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Serological Prevalence of Sars-Cov-2 Infection Among Chronic Myeloid Leukemia Patients Undergoing Tyrosine Kinase Inhibitor Treatment in Italy (COVID-19-HEM Study)

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Background. Clinical course of the novel Coronavirus (SARS-CoV-2) Disease 2019 (COVID-19) is extremely heterogeneous, and infected individuals may be asymptomatic or develop acute respiratory manifestations. Elderly people and patients with pre-existing comorbidities, including malignancies, may be at higher risk due to their immunological impairment. On the other hand, still limited evidence suggests that some target drugs used to treat hematological cancers, including tyrosine kinase inhibitors (TKI), may have a direct antiviral action or an indirect immunomodulatory effect on the abnormal inflammatory host response to SARS-CoV-2.
**Aims.** To describe the prevalence of symptomatic and asymptomatic SARS-CoV-2 infection in a cohort of chronic myeloid leukemia (CML) patients.

**Methods.** This is an ongoing prospective study ideated and conducted in the Centers of the regional network Rete Ematologica Veneta (REV). According to the Italian Ministry of Health data as of Jul 22, 2020, prevalence of SARS-CoV-2 infection in Veneto, as documented by molecular test on pharyngeal swab, was 0.4%. For comparison, two other centers from Regions with lower prevalence (Lazio and Friuli-Venezia Giulia) were included. All consecutive CML patients coming to the participating Centers were offered to participate to the study, which was approved by local IRBs. Patients in Treatment Free Remission (TFR) phase (i.e. not taking TKI at the time of pandemic) were included as a control group. After collecting information about risk factors for COVID-19 (travels, work exposure, cohabitation with infected subjects) and respiratory or general symptoms experienced from mid Feb 2020, patients were tested for anti-SARS-CoV-2 IgM and/or IgG antibodies through a immunochromatographic qualitative assay (COVID-19 IgG/IgM Rapid Test Cassette, Menarini Diagnostics, IT; sensitivity IgG 97.2%, IgM 87.9%, specificity IgG/IgM 100%). Patients with positive results underwent a pharyngeal swab for molecular detection of the virus.

**Results.** From May 18 to Jul 29, 2020 a total of 339 patients were enrolled (238 from REV centers and 101 from other centers). Males were 183 (54%), median age was 63.2 (range 26.5-93) years. Median time from CML diagnosis was 8 (range 0.1-29.6) years. The majority of patients were in frontline TKI treatment (n=174, 51.3%), and the remaining were in 2\(^{nd}\) line (n=80, 23.6%), 3\(^{rd}\) or further line of treatment (n=35, 10.3%), or in TFR (n=50, 14.7%). The type of TKI currently assumed was imatinib (n=134, 39.5%), nilotinib (n=63, 18.6%), dasatinib (n=52, 15.4%), bosutinib (n= 24, 7.1%), ponatinib (n=14, 4.1%) or experimental (n=2, 0.6%). The majority of patients was in major (n=79, 23.3%) or deep molecular response (n=204, 60.2%).

Thirteen and 3 patients declared close contact with COVID-19 infected individuals at work and/or at home, respectively. The frequency of newly onset or worsening symptoms during the last months was as follows: anosmia (2.4%), ageusia (2.1%), cough (4.7%), pharyngitis (2.6%), dyspnea (2.4%), fever (3.2%), headache (7.7%), asthenia (13.6%), arthralgia (14.9%), dizziness (6.5%), nausea/vomiting (2.7%), and diarrhea (4.4%).

Five patients out of the 238 in the REV cohort (2.1%) had a positive IgG test, and two of them were also IgM-positive. All resulted negative at swab performed after the serological assay. They were 4 males and 1 female, aged between 53 and 72 years. One of them, in treatment with nilotinib, had a symptomatic infection in early March, confirmed at that time by molecular tests, and reported close contact with infected subjects both at work and at home. All the other patients (2 in treatment with imatinib, 1 with
nilotinib and 1 with bosutinib) reported no or only mild symptoms and had not performed diagnostic tests for SARS-CoV-2 before. Anosmia, ageusia and fever were the only symptoms significantly associated with anti-SARS-CoV-2 IgG positive test (p<0.001). All the patients from the other two Regions and all the patients in TFR had a negative IgG/IgM test.

**Conclusions.** We reported for the first time the serological prevalence of SARS-CoV-2 infection in CML patients. Serological studies in the general Italian population are ongoing and will be used to make comparisons with our cohort. Prospective enrollment in the present study is ongoing and updated results will be presented at the Meeting.

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**Disclosures**

**Semenzato:** Abbvie: Honoraria; Roche: Honoraria; Takeda: Honoraria. **Pizzolo:** janssen: Speakers Bureau; Abbvie: Speakers Bureau. **Krampera:** Novartis: Membership on an entity's Board of Directors or advisory committees; Janssen: Membership on an entity's Board of Directors or advisory committees.

**Author notes**

* Asterisk with author names denotes non-ASH members.

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