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المجلة العلمية لنشر البحوث
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‘Complications of COVID-19 Vaccines on Diabetic Patient in Saudi Arabia’’

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Abstract

COVID-19 increases the risk of serious infection and mortality in diabetic patients. Considering the limited efficacy of pharmacological treatments currently available, vaccination remains one of the most effective strategies of pandemic control. The main aim of this study was to evaluate the side effects and perceptions of COVID-19 vaccinations among diabetes patients in Saudi Arabia post vaccination. The objectives of this study were evaluated using a quantitative research approach and a cross-sectional study design. The study was conducted on adult's diabetic patients 18 years and older who had received one or both COVID-19 vaccination doses. The self-reported questionnaire used in this study was adapted from prior studies and frameworks used to assess vaccine adverse effects after vaccination. This study identified the most common side effects of the COVID-19 vaccine in Saudi Arabia, rendering them predictable. As booster doses become available, this information will assist lessen vaccine apprehension.

Key Words: COVID-19, Vaccines, Diabetes, Saudi Arabia, Patient, Chronic Disease.

الملخص

من خطر الإصابة بعدوى خطيرة والوفاة لدى مرضى السكري. بالنظر إلى الفعالية المحدودة للعلاجات الدوائية المتاحة حاليًا، يظل COVID-19 يزيد التطعيم أحد أكثر الاستراتيجيات فعالية لمكافحة الجائحة. كان الهدف الرئيسي من هذه الدراسة هو تقييم الآثار الجانبية وتصورات لقاحات COVID-19 بين مرضى السكري في المملكة العربية السعودية بعد التطعيم. تم تقييم أهداف هذه الدراسة باستخدام نهج البحث الكمي وتصميم دراسة مقطعية. أجريت الدراسة على مرضى السكري البالغين الذين يبلغون من العمر 18 عامًا فما فوق والذين تلقوا جرعة واحدة أو جرعتين من لقاح COVID-19. تم تكييف الاستبيان المبلغ عنه ذاتيًا والمستخدم في هذه الدراسة من الدراسات والأطر السابقة المستخدمة لتقييم الآثار الضارة للقاح بعد التطعيم. حددت هذه الدراسة الآثار الجانبية الأكثر شيوعًا للقاح COVID-19 في المملكة العربية السعودية، مما يجعلها متوقعة. عندما تصبح الجرعات المنشطة متاحة، ستساعد هذه المعلومات في تقليل مخاوف اللقاح.

الكلمات المفتاحية: كوفيد -19، لقاحات، سكري، السعودية، مريض، مرض مزمن.

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Introduction

The outbreak of coronavirus disease 2019 (COVID-19) in December 2019 has caused an ongoing global disaster with devastating effects on the global community, as well as the lives and health of individuals, their livelihoods, economies, and their behaviors. As of 23 July 2021, there were over 192 million cases of COVID-19 worldwide, resulting in 4.14 million deaths. However, not all persons are impacted by COVID-19 in the same way (Kumar, Malla & Dubey, 2020).

The arrival of the COVID-19 pandemic had lasting effects on the health, economy, and social life of people worldwide. Several vaccinations have been developed to lower morbidity and death as a result of the pandemic, which has resulted in a global epidemic of disease (Roberton et al., 2020). In addition, the most recent estimates show that over 20 million years of life have been lost to COVID-19 to date, and despite the introduction of vaccines in many countries throughout the world, millions of new cases of COVID-19 are still being documented each week.

People with a preexisting chronic disease, such as cardiovascular disease, hypertension, diabetes, cancer, respiratory disorder, or kidney disease, have an increased risk of developing severe consequences and, consequently, a higher risk of death from COVID-19 infection. Patients with cardiovascular illness and diabetes, for instance, had a 2.5–3.9-fold increased risk of infection (Amin-Chowdhury et al., 2021). In addition, cancer patients are more susceptible to infection due to the immunosuppression caused by chemotherapy and radiation therapy.

Vaccination against any disease is crucial for the improvement and maintenance of public health. Vaccines can restrict the spread of infectious illnesses; nevertheless, a vaccine's overall effectiveness is mainly dependent on the population's willingness to accept it. A global assessment regarding the possible acceptance of COVID-19 vaccines revealed different acceptance rates among nations, ranging from over 90% in China to 55% in Russia (Sallam, 2021). In Australia, 80% of respondents held generally favorable attitudes concerning COVID19 immunisation, whereas in Chile, 91% of the sampled population were willing to be vaccinated. In contrast, a study conducted in the Kingdom of Saudi Arabia (KSA) revealed that only 48 percent of the public was willing to get the COVID-19 vaccine.

In the latter quarter of 2020, the vast majority of nations began implementing COVID19 vaccination programmes. As a result, it became crucial to assess people's willingness to receive the COVID-19 immunizations. Even in industrialized nations, knowledge concerning people's willingness to receive the COVID-19 vaccine was quite limited. Often, perceptions and attitudes regarding the advantages and hazards of vaccination are predicated on the safety and effectiveness of vaccinations. COVID-19 vaccinations have been the subject of numerous rumors since their development. Infertility, reports of blood clots, multiple cases of mortality, immunological thrombocytopenia, internal bleeding, low platelet counts, and cerebral venous thrombosis have been associated to COVID-19 vaccines by these rumors. These adverse effects have greatly impacted immunisation initiatives in numerous nations.

According to the World Health Organization, there have been 742,541 confirmed cases of COVID-19 and 8,991 documented deaths in the KSA as of February 26, 2022 (Al-Hanawi et al., 2022). Public health officials in the KSA have implemented a number of COVID-19 guidelines and preventative measures, such as social separation, mask use, and hand sanitizer use. Nonetheless, vaccination is one of the most efficient means of preventing the spread of COVID-19 and minimizing its effects. Multiple countries, including China, the United States, Italy, and Saudi Arabia, have examined the acceptance of the vaccine and the associated beliefs and barriers, revealing that certain negative perceptions, beliefs, and attitudes prevent certain segments of the population from receiving the COVID-19 vaccine.

Since the commencement of the current epidemic, more than five million deaths and around 395 million confirmed cases of COVID-19 have been reported worldwide. In addition to immunisation, preventative measures are the most effective strategy to reduce its spread and/or admissions (WHO, 2022). Currently available vaccinations include RNA/DNA vaccines, viral vector vaccines, protein-based vaccines, and inactivated virus vaccines with different safety and efficacy. However, a high acceptability and uptake rate of the vaccine is necessary for the effectiveness of COVID-19 immunisation in the population. The COVID19 vaccination is strongly recommended for those with preexisting chronic conditions since they are susceptible to developing severe consequences and are therefore at a higher risk of death from a COVID-19 infection. Diabetes mellitus (DM) is a chronic disease associated with severe illness, hospitalizations to the intensive care unit, and increased mortality in COVID-19-infected patients. Moreover, diabetes and hypertension frequently co-occur.

Under light of the fact that viable pharmacological treatments for COVID-19 are still in development, immunisation has become an essential component for managing the COVID-19 pandemic. As numerous types of vaccines have

demonstrated efficacy and are now available for clinical use, it is crucial that diabetic people receive vaccinations to prevent a severe, devastating COVID-19 infection. Pfizer-BioNtech was the first COVID-19 vaccine to be licensed by the Saudi Food and Drug Authority (SFDA) and subsequently released in Saudi Arabia on 10 December 2020. This was followed by the approval and launch of the Oxford-AstraZeneca and Moderna vaccines in Saudi Arabia on 18 February 2021 and 11 July 2021, respectively (Tourkmani et al., 2022). As a result, three vaccines are currently available in Saudi Arabia, and additional efforts are made to expeditiously urge vaccination of all eligible individuals. On 17 December 2020, the countrywide vaccination program for COVID-19 was initiated.

Clearly, COVID-19 and diabetic mellitus (DM) have a profound impact on global health, particularly in Saudi Arabia. From the beginning of the COVID-19 pandemic, it has been reported that people with diabetes had a higher vulnerability to the infection and a higher death risk from this condition. Moreover, in earlier infectious illness epidemics (SARS and MERS), a high glucose concentration has been demonstrated to be an independent predictor of mortality and morbidity; this is likely to be the case for COVID-19 (Robert, Al Saeed & Al Dawish, 2021).

Given the high national prevalence of diabetes in Saudi Arabia, these individuals form a sizable vulnerable sector of the COVID-19. Saudi Arabia has recorded 506,125 cases (486,918 recovered) and 8035 confirmed deaths as of July 15, 2021. The growing rate of diabetic patients in Saudi Arabia, coupled with the presence of COVID-19, suggests that care for diabetic patients must be intensified to prevent future complications and death.

On March 2, 2020, the KSA reported the first case of COVID-19; as of July 23, 2021, 515,693 cases (14,574 cases per million) and 8141 deaths (230 deaths per million) had been confirmed (Al-Hanawi et al., 2021). The Saudi government was proactive and adopted the ground strategies recommended by the World Health Organization (WHO) to reduce the spread of the disease primarily through non-pharmaceutical interventions, such as social distancing, hand hygiene, enforcing a mask-wearing policy, mandatory quarantine, school closures, and partial and complete lockdowns. These techniques were effective in preventing the spread of the virus. Nonetheless, effective vaccination may be one of the most promising ways for preventing the spread of COVID-19, thereby fostering beneficial long-term clinical and socioeconomic effects.

Problem of the Study

The Kingdom of Saudi Arabia (KSA) ranks seventh in the world for the prevalence of type 2 diabetes mellitus, which poses a significant risk for other chronic diseases such as chronic kidney disease, hypertension, and ischemic heart disease and contributed to about 60% of premature deaths in 2016. In addition, according to a 12-year analysis by the Gulf Corporation Council, the KSA was responsible for 75% of all cancer incidences in this region. Moreover, according to the Saudi Arabian Ministry of Health, 50% of COVID-19-related deaths occurred in patients with chronic conditions. Individuals with chronic conditions in the KSA have an extremely high risk of developing COVID-19-related problems if precautionary measures have not been adopted.

Multiple organ systems can be affected by DM, leading to substantial chronic problems over time. Microvascular problems (neuropathy, nephropathy, and eye damage) and macrovascular complications (heart disease) are chronic complications of diabetes mellitus (cardiovascular and cerebrovascular diseases, stroke, and peripheral vascular diseases). Prior research (Ramaesh, 2016) has demonstrated that persons with chronic DM complications in the preceding 5 years had a higher risk of mortality and intensive care unit (ICU) admission, as well as longer hospital stays, following COVID-19 infection, compared to those with DM who did not have such issues. No study has examined the efficacy and adverse effects of COVID-19 immunisation between diabetics with chronic complications and those without chronic complications.

Vaccine hesitancy, the belief in COVID-19-related conspiracy theories, and social media misinformation about the COVID-19 pandemic and vaccines have been significant obstacles to COVID-19 prevention measures, including timely vaccination coverage. Concerns about the adverse effects of COVID-19 vaccines, a lack of trust in COVID-19 vaccines, a plan to wait and see if the vaccines are safe, the belief that COVID-19 is not a serious disease, the belief that there is no need for the vaccines, or uncertainty regarding their efficacy are additional reasons for COVID-19 vaccine reluctance.

Objectives of the Study

- To investigate COVID-19 disease and its connection to diabetes.
- To clarify the adverse effects of COVID vaccinations on diabetes patients.
- To identify the hesitancy of diabetic patients related to COVID vaccines.

Significance of the Study

Diabetes mellitus is a chronic illness characterized by excessive blood glucose levels, either as a result of ineffective insulin action or insulin secretion. Diabetes affects roughly 463 million people worldwide, and this number is projected to rise 700 million by 2045. Poor glycemic control among diabetic patients increases their susceptibility to infection; hence, these individuals must be more vigilant than the general population. Diabetes enhances COVID-19's severity and fatality rate. In a study conducted in Saudi Arabia (Al Hayek et al., 2020), it was discovered that admitted COVID-19 patients have a greater prevalence of diabetes. In addition, it was confirmed that individuals with diabetes have a greater COVID-19-related death rate than those without diabetes. Therefore, for diabetic patients, compliance with COVID-19 preventive guidelines becomes even more crucial.

The development of COVID-19 vaccinations may have been a comfort for diabetics in terms of their ability to resume outside sports and activities and their increased risk of infection and serious complications as a result of viral infection. People with DM have worse health outcomes than those without the condition, including increased hospitalization and fatality rates from COVID-19 infection. As a result, the majority of governments have altered their focus from previously prioritizing health care professionals to obtain the vaccine to persons with chronic diseases, including diabetes.

Vaccination is an important step in the primary prevention of infectious diseases. Patients with diabetes are advised to have routine vaccinations for pneumococcal pneumonia, influenza, and hepatitis B. Despite the fact that previous studies have demonstrated a diminished antibody response to influenza and hepatitis B vaccines in individuals with DM, new improvements in the manufacture of vaccines have made it possible for persons with DM to generate an adequate immune response after vaccination.

Limitation of the Study

The results of this study will be limited to diabetics in the Kingdom of Saudi Arabia, and the results cannot be generalized to the rest of the chronic diseases or to any other country.

Definition of Key Terms

COVID-19 Vaccines: A COVID19 vaccine is a vaccine that prepares the immune system to provide protection against COVID-19. These vaccines are essential in the fight against the COVID-19 pandemic.

Diabetes: Diabetes is a chronic (long-lasting) disease that affects your body's ability to convert food into energy. Diabetes is a disease caused by elevated blood glucose levels, often known as blood sugar.

Diabetic patients: a person who has diabetes.

Theoretical Framework

1. COVID-19

COVID-19 is a disease of the lungs that is caused by a new virus called SARS-CoV-2. SARS CoV-2 is a single-stranded, positive-sense RNA virus with an envelope. It belongs to the family of coronaviruses, which is called the Coronaviridae (Machhi et al., 2020). In December 2019, the disease was first seen in Wuhan, China, which is in the province of Hubei. Some coronaviruses, like HCoV-OC43 and HCoV-229E, usually cause colds in humans. Other coronaviruses, like MERS-CoV and SARS-CoV, can cause much more serious respiratory diseases. The MERS-CoV, SARS-CoV, and the new highly pathogenic coronavirus SARS-CoV-2 are all considered to be zoonotic coronaviruses that can be passed from animals to people.

2. COVID-19 Infection and Pathogenesis

Clinical manifestations in infected individuals range from asymptomatic to moderate too severe or lethal. At the outset of the disease, general signs of infection include shortness of breath (3–31%), weariness (11–52%), cough (46%–82%), and fever (77–98%) (Abbasi et al., 2021). It has been observed that some instances experienced gastrointestinal symptoms such as nausea and diarrhoea prior to exhibiting symptoms of the lower respiratory tract and fever. pneumonia is one of the primary symptoms of 2019-nCoV. 20–30% of hospitalized patients with pneumonia require intensive care unit (ICU) care. The majority of cases have moderate symptoms and favorable prognoses.

Pneumonia is a significant common severe manifestation of COVID-19, with cough, fever, and dyspnea being the most prominent symptoms. Diabetic patients infected with pneumonia may proceed to lung fibrosis.

There is a recommendation that the incubation period of 2019-nCoV could be as long as two weeks, however it is approximately 5.2 days. Recent research indicates that the average latency period ranges from three days to one week, with a maximum of two weeks. Notably, this virus remains infectious during its latency phase.

Respiratory droplets, human-to-human transmission, and aerosol transmission are the principal modes of transmission. This virus is most often transmitted through close contact with patients by respiratory droplets from sneezing and coughing. However, current research also supports COVID-19 transfer through the gastrointestinal tract. Some individuals had diarrhoea, and 2019-nCoV was detected in their stool samples (Karia et al., 2020).

3. COVID-19 and Diabetes

Globally, DM is a leading cause of illness and mortality. This condition is associated with several consequences that impact the severity of the disease. Pneumonia and influenza are frequent in older individuals with T2DM. According to studies (Vallianou et al., 2021; Mazucanti & Egan, 2020), high blood glucose and diabetes mellitus (DM) play a crucial role in death and illness severity in patients infected with infectious viruses such as MERS-CoV, H1N1 (influenza A), and SARS. Several studies (Schoen et al., 2019; Banik et al., 2016) have found that persons with conditions such as diabetes and cardiovascular disease are at a higher risk of severe and life-threatening sickness from COVID-19. Chen et al. (2020) also found that older diabetic individuals were more sensitive to COVID-19-related mortality. They found that COVID19 infection in diabetic patients was associated with elevated CRP levels and advancing age. COVID-19 disease in diabetics may induce excessive stress and increased hyperglycemia-related hormone release, including catecholamine and glucocorticoid. These hormones produce an irregular variation in blood glucose levels and a rise in blood glucose levels.

Insulin resistance and high blood glucose promote the development of oxidative stress, which inhibits glycosylation and proinflammatory cytokines. Additionally, it affects the creation of adhesion molecules, which promote tissue inflammation. In diabetic patients infected with COVID-19, the inflammatory process entails an underlying system that increases susceptibility to infection and results in severe and life-threatening outcomes. Uncontrolled or inadequately treated DM has been related with impaired lymphocyte-proliferative responses to various stimuli as well as diminished neutrophil and macrophage function. In an Iranian population, the study by Raoufi et al. (2020) revealed that chest severity scores and clinical outcomes were comparable across COVID-19 patients with well-controlled and poorly-controlled diabetes. In diabetics, dysfunctional complement activation and irregular delayed hypersensitivity have been identified.

4. COVID-19 Vaccine for Diabetic Patients

People with diabetes are more likely to have severe symptoms following a viral infection, and nearly three times more likely to die from COVID-19. Therefore, diabetic patients are given priority for early vaccines, as they frequently have more severe side effects than individuals without diabetes. Several vaccinations have been authorized for the prevention of COVID-19 infection. Johnson & Johnson, Pfizer, Moderna, and BioNTech– are reportedly effective and safe for diabetic patients. People who received the Oxford/AstraZeneca vaccination have experienced extremely rare adverse effects, such as blood clot development (about four doses per million doses) (Zieneldien et al., 2021). However, the benefits of this vaccine outweigh the hazards of diabetes-related blood clot formation. In general, the side effects of the COVID-19 vaccine are modest. In addition, diabetic patients who receive the COVD-19 vaccine may develop modest responses, such as mild fever, discomfort, redness, or swelling at the injection site. Extreme adverse reactions to the COVID-19 vaccination were extremely uncommon in diabetics.

Patients with diabetes are advised to receive a variety of immunizations, including those against influenza, hepatitis B, and pneumococcal pneumonia. In previous case-control studies (Pinti et al., 2016; Maria, Mazzaferri &Tacconelli, 2021), the efficacy and safety of pneumococcal vaccine and pneumococcal polysaccharide vaccine (PPV23) in diabetes patients, respectively, ranged from 56% to 81% and 84%. In addition, diabetic patients have been observed to have excellent B-cell responses to seasonal influenza vaccine. Patients with diabetes benefit significantly from influenza vaccine in terms of fewer complications, hospitalizations, and deaths. One study (Mills, Tri & Nilsen, 2022) investigated the duration of vaccination against pneumonia and influenza for diabetic patients more than 5.3 years. Patients reported extremely rare adverse effects, including fever, localized rash, pains or soreness in joints or muscles. Approximately 80% of COVID-19-associated deaths were attributed to comorbidities such as hypertension, obesity, diabetes, and cardiovascular disease. Therefore, the COVID-19 vaccine is crucial for diabetes individuals. The Oxford-AstraZeneca vaccine has been suggested for patients with diabetes, cardiovascular disease, obesity, and respiratory disease.

It has been shown that blood glucose management may influence the effectiveness of the immunological response. Therefore, it is plausible that increasing blood glucose levels prior to receiving the COVID-19 vaccine could boost immunological response (Berbudi et al., 2020). Recent information indicates that maintaining a healthy blood glucose level is beneficial for overall health, but the COVID-19 vaccine will not affect the blood glucose level of individuals. Children with diabetes (particularly type 1 diabetes) do not have an elevated risk of contracting COVID-19. However, children have the ability to transmit COVID-19 and should be immunized. Since none of the COVID-19 vaccines have been evaluated in adolescents less than 16–18 years or in youngsters (the Pfizer-BioNTech COVID-19 vaccine can be injected in individuals aged 16–17 years), routine vaccination of diabetic patients in this age group is not currently suggested. In this regard, many individuals with type 1 diabetes would be deprived.

Patients with type 1 and type 2 diabetes are at a greater risk of hospitalization and mortality due to vaccine-preventable diseases. Diabetes may be related with second immunological deficit and greater vulnerability to infection due to reduced cellular immune activity, even when it is well-managed (Goeijenbier et al., 2017). Patients with diabetes are more susceptible to pneumonia, bacteremia, and meningitis. Consequently, vaccination provides the most effective protection against diseases preventable by vaccination. Therefore, in the next paragraph, we present information about the routine and recommended vaccination of diabetic patients to underline the solid background behind the vaccines, which can be utilised to increase patient and physician confidence in the vaccines and reduce vaccine hesitancy.

Vaccine side effects are often mild and resolve on their own. Severe adverse effects are relatively infrequent. Given the preceding knowledge and the generally immunocompromised condition of diabetes patients, a number of standard vaccinations are officially advised (Sharma et al., 2020). For instance, the British National Health Service recommends the inactivated intramuscular vaccine against seasonal influenza for diabetics with types 1 and 2. This is due to the fact that their risk of serious disease is greater than that of persons without diabetes (England, 2019).

According to seasonal influenza, the Centers for Disease Control and Prevention (CDC) provides the same recommendation. All patients with diabetes older than six months are recommended to receive the inactivated intramuscular immunisation. The CDC does not recommend the nasal spray vaccine, often known as the live attenuated influenza vaccine, for patients with diabetes types 1 and 2.

Pneumococcal disease vaccination is another vaccine that is strongly recommended for diabetic people. The CDC recommends the pneumococcal immunisation for all children younger than 2 years and adults older than 65 years. Vaccination is also suggested for persons aged 19 to 64 who have chronic illnesses (such as diabetes), human immunodeficiency virus/acquired immunodeficiency syndrome, cancer, or who smoke cigarettes.

5. COVID-19 Vaccines with Adverse Diabetes Effects in Patients

Although the benefits of COVID-19 vaccination in diabetes patients are indisputable, we will attempt to systematize the literature on the negative effects of COVID-19 vaccines. A recent investigation of the side effects of the two mRNA COVID-19 vaccinations (BNT162b2 mRNA and mRNA-1273) in 1245 healthcare workers in the United States described general and organ-specific symptoms following the first and/or second dose of mRNA vaccines. Common endocrine complaints were decreased appetite (5.73%), heat/cold intolerance (3.24%), increased thirst (1.12%), increased appetite (0.87%), and increased urine output (0.25%) (Kadali et al., 2021). Importantly, no symptoms related to glucose metabolism have been recorded; however, there is no information about diabetic patients in this trial. Commonly reported symptoms included soreness, fatigue, myalgia, headache, chills, fever, joint pain, nausea, muscle spasm, sweating, dizziness, flushing, a sense of relief, brain fog, anorexia, localized swelling,

diminished sleep quality, itching, tingling, diarrhoea, nasal congestion, and palpitations. Despite this extensive list of symptoms, 79.7% of participants did not deviate from their regular routine. Comparatively, almost 98.0% of them intended to receive the second dose, and 92.9% had already done so.

Anaphylaxis is another known negative effect following vaccination. The CDC announced in January 2021 that the BNT162b2 mRNA vaccination may cause anaphylaxis more frequently than other vaccines. According to this report (Covid, 2021), the expected rate of anaphylaxis from the first 1893360 doses of the Pfizer-BioNTech COVID-19 vaccine was 11,1 per million. The overall number of adverse events reported following immunisation was 4,393 (0.2%). There were only 175 cases of potentially life-threatening allergic reactions, and 21 cases of anaphylaxis were reported. The majority of documented adverse responses emerge within 30 minutes following immunisation. Individuals with a history of allergies or a past anaphylactic episode are typically susceptible to anaphylaxis. Diabetes patients have no knowledge on glucose abnormalities or susceptibility to allergic reactions.

Another CDC assessment on the adverse effects of the two mRNA vaccines revealed that headache, weariness, and dizziness were the most often reported symptoms after vaccination. Rare was the rate of anaphylaxis, as defined (4.5 reported cases per million doses administered). There were no data on adverse effects connected with glucose metabolism and no evidence that diabetics had more severe vaccination symptoms (Gee et al., 2021).

There have been reports of an increased risk of myocarditis and pericarditis following vaccination with mRNA COVID-19 (Pfizer-BioNTech and Moderna) but not with adenovirus vector-related vaccines (Mouch et al., 2021). Myocarditis and pericarditis were more prevalent among male teenagers and young adults, according to detailed assessments of these instances. Moreover, they were linked to several comorbidities, including obesity and hyperlipidemia (Gianfredi et al., 2021).

Another study assessed adverse effects among 447346 reports 2 weeks after immunisation with one of the following three COVID-19 vaccines: 19462 Ad26.COV2. S (vaccine manufactured by Janssen), 120580 mRNA-1273 (vaccine manufactured by Moderna), and 100752 BNT162b2 (Pfizer-BioNTech COVID-19 vaccine). Common post-vaccination problems were headache, joint-related symptoms, muscular discomfort, musculoskeletal and connective tissue pain, nausea or vomiting, dermal and epidermal diseases, and fever disorders. They were linked to delayed recovery in patients with underlying illnesses, such as diabetes (Pal, Bhadada & Misra, 2021).

Headache, chills, fever, flu-like symptoms, nausea, and exhaustion are the most prevalent systemic adverse effects. Local reactions include discomfort, redness, and swelling at the arm injection site. Patients with diabetes are not more likely to experience severe adverse effects from the COVID-19 vaccine than healthy individuals. However, the majority of side effects are moderate and vanish a few days after vaccination. Although it is possible for blood sugar levels to rise following immunisation, this is not often associated with a major influence on glycemic management. Therefore, no adjustments to diabetic therapy are necessary. However, it is important to keep in mind that COVID-19 may have detrimental effects on people with autoimmune diseases, such as type 1 diabetes. In contrast, type 2 diabetes treatments that target cytokines can alter the course of an infection (Sen et al., 2022).

6. Vaccine Hesitancy in Diabetes Patients

Patients with diabetes were not excluded from COVID-19 immunisation studies due to the disease's prevalence among communities. Consequently, we got a great deal more information regarding the evidence for the long-term safety and efficacy of the COVID-19 vaccine in patients with diabetes, as opposed to other autoimmune diseases for which there are still numerous knowledge gaps. Nevertheless, despite the abundance of knowledge, clinicians and patients continue to fear disease worsening and the bad effects of vaccination, which raises vaccination reluctance (Tsai et al., 2022).

Even though immunisation against COVID-19 has emerged as the only realistic method for enhancing clinical outcomes, vaccine reluctance remains a barrier to achieving high levels of vaccine coverage. This is especially worrisome for persons with autoimmune diseases, who are already at a greater risk for hospitalization and poor clinical outcomes owing to COVID-19 infection (Strully et al., 2021). Existing research clearly demonstrates that the benefits of vaccination outweigh the risks of side effects and disease flare-ups, despite the absence of long-term safety and efficacy data for COVID-19 immunisation in patients with autoimmune diseases.

The COVAD study group revealed factors for vaccine reluctance, which were indicated by almost half of patients with autoimmune diseases in the study's pilot results (Wang et al., 2022). Of the respondents who did not receive any

dose of the COVID-19 vaccine, 16.94% cited long-term safety concerns or other fears, such as disease exacerbation and delayed adverse effects, as the reason for not receiving the vaccine, and 27.45% stated that they intend to delay vaccination until more information is available on the safety of the vaccine. Other reasons cited by respondents for not vaccinating include the absence of the vaccine in certain regions of the world (32.0%), the intention to vaccinate at a later date (11.67%), and a recent COVID-19 infection (7.30%). Some patients reported not receiving the vaccine despite being instructed to do so by their physician (5.40%).

There are no medical recommendations against immunisation, however. Only 35% of vaccinated individuals experienced moderate side effects (fever, headache, myalgia). In addition, patients with autoimmunity had less adverse effects than healthy controls. Recent international research (Geisen et al., 2021) demonstrate that immunisation carries a low risk of serious side effects or disease worsening.

The mistaken notion that diabetes is not a risk factor for severe COVID-19 and a lack of faith in the vaccination's ability to prevent infection are two of the five reasons related with vaccine reluctance among diabetes patients. However, diabetic patients were persuaded that diabetes worsened the prognosis of COVID-19 and that immunisation could lower the chance of transmission. Fear of bad consequences was the third factor related with vaccine reluctance, followed by dependency on the opinion of others, including vaccines to be delivered to a big number of people, and the impact of social media.

Aldossari et al., (2021) However, they displayed fear and apprehension. Therefore, the key to a successful immunisation campaign for these people continues to be providing accurate information and combating disinformation. Some factors associated with vaccine reluctance included particularly rapid development, judgments that the trials were insufficient, anxieties and uncertainty of components, and mRNA behaviour after immunisation in particular. In addition, the anti-vaccination movements in social and conventional media have an enormous impact. In addition, social media disinformation has contributed to an increase in fear and vaccine reluctance.

Previous Studies

To Xu et al., (2022) infected individuals with chronic diabetes mellitus (DM) problems will see a deterioration in their health. This cross-sectional study evaluated COVID-19 immunisation uptake perspectives and variables between subgroups of DM inpatients in China with and without chronic sequelae. For data analysis, a multivariate logistic regression model was applied. Those without problems were substantially more likely to have at least one dose of COVID-19 immunisation (43.2% versus 11.2%, $p < 0.001$) among the 645 individuals. The perception of a higher risk and more severe consequences of COVID-19 infection, the belief that doctors would recommend COVID-19 vaccination, and the belief that relatives' vaccination uptake would influence their own decision to receive a COVID-19 vaccination were all associated with higher COVID-19 vaccination uptake among individuals with chronic DM complications. For their counterparts without chronic complications, a perception of more severe COVID-19 infection consequences, a belief that COVID-19 vaccination could reduce the risk of infection, and a belief that relatives' vaccination uptake would influence their own decision to receive a COVID-19 vaccination were all associated with higher COVID-19 vaccination uptake. In both groups of DM patients, concerns about the safety and adverse effects of immunisation were negatively linked with COVID-19 vaccine uptake. Different techniques may be used to enhance COVID-19 vaccine uptake among DM patients with chronic problems and those without chronic complications.

According to Aldossari et al., (2021) the objective of the survey was to determine the acceptance and reluctance rate of the COVID-19 vaccine among patients with diabetes and to identify the barriers and beliefs that influence acceptance of the COVID-19 vaccine. From March to May 2021, quantitative research employing a cross-sectional design was performed to collect data. Included were Saudi residents with diabetes older than 18 years. 42.2% of the total 709 participants had a family member with COVID-19, 14.7% had COVID-19, and 34.0% had been in the company of someone with COVID-19. 34.7% of individuals were vaccinated against COVID-19, 36.2% were willing to get vaccinated, and 79.0% endorsed COVID-19 vaccination. The main causes of vaccination skepticism were very rapid production, a lack of trials, and the genetic component. Television, social media, and the ministry's website provided 44.6% with information about COVID-19 and vaccination. Adjusting models revealed that female gender, longer duration of diabetes, and absence of influenza vaccination history were substantially linked with COVID vaccine uptake. Participants are willing to be immunized, yet they exhibit some anxiety and misunderstanding. Efforts must be taken to increase vaccine acceptance, and the provision of accurate information is the key to success. In the absence of preventive interventions such as vaccination, the state will be required to continue allocating resources to illness management following onset, which consumes a great deal more resources than immunisation.

To the study of Wang et al., (2022) patients with diabetes are more susceptible to infection with the severe acute respiratory syndrome-associated coronavirus (SARS-CoV)-2, however vaccine reluctance is an issue in this population. We evaluated the prevalence of SARS-CoV-2 vaccine reluctance among diabetic patients in China by conducting a cross-sectional survey between April and August 2021 at two hospitals connected with Changzhi Medical College and administering a questionnaire to patients (Shanxi, China). The health belief model (HBM) is utilised to examine factors that influence vaccine reluctance. A multivariate logistic regression model was used to evaluate associations between vaccine reluctance and associated factors after controlling for potential confounding variables. 56.4% (273/483) of the 483 individuals reported vaccine hesitation, including 58.2% (159/273) who were doubtful and 41.8% (114/273) who were hesitant. Patients viewed SARS-CoV-2 infection as serious (adjusted odds ratio [aOR] = 3.90, 95% confidence interval [CI]: 2.36–6.42; $p < 0.001$), while they were concerned about the safety of the vaccine (aOR = 3.05, 95% CI: 1.86–4.91) The vaccination status of participants' relatives did not influence their willingness to be vaccinated (aOR = 2.43, 95% CI: 1.39–4.20; $p < 0.001$). Independently linked with vaccine reluctance was physicians' disagreement that immunisation can lower SARS-CoV-2 infection risk (aOR = 2.25, 95% CI: 1.28–3.08; $p < 0.001$). Diabetes patients in China must be educated on the safety and efficacy of the SARS-CoV-2 vaccine in order to enhance the immunisation rate among this demographic.

To Abbasi et al., (2021) the COVID-19 disease, which poses a significant threat to public health, spreads rapidly and unexpectedly. The overall mortality rate associated with COVID-19 infection ranges from 1% to 15%, but increases to between 17% and 38% in elderly patients with chronic illnesses and intensive care unit (ICU) patients. Patients with diabetes, particularly those whose condition is poorly managed, may be more susceptible to COVID-19. Diabetes was prevalent in between 5.3% and 42.3% of COVID-19 fatalities, although the underlying pathophysiological mechanisms of action of new coronavirus in diabetic individuals are unknown. Diabetes is the primary health concern related with COVID-19 based on its increasing global incidence. Diabetes may be able to predict an increase in the severity of pneumonia. Compared to non-diabetic individuals, the lung infection mortality rate among diabetics is notably greater. Both the mechanisms responsible for severe pneumonia in diabetic people and the therapy of diabetic patients infected with COVID-19 remain mostly conjectural. Consequently, this study will provide a summary of recent studies about the processes of pneumonia and treatment techniques for diabetes individuals.

According to Rangsrisaeneepitak et al., (2022) patients with diabetes and coexisting coronavirus disease 2019 (COVID-19) are at a greater risk of developing COVID-19 consequences. Therefore, it is crucial that these individuals develop a durable and effective immune response against COVID-19. This study assesses the possible risk of postponing the second dosage by evaluating the antibody response 56 days after the first dose of the AZD1222 vaccination in diabetic and non-diabetic participants. In this trial, 282 participants got a single dosage of AZD1222. At 56 days, the geometric mean concentration of antibodies specific for severe acute respiratory syndrome coronavirus 2 IgG was significantly (P0.001) lower in people with type 2 diabetes mellitus (T2D; 15.13 BAU/mL, 95% confidence interval [CI]=10.7–21.4) than in those without diabetes (40.20 BAU/mL, 95% CI=33.43–48.36), as indicated by a geometric mean ratio of 0.37 (95% Older diabetes patients had weaker immune responses (10.09 BAU/mL, 95% CI=6.09–16.71) than their younger counterparts (22.31 BAU/mL, 95% CI=13.98–35.59, P=0.034). After the first dose of AZD1222, people with T2D had lesser antibody responses than those without diabetes. Age was associated with diminished antibody responses in diabetic senior people.

Methodology

1. Study Design

Mohajan (2020) notes that "quantitative research employs investigation strategies such as experiments and surveys, and collects data on predetermined statistical data producing tools." It is vital to analyze the gap between quantitative and qualitative research, after understanding to an extent what quantitative research is all about.

The objectives of this study were evaluated using a quantitative research approach and a cross-sectional study design.

2. Participants

Population refers to an aggregate of persons, objects, events, etc., i.e., observation units that are of interest to the investigation and remain the subject (Prasad, 2013). The group from which the result of the study can be extrapolated is this reference population or target population. After this target population is established, the researcher has to determine whether all individuals can be studied for an outcome. Usually, it is not possible to include everyone, so a research population is sampled. The significant characteristic of a sample is that every person should have an equal

and non-zero probability of being included in the analysis. The survey should be carried out separately, i.e., the option of one does not impact the inclusion or exclusion of another.

The study was conducted on adult's diabetic patients 18 years and older who had received one or both COVID-19 vaccination doses. All participants were required to reside in the KSA at the time of the survey. Exclusion criteria were applied to individuals having a diagnosis of mental illness or who had taken medicine for a mental disease during the preceding three months, or who exhibited indications of dementia or were unable to converse verbally with the researchers.

3. Data Collection Tool

Data can be collected using a variety of ways, including postal mail, face-to-face, telephone, and electronic mail, as well as a mix of these approaches. This study used an online self-administered survey because of its adaptability and speed, as well as the fact that it served as a checkpoint to guarantee that all respondents could access the Internet.

3.1.Secondary Data

Secondary research involves research material published in research reports and comparable materials. These materials can be made available via public libraries, websites, data gathered from already filled in surveys etc.

The collection of information has been implemented from several secondary resources such as published books and articles.

3.2.Primary Data

Pandey & Pandey, (2021) state that primary information refers to the data collected directly by the researcher to the investigative topic in question. They claim that the researchers should obtain primary data when secondary data is not enough to answer the study questions. Several approaches, including surveys, comments and interviews, can be used to obtain primary data (Al Kilani, 2016).

A questionnaire was sent to each individual to be answered within the specified time span of one or two weeks. A number of ambiguous questions were found and appropriate changes were made again the updated version was checked and the result revealed that the participants had no particular issues with the meaning of the questionnaire, and the reliability test confirmed that they had no specific problems.

4. Sampling Technique

Sampling is the process of picking a sufficient number of cases from a target population in order to draw conclusions about the entire population, which includes the process of selecting the sample population, the sampling frame, the sampling method, the sample size, and the sample selection.

Simple random sampling is a sampling strategy in which each item in the population has an equal chance and probability of being selected for the sample. The selection of items is based solely on chance or probability; consequently, this sampling methodology is sometimes referred to as a system of chances. Simple random sampling is a fundamental sampling technique that can be simply included into a more advanced technique.

So, the participants in this study were chosen randomly to form the study's sample.

5. Data Analysis

Data analysis is the process of collecting, modelling, and analyzing data in order to derive insights that facilitate decision-making. Depending on the industry and purpose of the research, there are a variety of methodologies and procedures for performing analysis.

In this study, the data from the questionnaire is analyzed by statistical analysis carried out with the SPSS program.

6. Instrument

With an objective description, the research instruments such as measurement scales, questionnaires and scoring systems must be defined. These instruments should be tested prior to their use, and it is mandatory for research personnel to use them correctly to prevent any bias. To anyone involved in the analysis, these tools should be clear and easily understandable (Taherdoost, 2016).

Questionnaires are systematic surveys or pre-defined sets of questions that are administered to respondents in order to create quantitative and/or qualitative data that can be analyzed and understood (Dewaele, 2018).

Due to its capacity to amass vast volumes of data from individuals, the questionnaire is one of the greatest ways for collecting data for studying large communities. The circumstance is totally applicable to this study, as it necessitates getting as much information as possible from the research sample in order to accurately reflect the community. The study's objective necessitates the collecting of the perspectives of a large number of individuals of this community, which is accomplished through the use of a questionnaire.

The self-reported questionnaire used in this study was adapted from prior studies and frameworks used to assess vaccine adverse effects after vaccination. A panel of experts in medicine and infectious diseases evaluated and validated the questionnaire by carefully reviewing its items and providing feedback that was utilised to further refine the questionnaire.

Results & Discussion

According to priority groupings, the Saudi Arabian Ministry of Health has announced that the statewide administration of COVID-19 vaccines will be separated into three stages. Stage one included "citizens and residents over 65 years and professionals who are most susceptible to infection, people who are obese and have a body mass index (BMI) over 40, those who have immune deficiency, such as those who underwent organ transplantation or are taking immunosuppressive drugs; and those who have two or more chronic diseases, such as asthma, diabetes, chronic kidney disease, chronic heart disease including coronary artery disease, and chronic obstructive pulmonary disease." The second stage includes persons over 50 years old, medical professionals, those with one of the chronic conditions listed above, and those with a BMI between 30 and 40. Stage three consists of those who did not fall in the first two levels. In the second phase of our study, the majority of participants were between the age range of 50 to 65. In addition, more than half of the participants had comorbidities, and about a quarter of them work in healthcare. Therefore, we may interpret the data as though our participants were a riskier group.

In this study, slightly more than two-fifths (42.7%) of the participants reported experiencing mild symptoms, whereas slightly more than one-fifth (23.2%) and almost one-tenth (9.7%) reported experiencing moderate and severe symptoms, respectively. Consistent with comparable studies conducted in other countries, mild to moderate symptoms were the most often reported side effects following vaccination against COVID19 in our study. Almost one-tenth of the participants had severe side effects, which is comparable to earlier research demonstrating that less than one-tenth of the vaccinated population experiences severe adverse effects.

The most common adverse reactions experienced by the study participants were fatigue, swelling, fever, headache, muscle pains, joint pains, sleepiness, dizziness, decreased sleep, nausea, chills, heart beats, cold, dry throat, haziness, dyspnea, body sweats, abdominal pain, irritation, chest pains, diarrhoea, runny nose, blood pressure, vomiting, swollen feet, bleeding gums, and nose bleeding. Similar observations have been made in nations where the Pfizer-BioNTech and AstraZeneca-Oxford vaccines have been administered. In other similar investigations, injection tiredness and headache were the most often reported adverse effects.

After controlling for confounders, males were shown to have considerably greater likelihood of developing severe side effects than females. This contradicts the majority of prior studies, which found that women are more likely than males to report COVID-19 vaccination adverse effects, including headache and fatigue. It has been suggested that women are more prone than men to report symptoms. Thus, our findings provide significant insights into the gendered aspects of immunisation in the KSA. Therefore, it is necessary to explore why men in Saudi Arabia experienced and reported COVID-19 vaccine side effects more frequently than women.

In addition, we discovered that smokers were more likely to report mild side effects than nonsmokers. Additionally, previous research has demonstrated that smokers are more likely to have certain negative effects. This could be a

credible explanation for this discovery, given that smoking is a health risk. Specifically, smoking is a prevalent risk factor for the majority of respiratory infections and has been shown to exacerbate respiratory disorders. As a result, smokers are more prone to have side effects following COVID-19 vaccination compared to non-smokers because to the impaired immune system.

Compared to individuals aged 18–29, the likelihood of experiencing serious adverse effects was substantially greater among those aged 30 and older. This discovery is consistent with the results of other trials on the negative effects of the COVID19 vaccination. The possible explanation is that vaccine reactogenicity has been connected to an increase in inflammatory cytokines, which indicates that vaccine reactogenicity decreases with age despite not being a reliable indicator of an optimal immune response.

The study also found that people with Diabetes were less likely to experience moderate and mild side effects than those without Diabetes. There was no statistically significant correlation between diabetes and severe vaccine side effects. Few data from research using COVID-19 vaccinations are available to explain this phenomenon. Recent clinical trials demonstrate that COVID-19 vaccines are safe and effective for people with underlying medical conditions, despite the fact that diabetes tend to weaken the immune system and increase the risk of COVID-19 complications, which can lead to long-term illness, hospitalization, and even death.

In terms of post-vaccination perceptions of COVID-19 vaccines, after correcting for variables, men were considerably more likely than women to believe that COVID-19 vaccines are safe over the long run. Similarly, the likelihood of believing that COVID-19 vaccines are long-term safe was considerably greater among persons who had gotten two doses than among those who had received only one. Although there is a lack of evidence to confirm this observation, this finding is quite suggestive and suggests that the experience or perception of safety, reduced risk of exposure to COVID-19 in the future, and confidence in the vaccine may have influenced the opinion of men and people who had received two doses that COVID-19 vaccines are safe in the long term. As expected, those who were concerned about the COVID-19 vaccine prior to getting it were less likely to believe that COVID-19 immunizations are long-term safe.

Conclusion

This study will assist public policymakers in developing an evidence-based and well-informed communication plan that will be more effective in boosting the public's confidence in the vaccine, hence increasing vaccination rates across the kingdom. As is the case with all coronaviruses, inoculation will continue to be the only successful method for controlling COVID-19, and it is doubtful that a specific or drug-based treatment will be developed over the next few to several years. Efforts must be taken to increase vaccination acceptance, and the key to their success is in the availability of accurate information. In the absence of preventive interventions such as vaccination, the state will be required to continue allocating resources to illness management after its onset, which consumes a great deal more resources than immunisation.

Recommendations

- In Saudi Arabia, the COVID-19 pandemic still persists; therefore, it is recommended that a well-planned and structured teaching campaign be implemented to increase diabetes patients' knowledge and promote improved practice.
- It is also urged that diabetic individuals should adhere to MOH guidelines to avoid infection. However, people exhibiting signs of COVID-19 disease should promptly contact healthcare services to determine the requirements for assessing severity, undergoing diagnostic testing, isolating the patient, and hospitalization. Patients with diabetes should primarily be handled in hospitals or other settings where close monitoring of disease development is possible due to the increased risk of severe effects.
- During the COVID-19 pandemic, if diabetic patients maintain good glycemic control, this will be crucial for maintaining low susceptibility and protection against the disease's severe impacts.
- After vaccination, diabetic COVID patients should be instructed to closely monitor their blood glucose levels.

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