some patients, dysfunctional immune response plays a crucial role during the second stage of the disease.

Expert opinion: The pharmacological treatment is considered as a key part of management strategies and needs to be tailored according to the stage and disease severity. Numerous pharmacotherapeutics have been introduced into the clinical practice despite low level of evidence from well-designed clinical studies or systematic reviews/meta-analyses. The strongest recommendations assume the use of new antiviral drugs (i. e. remdesivir), systemic corticosteroids, neutralizing antibodies targeted to the viral S-protein. In patients with systemic hyperinflammation the indication of anti-IL6 monoclonal antibodies, JAK/STAT inhibitors and anakinra may be justified. To achieve a more efficient immune response, multiple methods could be applied, including regulation of the immune response, augmentation of the immune system against the virus, inhibition of the dysfunctional immune response, and inhibition of the viral replication/infection.

Conclusion: Pharmacological research represents a major challenge and unmet need for the entire scientific and clinical community, as it has the potential to get through the ongoing pandemic.

Analysis of Reported Adverse Events Following Covid 19 Vaccination in the Slovak Republic

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Introduction: The COVID-19 pandemic has resulted in more than 4.5 million deaths worldwide. Vaccination against the SARS-CoV-2 virus is the only way out of the pandemic, however, reaches only 39 % in the Slovak Republic. Concerns about side effects (ADRs) of vaccines are the one of the reasons for low vaccination rate.

Objective: The aim of this presentation is to analyse reported suspicions of adverse reactions of registered COVID-19 vaccines (Comirnaty, Vaxzevria, Spikevax), which State Institute for Drug Control received from healthcare professionals and patients in the time period from 1st January 2021 to 31st May 2021.

Methods: The program R, language and environment for statistical calculations, version 3. 6. 3, R Foundation for Statistical Computing, Vienna, Austria, GNU GPL license was used for data analysis.

Results: During the evaluation period, 5763 reported suspicions of ADRs were analysed, overall there was a significant ($p < 0.0001$) increase in the number of reported ADRs fivefold. 93 % of ADRs (n = 5346) were reported for COVID-19 vaccines. No statistically significant difference ($p \leq 0.238$) was identified between Spikevax and Comirnaty in the proportion of serious ADRs. However, a significantly higher ($p \leq 0.00001$) proportion of reported suspicions of severe NU was observed with Vaxzevria. There is a statistically significant difference in the ratio of serious ADRs between the sexes for all COVID-19 vaccines ($p < 0.00001$); in woman this ratio is in all cases statistically significantly higher than in men ($p < 0.0001$), whereas the most often were ADRs reported by patients ($p < 0.0001$), of which up to 66 % were women.

Conclusion: In the Slovak Republic, the rate of spontaneous reporting of suspected ARDs has been low for a long time; in the period January – May 2021 rate increased as a result of active calls for ADRs reporting, patients reported the most often. According to European data, Vaxzevria has a significantly higher ratio of reported suspicions of serious ADRs. For all vaccines, the incidence of severe NUs is statistically significantly higher in women.

Analýza nežiaducich účinkov hlásených po vakcinácii COVID-19 vakcínami v Slovenskej republike

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Úvod: Pandémia ochorenia COVID-19 si celosvetovo vyžiadala viac ako 4,5 milióna úmrtí. Jediným východiskom z pandémie je vakcinácia proti vírusu SARS-CoV-2, ktorá však v SR dosahuje iba 39 %. Jedným z dôvodov nízkej zaočkovanosti je aj obava z nežiaducich účinkov (NÚ) vakcín.

Cieľ: Cieľom práce je analýza hlásených podozrení na NÚ v tom čase registrovaných COVID-vakcín (Comirnaty, Vaxzevria, Spikevax), ktoré Štátny ústav pre kontrolu liečiv prijal od zdravotníckych pracovníkov a pacientov v období od 1. 1. 2021 do 31. 5. 2021.

Metodika: Pre vyhodnotenie súboru bol použitý program R, jazyk a prostredie pre štatistické výpočty, verzia 3. 6. 3, R Foundation for Statistical Computing, Viedeň, Rakúsko, licencia GNU GPL.

Výsledky: Za dané obdobie sa analyzovalo 5763 hlásených podozrení na NÚ, celkovo došlo k signifikantnému ($p < 0,0001$) nárastu počtu hlásených NÚ päťnásobne. Z celkového počtu hlásení sa 93 % (n = 5346) týkalo COVID-vakcín. V zastúpení závažných NÚ nebol medzi vakcínami Spikevax a Comirnaty identifikovaný štatisticky významný rozdiel ($p \leq 0,238$). Signifikantne vyšší ($p \leq 0,00001$) podiel hlásených podozrení na závažné NÚ bol ale zaznamenaný pri vakcíne Vaxzevria. V zastúpení závažných NÚ medzi pohlaviami je pri všetkých COVID-vakcínach signifikantný rozdiel ($p < 0,00001$), u žien je tento podiel vo všetkých prípadoch štatisticky významne vyšší, než u mužov ($p < 0,0001$), pričom signifikantne najčastejšie hlásili NÚ pacienti ($p < 0,0001$), z toho až 66 % tvorili ženy.

Záver: V SR je miera spontánneho hlásenia podozrení na NÚ dlhodobo nízka. Za obdobie 1–5/2021 sa zvýšila v dôsledku aktívneho vyzývania na hlásenie NÚ, ktoré najčastejšie hlásili pacienti. V súlade s európskymi dátami má signifikantne vyšší podiel hlásených podozrení na závažné NÚ Vaxzevria. Pri všetkých vakcínach je výskyt závažných NÚ štatisticky významne vyšší u žien.