

# Feasibility of cabotegravir and rilpivirine long-acting injection specific program in a large center in Northern Italy: adherence, tolerability and costs

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## Introduction

- Another milestone in people living with HIV (PLWH) management is the introduction of long-acting injectable (LAI) therapy [1], which holds the potential to enhance medication adherence and improve compliance for PLWH [2,3].
- This analysis aims to investigate demographic aspects, tolerability, and cost savings in our cohort of PLWH currently receiving cabotegravir/rilpivirine (CAB/RPV) LAI therapy.

### Methods

- We included all outpatients currently receiving CAB/RPV LAI therapy followed at the Unit of Infectious Diseases (IDs), ASST Spedali Civili of Brescia.
- Demographic data, adverse drug reactions (ADR), reasons for treatment discontinuation and the annual number of accesses have been collected.
- A descriptive and pharmacoeconomic analysis has been conducted considering the patients on CAB/RPV LAI therapy to date.
- The prediction of cost savings associated with the switch from each oral regimen to the LAI was also assessed.
- For treatment costs (€), reference was made to 2023 Lombardy Regional HIV treatment recommendations (PDTA).

#### Results

- Our IDs Unit routinely follows 3848 PLWH.
- A total of 63 (63/3848, 16.4%) PLWH are currently undergoing therapy with CAB/RPV LAI, the majority of whom are male (53/63, 84.1%), with a median age between 46 and 60 years (25/63, 39.7%).
- The most common pre-switch oral regimens were DTG/RPV (14/63, 22.2%), DTG/3TC (14/63, 22.2%), and RPV/FTC/TAF (11/63, 17.5%).
- Twenty-eight patients (28/63, 44,4 %) received oral lead-in,
- Thirty-three ADRs were identified, mostly mild-to-moderate (32/33, 97.0%)
- The most frequently reported ADR was injection-site pain (16/33, 48.5%), followed by asthenia (3/33, 9.1%) and fever (3/33, 9.1%).

- Only one severe ADR reported: a case of erectile dysfunction, which resolved after suspension.
- There were 5 reported instances of treatment discontinuation, mainly due to ADRs and patient preference (4/5, 80%), or significant drug interactions (1/5, 20%).
- LAI treatment, requiring bi-monthly administrations, involves 6 outpatient accesses/year without increase in the accesses in respect of those under the previous oral treatment received.
- All patients kept their scheduled appointments except for two, who had to postpone their administration by 2-3 days, but still within the seven-day time window.

The annual overall cost savings associated with the switch to the LAI regimen amount to €23,042.87 compared to the previous oral regimen received in the last year.

### Conclusion

- Our cohort reported few ADRs, predominantly mild-to-moderate, consistent with existing literature [4].
- The adoption of LAI antiretroviral therapy may present an enduring opportunity for cost savings.
- In addition to its clinical benefits. Healthcare practitioners should acknowledge the feasibility of a LAI regimen.

Figure	1 Adverse reactions to LAI CAB/RPV				
Injection site reactions					
$\succ$	Pain, n (%)	16 (48.5)			
$\succ$	Itching, n (%)	1 (3.0)			
Neurological and psycological reactions					
$\succ$	Asthenia and/or malaise, n (%)	3 (9.1)			
$\succ$	Mood deflection and/or anxiety, n (%)	2 (6.1)			
$\succ$	Nightmeres and/or sleepiness, n (%)	2 (6.1)			
$\succ$	Headache, n (%)	1 (3.0)			
Gastrointestinal reactions					
$\succ$	Oral pain, n (%)	1 (3.0)			
$\triangleright$	Mouth ulcers, n (%)	1 (3.0)			
$\succ$	Disgeusia, n (%)	1 (3.0)			
Other reactions					
$\succ$	Referred erectile dysfunction, n (%)	1 (3.0)			
$\succ$	Fever and/or generalized pain, n (%)	3 (9.1)			
Lab test alterations					
$\triangleright$	Alanine aminotransferase increase, n (%)	1 (3.0)			

# igure 2 Analysis of the costs saved during one year of treatment in LAI compared to the expense for oral reatment received in the previous year

Oral ARV Therapy	Annual Therapy cost/patient (€)	Annual CAB/RPV LAI cost/patient (€)	Annual cost saving/patient (€)	Patients switched to CAB/RPV LAI	Total Annual cost saving/patient (€)
FTC/TAF/DRV/c	7.150,92	5.631,18	-1.519,74	1	-1.519,74
DTG/ABC/3TC	7.029,84	5.631,18	-1.398,66	5	-6.993,30
BIC/FTC/TAF	6.533,16	5.631,18	-901,98	10	-9.019,80
DTG/RPV	5.992,32	5.631,18	-361,14	14	-5.055,96
RPV/FTC/TAF	5.879,04	5.631,18	-247,86	11	-2.726,46
DTG/3TC	5.431,68	5.631,18	199,50	14	2.793,00
DOR/TDF/3TC	5.243,59	5.631,18	387,59	2	775,18
DRV/COBI+RPV	6.926,97	5.631,18	-1.295,79	1	-1.295,79
TOTAL					-23.042.87

Acronym used: DTG, dolutegravir: ABC, abacavir: 3TC, lamiyudine: RPV, rilpivirine: CAB, cabotegravir, FTC, emtricitabine: TAF, le; TDF, tenofovir disoproxil fumarate; BIC, bictegravir, DRV, darunavir, /c, cobicista

#### References

- Ambrosioni J, et al. Major revision version 12.0 of the European AIDS Clinical Society guidelines 2023. HIV Med. 2023 Nov;24(11):1126-1136. Nachega JB, et al. Long-acting antiretrovirals and HIV treatment adherence. Lancet HIV. 2023 May;10(5):e332-e342.

Chaudhary K, et al. Long-Acting Injectables: Current Perspectives and Future Promise. Crit Rev Ther Drug Carrier Syst. 2019;36(2):137-181. Parker B, et al. Cost-effectiveness of the long-acting regimen cabotegravir plus rilpivirine for the treatment of HIV-1 and its potential impact on adherence and viral transmission: A modelling study. PLoS One. 3. 4. 2021 Feb 2;16(2):e0245955.