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

Dr J Shaw, Dr S Ahmad
University Hospitals of South Manchester (UHSM), Manchester, UK

Background
Existing evidence suggests Etravirine (ETV) is an effective switch option for patients intolerant of Efavirenz. Data on ETV as once daily first line therapy is scant. ETV is licensed as a 200mg twice daily regimen but evidence suggests it is as effective delivered once daily at a dose of 400mg. 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)

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

References: