Safety and Efficacy of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Disoproxil Fumarate in Treatment-Naïve Japanese Patients with HIV-1 Infection.

Keishiro Yajima[1], Hiroki Yagura[1], Satomi Yukawa[1], Kazuyuki Hirota[1], Motoko Ikuma[1],Yoshihiko Ogawa[1], Daisuke Kasai[1], Dai Watanabe[1], Yasuharu Nishida[1], Tomoko Uehira[1],Takuma Shirasaka[1]

[1] AIDS Medical Center, National Hospital Organization Osaka National Hospital

Background and objectives

Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Disoproxil Fumarate (E/C/F/TDF), one of the novel integrase inhibitor-based single-tablet regimens (STRs), is expected to be a pillar of antiretroviral therapy. However, there have been few reports of the antiviral effects and adverse events in cases of its use as initial therapy for Asian patients.We examined our data to evaluate the safety and efficacy of E/C/F/TDF in treatment-naïve Japanese patients with HIV-1 infection.

Methods

We retrospectively reviewed the medical records of 110 patients treated with a single-tablet regimen of E/C/F/TDF once daily in the AIDS Medical Center, Osaka National Hospital, between May 2013 and October 2014. Patients with insufficient data and those with conditions such as chronic renal failure or viral hepatitis were excluded. Data from 106 of the 110 patients were analyzed.

Results

Table 1. Demographics and Baseline Characteristics

Number of subjects	N	106
Age	Years, median(range)	37 (21-66)
Sex	Male, n (%)	105 (99)
Country of origin	Japan	106 (100)
Weight	kg, median (range)	66 (45-99)
eGFR(Cockcroft-Gault)	mL/min/1.73 m^2, median (range)	94 (70-149)

Table 2. HIV disease characteristics

Baseline HIV-1 RNA	log10 copies/mL, mean (range)	4.90 (3.30-6.95)
	≤ 100,000 copies/mL, n (%)	73 (69)
	> 100,000 copies/mL	33 (31)
Baseline CD4 count	cells/μL, median (range)	260 (6-521)
Mode of infection	MSM, n (%)	99 (93)

Figure 1. Changes from baseline in HIV-1 viral load

Figure 2. Changes from baseline in eGFR-sCre *

Figure 3. Changes from baseline in eGFR-cystatin C*

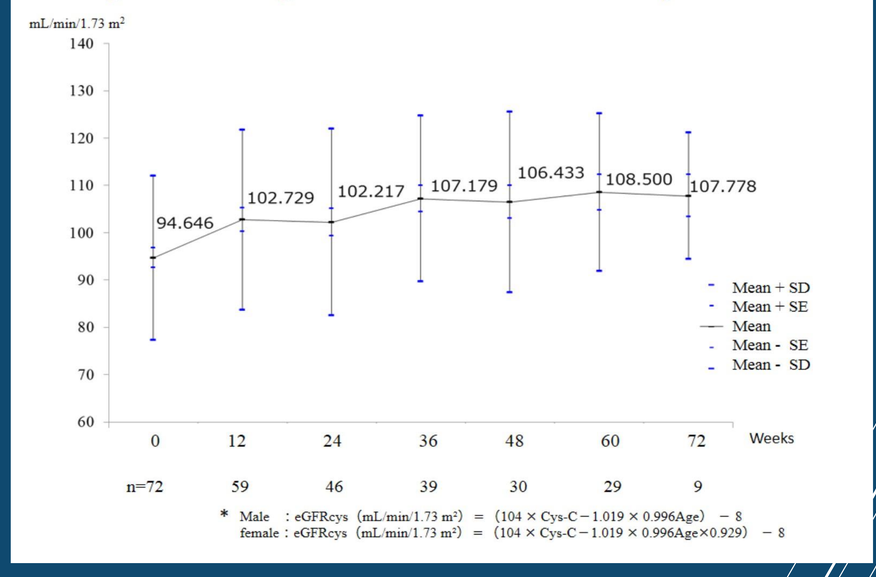

Figure 4. Changes from baseline in fasting lipids

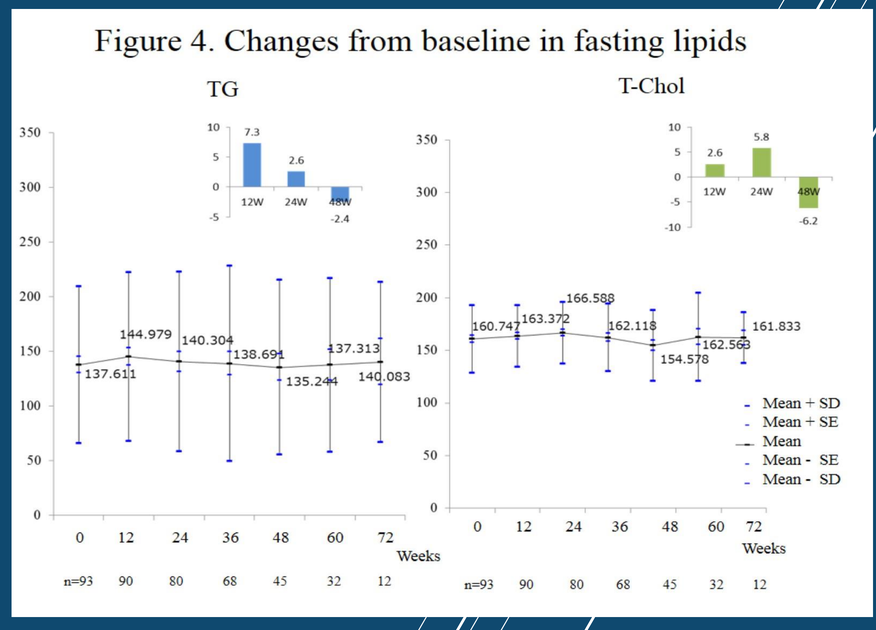

Table 3. Summary of adverse events

	N=106, n(%)
Adverse events (AEs) grade 3 or 4	3(2.8)
Serious AEs	0(0)
Death	0(0)

Table 4. Common adverse events (all grades)

AEs	N=106, n(%)
Vivid dreams, insomnia	5(4.7)
Dizziness	4(3.8)
Abdominal fullness	4(3.8)
Headache	3(2.8)
Nausea	3(2.8)
Fatigue	2(1.9)

Table 5. Efficacy at week 24

category	Patients N=78 %
Virological Success at Week 24	96.2
HIV-1 RNA <50 copies/mL	96.2
Virological failure at Week 24	3.8
Discontinued due to AEs	1

Table 6. Demographics of patients with virological failure

	Sex	Age (y)	Baseline VL (copies/mL)	Time to discontinuation	INSTI resistance
1	male	58	441,000	12 weeks	N155H
2	male	32	9,070,000	20 weeks	N155H,E92Q, S153FS
3	male	42	691,000	20 weeks	T66I
4	male	36	23,000	16 weeks	E92Q, N155H

Conclusion

A high virological response was seen in patients receiving E/C/F/TDF. This regimen was well tolerated, and no unique AEs occurred compared to previous reports. These data support the use of E/C/F/TDF as a potential new regimen for initial treatment of Japanese patients with HIV-1 infection.

Reference

Hardy D, Gathe J, Workowski K, et al. ICAAC 2014. September 5-9, 2014. Washington DC. Abstract H-1001.

Zolopa A, Sax PE, DeJesus E, et al. J Acquir Immune Defic Syndr. 2013;63:96-100.

Chokephaibulkit K, Gaur A, Fourie J et al. IAS 2014. July 20-25, 2014 Melbourne Poster THPDB0104