Tenofovir alafenamide - real life data from a large teaching hospital

Belfast Health and Social Care Trust

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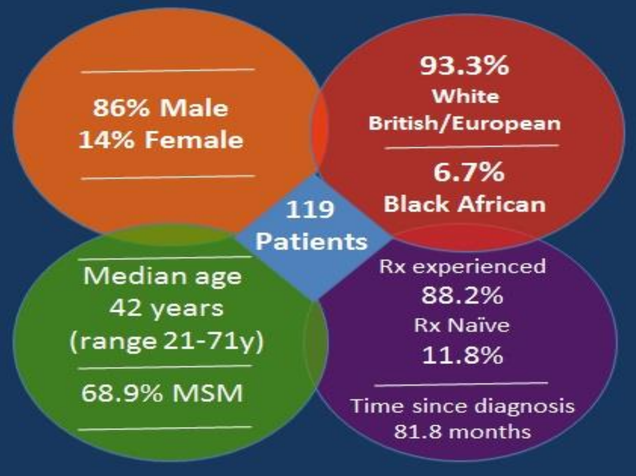
Background

Tenofovir alafenamide (TAF) is a novel tenofovir prodrug with 90% reduction in plasma tenofovir concentration. To date, several large Phase 3 studies have been conducted looking at TAF efficacy, tolerability and long-term effects on renal & bone parameters. We present data based on early experience of this drug in our HIV cohort.

Methods

All patients prescribed a TAF containing regimen in May to November 2016 were identified from pharmacy records. Data collected included demographics, reason for TAF initiation, virological response, renal markers and patient reported side effects.

Results



Treatment Experienced (105/119)

-Pre-switch backbone was TDF/FTC in 85% and ABC/3TC in 10%. (5% other)
-Pre-switch 3rd agent was ELV/c in 54.3%, PI in 22.9%, other II15.2% and NNRTI in 7.6%

-Post-switch 3rd agent was ELV/c in 90.5%, other II 3.8%, NNRTI 3.8% and PI 1.9%.

Reason for switch: 53.3% procurement reasons (TDF/FTC/ELV/c to TAF/FTC/ELV/c); 15.2% renal indication; 12.4% treatment simplification; 10.5% side effects; 4.8% bone health and 3.8% other reasons.

-CD4 - Median CD4 500 cells/mm^3 at week 0 and 530 cells/mm^3 at week 24.

-Viral Load – 92.2% of patients had viral load below level of quantification (<70 IU/ml) at switch. 98.1% at week 4 and 100% at week 24. (Chart 1)

Chart 1 – Percentage of Patients VL BLQ (Treatment Experienced)

Treatment Naïve (14/119)

All commenced on TAF/FTC/ELV/c due to desire for single tablet regimen.

-CD4 - Median CD4 410 cells/mm^3 at week 0 rising to 510 cells/mm^3 at week 24. (Chart 2)

-Viral Load – Median viral load 147774 IU/ml at week 0 falling to 210 IU/ml at week 4. All patients virologically suppressed by week 12. (Chart 3)

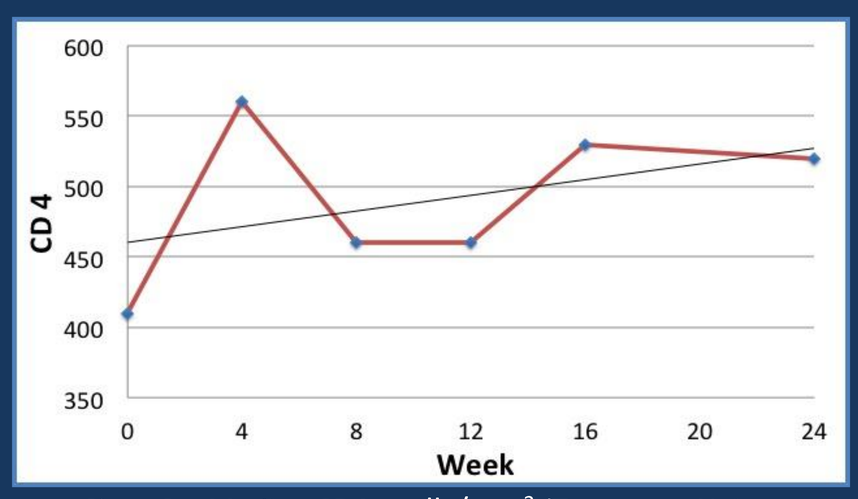


Chart 2 – Median CD4 - cells/mm^3 (Treatment Naive)

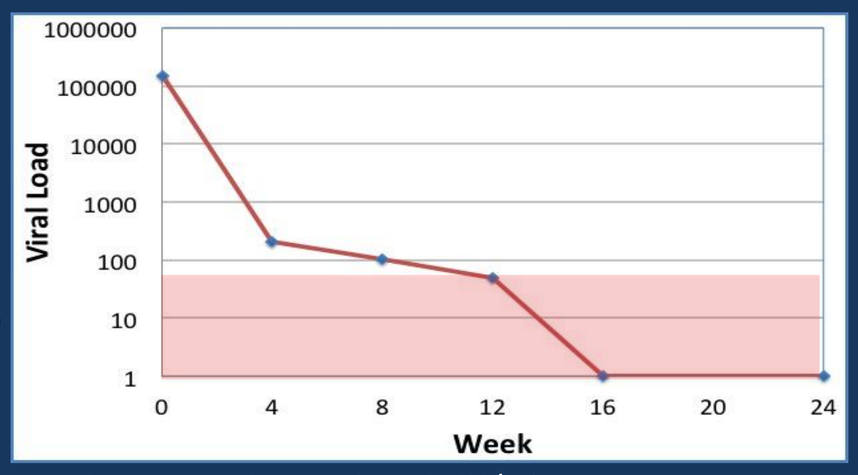


Chart 3 – Median Viral Load - IU/ml (treatment naive). Shaded area indicating BLQ

Renal Parameters

-**Median creatinine** at week 0 was 87 mmol/L (77_{q25}-102_{q75}) and 91 mmol/L (80_{q25}-99_{q75}) at week 24. (Chart 4) *A 1.7% rise is noted at week 4 in keeping with cobicistat initiation.
-Median urine protein creatinine ratio (uPCR) at week 0 was 12mg/mmol (9_{q25}-17_{q75}) and 13mg/mmol (9_{q25}-18_{q75}) at week 24. (Chart 4)
-Median phosphate 0.97 mmol/L at week 0 and 1.01 mmol/L at week 24.

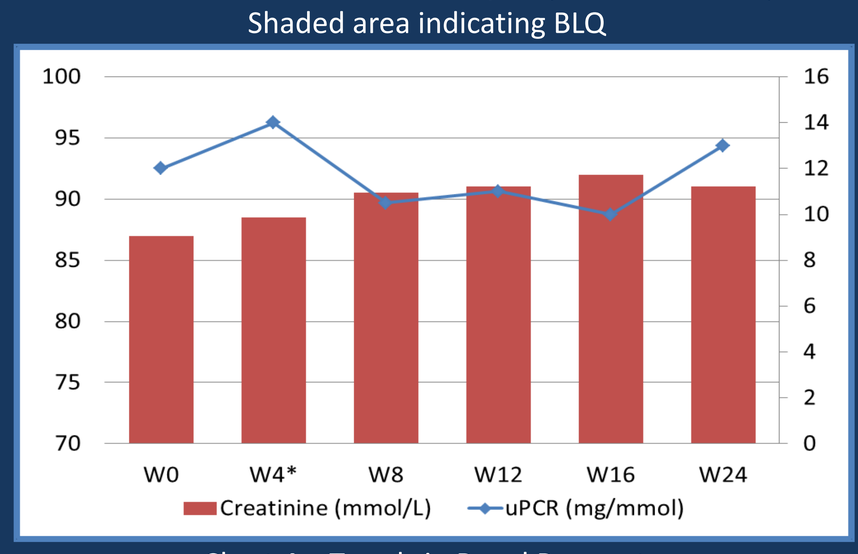


Chart 4 – Trends in Renal Parameters

Tolerability

10/119 (8.4%) patients reported side effects. These included 3 patients who reported GI symptoms, 2 rash, 1 sleep disturbance, 1 anxiety, 1 palpitations, 1 dizziness and 1 with eye irritation. Side effects led to discontinuation in 1 patient with rash which was directly attributed to TAF.

Conclusions

Results indicate that tenofovir alafenamide is well tolerated in our cohort with only 1 discontinuation reported. Virological control is satisfactory in both treatment naive and experienced patients and is comparable to that reported in Phase 3 studies.

Acknowledgements – Consultants and Pharmacy staff at GUM RVH.