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Determination of COVID-19 Late Disorders as Possible Long-COVID and/or Vaccination Consequences

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Abstract

In this era in which the vast majority of the global population have developed COVID-19 infection and/or got vaccinated against it, identification of the late disorders as the vaccines' side effect or long-COVID manifestation seems essential. This study included the vaccinated individuals of 4 different vaccine regimens including inactivated virus-based, subunit protein, and adenovirus-based vaccines in a follow-up schedule 6-month post the booster shot. All the documented vaccine adverse events were thoroughly assessed considering the cases' medical history by Adverse Events Committee of Pasteur Institute of Iran. Totally 329 individuals who got 3 doses of vaccination were followed 6 months after the booster shots among whom 41 (12.4%) cases with the mean age of 40.9 ± 10.48 years had a type of disorder. Gynecological and osteoarticular involvements were the most common recorded disorders of which 73.1% were possibly linked to vaccination outcomes and the rest were affected by both long-COVID-19 and vaccination. Notably, the average time of symptoms persistence was 155 ± 10.4 days. This study has the advantage of long-term follow-up which presents various forms of late events in each episode of COVID-19 infection and vaccination. About 26.8% of people with persistent complications suffered from both long-COVOD/ vaccination in whom the differentiation between the vaccine side effect and long-COVID manifestation was quite challenging. Long-term follow-up studies in large population seems essential to outline the role of long-COVID and vaccination regarding persistent complications.

Keywords

late AEs, long-COVID, long-VAX, long-term disorders, vaccine outcome

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Introduction

As the world has overcome the recent COVID-19 pandemic, owing to the great effort on vaccine development, the struggle against the long-term effects of the infection has emerged as a pandemic post the other one called "long-COVID."[1,2] Long-COVID is a condition occurring in individuals with a background of any probable or confirmed SARS-CoV-2 infection in which the symptoms usually appears 3 months after the COVID-19 symptoms onset and continue at least for 2 months This condition can affect a wide range of organs in the body with various presentations.[3,4]

On the other hand, vaccinated individuals against COVID-19 might develop asymptomatic form of the infection or even suffer from mild to moderate forms of COVID-19.[5] There have been many case reports of individuals who had new onset of a disorder post vaccination with or without a history of COVID-19.[6] Although vaccination against COVID-19 has been a crucial step to manage the pandemic and has undoubtedly decreased the severity of the disease as well as the risk of hospitalization, uncertainties about the late side effects have brought concerns in the general population. This issue may cause vaccine hesitancy which is potentially important for next probable new COVID-19 peaks and need of booster doses.[7,8] Therefore, COVID-19 vaccines could possibly affect long-COVID

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symptoms though when a late disorder or a new onset appears, it might stem from either the infection or the vaccination.

There have been studies showing that vaccines might reduce the risk of long-COVID.[9,10] A crucial factor to determine this issue is the time of infection and vaccination. It seems that vaccination before infection might limit the risk of long-COVID incidence.[11] What is still unknown, is the re-infection impact which could give a rise to long-COVID persistence and more unsolicited events. From another point of view, long-term manifestations of vaccination have been also come to attention by evidences and case reports worldwide. The late adverse events are thought to be rare, however, they may cause seriously durable problems and influence the life quality as well. Furthermore, the majority of the global population have already been immunized and may still develop the infection in this era. To determine that a long-term symptom is the long-COVID manifestation or the vaccination-related side effects is a challenging issue to address.[12] Therefore, in addition to the current vaccine safety reports and long-COVID studies, it is of high value to investigate the symptomology of SARS-CoV-2 infection before and after vaccination and also to estimate associations between long-COVID symptoms and vaccination consequences. The long-term assessment of late disorders post-COVID-19 vaccination was previously investigated.[13] This study aimed at studying the possible cause of long-term complications in different population to assess the role of SARS-CoV-2 as long-COVID and vaccines' late adverse events.

Methods

In this follow-up study, we investigated vaccinated individuals from the first dose of COVID-19 vaccination up to at least 6-month post the booster shot. The studied population are selected from participants of vaccination program in Pasteur Institute of Iran, a subgroup from conducted studies, and also new cases with a sort of late complication who attended the assessment sessions, provided sufficient data, and completed the study requirements. The participants were classified by the vaccine regimes including standard and combinational ones as:

(1) The individuals who got 2 doses of Sinopharm and got a booster dose of PastoCovac or PastoCovac Plus (protein subunit vaccines),[14]
(2) The individuals who got 2 doses of AstraZeneca and got a booster dose of PastoCovac Plus,[15]
(3) The individuals who got 3 doses of Sinopharm, and
(4) The individuals who got 3 doses of AstreaZeneca.

After each dose of vaccination, the researcher-designed questionnaire was completed by a trained expert face-to-face. The long-term follow-up was done through phone-calls on days 7, 14, 28, and 180 post each dose. The full medical history of the participants was collected through face-to-face interview or on call including any underlying diseases, COVID-19 history, time of incidence, symptoms, vaccine doses, any kind of adverse events (AEs), medical care, hospitalization, and symptoms persistence. The collected AEs during an 18-month period (6 months after the booster dose) were then evaluated by AEs assessment committee of Pasteur Institute of Iran, to associate any causal inference of AEs with the vaccine/COVID-19.

The documented disorders were categorized according to the opinions of AEs assessment committee' members including Immunologists, Gynecologists, Internal Medicine Specialists, Epidemiologists, and Infectious Diseases Specialists.

Descriptive statistics are presented as means (SD) for quantitative variables and as frequency (percentage) for categorical variables. All statistical analyses were performed with Stata software (version 17).

All the participants were provided with informed consent prior to enrollment and the study protocol was in accordance with the Declaration of Helsinki (Anonymized).

Results

Participants

Totally, 329 individuals participated in the follow-up study (171 females, 158 males) with the mean age of 40.9 (SD = 13.2) and the mean BMI of 26.56 (SD = 4.58).

The medical history showed that the most common underlying diseases were thyroid disorders (7.2%), hypertension (5.4%), and diabetes mellitus (4.5%), respectively.

Of the total population, 76 ones received 3 doses of Sinopharm vaccine, 109 individuals got 2 doses of Sinopharm + 1 dose of PastoCovac Plus, 54 participants got 2 doses of Sinopharm + 1 dose of PastoCovac, 69 persons got 2 doses of AstraZeneca + 1 dose of PastoCovac Plus, and 21 individuals received 3 doses of AstraZeneca vaccine.

Long-term symptoms classification

During the follow-up all the reported disorders were collected into a researcher made form by trained experts according to the time of the incidence and duration. Only, the late AEs which started post-21-day after each dose of vaccination were considered in this study.

The collective data showed that in total, 41 individuals (12.46%) had at least 1 disorder following vaccination (31 females, 12 males) with a mean age of 40.9 ± 10.48, among whom menstrual problems (discussed elsewhere), hair loss, osteoarticular disorders, neuritis at the injection site, headache, and skin manifestations were the most common, respectively (Table 1).

Table 1. The Clinical Characteristics of Vaccinated Cases Against COVID-19 With Persistent Complications.

Case no.	Gender	Age (years)	BMI	Disorder type	COVID-19 vaccine regimen	Time of disorder initiation	Persistency of the disorder (days)	Underlying medical conditions	COVID-19 history	Vaccine	Long –COVID-19
										Possible cause	
1	Female	44	22.5	Menstrual	Sinopharm/ PastoCovac plus	After each dose	30	—	9 months after the booster dose	✓	—
2	Female	31	25.1	Menstrual and hair loss	Sinopharm/ PastoCovac plus	Post the booster dose	180	—	2 weeks after the booster	✓	✓
3	Female	41	24	Joints involvement	Sinopharm/ PastoCovac plus	Post the booster dose	180	hypertension	3 months before vaccination	✓	—
4	Male	51	25.7	Morphea	Sinopharm/ PastoCovac plus	Post the booster dose	180	—	6 months before vaccination	✓	—
5	Female	46	35.3	Skin rashes	Sinopharm/ PastoCovac plus	Post the booster dose	180	Endometriosis & polycystic ovary	1 month after the booster	✓	✓
6	Male	42	22.7	Skin rashes	Sinopharm/ PastoCovac plus	Post the booster dose	180	IBS	—	✓	—
7	Female	52	23.3	Hair loss	Sinopharm/ PastoCovac plus	Post the booster dose	90	—	—	✓	—
8	Female	42	30.9	Joints involvement	Sinopharm/ PastoCovac plus	Post the first dose	180	Asthma	2 months before vaccination and shortly after the first dose	✓	✓
9	Female	54	34.9	Joints inflammation worsening	Sinopharm/ PastoCovac plus	Post the booster dose	180	Joints inflammation	2 months before vaccination	✓	—
10	Female	37	31.9	Hair loss	AstraZeneca/ PastoCovac plus	Post the booster dose	180	Hypothyroidism	6 months after the booster shot	✓	—
11	Female	50	26.5	Pain at the injection site	Sinopharm/ PastoCovac plus	Post the booster dose	180	—	—	✓	—
12	Female	37	25.2	Pain at the injection site	Sinopharm/ PastoCovac	Post the booster dose	30	—	—	✓	—
13	Male	38	32.7	Blurred vision	Sinopharm/ PastoCovac	Post the booster dose	180	—	1 year before vaccination	✓	—
14	Female	44	28.7	Menstrual and hyperlipidemia (worsening)	AstraZeneca/ PastoCovac plus	Post the booster dose	180	hyperlipidemia	8 months after the booster dose	✓	—
15	Male	42	27.2	Joints inflammation	AstraZeneca/ PastoCovac plus	Post the booster dose	90	hyperlipidemia	2 months after the booster	✓	—
16	Female	66	25.9	Hair loss	AstraZeneca/ PastoCovac plus	Post the first dose	180	—	1 year before vaccination	✓	—
17	Female	33	22.5	Menstrual	AstraZeneca/ PastoCovac plus	Post the first dose	180	—	1 month post the booster	✓	—
18	Male	37	25	headache	AstraZeneca/ PastoCovac plus	Post the second dose	180	—	7 months before vaccination and post each dose	✓	✓
19	Female	27	20.8	Hair loss	AstraZeneca/ PastoCovac plus	Post the booster dose	180	—	—	✓	—

(continued)

Table 1. (continued)

Case no.	Gender	Age (years)	BMI	Disorder type	COVID-19 vaccine regimen	Time of disorder initiation	Persistency of the disorder (days)	Underlying medical conditions	COVID-19 history	Vaccine Possible cause	Long –COVID-19
20	Female	32	26	Menstrual	AstraZeneca/ PastoCovac plus	Post each dose	90	Hypothyroidism	2 months after the first dose and 2 months after the booster dose	✓	✓
21	Female	42	29.1	Menstrual	AstraZeneca/ PastoCovac plus	Post the second dose	180	—	7 months before vaccination	✓	—
22	Female	45	23.6	Menstrual	AstraZeneca/ PastoCovac plus	Post the first dose	60	Hypothyroidism & hyperlipidemia	6 months post the booster dose	✓	—
23	Female	37	36.2	Joints inflammation	Sinopharm/ PastoCovac	Post the booster dose	180	—	10 months before vaccination	✓	—
24	Male	52	30.7	Joints involvement	Sinopharm/ PastoCovac	Post the booster dose	180	Hypertension	3 months before vaccination		—
25	Female	22	29.8	Flu-like symptoms	Sinopharm/ PastoCovac	Post the booster dose	180	—	1 month after the booster shot	✓	✓
26	Female	38	21.6	Hair loss	Sinopharm/ PastoCovac	Post the booster dose	180	—	5 months post booster	✓	—
27	Female	23	23.9	Hair loss	Sinopharm/ PastoCovac	Post the booster dose	180	—	Shortly after the second dose	✓	✓
28	Female	44	24.1	Hypothyroidism worsening	Sinopharm/ PastoCovac	Post the booster dose	180	Hypothyroidism	4 months before vaccination	✓	—
29	Female	42	19.4	Headache	Sinopharm/ PastoCovac	Post the booster dose	180	Anemia	2 months before vaccination and 2 months after the second dose	✓	✓
30	Female	24	23.2	Hair loss	Sinopharm/ PastoCovac	Post the booster dose	180	—	2 months after the second dose	✓	✓
31	Male	55	34.7	Hyperglycemia	Sinopharm/ Sinopharm	Post the booster dose	180	Hypertension	—	✓	—
32	Male	42	34.5	Gastritis	Sinopharm/ Sinopharm	Post the booster dose	180	—	4 months before vaccination	✓	—
33	Female	56	23	Muscles involvement	Sinopharm/ Sinopharm	Post the booster dose	180	Hypothyroidism	—	✓	—
34	Male	22	22.5	Hypertension	Sinopharm/ Sinopharm	Post the booster dose	180	—	—	✓	—
35	Female	21	23.7	Muscles involvement	Sinopharm/ Sinopharm	Post the booster dose	180	—	5 months before vaccination and 2 months post the second dose	✓	

(continued)

Table 1. (continued)

Case no.	Gender	Age (years)	BMI	Disorder type	COVID-19 vaccine regimen	Time of disorder initiation	Persistency of the disorder (days)	Underlying medical conditions	COVID-19 history	Vaccine	Long –COVID-19
										Possible cause	
36	Female	59	25.6	Pain at the injection site	Sinopharm/ Sinopharm	Post the booster dose	180	—	—	✓	—
37	Female	44	29.4	Menstrual and headache	Sinopharm/ Sinopharm	Post the booster dose	180	—	1 month after the first dose	✓	✓
38	Female	42	23.7	Pain at the injection site	Sinopharm/ Sinopharm	Post the booster dose	180	Hypothyroidism	—	✓	—
39	Female	37	25.7	headache	Sinopharm/ Sinopharm	Post the booster dose	14	Hypothyroidism	8 months before vaccination	✓	—
40	Female	49	21.6	Hives and bruises	AstraZeneca/ AstraZeneca	Post the first dose	14	—	Shortly after the booster	✓	—
41	Female	37	32.1	Menstrual	AstraZeneca/ AstraZeneca	Post the first dose	180	Hypothyroidism	8 months before vaccination and 6 months post the booster	✓	—

A total of 18 individuals (44%) had a form of underlying diseases among whom hypothyroidism was the most frequent. In fact, 8 out of 41 (19.5%) individuals with a sort of late complication suffered from hypothyroidism.

Nevertheless, the compatible comorbidity with the AEs/side effect were only hyperlipidemia and joints inflammation in 2 cases who reported worsen pre-existing condition after the vaccination. In other words, these conditions got worse after vaccination but were also manifesting before it. In general, the identified symptoms were mostly persistent up to the end of the study with a mean duration of 155 ± 10.4 days.

In order to explore the probable cause of each complication, the medical background of each case was thoroughly assessed. In addition, the duration between the symptoms initiation and COVID-19 infection/vaccination were considered as well as the SARS-CoV-2 infection /vaccination coincidence which could play as a dual effect cause of the late symptoms.

The history of COVID-19 infection and the time of vaccination showed that 39% of the individuals (n = 16) experienced COVID-19 before vaccination whereas 36.58% (n = 15) who developed COVID-19 post vaccination. Furthermore, 24.39% (n = 10) had no documented COVID-19 history or symptoms during the follow-up.

The data showed that in 26.8% (n = 11) of the studied cases both vaccination and long-COVID could be the possible causes of the persistent complication according to the AEs committee members' opinion in whom the differentiation of the main cause was challenging due to the fact that all the individuals were vaccinated and also had a history of SARS-CoV-2 infection (Tab.1). Therefore, both COVID-19 infection and vaccination could lead to the symptom initiation. Although, the comparison between the disorder initiation, COVID-19, and vaccine dose are in favor of long-COVID, we could not consider it as the certain cause. In other words, vaccine administration could act as a trigger and played like a cofactor along with COVID-19 (Figure 1).

On the other hand, in 30 cases (73.1%), the findings were in favor of vaccine effect from whom 10 cases had no documented history of the infection and therefore vaccine was considered as the main cause of the symptom initiation. In other 20 cases (of 30), also vaccination was the possible cause according to the duration between the late symptom/disorder presentation COVID-19 incidence and the cumulative data based on the comprehensive literature review.

By evaluating the vaccine doses and the incidence of the complications we found that the vast majority of the cases (75.6%) experienced a sort of disorder post the booster dose whereas 14.6% post the first dose and nearly 5% after the second injection. In fact, as the number of the vaccine doses increased, the disorder frequencies expanded. Moreover, 4.8% reported the problem post-each vaccine dose. It seems that immune system of these population responded to each vaccine antigen regardless the vaccine type.

Discussion

Persistent symptoms of COVID-19, as the long-term effect of COVID-19 has evolved recently. It is stated that nearly two-thirds of COVID-19 experienced individuals report at least 1 residual symptom even after 3 months.[16] More recently, some other reports on long-term AEs came to attention by COVID-19 vaccine implementation. This fact makes long-COVID incidence or vaccination consequences really undistinguishable. In addition to long-COVID, there is another condition which appears in a number of vaccinated individuals against COVID-19 called "Long Vax" due to the fact that symptoms have resembled long-COVID. Therefore, it could be stated that the late and persistent symptoms which initiated after the vaccination might be considered as the long-vaccine syndrome.[17] According to the urgent need of an effective vaccination against SARS-CoV-2, different platforms have been examined in clinical studies. Moreover, mix-and-match strategy has been also recommended according to the safe and effective previous vaccine studies against other infectious diseases.[18-20] and also has come to attention for COVID-19. Notably, the present studied cases were of the different platforms. Thus, the prevalence of the late AEs could be related to a specific platform. Initially, the impact of the applied vaccine was considered as the potential cause. Nevertheless, some cases had a coincidence of COVID-19 infection and a vaccine dose (shortly after the vaccine).

Generally, long-Vax symptoms and signs could be highly variable. It has been shown that long long-Vax syndrome can occur in individuals of any age, gender, and with any vaccine type.[21] In the present study, 78% of the late disorders were captured in females mostly regarding menstrual abnormalities. It might seem that the associated abnormality in women would be connected to the age or previous health condition. The both variables were taken to attention and also the history of COIVD-19 was considered as a trigger to the condition and the possible cause was accordingly presented in Tab.1. In agreement with our observation, a study in Indian population also showed that females are at a higher risk of long-term AEs post COVID-19 vaccination.[22]

It has been claimed that vaccination could possibly reduce the rate of long-COVID incidence in those who develop the infection after vaccination.[23] A long-term follow-up of a vaccinated case showed that osteoarticular and neurological complications manifested over a long period of time post primary series of vaccination by COVAXIN. Interestingly, upon the administration of the booster shot of a different platform, the symptoms improved substantially.[24] Kaur et al,[22,25] studied COVID-19 vaccine recipients 1 year post vaccination and observed high rates of long COVID/long-term AEs in those who got vaccinated after COVID-19 infection compared to whom immunized before COVID-19 infection. Nonetheless, we found no significant difference in terms of vaccine or infection priority as 39% (n = 16) of the

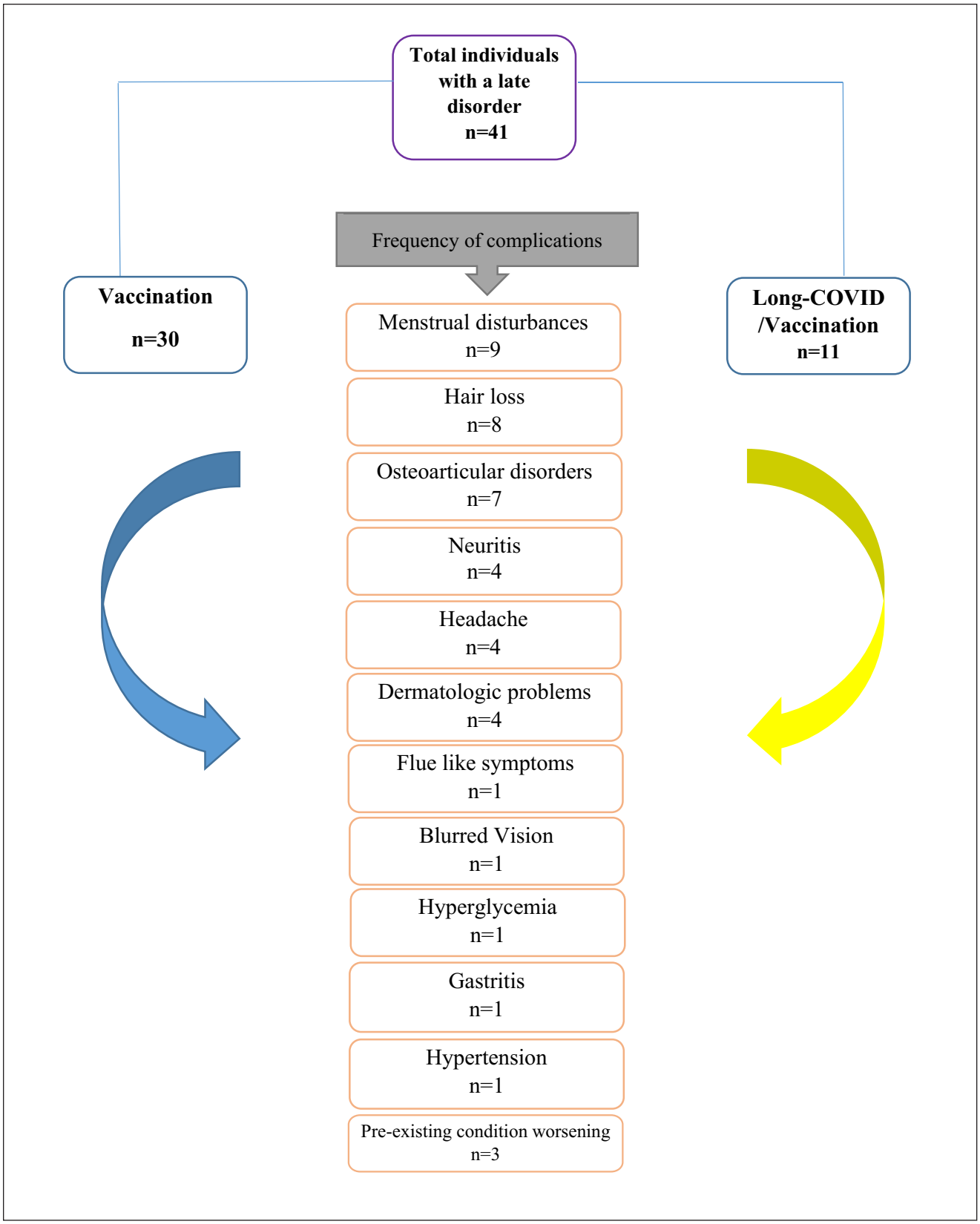

Figure 1. Characterization of persistent symptoms post COVID-19 vaccination/infection. Totally 44 complications were recorded in 41 individuals post COVID-19 and/or vaccination. Three individuals had more than 1 complication and the rate of the disorders indicate the high prevalence of menstrual disturbances and hair loss following joints and muscles involvements.

individual who experienced long-COVID/long-Vax, developed COVID-19 infection before vaccination whereas 36.58% (n = 15) who got COVID-19 after vaccination. In 24.39% of the subjects, no documented history of COVID-19 infection or symptoms was recorded. Moreover, Kaur et al.[22,25] found that hypothyroid individuals had an increased risk of long-COVID and long term AEs. In line with their results, the total prevalence of hypothyroidism in our data was 7.2%. Notably, this condition was the most frequent comorbidity among individuals with a kind of long-term disorder standing for 19.5%. Therefore, it could be a warning that hypothyroidism cases have a potential risk to experience long-term AEs post vaccination or experience long-COVID. It has been suggested that SARS-CoV-2 could trigger the activation of pre-existing autoimmune diseases. Thyroid dysfunction could directly stem from infection of the thyroid or autoimmune effects through cytokine storm-mediated effects.[26] Nevertheless, it should be considered that individuals with hypothyroidism are predisposed to some irregularities like hair loss and menstrual disturbances in whom vaccination could be a trigger as well. In this study, 3 cases with hypothyroidism experience hair loss and/or menstrual problems. Although this irregularity started after vaccination and/or a history of COVID-19, the hypothyroidism as a trigger should not be neglected.

Although we attempted to associate the incidences to the COVID-19 infection and/or vaccination, it should be taken to attention that the discussed disorders might be only spontaneous events as age, life style, or other conditions.

The advantage of this study is the long-term follow-up of vaccinated individuals through different vaccine regimens. Long-COVID could be a situation caused by the infection itself which could be similar to long-VAX condition as they both result in similar symptoms. The difficulty of defining this issue stems from largely vaccinated people who had a previous infection, a post-exposure, or reinfection. The present data evaluated some late disorders in vaccinated individuals as possible long-COVID, the vaccine side effects or the both. Further studies on probable mechanism thorough which the host cells' microenvironment could be affected by the vaccine component of different platforms are required as well as the cohort studies in nation scale to come up with the clear vision of the unknown COVID-19 aspects. However, there were some limitations in this study including small sample size, difficulty in excluding asymptomatic or mild COVID-19, and lack of unvaccinated group.

Conclusion

We experience the era in which the vast majority of people have infected by SARS-CoV-2 and/or got vaccinated against it. The vast majority of the cases, 73.1%, were suffering from vaccination outcomes. Furthermore, in 26.8% of people with persistent complications the differentiation between the vaccine side effect and long-COVID manifestation was quite challenging. The rate of late symptoms in the present study also highlights the importance of long-term follow-up studies among population worldwide. It seems that some comorbidities like hypothyroidism may lead to an increase risk of long-term adverse events post-vaccination or experiencing long-VAX. Therefore, individuals with a sort of underlying disease should be monitored during vaccination programs and more importantly be followed up post vaccination in order to detect any new onset of a disorder or even worsening of the pre-existing condition. Furthermore, the gender-related differences in the occurrence of long-term adverse events should be investigated in other studies. Considering the various rates of COVID-19 breakthrough in different populations and increasing reports on adverse events' rate in the vaccinated populations, the vaccine recommendation should be based on a revised strategy.

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