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Safety and Side Effects of COVID-19 Vaccines

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Abstract

Introduction: COVID-19 is a respiratory disease caused by the SARS-CoV-2 virus. The types of COVID-19 vaccines have been distinguished, ie vector viral vaccines, mRNA, subunit vaccines. These include traditional approaches - inactivated, live-attenuated and protein / adjuvant-based, as well as novel, as yet unlicensed - viral vectors and nucleic acids. There are scientific publications showing the safety and possible side effects of vaccines from various companies.

Purpose of the work : Analysis of the safety of COVID-19 vaccines on the basis of scientific publications published on the PubMed scientific platform. Publications have been published in the last 12 months. The safety and adverse effects of vaccines were assessed in the course of clinical trials.

Results: Among the main side effects so far were mild / moderate pain at the injection site, redness, hives and rash. Allergic reactions to vaccines are - apart from pronounced local reactions (> 10 cm) at the injection site - very rare and are usually caused by the vaccine's

allergy to the components of the vaccine. In addition, there may be swelling or tenderness of the lymph nodes in the armpit, headache, pain in the muscles and joints, nausea and vomiting.

Conclusions: Regardless of the concern, these vaccines are characterized by similar mild, systemic side effects, which indicates the similarity in the safety of these vaccines. Severe adverse reactions occur in extreme cases. More patients only experienced side effects after the second dose.

Key words: vaccines; coronavirus; COVID-19; safety of COVID-19 vaccines; side effects

Introduction:

Coronaviruses are virus species belonging to the subfamily Coronavirinae of the family Coronaviridae, in the order Nidovirales. The Coronavirinae subfamily is divided into four types: alpha, beta, gamma, and deltacoronaviruses. These are single-stranded enveloped viruses with positive (+) ssRNA sensitivity and helical symmetry. The name "coronavirus" comes from Latin as "corona" means a crown or a wreath. In electron microscopy, the virus envelopes appear "crowned". The virus strain was first identified in 1962. in the form of symptoms of a classic cold. Then, a slightly more dangerous mutation was identified in 2002 in the Chinese province of Guangdong. It caused Severe Acute Respiratory Syndrome (SARS), which gave the virus the name SARS-CoV. At that time, it caused a wave of cases, during which 775 deaths were confirmed. In November 2019, a respiratory disease - COVID-19 was diagnosed in central China (Wuhan city, Hubei province). It is an acute infectious disease caused by another mutation of the SARS-CoV-2 virus. The course of the disease is not the same, hence the course of the disease may vary in every patient. Even in 81% of patients it may be asymptomatic or mild. However, in 14% it can be harsh, and in 5% even critical. The most common symptoms are fever, dry cough and tiredness. Less common symptoms include pain in the muscles, throat, diarrhea, conjunctivitis, headache, loss of taste or smell, and skin rash or discoloration of the fingers and toes. You may experience serious

symptoms such as difficulty breathing or shortness of breath. chest pain or pressure, and even loss of speech or movement. Infection occurs via droplets.

Three types of vaccines against COVID-19 have been distinguished, ie viral vector vaccines, mRNA, "subunit" vaccines. These include traditional approaches - inactivated, live-attenuated and protein / adjuvant-based, as well as novel, as yet unlicensed - viral vectors and nucleic acids.¹An mRNA vaccine is a vaccine that 'teaches' cells in the body how to make a protein (or even a fragment of it) that triggers an immune response. During it, antibodies are produced that protect against infection if the virus enters the human body. These vaccines contain fragment of the genetic material of the SARS-CoV-2 virus. T and memory B lymphocytes are produced.²³⁴

Discussion:

The BIONTECH / PFIZER vaccine is an mRNA vaccine. After administration of the vaccine, vaccinated persons experienced local reactions such as pain, erythema and swelling, and systemic reactions such as fever, headache, and muscle aches were also noticed. An increased frequency of reactions was noted after the second dose of the vaccine.⁵ Most symptoms were mild to moderate and disappeared quickly.⁶ Its main side effects are fatigue, headache, muscle

¹Ahn DG, Shin HJ, Kim MH, Lee S, Kim HS, Myoung J, Kim BT, Kim SJ. Current Status of Epidemiology, Diagnosis, Therapeutics, and Vaccines for Novel Coronavirus Disease 2019 (COVID-19). *J Microbiol Biotechnol.* 2020 Mar 28; 30 (3): 313-324. doi: 10.4014 / jmb.2003.03011. PMID: 32238757.

²Haynes BF, Corey L, Fernandes P, Gilbert PB, Hotez PJ, Rao S, Santos MR, Schuitemaker H, Watson M, Arvin A. Prospects for a safe COVID-19 vaccine. *Sci Transl Med.* 2020 Nov 4; 12 (568): eabe0948. doi: 10.1126 / scitranslmed.abe0948. Epub 2020 Oct 19. PMID: 33077678.

³Haynes BF, Corey L, Fernandes P, Gilbert PB, Hotez PJ, Rao S, Santos MR, Schuitemaker H, Watson M, Arvin A. Prospects for a safe COVID-19 vaccine. *Sci Transl Med.* 2020 Nov 4; 12 (568): eabe0948. doi: 10.1126 / scitranslmed.abe0948. Epub 2020 Oct 19. PMID: 33077678.

⁴Ovsyannikova IG, Haralambieva IH, Crooke SN, Poland GA, Kennedy RB. The role of host genetics in the immune response to SARS-CoV-2 and COVID-19 susceptibility and severity. *Immunol Rev.* 2020 Jul; 296 (1): 205-219. doi: 10.1111 / imr.12897. Epub 2020 Jul 13. PMID: 32658335; PMCID: PMC7404857.

⁵Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, Perez JL, Pérez Marc G, Moreira ED, Zerbini C, Bailey R, Swanson KA, Roychoudhury S, Koury K, Li P, Kalina WV, Cooper D, Frenck RW Jr, Hammitt LL, Türeci Ö, Nell H, Schaefer A, Ünal S, Tresnan DB, Mather S, Dormitzer PR, Şahin U, Jansen KU, Gruber WC; C4591001 Clinical Trial Group. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. *N Engl J Med.* 2020 Dec 31; 383 (27): 2603-2615. doi: 10.1056 / NEJMoa2034577. Epub 2020 Dec 10. PMID: 33301246; PMCID: PMC7745181.

⁶Walsh EE, Frenck RW Jr, Falsey AR, Kitchin N, Absalon J, Gurtman A, Lockhart S, Neuzil K, Mulligan MJ, Bailey R, Swanson KA, Li P, Koury K, Kalina W, Cooper D, Fontes-Garfias C , Shi PY, Türeci Ö, Tompkins KR, Lyke KE, Raabe V, Dormitzer PR, Jansen KU, Şahin U, Gruber WC. Safety and Immunogenicity of Two RNA-Based Covid-19 Vaccine Candidates. *N Engl J Med.* 2020 Dec 17; 383 (25): 2439-2450. doi: 10.1056 / NEJMoa2027906. Epub 2020 Oct 14. PMID: 33053279; PMCID: PMC7583697.

pain, injection site pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, malaise, swollen lymph nodes (lymphadenopathy).⁷

Moderna / NDIAD brand vaccine is also an mRNA vaccine. Most vaccine reactions were mild to moderate and resolved within 1-3 days. Pain and swelling at the injection site, fatigue, chills, fever, swollen or tender lymph nodes in the armpit, headache, muscle and joint pain, nausea and vomiting have been reported in more than 1 in 10 people. Redness, hives and rash at the injection site, and rash have been reported in less than 1 in 10 people. Consecutively, less than 1 in 100 people developed itching at the injection site. In contrast, less than 1 in 1,000 people have reported facial swelling, which can occur in people who have received facial cosmetic injections in the past, and weakness in the muscles on one side of the face (acute peripheral facial palsy or infantile palsy).⁸

Unlike the two companies mentioned above, Astra Zeneca vaccine is a vector vaccine. The vaccine was good safety in all studies. 168 participants experienced serious side effects, 79 of whom received ChAdOx1 nCoV-19 and 89 of them received MenACWY or a placebo. More than 1 in 10 people experienced symptoms such as tenderness, pain, warmth, redness, itching, swelling or bruising at the injection site, generally feeling unwell, feeling tired (tiredness), chills or fever, headache, feeling sick (nausea) joint pain or muscle pain. Consecutively, less than 1 in 10 people had a lump at the injection site, fever, vomiting, and flu-like symptoms such as high fever, sore throat, runny nose, cough and chills. In contrast, less than 1 in 1,000 people experienced dizziness,⁹

⁷Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, Perez JL, Pérez Marc G, Moreira ED, Zerbini C, Bailey R, Swanson KA, Roychoudhury S, Koury K, Li P, Kalina WV, Cooper D, Frenck RW Jr, Hammitt LL, Türeci Ö, Nell H, Schaefer A, Ünal S, Tresnan DB, Mather S, Dormitzer PR, Şahin U, Jansen KU, Gruber WC; C4591001 Clinical Trial Group. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. *N Engl J Med.* 2020 Dec 31; 383 (27): 2603-2615. doi: 10.1056 / NEJMoa2034577. Epub 2020 Dec 10. PMID: 33301246; PMCID: PMC7745181.

⁸Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R, Diemert D, Spector SA, Rouphael N, Creech CB, McGettigan J, Khetan S, Segall N, Solis J, Brosz A, Fierro C, Schwartz H, Neuzil K, Corey L, Gilbert P, Janes H, Follmann D, Marovich M, Mascola J, Polakowski L, Ledgerwood J, Graham BS, Bennett H, Pajon R, Knightly C, Leav B, Deng W, Zhou H, Han S, Ivarsson M, Miller J, Zaks T; COVE Study Group. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. *N Engl J Med.* 2021 Feb 4; 384 (5): 403-416. doi: 10.1056 / NEJMoa2035389. Epub 2020 Dec 30. PMID: 33378609; PMCID: PMC7787219.

⁹Hill AVS, Lambe T, Gilbert SC, Pollard AJ; Oxford COVID Vaccine Trial Group. Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomized controlled trials in Brazil, South Africa, and the UK. *Lancet.* 2021 Jan 9; 397 (10269): 99-111. doi: 10.1016 / S0140-6736 (20) 32661-1. Epub 2020 Dec 8. Erratum in: *Lancet.* 2021 Jan 9; 397 (10269): 98. PMID: 33306989; PMCID: PMC7723445.

Conclusions:

Currently, COVID-19 vaccines have been released on the market under the patronage of many pharmaceutical companies. However, irrespective of the concern, these vaccines have similar mild side effects to the system, which indicates the similarity in the safety of the vaccines. In addition, severe adverse reactions are rare, and most patients only experienced side effects after taking the second dose. Swollen or tender lymph nodes in the armpit, headache, muscle and joint pain, nausea and vomiting may occur. Possible adverse reactions after vaccination include - apart from the very rare anaphylaxis - increased local reactions, worsening of symptoms of an existing allergic disease, e.g. asthma, rhinoconjunctivitis or atopic eczema,

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