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# Real-life efficacy and satisfaction of long-acting ART Cabotegravir-Rilpivirine in HIV-infected individuals

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***ABSTRACT:***

***Objective:*** Switching from oral anti-retroviral therapy (ART) to intramuscular administration of Cabotegravir-Rilpivirine (CAB+RPV) has been observed to decrease the number of pills that patients need to take, enhance patient satisfaction, and promote better adherence to treatment. Clinical trials have reported not only the virological and immunological effectiveness of these intramuscular medications but have also assessed their safety and patient satisfaction. This transition eliminates the challenges related to patient adherence and compliance with daily oral regimens.

***Patients and Methods:*** Our observational study included 14 people living with HIV (PLWH) who were under medical care at the "Gaetano Martino" University Hospital in Messina, Italy. These individuals were virologically suppressed and had been adherent to ART for at least 6 months. Importantly, they did not have documented or suspected resistance mutations to Cabotegravir + Rilpivirine (CAB+RPV). Data were collected at different time points: at the beginning of the study, one month after the lead-in phase with oral CAB+RPV, and one month after the first and second injections of CAB+RPV. Additionally, we routinely measured CD4+, CD8+, CD4+/CD8+ ratio, HIV-RNA plasma viral load, and clinical chemistry parameters. Statistical analysis was performed with Jamovi 2.0 for MacOS. Patient treatment satisfaction was assessed through a questionnaire, where we formulated and administered a series of questions to our patients to gauge their satisfaction with the intramuscular administration of these long-acting medications. Specifically, we asked them a simple question to determine whether they were satisfied or dissatisfied with the new method of administering CAB+RPV.



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— ***Results:*** In our study, we enrolled 14 individuals living with HIV (PLWH), predominantly males (92.9%), with a median age of 36 years (IQR: 30.25-39.75). Of these participants, 85.7% had transitioned from an integrase strand transfer inhibitor (INSTI)-based regimen, 7.1% from a non-nucleoside reverse transcriptase inhibitor (NNRTI)-based regimen, and 7.1% from a protease inhibitor (PI)-based regimen. Notably, HIV-RNA remained undetectable throughout the assessment period. Following the first intramuscular (IM) injection, 78.5% reported moderate to severe pain, decreasing to 57.1% after the second injection. While not statistically significant, we observed a positive trend in CD4+ percentage ($p$=0.641) and CD4/CD8 ratio ($p$=0.368), with a non-significant decrease in CD4+ T-cell count ($p$=0.882). The transition to IM CAB+RPV did not significantly impact low-density lipoprotein cholesterol (LDLc) levels ($p$=0.417). When questioned about satisfaction with the new treatment regimen, 71.4% of PLWH expressed contentment with the injectable regimen, while 21.4% chose not to respond.

— ***Conclusions:*** People living with HIV (PLWH) who were on long-acting ART (LA-ART) with CAB+RPV expressed satisfaction with their new treatment regimen, and viral load remained undetectable in all cases. Pain, as reported in clinical trials, emerged as the primary side effect. Our real-life experience affirmed the virological and immunological effectiveness, safety, and patient satisfaction associated with long-acting ART using CAB+RPV.

— ***Keywords:*** *HIV, Cabotegravir, Rilpivirine, ART, Long-acting.*

— ***Abbreviations:*** *PLWH: people living with HIV; ART: anti-retroviral therapy; DDIs: drug-drug interactions; LA: long-acting; LAI: long-acting injectable; LA-ART: long-acting anti-retroviral therapy; LAI-ART: long-acting injectable anti-retroviral therapy; CAB+RPV: cabotegravir + rilpivirine; INSTI: integrase strand transfer inhibitor; NNRTI: non-nucleosidic reverse transcriptase inhibitor; PI: protease inhibitor; LDLc: low-density lipoprotein cholesterol; IM: intramuscular.*

## INTRODUCTION

Since the introduction of highly active antiretroviral therapy (ART), the landscape of HIV treatment has evolved significantly, transitioning from complex medication regimens to single fixed-dose combinations[1]. This shift has led to a dramatic reduction in HIV-1-related morbidity and mortality[2]. The efficacy and tolerability of these newer ART regimens have not only extended the length of life but also improved the quality of life for people living with HIV (PLWH)[3-9]. In the absence of curative treatments or an effective vaccine, ART remains the cornerstone of HIV management and prevention[7-12]. Current ART regimens have achieved optimal anti-retroviral effectiveness and tolerability, effectively transforming HIV from a life-threatening illness into a manageable chronic condition. Hence, adherence to daily oral medication intake is paramount to maintaining sustained viral suppression and preventing the emergence of drug-resistant viral strains[11,12]. The complexity of managing co-medications and drug interactions, especially in the aging PLWH population, adds further challenges[3-10]. The effectiveness of current ARTs hinges on the need for consistently high levels of adherence to sustain virologic suppression[13-16]. Factors related to regimen complexity, such as dosing frequency, the number of pills, dietary considerations, stigma, and drug interactions between oral antiretrovirals and commonly prescribed non-ART medications, contribute to these challenges[2-9]. Additionally, the emotional burden of daily oral pill-taking can compound the challenges of living with HIV. Consequently, there is a significant interest in developing long-acting (LA) treatments that can address these issues and simplify ART for PLWH[10-17]. Non-boosted integrase inhibitor-based regimens are currently the preferred choice for initial treatment. They have demonstrated[12,13] high rates of viral suppression, good tolerability, and a high resistance barrier. Some virologically suppressed HIV patients may benefit from switching their ART regimen. Reasons for switching can include side effects, pill burden, the emergence of new or worsening medical comorbidities (such as chronic kidney disease), drug-drug interactions, or the use of older regimens associated with a higher risk of long-term toxicity[8,11]. When switching regimens, both oral and injectable options are available. Long-acting ART not only improves patient privacy but also reduces the social stigmas associated with HIV[3,5]. Eligible patients who opt for long-acting injectable ART are particularly interested (reportedly up to 70%) in the enhanced convenience, freedom, confidentiality, and emotional benefits that come with no longer having to take daily pills, which constantly remind them of their HIV status[4]. The introduction of long-acting formulations of the CAB+RPV combination administered *via* intramuscular injection has made it possible to treat PLWH without the need for daily pills, marking a historic milestone in HIV treatment[8-11]. Clinical trials[6] have demonstrated that transitioning from oral ART to injectable CAB+RPV is effective and safe, reduces pill burden, increases patient satisfaction, and enhances adherence. This study presents real-world experience with the use of the long-acting injectable regimen CAB+RPV for HIV treatment in patients with virologic suppression within our clinical setting[6-11].

## PATIENTS AND METHODS

Our observational study was conducted at the "G. Martino" University Hospital in Messina, Italy. We enrolled people living with HIV (PLWH) who had switched to intramuscular (IM) ART with CAB+RPV. These individuals had been virologically suppressed for a minimum of 6 months, were on the same oral regimen for at least 6 months, and did not have any reported resistance mutations that would affect their susceptibility to either CAB or RPV. All PLWH on the IM CAB+RPV regimen were consecutively included in our study. We collected data related to viro-immunological effectiveness, which encompassed HIV-RNA plasma viral load (pVL), CD4+ T-cell count and percentage, CD4/CD8 ratio, and metabolic safety parameters, such as creatinine and LDL cholesterol. These data were collected at various time points: baseline, at the conclusion of the lead-in phase with oral CAB+RPV (consisting of 2 pills), and one month after the first injection. The end of the lead-in phase coincided with the day of the first IM injection, while the second injection was administered one month later, according to the study protocol. After each IM administration, we inquired with PLWH about their satisfaction with the treatment and their pain experience. We administered a questionnaire to our patients, which included a specific question to assess their satisfaction with the new intramuscular long-acting treatment compared with their previous regimen. Furthermore, we provided them with a concise questionnaire in which we inquired about the level of pain they experienced after the first and second intramuscular administrations of CAB+RPV. We used a scale ranging from 1 to 3, with these values correlated to different pain thresholds: 1 indicating mild pain, 2 indicating a moderate pain threshold, and 3 indicating a severe pain threshold.

### Statistical Analysis

Statistical analysis was performed with Jamovi 2.0 for MacOS (available at: https://www.jamovi.org). Categorical variables were described using count and percentages, while quantitative variables were described using median (interquartile range, IQR). Inferential tests comparing quantitative variables were performed with Friedman test for repeated measures when non-normally distributed, or with ANOVA when normally distributed. Variables' distribution was tested with the Shapiro-Wilk test. The statistical significance of the *p*-value is 0.05.

## RESULTS

We included a total of 14 people living with HIV (PLWH) in our study, of whom 13 were males (92.9%), and the median age was 36 years (IQR: 30.25 - 39.75). Among these participants, 12 PLWH (85.7%) had switched from an integrase strand transfer inhibitor (INSTI)-based regimen, one (7.1%) from a non-nucleoside reverse transcriptase inhibitor (NNRTI)-based regimen, and one (7.1%) from a protease inhibitor (PI)-based regimen. Importantly, HIV-RNA remained undetectable at both assessment time points. After the first intramuscular (IM) injection, 78.5% of cases reported moderate to severe pain, while after the second injection, 57.1% still experienced moderate to severe pain (see Table 1). Although not statistically significant, we observed a positive trend in CD4+ percentage ($p$=0.641) and CD4/CD8 ratio ($p$=0.368), while the CD4+ T-cell count showed a decrease ($p$=0.882). The switch to IM CAB+RPV did not significantly impact low-density lipoprotein cholesterol (LDLc) levels ($p$=0.417) (see Table 2). When queried about their satisfaction with the new treatment regimen, 10 out of 14 PLWH (71.4%) reported that they were content with the new injectable regimen, while 4 (21.4%) preferred not to respond.

## DISCUSSION

In our observational study, we have found that the administration of injectable CAB+RPV is both safe and effective in real-life conditions, demonstrating positive

**Table 1.** Patients' characteristics, previous ART regimens, LA-ART satisfaction, pain at first and second dose.

| Variable | Count | Percentage |
|---|---|---|
| Age (yrs, median, IQR) | 36 | 30.25-39.75 |
| Sex | | |
| Male | 13 | 92.9 |
| Female | 1 | 7.1 |
| Previous ART | | |
| BIC/FTC/TAF | 3 | 21.4 |
| DOR/3TC/TDF | 1 | 7.1 |
| DTG + FTC/TAF 25 | 2 | 14.3 |
| DTG/3TC | 3 | 21.4 |
| DTG/RPV | 1 | 7.1 |
| DRV/c/FTC/TAF | 1 | 7.1 |
| DTG/ABC/3TC | 2 | 14.3 |
| DTG + FTC/TDF | 1 | 7.1 |
| Satisfaction | | |
| Yes | 10 | 71.4 |
| No | 1 | 7.1 |
| Not answering | 3 | 21.4 |
| Pain at 1st IM dose | | |
| None | 0 | 0.0 |
| Mild | 1 | 7.1 |
| Moderate | 5 | 35.7 |
| Moderate/Severe | 3 | 21.4 |
| Severe | 3 | 21.4 |
| Not answering | 2 | 14.3 |
| Pain at 2nd IM Dose | | |
| None | 0 | 0.0 |
| Mild | 0 | 0.0 |
| Moderate | 5 | 35.7 |
| Moderate/Severe | 2 | 14.3 |
| Severe | 1 | 7.1 |
| Not answering | 6 | 42.9 |

**Table 2.** Virological and immunological characteristics: switch os (baseline before switch per os), Switch IM (before Switch IM, after one month of oral therapy), 1st month IM (after one month from the first injection). All values are median (IQR).

| | Switch os | Switch IM | 1st month IM | *p*-value |
|---|---|---|---|---|
| HIV-RNA (cps/mL) | TND | TND | TND | N/A |
| CD4 (%) | 38.5 (36.1-45.0) | 41.6 (37.1-46.4) | 42.1 (38.7-42.4) | 0.641 |
| CD4 (cells/µL) | 975 (764-1194) | 944 (633-1243) | 737 (652-959) | 0.882 |
| CD4/CD8 | 1.26 (0.94-1.40) | 1.27 (1.10-1.50) | 1.35 (1.12-1.50) | 0.368 |
| LDLc | 99 (89.5-128) | 88 (76-124) | 94.5 (84-122) | 0.417 |

results in both immunological and virological aspects. All patients achieved undetectable viral loads within two months of starting CAB+RPV, and none of them requested a return to their previous regimen. The primary side effect reported was injection site pain, which notably decreased after the second dose. The challenge of adherence to daily oral drug regimens persists, as it remains the most critical factor for maintaining sustained viral suppression and preventing the emergence of drug-resistant viral strains. Managing additional co-medications and potential drug-drug interactions adds complexity, particularly among the aging population of people living with HIV (PLWH)[6-18]. The introduction of long-acting formulations of CAB+RPV, administered through intramuscular injection, represents a significant milestone in HIV treatment, allowing PLWH to manage their condition without daily pills for the first time in history[13-15]. Clinical trials[10-12], along with our real-world study, have demonstrated that transitioning from oral ART to injectable CAB+RPV is not only effective and safe but also reduces the burden of daily pill intake, increases patient satisfaction, and improves adherence. From an immunological standpoint, we observed an increase in CD4+ percentage and CD4/CD8 ratio, indicating positive impacts on immune health. Furthermore, the switch to intramuscular (IM) CAB+RPV did not significantly affect LDL cholesterol levels. Regarding patient satisfaction with the IM regimen, the majority of our patients expressed contentment and satisfaction with the injectable treatment. However, it is worth noting that four patients chose not to respond. In alignment with clinical trials and prior research[15,16], eligible patients who opted for long-acting injectable ART were particularly interested in the improved convenience, freedom, and emotional benefits that come with no longer being constantly reminded of their HIV status through daily pill use.

## CONCLUSIONS

The use of injectable formulations of potent and long-lasting molecules, such as CAB+RPV, is poised to become more widespread on a global scale[12-16]. The long-acting injectable (LAI) CAB+RPV formulation, with its ability to maintain effective plasma concentrations for two months, holds significant promise for transforming HIV management in the years ahead[14-16]. While our real-life experience involved a limited number of people living with HIV (PLWH), it demonstrates that the transition to IM CAB+RPV is well-received by PLWH[14,15]. However, the successful implementation and deployment of such revolutionary treatment and prevention approaches for HIV infection require careful patient monitoring[6-11]. This monitoring should encompass the assessment of viral suppression and CD4 counts, as well as the measurement of anti-retroviral drug levels in plasma, and potentially in body tissues and cellular compartments. Further studies are needed to fully exploit the remarkable therapeutic and prophylactic potential of long-acting ARTs in real-life scenarios[7-19]. Our future goal is to expand our study by evaluating a larger cohort of patients, with the aim of confirming and expanding upon the data we have gathered thus far.

### Informed Consent:
The informed consent form was signed by every patient and stored according to the SHIC Cohort protocol.

### Ethics Approval:
The study was conducted in accordance with the Declaration of Helsinki and approved by the Provincial Ethics Committee of Messina (protocol code: 34/17 of 22/03/2017, date of approval: 22/05/2017).

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The authors declare no conflict of interest.

### Availability of Data and Materials:
All data generated or analyzed during this study are included in this published article.

**Authors' Contributions:**
Conceptualization: S.S. and A.S.; validation: E.V.R. and A.M.; investigation: S.S.; resources: E.V.R. and G.F.P.; data curation: S.S., Y.R., and M.C.; writing—original draft preparation: S.S. and A.S.; writing—review and editing: S.S. and A.S.; visualization: G.N., G.F.P., M.C., and CM; supervision: G.N.; project administration: G.N. and E.V.R. All authors have read and agreed to the published version of the manuscript.

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