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Transient therapy with quadruple NRTI provides immune stability in patients with multidrug resistant HIV-1 and no options for suppressive regimens

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Purpose of the study

Preventing immunological deterioration is essential in highly-experienced HIV-1-infected patients who have no options for fully suppressive therapies. We explored a holding regimen aimed to preserve the immunologic status of patients with multidrug resistant virus while awaiting new active drugs.

Methods

Exploratory, randomized study in heavily pretreated patients on failing therapies. The objective was to determine if a holding regimen integrated by co-formulated zidovudine/lamivudine/abacavir and tenofovir was able to maintain immunological status. Virologic outcomes, genotype evolution and clinical safety were also evaluated. Control arm received a genotype-guided salvage regimen.

Summary of results

Twenty-three patients (pts) were recruited; 13 were assigned to the holding-arm and 10 to the control-arm. 76% and 80%, respectively, had ≥3 TAMs at baseline (BL). Genotype sensitive score was 0.5 (0.5; 0.75) and 0.5 (0.5; 1), respectively. Median (IQR) BL CD4 count was 366 (293; 448) in holding- and 420 (189; 456) cells/μL in control-arm (p = 0.9), and median BL viral load (VL) was 3.5 (3; 4) and 4.12 log10 (3.3; 4.5), respectively. After 48 weeks, 62% in the holding- and 100% of the control-arm maintained their CD4 count (p = 0.09). VL decreased a median of 0.6 (0.2; 1.9) and 2 log10 (0.5; 2.7) in the holding- and control-arm (p = 0.1). 27% of the pts in the holding- and 50% in control-arm achieved undetectable VL. Number of TAMs and mutations in the protease gene were maintained in both groups. No clinical progression was observed. Adverse events were detected in 16% in holding- and 90% in control-arm, respectively (p = 0.001). When a fully suppressive therapy could be initiated, 69% of the pts from holding-arm (nine subjects) and 60% (six pts) from the control-arm achieved VL<50 copies at 48 weeks of follow-up after the study ending.

Conclusion

Our results showed better virological and immunological outcomes with standard salvage therapy than a holding therapy with TZV+TDF. However, this approach provided a stable immunologic status, better tolerability and it was not associated with clinical progression for 48 weeks of follow-up. This strategy did not jeopardize a posterior complete viral suppression when a fully active regimen could be initiated. This transient approach could be useful in pts with multidrug resistant HIV-1, toxicities or other condition that restrict active drugs while awaiting a fully suppressive regimen.