Effects of Rapid Initiation of Antiretroviral Therapy in an Urban Clinic Setting

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Background

- Rapid initiation is defined as "initiation of antiretroviral therapy (ART) **at the time of diagnosis** in ART-naïve adults, and **ideally, on the same day, or within 72 hours**…"
  - Standard initiation refers to ART deferral pending pertinent labs
- Rapid initiation of ART in people living with HIV (PLWH) has several **benefits compared to standard initiation** of ART, including:
  - Improved viral suppression
  - Improved medication adherence
  - Improved retention in care
  - Decreased rates of HIV transmission
- **More real-world experience with rapid initiation programs is needed**, particularly in clinics within resource-limited settings
- In 2017, our HIV clinic implemented rapid initiation in select PLWH

Objectives

- To assess the effects of rapid compared with standard initiation of ART in a unique population of PLWH in New York City

Methods

- Retrospective chart review of SUNY Downstate Medical Center, Brooklyn, NY HIV clinic intakes between January 2016 and June 2021
- **Rapid start** = ART initiation within 72 hours of clinic intake
- **Inclusion Criteria**:
  - ART-naïve, or
  - ART-experienced and not on ART for > 3 months prior
- **Exclusion Criteria**:
  - Baseline undetectable HIV RNA
  - Perinatal HIV infection
- **Primary Outcome:** Proportion of HIV RNA < 50 copies/mL at week 52
- **Secondary Outcomes**:
  - Proportion of HIV RNA < 200 copies/mL at week 52
  - Retention in care at week 52
  - Time from intake to ART initiation
  - Time from ART initiation viral suppression
  - Time from intake to viral suppression

References

1. Ford N, et al. *AIDS*. 2018;32:17-23.
2. Radix A, Shalev N. New York State Department of Health AIDS Institute. 2021.

Results

Table 1. Baseline characteristics	Rapid (n=113)	Standard (n=77)
Age (years), mean ± SD	37.3 ± 11.4	40.7 ± 14.1
Male sex, n (%)	68 (60.2)	52 (67.5)
Race, n (%)		
Black/African American	101 (89.4)	68 (88.3)
White	10 (8.8)	7 (9.1)
Other	2 (1.8)	2 (2.6)
Weight (kg), mean ± SD	75.8 ± 19.9	81.4 ± 18.9
New intake, n (%)†	**79 (69.9)**	**66 (85.7)**
eGFR ≥ 80 mL/min/1.73m², n (%)	99 (87.6)	65 (84.4)
Baseline HIV laboratory tests		
VL (copies/mL), median (IQR)	25,271 (11,462)	28,901 (58,412)
VL > 1x10⁶ copies/mL, n (%)	31 (27.4)	16 (20.8)
CD4 (cells/µL), median (IQR)	300 (444)	319 (367)
CD4 < 200 cells/µL, n (%)	44 (38.9)	24 (32.4)
Hepatitis history, n (%)		
Hepatitis B	18 (15.9)	10 (13)
Hepatitis C	7 (6.2)	3 (3.9)
Prior use of ART, n (%)†	**57 (50.4)**	**25 (32.5)**
Initial ART regimen, n (%)		
BIC/FTC/TAF	56 (49.6)	24 (31.2)
EVG/COBI/FTC/TAF	17 (10.6)	22 (28.6)
EVG/COBI/FTC/TDF	8 (7.1)	7 (9.1)
DTG/ABC/3TC	0 (0)	7 (9.1)
DTG plus (FTC/TDF or FTC/TAF)	12 (10.6)	7 (9.1)
Other	25 (22.1)	10 (13)
Time from intake to ART initiation (days), mean ± SD†	**0.1 ± 0.4**	**35.8 ± 42.5**
HIV acquisition risk factors, n (%)		
0	1 (0.9)	2 (2.6)
1	52 (46.0)	29 (37.7)
2	32 (28.3)	19 (24.7)
3+	38 (24.8)	27 (35.1)

†Indicates a statistically significant difference (p < 0.05).

Table 2. Primary outcomes	Rapid (n=113)	Standard (n=77)	p-value
Primary outcome			
VL < 50 copies/mL at week 52, n (%)†	61 (54.0)	55 (71.4)	**p < 0.001**
Related outcomes of interest			
VL at week 52 (copies/mL), mean ± SD‡	26,483 ± 70,768	1,242 ± 5,633	**p = 0.012**
VL at week 24 (copies/mL), mean ± SD‡	8,204 ± 29,005	1,282 ± 5,259	p = 0.067
CD4 at week 52 (cells/µL), median (IQR)	371 (620)	428 (391)	p = 0.567
CD4 at week 24 (cells/µL), median (IQR)	312 (525)	504 (394)	p = 0.272

†For patients with missing data at week 52, the most recent VL was used.
‡Patients with missing data at weeks 52 and 24 were excluded. 115 and 122 had data at weeks 52 and 24, respectively.

Table 3. Secondary outcomes	Rapid (n=113)	Standard (n=77)	p-value
In care at week 52, n (%)	82 (72.6)	56 (72.7)	p = 0.981
VL < 200 copies/mL at week 52, n (%)†	77 (68.1)	61 (79.2)	p = 0.064
Therapy switch by week 52, n (%)	12 (10.6)	15 (19.5)	p = 0.067
Switch due to adverse effects, n (%)	8 (7.1)	3 (3.9)	p = 0.367
Weight difference from baseline to week 52 (kg), mean ± SD	3.8 ± 9.7	6.3 ± 8.3	p = 0.125

†For patients with missing data at week 52, the most recent VL was used.

Table 4. Secondary outcomes, cont.	Rapid	Standard	p-value
VL at week 52, n (%)†	n=66	n=49	
< 50 copies/mL	43 (65.2)	41 (83.7)	n/a
50-199 copies/mL	9 (13.6)	4 (8.2)	
200-99,999 copies/mL	7 (10.6)	4 (8.2)	
≥ 100,000 copies/mL	7 (10.6)	0 (0)	
Time from ART initiation to:‡	n=79	n=62	
VL < 50 copies/mL (weeks), mean ± SD	18.0 ± 14.5	13.9 ± 11.5	p = 0.378
VL < 200 copies/mL (weeks), mean ± SD	13.8 ± 11.9	11.8 ± 10.2	p = 0.396
Time from intake to:‡	n=79	n=62	
VL < 50 copies/mL (weeks), mean ± SD	18.0 ± 14.5	17.9 ± 12.3	n/a
VL < 200 copies/mL (weeks), mean ± SD	13.8 ± 11.9	15.8 ± 11.3	

†Patients with missing data at week 52 were excluded. 115 (60.5%) were included.
‡Patients who did not attain the specified VL at week 52 were excluded. 141 (74.2%) were included.

Discussion

- Despite initiation of ART a median of 5 weeks earlier in the rapid vs. standard group, **rapid initiation did not improve viral suppression or retention in care at week 52 in our clinic**
  - **HIV RNA also increased from week 24 to 52 in the rapid group**
- There was an approximate 2 week decrease in time from clinic intake to an HIV RNA < 200 copies/mL in the rapid vs. standard group
  - This, however, was **not a statistically significant difference**
- **Limitations included potential confounders**, such as prescriber bias and a significantly greater proportion of re-intakes in the rapid group
- **Other limitations** included inability to quantify time from HIV diagnosis to clinic intake as well as to assess medication adherence

Conclusions

- Our study highlights the need for a multifaceted approach to engaging PLWH throughout the care continuum to ensure retention
- **Future studies may focus on PLWH being re-engaged into care and considered for rapid initiation of ART**, given the paucity of data in this crucial subset of patients

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