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COVID 19 and vaccine safety

COVID-19 i bezpieczeństwo szczepionek

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Abstract

Introduction. COVID-19 disease, caused by the SARS-CoV-2 virus, has been recognised as a pandemic by WHO since 11 March 2020. It has been estimated that the disease is responsible for the death of 3.11 million people worldwide. Although several therapeutic agents have been evaluated for the treatment of COVID-19 disease, vaccines are considered to be the safest form of protecting patients against COVID-19.

Objective. The aim of this review was to present the literature data and the latest recommendations on risks related with COVID-19 vaccines.The latest literature was reviewed based on PubMed and Google Scholar databases, using the following keywords: COVID-19; vaccines; safety

Brief description of the state of knowledge. The safety of each vaccine is vital for controllling the pandemic. Due to the fact that vaccines have been launched quite recently and their production technologies are different, the safety of each preparation should be looked into separately. Nucleic acids do not trigger such a strong immune response on their own as viral vectors, chich is why mRNA vaccines seem to be the safest types of vaccines. In December 2020, a year after detection of the first case of by SARS-CoV-2 infection in humans, the first anti-COVID-19 vaccine became available.

Conclusions. Anti-COVID-19 vaccines do not seem to cause many adverse events and side-effects, such as fever, chills, muscle pain, headache and fatigue. These are not serious and subside after taking over-the-counter pain relievers. Currently, there is no information on the safety and efficacy of vaccines in pregnant and breast-feeding women; international expert recommendations leave the decision about vaccination with the woman, who should previously consult with her doctor about the benefits and risks involved.

Key words

COVID-19, vaccines, safety

Streszczenie

Wprowadzenie i cel pracy. 11 marca 2020 roku choroba COVID-19, wywoływana przez wirusa SARS-CoV-2, została uznana przez WHO za pandemię. Szacuje się, że jest ona przyczyną śmierci 3,11 mln ludzi na całym świecie. Chociaż oceniano kilka środków terapeutycznych pod kątem leczenia COVID-19, szczepionki są uważane za najbezpieczniejszą formę ochrony pacjentów przed tą chorobą.

Celem tego przeglądu było przedstawienie danych literaturowych i najnowszych zaleceń dotyczących zagrożeń związanych ze szczepionkami przeciw COVID-19. Najnowsza literatura została zweryfikowana na podstawie baz danych PubMed i Google Scholar, przy użyciu następujących słów kluczowych: COVID-19, szczepionki, bezpieczeństwo.

Opis stanu wiedzy. Bezpieczeństwo każdej szczepionki ma kluczowe znaczenie dla opanowania pandemii. Z uwagi na to, że szczepionki pojawiły się całkiem niedawno, a technologie ich produkcji są różne, bezpieczeństwo każdego preparatu należy rozpatrywać osobno. Kwasy nukleinowe nie wywołują tak silnej odpowiedzi immunologicznej jak wektory wirusowe, dlatego najbezpieczniejsze wydają się szczepionki mRNA. W grudniu 2020 roku, po roku od wykrycia pierwszego przypadku zakażenia SARS-CoV-2 u ludzi, pojawiła się pierwsza szczepionka przeciwko COVID-19.

Podsumowanie. Wydaje się, że szczepionki przeciw COVID-19 nie powodują wielu działań niepożądanych i skutków ubocznych, takich jak gorączka, dreszcze, bóle mięśni, bóle głowy i zmęczenie. Jeśli takie działania występują, nie są one poważne i ustępują po zażyciu dostępnych bez recepty leków przeciwbólowych. Obecnie brak informacji na temat bezpieczeństwa i skuteczności szczepionek u kobiet w ciąży i karmiących piersią, międzynarodowe zalecenia ekspertów pozostawiają decyzję o szczepieniu kobiecie, która wcześniej powinna skonsultować korzyści i zagrożenia z lekarzem.

Słowa kluczowe

COVID-19, bezpieczeństwo, szczepionki

INTRODUCTION

Numerous research has made it possible to recognise a genome and the structure and virus replication cycle, as well as immune response to the infection. The studies are aimed at preventing the further spread of COVID-19 and designing and launching effective and safe vaccines and medicines. Although several therapeutic agents have been evaluated for the treatment of coronavirus disease (COVID-19), so far no antiviral agents have been shown to be efficacious [1]. Treatment schedules for remdesivir, hydroxychloroquine, lopinavir and interferon have had negligible or no influence on hospitalized patients with COVID-19, which was indicated by general mortality and the length of hospital treatment [2]. Another drug which has been tested is amantadine. The *in vitro* research results published

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in June 2020 suggest that amantadine, while reducing L gene expression, may disrupt the replication of SARS-CoV2 [3]. Due to the controversial effectiveness of amantadine in the treatment of COVID-19 disease and its numerous side-effects, it is necessary to perform further clinical tests since the efficacy of this medication is still uncertain.

Vaccines are regarded as the safest form of protecting patients against the COVID-19 disease because they stimulate cell-mediated immunity and humoral immunity. Vaccines imitate contact with the real infectious agent, activate B cells and antibody production. A immunological memory is then created in order to effectively fight a pathogen in the case of a repeated contact [4]. Due to a similar structure of peripheral membrane protein (S) of different pathogenic strains of viruses from the Coronaviridae family, there is a possibility that recovering from a disease caused by one strain may, to some extent, protect against SARS-CoV-2 (Severe acute respiratory syndrome coronavirus 2) infection. It seems that this is analogous to vaccinations. Studies have confirmed the effect of vaccines against new strains of the virus recently discovered in South Africa and the United Kingdom, but their effectiveness is lower [5]. In December 2020, about a year after the first case of SARS-CoV-2 infection in humans was detected, the first available vaccine against COVID-19 was introduced [6]. Currently, the following products are available in Poland: Comirnaty (Pfizer-BioNtech), Moderna, Vaxzevria (AstraZeneca) and Vaccine Janssen (Johnson & Johnson) [7].

OBJECTIVE

A constantly growing number of new infections with the SARS-CoV-2 virus and the related widespread anxiety among society prompt us to try to organize information on the risk of COVID-19 vaccines. The purpose of this review is to present the literature data and the latest recommendations on risks related to COVID-19 vaccines. The latest literature was reviewed based on PubMed and Google Scholar databases, using the following keywords: COVID-19, vaccines, safety.

STATE OF KNOWLEDGE

The mRNA vaccines encode an antigen that induces an adaptive immune response. The transfected cells enable expression of the transgene and biosynthesis of specific viral proteins. By endocytosis, the antigen enters antigen-presenting cells, which present it to T-CD4+ and T-CD8+ lymphocytes on their surface [8]. The expression of mRNA is temporary. As a result of the function of cells enzymes, mRNA is rapidly degraded. In human cells, the process of mRNA translation takes place in ribosomes, therefore, there is no danger of causing mutations or integrating it with the host DNA. As nucleic acids do not trigger such a strong immune response on their own as viral vectors, a subsequent dose of the vaccine is necessary. The advantage of vaccines is that they can be produced easily and quickly. Also, the nucleic acid sequence can be easily changed. This is particularly important whenever there is a need to modify the mRNA sequence in case of a mutation of the viral S protein, or when resistance to a new strain of existing vaccines occurs. It is estimated that it may take about six weeks to develop a vaccine based on a new mRNA sequence. The disadvantage of mRNA-based vaccines is the need of proper stabilisation of mRNA molecule [8, 9]. On 21 December 2020, by a decision of the European Medicines Agency (EMA), the Comirnaty vaccine (BNT162b2), developed by BioNTech and Pfizer, was authorised in the European Union. On 6 January 2021, the COVID-19 Vaccine (mRNA-1273), developed by Moderna Inc. received EMA approval for use in European Union member states.

The mRNA vaccines from Pfizer-BioNTech and Moderna were the first to record the results of the third phase of the study. Preliminary results suggested an efficacy at a level above 90% [10]. In the United States, vaccine safety was monitored by the Vaccine Adverse Event Reporting System (VAERS). In the period from 14 December – 13 January 2021, 13,794,904 doses of the Pfizer-BioNTech and Moderna vaccines were administered. VAERS received 6,994 (0.05%) post-vaccination adverse event reports, of which 6,354 were classified as minor, and 640 (0.005%) as serious. The symptoms most commonly reported to VAERS were headaches (22.4%), fatigue (16.5%) and dizziness (16.5%). The available information from death certificates, autopsy reports, medical records and clinical descriptions from VAERS reports, did not indicate any causal relationship between COVID-19 vaccination and death [11].

In research published in *The New England Journal of Medicine,* 21,720 participants were vaccinated with BNT162b2 and 21,728 received a placebo. The aim of the study was to evaluate the safety and efficacy of two doses of BNT162b2 administered intramuscularly over 21 days, compared to the control group. More BNT162b2 recipients (27%) than placebo recipients (12%) reported any adverse events. The most reported systemic symptoms were fatigue and headache. After the second dose of the vaccine, 52% of the younger vaccinated and 39% of the older vaccinated persons reported these symptoms. Fatigue and headache were also reported by 24% of the younger and 14% of the older placebo recipients. Of 21,720 persons vaccinated with BNT162b2, only four had serious adverse events. Two recipients of BNT162b2 and four recipients of the placebo died. The researchers concluded that these deaths were not related to the vaccine. No deaths related to COVID-19 were observed. The two-dose BNT162b2 scheme was found to be safe and 95% effective against COVID-19 [12].

According to another study published in *The New England Journal of Medicine*, 195 participants were randomly assigned to 13 groups of 15 people each. In each group, 12 participants received the vaccine and three received a placebo. Patients reported mild to moderate systemic events, mainly pain at the injection site. Local reactions were more frequent after the second dose. No serious adverse events were reported. The greatest changes in laboratory values were transient decreases of lymphocyte count that retreated within a week after vaccination. [13]

The results of studies [12, 13] seem to confirm similar side-effects (Systemic Events, Local Reactions) in the case of taking two doses BNT162b2 (Table. 1).

The study by Walsh et al. showed good tolerance of the BNT162b2 vaccine in cancer patients [14]. One dose of 30 ug of BNT162b2 resulted in poor vaccine efficacy, but the second dose significantly improved resistance to COVID-19.

In an article published by *The Lancet* it was shown that people with previous SARS-CoV-2 infection generated

Table 1. In the study [12], the elderly were over 55, and in the study [12] the age range of older people was 65–85

People vaccinated with 2 doses of BNT162b2	Systemic Events: Fatigue		Systemic Events: Fever		Local Reactions: Pain in the injecton site		Serious Adverse Events
	young people	older people	y.p.	o.p.	y.p.	o.p.	
21 720[12]	52%	39%	16%	11%	78%	66%	4
156[13]	75%	42%	17%	8%	83%	67%	0

strong humoral and cellular responses to a single dose of the BNT162b2 vaccine. Contrary to the above, most people who had not been previously infected, generated a weak T-cell response and low levels of neutralizing antibodies. The administration of one dose of the vaccine in people who had had an episode of COVID-19 was considered safe [15].

The research by Nicola Cirillo reported adverse effects in the oral cavity and orofacial area after the administration of the BNT162b2 vaccine and mRNA-1273 [16]. These symptoms were very rare and included peripheral facial nerve paralysis (Bell's palsy), facial swelling, and anaphylaxis-related swelling of the lips, face or tongue. Among 73,799 volunteers (36,901 who received at least one dose of the vaccine) participating in the third phase of two large studies, there were eight cases of Bell's palsy (seven in a group of those vaccinated and one in the placebo group). Both BNT162b2 and mRNA-1273 vaccines were found to be associated with adverse drug reaction (ADR) in the oral cavity and face, but the risk of its occurrence is very low [16].

Vector vaccines are based on non-pathogenic, genetically modified viruses lacking the genes that enable them to replicate. Information encoding the viral antigens (against which this vaccine should work) are pasted into the genome of viral vectors [8]. The advantages of these vaccines include efficient gene transduction and thus protein expression. The vector vaccine stimulates both mechanisms of innate and adaptive immunity – controlled by B and T lymphocytes. The disadvantage of this type of vaccine is the possibility of acquiring immunity to the vector in the case of prior contact with the virus used as a vector [17]. On 29 January 2021, by the decision of the EMA, the COVID-19 Vaccine AstraZeneca (ChAdOx1 – S) was approved for use in EU member states. It is a monovalent vaccine that contains the recombinant replication-defective chimpanzee adenovirus (ChAdOx1), which encodes the S protein of the SARS-CoV-2 virus. On 11 March 2021, by decision of the EMA, the COVID-19 Vaccine Janssen containing recombinant, replication-defective adenovirus Ad29 was approved for use in EU member states.

Between 23 April – 21 May 2020, 1,077 participants were enrolled and assigned to receive the ChAdOx1 vaccine. Systemic events and local reactions, such as pain, fever, chills, muscle aches, headache and malaise (aa $p<0{\cdot}05$), were reduced by the use of paracetamol. There were no serious adverse events related to ChAdOx1. ChAdOx1 vaccine showed an acceptable safety profile and increased antibody responses [18]. An article published in *The Lancet* described the safety and immunogenicity of the same vaccine in a wider range of participants, including adults aged 70 and older [19]. The safety profile of ChAdOx1 was compared to vaccine against ACWY meningococci. Systemic events and local reactions were more common among people vaccinated with ChAdOx1 than a control vaccine, and were similar to those previously reported (injection site pain, fever, muscle pain, headache). These reactions were also less common in older adults (≥ 56 years of age) than in younger ones. In people receiving the second standard dose of ChAdOxq, local reactions occurred in 43 (88%) out of 49 participants in the 18–55 age group and 32 (65%) in 70-year-olds and older. During the period of study there were reported 13 serious adverse events, but none of them were related to the vaccine. ChAdOx1 appears to be better tolerated in older than in younger adults, but has a similar immunogenicity in all age groups after a booster dose.

Some countries, including Denmark and Norway, have decided to temporarily suspend administering AstraZeneka vaccine because of reports of thrombosis. A few cases of unusual thrombotic events and thrombocytopenia have emerged. More data about the pathogenesis of this bleeding disorder is needed. On 7 April, the EMA announced that blood clots are very rare side-effects of the AstraZeneka vaccine [20]. According to the EMA, the benefits of receiving the vaccine outweigh the risk. In the research published in the *New England Journal of Medicine,* the cause of thromboembolic episodes after receiving Oxford-AstraZeneca vaccine (16 patients in total) was indicated [21, 22]. The mechanism of these incidents is very similar to that connected with heparin-induced thrombocytopenia. All cases can be associated with the received vaccine, but they are extremely rare (about 1 in 100,000). For comparison, the use of hormonal contraception in women increases the risk of thromboembolic episodes more than the vaccine described above (100–500 in 100,000) [23]. The vaccine presents a positive safety profile, which means that the benefits of receiving this medication are greater than the risk of side-effects.

The *New England Journal of Medicine* published the results of the third phase of Ad26.CoV2.S (Johnson & Johnson) vaccine clinical test [24]. The efficacy results were very promising (study group of 39,321 people: 19,630 received the vaccine and 19,691 received a placebo). Studies showed that 28 days after vaccination,the preparation provided protection against the severe/critical course of COVID-19. Three non-COVID-19 related deaths were recorded in the vaccinated group and 16 deaths in the placebo group, of which five were related to COVID-19. The side-effects following vaccination were no different from those caused by the other COVID-19 vaccines. Post-vaccination symptoms were mild to moderate in intensity and were transient. There were no serious adverse events.

The vaccination of pregnant women is under consideration in the 'discussion' section of this review. This topic mainly concerns the mRNA vaccines (Pfizer-BioNTech; Moderna) due to their greater safety profile. The American College of Obstetricians and Gynaecologists (ACOG) recommends not to refuse COVID-19 vaccines to pregnant women who choose to be vaccinated. On the other hand, the British Fertility Society recommends vaccines only when a pregnant woman is at risk because of possible infection at work, or health

problems. Unless there is an increased risk connected with COVID-19, it is recommended that vaccination should be postponed until after pregnancy. Due to the fact that pregnant women were excluded from the initial third phase of clinical studies of COVID-19 vaccines, limited data is available on their efficacy and safety during pregnancy. However, there is no reason to expect that mRNA vaccines will work in a different way in pregnant women than in other adults [25]. The pregnancy period and lactation are not mentioned in the contraindications listed in the summary of product characteristics of the registered mRNA vaccines against COVID-19. International recommendations of experts, incl. the CDC (Centers for Disease Control and Prevention) and ACIP (Advisory Committee on Immunization Practices) leave the decision about vaccination to a woman following the risk-benefit analysis and the degree of exposure to SARS-CoV-2 infection discussed with a physician. The priority groups are healthcare workers and premature babies' mothers staying in hospitals. Animal studies do not show harmful effects on pregnancy, foetal development, parturition or postnatal development [26, 27].

Numerous studies have confirmed passive immunisation of a child by a nursing mother. In one study, researchers tested the milk of 10 mothers vaccinated against COVID-19 (6 – Pfizer-BioNTech; 4 – Moderna) two weeks after the second dose of the vaccine. They observed the presence of a significant titre of anti-SARS-CoV-2 antibodies in the IgG class in the breast milk. The results of other researchers were similar [28]. A small Israeli study detected that antibodies present in the milk of women vaccinated against COVID-19 show neutralising activity against SARS-CoV-2. This data does not guarantee that every child fed with the milk of a mother vaccinated against COVID-19 will be protected; however, the results of the research described above may indicate such an effect [29].

DISCUSSION

Since the invention of the first vaccine by Edward Jenner in 1796, vaccines have played a key role in fighting many viral diseases. Nowadays, a rapid implementation of SARS-CoV-2 vaccines is a global priority in healthcare. Successful results of the third phase studies have been described in the context of vaccines that elicit strong humoral and cellular immune responses against SARS-CoV-2 virus.

In the 25-year-old age group, the risk of serious side-effects from vaccination against COVID-19 with Oxford-AstraZeneca preparation is 11 in a million. Compared to this, the risk of death from SARS-CoV-2 infection is 23 in a million [23]. In the 55-year-old age group, the risk of serious side-effects from vaccination against COVID-19 with Oxford-AstraZeneca preparation is four in a million [23]. The risk of death from SARS-CoV-2 infection in this group is 800 in a million. In 21,720 people vaccinated with Pfizer-BioNtech BNT162b2 vaccine, only four serious adverse events have been reported [12]. The benefits of vaccination outweigh the risks and this fact should not be questioned.

Scientists claim that they know enough about the influence of vaccines on breast milk and we should not be concerned about it. The only uncertainty that should be taken into consideration is the fact that breastfeeding patients were not included in clinical tests. However, the knowledge about mRNA technology and vaccine mechanism allows us to conclude that there is no relationship between the use of these substances and lactation. The mRNA molecules that constitute the base of COVID-19 mRNA vaccines are removed from the body extremely quickly; therefore, there is no possibility of their transfer to breast milk [30, 31].

If a breastfeeding woman has no contraindications for receiving an mRNA vaccine against COVID-19, she can be vaccinated. If she additionally lives in an area where the risk of SARS-CoV-2 infection is high and/or there is a risk of a severe course of COVID-19, she should be vaccinated. It seems that children systematically fed with the breast milk of mothers vaccinated against COVID-19 with mRNA preparations have sufficient passive immunity against SARS-CoV-2 infection. Many pregnant women have chosen to be vaccinated. By monitoring the results in these mothers and their children, it will soon be possible to develop evidence-based recommendations regarding the potential wider vaccination of pregnant women.

Pfizer-BioNTech and Moderna have begun clinical tests concerning dosage, safety and efficacy of their preparations among children from the age of six months. Currently, the Pfizer-BioNTech vaccine is available form the age of 16, while Moderna from the age of 18. Among the currently licensed or under development vaccines against COVID-19, the Oxford-AstraZeneca preparation has been chosen by many countries because of its low cost and ease of storage, compared to other vaccines.

CONCLUSIONS

COVID-19 vaccines do not appear to show serious adverse events. Isolated cases can be qualified as casuistry. Side-effects after vaccination (fever, chills, muscle pain, headache and malaise) occur in up to 88% of subjects depending on the type of vaccine and the age group. The symptoms are not serious and disappear after taking over-the-counter pain relievers.

Monitoring the safety of patients will be continued for two years after administration of the second dose of vaccine [12, 13]. This way will enable an answer the question whether the vaccinations have adverse events about which we are not aware at this time.

Currently, there is no information available about the safety and efficacy of vaccines in pregnant and lactating women. Due to the above, international experts recommend leaving the decision about vaccination with the woman, after consulting with her physician about the benefits, risks and degree of exposure to SARS-CoV-2 infection.

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