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Safety and Efficacy of Treatments for COVID-19: A Pharmacovigilance Perspective

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ABSTRACT

Objective: COVID-19 has generated the development of safe and effective against viral disease. In this context, the Pharmacovigilance emerges as a crucial tool to provide detailed follow-up of treatments administered to infected patients. The objective of this review is to understand the role and progress of pharmacovigilance in the COVID-19 pandemic by supporting healthcare professionals and providing information about possible Adverse Drug Reactions in patients.

Methods: A review of Pharmacovigilance related to COVID-19 was conducted, addressing aspects such as the monitoring of Adverse Drug Reactions, virus structure and therapeutic advances, since 2019 to 2022, databases such as Pubmed, Scielo, Science Direct, JAMA y Redalyc were used, analyzing clinical trials, observational studies and case reports to assess the safety of drugs used in the treatments of COVID-19.

Results: Pharmacovigilance provides information of risk and benefits of drugs. Reports have been implemented to detect Adverse Drug Reactions and seek pharmacological alternatives to reduce serius symptoms and complications.

Conclusion: Pharmacovigilance in the COVID-19 pandemic requires efficient communication between healthcare professionals and pharmacists ensuring quality treatments and detecting possible Adverse Drug Reactions.

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Introduction

Since the beginning of the pandemic caused by the SARS-CoV-2 virus, Pharmacovigilance has emerged as an essential tool to carry out detailed clinical and pharmaceutical surveillance focused on health of patients affected by this virus. The fundamental purpose of this comprehensive analysis is to obtain a clear and complete view of patients' health, taking into account the diversity of treatments used. The review seeks to evaluate whether there is an improvement in health or, on the contrary, there is the presence of adverse effects associated with the use of the drugs used and the risks inherent to such treatments. In parallel, a timely analysis of the most promising therapeutic approaches that have emerged during the course of the pandemic will be carried out.

The assessment aims to determine the safety of these therapeutic treatments based of the available information. The information gathered through clinical trials, observational studies and case reports will be carefully analyzed, providing healthcare professionals and decision-makers with a solid basis for the selection of more appropriate treatments for the context of the management of patients with COVID-19.

Materials and Methods

Data collection was by reviewing scientific articles, clinical trials and previous cases related to the disease caused by SARS-CoV-2 virus. Data from Pharmacovigilance reports were included, since 2019 to 2022 in search engines such as Pubmed, Scielo, Science Direct, JAMA and Redalyc.

The articles focused on Pharmacovigilance in context of COVID-19, addressing aspects related to Adverse Drug Reactions (ADRs), including treatment with antivirals, immunomodulators, corticosteroids, monoclonal antibodies, hormone therapy, antigouts, antiplatelets and anticoagulants The main objective was to identify sources that provide information of the most frequent ADR´s in patients classified by type of drug and severity of the disease. Available data were examined, allowing an understanding of the relationship between pharmacological treatments and ADR's in clinical settings.

Pharmacovigilance: The Importance of Clinical and Pharmaceutical Surveillance of Healthcare Systems

Pharmacovigilance has its beginnings 169 years ago, when a pediatric patient in the north of England died after receiving chloroform anesthesia, leading to the creation of the first "Pharmacovigilance" commission in England. This commission documented about 107 cases of ADR's, including deaths formed Sulfanilamide elixir and the Thalidomide experiment. In 1938, in the USA, the Federal Food, Drug and Cosmetic Act was established, introducing premarket drug evaluation requirements.

Pharmacovigilance as a Pharmaceutical Science was developed approximately 45 years ago as a global initiative to detect risks associated with the medicines. The term "Pharmacovigilance" was coined in 1970's by a scientific group in the south of France. The Uppsala Monitoring Center in Sweden and the International Drug Monitoring Program are pioneers in the monitoring and reporting of adverse reactions.

Nowadays, Pharmacovigilance plays a crucial role in management and an analysis of information on Adverse Drug Reactions (ADR's). Its main objective is to reduce risk and increase benefits of treatments, making it AN essential science for the patient's safety.

Mexico in the Eyes of the Pharmacovigilance

In 1989, in Mexico, Pharmacovigilance began with the Voluntary Reporting of Program for Suspected Adverse Drug Reactions (ADR's). Ten years later in 1999, the country joined the International Drug Monitoring Program in Sweden, the impulse of the World Health Organization (WHO), which has urges to strengthen pharmaceutical surveillance to detect and prevent the risk for ADR´s [1]. Although the role of the Pharmacist professional in drug monitoring isn´t fully recognized in Mexico, the WHO has promoted the participation of these professionals. In 2012, a Pharmacist in northeast of the country drafted the First Manual of Procedures for the Reception, Evaluation and Notification of Adverse Events, along with the first version of the rule NOM-220 Standard for the Installation and Operating of Pharmacovigilance [2]. Pharmacovigilance in Mexico, as a young discipline, has gained importance due to the need to monitor drugs in a growing population exposed to health changes. In addition to the Federal Commission for Protection Against Health Risks (COFEPRIS), the National Pharmacovigilance Centre Center for Pharmacovigilance and the Permanent Pharmacovigilance Program as have been established as essential structures for reporting adverse events and problems related to the safety drugs, vaccines and medical devices [3]. This discipline has become a crucial basis for data collection and response to new health and medication needs, especially in situations of health emergencies and emerging diseases.

As a tool to support Pharmacovigilance, COFEPRIS, with the support of the Ministry of Health, has established the Adverse Drug Reactions Report, which provides information on the aspects shows in Table 1 [4].

Table 1: Data Needed to Report Adverse Drug Reactions

Description of what happened	Medicament		Additional information
• Reaction or symptom	• Medication name	Administration Start and End Date	Previous or current illnesses
• Reaction Onset Date	• Pharmaceutical Company	Duration of administration	Additional Comments
•End Date	• Lot Number	Indication for administration	
•Duration of reaction/ discomfort	• Concentration Dose	Action taken	
•Current Status	•Route of administration		

The development of this tool makes it possible to constantly update the treatments administered to patients with COVID-19 that have been positive or detrimental to their health [4].

The News Challenges of Pharmacovigilance as A Response to Its Clinical and Pharmaceutical Importance

Pharmacovigilance is the science focused on the detection, identification, evaluation and prevention of risks derived from medicines. It focuses four key points

- Plan, develop, and establish: timely surveillance programs and structures focused on the patient, treatment and risk-benefit.
- Assess, organize, and analyze data: countering clinical signs and symptoms against suspected negative events attributable to medication [5].
- Exchange regulatory information: as a coordinated strategy international regulatory measures, motivated by the contrast of information and the enrichment monitoring programs.
- Promote the good practices to safe use of medicines: through timely, clear, and pleasant language that responds to requests for information to prevent, educate, and assist patients' safety needs with their medical treatment [6].

Pharmacovigilance plays a key role in improving medical care, patient safety and treatment efficacy. In addition to preventing unexpected risks, it contributes to the reduction of expenses related Adverse Drug Reactions [7]. Pharmaceutical professionals in the area face challenges such as emerging situations and lack of data on developing pathologies, requiring accurate research and information technologies to detect adverse reactions and improve population health [8].

To ensure the functioning of Pharmacovigilance systems, it is essential to understand and effectively manage each area of competence. Collaboration among healthcare professionals, including doctor, pharmacists and researchers, is essential to obtain a comprehensive view of the risks associated with medications [9]. Fostering a culture of open and transparent communication among professionals facilitates early detection of adverse reactions, knowledge sharing and timely implementation of preventive and corrective measures.

Clinical approaches and Pharmaceutical Challenges in the Face of the Sars-COV-2 Emergency

In late 2019, the SARS-CoV-2 virus causing COVID-19 was identified in Wuhan China. This triggered a global alert and the WHO declared health emergency. In Mexico, the first case was recorded in February 2020, prompting measures such as the closure of no-essential activities and the used face mask. In March 2020, in State of Mexico, the first case and death were reported.

Despite the National Vaccination Plan, patients in serious condition continued to receive supportive treatments in search of more effective therapeutic options in order to improve their health.

Sars-COV-2: An Overview from the Clinical and Epidemiological Search that Triggers the Emergency

From the clinical significance of human coronavirus, SARS-CoV-2 is estimated to have originated with the particularity of being zoonotic betacoronavirus widely related to bat coronavirus, which is stipulated to have been the source of infection and contagion directly or indirectly [10]. Morphologically, it is an alphavirus with a spherical or irregular structure with a diameter of approximately 125mm, whose genome consists mainly of single chains of Ribonucleic Acid (RNA) with positive polarity, length approximately 30,000 ribonucleotides, helical symmetry capsid and whose genome is shaped like a rosary as shown in Figure 1

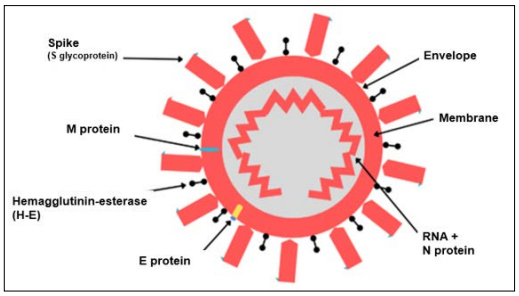


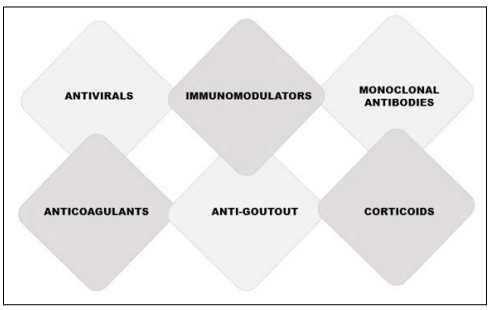
Image 1: SARS-CoV-2 structure

Structurally, the virus consists of a biphospholipid nucleocapsid, on its surface, it has structural proteins in the form "S", membrane proteins "M" and envelope protein "E". The "S" protein allows the virus to bind to ACE-2 receptors present in organs such as lungs, heart, kidneys, stomach, bladder and intestines [11]. The clinical picture can vary, some patients are usually asymptomatic facilitating the spread of virus. The most common symptoms include fever, dry cough, sore throat, headache, nasal congestion, fatigue and weakness. In severe cases, respiratory distress, shortness of breath, cyanosis, and hypoxia may develop. Three years into the COVID-19 pandemic, six types of clinical manifestations with symptoms variability have been identified. Diagnostic is made by taking biological samples from the respiratory tract, such as sputum or nasopharyngeal swab, analyzed with molecular, serological or antigen detection assays [12]. The groups at greatest risk are adults over 60 years of age, especially those with pathological conditions such as obesity, diabetes or immunocompromised system, who have higher mortality and morbidity [13]. Recent studies indicate that the young adult's population (19-30 years) are the next in morbidity-mortality rates, while children are considered to be suspected of being active carriers of virus [14].

Pharmacological Therapy and Challenges of Health Emergency

COVID-19 disease is transmitted through biological droplets and has an incubation period of two to 14 days. Initially, there was no specific treatment for SARS-CoV-2 and more than 200 drugs were being investigated to combat it. The search for pharmacological alternatives has focused on reducing the several symptoms and complications associate with disease. More than two years after the onset of the COVID-19 pandemic, significant progress has been made in the development of evidence-based therapies. These therapies fall into categories encompassing anti-inflammatory agents, antivirals, antithrombotic, respiratory therapies, neutralizing test therapies and modulators of the renin-angiotensin-aldosterone system [15].

In general terms, the drugs currently used for COVID-19 are classified into different categories according to their function, as show in the following scheme.



Scheme 1: Therapeutic approaches in COVID-19

In a context of pharmaceutical challenges, where health emergencies are constantly surprising, pharmaceutical professionals have faced, since the beginning of the COVID-19 pandemic, the challenge of seeking quality in drug therapy. This includes the detection of possible Adverse Drug Reactions (ADR's), with the objective of providing a health panorama that optimizes therapeutic benefits and serves as a tool to prepare the health, pharmaceutical, technological and organizational sectors for future health emergencies with effective and efficient responses.

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