

Original Article

# Has Coronavirus Disease 2019 Changed the Incidence and Outcome of Bell's Palsy?

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**BACKGROUND:** Objectives: (1) To determine whether the incidence of Bell's Palsy (BP) increased during the pandemic. (2) To investigate whether the outcomes of patients with BP and COVID-19 infection or vaccination differ from those in the pre-pandemic era.

**METHODS:** Patients with BP were studied in 2 periods retrospectively (March 2021–March 2022 and August 2018–August 2019). A prospective study from March 2021 to March 2022 was also performed. Primary outcome was grade  $\leq$  II in the House–Brackmann (HB) and/or  $>70$  in the Sunnybrook facial grading system (SFGS) scales at the 12-week visit. Reverse transcriptase polymerase chain reaction (PCR) for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and enzyme-linked immunosorbent assay-based SARS-CoV-2 immunoglobulin G (IgG) test (blood) were measured.

**RESULTS:** About 162 and 196 patients with BP were identified between March 2021 and March 2022 and August 2018 and August 2019, respectively. Forty-seven patients (29%) entered the prospective study; 85% had HB grades I or II, while 92% had an SFGS score of 71–100 at the last visit. Only 3 patients (6.5%) had a positive PCR during the initial episode, whereas 35 patients (77%) had positive IgG SARS-CoV-2. There was no association between positive PCR and facial function outcomes. Of the 162 patients, 105 (67%) had received COVID-19 vaccine. In 23 of them (22%), the paralysis appeared within the first 30 days after a vaccine dose.

**CONCLUSION:** Coronavirus disease 2019 did not increase the incidence of BP. A direct association between the coronavirus and BP outcome cannot be established. The considerable number of patients developing BP within the first month suggests a possible association between COVID-19 vaccines and BP.

**KEYWORDS:** SARS-CoV-2, COVID-19, Bell's palsy, facial paralysis, vaccination

## INTRODUCTION

Bell's palsy (BP), also known as idiopathic facial paralysis (FP), is the most common form, representing about 60%–75% of all unilateral cases of FP. It has an annual incidence of 20–30 cases/100 000 inhabitants. It consists of a sudden paralysis of the facial muscles on one side of the face, causing facial asymmetry. Herpes simplex virus (HSV) reactivation within the geniculate ganglion with subsequent inflammation of the nerve has been proposed to be the pathogenetic mechanism.<sup>1</sup> Some factors have been reported to increase the risk of BP. These include pregnancy, obesity, diabetes, high blood pressure, upper respiratory disease, and preeclampsia. The treatment of BP is based on oral corticosteroids. In about 85% of the cases, facial function is spontaneously recovered in the first 3 weeks, although only 60% of patients presenting with total paralysis recover completely without treatment.<sup>2</sup>

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During the last 2-3 years, the coronavirus disease 2019 (COVID-19) pandemic has escalated and spread widely throughout the entire world. Although this disease consists mainly of respiratory symptoms, its clinical presentation is variable.<sup>3</sup> The severity of the symptoms is extremely variable, ranging from asymptomatic patients to advanced stages that may even lead to death. Among otolaryngologic manifestations, acute facial paralysis has been reported in patients with COVID-19 since the pandemic started.<sup>4-6</sup>

Some studies have suggested an increase in the incidence of BP in patients with COVID-19 compared to the pre-pandemic era.<sup>7</sup> Srinivas et al<sup>8</sup> reported a higher incidence of BP in 2020 as compared to previous years. In a similar way, Codeluppi et al<sup>9</sup> demonstrated a higher incidence of BP during the pandemic compared to a similar period in the previous year. On the other hand, some studies have not found an increase in the incidence of BP cases in relation to the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus infection.<sup>10</sup>

It is also unclear if the severity of BP cases related to COVID-19 infection and/or vaccination is somehow different to that of BP cases prior to the SARS-CoV-2 outbreak, with the precise link between SARS-CoV-2 and BP being still unclear.<sup>11-13</sup>

Bell's palsy has been reported during the trials of the main COVID-19 vaccines.<sup>14</sup> Although reactivation of a latent dormant virus could be the pathogenesis of these cases, the variation in the days between vaccination and BP questions the existence of a unique explanation for this event.

The aim of this study was to answer the following questions:

1. Was the incidence of BP during the pandemic higher than in a similar period of time previous to the pandemic? Is there an impact of the COVID-19 waves on the incidence of FP during the period March 2021–March 2022?
2. Is there a relationship between COVID-19 infection and BP? Does COVID-19 infection influence the outcome of BP? Is the outcome of patients with BP and COVID-19 infection different to that of the pre-pandemic era?
3. Is there a relationship between COVID-19 vaccination and BP? Does COVID-19 vaccination increase the risk of developing BP?

## MATERIAL AND METHODS

In order to answer these questions, 3 different studies in 2 different periods were performed.

### MAIN POINTS

- Association between coronavirus disease (COVID-19) infection and Bell's palsy cannot be established.
- Coronavirus disease 2019 infection does not influence facial function outcomes.
- There may be a potential link between COVID-19 vaccines and Bell's palsy.

## Type of Study, Inclusion and Exclusion Criteria, and Main Variables

### 1. Retrospective Study 2021-2022

The database of the Emergency Department (ED) at a hospital in Spain from March 1, 2021, to March 31, 2022, was reviewed and analyzed to identify the total number of patients with BP who attended the ED irrespective of their participation in the prospective study.

Recorded clinical variables included age, sex, side of facial involvement, and history of SARS-CoV-2 vaccination.

### 2. Retrospective Study 2018-2019

In addition, a 13-month period prior to the beginning of pandemic (August 2018 to August 31, 2019) was analyzed in order to record the number of patients who attended the ED due to BP as a control group. Recorded clinical variables included age and sex.

The distribution of BP by months was compared between both retrospective periods. The impact of "official" COVID-19 waves on the number of patients was also analyzed.<sup>15</sup>

### 3. Prospective Study 2021-2022

A prospective study was conducted among patients diagnosed with BP admitted to the Emergency Department (ED) during the same period (March 1, 2021—March 31, 2022).

The inclusion criterion was acute facial nerve paralysis confirmed by the doctor at the adult ED. At the ED, patients were informed about the study, and those willing to enter signed the informed consent.

A detailed anamnesis, ear–nose–throat examination, and neurological evaluation, including facial function, were performed by the otorhinolaryngologist physician on call.

If no etiologic reason was found clinically at the ED, the patients with acute FP were diagnosed as BP, and treatment was started. All the patients had similar therapeutic corticosteroid protocols (oral prednisone mg/kg/day for 5 days with a 10 mg/day taper).

The exclusion criteria included patients younger than 18 years old, known etiologies of FP such as otitis media or mastoiditis, zoster infection, trauma, known central or peripheral neurologic disorders, autoimmune diseases, or tumors. Should have no contraindications to steroid therapy.

The institutional ethics committee of La Paz University Hospital approved the study protocol PI-4632 for data collection of routine and anonymized hospital data. All patients signed written informed consent.

Recorded clinical variables included age, sex, side of facial involvement, and history of previous FP.

## Facial Function

Facial nerve function was assessed using both the House–Brackmann (HB) and the Sunnybrook facial grading system (SFGS) grading scales 72 hours following the ED visit, 3, 6, and 12 weeks following the initial ED visit. All the evaluations following the ED visit were made by 4 senior doctors from the Otorhinolaryngology Department with high level of expertise in FP. An HB grade of I indicates normal facial function, whereas an HB grade of grade VI indicates total paralysis. The SFGS has been recently validated in Spanish.<sup>16</sup> This scale has 3 components, including resting symmetry (0–20), synkinesis (0–15), and voluntary movement (0–100). The total score is calculated by subtracting the resting symmetry and

synkinesis scores from the voluntary score. A score of 100 is normal, whereas 0 indicates paralysis.

Good outcome criterion was achieving a grade  $\leq$  II in the HB and/or  $>70$  in the SFGS<sup>17</sup> at the 12-week visit. Grade I in the HB and/or 100 in the SFGS at the 12-week visit was considered full recovery.

#### Microbiological Tests (Nasopharynx and Blood)

In all patients with BP, reverse transcriptase polymerase chain reaction (PCR) for SARS-CoV-2 (nasopharynx) and enzyme-linked immunosorbent assay-based SARS-CoV-2 IgG (total) test (blood) were measured.

#### Coronavirus Disease 2019 Vaccines

The vaccination status of the patients was recorded, with COVID-19 vaccines including Pfizer-BioNtech (BNT162B2), Moderna (1273 mRNA), Janssen (Ad26.COV2-S), and Oxford-AstraZeneca (ChAdOx1-S). The vaccination date and the time elapsed between vaccination and BP were recorded. BP cases related to vaccination were expected to occur within 30 days after the last (first, second, or third) vaccine dose, as reported by Shemer et al (2021).<sup>18</sup>

#### Statistical Analysis

Statistical analyses were done in the Statistical Package Social Science software version 24.0 (IBM SPSS Corp.; Armonk, NY, USA). Numeric variables were reported as mean and SD. Variables within categories were reported as percentages. The chi-squared or Fisher test was used for qualitative variables. All statistical tests were considered bilateral and received the same level of significance ( $P \leq .05$ ).

## RESULTS

#### Retrospective Study: Incidence of Facial Paralysis During Pandemic 2021–2022

A total of 162 patients with acute FP were identified in the ED database during the period from March 1, 2021, to March 31, 2022 (Table 1). The mean age was  $52 \pm 18$  years (19–91), with 54% of them being female. About 52% ( $n=84$ ) of them occurred within the sixth epidemic period (November 2021–March 2022). November and February were the months with more reported cases (Figure 1).

#### Retrospective Study: Incidence of Facial Paralysis before Pandemic 2018–2019

Table 2 shows the number of patients who attended the ED due to BP between August 2018 and August 2019. During this period, 196 patients were identified. The mean age was  $50 \pm 18$  years (18–95), with 56% of them being female. About 44% of them ( $n=86$ ) occurred between November and March. January and March were the months with more reported cases.

#### Prospective Study During Pandemic March 2021–March 2022

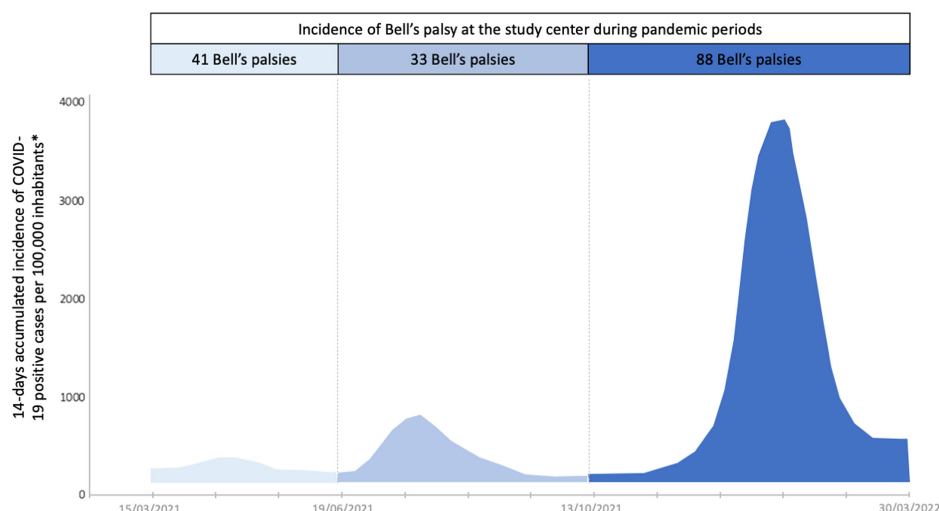
Forty-seven of the 162 patients (29%) with BP between March 2021 and March 2022 fulfilled the inclusion criteria and gave their consent to take part in the prospective study. There were 24 (51%) male and 23 (49%) female patients with a mean age of 52 years ( $SD=17$ , range 19–85).

#### Facial Function Outcome

The 47 patients who entered the prospective study underwent exploration of their facial function (Table 3). Three months following

**Table 1.** Clinical Findings of the 162 Patients Registered to the Emergency Department Between March 2021 and March 2022

Year	2021												2022		
	Month	March	April	May	June	July	August	September	October	November	December	January	February	March	
Number of patients ( $n=162$ )		12 (7%)	10 (6%)	11 (7%)	11 (7%)	7 (4%)	4 (2%)	14 (9%)	9 (6%)	18 (11%)	11 (7%)	16 (10%)	22 (14%)	17 (10%)	
COVID-19		Fourth epidemic period (27%)			Fifth epidemic period (21%)			Sixth epidemic period (52%)							



**Figure 1.** COVID-19 pandemic periods in Spain and incidence of BP in the study center. Fourth period: from March 15, 2021, to June 19, 2021. Fifth period: from June 20, 2021, to October 13, 2021. Sixth period: from October 14, 2021, to March 27, 2022. \*Modified from: Informe no 124. Situación de COVID-19 en España [Internet]. Informes covid-19. Red Nacional de Vigilancia Epidemiológica. Instituto de Salud Carlos III; 2022 [cited 2022Dec5]. Available from: <https://www.isciii.es/QueHacemos/Servicios/VigilanciaSaludPublicaRENAVE/EnfermedadesTransmisibles/Paginas/InformesCOVID-19.aspx>

the initial episode, 85% of the patients had HB grades I or II, while 92% had an SFGS score of 71–100.

### Laboratory Results

Of the 47 patients with BP who entered the prospective study, only 3 (6.5%) had a positive PCR during the initial episode. The 3 positive PCR patients had HB grades III, III, and V at the first evaluation (48 hours) and HB grades III, I, and II respectively, at the last evaluation. There was no association between positive PCR and facial function outcome (Fisher test,  $P = .378$ ). Thirty-five patients (77%) had positive IgG SARS-CoV-2. There was no association between positive IgG SARS-CoV-2 and facial function outcome (Fisher test,  $P = .692$ ).

### Vaccines

Of the 162 patients included in the retrospective study (BP between March 2021 and March 2022), 105 patients (67%) had received at least 1 dose of the COVID-19 vaccine prior to presenting BP (Table 4). In 23 of them (22%), the paralysis appeared within the first 30 days after a vaccine dose, with a mean time from vaccination to occurrence of palsy of  $14.7 \pm 8.9$  days. No statistical differences were found between vaccination groups.

## DISCUSSION

### Incidence of Facial Paralysis During the Pandemic

In this study, we did not find an increased incidence of BP cases during the pandemic period 2021–2022 when compared to a similar pre-pandemic period from 2018 to 2019. The literature shows diverse results about this issue. Zammit et al<sup>19</sup> compared their facial nerve palsies from January to June 2020 to those of the previous year and reported that the facial nerve palsy rate was 2.7% higher. Andina-Martinez et al<sup>20</sup> reported a substantial increase in hospital presentations for facial nerve palsy among children and adolescents during the first year of the pandemic. Tamaki et al<sup>6</sup> reported a total of 348088 patients with COVID-19 between January 1, 2020, and December 31, 2020, from 41 health care organizations worldwide. Of these patients, 284 (0.08%) were diagnosed with BP within 8 weeks of

the initial COVID-19 diagnosis, suggesting a higher incidence of BP in patients with COVID-19. Other studies have also reported an increase in the incidence of BP during the pandemic.<sup>7–9</sup> Conversely, Martin-Villares et al<sup>10</sup> did not find an increase in a population of over 530 000 people in Spain. Apart from being diverse, the increase or decrease of BP incidence in each study may be also affected by the current number of patients with BP coming to the hospitals during the pandemic, which may be different to that of other periods. Patients' fears during the pandemic may play a role in their delaying or even foregoing access to healthcare.<sup>9</sup> This may also explain the low percentage of patients (30%) participating in our prospective study. Therefore, it is still unclear if there was a clear increase of BP cases during the COVID-19 outbreak and if this could be related to the COVID-19 infection.

### Months with More Bell's Palsy Cases

In our study, BP cases identified during the pandemic occurred mainly during the period between November 2021 and March 2022, which corresponded to the sixth epidemic period in Spain. In the control group, a higher incidence during the autumn–winter months was also observed. An association between BP and low temperatures has been suggested. Lee et al<sup>21</sup> studied the epidemiological trends of BP in Korea between 2008 and 2018 and reported a higher incidence of cases between October and March. In this study, the monthly incidence was highest in January and lowest in June, suggesting an inverse correlation with the temperature. Codeluppi et al<sup>9</sup> reported a higher incidence of BP cases between February and May 2020 when compared to those months in 2021 (38 vs. 22). As COVID-19 cases are also higher during autumn and winter, it is unclear if the higher number of BP cases occurring in the coldest months is related to COVID-19 evolution.

### Patients with Positive Coronavirus Disease 2019 Polymerase Chain Reaction Among Patients with Bell's Palsy

In this study, of the 47 patients with BP who entered the prospective study, only 3 (6.5%) had a positive PCR during the initial episode. The 3 positive PCR patients had HB grades III, III, and V at the first evaluation (48 hours) and HB grades III, I, and II respectively, at the

Table 2. Distribution of Patients with BP Between August 1, 2018, and August 31, 2019

Year	Month	2019											
		August	September	October	November	December	January	February	March	April	May	June	July
	Number of patients (n = 196)	18 (9%)	14 (7%)	9 (5%)	17 (9%)	17 (9%)	20 (10%)	10 (5%)	22 (11%)	16 (8%)	12 (6%)	19 (10%)	14 (7%)
													8 (4%)

Table 3. House–Brackmann and Sunnybrook Facial Grading System Scores in the First and Last Visit

	House Brackmann			Sunnybrook		
Facial function	First Visit (48 hours)	Last Visit (12 weeks)		First visit (48 hours)	Last visit (12 weeks)	
	I	0	32 (68%)	100-91	0	36 (77%)
	II	6 (13%)	8 (17%)	71-90	11 (23%)	7 (15%)
	III	18 (38%)	6 (13%)	70-43	11 (23%)	3 (6%)
	IV	6 (13%)	0	26-43	8 (17%)	0
	V	8 (17%)	0	25-14	6 (13%)	0
	VI	9 (19%)	1 (2%)*	< 14	11 (23%)	1 (2%)

\*This patient continued follow-up after completing the study and showed recovery up to grade IV HB after 6 months from the onset of the paralysis and up to grade II-III HB after 9 months. She remains under follow-up.

last evaluation. There was no association between positive PCR and facial function outcomes. In recent years, several cases of FP have been reported in patients with COVID-19 infection. However, in most cases, microbiologic testing has not been able to confirm a direct link between SARS-CoV-2 infection and BP.<sup>20</sup> The low rate of detection of SARS-CoV-2 viral genome among BP patients has been previously reported by Martin-Villares et al.<sup>10</sup>

#### Outcome of Bell's Palsy With and Without Coronavirus Disease 2019

The spontaneous evolution of BP is towards an almost complete recovery in between 70% and 85% of cases.<sup>22,23</sup> It is unclear if the outcome of BP cases during the COVID-19 outbreak is different to that of the pre-pandemic era. In our prospective study, 85% of patients with BP during the period 2021-2022 had HB grades I or II 3 months following the initial episode, while 92% had an SFGS score of 71-100. Gupta et al,<sup>24</sup> in a systematic review about BP in the pandemic, reported that 71.7% of cases showed complete recovery, whereas 21.7% showed partial relief, whereas in another study with their own data, the percentages were 80% and 20%.<sup>25</sup> Although the probability of total recovery is variable in BP, it appears that COVID-19 has no clear deleterious effect on its outcome.

#### Association Between Coronavirus Disease 2019 and Bell's Palsy

As stated by Gupta et al,<sup>25</sup> "It is still a dilemma whether BP with COVID-19 is causal or casual." While the exact link between COVID-19 and BP is yet to be established, the potential role of the coronavirus injuring

Table 4. Vaccination Details of Patients with Bell's Palsy Between March 2021 and March 2022

Vaccination	Status n = 162	105 (67%) yes 37 (21%) no 20 (12%) unknown
	Vaccine (last dose before BP) n = 105	72 (68%) BNT162b2 mRNA Pfizer 24 (23%) 1273 mRNA Moderna 4 (4%) ChAdOx1-S Astra Zeneca 4 (4%) Ad26.COVS-2 Janssen 1 (2%) unknown
Time between vaccine and Bell's palsy	Days (mean ± SD) (range) n = 105	108 ± 85 (1-376) BNT162b2 mRNA 79 ± 60 (9-241) 1273 mRNA
		104 ± 57 (24-156) ChAdOx1-S 102 ± 79 (14-206) Ad26.COVS-2



the facial nerve and causing BP has been demonstrated. Different mechanisms include (i) ischemia of vasa nervorum and inflammation resulting in nerve demyelination; (ii) microvascular changes and microthrombi leading to facial nerve ischemia; and (iii) direct viral damage causing inflammation or an autoimmune disorder.<sup>26</sup>

A possible association with the multiinflammatory syndrome has also been suggested, with this entity being the consequence of hyperinflammatory responses after SARS-CoV-2 infection in genetically susceptible individuals.<sup>27</sup>

### Facial Paralysis and Coronavirus Disease 2019 Vaccination

In Spain, as in most countries in Europe, 3 COVID-19 vaccines have been widely used. Bell's palsy has been reported during the trials of these main COVID-19 vaccines, including Pfizer-BioNtech (4 cases, 0.0105%), Moderna (3 cases, 0.0098%), and Oxford-AstraZeneca, (3 cases, 0.025%).<sup>14</sup>

Of the 162 patients included in the retrospective study (BP between March 2021 and March 2022), 105 patients (67%) had received at least 1 dose of COVID-19 vaccine prior to presenting BP. In 23 of them (22%), the paralysis appeared within the first 30 days after a vaccine dose, with a mean time from vaccination to occurrence of palsy of  $14.7 \pm 8.9$  days. This finding rises a possible effect of the COVID-19 vaccines in the development of BP.

Although there has been no clear evidence of association between COVID-19 vaccination and facial paralysis so far, some studies have suggested a possible link, with the pathogenesis still being unclear. Both a decrease in protection due to a decrease in IgG positivity and the reactivation of a latent, dormant virus have been proposed as possible mechanisms.<sup>14</sup>

Tamaki et al<sup>6</sup> collected the data from queries made in April 2021 from 41 healthcare organizations. Around 348 088 patients with COVID-19 were identified, and 284 (0.08%) had BP within 8 weeks of the COVID-19 diagnosis. The authors matched patients with COVID-19 to vaccinated individuals ( $n=63\,551$ ), finding an increased relative risk of 6.8 (95% CI, 3.5–13.2,  $P < .001$ ) of presenting BP in those with COVID-19 compared with those who had received a vaccine. In a similar way, Eric Wan et al<sup>13</sup> found an increased risk of BP after immunization with CoronaVac, a vaccine that uses the inactivated virus. On the other hand, Shemer et al<sup>18</sup> conducted a case-control study including 37 cases of BP and 74 controls, in which no clear association between both was found. Even though a possible association between COVID-19 and BP is supported by the literature, the absolute risk of BP attributable to the vaccination is low. Therefore, it does not call into question its utmost importance in limiting the spread of COVID-19.

### Limitations

The incidence of BP cases during the pandemic period studied could have been higher, but patients might have avoided going to the hospital due to fear of COVID. The limited number of patients willing to participate in the prospective study may have been conditioned by the same reason.

Since FP assessments with HB and SB scales are subjective, this may introduce bias. This possibility has been minimized because the 4

senior doctors evaluating the patients have previously demonstrated strong intra- and inter-rater correlation while assessing FP.<sup>16</sup>

Coronavirus disease 2019 infection does not increase the incidence of BP. A direct association between the coronavirus and BP cannot be demonstrated, and whether it is a cause or consequence still remains unclear. The outcome of BP is not different in patients during the pandemic or with demonstrated COVID-19 infection. However, the significant number of patients developing BP within the first 30 days after a vaccine dose suggests a possible association between COVID-19 vaccination and BP.

Further investigation is needed to determine the precise mechanisms that may play a role in the development of BP in the context of COVID-19 infection and/or vaccination.

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Ethics Committee Approval: This study was approved by Ethics Committee of La Paz University Hospital (Approval No: PI-4632, Date: March 10, 2021).

**Informed Consent:** Informed consent was obtained from the patients who agreed to take part in the study.

**Peer-review:** Externally peer-reviewed.

**Author Contributions:** Concept – L.L., J.M.M.P.; Design – L.L., J.M.M.P., I.S.C.; Supervision – L.L., J.G.; Resources – C.O.H.C.G.; Materials – T.M.P., J.P., M.A.R.N., R.M.T.S.O.; Data Collection and/or Processing – I.S.C., T.M.P., J.P., J.M.M.P., C.O.H.C.G.; Analysis and/or Interpretation – L.L., J.M.M.P.; Literature Search – I.S.C., T.M.P., J.P., M.A.R.N., R.M.T.S.O., L.L., J.M.M.P.; Writing – L.L., J.M.M.P.; Critical Review – I.S.C., J.G.

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