SUBGROUP ANALYSIS OF PATIENT-REPORTED OUTCOMES AMONG PARTICIPANTS IN 2 PHASE III CLINICAL TRIALS OF LONG-ACTING CABOTEGRAVIR AND RILPIVIRINE (ATLAS AND FLAIR)

P012

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Introduction

- The phase III ATLAS and FLAIR trials demonstrated noninferiority of long-acting (LA) CAB + RPV to daily oral ART in virologically suppressed participants with HIV-1[1,2]
- Patient satisfaction and acceptance of therapeutic options are crucial components for ensuring treatment adherence in PLHIV[3]
- Patient-reported outcomes in ATLAS and FLAIR indicated higher levels of treatment satisfaction and acceptance with CAB LA + RPV LA compared with daily oral ART[1-3]
- This analysis describes the association between participant demographics/treatment factors and treatment satisfaction/acceptance rates of CAB LA + RPV LA

Methods

- Multivariable analyses for baseline treatment satisfaction were performed using the HIV Treatment Satisfaction Questionnaire, status version (HIVTSQs); treatment acceptance was assessed using the "general acceptance" domain of the Chronic Treatment Acceptance Questionnaire (ACCEPT) and acceptability of injection-site reactions (ISRs) with the "acceptance of ISRs" domain of the Perception of Injection (PIN) questionnaire
- Data were analyzed by region, sex, age, race/ethnicity, body mass index (BMI), Centers for Disease Control and Prevention HIV stage, number of comorbidities, baseline third agent class, prior single- or multi-tablet ART, and time on ART at study entry for HIVTSQs total score and ACCEPT general acceptance score
- Similar factors influencing baseline (Week 5) acceptability of ISRs with CAB LA + RPV LA according to the "acceptance of ISRs" domain of the PIN were explored
- Change from baseline for parameters influencing baseline scores was estimated for Weeks 44 and 48

Results

Factors Influencing Baseline HIVTSQs and ACCEPT Scores

- The factors appearing to be significantly influencing both baseline HIVTSQs and ACCEPT scores ($P<0.05$) were baseline third agent class, time on ART, and prior single- or multi-tablet ART; these factors were the focus of this analysis
- Within the identified common baseline factors, the lowest levels of baseline treatment satisfaction and acceptance were reported by participants on PI-based regimens at baseline, those with prior use of multitablet regimens, and those with 48 to 72 weeks of prior ART experience (Figure 1)
- The highest levels of baseline treatment satisfaction and acceptance were observed in participants receiving INI-based regimens at baseline, those with prior use of single-tablet regimens, and those with <24 weeks of prior ART experience (Figure 1)

Figure 1. Mean Baseline (A) Treatment Satisfaction Based on HIVTSQs Score and (B) Acceptance Based on ACCEPT Score by Subgroup
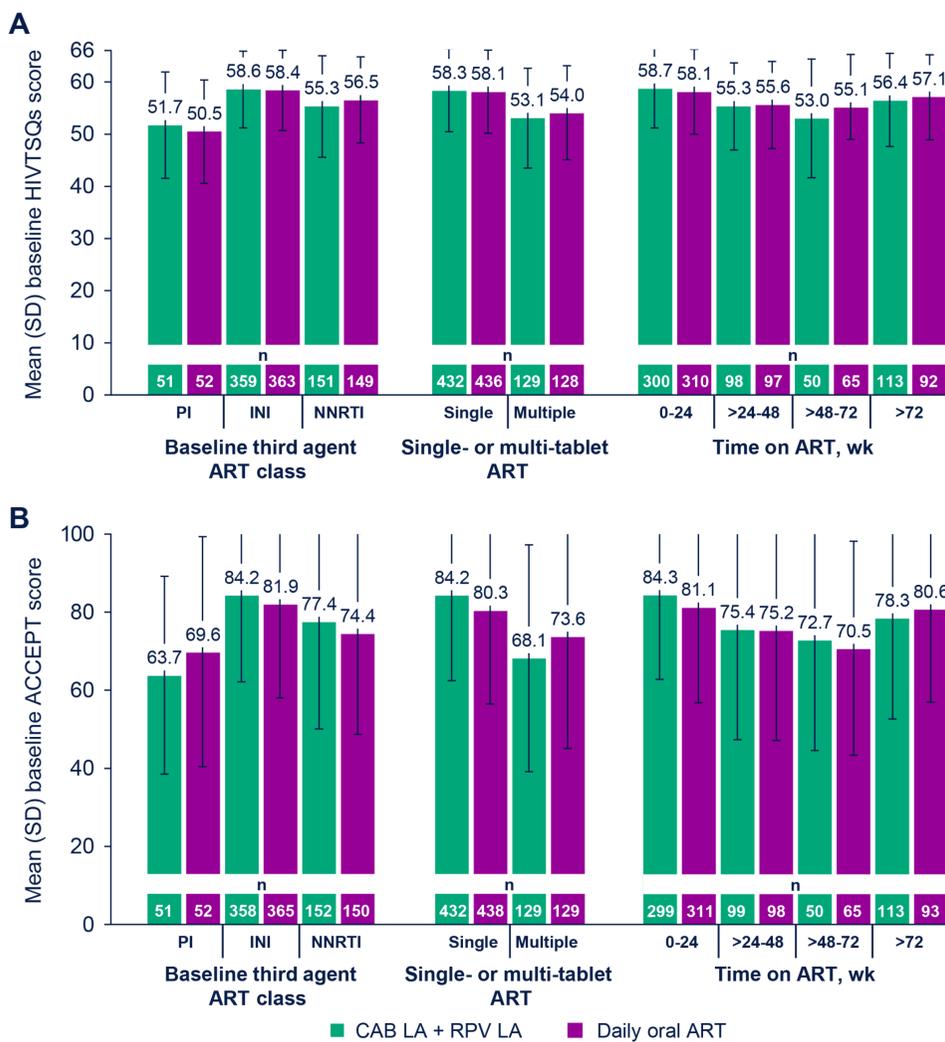

The maximum score for the HIVTSQ is 66, and the maximum score for the ACCEPT is 100.

Week 44 and 48 Treatment Satisfaction and Acceptance by Subgroup

- For participants reporting lower baseline scores, improvements in treatment satisfaction and acceptance scores after approximately 1 year of therapy with CAB LA + RPV LA were more pronounced vs those with higher baseline scores (Figure 2)
- Improvements from baseline in treatment satisfaction at Week 44 and acceptance at Week 48 were greater in all participants receiving CAB LA + RPV LA compared with those receiving daily oral ART, reaching very high levels regardless of baseline values

Figure 2. Change From Baseline in (A) Treatment Satisfaction Based on HIVTSQs Score at Week 44 and (B) Treatment Acceptance Based on ACCEPT Score at Week 48
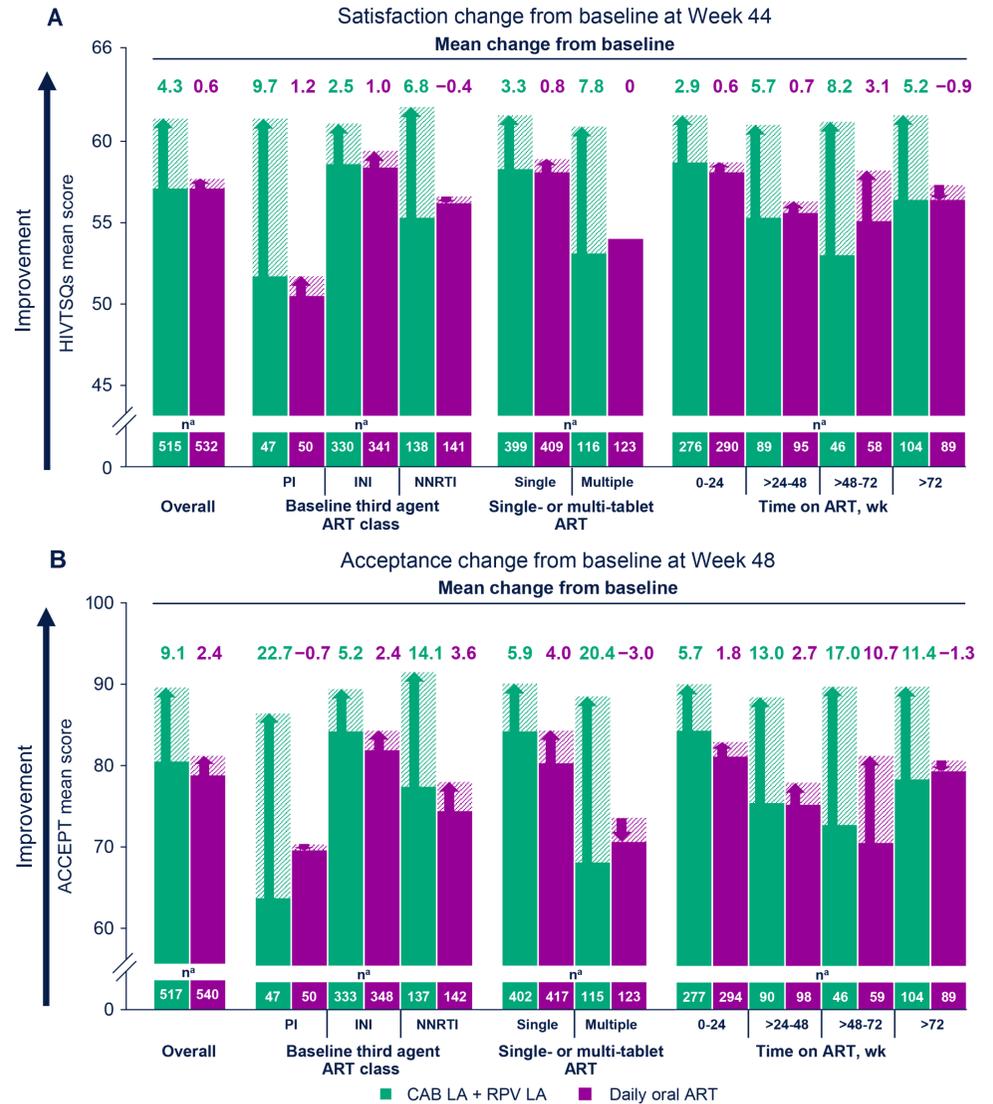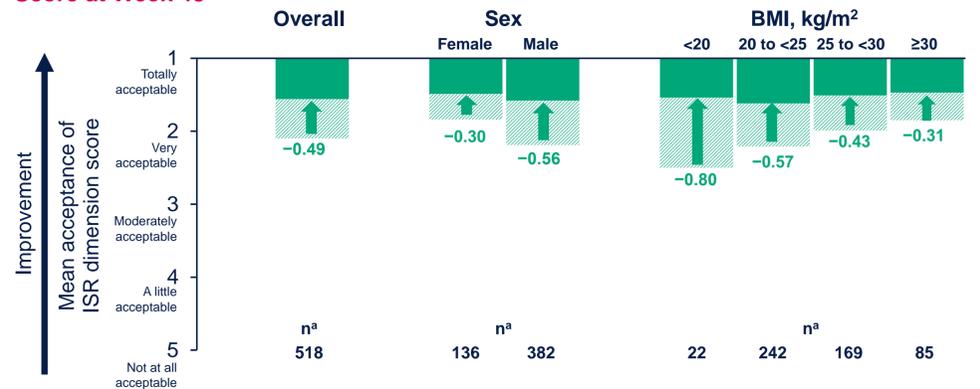

Dashed bar represents absolute change from baseline at each time point and arrow direction indicates increase or decrease from baseline.
[a]n for change from baseline groups at Week 44 for satisfaction and at Week 48 for acceptance.

Acceptance of ISRs

- Overall initial acceptability of ISRs was high 1 week after the first injection (Week 5) in participants receiving CAB LA + RPV LA
- Sex and BMI appear to be significant influencing factors for initial acceptability of ISRs ($P<0.05$)
  - At Week 5, female participants and those with higher BMI were more accepting of pain and local reactions after injections with CAB LA + RPV LA
- Acceptability of ISRs at Week 48 consistently improved from Week 5 for all subgroups, reaching similar high levels regardless of initial "Acceptance of ISRs" scores (Week 5; Figure 3)

Figure 3. Mean Change From Baseline (Week 5) in Acceptance of ISRs Dimension Score at Week 48

Dashed bar represents absolute change from baseline at each time point. Upward arrow direction indicates improvement from baseline in acceptability of ISR dimension score. BMI, body mass index; ISR, injection-site reaction. [a]n for change from baseline groups at Week 48.

Conclusions

- Baseline third agent class, time on ART, and prior single- or multi-tablet ART were shared predictors of lower baseline satisfaction and acceptance, indicating a higher level of unmet need with current regimens among participants taking PI-based regimens, those with prior use of multitablet regimens, and those with longer ART experience
- High levels of treatment satisfaction and acceptance were reached for participants receiving CAB LA + RPV LA for approximately 1 year, demonstrating marked improvements from baseline vs daily oral ART, regardless of participant demographics and baseline treatment factors
- Acceptability of CAB LA + RPV LA injections was high and improved over time, regardless of baseline demographics

References: 1. Orkin et al. *N Engl J Med.* 2020;382:1124-1135. **2.** Swindells et al. *N Engl J Med.* 2020;382:1112-1123. **3.** Murray et al. *AIDS Behav.* 2020 [Epub ahead of print].