

Letter to the Editor

How to use Safely COVID-19 Vaccines in Patients on Anticoagulants or Antiaggregants

Toni Velikov¹, Georgi Keremidchiev², Tsvetelina Velikova³

¹Department of Internal Medicine, Clinic of Cardiology, University Hospital Alexandrovska, Sofia, Bulgaria.

²Assoc. Medical Director, Global TMA at IQVIA, Cardiovascular and Metabolic Diseases, Therapeutic Science and Strategy Unit, Bulgaria.

³Department of Clinical Immunology, University Hospital Lozenetz, Medical Faculty, Sofia University, St. Kliment Ohridski, 1407 Sofia, Bulgaria.

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Corresponding Author:

Tsvetelina Velikova, Department of Clinical Immunology, University Hospital Lozenetz, Medical Faculty, Sofia University, St. Kliment Ohridski, 1407 Sofia, Bulgaria.

E-mail Id:

tsvelikova@medfac.mu-sofia.bg

Orcid Id:

<https://orcid.org/0000-0002-0593-1272>

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Dear editor,

The current pandemic affected the lives of billions of individuals. The correlation between COVID-19 and cardiovascular diseases has also been documented in clinical studies. This is especially valid for patients with pre-existing cardiovascular conditions who are more prone to severe COVID-19, poorer outcomes, and elevated risk of hospitalizations and death.¹ COVID-19 itself can also cause cardiac damage with the respective manifestations mainly affecting pericardium/ myocardium, as well as vascular damage (arterial and venous), primarily causing endothelial dysfunction. The latter is observed not only in the pulmonary circulation but also in other organs. Cardiac and vascular damage are associated with various well-observed and established complications. In line with this, COVID-19 vaccines are strongly recommended to patients with Cardiovascular Diseases (CVDs).

The sole medical concern regarding COVID-19 jabs is the intramuscular injection in patients receiving anticoagulants and/ or antiaggregants. It is well-accepted that these patients should avoid intramuscular injections. However, COVID-19 vaccines are recommended for patients with CVD and bleeding disorders. Thus, they can be safely given if simple rules are applied.

Based on the previous experience with an intramuscular flu vaccine administration in patients on anticoagulant treatment, we can apply the results to the COVID-19 vaccines. A single-blinded multi-center randomized controlled clinical trial of patients on acenocoumarol and warfarin demonstrated that the intramuscular route does not lead to more side effects than the route of subcutaneous administration.² After intramuscular injection of a flu shot, the most common local reactions were: erythema (31,3%), plaque, and pruritus, whereas hematoma was observed in 0.8% of patients. Sides effects had disappeared by the 10th day after the shot. Additionally, the trial concluded that intramuscular injections of flu vaccine are safe for patients with artificial valves and higher INR levels (2,5 to 3,5), as well as for those with INR range of 2,5-4, and below 2,5, as the skin lesions in the administration area

were similar as frequency (16-18%) and according to Visual Analog Pain Scale² between the compared groups.

The Green Book (Chapter 14a) of Public Health England's Immunisation Against Infectious Disease³ states that the COVID-19 vaccine can be administered intramuscularly to persons on vitamin K antagonists (such as warfarin or acenocoumarol (Sintrom)) who are up-to-date with their planned INR tests and whose latest INR is within the upper end of the therapeutic range. However, a fine needle gauge (23-25) is recommended for vaccination, followed by an intense pressure applied to the injection site without scratching for at least two minutes. The risk of hematoma from the injection should be disclosed to the patient. Preferably, the clinician responsible for administering and controlling anticoagulant therapy should be contacted before vaccination.

People on Direct Oral Anticoagulant Treatment (DOAT) (i.e. apixaban (Eliquis), dabigatran (Pradaxa), rivaroxaban (Xarelto), edoxaban) can also have the vaccine delivered intramuscularly, according to the Green Book. The risk of hematoma after the injection can be reduced by adhering to the instructions above.

Generally speaking, the attending physicians of patients on anticoagulant treatment have the following options:

- Discontinuation of DOAT around vaccination if possible and then re-introduced
- Performing the vaccination if the anticoagulant should not be stopped with taking the above-described measures (pressing without rubbing for at least 2 minutes, etc.)

On the other hand, people with concomitant diseases such as liver and kidney failure and poor compliance may be more problematic. The reason for that is the less satisfactory dilution control with a huge-ranged fluctuation of plasma levels of coumarin and other anticoagulants. Therefore, the risk of bleeding or hematoma at the puncture site should be further considered. It is crucial to strictly monitor the INR to decide the right time for intramuscular vaccination in such cases.

Individuals with bleeding disorders may be vaccinated intramuscularly as well. Again, Intramuscular injections should be performed in a controlled way along this path. In case the individuals are administered medication/ therapy for the bleeding disorder, e.g., treatment for Haemophilia, the intramuscular vaccine can be scheduled immediately after such medication.

Conclusion

COVID-19 pandemic is continuously generating huge challenge globally for almost a year now. Despite the already quite significant amount of time, the currently

available, evidence-based therapeutic options for severe and life-threatening infection have a relatively modest effect on survival, complications, and long term consequences. However, the efforts in terms of finding prevention have achieved remarkable progress, and now there are already a number of safe and effective vaccines approved for use and already actively applied to the population. Undoubtedly, vaccines have the potential to change the course of the battle with the pandemic on a personal and population level. However, an individual approach to evaluate the appropriateness of vaccine application should be adopted. An important subgroup of patients with increased risk of periprocedural complications at the vaccine application site is those receiving anticoagulant therapy to prevent thrombo-embolic incidents or those with bleeding disorders. Currently available data from previously conducted studies with similar patients undergoing intramuscular vaccine injection suggest that many subjects in this group can be vaccinated with a reasonable periprocedural risk, where the expected benefit clearly outweighs it.

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