

Improvements in Patient-Reported Outcomes in Older Adults Aged ≥ 50 Years With HIV-1 After Switching to a 2-Drug Regimen of Fixed-Dose Combination DTG/3TC: 48-Week Results From the SALSA Study

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Key Takeaways

- Patient-reported health outcomes in participants aged ≥ 50 years were evaluated 48 weeks after switching to DTG/3TC in the SALSA study

- Among older adults living with HIV (OALWH), switching to DTG/3TC resulted in greater treatment satisfaction early after switch compared with those continuing a 3- or 4-drug antiretroviral regimen and remained high through 48 weeks

Introduction

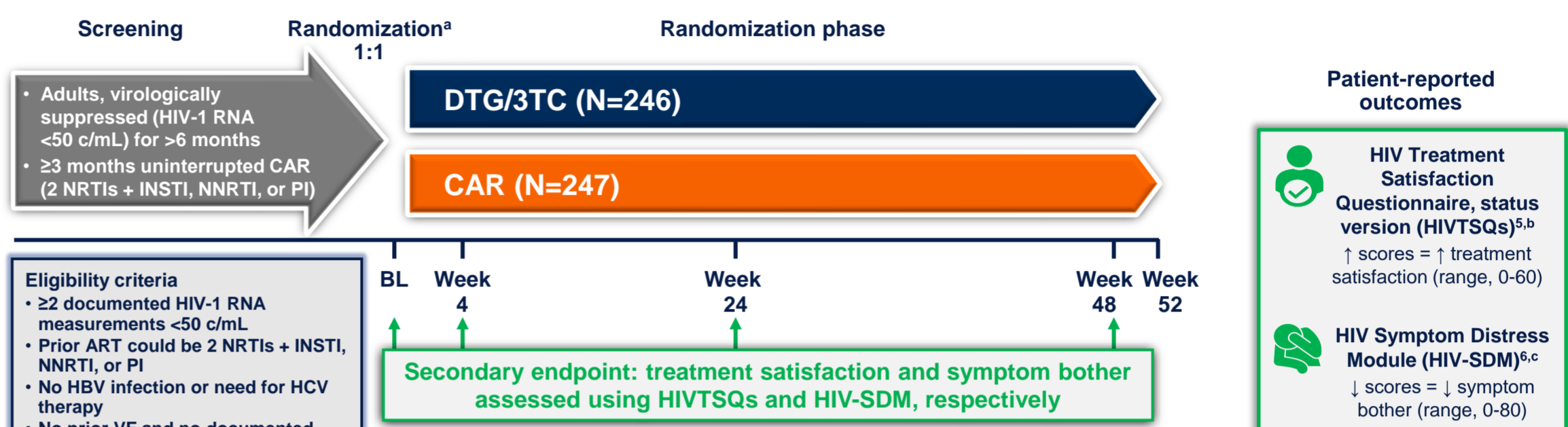
- Due to significant improvements in HIV treatments and consequently longer life expectancies, OALWH are a growing and important population¹
- Patient-reported outcomes provide insight into unmet needs beyond virologic suppression in OALWH²
- In the SALSA study (NCT04021290), switching to the 2-drug regimen DTG/3TC was non-inferior in maintaining virologic suppression at Week 48 compared with continuing a variety of 3- or 4-drug current antiretroviral regimens (CAR) in virologically suppressed adults, including OALWH³
- Secondary analyses of patient-reported outcomes in SALSA demonstrated greater early improvements in treatment satisfaction and less symptom distress in participants switching to DTG/3TC vs those continuing CAR through 48 weeks of treatment⁴
- Here, we present a post hoc analysis of patient-reported outcomes through Week 48 in SALSA analyzed by age at baseline

Methods

- SALSA is a randomized, open-label study of virologically suppressed adults (HIV-1 RNA < 50 c/mL) on a stable 3- or 4-drug regimen for ≥ 3 months who were randomly assigned to switch to DTG/3TC or continue CAR (Figure 1)

- A post hoc analysis of treatment satisfaction and symptom bother by age (≥ 50 and < 50 years) using the HIV Treatment Satisfaction Questionnaire, status version (HIVTSQs) and HIV Symptom Distress Module (HIV-SDM), respectively, was performed at Weeks 4, 24, and 48
- Adjusted mean change from baseline to Week 48 for HIVTSQs and HIV-SDM were compared between treatment groups using mixed-model repeated-measures analyses adjusting for relevant baseline variables as specified in the respective figures below

Figure 1. Study Design



BL, baseline. *Stratified by BL third agent class (PI, INSTI, or NNRTI). [†]10-item, self-reported Likert scale (score of 0-6 per item). [‡]20-item, self-reported Likert scale (score of 0-4 per item).

Results

Participants

- Of 493 participants, 39% were aged ≥ 50 years (Table)
- Participants aged ≥ 50 years had greater concomitant medication use and more comorbidities at baseline; baseline characteristics were otherwise similar between age groups

Table. Demographics and Baseline Characteristics by Age and Overall

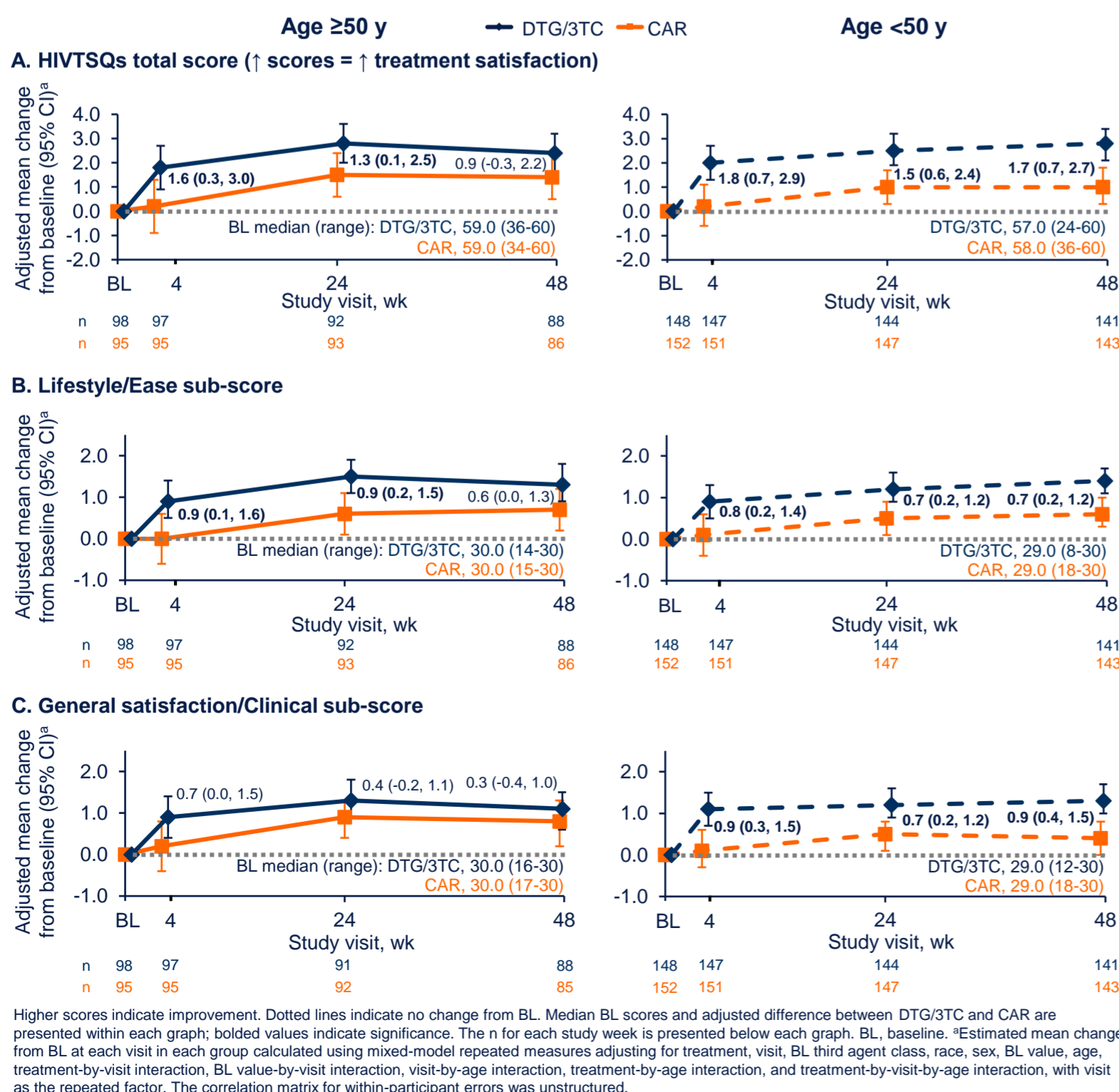
Parameter	Age ≥ 50 y		Age < 50 y		Overall	
	DTG/3TC (N=98)	CAR (N=95)	DTG/3TC (N=148)	CAR (N=152)	DTG/3TC (N=246)	CAR (N=247)
Age, median (range), y	56 (50-74)	56 (50-83)	38 (22-49)	39 (23-49)	45 (22-74)	45 (23-83)
CD4+ cell count, median (range), cells/mm ³	690 (176-2089)	712 (193-1530)	666 (154-1825)	647 (94-1954)	675 (154-2089)	668 (94-1954)
BMI, median (range), kg/m ²	25.2 (18-43)	26.5 (14-44)	25.4 (18-51)	25.3 (17-69)	25.3 (18-51)	25.6 (14-69)
Baseline NRTI, n (%) ^a						
TDF	39/95 (41)	36/92 (39)	69/141 (49)	73/142 (51)	108/236 (46)	109/234 (47)
TAF	32/95 (34)	38/92 (41)	51/141 (36)	53/142 (37)	83/236 (35)	91/234 (39)
ABC	24/95 (25)	18/92 (20)	21/141 (15)	16/142 (11)	45/236 (19)	34/234 (15)
Baseline use of ≥ 1 non-ART medication, n (%)	75 (77)	81 (85)	77 (52)	82 (54)	152 (62)	163 (66)
≥ 1 Baseline comorbidity, n (%)	76 (78)	80 (84)	88 (59)	97 (64)	164 (67)	177 (72)

^aOther NRTI backbone regimens were included in SALSA (zidovudine, tenofovir disoproxil succinate, bicovir [NOS]).

HIVTSQs

- Baseline HIVTSQs total score and lifestyle/ease and general satisfaction/clinical sub-scores were similar between the DTG/3TC and CAR groups among participants aged ≥ 50 and < 50 years
- Participants aged ≥ 50 years who switched to DTG/3TC had greater improvements (higher increases from baseline) compared with those continuing CAR in mean HIVTSQs total score and lifestyle/ease sub-score at Weeks 4 and 24, which remained stable through Week 48 (Figure 2)
- General satisfaction/Clinical sub-score was comparable between treatment groups over time
- Participants aged < 50 years who switched to DTG/3TC had greater improvements in mean HIVTSQs total score and both sub-scores compared with those continuing CAR at all time points assessed

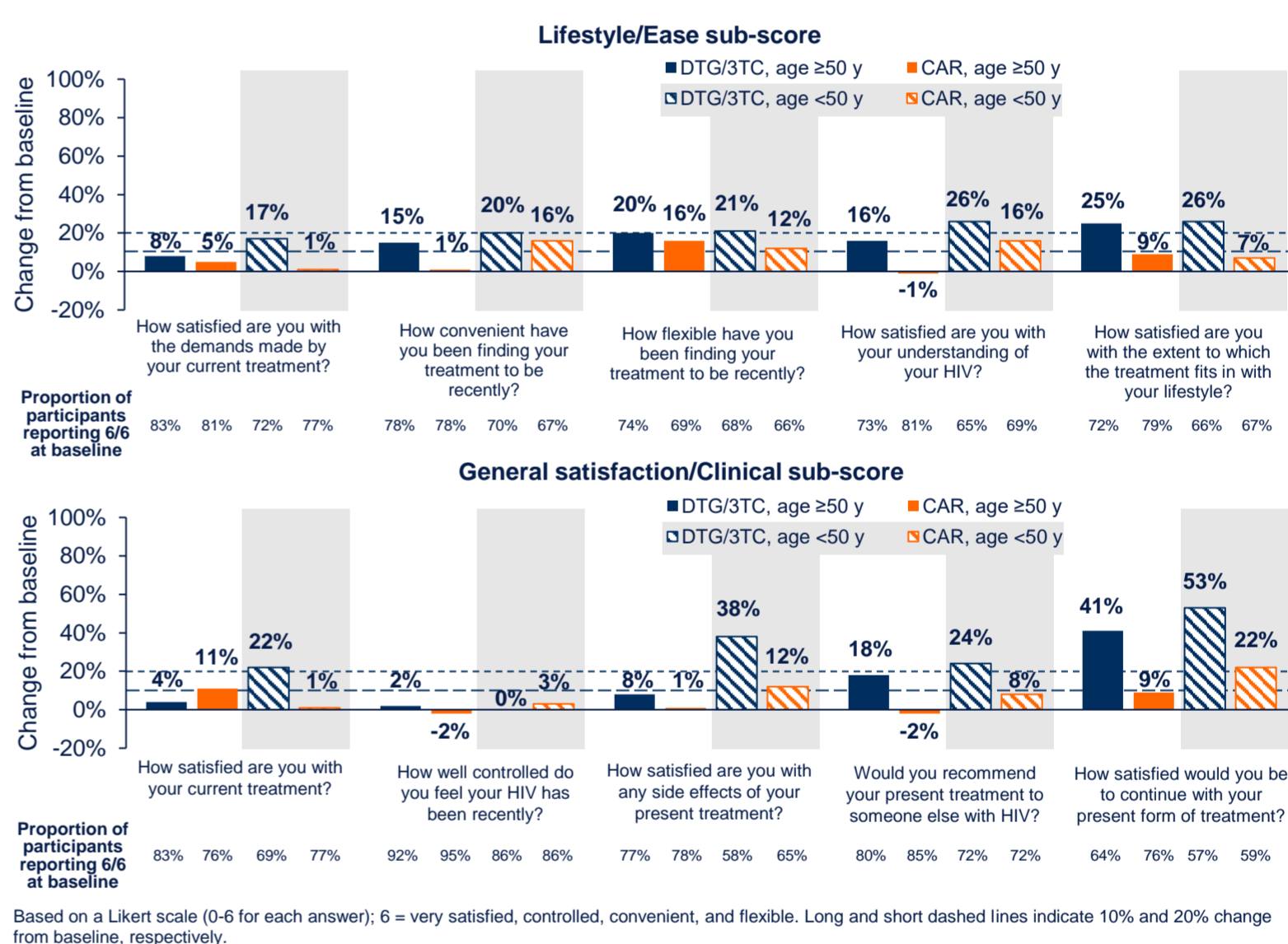
Figure 2. Adjusted Mean Change From Baseline (95% CI) in HIVTSQs (A) Total Score, (B) Lifestyle/Ease Sub-score, and (C) General Satisfaction/Clinical Sub-score Through Week 48 by Age



Higher scores indicate improvement. Dotted lines indicate no change from BL. Median BL scores and adjusted difference between DTG/3TC and CAR are presented within each graph; bolded values indicate significance. The n for each study week is presented below each graph. BL, baseline. *Estimated mean change from BL at each visit in each group calculated using mixed-model repeated measures adjusting for treatment, visit, BL third agent class, race, sex, BL value, age, treatment-by-visit interaction, BL value-by-visit interaction, treatment-by-age interaction, and treatment-by-visit-by-age interaction, with visit as the repeated factor. The correlation matrix for within-participant errors was unstructured.

- From baseline to Week 48, the proportion reporting a score of 6/6 (very satisfied, controlled, convenient, and flexible) increased by $\geq 20\%$ across 3 and 8 individual HIVTSQs items among participants aged ≥ 50 and < 50 years, respectively, in the DTG/3TC group (Figure 3); in the CAR group, this was not achieved in participants aged ≥ 50 years and was achieved for 1 item in participants aged < 50 years
- At Week 48, treatment satisfaction was high in both treatment groups, with most participants reporting they would be satisfied continuing their present treatment among those aged ≥ 50 years (DTG/3TC, 100%; CAR, 99%) and < 50 years (DTG/3TC, 99%; CAR, 94%)

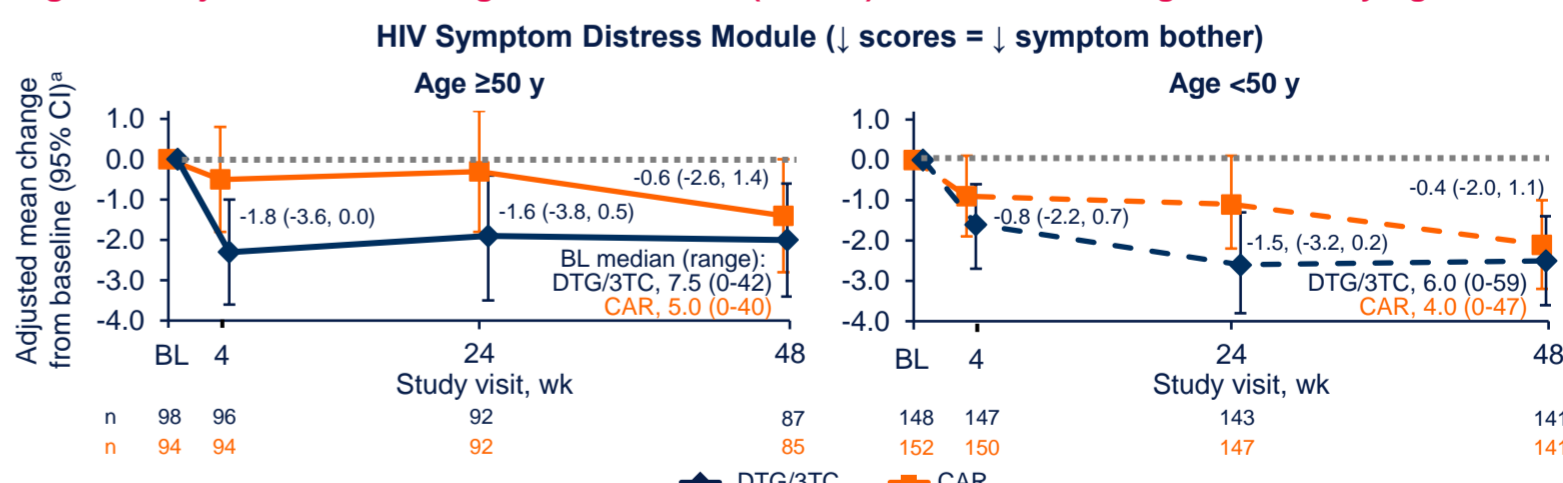
Figure 3. Percent Change From Baseline in Proportion of Participants With 6/6 Score by Each Individual HIVTSQs Item Through Week 48 by Age



HIV-SDM

- Baseline symptom bother scores were similar between treatment groups in both age groups
- Participants aged ≥ 50 years in the DTG/3TC group had numerical improvements in symptom bother score vs CAR at Weeks 4 and 24, which remained stable through Week 48 (Figure 4)
- Participants aged < 50 years in the DTG/3TC group had symptom bother scores comparable to CAR at Week 4 and numerical improvements vs CAR at Week 24, which remained stable through Week 48

Figure 4. Adjusted Mean Change From Baseline (95% CI) in HIV-SDM Through Week 48 by Age



Lower scores indicate improvement. Dotted lines indicate no change from BL. Median BL scores and adjusted difference between DTG/3TC and CAR are presented within each graph. The n for each study week is presented below each graph. BL, baseline. *Estimated mean change from BL at each visit in each group calculated using mixed-model repeated measures adjusting for treatment, visit, BL third agent class, race, sex, BL value, age, treatment-by-visit interaction, BL value-by-visit interaction, treatment-by-age interaction, and treatment-by-visit-by-age interaction, with visit as the repeated factor. The correlation matrix for within-participant errors was unstructured.

- Among participants aged ≥ 50 years, greater reductions from baseline to Week 48 in the DTG/3TC vs CAR group, respectively, were observed in individual HIV-SDM symptoms of nausea or vomiting (-27% vs 17%); feeling sad, down, or depressed (-44% vs -13%); feeling nervous or anxious (-37% vs -14%); headache (-26% vs 5%); and problems with having sex (-43% vs -28%)
- Greater reductions from baseline to Week 48 were also observed in participants aged < 50 years reporting these symptoms with DTG/3TC vs CAR, except for feeling sad, down, or depressed (-25% vs -28% , respectively)

Conclusions

- Through 48 weeks in the SALSA study, OALWH reported rapid and stable improvements in treatment satisfaction and less symptom distress after switching to DTG/3TC
- Comparable improvements were observed among participants aged < 50 years who switched to DTG/3TC
- Higher proportions of participants who switched to DTG/3TC vs continued CAR reported greater treatment satisfaction at Week 48 vs baseline across both age groups and would recommend their regimen to others
- These findings support improved patient outcomes among OALWH after switching to DTG/3TC vs continuing CAR

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