Outcomes of Tixagevimab/cilgavimab pre-exposure prophylaxis in Chronic lymphocytic leukemia patients- a single center experience.

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INTRODUCTION

- Patients with CLL have an increased susceptibility to infections secondary to complex immune interactions, innate immunity dysfunction, and with treatment with immunosuppressants.
- This leads to infections accounting for the majority (60%) of deaths in CLL [1].
- SARS-CoV-2, the virus, which causes COVID-19 infection has been an infectious etiology of concern. Development of tixagevimib/cilgavamib shows in vitro neutralizing capacity against the earlier omicron variant in addition to earlier SARS-CoV-2 strains (alpha, beta, gamma, and delta) [2].
- Tixagevimib/cilgavamib, a combination of two long-acting antibodies, was authorized for emergency use for pre-exposure prophylaxis of SARS-CoV-2 infection in moderate to severely immunocompromised patients by the FDA from December 2021-January 2023 [3].
- CLL patients were not studied specifically in the pivotal clinical trials, of tixagevimib/cilgavamib, so the CLL-specific outcomes are not well described

OBJECTIVE

- **We aimed to observe SARS-CoV-2 infection rates in primary series vaccinated (BNT162b2,mRNA1273, and AD26.COV2.S) CLL patients and infection rates in patients post tixagevimab/cilgavimab administration.**

METHODS

- We conducted a single institution, IRB approved, retrospective study evaluating tixagevimab/cilgavimab administration for use of pre-exposure prophylaxis in patients with confirmed CLL treated at our institution from January 2021 to January 2023.

METHODS

- 90 CLL patients vaccinated with the primary SARS-CoV-2 series at our institution who were included in this retrospective review.

RESULTS

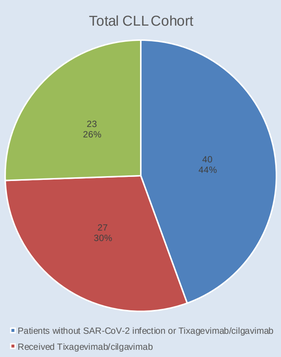
90 CLL patients

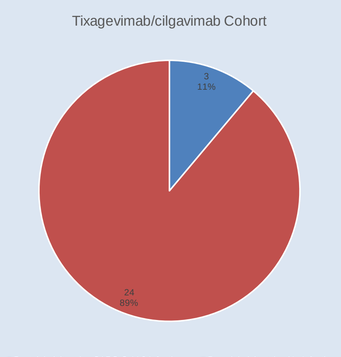
27/90 (30%) received Tixagevimab/cilgavimab prior to Jan 2023.

23/90 (25.6%) had one bout of SARS-CoV-2 infection
- 21 patients having mild infections (treated in the ambulatory setting)
- 1 patient with moderate disease (requiring supplemental oxygen and hospitalization)
- 1 patient with severe disease (requiring ICU stay)

27 CLL patients that received Tixagevimab/cilgavimab

- 3/27 (11.1%) had SARS-CoV-2 infection post-administration, all with mild disease. Of note, these patients that were infected post-administration did receive treatment with monoclonal antibodies post-diagnosis. Of the 3 patients with post administration SARS-CoV-2 infections, 2 patients also had a SARS-CoV-2 infection prior to administration.
- 4/27 had SARS-CoV-2 prior to and did not have any documented infections post administration.





CONCLUSION

- Tixagevimab/cilgavimab has been part of the advances in SARS-CoV-2 pre-exposure prophylaxis for immunocompromised patients including CLL patients.
- As our data suggests we have observed a general trend towards decreased rates of infections in patients that were treated with tixagevimab/cilgavimab.
- In addition, it appeared that even for patients that were infected post administration of tixagevimab/cilgavimab, 2/3 of those patients had a documented SARS-CoV-2 infection prior to administration as well.
- As of January 2023 the FDA revised the recommendation regarding tixagevimab/cilgavimab use given that it appeared that the majority of current SARS-CoV-2 strains in the community are not susceptible to tixagevimab/cilgavimab.
- While tixagevimab/cilgavimab is not currently approved for use given its lack of efficacy to current strains, previous RCTs and the data that we have observed in our study does appear to indicate that a pre-exposure prophylaxis strategy may be beneficial in CLL patients, and warrants continue exploration in clinical studies specifically for current and future SARS-CoV-2 strains [3].

LIMITATIONS

- Our study has a limited sample size and we could not control of variable such as use of masks, frequency of potential exposures, contribution of multiple vaccinations to immunity.
- Tixagevimab/cilgavimab is no longer FDA approved for the current strains of SARS-CoV-2.

FUTURE WORK

- Future guidance on pre and post exposure prophylaxis in CLL patients exposed to SARS-CoV-2 virus.
- Large scale observations of SARS-CoV-2 infection rates in patients who have received both primary series vaccination and subsequent booster

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