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Dual therapy (ritonavir boosted atazanavir + raltegravir) versus standard triple therapy (ritonavir boosted atazanavir + tenofovir/emtricitabine) in patients failing first line therapy: 48 week results from a randomized pilot study

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Background: Dual therapy has emerged as a novel concept in treatment optimization in naive and supressed HIV patients. This study aimed at exploring virological response, safety and inflammation markers of a nucleoside-sparing dual regimen consisting of ATV/r + RAL (DT) vs standard therapy of ATV/r + TDF/FTC (TT) among patients failing first NNRTI-containing treatment.

Methods & Materials: Randomized open label pilot study. Primary outcome measures were proportion of subjects with plasma HIV-1 RNA below the limit of detection (<50 copies/uL) and proportion of subjects discontinuing due to adverse events (AEs) during the first 48 weeks. ClinicalTrials.gov Identifier: NCT01829802.

Results: Out of 57 patients screened, 34 were randomized to receive: DT (n: 18) or TT (n: 16). At baseline 80% males, 50% MSM, median age 38 years, CDC stage C:35%, Median pVL: 3.9 Log10, CD4: 289 cells/uL.

At week 48, data from 32 participants (2 did not reach week 48 yet) showed virological response in 69% (n: 11/16) of participants receiving DT and 88% (n: 14/16) receiving TT by FDA snapshot analysis (p = NS) and 73% (DT) and 93% (TT) by per-protocol analysis (p = NS). CD4 cell count median change from baseline to week 48 was +119 and + 52 cell/uL in DT and TT, respectively.

No deaths were recorded. Three SAEs occurred in 2 participants (pneumonia and stroke and, Bellś paralysis), none related to study drugs. Eight Grade 2, probably drug-related AEs were observed: 1 in DT (gastrointestinal) and 7 in TT (5 gastrointestinal, 1 renal stone and 1 rash). Hyperbilirubinemia Grade 2/3 was seen in 77% in DT and 94% in TT, none requiring stopping ART.

Two participants were discontinued due to loss of follow-up, one in each arm. Five participants had virological failure at W48, 4 in DT and 1 in TT, all with low pVL (52-589 copies/uL). One participant developed integrase resistance mutation and suppressed later on TT.

Conclusion: ATV/r+RAL as second-line therapy showed a trend to more frequent virological failure, compared to TT, although the study was unpowered to prove this difference. No major differences were seen in tolerance or toxicity.

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HIV viremia, vertical transmission and loss to follow up on HIV pregnant Chilean and immigrant woman: comparative study at 3 years of delivery

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Background: The meaningful rising immigration over the last years in Chile, most of the time on precarious conditions, has brought an increasing incorporation of HIV pregnant woman to HIV perinatal care program. The impact of this situation on HIV vertical transmission risk or treatment failure is not known.

Methods & Materials: We analyzed the pregnancy database at Fundación Arriarán,wich contains all the HIV+ pregnancy woman deliveries occurred at Hospital San Borja Arriarán since 2002. Baseline characteristics, pregnancy data, prepartum virological response and vertical transmission rates were compared between Chilean and immigrant woman. The data was also analyzed before and after de application of 2012 Chilean guideline for the prevention on vertical transmision. On the subset of patients who continue with antiretroviral therapy (ART) in the postpartum (since 2013) virological failure and loss to follow was evaluated up to three years. For the statistical analisis Chi2, T test, Mann-Whitney and Exact Test Fisher were used to compare distributions. Kaplan-Meier survival curves were used to explore diferences on postdelivery follow up

Results: 134 pregnancies (128 patients);80 chilean and 48 foreigners were included. The median age was 28 and 27 years (p 0.31), the beginning of ART was 18 and 23 weeks(p0.004), duration of prepartum ART were 136 and 105 days (p 0.007) and the baseline pregnancy viral load (VL) were 644 copies/ml vs 7540 copies/ml (p 0.019) between Chilean and foreign respectively. At delivery 32% of foreigners vs 47% of chileans had undetectable VL (p 0.07) Of prepartum viremic patients, 41% had high level viremia (>1000 copies/ml). When comparing before and after 2012, there was an 24% increase in undetectability at delivery (61% vs 37%) (p 0,03). It is remarkable that 63% of foreign women never reached undetectability during pregnancy. Vertical transmission reached 3.5% only from Chilean before 2012. At 3 years a 51% and 30% of virologic failure and 57% and 85% of retention was observed on Chilean and immigrant women.

Conclusion: A high rate of suboptimal viral response during pregnancy and loss to follow up after delivery was observed in HIV+ immigrant woman.

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