ABSTRACT

Follow-up of patients after COVID-19 monoclonal antibodies administration

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Introduction: At height of COVID-19 pandemic surge of Delta variant, monoclonal antibodies became a vital treatment option for SARS-CoV-2 positive outpatients at high risk of severe disease progression. Casirivimab and imdevimab (C/I) were used as an unauthorised medicinal product REGN-COV2 under European Medicines Agency emergency use authorisation (EUA). There was paucity of real-world data on safety and effectiveness.

Objective: The study aimed to describe REGN-COV2 drug safety, self-reported symptom burden in SARS-CoV-2 positive outpatients within 90 days post C/I infusion**.**

Methods: Prospective multicentric study of SARS-CoV-2 positive outpatients with mild symptoms at high-risk of severe COVID-19 progression (defined criteria under EUA authorization for C/I ambulatory administration) was conducted from September 2021 till April 2022 in three teaching hospitals in Czech Republic and Slovakia. The data collected using electronic medical records comprised: patient details, vaccination status, date of SARS-CoV-2 positive test, indication criteria, adverse drug reaction to infusion, need for hospitalization. Structured telephone questionnaire with symptom scoring was used on D (day) 0, D+7, D+29 and D+90 post C/I infusion. Data were analyzed using Microsoft Excel. Ethics Committee approval was obtained for monitoring of patients.

Results: Within studied period 401 (median age 66 years, 57.9 % females) were followed. The most frequent indications included hypertension (57.1 %), age over 65 years (55.9 %), diabetes mellitus (21.2 %). Adverse events were reported by 13.5 % of patients, most commonly fever, chills, diarrhea. Subjective worsening of symptoms after C/I infusion was reported by 3.5 % subjects by D+7. 11.7 % patients observed no difference in symptom score between D0 and D+7. Altogether 84.8 %; 91.8 % and 93.5 % patients reported improvement in symptom burden score by D+7, D+29 and D+90, respectively.

Conlusion: After administration of REGN-COV2, most patients reported reduction of the symptoms of the COVID-19 and improved health status in seven days after administration. More

than half of the patients experienced subjective improvement in health within three days of administration. Less than 4.0 % of patients experienced subjective worsening of symptoms. Adverse reactions associated with infusion were the most commonly observed. The administration of monoclonal antibodies has made a significant breakthrough in the treatment of the disease COVID-19. The benefits of therapeutic administration outweigh the risks.