Abstracts of the HIV Drug Therapy Glasgow Congress 2014
Llibre JM et al. *Journal of the International AIDS Society* 2014, **17(Suppl 3)**:19810
http://www.jiasociety.org/index.php/jias/article/view/19810 | http://dx.doi.org/10.7448/IAS.17.4.19810

Long term effectiveness of once-daily unboosted atazanavir plus abacavir/lamivudine as a switch strategy in subjects with virological suppression

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Background: Use of unboosted atazanavir (ATV_{400}) is approved in the US but not in Europe [1]. Due to pharmacokinetic interactions it should not be used with tenofovir but can be used with abacavir/lamivudine (ABC/3TC) [1,2,3]. Effectiveness data of ATV_{400} + ABC/3TC as a switch strategy in clinical routine however are scant.
Methods: We evaluated treatment outcomes of ATV_{400} + ABC/3TC in pre-treated subjects in the EuroSIDA cohort with undetectable HIV-1 RNA, and previous ABC experience or assumed previous HLA B57*01 testing. We performed a time to loss of virologic response (TLOVR below 50 c/mL) and a snapshot analysis at 48, 96 and 144 weeks. Virological failure (VF) was defined as a confirmed plasma HIV-1 RNA >50 c/mL.
Results: We included 258 subjects: 176 (68%) male, median age 46 (IQR 41, 53) y, 225 (87.2%) white, hepatitis virus co-infection 36%, median baseline CD4 at switch 540 cells (360, 700), time with VL $\leq$ 50 c/mL 45 (24, 69) months. The median calendar year of switching was 2008 (2006, 2010). The 3rd drug in previous regimen was ATV/r in 70 (27.1%), other PI/r in 25 (9.7%), and other 163 (63.2%); 85 (32.9%) had previously failed with a PI. The virological response at 48/96/144 weeks was, respectively, 89.5 [95% CI 85.1, 92.9]/88 [83.4, 91.7]/86.3% [81.6, 90.4] (TLOVR, composite endpoint failure or stop for any reason) and the risk of VF was 8.3/7.6/7.6%. In the snapshot analysis HIV-RNA was below 50 c/mL in 72.5/65.9/51.6%, respectively, and >50 c/mL in 6.6/5.4/4.3%. Only 0.8/1.9/3.5% discontinued due to adverse events. There was a high rate of discontinuations due to other reasons or with VL missing in window. In a multivariate adjusted analysis, we observed an association between VF and nadir CD4 count (RH 0.60 [0.39, 0.93] per 100 cells higher), time with VL $\leq$ 50 c/mL (RH 0.89 [0.81, 0.98] per 6 months longer) and previous failure with a PI (3.04 [1.36, 6.80]). There was no association with gender, age, hepatitis virus co-infection, CD4 count at time of switching or third drug used in the previous regimen.
Conclusions: A switch to ATV_{400} + ABC/3TC in selected subjects with HIV-RNA below 50 c/mL is associated with relatively low rates of VF and discontinuation due to adverse events. Use might be considered in those with long-term suppression and without prior PI failure. Larger cohorts are required to further define the appropriate selection criteria.

References

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Published 2 November 2014

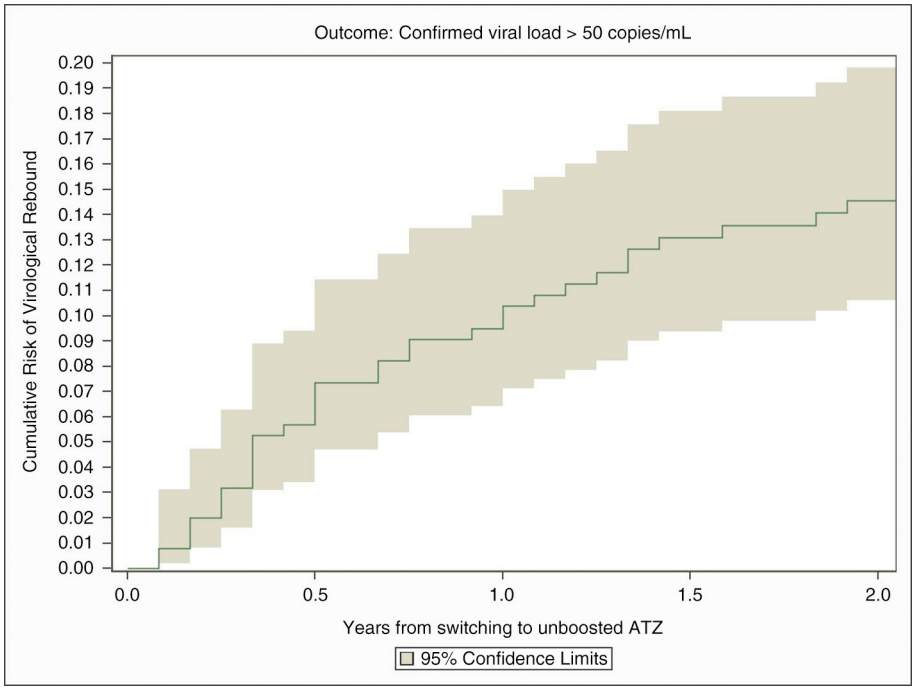

Figure 1. Cumulative Risk of loss of virological suppression.