First line Etravirine use – can you swallow it?: real world data from one UK centre cohort

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Background

Existing evidence suggests Etravirine (ETV) is an effective switch option for patients intolerant of Efavirenz[1,2]. Data on ETV as once daily first line therapy is scant[3]. ETV is licensed as a 200mg twice daily regimen but evidence suggests it is as effective delivered once daily at a dose of 400mg[4]. This UK unit has offered ETV as an option to treatment naïve patients for the last 2 years and we present our experience with its use.

Methods

All treatment naïve patients prescribed ETV prior to 30/06/11 were identified via pharmacy records, providing at least 6 months follow up. Data on sex, age, orientation, ethnicity and hepatitis co-infection were collected. CD4 count, viral load (VL) (Abbott Realtime), liver enzymes and lipid data at baseline & 6 months were recorded.

Results

23 patients were identified with one patient lost to follow up (transferred). 22 patients were evaluated (22 male, 0 female; 17 white British, 2 black African, 2 Pakistani, 1 white European; 18 MSM, 4 heterosexual) with a mean age of 39 years (range 26-57). No patients were hepatitis co-infected.

All patients received ETV 400mg once daily, with a nucleoside backbone (Truvada [21/22, 95.5%], Kivexa [1/22, 4.5%]).

During the study period 13.6% (3/22) patients discontinued therapy; 9.1% (2/22) discontinued due to an erythematous rash, 4.5% (1/22) found the preparation "unpalatable". 10 others reported unpalatability and chose to dissolve the ETV.

Median baseline viral load (VL) was 36000 c/mL (1900-1,400,000) with 5 patients having a starting VL >100,000 c/mL. At 6 months, 21 (95.5%) patients had VL <40, 1 patient had a VL of 53 c/ml and declining.

Median baseline and six month data (range in brackets)

	Baseline	6 Months
CD4 cells/μL	325 (66-523)	478 (195-932)
Alanine transaminase (ALT) IU/L	35 (18-80)	26 (10-78)
Bilirubin μmol/L	8 (2-29)	8 (5-25)
Total cholesterol mmol/L	4.4 (3-6.4)	4.7 (3.3-6.8)
HDL mmol/L	0.9 (0.2-1.4)	1.1 (0.6-1.8)
Triglycerides mmol/L	1.5 (0.7-5.5)	1.4 (0.8-3.6)

Discussion

At treatment initiation all our patients are offered a choice of NNRTIs or Raltegravir with a nucleoside backbone. Patients choosing ETV were offered a choice of a once or twice daily dosage regimen. Although unlicensed, patient preference was clearly for a once daily treatment. All patients received their dose as 4 x 100mg tablets.

Viral suppression at 6 months was acceptable with 95.5% (21/22) <40 c/ml with one other patient suppressing from an baseline viral load of 1,400,000 c/mL to 53 c/mL and declining. There were no virological failures or unexpected adverse events.

The data is limited by low patient numbers with a bias to Caucasians, the lack of female patients in the cohort, and under representation of hepatitis co-infections compared with our population as a whole.

Conclusions

In this centre, ETV has proven to be an acceptable, effective and well tolerated first-line treatment option. The data indicate high anti-viral efficacy in naïve patients and no adverse trend in liver enzyme or serum lipid biomarkers. Side-effects and discontinuation rates were consistent with product literature. Difficulty swallowing ETV was the most common reported complaint. In view of the paucity of current evidence for first-line ETV use we plan to continue collecting data for future presentation.

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