The ATASAFE women cohort: outcome of atazanavir/r use after 2 years

C Michalik, A A Skalezt-Rorowski, A Potthof, B Haastert, C Stephan, P Khaykin, H Jaeger, A Plettenberg, S Esser, N Brockmeyer, A Haberl

1Competence Network for HIV/AIDS (KompNet), Ruhr-Universität Bochum, Germany; 2Clinical Trial Centre, University Cologne, Cologne, Germany; 3St Josef Hospital, Clinic for Dermatology, Allergology and Venerology, Ruhr-Universität Bochum, Germany; 4medStatistica, Neuenrade, Germany; 5HIVCENTER, Hospital of the JW Goethe University, Frankfurt, Germany; 6MVZ Karlsplatz, HIV Research and Clinical Care Centre, Munich, Germany; 7Ifli-Institut, Hamburg, Germany; 8Clinic for Dermatology and Venerology, University Hospital Essen, Germany

Background

Women living with HIV are often underrepresented in clinical trials and cohort studies; as a result, data on gender-specific treatment responses to antiretroviral therapy (ART) are limited. In clinical trials, atazanavir/ritonavir (ATV/r)-based regimens have demonstrated efficacy and a good tolerability profile in both ART-naive and ART-experienced patients.

The German ATASAFE cohort study aims to analyse long-term (4-year) data from routine clinical practice in order to characterise more fully the efficacy and safety of ATV/r treatment in women living with HIV. This interim analysis reports 2-year data from the ATASAFE cohort.

Objectives

The objective of the ATASAFE cohort study is to describe the effectiveness of ATV/r-based ART in treatment-naive and treatment-experienced women living with HIV-1 infection, using clinical practice data obtained over a 4-year period. The primary endpoint is time to any of: therapeutic failure, loss of virologic response (viral load > 400 copies/ml), treatment change for any reason, clinical progression to AIDS, death, study drop-out, loss to follow-up. Secondary endpoints include the effectiveness of ATV/r in different subgroups, immunological response and tolerability profile.

Methods

ATASAFE is a 4-year, multicentre, retrospective and prospective, non-interventional cohort study conducted by the KompNet HIV/AIDS (Competence Network for HIV/AIDS) and the HIVCENTER Frankfurt.

Inclusion criteria included: female, HIV-1 diagnosis, age ≥ 18 years, ATV/r + 2NRTI ART for ≥ 3 months, women of childbearing age had to agree to use appropriate contraception for the duration of the study.

For this 2-year interim analysis, immunological status time-course analysis was conducted in subpopulations of women who had paired baseline and 2-year values for CD4 and viral load. Missing CD4 and HIV-1 RNA values after 2 years were imputed using the last observation carried forward method from values 1 year onward. Discontinuations were included in the intent-to-treat (ITT) analysis.

Statistical analyses included paired t-test for the CD4 change from baseline to year 2, and McNemar’s symmetry test for the proportions of patients with undetectable viral load at baseline and year 2.

Results

In total, ATASAFE has enrolled 140 women living with HIV. This interim analysis includes data from 92 women living with HIV (n=9 with imputed values). Baseline demographics and treatment characteristics for this population were representative of the overall German population of women living with HIV, as shown in Table 1.

In total 89 women remained on ATV/r treatment and 3 discontinued during the first 2 years of ATASAFE. All 3 discontinuations were for unknown reasons (mean duration of treatment 0.7 years, range 0.6–0.9). Of the women who discontinued, 2 had viral load ≤ 400 copies/ml before discontinuation.

The proportion of women with viral load ≤ 400 copies/ml increased by 50% between baseline and year 2 (p < 0.0001; Figure 1). After 2 years’ treatment, 96% of treatment-naive patients and 95.5% of treatment-experienced patients had viral load ≤ 400 copies/ml.

Mean detected viral loads for treatment-naive and treatment-experienced patients at baseline and year 2 are shown in Table 2.

The proportion of women with CD4 cell count ≥ 350 cells/µl at baseline and after 2 years of treatment is shown in Table 3.

Discussion and Conclusions

In this 2-year interim analysis of data from the ATASAFE cohort, ATV/r-based ART resulted in good virologic and immunologic outcomes, with a low rate of discontinuations, supporting the durability of ATV/r-based ART in real-world treatment.

ATASAFE provides valuable long-term data to support physicians in their care of women living with HIV.

References

1. d’Amore Boffito A et al. Antiretroviral Therapy 2013,18(52) 27–34.

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