

POSTER PRESENTATION

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# Clinical significance of hyperbilirubinemia in the CASTLE study

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## Purpose of the study

While unconjugated hyperbilirubinemia is associated with the use of ritonavir-boosted atazanavir (ATV/r), the nature of the hyperbilirubinemia over time and its clinical significance has not been well-characterized in controlled studies. The purpose of this study is to describe the patterns and clinical significance of hyperbilirubinemia in patients treated with ATV/r in the CASTLE study.

## Methods

CASTLE was a randomized, 96-week study to assess the efficacy and safety of ATV/r vs. lopinavir/r, each with tenofovir/emtricitabine, in treatment-naïve patients. This analysis included only ATV/r patients. The proportions of patients with hyperbilirubinemia (grades 3-4 total bilirubin elevation) were tabulated for each study visit. The impact of hyperbilirubinemia on symptoms (jaundice or scleral icterus), ASL/ALT elevations, quality of life (MOS-HIV physical and mental summary scores),

and adherence (MACS adherence questionnaire) were described.

## Summary of results

Although the proportion of patients with hyperbilirubinemia at any time throughout the study was 44%, the proportion of ATV/r patients with hyperbilirubinemia at any single visit was between 12.5% and 21.6%. Of patients with hyperbilirubinemia at any time, 11% had grades 2-4 treatment-related jaundice or scleral icterus at any time (0 of patients without hyperbilirubinemia), and 4% had grades 3-4 AST/ALT elevations at any time (3% of patients without hyperbilirubinemia). Quality of life and adherence in patients without and with hyperbilirubinemia. Table 1.

## Conclusions

Hyperbilirubinemia, while common in patients on ATV/r at any time through 96 weeks in the CASTLE study,

**Table 1**

	Patients without hyperbilirubinemia	Patients with hyperbilirubinemia
MOS-HIV Physical Summary Score Categories at Week 96		
Improvement	76/138 (55%)	70/128 (55%)
No change	35/138 (25%)	29/128 (23%)
Worsening	27/138 (20%)	29/128 (23%)
MOS-HIV Mental Summary Score Categories at Week 96		
Improvement	97/138 (70%)	92/128 (72%)
No change	25/138 (18%)	18/128 (14%)
Worsening	16/138 (12%)	18/128 (14%)
Adherence Through Week 96		
To regimen	154/186 (83%)	147/176 (84%)
To ATV	159/186 (85%)	153/176 (87%)

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was less frequent at any single time point and not associated with related symptoms in most patients. The presence of hyperbilirubinemia did not affect AST/ALT elevations, quality of life, or adherence. These data suggest that hyperbilirubinemia observed with ATV/r does not impact clinical outcomes.

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