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Poster **Session/Topic:** **Antiretroviral therapy**

N. **Title:**

P 8 **Efficacy and safety of 2-drug combination antiretroviral therapy in clinical practice: results from a single center study**

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Abstract:

Background: Current guidelines recommend 2-drug regimens as alternative to triple antiretroviral therapy (ART) in selected patients to reduce long-term toxicity and costs. The aims of study were to evaluate virological efficacy, safety and tolerability of 2-drug regimens in treatment-experienced HIV-1 infected patients in a real life setting.

Methods: All HIV-1 infected treatment-experienced patients treated with dual therapy at Siena University Hospital from 03-2006 to 10-2017 were enrolled retrospectively. The treatment failure (TF) was defined as virological failure, VF (2 HIV-1 RNA, VL, >50 cp/mL or 1 VL >1,000 cp/mL) or treatment change for any reason. Predictors of blips, VF or TF were investigated by regression analysis. Survival analysis was used to estimate cumulative probability of TF. CD4, total cholesterol (TC), eGFR (by CK-EPI) changes from baseline values at week 24 and 48 were assessed using Student's t-test for paired samples.

Results: We included 81 patients: 65% males, 42% homo/bisexuals, 5% non Caucasians. At 2-drug ART initiation their median age was 51 years (IQR, 45-55), they had 15 (7-22) years from HIV diagnosis, 11 years of ART (5-17), nadir CD4+ 267 cells/ul (150-390), baseline CD4+ 580 cell/µl (373-724), 74% had VL <50 cps/mL and 18 months since last VL >50 cps/mL (0-67). A previous AIDS-defining event was reported in 22%. The reason for dual therapy start was simplification (44%), toxicities/proactive switch (44%) and salvage therapy (12%). 2-drugs regimens included bPI+NNRTI (36%), bPI+INSTI (16%), bPI+3TC (12%), INSTI+3TC (5%) and others (31%). Median GSS of cART was 1.5 (1-2), GSS was <1 in 20%. Previous regimen included a single tablet regimen (STR) in 7%; NRTIs were previously used in 95%, NNRTI in 68%, PI in 93% (bPI 76%), INSTI in 22%, MVC or T20 in 6%. Pre-switch regimens included tenofovir disoproxil fumarate (TDF) in 63%. During a median observation time of 162 wks (IQR 96-218) TF occurred in 22 cases, with an estimated probability of 23% at 48 wks (CI 95% 18-28): 5 for VF (23%), of which 3 VL >1,000 cp/mL, and 17 for treatment change (77%) of which 35% for switch to STR or monotherapy, 35% for patient's choice, 18% for adverse events or intolerance, 2 for drug-drug interactions. Blips occurred in 20% of patients. Observed mean changes from baseline values were for CD4+ counts at 24 wks +46 cells/µL (-84;+130), at 48 wks +44 cells/µL (-97;+190), for CD4/CD8 ratio at 24 wks +0.1 (-0.1;+0.2) p <0.001, at 48 wks 0 (-0.1;+0.2), for TC at 24 wks +17 mg/dL (-12;+54) p=0.005, at 48 wks +11 mg/dL (-19;+42), and eGFR at 24 wks +0.01 ml/min/1.73m2 (-12;+9), p <0.001, at 48 wks +0.001 ml/min/1.73m2 (-19;+12). At univariate analysis, the only predictor of TF was the time since VL <50 cps/mL (OR 0.99, CI 95% 0.99-1.00, p=0.049).

Conclusions: Following switch to 2-drug regimens in a real life setting, VF was uncommon and there were durable benefits in terms of safety, immunological recovery and preservation of renal function.