Safety of BNT162b2 mRNA COVID-19 vaccine in a cohort of elderly, immunocompromised patients with systemic vasculitis

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The critical spreading of Coronavirus disease 2019 (COVID-19) has led to the implementation of mass vaccination campaigns against severe acute respiratory syndrome coronavirus 2 (SARS-COV-2). The safety of anti-SARS-COV-2 mRNA vaccines in patients with autoimmune inflammatory rheumatic diseases (AIIRD) undergoing immunosuppressive treatment represents an issue of concern (1), as these individuals were excluded from vaccine trials (2). COVID-19 vaccination is priority for patients with giant cell arteritis (GCA), due to the selective involvement at older age, frequent comorbidities and chronic immunosuppressive treatment which poses these patients at particular high risk in case of COVID-19.

Here, we describe for the first time the safety profile of anti-SARS-COV-2 mRNA vaccines in a large cohort of immunosuppressed patients with GCA.

Patients with GCA who received BNT162b2 mRNA COVID-19 vaccine (Pfizer/BioNtech) up to 30th April 2021 were enrolled. Participants completed a written questionnaire investigating the previous occurrence of SARS-COV-2 infection and detailing any adverse events (AE) or symptoms attributable to disease relapse experienced within 4 weeks from the second vaccine dose. All patients provided written informed consent.

We studied 81 patients with GCA (female 67.9%, mean age 75.8±6.9 years). At time of vaccination, 15 patients (18.5%) were receiving a prednisone-equivalent dose ≥10 mg/day (mean dose 6.4±7.1 mg/day), whereas 27 (33.3%) and 6 patients (7.4%) were treated with methotrexate (mean dose 12.2±3.4 mg/week) and tocilizumab (162 mg/week), respectively. Median duration of glucocorticoid therapy was 40.0 months (interquartile range 20.0–77.0 months). Glucocorticoids and/or immunosuppressive agents were maintained at a stable dose during the entire observation period. Five patients (6.2%) reported previous COVID-19, confirmed by rhinopharyngeal swab.

A detailed representation of vaccine-induced AE occurring after each vaccine dose is shown in Figure 1. Forty-nine patients (60.5%) experienced ≥1 AE. Local injection site reactions were the most common AE, reported by 40 patients (49.4%); fatigue was the most frequent systemic symptom (23.5%), followed by arthralgia (8.6%), myalgia (7.4%), low-grade fever (6.2%), chills (3.7%), gastrointestinal symptoms (3.7%) and lymphadenopathy (1.2%). Headache occurred in 5 patients (6.2%). Due to their transient course (mean symptom duration 1.2±1.0 days), isolated presentation and different qualitative characteristics, none of these events were attributed to a GCA relapse. No severe allergic reactions were reported.

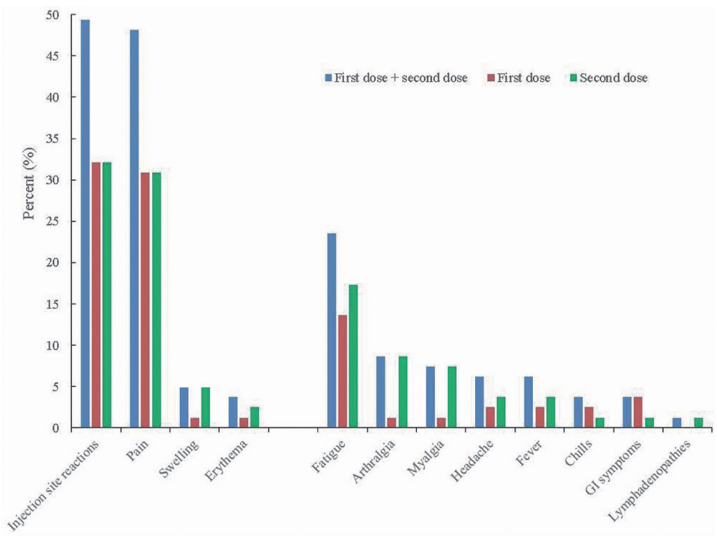

Fig. 1. Local site and systemic adverse events in patients with giant cell arteritis after the first vaccine dose and within 4 weeks following the booster dose of anti-SARS-COV-2 vaccination.

Age had no impact on the overall rate of vaccine-induced AE (p=0.28); however, arthralgia was more common in GCA patients >75 years compared to patients ≤75 years old (16.7% *vs*. 0%, p=0.08). Safety profile did not differ between patients treated with methotrexate and/or tocilizumab compared to those receiving glucocorticoid monotherapy (p=0.2). Among patients treated with glucocorticoids alone, no difference in safety was observed between prednisone-equivalent dose ≥10 mg/day and <10 mg/day (p=0.06).

This study provides, for the first time, real-world data on the safety of BNT162b2 vaccine in GCA patients receiving immunosuppressive treatment. In our cohort, the frequency of local and systemic events seems to be lower compared to that observed in clinical trials (2) and in retrospective studies including heterogenous cohorts of patients with AIIRD (3, 4). Our patients did not experience any severe AE. Older age and concomitant immunosuppressive treatment limiting reactogenicity might potentially explain this discrepancy.

Further studies are needed to evaluate the long-term efficacy and safety of the vaccine in immunosuppressed patients with AIIRD. Our early and encouraging results may positively assist physicians dealing with vaccination of vulnerable patients against SARS-COV-2, as minimising reticence towards COVID-19 vaccines (5) will be crucial for implementing vaccination campaigns in patients with AIIRD.

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