

Dr. Rohit Aggarwal answers questions about the COVID-19 vaccines for myositis patients

The following is the transcript of Dr. Aggarwal's answers to the most common questions asked by myositis patients. Thanks to all TMA members who sent questions.

Were the vaccines tested on people with autoimmune conditions and on immunosuppressive drugs?

Patients with autoimmune conditions and patients in immunosuppressed conditions were generally excluded from all of the vaccine trials. In fact, there's nothing wrong with this approach. Most vaccine trials and other trials are done like that.

It does not mean that these vaccines are not safe in autoimmune conditions or for patients in immunosuppressed conditions. Most vaccines, except the live vaccines, are safe in these patients, and we have no reason to believe that this vaccine will be any different.

More data will be available on these patients as these trials go into phase IV, or post-marketing surveillance, which is an appropriate place to evaluate autoimmune disease and immunosuppressed conditions.

To take or not take the vaccine is an individual patient decision, which should be taken after being weighing all the risks and benefits, and should be based on a discussion with your doctor

Is the vaccine effective in patients with autoimmune disease and in immunosuppressed conditions?

What we know from the data is that the vaccine was highly effective even in patients with diabetes and other co-morbid conditions, as well as elderly patients, patients above the age of 65, and patients above the age of 75. These patients with diabetes, other co-morbid conditions, and patients who are 60 or 70 years old have somewhat compromised immune systems, so if you extrapolate that result to our immunocompromised patients you would say perhaps the vaccine would be effective in this population as well. We do know that our immunosuppressed patients generally mount a less strong response to any vaccine.

In most cases, this less strong response is significant enough or sufficient enough to protect even those patients from serious viral and other illnesses.

Lastly, from the experience of previous vaccine development, we know that generally the vaccines are effective in patients with autoimmune conditions as well as patients taking immunosuppressive medications.

Is the COVID-19 vaccine safe in patients with autoimmune conditions and on immunosuppressive medications?

Typically we do not recommend live vaccines in patients in an immune suppressed condition. However, fortunately none of the late-stage vaccines currently in development in the U.S. are live vaccines, so we don't have any infection risk from these COVID-19 vaccines, even in our immune-suppressed patients.

We also know that these vaccines were very safe even in patients with diabetes and other co-morbid conditions, including lung problems, as well as the elderly population (patients 65 or 75 years of age). There is no theoretical safety risk in patients with autoimmune conditions or patients on immunosuppressive medications from these vaccines as compared to any other vaccines previously developed. Overall, to my knowledge, there are no major safety concerns about the COVID-19 vaccine. Granted, we only have average data for two to three months, and the maximum amount of data has been six months.

Should patients receiving the COVID-19 vaccine hold their immune suppressive medication before or after getting the vaccine?

We know from the flu, another vaccine, that the effectiveness of the vaccine is better if we hold immune suppression for a few weeks (perhaps two weeks) and, although we don't have any specific data for the COVID-19 vaccine, the same logic could be applied for the COVID-19 vaccine.

On the other hand, there is a risk in holding immune suppression, which can increase the risk of flare-up or worsening of the disease. We do know that even when patients on immunosuppressive medication get vaccines such as flu vaccines, they are generally protected against the virus, although this may not include everybody. Therefore, I believe that the decision of holding immune suppression—or what medication to hold and how long to hold it—should be taken by patients after discussing it with their doctors, and considering all the risks and benefits involved. We do know that there are certain medications that should be avoided prior to the vaccine. These are Rituximab, IV steroids or high doses of steroids. There are certain medications which could be taken safely while receiving vaccines. For example, IVIG and hydroxychloroquine may not affect the vaccine response at all.

Are there greater risks or side effects of the vaccine in patients with autoimmune conditions or patients with ongoing arthritis or myositis?

Although we don't have specific data on patients with autoimmune conditions, we know that generally the COVID-19 vaccine is very safe. It has been studied on tens of thousands of patients. It does have some common side effects, which are seen in any vaccine: for example, an injection-site reaction with pain and swelling, which generally resolves in a few days. Patients can develop fever, muscle pain, joint pain, chills, headache, fatigue, or nausea. These are common side effects and generally go away within a few days. In fact, taking a Tylenol post-vaccine might help mitigate even these side effects.

Will patients with autoimmune conditions get priority for these vaccines?

Regulatory bodies are developing a whole framework to decide the priority for these vaccines and it is generally divided into four phases. Phase one includes healthcare workers, patients who are elderly (above 65 years of age) and patients who have co-morbid and other underlying conditions that put them at significantly higher risk. I am not certain, but I believe patients with autoimmune conditions, especially those who are on immunosuppressive medications should be considered in phase one, as there is a high risk of developing an infection.

Were there any shortcuts taken in the development of the vaccine that may compromise the safety of the vaccine in general?

The short answer is “no.” Vaccine development is a highly-organized and monitored process. There are several regulatory bodies that monitor the clinical trial data for safety throughout the trial. Moreover, the FDA reviews all the data before giving approval. In this case, for COVID-19, the CDC has put in an extra surveillance process, given the severity and the extent of the pandemic. Everybody made this a priority and allocated their time, manpower and other resources in the development of the vaccine, including the regulatory government agencies and all Pharma. Also, COVID-19 vaccine trials were some of the largest vaccine trials ever done. Basically, the fast vaccine development is a testament to our scientific community and, as per my understanding, all steps were religiously followed.

How much and how long will the COVID-19 vaccine protect us from infection?

The Pfizer vaccine we know is 95 percent effective against COVID-19 infection.

That's a rockstar performance for any vaccine ever developed. However, durability of the response (or how long the vaccine will work) is a more difficult question. We know that there were patients who were protected for up to six months in the clinical trial and, on an average, these patients were followed for about two to three months, so we certainly hope this vaccine works at least a year or perhaps even more. but we don't know that yet. It is also possible that the vaccine can give us long-lasting immunity, but we still have to see the data.

Do I take the vaccine if I have previously recovered from COVID-19 infection?

Generally, yes. You should take the vaccine even if you have had the infection in the past. The reason is that we don't know if the antibodies that you've developed after the infection are neutralizing antibodies or not, and how long they will last in your body.

How much will the vaccine cost me as a patient?

There should be no cost to you, because the vaccine is free in the U.S and several other countries around the world. However, there may be some administrative fee or some other small fee that a patient may have to pay, which in most cases should be covered by insurance.

If I take the vaccine, does that mean that i can stop taking precautions and go about my life as usual as pre-COVID?

No, you should still continue to take precautions because we need 70 percent of the population to develop immunity to the virus, either by vaccine or by infection, for us to stop taking precautions and prevent the spread of the infection or the virus. Until then, we should continue to wear masks, perform social distancing, and continue other general measures that we are currently taking.

Do I recommend the vaccine in my autoimmune disease patients or for patients who are on immunosuppressive medications?

Absolutely yes, because the benefits of the vaccine to individual patients as well as society at large significantly outweigh some unknown long-term risk. In general, the vaccine has been proven to be very safe on tens and thousands of patients, so my last advice for you is go ahead and take the vaccine after discussing it with your doctor.