REAL-WORLD EFFECTIVENESS AND SAFETY OF TIXAGEVIMAB/CILGAVIMAB LOWER DOSAGE REGIMEN IN PRE-EXPOSURE PROPHYLAXIS IN PATIENTS UNDERGOING TREATMENT FOR CHRONIC LYMPHOCYTIC LEUKEMIA

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1. Introduction

1. SARS-CoV-2, emerging in late 2019, hit vulnerable groups hard, especially CLL patients due to age, comorbidities, and immune issues.
2. Patients with CLL had diminished response to SARS-CoV-2 vaccines, especially when on or therapy by anti-CD20 antibodies and / or targeted oral inhibitors.
3. The tixagevimab/cilgavimab (T/C) combo offered effective pre-exposure protection against SARS-CoV-2, notably pre-Omicron.
4. Despite Omicron's milder impact on the masses, older immunocompromised individuals still need early and preventive treatments.

2. Objectives

- Examine the efficacy and safety of T/C in preventing severe COVID-19 cases.
- Include CLL patients who meet the IWCLL criteria, are undergoing treatment, and received T/C at the approved dose in a tertiary hematology center in the Czech Republic.
- Use SPSS software (v25.0) for statistical analysis, with Kaplan-Meier curves to assess time to COVID-19.

3. Results

- 81 patients on active CLL treatment were included, having received T/C prophylaxis between April 8 and December 15, 2022.
- At 47 weeks median follow-up, **31 patients (38%)** **contracted SARS-CoV-2** despite T/C prophylaxis.
- **None of the patients in the cohort died or were admitted to the ICU**; 10% were hospitalized, and 6% required oxygen therapy.

Table 1. Patient Demographics and Baseline Characteristics

Total number of patients	81
Age at CLL diagnosis, median (range)	62 (37-79)
Age at tixagevimab/cilgavimab administration, median (range)	71 (42-90)
Males, n (%)	44 (54)
Prognostic markers	
Unmutated IGHV, n (%)*	57 (73)
Del(17p) and/or mutation *TP53*, n (%)	20 (25)
Del(11q), n (%)	32 (40)
Trisomy 12, n (%)	13 (16)
Del13q as a sole abnormality, n (%)	15 (19)
Complex karyotype, n (%)	11 (14)
Hypogammaglobulinemia, n (%)†	38 (52)
Obesity, n (%) ‡	28 (35)
CIRS score, median (range)	6 (2-14)
Major comorbidities, n (%)	49 (60)
SARS-CoV-2 vaccine in history, n (%)	73 (90)

*IGHV available in 78 pts, †data available in 73 pts, ‡defined as body mass index (BMI) ≥ 30, abbreviations: n, number of patients, CLL, chronic lymphocytic leukemia, IGHV immunoglobulin heavy chain variable region, TP53, tumour protein p53, BTK, Bruton tyrosine kinase

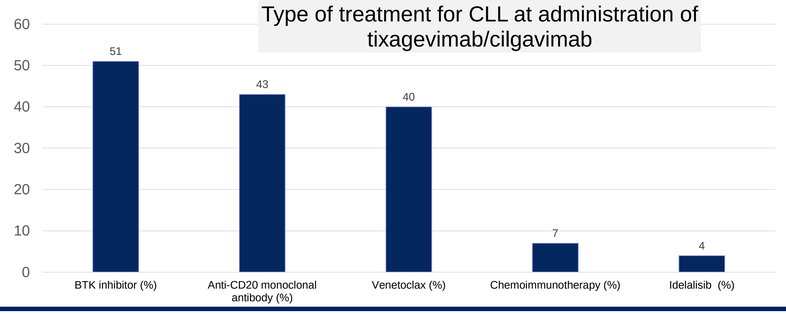
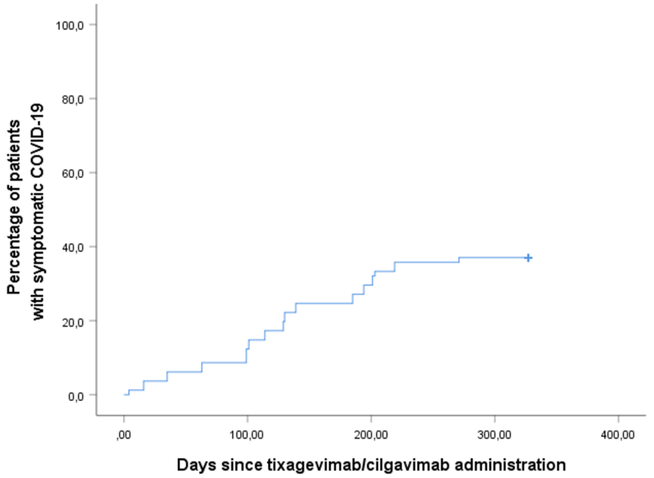


Fig. 1 Time to First SARS-CoV-2 RT-PCR-Positive Symptomatic Illness



4. Key Findings

- **Tixagevimab/cilgavimab at 150/150 mg didn't prevent COVID-19 in about a third of patients undergoing CLL treatment.**
- **However, most CLL patients who contracted COVID-19 post T/C prophylaxis experienced a mild infection and low hospitalization rate.**

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