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Clinical Communications

COVID-19 vaccination in the setting of mastocytosis—Pfizer-BioNTech mRNA vaccine is safe and well tolerated

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Clinical Implications

Here, we report our experience with coronavirus disease 2019 (COVID-19) vaccination in a series of 73 fully vaccinated patients with mastocytosis. Pfizer-BioNTech vaccine was safe under antihistamine premedication and an extended observation of 45 minutes because only 2.7% reacted with mild, immediate symptoms.

Of 255 patients, 73 were identified for COVID-19 vaccination. Patients either made contact with the clinic themselves due to vaccine-related anxiety or were undergoing regular follow-up in the clinic for venom immunotherapy (VIT) or treatment with biologic drugs. Of 73 enrolled patients, 62 were diagnosed with SM (60 patients had indolent SM, 1 patient had SM with hematological neoplasm, and 1 had aggressive SM); 2 patients obtained a diagnosis of mastocytosis in the skin because they refused to undergo bone marrow investigation. In addition, 9 patients had a diagnosis of MMAS (Table I). Informed consent was obtained according to the guidelines of the Stockholm’s Ethics Review Board (Dnr: 2011/1750/31/3 and Dnr: 2018/2621-31).

All vaccinations were performed in our allergy outpatient clinic using a special protocol, which is derived from our VIT setting for patients with mastocytosis. Accordingly, all patients received premedication with antihistamine (AH) (2 tablets of desloratadine 5 mg) 30 to 60 minutes prior to vaccination (51 patients were on scheduled AHs and took 2 additional tablets). Subsequently, 30 μg (0.3 mL) of Pfizer-BioNTech (Comirnaty) vaccine (which was the only available vaccine at that time) was given. Afterward, patients remained for a 45-minute observation. The second doses were administered 3 to 4 weeks after the first dose. The vaccine was administered at least 7 days after or before in those who were treated with VIT or biologic drugs (eg, omalizumab).

In our series, 2 of 73 patients (2.7%) developed mild, immediate (within 20–40 min after vaccination) reactions in 3 of 146 injections. Both patients were females and experienced facial flushing, tingling in mouth and/or tongue, or a sense of general discomfort; however, cardiorespiratory parameters were stable. Patients responded well to 2 extra AH tablets (desloratadine 5 mg) and were observed for an additional 2 hours without further progress of their reactions. Both patients had diagnosis of indolent SM and had no history of anaphylaxis or anaphylactoid. Interestingly, 1 patient reacted to both doses (more recently, even reacted with the third dose) with same reaction pattern, whereas the second patient only reacted to first dose. Moreover, none of the patients in our cohort developed severe, immediate allergic reactions requiring epinephrine. In a recent study on highly allergic nonmastocytosis patients, immediate reaction rate was 2%, which is comparable with 2.7% found in this study. Furthermore, the rate of delayed hypersensitivity reactions (including skin eruption, itching, or urticaria) was 14.7% in this highly allergic cohort. Interestingly, however, none reported delayed hypersensitivity reactions in our cohort, as documented prior to the second dose of immunization (ie, ≥3 wk after the first dose). Nevertheless, nonallergic adverse reactions including injection-site pain or tenderness, myalgia, malaise, or chills were common among our patients.

The main strength of this single-center study was the homogeneity of the subjects enrolled and protocols applied. Patients were investigated in a standardized manner and underwent a comprehensive allergy workup to confirm atopic status and history of anaphylaxis.
(48%) had a history of venom-induced anaphylaxis, whereas only 1 had drug-induced anaphylaxis (caused by diclofenac). However, our cohort contained no patients with a history of anaphylaxis with prior vaccinations or polyethylene glycol polysorbate.

At present, it is difficult to assess whether premedication with AH might have been lowered the risk for potential anaphylaxis. We do not routinely recommend premedication with AH in mastocytosis patients, for instance, prior to other vaccinations. Nevertheless, some mastocytosis patients are regularly on AH prophylaxis. Therefore, randomized trials are needed to assess the exact role of premedication with AH in mastocytosis patients before providing general or patient-based recommendations. Until then, the usage of AH as premedication prior to COVID-19 vaccination should be encouraged, which is also in compliance with current recommendations regarding COVID-19 vaccination in mastocytosis.2

In conclusion, we report that, in our settings, COVID-19 vaccination of mastocytosis patients was safe and well tolerated, even those with an anaphylactic history. Furthermore, 39 of 73 patients (53%) received a third dose of Pfizer-BioNTech vaccine and only 1 (the patient who reacted to the first 2 doses) reacted with mild symptoms. Thus, we suggest that, because anaphylaxis is more severe in mastocytosis,2 patients should be given premedication with an AH prior to COVID-19 vaccination and should pursue their daily medications (if any). Further, we recommend an extended observation period of 45 minutes after vaccination. Moreover, COVID-19 vaccinations can be administered in vaccine sites with resuscitation equipment readily available and staff trained in recognizing and managing anaphylaxis.

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| Characteristics | Total cohort (n = 73) | SM (n = 62) | MIS (n = 2) | MMAS (n = 9) |
|-----------------|----------------------|------------|------------|-------------|
| Female gender, n (%) | 38/73 (52) | 35/62 (56) | 2/2 (100) | 4/9 (44) |
| Age at diagnosis, (y) median (range) | 54 (18–79) | 54 (18–79) | n/a | 47 (36–67) |
| Baseline tryptase (ng/mL), median (range) | 19 (3.2–160) | 22 (5.3–160) | n/a | 8.5 (3.2–15) |
| Total IgE (kU/L), median (range) | 16 (1–1,000) | 16 (1–1,000) | n/a | 28 (8.3–250) |
| Presence of MC aggregates in bone marrow biopsy, n (%) | 29 (41) (2 NA) | 29 (47) | 2 NA | 0 (0) |
| Presence of atypical morphology in bone marrow biopsy, n (%) | 61 (86) (2 NA) | 58 (94) | 2 NA | 3 (33) |
| Presence of CD25 in bone marrow MCs, n (%) | 71 (100) (2 NA) | 62 (100) | 2 NA | 9 (100) |
| Presence of D816V mutation, n (%) | 59 (81) | 55 (89) | 2 (100) | 2 (29) |
| Presence of mastocytosis (skin lesions), n (%) | 38 (52) | 36 (58) | n/a | n/a |
| Presence of atopy, n (%) | 19 (26) (1 n/a) | 16 (26) | 1 (50) | 2 (25) |
| Presence of atopic diseases (rhinoconjunctivitis and/or asthma), n (%) | 16 (22) (1 n/a) | 13 (21) | 1 (50) | 2 (25) |
| History of any kind of anaphylaxis, n (%) | 48 (66) | 39 (63) | None | 9 (100) |
| History of venom-induced anaphylaxis, n (%) | 35/73 (48) | 28/62 (45) | None | 7/9 (78) |
| History of food/drug-induced anaphylaxis, n (%) | 2/73 (2.7) | 2/62 (3) | None | None |
| History of idiopathic anaphylaxis, n (%) | 11/73 (15) | 9/62 (15) | None | 2/9 (22) |

IgE, Immunoglobulin E; MIS, mastocytosis in the skin; n/a, not applicable; NA, not analyzed.

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