Polymyalgia Rheumatica After COVID-19 Vaccination: Data from the EudraVigilance Database

Polimialgia Reumática Após Vacinação Contra COVID-19: Dados da Base EudraVigilance

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Palavras-chave: Farmacovigilância; Monitorização de Fármacos; Polimialgia Reumática; Vacinas Contra COVID-19; Sistemas de Notificação de Reações Adversas de Fármacos

Dear Editor,

Recently, the novel coronavirus (COVID-19) pandemic led to the rapid development of vaccines. Potential side effects have been notified on global pharmacovigilance databases, such as EudraVigilance, which contains reports of suspected adverse reaction (SAR) for drugs authorized in the European Union. These reports are generated by national competent authorities [such as Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED), the Portuguese medicines agency], marketing authorization holders, and sponsors of clinical trials. The Individual Case Safety Reports (ICSR) can be signaled by healthcare or non-healthcare professionals. Although incapable of establishing causality, the reporting of SAR can detect emerging safety signals concerning a specific drug, prompting further investigation.

Polymyalgia rheumatica (PMR) is an inflammatory disease characterized by pain and stiffness in the shoulder and pelvic girdle of older individuals. Although its cause remains unknown, environmental triggers, such as vaccination, might play a role.[1] It has been postulated that molecular mimicry and certain vaccine adjuvants might induce autoimmune syndromes after vaccination.[2] Indeed, reports of suspected cases of PMR following COVID-19 vaccination have been recently published.[3]

We aimed to identify suspected cases of PMR following COVID-19 vaccination, using data from the public version of EudraVigilance. We retrieved all ICSR signaled by healthcare professionals within the European Economic Area, containing a SAR of PMR between January 1, 2021, to May 1, 2023, attributed to COVID-19 vaccines approved by the European Medicines Agency. A detailed analysis of each ICSR was carried out to eliminate potential duplicates or cases of aggravated preexisting PMR. We performed a descriptive analysis of the available data, including sociodemographic variables, severity, and outcome of SAR.

During this period, of the 1 426 786 reports in EudraVigilance concerning SAR associated with COVID-19 vaccines, 433 (0.03%) included suspected PMR and met our inclusion criteria (Table 1). Most cases concerned women (n = 227; 52.4%) and individuals within an age range of 65 - 85 years (n = 273; 63.0%). mRNA vaccines were more frequently involved (n = 359; 82.9%) than viral vector-based vaccines. At least one criterion of seriousness was reported in 363 cases (83.8%), such as medically important conditions and hospitalization.

In conclusion, we found, through the use of the EudraVigilance database, a small number of PMR cases following COVID-19 vaccination, in comparison with the magnitude of other SAR. Although these findings are somewhat reassuring, COVID-19 vaccines will probably remain under close pharmacovigilance scrutiny over the next few years, and new potential adverse events might be encountered. The possibility of a causal effect between COVID-19 vaccines and the development of PMR is still poorly understood, requiring further data for clarification.

AUTHOR CONTRIBUTIONS

CPO: Study design, data collection and analysis, writing of the manuscript.

SFA, CV, ARP, AB: Study design, critical review of the manuscript.

All authors approved the final version to be published.

PROTECTION OF HUMANS AND ANIMALS

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the Helsinki Declaration of the World Medical Association updated in 2013.

DATA CONFIDENTIALITY

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

COMPETING INTERESTS

The authors have declared that no competing interests exist.

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Table 1 – Characteristics of individual case safety reports in the EudraVigilance database, containing a suspected adverse reaction of polymyalgia rheumatica from January 1, 2021 to May 1, 2023, attributed to COVID-19 vaccines approved by the European Medicines Agency.

Characteristic	n (%)
Year of Reporting	
- 2021	186 (43.0)
- 2022	203 (46.9)
- 2023[a]	44 (10.2)
COVID-19 vaccine type	
- mRNA vaccine	359 (82.9)
- Viral vector vaccine	74 (17.1)
Sex	
- Female	227 (52.4)
- Male	203 (46.9)
- Not specified	3 (0.7)
Age range	
- 18 to 64 years	119 (27.5)
- 65 to 85 years	273 (63.0)
- Older than 85 years	26 (6.0)
- Not specified	15 (3.5)
Suspected adverse reaction considered serious	363 (83.8)
Seriousness criteria[b]	
- Resulting in medically important conditions	259 (59.8)
- Requiring or prolonging hospitalization	80 (18.5)
- Resulting in disability/incapacity	42 (9.7)
- Resulting in death	1 (0.2)
Reaction outcome at time of report	
- Not recovered	194 (44.8)
- Recovering	154 (35.6)
- Recovered	29 (6.7)
- Recovered with sequelae	11 (2.5)
- Fatal	1 (0.2)
- Unknown	44 (10.2)
Suspected drug	
- Only COVID-19 vaccine	421 (97.2)
- Other suspected drug	12 (2.8)

[a]: Until May 1, 2023
[b]: Each case might meet more than one criterion

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