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### **Sub-Analysis of Patients with COVID-19 in Chronic Myeloid Leukemia on TKI Treatment: Update from the International CML Foundation (iCMLf) CML and COVID-19 (CANDID) Study**

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#### **Abstract Text:**

#### **Introduction:**

The iCMLf CANDID study represents the largest global real world cohort study characterizing COVID-19 in CML. Data were collected from 157 centers in 49 countries with contributions from CML physicians and partner organizations. Outcomes of the entire cohort were previously communicated.

#### **Objective:**

We propose to assess a sub-analysis of CML patients with COVID-19 in the CANDID Study, describing the role of tyrosine kinase inhibitors (TKIs) on clinical evolution and outcome.

#### **Patients and Methods:**

Patients were included between March 2020, and November 2021. Severity and mortality of COVID-19 was analyzed according to age, type of TKI, line of treatment, disease stage, TKI response, treatment interruption during infection, standard or modified dose of imatinib, and number of comorbidities. Univariate and multivariate analysis were performed using logistic regression and Kaplan Meier was used for survival analysis.

#### **Results:**

Of the entire cohort of 1050 patients, 58.8% are male, the median age is 52.04 years and the median time with CML diagnosis is 8.23 years (0-34). 82.2% (864 patients) were on TKI treatment at the moment of COVID-19 infection. Patient's CML and COVID-19 characteristics are described in Table 1. Within 20 months of follow up, overall survival was 93.7%. 88% of deaths occurred in the first 2 months since COVID-19 diagnosis. Taking into account only symptomatic patients (785); TKI type, TKI line of treatment and imatinib dose are not significant risk factors of the severity and mortality of COVID-19. In univariate analysis, risk factors for severity were age  $\geq 75$  y (p 0.004), 2 or more comorbidities (p 0.000031), BP/AP phase (p 0.000289), no MMR status (p 0.001529) and TKI interruption (p  $< 0.001$ ). Risk factors for mortality were similar: age  $\geq 75$  y (p  $< 0.001$ ), 2 or more comorbidities (p 0.046), BP/AP phase (p  $< 0.001$ ), no MMR status (p 0.000261) and TKI interruption (p  $< 0.001$ ). Age and TKI interruption remained as significant risk factors for death in multivariate analysis, but there is a significantly higher proportion of TKI interruption in severe or critical patients. As expected, the severity COVID-19 infection is a risk factor of death (OR 38.39, 95%IC: 20.095-73.354. p $< 0.01$ .)

## **Discussion:**

Based on real-life experience, severity and mortality of COVID-19 in CML patients on TKI is independent of the type of TKI, line of TKI treatment or imatinib dose. As previous communications, age, comorbidities, CML phase and TKI response status and those who discontinued, presented an adverse outcome.

## **Conclusion:**

Survival of COVID-19 of CML patients on TKI is remarkable high, and there is no difference within the type of TKI, supporting that is safe to maintain TKI treatment during COVID-19 infection.

## **Acknowledgment**

The authors thank the iCMLf for case collection and the 189 physicians and partner organizations from 49 countries who contributed case reports.

Univariate analysis symptomatic patients								
	SEVERITY				MORTALITY			
	OR	CI lower	CI upper	p	OR	CI lower	CI upper	p
Age ≥ 75 y	2.599	1.356	4.983	0.004	5.912	2.914	11.997	<0.001
Disease Stage AP/BP	6.683	2.393	18.667	0.000289	11.603	3.666	36.726	<0.001
TKI treatment								
Asciminib	2	0.108	36.954	0.641	3.062	0.247	37.83	0.382
Bosutinib	1.333	0.137	12.948	0.804	1.427	0.164	12.38	0.747
Dasatinib	2.492	0.311	19.967	0.39				
Imatinib	2.538	0.328	19.65	0.372	1.334	0.162	10.96	0.788
Nilotinib	1.694	0.208	13.807	0.623	2.5	0.273	22.86	0.417
Ponatinib	0.412	0.024	7.053	0.54				
Comorbidities 2 or more	2.66	1.679	4.214	0.000031	1.961	1.012	3.802	0.0460
Non MMR	2.482	1.415	4.356	0.001529	4.162	1.936	8.947	0.000261
TKI interruption	10.239	6.372	16.455	<0.001	9.732	4.877	19.42	<0.001
Imatinib non standard dose	1.742	0.985	3.081	0.057	1.86	0.869	3.981	0.11
TKI 2nd line or more	0.824	0.503	1.353	0.445	1.137	0.606	2.132	0.69
Multivariate analysis symptomatic patients								
Age ≥ 75 y	2.343	0.857	6.405	0.097	6.242	1.533	25.421	0.011
Disease Stage AP/BP	1.784	0.256	12.414	0.559	2.618	0.29	23.624	0.391
Comorbidities 2 or more	1.609	0.748	3.464	0.224	0.388	0.084	1.791	0.225
Non MMR	1.534	0.427	5.509	0.511	3.79	0.69	20.815	0.125
TKI interruption	7.488	3.77	14.871	<0.001	5.063	1.708	15.006	0.003434

Variable	Total (n=864)	%
Age		
>- 75 years	62	7.18
<75 years	801	92.71
Unknown	1	0.12
Sex		
Male	508	58.80
Female	356	41.20
Comorbidities		
<-1	694	80.32
>-2	170	19.68
ITK Interruption due to COVID-19 Diagnosis		
Yes	185	21.41
No	631	73.03
Unknown	46	5.32
does not apply	2	0.23
Current TKI		
Imatinib	446	51.62
Dasatinib	153	17.71
Nilotinib	150	17.36
Bosutinib	52	6.02
Ponatinib	37	4.28
Asciminib	10	1.16
HQP1351	1	0.12
Combination of two drugs	12	1.39
PF-114	1	0.12
Vodobatinib	1	0.12
Chemotherapy	1	0.12
Standard dose of Imatinib		
Yes	321	37.15
No	123	14.24
Unknown	2	0.23
Treatment line		
First line	483	55.90
>-2 two lines	230	26.62
Unknown	151	17.48
Severity of COVID-19		
asymptomatic	60	6.94
mild	502	58.10
moderate	177	20.49
severe	106	12.27
Unknown	19	2.20

Title:

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**Category:**

Clinical

**Comments to Organizers:**

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