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IMPACT OF COVID-19 VACCINATION IN DIABETIC PATIENTS FROM CONSTANTA COUNTY – GLYCEMIC PROFILE BALANCE, ADVERSE REACTIONS, GENERATED IMMUNE RESPONSE

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The COVID-19 pandemic, which began at the end of 2019, has experienced an extremely rapid evolution, globally, affecting all categories of people. Certain categories of the general population, such as diabetic patients, have an increased susceptibility of developing severe forms of the disease, which can progress to death.[1, 2]

The resources to combat the disease are currently represented by supportive therapy, various experimental drugs and vaccines that promise exceptional results. Some of these are based on new technologies, which raise suspicions in the general population regarding efficiency and side effects.[3, 4]

The present study consists of two groups of patients and aims at a comparative assessment of diabetes patients with the general population. Thus, the occurrence of side effects and the variability of the glycemic profile will be noted, in order to establish the clinical and biological impact that the vaccine imposes on patients.

The second part of the study aims at the appearance and dosing of specific antibodies, IgG and IgM anti SARS-COV-2 in a group of 141 patients, of which 16 diabetics and proposes the analysis of the immune response at least 10 days after the second dose of the vaccine. establishing the risk-benefit ratio, compared to the general population.

Keywords: COVID-19, vaccination, diabetes mellitus**.**

INTRODUCTION

The new pathogen of the corona virus family causes the disease called COVID-19 (coronavirus disease 2019), which was discovered in late 2019, in China and is responsible for a systemic but especially respiratory damage, often with a severe prognosis.

Due to the accentuated community transmission, at global level, the World Health Organization framed on March 11, 2020 COVID 19 at pandemic level, starting a race against the clock for the diagnosis, treatment and effective prevention of this disease.[5]

The year 2020 allowed the medical system to observe certain characteristics of this new virus, as well as the evolution towards severe forms of the disease and even the death of certain categories of people.

The clinical and biological variability of COVID-19 is particularly important, from asymptomatic patients to patients requiring intensive care. It has been observed that some conditions involve an increased risk of developing a severe form of COVID-19 – diabetes (especially type II), obesity, chronic lung disease, neoplasms, chronic heart failure, chronic kidney disease. [6, 7]

Since the onset of the pandemic, researchers have studied treatments and vaccines to combat the disease and on December 11, 2020, the first vaccine against Covid-19 was approved in United States, following approval for Europe on December 21. The technology on which this vaccine is based is the injection of messenger RNA, protected by a lipid structure, which once in the body, forms a spike protein, similar to that of coronavirus, which the immune system destroys, forming antibodies.

Phase 3 studies showed a 95% success rate in antibody production and the present study aims to dose the antibodies at least 7 days after the second dose of the vaccine, in order to verify its effect in diabetic patients, as well as post-vaccination side effects, in relation to the general population.[8, 9, 10]

MATERIAL AND METHOD

The presented study has two components, a prospective component and a retrospective component.

The prospective study was carried out on a group of 62 patients, registered by the Diabetology Services in Constanta, for which we imposed inclusion / exclusion criteria, in order to obtain scientifically conclusive results.

The study was not restrictive, accepting patients of both sexes, adults, the main criterion for inclusion being the diagnosis of type 1 or type 2 diabetes, regardless of current treatment (oral antidiabetics / insulin). Patients with mental illness or non-compliance were not enrolled.

The main objective was to evaluate the post-vaccination glycemic profile, as well as to monitor the side effects, in relation to the general population. Methods were used to collect and record data based on patient's medical history and medical or personal documents, which concerned the patient's history and in particular, the glycemic profile before vaccination and the presence / absence of acute pathology / decompensation of a chronic disease at the time of vaccination .

The second retrospective study was performed on 141 vaccinated patients, 16 of whom were diagnosed with diabetes, for whom COVID-19 antibodies (IgG and IgM) were dosed.

The time period of the study was 2 weeks, the inclusion criteria targeting adult patients, men and women, who were immunized according to the vaccination schedule (two doses – Comirnaty), with special attention to diabetic patients, which represents a major differential criterion for the study.

The technique used to detect IgG and IgM anti SARS-COV-2 is based on ELFA (Enzyme Linked Fluorescent Assay) in serum / plasma and is a qualitative index test. With the help of these reactions, antibodies specific for the receptor binding domain of the "Spike" proteins of the SARS-COV-2 virus are detected. [11]

The dosing of COVID-19 antibodies for the studied group was performed at least 10 days after the booster.

The main objective of the study is comparative, evaluating the immune response of patients diagnosed and treated for diabetes, compared to that of individuals without diabetes.

RESULTS

The study group included a total of 62 patients, of both sexes, aged between 21 and 83 years, from rural and urban areas, with primary, secondary and university studies.

Although diabetes has a higher incidence in males than females, the study group has a close gender ratio, with a slight predominance of women (33 F> 29 B), probably explained by greater adherence to vaccination and studies. [12]

The number of cases has a gradual increase in terms of age, the first decades being characterized by type 1 diabetes and after the fifth decade, there is a significant increase, represented in principle by type 2 diabetes.

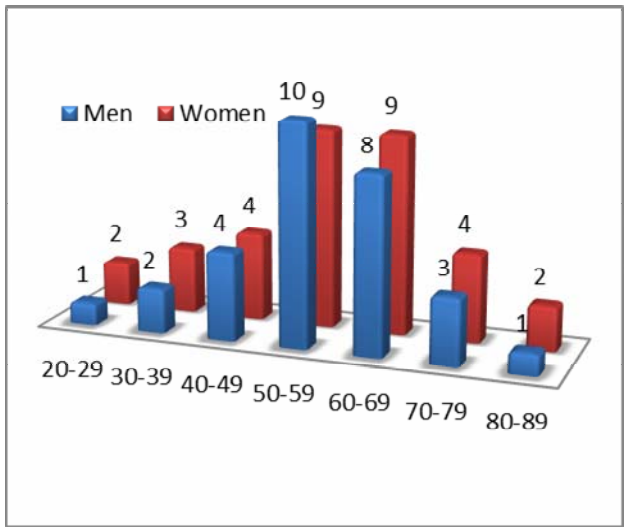


Figure 1. Distribution by sex and age.

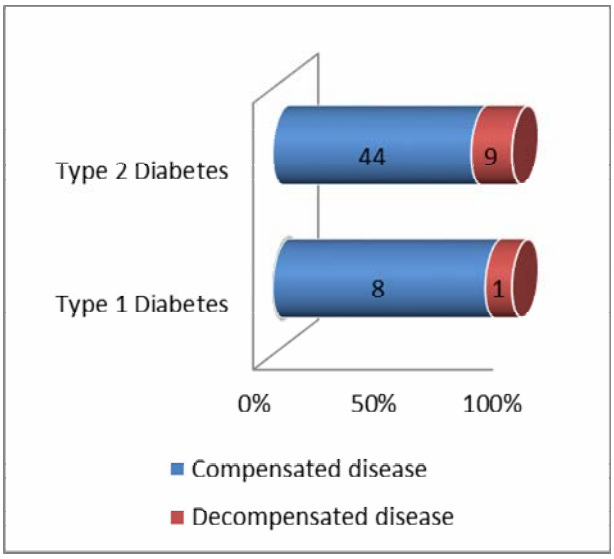


Figure 2. Type of diabetes and disease control rate at the time of vaccination against COVID19.

	Type 1 Diabetes	Type 2 Diabetes
Alteration of the glycemic profile	3	10
Fatigue	3	13
Headache	2	7
Myalgias / Arthralgias	2	7
Subfebrile	2	6
Fever	1	4
Chills	0	2
Pain at the injection site	4	21
Nausea	1	2
No side effects	5	29

Figure 3. Post-vaccination side effects.

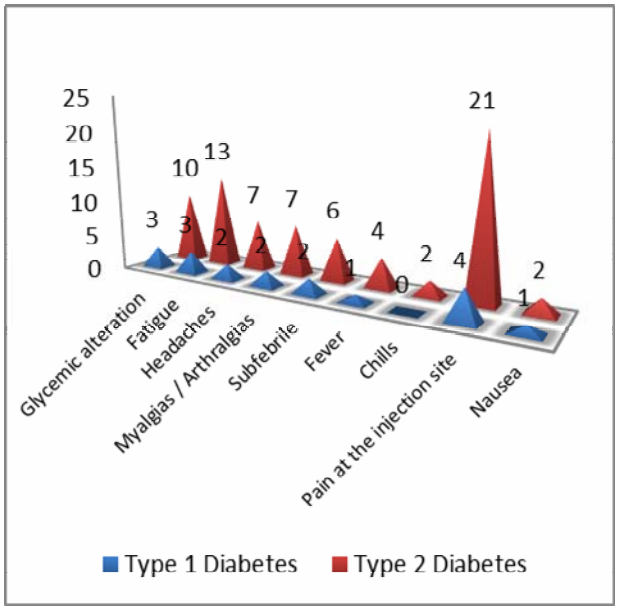


Figure 4. Ratio of those who had side effects and those without reactions, depending on the type of diabetes.

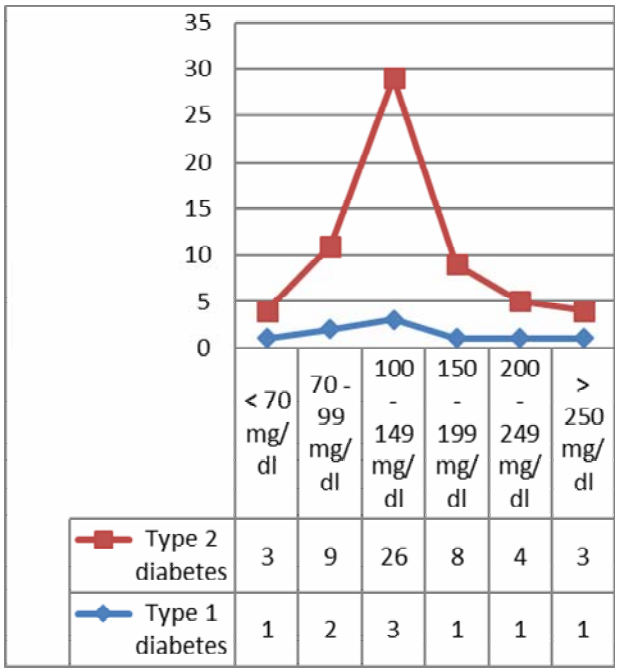


Figure 5. Report on post-vaccination reference glycemic intervals.

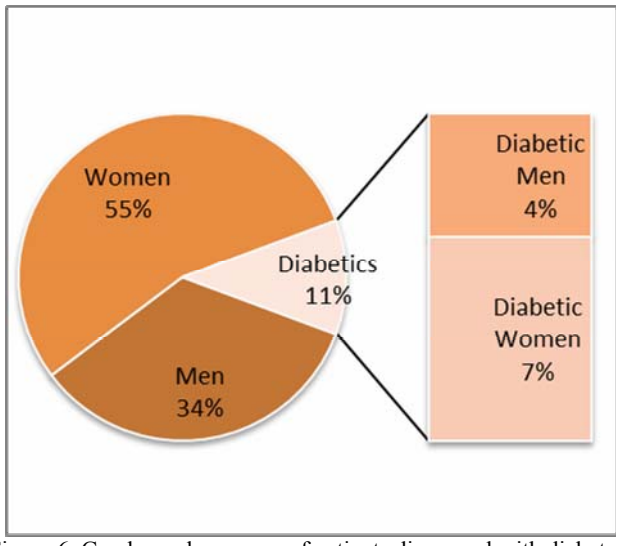


Figure 6. Gender and presence of patients diagnosed with diabetes.

Out of a total of 62 patients, a number of 9 have the diagnosis of type 1 diabetes, with a very high rate of disease control – in the targets of basal glycemia and glycosylated hemoglobin, due to the extremely careful monitoring, characteristic of this condition. For type 2 diabetes, the number of representatives is higher, 53, of which 44 in therapeutic targets and 9 outside them.

Side effects were considered regardless of the first or second dose of the vaccine and regardless of the length of time after vaccination, with a limit of 48 hours.

Approximately equal numbers are observed for each adverse reaction, in terms of the type of diabetes present for the patients studied.

They will be considered as reference intervals for glycemia in therapeutic targets 70–99 mg / dL and 100–149 mg / dL, as no fasting was required before vaccination.

Thus, for patients with type 1 diabetes, there are a number of 5 cases that fall within the target range, one case of hypoglycemia and 3 cases of hyperglycemia.

In the case of patients with type 2 diabetes, a number of 35 patients presented with glycemias in the therapeutic targets, 3 hypoglycemias and 15 cases of hyperglycemia were noted.

I note that prior to vaccination, 9 patients confirmed a hyperglycemic status of the disease,

falling into the group with glycemic values of over 150 mg \ dL.

The second part of the study targeted a group of 141 patients, men and women, aged between 20 and 78, from rural and urban areas.

Out of a total of 141 patients, 54 male and 87 female representatives were reported, of whom 6 men and 10 women diagnosed with diabetes were treated with oral antidiabetics and / or insulin.

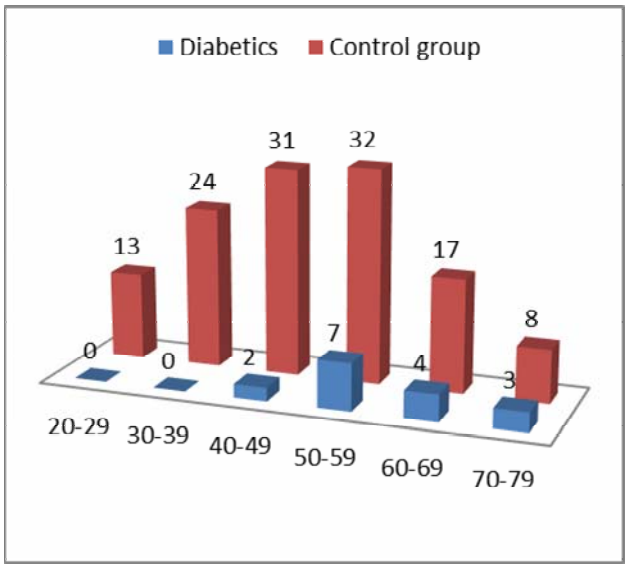


Figure 7. Age-to-age ratio for diabetic patients and control group.

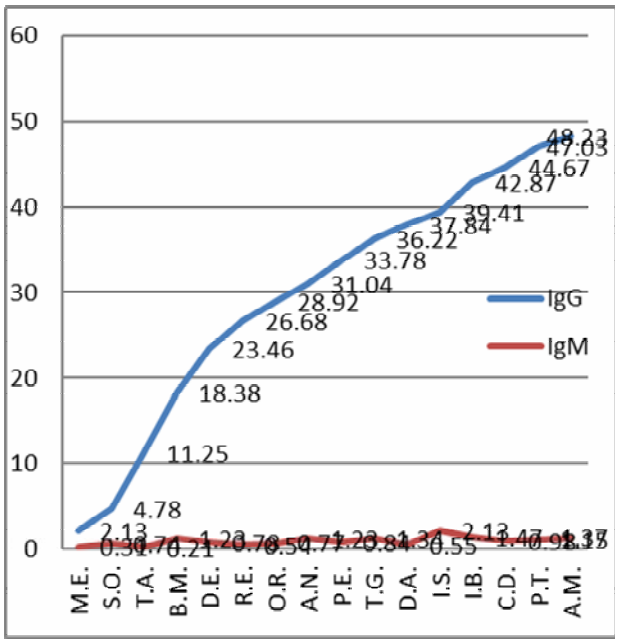
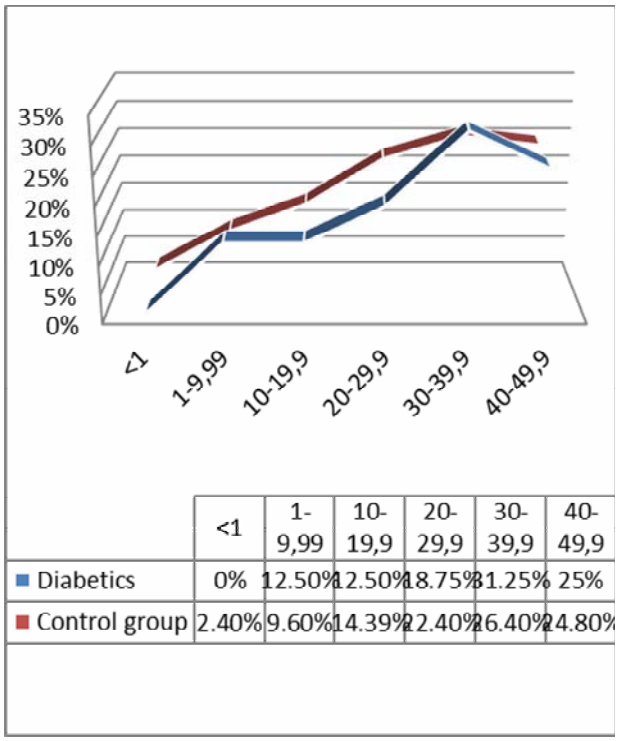


Figure 8. Anti-SARS-COV-2 IgG and IgM values of diabetic patients.

	Diabetics	Control group
< 1	0	3
1 – 9,99	2	12
10 – 19,9	2	18
20 – 29,9	3	28
30 – 39,9	5	33
40 – 49,9	4	31

Figure 9. Ratio between diabetic patients and control group for predetermined antibody intervals.



	<1	1-9,99	10-19,9	20-29,9	30-39,9	40-49,9
Diabetics	0%	12.50%	12.50%	18.75%	31.25%	25%
Control group	2.40%	9.60%	14.39%	22.40%	26.40%	24.80%

Figure 10. Percentage ratio of predetermined antibody intervals for diabetics and control group.

DISCUSSIONS

The first study group, represented entirely in diabetic patients, showed a major benefit through the increased rate of disease control (84%), as it allowed a more accurate assessment of the effects of vaccination on the glycemic profile.

Patients diagnosed with type 1 diabetes showed a significantly higher rate of glycemic variability compared to the group of patients with type 2 diabetes, the fluctuating nature of the disease being well known.[13]

In the case of patients with type 2 diabetes, a hyperglycemic status was confirmed before vaccination in 9 cases, which was maintained even after the administration of the vaccine, with values that did not influence the patient's condition.

Blood glucose monitoring for diabetic patients is a fundamental aspect in the control of the disease and it is recommended to test the blood glucose level after vaccination, in order to avoid hypo / hyperglycemic decompensation, especially for type 1 diabetes.

The side effects confirmed in the study group are comparable to those described in clinical trials and did not endanger any patient. Pain at the site of administration was the most common symptom, followed by manifestations specific to an inflammatory / infectious syndrome – headache, low-grade fever / fever, chills, myalgias / arthralgias.[10]

Nearly half of the patients reported no post-vaccination side effects, which supports the recommendation of immunization for diabetics – given the risk-benefit ratio to the general population. The affinity of the SARS-COV-2 virus to high glucose levels and obesity is known, as it promotes viral multiplication and aggravation of the disease through its pro-inflammatory status. [2, 14]

The second group of studies showed a percentage of 11% diabetic patients, who managed to generate a post-vaccination immune response, regardless of age, sex, antidiabetic treatment.

IgG and IgM antibody levels are comparable to the control group of 125 patients without diabetes, ranging from 2.13 to 48.33 for diabetics. Although not a quantitative test, but a semi-qualitative one was used, the presence of antibodies (over 1) indicates an immune response aimed at protection against COVID-19.

Also, there were 3 cases in the control group that did not develop specific post-vaccination antibodies, results comparable to the available data from other studies. [10]

CONCLUSIONS

Systematic glycemic monitoring is essential, both before and after vaccination – in order to promptly correct any imbalance in the course of diabetes.

Post-vaccination side effects in diabetic patients do not show significant differences from the general population and glycemic variability is present, especially in type 1 diabetes.

The immune response of diabetic patients to the COVID-19 vaccine is superior but without statistical significance.

The results of the present study certify the priority indication of diabetic vaccination compared to the general population, given the benefits obtained.

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