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LETTER TO THE EDITOR

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ADVERSE REACTIONS OF COVID-19 VACCINATION: WHERE DO THEY COME FROM?

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To the Editor,

Vaccination against SARS-CoV-2 is one of the most important elements to fight against the global pandemic of this virus. Implementation of the first vaccines against SARS-CoV-2 has been a breakthrough that may change the course of the pandemic. Concurrently, the first reports regarding the adverse reactions of vaccines have become available, raising concerns about the risk-to-benefit ratio.

In the study which investigated the efficacy and safety of the mRNA-1273 SARS-CoV-2 vaccine (Moderna) in 30.420 volunteers, the most frequent adverse effects in the study group included pain at the injection site (83.7% in the vaccine group vs. 17.5% in the placebo group), fatigue (37.2% vs. 27.3%), headache (32.7 vs 26.6%), myalgia (22.7% vs. 13.7%), arthralgia (16.6% vs. 11.8%), axillary swelling or tenderness (10.2% vs 4.8%), chills (8.3% vs. 5.8%), nausea and vomiting (8.3% vs. 7.1%), swelling (6.1% vs 0.3%), erythema (2.8% vs. 0.4%) and fever (0.8% vs 0.3%) [1]. At the median of 9 weeks after the second vaccine dose, serious adverse reactions were reported by 1% of the recipients in the vaccine group and 1% in the placebo group. These reactions included one Bell's palsy and two facial oedemas in patients previously undergoing aesthetic medicine interventions, suggesting allergic background. There were no neurologic, thrombotic and inflammatory reactions.

Similarly, in the study evaluating the BNT162b2 vaccine (Pfizer) among 43.548 participants, the most commonly reported reaction was mild-to-moderate pain at the injection site. Pain was reported less frequently among older participants (> 55 years of age; 71% and 66% after the first and second dose, respectively) than among younger participants (83% and 78% after the first dose and second dose, respectively) [2]. The most commonly reported systemic events were fatigue and headache (59% and 52% after subsequent doses among younger recipients; 51% and 39% among older recipients). However, fatigue and headache were also reported by many placebo recipients (23% and 24%, after subsequent doses in younger participants; 17% and 14% among older recipients). Severe systemic events were reported in less than 2% of vaccine recipients after either dose. Fever defined as temperature ≥ 38°C was reported by 16% of younger vaccine recipients and by 11% of older recipients, with the temperature mostly below 39°C [3].

The Centres for Disease Control and Prevention (CDC) reported that there have been 21 cases of anaphylaxis after the BNT162b2 vaccine between 14 and 23 December 2020 (11.1 cases per 1 million doses), with 71% of them occurring within 15 min-

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utes following the vaccination [3]. Twenty of these patients (95%) were successfully rescued and only 1 patient died. The probable cause of anaphylaxis was polyethylene glycol (PEG), also called macrogol, which is an excipient and lipid facilitating the transport of mRNA-containing nanoparticles into cells and allowing for the synthesis of spike-protein — an antigen triggering immunity to SARS-CoV-2 [4]. PEG is an ingredient of multiple tablets, cosmetics and household products. Patients oversensitive to PEG usually had repeated systemic allergic reactions/anaphylaxis before diagnosis. Also, 81% of patients who experienced anaphylaxis after SARS-CoV-2 vaccine had known history of allergic reactions to medical products, supporting the hypothesis of allergic background underlying anaphylaxis.

Altogether, nearly 90% of patients experience any adverse reaction, compared to as much as 50% in the placebo group. The vast majority of these reactions are mild and resolve within 2 to 3 days. Serious adverse events are rare, and their incidence is similar in the vaccine and placebo group. The hitherto reported cases of anaphylaxis seem to results from oversensitivity to the excipients of the vaccine, rather than the vaccine itself. To summarize, the available evidence clearly shows that the benefits from vaccination substantially overweight the risks of COVID-19 disease, especially in the high-risk populations. Nevertheless, special caution should be taken in patients with established allergy to PEG, or a history of allergic reactions to other medications. Further research is required to evaluate the long-term efficacy and safety of the currently available COVID-19 vaccines.

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REFERENCES

1. Baden LR, El Sahly HM, Essink B, et al. COVE Study Group. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. N Engl J Med. 2021; 384(5): 403–416, doi: 10.1056/NEJMoa2035389, indexed in Pubmed: 33378609.
2. Polack FP, Thomas SJ, Kitchin N, et al. C4591001 Clinical Trial Group. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med. 2020; 383(27): 2603–2615, doi: 10.1056/NEJMoa2034577, indexed in Pubmed: 33301246.
3. CDC COVID-19 Response Team, Food and Drug Administration. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine - United States, December 21, 2020-January 10, 2021. MMWR Morb Mortal Wkly Rep. 2021; 70(4): 125–129, doi: 10.15585/mmwr.mm7004e1, indexed in Pubmed: 33507892.
4. Garvey LH, Nasser S. Anaphylaxis to the first COVID-19 vaccine: is polyethylene glycol (PEG) the culprit? Br J Anaesth. 2021; 126(3): e106–e108, doi: 10.1016/j.bja.2020.12.020, indexed in Pubmed: 33386124.