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Tachycardia as an undescribed adverse effect to the Comirnaty© vaccine (BNT162b2 Pfizer-BioNTech Covid-19 vaccine): Description of 3 cases with a history of SARS-CoV-2 disease☆

Taquicardia como efecto adverso no descrito en la vacuna Comirnaty© (Vacuna COVID-19 mRNA BNT162b2 de Pfizer-BioNTech): descripción de 3 casos con antecedentes de SARS-CoV-2

Multiple side effects were reported in the trial of the efficacy and safety of the Comirnaty© vaccine (Pfizer-BioNTech BNT162b2 mRNA COVID-19 vaccine)[1]. Following the recent vaccination of healthcare professionals, given that 24% of this population has had the disease[2], adverse effects not reported to date in the subpopulation of 540 subjects seropositive for SARS-CoV-2 in which the safety profile was no different from that observed in the general population have begun to be reported in the summary of product characteristics[3].

We report three cases of healthcare professionals, specifically physicians, who received the first dose of the vaccine on 18 January 2021 (1:15 PM). These individuals worked in the same department and developed the disease in March 2020, following an outbreak of SARS-CoV-2 in their workplace; none of them required hospital admission.

Their shared adverse effect, unpublished as of today and also not mentioned in the latest pharmacovigilance report from the Agencia Española de Medicamentos y Productos Sanitarios [Spanish Agency of Medicines and Medical Devices][4], was tachycardia unrelated to hyperthermia as a first sign of the onset of a systemic reaction in all three cases. It was therefore reported to the Centro Autonómico de Farmacovigilancia [Regional Pharmacovigilance Centre] within 48 h of vaccine administration.

On 21 January 2021, the Sociedad Española de Inmunología [Spanish Society of Immunology] prepared a briefing note on reactions to the first dose of the vaccine in individuals having already recovered from the disease, warning that vaccination would act as a second contact with the virus and trigger a more vigorous immune system response in them[5].

Case 1

The first case was a 60-year-old woman with a history of hypertension, dyslipidaemia and total thyroidectomy who was a heterozygous carrier of factor V Leiden mutation. She was on treatment with ramipril, rosuvastatin and levothyroxine. Her latest yearly thyroid check-up had the following results: thyroid-stimulating hormone (TSH) 1.12 μUI/mL (reference range: 0.270–4.200) and free thyroxine (T4) 1.44 ng/dl (reference range: 0.93–1.70).

She presented acute COVID-19 on 8 March 2020, and her signs and symptoms disappeared over the following two weeks. The clinical picture consisted of tiredness, fever, dry cough, muscle pain, joint pain, diarrhoea, scalp hypersensitivity and parosmia.

A polymerase chain reaction (PCR) test was negative. Two months later, a rapid test for SARS-CoV-2 IgG antibodies yielded a positive result.

The result of her latest serology (enzyme-linked immunosorbent assay [ELISA]) was IgG 2.1 U (positive >0.8) on 2 December 2020.

Fourteen hours after receiving the vaccine, she developed observed tachycardia of 110 bpm which spontaneously remitted in approximately 16 h, along with gastrointestinal abnormalities, pain at the puncture site with locoregional lymphadenopathy, tiredness, fever and scalp hypersensitivity.

Case 2

The second case was a 55-year-old woman with a history of Hashimoto's disease on treatment with levothyroxine. Her latest yearly thyroid check-up yielded the following results: TSH 0.608 μUI/mL (reference range: 0.270–4.200) and free T4 1.63 ng/dl (reference range: 0.93–1.70).

She presented acute disease on 6 March 2020; her symptoms consisted of tiredness, chills, fever, muscle pain, dry cough, frontal headache and parosmia, with a duration of 10 days. After eight days with no symptoms, her fever recurred for six additional days.

She had a positive PCR test on 15 March and a negative one on 5 April 2020.

The result of her latest serology (ELISA) was IgG 0.9 U (positive >0.8) on 2 December 2020.

Ten hours after vaccine administration, she developed tachycardia of up to 120 bpm, not co-occurring with hyperthermia, that made it difficult for her to sleep and spontaneously remitted 24 h

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later; pain at the puncture site; and, eight hours later, tiredness, chills, fever, muscle pain, joint pain and runny nose.

Case 3

The third case was a 51-year-old woman with no personal history of note.

She presented acute disease on 6 March 2020, with tiredness, muscle pain, joint pain, headache, fever, skin hypersensitivity, dry cough and diarrhoea.

She had a positive PCR test on 19 March and a negative one on 2 April 2020.

The result of her latest serology (ELISA) was IgG 1 U (positive >0.8) on 2 December 2020.

At 4:00 AM on 19 January, she woke up with tachycardia of up to 136 bpm and extrasystoles. Subsequently, she developed pain at the puncture site, tiredness, chills, fever, muscle pain, joint pain, headache and generalised skin sensitivity. All these symptoms resolved after 36 h, except her symptomatic extrasystoles, for which she was assessed by the cardiology department and prescribed drug treatment with follow-up. Her extrasystoles have not remitted even though more than one week has elapsed since the administration of the first dose of the vaccine.

It so happens that two out of the three cases had a history of thyroid disease, which in itself might be a cause of tachycardia; however, this association was ruled out since both cases showed stable thyroid laboratory test results in recent years.

We find it necessary to confirm the onset of this adverse reaction after vaccine administration in subjects with a history of prior SARS-CoV-2 infection and, if it is confirmed, take the required measures in subjects with prior heart disease.

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Therapeutic drug monitoring of colistin in plasma and cerebrospinal fluid in meningoventriculitis caused by a carbapenem-resistant *Enterobacter cloacae*

Monitorización terapéutica de niveles de colistina en plasma y líquido cefalorraquídeo en meningoventriculitis causada por Enterobacter cloacae *resistente a meropenem*

Clinical case

A 35-year-old 80 kg man was admitted in the Resuscitation Unit after a craniotomy and the placement of a double external ventricular drainage for a malignant midline glioma with obstructive hydrocephalus. After three weeks, when the patient presented septic symptoms (C-reactive protein of 23 mg/dL, 4220 leukocytes/mm^3) the drainages were replaced. The cerebrospinal fluid (CSF) biochemistry was compatible with a bacterial central nervous system (CNS) infection (glucose < 2 mg/dL and proteins 550 mg/dL). Broad spectrum antibiotic therapy was started with intravenous (IV) linezolid 600 mg q12h and meropenem 2000 mg q8h in a 4h extended infusion.

Five days later, a Class B carbapenemase (metallo-β-carbapenemase)-producing *Enterobacter cloacae* with intermediate susceptibility to meropenem with minimum inhibitory concentration (MIC) of 8 mg/L and susceptible to colistin (MIC = 0.20 mg/L) was isolated in both CSF and blood cultures (drainages were not cultured). In addition, a Class A carbapenemase (KPC)-producing *Klebsiella pneumoniae* (colistin MIC ≤ 2 mg/L) and an extensively drug-resistant *Pseudomonas aeruginosa* (colistin MIC ≤ 0.5 mg/L; meropenem MIC = 8 mg/L) were isolated in blood cultures. These nosocomial microorganisms were not isolated in any other culture and they could be a consequence of an incorrect drainage manipulation in a COVID pandemic situation, with a higher prevalence of multi-drug resistant bacteria. Linezolid was stopped and intravenous colistimethate sodium (CMS) at a dose of 6 MIU q12h was added to meropenem due to the synergic effects of both antibiotics.[1] In addition, intraventricular colistin (10 mg q4h administered through each CSF drainage) was added to try to ensure therapeutic concentrations into the CSF, as described in exceptional cases.[2,3]

Table 1
Colistin levels in plasma and CSF.

Day of CMS treatment	Extraction time	Extraction site	Colistin concentration (mg/L)
7	Trough or pre IV dose	Plasma	1.0
7	Trough or pre IT dose	Right CSF drain	2.5
7	Peak (3 h after IT administration)	Right CSF drain	5.6
7	Trough or pre IT dose	Left CSF drain	2.5
7	Peak (3 h after IT administration)	Left CSF drain	4.4
15	Trough or pre IV dose	Plasma	1.0