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LETTER TO THE EDITOR

# Peripheral facial palsy following COVID-19 vaccination: a practical approach to use the clinical situation as a guide

## *Paralisi facciale periferica dopo vaccinazione per COVID-19: una guida per un approccio pratico alla problematica clinica*

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**KEY WORDS:** COVID-19 vaccination, peripheral facial palsy, pharmacovigilance data, adverse effect, guidelines

**PAROLE CHIAVE:** *vaccinazione anti COVID-19, paralisi facciale periferica, farmacovigilanza, effetti avversi, linee guida*

Dear Editor,

in the face of the various phases of the COVID-19 epidemic, governments have called for a massive vaccination of the population. As soon as randomised Phase 3 clinical trials were set up to test the efficacy of mRNA vaccines in protecting against COVID-19, the occurrence of peripheral facial palsy (PFP) was reported with a higher incidence than that observed in the placebo group<sup>1</sup>, and confirmed worldwide in larger populations. However, it should be noted that the incidence remains low, and seems comparable to that of PFP following administration of other vaccines such as anti-influenza<sup>2</sup>. The two types of vaccines [messenger RNA (mRNA) vaccines and viral vector vaccines] seem

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to promote herpetic viral reactivation<sup>3</sup> with a risk of PFP. To date, research in the worldwide pharmacovigilance database has found more than 19,000 reported cases (including nearly 1,100 in France) of PFP following vaccination against COVID-19, with the following breakdown: 85% with mRNA vaccines and 15% with viral vector vaccines. In this context, from June 2021 to January 2022, we managed 41 cases of PFP following expansion of the COVID-19 vaccination to the general population in June 2021. We received numerous calls for advice by our colleagues at other sites. We are also solicited daily by patients themselves, who are worried about the risk of recurrence of PFP described in the prescribing information of the different vaccines.

To provide an answer to these patients and our colleagues, and in the absence of definitive scientific data, we have locally gathered a group of experts from different specialties (ENT, infectiology, neurology, pharmacovigilance, pharmacy, virology) in order to give advice on a case-by-case basis and have established local guidelines according to the different situations that may arise. Our proposals as an expert group are summarised below.

### Initial management of PFP

Any acute or subacute (< 72 hours) onset PFP following primary vaccination against COVID-19 or following a booster vaccination should be reported to pharmacovigilance as soon as possible (after informing the patient). As this is a diagnosis of exclusion, a standardised clinical examination and complementary explorations should be systematically performed according to French ENT guidelines<sup>4</sup>. Any PFP that occurs after COVID-19 vaccination should be treated as soon as possible in the same way as idiopathic PFP according to the French ENT guidelines<sup>4</sup> (high-dose corticosteroid, 1 to 2 mg/kg/day depending on severity) for 8 to 10 days and antiviral treatment with valaciclovir (3 g/day for 7 days).

### High-dose corticosteroid therapy on vaccine response

The French High Council of Public Health, in its 2014 report, contraindicates live vaccines when the doses used are considered immunosuppressive (10 mg prednisone equivalent per day for more than 2 weeks or bolus corticosteroids ( $\geq 500$ mg/day). Regarding vaccination against COVID-19, data on long-term corticosteroid therapy shows a decreased vaccine response for the BNT162b2 COVID-19 mRNA vaccine (Comirnaty®, BioNTech-Pfizer). One study identified a decrease in immunogenicity of ChAdOx1 nCoV-19

adenovirus vector vaccine (Vaxzevria®, Oxford-AstraZeneca) for short, low-dose corticosteroid therapy (< 30 mg prednisone)<sup>5</sup>. Another study showed a trend towards lower immunogenicity of BNT162b2 for patients on low-dose steroids for an extended period<sup>6</sup>. Consequently, in the case of high-dose corticosteroid therapy prescribed close to vaccination (< 15 days), it seems legitimate to ensure a good vaccine response, as suggested by the French recommendations of the “Conseil d’Orientation pour la Stratégie Vaccinale” (COSV) dated 19 November 2021. Thus, quantitative IgG anti-Spike serology monitoring would be recommended after 15 days of the booster. If the antibody level is > 260 BAU/mL, the protection conferred by vaccination is considered sufficient. Serological follow-up may be suggested if immunosuppression persists.

### Attitude towards COVID-19 vaccine and boosters

Given the severity of the pandemic and the risks associated with COVID-19, we agree that the development of PFP following SARS-Cov2 vaccination should not always contraindicate subsequent booster vaccinations. Our practical approach for the vaccination in the case of PFP after vaccination against COVID-19 is summarised in Table I.

After discussion and review of scientific data, we consider that in cases of mild post-vaccine PFP (grades II, III, IV according to the House and Brackmann classification<sup>7</sup>), where the prognosis for recovery is favourable<sup>8</sup>, the initially planned vaccination schedule should be maintained. Clinical examination should be systematically performed before the next vaccine dose to assess the degree of recovery.

In cases of severe PFP following vaccination against COVID-19 (grades V and VI<sup>4</sup>) with poor prognostic factors for recovery<sup>8</sup>, and in the absence of early recovery (< 3 months) of symptoms, it is proposed that further doses be deferred. In this case, the patient should be discussed at a dedicated multidisciplinary consultation meeting (MCM) to assess the benefit-risk balance as best as possible according to the individual case, context and degree of recovery from PFP (clinical re-evaluation every two months).

A severe PFP without favourable evolution at 6 months, whether it occurs in a post-vaccine context or not, should be the subject of a new clinical and MRI imaging assessment.

Data from the literature suggest an overall increased risk of PFP after COVID-19 vaccination<sup>1</sup>. However, the beneficial and protective effects of the COVID-19 vaccine far outweigh the risk of this generally self-limiting adverse event. Thus, despite severe PFP without recovery at 3 months, a

**Table I.** Practical approach for vaccination in case of PFP following vaccination against COVID-19.

|  | Recommended vaccination   | Authorised vaccines  |
|--|---|--|
| History of PFP other than vaccine  | Yes   | All  |
| PFP grade II, III, IV post-vaccine   | Yes   | All, including those suspected of being responsible for the PFP  |
| PFP grade V, VI post-vaccination with rapid clinical recovery  | Yes   | Propose to continue the vaccine regimen with another modality (mRNA or viral vector)   |
| PFP grade V, VI post-vaccine without recovery or with severe after-effects   | Suspended;<br>Assessment of the benefit-risk balance according to the patient's comorbidities and context; Regular re-evaluation according to clinical evolution;<br>Decision to be made in MCM | If the benefit-risk balance is in favour of a booster vaccination, continue the vaccination schedule with another type of vaccine; If no, suspend booster for 6 months and then reassess |
| History of post-vaccination PFP, patient requesting a complete vaccination scheme, regardless of the severity of the PFP | Yes,<br>Exhaustive information given to the patient   | Propose to continue the vaccine scheme with another modality (mRNA or viral vector)  |

\* Following House and Brackmann grading scale 7; PFP: peripheral facial palsy; MCM: Multidisciplinary Consultation Meeting.

patient requesting vaccination may be vaccinated later depending on the disease progression after being informed of the benefits and risks.

In the case of PFP in a post-vaccination context, the patient might be offered to change the type of vaccine for the subsequent injections if it is adapted to the general context of the patient and national recommendations. If an mRNA vaccination was used, a booster with another vaccine, either the other mRNA vaccine or an inactivated SARS-CoV-2 vaccine, may be preferred.

## What to offer in case of prior history of PFP before COVID-19 pandemic?

From a clinical, patient-oriented perspective, none of the studies published so far provide definitive evidence to inform the choice of a specific vaccine in individuals worldwide with a history of PFP (idiopathic or not) <sup>9</sup>. While waiting for conclusive evidence on vaccine-associated facial palsy, one certainty remains: the benefit of getting vaccinated outweighs any possible risk.

In the case of a history of PFP other than vaccination against COVID-19, and regardless of the degree of recovery, there is no contraindication to vaccination, irrespective of the specialty used. According to the current recommendations, the COVID-19 vaccination scheme must then be completed. The risk of recurrence of idiopathic PFP, outside of a vaccine context, is about 6.5% <sup>4</sup>. Further studies are needed to determine whether this risk is higher in vaccinated patients with a history of PFP prior to vaccination against COVID-19. Finally, a recent study suggests that rates of PFP are higher in patients with COVID-19, and this incidence exceeds the reported incidence of PFP in those who have received a COVID-19 vaccine <sup>10</sup>. Otherwise, the

COVID-19 vaccine should protect against the risk of post-COVID PFP.

In conclusion, the risk of PFP after vaccination against COVID-19 is low and seems comparable to that of PFP following the administration of other vaccines such as anti-influenza vaccines. Herein, we propose a practical transdisciplinary approach for management of PFP in the context of a recent vaccination against SARS-CoV-2. Further studies are needed to evaluate the impact of a booster vaccine on the facial nerve.

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The authors declare no conflict of interest.

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### Authors' contributions

CF, KB, EC, VF and NW collected the information, and wrote the Letter. CF, FT, AV, MC and GL provided the ENT expertise and reviewed the article. KB, HJ provided the pharmacological expertise and reviewed the article. SD, RD, EM, CLF and NW provided the neurological expertise and reviewed the article. EC and VP provided the infectious diseases expertise and reviewed the article.

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