

Characterizing Gastrointestinal Symptoms in HIV Patients Taking Antiretroviral Therapy

Patrick G. Clay, PharmD, AAHIVP, CCTI, FCCP¹; Tiffany Surlles, PharmD²; Andrew C. Barrett, PhD²; Richard Perry, BSc³; Anna Hadfield, MChem³

¹University of North Texas System College of Pharmacy, Fort Worth, TX, USA; ²Salix Pharmaceuticals, Inc., Raleigh, NC, USA; ³Adelphi Real World, Manchester, UK

INTRODUCTION

- Newer antiretroviral therapies (ARTs) for the treatment of human immunodeficiency virus (HIV) have improved safety and tolerability compared with older ARTs^{1,2}
- Switching of first-line ART regimens continues to occur, primarily because of gastrointestinal (GI) toxicity²

OBJECTIVE

- To characterize GI symptoms reported by patients with HIV receiving ARTs

METHODS

Patient and Healthcare Provider Populations

- Patients ≥18 years of age with HIV were eligible for inclusion in the study
 - Healthcare providers (HCPs) recorded details for the next 10 consecutive patients diagnosed with HIV
 - This analysis is based on the patients with both a self-completion form and a detailed patient record form completed by their HCP
- HCPs were infectious disease specialists, primary care physicians, and nurse practitioners who were currently making drug treatment decisions for patients with HIV
 - Infectious disease specialists were required to see ≥10 patients with HIV receiving ART per week
 - Primary care physicians and nurse practitioners were required to see ≥5 patients with HIV receiving ART per week

Study Design and Assessments

- A subanalysis of a cross-sectional, multinational, observational, patient-record survey using the Adelphi Disease Specific Programme (DSP) methodology was conducted between July 2014 and September 2014
 - HCPs in the United States were identified from public lists of HCPs and evaluated for their eligibility to participate in a DSP, including treating a specified minimum number of patients with HIV receiving ART each week
 - Patient record forms were prospectively completed by HCPs and then matched to patients participating in the study by means of study numbers, assigned to both HCPs and patients to maintain anonymity and allow data linkage
 - Data collected from HCPs included patient demographics, treatment history, disease symptoms and severity, and patient management information
 - Immediately after seeing their HCP, patients filled out a self-completion form, which included questions about disease symptoms from the previous 6 months, disease impact, and reasons for treatment discontinuation

RESULTS

Patients and Healthcare Providers

- A total of 131 HCPs took part in the study, providing matched patient forms completed by themselves and their patients with HIV (n = 485; Table 1)
 - The majority of HCPs were infectious disease specialists (61%), contributing 54% of patients to the study
 - Infectious disease specialists were recruited mostly from the Northeastern (22%), Western (18%), and Midwestern United States (17%), based on the total HCP population

RESULTS

Table 1. Healthcare Providers and Patients, by Provider Specialty

	Healthcare providers (n = 131)	Patients (n = 485)
Infectious disease specialists	80	262
Primary care physicians	42	197
Nurse practitioners	9	26

- Of the 485 patients with HIV, current ART prescriptions were provided by infectious disease specialists (54%), primary care physicians (39%), and nurse practitioners (4%)

Patient Disposition and Disease Characteristics

- Most patients were male (77%), with a mean CD4 count of 506 (Table 2)

Table 2. Demographic and Disease Characteristic

Characteristic	Patients With HIV (n = 485)
Age, y, mean (SD)	40.3 (12.3)
Sex, male, n (%)	373 (77)
BMI, mean (SD)	27.1 (4.6)
CD4 count ^a , mean (SD)	506 (279)
CD4 ^b , %, mean (SD)	29.5 (11.0)
Viral load ^c , copies/mL, mean (SD)	11,194 (39,372)
Time since HIV diagnosis, y, mean (SD)	6.2 (6.7)
Mean duration of ART ^d , y, mean (SD)	2.4 (3.0)
Current ART treatment regimen ^e , n (%)	
Non-ritonavir-containing regimen	369 (76)
Ritonavir-containing regimen	100 (21)
Ritonavir only	2 (0.4)
No drug	14 (3)

^aMost recent CD4 count (n = 472).

^bMost recent CD4 percentage (n = 286).

^cMost recent viral load (RNA; n = 166).

^dFor the patients currently receiving ART (n = 471).

^eTreatment regimen patients were receiving at most recent consultation, even if treatment was not prescribed at this consultation.

BMI = body mass index; SD = standard deviation.

- Overall, 471 of 485 patients (97%) were receiving ART; 265 patients (55%) were receiving first-line ART
 - Of the 485 patients, 126 (26%), 102 (21%), 65 (13%), 59 (12%), 35 (7%), 27 (6%), 23 (5%), 12 (2%), and 11 (2%) patients were currently prescribed ART regimens containing emtricitabine/tenofovir disoproxil fumarate, ritonavir, raltegravir, darunavir, atazanavir, abacavir/lamivudine, lamivudine/zidovudine, etravirine, and tenofovir disoproxil fumarate, respectively

Symptoms Reported by Patients With HIV

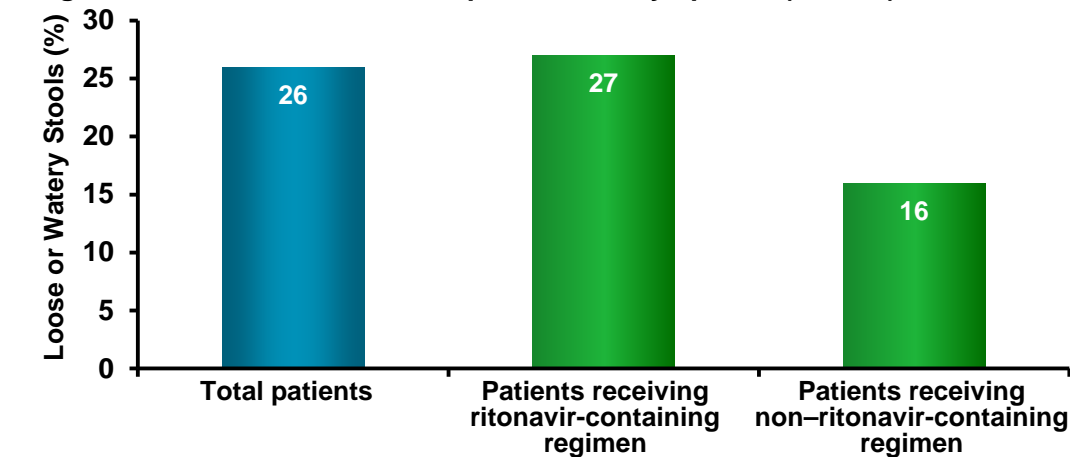
- The majority of patients with HIV (65%) reported comorbid conditions
 - Patients reporting at least 1 comorbid condition reported a mean of 2.4 comorbidities
 - The most common comorbid conditions overall were depression (21%) and anxiety (18%); the most common GI comorbidities were gastroesophageal reflux disease (9%) and chronic diarrhea (8%)

RESULTS

HCP Reported Symptoms in Patients With HIV

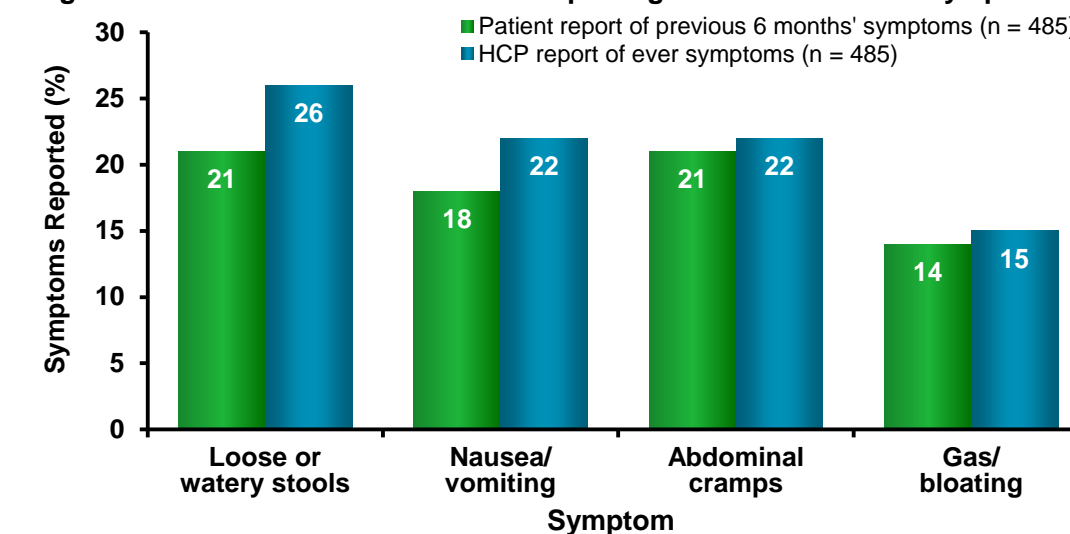
- HCPs indicated that loose or watery stools was the most common GI symptom experienced by patients at any time (Figure 1)

Figure 1. Healthcare Provider Report of Ever Symptoms (n = 485)



- 57% of 485 patients self-reported, or were reported by their HCPs, to have experienced GI symptoms (Figure 2)
 - HCPs reported that 51% of patients had experienced GI symptoms (Figure 2)
 - In 56 cases, the HCP indicated that a patient had experienced GI symptoms while the patient did not; 31 patients reported having experienced GI symptoms not recorded by the HCP
- According to HCPs, the most commonly reported non-GI symptoms experienced by patients at any time since diagnosis were lack of energy or fatigue (38%), depression (29%), anxiety (24%), and weight loss (24%)

Figure 2. Health Provider and Patient Reporting of Gastrointestinal Symptoms



- HCPs reported that loose or watery stools occurred with greatest frequency in patients in the asymptomatic latent stage of HIV infection (51%; Table 3)

RESULTS

Table 3. Presence or Absence of Loose or Watery Stools, by Current Phase of HIV

Current phase of HIV, n (%)	Symptom ^a	
	Loose or watery stools (n = 88)	No loose or watery stools (n = 397)
Primary HIV infection phase	5 (6)	34 (9)
Asymptomatic latent phase	45 (51)	271 (68)
Symptomatic phase	23 (26)	48 (12)
AIDS	14 (16)	39 (10)
Not provided	1 (1)	5 (1)

^aSymptoms and disease stage as reported on physician record form. AIDS = acquired immune deficiency syndrome.

- Patients and HCPs reported loose or watery stools to be the most bothersome GI symptom experienced by patients (14% and 9%, respectively)
 - HCPs reported that the mean duration of the patients' most recent episode of loose or watery stools was 12.7 days (SD, 15.0)

CONCLUSIONS

- Patients with HIV on newer ART regimens frequently experience GI symptoms, with loose or watery stools being the most commonly reported and most bothersome symptom
- Occurrence of GI symptoms in patients with HIV are recognized by both HCPs and patients
- Occurrence of loose/watery stools was comparable in patients receiving ritonavir- and non-ritonavir-containing treatment regimens

REFERENCES 1. Elzi L, et al. *Arch Intern Med*. 2010;170(1):57-65. 2. de la Torre-Lima J, et al. *HIV Clin Trials*. 2014;15(1):27-35.

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