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SHORT REVIEW

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Analysis of adverse effects caused by mRNA vaccines used in the fight against COVID-19

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Introduction

With the death of more than three million people around the world, the need to develop effective vaccines capable of controlling the virus that caused the pandemic of COVID-19 was realized to ensure the safety of the population through the immunity developed [1].To start the process, scientists released the genetic sequence of the virus in January 2020, thus, researchers used new platforms of vaccine technology in order to develop an effective vaccine against the pathology, however, the first vaccine started clinical trials in humans in March 2020, being considered one of the fastest vaccine development programs in history [2,3].

Several production technologies have been evaluated, among them: viral vaccines (inactivated or attenuated), nucleic acids (DNA and RNA), protein vaccines (recombinant or VLP) and those that use viral vectors (replicating or non-replicating) [4]. However, the vaccines studied for COVID-19 aim to induce neutralizing antibodies against viral subunits, containing, most of them, as a target, the RBD region preventing the virus uptake by the human ACE2 receptor [5].

To produce a vaccine it is necessary to follow the phases of clinical study, in general, animal models, to evaluate the dose and the level of toxicity in this population. However, clinical trials in humans need to go through three stages, namely: safety of the product; evaluation of immunogenicity, dose and frequency of administration; and the efficacy of the product involving volunteers. After going through this process, involving the publication of scientific data involved in the research, the vaccine in question is submitted for evaluation by regulatory agencies, so that it can then be produced and distributed to the population. Finally, post-approval studies aim to analyze the possible effects and adverse events after the application of the vaccine in large quantities in the target population [6]. However, this entire process is estimated to take months to years, but the development of the COVID-19 vaccine was performed within a period of approximately 18 months, which calls into question its efficacy and safety [7].

Among all the aforementioned types of vaccines, those that most caused adverse effects were the mRNA vaccines, and their benefit was questioned by studies on their safety and efficacy that were carried out in thousands of volunteers, showing a 95% rate for the BNT162b2 mRNA vaccine [8], and a 94% rate for the mRNA-1273 SARS-CoV-2 vaccine 9. The mRNA vaccines, Pfizer and Moderna, showed adverse events after the second dose, especially after researchers were alerted to evidence of a relevant number of people who developed heart diseases, such as myocarditis and pericarditis; however, these data are reports from other countries, since these vaccines have only recently arrived in Brazil [9].

However, the Vaccine Adverse Event Reporting System (VAERS) has reported the development of myocarditis after doses administered to persons under 30 years of age. In addition, the mRNA vaccine has been authorized for use in children between 12 and 15 years of age, but there have been no reports in this age group. In a comparative study, among the cases of myocarditis after vaccination, a higher prevalence was noted in males between 18 and 30 years of age. Another system that tracks adverse events in hospitals, the Vaccine Safety Datalink, noted that inflammation was more likely after the second dose of vaccine, thus, reported in a case of seven adolescents who developed myocarditis 4 days after the second dose [10].

Furthermore, there were patients who developed

other cardiovascular diseases after infection with the virus that causes COVID-19 besides myocarditis, such as arrhythmia, heart failure, AMI, cardiac arrest, and cases of myocardial lesions with increased troponin I [11,12,13] were found. However, regarding adverse events caused after COVID-19 vaccination of vaccines using mRNA, there were no reports of cardiovascular diseases other than myocarditis, which was prevalent, and pericarditis. However, mRNA vaccines, such as Pfizer and Moderna, have included cardiopathies during their studies, reporting such efficacy for the group under discussion. The effects caused were local and less common in the elderly, and during the vaccine evaluation period, they noted that cardiovascular effects had a frequency of less than 0.1% [14,15,16].

Thus, this review study aimed to analyze the efficacy of mRNA vaccines and their adverse events.

Methods

This is a Systematic Literature Review, with a search conducted through the electronic platforms Pubmed, Scielo, Google Acadêmico, and LILACS (Latin American and Caribbean Literature on Health Sciences), between the years 2020 and 2021. The descriptors "Vaccine", "mRNA", "COVID-19", and "Coronavirus" were used, associated with the Boolean operator "AND" as the only crossing strategy. A total of 143 articles were found and 14 were selected. Among the inclusion criteria were texts available in full, without language restriction, with publication date from 2020 to 2021. Texts not corresponding to the delimited period, duplicates and articles that did not address the thematic proposal were excluded.

Results and Discussion

More than 12 million doses were administered to 16- to 24-year-olds; among these, 275 people developed myocarditis after vaccination in this age group; in addition, 475 cases were in people younger than 30 years of age. The vaccines that caused this event are mRNA, Pfizer and Moderna. In addition, Pfizer has been authorized for application in children between 12 and 15 years of age, but data for this age group are not yet available. The incidence of myocarditis after vaccination was 50 cases per million for men aged 18 to 30 years [16]. Another system that tracks adverse events in hospitals, the Vaccine Safety Datalink, showed no reports of heart inflammation above the numbers typically seen in the population, but it did show that inflammation was more likely after a second dose of vaccine. This condition appeared to be more common in young people and male individuals than in women and the elderly, and may occur in 16 people out of every 1 million who received both doses of the vaccine [17]. The individuals who presented myocarditis achieved a quick recovery, considering that three of them needed to be admitted to the Intensive Care Unit, among those cases analyzed, 81% showed improvement of the condition and 19% had symptoms until the moment. Another study revealed seven cases of myocarditis reported in a hospital in Oregon, USA, involving male patients belonging to the age group of 14 to 19 years old; this case developed approximately four days after the application of mRNA vaccine; furthermore, there was no evidence of infection in the acute phase by SARS-coV-2; however, after treatment, all were discharged from the hospital and none required ICU admission [9].

Conclusion

The vaccines under analysis were 95% effective; however, they showed adverse events after the second dose, such as myocarditis. Thus, there was an increase in reports of myocarditis in male patients and young people who received mRNA vaccine, which cast doubts on the safety and efficacy of these vaccines. However, there are still few reports of myocarditis after vaccination because some countries do not report or publish the data and other countries do not apply the vaccines in question for the time being. However, it is necessary to have the agencies responsible for notifying these adverse effects to have available data that can prove or disprove the relationship of the application of these vaccines with the development of pathologies after COVID-19 vaccination.

Keywords: Vaccine. COVID-19. mRNA. Adverse Events.

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Data sharing statement

No additional data are available.

Conflict of interest

The authors declare no conflict of interest.

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