Abstract Preview - Step 3/4

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Topic: Antiretroviral Randomized Clinical Trials

Title: Individual patient data meta-analysis of randomized controlled trials of dual therapy with a boosted protease inhibitor plus lamivudine for maintenance of virological suppression

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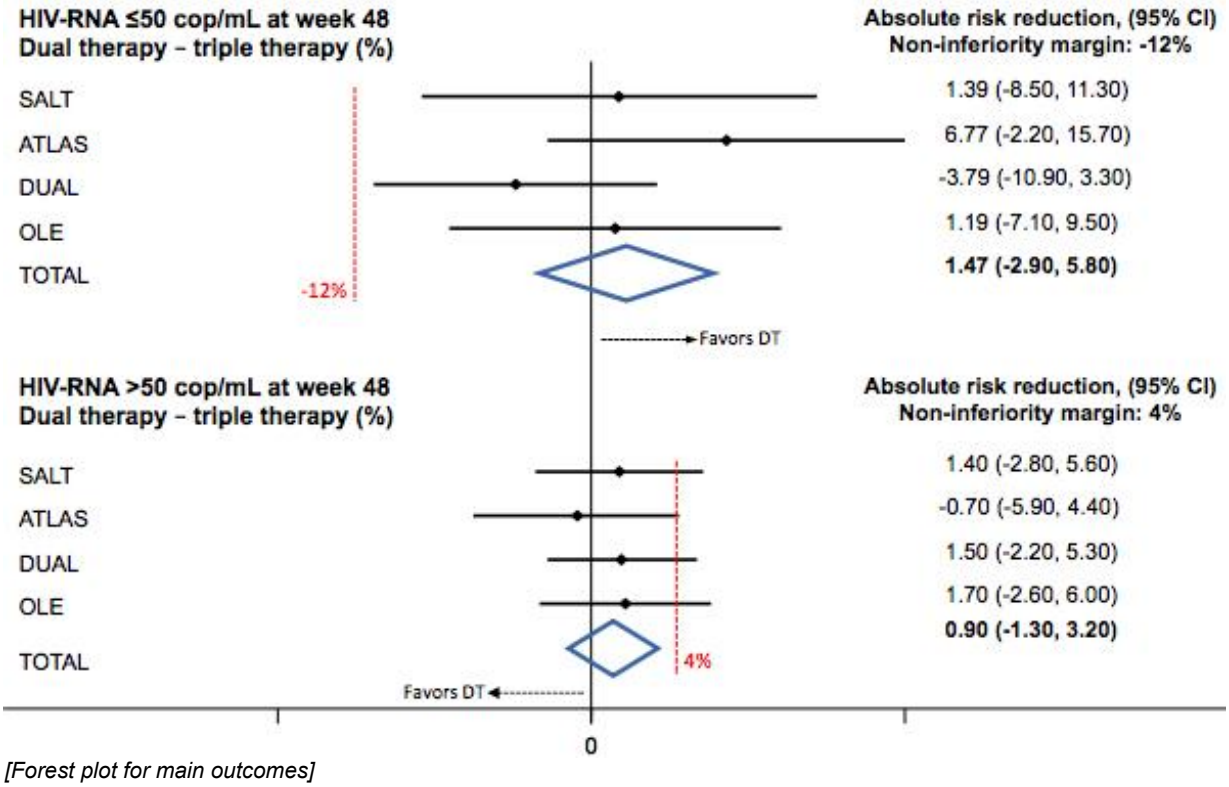
Text: **Objectives**: to compare the efficacy of switching to a boosted protease inhibitor (PI) plus lamivudine Dual Therapy (DT) vs. continuation of triple therapy (TT) with two nucleos(t)ides plus a PI for maintenance of virological suppression and whether efficacy was modified by gender, active HCV infection and type of PI.

Methods: We performed a systematic search of PubMed, EmBase, BIOSIS, Cochrane-CRCT and of the main scientific meetings about HIV infection (Jan/1990-Mar/2017). Only randomized controlled trials were included. Principal investigators were contacted and agreed to share study databases. Primary endpoint was to demonstrate the non-inferiority of DT vs. TT with the current FDA endpoint (4% non-inferiority margin for virologic failure defined as HIV-RNA≥50 cop/mL at week 48; snapshot algorithm). We also analysed the difference in the proportion of patients with HIV-RNA< 50 cop/mL at week 48 (non-inferiority margin: 12%). Effect estimates and 95%CI were calculated using GEE models.

Results: We found 886 references that finally yielded 9 articles corresponding to 4 clinical trials: ATLAS-M, SALT, DUAL and OLE (1051 patients). The studies were reanalysed under the same conditions than the original analysis to check for consistency. At week 48, 4% of patients on DT vs. 3.04% on TT had HIV-RNA≥50 cop/mL: difference 0.9% (95%CI, -1.2% to 3.1%) (Figure). Also, at week 48, 84.7% of patients on DT vs. 83.2% on TT had HIV-RNA< 50 cop/mL: difference 1.4% (95%CI, -2.8% to 5.8%). Gender, active HCV infection or type of PI had no effect on treatment efficacy differences between DT and TT (non-significant interactions).



[Forest plot for main outcomes]

Conclusion: In this invidual patient data meta-analysis of 1051 participants, DT was non-inferior to TT using both current and past FDA end-points for trials of antiretroviral therapy switch. The efficacy of DT was not influenced by patient's gender, active HCV infection status or type of PI.

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