

Outdated Antiretroviral Regimens (OLD-ART): A Cross-Sectional Study on the Achilles' Heel of Outpatient Care

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Background

- Despite the significant advancements in antiretroviral therapy (ART), [1] instances of PLWH persisting with outdated treatment regimens (OLD-ART) continue to come to our attention. [2]
- Therefore, we conducted a cross-sectional analysis to explore demographic characteristics, viro-immunological profiles, adverse effects (ADR), and potential alternative therapeutic options within our cohort of PLWH currently undergoing OLD-ART therapy.

Methods

- We included all outpatients currently receiving an OLD-ART who were under follow-up at the Unit of Infectious Diseases, ASST Spedali Civili di Brescia.
- We defined OLD-ART as a combination of antiretroviral drugs that included at least 1 agent not recommended as first- or second-line treatment according to the EACS 2023 guidelines.
- We excluded patients whose last visit occurred more than 1 year ago.
- Demographic data, viro-immunological profile, ADR, reasons for persistence of an OLD-ART regimen, and reasonable alternative were collected.
- A historical HIV-RNA resistance test was carried out using the HIV Drug Resistance Database (Stanford University) to address a reasonable alternative regimen.

Results

CHARACTERISTICS OF PATIENTS

- Forty-eight (48/3848, 1.2%) PLWH were included as currently undergoing treatment with OLD-ART, prevalently female (27/48, 56.3%), with a median age of 56 years (range 40-88), and of European origin (36/48, 75%). (Table 1)

Table 1. Characteristics of patients

Number of patients with available data	48 (100)
Years on-treatment, median (min-max)	22.5 (8-36)
HIV-RNA zenit (cp/mL), mean (±SD)	240,294 (±281,346)
CD4 nadir (cells/mcL), mean (±SD)	180 (±164)
Comorbidities	
Dyslipidaemia, n (%)	28 (58.3)
Arterial hypertension, n (%)	22 (45.8)
Smoking, n (%)	
Substance abuse, n (%)	17 (35.4)
Psychiatric diseases, n (%)	15 (31.2)
Neoplasia, n (%)	15 (31.2)
Diabetes, n (%)	7 (14.6)
Alcohol-abuse, n (%)	5 (10.4)
	2 (4.2)

OLD ART REGIMEN

- Twenty-nine (60.4%) PLWH maintained a stable viro-suppression (<50 cp/mL) during the OLD-ART with a mean CD4/CD8 ratio of 0.90 (±0.49). A regimen including a drug with a new mechanism of action was deemed necessary only in 1 case (2.5%). (Table 2)

Table 2. OLD-ART regimen and ADR

Number of patients with available data	48 (100)
<ul style="list-style-type: none"> ➢ ATV-containing, n (%) ➢ Boosted ATV, n (%) ➢ Unboosted ATV, n (%) ➢ ETV-containing, n (%) ➢ MVC-containing, n (%) ➢ NVP-containing, n (%) 	31 (64.6) 19 (61.3) 12 (38.7) 10 (20.8) 6 (12.5) 3 (6.6)
OLD-ART duration (months), mean (±SD)	115 (±66)
Voluntary OLD-ART temporary suspension, n (%)	11 (22.9)
Blip, n (%)	14 (29.2)
Current CD4 count, mean (±SD)	843 (±393)
Current CD8 count, mean (±SD)	1101 (±547)
Current CD4/CD8 ratio, mean (±SD)	0.90 (±0.49)
ADR, n (%)	28 (58.3)
Lab test abnormalities, n (%)	25 (89.3)
Dermatological side effects, n (%)	2 (7.1)
Psychiatric side effects, n (%)	1 (3.6)

- Based on the historical HIV-RNA resistance tests available (40/48, 83.3%), more than 2 reasonable treatment alternatives were available in 25 (62.5%) cases. (Table 3)

Table 3. Reasonable alternative on a historical HIV-RNA resistance test-basis

Number of historical HIV-RNA resistance tests available	40 (83.3)
<ul style="list-style-type: none"> ➢ At least 1 reasonable alternative, n (%) ➢ More than 2 reasonable alternative, n (%) ➢ Need for drugs with a new mechanism, n (%) 	40 (100) 25 (62.5) 1 (2.5)
Reasons for the OLD-ART regimen persistence	
Number of patients with available data	31 (64.6)
<ul style="list-style-type: none"> ➢ Patient's will, n (%) ➢ Referred impaired tolerance to other classes, n (%) ➢ Therapy modification in the footnote, n (%) ➢ Allergic reactions to other classes, n (%) 	16 (51.6) 6 (19.4) 5 (16.1) 4 (12.9)

ADVERSE EFFECTS

- Twenty-eight (58.3%) ADRs were identified, predominantly lab tests abnormalities (25/28, 89.3%) including mild-to-moderate hepatic toxicity (18/28, 64.3%). (Table 2)

REASONS FOR THE PERSISTENCE OF THE OLD ART

- The primary reason for persistence with the OLD-ART was patient's will (16/31, 51.5%), followed by referred impaired tolerance (6/31, 19.4%), and allergic reactions (4/31, 12.9%) to other classes.
- In 5 cases (16.1%) a therapy modification suggestion was written in the footnote to be considered at the subsequent follow-up visit. (Table 3)

Conclusions

- OLD-ART regimens persist in clinical practice, particularly among extensively treated patients. often because of patient preference.
- Nevertheless, numerous alternative regimens with improved tolerability are currently available and should be advocated during follow-up visits.

References

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