P077

Patient-Reported Symptom Outcomes Following DTG/3TC Use in a Test-and-Treat Setting: Results From the STAT Study

Alan Oglesby,[1] Jessica E. Matthews,[1] Konstantinos Angelis,[2] Peter A. Leone,[1] Michael Cupo,[3] Brian R. Wynne,[1] Deanna Merrill,[1] Christopher Nguyen,[1] Jan van Wyk,[4] Andrew R. Zolopa[1,5]

[1]ViiV Healthcare, Durham, NC, USA; [2]GSK, Brentford, UK; [3]GSK, Upper Providence, PA, USA; [4]ViiV Healthcare, Brentford, UK; [5]Stanford University, Palo Alto, CA, USA

Key Takeaways

- **Rapid initiation of HIV-1 treatment with dolutegravir/lamivudine (DTG/3TC) has previously been demonstrated to be feasible in a test-and-treat model of care, with high rates of virologic suppression and few treatment modifications required**
- **Rapid improvement in patient-reported symptoms commonly associated with HIV were also observed among participants who initiated DTG/3TC in a test-and-treat setting**

Introduction

- Rapid treatment of HIV-1 infection has been associated with improved linkage to and retention in care and reduced time to virologic suppression in people living with HIV (PLWH)[1]
- DTG/3TC is indicated for treatment-naive and treatment-experienced PLWH
- The STAT study (ClinicalTrials.gov, NCT03945981) is a phase IIIb, multicenter, open-label, single-arm, pilot study conducted in the United States (US) to assess the feasibility, efficacy, and safety of using DTG/3TC as a first-line regimen in a test-and-treat model of care in newly diagnosed individuals in whom potential transmitted resistance and baseline (BL) hepatitis B virus (HBV) co-infection are unknown[2]
  - In both the primary Week 24 and follow-up Week 48 analyses, high virologic suppression rates (HIV-1 RNA <50 c/mL) were observed, including in those with very high baseline viral load[2,3]
- Here we present data on patient-reported symptom burden through Week 48

Methods

- STAT included treatment-naive adult PLWH who initiated DTG/3TC ≤14 days after HIV-1 diagnosis before knowledge of screening/baseline laboratory results
  - Modification to DTG/3TC therapy was permitted if baseline testing indicated resistance to DTG or 3TC, HBV co-infection, or creatinine clearance <30 mL/min/1.73 m^2
- Symptom burden was assessed at BL and through Week 48 while under treatment with DTG/3TC using the HIV Symptom Distress Module (SDM) questionnaire, which measures the presence and symptom bother level of 20 specific symptoms associated with HIV or its treatment[4]
  - The bothering level of each symptom ranges from 1 to 4, with 4 indicating the highest level of symptom bother; if the symptom is not present, the bothering level is 0
- The Symptom Count Score (SCS) is the unweighted sum of the number of symptoms that are present and ranges from 0 (ie, no symptom is present) to 20 (ie, all symptoms are present)
- The Overall Symptom Bother Score (SBS) is the unweighted sum of the bothering level for each symptom and ranges from 0 (no symptoms present) to 80 (all symptoms present at highest bothering level)
- Individual bothersome symptoms were defined as those symptoms with bothering levels ≥3
- Change from BL in SCS and SBS was calculated at Weeks 4, 8, 12, 24, 36, and 48
- The proportion of participants with bothersome symptoms was also assessed at each time point
- Analysis was conducted using a last-observation-carried-forward (LOCF) approach for participants who withdrew from study or switched treatment from DTG/3TC or missed assessments

Results

Participant Characteristics

- Overall, 131 participants were enrolled in the study across 16 sites in the US (Table 1)
  - 2 participants had false-positive HIV tests at diagnosis and were enrolled, but subsequent HIV-1 RNA testing failed to reveal viral replication and they were withdrawn

Table 1. Selected Baseline Demographics and Characteristics

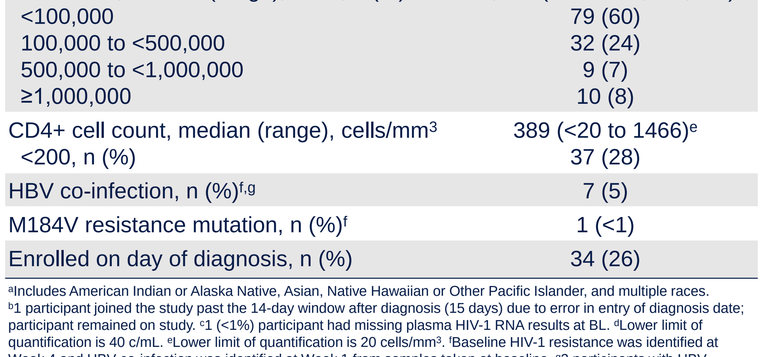
Characteristic	DTG/3TC (N=131)
Age, median (range), years	31 (18-63)
≥50 years, n (%)	20 (15)
Cisgender female, n (%)	10 (8)
Transgender female, n (%)	1 (<1)
Ethnicity, n (%)	
Hispanic/Latinx	38 (29)
Not Hispanic/Latinx	93 (71)
Race, n (%)	
Black/African American	61 (47)
White	65 (50)
Other races[a]	5 (4)
Weight, median (IQR), kg	74.2 (66.0-86.7)
BMI, median (IQR), kg/m^2	24.3 (21.1-27.2)
Time to enrollment since diagnosis, median (range), days	5 (0-15)[b]
HIV-1 RNA, median (range), c/mL, n (%)[c]	63,056 (<40 to 68,706,840)[d]
<100,000	79 (60)
100,000 to <500,000	32 (24)
500,000 to <1,000,000	9 (7)
≥1,000,000	10 (8)
CD4+ cell count, median (range), cells/mm^3	389 (<20 to 1466)[e]
<200, n (%)	37 (28)
HBV co-infection, n (%)[f,g]	7 (5)
M184V resistance mutation, n (%)[f]	1 (<1)
Enrolled on day of diagnosis, n (%)	34 (26)

[a]Includes American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, and multiple races. [b]1 participant joined the study past the 14-day window after diagnosis (15 days) due to error in entry of diagnosis date; participant remained on study. [c]1 (<1%) participant had missing plasma HIV-1 RNA results at BL. [d]Lower limit of quantification is 40 c/mL. [e]Lower limit of quantification is 20 cells/mm^3. [f]Baseline HIV-1 resistance was identified at Week 4 and HBV co-infection was identified at Week 1 from samples taken at baseline. [g]2 participants with HBV co-infection but no evidence of ongoing HBV viral replication remained on DTG/3TC.

Symptom Count Score

- Participants reported a mean (SD) SCS of 6.2 (5.4) at BL, which decreased to 4.6 (5.4) and 3.9 (4.9) at Weeks 24 and 48, respectively, under treatment with DTG/3TC
- SCS decreased from BL at each time point assessed (Figure 1)

Figure 1. Change From Baseline in SDM Symptom Count Score



Overall Symptom Bother Score

- Participants reported a mean (SD) Overall SBS of 13.8 (14.7) at BL, which decreased to 8.5 (11.3) and 7.7 (11.1) at Weeks 24 and 48, respectively, under treatment with DTG/3TC
- Overall SBS decreased from BL at each time point assessed (Figure 2)

Bothersome Symptoms

- Of the 20 symptoms assessed, 19 were reported as bothersome at BL by ≥5% of participants (Figure 3)
- All improved by Week 4, except for problems having sex, which was improved by Week 8 (BL: 10%, Week 4: 11%, Week 8: 6%) and sustained thereafter
- The most frequently reported (≥15% of participants) bothersome symptoms at BL were difficulty sleeping (BL: 27%, Week 4: 16%, Week 48: 10%); fatigue (21%, 10%, 7%); feeling sad or depressed (19%, 15%, 11%); anxiousness (17%, 16%, 10%); and fever, chills, or sweats (15%, 5%, 3%)

Figure 2. Change From Baseline in SDM Overall Symptom Bother Score

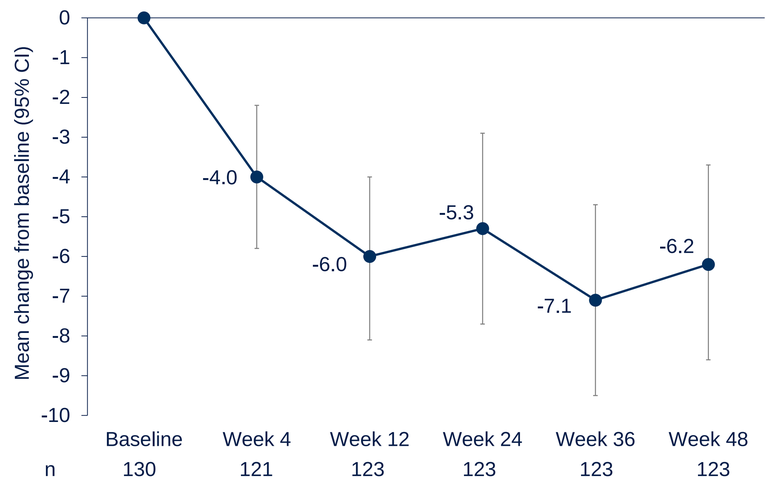
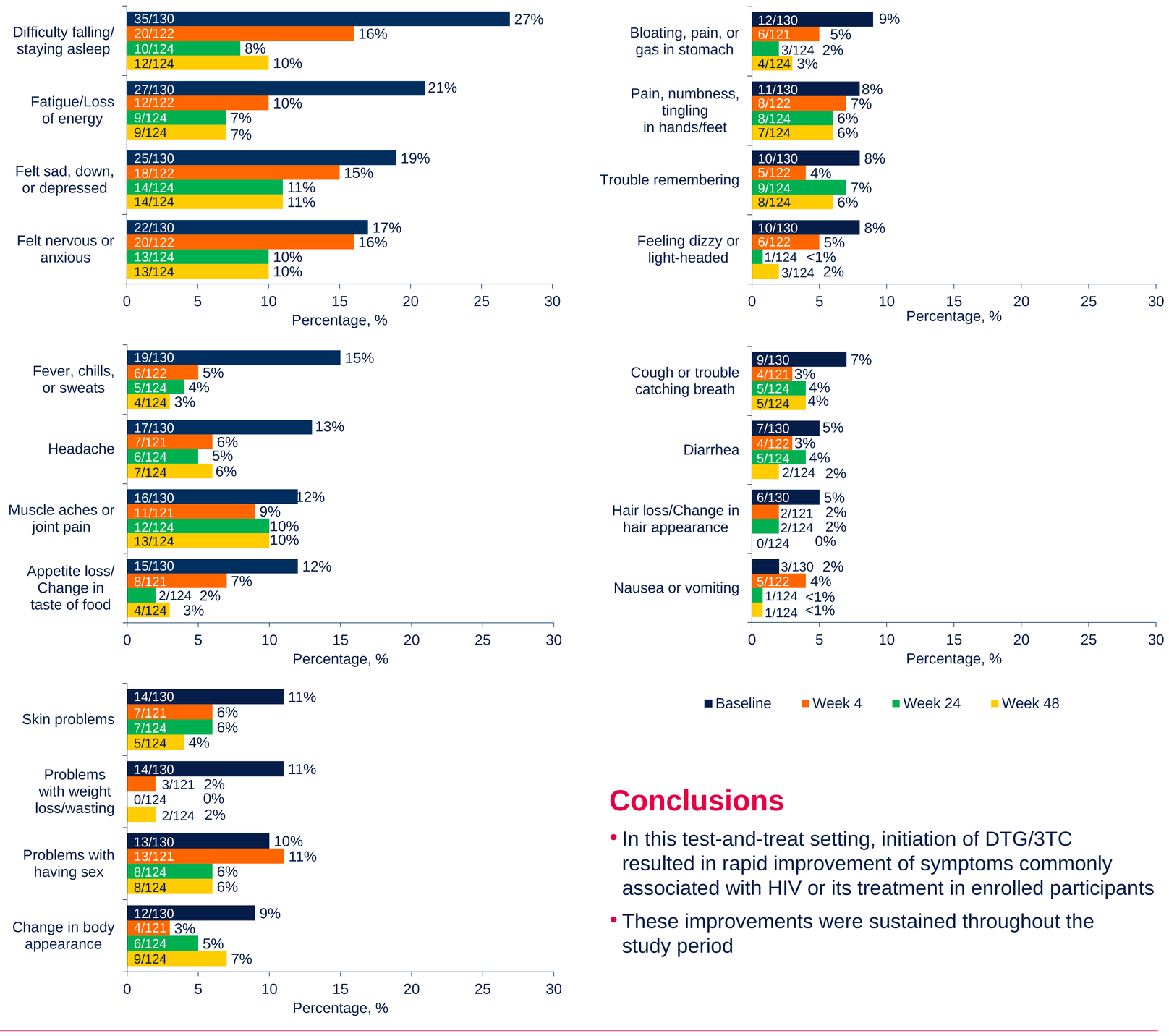


Figure 3. Proportion of Participants Reporting Bothersome Symptoms (SDM Score ≥3) by Visit, LOCF



Conclusions

- In this test-and-treat setting, initiation of DTG/3TC resulted in rapid improvement of symptoms commonly associated with HIV or its treatment in enrolled participants
- These improvements were sustained throughout the study period

Acknowledgments: This study was funded by ViiV Healthcare. The authors thank all participants in the STAT study, all investigators and site staff, the study teams, and all contributors from ViiV Healthcare and GSK. Editorial assistance and graphic design support for this poster were provided under the direction of the authors by MedThink SciCom and funded by ViiV Healthcare.

References: 1. Centers for Disease Control and Prevention. Understanding the HIV Care Continuum. 2019. **2.** Rolle et al. *AIDS*. 2021;35:1957-1965. **3.** Rolle et al. *Open Forum Infect Dis*. 2021;8(suppl 1):S49. **4.** Justice et al. *J Clin Epidemiol*. 2001;54(suppl 1):S77-S90.

Presenting author: Deanna Merrill; deanna.l.merrill@viivhealthcare.com

This content was acquired following an unsolicited medical information enquiry by a healthcare professional. Always consult the product information for your country, before prescribing a ViiV medicine. ViiV does not recommend the use of our medicines outside the terms of their licence. In some cases, the scientific Information requested and downloaded may relate to the use of our medicine(s) outside of their license.