were identified through our systematic search method. Of these, 180 were removed because they were duplicate records. Thereafter, 463 records were screened by title and abstract, and 84 remained for further evaluation. All 84 records were retrieved, and full texts were assessed in terms of eligibility for our study. Among them, 17 records overlapped other studies, 9 records were commentaries and corrections on other articles, and 8 did not meet the inclusion criteria. Thus, 34 records were excluded, and the remaining 50 records entered our study. Of the 50 studies, 17 articles[35-46,54-58] comparing BP incidence in SARS-CoV-2–vaccinated and control groups that could be pooled were included in the meta-analysis, and the remaining 33 articles[30,59-90] were included only in the qualitative synthesis (ie, the characteristics of which were extracted and formatted into eTable 2 in Supplement 1).

Of the excluded studies, 3 records[91-93] were the reports of preliminary results of the major SARS-CoV-2 vaccine phase 3 clinical trials, of which the records reporting the final analyses were included instead. In the case of overlapping studies, the study with the highest score in terms of quality assessment was deemed appropriate and was included in the study. Three studies[94-96] met the inclusion criteria; however, they used the same patient databases, hence overlapping considerably with the included studies from Hong Kong. Last, 4 over-

lapping studies reported on data retrieved from the Vaccine Adverse Event Reporting System (VAERS) database, of which 1 study[59] was included with the highest quality score and the remainder were excluded.[29,97,98] Similarly, 3 overlapping studies used the data obtained from the World Health Organization VigiBase database, 2 of which were excluded.[99,100]

Study Characteristics

The 50 included studies comprised 22 case reports and case series,[30,60-80] 2 SCCSs,[54,81] 2 case-control studies,[39,40] 3 cross-sectional studies,[55,82,83] 16 cohort studies,[41-46,56,57,59,84-90] and 5 RCTs.[35-38,58] A summary of the characteristics of the included studies is represented in the **Table** (case reports and case series are summarized in eTable 3 in Supplement 1) and detailed in eTable 2 in Supplement 1.

Quality Appraisal

Three of the 5 RCTs had a low risk of bias,[35-37] and 2 were unclear[38,58] in the criterion D5: detection bias of the Cochrane assessment tool but were low risk in the rest of the criteria. The mean NOS scores were 6.87 for cohort studies, 7.50 for case-control studies, 4.00 for cross-sectional studies, and 8.50 for SCCSs. All records included in the meta-analysis had NOS scores of 7 or higher. The results are given in eFigure 2 and eTables 4 through 7 in Supplement 1.

RCTs: Vaccinated vs Saline Placebo

Four RCTs[35-38,101] that reported BP as an adverse event were included in the first meta-analysis. These RCTs consisted of the final results of the phase 3 trials of the 4 major SARS-CoV-2 vaccines approved and widely administered worldwide (Pfizer/BioNTech, Moderna, Janssen, and Oxford/AstraZeneca). Of note, the study by Voysey et al[58] was not included in the meta-analysis because these investigators reported 4 RCTs of Oxford/AstraZeneca in 3 distinct geographic regions in which the placebo was not solely specified as saline but was a viral vaccine other than a SARS-CoV-2 vaccine (ie, meningococcal group A, C, W, and Y conjugate vaccine).

The meta-analysis was composed of 2 subgroups of mRNA vaccines (Pfizer/BioNTech and Moderna) and viral vector vaccines (Janssen and Oxford/AstraZeneca) (**Figure 1**). For the mRNA vaccine subgroup, there were significantly increased odds of BP in the vaccinated group compared with the placebo group (OR, 3.57; 95% CI, 1.09-11.67; I^2 = 0%; Cochran *Q* *P* value = 0.46). However, for the viral vector vaccine subgroup, the analysis yielded insignificant results (OR, 1.80; 95% CI, 0.26-12.35; I^2 = 0%; Cochran *Q* *P* value = 0.89). Overall, in all 4 trials, BP incidence was significantly higher in the vaccine group (77 525 recipients) vs placebo (66 682 recipients) (OR, 3.00; 95% CI, 1.10-8.18; I^2 = 0%; Cochran *Q* *P* value = 0.84). Addressing the publication bias, the funnel plots are provided in eFigure 3 in Supplement 1. The Egger and Peter tests both yielded nonsignificant results; hence, no publication bias was detected.

Observational Studies on mRNA Vaccines: Vaccinated vs Unvaccinated

Eight observational studies[39-46] reported adverse events, including BP, following the administration of the first and/or second dose of the SARS-CoV-2 mRNA vaccines. These vaccines included Moderna and Pfizer/BioNTech among patients 12 years or older. Overall, 13 518 026 vaccine doses as the vaccinated group were compared with 13 510 701 matched unvaccinated individuals (**Figure 2**). Because of the high heterogeneity, a random-effects model was implemented, and a subgroup analysis was performed based on the study design (cohort or case-control study). In the cohort studies,[41-46] the analysis indicated no significant evidence of increased odds of BP in the vaccinated group compared with the unvaccinated group (OR, 0.59; 95% CI, 0.34-1.01; I^2 = 94%; Cochran *Q* *P* value < .001). Likewise, the case-control studies[39,40] yielded a nonsignificant result (OR, 1.37; 95% CI, 0.64-2.90; I^2 = 54%; Cochran *Q* *P* value = .14). Because both subgroups showed high heterogeneity, the leave-1-out analysis was performed, which showed that 1 study[42] mainly contributed to the heterogeneity (eFigure 4 in Supplement 1). The analysis yielded insignificant results with no effect from individual studies (OR, 0.70; 95% CI, 0.42-1.16; I^2 = 94%; Cochran *Q* *P* value < .001). Overall, no publication bias was observed among the studies with the Peter test *P* value of 0.34 (eFigure 5 in Supplement 1).

Pfizer/BioNTech vs Oxford/AstraZeneca Vaccines

Events of BP in a 21-day interval after the vaccination were compared between 22 760 698 first-dose Pfizer/BioNTech recipients and 22 978 880 first-dose Oxford/AstraZeneca recipients[54,56,57] (**Figure 3**). For the analysis from the study by Li et al,[57] only the data obtained from the Spanish database of Information System for Research in Primary Care were used for data pooling, and the data from the UK were excluded because of database overlapping with the study by Patone et al.[56] The odds of developing BP after receipt of the Pfizer/BioNTech vaccine compared with the Oxford/AstraZeneca vaccine were deemed insignificant (OR, 0.97; 95% CI, 0.82-1.15; I^2 = 0%; Cochran *Q* *P* value = .67). The funnel plots for the publication bias are represented in eFigure 6 in Supplement 1. The Egger test yielded a *P* value of .64; hence, no publication bias was present.

SARS-CoV-2 Infections vs SARS-CoV-2 Vaccine

We compared a total of 2 822 072 SARS-CoV-2–infected individuals with 37 912 410 SARS-CoV-2 vaccine recipients regarding the occurrence of BP[41,55-57] (**Figure 4**). The risk of developing BP subsequent to SARS-CoV-2 infection significantly surpassed the risk of developing BP after receipt of the SARS-CoV-2 vaccine (RR, 3.23; 95% CI, 1.57-6.62; I^2 = 95%; Cochran *Q* *P* value < .001). With a high heterogeneity, a random-effects model was used, and a leave-1-out analysis was performed, which showed that 1 study[57] mainly contributed to the heterogeneity (eFigure 7 in Supplement 1). Of the pooled studies, only Tamaki et al[55] reported a precalculated RR (eFigure 8 in Supplement 1). The Egger test yielded a *P* value of .96, thus showing no publication bias.

Discussion

To the best of our knowledge, this is the first systematic review and meta-analysis addressing the incidence of BP

Table. Summary of Studies Included in the Meta-analysis on Bell Palsy and SARS-CoV-2 Vaccination

Source	Design	Vaccine type/ No. of doses	Vaccinated, No. (% total)	Age, y	No. (%) of female patients	No. (%) of patients with Bell palsy
El Sahly et al,[35] 2021, US	RCT[a]	Moderna/1 or 2	14 287 (50.2)	Mean (range): 51.3 (18-95)	Vaccinated: 6848 (48); placebo: 6670 (48)	Vaccinated: 8 (<0.1); placebo: 3 (<0.1)
Sadoff et al,[37] 2022, multinational	RCT[a]	Janssen/1	21 898 (50)	Median (range): 52.0 (18-100)	Vaccination: 9828 (44.9); placebo: 9907 (45.3)	Vaccinated: 2 (<0.1); placebo: 1 (<0.1)
Thomas et al,[36] 2021, US	RCT[a]	Pfizer/BioNTech/ 1 or 2	22 026 (50)	Median (range): 51.0 (16-91)	Vaccinated: 10 704 (48.6); placebo: 10 923 (49.6)	Vaccinated: 4 (<0.1); placebo: 0
Falsey et al,[38] 2021, US, Chile, and Peru	RCT[a]	Oxford/AstraZeneca/ 1 or 2	21 635 (66.66)	Median (range): 51.0 (18-100)	Vaccinated 9575 (44.4); placebo: 4789 (44.4)	Vaccinated: 1 (<0.1); placebo: 0
Voysey et al,[58] 2021, Brazil, South Africa, and UK	RCT[a]	Oxford/AstraZeneca/ 1 or 2	12 082 (50.67)	NA[b]	7045 (60.5)	Vaccinated: 3 (<0.1); placebo: 3 (<0.1)
Barda et al, 2022,[41] Israel	Cohort[a]	Pfizer/BioNTech/1	884 828 (50)	Median (IQR): vaccinated: 38 (27-53); unvaccinated 38 (27-53)	Vaccinated: 423 238 (48); unvaccinated: 423 238 (48)	Vaccinated: 81 (<0.01); unvaccinated: 59 (<0.01)
Davidov et al,[84] 2021, Israel	Cohort	Pfizer/BioNTech/1	76 (100)	Median (IQR): 64 (49-69)	33 (43.4)	1 (1.3)
Filippatos et al,[85] 2021, Greece	Cohort	Pfizer/BioNTech/1 and 2	502 (100)	Mean (SD): 48.2 (12.97)[c]	393 (78.3)	1 (0.2)
Tan et al,[86] 2021, Singapore	Cohort	Pfizer/BioNTech/1 or 2; Moderna/1 or 2	127 081 (100)	Median (IQR): 22 (20-30)	4929 (7.6)	1 (0.02)
Klein et al,[42] 2021, US	Cohort[a]	Pfizer/BioNTech/1 or 2; Moderna/1 or 2	11 845 128 (100)	Mean: 49	Vaccinated: 6 424 685 (54); unvaccinated: NA	Vaccinated: 543 (<0.01); unvaccinated: 2379 (0.02)
Shasha et al,[43] 2022, Israel	Cohort	Pfizer/BioNTech/ 1 or 2	364 192 (50)	Mean: 45.8[d]	Vaccinated: 118 525 (51); unvaccinated: 111 706 (51)	Vaccinated: 31 (<0.01); unvaccinated: 12 (<0.01)
McMurry et al,[44] 2021, US	Cohort[a]	Pfizer/BioNTech/1 or 2; Moderna/1 or 2	68 266 (100)	Median (IQR): 51.0 (16-91)	31 099 (60.0)	Pfizer/BioNTech: 22 (<0.1); Moderna: 4 (<0.1); unvaccinated: 75 (0.06)
Shibli et al,[87] 2021, Israel	Cohort (no BP history; cohort (BP history)	Pfizer/BioNTech/ 1 or 2	2 594 990 (100)	46.8 (19.6)[c]	1 338 032 (51.6)	284 (<0.1)
		Pfizer/BioNTech/ 1 or 2	7564 (100)	50.2 (18.7)[c]	3388 (44.8)	14 (<0.1)
Bardenheier et al,[45] 2021, US	Cohort[a]	Pfizer/BioNTech/1 or 2; Moderna/1 or 2	10 356 (48.8)	NA[e]	13 123 (61.9)	1 (0.01)
Koh et al,[88] 2021, Singapore	Cohort	Pfizer/BioNTech/1 or 2	1 398 074 (100)	Median (IQR): 59 (15-121)	636 124 (45.5)	11 (2.4)
Patone et al,[56] 2021, UK	Cohort[f,a]	Pfizer/BioNTech/1; Oxford/AstraZeneca/1	34 557 814 (100)	Pfizer/BioNTech: 55.9 (20.1)[c]; Oxford/ AstraZeneca: 55.1 (14.8)[c]	Pfizer/BioNTech: 6 608 730 (57); Oxford/AstraZeneca: 10 150 568 (52.3)	Pfizer/BioNTech: 250 (<0.01); Oxford/AstraZeneca: 435 (<0.01)
Li et al,[57] 2022, UK and Spain	Cohort[f,a]	Oxford/AstraZeneca/ 1 or 2; Pfizer/BioNTech/1 or 2; Moderna/1 or 2; Janssen/1	4 497 003 (96.1)	Median (IQR): 47 (36-63)	2 391 109 (51.1)	247 (<0.1)
Lai et al,[89] 2022, Hong Kong (adults)	Cohort[a]	Pfizer/BioNTech/1; CoronaVac/1	335 620 (38)	Pfizer/BioNTech: 56.81 (13.43)[c]; CoronaVac: 61.58 (11.08)[c]; unvaccinated: 62.11 (12.85)[c]	Pfizer/BioNTech: 80 592 (52.6); CoronaVac: 93 561 (51.3); unvaccinated: 318 005 (58.1)	Pfizer/BioNTech: 4 (<0.1); CoronaVac: 9 (<0.1); unvaccinated: 24 (<0.1)
Hüls et al,[83] 2022, multinational	Cohort[a]	Pfizer/BioNTech/1 or 2; Moderna/1 or 2; Oxford/AstraZeneca/1 or 2; Janssen	3696 (94.9)	27.57 (12.09)[c]	996 (45.9)	1 (0.1)
Frontera et al,[59] 2022, US	Cohort[f]	Pfizer/BioNTech/1 or 2; Moderna/1 or 2; Janssen/1	306 907 (100)	Median (IQR): vaccinated: 50 (35-64); Pfizer/BioNTech: 49 (35-64); Moderna: 52 (37-66); Janssen: 44 (31-57)	63 945 188 (71)	Pfizer/BioNTech: 917 (<0.01); Moderna: 809 (<0.01); Janssen: 117 (<0.01)

(continued)

Table. Summary of Studies Included in the Meta-analysis on Bell Palsy and SARS-CoV-2 Vaccination (continued)

Source	Design	Vaccine type/ No. of doses	Vaccinated, No. (% total)	Age, y	No. (%) of female patients	No. (%) of patients with Bell palsy
Lai et al,[46] 2022, Hong Kong (adolescents)	Cohort[a]	Pfizer/BioNTech/ 1 or 2	First dose: 138 141 (50.25); second dose: 119 664 (50.29)	First dose: 14.17 (1.82)[c]; second dose: 14.44 (1.80)[c]	First dose: 68 569 (49.64); second dose: 58 496 (48.88)	First dose: 1 (0.00072); unvaccinated 3 (0.0021); second dose: 4 (0.0033); unvaccinated: 2 (0.0016)
Shemer et al,[39] 2021, Israel	Case-control	Pfizer/BioNTech/ 1 or 2	65 (58.5)	50.9 (20.2)[c]	15 (40.5)	21 (32.3)
Wan et al,[40] 2022, Hong Kong	Case-control[a]	Pfizer/BioNTech/ 1 or 2; CoronaVac/ 1 or 2	126 (8.5)	Pfizer/BioNTech: 52.38 (16.35)[c]; CoronaVac: 56.76 (15.11)[c]	Pfizer/BioNTech: 6 (37); CoronaVac: 9 (32)	NA
El-Shitany et al,[82] 2021, Saudi Arabia	Cross-sectional	Pfizer/BioNTech/ 1 or 2	455 (100)	NA[e]	292 (64.2)	3 (1.3)
Noseda et al,[90] 2021, Switzerland	Cross-sectional[f]	Pfizer/BioNTech/1 or 2; Moderna/1 or 2; Oxford/AstraZeneca/ 1 or 2; Janssen/1; CoronaVac/1 or 2; Convidecia/NA	780 073 (100)	Median (IQR): 54 (42-68)[d]	566 179 (72.58)[d]	3320 (0.42)
Tamaki et al,[55] 2021, US	Cross-sectional	NA	63 551 (50)	NA	NA	NA
Walker et al,[81] 2022, England[g]	SCCS[a]	Moderna/1	255 446 (100)	Median (IQR): 34 (27-45)	36 (46)	78 (0.03)
Ab Rahman et al,[54] 2022, Malaysia	SCCS[a]	Pfizer/BioNTech/1 or 2; CoronaVac/1 or 2; Oxford/AstraZeneca/ 1 or 2	35 201 509 (100)	50.1 (15.2)[c]	10 282 321 (50.9)	Pfizer/BioNTech: 27 (<0.1); Oxford/AstraZeneca: 5 (<0.1); CoronaVac: 21 (<0.1)

Abbreviations: NA, not available; RCT, randomized clinical trial; SCCS, self-controlled case series.

[a] Received governmental and/or industrial funding.

[b] Varied between the included trials; majority were between 18 and 55 years of age.

[c] Mean (SD).

[d] Only in individuals reporting Bell palsy.

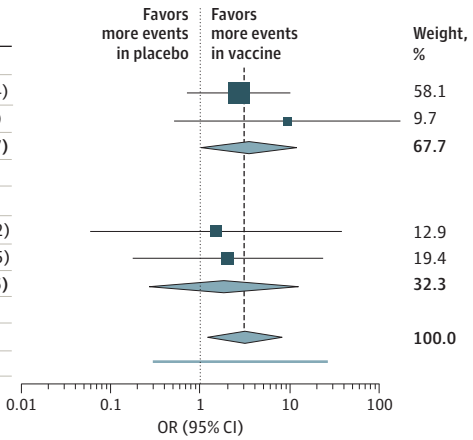
[e] In El-Shitany et al,[82] 299 participants (65.7%) were younger than 60 years and 156 (34.3%) were 60 years or older. In Bardenheier et al,[45] 4981 participants (23.5%) were aged 65 to 74 years, 5912 (27.9%) were aged 75 to 84 years, and 6328 (29.8%) were 85 years or older.

[f] Data in Noseda et al[90] were from the VigiBase database accessed as of May 16, 2021. Data in Patone et al[56] were from the English National Immunisation database. Data in Frontera et al[59] were from the Vaccine Adverse Event Reporting System accessed between January 1, 2021, and June 14, 2021. Data in Li et al[57] were from the Spanish database of Information System for Research in Primary Care.

[g] This study also included individuals receiving the Oxford/AstraZeneca vaccine but overlapped with other studies.

Figure 1. Bell Palsy Events in Groups of Vaccine Recipients vs Saline Placebo Recipients, With Data From Randomized Clinical Trials

Source	Vaccine group Events, No.	Vaccine group Participants, No.	Placebo group Events, No.	Placebo group Participants, No.	OR (95% CI)
mRNA vaccine platform					
El Sahly et al,[35] 2021 (Moderna)	8	15 184	3	15 162	2.66 (0.71-10.04)
Thomas et al,[36] 2021 (Pfizer/BioNTech)	4	18 860	0	18 846	9.00 (0.48-167.09)
Total		**34 044**		**34 008**	**3.57 (1.09-11.67)**
Heterogeneity: $\chi^2_1 = 0.55$ ($P = .46$), $I^2 = 0\%$					
Viral vector vaccine platform					
Falsey et al,[38] 2021 (Oxford/AstraZeneca)	1	21 587	0	10 792	1.50 (0.06-36.82)
Sadoff et al,[37] 2022 (Janssen)	2	21 894	1	21 882	2.00 (0.18-22.05)
Total		**43 481**		**32 674**	**1.80 (0.26-12.35)**
Heterogeneity: $\chi^2_1 = 0.02$ ($P = .89$), $I^2 = 0\%$					
Total		**77 525**		**66 682**	**3.00 (1.10-8.18)**
Prediction interval					**(0.29-26.13)**
Heterogeneity: $\chi^2_3 = 0.84$ ($P = .84$), $I^2 = 0\%$					
Test for subgroup differences: $\chi^2_1 = 0.35$ ($P = .55$)					

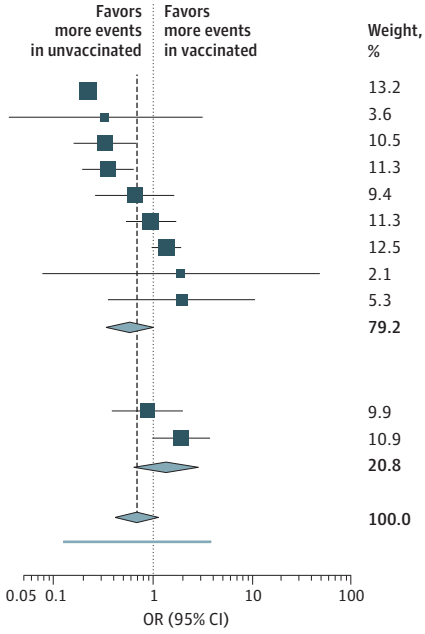


Dashed line indicates the point estimate of the overall effect; dotted line, no effect; diamonds, overall effects. OR indicates odds ratio.

subsequent to SARS-CoV-2 vaccination. This study has pooled data on more than 53 million vaccine doses for meta-analysis. In this context, we have compared 2 major SARS-CoV-2 vaccine platforms in terms of BP occurrence in more than 50 million doses. The BP occurrence following SARS-CoV-2 infection was also compared with receipt of

Figure 2. Bell Palsy Events in Groups of mRNA-Vaccinated Participants vs Unvaccinated Participants, With Data From Observational Studies

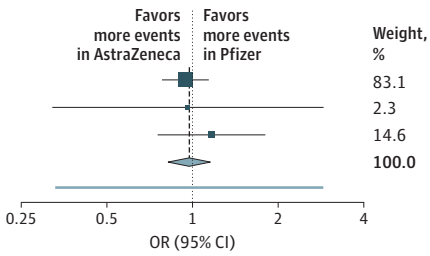
Source	Vaccinated group Events, No.	Vaccinated group Participants/doses, No.	Unvaccinated group Events, No.	Unvaccinated group Participants, No.	OR (95% CI)
Cohort subgroup					
Klein et al,[42] 2021	543	11 845 128	2379	11 845 128	0.23 (0.21-0.25)
Lai et al,[46] 2022 (first dose)	1	138 141	3	136 743	0.33 (0.03-3.17)
McMurry et al,[44] 2021 (second dose)	10	41 909	30	41 909	0.33 (0.16-0.68)
McMurry et al,[44] 2021 (first dose)	16	68 266	45	68 266	0.36 (0.20-0.63)
Shasha et al,[43] 2022 (second dose)	8	131 033	12	131 033	0.67 (0.27-1.63)
Shasha et al,[43] 2022 (first dose)	23	233 159	24	233 159	0.96 (0.54-1.70)
Barda et al,[41] 2021	81	923 692	59	923 692	1.37 (0.98-1.92)
Bardenheier et al,[45] 2021	1	16 924	0	11 072	1.96 (0.08-48.19)
Lai et al,[46] 2022 (second dose)	4	119 664	2	118 300	1.98 (0.36-10.80)
Total		**13 517 916**		**13 509 302**	**0.59 (0.34-1.01)**
Heterogeneity: $\chi^2_8 = 133.4$ ($P < .001$), $I^2 = 94\%$					
Case-control subgroup					
Shemer et al,[39] 2021	21	65	16	46	0.89 (0.40-1.99)
Wan et al,[40] 2022 (Pfizer/BioNTech subset)	14	45	256	1353	1.94 (1.01-3.69)
Total		**110**		**1399**	**1.37 (0.64-2.90)**
Heterogeneity: $\chi^2_1 = 2.17$ ($P = .14$), $I^2 = 54\%$					
Total		**13 518 026**		**13 510 701**	**0.70 (0.42-1.16)**
Prediction interval					**(0.13-3.83)**
Heterogeneity: $\chi^2_{10} = 175.75$ ($P < .001$), $I^2 = 94\%$					
Test for subgroup differences: $\chi^2_1 = 3.18$ ($P = .07$)					



Dashed line indicates the point estimate of the overall effect; dotted line, no effect; diamonds, overall effects. mRNA indicates messenger RNA; OR, odds ratio.

Figure 3. Bell Palsy Events in Groups of Pfizer/BioNTech Recipients vs Oxford/AstraZeneca Recipients, With Data From Observational Studies

Source	Pfizer Events, No.	Pfizer Participants, No.	AstraZeneca Events, No.	AstraZeneca Participants, No.	OR (95% CI)
Patone et al,[56] 2021	176	12 134 782	315	20 417 752	0.94 (0.78-1.13)
Ab Rahman,[54] 2022	17	8 735 482	4	1 968 763	0.96 (0.32-2.85)
Li et al,[57] 2022 (SIDIAP database)	100	1 890 434	27	592 365	1.16 (0.76-1.78)
Total		**22 760 698**		**22 978 880**	**0.97 (0.82-1.15)**
Prediction interval					**(0.33-2.87)**
Heterogeneity: $\chi^2_2 = 0.79$ ($P = .67$), $I^2 = 0\%$					



Dashed line indicates the point estimate of the overall effect; dotted line, no effect; diamond, overall effect. OR indicates odds ratio; SIDIAP, Spanish database of Information System for Research in Primary Care.

the SARS-CoV-2 vaccine in approximately 40 million individuals.

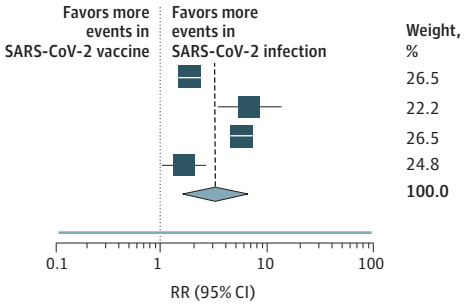
Our analysis of the RCTs shows that among all SARS-CoV-2 vaccine recipients, the odds of BP occurrence were significantly increased in the mRNA vaccine subgroup compared with the saline placebo recipients. In the viral vector vaccine subgroup, however, no such significant difference was observed. The analysis of observational studies shows that the odds of BP incidence after SARS-CoV-2 mRNA vaccines did not significantly differ from those who did not receive any vaccine. Furthermore, a comparison of the first-dose recipients of the Pfizer/BioNTech and Oxford/AstraZeneca vaccines found that the risk of developing BP within 21 days of the vaccination was not significantly different. Finally, on the basis of our analysis, the SARS-CoV-2 infection contributes to a significant 3.23-fold increase in BP risk compared with SARS-CoV-2 vaccines.

Importantly, although this study shows evidence of increased BP incidence following SARS-CoV-2 vaccination compared with placebo receipt, SARS-CoV-2 infection was associated with a 3.23-fold increase in BP incidence. Thus, our results suggest that vaccinating against SARS-CoV-2 can significantly diminish the odds of BP compared with SARS-CoV-2 infection. Considering that the overall BP incidence is approximately 15 to 30 per 100 000 annually in the general population,[1] our analysis of RCTs suggests a similar BP incidence of 18 per 100 000 among SARS-CoV-2 vaccine recipients (eFigure 9 in Supplement 1). This rate is comparable with the previous reports[55,57] with an incidence of 19 or lower per 100 000 population after SARS-CoV-2 vaccination. With SARS-CoV-2 infection, however, the reported BP incidence is significantly higher at 32.3 to 82 per 100 000 patients.[55,57] These results overall suggest that the BP incidence after SARS-

Figure 4. Bell Palsy in Groups of SARS-CoV-2 Infection vs SARS-CoV-2 Vaccine Recipients, With Data From Observational Studies

Source	Total No. of infected patients	Total No. of vaccine recipients/doses	RR (95% CI)
Patone et al,[56] 2021	2 005 280	32 552 534	1.84 (1.45-2.33)
Tamaki et al,[55] 2021	348 088	63 551	6.80 (3.50-13.21)
Li et al,[57] 2022 (SIDIAP database)	288 030	4 372 633	5.71 (4.50-7.25)
Barda et al,[41] 2021	180 674	923 692	1.64 (1.06-2.55)
Total	**2 822 072**	**37 912 410**	**3.23 (1.57-6.62)**
Prediction interval			**(0.11-96.91)**

Heterogeneity: $\chi^2_2 = 57.14$ ($P < .001$), $I^2 = 95\%$



Dotted line indicates no effect; diamond, overall effect. RR indicates risk ratio; SIDIAP, Spanish database of Information System for Research in Primary Care.

CoV-2 vaccines is comparable with the overall incidence in the general population, whereas it clearly exceeds that with SARS-CoV-2 infection. In line with this finding, prior studies[56,57] also found that the risk of neurologic adverse events from SARS-CoV-2 infection is markedly higher than from the SARS-CoV-2 vaccines. These complications may include encephalomyelitis, meningitis, GBS, or transverse myelitis.[57]

Several mechanisms have been considered to explicate the underlying pathophysiology of BP. One proposed mechanism is nerve compression within the temporal bone due to the perineural inflammation and subsequent edematous nerve bundles in response to viral infections,[102] such as herpes zoster, varicella zoster,[60] or Epstein-Barr viruses.[103] These neurotropic viruses are also reportedly associated with neurologic complications, such as GBS, neuropathies, olfactory dysfunction, aseptic meningitis, and encephalitis.[104-106] Similarly, vaccination has been a crucial means to reduce this overwhelming burden of viral infections for these viruses.

As an adverse event of vaccination, BP is not only encountered with SARS-CoV-2 vaccines. It is speculated that the vaccine antigens that can reactivate T cells by mimicking human cell surface molecules may elicit an autoimmune response.[40] To look for evidence of vaccines triggering BP, Ozonoff et al[107] conducted a brief review that found an association of BP with intranasal influenza vaccine, seasonal influenza vaccine, H1N1 influenza vaccines, and meningococcal conjugate vaccine. The intranasal inactivated influenza vaccine was suggested to be strongly linked with BP through mediating inflammation due to containing *Escherichia coli* heat-labile enterotoxin. However, such an association is confirmed solely in animal studies.[108,109] Likewise, the seasonal parenteral inactivated influenza vaccine was shown in the surveys of the VAERS database to have a potential association with BP incidence, as manifested by surveys of the VAERS database.[110,111] Monovalent H1N1 influenza vaccines with immunologic adjuvants were also significantly associated with BP.[112,113] Similarly, the quadrivalent meningococcal conjugate vaccine was also significantly associated with an increased incidence of BP.[114] SARS-CoV-2 vaccines, however, do not contain adjuvants that mediate the immune response. Instead, the virus mRNA in the vaccines might interact with the immune cellular membranes and elicit an innate immune response,[107] which in turn may trigger BP, similar to the cases reported with interferon treatment.[115,116]

Limitations

This study has several limitations. Most importantly, we used previously published data, and no individual patient-level data were available in this study. This limitation hampered our ability to perform subgroup analyses based on parameters such as age, sex, vaccine dose, or vaccination-to-event time span. It was also not possible to control for some of the known BP risk factors, such as diabetes, obesity, hypertension, upper respiratory tract disease, or pregnancy, because most studies have not provided sufficient data on these risk factors.[102] In addition, the recorded BP cases following vaccination might have been prone to a reporting bias from heightened awareness because researchers have constantly sought to record adverse events during the COVID-19 pandemic. Not all of the studies have split the results of the first and second vaccine doses. Instead, they have reported the combined data, and their analyses were based on the events per vaccine dose and not based on the events per participant. Notably, none of the studies had any data from children younger than 12 years, and this inclusion bias impedes the generalizability of the findings to this younger age range. Furthermore, studies comparing the BP incidence after SARS-CoV-2 infection with SARS-CoV-2 vaccines included different study intervals and did not mention the prevalent SARS-CoV-2 subtypes at the time each study was conducted. Finally, there was some heterogeneity among the studies that compared BP incidence in mRNA vaccinated vs unvaccinated individuals and among the studies that compared vaccination with SARS-CoV-2 infection. This heterogeneity could be attributable to different inclusion criteria or sampling methods. Because RCTs and major observational studies did not report treatment outcomes and recurrence, we were not able to draw a meaningful conclusion on whether there were any differences in the treatment outcome for BP with the SARS-CoV-2 vaccine, with SARS-CoV-2 infection, or in spontaneous cases. Only a small number of studies (mostly case reports) reported data on the treatments and outcomes and mainly used steroids and antivirals as the treatment of choice (eTable 2 in Supplement 1). When attempting to compare with other vaccines and diseases, SARS-CoV-2 vaccine studies did not provide sufficient data for pool-

ing. All in all, these limitations may have affected heterogeneity among studies, leading to potential confounders for analysis.

Conclusions

SARS-CoV-2 vaccines (mRNA and viral vector) in the analysis of RCTs demonstrated significantly increased odds of developing BP vs placebo. The analysis of the observational studies showed that mRNA SARS-CoV-2–vaccinated participants had no significant increase in BP incidence vs the unvaccinated participants. The incidence of BP in those who received the Pfizer/BioNTech or Oxford/AstraZeneca vaccines did not differ significantly. Because this study found a strong association between the SARS-CoV-2 vaccine and BP in 4 RCTs, we conclude that BP is a result of SARS-CoV-2 vaccine exposure. However, no association between the mRNA vaccines and BP was seen in the observational studies. Notably, SARS-CoV-2 infection was linked with a 3.23-fold increased risk of BP compared with SARS-CoV-2 vaccines, which favors a protective role of the vaccine in reducing the incidence of BP associated with exposure to SARS-CoV-2. Further research is required to verify this association and investigate possible mechanisms.

ARTICLE INFORMATION

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