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Poster presentation

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Antiretroviral tolerability and efficacy after switch to saquinavir in PI-experienced patients: 48-week analysis of the German Rainbow Cohort

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Purpose of the study

The aim of the Rainbow Cohort is to assess the tolerability and efficacy of initiating treatment with, or switching treatment to the saquinavir (SQV) 500 mg film-coated tablet formulation. We present the final 48-week subgroup analysis of PI-experienced, but SQV-naïve patients.

Methods

Multicenter, prospective, open label, observational cohort study. Tolerability assessment included changes in lipids – stratified according to baseline (BL) levels – from BL to week 48. Efficacy assessment included changes in CD4 count and viral load (VL). Changes to baseline were tested for significance with Wilcoxon signed rank test.

Summary of results

Median BL characteristics from evaluable patients (n = 426): 84% male; age 43 years; time since first HIV diagnosis 9 years (IQR 4; 14); VL 599 cp/mL (IQR <50; 31,291); VL<50 cp/mL 33.6%; CD4 count 320 cells/mm³ (IQR 177; 506). Week 48 results: Median CD4 increase was +61 cells/mm³ (IQR -9; 170; $p < 0.01$); 60.3% of patients achieved a VL <50 cp/mL (ITT, LOCF analysis). SQV treatment was stopped in 22% of the patients (6% due to side-effects, 4% due to virological failure). Stratified according to BL triglyceride levels, median changes (ITT, LOCF analysis) were +14 mg/dL (IQR -8; 57) for patients with <200 mg/dL ($p < 0.01$; n = 196); -50 mg/dL (IQR -139; 0) for patients with 200–750 mg/dL ($p < 0.01$; n = 136) and -656 mg/dL (IQR -1024; 0) for patients with >750 mg/dL ($p < 0.01$; n = 15), respectively. Stratified according to BL total cholesterol levels, median changes (ITT, LOCF analysis) were +16 mg/dL (IQR -3; 43) for patients with <200 mg/dL ($p < 0.01$; n = 206); -3 mg/dL (IQR -25; 25) for patients with 200–300 mg/dL ($p = 0.4$; n = 121) and -47 mg/dL (IQR -87; -4) for patients with >300 mg/dL ($p < 0.01$; n = 11), respectively. No significant changes of ALT, AST, γ-GT, or bilirubin were observed. See Figure 1.

Conclusion

These data confirm that SQV/r is effective and well tolerated in PI-experienced, SQV-naïve patients in a real-life clinical setting. Most relevant improvements in triglycerides and total cholesterol levels were observed in patients with baseline grade III–IV elevation.

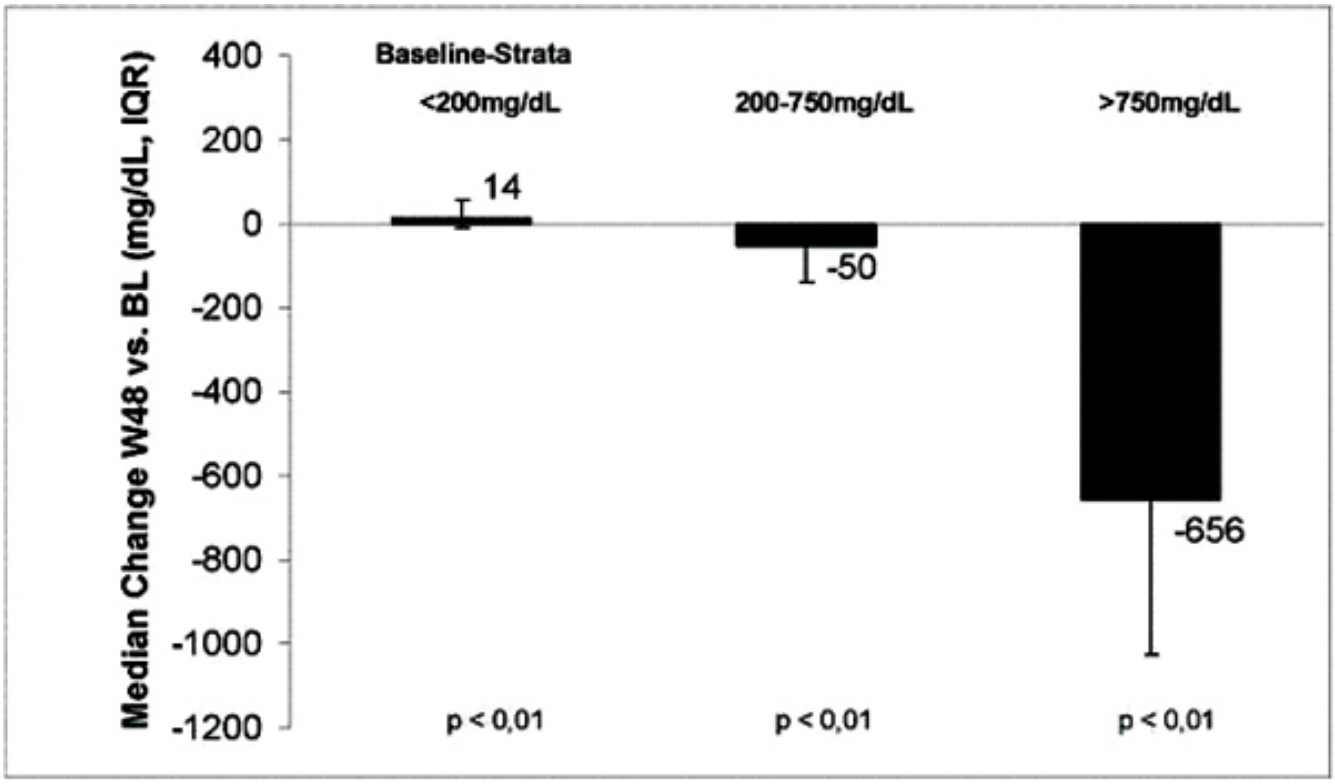

Figure 1
Median changes in triglycerides (LOCF) from baseline to week 48 – stratified according to baseline level – after start of an SQV/r containing antiretroviral therapy in PI-pretreated, but SQV-naïve patients.