IMPACT OF COVID-19 PANDEMIC ON THE NEWLY DIAGNOSED PWH: DATA FROM TWO CLINICAL CENTRES IN ITALY

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BACKGROUND

In Italy, particularly in the North, the COVID-19 pandemic have significantly affected access to healthcare services, including HIV screening and management of people with HIV (PWH). We compared data from two clinical centres, one in the North and one in the Centre of Italy, regarding newly diagnosed people with HIV (ndPWH), before, during and after the pandemic.

AIM

Evaluation of clinical presentation at diagnosis and time to virological success (VS) at 12 months after starting ART.

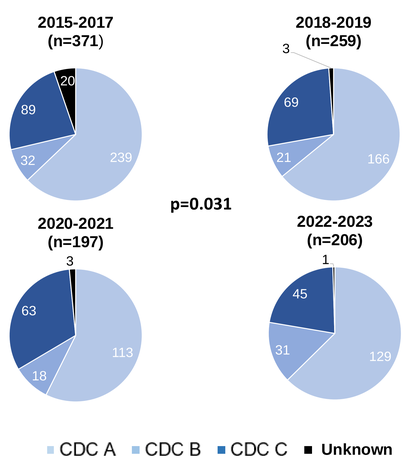
METHODS

- We conducted a retrospective observational study involving PWH diagnosed between 2015 and 2023 at two Italian large referral centres (North n=603 and Centre n=430)
- ndPWH with at least two HIV-RNA measurements within 12 months, 6±2 months apart
- ndPWH were categorized into four periods:

I. Pre-pandemic 2015-2017
II. Pre-pandemic 2018-2019
III. Pandemic 2020- 2021
IV. Post-pandemic 2022-2023

- Kaplan-Meier analysis assessed the probability at 12 months of achieving overall VS (HIV-RNA≤50 cps/mL)
- Cox regression model with fixed covariates after controlling for age, sex and time to ART initiation was used to determine independent predictors of VS.

CDC stage according to the four periods



PWH diagnosed during pandemic had worse initial clinical and viro-immunological conditions. However, this did not impact virological response

Table 1. Characteristics of the ndPWH at diagnosis according to the four periods

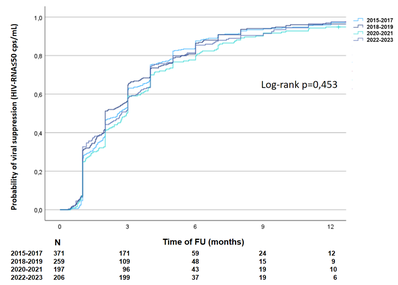
Variables	2015-2017 n= 371	2018-2019 n=259	2020-2021 n=197	2022-2023 n=206	Total n=1033
Gender, n (%)					
Cis-gender man	304 (81.9)	240 (92.7)	177 (89.8)	182 (88.3)	903 (87.4)
Cis-gender woman	67 (18.1)	19 (7.3)	20 (10.2)	24 (11.7)	130 (12.6)
Age, years, median (IQR)	46 (37-56)	46 (37- 56)	43 (34-54)	45 (36-56)	45 (36-56)
Risk Factor, n (%)					
MSM	148 (39.9)	87 (33.6)	73 (37.1)	64 (31.1)	372 (36.0)
Heterosexual	172 (46.4)	115 (44.4)	78 (39.6)	103 (50.0)	468 (45.3)
PWID	9 (2.4)	9 (3.5)	6 (3.0)	6 (2.9)	30 (15.8)
Unknown	42 (11.3)	48 (18.5)	40 (20.3)	33 (16.0)	163 (15.8)
Ethnicity, n (%)					
Caucasian	300 (80.9)	205 (79.2)	156 (79.2)	164 (79.6)	825 (79.9)
Latin america	18 (4.9)	17 (6.6)	11 (5.6)	9 (4.4)	55 (5.3)
Asian	13 (3.5)	10 (3.9)	7 (3.6)	15 (7.3)	45 (4.4)
African	40 (10.8)	27 (10.4)	23 (11.7)	18 (8.7)	108 (10.5
Hospitalized PWH at diagnosis, n (%)	127 (34.2)	103 (39.8)	86 (43.7)	68 (33.0)	384 (37.2)
Zenith HIV-RN, log_{10} copies/mL, median (IQR)	4.80 (4.25-5.42)	4.97 (4.37-5.46)	5.01 (4.46-5.61)	5.22 (4.49-5.76)	4.95 (4.36-5.55)
CD4 cells/mm^3, median (IQR)	311 (103-502)	258 (72-461)	245 (56-456)	253 (88-427)	265 (77-468)
CD4/CD8 ratio, median (IQR)	0.30 (0.13-0.52)	0.29 (0.12-0.54)	0.30 (0.11-0.52)	0.26 (0.11-0.44)	0.29 (0.12-0.52)
Time of ART initiation from HIV diagnosis, days, median (IQR)	33 (14-62)	18 (7-50)	14 (7-38)	14 (7-28)	20 (8-50)
First Antiretroviral regimen, n (%)					
Triple therapy	**354 (95.4)**	**244 (94.2)**	**164 (83.2)**	**196 (95.1)**	**957 (92.6)**
-2NRTI+INSTI	259 (73.2)	212 (86.9)	147 (89.6)	181 (92.3)	799 (83.5)
-2NRTI+PI	56 (15.8)	22 (9.0)	13 (7.9)	13 (6.6)	104 (10.9)
-2NRTI+NNRTI	39 (11.0)	10 (4.1)	4 (2.4)	1 (0.5)	54 (5.6)
Dual therapy (3TC/DTG)	0 (0)	9 (3.5)	29 (14.7)	10 (4.9)	48 (4.6)
Others	17 (4.6)	6 (2.3)	4 (2.0)	0 (0)	28 (2.7)
HBsAg positive, n (%)	17 (4.6)	14 (5.4)	8 (4.1)	4 (1.9)	43 (4.2)
HCV IgG positive, n (%)	25 (6.7)	18 (6.9)	13 (6.6)	10 (4.9)	65 (6.3)
AIDS defining illness, n (%)					
Toxoplasmosis	8 (2.2)	6 (2.3)	6 (3.0)	5 (2.4)	25 (2.4)
Wasting Syndrome	8 (2.2)	1 (0.4)	6 (3.0)	4 (1.9)	19 (1.8)
CMV (cerebral, chorioretinitis, disseminated)	9 (2.4)	16 (6.2)	12 (6.1)	9 (4.4)	46 (4.5)
Kaposi Sarcoma	16 (4.3)	15 (5.8)	6 (3.0)	10 (4.9)	47 (4.5)
Dementia AIDS related	5 (1.3)	4 (1.5)	6 (3.0)	4 (1.9)	19 (1.8)
PML	4 (1.1)	6 (2.3)	0 (0)	1 (0.5)	11 (1.1)
Pneumocystis pneumonia	29 (7.8)	23 (8.9)	23 (11.7)	20 (9.7)	95 (9.2)
Cryptococcosis	1 (0.3)	1 (0.4)	2 (1.0)	1 (0.5)	5 (0.5)
Lynphoma	6 (1.6)	12 (4.6)	7 (3.6)	3 (1.5)	28 (2.7)
Mycobatteriosis	6 (1.6)	8 (3.1)	5 (2.5)	4 (1.9)	23 (2.2)
Tubercolosis	9 (2.4)	5 (1.9)	7 (3.6)	1 (0.5)	22 (2.1)
Esophageal candidiasis	24 (6.5)	14 (5.4)	7 (3.6)	2 (1.0)	47 (4.5)
AIDS related death (within the year), n (%)	10 (2.7)	10 (3.9)	4 (2.0)	6 (2.9)	30 (2.9)
Virological suppression at 12 months, n (%)	353 (95.1)	241 (93.1)	183 (92.9)	194 (94.2)	971 (94.0)
Time to virological suppression, months, median (IQR)	2.60 (1.00-4.00)	2.00 (1.00-4.61)	2.97 (1.05-5.00)	2.73 (1.00-4.17)	2.67 (1-4.48)

RESULTS

We enrolled 1,033 ndPWH, main characteristics are shown in **Table 1**.

- NdPWH during pandemic were younger (p=0.050) and had a higher viral zenith (p<0.001) compared to those diagnosed pre-pandemic. During the pandemic period, the use of triple therapy declined markedly (p<0.001) while dual therapies as first line regimen increased (p<0.001).
- By KM the overall probability of experiencing VS at 12 months was 96.6%, with no significant differences among the periods **(Fig. 1)**.

Fig.1 Kaplan-Meier survival curve of months from ART initiation to achieving viral suppression among four periods.



- Multivariable Cox regression analysis adjusted for age, sex, time to ART initiation, confirmed no significant difference among the four periods in experiencing VS at 12 month (p=0.448) (Table 2).

Table 2. Cox proportional hazards regression analysis of time to VS

Factors		aHR	95 %CI		p
			Inferior	Superior	
Clinical centres	**Centre Italy**	0,00			
	North Italy	0.74	0.65	0.85	0.001
CDC C		0.81	0.69	0.96	0.014
Zenith HIV-RN (1 log_{10} copies/mL increase)		0.68	0.64	0.73	0,000
CD4 (100 cells/mm^3 increase)		1.04	1.01	1.07	0.007
INSTI-based regimen	**Triple**	0,00			
	Dual	1.67	1.43	1.96	0.001

CONCLUSIONS

In this two-centre observational study, we found that ndPWH diagnosed during pandemic:

- had worse initial clinical and viro-immunological conditions
- There was no difference in achieving virological suppression among four periods, likely due to the increasing availability of third-generation INSTIs in the recent years.
- Northern centre's participants had a lower likelihood of VS, possibly reflecting other unexplored confounders in addition to the greater impact of pandemic in that area.

ADDITIONAL KEY INFORMATION

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