

79% had minor and only 3% had major vaccine ADEs requiring urgent medical attention overall. In adjusted analysis, among minor ADEs, abdominal pain [multivariate OR 1.6 (1.14-2.3)], dizziness [multivariate OR 1.3 (1.2-1.5)], and headache [multivariate OR 1.67 (1.3-2.2)], were more frequent in SAIDs than HCs. Overall major ADEs [multivariate OR 1.9 (1.6-2.2)], and throat closure [multivariate OR 5.7 (2.9-11.3)] were more frequent in SAIDs though absolute risk was small (0-4%) and rates of hospitalization were similarly small in both groups, with a small absolute risk (0-4%). Specific minor ADEs frequencies were different among different vaccine types, however, major ADEs and hospitalizations overall were rare (0-4%) and comparable across vaccine types in patients with SAIDs (Figure 1).

Conclusion: Vaccination against COVID-19 is relatively safe and tolerable in patients with SAIDs. Certain minor vaccine ADEs are more frequent in SAIDs than HCs in this study, though are not severe and do not require urgent medical attention. SAIDs were at a higher risk of major ADEs than HCs, though absolute risk was small, and did not lead to increased hospitalizations. There are small differences in minor ADEs between vaccine types in patients with SAIDs.

REFERENCES:

[1] Boekel L, Kummer LY, van Dam KPJ, Hooijberg F, van Kempen Z, Vogelzang EH, et al. Adverse events after first COVID-19 vaccination in patients with autoimmune diseases. *Lancet Rheumatol*. 2021 Aug;3(8):e542-5.

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POS1261 CLINICAL RESPONSE PREDICTORS OF TOCILIZUMAB THERAPY IN PATIENTS WITH SEVERE COVID-19

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Background: Aberrant immune response is hallmark of severe COVID-19, irrespectively from viral replication. Immunomodulatory therapies such as interleukin-6 (IL-6) receptor inhibitors were proven to be beneficial in reducing in-hospital mortality¹. Yet, it remains unclear which patients can benefit most from such therapy.

Objectives: To identify predictors of clinical response to tocilizumab (TCZ) added to dexamethasone in patients hospitalized with severe COVID-19.

Methods: We prospectively assessed clinical and laboratory details of 120 patients hospitalized due to severe COVID-19 treated with TCZ (two doses of 8mg/kg 24h apart) in our ward between 1st Feb 2021 and 31st Dec 2021. Severe COVID-19 was defined as SpO₂ <94% on room air with ground glass opacities in chest computed tomography (CT). Clinical response was defined as respiratory improvement on day 5 after TCZ infusion compared to day of treatment initiation, no further deterioration and survival. Decision of adding TCZ to dexamethasone as emergency therapy was made collectively by rheumatologists experienced in COVID-19 treatment. Laboratory and clinical parameters from hospital admission day and from TCZ institution day were analyzed. Statistical analysis was conducted with PQStat v.1.8.2 and predictors were identified in univariate logistic regression.

Results: We identified 86 (71.7%) clinical responders and 34 (28.3%) non-responders. 20 (58.8%) of the second group needed ICU admission, 18 (52.9%) died on ICU and 2 patients (5.9%) died on the ward. Responders were significantly younger (mean age 56.1 vs. 63.5 years, p=0.006), had lesser comorbidity burden (median Charlson Comorbidity Index 2 vs. 3, p=0.005), lower median lung involvement (50 vs. 70%, p<0.001), higher median baseline PaO₂/FiO₂ index (203 vs. 106, p<0.001) and less of them needed high-flow oxygen therapy on TCZ initiation day (12.7% vs 32.4%, p=0.025). Identified predictors of clinical response are shown in Table 1.

Conclusion: Administration of TCZ early in severe disease, with moderate IL-6 concentration and low organ damage indices is most beneficial in patients with severe COVID-19, especially in younger patients without respiratory and cardiac comorbidities.

REFERENCES:

[1] RECOVERY Collaborative Group. Tocilizumab in patients admitted to hospital with COVID-19 (RECOVERY): a randomised, controlled, open-label, platform trial. *Lancet Lond Engl*. 2021;397:1637-1645.

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