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A new complication after receiving the MRNA12-73 (Moderna) vaccine for Coronavirus disease (COVID-19) in Iran: A case report

Shahla.Abolghasemi
Assistant Professor, Division of Rheumatology, Department of Internal Medicine, Faculty of Medicine, Tehran Medical Sciences, Islamic Azad University, Tehran, Iran

Mahnaz Valizadeh
Assistant Professor, Department of Internal Disease, Faculty of medicine, Amir-al-Momenin Hospital Tehran Medical Sciences Branch, Islamic Azad University Tehran, Iran

Maedeh.Olya
MD, Young Researchers and Elite Club, Tehran Medical Sciences, Islamic Azad University, Tehran, Iran

Maedeh Olya
MD, Young Researchers and Elite Club, Tehran Medical Sciences, Islamic Azad University, Tehran, Iran
Medical Sciences Research Committee (MSRC) Tel: +98 9333955381
Corresponding Author, email: maedeh.olya297@gmail.com

Abstract---Introduction: The recent pandemic of the SARS-CoV-2 virus has significantly increased the mortality and disability burden in many people worldwide. Several effective vaccines have been introduced since the outbreak of the coronavirus. These vaccines work through several different immunization pathways to create effective immunity. In this respect, there have been no reports of patients with symptoms of lumbar radiculopathy and puffiness of the hands after receiving corona vaccines. This article presents a clinical case report of these symptoms after receiving the MRNA12-73 (Moderna) vaccine. Overall, finding effective, low-complication, and safe solutions against this virus can have a beneficial effect in reducing the side effects of the Corona vaccine and maintaining the health and lives of people. Case history: A 73-year-old male patient developed lumbar radiculopathy and puffy hands after receiving the corona (COVID-19) vaccine. He was infected with COVID-19 about 60 days after receiving the MRNA12-73 (Moderna) vaccine. Conclusion: Attention to the

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occurrence of any side effects after injecting corona vaccines requires additional studies. It is also important to follow up on any clinical signs of suspected coronary involvement, even after the vaccination. It is hoped that this case contributes to the research literature in this field and raises awareness about this type of supply after receiving the MRNA12-73 vaccine.

Keywords---*MRNA12-73 vaccine; Corona pandemic (SARS-CoV-2); Lumbar radiculopathy; Puffy hands; Vaccine side effects.*

Introduction

The pandemic SARS-CoV-2 virus, first recognized in China in 2019, is one of the most challenging events of the last century [1]. This highly contagious virus spread rapidly from China to other countries worldwide [2] and caused symptoms from mild to life-threatening and even acute respiratory syndromes. Although the symptoms are mild in most cases, the symptoms occur more severely in 5 to 10% of people. So far, 4,995,412 people in the world have died due to the disease, and many patients suffered decreased function and increased disability [3]. Despite numerous treatment regimens proposed since the beginning of the pandemic, none of them is a definitive solution for the complete cure of this disease and elimination of complications. As the risks of this illness are high and some complications last long, prevention can be the best measure to reduce mortality and disability [4].

Currently, vaccine intake is considered to deal with this virus such that different types of corona vaccines have been produced for this purpose [4, 5]. The Moderna vaccine (mRNA-1273) is one of the vaccines approved by the US Food and Drug Administration (FDA) in 2020 to prevent COVID-19 infection [6-8]. According to the Advisory Committee on Immunization Practices (ACIP) recommendation, two doses of this vaccine are prescribed intramuscularly with a 28- day interval for people above 18 years. The efficiency of this vaccine has been reported about 94.1% [9]. Moderna contains mRNA and encodes one of the proteins of the COVID-19 virus. The vaccine is contained in a capsule of lipid nanoparticles [10]. The immunogenicity and efficacy of the Moderna vaccine have been evaluated on some adults in several clinical trials. Different age groups, races, genders, and susceptible groups proved no difference in this vaccine's effectiveness and efficacy levels [9]. A large population-based study reported an allergic reaction to this vaccine at a rate of 1.31 cases per million doses of vaccine (95% confidence interval, 0.9-1.840; no mortality was reported [11].

Although the vaccination is being performed globally, people are still likely to get infected and show side effects. Some studies have reported that certain compounds and adjuvants in different vaccines can induce other autoimmune and inflammatory reactions through stimulating immunogenic cross-reactions in susceptible individuals [12]. While some of these complications have been predicted, new complications can also emerge. Overall, the messenger RNA-based immunization program COVID-19 (mRNA) has raised ongoing concerns, questions, and debates among the public population in the United States about

the safety issues of both new mRNA vaccines [13-15]. However, there is limited data and literature on complications through examining organ systems and demographic factors such as age, gender, education level, and ethnicity. To date, there have been no reports of lumbar radiculopathy and puffiness following the vaccine intakes. Therefore, this study examined a human case with a new complication (lumbar radiculopathy and puffy hands) after receiving the Moderna vaccine (MRNA12-73).

Patient Introduction:

A 73-year-old man suffered radicular pain in his back and puffiness of both hands in the wrists area and his hands 12 h after receiving the first dose of MRNA12-73 vaccine on 17/04/2021 in Canada (Fig1). These symptoms were recovered after two weeks, but they relapsed more severely after receiving the second dose of the vaccine. Before leaving Iran to receive the Corona vaccine in Canada, the patient underwent a Realtime-PCR test to determine whether he was infected with the coronavirus and the test result was negative.

After returning to Iran from Canada, the patient was referred to the Rheumatology Clinic of Bouali Hospital on 27/05/2021. The first visit revealed stability of the patient's vital signs (HR: 82, RR: 13, BP: 130/80, BT: 5.36) and body mass index (BMI) was also in the normal range. The patient had no underlying disease other than hypertension, which required treatment and follow-up. The patient's medications included losartan 25 mg daily, amlodipine 5 mg daily, 500 mg calcium tablets every night, and D-pearls 50,000 units 1 per month. In clinical examination, the left leg LASIK test was positive at a 60° angle, and restriction of active and inactive movements was found in metacarpophalangeal (MP) and proximal interphalangeal (PIP) joints in both hands. Weight loss of about 2.5 kg from the first dose intake until now was recorded in the patient's file. According to the patient's condition and clinical examination, the following necessary tests were requested:

Complete Blood Count (CBC), Fasting Blood Sugar (FBS), Blood Sedimentation Rate (ESR), Alanine Transaminases (ALT-AST), Alkaline Phosphatase (ALKP), Hepatitis B Antigen (HBS-Ag), Hepatitis C Antibody (HCV-ab), Prothrombin time (PT), partial thromboplastin time (PTT), international normalized ratio (INR), blood albumin (Alb), protein total, activated protein c (CRP), total bilirubin, direct bilirubin, fibrinogen , Aldolase, thyroid function tests, rheumatoid factor (RF), uric acid, antinuclear antibody (ANA), anti-smooth muscle antibody (ASMA), prostate specific antigen (PSA), liver and kidney microsomal antibody type 1 (ALKM1- AB), Anti-mitochondrial antibody (AMA), Anticardiolipin antibody, Anti-neutrophil cytoplasmic antibody (C-ANCA), Myeloperoxidase (P-ANCA) antibody, examination of 24-hour stool and urine samples, lactate dehydrogenase enzyme, ferritin, creatinine phosphokinase (CPK), serum iron, lupus coagulant antibody, anti-DNA (Anti. dsDNA), acquired human immunodeficiency virus (HIV) antibody, serum protein electrophoresis, Urea (BUN), Creatinine (CR), complements (CH50, C4, C3), sodium (Na), calcium (Ca), potassium (k), and phosphorus (P) (Table1).

The graphic image of the patient's hand was normal. After witnessing the available evidence and unwanted weight loss, the patient was asked for a without-

contrast CT scan of the abdomen, pelvis, and lungs to rule out malignancies and an MRI of the intervertebral disc L5-S1 (lumbosacral joint) to evaluate radicular pain. In addition, the patient underwent an ultrasound of both hands and axillary areas on 29/05/2021. The test results showed no evidence in favor of lymphadenopathy, and the axillary lymph nodes of both hands had oval central helium with normal dimensions. A lumbosacral MRI performed on 30/05/2021 showed no evidence of intervertebral disc herniation, fracture, and vertebral dislocation. Overall, normal soft tissue was reported for this case.

The patient returned to the Rheumatology Clinic on 09/06//2021 to present the requested tests. As shown in Table 1, all the requested factors except CRP and ESR were within the normal range. This time, the patient experienced a reduction in radicular pain and puffiness of his hands. The patient was referred eight days later due to suffering from fever and dry cough that started three nights before. Depending on his conditions, CT scans were recommended. The patient referred again three days later with worsened weakness and lethargy. A pulmonary CT scan showed lesions suspected of COVID-19 involvement (Fig2). About 24 hours after hospitalization, the patient's PCR test was positive. An infectious disease specialist treated him, and a five-day regimen of remdesivir, heparin, and oxygen therapy was prescribed for him. Finally, after 9 days, the patient was discharged while he was in stable general conditions (HR: 98, RR: 15, BT: 37.8, BP: 140/70, SPO2: 89%) with reduced severity of symptoms following hospitalization and increased percentage of blood oxygen saturation.

Discussion:

There are significant global efforts to develop an effective and safe vaccine to reduce mortality and the incidence of COVID-19 in the general population. Reports of SARS-CoV-2 vaccination indicate a reduction in infection rate, length of hospitalization, and mortality rate [16]. Currently, several vaccines are being used that reduce the complications and death rate [17]. However, some people are still in doubt about getting the vaccine, and they are even worried and afraid to receive it. In a study conducted on American medical students, although all vaccines had a positive attitude toward the vaccination, only 53% of the samples participated in the vaccination intake, and 23% were reluctant to get the vaccine licensed to be used in emergency conditions. These results indicate the need to hold educational workshops to explain the benefits and effects of vaccination and compare them with the possible side effects [18, 19].

The side effects of vaccination include systemic, topical, immune, and non-immune issues that can occur acutely or chronically. Fever, allergic skin reactions, injection site pain, flu-like symptoms, headache, fatigue, joint pain, sweating, hypotension, nausea, bronchospasm, angioedema, and anaphylactic shock are common complications of the vaccine intake [9, 20]. Typically, non-immune reactions occur more commonly than immune ones, each with different prevalence. For example, anaphylactic shock often occurs in people with an atopic background and with a probability of 11.1 in 1,000,000 in the Pfizer vaccine and 2.5 in 1,000,000 in the MRNA12-73 vaccine. Immune reactions types-1 to -4 are effective in arising side effects. Moreover, increased activity of interleukins 9, 17,

13, 10, and 8 and immunological reactions can occur in response to antigens, stabilizers, and other elements in the vaccine [21].

To date, no unexpected and far-fetched side effects have been reported for the MRNA12-73 vaccine intake. The Centers for Disease Control and Prevention (CDC) estimated that anaphylactic reactions (including symptoms of difficulty in breathing, swelling and puffiness of the face and throat, skin rash, and low blood pressure) occur immediately after vaccination in 2.5 cases per million doses in people receiving mRNA-1273 vaccine [22]. In this respect, chronic underlying conditions such as heart disease, cancer, stroke, pulmonary embolism, and even poor immune system and health status of the patient are considered the causes of death [23]. Common adverse reactions to mRNA vaccines (e.g., fever, nausea, and diarrhea) may lead to mortality in some weak patients. Besides, headache and arthralgia (joint pain) are the most common issues after receiving this type of vaccine in 50% of the recipients. Most of the less common problems occur about 14 days following the vaccine intake. However, in the reported case, the puffiness of the hands began within 12 h. Niebel D. et al. (2021) reported severe joint pain, skin symptoms similar to lupus erythematosus, fatigue, and vomiting, but no fever, after MRNA12-73 vaccine intake in a 22-year-old female patient with hypothyroidism. The test results and lack of family history of lupus erythematosus made the specialists attribute these symptoms to corona vaccination [24]. Another study divided the skin side effects of the MRNA12-73 vaccine into early and late (on average after eight days). Contrary to the discussed patient, most of the less common skin complications, such as lesions larger than 10 cm, also appeared late [16, 25].

Puffiness of the organs may happen during specific diseases such as lymphatic system disorders, malignancies, rheumatic, heart, and kidney diseases, which are also mentioned in the differential diagnosis with puffy hand syndrome. This syndrome, similar to the one studied, may lead to arrhythmias, swelling, non-concave edema, and limited movement of hands. This rare syndrome occurs in 7 to 16% of injecting drug users, and the diagnosis will be confirmed after the other causes are rejected. Meanwhile, in this case, without any underlying cause, the complication arose after the vaccine intake and resolved spontaneously. The recurrence of complications following the second injection strengthens the link between these side effects and vaccination [26]. In a study by Austria et al., the first report of puffiness and edema in the eye area was reported in three patients 1 to 2 days after injecting the Pfizer vaccine containing mRNA [27]. The authors of this study have linked swelling in the eye area (mainly more in the eyelid area) to completed activation after vaccine intake, which increased the completion of plasma mediators and tears film.

Radiculopathy in the lumbar area is another complication observed in the patient under investigation. The previous studies proved no such complication in any healthy patient with no underlying problem after injecting the Moderna vaccine. Although the cause of the side effects or reaction to the mRNA-1273 vaccine is not yet fully understood, various side effects are likely to occur after corona vaccines intake. Careful follow-up of patients from the moment of injection to a relatively long time is required to record the side effects of corona vaccines. According to CDC guidelines, anyone vaccinated with the Moderna vaccine should be

monitored for at least 15 min after receiving the vaccine, and epinephrine should be available at the vaccination site in case of emergency need. The vaccine contains an inactive or auxiliary substance (including egg protein, gelatin, formaldehyde, thimerosal, or neomycin) and has no active ingredients that can cause allergic reactions. The CDC prohibits using any COVID-19 vaccine containing mRNA in individuals with anaphylaxis history to polyethylene glycol (PEG), PEG derivatives, or polysorbate. Auxiliaries (used in vaccines to stimulate stronger immune responses, prevent bacterial contamination, and stabilize vaccine potency during transport and storage) are major triggers for specific IgE reactions and vaccine-related immediate reactions [9, 28]. Several SARS-CoV-2 proteins cross-react with human proteins and can lead to autoimmunity. Moreover, glycoprotein antibodies of mRNA vaccines can elicit an acute autoimmune response [27].

Overall, vaccination can reduce the severity of clinical symptoms and the length of hospitalization depending on the individual's condition. As a result, the patient does not suffer long-term and annoying complications. Despite the positive and outstanding effects and high efficacy of vaccines, there is still the possibility of getting infected by the coronavirus. This result indicates the necessity of implementing health instructions until the majority is fully vaccinated. Also, enough attention must be paid to any clinical symptoms even after the vaccine intake, and referring early to medical centers should be taken seriously.

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There was no fund.

Conflict of interests:

There was no conflict of interest in this study.

Ethical Approval:

The ethical approval of this research was issued by the Medical Ethics Committee of Islamic Azad Tehran Medical Science University Pharmacy and Pharmaceutical Branches Faculty, Iran (IR.IAU.PS.REC.1400.441).

Consent to practice and consent to participate:

The patient provided informed consent about data collection and publication in a scientific paper. He was briefed about the data collection process and data publication. In addition, he was ensured about the confidentiality of his personal information orally and in writing through an informed consent form signed by him.

Availability of data and material:
Not applicable

Code availability (software application or custom code):
Not applicable

Authors' contributions:
all of us collected the information, wrote and edited the manuscript together.

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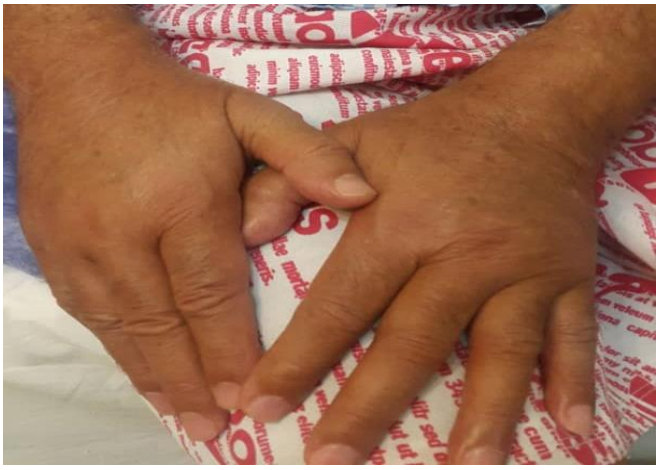

Fig. 1. Swelling and puffiness of the hands following the injection of MRNA12-73 vaccine

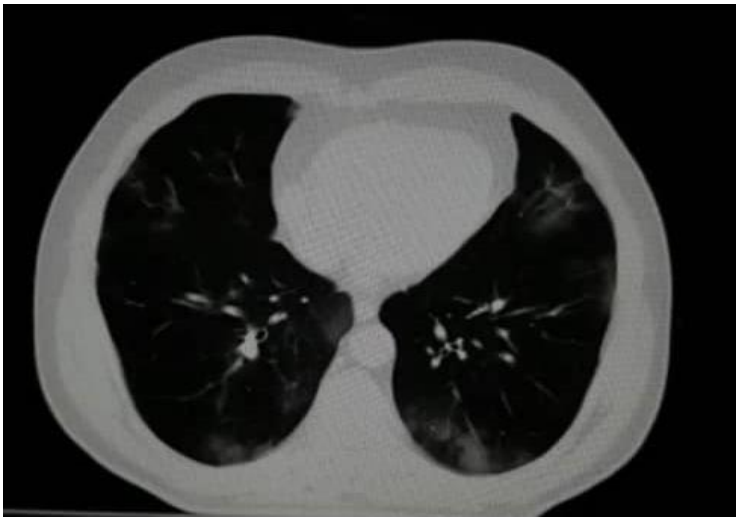

Fig. 2. CT scan of the patient's lung after the emergence of clinical symptoms of suspected COVID-19

Table 1. Results of the patient's tests

Parameters	Result	Normal range	Unit
FIBRINOGEN	172	200-400	Mg/dl
ALDOLASE	3.1	Up to 7.6	U/L
TSH	2.1	0.3-5.2	uIU/ml
RF	3	Up to 14	IU/ml
URIC ACID	5.1	4.4-6.7	Mg/dl
ANA	Negative	<1/10	Negative/Positive
ASMA	Negative	<1/20	Negative/Positive
PSA	5.1	<6.4	ng/dl
ALKM1	11	<20	Ru/ml
AMA	Negative	<1/20	Negative/Positive
C-ANCA	1	<5	U/ml
P-ANCA	1.1	<5	U/ml
LDH	111	100-190	U/L
FERITTIN	58	20-300	ng/dl
CPK	96	24-195	U/L
ANTI.DS.DNA	9	<70	Iu/mL
BUN	11	7.9-20	Mg/dl
CR	0.9	0.8-1.3	Mg/dl
C3	109	75-135	Mg/dl
C4	51	12-72	Mg/dl
CH50	161	100-300	U/ml
NA	141	134-145	mEq/l
CA	9.1	8.5-10.5	Mg/dl
K	4.1	3.5-5	mEq/l
P	3.9	3-4.5	Mg/dl
ANTI.CARDIOLIPIN	0.9	<10	U/ml
LUPUS.ANTICOAGULANT	8	<20	Ru/ml
HB	13.6	13-17.5	g/dl

WBC	9.00	4.20-11	1000/UL
PLT	278	140-440	1000/UL
FBS	91	70-99	Mg/dl
ESR	42	<30	Mm/hours
ALT	39	<41	U/L
AST	34	<37	U/L
ALKP	225	64-306	U/L
PT	11	10-14	Seconds
PTT	38	32-45	Seconds
ALB	4.2	3.5-5	g/dl
BIL (D)	2.2	0.1-0.3	Mg/dl
BIL (T)	0.8	0.3-1	Mg/dl
CRP	13	<6	Mg/dl