



Management with Sonidegib of Advanced BCC in COVID-19 Era

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Abstract

Background: The COVID-19 pandemic is having a serious effect on the management of cancer patients. Patients suffering from locally advanced Basal Cell Carcinoma (laBCC) are at a high risk for severe COVID-19, mainly in terms of age and presence of comorbidities.

Case Presentation: Here we report the case of an 89-year-old female with a laBCC on the forehead and on concomitant use of antipsychotic medications. After several recurrences and different unsuccessful treatments, the patient refused a further surgery and a multidisciplinary board decided to start treatment with sonidegib, a hedgehog inhibitor approved as first-line treatment in laBCC. We started with sonidegib 200 mg every day and then, due to mild adverse events most probably related to the concomitant antipsychotics, we switched to the in-label dose modification of 200 mg every other day. Due to the COVID-19 outbreak, we decided to follow the patient *via* telemedicine. Response was impressive and clinically evident after one month of therapy. Currently, after 3 months from the start of sonidegib treatment, the patient presents an almost complete response with residual crust and is still on treatment with sonidegib.

Conclusion: Even though laBCC patients are more susceptible to severe complications of COVID-19 than the general population, there is so far no evidence in favor of preventively stopping treatment.

Approved dose modifications and telemedicine are interesting strategies not only to control adverse events but also to manage treatment more flexibly during COVID-19 pandemic.

Introduction

The COVID-19 pandemic is having a serious and disruptive effect on the management of cancer patients. Available data indicate that individuals with active cancer are more vulnerable to severe COVID-19 [1]. Additional risk factors are older age (≥ 80 years old) and presence of underlying chronic comorbidities [2]. Moreover, due to resource rationing, it is difficult to foresee which effect delays in surgeries and drug therapy administration will have on the long-term health of cancer patients. Ensuring the safety of patients and health care professionals during the current pandemic is of utmost priority. Government agencies, professional societies and hospitals have provided initial guidance on the implementation of measures such as telemedicine and reducing or postponing oncologic visits when feasible to achieve the best possible risk/benefit balance [3-5]. Data on COVID-19 and malignancy remain limited at present and there are no guidelines or evidences recommending preventively discontinuing treatment.

The patient suffering from locally advanced basal cell carcinoma (laBCC) frequently fits well into the criteria that define an individual at high risk for severe COVID-19, mainly in terms of age and presence of comorbidities. Recently, a case series of laBCC patients under hedgehog pathway inhibitors has been published, focusing on their follow-up in time of pandemic [6,7].

Case Presentation

In this report, we describe our own experience regarding the management of an elderly patient with a difficult-to-treat laBCC in treatment with the hedgehog pathway inhibitor sonidegib and the preventive measures we adopted during COVID-19 period. The patient is an 89-year-old female with a laBCC on the forehead who presented at our center after at least 4 years of lesion evolution. In June 2016, the tumor was histologically diagnosed as a BCC and surgically removed. In March 2018, the patient suffered a recurrence and underwent treatment with topical therapy (electrocoagulation), an immunomodulator (imiquimod) and chemotherapies (5-fluorouracil) with unsuccessful results. In October 2019, the lesion was treated with topical antibiotics and reepithelializing creams. At the time

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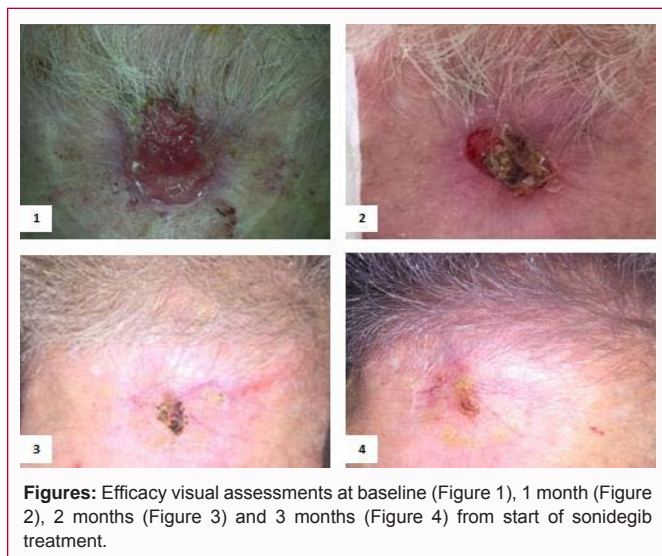
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Figures: Efficacy visual assessments at baseline (Figure 1), 1 month (Figure 2), 2 months (Figure 3) and 3 months (Figure 4) from start of sonidegib treatment.

of our first assessment in January 2020, the tumor measured 4 cm in diameter and appeared ulcerated with clear borders characterized by pearly papules (Figure 1). A biopsy confirmed the relapsed BCC. Patient referred concomitant use of antipsychotic medications (olanzapine and quetiapine). A multidisciplinary board defined the lesion operable but patient refused surgery. No other local treatment was considered suitable; therefore, the board advised a systemic targeted therapy. Therapy with sonidegib was started in February 2020 at the dose of 200 mg daily. After ten days of treatment, patient reported drowsiness and tachycardia. After reviewing the drugs' metabolism, we hypothesized that these AEs were most probably related to the antipsychotics use. However, to increase chances of AEs resolution, we prescribed an in-label sonidegib dose reduction from 200 mg daily to 200 mg every other day.

Thereafter, due to the worsening of the COVID-19 pandemic, we started following the patient's treatment remotely. Patient's caregiver took photos of the lesion at agreed time points and under our instructions and shared the photos with us. We could then assess them virtually and provide advice over the phone. Blood tests could be performed in a laboratory closer to patient's home and results sent to us.

Despite reducing sonidegib dose from 200 mg every day to 200 mg every other day and the necessity to follow the patient remotely, clinical response after 1 month from the start of sonidegib treatment was impressive (Figure 2). At two months, lesion improved further (Figure 3), no adverse events were reported and routine blood tests were in the norm.

Currently, patient is still on alternate day treatment, presenting an almost complete response with residual crust (Figure 4) and only a mild decreased appetite (grade 1) at the time of writing of this report (May 2020; after 3 months from start of therapy).

Conclusion

Despite the unprecedented time for health care systems globally, it is still possible to manage laBCC patients in an efficacious and safe manner. Even though they are more susceptible to severe complications of COVID-19 than the general population, there is so far no evidence in favor of preventively stopping treatment.

Several factors, including the possibility of alternative in-label dosage and patient's refusal of surgery, led the multidisciplinary board to suggest treatment with sonidegib. Approved dose modification is an interesting strategy not only to control adverse events but also to manage treatment more flexibly during COVID-19 pandemic. Finally, telemedicine allows laBCC patients to have access to high-quality care without traveling to the clinic and thus minimizing infection chances for this high-risk population.

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