First cycle treatment in a case of an

AML FAB M2 and COVID-19 pneumonia

ABSTRACT

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| In this chapter, one describes the first cycle treatment in a case of a newly diagnosed COVID-19 pneumonia. Pneumonia is a major cause of death among pacients with leukemia. The BH3-mimetic and selective BCL-2 inhibitor Venetoclax is a medication used to treat adults with chronic lymphocytic leukemia (CLL), acute myeloid leukemia (AML) and small lymphocytic lymphoma (SLL). Soon after being diagnosed with endocarditis with Aerococcus Viridans after a third molar extraction followed up by persistent fatigue, fever, weakness, nausea and excessive sweating, especially at night, a 70 years old normotensive, non-diabetic male was also diagnosed with AML M2/FAB. In this severe COVID-19 case the venetoclax treatment functioned, even in its first cycle and moreover even without increasing the daily dose over 100 mg. One observed that the initial high value of monocytes (12620/µL) dropped after the 28 days period close to the normalization threshold (2500/µL), more exactly to 2360/µL. The positive response to venetoclax occurred even if the patient developed other comorbidities at that point such as for example severe anemia within the disease, thrombocytopenia, SIRS (systemic inflammatory response syndrome). |

*Keywords: Post-Covid Syndrome, hemoptysis, thrombocytopenia, acute myeloid leukemia,* *SARS-CoV-2*

1. INTRODUCTION

Pneumonia is a major cause of death among pacients with leukemia. The BH3-mimetic and selective BCL-2 inhibitor Venetoclax is a medication used to treat adults with chronic lymphocytic leukemia (CLL), acute myeloid leukemia (AML) and small lymphocytic lymphoma (SLL). AML increases the risk of infections. Venetoclax was recently approved by the Romanian Health Ministry ([2]) for the treatment of patients diagnosed with acute myeloid leukemia (AML). Unfortunately, Romania remained until 2022 the only EU country where the cost of Venetoclax was neither fully nor partially supported by the National Health Insurance House ([3]) hence the leukemia patients had to either seek the aid of compassionate care organizations or purchase it on their own expense. By selectively binding to BCL-2 protein family and displacing pro-apoptotic proteins, Venetoclax helps restoring the process of apoptosis. Venetoclax, sold under the brand names Venclexta and Venclyxto, is used for adults either over 75 years old or who have comorbidities that would not permit the use of intensive induction chemotherapy. Furthermore, Venetoclax is indicated to be used for the treatment of AML in adults in combination with either azacitidine or decitabine or low-dose cytarabine ([4]). In this chapter we describe a rare case of a venetoclax first cycle treatment for a patient diagnosed with COVID-19 pneumonia and show how the venetoclax treatment worked against AML.

2. PRESENTATION OF THE CASE

Soon after being diagnosed with endocarditis with Aerococcus Viridans after a third molar extraction followed up by persistent fatigue, fever, weakness, nausea and excessive sweating, especially at night, a 70 years old normotensive, non-diabetic male was also diagnosed with AML M2/FAB. Until that time, he had no history of surgeries, comorbidities or other disease. His blood was thoroughly investigated. There was severe thrombocytopenia on the peripheral smear (PLT= 89 K/µL < 150K/µL), Hemoglobin was 9.6 g/dl, with 42% Myeloblasts, 59% Neutrophils, 4% Lymphocytes, 3% Erythroblasts, 3% Metamyelocytes, 13% Myelocytes, 2% Monocytes, 3% Erythroblasts, 2% Plasmocytes. The patient was initially treated for endocarditis with the antibiotics teicoplanin and ceftriaxone and also had a heart valve replacement surgery with Edwards Lifescience Perimount no.25 biological valve followed by the same antibiotic treatment. The first 2 months, other than blood transfusions no AML treatment has been performed. The AML karyotype formulae was: 45, X, -Y, t(8;21)(q22; q22.1)[2]/46,XY[1]; based on the affected genes it was categorized as per the WHO 2016 classification as AML with t(8;21)(q22; q22.1);RUNX1- RUNX1T1.

Due to the installation of biocytopenia (neutropenia and thrombocytopenia as Table 1 shows) after these first 2 months, he started being treated for AML with hypomethylating agents: Azacitidine 75 mg/mL for 10 cycles of 28 days, the first 9 cycles 3mLx2, the days 1-7 (14 injections per cycle) and half dose only, that is 3mL the 10th cycle. After the 10 cycles there was a 28-days pause period while waiting on venetoclax supply to arrive and next finally a 28 day-cycle of Venetoclax combined with half dose Azacitidine. In addition, he received Acyclovir 400mg x2 tablets/day x 3days/week (to prevent viral infections) and Tagremin (sulfamethoxazole 400mg trimethoprim 80 mg)x2 tablets/day x 3days/week (to prevent fungal infections). Blood tests results for all cycles are presented in Table 1.

**Table1. Component results since diagnosed with AML**

|  |  |  |
| --- | --- | --- |
|  | **Month** | **Cycle** |
| **Component** |  **1** |  **2** |  **1** |  **2** |  **3** | **4** |  **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **Unit** |
| WBC  | 4.09 | 6.03 | 3.85 | 3.51 | 2.86 | 1.40 | 1.95 | 2.01 | 2.25 | 2.18 | 2.12 | 4.68 | 6.29 | 22.14 | 4.09 | K/µL |
| RBC | 2.53 | 2.61 | 2.45 | 2.55 | 2.59 | 3.31 | 3.66 | 3.66 | 3.99 | 4.05 | 4.11 | 3.42 | 3.32 | 2.88 | 2.69 | M/µL |
| HGB | 8.6 | 9.3 | 8.4 | 9.6 | 10.6 | 12.9 | 13.5 | 12.9 | 13.8 | 13.6 | 14 | 11.7 | 11.6 | 9.3 | 8.4 | g/dL |
| HCT | 26.2 | 27.8 | 25.6 | 28.2 | 30.5 | 37.5 | 38.8 | 37.3 | 39.2 | 40.1 | 40.7 | 33.4 | 33.6 | 27.1 | 24.8 | % |
| MCV | 103.6 | 106.5 | 104.5 | 110.6 | 117.8 | 113.3 | 106 | 101.9 | 98.2 | 99 | 99 | 97.7 | 101.2 |  94.1 | 92.2 |  fL |
| MCH | 34 | 35.6 | 34.3 | 37.6 | 40.9 | 39.0 | 36.9 | 35.2 | 34.6 | 33.6 | 34.1 | 34.2 | 34.9 | 32.3 | 31.2 | pg |
| MCHC | 32.8 | 33.5 | 32.8 | 34 | 34.8 | 34.4 | 34.8 | 34.6 | 35.2 | 33.9 | 34.4 | 35 | 34.5 | 34.3 | 33.9 | g/dL |
| PLT | 89 | 48 | 74 | 121 | 145 | 179 | 189 | 192 | 180 | 161 | 115 | 70 | 58 | 8 | 14 | K/µL |
| RDW-CV | 18.4 | 21.2 | 21.9 | 23.3 | 15.6 | 11.9 | 12 | 12.7 | 13.6 | 15.0 | 16.1 | 16.8 | 17.3 | 17.9 | 15.9 | % |
| PDW | 8.3 | 9.3 | 10.2 | 9 | 9.1 | 10.2 | 10.6 | 12.3 | 13.6 | 11.6 | 10.3 | 11.2 | 12.2 |  13.2 |  9.7 |  fL |
| MPV | 8.9 | 10 | 10.1 | 9.7 | 9.2 | 10 | 10 | 10.6 | 11.1 | 10.5 | 10.2 | 10.1 | 10.2 |  11.6 |  9.5 |  fL |
| PCT | 0.08 | 0.1 | 0.1 | 0.1 | 0.13 | 0.18 | 0.19 | 0.2 | 0.2 | 0.17 |  0.1 | 0.1 | 0.06 |  0 |  0 |  % |
| NRBC | 0 | 0 | 0 | 0.3 | 0 | 0 | 0.5 | 0 | 0 | 0 | 0 | 0.2 | 0.01 |  0.05 |  0 |  % |
| NEUT  | 2.85 | 2.58 | 2.31 | 2.2 | 2.1 | 0.78 | 1.06 | 1.2 | 1.24 | 1.25 | 1.03 | 1.07 | 1.97 | 8.39 | 1.59 | K/µL |
| NEUT% | 69.8 | 42.8 | 60 | 62.7 | 73.5 | 55.8 | 54.4 | 59.7 | 55.2 | 57.3 | 48.5 | 22.9 | 31.3 | 37.90 | 38.9 |  % |
| LYMPH | 0.66 | 1.46 | 1.12 | 0.91 | 0.56 | 0.52 | 0.61 | 0.62 | 0.73 | 0.7 | 0.72 | 1.09 | 1.14 |  1.11 | 0.14 | K/µL |
| LYMPH% | 16.1 | 24.2 | 29.1 | 25.9 | 19.6 | 37.1 | 31.3 | 30.8 | 32.4 | 32.1 | 34 | 23.3 | 18.1 |  5 | 3.4 |  % |
| MONO | 0.57 | 1.98 | 0.41 | 0.4 | 0.19 | 0.1 | 0.25 | 0.16 | 0.24 | 0.2 | 0.35 | 2.49 | 3.13 | 12.62 | 2.36 | K/µL |
| MONO% | 13.9 | 32.8 | 10.6 | 11.4 | 6.6 | 7.1 | 12.8 | 8 | 10.7 | 9.2 | 16.5 | 53.2 | 49.8 |  57 | 57.7 |  % |
| EO  | 0 | 0 | 0 | 0 | 0 | 0 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0 | 0.01 |  0 |  0 | K/µL |
| EO% | 0 | 0 | 0 | 0 | 0 | 0 | 0.5 | 0.16 | 0.4 | 0.5 | 0.5 | 0 | 0.2 |  0 |  0 |  % |
| BASO | 0.01 | 0.01 | 0.01 | 0 | 0.01 | 0 | 0.02 | 0.02 | 0.03 | 0.02 | 0.01 | 0.03 | 0.04 | 0.02 |  0 | K/µL |
| BASO% | 0.2 | 0.2 | 0.3 | 0 | 0.3 | 0 | 1 | 1 | 1.3 | 0.9 | 0.5 | 0.6 | 0.6 |  0 |  0 |  % |
| IG | 0.4 | 0.78 | 0.4 | 0.19 | 0.18 | 0.09 | 0.05 | 0.02 | 0.04 | 0.09 | 0.14 | 0.55 | 0.85 | 1.04 | 0.31 | K/µL |
| IG% | 9.8 | 12.9 | 10.4 | 5.4 | 6.3 | 6.4 | 2.6 | 1 | 1.8 | 4.1 | 6.6 | 11.8 | 13.5 | 4.7 |  7.6 |  % |

He started the first venetoclax cycle in a romanian hospital. First day after the new elected major and part of his staff came to the hospital on an inspection, this being the 8th day of the patient’s hospitalization there, his antigen test was still negative. Even though, he started developing fever and he was isolated along with 2 new patients. While still being hospitalized there, the 10th day he started showing less common COVID-19 symptoms such as hemoptysis (see [5]), his blood oxygen level dropping below 95% and 3 days later he was diagnosed with COVID-19 after taking the antigen test followed by a Real Time PCR. The hospital had a screening process, all future patients had to pass the antigen and RT-PCR tests in order to be admitted; as studies show the antigen tests sensitivity is only 73% in symptomatic patients and 54,7% in non-symptomatic whereas the RT-PCR’s confidence interval is 95% ([6]). The above proves the patient acquired the SARS-CoV-2 in the hospital. Hemoptysis was followed by brain fog and extreme fatigue starting day 6 of his COVID-19 infection. The patient was moved to another Romanian hospital designated for COVID-19 in addition to being specialized in leukemia treatment. There he received the remdesivir treatment for COVID-19 (see [7]) in combination with doxycycline, variconazal, sumetrolim (to prevent fungal infections), furosemide (to avoid tumor lysis syndrome - TLS), acyclovir (to prevent viral infections). He continued receiving the venetoclax - kept at 100 mg tablet daily dose – in order to try to maintain a balance in protecting the patient’s weakened heart while fighting against both AML and COVID-19. Meanwhile, he also received oxygen and dexamethasone to protect the respiratory function. The patient’s condition improved after the 8th day and he lived beyond the critical days of the evolution of SARS-CoV-2 infection. Nevertheless, as the COVID-19 pneumonia does not heal in14 days, the Post Covid Syndrome (the lungs sequel) persisted (see [8] and [9]). After an almost 3 weeks struggle, the patient still being under oxygen support, his fluid leaking lungs failed due to the acute respiratory insufficiency caused by the hemorrhagic sequels and lungs lesions. Hemoptysis reoccurred abruptly along with a drop below 90% of the blood oxygen level (hypoxemia) during the last day of the patient’s life.

3. discussion

Using venetoclax for patients with COVID-19 has not been extensively studied so far (see [10]). In this severe COVID-19 case the venetoclax treatment functioned, even in its first cycle and moreover even without increasing the daily dose over 100 mg. One observed that the initial high value of monocytes (12620/µL) dropped after the 28 days period close to the normalization threshold (2500/µL), more exactly to 2360/µL as shown in Figure 1. Neutrophils were normalized within the normal range of [1500-8000] as shown in Figure 2 more exactly to 1590/µL. As shown in Figure 3, WBCs were also normalized from 22140/µL to 4090/µL. Moreover, the response of leukemia is also quantified by the D-Dimer values. The initial high value of the D-Dimer, namely 1.18 µg/mL got normalized along with the normalization of the leukocytes, in the end the D-Dimer value being 0.36 µg/mL which is normal D-Dimer. However, since severe thrombocytopenia was revealed soon before death (PLT=14000/µL), more time would still have being needed under venetoclax to recover the healthy bone marrow in order to produce platelet precursors. One observed that the furosemide treatment and the hydration for the TLS prophylaxis to support the kidney in filtering out the destroyed leukemia cells was successful, and the kidney responded well to prophylaxis: the high patient’s creatinine value namely 1.3 mg/dL the day he was positively tested for COVID-19, lowered to 0.72 mg/dL after 2 weeks. The kidney responded well since it maintained a normal filtration rate, without the accumulation of toxic nitrogenous products in the body. Interleukin-6 dropped from 77 pg/mL when diagnosed with COVID-19 to 4.9 pg/mL at the end of the cycle. One observed that even in COVID-19 cases the venetoclax treatment works against AML. Note that no hydroxychloroquine was used during the treatment though there are studies (see [11]) showing that hydroxychloroquine (aka plaquenil) is efficient in clearing the viral nasopharyngeal carriage of SARS-CoV-2 up to six days in most COVID-19 patients and, in addition, hydroxychloroquine proved to be efficient in haematological cancers (see [12] and [13]),. The current epidemiology data of the COVID-19 pandemic can be found at (see [14]).

**Fig. 1. Effect on monocytes of 10 cycles of azacitidine followed by a pause of one cycle and one cycle of venetoclax combined with azacytidine**

**Fig. 2. Effect on neutrophils of 10 cycles of azacitidine followed by a pause of one cycle and one cycle of venetoclax combined with azacitidine**

**Fig. 3. Effect on leukocytes of 10 cycles of azacitidine followed by a pause of one cycle and one cycle of venetoclax combined with azacitidine**

Ghandili et al. [15] have described 12 cases of acute leukemia and COVID-19 patients, out of which 67% (8 patients) had acute myeloid leukemia (AML) and 33% (4 patients) had either acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL). The median age of the patients was 60 years (range: 32-76) and 75% were male. Three out of the 8 AML patients had newly diagnosed untreated AML, 4 had refractory/relapsed AML and one patient was in complete remission with incomplete hematologic recovery (CRi). The latest one received high-dose cytarabine for the consolidation therapy and due to severe acute respiratory distress syndrome (ARDS), he died 3 weeks after the COVID-19 infection. Their finding was that all 3 AML patients with newly diagnosed AML developed severe ARDS but the only one treated with intensive chemotherapy died. Moreover, none of the 4 refractory AML patients treated with azacitidine/venetoclax developed ARDS.

Ferra F et al. [16] describe the treatment results of ten consecutive COVID-19 patients with AML their median age being 60 (range: 31–69) and M/F ratio 5/5. Two patients were newly diagnosed, 6 in CR (complete remission) and 2 in relapse. COVID-19 imposed In their study hematological treatment modifications in 7 patients. Three patients discontinued the therapy, venetoclax/azacitidine and venetoclax/enasidenib used in 2 relapsed patients, high-dose cytosine-arabinoside as first consolidation in one CR patient and one died before any treatment. Seven out of the 10 patients, encountered abrupt worsening of the respiratory function. 50% (5 patients) died after a median time of 8 days.

SARS-CoV-2 infection has a major impact on AML patients survival. As also described in this chapter, most patients with acute leukemia develop a severe form of COVID-19. Similarly, in one of the largest studies for patients with haematological malignancies and COVID-19, Passamonti et al. [17] emphasize the need for aggressive infection prevention strategies due to their increased risk of mortality (536 enrolled patients out of which 37%, that is 198, died).

NHS England granted emergency approval of venetoclax and gilteritinib for leukemia patients (see [18]). [19] and [4] show the Leukemia-specific risk factors for COVID-19 as well as treatment alternatives and guidelines for patients with leukemia during COVID-19 high-risk periods.

Mortality in patients with risk factors in addition to AML can be also consulted in [20] and [21]. The study [22] revealed the fact that 46.9% patients with AML did not survive the COVID-19.

4. Conclusion

Venetoclax first cycle treatment in SARS-CoV-2 infected patients is a very rare case. In this chapter, one proved that the venetoclax treatment worked against AML in this COVID-19 case. Moreover, due to his response to venetoclax, in the event this patient would have not been infected with SARS-CoV-2, his life expectance would have been over 12 months with a probability of about 75% (see [23]) in which case he would have continued with the next phases of the venetoclax treatment with a high probability of living at least 18 more months as per [23], the median overall survival rate being 14.7 months ([24]). The positive response to venetoclax occurred even if the patient developed other comorbidities at that point such as for example severe anemia within the disease, thrombocytopenia, SIRS (systemic inflammatory response syndrome).

Consent

The author declares that written informed consent was obtained from the patient for publication of this case report and accompanying images. As per international standard, patient’s written consent has been collected and preserved by the author.

ETHICAL APPROVAL

As per international standard or university standard ethical approval has been collected and preserved by the author.

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